VASCULAR SURGERY
Why When How

a Reasoned Approach to Decision Making through Experience

Foreword by P. Gloviczki

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EDIZIONI MINERVA MEDICA
Foreword

“The glory of medicine is that it is constantly moving forward, that there is always more to learn.”
Dr. William J. Mayo

Success of a vascular intervention depends greatly on selection of the right patient for the right intervention that is performed with flawless surgical or endovascular technique. Attention to details pays dividends but it also takes additional effort, it is time consuming and frequently requires extra resources in personnel and equipment. This textbook entitled Tips And Tricks And Decision Making In Vascular Surgery contains essential information we need to achieve the best results with an intervention in our patients with vascular disease. A world expert in his profession and an international authority, Professor Piergiorgio Settembrini from the University of Milan, Italy, compiled a wide-ranging yet easy to read textbook with 46 chapters and plenty of line drawings and color illustrations to guide us through the different procedures and to help deliver the latest and best treatment to our patients. In addition to inviting eminent authors from his home country, an almost the full list of “Who is Who in Vascular Surgery in Italy?”, this volume also includes outstanding contributions of international experts. The textbook focuses on critical details of indications, patient selection, technique and follow-up. It covers aortic and arterial diseases and emergencies, and includes valuable chapters on embryology, atherosclerotic risk factors, deep vein reconstructions and on management of lymphedema and arteriovenous malformations as well. Treatment of thoracic and thoracoabdominal pathology, including open and endovascular treatment is presented in great detail with splendid illustrations by prominent authorities of the field.

Medical technology has progressed by leaps and bounds and we treat patients today with endovascular techniques unthinkable just a decade ago. Together with new technology, indications for interventions, imaging studies and management of the patients with vascular diseases has also changed rapidly. A constant update of medical knowledge is more important today than perhaps anytime before. This textbook of Professor Piergiorgio Settembrini and his expert contributors helps us stay in the forefront of vascular surgery and provides valuable assistance in our quest to deliver the best care to our vascular patients, every day.

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“Tempora mutantur nosque mutamur in illis”  
(Ovidius, Fasti)

This poetic verse dates back to the Latin poet Ovidius who composed the poem *Fasti* (Splendours) at the turn of the new era A.C. to celebrate the glory of the Roman emperor Augustus for giving durable peace to the vast empire he had built. The sense of the verse, which was used by a very famous Professor of Civil Law (Alberto Trabucchi, from the University of Padua) to preface his treaty, is that times and circumstances are always changing, though the mankind does not notice it. In reality, all individuals suffer the action of historical events, not only in their specific or personal interests, but also in other fields (“…the outrageous arrows of the fortune…” - W. Shakespeare, Hamlet). Is this true also in the field of vascular surgery? This question can be answered by tracking its historical development along the centuries, so as to identify its fundamental steps that strictly depend on the evolution of the thought. Why? At the basis of surgery are not the hands, but the head. We know that it all started from Harvey’s observation and interpretation that blood flows in the vessels. Decisive was his meeting with Girolamo Fabrici (Fabricius) d’Acquapendente at the University of Padua, who stimulated him to deepen his studies on blood circulation. At that University, Harvey received the title of *Doctor in Medicine* in 1602. Harvey focused much of his research on the mechanics of blood flow in the human body. Most physicians of the time felt that the lungs were responsible for moving the blood around throughout the body. Harvey’s famous “*Exercitatio Anatomica de Motu Cordis et Sanguinis in Animalibus*”, commonly referred to as “de Motu Cordis” was published in Latin in 1628 in Frankfurt, when Harvey was 50 years old. The first English translation did not appear until two decades later. He discovered that blood is distributed through the arteries to all districts of the body and comes back to the heart through the veins. In the history of medicine, Harvey remains a milestone. Harvey, observing the notion of the heart in living animals, was able to see that the systole was the active phase of the heart’s movement, pumping out the blood by its muscular contraction. *Having perceived that the quantity of blood issuing from the heart in any given time was too much to be absorbed by the tissues*, he was able to show that the valves in the veins allow the blood to flow only in the direction of the heart and to prove that the blood *circulated around the body and returned to the heart*. Fabricius d’Acquapendente, his teacher in Padua, had discovered the valves in the veins.

