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Safety and effectiveness of combined scoring balloon and paclitaxel-coated balloon angioplasty for stenosis in the hemodialysis access circuit

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Angioplasty;
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Vascular stenosis

Abstract
Purpose: To evaluate the safety and effectiveness of combined scoring balloon (SB) and paclitaxel-coated balloon (PCB) angioplasty for stenosis in the dysfunctional hemodialysis access circuit.
Material and methods: Patients were referred from outpatient dialysis centers by their nephrologists because of dysfunctional dialysis access circuit. Fistulogram/graftogram was performed by experienced interventional radiologists. Those with in-stent stenosis, stent edge stenosis or vessel diameter at the culprit segment larger than 6 mm were excluded. Angioplasty of the stenotic segment was performed with SB and followed by PCB. All study outcomes were defined according to the Society of Interventional Radiology technology assessment committee reporting standards for percutaneous interventional procedures in dialysis access circuit.
Results: A total of 23 patients received combined SB/PCB angioplasty for stenosis of hemodialysis access circuit which included 15 fistulas and 8 grafts. There were 10 men and 13 women with a mean age of 63.3 ± 2.7 (SD) years (range: 37—85 years). The technical success and clinical success rates were both 100%. There were no complications during or after the procedures. The target lesion primary patency rates at 3, 6 and 12 months were 91.3%, 69.6%, and 45.2%, respectively and the estimated median target lesion restenosis (TLR) free duration was 11.0 months (95% confidence interval [CI]: 5.1—16.9 months). In patients with a recurrent stenosis,

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the median TLR-free duration of combined angioplasty was significantly higher than that of prior angioplasty with plain balloon (10.2 months [95% CI: 6.4—14.0 months] vs. 4.2 months [95%CI: 2.1—6.4 months]) ($P = 0.047$). The mean TLR-free duration was significantly higher in patients with a juxta-anastomotic stenosis than those with non-juxta-anastomotic lesion (21.3 months [95% CI: 14.7—28.0 months] vs. 8.2 months [95% CI: 5.1—11.4 months]) ($P = 0.004$).
Conclusion: Combined SB/PCB angioplasty is safe and effective for the hemodialysis access stenosis.

Clinical trials showed that paclitaxel-coated balloons (PCB) gave significantly lower hemodialysis access restenosis rate compared to plain balloons (PB). In series involving 10 patients with two separated inflow lesions in the radiocephalic arteriovenous fistula, PCB and PB were used to treat one lesion and PB alone was used for the other [1]. Compared to the PB group, the PCB + PB group had a significantly longer target lesion restenosis (TLR) — free duration and a significantly higher 6-month patency rate [1]. A larger trial on 40 patients with failing dialysis access caused by venous stenosis reported a significantly higher 6-month and 12-month primary patency after PCB application compared to PB treatment alone [2,3].

Although PCB is effective against restenosis, the high-speed blood flow in dialysis circuits washes a large amount of the paclitaxel away from the target lesion (TL) soon after PCB application. A measurement in swine showed that only 20%—30% of paclitaxel was taken up into the coronary artery wall in vivo 15—25 minutes after PCB application [4]. The scoring balloons (SB) create cleavages in the lesion which can theoretically provide a larger contact surface for subsequent PCB and facilitate drug transfer into the inner layer of the lesion [5,6]. We hypothesize that the combined SB/PCB angioplasty is more effective in preventing restenosis than PCB alone. However, there are no reports about combined SB/PCB angioplasty for stenosis of hemodialysis access circuit until now.

The purpose of this study was to evaluate the safety and effectiveness of combined SB/PCB angioplasty for stenosis of dysfunctional hemodialysis access circuit.

