Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial

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ABSTRACT

Purpose: To compare the clinically-assessed intervention-free period (IFP) of paclitaxel-coated balloon (PCB) vs conventional balloon angioplasty (CBA) for the treatment of symptomatic central venous stenosis (CVS) in dialysis access.

Materials and Methods: Within 20 months, 40 dialysis patients (19/40 arteriovenous fistulae [AVFs] and 21/40 arteriovenous grafts [AVGs]) were randomized to undergo angioplasty either with a PCB (PCB group, n = 20; 14/20 male; age: 56.7) or CBA (CBA group, n = 20; 15/20 male; age: 57). There were 15/20 restenotic lesions in PCB group and 12/20 in CBA group. In 25/40 cases, patients had an ipsilateral catheter insertion in the past. Primary endpoint was clinically-assessed intervention-free period (IFP) of the treated segment at 6 months, while secondary endpoints included complication rates during follow-up period and identification of factors influencing IFP.

Results: Median IFP was significantly better in PCB group (PCB group: 179 days, vs CBA group: 124.5 days, $P = .026$). Mean follow-up period was 180 days (range, 5–479). There was no significant difference between AVGs and AVFs ($P = .17$), treatment of de novo vs restenotic lesions ($P = .33$), or prior presence of catheter insertion ($P = .21$). No complications were observed. In restenotic lesions in PCB group, longitudinal comparison between treatments also showed a significant difference in favor of PCB treatment (median IFP in PCB* group 177 vs 91 days in CBA* group; $P = .01$).

Conclusions: In this prospective study, PCB had significantly better results compared with CBA for the treatment of symptomatic central venous stenosis in dialysis access. Retrospective longitudinal comparison of treatments in the same patients also showed a significant difference in favor of PCBs.

ABBREVIATIONS

CBA = conventional balloon angioplasty, CI = confidence interval, CVS = central venous stenosis, DSA = digital subtraction angiography, HR = hazard ratio, PCB = paclitaxel-coated balloon, QVA = quantitative vessel analysis, SVC = superior vena cava

Although it is an incidental finding in many cases, central venous stenosis (CVS) could become symptomatic, resulting not only in inadequate dialysis performance but also in clinical manifestations such as ipsilateral neck, arm, or breast swelling (1). Previous insertion of foreign materials, mainly central venous catheters, accompanied by actual use of the access circuit for dialysis, are the main causes of CVS in dialysis recipients (2).

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Standard interventional practice for CVS is conventional angioplasty, but this is associated with patency rates as low as 28.9% at 6 months and 25% at 1 year (3,4). These patency rates may be twice as high when high-pressure balloons are used (eg, 60% at 6 mo) (5,6). Immediate elastic recoil is another possible problem in the treatment of CVS (subclavian vein, brachiocephalic vein, superior vena cava [SVC]) (7–9). Placement of a bare metal stent (BMS) is proposed in these "bailout" cases and in cases in which restenosis occurs in less than 3 months after conventional balloon angioplasty (CBA), and has been reported to be associated with assisted patency rates between 33% and 56% at 1 year (10,11). Data from recently published studies suggest stent grafts as a valid alternative for persistent CVS even in the setting of in-stent restenosis (12,13).

Paclitaxel-coated balloons (PCBs) have been tested for their safety and efficacy in the treatment of dysfunctional dialysis access in a few randomized studies and retrospective analysis of cases, with encouraging results so far (14–18). In two randomized controlled trials that used PCBs in arteriovenous fistulae (AVFs) and the venous outflow of arteriovenous grafts (AVGs) (14,15), the use of PCBs demonstrated significantly better results than conventional angioplasty. However, central venous stenoses were not treated in any of these studies.

The present randomized controlled trial was designed to investigate the safety and effectiveness of PCB use in the treatment of symptomatic CVS in dialysis access compared with CBA.

