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Role of Endovascular Intervention in the Management of Failing Hemodialysis Arteriovenous Fistula

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Abstract

Background: The management of failing hemodialysis arteriovenous fistulas (AVFs) is critical to ensuring continued dialysis access. This study evaluates and compares the effectiveness of drug-coated balloons (DCBs) versus plain old balloon angioplasty (POBA) in treating AVF stenosis, with a focus on primary patency rates, reintervention rates, and overall clinical outcomes.

Methods: In this prospective randomized controlled trial, 48 patients with failing AVFs were enrolled and treated at Shebin Elkoom Teaching Hospital and Ain Shams University Hospital between 2023 and 2024. Participants were randomized into two equal groups: DCB group and POBA group. The primary outcome measures included primary patency rates at 6 months and 1 year, as well as the number of interventions required to maintain target lesion patency. Secondary outcomes included assisted primary patency, secondary patency rates, and safety outcomes, such as adverse events related to the arteriovenous access circuit.

Results: At 6 months, the primary patency rate was significantly higher in the DCB group compared to the POBA group (83.3% vs. 58.3%, p=0.002). This superiority persisted at 1 year (75% vs. 41.7%, p=0.020). The mean number of interventions required to maintain patency was significantly lower in the DCB group (0.3±0.7 vs. 0.9±1.0, p=0.03). There were no significant differences between groups in assisted primary patency or secondary patency rates. Serious adverse events were similar between groups (25% in DCB vs. 29.2% in POBA, p=0.74), with vein rupture and AV fistula occlusion being the most common complications.

Conclusion: Drug-coated balloon angioplasty offers superior primary patency and requires fewer reinterventions compared to conventional angioplasty in the treatment of AVF stenosis. Despite similar safety profiles, the enhanced effectiveness of DCBs makes them a preferred option for maintaining long-term AVF patency in dialysis patients.

Keywords: Hemodialysis, Arteriovenous Fistula, Drug-Coated Balloon, Balloon Angioplasty, Endovascular Intervention.

Introduction

Globally, around 2 million individuals require dialysis for end-stage renal disease, typically managed through hemodialysis (1). Among dialysis access options, the autogenous arteriovenous fistula (AVF) is preferred (2), though its prolonged use often leads to complications such as AVF stenosis or occlusion. Studies indicate that AVF patency rates are generally only 60%–65% one year post-surgery (3–5).

While a secondary operation can restore AVF functionality, it also depletes the patient's vascular resources (6,7). To address AVF stenosis, percutaneous transluminal angioplasty (PTA) has become a common treatment (8); however, high restenosis rates, driven mainly by intimal hyperplasia, have been reported (9). This has led to the development of the drug-coated balloon (DCB) as a potentially more effective treatment.

Drug-coated balloons (DCBs) were originally developed for use in coronary and lower extremity artery interventions. These balloons are coated with antiproliferative drugs, primarily paclitaxel, which has a high lipid affinity that enhances tissue absorption (10). Paclitaxel effectively inhibits smooth muscle cell migration and proliferation at low concentrations (11). When a paclitaxel-coated balloon is inflated to treat stenotic blood vessels, it releases the drug quickly into the vessel wall, helping to prevent restenosis (12).

Two randomized clinical trials, along with numerous smaller studies, have explored this issue, yielding mixed results. While the treatment is generally deemed safe (13–15), some research has reported benefits in terms of improved primary patency and fewer reinterventions (16,17), while other studies have not observed these advantages (18,19).

The aim of this study is to evaluate and compare the effectiveness of drug-coated balloons (DCBs) versus plain old balloon angioplasty (POBA) in treating arteriovenous fistula (AVF)

stenosis in dialysis patients, focusing on primary patency rates, reintervention rates, and overall clinical outcomes.

