Original Article

Comparison of drug-coated balloon versus plain balloon angioplasty for autogenous hemodialysis access dysfunction: A prospective cohort study

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ABSTRACT

Background: Both drug-coated balloon (DCB) angioplasty and conventional plain balloon angioplasty can be implemented to treat hemodialysis dysfunction. The present study aims to compare the safety and efficacy of these two approaches by conducting a prospective cohort study.

Objective: The study aims to evaluate DCB safety and arteriovenous fistula effectiveness in relation to plain balloon for hemodialysis access dysfunction.

Patients and Methods: All patients were allocated and blinded, randomized during the period of study into two groups. Group A: patients were operated on with drug-eluting balloons (n=40), while group B patients were operated on with standard balloons (n=40). The results of both groups were analyzed and compared.

Results: DCB was used to treat 40 patients (mean age, 49.48±8 years) with failed arteriovenous fistulas. These patients were compared with a reference group of 40 patients, mean age 50.6±9.4 years, who had just simple balloon PTA. Regular PTA balloons were used to dilate every case of stenosis. In the research group, DCBs were used for medication delivery after hemodynamic success (30% residual stenosis). The 6-, 12-, and 24-month follow-up intervals were used. Comparisons were made between primary, primary assisted, and secondary patency. At 0.05, the statistical significance was established. When primary patency was evaluated between the two groups, it was shown that the study group (DCB) had substantially greater results at 12 months (75.0 vs. 52.5%; *P=0.036*) and 24 months (52.5 vs. 30.0%; *P=0.041*). At 24 months, there were notable variations in secondary patency (52.5 vs. 30.0; *P=0.041*).

Conclusion: In addition to lowering the number of interventions and improving target lesion primary patency over the first 12 and 24 months, DCB also improves secondary patency at the 24-month mark.

Key Words: Arteriovenous fistula, drug-coated balloon angioplasty, hemodialysis dysfunction, plain balloon angioplasty.

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INTRODUCTION

Approximately 1.2 million fatalities per year worldwide are caused by chronic renal disease. For individuals with renal failure, hemodialysis (HD) using an arteriovenous fistula (AVF) or an arteriovenous graft (AVG) is a life-saving procedure[1].

But the most prevalent reason not to allow HD and the one most often associated with death and morbidity is vascular access failure, mostly caused by stenosis. When the access matures, it leads to higher patency rates and lower complication rates than other dialysis options, such as prosthetic grafts and cuffed, tunneled dialysis catheters[2]. For patients with end-stage renal disease receiving HD, the autogenous AVF is thought to be the best access. However, a major risk linked with AVFs is juxta-anastomotic venous stenosis, mostly due to neointimal hyperplasia. AVF failure has been attributed mostly to the existence of this occlusive neointimal hyperplasia at the anastomosis and/or the outflow veins, which may be increased by chronic renal disease[3].

For HD access stenosis, the Kidney Disease Outcomes Quality Initiative's clinical practice guideline suggests angioplasty as the primary treatment. Because the coating agent inhibits cell proliferation and reduces neointimal hyperplasia, drug-coated balloon (DCB) angioplasty has been demonstrated to be successful in extending patency rate in patients with peripheral artery disease and coronary artery disease[4]. By mechanical dilatation, conventional plain balloon angioplasty (PBA) can enlarge the lumen of the stenotic artery[5].

Theoretically, a method that simultaneously prevents negative artery wall remodeling and inhibits the development of fibromuscular hyperplasia following conventional balloon angioplasty may enhance vascular

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access patency. One such method might be the use of DCBs, which are now proven to effectively reduce vascular restenosis and neointimal hyperplasia after superficial femoral artery angioplasty for leg ischemia[6].

Paclitaxel-coated balloons have been tested for their safety and efficacy in the treatment of dysfunctional dialysis access in randomized studies and retrospective analysis of cases, with encouraging results so far. The use of paclitaxel-coated balloons demonstrated significantly better results than conventional angioplasty, but there still a need for more studies in this area to create a solid evidence for clinicians[7].

