Early Access to Next-Generation EVAR Technologies

Hence J.M. Verhagen, MD, PhD, talks about the advantages to early adoption of new devices, his follow-up protocols, and his current clinical trial efforts.

As an interventional physician in Europe, as well as a leading clinical investigator, you have access to some technologies before they are available in other parts of the world, including the United States. In some instances, you're up to a full device generation ahead, with follow-up data. What are some of the advantages and disadvantages of being an early adopter?

Dr. Verhagen: I consider it a great advantage to have access to technology long before it is available in other parts of the world. In general, new technology brings better treatment options, and patients usually benefit greatly from this. Furthermore, it speeds up development, because real-life experiences guide technological improvements. It's strange to see that patients in other parts of the world receive treatment using technology that is not exactly "cutting-edge," while it is obvious that better devices are available. Of course, a possible drawback of the early adoption of new technology is that imperfections of design may appear in our patients.

What are some of the endovascular aneurysm repair (EVAR) devices you have used extensively that you feel will have a significant impact in the United States and other global markets where they are not yet currently available outside of clinical trials?

Dr. Verhagen: Basically, all next-generation EVAR and TEVAR devices perform significantly better than their predecessors. Good examples of this are the Endurant and Valiant stent grafts (Medtronic, Inc., Minneapolis, MN), which have an added a hydrophilic coating and the company's Captivia deployment system. Also, the Relay thoracic endograft (Bolton Medical, Inc., Sunrise, FL) brings significant improvement in deployment accuracy, especially in the aortic arch.

In which EVAR device trials are you currently participating? How would you describe the devices that are being studied?

Dr. Verhagen: I'm the principal investigator for the European trial of the Endurant stent graft in abdominal aortic aneurysm (AAA) patients. This device has performed considerably above expectations and has broadened the amount of AAA patients suitable for EVAR in our practice. Because of its ease of use, accuracy, and capabilities in treating hostile anatomies, the vast majority of our patients with ruptured AAAs can now be treated by EVAR. It has truly had a huge impact on our EVAR treatment patterns.

Very soon, we'll start using the Excluder (W. L. Gore & Associates, Flagstaff, AZ) with its modified deployment system. I have very high expectations for this improvement.

In your opinion, what is the optimal follow-up protocol for EVAR patients?

Dr. Verhagen: The answer to this question really depends on the original anatomy of the patient's AAA. If the anatomy is favorable and the device is sized well and deployed at the optimal position, a yearly duplex scan will be enough. To be honest, I'm convinced no follow-up should be necessary for many years if everything was fine after 1 year.

However, if the anatomy were unfavorable or challenging, I keep my patients on a follow-up plan of yearly

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computed tomographic scans. Generally, this can be done without contrast.

How do patient compliance and cost-efficiency affect standards for follow-up scheduling?

Dr. Verhagen: Patient compliance in a small country like the Netherlands is not a big issue; most patients will show up for their appointments. For cost-effectiveness issues, obviously, it's of utmost importance to do as little follow-up as possible. I believe many EVAR patients would be fine with a minimum amount of follow-up appointments, but not many physicians are ready for this step.

In which area do you believe current stent graft systems have the greatest opportunity or need for improvement (ie, fixation, deliverability, material, components, ability to accommodate branch vessels, etc.)? How would you like to see this improved?

Dr. Verhagen: The greatest need for improvement is the size of the introduction system, especially for thoracic devices. Furthermore, "off-the-shelf" fenestrated or branched devices would be very welcome. However, these will unfortunately not be available in the foreseeable future.

As someone who has trained and proctored in several very different countries, what is one thing you have learned about the performance of EVAR that you might not have known had you only trained in the Netherlands?

Dr. Verhagen: Everywhere I proctor, every case I see, teaches me something new. I have encountered many new tips and tricks. Sometimes I'll learn from the treatment itself, but frequently, the benefit comes from an imaging or logistic perspective. One of the greatest lessons I have learned is that there are often many different ways to reach your goal. Unfortunately, I've also seen technology used in places where the centers weren't ready for it. EVAR and TEVAR may look easy to perform, but the learning curve is significant, and there are many, many extremely important details to be known. A central discussion on availability of new technology is not always a bad idea. ■

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