Patients and Methods

Study Design and Ethical Considerations

This prospective study was conducted on 48 patients who presented to the Vascular and Endovascular Department at Shebin Elkoom Teaching Hospital and Ain Shams University Hospital with failing hemodialysis access. These patients were scheduled for percutaneous transluminal angioplasty (PTA) between 2023 and 2024. The study received ethical approval from the Shebin Elkoom Teaching Hospital Institutional Review Board (IRB). Informed consent was obtained from all participants, ensuring confidentiality and the right to withdraw from the study at any time.

Study Objectives

The primary aim of the study was to evaluate the effectiveness of endovascular salvage of dialysis AVFs. The focus was on establishing a proper plan, utilizing a simple technique, and assessing the benefits of such a procedure. Additionally, the study aimed to evaluate primary and secondary patency rates following PTA in non-maturing or failing AVFs.

Inclusion and Exclusion Criteria

Patients were included in the study based on specific criteria:

- **Inclusion criteria:** Dysfunctional native AV access evidenced by decreased/absent thrill, increased pulsatility, collateral veins, limb swelling, cannulation difficulty, prolonged bleeding post-hemodialysis, high venous pressure during hemodialysis, decreased hemodialysis flow rate (<500 ml/min), and abnormal recirculation (>10%).

- **Exclusion criteria:** Severe allergy to contrast agents, infected fistulas, large aneurysmal dilatation with impending rupture, hypotension when starting dialysis, low cardiac output, previous history of steal syndrome, venous hypertension, and undiagnosed central venous occlusion or thrombosis.

Randomization and Grouping

Patients who met the inclusion criteria were randomly assigned to one of two treatment groups: the DCB group or the POBA group. Randomization was conducted using a computer-generated random sequence to ensure unbiased allocation. Each group consisted of 24 patients. The DCB group received angioplasty with drug-coated balloons, while the POBA group underwent conventional balloon angioplasty. The randomization process was designed to balance potential confounding variables between the two groups, ensuring that the study's outcomes could be attributed to the treatment interventions rather than external factors.

Pretreatment Evaluation

A comprehensive pretreatment evaluation was performed, which included a detailed history and physical examination. This evaluation covered aspects such as age, gender, cause of renal failure, cardiovascular comorbidities, prior access sites, current access type, location, and duration. Each patient was also assessed for congestive heart failure, and the upper limb was examined for scars, edema, and dilated veins. Pulses were palpated, Allen's test was performed, and blood pressure was measured in both arms to identify proximal arterial disease. The AVF was assessed for thrill quality, aneurysmal dilatation, skin status, and external compression by hematoma.

Imaging and Procedure

Doppler/duplex scans were performed to visualize the feeding artery from the axillary to the subclavian vein and assess perivascular space. Significant stenosis was indicated by a peak systolic velocity (PSV) ratio of 3 or more, PSV greater than 375 cm/s, or 50% or more narrowing on grayscale imaging.

The procedure involved the insertion of a 6 French radial sheath, either percutaneously or via an open technique. The field was sterilized, and patients were monitored clinically and by pulse oximetry. Local anesthesia (2% lidocaine hydrochloride) and light sedation were used during balloon inflation. The radial artery served as the primary endovascular access site, with the brachial artery used in some cases. Combined venous and arterial access was employed in 3 cases. All access sites were obtained using a percutaneous Seldinger technique, except in 14 cases where the open technique was applied.

A radial sheath was tested for free blood flow, and 5000 units of heparin were injected to prevent thrombosis. A diagnostic fistulogram was performed via the sheath. A 260 cm 0.035" angled hydrophilic guide wire (Terumo) was inserted through the sheath over a 5 or 4 French selective Bern catheter under angiographic guidance. The wire and catheter were advanced to the anastomotic site. Angioplasty was performed using a high-pressure short angioplasty balloon. A completion fistulogram ensured patency and excluded residual stenosis or thrombi. Good compression and hemostasis were ensured post-procedure.