MATERIALS AND METHODS

Study Design

This was a prospective, single-center, single-blinded, randomized controlled trial approved by the hospital's ethics and scientific committee. A dedicated informed consent form was signed by all patients recruited in the study. Patients and referring physicians were blinded to the treatment received, but, because of the special characteristics of the catheters, operators were not.

Randomization

Patients referred from their dialysis center with clinical signs of CVS (arm swelling; pain, tenderness, and/or erythema of the ipsilateral extremity; breast or neck swelling; visible collateral venous network; or access dysfunction) ipsilateral to their dialysis circuit were subjected to digital subtraction angiography (DSA). Patients with CVS observed and estimated as nonsignificant (< 50% stenosis) or a vessel > 12 mm in diameter by visual estimation were excluded from the trial (Fig 1). Other exclusion criteria were presence of a BMS or stent graft or vascular access thrombosis. In cases of contrast medium allergy, the procedure was performed with the use of CO_2. If the aforementioned factors did not occur and the rest of the inclusion and exclusion criteria were fulfilled (Table 1), patients were randomized to receive CBA or CBA plus PCB angioplasty in separate procedures on the same day. Randomization was performed on a 1:1 basis by using sealed opaque envelopes.

Study Characteristics

From January 2014 to August 2015, 59 patients visited our department with clinical signs of CVS. Of those, 19 patients were excluded from the study because they did not meet the inclusion and exclusion criteria, and 40 patients were finally recruited: 20 in each group (Fig 1). The lesions treated were situated in the subclavian vein in the majority of cases (n = 12 in the PCB group; n = 13 in the CBA group). Lesions were also located in the brachiocephalic vein (n = 5 in each group) and SVC (n = 3 in the PCB group; n = 2 in the CBA group). No concomitant lesions were present. Additionally, most lesions were restenotic; that is, they had been treated with CBA before patient recruitment in the study (15 of 20 [75%] in the PCB group and 12 of 20 [60%] in the CBA group). There was a balance between AVFs and AVGs in both groups, and previous ipsilateral catheter insertion was common (13 of 20 [65%] in the PCB group and 12 of 20 [60%] in the CBA group; Table 2).

Device

The device under investigation was the Lutonix balloon (Bard Peripheral Vascular, Tempe, Arizona), which is coated with paclitaxel at a dose of 2 μg/mm^2. Paclitaxel exerts its potent cytotoxic action by inhibiting the disassembly of microtubules in the mitotic phase of the cell cycle, thereby causing cell apoptosis. The role of PCBs in the peripheral arterial bed has been well investigated, mainly in the superficial femoral artery (19). This specific device is available in diameters as large as 12 mm. It is a semi-compliant balloon with a maximum burst pressure of 12 atm and is mainly used as a drug delivery device rather than a percutaneous transluminal angioplasty balloon catheter. Therefore, vessel wall preparation is necessary for better contact of the drug to the vascular wall during inflation and therefore better drug distribution.

Procedure

Access was gained, and a hydrophilic catheter (Terumo Europe, Leuven, Belgium) was advanced to the inferior vena cava. A new DSA study was performed before angioplasty. When the wire had been placed in the inferior vena cava, 5,000 IU of heparin was administered.

In the CBA group, angioplasty was performed with a 2-minute inflation of one of several high-pressure balloons (Atlas, Conquest, Dorado [Bard Peripheral Vascular], or Mustang [Boston Scientific, Marlborough, Massachusetts]). In case of residual stenosis (> 30% by visual estimation), a second prolonged inflation was performed (4 min). If judged necessary by the physician, a balloon 1 mm larger in diameter was used. The aim was to achieve residual stenosis of < 30% by visual estimation on orthogonal projections

