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With many treatment choices available for SFA disease, Dr. Garcia shares how he determines which therapy is right for each patient, as well as his current research endeavors.

What level of symptoms dictates that a patient should undergo vascular intervention for superficial femoral artery (SFA) disease?

The answer may be elusive in some patients. The typical response is that revascularization is necessary when lifestyle-limiting claudication occurs. This limitation, however, takes several forms, which to one person may not be critical, but to another may be significant. For example, a grandparent with limited mobility would be happy to ambulate enough to follow his or her grandchildren through the course of a day, which may only necessitate walking 200 to 500 feet at any one time. But this distance may not be enough for a golfer, for example, who can only walk two holes instead of his or her usual nine or 18.



With all of the device options available for treating SFA disease, how do you decide which platform is best for a particular patient?

The SFA remains a very difficult location to determine the best endovascular treatment method based on current evidence. If we look at all of the currently available devices, we can generally place them into several key categories: medical therapy, balloon angioplasty, stent placement (open or graft), and atheroablative technology (excisional, laser, or rotational). All patients, regardless of lesion status, should receive best medical therapy and include an exercise program (when appropriate), hypertension control, and lipid/diabetes control. To me, the data, although not crystal clear, have suggested that for short focal lesions (TASC A) in this territory, percutaneous transluminal angioplasty (PTA) is a very good start, with acceptable patency rates of 70% or higher. Other forms of revascularization—stenting or the atheroablative technologies—have equally good results, but the general costs of the atheroablative technologies make this approach for these lesions less attractive unless proven to be more cost effective.

For longer or more complex TASC B or C lesions, ABSOLUTE and the subsequent DURABILITY trials suggest stenting to be far better in the first year than angioplasty alone (63% vs 37%, respectively). However, the benefit of this approach quickly dwindles in the second year such that

the endoprosthesis benefit is nearly lost, although still with a higher primary patency rate compared with angioplasty alone, demonstrated in the 2-year ABSOLUTE data (54% vs 33%, respectively). For longer lesions, the use of covered stent technologies has not translated to improved primary patency rates at the end of the first year, as shown in

VIBRANT (53%). Further, the alternative atheroablative therapies have a poor primary patency rate in the first year at nearly 40% to 50% at this length; the benefit through the second year is similar to that of stents and provides some evidence that a nonstenting approach may afford a long-term clinical and anatomic benefit comparable to stents.

No device to date has shown great utility in long total occlusions and calcified arteries (TASC D) in the SFA. Currently, there are no compelling data in this patient

subset to the point that no trial (with the exception of VIBRANT) has enrolled this type of patient with highly difficult long occlusions or stenoses, and no trial likely will. We have very little data on calcified lesions. What is the best way to treat these lesions? Should we use PTA alone or does this lesion subset require changes in arterial compliance through rotational atherectomy devices to then plaque the artery to then balloon or stent? These data are early in their formulations, and no definitive conclusions can be drawn as of yet on their usefulness or applications in these specific locations.

How would you summarize your own approach to the various lesion types?

For TASC A lesions, I perform PTA first, with provisional stenting second. Atheroablative treatment is acceptable, although the costs may be prohibitive. For TASC B and C, I perform stenting primarily with the understanding that I will have a 50/50 chance that the stent is patent at the end of 2 years. Patients need to be aware of and understand this possibility. Atheroablative technologies may provide primary patency rates in the same ballpark as stents at the end of 2 years and thus may be an attractive approach in this patient group for both clinical and anatomic patency. For TASC D lesions, I suggest starting with stenting. If this

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fails at the end of 6 to 12 months, it is time to consider surgical revascularization.

What remains unclear is in which lesions, if any, drug-eluting balloons or drug-eluting stents will play a role in the SFA. The THUNDER trial and the early registry data from Silver PTX (Cook Medical, Bloomington, IN) seem to show us that in the future, revascularization in the SFA will incorporate these antirestenotic technologies in some form. However, the expectation is high that they will provide a great benefit in this very difficult territory.