But what is more valuable in his discovery is the *thought* that blood flows in dedicated pipelines. This result was achieved only by reasoning on the facts he has noted. This is an example of how facts can be observed and can lead the thought to new ideas. This method was used by the French thinker, philosopher and scientist René Descartes, better known as Cartesius, who followed the same route to form concepts, starting from observing facts (*tempora mutantur…*). The appearance of the experimental method is a conquest of that century (XVII). However, the discovery remained confined to the scientific world. The reappraisal started in the XIX and XX centuries when terrible wars developed all over in Europe. Soldiers suffered terrible wounds in infantry giant clashes in war theatres. The battle simply meant infantry. The vast majority of wounds reported at the inferior limbs were resolved by limb amputation. Every decision had to be taken very rapidly, because of bleeding or infection.

The first use of vascular substitutes was attempted in WWI, when German surgeons employed magnesium conduits, which unfortunately unleashed a violent reaction of the host organism concluding with destruction of the conduits themselves. The modern history of vascular reconstructive surgery started during the last period of WWII and particularly during the Korean War by American surgeons (De Bakey and Simeone), who could utilize the new *plastic fabrics*, like nylon, Vinyon and Dacron. In the last 50 years, vascular grafting spread largely and allowed to save numberless limbs. Obviously, the scope was to save the affected limb, but this has not fully been achieved because another field has developed in the last years: the endovascular treatment of vascular obstructions and the introduction of endovascular grafts. The introduction of endovascular grafts, however, con-
ditioned another risk: the infection of indwelling grafts themselves. In our opinion, the time has come to slow down this hectic run towards more and more newer solutions and to meditate on how and whether it is necessary to research new materials or to correctly evaluate the results obtained until now. Therefore, I tried to collect the best experience of the most notable authors and their surgical schools in Europe and North America to try to introduce and design the concept of a tailored treatment for each patient, because we are not all the same “thing” and our bodies are different.

Every surgeon has developed tips and tricks to ameliorate his results, by minimizing the risks for the patients and shortening the duration of surgery and hospital stay. It is simply what we name “experience”!

This effort we made also represents the best explanation of the title of the book, so that the experience of the masters can be transmitted to young vascular surgeons, also by means of a continuous intellectual exchange of ideas, because even the youngest of us can have great ideas.

Finally, I want to thank wholeheartedly all authors who contributed with great enthusiasm to my proposal, whilst still appreciating our founding idea. In particular I am deeply grateful to Peter Gloviczki and his marvelous disciples of Mayo Clinic for honoring me with his distinguished words in the preface.

PIERGIORGIO SETTEMBRINI
Piergiorgio Settembrini was born in Villorba (Treviso) in 1944. He graduated in Medicine and Surgery in 1968 at the University of Padua and was immediately taken into the school of Surgery of Prof. Giuseppe Pezzuoli, then following him to the University of Milan when he was unanimously called to the Chair of Surgical Clinic in 1979. Since the beginning of his surgical experience, he has always been attracted to Vascular Surgery, which began to be practiced in Italy in the sixties and seventies of ’900s and had yet to be recognized as an independent branch of surgery. The University of Padua was the only vascular center for arterial reconstructive surgery in North Eastern Italy. This is why he has a unique possibility to see and to treat a numerous amount of patients coming from the surrounding regions.

He performed his first operations on carotid arteries and abdominal aorta as first operator in 1973. It was the time of the “Houston Cowboys” (De Bakey, Cooley, Noon, Crawford), who transmitted everywhere their courage to accomplish innovative ideas in performing vascular surgery towards new targets. In order to sharpen his preparation, he moved to the Netherlands where he was a pupil of Prof. van Dongen in Utrecht and then in Amsterdam.

He was the one who introduced the technique of the so-called profundaplasty in Italy. Moreover, in 1974, he proposed the cross clamping of the aorta between diaphragmatic crura in case of difficult clamping below renal arteries. He is author of more than 200 scientific papers in indexed journals and he participated as speaker in over 300 conferences.

