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Patterns of Restenosis: What Are the Data Telling Us?

WITH MICHAEL R. JAFF, DO

In your experience managing a major core laboratory and based on the latest clinical data, have you observed any differences in the pattern of restenosis between drug-coated balloons (DCBs), drug-eluting stents (DESs), bare-metal stents (BMSs), and standard percutaneous balloon angioplasty? Do the data suggest a reason for these differences?

Restenosis continues to remain the limitation of broader adoption of endovascular therapies for peripheral artery disease, and although technologies and skill of operators have both advanced, there remain opportunities for improvement in patency. Many experts believe that different patterns of restenosis are easier to revascularize and therefore may offer advantages over the life of the patient. Although I cannot provide any definitive answer today, there are clearly differences in patterns of restenosis across different endovascular strategies that may offer advantages in the near future. If so, these "patterns" may result in fewer revascularizations, lower complication rates, and potentially lower costs.

What is the typical timeframe in which lesions develop restenosis in the superficial femoral artery (SFA)? How does this vary between the different treatment options?

Across all treatments, endovascular or surgical, the first 12 months are critical. Maintaining patency through 12 months is not only appealing to physicians, but patients clearly choose to have interventions for disabling claudication for a durable outcome. We classically see restenosis within 12 months, and then the restenosis rates tend to level off. The most modern example of that is the impressive publication of 5-year data in the Zilver PTX (Cook Medical) randomized trial. Once patients made it out to 12 months following randomization and treatment, the progressive restenosis rates were very small. Presented data from the MAJESTIC trial also suggest that reintervention rates were quite low out to 2 years. Undoubtedly, the longer we can prevent restenosis, the lower the risk of requiring reintervention.

What do the latest data suggest about the durability of the different SFA treatment options?

It is actually fascinating to watch the evolution of primary patency as technology improves. We have seen improved primary patency as we have moved from uncoated percutaneous transluminal angioplasty to BMSs, DESs, and DCBs. It will be very interesting to see what happens with third- and fourth-generation technologies within these categories of endovascular intervention. For example, the second generation of DESs, although with limited data, appears to demonstrate impressive improvements in reintervention rates, and are, in fact, better than any other category of intervention to date.

What do the latest data tell us about the potential benefit of scaffolding to reduce the progression of restenosis?

As BMSs have evolved since the initial technology hit the market many years ago, we have seen a reduction in restenosis rates and associated fractures. For example, the SUPERB trial demonstrated impressive primary patency rates at 12 months with no identifiable fractures at the same time period. More recently, MAJESTIC data to 2 years have demonstrated no fractures.

How do you believe the SFA treatment algorithm will change in the next 3 to 5 years? What will drive those changes?

I imagine that the algorithm will continue to evolve. As technology has advanced, adoption of novel therapies have

mirrored the technology expansion. However, the strongest push to technology adoption will be the results of randomized clinical trials. The caliber of trial design has clearly met expectations from stakeholders, including physicians, regulators, payers, and most importantly, our ability to provide our patients with the most scientifically sound therapies.

Data from several clinical trials suggest that DCBs may not maintain patency as effectively as DESs or even BMSs after 2 or 3 years. How do you believe the treatment algorithm for SFA lesions will change if the clinical data confirm that DCBs are not able to deliver long-term patency as effectively as other treatment options?

The jury is out on this statement, and I would not rush to judgment. However, if longer-term durability with DCBs is limited compared to other technologies, I suspect that physicians will choose the "sweet spot" of relatively short, noncalcified lesions for treatment with DCBs.

Provisional stenting is used in up to 40% of DCB cases in longer lesions. How should the high provisional stenting rate when using DCBs in "real world" lesions affect the decision to use DCBs?

The pivotal trials of DCBs available on the United States market today kept the lesion length and complexity relatively straightforward. As with any other new technology in peripheral artery disease interventions, once the devices have approval, physicians tend to extend the applicability of the technology to tougher, more demanding lesions. This has been the case with the "real world" SFA and popliteal artery lesions seen in postapproval registries. I suspect that physicians will continue to work to improve procedural outcomes with DCBs in longer lesions, trying to minimize bailout stents. ■

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