FP Angioplasty Versus Stenting:

Comparative Data Are Still Necessary

BY BARRY T. KATZEN, MD

Endovascular therapy has clearly come a long way in recent years. Our techniques and technology have improved, and we continue to see new therapeutic options enter the arena, each of which has the potential to raise the level of minimally invasive care we provide our patients. During this period, we have seen stenting results improve significantly, and in my opinion, stenting is currently the superior therapeutic option in most anatomical locations and patient populations. The road to establishing proven safety and efficacy has not been easy, however.

ADOPTING NEW GOLD STANDARDS

In order to gain widespread acceptance among the challenging and sometimes skeptical thought leaders in the interventional community, most new procedures or applications must endure exacting clinical trials yielding level 1 evidence via randomization against the acknowledged "gold standard." For stenting, this gold standard adversary has been either surgery or percutaneous transluminal angioplasty (PTA), depending on the anatomy and, perhaps more importantly, what type of specialist you ask. Regardless of which gold standard stenting has been evaluated against, it has shown either increased or equivalent (in the case of carotid endarterectomy) safety and efficacy in nearly every anatomic location in which it has been randomized.

Many interventionists believe the success and superiority seen in these anatomies will likely correlate to comparable outcomes in locations wherein we have seen favorable anecdotal and single-center results from nonrandomized studies, but as yet no level 1 evidence, such as has been the case with the femoropopliteal (FP) segment. It is my opinion and that of others who have had many years of experience with both PTA and stenting over long periods of time that a cautious approach to adopting new standards of care must be taken.

In longer, more complex lesions, stenting—either direct or adjunctive—may in fact be superior to PTA alone, or "plain old balloon angioplasty," as it has come to affectionately be called. But in order to provide the highest level of care for our patients, shouldn't this possibility be tested with the highest level of reasonable scrutiny? Of course, defining "reasonable scrutiny" in today's endovascular community may prove more difficult than the trial itself, but this does not discount the sustained importance and viability of randomization against established standards.

LEARNING FROM 20/20 HINDSIGHT

One of the best arguments against the call for randomization of self-expanding stents and other emerging FP therapies against PTA is that PTA itself did not gain its contested role as the established gold standard by demonstrating superior results over surgery or best medical therapy. In the 3 decades this procedure has been performed, there have been few data showing its safety and efficacy, much less superiority to other procedures, in long and/or complex FP lesions. I agree that the interventional community would have benefited from such trials, but should the fact that they were not allow the same mistake to be made with stenting? Regardless of whether PTA deserves to be considered the percutaneous gold standard, a randomized trial of stenting with newer self-expanding, nitinol designs versus PTA would serve to teach us a great deal about each procedure, and perhaps most importantly, about revascularization in the FP segment in general.

FP STENTING: NOT WITHOUT ITS DRAWBACKS

In my experience, 1-year patency with stenting is only about 10% better than what we have seen with PTA. The only published data comparing stenting to

PTA in this anatomy involved the previous generation of technology, and in any case did not demonstrate substantial benefit for stenting versus PTA. In other words, the only evidence we have does not warrant the added risk of leaving a device behind, especially considering that treating in-stent restenosis is more problematic than is treating restenosis after PTA. Stenting also brings with it the potential for stent fracture, which has been associated with restenosis and other clinical sequelae, although admittedly not at a terribly alarming rate. The TASC Recommendations for FP stenting were based on these data, and just as those recommendations are in need of revision based on today's new technologies, so too are those technologies in need of thorough, comparative evaluation.

We currently stent approximately 50% to 60% of our femoral artery cases, whereas some centers stent nearly every candidate. Of course, we perform stenting in patients with occlusions >15 cm, whereas those with shorter and less complex lesions will receive angioplasty. In any event, no patient is left with a suboptimal acute result. We have yet to see a femoropopliteal procedure that eliminates the need for repeat revascularization in more than 90% of cases; we reserve our treatment options for use in a sequential manner.

RANDOMIZED TRIALS NOW UNDERWAY

It has largely been difficult to stir interest among industry to support a trial randomizing stenting against PTA. Certainly, there are physicians who would not agree to randomize patients due to their ardent beliefs in stenting or other therapies in certain patients and lesions; however, with randomization comes greater risk for trial results to perhaps not be as glamorous as a sponsor would hope, which significantly reduces their financial incentive in initiating a trial, and these factors are likely the primary reasons we have not seen such a trial to date. Also, as mentioned previously, many physicians are satisfied with the idea that favorable results in other anatomical locations are indicative of similar potential in the FP segment, so rather than risk paying for a trial that could yield unfavorable results, some companies have sacrificed US marketing capabilities in the hopes that physicians will use the products off-label as they see fit.

Edwards Lifesciences (Irvine, CA) and C.R. Bard, Inc. (Murray Hill, NJ) have each decided to commence clinical trials randomizing stenting against PTA. My fellow *Endovascular Today* Chief Medical Editor, John R. Laird, Jr, MD, and I have agreed to be co-Principal Investigators for the Edwards RESILIENT Trial, which will randomize more than 200 patients at up to 25 sites with the goal of gaining a true superficial femoral and proximal popliteal artery indication approval from the FDA. The lesion lengths included will be 15 cm or shorter, and the efficacy endpoints are target lesion revascularization and target vessel revascularization.

CONCLUSION

Just as it has in other anatomical locations, stenting may soon come to be considered the therapy of choice for most FP lesions longer than 5 cm. However, as was necessary in those vessels, comparative data showing superiority must first be obtained. Not only will these data and experience go a long way toward erasing doubt and silencing critics, it will also achieve the important goal of educating us regarding the nature of FP anatomy and disease, as well as what we can expect acutely and in the mid- and long-term periods. ■

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