Alan Dardik
Editor

Vascular Surgery

A Global Perspective

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Preface

Technology continues to make the world a smaller place. Advances in communication, especially the ubiquity of cell phones and the computer-related communications such as the World Wide Web and e-mail, have led to an unprecedented ability to bring people together. One of the truly important outcomes of this communication has led to the awareness of global disparities in many areas of concern to all humans, including nutrition, education, economy, and health care. But with recognition comes the ability to propose and attempt solutions. The Lancet Commission on Global Surgery advocates for universal access to safe and affordable surgery and anesthesia care and is aided by initiatives such as the Disease Control Priorities Network that reinforce the value and impact of global surgery.

Vascular surgery is a field of medicine that has continually embraced technology. The roots of this specialty are frequently claimed to be germinated in the wars of the 1940s and 1950s, but our science and exploration by bold pioneers preceded the wartime efforts by decades. Each new technology was incorporated into the vascular surgeon's armamentarium, culminating with the recent disruptive technology of the endovascular revolution. It is an exciting time for medicine and vascular surgery in particular. I will boldly predict that our three traditional index procedures, carotid endarterectomy, peripheral bypass, and open aneurysm repair, are transforming into the broader categories of open repair or bypass of medium-diameter vessels, central and peripheral angioplasty with stenting, and endovascular aortic repair of aneurysms and dissections; this evolution reflects our specialty's particularly unique ability to perform hybrid procedures as well as prevent deaths in the face of emergent arterial trauma and rupture. Vascular surgeons of the future will not look like us, just as we do not look like the previous generation's vascular surgeons, who did not look like their ancestors.

Despite the French and American assertions that all people are created equal, we know that this aspiration has not translated into reality. So it is for vascular surgery. Vascular surgeons must diagnose and treat local variations of disease in their indigenous, transient, or visiting patient populations, doing so within their local culture, social customs, patient beliefs, ethical and moral framework, available healthcare resources, government regulations, local economics, and occasionally even with questionable availability of basic supplies such as water, electricity, or even shelter. The similarities are almost more amazing than the differences. I am very proud of the scope of practice achieved in this book. It is clear that the specialty of Vascular Surgery is

strong, with advancing research and clinical abilities driving outstanding care of patients with vascular disease. However it is also clear that disparities exist. We can learn from the resource-poor countries of Africa and Haiti, from the trauma in Palestine, from the clever ability to deal with financial hurdles in Greece and Romania. We can continue to push vascular care ever harder to make our patients better.

As an academic vascular surgeon and the president of the International Society for Vascular Surgery (ISVS), I have had the privilege of meeting, befriending, and working with a group of friends and colleagues around the world, a privilege that would be difficult to imagine not so many years ago. Technology has enabled our meeting and growing our friendships and work, from inexpensive airplane travel that enables face-to-face meetings and stealing the time to write this Introduction to the Internet-based communication that allows real-time working, creating, complaining, commiserating, and even comforting. One side effect of this technology is a never-ending stream of messages that can be overwhelming, especially to our spouses and significant others who bear the brunt of our passions to help our patients.

This book is the product of so many friendships. First I thank my coeditors who have provided incredible guidance from and to their corners of the world; this book would not exist without their expertise. Next I thank Pauline Meyer, the executive director of the ISVS, who has kept that organization alive, enabling ISVS members to come together for our patients, wherever in the world they may be. So importantly, my colleagues at Springer, Richard Hruska who believed in this project and Patrick Carr who put it together, are magnificent; without them, we surgeons could not reach each other through this medium. In their publishing this book, they enable us to help our patients, and by higher mathematics, they are helping patients in a very meaningful and tangible way.

My parents, Herbert (Chaim) and Janet Dardik, get a special thank you. They brought the world into our home. In the 1980s and 1990s, vascular surgeons flocked to Englewood, New Jersey, to see the Dardik umbilical vein biograft, the first tissue-engineered vascular graft that was used in human patients. My parents welcomed these surgeons in our home for dinner and conversation, showing our family that we have friends all around the world and affirming to our visitor friends that vascular surgeons are people too. I am still friendly with some of these visitors, Shervanthi Homer-Vanniasinkam from England to speak of my closest. My parents also showed me the value of travel, both for enjoyment and being a method to connect vascular surgeons in such meaningful ways. I sincerely and humbly thank Toshiya Nishibe from Japan, Chang Shu and Yong-quan Gu from China, Serge Declemy and Nirvana Sadaghianloo from France, and Tulio Navarro from Brazil, for opening their operating rooms to me. This is truly the highest honor among friends and colleagues. And I do not neglect to acknowledge and appreciate my Yale partners who continually cover my practice, allowing me the academic freedom so vital to complete this project. I especially thank Robert Udelsman, chairman of Yale's Department of

Surgery, who has continually believed in and supported my academic career.

Finally I must thank my loved ones who endured my endless nights and days, weekends and weekdays, putting this project together, continually supporting with never-ending complaints. My children, Ian, David, and Kevin, thank you for allowing your father to achieve his dreams of connecting vascular surgeons around the world; may you achieve your dreams with grace and ease. My wife Susan, I love you and thank you for your continued encouragement and tolerance. I will finally get off my laptop, but only until the next project.

New Haven, CT, USA Alan Dardik

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1 Disparities in Global Surgical Access and Outcomes: Current Estimates and Models of Global Engagement

Doruk Ozgediz

In this chapter, we will briefly outline some of the current initiatives in global surgery that focus on surgical care for vulnerable populations primarily in low and middle-income countries (LMICs).

In recent years, global disparities in surgical access and outcomes have gained greater attention. In 2015 specifically, a number of related initiatives have launched and may provide a template for further work in various surgical specialties. In this chapter, we will outline some of these initiatives within the context of global health initiatives, discuss models for global engagement, and propose possible areas of consideration to increase vascular surgery capacity in resource-poor areas.

Recent Global Health Initiatives

In the past 15 years, global health initiatives have been led by the eight United Nations Millennium Development Goals (MDGs), with several of these goals impacted by treatment of surgical conditions [1]. As the time frame of the MDG's have come to an end, significant debate in the last year has surrounded the adoption of a new set of seventeen Sustainable Development Goals (SDGs) as a guide for low and middle-income countries. Great controversy has surrounded the metrics for the SDGs, with few metrics directly dealing with surgical care, although many of the thirteen targets within the SDG focused on health, require surgical and anesthesia care [2].

Within the broader context of global health, there has also been great debate around the approach of programs, with the emergence of a predominance of "vertical" health initiatives—initiatives focused on a single disease, or group of diseases with a high burden in low-income countries. The best example of this approach has been initiatives such as the Global Fund for HIV, tuberculosis, and malaria, and other programs directed at these three infectious diseases. Simultaneously, there has been recognition that while infectious diseases do pose a significant burden on poor countries, the burden of non-communicable diseases (NCDs) is steadily growing and the burden is currently greater than that of infectious diseases [3]. NCDs include diabetes, coronary disease, and cerebrovascular disease, as well as cancers.

Many of the risk factors that contribute to coronary disease also predispose populations to vascular disease. Many LMICs are seeing a undergoing an epidemiologic transition from primarily infectious diseases, and vaccine preventable illnesses, to a double burden of communicable and non-communicable diseases. Thus a growing emphasis has also been on the development of programs directed at these conditions. In addition, there has

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been concern that programs directed at vertical initiatives have failed to improve the "system" as a whole, with surgical programs, those that depend on a functioning health system, failing to develop as readily. Numerous recent initiatives have attempted to raise the profile of surgery in global health, and the following section will address some of those that emerged in the last year.

Lancet Commission on Surgery (LCOS)

The Lancet Commission on Global Surgery assembled a large group of global experts and through a series of meetings and an extensive research program made numerous estimates about the global burden of surgical disease, and global capacity for surgery. Estimates from the LCOS were that approximately 30% of the global burden of disease is amenable to surgical intervention [4]. The five key messages of the LCOS were:

- *an estimated five billion people globally lack access to surgical* care—The Commission proposed a group of three "bellwether" procedures (caesarean section, laparotomy, treatment of open fracture) as those that signify a system operating at a sufficient level of complexity to do most other surgical procedures; efforts to validate this group of procedures are underway.
- *33 million people face impoverishing expenditure related to surgical care yearly*; modeling work based on smaller studies confirms that many patients pay high out-of-pocket expenditures for surgical care, and are not protected from financial risk.
- *Investment in surgical and anesthesia services is affordable, saves lives, and promotes economic growth*—much of this data has been based numerous analyses of the cost-effectiveness of surgical care that have demonstrated favorable estimates especially for emergent conditions.
- *Surgery is an indivisible, indispensable part of health care*—specifically, universal health coverage is an essential component of the global health agenda post-2030, but the roadmap to achieve this coverage, especially across the various surgical disciplines, is less-well defined.

One of the early priorities since the Commission launch has been the promotion of surgical indicators amongst other health-related development indicators, and the documentation of country-level "dashboards" to profile these priority areas above as a component of public health, as has been done in Zambia.

Disease Control Priorities, 3rd Edition (DCP-3)

As another guide for policymakers, health planners, and donors, a third edition of the Disease Control Priorities in Developing Countries was launched earlier in 2015, including a volume on Essential Surgery [5]. The group, as previous groups had done, defined a group of essential surgical procedures based primarily on burden and cost-effectiveness of treatment. Key messages from this group also have direct implications for surgical development globally:

- *1.5 million deaths could be averted each year through essential surgical procedures*; a majority of these essential procedures cover trauma and emergency general and obstetric surgery.
- *essential surgical procedures are cost-effective, and 28 of 44 procedures can be provided at a first-level hospital*. While this specific "package" of conditions and required procedures has not been evaluated in LMICs, several studies have examined the capacity of selected facilities in LMICs to treat these conditions, showing numerous gaps and a limited coverage for both emergency and elective procedures. Gaps cover human resources and infrastructure required to deliver care.
- *Strategies such as "task shifting" (performance of a range of procedures by a cadre of non-physicians) have expanded coverage, especially in rural areas, for numerous countries that have*

adopted this policy (such as Malawi, Mozambique, Tanzania, Zambia). Some countries have chosen not to adopt such a policy due to concerns within their medical community.

- *Substantial disparities remain in perioperative mortality rates between HICs and LMICs, thus underscoring the need for safe perioperative care*. The provision of safe anesthesia care remains a critical step for any scale-up effort. Numerous groups such as the World Federation Societies of Anesthesiologists (WFSA) are critical in this regard, as are programs such as the Global Pulse Oximetry Initiative, and those training more providers for safe anesthetic care.
- *The cost-effectiveness of essential surgical procedures supports the need to invest in surgical care to achieve universal coverage*—a very similar message to the LCOS and one that highlights the need for providers of children's surgery to continue estimating the cost-effectiveness of the interventions we currently provide or scale up (by adding providers, infrastructure, services, etc).

World Health Assembly (WHA) Resolution on Emergency and Essential Surgical Care

Another recent critical development is the passage of the WHA Resolution 68.15 to "Strengthen Emergency and Essential Surgical Care as a component of universal health coverage" [6]. This was a key event in terms of advocacy for surgical providers and groups focused on care in LMIC settings. The resolution suggests many critical areas of action, including the integration of emergency and essential surgical care within primary care facilities and first-level hospitals as a key element to reaching universal health coverage. This resolution thus lends even greater urgency to adapting locally endorsed "packages" of surgical care that can be integrated through health facilities and other elements of the health system. Within other surgical specialties, the Global Pediatric Surgery network has also proposed a similar capacity guideline for a broader group of pediatric surgical conditions [7]. In the trauma community, basic resources at various levels of the health system have been proposed and used as capacity guidelines [8]. This type of approach is critical at national and regional levels, detailing resource needs and gaps, based on evidence of local outcomes. Such a process will most likely be successful if driven by local stakeholders, and supported by the donor community and other groups engaged in global surgery provision. This type of approach could be tailored to any surgical specialty and integrated into local surgical development plans depending on local priorities.

The type of work done through these initiatives may inform the approach that could be taken for vascular surgery. For example, some of the questions below may highlight an approach that could be useful:

- What is the burden of conditions amenable to vascular surgery in LMICs and how are they distributed geographically?
- What are the "essential" vascular surgery conditions that are prevalent, and treatable, and how cost effective are they in LMICs?
- How many lives could be saved and how much disability averted if the needed care could be provided?
- What are key components of vascular surgery capacity in LMICs in terms of workforce and infrastructure and what are the capacity deficits?
- How can the diagnosis and treatment of these conditions be integrated into existing surgical and other health initiatives?
- How have these services been scaled up in resource-poor areas and what lessons can be learned?
- What is the estimated cost of scale up and are there low cost alternatives to diagnosis and management (compared to high income settings)?
- Are there skills in diagnosis and treatment that could be provided by non-physicians or general doctors, especially in rural parts of LMICs?

Models of Global Surgery Engagement

Numerous models of global surgery engagement have been used to augment capacity and increase access to surgical care in LMICs. This may be relevant to groups with an objective to attempt this for vascular surgery.

Most charitable programs primarily address elective conditions. They range from free standing faith-based hospitals such as CURE that provide neurosurgery and other specialized children's surgical care in low-income countries; to groups such as Operation Smile and Smile Train that treat craniofacial anomalies [9]. While the former funds teams from high-income countries to travel and provide care in LMICs, the latter funds local providers to perform operations for specific conditions such as cleft lip and palate. Many primarily service-based surgical charities such as the above have in recent years shifted more to a model of capacity building, as exemplified by Operation Smile that created a specialty hospital India. Others, such as Mercy Ships and The Comfort, that provide surgical care on ships for populations in need, remain primarily service-based. Other organizations such as the Red Cross and Doctors Without Borders, provide primarily surgical care to populations in conflict settings.

Specialty hospitals have been shown to be cost-effective in treating niche conditions, but a bigger question and challenge for global surgery has been about how surgical systems can be developed as a whole. For example, the types of systems in place to treat injuries and abdominal emergencies require a certain level of development across the entire range of hospital services and cannot be addressed as readily through models that focus exclusively on elective conditions.

In addition to these charitable platforms, academic partnerships between HICs and LMICs have also proliferated in recent years with a focus on collaborative capacity building activities [10]. These activities have included a wide range of activities such as

- visiting faculty from HICs to LMICs for various time periods;
- collaborative research activities;
- development of training courses suited to the resource poor area;
- clinical training opportunities for LMIC faculty and trainees in HICs.

In addition, faith-based groups such as the Pan-African Academy of Christian Surgeons have established post graduate training programs in LMICs and have made major contributions to the surgical workforce in these countries [11]. A unique program in Rwanda is midway through a 7-year grant from the United States Agency for International Development to the Rwandan Ministry of Health to fund post-graduate training mainly through visiting American faculty. The outcomes of this program may also inform future efforts. In addition, academic societies and professional organizations in HICs have increasingly devoted segments of their scientific programs devoted to LMIC surgical care, and have assisted LMIC surgeons to attend their conferences and visit selected institutions.

Other areas of focus include programs to innovate technology appropriate in resource-poor areas. The last several years have seen an increase in device development such as prosthetic limbs, ventilators, and anesthesia machines, to name a few designed for "extreme affordability" [12]. The concept of reverse innovation—i.e. harnessing the economy of care in resource poor areas to inform more efficient surgical care in HICs, is also gaining traction. However, much more work is needed to identify and promote innovation of technology appropriate to the resource poor setting.

Conclusion

Global surgery has gained great momentum in the last several years, especially in 2015, with great opportunities to integrate with the changing context of global health initiatives and priorities. The burden of surgical conditions is gaining greater

recognition in global health, as are the substantial disparities in access and outcomes for surgical care. There is a substantial need for scholarly work relevant to the resource-poor setting to augment surgical capacity in these areas. Many models of global surgical collaboration exist, all with varied areas of focus, but most successful collaborations depend on the presence of "local champions" or "change agents" to move the agenda forward. Surgeons must take the lead, through collaborative teams, to ensure that progress in the surgical specialties reaches those in greatest need.

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Part I

Aorta

Aortic Aneurysms: Definition, Epidemiology and Natural History

2

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Rupture and death! *Galenus*, 18 centuries ago, described with clearness of mind this fatidic association, the natural evolution of the pseudoaneuryms that he observed in the wounded gladiators under his care in Pergamon and later in the Coliseum of Rome [1]. The rupture of an aortic aneurysm (AA) is the dreadful final event of the evolution of this potentially lethal disease. Although AA can present with other complications, as compression of adjacent structures and peripheral embolism, the potential of catastrophic rupture is the crucial end of its the natural history [2–5].

Aortic Aneurysms: Definition and Brief Classification

Aneurysm is a term derived from the ancient Greek, meaning "a widening". An aneurysms is defined by a permanent localized dilatation of an artery, having at least a 50 % increase over the expected normal diameter. Smaller arterial dilatations are termed ectasias [6]. True aneurysms involve the three layers of the artery—intima, media and adventitia. Pseudo aneurysms do not involve all layers, but are due to rupture of the arterial wall and formation of a perivascular hematoma. In this chapter, we will limit our discussion to the Aneurysms of the Abdominal Aorta (AAA), by far the most frequent of all the aneurysms of the aorta.

Aortic Aneurysms: Epidemiology

The prevalence of AAA is increasing. This is due to three main factors: the progressive increase of life expectancy, the accuracy of the diagnostic methods and the awareness of doctors regarding this disease as well as the benefits of its treatment. The later, has prompted many physicians to request abdominal ultrasound exams of their patients, mainly elderly white men, the most affected by the problem [7]. In fact, AAA is a disease of elderly white men, occurring 3 times more than in black men of the same age [8]. The incidence increases progressively after the

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fifth decade and, in our material, with more than 2000 AAA treated, men outnumber women in a ratio of 7:1. The likelihood to develop a AAA varies broadly in the literature, ranging from 3 to 117 per 100,000 person-years; this broad variation is due to the diversity of the individuals screened [9].

The importance of AAA can be measured by the high mortality its rupture determines. It is the 13th cause of death in the USA in men over 65 years, and the 10th in the same group in Canada [10, 11]. Parallel to the increase of the aging population, the mortality due to rupture of AAA also increases, as demonstrated by many authors, as Fowkes et al. in 1959—404 deaths in England and Wales, and in 1984—7259! [12] In the late decades, great interest has been aroused to determined the real prevalence of AAA. So, with that objective, autopsy and especially abdominal ultrasound population screening studies have been conducted. Bengston et al. published what is probably the landmark of the autopsy studies in 1993, reporting the prevalence of AAA in Malmö (Sweden), those days with a population of 230,000 (45,838 autopsies performed between 1858 and 1986). In the period of 1971–1986 they identified 215 ruptures (155 men and 60 women). Of these, 91 died at home, 63 in the hospital without treatment and, of the 69 that were operated on, 33 died to. In the same time frame, they have operated electively on another 130 cases [13]. Several population screening studies were conducted after the seminal publication by Colin et al.—The Oxford Study. In that study, 426 men with age between 65 and 64 years were screened for AAA by abdominal ultrasound: an incidence of 5.4 % was detected [14]. Bonamigo published a meta analysis of ten studies, including his one and found a percentage that varied from 1.7 to 10.7 %, depending on the population studied [7]. It is clear that there are population subgroups that have increased risk of AAA, patients with coronary artery disease, those with peripheral arterial occlusive disease, mainly those with carotid artery involvement and amputees. Old age is an independent predictor [8, 9]. History of smoking is very prevalent, being the risk factor most strongly associated with AAA [7–9]. Last but not least, heredity has an important role: relatives of patients with AAA present a higher incidence of the disease than other individuals without history of the disease in their families. The first paper addressing the subject, was published by Tilson and Seashore in 1984, later confirmed by others, in several countries [15]. Johansen and Koepsell estimated that first-order relatives have a 12-fold increased risk for developing a AAA themselves [16]. In Brazil, Barbosa et al. confirmed the disease in 25 % male relatives and in 4.6 % of female, both of first-order relatives [17]. It seems that tobacco abuse has a triggering effect in developing aneurysms in these subjects.

Aortic Aneurysms: Natural History

In the past, when there was no effective diagnosis and treatment for AAA, the observation of the natural history of the disease was based in clinical observation of the patients. Many presented growth of the aneurysm, with progressive expansion and finally rupture, leading to death. Commonly, rupture and death occurred before any evident symptoms. Although AAA can present many complications in their evolution, listed in Table 2.1, rupture is the crucial one in the natural history of this disease.

In parallel, many patients with AAA died of other causes associated with old age, mainly from cardiovascular or other degenerative diseases, as cancer or renal insufficiency [18].

Despite the fact that the exact etiology of AAA is unclear, extensive and well conducted epidemiological studies, some cited above, clarified much about its evolution. It is a disease in ascension in all western world. Ultrasound studies in a large number of individuals in the age of

Table 2.1 Complications of abdominal aortic aneurysms

Rupture
Embolization (macro and micro)
Inflammatory aneurysm
Acute thrombosis
Adjacent venous, ureteral and intestinal compression
Rupture into adjacent organs (digestive tract, more commonly to the duodenum, vena cava)
Infection

higher prevalence of aneurysmal aortic degeneration, allowed a clear view of the pathology, formerly based only in *post mortem* evaluations [4, 5]. Being rupture the most dreadful complication, it seems logical that it is the most studied in the natural history of AAA, and form the base if this Chapter.

In 1950, Estes et al. published a classical paper on the natural history of AAA: rupture was the *causa mortis* of 63 % of the 102 patients followed up for 5 years. Survival at 5 years was only 18.9 %, contrasting with the life expectancy of 79.1 % of the matched population! [19] Important publications followed, confirming this findings, in clinical research and autopsy studies [7–9, 11, 13, 18]. A percentage of rupture of 27.7 % in non operated cases was reported by Gore and Hirst in 1973, stressing the importance of the diameter of the AAA in this final event: 9.5 % of small AAA's (less than 5 cm in diameter) ruptured; in medium size (5–7 cm), the rate was 36 % and in large ones, with more than 7 cm in cross section—76 %! [20] Darling et al., in 473 autopsies of patient who passed away due to AAA rupture, stressed that small aneurysms, with less than 4 cm in diameter, could rupture too, in a rate of 9.5 % of the cases [21]. Another Swedish study, by Glimacker et al., detected a rate rupture of 2.5 % for AAA with less than 5 cm in diameter, in contrast with those with more than that size, who had a rupture rate of 28 %! We must observe that in all these studies, the aorta was not pressurized [22]. Silva et al. were the first to measure the diameter of pressurized the aortas in necropsy evaluation. They pressurized the specimens at 80 mmHg, in patients that died from ruptured AAA and found that none ruptured with less than 5 cm in diameter [23]. This study also confirmed the finding of others, that the fusiform shape of the AAA is associated with a higher risk of rupture than the spherical form. The numbers were too small to establish a clear relation with the saccular form, thought to be the most prone to rupture [23]. Interestingly, as it was formerly believed, they confirmed the findings of other investigators that the presence of thrombus did not prevent rupture, but rather facilitated it, since thrombi were found next to the rupture site in 80 % of the specimens, maybe acting as precipitating factor through the enzymatic activation contained in viable macrophages inside the thrombus [23]. A subgroup that deserves special attention are women: their native aortas have generally smaller size and are prone to rupture with smaller diameters than in men, being considered at risk with diameters of more than 2.5 times their original diameter.

In our material, observing and following up more than 3000 patients with AAA in 35 years, we never observed ruptures in asymptomatic patients with diameter smaller than 5 cm. We stress the point that those patients were asymptomatic, bearers of fusiform or spherical degenerative aneurysms. Symptomatic aneurysms, as well as saccular and aneurysms of other etiologies are exceptions and must be individually addressed.

It is current belief that biochemical alterations within the aneurysm produce weakening of the arterial wall; histological and anatomical features predispose their localization and the hemodynamic effect contributes to the arterial widening. This last fact explains the relevance of the diameter, as well as the morphology, in the natural history of these dilations [23].

Inheritance has an outmost importance in the dilatation of the aorta. Members of the same family of a patient operated on for AAA have a 10 times chance of developing an aortic aneurysms, when compared to someone who never has a case in his relatives [13, 24]. Bengston et al. observed that in male children of patients operated on for AAA, the probability of developing an aneurysm is 30 and 4 % in women. Several other publications come to the same conclusions [24, 25]. The publication already quoted of Johansen and Koepsell evaluated 250 relatives of patients operated on for AAA and found aneurysms in 19.2 %; in 250 individuals of same age and gender in the general population, the incidence was 2.4 % [16].

The concentration of AAA in members of the same family has driven many investigators to investigate the genetic importance of the disease. Powell et al. proposed that abnormalities in the long chromatid arm of human chromosome 16 are responsible for the familial tendency to

develop the disease [25]. Gene expression leading to abnormalities in the content and structure of elastin and collagen in the arterial wall was reported as early as 1992 [26]. A thorough review was published by Tilson et al. [27]. In 2015, only in the English literature, there are more than 1000 publications linking AAA to genetics and of course, inheritance. Certainly in the future we will be able to identify individuals at risk of developing AAA and even other aneurysms. Currently, we must screen relatives of AAA bearers, because it is in this group that the diagnosis of the problem is more frequent [18].

Patients with AAA, independent of their size, have a reduced life expectancy, in comparison with individuals matched for age [26, 28]. Someone with a AAA has a yearly 7 % chance of dying, of many causes [28]. The data regarding larger aneurysms are even worse, and have already been addressed in this Chapter. The impact of the diagnosis of AAA usually is enormous for the patient. The majority presents anxiety and fear or rupture, with profound implications in their quality of life. Although the medical literature does not have precise reports of this impact, this fact is confirmed in our daily practice. The current knowledge of the natural history of AAA allows a sincere and ethical counseling about the best management of each individual patient. Albeit being nowadays a curable disease by surgery, in most cases with small AAA, a conservative approach is the best management, until size, shape or complications will change it [29]. Regular evaluations, especially with abdominal ultrasound, are fundamental.

In operated patients, the most frequent *causa mortis* are circulatory degenerative diseases, specially of the coronary and cerebral circulations [30]. Surgery is able to cure aneurysms, although not aneurismal disease. A small percentage of treated patients will develop new aneurysms proximal and/or distal to the treated segments, along their lives. These dilatations, the para anastomotic or para endoprothetic aneurysms can present a new risk of rupture or other complications. As this occurs generally many years after the initial treatment, it is uncommon the need of treatment of this situation [31].

The Role of Population Screening, Based on the Natural History of AAA

The majority of the patients that die from AAA rupture did not had previous knowledge of their disease. Despite all advances, even in developed countries more patients die of rupture AAA than are operated electively [32]. Moreover, studies relying on necropsy findings have reported that between 75 and 85 % of individuals with aneurysms died of other diseases, in particular from cardiovascular disorders [18, 21, 23, 28]. Although surgical management eliminates the rupture probability in most of the treated patients, a large contingent of individuals with small aneurysms do not need to endure a surgical procedure, because many aneurysms remain stable or grow very slowly [22, 23].

The impact of this high mortality in the rational for the screening studies, especially in populations with high prevalence of AAA. In 1988, we have proposed what today is unanimously accepted: to screen all male population over 60 years. Those days, that proposal was regarded as exaggerated or unnecessary [33]. The individuals at high risk of developing a AAA are well identified: those with aneurysms in other sites, men in the sixth and seventh decade of life, relatives of patients with AAA and patients with coronary, cerebrovascular or peripheral arterial obstructive disease. Current or previous smokers and hypertensive patients that that fit into the above categories have an even higher chance of bearing a AAA. In these groups, despite the economical difficulties found in developing countries like Brazil, screening is needed.

The natural history of AAA may be influenced by several factors, such as diameter, rate of expansion, morphology–geometry, mechanical properties of the arterial wall, enzymatic activity, arterial hypertension, chronic obstructive pulmonary disease, genetic propensity, recent laparotomy and use of certain medications [2, 3, 23]. In 2016, we know that most AAA are asymptomatic until they rupture; usually, only patients with abdominal or lumbar pain have their AAA diagnosed without screening; in practice, almost half

of the AAA have a evolution to rupture; by the current methods of emergency treatment, only one of every five patients that ruptures, survives. In contrast, mortality for AAA treatment, especially by the endovascular method, can be lower than 2 %. We also know that patients that survive treatment have a life expectancy only slightly lower than individuals of their age. Prevention of rupture, which prevents all the other complications as well, is the only effective way of treatment.

As everything in Medicine, we must take into account individual variations, clinical evidences and all the accumulated knowledge, that points to a diameter of 5 cm as a flow divider between living with, or risking to die as a consequence of a AAA.

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History of Endovascular Aneurysm Repair

3

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The first report in this field is "The Ebers Papyrus" (2000 BC). The writer describes a probable peripheral aneurysm, and recommends "treat it with a knife and burned it with a fire so that it bleeds not too much." Many others reports by other authors described the problem and proposed different kinds of treatments, like Galen (A.D. 131–200), Antyllus (a second century Greek surgeon), Aetius of Amida in his book "De Vasorum Dilatatione" (77th century), Ambroise Paré (1510–1590), Andreas Vesallius, John Hunter (1785), Astley Paston Cooper (1817), Rudolph Matas, (April 9, 1923). All of them developed and continued the concept of "ligation and treat the sac." But the new era of aneurysm repair were made possible by Alexis Carrel (1873–1948), an expert who prepared and used his own silk sutures with vaseline. He demonstrated in animals that a segment of aorta could be replaced with a piece of another artery or vein, and successfully anastomosed blood vessels. In 1912, he was awarded with the Nobel Prize for his work. He wrote about the intubation of blood vessels, the seeds of the endovascular concept".

The treatment of the aneurysm evolved from "coagulation", to "ligation", and finally "replacement", however the "endovascular treatment", in the middle of the twentieth century, still needed to be developed through new techniques and specialized tools.

The "Endovascular Era"

In November 8, 1895, Wilhelm Konrad Roentgen discovered the X-rays (Nobel Prize in 1901). In 1929, Reynaldo do Santos (Portugal), performed the first translumbar aortogram. In the same year, Werner Forssman (1904–1979) inserted a "well oiled ureteral catheter" in his own antecubital vein, to perform an angiocardiography (Nobel Prize in 1956). In 1941, Pedro Fariñas from Cuba, described the complete examination of the aorta by the translumbar approach plus the catheterization of the femoral artery. Nevertheless in 1953, a revolutionary method that will persist till this era was described by a Swedish cardiologist named Sven-Ivar Seldinger, the percutaneous puncture and catheterization of the arterial system, "The Seldinger Technique." Before graduation as a doctor, in 1960 Thomas Fogarty,

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developed the embolectomy balloon catheter with a urethral catheter with the tip of a five-size latex glove, attached in the distal end like a "fly-fishing flies". In 1965 he published a "new method for extraction of arterial emboli and thrombi." The first device of the endovascular era was created …!

In January 1964, Charles Dotter, a radiologist from Portland, Oregon, performed the first peripheral angioplasty using a Teflon dilating catheter (co-axial system). Five years later, he reported successful endovascular placement of open coil-spring tube graft in canine popliteal arteries (not applied clinically due to significant intracoil stenosis). By the end of the 1970s, the techniques, the tools, and the images had evolved, but the last detail that vascular surgeon needed to start the revolution of EVAR was a simple and bright concept.

In 1976, Juan Carlos Parodi, a resident at the Cleveland Clinic in Ohio, conceived the idea of introducing a polyester graft into an artery from a remote site under fluoroscopy. This approach would change the horizons of vascular surgery for the next decades until the present. The initial device was made from two pieces of stainless steel, called "cages", united by two bridges of wires forming a cylinder, which was covered by a polyester graft. The device was loaded into a sheath. The initial experimental results were disappointed but the idea persisted in Parodi's mind. In 1984, LeMolle described the insertion of a prosthetic graft into aorta. In 1986, A. Balko et al. demonstrated that intraluminal AAA exclusion could be achieved in dog models. The prosthesis consisted of biomedical grade elastomeric polyurethane with a nitinol frame and was designed in such a configuration that it could be compressed inside a 15Fr catheter and then return to its original shape after being deployed inside the aorta. Preclinical developments followed in several centers around the world focused predominantly on three areas: determining the best mechanism to provide graft fixation; identifying an ideal conduit to repair the vascular defect; and developing techniques to deliver an endograft. Lawrence et al. used a Dacron-wrapped Gianturco stent. Mirich et al. tested a modified Gianturco stent covered with nylon, and Laborde et al. tried a weft-knit Dacron tube with balloon-expandable stents in dogs for the same purpose. Although these devices could be percutaneously implanted to bridge and exclude an aneurysm, complications such as stent thrombosis and renal ischemia from placement across arterial branches occurred due to the design of the device.

In the meantime, Julio Palmaz, radiologist at the Health Science Center of the University of Texas, developed the balloon expandable stent. Parodi took the Palmaz's stent and in conjunction with an engineer in Buenos Aires, Hector Barone, (vascular graft manufacture), continued their research with the EVAR feasibility study. In 1987, after having created aortic aneurysms in dogs, they inserted a knitted Dacron tube fixed proximally with the balloon expandable stents.

In September 6, 1990 Parodi performed the two first cases. The procedure in a 70-year-old-male concluded successfully (Fig. 3.1). The second patient was converted to open repair. That night, since the second patient was still under mechanical respiratory support, the first one took his dinner. This and four more successful procedures were encouraging to the group. The first five cases of AAA endovascular repair were reported in 1991, at the Annals of Vascular Surgery by Dr. Parodi. Soon, they realized that the Dacron graft had to be attached at both ends to prevent retrograde leaking at the aortic bifurcation (Fig. 3.2). In 1995, once again reported the large clinical series of 50 patients, not only aorto-aortic but also the new aorto-uni-iliac + fem-fem by-pass configurations, as a response of different anatomies (Fig. 3.3). All grafts were "hand-made" by Dr. Parodi and his team, attaching tubes of polyester graft or over-expanded 8 mm PTFE grafts, with 6 "0" prolene to the stents, adding radiopaque gold marks on the top, mounted over a super size aortic angioplasty balloon, into a 28Fr sheats, always following the drawings of the team leader. To create a noose-comb at the proximal end of the stent-graft, they used the aortic balloon slightly inflated. The last step was to load inside the 28fr. sheats, using a long suture of silk, to constrain the device. And adventure of 2 or 3 h … To "navigate" with those rigid and big deliv-

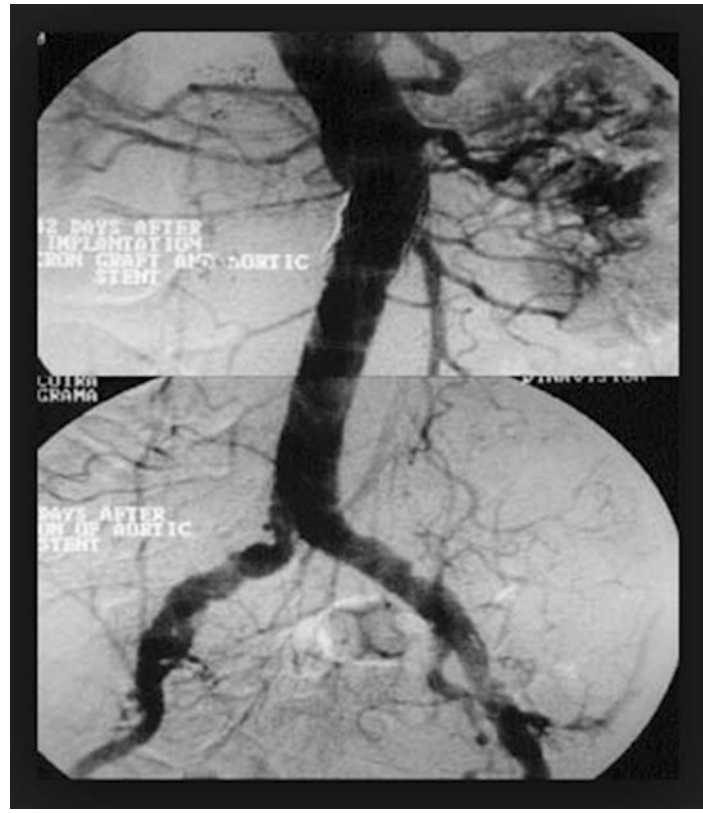

Fig. 3.1 Aortography of Patient Number 1 treated with implantation of graft-stent combination. After: Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg. 1991;5(6):491–9

ery systems into the artery, in most of the cases they performed the "throw and throw technique brachial to femoral". There was a lot of accidents: occlusion or dissections of vessels access, disconnection (graft to stents), graft twisting, and iliac ruptures. Long hours of bench working to manufacture the devices, as well as long surgery hours (more than 10, in some cases), and too much radiation. There were hard times, with sweet and bitter moments. Usually the patients were not ideal (anatomically less than 30%). But the most difficult part was to persist with the endovascular idea, even in the worst moments, sometimes with poor results, against the different opinions of famous and traditional surgeons all over the world, performing "open" surgery with the "endovascular approach" always in mind. Every time, every surgery, became in a "brainstorming" moment, thinking how to resolve different problems with endovascular skills. Then, the Parodi's World Tour started. The first TEVAR, in the setting of type A dissection, was performed in 1991 by the same group in Argentina.

The term "transluminal placement of endograft" was introduced in 1994 by Dr. Frank Veith from the Montefiore Medical Center in New York. He performed, with Juan Parodi and Michel Marin, the first case in United States in November 23, 1992 (Fig. 3.4). The logical extension of the ESG concept to long segment arterial occlusive disease, aneurysms of the thoracic aorta and peripheral arteries and vascular trauma soon followed.

On the opposite site of the globe, Nicholas Volodos from Karkhov, Ukraine, had been developing a Z-shaped radial cylindrical spring, for the treatment of occlusive and aneurysmatic disease.

The next step was the development of a bifurcated stent-graft. In 1992, Timothy Chuter from UCLA, developed the technique of endovascular placement of one-piece bifurcated non-sup-

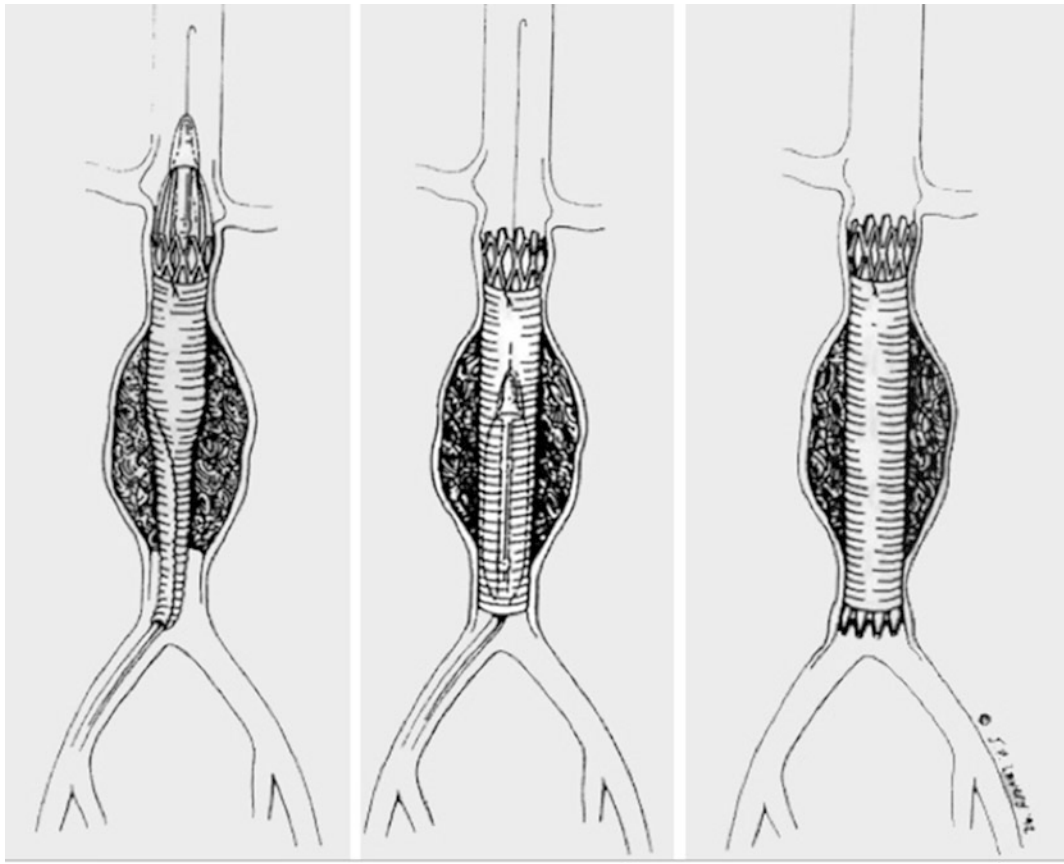

Fig. 3.2 Deployment and distal sealing of a graft-stent combination with cephalic stent. After: Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg. 1991;5(6):491–9

ported endograft. The first patient was operated on in October 1993. The non-fully supported Endovascular Technology Endograft (EVT) was the first industry-made device to undergo clinical trials. Unfortunately, the results were disappointing, and the device was recalled. The complications related to it, led to the design of modular, fully supported stent grafts, commercially available in 1994. Those thermo-expandable, modular and lower profile devices came from Mintec, called Stentor, then acquired and launched by Boston Scientific under the name of Vanguard. The first Stentor was deployed in Argentina at the beginning of 1995. The era of the home-made devices had finished. Migration, distal embolization and arterial rupture were related to the profile and flexibility of the former devices. One year later, Parodi and coworkers implanted the first Vanguard. At that time, less than 40 % of the patients were operated endoluminally and only in few institutions in Argentina. There followed a rapid progression from a tube graft design to the currently used bifurcated systems. The first Zenith was implanted at the Instituto Cardiovascular de Buenos Aires at the end of 1999, assisted by R. Greenberg. The first EVAR with Excluder was performed in 2000. In October 14, 1997, a stent-graft named "ProGraft" (a predecessor of Hemoband an Viabhan) was implanted at the same institution in Buenos Aires by Dr. Parodi and his team (first implant in the world), by a contralateral approach, with poor results, to treat an iliac lession. Another device tested for the same team in those years was Corvita from Schneider. A self-expandable elgiloy + polyurethane stent graft, that was discontinued due to its poor results.

Unfortunately, within a short time, some of these second-generation devices were withdrawn

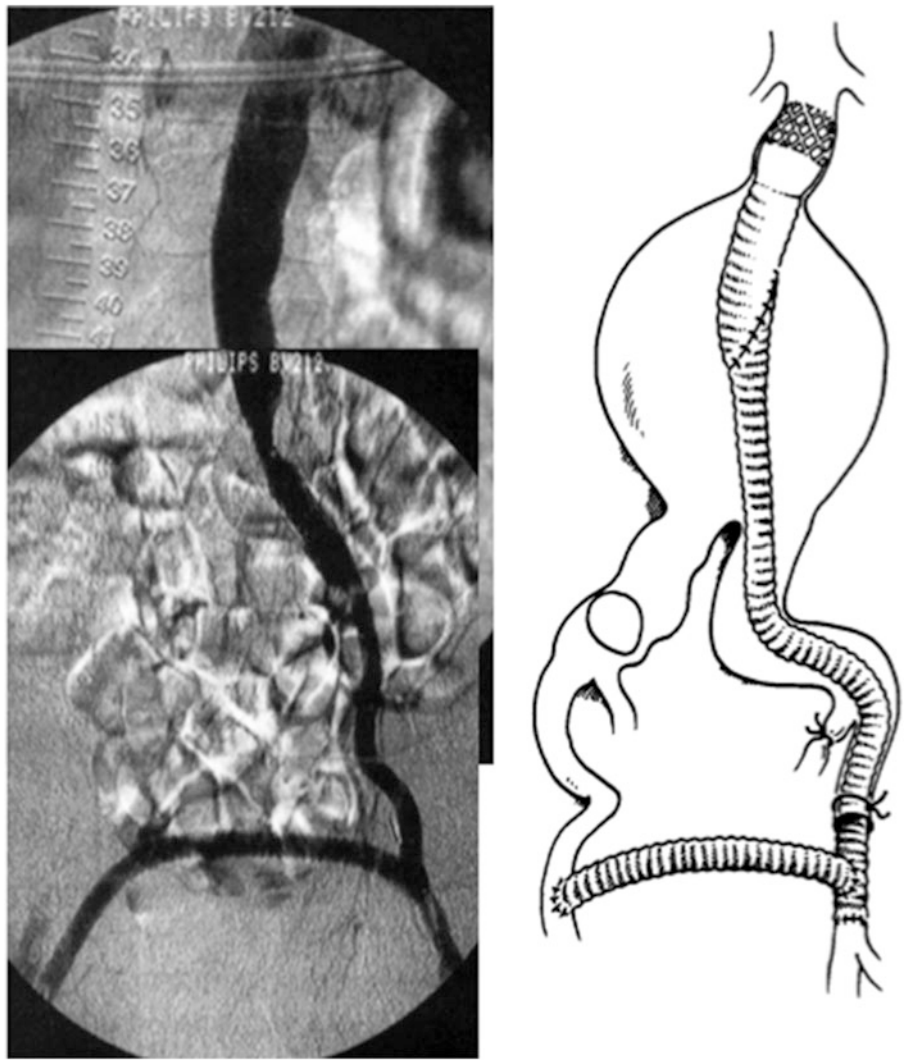

Fig. 3.3 Completion angiogram of aneurysm treated with unilateral stent graft and crossover femoral-femoral graft. After: Marin ML, Veith FJ, Cynamon J, Sanchez LA, Wengerter KR, Schwartz ML, Parodi JC, Panetta TF, Bakal CW, Suggs WD. Transfemoral endovascular stented graft treatment of aorto-iliac and femoropopliteal occlusive disease for limb salvage. Am J Surg. 1994;168(2):156–62

due to structural failures, such as hook fractures, disruption between stents rows with the clinical consequences of migration and leaks.

Currently, more than 15 improved stent-grafts are available in our market. Nowadays, EVAR has become a routine procedure in most patients with AAA. Recent data show that more than 70 % of AAA repairs in our country were done via an endovascular approach.

Within 5 years, commercially manufactured endografts began to undergo clinical trials in the United States, culminating in the first commercially available devices for endovascular aneurysm repair (EVAR) in September 1999. In Europe and Australia, aortic endografts were available earlier because of differences in governmental regulation. Second and third-generation endografts provided improvements in fixation, sizing versatility, and delivery profile. All devices underwent refinements after their initial release, improving both long-term outcome and the applicability of EVAR. Endografts for thoracic endovascular aortic repair (TEVAR) began clinical trials at the turn of the twenty-first

Fig. 3.4 Photograph showing performance of the first EVAR in New York

century, culminating in the first commercially available device in the United States in 2005. In Europe the AneuRx bifurcated aortobiiliac stent-graft received the Regulatory Approval in 1996, the Excluder bifurcated aortobiiliac stent-graft in 1997, Talent bifurcated aortobiiliac stent-graft in 1998, Zenith bifurcated aortobiiliac stent-graft in 1999 and the Aorfix bifurcated aortobiiliac stent-graft in 2001.

Anaconda bifurcated aortobiiliac stent graft was approved in 2005. In the United States, AneuRx bifurcated aortobiiliac stent-graft was approved in 2001, the Excluder SG in 2002, and the Zenith SG in 2003.

Endovascular repair has become the preferred treatment modality for the majority of abdominal and thoracic aortic aneurysms. Other thoracic pathology, including traumatic transection and type B dissection with malperfusion, is also being treated preferentially with endografts. This is because endovascular repair has demonstrated improved perioperative mortality and major morbidity in both infrarenal and thoracic locations when compared with traditional open repair. These improvements in perioperative safety and the technique's minimally invasive nature have been the primary drivers of these remarkable changes in our practice.

The results of endovascular repair of abdominal aortic aneurysms have improved steadily over the past 25 years as the lessons of clinical experience were incorporated into device designs. Those writing the history of aneurysms in the future will have to deal with the development of screening and its influence on aneurysm mortality in the population, with better ways of selecting patients according to the rupture risk, with more durable endovascular technology, and with more detailed knowledge in order to prevent the disease through pharmacological methods.

Current Management of Abdominal Aortic Aneurysm in Australia

4

D.A. Robinson and J. May

The advent of endovascular technology has led to a major shift in the way that patients with vascular disease in general and AAA in particular are treated throughout the majority of the developed world. Australia is no exception, due in no small part to the early adoption and development of endovascular technology on these shores.

Australian Experience in the Early Stages of EVAR

The first endovascular AAA repair in Australia was performed on 27 May 1992 by the Sydney group based at the Department of Surgery, University of Sydney and the Royal Prince Alfred Hospital. At this time Parodi [1] had performed 15 endovascular AAA repairs. He was incredibly generous in sharing his knowledge and experience when the senior author visited him in Buenos Aires in that year and in December 1993 as an invited member of faculty at the First International Endovascular Symposium held at Royal Prince Alfred Hospital. Endovascular repair of AAA using endografts constructed from component materials currently in use at that time in vascular surgery was approved by the Institutional Review Board. By September 1994 there were three groups in the world with an experience of endovascular AAA repair exceeding 50 patients each. These were:

1. Parodi and his colleagues,
2. Endovascular Technologies (EVT), a Californian based company who were conducting a multicentre FDA approved pilot study of their device and
3. The Sydney group.

The main objective of the Sydney group was to validate the endovascular method of AAA repair and more importantly to document the complications of the procedure. The latter was particularly important as there was a general impression amongst vascular surgeons that the procedure would be straight forward and free from major problems. It was also important of course since most of the complications were unknown and did not occur following open AAA repair. The particular contributions by Sydney group included:

1. By 1994 the feasibility of endovascular AAA repair had clearly been established. However, the risks and long term outcome remained unclear. With the enthusiasm that accompanies

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any new technology there is a tendency for these to be overlooked. With this in mind the group presented their experience of endovascular AAA with special emphasis on complications and their surgical management at the European Society for Vascular Surgery in 1994 which was subsequently published in the *European Journal of Vascular and Endovascular Surgery* [2]

2. A prospective study of changes in morphology and dimensions of AAA following endovascular repair was published in the *Journal of Endovascular Surgery* in November 1995 [3, 4]. This documented, for the first time, that the majority of AAAs in which the sac had been excluded from the circulation diminished in size following successful endovascular repair. An increase in size was also reported in those AAAs in which a communication existed between the aortic lumen and the sac.
3. First report of endovascular repair of a false aneurysm [3]
4. First report of endovascular repair of a dissecting aneurysm of descending thoracic aorta and fusiform aneurysm of the abdominal aorta [5].
5. The enthusiasm which followed the demonstration of the feasibility of endovascular AAA repair led some proponents to suggest that the method may be attempted and, if unsuccessful, be converted to an open repair with little disadvantage to the patient. The Sydney group presented a paper at the European society for Vascular Surgery in Venice in 1996 titled "*Conversion from Endoluminal to Open Repair of AAA: A Hazardous Procedure*". In this paper, subsequently published in *Eur J Vasc Endovasc Surg* [6, 7] it was pointed out why this was an oversimplification. Firstly, the technique of open repair following failed endovascular repair is more complicated than a standard elective open repair. Secondly most conversions come after a prolonged radiological guided procedure using large quantities of contrast.
6. The introduction of the term *endoleak* as a complication unique to endovascular grafting, its division into Type 1 (graft related) and Type 2 (collateral artery related) [7] and subsequent classification extending to Types 3, 4 and 5 were published in the Journal of Endovascular Surgery [7, 8].

Perth Group Contributions

The Perth group performed their first endovascular repair of AAA in 1993. They worked in conjunction with the Cook Company, commencing with the basic physics and the established laws of flow in liquids to design an endovascular device for repair of AAA. They worked through several iterations of devices which led to what is now known as the Zenith endograft. An example of how this methodology favourably influenced their design was the increased length of the body of the endograft which reduces the downward force compared with a short body and long limbs.

Their studies also demonstrated that the bare stent struts across the orifices of the renal arteries would not have harmful side effects but would add considerably to the stability of the endograft.

One of the major contributions of the Perth Group, in conjunction with John Anderson from Adelaide, was to design and clinically trial the first commercially produced endograft with fenestrations for the renal and visceral segment of the abdominal aorta.

Current Australian Experience with EVAR and the Management of AAA

There is some epidemiological evidence to suggest that there has been a decrease in the incidence of AAA in Australia [9] possibly attributable to a decrease in smoking seen since the early 1990s. Nonetheless, the number of admissions and procedures for AAA seems to have been relatively stable since the introduction of the Australasian Vascular Audit in 2010. The Australasian Vascular Audit is a binational audit of vascular surgery in Australia and New Zealand, and captures procedures done in the public health

system and a majority of procedures done in the private system (not all private hospitals participate in the audit). The majority of information regarding aortic procedures in this article has been derived from the AVA for the period 2010–2014. In the case where data is not available from the AVA, we have based the discussion on the standard practice of our unit, and the experience of the first author in the units in which he has worked.

Despite studies that have shown a benefit to screening for AAA [10, 11] there has not been a move to establish a formal screening program in Australia. Nonetheless, universal insurance in the form of Medicare and the widespread availability of routine radiology in both the public and private sector mean that many AAA are found at an early stage of their development. The majority of patients diagnosed with a small AAA will be entered into some form of surveillance program; this entails a referral either to a vascular surgeon or a vascular unit at a public hospital. The frequency of surveillance is generally guided by SVS recommendations [12] although adherence to these guidelines is variable. Both ultrasound and computed tomography are readily available in most communities, and as an initial test are performed fairly equally. Most vascular surgeons overseeing the surveillance of AAA will follow up with duplex ultrasound in view of savings in cost, and a decrease in exposure to radiation and complications related to contrast. However, patients with an AAA that reaches a size requiring repair will have a CT angiogram to assess the AAA and look for suitability for endovascular repair. The previous practice of catheter angiography to assess AAA prior to EVAR has become much less common and now is confined mostly to patients having complex endovascular repairs such as fenestrated grafts, where pre-procedural angiography can flag difficulties with cannulating significant branches and other possible intraoperative issues. The threshold for AAA repair in Australia does vary slightly from unit to unit—the majority of surgeons use 5.5 cm as their cut off, although some units use 5.5 cm for males and 5 cm for women, while other units use 5 cm for all comers. Occasionally AAA will be repaired at a diameter of less than 5 cm—generally in cases where the AAA is saccular, has enlarged significantly during surveillance, or where the AAA is symptomatic. Suggestions that AAA should be repaired via an endovascular approach at a smaller size (due to decreasing suitability for EVAR at larger sizes) have not been adopted by the vascular community at large. The results from trials to date looking at EVAR in smaller AAA [13, 14] suggest that it unlikely that this policy will change in the near future.

Once the decision has been made to treat a AAA, most patients will be assessed preoperatively as an outpatient. The majority of surgeons will refer a patient with a AAA for a cardiology review preoperatively, even if they are asymptomatic from a coronary point of view. The association between AAA and coronary artery disease is well known, although the advent of less invasive techniques to treat AAA have decreased the incidence of postoperative cardiac complications. The majority of patients being worked up for AAA repair will have an echocardiogram and some form of stress test, with a general preference for a nuclear medicine myocardial perfusion scan, depending on availability. A significant abnormality on the perfusion scan may lead to a coronary angiogram, depending on the clinical context. Even in patients who do not have a coronary intervention, early involvement of a cardiologist leads to a high degree of continuity of care throughout the perioperative period.

Preoperative anaesthetic review is also carried out routinely in the public sector—in the private hospital setting this may be less routine. Review of the patient, possible problem areas and review of medications and other pertinent issues usually take place at this point. The aim of this exercise is to enable day of surgery admission for these patients with a view to minimising length of stay, and in the majority of cases this is able to be done. Exceptions are made for complex patients and occasionally for those from remote areas.

In selecting the appropriate operation for patients with a AAA, the evidence suggests that most units are adopting an EVAR first policy, with a significant majority (72 %) of patients having the AAA repaired in this fashion [15].

Nonetheless, there are some units that have a clear preference for open repair of AAA. In general terms, young patients and those who are unlikely or unwilling to be followed up on a regular basis are the only other group who will be offered open repair in preference to EVAR, in the majority of Australian units. The preferred EVAR graft continues to be various iterations of the Cook bifurcated device. The next most commonly used devices are the Medtronic Endurant and then the Gore Excluder. Other devices have been used in Australia in small amounts, including the Anaconda, and the Ovation. However, apart from the Anaconda that has seen some fairly regular usage, none of the other devices have seen significant uptake in the Australian market. The availability of the Nellix EVAS (endovascular aneurysm sealing) device has been awaited in Australia for some time now and its unique approach to the prevention of type 2 endoleaks appears promising. The device has had its initial deployment in several units in Australia as of the writing of this article. Planning grafts is done by the treating surgeon, but in addition, up to 75 % will submit the patient's imaging for planning by a representative of the company supplying the device they intend to use. In those cases where the surgeon plans the graft themselves, Osirix for the Mac platform is a popular option for assessing the anatomy. The use of more sophisticated planning software seems to be confined to the device companies.

Most EVAR are done under general anaesthesia (92 %) [15], although some units have adopted a predominantly regional anaesthesia policy. The venue varies depending on available resources—at the time of the first author's training in the late 1990s and early 2000s, the majority were done in a standard operating theatre with a mobile C-arm, while now increasing numbers of hospitals have dedicated hybrid theatres that provide superior imaging while maintaining the advantages of a theatre setting as opposed to a radiology suite. The trend overall has been to the establishment of hybrid theatres in units performing elective vascular surgery although there is still some way to go. At of the time of writing, in Australia there were 38 hybrid theatres. The remaining units are fairly evenly split between those performing their EVAR procedures in a radiology suite, and those using mobile imaging in the operating theatre.

Percutaneous access, using the Proglide device as part of a preclose technique, has been enthusiastically adopted, with 65 % of EVAR done using this technique [15]. In the public sector, generally patients are sent to the vascular ward postoperatively, while in private it would appear that the majority are sent to ICU overnight for monitoring. Postoperative follow up varies widely between units. In our unit currently the protocol is simply for a postoperative duplex prior to discharge, unless there has been an area of concern on the completion angiogram such as a type 1 that fails to resolve despite adjunctive measures such as further angioplasty or cuffing. This practice has recently had further validation with research demonstrating that patients with an absence of concerning features on their early postoperative imaging are unlikely to require late reintervention for endoleaks or other graft related problems [16]. However, it is still common practice in many units to obtain a CT angiogram prior to discharge. The utility of adjunctive imaging procedures intraoperatively such as fusion of preoperative CT information and intraoperative fluoroscopy is still being assessed in some units with such capability and is not widely used at the present time. In some units performing fenestrated and branched repair, this technique is used more regularly. There is some experience in Australia with the use of CO_2 angiography for the deployment of endografts in patients with significant renal impairment or contrast allergy, although the use of this technique has certainly not become widespread.

Although it appears there is a clear preference amongst both surgeons and patients for EVAR, a significant minority of repairs are performed open. Given that the number of surgeons performing open repairs and EVAR are similar, it is unlikely that there is a substantial number of surgeons who now continue to offer open repair only, although this was certainly the case in the early days of EVAR. In those patients having open repair, the length of stay is somewhat longer, as is the length of ICU admission, as would be expected. The perioperative mortality is

greater than EVAR (3.5 % vs 0.7 %) [15]. The use of high dependency units on the vascular ward as seen in some of the vascular units in the UK has never really taken off in Australia, with most patients having open repair returned to a general ICU postoperatively. Cell saver is routinely used in most units for these cases. The practice of banking blood preoperatively has remained relatively uncommon in Australia for elective vascular surgery.

An anecdotal observation amongst vascular surgeons in Australia is that the rate of patients presenting with ruptured or symptomatic AAA has decreased significantly over the past 10 years or so. Despite the preference for EVAR in the elective situation, in those patients presenting with a rupture the majority still have an open repair (73 %) [15]. Most of these repairs are done in major metropolitan centres, although the drive for centralisation of emergency services seen in the NHS has not manifested to the same degree in Australia. Those centres that have the capability of performing EVAR will generally offer EVAR for emergency repair, although this depends to a great degree on the availability of suitable support services in the form of anaesthesia and nursing out of hours. The introduction of appropriate hybrid theatres means that in a person presenting with a ruptured AAA, they can be taken immediately to the OR where an occlusion balloon can be introduced and further imaging performed to assess the suitability for emergency EVAR; in those patients who are unsuitable, a laparotomy can be performed without the necessity to transfer the patient.

In those patients unsuitable for standard EVAR, an increasing number of units now perform fenestrated or branched grafts, and iliac bifurcated devices are also becoming increasingly common in order to preserve the pelvic circulation in those patients with suitable anatomy. Nonetheless, these techniques are still relatively uncommon and the surgery tends to be concentrated in a small number of units. Overall, this group constituted about 10 % of the total AAA repairs performed during the period 2010–2014.

The majority of patients following EVAR are discharged to their home, although a substantial proportion of those having a rupture repaired will have a period in a rehabilitation facility prior to returning home. The majority of surgeons will follow up their own patients, although with people from remote centres, this may be outsourced to the family physician. The follow up protocol varies between individual surgeons. Early in the EVAR experience, the majority of follow ups were done with sequential CT angiography. There has been a move away from this recently in order to minimise long term exposure to contrast and ionising radiation. In the first author's practice, patients with an uncomplicated repair and no expectation of problems will often be followed up with duplex alone, as long as the examinations are done in a radiology or vascular surgery practice with suitable experience—studies that are performed in general radiology practices may to be uninformative, especially in the setting of an endoleaks or other technical problem, and end up needing to be repeated. Some surgeons will perform alternate CT angiography and duplex examinations. Our practice is only to perform CTA if the duplex demonstrates sac enlargement or other problems, and is usually performed with a view to planning the appropriate intervention. One of the problems that we have identified that will be common to anywhere with a relatively decentralised population similar to Australia, is that people who come from a rural setting may have an endovascular repair offered in a metropolitan centre and then fail to attend their follow up, only to present at some time in the future with a rupture from an unrecognised technical problem with the graft or endoleak. It has certainly happened often enough in our practice to suggest that those patients who are unlikely to attend follow up should be offered an open repair, or at the very least counselled vigorously about the necessity of attending follow up. Of course, there is no guarantee that an open repair will not have long term complications either, and the majority of surgeons in Australia tend to follow up their open repairs over time, although less often than patients having EVAR.

Conclusion

Endovascular repair of aortic aneurysm is clearly established as the preferred treatment of abdominal aortic aneurysm in Australia, due at least partly to the pioneering spirit of the surgeons involved in the early development of the technology. The current changes to the regulatory environment curtail that spirit to some extent, but we hope that Australian surgeons will continue to innovate and lead the field in this technology.

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Endovascular Aneurysm Repair: Indications for Treatment

5

Luis Mariano Ferreira and Elvio Demicheli

There is general agreement that small fusiform aneurysms, less than 5 cm maximum diameter, are at low risk of rupture and should be monitored. On the other hand, a fusiform aneurysm greater than 5.4 cm in maximum diameter should be repaired, especially in a healthy patient. Evidence is based on two trials, the United Kingdom Small Aneurysm Trial (UKSAT) [1] and Aneurysm Detection and Management (ADAM) Trial [2]. Investigators found no statistically significant difference in long-term survival between the immediate surgery and surveillance groups. Other two more recent trials The Comparison of Surveillance vs Endografting for Small Aneurysm Repair (CAESAR) [3] and Positive Impact of Endovascular Options for Treating Aneurysm Early (PIVOTAL) [4] trials compare immediate EVAR with surveillance and selective EVAR. Again, potential benefits of early surgery were noted in younger patients and those with aneurysms in whom the anatomically endovascular suitability can be lose. However in Argentina most of the recommendations are based on 5 cm cutoff. There some specific indications in those patients with short and thrombus lined proximal neck, especially if the EVAR approach was selected. The question is related to the timing of repair. Surveillance can be associated to dilatation of the neck. Interested in the CEASAR trial, mortality and rupture rates in AAA <5.5 cm are low and no clear advantage was shown between early or delayed EVAR strategy. However, within 36 months, three out of every five small aneurysms under surveillance has grown to require repair and one out of every six has lost feasibility for EVAR [3].

The second important aspect in this chapter is the indicated approach. The approach to aortic pathology is nowadays more endovascular at both thoracic and abdominal segment. Thoracic endografting has gained worldwide acceptance as first intention to treat pathologies of the descending thoracic aorta. Indications have been extended to aortic arch aneurysms and also to diseases of the ascending aorta. Certainly, the choice of the endograft depends on the thoracic pathology and the anatomical suitability. The technological evolution of the abdominal aortic endografts was very rapid, arriving now at the fourth generation devices. The overall mortality is less than 2%. EVAR tends to become the gold standard for abdominal aortic aneurysm repair. Technological development of the devices with lowest profile introduction systems and more adaptability to the proximal and distal necks will permit to extend the anatomical indications to new frontiers.

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Unfortunately, the current recommendation from our Argentinean Society of Cardiology relegates EVAR only for high-risk patients, or those with contraindications to open surgery (hostile abdomen, for example) [5]. However a recent publication of our CELA Society (Cirujanos Endovasculares de LatinoAmérica, Endovascular Surgeons of Latin-America) [6], supported by the American and European recommendations, and in the same way of our practice, makes it clear that the decision should be based on the anatomical aspects and preferences of both the surgeon and the patient.

Current Indications of Endovascular Treatment (CELA Recommendations)

- Open or endovascular repair of infrarenal AAA and/or common iliac aneurysm should be indicated in patients who are good surgical candidates (recommendation I, level of evidence A).
- It should be considered the patient's preference for the type of repair. (Recommendation II. Level B)
- Endovascular repair of infrarenal AAA is reasonable in patients at high risk of complications during open surgery, cardio-respiratory diseases or another severe comorbidities. (Recommendation IIb Level C)
- All patients with aneurysms over 5.5 cm in men and 5.2 cm for women should be referred for urgent surgical opinion (within 2 weeks from diagnosis) and for planning intervention before aneurysm rupture. (Recommendation IIa, Level of Evidence C).
- A patient may be considered for emergency EVAR when the aneurysm is larger than 9 cm in diameter. (Recommendation IIb, Level C)
- In symptomatic patients with adequate anatomical morphology (IFU recommendation), EVAR should be offered first, associated with lower operative mortality. (Recommendation IIa, level of evidence A).

Unofficial data showed that almost 80 % of our patients are treated endoluminally, but less than 10 % in the emergency fashion did, most related to logistic complications.

The appropriate size for the aortic endograft must be selected based on patient anatomy: according to the instructions for use, the diameter of the device should be oversize 15–20 % greater than the diameter aortic neck for optimal sealing. Several devices are available today for treating abdominal aneurysms, almost twelve in Argentina, which differ in design, profile, modularity, metal composition and structure of the stent, porosity and the presence or absence of an active method of anchoring to the aortic wall. The overall performance among the current generation of aortic devices is quite similar and the data seem to confirm the low rate of complications.

Endovascular repair of complex aneurysms involving the visceral arteries has become a reality. Fenestrated endovascular aortic repair (FEVAR) has been used with increasing frequency to treat complex aortic aneurysms. Nowadays we have also the possibility to offer custom made devices (CMD) for patients with complex anatomy. In cases of short or unsuitable proximal neck, we are using CMD with fenestrations, showing promising results. Mortality and morbidity are low in properly selected patients treated in centers with experience in these procedures. Nevertheless, FEVAR is a complex procedure that demands accurate planning, advanced endovascular skills, and excellent perioperative patient care to achieve optimal outcomes.

There are alternative techniques such as the chimneys or 'snorkel', in which parallel to the aortic endograft (between the wall of the aorta and the device) another covered stent is implanted to preserve flow to some or all branches of the visceral aorta. This technique, although it was initially introduced as a rescue procedure in occluded accidentally branches, it is being used in elective patients as an alternative treatment with fenestrated endograft. In the few existing publications, usually personal experiences, this approach clearly produced more type I endoleak when compared with fenestrated stent. In recent years, chimneys also has been used to treat electively juxtarenal aneurysms, especially at centers where treatment by fenestrations still not available or are not reimbursed.

Rupture is the most serious and lethal complication of the abdominal aortic aneurysm. Despite all improvements during the past 50 years, ruptured abdominal aortic aneurysms are still associated with very high mortality. Namely, including patients who die before reaching the hospital, the mortality rate due to abdominal aortic aneurysm rupture is 90 %. On the other hand, during the last 20 years, the number of abdominal aortic aneurysms significantly increased. One of the reasons is the fact that in majority of countries the general population is older nowadays. This is also the case for patients with abdominal aortic aneurysm rupture. Optimal therapeutic option should be found. Options in undeveloped countries are apply without a sufficient level of evidence. Thirty-day-mortality after repair of ruptured abdominal aortic aneurysms is significantly lower in high-volume hospitals. Due to different reasons all ruptured abdominal aortic aneurysms are not suitable for EVAR. There is no ideal procedure for the treatment of AAA. Open repair of ruptured abdominal aortic aneurysm should be performed by experienced open vascular surgeons. This could also be said for the treatment of endovascular complications that require open surgical conversion. Each has its own advantages and disadvantages, its own limits and complications, as well as indications and contraindications. Future reductions in mortality of ruptured abdominal aortic aneurysms will depend on implementation of population-based screening programme.

- The emergency endovascular treatment should be considered for treating a rAAA, if anatomically feasible. (Grade of recommendation I, level of evidence: A) [6]

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6 Endovascular Aneurysm Repair Versus Open Repair in Patients with Abdominal Aortic Aneurysm

Alvaro Razuk-Filho, Jong Hun Park, and Thiago Barroso

Nowadays aortic aneurysms repair are performed by two techniques: open and endovascular surgery. New technologies are constantly transforming and improving the daily surgical and clinical practice. However, caution and criticism should be adopted when we intend to incorporate these innovations in our current practice. Solid scientific studies must prove their safety and effectiveness over the years.

Main trials comparing endovascular and open aneurysm repair showed lower mortality rates, lower hospitalization time and faster recovery for EVAR group. However one must consider that these are short and mid-term results. What about the long-term results?

A new technology must fullfill some criteria to overcome a standard surgical practice. In such scenario, its results must be equivalent or better than the standard one.

The main purpose of this chapter is to analyse the results from the three most important trials that compares OPEN and EVAR regarding the safety and effectivenes. They are multicentric, prospective and randomized controlled trials with strong level of scientific evidence (Level 1 evidence).

They are:

- EVAR-1 (Endovascular Aneurysm Repair 1) from the United Kingdom [1–3]
- DREAM (Dutch Randomised Endovascular Aneurysm Management) from Netherlands and Belgium [4]
- OVER (Open versus Endovascular Repair) from the USA [5].

Safety

The safety for both techniques was evaluated with 30-day mortality, which is defined as every death related to the procedure under the first 30 days of postoperative period. The results of these trials are summarized in Table 6.1.

According to these data, EVAR is safer than open surgery. For example, the risk of death in EVAR-1 is 1:60 with EVAR versus 1:20 with open surgery. It represents a relative risk reduction of 65 % [1, 2].

In this respect, endovascular repair is superior to open repair.

Efficacy

The best predictor to evaluate long-term efficacy is aneurysm-related mortality. Since the majority of the patients suffering from abdominal aortic aneurysm are elderly and have significant

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Table 6.1 Mortality rates from EVAR-1, DREAM and OVER

	OPEN (%)	EVAR (%)	p
EVAR-1	4.7	1.7	0.009
DREAM	4.6	1.2	0.01
OVER	3	0.5	<0.05

cardiovascular comorbidities, mortality rates might be misrepresentative.

EVAR-1 showed similar death rate in 4 years (mid-term results), with the two modalities. However, once aneurysm-related death rates were analysed there was a susteined 3 % difference between the groups, similar to 30-day mortality rate. Therefore, it looks clear that EVAR is superior to conventional repair in preventing aneurysm-related death.

Lederle et al. published the 2-year results from OVER in 2009, reporting 3 % for open surgery and 1.3 % for EVAR [5].

In this respect, the trials showed a difference of at least 3 % between the modalities in favour of endovascular repair.

There is no doubt that endovascular repair is superior to open repair in preventing aneurysm-related death. It does not matter whether this benefit is accrued early or late after the operation.

Demographic Data

What about the real world? How should we analyse these results under real world practice? Definitely, the best strategy is to analyse the national health regulatory agencies reports.

Demographic data are very limited and underreported in Brazil. It is a country with continental dimensions and great heterogenety and disparities between its states. DATASUS is the pubic healthcare system's database and the reports concerning to the referred subject (endovascular versus open surgery) is represented by southeast sates basically. So we present avarege data from January to June 2015 (SUS-Sistema Único de Saúde).

We compared the data from southeast region and whole country (Brazil). These data are summarized in Table 6.2 and indicates better results for endovascular technique.

Table 6.2 Comparison between data from Southeast (SE) states and Brazil. Reports from DATASUS [6]

	Open surgery		Endovascular surgery	
	Brazil	SE	Brazil	SE
Average hospital stay (days)	12.1	14.5	8.2	6.8
Mortality rate (%)	23	17	3	0
Hospitalization number	303	149	83	25

We noted a difference between the number of hospitalizations (452 for open surgery versus 108 for endovascular surgery). And this difference is beacuse of there is few sites allweded to do endovascular repair.

With the DATASUS population, the mortality rate is higher at the open surgery group. It is perceivable that there is great difference between both techniques in terms of mortality rates and average days of hospital stay, with clear advantages for endovascular technique. This trend has been sustained in the analysis of previous months.

As expected, lenght of stay after open repair is more than double of EVAR (mean 14.5 days at southeast vs. 6.8 days).

In the USA, the most representative data are Medicare's reports. Schermerhorn et al. [7] published a review from these data in 2008. The patients submitted to endavascular therapy are mostly male, elderly (over 85 years old) and presented several comorbidities such as prior conorary ischemic disease, congestive heart failure, chronic renal disease and obesity. Most of the patients treated with open surgery were under 75 years old. The mortality results from both techniques were similiar to the forementioned RCT's results (EVAR 1.2 % vs Open surgery 4.8 %).

Open surgery represents an independent mortality risk factor for elective abdominal aortic surgeries. Another important mortality predictive factors are age and female sex. Giles et al. [8] reported morbid obesity as a risk factor for both techniques.

Huber et al. [9] demonstrated high complications rates after open surgery in 2001 (32 %). Shermerhorn et al. [7] found a lot of complications

related to open surgery: acute renal insufficiency (RR 2.0), pneumonia (RR 1.89), traqueostomy (RR 7.46), acute mesenteric ischemia (RR 2.2), graft infection (RR 7.0) and major amputation (RR 3.0). In this same report, reintervation rate was 9 % for EVAR patients and 1.7 % for open surgery's ($p < 0.001$).

There has been a great evolution in endovascular technique by vascular surgeons worldwide and we stand in front of an incredible and continuous development of the surgical materials and solutions. According to the results of many scientific publications and important trials concerning this important matter, endovascular technique seems to do better compared to open surgery with improved outcomes and lesser complications rates.

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Thoracic Aortic Aneurysms in Brazil

7

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Thoracic aortic aneurysms (TAA) are true aneurysms located at the segments of the thoracic aorta [1, 2]. Ascending aortic aneurysms arise anywhere from the aortic valve to the innominate artery and affects 60 % of these patients. Aortic arch aneurysms, seen in 10 % of the patients, include any thoracic aneurysm that involves the brachiocephalic vessels. Descending aortic aneurysms are those distal to the left subclavian artery and are present in 40 % of these. Thoracoabdominal aneurysms, accounting for 10 %, involve any extension of the thoracic aorta, including the visceral segment. These categories help to stratify the approach to management.

Occur most commonly in the sixth and seventh decade of life and affect males approximately two times more commonly than females [3, 4].

It is generally accepted that the aneurysm diameter that indicates surgical TAA intervention should be larger than 6.5 cm [5] for the general population and 6.0 cm for patients with connective tissue disorders or with positive family history for aortic rupture or dissection [6]. Saccular configuration, symptomatic and the ruptured aneurysms also dictates intervention. The size recommendations are somewhat variable because no randomized trials exist to guide the decision-making process.

In Brazil, during the years 2008–2013, 3109 public health system users underwent surgical treatment of TAA. The median number of patients who underwent conventional or endovascular surgery were 86 and 443 respectively a year. It is observed a marked reduction in the number of conventional surgery over time and, conversely, increasing the number of endovascular surgery (http://www2.datasus.gov.br) (see Fig. 7.1).

Comparing the extremes of the period analyzed, it was observed that there was an increase of 1.2 % in the number of procedures performed by conventional means and increase of 48.72 % in endovascular procedures performed (http://www2.datasus.gov.br). In the United States between 2004 and 2007 there was an increase in the total number of procedures performed, with slight decrease in the frequency of procedures by the conventional method and sharp increase in the frequency of procedures by the endovascular method [7].

Though, considering the Brazilian population (more than 200 million people), we observe that the number of operated patients are very small.

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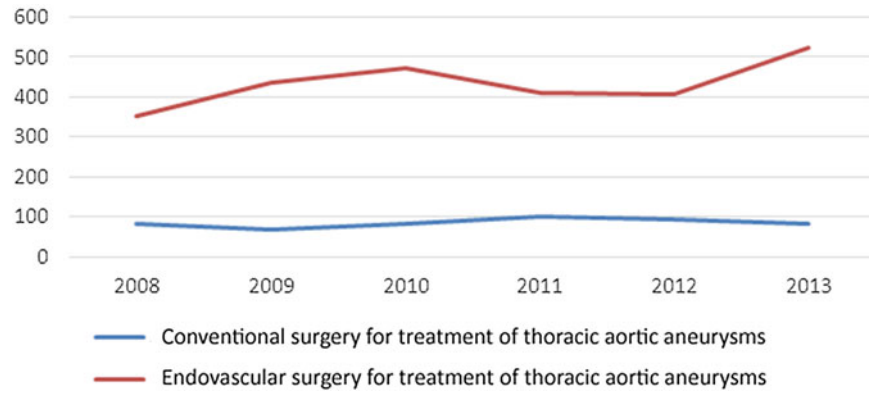

Fig. 7.1 Frequency of endovascular and conventional surgeries to treat thoracic aneurysm in Brazil, 2008–2013

So, we could assume that there are still many people dying from ruptured thoracic aneurysms.

The median number days of hospitalization of the patients undergoing conventional or endovascular surgery for TAA were 13 and 11 days in Brazil respectively (http://www2.datasus.gov.br). The mortality was 35.8 % for the conventional surgery and 8.76 % for endovascular surgery group (see Fig. 7.2). These mortality rates are significantly higher when compared to US and UK trials [8].

In Brazil, one can justify the high mortality observed, compared with American and European data, due to the fact that there is no specialized centers for thoracic aortic aneurysm. Some hospitals with small number of cases operate fewer patients and get worse results. Therefore, one could suggest that patients with TAAs would benefit from treatment at a high-volume center [8].

The UK implemented specialized centers, with an available vascular surgeon and a trained and focused multidisciplinary team, in order to concentrate therapy and generate high surgical volumes facilities, aiming at improved results. There is evidence that such changes achieved the desired result as the mortality rate of AAA intervention in England and Wales fell to 2.4 %, between 2008 and 2010 [9].

Similar to what occurred in the UK, the Brazilian health system should adopt policies to overcome their current rates. It should be proposed the development of reference centers, with well trained and specialized medical staff and a multidisciplinary team, besides adequate infrastructure. This would make possible concentrate the treatment in some hospitals, generating best surveillance and care of the Brazilian TAA's patients, as well high volume centers, in a way to take the Brazilian results close to the American and European's.

Brazil also shares the trend, similar to others countries, regarding the preference for endovascular procedure over conventional surgery for treatment of TAA. The main considerations for the TEVAR preference (Thoracic Endovascular Aneurysm Repair) are based on anatomy and comorbidities. There should be an appropriate landing zone (typically >15–20 mm) both proximally and distally to allow adequate sealing and exclusion of the aneurysm from the circulation, as well as appropriately sized arterial access to deliver the stent-graft to its desired location.

Anatomy, after all, is not the only parameter in treatment planning. Age and operative risk assessment also play a significant role in selecting the appropriate treatment modality. The majority of patients, on the other hand, do not have "ideal" anatomy for TEVAR, and the risk/benefit assessment becomes more complex. Many aneurysms impinge on a major arterial

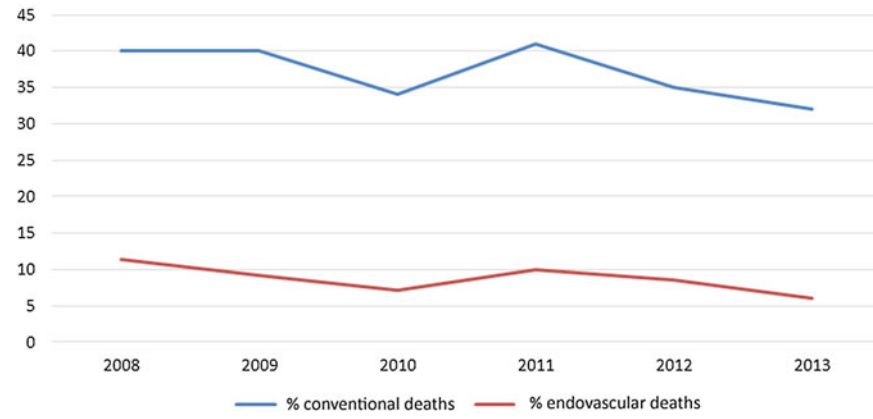

Fig. 7.2 Mortality rate related to conventional and endovascular surgery in Brazil, 2008–2013

branch that must be covered for adequate sealing.

In order to achieve technical success in the exclusion of the aneurysm procedure, there is often the need to overcome the anatomical difficulties, particularly where there is no adequate proximal landing zone, and for this it is necessary transposition or occlusion of large supraortic vessels. Ishimaru et al. [9] proposed a classification according to proximal landing zones.

Aneurysms located in zones 3 and 4 with a good zone of proximal anchor, greater than 1.5–2.0 cm in length, are treated as a regular TEVAR procedure [10].

Any how, many Brazilian patients do not have this ideal anatomy, what would require landing the endograft at zones 1 and 2. The most of these, being considered high-risk patients for conventional surgery, are directed for TEVAR (endovascular first approach).

In the case of landing the endograft in zone 2, it is necessary to cover the left subclavian artery, leading to complications inherent in this procedure, or to go for a hybrid procedure. The most common solution is a carotid-subclavian arterial bypass.

This approach is no different from others parts of the world.

Nevertheless, we have performed around 35 patients with left subclavian artery chimney in order to avoid the carotid subclavian artery by-pass. Anyhow, it was found a short term postoperative 11 % proximal endoleak rate, especially in aneurysms related to chronic dissections. Therefore, this approach was abandoned.

When the dilatation reaches the origin of the left carotid artery, Zone 1, there is a need for covering the subclavian and the left common carotid artery as well. To ensure cerebral blood circulation, we perform a carotid-carotid by-pass. The left subclavian artery may be or may be not revascularized with a carotid-subclavian bypass.

Some years ago, after an unintended occlusion of the left carotid artery, a stent was delivered to this artery using a chimney technique. The patient recovered well, with no neurologic deficts and no leaks. So we decided to use this technique in others high risk patients with lesions reaching zone 1 (see Fig. 7.3). We performed five more cases without stroke or endoleaks.

In lesions of Zone 0, when the whole aortic arch is involved, a complete transposition of the aortic arch and supraortic vessels are mandatory. Typically, one performs an aortic-bifurcated bypass in order to revascularize the brachiocephalic artery and the left carotid artery. Sometimes the left carotid branch is taken to the left subclavian artery too. Other times, a carotid-subclavian artery bypass is the solution. It is carried through a median sternotomy. A healthy ascending aorta is needed. Afterwards, a TEVAR endograft is delivered with the proximal landing zone at the

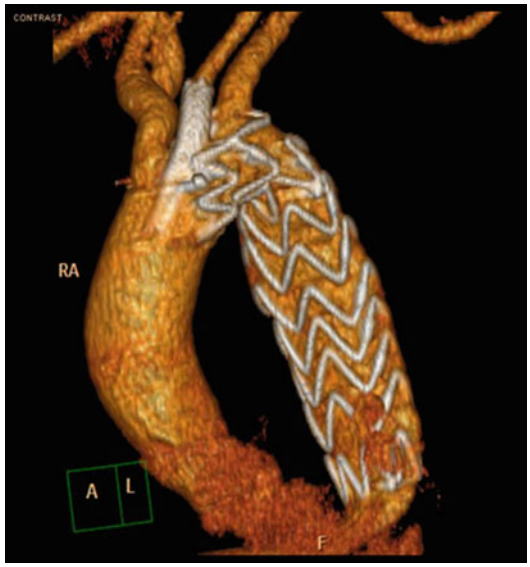

Fig. 7.3 Photography of a CAT scan showing a left carotid artery chimney

ascending aorta, distally to the aortic bypass to ensure the aneurysm exclusion.

On the other hand, there are some patients with aortic arch aneurysms and high operative risk with several comorbidities, which we should avoid sternotomy due to high risk of morbidity and mortality. In such cases, we perform a carotid-carotid bypass graft. Through the right carotid access, a endograft AAA limb extension is placed at the ascending aorta, with the proximal landing zone above the sinus-tubular junction and the distal landing zone at the proximal portion of the brachiocephalic artery. Subsequently, a thoracic endograft is deployed covering the distal ascending aorta, the whole aortic arch and the proximal part of the descending aorta. The cerebral circulation is maintained by the chimney limb extension, deployed over the brachiocephalic artery and through the carotid-carotid by-pass graft (see Fig. 7.4). We have performed seven cases. No strokes or endoleaks were reported [11].

And last, but not least, in high risk patients with lesion located exclusively at the ascending aorta, we performed the endovascular treatment of the zone 0 [11]. It was used a regular TEVAR device through a femoral approach, with the nose cone of the graft crossing the aortic valve (see Fig. 7.5).

From 2007 to 2012, 69 patients presented to our center in Belo Horizonte, Brazil, with acute type A aortic syndrome or its chronic complications. Of the 69 patients, seven high-risk patients were submitted to endovascular repair: four had penetrating ulcers, two had acute dissections, and one had chronic dissection with an aneurysm.

The anatomic inclusion criteria were as follows:

1. Presence of distinct proximal and distal landing zones
2. Absence of aortic valve insufficiency or pericardial effusion
3. Site of the entry tear of the acute aortic syndrome in the middle and distal third of the ascending aorta (all above the sinotubular junction)
4. Absence of signs of ischemia of the supra-aortic branchs
5. Absence of ventricular arrhythmia
6. Absence of a connective tissue disorder
7. Adequate femoral and iliac arteries

The proximal landing zone was, on average, 21 mm above the aortic valve. Three patients required intraoperative cervical debranching due to a lesion in the distal third of the ascending aorta, compromising the supra-aortic branches. The distal landing zone was at zone 0 in four patients, zone 2 in one patient, and in zone 4 in two patients.

The regular length of the ascending aorta ranges from 5 to 8 cm. Nonetheless, in the diseased aorta, its extension ranges from 10 to 13 cm, allowing the deployment of a non dedicated tubular graft (10 cm in length).

The technical success rate was 87 %, with one intraoperative death from acute aortic valve insufficiency.

The mean follow-up was 26.3 months. Two repeat dissections developed an average of 2 months after treatment. Both presented with acute dissection that was treated with additional open surgery and both patients survived. Thereafter, no patient had presented again with an acute aortic syndrome or other referable symptoms.

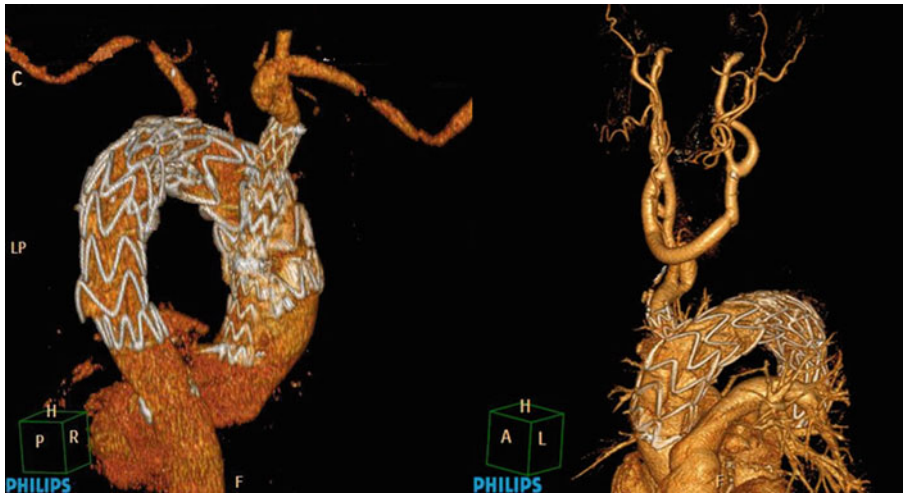

Fig. 7.4 Postoperative photography of a CAT scan showing a endograft AAA limb extension placed at the ascending aorta and the endogratf covering the aortic arch. Photography also show the carotid-carotid arterial bypass

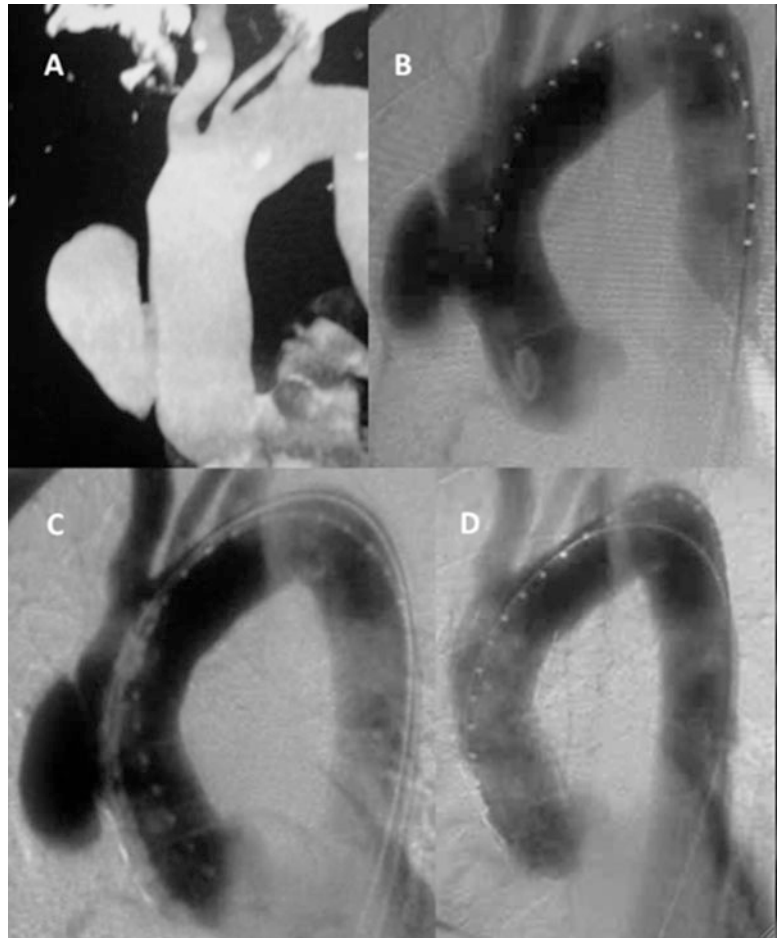

Fig. 7.5 Photography of intraoperative angiogram showing aneurysm located exclusively at the ascending aorta (Zone 0), treated with a thoracic endoprosthesis. Note the proximal landing zone at the sinus-tubular junction

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Branched and Fenestrated Devices for Treatment of Juxtarenals and Thoracoabdominal Aneurysms

8

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Introduction

Aortic aneurysms are a degenerative disease which affects between 3 and 10 % of the population over the age of 50 in Brazil and the USA. It has a multifactorial etiology, principally related to genetic and inflammatory factors and atherosclerosis [1, 2].

The treatment of aneurysms can be made through open repair or an endovascular approach (EVAR). Nowadays, EVAR is the first choice for patients with a suitable anatomy. However, we are still faced with important constraints related to the proximal neck, mainly in juxtarenal aneurysms. Only 30–40 % of infra-renal aneurysms are suitable for endovascular treatment with a regular endoprosthesis when following the instructions of use (IFU). In spite of the anatomical challenges, endovascular treatment of these patients is still growing, and with this, the number of complications and re-interventions is also increasing. The same limitations can be observed in aneurysms that involve the visceral trunks (Celiac Artery and Superior Mesenteric Artery) and renal arteries. Aneurysms, which compromise these arteries, are found in 10–15 % of all cases [3, 4].

In recent years, the majority of this subgroup of patients has been treated by off label endovascular techniques. The complexity of the anatomy of these aneurysms limit the development of endovascular solutions. Although off the shelf branched devices are available nowadays, we still lack options when fitting complex anatomies. One further option is custom made devices (CMD), which can provide solutions for these aneurysms, obviously theses devices can not be used in emergency situations, limiting their use.

Despite these limitations, the endovascular treatment of aneurysms with unfavorable anatomy is realized with more frequency every day.

In Brazil, endovascular surgery started in the mid-1990s in the hands of a few vascular surgeons, cardiologists and radiologists. Two Brazilian companies developed endografts; one thoracic and another abdominal. This fact contributed to the development of the skill and knowledge of physicians in this field. Particular

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characteristics of the local health system and regulatory affairs encouraged the intervensionists to face new challenges in endovascular aortic aneurysm repair (EVAR). In 2000, several international companies offered their own devices to the community and the local health system started to reimburse this kind of procedure. Brazil has one of the largest Societies of Vascular Surgeons in the world, with more than 3000 members, a high number having had formal training in endovascular techniques. The association of these variables has resulted in important progress in endovascular treatments.

Therapeutic Planning

In addition to clinical history and examination, the endovascular treatment of thoracoabdominal and juxtarenal aneurysms, needs high quality computed tomography to classify the aneurysm and to plan the repair.

CT angiography of the aorta and iliac arteries with three-dimensional reconstruction is the most commonly used exam for planning the procedure and choosing the endoprosthesis. Such reconstructions are essential because they allow the study of aortic angulation and the exact location of the visceral branches and renal arteries [5].

The main objectives of the analysis of images of juxtarenal or thoracoabdominal aneurysms by CT angiography are: define the anatomy of the aneurysm and the iliac axis, size, extension and relationship to the main branches of the aorta (left subclavian, celiac, superior mesenteric and renal arteries), as well as identifying calcifications on the artery wall and the presence of thrombosis; identify and assess the dimensions of the proximal and distal necks of the aneurysm; detecting relevant anatomical variations, such as accessory renal arteries; diagnose vascular and extra-vascular abnormalities that may alter the treatment of the patient.

The use of sophisticated software tools for the study, reconstruction and the measurement of aortic anatomy are increasingly being used to complement and assist the planning of the procedure, principally in those cases where branched or fenestrated devices will be deployed. The use of these tools minimizes complications related to anatomical complexities found in this group of patients [6, 7].

Treatment

In the past, treatment of juxtarenal and thoracoabdominal aneurysms through conventional open surgery was always the first choice in the management of this group of patients. However the need for clamping supra-renal, the left renal vein section, as well as the time of ischemia significantly increased the complications and the mortality of open surgery.

In spite of the technical limitations of the endovascular approach, when comparing series of patients treated by this technique with groups treated by open surgery there is a marked superiority in the results of the endovascular surgery group, especially in regard to renal dysfunction and mortality rates.

Different technical alternatives for endovascular treatment depend directly on the proximal neck anatomy and sealing area, these characteristics are the key predictors for obtaining good results in the long term. The techniques considered off-label or outside formal instructions of use have been applied widely in the treatment of this group of patients, although there is a gap in relation to consistent scientific evidence or long-term studies [4].

Parallel stent techniques, either chimney or snorkel, are being increasingly used, especially in juxtarenal cases where there is no possibility of waiting for the customization of a device. This is a procedure which is easy to perform and can be accomplished without the need for specially constructed devices.

The use of devices customized by the industry (CMD), using the anatomical information of each patient or modified by the surgeon offer other possibilities of therapeutic approach.

Stent grafts customized by the manufacturer, are undoubtedly the best and safest form of treat-

ment of these patients because the devices are manufactured based on the information of the morphology of the aneurysm of each patient. The main problem with this type of device is its construction and delivery time, which can vary between 20 and 90 days, depending on the country where it is required. Another factor refers to the need for specific training of the surgeon, this requirement is imposed by the manufacturers, consequently there is an important limitation in performing procedures with this type of device as well as the inability to use it in urgent cases or emergencies.

An endoprosthesis customized by the surgeon, can also be used in such cases however the structural modifications may be carried out in unsuitable environments; in addition, there may be inaccuracies in measurements which can result in a poor outcome and associated serious complications.

The availability of an off the shelf branched device would be the best scenario for the treatment of complex aneurysms in urgent cases, although some cases with a very complex anatomy limit this kind of solution. Chuter et al. shows in a study that more than 80 % of patients can be treated with a standard device configuration.

Actually, there is only one device, commercially available in some countries, to be used for this purpose. Other devices in development are in the initial phases of clinical study. In 2014, the local regulatory agency in Brazil approved the use of a unique off the shelf device from Cook, the Zenith T-Branch. This device allows treatment of thoracoabdominal and juxtarenal aneurysms in a high number of cases.

We can classify off label techniques in two main subgroups; first of these is without any structural change in the device, such as parallel endografts. The second subgroup refers to devices that are modify by the surgeon before the implant.

Parallel endografts can be used in several configurations, these depend on the kind of anatomy to be treated. These include Chimney or Snorkel, sandwich and octopus, for juxtarenal and thoracoabdominal aneurysms respectively.

Chimney, Snorkels and Parallel Endografts

The chimney technique was first described by Greenberg in 2003 [8]. Originally used in the rescue of a renal artery during an endovascular procedure. This is a technique in which bare stents or stent grafts are positioned within the renal arteries in parallel to the aortic endoprosthesis to preserve flow in these vital branches. It is necessary to catheterize both renal arteries, this is achieved through access by either the brachial or axillary arteries. These stents take a position parallel to the proximal neck of the endoprosthesis, thus allowing an increase in the sealing area near the proximal neck of the aorta. In special cases where the distance of the superior mesenteric artery and the renal arteries is very short, the selective catheterization of the superior mesenteric artery is necessary. After catheterization of the renal arteries and the correct positioning of the stent, the aortic stent is first released and then the renal stents, so that the covered stents are positioned between the aortic wall and the endoprosthesis.

This technique can be used both for elective planning or to rescue a renal artery accidentally compromised by the aortic stent, or a variant of the technique can be used, the "snorkel" or "periscope" in which the branches are perfused by retrograde flow [9].

A recent retrospective study in patients with juxtarenal aneurysms in the United States, who had been submitted to this technique demonstrated a high rate of success for the procedure (98.2 %), and 30-day mortality of 7.1 %. The postoperative monitoring of approximately 10 months showed that 89.3 % of patients survived with a primary patency rate of 98.2 %, however, the rate of endoleak (type I, II, III) after 30 days was 12 % [10, 11].

The possible advantages of these techniques are; the fact that it is not necessary to customize the stent for each patient, using devices that are already available on the market, there is no need to catheterize the branches of the endoprosthesis as in the case of branched or fenestrated, and no change in the stent structure with a long period of customization in the operating room as occurs in

cases where the surgeon modifies the device. However, their use still requires caution in the medium and long term.

The use of parallel endografts to treat a complex aneurysm such as a thoracoabdominal, are performed using a sandwich technique described by Lobato in 2012, this technique showed good results in Lobato's personal series of patients or alternatively an octopus technique described by Kasirajan and modified by our group in 2011 [12, 13].

The sandwich technique uses long conduits positioned between two aortic stentgrafts with anterograde flow to re-vascularize the visceral and renal arteries. This technique can be used in all segments of the thoracic aorta. The main concern is related to the gutters that can persist between the connections, the frequency and consequences of this kind of endoleak is still unknown.

The sandwich technique, is just one of several other parallel endograft configurations, all of which are very useful, principally in patients who are unable to wait for a custom made device. One of these other configurations was described by Dr. Kasirajan, he used two bifurcated endografts in parallel in the descending aorta and through the four legs he created bridges to the visceral and renal arteries.

Our group recently treated some patients with off the shelf endografts following a different approach. Instead of using two parallel endograft main bodies and constructing four branches (three visceral and one aortic) we used a standard bifurcated main body in the descending thoracic aorta, and if necessary this was combined with a proximal TAG device to accommodate larger aortic diameters. Following this we deployed three 8 mm Viabhans inside the short leg (13-mm diameter) through an auxillary conduit which had been prepared earlier. These Viabahns were subsequently extended to the Celiac Trunk, Superior Mesenteric Artery and Right Renal Artery. In the remaining long limb of the Excluder we deployed a Viabahn with a parallel bell-bottom extension. The bell-bottom was connected to a new bifurcated device and the Viabahn was extended to the Left Renal Artery. With the above described technique we are able to revascularize all four visceral branches (Fig. 8.1).

Despite the good preliminary results, long-term data will be required to prove safety and efficacy of these techniques for endovascular treatment of thoracoabdominal aneurysms [14].

Customized Endoprosthesis

Customized stent grafts are manufactured according to the anatomy of each patient and the greatest limitation for their use is the fact that the customization and delivery of each stent takes from 20 to 90 days, which precludes its use in cases of great urgency such as patients with pain, acute expansion and signs of rupture.

Some manufacturers of these devices now provide standardized templates that according to complex statistical evaluations of the anatomy of the aorta and its branches could serve the majority of patients with juxtarenal aneurysms without the need for the wait of customization. However, these products are only available in a few centers.

The companies responsible for the customization of the devices used today are: Cook Medical, with fenestrated and branched stents; Terumo Company Anaconda® with fenestrated stents; Jotec® with fenestrated and branched stents.

The criteria for use of the Zenith® fenestrated (Cook Medical) device are: access vessel compatible with 14 F access sheath through the upper member and at least 22 F in femoral, proximal aortic angulation less than 45°, infra-renal neck of at least 4 mm and the oversizing of the device should not be greater than 10 % in aortic diameter in the sealing area. Other limitations are related to the manufacture of devices, such as a maximum of three fenestrations or two fenestrations and a scallop.

A recent multicenter study analised 57 patients with juxtarenal aneurysms who underwent implantation of this endoprosthesis, and demonstrated 100 % effectiveness in aneurysmal exclusion, death of only one patient, type II endoleak at 14 %, and type III endoleak in 3.5 % of patients over 6 months of the study. In total, 120 vessels were treated, 117 successfully, showing a primary patency rate of 97.5 % [15]

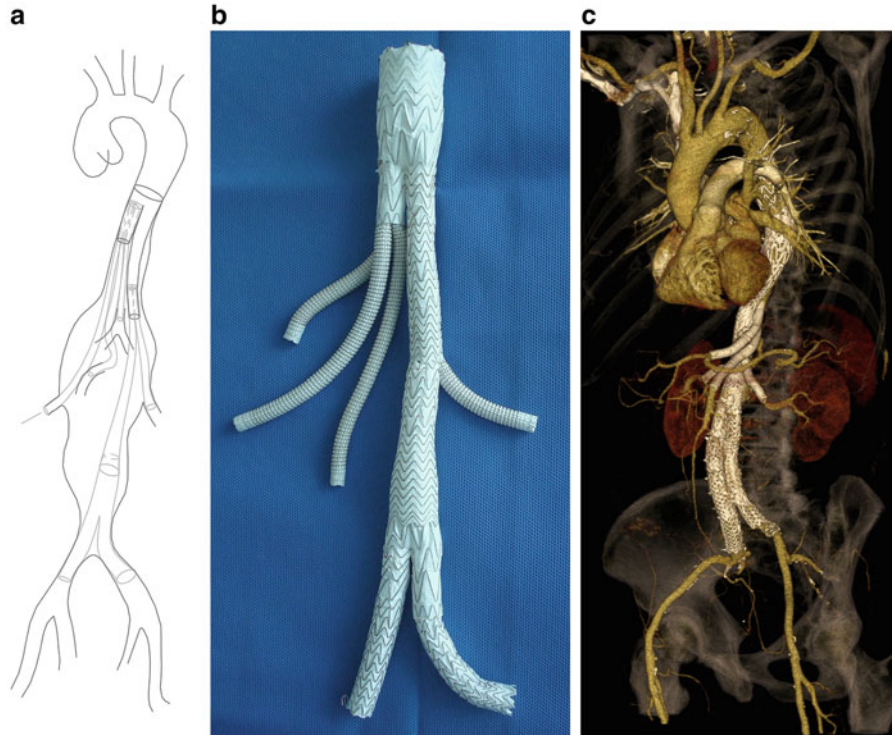

Fig. 8.1 (**a**) Diagram of an "octopus" technique. (**b**) Final assembly before implant. (**c**) 3D reconstruction CT scan of 24 months follow up

The Anaconda® fenestrated (Vascutek) is a repositionable endoprothesis with two proximal rings, 2–4 fixing hooks, a body without support wires which facilitates the selective catheterization of the fenestrations, reinforced with a nitinol frame. It allows configurations of 2–4 fenestrations. The operating instructions recommend an oversizing of 10–20 % in the main body, and an access vessel that supports an introducer of 20–23 F. The classic indications of this stent are: an aortic neck smaller than 15 mm, a tapered neck with an angle greater than 60°. A recent study from Holland demonstrated the results of 25 cases, 30 days without endoleaks and two deaths at the end of 11 months. There were 56 fenestrations, 53 of these were properly catheterized. Despite the small number of patients in the study, it has shown greater versatility in more complex cases when compared to devices from other companies [16, 17].

Fenestrated or Branched by the Surgeon

The fact that there are cases of thoracoabdominal or juxtarenal aortic aneurysms in need of urgent treatment has caused some surgeons to begin to modify stent grafts available in the market by building branches and fenestrations.

Some publications have shown good results when selecting critically ill patients without the possibility of open repair or of waiting for the customization. However, studies are limited to case reports or small case series.