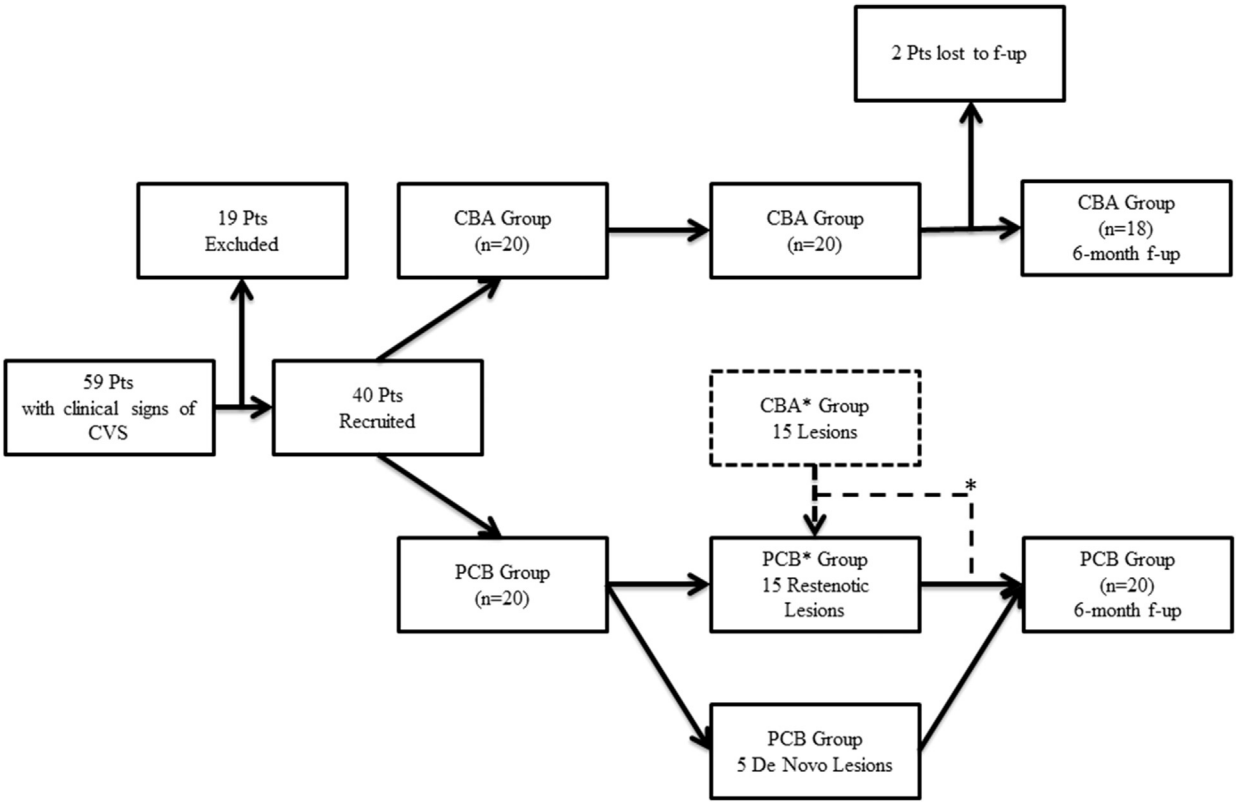


Figure 1. Study flowchart. Among 59 patients visiting our department within a period of 20 months, 40 were recruited for the study and divided into two groups at a 1:1 ratio. In the PCB group, 15 cases were restenotic lesions that had been treated with CBA before patient enrollment in the present study (dotted box). The dotted line with the asterisk shows the longitudinal comparison between the previous CBA and the PCB angioplasty performed in the same patient as part of the present study.

(in conjunction with loss of collateral vessels, angiographic flow, and stenotic "waist" effacement during inflation). The same sequence of steps was followed in the PCB group. When the vessel had been properly prepared (ie, residual stenosis < 30% by visual estimation), the PCB used was the same diameter as the predilation balloon or 1 mm larger, but 5 mm longer on each side. Inflation time was 2 minutes. In cases in which two PCBs were used, there was an inflation crossover to avoid geographic misplacement in accordance with the instructions for use. The patient was blinded to the balloon type used for treatment. Follow-up was performed with telephone interviews at 1 and 3 months and a clinical visit to a physician blinded to the balloon type at 6 months unless the patient was referred to our department as a result of recurrent or new clinical symptoms. In this case, the patient was asked and examined in regard to symptom recurrence and dialysis performance. No further follow-up was performed after repeat intervention.