Follow-up and Data Collection

Patients were advised to attend follow-up visits, including physical examinations and duplex scans, within a month post-procedure and every 3 months thereafter for up to 24 months. Follow-up was conducted through regular visits or phone calls. Data on patients and their AVFs

were collected, presented, and statistically analyzed to determine success rates, complications, and patency durations.

Statistical Analysis

Data were analyzed using SPSS version 26 (IBM, Armonk, New York, United States). Descriptive statistics were used to summarize patient characteristics and procedural outcomes. Continuous variables were presented as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Kaplan-Meier survival analysis was employed to calculate primary and secondary patency rates, with comparisons made using the log-rank test. Continuous variables were compared using the independent t-test or Mann-Whitney U test, and categorical variables were compared using the chi-square or Fisher's exact test. A p-value of <0.05 was considered statistically significant.

Results

In this trial, 64 patients were evaluated for eligibility; 16 did not meet the inclusion criteria. The remaining 48 patients were randomly assigned into two groups of equal size, with 24 patients in each group. All patients were then followed up, and no loss of follow-up was reported. The data from all patients were included in the final statistical analysis. **Figure 1**

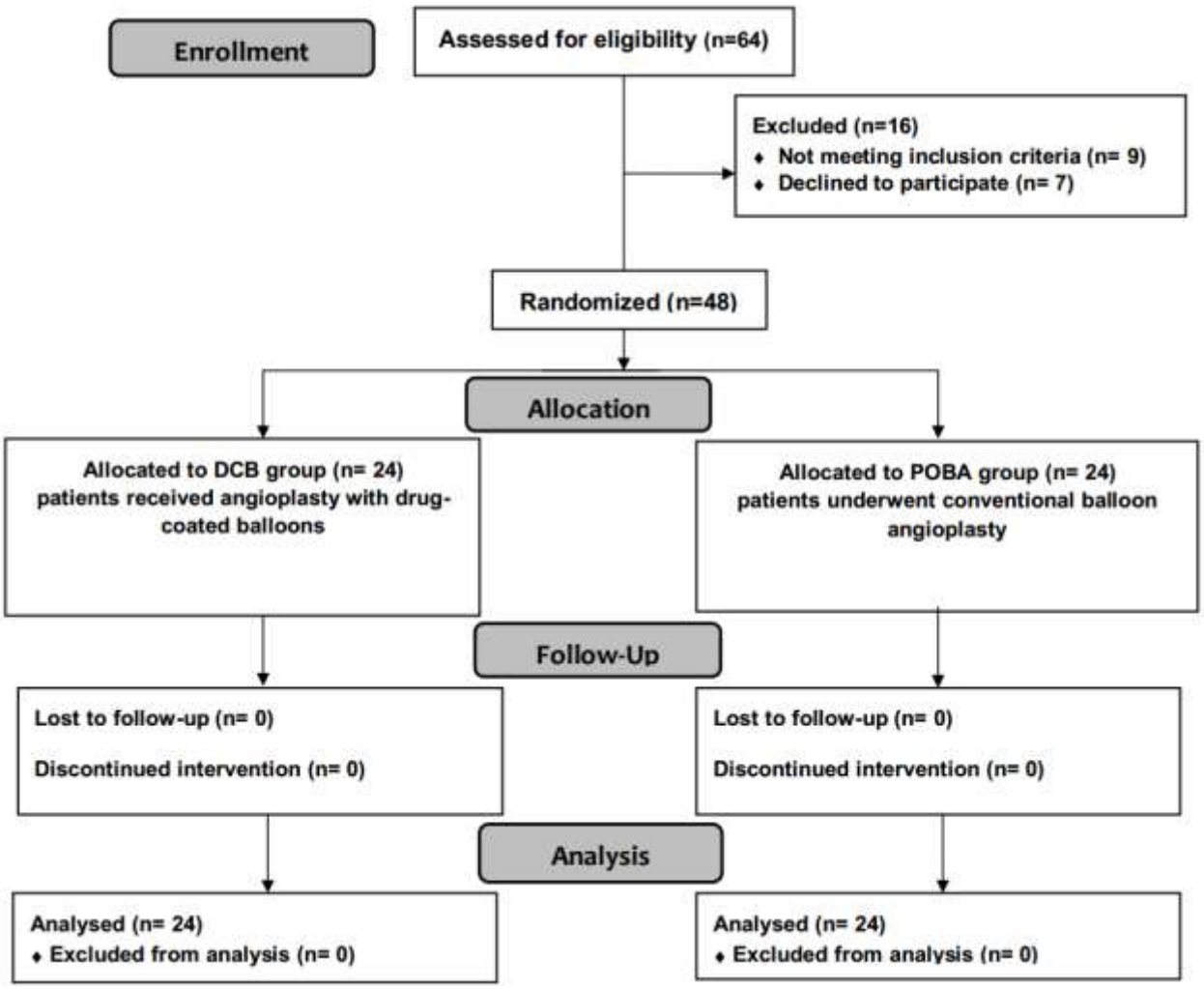

Figure 1: CONSORT flow diagram of the studied patients

The mean age was 52±13 years for the DCB group and 52.5±12 years for the POBA group. Males comprised 54.2% of the DCB group and 50% of the POBA group. Renal insufficiency was present in all participants. Comorbidities like diabetes, hypertension, dyslipidemia, ischemic heart disease, and carotid artery disease were observed in both groups. Most participants were non-smokers, with 20.8% in the DCB group and 29.2% in the POBA group being smokers **(Table 1)**.

