CLINICAL STUDY

Multicenter, Randomized Trial of Conventional Balloon Angioplasty versus Paclitaxel-Coated Balloon Angioplasty for the Treatment of Dysfunctioning Autologous Dialysis Fistulae

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ABSTRACT

Purpose: To investigate the potential added value of paclitaxel-coated balloon (PCB) angioplasty to reduce fistula dysfunction related to recurrent stenoses in patients undergoing hemodialysis.

Materials and Methods: A prospective, randomized study was conducted in 3 dialysis referral centers. From January 2013 to October 2015, 64 patients (22 female, 42 male) with dysfunctional autologous dialysis fistulae were randomized to undergo conventional percutaneous balloon angioplasty (n = 31) or PCB angioplasty (n = 33). Procedural and postprocedural data were assessed. Primary patency of the fistula was evaluated at 3, 6, and 12 months following the procedure. Statistical analysis was based on the Fisher exact test and independent *t* test.

Results: There were no procedural or postprocedural complications. After 3, 6, and 12 months of follow-up, primary patency rates after PCB angioplasty and percutaneous transluminal angioplasty (PTA) were 88% and 80% ($P = .43$), 67% and 65% ($P = .76$), and 42% and 39% ($P = .95$), respectively.

Conclusions: Although primary patency rates after PCB angioplasty in autologous dialysis fistulae at 3, 6, and 12 months of follow-up are slightly better than those after PTA, the difference is not statistically significant.

ABBREVIATIONS

AVF = arteriovenous fistula, KDOQI = Kidney Disease Outcomes Quality Initiative, PCB = paclitaxel-coated balloon

An autologous arteriovenous fistula (AVF) is the access of choice for chronic hemodialysis in patients with end-stage renal disease (1). Unfortunately, dysfunction of surgically created autologous AVFs is a common problem in daily clinical practice (2,3); the fistula survival rate 2 years after access surgery has been reported to be as high as 50% (4), independent of the patient's age or ethnicity (4,5). The standard endovascular treatment recommended by the 2006 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines (1–3,6) is percutaneous transluminal angioplasty (PTA) with conventional angioplasty balloons, despite relatively low primary patency rates at 1 year ranging between 26% and 62% (2,3,6).

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The use of drug-coated angioplasty balloons has been compared versus conventional angioplasty in dysfunctioning arteriovenous grafts and AVFs with regard to primary patency rates. However, these data are uncontrolled (7,8) or were all generated at the same institution (9–11). Recently, paclitaxel-coated balloon (PCB) angioplasty has been used in the arterial circulation with favorable primary patency rates compared with the use of conventional angioplasty balloons (12,13). Repeat balloon angioplasty is the standard treatment for recurrent fistula dysfunction; however, this treatment might be associated with high cost and may negatively affect patients' quality of life (9).

The present multicenter study was undertaken to assess the safety and efficacy of PCB angioplasty compared with conventional PTA in the treatment of dysfunctioning AVFs.

MATERIALS AND METHODS

Study Design

This was a prospective, multicenter, nonblinded, randomized study comparing the short and midterm clinical outcomes of balloon angioplasty of dysfunctional autologous dialysis fistulae with use of a PCB versus a PTA balloon. The study protocol was approved by the local ethics committees of all participating institutions.

Patient Selection

Patients referred to the interventional radiology departments of participating centers for angiographic diagnosis and treatment of dysfunctional hemodialysis fistulae were considered for the study. Inclusion and exclusion criteria are summarized in Table 1. Patients were randomized to one of the two study arms with a sealed envelope system by the attending interventional radiologist. Patient enrollment and randomization were done when the diagnostic fistulography had been performed.

Demographic Data

A total of 64 patients were randomized to undergo PTA (n = 31) or PCB angioplasty (n = 33). Demographic data are summarized in Table 2. The majority of patients were male (n = 42; 65.6%) and presented with a dysfunctional radiocephalic (n = 30; 46.9%) or brachiocephalic (n = 26; 40.6%) fistula. Half of the patients had been previously treated with endovascular techniques (n = 32; 50.0%).

Interventional Technique

Under local anesthesia, the efferent vein was punctured, and a 5- or 6-F vascular high-flow sheath (Merit Medical, South Jordan, Utah) was placed in an antegrade or retrograde direction depending on clinical evaluation of the dysfunctional fistula. Fistulography was performed from the surgical anastomosis to the right atrium. All angiographic images were obtained in anteroposterior view; in case of doubt, oblique views were obtained to confirm the degree of stenosis. After intravenous administration of 2,000 IU of heparin, the target lesion was catheterized, and angioplasty was performed with the use of a regular PTA balloon catheter (Admiral Extreme; Invatec/Medtronic, Frauenfeld, Switzerland) with an inflation time of 2 minutes. If the patient was randomized to the PCB angioplasty arm, predilation with a PTA angioplasty balloon (Admiral Extreme; Invatec/Medtronic) was performed with an inflation time of 2 minutes, followed by angioplasty with a PCB (IN.Pact Admiral; Invatec/Medtronic). The nominal balloon diameter (for PTA or PCB angioplasty) was the same as the diameter of the efferent vein segment just below and above the target lesion. Balloon inflation was performed with use of an inflation device for at least 2 minutes for both types of angioplasty balloons.

If a residual stenosis persisted, repeat angioplasty and eventual placement of a stent were performed. If repeat balloon angioplasty was required in the PCB angioplasty arm, only the same PCBs were used. No repeat angioplasty was performed with conventional PTA balloons before PCB angioplasty. After the procedure, patients were referred to the dialysis department with or without high-flow sheaths in place. Patients were followed up by the attending nephrologist before each dialysis session and were evaluated by the interventional radiologist at 3, 6, and 12 months after the initial angioplasty procedure. Based on clinical and hemodynamic evaluation, the attending nephrologist, who was blinded to the patient's randomization arm, decided if the fistula was functioning.

Table 1. Inclusion and Exclusion Criteria for Study Patients

Inclusion criteria
Age ≥ 18 y
Patient able/willing to sign informed consent
Hemodialysis via autologous AV fistula
Stenosis located in efferent vein
Hemodialysis access dysfunction related to efferent vein stenosis > 50% on fistulography
Efferent vein diameter above/below stenosis of 4–8 mm
Exclusion criteria
Enrollment in other trials
Known/documented severe allergic reaction to iodinated contrast material
Active infectious status
Pregnancy
Hemodialysis via AV graft/loop
Stenosis located in central venous veins (axillary/subclavian/innominate/brachiocephalic/SVC)

AV = arteriovenous; SVC = superior vena cava.

Definitions

Technical success was defined as < 30% residual stenosis by visual estimate associated with a palpable thrill over the