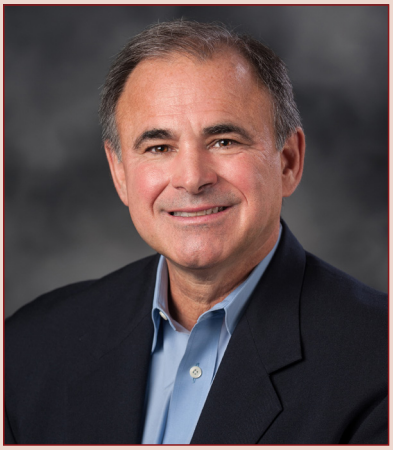
Extreme Caution Is Needed When Treating In-Stent Restenosis With Mechanical Devices



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Hello and welcome to the December issue of Vascular Disease Management. I have chosen to comment on Deepika Kalisetta and colleagues case report on Balloon Assisted Dislodgement of a Trapped Directional Atherectomy Catheter (the Ocelot device) During Treatment of In-Stent Restenosis (ISR).

Stenting of femoropopliteal arterial obstructive lesions has been demonstrated to result in higher primary patency than standard balloon angioplasty. Stenting is also routinely utilized to treat flow-limiting dissections following PTA and atherectomy. Therefore, stenting is commonly utilized in treating symptomatic femoral and popliteal arterial obstructions. Unfortunately, restenosis and reocclusion are common following stenting. Whereas stent grafts tend to develop recurrent stenosis only at the edge of the stents, standard nitinol self-expanding stents often develop diffuse in-stent restenosis secondary to neointimal hyperplasia and reocclusion when there is superimposed thrombus. Stent restenosis can occur early or many years after implantation. Treatment of femoropopliteal ISR with standard balloon angioplasty has been associated with poor long-term patency and significant risk of embolic sequelae. As ISR is a commonly faced clinical problem, attempts at improving patency and decreasing complications such as stent injury and embolization with interventional therapy ISR are of utmost importance.

There are presently 3 modalities that are approved by the US Food and Drug Administration (FDA) and have been demonstrated to be superior to plain balloon angioplasty in treating ISR.

The first modality to gain FDA approval for treating ISR was the 308 nm excimer laser followed by percutaneous transluminal angioplasty (PTA). The randomized controlled EXCITE trial demonstrated that excimer laser energy effectively ablates obstructive neointimal hyperplasia and thrombus. This trial demonstrated better patency and safety than plain old balloon angioplasty. The improved outcomes were greatest in long lesions in which there was substantial ablation of the obstruction. Importantly, there was no evidence of stent damage from the laser demonstrated in this trial. However, at 1 year, restenosis rates were better than PTA but remained suboptimal with 308 nm excimer laser and PTA alone.

The second treatment approved by the FDA was the Viabahn stent graft, which actually creates a physical barrier that prevents recurrent intimal ingrowth and tissue or clot prolapse within the stent graft. The potential failure mechanism of these stent grafts is restenosis at the edges of the stent rather than the entire stent. The RELINE study demonstrated dramatic restenosis benefit at 1 year in long lesions with no evidence of stent injury or increased complications.

The third FDA-approved therapy for treating ISR was the drug-coated balloon (DCB). This clearly showed a restenosis benefit with no evidence of stent injury in the IN.PACT Global study.

A subsequent single-center randomized trial by Gandini demonstrated that laser atherectomy followed by DCB was associated with better patency and limb salvage than DCB alone. This has created interest in combination therapy in which ISR obstructive material is first removed by atherectomy, after which treatment with either Viabahn covered stents or DCBs is utilized.

In this case report, Dr Kalisetta and colleagues attempted to use directional atherectomy to debulk a long stent occlusion. As noted by Dr Kalisetta, there have been reports of complications and high restenosis rates with directional atherectomy without OCT guidance. The premise in the therapy of this patient with directional atherectomy was that OCT guidance would allow precise device guidance and removal of the obstructive hyperplasia and thrombus, resulting in a larger initial lumen and less

barotrauma, and possibly lessening restenotic risk. Unfortunately, the device became entangled with the stent despite careful OCT guidance, necessitating an additional access site and rescue PTA to dislodge the device from the stent. Subsequent angiography disclosed the vessel segment to be patent with moderate residual stenosis.

This article highlights the need to proceed with extreme caution to avoid potential stent injury and entrapment when treating ISR with mechanical devices. I think this article should also focus practitioners on the need for greater standardization of therapies in treating peripheral vascular disease in general and in treating ISR specifically. At present, there is dramatic variation amongst practitioners with little randomized data to serve as a guide.

Specifically, the interventional treatment of femoropopliteal ISR is becoming progressively more commonly utilized as many patients have been treated with stenting, and primary and secondary restenosis is common. The ultimate goals of therapy are to create a large channel, cause no stent injury, have no embolic complications, and have no subsequent restenosis. Although intuitively the combination of debulking followed by a restenotic treatment is appealing, there are no large trials evaluating combination therapy, and this combination is associated with higher initial costs. As demonstrated in this case report, great caution must be taken when utilizing forms of mechanical atherectomy, which may become entangled with the stents and potentially cause injury. Embolic protection, particularly with limited outflow, is often essential.

Although there have been great strides made in the interventional treatment of femoropoliteal ISR, we are far from discerning the ideal therapy in individual case scenarios at this time. Stent fractures, vessel size, stent site, length of occlusion, presence of thrombus, runoff vessel status, and patient compliance are some of the variables that will need to be considered. If combination therapy is to gain widespread acceptance, it will have to demonstrate cost-effectiveness. Randomized trials are needed.