Table 1: Comparison of the baseline demographic and clinical characteristics of the Participants.

Characteristic	DCB Group (N=24)	POBA Group (N=24)	P-value
Age (y), mean ±SD	52±13	52.5±12	**0.877**

Sex, N (%)			0.78
• Male	13 (54.2%)	12 (50%)	
• Female	11 (45.8%)	12 (50%)	
Comorbidities, N (%)			
Diabetes	13 (54.2%)	14 (58.3%)	0.72
Hypertension	16 (66.7%)	15 (62.5%)	0.76
Dyslipidemia	18 (75%)	17 (70.8%)	0.65
Renal insufficiency	24 (100%)	24 (100%)	1
Ischemic heart disease	8 (33.3%)	7 (29.2%)	0.57
Carotid artery disease	1 (4.2%)	2 (8.3%)	0.56
Medical history, N (%)			
Smoking status			0.58
• Current smoker	5 (20.8%)	7 (29.2%)	
• Former smoker	7 (29.2%)	4 (16.7%)	
• Never	12 (50%)	13 (54.2%)	
Antiplatelet therapy	12 (50%)	13 (54.2%)	0.73
Anticoagulation therapy	8 (33.3%)	9 (37.5%)	0.73
Vascular access, N (%)			
Type of dialysis access			0.76
• AVF	16 (66.7%)	17 (70.8%)	
• AVG	8 (33.3%)	7 (29.2%)	
Fistula location			0.55
• Right arm	8 (33.3%)	10 (41.7%)	
• Left arm	16 (66.7%)	14 (58.3%)	
Lesion type			0.76
• De novo lesion	8 (33.3%)	9 (37.5%)	
• Recurrent stenosis	16 (66.7%)	15 (62.5%)	
Lesion classification			0.68
• Single	20 (83.3%)	21 (87.5%)	
• Tandem	4 (16.7%)	3 (12.5%)	
Prior intervention in fistula, N (%)	19 (79.2%)	20 (83.3%)	0.65
No. of prior interventions, mean ±SD	4±2.5	3.4±2.1	0.318
No. of months on dialysis, mean ±SD	39±22	37±23	0.732

DCB, drug-coated balloon; POBA, conventional angioplasty; AVF, arteriovenous fistula; AVG, arteriovenous graft, P-values for continuous variables were based on the independent t-test, and those for categorical variables were based on the Chi-square-test; significant p-value < 0.05.

