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ORIGINAL RESEARCH

Comparative Efficacy and Safety of Drug-Coated Balloon Angioplasty versus Conventional Balloon Angioplasty for Arteriovenous Access Stenosis in Hemodialysis Patients

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Objective: To compare the safety and efficacy of drug-coated balloon angioplasty (DCBA) versus conventional balloon angioplasty (CBA) in the treatment of autologous arteriovenous fistula (AVF) stenosis in hemodialysis (HD) patients.

Methods: A prospective observational cohort study was conducted on 189 hemodialysis (HD) patients aged 18–80 years with arteriovenous fistula (AVF) stenosis admitted to Nanjing Drum Tower Hospital Group Suqian Hospital from June 2022 to December 2024. The cohort included 107 male (56.6%) and 82 female (43.4%) patients. Patients were stratified into the conventional balloon angioplasty (CBA) group (n = 92) and the drug-coated balloon angioplasty (DCBA) group (n = 97) based on the intervention received. All patients underwent ultrasound-guided percutaneous transluminal angioplasty (PTA), with the DCBA group receiving additional paclitaxel-coated balloon dilation after conventional pre-dilatation. The primary endpoint was 6-month target lesion primary patency (TLPP); secondary outcomes included 3-month TLPP, stenotic segment diameter, HD blood flow, AVF blood flow (AVFB), serum levels of vascular endothelial growth factor-A (VEGF-A), angiotensin II (Ang II), monocyte chemoattractant protein-1 (MCP-1), and complication rates.

Results: Baseline characteristics were comparable between the two groups (all $P>0.05$). Clinical success rates were 100.00% in both groups. 1-month ($P=0.571$) and 3-month ($P=0.350$) TLPP showed no significant differences, but the DCBA group had a significantly higher 6-month TLPP (91.75% vs 80.43%, $P=0.022$). At 1 and 6 months postoperatively, the DCBA group exhibited larger stenotic segment diameter, higher HD blood flow, and higher AVFB than the CBA group (all $P<0.001$). Serum VEGF-A, AngII, and MCP-1 levels in the DCBA group were significantly lower than those in the CBA group at 1 and 6 months postoperatively (all $P<0.001$). There were no significant differences in total complication rates (17.53% vs 13.04%, $P=0.350$) or individual complication incidences (all $P>0.05$) between the two groups.

Conclusion: Our study suggests that DCBA is superior to CBA in treating AVF stenosis, as it improves long-term hemodynamic parameters, suppresses inflammatory factor levels, and enhances 6-month TLPP while maintaining equivalent safety. It may be a preferred intervention for AVF stenosis in HD patients.

Keywords: autologous arteriovenous fistula, stenosis, hemodialysis, drug-coated balloon angioplasty, conventional balloon angioplasty, primary patency

Introduction

End-stage renal disease (ESRD) has evolved into a pressing global healthcare challenge, with its prevalence escalating steadily over the past decade.[1,2] For the majority of ESRD patients dependent on long-term hemodialysis (HD) to sustain life, the establishment and maintenance of a functional vascular access are paramount—this access serves as the "lifeline" for effective clearance of uremic toxins and excess fluid.[3] Among all vascular access options, the autologous

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arteriovenous fistula (AVF) remains the gold standard recommended by international clinical guidelines, owing to its superior long-term patency, lower infection rates, and reduced need for repeated interventions compared to synthetic arteriovenous grafts (AVGs) or central venous catheters.[4,5] Moreover, A nationwide cohort study in Japan reported that arteriovenous fistula was associated with a lower risk of infection-related and all-cause mortality in patients undergoing maintenance hemodialysis.[6] Therefore, arteriovenous fistula is the preferred vascular access. However, the durability of AVFs is severely compromised by the high incidence of vascular access dysfunction, with stenosis emerging as the primary culprit behind AVF failure.[4]

AVF stenosis, predominantly localized at the anastomotic site or within the venous outflow tract, arises from a complex interplay of pathological processes. The core histopathological feature underlying this stenosis is neointimal hyperplasia (NH), characterized by aberrant proliferation and migration of vascular smooth muscle cells (VSMCs) from the media to the intima, coupled with excessive deposition of extracellular matrix components (eg, collagen and fibronectin).[7] This pathological cascade is further exacerbated by repeated vascular punctures during HD, chronic inflammation in uremic patients, endothelial cell injury, and altered hemodynamic shear stress—factors that collectively disrupt the homeostatic balance of vascular remodeling and drive progressive luminal narrowing.[8] Once stenosis develops, it manifests clinically as reduced HD blood flow (<200 mL/min), increased venous pressure during dialysis, diminished thrill or bruit over the AVF, and ultimately, failure to maintain adequate dialysis, which directly impairs patient survival and quality of life.[9]

Percutaneous transluminal angioplasty (PTA) using conventional balloons (CB) has long been the first-line interventional strategy for symptomatic AVF stenosis.[10] By mechanically dilating the stenotic segment to restore luminal patency, CB-PTA achieves immediate technical success in most cases. However, its long-term efficacy is severely limited by the "re-stenosis paradox": the mechanical force applied during balloon inflation inevitably causes iatrogenic injury to the vascular intima and media, triggering a robust reparative response that recapitulates the NH process.[11] Clinical data consistently show that the 6-month primary patency rate of CB-PTA for AVF stenosis ranges only from 21% to 58%, with nearly half of patients requiring repeat PTA within 1 year.[12] This cycle of repeated interventions not only increases the financial burden on healthcare systems but also exhausts the patient's limited vascular resources, eventually necessitating the placement of less optimal access devices.