The techniques, which modify the device structure with makeshift construction of fenestrations and branches, can lead to a significant change with questionable effect and durability. In addition, these techniques involve intense teamwork, prolonging the time of surgery/anesthesia,

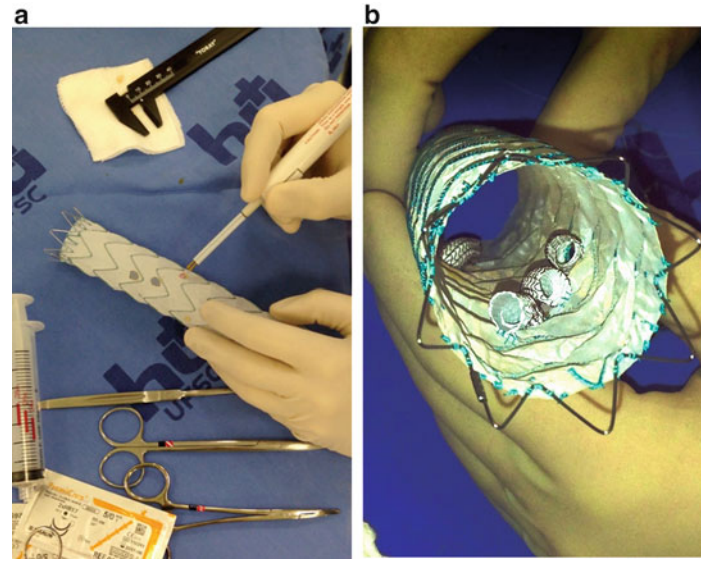

Fig. 8.2 (**a**, **b**) Photographs showing surgeon customization of a branched stent graft

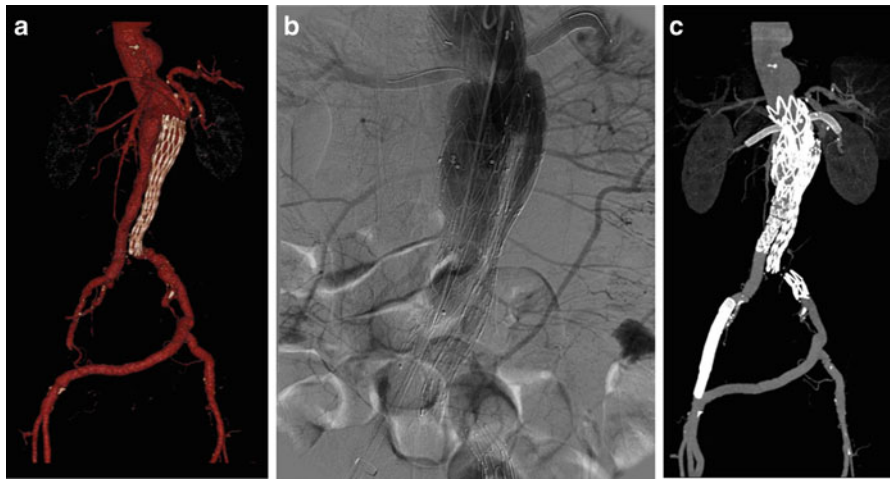

Fig. 8.3 (**a–c**) Sequence of scans showing a complex case of anastomotic aneurysm treated with a surgeon customized branched endograft

they require a complex implantation technique with higher complication and failure rates, and that the device is handled in an in appropriate environment [17, 18] (Figs. 8.2 and 8.3).

Off the Shelf Fenestrated and Branched Device

The Ventana® Endologix and the Pivot Branch (P Branch, Cook) systems attempt to combine the benefits of customized fenestrated grafts while avoiding the cost and prolonged fabrication time. The Ventana Fenestrated System (Endologix, Inc., Irvine, CA) is an investigational device in the United States based on the AFX stent graft (Endologix, Inc.) indicated for the treatment of juxta and pararenal aneurysms. The main important feature is that it allows that the surgeon steers, in situ, the fenestration radially 90–120° and up to 30 mm longitudinally. The device contains two 3 mm pre-cannulated fenestrations and during the implant and the selective catheterizations of the renal arteries,

the device remains fully constrained facilitating its maneuverability.

The Pivot graft from Cook is constructed using the same platform as both the Zenith graft and Zenith Fenestrated devices. Like the Ventana graft, it has two 15 mm pre-cannulated domed fenestrations, this configuration allows pivoting of the fenestrations to access the renal arteries. Additionally, the device design includes a fixed 8 mm fenestration positioned at 12 o'clock for the superior mesenteric artery [19].

The Zenith T-Branched graft is the first off the shelf branched device available. It is a unique four branched configuration. The tapered main body has standard measurements, 34 mm in the proximal neck, 18 mm in the distal neck and 202 mm in length. In the middle section there are four branches. The upper most is located at 1 o'clock, it is 8 mm in diameter and 18 mm in length, to accommodate the side branch to the celiac trunk. The second one is positioned at 12 o'clock, it has measurements of 8 mm by 21 mm, and is the side branch to superior the mesenteric artery. The last two branches are designed for the renal arteries and are positioned at 10 and 3 o'clock, they are both 6 mm wide and 18 mm in length.

To complete the procedure and treat the aneurysm all the way to the iliac arteries a modular bifurcated device was developed, which is available in four lengths: 81, 98, 115 and 132 mm, all of them in a 20 F delivery system. This can be used in conjunction with t-Branch and other Zenith customized devices.

In June of 2012, Cook Medical received the CE mark for the Zenith t-Branch Thoracoabdominal Endovascular Graft. Following this, some publications demonstrated that use of off-the-shelf t-Branch devices in the treatment of TAAAs is feasible and safe, with encouraging early clinical outcomes. It was 2 years before Anvisa approved the use of the device in Brazil and the first procedures were performed in 2014. Since then, more than 70 procedures have been performed in Brazil. In the US, this graft is still under clinical investigation.

Despite the low number of publications, the initial results are encouraging. In a recent comparison between custom-made versus off-the-shelf multi-branched devices, the T-branch showed an advantage of direct implantation without any delay for manufacturing, it showed 100 % technical success and comparable clinical outcomes to the traditional custom-made endografts. Further long-term evaluation remains mandatory [20, 21].

Upcoming Devices

Recently W.L. Gore presented the first cases of a first "all in one" pre-cannulated off-the-shelf system, including an aortic component and side branch stent grafts. The device, known as the GORE EXCLUDER® *Thoracoabdominal Branch Endoprosthesis* (TAMBE), started a PHASE I study in Brazil in November of 2014. The results of first implants have been promising and a similar protocol is expected to be run in the USA this year.

The TAMBE Device is an off the shelf device, with special characteristics that will improve the ease of implantation in different anatomies. The fact that the device allows for the side branch portals to be pre-cannulated minimizes the steps of the selective catheterization of visceral trunks and renal arteries. In addition, the three-stages delivery system permits the opening of the proximal and distal neck ends, without losing control of the proximal neck. This feature allows for fine positional adjustments and for the selective catheterization of the branches in a less congested environment. The second stage fully opens the proximal section and the third stage is to open the mid-section of the main body and finalize the placement of the main trunk. We expect that in the next few years this device will be available for use.

Recently, Medtronic announced an exclusive patent license agreement and are planning to develop a stent graft system for endovascular repair of thoracoabdominal aortic aneurysms. The idea is based on a novel endovascular debranching technique using a mix of Valiant and Endurant endograft. The first stent graft is used to assemble a thoracic bifurcation, and the second, using an Endurant and four 7 mm Viabahn stent grafts as a visceral manifold, physician customized and described by Kelly et al. [18].

Conclusion

The management of thoracoabdominal and juxtarenal aortic aneurysms is one of the most complex situations faced by the endovascular surgeon. It requires a detailed planning of treatment and extensive knowledge of materials and endovascular techniques. Fenestrated or branched stents, customized by the manufacturer as well as those available off the shelf present the most promising results in the treatment of this type of aneurysm. However, we still lack an ideal method for every case and, according to the clinical condition of the patient and the anatomy of the aneurysm, the use of alternative strategies may be required.

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Aortic Disease and Its Treatment in Hong Kong

9

Stephen W.K. Cheng

The Prevalence and Epidemiology of Aortic Diseases in Hong Kong

Hong Kong's seven million predominantly ethnic Chinese population has one of the world's highest life expectancy of 81.2 and 86.7 years for males and females respectively. About one million population is aged 65 and above.

There are no territory wide database on aortic diseases in Hong Kong. The Hospital Authority, a government funded public health care institution, provides for more than 90 % of in-patient care to the population of Hong Kong. A limited statistical audit [1] of Hospital Authority admission data from 2005 to 2014 (Tables 9.1 and 9.2) showed a trend of increased detection of aneurysmal diseases, reaching an annual prevalence of 450–500 new admissions or about seven per 100,000 population, which is still very low compared to Western countries. More than 75 % were abdominal aortic aneurysms. The ratio of rupture to intact aneurysms has improved slightly from 23 % to 18 %, mainly in the reduction of ruptured abdominal aortic aneurysms. The overall mortality for ruptured aneurysms remained high, at 60–65 %.

The male to female ratio of aortic aneurysms is 3:1, similar to the distribution in the West. There is a slow trend of rising male prevalence to 3.7:1 in 2014. The mean age of patients with aneurysmal diseases is 74.2 for men and 77.3 for women.

Acute aortic dissection is very common in mainland China amongst younger patients, likely due to a prevalence of hypertension, and smoking. However this high incidence of acute dissection is not observed in Hong Kong, probably as a result of better primary care. Patients with acute dissections numbered about 150 per year, and is comparatively older. There is a slight male predominance of 2.5:1, with a slightly higher mortality amongst females (M:F of 1.5:1 deaths due to dissection). The mean age for males and females with aortic dissections in Hong Kong is 62.3 and 70.4 respectively.

Structure of Health Care for Aortic Diseases

Primary Care

There is still a lack of good patient and physician education on the latest treatment modality for aortic diseases. The patient population, predominantly elderly Chinese, had traditionally adopted a very conservative approach to dealing with diseases without disabling symptoms or immediate threat to life. Many still refused intervention of their sizeable aneurysms, for fear of hospitalization and perceived

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Table 9.1 Hong Kong hospital authority statistics on trends of aortic aneurysms and dissections in 2005–2014 [1]

	2005		2010		2014	
	Number	Deaths	Number	Deaths	Number	Deaths
Aneurysms						
Arch	13	0 (0)	39	2 (5.1 %)	71	5 (7 %)
Thoracic/thoraco-abd	102	18 (17.6 %)	50	10 (20 %)	70	18 (25.7 %)
Abdominal	363	66 (18.2 %)	455	87 (19.1 %)	493	73 (14.8 %)
(Ruptured, included above)	112	72 (64.3 %)	128	82 (64.1 %)	115	69 (60 %)
Dissections	156	17 (10.9 %)	111	16 (14.4 %)	139	27 (19.4 %)

Table 9.2 Hong Kong hospital authority total numbers of surgery for abdominal aortic aneurysms in 2005–2014 [1]

	Elective	Urgent (intact)	Emergency (rupture)
All operations	1241	185	537
Deaths	39	19	298
Mortality (%)	3.3	10.3	55.5
Open repair	423	36	387
Deaths	19	3	219
Mortality (%)	4.5	8.3	56.5
Endovascular repair	784	102	120
Deaths	11	8	43
Mortality (%)	1.4	7.8	35.8

complications. This is not helped by the relative lack of sound medical advice from primary health practitioners, who still considered all aortic surgery to be extremely risky and therefore not worthwhile.

Vascular diseases unfortunately has not attracted enough attention in the government and Department of Health policy makers, and development has not kept pace with the growth in technology. The priority of territory wide screening programs has remained to address malignancy, and to date there are no screening for aortic aneurysms in Hong Kong.

Specialized Care

Due to its complexity, expense, and equipment requirements, surgical treatment of aortic diseases is predominantly done in major public hospitals, whereas the largely under-insured aged population are unable to avoid the very expensive private health care, especially when costly consumables are involved. Traditionally Vascular Surgery outside of the heart and proximal thoracic aorta was performed largely by General Surgeons, with full time specialized vascular surgery practice confined to major tertiary university hospitals. This is in direct contrast to cardiac surgery, who has been a separate specialty since the 1970s [2].

Endovascular aortic stenting grafting in Hong Kong has largely remained in the hands of Vascular Surgeons, and this situation is likely to remain with the current generation of surgeons fast embracing endovascular skills. In some centers where the surgeons are less experienced with catheter skills a team-approach is generally adopted with a surgeon working closely with a radiologist. Cardiologists, with few exceptions, are not involved in aortic interventions.

Over the last 10 years there has been a growth in the interest of younger surgeons to pursue specialized endovascular training, largely from overseas centers in Australia. Newer vascular surgery services has been established in larger Hospital Authority hospitals. Today three major public hospitals (Queen Mary, Queen Elizabeth and Prince of Wales Hospitals) perform the bulk of aortic surgery in Hong Kong [3] (Fig. 9.1). These are also the three hospitals with a dedicated hybrid endovascular operating room, albeit all funded by private donations. Two additional hybrid theatre however are being built in two private hospitals.

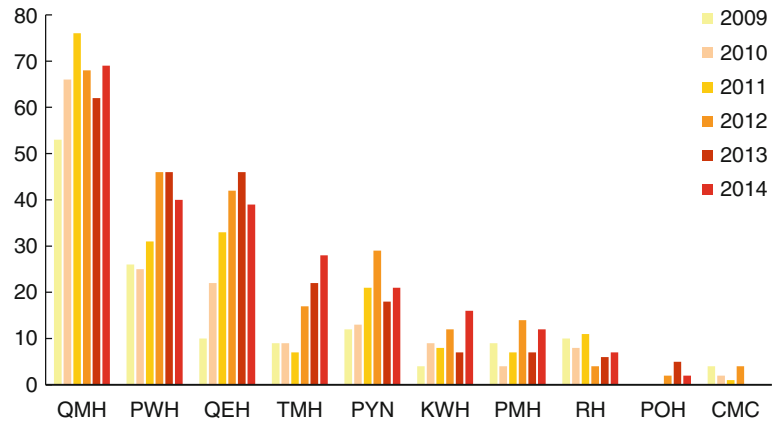

Fig. 9.1 Aortic aneurysm surgery in Hong Kong hospitals [3]

Reimbursement

The cost of endovascular consumables used to be a major obstacle to the advancement of the endovascular program in the early 2000s, when patients have to pay for endografts out of their own resources. Since 2011 however the government has unified a policy of reimbursement of all endografts for public patients with aneurysms as long as the conditions of treatment (maximum diameter of 5 cm for abdominal, and 6 cm for thoracic aortic aneurysms) met a set of guidelines, or the procedure considered immediately life saving. However other indications such as acute Type B dissections, expanding chronic dissections, pseudoaneurysms and mycotic aneurysms, or common iliac aneurysms, remained unaddressed and currently not funded at this time.

Nevertheless the provision of government funding saw a phase of rapid growth of EVAR and TEVAR procedures in Hong Kong. This also enabled more complex procedures such as fenestrated and branched endografts to be financially viable and sets the foundation stone for complex endovascular therapy.

Regulations

Hong Kong has no stringent regulation in the use of novel medical technologies. Generally any medical devices in possession of a CE mark is automatically approved for registration. The local market is comparatively small and saturated in the region compared to sales in China and Japan. The main attraction of Hong Kong to the potential device manufacturers is a stepping stone to the introduction of newer devices in Asia, with their eye on more lucrative markets such as China, Taiwan, and Thailand. As an example there were 11 EVAR graft systems available in Hong Kong, competing for a market of 300 procedures a year, with nine new endografts being introduced in the last 3 years alone. In the current business environment, the main limitation is to secure good technical support, have adequate stock, and training of local personnel to make this sustainable. It is anticipated that the majority of companies would not survive in this region.

Current Status of Aortic Surgery

Aortic Aneurysms

In keeping with the world trend, there has been a rapid growth in the use of endovascular repair for aortic aneurysms in Hong Kong. This is largely a result of increased detection of diseases from more widespread use of imaging technology, and an aging population. In the Queen Mary Hospital, the major vascular surgery referral center, the number of aortic interventions has increased fourfold in the last 15 years, due to increased use of endovascular repair in patients with significant co-morbidities. Currently EVAR is the main stay

of treatment, numbering about 300 per year in the territory, largely confined to a few key public hospitals (Fig. 9.1). The 30-day mortality of EVAR in Hong Kong has been 2.5 %. Open aneurysm repair has remained static and accounted for only 15–20 % of all aortic aneurysm surgery, with an overall mortality of 6.4 %.

Currently the abdominal endograft market is dominated by Cook Medical (Zenith Flex and LP) and Medtronic (Endurant II and IIs). The larger companies have direct representation and have the advantage of good support and stock. The other players in Hong Kong include Bolton Medical Treovance, Endologix Nellix, Gore C-3 Excluder, Jotec E-Vita and E-Tegra, Lifetech Ankura, Lombard Medical Aorfix, Trivascular Ovation Prime, and Vascutek Anaconda.

There appears to be no special morphological characteristics of abdominal aortic aneurysms in Hong Kong, although it is well known that the Chinese patients have a shorter common iliac arteries averaging 2–2.5 cm long which may have an impact when endovascular repair is considered [4]. Patients generally also presented later with large aneurysms of unfavorable anatomy. As a result planning and execution of EVAR is generally more taxing. The choice of three-piece systems is generally preferred to allow for greater flexibility to achieve the greatest cover in short distal landing zones.

Female patients generally have a smaller statue but access has not been a major issue with the development of the low profile devices. A complete percutaneous approach has been popular in the last few years, which significantly shortens the hospitalization to almost a day procedure. A few smaller units is still performing EVAR using mobile fluoroscopic units. In experienced centers, ruptured aneurysms are routinely performed using endovascular repair with results comparable to open surgery.

The majority of complex endovascular interventions for aneurysms are performed in 2–3 centers. While not a large experience, procedures such as fenestrated EVAR, chimneys, and iliac bifurcation devices are routinely used with increasing numbers due to government funding. Due to flexible regulation, we have been able to maintain a leading position in terms of using novel products. The Department of Surgery at the University of Hong Kong, Queen Mary Hospital have been performed first-in-human implant of the Cook Zenith Bi-Branch device and involved with the Zenith LP pivotal trial, and were first in Asia in using the Treovance and Trivascular devices, as well as involved in registries such as ENGAGE and RATIONALE.

Thoracic Aortic Aneurysms and Dissections

Three major cardiac surgery centers in Hong Kong provide emergency surgery for acute aortic dissection. Type A dissection is traditionally managed by cardiac surgeons using a very conservative ascending aortic replacement under cardiopulmonary bypass and antegrade cerebral perfusion. It is only very recently that the cardiac surgeons have adopted a more aggressive approach of hemiarch or total arch replacement for younger patients, with a frozen elephant trunk.

As a result, there has been a higher number of patients who suffered from chronic dissection with a residual aneurysmal arch and descending thoracic aorta.

Type B dissections are generally managed conservatively in cardiology units. Vascular surgeons became increasingly involved in managing acute complicated type B dissections with thoracic stent grafts. However uncomplicated acute Type B dissections are often managed conservatively, as most patients would decline even endovascular interventions.

In 2012, surgery for aortic dissection comprise approximately 60–70 % of aortic surgery in the major cardiac center [5]. The two university centers reported 36 and 29 surgery for acute dissections respectively, with the Prince of Wales hospital reporting an operative mortality of 9.2 % and stroke rate of 3.8 % [6].

Open repair of thoracic and thoraco-abdominal aneurysms and dissections still is a major undertaking with significant mortality and morbidity of stroke and paraplegia, and patient acceptance is

low. With the success of EVAR and an established skill set, the Vascular Surgeons have took up a pioneering position in establishing TEVAR in Hong Kong. The major stent graft systems in use are the Zenith TX2 and Alpha, Medtronic Valiant, Gore c-TAG, and Bolton Medical Relay. In some hospitals for political reasons, the cardiac surgeons have been performing thoracic procedures with radiologists and therefore diluting clinical experience of vascular surgeons. While we do not have a large number of acute dissections for reasons stated above, chronic aortic dissections and aneurysms still comprise at least 30 % of non-emergency work. With the introduction of the next generation of low profile thoracic devices, TEVAR has fast becoming a percutaneous procedure, and access related limitations and complications will soon be a thing of the past.

While TEVARs including debranching hybrid procedures became routine, currently advanced thoracic endovascular interventions is largely done at Queen Mary Hospital, where vascular surgeons have performed fenestrated and branched stent graft implants. Recently we have also successfully started a program for total endovascular repair of arch pathologies using the Cook A-Branch device, also a first in Asia.

Future Development

Hong Kong is in a good environment where skilled team of surgeons and good imaging equipment are not in short supply. What is lacking is a central concerted policy of education, primary health care, training and delivery.

The major problem of aortic surgery is securing a sustainable workforce for training and advancement. For political reasons simple endovascular work is still scattered amongst ten hospitals with little cross-referral, where almost 70 % perform less than 25 procedures a year. Smaller units are understaffed yet overworked for emergency cover, and trainees do not get adequate exposure due to the small case volume.

Last year the College of Surgeons have dedicated Vascular Surgery as a Sub-specialty offering post-fellowship training for a 2 year program, but only two center were recognized as full time training centers. The Hospital Authority has also taken up an initiative to revisit and reorganize vascular surgery services in Hong Kong, in consideration of manpower, population, and equipment. It is hoped that in future major aortic surgery can be consolidated in three training centers in the territory providing comprehensive care for thoracic and abdominal aortic diseases, both open and endovascular.

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Aortic Aneurysm Management in Europe

10

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Abbreviations

CVD	Cardiovascular disease
TEVAR	Thoracic endovascular aortic repair
EVAR	Endovascular aortic repair
TAA	Thoracic aortic aneurysm
AAA	Abdominal aortic aneurysm
CT	Computed tomography
MRI	Magnetic resonance imaging
ECG	Electrocardiogram

Introduction

Cardiovascular disease (CVD) is the number one cause of death in Europe, accounting for >4 million deaths per year, almost half of all mortality. More specifically, 51 % of deaths among females and 42 % among men are caused by CVD, compared to 19 and 23 % due to cancer, respectively (Fig. 10.1). Recent data showed in Europe a decrease of CVD mortality in many countries and a great variety of incidence among them [1].

In Europe the prevalence of abdominal aortic aneurysm is estimated to be around 2.5 % [2]. Thoracic aneurysms show an incidence of up to 10.4 cases per 100.000 [3]. Similarly to CVD, the incidence of aneurysms is also in decline [4].

This chapter will focus on the European approach to the management of both thoracic aortic aneurysms (TAA) and abdominal aortic aneurysms (AAA).

Diagnosis and Evaluation

In Europe, when an aortic aneurysm is identified, assessment of entire aorta and aortic valve is performed at baseline and during follow-up, since simultaneous aortic disease may exist. In particular, both TAA and AAA may be detected simultaneously in up to 20–27 % [5, 6]. Aortic diameters are measured at specific anatomical landmarks, and the measurements are done perpendicular to the longitudinal axis of the aortic lumen. In order to assess change in diameter between baseline and a follow-up imaging study, the use of the same modality is usually encouraged [7].

For the diagnosis and evaluation of AAA, screening is recommended in men >65 years of age. Several countries in Europe have started screening for AAA in high-risk populations, in an attempt to decrease mortality due to aortic

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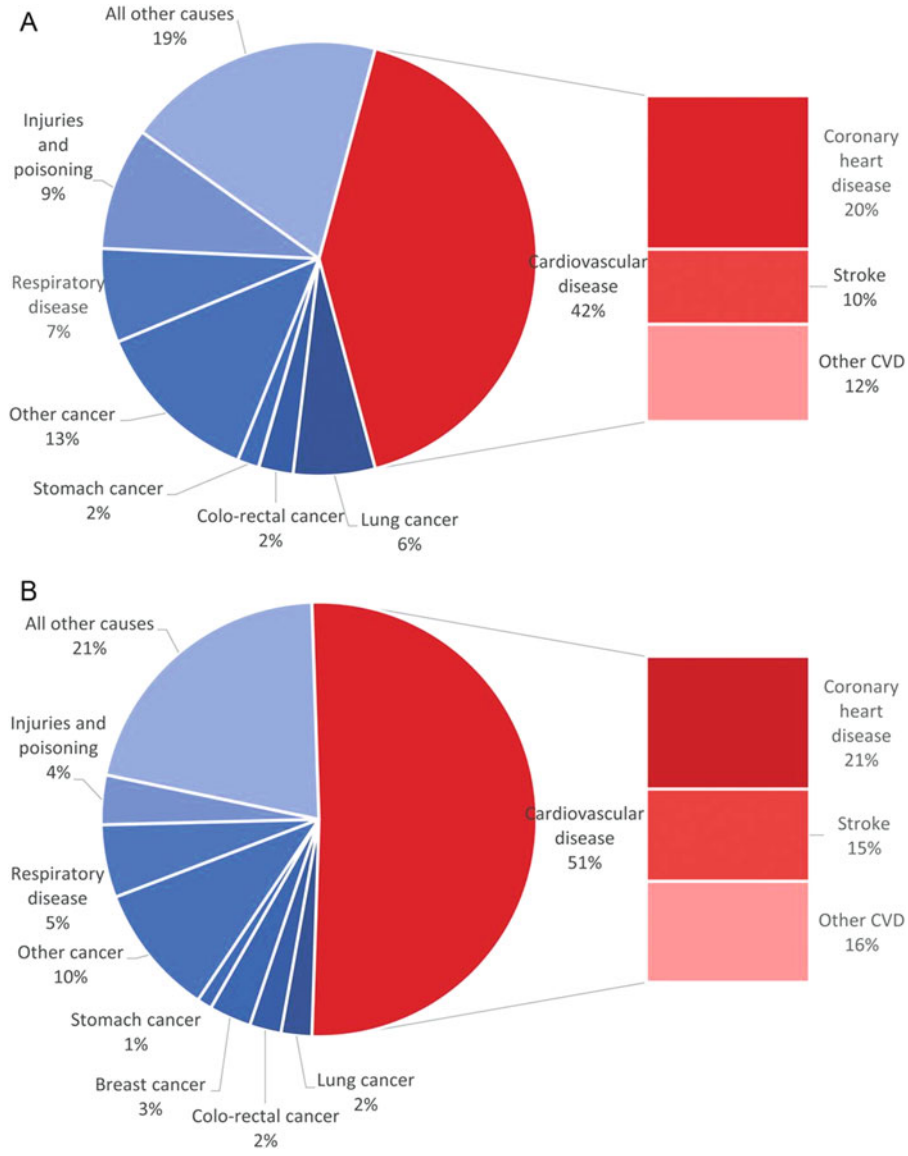

Fig. 10.1 Causes of death in Europe in 2014 (Adapted from Nichols et al. European Heart Journal 2014)

rupture. Such high-risk cohort would include men >65 years of age, smokers and patients with a family history of aortic aneurysm. Ultrasound is the established and non-invasive screening tool for AAA's. For TAA, ultrasound is not feasible as a diagnostic tool, since the thoracic wall prevents clear visualization of the aorta due to air artefacts. For a clear identification of diseased aortic segments, the gold standards in Europe are CT and MRI, with the new ECG-gated MRI techniques which also allow for dynamic aortic wall motion and blood flow imaging [8].

Pre-operative assessment of aneurysms includes maximum axial diameter and evaluation of involvement of the visceral arteries. For an accurate planning of endovascular aneurysm repair (EVAR), the proximal and distal landing zones, the aneurysmal neck angulation and aortic tortuosity are inspected. For thoracic endovascular aortic repair (TEVAR), proximal and distal

landing zones are also inspected, as well as possible involvement of the aortic arch and the arch vessels. Furthermore, the aorta is examined for co-existing diseases such as aortic dissection, intramural hematoma and/or penetrating aortic ulcers.

Management

In Europe, optimal medical therapy is always part of the treatment of patients with an aortic aneurysm, whether abdominal or thoracic. Beta-blockers, ACE-inhibitors and statins are considered first-line medication [9], however the exact role and impact of these drugs remain controversial. Antiplatelet therapy is considered, because of the increased risk of cardiovascular events in AAA and TAA patients [10]. Surveillance has proved to be safe in AAA's with maximum diameter of <55 mm and limited (<5 mm/year) aortic growth [11]. Quitting smoking is another important focus point in the management, since this reduces the expansion rate of the aorta [12].

Currently, in the European countries the decision for aortic aneurysm repair is based on the aortic diameter [7]. The threshold to operate has been set at 55 mm in diameter, regardless of the etiology. For TAA's, in patients with Marfan syndrome, or ascending aortic aneurysm of ≥50 mm, surgery is also recommended [13]. An intervention could also be planned when the aorta is 45 mm and the patient has additional risk factors such as a family history of aortic disease, rapid enlargement or severe aortic regurgitation [7]. Aortic repair is always advised for symptomatic AAA's or those with an expansion rate >10 mm/year [7]. Although no separate indications for men and women currently exist, operating female patients at a threshold of 50 mm may be justified in AAA's. In borderline cases, the choice of management is not based only on the aortic diameter. It is a well-weighed patient specific decision, taking into account relevant patient characteristics, aortic dimensions, level of activity before the surgery, life expectancy and the anticipated level of activity/quality of life afterwards. Frequently, a multidisciplinary team decides which management is the preferred choice, while maintaining good consultation with the patient.

Actually, management of TAA in Europe is largely TEVAR based [14] because TEVAR has shown lower early mortality compared to open repair, but there is a lack of publications discussing long-term results [15]. TEVAR (Fig. 10.2a) is considered in patients with a maximum aortic diameter of ≥55 mm. The proximal and distal landing zones should be at least 2 cm and an oversizing of 10–15 % is commonly adapted. TEVAR potentially has very serious complications, including spinal cord ischemia, endograft migration or failure, and endograft induced new entry tears. In patients with a connective tissue disorder, TEVAR is sometimes as an emergency procedure, to stabilize the patient as a bridge to definitive open surgical management [16].

Depending on the location of a TAA, different management strategies are advocated throughout Europe. In the ascending aorta, there may be involvement of the aortic valve or the aortic arch branch vessels. The choice between a total replacement of the ascending aorta with coronary re-implantation or a segmental approach is based on the diameter of the different aortic segments, in particular the sinuses of Valsalva. In case of aortic root aneurysm, the aortic valve function and anatomy is the deciding factor for the choice between valve-sparing and valve-replacing therapy. The surgical management of aortic arch aneurysms is complex, mainly due to the fact that the brain needs continuous perfusion during the operation. Currently, the gold standard for treating such aortic segment is the arch replacement using deep hypothermic circulatory arrest and antegrade/retrograde perfusion. Arch vessel debranching with subsequent TEVAR is performed in cases that are unfit for hypothermic circulatory arrest, e.g. high-risk patients. Such procedure has been associated with promising results, however an increased risk of new complications, like retrograde type A aortic dissection, have been reported [17]. For descending aortic aneurysms, TEVAR is typically done when suitable anatomy is present. An open approach is reserved for those patients in whom the aortic anatomy is not proper for TEVAR.

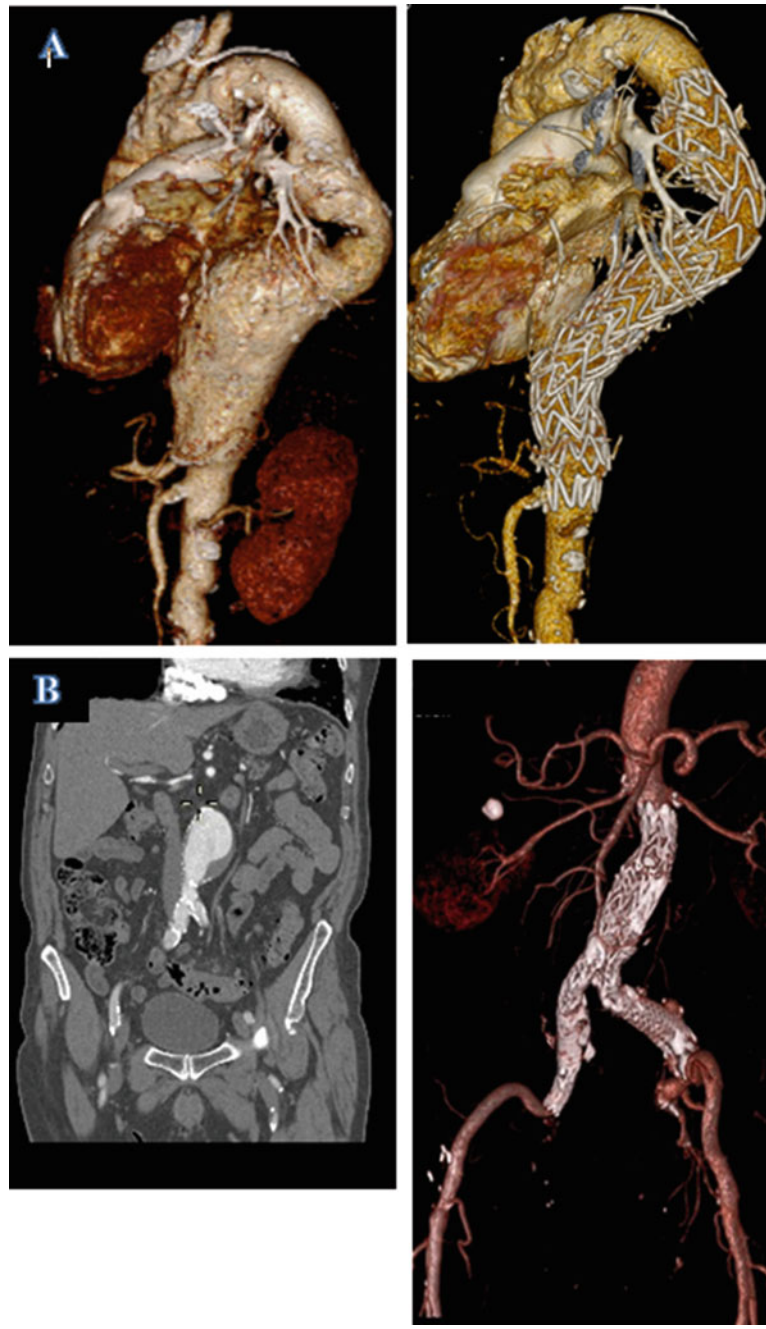

Fig. 10.2 Different types of aortic repair. (**a**) Pre- and post-TEVAR. (**b**). Pre- and post-EVAR

For AAA, open surgical repair is associated with an operative mortality of 1–8 % and postoperative cardiovascular events may be present. Preoperative clinical conditions are the most important risk factor for mortality, i.e., the presence of cardiac or respiratory diseases or decreased renal function. However, open repair is a very durable management strategy, associated with low late graft-related complications [18]. Assessment of the clinical cardiac status is needed before surgery, since coronary artery disease may be frequent in these patients and is

related to a higher perioperative mortality rate, primarily due to aortic clamping and blood loss. EVAR has a lower mortality rate, but needs more strict follow-up and is associated with additional risks related to endograft failure and presence of endoleaks [19]. Currently, EVAR (Fig. 10.2b) has been used for >20 years and because of the less-invasive nature of the procedure the implementation has become more common also in high-risk patients [19]. It is also important to note that EVAR is not suitable for all patients, since it requires femoral arteries that are not overly tortuous, a decent proximal and distal landing zones and acceptable aortic neck angulation.

Thoracoabdominal aneurysms can be managed with branched and fenestrated endografts [20]. These grafts are constructed in a custom made fashion, for an optimal match of the patient specific situation. The branched and fenestrated grafts show similar or even improved short-term outcomes compared to open repair, but long-term outcomes are lacking currently. Because the procedure is challenging, requiring advanced skills in endovascular manipulation of the graft, it is limited to high-volume specialist centers [21].

Follow-Up

After any type of aortic repair, the first follow-up visit should be scheduled after 3 months to check for signs of early complications. After this, the patient should be checked after 6–9 months, and yearly thereafter. For patients affected by TAA or AAA and not operatively treated, initial follow-up can safely be planned after 6 months. After TEVAR imaging is conducted using either CT or MRI. The choice depends on the type of stent used (stainless steel cannot withstand MRI and nitinol results in major artifacts) and the patient (MRI if radiation reduction is needed and/or in presence of impaired renal function). After EVAR, duplex ultrasound is commonly used to identify endoleaks. MRI can also be employed. Imaging after open surgical repair for TAA is performed to focus on surgery related complications, such as pseudoaneurysms. The imaging interval is usually less strict compared to TEVAR. Follow-up after open surgery for AAA is performed every 5 years, which makes the interval even less stringent.

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Abdominal Aortic Aneurysm in Jordan: Status and Management Strategy

11

Mamoun Al Basheer

There are very few epidemiological studies in the Middle East to elucidate the incidence and prevalence of abdominal aortic aneurysms in the region [1]. There is no good reason however to think it might be greatly different in Jordan than western data. The average life expectancy in Jordan is 74 years [2] which is lower than western life expectancy however this is offset by a higher prevalence of risk factors and most significantly smoking where 62 % of adult males smoke [3].

A specialized vascular surgery service has been in existence in Jordan for about three decades with a training vascular surgery unit that qualifies trainees with Jordan Vascular Board established in 1993. We have noticed over the last two decades a huge increment in the number of cases diagnosed with abdominal aortic aneurysms. This is mainly due to better awareness of the condition and the widespread availability and use of diagnostic modalities like ultrasound and CT.

The etiology is mainly atherosclerosis, however we do see a fair number of unusual etiologies like Behcet's disease [4] and mycotic aneurysms mainly due to the large catchment area of around six million population and referrals from adjacent countries, as Jordan tends to be a popular medical tourism destination.

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The most commonly encountered elective presentation is incidental finding during imaging for other complaints [5].

What comes also with the improved diagnostics and advance in the standard of specialized care is timely diagnosis and treatment of ruptured aneurysms.

The full spectrum of diagnostic modalities is available even in peripheral hospitals in the south of the country. The main vascular unit in the country is at King Hussien Medical Center, Amman. It has a specialized vascular laboratory, which undertakes size surveillance for smaller aneurysms not indicated yet for treatment.

Repair of aortic abdominal aneurysm (AAA) is performed to prevent progressive expansion and rupture [6]. The surgical repair first reported in 1962 remains the treatment with the best long-term results. It is a major surgical procedure done under general anesthesia, usually consisting of a mid-line laparotomy and cross clamping of the aorta and the iliac vessels. Open surgery has non-negligible mortality (3–7 %) and postoperative complications associated with along hospital stay (10.8 days average) [7].

In our practice surgery is reserved these days to fit younger patients and those not appropriate for endovascular repair. Our aneurysm practice has taken a paradigm shift towards endovascular repair driven by outcomes and patient wishes.

In our aortic surgery practice we have developed mini-laparotomy aortic surgery either

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through a midline or transverse incision into the standard and as such when appropriate we do mini-laparatomy aneurysm repair, which seem to have shorter hospital stay, faster recovery and less perioperative morbidity. A bias selection towards fit non obese patients tends to exist.

Since first reported nearly 25 years ago, endovascular aneurysm repair (EVAR) has been established as a safe and effective alternative to open surgical repair in the treatment of infrarenal AAAs [8].

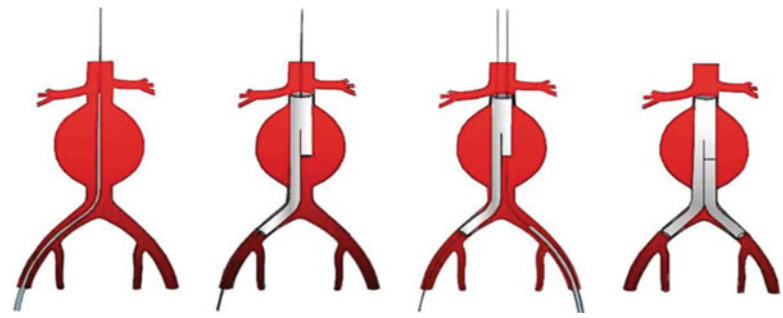
Equated to the gold standard of open repair, EVAR, as a "one-time procedure," substantially reduces operative morbidity, hospital stay, costs, and utilization of intensive care facilities if performed in a high-volume center [9].

Converge includes EVAR procedures, which has been a boost to our practice since our first EVAR back in 1999.

We have also formulated a working relationship with industry that makes a large spectrum of devices available on shelf for emergencies including ruptures.

Our endovascular practice is the second biggest in the region with around 75 grafts deployed annually and close to 500 have been done so far.

We also tend to get the more complex cases either from other health institutions in Jordan or from adjacent countries. We have recently presented our experience with extension of proximal landing zone by use of chimney or hybrid



With improvements in devices, the main problems with EVAR are being tackled. These include the need for followup imaging and repeat interventions, endoleak, and late ruptures.

EVAR is best performed in specialized centers.

Our vascular surgery unit is one of the few specialized centers in the region. The service is also provided in the private sector in many of the larger hospitals in Amman.

Jordanian nationals enjoy a near universal free health coverage where all those that have a national number have access to treatment in our vascular surgery unit.

procedures. Recent publications on the chimney technique [10] encourage us to use it more where it is indicated.

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Aortic Disease and Management in India

12

Madathipat Unnikrishnan, Ajay Savlania, Prakash Goura, and Ramesh K. Tripathi

Ancient History

It is well known from the excavations of Mohen Jo Daro and Harappa 3000 BC that Indians were one of the first humans to practice medicine and surgery [1]. By the era of Atreya (1500 BC), there was already a specialty of surgery established by the sage surgeons called "shalya tantra". The first written evidence of abdominal aortic aneurysm goes back to 'Book of Hearts' from the Eber Scrolls of ancient Egypt, dating back to 1550 BC [2]. In India, Sushruta in 800–600 BC had described aneurysm as 'Sira Granthi' or tumour of blood vessels (Chap. 17 of his great medical text 'Sushruta Samhita') (Fig. 12.1) [3].

The first aortic surgery in India was performed in the late 1950s mainly due to the efforts of cardiothoracic and vascular surgeons at KEM Hospital, Bombay. Dr PK Sen, Dr GB Parulkar, MD Kelkar and TP Kulkarni were the pioneers who laid the foundation of Aortic surgery in India.

Dr Sen performed India's first and world's sixth cardiac transplant in 1968. He was very much influenced by Soviet Cardiac surgeons and collaborated extensively with Professor VP Demikhov and used a modified technique of cerebral perfusion by right subclavian-left common carotid bypass to perform the first successful aortic arch replacement for arch aneurysm in 1973. He also published extensively on nonspecific aortitis and he published the first monograph on Middle Aortic Syndrome [4].

Dr GB Parulkar established hypothermic circulatory arrest technique of resection of aortic aneurysms in India This he used for surgery of thoracic as well as abdominal aortic aneurysms at KEM Hospital, Bombay in the late 1950s and early 1960s. He also described his technique of left heart bypass for thoracic aortic aneurysms.

Dr TP Kulkarni described Tuberculous Aortitis and published widely on mid-aortic syndrome, thrombosis of small aortic aneurysms and aortoarteritis in India. Saibal Gupta from NRS Medical College, Calcutta in 1979 described the surgical and hemodynamic considerations in middle aortic syndrome and showed that aorto-aortic bypasses are effective for this condition. Prof. MS Valiathan was a true pioneer of aortic surgery in south India. He described the Gott shunt and developed Sree Chitra tilting disc prosthetic cardiac valve.

The 1990s brought a major shift in the practice of aortic surgery in India. Firstly, the introduction of computerised tomography scan, digital subtraction angiography and improved ultrasound scanning enhanced the diagnostic capability of picking up thoracic and abdominal aortic aneurysms. Secondly, the return of a new

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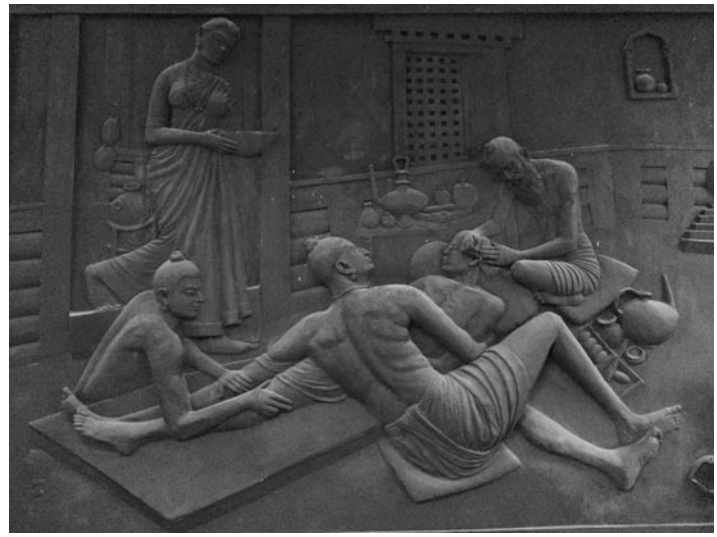

Fig. 12.1 Susruta operating on a patient 600–900 BC

breed of fully trained aortic/vascular surgeons from abroad and the formation of Vascular Society of India in 1994 opened the way for aortic surgery to be performed by vascular surgeons predominantly. Thirdly, the introduction of endovascular techniques for aortic aneurysm repair by Juan Parodi in 1991, fired the imagination of vascular surgeons who went to specifically train in these techniques and subsequently perform EVAR in India.

Dr AK Gupta and his colleagues from Sree Chitra Institute of Medical Sciences, Trivandrum were the first to report aneurysmal form of Takayasu's disease in 1990. This was followed by a new classification of Takayasu's arteritis by Dr BK Sharma and Dr Numano in 1997 [5].

Dr Ramesh Tripathi's group in Bangalore was already exploring endovascular repair of aortic aneurysm after an advanced training at University of Cologne. Before custom grafts were available, Dr Tripathi's group had already performed a home-made stent grafting of an external iliac artery pseudoaneurysm.

Dr Tripathi performed the first successful EVAR in India with a custom designed modular bifurcated Vanguard™ stent graft (Boston Scientific Inc, Natick, USA) in June 1997. In 1998, World Medical Inc. introduced its Talent stent graft for Thoracic aortic aneurysm and on the heels of his EVAR success, Dr Tripathi ably assisted by his fellow Dr Sanjay Desai performed the first successful TEVAR in India in MS Ramaiah Medical College, Bangalore on 12th November 1998.

In 1999, Dr Sanjay Tyagi reported the first experiences of stenting for failed angioplasty of stenotic aorto-arteritic lesions [6]. During this time, Dr K Neelakandan and Dr M Unnikrishnan from Trivandrum pioneered repair of Thoraco abdominal aneurysms in India [7] in Trivandrum.

In 2005, Dr Tripathi performed experimental work on in-situ fenestration of thoracic endografts and showed that preservation of subclavian and carotid perfusion was possible safely [8]. In 2012, Verma, George and Tripathi from Bangalore and Sen, Stephen and Agarwal reported their experience with occlusive aortic diseases [9, 10].

Fenestrated grafts were adopted for complex anatomy in India by the Vellore and Mumbai groups as early as 2011 and adopted by other groups in Bangalore and New Delhi by 2013. Surgeon fenestrated grafts have been popularized by the Vellore group with the development of metal sizers to allow easy and accurate fenestrations [11].

Current Practice

In India, Atherosclerosis constitutes the principal aetiopathogenesis for aortic diseases that are classified into chronic disease states and acute aortic syndromes.

Chronic Disease States

1. Congenital—Coarctation of aorta
2. Degenerative—Aortic aneurysm and aorto-iliac occlusive diseases
3. Connective tissue disorders—Aortic dissection and aneurysm.
4. Inflammatory—Aortoarteritis, aortic aneurysm, aorto-arterial steno-occlusive disease

Acute Aortic Syndromes

1. Ruptured aortic aneurysm
2. Acute aortic dissection
3. Penetrating atherosclerotic ulcer (PAU)
4. Intramural hematoma (IMH)

Of the numerous clinical conditions, abdominal aortic aneurysm constitutes the commonest of aortic diseases forming the flagship clinical entity that has been the prototype around which nearly all refinements in diagnosis and treatment strategies occurred in vascular surgery.

Although, coronary artery and extracranial carotid artery diseases are prevalent in India like in the developed countries, aortic diseases appear to be of much less incidence compared to developed countries as per the number of patients treated by vascular surgeons across our country. Longer life expectancy, dietary habits and Caucasian ethnicity may be predisposing factors for higher prevalence in western world.

This chapter will mainly focus on aortic aneurysmal disease in detail, mentioning the other clinical disease entities in brief, as practised between the two largest centers of Aortic surgery in India where the authors come from:

Abdominal Aortic Aneurysm

Clinical Evaluation

1. Presentation—Unlike elsewhere in the world, a good subset of patients (50 %) present with symptoms referable to abdominal (and likewise thoracic too) aortic aneurysms. Only 10 % of patients present with rupture in abdominal aortic domain and another 40 % detected incidentally while being evaluating for unrelated causes.
2. Age group: Most patients belong to 55–65 year group, with only 10 % presenting beyond 75 years, having male preponderance, with 9:1 male to female ratio. Comorbidities are usual with high incidence of hypertension, COPD and smoking.
3. Investigations: Ultrasonography is the initial preferred diagnostic modality. Specific investigation, computerized tomography (CT) aortogram of abdomen including lower chest, is performed in every single patient for delineation of surgical anatomy for the last three decades. Whenever renal dysfunction is detected or ruptured aneurysm is suspected by the classic clinical triad, contrast injection is avoided, utilising ultrasonography and noncontrast CT scan for abdominal aortic aneurysm.
4. Complete hematologic and biochemical investigations, coronary work up and respiratory evaluation is mandatory for all patients with aortic aneurysmal disease.
5. Threshold for AAA repair is ≥5.5 cm and thoracic aneurysm ≥6 m. In female patients ≥5 cm is taken as threshold, although number of afflicted and treated patients is small in number [12, 13].

In studies of abdominal aortic size in CT scan performed for vascular and nonvascular indications and based on body surface area calculated using Mosteller formula from individual patient's weight in kilograms and height in meter [14], a personalised threshold is derived, helping to choose the appropriate size and time to decide intervention in asymptomatic, the so called small AAA patients measuring 4.0–5.4 cm in size.

Surgery

1. Open surgical repair is performed in standard fashion using transperitoneal midline xiphopubic laparotomy in almost all patients. Endovascular repair is performed only on

selective indications. From 1998 till date in all 716 patients have been treated for AAA of which 554 (77.4 %) patients [467 (84.3 %) elective and 87 (15.7 %) ruptured] have been surgically operated upon by the authors. Coated polyester straight tube graft inclusion repair could be achieved in 70 % of patients and rest required uni/bilateral iliac aneurysm repair mandating bifurcated aortic prosthesis. Sri Chitra Institute uses albumin/gelatin coated dacron grafts where as the Narayana group uses a variety of grafts including ePTFE (Goretex, Atrium) and gelatin and albumin coated dacron grafts (Maquet, Hemashield and Vascutek). Elective open surgery mortality is currently 3.2 and 25 % in ruptured AAA patients which justifies our heavy bias towards open repair then and now (four). Our patients arrive late due to poor transportation and are mostly hemodynamically unstable on presentation. In the same period, 162 (22.6 %) endovascular aneurysm repairs (EVAR) (144 (88.9 %) elective and 18 (11.1 %) ruptured) were performed. In EVAR group, secondary intervention was necessary in 3.08 %. Elective EVAR mortality is currently 0.69 and 27.7 % for ruptured AAA patients. There were 11 (6.8 %) endoleaks: Type 1 (9.1 %), Type II (81.8 %) (stable 7/9 (77.8 %); reintervened 2/9 (22.2 %), Type III (9.1 %). There were two limb occlusions treated by femoro-femoral cross over bypass.

2. During the last 4 years, 18 patients with juxta renal AAA underwent open surgery. A modified top end strategy, essentially a triad of surgical adjuvants namely, (a) division and suture closure of left renal vein flush with IVC, (b) inter renal aortic clamping maintaining visceral and upper renal artery perfusion and (c) renal preservation fluid through lower renal artery during proximal anastomosis. One patient required right renal artery stenting for acute renal failure subsequent to snow ploughing effect into the right renal artery ostium following inter-renal aortic cross clamp (five). Seven (8.6 %) patients had transient rise in creatinine of which one patient required temporary dialysis.

Thoracic Aneurysms

Vascular surgeon's domain starts from aortic arch moving across to descending thoracic aorta (DTA) followed by thoracoabdominal aortic aneurysm (TAAA). Till 2007 open repair was resorted to, in all patients needing intervention. However thereafter, aortic stentgrafting became the frontline therapy for thoracic domain except in selected patients in good health, aged < 60 years and large aneurysms presenting with dysphagia.

Presently Thoraco-abdominal Aortic Aneurysms (TAAA) form the main indication for open repair. Open repair of TAAA is performed using thoracophreno-retroperitoneal approach to reconstruct the aneurysm and additional upper thoracotomy in case of Crawford type-I & II extent, with inclusion graft technique, reimplanting viscero-renal arteries and intercostal arteries [15]. Whenever possible large intercostal arteries are included in bevelled proximal/distal aortic anastomosis and smaller ones are sutured off. Cerebrospinal fluid drainage is employed in all patients since 2005 onwards. Distal aortic perfusion is achieved using temporary aorto-femoral bypass (Fig. 12.2), from where blood is siphoned out to provide perfusion to viscero-renal arteries using Pruitt- Inahara shunts. Cold renal preservation solution (Custodiol™) is used in most of the procedures prior to transostial blood perfusion.

Vascular registry documented 168 patients with thoracoabdominal aortic aneurysm (TAAA) having undergone elective conventional open repair. There were Crawford 29 (16.4 %) Type I, 42 (25.0 %) Type II, 7 (4.2 %) Type III, 86 (51.2 %) Type IV and 4 (4.2 %) Type V TAAAs.

There was an overall mortality of 35/168 (20.8 %) and all survivors discharged to their homes, without needing to enter into secondary high dependency centres (for spinal cord or renal dysfunction). 30 % patients had Takayasu's arteritis as aetiopathogenesis for TAAA in our series. Poor outcomes were recorded in patients with prior ischemic heart disease, respiratory dysfunction, prior abdominal surgery and extent of surgery.

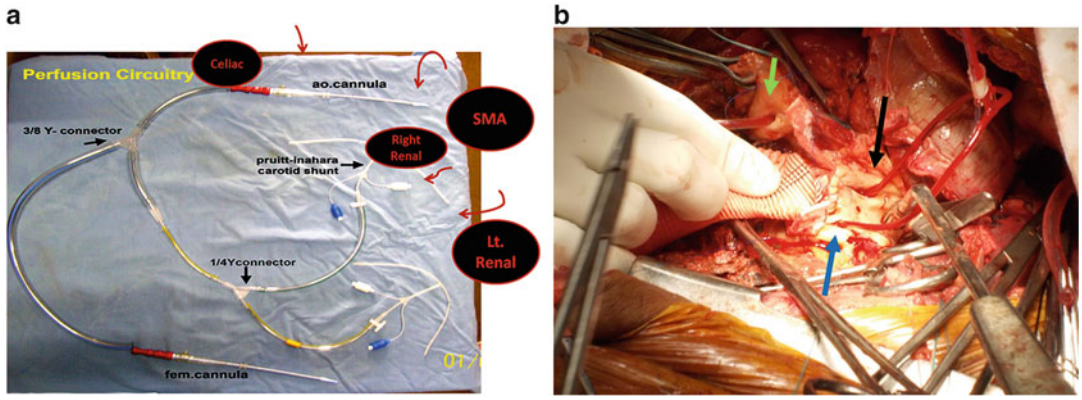

Fig. 12.2 (**a**) Picture showing indigenous Aortofemoral and viscerorenal circuitry for distal aortic and viscerorenal perfusion during the conduct of thoracoabdominal aortic aneurysm repair (all limbs are labeled). Y connector between aortic and femoral cannulae facilitates homemade circuitry to siphon out blood from aorta through two Pruitt Inahara [9F] shunts for transostial perfusion of viscerorenal arteries while aneurysm is opened between clamps. (**b**) Intra operative picture showing in situ limbs of Pruitt-Inahara shunts perfusing SMA (*black arrow*), right renal (*blue arrow*) and button of left renal artery (*green arrow*) during the repair of TAAA

Coarctation of Aorta

Patients with Coarctation of Aorta in adulthood, in particular, presents with severe/intractable cephalobrachial hypertension. Primary choice at Sri Chitra Institute is open repair by excision of coarctation segment followed by reconstruction of aorta in majority with interposition prosthetic graft [16]. In a small subset, graft bypass from left subclavian artery to descending thoracic aorta was also chosen due to technical reasons. We have performed 87 adult coarctation reconstructions without mortality or major morbidity [17]. The Narayana Institute utilizes endovascular technique preferentially in coarctation of aorta. 106 procedures have been performed with no mortality. Covered stents were used in 40 % of cases.

Aortoiliac Occlusive Disease and Middle Aortic Syndrome

Former as a result of atherosclerosis and latter Takayasu's disease are dealt with ballon aortoplasty in majority of patients. Flush aortic occlusions are addressed by open surgical approach. Aortic thromboendarterectomy is facilitated by supraceliac aortic cross clamping, vertical aortotomy 5 mm below the lower renal artery allowing disobliteration of aorta in about 10 min and aortic graft anastomosis performed after shifting the aortic cross clamp to infra renal aortic position. Aortobifemoral bypass graft procedure accomplished in usual fashion.

Aortic Stentgraft Procedure

Beyond 2007 till date, 110 endovascular aortic repair was performed, of which EVAR was only ten in number in selected AAA patients. Hybrid aortic arch, for degenerative aneurysms and Stanford B aortic dissection (Juxta subclavian intimomedial tear in Stanford-B aortic dissection) was employed in 44 patients. Standard TEVAR was performed in 56 patients, two patients in TEVAR group required visceral artery debranching. Endovascular repair is the first choice in thoracic domain except for patients with low morbidity index, age less than 65 years and presenting with dysphagia (six) wherein open repair is the preferred strategy.

Aortic Dissection

Stanford A aortic dissection (AD) with its intimomedial tear and intimal flap commencing in supracoronary ascending aorta is beyond the scope of vascular surgeon's domain. Stanford-B AD with intimomedial tear starting in post subclavian descending thoracic aorta is initially treated in the line of modified Wheat and Palmer regimen [18]. In complicated cases, early TEVAR with or without fenestration or covered stent to treat malperfusion, was used in four patients out

of the 57. In eight patients above >75 year and having high comorbidity index, medical management was pursued. Eleven patients underwent open surgical repair using cardiopulmonary bypass and deep hypothermic circulatory arrest with nine survivors. Total 53 patients underwent standard/hybrid TEVAR as dictated by the close proximity of intimomedial tear to the left subclavian artery origin. Mortality rate was 4/54 (7.0 %). One patient succumbed to visceral malperfusion in perioperative period, second patient expired during the conversion to open repair at 18 months following TEVAR due to aneurysm dilatation of dissected aorta and two patients died during follow up.

Acute Aortic Syndromes

Four in all, acute aortic syndromes cause severe distress and a subset mandates immediate attention (Ruptured aortic aneurysm and Stanford B AD with complication) and others at planned time line.

Having had poor results with ruptured TAAA, no surgical option is given to these patients. In contradistinction during last 5 years, 57 AAA patients presented with rupture, for which our only option was open surgery leading to 75 % early survival. In our setting we do not offer EVAR in rupture instance. We have had only few patients with IMH and PAU, who were given open/endovascular repair.

Primary Aortic Mural Thrombosis

Primary Aortic Mural Thrombus (PMAT) is an uncommon condition but important source of non cardiogenic emboli with a difficult diagnosis and a high rate of complications including high mortality. We reported our experience (largest in the world) of thrombo-embolic disease from PMAT and reviewed its contemporary management. A total of 88 patients presented with acute occlusion of the extremities or visceral arteries between January 2011 and September 2013 were included in this study. Of these, 19 patients (mean age 41.2 years; Male: Female ratio 1: 2.1) had a major thrombotic or embolic source within an otherwise normal aorta after thorough evaluation of heart and great vessels. In ten patients thrombus was located in thoracic aorta, three in perivisceral abdominal aorta and six in infra-renal aorta. Thrombus in thoracic aorta was treated with stentgrafts in four, bare metal stents in three and anticoagulation alone in two patients. In suprarenal abdominal aorta all three patients underwent trapdoor aortic thrombectomy. Infra-renal aortic thrombus was managed by aorto-bifemoral embolectomy in two, aortic stenting in two, surgical thrombectomy in one and oral anticoagulation alone in one patient.

Successful treatment defined as freedom from further embolic events or recurrence of thrombus was achieved in (14/19) 76.4 % patients with mean follow-up period of 16.2 months (range 2–28 months). There were four (21 %) thrombus related deaths, all due to primary thromboembolic insults. One patient needed a below knee amputation due to recurrent thrombotic episode.

Symptomatic Primary Aortic Mural Thrombus (PAMT) is an uncommon but important source of non-cardiogenic embolus. It appears to occur more frequently in young female adults. Endovascular coverage of the aortic thrombus, when feasible, appears to be an effective and safe procedure using either stentgrafts or closed cell metal stents. When thrombus is located adjacent to visceral vessels, it should be managed with an open trapdoor thromboembolectomy [19].

Summary

Our experience at two major institutes in India reflect aortic practice in our country. There is no National vascular registry available as of now.

In India, currently endovascular aneurysm repair have largely broadened the therapeutic strategy for aortic aneurysm. It is estimated that on an average 500 procedures being performed by vascular surgeons, interventional radiologists and cardiologists of which 150 open surgery and 350 endovascular aortic repair annually.

Taking a leaf from worldwide burden of surveillance, the need for secondary reinterventions, a small but distinct (continued) risk of rupture of aneurysms treated by endovascular repair and availability and affordability of endovascular repairs, we have in place a robust and perseverant protocol of conventional open surgery for AAA and select EVAR for elderly patients reporting with high comorbidity index, hostile abdomen or

stable hemodynamics allowing procurement of devices and planning repair.

In view of the fact that, our patient's body surface area is between 1.4 and 1.8 m^2, accepted threshold to intervene is ≥5.5 which may not be suitable for intervention/surgery in India. We have worked out a personalised threshold to decide optimal size and time to intervene since we believe personalised and not universal threshold is pertinent to our patients.

A triad of surgical adjuvants described earlier has helped to treat juxta renal AAA successfully although only in 18 patients recently. These adjuvants are already of proven value individually, but three components judiciously used during surgery has benefitted the complex subgroup of juxtarenal AAA with excellent recovery and quality of life.

Endovascular aortic repair has evolved as primary therapeutic strategy across India, wherein paradigm shift to perform aortic stentgrafting for aneurysm and Stanford-B aortic dissection in varying proportion exists today. Though numbers are small, vascular practice has kept up with changing trends and strategies across the country with excellent results. However, we believe, in a country like India with limited resources and access to endovascular surgery, AAA seems to be a domain for open surgery with its proven durability and easy surveillance with EVAR being used in selected patients. Although data from the recent trials shows the early survival benefit with EVAR compared to open repair at 1 month but survival at 2 years equalizes with open and EVAR groups for AAA repair.

In thoracic aortic domain, in contradistinction, endovascular repair is going to be therapy of choice for all thoracic aortic pathologies for obvious reason of early and late success in most institutions world over.

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Aneurysms: North America

13

Samir K. Shah and Matthew T. Menard

Abdominal Aortic Aneurysms

Based on an analysis of abdominal aortic aneurysm prevalence in 21 global regions, North America has one of the highest rates at 256 cases per 100,000 in the world; only Australasia has a higher rate [1]. This 2010 rate represents a substantial decrease from the 1990 prevalence estimate of 300 per 100,000, and possibly reflects a parallel drop in smoking patterns over this same time period [1]. Given current epidemiologic data, the United States Preventative Services Task Force recommends a single ultrasound screening of males aged 65–75 years who have smoked at least 100 cigarettes [2]. Selective screening based on medical and family history and goals of care is suggested for males in this age category who have not smoked. Screening is not recommended for women who have never smoked and the task force found insufficient data to recommend for or against screening of women aged 65–75 who have smoked.

Examination of the Nationwide Inpatient Sample (NIS) provides more granular data on the United States aneurysm population. The NIS is the largest American all-payer database and accrues data on roughly eight million discharges a year. Data from 2000, the first year endovascular aneurysm repair (EVAR) had a unique code, to 2010 includes 90,690 unruptured aneurysms and 11,288 ruptured aneurysms [3]. Seventy-nine percent of this cohort was male, 90 % was white and the mean age was 72.6 years. There was a 3 % in-hospital mortality rate for unruptured aneurysms with a median hospital length of stay of 5 days. Ruptured aneurysm patients, in contrast, had a 39 % in-hospital mortality and a 9-day median length of stay.

Stratifying by rupture status, 42,642 patients underwent open repair of unruptured aneurysms while 48,048 underwent endovascular treatment [3]. The latter cohort was more likely to be male (83 % vs. 76 %) and older (74 vs. 71 years). With EVAR, in-hospital mortality was better (1 % vs. 4 %, $p<0.001$) and length of stay was shorter (2 vs. 7 days, $p<0.001$). Nine thousand five hundred and thirty-eight patients had open repair of ruptured aneurysms and 1750 had endovascular repair [3]. Patients undergoing endovascular repair were older but there were no racial or age differences compared to the open cohort. As for unruptured aneurysms endovascular repair was associated with lower inpatient mortality (27 vs. 41 %, $p<0.001$) and a shorter length of stay (6 vs. 9 days, $p<0.001$).

There is a clear trend towards increasing use of EVAR in the US: in 2000, 5.9 % of unruptured and 0.8 % of ruptured aneurysms underwent

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endovascular repair compared to 77.8 % and 38.4 %, respectively, in 2010 [3]. One consequence of the rising frequency of endovascular repair is that open repairs are more likely to occur in anatomically complex patients. Barshes and colleagues used a prospectively maintained single-center registry to examine 1188 consecutive aneurysm repairs and found that, indeed, contemporary open aneurysm repair (2004–2010) was more likely to have greater blood loss and require suprarenal clamping than those that occurred in an earlier period from 1995 to 2004 [4]. Despite the apparent shift in complexity, there were no statistically significant changes in short- or long-term patient survival, length of stay, or complication rates.

Decreasing American trainee experience with open aneurysm repair is an additional effect of the changing paradigms of aneurysm therapy. In 2010, the average vascular surgery trainee in the US graduated with 21.7 open aneurysm cases, while the typical graduate in 2015 is expected to have completed only ten cases [5]. If current projections are accurate, this number will fall to only five cases by 2020 [5]. The predictions do not take into account fenestrated and branched endografts, which may further reduce open experience. These are understandable but nevertheless alarming changes that will be need to be addressed at a national level.

Descending Thoracic Aortic Aneurysms

As with abdominal aortic aneurysms, the therapy of descending thoracic aortic aneurysms has been revolutionized by the advent of stent grafts. This point is demonstrated by Kilic's analysis of NIS data spanning the decade beginning in 1998 [6]. This study includes 20,568 patients who underwent repair and covers the pre- and post-thoracic endovascular aneurysm repair (TEVAR) era. 17,780 aneurysms, or 86.4 %, were unruptured and the mean age overall was 64.7 years. 58.2 % of the cohort was male and the most common comorbidities were chronic obstructive pulmonary disease (COPD) (24.7 %), congestive heart failure (11.1 %), and stroke (10.9 %). The repairs took place principally at teaching hospitals (78.9 %) in an urban location (98.7 %).

Operative mortality decreased through the study period for all descending thoracic aortic aneurysm repairs [6]. The mortality associated with unruptured aneurysms diminished from 10.3 % in 1998 to 3.1 % in 2008 ($p < 0.001$) while peri-operative repair of ruptured aneurysms decreased from 52.6 % to 23.4 % ($p = 0.002$) over the same period. This improvement occurred despite the increase in comorbidities in the population: patients undergoing repair of unruptured aneurysms from 2005 to 2008 had higher rates of diabetes, renal insufficiency and COPD compared to those repaired from 1998 to 2004. They also had a higher Charlson index, a common weighted comorbidity scale. Similarly, patients undergoing repair of ruptured thoracic aneurysms had higher rates of renal insufficiency and worse Charlson indices in the second study period.

Diminished mortality in the face of sicker patients is likely largely due to more frequent endovascular repair. Multivariate analysis shows that open repair is independently associated with operative mortality [6]. Indeed, the rate of open thoracic aortic aneurysm repair went from 3.8 in 2005 to 4.4 per million in 2008, while endovascular repair increased from 1.0 to 6.2. A similar trend is seen for ruptured aneurysms. Overall repair rates increased from 2.2 in 1998 to 10.6 per million, suggesting that more patients were offered treatment in the endovascular era despite an overall worsening of their comorbid status.

The results of endovascular repair must be viewed critically, however. Goodney and colleagues used Medicare data from 1998 to 2007 to examine both perioperative and long-term outcomes [7]. This included 12,573 open repairs and 2732 endovascular repairs. 1307 (1008 open and 299 endovascular) were for ruptured aneurysms while the remainder was for intact aneurysms. They found that 30-day operative mortality was comparable between endovascular and open approaches for intact aneurysms: 6.1 % versus 7.1 % ($p = 0.07$). However there was a clear difference favoring endovascular therapy in ruptured aneurysms: 28.4 % vs. 45.6 % ($p = 0.0001$).

The survival advantage associated with endovascular repair of intact aneurysms disappears within 1 year once the results are adjusted for age, sex, race, timing of procedure, and Charlson index. Indeed, patients undergoing TEVAR have worse 5-year survival than those who undergo open repair (79 % vs. 89 %). The authors noted similar findings for repair of ruptured thoracic aortic aneurysms, with a disappearance of the TEVAR advantage within 90 days of surgery. The ability to repair aneurysms in sicker patients via TEVAR may not yield a long-term survival advantage, a topic that merits further investigation.

Thoracoabdominal Aortic Aneurysms

In contradistinction to abdominal and thoracic aortic aneurysms, data on national trends of thoracoabdominal aortic aneurysm (TAAA) therapy are sparse. Broadly, there are three principal categories of repair—open, endovascular, and hybrid—each of which has its advocates.

Cowan used 1988–1998 NIS data to examine trends in open repair [8]. While the overall mortality for the cohort of 1542 patients was 22.3 %, he found a statistically significant improvement in in-hospital mortality from 1988–1993 (25.7 %) to 1994–1998 (19.3 %). Mortality was significantly higher in low-volume hospitals and for low-volume surgeons. Indeed, there are multiple single-center reports from high-volume institutions with exceptionally low mortality and morbidity [9, 10]. This observation is particularly noteworthy given that only 32.8 % of TAAA repairs were performed at high-volume centers [8].

There is no quintessential North American approach to TAAA repair. There appears to be a trend away from the historical "clamp and sew" technique for open repair toward a greater use of left heart bypass [11]. Deep hypothermic circulatory arrest is typically reserved for patients with more complicated aortic anatomy, particularly in the area of the planned proximal anastomosis. Cerebrospinal fluid drainage remains a mainstay of efforts to prevent spinal cord ischemia, and is one of few strategies to be well-supported by the literature [12, 13]. Monitoring of motor- and somatosensory-evoked potentials has also been gaining in popularity in the more recent era [11, 14].

Using the 2005–2008 NIS database, Liao et al. reviewed trends on open surgical repair of TAAA, along with a combined group of patients undergoing either endovascular or hybrid repair [15]. The report included 2911 open and 1838 endovascular repairs, with the latter group including an unknown number of hybrid repairs. The authors found that the incidence of open repair rose from 7.5/100 patients in 2005 to 10.1/100 patients in 2008, a non-significant increase. The rate of endovascular or hybrid repair, in contrast, increased from 1.4 to 6.3 per 100 cases ($p < 0.0001$).

Current era endovascular repair of TAAA is typically achieved with fenestrated stent grafts, which often take several weeks to be custom manufactured to match the patient anatomy. This technique is limited to high volume centers and has incomplete long-term follow up. The Cleveland Clinic reported a series of fenestrated endovascular repairs for 258 juxtarenal and 349 type IV TAAAs [16]. Of these, 46.5 % required an SMA fenestration or scallop, 31.1 % had a celiac scallop, and 9.6 % had a supraceliac landing zone. Technical success was 97 % and 8-year aneurysm-related mortality was only 2 %. Spinal cord injury occurred in only 1.2 %.

Hybrid TAAA repair usually involves open surgical debranching of the visceral and/or arch vessels followed by interval stent graft deployment. This approach is intended to preserve some of the advantages of endovascular repair, such as avoidance of a thoracoabdominal incision, aortic cross-clamping and prolonged visceral ischemic times, while still allowing execution of the operation without the need for custom-made stent grafts. Kabbani et al. reported an experience of 36 hybrid repairs, including 31 TAAAs and two pararenal aortic aneurysms [17]. Two patients did not go on to receive the endovascular component after debranching because of death or prolonged recovery. Three patients received a single-stage procedure. In-hospital mortality was 8.3 % and 6-month survival was 80 %. There were no cases of permanent paraplegia. Other authors have

noted less favorable results and enthusiasm for hybrid repair of TAAA has considerably dimmed in recent years as the substantial associated operative morbidity and mortality has become more evident.

Popliteal Artery Aneurysms

Popliteal artery aneurysms are increasingly being repaired using endovascular means. An analysis of Medicare claims from 2005 to 2007, including 2962 repairs, showed an increase in endovascular repairs from 11.7% in 2005 to 30.9% in 2007 ($p<0.0001$) [18]. There were significantly more males in the open cohort and more octogenarians in the endovascular cohort but otherwise no differences. In-hospital, 30-day, and 90-day mortality were comparable in both groups. Postoperative complications were also equivalent, although the types of complications were distinctive. The open group had more cardiac, pulmonary, and infectious complications while the endovascular group had more hematomas. The 30- and 90-day rates of reintervention, including thrombolysis, repeat angiogram, and thromboembolectomy, were considerably higher in the endovascular group (7.42% vs. 2.11% and 11.84% vs. 4.55%, $p=0.001$), respectively. Predictably, length of stay was higher in the open group (4 days vs. 1 day, $p<0.0001$) while hospital charges were higher in the endovascular group ($35,052 vs. $ 28,298, $p<0.0001$).

Eslami et al. used data from a prospectively maintained multicenter American and Canadian registry, the Vascular Quality Initiative, to gain another perspective on repair of asymptomatic popliteal aneurysm. The report focused on 221 open and 169 endovascular repairs undertaken between 2010 and 2013 [19]. The endovascular group was an older cohort (mean age of 73.5 vs. 68.4), with more smokers, congestive heart failure, and COPD, but fewer prior lower extremity bypasses. Outcomes were superior in the open group; specifically, those undergoing open repair had a lower 1-year risk of major adverse limb events (MALE, a composite of major limb amputation and major reinterventions, HR 0.35, $p=0.02$), MALE and 30-day postoperative death (HR 0.28, $p=0.002$), and loss of primary patency (HR 0.25, $p=0.001$). The Vascular Quality Initiative database lacks some salient information, such as diameter of bypass conduits and the types and lengths of stents, which could feasibly impact outcomes. The Open Versus Endovascular Popliteal Artery Aneurysm Repair (OVER-PAR) trial is a multicenter, randomized trial that will shed more light on the role of endovascular stent grafting in the treatment of popliteal aneurysms [20].

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Part II

Peripheral

14 Peripheral Vascular Disease and Endovascular Therapy in Singapore

T.Y. Tang, S. Kum, P. Ho, and Y.K. Tan

Introduction

Peripheral arterial disease (PAD) is a significant complication of diabetes mellitus and accounts for the majority of amputations among these patients [1]. A major lower limb amputation due to complications from diabetes occurs once every 30 s worldwide. In Singapore, it is estimated that about 1500 major lower limb amputations take place a year (approximately four per day). In addition, PAD is a manifestation of systemic atherosclerosis and is associated with increased risk of mortality and ischaemic events [2]. Despite its associations with increased morbidity and mortality, PAD is under-diagnosed and under-treated in the general Singaporean population. Patients with diabetes have unique problems with PAD, as the disease appears to affect predominantly the tibial blood vessels where open bypass surgery is often difficult with generally poor results and angioplasty generally the better option. Furthermore, pain is often not prominent due to superimposed neuropathy, and this puts them at risk of seeking medical attention only in advanced stages when there is a significant wound to heal [3]. This in turn leads to increased costly consequences such as hospitalisation for ulcers, revascularisation, amputation, need for rehabilitation and loss of employability and income.

The prevalence of PAD among patients with diabetes in the Western population ranges from 16 to 22 % [4, 5]. Comparatively, less is known about PAD among Asian populations although some studies have found lower prevalence rates ranging from 6 to 10 % [6, 7]. The Singapore REACH registry [8] reported that PAD is estimated to affect about 8.1 % of the local population, and this percentage increases with age. The incidence of PAD is expected to increase in an aging population with advancing longevity. Although this disparity in PAD prevalence between Asian and Western populations may well be true, it is likely to be attributed to underdiagnosis of this condition among Asian diabetic patients.

Narayanan et al. [9] measured the prevalence and associated factors of PAD in diabetic patients from multi-ethnic communities in Singapore. They systematically sampled 697 patients from the 3607 patients with diabetes who visited nine polyclinics during the study period, giving an overall sampling rate of 19.3 %. The population consisted of 67.0 % Chinese, 15.2 % Malays, 16.1 % Indians and 1.7 % of other ethnic groups. The prevalence of PAD among the patients with diabetes was 15.2 %, with significant differences among Chinese, Malays and Indians. Among Chinese patients, 12.6 % had PAD, compared to 17.9 % among Indians and 22.8 % among Malays.

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Patients with PAD tended to be older (66.8 vs 59.1 years of age; $P<0.001$) and had longer duration of diabetes (13.9 vs 9.8 years; $P<0.001$). From a prevalence of nearly 5 % in those below 40 years of age, the rates increased across the age groups, with nearly one in three patients above 70 years of age having PAD. Less than 10 % of patients with duration of diabetes less than 6 years had PAD, but prevalence increased with increasing duration, reaching nearly 25 % in those who had diabetes for more than 20 years. Diabetic patients with PAD were more likely to have ischaemic heart disease, stroke, peripheral neuropathy, nephropathy and retinopathy compared to patients without PAD. Factors associated with PAD in a multivariate model found increasing age, Malay ethnicity, having low serum HDL-cholesterol and insulin treatment to be factors significantly associated with an increased prevalence of PAD in this cross-sectional study. The prevalence of PVD in another Singaporean- based study was found to be 4.3 % [10]. This large, multi-ethnic, Asian population based cohort found that PAD was commonest in Indians, followed by Malays and Chinese. Apart from traditional vascular risk factors, pulse pressure, renal impairment and past history of stroke were important determinants of PAD.

Distribution of PVD in Asians

To date, there is limited data on the arterial disease distribution in diabetic patients in the Asian population. Similar European studies have shown that the arterial disease pattern in diabetics tend to be confined to the infra-popliteal vessels.

A retrospective study of consecutive diabetic patients with critical lower limb ischaemia who underwent endovascular revascularization over a 6-month period in Changi General Hospital (CGH) was carried out [11]. Fifty-seven subjects were enrolled in the study. The mean age of patients was 70 years old with a male predominance (60 %). Fifty-eight percent of the subjects enrolled were Chinese followed by Malay (30 %), Indian (7 %) and others (5 %). Of all co-morbidities, 35 % of subjects had end stage renal failure. Seventy-six percent of subjects had major tissue loss (Rutherford Grade IV and V). Arterial disease was predominantly confined to the infra-apopliteal vessels with significant percentage of patients having long segment occlusions in this group (occlusion > 50 % of vessel length) (See Figs. 14.1 and 14.2). There was also significant disease involving the pedal vessels as well (dorsalis pedis and plantar artery). This study concluded that infrapopliteal vessels were more

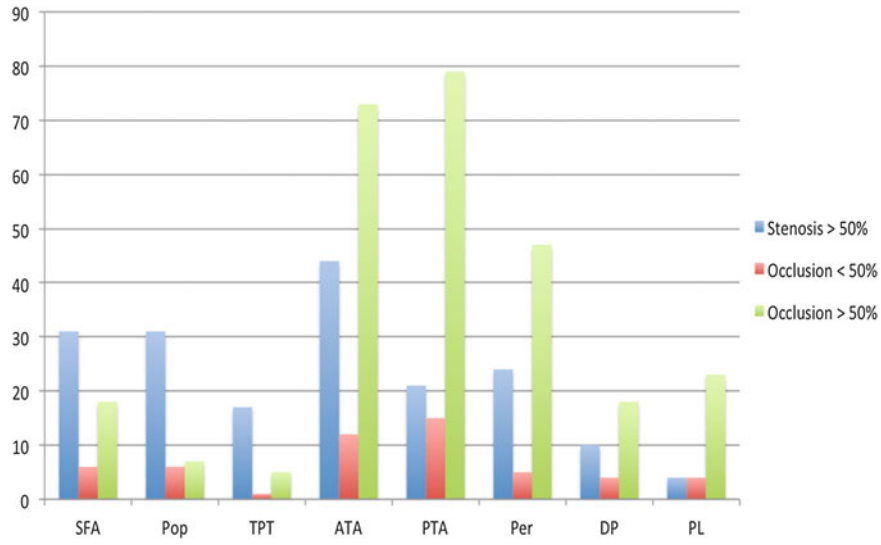

Fig. 14.1 Categorization of arterial disease pattern according to individual vessels

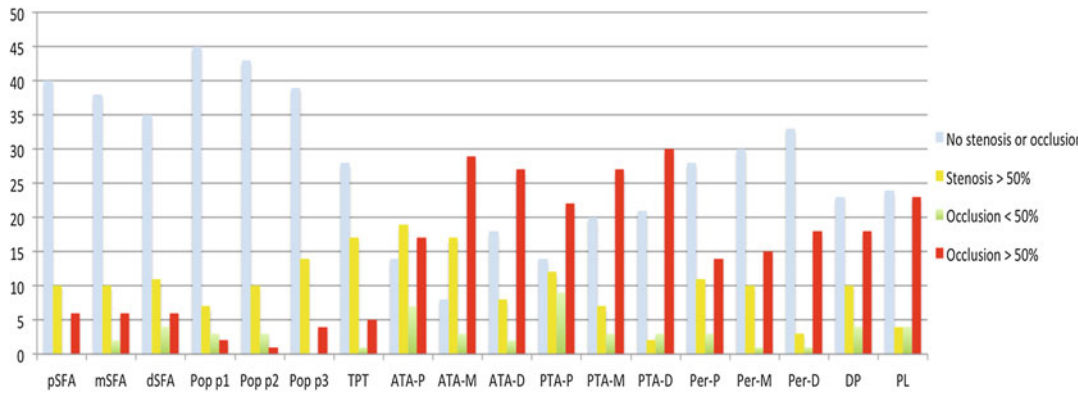

Fig. 14.2 Categorization of arterial disease pattern according to individual vessels with further subdivisions of each vessel into proximal, middle and distal segments

commonly diseased in diabetics in the Asian population and tend to present with long segment occlusions. As such, this would pose a higher technical difficulty in terms of revascularization, be it endovascular or open bypass procedures, where there would be limited availability of appropriate distal arteries to bypass to.

Intervention for PAD

One of the foremost programs launched by the Ministry of Health in studying the treatment of patients with PAD was conducted in Tan Tock Sing Hospital (TTSH) by the Vascular Surgery team. The LEAP (Lower Amputation Prevention) for Life program was first proposed by the late Dr Alexandre Chao who successfully managed to institute a 4 year program in TTSH. The program began in 2001 and was completed in 2005. During this period, a total of 413 patients were enrolled. These patients were assessed and treated with a combination of modalities including bypass surgery, limb angioplasty, pneumatic compression therapy or hyperbaric oxygen therapy. Early analysis of the results has shown successful prevention of lower limb amputations with successful limb salvage in 81.3 % of patients. Patients have also managed to retain their functional status following successful intervention, with at least 80 % of patients being able to resume their premorbid daily activities.

Endovascular Therapy

The trend of clinicians to adopt endovascular interventions for PAD has increased more than threefold in the past decade [12]. Many researchers suggested that endovascular intervention could be the first line of treatment in PAD patients [13, 14]. They indicated that endovascular intervention is safe and provides acceptable clinical improvements. The prevalence of endovascular therapy for PAD is moderate and rising in Singapore. Greater awareness by patient and referring physicians in addition to improvements in endovascular proficiencies continue to drive demand for endovascular solutions in Singapore. Disease-specific devices, relatively open regulatory environment allow today's physicians to offer cutting edge technologies to patients who otherwise could not have been treated by endotherapy. Vascular surgeons are increasingly adopting an endovascular-first approach, which probably accounts for a large proportion of the rising trend because our pool of patients is mostly elderly with multiple co-morbidities. Surgical risk profile is high. Secondly, below the knee disease is the predominant lesion in our patient population. Tibial bypass usually lands on only one target distal vessel, whereas endovascular therapy can open up as many tibial arteries as feasible, depending on the disease status and clinician's skill, which may in turn result in better revascularization to the foot and toes. Patients'

preference of a minimally invasive therapy also makes endovascular intervention a more acceptable treatment option. Asian patients are in our opinion particularly adverse to an amputation (minor or major) due to religious and cultural beliefs. Some patients believe they should go to their maker with intact body/appendages. Older patients are generally adverse to a big incision (e.g. a bypass). Endovascular Therapy is therefore a safe and attractive option for both the physician and elderly patients. However, some Asian patients are adverse to having metallic implants such as stents.

May et al. [15] reviewed the outcome of PAD patients managed with an endovascular first approach for revascularization in a tertiary referral centre in Singapore. Over a 2-year period, revascularization procedures were performed for 202 PAD patients with 229 symptomatic limbs. Angiogram was performed in all patients except those contraindicated for contrast agent. Angioplasty revascularization was carried out on the same setting whenever feasible based on the angiogram findings. Bypass surgery was performed in patients with arterial condition not feasible for endovascular intervention or in those with unsatisfactory revascularization after endovascular treatment. Among 229 symptomatic limbs, 194 limbs presented with critical ischaemia and 35 with severe claudication. Endovascular intervention was successfully performed in 198 limbs (86 %). Bypass surgery was required in 31 (15 %) patients with two of them had sequential endovascular intervention performed due to multi-level arterial involvement. Another 16 (8 %) patients required a bypass after endovascular intervention due to unsatisfactory wound healing. All cause 30 day mortality was 5.2 %. The Kaplan-Meier estimated survival and amputation free survival were 80 % and 75.5 % at 1 year and, 73 % and 57.6 % at 2 years respectively. They concluded that satisfactory limb salvage rate can be achieved in PAD patients managed with an endovascular first approach. The same group also investigated patients with intra-procedural acute thrombosis (IPAT) due to emboli or thrombosis during an endovascular salvage procedure. Indian ethnicity, in-stent occlusion and prior IPAT are associated with IPAT occurrence during endovascular interventions. Despite successful salvage, patients with IPAT appear to have poorer post-procedural runoff and are more likely to require subsequent endovascular procedures or arterial bypass when compared to patients from the control group. However, major amputation rates, overall survival and amputation –free survival are not significantly worse in IPAT patients [16].

Device Availability, Reimbursement and Training

Singapore is home to regional headquarters of several medical device companies. Devices from various companies are readily available and competition within each class of device is stiff, pushing companies to be more performance and evidence-based driven. In addition, sale of devices based on transparency and meritocracy allow companies to compete on a more level playing field. Singapore is a financial and medical bell weather for the region so this encourages companies to continue having a presence here. The regulatory environment is considered both friendly and competitive currently.

Reimbursement for medical devices is certainly a major factor all around the world. Patients still have to fork out from their pockets substantial amount of cash for devices, although the situation is improving with better conditions and subsidy given from the government MediShield program. We believe that patients will be willing to pay for the devices if a physician is able to communicate the benefits of endovascular therapy over open surgery and is competently able to deliver good results. Patients with private insurance are however well covered for medical devices. Regardless, in a cost conscious environment, knowledge of the limitations and strengths of each device will ensure physicians adopt a rational use of devices.

Endovascular training is an on-going lifelong process even for experienced physicians as long as medical device companies continue to innovate.

Training is mainly by hands-on apprenticeship, although the use of endovascular trainers is certainly helpful. We regularly run live case workshops in our hybrid suite at CGH to help train local and regional physicians across all disciplines to adopt these techniques.

Strategies for Dealing with Short Focal Lesions, Long Lesions, Calcified Lesions, CTOs, In Stent Restenosis (ISR) in the Superficial Femoral Artery and Claudicants

The following is an algorithm for treating the above-named lesions and is based on the personal experiences of the authors, treating a heavy cohort of multi ethnic patients with PAD in Singapore.

Short, Focal Lesions

There is good evidence for utilising drug eluting balloons (DEBs) for short focal SFA lesions and this is the strategy we would generally employ. If the mechanical recoil or dissection is severe after pre-dilatation, we may consider a drug eluting stent (DES).

Long Lesions

These are the common real world lesions. The patency is generally poor for plain old balloon angioplasty (POBA) and although better with stents, in stent restenosis (ISR) continue to pose a real problem. Very often, we end up sub-intimal in a long Complete Total Occlusion (CTO) and in a calcified vessel, stents are the only practical alternative to provide a mechanical solution to what will likely be a heavily dissected vessel. We try to limit the length of stents as much as we can. Scoring Chocolate balloons (QT Vascular) are occasionally used to limit the severity of dissection. If the mechanical result is good, we would consider DEBs although the evidence for long lesions is mostly registry-based.

In the occasional long diffuse stenotic lesions (especially calcified ones), we would like to consider the patient for Rotational Atherectomy (Jetstream) to initially debulk the lesion and then to line it with a DEB. This is to avoid dissection and then expose the vessel wall to the Paclitaxel drug. The results from the DEFINITIVE AR Study (REF) are encouraging for directional atherectomy in combination with DEBs and we would like to think that this can be extrapolated for Rotational Atherectomy. We are hesitant to do atherectomy in a long CTO where the wire is frequently in the subintimal plane because the risk of perforation is high.

Calcified Lesions

This is often a stubborn problem and the solutions are mainly mechanically based. Lesions that respond poorly to POBA need to be stented with dedicated stents that can deliver high radial resistive forces. We have employed the PIERCE technique (Percutaneous Direct Needle Puncture of Calcified Plaque) [17] in the SFA and BTK with good results. It is safe and improves the compliance of the vessel for a better POBA or stent result in the event high pressure POBA not working. We occasionally use it during vessel preparation before stenting.

CTOs

POBA has poor results and adjunctive techniques are employed to improve acute and long term results. As per long lesions above.

In-Stent Restenosis (ISR)

With growing utilisation of stents ISR has been a real problem and the results of POBA are poor. For symptomatic ISRs or occlusions, we employ DEBs with or without Rotarex thrombectomy and there are good results from several registries. We generally avoid covered stents as our SFAs are generally smaller in Asia (5 mm) and there is

concern about stent thrombosis should we have a stent in stent strategy. It is frustrating that heparin coated covered stents are not available currently in Singapore.

Below Knee Disease and Bio-Absorbable Vascular Scaffolds (BVS)

Below knee diseases (BTK) are challenging to treat. This is due to the extent of burden of disease, particularly in diabetic and high post-PTA restenosis rates.

With advances in drug eluting technologies, prospective clinical trials in relatively small CLI patient cohorts, tibial vessel drug-eluting balloon (DEB) angioplasty was associated with significantly reduced restenosis rates and late lumen loss (LLL) [18]. However, DEBs do not provide the mechanical advantage of endo-luminal stents. Stenting of infrapopliteal lesions are often limited by a relatively high restenosis rate and subsequent late in-stent thrombosis. The bioabsorbable stent (BVS) is a novel development that provides initial scaffolding support, elutes anti-proliferative drugs to prevent vessel restenosis and reabsorbs subsequently to reduce risk of in stent thrombosis. It hopes to address issues with pre-existing stents and promises to be the next frontier in endovascular revascularisation.

At CGH, we have investigated the early outcomes, efficacy and safety of a biorebsorbable stent (ABSORB BVS) in patients with below knee critical limb ischaemia. A case series of 13 patients with median age 67 (range 46–89) who underwent stenting of below knee arterial diseases with Bioabsorbable Everolimus Eluting Bioresorbable Vascular Scaffold System developed by Abbott Vascular (Abbott, Illinois, USA). The primary outcomes measured were stent patency, target lesion revascularization (TLR) and limb salvage rates. Thirty BVS were inserted for 14 below knee lesions. The median length of the lesions was 25 mm (range 10–70). Majority of patients has significant critical limb ischemia (Rutherford 5–6). Technical success was 100 %. Six months vessel patency, TLR and limb salvage rates were 75, 8.3 and 91.7 % respectively. There were no procedure related complications or deaths. Our study shows that BVS for below knee diseases have fairly good early outcomes, is safe and technically feasible. Longer follow-up and more rigorous clinical trials for BVS are required to determine its clinical benefits over pre-existing stents.

Claudicants

Claudicants have a good life expectancy and low risk for limb loss. Patency is required to keep them symptom free. In the absence of a good long term solution for In-Stent Occlusions/restenosis, we like to avoid stents as much as possible. We would generally consider DEBs with bailout stenting for short lesions (as evidenced by the trials on the SFA by Medtronic and Lutonix), which give us good freedom from TLRs. For longer lesions, DEBs and bailout stenting is employed although the majority of the evidence is registry-based and we have had good results with this strategy. The caveat is that after pre-dilatation, the mechanical result has to be reasonably good (i.e. no severe recoil or dissection). The lesions that have a mechanical predominant problem are probably best served with dedicated new generation stent with low Chronic Outward Force but high Radial Resistive Force. The combination concept of deliberate DEB and Stenting is interesting and we await the results earnestly

The strategy is in contrast to CLI patients who need maximum effort for limb salvage (a Femoral -Popliteal Bypass equivalent in the SFA). These patients have a limited life expectancy and may not be symptomatic from a SFA ISR. Lesion for lesion, we tend to stent these as compared to the claudicants.

Deep Venous Arterialization

It is common to see a presentation of a so-called "*desert foot*" without discernible targets for bypass or intervention. Many patients have already undergone multiple interventions. This is coined the "no-option" end-stage CLI patient. Stem cell therapy may offer some promise but is still in a relatively early phase of evaluation.

Deep venous arterialization (DVA) is not a new concept. It involves shunting arterial blood to the deep veins. Early surgical attempts and more recent surgical series reported good safety and clinical outcomes [19, 20]. These surgical approaches were plagued by valves, which are a hindrance to blood flow and would need to be made incompetent. In addition, numerous draining venous collaterals would "steal" the blood flow to the extremity. At CGH, we sought to implement this concept of DVA using a completely percutaneous approach (Fig. 14.3), percutaneous deep venous arterialization (PDVA), and have achieved some initial angiographic and clinical success.

This proof-of-concept and safety study was carried out in CGH in Singapore. This was a pilot, prospective, open-label, single-center, single-arm study under the auspices of our Institutional Review Board.

All patients were deemed "end stage" with no remaining conventional open or endovascular options as verified independently by another vascular surgeon or interventionist. Extensive bench, in vivo animal, and cadaver studies were successfully performed prior to the study.

The inclusion criteria allowed for enrolment of adult patients at imminent risk of major amputation as a result of CLI. These included Rutherford class 5 or 6 patients with an absence of a reasonable target vessel for bypass or endovascular intervention or severely diseased plantar arch or digital vessels.

Seven patients were included in the study with the following conditions: five chronic non-healing wounds/gangrene, one severe rest pain, and one severe rest pain and chronic non-healing wound. All patients had diabetes and were between the age of 49 and 94 years. Five of the seven patients had PDVA with the LimFlow device (MD Start).

The primary objective of the investigation was to determine the safety of PDVA. Secondary objectives included clinical efficacy at 6 months with outcome measures such as thermal measurement, limb oxygenations, clinical observation, and wound healing during the 6-month follow-up period.

Subjective and objective markers of perfusion were evaluated with infrared thermography (FLIR, FLIR Systems), transcutaneous oximetry measurements, and wound healing time.

The LimFlow device consists of a 7-F arterial catheter, a 5-F venous catheter, and a console to facilitate the crossing procedure with a needle. An antegrade arterial 7-F sheath and a retrograde posterior tibial vein 5-F sheath are both placed under ultrasound guidance.

Control angiography is performed to show the crossover point, the area where a needle from

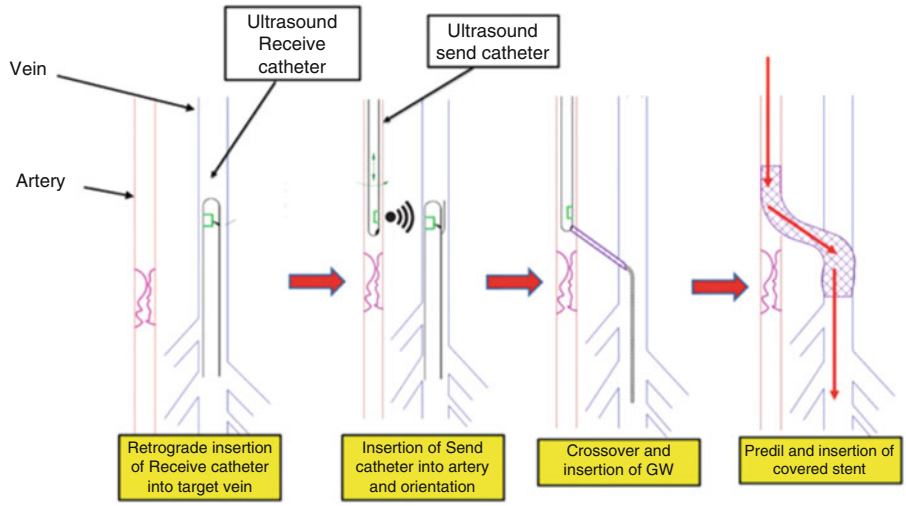

Fig. 14.3 Overview of the LimFlow approach to percutaneous deep venous arterialization

the arterial catheter is anticipated to traverse into the vein. The arterial and venous catheters are aligned with a proprietary ultrasonic system. A 0.014-in. guidewire is then driven across the crossover point and into the retrograde sheath, supported by a 3- × 40-mm balloon, which is also used to predilate the arteriovenous fistula. The 0.014-in. guidewire is then exchanged for a 0.018-in. guidewire over a 0.018-in. support catheter and used to cross the valves. A proprietary reversed valvulotome is used to disrupt the valves, in order to allow uninhibited proximal-to-distal blood flow.

The length of posterior tibial vein up to the patent posterior tibial artery is lined with a covered stent, which serves to cover the venous collaterals and also disrupt blood flow to the proximal valves. In addition, it guarantees a large conduit for blood flow by forcefully rupturing the proximal veins.

Pre- and post-procedure results of angiography using an iFlow postprocessing program (Siemens) are shown in Fig. 14.4a, b. The post-procedure angiogram demonstrates rapid arrival of contrast from the time of acquisition of the DSA (coded yellow/red) (Fig. 14.4b). This is compared to the pre-procedure iFlow (Fig. 14.4a). An angiographic "blush" is also seen at the edge of the wound, as well as multiple collateral vessels at the foot that serve as runoffs. Skin temperature also improved, as seen on FLIR thermography (Fig. 14.5).

Clinical success was also seen in another patient, with wound healing after 115 days and the resolution of opioid-dependent rest pain immediately after the procedure (Fig. 14.6). Increased transcutaneous oximetry levels were seen in four out of the five patients who underwent PDVA with LimFlow. Of the six patients with wounds, four healed, one is still healing, and one had to undergo amputation for systemic infection (the patient had heel gangrene with osteomyelitis but had evidence of good perfusion and granulation).

Percutaneous DVA represents a new concept in perfusing the foot by routing blood into the deep venous circulation. We were able to perform this safely, with no major adverse events observed within the first 30 days.

From our initial experience with LimFlow, the crossing was easily performed, and the valvulotome assisted in disrupting the valves and diverted blood to the wound bed, allowing us to achieve the goals of wound healing, resolution of rest pain, and a rise in transcutaneous oximetry. This technique represents a novel way to percutaneously treat the "no-option" end-stage CLI patient. It marries the advantage of surgical DVA with

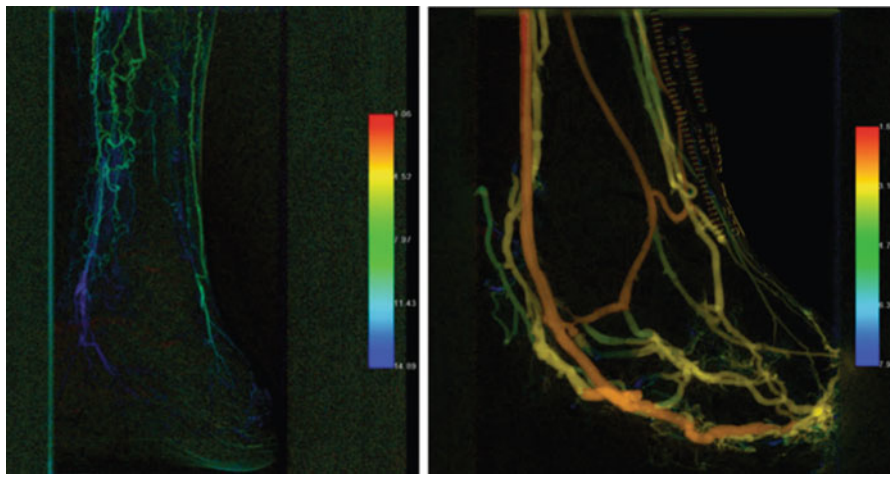

Fig. 14.4 Preprocedure (**a**) and postprocedure (**b**) angiograms using iFlow. Note the angiographic blush at the wound on the extreme lower right

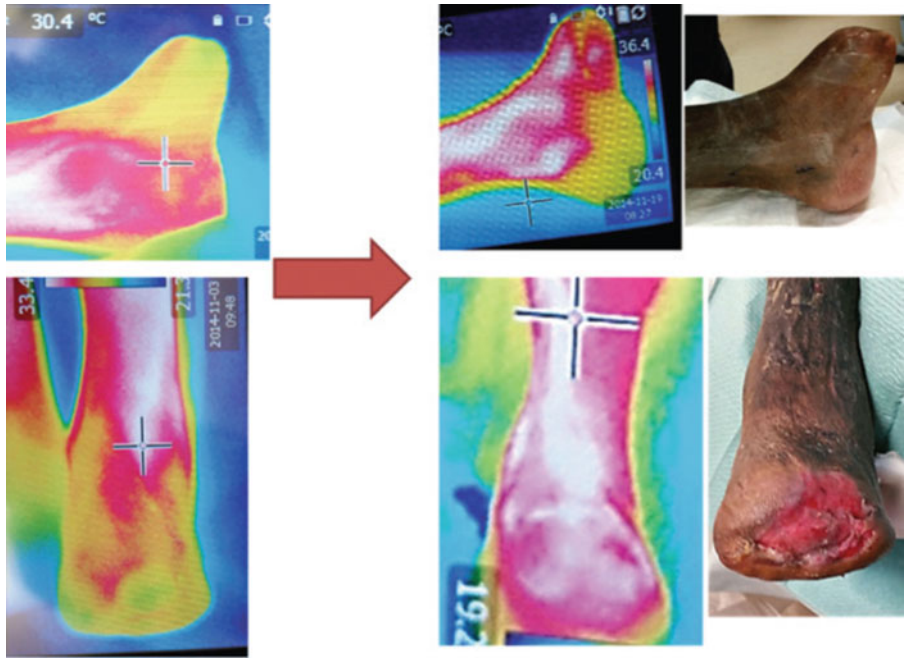

Fig. 14.5 Preprocedure versus postprocedure FLIR thermography

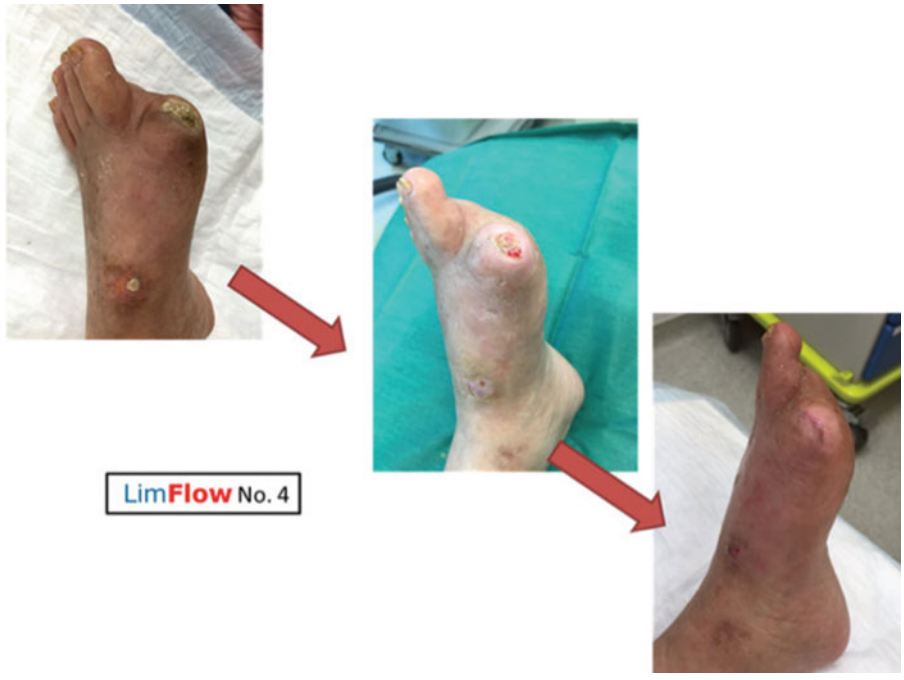

Fig. 14.6 An example of wound healing in a patient who underwent percutaneous deep venous arterialization using LimFlow

those of a minimally invasive procedure, aided by the LimFlow device.

Challenges clearly remain in the treatment of CLI. Wound healing still demands a multiprong approach with revascularization, control of infection, and meticulous wound care. The device is still undergoing improvements, and we continue to grow our experience of operating in the venous environment of the leg.

A CE Mark study is currently underway in Singapore, Germany, and Italy. A pre-investigational device exemption application has been submitted to the US Food and Drug Administration and accepted into an early feasibility study program.

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Vascular Surgery in North America: Current Perspectives in Peripheral Arterial Disease

15

Jeffrey J. Siracuse and Alik Farber

Practice Patterns

Over the course of the last decade, the total number of lower extremity vascular interventions have nearly doubled, while amputation rates have diminished [1]. Endovascular therapy of PAD, to treat both IC and CLI, has become more common as first line treatment in North America [2–4]. An analysis of the Medicare database revealed that over a 10 year period (1996–2006), Medicare beneficiaries had a more than threefold increase in endovascular interventions for lower extremity PAD and an associated almost halffold decrease in surgical bypass [1].

Increasing utilization of endovascular therapy in North America has led to increased costs. A charge analysis within the National (Nationwide) Inpatient Sample (NIS) from 1997 to 2007 demonstrated an increase in the average cost for endovascular intervention for both IC ($8670–$14,084) and CLI ($13,903–$23,196). The average cost per procedure for endovascular intervention was higher than for bypass in both IC ($13,903 vs $12,681; P = 0.02) and CLI ($23,196 vs $22,910; P = 0.04) cohorts [5, 6]. In addition, there has been a significant regional variation in spending on vascular care with regions most aggressively using endovascular therapy having highest costs but not necessarily lowest regional amputation rates [6].

In the past, endovascular procedures were mostly performed by interventional radiologists, while vascular surgeons performed open vascular surgery such as endarterectomy and bypass and interventional cardiologists focused on treating the heart. Over the course of the past two decades, this pattern has shifted to endovascular procedures being mostly performed by cardiologists, who expanded their practice to the periphery, and vascular surgeons, who acquired endovascular skills [1, 7]. Endovascular skills were learned by established vascular surgeons who sought out 1–3 month "mini-endovascular fellowships" while incorporation of endovascular training into the formal vascular fellowship made these procedures a mandatory part of vascular fellowship accreditation [8].

Analysis of specific provider endovascular practice patterns in the State Inpatient Databases for New Jersey (2003–2007) revealed that interventional cardiologists, in comparison with vascular surgeons, were more likely to treat patients with IC (80.7 % vs 60.7 %, P = 0.002) and less likely to treat patients with rest pain (6.2 % vs 16.0 %, P = 0.002) or tissue loss (13.1 % vs 23.3 %, P = .002). Stent use was similar. Cardiologists had higher hospital ($49,748 vs $42,158, P < 0.0001) and supply/equipment ($19,128 vs $12,737, P < 0.0001) charges.

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Finally, only 10.7 % of cardiologists, compared with 36.8 % of vascular surgeons ($P < 0.05$), were classified as high volume practitioners [9].