Materials and methods

Study design

The study was approved by the Institutional Review Board and the requirement for informed consent was waived. Patients were referred from outpatient dialysis centers by their nephrologists because of dysfunctional dialysis access. Fistulogram/graftogram was performed by experienced interventional radiologists. Significant stenosis was defined as a reduction in luminal diameter of at least 50% in the access angiogram. Those with in-stent stenosis or stent edge stenosis were excluded. Because the maximum size of Lutonix drug-coated balloon (DCB) (Bard Peripheral Vascular, Inc, Tempe, AZ, USA) during this review timeframe was 6 mm, those with vessel diameter at the culprit segment larger than 6 mm were also excluded from this approach. Angioplasty of the stenotic segment was performed with a VascuTrak scoring balloon (Bard Peripheral Vascular, Inc, Tempe, AZ, USA) and followed by a Lutonix DCB with near 1:1 sizing. All patients were followed up by access coordinators and the effectiveness of dialysis treatment was obtained from outpatient dialysis units. Patients' records were reviewed to collect demographic and clinical information including age, gender, date of access creation, type and location of access circuit, and prior procedures on access circuit.

Technique

Fistulogram/graftogram was performed in an interventional radiology suite according to standard techniques. Midazolam (Roche Laboratories, Nutley, NJ, USA) and Fentanyl (Abbott Laboratories, Abbott Park, III, IL, USA) was administered intravenously for conscious sedation and analgesia, as needed for patient comfort. The site and initial direction of the access were selected by the primary operator on the basis of the physical examination findings and prior studies. After wide-area sterile skin preparation with 2% chlorhexidine gluconate and subcutaneous administration of 1% lidocaine as the local anesthetic, the fistula/graft was accessed using a 21-gauge needle and 0.018-inch guidewire from a micropuncture set (Cook Medical, Bloomington, IN, USA). An initial diagnostic fistulogram was obtained by using a 5-F micropuncture sheath. Stenosis was identified by visible narrowing of the lumen more than 50%; if there was any question, orthogonal projection images were obtained. The anastomosis was evaluated by reflux angiography (temporarily occluding the fistula/graft manually or by balloon inflation) or catheterization of the parent artery in cases of retrograde access. Once a stenosis was identified on the diagnostic angiogram, a 6 or 7-F sheath (as determined by intended treatment balloon size) was placed, and the lesion was crossed with a hydrophilic 0.035-inch guidewire (Boston Scientific, Natick, MA, USA). The size and type of the angioplasty balloons were determined by the procedure's operator based on the diagnostic fistulogram/graftogram findings. In general, the diameter of the balloon was chosen to match

the caliber of the adjacent normal vessel. The stenosis was treated with SB angioplasty inflated to nominal pressure using an inflation device. Inflation was maintained for a minimum of 120 seconds. If stenosis persisted, these lesions were excluded from subsequent PCB angioplasty. Other devices were considered but felt to be little more aggressive and risk of damaging the vessel had to be minimized if follow-up PCB treatment was the goal. Balloon preparation, transit to target lesion and inflation time were all as per IFU. A polytetrafluoroethylene-covered stent would be deployed if the angiographic results were more than 30% residual stenosis at the treated site or if the angioplasty was complicated by vessel rupture which did not respond to balloon tamponade technique. All efforts were made to avoid stent placement in the juxta-anastomotic and access zones. All patients were monitored with electrocardiography, pulse oximetry, and standard blood pressure monitor.

All procedures related to dialysis access circuit were registered in a local database managed by two dialysis access coordinators. The images of each fistulogram/graftogram were reviewed independently by two experienced interventionalists to determine the type and location of the access circuit, location of the lesions in the access circuit and the degree of residual stenosis after treatments.

Technical success and complications evaluation

All study outcomes were defined according to the Society of Interventional Radiology technology assessment committee reporting standards for percutaneous interventional procedures in dialysis access [7]. Technical success was defined as less than 30% residual stenosis immediately after the procedure; clinical success was defined as the reduction of abnormal dialysis parameters with concomitant improvement of the quality of dialysis for stenosis treatment. Target lesion (TL) primary patency was defined as < 50% angiographic restenosis with no need for any additional percutaneous or surgical procedure within the previously treated area.

Statistical analysis

Continuous data were reported as mean ± standard deviation (SD), and categorical data were reported as numbers and percentages. Kaplan-Meier analysis with log-rank test was used to estimate the patency rate and difference in target lesion restenosis (TLR) event during the follow-up period. The patency rates of two groups were compared with Fisher Exact test. A *P*-value < 0.05 with a two-sided 95% confidence interval (CI) was considered statistically significant. Statistical analysis was performed using SPSS software (IBM SPSS, version 19.0, SPSS Inc. Chicago, IL, USA).