To address the limitations of CB-PTA, numerous alternative interventional modalities have been explored, including bare-metal stents, covered stents, cutting balloons, and cryoplasty. Unfortunately, these approaches have failed to yield substantial improvements in long-term patency.[13,14] In this context, drug-coated balloons (DCBs) have emerged as a promising innovation. DCBs combine the mechanical dilatation of conventional balloons with the localized delivery of anti-proliferative agents (most commonly paclitaxel) to the vascular wall.[12] During inflation, paclitaxel is transferred to the intima and media, where it exerts its pharmacological effect by stabilizing microtubules, arresting VSMC proliferation in the G2/M phase of the cell cycle, and thereby suppressing NH—targeting the root cause of post-PTA restenosis.[15] Despite the theoretical advantages of DCB-PTA, the impact of DCB-PTA on systemic and local inflammatory responses, a key driver of AVF stenosis, remains incompletely characterized.[16] Biomarkers such as vascular endothelial growth factor-A (VEGF-A), angiotensin II (Ang II), and monocyte chemoattractant protein-1 (MCP-1) have been implicated in the regulation of endothelial dysfunction, VSMC activation, and monocyte recruitment during NH;[15,17] however, how DCB-mediated paclitaxel delivery modulates these inflammatory mediators in the context of AVF stenosis requires further investigation.

Against this backdrop, the present study conducts a rigorous comparative analysis of the safety and efficacy of DCB-PTA versus CB-PTA for symptomatic AVF stenosis in HD patients by evaluating the primary patency rate of the target lesion, hemodynamic parameters, inflammatory biomarkers, and complication rates during the follow-up period. It aims to provide evidence-based guidance for clinical decision-making and to optimize the management strategy for AVF stenosis—a key unmet need in the care of ESRD patients.

Materials and Methods

Study Participants

This study enrolled the clinical data of hemodialysis (HD) patients with autologous arteriovenous fistula (AVF) stenosis and arteriovenous graft (AVG), who were admitted to Nanjing Drum Tower Hospital Group Suqian Hospital between

June 2022 and December 2024. This study was approved by the Medical Ethics Committee of Nanjing Drum Tower Hospital Group Suqian Hospital (approval number: 2023034) and was registered in the Chinese Clinical Trial Registry (registration time: 2021; registration number: ChiCTR2100051760).

Inclusion criteria were defined as follows: age 18–80 years; mature AVF with a history of at least one successful HD session; clinical evidence of hemodynamically significant stenosis (eg, inadequate HD blood flow, difficult cannulation, diminished thrill/bruit over the AVF, or elevated venous pressure during dialysis) confirmed by ultrasound or angiography (stenosis degree ≥50%); and inability to maintain effective HD due to the aforementioned manifestations. Exclusion criteria included: incomplete follow-up data; occlusive vascular thrombosis; prior placement of bare-metal stents or covered stents at the stenotic AVF segment; metastatic cancer or other end-stage diseases with an estimated survival <12 months; coagulation disorders; sepsis or active infections; contrast agent allergy; paclitaxel drug-coated balloon (DCB) allergy; and pregnancy.

A total of 189 patients who met the study criteria were enrolled and stratified into two groups according to the interventional method received: 92 patients were assigned to the conventional balloon angioplasty (CBA) group, and 97 patients were assigned to the drug-coated balloon angioplasty (DCBA) group. The allocation results were concealed using sequentially numbered, opaque, identically sealed envelopes. During follow-up, two patients in the CBA group and three patients in the DCBA group discontinued the intervention or were lost to follow-up for the primary outcome. Ultimately, 90 patients in the CBA group and 94 patients in the DCBA group were included in the final analysis. The patient flow is summarized in a CONSORT flow diagram (Figure 1).

Treatment Procedures

Data Collection

Detailed medical histories of all patients were collected, and preprocedural ultrasound assessments were performed. Baseline variables included: gender, age, body mass index (BMI); comorbidities (hypertension, diabetes mellitus, hyperlipidemia); access type (forearm/upper-arm autologous AVF or AVG); stenosis type; presence of non-flow-limiting mural thrombus; and history of prior percutaneous transluminal angioplasty (PTA).

Preprocedural Preparation for PTA

All patients underwent pre-angiographic Doppler ultrasound screening to identify the location and etiology of HD access dysfunction, assess the degree of stenosis, and determine the optimal site for ultrasound-guided percutaneous puncture. For AVG lesions, interventions were focused on the AVG-venous anastomosis and venous outflow tract; for AVF lesions, the primary target was type I stenosis. In cases of multiple lesions, only the single lesion responsible for the current access dysfunction was treated with DCB. All surgeries were performed by two physicians with 5 or more years of experience, following standardized protocols. Before the procedure, patients were fully informed of the benefits and potential risks of DCB angioplasty (DCBA) and conventional balloon angioplasty (CBA), and the choice of intervention was made voluntarily by the patients.