Ambulatory Practice

In 2008, the Centers of Medicare and Medicaid Services (CMS) changed the reimbursement rates for endovascular interventions to encourage more of these procedures to be performed in the outpatient setting to avoid higher costs associated with inpatient procedures. The focus was originally on the percutaneous treatment of venous disease, however it was expanded to the treatment of PAD. This has resulted in an increased volume of endovascular interventions in the outpatient, office based setting. Overall the shift from the inpatient to the outpatient facilities consisted of approximately 25 % of cases which resulted in a fivefold increase in outpatient treatment. This shift correlated with a concomitant increase in physician ownership of outpatient intervention rooms where these procedures were performed. The use of atherectomy, which has higher reimbursement than angioplasty, has also significantly increased in the outpatient setting from 7 to 125 procedures per 100,000 Medicare beneficiaries in 2003 and 2011, respectively. This change has occurred despite a lack of evidence supporting improved efficacy of this technique and was most likely due to increased reimbursement [10]. The expected savings from performing endovascular procedures in the inpatient setting may have been partially offset by the increased use of the more expensive atherectomy procedures [10].

An example of this phenomenon is highlighted by a physician practice in Michigan that documented a greater than twofold increase in treating patients in the outpatient setting from May 2006–April 2007 (period 1) to June 2007–May 2008 (period 2). There was a concomitant increase in office based endovascular cases from 1.5 % during period 1 to 31 % in period 2. This led to a fivefold increase in revenue to the group from these procedures. No deaths or amputations occurred as a result of procedures performed in the office. Total payment by Medicare, payment to the hospital and to the physicians were higher in all the cases [11].

Analysis of the New York State Inpatient Hospitalizations and Outpatient Surgeries Discharge Databases from 1998 through 2007 was used to assess changes in practice patterns. There was a threefold increase in endovascular revascularization procedures performed in an outpatient setting. Outpatient data analysis revealed a fivefold increase in vascular intervention for IC and CLI. The number of endovascular interventions doubled for IC and quadrupled for CLI. Notwithstanding, patient comorbidities treated in 2006 were substantially greater than those in the previous decade while cardiac and bleeding complications have significantly decreased [12].

Recommendations for Treating Intermittent Claudication

The SVS, the most prominent vascular society in North America, recently published consensus guidelines for the treatment of IC. A limited amount of level 1 evidence was cited to guide decisions [13]. Emphasis was placed on risk factor modifications including smoking cessation, medical therapies and increasing the use of exercise programs to improve both cardiovascular and functional status for patients with PAD. Screening for PAD with non-invasive studies was not recommended. For patients with a suspicion for IC, non-invasive studies using some combination of ankle brachial indices, toe pressures, pulse volume recordings and doppler studies were recommended upon initial evaluation. If initial non-invasive studies were normal then an exercise study was recommended. Additional imaging was only recommended if an intervention was planned.

The guidelines further suggested that initial treatment for symptomatic IC should consist of medical therapy and risk factor reduction. This includes smoking cessation, statin therapy, optimization of diabetes management, single agent antiplatelet therapy and medications such

as cilostazol, pentoxyfylline, and ramipril, when not contraindicated. An exercise program was recommended at a minimum of three sessions per week for at least 12 weeks when possible. Revascularization for IC was thought to be appropriate for selected patients with disabling symptoms after a careful risk-benefit analysis. Invasive treatments for IC should provide a predictable functional improvement with a reasonable durability. The recommended minimum threshold of a >50 % likelihood of sustained efficacy for at least 2 years was suggested as the benchmark and anatomic patency was considered a prerequisite for sustained revascularization efficacy. Endovascular approaches were preferred for most candidates with aortoiliac disease and for select patients with femoro-popliteal disease when anatomic durability was expected. Factors thought to limit endovascular durability included extensive calcification, small-caliber arteries, diffuse infrainguinal disease and poor runoff and, as such, supported the use surgical bypass which was also recommended to those who failed endovascular intervention. Common femoral artery disease was advised to be treated surgically and saphenous vein was suggested as preferred conduit for infrainguinal bypass grafting. Regular follow up in patients undergoing intervention was advised [13].

Critical Limb Ischemia: Unresolved Challenges

Patterns of treatment for CLI vary widely across North America and there is a paucity of good quality scientific evidence to guide clinical practice. The Bypass vs. Angioplasty in Severe Ischaemia of the Leg (BASIL) trial, the only randomized, controlled trial (RCT), in this space was a valiant attempt to create an evidence based standard of care but failed to do so due to numerous shortcomings including use of a suboptimal primary endpoint, lack of lesion standardization, adequate power and limitation of intervention in the endovascular arm to angioplasty alone.

In October of 2013 the United States National Institutes of Health (NIH) funded the BEST-CLI trial. This prospective, multicenter, open label, superiority RCT initiated recruitment in the autumn of 2014 and aims to enroll 2100 patients at 140 sites in North America. This trial will compare treatment efficacy, functional outcomes and total cost in patients with CLI and infrainguinal PAD undergoing best open surgical or best endovascular revascularization. As such, BEST-CLI focuses on patients who are candidates for both infrainguinal bypass and endovascular therapy. It is designed as a pragmatic trial in that the definition of best therapy is left up to the individual investigator. All commercially available standard of care endovascular therapies are allowed, as are all surgical bypass techniques and types of conduit. At the risk of increasing heterogeneity, this feature will keep the trial relevant to clinical practice, over time. The BEST-CLI has a two-cohort design. The first cohort will evaluate outcomes in patients who have adequate single segment great saphenous vein (SSGSV) available for bypass, while the second cohort will include patients without adequate SSGSV. Since quality of conduit is paramount to infrainguinal bypass success Cohort 1 will compare bypass with best conduit to endovascular therapy. The question of how bypass with suboptimal conduit compares with endovascular therapy will be answered within Cohort 2. In each cohort, subjects will be randomized within four strata defined by two dichotomous factors based on clinical presentation (ischemic rest pain alone vs. tissue loss) and anatomical classification (presence or absence of significant tibial disease). The primary endpoint in the BEST-CLI is Major Adverse Limb Event (MALE)-free survival. Other endpoints include amputation-free survival, reintervention and amputation free survival, which incorporates MALE and minor reinterventions and freedom from hemodynamic failure, which evaluates the end result of enhanced limb perfusion. Lastly, BEST-CLI includes a robust health related quality of life and cost effectiveness analysis [14].

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Peripheral Arterial Disease: A European Perspective

16

Janice Tsui, Luke Morgan-Rowe, and Mark Portou

Introduction

Lower limb peripheral arterial disease (PAD) is a global health burden, estimated to affect 202 million people worldwide [1]. Between 2000 and 2010, the number of people living with PAD increased by 23.5 %, mainly due to increased life expectancy [1]. In Europe, at least 40.5 million people are affected by PAD [1]. In most countries in Europe, PAD remains a disease that affects the older population, with prevalence of 7–24 % in those over 55 years of age; males and females are almost equally affected [1] (Fig. 16.1).

Patients with PAD have impaired quality of life, high disability and increased mortality. The economic burden of PAD is also high: in the UK, the management of patients with critical limb ischaemia (CLI) has been estimated to cost the NHS over £200 million (€225 million) [2] whilst average 2-year cardiovascular-related hospitalization costs for patients with PAD in France (€3182) and Germany (€2724) were higher than those with coronary artery disease or cerebrovascular disease [3].

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Management of PAD

National and international guidelines concur with the overall management of PAD where intermittent claudication is managed predominantly conservatively with risk factor management and exercise whilst revascularization is the main treatment aim for critical limb ischaemia (CLI) (http://www.sign.ac.uk/pdf/sign89.pdf; http://www.nice.org.uk/guidance/CG147) [4–6]. The management of patients with PAD by multidisciplinary teams (MDTs) consisting of vascular surgeons/specialists, interventional radiologists, diabetologists, specialists podiatrists, tissue viability nurses and other specialties is advocated (http://www.nice.org.uk/guidance/CG147) [6]. However, whilst diabetic foot complications are increasingly managed within similar multidisciplinary teams with improved outcomes, this strategy for PAD is less well defined. A review in 2012 of healthcare trusts in the UK showed that 28 % of trusts who responded did not have MDTs for PAD; this was highlighted as an area which needed urgent attention in order to improve outcomes of PAD (http://appgvascular.org.uk/media/reports/2014-03tackling_peripheral_arterial_disease_more_effectively__saving_limbs__saving_lives.pdf).

In many European countries, the important role of angiologists/vascular physicians in the management of cardiovascular risk factors and in the prevention of PAD is increasingly recognized. However, there remains geographical

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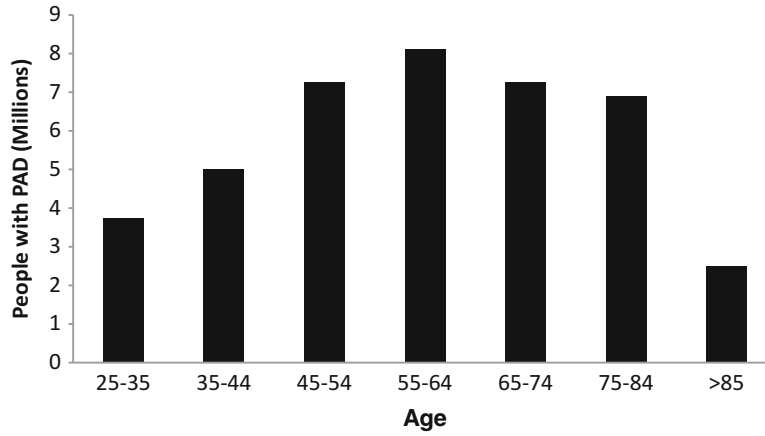

Fig. 16.1 Estimated European prevalence of PAD by age (2010). Adapted from Figure 3. Fowkes FG et al. Lancet. 2013;382(9901):1329–40

variation in terms of the specialty/subspecialty status of angiology, training requirements and opportunities, and indeed the inclusion of angiologists in vascular units.

Despite firm evidence for their benefits, risk factor management in patients with PAD remains suboptimal in many areas and access to supervised exercise classes limited. A multidisciplinary approach with the involvement of angiologists/vascular physicians may lead to improvements in these areas.

Areas of Uncertainty

There remain areas within PAD management where the evidence is less certain particularly where technology is rapidly evolving. Some of these have been outlined in the recent guidelines, including the NICE 2012 guidelines and include: angioplasty vs. bypass first for the management of CLI; stenting for infra-geniculate disease in CLI and chemical sympathectomy for the management of CLI (http://www.nice.org.uk/guidance/CG147). Geographical variation in practice occurs across Europe in some of these areas.

Angioplasty vs. Bypass First in CLI

NICE specifically questioned the clinical and cost effectiveness of endovascular vs. open surgical approaches in treating infrageniculate disease, which the BASIL (Bypass versus Angioplasty in Severe Ischaemia of the Leg) -2 trial that is currently ongoing aims to address. This is a randomized, multi-center, pragmatic, open trial of vein bypass vs. best endovascular intervention first for the management of severe limb ischaemia due to infrapopliteal disease (with or without femoropopliteal disease). Six hundred patients will be recruited from centres in the UK. The primary outcome measure will be amputation free survival; secondary outcomes include overall survival, in-hospital and 30-day morbidity and mortality, major adverse limb events, major cardiovascular events, symptom relief, ulcer healing, quality of life, re-intervention and haemodynamic changes (http://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/portfolio-v/Basil-2/index.aspx).

The original BASIL trial was a randomized controlled trial comparing open surgical bypass with endovascular therapy for severe limb ischaemia across 27 UK centres involving 452 patients with infrainguinal disease. The final intention-to-treat analysis demonstrated no difference in amputation free survival and overall survival between the groups, however, a benefit of open surgery for patients surviving ≥2 years (70% of study cohort) was seen with significantly improved overall survival and a trend towards increased amputation free survival [7]. Of note, outcomes of patients who underwent surgery after an initial failed angioplasty were worse than those of patients who were treated

initially with open surgery. Overall health-related quality of life measures and costs of treatments were not significantly different.

Despite these findings, the endovascular treatment first strategy is still common in many centres in Europe and indeed the recent European Society of Cardiology (ESC) guidelines continue to support this strategy [6]. Reasons for this include the reported higher morbidity of surgical bypass, particularly in a group of patients with reduced life expectancy and significant comorbidities; the increasing use of hybrid approaches and rapidly evolving endovascular technology. BASIL was also criticized for its study population selection, patient enrollment, choice of study outcomes, inclusion of prosthetic conduits in the surgery arm and use of angioplasty only in the endovascular arm. However, it remains a landmark study and these issues have informed the design of subsequent studies including BASIL-2.

Stenting for Infra-Geniculate Disease in CLI

Whilst the use of balloon angioplasty for treating infra-geniculate disease is established, the role of adjuncts including bare metal stents (BMS), drug eluting stents (DES) and drug eluting balloons (DEB) has developed more recently. Restenosis following angioplasty only in the tibial arteries has been reported to occur in up to 2/3 of patients after 3 months with high clinically driven target lesion reintervention rates [8]. Early elastic recoil and neointimal hyperplasia are likely to be important mechanisms [8]. BMS may potentially reduce elastic recoil whilst drug eluting balloons and stents may also address neointimal hyperplasia. Stents are often used as 'bail out' options following suboptimal or complicated angioplasty (Fig. 16.2), however recent studies provide more evidence for the effectiveness of primary stenting in this area. In Europe, many centres have published their excellent results on angioplasty ± stents in the infrageniculate vessels in patients with CLI and have contributed to RCTs.

The recent TASC II update of recently published data summarized four RCTs and four meta-analyses of studies assessing the results of DES vs. balloon angioplasty or BMS in infrageniculate disease and concluded that primary stenting with BMS offered no benefit over balloon angioplasty whilst the evidence provided support for primary DES use. The limitations of the studies however were also discussed, such as the inclusion of claudicants, selection of short,

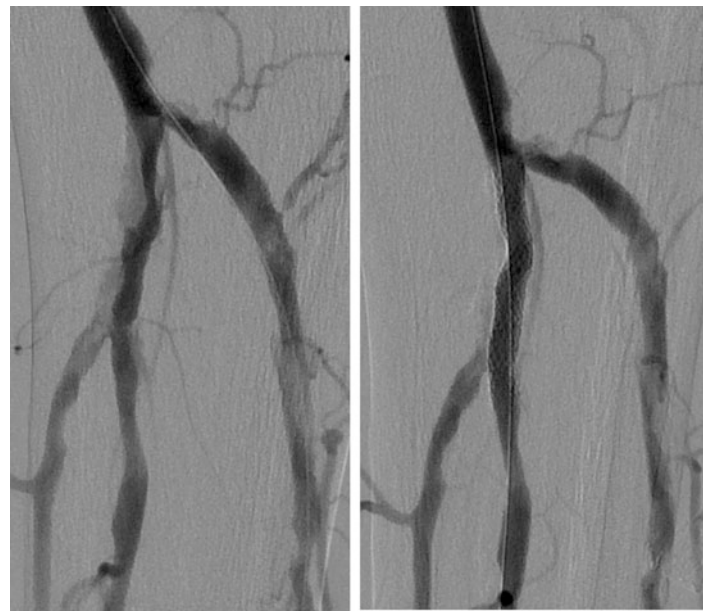

Fig. 16.2 *Left hand panel* demonstrates a significant residual stenosis in the TPT with a dissection following repeated prolonged angioplasty. *Right hand panel* shows the lesion has been overcome by placement of a 3 mm uncovered bare metal stent

stenotic lesions and the infrequent use of firm clinical endpoints in these studies [9]. Current data do not support the use of DEB in infrageniculate vessels.

Chemical Sympathectomy

Current guidelines do not recommend the use of lumbar chemical sympathectomy (LCS) in the management of CLI except in the context of a clinical trial. This is based on the lack of evidence demonstrating its benefits in terms of endpoints such as amputation rate, mortality or improvement in ankle-brachial pressure index. Cohort studies have however shown the benefits of chemical and surgical lumbar sympathectomy in symptom control for CLI. Currently LCS continue to be used in vascular centres and a survey of members of the Vascular Society of Great Britain and Ireland had revealed that 75% of respondents felt that LCS had a role in current practice, mainly for inoperable PAD with rest pain [10].

Conclusion

PAD is now recognized to be a global pandemic. In Europe, available data suggest that variations in patient characteristics, healthcare systems, management and outcomes exist. For example, baseline characteristics of patients with documented PAD included on the Reduction of Atherothrombosis for Continued Health Registry revealed a higher proportion of smokers in the Eastern European compared to Western European patients whilst diabetes was more prevalent amongst Western European PAD patients. PAD patients in Eastern Europe also had more cardiovascular events, cardiovascular death, nonfatal MI and nonfatal stroke than those in Western Europe [11]. These differences have implications on public health as well as on the design of international clinical trials. Similarly, variations in practice occur across Europe and even between units within the same country, particularly in the rapidly evolving field of endovascular therapies, adding to the complexities of designing RCTs in this area. Large registries involving multiple centres across the continent are therefore important, and registries such as REACH and the Eurodiale study of diabetic ulcers [12] illustrate this.

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Peripheral Artery Disease: A Brazilian Perspective

17

Nelson De Luccia, Karen Utsunomia, Simon Benabou, and Karina Rosa Schneidwind

The Brazilian population profile for development of PAD is similar to many other western countries. PAD is one of the major causes of hospital admission for vascular disease of the population, particularly in the emergency setting.

Diabetes and tobacco use are still prevalent among the population. Related to tobacco use, Brazil's Ministry of Health has programs for tobacco control. One, as suggested by international agencies of public health includes pictorial health warnings (ash.org.uk/files/documents/ASH) on cigarette packages. This is very useful considering that PAD consequences of smoking, like the risk of amputation and gangrene, is poorly understood by the population.

The prevalence of smoking declined in the population above 18-year age from 34 % in 1989 to 22 % in 2003 and to 16 % in 2006. General cigarette consumption between 1989 and 2005 fell 32 % [1].

A population study conducted in the Rio de Janeiro city showed estimation of major lower limb amputations in the age group between 55 and 74 years of 31.3/100,000 inhabitants, 209/100,000 diabetics and 359/100,000 PAD patients annually [2].

The overall urban Brazilian population rate of diabetes is estimated to be 7.6 %. Men (7.5 %) and women (7.6 %) had similar rates of diabetes. Similar rates were present in whites (7.8 %) and nonwhites (7.3 %). Diabetes prevalence increased from 2.7 % in the 30–39-year age group to 17.4 % in the 60–69-year age group [3].

Brazil has a universal system of health care called SUS (Sistema Único de Saúde) inspired and somewhat similar to the National Health Service of the United Kingdom. The meaning is that every Brazilian citizen may have free access to the public hospitals and free medical care. With a population of more than 200 million people, and around 8 % below the line of extreme poverty, social problems are still a major concern in Brazilian health care, and public hospitals work at the limit of their capacity. This creates a very unfavorable scenario in which many patients come on first time evaluation with unsalvageable limbs, related both to PAD or diabetic neuropathy complications, mainly infection in which a major amputation should be considered as the only possible treatment.

Brazilian Vascular Surgeons take care of diabetic patients with infected lesions in the feet, even if they are not ischemic, and palpable distal pulses are present. That seems a logical approach

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from a certain point of view. If vascular surgeons perform all kind of amputation and surgical debridement in lower limb lesions after revascularization, they may as well treat non-ischemic patients. That also makes sense as some of these patients may require Vascular Evaluation when treated by other specialties. In Brazil there is no formal practice of podiatry like in the USA or some other European countries. The care of diabetic patients with foot lesions is shared between Orthopedic and Vascular Surgeons, but mainly by the Vascular Surgery team as the responsible medical specialty.

It's very impressive in our series the number of patients with gas gangrene, what may be referred to anaerobic infections presented. Although regular anaerobic cultures are not routinely performed to confirm diagnostic, the clinical presentation with gross infection, crepitation sensation at the subcutaneous level and eventually presence of gas on limb X-ray make the assumption of diagnosis pretty reasonable.

Figures 17.1 and 17.2 show demography of 168 patients in which any kind of amputation was performed from 2012 to 2013.

As can be observed in Fig. 17.1, infections (aerobic and anaerobic) are responsible for 33 % of all amputation; 42 % of primary major amputation, which means patients that presented with unsalvageable limbs, are caused by PAD; 19 % are amputations secondary to a revascularization procedure.

The distribution by level shows that 42 % are minor amputation, considered below the ankle joint, and 56 % are major amputation. Proportion of transtibial amputation over transfemoral is 1.42, as a program of level preservation, including eventually revascularization procedure even just for that purpose is proposed [4]. Knee disarticulation as an amputation level is superior to the transfemoral under the rehabilitation point of view is also routinely practiced.

Although this high incidence of amputations is somber, strong programs of revascularization, by open or endovascular procedures, are widespread practiced in the country. The concept of limb salvage and the result enhanced quality of life when this purpose is achieved is well known, and supported by local published data [5].

A locally produced meta analysis [6], and practical aspects of the procedures also supports the policy of an angioplasty-first approach to the management of critical ischemia.

Patients in public hospitals, with critical limb ischemia and gangrene, but still with salvageable

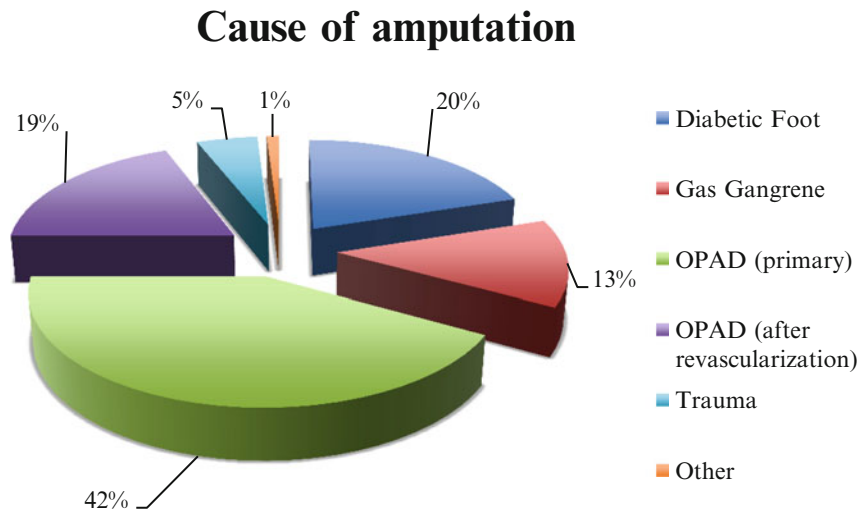

Fig. 17.1 Distribution of amputation by cause

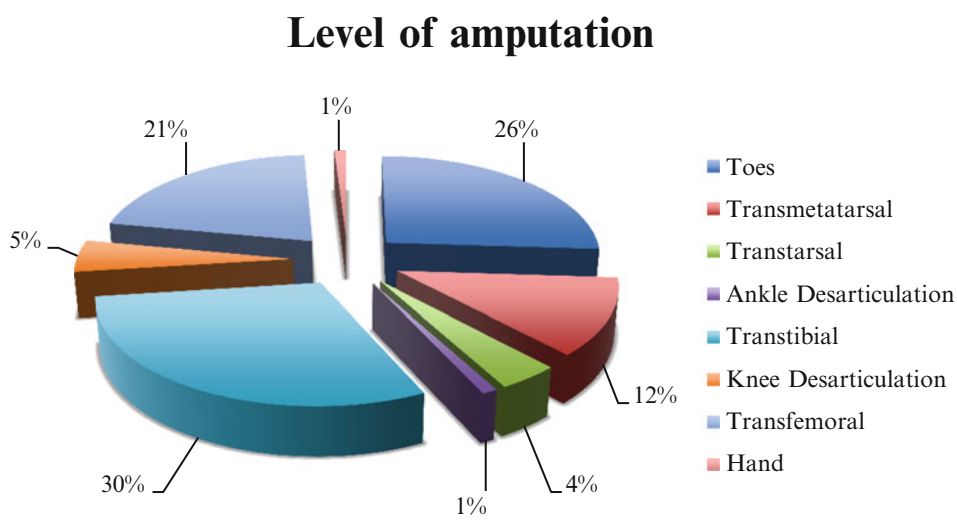

Fig. 17.2 Distribution of amputation by level

limbs, still may have to wait an average of 15 days to have initial treatment established, or by angioplasty or open surgery. That is due to the particular presentation of the clinical condition of patients with critical ischemia. Gangrene is not generally considered as urgent as a ruptured aneurysm, for obvious reasons, or as many other surgical emergencies. This way, in a system overloaded by surgical emergencies, toe gangrene patients may be waiting in line, and eventually losing the opportunity to have their limbs saved.

Commonly a patient with critical limb ischemia will be evaluated with an angioCT, as this is a simple and available exam in the emergency setting. Based on these examinations, patients are conducted to either angioplasty or open surgical procedures. Regular angiography are still done, but mainly by the surgeon at the Operating Room setting, and eventually progressed to angioplasty when judged feasible.

The policy of angioplasty first, besides having support from medical literature, represents a practical approach to limb threatening ischemia. Patients can be conducted faster to the operating room were mainly are treated with a portable C-arm, eventually under local anesthesia and not demanding intensive care unit for the post operative period, what is usually critical in a system with shortage of hospital beds.

At least in the public hospitals setting only critical ischemia patients are considered for treatment. Usually no intermittent claudication patients are treated, except few situations at the aorto iliac territory.

Review of one single institution, the major Brazilian public hospital, from the University of São Paulo, during the period of 1 year (2013–2014) showed that from 523 vascular interventions, 139 (26.5%) were for PAD and critical ischemia, of these 51.3% being angioplasty, 39.5% bypass grafts and 9.2% endarterectomy. Distribution by territory showed 24 (17.1%) at the aortoiliac segment (14 grafts, 10 angioplasties), 82 (59.2%) femoro popliteal (21 grafts, 50 angioplasties and 11 endarterectomies) and 33 (23.7%) femoro distal (11 grafts and 22 angioplasties).

General data from the Brazilian National experience (datasus) of the month of May 2015, in the southeast region of the country reported 133 angioplasties over 30 grafts done for PAD.

Although this documented shift towards endovascular procedures, open surgery experience is very consistently done for limb preservation, when its judged that the case is not amenable to angioplasty, by the extension of arterial disease, or after failed attempt of angioplasty.

Autogenous reconstruction by the use of the saphenous vein is the technique more consistently

used. Variations include the reversed vein, "in situ" or the non-reversed technique. Personal experience of the major Brazilian service is the use of the saphenous vein by the non reversed technique, removed from its bed by small bridge incisions so the best vein segment is interposed between the best donor and recipient arteries.

The use of arm veins [7], revascularizarion of perigeniculate arteries [8], and alternative access to leg arteries [9] exemplify the trend and tradition of Brazilian Vascular Surgery towards open procedures to limb salvage.

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18 Peripheral Atherosclerotic Occlusive Disease and Lower Limb Ischemia in Egypt: Current Status

Emad A. Hussein

Peripheral Atherosclerotic Occlusive Disease (PAOD) and lower limb ischemia is common among the Egyptian population, taking in consideration the presence of traditional risk factors, and especially smoking, hyperlipidemia and a high prevalence of diabetes mellitus (DM) which is steadily rising annually to reach even higher values than was originally reported in 1995 to be 9.3 % in age groups 20 years or older [1] (Fig. 18.1). Men and women are equally affected, with higher prevalence in men, as in some other parts of the world [2].

Clinical Spectrum and Peculiarities of Health Care System

All different forms of PAOD and lower limb ischemia are encountered, ranging from mild to crippling claudication up to critical limb ischemia (CLI) with rest pain and tissue loss or gangrene, characteristic of Rutherford stages III and IV. Multilevel disease is also quite common. Lack of nationwide awareness of the disease, as well as shortcomings of the health care system (with only 25 % of the population enjoying public health insurance) further aggravate the problem [3]. Some of the commonly presenting lesions in the greater Cairo area are shown, with localized focal (Fig. 18.2a, b), and diffuse disease (Fig. 18.3).

Current Status of Vascular Practice

There are currently six major specialized university vascular centers, three ministry of health vascular centers as well as two other centers run by military hospitals. They cover most of the country. Modern non-invasive and invasive diagnostic equipment are available in most of them. In 2014 /2015, the Ain Shams University Vascular Surgery department has received over 2650 arterial cases at OPD and ER in both old teaching and new specialized hospitals, of which 658 have been operated [4]. More than half of this patient cohort (55 %) were critical limb ischemia operated either on emergency or semi urgent basis. Infragenicular, femoropopliteal PTA with and without stenting, venous stenting for focal stenotic lesions in hemodialysis patients with indwelling permacath are the most commonly performed endovascular procedures, while Aortobifemoral and femoropopliteal bypasses are the frequently performed open vascular surgeries. Health care system tries to cover most of the patients, with several difficulties though. Private medical insurance has come to add some further coverage for a fraction of the population. Our OR facilities do not comprise hybrid rooms, but we do have modern mobile C-Arm imaging

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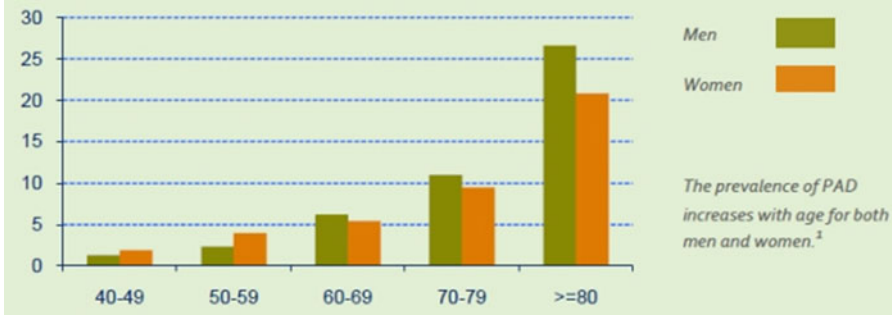

Fig. 18.1 Prevalence of PAD (%) by age group (years)

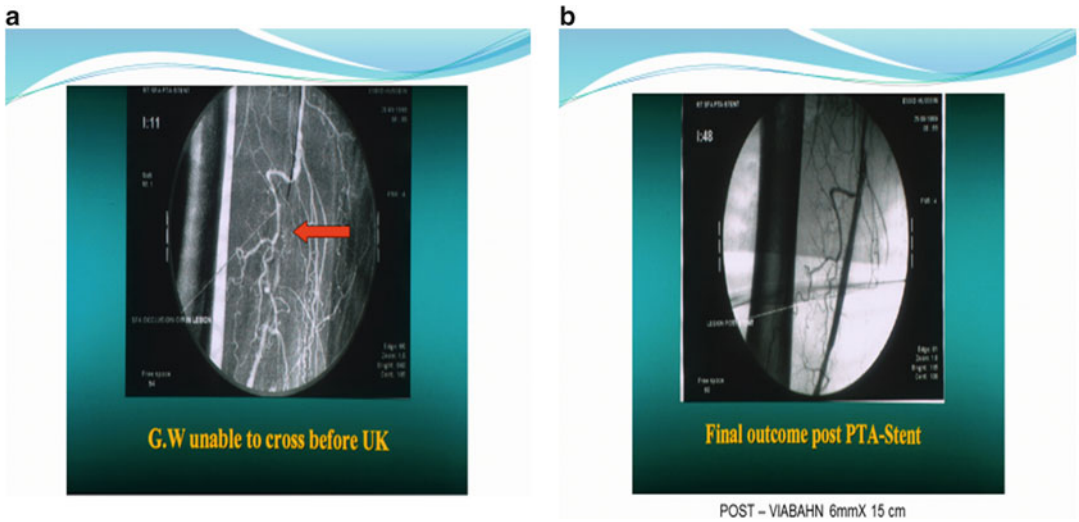

Fig. 18.2 (**a**) Guidewire unable to cross calcified lesion initially (**b**) Final outcome post Viabahn Stent graft

and a wide array of instruments for open and catheters, balloons, wires and stents for endovascular procedures.

Different modalities of diagnosis and treatment are being offered to the PAOD patients as per the standard guidelines [5, 6]. For claudicants, control of the different risk factors including smoking cessation, as well as treatment of any hyperlipidemia, hyperglycemia and hypertension is a common policy. Exercise training programs are non supervised in the vast majority of cases. Lack of patients' compliance, deficient database systems and difficulties encountered in summoning patients are the main obstacles. However, patients' education and counseling for their near family is rigorously implemented whenever possible. This is coupled with Aspirin and Naftidrofuryl. In disabling cases, Cilostazol is added. Rutherford 2 b cases and above are often managed by endovascular or open revascularization. Figure 18.4 depicts one of our cases (a) before and (b) after endovascular revascularization of a total left iliac occlusion. A national training program for vascular fellows and nurses is in place since 2007.

Non Reconstructible Limb Ischemia

Due to a lack of awareness, and prevalent DM as a compounding factor for CLI and patients arriving late as they often come from remote areas, a

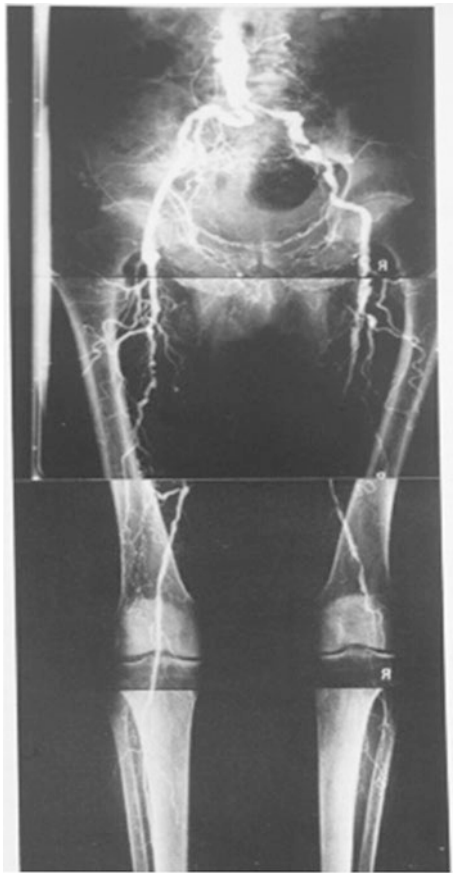

Fig. 18.3 Non reconstructible CLI

sizeable proportion of these patients present at a very advanced stage of non reconstructible limb ischemia. Unless the limb shows an infective wet gangrene (diabetic type) which calls for a semi urgent amputation, those cases are given a trial of several weeks of Heparin, antiplatelets + Prostavasin IV and local care of any ulcer. Recently, early trials have started with the use of stem cell therapy in these cases.

Stem Cell Therapy for PAOD in Egypt

More than one center have been involved in the last 3 years with regards to cell therapy of non reconstructible CLI; but with only limited therapeutic benefit [7]. Main obstacles for optimizing such therapeutic modality are the cost, still non identification of the best cell source, most efficient mode of delivery and some medicolegal issues which are commonly faced in most of the middle east region as well.

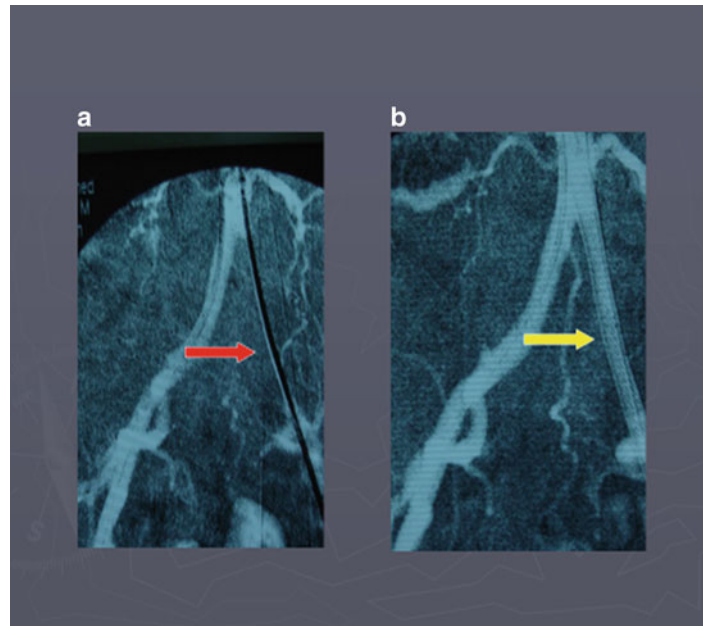

Fig. 18.4 (**a**) Total occlusion left common iliac artery (**b**) After primary Stenting

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Peripheral Arterial Disease: An Australian Perspective

19

Jennifer Chambers and Isuru Nammuni

Peripheral Arterial Occlusive Disease: An Australian Perspective

As in many other parts of the developed world, peripheral arterial occlusive disease is an ever increasing problem in Australia. We have seen an evolution of the disease over the years in terms of aetiology, epidemiology, and disease patterns. This has required various changes in our practice to achieve good outcomes for our patients. These changes in approach to management have however increased the ever-growing burden of health care costs, and also introduced new challenges with training of future vascular surgeons.

Peripheral arterial disease (PAD) is a relatively common disease in Australia, affecting an estimated one eighth of the elderly population. As in other areas of the world, it is more common in males, and one Western Australian study [1] found a prevalence of 16 % in males aged 65–83 years. Much of PAD is asymptomatic, with a recent study [2] of patients presenting to an Australian emergency department finding a prevalence of 10.3 %, but only 6.4 % of these were symptomatic.

Smoking still remains the most powerful risk factor for PAD, but we have seen a decline in the incidence in smoking over the last few decades. In 1991 24.3 % of Australians over 14 years smoked on a daily basis, and by 2013 this had fallen to 12.8 % [3]. This had been achieved through widespread education and awareness programs, coupled with legislated prohibition of smoking in public places, and restrictions on advertising. There does still however remain a disparity between metropolitan areas and more regional and remote areas with smoking rates still very high in many rural areas across Australia. Unfortunately, although overall vast progress has been made with smoking cessation, this has been met with a concomitant rise in the metabolic syndrome and its associated health problems. The 2011–2012 Australian Bureau of Statistics Health Survey showed that 63 % of Australians were overweight or obese [3]. Around 10 % of Australians had impaired glucose intolerance, with 4.2 % having full blown diabetes, in contrast to only 1.4 % in 1989 [3]. Other risk factors such as hypertension and hyperlipidaemia have also risen over the last few decades. It is also important to note that Australia's indigenous population has significantly higher rates of risk factors for PAD, and as such have a much larger burden of disease and consequently have much worse outcomes from PAD. Diabetes affects 39 % of the indigenous

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population over 55 years, and smoking rates are double the non-indigenous population [3].

With the alteration in demographics in the PAD population there has also been an emerging change in pattern of disease. As smoking related PAD declines, we are seeing less proximal aortoiliac and focal femoropopliteal disease. The rise in diabetes has however caused a shift towards more peripheral tibial and pedal vessel disease and diffuse, multifocal occlusive disease. This change in disease pattern has also led to a shift in disease presentation, with more patients presenting with critical limb ischaemia, especially in the diabetic population [4].

In response to these changes in disease patterns there has been a paradigm shift in the management of PAD in Australia. Vast improvements in techniques and technology have also played an integral part in the driving force behind this progress and evolution. Australian vascular surgeons have been at the forefront of innovation throughout the evolution of endovascular surgery both on a national and international level. This has allowed vascular surgeons to remain the primary physicians treating patients with vascular disease, either by open surgical or endovascular means. This has been facilitated by a dedicated vascular surgery training program separate from general surgery since 1995. This is in contrast to many other areas across the world where vascular surgeons have been slow to embrace endovascular techniques and consequently other specialists such as cardiologists, radiologists and angiologists have taken on the management of patients with PAD.

The management of aortoiliac occlusive disease has undergone a huge shift towards endovascular management, predominantly with bare metal or covered balloon expandable stents. Even complex TASC C and D lesions are able to be treated by endovascular means, largely due to advancements in device technology such as re-entry devices [5]. The endovascular approach is certainly much less morbid than open aortoiliac endarterectomy or bypass operations, and has comparable results to open surgery at least in the medium term [6].

Occlusive disease of the femoropopliteal segment is still often managed with open surgical techniques, although increasingly endovascular and hybrid techniques are employed. In 2002–2003 roughly 2800 femoropopliteal bypasses were performed, and by 2012–2013 this had halved to just 1300 bypasses. The vast majority of these were autogenous veins bypasses, with only 300 synthetic grafts used [7]. There has also been a sharp decline in above-knee bypasses performed, as many of these TASC B and C lesions are now routinely treated with endovascular means. In particular, sub-intimal recannalisation are routinely performed for long-segment SFA occlusions which would have previously been treated with bypass surgery. There has consequently been a dramatic rise in endovascular interventions over the corresponding period. The number of angioplasties has risen from 6500 in 2002–2003 to 10,270 in 2012–2013. The use of stents has also increased three-fold from 3600 to nearly 10,000 in the same period. Self-expanding laser cut nitinol stents are predominantly used for the femoropopliteal segment when required, although interwoven nitinol stents and covered stents are increasingly being utilised, as are drug-eluting balloons.

The shift towards endovascular management has been even more marked in the infragenicular segment, as shown in Fig. 19.1. This has largely been driven by the advancements in wire and balloon technology, particularly in the development of dedicated low profile chronic total occlusion (CTO) wires for tibio-pedal vessels. The use of the SAFARI technique [8] with retrograde pedal access to facilitate sub-intimal recanalisation of tibial CTO lesions has also allowed more patients to be treated endovascularly. The mainstay of intervention is plain balloon angioplasty as stent patency in tibial vessels has thus far been disappointing, with the exception of very short proximal lesions. Drug eluting balloons are currently in limited use due to concerns of poorer outcomes in patients with critical limb ischaemia, although these concerns are yet to be fully evaluated.

Overall, the management of Peripheral Occlusive Arterial disease in Australia has had a sharp shift towards endovascular intervention. Figure 19.2 shows this change, and although there is a degree of re-intervention in the endovascular

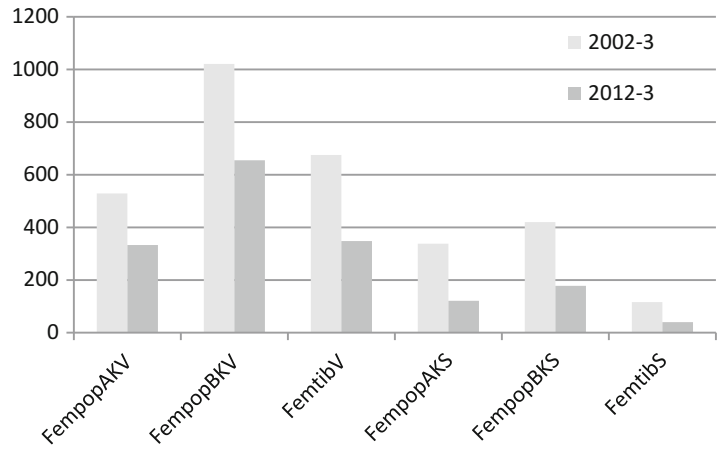

Fig. 19.1 Open surgery rates—infrainguinal

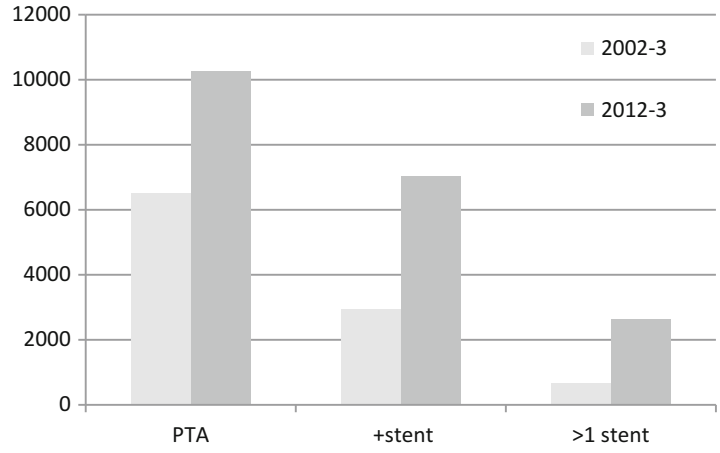

Fig. 19.2 Endovascular rates

group, it illustrates the change in scope of practice for Australian vascular surgeons.

With this shift in endovascular management there is emerging evidence that this is improving outcomes for patients. As endovascular management is minimally invasive, many PAD patients are able to be treated in an outpatient setting. As a consequence, there has been a decline in hospitalisation rates for PAD by 23 % from 1999–2000 to 2007–2008 despite an increase in prevalence [3]. Mortality rates have also declined from 25 per 100,000 in 1987 to 9 per 100,000 in 2007 [3]. Similarly, amputation rates have decreased with below knee amputations falling from 1490 in 2002–2003 to 1180 in 2012–2013, and above knee amputations falling from 1128 to 723 over the same time period [7]. A single institution's data suggests an improvement in freedom from amputation, ICU stay, and overall hospital stay with an "endovascular first" strategy for patients presenting with critical limb ischaemia [9] and supports the above observations.

It is once again important to note however, that there is a significant disparity in outcomes between metropolitan and regional and remote areas. Although the majority of Australia's population is concentrated in a few major cities along the seaboard, much of the population live in isolated areas where access to specialist vascular services is extremely limited. The rise of endovascular surgery has also seen a need for centralisation, partly due to the added expertise required, and partly due to the extensive equipment and resources required such as angiography and hybrid operating suites.

Dedicated vascular units are therefore only located in major cities and a few regional centres around the country. As a result this has required improvements in our retrieval service, and many patients travel by rotary or fixed wing aircraft to major centres for treatment.

Although the advancements in endovascular management of PAD patients in Australian have achieved an overall improvement in outcomes, like many other developing world countries there are growing concerns over the ever increasing costs of delivering health care. From 2003 to 2033 total health care costs in Australia are projected to increase from $85 to $246 billion, with cardiovascular disease costs increasing by 142 % [10]. Most of these costs are due to an increasingly ageing population and volume of services provided, but some of this is due to health price inflation, or the increasing cost of treating individual patients. Audit of clinical practice and outcomes is therefore imperative to ensure vascular services are delivered successfully, and also in a cost-effective manner. The Australian and New Zealand Society of Vascular Surgery has initiated a society based national audit to capture all relevant data and enable analysis of outcomes for vascular patients.

Another challenge that has become evident through the shift towards endovascular management of PAD is the difficulties in providing a complete breadth experience for trainee vascular surgeons. Exposure to open vascular surgery is becoming increasingly limited and there are concerns that many trainees may complete their training programs without the necessary experience for all aspects of vascular surgery. Trainees are increasingly seeking out fellowship years in specific open surgery centres either in Australia or in overseas countries such as the United Kingdom. This challenge is not unique to vascular surgery and similar issues have been encountered in areas such as the rise of laparoscopic surgery. Ultimately this progression will increasingly require the spoke and wheel model of vascular surgery service delivery with centralisation of major open surgical services to a few specialised centres.

Peripheral occlusive arterial disease in Australia has had a considerable evolution over the last few decades. The prevalence of PAD has steadily increased, but changes in demographics have led to alterations in disease patterns and clinical presentation. Consequently we have had to adapt to these changes in the methods of treatment for these often complex disease processes, and this has been largely facilitated by advancements in technology and techniques. Evidence suggests we are succeeding in achieving better outcomes for our patients with peripheral arterial disease, however we need to continue to improve our service delivery and methods to achieve the very best for our patients, understanding the various challenges that lie ahead.

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Diabetic Foot in Colombia

20

Alberto Muñoz

The prevalence of diabetes is increasing worldwide and particularly in developing countries. Studies by the Colombian Association of Diabetes (ACD) have demonstrated that in Colombia 7 % of the population living in urban areas and older than 30 are diabetics and that annually there are 3 or 4 new cases of type 1 diabetes per 100,000 children, less than 15 years old per year [1, 2]. A substantial proportion of individuals with diabetes remain undiagnosed in Colombia and untreated and the percentage of treated individuals reaching International Diabetes Federation treatment goals for blood glucose, blood pressure and serum cholesterol is low. These low rates of diagnosis, treatment and control reflect the lost opportunity for reducing the burden of diabetes [3]. The principal cause of morbidity in the diabetic population in Colombia is diabetic foot, 20 % of all hospital admissions for diabetics in the country [4]. The presence of arterial disease, neuropathy and the sequence of ulceration, infection and gangrene, precedes lower limb amputations in diabetics in Colombia and is no different than in other regions of the world. Every year, more than 1 million of diabetics suffer an amputation related to the disease and has been estimated that every 20 s a lower limb is lost to diabetes somewhere in the world [5]. In Colombia this is equally true and amputation was frequently performed without an attempt of limb salvage, before the implementation of Diabetic Foot Teams.

In 1990 the ACD established in Bogota D.C., a multidisciplinary program for treatment of Diabetic foot. This diabetic team included a diabetes specialist, orthopaedic surgeon, podiatrist, nurse and a vascular surgeon. An important reduction of amputation was demonstrated [6]. The results obtained by this diabetic foot program, were extensively diffused and presented throughout the country and followed by the creation of other units in different cities. The need for a proper strategy of education and prevention of this devastating problem was observed. In 1999 Colombia started it's participation in The International Working Group on the Diabetic Foot (IWGDF) and the Colombian Federation of Diabetes (FDC) received the consensus document. The FDC has been committed to it's diffusion and teaching to health care providers in the country. The ACD in the year of 2004 created the Center for Education in Diabetic Foot and the same year the Colombian Group of Diabetic Foot (COLPEDIS) was founded by the FDC. COLPEDIS dedicated a full day pre-congress Course during the XVIII Colombian Congress of Internal Medicine and since then has maintained continued education to

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health professionals related to problems of the foot in diabetic patients. COLPEDIS published the Colombian Guidelines for Prevention, Diagnosis and Treatment of Diabetic Foot in 2007 and 2013 and has continued promoting the creation of multidisciplinary diabetic foot teams all over the country and actively participates in education to professionals and the community.

Definition

Diabetic foot is defined as the manifestation of vascular, neuropathic or biomechanical alterations of diabetes, with the presence of ulceration, infection and/or tissue destruction.

Pathophysiology

The principal components of diabetic foot are neuropathy, peripheral vascular disease, infection and biomechanical alterations [6, 7]. Neuropathy is present in a high percentage of cases. Ischemia not as often, but when present, increases the risk of limb loss.

Peripheral neuropathy is a common complication of DM, both type I and type II, and its incidence increases parallel to the length and severity of hyperglicema. It is a chronic sensitive and motor polyneuropathy, frequently associated with autonomic dysfunction described as Distal Symmetrical Polyneuropathy [8, 9]. Sensory neuropathy causes the foot to be insensitive to painful stimuli, temperature or touch. Nerve fiber alteration may cause also a deficit of vibration and proprioception. Motor neuropathy produces atrophy of the intrinsic muscles of the foot and in addition to thinning of the fat pad.

Autonomic neuropathy decreases sweating of the foot and produces dry skin, intense hyperkeratosis and cracks, gateways to infection.

Arterial disease in diabetes is an accelerated atherosclerosis, *macroangiopathy*, characterized by lesions of the coronary, carotid and peripheral arterial circulation [10]. The Framingham Heart Study established that arterial occlusive disease prevalence is 2 times higher in men and 3 in women with diabetes [11, 12]. Typically arterial pattern and location of atherosclerotic lesions is different, having preference for the infra geniculate vessels. Arteries more frequently diseased are the anterior tibial, peroneal, and/or posterior tibial in the leg, with patency of distal circulation of the foot. Fortunately the term of small vessel disease, does not mean occlusion of distal arteries, as described by Strandness and Conrad [13, 14] and has allowed successful distal revascularization of the crural vessels.

At the level of the microcirculation there is a thickening of the capillary basement membrane, *microangiopathy*, with a nonocclusive microcirculatory dysfunction involving the capillaries and arterioles of the kidneys, retina, and peripheral nerves. This is the dominant structural change in retinopathy and nephropathy. The result is an increase in capillary permeability and deterioration in the self-regulation of the flow in the kidney that is manifested by micro albuminuria and in the eye by the formation of exudates. This microangiopathic changes are more functional than structural and therefore are influenced by local and systemic factors. Changes in the vassa nervorum are structural and functional and intimately involved in genesis of peripheral polyneuropathy.

Why diabetics are susceptible to *infection* is not entirely clear. Experimentally, defects in leukocyte function both in chemotaxis, phagocytic response and in the capacity of intracellular death. Diabetic patients due to vascular insufficiency and to the neuropathy, have a greater risk for injuries to the feet that the non-diabetic subjects and once infection is established a greater severity and refractoriness to treatment exists. An ischemic limb does not respond to infection with increment of local perfusion, edema and leukocyte infiltration, in the same manner as the well vascularized limb. Antibiotics are not delivered appropriately to the infection site in a suitable concentration, due to inadequate tissue perfusion. All this factors contribute to the susceptibility and severity of infections in the diabetic foot.

The *biomechanical alterations* of diabetic foot are determinant in the genesis of ulceration. The footprint is the clearest sign of the load points of the foot. Body weight is distributed

equally between the calcaneus and the metatarsal heads. Deformity in diabetic foot is secondary to motor neuropathy and may lead to skin damage and ulceration.

Classification of Diabetic Foot

We have traditionally classified diabetic foot according to the predominant component that produces the injury in: neuropathic, ischemic, infectious or mixed. In the great majority of cases there will be a participation of more than one of these factors. The wound is classified based on Wagner Classification [15] that provides an excellent correlation with both the percentage of amputations as with the morbidity and mortality. For chronic limb ischemia the Colombian Association of Vascular Surgery and Angiology has adopted the Fontaine Classification [16]. This classification has important therapeutic implications.

Diagnosis

Accurate diagnosis is the foundation of diabetic foot care. History and physical examination are the primary means of obtaining the correct initial diagnosis for the most common types of foot lesions. Diabetics should be examined for neuropathy. The simplest and most effective means of detecting neuropathy we use in Colombia is a 10-g monofilament. An inability to detect the monofilament when applied under the metatarsal heads or digits is indicative of neuropathy.

Diagnosis of the vascular component begins with and a complete history and physical examination. A strong palpable pulse rules out ischemic diabetic foot and indicates that there is no obstruction to the flow between the heart and the point where it is examined. A diminished or absent pulse needs complementary studies to evaluate a proximal stenosis or obstruction [17]. Auscultation is a simple and valuable method to detect bruits over the examined vessels [18].

Doppler, plethysmography and ultrasonography is for us an integral part of the evaluation and care of the patient with diabetic foot. We rely in the measurement of systolic blood pressure and the ankle-brachial index (ABI) [19]. Values less than 0.9 are abnormal and reflect decreased perfusion to the lower extremity. Medial calcification of the tibial vessels, which is common in diabetics, may falsely elevate the ankle pressure. In the presence of an ABI greater than 1.3, we perform pulse volume recordings, segmental pressures toe/brachial index, to determine the presence and severity of ischemia [20, 21]. Duplex scan provides anatomical and hemodynamic information of great value to determine the extent of disease, inflow and outflow, many times is enough to decide endovascular treatment or surgical revascularization [22–26].

Computerized axial tomography Angiography (CTA) or MRA are of great value to complete the arterial evaluation of the lower limbs. Its cost is higher, but enable us to obtain an anatomical map of the arteries. These studies have replaced in most cases conventional angiography previous to surgical intervention or endovascular therapy.

Treatment

Due to the complexity of diabetic foot management, in the ACD, we perform treatment by a multidisciplinary team. The goal is obtaining prompt healing and limb salvage. Treatment is directed towards the pathogenic factors mentioned earlier with order of priority: control of infection, evaluation for ischemia, arterial reconstruction and other procedures (debridement, toe amputations, wound healing or surgical flaps in the vascularized foot).

We manage as outpatient in Wagner I and II lesions. Wagner 3, 4 and 5 in hospital. An X-ray of the foot is of important to evaluate for the existence of foreign bodies, gas in the soft tissues and bone involvement. Bone scanning and magnetic resonance imaging (MRI) are also useful for establishing the diagnosis of bone infection. Bone culture is the method to diagnose osteomyelitis.

Most chronic diabetic foot ulcers are colonized by microbiological flora, which includes aerobic and anaerobic organisms and fungi. The ulcer base should be inspected and probed,

because they may reveal a tract under the skin with an abscess and probing helps to assess the depth of the ulcer. A wound culture has a limited value in comparison with the deep tissue biopsy culture or of the purulence, is helpful in establishing the microbiology of the infection.

When infection is present it is necessary to use oral or systemic antibiotics. We must bear in mind that the flora present in these lesions is mixed, aerobic and anaerobic. Antibiotic treatment is started and modified once the results of the microbiological studies are available and according to clinical response.

Revascularization Strategies

In diabetic foot we consider revascularization in patients with ischemic endangered extremities for amputation. Fortunately primary amputation for an ischemic diabetic foot lesion is currently less frequently done, in Colombia. A comprehensive study to evaluate ischemia is recommended, in order to confirm it and to find if a revascularization procedure is needed.

For aortoiliac disease endovascular treatment with balloon angioplasty (with or without stenting) is an effective therapeutic modality. The best results of early success and long-term patency, are obtained for task A and B lesions [27]. We do not use it in patients with extensive aortoiliac disease (Task C and D), were we favour open surgery. We consider endovascular treatment as a good alternative and indicated in high surgical risk patients. There are a variety of surgical procedures that can be used in the treatment of aortoiliac obstruction. The decision of which to use, depends on each particular case, based on the general condition's, the extent and distribution of disease and the surgeon's experience. The best and most lasting results are obtained with aortofemoral bypass, although morbidity and mortality increases [28–30]. Extra anatomic axilofemoral femoral or femoro-femoral bypasses are reserved for patients in high surgical risk or with simultaneous pulmonary, cardiac, stroke, renal disease or intra-abdominal infection and when an endovascular or hybrid approach is not possible.

In infrainguinal revascularization, open surgery has demonstrated good results in our hands, so we favour it and consider endovascular procedures in patients at high surgical risk. Surgical revascularization with autologous saphenous vein, inverted or in situ, offers good results in this segment. Long-term patency is similar with one or the other technique, but we favour in situ [31]. The use of autogenous vein bypass to the dorsalis pedis artery provides durable and effective limb salvage, having the advantage of direct good perfusion to the foot [32]. We decide which artery to bypass depending on the size and quality of the vessel, but don't have any doubt to use any patent vessel distally. In some patients saphenous veins are of poor quality, have been stripped or ablated, in this situation we harvest the lesser saphenous or upper extremity veins for bypass [33]. In general, our policy is to use autologous vein as first alternative, second endovascular if it is feasible but when not, polytetrafluoroethylene (PTFE) is an alternative, using a distal vein cuff or adjuncts [34–36].

The role of angioplasty and stenting compared to open surgery, has been growing in Colombia. Restoration of flow provides a valuable benefit to save a foot threatened by ischemia, allowing the lesion to heal. Despite multiple publications on surgical and endovascular revascularization [37–54] until the BASIL study (Bypass versus Angioplasty for Severe Ischaemia of the leg), evidence of randomized controlled studies comparing surgical revascularization versus endovascular were not available. In the initial findings published in 2005 [55] similar results were observed comparing both therapeutic modalities, in the short term, with a higher cost and morbidity for bypass surgery. In the publications of 2010 [56–58] after a longer follow-up, patients randomized to surgery and with possibilities of living more than 2 years demonstrate better results than angioplasty. Those patients with probable survival less than 2 years or that do not have vein available, are best served with angioplasty. They will not live long enough to reach the benefits of a surgical revascularization and are at higher risk of surgical morbidity and mortality.

Conclusion

In Colombia diabetic foot is a growing problem and is responsible for 20 % of hospitalizations in diabetic patients. The ACD established a diabetic foot program that has promoted the implementation of diabetic foot teams over the country. Adequate and rational treatment of diabetic foot includes adequate diagnosis of aetiology, pathogenesis and extension of the lesion. If ischemia is present the possibility of amputation is high. Revascularization by surgical bypass or endovascular means, are currently employed in our country for limb salvage. A structured multidisciplinary team of health professionals is ideal for the management of Diabetic Foot.

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Integrated Management of Diabetic Foot in Oman

21

Khalifa Alwahaibi

Diabetes mellitus is a major health identity with a very high prevalence that is on the rise worldwide. The total number of people with diabetes has increased dramatically, from 171 million in 2000 to 382 million in 2013. This figure far exceeded expectations; the projection in one study was for 366 million in 2030. The number of people with diabetes is expected to increase by 55 % by the year 2035. Another 316 million have impaired glucose tolerance and are at high risk of contracting the disease [1, 2]. Diabetes mellitus carries a large number of complications and mortality. It represents an overwhelming burden on countries and individuals socially and economically. Diabetic foot problems are among the major complications facing diabetic patients at any point in their lives. Diabetic foot disease represents a real challenge to health providers and health systems in general.

Diabetes mellitus is a systemic disease affecting all organs in the body. The three main types of diabetes are type 1 (insulin-dependent diabetes mellitus), type 2 (non-insulin-dependent diabetes mellitus, and gestational diabetes. It occurs when the body cannot produce enough of the hormone insulin or cannot use insulin effectively. Insulin acts as a key that lets the body's cells take in glucose and use it as energy. Type 1 diabetes mellitus is an autoimmune disease with very sudden onset that occurs early in life and whose treatment requires insulin therapy. Type 2 diabetes mellitus occurs later in life and can go unnoticed and undiagnosed for years. People with undiagnosed diabetes mellitus who are unaware of existing risks are not protected from diabetes-related complications. Unfortunately, they are at higher risk of developing devastating and life-threatening complications. Gestational diabetes, which appears during pregnancy, can lead to serious health risks to the mother and her infant and increase the risk for developing type 2 diabetes later in life. Consistently high blood glucose levels can affect blood vessels, heart, kidneys, eyes, brain, and nerves. Diabetes is a major risk factor for developing atherosclerosis, which has proved to be the main etiology for cardiovascular diseases, kidney failure, blindness, and lower limb amputations. High blood glucose levels are known to carry increased risk for developing superficial and deep-seated infections and tend to cause delayed wound healing.

Over the last four decades, major socioeconomic changes in the Gulf region have transformed its countries and people. There had been tremendous urbanization, reduced infant mortality rates, increased life expectancy, sedentary life style changes, poor quality nutritional habits, and

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reduced physical activity. With aging populations, the number of people with diabetes and its complications has increased dramatically. The Sultanate of Oman and other Gulf nations are among the world's top countries with the highest incidence of diabetes according to the estimated prevalence of diabetes obtained from International Diabetes Federation statistics (years 2005, 2007, 2009, and 2013) [2].

According to estimates by the National Center for Statistics and Information (NCSI), the mid-year 2013 population in the Sultanate of Oman was 3.855 million, of which 2.172 million are citizens and 1.683 million are expatriates. The sex ratio in the country is 103 males per 100 females. It is a young population, with approximately 14.3 % and 34.3 % of the population under 5 years and under 15 years of age, respectively, and only 6 % are at least 60 years old [3]. Although the prevalence of diabetic patients in Oman is 12–16 % according to community-based surveys [4, 5], the registered total diabetic cases on a national level are 82,082, according to the 2013 Ministry of Health annual report. Of the 5139 new cases registered during 2013, females constituted 50.1 %. Approximately 14.7 % of the cases registered were in the 45–49 age group, followed by the 40–44 (14 %) and 50–54 age groups (13.8 %). The actual number of patients with diabetic foot disease is not known, but the registered number for amputation and disarticulation of limbs during 2013 was 305. This number has shown a significant decline over the last 10 years, and there were certainly patients who were not in the registry. Of the registered limb amputations, 50 % resulted from complications related to diabetes [3].

Diabetic Foot

Consistently high blood glucose levels cause variable damage to blood vessels and nerves. People with diabetes may present over the course of their disease with different manifestations of foot problems. These problem can vary from superficial skin infections and ulcerations to deep-seated infections, osteomyelitis, foot abscesses, infected gangrene, deformed foot, and threatened limb, or even to amputations. Diabetic foot-related problems are the leading cause of hospitalization in patients with diabetes.

People with diabetes face a risk of amputation that may be more than 25 times greater than that in people without diabetes. Epidemiological studies have indicated that between 40 and 70 % of all lower-extremity amputations are related to diabetes. Research has shown that 85 % of all amputations related to diabetes are preceded by foot ulcers and that between 49 and 85 % of all amputations are preventable [2].

Amputations carry a major social and financial burden on individuals, their families, their communities, and on their country's health care system. Amputations should be avoided, first, by good preventive measures and improvements in medical therapy, regular foot examinations, and foot care for people with diabetes, second, by prompt diagnosis, proper treatment, and foot care, and, finally, by subsequent follow-up treatment of minor foot problems to avoid amputations or, in those who have had minor amputations, to avoid major amputations.

Owing to a lack of publications on diabetes and its complications in the Arab world, we usually encourage our readers to apply the rule of 15 to understand the significance of this problem [6]. According to this rule, 15 % of people with diabetes develop ulcers, 15 % of ulcers develop into osteomyelitis, and 15 % of ulcers result in amputation [7].

Diabetic Foot Diseases

Patients with diabetes can develop various foot problems, which can vary in presentation and severity. Minor foot complaints, like tingling, mild pain, calluses, minor structural deformities, and superficial skin infections, can get worse and lead to serious complications like ulcerations, poor blood supply, nonhealing, deep-seated infections, sepsis, and limb loss. Diabetic foot complications are most common and serious among patients with diabetes, yet they are potentially the most preventable complications by awareness, education, and proper foot care.

Several existing structural foot deformities can predispose diabetic patients with diabetes to developing diabetic foot complications, and they may worsen the outcome of subsequent treatment if not addressed properly. Diabetic foot diseases include peripheral neuropathy, skin changes, structural deformities, infections, ulceration, ischemia, and digit and limb loss.

Diabetic Neuropathy

Excessively elevated blood glucose levels can provoke damage to nerves throughout the body, manifesting as different forms and degrees of neuropathy. They can cause sensory, motor, and autonomic neuropathy, as well as gastric neuropathy, interfering with gastric emptying. They can affect urination and result in erectile dysfunction. The most commonly affected areas are the extremities, in particular the feet; this is known as peripheral neuropathy. Approximately 40 % of cases of diabetic neuropathy involve the upper limbs. Existing high blood glucose levels with other risk factors, in particular high blood pressure, can accelerate nerve damage and cause early manifestations of complications related to neuropathy. Studies in the Arab world have shown a prevalence of neuropathy ranging between 38 and 94 % in diabetic foot cases [8].

Diabetic peripheral neuropathy is the most common symptomatic complication of diabetes. It involves symptoms and signs of peripheral nerve dysfunction and is characterized by a decline in and damage to nerve function, leading to a loss of sensation, ulceration, and subsequent amputation. Nerve damage in diabetes could be largely due to axonal damage and subsequent regeneration of nerve fibers or, to a lesser extent, to demyelination. Poor glycemic control and duration of diabetes are the two main risk factors associated with the onset of diabetic neuropathy. Other risk factors include genetic susceptibility, smoking, alcohol ingestion, increased LDL cholesterol, and coexisting cardiovascular diseases [9].

Peripheral neuropathy in diabetes can affect sensory, motor, and autonomic innervations. Peripheral sensory neuropathy can lead to different types of pain, tingling, and loss of feeling. Loss of feeling can allow trivial and subsequent major injuries to go unnoticed, leading to the development of ulcers, nonhealing wounds and superimposed infections, and, subsequently, deep-seated infections. This will worsen diabetic food disease and can lead to limb loss. The loss of protective sensations, such as pain, may predispose patients to recurrent injuries without feeling its occurrence.

Fig. 21.1 Open style shoes, which predominate in the region

Peripheral motor neuropathy in the feet can lead to atrophy of the small muscles of the foot, which will lead to foot deformities. The development of foot deformities with a lack of foot care awareness and lack of proper footwear contributes significantly to increasing problems of foot complications in our diabetic patients.

Peripheral autonomic neuropathy that leads to dry, cracked skin with fissures is a common presentation in clinical practice. The unique character of weather, which is hot and dry, in most Gulf countries makes it very difficult to change the suitability of protective footwear. Sandals are the most common footwear in the region (Fig. 21.1).

Combined forms of peripheral neuropathy with high blood sugar levels and repeated forms of trauma will eventually lead to the formation of charcot foot, a condition in which the bones of the foot are weakened and destroyed with repeated cycles of fracture and abnormal ossification, leading to changes in the foot shape and making the foot more vulnerable to other complications, mainly infections.

Structural Foot Deformities

Structural foot deformities are common in the general population. Deformity appearance and pathophysiology vary. A small number of them are congenital, they arise at birth. remaining appear later during adulthood. Improper footwear, disturbed walking mechanics, external trauma, and friction are known factors in the development and maintenance of certain structural foot deformities.

Structural foot deformities are significant issues in diabetic patients because of other factors related to diabetic complications, mainly decreased vision (diabetic retinopathy), lack of sensation (peripheral sensory neuropathy), limited joint mobility (peripheral motor neuropathy), dry skin and disturbed sweat mechanisms (peripheral autonomic neuropathy), ischemic changes and coexisting atherosclerotic arterial stenosis, peripheral edema, and delayed wound healing.

Structural foot deformities in patients with diabetes include bunions, calluses, hammer toe, cracked heels, ingrown toenails and claw toes, loss of the palmar arch (flat foot), and charcot joints. These deformities lead to local areas of high pressure and subsequently predispose diabetic patients to the formation of ulcers, nonhealing wounds, and limb loss [10].

Foot Ulcer

Foot ulcers in patients with diabetes precede 85 % of nontraumatic lower limb amputations. Fifteen percent of patients with diabetes develop ulcers in their lifetime. This is a major burden on the patient, family, and society. The quality of life of these patients is significantly affected, and efforts and expenses required for treatment are negatively reflected in the health care system. Prevention, regular foot examinations, early detection, and proper treatment of patients with foot ulcers can prevent the progression of these ulcers and reduce limb loss.

The etiology of diabetic foot ulcers is multifactorial. Most of these ulcers occur in feet with preexisting structural foot deformities with peripheral sensory neuropathy and superimposed trauma or infections. Structural foot deformities and callus formation can result in focal areas of high pressure that predispose a person to ulcer formation. Decreased vision in patients with diabetic retinopathy and loss of protective sensations with peripheral neuropathy will mask trivial injuries and cause them to go unnoticed for some time, allowing the development of foot ulcers in diabetic patients. Stepping on sharp objects, being burned by a heating machine, and receiving direct burns or coming into contact with flames, combined with decreased vision and loss of protective sensations, are oft-repeated scenarios among patients with diabetes. Patients with peripheral autonomic neuropathy experience decreased sweat production, which makes diabetic feet and existing skin fissures even drier and more vulnerable to breakdown and the formation of ulcers. Restricted joint mobility with peripheral motor neuropathy in patients with diabetes predisposes certain areas in the foot to repeated friction and abnormal pressure, which play a major role in the formation of calluses, skin fissures, subcutaneous hematoma and loss of skin integrity, and the triggering of protective mechanisms against ulcer formation. A combined loss of protective sensation and repeated amounts of trauma, friction, and abnormal loads on the skin will lead to blistering and subsequent full-thickness skin loss. Subcutaneous edema, leg swelling, venous insufficiency, and tight footwear represent additional major factors in the worsening of foot ulcers. Superficial skin infections play a major role in the pathogenesis of diabetic foot ulcers in the region, especially when it comes to walking in bare feet and using nonprotective footwear. Jeopardized blood supply and varying degrees of ischemia play major roles in delayed wound healing and nonhealing of these ulcers. Poor control of blood glucose levels, in combination with smoking, delays wound healing, which can prolong the duration of ulcers, predispose a person to further ulceration, and lead to limb loss. Chronic ulcers with partial or nonhealing and healed ulcers with scars can predispose someone to recurrent ulcer formation, either at the same site or at adjacent sites [10] (Table 21.1).

Table 21.1 Emphasis on recognized risk factors for developing foot ulcers in patients with diabetes

Structural foot deformity
Callus formation
Peripheral sensory neuropathy
Peripheral autonomic neuropathy
Peripheral motor neuropathy
Peripheral edema
Impaired vision
Trauma (trivial and major)
Previous ulcers and scars
Poor footwear
Peripheral arterial insufficiency
Smoking
Poor glycemic control

Foot Infections

Patients with diabetes mellitus with the aforementioned peripheral sensory, motor, and autonomic neuropathies, combined with structural abnormalities, are more prone to foot infections. Diabetic foot infections can vary from simple superficial cellulitis to deep-seated infections and acute and chronic osteomyelitis (Fig. 21.2). Repeated local trauma and compromised vascular supply play a major role in exacerbating foot infections in diabetic patients. Gram-positive bacteria and anaerobes are common flora in diabetic foot infections, but it is not unusual for deep-seated infections in diabetic patients to be associated with gas-producing Gram-negative bacilli. These infections can appear as necrotizing fasciitis, myositis, and compartment syndrome. Early detection of diabetic foot infections and prompt management will significantly reduce limb loss in diabetic patients. Periodic foot care and foot examinations will help in the early detection of diabetic foot infections. Proper use of antibiotics and early surgical foot care procedures will prevent the progression of simple foot infections into debilitating conditions requiring major interventions. Podiatry or foot care services in Oman have improved over the last few years, covering a wide spectrum of education, early detection, and appropriate surgical intervention, which has played a significant role in preventing the progression of diabetic foot infections and ulcerations and therefore reduced rates of limb loss.

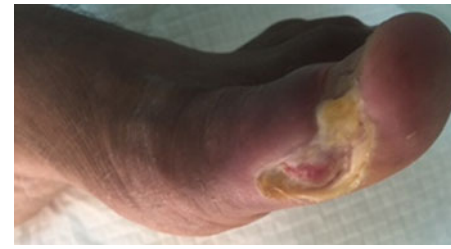

Fig. 21.2 Nonhealing ulcer with underlying osteomyelitis

Peripheral Artery Disease in Diabetic Patients

Diabetes is a major risk factor for atherosclerosis. Identifying patients with diabetic foot and coexisting peripheral artery disease is crucial in promoting healing and preventing limb loss. The absence of foot pulses must alert caregivers to the existing problem of peripheral arterial compromise, which would necessitate urgent assessment and intervention. Ulcers and gangrene at the toes and on the margins of the foot and an absence of callus and structural foot deformities should alert caregivers to the seriousness of the condition (Fig. 21.3). Recurrent and nonhealing ulcers are indications for urgent arterial assessment. Diabetic patients can have varied manifestations of peripheral artery disease. The misconception or misunderstanding of microvascular disease in patients with diabetes and the underestimation of the success of peripheral arterial interventions in diabetics have evolved over the last two decades, and patients with diabetes have similar outcomes in connection with peripheral vascular and endovascular interventions compared with nondiabetics. Absent pulses, toe ulcers and gangrene, ulcers in nonpressure areas, and recurrent and nonhealing ulcers in patients with diabetes are indications for comprehensive arterial assessment and the subsequent angiographic assessment of limbs. Ankle brachial pressure indices

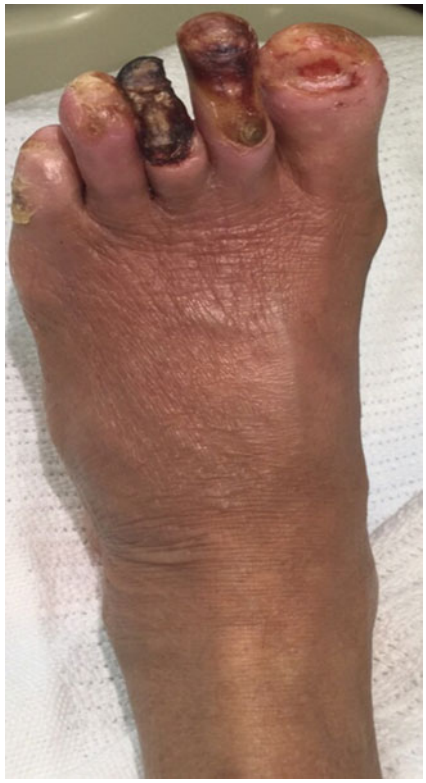

Fig. 21.3 Toe gangrene and ulcers with absent foot pulses are indications for detailed vascular assessment and angiography

might be falsely high in patients with diabetes because of arterial calcinosis and failure of arteries to undergo wall recoil during arterial waveform. Patients with identified peripheral arterial disease should undergo urgent appropriate intervention, either distal revascularization surgery or endovascular treatment.

Multidisciplinary Team Approach

The high incidence of diabetes and diabetic foot complications serves as an emergency call for specialized foot care clinics. The Sultanate of Oman and other Gulf countries have established foot care clinics to treat diabetic patients in terms of both educational preventive measures for diabetic patients and early diagnosis and appropriate management of diabetic patients with foot-related complications. Diabetic foot clinics function within the framework of a multidisciplinary team approach to treating diabetes and providing wound-care-related specialties. This approach involves general practitioners, family doctors, endocrinologists, diabetologists, podiatrists, wound care nurses, community-trained foot and wound care nurses, social workers, and, most importantly, patients themselves. Patients are seen regularly and referred to these clinics as soon as they are diagnosed with diabetes. Educational and preventive measures are given in the form of collective lectures and individual one-on-one conversations with patients, community posters, and booklets. Regular follow-up is conducted with patients with early onset diabetic foot problems, and early clinical evaluations and appropriate diagnostic tools are provided for these patients. Early referral for vascular assessment is key for limb salvage in diabetic foot patients. Early referrals to specialized centers with vascular surgery and orthopedic foot practices are encouraged so patients can arrange appropriate early or urgent consultations to avoid delays and subsequent undesired consequences (Fig. 21.4). Early referral for hyperbaric oxygen therapy is readily available in Oman. Hyperbaric oxygen therapy is available on Oman naval and diving bases, which receive a large number of cases of diabetic foot with nonhealing ulcers.

The Sultanate of Oman has opened 25 specialized diabetic foot clinics, with an additional 5 clinics slated to open in the next 6–12 months. All nurses at diabetic foot clinics are trained nurses; initially they were sent abroad for special courses, but there is currently a year-long national diabetic foot training program. In addition to diabetic foot nurses at diabetic foot clinics, other nurses have been trained as focal point nurses at primary health care centers and home care since they encounter diabetic patients at an early stage. This allows the nurses to implement preventive measures, make early diagnoses, and plan patients' early treatment and intervention.

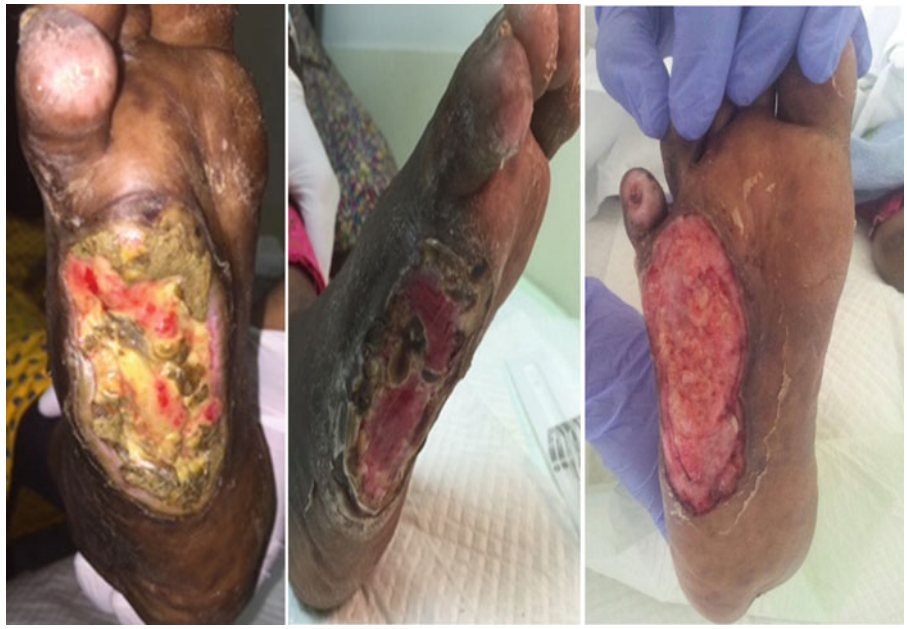

Fig. 21.4 Nonhealing ulcer following femoral popliteal bypass and repeated sessions of ulcer debridement

Prevention Is Better Than Cure

Given the significantly high incidence of and genetic predisposition to diabetes in Oman, it is strongly recommended to check all patients for their baseline and fasting blood glucose levels. Those who receiving a diagnosis of glucose intolerant and diabetic patients undergoing diet and lifestyle modifications should enroll in educational programs to identify diabetes-related complications and diabetic foot complications and with the goal of avoiding them. Diabetic patients should undergo regular monitoring of their glycated hemoglobin and have periodic check-ups for retinopathy, nephropathy, neuropathy, and regular foot care. There is substantial evidence showing the benefits of screening all patients with diabetes for periodic foot assessment and for the identification of risk of foot ulceration. These patients might benefit from certain prophylactic measures, including education, proper footwear, offloading, intensive podiatric care, vascular evaluation, and early surgical intervention. The specialized diabetic foot care clinics in the Sultanate of Oman and other Gulf countries, with their multidisciplinary team approach, have been publicized through community-based educational posters and booklets that encourage regular foot check-ups. In Oman annual foot check-up are encouraged, and patients in whom diabetic foot issues are identified are closely monitored so that they many avoid foot-related complications.

Oman has a largely Muslim population that prays five times a day, and feet must be washed before praying. These practices make it easy for patients to inspect and clean their feet. The act of praying itself offers physical exercises for the feet. Trimming nails is a social and religious habit that encourages people to take care of their feet and should be practiced properly.

Oman has a hot and humid climate and few social habits and life circumstances that are different from those found in Western countries; therefore, the country should adapt customized guidelines for foot care (Table 21.2).

Table 21.2 Customized guidelines for diabetic foot care in hot climates

Closely monitor blood sugar levels[a]
Do not smoke
Inspect feet daily for cuts, blisters, swellings, redness, or nail problems[a]
Use a mirror to look at bottom of feet[a]
Wash feet with warm (not hot) water daily
Dry feet using a washing towel, especially between toes
Moisturize feet to avoid skin cracks, but not between toes
Do not moisturize between toes (could encourage fungal infections)
Use proper/protective footwear
Wear clean, dry cotton socks to avoid humidity due to excessive heat; change daily
Avoid tight, elastic, compressive, bulky, synthetic socks
Shake out and feel inside footwear before wearing to check for foreign bodies
Never walk barefoot
Cut nails carefully and straight, and file edges; do not cut nails too short
Do not treat corns/calluses yourself; see your doctor for appropriate treatment[a]
Undergo regular foot examinations by a podiatrist or a diabetic foot nurse specialist

[a]Call your doctor early with any concerns

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22 Comparison of Diabetic Foot Amputation in Egypt with the United States

Sherif Y. Shalaby and Alan Dardik

The Middle East and North Africa (MENA) is the world region that has the highest prevalence of diabetes, with Egypt making the top 10 ranking [1]. The International Diabetes Federation (IDF) estimates that 7.5 million adults are affected by diabetes in Egypt, and by 2030, this number will increase to 13.1 million [2]. The increasing diabetic population is contributing to the rise of expenditure and utilization of healthcare services [3]. The prevalence of complications in the Egyptian diabetic population is quite high. The prevalence of retinopathy is 20.5 %, albuminuria 21 %, nephropathy 6.7 %, and neuropathy is 21.9 % [4, 5]. In contrast, the prevalence of diabetic foot complications is low with active diabetic foot ulcers relatively constant at 1 % from 1998 to 2013 [6, 7]; major diabetic foot amputation has the same prevalence of ≤ 1 %. [7]. In developing countries, foot ulcers and amputations are very common, with a prevalence of diabetic foot ulcers of 10 % and amputations can be as high as 9 % [8]. On the contrary, in most developed countries, the annual incidence of foot ulceration amongst people with diabetes is about 2 % [2]. In these countries, approximately 1 % of people with diabetes suffer a lower-limb amputation [2]. The United States' diabetic foot complications are similar but slightly higher to developed countries where foot ulcers is 8 % and major diabetic foot amputation 1.8 % [9]. Similarly to Egypt, diabetic foot ulcers and diabetic foot amputations rates are steady from 1988 to 2008 despite increased health care expenditure [9].

How does this contrasting prevalence between Egypt and United States diabetic foot complications be deciphered to further our understanding in preventing major diabetic foot amputations? The comparison of two distinct populations is hindered by many factors that need to be analyzed to validate and understand this phenomenon. These factors include, but are not limited to, medical expenditure, social, genetic, economic, and dietary factors. Concerning genetic factors, a recent study observed the same phenomenon that Arab inhabitants of MENA are at a lower risk of diabetic foot complications compared to non-Arabs living within the same region [10, 11]. These studies were conducted in Saudi Arabia, another MENA country with many similarities to Egypt and is also suffering with a diabetes epidemic. Saudi Arabia ranks number 4 with 3.6 million diabetes cases, the highest diabetes prevalence (23.9 %) in the MENA region [12]. The prevalence of foot ulcers and amputations in this Saudi population was 10 %, which is similar to developing countries [10]. It has been reported that non-Saudi nationality, which represents one third of the nation, was associated with higher prevalence of foot complications, such as ulcer, gangrene, and amputation, than

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present in a Saudi population [10]. Interestingly, despite Saudi Arabia having one of the highest diabetes prevalences, overall foot complications were lower for Saudis than non-Saudi nationality that are exposed to the same environmental conditions and dietary habits; Saudis are also at lower risk of developing diabetic neuropathy than non-Saudis [11]. This observation could be due to many factors including inequalities of access to healthcare in Saudi Arabia. Healthcare treatment patterns are not universal as there are public hospitals, private hospitals, and different types of health insurance coverage [13]. As such it is possible that healthcare access and quality of healthcare might vary significantly between Saudis and non-Saudi nationals. Also, healthcare access in Saudi Arabia is direct, i.e. does not require referrals, and it is possible that some groups of people could receive referral for healthcare in a more timely fashion than others. White collar positions in business, healthcare, trade, government, and law may also be associated with the high prevalence of diabetes among Saudis [14]. These issues contrast with Egypt, where healthcare is universal and access is direct, and may contribute to the lower prevalence of diabetic foot complications. Variation of access to healthcare may also explain the varying difference of major diabetic foot amputation in Egypt compared to the United States. However, further studies are necessary to understand this phenomena.

Similarly, evidence of environmental factors contributing to disease progression independent of genetic factors is found in the Japanese migrant population to the mainland United States. Asians are thought to be at a higher risk of type 2 diabetes compared to Caucasians, despite a lower basal metabolic index (BMI) [15]. However, Japanese migrants are at a higher risk of type 2 diabetes and develop coronary heart disease earlier to their non-migrant counterpart [16, 17]. It may be possible to delay or prevent the development of diabetes through dietary and exercise interventions in individuals having impaired glucose tolerance [16]. Another observation on health and environmental factors is the 'French paradox', which describes the phenomenon of low heart disease rates in France 'despite' a diet rich in saturated fat [18]. However, France and Finland, with similar intakes of cholesterol and saturated fat, consistently have had very different coronary heart disease mortality rates. This paradox may be explained via several factors including differences in genetics and diet [19].

Diverse forces, including environmental factors, genes, and universal access to healthcare may play pivotal roles in the prevalence of diabetic foot amputation as they drive cardiovascular disease progression among the world across all ethnic boundaries. Further research is required to investigate environmental risk factors that could be avoided to lower diabetic foot amputation worldwide.

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Cell Therapy for Vascular Diseases in Israel

23

Yael Porat, Michael Belkin, Shlomo Bulvik, Michael Frogel, Offer Galili, and Mark Niven

In Israel, as elsewhere in the world, people with vascular disease suffer severe complications, including critical limb ischemia, which can result in gangrene and amputation. This chapter describes the step-wise progression in translational medical research as a scientific breakthrough progresses from a laboratory invention to the start of a clinical trial. The novel idea is a method whereby a sub-population of non-mobilized peripheral blood cells can be turned, within a day, into a cellular therapeutic product code-named BGC101, composed of endothelial progenitor cells (EPCs) and Stem/progenitor cell (SPCs). In addition, the benefits of collaboration between an Israeli biotechnology company and an Israeli medical center in overcoming the hurdles of bringing the idea to fruition will be described.

In order to achieve the goal of bringing innovative therapy to the market, one has to undertake complex tasks involved in translating the idea from a concept to a novel technology with the purpose of prevention, diagnosis or treatment of diseases.

The inventor has to surmount many hurdles before initiating a translational research project:

1. About 80 % of inventions are made by employees of universities, hospitals, government agencies etc. These inventions, by law, belong to the employer. In order to foster innovation, most of these institutions have regulations by

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which they share the monetary rewards of a successful invention with its originator. Therefore the inventor has to face the bureaucracy of the institution's office, usually termed the "Technical Transfer Office", dedicated to evaluating, patenting and commercializing innovations.
2. The intellectual property of the new idea has to be protected by applying for patents that protect the invention and guarantee the inventor's freedom to operate. Furthermore, without patent protection the chances of anyone financing the project are practically nil.
3. A translational issue unique to cellular therapy is the problem that pharma companies are not accustomed to dealing with the special requirements for marketing of products in the new era of personalized regenerative medicine.

This onerous process can be facilitated by collaboration between academic medical centers and biotechnology companies whereby the product and clinical application development are managed together by multi-disciplinary teams. The outcome is not only faster but also provides academic validation to the technology. At the same time the academic medical center enhances its reputation by serving as an integral part in the vision and development of cutting edge technologies that will constitute the next generation of medical practice.

We describe here one example of an Israeli biotechnology company's pathway to develop an innovative technology platform utilized for the generation of SPC cell-based regenerative therapy to treat vascular diseases and its successful collaboration with an academic medical center.

The process was started based on a patented method for generating specific populations of therapeutic SPC cells using immune system dendritic cells (DCs) for guiding specific differentiation of the cells in vitro towards pro-angiogenic cells. In order to pursue the project with all its complexities, a company, BioGenCell, was established. Cooperation was then established with Laniado Medical Center, Netanya, Israel, an academic affiliate of the Technion School of Medicine. Laniado Hospital serves as the only medical center for a growing population of 400,000 people in the city of Netanya and surrounding suburbs. Laniado Hospital was founded by The Grand Rabbi of Klausenberg, a survivor of Auschwitz, who lost his wife and 11 children in the Holocaust. As a direct result of this, he included in the medical center's charter a request for participation in innovative medical research projects whose ultimate purpose is the improvement in patient care and outcomes.

The collaboration with BioGenCell enabled the growing Medical Center to support this innovative regenerative medicine research from its inception. BioGenCell conducted the research, providing proof-of-concept for the patented technology, completion of the preclinical phase and the establishment of a stem cell research laboratory and GMP compliant clean room manufacturing facility that produces BGC101 for clinical trials. The company was able to maintain control of the intellectual property while working toward the common goal of developing an innovative technology platform with the promise of treating vascular diseases, reversing disability, and improving the quality of life. The team worked together on developing the clinical trial as one of the first studies in which Laniado is the lead hospital, as well as, obtaining regulatory approval from the Ministry of Health in Israel to begin human trials. Clinicians, researchers, academicians and company personnel will provide the needed input and skills for conducting this first in human trial directly at the Medical Center. Once the initial safety and efficacy trial in 30 patients is completed at Laniado, trials will be expanded to the United States and the European Union. This rapid trajectory has been made possible by the combined efforts of the multidisciplinary joint team approach that benefits the company, the medical center and most importantly the patients.

Patients suffering from cardiovascular diseases were chosen as the first target of the collaborative effort.

Etiology of Vascular Diseases

Degenerative vascular diseases are the major cause of morbidity and mortality worldwide. Cardiovascular Diseases (CVD) including

coronary ischemic heart disease (IHD), cerebrovascular disease (Stroke) and Peripheral Artery Disease (PAD) are the primary cause of death worldwide (in the US 31 % with over 750,000 deaths/year) [1–3]. The estimated yearly cost of CVD in the US exceeds $320 billion with projected costs of $918 billion in 2030. By then 43.9 % of the US population will have some form of CVD [4]. A dramatically increased risk for the development of vascular diseases is related to diabetes that currently affects 10 % of the US population, and by 2020 will affect more than 20 million people in the USA alone [4].

Critical Limb Ischemia

BioGenCell has chosen peripheral artery disease (PAD), which affects more than 12 million people in the US, and its most serious form, critical limb ischemia (CLI), as its initial vascular disease target. PAD is characterized by partial or total blockage of blood supply to a limb, usually the leg. As the disease progresses it reaches the stage of intermittent claudication, followed by the development of critical limb ischemia (CLI).

CLI is defined as a severe obstruction of the vasculature, manifested by poor physical functioning due to leg or foot pain, and/or non-healing ulcers with tissue loss [5]. It is estimated that by 2020 CLI will affect one million patients in the USA. About 30 % of CLI patients are defined as 'No Option' and require amputation. CLI has an increased risk of comorbidities mainly due to cardiovascular ischemic events with a 1 year mortality, after the development of CLI, of 25 % [6].

Current best practice treatments of CLI include treatment of ulcers and gangrene, revascularization and/or medication therapy, depending on the location of the obstruction to flow. Revascularization options are either endovascular or bypass surgery. However, in many cases the disease occurs in capillaries and small vessels, too numerous and small to revascularize by currently available procedures. Therefore patients are treated with medications aimed at improving blood flow (such as the phosphodiesterase inhibitor cilostazol), reducing blood viscosity (antiaggregants and anticoagulants), and reducing pain (including several levels of analgesics). In addition, due to the ulcers and subsequent gangrene and recurrent infections, these patients often need antibiotic therapy.

Amputations have devastating psychological and diminished quality-of-life effects on patients [7]. They also can have a tremendous negative impact on their survival.

Amputations are also associated with significant expenses (e.g., hospitalization, surgery, constructing and fitting of prosthesis, rehabilitation, home health aides, construction and adaptations at the patients' homes, influence on family and productivity economics, long-term health care costs, etc.) [8]. The economic burden per CLI amputee exceeds $100,000 in the first year and an additional cost of $15,000 for each consecutive year for outpatient care (~85 % of the patients) or $70,000–100,000 for nursing home care (~15 % of the patients).

Based on all these statistics there is an obvious pressing need for new therapeutic modalities that promote regeneration of blood perfusion in the limbs, such as the use of SPC-based products.

Results and Challenges of SPC Cell-Based Therapy in CLI

The rationale for using SPC as a therapeutic modality to treat CLI is the assumption that their plasticity allows them to differentiate in vivo or in vitro in response to the environmental cues and, more specifically, to support tissue revascularization and resultant reperfusion. Tissue sources, including healthy donors and patient-derived cells, are currently under research and development or have already been tested in patients. A variety of allogeneic and autologous tissues have been suggested as sources for SPC and EPC cell treatment, such as bone marrow (BM), peripheral blood mobilized cells, and from various mesenchymal organs.

A meta-analysis by Benoit et al. summarized 45 clinical trials of open-label and randomized clinical trials (RCTs) with 1272 patients who received cell therapy. Safety analysis included evaluation of death, cancer, unregulated angiogenesis, and procedure-related adverse events (AE) such as bleeding. The overall AE rate was low (4.2%). Cell therapy patients did not have a higher mortality rate than control patients and demonstrated no increase in cancer incidence when analysed against standard population rates. Efficacy analyses included the clinical endpoints of amputation and death as well as functional and surrogate endpoints. Cell therapy patients had a significantly lower amputation rate than control patients (OR 0.36, $p=0.0004$). In addition, efficacy was demonstrated in a variety of functional and surrogate outcomes (such as ABI, TcPO2 and QoL) [9, 10].

These studies show that cell implantation is well tolerated. However, most of the reported AE stemmed from pre-procedural treatments connected to acquiring cells for the treatment [11–13]. For example, procedures for directly aspirating BM cells require the use of anaesthesia and entail pain and discomfort for these chronically ill patients. An alternative method for obtaining large amounts of BM cells is by extraction of mobilized BM cells from peripheral blood by aphaeresis. In the mobilization process, an inflammatory process is mimicked by the pretreatment of patients with high doses of granulocyte colony-stimulating factor (G-CSF; 1400 μg daily for 4–5 days). This has been reported to result in fever and chills, headache, muscular pain and bone pain, as well as, increased blood viscosity and platelet counts, which are problematic especially in patients suffering from microvascular diseases [11, 14, 15].

A further hurdle to commercialization of SPC technologies is lack of accessibility and high cost. For BM extraction there is a need for an operating theatre and team. This is both costly and accessible only in hospitals. Cell collection after mobilization requires aphaeresis utilizing specialized machines and dedicated teams. This process, similar to BM harvesting, is also costly and not available in every medical facility.

Beyond the State-of-the-Art

In order to overcome the above mentioned issues, BioGenCell applies a patient-oriented approach in the development of its novel technology for producing the therapeutic cell population (BGC101 enriched with EPCs) from a standard peripheral blood draw of 250 ml within a short culture period of 1 or 3 days. Most importantly, both the blood collection and the treatment can be performed in *any* outpatient setting.

Furthermore, this standardized and highly reproducible method enables development of a fully automated production process in a closed system device that will make the product much safer and accessible.

Since the number of EPCs and SPCs in the blood is relatively low, an ex vivo method for the enrichment and augmentation of specific cells was invented.

The breakthrough innovation of BioGenCell is the utilization of autologous DCs with anti-inflammatory and angiogenic effects to mix in vitro with select SPCs in culture to create a final product for human use that specifically targets areas of ischemia and regenerates the microvasculature necessary for tissue repair (Fig. 23.1). At the time of the invention of BGC101 there were no published reports that utilized DCs to directly activate and differentiate SPC in vitro, outside of the immune system niche. In a set of experiments summarized by Porat et al. in Diabetes Metabolism Research and Reviews [16] selected immature plasmacytoid and myeloid DCs from 24 healthy and 2 diabetic donors were activated with anti-inflammatory and pro-angiogenic molecules to induce specific activation signals. Co-culturing of activated DCs with SPCs generated $83.7 \pm 7.4 \times 10^6$ BGC101 cells with 97% viability from 250 ml of blood. BGC101, comprising 52.4 ± 2.5% EPCs (expressing Ulex-lectin, AcLDL uptake, Tie2, vascular endothelial growth factor (VEGF) receptor 1 and 2, and CD31), 16.1 ± 1.9% SPCs (expressing CD34 and CD184), and residual B and T helper cells, demonstrated angiogenic, colony formation (stemness) potential and secretion of IL-8, IL-10, VEGF, and osteopontin.

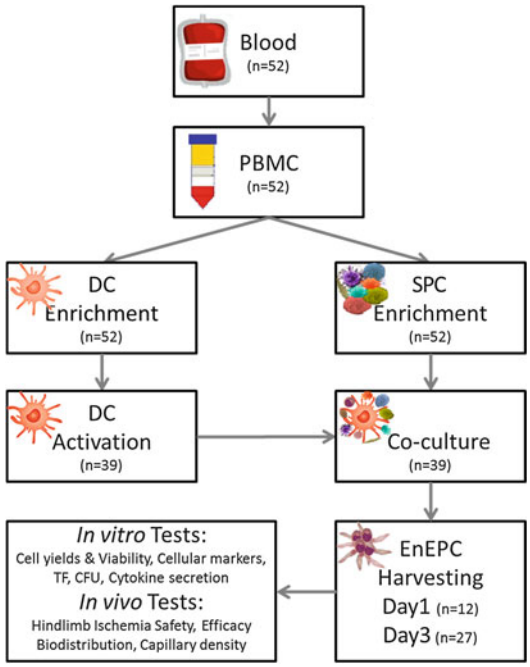

Fig. 23.1 Blood-derived SPC specifically activated by DCs [16]. Flow chart depicting the generation of potentially therapeutic enriched endothelial progenitor cells (EnEPCs). Non-mobilized blood-derived plasmacytoid and myeloid DCs activated with toleragenic and pro-angiogenic cytokines (such as IL-10, VEGF) are used in vitro to specifically direct the activity of SPCs which were enriched from the same blood sample and co-cultured for 1 or 3 days

BC101 is a typical biotechnology product that is defined in the US as 'Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)' and is regulated by the FDA Center for Biologics Evaluation and Research (CBER). In EU it is defined as an advanced-therapy medicinal product (ATMP) and is regulated by the Committee for Medicinal Products for Human Use (CHMP) part of the European Medicines Agency (EMA) [17, 18].

In animal studies BGC101 cells administered to immunodeficient mice with limb ischemia (n = 40) yielded a high safety profile and significantly increased blood perfusion, capillary density, and leg function after 21 days. BGC101 cells tracked 21 days post-administration by hCD45 demonstrated homing and engraftment along the ischemic areas in the injured leg. Assessment of new blood vessel generation based on staining with hCD31 revealed enhanced vascularization that was restricted to the injected leg. Capillary density was significantly higher in the BGC101-treated mice than in the Vehicle Control treated group (105.2 ± 5.0 compared with 56.7 ± 2.7 capillaries/field; Figs. 23.2 and 23.3).

Importantly, blood from diabetic patients yielded cells similar to those obtained from healthy donors (Table 23.1). Thus, in addition to its scientific merit this novel technology can facilitate the development of a series of standardized products as it only requires a blood volume of 250 ml that can be safely and easily acquired even from chronically ill patients.

Conclusion

For CLI patients, BGC101 will be used with the intention of rescuing ischemic limbs. This, we hope, will be achieved by promoting the formation and function of new blood vessels that will improve circulation, enhance tissue perfusion, alleviate signs and symptoms, delay or even prevent the need for amputations, and increase survival with improved quality of life. It is therefore our goal to bring BGC101 to market as soon as possible.

The cooperative efforts between BioGenCell and Laniado Medical Center have enabled the development of an efficient and timely plan that addresses safety and efficacy, as well as technical and regulatory issues, related to each step in the clinical treatment and manufacturing processes. Furthermore, this new therapy should be an accessible and affordable solution for patients, as well as healthcare providers.

In conclusion, the collaboration between a biotechnology company and medical center in Israel has overcome many of the significant hurdles in bringing a new concept from the bench to the bedside and has led to the rapid development of a novel technology for producing a therapeutic cellular product within a single day from a standard blood draw for the treatment of vascular diseases.

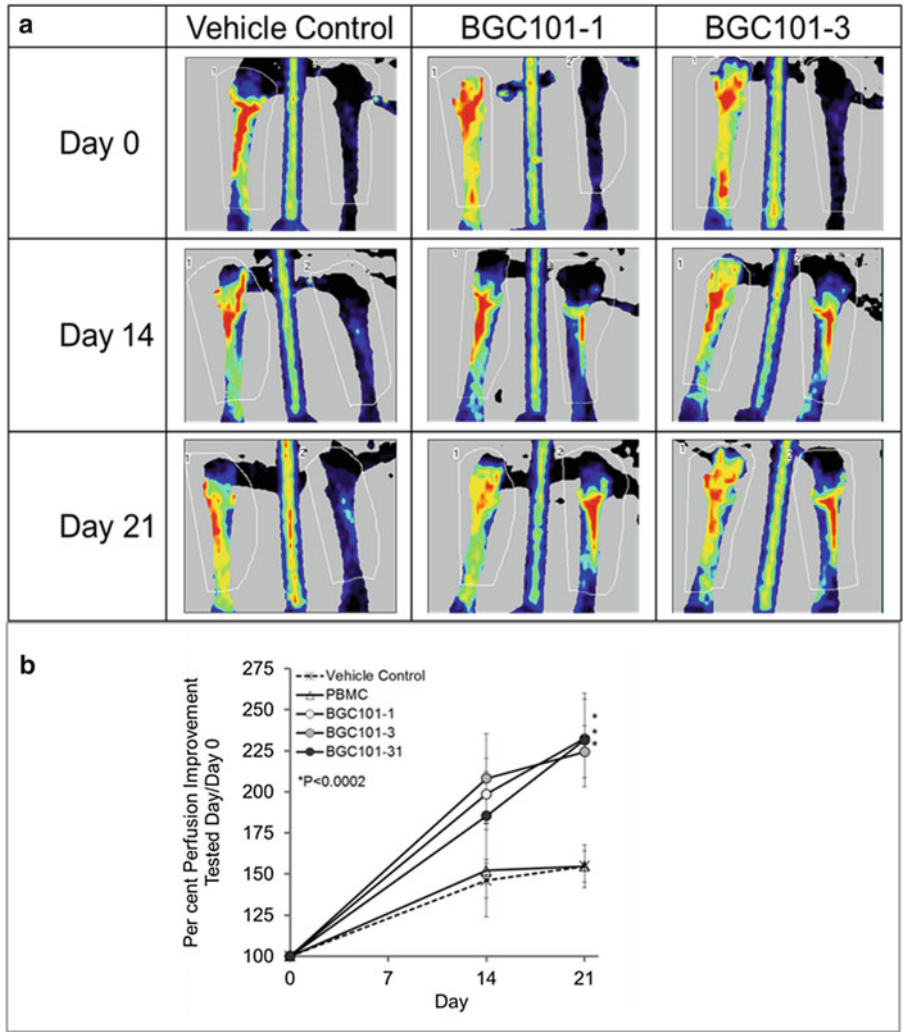

Fig. 23.2 In vivo efficacy of BGC101 in a mouse model of hind limb ischemia [16]. In vivo efficacy of BGC101 in a mouse model of hind limb ischemia, showing significant improvement in perfusion. Ligation and dissection of a femoral artery section led to ischemic damage, which was followed by intramuscular cell injections. (**a**) Representative laser Doppler scans following infliction of damage to the left leg (day 0), and repeated scans 14 and 21 days after treatment. During the experiment the per cent Perfusion was tested in the Vehicle Control treated group (n = 12), the peripheral blood mononuclear cell treated group (PBMC, 2.5×10^6 cells/mouse, n = 5), and in the BGC101 treated groups BGC101-1 (cells from 1-day culture, 2.5×10^6 cells/mouse, n = 10), BGC101-3 (cells from 3-day culture, 2.5×10^6 cells/mouse, n = 10), and BGC101-31 (cells from 3-day culture, 0.5×10^6 cells/mouse, n = 5) ($P < 0.0002$). (**b**) Percent perfusion improvement at each time point in each group versus that of day 0 compared with that of the Vehicle Control group at the same time point ($P < 0.0002$)

Successful implementation of this technology in clinical trials will place Laniado Medical Center and BioGenCell at the forefront of a new standard of care utilizing personalized regenerative medicine cell therapies. This novel technology could then be studied for other uses such as heart disease, ischemic stroke, pulmonary hypertension and even vascular dementia and several kinds of blindness.