Since 1975, he has been working in the research field on the different types of vascular grafts joining pathologists and engineers, beginning to use the umbilical cord in toto as arterial substitute in dogs, thus obtaining long-term survival of the animals. In recent times, he has dedicated himself to the evaluation of the urgent treatment of carotid stenosis and to the treatment of vascular graft infections.

As far as the academic world is concerned, he became Associate Professor of Surgery at the University of Milan in 1980 and later in 1990 Full Professor of Vascular Surgery. Before then, he worked at the University of Modena and the University of Milan and was director of the residency program of Vascular Surgery at the University of Milan.

He has performed more than 14,000 operations in all vascular districts (carotid, thoracic and abdominal aorta, renal and lower limbs) as first operator. He introduced the new trilaminar PTFE grafts for lower limbs that are very promising for femoro-popliteal grafting procedures.

He has established contacts with the Mayo Clinic and several centers in Europe (University of Poitiers, Lugano Hospital (Switzerland), University and Academic Hospital of Innsbruck, University of Athens) and he was recently called to the University of Tashkent (Uzbekistan) for a leading role in Vascular Surgery. He is reviewer for many journals of vascular surgery (Journal of Vascular Surgery, European Journal of Vascular and Endovascular Surgery, Journal of Cardiovascular Surgery, Annals of Vascular Surgery, Italian Journal of Vascular and Endovascular Surgery).

He is also founder member of SICVE (Società Italiana di Chirurgia Vascolare), full member of SVS, member of the European Society for Vascular Surgery and fellow of the European Board of Vascular Surgery. For many years, he has also been part of the Board of Vascular Surgery of the UEMS (Union Européenne des Médecins Spécialistes - European Union of Medical Specialists).
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Key issues on decision making in vascular surgery: focus on abdominal aortic aneurysm

L.G. Mantovani, L. Scalone

In the past decades, the prevalence of abdominal aortic aneurysm (AAA) and mortality rates have decreased for several reasons: the prevalence levels of AAA are decreasing in some countries as a result of some phenomena (e.g., declining smoking rates and large use of statins to treat hypertension and hyperlipidemia). Also, screening and surveillance programs have allowed for identifying and treating patients at an early stage of the disease, before the rupture of an AAA.\(^1\)\(^-\)\(^3\) For patients requiring treatment, modern surgical procedures allow for treating a larger number of patients and achieving more satisfactory results.\(^1\)\(^-\)\(^4\)\(^6\)

However, decisions on how to manage target individuals are often not easy as they require taking into account different and complex aspects. Generally, when considering the overall value of a strategic healthcare program targeted at a category of individuals such as those affected with AAA, many interacting aspects (clinical risks and outcomes, patients’ reported outcomes, medical and non-medical costs, productivity loss etc.) must be considered at each stage from the diagnosis to the final outcome: screening, surveillance, elective intervention, urgent intervention for rupture, post surgical management. In the area of health technology assessment (HTA), many works have been conducted and published so far to address these issues, however, there are still uncertainties regarding the best strategy to follow for the diagnosis and treatment of AAA in different subjects, considering their own perspective but also the perspective of the third party payer and society as a whole.

This chapter focuses on some key issues related to the diagnosis, monitoring and elective treatment of AAA, and with the decision making process that can involve clinicians, budget holders, patients and perhaps even their family caregivers. It is mainly based on an overview of the most recent and relevant published works, which focus on economic evaluations, assessment of patients’ reported outcomes such as health related quality of life (HRQoL), and preferences towards treatment technologies and services.

OVERVIEW OF SCREENING AND SURVEILLANCE FOR THE DETECTION AND MANAGEMENT OF AAA

The recently published reviews in the literature make us aware of the many research works conducted so far in different countries regarding the implications of screening for AAA detection and surveillance of small AAAs. The Preventive Services Task Force in the USA recently commissioned a systematic literature review\(^3\) as an update on a first recommendation published in 2005 on benefits and harms of AAA screening and treatment of screen-detected small AAA (3 cm to 5 cm). From the review, a one-time invitation for AAA screening in men aged 65 years and older would correspond with more elective surgeries but fewer emergency operations due to decreased AAA rupture, a decreased 30-day operative mortality and AAA-related mortality for up to 10 years, but no effect on all-cause mortality up to 15 years. However, there is still insufficient evidence to demonstrate a benefit to women. Treatment of small screen-detected AAA with early surgery would not result in improved health outcomes compared with surveillance. Only insufficient or unclear data are available to make conclusions about various high-risk screening approaches and about rescreening.

