Evaluating Patency Rates of an Ultralow-Porosity Expanded Polytetrafluoroethylene Covered Stent in the Treatment of Venous Stenosis in Arteriovenous Dialysis Circuits

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ABSTRACT

Purpose: To evaluate the efficacy of an ultralow-porosity expanded polytetrafluoroethylene (ePTFE) covered stent in the treatment of autogenous arteriovenous fistula (AVF) and prosthetic arteriovenous graft (AVG) venous outflow stenoses.

Materials and Methods: Clinical and angiographic outcomes of 20 consecutive patients with arteriovenous dialysis circuits treated with the endoprosthesis were reviewed following institutional review board approval. Patients were followed routinely at 2 months and 6 months after stent placement, or earlier if clinically warranted. The primary endpoint was 2- and 6-month primary treatment area patency. Secondary endpoints included primary circuit patency, primary assisted patency, and secondary patency.

Results: Eleven patients with AVFs and nine patients with AVGs were treated successfully with the covered stent. Primary treatment area patency rates were 85% ± 16 at both 2 months and 6 months. Primary circuit patency rates were was 65% ± 21 and 45% ± 22, respectively; primary assisted patency rates were 90% ± 13 and 85% ± 16, respectively; and secondary patency rates were 100% and 90% ± 13, respectively. Of the three cases of lost primary treatment area patency, two developed thrombosis and one developed recurrent stenosis. No significant differences were found between patients with AVFs and AVGs.

Conclusions: Data from this preliminary study suggests that the ultralow-porosity ePTFE covered stent may be a clinically viable option for treatment of venous outflow stenoses in arteriovenous vascular access circuits.

ABBREVIATIONS

AVF = arteriovenous fistula, AVG = arteriovenous graft, ePTFE = expanded polytetrafluoroethylene, FDA = Food and Drug Administration, VAC = vascular access circuit

The increased prevalence of end-stage renal disease in the United States has resulted in a corresponding increase in the number of hemodialysis-dependent patients (1), with many patients requiring autogenous arteriovenous fistulae (AVFs) or prosthetic arteriovenous grafts (AVGs). Vascular access circuit (VAC) dysfunction or failure is most commonly associated with development of stenoses in the venous outflow tract. Although balloon angioplasty has been the mainstay of treatment for such lesions (2–7), stent treatment of venous outflow anastomotic stenoses in AVGs with the FLAIR stent-graft (Bard Peripheral Vascular, Tempe, Arizona), a medium-porosity expanded polytetrafluoroethylene (ePTFE) covered stent, has recently been shown to provide superior results compared with angioplasty alone in a randomized controlled trial (8). Given that only the FLAIR stent has emerged with Food and Drug Administration (FDA) approval for use in AVGs, and that no stents are currently approved for use in AVF venous outflow stenoses, options that might

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provide even better patency rates would be valuable. Therefore, further investigation into other possible alternatives for treatment of vascular access stenoses in AVFs and AVGs is needed.

The VIABIL endoprosthesis (W.L. Gore and Associates, Flagstaff, Arizona) is a covered stent with a flexible nitinol exoskeleton, currently FDA-approved for use in the biliary system. It employs an ultrathin, ultralow-porosity ePTFE graft component coated with fluorinated ethylene polypropylene, which essentially renders the graft functionally nonporous (9,10). This composition endows the graft with several potentially useful biologic properties compared with traditional medium-porosity ePTFE grafts currently used in the vascular system, such as complete impermeability to cellular transgraft migration, as well as impairing cellular adhesion along the graft's luminal surface, both of which have been implicated as mechanisms of restenosis in the vasculature (11–15). However, the nonporous graft material in the VIABIL stent-graft has not been studied to date in the treatment of outflow stenosis in hemodialysis access fistulae or grafts, and may offer a different performance profile than traditional medium-porosity endografts. The purpose of the present study was to evaluate the efficacy of an ultralow-porosity expanded ePTFE covered stent in the treatment of dialysis access AVF and AVG stenoses.

MATERIALS AND METHODS

Patient Selection

In this institutional review board–approved, Health Insurance Portability and Accountability Act–compliant study, we performed a single-institution review of observational data of consecutive patients treated for hemodialysis access AVF or AVG venous outflow stenoses with off-label use of VIABIL stent endoprostheses placed between September 2005 and August 2007. Twenty consecutive patients were included in this period and reviewed. In light of literature suggesting that AVFs and AVGs have similar long-term patency, both types of circuits were treated equivalently and patients were nonselectively accrued in this study (16).

Patients included had an AVF or AVG peripheral outflow stenosis greater than 50% (by diameter) versus the reference vessel (normal-appearing vessel segment at least 5 mm central [downstream] from the stenosis) or had previously undergone failed balloon angioplasty (recurrent stenosis after previous procedure and/or acute elastic recoil > 30%), and had clinical indicators of failure (low flow rates on dialysis or evidence of thrombosis). AVF peripheral outflow stenosis was defined as a stenosis involving the downstream vein at least 5 cm from the arterial anastomosis, whereas AVG anastomotic stenoses were defined as stenoses that included the region of the surgical graft–vein anastomosis (17). In the study institution, AVFs consisted of midarm brachial–brachial or brachial–basilic transposition vein grafts (18). All patients had VACs that had matured and had been successfully used for dialysis before requiring intervention. No limitation was placed on lesion length. Reasons for not placing a stent included the following: reference vessel less than 6 mm in diameter (in view of available stent sizes), lesion located less than 5 cm from arterial anastomosis, previous stent or stent-graft placement anywhere within the VAC, and evidence of active infection.

Data were obtained from intervention reports, angiographic images, and medical records. Routine clinical and angiographic follow-up was planned at 2 months and 6 months on all patients, or earlier if clinically warranted (ie, because of poor dialysis flow). There was no industry involvement in study design, conduct, financial support, or analysis of the study.

The **Table** describes the demographic profile of study patients. In total, 20 patients (eight men, 12 women) received 21 stent-grafts to treat 20 discrete outflow stenoses in their respective hemodialysis access circuits. One patient had a 12-cm stenosis treated with two overlapping stent-grafts.

Patients ranged from 37 to 92 years of age, with an average age of 61 years. On average, the VACs had been in place for 18 months and had undergone an average of 1.5 previous interventions. Vessels treated included the basilic vein (n = 12), brachial vein (n = 6), common femoral vein (n = 1), and saphenous vein (n = 1). Ten patients (50%) had thrombosis of their VACs before or at the time of stent-graft placement. Six patients (30%) had been treated for thrombosis in their VACs (two AVFs, four AVGs) before the interventional procedure during which the stent-grafts were placed. Eight patients (40%), four with AVFs and four with AVGs, had acute thrombosis at the time of stent placement. Four patients had thrombosis present before and at the time of stent-graft placement (one AVF, three AVGs).

At the time of presentation, patients had an average of 1.9 lesions (range, 1–3) in their circuits treated with angioplasty, even though stent-grafts were used to treat only one lesion each according to the criteria previously specified in Materials and Methods. The stents used were, on average, 8.8 mm in diameter and 76 mm in length. On average, treated stenoses were 46 mm long (range, 10–120 mm) with 70% narrowing (range, 30%–90%).

Technique

Stent-graft placement was performed at a single institution by fellowship-trained interventional radiologists. The nonporous VIABIL endoprosthesis was available in 8-mm and 10-mm diameters and in 2-cm incremental lengths from 4 cm to 10 cm. No mixture of different types of stents or stent-grafts was permitted within the VAC in any given patient. Thrombosed VACs were

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