

The VIBRANT Trial

Comparing bare-nitinol stents to stent grafts in long superficial femoral artery lesions in this unique trial.

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Management of patients with femoropopliteal peripheral artery disease must be directed so that maximum clinical efficacy is obtained with acceptable short- and long-term safety. The adoption of endovascular therapy for the superficial femoral artery (SFA), often without supporting data, has inspired considerable debate. Unfortunately, many of the issues raised in these debates are difficult to resolve due to disparate reporting standards in the literature. Results of percutaneous transluminal angioplasty (PTA) of moderately complex SFA lesions have demonstrated poor sustained patency.¹ Both adjunctive nitinol stenting and stent grafting have published data demonstrating superiority to PTA in moderately complex lesions at 1-year follow-up.²⁻⁴ Although surgical venous bypass can achieve similar or better patency, use of bare and expanded polytetrafluoroethylene-lined stents offers a significantly less invasive approach to restoring artery flow. Recently, a single-center, randomized trial comparison of stent grafting to surgical prosthetic bypass demonstrated equivalence in complex SFA lesions.⁵

THE VIBRANT TRIAL

The VIBRANT (Viabahn Versus Bare Nitinol Stent in the Treatment of Long Lesion [≥ 8 cm] Superficial Femoral Artery Occlusive Disease) trial was developed to compare bare-nitinol stenting in complex real-world patients to the Viabahn stent graft (W. L. Gore & Associates, Flagstaff, AZ). This investigation has several unique and independent features: (1) evaluate SFA treatment with femoropopliteal lesion lengths > 8 cm, allowing for stent overlap; (2) evaluate independent core lab adjudication of all major outcomes; (3) evaluate prospective correlation of various duplex ultrasound systolic velocity ratios with recurrence of clinical symptoms; (4) evaluate potential predictors of patency with a focus on longer-term follow-up (3 years); and (5) evaluate the significance of device fractures on clinical and restenosis endpoints.

Study Design

VIBRANT is a prospective, multicenter, randomized trial



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Figure 1. The Gore Viabahn endoprosthesis.

comparing the nonheparin-bonded Viabahn stent graft to bare-nitinol stents. Eighteen centers from around the United States representing all three disciplines that practice endovascular treatment were included. VasCore (Massachusetts General Hospital, Boston, MA), the vascular ultrasound core laboratory, performed independent assessments of all duplex ultrasound and radiographic images for evidence of restenosis and stent fracture, respectively. The study hypothesis states that in comparison to the use of bare-nitinol stents in treating chronic SFA long lesions (≥ 8 cm), stenoses, and occlusions, the use of the Gore Viabahn endoprosthesis will result in greater midterm (24 months) and long-term (36 months) patency of the treated arterial lesion.

Study Devices

The Gore Viabahn endoprosthesis (US Food and Drug Administration approved for SFA indication on June 14, 2005) is constructed with a very flexible but durable, reinforced, biocompatible, expanded polytetrafluoroethylene liner attached to an external nitinol stent structure and is indicated for improving blood flow in patients with symptomatic peripheral artery disease due to SFA lesions with reference vessel diameters ranging from 4 to 7.5 mm (Figure 1).

Bare-nitinol stents, as determined by the institutional standard of care when treating SFA occlusive disease, were also used. Permitted device diameters for the study were 6, 7, and 8 mm only.

Study Guidelines

The study population includes 150 patients randomized into the test and control groups. Inclusion criteria included Rutherford class 1 to 4. De novo stenosis or post-PTA restenosis ($> 50\%$ by visual estimate) or occlusion of the native SFA ≥ 8 cm (TASC lesion types C and D) in length were located in the region beginning 1 cm below the origin of the profunda femoris artery and ending 5 cm above the radiographic knee joint. Any previous PTA, if on the target lesion, must have been performed before the study procedure by at least 6 months. Acceptable reference vessel diameters were 4.8 to 7.5 mm in the treatment segments within the SFA and proximal popliteal artery.

Stenoses were predilated with angioplasty balloons sized to a diameter slightly smaller than the native vessel. Investigators were directed to completely cover the treated site plus 5 mm on both ends with either the stent or stent graft. Postballoon dilation was to be performed within the stent graft or stent to the diameter of the native vessel. If the patient was not currently taking clopidogrel, a 600-mg oral loading dose was administered immediately after successful intervention; a 75-mg oral dose of clopidogrel was continued once daily for a minimum of 6 months after the procedure. An oral dose of aspirin (81 or 325 mg) was continued once daily through study follow-up. Flat plate x-ray images for determination of stent fracture were made at multiple angles with patient extremities straight and flexion.

Study Endpoints

Primary endpoints included 3-year primary patency (duplex peak systolic velocity ratio < 2 based on core lab determination) for efficacy, with a 30-day composite safety endpoint inclusive of major complications. Secondary endpoints included primary assisted patency, secondary patency, technical success, target vessel revascularization, target lesion revascularization, clinical success, change in ankle-brachial index from baseline, alternate peak systolic velocity ratios of 2.5 and 3, and stent fracture on plain radiographs. Quality of life and standardized claudication questionnaires were administered at baseline, postprocedure, and annual follow-up.

Study Status

To date, all patients have been enrolled and followed for 1 year. Interim results were presented at the 2009 VIVA meeting in Las Vegas, Nevada. Longer-term follow-up con-

tinues on the entire cohort, and the primary endpoint will be adjudicated in 2011.

Since the start of the VIBRANT trial, the Viabahn endoprosthesis has undergone several iterative modifications. The device now has a lower delivery profile, heparin bonding, and, most recently, the proximal edge has been contoured. The VIPER registry trial, discussed by Richard R. Saxon, MD, on page 66 in this issue, is underway to evaluate patency in a similar population as VIBRANT. ■

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