Use of the Peripheral Cutting Balloon to Treat Hemodialysis-related Stenoses

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PURPOSE: To compare the effectiveness and safety of use of the peripheral cutting balloon (PCB) versus standard percutaneous transluminal angioplasty (PTA) for the treatment of hemodialysis-related stenoses.

MATERIALS AND METHODS: This prospective, randomized multicenter clinical trial included 340 patients with stenotic or thrombosed hemodialysis grafts who were randomized to receive treatment with the PCB or PTA for venous outflow stenosis. One hundred seventy-three patients underwent treatment with the PCB, 101 with stenotic grafts and 72 with thrombosed grafts. PTA was used to treat 167 patients, 94 patients with stenotic grafts and 73 with thrombosed grafts. The follow-up period extended for 6 months.

RESULTS: The procedural success rates were 80.8% and 75.4% for the PCB and PTA groups, respectively ($P = .24$). With use of the PCB, the primary patency rates of the target lesions were 84.3%, 65.8%, and 47.9% at 1 month, 3 months, and 6 months, respectively. With PTA, the primary patency rates of the target lesions were 77.7%, 63.4%, and 40.5% at 1 month, 3 months, and 6 months, respectively. The primary patency rates of the entire vascular access circuit were 82.6%, 61.0%, and 43.3% at 1 month, 3 months, and 6 months, respectively, with use of the PCB. For patients who were treated with PTA, the primary patency rates of the vascular access circuit were 75.9%, 61.0%, and 36.3% at 1 month, 3 months, and 6 months, respectively. When comparing the PCB and PTA, there was no difference in the 6-month primary patency rates in the target lesion ($P = .373$) or the entire vascular access circuit ($P = .531$). There were nine device-related complications in the PCB group (5.2%): five venous ruptures (2.9%), three venous dissections (1.7%), and one case of thrombosis (0.6%). There were no device-related complications in the PTA group.

CONCLUSION: This prospective, randomized trial comparing use of the PCB versus standard PTA for treatment of hemodialysis-related venous stenoses demonstrated that the PCB provides equivalent 6-month patency to PTA for stenotic and thrombosed grafts.

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Abbreviations: PCB = peripheral cutting balloon, PTA = percutaneous transluminal angioplasty, PTFE = polytetrafluoroethylene

THE natural history of a polytetrafluoroethylene (PTFE) hemodialysis graft is the gradual development of neointimal hyperplastic stenoses. Although these lesions most commonly occur at the venous anastomosis, they can be found anywhere along the venous outflow tract (1). The characteristic neointimal hyperplastic stenosis is a concentric, focal thickening of the vascular wall consisting of smooth muscle cells and extracellular matrix (2). The progression of a neointimal hyperplastic stenosis creates a focal narrowing in the graft or native vein, which reduces blood flow and thereby decreases the performance of the vascular access. If left untreated, a venous anastomotic stenosis will eventually lead to thrombosis of the hemodialysis graft.

Balloon angioplasty is the primary endovascular technique for treatment of vascular access–related stenoses. The neointimal hyperplastic stenoses associated with hemodialysis grafts are more difficult to dilate and tend to recur rapidly compared with arterial atherosclerotic lesions (3). The use of high-pressure (>20 atm) and ultra–high-pressure (>30 atm) angioplasty balloons has improved our ability to successfully dilate vascular access–related stenoses (4,5). However, despite these improvements in angioplasty balloon technology, the long-term results of angioplasty remain dismal.

