Timur Sarac, MD

Yale's new Chief of Vascular Surgery discusses aneurysm treatment thresholds, malperfusion syndrome, serving with the United States Army, and developing a novel type of stent.

Before becoming Chief of Vascular Surgery at Yale, you were with the Cleveland Clinic for 15 years. What are the challenges and advantages of practicing in a large institution in today's health care environment?

One of the greatest benefits of being in a place such as the Cleveland Clinic or another large clinical institution is that it is truly able to put together a consortium of clinicians who are experts. You are interacting with the top physicians, and it is very good for patient care because you can always get an expert opinion from someone who is highly specialized in a specific disease process. The Cleveland Clinic is primarily an institute-based clinical program, and that is a huge benefit for patient care due to the highly focused subspecialties.

Another benefit is having a multispecialty group; the collaborative approach is unbelievable. I think there is currently a shift to a different level of provider-based care, in which the hospital owns the practices and the physicians are employees of the hospital; there is more of a salary-based reimbursement than on an individual patient basis. The reason is that it makes health care much more efficient. Physicians utilize the joint resources and do whatever is possible to make patient care better. This approach may hurt some of the smaller hospitals, so they are more often merging with the bigger groups and practices. The Clinic started acquiring smaller centers 15 years ago and now has nine hospitals, and it does improve resource utilization.

The disadvantage of an institution that large is that sometimes the left hand doesn't know what the right hand is doing. The Clinic does a really good job communicating with everyone, and that's the key—communicating with the staff and keeping pace with all of the changes going on in health care. There are 14 doctors in the Clinic's main campus vascular surgery department alone, so there are great efforts to communicate and have everyone understand what is happening.

The Cleveland Clinic has played a significant role in studying the endovascular treatment of abdominal aortic aneurysms at both ends of the size and complexity spectrum. After serving as an investigator in PIVOTAL, studying the treatment of small aneurysms, what is your current threshold for offering therapy?

The PIVOTAL trial looked at aneurysms between 4 and 5 cm. There were also two other small aneurysm trials: the ADAM trial, which looked at aneurysms ≥ 4 cm and ≤ 5.4 cm, and the UK Small Aneurysm trial, which looked at aneurysms that reached 5.5 cm.

The results of the trials demonstrated that you can provide conservative therapy for patients with aneurysms up to 5.5 cm and the risk of rupture is quite low. However, you have to take things into context. One of the best articles was by Ouriel et al and looked at aneurysms by patient size. In that article, which is 15 or 20 years old now, they found that the size of the aorta relative to the patient's body size (vertebra size) might be a better indicator than absolute aortic size. So, a 5-cm aneurysm in a woman who is 4'11" is going to pose a greater risk than an aneurysm of the same size in a man who is 6'3".

The study didn't change the threshold, but it taught us that we should take everything into context regarding the specific patient. Additionally, we are much more cognizant of risk factor reduction, such as antihypertensive control and tobacco use cessation.

What advice can you offer regarding counseling patients whose aneurysms do not yet require treatment, but who would still prefer to have something done to protect them from rupture?

Many times, a patient will come to us and say, "I just want it fixed," and we have to explain the risks versus benefits of having the aneurysm repaired. If a 50-year-old patient with a 4.8-cm aneurysm says he wants the aneurysm repaired, you have to say, "What are the odds that the aneurysm is going to go from 4.8 to 5 to 5.5 cm?" It is likely the patient's aneurysm will increase in size to reach the threshold of repair.

On the other hand, if you have an 84-year-old patient who is on home oxygen, in kidney failure, and has a 4.8-cm aneurysm, you're probably going to say the risk of this rupture is under 1% and not to worry. Most patients really trust what we are telling them, but with the Internet, patients are researching online and usually have a good understanding of the disease process. However, our job is to educate the patients about what information is truly relevant to their specific situation.

What is your strategy for managing malperfusion syndrome from type B dissections?

Most of the patients who present with malperfusion syndrome fall under one of two categories. There are patients

(Continued on page 97)

(Continued from page 98)

who are acute, who have to be treated immediately, or the risk of end-organ ischemia will be catastrophic. They really need to be treated in under an hour; you want to get these patients with symptoms of mesenteric ischemia, limb ischemia, or spinal cord ischemia to the operating room quickly.

