Pitfalls and New Options for Treatment of Femoral and Popliteal In-Stent Restenosis

The September issue of Vascular Disease Management features excellent articles and a short editorial commentary that will be of great interest. I have chosen to comment on the article by Jos C. van den Berg, MD, in which he discusses the contemporary treatment of femoral and popliteal in-stent restenosis (ISR) within self-expanding nitinol stents. This is an extremely common and perplexing problem faced by peripheral interventionists. As Dr. van den Berg clearly indicates, this is a problem that will be faced for many years.

Historical treatment of ISR with percutaneous transluminal angioplasty (PTA) alone has been associated with poorer long-term patency and higher complication rates (particularly clinically relevant embolization) than de novo lesions. Dr. van den Berg clearly explains the associated histopathology that results in poor outcomes with PTA as primary therapy. Typically, femoral and popliteal ISR occurs within fully expanded stents, and therefore positive vessel remodeling is limited. The obstructive in-stent lesion is almost never calcified. The restenotic lesion is typically composed primarily of noncellular, extracellular matrix that has a high water content with behavior much like that of a sponge following PTA. Fluid is squeezed out of the lesion, resulting in initial luminal gain, and after PTA, the lesion quickly rehydrates, causing loss of much of that initial gain. Also, there is often superimposed thrombus in cases of total occlusion that poses a high risk of embolization. Longer, more complex lesions typically fare worse than short lesions. Although not mentioned in this article, poor run-off and severe stent fractures affect initial treatment success and long-term outcomes.

Dr. van den Berg clearly delineates the data on the treatment of ISR. At present, there are 2 FDA-approved devices for treating femoral/popliteal ISR, the Viabahn endoprosthesis (W.L. Gore) and the Spectranetics 308-nm excimer laser. These products have shown clear superiority compared to PTA alone in randomized controlled trials. Although not presently FDA approved for femoral/popliteal ISR therapy, several studies have shown improved outcomes with drug-eluting balloons (DEB). Also not FDA approved for this indication, placement of a stent within a stent has been reported to be beneficial in some, particularly when using drug-eluting stents. Combination therapy utilizing debulking followed by DEB in small studies has been promising, yielding single-digit rates of restenosis at 1 year.

My present algorithm of treatment of ISR is based on vessel size, length of lesion, outflow, associated thrombus, and severity of stent fractures. I believe that removal of the obstructive lesion and thrombus is important whether I’m planning subsequent DEB or covered stent therapy. I utilize the 308-nm excimer laser to debulk the lesion. This excimer laser has been clearly shown to be superior to PTA and to not injure stents. It typically results in the establishment of a significant channel with TIMI 3 flow. Following this, if there are stent fractures and good run-off, I utilize covered stents to treat the segment. If there are no fractures, or there is poor run-off, I follow debulking with DEB. Given the high rate of ISR recurrence with conventional therapy, I believe that there are financial (overall cost savings) as well as clinical reasons to employ this combination approach. Repeat interventions are far more costly and carry more risk.

As clinicians we will be treating femoral and popliteal ISR for decades. We must determine the best therapy.