Ken Ouriel, MD

The Cleveland Clinic's Chief of Surgery and Vascular Surgery offers insights on EVAR, CAS, and the need for board certification in vascular surgery.

How would you describe the current state of endovascular aneurysm repair?

I think endovascular repair is a huge advancement for both the patient and the practitioners. The procedure is not yet where we would like it to be in terms of our results or long-term durability, but it competes very favorably with open surgical repair, and many patients are willing to accept a decrement in durability to have less time in the hospital, less pain, and a quicker return to normal activities. We have, however, perhaps adopted some unreal expectations for a new technology. Vascular surgeons in particular have been dissatisfied with the results, but I think the problem is in the level of expectation. If we have our expectations in line with what a new technology can do, we should be willing to wait for newer devices with which our results will eventually be equal to or even superior to open surgery.

What has been the experience with this technology and its implementation at The Cleveland Clinic?

The Cleveland Clinic wants to be at the forefront of just about every major advance in medicine, so for endovascular aneurysm repair, we started early. In 1996, we began to enroll patients in trials, and we were fortunate enough to have a great number of patients; over the last 7 years, we have an experience of over 1,000 endovascular aneurysm repairs. We've used just about every device that has come out, and we also have been a part of most of the trials, in terms of managing those trials. Rather than just being a participating center, we want to actually run the trials. For example, Dr. Roy Greenberg's been the principal investigator for the Cook Zenith trial, and I've been the principal investigator for the Cordis endograft trial. We are the core lab for a variety of trials, including the Ancure trial, the Zenith trial, the Gore trial, the Anaconda trial, and the Cordis trial.

Will endovascular AAA repair become the gold standard? If so, when?

Yes, I think it will eventually replace open surgery for the vast majority of patients. There will always be some cases that require open surgery, but for the most part, it will comprise most of the procedures we do, at least for infrarenal aneurysms. I think that endovascular repair is awaiting the development of new technology, as well as the completion of some ongoing trials. We have two randomized trials—the DREAM trial in Europe and the OVER trial from the VA group. When that data become available and with the development of newer, more durable devices, I think we'll see the market being increasingly endovascular rather than open surgery. How long will it take? It depends at which threshold you put it. If we're currently close to 30% endovascular and 70% open, to get to 80% endovascular and 20% open, I think we're looking at 5 to 10 years.

What kinds of advancements need to be made on the technology side?

Durability. When you put a device in, you don't want to have to go back and perform secondary procedures for different problems. Honestly, I think that the diameter needs to get smaller. There's no reason, in my mind, that we shouldn't be striving for a percutaneous technology, as long as it does not compromise durability.

What improvements do you see being made or that need to be made in the early diagnosis of aneurysms?

We obviously need screening, and I am very optimistic that we're going to get a bill with screening in it from Congress, perhaps even this year. My guess is that the screening will be reimbursed for Medicare-aged patients—for all males and a select subset of females with risk factors.

What are your thoughts on a "Centers of Excellence" approach to endovascular aneurysm repair?

I actually have thoughts about that for every procedure, not just endovascular aneurysm repair. I think that it makes sense for patients to go to a place where doctors are performing a high volume of any particular procedure, be it carotid endarterectomy, aortic aneurysms, open or

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endovascular, it doesn't matter. I ascribe to the philosophy of having centers of excellence, but, that said, I don't think it's something that's going to happen instantaneously in this country. It may never happen, so I think it's "buyer beware." The patients have to do some research and make sure that the facility they go to performs enough of their specific procedure and has excellent results with that procedure.

What kind of improvements do you think can be made in terms of credentialing and training for procedures such as these?

Credentialing is really a local issue. It's done by the hospitals, and we can't mandate credentialing from a society or national level. I think that's reasonable, because different facilities and geographic regions may need to have different standards. If you're out in the middle of the wilderness, and you've got only general surgeons, it would be silly not to give your general surgeons privileges to do aneurysm repair, because how else could they save a patient with a ruptured aneurysm? I think we should keep credentialing local, but we should provide guidelines on a national level, and hospitals can choose to follow them or perhaps have more lax or more strict credentials.

What are your thoughts on vascular surgery needing its own board certification?

