EVAR: Raising the Bar

Roy K. Greenberg, MD, explains how endovascular aneurysm repair procedures continue to progress, enabling the treatment of more patients and challenging anatomies.

Several years ago, after the approval of endovascular aneurysm repair (EVAR) in the United States and during the growing acceptance among clinicians, studies continued to pinpoint which patients could and should be treated endovascularly. At this time, several studies looked at EVAR in smaller aneurysms, but you were more interested in larger and more complex aneurysms. What made you go that direction?

Dr. Greenberg: I believed then as I believe now that it is very rare for small aneurysms to rupture. As such, the margin of error that would be acceptable in treating a small aneurysm is close to zero, and I don't think anyone can perform aneurysmal intervention at an error margin of zero. The acceptance of potential procedural complications and risk is much more reasonable when the risk of not treating the aneurysm is greater. Logically, the risk of nonintervention in larger or more complex aneurysms is far greater than that of the intervention in our hands, although this remains to be proven in a purely scientific manner. Not surprisingly, there seems to be a growing number of patients with complex aneurysms.

In abdominal aortic aneurysm (AAA) patients with more complex anatomies, how should the operator know when to push the envelope versus when to stay within defined boundaries, whether they are regulatory limitations or self-imposed based on previous experiences?

Dr. Greenberg: This question focuses on clinician judgment—the larger question of how a doctor knows when he is doing the right thing—and that's not an easy thing to answer. With EVAR, it makes sense in my opinion to learn things in stages; I didn't start out treating the most complex aneurysms. My first aneurysms were treated with a homemade aorto-uni-iliac device, which is arguably the simplest of the devices. That evolved into studying a bifurcated device, which is essentially the standard device now. Then we added simple fenestrations for juxtarenal aneurysms, followed by simple branches for common or internal iliac aneurysms. It wasn't until after that that we started to tackle more complex aneurysms that require replacement of the whole visceral segment of the aorta, or dealing with the supra-aortic trunk branches.

I did this in a very stepwise manner during which I gained confidence at each level of repair complexity before I went to the next step. I believe clinicians should approach the performance of EVAR on the spectrum of aneurysm difficulty levels, mastering the treatment of simpler aneurysms and developing a certain comfort level before attempting those that are more complex.

How would you describe the current regulatory restrictions on EVAR in the United States?

Dr. Greenberg: In my opinion, the US Food and Drug Administration doesn't tell us how to practice medicine. The current system is designed for the safety of patients and to ensure that companies are studying their devices for their intended usages. With EVAR, the instructions for use element that is most frequently discussed is proximal neck length. This length is supposed to be at least 15 mm for most of the currently approved devices. But it's really a gray area; no one has really defined how to measure the difference in a proximal neck that is 10 mm versus one that is 15 mm. Does it change by a 10% diameter increase? What happens in the setting of tortuosity? Every day, even within the boundaries of marketing approvals, clinical judgment is involved.

Many vascular surgeons have become, to a certain degree, what we once criticized in radiologists 10 or 15 years ago, in that they focus on a postprocedural angiogram or computed tomographic (CT) scan, with-

out as much concern for the long-term result. I believe it is the long-term result that poses the greatest challenge for devices that are used outside of their instructions for use. I hope that when we do see failures, we look at them seriously, as failures of our intended treatment paradigms, rather than blowing them off and saying, "We did our best." There are alternatives.

As new generations of EVAR systems continue in development, do you feel that the current means of evaluating these devices for marketing approval in the United States continue to be sufficient?

Dr. Greenberg: Overall, yes. In an ideal world, we would like to have safety and efficacy demonstrated in large, prospective, randomized trials for every iteration that comes through the pipeline, and everyone wants to see superiority over a previous standard of care. But with AAAs, we don't actually have clear a standard of care for all patients. I would argue that the standard of care for a normal infrarenal aneurysm is now endovascular repair. We also do not have the numbers of patients to conduct randomized trials looking at every individual device for which approval is sought. Consequently, it makes sense to aim for a certain number of patients to be studied that can give us reasonable assurance of the device's safety and efficacy of the aneurysm repair in the short term, but this has to be supplemented with solid engineering data showing that the new devices being proposed are at least as good as the devices that are already on the market.