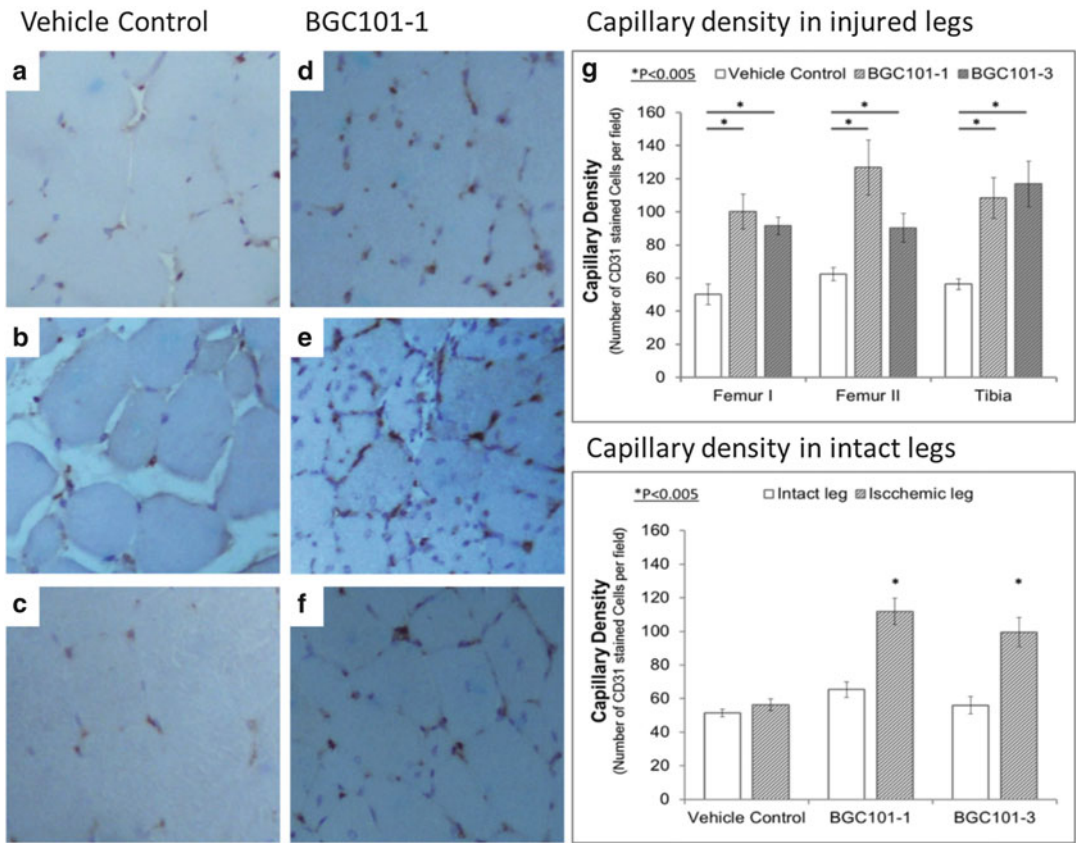

Fig. 23.3 Increased capillary density in BGC101 treated mice is restricted to the injured leg [16]. (**a**–**f**) are representative photomicrographs (×630) of tissue sections from ischemic and intact legs on day 21. New capillaries in tissue sections from femur at the site of damage (Femur I), femur at the implantation site (Femur II), and distally at the diaphysis of the tibia (Tibia), were stained with hCD31 (mouse cross-reactive) and H&E (**a**–**c**); (**d**–**f**) Analogous tissue sections from a BGC101-1 treated mouse. (**g**) Capillary density (average capillary count per field) in injured legs of mice treated with Vehicle Control, BGC101-1, and BGC101-3 ($P < 0.005$). (**h**) Capillary density in tissue sections from treated ischemic legs and from intact legs ($P < 0.005$)

Table 23.1 Per cent perfusion following treatment with EnEPCs originated from healthy and diabetic donors. Per cent Perfusion on Day 21 is presented in the Vehicle Control treated group (n = 12), the PBMC group (2.5×10^6 cells/mouse, n = 5, all from diabetic donor), and in the BGC101 treated groups BGC101-1 (cells from 1-day culture, 2.5×10^6 cells/mouse, n = 10, four from healthy donor and six from diabetic donor), BGC101-3 (cells from 3-day culture, 2.5×10^6 cells/mouse, n = 10, five from healthy donor and five from diabetic donor), and BGC101-31 (cells from 3-day culture, 0.5×10^6 cells/mouse, n = 5, all from diabetic donor) groups ($P < 0.0002$). Per cent Perfusion was calculated for all mice (All), as well as separately for mice that received cells from healthy (Healthy Donor) or diabetic (Diabetic Donor) donors

Group	Sub-group	%Perfusion Day 21	P Value Tested Group vs. Vehicle Control
Vehicle Control	All (n = 12)	35.1 ± 1.2	
PBMC	All (n = 5)	40.0 ± 4.4	$P = 0.167$
	Healthy donor (–)	–	
	Diabetic donor (n = 5)	40.0 ± 4.4	
BGC101-1	All (n = 10)	53.7 ± 2.7	$P < 0.0002$
	Healthy donor (n = 4)	56.8 ± 5.8	
	Diabetic donor (n = 6)	49.5 ± 2.1	
BGC101-3	All (n = 10)	47.7 ± 2.4	$P < 0.0002$
	Healthy donor (n = 5)	48.9 ± 4.1	
	Diabetic donor (n = 5)	46.4 ± 3.0	
BGC101-31	All (n = 5)	51.8 ± 4.0	$P < 0.0002$
	Healthy donor (–)	–	
	Diabetic donor (n = 5)	51.8 ± 4.0	

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Part III

Carotid

The Treatment of Carotid Disease Within Australia

24

Ramon L. Varcoe, Bernard M. Bourke, and C. Barry Beiles

Abbreviations

AIHW	Australian Institute of Health and Welfare
AVA	Australasian Vascular Audit
CAS	Carotid artery stenting
CEA	Carotid endarterectomy
CTA	Computed tomographic angiography
DSA	Digital subtraction angiography
ECST	European Carotid Stroke Trial
EEG	Electroencephalography
MRA	Magnetic resonance angiography
MVSA	Melbourne Vascular Surgical Association
NASCET	North American Symptomatic Carotid Endarterectomy Trial
OECD	Organisation for Economic Co-operation and Development
TIA	Transient ischaemic attack
TCD	Transcranial Doppler
TOF	Time-of-flight

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Introduction

Background

Stroke, or cerebral infarction places a significant burden on to Australian patients, their families, the healthcare system and aged-care services. Occlusive disease of the extra-cranial carotid artery is a leading cause of stroke and whilst its true incidence is unknown it is estimated that in 2009 approximately 375,000 Australians had experienced a stroke at some time in their lives.

In 2009–2010 there were 35,345 hospitalisations with a principal diagnosis of stroke and 15,704 for transient ischaemic attack (TIA). Those numbers had decreased over the 12 years prior to that by 15 % for men and 17 % for women, reflecting a reducing incidence of the disease. Those rates increase substantially with age to be highest in the over 85 year category. The gender distribution was evenly spread with 52 % of those hospitalisations for males. Forty-eight percent of hospitalisations were for ischaemic stroke, 29 % for haemorrhagic stroke with the remaining 23 % unspecified [1].

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In the year 2010 stroke was the underlying cause of just over 8300 deaths in Australia, which equates to 23 deaths every day, attributable to the condition. Those rates have also been falling steadily since 1979, with a 71 % reduction over the 32 year period up to 2011, likely due to advancements in acute stroke treatment [1].

Stroke represents approximately 4.5 % of the total burden of disease in Australia and accounts for $606 million or 0.5 % of the country's total healthcare expenditure (8 % of healthcare expenditure for all cardiovascular disease). Australia's age standardised stroke death rate was ranked eighth lowest of all OECD countries in 2008 [1].

The Contribution of Carotid Disease to Stroke

Approximately 20–30 % of ischaemic cerebral infarction result from atherosclerotic disease of either the intracranial or extracranial cerebral blood arteries. This may result from progressive stenosis causing an area of watershed ischaemia, or more commonly turbulence, plaque rupture and embolisation lodging in the terminal cerebral circulation. Around 30 % of all cerebral infarctions come from a cardio-embolic source and that proportion may be higher in young people [2]. Carotid artery stenosis or occlusion is thought to be associated with 11.5 % of ischaemic stroke [3].

The risk of stroke is thought to increase with the severity of stenosis, previous stroke or TIA, age, tobacco use and presence of diabetes. Strokes related to the carotid artery typically affect the brain in the territory of the anterior and middle cerebral arteries [2].

Carotid Imaging

There are a variety of methods of non-invasive detection and measurement of carotid artery stenosis. These include duplex ultrasound, computed tomographic (CTA) and magnetic resonance (MRA) angiography. However, the gold standard remains catheter-directed, digital subtraction angiography (DSA) which uses criteria based on two randomised symptomatic carotid trials published in 1991; the ECST (European Carotid Stroke Trial) and NASCET (North American Symptomatic Carotid Endarterectomy Trial) [4, 5]. DSA is invasive and carries a procedural stroke-risk of 0.5–1 % however it remains the standard by which all other investigations are judged.

Colour Duplex Ultrasound

Duplex ultrasound combines Doppler flow and B-mode imaging to give both anatomical and physiological information. It is relatively inexpensive, simple to perform, reliable and widely available in Australia. However, it is operator dependant and may occasionally be discordant with angiography. It has a sensitivity of 94 %, specificity of 83 %, is limited in its detection of proximal common carotid artery stenoses below the clavicle and may be unreliable in heavily calcified disease or slow flow situations.

CT Angiography

With the advent of multi-slice CT scanners CTA can be performed quickly and give excellent contrast based images of the arterial circulation from the heart to the circle of Willis. This has the advantage of complete arch anatomy assessment which may be beneficial if the patient is being considered for a carotid artery stenting procedure. It has therefore been widely adopted in Australian vascular centres.

A bolus of contrast is injected through a peripheral venous cannula without the requirement for aortic arch cannulation. This reduces the stroke risk seen with DSA. It is accurate in detecting trickle flow stenoses through diseased arterial segments. However CTA may be contraindicated in patients with significant renal impairment or contrast allergy and windowing techniques are required to remove calcium artefact which can obscure luminal flow.

MR Angiography

MR angiography can be performed using time-of-flight (TOF) technology or enhanced with intravenous gadolinium contrast. It gives physiological information with TOF able to determine flow rates and direction. It gives excellent images of the intracerebral circulation in addition to the supra-aortic branches and aortic arch anatomy. It is less affected by heavy calcification than CT, however it has a tendency to overestimate the degree and length of the stenosis. It is able to detect acute stroke with a high degree of sensitivity (diffusion weighted imaging) at the same time as assessing the arterial vasculature, which is a major advantage. It cannot be performed in patients who have a permanent pacemaker or incompatible stent and the experience may be challenging for those with claustrophobia. It has been less enthusiastically embraced by carotid specialists within Australia due to its relative cost and lack of reimbursement for the assessment of arterial disease in the private medical sector.

Digital Subtraction Angiography

Although catheter based DSA remains the gold standard in detecting carotid stenosis it is used infrequently due to the risks of local complications (6%), stroke or TIA (0.5–1%), combined with its invasive nature and cost. When they occur, neurological complications are often transient however a permanent deficit or even mortality remains a possibility. It is most commonly used as a method of adjudication when there is discordance between duplex ultrasound and CTA/MRA, which may influence the choice of treatment offered.

Carotid Endarterectomy

History and Development of Carotid Surgery in Australia

John Connell carried out the first CEA in Australia in 1957 at St Vincent's Hospital, Melbourne. He reported his early experience in the ANZ Journal of Surgery in 1958 [6]. While much of what was written in that article still holds true, there was more emphasis on the danger of thrombotic occlusion than plaque embolism, which is considered extremely important today. Carotid endarterectomy was also performed at St Vincent's Hospital in Sydney in the late 1950s by Justin Fleming and then Tom Nash who had benefited from vascular surgery training in London. In Brisbane the first carotid surgery was performed by Sam Mellick in the late 1950s at the Princess Alexandria Hospital under hypothermia conditions and Claude Mann also performed a number of CEA procedures at the Greenslopes Hospital. The St Vincent's unit in Sydney was expanded by the appointment of Reg Lord in 1969 who had received vascular training in CEA during fellowships in London and California. At Sydney's Royal Prince Alfred Hospital CEA was commenced in the late 1950s and early 1960s by John Lowenthal and then carried on by James May.

Michael DeBakey, the father of carotid surgery had an influence in Australia, training Victorian surgeons Donald McLeish, Peter Field, Peter Milne and Queensland surgeons Wally Foster and Gerald Lawrie. In 2000 Peter Field presented a personal series of 2000 carotid endarterectomies to the Australian & New Zealand Society for Vascular Surgery and was also instrumental in establishing Australia's place in major carotid endarterectomy and stenting trials being undertaken throughout the world at the turn of the century. Over that same period John Connell had become a proponent of the procedure being performed under local anaesthesia in association with Melbourne anaesthetist Michael Davis.

John Frawley, who had trained in Chelmsford England, performed carotid endarterectomy under deep thiopentone general anaesthesia, reporting excellent neurological outcomes in conjunction with his colleagues John Niesche and Laurie Gray at Prince of Wales Hospital in Sydney [7]. Sydney's Royal North Shore Hospital was strengthened in the late 1970s by the appointment of Michael Appleberg as its first dedicated vascular surgeon. Appleberg along with John Royle in Melbourne championed carotid endarterectomy, performing the procedure under general anaesthesia with routine shunting.

Bob Paton pioneered carotid and vertebral surgery in Western Australia in the mid to late 1980s and Perth surgeons Michael Lawrence-Brown and Marcel Goodman were early proponents of CEA performed under local anaesthesia.

Vascular surgery as a specialty took some years to define itself in South Australia. As a result the first carotid endarterectomy in that state was attributed to a neurosurgeon named Dinning. In the years that followed vascular surgeons Jepson, Harris and Justin Miller came to regularly perform CEA.

In 1996, Frydman et al. carried out a survey of the practice of carotid endarterectomy in Australia with the results published in the ANZ Journal of Surgery [8]. The survey demonstrated that the practice of CEA by Australian surgeons reflected the trends reported in earlier world literature with most performing CEA for both symptomatic and asymptomatic disease, and 40 % performing the procedure on the basis of duplex scanning alone.

In 2002, Middleton et al. conducted a study whereby they performed an independent and validated audit of CEA outcomes for Australia's largest state [9]. That study was unique for Australia in auditing both private and public hospitals where the performance of carotid surgery is evenly distributed. They found that 69 % of CEA patients were symptomatic and that 34 % were older than 75 years. Most procedures were performed by vascular surgeons (87 %), with a smaller number of neurosurgeons (9 %) and cardiothoracic surgeons (4 %) also performing CEA. They found that the majority of surgeons relied on duplex scanning alone before conducting CEA, perhaps illustrating the high quality of duplex scanning conducted within vascular-surgeon-run diagnostic ultrasound laboratories and the degree of confidence in the results obtained. The study came to the conclusion that Australian surgeons were achieving 30-day outcomes comparable with international standards of the time.

Australian Carotid Treatment Data

Carotid intervention rates have been estimated by an external analysis of data collected by the Australian Institute for Health and Welfare (AIHW) [10], the principal Australian health data manager. The AIHW collects procedures performed at all private and public hospitals and is the most complete data record kept. Procedure data cubes were used to construct Table 24.1

Table 24.1 Data from the Australian Institute of Health and Welfare showing total numbers of endarterectomy and carotid artery stents performed per financial year as a percentage of total population (population data derived from the Australian Bureau of Statistics)

Year	Conventional CEA	Eversion CEA	Total CEA	Population (million)	CEA/pop (%)	Total CAS
2000/2001	3415	249	3664	19.1	0.019	N/A
2001/2002	3564	244	3608	19.3	0.019	N/A
2002/2003	3218	224	3442	19.6	0.018	N/A
2003/2004	2942	203	3145	19.8	0.016	N/A
2004/2005	2754	205	2959	20.0	0.015	N/A
2005/2006	2576	196	2772	20.3	0.014	N/A
2006/2007	2437	167	2604	20.6	0.013	N/A
2007/2008	2449	193	2642	21.0	0.013	N/A
2008/2009	2376	200	2576	21.4	0.012	525
2009/2010	2515	237	2752	21.8	0.013	530
2010/2011	2409	230	2369	22.0	0.011	578
2011/2012	2337	231	2608	22.7	0.011	500
2012/2013	2405	210	2615	23.3	0.011	415

CAS Carotid artery stenting, *CEA* Carotid endarterectomy, *N/A* not available

which demonstrates the total number of carotid interventions for each financial year from 2000/2001–2012/2013. It is noteworthy that data for carotid artery stenting procedures has only been available since 2008 when it was allocated a specific operation code.

Population data sourced from the Australian Bureau of Statistics has also been tabulated by year as a reference denominator with which to calculate an incidence for CEA. From these data it is clear that there has been a significant reduction in the rates of carotid endarterectomy surgery, by 42 % over that 12-year period, despite a steady rise and ageing of the Australian population. This effect is likely to be multifactorial, however may be explained in part by the falling rates of CEA in asymptomatic patients.

The Australasian Vascular Audit and the Melbourne Vascular Surgical Association Audit

Between 1999 and 2009 carotid data has been prospectively collected by vascular surgeons in the second most populous Australian state of Victoria, under the auspices of the Melbourne Vascular Surgical Association (MVSA). In 2010 that database was superseded by the Australasian Vascular Audit (AVA), an online electronic database created and maintained by the Australian and New Zealand Society for Vascular Surgery [11, 12]. It is thought that the AVA collects approximately 70 % of the data collected by the AIHW as there remain a minority of non-participating surgeons and some private hospitals which do not take part in data collection. It is also unable to capture data from carotid procedures performed by operators who are not members of the Australia and New Zealand Society of Vascular Surgery.

Over that total 16-year period from 1999 to 2014 the mean age of those undergoing carotid revascularisation was 71.8 years, with a male to female ratio of 2.4–1. Vascular risk factors of ischaemic heart disease 50 %, diabetes 23.4 %, hypertension 85.6 %, and ex or current smoking history in 74.8 % were typical of this population with advanced atherosclerosis.

According to the AVA, between 2010 and 2014 there were 10,778 carotid endarterectomies performed within Australasia. In addition there were another 31 open carotid procedures performed to treat subclavian steal syndrome, carotid dissection or an infected carotid patch. Those carotid endarterectomies were performed by 222 surgeons who averaged 49 CEA (range 1–238) operations each over that 5-year period. If the MVSA and AVA datasets are combined over a total of 16 years the number of CEA recorded is 15,029 and it was observed that the proportion of CEA operations performed in asymptomatic patients dropped significantly from 38 to 30 % ($p<0.001$). This may reflect the perceived improvements in medical therapies, particularly with the common use of lipid lowering therapy and anti-hypertensive medication.

Indications

The most frequent indication for CEA was TIA, with 38 % of operations performed for that indication. The remaining indications are presented in Fig. 24.1. It is noteworthy that only 29 % of patients treated with CEA were asymptomatic.

Surgical Technique

The majority of CEA (86 %) were performed utilising a longitudinal arteriotomy, followed by endarterectomy (with or without shunt) and patch or primary closure. 1529/10,778 (14 %) of CEAs were performed using the eversion technique which entails an oblique transection of the ICA from the carotid bulb opposite the ECA origin. The ICA is then fully everted over the plaque until the end point has been reached. Usually the intima of the distal CCA is cut with a scalpel blade to allow an endarterectomy plane to be developed, which in turn facilitates endarterectomy of the distal CCA and also eversion endarterectomy of the ECA for a further 2–4 cm. This technique found particular favour in Australia

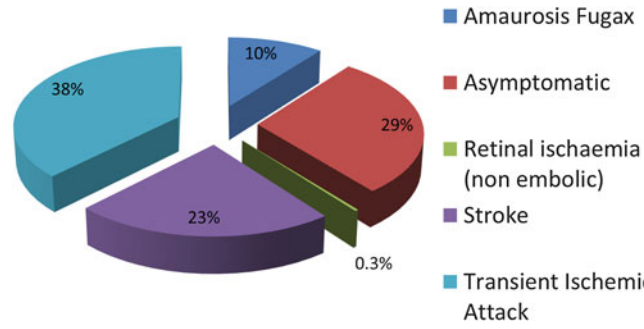

Fig. 24.1 Indications for carotid endarterectomy (data derived from the Australasian Vascular Audit)

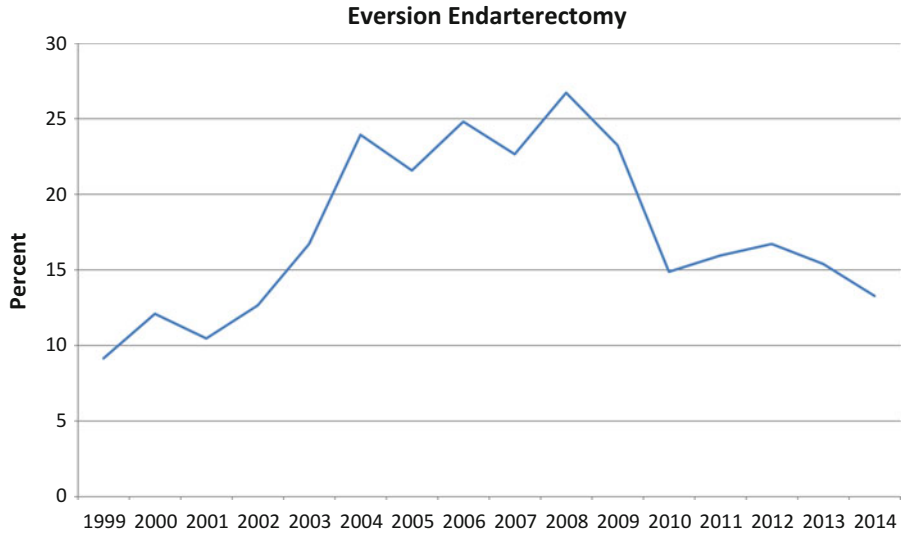

Fig. 24.2 Carotid eversion endarterectomy rates by year (data derived from the combined Melbourne Vascular Surgical Association and Australasian Vascular Audits)

during the decade between 2000 and 2010, when at times it made up more than 25 % of total endarterectomies (Fig. 24.2).

Patching

Patches were used to facilitate arteriotomy closure and assuage restenosis in 92 % of all non-eversion CEA over the 5-year AVA period. The most common patch materials were polyurethane (4044/9014; 49 %) and Dacron (2385/9014; 26 %) however there were a wide variety used across the sample. A full list of patch types can be found in Table 24.2.

Table 24.2 Patch materials used during non-eversion carotid endarterectomy (data derived from the Australasian Vascular Audit between 2010 and 2014)

Patch	Total
Dacron	2385
External carotid artery	16
Great saphenous vein-non reversed	6
Great saphenous vein	413
Homograft	1
Neck vein	46
Omniflow	4
Pericardium	1315
Polyurethane	4044
Prosthetic (other)	254
Poly-tetra-fluoroethylene	498
Small saphenous vein	1

Anaesthesia Technique

Both general anaesthesia and loco-regional block are used extensively throughout Australia with techniques favoured by certain institutions and regions. General anaesthesia was used in the majority of CEA (78 %) patients between 2010 and 2014. Light sedation is commonly used in conjunction with loco-regional block, with the patients' conscious state maintained to monitor cerebral function through voice prompts and contralateral upper limb motor function. Invasive blood pressure monitoring is frequently employed with clear blood pressure targets adopted by most surgical units.

Cerebral Protection

A number of methods are used to protect the brain from hypoperfusion injury during arterial clamping. Certain centres favour the use of routine shunting, commonly with the Javid (Bard) or Pruitt-Inahara (LeMaitre Vascular) devices. Others selectively apply shunting techniques based on stump pressures, visual back bleeding estimates or preoperative imaging assessment of the circle of Willis and contralateral-carotid/vertebral circulation. Rates of shunting have been relatively stable over the last 16 years, being used in approximately 50 % of all CEA procedures (Fig. 24.3). Routinely, proponents of CEA under loco-regional block will employ the use of selective shunting to protect the brain in cases of clamp intolerance or intraprocedural neurological deterioration.

The historical methods of hypothermia and deep thiopentone general anaesthesia are no longer routinely used in Australia.

Cerebral Monitoring

Cerebral monitoring is selectively employed to avoid the use of shunts by some. Those proponents seek to avoid the small but undeniable morbidity associated with the use of those devices. Electroencephalography (EEG) is a recognised method of determining cerebral ischaemia and is used to determine the need for shunting in the patient under general anaesthesia. Transcranial Doppler (TCD) is an alternative method used to determine the burden of microembolic signals both during carotid surgery and

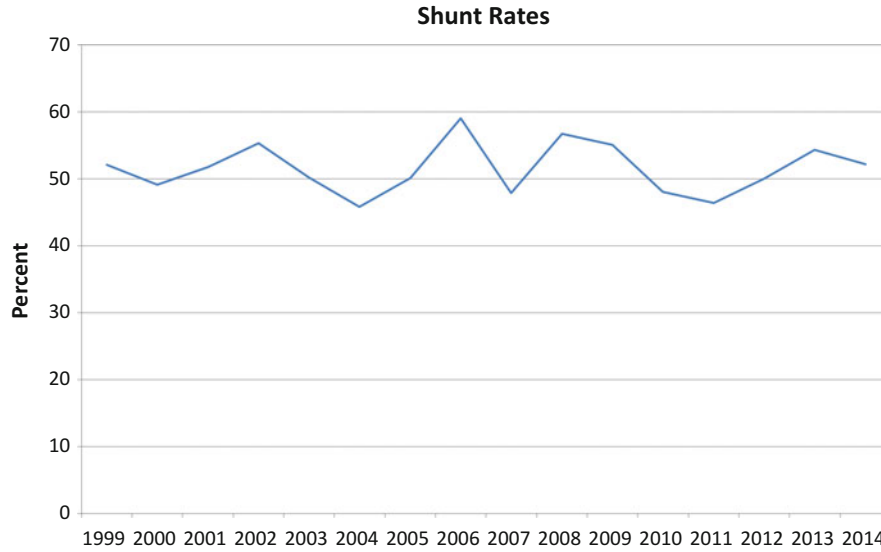

Fig. 24.3 Rates of shunting in Australia in non-eversion carotid endarterectomy by year (data derived from the combined Melbourne Vascular Surgical Association and Australasian Vascular Audits)

in the immediate post-operative period [13]. The frequency of those signals is sometimes used to tailor the pharmaceutical regimen to protect from embolisation.

Adjunctive Pharmaceutical Regimen

Intra-Operative

It is commonplace within Australia for most surgeons to utilise a single antiplatelet agent such as aspirin or clopidogrel preoperatively and throughout the short and mid-term post-operative periods, if not for life. Dual antiplatelet therapy is avoided by most due to the higher incidence of neck haematoma but does not preclude one from performing carotid endarterectomy where necessary.

Intraoperative heparinisation is utilised prior to clamping the carotid artery. The dose is variable with some operators using a single standard dose and others titrating to body weight at a dose that ranges between 70 and 100 IU/Kg. Other operators will monitor their dose based on activated clotting time and titrate accordingly.

Perioperative Dextran 40 has been used by a number of surgeons due to its antithrombotic and antiplatelet effects, shown to reduce microembolic signals on TCD during and immediately after CEA [14]. Michael Appleberg at the Royal North Shore Hospital in Sydney was a proponent, using it as early as 1977, and a number of other vascular surgeons have been using it concurrently for many years. Recently supply has become more challenging and the "special access scheme" process must be completed through the Therapeutics Goods Administration for its use. Rarely, anaphylaxis has been described, however this can be prevented with a single administration of Dextran 1 immediately prior to commencing the Dextran 40 infusion, some hours prior to the CEA.

Pre- and Post-operative

The medical management of atherosclerosis once significant disease of the carotid has been established is fastidiously managed in Australia. Lipid lowering medication is liberally and aggressively employed with statins being the favoured class of agent. Blood pressure lowering medications are utilised to bring each patient into a normotensive range and diabetes is meticulously controlled in conjunction with endocrinology colleagues. There is a focus on smoking cessation with nicotine replacement therapy, hypnosis and newer smoking cessation therapies such as varenicline.

Complications After Carotid Endarterectomy

Complications after carotid endarterectomy in Australia are rare. Any-stroke or death rates are reported at 1.7 % (262/15,029) over the 16-year period of the MVSA and AVA. The 30 day mortality was 0.6 % (96/15,029). Any-stroke (major or minor) rate was 1.3 % (200/15,029) with 34 of those patients eventually succumbing after suffering a stroke. Post-operative myocardial infarction 1.1 % (170/15,029), cerebral hyperperfusion syndrome 0.1 % (19/15,029), cranial nerve injury 0.5 % (68/15,029) and reoperation for haemorrhage in the neck incision 2.6 % (390/15,029) were also extremely uncommon. A full list of complications from the two datasets is presented in Table 24.3.

Training

In Australia vascular surgeons undergo at least 5 years of formal specialist training in vascular surgery. This includes both open and endovascu-

Table 24.3 Complications reported after carotid endarterectomy (data derived from the combined MVSA and Australasian Vascular Audits 1999–2014)

Complication	%
Haemorrhage requiring exploration	2.5
Cranial nerve trauma	1.1
Myocardial infarction	0.9
Major or minor stroke	1.4
Transient ischaemic attack	0.5
Hyperperfusion	0.2
Death	0.5
Any stroke or death	1.7

lar surgical skills whilst working on specialty units in 12 month rotations. Trainees are required to spend at least 1 year interstate or abroad.

Logbooks are kept with number requirements related to carotid endarterectomy surgery. Carotid stenting has no formalised minimum requirement by the vascular training program however there is an external body that accredits performance in carotid stenting based on minimum numbers of 25 CAS and satisfactory referee reports. That Conjoint Committee of Peripheral Endovascular Training encompasses representatives from the Royal Australasian colleges of Surgery, Radiology and Physicians.

The exit examination in vascular surgery takes place during the trainees' final year and includes a large component of carotid pathology, imaging, interventional and medical management.

Carotid Stenting

History

Carotid artery stenting (CAS) is an endovascular alternative to carotid endarterectomy surgery which began its development in the late 90s and early 2000s in Australia. Most of the initial enthusiasm came from a desire for a less invasive alternative to open surgery and CAS was proving to be a reasonable choice in the early world literature of the time. The technique was embraced in many centres by cardiology colleagues whose catheter and wire skills, in combination with their familiarity with the 0.014-in. platform made them well suited to perform the procedure. Many vascular surgeons teamed up with cardiologists to perform these procedures, whilst others worked alongside interventional radiologists and a number also worked alone.

Results from the SAPPHIRE trial in 2004 showed equivalence between CAS and CEA with regard to stroke and death rates in high risk patients, with lower rates of perioperative myocardial demonstrated in the endovascular arm [15]. This accelerated the adoption of the technique with many endovascular surgeons adopting this new procedure, in some cases pushing the boundaries of anatomical limitation.

Table 24.4 Types of cerebral protection devices used in Australia over the period 2010–2014 (data retrieved from the Australasian Vascular Audit)

Filter	Total
Accunet (Abbott Vascular)	5
Angioguard (Cordis)	231
Emboshield (Abbott Vascular)	203
Filterwire EX (Boston Scientific)	126
Flow Reversal (Medtronic)	18
Nav 6 (Abbott Vascular)	250
Neuroshield (MedNova)	3
SpiderFX (Covidien)	3
Trap (Microvena)	2
None	23

Training workshops were common and live case demonstrations were frequently employed out of centres such as the Epworth Hospital in Melbourne and the International Endovascular Symposium in Sydney, which Geoff White ran between 1997 and 2006. A Medicare item number and reimbursement code became available for the technique in 2008 opening the door for widespread application of the technique.

According to the AIHW annual numbers of CAS procedures peaked in 2010/2011 at 578/year and since that time those numbers have been in decline (Table 24.1).

Indication

The majority of carotid artery stenting procedures are performed in symptomatic patients with treatment indications visually represented in Fig. 24.4. Forty-two percent were for asymptomatic, high-grade stenoses, a figure slightly greater than for CEA over that same period.

CAS has been used in preference to carotid endarterectomy for a variety of indications that would make CEA less favourable due to higher risk. Such indications include the hostile neck with previous open surgery, neck dissection or radiotherapy, contralateral carotid occlusion, high carotid bifurcation or the short, bull neck. In this context, Beiles performed an instructive study in

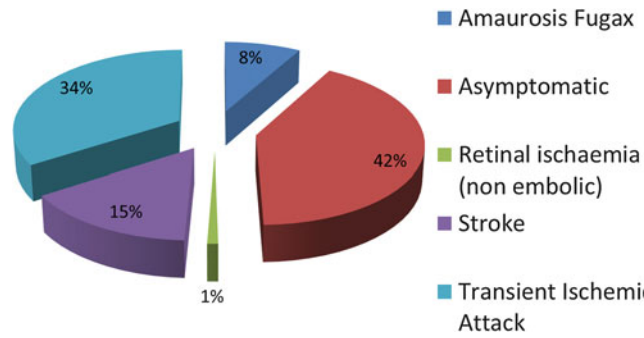

Fig. 24.4 Indications for carotid artery stenting (data derived from the Australasian Vascular Audit)

2003 which demonstrated a negative correlation between the length of the ICA plaque and the height of the carotid bifurcation [16]. Certain medical comorbidities may also increase patient risk for perioperative complication following CEA and are therefore also used as an indication for CAS.

Cerebral Protection Methods

Most Australian interventionalists performing CAS are likely to use some form of cerebral protection (97.3 %). Distal-filter cerebral protection devices are by far the most commonly used (97.9 %), with very few proximal, flow-reversal devices (2.1 %).

Stent Types

A wide variety of stent devices are used. The majority are dedicated carotid stents on 0.014-in. platforms. There seems to be no preference for open versus closed cell configurations or any particular manufacturer according to numbers used (Table 24.5). Angioplasty without stenting was performed only rarely in 0.2 %.

Table 24.5 Types of carotid stent devices used in Australia over the period 2010–2014 (data retrieved from the Australasian Vascular Audit)

Stent	Total
Acculink (Abbott Vascular)	33
ADAPT (Boston Scientific)	4
Medtronic Cristallo Ideale (Medtronic)	25
Precise (Cordis)	258
Protege RX (Covidien)	9
Smart (Cordis)	11
Tapered (Any)	18
Wallstent (Boston Scientific)	101
Xact (Abbott Vascular)	403
Angioplasty only	2

Adjunctive Pharmaceutical Regimen

Intra-Operative

Routinely CAS in Australia is performed after the patient is preloaded with the dual antiplatelet agents of aspirin and clopidogrel. Most practitioners would target 5–7 days of preoperative therapy to achieve maximal antiplatelet activity however an initial loading dose the day prior to the procedure has been considered acceptable in the past. This would usually take the form of a single dose of 300 mg of clopidogrel and 600 mg of aspirin, both of which would then continue at a standard daily dose of 75 mg and 100 respectively. Patients who are already anticoagulated for other indications would normally be commenced on a single antiplatelet agent in addition to warfarin (or new oral anticoagulation therapy).

Intravenous heparin is administered routinely during the procedure once femoral artery access has been achieved. Most interventionalists would use a dose between 70 and 100 IU/Kg and aim for an activated clotting time of 300 s.

Post-Operative

The length of post-operative antiplatelet therapy will vary between individual practitioners and vascular units. Most would recommend a minimum of 6 weeks of dual antiplatelet therapy or anticoagulation with the addition of a single

antiplatelet agent. Some would extend this indication out to 6 months, or even lifelong if it was being tolerated without side-effects.

Local Results

Results from the Australasian Vascular Audit found that between 2010 and 2014 there were nine strokes and six deaths following 864 reported CAS. Two of those deaths were patients who had had a stroke from the procedure, giving a death/any-stroke rate of 1.7 %. A further 15 patients had a post-operative TIA (1.7 %), one had a myocardial infarction (0.1 %), there were four arrhythmias (0.5 %) and four episodes of significant renal impairment (0.5 %).

Staged Carotid Artery Stenting Followed by Coronary Artery Bypass Grafting

At St Vincent's Hospital in Sydney a study was published in 2006 describing their approach to preoperative carotid artery stenting in concomitant severe carotid artery and coronary artery stenotic disease [17]. In mostly asymptomatic patients 26 carotid arteries were stented at a mean interval of 69.6 days prior to staged coronary bypass. They saw one minor stroke and one myocardial infarction in their cohort, concluding that this method was a viable way to approach coexistent carotid and coronary atherosclerosis.

Carotid Artery Stenting Using Adjunctive Ultrasound to Minimise Contrast Use

At Sydney's Prince of Wales Hospital a randomised controlled trial was conducted in 2012 that explored the use of duplex ultrasound to guide the carotid stenting procedure, thus reducing reliance on angiography and reducing contrast load [18]. They randomised 23 carotid stenting procedures to adjunctive Ultrasound or standard CAS and saw no deaths, stroke or major adverse cardiac events. They demonstrated a reduction in contrast use by 61 % and the number of selective cerebral injections by 49 % with no increase in time taken to perform the procedure.

Guidelines

In 2010 a committee representing the Royal Australasian Colleges of Surgery, Radiology and Physicians published guidelines for patient selection and performance of carotid artery stenting [19]. Released just 1 month before the largest and most rigourous randomised trial ever to compare carotid stenting with endarterectomy [20] these guidelines concluded that based on the evidence of the time carotid endarterectomy remained the gold standard for the majority of patients and recommended that CAS be reserved for those with severe carotid stenosis technically unsuitable for CEA or those who were medically unfit. They recommended that as further randomised controlled trial data were to become available it would be prudent to make revision to those guidelines, however those revisions have not eventuated.

Conclusion

The Australian discipline of vascular surgery developed at an early stage on the international timeline. The development of that sub-speciality facilitated a fundamental interest in the treatment of extra-cranial carotid atherosclerosis and that group participated in many of the early carotid surgery trials. The current landscape encompasses an aggressive approach to both primary and secondary prevention with a focus on medical and surgical/interventional treatment. Australian vascular surgeons who report their results to the AVA are technically skilled and able to achieve standards comparable to international benchmarks for both CEA and CAS.

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Treatment of Carotid Disease in North America

25

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Background and Incidence

Strokes are the third leading cause of death in the United States and remain a significant burden on the health care system, with over 795,000 strokes leading to 140,000 deaths every year [1]. As such, stroke prevention is the goal for physicians from medical and surgical specialties alike. NASCET and ACAS were two landmark randomized control trials that helped establish the guidelines for when carotid revascularization, in addition to best medical therapy, should be implemented [2, 3]. These guidelines have since been challenged by critics who state that BMT, especially for asymptomatic carotid artery stenosis, has improved since the original trials. BMT for carotid stenosis aims to reduce the modifiable risk factors that can lead to atherosclerosis and its complications. This includes control of hypertension, diabetes mellitus, smoking cessation, and weight loss. In patients with ischemic strokes, antithrombotic therapy with aspirin, aspirin and extended-release dipyridamole, or clopidogrel is recommended to reduce risk of cerebrovascular or cardiovascular events. In addition, BMT has evolved to include statin therapy with a goal of LDL <100 mg/dL in patients with atherosclerotic disease affecting one vascular system and LDL <70 mg/dL in high risk patients with involvement of multiple vascular beds [4].

A 20-year review of Medicare data (1988–2008) for patients with diagnoses of ischemic or hemorrhagic strokes demonstrated significant decreases in incidence of first stroke [5]. In particular, rates of ischemic strokes decreased from 927 per 100,000 patients in 1988 to 545 per 100,000 patients in 2008 (Fig. 25.1). This decrease has been attributed to improved BMT, in particular, the use of statins that has been suggested to stabilize atherosclerotic plaque, decreasing its risk of core rupture, and subsequent embolic events. Over the studied period, the use of antihypertensive and antiplatelet medications saw a steady increase while statin use markedly increased after 1996 (Fig. 25.2).

Carotid revascularization, particularly CAS, has also seen significant improvement in the past two decades with contemporary trials reporting stroke and complication rates significantly lower than those reported in NASCET or ACAS. The peri-procedural stroke and death rates in CREST were 2.3 % for CEA and 4.4 % for CAS compared to the 6.5 % rate in NASCET and 5.1 % rate in ACAS [2, 3, 6]. With improvements in both carotid revascularization and BMT, a multidisciplinary team has put together the CREST-2 trial with an objective to determine: (1) if intensive BMT alone is different from CAS with BMT and (2) to determine if intensive BMT alone is

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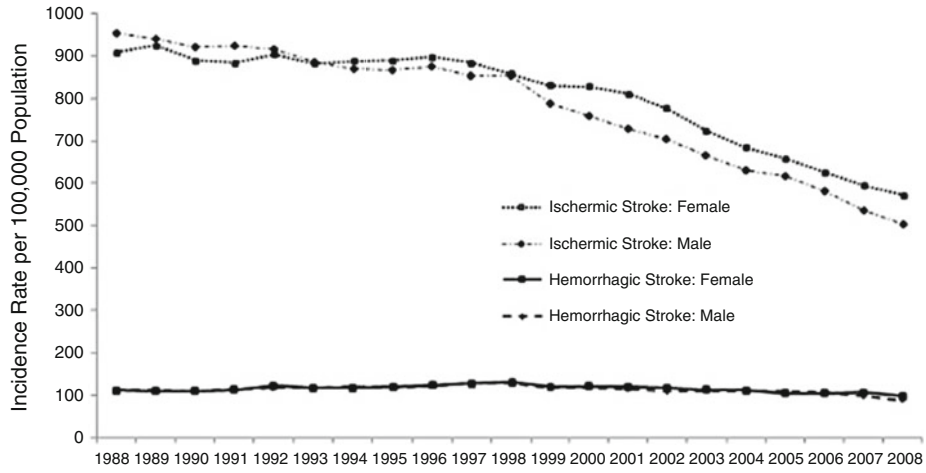

Fig. 25.1 Age-adjusted incidence of ischemic and hemorrhagic stroke in the US Medicare population from 1988 to 2008. Adapted from Fang et al. [5]

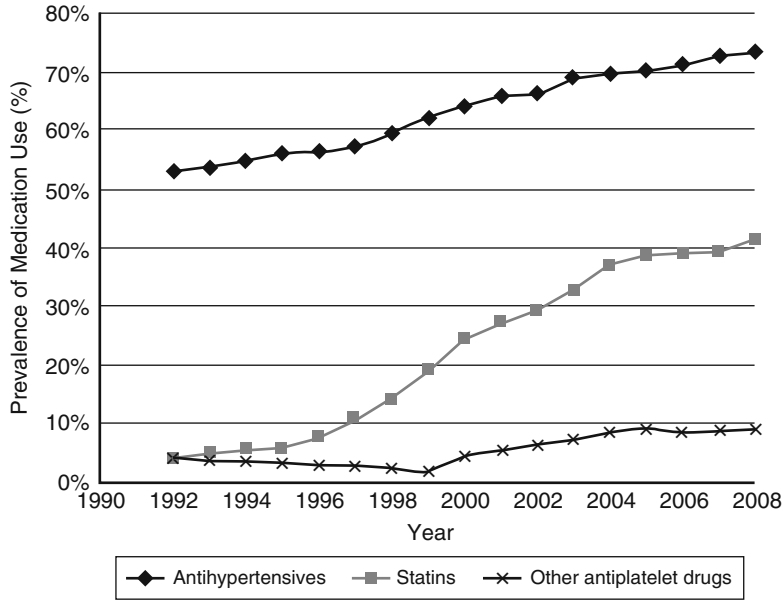

Fig. 25.2 Prevalence of medications used to prevent stroke among 138,821 participants aged ≥65 years in the MCBS (1992–2008). Adapted from Fang et al. [5]

different from CEA with BMT. The trial is currently in its enrollment phase, recruiting patients with asymptomatic carotid artery stenosis ≥70 % on duplex ultrasound and will add valuable data to determine optimal management of patients with extracranial carotid disease.

Diagnostic Evaluation and Imaging

The goal of diagnostic imaging in carotid artery stenosis is to determine the degree of stenosis of the internal carotid artery (typically reported in

percentage of lumen diameter) and characterize the plaque morphology to identify patients who are at high risk of developing a stroke. Carotid artery imaging is currently recommended in patients who have symptoms consistent with carotid territory ischemia. Routine screening of asymptomatic patients is not recommended, but should be selectively considered in patients with multiple risk factors such as smoking, age >65 years, hyperlipidemia, and atherosclerosis of other vascular beds including peripheral and coronary artery disease [4].

Duplex Ultrasound: Carotid duplex ultrasonography is the recommended imaging modality of choice for both symptomatic and asymptomatic patients as it is a non-invasive test with high sensitivity and specificity. The diagnostic criteria was established by the Society of Radiologists in Ultrasound and correlates a peak systolic velocity (PSV) ≥230 cm/s with a ≥70 % stenosis (sensitivity 99 %, specificity 85 %) and PSV of 125–230 cm/s with a stenosis of 50–69 % (sensitivity 93 %, specificity 68 %) [7]. Some authors have advocated for adjustments of these criteria, stating that utilizing a PSV range of 140–230 cm/s yields improved diagnosing of 50–69 % ICA stenosis (sensitivity 94 %, specificity 92 %) [8].

In addition to velocity measurements, duplex ultrasound can characterize the echogenicity of the plaque. While plaque morphology has yet to be correlated to stroke risk, some authors advocate the gray-scale median (GSM) measurement that provides a numerical value to the overall echogenicity of the plaque. Following the Imaging in Carotid Angioplasty and Risk of Stroke (ICAROS) study from Italy, a few studies in the United States have also correlated that symptomatic plaques are more echogenic with lower GSM scores [9, 10]. A study evaluating preoperative GSM scores in patients undergoing carotid stenting demonstrated increased embolic potential for plaques with GSM <20 [11].

Cross-Sectional Imaging: Both CTA and MRA have comparable sensitivity and specificity for diagnosing carotid artery stenosis to duplex ultrasound. MRA has been criticized as having a greater tendency to overestimate degree of carotid stenosis whereas large calcium burden can limit the imaging on CTA. While MRA and CTA are not recommended for use in initial screening of patients, they can be helpful in confirming the presence of carotid artery stenosis in equivocal or non-diagnostic duplex ultrasound exams [12].

MRA has also been used with increasing frequency for characterization of carotid plaques. Improved protocols utilizing 3-T high resolution magnetic resonance sequences can provide information on lipid core, intraplaque hemorrhage, fibrous cap rupture, and gadolinium enhancement, which can help identify features associated with plaque vulnerability [13].

Digital Subtraction Angiography: Many physicians still consider catheter-based angiography to be the gold standard for evaluation of carotid artery stenosis. Due to its invasive nature with an associated cerebrovascular incident rate of 1–2 %, however, catheter-based angiography is reserved for patients with conflicting preoperative imaging studies or patients being evaluated for carotid artery stenting [12].

Carotid Revascularization

The Society for Vascular Surgery (SVS) and the American Heart Association (AHA) both released guidelines for the treatment of carotid stenosis [1, 12]. While largely similar, there exist some differences between the recommendations, particularly in regards to the role of carotid artery stenting. Both societies recommend against carotid revascularization for lesions with stenosis <50 %.

Indications and Considerations for Carotid Endarterectomy: For patients who experience a non-disabling stroke or transient ischemic attack (TIA) who have a stenosis of more than 70 %, both SVS and AHA advocate intervention with carotid endarterectomy (CEA). In symptomatic patients with 50–69 % stenosis, carotid revascularization with CEA should still be performed with consideration for the patients' age,

risk factors, and severity of symptoms. For asymptomatic patients, the SVS and AHA both recommend revascularization with CEA for stenosis ≥60 % if a perioperative stroke and death rate of below 3 % can be accomplished [1, 12]. Many surgeons, however, will only perform carotid revascularization for lesions resulting in >70 or 80 % stenosis.

Contraindications to CEA include an anatomically hostile neck that is significantly scarred following prior surgery, trauma or external radiation treatment. The risk of nerve damage is significantly increased in these patients due to the loss of dissection planes leading to considerable difficulty in carotid exposure. Patients with high lesion locations at or above the C2 cervical vertebra can also provide significant challenges during CEA. While certain measures including nasotracheal intubation, division of the digastric muscle, and subluxation of the mandible can be performed to optimize access to a high carotid lesion, the risks that these adjuncts can pose must be weighed against the benefits of the procedure. Relative contraindications include high risk patients with significant cardiac and/or pulmonary disease.

CEA can be performed with comparable outcomes under general anesthesia, regional anesthesia, or local anesthesia based on patient selection and surgeon preference. Both conventional and eversion endarterectomy has been described with equivalent outcomes, though some studies have suggested a higher incidence of postoperative hypertension in patients undergoing eversion endarterectomy [14]. For patients undergoing conventional endarterectomy, carotid reconstruction with patch angioplasty is associated with lower rates of restenosis outcomes compared to primary closure [15]. A variety of patch choices are available including autologous vein, bovine pericardium, Dacron, and polytetrafluoroethylene (PTFE).

Neurologic deterioration upon cross-clamping of the internal carotid artery is an absolute indication for shunting during CEA performed under regional anesthesia. The neurologic status is easy to evaluate in an awake patient undergoing CEA, but for those under general anesthesia, identifying patients who cannot tolerate carotid ischemia is critical to avoiding periprocedural strokes. Some surgeons advocate the measuring of back pressures following clamping of the common carotid (CCA) and external carotid (ECA) arteries. An arterial tracing with pressures >50 mmHg has been suggested to be evidence of adequate collateral circulation to the brain. Others have advocated monitoring with intraoperative neurooximeters and/or EEG with drops in O_2 saturation or dampening of the EEG waveforms, respectively, to determine which patients to selectively shunt. Finally, some physicians routinely shunt every patient to eliminate the need to determine who can tolerate carotid clamping. Other relative indications for shunting include contralateral occlusion and/or recent stroke.

CEA is an effective, safe, and durable procedure with excellent long-term results. For patients undergoing CEA following a prior stroke, the annual risk for another stroke was 6.2 % versus 2.8 % for those with TIAs, and 0.6 % for asymptomatic patients [16]. Rates of recurrent restenosis vary per studies and ranges from 3 to 25 %. Some have argued that this may be due to limitations in the current duplex criteria for postoperative carotid evaluation. The majority of restenotic lesions occur within 2 years following the procedure secondary to intimal hyperplasia. As opposed to atherosclerotic plaques, stenosis due to intimal hyperplasia is rarely symptomatic and the indications for re-intervention remain unclear. Many physicians will defer intervention in asymptomatic patients until the stenosis becomes >80 %.

Indications and Considerations for Carotid Stenting: The AHA guidelines recommend CAS as an alternative to CEA in patients with symptomatic, >70 % ICA stenosis with anatomic challenges or high risk medical conditions. While somewhat similar, the SVS guidelines recommend CEA as the first line treatment for carotid revascularization, with CAS only performed for patients who are not suitable for CEA due to increased cardiac or anatomic risk. For asymptomatic patients, the AHA suggests that prophylactic CAS may be considered in carefully

selected patients with >60 % stenosis by angiography or >70 % by Doppler ultrasound. In contrast, the SVS does not support CAS in asymptomatic patients except in centers with low, <3 % periprocedural stroke and death rates. A post-hoc analysis of the CREST trial demonstrated that CAS in octogenarians leads to inferior results with significantly higher risk of post-procedural cerebrovascular events [6]. This has been attributed to significant atherosclerotic disease in the aortic arch more susceptible to embolization during carotid catheterization and as such, CAS in older patients is not recommended.

Pre-procedural evaluation for CAS involves examination of the vessels that need to be navigated to deliver the sheath, balloons, stents, and the distal protection device. Significant disease in the femoral vessels may limit the ability to use larger devices or flow cessation/reversal devices that often require larger introducer sheaths. Type II and III aortic arches can pose a challenge for cannulation of the carotid as it must traverse more turns to reach its destination. Significant calcification and disease along the aortic arch increase the risk for embolic debris generation during catheter manipulation for cannulation of the carotid. Severe stenosis or occlusion of the external carotid artery can prevent the use of flow reversal devices that rely on external carotid occlusion.

The procedure is generally performed in an awake patient through the common femoral artery. Following a diagnostic arch aortogram, the appropriate carotid artery is selected. Multiview diagnostic carotid and cerebral angiograms are performed to determine patient's baseline. We advocate the placement of a long shuttle sheath into the proximal common carotid artery over a stiff wire to provide a stable system during the stenting procedure. A distal embolic protection device is placed. If a filter wire is used, the ICA lesion is carefully crossed using a .014 in. wire and the filter is deployed in a straight segment of the distal ICA. We routinely perform pre-dilation of the lesion with a non-compliant balloon prior to stenting. A closed-cell stent is most commonly utilized, though for very tortuous carotid arteries, a more flexible open-cell stent can be considered. A diagnostic angiogram is performed to demonstrate proper opening of the stent and resolution of the stenosis. Selective post-dilatation is performed for stents with residual stenosis >30 %. The filter is checked for filling defects, then recaptured into its delivery sheath and removed.

If a flow reversal system is used, the femoral sheath is upsized to the appropriate introducer sheath. The flow reversal system is advanced over stiff wire, with the distal balloon tracking into the external carotid artery. The lesion is crossed with a .014 in. wire. The CCA and ECA balloons are inflated and a diagnostic angiogram performed to demonstrate flow cessation/reversal. The carotid lesion is then expeditiously predilated, stented, and post-dilated. Approximately 60 cc of stagnant blood from the carotid is aspirated and discarded. The ECA followed by CCA balloons are released to re-establish cerebral perfusion.

Of the trials evaluating results following extracranial carotid intervention, CREST is the most recent large, multicenter prospective trial that evaluated the two modalities of carotid revascularization by randomizing 2502 symptomatic and asymptomatic patients with carotid stenosis to CAS or CEA [6]. The study reported favorable outcomes following CAS. Both CAS and CEA resulted in comparable outcomes with 30-day stroke rate, death, and MI of 7.2 % versus 6.8 %, respectively (p = NS). At 4 years, the primary endpoint was 5.6 % with CAS versus 4.9 % with CEA in asymptomatic patients (p = NS) and 8.6 % with CAS versus 8.4 % with CEA in symptomatic patients (p = NS).

Trends and Future of Carotid Revascularization

A recently conducted retrospective study on the trends and outcomes of carotid revascularization using data from the Nationwide Inpatient Sample (NIS) database from 2001 to 2010 demonstrated that the total number of carotid procedures decreased by 34 % from 737 procedures per million adults in 2001 to 483 procedures per million adults in 2010 (Fig. 25.3) [17]. While carotid endarterectomy (CEA) remained the

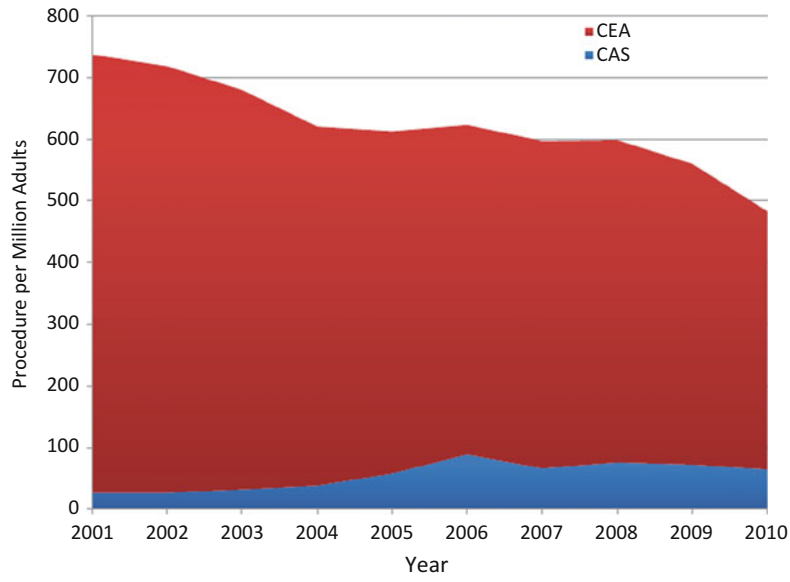

Fig. 25.3 Revascularization procedure rates of carotid artery stenting (CAS) and carotid endarterectomy (CEA) per million adults per year between 2001 and 2010. Adapted from Kim et al. [17]

gold standard, comprising the majority of all performed procedures, the overall number of CEAs performed decreased over this time while carotid artery stenting numbers continued to increase. The authors reported that 52,416 fewer CEA surgeries and 9621 more CAS procedures were performed in 2010 versus 2001. Another study evaluated patients registered in the Premier Perspective database undergoing CEA and CAS between 2006 and 2013 [18]. While the number of CEA performed remained constant through this study period, a marked increase in the overall number of CAS procedures were noted following the publication of the CREST trial in 2010.

The evolving trends in carotid revascularization are evidence that more data is needed to determine optimal treatment of carotid artery stenosis. Improving imaging modalities and characterization of high risk plaque may better identify which patients are in need of operative intervention. New pharmacotherapy has allowed BMT to become more effective in stroke reduction. CEA remains a durable and safe operation. And CAS continues its evolution with improving physician familiarity and skill, better embolic protection devices, and new technology that aims to bypass suboptimal access and arch anatomy. The results from the CREST-2 trial should help establish guidelines that will assist in identifying patients who will benefit from carotid revascularization as well as selecting the procedure that would most benefit the patient.

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Carotid Disease in Brazil

26

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Epidemiology and Natural History of Disease

In recent decades, Brazil has been changing its morbidity and mortality profile, with chronic diseases leading among the major causes of death. Among the most important chronic disease is stroke, which is a major cause of hospitalization and mortality, causing disability, whether partial or complete, in the vast majority of patients [1]. Cerebrovascular diseases recorded 160,621 hospitalizations in 2009, according to data in the public domain of the Unified Health System (DATASUS), Health Ministry, Brazil. The mortality rate was 51.8 every group of 100,000 inhabitants. The group above 80 years accounted for nearly 35 % of 99,174 deaths [1]. According to Lessa et al., around 250,000 strokes occur each year in Brazil, and 85 % have ischemic etiology [2].

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Cerebrovascular extracranial disease is one of important causes of death and disability not only in Brazil but worldwide. It is the leading cause of death in Brazil. While it is observed that in the United States of America the number of deaths from cerebrovascular diseases is under constant decline, in Brazil from 1996 to 2012, mortality showed a steady increase which exceeded 100,000 deaths in 2012. It is corresponding to about one death every 5 min in the same year. Moreover Brazilian data show an increased risk of stroke in women, although deaths due to stroke are more common in men (Available in http://www2.datasus.gov.br/DATASUS/index.php?area=02. Accessed 25 July 2015).

In the United Kingdom, about 12 % of all deaths are caused by stroke, consuming 4 % of gross national product with treatment and care of these patients. In the United States of America, there are around 730,000 cases of stroke per year, with the frightening rate of 20 % of deaths in 30 days and about 50 % of the survivors need special care, burdening the health care system. The direct and indirect costs are estimated at US$30 billion/year. All these alarming statistics show us the real need for a national public policy aimed at prevention and treatment.

Asymptomatic critical carotid lesions can be divided into: (1) pre-occlusive injury with hemodynamic compromise and (2) ulcerated/irregular lesions with increased risks of embolization, independent if they cause hemodynamic changes or not. These asymptomatic lesions are the potential

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cause of futures strokes and can be identified with noninvasive tests. But the natural history is not linear, with presentation in variable and controversial ways.

Three prospective randomized studies were done to determine the effectiveness or not of carotid endarterectomy in asymptomatic patients. The European study CASANOVA showed no benefits of endarterectomy versus medical therapy, but unfortunately during the study were serious methodological problems [3]. The Asymptomatic Carotid Atherosclerosis Study (ACAS) is the largest trial ever completed about asymptomatic carotid lesions. It presents evidence that surgical treatment of asymptomatic lesions greater than 60% by arteriography is better than just clinical treatment, with decreased morbidity and mortality in the surgical group. With this publication, the doubts of managing asymptomatic lesions were clarified [4]. More recently the European study Asymptomatic Carotid Surgery Trial (ACST) [5] included 3120 patients with over 60% stenosis (NASCET method [6]). According to this study, are indicated for surgery asymptomatic patients aged less than 75 years old, male, and stenosis greater than 60%. The benefit is not clear to patients over age 75 and women.

Regarding transient ischemic attack (TIA), which is defined as a neurological deficit that does not last for more than 24 h, many affected patients never reach the hospital, so the studies of hospitalized patients are not a true reflection of the disease.

The best studies are conducted in specific communities, such as Rochester, Minnesota [7, 8]. In this population, the incidence of TIA was 31 patients per 100,000 inhabitants per year in all ages, with the increased incidence is taken into account older age within the community. It was also seen a higher incidence in men than in women in the same age group: 1.3 men for every woman. There are conflicting data when studying the natural history of TIA, mainly by the lack of definition of the base damage of the study population. If the population studied has predominantly critical lesions with ulcerated plaques then it likely presents with subsequent stroke rates to a greater extent than other populations with minor lesions. Predisposing factors for stroke after TIA were: age, transient ischemia, hypertension and heart disease.

Currently TIAs are classified as small strokes with better lesions identified by the most accurate imaging methods [9]. Grigg et al. correlated TIAs with heart attacks and brain atrophy [10]. Therefore, TIAs should be seen not as benign pathology, but as a sign of something worse may be to come, and we must deal with injuries before clinically permanent damage is evident.

Indications for Treatment

The characterization of cerebrovascular ischemic signs and symptoms is important to determine the treatment and prognosis. Most patients with extracranial carotid artery stenosis are asymptomatic and have their diagnosis made by identifying neck bruit on physical examination or imaging the carotid [11].

Indications of treatment are done after imaging the carotid bifurcation that can be (1) for imaging the neurologically symptomatic patient or (2) for imaging the neurologically asymptomatic patient. Imaging of the cervical carotid artery is recommended in all patients with symptoms of carotid territory ischemia. There are two basic indications for screening asymptomatic patients: (1) patients with evidence of clinically significant peripheral vascular disease regardless of age and (2) potential "high-risk groups" who might benefit from screening for asymptomatic stenosis. But screening is not recommended for presence of a neck bruit alone without other risk factors. The potential high-risk group includes patients aged 60 years and had one or more of the following risk factors: history of hypertension, carotid artery disease, current smoking, and a first-degree family relative with a history of stroke. The prevalence of carotid artery stenosis was only 2% if no risk factor was present, 6% with one risk factor, which increased to 14% for two risk factors, to 16% for three risk factors, and to 67% for four risk factors [12].

The treatment of extracranial carotid stenosis is usually composed of three strategies: medical, carotid endarterectomy (CEA) and carotid

angioplasty with stent (CAS). Management of carotid bifurcation stenosis is particular for stroke prevention and has been the subject of extensive clinical investigation. The appropriate treatment of patients with carotid bifurcation disease is of major interest.

The biggest predictor of a future stroke risk is the recent ipsilateral neurological symptoms and not only the degree of carotid stenosis. The NASCET and ECST demonstrated that the risk of stroke is greater in the first month after an initial event and this neurological risk approaches the same risk of an asymptomatic patient 6 months after an event [6, 11].

The role of medical management has been re-emphasized for carotid disease treatment [12]. A national reference document drafted by the Brazilian Society of Angiology and Vascular Surgery is in production phase and should also highlight the importance of best medical practice (BMP) (Available in http://www.projetodiretrizes.org.br/novas_diretrizes_sociedades.php. Accessed 25 July 2015). This BMP includes hypertension control, smoking cessation, lowering cholesterol levels and use of antiplatelet agents.

Nowadays systematic reviews of randomized controlled trials are considered the best evidence to contribute for decisions making in medical intervention [13]. They address all the well-done randomized clinical trials about a certain subject. A Cochrane systematic review [14] about CEA for symptomatic carotid stenosis, with 35,000 patient-years of follow-up (NASCET [7], ECST [12] and VACSP [15]), found that benefit from surgery was greatest in men, patients aged 75 years or over, and patients randomized within 2 weeks after their last ischaemic event and fell rapidly with increasing delay. Endarterectomy was of some benefit for 50–69 % symptomatic stenosis and highly beneficial for 70–99 % stenosis without near-occlusion. Benefit in patients with carotid near-occlusion is marginal in the short-term and uncertain in the long-term. These results are generalizable only to surgically-fit patients operated on by surgeons with low complication rates (less than 7 % risk of stroke and death). Benefit from endarterectomy depends not only on the degree of carotid stenosis, but also on several other factors, including the delay to surgery after the presenting event.

In the same way, the Society for Vascular Surgery committee [12], USA, recommends CEA as the first-line treatment for most symptomatic patients with stenosis of 50–99 % and asymptomatic patients with stenosis of 60–99 %. The perioperative risk of stroke and death in asymptomatic patients must be <3 % to ensure benefit for the patient. CAS should be reserved for symptomatic patients with stenosis of 50–99 % at high risk for CEA for anatomic or medical reasons. CAS is not recommended for asymptomatic patients at this time. Asymptomatic patients at high risk for intervention or with <3 years life expectancy should be considered for medical management as the first-line therapy.

In another Cochrane systematic review [16], with a total of 5223 patients included of three randomized clinical trials (ACAS [5], ACST [6] and VA [17]) show that despite about a 3 % perioperative stroke or death rate, CEA for asymptomatic carotid stenosis [greater than 50 % (VA) or 60 % (ACAS, ACST)] reduces the risk of ipsilateral stroke, and any stroke, by approximately 30 % over 3 years. However, the absolute risk reduction is small (approximately 1 % per annum over the first few years of follow up in the two largest and most recent trials) but it could be higher with longer follow up.

Likewise these global results, the Brazilian vision is with more carefully, especially about the results for asymptomatic patients. CEA and CAS would be made only in reference centers with that minimal perioperative risks (<3 % for asymptomatic and <7 % for symptomatic). This would guarantee better results for patients. The CAS has restricted indications for symptomatic, and is not recommended at this time for asymptomatic patients.

Surgical Results: Endovascular vs. Open Surgery

Few operations are so studied in scientific circles as CEA. In 2005 135,701 carotid interventions were made in the USA [18]. Of these, 122,986 (92 %) were in asymptomatic patients (91 % CEA and 9 % carotid stenting), while in the UK alone 20 % of the procedures were in asymptomatic

patients [19]. The main paradox of this intervention is the fact that it is intended to prevent the long-term stroke but in the course of its execution, may be directly responsible for the occurrence of the same event in a small proportion of patient. Therefore it is an intervention that is justified only if the neurological morbidity, cardiac morbidity and mortality associated with the procedure are significantly lower than what can be expected with medical treatment alone.

Endovascular treatment by transluminal balloon angioplasty and stent insertion may be a useful alternative to carotid endarterectomy for the treatment of atherosclerotic carotid artery stenosis. Bonati et al. published a Cochrane Systematic Review in 2012 [20], updating three previous versions (1997, 2004 and 2007), to assess the benefits and risks of CAS compared with CEA or medical therapy in patients with symptomatic or asymptomatic carotid stenosis. They utilized for this 16 randomized clinical trials involving 7572 patients. CAS was associated with a higher risk of the following outcome measures occurring between randomization and 30 days after treatment than endarterectomy in patients with symptomatic carotid stenosis and standard surgical risk: death; or any stroke; or myocardial infarction and any stroke. The rate of death or major/disabling stroke did not differ significantly between treatments. In patients with asymptomatic carotid stenosis, treatment effects on the primary safety and combined safety and efficacy outcomes were similar to symptomatic patients, but differences between treatments were not statistically significant. They concluded that endovascular treatment is associated with an increased risk of peri-procedural stroke or death compared with endarterectomy. However, this excess risk appears to be limited to older patients (older than 70 years). The longer-term efficacy of endovascular treatment and the risk of restenosis are unclear and require further follow-up of existing trials. Further trials are needed to determine the optimal treatment for asymptomatic carotid stenosis.

In Brazil, from 2008 to 2013, by data from DATASUS (Available in http://www2.datasus.gov.br/DATASUS/index.php?area=02. Accessed 25 July 2015) about carotid disease there was an absolute frequency of 7461 CEA and 783 CAS performed. The expenses for the total procedures were US$10,533,233.41 for CEA and US$1,648,300.65 for CAS. See Fig. 26.1 for the annual evolution of total costs in this period by surgery type. The average cost and average hospital stay per procedure was US$1357.09/9 days for CEA and US$2086.57/5 days for CAS but the professional who performs the surgery receives only an average of 23.61 % (US$333.14) and 13.03 % (US$273.31) of this amount, respectively. It was found that, of the total spent on each surgical procedure, a rate of 36.2 % (US$645,570.10) is related to the cost of intensive care unit after CEA and 11 % (US$30,645.78) after CAS. Despite the total cost with CEA was bigger than with CAS from

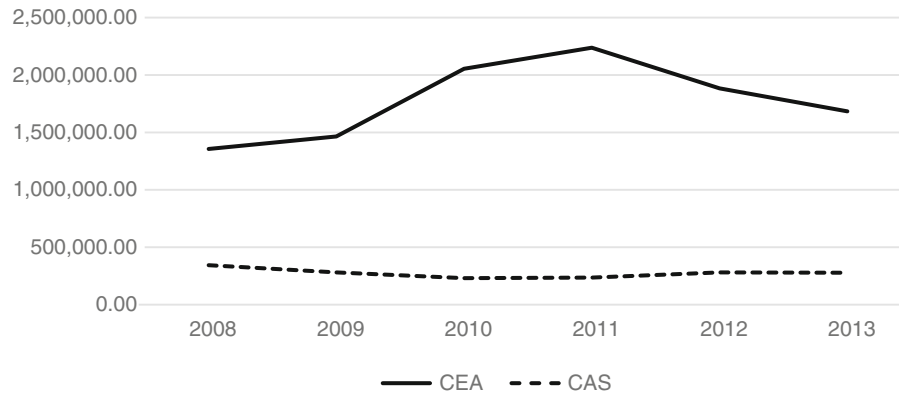

Fig. 26.1 Absolute costs in Brazil for carotid surgery (US dollars X years). *CEA* carotid endarterectomy, *CAS* carotid angioplasty with stent

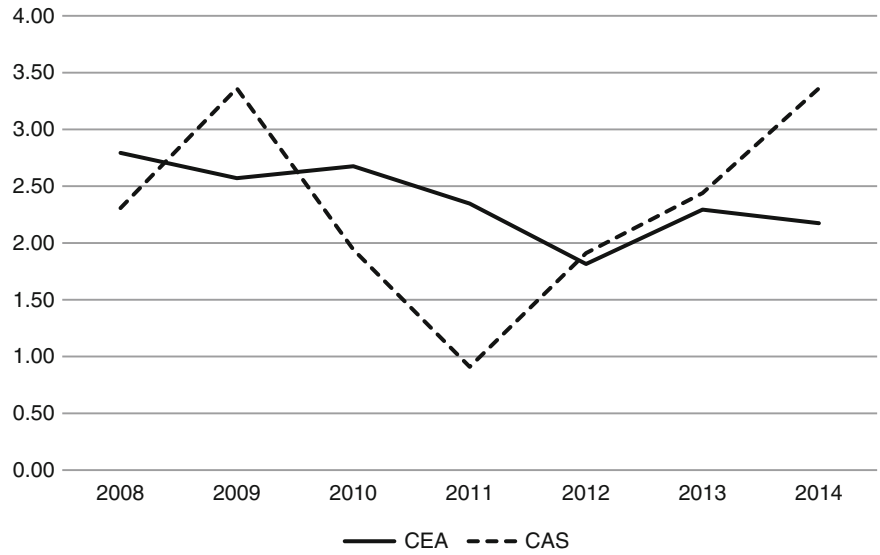

Fig. 26.2 Brazilian mortality rate by type of carotid surgery (% X year). *CEA* carotid endarterectomy, *CAS* carotid angioplasty with stent

2008 to 2013 in Brazil, the endovascular technique had a major relative cost when evaluated by number of procedures. The American study "The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST)" [21] showed that the initial spending on CAS is more expensive, costing US$1025/patient more when compared to CEA, which featuring agreement with Brazilian data. In spite of it CREST investigators concluded that there is insufficient evidence in favor of CEA or CAS on economic aspects.

The Brazilian mortality rate was 2.42% for CEA and 2.14% for CAS in 2008–2014 interval. See Fig. 26.2 for evolution of mortality per type of surgery per year (Available in http://www2.datasus.gov.br/DATASUS/index.php?area=02. Accessed 25 July 2015). These results differ from the reality found in countries such as USA, Canada and from Europe. In Brazil not only the mortality percentages for both types of treatment are higher, but also not reproduce the great inequalities in the risk of death between the two surgical modalities. The mortality risk in the periprocedural period in CREST ranged from 0.3% for CEA and 0.7% for CAS [22].

So, it turns out that Brazil presents trends similar to that of other countries in North America and Europe in some aspects, observing maintenance of CEA as the main indication for the treatment of carotid stenosis and CAS is reserved for cases where there are contraindications to the first. But we have to improve our results, reducing complications and perform these procedures in referral centers maybe can help.

Public vs. Private Practice: Reimbursement

The reimbursement to the Unified Health System in Brazil (*Sistema Único de Saúde*—SUS) established by Article 32 of Law No. 9,656/1998 and regulated by the norms of the National Health Agency is the legal obligation of private insurance providers of health care to restore the SUS expenses in any service beneficiaries who are covered by their plans (Available in http://www.ans.gov.br/planos-de-saude-e-operadoras/espaco-da-operadora/18-planos-de-saude-e-operadoras/espaco-da-operadora/263-ressarcimento-ao-sus. Accessed 25 July 2015). It is known that in Brazil, many public health services are provided to patients that have private health care plans too, burdening the public health services. The public health services do not get financial return in the vast majority of this cases. This makes the public service be always in deficit, further worsening the public attendance, decreasing public resources

and expecting private reimbursement that does not happen often.

Apart from that, the reimbursement procedures by SUS are outdated. According to DATASUS (Available in http://www2.datasus.gov.br/DATASUS/index.php?area=02. Accessed 25 July 2015), a CAS in 2014 was repaid in US$1213 for each procedure and only one stent in the same region and time costs about US$3428.

In the Brazilian private service, with the easiness of current online information, the Vascular Surgeon should have consistent scientific evidence to indicate the best procedure for the patient, who often comes to the office with a formed view on open or endovascular surgical procedures. The opinion of the patient should be taken into account along with current best clinical evidence. The vascular surgeon must be careful not to perform procedures that may increase the risk for the patient.

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Current Status in Management of Carotid Disease in Korea

27

Young-wook Kim and Seon-Hee Heo

The total population of South Korea is around 50 million with average life expectancy of 81.9 years (male 79.5 years and female 85.1 years of age) [1]. According to the Korean National Statistical Office, Korea has a jar shaped population pyramid now and it is expected to change to an inverted pyramid by 2060 [2]. A very low birth rate and lowered death rate might attribute to this phenomenon. With growing elderly population, we encounter an increased number of old-age patients with old-age diseases and there have been many changes in disease pattern and medical practice in Korean society.

According to statistics of Korean Center for Disease Control and Prevention in 2012, prevalence of risk factors for atherosclerosis was summarized in the Table 27.1 [3]. Over the last 10 years, the prevalence of hypertension decreased slightly, but the prevalence of diabetes, hypercholesterolemia, and obesity increased. Smoking prevalence in male adults has decreased, but is still as high as 48 % [4].

Figure 27.1 shows changing trend in causes of death in Korean people. According to the report by Korean National Statistical Office, malignant tumor, cerebrovascular disease and cardiac disease account for 28.3 %, 9.6 %, and 9.5 % of death of all Koreans in 2013, respectively [5].

While there was change in the cause of death, there also was a change in the causes of stroke in Korea (Fig. 27.2).

The Korean Stroke Society (http://www.stroke.or.kr/) and the Clinical Research Center for Stroke (http://www.stroke-crc.or.kr/) published nationally representative data on stroke and presented them in a single document of Stroke Statistics in Korea, mainly focusing on stroke epidemiology and its risk factors [7]. According to the report, approximately 105,000 people experience a new or recurrent stroke and more than 26,000 people die of stroke annually. Stroke accounts for roughly one of every ten deaths. The estimated stroke prevalence is about 795,000 in people aged ≥30 years.

According to an estimation from the database of Korean Health Insurance Review Agency during the period from 1995 to 2003, the age-standardized incidence of ischemic stroke in the population 35–74 years of age increased annually by 7.2 %, whereas hemorrhagic stroke decreased annually by 1.8 % and unclassified stroke by 9.2 % [6]. Moreover, the proportion of ischemic stroke has steadily increased showing that the proportion of ischemic strokes among all strokes increased from 43 % in 1995 to 65.2 % in 2003 and accounted for 76 % of all strokes in 2009 (Fig. 27.2).

Data of ischemic stroke subtype from population-based studies are not available. According to a nationwide hospital-based stroke

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registry study which evaluated the Trial of ORG 10172 in Acute Stroke Treatment (TOAST) classification [8] for 36,191 ischemic strokes between 2002 and 2010, large artery atherosclerosis (LAA, 36.1 %) was the most common type, followed by small vessel occlusion (SVO, 25.4 %) and cardioembolism (CE 17.1 %). Over the 9 years, the relative proportion of CE increased, LAA remained stable, and SVO and stroke due to undetermined etiology decrease. And the proportion of ischemic stroke admissions increased from 64.7 % in 2000 to 76.1 % in 2009 [9]. The study did not include patients who were admitted to non-neurology departments or who arrived at the emergency department but were not hospitalized. However, data of the excluded patients are unlikely to substantially change the study findings.

SVS Guideline 2011 recommended carotid endarterectomy (CEA) as the first line treatment for most symptomatic patients with carotid stenosis (CS) of 50–99 % and asymptomatic patients with CS of 60–99 %. Carotid artery stenting (CAS) is not recommended for asymptomatic patients

Table 27.1 Prevalence of risk factors for atherosclerosis in Korean adults (2012)

Risk factors	Prevalence (%)		Subject
	Male	Female	
BMI >25 kg/m^2	36.3	28.0	Age ≥19 years
Hypertension	32.2	25.4	Age ≥30 years
Diabetes mellitus	10.1	8.0	Age ≥30 years
Hypercholesterolemia	12.2	16.4	Age ≥30 years
Current smoker	43.7	7.9	Age ≥19 years

BMI body mass index
Source: National Health and Nutrition Examination Survey, 1998–2012

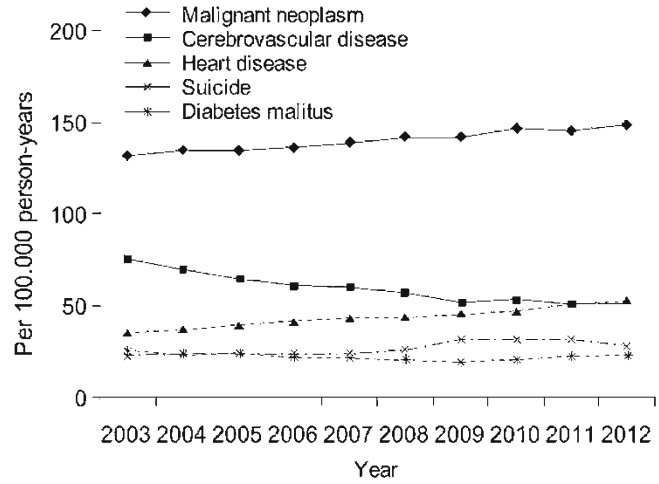

Fig. 27.1 Changing trend in causes of death in Korean people (*Source*: Korean National Statistical Office [5]). (From Kim YW. Thirty year-old Korean Society for Vascular Surgery: challenging issues to overcome. Vasc Spec Int. 2014;30(2):43–8.)

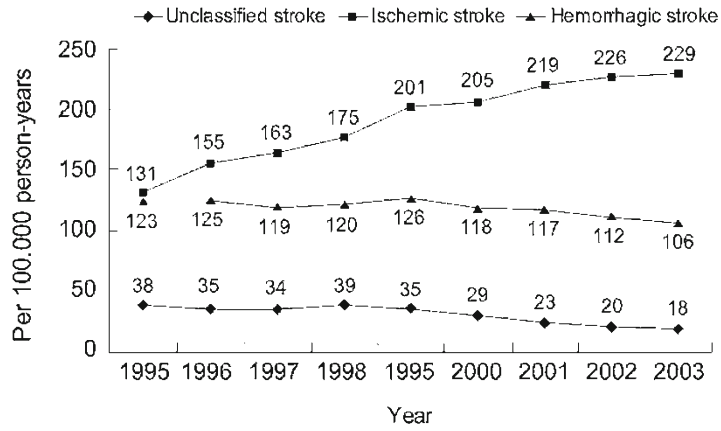

Fig. 27.2 Age- and sex-standardized stroke incidence in population with 35–74 years (*Source*: Korean Center for Disease Control and Prevention [6]). (From Hong et al. [7])

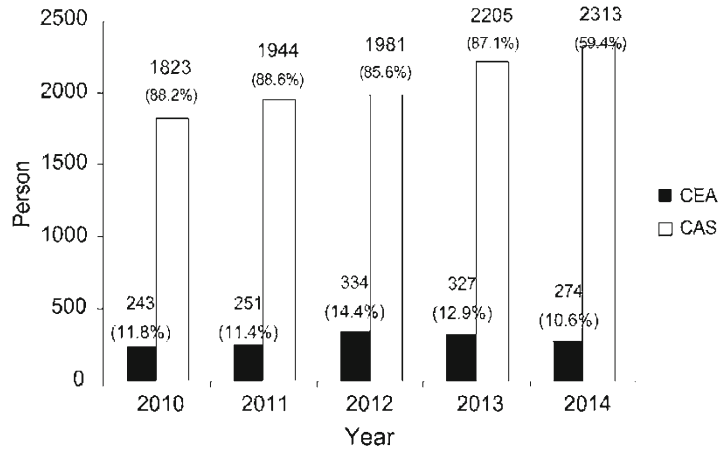

Fig. 27.3 Trend in treatment of carotid artery stenosis in Korea in 2010–2014 (*Source*: Health Insurance Review and Assessment Service, Korea)

and it should be reserved for symptomatic patients with CS of 50–99 % at high surgical risk for CEA due to anatomic or medical reasons [10].

After release of some clinical trial results concluding CAS as an alternative to CEA and approval of CAS by US FDA, number of CAS has increased in the US. However, CEA is still a major treatment option in US and European countries. According to a report of population-based estimates of carotid artery revascularization procedures in the US, majority of carotid reconstructions was CEA rather than CAS in US (CEA, 94.1 % vs CAS, 5.9 %, 1998–2007), though there was some regional variations in the US [11].

In Korea, we have the exact reversed proportion of CEA vs CAS compared to the US (Fig. 27.3). Characteristically, CAS was significantly more frequently performed in Korea compared to CEA. This is opposite to treatment patterns in the Western countries. The causes of the reversed ratio of CEA vs CAS in Korea can be explained by less learning opportunity of CEA compared to other arterial surgery in the earlier days and relatively low cost of CEA compared to other vascular surgical procedure. For example, operation fee of CEA is lower than that of the stent insertion in the superficial femoral artery. CEA is usually performed at large hospitals whereas CAS has been performed sporadically in Korea under the relatively wide indications even in asymptomatic CS patients.

Considering the information described above and that the aged (≥65 years) population is currently over 5.5 million, 2500 carotid interventions including CEA and CAS that are being performed in a year seem to be much lower than the expected number of carotid interventions that should be performed in Korea.

In our recent review of early results of CEA and CAS which was performed in a tertiary referral center in Seoul, Korea, CAS showed significantly higher rates of symptomatic (CAS, 9 % vs. CEA, 3.2 %, P = 0.007) and asymptomatic (CAS, 7.2 % vs. CEA, 2.2 %, P = 0.002) neurologic events in the early (<30 days) postoperative period [12].

To search for clinical outcomes of CEA and CAS performed in Korea, we reviewed SCI journals reporting CEA and CAS outcomes from Korea, which was summarized in Table 27.2 [12–18]. Though CEA is not as popular as CAS in Korea, the outcome of CEA was comparable to the reported outcomes from other countries.

In Korea, almost all CAS are performed by interventional neuroradiologists or interventional cardiologists not by vascular surgeons. According to a retrospective analysis of treatment outcomes in patients with carotid artery disease from five major hospital in Korea, 30-day stroke rate was significantly higher in CAS group compared to CEA group (4.9 % vs 1.8 %, p-value = 0.026) [19].

Recently, we conducted a nation-wide survey (not yet published) targeting all members of Korean Society for Vascular Surgery to evaluate the current trend in management of carotid disease in Korea during the past 3 years. The questionnaire

Table 27.2 Published outcomes of CEA and CAS from Korea

Author, publication, year	Stroke[a] or death rates (%) <30 days	
	CEA	CAS
Yun et al., 2011, J Korean Surg Soc [13]	1.0	10
Han et al., 2014, Stroke [14]	1.9	NR
Lee and Suh, 2014, Ann Surg Treat Res [15]	5.8	NR
Lee, 2014, J Neurointerv Surg [16]	NR	8.0
Yang et al., 2014, J Vasc Surg [12]	1.3	6.8
Kim et al., 2012. Ann Vasc Surg [17]	2.2	NR
Hong et al., 2015, Cardiovasc Intervent Radiol [18]	NR	3.4

[a]Includes any stroke within 30 days after CEA or CAS
CEA carotid endarterectomy, *CAS* carotid artery stenting, *NR* not reported

included annual patient volume of CEA, proportion of symptomatic carotid disease among CEA cases, the first-line treatment for asymptomatic severe carotid stenosis, procedural details of CEA, and early postoperative stroke or death rate. According to the survey, 56.3 % of CEA was performed for symptomatic patients. Among them 47.8 % was performed within 2 weeks after index neurologic event. Regarding the question about the first-line treatment for asymptomatic patients with carotid stenosis >70 %, they replied CEA in 35 %, CAS in 30 % and optimal medical treatment in 35 %. To the question about surgical procedures of CEA, 73.4 % of the CEA was standard carotid endarterectomy with patch closure. Early (<30 days) postoperative stroke or death rate after CEA was 2.1 % after CEA during the past 3 years according to the survey.

Before describing the cost-benefit analysis comparing CEA and CAS in this country, we have to write about Korean health insurance system. We have a government-run health insurance system in Korea. In this system, operation fee of CEA is lower than that of femoral artery stenting. The low cost for CEA may partly attribute to lower performance of CEAs in this country compared to Western countries.

To summarize, we think that many patients with carotid disease were still undetected or untreated in Korea considering number of total population and annual number of stroke patients. To solve this problem, increased public health education for stroke prevention and awareness about carotid diseases by Korean doctors are needed.

Regarding the management of carotid disease in Korea, it is deviated from that of other countries. Particularly, CAS is too frequently performed compared to CEA. The reversed ratio of CEA vs CAS performance favoring CAS should be reassessed to optimize risk versus benefit and get an optimal treatment outcome.

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Carotid Disease in Europe

28

A. Ross Naylor

Aetiology of Stroke in Europe

As is typical of most western nations, 80 % of all strokes are ischaemic and 20 % haemorrhagic. About 20 % of all ischaemic strokes affect the vertebrobasilar territory, leaving 80 % affecting the carotid territory. Approximately 50 % of all carotid territory, ischaemic strokes are secondary to embolism from an ipsilateral internal carotid artery (ICA) stenosis, but only one third of these will have a 'surgical' stenosis (>50 %). Intracranial small vessel disease is responsible for 25 % of all carotid territory ischaemic strokes, cardiogenic brain embolism (15 %), whilst haematological and non-atheromatous disorders make up the remainder. Risk factors for carotid disease include; increasing age, smoking, hypertension, ischaemic heart disease, preceding transient ischaemic attack (TIA), diabetes, peripheral vascular disease, and hypercholesterolaemia. Only 15–20 % of stroke patients in Europe will suffer a herald TIA.

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Management of Carotid Disease in Europe

Guidelines of Practice

Across the 51 countries that make up Europe, there are considerable variations in practice according to wealth, health systems and politics. The 2009 European Society of Vascular Surgery (ESVS) Carotid Guidelines advised that carotid endarterectomy (CEA) was recommended in symptomatic patients with 50–99 % stenoses, provided the peri-operative stroke/death rate was <6 %, and preferably performed within 2 weeks of the patient's most recent symptoms [1]. CEA was also recommended in asymptomatic males aged <75 years with 70–99 % stenoses, provided the perioperative stroke/death rate was <3 %. The benefit from CEA in asymptomatic women was considered to be significantly less than in men and the ESVS advised that CEA should only be undertaken in younger, fitter females [1]. The ESVS guidelines also advised that carotid artery stenting (CAS) was only appropriate (outwith trials) in 'high-risk for CEA' symptomatic patients. However, much has changed and (in the absence of updated ESVS guidelines due to be published in 2016), many European countries have adopted the 2011 American Heart Association (AHA) guidelines, which advise that carotid artery stenting (CAS) is now an alternative to CEA in 'average risk' patients [2].

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Table 28.1 Variations in carotid intervention practice across Europe[a]

	Symptomatic (%)	Asymptomatic (%)	Emergency (%)	Proportion CAS (%)	Eversion endarterectomy (%)	Patch angioplasty (%)	Local anaesthesia
Denmark	100	0	4	<1	27	39	67
Finland	84	16	7	3	1	37	41
Hungary	54	46	10	4	88	54	22
Italy	31	69	2	17	62		51
Norway	79	21	6	3		62	
Sweden	77	23	9	7	28	40	
Switzerland	60	40	1	1		70	57
United Kingdom	83	17	11	5	7	69	50

[a]Data derived from Vikatmaa P, Mitchell D, Jensen LP, Beiles B, Bjorck M, Halbakken E et al. Variation in clinical practice in carotid surgery in nine countries 2005-2010: Lessons from VASCUNET and recommendations for the future of national clinical audit. Eur J Vasc Endovasc Surg 2012;44:11-17

Symptom Status

Across Europe, there is considerable variation in indications for CEA, most notably the rationale for intervening in asymptomatic patients. Table 28.1 summarises the proportion of symptomatic and asymptomatic patients that underwent carotid interventions across a range of European countries between 2005 and 2010 [3]. Italy undertook the highest proportion of asymptomatic interventions (69 %), while Denmark did not perform any carotid interventions in asymptomatic patients [3]. At the time VASCUNET undertook their audit, there was less impetus to perform CEA as soon as possible after onset of symptoms. This is reflected in low rates of emergency carotid interventions across the whole of Europe (Table 28.1). Overall, the indications of 92 % of CEAs included within the 2012 VASCUNET report complied with the 2009 ESVS guidelines of practice [1, 3].

Pre-operative Imaging

There is very little data on imaging strategies around Europe. The UK CEA Audit [4] observed that initial imaging almost always involved Duplex ultrasound (94 %). In an audit of 10,452 CEAs, 16 % had a 50–69 % ICA stenosis; 54 % had a 70–89 % stenosis, while 29 % had a 90–99 % stenosis. About 1 % either underwent CEA in the presence of a stenosis <50 % or in a patient who had an ipsilateral occlusion [4]. The decision to undertake CEA in the former group of patients would have been made after a multidisciplinary review of each case. Two-thirds of UK patients currently undergo some form of corroborative imaging, as recommended by the 2008 Health Technology Assessment Guidelines [5]. A second Duplex scan was performed in half of the CEA patients, while a quarter underwent MR angiography. Interestingly, the second scan (whether it be ultrasound or CT/MR) 'increased' the apparent degree of stenosis in 21 % of patients, while stenosis severity was reduced (following the second scan) in 9 % of patients [4].

Pre-operative Medications

In the UK CEA Audit, 97 % of patients were taking an antiplatelet agent at the time of their surgery. Most (87 %) were taking aspirin, but in the latter part of the audit, the proportion taking Clopidogrel had increased to 19 % [4]. Aspirin therapy was stopped prior to surgery in 8 % of UK patients and in 46 % of those prescribed Clopidogrel [4].

Interval Between Symptom and Surgery

Europe (most notably the UK and Sweden) has led the drive towards intervening as soon as possible after onset of symptoms. This is based on evidence that CEA confers maximum benefit if performed soon after symptom onset, in conjunction with compelling evidence that the 'natural history' risk of early recurrent stroke is much higher than previously thought, especially in the first 7 days [6]. NICE and ESVS recommend that CEA (CAS) be performed within 14 days of the index symptom [1, 7], while the UK Government's '*Strategy for Stroke*' document advises that CEA should be performed within 48 h [8]. With the exception of Denmark, no other European country has adopted this '48-h' time threshold.

In Sweden, the median delay from symptom to surgery has declined over the last decade and is currently 7 days and 81 % of CEAs are performed within 14 days [9]. In Germany, the median delay has fallen from 25 days in 2003 to 8 days in 2013 [10]. In the UK, the median delay between index symptom and undergoing CEA is 11 days [11]. The UK Government now publishes median delay data (from symptom to surgery) for every vascular unit in the country so that professionals and the public can be made aware of just how well their local/regional vascular unit is doing [12]. Interestingly, delays to CEA were lowest in the UK where patients were initially seen by Stroke Physicians and highest where patients were referred to 'Care of the Elderly' Physicians [4]. The UK CEA Audit has estimated that if all symptomatic patients underwent their CEA within 14 days, 2000 strokes would be prevented each year [4].

CEA or CAS?

Table 28.1 details the proportion of CAS procedures undertaken between 2005 and 2010 around Europe (i.e. before the AHA liberalised indications in 2011). Italy performed the greatest proportion of CAS procedures in Europe (17 %) with Denmark and Switzerland performing the least [3]. In the UK, CAS comprised only 5 % of all carotid interventions between 2006 and 2012, with no evidence that numbers were trending upwards. By contrast, the annual number of CEAs increased during the same time period [13]. This reflects the ongoing debate about the role of CAS, despite 13 randomised trials having been performed!

In reality, because most European countries focus (primarily) on treating symptomatic patients as soon as possible after onset of symptoms, CAS practitioners have found it difficult to overcome their learning curve in an environment where the majority of patients needing treatment are very recently symptomatic with a high likelihood of having unstable thrombus overlying their carotid plaques (i.e. procedural risks will be much higher). As a consequence, most European centres probably favour CEA (over CAS) in the hyperacute period after onset of symptoms.

Performance of CEA Around Europe

In the UK, CEA is performed less frequently compared with a number of European nations. The number of CEAs per 100,000 population in the UK for 2005–2009 was 5.1. This compares with 7 per 100,000 for Denmark (which does not operate on asymptomatic patients), 12.4 per 100,000 for Sweden and 31.7 per 100,000 in Germany [4]. In the latter country, however, over 50 % of all carotid interventions are undertaken in asymptomatic patients. In the UK, a consultant surgeon either performed or assisted a trainee in 98 % of cases, while a consultant anaesthetist was present at 97 % of procedures [4].

The mean age at the time of undergoing CEA was lowest in Hungary (66 years) and highest in the UK (73 years). This is reflected in the fact that the proportion of patients aged >75 years undergoing CEA in Hungary was only 19 %, while 46 % of all carotid surgical procedures in the UK were undertaken in patients aged >75 years [3].

Table 28.1 summarises how CEA is performed around Europe in an audit of practice between 2005 and 2010 [3]. Approximately half of all

CEAs were performed under locoregional anaesthesia, with the highest proportion being in Denmark (67 %) and the lowest in Hungary (22 %). There was a wide range in practice regarding whether CEA was performed in the 'traditional' manner (with a patch or primary closure) or via eversion endarterectomy. Eversion endarterectomy is very popular in Hungary (88 % of cases) and virtually not performed in Finland (1 %). In the UK, only 7 % of all CEA procedures used the eversion technique [3].

In Germany, an audit of practice between 2003 and 2013 observed that the proportion of CEAs being performed under locoregional anaesthesia increased from 10 % in 2003 to 28 % in 2013 [10] and this was reflected in a small decline in shunt rates from 48 % in 2003 to 44 % in 2013. Some form of monitoring or completion assessment was undertaken in 61 % of CEAs in Germany in 2013 [10]. In the UK, a shunt was used in 73 % of CEAs performed under general anaesthesia and in 10 % of procedures done under locoregional anaesthesia [4]. Some form of completion assessment was only undertaken in 37 % of CEAs [4].

Peri-Operative Complications Around Europe

One of the limitations of most CEA registries is that outcome data are usually not validated or checked by an independent observer. Validation studies have been performed in a number of national vascular registries. In Sweden, external validity was 93 % and was 90 % in Denmark, 84 % in Norway and 81 % in Finland [14]. Hence, some of the published death/stroke rates from individual and pooled registries may not be reliable. In VASCUNET, 30-day death/stroke rates in asymptomatic patients averaged 1 % and ranged from 0.5 % (Italy) to 2.7 % in Sweden [3]. The average 30-day death/stroke rate in symptomatic patients undergoing CEA in Europe was 2.4 % and ranged from 0.9 % (Italy) to 3.8 % (Norway).

There was no evidence that procedural risks around Europe increased in elderly patients. In asymptomatic patients, the average 30-day death/stroke rate in asymptomatic patients aged >75 years was 1.0 % and this was identical to that reported in patients aged <75 years [3]. An identical finding was also evident in symptomatic patients, where the 30-day death/stroke rate was 2.4 % for irrespective of age. In the UK CEA Audit, approximately half of all deaths and a quarter of all post-operative strokes occurred between hospital discharge and review in the outpatient clinic [4]. This emphasizes the importance of using 30-day, as opposed to in-hospital statistics, as the latter will under-estimate the true risk of CEA to the patient.

In 1994, an audit revealed that 26 % of European Surgeons routinely reversed heparin with protamine [15] and the GALA trial (which recruited mostly from Europe) published a post hoc analysis in 2107 patients randomised to CEA [16]. There was a significant increase in neck haematomas in patients not receiving protamine (10.4 vs 7.4 %), but this did not translate into increased rates of re-exploration [16]. In a review of practice across Europe, Wakefield observed that 5 % of patients suffered an adverse event following protamine administration [15]. The commonest was systemic hypotension (5 %), pulmonary artery hypertension affected 0.2 % of patients, while anaphylaxis occurred in 0.16 % and 0.02 % of patients died as a consequence.

There have been concerns that intervening early would significantly increase procedural risks. These were acutely heightened when the Swedish Vascular Registry published a report indicating that patients undergoing CEA within 48 h of the index symptom incurred an 11.5 % death/stroke rate [17]. After 48 h had elapsed, procedural risks were between 3 and 5 %. A single centre audit from the UK has, however, found no evidence of an increase in procedural risk when CEA was performed within 48 h [18] and this has been corroborated by a larger, Austrian study [19]. In the UK CEA Audit, 1600 CEAs were performed within 7 days of the index symptom with a 2.7 % death/stroke rate [11], suggesting that (nationally) CEA can be performed safely within the hyperacute period after onset of symptoms.

In the UK, 2 % of patients returned to theatre for control of bleeding in the national audit, while 4 % of procedures were complicated by cranial nerve injury [4]. The most commonly affected cranial nerve was the hypoglossal nerve, followed by the mandibular branch of facial nerve and the recurrent laryngeal nerve. In a 2011 VASCUNET audit report of pooled outcomes in 383 centres, cranial nerve injury occurred after 3.6 % of all CEAs [14].

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Part IV

Veins

Venous Disease: An Australian Perspective

29

Yew Toh Wong

Abbreviations

CVI	Chronic venous insufficiency
GSV	Great saphenous vein
IVC	Inferior vena cava
POL	Polidocanol
SFJ	Saphenofemoral junction
SPJ	Saphenopopliteal unction
SSV	Small saphenous vein
STS	Sodium tetradecyl sulfate
TGA	Therapeutic Goods Administration
DVT	Deep vein thrombosis

Varicose Veins

Varicose veins are the most common condition treated by most vascular surgeons in Australia. They are prominent, dilated tortuous superficial veins usually on the legs but occasionally can be found on other parts of the body such as the lower abdominal wall and perineal area. The size of varicose veins varies ranging from spider veins (telangiectasia) to large bulbous varicose veins. Telangiectasias are spider veins that often have connections with the larger reticular veins and varicose veins.

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Varicose vein >3 mm
Reticular vein 1–3 mm
Telangiectasia <1 mm

There is no data on the prevalence of varicose veins specific to Australia, however other western countries with similar ethnic makeup to Australia report prevalence in the region of 30 % [1].

Risk Factors for Varicose Veins

- Older age
- Family History: A significant proportion of patients with varicose veins have other family members with varicose veins
- Female gender: Hormonal changes during puberty and pregnancy induce changes in the vein wall making them more likely to dilate. The gravid uterus during pregnancy compresses on intra-abdominal major veins leading to venous hypertension in the lower extremities. Pregnancy related varicose veins usually regress after 3–12 months
- Obesity: Obese patients have higher intra-abdominal pressure with higher venous pressure within the iliac veins and inferior vena cava (IVC). This leads to increased venous pressure in the lower extremities
- Sedentary lifestyle: The pumping action of the calf muscles is crucial in assisting venous return to the heart from the lower extremities. Patients with sedentary lifestyle often have ineffective calf muscle pump

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- Occupational: People working in occupations requiring prolonged periods of standing or sitting such as hairdresser, surgeon, secretary, truck driver, may suffer from varicose veins more frequently.

Pathophysiology

Varicose veins are due to defective functioning of the valves within the vein, allowing reflux of blood. They can cause symptoms of pain, ankle swelling, heaviness, and itchiness. Symptoms are often worse at the end of the day and after prolonged standing. More severe signs of long standing venous hypertension (chronic venous insufficiency) such as bleeding, brown staining of skin, eczema, and ulcer can develop over many years if left untreated.

The CEAP (**C**linical; Etiology; **A**natomy; **P**athophysiology) classification was established to allow standardized reporting of outcomes of management of chronic venous disease [2]. The classification is rather cumbersome and therefore other than the clinical class, the other classes are not commonly used.

Clinical Examination

A thorough history and clinical examination should be performed in patient with varicose veins. History should include symptoms of varicose veins, occupational history, past history of deep venous thrombosis (DVT) and potential trigger for DVT, past surgical treatment for varicose veins, medications, significant family history and history of peripheral arterial disease.

Patients should be examined in the standing position to look for the distribution of the varicose veins. Signs of complications of chronic venous hypertension such as oedema, skin pigmentation, lipodermatosclerosis, atrophie blanche, eczema and ulceration should be noted and documented. Increasingly photographic documentation is used to compare pre and post treatment outcomes. Examination of the foot pulses is a critical part of the varicose veins examination to avoid surgical removal or ablation of great saphenous vein that could potentially be used as a bypass conduit in patients with mixed arterial and venous disease. Significant arterial disease should be treated prior to treatment of varicose veins. Trendelenburg test, although it continues to be taught in medical school, has largely not been used by practising vascular surgeons, who tend to perform formal venous duplex ultrasound either themselves or by a sonographer.

Investigations

Venous duplex is the standard of care for patient with varicose veins. Endovenous treatment of varicose veins is increasingly popular among vascular surgeons and demanded by the patients. A significant proportion of vascular surgeons prefer to scan the patient themselves to allow them to better decide the best approach to endovenous and surgical treatment.

Venous duplex should document

- patency and competency of the deep and superficial venous system
- diameter, depth and tortuosity of the great saphenous vein (GSV)
- significant incompetent branches of the GSV and its distance from the saphenofemoral junction (SFJ)
- location and relationship of the saphenopopliteal junction (SPJ) with its connecting veins
- location of perforators in the thigh and calf and their diameter
- refluxing pelvic veins feeding into the varicose veins (especially in recurrent varicose veins)

Arterial Doppler studies may be required to assess adequacy of arterial circulation.

Treatment

The National Institute for Health and Care Excellence (NICE) in the United Kingdom has published updated guidelines on the management

of varicose veins [3]. Treatment options are reassurance and conservative management (compression stockings), endovenous ablation and treatment by surgery. NICE has recommended endovenous ablation as a first line treatment and those who are not suitable for endovenous therapy to be treated with surgery. Compression stockings are recommended when endovenous or surgical approaches are not suitable. Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIPS) has conducted systematic review on the treatment of varicose veins and the recommendations are similar to the NICE guidelines (http://www.surgeons.org/media/300823/Varicose_Veins%28SR%29.pdf).

Endovenous Thermal Ablation

Endovenous treatment of varicose veins involves ablation of the refluxing great saphenous or small saphenous vein with thermal energy (radiofrequency and laser). Laser and radiofrequency ablation has been used in the treatment of refluxing veins for several years. Their results in terms of recurrence of varicose veins have been found to be comparable to surgical stripping of the GSV [4]. Endovenous thermal ablation has the advantage of less pain and faster recovery to normal activities. Both modalities attract Medicare Australia rebate. Laser fibre was used initially for endovenous thermal ablation, however more recently radiofrequency ablation catheter is gaining popularity. Laser safety goggles are not required during radiofrequency ablation procedure and there is evidence to suggest that radiofrequency endothermal ablation is associated with less painful post-operative recovery [5]. Radiofrequency endovenous ablation of GSV is equally efficacious compared to laser, except for the very large diameter vein (>10 mm) and the perforator vein where laser endothermal ablation is preferred. See Table 29.1.

Table 29.1 Endovenous thermal ablation versus conventional surgery

Endovenous thermal ablation	Conventional surgery
Procedure can be performed under local anaesthesia	Procedure performed under general anaesthesia or spinal anaesthesia
Suitable anatomy- non tortuous, reasonable calibre saphenous vein with no significant incompetent proximal branches close to saphenous junction	Suitable for all anatomy
Thermal ablation of recurrent varicose veins technically similar to primary varicose veins	Saphenous junctional ligation for recurrent varicose veins can be hazardous
Procedure can be performed without stopping warfarin	Anticoagulation needs to be stopped prior to surgery
Results equivalent or better than surgery	Surgery was previously the "gold standard" for varicose veins treatment
Reduced wound infection and haematoma	Wound complications more common than endovenous thermal ablation
Less pain and quicker return to normal activities	More painful and more prolonged recovery
Cutaneous nerve injury uncommon	Cutaneous nerve injury 5–10 %
Risk of skin burn	No risk of skin burn
Superficial thrombophlebitis 5 %	Superficial thrombophlebitis uncommon
Needs to combine with ambulatory phlebectomy or sclerotherapy to treat varicosities	Able to remove varicosities at the time of surgery

Both radiofrequency and laser endothermal ablation procedures are carried out in a similar fashion. Ultrasound is used to guide treatment. The procedure is carried out as day case under local anaesthesia with or without sedation. The GSV or SSV is accessed under ultrasound guidance and a sheath is inserted into the vein. The laser or radiofrequency catheter is then passed up the refluxing vein and the position of the catheter tip is checked with ultrasound. The tip of the catheter is placed about 1 cm beyond the saphenofemoral junction and as the SSV dives into the popliteal fossa to join the popliteal vein. Dilute local anaesthetic is then injected along the outside of the vein (tumescent anaesthesia) within the saphenous sheath. Tumescent anaesthesia is made easier with the use of a tumescent infiltration

pump (roller pump). A 27 g spinal needle is directed towards the catheter and placed outside the saphenous vein but within the saphenous sheath. Correct positioning of the infiltration needle will allow spreading of the local anaesthetic along the saphenous sheath. Tumescent anaesthesia provides analgesia during the procedure, and it also compresses the treated vein to prevent pooling of blood, thereby reducing post-operative phlebitis and increasing the success rate of occlusion of the treated vein. Tumescent anaesthesia also prevents burn injury to the surrounding tissue such as the nerve and the skin by acting as a heat sink between the treated vein and the surrounding structures. Ambulatory phlebectomy, or sclerotherapy, can be combined with the procedure to treat the tributaries of the refluxing vein (the visible varicosities). Although ambulatory phlebectomy can be carried out under local anaesthesia, it is probably best done under general anaesthesia or heavy sedation as some patients are unable to tolerate the pulling sensation during the procedure. A compression bandage is applied for 24 h, and after removal, is replaced by a graduated compression stocking for a further 2 weeks. Walking is encouraged immediately after the procedure. Patients are told that phlebitis can cause pain in the treated leg after 4–5 days and over the counter non-steroidal medication and heparinoid cream applied topically are useful in the treatment of the phlebitis. In our unit, an ultrasound scan is performed within 4 weeks, prior to post-operative clinic visit to ensure successful occlusion of the treated vein. Earlier ultrasound examination is performed if there is any suspicion of DVT. See Fig. 29.1.

