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ORIGINAL ARTICLE

Drug-eluting versus plain balloon angioplasty for haemodialysis vascular access stenosis: a retrospective analysis.

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ABSTRACT

INTRODUCTION: Arteriovenous fistulas (AVFs) and grafts (AVGs) are the preferred vascular access for hemodialysis, but they often become dysfunctional because of stenosis. Although plain old balloon angioplasty (POBA) remains the standard treatment, drug-coated balloons (DEBs) have been proposed to reduce restenosis. However, their long-term efficacy in this setting remains uncertain.

METHODS: We conducted a retrospective, single-center study of 96 patients who underwent index percutaneous transluminal angioplasty (PTA) for dysfunctional AVFs or AVGs between November 2018 and July 2025, comparing POBA with paclitaxel-coated DEBs. We excluded patients with prior interventions or stents. The primary endpoint was primary patency at 6 and 12 months, defined as the time from the index angioplasty to the first clinically driven reintervention at the treated lesion, thrombosis, or surgical revision. Secondary endpoints included secondary patency and overall mortality. We used Kaplan–Meier survival analysis and Cox regression.

RESULTS: Of 96 patients (median age 62.5 years; 53.1% female), 81.3% had AVFs. POBAs were used in 79 cases, and DEBs in 17. Technical success was achieved in 93/96 patients (96.9%), with no significant difference between the POBA and DEB groups (96.2% vs. 100.0%; p = 1.0). Clinical success was 94.9% vs. 94.1% (p = 1.0). No significant difference in primary patency was observed between POBA and DEB at 6 months (58% vs. 43.8%) or 12 months (38% vs. 37.5%). Secondary patency and mortality rates were also similar. Multivariate analysis identified female sex as associated with an increased risk of primary patency loss (HR = 1.86; 95% CI: 1.08–3.19; p = 0.025), whereas balloon type was not associated with primary patency loss (POBA vs. DEB: HR = 1.00; 95% CI: 0.52–1.93; p = 0.991). Access type was not statistically significant (AVG vs. AVF: HR = 1.85; 95% CI: 1.00–3.45; p = 0.052). We did not include periprocedural complications in the multivariable model because of the small number of events.

CONCLUSION: DEB angioplasty did not show a significant advantage over POBA in maintaining primary patency at 6 or 12 months. Female sex and procedural complications were associated with a higher risk of primary patency loss, whereas balloon type was not associated with the outcome. Access type showed a borderline, non-significant association with primary patency loss. Larger prospective studies are needed to further assess the role of DEBs in vascular access maintenance.

Keywords: Hemodialysis; Arteriovenous fistula; Vascular access; Drug-eluting balloon; Plain old balloon angioplasty.

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INTRODUCTION

In patients with end-stage renal disease (ESRD), creating an arteriovenous fistula (AVF) or graft (AVG) is essential for optimal hemodialysis. However, these vascular accesses are associated with high rates of restenosis and failure.

Currently, the standard treatment for AVF or AVG stenosis is percutaneous transluminal angioplasty with plain old balloon angioplasty (POBA). Building on experience with coronary and peripheral artery disease, drug-eluting balloons (DEBs) have been introduced into vascular access interventions.[1] However, randomized controlled trials and meta-analyses comparing POBA with DEBs have shown inconsistent benefits in 12-month primary patency outcomes.[2,3] Other strategies to improve the durability of angioplasty include high-pressure balloons (HPBs), cutting balloons (CBs), stents, and stent grafts. According to the 2019 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, balloon angioplasty remains the primary treatment for clinically significant AVF and AVG stenosis, while stent grafts may be considered in selected situations, including recurrent clinically significant lesions and selected complications.[4]

Our aim is to compare the efficacy of DEB angioplasty versus POBA in reducing restenosis in patients with primary lesions in native AVFs or AVGs.

METHODS

Study Design and Population

This single-center retrospective study was conducted at our institution and analyzed patients who underwent index percutaneous transluminal angioplasty (PTA) for dysfunctional (AV) accesses used for hemodialysis between November 2018 and July 2025. The term index PTA refers to the first recorded angioplasty performed on the access during the study period, with no prior endovascular interventions on the same access. The local institutional ethics committee approved the study (n°1560).