In the DCB group, 33.3% used arteriovenous graft (AVG) and 66.7% used AVF, while in the POBA group, 29.2% used AVG and 70.8% used AVF. The left arm was the predominant access location in both groups. Recurrent stenosis occurred in 66.7% of the DCB group and 62.5% of the POBA group. Most cases were single lesions: 83.3% in the DCB group and 87.5% in the

POBA group. Prior interventions were noted in 79.2% of the DCB group (mean 4±2.5) and 83.3% of the POBA group (mean 3.4±2.1). The mean dialysis duration was 39±22 months for the DCB group and 37±23 months for the POBA group **(Table 2)**.

Table 2: Comparison between studied groups regarding target lesion

Variable	DCB Group (N=24)	POBA Group (N=24)	P-value
Target lesion location			0.97 [a]
• **Anastomosis;** near the surgical connection between the artery and vein	6 (25%)	7 (29.2%)	
• **Cephalic arch;** in the curved portion of the cephalic vein	5 (20.8%)	6 (25%)	
• **Cannulation zone;** occurs where needle insertion happens during dialysis	4 (16.7%)	3 (12.5%)	
• **Arterial inflow**	1 (4.2%)	1 (4.2%)	
• **Venous outflow**	6 (25%)	6 (25%)	
• **Swing point;** found at the transition area between inflow and outflow	2 (8.3%)	1 (4.2%)	
Vessel			0.212
• Subclavian	1 (4.2%)	0 (0)	
• Brachial	2 (8.3%)	1 (4.2%)	
• Cephalic	11 (45.8%)	12 (50.0%)	
• Basilic	7 (29.2%)	7 (29.2%)	
• Other	3 (12.5%)	4 (16.7%)	
Access failure presentation			0.77 [a]
• Poor thrill	15 (62.5%)	16 (66.7%)	
• Pulsatile access	9 (37.5%)	8 (33.3%)	

DCB, drug-coated balloon; POBA, conventional angioplasty, Indicates the use of Fisher Exact test, [a] Indicates the use of Chi-square test.

Target lesion locations in the DCB group were anastomotic vessels (25%), venous outflow (25%), cephalic arch (20.8%), cannulation zone (16.7%), swing point (8.3%), and arterial inflow (4.2%). In the POBA group, target lesions were anastomotic vessels (29.2%), cephalic arch (25%), venous outflow (25%), cannulation zone (12.5%), swing point (4.2%), and arterial inflow (4.2%). Access failure, defined as poor thrill or pulsatile access, occurred in 62.5% and 37.5% of the DCB group and 66.7% and 33.3% of the POBA group, respectively **(Table 3)**.

Table 3: Procedural Characteristics of Angioplasty.

Variable	DCB Group (n = 24)	POBA Group (n = 24)	P-value

Pre-procedural stenosis (%)	76.6 ± 11.3	75.2 ± 11.7	0.639
Lesion length (mm)	42.3 ± 25.2	39.0 ± 23.7	0.603
Balloon length (mm)	56 ± 21.3	49.3 ± 17.7	0.19
Balloon diameter (mm)	7.3 ± 1.0	7.2 ± 2.0	0.81
Total duration of inflation (sec), mean ±SD	120 ± 30	100 ± 43	**0.04**
Residual stenosis (%)	14.5 ± 11.7	19.2 ± 15.4	0.185

Independent t-test; significant p-value < 0.05.

Pre-procedural and residual stenosis showed no significant differences between the groups (p-value > 0.05). The DCB group required longer inflation duration (p-value=0.04). At 6 months and 1 year, DCB showed superior primary patency rates (83.3% vs. 58.3%, p-value=0.002; 75% vs. 41.7%, p-value=0.020). Assisted primary and secondary patency rates showed no significant differences. The mean number of interventions to maintain patency was 0.3±0.7 for the DCB group and 0.9±1.0 for the POBA group (p-value=0.03). Device, procedural, and clinical success rates were similar between groups **(Table 4)**.