PTA Technical Protocol

The technical site was disinfected with povidone-iodine and draped in a sterile manner. Local anesthesia was administered using 1% lidocaine. Under ultrasound guidance, percutaneous puncture was performed on the cephalic vein, basilic vein, or AVG; if puncture failed, ultrasound-guided radial artery puncture was adopted as an alternative. After successful puncture, a 6F short sheath (Terumo Corporation, Japan) was inserted, and systemic heparinization was administered at a dose of 0.5 mg/kg based on body weight. The balloon size is selected based on the reference vessel diameter, with an average balloon diameter of 5 to 7 millimeters.

A 0.035-inch hydrophilic guidewire (Terumo Corporation, Japan) was advanced through the sheath and catheter to the arterial end of the AVF, followed by angiography to localize the target stenotic lesion. For the CBA group, a conventional balloon (MicroPort Scientific Corporation, China) was delivered to the center of the target lesion under guidewire guidance. The diameter of the conventional balloon was selected to match or exceed the diameter of the adjacent normal vessel by 1 mm. For patients with severe calcification or refractory stenosis, high-pressure balloons were used for

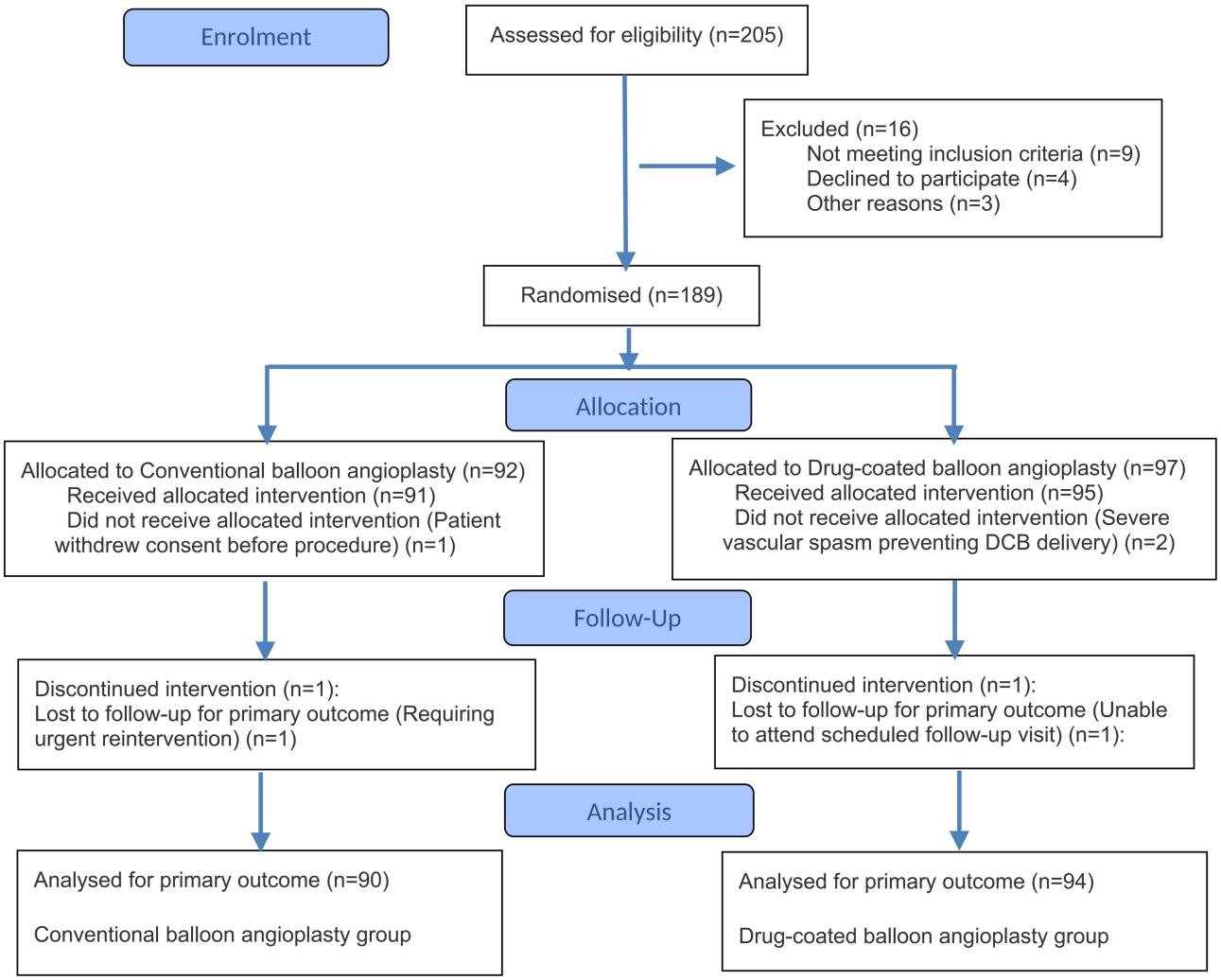

Figure 1 The research flowchart.

dilatation. Balloon inflation was performed incrementally (from lower to higher pressure) until the "waist" sign (indicating residual stenosis) disappeared, and this inflation state was maintained for 60 seconds. Angiography was repeated to confirm technical success (residual stenosis <30%), after which the procedure was concluded for the CBA group.