PATIENTS AND METHODS:

Our study is a prospective cohort study, conducted on 80 patients presented with HD access dysfunction during the period from September 2021 to September 2023 recruited from Ain Shams University hospitals, Menoufia University Hospitals and other authorized hospitals under supervision of thesis supervisors.

All patients with HD access was presented to the study centers complained of HD dysfunction. The study was approved by the ethics committee of Ain Shams University. Oral and written consent was taken from patients for approval.

Inclusion criteria: autogenous AVF in the arm or forearm actively used for HD. Clinical signs of failing access in the form of either poor thrill over the access or a palpable pulse over the access. Patient referred from an HD unit with insufficient HD due to a high percentage of recirculation, measured either by urea reduction rate or K level. Imaging either by ultrasound- or venography proven-venous outflow stenosis less than 50% as compared with proximal segment of the reference vein diameter.

Exclusion criteria: a central venous constriction of hemodynamic significance, metastatic cancer or other terminal illness, blood coagulation problems, sepsis or active infection, previously implanted bare metal stent or stent-graft.

All patients were allocated and blinded, randomized during the period of study into two groups: group A: patients were operated by drug-eluting balloons (n=40). Group B: patients were operated by standard balloons (n=40).

Parameters of assessment will be recorded regarding target lesion primary patency of AVF, assisted primary patency, secondary patency of AVF, and complication related to the procedure (access hematoma, spasm, and thrombosis vein rupture).

The follow-up protocol including clinical surveillance, routine duplex ultrasound examination of AV access and angiogram of arteriovenous access was performed if there is evidence of significant restenosis (>50%) proven by duplex ultrasound.

Procedure

All procedures were performed on dysfunctional fistulas. The Kidney Dialysis Outcomes and Quality Initiatives[8] states that a dysfunctional AVF can be diagnosed based on a combination of physical examination findings and surveillance techniques. Physical examination involves inspecting, palpating, and auscultating the AVF for specific signs of dysfunction, including a soft continuous thrill along the outflow segment and a low-pitched continuous bruit in both systolic and diastolic phases of the cardiac cycle. Signs of stenosis, such as weak pulse, loss of augmentation, or absence of thrill, may also indicate dysfunction. Surveillance techniques include measuring access blood flow and intra-access pressure, as well as monitoring for access recirculation. A dysfunctional AVF exhibit reduced blood flow of less than 400–500 ml/minute, abnormal intra-access pressure ratios, or evidence of access recirculation.

The afflicted limb's radial artery, ulnar artery, or the fistula itself were the routes by which percutaneous access was obtained. A puncture was made following the administration of a 1–3 ml 1% lidocaine local anesthetic. A 6-F vascular sheath was placed and a hydrophilic guidewire (Tokyo, Japan) measuring between 0.035 and 260 cm inch was inserted to ensure vascular access. To prevent thrombotic events, 2500 U of unfractionated heparin were injected intravenously. To define the anatomy and the location and morphology of the stenosis, selective digital subtraction angiography of the access circuit was carried out, either from the sheath or through a 5-F diagnostic catheter.

The lesion was crossed with routinely used catheters, while the size of the DCB or plain high-pressure balloon chosen in accordance with the closest nonaneurysmal vein segment's reference diameter. Balloon catheters with high pressure (>18 atmospheres) were thought to be the best tool for dilatation of extremely resistant venous stenosis that develops in AVFs (Table 1, Fig. 1). DCB dilatation was carried out in the active comparator group utilizing high pressure balloon predilatation (Table 2, Figs 2 and 3). In all situations, the balloon will inflate for 2–3 min at the suggested nominal inflation pressure. To rule out any imminent difficulties, a final angiography of the full dialysis vascular access, including the vein outflow circuit and the arterial input, was done. Hemorrhage at the puncture site and pseudoaneurysm were caused by postoperative complications.