The inclusion criteria were as follows: (i) adult patients aged ≥18 years; and (ii) Patients with a mature AV fistula or graft used for dialysis, presenting with a dysfunctional access during hemodialysis. We defined dysfunctional access as one that compromised the effectiveness of the hemodialysis procedure. Dysfunction was multifactorial and included inflow problems such as low access flow, reduced dialysis adequacy (low Kt/V), or circuit recirculation, as well as outflow problems such as elevated venous pressures and prolonged bleeding times after needle withdrawal. We excluded patients with a history of prior intervention at the access site, those who received a stent during the procedure, those who were pregnant, those under 18, or those with incomplete clinical or imaging records.

We evaluated all AV accesses and their dysfunction using duplex ultrasonography (General Electric, Logic F6®). We defined significant stenosis as luminal narrowing greater than 50% on Doppler ultrasound.

Endpoints

The primary endpoint was access circuit primary patency (ACPP), assessed at 6 and 12 months and defined as the time from the index angioplasty to the first clinically driven reintervention anywhere within the access circuit, access circuit thrombosis, or surgical revision. Secondary endpoints included secondary patency, defined as the time from the index successful angioplasty to permanent access abandonment, including all subsequent interventions performed to maintain or restore access function, and overall mortality, defined as death from any cause during the follow-up period.

Data Collection and Variables

We retrospectively collected clinical, demographic, and procedural data from institutional electronic medical records and angiographic reports. Collected variables included patient age, sex, and relevant comorbidities, including diabetes mellitus, hypertension, dyslipidemia, cardiovascular disease, and cerebrovascular disease. Cardiovascular disease was defined as a documented history of coronary artery disease, including previous myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, angina, chronic heart failure, cardiac arrhythmias, and valvular heart disease.

Cerebrovascular disease included a prior history of ischemic or hemorrhagic stroke or transient ischemic attack (TIA), confirmed by neurological evaluation or imaging studies. We assessed each patient's antithrombotic status at the time of the index procedure, specifically noting whether the patient was on antiplatelet or anticoagulant therapy. Any changes to antithrombotic treatment following the procedure were also recorded, including initiation, discontinuation, or continuation of therapy during the follow-up period. Each vascular access was classified as either an AVF or AVG, and its laterality (left or right side) was noted.

The type of balloon used – POBA or DEB – along with its diameter and length (in millimeters) were recorded. DEBs were paclitaxel-coated balloons (IN.PACT™ Admiral™/ Pacific™, Medtronic, Minneapolis, MN, USA) with a paclitaxel dose density of 3.5 µg/mm². POBA included standard balloons such as Armada™ (Abbott Vascular, Santa Clara, CA, USA) and Pacific Plus™ (Medtronic, Minneapolis, MN, USA), as well as HPBs, specifically Fortrex™ (Medtronic, Minneapolis, MN, USA). All HPBs were analyzed within the POBA group.

Technical success was defined as vascular access patency on control angiography with residual stenosis <30% after angioplasty. Clinical success was defined as the ability to perform a successful hemodialysis session through the treated access after the index intervention.

Procedural complications were defined as adverse events occurring during or immediately after angioplasty that compromised technical success, including access rupture, vessel dissection requiring additional intervention, or any event that led to premature termination of the procedure.

Secondary interventions were defined as any subsequent procedures performed on the vascular access after the index angioplasty to maintain or restore access function, including

those for thrombosis, restenosis, or other causes of access dysfunction.

Follow-up duration was calculated from the procedure date to the last clinical evaluation, reintervention, access abandonment, or study end date.

Procedure

Vascular surgeons experienced in endovascular interventions performed all procedures under local anesthesia. An initial diagnostic fistulogram was performed to evaluate vascular access in dysfunctional accesses. If a significant stenotic lesion identified on Doppler ultrasound was confirmed angiographically and deemed amenable to angioplasty, the patient proceeded to treatment and was included in the study. The operating surgeon selected the angioplasty balloon type based solely on vessel and stenosis diameter.

In all cases where DEBs were used, vessel preparation was performed first with either a POBA or an HPB during the same procedure. This step aimed to ensure adequate lesion preparation and optimal vessel wall contact to enhance drug transfer, consistent with current DEB recommendations. When non-drug-coated balloons were used, the choice between a POBA and a HPB was made at the operator's discretion, based on lesion characteristics such as recoil or residual stenosis after initial angioplasty. Operators also administered heparin at their discretion.

