A prospective randomized study of stent graft placement after balloon angioplasty versus balloon angioplasty alone for the treatment of hemodialysis patients with prosthetic graft outflow stenosis

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ABSTRACT

Background: Hemodialysis graft outflow stenosis is a significant complication occurring in hemodialysis patients with prosthetic grafts for vascular access. Balloon angioplasty remains the first-line endovascular treatment of this complication, although covered stent graft implantation after balloon angioplasty also appears to be an effective and promising treatment. The aim of this study was to evaluate the efficacy and durability of stent graft placement after balloon angioplasty in comparison to balloon angioplasty alone for the treatment of graft outflow stenosis in hemodialysis patients.

Methods: We conducted a prospective randomized study of 98 patients with clinically significant dialysis graft outflow stenosis treated in the vascular surgery section of a tertiary medical center. The patients were randomized into two groups; 49 patients were treated with stent graft placement after balloon angioplasty, and 49 patients were treated with balloon angioplasty alone. All patients underwent angiography of the graft site at 3 and 6 months after intervention, and restenosis rates were compared between the two groups. In addition, the duration of postintervention primary patency in the two groups was recorded and analyzed.

Results: The postintervention restenosis rate of the stent graft placement group was superior to that seen in the balloon angioplasty alone group (9% vs 69% at 3 months [$P < .0001$] and 29% vs 72% at 6 months [$P < .0001$]). The mean postintervention primary patency duration was 380.22 ± 28.54 days for the stent graft placement group and 151.08 ± 16.79 days for the balloon angioplasty alone group ($P < .0001$).

Conclusions: The use of stent grafts in hemodialysis patients with graft outflow stenosis yielded superior results compared with the results seen in hemodialysis patients treated with balloon angioplasty alone. Patients treated with stent grafts after balloon angioplasty had a lower restenosis rate and a longer duration of postintervention primary patency. The placement of a stent graft after balloon angioplasty appears to be an optimal therapeutic approach for the treatment of hemodialysis patients with graft outflow stenosis. (J Vasc Surg 2018;■:1-8.)

Vascular access is required for patients undergoing chronic hemodialysis. The optimal type of vascular access for each individual patient depends on a multitude of factors.[1] Although an autogenous arteriovenous fistula is the most favorable type of access, some patients require an artificial graft because of inadequacies of the native venous system or advanced age.[2] Complications of dialysis grafts, such as graft outflow stenosis, graft thrombosis, and graft infection, are frequent problems plaguing hemodialysis patients and the physicians trying to maintain vascular access in these patients.

Prosthetic graft outflow stenosis is a significant graft complication that may lead to thrombosis unless it is properly managed.[3] Balloon angioplasty is currently the first-line endovascular treatment for this complication, followed by surgical revision. However, frequent and rapid restenosis remains a significant problem. To improve the treatment of dialysis graft outflow stenosis, vascular access physicians have sought an endovascular treatment with a lower recurrence rate than that seen with balloon angioplasty.

Balloon angioplasty usually provides a satisfactory early result for the treatment of patients with graft outflow stenosis. However, the midterm and long-term durability of balloon angioplasty is less impressive.[4] To obtain a longer duration of patency and to retard future restenosis, additional scaffolding with a supportive force may be beneficial. In addition, the placement of a barrier between the endothelium and the bloodstream may prevent further ingrowth of neointimal hyperplasia, which may be helpful in decreasing future in-stent restenosis. Stent grafting over graft outflow stenoses after

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balloon angioplasty may represent a useful approach. The aim of this study was to evaluate the efficacy and durability of stent graft placement after balloon angioplasty in comparison to balloon angioplasty alone for the treatment of graft outflow stenosis in hemodialysis patients.

