FP Angioplasty Versus Stenting:

Stenting in Long, Complex Lesions Is Superior to the "Old Standard"

BY MARK W. MEWISSEN, MD

Endovascular treatment strategies for the relief of symptomatic lower-extremity peripheral vascular disease, secondary to femoropopliteal (FP) artery disease are changing at an unprecedented rate. Improved metallic stent designs, novel devices and techniques, and improvements to past therapeutic concepts have recently emerged, providing new and challenging options to the mainstay of percutaneous transluminal angioplasty (PTA) and surgery. The emergence of these new therapies has unequivocally brought with it contention and controversy; much of this debate is borne of the strong desire held by many to see data that compare the new treatment options to existing therapies. PTA is considered by its proponents to be the endovascular FP disease treatment by which all new technology must be judged. PTA should, in fact, be the first line of therapy for some focal, uncomplicated lesions. However, for long and complex lesions, newer nitinol self-expanding metallic stents have to date yielded results that are challenging PTA to garner the proclaimed title of "gold standard."

THE TASC RECOMMENDATIONS

In 2000, the TransAtlantic Inter-Society Consensus (TASC) Document proposed treatment strategies and recommendations for the management of peripheral arterial disease.[1] For instance, in the FP segment, each type of vascular lesion can be assigned a lesion grade based on morphology and variables known to affect the success and patency rates of PTA. Per recommendation, TASC A lesions are most suitable for endovascular procedures, whereas surgery is recommended for TASC D lesions. The TASC document clearly states that more evidence is needed to make firm recommendations about the role of PTA for TASC B and C lesions. Although such lesions are amenable to PTA, a lower technical success rate and poorer long-term patency are expected.

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Five years ago, early intravascular metallic stents (Palmaz, Cordis Corporation, a Johnson & Johnson company, Miami, FL; and Wallstent, Boston Scientific Corporation, Natick, MA) were used in the FP segment, but to a lesser extent than in the iliac arteries. They provided excellent early technical results, particularly in the role of "bailing out" a failed PTA due to extensive dissection, recoil, or acute thrombosis.[1,2] However, their usefulness in preventing intimal hyperplasia and long-term restenosis has been very limited in the infrainguinal region.[3] Per the TASC document, FP stenting as a primary approach to the interventional treatment of intermittent claudication or chronic limb ischemia is not indicated. Stents may, however, have a limited role in salvaging acute PTA failures or complications (Recommendation 36).[1] This recommendation is obviously based on earlier stents, and although it remains valid for balloon-expandable stents as we know them today, it does not apply to the newer technologies that have emerged in the past few years.

Clearly, there are strong data indicating that PTA has a role in treating FP lesions, but this role is limited to those that are small (<5 cm) and focal, whereas new self-

expanding stents, such as the nitinol Smart stent (Cordis) are more effective in longer, more complex lesions.

FP PTA: A NICHE THERAPY

In the FP arterial segment, the technical success and durability of PTA strongly correlate with lesion morphology.[1,4-8] In general, the results obtained after treating longer stenoses and/or occlusions have not been encouraging. For instance, a 5-year cumulative patency rate of 75% can be expected for short, focal stenoses, but the 1-year cumulative patency rate for occlusions longer than 3 cm is significantly lower.[5] Similarly, reported 6-month cumulative patency rates have been 86.8% for stenoses shorter than 7 cm and 23.1% for those longer than 7 cm.[6] In a recent review article that compiled a literature summary of current treatment modalities for the treatment of superficial femoral artery disease, the primary patency for lesions that are 5 cm or less at 1 and 2 years after PTA were 58% and 51%, respectively.[7] In general, PTA of lesions shorter than 5 cm is more durable than PTA of lesions longer than 10 cm.[8]

Accordingly, for focal lesions less than 5 cm in length, PTA remains the best treatment option available. Short focal lesions, however, do not comprise the majority of cases presenting for revascularization procedures. In centers such as ours, most patients present with complex lesions involving a combination of conditions, including long disease segments, previous revascularizations, advanced age, diabetes, renal failure, and veins harvested for coronary bypass. The reported durability of PTA alone in this patient population is dismal.

STENTING IN THE FP SEGMENT

The advent of self-expanding nitinol stents, combined with lower-profile (6-F) delivery systems and longer stent lengths, has dramatically changed the landscape of endovascular FP treatment. Primary stenting of complex FP lesions has proven to be a safe and highly technically successful percutaneous intervention. In our own study,[9] evaluating the safety and efficacy of self-expanding Smart nitinol stents in 122 patients with chronic limb ischemia demonstrating TASC B or C lesions (mean, 12.2 cm), the technical success was 98% for 137 lower limbs, irrespective of lesion grade. With the availability of low-profile stent delivery systems, the vast majority of complex lesions including long occlusions can be traversed without the need of predilatation. This technique allows for primary deployment and flaring of the stent edges in a relatively normal caliber artery, not traumatized by a predilatation. All deployed stents require a balloon inflation for full expansion, but this critical step can be targeted at the sites of stent constriction only, thereby avoiding dilatation of the stent edges. It is possible that this step alone reduces the incidence of in-stent stenosis as well as the development of an "edge" stenosis, frequently seen with balloon-expandable stent technology (the "candy wrapper" effect). In addition, unprotected plaque fracture with potential resultant embolization is probably reduced with primary stenting, as evidenced by a less-than-1% embolic risk rate in our data.