Statistical Analysis

We used descriptive statistics to summarize baseline characteristics. Continuous variables were tested for normality using the Shapiro–Wilk test. Because none followed a normal distribution, we presented them as the median with interquartile range (IQR). Comparisons between groups (POBA vs. DEB) were performed using the Mann–Whitney U test. Categorical variables were reported as frequencies and percentages. Associations between categorical variables were assessed using Pearson's chi-square test. When the expected frequency in one or more cells was less than five, Fisher's exact test was used instead. A P-value < 0.05 was considered statistically significant.

Survival analyses of access circuit primary patency, secondary patency, and overall mortality were performed using the Kaplan–Meier method, and group comparisons were conducted using the log-rank test. Univariable Cox proportional hazards regression analyses were performed to identify potential predictors of access circuit primary patency loss.

Variables considered clinically relevant and those showing an association with primary patency loss in univariable analysis (P < 0.10) were included in the multivariable Cox regression model. Balloon type was retained in the multivariable model irrespective of its univariable P-value, as it was the primary exposure of interest. The proportional hazards assumption was verified for all models. Hazard ratios (HRs) with corresponding 95% confidence intervals (CIs) were reported. Statistical significance was set at a two-sided p-value < 0.05. All statistical analyses were performed using IBM SPSS Statistics (version 30, IBM Corp., Armonk, NY, USA).

RESULTS

Study Population

Of the 156 patients assessed for eligibility, 43 were excluded for prior intervention at the same vascular access site, and 17 were excluded for incomplete clinical or imaging data. The final study population therefore included 96 patients, with a median age of 62.5 years (IQR 50.3–72.0). Age did not differ significantly between the POBA and DEB groups (p = 0.840). Gender distribution was also comparable, with females accounting for 53.1% of the total sample (51.9% in the POBA group and 58.8% in the DEB group; p = 0.604).

Regarding comorbidities, 50% of patients had diabetes, and the prevalence of hypertension (96.9%), dyslipidemia (97.9%), cardiovascular disease (58.3%), and cerebrovascular disease (16.7%) did not differ significantly between groups (Table 1).

Antiplatelet therapy was used by 50.0% of patients, and anticoagulation therapy by 19.8%, with no significant differences between groups (p = 0.181 and p = 1.0, respectively).

With respect to vascular access, 81.3% of patients had an arteriovenous fistula (AVF), and access site distribution was evenly split between right and left upper limbs (50% each), with no significant differences between groups (p > 0.1). The median balloon length was 60.0 mm (IQR 40.0–75.0), with no significant difference between POBA and DEB groups (p = 0.147). Balloon diameter tended to be larger in the POBA group (median 7.0 mm vs. 6.0 mm in the DEB group), approaching but not reaching statistical significance (p = 0.056).

Technical success

Technical success was achieved in 93/96 procedures (96.9%). Rates were similar between groups, with 96.2% in the POBA group and 100% in the DEB group (p = 1.0). Clinical success was also high (91/96; 94.8%), with no significant difference between groups.

Median follow-up was 178 days (IQR: 58–586) in the POBA group and 356 days (IQR: 110–892) in the DEB group. Complications were rare (3.1% overall) and occurred only in the POBA group (3.8%), with no significant difference (p = 1.0).

Primary Patency at 6 and 12 Months

Access circuit primary patency at 6 months did not differ significantly between the POBA and DEB groups (58% vs 43.8%, respectively, p = 0.746). At 12 months, primary patency rates were 38% in the POBA group and 37.5% in the DEB group (Figure 1A).

The median time to loss of primary patency was 231 days (95% CI: 160.8–301.2) for POBA and 125 days (95% CI: 97.6–152.4) for DEB.

Primary Patency, Secondary Patency and Access Survival

Primary patency was lost in 60.4% of patients, with a higher incidence in the DEB group (76.5% vs. 57%), although this difference was not statistically significant (p = 0.136). Among the 58 patients who experienced loss of primary patency, thrombosis was the most frequent cause, occurring in 31 patients (53.4%), followed by restenosis in 26 patients (44.8%) and aneurysmal degeneration in 1 patient (1.7%).