Results

Clinical features

Twenty-three patients received combined SB/PCB angioplasty for stenosis in hemodialysis access circuit between November 2014 to October 2016. There were 10 men and 13 women with a mean age of 63.3 ± 2.7 (SD) years (range: 37—85 years). The hemodialysis access circuits comprised of 15 fistulas and 8 grafts, with 10 brachiocephalic, 9 brachiobasilic and 4 radiocephalic. The mean age of access circuit was 23.3 ± 5.8 (SD) months (range: 1.8—113.5 months). The referral reasons included failure

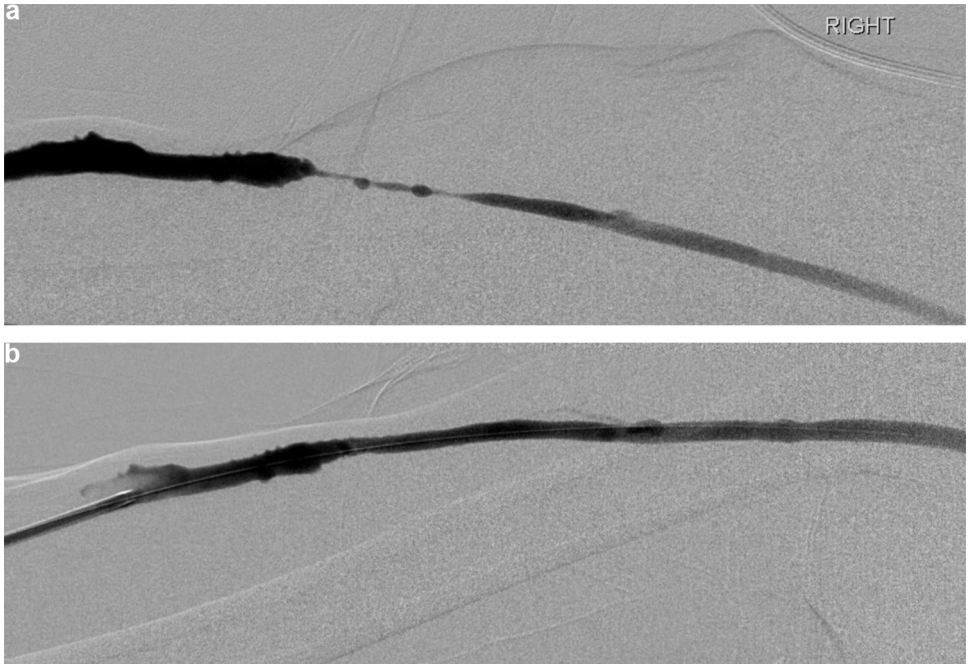

Figure 1. a: 71-year-old man with prolonged bleeding of brachiocephalic fistula; b: initial fistulogram showed a segment of severe stenosis in the venous outflow. The stenotic lesion was angioplastied with 5 mm × 40 mm scoring balloon followed by 5 mm × 60 mm paclitaxel-coated balloon. Repeat fistulogram showed complete resolution of the prior stenosis.

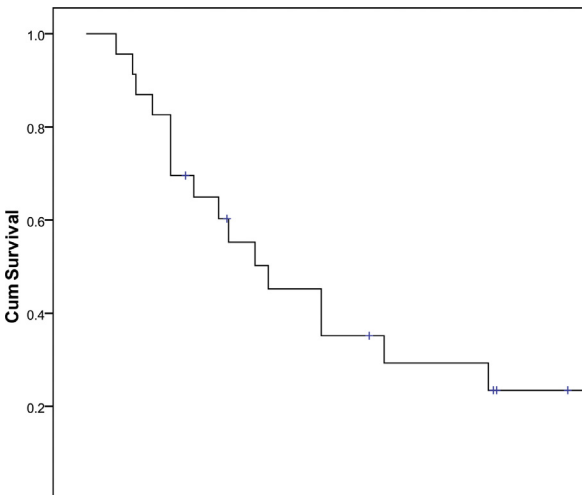

Figure 2. Diagram shows Kapla-Meier analysis for the TLR-free duration of target lesion ($n = 23$).

to mature in 6 (26.1%), high venous pressure in 4 (17.4%), weak thrill in 4 (17.4%), difficult cannulation in 3 (13.0%), prolonged bleeding in 3 (13.0%), decreased clearance in 2 (8.7%), and swollen arm in 1 (4.3%) patient. Twelve (52.2%) of them with the culprit stenosis were in the juxta-anastomotic area, 7 (30.4%) in the venous outflow, 2 (8.7%) in the access zone, and 2 (8.7%) spanned the juxta-anastomotic and access zone. Twelve patients presented with a recurrent stenosis and had prior angioplasty procedures with PB.