For the DCBA group, after achieving technical success with conventional balloon pre-dilatation (as described above), a 3.3 μg/mm^2 paclitaxel-coated balloon (MicroPort Scientific Corporation,) was used to dilate the target lesion. The DCB diameter was equal to or 1 mm larger than the final conventional balloon diameter to ensure adequate vascular wall contact; the DCB length exceeded the target lesion by at least 1 cm to avoid missed segments. Inflation was maintained at the manufacturer-recommended standard pressure for 3 minutes. Finally, angiography of the entire HD access was performed to rule out immediate complications (eg, dissection, perforation) and latent lesions (see Figure 2). Postprocedural use of anticoagulants or antiplatelet agents was not restricted.

Definitions and Outcome Measures

Technical success of PTA: Residual stenosis <30% confirmed by postprocedural angiography (Figure 2).

Clinical success of PTA: Completion of at least one HD session postprocedure without evidence of access dysfunction. Patients with technical or clinical failure were still included in the analysis.

Primary patency: Absence of restenosis (≥50% luminal narrowing) at the target lesion during follow-up.

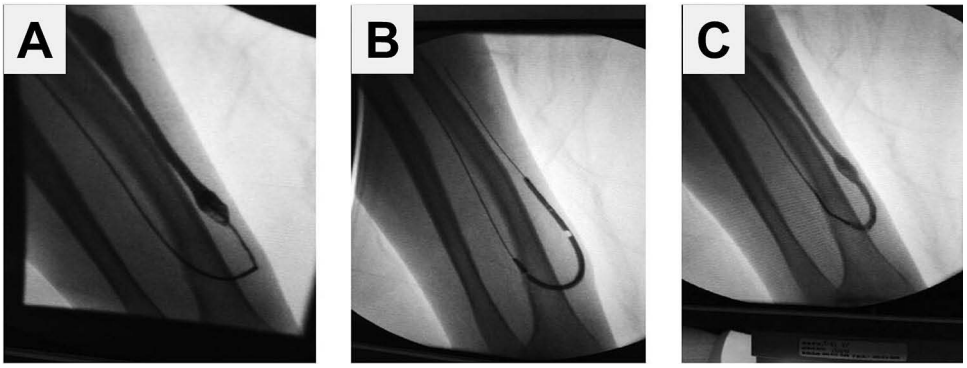

Figure 2 (**A**) Preoperative angiography; (**B**) Balloon dilation during PTA; (**C**) Stenosis disappears on angiography after PTA.

The primary endpoint was the 6-month target lesion primary patency (TLPP) and the 3-month TLPP. Additional outcome measures included:

1. Stenotic segment diameter: Measured by ultrasound pre- and postprocedure to assess dilatation efficacy.
2. HD blood flow and AVF blood flow (AVFB): Quantified using Doppler ultrasound pre- and postprocedure to evaluate hemodynamic improvement.
3. Concentrations of vascular endothelial growth factor-A (VEGF-A), angiotensin II (Ang II), and monocyte chemoattractant protein-1 (MCP-1) were measured using enzyme-linked immunosorbent assay (ELISA) at baseline (pre-procedure) and at 1 and 6 months after the intervention. Blood samples were collected at a consistent dialysis phase for all time points. Longitudinal changes in these systemic inflammatory biomarkers were analyzed to evaluate inflammation-related responses associated with vascular intervention during follow-up.
4. Complication rate: Documented intraoperatively and during follow-up (eg, thrombus formation, bleeding, local swelling, infection). The safety results were categorized according to the SIR classification system and then compared in a standardized manner between the groups.
5. Quality of life (QoL): Evaluated using the Generic Quality of Life Inventory-74 (GQOLI-74) preprocedure and at 1 month, 6 months postprocedure. The questionnaire assesses four dimensions (social function, physical function, material living conditions, and psychological function), with standardized scores ranging from 0 to 100 (higher scores indicate better QoL).

Statistical Analysis

All statistical analyses were performed using SPSS 26.0 software (IBM Corp., Armonk, NY, USA). Normality of continuous variables was assessed using the Shapiro–Wilk test, and homogeneity of variances was evaluated with Levene's test. Continuous variables are presented as mean ± standard deviation and compared using appropriate parametric or non-parametric tests as indicated. Categorical variables were compared using χ^2 or Fisher's exact test. Kaplan–Meier analysis was used to estimate target lesion primary patency, with between-group comparisons performed using the Log rank test. Cox proportional hazards model was used to estimate hazard ratios (HRs) with 95% CI.

Results

Baseline Characteristics of Study Participants

A total of 189 patients with AVF stenosis were enrolled, including 92 cases in the CBA group and 97 cases in the DCBA group. The baseline clinical data of the two groups are shown in Table 1. There were no statistically significant differences in gender, age, BMI, dialysis duration, access type, AVF location, AVF usage time, comorbidities (hypertension, diabetes mellitus, hyperlipidemia), stenosis type, presence of non-flow-limiting mural thrombus, history of prior PTA, and preoperative laboratory indicators (hemoglobin, serum creatinine, blood urea nitrogen, total cholesterol, triglycerides) between the two groups (all $P>0.05$), indicating good comparability.

