



Increasing Roles for Both Endovascular and Open Repair

BY HENCE J. M. VERHAGEN, MD, AND JAN D. BLANKENSTEIJN, MD

In 2002, when the last statistics were generated, there were approximately 1,600 endovascular and open abdominal aortic aneurysm (AAA) repairs performed in the Netherlands. Of those cases, roughly 30% to 40% were endovascular aneurysm repair (EVAR) procedures. If the patient were young with low or no comorbidity, there was approximately a 75% preference for treating with open repair; if the patient were older with mild comorbidity, there was a 75% preference for EVAR in the Netherlands. However, a large variability between hospitals exists, with some treating up to 75% of all AAAs with EVAR.

Of the centers in the Netherlands, less than a handful have a strong preference for EVAR. Most AAA procedures take place at university-based hospitals or large peripheral teaching hospitals, with about 50 of the country's approximately 100 hospitals offering endovascular treatment for aortic pathologies. Most university centers tend to treat 50% of AAAs endovascularly.

REGULATORY AND REIMBURSEMENT CONSIDERATIONS

As is the case in many European Union countries, there are few barriers for the delivery of AAA care in the Netherlands from a purely technological standpoint. The only regulatory restriction is that the device used must have received Conformité Européenne (CE) mark approval. If a device is not yet approved, ethical clearance from the hospital and written consent from the patient are required to proceed with treatment. For example, the Endurant device (Medtronic, Inc., Santa Rosa, CA) is part of a current clinical trial aimed at obtaining a CE mark, so the participating centers need to have clearance from their local ethical committee to join the trial, and each patient needs to sign a consent form.

There is virtually no private health care in the Netherlands (except for reconstructive surgery proce-

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dures). Basically, the entire population is insured the same way and receives the same options for treatment. Open repair is considered the standard of care and is always reimbursed; EVAR, however, is somewhat more limited in its availability because its use must be negotiated between the treating hospitals and insurance companies on an annual basis.

AVAILABLE DEVICES AND MARKET SHARE

Although most, if not all, EVAR devices are approved for use in the Netherlands, the majority of patients are treated with one of three devices: the Zenith (Cook Medical, Bloomington, IN), the Talent (Medtronic), or the Excluder (Gore & Associates, Flagstaff, AZ). Approximately 30% to 35% of cases involve the Zenith, 30% to 35% the Talent, and 15% the Excluder. Other devices, such as the Aorfix (Lombard Medical Technologies PLC, Didcot, Oxfordshire, UK) and the Anaconda (Vascutek, a Terumo company, Glasgow, Scotland, UK), account for the remaining 15%.

Fenestrated grafts have been on the market for approximately 7 years, but only a few centers currently use them on a regular basis worldwide. However, the technology is promising, and many of the stent graft companies are exploring fenestration and branch technology. The prohibitive cost of these devices must still be overcome for more widespread adoption to become a reality. In our practice, the least-expensive abdominal fenestrated graft will cost approximately €25,000; what is



EVAR in the Netherlands

spent treating one patient with a fenestrated graft could be spent on almost four patients receiving standard devices. However, this may change over time, and then it might be considered the next generation of stent grafts.

INCREASED ADOPTION

With the introduction of new devices and the findings of the DREAM, EVAR 1, and EVAR 2 trials, there has been an increase in both open and EVAR in the Netherlands. A Dutch survey presented at the 2006 Charing Cross Symposium explained that although the trials did not provoke major changes in surgical decision making for patients fit for both EVAR and open repair, there was a general increase in awareness and the amount of aortic repairs performed. Before the trials, it was more likely a patient would receive open repair; after the trials, the probability that the patient would receive open repair was still higher.

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SPECIALTIES PERFORMING EVAR

In the Netherlands, EVAR is commonly performed jointly between vascular surgeons and interventional radiologists. At a few hospitals, however, interventional radiologists are not involved at all. The procedure is usually not performed without a vascular surgeon present, but not all surgeons are actively involved during the procedure after opening the groin. In general, cardiologists are currently not actively involved in AAA or thoracic endograft placement. However, the Netherlands may follow the example of the US and other countries and soon see an increase in the number of interventional cardiologists involved in the procedures.

SURVEILLANCE

Surveillance is rather efficient in the Netherlands, in part because it is a small and well-organized country when it comes to medical care; patients regularly follow-up with their doctors. In general, smaller centers commonly abide by the EUROSTAR protocol, and large centers usually follow up with a yearly CT evaluation. Some centers are shifting toward ultrasound and standard x-rays, with a CT scan every few years, but the ideal surveillance protocol has yet to be determined. The amount of radiation and

contrast that patients are exposed to during follow-up is somewhat alarming, and it should be considered over the next few years. However, this does not change our opinion on whether or not we should treat patients using EVAR. In all likelihood, if a patient has ideal anatomy and is treated with EVAR, surveillance may not be truly necessary for the first 5 years after the procedure. However, if a patient has difficult anatomy, follow-up imaging should probably be performed on a more regular basis.

What complicates the issue of EVAR surveillance is that much of our research is rooted in our follow-up evaluations, so if we were to stop doing as many follow-up studies, we would learn less about the procedures we perform. Surveillance is very important to learning from a wide perspective. As long as the long-term data are unclear, physicians should continue to conduct follow-up as they have been the last few years. In the Netherlands, this is perhaps one of the biggest controversies pertaining to EVAR.

THE EXPANDING ROLE OF EVAR

The prevalence and inclination toward EVAR in the Netherlands is increasing. New devices will come onto the market that can treat new patient groups, such as those with short or angulated necks or complex anatomies. With the increasing experience of every surgeon, more difficult cases will be treated. Patients themselves are becoming more aware of EVAR with the availability of information on the Internet; we believe this is a safe and positive trend. The Netherlands is still very much influenced by evidence-based medicine culture. We do not think that many patients will have aneurysms treated if they are less than 5.5 cm, so we do not believe that the indication itself is changing. Because the Netherlands is a small and affluent country, treatment of AAAs is available throughout the nation, and the frequency with which it is performed will probably increase even more over the next few years. ■

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