Technical success was defined as the reduction in percent stenosis (a reduction of 30% or more), increase in vessel diameter, attainment of the normal blood flow rate (600–1500 ml/min), and improvement in access patency

duration. The functional success was confirmed (i.e. an increase in the flow volume of the draining vein of >400 ml/min, a decrease in PSV ratio of <2). Furthermore, technical success was also by successful dialysis through the AV shunt 2–3 days postprocedure.

Primary patency was defined as measurement of the time from AVF creation until the first access thrombosis or any intervention to maintain or restore blood flow.

Assisted primary patency was defined as any interventions performed to maintain or restore blood flow.

Secondary patency was defined as the entire duration from AVF creation until abandonment, regardless of any interventions.

Table 1: Most common available high pressure balloon dilatation catheters

Company	Boston	Medtronic	Bard	Biotronik
Device name	Mustang	Fortrex	Conquest 40, Dorado	Passeo-35 HP
Catherter type	OTW	OTW	OTW	OTW
Size	6, 7, 8 mm	6, 7, 8 mm	6, 7, 8 mm	6, 7, 8 mm
Length	60 mm	80 mm	80 mm	60 mm
Site of manufacture	USA	USA	USA	Ireland

High-pressure balloon catheters available in the market were used in patients randomized in the experimental comparator group (plain balloon group) according to the availability at the time of each procedure.

Table 2: Most common available drug-eluting balloon dilatation catheters

Company	Boston	Medtronic
Device name	Ranger	In.Pact
Catherter typetype	OTW/RX	OTW
Drug coating	Paclitaxel	Paclitaxel
Concentration	2 μg/mm^2	3.5 μg/mm^2
Size	6, 7 mm	6, 7 mm
Length	60 mm	60 mm
Site of manufacture	USA	USA

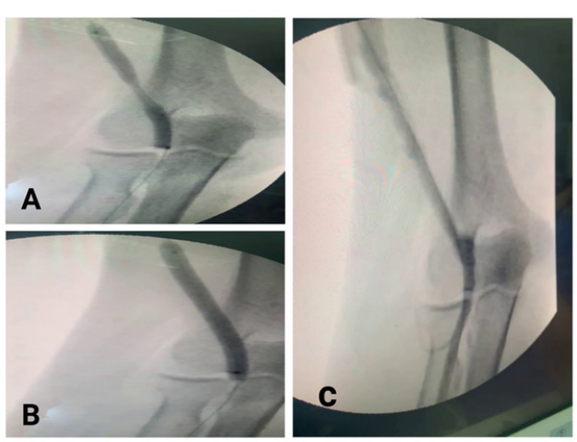

Fig. 1: (a)A stenotic lesion of the main cephalic vein stem which have been selected for dilatation by plain balloon. (b) The lesion have been dilated using Mustang 0.35 balloon 7 mm diameterx60 mm length with apparent waist. (c) Final postdilatation venogram showing full dilatation of the mid-vein stenotic lesions and rapid flow of the dye.

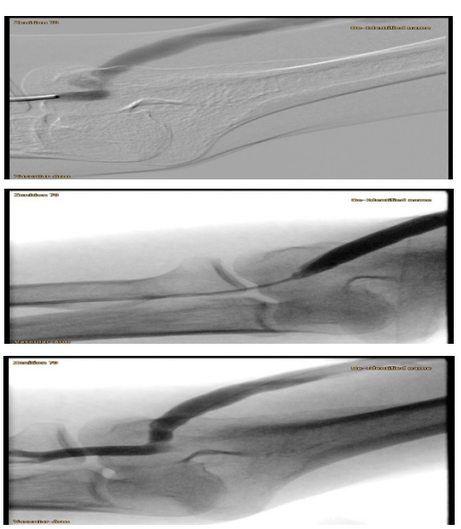

Fig. 2: Serial fistulograms showing the study procedures in (a) stenotic lesions at juxta-anastomotic cephalic A-V fistula, which have been selected for dilatation by drug-coated balloon. (b) The lesion have been dilated by IN.PACT balloon size 6 mm diameter×60 mm length with gradual disappearance of the lesion. (c) Final postdilatation venogram showing full dilatation of the stenotic lesions and rapid flow of the injected dye.