Fig. 29.1 Radiofrequency ablation of great saphenous vein

Equipment Needed for Tumescent Anaesthesia

- 20 ml of 2 % lignocaine with adrenaline
- 5 ml of 8.4 % sodium bicarbonate
- Mixed with 475 ml of normal saline
- Spinal needle 27G
- Tumescent infiltration pump (roller pump)

Potential Complications Associated with Endovenous Ablation

- Technical difficulties in cannulation or catheter advancement
- DVT 1 %
- Skin burns 1 %
- Superficial thrombophlebitis 5 %
- neuralgia 5 %
- Recurrent varicose veins 10 %

Non thermal Endovenous Ablation

Endovenous thermal ablation of saphenous vein requires the application of tumescent anaesthesia around the saphenous vein and this requires good interventional skills and ultrasound skills. It constitutes the potentially painful part of the procedure if carried out under local anaesthesia and the most time consuming part of the procedure. Non thermal endovenous ablation does not require tumescent anaesthesia and therefore the procedure is painless and can be completed more rapidly. Non thermal endovenous ablation can complement endothermal endovenous ablation as it can be used to treat saphenous vein incompetence at the calf level with less risk of saphenous and sural nerve neuralgia. There are two main non thermal endovenous ablation systems on the market currently in Australia, Clarivein and Sapheon.

Clarivein uses mechanical chemical means of ablating the vein. The device consists of a battery powered rotating wire that rotates at 3500 rpm inside the saphenous vein, inducing endothelial damage, and at the same time a sclerosant such as polidocanol or sodium tetradecylsulphate is injected to enhance destruction of the intimal lining of the vein. Results for Clarivein have been reported at greater than 90 % success at 2 years, however long term follow up data are not available [6].

VenaSeal induces closure of the saphenous vein with cyanoacrylate adhesive. Cyanoacrylate adhesive induces an inflammatory reaction within the treated vein and causes occlusion of the treated vein. Short term published data on the use of VenaSeal in the treatment of saphenous vein reflux reported greater than 90 % occlusion rate at 3 months [7] and several investigators have reported similar results at 1 year on the company website (http://www.venaseal.com/2012/08/sapheon-announces-one-year-follow-up-data-in-38-patient-study-of-varicose-vein-treatment/). Both Clarivein and VenaSeal have not been approved for Medicare Australia rebate, however these modalities are likely to gain popularity due to ease of use if long term efficacy is proven.

Endovenous treatment of varicose veins in Australia is available both in the public and private sectors. In the public sector, this work is virtually exclusively performed by the vascular surgeon, however, in the private sector; many different specialities offer this treatment including general practitioner, radiologist, dermatologist, plastic surgeon and vascular surgeon. The Australasian College of Phebology is a society in which medical practitioners from various disciplines and allied health professionals who have a dedicated interest in the treatment of venous disease came together with the aim of improving care for venous disease. The college has established a 3 year formal training program which culminates in award of fellowship after successfully completing all requirements for the fellowship. The Royal Australasian College of Surgeons and the Australasian College of Phlebology advise the government and industry concerning venous disease and new developments in the area.

Sclerotherapy

This treatment involves injecting a sclerosing agent into the vein to achieve sealing of the refluxing vein. It works best on the smaller calibre veins or spider veins. Sclerosant can be injected as foam or liquid. Sclerosant can be mixed with carbon dioxide gas or air to become foam (Tessari method). Foam sclerotherapy is more effective than using the liquid sclerosant directly, because the gas medium breaks up the liquid sclerosant into small bubbles and allows them to act on a greater surface area. Foam sclerotherapy however may not be suitable for the smallest spider vein, as it is too strong, and can cause significant skin staining [8]. The most commonly used sclerosants in Australia are Polidocanol (Aethoxysklerol) and Sodium Tetradecyl Sulphate (Fibrovein) which belong to the detergent group of sclerosants. Other sclerosants that can be used include hyperosmolar agents (e.g. hypertonic saline) and chemical irritants (glycerine and alcohol). See Figs. 29.2 and 29.3.

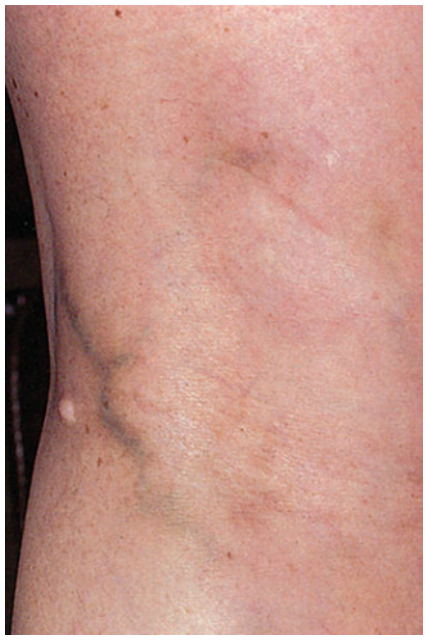

Fig. 29.2 Skin staining post injection sclerotherapy (reproduced with permission from Elsevier)

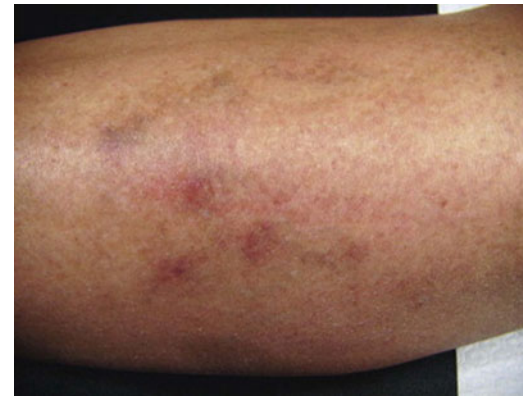

Fig. 29.3 Telangiectasia matting after injection sclerotherapy (reproduced with permission from Elsevier)

Common Used Sclerosants Concentrations and Amount

Vessel diameter	Sclerosant concentration (maximum amount in ml)
Less than 1 mm	STS 0.2 % (10 ml) or POL 0.5 % (12 ml)
1–3 mm	STS 0.5 % (10 ml) or POL 1 % (12 ml)
4–6 mm	STS 1 % (10 ml) or POL 3 % (5 ml)
Branch varicosities	STS 3 % (5 ml) or POL 3 % (5 ml)

POL polidocanol, *STS* sodium tetradecyl sulfate

Potential Complications of Sclerotherapy

- Cutaneous pigmentation
- New telangiectasia (matting)
- Oedema of injected extremity
- Pain (not usually significant with polidocanol)
- Localised urticaria
- Tape blister
- Tape folliculitis
- Skin necrosis
- Systemic allergic reaction- rash, anaphylaxis
- DVT
- Visual disturbance
- Cortical stroke
- Inadvertent arterial injection

Skin staining is the most common adverse effect from injection sclerotherapy. Its resolution requires patience and most settle within a few months. Removal of coagulum post sclerotherapy is an effective way of reducing skin staining in the bigger vein. Post treatment patients should avoid taking iron supplements for 1 month as serum ferritin level has been correlated with pigmentation in some studies [9]. Patients should also avoid sun exposure until the treated site is completely healed. Topical retinoic acid (Retin-A cream) may help speed up resolution of skin staining by enhancing fibroblast removal of hemosiderin in skin [10]. Tri-Luma cream (not readily available in Australia) consisting of a combination of Fluocinolone (mild steroid reducing inflammation), Hydroquinone (depigmenting agent) and Tretinoin (helps skin exfoliate) may also help with reducing skin staining post injection sclerotherapy.

Varicose Vein Surgery

Traditional varicose veins surgery, consisting of junctional ligation and stripping of the saphenous vein, is still performed in Australia, however its popularity is decreasing. Results from open surgery are good with recurrence rates in the region of 10% on long term follow up. Multiple stab avulsions can be carried out at the same time. Surgery can still be a useful solution for people with multiple large varicosities that require removal at the time of surgery and those who have incompetent branches of the great saphenous vein arising very close to the saphenofemoral junction. Endovenous technology in combination with foam sclerotherapy has matured sufficiently that it can treat nearly all varicose veins without resorting to open surgery. In many cases, endovenous surgery is associated with less morbidity, especially in repeat surgery and saphenopopliteal junction interruption.

Graduated Compression Stockings

Graduated compression stockings form the mainstay of treatment for people who suffer from varicose veins, but who are not suitable for endovenous or open surgical treatment. The most common situation where this occurs is when there is incompetence or obstruction of the deep veins and other medical conditions that preclude the safe performance of interventions. Grade two graduated compression stockings are usually prescribed and are effective in prevention of complication from chronic venous hypertension [11]. Compliance rate is low due to difficulty in putting them on and also many patients are unable to tolerate stockings, especially in the heat. Endovenous ablation with its low morbidity, is especially attractive in dealing with patients who are not suitable for traditional open surgery and should be utilized as first line treatment for varicose veins where feasible. We and others have utilized endovenous ablation for superficial axial venous reflux in the setting of deep venous incompetence and ulceration with good results for ulcer healing [12], however the recurrence rate of varicose veins is high.

Chronic Venous Insufficiency and Venous Ulcer

Chronic venous insufficiency (CVI) is a condition where the venous system in the lower extremities is dysfunctional either from obstruction or reflux. In normal circulatory physiology, blood in the vein travels towards the heart, assisted by the valves in the vein and the calf muscle pump. In chronic venous insufficiency, the valves are damaged by the disease process and become dysfunctional, allowing reflux of blood along the vein resulting in high venous pressure. The high hydrostatic pressure results in leakage of serous fluid, protein and red blood cells into the tissue and causes ankle oedema and pigmentation in the gaiter region. Chronic inflammation around the ankle leads to ulceration and scarring. The clinical manifestations of CVI are swelling, induration, eczema, inflammation, skin discolouration, ulcer, and bleeding varicosities.

Treatment of CVI is directed at the underlying refluxing vein. In superficial venous reflux, endovenous or surgical treatment of the refluxing vein is appropriate. Effective treatment of deep venous reflux is lacking and therefore the mainstay of

treatment for deep venous reflux is compression therapy. In people with combined deep and superficial venous reflux, treatment for the superficial venous reflux may be appropriate in certain cases [12], however recurrence is likely, in the region of 50 %, in our experience. Deep venous valvular reconstruction is not widely practised in Australia.

Venous occlusion can similarly result in venous hypertension with the same clinical manifestation of chronic venous insufficiency as in venous reflux. Currently most cases are still treated conservatively in Australia. Compression therapy forms the mainstay of treatment, however there is currently an increasing interest in recanalization of venous occlusion in younger fit patients with significant symptoms of venous claudication. Iliac veins and IVC occlusion can be recanalized and stented with large diameter venous stents with significant improvement in symptoms [13].

Venous Thromboembolism

Extensive iliofemoral DVT carries significant morbidity. Standard treatment for DVT consists of anticoagulation and compressive stockings for a minimum of 2 years [11]. This approach reduces immediate complications, however about half of the patients will suffer from post phlebitic syndrome with pain, swelling, skin discoloration and ulceration within a year of the venous thromboembolic event. Recent advances in technology allows for rapid lysis of the thrombus using pharmacomechanical device such as Trellis device and Angiojet and this has resulted in reduced requirements for thrombolytic agents and thus reducing the incidence of major bleeding associated with venous thrombolysis [14]. These pharmacomechanical lysis devices can be used in conjunction with IVC filter to prevent pulmonary embolism during procedure. Trellis device has two occlusion balloons with an oscillating infusion wire in between the two occlusion balloons. The occlusion balloon is sufficiently large to occlude the iliac vein when inflated, and when used in iliac vein DVT with no free floating thrombus in the IVC, allows safe performance of pharmacomechanical lysis without the need for an IVC filter. IVC filter adds to the complexities of the procedure and significant numbers of IVC filters are not removed after the acute event due either lost to follow up or technical reasons preventing removal. IVC filters reduce pulmonary embolism with no influence on mortality outcome, however they are associated with an increased incidence of recurrent DVT [15]. Patients who have pharmacomechanical thrombolysis for extensive DVT often have an underlying stenosis in the iliac vein from previous scarring or external compression from right common iliac artery (May-Thurner syndrome) requiring venous stenting post thrombolysis to prevent recurrent DVT. Patients who underwent venous stenting have good results from relief of venous obstruction with rapid reduction of leg swelling and discomfort [14]. They are anticoagulated for a period of at least 3 months. Venous duplex scan at this point is used to guide the need for prolonged anticoagulation. If the deep venous system shows no residual thrombus and competency of the deep veins is restored, anticoagulation can be ceased and aspirin used to prevent stent thrombosis. Newer oral anticoagulants that do not require regular laboratory monitoring such as dabigatran, rivaroxaban and apixaban have better bleeding risk profiles and are increasingly used as anticoagulants post DVT [16]. Rivaroxaban is currently the only one that has been approved by Therapeutic Goods Administration (TGA) for secondary prevention in venous thromboembolism. Reversal agents are not currently widely available for the newer anticoagulants, however most have short half-lives (11–14 h) and bleeding episodes can usually be managed by stopping the anticoagulant and institution of supportive treatment. Prothrombinex and tranexamic acid can be used in life threatening bleeding. Despite the lack of reversal agents, the low risk of bleeding associated with the newer oral anticoagulants actually make them safer compared to warfarin.

Indication for Thrombolysis Post DVT

- Extensive DVT (iliofemoral or femoral vein)
- DVT causing threatened limb viability
- Good physiological reserve (18–75 years old) with life expectancy over 1 year
- Recent onset of symptoms (<14 days)
- No contraindications to thrombolysis

Contraindications for Thrombolysis

- recent cerebrovascular accident, gastrointestinal bleed, surgery, or trauma, cardiac arrest
- Bleeding diathesis/thrombocytopenia
- Renal or hepatic failure
- Malignancy with large tumour
- Pregnancy

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Venous Disease in Hong Kong

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Skyi Pang Yin Chun

Varicose Vein Disease in Hong Kong

Cultural Difference and Clinical Presentation

It is not surprising that varicose vein disease is the commonest disease encountered in vascular surgery clinic in Hong Kong. Both the climate of South-East Asia and the culture of Hong Kong have great impact on the management of this condition.

Hong Kong has a huge population on very scarce land. The quick pace of life and long working hours here contribute to the increase in prevalence of varicose vein in our locality. There are some specific occupations, are at high risk of developing varicose vein disease, like the bartender in Hong Kong-style Teahouse, butcher in wet market, chef in Chinese noodles shop, etc.

Although through education public awareness has improved a lot, there is still significant proportion of patients presented late as C5-6 disease. Late presentation does not exclusively appear in elderly but also in working class. Compliance to treatment in this group of patients is generally poor, partly related to the hot and humid weather in Hong Kong. Therefore venous ulcer management remains one of the major workload for wound nurse in vascular clinic.

Investigation/Work Up

General surgeons, whom declare the sub-specialty interests on vascular surgery, manage the majority of varicose vein disease in Hong Kong.

Vascular surgeons adopt surgeon-performed ultrasound nowadays, especially for the assessment for feasibility and to determine the choice of endovenous therapy. A better understanding of venous mapping does improve the completeness of surgery and patient's satisfaction.

Duplex ultrasound scanning is believed to be an essential pre-operative investigation, which is noninvasive, safe, reliable and cost-effective test to evaluate the deep venous system and locate the site of reflux or incompetence [1]. However this is still not a routine practice in Hong Kong. This is not solely because of the inadequacy of the vascular laboratory service, as many surgeons still prefer to offer surgery based on clinical examination.

Venous plethysmography is not often used for patients suffering from simple varicose veins, but for patients who have more advanced stages of varicose veins and chronic venous disease. It is considered to be complementary to venous duplex scanning when venous reflux or outflow obstruction is suspected but is not visualized with the duplex scan [1].

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CT scans and MRIs are seldom indicated for varicose vein disease unless there is suspicious obstructive component of deep venous systems in pelvis.

Conservative Management

Lifestyle modification is important in alleviating the symptoms for varicose vein patients. Education including skin care, elevation of legs, lower limb exercise and avoidance of prolonged standing is delivered in every clinic visit by physician or specialty nurse. However, Hong Kong is a fast paced city where people are constantly on the go and life can get a bit hectic, compliance to lifestyle modification is poor in general.

It is a common phenomenon for Chinese patients to be afraid of surgical treatment of any kind. Compression therapy is often considered as first-line treatment for patient with symptomatic varicose veins. It has been shown to be effective in symptoms control such as pain, hyperpigmentation and edema [2]. Careful assessment for choosing the correct size of compression stocking is required. Commercially available or tailor-made compression stocking with regular follow-up by occupational therapist is available in majority of the public hospitals. Nevertheless, the hot and humid climate is one of the common reasons for the non-compliance to compression therapy in South-East Asia.

Surgical Management

The efficacy and benefit of endovenous therapy with faster recovery and less post-operative pain had been demonstrated by one of the largest randomized clinical trial by Rasmussen [3].

Despite the *NICE clinical guideline 168* published recently in 2013 suggested that thermal-based endovenous therapy is regarded as first line treatment [4]. From the current health care system in Hong Kong, endovenous therapy is still not a reimbursed item.

Conventional surgery i.e. Trendelenburg's operation with stripping remains the first-line treatment in many public hospitals in Hong Kong. Like in many other countries are also regarded as the fundamental operation for surgical trainees.

Long waiting time for conventional surgery, which usually requires general or spinal anaesthesia, is a common phenomenon in public hospitals in Hong Kong. Recently some of these hospitals have set up varicose vein integrated clinic or projects providing endovenous therapy to the public. Endovenous therapy is usually performed in treatment room or operation theatre in day surgery centers under local anaesthesia (Fig. 30.1).

With reference to Fig. 30.2 (Fig. 30.2), the overall number of varicose vein surgeries in Hong Kong is increasing with a rapid rise in the proportion of endovenous therapy in recent 2–3 years.

Fig. 30.1 (**a**) Set up of Nurse-led clinic (**b**) Varicose vein integrated clinic. Pictures provided from Department of Surgery, Princess Margaret Hospital, Hong Kong

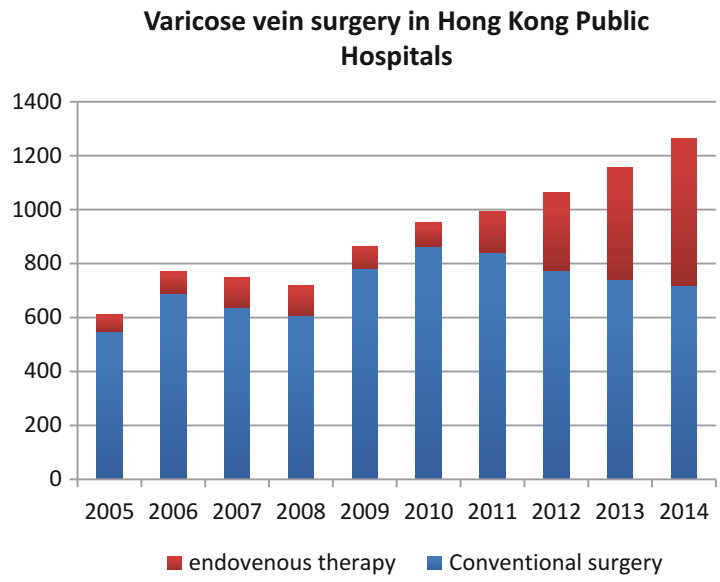

Fig. 30.2 Number of varicose vein surgery per year in Hong Kong Public Hospitals. Data retrieved from Clinical Date Analysis and Reporting System CDARS

Subfascial endoscopic perforator surgery (SEPS) is also performed in some of the hospitals for patients with chronic venous disease with incompetent perforators, with the aim to improve the ulcer-healing rate [5]. As a concomitant treatment with superficial venous surgery, it is also proven to be effective in reducing deep vein reflux and resulting in clinical improvement in patients with advanced primary chronic venous insufficiency [6].

Thermal based endovenous therapy such as laser or radiofrequency ablation is the predominant options. Procedure is usually performed under local anaesthesia in operation theatre at day surgery centers. In recent years, non-thermal based endovenous treatment including the glue injection (VENASEAL®) or Mechanico-chemical ablation (Clarivein®) become more popular. The avoidance of tumescent anaesthesia may lessen post-operative pain. Besides, these new procedures require less spacious room. Many surgeons prefer to operate in treatment room or as office-based procedure.

Endovenous treatment for short saphenous veins and perforators are also available with different devices (Fig. 30.3).

Different varicose vein symposiums had been organized in Hong Kong for surgeons, nurses and allied health staff to share and update the treatment for venous disease.

Conclusion

Health education and promotion are essential to improve the public awareness on varicose vein disease. While long waiting time for operations with benign condition is the main health care issue that needs to be tackled in Hong Kong, endovenous therapy gains popularity with its advantage of early recovery and the feasibility as office-based procedure. With cumulative experience and the advancement in technology, endovenous therapy is expected to be the dominant treatment option in the future.

Deep Vein Disease in Hong Kong

Incidence in Asian patients

Although many studies demonstrate the lower incidence of venous thromboembolism in Asian patients [7–9], this idea has been opposed by various recent studies [10–12]. This phenomenon is either due to the increasing prevalence in Asian patients or the under-diagnosis of venous thromboembolism in the past. One of the autopsy studies in Hong Kong reported the pulmonary thromboembolism prevalence of 4.7 %, which is comparable to Caucasian patients [13]. The SMART study, a larger epidemiological study

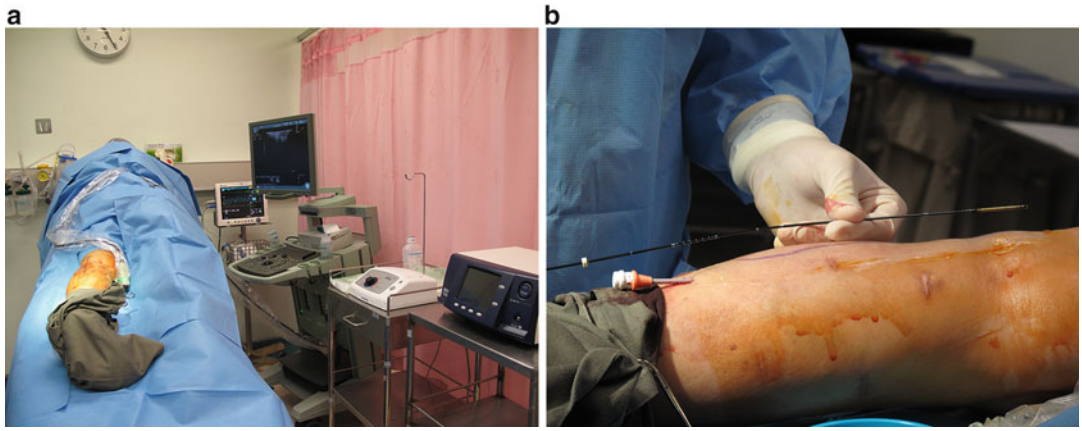

Fig. 30.3 (**a**) Endovenous radiofrequency ablation for short saphenous veins in treatment room at day surgery center (**b**) 3cm radiofrequency ablation catheter for short saphenous vein closure

published in 2005, concluded that the incidence of venous thromboembolism after orthopaedic surgery in Asian patients is not low [14].

On the other hand, the increased use of CT scan in recent decade has led to over-diagnosis of thromboembolism. This can result in complications from anti-coagulation, unnecessary costs to patients and burden on health-care systems. Doppler ultrasound is the current standard for the diagnosis of deep vein thrombosis (DVT) with very high sensitivity of 98% in symptomatic patients [15].

Management of DVT

Anticoagulation is the mainstay of treatment for deep vein thrombosis. It is recommended for all proximal DVT and selected patient with distal DVT when there is no contraindication. The use of low molecular weight heparin during the initial phase followed by warfarin titration is the standard treatment regimen for all public hospitals in Hong Kong. Duration of treatment is determined by the clinical nature of the disease.

Patients whom are put on warfarin will be monitored in anticoagulation clinic as a regular basis to monitor the international normalized ratio (INR). Some of the anticoagulation clinic in Hong Kong is a nurse-led based clinic. The trained nurses in this protocol driven clinic are able to provide safe and effective service as well as education to patients. This has lessened the burden in the specialty outpatient clinic in Hong Kong.

New oral anti-coagulants (NOAC) are still regarded as self-purchased medication in public hospital. With the recent evidence on the efficacy of rivaroxaban and apixaban as monotherapy, it is commonly used especially in the private clinic setting [16, 17].

The Use of Inferior Vena Cava Filter

The insertion of a caval filter is effective in preventing the development of pulmonary embolism and is indicated in DVT patients who have a contraindication to anticoagulant therapy.

In Hong Kong, intervention radiologists perform the majority of the caval filter insertion. With reference to Fig. 30.4 (Fig. 30.4), the number of cases per year is quite low before 2010. This is a fourfold increase in total number after the cost was covered by the Hospital Authority.

Thrombolytic Therapy and Thrombectomy

While anti-coagulation still remains the mainstay of treatment for proximal lower extremities DVT, thrombolytic therapy or thrombectomy are occasionally performed except for phlegmasia cerulean dolens or massive iliofemoral thrombosis. Systemic thrombolysis is seldom performed due

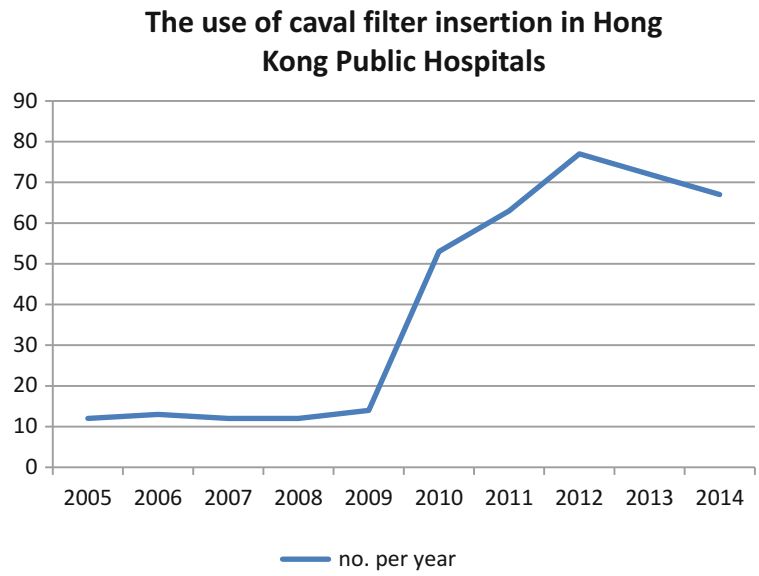

Fig. 30.4 Number of caval filter insertion per year in Hong Kong Public Hospitals. Data retrieved from Clinical Date Analysis and Reporting System CDARS

to the belief that risk of bleeding outweighs the potential benefit of lowering the post thrombotic syndrome. Catheter-directed thrombolysis carries lower bleeding risk as lower dose and local delivery of thrombolytic agent is used. However, this treatment requires prolonged periods of infusion and the patient has to be monitored in a high dependency unit or intensive care unit during treatment. Besides, the contrast load for patients is high as repeated venography is required.

Pharmacomechanical thrombolysis such as Angiojet® system or Percutaneous mechanical thrombectomy like Aspirex® catheter are available in Hong Kong and both of them are expected to gain popularity with the advantage of shortening treatment duration and lowering the amount of lytic agents. Overall, these procedures are not commonly performed especially in government hospital setting. Lack of experienced expertise and high cost of treatment are the reasons behind.

Advanced Chronic Venous Insufficiency and Venous Ulcer

Advanced chronic venous insufficiency and venous ulcers are not uncommonly encountered problems in Hong Kong Chinese. It has important socio-economical impact on our society with the increase in workload for the wound care clinic and community nurse services and the lost of productivity in this group of patients.

Mixed reflux in deep and superficial systems is common in this group of patients. Primary chronic venous insufficiency is predominant in Hong Kong as the incidence of deep vein thrombosis is relatively low [7, 18].

It is difficult to differentiate whether it is due to primary valvular dysfunction or secondary to venous overload as a result of superficial venous reflux. Surgical intervention targeted at superficial and perforator system maybe the most appropriate strategy. Subfascial endoscopic perforator surgery (SEPS) has been adopted which achieves a high ulcer healing rate [5].

There is not yet a standardized protocol or regimen in managing patients with chronic lower limb ulcers in Hong Kong. Patients may be followed up in different subspecialty clinics like Orthopaedics, Vascular Surgery, Diabetic or Endocrine, Podiatry or wound nurse clinics. For those working class patients they usually prefer to learn self applied dressing with regular review in one of the clinics. For home bound or elderly patients, community nurse service in Hong Kong provide out-reach wound care service. The number of patients with leg ulcer being taken cared by community nurse is high, which is also considered as one of the major workload for them. Wide variations in wound

management with little attention paid to the treatment of underlying cause was reported in a recently published literature by a wound nurse from a regional hospital [19]. Collaboration between different specialties or the formation of a multi-disciplinary working group for patients with leg ulcer is the trend in Hong Kong so as to improve the quality of care.

Chinese Medicine in Hong Kong

Chinese Medicine shares a different concept in venous disease. Circulation of meridians and homeostasis are the principles in Chinese medicine. Venous disease or varicose disease occurs when the circulation is disturbed resulting in the stagnation of blood. There is a group of patients, especially the elderly, who prefer to receive treatment from Chinese Medicine Practitioners.

The herbs (Figs. 30.5 and 30.6) which were believed to eliminate the stagnant blood and enhance the circulation of meridians are widely used clinically, such as astragalus root, Caulis Spatholobi, Red Paeoniae Trichocarpae, Amur Corktree Bark, Mongolian Dandelion Herb, Chinese Angelica, Medicinal Cyathula officinalis Root, etc. [20].

Acupuncture is commonly used to treated varicose vein disease. It is believed that acupuncture helps releasing the blockage throughout the meridians and re-distribute the abnormal flow of blood [21]. Acupuncture often goes hand in hand with moxibustion, a therapy that involves burning mugwort on acupuncture points, to achieve the most effective result.

Except for applying herbs, acupuncture and moxibustion, some CMPs may also apply different maneuvers like cupping, massage, and pricking blood with pyrolysis therapy.

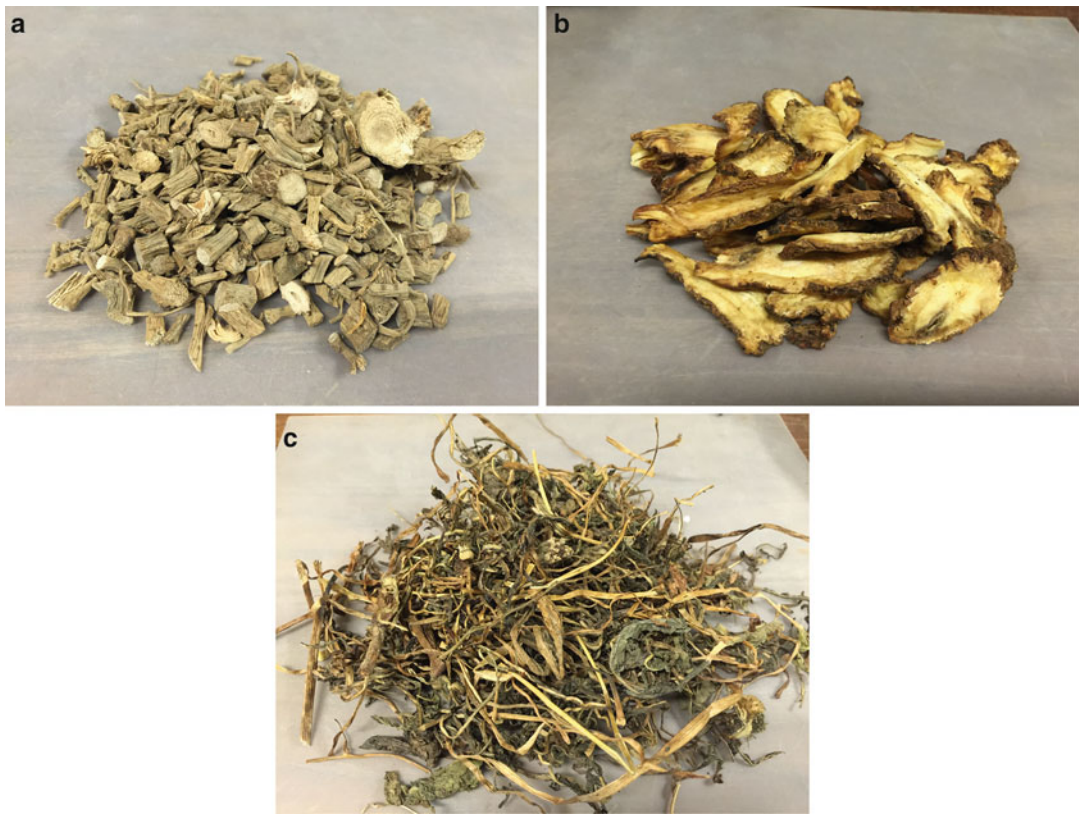

Fig. 30.5 (**a**) Medicinal Cyathula officinalis Root. (**b**) Chinese Angelica. (**c**) Mongolian Dandelion Herb

Fig. 30.6 (**a**) Red Paeoniae Trichocarpae. (**b**) Amur Corktree Bark. (**c**) Astragalus root. Pictures from Dr. Lee Ho Wang, registered Chinese Medicine Practitioner (PhD)

Many Chinese patients believe these theories despite lack of strong clinical evidence to support their use. Although many of the clinics for Traditional Chinese Medicine in Hong Kong are modernized, spreading cellulitis after these interventional treatments may arise. Severe consequences may occur especially for those delayed presentations. Precaution has to be taken for the potential interaction between different herbs and western medicine like warfarin, which is commonly used in patients with deep vein disease, i.e. DVT or post-thrombotic limb.

Although under a different concept from western medicine, Traditional Chinese Medicine does play a role in managing venous disease in our locality. Perhaps more scientific clinical study is required to prove the efficacy of treatment. Special precaution and high index of suspicion are required in avoiding and picking up early complications.

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Varicose Vein Treatment in South Korea

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Jin Hyun Joh

Chronic venous insufficiency (CVI) is one of the most commonly reported medical conditions worldwide. It can be a cause of decreased quality of life, high healthcare costs, and economical concern. The underlying pathophysiology of CVI is venous hypertension of the lower extremities due to the incompetence of the venous valve. CVI can lead to various clinical problems, including dilated leg veins, pain, swelling, skin changes, and ulcerations. Varicose veins, a less severe manifestation of CVI, carry not only cosmetic problems, but also troublesome symptoms, such as pain, discomfort, heaviness, and cramping. Furthermore, varicose veins can progress to CVI due to the continuous effect of increased ambulatory venous hypertension, which initiates a series of changes in the subcutaneous tissue and the skin, such as limb swelling, pigmentation, lipodermatosclerosis, eczema, or venous ulcerations. Varicose veins are dilated, palpable subcutaneous veins larger than 3 mm in diameter; reticular veins are dilated nonpalpable subdermal veins 1–3 mm in diameter; telangiectasias are dilated intradermal venules less than 1 mm in diameter [1]. The treatment of varicose vein differs from that of reticular veins or telangiectasias. In this chapter, the epidemiologic features, referral pattern and reimbursement, diagnostic modalities, and overall treatment patterns in South Korea will be described.

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Epidemiology

South Korea has an universal health coverage system. The National Health Insurance covers approximately 98 % of the Korean population. The prevalence of varicose veins has been released by Statistics Korea. Statistics Korea allocates the code of the Korean Standard Classification of Diseases (KCD) for all diseases. There are four KCD codes for varicose veins: I83.0 for varicose veins of the lower extremities with ulcer; I83.1 for varicose veins of the lower extremities with inflammation; I83.2 for varicose veins of the lower extremities with both ulcer and inflammation; and I83.9 for varicose veins of the lower extremities without ulcer or inflammation. The annual numbers of patients with varicose veins for the past 5 years are shown in Fig. 31.1. The number of admission is the total number of patients who were treated for varicose veins after admission for at least 6 h during the period of reference year. The number of office is the number of patients with office-based management. If the patent comes to an office twice for the period of reference year, it will be counted as two. The total number means the actual number of patients. About 140,000–156,000 patients were managed for varicose veins annually. About 25 % of the

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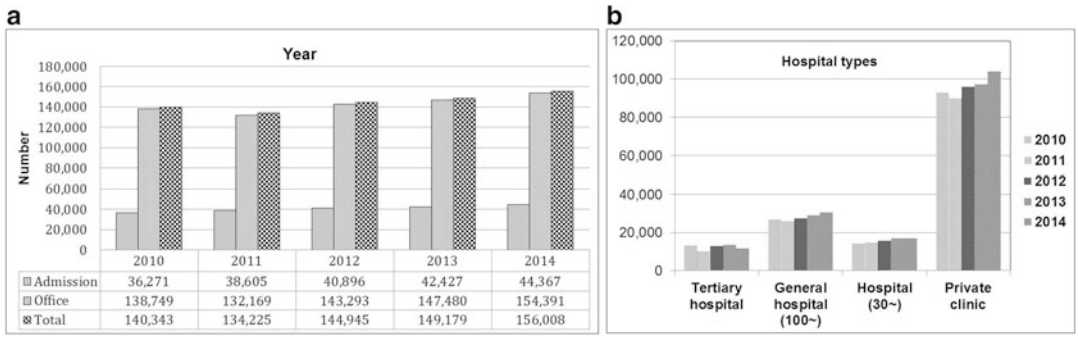

Fig. 31.1 Epidemiology of varicose veins in Korea. (**a**) The number of varicose vein patients who were treated after admission and in an office setting and (**b**) the total number of varicose vein patients according to the hospital type

varicose vein patients were managed after admission (Fig. 31.1a). Figure 31.1b shows the annual numbers of patients with varicose veins according to types of hospital where they managed. There are four types of hospital in Korea. The tertiary hospital is the tertiary referral hospital, mostly university hospitals. General hospitals have more than 100 beds, whereas hospitals have more than 30 beds. Finally, a private clinic is the facility with less than 30 beds. About 70% of the patients with varicose veins were managed in the private clinic, followed by general hospital, hospital, and tertiary hospital.

The number of patients who undergo procedures or surgery for varicose veins is tabulated by the Health Insurance Review and Assessment (HIRA) in South Korea. For the evaluation of the prevalence and annual trend of the procedures for varicose veins, HIRA data are commonly used. The claims data of HIRA is a national data set compiled from healthcare providers across the country corresponding to the number of claims submitted by patients. HIRA allocates an Electronic Data Interchange (EDI) code for each procedure or operation. There are seven EDI codes for the conventional open surgery for the varicose vein: two codes for the saphenous vein ligation and stab avulsion with/without perforator ligation, two codes for segmental stripping of saphenous vein and stab avulsion with/without perforator ligation, two codes for total stripping of saphenous vein and stab avulsion with/without perforator ligation, and one code for other open surgeries for varicose veins. The endovenous ablation procedures, such as radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) are not reimbursed by the national insurance. Therefore, there is no code for endovenous ablation. Figure 31.2a shows the annual numbers of patients who undergo the conventional open surgery, including the procedures of the seven codes according to the type of hospital. The open procedure was most commonly performed in the private clinic, followed by the general hospital, hospital, and tertiary hospital. A total of 17,008 patients underwent open surgery in 2010 and 15,527 patients in 2014, showing a slightly decreasing trend. It is not possible to count the actual number of patients with endovenous ablation because of the lack of EDI codes for these procedures. The number of RFA procedures can be estimated by the number of radiofrequency (RF) catheters used for this procedure. Figure 31.2b shows the RF catheter used in Australia/New Zealand, Southest Asia, and South Korea. In South Korea, RFA was performed to 589 patients in 2011, 1079 in 2012, 2153 in 2013, and 2796 in 2014, demonstrating an increasing trend. Unfortunately, it was impossible to obtain the number of EVLA procedures.

Referral Pattern and Healthcare Cost

Korean patients are not limited with respect to their doctor or choice of medical institution or hospital. The referral arrangement system in

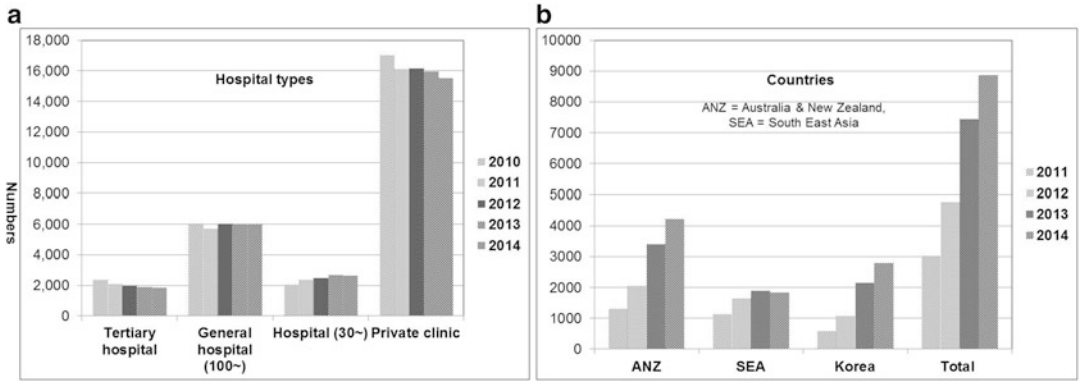

Fig. 31.2 Annual number of patients who underwent conventional open surgery. (**a**) The number of patients with open surgery according to the hospital type and (**b**) the number of radiofrequency ablation procedures

Korea is divided into two steps. The patient can first go to any medical practitioner office, except specialized general hospitals. If the patient wants to go to a general or tertiary referral hospital, they have to present referral documents issued by the medical practitioner who diagnosed them first. Therefore, the patients with varicose veins can choose any practitioner or any hospital. As a generally accepted concept, it is more convenient to use the private clinic. Therefore, about 70 % of the patients with varicose veins were managed in the private clinic (Fig. 31.1b).

Korea has adopted the co-payment system. The co-payments differ according to the level and type of medical care institution. When the patient was treated in an outpatient facility, the cost was determined based on the level of the medical institution. The patient should pay a consultation fee and 50 % of the total treatment cost in the tertiary hospital, 50 % of the sum of treatment cost and consultation fee in the general hospital, 40 % of the sum of treatment cost and consultation fee in the hospital, and 30 % of the sum of treatment cost and consultation fee in the private clinic. If the patient received the medical service on an inpatient basis they pay 10 %–20 %, according to the disease category. The patients with rare, intractable, and chronic diseases pay smaller percentages. For varicose vein treatment, the patient pays 20 % of the total cost. The total cost for the open surgery of a varicose vein consists of basic costs (245,420 KRW–354,620 KRW, depending on the surgery and perforator ligation) plus 30 % of the specialist's basic cost plus 15–30 % of the fee for the hospital grade (15 % for private clinic, 20 % for hospital, 25 % for general hospital, and 30 % for tertiary hospital). The remaining cost is paid by the National Health Insurance. The National Health Insurance Program has three sources of funding. The first source of funding is the payments made by the insured. Employer-insured individuals are required to contribute 5.08 % of their salary. The second source of funding is the government. The National Government provides 14 % of the total annual projected revenue. The third source of funding is the surcharge on tobacco. This provides 6 % of the total annual projected revenue [2].

Diagnosis

The main pathologic feature of varicose veins is valvular insufficiency. The accurate diagnosis of valvular insufficiency can be made by physiologic and anatomic tests. Physiologic test includes plethysmography. Plethysmography is used for the noninvasive evaluation of calf muscle pump function, global venous reflux, and venous outflow obstruction. For the evaluation of the global venous reflux, the photoplethysmography (PPG) is most commonly used in Korea. The venous refilling time is calculated by PPG to diagnose valvular insufficiency. Another phlethysmography is air-phlethysmography (APG). APG is used to evaluate calf muscle pump function and

other venous hemodynamics. Park et al. reported the utilization of APG to evaluate the changes in venous hemodynamics after the surgery for the primary varicose veins [3]. They evaluated the venous hemodynamic parameters, including venous volume (VV), venous filling index (VFI), residual volume fraction (RVF), and ejection fraction (EF) in 1756 limbs of 1620 patients.

Duplex scanning is recommended as the first diagnostic test for all patients with suspected varicose veins. The test is safe, noninvasive, and reliable. It has much better diagnostic accuracy in the assessment of venous insufficiency than PPG or hand-held Doppler. The patient should be examined while standing. The limb to be examined should be slightly abducted and externally rotated. The body weight should be resting on the opposite limb. The standing position also allows the veins to be distended, which is even more pronounced when the valve is incompetent. Some old, obese patients or patients with other disabilities like osteoarthritis who cannot stand for longer durations can be examined on a bed that is adjustable to the reverse Trendelenburg position, upper body elevation, or seated with their legs dangling over the side of the examination table. Gray-scale imaging permits the accurate measurement of the diameter of the saphenous vein and placement of the pulsed Doppler sample volume for the evaluation of reflux time. Color Doppler imaging makes it easier to establish obstruction, turbulence, and the direction of venous flow. The spectral Doppler waveform with pulsed waved Doppler permits the measurement of several venous parameters including peak reflux velocity, reflux time, time average mean velocity, flow volume, and absolute displaced volume. Among these parameters, reflux time is generally used to diagnose the valvular reflux. Reflux can be demonstrated either using a Valsalva maneuver or by augmentation of the flow by squeezing the calf. The Valsalva maneuver is useful for proximal veins close to the abdomen. More distally, manual compression is more useful because abdominal pressure on the vein may not be forcefully transmitted distally, especially if some intervening valves remain competent. An automated cuff inflator is a useful adjunct for a more consistent pressure. International consensus documents recommend 0.5 s as a cutoff value for all veins to use for lower limb venous incompetence, except for femoral and popliteal veins, where the cutoff is 1 s. For the perforating veins, a diameter of more than 3.5 mm and perforator located beneath a healed or active venous ulcer is added as the definition of "pathologic perforator" [1].

The criteria of saphenous diameter to predict reflux may not be used in clinical settings because the venous diameter can be affected by many variables, such as patient position, central abdominal pressure, temperature of examination room, and heart disease. However, it can be used as an additional parameter to predict the valvular reflux. There may be three types of spectral Doppler waveform during duplex scanning for evaluation of reflux (Fig. 31.3) [4]. The first type is the typical finding of a normal saphenous vein (no significant reversal flow and small diameter). It is readily interpreted as the absence of reflux. The second type is the typical finding of the presence of reflux; a large diameter and a reversal flow more than 0.5 s. It is easily interpreted as valvular insufficiency. The third type is an equivocal finding, which is shown as the presence of a reversal flow more than 0.5 s with a very low retrograde flow. It is rather difficult to interpret as the presence of reflux. In this case, the diameter criteria can be used as an additional parameter for interpretation in the clinical setting. We examined 1554 limbs in 777 patients to investigate the correlation between saphenous vein reflux and diameter changes. A GSV diameter of $\geq$5.05 mm had the best positive predictive value for pathologic reflux. For the pathologic reflux of SSV, the best cutoff diameter was 3.55 mm [4].

In Korea, duplex scanning is not reimbursed by the National Health Insurance. But, computed tomography (CT) is in a category of reimbursement from the National Health Insurance. Therefore, the actual medical fee paid by a patient is lower than that of duplex scanning. Moreover, three-dimensional (3D) images provide an easy and thorough understanding of the varicose vein anatomy. Min et al. utilized CT venography with a 16-multidetector CT scanner and 3D reconstructed

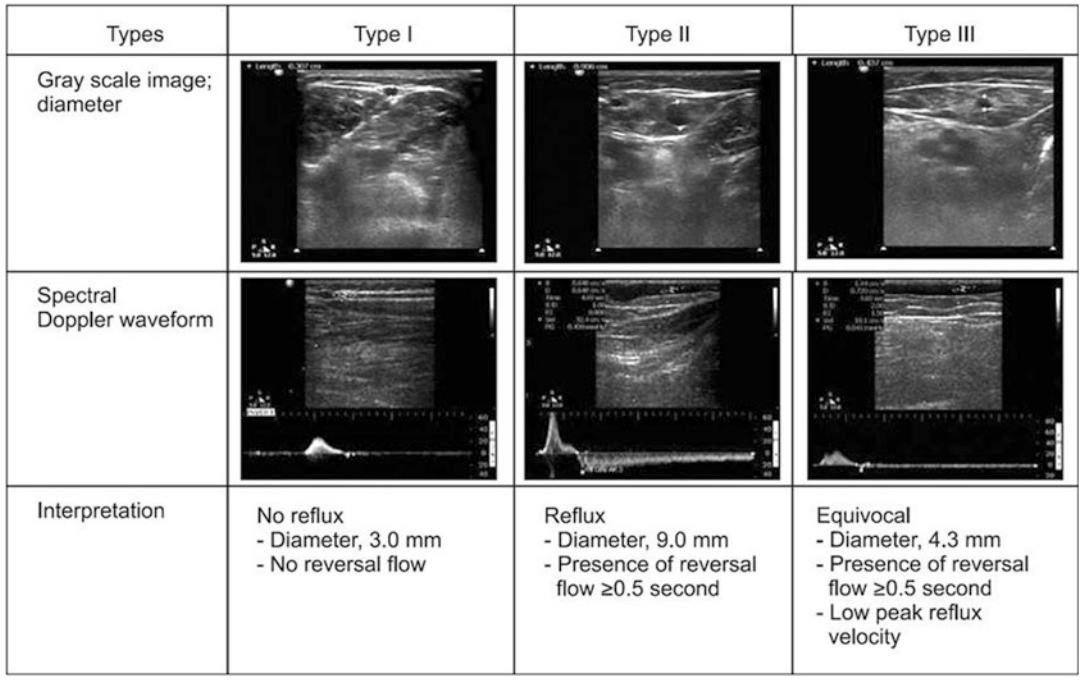

Fig. 31.3 Duplex findings and each interpretation for the evaluation of superficial venous insufficiency of the lower extremity. Type I is a typical finding of the absence of reflux; a small diameter and no reversal of flow. Type II is a typical finding of the presence of reflux; a large diameter and a reversal flow more than 0.5 s. Type III is an equivocal finding. In the spectral Doppler waveform, it shows the presence of reversal flow more than 0.5 s with a low peak reflux velocity. Diameter criteria can be used as an additional parameter in this case

images for the preoperative evaluation of varicose veins [5]. They concluded that CT venography provided a thorough understanding of the complex variable saphenous anatomy and the position of the perforator. In the same center, they reported unusual causes of varicosities such as vulvoperineal varicosity, intraosseous perforating vein incompetence, round ligament varicosity, persistent sciatic vein incompetence, Klippel–Trenaunay syndrome, and portosystemic collateral pathways with CT venography 3D imaging [6].

Treatment

The conventional surgical treatment of superficial vein incompetence is high ligation and stripping of the saphenous vein. Since the introduction of endovenous ablation in 2002, it has largely replaced the conventional surgery of the great saphenous or small saphenous vein in Korea. It is gaining popularity as a result of advancement in the duplex scan and the ease to perform this procedure on an outpatient basis. However, endovenous thermal ablation inevitably requires the infiltration of a tumescent solution to avoid thermal injury during the procedure. Ultrasound-guided foam sclerotherapy (UGFS) has been shown to be clinically effective when patients are selected correctly and the procedures are performed by an experienced practitioner, in spite of concerns that UGFS may lack durability compared with surgery and endovenous thermal ablation. Recently, a new generation of technology has emerged in the form of non-thermal, non-tumescent (NTNT) procedures of endovenous ablation: mechanochemical ablation (ClariVein, Vascular Insights LLC, Quincy, MA, USA), Cyanoacrylate glue (VenaSeal, Sapheon, Inc., Morrisville, NC, USA), Polidocanol endovenous microfoam (Varithena, BTG International Inc., West Conshohocken, PA, USA), and V-Block

(VVT Medical Ltd, Kfar Saba, Israel). In Korea, NTNT procedures are currently not available for use. Therefore, conventional stripping and endovenous thermal ablation (RFA and EVLA) have been used as the mainstay of varicose vein treatment.

Conventional stripping of the saphenous vein has been frequently performed in many institutions in Korea. Although there is a decreasing trend of its utilization, from 27,396 patients in 2010 to 25,972 in 2014, stripping has been used in all types of institutions (Fig. 31.2a). It has been most frequently performed in the private clinic. In terms of the technical point, the saphenofemoral junction (SFJ) is dissected through a 3–4 cm oblique or longitudinal skin incision made in the inguinal crease just lateral to the femoral artery. All tributaries are ligated and divided. The saphenous vein is tied to the tip of the stripper, and the vein is inverted into its lumen as the stripper is pulled down through a small incision made around the knee joint. Complete stripping of the great saphenous vein (GSV) is rarely performed today because of possible injury to the saphenous nerve. For stripping of the small saphenous vein (SSV), ligation of the SSV through a small transverse incision in the popliteal fossa can be made together with a limited invagination stripping of the vein to the mid-calf, using the same technique described for GSV stripping. According to a report examining a large series of stripping, the reduction rates of VV, VFI, and RVF were higher in the stripping group and in the endovenous thermal ablation group than in those of the valvuloplasty group ($P<0.001$) [3]. Park et al. compared high ligation and stripping and RFA in terms of quality of life (QoL) using the Chronic Venous Insufficiency Questionnaire 2 (CIVIQ2) and recurrence occurred in 194 patients with stripping and 78 patients with RFA [7]. Although the pain score was significantly in favor of RFA at both 3 months (-2.32 ± 1.12 in HS group vs. -2.82 ± 1.74 in RFA group, $P=0.015$) and at the last follow-up (-0.62 ± 3.31 vs. -1.91 ± 4.20, $P=0.046$), the overall QoL was similar between the two modalities. Recurrence was observed in 23 limbs from 18 patients in the stripping group, and 10 limbs from 10 patients in the RFA group. They concluded that recurrence rate was similar between the two groups.

Cryostripping is an alternative method to invagination stripping, and is performed by using a cryostripper (Erbokryo CA,ERBE Elektromedizin GmbH, Tübingen, Germany), powered by liquid nitrogen. The surgical procedures may be similar to conventional stripping, except they avoid the distal incision to insert the stripper. After the routine high ligation is completed, the cryoprobe is inserted into the saphenous vein and passed down to the level of the knee in a retrograde direction. When the probe tip reaches the desired segment of the GSV, freezing is initiated. After freezing for a couple of seconds, the GSV is invaginated in an upward direction. Another advantage is that it achieves the removal of varicosity with an extraluminal application of the cryoprobe. Yi EJ et al. reported 6 months follow-up results of cryostripping in 40 patients in Korea [8]. During the follow-up period, there was no recurrence. There were three cases of minor complications; two patients had paresthesia and one had thrombophlebitis.

Endovenous thermal ablation of the saphenous vein is a minimally invasive procedure with several advantages over conventional stripping: no skin incision, less pain, earlier recovery, and an earlier return to work. The procedure is done under ultrasonographic guidance using percutaneous catheter placement and the infiltration of tumescent anesthesia. The procedure of endovenous thermal ablation using EVLA or RFA is similar. For GSV ablation, the patient is positioned in the reverse Trendelenburg position and the GSV is accessed just around the knee joint under ultrasonographic guidance. Then, a guidewire is inserted into the vein, followed by placement of a 5F introducer sheath for insertion of the laser fiber or a 7F introducer sheath for the RF catheter. The laser fiber or RF probe is inserted through the sheath into the GSV and advanced proximally to the SFJ. The tip of the catheter is then positioned 2 cm distal to the SFJ. The patient is then placed in the Trendelenburg position to empty the blood, followed by the infiltration of perivenous tumescent anesthesia with a diluted anesthetic solution into the saphenous compartment. The vein is then ablated in a retrograde

fashion to just above the puncture site. The ablation of the SSV is same as the GSV ablation except the tip of the catheter is placed 2 cm distal to the saphenopopliteal junction (SPJ). At the end of the procedure, ultrasonographic evaluation should be done to confirm the successful occlusion of the saphenous vein and the absence of a thrombus protrusion into the femoral vein or into the popliteal vein if the SSV was treated.

Although the exact number of EVLA procedures cannot be counted in Korea, it can be estimated that EVLA is the most frequently performed procedure. EVLT can be performed using various wavelengths, including 810, 980, 1320, and 1470 nm. Each wavelength has different absorption rates and characteristics. Lee JM et al. retrospectively reviewed the safety and efficacy of ablation using an 810 nm or 1320 nm laser [9]. There was no statistically significant difference between the two groups in terms of overall complication rates or for each individual complication. But, recanalization rates 1 year after surgery were 11.1 % for the 810 nm group and 6.5 % for the 1320 nm group ($p<0.05$). EVLA can be an effective modality to treat the varicose vein with SSV insufficiency. Park SJ et al. evaluated the safety and efficacy of the 980 nm laser for the treatment of SSV reflux [10]. Although bruising and tightness along the course of the treated vein were common complications, the occlusion rate was 94.4 % at the 12 month follow-up. In Korea, evaluation of the clinical efficacy and QoL of EVLA with a randomized controlled trial is still needed.

RFA was first performed in the early 2000s, just after the US Food and Drug Administration approved it in 1999. At the earlier period, the first generation of RF catheters, a ClosurePlus catheter (VNUS Medical Technologies Inc., San Jose, CA, USA), was used. Continuous pull-back was required for ablation of the saphenous vein. In 2006, the ClosureFast catheter (VNUS Medical Technologies Inc., San Jose, CA, USA) catheter was introduced. This new catheter allowed for segmental ablation as opposed to continuous pull-back. This catheter treats a 7-cm vein segment in one 20-s energy cycle. The vein wall is heated conductively by a 7-cm coil at the distal end of the catheter. The treatment temperature is 120 °C. The newer RF catheter has been available in Korea since 2007. We evaluated the occlusion rate and patterns with duplex scanning after RFA [11]. The occlusion rate was 94.6 % (53/56) in GSV and 94.5 % (17/18) in SSV. The most common occlusion pattern in GSV was total occlusion of main trunk with patent superficial inferior epigastric vein in 41.1 %. The most common pattern in SSV was the total occlusion of SSV with a stump in 66.7 %. In December 2013, a multicenter registry for RFA using the ClosureFast catheter was established in Korea. The retrospectively collected data from this registry was analyzed to assess the clinical outcomes after RFA using the ClosureFAST (Covidien) catheter [12]. The most common complication was ecchymosis, which occurred in 41 patients (5.9 %). All clinical parameters including CEAP score, venous clinical severity score (VCSS), and QoL score were significantly improved. At the mean follow-up of 13.9 months, the occlusion rate was 94.6 % in the GSV and 94.5 % in the SSV. In 2014, a consensus working group for RFA was established in Korea. The working group had thorough, step-by-step discussions about the procedure details. After the Delphi meeting, the working group published the "Consensus for the Treatment of Varicose Vein with Radiofrequency Ablation" [13].

For the treatment of pathologic perforator, open subfascial ligation of the perforators has been performed in the past when the duplex scan is not available or when the pathophysiology of the venous disease is not well understood. With the introduction of laparoscopic surgery in the 1990s, it has been used to treat pathologic perforators. Subfascial Endoscopic Perforator Ligation (SEPS) has become popular and has the advantage of being minimally invasive and allowing perforator ligation through the non-affected site of the skin, away from the ulcer. After a short period of anecdotal use of SEPS in Korea, endovenous ablation replaced it because the new method was simple and even more minimally invasive. Stylet RF catheter for perforator ablation has been introduced since 2015 in Korea. Currently, surgical ligation of the perforator and

endovenous ablation of the perforator with EVLA or RFA are available in Korea.

Special issue to manage the varicose veins is whether to treat the varicosities simultaneously or separately. Almost all practitioners in Korea have adopted the simultaneous phlebectomy to avoid the secondary or tertiary reintervention or to meet the patient's desire. Jung IM et al. assessed the effectiveness of EVLA combined with ambulatory phlebectomy as a single procedure for treating saphenous vein incompetence in 148 patients [14]. Residual varicosities were found in 11.4 % of the patients 3 months after the procedure, but only 2.3 % of those required subsequent interventions.

Anesthesia is other issue because the procedures are frequently performed in inpatient settings. Although the EVLA or RFA can be performed in an office setting with local tumescent anesthesia in many countries, all types of anesthesia including general endotracheal, spinal, and local sedation are used in Korea. Moon EJ et al. investigated the effectiveness and safety of monitored anesthesia care (MAC) during endovenous thermal ablation [15]. They divided the subjects into the MAC group (n = 20) or the spinal anesthesia group (n = 22) for a randomized clinical trial. In the MAC group, dexamedetomidine was administered by a loading dose of 1 μg/kg for 10 min, followed by a maintenance infusion of 0.2–1.0 μg/kg/h. Ketamine was used for intermittent injection. In the spinal anesthesia group, midazolam was used for sedation. In the recovery period, patients in the MAC group had a positive perception. In addition, without significant adverse events, the MAC group had a shorter time to possible ambulation.

Conclusion

About 140,000–156,000 patients underwent treatment for varicose veins per year in Korea. About 15,000–17,000 patients underwent open surgery, but the number was declining slightly. The open procedure was most commonly performed in the private clinic, followed by general hospital, hospital, and tertiary hospital. Although the exact number of endovenous procedures was unknown, it could be estimated that endovenous thermal ablations, such as EVLA and RFA, were the most commonly performed and replaced conventional open surgery in Korea. With the early introduction of RFA, the registry and consensus for the standard procedure for RFA were made in Korea. However, further study with a higher level of evidence is needed to evaluate the safety and effectiveness of the procedure in Korea.

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The Treatment of Venous Disease in North America

32

Michael J. Singh and Eric S. Hager

Practice Patterns

Over the course of the last decade and a half, the total number of office based vein procedures has dramatically increased while hospital based procedures have diminished. Endovenous treatment of CVI has become the standard of care in North America. In 2005, the Centers of Medicare and Medicaid Services (CMS) established a fee schedule for office based facilities and in 2008 changed the reimbursement rates for office based endovascular interventions to promote more outpatient procedures so as to decrease hospital based expenses. This resulted in a record number of office based vein centers opening and a significant increase in the number of vein procedures being performed. An analysis of the Medicare database revealed that over an 8 year period (2005–2013), Medicare beneficiaries had a 586 % increase in total number of vein ablation procedures and an associated decrease in stripping and ligation [1–4]. Increased utilization of office based endovenous therapy in North America has led to a decreased expense. Today 90 % of Medicare beneficiaries undergo office based vein procedures compared to only 1 % in 2006. In 2009 a charge analysis demonstrated a 2–3× increase in the average reimbursement for office based thermal endovenous procedures ($335 vs. $1699) [5]. In addition, Medicare and private insurance companies have recognized the economic savings associated with office based procedures [4–6].

In the past decade, venous procedures were primarily performed by general surgeons, interventional radiologists and vascular surgeons. These credentialed specialists were assumed to possess advanced surgical skills and a sound comprehensive knowledge of venous pathology in order to perform various vein related procedures. However, over the course of 5–7 years this practice pattern has drastically shifted and presently a large percentage of vein procedures are performed by cardiologists, internists, family practitioners, dermatologists, gynecologists and cardiothoracic surgeons who have expanded their practice for various reasons. Table 32.1 shows a comparison of specialists performing vein procedures in 2006–2012 [4].

Recommendations for Treatment of Saphenous Vein Incompetence

Modern practitioners encounter superficial venous insufficiency with increasing frequency. Today, estimates of CVI range from 40 to 60 % in the United States alone [1]. In 2011, the SVS and AVF published practice guidelines using evidence-based medicine [2]. In the US, high

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Table 32.1 Summary of Specialities Performing Vein Procedures in the US

	2006 (%)	2012 (%)
Vascular surgery	22	28
General surgery	31	22
Cardiology	7	20
Radiology	10	9
Other specialties	31	22

ligation and stripping of the saphenous vein has been supplanted by endovenous ablation techniques including radiofrequency ablation (RFA), endovenous laser therapy (EVLT) and chemical ablation. In 1999, great saphenous vein high ligation accounted for 155,000 cases, this number decreased to 30,000 in 2012 and this downward trend has continued through 2015 [4]. Endovenous laser techniques were first introduced in United States in 1999 but were routinely used in Europe long before that. In a short period of time EVLT procedures increased from 80,000 procedures in 2004 to 300,000 in 2012 [7]. The RFA and EVLT procedures avoid many of the disadvantages of phenous vein high ligation and stripping including neovascularization and prolonged post-operative recovery. The RECOVERY trial was a multicenter comparative study evaluating outcomes of RFA and EVLT, it was published in 2009. The early complication rate of the laser group (swelling, pain, ecchymosis) was 22 % versus only 4.4 % in the RFA group (P = 0.02) although both groups had similar vein closure rates. The authorsr concluded that RFA and EVLT had similar anatomic success rates and that RFA patients had improved 30-day periprocedural pain scores and better quality of life scores [8]. Rasmussen concluded that both EVLT and RFA modalities are safe, effective and superior to stripping and ligation [9].

The state of the art treatment for great saphenous vein reflux with non-thermal ablation techniques has rapidly been incorporated in the US. The appeal of non-thermal ablation is that it avoids the need for tumescent anesthesia and minimizes procedure related discomfort. In addition, fewer catheter exchanges are required, less bruising and a lower risk of nerve injury have been observed. In 2015, the VenaSeal Closure System (Medtronic, Minneapolis, MN) received premarket approval from the U.S. Food and Drug Administration. The catheter-based technology uses an advanced medical adhesive (cyanoacrylate) to close refluxing saphenous veins without the need for tumescent anesthesia or thermal energy. The VenaSeal closure system has proven to be safe and effective in three clinical studies. The VenaSeal U.S. feasibility study demonstrated safety and efficacy with 92 % closure at 12 and 24 months. The US Pivotal VeClose Study demonstrated safety and efficacy of the procedure with 98.9 % closure rate [10, 11]. In 2014, Varithena (BTG) was approved by the US FDA. Varithena microfoam is a uniform combination of oxygen and carbon dioxide, combined with 1 % aqueous polidocanol. It is generated and contained in an aerosol canister. The technique for use is carried out with ultrasound guidance in five stages carefully monitoring foam advancement with ultrasound imaging, once it arrives at the junction with the deep venous system compression is applied to prevent it from passing into the deep system. Two US Pivotal trials were completed and Varithena was found to be more efficacious than liquid sclerosants in the treatment of saphenous veins [12]. The VANISH-1 data noted that a single treatment demonstrated improved efficacy with increasing concentrations and that efficacy was similar between doses of 1 and 2 % [13]. The VANISH-2 study showed that the microfoam provided meaningful benefit in treated varicose veins and great saphenous veins with reflux [14]. The Clarivein System (Vascular Insights, LLC) utilizes a mechanical occlusion chemical ablation technique which scleroses saphenous veins. A rotating catheter tip causes mechanical injury to the endothelium and induces venospasm. A sclerosant is then sprayed from the catheter tip as it is withdrawn. To ensure maximum effect low volume and high concentrations of sclerosants are recommended. Elias et al. reported 96 % successful closure rates at 1 year in a US based study [15]. Early data from the Dutch MOCA Study has shown 88 % closure and clinical success of 93 % at 1 year [16]. In summary, FDA approved endovenous treatment of great saphenous vein reflux has revolutionized venous

therapy, improved outcomes and increased patient satisfaction. However, it must be recognized that non-thermal vein ablation has yet to receive CMS approval.

Sclerotherapy

Advancements with sclerotherapy have significantly improved today's treatment of telangiectasia, reticular veins, varicose veins, perforator veins and saphenous veins with axial reflux. Sclerotherapy may be used in conjunction with other technology or as a standalone procedure. Improvements in sclerotherapy techniques and the addition of newer agents have improved the overall safety and efficacy. Polidocanol, sodium tetradecyl sulfate, sodium morrhuate and glycerin are FDA approved for use in the US. Compounding detergent solutions was made popular by the dissemination of the Tessari technique [12]. This technique allows for creation of a foamed solution, which facilitates treatment of large veins by displacing blood and increasing the surface area of contact. Foam sclerotherapy has become an established treatment for small and large veins. Even though foam sclerotherapy has been deemed safe and effective, its use in the US has been closely scrutanized [12]. The FDA has stated that compounding liquid sclerosants is not approved and the liability will be placed on the physician who chooses to do so. The use of an illegally compounded drug may invalidate malpractice insurance and the FDA and Medicare can impose criminal charges and significant fines against anyone convicted of using illegally compounded drugs. Aside from these legal concerns, a large collection of data has proven that sclerotherapy and foam sclerotherapy are safe, efficacious and cost effective for treating accessory varicosities [12].

Current Management of Perforator Veins

Patients that suffer with advanced venous insufficiency and/or venous ulceration (CEAP 4-6) often have multiple levels of venous insufficiency (axial reflux, perforator reflux and/or deep venous reflux). Incompetent perforating veins (IPV) have been shown to induce localized ambulatory venous hypertension and promote venous ulceration. Successful prevention and timely healing of venous ulcers is predicated on by eliminating pathologic perforator veins [17]. For patients with advanced CVI that have pathologic perforating veins, a variety of treatment options are available. Current SVS guidelines define incompetent perforating veins (IPV) as >3.5 mm in diameter, >500 msec of reflux and associated with C4-6 disease [2]. Traditional open ligation of perforating veins, first described by Dr. Linton is for historic interest only. Subfascial perforator ligation (SEPS) was developed as a less invasive means to treat perforator reflux but was mired with high rates of wound complications secondary to extensive surgical dissection. Recently, ultrasound guided percutaneous endovenous heat or sclerosant ablation techniques have gained traction and are now commonplace in contemporary practice [18, 19]. In the US, three modalities are routinely used for ablating IPVs: ultrasound guided foam sclerotherapy (UGFS), radiofrequency ablation (RFA) and endovenous laser ablation (EVLA). The modality of choice is left to the discretion of the operating physician and each modality has its own inherent strengths and weaknesses. Radiofrequency ablation of IPVs can be technically challenging due to the rigidity of the ablation stylet and retrotibial location of the perforator vein. The RFA system uses thermal ablation to close the IPV. One of the first major RFA studies in the United States was published by Hingorani in 2009 and noted an immediate success rate of 88 %. Subgroup analysis identified venous pulsatility as the only independent predictor of failure [20]. UGFS offers several attractive features when compared to thermal ablation. It avoids the need for tumescent anesthesia, is relatively pain free, is cost effective and can be performed with minimal preparation. The ultrasound guided foam sclerotherapy method was improved by Tessari who recommended using a stop cock and two syringes with 1 cc^3 of 1 % polidocanol agitated with 4 cc^3 room air until a homogenous foam is created. The foam is slowly injected through an 18-gauge needle into the perforator

vein that is guided by ultrasound. Pressure is held over the junction of the perforator and deep veins to assure minimal foam enters the deep system. Masuda published their initial results of UGFS and documented an initial closure rate of 98 % that was maintained at 20 months [21]. In 2014, Kiguchi published results of UGFS in 62 patients with venous ulceration and 189 injections over the study period with a success rate of 54 % and higher ulcer healing rates in those with a successful closure (69 % vs 38 % P<0.001) [18]. Endovenous laser ablation has gained popularity in contemporary US practices because the device has a lower profile and is less rigid. The laser fiber (Angiodynamics, Latham, NY) is inserted into the IPV through a 21-gauge micropuncture needle using ultrasound guidance and positioned 5–10 mm above the deep venous system. Tumescent anesthesia is administered and the IPV is ablated. In 2012, Dumantepe successfully ablated 23 veins with a 1-year closure rate of 87 % and found a sustained improvement in the venous clinical severity score (p<0.001) at 1 year [22]. Of the IPV techniques described, only RFA has been approved for use by CMS.

Physician and Site Credentialing

Currently, no specialty specific licensing is required to validate the safety and quality of performing procedures in the office setting. Unfortunately, physician licensing is no longer satisfactory due to the wide range of specialists performing these procedures. Recent efforts focusing on maintenance of certification have been met with resistance. Rather than focusing on the practitioner, accreditation is now focusing on the out patient and office based centers. The Intersocietal Accreditation Commission (IAC) is a nonprofit organization that focuses on quality health care through accreditation. The IAC vein center (VC) accreditation process was initiated in 2012, standards accepted in 2013 and then published. Since that time, 51 vein centers have been granted accreditation and 88 additional sites are under review. The IAC-VC has recommended the facility medical director possess board certification and have 2 years of experience after training. The center should have performed >200 vein procedures over a 3 year period (75 during the preceding year), and completed 100 ultrasound studies. Staff physicians requirements are slightly less demanding but do require 30 h of venous specific continuing medical education over a 3 year period. The benefits of venous accreditation are immense and include utilization of established practice guidelines, comparative outcome assessments and implementing consistent quality metrics. In contrast to hospitals and ambulatory surgery centers, there continues to be concern for verification and certification of free standing centers. Free standing centers may not have oversight of credentialing criteria which has justified the need for formal credentialing of this facilities. In September 2013, a multi-specialty group of 15 physicians convened to addressed concerns about free standing centers. The Outpatient Endovascular and Interventional Society (OEIS) was created and established a set of practice guidelines focused on patient safety and efficacy, successful porcedure outcomes, indications for intervention, education and fiscal responsibility. It has been recommended that each free standing center obtain some form of accreditation. There are three nationally recognized accreditation organizations: The Accreditation Association for Ambulatry Health Care, The Joint Commission and The American Association for Accreditation of Ambulatory Surgery Facilities. Presently, 30 states require accreditation and it is expected that many other states will follow suit. The increasing volume and advanced complexity of cases mandate the need for uniform credentialing and oversight which should improve patient safety and quality [23].

Conclusion

Chronic venous insufficiency (CVI) is a common diagnosis and affects millions of Americans. Today, estimates of CVI range from 40 to 60 % in the US. With improvements in technology, traditional open surgical procedures have been supplanted by minimally invasive techniques. Current therapy utilizes minimally invasive

office-based procedures that subject patients to minimal peri-procedural pain and low risk while delivering effective and durable therapy. With a seemingly endless number of treatment modalities and a better understanding of the pathophysiology of chronic venous insufficiency, physicians have more options than ever before for treating venous disease. Less invasive treatment strategies and appear to be superior when compared to traditional techniques based on symptom resolution, patient satisfaction and discomfort. Each approach should be carefully evaluated with respect to its risks and benefits and utilized accordingly.

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Venous Disease: Brazilian Overview

33

Maria Elisabeth Rennó de Castro Santos

Venous Disease

Chronic venous disease affects a large portion of the world population. Studies in different countries show an overall prevalence of 1–73 % in females and 2–56 % in males [1]. The reported ranges in prevalence reflect differences in the population and application of diagnostic criteria of each individual study. Recent studies with better methodology and using the CEAP Classification indicated a prevalence of more than 60 % of classes C0 and C1 in general, and varicose veins—Class C2—are present in more than 20 % of the population. Trophic changes, including venous ulcers, affect less than 10 % of the population with a prevalence ranging from 0.6 to 1.4 % of healed ulcers and from 0 to 0.5 % of active ulcers [1].

In Brazil, there are few epidemiological studies assessing the prevalence of chronic venous disease in the population. Maffei in 1986, evaluated 1755 adults (443 men and 1321 women) aged over 15 years, who attended the Health Center of the University of Botucatu, São Paulo and found an overall prevalence of 47.6 % of chronic venous disease, excluding telangiectasias and reticular veins. The prevalence varied in relation to gender, with males accounting for 37.9 % and females 50.9 % of the total. Healed or open ulcers were present in 3.6 % of patients (2.3 % of men and 4 % of women). The prevalence was higher with age and with multiple pregnancies. These data suggest prevalence greater than or equal to Western developed countries [2].

Scuderi, in 2002, assessed the prevalence of venous disease in 2104 subjects (740 men and 1364 women) randomly recruited from the outpatient clinics of the University Hospital and Health Centers of Campinas and Sorocaba and sorted according to the Class C of the CEAP Classification, to age and to number of pregnancies. Most women (62.79 %) had symptoms and varicose veins, while in males only 34.46 % had signs of venous disease. The prevalence was also higher according to age and number of pregnancies. About 50 % of young women had visible varicose veins in the lower limbs [3].

The prevalence of venous disease found in Vein Consult Program in Latin America, including Brazil, was higher than that of Western Europe and the Far East, and equivalent to the prevalence rates found in Central Europe, Eastern Europe and the Middle East. Following the CEAP Clinic Classification, 1753 women aged 51–64 years were evaluated in Latin America. A percentage of 11.7 % was found in Class C0, 47.8 % in the C1 and C2 classes and 36.7 % in Class C3 to C6. As for the male gender, constituted by 525 individuals in the same age group,

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the proportion was 28.8 % for class C0, 26.5 % for classes C1 and C2 and 34.4 % among Class C3 to C6 [4].

In a study of 201 patients referred for surgical treatment of lower limb varicose veins, the majority (87.1 %) was female, aged 40–50 years (32.3 %), and reported prolonged standing during work activity (82.1 %). The most common level of education (83.2 %) was elementary and middle school. Sedentary lifestyle accounted for 69.2 % of the total [5].

Barros Jr. [6] performed a study on pregnant women at the prenatal care of Maternal Hospital Amparo, with the aim of analyzing prevalence of varicose veins disease, risk factors and symptoms during pregnancy. The study showed a high prevalence of venous disease (72.7 %), and the most prevalent risk factors were age and positive family history for varicose veins.

Silva de Moraes, in a study conducted in patients with venous disease in the city of Vitoria da Conquista—State of Bahia, found a prevalence in different CEAP clinical classes of: C1 6, C2 37, C3 40, C4 13, C5 14 and C6 0 %. Limitation of work activities was reported by 40 % of the patients, first degree relatives has been mentioned by 63 %, two or more pregnancies by 73 % and maintenance of the same posture for extended periods has been declared by 77 % of the patients. The Veines-QOL and Veines Sym questionnaires showed a worse quality of life in the individuals with venous disease, according to the obtained total scores (QOL −50.00 and Sym −32.95), and evidenced that the disease causes a negative impact on the functional performance of the patients, even those that are included in the classes considered less compromised according to CEAP classification [7].

Another study, analyzing the quality of life by SF-36 (Medical Outcomes Study—36-Item Short-Form Health Survey) found statistically significant differences between groups of CEAP classes 1, 2, 3 and CEAP classes 4, 5, 6, regarding items: functional capability, restriction due to physical aspects, pain, vitality and social aspects ($p < 0.0001$) [8].

Dias evaluated patients with venous ulcer (CEAP C6) comparing them with others groups of the CEAP Clinical Classification in Natal, State of Rio Grande do Norte. The presence of venous ulcers was more common among people over 60 years of age, with low education level, professionally active and earning less than Brazilian minimum wage. Chronic diseases, such as hypertension and diabetes mellitus were found in 50.5 % of patients with venous disease, but were significantly more prevalent in patients with venous ulcers. The patient's quality of life with and without venous ulcer was different in the eight sections and the two categories of Short Form-36. The mean scores of patients with venous ulcer were smaller in all categories and sections of the SF-36 compared to patients without it, particularly in relation to physical health and functional capacity, with very low average scores. Furthermore, the low average scores in the section of physical health and in the social aspects should be highlighted [9].

Isolated studies in several regions of Brazil confirm the data found in the literature. The prevalence of venous disease is significantly higher in women, increases with age and the number of pregnancies. Correlation has been demonstrated with posture at work, socioeconomic status and obesity. Venous disease alters significantly the patient quality of life, with a greater impact on the more advanced CEAP Clinical Classes.

The high morbidity of venous disease in Brazil was evidenced by Castro Silva in his study. Based on data of the Brazilian Ministry of Social Security, in the year of 1983, chronic venous disease was the 14th cause of absence from work and the 32nd cause of early retirement [10].

More recent data from the Brazilian Ministry of Social Security demonstrate that the panorama has not changed: varicose veins (ICD I83) still remains as the 14th cause of absence from work, with a great socioeconomic impact (Table 33.1). The cost to the public funds, in the year of 2011, was R$2,087,057,509.91, or about US$9,617,168.98 [11].

In Brazil, health assistance is provided in two ways: the Public Health System (SUS), created by the Federal Constitution of 1988, which established that "health is everyone's right and duty of the State", covering the entire population,

Table 33.1 The 20 ICD-10 with higher occurrences for the benefit "Disease Assistance" between the years of 2000 and 2011[a]

	ICD-10		2000–2011	%
1	M54	Dorsalgia	930.771	7.03
2	S62	Fracture at wrist and hand level	643.761	4.86
3	Z54	Convalescence	536.112	4.05
4	S82	Fracture of lower leg, including ankle	485.637	3.67
5	F32	Depressive episode	469.591	3.55
6	M65	Synovitis and tenosynovitis	407.334	3.08
7	S92	Fracture of foot, except ankle	353.610	2.67
8	M51	Other intervertebral disc disorders	330.293	2.49
9	S52	Fracture of forearm	313.233	2.37
10	M75	Shoulder lesions	274.241	2.07
11	S42	Fracture of shoulder and upper arm	238.090	1.80
12	K40	Inguinal hernia	232.014	1.75
13	S83	Dislocation, sprain and strain of joints and ligaments of knee	224.914	1.70
14	**I83**	**Varicose veins of lower extremities**	**193.403**	**1.46**
15	O20	Haemorrhage in early pregnancy	188.748	1.43
16	M23	Internal derangement of knee	184.867	1.40
17	I10	Essential (primary) hypertension	162.925	1.23
18	F41	Other anxiety disorders	160.731	1.21
19	S61	Open wound of wrist and hand	158.604	1.20
20	S93	Dislocation, sprain and strain of joints and ligaments at ankle and foot level	155.009	1.17

Source: Ministry of Social Security—Benefits of Public Health System—SUB

[a]These 20 diseases account for 50.17 % of all work absences observed in Brazil between 2000 and 2011 and are limited to insured employees of registered companies

with the government's participation in federal, state and municipal levels and the Supplementary Health System, which consists of private health insurance providers. There are significant differences regarding the scope and type of coverage offered by each of these systems.

Duplex scan is currently the most widely diagnostic method indicated in Brazilian Health Systems, Public and Supplementary, because it allows qualitative and quantitative assessment. It provides both anatomic and functional information, thus allowing a more complete and detailed assessment of the venous system.

As for treatment, clinical measures are adopted broadly: changes in lifestyle are advised, as well as it is prescribed the use of elastic contention and guidance to practice adequate physical activities. The use of Unna boot in the treatment of ulcers is also widespread and used in public clinics.

However, differences exist regarding the technique of choice for invasive treatment. Conventional surgery is still the practice most used, being the sole technique authorized by Public Health System and, therefore, the most frequent.

The Ministry of Social Security indicate that in the year of 2014 were carried out about 90,000 hospitalizations nationwide with ICD I83, namely lower limbs varicose veins, through the Public Health System, with the completion of 79,363 elective varicose veins surgeries (Table 33.2) [12]. Data on the Supplementary Health System are not available, but it is estimated that the coverage thereof is about 25 % of the population with attendance around 50 million users across the country, with frequent elective procedures on varicose veins.

Conventional surgery, with the removal or the preservation of the saphenous vein, is the most widely used technique of surgical treatment in the Supplementary Health System too. Chemical or thermal ablation methods are not yet authorized by the Public Health System, but are gaining increasing acceptance in the Supplementary Health System. Few studies exist regarding the use of venous ablation methods, but its use is spreading more and more across the country.

Table 33.2 Number of varicose veins surgery performed by the SUS in the year of 2014

Varicose veins surgery SUS/2014	Unilateral	Bilateral	Total
January	2.098	3.738	5.836
February	2.166	4.460	6.626
March	2.344	3.970	6.314
April	2.572	4.011	6.583
May	2.583	4.495	7.078
June	2.682	4.013	6.695
July	2.433	4.167	6.600
August	2.533	4.195	6.728
September	2.707	4.307	7.014
October	2.758	4.297	7.055
November	2.935	3.998	6.933
December	2.373	3.528	5.901
Total	30.184	49.179	79.363

Source: Ministry of Social Security—Benefits of Public Health System—SUB

Studies with the use of dense foam, in particular in the classes CEAP C5 and C6, are the most common [13].

The Guidelines of Varicose Veins Surgical Treatment, of the Brazilian Society of Angiology and Vascular Surgery (SBACV), in partnership with the Brazilian Medical Association (AMB), of 2012, related the radiofrequency ablation or laser ablation with less pain in the immediate postoperative, shorter period of recovery and improvement in symptoms evaluated in the follow-up period of 12 months, in patients with chronic venous disease of the lower limbs (CEAP classification C2 to C4). However, they emphasize the need for long-term scientific studies, both for thermal ablation as for chemical ablation with dense foam [14].

Because Brazil is a tropical country, aesthetic requests are great. Increasing demands for better aesthetic results gave rise to new methods to minimize surgical scars. The use of the crochet hook as a micro hook favored by Tavares [15] in 1978 allowed approach of varicose veins through smaller incisions that do not require stitches. Following this procedure, in 1992, Ivo and Caldeira [16], as Stehling and Miguel [17], further improved the technique and introduced the use of hypodermic needles as elements for pricking the skin through which the crochet hook is introduced with subsequent removal of the varicose veins.

The sclerotherapy of telangiectasias and reticular veins (CEAP C1) is also a widespread technique among angiologists and Brazilian vascular surgeons. In Brazil, there is no data on the amount of sclerotherapy procedures performed annually. Figueiredo M and Figueiredo MF conducted a survey on the sclerotherapy technique used among members of the Brazilian Society of Angiology and Vascular Surgery. There was agreement of the majority of respondents about the association of sclerotherapy to the conventional surgical treatment (66.81 %). Mechanisms to reduce pain as ice bags and skin coolers were not routinely used (45.37 %). Hyperpigmentation was the most common complication reported (45.16 %); and the sclerosing solution most commonly employed was glucose at 75 % (used by 35.35 % of the interviewed), 14.66 % declare the use of the polidocanol associated with glucose [18].

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Chronic Venous Disease: A European Perspective

34

Michael E. Gaunt

Introduction

Epidemiology and Risk Factors

Chronic venous disease as a very common and important cause of patient morbidity which significantly impacts on European healthcare systems with varicose veins affecting 20–64 % of the population with more advanced venous disease (C3–C6) affecting 5 % and venous ulceration (healed and active; C5/C6) affecting 1–2 % [1].

Chronic venous disease (CVD) can be defined as "any morphological and/or functional abnormality of the venous system of long duration manifest either by symptoms and/or signs indicating the need for investigation and/or care" [2].

Risk Factors

CVD is more common with advancing age and female gender, particularly after pregnancy, but can affect any age and gender. In the Bonn Vein study over half the general population reported CVD type symptoms affecting 49.1 % males and 62.1 % females, however, obesity, family history and ethnicity can all affect incidence rates [3].

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Pathophysiology

The commonest form of CVD consist of superficial varicose veins and telangiectasias but deep venous obstruction and/or reflux may occur independently or in conjunction with these. Reflux caused by primary valvular incompetence is the commonest pathology affecting superficial veins while 80 % of deep venous reflux occurs as a result of post-thrombotic valvular damage with only 20 % because of primary valvular incompetence [4]. Two thirds of cases of iliofemoral thrombotic occlusions will remain significantly stenosed or occluded compensated for by varying degrees of collaterisation [1].

Disease Classification and Diagnosis

Disease Classification

The clinical symptoms and signs of CVD are well known but increasingly in Europe there is a move to encourage clinicians to use various classification schemes to grade and define patterns of disease in order to help direct clinical management and aid research and audit. The commonest applied system is the CEAP classification supplemented by the Venous Clinical Severity (VCSS) score to assess severity; the Venous Segmental Disease Score (VSDS) to define the venous anatomy and disease specific scores such as the

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Venous Disability Score (VDS) to assess post-thrombotic syndrome. For research assessing venous disease and comparing treatments additional assessments using generic health related tools such as Short Form-36 and EuroQoL as well as disease specific Aberdeen Varicose Vein Questionnaire (AVVQ), the Chronic Venous Insufficiency Questionnaire (CIVIQ) and Venous Insufficiency Epidemiological and Economic (VEINES) study tool are also recommended [1].

Diagnostics

In Europe colour Duplex ultrasonography is now the recommended venous imaging modality to supplement careful clinical history and examination. Duplex has largely replaced older techniques such as hand-held Doppler with venography/varicography reserved for specific indications such the assessment of pelvic/gonadal vein obstruction/reflux or venous malformations. Magnetic resonance and CT venography are useful in the assessment of abdominal and pelvic venous disorders such as post-thrombotic obstruction, Nutcracker syndrome, May–Thurner and pelvic varicocele with transvaginal ultrasound becoming increasingly used to assess pelvic vein reflex. Intravascular ultrasound (IVUS) has been advocated for assessing ilio-caval pathologies in more specialist centres.

Older physiological methods such as strain gauge, photo and air phlethysmography, foot volumetry have largely been supplanted by modern techniques.

Treatment

Compression therapy in form of compression hosiery has a role in controlling symptoms from venous disease in patients awaiting more definitive treatment or long term for patients unsuitable for intervention. Compression bandaging, particularly four layered bandaging techniques, generating in the region of 40 mmHg compression at the ankle, have been shown to be more effective at ulcer healing than other modalities. However, other techniques such as short stretch bandaging, two and three layer high pressure bandages, the Unna boot, paste bandages or high compression stockings are often used as alternatives sometimes on the grounds of practicality or other specific indications. The use of intermittent pneumatic compression for venous ulcer healing is not currently recommended until further evidence of efficacy is provided [1].

Intervention can be used in conjunction with compression therapy to help and maintain ulcer healing and reduce [1] recurrence. For non-correctable venous conditions long term compression hosiery is recommended to control symptoms, prevent venous complications or reduce ulcer recurrence.

Compression after various venous interventions is recommended for symptom relief and efficacy of the technique as well as reducing thrombotic risk. The duration of compression is variable but at least 1 weeks' compression after endovenous varicose vein interventions is recommended.

Medical treatment varies in use from across Europe being very popular in some countries and hardly used at all in others. Available medications include natural and synthetic drugs and there are varying levels of evidence to support their use. A 2005 Cochrane review of 44 studies concluded there was insufficient evidence to support widespread use however, there was some evidence that products such as micronized purified flavonoid fraction (MPFF) and calcium dobisilate reduced symptoms of oedema, cramps, restless legs and MPFF helped ulcer healing [5]. Red vine extract has been shown in one RCT to reduce venous symptoms and leg swelling [1].

Sclerotherapy, both liquid and foam can used to treat venous disorders from telangiectasia to extensive varicose vein. Commonly used agents in Europe include Sodium tetradecyl sulphate (STD) and polidocanol, and hypertonic saline. Ultrasound guided foam sclerotherapy (UGFS), both polidocanol and STD, have been demonstrated to be effective in the short term treatment of varicose veins but some studies show high recurrence rates at 5–6 years follow-up

[6]. Therefore, UGFS is not recommended as a first line treatment for the majority of truncal varicose veins but the technique remains an important therapy in selective patients particularly those unsuitable for surgery. The advantages of UGFS include its simplicity, low cost and repeatability and remains a very valuable technique for low cost healthcare systems treating large numbers of patients. Initial concerns about air embolic complications and thrombosis have not proved to be widespread but the introduction of commercially produced Ultra Low Nitrogen (ULN) foam preparations may decrease complication further while adding to the initial cost of the technique [7].

Liquid sclerotherapy has been shown to be effective for the treatment of all forms of reticular veins and telangiectasia but no evidence of superiority of one agent over another. Common agents used include various strengths of Polidocanol, STD and hypertonic saline. Alternative agents such as ethanol and 50% glucose have some proponents but their use in Europe is not as widespread as other regions of the world. *Transcutaneous laser* (TCL) also appears to be an effective treatment but studies suggest it is less effective in general compared to liquid sclerotherapy [1]. Selective indications for TCL include needle phobia, allergy to sclerosant, telangiectic matting and vessels less than 0.5 mm and failure of sclerotherapy.

Endovenous treatments for varicose veins have become increasingly popular in Europe and are now considered to be the primary treatment modality for primary symptomatic truncal varicose veins compared to UGFS and conventional surgery [8]. Recent evidence published in Europe have established that for the majority of varicose vein patients intervention is more effective for symptom relief and improvement in quality of life parameters than conservative treatment with long term compression hosiery.

Endothermal venous ablation using RF Frequency and endovenous laser ablation are equally effective for the treatment of main truncal varicose veins and have proved superior to both conventional high ligation and stripping and UGFS. Compared to conventional surgery, endothermal methods have proved to be as effective with less post-operative complications and much lower recurrences rates at 1 and 2 years—mainly due to avoidance of junctional neovascularisation.

Both RF Frequency and endovenous laser methods continue to evolve. New catheter designs and thermal delivery methods make historical comparisons difficult. Older laser methods used bare-tipped fibres and higher energy levels while newer designs such as radial and tulip fibre tips and higher wavelengths (e.g. 1470 nm) enable lower energies to be used to achieve the same occlusion rates. There is some evidence that RF frequency is associated with less postoperative pain and bruising but this was compared with older bare-tipped laser fibres [1].

Mechanochemical endovenous ablation is a new non-thermal occlusion method which uses a long catheter with a high-speed rotating angled tip through which sclerosant is simultaneously infused to achieve similar main trunk closure rates to endothermal methods without the need for tumescent anaesthesia (Fig. 34.1). The technique is under development with regard to the optimal dose of sclerosant and other parameters but appears safe and effective in selected patients [9].

Cyanoacrylate glue via a long catheter technique has been developed to seal main venous trunks and initial small studies have shown promising results with regard to short

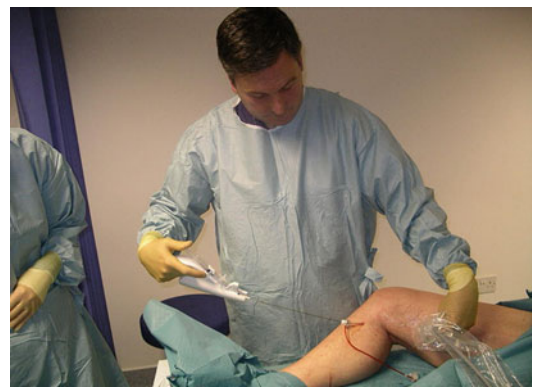

Fig. 34.1 Mechano-chemical ablation of varicose veins: one of a number of minimally invasive techniques for the treatment of varicose veins

term results and safety. One drawback may be the relative expense of the system and further studies are required to establish durability of results and its comparison with other techniques [10].

Phlebectomies remain an important element of varicose vein treatment but debate continues as to whether these should be performed simultaneously with truncal ablation or performed separately as a staged procedure if required [11]. Protagonist of the staged approach point to evidence that secondary procedures are required in 17–62.5 % of cases while protagonist of simultaneous approach point to improved VSS and AVVQ scores in the early postoperative period and minimal requirement (1–4 %) need for secondary procedures [1]. An alternative to staged phlebectomy is staged foam sclerotherapy but evidence suggests that phlebectomy is more effective, causes less complications e.g. skin staining, and is associated with less recurrence.

Phlebectomies can also be considered as a stand-alone treatment performed under local anaesthetic for isolated varicosities or as part of a strategy to preserve the main venous trunks. Transilluminated Powered phlebectomy (TIPP) was introduced to reduce the number of incisions required but initial studies reported a high incidence of complications such as haematoma and paraesthesia and has not found wide acceptance [12].

Another conservative approach is CHIVA (cure conservatrice et haemodynamique de l'insuffisance Veineuse en ambulatoire) based on very detailed Duplex assessment of venous reflux patterns to accurately identify entry and re-entry points for circuits of venous insufficiency between superficial and deep veins and to direct surgery specifically to eliminate these reflux circuits. More evidence of efficacy is required and at present the use of this technique is confined to specialised protagonists within certain countries in Europe [13].

Treatment of Deep Venous Pathology

Deep venous lesions can be divided into deep venous obstruction and deep venous reflux, although in many causes, a combination of the two often exists.

The commonest cause of obstruction is deep vein thrombosis affecting 0.1–0.2 % of the general population per year and for the majority the management is medical consisting of identifying and treating any predisposing causes, anticoagulation and compression stockings. Catheter thrombolysis or surgical venous thrombectomy is not widely practised and is reserved for special circumstances.

There is an increasing trend for the endovenous insertion of vena caval filters into DVT patients to reduce the risk of pulmonary embolism. Often the filters are designed to be retrievable and removed once the acute risk of PE is passed. Frequently, however, for a variety of technical factors, filters may not be retrieved and in the medium to long term can result in complications such as stent fracture, perforation of the cava, sometimes causing injury to adjacent organs, and thrombosis of the vena cava leading bilateral lower leg venous hypertension [14].

It has been estimated that despite adequate medical treatment some 20–50 % of DVTs result in residual venous lesions which can lead to post thrombotic syndrome (PTS) which can result from residual deep venous obstruction, valvular incompetence secondary to inflammatory destruction or a combination of the two. Extensive caval or iliac vein thromboses are less likely to fully recannalize than more distal DVTs and proximal deep venous obstruction can be a cause of more deep venous reflux due to distension of distal leg veins causing valvular incompetence.

A non-thrombotic cause of iliac vein compression is May–Thurner syndrome where the left common iliac vein is compressed under the right common iliac artery. Treatment with venous angioplasty and stenting is increasingly performed for patients with serious intractable complications of venous hypertension not responding to compression. Similar procedures can be considered for carefully selected cases of caval and iliac vein post-thrombotic obstructions.

Deep venous bypass procedures for similar more distal obstructions (e.g. popliteal—May–Husni procedures) appear to have lower clinical success rates and are reserved for specialized indications. Routine deep venous bypass is not recommended in Europe at this time [1].

Deep venous reflux can be primary or secondary (usually to DVT). Primary reflux may be amenable external or internal valvuloplasty. The inflammation resulting from DVT usually results in sclerotic damage of the valves and vessel wall and these cases translocation of competent vein segments is preferred but European guidelines recommend surgery is reserved for patients with severe pathology and that any superficial vein or perforator reflux and/or any associated obstruction is corrected first [1]. Most patients with deep venous incompetence can be managed with conservative measures only.

Pelvic vein and ovarian vein incompetence are increasingly recognised as a cause of recurrent varicose veins and part of the pelvic congestion syndrome usually in multiparous women. Abnormal distribution of leg veins originating from the vulva or buttock region suggest a pelvic origin, the source of which can be investigated by a combination of transvaginal ultrasound, MRI/CT venography and catheter directed descending venography. The two main sources of incompetent pelvic veins are ovarian veins and internal iliac vein branches. Operative ligation of these veins is increasingly giving way to endovascular coil embolization. Further studies are required to determine the exact indications for this therapy as well as its effectiveness compared to conservative measures or conventional endovenous therapy [1]. Complications of embolization include pelvic thrombophlebitis and coil migration to the heart or lungs [15].

Summary

Venous pathology represents a significant healthcare problem which represents a significant workload for healthcare systems in economically developed European countries. This chapter highlights the transition of vein treatments from open surgery to less invasive endovenous therapies many performed under local anaesthetic.

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Part V

Access

Hemodialysis Access Management in Singapore

35

Jackie Pei Ho

Singapore sees an improving gross domestic product GDP and life expectancy but also a rising trend of diabetes as well as chronic kidney disease CKD over the last decade (https://www.moh.gov.sg/content/moh_web/home/statistics/Health_Facts_Singapore/Disease_Burden.html). Renal failure ESRF is an expanding health issue in Singapore. The age standardized prevalence of dialysis patients increased drastically from 691.2/million population in 1999 to 991.9/million in 2014 [1]. The cause of renal failure is predominantly (>60 %) diabetic nephropathy, highest in the world according to United State Renal Data Report [2]. Hemodialysis HD remains the main modality (more than 80 %) of renal replacement therapy [1].

In Singapore, majority of local HD patients are managed in public healthcare system. Small percentage of patients with private insurance or foreigner patients will seek medical care in private sector. The estimated cost for hemodialysis per month in 2004 was reported between SGD2000 and SGD3500. Hemodialysis cost is heavily subsidized by national medical insurance program as well as charity organization based on individual's financial condition. About 70 % of hemodialysis service is provided by voluntary welfare organization and restructured hospitals (public hospital). Another 30 % service is provided by private sector. Even though there are nephrologists visit to each HD center, most ESRF patients follow-up with nephrologist in restructured hospital. The nephrologists determine when a patient is suitable for consideration of vascular access creation (both for pre-emptive and those already on hemodialysis), provide counsel on modality of dialysis and optimize their medical health. Nearly all surgical hemodialysis access creations are performed by Vascular surgeons. Interventional radiologists predominantly, and also vascular surgeons and interventional nephrologists, insert tunnelled central venous catheters. Both the vascular surgeons and the nephrologists play the role of HD access monitoring. Majority of the work of accesses maintenance and salvage for failing or failed accesses are performed by vascular surgeons and interventional radiologists, few interventional nephrologists also provide this service.

ESRF Patient Characteristics

Diabetic nephropathy is the main cause of renal failure in Singapore (66 % according to 2014 statistics) [2]. Prevalence of ischemic heart disease (>40 %) and peripheral arterial disease (~20 %) is

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relatively high. The proportion of elderly patients (>65 years old) is also increasing. Renaud et al. [3] reported 31.8 % of HD access creation patients between January 2008 and December 2010 were age >65 years old. The other special features of ESRF patients in Singapore is multi-ethnicity. Singapore is a multi-ethnic countries composed mainly of Chinese, Malay, and Indian. Different ethnic patients may have different vascular responses to dialysis access creation or salvage procedure. Furthermore, clinicians have to understand the unique culture in each ethnicity, e.g. Malay patients tends to avoid any surgical intervention in the Ramadan period and Chinese patients are reluctant to go for surgery in the Hungry Ghost month.

Surgical Hemodialysis Access Creation

Even with lots of effort to encourage pre-emptive HD access creation, majority of patients already started their hemodialysis with a tunnelled central catheter before first seen in clinic for access creation. Only about 20–30 % of referred patients are for pre-emptive access. Some of the patients already carried the tunnelled catheter for more than 6 months before their first consultation for HD access creation. This resulted in frequent encounter of central vein stenosis along the years of their hemodialysis.

Fistula (AVF) first is the strategy adopted by all surgeons. It is the common practice of vascular surgeons in Singapore to have patient's upper limb superficial vein and artery Ultrasound Duplex assessment (Fig. 35.1) performed before clinic assessment for access decision. Nonetheless, discrepancy of actual vein size and Ultrasound study may exist if the room temperature of examination room is too cold, or patient is very anxious. Standardization of Ultrasound Duplex examination is required including patient's position (recombinant), room temperature (or using warmer), and tourniquet application or not. Beside Ultrasound Duplex assessment as pre-clinic assessment, quick Ultrasound examination during the clinic visit is also helpful especially in difficult access conditions. Quick Ultrasound examination in clinic also facilitate clinicians to determine if the fistula is mature for cannulation and which segment is more superficial for initial cannulation.

The lower threshold of cephalic or antecubital vein size for AVF creation is 2.5 mm. However, the ultimate decision of using or abandon a smaller size vein is under individual surgeon's discretion after considering all the clinical conditions of a patient. In a review study conducted in the author's institution, AVFs maturation rate by 6 months was 71.7 % if the vein size measured by Ultrasound was ≥3 mm. Whereas the 6 months AVFs maturation rate dropped to 53.5 % if the Ultrasound measured vein size is <2 mm. The overall AVFs maturation (including assisted maturation) by 6 months was 65.6 %. Brachiocephalic AVFs having the highest rate of maturation followed by radiocephalic then brachio-basilic AVFs (71.6 vs 61.3 vs 58.4 %). Nonetheless, the mean maturation time was 16.1 ± 10.7 weeks. Similar 6 months maturation rate was reported in an earlier published study [3].

Most surgeons also use Ultrasound to assess and locate the superficial vein in the operating theatre immediately before the access creation surgery. Local anesthesia together with moderate sedation or regional (brachial plexus block) anesthesia are the preferred mode of anesthesia for AVF creation. General or regional anesthesia are required for AVG creation and brachio-basilic fistula transposition.

With the principle of "fistula first" in mind, clinicians also have a learning curve to go through in access creation. In the author's institution, the trend of arteriovenous fistula graft AVG dropped from more than one quarter of all accesses created to about one sixth over 6 years period (Table 35.1).

Chia et al. [4] reported the clinical outcomes of AVGs in Singapore. The functional patency of the studied 92 AVGs were 61 % at 2 years and 38 % at 3 years. Majority of AVGs were lost due to infective complications. The incidence of various complications during the study period were graft infection 20.7 %, pseudoaneurysm 10.9 %, graft thrombosis 26.1 %, steal syndrome 1.1 %,

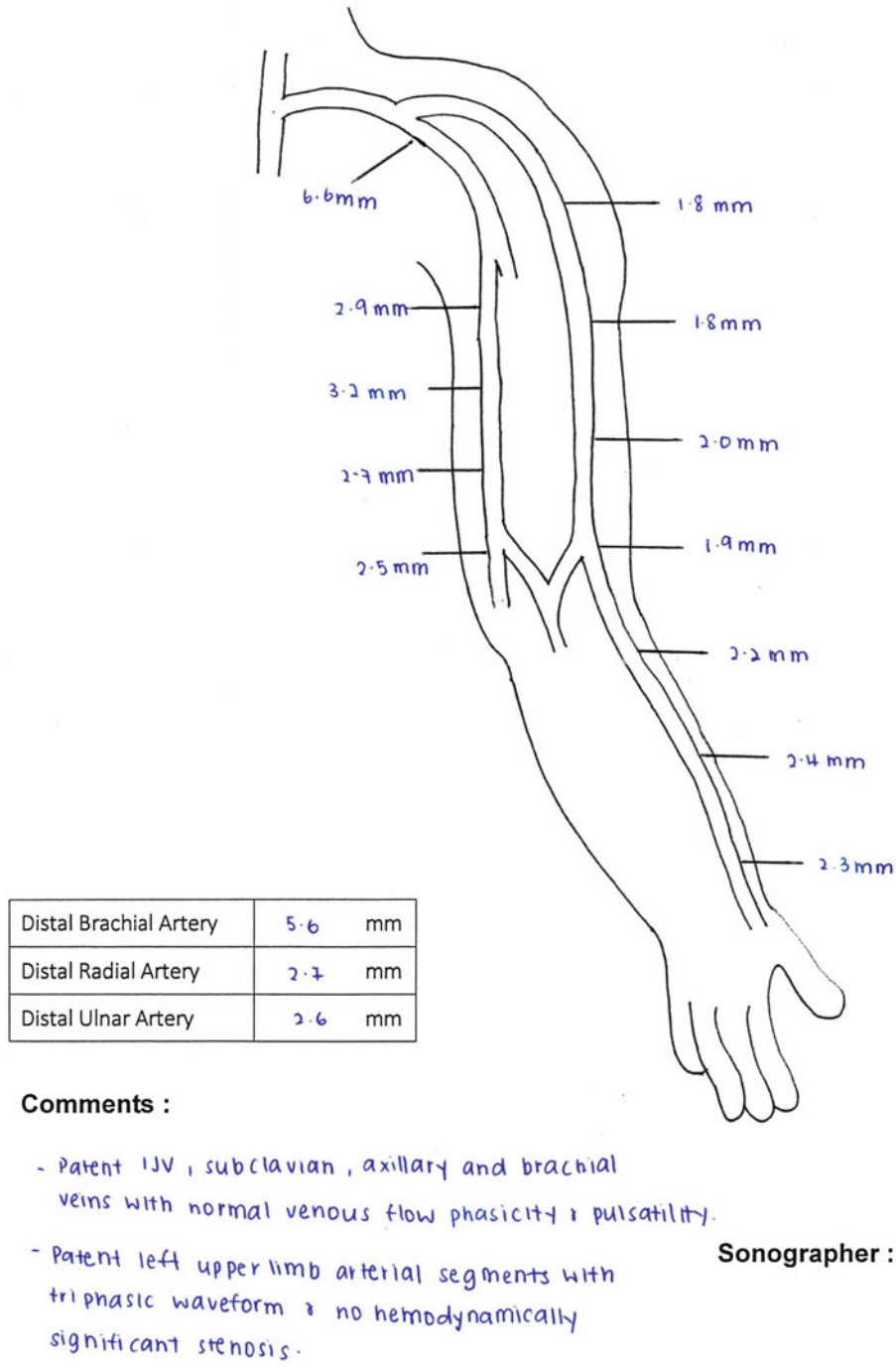

Fig. 35.1 Duplex ultrasound assessment of the arterial and venous system of ESRF patient before planning for HD access

and venous congestion 1.1 %. The synthetic graft used for AVG creation mostly are made of Polytetrafluoroethylene PTFE or expanded PTFE (ePTFE). Besides standard ePTFE graft, grafts with additional features including carbon lining (Carboflo, BARD Peripheral Vascular Inc. Tempe, AZ, USA), heparin bonded (Propaten, W. L. Gore & Associates, Inc. Flagstaff, AZ,

Table 35.1 Yearly percentage of AVG surgery among all HD access creation procedures in National University Health System

Year	AVF creation	AVG creation (%)	Total
2009	94	37 (28.2)	131
2010	236	79 (25.1)	315
2011	186	59 (24.1)	245
2012	246	78 (24.1)	324
2013	294	56 (16.0)	350
2014	268	52 (16.3)	320
Total	1324	361	1685

USA), composite graft construction with film lamination process (Flixene, Atrium Maquet Getinge group, Hudson, NH, USA) are commonly used. Biosynthetic graft Omniflow (LeMaitre Vascular, Inc. Burlington, MA, USA) is also available in Singapore. The limited experience with this biosynthetic graft in the author's institution did not show obvious patency or infection prevention superiority over ePTFE grafts.