Study Endpoints

Endpoints were defined according to Society of Interventional Radiology (SIR) reporting standards (20). The primary endpoint was the clinically assessed intervention-free period (IFP) in the treated segment at 6 months. This was defined as a dialysis access circuit with no need for clinically driven target lesion repeat intervention for symptom recurrence and angiographic verification of the presence of CVS. Secondary endpoints were anatomic success (ie, < 30% residual diameter stenosis by visual estimation or decrease of collateral vessels), procedural success (ie, anatomic success and initial symptom resolution, improvement of dialysis), and procedure- and device-related major and minor complications defined per SIR reporting standards for percutaneous vascular access procedures (20).

As 15 of 20 cases (75%) in the PCB group were restenotic lesions, a longitudinal comparison was made between treatments in these patients: the previous CBA treatment versus the PCB angioplasty performed as part of the present study. Previous CBA treatment was performed in these patients before their recruitment for the present study, and therefore data collection for angioplasty and follow-up is retrospective for this comparison.

Statistical Analysis

Overall sample size was calculated on the assumption of a 50% expected rate of freedom from intervention at 6 months in the control group (according to the literature) and an anticipated 75% intervention-free rate at 6 months in the PCB group, with a superiority margin (δ) of 15% (3). Numbers of participants were calculated to be 17 in each group with a type I error (α) of 5% and a type II error (β) of

Table 1. Enrollment Criteria

Inclusion criteria
Age > 18 y and < 90 y
Patient receiving dialysis with ipsilateral AVF or AVG
Stenosed central vein (subclavian vein, brachiocephalic vein, SVC)
Clinical signs of central venous stenosis
Arm swelling, pain, tenderness, and/or erythema of ipsilateral extremity
Ipsilateral breast swelling
Neck swelling
Visible collateral venous network
Inadequate dialysis performance
Exclusion criteria
Stenosis < 50% verified with DSA by visual estimation
Vessel diameter of > 12 mm verified with DSA by visual estimation
Dialysis access thrombosis
Presence of BMS or stent graft
Pregnancy
Infected vascular access

AVF = arteriovenous fistula; AVG = arteriovenous graft; BMS = bare metal stent; DSA = digital subtraction angiography; SVC = superior vena cava.

20%. Hence, study power was set at $1 - \beta$, or 80%. It was decided to recruit 20 participants in each group to account for an approximate 15% rate of loss to follow-up.

Statistical analysis was performed with the GraphPad Prism statistical software package (version 5; GraphPad, San Diego, California). Discrete variables are presented as counts and percentages, with proportions compared with a χ^2 test. Continuous variables are expressed as medians and interquartile ranges in parentheses in case of skewed distributions and compared with nonparametric tests, or as means ± standard deviation (21) in case of normal distributions and tested with the Student *t* test. Kaplan–Meier survival analysis curves regarding the primary endpoint of IFP between the two study groups and subgroup analysis of possible factors affecting IFP were compared with the log-rank test. The threshold of statistical significance was set at $P = .05$.