Table 1. Baseline and follow-up characteristics stratified by balloon type

Variable	Total (n = 96)	POBA (n = 79)	DEB (n = 17)	p value
Age, years (median, IQR)	62.5 (50.3–72.0)	-	-	0.840
Gender, n (%)				0.604
Female	51 (53.1%)	41 (51.9%)	10 (58.8%)	-
Male	45 (46.9%)	38 (48.1%)	7 (41.2%)	-
Diabetes, n (%)	48 (50.0%)	38 (48.1%)	10 (58.8%)	0.423
Hypertension, n (%)	93 (96.9%)	77 (97.5%)	16 (94.1%)	0.447[a]
Dyslipidaemia, n (%)	94 (97.9%)	77 (97.5%)	17 (100.0%)	1[a]
Cardiovascular disease, n (%)	56 (58.3%)	46 (58.2%)	10 (58.8%)	0.964
Cerebrovascular disease, n (%)	16 (16.7%)	14 (17.7%)	2 (11.8%)	0.729[a]
Antiplatelet therapy, n (%)	48 (50.0%)	37 (46.8%)	11 (64.7%)	0.181
Anticoagulation, n (%)	19 (19.8%)	16 (20.3%)	3 (17.6%)	1[a]
Access type, n (%)				0.515[a]
AVF	78 (81.3%)	63 (79.7%)	15 (88.2%)	-
AVG	18 (18.7%)	16 (20.3%)	2 (11.8%)	-
Access side, n (%)				0.181
Right upper limb	48 (50.0%)	37 (46.8%)	11 (64.7%)	-
Left upper limb	48 (50.0%)	42 (53.2%)	6 (35.3%)	-
Balloon length, mm (median, IQR)	60.0 (40.0–75.0)	60.0 (40.0-75.0)	57.0 (37.5–70.0)	0.147
Balloon diameter, mm (median, IQR)	7.0 (5.6–7.0)	7.0 (6.0–7.0)	6.0 (5.0–7.0)	0.056
Technical success, n (%)	93 (96.9%)	76 (96.2%)	17 (100.0%)	1[a]
Follow-up	185 (62-597.5)	178 (58-586)	356 (110-892)	0.270
Clinical success, n (%)	91 (94.8%)	75 (94.9%)	16 (94.1%)	1[a]
Complications, n (%)	3 (3.1%)	3 (3.8%)	0 (0.0%)	1[a]
Loss of primary patency, n (%)	58 (60.4%)	45 (57%)	13 (76.5%)	0.136
Cause of first loss of primary patency, n (%)				0.029[a]
Thrombosis	31 (53,4%)	20 (44,4%)	11 (84,6%)	-
Restenosis	26 (44,8%)	24 (53,3%)	2 (15,4%)	-
Aneurysmal degeneration	1 (1,7%)	1 (2,2%)		-

[a] Fisher's Exact Test used due to low expected cell counts

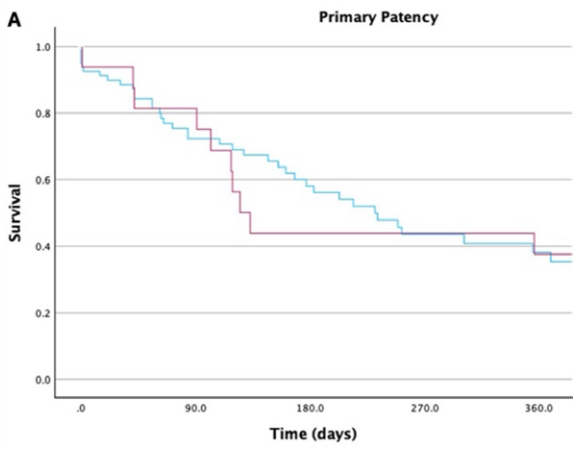
The distribution of causes of primary patency loss differed significantly between groups (*Fisher* exact test, p = 0.029). Thrombosis accounted for 84.6% of events in the DEB group compared with 44.4% in the POBA group, whereas restenosis accounted for 15.4% and 53.3%, respectively. Secondary patency did not differ significantly between the POBA and DEB groups (p = 0.177).

At 6 months, the estimated secondary patency was 77.6% for POBA and 62.5% for DEB. By 12 months, patency had declined to approximately 70.2% for POBA and 55.6% for DEB (Figure 1B). The mean secondary patency time was longer in the POBA group (1231 ± 138.7 days, 95% CI 959.4–1503.0) than in the DEB group (915.6 ± 237.3 days, 95% CI 450.5–1380.6), but the confidence intervals overlapped.