Table 4: Comparison between studied groups regarding Effectiveness outcomes.

Variable	DCB Group (N=24)	POBA Group (N=24)	P-value
Effectiveness outcome			
Primary patency rate at 6 m	20 (83.3%)	14 (58.3%)	**0.002**
Primary patency rate at 1 year	18 (75%)	10 (41.7%)	**0.020**
Assisted primary patency rate at 6 m	22 (91.7%)	18 (75%)	0.12
Assisted primary patency rate at 1 year	20 (83.3%)	16 (66.7%)	0.18
Secondary patency rate at 6 m	24 (100%)	23 (95.8%)	0.31
Secondary patency rate at 1 year	21 (87.5%)	17 (70.8%)	0.15
Number of interventions required to maintain target lesion patency	0.3 ± 0.7	0.9 ± 1.0	**0.03**
Periprocedural endpoints			
• **Device success**	24 (100%)	24 (100%)	>0.999
• **Procedural success**	18 (75%)	19 (79.2%)	0.731
• **Clinical success**	22 (91.7%)	23 (95.8%)	0.55

DCB, drug-coated balloon; POBA, conventional angioplasty.

Device success was defined as successful delivery, inflation, deflation, and retrieval of the intact study balloon device without burst at or below-rated burst pressure at the index procedure.

Procedural success was defined as the maintenance of patency (≤30% residual stenosis as reported by the core laboratory or by the investigator if core laboratory data are not available) in the absence of a periprocedural serious adverse device effect.

Clinical success was defined as the resumption of successful dialysis for at least 1 session after the index procedure.

P-values for continuous variables were based on the independent t-test, and those for categorical variables were based on the Chi-square test; significant p-value < 0.05.

Adverse events were not significantly different (p-value > 0.05). Serious complications occurred in 25% of the DCB group and 29.2% of the POBA group. DCB complications included vein rupture (3 cases), AV fistula thrombosis (1 case), AV fistula occlusion (1 case), and AV fistula aneurism (1 case). POBA complications included vein rupture (2 cases), AV fistula occlusion (2 cases), AV fistula thrombosis (1 case), vasospasm (1 case), and puncture site hematoma (1 case) **(Table 5)**.

Table 5: Comparison between studied groups regarding Safety outcomes.

Safety outcome	DCB Group (N=24)	POBA Group (N=24)	P-value
Serious adverse events involving the arteriovenous access circuit	6 (25%)	7 (29.2%)	0.74
Arteriovenous fistula aneurysm	1 (4.2%)	0 (0)	
Arteriovenous fistula occlusion	1 (4.2%)	2 (8.3%)	
Arteriovenous fistula thrombosis	1 (4.2%)	1 (4.2%)	
Vein Rupture	3 (12.5%)	2 (8.3%)	
Vasospasm	0 (0)	1 (4.2%)	
Vessel puncture site hematoma	0 (0)	1 (4.2%)	

DCB, drug-coated balloon; POBA, conventional angioplasty, Fisher exact test; significant p-value < 0.05.

Discussion

Vascular access is a critical component for patients undergoing hemodialysis, serving as their lifeline for effective treatment. Despite advances in medical technology and surgical techniques, maintaining the patency and functionality of dialysis access sites remains a significant challenge (3). Stenosis, the abnormal narrowing of blood vessels, is a common complication that compromises the effectiveness of dialysis, often necessitating frequent interventions to restore adequate blood flow (19).

Angioplasty, both with DCB and POBA, has emerged as a primary intervention to address stenosis (20,21). While both techniques aim to dilate the vessel and improve blood flow, they differ in their mechanisms. POBA relies on mechanical dilation alone (22), whereas DCB incorporates an antiproliferative drug to inhibit neointimal hyperplasia and prolong vessel patency (21).

