

Covered Stents for the Treatment of SFA Occlusive Disease

A case-based discussion of stent graft use in this challenging anatomy.

BY SUBHASH BANERJEE, MD; EMMANOUIL S. BRILAKIS, MD, PhD; AND TONY S. DAS, MD

Covered stents are composed of fabric or synthetic material supported by a metal mesh or stent platform. Although initially conceived to exclude peripheral arterial aneurysms and treat vessel perforations, the use of covered stents has expanded to act as a barrier to neointimal formation by excluding the vessel wall from the lumen. One such device is the Viabahn Endoprosthesis (Gore & Associates, Flagstaff, AZ), a tube of expanded polytetrafluoroethylene with a self-expanding helical nitinol stent mounted to the outside surface (Figure 1). It is currently approved by the US FDA for use in patients with symptomatic superficial femoral arterial (SFA) lesions with reference vessel diameters of 4.8 to 7.5 mm. This article seeks to provide a case-based review of the various clinical applications of covered stents in the SFA distribution.

In 1993, Cragg et al¹ reported the use of the first “homemade” covered stent, which was a polytetrafluoroethylene membrane mounted on a Palmaz stent (Cordis Corporation, Warren, NJ) platform for the treat-

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ment of long segments of diffuse SFA disease. In 1994, Henry et al published the first report of a manufactured covered stent used in 21 patients with peripheral arterial disease.² Primary patency rates of 29% to 87% have been reported.³ Use of the Cragg EndoPro System endoprosthesis (Minimally Invasive Technologies SARL, La Ciotat, France), a woven polyester fabric over a nitinol stent platform, was associated with a 59% primary patency rate in the femoropopliteal vessels and a high complication rate. These complications primarily included early and late thrombosis, graft misplacement, and distal embolization.⁴ The advent of the highly flexible Gore Viabahn Endoprosthesis has provided



Figure 1. Gore Viabahn Endoprosthesis.

endovascular specialists a reliable tool for the treatment of long segments of occlusive disease in the SFA distribution. It is, however, important to point out that sustained complication-free success rates can best be achieved in the backdrop of aggressive antiplatelet therapy (aspirin and clopidogrel), proper vessel preparation with balloon predilations, and preferably in the setting of at least two-vessel distal runoff.

We present three cases to highlight the contemporary use of the Gore Viabahn Endoprosthesis in the SFA distribution.

CASE 1

A 56-year-old obese, diabetic man with recurrence of left lower extremity Rutherford category 3 claudication, after a recent left SFA revascularization with multiple overlapping self-expanding nitinol stents, underwent peripheral angiography. Ankle-brachial indexes were 0.6 and 0.7 in the left and right extremities, respectively. Diagnostic angiography revealed a proximally occluded long left SFA with distal above-the-knee reconstitution via collaterals and preserved sluggish three-vessel infrapopliteal runoff (Figures 2A through 2D). The lesion, after successful crossing (Figure 2E) and distal confirmatory angiography, underwent excimer laser debulking (Figure 2F), with an improved but suboptimal angiographic result (Figure 2G), and was subsequently treated with two overlapping 6- X 150-mm Viabahn stent grafts (Figure 2H). The stented segments were then postdilated with a 6- X 100-mm Savvy balloon (Cordis Corporation) (Figure 2I) with excellent angiographic results and brisk infrapopliteal three-vessel flow (Figure 2J).

CASE 2

A 46-year-old woman with a history of left femoropopliteal bypass using an autologous vein 4



Figure 2. Gore Viabahn Endoprosthesis treatment of left SFA in-stent restenosis. See text for details (case 1).

years ago presented with progressive left lower extremity claudication symptoms after walking 30 yards during the previous week and a resting ankle-brachial index of 0.4 in the symptomatic leg. Diagnostic angiography revealed a “no-nub” ostial chronic total occlusion of the left SFA with distal above-the-knee reconstitution and slow filling of infrapopliteal vessels (Figure 3A to 3C). An ipsilateral lateral angiogram revealed the left SFA ostium, which was crossed using a standard Terumo Glidewire-Glide catheter technique (Terumo Interventional Systems, Somerset, NJ). Given the recanalization was of the venous graft and the subacute nature of the patient’s symptoms, the occluded venous graft segment was treated with intra-arterial tissue plasminogen activator (tPA) with restoration of distal flow (Figure 3D). The mid and proximal graft segment was subsequently dilated with a Savvy 5- X 60-mm balloon at 10 atmospheres with angiographically



Figure 3. Gore Viabahn Endoprosthesis treatment of left SFA perforation. See text for details (case 2).



Figure 4. Gore Viabahn Endoprosthesis treatment of left femoropopliteal venous bypass graft aneurysm. See text for details (case 3).

evident perforation (Figure 3E). Immediate control over the perforation was obtained by reversing the anticoagulation with intra-arterial protamine sulfate and inflation of the same 5- X 60-mm balloon at 4 atmospheres; two overlapping 6- X 150-mm Viabahn stent grafts were then deployed (Figure 3F), and the stented

segment was postdilated with a 6- X 60-mm balloon (Figure 3G) with excellent angiographic result, brisk distal flow (Figure 3H), and maintained patency at 6 month follow-up.