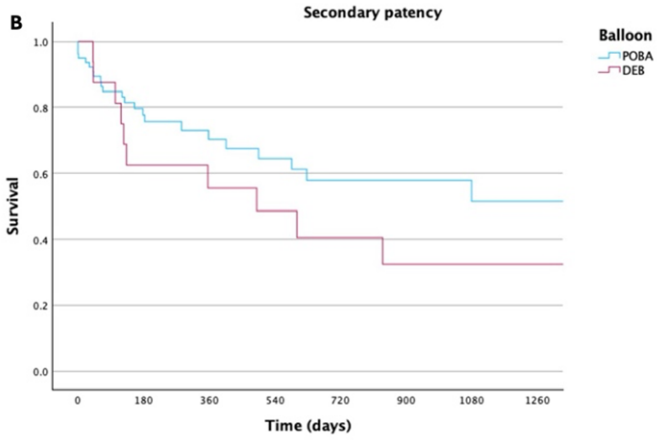
Overall mortality

Overall mortality during the follow-up period was low in both groups, with 10 deaths among 96 patients (10.4%). Specifically, mortality occurred in 8 patients (10.1%) in the POBA group and 2 patients (11.8%) in the DEB group. Survival

Figure 1. A: Kaplan-Meier analysis of access circuit primary patency comparing POBA and DEB groups. Summary values below the graph indicate estimated patency rates at 3, 6, and 12 months for each group; B: Kaplan-Meier analysis of secondary patency comparing POBA and DEB groups. Summary values below the graph indicate estimated patency rates at 6, 12, 24, and 36 months for each group.



		3 months	6 months	12 months
POBA	Estimate (%)	72.2	58.0	38.0
	Std. error	.053	.062	.069
	Remaining cases (N)	47	30	14
DEB	Estimate (%)	75.0	43.8	37.5
	Std. error	.108	.124	.121
	Remaining cases (N)	12	7	6



		6 months	12 months	24 months	36 months
POBA	Estimate (%)	77.6	70.2	57.9	51.4
	Std. error	.052	.062	.076	.091
	Remaining cases (N)	39	26	17	8
DEB	Estimate (%)	62.5	55.6	40.5	32.4
	Std. error	.121	.126	.130	.127
	Remaining cases (N)	10	8	5	4

did not differ significantly between the groups (p = 0.891) (Figure 2).

All deaths were attributed to patients' pre-existing comorbidities and were unrelated to the vascular access or endovascular procedures. These findings suggest that the type of balloon used does not significantly affect overall patient survival.

Predictors of Patency and Access Failure

We used univariate Cox proportional hazards regression to assess the association between individual clinical and demographic variables and primary patency. Female sex (HR = 1.87; 95% CI: 1.09–3.20; p = 0.023) and access type (AVG vs. AVF; HR = 1.87; 95% CI: 1.02–3.43; p = 0.044) were potential predictors of primary patency loss. We observed no statistically significant associations for the other clinical, antithrombotic, or procedural variables analyzed (Table 2).

In a multivariable Cox proportional hazards model including sex, access type, and balloon type, female sex remained independently associated with a higher risk of primary patency loss (HR = 1.86; 95% CI: 1.08–3.19; p = 0.025). Access type was not statistically significant (AVG vs. AVF: HR = 1.85; 95% CI: 1.00–3.45; p = 0.052), and balloon type was not associated with primary patency loss (POBA vs. DEB: HR = 1.00; 95% CI: 0.52–1.93; p = 0.991). We excluded periprocedural complications from the multivariable model because the very small number of events (n = 3) could yield an unstable effect estimate.

Subgroup Analysis by Access Type (AVF vs. AVG)

We conducted a subgroup analysis by dividing the cohort into patients with AVF and AVG. We compared primary patency between treatment modalities (POBA vs. DEB) within each subgroup. For the AVF subgroup, 78 patients (63 with POBA and 15 with DEB) were included in the analysis. The survival analysis showed no significant difference in primary patency between POBA and DEB (p = 0.706) (Figure 3A). The median primary patency for POBA was 249 days (95% CI: 157–340 days), whereas for DEB it was 133 days (95% CI: 0–567 days). For the AVG subgroup, we analyzed 18 patients (16 with POBA and 2 with DEB) (Figure 3B). However, given the low number of patients, further assessment was not possible.

Figure 2. Kaplan-Meier analysis of overall survival for POBA and DEB groups.