Regarding HRQoL, short-term but not long-term differences in quality of life have been seen with screening for AAA in patients who screen positive. In this regard, a recent retrospective study not included in the review by Guirguis-Blake\(^3\) aimed to understand the long-term HRQoL levels of patients with small AAA undergoing surveillance and those who have undergone repair with either technique, in comparison with the norm HRQoL levels of the German population matched for gender and age.\(^7\) Patients under surveillance reported lower levels of HRQoL at least 1 year after the AAA diagnosis, while those receiving the HRQoL questionnaires after an average of 2.5 years from elective endovascular repair (EVAR) and after an average of 5 years from elective open repair
reported significantly higher levels of HRQoL, and those who received the questionnaire after 4.5 years on average from open repair for ruptured AAA reported similar levels of HRQoL compared to the average population. According to the authors, the impaired levels of HRQoL in patients under surveillance suggest the need for more intense patient education about the disease at various stages and related treatment.

Currently, due to increasing health care resource constraints, the evaluation of the cost-effectiveness of screening programs is necessary to decide whether to start, stop or expand them. Cost-effectiveness of screening for AAA has been found in several studies conducted in different countries: some recent examples include Svensjö et al. in Sweden,8 Glover et al. in the UK,9 Giardina et al. in Italy,10 and Spronk et al. in the Netherlands and Norway.11 However, it must be noted that although the use of HRQoL indicators such as the quality adjusted life years (QALYs) is recommended to be included in the effectiveness for economic evaluations by institutions like the National Institute for Health and Care excellence,12 these indicators are rarely available and evaluations are generally conducted using HRQoL data from external and non-specific sources, rendering results and conclusions less robust.8-11 In this regard, some years ago, it was shown from the S.A.Ge screening program implemented in Italy that a routine assessment of HRQoL in individuals undergoing screening and surveillance for AAA detection is feasible, well accepted and provides useful long-term data on health for a large number of subjects that are observed for years.13 Furthermore, if assessed with an instrument that is suitable for utilities calculations such as the EQ-5D, it is possible to obtain QALYs to conduct cost-effectiveness analyses. Finally, the use of country specific social tariffs to obtain these indicators, which for instance have recently been introduced in Italy,14 is recommended to obtain more accurate estimates. Hence, the assessment of HRQoL within screening and surveillance can be considered as a routine approach to optimizing the informative role of these programs in guiding other investigations or interventions.

Regarding cost-effectiveness of screening programs, in a recent editorial Björck et al.2 underlined that despite the positive results shown in the literature, there are still significant differences between the screening protocols in the different health care systems, and numerous challenges to be overcome. Among the aspects that can influence the cost-effectiveness of screening they focused on the prevalence levels of AAA, which in some countries are decreasing for reasons such as declining smoking rates and intensive treatment of hypertension and hyperlipidemia with statins.3 Other aspects that can influence the cost-effectiveness of screening are the surveillance intervals, which could be increased for people with smaller AAAs, the method for ultrasound measurement of infra-renal aortic diameter, the selection of the target population, e.g., accurate selection of higher risk populations according to age and gender, smoking habits, and some socio-economic factors that have been shown to be associated with lower attendance (recent immigration, low income, long travel distances to the screening center etc.). Finally, the benefits and related cost-effectiveness of screening could be increased by determining if secondary cardiovascular prevention in high-risk groups based on the measurement of the infra-renal aortic diameter confers a reduction in cardiovascular mortality.

A further possible opportunity to make screening for AAA cost-effective is to include it in a bundled community-based screening: an interesting study conducted in the USA15 showed in a preliminary study that a bundled community-based screening for carotid artery stenosis, peripheral artery disease and AAA is cost-effective for self-funded employer’s beneficiaries including men and women aged ≥50 and ≤65 years naive to these conditions.