Both groups had similar mean ages (52±13 years for DCB and 52.5±12 years for POBA) and gender distributions (54.2% males in DCB and 50% in POBA). All participants had renal insufficiency, with common comorbidities like diabetes and hypertension. Most were non-smokers (20.8% in DCB and 29.2% in POBA). Dialysis access types were similar, with DCB having 33.3% AVG and 66.7% AVF, and POBA having 29.2% AVG and 70.8% AVF. The preference for AVF over AVG is well-documented due to lower complication rates and better long-term patency (2,23).

Recurrent stenosis occurred in 66.7% of the DCB group and 62.5% of the POBA group, with single lesions predominant (83.3% in DCB and 87.5% in POBA). Prior interventions were common, affecting 79.2% of the DCB group and 83.3% of the POBA group. These findings are comparable with previous studies indicating high rates of recurrent stenosis and multiple interventions in dialysis access patients (3).

In the DCB group, target lesions were mainly in anastomotic vessels and venous outflow (25% each), with fewer in the cephalic arch (20.8%). In the POBA group, lesions were also common in anastomotic vessels (29.2%) and cephalic arch (25%). Both groups most frequently had lesions in the cephalic or basilic vein. The DCB group had 62.5% with poor thrill and 37.5% with pulsatile access, while the POBA group had similar results: 66.7% with poor thrill and 33.3% with pulsatile access. The distribution of target lesion locations aligns with previous studies that identify anastomotic vessels, venous outflow, and the cephalic arch as common sites for stenosis in dialysis access (24). The predominance of these locations can be attributed to the high hemodynamic stress and turbulent blood flow in these regions, which contribute to endothelial injury and subsequent stenosis (25). The similar rates of access failure in both groups suggest that the type of angioplasty may not significantly impact short-term access functionality.

There was no significant difference in pre-procedural and residual stenosis between groups, though inflation duration was longer for the DCB group. At 6 months, primary patency rates were significantly higher in the DCB group (83.3% vs. 58.3%, p-value = 0.002) and continued at 1 year (75% vs. 41.7%, p-value = 0.020). No significant differences were found in assisted primary and secondary patency rates. The DCB group required fewer interventions to maintain patency (0.3 ± 0.7) compared to POBA (0.9 ± 1.0, p-value = 0.03). Device, procedural, and clinical success rates were similar between groups.

The lack of significant difference in pre-procedural and residual stenosis aligns with previous studies, which report that both DCB and POBA effectively reduce stenosis to similar extents initially (22). The longer inflation time for DCBs is consistent with the need for adequate drug transfer to the vessel wall. Koch et al. report that longer DCB inflation times could enhance lesion failure (TLF) rates and reduce the incidence of TLR at 12 months. Specifically, the study found that a DCB inflation time of less than 30 seconds was associated with higher TLF rates, whereas inflation times extending beyond 60 seconds resulted in a TLR rate of 6.0% compared to 12.5% for shorter inflation times. Significant differences in clinical outcomes were observed based on the duration of DCB inflation, highlighting the importance of optimal inflation time for improving patient outcomes. The lack of difference in assisted primary and secondary patency rates suggests that while DCBs may reduce the need for initial re-intervention, they do not significantly impact long-term outcomes once restenosis occurs, a finding also noted in other studies (26).