What is one of the most important techniques or strategy adjustments you have made since your initial experiences using atherectomy in the SFA?

Early in our experience, we believed that atherectomy was a sound alternative to stenting given the extremely dynamic nature of the SFA; leaving an endoprosthesis behind was less attractive. I would still argue that the clinical benefit of atheroablative technologies is very good. However, clinical benefit and durability are not the same, with the primary patency rates of atherectomy in longer lesions or multilevel disease being near or below 50%. My biggest adjustment has been that we treat longer lesions, TASC C, or the totally occluded, TASC D, arteries with stenting rather than atherectomy with the understanding that we will likely be returning to retreat in 12 months and perform surgical revascularization in 2 to 3 years.

What is the current focus of your research in the SFA?

My principal research focus has been technologic development in the SFA—searching for the “perfect” combination therapy to obtain the best primary patency rate and durable clinical benefit in patients with claudication or limb ischemia.

DEFINITIVE LE is a registry trial evaluating SilverHawk atherectomy (ev3 Inc., Plymouth, MN) in a real-world registry. This trial, in which I serve with Jim McKinsey, MD, of New York, as global principal investigators, will be the largest peripheral trial ever completed to date, evaluating 800 patients with peripheral arterial disease. The protocol includes patients with infrainguinal disease and will treat patients with claudication as well as critical limb ischemia. Patients with diabetes will be evaluated regarding their outcomes with SilverHawk, and we will also perform plaque analysis in a subgroup to further define some proteomic signals in the treatment of our patients with peripheral vascular disease. Primary endpoints will be primary patency rate of the lesions at 12 months, followed further for the claudicant group, and limb salvage rates for the critical limb ischemia patients. The trial is currently enrolling and will likely be completed in late 2010.

SUPERB is a stent registry evaluating the Supera stent (Idev Technologies Inc., Webster, TX) in an objective performance criteria-driven evaluation of the stent for infrainguinal disease. This trial, for which I serve as a co-national principal investigator with Ken Rosenfield, MD, of Boston, will seek US Food and Drug Administration approval for the stent in the SFA. This unique stent with an interwoven nitinol design allows unusually high flexibility without any significant compromise of radial strength. This design allows for the unique vessel forces of the SFA to be relatively unchanged despite the stent presence but still allows significant radial force to scaffold the artery where needed. This trial is currently enrolling and should be completed in 2010.

I also serve as the Data and Safety Monitoring Board chairman for other trials and serve on the steering committees of several other trials.

What are the most significant unanswered clinical questions that future trials and studies must seek to address?

Unfortunately, it remains the same issue that Andreas Grüntzig raised after his PTA result in 1978: PTA may be useful if we can show scientifically that it is superior to surgery. Unfortunately, the data as we know it in the SFA territory are exceedingly poor. In lieu of “getting an indication” for the SFA by enrolling short lesions or the patient subset in which we know the technology performs well, we need to see the data in real-world patients with long SFA lesions and occlusions to know the best evidence-based approach for our patients. We need to be able to effectively discuss with them all of these issues and understand their expectations for any and all outcomes to make the best decision available.

With the economics of health care under intense scrutiny, is there any push to use fewer devices to achieve revascularization? To what degree do economics have an impact on decision making in your practice?

Economics will play an ever-increasing role in our patients’ therapy as it does currently. This is critical to understand in that if a new device looks good or can achieve an open artery but costs several thousand dollars before balloon or stenting, the marginal costs will be exorbitant if the device is used routinely. If, however, that same device is used once with adjunctive therapies that may cost an additional amount but affords greater primary patency and clinical durability compared with other technologies, then I would argue this device would become the default device in the SFA if not elsewhere. It could then be shown to have significant cost savings at the end of 1 year and beyond due to fewer repeat revascularizations compared to other current technologies. ■