The Long and Winding Road

For several years now, we have seen the arsenal of techniques used to treat superficial femoral artery (SFA) disease continually expand. New classes of devices have emerged, and seemingly countless next-generation iterations of previous designs have been developed. There are numerous stents and stent grafts, some approved for this anatomy and others widely used off-label. There are no less than four atherectomy devices available in the United States, as well as a growing array of balloon technologies ranging from standard angioplasty to cryoplasty, cutting and scoring balloons, plaque-modifying (warm) balloons, and balloons with embolic protection, just to name a few. We also have the prospect of exciting new technologies such as drug-eluting balloons and drug-eluting stents becoming available sometime in the near future.

The reason for all of this development? Simply put, not much works well for SFA disease. We have learned over the years that plain old balloon angioplasty only provides satisfactory long-term patency for focal (< 4 cm) lesions. Nitinol stents seem to improve results for lesions up to 15 cm in length, but there remain concerns about the problems of in-stent restenosis and stent fracture. There are very little data about the effectiveness of stents for longer (>15 cm) lesions or those pesky occlusions over the entire length of the SFA. The data regarding stent grafts are mixed, with the recent VIBRANT trial not demonstrating clear benefit of stent grafts over bare-metal stents in the SFA.

Despite the wide variety of devices being used every day in the SFA, the data supporting these technologies are limited. Many of the currently available devices were not cleared through the more rigorous premarket-approval evaluation route, instead gaining 510(k) marketing clearance based on predicate devices and limited data. Many other devices have gained 510(k) approval through small, prospective registries. The safety and immediate efficacy of the new devices is sufficiently validated by these small studies, allowing for responsible clearance by the Food and Drug Administration, but the lack of comparative data leaves clinicians wondering whether these newer (and often more expensive) technologies are any better than existing devices.

The simple fact is we need more data. We need more comparative data, and we need more carefully done, prospective multicenter registries. In this difficult economic environment in which government funding for this type of research is limited, we must continue to forge partnerships with industry and push them to do the types of studies that will address many of our concerns and questions. We also need our partners in industry to conduct more studies to gain vascular indications for their devices so that we can stop using so many devices in an off-label manner. Thankfully, this is happening.

It is in this spirit that we bring you this issue of *Endovascular Today*, which focuses on current studies pertaining to devices for SFA intervention. Although this is by no means an all-inclusive catalog, and many of these studies are still ongoing, these articles will provide you with a snapshot of the important ongoing research in this area. Some of this investigation involves technologies that have not yet achieved market approval, and other studies provide new data on previously approved devices. Many of the lead investigators for these studies will describe the rationale for these trials, their designs and goals, and, where available, some of the preliminary data.

We will continue to update these studies as they report their milestones and provide commentary on the larger trends observed. Until then, we hope these in-progress reports help to spread the word about the efforts that are underway, with an eye toward furthering our knowledge about how best to care for patients with SFA disease. ■

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