Comparison of Stenotic Diameter, Dialysis Blood Flow, and AVFB

Preoperative stenotic segment diameter, dialysis blood flow, and AVFB showed no statistically significant differences between the CBA group and DCBA group (all $P>0.05$). At 1 month and 6 months postoperatively, both groups demonstrated improvements in these three indicators compared with preoperative values; notably, the DCBA group exhibited significantly larger stenotic segment diameter, higher dialysis blood flow, and higher AVFB than the CBA group (all $P<0.05$). Detailed data are presented in Table 2.

Between-Group Comparison of Serum VEGF-A, AngII, and MCP-1 Levels

Preoperative serum levels of VEGF-A, AngII, and MCP-1 showed no statistically significant differences between the CBA group and DCBA group (all $P>0.05$). At 1 month and 6 months postoperatively, both groups exhibited decreased levels of the three inflammatory factors compared with preoperative values; the DCBA group had significantly lower serum VEGF-A, AngII, and MCP-1 levels than the CBA group (all $P<0.05$). Detailed data are presented in Table 3.

The visualized results are presented in Figure 3.

Between-Group Comparison of Complication Rates

During the perioperative period and 6-month follow-up, the main complications observed in both groups included thrombus formation, puncture site bleeding, local swelling, and infection. There were no statistically significant differences in the incidence of single complications or total complications between the CBA group and DCBA group

Table 1 Baseline Characteristics of Patients in the Two Groups

Characteristics	CBA Group (n=92)	DCBA Group (n=97)	$t/\chi^2/Z$	*P*
Gender, n (%)			0.328	0.567
Male	51 (55.43)	56 (57.73)		
Female	41 (44.57)	41 (42.27)		
Age (years, x±s)	61.35±10.28	62.14±11.05	0.526	0.599
BMI (kg/m^2, x±s)	23.12±2.41	23.28±2.53	0.438	0.662
Dialysis duration (years, M (Q1, Q3))	4.20 (2.10, 7.30)	4.50 (2.30, 7.80)	0.419	0.675
Access type, n (%)			0.018	0.893
AVF	78 (84.78)	82 (84.54)		
AVG	14 (15.22)	15 (15.46)		
AVF location, n (%)			0.186	0.666
Forearm	58 (74.36)	61 (74.39)		
Upper arm	20 (25.64)	21 (25.61)		
AVF usage time (months, x±s)	22.56±8.14	23.12±8.57	0.453	0.651
Comorbidities, n (%)				
Hypertension	58 (63.04)	62 (63.92)	0.031	0.861
Diabetes mellitus	37 (40.22)	40 (41.24)	0.024	0.877
Hyperlipidemia	44 (47.83)	48 (49.48)	0.071	0.790
Stenosis type, n (%)			0.295	0.587
De novo stenosis	59 (64.13)	64 (65.98)		
Restenosis	33 (35.87)	33 (34.02)		
Non-flow-limiting mural thrombus, n (%)	20 (21.74)	23 (23.71)	0.132	0.716
History of prior PTA, n (%)	43 (46.74)	47 (48.45)	0.075	0.784
Preoperative laboratory indicators				
Hemoglobin (g/L, x±s)	115.68±14.23	116.92±15.07	0.552	0.582
Serum creatinine (μmol/L, x±s)	892.35±120.67	901.58±125.34	0.468	0.640
Blood urea nitrogen (mmol/L, x±s)	23.45±5.12	24.01±5.36	0.731	0.466
Total cholesterol (mmol/L, x±s)	3.92±0.95	3.87±0.98	0.364	0.716
Triglycerides (mmol/L, M (Q1, Q3))	1.48 (1.05, 2.52)	1.52 (1.08, 2.60)	0.321	0.748

Abbreviations: CBA, conventional balloon angioplasty; DCBA, drug-coated balloon angioplasty; AVF, autologous arteriovenous fistula; AVG, arteriovenous graft; PTA, percutaneous transluminal angioplasty.

Table 2 Comparison of Stenotic Segment Diameter, Dialysis Blood Flow, and AVFB Between the Two Groups

Indicators	Groups	Preoperation	1 Month Postoperation	6 Months Postoperation
Stenotic segment diameter (mm, x±s)	CBA	1.42±0.31	3.38±0.45	3.25±0.47
	DCBA	1.40±0.29	3.79±0.58	3.62±0.52
	t value	0.482	4.963	4.817
	P value	0.630	<0.001	<0.001
Dialysis blood flow (mL/min, x±s)	CBA	151.89±12.96	219.75±13.68	211.52±13.45
	DCBA	149.23±12.05	248.61±12.93	238.94±12.38
	t value	1.374	12.842	13.015
	P value	0.171	<0.001	<0.001
AVFB (mL/min, x±s)	CBA	816.72±45.93	855.31±54.82	850.64±55.91
	DCBA	810.35±52.86	930.87±60.94	924.58±59.73
	t value	0.885	8.926	8.753
	P value	0.377	<0.001	<0.001

Abbreviations: CBA, conventional balloon angioplasty, n=90; DCBA, drug-coated balloon angioplasty, n=94; AVFB, arteriovenous fistula blood flow.