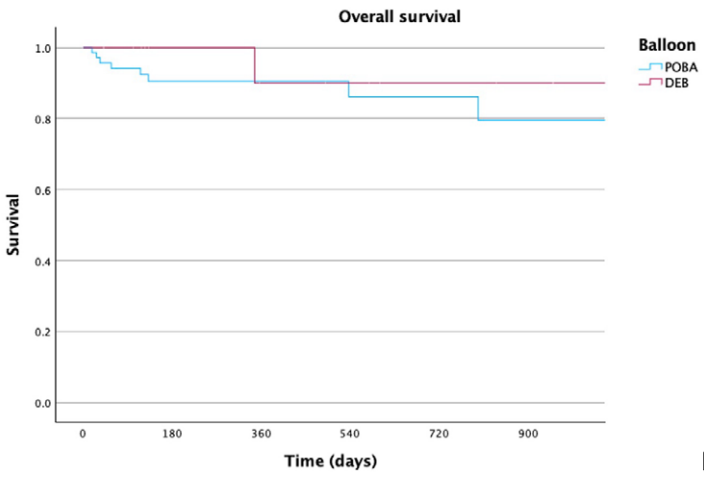
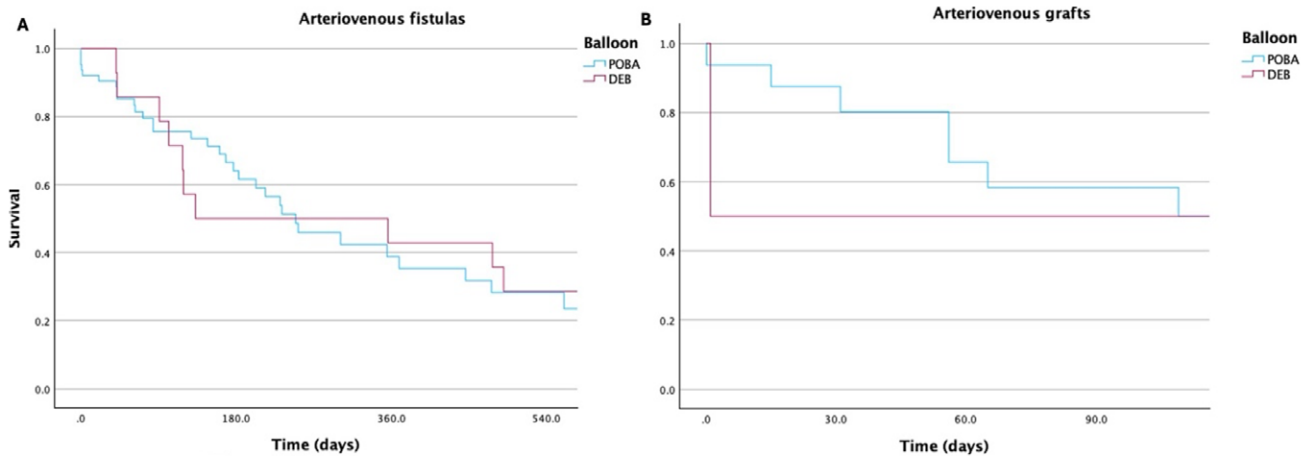


Table 2. Cox proportional hazards regression analysis of predictors of primary patency loss. (Hazard ratios -HR, 95% confidence intervals - CI).

Variable	Predictors of Primary Patency Loss Univariable			Multivariable		
	HR (Exp(B))	95% CI for HR	p value	HR (Exp(B))	95% CI for HR	p value
Age	1.011	0.991 – 1.031	0.283		-	
Sex (Female vs Male)	1.866	1.088 – 3.198	0.023	1.858	1.083-3.190	0.025
Diabetes	0.879	0.522 – 1.480	0.628			
Hypertension	0.702	0.169 – 2.905	0.625			
Dyslipidaemia	0.956	0.131 – 6.957	0.965			
Cerebrovascular disease	1.655	0.882 – 3.105	0.117		-	
Cardiovascular disease	0.823	0.487 – 1.390	0.466			
Anticoagulation	1.029	0.532 – 1.992	0.932			
Antiplatelet Therapy	0.896	0.530 – 1.516	0.683			
Access type (AVG vs AVF)	1.866	1.016 – 3.428	0.044	1.853	0.995-3.449	0.052
Laterality	1.236	0.731 – 2.090	0.428		-	
Balloon type (POBA vs DEB)	0.898	0.469 – 1.720	0.747	0.996	0.515-1.927	0.991
Lesion diameter (mm)	0.916	0.772 – 1.087	0.314		-	
Balloon length (mm)	0.994	0.984 – 1.004	0.229			
Complications	94.608	9.745 - 918.462	< 0.001		-	

Figure 3. A: Kaplan-Meier survival curves for access circuit primary patency in patients with arteriovenous fistulas (AVF), comparing POBA and DEB treatments; B: Kaplan-Meier survival curves for primary patency in patients with arteriovenous grafts (AVG), comparing POBA and DEB treatments.