Hemodialysis Access Monitoring and Surveillance

Both vascular surgeons and nephrologists share the role of monitoring the performance of HD accesses. The assessment includes clinical assessment and HD parameters review. Most HD centers provide the clinicians with blood flow rate Qb, arterial and venous pressure of three consecutive dialysis sessions before the follow-up day. The National Kidney Foundation (largest charitable organization for dialysis in Singapore) HD centers share one Doppler Ultrasound access flow machine to measure the access flow for HD patient once a month (Fig. 35.2). Most of the situations, a diagnosis of failing hemodialysis access and the need for salvage intervention can be made based on clinical findings and HD parameters. The more costly Duplex Ultrasound examination is reserved for patients with non-congruent clinical findings and dialysis parameters, or for patients high risk for diagnostic angiogram. Other complications of hemodialysis access including steal syndrome, pseudoaneurysm formation, skin erosion or access infection are also being monitored during clinical follow-ups.

Salvage of Failing and Failed Hemodialysis Access

Balloon angioplasty remains the most commonly adopted salvage modality for failing hemodialysis access with stenosis. Our retrospective review showed [5] a high technical success rate of salvaging failing accesses can be achieved with balloon angioplasty. The median time from initial access creation to first balloon angioplasty was 13 months (2–146 months) for AVFs and 8 months (2–71 months) for AVGs. However, recurrence of stenosis was common. 43.2 % of patients developed restenosis during the study period. Median time for restenosis or access failure was 11 months (1–18 months) for AVFs and 5 months (1–10 months) for AVGs. Kaplan–Meier analysis for overall access patency after endovascular intervention was 72 % patency at 6 months and 32 % at 12 months.

In Singapore, various clinicians had used simple angioplasty balloon, high pressure balloon, cutting/scoring balloon and drug coated balloon for failing HD accesses. Aftab et al. [6] conducted a randomized clinical trial on cutting balloon and high pressure balloon angioplasty for resistant stenotic lesions of HD accesses. Cutting balloon angioplasty provided significantly better primary as well as secondary target lesion patency rate than high pressure balloon angioplasty for resistant access lesions.

Bare metal stents and covered stents were used occasionally for recurrent resistant lesion or perforation after balloon angioplasty.

Practice in Hemodialysis Centers and Communication with Access Clinicians in Hospital

The HD accesses are created and salvaged in hospital but cannulation mostly occur in community HD centers. The care for the HD accesses will be

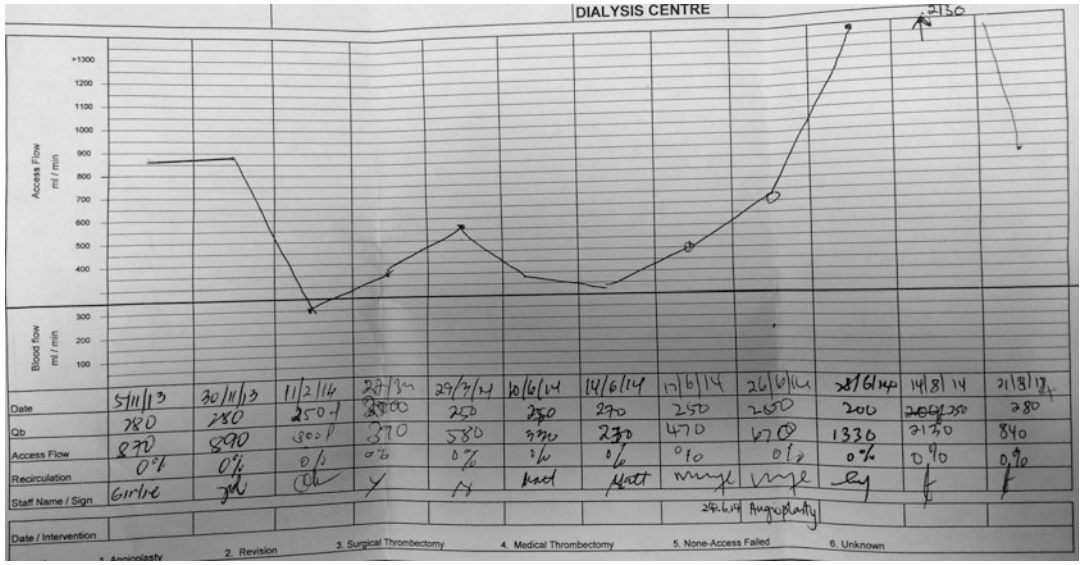

Fig. 35.2 Trend of access flow provided by the HD center to clinicians during patient's follow-up

fragmented if there is no good communication between the vascular surgeons, nephrologists in the hospital and HD nurses in the community. Nurse specialists for HD accesses play a very important role to fill in this communication and continuation of care gap. This nurse specialist becomes the first point of contact for HD nurses if a patient's access is noted to have problem. An early clinic follow-up or even access salvage procedure can be arranged in a speedy manner. The nurse specialist could help pulling the resources from medical social workers for patients with financial difficulty. The author's center started to have nurse specialist in HD access 4 years ago and sees tremendous improvement in service quality.

In Singapore, nearly all patients go to HD centers to receive hemodialysis 2–3 times a week. Only very few patients perform home hemodialysis. A team lead by the nephrologists, together with vascular surgeons and National Kidney Foundation members is exploring to develop home hemodialysis program. Currently, in the HD centers, majority of dialysis nurses adopt area cluster method to cannulate the HD accesses. Only a few perform step ladder method. A small number of clinicians and HD nurses know the proper way of forming button hole for AVF. Problems related to area cluster cannulation are frequently seen including stenosis, thrombus formation and pseudoaneurysm development. More education to encourage the practice of step ladder and button hole cannulation method is needed and more clinicians and nurses to acquire the technique of button hole cannulation is required especially if home hemodialysis program will be roll out.

Preservation of Native Veins for Hemodialysis Access

A healthy and reasonable size superficial vein in the forearm and arm is one of the major prerequisite for successful AVF creation. Many diabetics and CKD patients may have been admitted to the hospital for various illnesses or infections. Intravenous cannula insertion is frequently needed for medications or fluid infusion. Many a time, an intravenous cannula was set over patient's cephalic or antecubital vein. This will damage or thrombose the vein and prevent the use for AVF creation in the future. In all the public hospitals, nurses and junior doctors are responsible for setting up intravenous cannula for patients. Current teaching encourage them to set

Fig. 35.3 Bright color wrist band for CKD and ESRF patients to wear to remind the healthcare workers to avoid damaging the forearm and arm superficial veins

the cannula over the forearm rather than dorsal vein of hand to reduce pain. Nursing staff and junior doctors may also encounter difficulty setting a cannula over the dorsum of hand because of the loose and mobile skin overlying the vein. The author's institution is conducting a campaign to preserve forearm and arm vein for CKD and ESRF patients. A wrist band (Fig. 35.3) with an instruction "No needle, blood draws or blood pressure" on it pass to all CKD3–5 and HD patients to wear during clinic visit and hospital stay. These wrist bands serve to remind the healthcare workers not to traumatize the forearm and arm veins. Talks to nurses and junior medical staff are arranged to advocate preservation of cephalic and antecubital vein in CKD patients. Long term effort is required to raise the awareness and to change the practices of healthcare workers.

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Access for Hemodialysis in Australia

36

Anantha K. Ramanathan

Introduction

Australia has a population of 24 million people. In 2013, 2544 (110 per million) new patients required renal replacement therapy (RRT) in Australia. The prevalent number of patients on RRT is 21,470 (928 per million). At entry, 47 % had diabetes and 30 % had coronary artery disease [1]. Eighty percent of patients on dialysis were on haemodialysis [2]. Eighteen percent were referred late (less than 3 months before RRT) [1].

In 2013, the crude unadjusted death rate for these patients was 13.1 per 100 patient years. The 5 year survival ranged from 92 % for those less than 25 years at entry to 20 % for those over 85 at entry [3].

Dialysis access is important for the survival of these patients. And since 80 % are on haemodialysis, haemodialysis access is their lifeline them. The perils of long term central venous catheters are well documented [4]. The use of synthetic grafts is also not recommended. Therefore creating and maintaining an arterial venous fistula in a timely manner becomes very important. The vascular surgeon plays a pivotal role in this. This chapter will deal with hemodialysis access only.

It may not be as glamorous as aneurysm or carotid surgery but haemodialysis access surgery makes an important and vital difference to the lives of the patients. The success of access surgery is very much dependent on team work. The operation itself demands technical exactitude no less than that for a carotid endarterectomy.

Pre-operative Assessment

Early referral is desirable as it takes at least 2 months to create and have the fistula up and running. A thorough pre-operative assessment is necessary to plan the fistula. The side and site of the fistula need to be chosen.

History will include the details of the renal disease and the estimated length of time before the patient will need dialysis. Detailed medical history is necessary to evaluate fitness for haemodialysis, fitness for anesthesia and also to obtain clues as to possible technical difficulties. Hemodialysis does place a strain on the heart and patients with intractable heart failure may not be good candidates. Furthermore the patient should be able to sustain a reasonable cardiac output for the fistula to function.

The best artery and vein should be selected irrespective of the side. If the vessels are equivalent, it is preferable to start with the non-dominant side as this will enable the patient to use

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their dominant hands for other activity such as reading, while connected to the dialysis machine. Also having a fistula on the non-dominant side will facilitate self-cannulation and home dialysis.

Diabetes and connective tissue disorders may compromise the usability of the forearm arteries for AV fistulas. Previous access should also be taken into account. Previous central venous cannulation, especially subclavian vein lines, should be a trigger for careful evaluation of central veins. Previous mastectomy on the side is not a contraindication as long as there is no significant lymphedema. Previous radial artery harvest for coronary bypass should not be a contraindication for a brachial cephalic or brachial basilic fistula.

Clinical evaluation should include measuring blood pressures in both arms and Allen's test to determine the radial/ulnar dominance of blood supply to the hand as well as the integrity of the palmar arches. If the supply is overwhelmingly radial, it may not be a good idea to place a radial cephalic fistula at the wrist, as significant steal may occur. Similarly the surgeon should also be wary if the palmar arches are incomplete. Presence of visible large cephalic vein in the forearm is a good omen but it may also indicate thrombophlebitis. The vein should be compressible and be able to be emptied. Presence of collaterals in the chest wall or upper arm should prompt evaluation for central vein stenosis. Clinical evaluation is completed by physical examination of the patient looking for systemic and other vascular problems.

In our practice we always do a pre-operative duplex scan [5]. Duplex of the arteries should be done to exclude proximal problems, anatomical anomalies and to make sure there are no areas of stenosis in the subclavian, brachial, radial and ulnar arteries on the chosen side. Our practice is to evaluate the non-dominant side first and if this is not adequate, look at the other side. Anatomical anomalies such as high origin of radial artery do adversely affect the outcomes be it a radial cephalic or brachial cephalic fistula, in our experience. The arterial sizes and presence of calcification are noted.

One of the most important factors is the size and compressibility of the vein. The entire cephalic and basilic veins should be insonated. Skipping areas may result in narrowed or damaged segments of the veins being missed. We do not use a tourniquet but ensure that the room is warm and the arm is dependent.

Choice of Fistula

A good functioning radial cephalic fistula, when it works, is the best outcome the surgeon can hope for, as this is the fistula with the longest durability and least incidence of steal. However historically radial cephalic fistulas have a primary failure rate of up to 30% [6]. Unfortunately many of the patients who present to us do not have a suitable vein in the forearm, due to previous cannulation. This is also a reflection of how effective a vein preservation strategy has been implemented. Many surgeons will not even attempt a forearm fistula in elderly women, as the outcomes are poor in this sub group.

While many surgeons advocate that a brachial cephalic fistula should be tried before a brachial basilic fistula, we have a lower threshold for placing a brachial basilic fistula, should there be any query at all about the suitability of the upper arm cephalic vein. There are occasions where none of the above fistulas will be feasible. In these circumstances the surgeon needs to be innovative.

An ulnar basilic fistula has the disadvantage that the patient needs to have his or her arm bent and pronated during dialysis. Other options include brachial and mid forearm radial cephalic or median cephalic fistulas. These will need to be superficialized. Looped grafts in different configurations (forearm loop, upper arm), are used as last options.

Anesthesia

Having selected the site, the operation is performed under elective circumstances. While radial cephalic fistulas can be placed under local anesthesia, the upper arm fistulas will need regional or general anaesthesia, in our experience.

Technical Points

Loupe magnification should be used for all anastomoses.

AV fistulas require a dedicated surgeon who is meticulous and pays attention to detail. In our experience it is not about joining a vein and an artery. There are specific technical points relating to each of the fistulas. This chapter is not intended to be a detailed narrative of each operation but we will highlight a few points that we have found useful in our experience.

Radial Cephalic Fistula

We have no experience with snuff box fistulas. We do our operations at the wrist. We have described our technique elsewhere [7]. The patient's cephalic vein, if palpable or visible, is marked with the help of a tourniquet. The site of arterial pulse is also marked. The WHO check list is followed and a timeout is performed. The entire upper extremity is free draped and placed on an arm table. The surgeon sits on the medial side and the assistant on the lateral side.

If the case is being done under local anesthetic we use plain lignocaine 1 %, for infiltration along the incision line. Further infiltration may be necessary for the deeper tissues. The use of cautery near the branches of superficial radial nerve is painful and it is better to use scissors for dissection in this area.

Once the cephalic vein is identified, we mobilize 5–6 cm of the vein. Depending on the travel distance a longer segment may need to be mobilised. All branches of this swing segment are ligated and divided. There is usually a dorsal tributary of the cephalic vein that travels from the extensor aspect of the hand. Very often this tributary is larger than the continuation of the main cephalic vein from the hand which is frequently fibrosed from previous cannulation. The dorsal tributary may be used, provided the travel distance is not too much, as it diverges from the artery. Whichever tributary is used, the other should be ligated and divided, lest it becomes a tenting point or a fulcrum for rotation. The distal end of the vein is ligated but we do not transect the vein until the anastomosis is half done. A longitudinal venotomy is performed on the anteromedial aspect of the vein. The vein is flushed and checked for patency and then gently dilated using heparinized saline. The vein may need to be controlled with a small bull dog clamp if there is back bleeding.

The artery is located by incising the deep fascia. The branches are ligated or clipped in continuity and about 3 cm of the artery is mobilised to enable comfortable anastomosis. The branches of the vena commitantes are ligated as necessary. The distal control is obtained by snaring the artery with a Silastic vessel loop. Before proximal clamping of the artery, heparin 3000 units is given intravenously via the venotomy. As the vein swings towards the artery it should be placed superficial to any intervening branch of the radial nerve.

It is being increasingly recognized that the angle of incidence as the vein approaches the artery should be as small as practicable. There are other techniques that describe laying the vein parallel to, and over the artery [8].

Furthermore in our experience the biggest bugbear of the operation is rotation and twisting of the vein. To achieve a small angle of incidence and to avoid rotation, we lay the vein parallel to the artery and make a longitudinal arteriotomy, about 1.5 cm long. We use 6′0 or 7′0 prolene for the anastomosis. The anastomosis is commenced halfway on the lateral (far) side and proceeds towards the heel, in the manner of a side to side anastomosis (Fig. 36.1). We stop on the corre-

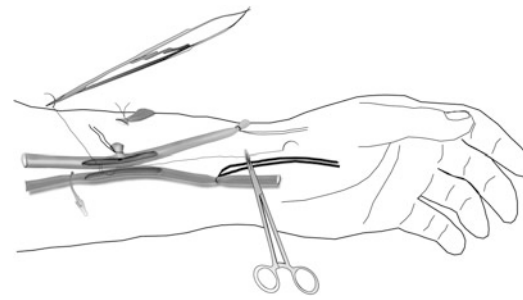

Fig. 36.1 Radial cephalic fistula 1. Distal vein is tied but not divided. The artery and the vein are lined up parallel to each other and the anastomosis is begun as with a side to side fistula, starting on the lateral side. The first throw is a horizontal mattress. Note the divided dorsal cephalic vein

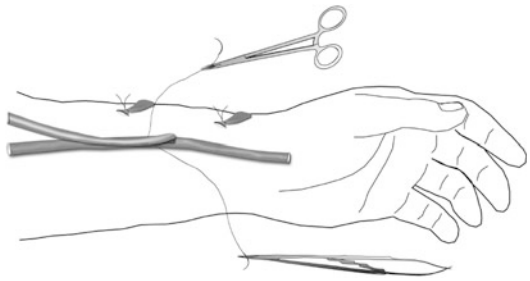

Fig. 36.2 Radial cephalic fistula 2. Suturing from inside, the anastomosis has progressed towards the medial side of the heel. The vein is now divided to appropriate size to form the hood

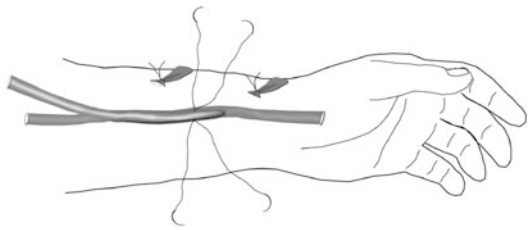

Fig. 36.3 Radial cephalic fistula 3. Another suture is begun (parachuted) from the toe to meet the first suture around the midpoint of the hood. Note the very small angle of incidence

sponding point on the medial side. At this point the vein is transected (Fig. 36.2) and the suturing commences from the toe (Fig. 36.3), using the parachuting technique. After completion of the anastomosis, if there is no thrill, the vein may have to be mobilised further and checked for rotation, missed branches etc. Haemostasis is achieved and the wound closed in layers. The distal circulation and patency of the fistula are checked before leaving the operating room.

The above technique has served us well, and provided the vein and artery are of good caliber, excellent results can be obtained.

Brachial Cephalic Fistula

We do this procedure under general or regional anesthesia. The arm is free draped after the time out formalities are completed.

We use a curvilinear incision starting medially in the elbow crease and curving upwards along the lateral border of the biceps muscle. Dissection in the subcutaneous tissue should progress carefully as the vein may be very superficial in the antecubital fossa.

Depending on the breadth of the elbow, the travel distance for the vein may be considerable. If the median cephalic and median basilic veins are of good caliber, they may be used. In that case the continuation of the forearm cephalic vein needs to be ligated and divided. We mobilise the cephalic vein generously so that the angle of incidence is acute and not perpendicular. The anterior aspect of the vein should be marked before dividing the vein, while it is in its natural lie. It is very easy to twist the vein. The vein is then divided checked for patency and gently dilated with heparinized saline. The vein may need to be controlled with a pair of bulldog clamps if there is troublesome back flow. The artery is then exposed by incising the bicipital aponeurosis. We aim to keep the entire anastomosis above the elbow crease and prepare the artery accordingly. The distal control is obtained by snaring while the proximal control is with bulldog clamps. The patient is given 3000 units of heparin before clamping.

An oblique arteriotomy running from superolateral to inferomedial will help to align the anastomosis to the direction of approach of the vein and hence minimise tension.

We use two polypropylene sutures starting from the heel and toe respectively, to complete the anastomosis. The toe is parachuted.

If there is no thrill, the vein should be examined for rotation, twisting, tenting, and for missed branches.

The operation is completed by achieving hemostasis and by closure in layers.

Brachial Basilic Fistula

We have moved away from one stage procedures and now advocate two staged basilic vein fistulas, although the evidence to support this is lacking in the literature [9]. The first stage is similar to brachial cephalic fistulas but the vein is closer to the artery and therefore does not need much

mobilization. In fact it is good to keep the tissue dissection as little as possible because the second stage operation becomes easier if there is less scarring.

The Achilles heel of this operation is the twisting of the vein and in our experience an arterialised vein is less likely to twist in the second stage. We leave 4–6 weeks between the two stages.

The second stage becomes easier if the vein is marked preoperatively using duplex scan, especially in the obese patients. The duplex scan will also diagnose any stenoses which can be addressed at the time of stage two.

The basilic vein needs to be brought to the surface. This can be achieved by superficialization or transposition. In superficialization the vein is placed in a subcutaneous shelf. In transposition the vein is placed in a subcutaneous tunnel. The latter will require a counter incision on the lateral aspect of the arm, overlying the biceps muscle.

We prefer to transpose the vein unless the patient is obese.

In transposition the entire basilic vein in the arm is mobilized and after marking, divided close to the original brachiocephalic anastomosis. A soft arterial clamp is used for proximal clamping, after administering 3000 units of heparin intravenously.

The branches of the medial cutaneous nerve of the forearm wrap around the basilic vein. The nerve branches can be preserved and the vein extricated from amidst them after transection near the anastomosis. The vein is then placed in a subcutaneous tunnel. A counter incision is required laterally. At every stage of tunnelling (i.e., to counter incision and then to the antecubital fossa) we gently pass an inflated size 3 Fogarty catheter in the direction of valves, thus ensuring that there is no twisting.

In obese patients there may not be enough length of the vein to "transpose" the vein. In these cases the vein is placed in a subcutaneous shelf. This necessitates one of the branches of the medial cutaneous nerve of the forearm to be divided. The patients should be pre-warned of the possibility of having numb patches in the forearm.

Arterial Venous Grafts

We seldom use synthetic grafts but sometimes we run out of other options and are forced to use them. In obese patients a forearm looped graft may be a good option before a brachial cephalic or basilic fistula simply because the graft may be easier to palpate and cannulate and obviates the need for superficialization of autologous fistulas. When the graft eventually fails there will be an arterialised vein that can be superficialized easier. The venous anastomosis can be done to the cephalic, basilic or brachial vein, whichever is most suitable on preoperative imaging.

When we run out of arm veins eventually we use a brachial artery to axillary vein graft, provided there is no central vein stenosis.

We find that externally supported heparin bonded grafts work best in our hands.

Once we exhaust all our options in the upper extremity we reluctantly place thigh looped AV grafts.

Results

The immediate results are usually good provided the appropriate vein and artery are selected and meticulous attention is paid to technical aspects. Our immediate patency rates are in excess of 90%. But immediate patency does not always translate into maturation. Historically 30% of radial cephalic fistulas fail primarily, as we saw earlier. These may need further procedures to facilitate maturation. We do not routinely do balloon assisted maturation (BAM) [10] but all fistulas that are not matured by 6 weeks are assessed with a duplex scan. Focal stenoses are easy to treat but a vein that is diffusely stenosed from early stages is unlikely to ever get better and it may be more appropriate to abandon the fistula and look for a new site. We do not routinely ligate branches but occasionally we ligate (or embolize) large accessory veins if the duplex scan shows significant flow in them.

The patency rates differ according to the type of fistula and from center to center depending on local practices, not the least being a clear vein

preservation strategy. Excellent assisted primary patency rates can be obtained if the fistulas are monitored and intervened on early when there are problems. Functional monitoring at dialysis alone does not always detect developing stenosis [11]. Duplex scan surveillance is not recommended in mainstream guidelines but we have had numerous instances where hemodynamically significant stenoses do not cause changes in dialysis parameters until quite late. It is our view that fistulas should undergo periodic surveillance duplex scans.

Problems in Fistulas

Stenosis and or Thrombosis in Fistulas

Mickley classified fistula stenoses according to the site of the stenosis [12]. Juxta anastomotic (Type I) stenosis is the commonest (up to 70 % of all stenoses). Needling segment stenosis (Type II) is the next common site. Cephalic arch stenosis (Type III) is an area which is difficult to treat. Further to this classification another area of stenosis is central venous stenosis.

Juxta anastomotic stenoses are further classified by Long et al as types (a) Venous side, (b) Anastomotic and (c) Arterial side [13]. In our experience arterial and anastomotic stenoses are rare. Venous side stenoses are the commonest type of juxta anastomotic stenosis.

Treatment of Stenosis

The initial treatment should be endovascular. The advantage is that the fistula can be used for dialysis soon after. We have a low threshold for doing fistulograms. A preoperative duplex mapping of fistulas is essential. This helps to plan the site of puncture and the direction of approach. First line treatment is balloon angioplasty. However recurrent stenoses are common after angioplasty. Drug eluting balloons may help obtain longer patency. High pressure (semi compliant) and cutting balloons are useful in overcoming fibrotic stenoses. Recalcitrant stenoses should be treated by stenting or surgical correction. Self-expanding nitinol stents can be punctured for dialysis safely. We acknowledge that this is a contentious issue. We have no experience with covered stents except in bail out situations where the fistula has been ruptured by the angioplasty.

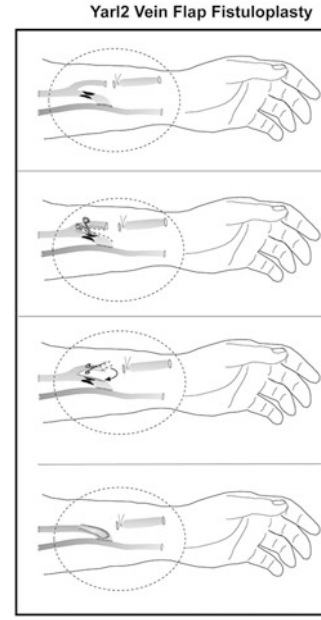

Fig. 36.4 Yarl 2 fistuloplasty. The vein and a suitably placed branch have been dissected out. The vein and the branch are divided along the dotted line (the angle of the Y/ the crotch of a trouser). Note that the venotomy should go beyond the stenosed segment of the vein. The Y becomes an I with a fatter upper half, and the trouser becomes a skirt. The stenosis is corrected (Reproduced with permission from Annals of Royal College of Surgeons of England)

Surgical correction gives longer lasting results. The techniques include proximalization, interposition grafts, flaps and patches. The surgeon should be prepared to innovate and we have described various surgical techniques for fistula correction [14, 15] (Fig. 36.4). Surgical treatment is an attractive option especially in thrombosed fistulas with a large clot load because thrombectomy may be necessary at the same time.

Juxta anastomotic stenoses and cephalic arch stenoses pose difficult challenges for treatment. Results of balloon angioplasty are poor in these situations. Use of stents in these T junctions will require the stent to straddle the T and jail the distal limb (of the distal radial artery or axillary vein).

We have successfully stented the anastomosis in radial cephalic fistulas but we do not do the same for brachial cephalic fistulas.

Central vein stenosis is another difficult problem. We try to avoid stenting in this area. The stents may be crushed between the clavicle and the first rib. But this may necessitate redo angioplasties frequently.

Treatment of Thrombosis

When there is a large burden of thrombus, our practice is to do a surgical thrombectomy and correct the underlying stenosis by endovascular or open correction. We do not have experience with thrombolysis or percutaneous thrombus removing devices in this scenario. Pre-operative imaging and surgical judgement should be used to plan the exposure and fistulotomy carefully. Many times the fistulotomy can be used to correct the underlying stenosis if planned well. Often there is more than one area of stenosis in a fistula that thromboses. The entire vein should be imaged intra operatively. This requires careful planning of the orientation of the arm table etc, unless there is access to a hybrid operating room. Fistulas with a small clot burden may be managed percutaneously.

Steal

Steal is a vast topic and is beyond the scope of this chapter. Fortunately significant steal is uncommon. Patients with steal should have the fistula flow checked and be evaluated for proximal and distal arterial disease. Arterial inflow stenoses can be treated endovascularly. In many of these patients the forearm arteries are compromised due to diabetes or connective tissue disorders. These may be amenable for endovascular treatment at the same time as a restrictive procedure such as Miller procedure. Other options include DRIL (distal revascularization interval ligation), RUDI (revision using distal inflow), and PAI (proximalization of arterial inflow). We have not had to sacrifice a fistula for steal yet.

Aneurysm

Aneurysmal dilatation is not uncommon in fistulas that have been used for some time. There is usually an underlying stenosis before or after the aneurysmal segment and this needs correction. The aneurysm itself can be treated with reductive surgical plication or covered stent placement.

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Hemodialysis Access Management in China

37

Zhidong Ye and Xueqiang Fan

The Current Condition of CKD in China

Rapid economic development, lifestyle changes and more aging population in China have led to higher incidence and morbidity of chronic disease in the past 30 years. Chronic kidney disease (CKD) is one of these examples. The statistics show that the incidence in China has reached 10.8 % with notable differences among regions. The incidence in the north (16.9 %) and the southwest (18.3 %) is higher than that of any other regions in China. It is estimated that there are about 119.5 million patients with CKD, but only 12.5 % of them aware of that, of which approximately 2 % (2–3 million) of CKD patients suffer from end-stage renal disease (ESRD) which requires hemodialysis [1].

In the past 10 years, the increasing incidence of hypertension, obesity, type 2 diabetes mellitus and environmental factors have exacerbated the burden of CKD in China [2–3]. Data from the Chinese Renal Data System, a national registry system for patients undergoing dialysis reveals that glomerular disease (57.4 %) is the most common cause of ESRD, followed by diabetic nephropathy (16.4 %), hypertension (10.5 %), and cystic kidney disease (3.5 %). However, a shift in the epidemiology of kidney disease has been reported in China. The leading causes of CKD among elderly Chinese patients are diabetes mellitus and hypertension, rather than glomerular disease. Moreover, it is possible that the prevalence of diabetic nephropathy in China will continue to rise, given the rapid increase in the prevalence of diabetes mellitus in this country [4]. The registry number in Beijing and Shanghai of ESRD on maintenance hemodialysis (MHD) was 107.3 and 114.8 per million people (PMP) in 2011. The mean age of patients with MHD becomes older. Cardiovascular and cerebrovascular events are the leading cause of death in those patients, and death due to infection decreased.

The Burden of HD in China

Hemodialysis, as a primary and effective treatment for ESRD patients, is a great challenge for individual and public health system due to the huge financial burden [5]. A survey by the Chinese Society of Blood Purification estimated that the prevalence of patients with ESRD on maintenance hemodialysis or peritoneal dialysis was 71.9 per million population (PMP) in mainland China in 2008, with an annual growth rate of 52.9 %. In Taiwan, the prevalence of patients with ESRD on dialysis reached 2584 PMP in 2010, whereas rates of 1106 PMP and 1870 PMP

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were reported in Hong Kong and the USA, respectively. The lower rate was largely due to unaffordable health care, especially in rural regions. These issues are currently being resolved according to the new Chinese health reform strategy. The government aims to expand health insurance to cover more chronic and critical diseases, focusing on reducing the financial burden for the individual patient. ESRD was among the list of major diseases control in 2012, which could promote and improve the life quality of hemodialysis patients in China.The medical insurance system in China includes three parts: 1. The basic medical insurance for urban workers both in cities and towns; 2. The basic medical insurance for urban residents, which covers all children, students and elderly people without employment; 3. The New Cooperative Medical Scheme (NCMS), which covers all residents of rural regions. By 2011, more than 1.3 billion people had joined the three basic medical insurance systems, and the total coverage rate increased from 87 % in 2008 up to 95 % in 2011. Both hemodialysis and peritoneal dialysis are covered by the three basic medical insurance systems, but the rate of reimbursement varies from 50 to 90 % according to different regions and socio-economic development [6].

Hemodialysis Centers and Access Usage in China

The distribution of hemodialysis centers in China are not balanced. Centers are more popular in developed areas, such as east and south regions and metropolises like Beijing, Shanghai, Guangzhou etc. However, the situation of unbalanced distribution of hemodialysis centers and improper access selection have improved a lot due to the publication of hemodialysis management guideline of Chinese medical instructions, which was issued by the Ministry of Health of the PRC in 2010.

At present, no specialist is specialized for the establishment of hemodialysis access in China. Many doctors including nephrologist, vascular surgeons, urologists, orthopedic surgeons, microsurgery doctors and cardiac surgeons can perform the operation. The lack of specially trained physician team for creating access is one of the main reasons for varied outcomes between various regions.

The first hemodialysis access selection for hemodialysis patients varies widely in different hemodialysis centers [7–10]: In Shanxi Province, the ratio of autogenous arteriovenous fistula (AVF) for the first dialysis access is 41.2 % and non-tunneled catheter (NTC) or non-cuffed catheter (NCC) is 53.3 %. In Shanghai Changzheng Hospital, the ratio of NTC/NCC for the initial dialysis access among the 667 patients is 81.2 %, tunneled cuffed (TCC) is 4.20 % and AVF is 14.54. As for the 435 MHD patients, the ratio of AVF is 83.91 %, TCC is 13.56 %, NTC/NCC is 1.84 %, and the arteriovenous fistula graft (AVG) is only 0.69 %. In Beijing, the ratio of AVF in initial dialysis patients ranges from 21 to 30.2 %. The single-center data in Shenzhen shows that the ratio of AVF is 95.23 %, TCC is 3.40 %, NTC/NCC is 0.68 %, AVG is 0.68 %. Another single-center data in Zhejiang Province shows that only 73 patients (8.73 %) use AVF as the vascular access for the first dialysis, the rest of 763 patients (91.27 %) use central venous catheter. Six months later after dialysis, 542 patients (81.5 %) use AVF as permanent vascular access, 123 patients (18.5 %) use TCC and 55 patients have converted to peritoneal dialysis.

The lower application rate of AVF on initial HD patients is affected by many factors, such as no formal follow-up for CKD patients by nephrologist more than one year and whether the patient has been advised to create AVF in advance [11]. Literature shows a high AVF application on nephrology patients who are followed up over 4 months than those who are followed up less than 1 month. The rate of AVF application in patients whose follow-up period is more than 12 months, is higher than that of the period between 3 and 12 months. The longer follow-up period the higher AVF utilization, and multivariate analysis also shows the earlier follow-up the higher AVF application. In addition, the education of dialysis access to the nephrology patients (especially CKD 4 patients)

is very important for AVF utilization in the initial dialysis. The awareness of CKD patients and the rate of receiving formal medical treatment are lower in China. Most patients have already reached the stage of uremia when they come to the hospital for the first time. Meanwhile, the etiology for the ESKD patients is DM and hypertension, therefore, the patients generally will ask for help from the outpatient department of endocrinology, cardiology and traditional Chinese medicine instead of from nephrologist. As a result, the current situation remains that the patients hardly receive any follow-up or advice of creating an AVF in advance by nephrologists.

The hemodialysis access, such as AVF, AVG and central venous catheter (NTC and TCC) are all available in China. According to K-DOQI, CPM, FFI guidelines, the first choice and recommendation is AVF, followed by AVG, and the final choice is central venous catheter. The lower ratio of AVF maturation and application is affected by many factors, such as the poor follow-up on ESRD patients, unbalanced technique in access creation between regions and doctors, as well as high incidence of diabetes and peripheral vascular disease (PAD). A consensus reached by Chinese experts about hemodialysis access was published in 2014 [12], aiming to improve the patients' awareness and standardize the application. The target proportion of AVF usage is over 60 % in the initial dialysis patients, over 80 % in MHD patients.

Chinese Experts Consensus on Hemodialysis Access in China: Timing of Surgery

Recommendation 1. Patients should receive a variety of healthy information about renal replacement therapy, including kidney transplantation, when GFR < 30 mL/min/1.73 m^2 (CKD4, MDRD formula). 2. GFR < 15 mL/min/1.73 m^2, serum creatinine >6 mg/dl (528 μmol/L) (GFR < 25 mL/min/1.73 m^2, serum creatinine >4 mg/dl (352 μmol/L) in diabetics), patients should take hemodialysis as renal replacement therapy, and are expected to accept dialysis in the next 6 months, AVF should be performed. However, AVG can be postponed to 3–6 weeks before dialysis. 3. Patients who have severe symptoms and have difficulty to control with support treatment should create AVF as soon as possible; residual renal function is not a necessary indicator.

Evaluation

Detailed preoperative examination is of great importance for fistula maturation. Previous central venous catheters or pacemaker placement is associated with significant incidence of central venous stenosis. A history of arterial punctures may have caused vascular injury. Advanced age and diabetes patients with peripheral artery disease are at increased risk of hand ischemia after access creation. Preoperative ultrasound will be helpful for patients with poor vessels condition. However, if the Doppler exam is not conclusive, venogram is indicated for those cases.

Surgical Approach

Local anesthesia injection (1 % lidocaine) is the preferred modality for AVF, and axillary block for AVG. According the guideline, AVF is first-line recommended, followed by AVG. The most practical anastomosis site for AVF is cephalic vein–radial artery end-side anastomosis, followed by basilic arteriovenous fistula, and cubital–brachial artery fistula. The principle of location is upper extremity priority to lower, distal priority to proximal, non-dominant priority to dominant arm.Fistula established on arm: wrist AVF is the first choice, then AVF on forearm (cephalic-radial, transposition of basilic vein to radial artery, transposition of basilic vein to brachial artery, transposition of cephalic vein to brachial artery), the final is AVF on elbow (brachial–cephalic, brachial–basilic, brachial–antecubital). Any type of AVG can be performed after bilateral forearm venous depletion. The forearm commends firstly because of the enlargement venous on upper arm is helpful for the upper arm AVG.

Standards of Fistula Maturation and Judgment

The definition of AVF maturation is easy to puncture with minimal bleeding risk and can provide sufficient blood flow during the entire process, and can also withstand more than three times a week puncture for dialysis. Inadequate blood flow is defined as: the pump control blood flow is less than 200 ml/min in dialysis. The judgment of maturation: Physical examination: thrill well at anastomotic site, no enhancement, weakening or disappearance; the shape of fistula vein goes straight lines, superficial, easy to puncture, sufficient area for puncture, and good elasticity of fistula vascular wall. Natural blood flow over 500 ml/min, the inner diameter greater than 5 mm, the depth from skin less than 6 mm.

Timing and Method of Access Puncture

It is recommended to puncture 8–12 weeks after surgery, at least 1 month after the fistula mature. Note the aseptic principle when doing dialysis. The order of puncture is from the distal to proximal, with stepped or button-type puncture method and avoid the anastomosis area. Needle selection: in the initial stage, it is recommended to use a small (17 G) needle and a lower blood flow (180–200 ml/min). After the dialysis, immediately perform compression when the needle comes completely out, with pressure adjusted to maintain a balance between the thrill and bleeding. Usually puncture the access graft at 2–3 weeks after surgery and the local swelling is subsided; before puncture, the configuration, thrill and palpation should be confirmed. If possible, recommend 3–6 weeks after the procedure to do a puncture. Direction of flow in synthetic grafts should be determined, the needle direction of "pull" and "return" are all to the apex. The main problem within the fistula is the lower proportion of maturation. One of the reasons is the high ratio of central venous catheterization (CVC) in ESRD patients due to subjective or objective factors. The early complications of fistula are often related to surgical/technical factors, including thrombosis, bleeding, infection, hand ischemia and paresthesia from nerve injury during the procedure. Late complications are related to dialysis practice and needle puncture. The most common are vascular stenosis, thrombosis, infection, false/true aneurysm, and swollen hand syndrome, and seldomly high-output heart failure [13]. Postoperative Doppler examination is very important for detection of complications. Stenosis often occurs in or near an anastomosis, previous intravenous catheter sites, and repeated puncture points. PTA as an innovative treatment can relieve the stenosis and prolong the life of fistula. Recently reported from the literature, balloon angioplasty also can promote fistula maturation. Thrombosis can occur at any level of the vein. It often starts at a stenosis or aneurysm site, if it locates at the anastomosis and the proximal vein is still open, re-creation of the fistula a few centimeters up from the anastomosis site is the usual practice. Also it can be declotted and the stenosis corrected with a patch or interposition graft. Anti-platelet drugs are helpful for the prevention of thrombosis, research shows more than 1 year duration aspirin can reduce the risk of fistula dysfunction, another shows that clopidogrel may reduce 37 % fistula thrombosis [14]. The incidence of ischemia in AVF is 19.7 %, mainly is grade I ischemia (71.4 %), mostly can be recovered after conservative treatment. However, the reason is not clear, maybe it relates to the advanced age, women, smoking, diabetes, hypertension, and high location fistula.

Arteriovenous Graft (AVG)

The proportion of AVG access ranges from 0.68 to 5 % in various dialysis centers in China. Most dialysis physicians take NCC/TCC as the second choice for patients who do not have suitable vein for AVF. Although many types of grafts are available, including autologous, allogeneic, xenograft and artificial vessels, ePTFE is still the preferred graft in practice. Most procedures of AVG are performed in big hospital by vascular surgeons. The guidelines of NKF-KDOQI suggest graft access shall be created at 3–6 weeks before dialysis,

as the maturity period is not more than 4 weeks. The condition in China is that most patients have accepted CVC in initial dialysis, thus leading injury to the central vein and also high percentage of central venous stenosis. If a subclavian stenosis is demonstrated or suspected, venogram should be performed to determine the extent of the process. The AVG creation in hybrid operating room is necessary for those patients, the inflow and outflow can be detected and deal with by endovascular techniques, thus improving the long-term patency rate of grafts.

The common complications of AVG are thrombosis and stenosis. They are also the main causes for graft dysfunction. Thrombosis can be classified into two types, early and late thrombosis, according to the time of post procedure. Less than 14 days is defined as early thrombosis, which is related to the patients' characteristics (hypotension, diarrhea, dehydration, diabetes, advanced age) and dialysis early. Thrombolysis can be used when rule out the curved graft, sometimes should combine with PTA in venous anastomosis. Thrombectomy is a routine treatment, an approach through a small transverse incision on graft by a 5.5 or 6 F Fogarty catheter.

Late thrombosis is the most common complication after 6 months, and mostly accompanied by venous site stenosis. Only 50–60% of grafts are patent in 2 years. The conventional practice is a hybrid procedure with Fogarty catheter and endovascular therapy. With the development of equipment, some cases can be finished totally under endovascular treatment. The different intervention methods will lead to different clinical outcomes. The present study shows that stent-graft is superior to bare-metal stent, and bare-metal stent is superior to balloon angioplasty. High-pressure balloon and cutting balloon angioplasty are better than conventional balloon, because of the significantly intimal hyperplasia in anastomosis point. Another common complication can cause graft loss is infection. The incidence is about 5–20%. Women, diabetes, repeated fistula on the same limb are the risk factors. The outcome of antibiotic treatment is not satisfactory, mostly the artificial vessels need to be removed completely.

Central Venous Catheter

The indications of CVC for dialysis in guidelines from Chinese Society of Nephrology (CSN) is described as below: ESRD patients requires dialysis immediately, but the AVF is not mature or scheduled for AVF surgery; patients with temporary catheter and no suitable vein for fistula creation; patients who have exhausted all other access options; patients with poor heart function and unable to tolerate any kinds fistula; patients who have received peritoneal dialysis, but have to stop temporarily for some reasons, and use it as a temporary method during the transition period; patients with severe system disorders or limited life expectancy.

Central venous catheters are defined as non-tunneled catheter (NTC) or non-cuffed catheter (NCC) and tunneled cuffed catheter (TCC), corresponding to the previous temporary and permanent catheter. Guidelines recommend NTC/NCC as a temporary catheter in the jugular vein that should be kept less than 4 weeks, in the femoral vein less than 1 week, and it can prolong to 2–4 weeks for ambulatory patients. If the expected dialysis is more than 4 weeks, TCC is recommended. The ultrasound is used to identify the target vein and puncture site. The procedure is performed under local anesthesia with the Seldinger technique, with the order of puncture vein is right internal jugular vein—left internal jugular vein—right femoral vein—left femoral vein. The desired catheter tip is located at 1/3 of right atrium, and the surface marker on skin is parasternal intercostal 3 and 4.

Catheter-related complications include infection, thrombosis, central vein stenosis, and fibrin sheath formation. The most common is catheter-related infections when the catheter is present for over 7 days, the probability of infection is higher in TCC than NTC/NCC, higher in femoral vein than in jugular vein. There are different degrees and severity catheter infections based on clinical findings, patients with low grade fever, occasional chills, especially during dialysis, are likely to present an intraluminal infection, and treated with antibiotics and catheter exchange using a

new exit site. Patients with symptoms and in addition a red, inflamed exit site or tender catheter tract would be removed. Another common complication of the catheter is central vein stenosis and thrombosis, directly thrombolysis or catheter thrombolysis and intervention are helpful to recover the conduit flow. Catheter-related venous stenosis is a tough problem due to the loss of the chance of fistula creation on the limb. Endovascular therapy (PTA, stenting) is the popular method to keep vessel patency.

Summary

China has a large population and a high prevalence of chronic kidney disease (CKD). The increasing incidence of hypertension, obesity, type 2 diabetes mellitus and environmental factors have exacerbated the burden and have changed the etiology of CKD in China. The creation and application of hemodialysis access indicate significant differences from region to region, but generally the current situation can be concluded that central venous catheters are more popular than AVF, which is caused by low follow-up rates and few patients having been informed about HD access in advance; however, such controllable factors can be changed through effort. Moreover, many doctors can perform dialysis, including dialysis physicians, vascular surgeons, microsurgery doctors, urologists, etc., but still there is not a uniform standard about the creation of hemodialysis access, thus leading to the heterogeneity in the quality of fistulae. A consensus reached by Chinese experts about hemodialysis access was published in 2014, aiming to establish a professional team on medical, nursing, access healthcare and management, bringing benefit for the ESRD patients.

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Hemodialysis Access in North America

38

Shipra Arya, Sidd Dalal, and Luke P. Brewster

Introduction

End Stage Renal Disease (ESRD) is a devastating disease affecting the health of many people worldwide. The primary goal of therapy for patients with ESRD is to maintain health throughout their life. The most effective therapy for ESRD is renal transplantation. Alternatively there are two modes of renal replacement therapy (RRT), peritoneal and hemodialysis. Peritoneal dialysis can be an excellent option for patients who have not undergone major abdominal operations, but does require wherewithal to perform peritoneal dialysis nightly. In North America many vascular surgeons do not perform placement of peritoneal dialysis catheters and as such this chapter will focus on hemodialysis.

Epidemiology of End Stage Renal Disease in North America

It is estimated that at the end of 2012 there were 636,905 prevalent cases of ESRD in the United States [1]. Since 1972, the diagnosis of ESRD has enabled all persons to apply for Medicare insurance in the United States (https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/Downloads/ESRDNWBackgrounder-Jun12.pdf). Patients with ESRD comprise 1.3 % of all Medicare beneficiaries, with the cost of coverage consuming 7.9 % of the Medicare budget [2]. In 2014, there were ~17,000 kidney transplants in the United States with ~5500 coming from living donors (http://optn.transplant.hrsa.gov/). Given the significant impact on resources, the United States Renal Data System (USRDS) was created to keep track of both patients and treatment outcomes. In North America, diabetes and hypertension are the two leading causes of ESRD and mirror the incipient morbid obesity and diabetes epidemics. There has also been an increase in atherosclerotic renovascular disease, which is associated with the general aging of the United States' population [3].

ESRD in Canada is covered for all citizens through healthcare plans offered by each province; this universal coverage may play a role in the relatively low prevalence of ESRD (0.1 %) [4]. Still the highest risk of developing ESRD is due to diabetes [5], and the costs of care for ESRD approaches $1.9 billion dollars [6]. The rate of kidney transplants is ~2/3 that of the United States [7]. There are also fewer dialysis stations in Canada compared to the United States, which translates into a higher rate of usage for home hemodialysis and peritoneal dialysis. While nephrologists see ~85 % of patients for

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more than 1 month prior to starting hemodialysis, central venous catheter (CVC) use approximates 33 % in established dialysis patients and 70 % in new patients [5]. This may be caused by the length of time from referral until permanent vascular access creation, which is 61.7 days compared with 29.4 days in Europe or 16 days in the United States [5].

Mexico has the second largest population in Latin America, and while there is no nationalized data agency, regional resources approximate that 109,000 individuals (out of a population of 112 million persons) receive RRT for ESRD [8]. In Mexico, the per capita income has doubled in the last decade, which has increased the average lifespan of its population [9]. Not surprisingly, this has led to a fivefold increase in the number of persons on RRT. The kidney transplantation population is relatively modest at 12,000 patients with functioning transplants. Peritoneal dialysis is used by 55 % of patients receiving RRT, but in recent years hemodialysis has become more common, and hemodialysis is now the most common RRT for persons with ESRD currently in Mexico. As of 2003, ~15 % of the population had access to private insurance, which does not limit access to RRT. The remainder of the population is subject to health care expenditure capitation, which can severely limit access to RRT. [9] These disparities are well documented and part of an ongoing social policy discussion [10].

Unique Populations

Children and the Homeless are unique populations world-wide that deserve particular attention in the United States, where healthcare access has considerable variability amongst its citizens.

Children

The prevalence of children with ESRD is increasing, and children with Chronic Kidney Disease (CKD) have been noted to have mortality rates 30–150 times higher than that of the general pediatric population [11, 12]. Cardiovascular disease, specifically hypertension, plays a predominate role in the morbidity rates of the pediatric population. Most commonly CVCs are the first choice of treatment for short-term dialysis, while children are waiting for renal transplant. As in the adult population, CVCs should only be considered for short-term dialysis needs, while arteriovenous fistulas (AVF) should be pursued when feasible for longer term dialysis needs [13].

Homeless Individuals

Homeless individuals are part of the fabric of North America and Europe, and their incorporation into health care systems is fragmented [14]. Since the divestment of resources to mental healthcare during the 1980s, there has been a significant growth in the number and diversity of homeless individuals in the United States [15]. The lack of integration into healthcare systems in the homeless population complicates the quality of care and resource utilization for this population. Thus, homeless patients often present with advanced renal failure, leading to urgent interventions, and CKD is considered a prominent predictor of mortality in the homeless population, as it is associated with various comorbidities [16]. The intermittent and transitory nature of medical care for homeless persons makes the quality of care very challenging. However in exceptional situations and with appropriate coordination of patients with transportation, RRT can be accomplished [16].

Vascular Access

Motivation to Improve Quality

The USRDS was formed in 1989 to report demographics of ESRD and its effect on patients [17]. In response to a significantly disproportionate number of arteriovenous grafts (AVG) compared to AVFs during the 1990s, the National Kidney Foundation established the Vascular Access Working Group, from which the Dialysis

Table 38.1 Summary of DOQI guidelines

Summary of National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI)™ 2006 vascular access guidelines for functional permanent access at the initiation of dialysis therapy
1. Patients should have a functional permanent access at the initiation of dialysis therapy.
1.a. A fistula should be placed at least 6 months before the anticipated start of HD treatments.
This timing allows for access evaluation and additional time for revision to ensure a working fistula is available at initiation of dialysis therapy.
1.b. A graft should, in most cases, be placed at least 3–6 weeks before the anticipated start of HD therapy.
Some newer graft materials (Acuseal®) may be cannulated immediately after placement.
1.c. A peritoneal dialysis (PD) catheter ideally should be placed at least 2 weeks before the anticipated start of dialysis treatments.
A backup HD access does not need to be placed in most patients. A PD catheter may be used as a bridge for a fistula in "appropriate" patients.

Adapted from [21]

Outcome Quality Initiative (DOQI) guidelines were established [18–20] Table 38.1

The major finding of this group as it relates to access surgeons was that the number of AVFs in the United States was unjustifiably low. From this work the Fistula First Breakthrough Initiative (FFBI) was established jointly by the Centers for Medicare and Medicaid Services (CMS) to increase the prevalence of AVFs to 66 % by 2009 [22]. Subsequent to these initiatives, survival trends in patients with ESRD have improved with mortality rates decreasing by 16 % after the first year and 51 % living an extra 3 years [2].

Beginning in 2014, this reporting to CMS included quality measures that could negatively impact overall reimbursement up to 2 % (www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/esrdqip/index.html). Currently in the United States, our nephrology colleagues shoulder the reporting on quality initiatives to payers. However given the opportunity for improvement in the care of patients using hemodialysis, the integration of all members of hemodialysis teams that provide hemodialysis access and maintenance for patients with ESRD may be useful in improving quality metrics, such as decreasing CVC days in these patients [23].

Preoperative Evaluation

Fistula maturation remains a major issue for hemodialysis patients. A recent Canadian study compared cumulative patency of fistulas and grafts from 2000 to 2010. They reported a primary fistula failure rate of 40 % in their series [24], and for subsequent access sites, primary failure was 2.6 times higher for fistulas than for grafts: 142 of 363 (39.1 %) and 36 of 237 (15.2 %), respectively ($P < 0.001$). This is consistent with existing literature from North America and Europe [25–29]. In order to improve both primary fistula maturation rate and incorporate prior access failures into decision-making, vascular access patients require a thorough history and physical examination.

History Due to the high incidence of prior procedures in the United States, it is of particular interest to know whether the patient has a prior history of CVC placement, pacemaker(s), arterial or venous catheters, or failed hemodialysis access sites in the past [30]. In addition congestive heart failure and diabetes are important co-morbidities to elicit. Heart failure can be exacerbated after hemodialysis access, and diabetes may pre-dispose patients to risk of steal syndrome [30]. Further patients with advanced malignancy or a pending living donor kidney transplant may be better treated with a CVC rather than permanent access.

Physical Examination Physical examination alone may be sufficient for successful hemodialysis site selection [31]. The examination should include a standard examination for fitness of a procedure, including general physical and mental health, respiratory, and cardiac examination. Both the arterial and venous systems of the planned extremities are of particular importance to hemodialysis creation. Arterial inflow can usually be assessed by manual blood pressure examination of both upper arms, and an Allen's test may be helpful to predicting the adequacy of

collateral flow to hand prior to placement of radiocephalic fistulae [30].

Venous examination should include evaluation for edema, prominent and/or abnormal localization of peripheral veins, comparison of arm size bilaterally, presence of CVC or AICD/pacemakers, all of which may suggest or predispose patients to central venous stenosis/occlusion [32]. Such stigmata warrant further workup prior to placement of an access site in that arm. Abnormal findings on physical examination warrant non-invasive vascular testing. Finally while the non-dominant arm is generally preferred as a way to minimize the impact of the access site on quality of life, the most important part of access creation is the maturation and use of the access site.

Non-invasive Vascular Evaluation While there is a dearth of information on exactly what diameter of vein is too small to develop into a mature fistula [33], there is general agreement that >2.5 mm is adequate (http://www2.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/va_guide1.htm). Interestingly ESRD patients can demonstrate variable vein diameters depending on their volume status [34], thus confirmatory ultrasound of vein diameters on the day of AVF creation may be useful.

While pulse examination is acceptable practice for the choice of donor artery, ultrasound measurement of the brachial and radial arteries may be useful in choosing the initial site of access. An artery with proximal stenosis or one that is prohibitively small (<1.5 mm) are not sufficient for hemodialysis access [35].

Choice of Access for Hemodialysis

There is broad agreement that an AVF is the hemodialysis access of choice for ESRD patients as it is associated with a lower frequency of complications, fewer hospitalizations, better long-term patency and cost profile than either AVG or CVC [18, 21, 30, 36, 37]. Regardless of whether an AVF or AVG is placed, there should be adequate flow documented across the anastomosis at the completion of the procedure.

CVC In the United States, most hemodialysis patients initiate dialysis with CVC catheter, but over half of these patients transition to an AVF within the first year (http://www.usrds.org/2014/download/V2_Ch_03_Clinical-Indicators_14.pdf).

However CVCs are the least preferred form of access because it has the highest risk of infectious and cardiovascular complications as well as mortality. AVG creation has decreased in both the United States and Canada, and CVCs have begun to decrease in the United States but not Canada. Here it is obvious that CVC use is still high world-wide and estimated at 70–80 % in the first 90 days of hemodialysis (Fig. 38.1).

AVF AVF is the preferred access for hemodialysis, but AVFs take time to mature and may require subsequent interventions prior to maturation. Thus DOQI Guidelines recommend that AVFs are placed at least 6 months prior to initiation of hemodialysis (http://www2.kidney.org/professionals/KDOQI/guideline_upHD_PD_VA/va_guide1.htm). To date it is not known in North America which fistula sites are most commonly created, mature, or are used in hemodialysis patients. However there is guidance for clinicians in the DOQI guidelines [37, 38]. The recommended sequence of AVF sites is snuff-box, followed by radiocephalic at the wrist, and then in the forearm. In the arm, a brachiocephalic fistula followed by a brachiobasilic fistula with transposition is recommended. However it should be noted that upper arm fistulas may be more likely to mature [39].

The most distal fistula is located in the anatomical snuffbox of the hand. Despite theoretical advantages of preserving a larger portion of veins and proximal vessels for future access, it may not be feasible in many patients requiring their first vascular access procedure [40]. Reported primary patency rates are excellent (up to 65 % in the first year and 45 % at 5 years) [40]. However,

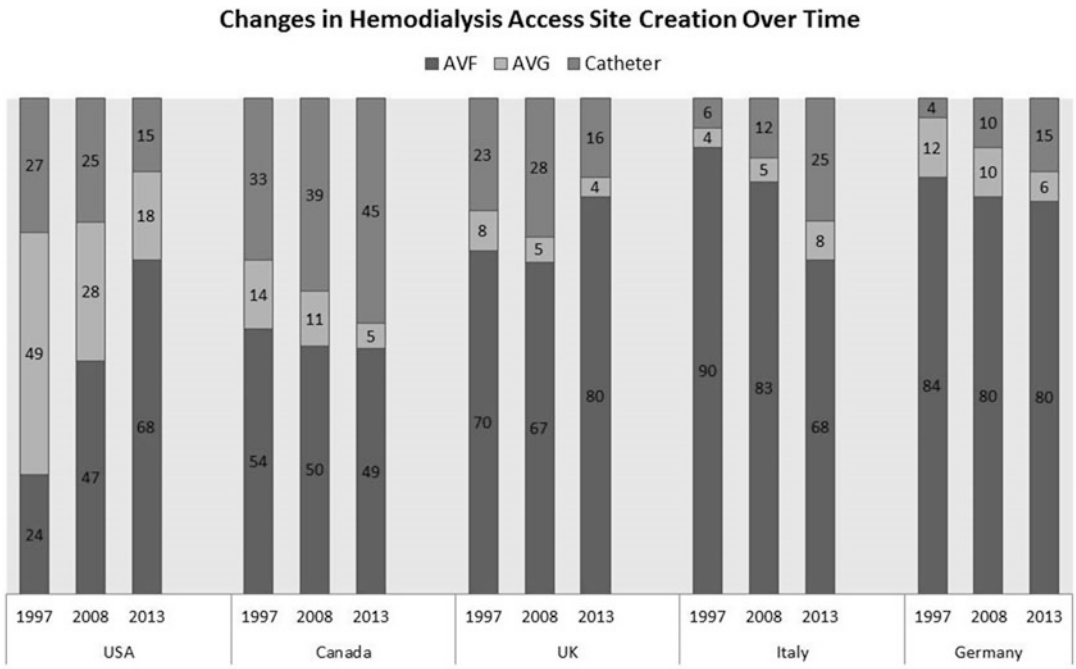

Fig. 38.1 Hemodialysis access site differences among countries over time. The Dialysis Outcomes and Practice Patterns Study (DOPPS) is an prospective observational study that has examined the international trends in HD access use and trends from 1996 to 2014 across 12 countries in five waves [DOPPS I (1996–2001), DOPPS II (2002–2004), DOPPS III (2005–2007), DOPPS 4 (2009–2011) or DOPPS 5 (2012–2014)] [5, 7, 8]

even in well-selected patients there is ~20 % occurrence of failure to mature within 6 weeks of the procedure [41]. The use of the cephalic vein is preferred to the basilic vein in both the forearm and upper arm because the cephalic vein's course is more accommodating for dialysis access. If the cephalic vein is unsuitable, the basilic vein in the forearm can be used for AVF creation. However its location requires it to be transposed to the radial artery. While relatively simple to perform and has suitable patency rates [42], there is not much literature suggesting that it is commonly performed in North America.

In the upper arm, it is recommended to perform the basilic vein transposition in two stages unless the patient has a good sized basilic vein and is already on hemodialysis. In that scenario, a single stage procedure is prudent. Otherwise the two stage procedure has the following benefits. The first stage operation is quick, uses a small incision that is unlikely to have wound healing problems, and can be done under local anesthesia. Since it has been estimated that up to 60 % of basilic vein fistulas never mature and/or are not used for hemodialysis, the two stage approach allows surgeons to transpose only the veins that arterialize well. In addition there is some suggestion that this may improve patency rates of small basilic veins, presumably from allowing arterialization to occur in the veins' native conformation [43, 44].

AVG Unlike AVFs, AVGs can be placed in close proximity to the initiation of dialysis (2–6 weeks prior to initiation of hemodialysis) [25, 30]. There are a number of conformations for AV grafts in the upper extremity. The DOQI recommendations for placement are: (1) forearm loop; (2) upper arm; (3) thigh. Probably the two most common are the forearm loop graft and the brachial artery-axillary vein graft. These are commonly employed in the setting of a patient already on (or quickly approaching) dialysis. The forearm loop graft may delay intrusion of fistulae in

the upper arm and assist in the arterialization of upper arm veins. In a secondary analysis of the Dialysis Access Consortium (DAC), Farber et al. found that the patency between a forearm loop graft and an upper extremity AVG were similar [45]. For those who prioritize avoiding CVC days, AVGs have been shown to be effective [46].

Vascular Access Outside of the Upper Extremity

The groin has been seen as a secondary site for hemodialysis, following the exhaustion of arm options. Groin access can have very high infectious complications [47]. However in properly selected patients, this site can yield reasonable success rates [47]. Because of the infectious and wound healing complications, guidelines from the Society for Vascular Surgery recommend greater saphenous vein, femoral vein, and then other conduits in this region [30]. The femoral vein transposition for thigh AVF was reported by Drs. Gradman et al., and their initial ischemic insults to the leg decreased over time by tapering of the femoral vein conduits and better patient selection [48].

Finally, inferior vena cava and hepatic vein catheters are used for patients who have exhausted all other means of vascular access for hemodialysis treatment [49]. The stepwise progression of femoral catheters from the iliac veins cephalad to the hepatic veins can be performed. As you would expect, these access sites are fraught with complications [49, 50]. One particular caveat in patient selection is that morbidly obese patients have a higher chance for IVC catheter displacement [49].

Novel Graft Conduits

There have been a number of novel conduits available for clinical use in North America. Among the prosthetic conduits, Acuseal® (W.L. Gore), is an immediate use graft composed of polytetrafluoroethylene (PTFE) with heparin bonding on its luminal surface. Acuseal can be accessed quickly after placement due to its wall design that limits extravasation from the graft prior to its incorporation into the subcutaneous tissue. W.L. Gore also manufactures the Gore Hybrid Vascular Graft®, which has a stent on its outflow side. This graft is also heparin coated, and the stent portion is delivered directly into the outflow vein in a restrained fashion. It is then deployed and secured in place with two sutures at the venotomy site. This removes the need of a graft to the outflow vein, which is a common place of failure with AVG [51]. The arterial anastomosis is performed in the standard manner. The HeRO graft® (Cryolife Inc.) is another interesting conduit. It has two separate components that require a connector for intraoperative assembly. The first section is a standard graft that is anastomosed to the brachial artery in the normal fashion. The second portion is a stent graft that is inserted into the superior vena cave/right atrium boundary through a pull-away sheath. The sheath itself is placed after serial dilation of the track over wire access. This allows CVC removal and enables upper extremity hemodialysis access in a patient with a dialysis catheter that is occupying the final vessel in patients with central venous occlusion. In this situation, the CVC can be wired and removed, and that wire can serve as the access site for HeRO placement. Obviously risks of infection for such a procedure are real, and triple antibiotic therapy is recommended perioperatively. If HeRO grafts become infected, they usually require the complete removal of both portions of the graft. Further the longer term benefit of an approach like this has not been demonstrated with average lifespans of ~6 months to 1 year [52, 53]. Challenges associated with this product include difficulty tracking the graft into correct position in patients with central venous occlusion and the need for excellent arterial inflow, sometimes requiring quite proximal placement in the arm. This can impact the risk of steal syndrome in these patients.

Newer biologic grafts available for hemodialysis access include: cryoartery or vein, also available from Cryolife Inc. These vessels are harvested and processed from cadavers. As one would expect the "vessels" are dead but retain much of the vascular matrix. As with all biologics (as compared to prosthetics), there may be

some resistance to infection, albeit without the expectation of improved patency [54]. Similarly, the bovine carotid artery graft, known as Artegraft, (Artegraft, Inc.; New Brunswick, NJ, USA) can be used as a biologic substitute AVG for patients who are poor candidates for AVF treatment or in sites where infection is not uncommon (groin access) [55]. A similar conduit, Procol® (Cryolife, Kennesaw, GA, USA) is a construct is composed of bovine mesenteric vein. Biologic conduits contain biologically compatible matrix, which allows the graft to exhibit new cell growth and ability to heal after needle punctures. In general, the xenografts must be treated with detergents to prevent immune responses and to increase patency rates, as detergents dissolve the cells, allowing the elastin matrix and collagen to remain present. Use of these biologic conduits should probably be restricted to situations that are high risk for infection without autogenous vein opportunities. Further there is no data on using such conduits for salvage of infected grafts, and we do not recommend doing so.

A couple of promising new bioengineered biologic grafts (Humacyte, Inc. [http://www.humacyte.com/products] and Cytograft, Inc. [http://www.cytograft.com/pipeline.html]) have recently been tested in First in Man studies. While the studies were not performed in North America, the investigators bringing these grafts to market have performed most of the preclinical testing in the United States. These grafts are proposed for use in patients with inadequate vein as a substitute for standard prosthetic grafts. They both have had promising early results, and they may be available as part of the hemodialysis access arsenal in the near future. One could imagine in the future having biologic grafts created with one's own cells (fibroblasts or other cell types) for use as autogenous vein substitutes.

Maturation and Maintenance

Access maturation is a complicated process that involves arterialization of the vein wall. This maturation requires the vein wall to adapt to conditions of arterial flow, which inevitably leads to vein wall thickening. This is a relatively rapid process that leads to vessel homeostasis ~2 weeks after placement in an arterial environment (Fig. 38.2).

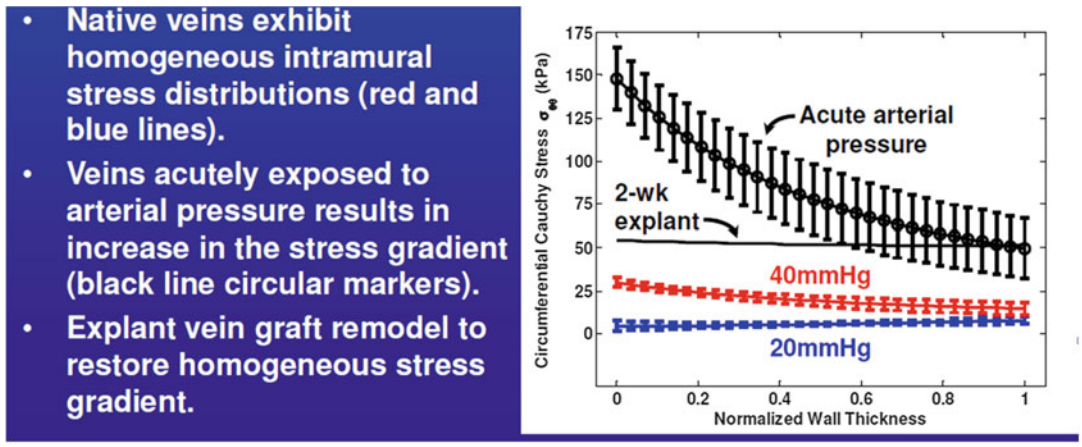

Fig. 38.2 Vein wall mechanics after arterialization. Veins exhibit homogenous intramural stress at low pressures (*red* and *blue* lines). When pressurized acutely, veins develop a stress gradient (*black line* with *circular markers*). Interestingly, by 2 weeks post-arterialization, the vein wall mechanics have developed to maintain a homogenous stress gradient despite arterial pressurization

This is likely part of the reason that AVF maturation should be evident by 4 weeks after formation [56].

Role of Surveillance Ultrasound Surveillance ultrasound itself has not been shown to increase utility and durability of fistulas, but it can identify stenoses and decrease fistula thrombosis [57].

Role of Antiplatelet Therapy The Dialysis Access Consortium Study Group (DAC) has evaluated the role of antiplatelet medications, (clopidogrel and dipyridamole) on fistula outcome. Their trials were negative with respect to increasing use of the fistula, but clopidogrel decreased thromboses of these fistulas [58]. Similarly the use of dipyridamole plus aspirin increased patency of fistulas but did not improve access failure [36].

Ready for Use According to DOQI guidelines [59], a working fistula must have all the following characteristics: blood flow adequate to support dialysis, which usually equates to a blood flow greater than 600 mL/min; a diameter greater than 0.6 cm, with location accessible for cannulation and discernible margins to allow for repetitive cannulation; and a depth of approximately 0.6 cm (ideally, between 0.5 and 1.0 cm from the skin surface). This combination of characteristics can be remembered easily as the Rule of 6s.

However at a minimum, all newly created fistulae must be physically examined by using a thorough systematic approach by a knowledgeable professional 4–6 weeks postoperatively to ensure appropriate maturation for cannulation. If the physical assessment has shown that the fistula is adequately matured, ideally, the next step is to perform a trial cannulation. If there is a question as to its maturity, duplex ultrasound or venogram is warranted. In general, the minimum findings for trial cannulation are a vein diameter greater than 0.4 cm, a flow greater than 500 mL/min [60], and at least 1 month since fistula creation. Brazilian investigators have recently published 85% accuracy of flow volumes for successful use of AVF [61].

Non-maturing AVF

Marginal AVFs should be followed closely for evidence of maturation. If not maturing a post-procedural ultrasound or fistulagram may help identify reasons for failing to mature. Successful interventions can assist the maturation of the vast majority of these fistulas [62, 63]. Adjunctive maturation with Balloon Assisted Maturation (BAM): Small veins that are not dilating after fistula creation may respond to BAM; thus increasing fistula maturation rates. However it is not clear that these fistulas, once matured, will function in the same manner as larger veins not requiring BAM [64].

Stenosis and Occlusion Within the Working Fistula

Similarly if an access that has functioned for hemodialysis, subsequently begins to demonstrates signs of dysfunction or impending failure, we recommend urgent diagnostic testing. Many AVF can be salvaged at this time point (Fig. 38.3), but may not be salvaged after thrombosis. Contrary to this, AVG may or may not benefit from pre-emptive interventions, but can frequently be re-opened at least for short times after presenting for occlusion.

A failing access is usually identified by the hemodialysis centers as they routinely measure flow and venous pressure [30]. Central venous occlusion can occur from prior use of dialysis catheters or from changes due to arterialization of the venous outflow. It is frequently manifest as aneurysmal dilation of the fistula, which always mandates fistulogram before repair. Other stigmata include arm/neck swelling and the development of collateral veins around the shoulders or chest wall. For moderate to high grade stenosis, DOQI guidelines recommend surgical or endovascular treatment [65]. More recently Illig has reported success in treating central venous stenosis with surgical decompression of the costoclavicular junction [66].

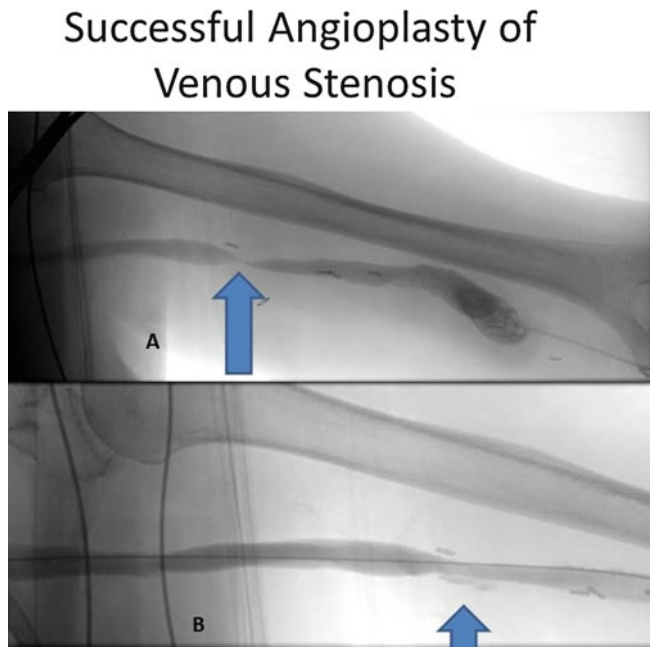

Fig. 38.3 Successful percutaneous treatment of vein stenosis. (**a**) Demonstrates a critical stenosis in a basilic transposition in the upper arm. The patient reported high pressures and clotting during dialysis sessions. On physical examination the fistula had a pulse but had lost its thrill. We decided upon a diagnostic arteriogram as the initial diagnostic test. Once visualized, we upsized the sheath and successfully treated the stenosis with a 9 mm high pressure balloon. (**b**) She has subsequently tolerated dialysis well for the past 2 months. Serial ultrasound examination may be useful in this subpopulation, but the clinical examination in the setting of access dysfunction can also help direct appropriate attempts at maintaining access

Unused Access Sites

AVF ligation after renal transplant should be considered thoughtfully and include a current assessment of the transplanted kidney and future risk of transplant failure. In patients with left ventricular hypertrophy (LVH), vascular access may worsen the cardiac performance after renal transplant [67]. Vascular access causes a decrease in a systemic vascular resistance, causing an increase in stroke volume and cardiac output leading to left ventricular stress, high cardiac output failure and eccentric LVH [68]. This result is dependent from patient to patient, as LVM and LVD measures are not universally the same. Fistula ligation has also been shown to improve right ventricular, and biatrial structure and function [69]. Improvements in endothelial cell dilation have also been reported [69]. Renal transplant patients with a higher risk of high cardiac output failure, venous hypertension, and palpitations are the better candidates for ligation [68]. Still physicians should consider the potential needs of future hemodialysis treatments for the patient. Yaffe et al. recommend against ligation because ligation of an asymptomatic AVF does not drastically enhance patient survival. Secondly, Yaffe et al., state that ligation should be deferred at least 1 year after transplant unless emergency ligation is needed [68].

Future Directions

There remains quite a bit to be understood regarding the optimal use of AVFs in hemodialysis access for patients with ESRD. Perhaps much of what we will learn may come from the hemodialysis fistula maturation study (HFM) study. HFM is a prospective multicenter observational study in the United States established by the

Hemodialysis Fistula Maturation Consortium to identify clinical and biological factors associated with AVF maturation. The primary outcome being evaluated is unassisted clinical maturation (use for dialysis for 4 weeks without intervention). Enrollment closed in the summer of 2014 and there are 602 patients being analyzed currently [70]. There were seven sites that enrolled patients and a variety of vein tissue/blood samples, endothelial dysfunction studies, and post-fistula vascular laboratory studies performed on these patients. There is great anticipation that this will yield worthwhile data in which to improve clinician decision-making capacity for fistula patients.

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Access for Hemodialysis in Brazil

39

André Valença Guimarães

Introduction

About 31 million individuals suffer from chronic renal disease in the USA. During the most recent census, it was classified as the ninth most common cause of death. Nine in every ten patients with Stage 3 CRD are unaware of the disorder. Women are more affected, whereas men are more likely to develop advanced stages. African Americans are four times more susceptible than Caucasians, and Hispanics are more affected than non-Hispanics [1].

According to the new census from the Brazilian Society of Nephrology (SBN), (2013) considering 703 registered units, 658 actively involved in programs treating chronic cases, 334 responded to the annual questionnaire (50.8 %), corresponding to a total of 50,961 patients, from a national population total of 201.03 million Brazilians [2] (Table 39.1).

Also, according to the SBN, occupancy rates for dialysis units were 82 %, 80 %, and 85 %, in 2011, 2012 and 2013 respectively. Figure 39.1 shows the occupancy rates from 2011 to 2013 [2].

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Since the census began to be carried out annually in 2000, constant growth has been observed, with the number reaching 100,000 in 2013, as can be seen in Fig. 39.2 [2].

Figure 39.3 shows the prevalence along with the growth rate since 1994, and continuing to the present day, where it has reached 499 per million [2].

For various reasons, as in the rest of the world, hemodialysis (HD) predominates over peritoneal dialysis (PD), as can be seen in Fig. 39.4 [2].

Diabetes Mellitus (DM), systemic arterial hypertension (HAS), glomerulonephritis (GNC), polycystic kidneys, and urological diseases are the main causes for chronic renal disease, as seen in Fig. 39.5 [2].

About 40 % of all diabetics will develop CRD [3]. In spite of great efforts from the Nephrology Societies and government agencies to stimulate transplants, the waiting lists for organ donations are long and growing, as can be seen in Fig. 39.6 [2].

Brazil demonstrates rates similar to those of other developing countries in regard to the number of patients with short and long term catheters, in addition to prostheses, as can be seen in Fig. 39.7 [2].

Worldwide, the number of new patients (incidence), who enter dialysis programs each year has grown (more than overall population growth), but has maintained stable in Brazil during the period from 2006 to 2013, as shown in Fig. 39.8 [2].

In the last decade, various studies analyzing patient survival during substitutive renal therapy were carried out, however, the results were

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shown to be incongruent, possibly the result of methodological differences, or intrinsic to the assemblage of groups populating the studies [4].

Also, according to the SBN, the estimated annual number of deaths involving dialysis patients appears to have diminished slightly in 2013, but remains around 18,000 (18 %), as is shown in Fig. 39.9 [2].

Temporary Access for Hemodialysis

Construction and maintenance of hemodialysis access continue to be important causes for morbidity and mortality in renal patients. Although the arteriovenous fistulae are considered to be the best definitive accesses, the possibility of implanting catheters always exists at the beginning of urgent treatment, and in later stages when there is a need to maintain an alternative to dialysis at the point when rescue methods are utilized, with the intention of guaranteeing the longevity of the fistulae. Despite the fact that catheter placement in a first-time patient is a relatively simple procedure, in patients who have already experienced much intervention, obtaining access puncture can become a significant challenge for the physician carrying out the treatment.

Despite the efforts from Nephrology Societies around the world, including the SBN, to indicate the appropriate moment for an AVF, the rates for using temporary accesses remain higher than desireable [5]. In Brazil, according to the 2013 census, 9.4 and 6.0 % are the respective averages for patients with short and long term catheters [2].

Usually, temporary accesses for hemodialysis are performed; for emergency dialysis, when dialysis is to be used for a foreseeable period of time, (estimated according to the possible recovery time for renal function), when there is the prospect of another treatment, or while waiting for maturation of a definitive access. These devices should only be implanted when there is immediate need for their utilization.

Table 39.1 Census from the Brazilian Society of Nephrology (SBN), (2013). Registered Units

Total renal units registered with the SBN	703
Total renal units registered with the SBN, and active with programs for treatment of chronic renal cases	658
Total of active units responding to the question form	334
Total of patients in the 334 responding units	50,961
Brazilian population in July of 2013	201.03 million

Source: Census from the Brazilian Society of Nephrology [2]

Short Term Temporary Accesses

These catheters are single or double lumen, not able to be tunneled, without protection/attachment cuffs, are intended for rapid deployment, can be placed without the aid of fluoroscopy, and are used in cases of emergency dialysis.

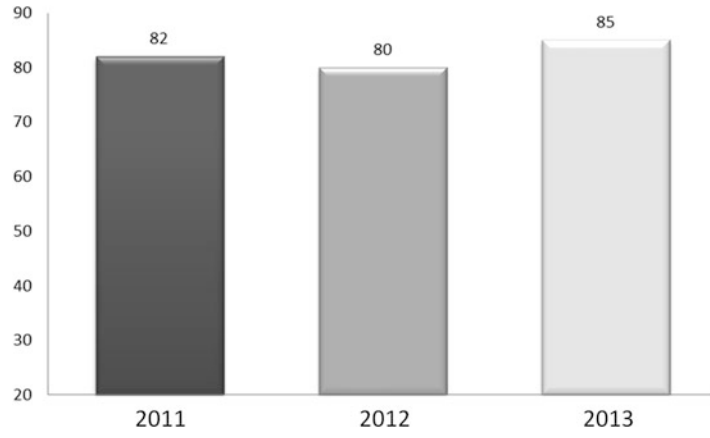

Fig. 39.1 Occupancy rates from 2011 to 2013 [2]

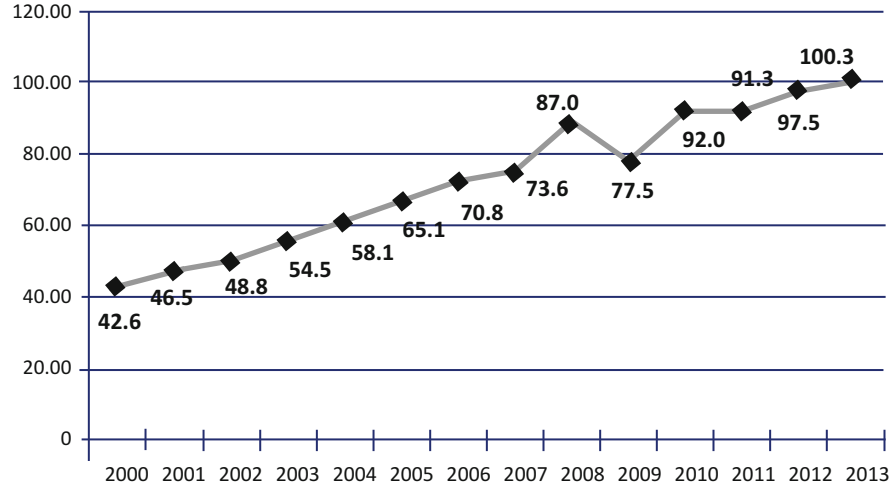

Fig. 39.2 Total estimated number of patients in dialysis treatment by year [2]

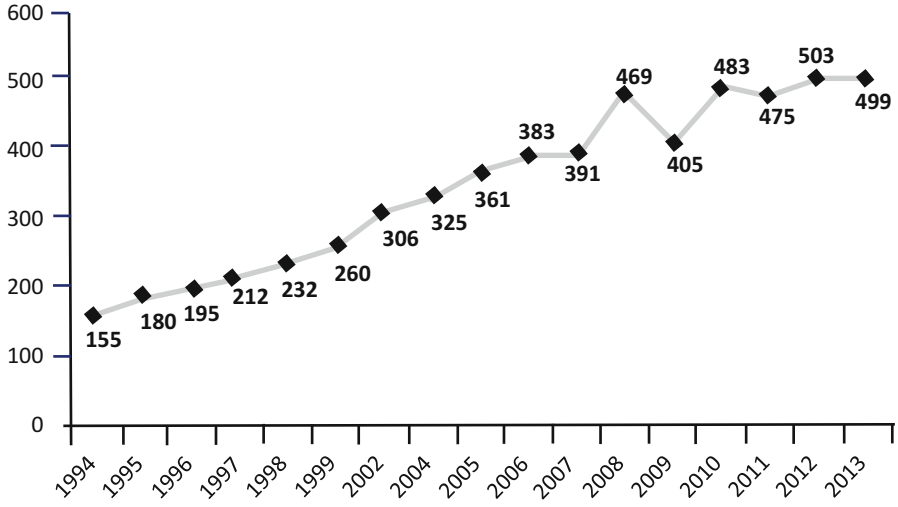

Fig. 39.3 Estimated prevalence rate of dialysis patients in Brazil. 1994–2013 [2]

They should be used for less than 4 weeks. When longer periods are necessary, they should be exchanged for long term catheters. With the objective of being able to achieve good performance for dialysis catheters in upper limbs, their terminations should be positioned in the superior vena cava, just above the cavo-atrial junction. The internal jugular vein should always be the first choice, with the subclavian avoided at all costs, since the latter is known to have a greater disposition for thrombosis, consequently limiting renewed access to the associated member. When access via the upper limbs is not possible, the common femoral vein should be the next option. In these cases, longer catheters (24–31 cm) should be used, and their terminations positioned in the inferior vena cava.

Long Term Temporary Accesses

Devices intended for this purpose have been developed in order to permit longer periods of hemodialysis while a fistula is in the maturation

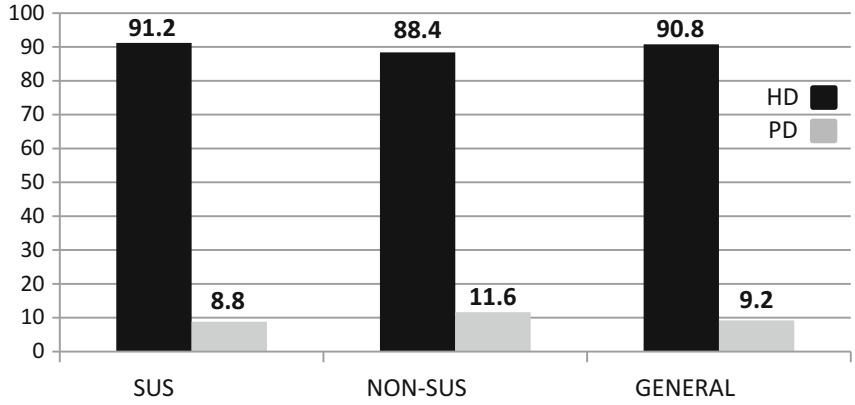

Fig. 39.4 Hemodialysis predominates over peritoneal dialysis. *SUS* Brazilian Public Health System

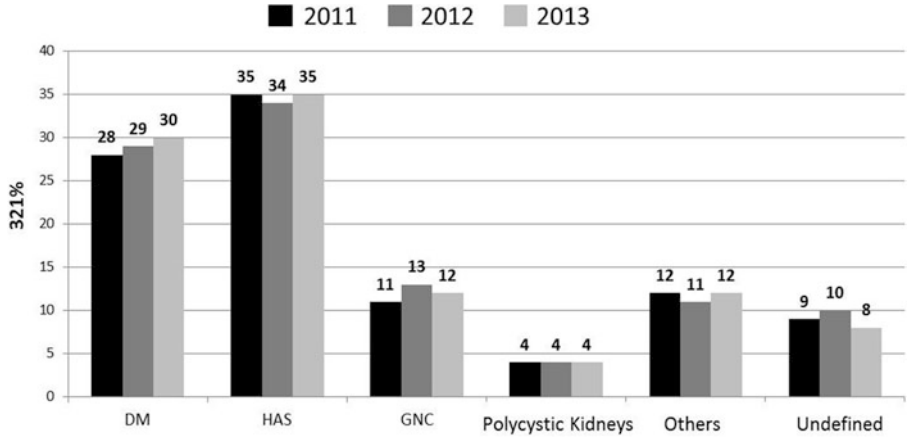

Fig. 39.5 Diagnostics based on dialysis patients

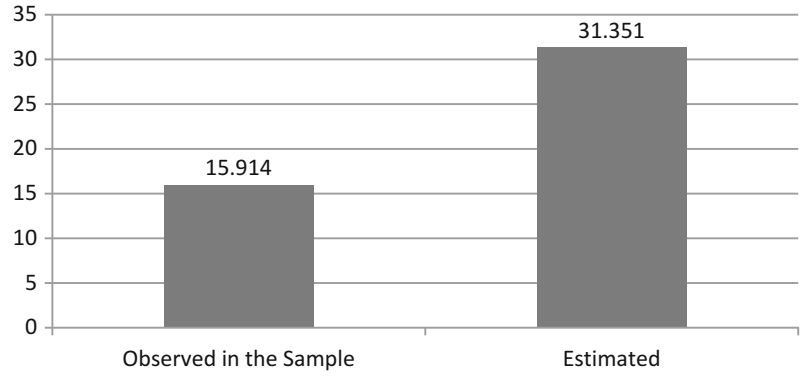

Fig. 39.6 Dialysis patients on waiting lists for kidney transplants [2]

process, or when a patient, for clinical reasons, is unable to undergo a surgical procedure. By the fact of having to remain in the organism for weeks, months, or at times up to an entire year, these catheters must be equipped with mechanisms to allow large blood flows (over 400 ml/

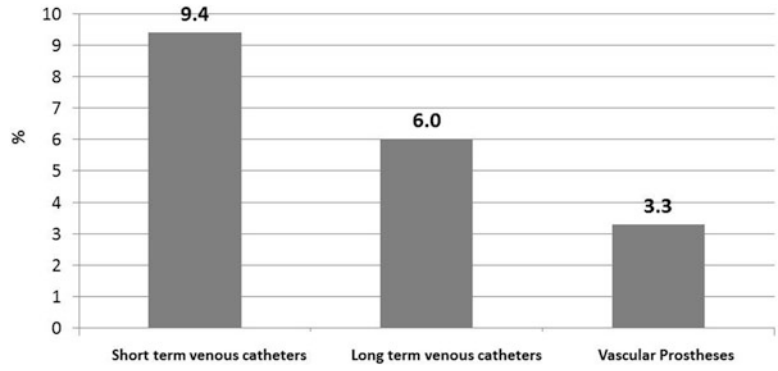

Fig. 39.7 Percentage of hemodialysis patients using short term and long term venous catheters, along with patients using vascular prostheses [2]

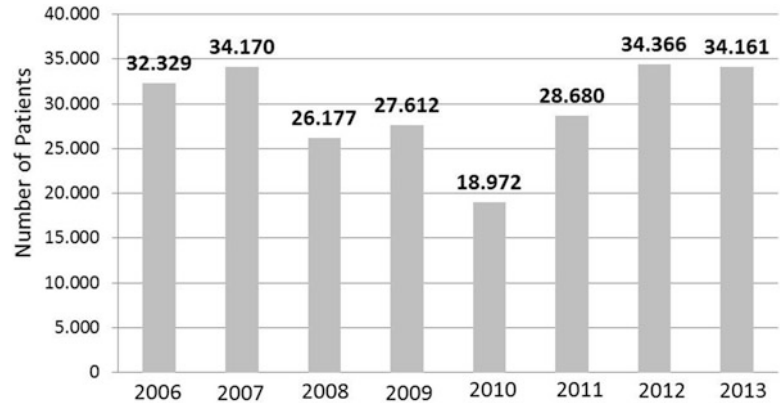

Fig. 39.8 Estimated number of new dialysis patients per year 2006–2013 [2]

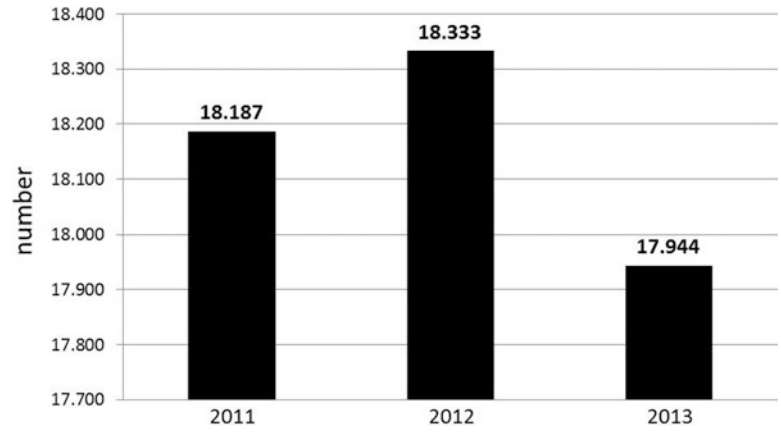

Fig. 39.9 Estimated annual number of deaths involving dialysis patients [2]

min), with two or even three lumens to diminish the risk of infection (tunneled Dacron cuffs), they should feature extremities with special characteristics to reduce the risk of occlusion by the fibrin sheath, and ensure minimal recirculation.

Similarly, and for the same reasons as short term catheters, long term devices should be deployed, whenever possible, on the opposite side of where there is preferred site selected for the upper members, and the common femoral vein in the lower members. The subclavian vein should be avoided at all costs, in view of the great likelihood of stenosis and occlusion, even when not clinically evident.

As these catheters have larger diameters their tips should be unequivocally well positioned in the superior vena cava, in the cavo-atrial junction, or even inside the atrium, their implantation should be performed under fluoroscopy.

Complications Involving Temporary Accesses

Despite the great advances in techniques and available materials for use in temporary accesses involving hemodialysis, a range of complications can occur, and from a didactic point of view, can be classified into: vascular, infectious, or by dysfunction.

Vascular Arteries (laceration, AVF and pseudoaneurysm), venous (dissection, laceration, thrombosis and embolism) and lymphatic (lymphatic thoracic duct injury). Thrombosis of catheters characterizes the most common complications, responding for up to 1/3 of the early withdrawals of these dispositives [6].

Infectious Infections are responsible for most of the complications involving long term catheters, and are blamed as being the most important cause for withdrawals. The additional fact that renal patients, in large part, are immunocompromised, subjected to repeated punctures, and are vulnerable for having foreign bodies in contact with the environment, consequently means they become particularly susceptible to infections from common germs.

Dysfunction Malfunction of the catheter is less common than complications from obstructions or infections, but can occur during implantation, or during the course of prolonged use. The main complications caused by poor implementation are: (1) implantation in an improper location, (2) improper positioning of the tip; (3) pinching of the catheter between a vessel and bone structure. Complications resulting from prolonged use may include: (1) formation of a "valve" produced from a fibrin sheath that might interfere at first only at reflux, but if not diagnosed early, can progress to occlusion; (2) fracture of the catheter, occurring from an error in implantation, or material fatigue after long term use.

Definitive Accesses for Hemodialysis

As noted above, despite the unquestionable usefulness of both short and long term catheters, elaboration of access through a good quality arteriovenous fistula (AVF) is indispensable for quality of life of patients with terminal kidney disease

The (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI), and the SVS (Society for Vascular Surgery) protocols, after extensive discussions with experts from various fields, suggest that patients with terminal kidney disease (creatinine clearance under 25 l/min) should be sent to vascular surgery to program the confection of an arteriovenous fistula, when hemodialysis is indicated for renal replacement therapy. A maturation period of at least 3 months should separate confection of the fistula, and its effective utilization. When a prostheses is implanted, the time period for initiating the punctions should be 2–4 weeks, in order to permit the integration of the plastic material with surrounding structures.

Preoperative Evaluation

Because many AVF candidate patients are elderly, diabetics, severely hypertense, suffer from heart failure and peripheral arterial disease (PAD), a carefully elaborated medical history is very important in order to identify and anticipate possible difficulties in establishing good accesses. Past surgical history involving failure of AVFs, the use of pacemakers, defibrillators, arterial catheterization, cardiac surgery and trauma in the limbs, allows us to anticipate additional considerations in elaboration of the fistula. The general clinical conditions of the patient, family structure, and life expectancy also should be taken into account.

Arterial Examination

The arterial examination of upper and lower members, carried out by a surgeon, with palpation of the brachial, radial, and ulnar arteries, along with the Allen test, can practically define the quality and condition of these vessels. Comparative measurement of arterial pressure among members can provide additional information, and together with Doppler ultrasound, complete the investigation. The selected artery should measure at least 2 mm of lumen diameter.

Venous Examination

Unlike the examination of the arteries, examination of the veins of the limbs is very much subject to individual variations between the sides. Placement of a tourniquet can help identify uninterruptable and distensible venous segments. The examination is more difficult in obese patients, however, for the same reason, they may have their superficial veins preserved of previous punctures. The veins selected should measure at least 2.5 mm in diameter, and not more than 5 mm from the skin, to permit puncture by the nephrology team.

Complementary Examinations

In developed countries, the systematic use of Doppler ultrasound for previous mapping of veins and arteries, not only in order to identity possible sites, but also to evaluate profundity of the veins, greatly facilitates the personal choice made by the surgeon. In Brazil, this examination is not always available to all patients, making the decisions relating to the best locations for performing an AVF more difficult. Arterial Doppler ultrasound can be particularly useful in identification of locations for high bifurcation of the brachial, and location of subclinical stenosis. In the venous segment, stenosis, parietal thickening, and non-distensible areas can be detected. Other examinations which can be utilized in selected cases include venography and arteriography.

Following is a list of the Author's preferences for access.

Forearm
• Autogenous
Direct AVF in the anatomical snuff box
Radial Fistula at the wrist (Cimino-Brescia)
Proximal Radial-cephalic
Radial-basilic Fistula in transposition
Brachial-basilic Fistula in transposition strap
Fistula with Brachial-basilic saphenous strap
• With Prostheses(4 % in author serie)
Straight Radial-antecubital Fistula
Brachial-antecubital Fistula in strap
Arm
• Autogenous
Direct Brachial-cephalic Fistula
Brachial-cephalic Fistula with transposition
Brachial-basilic Fistula with transposition
Brachial-brachial Fistula with transposition
Brachial-axillary Fistula with interposition of the saphenous vein
• With prostheses
Brachial-axillary Fistula (straight or loop)
Thorax
• With prosthesis
Axillo-axillar AV Fistula

These are the sites most utilized by the author, although many variations and atypical conformations may ultimately be employed.

Techniques

It is understood that deployment of a direct AVF in the forearm is a relatively simple procedure to be carried out. However we must never underestimate difficulties, even for experienced surgeons, in obtaining fistulas. Therefore, it is recommended that all the technical refinement utilized in other surgeries, also be employed here. Optical magnification using loupes, use of vessels loops, monitored dilation of veins to avoid over inflation, the use of evoked thrill to test the quality of the conducting vein, careful side to end anastomose, the use of papaverine solutions, and extra caution to prevent twisting the venous axis should all be

considered as routine techniques and principles. In the author experience in the past 26 years, 3035 vascular accesses were performed. From the total casuistic, 691 cases were selected for analysis from March 2007 to March 2013. From these, 525 (75.8 %) were direct native AVF fistula, 2 (0.2 %) saphenous loop, 22 (3.1 %) forearm basilic transposition, 101 (14.6 %) arm basilic superficialization, 26 (3.7 %) brachial-axillar prostheses, 3 (0.4 %) thigh fem-fem ipsilateral prostheses, 13 (1.8 %) others sites respectively. Mean previous access 3.1 (range 0–6), mean maturation time 52 days (range 25–91), surgical time 85 min (range 70–103). One year (82 and 84 %), 2 years (77 and 78 %), 3 years (67 and 69 %), 4 years (49 and 50 %) primary and secondary patency respectively. Close primary and secondary patencies could mean a poor surveillance [7].

Post-Operative Follow-Up

A good quality fistula should be ready for use within 3 months or less. During this maturation interval, a Doppler ultrasound examination should be performed. When the diagnosis is not clear, venography or arteriography should be requested.

Secondary patency of the fistula can be obtained from open, or endovascular procedures. Open surgery may include venous patches, interposition of vein segments, re-anastomosis in arteries located close by, ligation of significant branches, and eventual superficialization of the venous path. Endovascular procedures, despite appealing for their simplicity, have not provided good mid-term results from the author's point of view, possibly because veins with stenosis of a fibrotic nature respond poorly to angioplasty with conventional balloons. However, when an arterial or a central venous stenosis is responsible for difficulty in maturation, the results of endovascular methods proved to be very satisfactory.

Complications

Hemodialysis represents the main form of treatment for patients suffering from terminal chronic renal failure, and complications regarding accesses are the most important causes for hospitalizations. The most common complication regarding access is thrombosis, followed by infection.

The most common causes for *thrombosis* are: intimal hyperplasia, technical error, wrong choice of anastomosis site, the selection of prosthetic material, coagulation disorders, and especially the quality of the patient's arteries and veins. Thrombosis can be triggered by the small size of vessels, situations involving severe dehydration, hypotension, and venous obstructions. With the passing of time, repeated punctures in the same location can cause fibrosis with subsequent thrombosis. In fistulae with prosthetic material, the principle causes for failure result from hyperplasia in the efferent vein.

Infections involving autogenous AVFs are infrequent, but are relatively common complications in the fistulae with prostheses, reaching levels as high as 20 % during their period of use. The most commonly encountered germ is S. aureus. It is characterized by the presence of erythema and pain around the graft, and the eventual output of pus through spontaneous drainage. When infection of a prostheses is proven, total removal of all the material is suggested. Despite the formidable adaptability of the body to the presence of arteriovenous communication, three major *hemodynamic complications* can occur: heart failure, induced steal syndrome and venous hypertension.

Another complication, less frequent than those previously described, is *vascular neuropathy* probably a multifactorial pathology produced by compression of the nerves, related to thickening of the carpal ligaments, and edema in the hand during dialysis, but in some cases it may represent a vascular steal.

The *vascular steal phenomenon* is characterized by distal ischemia of the extremity after creation of a fistula, especially in the proximal (brachial) accesses, and when using a prostheses. This phenomenon occurs in the majority of fistulae, but only becomes symptomatic in a few patients, especially diabetics, and those with peripheral diffuse atherosclerosis. Symptoms may be mild, or extremely uncomfortable, to the point of changing the quality of life. In more severe cases, limb viability may be threatened.

True *aneurysms* of an autogenous fistula usually develop in sites experiencing repeated punctures, through weakening of their walls, or in efferent veins after years of use.

Pseudo-aneurysms are formed from small lacerations on the fistula trajectory, with development of a clot parallel to the axis of the vessel, which is organized by formation a shell, perpetuates itself, and has a tendency to grow due to an association with the flow of blood. This degeneration can occur in up to 5–6 % of the fistulae, developing an embolism, thrombosis, infection, and eventually burst [8]. In our experience, when the skin becomes shiny, painful, and wine colored, there is imminent danger of rupture. In this circumstance, treatment becomes imperative. Resection and interposition of a venous segment, or connection with the same vein is normally carried out

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Renal Replacement Therapy: A European Perspective

40

Faisal M. Shaikh and Stewart R. Walsh

The creation and long term management of vascular access (VA) for chronic haemodialysis (HD) patients has been and remains a challenging aspect of vascular surgery practice. VA dysfunction is a major determinant of morbidity and hospitalization among the HD patients [1, 2].

Like elsewhere, patients with end stage renal disease requiring renal replacement therapy (RRT) has increased appreciably in European Union (EU), reflecting an increased prevalence of hypertension, coronary artery disease, type 2 diabetes mellitus, and an ageing population. Recent epidemiological studies have indicated stabilization in the incidence rates of RRT in a number of European countries [3–5]. The tendencies of stabilization of RRT incidence rates in Europe was reported for the first time in 2004 [6] and confirmed in the publications in following years [3, 7]. The figures have now stabilized at 125 persons per million population, less than half of that observed in the USA at the time of the halting incidence growth [8].

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Vascular Access in Europe

European Renal Best Practice (ERBP) is an international organisation that creates clinical practice guidelines targeting health professionals who deliver care to renal patients in Europe and surrounding regions (www.european-renalbest-practice.org). The National Kidney Foundation, a US based international organization, proposed guidelines that arteriovenous (AV) fistulae be constructed in at least 50 % of permanent HD access procedures, to improve quality of life and outcome in patients with end-stage renal disease [9]. Likewise ERBP strongly prefers and promotes autogenous AVF over AV grafts and AV grafts over catheters [10].

The Dialysis Outcomes and Practice Patterns Study (DOPPS) established since 1996 is a prospective, observational study of HD treatment and patient outcomes. DOPPS published their first series of data on VA in 2002 with the goals of examining vascular access use in United States (US) and in five European countries (France, Germany, Italy, Spain, and the United Kingdom (UK). In Europe, native AV fistula accounted for 80 % of all accesses while AV grafts use was around 10 % and 8 % were catheter use. High native AV fistula use was seen in all five European countries, ranging from 67 % in the U.K. to 90 % in Italy. In contrast, grafts were the predominant access type in US, comprising 58 % of all accesses, with only 24 % of US patients using a

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native AV fistula [11]. However over the years, studies have shown a decreasing trend in the use of native AV fistula in Europe and an increasing trend in the use of Central Venous Catheters (CVCs) at the start and after the start of HD. A similar evolution pattern has been observed for the prevalence; the use of native AV fistula has decreased to 62 % and use of CVCs increased to 32 % in the most recent report. Moreover a large international variation was noted in the use of the different VA types. Female patients [adjusted odds ratio: 0.84, 95 % confidence interval (CI): 0.78–0.90] and those ≥80 years (0.77, 95 % CI: 0.67–0.90) were least likely to start HD with an AVF [12].

Recently published national UK audits show even more discouraging data, although 73 % of patients start RRT with HD [13], however only 40 % start on a native AV fistula and even after 3 months, the number of patients on a native AV fistula dialysis remains only 41 %. The study further states that the referral to a surgeon was an important determinant of mode of access at first dialysis. However, referral to a surgeon occurred in only 67 % of patients who were known to the nephrologist for over a year and in 46 % of patients who were known to nephrology less than a year but more than 90 days. Best practice tariffs of the National Health Service payment by results program have set a target of 75 % of prevalent HD occurring via a native AV fistula or AV Graft in 2011/2012, rising to 85 % in 2013/2014. Authors suggest that this target is best achieved by increasing timely referral to a surgeon for creation of access before HD is needed.

Organisation of Vascular Access

The three types of haemodialysis access in order of preference are native AV fistulae, polytetrafluoroethylene (PTFE) AV grafts, and temporary CVCs. In an emergency setting, access is achieved by CVCs, which is often placed by the nephrologist or intensivist. However creation of a native AV fistulae or synthetic AV graft requires a specific vascular surgical expertise.

In the early days of hemodialysis nephrologists often constructed the AV fistula. Subsequently Urologist and Transplant surgeons took over access surgery. However, since the establishment of peripheral dialysis centers, vascular surgeons have become increasingly involved in hemodialysis access. Although HD centers are available across EU in almost all district hospital, vascular and endovascular expertise are only available in regional centers and therefore patients need to travel if they require such procedure. Currently the program of creating and maintaining reliable vascular access in hemodialysis patients is seen as a multidisciplinary task that may include the collaboration of nephrologists, vascular surgeons, interventional radiologists, ultrasound technicians and dialysis nurses [14]. Emerging evidence suggests that such an approach markedly improves patient overall survival, reduce AV fistula creation waiting times, decreases catheter requirements, reduce complications of access surgery and decreased access failures.