Table 3 Comparison of Serum VEGF-A, AngII, and MCP-1 Levels Between the Two Groups

Indicators	Groups	Preoperation	1 Month Postoperation	6 Months Postoperation
VEGF-A (pg/mL, x±s)	CBA	386.42±45.18	298.75±32.64	312.58±34.91
	DCBA	390.15±47.32	245.31±28.79	259.84±30.65
	t value	0.521	9.876	9.243
	P value	0.603	<0.001	<0.001
AngII (pg/mL, x±s)	CBA	128.65±18.42	95.32±14.27	102.46±15.38
	DCBA	130.28±19.56	78.54±12.63	85.72±13.41
	t value	0.547	7.982	7.615
	P value	0.585	<0.001	<0.001
MCP-1 (pg/mL, x±s)	CBA	265.38±32.74	198.64±25.19	210.37±27.45
	DCBA	268.72±34.15	162.48±22.36	175.62±24.89
	t value	0.683	9.751	8.964
	P value	0.496	<0.001	<0.001

Abbreviations: CBA, conventional balloon angioplasty, n=90; DCBA, drug-coated balloon angioplasty, n=94; VEGF-A, vascular endothelial growth factor-A; AngII, angiotensin II; MCP-1, monocyte chemoattractant protein-1.

(all $P>0.05$). All complications were classified according to the SIR system, and no major complications occurred in either group. Detailed data are presented in Table 4.

Comparison of Technical Success Rate and Primary Patency Rate (1, 3, 6 Months)

The clinical success rate of both groups reached 100.00%. At 1 month and 3 months postoperatively, there were no statistically significant differences in the primary patency rate between the CBA group and DCBA group (both $P>0.05$). At 6 months postoperatively, the primary patency rate of the DCBA group was significantly higher than that of the CBA group ($P<0.05$). Detailed data are presented in Table 5. Kaplan-Meier survival curves were used to plot target lesion primary patency rates in the DCB and CBA groups. The results showed that the AVF patency duration was longer in the DCB group than in the CBA group (Figure 4). Consistently, Cox proportional hazards analysis showed that treatment with DCBA was associated with a significantly different hazard of loss of primary patency compared with CBA (HR = 1.872, 95% CI: 1.107–2.862, $P = 0.008$).

Discussion

This study demonstrates that DCBA provides superior 6-month primary patency and hemodynamic outcomes compared to CBA for treating arteriovenous access stenosis, with a comparable safety profile. The observed modulation of peri-

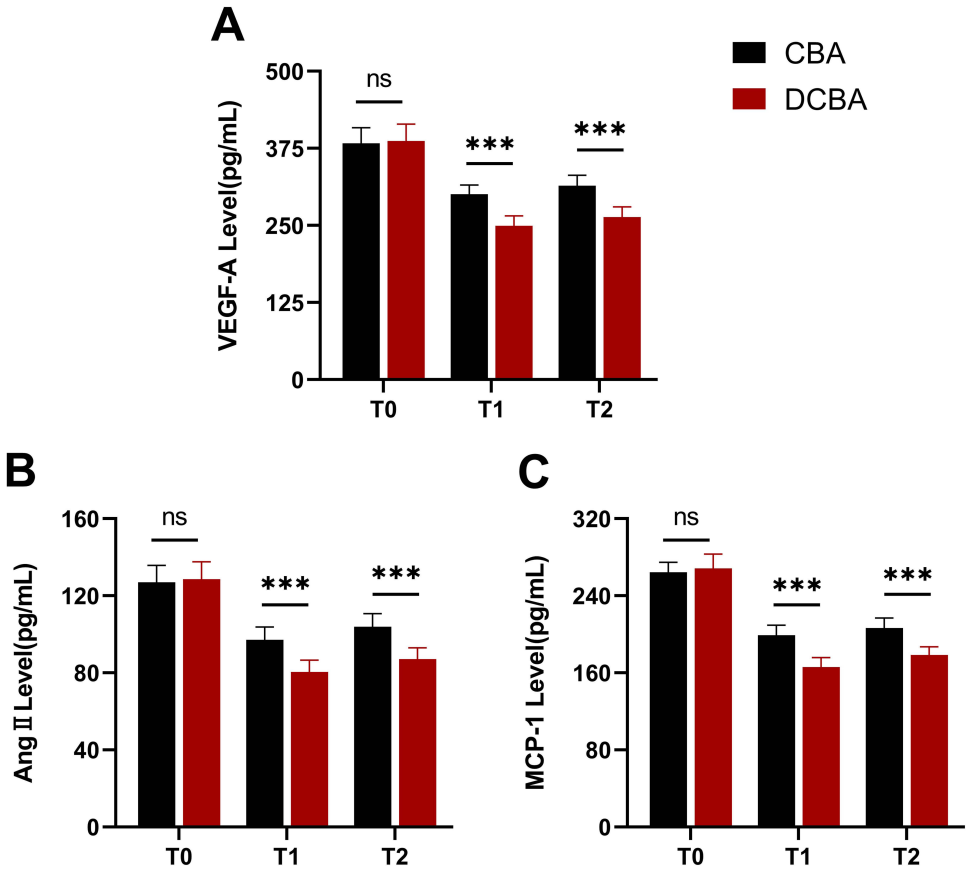

Figure 3 Serum VEGF-A, AngII, and MCP-1 levels comparison between the two groups. (**A**–**C**) Respectively show the levels of VEGF-A, AngII, and MCP-1 in different groups (CBA group: black bars; DCBA group: red bars) at different time points. Among them, T0 is the baseline time point (preoperation), and T1 and T2 are 1 month and 6 months after operation, respectively. Data are mean±SD (***P < 0.001).

