Use of Expanded Polytetrafluoroethylene–covered Nitinol Stents for the Salvage of Dysfunctional Autogenous Hemodialysis Fistulas

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The use of expanded polytetrafluoroethylene (ePTFE)–covered nitinol stents for salvage of hemodialysis fistulas was retrospectively examined. Seven covered stents were placed in five patients with failing fistulas considered unsalvageable. Indications included recurrent stenoses, thrombosis, and pseudoaneurysm formation. Before intervention, all patients required multiple interventions. The technical success rate was 100%. The primary patency rate was 80%, with secondary patency and lesion patency rates of 100% at 9 months. The incidence of follow-up repeat intervention was 0.3 per year. There were no complications. The use of ePTFE-covered stent placement in dysfunctional autogenous fistulas is technically feasible and, in this small series, was effective in preserving function and preventing access abandonment.

J Vasc Interv Radiol 2008; 19:950–954

Abbreviations: ePTFE = expanded polytetrafluoroethylene, PET = polyethylene terephthalate, PTA = percutaneous transluminal angioplasty

THE management of hemodialysis access greatly impacts the survival and quality of life of patients with end-stage renal disease. With strong evidence from the Kidney Disease Outcomes Quality Initiative that autogenous fistulas are more durable and less likely to have complications than hemodialysis grafts (1,2), the North American medical community is starting to rediscover native fistulas for hemodialysis access. However, autogenous fistulas are not without problems. Recurrent stenosis resistant to percutaneous transluminal angioplasty (PTA), thrombosis, and pseudoaneurysm formation are all potential complications. Current practice for failing fistulas has traditionally included surgical revision, PTA, and bare nitinol stent placement. Failing these, fistulas are often abandoned.

One possible treatment option for failing fistulas that has yet not been thoroughly investigated is the use of covered nitinol stents. The use of covered stents has shown initial promise in the treatment of failing hemodialysis grafts (3–8); accordingly, their use may also be of clinical value in salvage of otherwise unsalvageable dysfunctional autogenous fistulas. In this study, we examined the feasibility and outcomes of the salvage of five dysfunctional autogenous fistulas with expanded polytetrafluoroethylene (ePTFE)–covered nitinol stents in cases in which other percutaneous interventions had failed.

MATERIALS AND METHODS

Patient Population

Approval for a retrospective review of patient records and medical images was obtained from the institutional review board. A study group was identified from all patients with dysfunctional autogenous fistulas referred to the interventional radiology department and treated with covered nitinol stents. Indications for fistula dysfunction treated with a covered stent included recurrent stenoses, thrombosis, and problematic pseudoaneurysms.

Five such patients were treated between September 2006 and July 2007. No patients with autogenous fistulas treated with covered nitinol stents during this time period were excluded from the study. The treated patients included four men and one woman with ages ranging from 65 to 77 years (mean, 73 y). Three patients had brachiobasilic fistulas and two had brachiocephalic fistulas. The age of the fistulas at the time of intervention ranged from 39 to 66 months (mean, 53 months). All fistulas were mature and in use within 3 weeks of the interventions. All five fistulas had recurrent stenoses, four contained problematic pseudoaneurysms, and two were completely occluded at the time of intervention. In total, seven covered stents were placed in five patients.

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None of the authors have identified a conflict of interest.

DOI: 10.1016/j.jvir.2008.03.016

Covered Stents

All covered stents placed were Fluency Plus stent-grafts (Bard, Tempe, Arizona). This device is a grid-like nitinol cylinder encapsulated within two layers of ePTFE. The stent assumes final configuration when exposed to body temperature. The stent-graft is compressed between an inner catheter and outer sheath within a deployment system that accepts a 0.035-inch guide wire. Stents used in this study ranged from 6 mm to 10 mm in diameter. The manufacturer recommends selection of a stent-graft diameter that is approximately 1 mm but no more than 2 mm greater than the lumen diameter. Currently, the Fluency Plus stent-graft is indicated for tracheoesophageal stenosis, so deployment in the vascular system constitutes off-label use in the United States.