Balloon angioplasty of a stenosis is a traumatic event that damages the vascular wall and incites a reparative process, the development of neointimal hyperplasia at the site of vascular injury. A new type of angioplasty balloon, the peripheral cutting balloon (PCB), creates microsurgical incisions in the vascular wall, which facilitates dilation of hemodialysis-related steno-

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Table 1
Clinical Criteria for Patient Enrollment

Clinical Inclusion Criteria
The patient has a synthetic hemodialysis graft located in the forearm or upper arm, and has alternative access sites available
The hemodialysis graft is > 3 months old
The patient has clinical or hemodynamic evidence of graft dysfunction, or the hemodialysis graft is thrombosed
The patient is ≥ 18 years of age
The patient understands the study requirements and is willing to comply with follow-up evaluations; patient is willing to provide informed consent
Clinical Exclusion Criteria
The patient has had any intervention of the vascular access circuit within the past 30 days
The patient has an existing stent within the vascular access circuit
Evidence of systemic infection or a local infection associated with the graft
Positive pregnancy test within 7 days before enrollment
Patient is scheduled for a kidney transplant
Patient is enrolled in another investigational study
Patient has comorbid conditions that may limit their ability to comply with the follow-up requirements
Life expectancy <6 months
Documented allergy to heparin or radiographic contrast material

Table 2
Angiographic Criteria for Patient Enrollment

Angiographic Inclusion Criteria
The patient has a stenosis (target lesion) causing >50% luminal reduction when compared to the reference vessel diameter
The target lesion is located ≤3.0 cm from the venous anastomosis
The target lesion is ≤3.0 cm in length
The patient may have a maximum of two secondary lesions (stenoses) if the following criteria are satisfied:
The secondary lesion is located in the graft or peripheral veins
The secondary lesion is ≤5.0 cm in length
The secondary lesion is located >1.0 cm away from the target lesion
The secondary lesion causes >50% luminal reduction compared to the reference vessel diameter
The secondary lesions are treated first, before randomization, using a conventional angioplasty balloon
Treatment of the secondary lesion(s) is successful with <30% residual stenosis and no complications
Angiographic Exclusion Criteria
The target lesion segment has an angulation >45° with respect to the adjacent vein or graft
The reference vessel has a diameter >8 mm
The patient has a significant (>50%) central venous stenosis
The patient has a pseudoaneurysm adjacent to the target lesion
In the opinion of the operating physician, the hemodialysis graft is unsuitable for endovascular treatment

ses. With use of this device, a stenosis can be effectively dilated with the least amount of radial force, thereby reducing trauma to the vessel wall. By using low-pressure dilation and minimizing vascular injury, the PCB may provide more long-lasting treatment of vascular access–related stenoses.

This prospective study was performed to compare the efficacy and safety of the use of the PCB versus conventional percutaneous transluminal angioplasty (PTA) for the treatment of hemodialysis-related stenoses.

MATERIALS AND METHODS

This clinical trial was performed at 27 medical centers in the United States (Appendix 1). The investigational protocol was approved by the institutional review board at each medical center before patient enrollment. Informed consent was obtained after the nature of the procedure was described to each patient. This study was funded by Boston Scientific Corporation, Natick, MA.

Study Design

This prospective, randomized clinical trial was performed to compare the safety and efficacy of the use of the PCB versus conventional PTA for the treatment of hemodialysis graft–related venous stenoses. The study patient population consisted of two groups: (i) patients with dysfunctional, stenotic hemodialysis grafts and (ii) patients with thrombosed hemodialysis grafts. Within each group, the patients were randomized to receive PTA or treatment with the PCB. The patients were followed for 6 months to determine the efficacy of the two treatment methods.

Enrollment Criteria

Patients receiving chronic hemodialysis treatment for dysfunctional or thrombosed PTFE hemodialysis grafts were eligible for enrollment. Informed consent was obtained from each patient before enrollment.

There were two categories of inclusion and exclusion criteria: clinical criteria and angiographic criteria. The clinical inclusion and exclusion criteria are presented in **Table 1**. The clinical and hemodynamic criteria that defined a dysfunctional hemodialysis graft were obtained from Guideline 19 of the National Kidney Foundation's Dialysis Outcomes Quality Initiative Clinical Practice Guidelines for Vascular Access (6). These criteria included increased recirculation values, increased venous pressures, decreased intragraft blood flow, and abnormal physical findings.

If at least one of the clinical criteria were satisfied, the patient was brought