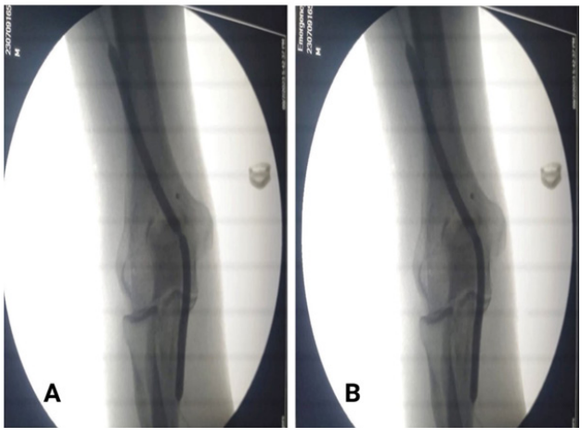

Fig. 3: (a) Tight stenosis of brachiobasalic fistula juxta-anastomotic was gradually dilated with 5/20 mm drug-coated balloon (b) with successful result as shown in the post-dilatation venography.

RESULTS:

Our study includes 80 patients who were double blinded and randomly categorized into two groups. Group A included patients who had failing AVFs who were treated with DCB (40 patients), while group B were treated with plain balloon PTA (40 patients).

There were no significant differences observed between the two groups in terms of age (*P=0.567*), sex (*P=0.501*), or comorbidities including diabetes mellitus (*P=0.651*), hypertension (*P=0.496*), hyperlipidemia (P=0.496), and smoking (*P=0.284*) (Table 3).

Comparison between DCB and PBA groups concerning the location of the target lesion and access failure presentation found no significant differences in the distribution of target lesion locations between the two groups (*P=0.988*). Moreover, the presentation of access failure, including poor thrill or pulsatile access, did not differ significantly between the groups (*P=0.819*) (Table 4).

At 6 months, primary patency was observed in 82.5% of the DCB group compared with 65.0% of the PBA group (*P=0.075*). At 1 year, statistically significant differences were noted, with 75.0% of the DCB group maintaining primary patency compared with 52.5% of the PBA group (*P=0.036*). Similarly, at 2 years, significant differences were observed, with 52.5% of the DCB group maintaining primary patency compared with 30.0% of the PBA group (*P=0.041*) (Table 5, Fig. 4).

At 6 months, 90.0% of patients in the DCB group and 75.0% in the PBA group maintained assisted primary patency, although this difference did not reach statistical significance (*P=0.078*). These data were compared between the DCB and PBA groups regarding assisted primary patency rates at 1 year, 2 years, and 1 year follow-up periods. According to (Table 6), although the DCB group showed greater rates of aided primary patency at 1 and 2 years, the differences were not statistically significant (*P>0.05* for both comparisons).

At 6 months, 1 year, and 2 years' follow-up: At all time points, there were no significant differences in secondary patency rates between the two groups (*P>0.05* for all comparisons), with high rates observed in both groups (Table 7, Fig. 5).

Comparing the final outcomes between the DCB and PBA groups in terms of clinical success and technical success, there were no significant differences observed in either clinical success (*P=0.745*) or technical success (*P=1*) between the two groups, with high rates of success seen in both (Table 8, Fig. 6).

Comparing the rate of complications between DCB and PBA groups, there were no significant differences in the incidence of pseudoaneurysm, vein rupture, arterial thrombosis, or puncture site hematoma between the two groups (*P>0.05* for all comparisons), with low rates of complications observed overall (Table 9, Fig. 7).

