Journal of the American College of Cardiology
© 2013 by the American College of Cardiology Foundation
Published by Elsevier Inc.
Vol. 62, No. 15, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.06.031

EDITORIAL COMMENT

# Stents for Femoropopliteal Disease

## Are Some Things Better Covered Up?*

John R. Laird, MD, Ehrin J. Armstrong, MD
*Sacramento, California*

Covered stents have proven useful for the treatment of complications after endovascular interventions, particularly vessel perforation and rupture (1). One such device (Graftmaster, Abbott Vascular, Santa Clara, California) has received approval from the U.S. Food and Drug Administration (FDA) through a Humanitarian Device Exemption for the treatment of coronary artery perforation, a life-threatening complication of percutaneous coronary intervention. Covered stents have also been widely used for the exclusion of aneurysms and pseudoaneurysms in a variety of vascular beds. A self-expanding covered stent (Flair, CR Bard, Tempe, Arizona) was recently shown to be superior to balloon angioplasty for the treatment of dialysis access graft stenosis (2).

See page 1320

An evolving body of literature (3–5) also supports the use of covered stents for the treatment of lower extremity arterial occlusive disease. The main advantage of a covered stent in the treatment of atherosclerotic disease is that the expanded polytetrafluoroethylene (ePTFE) graft material lining the stent serves as a barrier to neointimal in-growth, thereby reducing the risk of in-stent restenosis. Use of a covered stent for the treatment of ulcerated/friable or thrombotic lesions might also reduce the risk of distal embolization. Although covered stents therefore have many theoretical advantages, they may also be associated with specific modes of failure (4). First, edge restenosis can occur after covered stent placement, especially if the stent is oversized. Second, covered stents have a higher risk of thrombosis, and large thrombus burden within the covered stent can complicate efforts to recanalize an occluded device. Third, covered stents may cover side branches or important collateral pathways. If the patient experiences subsequent stent thrombosis, there is the possibility that he or she could present with acute limb ischemia or symptoms that are more severe than the initial presenting symptoms. This would be a violation of the fundamental principal of primun non nocere. For all of these reasons, covered stents need to be studied in carefully designed trials and compared with their noncovered counterparts.

The greatest experience to date with covered stents in peripheral arterial disease is with the iCAST balloon expandable covered stent (Atrium Medical, Hudson, New Hampshire) and the Viabahn self-expanding covered stent (WL Gore, Flagstaff, Arizona). The iCAST is a balloon expandable, stainless steel stent fully encapsulated in 2 layers of ePTFE. A single-center, retrospective case series demonstrated improved patency at 2 years with the iCAST stent compared with bare-metal stents (BMS) for the treatment of aortic bifurcation disease (6). In the COBEST (Covered Versus Balloon Expandable Stent Trial) trial, a multicenter, randomized study, the iCAST stent was superior to balloon expandable BMS for the treatment of complex, TransAtlantic Inter-Society Consensus class C and D aortoiliac occlusive disease (7). A prospective, multicenter, U.S. registry evaluating the iCAST for iliac artery disease (iCARUS [iCast Atrium Registry Ultrasound Study] was recently completed, and the data have been submitted to the FDA as part of a pre-market approval application.

The Viabahn endoprosthesis is FDA approved for the treatment of iliac and femoral artery disease. This device consists of a self-expanding nitinol stent encapsulated in ePTFE. There have been several improvements in Viabahn-covered stents over time, including the addition of a heparin bioactive surface to reduce device thrombogenicity. The proximal edge of this device was also contoured to decrease the risk of proximal edge restenosis, and a lower profile delivery system was developed to decrease the sheath size needed for delivery. The Viabahn stent graft has been used extensively for the treatment of femoropopliteal occlusive disease, and there are numerous publications of single and multicenter experiences with the device (3,4). A single-center randomized trial compared the results of the Viabahn-covered stent versus above-knee femoropopliteal bypass surgery with prosthetic graft material for long-segment femoropopliteal occlusive disease (5). At the 4-year follow-up, there was no difference between the 2 treatment strategies with regard to primary or secondary patency.

The VIBRANT (Viabahn Versus Bare Nitinol Stent in the Treatment of Long Lesion [≥8 cm] Superficial Femoral Artery Occlusive Disease) trial was the first to compare covered stents with BMS in the superficial femoral artery. This multicenter, randomized trial compared an earlier version of the Viabahn (nonheparin bonded, no proximal contoured edge) with bare nitinol stents for long-segment

*Editorials published in the *Journal of the American College of Cardiology* reflect the views of the authors and do not necessarily represent the views of *JACC* or the American College of Cardiology.

From the Division of Cardiovascular Medicine and The Vascular Center, University of California, Davis Medical Center, Sacramento, California. Dr. Laird serves on the scientific advisory board and receives consulting fees from Abbott Vascular, Boston Scientific, Covidien, Medtronic, and Bard Peripheral Vascular; and receives research support from WL Gore and Atrium Medical. Dr. Armstrong has reported that he has no relationships relevant to the contents of this paper to disclose.

femoropopliteal disease. There was no difference in outcomes between the 2 treatment groups, with disappointing 12-month primary patency for both the Viabahn and bare nitinol stents (53% vs. 58%; p = NS). The final results of this study remain unpublished. The VIBRANT randomized trial was followed by a single-arm, multicenter prospective registry (VIPER [Viabahn Endoprosthesis With Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease]) that evaluated the heparin-bonded Viabahn in 120 patients with long superficial femoral artery stenosis or occlusion (mean lesion length 19 cm) (8). The 12-month primary patency in VIPER was 73%, suggesting a potential favorable impact of the heparin bioactive surface on stent patency.