At the preclinical level, I think we can be innovative with mechanical testing techniques and analysis methods. Our knowledge of metals in the aorta has changed drastically. It may not be necessary for every iteration of a device to be tested in the same number of patients as the initial device trials required. In some of the earlier trials, there were more than 700 patients enrolled, and we will never get those patient numbers in new device trials. The burden of proof must evolve along with the long-term follow-up to very solid preclinical data, as well as sufficient clinical data, to justify the use of these new devices.

What are your views on the current level of physician-industry relationships and interactions?

Dr. Greenberg: In terms of how companies interact with physicians regarding devices that are already approved, I think that companies are overstepping their bounds, and physicians are falling short of our marks. I've seen it time and time again, instances in which companies plan and size the procedure for the physicians, and the physicians at times are not even capable of planning or sizing a given procedure—yet they feel comfortable implanting the device. For physicians to know that a device is appropriate, they must be able to critically look at the imaging and understand where the challenges are with the patient's anatomy as well as any potential shortcomings of a device in that particular setting. Physicians need to take this back into their own hands, and I don't think company representatives should be planning and sizing devices for physicians. Some surgeons need to learn a bit of radiology, perhaps.

What are your criteria for deciding that surgery is the better course for a particular AAA patient?

Dr. Greenberg: I tended to recommend surgery for patients who have severe connective tissue diseases, in cases of complex anatomies that require urgent repair, as well as in patients in whom there is a combined problem of aneurysm and atherosclerosis. If there are focal regions that appear to pose a higher risk of embolization with one approach versus the other, I would go in the other direction.

What percentage of your patients are treated surgically?

Dr. Greenberg: Probably between 5% and 10%. However, my referral basis is largely from surgeons who think that open surgery is contraindicated and thus refer the patient for a complex endovascular solution.

What are some of the ways that new imaging technologies have enabled you to perform cases you might not have been able to complete—or complete as easily—5 years ago?

Dr. Greenberg: The importation of CT scans into the operating room and the work we have been doing with fusion imaging has even allowed us to perform four-vessel branch cases, replacing the renals, superior mesenteric, and celiac arteries, without using any contrast. We take a CT scan of the patient using our C-arm in the operating room, and we fuse the bones of that CT scan with one that was obtained preoperatively with contrast. The arteries overlay on the bones, and we can use that arterial map along with our catheters and wires to place the entire device. The average amount of contrast I now use on a branch case is between 40 and 80 mL. The system we're currently using is called the Artis zeego (Siemens Healthcare, Malvern, PA).

At what point do you think branched and fenestrated EVAR procedures will be approved and more prevalent in the United States?

Dr. Greenberg: They are already becoming more prevalent, with more of these procedures being performed every year than the last. Our volume of branched

and fenestrated cases has increased steadily every year, even in the past year when I did not perform the majority of our cases. I also look at our practice and see that about 40% of the patients are from the 100-mile area surrounding Cleveland; I often wonder what size the practice would be if it were located in New York City, Chicago, or Los Angeles, because the volume of patients who would benefit from these types of procedures is huge. As far as greater dissemination is concerned, this goes back to your earlier question on learning how to do these procedures safely. Every physician who performs EVAR can place a standard bifurcated stent graft. After that procedure is mastered, they can move on to learning EVAR for juxtarenal aneurysms, followed by the thoracoabdominals. The internal iliacs can probably be learned at any time in the progression, because the risk of failure of an iliac branching is essentially the same as the result with the standard-of-care EVAR procedures—you have a functionally embolized branch.

I think that in 2010, the fenestrated grafts by Cook Medical (Bloomington, IN) will be approved for use in the United States. Other companies such as Endologix, Inc. (Irvine, CA), Medtronic, Inc. (Minneapolis, MN), and W. L. Gore & Associates (Flagstaff, AZ) are all looking at fenestrated and branched grafts and contemplating how to put their own programs together. This year will be a big year for this type of technology, but the bar for success is also continually rising.

What are some of the new EVAR technologies you are using or looking forward to using?

Dr. Greenberg: I think the iliac branch technology is going to be much more important than people believe. It has the potential to be a technology that is used on a daily basis in many hospitals that treat patients with aortoiliac aneurysms. At all the meetings, we hear discussions over whether or not to embolize the internal iliac, does this cause claudication, etc. Perhaps 2010 will prove to be a year that ends some of those debates; once there is an option for avoiding the creation of claudication, everyone should embrace it. We spend more than $1 billion each year trying to treat claudication in the superficial femoral artery, so I can't understand how people will be able to justify creating claudication in the setting of an aneurysm when there is another option. ■

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