Table 3: Demographic characteristics and comorbidities of studied groups

Variables	DCB (*N*=40) [*n* (%)]	PBA (*N*=40) [*n* (%)]	Test of significance (χ^2)	*P* value
Age (years)				
Mean±SD	49.48±8	50.6±9.4	*t*=0.575	0.567
Range	28–70	28–70		
Sex				
Male	20 (50.0)	23 (57.5)	0.453	0.501
Female	20 (50.0)	17 (42.5)		
Comorbidities				
DM	22 (55.0)	24 (60.0)	0.205	0.651
HTN	25 (62.5)	22 (55.0)	0.464	0.496
Hyperlipidemia	15 (37.5)	18 (45.0)	0.464	0.496
Smoking	7 (17.5)	11 (27.5)	1.147	0.284

DCB, drug-coated balloon; DM, diabetes mellitus; HTN, hypertension; PBA, plain balloon angioplasty; t, Student's t test; χ^2, χ^2 test.

Table 4: Comparison between studied groups regarding access lesion

Variables	DCB (*N*=40) [*n* (%)]	PBA (*N*=40) [*n* (%)]	Test of significance (χ^2)	*P* value
Location of target lesion				
Juxta-anastomotic segment	14 (35)	13 (32.5)	0.604	0.988
Proximal cephalic	6 (15)	8 (20)		
Cannulation site	5 (12.5)	4 (10)		
Proximal basalic	4 (10)	5 (12.5)		
Cephalic arch	9 (22.5)	8 (20)		
Mid-cephalic	2 (5)	2 (5)		
Access failure presentation				
Poor thrill	24 (60.0)	25 (62.5)	0.053	0.819
Pulsatile access	16 (40.0)	5 (37.5)		

DCB, drug-coated balloon; PBA, plain balloon angioplasty; χ^2, χ^2 test.

Table 5: Comparison between studied groups regarding target lesion primary patency at 6 months, 1 year, and 2 years' follow-up

Variables	DCB (*N*=40) [*n* (%)]	PBA (*N*=40) [*n* (%)]	Test of significance (χ^2)	*P* value
At 6 months				
Yes	33 (82.5)	26 (65.0)	3.164	0.075
No	7 (17.5)	14 (35.0)		
At 1 year				
Yes	30 (75.0)	21 (52.5)	4.381	0.036*
No	10 (30.0)	19 (47.5)		
At 2 years				
Yes	21 (52.5)	12 (30.0)	4.178	0.041*
No	19 (47.5)	28 (70.0)		

DCB, drug-coated balloon; PBA, plain balloon angioplasty; χ^2, χ^2 test.
**P value* of less than 0.05: statistically significant.

Table 6: Comparison between studied groups regarding assisted target lesion primary patency at 6 months, 1 year, and 2 years' follow-up

Variables	DCB (*N*=40) [*n* (%)]	PBA (*N*=40) [*n* (%)]	Test of significance (χ^2)	*P* value
At 6 months				
Yes	36 (90)	30 (75)	FE=3.117	0.078
No	4 (10)	10 (25)		
At 1 year				
Yes	33 (82.5)	27 (67.5)	2.4	0.121
No	7 (17.5)	13 (32.5)		
At 2 years				
Yes	23 (57.5)	18 (45)	1.251	0.263
No	17 (42.5)	22 (55)		

DCB, drug-coated balloon; FE, Fisher's exact Test; PBA, plain balloon angioplasty; χ^2, χ^2 test.

Table 7: Comparison between studied groups regarding secondary patency at 6 months, 1 year, and 2 years' follow-up

Variables	DCB (*N*=40) [*n* (%)]	PBA (*N*=40) [*n* (%)]	Test of significance (χ^2)	*P* value
At 6 months				
Yes	40 (100.0)	39 (97.5)	FE=1.013	1
No	0	1 (2.5)		
At 1 year				
Yes	35 (87.5)	31 (77.5)	1.358	0.239
No	5 (12.5)	9 (22.5)		

At 2 years				
Yes	29 (72.5)	20 (50.0)	4.266	0.039*
No	11 (27.5)	20 (50.0)		

DCB, drug-coated balloon; FE, Fisher's exact test; PBA, plain balloon angioplasty; χ^2, χ^2 test.
**P value* less than 0.05: statistically significant.

