Polytetrafluoroethylene Stent Grafts Improve Dialysis Access Graft Patency: Results of the US Randomized Multicenter Trial

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Purpose
The purpose of this study was to evaluate the effectiveness of an expanded polytetrafluoroethylene (ePTFE) stent graft compared with balloon angioplasty for treating stenotic venous anastomoses in malfunctioning synthetic arteriovenous access grafts.

Methods
This randomized, controlled, multicenter study enrolled 190 patients with failing (nonthrombosed) arm and forearm grafts. Enrollees had both functionally significant and anatomic stenoses (> 50%), as defined by DOQI guidelines. At follow-up, clinical and hemodynamic efficacies and 2- and 6-month obligate venography were assessed and performed and were later reviewed by a core laboratory. Patients were equivalent by > 20 clinical, demographic, anatomic, and dysfunction criteria.

Results
Ninety-three patients were randomized to PTA and 97 to straight or flared stent grafts (Bard Peripheral Vascular) at 16 centers after a phase I roll-in of 37 stent graft patients. The mean stent length was 5.4 ± 2.8 cm. Stent graft delivery success was 99%. The immediate reduction of stenosis to < 30% was 94% for stent grafts and 73% for PTA ($p < .001$). Adverse events were statistically equivalent in both groups. Two- and 6-month treatment area (anastomosis) primary patency was 77.4% and 29% for the PTA group and 80.4% and 53.6% for the stent graft group ($p < .001$). Two- and 6-month dialysis access circuit primary patency was 77.4% and 25.8% for the PTA group and 79.4% and 41.2% for the stent graft group ($p = .031$). Freedom from the need for reintervention was significantly better for stent graft patients compared with PTA ($p = .028$). Lesion length did not affect stent graft patency (4 vs 5 vs 6 cm long; $p = .15$). Anticoagulation and antiplatelet therapy did not affect stent graft patency ($p > .05$). Six-month binary restenosis rate (< 50%) was 77.6% for the PTA control and 26.7% for stent graft group ($p < .001$).

Conclusions
The Bard ePTFE stent graft yielded unambiguous 6-month patency superiority over balloon angioplasty and reduced the need for graft reintervention when used for treatment of venous anastomotic stenoses in arteriovenous access grafts.