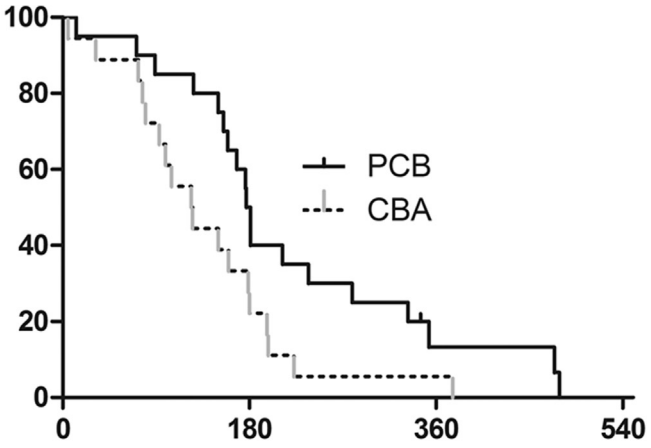
RESULTS

Within 20 months, 40 patients were recruited. Baseline variables with regard to patient, circuit, and lesion characteristics were equally distributed between the two groups (Table 2). Inadequate dialysis was the main reason for patient recruitment (27 of 40 patients; 67.5%). In the PCB group, 23 devices were used in 20 interventions (operators used two devices per lesion in three cases of subclavian vein treatment). Anatomic success rate was 100% in both groups, and no stent placement was needed. No device- or procedure-related adverse events were noted during follow-up. Two patients were lost to follow-up in the CBA group (Fig 1). Mean follow-up period was 180 days (range, 5–479 d). Patients who presented with clinical recurrence during follow-up underwent DSA to confirm the recurrence of the target treated central lesion and exclude the presence of new lesion(s). All patients who presented with recurrence of symptoms had angiographically confirmed target lesion restenosis or reocclusion, and no new lesions (central, peripheral, or within the vascular access) were detected by DSA.

Table 2. Study Variables

Variable	PCB Group	CBA Group	*P* Value
No. of patients	20	20	
Male sex	14	15	1.00
Age (y)			.87
Mean	56.7	57	
Range	25–81	33–81	
Comorbidities			
Diabetes	11	13	.75
PAD	5	4	1
CVD	8	6	.74
Clinical symptoms			
Inadequate dialysis	14	13	1
Neck swelling	1	0	1
Ipsilateral hand swelling	5	7	.73
Previous catheter insertion	13	12	1
Vascular access			
AVF	10	9	1
AVG	10	11	1
Access age (y)			.25
Mean	2.83	2.42	
Range	1.2–6.1	0.7–4.4	
Lesions			
Site			
Subclavian vein	12	13	1
Brachiocephalic vein	5	5	1
Superior vena cava	3	2	1
Previous intervention			
De novo	5	8	.5
Restenotic	15	12	.5
Occlusions	4	4	1
Procedure			
No. of devices	23	20	
Postdilation	11	–	
Balloon size			
Diameter (mm)			.49
Mean	9.75	9.45	
Range	8–12	8–12	
Length (mm)			.87
Mean	58	59	
Range	40–120	40–100	

AVF = arteriovenous fistula; AVG = arteriovenous graft; CBA = conventional balloon angioplasty; CVD = cardiovascular disease; PAD = peripheral arterial disease; PCB = paclitaxel-coated balloon.



PCB Group	20	11	3	1	Subjects at Risk
CBA Group	18	5	2	0	

Figure 2. Kaplan–Meier survival curve shows the comparison between the PCB group and the CBA group with regard to IFP. Median survival was 179 days in the PCB group, compared with 124.5 days in the CBA group ($P = .026$; HR, 0.445; 95% CI, 0.22–0.9). Subjects at risk are also presented.

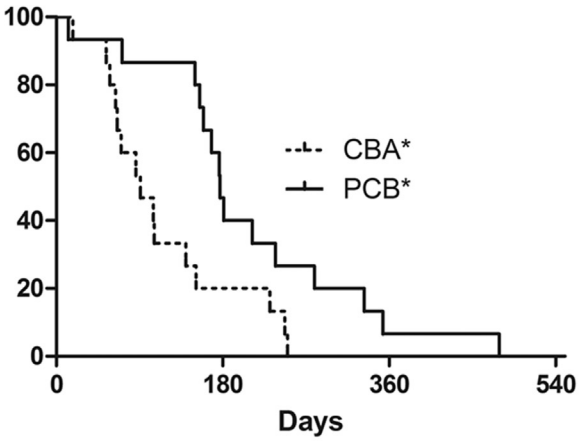
Clinically assessed IFP was significantly in favor of the PCB group according to Kaplan–Meier survival analysis (median survival, 179 d in the PCB group vs 124.5 d in the CBA group; $P = .026$; hazard ratio [HR], 0.445; 95% confidence interval [CI], 0.22–0.91; **Fig 2**). There was no statistically significant difference between AVGs and AVFs (median survival, 196.5 d for AVFs vs 168.0 d for AVGs; $P = .17$; HR, 0.552; 95% CI, 0.21–1.42) or restenotic versus de novo lesions (median survival, 181 d for de novo lesions vs 177 d for restenotic lesions; $P = .56$; HR, 1.362; 95% CI, 0.48–3.88). Previous ipsilateral central venous catheter presence showed no significant impact on the primary endpoint (median survival, 237 d for no previous catheter insertion vs 176 d for previous catheter insertion; $P = .2$; HR, 0.55; 95% CI, 0.21–1.41).