Table 8: Comparison between studied groups regarding final outcomes

Variables	DCB (*N*=40) [*n* (%)]	PBA (*N*=40) [*n* (%)]	Test of significance (χ^2)	*P* value
Clinical success				
Yes	35 (87.5)	34 (85.0)	0.105	0.745
No	5 (12.5)	6 (15.0)		
Technical success				
Yes	37 (92.5)	36 (90.0)	FE=0.157	1
No	3 (7.5)	4 (10.0)		

DCB, drug-coated balloon; FE, Fisher's exact test; PBA, plain balloon angioplasty; χ^2, χ^2 test.

Table 9: Comparison between studied groups regarding complications

Variables	DCB (*N*=40) [*n* (%)]	PBA (*N*=40) [*n* (%)]	Test of significance (FE)	*P* value
Pseudoaneurysm				
Yes	1 (2.5)	0	1.013	1
No	39 (97.5)	40 (100.0)		
Vein rupture				
Yes	2 (5)	1 (2.5)	0.346	1
No	38 (95)	39 (97.5)		
Arterial thrombosis				
Yes	1 (2.5)	2 (5)	0.346	1
No	39 (97.5)	38 (95)		
Puncture site hematoma				
Yes	3 (7.5)	2 (5.0)	0.213	1
No	37 (92.5)	38 (95.0)		

DCB, drug-coated balloon; FE, Fisher's exact test; PBA, plain balloon angioplasty.

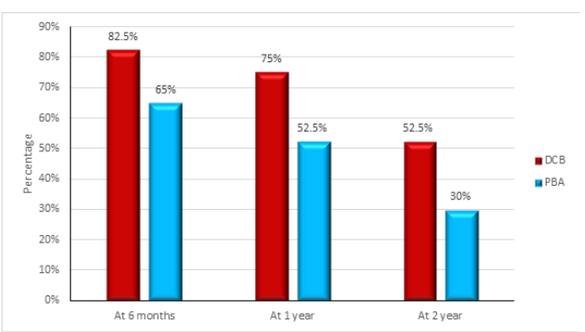

Fig. 4: Comparison between studied groups regarding target lesion primary patency at 6 months, 1 year, and 2 years' follow-up.

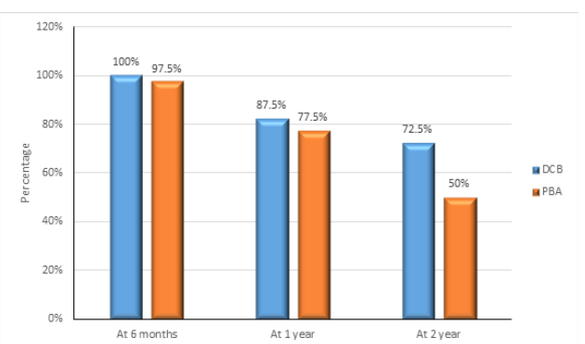

Fig. 5: Comparison between studied groups regarding secondary patency at 6 months, 1 year, and 2 years' follow-up.

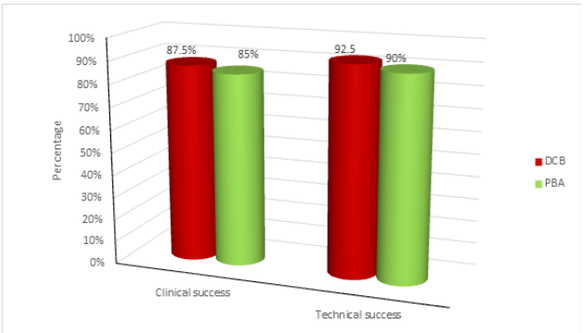

Fig. 6: Comparison between studied groups regarding final outcomes.

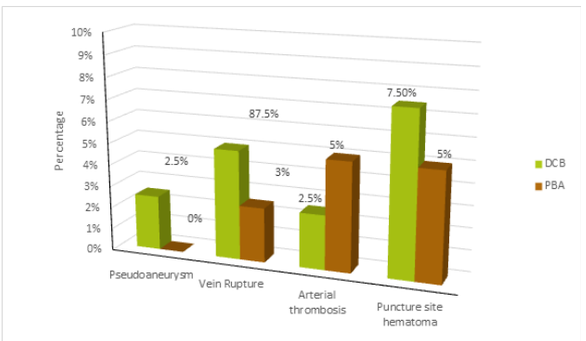

Fig. 7: Comparison between studied groups regarding complications.