**DECIDING WHEN IT IS TIME TO TREAT AAA**

When asymptomatic AAA is diagnosed, the decisions to be made include when the AAA repair should be performed and which method should be used to repair the AAA. From the literature in this respect, Filardo et al.4 underlined that a debate continues over the appropriate roles of immediate repair versus surveillance with repair in people diagnosed with asymptomatic AAAs. A literature review was conducted to compare mortality, quality of life, and cost-effectiveness of immediate surgical repair versus routine ultrasound surveillance in people with asymptomatic AAAs between 4.0 cm and 5.5 cm in diameter. They analyzed four randomized clinical trials (RCTs) focusing on this topic. Results showed an early survival benefit in the surveillance group due to the 30-day operative mortality with surgery, but no significant differences in long-term survival, while HRQoL results were conflicting. To conclude, neither immediate open nor immediate endovascular repair of small AAAs was supported by currently available evidence.

A recent HTA report1 was conducted within the National Health Service (NHS) in the UK to develop an algorithm to help decide when to intervene with elective AAA repair to optimize survival in individual patients: the Aneurysm Repair Decision Aid (ARDA) provides an individualized evaluation of the relative benefits of continued surveillance or repair for patients with AAA, and identifies the optimal timing of repair intervention for each individual patient, to maximize survival and facilitate cost-effective use of resources and optimal clinical care. The authors concluded that although being focused on the NHS in the UK and hav-
DECIDING BETWEEN OPEN AND ENDOVASCULAR REPAIR OPTION

In the past years, many studies have been conducted to compare the two treatment options for patients with AAA with different characteristics such as age, presence of risk factors or comorbidities, anatomic suitability for EVAR, and dimension of the aneurysm. The comparisons have focused on the different aspects that are relevant for decision making, such as clinical effects and risks, HRQoL, economic consequences, physicians’ opinion and patients’ preferences.

More recently, some literature reviews have been published to sum up and discuss key issues related to the choice between EVAR and open repair.

Regarding cost-effectiveness, in 2014 Epstein et al. published the results of Markov models based on RCTs conducted in Europe and in the USA to compare EVAR and open repair in the elective setting. Lifetime costs (procedure costs, surveillance costs, re-intervention costs) from a UK perspective, aneurysm-related mortality and other-cause mortality and QALYs were included in the models. Alternative scenarios about complications, re-interventions and deaths beyond the trial were explored. EVAR was found to not be cost-effective at the standard thresholds used in the UK (20,000-30,000/QALY) but seemed cost-effective according to the model based on the trial conducted in the US. Interestingly, in their review Mandavia et al. who analyzed the results of several economic evaluations conducted for three vascular surgery areas, i.e., superficial venous interventions, AAA elective repair, and carotid endarterectomy, claimed that actually cost-effectiveness analyses do not appear to give a high contribution of guidance regarding the allocation of health care resources in the UK. In particular for AAA, the authors found that from the available studies EVAR is unlikely to be cost-effective compared with open repair in Europe, however NICE recommends EVAR for all patients who are suitable for both EVAR and open repair. The authors concluded that research is required to explore the purpose of health economic analyses if recommendations are not implemented. Furthermore, they wondered about the type of information that should be included in the evaluations to obtain a picture of cost-effectiveness in order to be comprehensive and interesting enough to be considered in practice for decision making processes. For instance, long-term aspects such as costs of surveillance and stent graft complications associated with EVAR, long-term HRQoL and preferences of patients, should be considered in the analyses.

Regarding HRQoL, in a prospective study involving patients undergoing elective AAA repair in a real-world, community hospital setting, the authors showed that those selected for EVAR had a trend of lower baseline physical components of HRQoL than those assigned to open repair. These results suggest that in real practice EVAR is probably assigned to patients with lower levels of health and at a higher risk of complications from open repair. After the intervention, patients treated with EVAR suffered less physical and emotional decline in the early postoperative period than those undergoing open repair; however, in both groups a return to near baseline status occurred at 90 days and after 1 year from the intervention. The authors underlined that information about HRQoL should be considered and discussed with patients in addition to traditional clinical parameters when making therapeutic decisions regarding AAA repair.