In 15 cases in the PCB group in which an intervention with CBA was performed before recruitment and randomization, the longitudinal comparison of treatments showed a significant difference in favor of the PCB treatment (median survival, 177 d for PCB angioplasty vs 91 d for CBA; $P = .01$; HR, 0.338; 95% CI, 0.148–0.774; **Fig 3**).

DISCUSSION

Symptomatic CVS constitutes a serious problem in vascular access maturation and maintenance. Previous foreign material insertion (mainly central venous catheters and cardiac rhythm–related devices) and the actual use of the vascular circuit for dialysis have been proposed as the main reasons for stenosis in central veins (1). Another interesting finding from cadaveric examinations is the presence of the "SVC valve" just at its entrance to the right atrium (22). The presence of such a valve may further compromise vascular access circuit function or become a thrombogenic area in case of previous central venous catheter insertion. Additionally, CVS treatment should be performed only in case the CVS becomes symptomatic. Treatment of a "silent" asymptomatic CVS could be associated with more rapid stenosis progression (23).

CBA has been the mainstay of endovascular treatment of symptomatic CVS in dialysis access (3). Although CBA is typically successful, it is not durable. The use of high-pressure balloons seems to enhance outcomes, but further improvement in patency rates is required (24). Apart from restenosis, another critical characteristic of CVS behavior is immediate elastic recoil, which occurred more frequently in central veins than in peripheral veins in a study conducted with the use of intravascular ultrasound (25). In such cases, BMS placement has been proposed as a bailout option. However, this is an aggressive approach with patency rates as low as 33% at 1 year (11). Nevertheless, endovascular revascularization of stent occlusion can be technically challenging. The use of stent grafts has been proposed as an alternative to BMS placement. Results from a retrospective study by Verstandig et al (13) showed a primary patency rate of 40% at 1 year. Falk et al (12) explored the use of stent grafts for the treatment of in-stent restenosis compared with balloon angioplasty. Stent grafts had significantly better results in terms of treatment area and circuit patency in subgroup analysis of central vein lesions. More specifically, at 2 years, the primary patency rate was 13.6% in the stent-graft group versus 4.3% in the balloon angioplasty group ($P < .001$) (12). Interestingly, results from a recent observational study by Rajan et al (7) suggest that elastic recoil, although common, does not influence primary patency after CBA of CVS. It is therefore of great importance to investigate the safety and efficacy of a new "nothing-left-behind" technique such as PCB angioplasty in the treatment of CVS in light of this new evidence.



PCB* Group	15	8	2	0	Subjects at Risk
CBA* Group	15	4	1	0	

Figure 3. Longitudinal comparison of treatments with regard to IFP: CBA before enrollment (*CBA**) versus PCB angioplasty as part of the present study (*PCB**) for 15 restenotic lesions. Median survival associated with PCB was 177 days, compared with 91 days for the previously performed CBA ($P = .01$; HR, 0.338; 95% CI, 0.148–0.774).