There is also a subset of patients who have waxing and waning symptoms because the aortic dissection flap is dynamic. Those patients must be followed closely, too, because the dynamic flap can change and lead to ischemia. In this group, there are also those with enlarging aortas and patients with near-total collapse of the true lumen. Those are the patients who we call subacute, and the symptoms can crescendo in nature. Although asymptomatic patients can be managed medically, we tend to be a little more aggressive in treating the patients with waxing and waning symptoms before they progress to end-organ ischemia.

Could you tell us about your experience serving with the United States Army during Operation Iraqi and Enduring Freedom and receiving the Commendation Medal? How did this come about, and has it affected your view on medicine or your daily practice in any way?

I was in the Reserves for 16 or 17 years. It was really an honor to be a part of it, and I met some of the most spectacular physicians and people to work with. Colonel Todd Rasmussen, MD, is still on active duty in the Air Force, and we remain collaborative to this day. I hold in the highest regard the incredible physicians and clinicians who were on the front line. I was at the Walter Reed Army Medical Center, and we had patients coming in to be treated 24 hours a day, but the guys who were being called to the front are the real heroes.

Even more spectacular were the soldiers we treated. They gave me confidence about the next generation of Americans. Those kids were unbelievable—they all wanted to go back and be with their groups after they were treated. Anybody who was hurt wanted to go back to the front line; there was not one patient I treated who did not want to go back and take care of his comrades in arms and fight for our country.

It was great working with Colonel Sean O'Donnell, MD, and Dr. Rasmussen to bring endovascular therapy to the military. It was not easy to do because the use of prostheses at that time was not understood, and it was not a sophisticated process. We had to navigate another layer of bureaucracy to be able to treat the soldiers with minimally invasive therapy. Both Drs. O'Donnell and Rasmussen really helped me, and they did this in a spectacular way because the next generation of physicians who came through had complete access to treating the injured soldiers with endovascular therapy.

You have patents for devices focused on lower extremity occlusive disease, percutaneous aneurysm repair with an M-stent, developments for percutaneous prosthetic valves, and you are the inventor of a tissue-lined stent. What can you tell us about the thought process that led to this invention?

When I was a resident, I worked with Dr. James DeWeese, one of the early pioneers in vascular surgery. In the middle of the night, we were operating on a patient with a ruptured aneurysm, and there was blood sticking to everything and clotting everywhere except on the peritoneal cavity.

It was a long time before I took the tissue-lined stent idea into the development process. When researching it, I realized the cardiac surgeons were 20 years ahead of us because they took similar tissue, the pericardium, as a thromboresistant surface, and all the heart valves were made of pericardium. The peritoneum is five times thinner than the pericardium, which allowed us to put it in stents.

The whole idea here is the hybrid technology of marrying tissue to the metal stent. We were initially working with using this as a platform technology to use in all stents, but it turns out that's probably not the best way of doing it. We had to make our own stent for this purpose, which is a very novel stent, too, and create a new delivery system because the tissue must be stored in moist conditions. It was a huge effort to create a delivery system because it has to be crimped on the table. Our initial delivery system took 15 minutes to crimp, which was not a commercially viable way of doing it. Now we do it in 30 seconds.

The difficult part of this, as in any startup company, is getting venture capital or industry to sponsor a large clinical trial. The cost of running a clinical trial is in the tens of millions of dollars, and that part of it has been frustrating.

Are you currently working on any new device ideas that are in a stage that can be discussed publicly?

There are two: one is a bioabsorbable tissue-lined stent graft, and the other is a large-bore closure device. As part of the military, we worry about putting stents in soldiers who are 18 years old and maintaining the durability for prostheses lasting 60 years. We are in the middle of working on a stent that dissolves with tissue. The tissue heals and the stent dissolves, so it mimics vessel autoregeneration. To date, that has been supported by grants from the United States military (Armed Forces Institute of Regenerative Medicine).

I've been working on that for 5 years and still have a long way to go. ■

Timur Sarac, MD, is Chief of Vascular Surgery, Yale University School of Medicine in New Haven, Connecticut and Co-Director of the Heart and Vascular Center at Yale New Haven Hospital. He has disclosed that he is founder and stock holder of PeriTec Biosciences and owns several patents. Dr. Sarac may be reached at (203) 785-2222; timur.sarac@yale.edu.