Abbreviations: CBA, conventional balloon angioplasty; DCBA, drug-coated balloon angioplasty; VEGF-A, vascular endothelial growth factor-A; AngII, angiotensinII; MCP-1, monocyte chemoattractant protein-1.

procedural inflammatory biomarkers further suggests that the benefits of DCBA extend beyond its mechanical action to encompass local biological effects.

According to current KDOQI guidelines,[18,19] AVF is recognized as the preferred vascular access for HD, and PTA is the standard intervention for access stenosis. Nevertheless, stenosis remains a critical challenge, necessitating repeated endovascular interventions and potentially leading to eventual access failure. Although balloon angioplasty is a well-

Table 4 Comparison of Complication Rates Between the Two Groups [n (%)]

Complications	CBA Group (n=90)	DCBA Group (n=94)	χ^2	*P*
Thrombus formation	2 (2.22)	3 (3.19)	0.168	0.682
Puncture site bleeding	4 (4.44)	5 (5.32)	0.092	0.762
Local swelling	5 (5.56)	6 (6.38)	0.083	0.773
Infection	1 (1.11)	2 (2.13)	0.341	0.560
Vascular dissection	0 (0.00)	1 (1.06)	1.012	0.314
Minor complications	12 (13.33)	17 (18.09)	0.875	0.350
Major complications	0	0		
Total complications	12 (13.33)	17 (18.09)	0.875	0.350

Notes: "Total complications" counts patients with at least one complication (no double-counting for multiple complications in the same patient). Complications were classified according to the SIR classification system; minor complications were defined as SIR A–B; major complications were defined as SIR C–F.

Abbreviations: CBA, conventional balloon angioplasty; DCBA, drug-coated balloon angioplasty.

Table 5 Comparison of Technical Success Rate and Primary Patency Rate Between the Two Groups [n (%)]

Indicators	CBA Group	DCBA Group	χ^2	*P*
Clinical success rate	90 (100.00)	94 (100.00)	–	–
Primary patency rate				
1 month postoperation	89 (98.89)	92 (97.87)	0.321	0.571
3 months postoperation	82 (91.11)	90 (95.74)	0.873	0.350
6 months postoperation	74 (82.22)	89 (94.68)	5.286	0.022

Abbreviations: CBA, conventional balloon angioplasty, n=90; DCBA, drug-coated balloon angioplasty, n=94.

established therapeutic option for AVF stenosis, the high rate of restenosis results in persistent access dysfunction. Clinical trials have confirmed that DCB technology effectively mitigates neointimal hyperplasia in peripheral arterial disease.[20]

DCB technology combines balloon angioplasty with drug elution, with paclitaxel—the most widely used antiproliferative agent—coated on the balloon surface.[21] Professor Scheller B and his team first reported in 2003 that paclitaxel effectively inhibited in-stent restenosis in a coronary artery animal model, attracting widespread attention.[22] In 2006, they completed the human study on stent restenosis, confirming that DCB was significantly superior to conventional balloons in treating this condition, laying a solid foundation for subsequent DCB research.[23] Since then, DCB has been applied to the treatment of various atherosclerotic stenoses, including coronary arteries and superficial femoral arteries, and gradually extended to carotid, vertebral, and subclavian artery lesions, consistently demonstrating advantages in inhibiting vascular intimal hyperplasia.[24–26] In recent years, its application in vascular access management has also shown great potential, offering a new approach to address AVF stenosis.[27,28]

For ESRD patients undergoing HD, international guidelines uniformly recommend AVF as the preferred vascular access.[18] However, patients with poor native vascular conditions may only rely on AVGs or long-term HD catheters, making the maintenance of functional vascular access critical.[29] Establishing new HD access is challenging, as factors such as vessel diameter, calcification degree, blood flow, diabetes status, surgeon experience, vessel tortuosity, and anastomotic size all influence AVF maturation.[29–32] AVF stenosis typically occurs at anastomotic sites, puncture points,

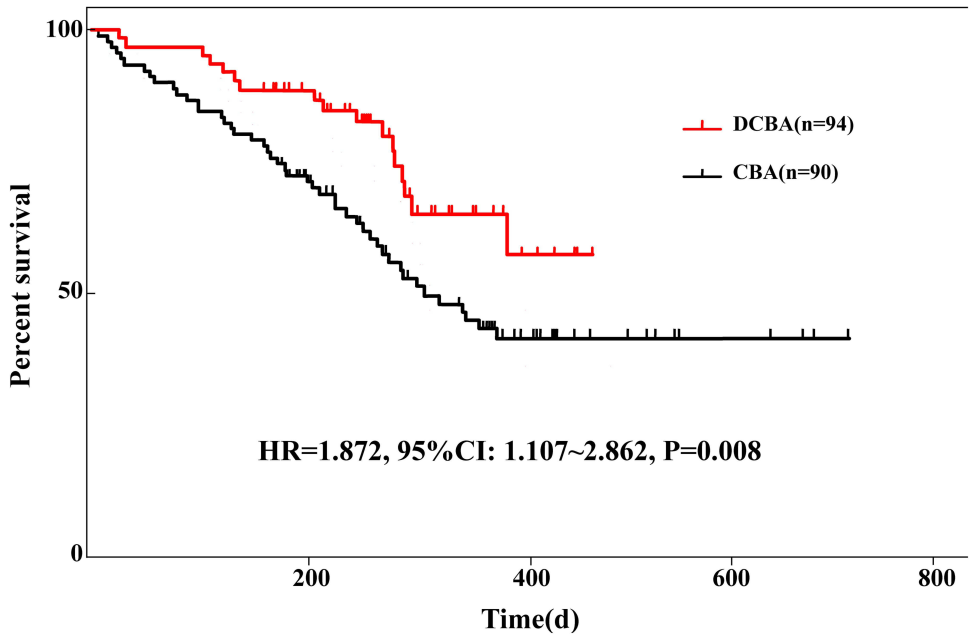

Figure 4 Kaplan-Meier survival curves of TLPP in the DCBA and CBA groups.

