Randomized Clinical Trial of Cutting Balloon Angioplasty versus High-Pressure Balloon Angioplasty in Hemodialysis Arteriovenous Fistula Stenoses Resistant to Conventional Balloon Angioplasty

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ABSTRACT

Purpose: To compare the efficacy and safety of cutting balloon angioplasty (CBA) versus high-pressure balloon angioplasty (HPBA) for the treatment of hemodialysis autogenous fistula stenoses resistant to conventional percutaneous transluminal angioplasty (PTA).

Materials and Methods: In a prospective, randomized clinical trial involving patients with dysfunctional, stenotic hemodialysis arteriovenous fistulas (AVFs), patients were randomized to receive CBA or HPBA if conventional PTA had suboptimal results (ie, residual stenosis $>$ 30%). A total of 516 patients consented to participate in the study from October 2008 to September 2011, 85% of whom (n = 439) had technically successful conventional PTA. The remaining 71 patients (mean age, 60 y; 49 men) with suboptimal PTA results were eventually randomized: 36 to the CBA arm and 35 to the HPBA arm. Primary and secondary target lesion patencies were determined by Kaplan–Meier analysis.

Results: Clinical success rates were 100% in both arms. Primary target lesion patency rates at 6 months were 66.4% and 39.9% for CBA and HPBA, respectively ($P = .01$). Secondary target lesion patency rates at 6 months were 96.5% for CBA and 80.0% for HPBA ($P = .03$). There was a single major complication of venous perforation following CBA. The 30-day mortality rate was 1.4%, with one non–procedure-related death in the HPBA group.

Conclusions: Primary and secondary target lesion patency rates of CBA were statistically superior to those of HPBA following suboptimal conventional PTA. For AVF stenoses resistant to conventional PTA, CBA may be a better second-line treatment given its superior patency rates.

ABBREVIATIONS

AV = arteriovenous, AVF = arteriovenous fistula, AVG = arteriovenous graft, CB = cutting balloon, CBA = cutting balloon angioplasty, CI = confidence interval, HPB = high-pressure balloon, HPBA = high-pressure balloon angioplasty, HR = hazard ratio, PTA = percutaneous transluminal angioplasty

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Percutaneous balloon angioplasty (PTA) is widely accepted as the first-line treatment of hemodialysis-related venous stenoses. However, in some patients, the venous stenoses can be resistant to conventional PTA as a result of dense fibrous strands incorporated into the venous neointimal layer or scar tissue from recurrent puncture trauma to the venous wall (1). These lesions are identified as a band-like "waist" in the balloon despite application of high inflation pressures. Traditional approaches to the problem include prolonged balloon inflations and balloon oversizing. Other less common methods that have been described include the use of atherectomy devices (2), laser angioplasty (3), parallel-wire techniques (4) and "infiltrate-and-perforate" techniques (5). The advent of high-pressure balloons (HPBs) capable of delivering inflation pressures greater than 20 atm to mechanically disrupt the dense fibrous tissue at the stenotic segment have improved PTA success rates in these lesions (6–11).

An alternative to HPB is the use of a cutting balloon (CB). In a CB, three or four fine cutting blades or atherotomes are incorporated into an angioplasty balloon. The atherotomes, which are exposed when the CB is inflated, cut and disrupt the fibroelastic continuity of the ring of neointimal hyperplasia. The application of CBAs in the treatment of resistant stenoses was first described in 1995 (1) in a case report. Since then, there have been multiple publications in the literature claiming the effectiveness of CBA in the treatment of resistant stenoses (12–18).

In our institution, an HPB catheter costs two times as much, and a CB catheter four times as much, as a conventional PTA balloon. As such, conventional PTA is our first line of treatment for hemodialysis access stenoses, and CB angioplasty (CBA) or HPB angioplasty (HPBA) are used only if conventional PTA yields suboptimal results. The objective of the present study was therefore to determine whether CBA or HPBA is more effective in treating venous stenoses that have shown a poor response to conventional PTA.

MATERIALS AND METHODS

This was an investigator-initiated clinical trial conducted at the Singapore General Hospital. The trial was funded by a research grant from the National Kidney Foundation Singapore (grant NKFRC/2008/06). Institutional review board approval was obtained for the investigation protocol before the start of the study. The nature of the procedure and the benefits and risks were explained to each patient, and informed consent was obtained before the patient was recruited into the study.

Study Design

This prospective randomized clinical trial was performed to compare the safety and efficacy of the use of CBA versus HPBA for the treatment of dialysis access–related venous stenoses following suboptimal conventional PTA results. The original trial design included patients with arteriovenous (AV) fistulae (AVF) or AV grafts (AVGs), but only six patients with AVGs were enrolled. This small group of patients was therefore excluded from the study analysis, which was conducted purely on patients with AVFs. We hypothesized that the primary patency of dialysis AVF following CBA is superior to that following HPBA in the treatment of venous stenoses resistant to conventional PTA.

The study patient population consisted of patients with dysfunctional dialysis AVFs. The patients were randomized to receive CBA or HPBA if conventional PTA was suboptimal (defined as > 30% residual stenosis). The design attempted to involve equal allocation of patients to the two treatment arms of the study. The patients were asked to return at 6 months for a fistulogram to be obtained to determine the 6-month target lesion patency rates to assess the efficacy of the two treatments.

Eligibility

Patients with malfunctioning dialysis AVFs referred for PTA were recruited and assessed for eligibility. Thrombosed AVFs were excluded. Informed consent was obtained from each patient before recruitment.

The inclusion and exclusion criteria are summarized in **Table 1**. Patients who were not excluded based on these criteria were eligible for enrollment in the study if, in the course of management of the malfunctioning AVF, they satisfied all inclusion criteria. The patients were treated first with conventional PTA with an appropriate size of conventional angioplasty balloon, employing inflation pressures as high as the manufacturer's stated burst pressures, with at least two inflation attempts as long as 1 minute each time. If there was residual stenosis of at least 30% observed (degree of residual stenosis documented by venogram and expressed in percentages), the patients were then randomized into the CBA or HPBA arm of the study.

Definitions of technical (ie, anatomic) success, clinical success, and primary and secondary patency were adapted from Society of Interventional Radiology reporting standards for percutaneous interventions in dialysis access (19) and are provided in **Table 2**.

Procedures

All procedures were performed by consultant-level interventional radiologists.

Diagnostic AV Fistulogram. Fistulograms were obtained with a 21-gauge butterfly needle inserted into the "A" needling site of the AVF. Sequential venograms of the draining outflow veins as well as the central veins were obtained. The AV anastomosis was opacified by way of contrast agent reflux with inflation of a blood