The importance of considering patients’ preferences when making decisions for treatment has been underlined in the last years and has been the focus of recent research. The research studies published so far on this topic are different regarding their specific objectives, the methods and instruments used to elicit individuals’ preferences, the context where data were collected and subjects involved. However, all the studies agreed on the importance of informing and making the patients aware of all the implications of their conditions and possible treatments, so as to involve them directly in the decision making process for the obtaining of more satisfactory results.

Some key differences and main results of these studies are summarized below. Landau et al. analyzed the following data from patients with AAA: their willingness to accept, in case they needed surgery in the future, longer travel distances to reach treatment centers that ensure lower periproductive mortality in comparison with local centers. Similarly, in the study by Holt et al., 92% of the respondents, who were attending an aneurysm screening program and completed a questionnaire before their ultrasound scan, reported a willingness to travel for at least 1 hour beyond their nearest hospital to access a service with 5% lower periproductive mortality rate, 2% lower amputation or stroke rate, a high annual number of aneurysm repairs and routine availability of EVAR.

Reise et al. investigated preferences of men with small AAA detected by population-based screening between EVAR and open repair for future treatment. The participants received a patient information pack at home to describe the treatment options, and a questionnaire to complete and return by post. The patient information pack increased preferences for EVAR (46% of the participants) against open repair (18%), however 14% of the participants declared they would be happy with either treatment
and 20% had no preference. The study by Winterborn et al.\textsuperscript{21} was somewhat similar to the one described above: patients with small AAA under surveillance program participated in a semi-structured telephone interview. The characteristics of EVAR or open repair were evaluated using a Likert scale and a ranking exercise. Eighty-four percent of the participants preferred EVAR. Not surprisingly, the risk of major organ failure and death were the most important characteristics. Postoperative morbidity and mortality were more important than the need for surveillance and risk of long-term problems with EVAR. Type of incision and radiation exposure and the risk of sexual dysfunction were considered less important than the other characteristics. The study conducted in Italy by Faggioli et al.\textsuperscript{19} focused on the factors influencing the choice between EVAR and open repair. In this study the participants were patients diagnosed with AAA assigned to, or already treated with, elective EVAR or open surgery, their family caregivers (spouse, children, friends etc.) and their surgeons. The patients and their family caregiver attending the hospital/physician office for a routine visit were asked to self-complete a paper questionnaire while waiting for the visit. Differently from the other studies, the technique of Discrete Choice Experiment (DCE) was used by Faggioli et al. With the DCE, possible scenarios were presented in which the different treatment options were described according to six characteristics that were previously selected for their relevance in a pilot study: anesthesia; recovery time to basic everyday activities; risk of re-intervention at 5 years; complexity of follow-up; risk of major complications; and additional cost of intervention, presented as out-of-pocket costs to the patients and relatives, and as additional hospital costs for the surgeons. Risk of death was not included in the scenarios because in the pilot study it was the most important characteristic, hence, it was excluded from the final study to avoid a dominant effect on the other characteristics. While some aspects of EVAR were preferred to open repair, other aspects of open repair were preferred to EVAR. Furthermore, patients, relatives and physicians did not always agree in their opinions, and experience with a treatment (i.e., whether it was performed and which treatment) seemed to change some preferences in the patients. Briefly, major complications and re-intervention risk were the most important characteristics for all the respondent categories. Patients and their relatives considered a possible additional out-of-pocket cost to be very important also. Recovery time and type of anesthesia were among the least important characteristics, including additional hospital cost for surgeons.

Finally, in their study, Letterstål et al.\textsuperscript{18} focused on differences in preferences according to individuals’ age. People from the general population rather than patients were interviewed via telephone with standard gamble and time-trade-off exercises to assess their risk attitude and preference for treatment with open repair procedure. The participants were asked to imagine that they were diagnosed with AAA and needed to be treated with open repair. The main results suggested that older persons (>80 years) were more inclined to prefer living with AAA without taking the immediate risk related to open repair and the postoperative impaired HRQoL.

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