DISCUSSION

This study compared the efficacy of POBA and DEB in maintaining vascular access patency among patients undergoing angioplasty for AVF or AVG stenosis. Our results showed no significant superiority of DEB over POBA in access circuit patency.

Access dysfunction arises from hemodynamic changes after creation and from repeated needle punctures that promote neointimal hyperplasia.[5] Stenotic lesions often cause access failure, leading to hospitalizations and suboptimal dialysis. Although angioplasty is the standard treatment, it induces barotrauma and inflammation, triggering restenosis. Drug-eluting technologies, which deliver antiproliferative agents such as paclitaxel or sirolimus, aim to reduce this risk.

Data from major randomized controlled trials have shown variable outcomes. These trials have primarily evaluated target lesion primary patency (TLPP), whereas the present study assessed access circuit primary patency (ACPP). Although these endpoints are not directly equivalent, these trials remain the principal reference for evaluating the efficacy of drug-coated balloons in hemodialysis vascular access interventions.

The IN.PACT AV Access trial was a randomized controlled trial that enrolled 330 participants to compare DEB angioplasty (n=170) with POBA (n=160) for treating de novo or restenotic lesions in native upper-extremity AVFs.5 Participants were followed for up to 36 months. At 36 months, TLPP was significantly higher in the DEB group than in the POBA group (43.1% vs. 28.6%; p < 0 .001).

The PAVE trial was another randomized controlled study evaluating paclitaxel-coated balloons versus standard angioplasty balloons for treating stenosis in AVFs for hemodialysis.[6] The primary outcome, time to loss of TLPP, showed no statistically significant difference between treatment arms (HR 1.18, 95% CI 0.78–1.79; p= 0.440).

A retrospective cohort study evaluating the Ranger™ paclitaxel-coated balloon found no statistically significant difference in target lesion primary patency (TLPP) compared with POBA at both 6 months (84.3% vs 71.6%, p = 0.08) and 12 months (49.2% vs 50.6%, p = 1.00).[7]

The Lutonix trial, which used a DEB with a lower paclitaxel dose (2.0 µg/mm²), reported significantly higher 6- and 12-month TLPP rates in the treatment arm than in the POBA arm (6-month TLPP DEB 58% vs POBA 46%, P = .023; 12-month TLPP DEB 44.4% vs POBA 36%, P = 0.045).[8] However, the differences at 18 months (34% vs 28%, p = 0.06) and 24 months (27% vs 24%, p = 0.09) did not reach statistical significance.

Sirolimus, another potent antiproliferative agent, has shown efficacy in preventing restenosis in the peripheral vasculature. Despite these advances, the MATILDA trial, which included 33 patients treated with the MagicTouch™ sirolimus-coated balloon (Concept Medical Inc., Tampa, FL, US), showed that 12-month outcomes with sirolimus-coated balloons are comparable to current paclitaxel data, with pooled TLPP rates of 75% and 53% at six and twelve months, respectively.[9]

A systematic review and meta-analysis comparing DEB angioplasty with POBA for the treatment of juxta-anastomotic AVF stenosis found no significant differences in primary assisted patency at 6 months (OR 2.03; 95% CI 0.64–6.45).[10] In line with the presented meta-analysis data, we also did not find a significant benefit of DEB angioplasty compared with POBA.

Female sex was identified as an independent predictor of primary patency loss. This association may be partially explained by inherent sex-related differences in vascular characteristics. Women generally have smaller-caliber vessels, which may complicate endovascular procedures and increase the risk of early restenosis. Anatomical variations, such as smaller or more tortuous arterial inflow and less developed venous outflow, may further reduce access durability. In the multivariable analysis, female sex remained independently associated with primary patency loss, whereas access type showed a borderline association that did not reach statistical significance. Balloon type was not associated with primary patency loss after adjustment. Given the very small number of periprocedural complications, we did not include this variable in the multivariable model because it could produce an unstable effect estimate.

Among patients who experienced loss of primary patency during follow-up, the causes of the first event were thrombosis, restenosis, or aneurysmal degeneration. Thrombosis was more common in the DEB group, whereas restenosis was more common in the POBA group. However, these findings should not be interpreted as evidence of a causal relationship between balloon type and the mechanism of primary patency loss, given the retrospective, non-randomized study design.