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The hemodynamic primary stent patency rates (defined by the occurrence of a >50% stenosis within the stented segment, measured by standard Duplex velocity criteria, obtained at various postintervention intervals) were 92%, 76%, 66%, and 60% at 6, 12, 18, and 24 months, respectively. These data provided objective evidence that endovascular treatment of long FP lesions using Smart stents in patients with chronic limb ischemia provides favorable safety and durability outcomes.

Our results are similar to those seen in several contemporary FP stenting studies. In the SIROCCO trials, the unanticipated good patency results of the bare nitinol stents probably resulted in failure of the drug eluting stent to show superiority. Eighteen-month duplex follow-up revealed a 20.7% binary restenosis rate in the sirolimus group versus 17.9% in the bare stent group,[10] very similar to objective duplex-derived hemodynamic patency data observed in our own data. The BLASTER trial,[11] which was halted early due to concerns over the stent fractures observed in the SIROCCO trials, reported 100% technical success in its 50 patients, and 88% primary patency at 9-month Duplex follow-up. Importantly, the average lesion length in this population was 15.1 cm (range, 7-31 cm).

It has long been recognized by many that clinical outcomes, such as limb salvage rates, remain sustained despite hemodynamic failures of the endovascular treatment site. This concept is important when treating patients with critical limb ischemia and non-healing wounds. The relatively long reported time of 6 to 9 months[9-11] before the occurrence of hemodynamic stent failure has had a large impact on the percutaneous treatment of FP disease in our practice. Highly predictable, safe, instantaneous and relatively prolonged improved perfusion to an ischemic ulcer is a prerequisite to wound

healing. Patency may not be the better outcome measure alone to be reported as proposed by Rutherford.[12] It has been recently suggested that the traditional reporting standards for limb salvage operations need modification to reflect the true outcome of procedures, such as clinical benefit and avoidance of procedural morbidity and mortality.[13] Select patients with critical limb ischemia are the ideal candidates most likely to benefit from FP stenting of long complex lesions.

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Overall, recent results evaluating stenting in TASC C and D lesions compare very favorably with contemporary data evaluating PTA in TASC A lesions, in which primary patency was shown to be 58% and 51% at 1 and 2 years, respectively.[7] By historical comparison, PTA alone for TASC C and D lesions would undoubtedly yield inferior results.

IMPROVEMENTS MUST STILL BE MADE

Although the advances made over the last several years have resulted in better patency rates and reduced need for revascularization, physicians and industry are aware that stent designs must continue to be improved upon. Hemodynamic nitinol stent failure secondary to in-stent stenosis continues to be observed, although improved compared to previously reported data with other metallic stents.[1-3] The characteristics intrinsic to nitinol stents that may be potentially responsible for superior durability are not completely understood. Factors such as radial strength, metal used, surface characteristics, cell size, and weaving patterns may all play a role. Stent fractures continue to occur and are an important factor involved in the triggering of myointimal hyperplasia. Of interest, fracture rates are noticeably higher with some devices than with others.[14] The important message here is not that one manufacturer has better devices than another, but rather that this discrepancy is a positive indication of the potential for all stent manufacturers and engineers to observe and correct any design flaws, leading to reduced fracture rates, a trend we have already noticed. The efficacy of drug-eluting and bioabsorbable stent platforms will also likely play a role, and mid- and long-term results from recent and currently enrolling trials will tell us much more about their potential impact.

TAKING TASC TO TASK

The TASC recommendations have certainly been a helpful set of standards, but in the last 5 years, the emergence of self-expanding nitinol stents and other improvements in stent design and integrity, as well as the availability of new therapeutic options such as plaque excision, cryoplasty, and laser atherectomy, have dramatically changed practice patterns in treating FP lesions. Long-term data on these devices must be acquired, but it is clear that early data warrant the consideration of revising of the TASC recommendations, particularly Recommendation 36. For those who are opposed to the acceptance of stenting and the use of other novel technologies based on the fact that there are as yet no long-term data, it is important to note that in the 30 years PTA has been used, there have been little if any published data showing its safety and efficacy in long, complex lesions, and yet PTA is accepted by many as the "gold standard." ■

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