Technical success and complications

Post-angioplasty fluoroscopy showed patent access circuit in all patients. The technical success rate was 100%, and there were no complications during or after the procedures. All access circuits were functional after treatment and the clinical success rate was 100%. Sample images are shown in Fig. 1.

Follow-up and patency rate

The mean follow-up time was 21.7 ± 1.9 (SD) months (range: 3.4—35.4 months) at the end of the follow-up period (October 2017). Two patients with patent hemodialysis access circuit died due to their underlying disease at 3.4 and 24.7 months respectively. One patient was lost to follow-up at 6.0 months. The TL primary patency rates at 3, 6 and 12 months were 87.0%, 69.6%, and 45.2%, and the estimated median TLR-free duration was 11.0 months (95% CI: 5.1—16.9 months) (Fig. 2).

Comparison between combined angioplasty and prior intervention

Twelve patients with a recurrent stenosis had received angioplasty with PB before combined SB/PCB angioplasty, and the result was compared between combined angioplasty and prior intervention. The estimated median TLR-free duration of combined angioplasty was significantly higher than that of prior one with PB (10.2 months [95% CI: 6.4—14.0 months] vs. 4.2 months [95% CI: 2.1—6.4 months], respectively) ($P = 0.047$) (Fig. 3). The TL primary patency rate of combined angioplasty was higher than that of prior one at 6 months (75.0% vs. 25.0%; $P = 0.039$), however, they did not statistically differ at 3 months (91.7% vs. 66.7%; $P = 0.317$), or at 12 months (36.4% vs. 16.7%; $P = 0.371$).

Comparison between juxta-anastomotic and non-juxta-anastomotic stenosis

The lesion within approximately 2 cm from the anastomotic point was defined as the juxta-anastomotic stenosis ($n = 12$), and the rest as the non-juxta-anastomotic stenosis ($n = 11$). The TLR did not reach the median in patients with a juxta-anastomotic stenosis at the end of the follow-up period, but TLR occurred in all the patients with a non-juxta-anastomotic lesion. The estimated mean TLR-free duration in patients with a juxta-anastomotic stenosis (21.3 ± 3.4 [SD] months; 95% CI: 14.7—28.0 months) was significantly higher than those with non-juxta-anastomotic lesion (8.2 ± 1.6 [SD] months; 95% CI: 5.1—11.4 months) ($P = 0.004$) (Fig. 4). The TL primary patency rates in patients with a juxta-anastomotic stenosis were higher, but did not have statistical difference compared with a non-juxta-anastomotic stenosis at 3 months (91.6% vs. 81.8%; $P = 0.590$), at 6 months (83.3% vs. 54.5%; $P = 0.193$), or at 12 months (60.0% vs. 27.3%; $P = 0.198$).

Discussion

PB angioplasty is the first-line treatment for hemodialysis access dysfunction [8—10]. It can be used to manage the problems that involve both AVF and grafts. However, restenosis rates and frequent need for further reinterventions remains to be solved [11,12]. Restenosis is mainly caused by intimal hyperplasia, in which smooth muscle cell (SMC) proliferation is one of the major mechanisms in the pathogenesis [13,14]. Chang et al. reported that the proliferation activity in post-PTA restenotic lesions of hemodialysis vascular access was much higher compared with that of primary stenotic lesions, although both lesions showed the similar histological changes [15]. So it is necessary to perform adjunctive anti-proliferative therapy for preventing restenosis in the vascular access after PTA. Lee et al. reported that the proliferation of aortic and venous SMC could both be obviously suppressed by paclitaxel, although it was different in the response of signaling pathways to anti-proliferative agents [16]. Kim et al. reported that venous SMC was more sensitive to the effects of paclitaxel compared with arterial SMC [17].