METHODS

Study design. This prospective randomized study was designed to compare stent graft placement after balloon angioplasty with balloon angioplasty alone for the treatment of hemodialysis patients with dialysis graft outflow stenosis. The study was approved by the Institutional Review Board of Chang Gung Memorial Hospital (No. 106-0858A3), and written informed consent was obtained from each study patient. The study was conducted by the clinical research team of the Section of Vascular Surgery in Chang Gung Memorial Hospital (Linko, Taiwan). After recruitment of patients with clinically significant hemodialysis graft outflow stenosis that required intervention (clinical presentation along with >50% stenosis on angiography),[3] we used simple randomization to assign patients to one of two treatment groups: stent graft placement after balloon angioplasty vs balloon angioplasty alone. The randomization was conducted by a third party by drawing an envelope from a container of evenly mixed envelopes, among which 49 had "balloon" written inside and 49 had "stent graft" written inside. The envelope was removed from the container permanently after being drawn. The container was resealed after an envelope was drawn. Patients were followed up clinically for a minimum of 1.5 years.

Population of patients. Ninety-eight patients were enrolled in the study from February 2012 through August 2013 according to the criteria listed later. G*Power[5] software was used to determine a sample size of 98 participants. Patients were randomly assigned to one of two groups after providing full consent for study participation. Group 1, the experimental group, was treated with balloon angioplasty and stent graft placement at the outflow tract using a Conquest balloon (Bard Peripheral Vascular, Tempe, Ariz) and a VIABAHN stent graft (W. L. Gore & Associates, Newark, Del), respectively. Group 2, the control group, was treated with balloon angioplasty alone. Both procedures were performed in the operating room under local anesthesia.

Inclusion criteria. Patients with end-stage renal disease undergoing regular dialysis treatment with expanded polytetrafluoroethylene (ePTFE) grafts were included in the study if they met the following criteria:

- Age between 18 and 90 years with full functionality and the ability to comply with the follow-up protocol
- Ability to understand and to provide informed consent

ARTICLE HIGHLIGHTS

- **Type of Research:** Randomized controlled trial
- **Take Home Message:** In this randomized controlled trial of 98 patients with hemodialysis graft outflow stenosis, balloon angioplasty and stent graft placement reduced 6-month restenosis rate to 29% vs 72% in those with balloon angioplasty alone ($P < .0001$) and prolonged mean primary patency duration to 380.22 ± 28.54 days vs 151.08 ± 16.79 days for balloon alone ($P < .0001$).
- **Recommendation:** The authors recommend routine stent grafting after angioplasty of hemodialysis graft outflow stenoses.

- Ability to present for follow-up in an outpatient clinic three consecutive times for worsening clinical or physiologic parameters, such as abnormal physical findings, decreased dialysis blood flow, elevated dynamic venous pressure, difficulty with hemostasis after needle withdrawal, or unexplained reduction in Kt/V.[6] Physical examination was conducted by a single senior staff member. Pertinent physical findings included swelling of the dialysis access limb on inspection; palpable strong thrills, weak or pulsatile thrills, pulsation only, or nothing felt (only audible bruits) on palpation; and continuous bruits or systolic bruits on auscultation.
- ePTFE graft outflow stenosis >50% on preintervention conventional angiography. The degree of stenosis was defined as the diameter at the narrowest section of venous outflow compared with the diameter of the nearest normal vein.[7]

Exclusion criteria. Patients were excluded from the study if they had a medical condition (such as terminal cancer) likely to result in death within 6 months (patients with clinical factors associated with the highest risk group[8,9] were excluded from the study), had a suspected prosthetic graft infection or ongoing systemic infection, were allergic to medications used in the study (eg, contrast medium or local anesthetic agents), and had clinically significant central vein stenosis.

Treatment and follow-up protocols. Vascular access was established using an angioplasty sheath in the ePTFE graft (6F for the control group and 8F for the experimental group) without systemic heparinization. Diagnostic angiography was then performed to define the outflow lesion. For the control group, an appropriately sized angioplasty balloon was used to dilate the lesion for 1 minute. Dilation was subsequently repeated for 1-minute intervals (but no more than a total of three times) if further stenosis was observed. The case was terminated if a clinically significant lesion with >30% stenosis was still encountered after repeated balloon angioplasty. For the experimental group, the lesion was

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