Pretreatment Evaluation

Access to the fistulas was initially obtained with a 19-gauge needle or a micropuncture set under ultrasound (US) guidance. Diagnostic fistulography was performed with a 4-F Kumpe access catheter (Cook, Bloomington, Indiana). If necessary, a second puncture directed in a retrograde fashion was made in a more central portion of the fistula and a catheter was passed into the brachial artery to enable visualization of the complete anatomic features of the arteriovenous anastomosis. At the discretion of the radiologist performing the intervention, venous pressures were measured across the suspected dysfunctional areas before and after intervention.

Treatment

All stenoses were treated according to standard angioplasty technique with noncompliant high-pressure balloons, and in cases in which inflation pressures greater than 20 atm were required, ultra–high pressure balloon catheters were used (Conquest; Bard, Covington, Georgia). When a lesion was considered clinically significant, a wire was passed into the fistula and the diagnostic catheter was removed and exchanged for an appropriately sized sheath. The balloon catheter was then advanced to the region of stenosis and the balloon was inflated until the stenosis was eliminated. Pressure was maintained for a minimum of 30 seconds at a maximum of 30 atm. If 30 atm was insufficient, peripheral cutting balloons were used (Boston Scientific, Natick, Massachusetts) and inflated until the waist resolved or maximum inflation pressure was reached. For occluded fistulas, thrombus was cleared as previously described with use of pharmacomechanical methods (9).

In cases in which angioplasty and thrombectomy were unsuccessful—or if the radiologist considered the fistula unsalvageable with traditional percutaneous techniques including a high chance of fistula dysfunction recurrence based on intervention history, persistent thrombus, or inability to achieve optimal flow—an ePTFE-covered nitinol stent was placed to salvage the fistula. In cases of repeat PTA, surgical revision to preserve the fistula was not considered possible by dedicated access surgeons. Stent-graft diameters ranged from 6 mm to 10 mm with lengths of 40–80 mm. Covered stents were oversized by approximately 10% compared with the adjacent normally sized fistula segment. After deployment, the stent-graft was expanded to its optimal size with a noncompliant angioplasty balloon of similar diameter.

Heparin was administered intravenously at the discretion of the treating radiologist in doses as high as 4,000 U. All patients were monitored with electrocardiography, pulse oximetry, and standard blood pressure determinations. Fentanyl citrate (Abbott Laboratories, North Chicago, Illinois) and midazolam hydrochloride (Versed; Roche, Nutley, New Jersey) were intravenously administered for moderate sedation during interventions. Prophylactic antibiotics were not routinely prescribed. After interventions, the catheters and sheaths were withdrawn and hemostasis was obtained with a modified purse-string suture technique (10). All interventions were performed as outpatient procedures. All patients were taking aspirin before and after intervention. No additional antiplatelet or anticoagulant medication was prescribed.

Study Endpoints and Definitions

Primary, secondary, and lesion patencies of the fistulas after percutaneous intervention were defined in accordance with the Society of Interventional Radiology reporting standards (11). Anatomic success was defined as a restoration of blood flow in the fistula with residual stenosis of less than 30% for any underlying significant stenosis. Clinical success was defined by the ability to provide adequate hemodialysis for at least one session.

Follow-up information for each patient was obtained from a vascular access database maintained by a dedicated vascular access coordinator and hemodialysis access team; no patients were lost to follow-up. Total access blood flow was measured monthly for fistula surveillance by US dilution (Transonic Systems, Ithaca, New York) to determine if possible repeat intervention was required. After intervention, transonic flow rate measurements were obtained within 10 days of intervention. Also, if a patient again developed findings suggestive of access dysfunction, including variable pump speeds, arm swelling, facial swelling, and extremity pain, they were referred for repeat fistulography. Routine fistulography in the absence of flow abnormalities or clinical signs or symptoms was not performed.

Anatomic variables documented were the side and type of fistula. Clinical variables included patient age, sex, diabetic status, fistula age, flow rates, and total interventions before and after stent placement. For this study, interventions included any procedure performed on a fistula by interventional radiology or vascular surgery personnel, including angioplasty, thrombectomy, stent placement, or surgical revision.

RESULTS

Seven ePTFE-covered nitinol stents were used to salvage dysfunctional fistulas in five patients (four men and one woman) in whom percutaneous interventions were considered to have failed. The anatomic and clinical success rate for covered stent placement was 100%. One patient died at home 3 days after intervention of a cardiac cause unrelated to renal failure or hemodialysis access; another patient died after 8 intervention-free months after voluntarily discontinuing hemo-