DISCUSSION

HD, the most popular form of renal replacement treatment, is seeing an increase in the number of patients due to the rising frequency of end-stage renal disease. Moreover, it has resulted in a rise in scientific research aimed at improving HD method and patient outcomes[9].

For HD, a sufficient vascular access is necessary, and the kind of vascular access has an impact on the morbidity and mortality of the patient. Because of its longer patency, lower mortality rates, and less complication rates, the AVF is the best vascular access for HD[10].

PTA was the accepted procedure for maintaining failed dialysis access; in the case of thrombotic blockage, it was occasionally combined with pharmacological or mechanical thrombolysis or thromboaspiration. AVF is now instantly available for HD and retains a bigger venous region thanks to this minimally invasive technological method[11]. According to Kidney Dialysis Outcomes and Quality Initiatives recommendations and significant worldwide findings, standard PTA is also advised for the treatment of AVF dysfunction. High rates of technical success and satisfactory patency rate are attained, but they require many angioplasties and frequent hospitalization[12].

Retrospective studies on DCB use in AVFs have typically produced encouraging findings for DCB use[13]. Despite the small sample sizes, nonetheless. Increased patency was seen 6 months after DCB in a comprehensive evaluation of the few randomized and nonrandomized trials that have been reported to date, but this difference disappeared after 12 months. There were 254 interventions in 162 patients in this study; however, because the data were deemed clinically diverse, it was not possible to make conclusions that would be applicable to the clinical setting[14].

Our results demonstrated a trend toward improved patency with DCB angioplasty compared with PBA, although statistical significance was not reached at the 6-month mark (82.5 vs. 65.0%, *P=0.075*). However, at 1 and 2 years, significant differences favoring DCB were observed, with higher rates of primary patency compared with PBA (75.0 vs. 52.5% at 1 year, *P=0.036*; 52.5 vs. 30.0% at 2 years, *P=0.041*). These findings are consistent with prior studies that have reported superior long-term outcomes with DCB angioplasty compared with conventional PBA in AVF intervention.

At 6 and 12 months, a prospective randomized experiment demonstrated that using DCBs was significantly more beneficial than using ordinary balloon. According to the Katsanos *et al*.[15] experiment, 5% BA versus 35% DCB of original lesions remained patent after a year.

Similar to our investigation, Çildağ and colleagues observed that there was a significant difference in the 12-month primary patency rate (65 vs. 35%, respectively, *P<0.05*) but not in the 6-month primary patency rate (77 vs. 65%, respectively, *P=0.45*)[16]. DBA was also linked to noticeably better patency According to Haave and colleagues, the DBA cohort had an estimated proportion of 61 and 31% of patients free of stenosis after 12 and 24 months, respectively, whereas the PBA group had an estimated proportion of 40 and 15%[17].

However, Maleux and colleagues could not find a significant difference in primary patency between DCB and PBA in a multicenter randomized controlled experiment. According to Maleux and colleagues, the main patency rates for DCB and PBA were 87.9 and 80.7% (*P=0.43*), 66.7 and 64.5% (*P=0.76*), and 43.4 and 38.7% (*P=0.95*) at 3, 6, and 12 months, respectively.[18]

It is important to note the inconsistent findings found in different meta-analyses. For example, a 2016 meta-analysis by Khawaja and colleagues including data from two RCTs and four cohort studies showed

that DBA led to better primary patency at 6 months than PBA. Nevertheless, a small participant pool and clinical heterogeneity were seen in these investigations[19]. However, a meta-analysis that included both AVFs and AVGs was carried out by Kennedy and colleagues, and the results showed that DBA significantly improved lesion patency at different intervals (3, 6, 12, and 24 months) as compared with PBA. Abdul Salim and colleagues meta-analysis from 2020, which included six RCTs of AVFs, revealed no discernible variation in primary patency between DBA and PBA at any of the time periods (1, 3, 6, 7, 12, and 24 months)[20]. These contradictory results highlight the necessity for further appropriately powered multicenter randomized studies to draw more firm conclusions[21].