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and venous outflow tracts, resulting from vascular injury during access creation, repeated punctures, venous arterialization, fibrosis induced by increased shear stress in thin-walled outflow veins, turbulence, endothelial dysfunction, and intimal injury from repeated PTA.[33,34] The core pathophysiological mechanism underlying stenosis is VSMC proliferation and migration, leading to NH.[35]

Although PTA is the most important current treatment for HD access dysfunction, it has inherent limitations.[36,37] Balloon dilation of target lesions inevitably tears the vascular intima and media—even the adventitia in severe cases—triggering VSMC proliferation, migration, and extracellular matrix production.[37,38] Moreover, uremic patients often have endothelial dysfunction, further promoting target lesion restenosis.[39] In contrast, paclitaxel-coated DCBs stabilize microtubules, block mitosis, and inhibit cellular DNA synthesis, thereby effectively suppressing VSMC proliferation, migration, and extracellular matrix formation, and ultimately preventing restenosis.[15,40] This mechanism explains the superior long-term efficacy of DCBA observed in the present study. Consistent with findings by Kocaaslan et al[41] our results showed comparable 1-month (P=0.571) and 3-month (P=0.350) primary patency rates between DCBA and CBA, but a significantly higher 6-month primary patency rate in the DCBA group (P=0.022). Kaplan-Meier survival curves further confirmed longer AVF patency duration in the DCBA group. This time-dependent advantage arises because CBA fails to inhibit NH, leading to gradual restenosis within 3–6 months, while paclitaxel from DCBs exerts sustained antiproliferative effects delaying restenosis. Our focus on AVF stenosis avoids biases from mixed access types, though DCBA efficacy in AVG lesions warrants future exploration.

Hemodynamic improvement ensures effective HD.[42] Preoperatively, stenotic segment diameter, dialysis blood flow, and AVFB were similar between groups (all P>0.05). Postoperatively, both groups improved, but DCBA achieved significantly superior outcomes at 1 and 6 months (all P<0.001). These improvements are clinically meaningful, stemming from paclitaxel's inhibition of NH preserving luminal integrity. Chronic inflammation drives AVF stenosis via VEGF-A, AngII, and MCP-1. Preoperatively, serum levels of these factors were comparable (all P>0.05). Postoperatively, both groups showed reductions, but DCBA achieved significantly lower levels at 1 and 6 months (all P<0.001). This anti-inflammatory effect likely involves paclitaxel-mediated suppression of macrophage activation, synergistically enhancing long-term patency.[43,44] Notably, the interpretation of inflammatory biomarkers in this study was based on changes from individual baseline values and between-group comparisons, rather than on absolute cutoff values. Safety is paramount for HD patients with multiple comorbidities. Perioperative and 6-month follow-up complications included thrombus formation, puncture site bleeding, local swelling, infection, and vascular dissection. Total complication rates (DCBA:17.53%; CBA:13.04%) and individual complication incidences showed no significant differences (all P>0.05; total P=0.350). No severe complications were observed, reflecting the safety of standardized ultrasound-guided procedures.

This study has limitations. First, 6-month follow-up is insufficient for long-term efficacy assessment. Second, no stratification by lesion characteristics was performed, with preliminary observations suggesting reduced DCBA efficacy in severe calcification or multiple stenoses. Third, lack of histopathological data and local drug concentration measurements limits direct verification of paclitaxel's mechanism. Nevertheless, this study also has notable strengths. In addition to standardized interventional procedures and longitudinal follow-up, the incorporation of peri-interventional inflammatory biomarkers provides complementary biological insight into the vascular response after DCBA, which has been less frequently explored in previous vascular access studies.

Conclusion

In summary, this study suggests that drug-coated balloon angioplasty (DCBA) is associated with improved 6-month target lesion primary patency and favorable hemodynamic outcomes compared with conventional balloon angioplasty (CBA) in patients with AVF stenosis, without an apparent increase in procedure-related complications. In addition, peri-interventional changes in selected inflammatory biomarkers were observed, providing supportive evidence for the biological effects of DCBA beyond mechanical dilation. Future prospective, multicenter studies with extended follow-up are needed to validate results, explore subtype-specific efficacy, and optimize DCB parameters.

Ethics Statement

The study was approved by the Medical Ethics Committee of Nanjing Drum Tower Hospital Group Suqian Hospital (Approval No. 2023034), and all patients or their legal representatives provided written informed consent prior to intervention. All methods were carried out in accordance with Declaration of Helsinki.

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Disclosure

The authors declared that they have no conflicts of interest regarding this work.

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