Vascular Access Planning: Pre-operative Investigation

The vascular access society recently published new European guidelines and clinical algorithms on access care. These show many similarities with earlier guidelines; however the emphasis is on the value of the preoperative duplex and the role of the interventional radiologist for fistula salvage [14].

A native AV fistula requires a period of maturation to allow arterialisation of venous outflow, therefore, early referral for access surgery is essential and should be within 6–12 months of the anticipated start of dialysis. This allows ample time for access maturation or for additional procedures in case of primary failure. In most European centres, if clinical examination confirms satisfactory arterial pulse and suitable forearm vein, patients proceed directly to primary AV fistula formation. However, addition of preoperative duplex examination has been proven to influence the choice of access placement and adds valuable information for the vascular surgeon. A recent meta-analysis by authors suggested that selective use of duplex ultrasonography enhances AV fistula success rates, but

there are insufficient data to recommend routine duplex screening of AV fistula candidates. Agreed vessel criteria are needed [15].

AV Fistula Outcome and Patency

In general, outcomes and patency for AV fistulae vary considerably in literature, owing to different patient characteristics and reporting of outcomes. In 1966, Brescia and Cimino [16] were the first to describe the AV fistula that provided persistent VA for patients requiring HD. Since then, the native AV fistula is considered the gold standard upon which other modes of VA are judged [17]. Compared with grafts or catheter based dialysis, AV fistula offer longer patency rates, fewer interventions, infections (one-tenth of AV Grafts) and thrombosis (one-sixth of AV Grafts), ischemic complications, and overall lower mortality rates [11, 18–23]. In addition, native AVF access has significantly lower costs than grafts or catheters [18]. Because of all the aforementioned reasons European guidelines for vascular access recommend that the autogenous fistulas should be the first-choice access procedure and should be created as distally as possible to preserve sites for future access [14]. The majority of procedure for creation and maintenance of HD access can be performed in an ambulatory setting with minimal morbidity as shown by Spanish colleagues more than two decades ago [24]. In authors experience ambulatory settings and local anesthesia is usually effective for majority of AV fistula cases, and the morbidity of the procedure is extremely low. As mentioned earlier after creation, AV fistula requires at least 4–6 weeks for maturation before cannulation. During the period of maturation, the blood flow and the vessel size increase over time and the initial blood flow is in a range of 200–300 ml/min.

Primary patency rates for AV fistula vary considerably among studies from EU. Chemla et al. from UK reported primary and secondary patency of native AV fistula at a median follow up of 22 months as 80 and 93 % respectively [25]. In a more recent prospective, multicenter study from the Netherlands, 11 centers participated in a guidelines implementation program. Seventy-six percent of the vascular accesses were native AV fistulae. A total of 491 AV fistulae in 395 patients were created. 6, 12, and 18 months secondary patency and functional patency were 75 ± 2.0, 70 ± 2.3, and 67 ± 2.7 % and 90 ± 1.9, 88 ± 2.2, and 86 ± 2.7 %, respectively. Primary failure rate was 40 %. Thrombosis rate was 0.14 per patient-year [26]. In another multicenter study authors randomised 105 patients (52 versus 53, respectively) with failed primary/secondary access or inadequate arterial and/or venous vessels for either brachial-basilic arteriovenous fistula (BBAVF) or prosthetic brachial-antecubital forearm loop (PTFE) loop creation for vascular access for HD [27]. Primary and assisted-primary 1-year patency rates were significantly higher in the BBAVF group: 46 % ± 7.4 % vs 22 % ± 6.1 % ($P = 0.005$) and 87 % ± 5.0 % vs 71 % ± 6.7 % ($P = 0.045$) for the BBAVF and PTFE group, respectively. Secondary patencies were comparable for both groups; 89 % ± 4.6 % vs 85 % ± 5.2 % for the BBAVF and PTFE group, respectively. Patients in the BBAVF group needed a total of 1.7 interventions per patient-year versus 2.7 per patient-year for the PTFE group. These finding led the authors to conclude a significantly better primary and assisted-primary patency for the BBAVF group compared with the PTFE group. Although concerns have been raised that native AV fistulae may not be not be appropriate for all age groups, however group from Bristol UK [28], found no differences in outcome although there respective primary patency rates were lower than reported in other studies and at 1 and 2 years for radiocephalic AV fistulae were 46.0 % and 27.1 % for patients <65, 47.0 and 36.0 % for those 65–79, and 45.7 % and 38.1 % for those ≥80.

Vascular Access Complication

About 10 % of AV fistulae never mature to adequate flow for HD. Stenosis and thrombosis are other potential causes of AV fistula failure. Early recognition and timely intervention are of critical value. Vascular surgeons and interventional radiologists have developed valuable tools to cope with access complication, however, it is not clear which treatment option is better because comparative

studies are lacking. Recently endovascular and catheter based therapy has replaced surgical revision as the treatment of choice for failing or thrombosed AV fistulae or grafts. In a German study, authors successfully managed to salvage 72 cases (88.9 %) out of 81 thrombosed native AVF using percutaneous thrombolysis and angioplasty techniques. Overall fistula patency was 75 % after 3 months, 65 % after 6 months, 51 % after 12 months, and 22 % after 24 months [29]. In another similar study from France authors found that the percutaneous catheter-directed thrombolysis of forearm fistula was effective in more than 90 % of cases and yielded 50 % primary and 80 % secondary patency rates at 1 year. However the results were poorer in upper arm fistulae [30]. The largest series reporting long-term outcome after radiological treatment of both stenosis and thrombosis in AV fistulae and prosthetic grafts also comes from France [31]. Authors reported an initial success rates ranged from 78 to 98 %. As seen in previous study primary patency rates at 1 year were twice as good for forearm AVFs (50 %) than for grafts (25 %) ($P<0.05$), and were 34 % for upper arm AV fistula.

Training and Education for Vascular Access

The regional education bodies and the European vascular society and European society of vascular surgery organises regular meetings and hands-on courses in different European cities as part of education and training for VA for HD. A number of studies have shown that the enhanced training in vascular access creation improves outcome [31, 32]. The majority of "experts" consented that there is a lack of appropriate training in access creation and maintenance to a great extent, however they pointed that the main deficit in access training is in the preoperative planning and decision making [33].

In summary vascular access through native AV fistula remains the Achilles' heel of haemodialysis in Europe. Although compared to US, native AVF use is high; however there has been an increase of synthetic grafts and catheter use. Due to the complexity of patients, procedures of access creation are mainly performed in major centres; however the program of creating and maintaining a reliable vascular access in hemodialysis patients is seen as a multidisciplinary task. In the last decade there has been a shift towards endovascular management of complications of AVF access. There is need to expand education and training in venous access to improve patient outcomes.

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Part VI

Status of Practice and Training

The Status of Vascular Surgery Practice in the United States

41

Tze-Woei Tan, Alireza Hamidian Jahromi, and Wayne W. Zhang

Vascular Surgery Training

Vascular surgery training in the United States (US) has evolved greatly over the last four decades [1]. Prior to 1980, there were no specific training programs and vascular surgeons gained initial experience mostly through apprenticeships. The Accreditation Council for Graduate Medical Education (ACGME), whose primary task includes oversight of graduate medical education in the US, started accrediting vascular surgery fellowship programs in the late 1980s [1]. The fellowship program at that time generally consisted of one dedicated vascular surgery training year, usually after completion of a 5-year of an accredited general surgery residency (5+1 model) [1]. Although vascular surgery was initially included under the umbrella of general surgery, the American Board of Surgery (ABS) started to formally recognize vascular surgery as a subspecialty in 1981 [1]. At that time, ABS certification in general surgery was required prior to qualifying for a subspecialty certification in vascular surgery [1]. Many of the vascular surgery fellowship programs started adding an additional second year of training (5+2 model) in the 1990s. Initially the second year was primarily research-oriented and often only the clinical year was accredited. With the widespread adoption of endovascular interventions and the added requirement for training in endovascular techniques, most of the fellowship programs had subsequently evolved into two full years of clinical training [1].

In 2005, the ABS received approval from the American Board of Medical Specialties (ABMS) to offer primary certification in vascular surgery, thus formally recognizing it as distinct specialty in surgery. This has also eliminated the prior requirements for primary certification in general surgery and provided flexibility to create new training paradigms in vascular surgery although the option for certifying in general surgery prior to vascular surgery training is still available. Currently, a number of training paradigms exist. A traditional independent (5+2) pathway includes a 5-year general surgery residency program followed by a 2-year independent vascular surgery training program. An early specialization program (ESP) consists of 4-year general surgery training followed by 2-year vascular surgery training at the same institution (4+2); this pathway can also lead to certification in both general surgery and vascular surgery. Two additional training pathways approved by ACGME are the integrated (0+5) and independent (3+3) programs that can lead to primary certification in vascular surgery without certification in general surgery. Most of the independent (3+3) programs have

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eventually converted to integrated (0+5) programs. As of 2015, there are total of 51 integrated training programs and 105 traditional 5+2 training programs in the US (acgme.org).

During vascular surgery training, trainees are expected to gain exposure and training in all essential fields of vascular surgery. They are required to participate in at least 500 operations with 250 major open vascular reconstruction cases as designated by ABS. Beginning from 2014, all candidates are additionally required to obtain qualification for Registered Physician Vascular Interpretation (RPVI) prior to applying for vascular surgery qualifying exam. This added requirement is to ensure that all vascular surgeons have satisfactory training and knowledge in non-invasive vascular laboratory testing. More recently, in conjunction with ACGME, the vascular surgery milestone project was developed to improve the evaluation process for the fellowship. Trainees are objectively evaluated utilizing milestone framework in six competency domains: patient care, medical knowledge, system-based practice, professionalism, as well as interpersonal and communication skills. Milestones are evaluated and reported to ACGME semi-annually by an institutional competency committee that consists of at least three core faculty members. Milestone reporting started in December 2014 for all accredited fellowship programs and is expected to be used to make recommendations for the fellows' progress during their training. The ACGME is also expected to use the milestone data to assess effectiveness of training programs during the continuing accreditation process.

Vascular surgeons who seek ABS certification are required to complete all their postgraduate training after medical school in an ACGME-accredited training program. Completion of two standardized exams including a qualifying exam and a certifying exam are required for board certification. The qualifying exam consists of multiple-choice questions aimed at assessing cognitive knowledge, whereas the certifying exam is an oral examination evaluating the surgeons' knowledge and ability to safely and effectively manage vascular surgical problems. Successful candidates will become ABS board-certified in vascular surgery. Over the last 5 years the passing rate for the qualifying and certifying exams ranged between 87–97 % and 80–89 %, respectively. All board-certified surgeons are required to participate in the maintenance of certification (MOC) program, which is an ABS-designated continuous professional development curriculum. The aim of MOC is to assess physician competencies in professional standing, lifelong learning and self-assessment, cognitive expertise, and evaluation of performance in practice on a continual basis. Recertification exams are required to maintain board certification every 10 years to ensure that all diplomats are competent and up to date in the practice of vascular surgery. The passing rate for recertification examination ranges between 94 and 97 %, and is generally higher than the initial qualifying and certifying exams.

Patterns of Vascular Surgery Practice in the United States

Over the course of the last two decades there has been a significant evolution in the field of vascular surgery. The emergence of catheter-based intervention, health care payment reform and national quality improvement efforts are some of the biggest changes that have affected our field [2–7]. These changes have taken place in the setting of continued, explosive growth and demand in vascular intervention over the last decade [2, 8]. With the aging US population resulting in increased prevalence of arterial occlusive disease and with relatively stable numbers of new graduates entering practice every year, it is projected that there will be a significant shortage of vascular surgeons over the next 40 years [9]. This might have a significant implication in the access to vascular surgery care in the US.

A major change is the shift of vascular procedures being performed by general surgeons to surgeons who have specialized vascular training [4, 10, 11]. In the past, many general surgeons performed substantial numbers of vascular surgery procedures including carotid endarterectomy, leg bypass, aortic aneurysm and dialysis access [10]. The rapid adoption of endovascular technology has however changed this landscape. In a

recent study by ABS evaluating the practice pattern of general and vascular surgeons seeking board recertification, the majority of practicing general surgeons were noted to not currently perform any major vascular procedures [11]. Although some older general surgeons continue to perform vascular procedures in their practice, younger general surgeons are performing far fewer vascular procedures [4, 11]. Conversely, although older vascular surgeons performed non-vascular procedures, this practice pattern is relatively rare in younger vascular surgeons [11].

Vascular surgery in US has also evolved from being a predominantly open surgical specialty to a modern hybrid practice combining both open surgery and catheter-based intervention. For most vascular surgeons, there has been a significant increase in endovascular intervention with the associated decline in the open surgery procedure [2, 3, 5]. These changes are reflected upon in the report from Vascular Surgery Board of the ABS, which evaluated the practice pattern of vascular surgeons who applied for the Vascular Surgery Recertification Examination between the years 1995 and 2009 [2]. The report noted that a majority of practicing vascular surgeons continue to have wide spectrum practice performing cases in different major categories [2, 5]. There is however a relatively small number of surgeons who concentrate on a specialized area such as diabetic foot, aortic aneurysm and dialysis access. The most commonly reported open cases are carotid endarterectomy (CEA) and hemodialysis access [2]. More than 75% of surgeons continue to report significant cases in other core vascular procedures including open aortic aneurysm repair and peripheral bypass [2]. Arteriovenous (AV) fistula has replaced AV graft as the most commonly performed hemodialysis access surgery, which is consistent with national guideline preferring autogenous access.

There are significant increases in endovascular procedures including endovascular aneurysm repair (EVAR), peripheral angioplasty and stenting, and inferior vena cava filter placement over the study period [2, 3, 5]. The increases in infrarenal EVAR has resulted in corresponding decreases in open abdominal aortic aneurysm (AAA) repair cases [2, 3]. For a lot of practicing surgeons, endovascular cases now account for more than 50% of workload [5]. Younger surgeons are more likely to have more endovascular cases than open cases in their practice compared to older surgeons (age >50 years) [5]. In addition to endovascular procedures, there are also notable increases in operations for chronic venous disease including sclerotherapy, catheter ablation and venography [2]. Selected cases including sympathectomy, lymphatic procedures, portal vein reconstruction and open surgery for venous ulcer have decreased significantly over time and are now rarely performed [2]. There is also a suggestion of potential regionalization of open complex cases in specialized centers. Cases including open thoracic aneurysm repair, aortic arch surgery, direct venous reconstruction and open visceral artery procedures are increasingly likely to be performed by the same 30% of practicing surgeons [2].

Most of vascular surgeons in the US work in urban areas. More than 90% of vascular surgeons seeking recertification from 2007 to 2009 practiced in metropolitan and urban areas, 5% in large rural areas and the remaining surgeons practiced in small, rural areas or isolated communities [11]. There are a number of different vascular surgery practice models in the US. In 2013, 30% of the Society of Vascular Surgery (SVS) members worked in academic settings and were employed by either a university or an academic medical center with postgraduate teaching appointments [5]. Sixty-five percent of surgeons were noted to be private practitioners, working either in physician-owned groups or are employed full time by a hospital and health care systems [5]. Among those who worked in physician-owned groups, more than half were in a single specialty group, one-third in multispecialty group and the remaining in solo practice [5, 11]. The percentage of surgeons who owned their own practice had decreased steadily. Possible reasons for this trend include high overhead and malpractice cost, increasing complex reimbursement systems, as well as competition from health care systems and large group practices. Group practices generally consist of two or three vascular surgeons. Around 5% of vascular surgeons are employed by the government and work in Veterans Affairs hospitals [2]. More than 80% of members exclusively practice vascular surgery

and up to 15 % of vascular surgeons dedicated 25–50 % of their practice to non-vascular surgery including general surgery, cardiothoracic surgery and trauma [5]. Younger surgeons were more likely have a pure vascular surgery practice compared to their older counterparts [5, 11].

Trends in Intervention for Peripheral Artery Disease

Peripheral arterial disease (PAD) affects more than five million adults in the US, and is likely to become an increasing problem with the ageing population. Endovascular interventions for PAD have increased substantially over the last two decades, replacing open surgery as the most commonly performed revascularization procedure [8, 12]. In one study evaluating PAD patients with Medicare, overall numbers of lower extremity interventions had doubled from 1996 to 2006, with more than three folds increased in endovascular interventions (Fig. 41.1). During the same time, however, open surgery had decreased more than 40 %, and the rate of major extremity amputations performed for PAD also gradually decreased [8]. Peripheral angioplasty was the most commonly used technique, and arterectomy was increasingly being used in conjunction with angioplasty during endovascular interventions [8]. This study however did not evaluate the use of intra-luminal stent and other newer endovascular techniques during these interventions. The pattern of endovascular interventions also shifted from predominately in iliac arteries to include femoral-popliteal and tibial vessels over the study period [8].

We have also observed significant changes in the landscape of the specialty providers performing peripheral arterial intervention. Among the providers which included vascular surgeons, cardiologists and interventional radiologists, radiologists were performing the majority of the percutaneous interventions in US prior to 2000 [8, 12]. In one study, more than 70 % of peripheral interventions were performed by interventional radiologists across the country in 1996 (Fig. 41.2) [8]. With the widespread adoption of endovascular technique, vascular surgeons had however overtaken radiologists to become one of the main providers performing endovascular procedure [8, 12]. The numbers of peripheral intervention performed by cardiologist also increased significantly [8, 12]. By 2006, although overall numbers of procedures remained stable, radiologists were performing less than 20 % of endovascular intervention [8]. Cardiologists and vascular surgeons were each performing around 40 % of endovascular procedures (Fig. 41.3).

In a separate study evaluating patients undergoing peripheral arterial intervention using the

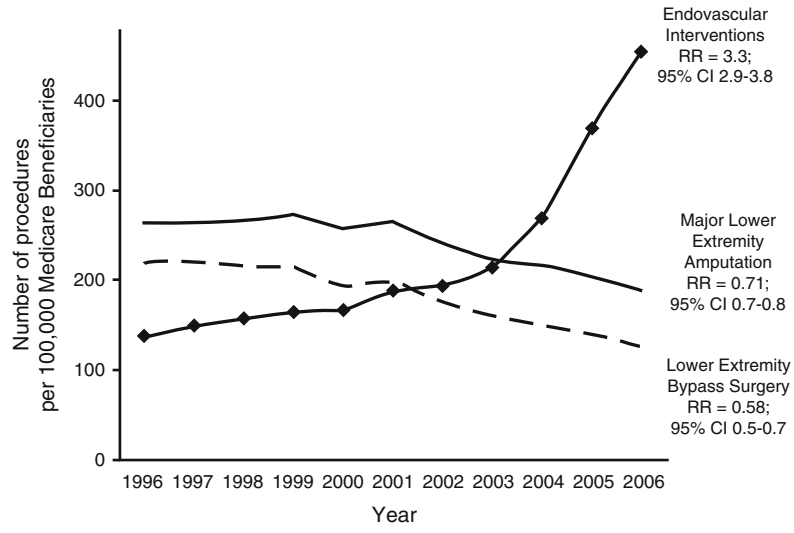

Fig. 41.1 Trends in endovascular interventions, major amputation and lower extremity bypass surgery for peripheral artery disease from 1996 to 2006 among the Medicare beneficiaries. *RR* risk ratio, *CI* confidence interval. (From Goodney PP, Beck AW, Nagle J, et al. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. *J Vasc Surg*. 2009;50:54–60 with permission.)

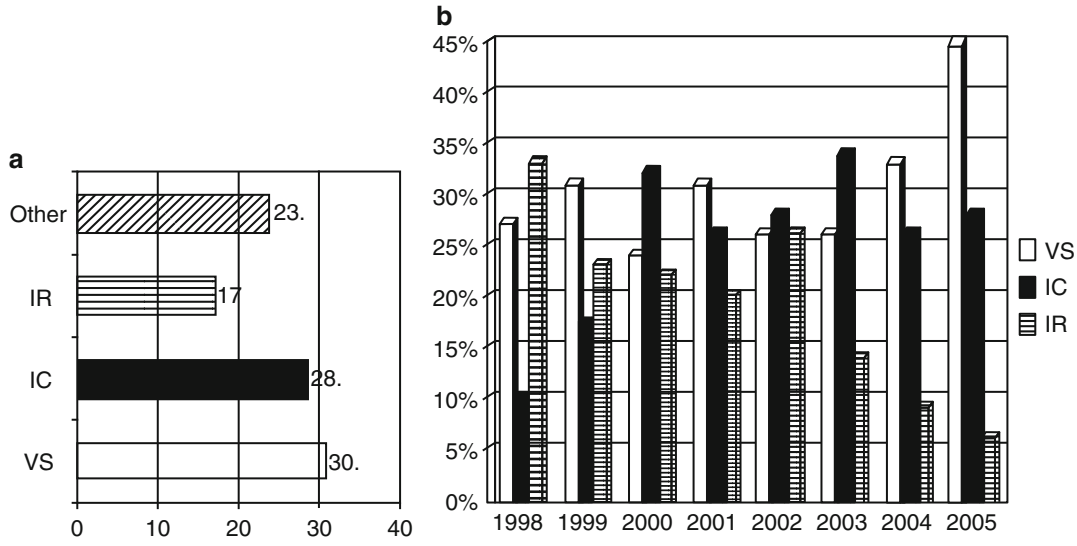

Fig. 41.2 Trends of specialties market share performing peripheral arterial interventions among interventional radiologist (IR), interventional cardiologist (IC) and vascular surgeon (VS). (From Eslami, MH, Csikesz N, Schanzer A, et al. Peripheral arterial interventions: Trends in market share and outcomes by specialty, 1998–2005. *J Vasc Surg*. 2009;50:1071–8 with permission.)

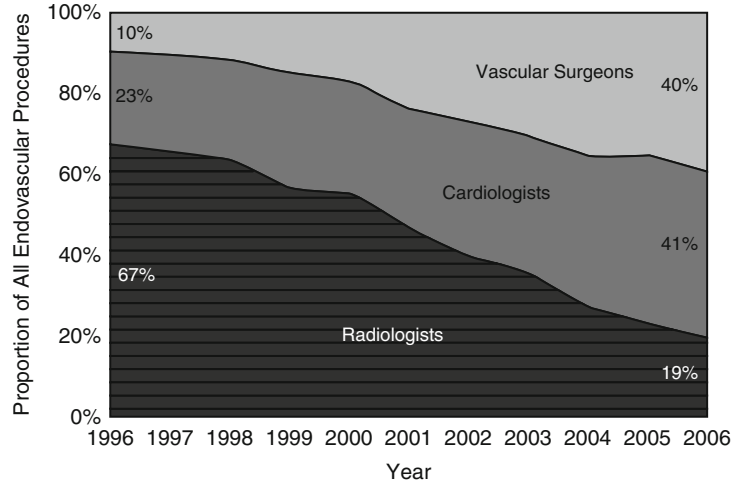

Fig. 41.3 Portion of endovascular interventions performed by specialty from 1996 to 2006. (From Goodney PP, Beck AW, Nagle J, et al. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. *J Vasc Surg*. 2009;50:54–60 with permission.)

National Inpatient Sample, the numbers of procedure had increased significantly during years 1998–2005 [12]. More than 50 % of the procedures were performed in teaching hospitals [12]. Vascular surgeons and cardiologists were two of the main providers performing endovascular interventions [12]. During the study period, the market share for radiologists had decreased from 33 % to 5.6 %, whereas there was a 27–43 % increase for vascular surgeons and a 10–28 % increase for cardiologists (Fig. 41.2) [12]. These changes were even more prominent in large academic teaching hospitals. The most common insurance payer for peripheral arterial intervention in this study was Medicare [12]. Approximately 70 % of patients who underwent peripheral arterial intervention had Medicare, up to 25 % had private insurance and 4 % were Medicaid recipients [12]. This study however did not report percentage of endovascular intervention that was performed in patients without any health care insurance. Among the specialties, cardiologists had the highest number of

patients with private insurance, whereas vascular surgeons had the most patients that were insured by Medicaid. All specialties were performing similar proportion of endovascular procedure among Medicare beneficiaries [12].

Vogel et al. evaluated the impact of specialty practitioner (vascular surgeon and cardiologist) on practice pattern of lower extremity endovascular intervention in State of New Jersey from 2003 to 2007 [13]. Patients treated with endovascular interventions by vascular surgeons were more likely to have critical limb ischemia including tissue lost and rest pain, whereas cardiologists were more likely to use a treat those with claudication [13]. Among patients who had stent placement during endovascular interventions, vascular surgeons were more likely to use a stent for patients with tissue loss and cardiologists were more likely to use a stent for rest pain [13]. The utilization of stent in patients with claudication was similar between two specialty providers. There was also suggestion that cardiologists utilized higher hospital resources during endovascular intervention compared to vascular surgeons, independent of indication for intervention and patients' medical comorbidities [13]. High volume practitioners, which included both vascular surgeons and cardiologists, had lower hospital resource utilization compared to their colleagues who performed less peripheral intervention [13].

Quality Improvement and Outcomes Research in Vascular Surgery

Clinical outcomes research and evidence-based medicine have impacted the practice of vascular surgery in the US over last two decades. [7] Randomized control trials and case controlled series from high volume centers had been used traditionally to evaluate the effectiveness of vascular procedures. More recently clinical studies utilizing large administrative data such as the Medicare and Nationwide Inpatient Sample databases have provided insight into the outcomes of "real world" vascular surgery practice. These databases collect information from wide varieties of hospitals and surgeons nationwide, across different geographical areas and various practice settings. Some of the important findings are observed volume-outcome relationship for commonly performed procedures such as CEA and AAA repair, as well as less commonly performed including open thoracoabdominal aneurysm repair [7].

Voluntary participation in national and regional quality improvement program has been shown to be associated in improvement of safety and efficacy of patient care in vascular surgery. The National Surgical Quality Improvement Program (NSQIP) is a nationally validated, risk-adjusted, outcomes-program run by the ACS to improve quality of surgical care (www.facs.org/qualit-programs/acs-nsqip). The 30-day outcomes data after major surgery, including vascular procedure are collected by trained surgical reviewers at participating hospitals. Risk adjusted outcomes are reported for each participating hospital to compare with other sites in the country. Participation in NSQIP has been shown to be associated with better perioperative outcomes with fewer complications, and reduction in overall cost for surgeons and hospitals. More recently the Vascular Quality Initiative (VQI) was developed to improve quality of care for patients undergoing vascular surgery (www.vascularqualityinitiative.org). The VQI collects perioperative and 1-year follow up data to assess quality of care and determine best practices in vascular surgery. More than 350 centers with over 2600 physicians across the United States are now involved in this regional quality collaboration, which is governed by the Society of Vascular Surgery. The VQI quality projects have been successful in improving quality of patient care such as reduction in surgical site infection after lower extremity bypass and reduction of length of stay after CEA.

Medicolegal Claim in Vascular Surgery

The rate of medical malpractice litigations in the US has increased significantly over last few decades, and continues to exceed those of other developed countries, including the United Kingdom. As a result, the practice of defensive medicine can leads to unnecessary diagnostic

tests and procedures. The malpractice insurance premiums continue to rise in the US, and are generally higher for physicians performing interventions or surgeries including the vascular surgeons. All these factors have contributed to the overall rising costs of health care in the US. A numbers of factors are associated with lower malpractice claims rate compared to their peers: surgeons who completed additional fellowship training, had clinical teaching faculty appointment, belonged to a professional society, were graduates of a US or Canadian medical school, had specialty board certification, and practiced in group practice were significantly less likely to have malpractice claim [14].

In a recent paper evaluating malpractice litigations after CEA in the US, perioperative complications including stroke and hypoglossal nerve injury were responsible for significant numbers of litigations [15]. Other complications were airway compromise, vocal cord injury, and death. The reasons for litigation were deficits in informed consent, performing procedures that were not clinically indicated, failure to recognize complications in timely fashion and postoperative complications requiring additional surgeries. The settlements and jury awards were between 0.9 million and 1.5 million US dollars, and the most litigated states were California and New York. In another study evaluating litigation claims in vascular surgery in the United Kingdom, the most common reason for successful claims were intraoperative problem, and failure or delay in treatment and diagnosis [16]. The main intraoperative problems were nerve injury and arterial or venous injury. Surgery for varicose vein was responsible for more than half of the successful claims, followed by procedures for PAD and abdominal aortic aneurysm.

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Current Status of Vascular Surgery in Japan

42

Toshiya Nishibe and Edward Barroga

The Japanese Health Insurance System

The Japanese public insurance system provides coverage to everyone in Japan (http://www.mhlw.go.jp/). In particular, the Japanese health insurance system which dates back from 1922 was initiated for the employees of enterprises. In 1961 after the war, it became a universal health insurance system which provided universal coverage. This universal system has been maintained for more than 50 years and has become a system that Japanese can rely on and be proud of. The universal health insurance system includes *Health Insurance* managed by the Health Insurance Society for the employees of enterprises, *Health Insurance Association-managed Health Insurance* for small- and medium-sized companies, and *National Health Insurance* operated by municipalities for people without any other insurance plans. People aged 75 years or older could also subscribe to the Late-Stage Medical Care System for the elderly.

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As stated earlier, everyone is covered by some form of public insurance system and therefore can receive the necessary medical services at low cost by paying certain insurance premiums and co-payments (10–30%) to a reception desk. In addition, under the High-Cost Medical Care Benefit System, a monthly medical care cost can be reduced to ¥57,600 to ¥252,600 or more according to a patient's income.

However, the financial management of the insurance system has witnessed quite a severe development in recent years owing to an increase in the national medical expenditure. The balance of the "country of debt" reached 1053 trillion 357.2 billion yen as of the end of March 2015, and the debt per capita calculated based on the population is about 8.3 million yen. The rise in medical expenditure has been mainly attributed to an increase in the medical expenditure for the elderly. This situation is expected to worsen as aging further advances in Japan.

Patients' Ability to Pay and Its Influence on Surgeon's Practice

In Japan, people can visit any medical institutions of their choice to receive medical care at a fairly low cost. This convenient and efficient environment that Japanese typically take for granted is rather uncommon in other countries where the type of medical care received can differ according to income. In most of these other

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countries, registered family doctors are responsible for providing primary medical care, and receiving medical examinations from specialized doctors typically takes much longer. This circumstance can become quite a major issue in other countries, but is not observed in Japan.

Legal Environment and Malpractice

Details of the current situation of medical malpractice and its handling by Japanese legal and social institutions have been described [1]. Traditionally, with respect to physician-patient relationships, a paternalistic paradigm has prevailed in Japan. Japanese courts have granted considerable deference to the medical profession, wherein malpractice claims have been few, and the malpractice insurance premiums that are uniform nationwide for physicians in private practice have been low. However, transparency principles have gained traction and public concern over medical malpractice has intensified. The overall numbers of malpractice claims annually per million patients in the court and out of the court are considerably higher in the United States (an estimated 50,000–60,000 claims for a total population of 301 million, or 170–200 per million) than in Japan (perhaps 5000–10,000 claims for a total population of 127 million, or 40–80 per million). Incidentally, there has also been a rapid increase in the number of physicians who take out physician liability insurance in Japan. At the urging of medical specialty societies, the Ministry of Health, Labour and Welfare has undertaken a "model project" to enlist impartial medical specialists in the investigation and analysis of possibly iatrogenic deaths in Japanese hospitals.

Board Certification in Vascular Surgery

There are large differences in training in peripheral vascular surgery between Japan and other countries possibly because of the existing associations between trainings in peripheral vascular and cardiovascular surgery (http://cvs.umin.jp). Board certification is awarded by The Japanese Board of Cardiovascular Surgery which was established in 2003 in conjunction with the Japanese Society of Thoracic Surgery, Japanese Society of Cardiovascular Surgery, and Japanese Society of Vascular Surgery. Board certification for peripheral vascular surgeons is achieved by completing the same pathway for cardiovascular surgeons. For these reasons, there are only 200–300 peripheral vascular surgeons from the total of 1873 board-certified cardiovascular surgeons in Japan.

Board certification is given to surgeons who have met the highest standards of education, training, and knowledge in cardiovascular surgery. *First*, board certification in general surgery is a prerequisite for board certification in cardiovascular surgery. *Second*, a minimum of 500 points from necessary operative procedures (Tables 42.1 and 42.2) is required to be considered as an operating surgeon, a first assistant, or a second assistant. *Third*, three peer-reviewed papers and three presentations are required. *Finally*, successful completion of the cardiovascular surgery certifying examination is required for board certification in cardiovascular surgery. The certifying examination is a 1-day multiple-choice examination held once a year in Tokyo. The examination passing rates were 71.7%, 71.1%, and 70.7% in 2012, 2013, and 2014, respectively. Certificates are valid for a period of only 5 years from the date of issuance through December 31 of the year of expiration. Certificate holders must perform at least 100 operations as an operating surgeon or as an instructor for 5 years to renew their board certification.

Table 42.1 Points of operations

	Operation		
Degree of difficulty[a]	A	B	C
Operator	3	4	5
First assistant	1.5	2	2.5
Second assistant	0.3	0.4	0.5

[a]A < B < C

Table 42.2 Degrees according to difficulty of operations

Degree of difficulty (A)	Degree of difficulty (B)	Degree of difficulty (C)
1. Congenital heart disease	1. Congenital heart disease	1. Congenital heart disease
(1) PDA closure	(1) Blalock-Taussig shunt	(1) TOF correction
(2) ASD closure	(2) Pulmonary artery banding	(2) TGA surgery
(3) VSD (Type 1) closure	(3) CoA operation	(3) DORV surgery
(4) Pulmonary	(4) VSD (Type 2) closure	(4) TAPVR repair
	(5) PAPVR repair	(5) AVSD(Complete) repair
2. Valve disease	(6) ASVD (partial) repair	(6) Fontan procedure
(1) Tricuspid annuloplasty	(7) Sinus of Valsalva aneurysm repair	(7) Truncus arteriosus repair
(2) Arterioventricular commissurotomy	(8) DCRV repair	(8) Ebstein's anomaly repair
	(9) RVOT plasty	(9) Norwood operation
3. Other cardiac surgeries	(10) Aortic valvotomy	(10) Surgery for anomalous origin of coronary artery
(1) Pericardial window technique	(11) Coronary artery fistula closure	(11) CoA (complex)/IAA surgery
(2) Pulmonary vein isolation	(12) Bidirectional Glenn procedure	(12) Peripheral pulmonary stenosis repair
		(13) Ross procedure
4. Arterial disease	2. Valve disease	
(1) Thromboembolectomy	(1) Aortic valve replacement	2. Valve disease
(2) Extra-anatomic bypass	(2) Mitral valve replacement	(1) Mitral valvuloplasty
(3) Peripheral aneurysm operation	(3) Pulmonary or triscupid valve repalcement	(2) Aortic valvuloplasty
(4) Percutaneous transluminal angioplasty		(3) Combined valve surgery
	3. Ischemic heart disease	(4) Aortic root enlargement
5. Venous disease	(1) Coronary artery bypass grafting (single)	(5) Aortic root replacement
(1) Thrombectomy		
	4. Other cardiac surgeries	3. Ischemic heart disease
6. Other vascular surgeries	(1) Cardiac tumor resection	(1) Coronary artery bypass grafting (> double)
(1) Surgical arteriovenous shunt	(2) Constrictive pericarditis pericardiectomy	(2) Surgery for complications of myocardial infarction
	(3) Maze procedure	
7. Other equivalent surgery		4. Other cardiac surgeries
	5. Aorta	(1) Pulmonary thromboendartectomy
	(1) Ascending aortic replacement	(2) Surgery for ventricular tachycardia
	(2) Descending aortic replacement	(3) Left ventricular reconstructive surgery
	(3) Abdominal aortic replacement	(4) Artificial heart implantation
	(4) Endovascular aortic repair (straight)	
		5. Aorta
	6. Artery	(1) Aortic arch replacement
	(1) Lower extremity revascularization (above-knee)	(2) Thoracoabdominal aortic replacement
	(2) Upper extremity revascularization	(3) Abdominal aortic replacement with suprarenal clamp

(continued)

Table 42.2 (continued)

Degree of difficulty (A)	Degree of difficulty (B)	Degree of difficulty (C)
	(3) Ruptured peripheral aneurysm operation	(4) Aortic dissection surgery
		(5) Mycotic/inflammatory abdominal aortic anuerysm surgery
	7. Vein	(6) Ruptured abdominal aortic anuerysm surgery
	(1) Peripheral vein revascularization	(7) Atypical CoA operation
		(8) Endovascular aortic repair (branched)
	8. Other vascular surgeries	
	(1) Vascular trauma operation	6. Artery
	(2) Thoracic outlet syndrome	(1) Lower extremity revascularization (below-knee)
	(3) Lymphoedema	(2) Carotid endarterectomy
		(3) Vertebral artery revascularization
	9. Other equivalent surgeries	(4) Splanchnic artery revascularization (including renal artery)
		7. Vein
		(1) Vena cava revascularization
		8. Other equivalent surgery

PDA patent ductus arteriosus, *ASD* atrial septal defect, *VSD* ventricular septal defect, *CoA* coarctation of the aorta, *PAPVR* partial anomalous pulmonary venous return, *ASVD* atrioventricular septal defect, *DCRV* double-chambered right ventricle, *RVOT* right ventricular outflow tract, *TOF* tetratogy of Fallot, *TGA* transposition of the great arteries, *DORV* double outlet right ventricle, *TAPVR* total anomalous pulmonary venous return, *IAA* interruption of the aorta

Paradigm Shift of Training for Vascular Surgery

The rapid development of endovascular techniques has had a significant impact on vascular surgery training. In fact, the number of endovascular procedures performed during vascular surgery training has dramatically increased over the last decade. However, opportunities for training residents in bypass surgery and open repair of abdominal aneurysms have been decreasing. We have a growing fear that the combination of poor training in open operations and increasing complexity of open surgical operations may lead to poor surgical outcomes. Current evidence suggests that the skills acquired through training with surgical simulators can be positively transferred to the clinical setting and this improves operative outcome. The value of dry or wet surgical simulators has been gradually but increasingly understood in Japan. Thus, an educational curriculum that incorporates surgical simulators is presently being developed.

The Environment for Referrals to Vascular Surgery, as Opposed to Cardiology

Historically, vascular surgeons had assumed the overall responsibility for managing patients with peripheral artery disease (PAD) in Japan (http://www.jsvs.org/ja/enquete/report2011/index.html). This situation has completely changed with the introduction of endovascular technology. Vascular surgeons have attempted to preserve and protect their primary role in the management of PAD patients, whereas interventional cardiologists have competed among themselves and have occasionally viewed vascular surgeons as irrelevant in light of endovascular therapy (EVT). In 2012, EVT for PAD was performed in approximately 30,000 patients by cardiologists and in 5792 patients by

vascular surgeons. Traditional vascular surgeons still stick to bypass surgery; however, they should embrace and validate newer technologies such as EVT if they are to remain competitive in the management of PAD.

Scientific Research Support

Grants-in-Aid for Scientific Research (called KAKENHI) are competitive funds that are intended to significantly develop all fields of scientific research (https://www.jsps.go.jp). KAKENHI are the largest competitive funding program in Japan, accounting for more than 55 % of all the competitive funding by the Japanese government (the budget for fiscal year 2014 was 227.6 billion yen). The screening for KAKENHI applications is implemented by the Japanese Society for the Promotion of Science Committee on KAKENHI. About one-third of the KAKENHI are allotted to medical science, dentistry, pharmacy, and nursing. The committee consists of approximately 6000 reviewers who have been selected from each academic field. In fiscal year 2013, there were approximately 98,000 new applications, of which approximately 26,000 proposals were adopted. Another competitive funding includes the Health Labour Sciences Research Grant given by the Ministry of Health, Labour and Welfare. There are also many research funds provided by private foundations.

Internet Use for Acquiring Medical Information

Over the past decade, Internet use by physicians and patients has become very popular in Japan. Takahashi et al. conducted a cross-sectional survey of a quasi-representative sample (n = 1200) of the Japanese general population aged 15–79 years in 2007 [2]. They reported that, although television (60.1 %, 721) and newspaper (50.3 %, 604) were widely used, Internet use (Web browser or email) via personal computers for acquiring health-related information reached 23.8 % (286), and 6 % (77) for Internet use via cell phones. The Internet was used via personal computers for acquiring medical information primarily by younger people, people with higher educational levels, and people with higher household incomes. Older people, people with lower educational levels, and people with lower household incomes were less likely to access the Internet via their cell phones. Recently, smart phones have been increasingly used in Japan. Thus, it is beyond doubt that more and more people are accessing the Internet for medical information via their smart phones.

Future Perspective for Vascular Surgery

Presently, the most serious problem is the absence of a specific type of surgery that can be performed only by peripheral vascular surgeons. EVT for PAD can be carried out by cardiologists or interventional radiologists; endovascular aortic repair for thoracic and abdominal aortic aneurysms by cardiac/cardiovascular surgeons or radiologists, and distal bypass for critical limb ischemia by cardiac/cardiovascular surgeons. However, percutaneous coronary interventions or coronary artery bypass grafting cannot be performed by peripheral vascular surgeons. Thus, there is a need to establish a new field in vascular diseases that can be performed by only vascular surgeons.

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Status of Vascular Surgery Practice in India

43

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Background and Demographics

India is a vast country in south-east Asia, often dubbed as a sub-continent. Straddling an area of 32,87,263 km^2, the land is diverse both geographically, ethnically, and culturally. Over 16 languages, and a 100 dialects are spoken across the land. The administrative regions comprise of 30 states and six small 'union territories'. Its current population of 1.3 billion is set to overtake that of China as the most populous nation in the world in another decade. The 2014 GDP was 2.067 trillion, with an annual GDP growth rate of 7.4 %. India is all set to become the worlds' third largest economy (after USA and China). The inflation rate is rather high at 6.4, and a cause for concern. The per capita income is USD 1352.3 per annum [1].

Despite the impressive growth of GDP, the Human Development Index is 0.586, pushing India to 135th place in the world on this parameter, 68 years after its independence from UK. The poverty rate is 21 %, with several economists arguing that it is actually much higher. The adult literacy rate is 73 %. Life expectancy at birth is 66 years. The Infant Mortality Rate (IMR) is 43.19 deaths/live births; and Maternal Mortality rate (MMR) is 140/100,000 live births [2]. These figures have improved considerably since 1998 [3]: IMR used to be 70, and MMR 410, yet these indicators of National Health are still worrisome. Communicable diseases like tuberculosis, malaria, respiratory and diarrheal disease remain a public health problem. This grim healthcare scenario is compounded by an epidemic of 'lifestyle' diseases like hypertension and coronary artery disease. India is also the diabetic capital of the world, with an estimated 140 million diabetics.

Healthcare Scenario

Health is a 'state' subject—that is to say that each region (state) is responsible for the healthcare delivery in that area; the Central (union) Government in Delhi largely issues guidelines and monitors central-sponsored programs. The annual GDP spend on health has risen from 0.6 % to about 1.2 %; obviously this is still grossly inadequate [4]. The medical education and healthcare system is largely modeled on the erstwhile British system. The 'modern

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western healthcare system' is the backbone of the healthcare system. However traditional (alternative) systems of medicine like Ayurveda, Tibbi, Unani, and Homeopathy also flourish in villages and rural areas. There is a division of 'AYUSH'—an acronym for Ayurveda, Unani, Siddhi, and Homeopathy in the Union Health Ministry. Personnel trained in these systems want to be allowed to practice the modern ('allopathic') system of medicine in urban areas; this is fiercely resisted by the regular doctors. This is a controversy that is yet to be resolved. There are over 250 medical schools (both, state-run and private) in the country that train doctors both at graduate and post-graduate level.

Hospitals run by the central and state governments are present in most towns and cities, where citizens are entitled to free health care. However it is impossible for the government to fulfil this obligation. Consequently a large number of private hospitals have come up across the nation. They provide facilities comparable to the best in the world. Needless to say they are expensive and the services are provided on payment. Comprehensive healthcare facilities are available at no cost for the personnel and the family members of the armed forces, the Railways, Central and State Governments, and Public Sector Undertakings—however these account for less than 2% of the population. For the remainder, there is no universal state-sponsored health insurance in the country, though some states like Karnataka provide limited insurance to farmers and rural population at a very nominal premium. Consequently, private insurance has seen a huge upsurge especially in urban areas and larger towns and cities.

Health insurance in India is somewhat peculiar—one pays a premium for a fixed overall sum payable (say $10,000). If this amount is exceeded during hospitalization (or in a calender year), the patient has to pay the remainder from his pocket. The patient can choose for a new technology to be paid for from his insured amount; the insurers normally do not raise an objection. The limiting factor is generally the sum insured, since newer technologies are expensive. For example, for infra-popliteal PAD (peripheral artery disease), the atherectomy device alone costs $2500; if one adds the hospital cost of procedure, and bailout stenting, the total bill can easily exceed $8000. Few amongst even the insured can afford this easily. Unless one works in a premier Government hospital (which centrally procures and provides these devices at a very low or no cost), a patient's ability to pay does affect the surgeon's practice and device selection. This is part of the reason why EVAR (endovascular aneurysm repair) is not performed in huge numbers in India—the total cost ($12-15,000) is much more than the cost of open surgical repair of the aneurysm ($5000).

Physicians working in private institutions come under the purview of 'Consumer Protection Act'; those working in Government Hospitals do not fall in its ambit. Dissatisfied patients can file a case with Consumer Courts for redressal of their grievance. However the legal environment is reasonably good for physicians in India, and malpractice suits by patients/their lawyers are very rare. Of course occasional cases do occur if there has been gross negligence, but this is hitherto unknown in field of vascular surgery. With the wide availability of the internet and the social media, the educated patient is reasonably well informed about his disease and the treatment options. These patients are a challenge; often the information on the internet is not very accurate, and convincing the patient can be trying for the physician.

Medical research facilities are very limited. Barring a handful of national hospitals of excellence, funds are simply not available. Given the sheer numbers and diversity of diseases, India should be in the forefront in producing cutting-edge research. The reality is completely the opposite.

Vascular Surgery

Vascular diseases often continue to be neglected in the country. The reasons are manifold. There is lack of awareness, both amongst the general population, as well amongst physicians. It is still not uncommon for a claudicant to be treated as a case

of 'sciatica' or 'arthritis' for long periods, often till gangrene sets in and amputation is the only alternative. A popular myth is that Indians do not suffer from PAD—much like the situation three decades ago when it was believed that coronary artery disease (CAD) is uncommon in India. Of course the fact is that CAD is as common as in the West—millions undergo coronary angioplasty/CABG (coronary bypass surgery) annually. With its huge diabetic population, it is surmised that thousands have undetected PAD, with many landing up with amputation (no national database is available). In fact, way back in 1980 Nigam published that 0.8 % of all admissions in Delhi were due to vascular disorders [5]. Another widely held belief is that majority of PAD is Buerger's Disease (thromboangiitis obliterans, TAO), or its variant, the South Indian Arteritis, first described by Vira Reddy [6]. This is certainly not true any longer; athrosclerotic accounts for over 90 % of cases of PAD. Because angioplasty/peripheral bypass surgery is not possible in TAO, the nihilistic attitude regarding PAD is difficult to erase from collective physician memory. Omental transfer has been an Indian innovation to salvage limbs in TAO [7]. A disease which is still seen often enough is Takayasu's Arteritis, also called non-specific aorto-arteritis [8]. This afflicts mostly young females, and is treated medically: angioplasty or surgery is infrequently required. One entity which is relatively uncommon is aneurysms of aorta—both thoracic and abdominal. In the absence of any screening program it is difficult to say whether they are truly uncommon, or they go undetected. Perhaps a bit of both, according to most Vascular Surgeons.

Historically, vascular surgery in India was part of the broad sub-specialty of cardio-thoracic vascular surgery (CTVS). Most CTVS units though—both in government and private institutions—practice exclusive cardiothoracic surgery. Majority of the CTVS surgeons are not trained in the management of peripheral arterial disorders. Yet this group is reluctant to allow vascular surgery to part from its fold. Because vascular surgery was part of CTVS subspecialty, virtually no training/teaching exists at the graduate (MBBS) level, or at the postgraduate general surgery training programs (MS general surgery) [9].

Training in Vascular Surgery

The first three-year sub-specialty training program in vascular surgery—MCh—started at Madras Medical College, Chennai (Tamilnadu State in southern India) in 1985. This was accredited by the MCI (Medical Council of India). This has trained over 50 vascular surgeons. However one serious drawback is that only doctors belonging to Tamilnadu state can gain admission in this training program. Subsequent MCh programs have been launched at Stanley, Madurai, and Sri Ramachandra Medical Colleges (all in Tamilnadu), Christian Medical College Vellore, Sri Chitra Thirunal Institute (Trvandrum, Kerala), Nizam's Institute (Hyderabad, Telangana), and MS Ramiah Medical College at Bangalore. A DNB (Diplomate in National Board) 3 year training program in vascular surgery is also offered by several institutions in Delhi, Bangalore and Hyderabad. The total number of surgeons being trained as vascular surgeons annually is about 15–20, far less than that required for the country.

Vascular Surgery was recognized as an independent specialty by the MCI in the mid-1980s, much to the chagrin of the conservative CTVS specialty. In 2001 the latter prevailed upon MCI to merge it back in CTVS fold [10]. Concerted action by the Vascular Society of India (VSI) led to the order being rescinded, and vascular surgery exists as an independent specialty in India. However it also continues to be a part of the CTVS specialty; this duality is not good—neither for the patients, nor for surgeons who exclusively practice vascular surgery. VSI was formed in 1994 by a group of 35 dedicated vascular surgeons. The society has grown in numbers with current membership in excess of 450. To be fair, less than half the members practice vascular surgery exclusively. VSI organizes an Annual Conference and a mid-term conference every year. In liaison with other societies like the SVS

(Society for Vascular Surgery), ESVS (European Society for Vascular Surgery) and ISVS (International society for Vascular Surgery) it organizes short overseas training program for Indian vascular surgeons. VSI is also a part of the World Federation of Vascular Societies (WFVS). The Indian Journal of Vascular and Endovascular Surgery was formally launched in November 2014.

Endovascular Surgery

Interventional vascular procedures (angioplasty/stenting/EVAR/embolization of vascular malformations etc.) are performed by a large number of vascular surgeons, mostly by those working in private institutions. Sophisticated procedures like fenestrated and branch grafts for aneurysm and tibial angioplasty are also performed on a regular basis. Access to cath-lab is however a challenge, especially for those working in Government institutions as cardiologists and interventional radiologists (who traditionally performed these procedures) are loathe to part with it. The problem of training of vascular surgeons in endovascular procedures has partly been overcome by the generosity of the world fraternity of vascular surgeons, who have trained over a dozen Indian vascular surgeons in this field. Clearly more need to be trained, not only overseas, but also within the country itself. The challenge to gain access to cath lab remains. The referrals in large cities are based on actual performance; vascular surgeons have to compete with the cardiologists and interventional radiologists. The argument—that vascular surgeons can both operate as well as do angioplasty and therefore will do what is best for the patient without any 'conflict of interest'—resonates well with the discerning patient. Referral to vascular surgeons for interventional procedures is steadily increasing.

Conclusion

In conclusion, vascular surgery is a young, vibrant and independent specialty in India. Complicated open and endovascular procedures, comparable to the rest of the world, are performed on a regular basis at many centers. Vascular Society of India has worked tirelessly for over two decades to promote the specialty. There is a need for a sustained campaign to increase awareness regarding vascular disorders, both amongst lay public, as well amongst the physicians. More institutions need to add training programs in vascular surgery, as there are too few vascular surgeons for this large country. More endovascular training programs need to be made available for the young vascular surgeon. Finally efforts need to continue to make vascular surgery a truly independent specialty in India.

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Status of Practice of Vascular Surgery in Singapore

44

Shin Chuen Cheng

Singapore is a small island state at the tip of the Malayan Peninsula in Southeast Asia. One of the four Asian 'Tigers' (the other three being Hong Kong, South Korea and Taiwan), as dubbed by the Western Press, Singapore saw dramatic economic growth in the 1970s and 1980s after her independence from British Colonial Rule in the 1960s.

Singapore was ranked number 6 [1] in WHO international rankings in terms of overall health systems performance in 1997 and the small population of five million residents enjoys modern healthcare provision with life expectancies similar to many developed Countries in the West or East Asia.

Within the context of a modern healthcare system, the practice of Vascular Surgery in Singapore has in many ways, seen an accelerated paradigm shift in the way Vascular Surgeons practice over the past 7–8 years.

A combination of factors have contributed to this and one major factor is the relatively 'open' philosophy adopted by the Vascular Surgery community in Singapore; in both recognizing the value of different 'foreign' practices and foreign Vascular Surgeons.

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Before elaborating on the various factors that affected our current practice, the author would like to articulate his view on the progression of specialty development so as to assess the stage of development we are currently at. At each stage of specialty development, two phenomena are essentially happening concurrently; the evolution of services offered to the patient and evolution of ability of the specialist to be the principal service provider.

Stages of Service Provision

Stage 0: Specialists do not have adequate skill sets to deliver services.

Stage 1: Specialists available and have adequate skill sets but the quantity of specialists only allow for only service provision. Training future specialists and internal accreditation of specialist training is not possible.

Stage 2: Critical number of competent Specialists available. Specialist Training and internal accreditation is possible. Specialists endeavor to form Clinical Databases and clinical research begins to audit and analyze current practice.

Stage 3: Clinical databases and Registries are well established in collaboration with local Universities, Teaching Hospitals and Device Industry. Specialists are routinely involved as investigators in multi-centre trials and involved in Specialist Society Consensus guideline formulation.

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Stages of Specialist Development

Stage A: Principal Specialists do not have adequate skill sets

Stage B: Principal Specialists have adequate skills sets in one spectrum of treatment modality but lacking in another significant treatment modality that forms a crucial treatment arm.

Stage C: Principal Specialists have adequate skill sets in all forms of treatment modality.

For example in a strictly hypothetical situation, a developed country may have been running trials and been involved in consensus statement formulation but if the Vascular Surgeons have limited or no Endovascular skill sets then at best, the country will be at Stage 3B level of development.

Ideally a country should be at a Stage 3C level of development. As this is just an arbitrary staging process, the stage of practice can easily overlap or regress. Even in a small country like Singapore with a population of five million, the various hospitals can be at different stages of development at one point or the other.

From the author's observation, a clinical specialty can be in any stage of development and you can have individuals of immense passion and drive who will still get involved in "bench to clinical" application research; whether in basic science research or device design. Reasonably, the available resources available to these individuals will be different in quantity and quality, depending on the stage of specialty development.

History of Vascular Surgery in Singapore

1950s–1960 Stage 0A

Vascular Surgery began undeniably with the first Dacron Graft Aneurysm repair by the late Dr Michael Debakey in the 1950s. The practice of Vascular Surgery then was mainly considered a subspecialty of Cardiothoracic Surgery. Surgeons were grounded in General Surgery before their Fellowship in Cardiothoracic Surgery. Singapore at this juncture was still under colonial rule and there were no local Cardiac or Vascular Surgeons.

1961–1990s Stage 1C

The late Dr Tan Ngoh Chuan was the first fully trained Cardiac Surgeon in Singapore. He completed his Surgery training in 1959 (being the first Malayan to obtain his Fellowship in Surgery from the Royal Australian College of Surgery). He completed his Cardiac Fellowship in Melbourne in 1961 and started the first Cardiac Surgery unit in Singapore at the Tan Tock Seng Hospital.

In 1961 it was also the time when the first private hospital in Singapore, Mount Alvernia Hospital opened.

This created a private/public divide in service provision in Singapore whereby Doctors who leave public service, do not hold on to their full time clinical posts in the public hospitals. Since then the public hospital system has always been where Surgeons underwent and completed their Specialist Training (a training ground, in a manner of speaking). Once a Surgeon leaves the public system (except for the rare exceptions), the skill transfer and mentorship offered by this Surgeon to his or her trainees ceases.

Up until the early 1990s, Cardiac Surgeons performed vascular surgery operations such as peripheral bypass, vascular access and Aneurysm repairs. Aneurysm surgery was shared with General Surgeons who had some exposure to Vascular Surgery.

The first few Vascular Surgeons in Singapore are Dr Tan Seck Guan and Dr Imran Nawaz. They completed their Vascular Surgery Fellowships overseas in the mid-1990s. Both surgeons were trained General Surgeons before embarking on a non-Cardiac Vascular Surgery Fellowship. Dr Tan completed his Fellowship in the United Kingdom and Dr Nawaz completed his in Australia. The British and Australian 'style' of Vessel dissection, vessel control and vessel anastomosis no doubt have a significant effect in how open vascular surgery is practiced in Singapore as seniors surgeons like Dr Tan, mentored generations of vascular surgeons passing through his team in Singapore General Hospital.

From the mid to the late 1990s the bulk of Vascular Surgery work is now performed by a handful of Vascular Surgeons.

As the twentieth century drew to a close in 1999, the population of Singapore stood at 3.9 million. This population was served by a total of seven Vascular Surgeons, of which six are in public hospitals and one in private practice.

At this point in time Open Aneurysm Repairs and Open Peripheral Bypasses were still the mainstay of first line treatment.

2000–2007 Stage 2B

During this period of relative stability, the higher number of trained Vascular Surgeons and the increase in vascular surgery workload from an aging population helped attract new trainees to this demanding discipline. The number of trained vascular surgeons grew to ten by the end of 2007.

Having a critical number of Vascular Surgeons made it possible for the local fraternity to play host to the 5th International Congress of the Asian Vascular Society in May 2002. This was considered a minor triumph, as there were only nine Vascular Surgeons for a population of 4.1 million.

In the international Vascular Community, Endovascular Surgery was starting to play a bigger role in the treatment of Vascular Diseases.

The late Dr Alexandre Chao, was instrumental in bringing Endovascular Surgery to Singapore. He completed his Vascular Surgery training in Sydney Australia in 2000, after training stints at Saint Vincent's, Saint George's and Liverpool Hospitals. He started performing Endovascular Aneurysm Repairs in Singapore in 2001 and aggressively promoted the use of angioplasty as first-line treatment in Below the Knee disease in Critical Limb Ischaemia.

The late Dr Chao, unfortunately passed away at the young age of 37 from SARS related complications on 5th April 2003. He contracted the infection from a patient he was looking after in the Intensive Care Unit in Singapore General Hospital. During his brief but illustrious career, Dr Chao inspired many trainee surgeons to take up Vascular Surgery and he played an undeniably pivotal role in the development of Endovascular Surgery in Singapore.

Despite the increasing use of Endovascular treatment modalities, many Vascular Surgeons during this era lacked basic Endovascular skillsets and the use of Endovascular interventions were subjected to the availability of Catheter Laboratory Facilities and Interventional Radiologists.

2008–Present Stage 2B/C

Having experienced a suboptimal delivery of care to the patient if Vascular Surgeons were not able to perform Endovascular procedures independently and in a facility accessible to them, many trainees during the period of 2005–2007 actively sought training in performing Endovascular procedures in the operating theatre. The understanding was that if one was able to perform endovascular procedures in the traditional home ground of Vascular Surgeons; the operating theatre, one will no longer be fettered by the whims of other specialists.

Again looking out of the country, trainees were fortunate to obtain solid training to underpin their future endovascular skills in Australia.

As serendipity was to have it, the circle was complete since the Country's first Cardiac/Vascular Surgeon completed his training in the 1960s, in Australia.

Since 2008, there was an exponential growth of Endovascular procedures performed independently by Vascular Surgeons. In most tertiary Public Institutions, the Operating Theatre has now become an accepted venue for independent Endovascular Procedures, without the assistance of Interventional Radiologists. A small number of foreign trained Vascular Surgeons with Endovascular skill sets who were recruited during this period of growth also contributed significantly to this.

Up until 2012, the private hospitals in Singapore lagged behind the public hospitals in terms of provision of endovascular interventions; Endovascular interventions for Below the Knee lesions in critical ischaemia were not considered a valid therapy in private hospitals. Starting from 2011, there was an accelerated exodus of Endovascular trained Vascular Surgeons from the

public hospitals to private hospitals for various reasons.

This created accelerated change in the local Vascular Surgery scene in two aspects; Firstly, Endovascular interventions were brought up to par in the private hospital setting (ironically these were the hospitals servicing the top 20–30 % of the population in terms of income). Secondly, public hospital administrators had to aggressively recruit foreign trained Vascular Surgeons to make up the missing numbers. The second situation arose because of the clear Public/Private divide that started since the 1960s.

As of the first half of 2015, there are currently 26 Vascular Surgeons in Singapore. Thirteen of these surgeons are trained locally with 13 being foreign trained. Nine Surgeons are working in the private hospitals (eight locally trained and one foreign trained) and 15 are working in the public hospitals (four locally trained and 11 foreign trained). Two Vascular Surgeons straddle both public and private hospitals (one locally trained and one foreign trained).

With a significant influx of foreign trained Vascular Surgeons over the past 4 years, they undoubtedly bring a fresh perspective to the local practice of Vascular Surgery. This is especially so when a sizeable number of the new surgeons are trained in the United States of America. This is a welcomed change, given the predominance of Australian and British influence in local vascular surgery training since the 1960s.

Moving forward, will the standard of practice in Singapore move to a true 3C level with our local fraternity involved in running trials and formulating consensus statements?

The author believes that these factors will influence the advancement of our surgical practice:

Patient/Caseload

For obvious reasons, Surgeons will not have technical expertise to perform more demanding procedures nor the academic clout to conduct clinical trials without reasonable Patient numbers.

Surgeon's expertise and bedside manners nonwithstanding, Patient caseload is in turn influenced by other non-Surgeon factors, namely Healthcare Funding and Disease awareness.

Healthcare Funding

Endovascular procedures are costly procedures with device costs ranging from the hundreds to the tens of thousands.

Singapore runs a healthcare funding system where the Singaporeans essentially pay for their own healthcare. When a Singaporean starts work and until his or her retirement, 8.5–10 % of his or her monthly salary goes towards a government held account called the Medisave account. This can only be utilized to pay only hospitalization fees and medical insurance fees but *not medications and devices*. The ceiling to the Medisave one can use for hospitalization is standardized across the board, computed according to complexity of procedures performed. Reasonably the 'cash-balance' amount a non-insured patient has to pay varies depending on the type of facility used (e.g. private hospital versus public hospital single air-conditioned room versus 8- bedded public common ward with only fans) and the devices and implants used (subsidies are very limited or non existent in public hospitals). Currently only 44.4 % [2] of Singaporeans have private healthcare insurance, another 22.13 % [2] only has medical insurance that covers public hospital. A significant 33.47 % of Singaporeans do not have any medical insurance and are reliant on their Medisave accounts and cash savings to pay for their hospitalization bills.

So paradoxically, a poor patient in Singapore will have to pay more in cash for a lower limb angioplasty with drug eluting balloons then to undergo a surgical bypass in a public hospital.

Singapore is now currently moving towards a limited Universal Healthcare coverage model that will take effect beginning of 2016. It is limited because though the details of device reimbursement are not released yet, it is widely expected to be significantly cap per year.

However, with any form of cash payment reduction, no matter how insignificant, we should reasonably see an increase in Endovascular procedures.

Disease Awareness

Based on the 2010 published data from the Ministry of Health Singapore, Hypertension, Smoking and Diabetes Mellitus are the leading cause of disease burden among Singaporeans [2]. All are important risk factors for Peripheral Vascular Disease. However in the bigger picture, the leading causes of death in Singapore are still Cancer, Pneumonia and Ischaemic Heart Disease [2].

Statistically speaking, Peripheral Vascular Disease (PVD) and Abdominal Aortic Aneurysmal (AAA) Disease don't figure high in the charts and neither do they figure prominently in public awareness. There are few initiatives in promoting peripheral arterial disease and aneurysm screening as compared to Colorectal, Prostate, Cervical and Breast Cancer screening.

Anecdotally however, the PVD and AAA numbers are steadily increasing in our public hospitals since 2005–2006 with Vascular Surgery Teams commonly being the busiest teams in a General Surgery Department.

Currently in Public institutions, Vascular Surgeons get most of the peripheral vascular disease and aneurysm referrals and this has been the case since 2000. In private hospitals, the bulk of the Aneurysm referrals (the numbers are very small compared to the public hospital, around 10-–14 per year) still go to the Cardiac surgeons who have been active since they left public practice in the early 1990s. The trend has been changing for the past 2 years though, with gradually more referrals (2–4 per year) being referred directly to Vascular Surgeons.

Specialty Recognition

The author believes that Specialty Recognition is a natural evolution of clinical excellence in a subspecialty field. Our non-vascular colleagues send us patients to manage because they believe we are the best people to offer the full spectrum of care to these patients. Eventually Vascular Surgeons become subspecialists, separate from their General Surgical colleagues because they offer an holistic and comprehensive Service that other specialists or General Surgeons cannot match.

Societies and Professional bodies are 'good-to-have' and will certainly help in the logistics of Conference, Training and Accreditation but Specialty Recognition starts with clinical competency and excellence.

Vascular Surgery is not a distinct specialist entity in our Specialist Register and Vascular Surgeons are still considered as General Surgeons with interests in Vascular and Endovascular Surgery.

However, in everyday practice, Vascular Surgery is a distinct specialty from General Surgery in terms of referral patterns and the fact that General Surgeons rarely perform Vascular Surgery procedures anymore. The advent of Endovascular Surgery has certainly hastened this, with the required skill sets quite distinct from any other General Surgery subspecialties.

Singaporeans Vascular Surgeons feel that we have to be good General Surgeons first before we can become Good Vascular Surgeons. With sound General Surgical Principles and skills, we build on that foundation to be competent practitioners in both open vascular and endovascular surgery.

This is reflected in current training where a Vascular Surgeon has to finish General Surgery training with conjoint exit qualifications of Fellow of the Royal College of Surgeons of Edinburgh (General) and Fellow of Academy of Medicine Singapore (General Surgery). Post exit-qualification, our Fellows undergo another 2 years of training in Vascular and Endovascular Surgery before qualifying as a Consultant Surgeon in our public hospitals. Newly qualified consultants need to practice for another 1 year in a public hospital before he or she can be practice as independent Specialist doctor in a private hospital.

The Section of Vascular Surgeons was formed under the auspices of the Chapter of General Surgeons in 2013. The Chapter reports to the College of Surgeons of Singapore and the College in turn reports directly to the Academy of Medicine of Singapore. The Academy oversees the delivery of Specialist Clinical Care in

Singapore (e.g. assigning subspecialty expert witnesses in medico legal situations and formulating clinical practice guidelines for the Ministry of Health).

It is hoped with the formation of the Section that the Fraternity can tap into Academy funds for training courses, conference/symposium organization and formulate practice guidelines. All this in turn should lead to better clinical service delivery and better patient outcomes.

Shades of Neo-Colonialism in Multinational Clinical Trial Design

As a practicing vascular surgeon, the author has seen the immense benefit of Endovascular interventions in reducing post-operative pain and length of stay and anesthesia risk for patients with vascular diseases.

Traditional open vascular surgery is dependent on skill set acquisition but endovascular surgery is dependent on device design and availability. Whether western based device companies accept it or not, the reality is that there exists significant anatomical variations in vessels and disease morphology between Caucasians and Asians. Caucasian or Western data may not directly correlate with Asian patients.

For various reasons, Western Device companies hesitate to collaborate with Singaporean centers for device data acquisition and trials despite the established and well-funded resources available in Singapore. In the rare situations whereby Singaporean centers are involved, it is usually in the laughable scenario where a CE Marked Device needs more clinical data from Europe and Asia before the Device can get the requisite regulatory body approval in the company's home country.

The reasons behind this are many and varied. Moving forward, it will be encouraging to see locally based Device companies collaborate more with local clinicians in clinical trials for data that we can practically use.

Conclusions and Looking Forward

Like our Vascular Surgery Colleagues around the world, Singaporean Vascular Surgeons have seen dramatic changes in the way Vascular Surgery is practiced over the past 15 years.

Our fraternity has caught up with the advances due in large part to visionary pioneers, hardworking colleagues and an open mind to take in new changes (and new colleagues). We are still lacking in many ways in terms of technique/device innovation and clinical research but the author is confident that the Fraternity will take up the gauntlet as it has before to progress in these areas.

Vascular Surgery remains an exciting field with new challenges everyday; Venous arterialization techniques perhaps heralding a Renaissance of Open Vascular Technique? Advances in laparoscopic suturing (Robotic assisted or otherwise) may again bring laparoscopic access vascular surgery back to the realm of feasibility. We can only be assured that if history is of any guide, of exciting new discoveries and technologies just around the corner that will make us all wide-eyed students again as in the Salad days of Blalock, Thomas and Debakey. These are indeed exciting times to be a Vascular Surgeon.

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Vascular Surgical Practice in North Queensland, Australia

45

Eugene Ng and Ramesh B. Velu

North Queensland, for the purpose of this chapter encompasses a wide area of the state of Queensland, north of Rockhampton and extends west up to Mt Isa. This region is much bigger than many countries. The population according to 2010 data is around 720,000. Within Australia, the indigenous population comprises of mainly aboriginal Australians (approximately 500,000) and Torres Strait Islander (approximately 35,000). Nearly two-thirds (64 %) of Australia' Torres Strait Islander population and about a quarter (24.8 %) of Australia's Aboriginal population were living in Queensland at the time of the 2011 Census. 41.5 % of these people were in the three Indigenous regions of North Queensland, mainly Cairns-Atherton, Townsville-Mackay and Rockhampton (Fig. 45.1).

Many parts of this region are harsh terrain (Australian outback) and distances are huge. Two major regional vascular centres provide tertiary level vascular service in this region with outreach clinics in smaller towns. The role of the Royal Flying Doctors (RFDS) cannot be overemphasised in timely transfer of patients to larger centres. Compared to national statistics, people living in regional centres in NQ have a higher private health insurance membership (Australian bureau of statistics 2003) with 45 % having hospital cover. In spite of this, only 24 % of inpatient beds are located in private hospitals.

The health of rural and regional populations in Australia is significantly worse than urban populations, with higher rates of preventative disease and all–cause mortality [1]. Inherent lack of understanding and cultural differences results in poor compliance among certain group of patients. This coupled with vast distances and climatic conditions make vascular surgical practice interesting in this part of Australia

Abdominal Aortic Aneurysm (AAA)

In 2011 there were 1881 elective AAA repairs in Australia (562 open and 1319 endoluminal) compared with 262 ruptures [2]. Delayed access to tertiary management centres due to geographical distance and lack of proper imaging facilities may account for the higher mortality associated with ruptured AAAs in rural communities. However, the literature comparing mortality rates in urban and rural communities for rupture AAAs is limited. Shiraev et al demonstrated no significant differences between rates of AAA rupture in rural and urban populations in Australia, nor a difference in mortality rate in these patients [3].

The first endovascular repair of AAA (EVAR) in NQ was performed in the late 1990s. Since

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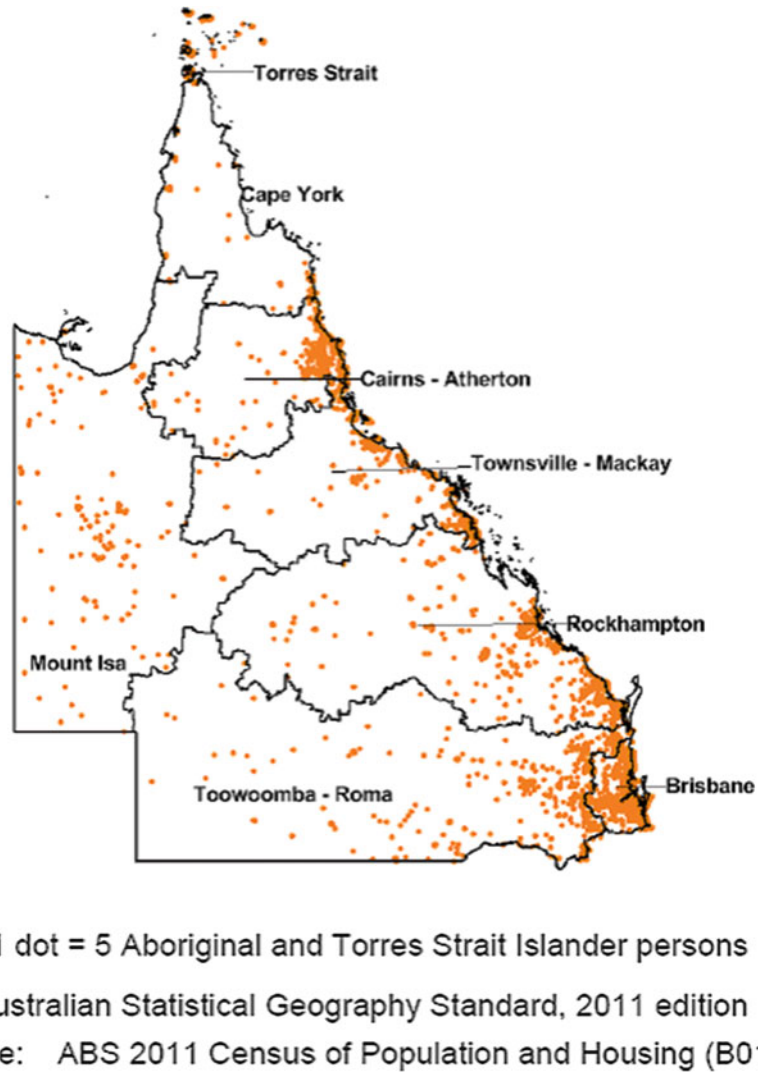


Fig. 45.1 Aboriginal and Torres Strait Islander peoples by indigenous region[a], Queensland, 2011. One dot = five Aboriginal and Torres Strait Islander persons. [a]Australian Statistical Geography Standard, 2011 edition. *Source:* ABS 2011 Census of Population and Housing (B01)

then, there has been an exponential increase in this technique compared to open repair. Review of data from the largest hospital in this region from 2000 to 2015 reveals a ratio of 60:40 in favour of EVAR, with more recent numbers indicating a trend towards the endovascular approach. During the initial years of EVAR, proper planning was needed due to a limited inventory of stent grafts and delay in obtaining grafts at short notice. At present day, graft companies have left a wide range of grafts, enabling treatment of acute presentations including ruptured AAAs, the first of which was performed in 2008. Since then, half a dozen of these cases have been done.

In the last 10 years more complex endovascular work including fenestrated endovascular repair (FEVAR) and iliac branch device (IBD) have been performed. Follow up of EVAR patients have been an issue with around 50 % lost to follow up after the initial 6 week scan (personal audit). This is once again due to lack of

awareness and long travel times involved for scans and clinic appointments.

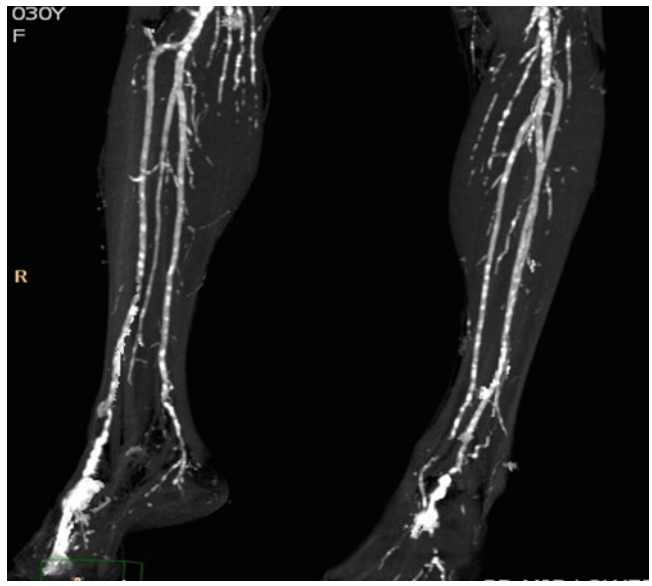
Peripheral Vascular Disease (PVD) and Diabetic Feet

The prevalence of diabetes is three times higher in indigenous Australians compared to non-indigenous people [4, 5]. The incidence is even higher in remote areas compared to those living in urban areas [6]. Indigenous people develop diabetes at a younger age compared to others. High levels of "central obesity" in indigenous people have been linked to diabetes [7, 8]. Nevertheless the role of western diet and lack of physical activity cannot be discounted as a cause, especially of type 2 diabetes.

Diabetes causes both microvascular and macrovascular complications resulting in early onset retinopathy, nephropathy explaining the higher incidence of visual loss and end stage renal disease (ESRD). The combination of diabetes, renal failure and smoking results in higher incidence of cardiovascular disease. The Fremantle Diabetes study [9] reported a significant difference of PVD—30.7 % in Indigenous people compared to 21.5 % in Anglo-Celtic people.

Many patients present in an advanced state of sepsis or gangrene, making limb salvage difficult. The disease pattern is predominantly infra popliteal and pedal. "Endovascular first' is the current practice here with Vascular surgeons being able to access the DSA suite readily. Advanced techniques including retrograde tibial punctures are used in suitable cases. A wide array of endovascular inventory is available including drug coated balloons (DEB). Aortic, Infrainguinal bypasses including tibial and pedal bypasses are done in appropriate patients. Arm vein harvest is used if no suitable conduit is available in the lower limbs. Prosthetic grafts are avoided if possible. Attempts at endovascular or open revascularisation is further hampered by small calibre of vessels and calcification. In spite of these, reasonable success is possible in patients who are compliant with their sugar control, abstinence from smoking and medications. A dedicated multidisciplinary service comprising of "high risk foot clinics" are run to manage these patients.

The incidence of major amputations is unacceptably high in Indigenous populations in North Queensland. O'Rourke et al. showed that the mean age at first lower limb amputation in Indigenous population was 56.3 years, 14 years younger than non-Indigenous people. More



women needed amputation with sepsis, chronic kidney disease and residing in remote communities being contributory factors [10].

Access for Haemodialysis

Studies have shown that there is an eightfold increase in the incidence of ESRD requiring dialysis in the Australian indigenous population when compared to non-indigenous people. A higher mortality rate has also been shown to be associated with indigenous people who are dialysis dependent [11]. These issues arise as a result of multiple factors.

The first is difficulty in accessing health services as many Indigenous Australians live in geographically remote locations and attend in-centre haemodialysis in large urban centres, which requires travelling for long periods of time and constant separation from family, community and the land [12]. This, coupled with the rigorous demands of the haemodialysis regime often results in delayed presentation, failing AVFs which are not amenable to salvage, loss to follow-up and a resultant increase in the already significant morbidity and mortality associated with these subgroup of patients.

The second reason is cultural differences inherent to the Indigenous population which can arise as a result of lack of education on the medical aspects of dialysis, unpleasant family experiences and possible racial overtures encountered by fellow Indigenous patients when engaging with government organizations [13]. In addition, patients with ESRD experience more fatigue than the general population [14]. This coupled with the sweltering tropical climate in North Queensland, exacerbates the problems associated with accessing haemodialysis services as mentioned above.

Maintaining vascular access in this special group of patients has always presented a unique challenge to the vascular surgeon. Prosthetic AVF grafts are in general avoided in these patients due to unacceptable infection rates. With increased use of endovascular techniques, the life span of AV fistulas has been prolonged. Many patients need fistulas in the lower limb and neck (necklace) after exhaustion of the usual avenues.

In NQ, the majority of presentations consist mainly of patients presenting late with fistulas which have been occluded for several weeks with systemic overload and electrolyte abnormalities. Many of them require either emergent thrombectomy/thrombolysis and fistuloplasty or creation of a new AVF. In the interim they need central venous access catheters. Multiple central venous catheter insertions result in high incidence of symptomatic central venous stenoses and present a complex challenge with regards to maintaining overall vascular access. Other presentations include central venous catheter associated complications such as systemic infection and occlusion secondary to poor catheter care personal hygiene.

Management comprises of a multi disciplinary approach involving early engagement of the patient to prevent late diagnosis and slow disease progression; implementation of haemodialysis access monitoring, early fistula salvage and judicious use of central venous catheters; education and managing fear of mainstream services. Involvement of government organizations as well as service provision shaped by culture through increased home dialysis, Aboriginal support groups goes a long way in improving survival in these unfortunate patients.

Carotid Disease

Interventions for carotid disease are common in North Queensland. For reasons unclear, carotid disease seems to be exclusive to the non-indigenous population. Carotid endarterectomy (CEA) is performed for both symptomatic and asymptomatic patients with high grade stenosis, though there is a recent trend to not to intervene in asymptomatic patients. Individual practices vary in relation to the type of anaesthetic, shunting etc. Issues related to delayed referral of symptomatic patients by General Practiontioners and hospital doctors have been addressed. A good working relationship has been established with Neurophysicians for early referral and intervention in symptomatic patients

Carotid stenting is not performed due to lack of adequate numbers required to maintain skill levels. They are referred to vascular centres in the state capital.

Venous Disease

Deep and superficial venous diseases are encountered frequently. Superficial venous disease is still treated by conventional ligation and stripping of truncal veins. Laser and radio frequency ablation (RFA) is available in the private sector as is sclerotherapy.

Acute DVT's are managed by physicians and Haematologists. Recently, pharmaco mechanical thrombolysis has been done in suitable cases. Chronic venous insufficiency patients with ulcers are managed in the ulcer clinic with a dedicated occupational therapy (OT) team involved in compression therapy. Venography and stenting of deep veins are done for patients suspected of iliac vein compression.

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Vascular Surgery in Southern Africa

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Martin Veller

The common perception that the population of Southern Africa has a low incidence of vascular disease has resulted in the management of these diseases often being given a low priority. With recent improved access to health care services being made available to the often very poor and at times remote populations in this region it has however become clear that this perception is not correct. The subcontinent is also home to multiple diseases and vascular risk factors such as HIV and increasing levels of diabetes mellitus which will in the future result in a dramatic increase in the number of people that will be afflicted with vascular pathologies.

As in most parts of the world, the work of a Southern African vascular surgeon is largely made up of the well- known complications of atherosclerosis and other age related degenerative vascular conditions. The heterogenous populations in Southern Africa, from the geographic, ethnic and socio-economic perspective, are however the reason that local vascular surgeons have encountered, in large numbers, a variety of vascular diseases that are not commonly encountered elsewhere. These conditions include:

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HIV Associated Arteritis

The HIV epidemic in Southern Africa has unearthed a number of conditions that are caused by this pathogen. In the vascular field an association with occlusive and aneurysmal arterial disease on the basis of an arteritic process has been described. In addition, the infection causes a pro-thrombotic state and is now recognized to be associated with venous thrombo-embolism (VTE).

Both arterial aneurysms and occlusive arterial disease have clinical and histological characteristics that differ from the other known causes of such vascular pathologies. Both are considered to be AIDS defining conditions as they are usually associated with low CD4 counts in patients with other manifestations of the infection.

HIV associated aneurysms have been found in most major arteries and are usually saccular in nature as a result of a localized region of cytoclastic activity in all layers of the arterial wall. Patients tend to present with multiple aneurysms. Treatment is based on the usual principles of care for aneurysms but because of the poor condition of patients endovascular modalities are favored.

Occlusive arterial disease caused by HIV infections is usually thrombotic in nature. The vessels most commonly involved are the iliac and femoral arteries, but the involvement of the coronary vasculature is also well described. Many affected individuals also smoke. Treatment of these patients is hampered by the underlying

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vasculitic process and is generally associated with a poor outcome.

The number of individuals in South Africa who have been on many years of antiretroviral agents is limited. As a consequence, our experience with the well described accelerated atherosclerosis associated with the proteolytic agents used in treating HIV, is limited.

The association between VTE and the HIV infection is conclusive. The reported incidence ranges from 0.19 to 18 % which is well in excess of what one would expect in a non-infected population (0.05 %). In a small study at the Charlote Maxeke Johannesburg Academic Hospital, 84 % of patients who presented with deep vein thrombosis were found to be HIV positive.

The severity of the HIV infection appears to be of significance in this association as several studies have confirmed that there is a greater incidence of venous thrombosis in patients with low CD4 counts, while the risk is even higher when individuals have confirmed AIDS. The reason for HIV infection's relationship with thrombosis has not yet been conclusively elucidated, but appears to be multimodal, with all three limbs of Virchow's triad being involved.

Thromboangitis Obliterans

This condition, which usually occurs in young usually male individuals after extended and ongoing exposure to tobacco smoke, is unusual in the South African setting in that it rarely is associated with thrombophlebitis. In our region it is also clear that other forms of smoking, such as cannabis, may cause a similar disease pattern. The fact that all patients, whether they smoke standard cigarettes or cannabis, have similar great difficulty in quitting and that smoking non-nicotene containing agents results in similar progression of disease is of interest and in our opinion is evidence that nicotine is not the primary agent causing this apparent immune modulated condition.

The other clinical manifestations, difficulties with treating these patients by interventional means and the poor prognosis in regard to limb preservation are no different to those encountered in other parts of the world. Similarly, treatment using prostanoids is not helpful.

Intimo-Media Mucoid Degeneration

This idiopathic condition, infrequently reported in the literature, was first described in South Africa in 1977 by George Dekker. The disease has also been described in East Africa and on the Indian subcontinent. Such aneurysms where initially considered only to occur in the aorta but we and others have encountered this pathology in more peripheral arteries as well. This condition appears to be confined to black Africans where it is nearly invariable found in individuals who have concomitant often poorly controlled hypertension with an equal distribution between the sexes. The youngest patients are in their 30s while most are in their fifth and sixth decades of life.

Approximately half of the patients present with acute syndromes of aneurysmal tenderness or rupture. Despite this the mortality of repair in this condition is low. This may be a reflection of the absence of associated cardiovascular and other co-morbidities. These aneurysms make up about 5 % of the aneurysmal diseases in Southern Africa.

The pathological finding consists of diffuse elastic tissue degeneration of the arterial intima and media with the deposition of large quantities of mucopolysaccharide (mucoid) within the intima and media. It is the mucoid deposition in the intima that histologically differentiates this condition from medial mucoid cystic degeneration. Characteristically these aneurysms have little or no mural thrombus and at operation have a smooth and glistening aneurysmal lining. This is thought to be as a result of an increased localised fibrinolytic activity of unknown origin.

Takayasu's Arteritis

This large vessel arteritis which is a T-cell driven, non-specific granulomatous inflammation of all layers of the vessel wall is encountered commonly in Southern Africa. The pattern of disease appears

to also be unique with a higher frequency of aneurysmal disease when compared to reports from other regions.

As elsewhere the diagnosis is most frequently made on the basis of the clinical manifestations an elevated ESR and CRP are during the active phases of the disease. Imaging is essential to delineate the full extent of the vascular involvement and in recent years PET scanning has proven to be useful.

Our preferred treatment consists of immunosuppression usually using high doses of prednisone in the acute phase but cyclophosphamide in our experience is also often required to achieve control of the inflammation. This regime is usually effective in addressing the acute inflammation and abating the early constitutional symptoms but approximately two thirds of patients with Takayasu's arteritis experience relapses of symptoms or progression of vascular disease. Methotrexate is usually used without prednisone during phases of remission in order to minimise the corticosteroid side effects. Agents such as infliximab are usually unaffordable in public health care sector that services the majority of our patients.

Surgical and endovascular interventions play an important role in treating occlusive and aneurismal manifestations. The indications for intervention are the same as they are for other pathologies, usually only when life or limb sparring. Fortunately, few interventions are required in the acute phase, as failure rates for procedures performed when acute inflammation is present, are high. Revascularisation in our practice is deferred, if at all possible, until pharmacological therapy has completely suppressed the inflammation, which we believe to be indicated by a normal CRP and ESR.

Carotid Body Tumours

Large parts of Southern Africa are located at high altitudes. As a consequence the number of spontaneous carotid body tumours encountered in these populations is similar to that found in other similar regions.

History and Current State of Vascular Surgery in Russia

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A.V. Pokrovsky and D.F. Beloyartsev

History of Russian Vascular Surgery

On October 27, 1913, Iustin Dzhanelidze (1883–1950), a surgeon from Saint Petersburg, was first in the world to successfully suture the ascending aorta after a knife-inflicted wound in a 20-year-old man. The operation was carried out under ether-morphine anesthesia and conducted through a 12-cm extrapleural access along the left edge of the sternum after resection of second and third ribs [1].

Although there were sporadic reports of successful attempts of iliofemoral embolectomy with femoral reconstruction in the 1930s, the real development of vascular surgery in the Soviet Union, as well as cardiovascular surgery in the world commenced as after World War II. In 1947, Boris Petrovsky (1908–2004) performed the first successful resection of a post-traumatic aneurysm of the thoracic aorta. In 1952, Alexander Bakulev (1890–1967) was the first who successfully perform resection of a saccular aneurysm of the aortic arch. In 1955, Evgeny Meshalkin (1916–1997) was the first in the USSR to perform successful resection of aortic coarctation with homograft repair. In 1958, Vladimir Zhmur (1899–1976) was the first surgeon in Russia to repair an abdominal aortic aneurysm using homograft replacement. A year later, B. Petrovsky performed the first aortofemoral bypass using a synthetic graft for Leriche syndrome. In 1960 aortic resection with same bifurcation repair for aortic occlusion was performed by Viktor Saveliev (1928–2013) [2].

In 1961, the first specialized Department of Vascular Surgery in the Soviet Union was established at the A. Bakulev Institute of Cardiovascular Surgery under the leadership of Anatoly Pokrovsky (1930-) [3]. During the 1960s, the USSR witnessed the continuing development of thoracic and abdominal aorta surgery followed and accompanied by growth in reconstructive operations involving the arch vessel, coronary, renal and visceral arteries. In 1962, A. Pokrovsky was first in the Soviet Union to carry out resection of a saccular aneurysm of the ascending aorta under cardiopulmonary bypass. In 1964, B. Petrovsky performed the first successful operation for DeBakey type II aortic dissection. In 1965, Gleb Soloviev (1928–2004) accomplished the first thoracoabdominal bypass grafting for nonspecific aorto-arteritis. In the same year, A. Pokrovsky, for the first time, successfully reconstructed the descending thoracic aorta using extracorporeal circulation in a patient with type DeBakey IIIB dissection. He was also the first, in 1968, to carry out aortoplasty for congenital supravalvular aortic stenosis with the help of cardiopulmonary bypass. Finally, in 1972, A. Pokrovsky was the first surgeon in Russia to

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successfully perform resection of a syphilitic aneurysm of the aortic arch with ascending-descending bypass grafting and prosthetic repair of all branches of the aorta [2].

On February 25, 1964 Vasily Kolesov (1904–1992) was the first in the world to establish a mammarocoronary anastomosis on the beating heart with the circumflex artery in functional class III angina pectoris via a thoracotomy and he was also the first in the world to successfully perform the same operation for unstable angina pectoris on May 17, 1968 [3]. The first autovenous coronary artery bypass grafting in the Soviet Union was performed by Marat Knyazev (1934–1984) in 1970, and later in the same year a similar intervention combined with aneurysmorrhaphy of the left ventricle was carried out by A. Pokrovsky. Further success in the development of methods of treatment for coronary artery disease turned out to be intracoronary thrombolysis in acute coronary syndrome carried out for the first time in the world on June 5, 1974 by Yevgeny Chazov (1929-) [2].

The first successful carotid endarterectomy in the Soviet Union was performed in 1960 by Efraim Zlotnik (1919–1993), and in 1962, the first graft interposition of the internal carotid artery was performed by Yury Bogatyrev (1922-?). In the same year A. Pokrovsky performed the first carotid endarterectomy with patch repair [4]. The first successful prosthetic grafting of the brachiocephalic trunk was performed by V. Saveliev in 1961 [2].

The first successful reconstruction of the renal artery for vasorenal hypertension was carried out by B. Petrovsky in 1960; in the same year, Anton Pytel (1902–1982) was the first to establish a splenorenal arterial anastomosis. In 1961, B. Petrovsky was the first in the Soviet Union to create a mesentericorenal anastomosis. In 1965 A. Pokrovsky performed the first bifurcation aortorenal bypass grafting, and in 1969, M. Knyazev carried out the first transaortic endarterectomy of the renal artery [2].

In 1962, A Pokrovsky was the first in the world to use in clinical practice a thoracophrenolumbotomic approach to the throracoabdominal aorta. In the same year, he also performed the first in the Soviet Union intervention on the celiac trunk, and somewhat later on, in 1968—the first successful bifurcation aortoceliac-renal grafting. On January 12, 1971, A. Pokrovsky was the first in the world to perform simultaneous transaortic endarterectomy from the aorta, superior mesenteric and both renal arteries [2].

In 1961, Alexander Shalimov (1918–2006) for the first time used iliac and femoral veins according to the in situ technique for iliac-femoral bypass grafting, excising the valves through separate multiple phlebotomies [2].

Further milestones of the development of vascular surgery in the Soviet Union were related to surgery of the ascending aorta and endovascular interventions. Thus, in 1973, Grigory Tsukerman (1923-) was the first in Russia to perform supracoronary resection of the ascending aorta with prosthetic repair of the aortic valve in Marfan syndrome; He also, in 1979, carried out the first operation according to the Bentall and De Bono technique, and in 1983 the Cabrol's operation for dissection of the ascending aorta. On March 27, 1984, Iosif Rabkin (1926-) for the first in the world to successfully perform stenting of the external iliac artery using a nitinol spiral [2]. On May 4, 1985, Nikolay Volodos (1934-) was the first in the world to carry out successful endografting for stenosis of the external iliac artery. In March 1987 he was first in the world to successfully accomplished endografting of the descending thoracic aorta for a post-traumatic aneurysm. Finally, on June 14, 1991 he carried out the world's first successful endografting of an aortic arch aneurysm with debranching of the aortic arch (replantation of the left common carotid artery into the brachiocephalic trunk and carotid-subclavian bypass grafting on the left). Finally, in August 1993, N. Volodos was the first surgeon in the world to successfully perform endografting of the descending thoracic aorta for a bleeding aortopulmonary fistula [5].

On November 28, 1989, Pavel Maltsev (1962-) and Dmitry Beloyartsev (1963-) were the first in the world to carry out successful laser-mediated recanalization in occlusion of the brachiocephalic trunk followed by balloon angioplasty [2].

In 1986, A. Pokrovsky founded the Russian Association of Angiologists and Vascular

Surgeons which he heads to this day. The Association holds annual conferences in Russia with participation of leading foreign vascular surgeons. Organization of such congresses has united vascular surgeons of various regions of Russia and has made it possible to draw up annual reports on the state of vascular surgery in Russia creating a registry of vascular interventions performed. Since the day of foundation of the Association, a total of 30 conferences were held in 18 cities across Russia. Efforts of the Russian Association of Angiologists and Vascular Surgeons made it possible work out national guidelines for management of critical limb ischaemia, abdominal aortic aneurysms and diseases of brachiocephalic arteries. The activity of A. Pokrovsky on the arena of the development of national vascular surgery was highly appreciated by international colleagues leading him to be the only Russian surgeon, to, in 2000, be elected as President of the European Society for Vascular Surgery.

Another important milestone in russian vascular surgery was the creation by A.V. Pokrovsky in 1994 of the first, in history of the Soviet Union, official quarterly bilingual (Russian/English), Internet-cited journal "Angiology and Vascular Surgery". The Editorial Board of this preeminent Journal, aside from leading Russian specialists, includes leaders of vascular surgery from virtually all European countries, the United States and the Commonwealth of Independent States. Angiology and Vascular Surgery publishes a considerable volume of foreign articles, making these available to Russian specialists and, in turn, acquainting foreign authors with the achievements of Russian vascular specialists. More than 80 issues of this journal have been published to date.

State of the Art of Vascular Surgery in Russia

In 2014, surgeons at 169 specialized Departments of Vascular Surgery in Russia carried out a total of 119,119 vascular operations (the data of those clinical facilities have been submitted to the Russian Association of Angiologists and Vascular Surgeons) [6]. Over the course of the past 5 years the volume of these procedures have increased by 14%. Of these, a total of 20,625 patients were operated on for lesions of brachiocephalic arteries (Table 47.1). For carotid stenosis, patch repair, eversion endarterectomy and graft interposition was utilized in 31%, 65%, and 4% of cases, respectively. The frequency of using shunt did not exceed 10%. Since 2010, the number of interventions on brachiocephalic arteries increased by 46%.

Table 47.1 Frequency and types of brachiocephalic reconstructions

	Open reconstructions	Endovascular interventions
Carotid bifurcation (%)	13,781 (84)	2671 (16)
Proximal lesions of branches of the aortic arch (%)	679 (37)	1151 (63)
Tortuosity of the ICA	1338	–
Vertebral arteries (%)	258 (33)	515 (67)
Extra-intracranial microanastomosis	232	–

Table 47.2 Other types of arterial reconstructions

	Open reconstructions	Endovascular interventions
Aneurysms of the descending thoracic and thoracoabdominal aorta	226 (68%)	105 (32%, of these, hybrid ones—7%)
Abdominal aortic aneurysms	1638 (83%)	329 (17%)
Leriche syndrome	6198 (64%)	3498 (36%)
Femoro-distal lesions	9384 (65%)	5138 (35%)
Renal arteries	71 (7%)	974 (93%)

Other types of arterial reconstructions are shown in Table 47.2.

Mention should be made that a total of 338 (20%) patients presenting with abdominal aortic aneurysms were operated on for rupture. The frequency of interventions for abdominal aortic aneurysms over the past 5 years increased by 31%. Amongst the open interventions for lesions of the aortofemoral segment, semi-closed endarterectomies of the iliac segment were carried out in 1194 (12%) cases.

Open femoro-distal reconstructions included: femoropopliteal bypass grafting above the

knee—27 %, below the knee—14 %, profundoplasty—12 %; femorotibial bypass grafting—12 %, popliteo-tibial bypass grafting—1 % (in 0.3 % of these arteriovenopus fistulae were contructed). Endovascular interventions in infrainguinal lesions distributed in the following manner: stenting of femoral arteries—17 %, stenting of tibial arteries—12 %, and stenting of the popliteal artery—6 %. The total number of infrainguinal interventions since 2010 increased by 38 %.

Most renal artery lesions were treated using endovascular stenting (93 %). A tendency towards a decrease in the specific amount of patients presenting with Buerger's thromboangiitis was noted. The approach to treatment of patients with nonspecific aortoarteritis has also changed. Thus, in bicarotid lesions, preference is given to stage-wise restoration of patency of common carotid arteries; in thoracoabdominal localization of aortitis, operations of thoracoabdominal bypass grafting have been rejected, with preference given to grafting of the thoracoabdominal aorta. Compulsory in comprehensive treatment of nonspecific aortoarteritis is, to date, the use of immunosuppressive therapy making it possible to provide a good remote effect of surgical treatment.

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Vascular Surgery in Romania

48

V.S. Costache, R. Popa, and S. Sultan

130 years ago, Bucharest was called "Le Petit Paris" in a Europe without borders

The start of vascular surgery in Romania was associated with the innovations in general surgery and general anesthesia. In the late nineteenth and early twentieth century, the medical system in Romania had the privilege to be advanced by physicians and surgeons who were coached in France and Germany. At that time all Romanian intelligentsia was taught in the western world so there was no gap between the level of knowledge and surgical techniques in Romania tallied to the rest of civilized world.

Contemporary developments in medicine at that time were promptly put into practice in Romania so the first surgical department with its own X-ray machine was founded by Dr. Constantin Dimitrescu-Severeanu (1840–1930), only 1 year after Wilhem Rontgen introduced this technology in medicine. Dr. Severeanu was the first surgeon to achieve an arterial reconstruction in Romania and he pioneered the principle of arterial anastomosis stressing upon the significance of the eversion of the arterial wall.

The scientific effervescence of Romanian physicians by Prof Thoma Ionescu who, before becoming Rector of the University of Bucharest in 1912, was appointed professor of anatomy and surgery in Paris, where he performed the first resection of the cervical sympathetic chain for epilepsy and Basedow disease, extending this procedure to relief for angina pectoris.

Interestingly, between 1909 and 1910, Prof Ionescu worked closely in Rochester with the Mayo brothers, performing surgical procedures on the upper segments of the body under high spinal anesthesia (Fig. 48.1). Another pioneer was Dimitrie Gerota, surgeon and anatomist, who developed his own method of studying lymphatic pathology after injecting a contrast agent developed by him for lymph vessels that he published in 1930 in Berlin as *Injections Technik Limfgefass*. This rapid understanding of vascular techniques led to the first successful forearm reimplantation, performed by Dr. Jianu in 1909.

However, vascular surgery in Romania emerged slowly as a separate specialty; at the beginning, it was developed by forerunners in general surgery and starting from the 1960s it

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Fig. 48.1 Professor Thoma Ionescu

was for a long time performed by cardiovascular surgeons. This craze was seen in many countries, however the brutal introduction of communism in Romania after the Second World War had a huge impact on all the aspects of the civil society in the country, reflecting in the development of vascular surgery as a single entity.

Currently vascular surgery units exist in Bucharest, Iasi, Cluj, Timisoara, Targu Mures, Sibiu, Constanta and Brasov.

Bucharest was the birthplace of vascular surgery in Romania, as Dr. Fagarasanu presented for the first time, the Dacron grafts and he operated his first successful Leriche syndrome in 1956.

Coltea Hospital opened the first angiography room in parallel with an investigational cardiovascular unit, where a team led by Dr. Hortolomei continued vascular surgery in parallel with open cardiac procedures.

Dr. V. Marinescu, former Ministry of Health of the communist regime, transferred this activity to the Fundeni Hospital where he organized cardiovascular surgery, cardiology and intensive care, while he inaugurated a long era where cardiovascular medicine developed in close connection with communist political activity and economical interests.

During that time, successful vascular practice is related to surgeons who somehow managed to find a political compromise in order to benefit of some training in western centers. A good example is Dr. Pop D. Popa, mainly a cardiac surgeon, but who is the official founder of vascular surgery in Romania, as he introduced it for the first time in the list of medical specialties recognized by the Romanian Ministry of Health.

After fellowships at the Bakulev Institute in Moscow and at the Brussaix Hospital, Dr. Pop D. Popa established the second official cardiac and vascular unit in Targu Mures, soon after his transfer from Cluj in 1962. While becoming a close adviser to the former dictator Ceausescu, Dr. Pop D. Popa took over the directorship of the Fundeni Institute in 1974 and he reorganized progressively the activity of the unit. Thanks to fellowships conducted in Texas Heart Center and in Portland, he improved postoperative results and manages to bring a part of Dr. Barnard's South African team for three consecutive years, making Romanian doctors aware of the existence of different standards of care outside the soviet ones.

Untill 1989, Romania had officially two vascular surgery centers for a country of over 24 million people, Bucharest and Targu Mures, where Dr. R. Deac successfully took over Dr. Pop D. Popa departure and developed the unit following the same model of organization.

During the last year of the communist regime, in Cluj, the chief of the cardiology clinic managed to secretly organize a cardiovascular institute affiliated to the university, but surgical activities only started in the 1990. This first breach in the monopole held for more than 30 years by Bucharest and Targu Mures, concomitant to the fall of the communist dictator in the country, was followed by a rapid reaction from the medical schools from Timisoara, Iasi and later Constanta and Sibiu who opened their vascular surgical facilities, all at the beginning, under the lead of a cardiovascular surgeon.

An interesting exception is Iasi, who developed a vascular surgical unit before the cardio-

vascular surgical institute opened in 2000, as its chief of department, Dr. Radu Popa underwent several fellowships on his own in Belgium and Israel.

Currently two departments of vascular surgery exist in the University of Iasi, an independent vascular surgical department in "Sf. Spiridon Hospital" and a vascular unit in the "Cardiological Insitute", functioning under the lead of cardiäc surgeon. The two units are the only ones providing vascular surgical care for the region of Moldavia, for approximate six million people.

Both are performing open surgical solutions for carotid disease, aortic disease and arterial peripheral disease and have an on call system covering all vascular emergencies. Last year's statistics for "Sf. Spiridon Hospital" show that they have performed 48 carotid artery endarterectomies, 246 peripheral bypasses and 53 aortic procedures.

The region of Muntenia in the south part of Romania has a population of eight million people and only the vascular surgical units from Bucharest provide vascular surgical assistance.

In 2015 three public vascular surgical departments exist in Bucharest: the "C. C. Iliescu" Cardiovascular Institute, the Military Institute for Cardiovascular Disease and one unit in the "Floreasca Emergency Hospital". In 2013 the first private vascular surgical department was opened in the Monza Hospital in Bucharest while the Sanador Hospital opened the second one in 2015; their organizations are similar, cardiac surgery functioning together with the vascular department.

Vascular surgery is performed in five institutions in Transylvania, providing this service for approximate seven million people. All of them are affiliated to the correspondent faculty of medicine; four of them are public—Timisoara, Targu Mures, Cluj and Brasov and a single private institute, functioning in the European Hospital in Sibiu.

The European Hospital from Sibiu is the most recent private health institution in Romania. It was structured following a different human resources policy; physicians trained outside the country were privileged for important positions. The result was a young and dynamic team who has several national premierships in cardiovascular medicine: first endovascular treatment of a thoracoabdominal aneurysm, first endovascular treatment of an aortic dissection (Fig. 48.2), first sutureless valve implantation, first trans aortic transcatheter valve implantation in Eastern

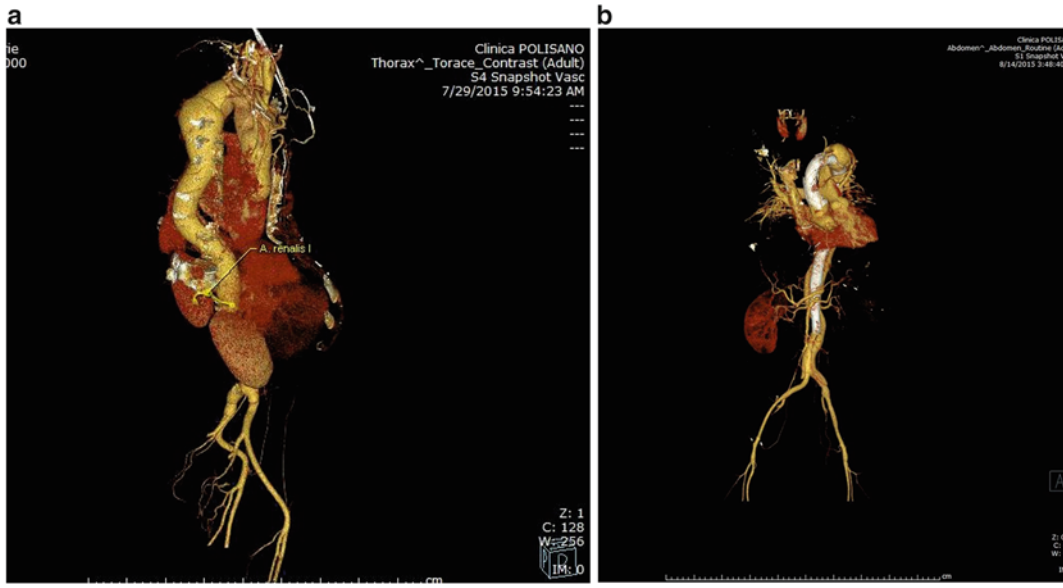

Fig. 48.2 Endovascular treatment of an aortic dissection

Europe. This new institute has numerous partnerships with well-known Western institutions and hosts the largest aortic endovascular program in the country and the only endovascular European training program due to a strong partnership with the National University of Ireland.

The largest volume of open surgical procedures took place in the Fundeni Institute in Bucharest, where they perform each year around 200 carotid and 200 aortic procedures and more than 400 surgeries on the peripheral arteries, while the other institutions usually perform half the number of these cases.