PCB can provide rapid delivery of the anti-proliferative drug to the local vessel wall and inhibition of neointimal hyperplasia. The safety and effectiveness of PCB have already been confirmed in the ambit of coronary artery disease and peripheral artery disease, and PCB angioplasty can produce a significant reduction in angiographic late lumen loss in both the disease conditions [18—21]. Nowadays a few studies focusing on venous stenosis of failing access circuit have shown that the patency can be significantly improved by PCB angioplasty compared with PB angioplasty [1—3,22,23]. The role of PCB during the process is to preserve the good result obtained on the day of intervention,

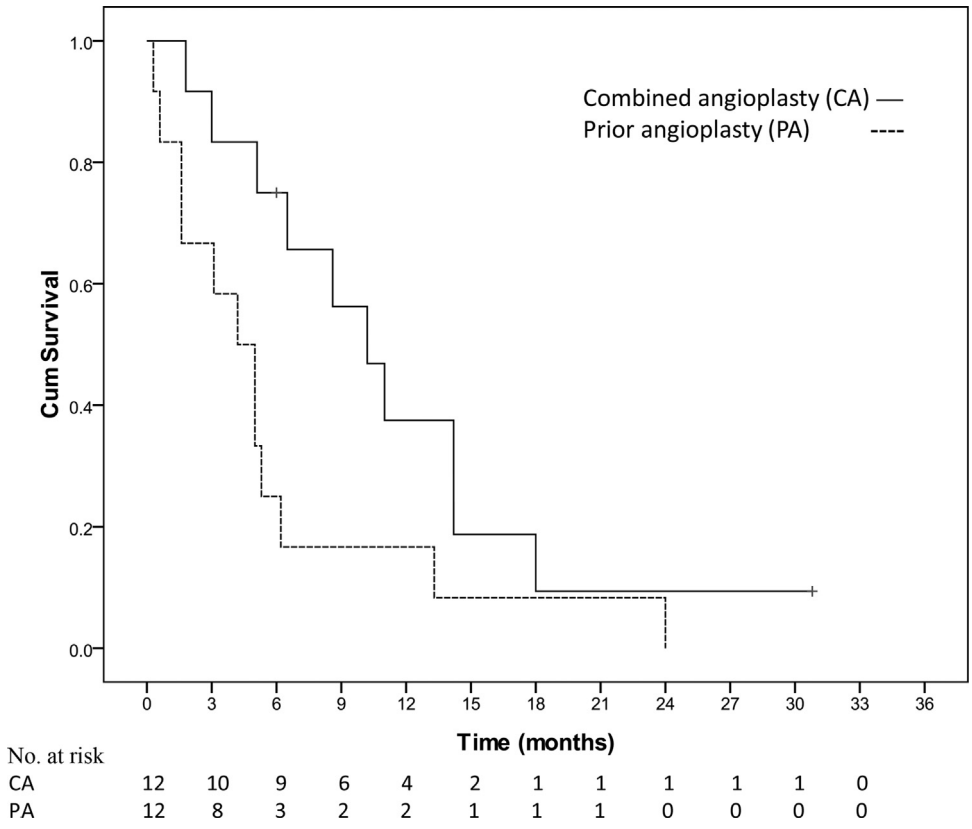

Figure 3. Kaplan-Meier analysis shows that TLR-free duration was significantly longer after treatment with combined angioplasty compared with prior intervention with plain balloon angioplasty in patients with recurrent stenosis ($n = 12$) ($P = 0.047$).

