Multispecialty EVAR Intervention

Interventional radiologist Barry T. Katzen, MD, FACC, FACR, FSIR, explains his role in the early development of endograft procedures and shares his perspective on device development and the value of live-case meetings.

As an interventional radiologist, what made you become so heavily involved in treating aortic aneurysms, commonly the domain of vascular surgeons in the United States?

Dr. Katzen: Endovascular aneurysm repair (EVAR) developed in the late 1980s and early 1990s as an offshoot of the development of stents. Very innovative people started thinking what could be done if stents and fabrics were combined. In fact, one of the first reports of using a covered stent to repair a hole in an artery actually was performed at our institution in 1990. In the early 1990s, I was aware of Dr. Juan Parodi's first endograft procedure, and I was also aware of one of the early endograft research trials in the United States. I became interested in the Ancure trial and approached the device manufacturer (Guidant Corporation) to become more involved, convincing them of the importance of having the skill set of an interventional radiologist in their trial. At that time, they were dealing with almost 100% vascular surgeons and approaching the technology challenges from a surgical perspective.

My career commitment had been and continues to be to less-invasive therapies, and the development of stent grafts represented the next step in being able to treat patients less invasively in the vascular system. I developed a very early interest, and as a result, I became the only radiology principal investigator in the first endograft trials.

Did you encounter any resistance, particularly given that you were among the earliest interventional physicians of any background to become involved in EVAR?

Dr. Katzen: There was not a political resistance; there was the question of why radiologists should be involved. To me, the question was the other way around—how can you do this procedure without radiologists? At that time, interventional radiologists had the technical skills with guidewires and catheters and understood these types of devices and how they perform in the body. We were developing this new application for aneurysm therapy, and vascular surgeons at that time had little or no experience with guidewires and catheters and the types of devices that would be necessary to treat aneurysm patients effectively. Interventional radiologists brought all of the technical skills to allow completing these challenging cases safely. As endograft trials developed, approximately 30% to 40% of the sites actually had surgeons and radiologists working together.

What are some of the more dramatic changes you have seen in the way EVAR is both performed and perceived?

Dr. Katzen: It has been exciting to see the transition of EVAR from a research tool, which was met with great skepticism by the surgical community in particular, to a procedure that is now considered a standard of care. Those of us involved in treating aneurysms are looking at whether this technology should be expanded to treat younger patients with more ideal anatomy rather than be reserved for older patients. That has been the biggest change—watching it go from an investigational procedure to a standard-of-care procedure. Additionally, EVAR has become progressively less invasive, with dramatic reductions in the incidence of conversion to open surgery.

Based on follow-up results from your early experience, what are your beliefs regarding long-term safety and efficacy of EVAR?

Dr. Katzen: I believe EVAR is a very effective procedure in both the short and long term. As devices have

improved, long-term efficacy seems to be getting better and better. Some of the concerns with earlier devices, such as limb thrombosis, device migration, loss of integrity of the devices, and the need to open a patient surgically, have decreased to negligible levels.

To what degree can those data be applied to newer device iterations with different designs, materials, and fixation modes?

Dr. Katzen: The data that we have so far have gradually become the standard against which all new EVAR devices are compared. In development of medical technology, new devices must bring improvements; they can't just be "me-too" devices. They must bring improvements to society, the operator, or the patient. There is still plenty of need in EVAR: we need smaller devices, we need to address the persistence of endoleaks, etc. There are still many patients who are not candidates for endografts because of unsuitable anatomy.

Do you think it is possible for EVAR to hit a point at which further device development is not necessary?

Dr. Katzen: We are on a steep upcurve. I believe it is possible with devices such as aortic valves that at some point the development curve is going to become flatter. There is still opportunity for increased utilization and improved development. I think there is a time, of course, in any technology when it reaches the pinnacle of its development and can't go much further. I do not think that is the case with EVAR yet.

With the cost of development and clinical evaluation, what level of outcomes would cross over the cost-versus-need threshold?

Dr. Katzen: It is very expensive in the United States to bring these devices to market—the regulatory environment needs to be modified to streamline things based on the knowledge that we already have. That is a long-range project. The FDA is very aware of it, and I believe that they are working to try and improve the situation. That being said, each incremental improvement has certain value. Currently, the mortality rate for an EVAR procedure is 1% to 2% for elective patients. It is going to be very difficult to get an incremental improvement for EVAR mortality rates based on technology. However, if devices could be deployed in 20% more of the population who need treatment, that would have value. If we could get a device that would eliminate or avoid the presence of endoleaks, that would have value.

The other factor in development is the cost of manufacturing. Industry, in developing these technologies, needs to look at the cost of manufacturing as a way of reducing overall cost. I believe that you can't say if we cut the mortality in half, that's worth x-thousand dollars. There is not room to do that. My personal vision is that endograft repair will one day be an outpatient procedure, and I believe that is the goal that we need to be collectively moving toward.

How would you describe the role of live-case CME meetings in helping physicians stay current on the latest EVAR techniques and approaches?

Dr. Katzen: Critical. Live-case meetings are the only way to work together with a large group of people on the technical issues in an interactive way. We can do it one on one with visiting fellowships and going to labs or operating rooms, for example, but live-case meetings provide such valuable information to a larger number of people simultaneously, and I think it is crucial to advancing technology.

And the role of multispecialty interaction at nonsocietal meetings?

Dr. Katzen: I am a huge believer in multispecialty collaboration. It is the fundamental foundation of Baptist Cardiac and Vascular Institute. What we have developed here in the last 20 years is built on a couple of important goals. One is synergy. We take attributes of people from various disciplines and get 1 + 1 = 3. We try and do that in all areas of cardiovascular care—not just the endovascular arena. There is so much we can learn from each other. Frankly, as technology becomes more complex and the pressures on us become more diverse, we ask who can be an expert in absolutely everything. A second goal is to make sure that everyone has opportunities for professional growth and development within the structure of health care delivery.

From my perspective, there are two options in regard to endograft procedures: one person does it all, or a team does it all. The team approach financially costs everybody a little bit more because everybody makes a little less on a specific patient and procedure, but there is much for everyone to do during a case. In the event of an adverse event, a technical challenge, or unexpected findings, you always have the skills of more than one individual available, which for us ensures extremely good outcomes. ■

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