In this issue of the *Journal*, Lammer et al. (9) present the latest chapter in the covered stent story. They report the results of the VIASTAR (Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease) trial, a European randomized trial comparing the heparin-bonded Viabahn-covered stent versus BMS for the treatment of complex femoropopliteal lesions. A total of 141 patients with symptomatic peripheral arterial disease were assigned to treatment with a Viabahn-covered stent or BMS. In the per-protocol analysis, the 12-month primary patency rate was 78.1% in the Viabahn group compared with 53.5% in the BMS group. For lesions ≥20 cm, the apparent benefit was even greater, with a primary patency rate of 73.3% for Viabahn versus 33.3% for BMS. Serious adverse events were infrequent in either treatment group, and importantly, the risk of stent thrombosis and development of acute limb ischemia was not increased by use of a covered stent.

The authors (9) are to be congratulated on successfully conducting a randomized trial on a challenging subset of patients that remains understudied. Although the results generally support use of Viabahn-covered stents for long femoropopliteal lesions, several aspects of the study should be taken into consideration. First, 12 of the subjects (6 in each group) who underwent randomization were considered protocol violations. Most of the results are therefore reported as per-protocol analysis. When the primary outcome was analyzed by using intention-to-treat analysis, the difference in 12-month primary patency between the Viabahn and the noncovered stents was not statistically significant. Second, clinically driven target lesion revascularization rates did not differ between groups, suggesting that the differences in duplex-derived restenosis may not have translated into differences in symptoms. Consistent with this finding, there was no significant difference between groups in walking distance at 12 months.

The VIASTAR trial has shown that implantation of a heparin-bonded covered stent is a reasonable treatment strategy for patients with long-segment femoropopliteal occlusive disease (9). These data confirm what has been known for some time: that the durability of femoropopliteal stenting with BMS is inversely related to lesion length. However, patency after implantation of the Viabahn stent graft seems to be independent of lesion length. Although the advantage of a covered stent over a BMS is apparent for these longer lesions, there is less certainty about the optimal treatment of short- or medium-length lesions. Newer BMS, drug-eluting stents, drug-coated balloons, and atherectomy devices have all shown promise for these shorter lesions. With the recent FDA approval of a paclitaxel-eluting stent, there will also be questions about whether a drug-eluting stent can provide results comparable to an ePTFE-covered stent for longer femoropopliteal lesions. Perhaps covering a stent with an antirestenotic drug is as effective as an ePTFE barrier. For the time being, however, it does seem that when it comes to stenting for the treatment of long-segment femoropopliteal disease, it is better if our stents are "covered up."

**Reprint requests and correspondence:** Dr. John R. Laird, Department of Internal Medicine, University of California-Davis, 4860 Y Street, Suite 3400, Sacramento, California 95817. E-mail: john.laird@ucdmc.ucdavis.edu.

## REFERENCES

1. Yeo KK, Rogers JH, Laird JR. Use of stent grafts and coils in vessel rupture and perforation. J Interv Cardiol 2008;21:86–99.
2. Haskal ZJ, Trerotola S, Dolmatch B, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. N Engl J Med 2010;362:494–503.
3. Lammer J, Dake MD, Bleyn J, et al. Peripheral arterial obstruction: prospective study of treatment with a transluminally placed self-expanding stent-graft. International Trial Study Group. Radiology 2000;217:95–104.
4. Saxon RR, Coffman JM, Gooding JM, Ponec DJ. Long-term patency and clinical outcome of the Viabahn stent-graft for femoropopliteal artery obstructions. J Vasc Interv Radiol 2007;18:1341–9; quiz 50.
5. McQuade K, Gable D, Pearl G, Theune B, Black S. Four-year randomized prospective comparison of percutaneous ePTFE/nitinol self-expanding stent graft versus prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. J Vasc Surg 2010;52:584–90; discussion 590–1, 591.e1–e7.
6. Sabri SS, Choudhri A, Orgera G, et al. Outcomes of covered kissing stent placement compared with bare metal stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation. J Vasc Interv Radiol 2010;21:995–1003.
7. Mwipatayi BP, Thomas S, Wong J, et al. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease. J Vasc Surg 2011;54:1561–70.
8. Saxon RR, Chervu A, Jones PA, et al. Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) trial. J Vasc Interv Radiol 2013;24:165–73.
9. Lammer J, Zeller T, Hausegger KA, et al. Heparin-bonded covered stents versus bare-metal stents for complex femoropopliteal artery lesions: the randomized VIASTAR trial (Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease). J Am Coll Cardiol 2013;62:1320–7.

**Key Words:** claudication ■ covered stents ■ peripheral arterial disease ■ restenosis ■ superficial femoral artery.