Vascular surgery is a subspecialty in and of itself. As such, it deserves to have a specialty classification and a separate board—there's no question in my mind. The American Board of Surgery, of which vascular surgery is a part right now, voted recently to approve a primary certificate in vascular surgery. What that means is, in order to have a certificate in vascular surgery, you would not have to be board certified in general surgery. It will take a couple of years for that to actually materialize, but it will change the paradigm from first getting your general surgery certificate and then getting added qualifications in vascular surgery; the new paradigm will be that individuals can choose to never be board certified in general surgery, but receive a certificate in vascular surgery. In fact, they voted on three options for such certification: one of having 3 years of a general surgical residency followed by 3 years of vascular surgery subspecialty training, in which you wouldn't be boarded in general surgery, but you would in vascular surgery, the second would be to have 4 years in general surgery and 2 years in vascular surgery, and the final choice is just to have it the way it is now—5 years of general surgery and 1 or 2 years of vascular surgery. It will take somewhere from 1 to 2 years for this plan to materialize; it has to be approved by other bodies before it can be implemented.

We need a primary certification, but I don't think it's enough. I don't think it makes sense for specialties such as colorectal surgery, which is very close to general surgery in what they do, to have their own separate board, but vascular surgery does not. Vascular surgery and general surgery are becoming increasingly divergent in what they do. To me, two specialties so different deserve separate boards.

FAST FACTS

- Appointed Chief of Vascular Surgery at the Cleveland Clinic in 1998
- Appointed Chief of Surgery at the Cleveland Clinic in 2003
- Completed the first large multicenter study of urokinase vs surgery (published in the *NEJM* in 1998)

What is the timetable? What is the likelihood that we'll see the vascular surgery board certification soon?

I think it's extremely unlikely that we'll see it soon, and we may not see it at all. But that said, I really think it should happen. I am just not optimistic that it will happen soon.

What are some of the more innovative ways that lytic therapies can be used today?

Some of the more innovative strategies for lytic therapies combine lytic therapy with mechanical thrombectomy devices. We've been interested in working with the Possis system and with the Bacchus devices to use them as adjuvants to pharmacologic lytic therapy. What we found is that although we love these mechanical devices, it's rare that they actually will replace the need for pharmacologic thrombolysis. In other words, even though we can clear out a lot of clot with these devices, we still have to infuse agents such as urokinase to get rid of the rest of the thrombus.

We also have some new lytic agents. One of the agents I'm interested in is called alfimeprase, which is a direct fibrinolytic agent. It doesn't require the conversion of plasminogen to plasmin to dissolve fibrin; it can directly dissolve it. This results in a quicker thrombolysis, or at least it has so far in animals. Alfimeprase also has the potential to be safer, because it is inactivated by a protein—alpha 2 macroglobulin—that is floating around in our blood. The agent is released systemically, because it always does leak into the circulation, is rapidly inactived by alpha 2 macroglobulin so that it can't dissolve clots in other places in the body. The bleeding risk is potentially diminished with this new agent.

Do you see any other developments in the field of lytic therapy on the way?

One thing I'm interested in is protection devices for lytic therapy. We use them during carotid stenting to catch the emboli that are released. We frequently see distal embolization when we perform thrombolysis in the leg, and why not have a protection device that will catch any embolus that is discharged? This is a development I think we'll see soon.

What are your thoughts on the near future of carotid stenting?

What is really important for carotid stenting right now is not simply getting an approval for a device. That's not going to help us perform carotid stenting. What is really important is to get CMS coverage. Every patient on whom we currently perform the procedure has to either pay for it themselves or be part of a trial that is formal enough that we have coverage for the IDE involved in that trial. So while we're all concerned whether the SAPPHIRE data are going to be acceptable to the FDA, an equally important issue is going to be CMS reimbursement.

What kind of work has to be done to get the CMS reimbursement?

First of all, CMS is not going to reimburse anything unless it's approved by the FDA, so the FDA has to approve the PMA for SAPPHIRE, which is the first PMA that will come up. Once we have FDA approval, then CMS needs to see some evidence in peer-review journals that show that this is a safe and effective form of therapy. Then, if all the specialties—radiology, cardiology, vascular surgery, and neurology—as a team are all in favor of carotid stenting, then CMS is going to fund its Medicare and Medicaid patients to undergo the procedure. On the other hand, if some specialties support it while others do not, then it will take a lot longer. In any event, carotid stenting is a procedure that is here to stay, and disharmony between specialty groups will do nothing more than delay its approval.

It is very clear that you are passionate about all things related to your profession. What are some of your passions outside of practicing medicine?

Number one is snow skiing, I'm an avid alpine snow skier. We have a place in Vail, and we spend 3 weeks a year there. We'll be in Snowmass again for the Peripheral Vascular Surgery Society meeting. I also enjoy biking, both on the road and mountain trails. I have three kids that I like to spend a lot of time with, one in college, two in high school, and my wife and I spend a lot of time with our kids doing mostly outside activities. ■

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