EVAR Use Expands in Germany

BY GIOVANNI TORSELLO, MD

Germany was among the first countries to use endovascular repair (EVAR) as a therapy for abdominal aortic aneurysms (AAAs). After the initial enthusiasm, German surgeons faced a period of criticism on the effectiveness of stent grafting. Because of the high complication rate, including AAA ruptures, durability of EVAR was a topic of concern. This skepticism was mainly due to structural failures of first-generation endografts such as the Vanguard (Boston Scientific Corporation, Natick, MA) device.

Introduction of more durable stent grafts, the increasing learning curve, and the better understanding of inclusion/exclusion criteria for endovascular repair have given the German physicians more confidence and trust in endovascular therapy. A recent multicenter trial (TARL study) evaluated the long-term outcomes after Talent (Medtronic, Inc., Santa Rosa, CA) endograft implantation for AAA treatment in Germany before December 1998. In comparison with first-generation grafts, the device showed superior durability for as long as 5 to 7 years after implantation. Data from the external quality assurance program of the German Society for Vascular Surgery show that endovascular treatment accounts for 30% of all operations. The endovascular adoption rate of well-equipped referral centers in Germany ranges between 70% and 80%.

GROWTH OF EVAR IN GERMANY

Compared with some other western European countries, the use of EVAR in Germany is still growing, as shown by both European Vascular and Endovascular Monitor (EVEM) and quality control data.

There is no compulsory registry for aneurysm procedures in Germany. Based on surveys, existing registries, and insurance company data, approximately 10,000 infrarenal aneurysms are treated per year. The 83 German centers, which reported data to National Quality Assurance, have performed 2,733 AAA procedures with an average of 33 AAA procedures per center in 2005. Eight hundred fifty-two (30.9%) of those were treated with endovascular techniques. Since 2001, the rate of EVAR has increased from 15.9% to 16.9% (2002), 18.1% (2003), and 25.4% (2004). Statistical analysis showed better operative results compared to the open procedure. Early mortality of EVAR was 2.6% versus 9.7% for open repair, including the patients treated for ruptured aneurysms.

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IMPACT OF TRIALS ON EVAR

The EVAR 1, EVAR 2, and DREAM trials have not negatively affected the usage of EVAR in Germany, provoking animated discussions at national and local congresses. Since both EVAR 1 and DREAM trials confirmed the reduced morbidity and reduced early mortality compared to open surgery, the endovascular adoption rate in Germany increased. The large number of crossover patients—screened for surveillance during EVAR 2 but treated by EVAR because of rupture—underscored the importance to also treat high-risk patients.

Of course, stent grafts are not offered to all the suitable patients. Patients with AAAs, in combination with severe comorbidities, are only treated in case of an acceptable life expectancy. Indications for treatment include AAAs with an aneurysm diameter >5 cm (fusiform aneurysm), any saccular aneurysm, and aneurysms with a diameter <5 cm in case of symptoms or a high growth rate. Treatment of small asymptomatic AAAs (<5 mm, with no sign of rapid growth) is still under evaluation. Right now, two randomized, multicenter studies are evaluating small aneurysm repair: CAESAR in Europe and PIVOTAL in the US. Three German centers are enrolling patients in the CAESAR study. Currently, treatment of small aneurysms is only recommended in cases of rapid growth, saccular morphology, or symptoms related to the aneurysm. The rate of ruptured AAAs and emergency procedures continues to be high (11.7% in 2000 and 11.1% in 2005). Patient screening programs are required for early diagnosis to reduce the number of patients dying from rupture.

INDICATIONS, TECHNIQUE, AND FOLLOW-UP

EVAR has its own indications and is very successful when performed by the hands of the experts who consider case selection inclusion criteria and use endovascular techniques frequently. Routine application of this technology should be limited to patients with suitable proximal and distal sealing zones. Short and angulated aneurysm necks, as well as extended occlusive or aneurysmatic disease of both iliac arteries, are anatomic contraindications for EVAR. Fenestrated and branched devices address unsuitable aortoiliac anatomy, expanding the applicability of endovascular treatment to patients with demanding anatomy. Therefore, the use of fenestrated and branched grafts is advancing, but long-term outcomes need to be evaluated, especially in view of branched-vessel patency.

Hybrid techniques are also performed in some centers of excellence in Germany. However, large, controlled studies have yet to be published. The follow-up requirements and examination are a burden for all German hospitals, especially the high-volume ones. An official, very demanding follow-up protocol is still in use, and the different centers try to apply their own system to make it less demanding. CT scan and plain abdominal radiograph studies are still essential for detecting endoleaks and structural changes of the endograft. CT scans, performed beyond 3 months after the procedure, and then yearly, were part of the routine follow-up at the beginning of the EVAR experience.

After the introduction of new-generation stent grafts and as a response to the increasing burden and cost of follow-up, duplex ultrasound scanning is now accepted for routine follow-up if no signs of endoleak and aneurysm growth are found. CT scan and aortography continue to be the methods of choice to detect endoleaks. To increase the efficacy and safety of endoleak detection, a wireless pressure-monitoring system has been developed. A recently published, prospective, multicenter trial showed the feasibility of remote aneurysm sac pressure sensing, but long-term studies are needed to prove its efficacy.

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All endografts are available in our country because Germany is very open to innovations, and most of the medical device companies target the German market first. The market leader in Germany is the Talent, followed by the Zenith (Cook Medical, Bloomington, IN). The Excluder (Gore & Associates, Flagstaff, AZ) has a smaller market share, followed by other products, which all together do not exceed 10% of the implants.

DIAGNOSIS-RELATED GROUP CODING

There was no specific diagnosis-related group (DRG) code for endovascular AAA repair at the beginning of the introduction of EVAR, thereby associating it with the DRG code for open surgery. Gradually, our reimbursement system moved from a common DRG system with negotiable reimbursement for stent graft, to a nonnegotiable reimbursement. Currently, we have a dedicated DRG code and reimbursement fee for endovascular treatment of AAAs, which makes the procedure more affordable for the hospitals from the pure economical point of view, giving a very promising sign of therapy acceptance. DRG reimbursement for implantation of fenestrated stent grafts is under evaluation. ■

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