Patients treated with DCB had significantly higher primary patency compared with those treated with PBA at 6 months [odds ratio (OR), 2.93; 95% confidence interval (CI), 2.13–4.03; *P<0.001*] and 1 year (OR, 2.47; 95% CI, 1.53–3.99; *P<0.001*), according to a recent meta-analysis comparing the safety and efficacy of DCB and PBA in 1752 patients. Furthermore, compared with patients treated with PBA, DCB-treated patients showed better dialysis circuit patency at 6 months (OR, 2.42; 95% CI, 1.56–3.77; *P<0.001*) and 1 year (OR, 1.91; 95% CI, 1.22–3.00; *P=0.005*)[23]. In addition, the DCB group was less likely than the PBA group to experience target lesion revascularization at follow-up (OR, 0.43; 95% CI, 0.23–0.82; *P=0.001* at 6 months and OR, 0.74; 95% CI, 0.32–1.73; *P=0.490* at 1 year)[23].

The incidence of pseudoaneurysm, vein rupture, arterial thrombosis, and puncture site hematoma did not differ significantly between the DCB and PBA groups, suggesting that both treatment modalities are associated with low rates of procedural complications, reaffirming their safety profiles in clinical practice. However, it is important to acknowledge the potential for underreporting or variability in complication assessment, which could impact the robustness of these conclusions.

Neointimal hyperplasia may occur at the anastomotic site of a newly formed HD access, resulting in outflow stenosis. This condition inhibits flow-mediated vasodilation, enlargement, and maturation in the case of AVFs; in the case of venous juxta-anastomotic AVG stenosis, it may lead to poor graft flow and early thrombosis[22].

In our study, 34 patients had site access lesion in cephalic vein, 18 in bacalic vein, and 28 in axillary vein. These patients presented with either a poor thrill or a pulsatile access, The site of stenosis was either at juxta-anastomotic or the main vein[22].

In our study, seven patients had unsuccessful angioplasty due to either resistant or elastic lesion. Three patients had resistant lesion for which we used ultra-high pressure angioplasty balloon up to 30 atm. Four patients had elastic lesion for which we used a balloon that was 1–2 mm larger.

At 1 and 2 years, there was a notable increase in the main patency. Similar to Lučev and colleagues's retrospective comparison analysis, PP was shown to be considerably greater in the DBA group at 6 months (90.3 vs. 61.3%; *P=0.016*), 12 months (77.4 vs. 29.0%; *P=0.0004*), and 24 months (45.2 vs. 16.1%; *P=0.026*) compared with the PBA group[24].

Secondary patency was significantly higher at 2 years only, in contrast to a study conducted by Patanè *et al*.[25], which showed no significant difference in two groups.

Paclitaxel, which had the effect of removing early elastic recoil with vascular scaffolding and considerably inhibiting neointimal hyperplasia, was responsible for the increased patency in individuals treated with DCB. It has been shown that systemic treatment is less successful than local therapy. Moreover, a large body of research and clinical trials on coronaries and the arterial districts of the superior and inferior limbs have highlighted the benefits of using drug-eluting stents and balloons to prevent the recurrence of arterial intimal hyperplasia. Antiproliferative medications may therefore be helpful in preventing or postponing the return of stenosis, much like they do for arteries. Scientific investigations that demonstrated a higher rise in the proliferation index inside the venous neointima and media in vascular access treated to PTA for recurrent restenosis than in initial stenosis provided strong support for this hypothesis[25].

CONCLUSION

This two-center study found that DCB angioplasty results in improved vessel patency and is superior to plain balloon dilation in the treatment of venous stenosis in failing native arteriovenous shunts used for dialysis access.

CONFLICT OF INTEREST

There are no conflicts of interest.

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