Overall mortality was relatively low (10.4%, with 10 deaths during follow-up). The POBA (10.1%) and DEB (11.8%) groups did not differ significantly.

Limitations

Despite valuable insights, several limitations remain. The non-randomized, retrospective design introduces selection and information biases. The small sample size, especially in the DEB group, limited statistical power to detect differences, particularly in subgroup analyses. Balloon choice was at the surgeon's discretion, potentially introducing selection bias based on lesion characteristics or operator preference. The longer median follow-up in the DEB group reflects the study's retrospective nature and the distribution of procedures over time, and may introduce temporal bias. Future studies should adopt prospective, randomized designs with larger, balanced cohorts and standardized balloon selection criteria. Incorporating anatomical and functional imaging may refine patient selection and better characterize lesion complexity, improving treatment comparisons.

CONCLUSIONS

Our study found no significant differences in 6- or 12-month primary patency of access circuits between POBA and DEB. Female sex was independently associated with an increased risk of primary patency loss, whereas access type

showed a borderline, non-significant association. Given the small number of periprocedural complications, we could not reliably assess their association with primary patency loss in the multivariable model. Larger randomized studies are needed to confirm these findings.

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Declaration of Generative AI and AI-Assisted Technologies in the Writing Process: No generative AI or AI-assisted technologies were used in the writing process.

REFERENCES

1. Kitrou PM, Katsanos K, Spiliopoulos S, Karnabatidis D, Siablis D. Drug-eluting versus plain balloon angioplasty for the treatment of failing dialysis access: Final results and cost-effectiveness analysis from a prospective randomized controlled trial. Eur J Radiol. 2015;84:418–23.

2. Liao MT, Chen MK, Hsieh MY, Yeh NL, Chien KL, Lin CC, et al. Drug-coated balloon versus conventional balloon angioplasty of hemodialysis arteriovenous fistula or graft: A systematic review and meta-analysis of randomized controlled trials. PLoS One. 2020;15:e0231463.

3. Chen X, Liu Y, Wang J, Zhao J, Singh N, Zhang WW. A systematic review and meta-analysis of the risk of death and patency after application of paclitaxel-coated balloons in the hemodialysis access. J Vasc Surg. 2020;72:2186-196..

4. Lok CE, Huber TS, Lee T, Shenoy S, Yevzlin AS, Abreo K, et al. KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. Am J Kidney Dis. 2020;75:S1–164.

5. Lookstein R, Haruguchi H, Suemitsu K, Isogai N, Gallo V, Madassery S, et al. IN.PACT AV Access Randomized Trial of Drug-Coated Balloons for Dysfunctional Arteriovenous Fistulae: Clinical Outcomes through 36 Months. J Vasc Interv Radiol. 2023;34:2093-102.

6. Karunanithy N, Robinson EJ, Calder F, Dorling A, Peacock JL, Wang Y, et al. Paclitaxel-assisted balloon angioplasty of venous stenosis in haemodialysis access: PAVE RCT. Efficacy and Mechanism Evaluation. NIHR Journals Library; 2021;8:1–36.

7. Soon SXY, Tan RY, Pang SC, Yap CJQ, Patel A, Gogna A, et al. RangerTM paclitaxel-coated balloon versus conventional balloon angioplasty for treatment of failing arteriovenous fistulas and grafts in haemodialysis patients: A retrospective cohort study. J Vasc Access. 2023;24:1032–41.

8. Trerotola SO, Saad TF, Roy-Chaudhury P. The Lutonix AV Randomized Trial of Paclitaxel-Coated Balloons in Arteriovenous Fistula Stenosis: 2-Year Results and Subgroup Analysis. J Vasc Interv Radiol. 2020;31:1-14.e5

9. Tang TY, Soon SXY, Yap CJQ, Chan SL, Choke ETC, Chong TT. Utility of Sirolimus Coated Balloons for Salvaging Dysfunctional Arteriovenous Fistulae: One Year Results From the MATILDA trial. Eur J Vasc Endovasc Surg. 2021;62:316–7.

10. Rokoszak V, Syed MH, Salata K, Greco E, de Mestral C, Hussain MA, et al. A systematic review and meta-analysis of plain versus drug-eluting balloon angioplasty in the treatment of juxta-anastomotic hemodialysis arteriovenous fistula stenosis. J Vasc Surg. 2020;71:1046-1054.e1.arteriovenous fistula stenosis. J Vasc Surg. 2020;71:1046-1054.