National Directives Needed for EVAR in Italy

BY PIERGIORGIO CAO, MD, FRCS; PAOLA DE RANGO, MD; GIANBATTISTA PARLANI, MD; AND FABIO VERZINI, MD

Endovascular aneurysm repair (EVAR) has gained popularity over open repair because of its short-term effectiveness, minimal invasiveness, and reduced convalescent time. It has been more than 10 years since the first commercial bifurcated device received a Conformité Européenne (CE) Mark of approval in Europe, and thereafter in Italy, under the name of Stentor (formerly MinTec, the Bahamas) and later as Vanguard (Boston Scientific Corporation, Natick, MA). Since then, EVAR device configurations have been totally renewed, but the advantages and disadvantages are still the objects of debate (Figures 1 and 2). In Italy, there has been little delay in the adoption of this new technology at most large, national hospitals. Primary forces that have accelerated the early adoption are: (1) nonrequirement of investigational device exemptions (IDEs) before clinical assessment of new devices can begin (mandatory in the US); (2) interest in establishing these new techniques as legitimate core components of a new vascular specialty; (3) industry-sponsored education and training programs designed to speed acceptance of new medical products; and (4) patient demand for new technologies with an increasingly well-informed public.

REIMBURSEMENT

Despite the increased endograft device costs (when compared to the cost of a traditional prosthetic graft), the advantages in reducing requirements for expensive resources, such as intensive care unit beds or blood products, together with a significantly shorter length of hospital stay, are in line with the National Health Service reimbursement policy. EVAR rapidly expanded, especially in national hospitals with governmental financial support, whereas only some EVAR repairs in Italy are funded by patient or hospital private insurance.

The Italian health care system is based on diagnosis-related groups (DRGs). There are 21 regions in Italy, and DRG levels vary from one region to another. Reimbursement for open and endovascular abdominal aortic aneurysm (AAA) repair is the same. Only four regions have a supplemental fee for the AAA endovascular device.

DEVICES

Currently, there are nine models of endografts (all CE marked) used in Italy to treat AAAs. The two most commonly used devices are the Talent (Medtronic, Inc., Santa Rosa, CA) and the Zenith (Cook Medical, Bloomington, IN), with a similar approximate market share; the Excluder (Gore & Associates, Flagstaff, AZ) is the next most commonly used device. The other devices cover about one-third of the Italian market and include the AneuRx (Medtronic), the PowerLink (Endologix Inc., Irvine, CA), the Anaconda (Vascutek, a Terumo company, Glasgow, Scotland, UK), the Endofit (Le Maitre Vascular, Burlington, MA), the Aorfix (Lombard Medical Technologies, Oxford, UK), and the Montefiore (Datascope, Montvale, NJ).

NATIONAL DIRECTIVES

Since the introduction of endovascular practice, a number of nonsponsored, voluntary, international (eg, EUROSTAR, European Vascular and Endovascular Monitor [EVEM] panel) or national (eg, Società Italiana Chirurgia Vascolare ed Endovascolare [SICVE] registry) registries were developed to monitor and record EVAR results. No definite national directives or governmental registries are available to drive the Italian EVAR practice.

The overall number of AAA repairs increased in recent years, with more than 11,322 cases recorded (EVEM data) and about 83.6% performed for AAA >5 cm in maximum diameter (SICVE registry). The choice of open repair, fitness for EVAR, threshold diameter to treat, etc, are not restricted

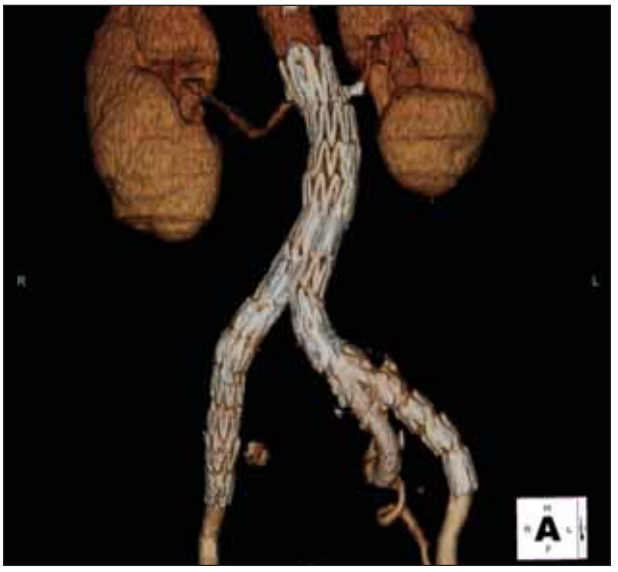

Figure 1. Last-generation device. Aortoiliac aneurysm treated with bifurcated endograft, adjunctive left hypogastric branch, and right hypogastric occluder system.