The superior primary patency rates at 6 months and 1 year for DCBs are in agreement with numerous studies, A recent meta-analysis of 1525 patients reported that DCBs significantly improved first-stage patency rates at 6 months (OR = 2.31, 95% CI: 1.69–3.15, $p < 0.01$) and 12

months (OR = 2.09, 95% CI: 1.50–2.91, p < 0.01) (27). Another meta-analysis with 979 patients found that DCB significantly reduced TLRs compared to balloon angioplasty (BA) at 6 months (OR 0.31, 95% CI 0.14–0.69, p=0.004) and 12 months (OR 0.45, 95% CI 0.21–0.97, p=0.04) (21). On more study systematic review reported that Patients who underwent DCB angioplasty had higher target lesion primary patency rates compared to those who received PBA, with OR of 2.93 (95% CI 2.13–4.03, P<0.001) at 6 months and 2.47 (95% CI 1.53–3.99, P<0.001) at 1 year. The DCB group also demonstrated better dialysis circuit patency at both 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). While the DCB group had lower odds of target lesion revascularization at 6 months (OR 0.43, 95% CI 0.23–0.82, P=0.001), no significant difference was observed at 1 year (OR 0.74, 95% CI 0.32–1.73, P=0.490) (28).

However, other studies reported no significant difference in target lesion primary patency. For example, a review of 11 randomized controlled trials with 487 patients receiving DCB angioplasty and 489 receiving common balloon (CB) angioplasty found no significant difference in target lesion primary patency at 6 months (RR 0.75, 95% CI 0.56–1.01, p = 0.06) and 12 months (RR 0.89, 95% CI 0.79–1.00, p = 0.06). This lack of benefit for DCB persisted across various subgroups, including arteriovenous fistula and studies excluding central vein stenosis (20). Another meta-analysis supported these findings. It analyzed 14 RCTs with 1535 patients and found no significant differences in target lesion primary patency (TLPP) rates at 3, 6, 9, and 12 months between the DCB group and the CB group. TLPP rates showed no significant variation across time points (RRs from 0.81 to 1.19, p-values from 0.065 to 1.000) (29).

The study found no significant difference in adverse events between the DCB and POBA groups (p > 0.05). In the DCB group, 25% (n=6) of participants had serious complications,

including vein rupture (3 cases), AV fistula thrombosis (1 case), AV fistula occlusion (1 case), and aneurysm (1 case). In the POBA group, 29.2% (n=7) experienced complications such as vein rupture (2 cases), AV fistula occlusion (2 cases), thrombosis (1 case), vasospasm (1 case), and puncture site hematoma (1 case). These findings align with existing literature that reports similar rates of complications in patients undergoing angioplasty for dialysis access. For example, **Liao et al.** also reported that procedure-related complications were similar between the two groups (RR 1.00, 95% CI 0.98–1.02, p = 0.95) (20). This suggests that the safety profiles of DCB and POBA are comparable. Additionally, it was reported that one-year survival from clinically driven target lesion revascularization (CD TLR) was similar between DCB (70.1%) and POBA (73.1%; p = 0.85) in below knee interventions. **Zhang et al.** reported there was no significant difference in all-cause mortality between the two groups at 6 months (OR = 0.85, 95% CI: 0.47–1.52, p = 0.58) and 12 months (OR = 0.99, 95% CI: 0.60–1.64, p = 0.97). DCBs showed a higher primary patency rate and delayed restenosis without increasing mortality compared to CBs (27). **Cao et al.,** Mortality rates at 12 months were comparable (OR 0.71, 95% CI 0.20–2.51, p=0.60) (21). **Luo etal.,** reported that both groups had comparable mortality rates (RR 1.00, p = 1.000) (29). Finally **Liu et al.,** reproted that mortality rates were similar between the two groups at both 6 months (OR 1.18, 95% CI 0.42–3.33, P=0.760) and 1 year (OR 0.93, 95% CI 0.58–1.48, P=0.750) (28).

Finally, this study is limited by its single-center design and relatively small sample size, which may affect the generalizability of the findings. Additionally, the short follow-up period may not capture long-term outcomes and complications.

Conclusion

DCBs improved short-term primary patency and required fewer interventions compared to POBA, but did not significantly affect long-term outcomes. Both treatments had similar safety

profiles and mortality rates. These results suggest DCBs offer short-term benefits but need further research to confirm their long-term value.

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