Suresh Vedantham, MD

The national principal investigator of the ATTRACT study shares his insights on DVT treatment, regulatory hindrances in the venous space, and the progression of interventional radiology fellowships.

What is the latest update on the ATTRACT study?

As of August 28, 2014, the ATTRACT consortium had enrolled 658 patients, which is 95% of its planned sample. We expect to complete enrollment in 2 to 3 months and have final study results in late 2016. I am proud of our network of investigators, coordinators, and other personnel for pushing on to complete the study as originally designed, which will ensure its scientific credibility. Given the historical challenges with enrolling patients to this kind of trial, I believe this will ultimately be recognized as an incredible collaborative achievement.

Outside of the procedure/therapy itself, what is the biggest barrier to improving DVT care?

I believe the most significant barrier is the basic socioeconomic issue we have with access to health care in the United States. It's heartbreaking how often one sees patients experience adverse outcomes after deep vein thrombosis (DVT) simply due to failure to access medications and treatments that we know work. We've never had so many choices for anticoagulant therapy, but for many patients, it is an insurance company—not a doctor—who decides what treatment will be used.

In addition, I continue to have concerns that although the need for data is better appreciated than before, the endovascular DVT community sometimes seems inclined to take the easy way out in terms of study design, rather than doing the hard work of conducting randomized clinical trials (RCTs) and training our investigators to be able to lead them. Ultimately, the only way for endovascular procedures to be evaluated in an unbiased way will be through RCTs. Registries have their place, but the future belongs to treatments that are validated in RCTs.

Finally, I still find that many medical physicians lack a strong understanding of endovascular DVT care, and many proceduralists fail to appreciate the benefits of traditional DVT care. Significant evolution in our educational paradigms is needed to ensure that all physicians appreciate what other subspecialists can offer. Only then will DVT care become a patient-centered enterprise, in which the patient can choose what approach he or she prefers from a menu of evidence-based treatment options, about which balanced information is provided.

How will the new SIR/CIRSE quality improvement guidelines for endovascular DVT treatment in the lower extremities affect practice?

The revised SIR/CIRSE guidelines provide a framework around which hospitals and practices can build quality improvement programs for DVT care. The most important changes from the previous (2006) guidelines are more stringent standards for complication rates (reflecting the evolution of practice), a focus on encouraging longitudinal care to assess late outcomes and avoid preventable complications such as those from caval filter implantation, and sections that summarize ways to avoid treatment-related bleeding and pulmonary embolism.

Can you tell us about your research in chronic DVT?

For many years, my clinical practice has been devoted to helping patients who have developed postthrombotic syndrome (PTS) from chronic DVT. Many of these patients experience profound disability from their disease. I have been very impressed with the results we have achieved by melding endovascular treatment strategies with standard elements of DVT care. In many cases, we have transformed the lives of patients who have experienced major disability from their PTS for 10 years or more. However, because these approaches are invasive and costly, with limited high-quality supporting evidence, endovascular treatment is only used in a tiny fraction of patients with PTS. We are also starting to see insurance companies challenge the ability of patients to receive these treatments, which is an ominous trend that can only be addressed with compelling, high-quality data from rigorously designed clinical trials.

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The good news: I am pleased to announce that in August 2014, the National Institutes of Health (NIH) awarded Washington University in St. Louis, under my direction as principal investigator, a new 2-year grant to develop a pivotal clinical trial to evaluate the endovascular treatment of severe PTS. This trial, the C-TRACT (Chronic Thrombosis–Relief with Adjunctive Catheter-Based Therapy) study, is seeking interested sites and will hopefully be underway in 2 to 3 years. To prepare for trial participation, I strongly encourage physicians with solid endovascular skills and experience with chronic DVT to build collaborations with wound care centers, primary care physicians, medical thrombosis experts, and others who can contribute to a multidisciplinary team approach to PTS care.

In the absence of a predetermined regulatory path for venous stenting, what are your thoughts on the best way to navigate the uncharted territory of working with the FDA in this space?

It's important for endovascular physicians to educate the US Food and Drug Administration (FDA) on the patients' needs by focusing not just on the technical aspects of stents, but also on the way venous outcomes are best evaluated and the integration of device-based procedures into overall strategies for venous disease treatment. Being product-focused, industry and the FDA naturally focus on the devices; however, the latter considerations are very important, and our efforts to address them with the FDA are underdeveloped. To expect a regulatory approach that is constructive and patient-centered, we need to help the FDA to understand how stents figure into the real world of clinical care, where a number of treatment options can be used in complementary ways. By doing so, we can also encourage our industry partners to design studies that best identify patient benefits where they exist.

How have interventional radiology fellowships and their goals changed from the time that you had your fellowship to now?

Interventional radiology is an incredible subspecialty and one that has literally reinvented itself during the last 20 years. In today's interventional radiology world, it is expected for trainees to receive robust exposure to image-guided therapeutic medicine in the clinic, outpatient-procedural, and inpatient-procedural settings. Whereas the trainees of my generation were focused on obtaining maximum technical expertise, today's trainees know that they must also obtain outstanding clinical skills and are willing to push the system forward to ensure it. I believe that we must, like many subspecialties that offer disease-based fellowships, robustly incorporate research education into interventional radiology fellow training—it is the only way we can expect to lead the pivotal research efforts of the future, and our health care system is going to be hungry for quality research on image-guided procedures. Overall, the evolution of interventional radiology training to a more balanced, integrated exposure to clinical management, imaging, and image-guided procedures, as envisioned by the new interventional radiology residency, will pay huge dividends for our field in the long run. ■

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