Karthikeshwar Kasirajan, MD

A leading vascular surgeon discusses the THRIVE and UNITE trials, his research on carotid stenting and thoracic endografting, and alternative indications for TEVAR.

The THRIVE (Descending Thoracic Aortic Aneurysm Endovascular Repair) trial recently began enrolling patients. As principal investigator, what can you tell us about this study? What primary and secondary endpoints will be collected?

THRIVE will enroll a total of 451 patients at a minimum of 15 sites in the United States. The study's primary endpoint is freedom from aneurysm-related mortality—defined as death from aneurysm rupture or from any procedure intended to treat the segment targeted by the Talent thoracic stent graft (Medtronic, Inc., Minneapolis, MN) system—at 5 years.

The study design incorporates the test group of 195 subjects from the earlier study that supported the device's US Food and Drug Administration (FDA) approval in 2008, as well as an additional 256 new subjects to be prospectively enrolled. All subjects will be followed for 5 years. A variety of secondary endpoints will also be collected, such as stroke, paraplegia, early and late endoleaks, device integrity, etc. Our team performed the first study implant on April 20, 2009, at Emory University Hospital in Atlanta.

You are also the Co-National Principal Investigator for the UNITE (Safety and Efficacy of the UniFit Aorto-Uni-Iliac Endoluminal Stent Graft for the Repair of Abdominal Aortic Aneurysms) trial. What can you tell us about the progress of this study?

This is a niche aorto-uni-iliac product, so enrollment has been slow—to date, roughly one-third of the enrollment has been completed. The main indications for this device are severe proximal neck angulations (> 60°), unilateral iliac occlusive disease, large proximal aortic neck diameters (up to 36 mm), or tight distal aortic bifurcations that exclude usage of commercial bifurcated devices. Additionally, patients cannot be open surgical candidates. The device (UniFit abdominal aortic stent graft, LeMaitre Vascular, Inc., Burlington, MA) is custom made for each patient and comes in lengths up to 24 cm with proximal diameters up to 40 mm. The FDA recently approved an upgraded delivery system for the device that incorporates hydrophilic coating and increased flexibility. In my practice, the availability of this device allows me to treat an additional 5% of patients who would have been denied therapy due to anatomic constraints or medical risk factors.

You have expressed interest in initiating your own (not industry sponsored) studies. What do you propose to research?

I had a great interest in carotid stents for a while due to a large referral of patients specifically sent to me for carotid stenting (these were typically patients with anatomic risk factors that increase the risk of open surgery, such as prior carotid endarterectomy [CEA], radiation to the neck, etc). In my own practice, the risk of clinically significant stroke is less than 1% in this patient subgroup. However, I had an interest in what is referred to as *silent infarcts*, which are visible in the postprocedural imaging studies of the brain. For a long time, these have been thought to be clinically insignificant; however, some recent data suggest that patients with these microinfarcts may be more likely to suffer from a gradual loss of cognitive function, referred to as *vascular dementia*, many years later. Interestingly, after CEA, very few of these microinfarcts are visible in the brain. It is my opinion that any endovascular procedure should be able to approach this safety benchmark established by CEA. Unfortunately, the need to cross the lesion and the pores in the filters that allow antegrade blood flow during the carotid artery stenting typically cause these microparticles to reach the brain. Recently, the FDA approved the Gore Flow Reversal System (W. L. Gore & Associates, Flagstaff, AZ)

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that does not require crossing the lesion without cerebral protection and allows total protection during the percutaneous transluminal angioplasty/stenting phase by reversing blood flow in the target carotid artery. I have been studying patients using transcranial Doppler imaging by comparing filters, flow reversal, and CEA; on average, flow filters have about 250 embolic high-intensity transients, and both flow reversal and CEA have < 10 microembolic particles that reach the brain. I'm interested in researching what this actually means for patients by means of long-term cognitive function tests and magnetic resonance angiograms posttreatment.

Another topic of interest is the use of thoracic endografts for the management of patients with chronic dissection with aneurysmal degeneration of the false lumen. This typically happens a few years after the acute type B dissection. Physicians have expressed concern that the dissection flap is too thick at this point to allow for remodeling. This theoretical concern is mostly based on the intraoperative findings when performing open surgery on this patient subset. My experience, and other larger series from Dr. Ted Dietrich's group and Dr. Rod White's group, has demonstrated that thoracic stent grafts (TSGs) can be effective in the management of these patients. I do not believe patient preference will allow a prospective randomized study. It has been my interest to have a registry to evaluate the long-term efficacy of this treatment.

Although thoracic endovascular aneurysm repair (TEVAR) is currently indicated only for use in treating descending thoracic aortic aneurysms, are there indications for treating nonaneurysmal thoracic patients with endografting?

TSGs can benefit a wide variety of disorders, which include traumatic transections, acute and chronic dissections, pseudoaneurysms, aortobronchial or tracheal fistula, "shaggy aorta," adult coarctation, and penetrating ulcers. I recently returned from a business trip to China and Japan. The incidence of thoracic aneurysm, especially dissections, appears to be larger than the overall incidence of abdominal aortic aneurysms in Asia. Physicians in this part of the world have been treating these with custom-made devices with great success for many years. Of the physicians I had the opportunity of observing in Japan, a few had a personal experience in treating > 1,000 TSGs, which dwarfs the experience of most surgeons in the United States. Custom-made fenestrated arch endografts and dissection-specific devices appear to have made these procedures quite safe compared with the open surgical approach, in their hands. I would not be surprised if in 5 or more years all dissections are treated with TSGs specifically designed for this purpose.

What developments for the treatment of thoracic aortic pathologies do you anticipate we will see over the next 5 years?

Branched and fenestrated grafts, and lower-profile devices with better approximation to the inner curve of the aorta, to name a few. Fixation by staples or screws, as used in the infrarenal Aptus endografts (Aptus Endosystems Inc., Sunnyvale, CA) (championed by Dr. David Deaton), may become the new standard of care. Hooks do not appear to offer reliable fixation in the thoracic aorta, especially in the arch. The tremendous interest in percutaneous aortic valves would soon make TSGs for the ascending aorta a reality. This would be a great advancement for the treatment of acute type A dissections, which are currently the most common acute aortic emergency seen in the United States. ■