If open vascular surgery is somehow developed in Romania, a huge gap has emerged in endovascular surgery compared to the Western world, at this time less than 150 endovascular aortic interventions having been performed in this 20 million people country since the very beginning of endovascular procedures.

Several factors are responsible for this lack of expertise. Historically, vascular surgery has been under the rule of influent cardiac surgeons, who used to control the funding of their institutions and redirect it mainly for cardiac activities.

Another explanation is the way medicine and vascular surgery in particular is funded in Romania. During the communist regime, the ministry of health used to fund vascular surgical activities according to the influence of the chief of the department. Compared to other surgical specialties, cardiovascular specialties used to be privileged, due to the proximity of some surgeons to communist leaders. At that time, the funding mechanism was very basic: the state was paying for everything the institution needed while many surgeons requested informal payments directly from the patients. These practices were known even in the high spheres of the communist party but were tolerated as at that time Romania was a closed country, so communist politicians tried to have a good relationship with the few cardiovascular specialists who were supposed to treat them in an emergency setting.

The fall of the regime in 1989 was followed by a long period of transition, the previous medical moguls started losing their influence as politicians and wealthy Romanians discovered that they can easily travel and receive better treatment abroad. A beneficial attempt to reform the system was the introduction in the late 1990s of the law nr.95 regulating the medical system, largely inspired by German and French health systems. Briefly this new text of law introduced a quota that each working Romanian was paying into the account of a new created institution, the National Social Security, who had autonomous branches in each economical region.

The general leading principle was that "the money will follow the patient" and a short period of relative prosperity followed, which gave birth to many private medical projects that appeared to general population as an attractive alternative to obsolete state institutions.

Unfortunately this sudden amount of cash rapidly attracted the attention of the newly formed socialist government in 2001, who abolished the autonomy of the national social security and transferred all the funds collected for the health system into an opaque melting pot administered by the ministry of finance. To make things worse, a law was introduced against private insurances in order to limit informal payments and ease the pressure off the centralized system, after gross manipulation of the public opinion.

Currently money doesn't follow the patient anymore and phantoms from the communist period emerged once more: only some institutions are funded and quotas for number of procedures, defying any logic, are established each year for each institution who is lucky enough to receive money for its cases. In this financial chaos another aberrance emerged—"the national health program for vascular surgery", who provides less than 200 euros per patient for each case treated in the institutions included in this program regardless of the type of pathology!

For an EVAR procedure, a 70 year old patient who has paid health contributions for all his life, will be forced to spend his savings or to get a loan in order to pay the 15,000 euros requested for the procedure.

The direct result of the above "reforms" is that in the last 7 years more than 20,000 doctors have fled the country followed by an incalculable

number of nurses and health technicians. Medical tourism has "flourished" but in the wrong direction as wealthy patients prefer to travel abroad to get treatment, while middle class patients are burdened by bank loans in order to get treatment either abroad or in one of the newly opened private clinics who are well equipped but receive no funding from the ministry of health or from the social security for patients treated for cardiovascular diseases.

The lack of funding and the influence of cardiac surgical priorities over vascular surgery led to the present day situation, when interventional cardiologist performs most endovascular procedures while surgeons are often used only for vascular access. However a new generation of surgeons emerged, mainly trained in western universities like their predecessors from the "golden period of Romanian surgery" before the Second World War and the brutal introduction of communism in Romania.

In 2015 the Romanian Society of Endovascular Surgery was founded and one of its main priorities is to abolish these aberrant centralized mechanisms, to rethink funding of vascular and endovascular surgery according to modern principles and provide properly training for the young generations of vascular surgeons.

49 Vascular Surgery in Sub-Saharan Africa: Challenges and Opportunities—The Experience of Uganda

Tom P. Mwambu, Ronald Kabuye, and Michael Oketcho

Introduction

Sub-Saharan Africa (SSA) is home to among the least developed nations in the world with the exception of the Republic of South Africa. The average annual economic growth rate for the region is estimated at 5 % [1] with about 42.7 % of the population living on less than USD 1.9 a day [2]. Communicable diseases such as malaria and respiratory tract diseases such as tuberculosis rank highest in the regions' disease burden however, due to changing lifestyles non-communicable diseases (NCDs) including cardiovascular disease are on the increase. Vascular surgical services do come with a high cost including availability of specialist human resource, necessary sundries and appropriate equipment which are all not readily available in sub-Saharan Africa including Uganda. In such low socio-economic settings allocation of resources to the health sector is a challenge and availing resources for appropriate vascular surgical care remains an uphill task.

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Human Resource

In Uganda there are no specialized vascular surgeons. With a doctor to population ratio of about 1:10,000,000 [3] in Uganda, general surgeons endeavor to be multi-tasked to provide human resource for the missing services in view of the few specialists available. Currently in most sub-Saharan countries including Uganda, vascular surgery is performed by both general surgeons and cardiovascular surgeons with the latter performing the more complex procedures as well as providing training opportunities at the Universities. In Uganda the current cardiovascular surgeons have initially trained at home as general surgeons and later abroad as cardiovascular and thoracic surgeons with greater emphasis in skills acquisition. Hence training has mainly been through fellowship programs in India but also through formal Masters' degree courses in cardiovascular and thoracic surgery in the Peoples Republic of China. Majority of the cardiovascular surgeons practice at the Uganda Heart Institute which is part of the national referral and teaching hospital and inevitably shoulders the burden of most of the cardiovascular and thoracic surgery in the country. With still limited resource, vascular surgery therefore, has to compete with cardiac and thoracic surgery for space, human resource as well as time and hence vascular surgery cases requiring elective interventions tend to be given less priority.

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Investigations

Basic haematological, biochemistry and microbiology investigations are readily available in Uganda though some may only be accessible at the national referral hospital (public health facility) in the capital city, Kampala. Radiological examinations on the other hand are best developed in the private health units (both private for profit and private not-for profit). Computerized tomographic scan (CT-scan) and magnetic resonance imaging (MRI) angiograms are available however, not all patients are able to afford the costs involved.

Vascular doppler is a user dependent test and the skills vary a lot between individuals making accurate reporting limited to a few well trained sonographists. The vascular surgeons in Uganda rely on trained radiologists to perform this task.

Table 49.1 Pattern of vascular surgery at Mulago National Referral Hospital—July 2010–September 2015 [7]

Vascular surgery	No.	%
Peripheral vascular aneurysm repair	7	4.4
Aortic aneurysmectomy + graft interposition	5	3.1
Peripheral limb arterial bypass surgery	3	1.9
Cervical paraganglioma excision	3	1.9
Peripheral vascular tumor excision	1	0.6
Thrombectomy and fasciotomy	4	2.5
Repair of post-traumatic vascular injury	6	3.8
Varicose vein surgery	49	30.8
Sclerotherapy for AVM	15	9.4
Distal A-V fistula creation (for ESRD)/ take down	41	25.8
Cath lab procedures		
Peripheral angiography	5	3.1
Peripheral vascular stenting	1	0.6
Endovascular aortic repair	2	1.3
IVC filter insertion	1	0.6
Others		
Amputations for gangrene	16	10.1
Total	159	100.0

Surgical Operations and Supplies

Peripheral venous insufficiency is among the commonest vascular conditions in the surgical out-patient clinics at UHI and varicose veins are the most frequent clinical presentation. The commonest indication for elective vascular surgery at UHI is varicose vein disease (Table 49.1). Other venous disease states seen at UHI include deep vein thrombosis, and arteriovenous malformations. Due to limited access to modern techniques in treatment of venous insufficiency such as laser and radio frequency ablation varicose vein stripping and ligation of incompetent perforators is the main surgical intervention performed for non-complicated varicose veins.

Arterial insufficiency due to arthrosclerosis, peripheral limb aneurysms, and aortic aneurysms are not uncommon and the incidence is rising due to increased prevalence of dyslipidaemia arising from changing life styles. In addition, Uganda has an HIV prevalence rate of 7.3 % [5] and use of anti-retroviral (ARV) therapy is common [6]. Some patients on combination ARV therapy develop dyslipidaemia [6] with subsequent arthrosclerosis and plaque formation as a side effect of protease inhibitors leading to arterial insufficiency. Not infrequently these patients suffer arterial thrombosis secondary to plaque rupture or occlusive vascular disease. In most cases presentation is late and as a result they cannot benefit from limb salvaging procedures and end up undergoing limb amputations.

Peripheral vascular tumors as well as cervical paragangliomas are not uncommon and in most cases present late due to ignorance about the diseases and traditional beliefs which paint a myth about tumors both benign and malignant (Fig. 49.1).

Chronic kidney disease and end-stage renal disease (ESRD) are frequently seen in Uganda and the number of cases requiring haemodialysis (HD) is on the rise. Most patients cannot access kidney transplant services and their lives are as such dependent on HD. In view of the limited specialists available, vascular surgeons in Uganda frequently perform distal arteriovenous shunts for patients requiring access for long term HD.

Most specialized sundries for vascular surgery including graft material and stents are either imported through public hospitals budgets or donated through charitable missions by expatriate visiting teams. Whereas these are freely supplied

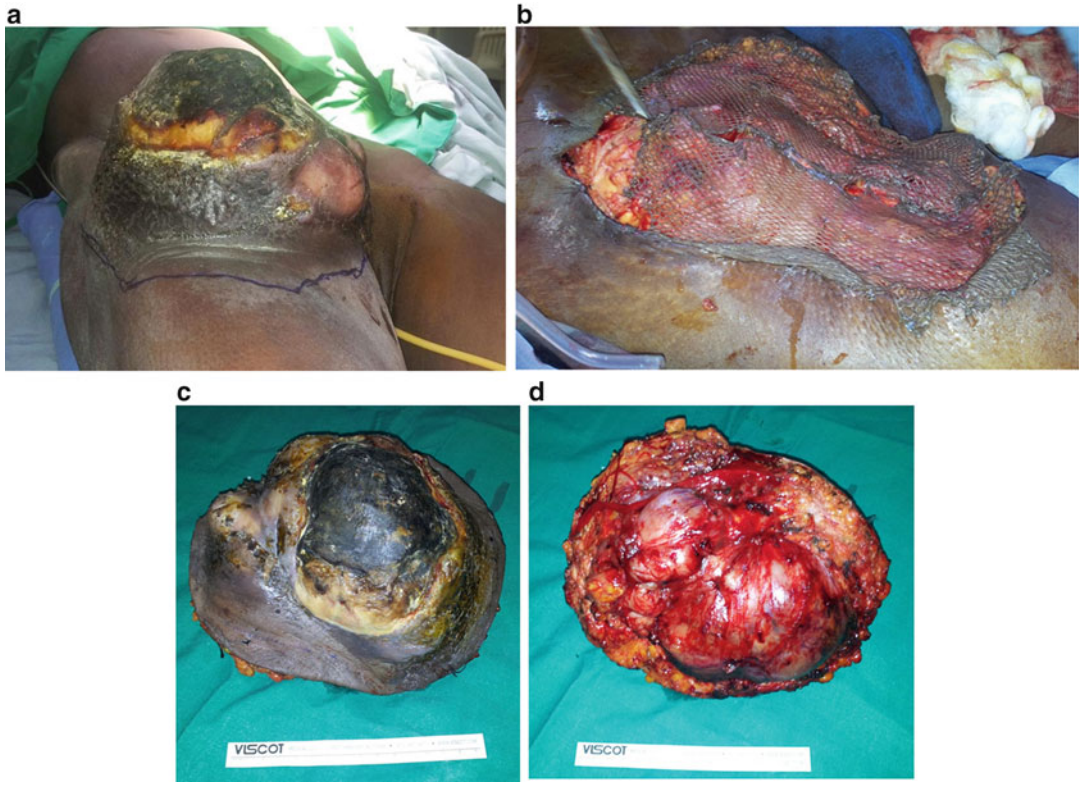

Fig. 49.1 (**a**) Late presentation of a right groin haemangiopericytoma, (**b**) split thickness skin graft after excision, (**c**) excised specimen, cutaneous surface, and (**d**) visceral surface [7]

to the patients they are frequently in short supply and a limiting factor in the availability of services. The government health budget cannot as yet avail these supplies in adequate quantities to address the needs and the private sector is still under developed to invest in such expensive sundries.

Artherosclerosis is the commonest aetiological factor for most aortic aneurysms in Uganda. Vascular surgeons in Uganda experience major challenges with aortic aneurysms due to limited availability of graft materials. This has been compounded by the low socioeconomic status of most patients who cannot readily afford the cost of the grafts and making service provision even more complex. Whereas infra-renal aortic aneurysms have been ably managed by aneurysmectomy and graft interposition using woven Dacron or Hemashield grafts suprarenal aneurysms have been a challenge. With regard to performing safe suprarenal aortic repairs, lack of appropriate cannulas for cardiopulmonary bypass, well controlled hypothermia as well as cerebral and spinal cord protection present technical challenges in the local environment (Fig. 49.2).

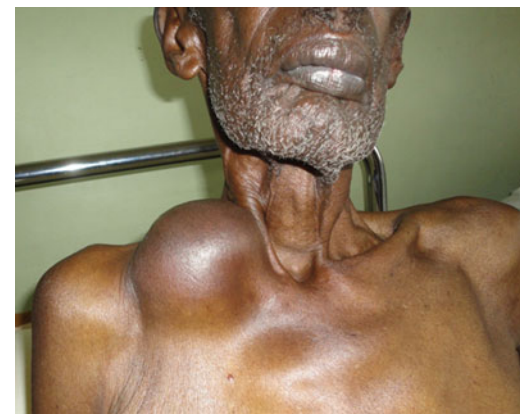

Fig. 49.2 Post-traumatic right subclavian artery aneurysm

The introduction of hybrid procedures such as thoracic endovascular aortic repair (TEVAR) has paved way for successful yet less invasive repair of suprarenal aortic aneurysms. This has been

possible with the installation of a cardiac catheterization laboratory by the government and training of both the interventional cardiologists and cardiovascular surgeons at home. There however, remains a challenge in availing the required sundries including stents on a regular basis. With no national health insurance scheme only those privileged few who can access such schemes can access the service due to the high cost of necessary supplies.

In Uganda the insertion of inferior vena cava filters for deep vein thrombosis as well as performing peripheral angiograms and implantation of stents is a task performed by the interventional cardiologists. However, like other vascular procedures the cost of supplies such as vena inferior cava filters is relatively high for a population with low socioeconomic status like that of Uganda and many deserving patients end up failing to access the service.

In order to cut down on the cost of supplies, ethylene oxide (EtO_2) gas sterilization has been introduced at UHI and hopefully will go a long way in enabling the process of availing safe recycled supplies.

Going Forward

With limited resources, Uganda as well as many other sub-Saharan countries need to design training programs that can be locally implemented to build capacity in vascular surgery. Where necessary task shifting could be done by training vascular surgeons to perform doppler studies and vascular angiographic investigative procedures as well as vascular stenting. This would enable patients have an expedited vascular surgical care from a "one stop shopping" for diagnosis and treatment where resources a limited. Such training could be arranged locally in form of periodic short workshops so as to have adequate hands on experience with foreign expatriate support.

In view of the high cost of supplies required to conduct investigations as well provide a service low income countries will need to adopt simple methods such as gas sterilization for reprocessing some of the supplies where feasible.

Local governments will need to include vascular disease in their non-communicable disease agenda and ring fence funding to develop both preventive and tertiary level surgical care for patients with vascular disease. Advocacy campaigns for health promotive behavioral change are necessary in order to limit risk factors that predispose to preventable non-communicable diseases including acquired vascular disease. This will in the near future curtail the patient load demanding vascular surgery services.

Patients on combination ARV therapy where protease inhibitors are included should have their lipid profile regularly monitored and where necessary receive lipid lowering drugs depending on the type of elevated lipid. Advice on dietary adjustments needs to be provided so as to limit development of arthrosclerosis. Surgical interventions such as arterial bypass surgery ought to be done early where progress to significant limb ischaemia is envisaged so as to avoid preventable limb loss.

The development of a national health insurance scheme will go a long way in addressing the costs of health care and enable the local population access tertiary level vascular surgical care.

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Vascular Surgery in Zambia

50

Alex Makupe

Zambia, a landlocked country in south-central Africa, is about one-tenth larger than Texas (740,724 km^2). It has a population of 14,638,505 (2014 estimation) and life expectancy of 51.83 years.

Medical Training

Until the year 2000, there has only been one medical school in the country—the University of Zambia, School of Medicine. Since the year 1973, we have seen about 1200 medical doctors graduating from this school. Until the early 1990s doctors that needed specialist training went to the United Kingdom and America for training. Very few of this came back home to develop the practice. In the 1990s the MMed programme was established to try and meet the Zambian demand for specialists like general surgeons, obstetricians and gynaecologist, paediatricians and physicians. Even with this kind of training the numbers for specialists have remained very low as a result of the increasing population. Currently all provincial hospitals have one or two locally trained specialist.

Sub Speciality Training

The Zambian government, through the ministry of health has invested a lot of money in procuring medical equipment like CT scans and MRI and in training of doctors especially in the field of medical and radio-oncology, emergency medicine and renal medicine. There are plans to set up a renal transplant centre soon. The training for all this programmes have to be obtained outside Zambia. We look forward to reversing this trend in the near future.

The training in vascular surgery in Zambia is very basic both at undergraduate and post graduate level due to lack of teachers and surgeons that can be seen to do these operations.

The Burden of Vascular Conditions in Zambia

The Zambian population is a young population therefore degenerative vascular conditions are not very common.

Among the vascular conditions seen in Zambia are:

Vascular Trauma

We have a lot of blunt trauma cases here as a result of motor vehicle accidents. Penetrating trauma is rare, seen mainly during the festive season.

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Severe blunt injuries to the abdominal and mediastinal viscera tend to be fatal because we don't have the expertise to the operations and the country has challenges with blood and blood products.

Peripheral Vascular Diseases

Our population is a young and not heavily smoking population, but there is always a patient or two with gangrene of the foot on the ward. Many of these cases are related to diabetes and HIV while a few are due to atherosclerosis.

HIV vasculopathy is common, presenting in the form of Deep vein thrombosis and distal small vessel disease causing critical limb ischemia.

We have a good number of patients with cardiac valvular disease or dilated cardiomyopathies. Many of our patients are not on warfarin because we don't have laboratories that can cheaply offer the test for monitoring levels. We therefore see patients with acute critical limb ischaemia. I have seen three cases in the past 4 years.

Aneurysmal Disease

Cases of abdominal aortic aneurysm are rare. Between one and three cases get sent to me every year for assessment. I have seen two cases of common femoral aneurysm for which only resection without reconstruction was done.

Carotid Disease

We have a lot of cerebral vascular accidents getting to the medical wards. Many are presumed to be haemorrhagic. We have limited studies to help us look for extra cranial causes of strokes. I have seen one patient with symptomatic carotid atheroma who can benefit from endarterectomy but we are limited in terms of staffing and equipment.

Investigations are limited. Supportive investigations like echo, stress ECG, Doppler, arteriograms can't be found. We now have 4 hospitals with CT scans allowing us to do CT angiography. Other investigations such as cardiac echo and ECG can be found in three major centres.

Some of my experiences in the year 2015:

Fifty kilometers from the central hospital where I am based is a rural health centre managed by American missionaries. They asked me to visit them so that I can go search for surgical consumables from their container that they had received from America some months prior. I was excited about it. I thank them.

As I searched, I came across boxes of central lines. They were already 1 year post expiry date. I got them and put them in my office. I could use them to teach my resident trainee surgeons how to insert central lines but also to use them on a critically ill surgical patient.

During the same search, I came across a box of embolectomy catheters and guide wires. They were expired but I picked them. I use them to show my students when teaching about embolectomy.

Three months later I was called to see a patient in a private clinic with a cold limb. He was visiting from South Africa and was known to be on warfarin at one time. The time I was seeing him his leg was pale and stiff-muscle had died but the thigh was a bit warm and alive. The femoral pulse on that side was absent while the opposite side had a good femoral pulse. He had an embolus. Took him to theatre, using the expired embolectomy catheters, did a successful embolectomy. He was later on evacuated to South Africa where above knee amputation was done. At least his thigh was saved.

In another case, my resident was called to the medical ward to see a 19 year old with severe backache. I was asked to go and see him immediately. He was haemodynamically stable but in a lot of pain. Ct reviewed a juxtarenal leaking aortic aneurysm of 7 cm. I had nowhere to refer him to. I called the parents and told them about the outcome. He died 2 days later

You can see from this the nature of help that we need in our country. We need training. If am trained as a vascular surgeon and supported with equipment, I can start to train the general surgeons.

Management options in Zambia

There three major management options for vascular condition worldwide.

Observe/conservative
Endovascular
Open surgery.

Our options are limited. We don't do revascularisation procedures. Many cases of gangrene end up with limb amputation.

Status of Vascular Surgical Care in Palestine

51

Raed M.A. Isayed

Palestine, which is located in the Middle East, has a population of around four million people and a small number of vascular surgeons despite having a large number of vascular patients. The Department of Vascular Surgery in Al-Ahli Hospital in Hebron/Palestine is a leading center of excellence in the provision of treatment of vascular diseases. Our hospital is a 200-bed facility, with 8 beds in the intensive care unit, 12 beds in the coronary care unit, 9 operating rooms, and an endovascular intervention unit (Fig. 51.1).

In this chapter I will briefly discuss the status of vascular surgery and my experience over 5 years in one center in the southern West Bank in Palestine that covers an area serving 1.3 million people in the city of Hebron. In this area, I am the only vascular surgeon who works at the hospital on a daily basis and is on call 24 h/day, 7 days/week. Four residents help me run the outpatient clinics, follow up with in-patient care, and assist me in the operating room. On average, I perform around 600 vascular interventions per year and sometimes see more than six cases of vascular injury a day.

Our operating room is well prepared and I have all grafts, catheters, and instruments that I need. The endovascular unit is equipped with all sizes of stents, balloons, and catheters. What is lacking are new devices, such as atherectomy devices or devices for aortic aneurysms.

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Management of Diabetic Foot and Peripheral Arterial Disease

Peripheral arterial disease is a common manifestation of atherosclerosis. The prevalence of peripheral arterial disease continues to increase. In our center, the sex distribution is 60 % males and 40 % females; the distribution of ages is as follows: 1 % below 49 years, 25 % 50–59 years, 61 % 60–69 years, and 13 % above 70 years (Fig. 51.2).

The clinical presentation of patients is as follows: 20 % present with claudication, 10 % with rest pain, 20 % with tissue loss, and 50 % with gangrene (Fig. 51.3).

On a case-by-case basis, revascularization (endovascular and bypass) procedures have been shown to save limbs and ultimately provide a better quality of life for patients. With appropriate care, even patients considered high risk can undergo these procedures, which are safe and effective.

We have documented a large number of successful patient case histories that detail how complex revascularization using distal bypass operations and angioplasty techniques has resulted in a healed foot and avoided amputation. If even a small portion of a foot can be saved, then the person can walk effectively and lead a reasonably normal life.

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Fig. 51.1 Ahli Hospital in Hebron, Palestine

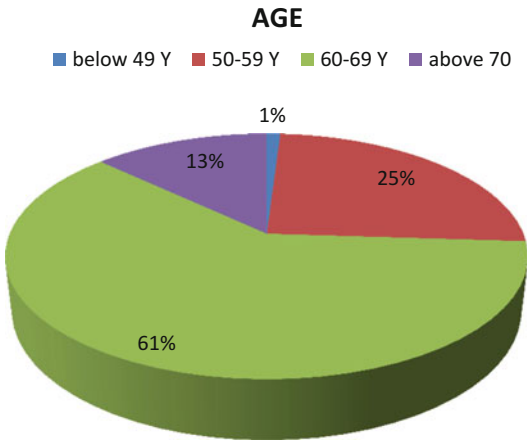

Fig. 51.2 Prevalence of peripheral artery disease by age

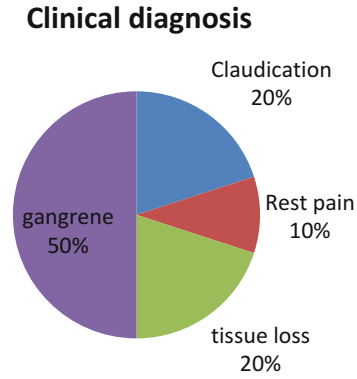

Fig. 51.3 Clinical presentation of peripheral arterial disease patients in our facility

Many cases that I face are in a delayed stage of disease with extensive atherosclerosis and multiple sites of occlusion, so managing the conditions is challenging, and sometimes I perform extra anatomical bypass or combined endovascular and bypass surgeries (Fig. 51.4).

Management of Venous Diseases

Varicose veins are a known cause of physical and psychological discomfort to patients, bringing about various conditions, from skin discoloration to venous ulcers. Varicose veins are more common in women, especially following childbirth. More than 90% of my varicose vein patients are treated effectively by injections of foam sclerotherapy; others are treated by open surgery. Patients with venous ulcers and venous hypertension are treated through wound management and compression therapy.

Deep venous thrombosis is a quite common disease, especially postpartum. We treat it by anticoagulation and compression therapy and use an inferior vena cava filter in indicated cases, which have been rare in our patients. In the last 2 years

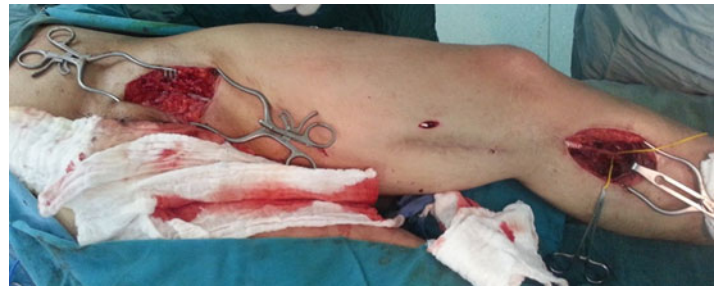

Fig. 51.4 Left femoral-posterior tibial artery bypass by composite graft

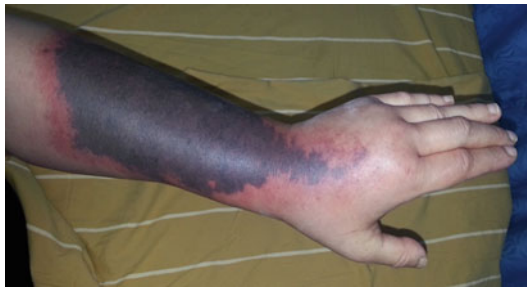

Fig. 51.5 Left forearm warfarin-induced skin gangrene

I have been using the new anticoagulation drug Rivaroxaban with excellent results. We have six documented cases of warfarin-induced skin gangrene over a 5-year period, one case in the forearm and the others in the lower limbs (Fig. 51.5).

Vascular Access Surgery for Hemodialysis and Management of Access Complications

We routinely provide expert advice and treatment of complicated access-related procedures like native arteriovenous (A-V) fistula, AV graft, and permcath, and in addition deal with all complications arising in patients requiring such interventions. On a monthly basis I perform an average of 25 to 30 AV fistula procedures and deal with one or two cases of access complications.

Vascular Malformations

Some patients have abnormally developed blood vessels that may be disfiguring or disabling. I treat cases of congenital hemangioma with propranolol with excellent results and other cases at peripheral sites with sclerotherapy. Complicated cases are transferred to Jordan because we do not have a specialized center to deal with those cases. This is difficult and expensive for the families.

Vascular Injury

I have considerable experience treating vascular injuries in the form of gunshots or motor vehicle accidents, penetrating trauma, and even iatrogenic intraoperative vascular injury. Over the course of 5 years, I have documented around 400 cases of gunshot accidents with vascular injury. Gunshot wounds occur mainly at the infrainguinal level and sometimes in the upper limbs, abdomen, and chest.

Femoral vessel gunshot injury (Fig. 51.6): My experience involves control and revascularization in femoral cases in 1.5 h; my approach is always to work directly and open an incision over the femoral artery at the injury site without doing proximal control; nearly all cases require grafting. I use the saphenous vein of the same limb if there is no venous injury, but if the vein is injured, I use the great saphenous vein of the contralateral limb. In cases of bilateral lower limb injury, I use the saphenous vein of each limb.

Popliteal vessel gunshot injury (Fig. 51.7): My experience includes control and revascularization in cases of popliteal vessel injury in 2 to 2.5 h. I used a prone position with an S-shaped incision to do a full exposure of the popliteal fossa with a careful exploration of arteries, veins and nerves. If the popliteal vein was not injured I used the short saphenous vein if

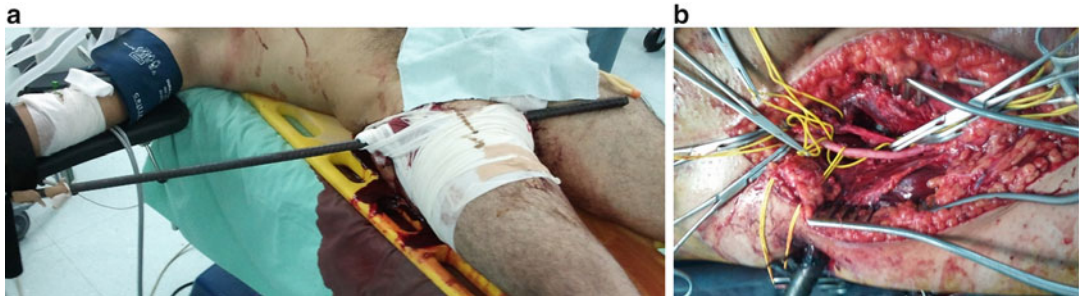

Fig. 51.6 (**a**) This is a male patient presented with penetrating injury to right upper thigh, causing injury to common femoral vein. (**b**) Femoral triangle after exploration and before removal of penetrating metal

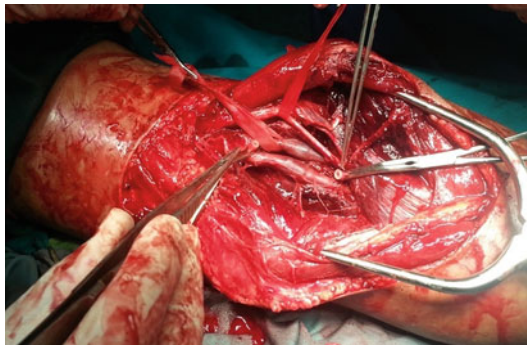

Fig. 51.7 Full exploration of popliteal fossa showing both ends of injured popliteal artery

it was intact or the great saphenous vein from the same leg to revascularize the popliteal artery; however, if the popliteal vein was injured, I used the great saphenous from the contralateral leg. If the nerves were injured, the injury is treated by the neurosurgeon in accordance with its degree of seriousness.

Sometimes, many cases arise at the same time, so I deal with cases involving active bleeding first, then cases with contained hematoma. I handle cases with lower limb vascular injury that have lasted more than 24 h. The difference in cases with delays is that edema makes exploration very difficult, and anterior and posterior leg compartment prophylactic fasciotomy must be performed. In most of cases closer of this fasciotomy occured on second day post operative with first dressing.

All cases involving arterial injury required anticoagulation (Rivaroxaban) only with 100 mg aspirin daily for 1 month, with aspirin alone continuing for 6 months. In cases with venous or arterial and venous injuries, I use Rivaroxaban with aspirin for 6 months then continue with aspirin only for another 6 months.

Management of Cases with Acute Ischemia

Cases with acute ischemia related to embolization or acute thrombosis are treated by open surgery and embolectomy or thrombectomy.

I have documented more than ten cases involving acute ischemia and bleeding from a ruptured femoral artery with pseudoaneurysm postcardiac catheterization. In those cases I opened the incision directly over the aneurysm, dissecting and removing the hematoma and directly repairing the site of the catheterization sheath.

The Status of Vascular Surgery in Nepal

52

Sandeep Pandey

Introduction

Vascular surgery has been slow to develop in Nepal. The widespread misconceptions that vascular diseases are uncommon and that the results of vascular reconstruction are poor has resulted in vascular surgery's being unpopular among medical students. Most students do not have enough knowledge of vascular diseases and treatment options. This lack of awareness has led to delays in the diagnosis of vascular problems, which results in poor outcomes. At present there are no training centers for vascular surgery only. Students receive adequate training in cardiothoracic surgical procedures, with only a few months in open vascular surgery, but endovascular training is still lacking. I have been providing vascular and endovascular treatment at Norvic International Hospital [200-bed tertiary center with 3 operating rooms (ORs) and 1 cathlab serving 50,000 patients annually) and Annapurna Neuro Hospital (50-bed tertiary center with 3 ORs and 1 cathlab serving 20,000 patients annually). I do all routine and emergency vascular ultrasound myself in accordance with my training to reduce misdiagnosis. After 2 years of fellowship in vascular and endovascular surgery from Medanta–The Medicity, India, and an externship from Christ Hospital, Cincinnati, USA, I proposed to correct these problems by initiating vascular services in different parts of the country, conducting a nationwide awareness campaign and leading continuing medical education programs and workshops for general surgical trainees. I started a Web site called Vascular Nepal for public awareness (https://vascularnepal.wordpress.com/;https://www.facebook.com/Vascular-Nepal-688755457854265/). Recently we formed vascular society of Nepal with 9 members involved more in vascular surgery. Dr. Uttam shrestha is the president and I am the secretary.

Pattern of Vascular Diseases

Buerger's disease is the most common cause of lower-limb ischemia in government hospitals, where most poor patients obtain treatment (amputation) free of cost. In private hospitals, atherosclerosis is the most common cause of lower-limb ischemia. Aneurysmal disease is common, with rapid enlargement and rupture being common as well. Diabetes mellitus is extremely common, and nearly 15 % of the population will be diabetic in the near future. Even though coronary disease is very common, peripheral vascular disease is known to occur in only 6–7 % of patients. Similarly, carotid disease is less common compared with its incidence in the

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West. Most diabetic patients present late with ulceration or gangrene of the toes and critical ischemia due to tibial artery occlusion. Aortoiliac blocks are relatively rare. Recently, I encountered a rare peripheral aneurysm of the external jugular vein and superficial temporal artery and treated it by open means. In winter, frostbite is more common. Frostbite patients are mainly foreigners who come for hiking. Raynauds is relatively common in winter.

Current Status of Vascular Surgery

Even today, vascular surgery has developed somewhat at a few centers, performed by general surgeons and cardiac surgeons who are interested in doing vascular surgery part-time. The country as a whole is lacking trained vascular surgeons, and patients must undergo considerable hardship as a result. Most patients in Nepal are not covered by health insurance and must pay for medical care themselves. This has been the most important factor in determining treatment options for these patients. Because a single procedure that is cheap and gives lasting benefit is the treatment of choice, open surgery is most often chosen as opposed to endovascular surgery. An abdominal aortic aneurysm endograft procedure is around three times as expensive as an open repair in Nepal.

When a case of thoracoabdominal aneurysm is diagnosed, it is mostly treated conservatively owing to the costs of treatment and postoperative complications (Fig. 52.1). I have started to do endovenous thermal ablations of varicose veins. It is now also done at two of our medical institutes by cardiothoracic & vascular surgeons. I mainly see on average 2500 patients annually on an outpatient basis. The most common surgery I perform is on varicose veins, using both open and endovenous techniques (average 100 annually). In addition, I perform 10–15 embolectomies, 2–3 aortic aneurysms, 5–6 vascular malformations, 10–15 peripheral angioplasties, and other procedures. annually. Most patients are not ready for interventions, so amputations are relatively common. Many modern devices seen abroad are lacking but ordered, usually from India, on a case-by-case basis.

Fig. 52.1 Excision of superficial temporal artery aneurysm

Outreach Programs

Creating Public Awareness

Public awareness of vascular diseases is extremely poor. I have been conducting several vascular camps in different cities of Nepal. I carry handheld Dopplers during remote vascular camps (Fig. 52.2). In addition, at one time I also served many earthquake-affected vascular patients (http://www.veinexperts.org/blog/2015-07-10-sandeep-raj-pandey-md-assists-earthquake-victims.asp). The 2015 earthquake affected me personally since its epicenter was near my practice. Personally, I was not injured, but my wife

Fig. 52.2 Handheld Doppler used in remote vascular camp

received a head injury and my newly built boundary and garage were destroyed. We ran around serving several hospitals to perform emergency surgery and even had to do suturing on the ground. A temporary OR was made for emergency surgeries. Postearthquake outpatient department patients decreased from outside the affected area to the capital (Fig. 52.3). The recent fuel crisis had a similar effect.

Creating Awareness Among Medical Students

Undergraduate medical students and postgraduate surgical trainees do not have sufficient exposure to vascular surgery because this specialized service is not available in many medical schools. General surgery residents have limited exposure to open varicose surgery and diabetic foot debridement. I perform vascular continuing medical education for awareness of the vascular diseases as well. Our newly formed vascular society of Nepal have lot of aims to create awareness on vascular diseases.

National Community

I perform vascular surgery independently at Norvic International Hospital and Annapurna Neuro Hospital. I run an organization called Vascular Nepal for public awareness (Fig. 52.4). Several vascular procedures are performed by skilled cardiothoracic & vascular surgeons at one of the nation's reputed medical institutes. We hope to attract international resources for the development of the vascular society of Nepal.

International Helping Hands

We are in direct contact with India and so are able to obtain regular help from international proctors whenever needed. We need collaboration with international forums. This would represent a great opportunity for young vascular surgeons like me to gain international exposure and learn the latest techniques to use at home in Nepal, so that young general surgeons would receive encouragement for joining the ranks of vascular and endovascular surgeons.

Fig. 52.3 Vascular camp in earthquake-affected areas

Fig. 52.4 Patient blessing at free vascular camps

Surgical Care in Haiti

53

David M. Vanderpool and Ruth L. Bush

Haiti, home to an estimated 10.1 million persons (2011 United Nations estimate), occupies the western three-eighths of the island of Hispaniola in the Caribbean. Decades of governmental instability followed by many recent natural disasters, including the devastating earthquake in January 2010, have left the country in shambles. It is, and has been, the poorest country in the western hemisphere for those decades. Although Haiti averages approximately 350 people per square kilometer (approximately 900 per sq mi.), its population is concentrated most heavily in urban areas, coastal plains, and valleys. Economically, there is a growing gap between Port-au-Prince and the rest of the country. More than 80 % of those living in extreme poverty do so in rural areas where access to any, albeit adequate, healthcare is woefully lacking. Most Haitians have no transportation or access (geographical and economical) to Haitian hospitals.

Basic medical care is challenging to deliver and to receive in Haiti. In 2012, it was estimated that children's vaccination rates were as low, with only 60 % of the children in Haiti under the age of 10 being immunized (http://www.cdc.gov/globalhealth/stories/haitian_children.html). Common causes of childhood death in Haiti (World Health Organization, WHO) are diarrheal diseases, HIV/AIDS, meningitis, and respiratory infections [1]. Ninety percent of Haiti's children continuously contract waterborne diseases and intestinal parasites which compound the malnutrition and starvation that is so widespread. HIV infection is found in at least 1.8 % of the population with the incidence of tuberculosis reported as more than ten times rates found in Latin America (http://www.paho.org/hq/index.php?lang=en). Thus, it could go without saying that surgically treatable conditions contribute significantly to the burden of disease in this very impoverished country [2].

Lack of clean water, along with inadequate housing and unsanitary living conditions, contributes to the high incidence of infectious diseases which include both bacterial and protozoal diarrhea, typhoid fever, hepatitis A and E, vector-borne diseases such as Dengue fever, Chikungunya, and malaria, and leptospirosis [3]. There is a chronic shortage of health care personnel and hospitals lack resources and equipment. The infant mortality rate in Haiti is one of the highest in the world, in 2013 was 55 deaths per 1000 live births, compared to a rate of six per 1000 in other countries (http://data.worldbank.org/indicator/SH.DYN.MORT) [4].

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In Haiti, a major cause of unnecessary sicknesses and deaths is the lack of trained professionals to provide health care for the population. There are only about 25 physicians per 100,000 Haitians [5–7]. In the United States, by comparison, there are approximately 280 doctors for every 100,000 Americans. In Haiti, one-half of physicians are trained as general practitioners who have completed medical school and a social service year but have not received any specialty training [8, 9]. There are only about 150 in-country residency positions for the 450 medical school graduates. Most residencies are based in hospitals that are ill-equipped and under-staffed, with limited supervision by experienced doctors. Even so, approximately 80 % of all physicians trained in Haiti leave within 5 years of graduation to obtain more training and eventually, practice abroad. Internationally trained physicians do provide much of the care, from the United States, France, and Cuba to name a few countries [2].

Surgical care in poor countries is essential. According to the WHO, the poorest third of the world receives less than 4 % of the world's available surgical services, while the richest third receives nearly 75 % (http://www.who.int/hac/crises/hti/en/). Surgical care in Haiti is relegated to the larger cities only, with much of the care provided by international surgical mission teams. For example, just north of Port-au-Prince, is the Hôpital Albert Schweitzer, a 122 bed facility serving a region of over 350,000 persons. Here over 2500 operations are performed each year despite limitations in laboratory work and antibiotics and only 32 beds allocated to surgical patients. Mainly, the surgical care consists of emergency and trauma care for victims of motor vehicle accidents. Renowned in Haiti, this hospital draws volunteer physicians and other healthcare professionals from around the world. Untreated surgical disease has enormous human, societal, and economic impacts which are pervasive and long-lasting. For example, a disabled parent who cannot access to safe medical or surgical care may not be able to care for his or her family leading to hardship for the parent, the family, and ultimately, society. As a result, the true economic impact of medical and surgical disease that goes untreated can profoundly affect a country for these reasons. Despite experts agreeing upon its cost-effectiveness, health care, and specific to this discussion, surgical care, remains inadequate in the poorest of countries.

In Haiti, surgical care is delivered in part by both public and private healthcare facilities [10–13]. In a recent publication reporting the results of a nationwide survey of Haitian hospital surgical capacity, 69 % of facilities reported having at least one fulltime surgeon and 33 % had an anesthesiologist [10]. Basic infrastructure is often lacking with continuous water supply found in 89 % and on grid electricity in 78 % of hospitals. Blood banks are available in 33 % of all hospitals. In terms of equipment, 89 % of hospitals report having at least one functional anesthesia machine and pulse oximeters available with postoperative care area located in 82 % of facilities. Table 53.1 lists some of the more common procedures offered in these facilities [2].

The international teams that provide care may do so at a city hospital, or more often, in rural communities which have the least access to surgical care. In addition to the surgical experience, international providers return with a greater appreciation of the healthcare needs in underdeveloped countries and the importance of teamwork, particularly under challenging circumstances [11, 14]. Following the devastating earthquake in 2010, the surgical care capacity was severely strained in Haiti. Following the widespread devastation, hundreds of nurses, surgeons, and anesthesiologists from around the

Table 53.1 Most common available surgical procedures [2]

Intervention	Percentage range of facilities providing intervention
Resuscitation	66–100
Acute burn management	95–100
Incision/drainage of abscess	95–100
Appendectomy	80–92
Hernia repair (strangulated and elective)	85–100
Laparotomy	80–92
Amputation	50–92
Closed treatment of fractures	50–88
Open treatment of fractures	35–64

world assisted in the needed trauma care. These persons were introduced to a different culture and a country that is very much in need and easily accessible from the U.S. and will undoubtedly provide continued care in years to come.

The co-authors, Drs. Vanderpool and Bush, are faculty members at Texas A & M Health Science Center College of Medicine and practicing surgeons. They have both performed medical and surgical mission work in Haiti for many years. Dr. Vanderpool, thorough his organization, Mobile Medical Disaster Relief, was one of the initial first responders in Haiti after the 2010 earthquake (http://livebeyond.org/). After spending 12 days in-country taking care of horrific injuries and performing dozens of operations, Dr. Vanderpool and his wife, Laurie Vanderpool, moved to the Thomazeau region of Haiti in 2013. Through their new (renamed) organization, LiveBeyond, they provide year round medical care to this region outside of Port-au-Prince in a freestanding medical clinic which they have built. His diligent work has led to improvements in the regional rates of childhood malnutrition and maternal and infant morbidity and mortality through healthcare, community outreach, as well as nutrition and education programs [15]. Recently, a team of faculty and students participated in a basic resuscitation educational program in which more than 125 Haitian laypersons, nurses, and physicians were trained. Teaching basic healthcare skills and competencies to native Haitians will augment the availability of basic services and improve access to quality healthcare services to this most vulnerable of populations. The planning is underway to provide much needed surgical and obstetrical care in the very near future. Dr. Vanderpool has implemented a very successful global health experience balancing service and education.

In another region of Haiti, in a small village on the south coast that is an 8 h car ride from Port-au-Prince, Dr. Bush has been providing yearly medical and surgical care since 2003. In this remote region, far from the closest hospital or clinic, even simple care is lacking. A fulltime native nurse is now available for daily needs. Surgical care is provided only yearly by a team of providers who work closely with a U.S. based organization, Living Word Haiti (https://livingwordhaiti.com/) (Director, Patrick Lataillade). From 2003 to 2015, surgical procedures have been performed in a this very rural village solely under local anesthesia as there is no electricity. Early on, procedures were performed in a large room with separate areas for pre and postoperative care. Later, an on-site multiroom clinic was constructed with sinks, improving sanitary conditions. Utilities are limited and alternative sterilization techniques often employed. The procedures performed that have been able to be performed have been ventral and inguinal hernias, lipoma excisions, abscess drainages, skin lesions (presumed cancerous due to appearance) and large keloid excisions, joint injections, and other minor procedures (Fig. 53.1).

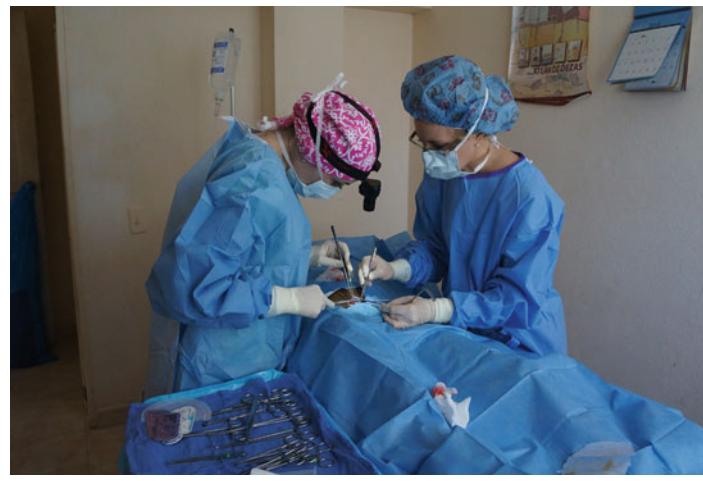

Fig. 53.1 Dr. Bush performing an inguinal hernia repair with 4th year surgery resident

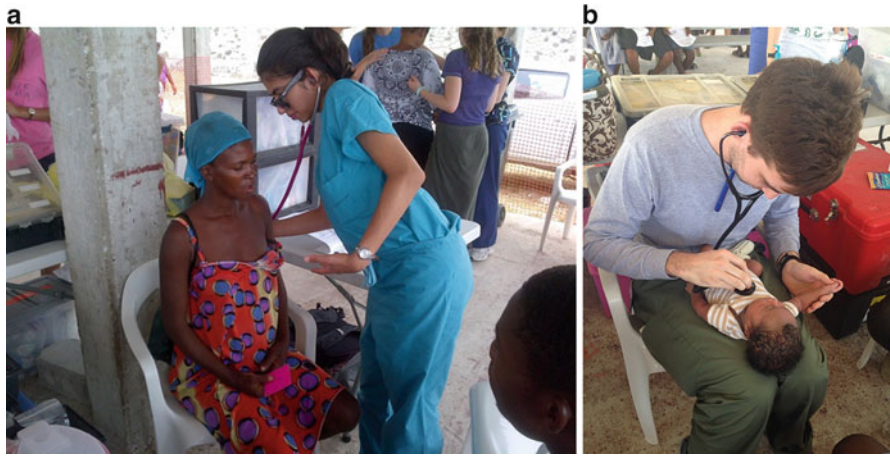

Fig. 53.2 Texas A & M Health Science Center College of Medicine students participating in a global health elective

In both above locations in Haiti, Texas A & M Health Science Center College of Medicine has established elective rotations for both surgical residents and medical students (Fig. 53.2). All levels of trainees have demonstrated a continued interest in global health. Overall, structured preparation, key objectives, and resident and student supervision are mandatory for global health electives to be successful. Along with core training competencies such as interprofessional and cross cultural education, as well as the considerable need for specialists in underserved areas of the United States, offering international health electives in resource-poor settings serves to augment resident and student training.

Conclusions

The global burden of surgical disease needs to be addressed on numerous fronts, including the most underserved and remote rural populations. The local conditions and volunteer expertise need to be matched so that excellent, appropriate, and safe care is provided. Trainees will benefit from the experience as well as on the addition of components of cultural education and global surgery ethics.

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Vascular Surgery in Greece in the Wake of Financial Crisis

54

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and Christos D. Liapis

Introduction

The health status of the Greek population has strongly improved over the last few decades and till recently seemed to compare favorably with other European Union (EU) countries. As of 2009 Greece's core health indicators (life expectancy, infant mortality rate and mortality rate) were either the same, or better than countries such as the UK and Germany [1, 2]. This was in line with a thriving economy that had recorded high growth rates, driven by buoyant private consumption and dynamic investment activity. In 2009 Greece ranked among the ten highest health spenders of the OECD (Organization for Economic Cooperation and Development) Group (9.6 % of gross domestic product (GDP)), spending more on health than Mediterranean and Scandinavian countries and countries such as Luxembourg and the United Kingdom [3].

Likewise, vascular surgery in Greece has been thriving over the past 20 years being one of the first European countries that implemented an independent specialty curriculum and got separated from General Surgery in 1989 [4]. The endovascular procedures got integrated early on into the vascular training curriculum and vascular surgeons hold the vast majority of aortic and a significant percentage of peripheral endovascular procedures against other specialties [5]. Indicative of the vascular evolution in Greece is that the growth of endovascular procedures between the years 2002 and 2007 exceeded 100 % [5, 6]. (Fig. 54.1)

In the midst of a global economic crisis and while Greek governments had been spending for years more than their means, Greece fell into recession in 2009 and the economy entered a deep structural and multi-faceted crisis. The main features of this crisis are a large fiscal deficit huge public debt, growing unemployment, continuous erosion of the country's competitive position, per capita GDP lagging behind the EU15 average, income inequality and poverty rate that remain higher than the EU27 average [3]. In 2010, the Greek government deficit was estimated at 13.6 % which was one of the highest in the world relative to GDP [7]. This situation brought on international disbelief in Greece's

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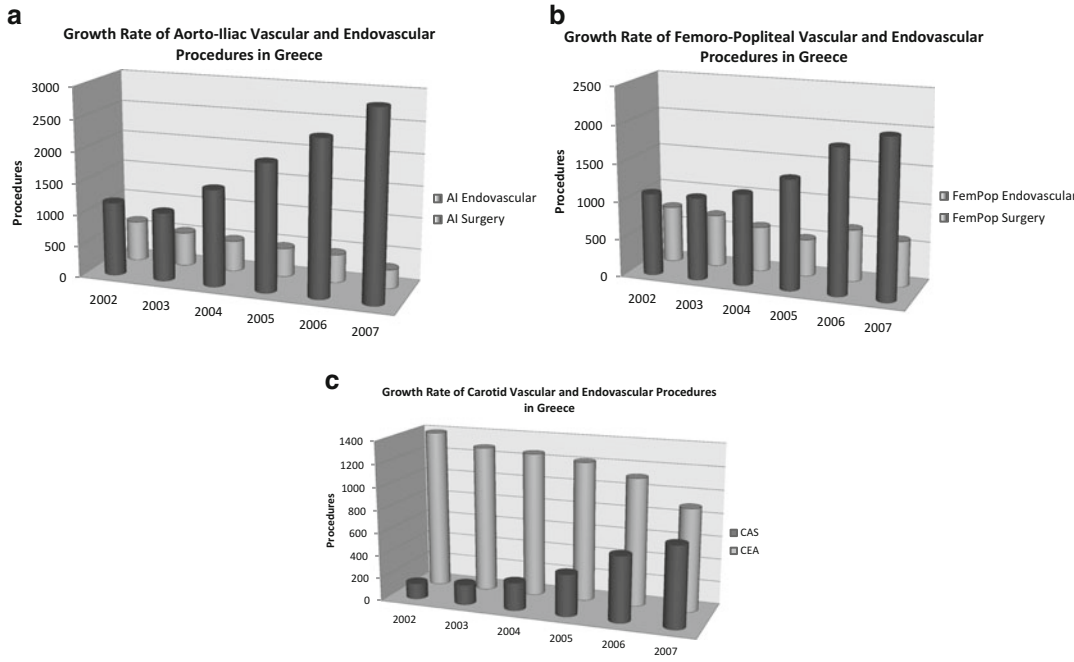

Fig. 54.1 Endovascular procedures have been flourishing during the pre-crisis years. Between 2002 and 2007 (**a**) aortoiliac and (**b**) peripheral endovascular procedures showed a nearly 100 % growth rate; (**c**) carotid endovascular procedures demonstrated a steady decline mirroring the emerging evidence from the relevant trials

ability to repay its sovereign debt. To avert such a default, the European Central Bank (ECB) the European Commission (EC) and the International Monetary Fund (IMF) agreed to a rescue package. To secure continuity of this funding, three Memoranda of Understanding (MOU) have been signed (2010, 2014 and 2015) [7, 8]. Greece has been required to adopt harsh austerity measures to control its deficit, with their implementation constantly monitored and evaluated by the ECB, the EC, and the IMF. This had an immediate impact in the health system structure and health expenditures. While this was otherwise necessary to rationalize a non-sustainable health policy, as this restructure is forcefully implemented the quality and efficiency of care are declining. The situation in Greece has been characterized as "alarming" with indications that its health system could potentially collapse [9, 10]. This chapter focuses on the impact of this financial crisis on Vascular Surgery.

Greek Health System Overview

The delivery of health care services in Greece is based on both public and private providers. The landmark in the development of the public Greek health care system was the creation of the national health system (NHS) in 1983. University and Military Hospitals also belong to the public sector, governed though by different political entities (Ministry of Education and Ministry of Defence). Health is consolidated in the Greek Constitution as a social right. Access to public services is based on citizenship and on occupational status. The system is financed by the state budget, social insurance contributions and private payments. While public hospitals are used more than private (75 % vs 25 %), Greece has the fifth largest share (approximately 40 %), among OECD countries, of private health expenditure, mainly in the form of out-of-pocket payments

(or through private insurances) in diagnostic centers and independent practices [3]. A large part of the private sector contracts with social health insurance/sickness funds to provide mainly primary care, and is financed on a fee-for-service basis according to predetermined agreed prices [11].

Despite the good outcomes, for the past 15 years the Greek health care system has faced serious structural problems concerning the organization, financing and delivery of services. Greece has a highly centralized health-care system, characterized by lack of public nursing facilities, lack of incentives and underdeveloped assessment mechanisms for the health providers, oversupply of specialists coexisting with a significant undersupply of general practitioners (GPs) and nurses [12]. At the same time the per capita demand for pharmaceuticals in Greece is the highest among OECD countries.

Multiple reforms have been attempted over the years targeting to structure a unified health care sector by modernization of public health services, reorganization of primary health care and of pharmaceutical policies to secure the financial viability of the health care system in the short term and its sustainability in the long term. Political instability and frequent government changes have resulted in a health policy that lacks continuity and the ability to bring about change.

Impact of Crisis in Greek Health System

As part of the conditions of a financial support package from the EU and IMF Greece adopted strict austerity measures aimed at reducing the fiscal deficit and restoring market confidence in the future of the economy. Major reforms in health policy, structure, and cost were implemented in three dominant directions: administrative sector reform, reduced drug spending, reduction in net hospital expenses [13, 14].

Positive Impact

Hospital budgets were found to be 20 % less in 2011 than in 2009 as a result of more efficient financial management (e.g., procurement, logistics, accounting systems, costing, pricing). Medical supplies and pharmaceuticals have been coded according to the Global Medical Device Nomenclature system (G-MEN) and that of the National Organization of Medicines ("ELF Barcode") [13, 14]. Reimbursement prices for medical devices were forced down and efforts are made to evaluate and monitor the volume of devices used, through the use of modern information technology and guidelines. It has been suggested that these trends might, in the short term, shrink but also rationalize the device market [15, 16]. Before 2009, it had not been fully recognized that prices of medical supplies were overpriced by approximately 20 %. All together the average price reduction achieved is estimated to be as much as 30 % for products that are almost the same as those purchased up to 2009 [13, 14, 17]. Alongside, NHS hospitals' chief executive officers were directed to redistribute resources from non-effective services to others that were more effective in an effort to offer citizens a better quality of public health services [13, 14].

Social insurance is also undergoing a significant positive reform. There used to be about 30 different social insurance organizations which provided health insurance and most of them were administered as public entities operating under state control. Each insurance institution was subject to different legislation and in many cases there were differences in contribution rates, coverage, benefits and conditions for granting these benefits, resulting in inequalities in access to and financing of services. After the social insurance law passed in July 2010, the social insurance funds are in the process of merging into three funds [11].

Negative Impact

While these structural reforms were long awaited, side effects could not be avoided [13–18]. Health care, health indices, medical research and education have been all challenged in the wake of this financial crisis.

Health Care

Health care reforms forced general wage cuts along with increased patient co-pays, personnel-hiring freeze and a greater control on professionals' decision-making freedom [8, 18]. Total health expenditure was reduced from 9.8 % of the GDP in 2009, shortly after the beginning of the crisis to 6 % in 2012 [19]. As part of this reduction, the existing personnel have seen their already low salaries reduced by 25 % for doctors and 14 % for nurses [20]. Despite the doctors' oversupply contracts for temporary staff are not renewed and replacement of retiring staff is limited. The problem is even more pressing with regard to nursing personnel. This status has inevitably stimulated the emigration of many young and well-qualified health professionals [21]. Greek hospitals now face significant shortages in human resources and medical supplies, resulting in a large number of intensive care units being shut down, hospital clinics functioning below their operational capacity and advanced surgical procedures requiring expensive equipment restricted to the minimum necessary [3, 8]. Still, not all hospitals have been affected equally by the economic recess. As hospitals—either University or NHS—are under prefectural management, depending on their physical residence there is a different size financial "hole" within a differently distributed annual expense budget from the Ministry of Health [11].

While the public health resources are reduced, the NHS witnessed a more than 20 % increase in admissions to its hospitals in 2011 compared with 2009, mainly because patients could no longer afford care from the private sector. The result is the emergence of long waiting lists. Surgical patients wait longer in the list of public surgical departments, and major surgical procedures, even for malignant diseases, are postponed, with self-explanatory implications on patients' outcomes [13, 14]. Considering the allocation of physicians and nurses in the different geographical regions of the country, favoring two or three major cities of Greece, there appear to be great inequalities. These inequalities, coupled with unequal regional allocation of beds, contribute to inequalities of access to services [3].

Noteworthy, Greece was among countries of the Mediterranean that saw a dramatic increase in refugee and migrant arrivals by sea. Last year (2014), around 43,500 people arrived via sea crossings, a 280 % increase from 2013. About 60 % were from Syria, but there were also substantial numbers of Afghans, Somalis and Eritreans [22]. Many move on to other EU states but all of them need to be provided for by the Greek Healthcare umbrella as per EU and Greek legislation [23] and this only deepens the financial dead-end of the system.

Health Indices

Thus far, there is a lack of systematic evaluation of health policy responses to the financial crisis, so it is hard to analyze and interpret its impact all health domains. While there is no clear impact on overall mortality rates, other health indicators have well worsened [9, 24, 25]. The effects of austerity include increased rates of still births, child poverty and undernutrition. Health promotion, health prevention, illegal-drug abuse and HIV-control policies have been inhibited leading to higher rates of new HIV infections and even tuberculosis. To reduce costs, cancer screening has been cut and the management of cancer, as with many other disorders, has suffered from serious drug shortages. Mental health has been directly affected; depression suicides and suicide attempts have increased. Moreover, violent crime, including armed robberies, thefts, break-ins and homicides were nearly doubled in 2012 compared to 2007, at the onset of the financial crisis [26].

Based on official data, during deep recession, the number of Greek and immigrant homeless people strikingly increased in 2011 (2781 homeless people in 2009 vs 11,000 in 2011) [27].

Medical Research and Education

Greece was always one of the lowest spenders on research among the EU countries, but the austerity measures are forcing research funds to elimination. Since 2010 academic institutions are not recruiting new scientists, the retirees are not replaced and the contracts of the temporary personnel are not renewed. The otherwise low salaries of the existing ones have been reduced by 20 % [15]. The Greek government has difficulties to meet its commitments in contributing its expected 15 % share to the funding obtained by Hellenic academic institutions from the European Commission's 7 Framework Programme [16, 28]. A long awaited modernization of academic institutions has been placed on hold [29]. Medical schools are losing access to the international literature as they cannot renew subscriptions with medical journals.

Vascular Surgery in Greece

Training/Specialty and the Impact of Crisis

By Presidential Decree Vascular Surgery is an independent specialty since 1989. The 7-year curriculum is divided in three distinct periods: 3 years core training in General Surgery, 3 years training in Vascular Surgery and 1 year training in Cardiothoracic Surgery (6 months cardiac surgery and 6 months thoracic surgery). Entry within a vascular residency program does not require examination and is solely based on waiting lists which may vary in length according to the popularity of the training center, usually between 2 and 6 years. Eligible to apply is anyone who has an acknowledged medical degree. The application is routed through the regional Prefectural authority and is separate for the core training and separate for the vascular training.

The vascular curriculum has not been officially updated since 1989 and according to the Greek Government Gazette requires a minimum of 150–200 vascular procedures (logbook), with no reference on endovascular procedures. All aspects of vascular training are integrated within the 3 year vascular curriculum including: operating room (open and endovascular procedures), perioperative care including intensive care, outpatient clinics, emergencies and vascular laboratory. Research is optional. Extracurricular training activities are plenty mainly run by the industry, the vascular departments and the Hellenic Society for Vascular Surgery. Since 2009, the Vascular Department of the University of Athens has established a 1-year postgraduate program "Endovascular Techniques" in collaboration with the Department of Surgical Sciences of the University of Milano-Bicocca in Italy. It is designed to address to both trainees and vascular professionals who wish to improve their endovascular knowledge and skills. The program includes theory, workshops, simulation and active involvement in endovascular procedures. Its high attendance during all the years of its operation attests to the educational and certification "gap" it fulfills for vascular physicians in Greece.

After completion of the 7-year training the vascular trainee has to undertake an examination, before of a three-member committee and an officer of the Greek Ministry of Health and Welfare. The examination is both written and oral, following assessment of the trainee's vascular logbook (beyond the non-updated Governmental Requirement of 150–200 procedures). Upon successful completion of the examination the trainee is awarded the certificate of completion of his training and license to practice vascular surgery by the Health Department of the Regional Prefecture under the auspices of the Ministry of Health and Welfare. In 2011, within the context of the state's intention to update all medical specialties' curricula, the Hellenic Society for Vascular and Endovascular Surgery proposed an amendment of the current Vascular Curriculum including the following:

1. Change of the title of the specialty to: "Vascular and Endovascular Surgery"
2. 3 years training in General Surgery
3. 2 1/2 years training in Vascular Surgery
4. 6 months dedicated endovascular training
5. 6 months training in cardiac surgery

6. 6 months dedicated vascular ultrasound training (which will eventually grant license to officially perform and bill vascular ultrasound)

Within the past years' financial and political turmoil the specialties' curricula amendment evaluation procedure has been put to a hold by the Ministry of Health. This makes evident that an even longer process is required for a positive reform of the specialty curriculum within the "hostile" environment of the evolving crisis. However, during the past 3 years the Ministry of Health has provided accreditation to a handful of vascular surgery departments to provide a 6-month program of training and subsequent certification on vascular ultrasound for vascular surgeons. Certification is acquired only after successful examination before a committee and gives the physician the right to perform, interpret and charge vascular ultrasound assessments.

Greece counts 14 vascular departments (11 are University affiliated) in 12 vascular training centers (teaching hospitals), altogether gathering approximately 55 trainees while the respective number of trainers within these centers is 50. Among centers a significant heterogeneity in both number and quality of procedures exist, while no formal quality control is currently implemented. Due to the fact that the trainee positions have been distributed in a fixed manner among training centers—regardless of the institution workload—leads to a respective heterogeneity in the quality and quantity of training received by the Vascular Surgery trainee in Greece.

Ideally, the number of trainee positions per training center as well as the number of accredited institutions to provide training should be regularly re-evaluated based on workload statistics and trainees' and trainers' feedback and evaluation. Instead, the lack of a structured re-evaluation program for Vascular Surgery trainee positions amidst a financial recess has led to phenomena of either very busy but trainee-understaffed vascular departments or departments with trainees in excess that receive low-quality and low quantity training due to reduced institution workload. In practice, vascular surgery training quality is not uniform and varies to an extent that leaves the vascular surgery trainee in uncertainty about his/her future professional competency.

The role of the European Board of Vascular Surgery (EBVS) is paramount as it acts as a clearinghouse for vascular competency and despite not being mandatory, many bright Greek vascular trainees are motivated to rotate to busier Greek or European vascular departments to fulfill the criteria of board eligibility. The minimum acceptable duration of surgical training for entry to the EBVS assessments is 6 years. This must include a minimum total of 2 years in specialist vascular surgical units. The minimum desired experience is 80 open and 50 endovascular experience before the candidate can be admitted to the European vascular assessment. The candidate is then eligible to proceed to a viva voce examination covering clinical, scientific and logbook assessment as well as a technical skills exercise to determine technical competence and correlation between log-book data and viva voce performance. Since 2008, endovascular skills are also assessed using the Simulator for Testing and Rating Endovascular SkillS (STRESS). To pass the examination, the candidates must achieve a 67% success rate in each part of the examination and those who pass qualify as "Fellow of the European Board of Vascular Surgery" (FEBVS) [30].

Amidst the financial crisis, the allowance of free-workforce movement within EU countries, leads many graduating vascular residents seeking more training and eventually work abroad. For many of them it is unlikely that they will ever return back. Greece is currently stripped off promising vascular surgeons, that is part of a wider scale expanding national brain-drain [31].

Vascular Practice in Greece and the Impact of Crisis

The deep economic recess the country has plunged into during the past 7 years seems only to be worsening. The overall impact was described in the previous section. Particularly for

vascular surgery, as it involves more high-cost interventions it is affected to a higher degree. This change is currently being perceived by Greek vascular surgeons and their patients. Both public and private practices have been affected.

In public hospitals, most vascular surgeons are noting an obvious lack of basic and advanced surgical equipment, although imparities in the provisional management between different types of surgical clinics are exhibited, most frequently in favor of university surgical departments. Provision of essential surgical equipment has shifted to new, less expensive manufacturers raising criticism on the quality certification of the purchased products, as reported by surgeons' experience with faulty devices, such as surgical staplers or clip applicators [13, 14]. However, an official register of these adverse events is still missing, and extrapolation to all manufacturers is illegitimate. Private sector hospitals have been "hit" harder by the crisis since out-of-pocket money is hard to find for the average tax payer and social security contractors take years to reimburse these hospitals. For unsettled reimbursements, the anticipated refund is expected to be significantly smaller (clawback and rebate procedures). Major providers of surgical consumables and materials have already denied further supplies to public hospitals until the settlement of a massive debt, and others have retracted their proprietary equipment and leased products from the operating rooms.

As contemporary vascular practice has shifted to minimal invasive expensive endovascular technology the ability of a financially-drained health system to sustain such expenditure is challenged. The flag operation of vascular surgery that is endovascular aneurysm repair (EVAR) has been flourishing in Greece for consecutive years before the crisis emerged (Fig. 54.1). However, due to reimbursement being delayed for years and subjected to claw-back and rebate, along with high-profit policies of intermediate endograft distributors' the prices were as much as threefold higher in Greece than in other EU member states. During the climax of the crisis (2011–2014), public high-volume EVAR hospitals were faced with harsh restrictions in accessing

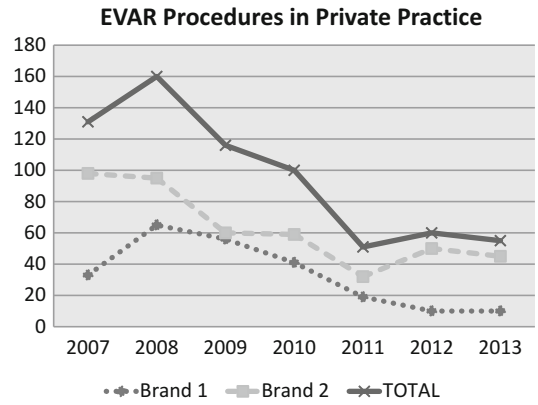

Fig. 54.2 Endovascular aortic aneurysm repair (EVAR) procedures have declined by nearly 65 % in the private sector, between 2008 and 2013. Numbers represent the two market-leading brands

endografts and were forced to switch to the traditional cheaper open aneurysm repair. At the same time, private sector hospitals refrained from these expensive procedures, while distributors "avoided" providing endografts for patients in private hospitals. Unofficial data from two major endograft-brands' sales in the private sector from 2008 to 2013 denote a marked decrease in EVAR procedures (Fig. 54.2). There have been various initiatives to overcome this problem, including forcing up to 50 % price cuts and removing local distributors from the equation. The results of these policies are awaited. It seems that the losses of the private sector are mirrored by a proportional increase of EVAR procedures in previously lower volume public hospitals and to an overall average increase of EVAR procedures in public hospitals. It was recently reported that the number of EVAR procedures in the public sector showed an increasing trend (30 cases/month in 2007 - 48 cases/month in 2012, $P = 0.05$) [32]. This trending growth is nowhere near to the 100 % growth of the 2002–2007 period (Fig. 54.1).

Due to high costs and as control mechanisms get more organized and efficient, EVAR procedures will become more and more scrutinized and thus more difficult to offer to patients in Greece. As the prices are forced even lower and when the health system finds a sustainable balance, it is anticipated that EVAR will again grow,

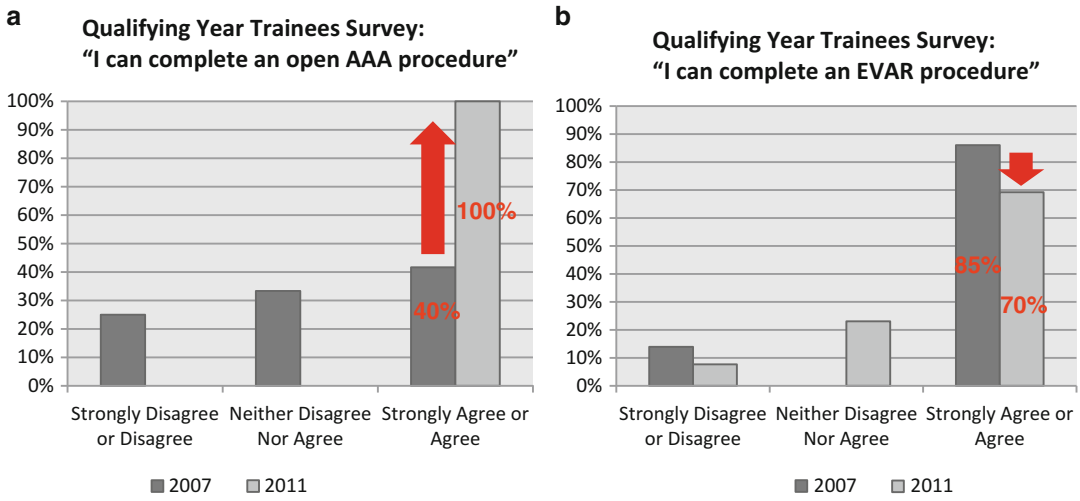

Fig. 54.3 The confidence of vascular trainees in performing an open aortic aneurysm has increased between years 2007 and 2011, that is partly due the increase of traditional open aortic cases

nobody though can predict this time point as the situation is still fragile. In the meantime, this shift toward "traditional" open surgery will probably not be devoid of adverse implications; this is anticipated to have an impact not only in perioperative mortality rates but ultimately to increased long-term health cost, which has been probably disregarded under the urgency of measures to restrict public health cost. An indirect side-benefit of this shift is the opportunity of trainees to be exposed to a higher volume of open procedures thus gaining back their competency in open vascular skills. A trainees' survey performed in 2007 and 2011 indicated a significant increase of the rate of graduating trainees that declare confidence in their ability to complete an open aneurysm repair (Fig. 54.3).

Conclusions

In the wake of financial crisis in Greece, fiscal restrictions in every aspect of everyday clinical practice are challenging the changing face of vascular surgery. While rationalization of endovascular technology pricing was much needed, interruption of vascular evolution has implications to both doctors and patients. Vascular surgeons are forced to adapt in a new environment with less resources, feeling less confident about their options, knowing that their patients would probably benefit from an endovascular procedure that they cannot get. Lack of supporting staff, salary deductions and payment delays have accentuated discouragement and poor motivation, rendering surgeons' self-esteem fragile, forcing many of them to leave abroad. Within such a volatile environment patients end up receiving suboptimal care, the consequences of which are yet to be seen.

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Current Status of Vascular Training Schemes in Europe: Recommendations for a New Global Teaching Curriculum

55

Sherif Sultan, Edel P. Kavanagh, and Niamh Hynes

Introduction

European vascular training, certification and practice takes on numerous forms in each of the 51 countries within the region, and within each of the 28 member states of the European Union. Currently a specialist registrar in vascular surgery, with all necessary qualifications and exit exams, may find it difficult to move freely under the free workforce movement in the European Union, owing to the diverse training strategies in each country. Training curricula, operative exposure, trainee evaluation, logbooks, examination processes, certifying bodies, training centres, and working hours all display substantial disparities [1]. This may contribute to unequal and unacceptable standards in order to qualify as a vascular surgeon.

Vascular surgical training and certification have progressively separated from general surgery and cardiothoracic surgery over the past 30 years. Widespread adoption of endovascular procedures, as well as advances in vascular laboratory investigations, vascular medicine, and vascular imaging have resulted in a positive trend towards vascular specialisation, which was initially resisted by general surgeons [2]. The paradigm in vascular surgical training is altering radically with the institution of didactic informative programs, where completion of a quantified training period in general surgery or cardiothoracic surgery is no longer mandatory [3].

In the current era of endovascular repair, where vascular surgery is slowly becoming a recognised mono-specialty independent of general surgery, it begs the question, are the vast variations in recognition, training schemes and standards good enough to facilitate the highest possible patient care? And would a European and eventual global unification of the vascular training scheme improve our future vascular surgeons? The aim of this review chapter is to explore the current status of vascular training schemes in Europe, and to highlight recommendations for a new global teaching curriculum, to improve both institutional training and individual ability.

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Ireland and United Kingdom Teaching Strategies

Vascular surgery was a sub-specialty of general surgery in Ireland, and has only been recognised as one of the ten independent surgical specialties since December 2014 (Fig. 55.1). Although it has now been recognised as a mono-specialty, it is still in its infancy and there is currently no specialised training scheme, or exit exam. Therefore trainees that are currently under the scheme must continue as general surgeons with a specialist interest in vascular surgery. All surgical training schemes in Ireland and the United Kingdom are overseen by specialty advisory committees and assessed by the Joint Committee on Intercollegiate Examinations. Therefore, it is expected that an Irish structured training scheme for vascular surgery, once available, will be sympathetic to the UK-based training structure, so that, as with other specialties the exit examination can be the same.

The current National Surgical Training programme in Ireland is an eight-year training programme. A trainee must complete a core training scheme in surgery [4]. This is competitive and offered to trainees who have completed their intern year. Trainees are expected to complete a rotation through each of the general surgical subspecialities, including vascular surgery (surgical training year one—ST1), followed by one-year basic specialty training (ST2). This is intended to give an introduction to the specialty in which trainees ultimately intend to practice. Progression to higher specialty training (ST3-ST8) then follows. Certification of basic surgical training is necessary in advance of ST3 entry, and registrars are expected to complete their MRCS and FRCS (Member/Fellow of Royal College of Surgeons) during higher specialty training.

During both basic and higher specialty training, surgeons are expected to reach a very high standard with regards to surgical technique and ability. They must fulfil the requirements of their logbook, without which they cannot progress to the next stage. It is entirely up to the trainees own competence what centre they conduct their training in, if it is a high volume centre, and which consultant to work with. This may ultimately lead to comprehensive training, but not in many cases. In regards to a dedicated Irish vascular curriculum, it has been proposed that a ten-year scheme be put in place, to include four years of intensive vascular training, coupled with a fellowship abroad (Table 55.1). Those who are interesting in improving their training to the highest standard are fully encouraged into academia to acquire qualifications such as a Doctor of Philosophy (PhD) or Doctor of Medicine (MD) in their chosen research topic. These qualifications can be conducting during a "gap" year, or concurrently during a training scheme.

Vascular surgery has recently become a recognised independent specialty in the UK (2012). It is a structured training system however, only available in a limited number of centres through the London Deanery. The UK system is known as the Intercollegiate Surgical Curriculum Programme (ISCP) [5]. It involves two core training years, which may (ST1) or may not

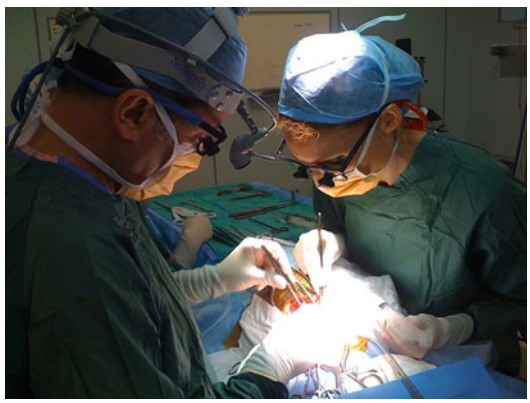

Fig. 55.1 Vascular surgeons at an Irish vascular centre

Table 55.1 Proposed vascular training scheme in Ireland

Year	Level
1	Internship
2–3	Basic surgical training
4	Gap year (research)
5–10	Higher surgical training (fellowship abroad)
5–6	General surgery
7–10	Vascular surgery

(CT1) contain the chosen specialty. This is followed by entry to specialised training into one of the ten disciplines (ST3). Unlike Ireland, the UK has a specialist "run-through" programme. This allows a student to choose their specialty during medical school and continue this specialty throughout the duration of their training. Those who are unsure of their choice will go through the regular "uncoupled" training programme, which involves two initial years of core training. Entry from core (CT2) to specialty training (ST3) is therefore by exam only. This ensures the trainee has achieved the same level as those already on the specialised route. Vascular training in the UK crosses over with interventional radiology. This is not unique and occurs in Austria, Germany and Spain [3].

European and Global Teaching Strategies

A number of studies have been conducted which assess the current status of vascular surgery as a mono or sub-specialty in Europe [1, 3, 6, 7]. Two survey based studies, conducted in 2008 and 2013 give a representation of the disparities that still exist in training schemes across Europe [1, 6]. Comparisons between these studies show that while there have been significant changes across the board between 2008 and 2013, further unification of training is necessary. The minimum mean duration of vascular surgical training in fourteen surveyed countries with independent certification (3.9 years, range 3–4.5 years) is significantly longer ($p=0.008$) than in countries with sub-specialty certification or no certification for vascular surgery (2.7 years, range 2–4 years) [6]. In a survey of 33 countries, the mean duration of dedicated vascular surgical training in mono-specialty training is significantly longer compared with sub-specialty training (3.8 vs. 2.9 years, $p=0.036$) or no specialty models (3.8 vs. 1 years, $p<0.001$) [1]. As of 2015, 21 European countries recognise vascular surgery as a mono-specialty, where certification in general surgery is not a prerequisite (Table 55.2). Three counties foresee the institution of mono-specialty certification in vascular surgery: Poland is targeting the end of 2015, Sweden is targeting 2016, and Ireland is targeting 2019.

Table 55.2 Vascular specialty status in Europe 2015 [1, 3, 6, 7]

Mono-specialty	Sub-specialty	Not a specialty
UK	Austria	Russia
Croatia	Belgium	Turkey
Cyprus	Norway	Albania
Czech Republic	Poland[a]	Slovenia
Denmark	Serbia	
Estonia	Sweden[a]	
Finland	Switzerland	
France	Ukraine	
Germany	Ireland[a]	
Greece		
Hungary		
Iceland		
Italy		
Latvia		
Lithuania		
Portugal		
Romania		
Serbia		
Slovakia		
Spain		
Netherlands		

[a]In transition stages from sub to mono-specialty

Studies also show that vascular surgical repair is no longer isolated to that discipline alone, particular procedures are shared among specialties, depending on the country. For example in the UK, interventional radiologists together with vascular surgeons conduct endovascular aneurysm repair [6]. In Germany and Italy, 20% of cases are handled by cardiologists, while peripheral endovascular procedures are generally performed by interventional radiologists [6]. In Belgium, France, Portugal and Spain vascular surgeons undertake the vast majority of peripheral interventions, while in Germany and Italy cardiologists intervene at a considerable rate [6]. Therefore there are a multitude of training pathways across each of these specialties.

Vascular surgery is a recognised sub-specialty of general surgery in the USA, but has specific vascular training programmes and an exit exam. According to the Society of Vascular Surgery, a

primary Certificate in vascular surgery eliminates the requirement for 5 years of training and certification in general surgery prior to certification in vascular surgery [3, 8].

European Working Time Directive

> Trainees are telling the Royal College of Surgeons they cannot gain enough experience to progress on the shortened hours. The choice for the nation is clear – do we want patients of the future to be treated by a group of highly skilled and experienced surgeons; or be passed around a wider group of lower skilled surgeons with less experience. This is a worry for today and tomorrow. John Black, President, Royal College of Surgeons of England (2009) [9].

The European Working Time Directive to adopt the 48-hour week has been implemented in all EU member countries with high unemployment for physicians, but largely ignored in countries where quality physicians are rare to recruit. This stance of two days working per week is followed by vascular trainees in ten out of 24 EU countries with vascular surgery certification (Austria, Denmark, Finland, Germany, Hungary, The Netherlands, Norway, Poland, Slovakia, and Switzerland) [1]. The effect of reduced working hours compromises the ability of training to be delivered in a satisfactory manner, within the timeframe allowed. [1] Vascular trainees within the remaining countries work in excess of 56 hours to gain the required experience that is mandatory for competence, that no augmented virtual simulation can attain. An independent curriculum compresses the total surgical training interval, while amassing training time devoted to vascular surgery. An independent curriculum also follows the changing trends of modern vascular surgery with recent disruptive technology, early adaptors and the incorporation of endovascular procedures into governmental training body logbooks [1].

> Surgeons in training should have a contract defined by their training needs and not by hours worked. John Black, President, Royal College of Surgeons of England (2009) [10].

In the USA, comparing surgeons graduating After a Training Hour Restriction (ATHR; 80-hour resident duty limits), to those who had graduated Before the restrictions (BTHR), 55 % of senior surgeons had less trust in ATHR graduates, with respect to patient care. Sixty-eight percent had less confidence in the ability of these residents to operate [11]. Program directors were significantly more likely to perceive that ATHR would decrease residents' ability to deliver high quality and safe patient care [11–13]. With this in mind, there has also been significant non-compliance in work-hour regulations, due to simultaneous continuation of education and patient care as the main reasons associated with non-compliance [14].

The consequence of apprenticeship methods of training in the workplace must not be underestimated when considering the full requirements of surgical training. Constraints executed by the European Working Time Directive will therefore have a negative effect on the practical learning curve of current and future trainees, leading to unscrupulous surgical training. There simply is no substitute for first hand experience [15].

Unification of the Training System

Examining the training schemes across Europe, it is still evident that unification in vascular training is needed. This will not only ensure ease of mobility for fully qualified surgeons, but also ensure that they are completing the same programme, regardless of country of origin. Currently, formal certification of trainees is most frequently performed by the National Vascular Societies, followed by the National Medical Associations, and government, while University certification is less common. [6] Unification of the training system needs to be a radical improvement upon the current apprenticeship method. Studies show that a trainee may select a low volume centre in which to study, where a high volume of surgeries in both open and endovascular repair are unavailable [16]. Trainees will not be exposed to a variety of surgeries, often enough. A question of availability of enough high volume centres must also be addressed in this regard, and whether trainees are required to move between centres during their training. European programmes

such as that in Ireland encourage trainees to move between centres on six-month rotations, and encourage registrars and consultants to go abroad to continue a specialty fellowship. Conversely, the US five-year programme occurs in one centre only. Are there advantages of moving to broaden experience or does the absence of enough high volume training centres make it feasible for trainees to move? Contemporary vascular surgery is an exceedingly challenging specialty that necessitates tertiary hospital facilities and a high volume of patients in order to guarantee exemplary patient outcomes and training standards. Thirty-eight percent of centres have no regular quality assessments to guarantee the efficiency of offered training [1]. This may contribute to unequal and unacceptable standards in relation to both trainee technique and ability.

Vascular training can benefit from one standardised exit exam. Since 1996 a European Vascular Examination has been conducted. It began as the EBSQ-VASC and became the Fellow of the European Board in Vascular Surgery (FEBVS) in 2005. The aim of the FEBVS is to harmonise training programmes in vascular and endovascular surgery between different European countries, establish defined standards of knowledge, skills and attitude required to practice vascular and endovascular surgery at secondary and tertiary care level, foster the development of a European network of competent tertiary care centres for vascular and endovascular surgery, improve the level of care for vascular patients, and to thereby further enhance the European contribution to clinical and academic vascular and endovascular surgery worldwide [17]. Qualification as a vascular surgeon by the European Board requires a demonstration of knowledge in vascular areas including diagnostic techniques and treatment of specific diseases. Technical and endovascular abilities are also evaluated. These include dissection and anastomotic skills, and surgical dexterity [18]. The FEBVS is currently a voluntary exam, however, it would be particularly beneficial in unifying European teaching strategies if implemented as a singular standardised exit exam to qualify as a vascular surgeon.

Open Versus Endovascular Surgical Repair

Since the introduction of minimally invasive, and endovascular repair, there has been a natural decline in the need for open surgical vascular repair. Open aneurysm repair cases dropped from 42,872 in 2000 to just 10,039 in 2011, while endovascular aneurysm repair rose from 2,358 cases in 2000 to 35,028 in 2011 [19]. This inherently reduces the amount of open surgeries for early career vascular surgeons to experience and learn from. Similarly in low volume centres where an acceptable number of surgeries do not occur often enough, contributes to inadequate learning curves. Decline in open surgery means that next generation vascular surgeons lack this expertise, while the introduction of new endovascular techniques also requires a great deal of expertise and training. Therefore a new surgical curriculum must incorporate both open surgical and endovascular training, which can be thought outside of surgical theatres, such as vascular training simulators.

Simulator Training

With the ever-evolving nature of endovascular surgery including branched, fenestrated and hybrid surgical options, simulator based training may become a mainstream training tool of the future. A specialist metrics based testing programme is needed to ensure trainees are reaching a particular level of technical expertise. Simulators and endovascular courses have already been incorporated into training curriculums in Europe, while the FEBVS recommendations have been revised to include mandatory training in endovascular procedures [6]. Medical simulators include those manufactured by Orzone (Goteborg, Sweden), SIMBIONIX (Ohio, USA), CAE Healthcare (Florida, USA) and Mentice AB (Gothenburg, Sweden). While there are significant costs associated with simulators, studies have shown theirs advantages [20, 21]. Duschek et al. reported that the use of a simulated

lifelike environment significantly improved techniques associated with a carotid endarterectomy with patch plasty [20]. Sigounas et al. reported that simulation improved surgical performance of femoral-popliteal bypass, carotid endarterectomy, and abdominal aortic aneurysm repair [21].

The Future

The proclamation that the relationship between possession of skills and clinical practice can be theatrically broken implies an insightful misinterpretation of the nature of medicine. A total patient care model where the vascular specialist performs vascular operations and treats the underlying co-morbidities is the apprenticeship method. This will be based on an internship of twelve months of basic surgical training, and further specialist training of 48–72 months, to include twelve months of research and eighteen months of radiological, cardiological and internal medicine training.

The decision by individual trainees to opt-out of the European Working Time Directive in the hope of accruing training through clinical osmosis may be beneficial, challenging a system focused more on service provision than training. However, rather than abandoning the protection afforded by the Directive, what is required is the remodelling of the apprenticeship model of training and changes in the relationship between trainees and the hospital setting. To meet such objectives, less routine patient care should to be handled by residents in training, while other hospital staff should be trained to fill the gap. For such a system to work, centralisation is the corner stone, with the establishment of deliberate practice volume centres as centres of excellence, along with the creation of two separate hospital groups: a leading hospital that is engaged in specialty training, and a subsidiary hospital that has primarily consultant led care, and employs a smaller cohort of core medical trainees. Changes must be made to job planning for trainers and trainees, and recognition must be given to all training roles [22, 23].

Conclusion

Examining the current status of vascular training shows that stratification does still exist. It is no longer acceptable to produce trainees with inadequate surgical skills when the tools to realising a more unified training system are readily available. We believe that implementing a singular curriculum with the aim of satisfying the European Board Examination is essential. This will ensure trainees reach a particular level of expertise, regardless of country. Continuous development of both open and endovascular surgical skills are critical for the future. A delicate balance of first hand experiences in a theatre environment, along with simulator-based experience must be established, which may or may not satisfy the European Working Time Directive. While simulator based training may become a mainstream going forward, the establishment of dedicated high volume centres for learning must also be addressed. Next generation vascular surgeons must not lack open surgical techniques simply due to the evolution of teaching practices towards endovascular repair methods. With more effective training for surgeons and facilities alike, there can only be an improvement in quality of care for patients entering hospitals for years to come.

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56 Vascular Surgery Training Paradigms in Asia, Europe, South America, the United Kingdom, and the United States

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Introduction

Around the world there are variations in the training pathway for vascular surgery. The time from high school graduation to the completion of vascular surgery training ranges from 11 to 15 years, and possibly more depending on research experience, other graduate degrees, or extracurricular experiences. This chapter gives a sampling of the similarities and differences across Asia, Europe, South America, the United Kingdom (UK), and the United States (US).

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Vascular Training

Asia [1]

1. Japan
   - Medical School: 6 years
   - Residency (General surgery): 3 years
   - Fellowship (Cardiovascular surgery): 3 years
     - Vascular surgery fellowship is part of the cardiovascular training. Thus fellows are trained in both cardiac and vascular surgery.
2. Korea
   - Medical School: 6–8 years
   - Residency (General surgery): 4 years
   - Fellowship (Vascular surgery): 2 years
     - Training may be with or without organ transplantation
3. Taiwan
   - Medical School: 7 years
   - Residency: 2–3 years
     - The trainee must complete either 3 years of general surgery or 2 years of cardiovascular surgery before eligibility for vascular surgery fellowship.
   - Fellowship (Vascular surgery): 2 years

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4. Singapore/Malaysia/India/Sri Lanka/Hong Kong
   - Medical School: 5–6 years
   - Residency (general surgery): 4–6 years
   - Fellowship (vascular surgery): 2 years

Europe [2]

1. France
   - Medical School: 6 years
     - In France, medical schools are part of public universities, and thus the combined education is 6 years. After "baccalaureat", a national examination that takes place at the end of high school, all students who successfully pass this examination can enter medical school. However, there is a local competitive exam at the end of the 1st year of med school. At this step, only about 10 % of the students may pass to second year of med school. At the end of the 6th year, there is a national competitive exam before residency. Students choose the specialty and the university hospital they want depending on their grades at this national examination.
   - Residency: 5 years
     - Students interested in vascular surgery must first enter a 5-year general surgery program in order to obtain the "Diplôme d'Etudes Specialisées de Chirurgie Générale" (Diploma of specialized studies in general surgery).
     - In order to be eligible for a fellowship in vascular surgery, residents must complete at least one 6-month rotation in vascular surgery within the first 2.5 years following the beginning of their residency, plus obtain the approval of both local and regional chairs of vascular surgery. The general surgery program includes ten semesters, one must be in general/GI surgery, and one must be in orthopedic surgery. For student interested in vascular surgery, it is recommended to also complete one semester in thoracic surgery and one semester in cardiac surgery within their residency.
     - After eight semesters (4 years), and while still continuing on his/her general surgery program, the resident can officially enter a vascular surgery program. If not completed before, he/she must complete at least one semester in cardiac or thoracic surgery.
     - Residents will be qualified for general surgery after they completed their ten semesters and passed a regional exam. They will continue on their vascular surgery program during their fellowship.
       - A new 0+7 program for vascular surgery will be implemented, within 2 years or so. It will be a direct path to vascular surgery after medical school, and include both residency and fellowship (but not board certification).
   - Fellowship: 2–3 years
     - Fellows need to complete at least a 2-year fellowship in vascular surgery. Added to the last year of residency when they were enrolled in the vascular surgery program, it takes a total of 3 years and a final regional exam to be qualified for the "Diplôme d'Etudes Spécialisées Complementaires de Chirurgie Vasculaire" (Diploma of Complementary Specialized Studies in Vascular Surgery).
     - Legally this diploma is recognized as being adequate to practice as a vascular surgeon in France. However, in order to be board-certified in vascular surgery, students need to complete 3 years of practice after their residency (2 years of fellowship +1 year of practice), document a detailed case-log (for 3 years), and pass a national exam.
     - Vascular surgeons are usually not qualified in duplex ultrasound examination. They have the option of enrolling in a short-term training program to acquire these skills.

2. Germany
   - Medical school: 6 years
     - Direct entry to medical school comes after high school. Students must pass three different exams during medical school, the final one is at the completion of the 6th year. They will then apply for several specialty programs in the country. The system is quite similar to the "match" in the US, with program directors choosing their future students based on their grades and interviews/recommendation.
   - Residency: 6 years
     - This includes 36 months of "basics" (general surgery) and 36 months of vascular surgery.
     - Optional rotations within the period include:
       - 12 months in another surgical specialty
       - 6 months in anesthesiology or internal medicine or angiology or radiology
       - 12 months in an accredited private practice.
     - This training as well as a detailed case-log are the requirements to apply for the final examination of vascular surgery. Students are qualified as vascular surgeons if they are successful at this examination.
3. Italy
   - Medical school: 6 years
     - Students enter directly into medical school after high school. At the end of 6 years, students must write a thesis, and pass a national examination in order to choose their specialty.
   - Residency (Vascular Surgery): 5 years
     - Students enroll directly into a vascular surgery program and are responsible to find rotations for 5 years. There are 12 months of general surgery and 48 months of vascular surgery. Residents are fully trained to perform duplex ultrasound.
     - All their rotations may be in different hospitals within the country, however the university may also fund 1 year of training abroad.
     - At the completion of training, residents are qualified for practicing vascular surgery. There is no fellowship necessary.

South America

1. Brazil
   - Medical School: 6 years
     - During these 6 years, the undergraduate student spend 2 years in basic sciences and 4 years in clinical training.
     - After graduation, the vascular candidate must pass two tests to enter into residency.
   - Residency: 5 years
     - The first test is in General Surgery. The resident must complete 2 years minimum training in general surgery.
     - Afterwards, he or she must pass another test for a 3-year training program in vascular surgery. Not all Vascular Residency Programs offers the fully training to perform duplex ultrasound and endovascular surgery. When this is the case, the resident usually look for extra-program courses (some are paid) to do so.
     - The National Committee for Medical Residency is the institution that regulates the medical programs all through the country. After the completion of an official Residency Program, the resident is qualified by the committee as "Vascular Surgeon", allowing him or her to practice phlebology, conventional vascular surgery and office vascular consultations. However, if they want to practice duplex ultrasound or endovascular surgery, they must apply for a national Exam (see below).
     - Brazil's Vascular society is the Brazilian Society For Angiology and Vascular Surgery (SBACV). The SBACV, in association with the Brazilian Society for Radiology and

the Federal Council of Medicine, certifies its members in the following areas:
    - Duplex scanning
    - Endovascular Surgery
- This certification is obtained through a National Test of Sufficiency in which the candidates must apply in order to have permission to practice for the Health Insurance Companies and/or the Public Health System. They must prove (supported by voucher) at least one year of training in the above options (duplex scanning and/or endovascular surgery) in order to be eligible for testing.
- The candidate can apply for both certifications (separately or at the same time).
- The SBACV has more than 3000 members, however, only around 30% are board certificated.

United States

- Undergraduate School: 4 years
    - After completing high school, the students must pass a national standardized test in order to apply for college. To be eligible for medical school, students must obtain a bachelor's degree in any field they choose, provided they complete the premedical courses, and they must pass a national medical school entrance exam. Students must then apply for medical school, and entrance is based on the exam grades, college grades, and other research/extracurricular experiences.
- Medical School: 4 years
    - Medical education is traditionally 2 years of basic science and 2 years of clinical rotations, however there is variability in how individual schools distribute the teaching. Students must pass a three-step exam in order to be eligible for a license to practice medicine in the US. The first two steps are completed by the end of medical school, and the last step is completed early in residency. Medical students must then apply for a residency position through "The Match." Students rank the programs they are most interested in, in order of preference, and conversely the programs rank applicants in the same way. A "match" occurs when an applicant and a program correspond to each other's rank list. Again, acceptance into preferred programs is based on exam grades, medical school and college grades, and other research/extracurricular experiences.
    - To become a vascular surgeon, there are currently two tracks in the US: 5+2 and 0+5
- Residency: 5 years
    - *General Surgery*
        - The traditional, or 5+2 track, to vascular surgery consists of 5 years of general surgery, followed by a 2-year fellowship. General surgery program content is overseen by the Accreditation Council for Graduate Medical Education (ACGME), and thus is standardized across the country. There are however some variations, for example with regards to subspecialty rotations, some programs may offer more vascular surgery exposure than others. All residents must pass a yearly national in-service exam, the American Board of Surgery In-Training Exam (ABSITE), in order to progress through their training. Upon completion, residents are eligible to take the general surgery boards if they wish to practice general surgery. However, if the resident will progress to a vascular fellowship, the general surgery boards are not a prerequisite for the vascular surgery boards.
    - *Vascular Surgery*
        - The integrated, or 0+5, vascular surgery training program consists of 2 years of surgical core rotations

(general surgery, intensive care, trauma, etc.) and 3 years of vascular surgery (open vascular, endovascular, and vascular lab). All residents must take a pass a yearly national in-service exam, the Vascular Surgery In-Training Exam (VSITE), in order to progress through their training. Toward the completion of their training, residents must pass the Registered Physician in Vascular Interpretation (RPVI) ultrasound exam in order to be eligible to take the vascular surgery boards. Finally, upon completion of training, vascular residents are eligible to take the vascular surgery boards.

- Fellowship: 2 years
    - After completion of 5 years of general surgery, the resident must apply for a fellowship if they wish to pursue specialty training. The process is also a "Match," and the applicant and program must align in their rank lists. Competitiveness of the applications is again based on previous standardized test grades, school transcripts, ABSITE scores, and other research/extracurricular experiences. All fellows must take a pass a yearly national in-service exam, the Vascular Surgery In-Training Exam (VSITE), in order to progress through their training. Toward the completion of their training, fellows must pass the Registered Physician in Vascular Interpretation (RPVI) ultrasound exam in order to be eligible to take the vascular surgery boards. Finally, upon completion of training, vascular fellows are eligible to take the vascular surgery boards. (Table 56.1 depicts a synopsis of the vascular training details across the countries).

Table 56.1 Vascular surgery training pathways across several countries

Country	Undergraduate	Medical school[a]	General surgery residency	Vascular surgery residency	Fellowship	Total regional/national exams
Hong Kong	–	5–6	7	NA	2	2
India	–	5	3	NA	3	2
Japan	–	6	3	NA	3	2
Korea	–	6–8	4	NA	2	–
Taiwan	–	7	2–3	NA	2	2
Singapore	–	5	5	NA	2	2
Malaysia	–	5–6	4–6	NA	3–4	2
Thailand	–	6	4	NA	5	2
France	–	6	5	NA	2–3	5
Germany	–	6	6	NA	None	4
Greece	–	6	3	NA	4	3
Italy	–	6	5	NA	None	2
Brazil	–	6	2	NA	3	3–4
UK		5–6	8	NA	2	
USA	4	4	NA	5–7	NA	5[b]
	4	4	5	NA	2	5–6[b]

Adapted from: Cronenwett JL, Liapis CD. Vascular surgery training and certification: an international perspective. *J Vasc Surg* 2007;46:621–9 [3]

[a]Countries without separate "undergraduate" typically have the undergraduate training combined with the medical school

[b]Does not include the yearly national in-training exams during residency

United Kingdom

- Medical School: 5–6 years
- Residency: 8 years
    - Post-graduate UK doctors complete two years' basic foundation training before entering 6 years surgical training culminating in the certificate of completion of training (CCT) and potentially Consultant appointment.
- Fellowship: 2 years
    - In practice most trainees undertake post-CCT fellowships lasting 2 years to gain further experience in their chosen sub-speciality. Progression is dependent on yearly appraisal and continuous in-service completion of competency based assessments of surgical and non-surgical skills.

Conclusions

Despite differences in the training pathways to become a vascular surgeon around the world, the commonality that these countries share is recognizing vascular surgery as its own entity. As the need for more vascular surgeons continues to grow and the treatment modalities to evolve, vascular training will likely continue its restructuring across the countries.

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An Industry Perspective on Establishing a Support Network Worldwide

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Mike O'Meara

As the treatment of vascular disease evolves world-wide, with treatment algorithms varying significantly from country to country, delivering support to the vascular surgery community is not an easy or straightforward task. It can, however, be very rewarding for an organization that is able to adapt to the unique needs and dynamics of each country.

C.R. BARD, Inc., headquartered in Murray Hill, New Jersey, is a world leader in the medical device industry. Our company is strategically-aligned into multiple divisions to focus on product development for many different diseases states. Our mission is to advance lives and the delivery of healthcare which speaks to the efforts we put in to establishing a global program of support for vascular surgery.

Bard Peripheral Vascular, Inc., headquartered in Tempe, Arizona and a subsidiary of C.R. Bard, Inc., is an innovative leader in the vascular device space that provides technologies that allow vascular surgeons to treat their patients both from an open surgical approach as well as an endovascular approach. We support physicians with new technologies introduced through a combination of in-house research and development efforts, and external acquisition of new, cutting-edge technology.

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Whether you are a vascular surgeon ready to take a patient to the operating room for a fem-popliteal bypass or an interventionalist trying to cross a chronic total conclusion (CTO) in a patient with critical limb ischemia (CLI) in an angiography suite, we have technologies that support most scenarios. Bard is one of the few companies that offer products designed for use in open surgery as well as endovascular repair making us a natural partner with vascular surgeons when discussing the development of vascular disease procedures and products in many countries throughout the world.

Bard has a vast and diverse vascular disease product portfolio that is organized by product category including percutaneous transluminal angioplasty balloons, drug coated balloons, self - expanding stents, balloon expandable stents, balloon expandable stent grafts, chronic total occlusion devices, peripheral and AV PTFE bypass grafts, and IVC Filters. This broad portfolio enables Bard to meet the needs of vascular surgeons practicing in virtually any country whether they are at a highly advanced or embryonic stage of practice.

A key area for our company's growth has been the expansion of our brand into emerging and under-developed markets that are untapped by other medical device companies.

It can be complicated to develop a global vascular surgery support structure. We often find that strategies that work well in some markets do not work at all in others. We do, however, focus

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on three key areas that we find key drivers of success in virtually every market.

1. New Product Launches
2. Physician Education and Training
3. Sales Training and Development

The foundation for our support for physicians globally begins with the new product launch process. This is a dynamic area where our Regulatory and Clinical Affairs teams work with each individual country's Ministry of Health to get our technologies authorized for commercial use. In the past, many countries would approve new products purely based on whether or not it was approved for use in the United States by the FDA or CE Marked in Europe. Increasingly, more and more countries are now adopting a unique set of requirements.

More countries are starting to require that manufacturers conduct a country-specific clinical trial to obtain marketing authorization, most notably China. Fortunately, we have a foundation of legacy products that have already been approved in most of these countries, so physicians have the tools they need to treat patients today. As we develop or acquire new technologies, requirements for in-country clinical trials can delay the introduction of these technologies. Unfortunately, in some cases, the demand for product may not outweigh the efforts and resources to get the product approved, which can limit access to new technologies.

Once we've obtained marketing authorization for a technology in a particular country, the second area we focus on is the need to ensure that clinicians have mastered the use of our devices and understand the indications or usages for which the products were designed.

The first way we accomplish this is by partnering with existing Key Opinion Leaders (KOLs) who are very familiar with our technology and are considered to be technical experts in the procedures we are focused on developing. For instance, a key focus for BARD is currently lower extremity Critical Lim Ischemia. With the diabetic foot population on the rise globally, the need for intravascular treatment options is increasing in many countries.

Certain products in our portfolio are designed to treat the toughest of all Critical Limb Ischemia patients. From our crossing devices, which help physicians cross calcified lesions, including chronic total occlusions, to our drug coated balloon technology, which helps safely deliver the drug Paclitaxel to inhibit restenosis, we have the technologies physicians need to help restore blood flow. Although vascular surgeons are highly skilled, any new technology has certain nuances and techniques for safe and effective use, and it is very important that physicians understand these. We find that sharing best practices in a peer-to-peer environment is the most successful way to train new operators.

Training can be provided in several different formats. We provide support for trainings that are didactic and hands-on, depending on the need and credentialing process at each hospital we partner with. One very effective way to deliver training is with hands-on workshops where we help facilitate training in a large institution where multiple physicians can come to learn at once. The clinicians are instructed on procedural techniques and associated technology building a vascular program, disease awareness and screening, working with residents and fellows, managing a multi-disciplinary approach, clinical trial management, vascular service marketing and more.

Another popular and effective way to train physicians is with a "road show" in which a selected KOL visits multiple hospitals in a given geography often being credentialed to perform hands-on cases with teams of physicians and their staff. This provides the KOL with a real-world look at the challenges some physicians face within the confines of the hospital, which can be anything from poor imaging capabilities, to lack of skilled support, to limited availability of devices and tools. This input is invaluable as we seek to support the host country practicing environment.

We have also started to partner with prestigious universities to setup fellowships based on the need specialty of the host country and university. Such programs can be scaled to many levels and are handled on a case-by-case basis.

We also make sure Bard has a presence at major medical conferences throughout the world and that we are aligned with the then-current focus of the Society of Vascular Surgery (SVS) and the International Society of Vascular Surgery (ISVS). Aligning with these societies ensures that we understand what is important for the overall development of vascular surgeons, as they are truly the experts.

The third key area of focus for Bard is sales training and development, in other words, the training of our own sales people and clinical specialists. In each country, our sales and specialists teams are responsible for clinically training on our products and supporting our physicians' cases. A successful case requires a team effort, and a part of that team should include the Bard representative when our products are being used. We expect our people to be experts on our products and a key technical point of reference for the operator using our technology. This real-time point of reference can be invaluable when done correctly and can even aid in cutting down on any unintended misusage of our products. We feel that it is our responsibility to make sure we provide the best possible product training we can to our own people in order to give vascular surgeons the best possible support.

Bard is dedicated to advancing lives and the delivery of healthcare, and we understand the importance of partnering with vascular surgeons to help improve the quality of care that patients, with vascular disease receive around the world. It is our mission to do everything we can to make sure the global vascular surgery community has the tools they need to deliver the high quality care that every patient deserves.

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