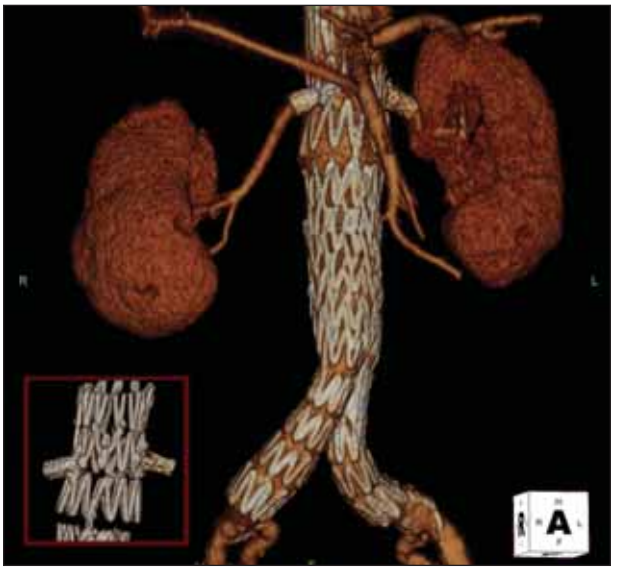

Figure 2. Last-generation device. Pararenal aortic aneurysm treated with fenestrated bifurcated endograft, bilateral renal stenting, and mesenteric scallop.

by mandatory guidelines, but are regulated by improvements in technique, devices, clinical expertise, and literature updates.

RANDOMIZED CONTROLLED TRIALS

Although open repair still covers more than half of all AAA repairs, an increasing number of patients are now considered for EVAR, especially after data from randomized controlled trials (RCTs) and a number of studies with first-, second-, and even third-generation devices have become available. The recent large multicenter RCTs on EVAR (EVAR, DREAM)[1,2] have established the role of this new technique as a realistic alternative to open surgery. Furthermore, long-term data with up to 12-year follow-up are emerging to support EVAR, indicating that contemporary devices are safe, effective, and durable.[3,4]

Italian registry data show that since 2001, the percentage of open repairs has steadily declined. In the last 2 years, this has become more evident (after publication of RCT results): from 71% of 10,530 AAA repairs (7,508 open vs 3,022 EVAR) during 2005, to 58% of 11,322 AAA repairs (6,588 open vs 4,734 EVAR) in the last year. In the same period, EVAR has seen a dramatic increase that approaches or even overcomes half of all aneurysm repairs in some selected specialist centers. National data from the EVEM panel demonstrated a 25% increase in EVAR in the third quarter of 2005, when compared to the same period of 2004 and a further increase of about 12% in 2006. In part, this may also be due to the expertise and experience acquired in tertiary referral specialist vascular centers where open infrarenal aneurysm repair now represents a small minority of elective cases. Obviously, not all patients with AAAs will be managed for endovascular repair because of inadequate suitability (eg, short angulated neck, difficult artery access), although some of these technical difficulties may be overcome with increasing endovascular experience and development of new technologies.

There are no national guidelines to reserve open repair for a particular category of elderly, high-risk patients, and the choice to offer EVAR as a first line of treatment is largely subjective. Nevertheless, EVAR is now more frequently offered to patients with suitable anatomy for endografting, regardless of comorbidities, preferring open surgery for young and fit patients with large AAAs and challenging anatomical features.

EVAR SUCCESS

Although it became evident that integrated and standardized training and multispecialty integration may be the roadmap to EVAR success, this is still not a reality for most of Italy. Unfortunately, there is no recognized endovascular training program, and the traditional model of apprenticeship based on "learning-by-doing" has only slightly changed the competitiveness between single specialists, particularly in nonreferral centers. The teaching of surgical trainees in radiological techniques often interferes with the teaching of radiology/vascular juniors. Furthermore, the lack of national guidelines negatively affects screening, surveillance, and management of AAAs.

THE CAESAR STUDY

For most patients with AAAs, aneurysm detection and follow-up is left mainly to single centers or voluntary

group protocols. In this regard, a prospective, randomized comparison between EVAR and surveillance for patients with small (<5.5 cm) AAAs, the CAESAR study, launched in Italy, is currently underway in Europe, and nine of the 18 actively participating centers are Italian.[5]

CONCLUSION

For many years, vascular surgery in Italy has been a subspecialty of general surgery or cardiac surgery—depending on local situations. At present, it is an independent monospecialty, as it is in most of the countries in the European Union. Although national regulatory directives to drive EVAR practice are lacking, the tendency is that of a steadily growing market. ■

Piergiorgio Cao, MD, FRCS, is Professor of Vascular Surgery and Chief of Vascular and Endovascular Surgery, University of Perugia, Ospedale S. Maria della Misericordia, in Perugia, Italy. He has disclosed that he receives grant funding from Cook Medical, Medtronic, and Boston Scientific. Dr. Cao may be reached at +39 075 5786437; pcao@unipg.it.

Paola De Rango, MD, is from the Division of Vascular and Endovascular Surgery, University of Perugia, Ospedale S. Maria della Misericordia, in Perugia, Italy. She has disclosed that she receives grant funding from Cook Medical, Medtronic, and Boston Scientific. Dr. De Rango may be reached at +39 075 5786436; pderango@unipg.it.

Gianbattista Parlani, MD, is from the Division of Vascular and Endovascular Surgery, University of Perugia, Ospedale S. Maria della Misericordia, in Perugia, Italy. He has disclosed that he receives grant funding from Cook Medical, Medtronic, and Boston Scientific. Dr. Parlani may be reached at +39 075 5786437; titta@unipg.it.

Fabio Verzini, MD, is from the Division of Vascular and Endovascular Surgery, University of Perugia, Ospedale S. Maria della Misericordia, in Perugia, Italy. He has disclosed that he receives grant funding from Cook Medical, Medtronic, and Boston Scientific. Dr. Verzini may be reached at +39 075 5786437; fverzini@unipg.it.

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