The role of PCBs in dialysis access has been of interest in the past 5 years. There are currently two published randomized studies comparing PCB angioplasty versus CBA in vascular access (14,15). PCBs were used in AVFs and outflow veins of AVGs in one study (15) and in only AVFs in the other (14). In both cases, primary patency results were in favor of PCBs at 1 year. Nevertheless, CVS was not treated in either of these studies, as balloons were available in diameters only as large as 7 mm, making them unsuitable for CVS treatment. The same group of investigators (18) recently published a retrospective analysis of the use of another PCB for the treatment of dysfunctional dialysis access. Data presented were comparable with those from the previous randomized studies. Other investigators have also tested PCBs from different companies with different paclitaxel dosages in vascular access circuits. In a study by Lai et al (16), 10 patients with two concomitant restenotic lesions in their AVF circuits were treated: one lesion with CBA and the other with PCB angioplasty. Primary lesion patency was significantly better after PCB at 6 months but not at 1 year (70% vs 0% [$P < .01$] at 6 mo; 20% vs 0% [$P > .05$] at 1 y) (16). Patane et al (17) treated juxtaanastomotic stenosis of AVFs in a single-center, single-arm prospective study and reported a 1-year primary patency rate of 91% in 26 patients. To our knowledge, the only study that actually explored the use of PCB in CVS was a retrospective analysis by Massmann et al (26) in which central and peripheral veins in dialysis access circuits were treated. In this study, 26 of 32 lesions treated with PCB angioplasty were situated in a central vein, and restenosis intervals were prolonged when PCB angioplasty was performed compared with CBA (median, 9 mo for PCB vs 4 mo for CBA; $P = .023$). In a review in which data from new techniques available for the treatment of vascular access were synthesized (27), PCB angioplasty showed a better odds ratio of target lesion primary patency. However, this study involved a small number of patients treated with this technology (27).

In the present study, PCB angioplasty had significantly superior results compared with CBA with high-pressure balloons. Another interesting finding was that, in 15 patients with restenotic lesions in the PCB group, when primary patency was compared with patency of the previous CBA treatment, there was still a significant advantage in favor of PCB, despite the fact that PCB angioplasty was performed later in the natural history of the specific vascular access and the bias of vascular access aging weighed against PCB. No other significant results were found in any of the subgroup analyses performed. A study by Trerotola et al (28) suggested that CVS is more frequent in AVGs than in AVFs. However, the current study detected a trend in improved intervention-free periods in cases in which no previous ipsilateral catheter was inserted in the patient (237 d vs 176 d; $P = .2$), without reaching a level of significance.

Among the limitations of the present study is the fact that it was powered only for the outcome of lesion primary patency, with a recruitment of 40 patients. No proper subgroup analysis could be performed to answer a wide spectrum of interesting questions that arose, such as the actual factors influencing the primary endpoint (eg, previous catheter insertion, different access circuits, or de novo vs restenotic lesions) or the existence of different behavior between different treatment sites. Additionally, the single-center nature and visual estimation of the final angiographic outcome are important limitations that might generate bias. The presence of hemodynamically significant remaining stenosis could have been a significant factor

influencing clinical outcomes. The use of quantitative vessel analysis (QVA) on site or by retrospective core laboratory analysis could have resulted in more objective assessment of anatomic success. Nonetheless, anatomic success was 100% in both groups, and the percentage of remaining stenosis is not the only factor in the detection of hemodynamically significant remaining stenosis. Fibrotic waist effacement during angioplasty, direct antegrade flow, and the decrease or absence of venous collateral vessels on final DSA are recognized factors of technical success in vein angioplasty (24). In addition, QVA is a semiautomated system, so its measurements are also subject to bias if not performed by independent blinded personnel. On-site, blinded QVA has been rarely reported in the literature. Finally, the study did not include angiographic outcomes, and patency was based on clinical symptoms (clinically assessed IFP); as a result, data on restenosis rates could not be provided. However, patients and physicians performing clinical follow-up were blinded to the balloon type used for treatment to avoid repeat intervention selection bias.

Outcomes from the present randomized controlled trial suggest that PCB use in CVS of dialysis access resulted in significantly better IFP compared with CBA. Multicenter trials with larger numbers of subjects are needed to validate these results.

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