CASE 3

An 82-year-old man with ischemic cardiomyopathy, stage 2 chronic kidney disease, and left lower extremity femoropopliteal venous bypass 10 years ago, was referred for diagnosis and treatment of a pulsating mass behind his left knee. Duplex ultrasound revealed a 3.5-cm aneurysm of the venous bypass graft. Because the patient was a poor operative candidate, it was decided the best option would be percutaneous treatment of the left venous bypass graft aneurysm (Figure 4A). The aneurysmal segment of the graft was excluded using an 8- X 15-mm Viabahn stent graft (Figure 4B). The stented segment was subsequently postdilated (Figure 4C) with an excellent angiographic result (Figure 4D).

DISCUSSION

The role of the Gore Viabahn covered stent and the evidence base for its use for revascularization of peripheral arterial segments has been discussed in the February 2007 supplement of *Endovascular Today*.⁵ This discussion mainly focuses on

procedural aspects for achieving durable results using the Gore Viabahn Endoprosthesis in the SFA distribution.

Delivery of this covered stent requires at least a 7-F sheath, and thus, the contralateral approach is favored. It is advisable to keep the large-caliber sheath in the distal external iliac artery to avoid sheath thrombosis as a result

of diminished flow in the common femoral and profunda femoris arteries. The Gore Viabahn Endoprosthesis is extremely flexible and resistant to fracture, making it a good choice for treating long SFA lesions. It is important to note that the presence of at least two-vessel infrapopliteal runoff is preferred, although we have used the Viabahn covered stent in select patients with single-vessel runoff with good outcomes. It is important to cover the diseased segment of the SFA in its entirety and avoid the first 5 mm of the SFA ostium. Other endovascular specialists have suggested avoiding the first 2 cm of the SFA. In case 2 of our series, a far ipsilateral lateral projection revealed the ostium of the left SFA allowing for precise positioning of the Viabahn covered stent without compromising the profunda femoris flow, which is crucial. Delivery and accurate, controlled placement of the Viabahn covered stent should be performed over a stiff .035-inch guidewire. Appropriate vessel preparation with debulking and/or predilation is strongly recommended. A minimal lumen size of 4.8 mm by intravascular ultrasound or angiography is recommended for successful deployment of a 5-mm Viabahn stent graft. If subintimal dissection technique is used to cross an SFA occlusion, graduated dilations of the subintimal space are recommended. Adequate vessel preparation allows the Viabahn stent graft to fully expand without fabric infolding and invagination, which may reduce the long-term patency rate and success of the device.

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The Gore Viabahn Endoprosthesis is oversized by 5% to 10% in the target vessel and postdilated with a 1:1 noncompliant balloon. It is important to avoid balloon injury on the outside edges of the endoprosthesis crucial to reduced edge restenosis rates. Like the profunda, every attempt must be made to preserve the genicular artery collateral pathway when using covered stents in the SFA. We recommend preserving all major collateral and genicular arteries in the distal SFA. Finally, we suggest administering 50 to 75 U/kg of unfractionated heparin, with an additional 1,000 units of heparin for each hour thereafter to maintain therapeutic anticoagulation, and not reversing anticoagulation at the conclusion of the procedure. All patients are pretreated with dual-antiplatelet therapy with aspirin and clopidogrel, which is continued indefi-

nately after the procedure. In case 2 of our series, unfractionated heparin was reversed after SFA perforation, Viabahn use was considered following tPA treatment and background aggressive dual-antiplatelet therapy.

Adoption of the above-mentioned tips, along with improvements in design of covered stents, have produced consistent primary patency rates of 85% at 1 year, 80% at 2 years, and up to 60% at 5 years, with nearly 0% stent thrombosis and fracture rates.⁵ Primary use of the Viabahn covered stent may be recommended over bare nitinol stenting after results of the VIBRANT trial comparing these modalities in a randomized fashion are published. We anxiously await the clinical trial results.

CONCLUSION

This case-based review highlights the use of the Gore Viabahn covered stent for the treatment of vascular disease in the SFA distribution. Indications for treatment, primary clinical objective, lesion complexity, and adequacy of collateral circulation need to be carefully assessed before considering an endovascular intervention in this challenging anatomic location using covered stents. ■

Subhash Banerjee, MD, is Acting Chief, Division of Cardiology, and Co-Director, Cardiac Catheterization Laboratory, at VA North Texas Healthcare System; and Assistant Professor of Medicine at University of Texas Southwestern Medical Center in Dallas, Texas. He has disclosed that he receives grant/research funding from Boston Scientific Corporation and Cardiovascular Systems Inc. Dr. Banerjee may be reached at mdcare@aol.com.

Emmanouil S. Brilakis, MD, PhD, is Director, Cardiac Catheterization Laboratory, at VA North Texas Healthcare System; and Assistant Professor of Medicine at University of Texas Southwestern Medical Center in Dallas, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Brilakis may be reached at esbrilakis@yahoo.com.

Tony S. Das, MD, is Director, Peripheral Vascular Interventions at the Presbyterian Heart Institute in Dallas, Texas. He has disclosed that he receives grant/research funding from Gore & Associates. Dr. Das may be reached at tdas@civadallas.com.

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