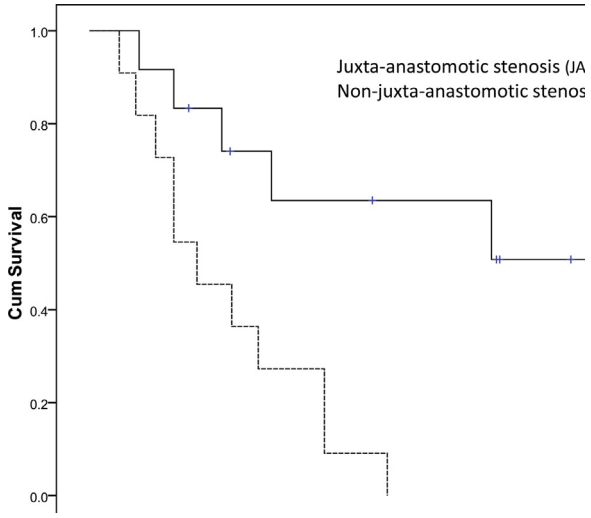

Figure 4. Kaplan-Meier analysis shows that TLR-free duration was significantly longer in the patients with juxta-anastomotic stenosis ($n = 12$) versus those with non-juxta-anastomotic stenosis ($n = 11$) ($P = 0.004$).

by delaying restenosis due to neointimal hyperplasia. So it is important to have an adequate predilation of the stenotic lesion in order that effective drug transfer can be achieved for therapeutic efficacy. Conventional angioplasty has a high rate of uncontrolled dissections and inadequate luminal expansion in patients with severe stenosis which can lead to neointimal hyperplasia and ultimately restenosis. SB can overcome the limitations of PB by a more controlled longitudinal score at low pressures, thereby resulting in less uncontrolled dissections, less barotrauma and more superior luminal expansion before PCB angioplasty [24,25]. So combined SB/PCB can theoretically produce a better clinical effect than single PCB.

The present study showed that the combined SB/PCB angioplasty had excellent technical and clinical success rates. Additionally, it gave an excellent TL primary patency, which at 3, 6 and 12 months was 91.3%, 69.6%, and 45.2%, and the median TLR-free duration was 11.0 months which was higher compared with previous studies. Kitrou and Katsanos et al. reported that the primary patency in a prospective randomized controlled trial was 70% in PCB group and 25% in PB group at 6 months; 35% in PCB group and 5% in PB group at 12 months with a median primary patency of 0.64 years (7.7 months) in PCB group [2,3]. Lai et al. reported that the primary patency in a pilot study was 70% in PCB/PB group and 0% in PB group at 6 months; 20% in PCB/PB group and 0% in PB group at 12 months with a mean TLR-free duration of 251.2 days (8.4 months) in PCB group [1]. The results of the present study support that combined SB/PCB angioplasty for dysfunctional dialysis access circuit is more safe and effective in preventing restenosis than PCB alone or combined PCB/PB angioplasty. We also compared the results between combined SB/PCB angioplasty and prior PTA with PB in patients with recurrent stenosis, which also showed that combined angioplasty could significantly prolong the TLR-free duration and improve the TL primary patency compared with PB angioplasty.

In addition, the baseline characteristics of the stenosis can also affect the clinical effect [24,26,27]. In our study, further subgroup analyses were performed after stratification for the location between juxta-anastomotic and non-juxta-anastomotic stenosis, and the results showed that the mean TLR-free duration was significantly higher in patients with a juxta-anastomotic stenosis compared with non-juxta-anastomotic stenosis ($P < 0.05$). Although the TL primary patency rate at 3, 6 and 12 months did not show significant differences between the two groups, a trend towards better results was detected with juxta-anastomotic stenosis. We note that the shorter lesion length could be a possible reason for the long TLR-free duration and high patency rate with juxta-anastomotic stenosis. However, valid conclusions regarding this particular subgroup cannot be drawn due to the small number of patients in each group.

The present study has several limitations. First, this study was an investigation at a single center and had a limited sample size, therefore, a larger sample is required in order to better investigate the effectiveness. Second, we were not able to initiate a clinical trial or an observational study comparing combined SB/PCB with PB alone or combined PB/PCB angioplasty, so it is difficult to tease out SB effect. Lastly, although the therapeutic effectiveness was improved, combined SB/PCB angioplasty does further increase the cost.

In conclusion, combined SB/PCB angioplasty is safe and effective for the treatment of stenosis in the hemodialysis access circuit. The TLR-free duration and TL primary patency rate can be significantly improved, especially in patients with juxta-anastomotic stenosis. The patency benefit here can only be further validated in a randomized investigation that should also include a cost-effectiveness analysis.

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Disclosure of interest

The authors declare that they have no competing interest.

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