

Comparison of Primary Patency Rates and Influencing Factors Between Drug-Coated Balloons and Drug-Eluting Stents in the Endovascular Treatment of Lower Extremity Arteriosclerosis Obliterans

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AIM: To compare the 1-year patency rates of drug-coated balloon (DCB) and drug-eluting stent (DES) in the treatment of lower extremity arteriosclerosis obliterans (LEASO), and to systematically analyze the factors influencing post-treatment patency.

METHODS: This retrospective study included 302 patients with LEASO who received treatment at Fuyang People's Hospital between January 2021 and December 2024. Based on the treatment modality, patients were divided into a DCB group (n = 152) and a DES group (n = 150). Comprehensive baseline demographic, clinical, and procedural data were collected. The 1-year primary patency rates of the two groups were compared using imaging assessment, primarily based on ultrasonography. Independent risk factors affecting patency were identified using a multivariate Cox proportional hazards regression model.

RESULTS: The 1-year primary patency rate was 87.5% (133/152) in the DCB group and 89.3% (134/150) in the DES group. No statistically significant difference in the 1-year primary patency rates was observed between the two groups ($p > 0.05$). Multivariate Cox regression analysis demonstrated that diabetes mellitus, lesion length, and severe calcification were independent risk factors affecting patency after endovascular treatment (all $p < 0.05$).

CONCLUSIONS: The 1-year patency rates did not differ significantly between the DCB and DES groups. Diabetes mellitus, long lesion length, and severe calcification were identified as key factors associated with reduced patency rates. Clinical management should emphasize individualized intervention strategies and postoperative management for these high-risk patients.

Keywords: lower extremity arteriosclerosis obliterans; drug-coated balloon; drug-eluting stent; endovascular treatment; patency rate; risk factors

Introduction

Lower extremity arteriosclerosis obliterans (LEASO) is a common chronic progressive vascular disease caused by atherosclerosis. Approximately 30% of LEASO cases involve the iliac arteries, while the remaining 70% more commonly affect the femoral, popliteal and distal arteries [1]. Its development is associated with the formation of atherosclerotic plaques in the lower extremity arteries. These plaques lead to thickening of the intima of lower extremity arteries, gradual stenosis and occlusion of the vascular lumen, resulting in insufficient blood supply to the affected limb [2]. Insufficient blood supply will, in turn, lead to symptoms such as intermittent claudication, limb numbness, pain, and gangrene due to chronic ischemia and hypoxia [1]. Pathological changes primarily occur in the vascular intima or media, and secondary thrombosis can induce severe complications, including amputation [3,4]. The

incidence of atherosclerosis continues to increase progressively [5]. Atherosclerotic peripheral arterial disease of the lower extremities is increasingly recognized as a major contributor to cardiovascular morbidity and mortality, affecting more than 230 million individuals worldwide [6]. Its incidence increases markedly with age. The prevalence of arteriosclerosis obliterans (ASO), particularly lower extremity arteriosclerosis obliterans (LEASO), is approximately 5% among individuals aged 45–49 years, rising to 10%–25% in those older than 55 years [7].

Pharmacotherapy, conventional surgery, and percutaneous endovascular intervention constitute the primary treatment modalities for LEASO [8,9]. Current international guidelines recommend drug-eluting stent (DES) implantation as a preferred reperfusion strategy [10]. Advances in this field have been driven by deeper investigation into stent design, such as the development of polymer coatings and antiproliferative drugs that prevent cell growth. These developments seek to minimize in-stent thrombosis and late restenosis by attenuating excessive immune and inflammatory responses [11]. However, stent implantation may lead to both short-term and long-term implant-related complications, including acute or subacute in-stent thrombosis, in-stent restenosis, and late or very late in-stent thrombosis [12]. These clinical challenges have promoted the development and ap-

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plication of drug-coated balloon (DCB) angioplasty. A DCB is a balloon catheter coated with antiproliferative and anti-inflammatory agents, commonly paclitaxel and related compounds. Balloon dilation enables close contact between the coated surface and the diseased vascular wall, facilitating effective drug delivery into the arterial wall and direct action on vascular smooth muscle cells, thereby inhibiting intimal hyperplasia. At present, DCBs are important therapeutic devices for the management of in-stent restenosis and recurrent reintervention lesions. Their clinical application has become well established in femoropopliteal lesions, coronary artery disease [13], and hemodialysis access dysfunction [14]. However, their use in infrapopliteal lesions remains controversial.

Although both DCBs and DESs have demonstrated favorable efficacy in the treatment of LEASO, comparisons of their therapeutic outcomes across different patient populations remain controversial. Currently, large-scale multicenter head-to-head comparative studies are limited. Therefore, the present study aimed to compare the 1-year patency rates of DCBs and DESs in the endovascular treatment of LEASO through a retrospective cohort analysis, while further evaluating the key factors influencing therapeutic outcomes.

Methods

Study Subjects

A total of 302 patients with LEASO were enrolled in this study. All patients underwent endovascular treatment in the Department of Vascular Surgery of Fuyang People's Hospital between January 2021 and December 2024. The inclusion criteria were as follows: (1) meeting the diagnostic criteria for LEASO, with lower extremity arterial lumen stenosis $\geq 70\%$ or occlusion confirmed by lower extremity arterial computed tomography angiography (CTA) or digital subtraction angiography (DSA) [15]; (2) age ≥ 18 years; (3) treatment with DCB angioplasty or DES implantation with procedural success, defined as residual stenosis of target vessel $< 30\%$ after surgery and absence of severe perioperative complications; and (4) complete clinical data and availability of 12-month (± 1 month) postoperative follow-up data.

The exclusion criteria were as follows: (1) severe hepatic or renal insufficiency (Child-Pugh Class C or serum creatinine $> 442 \mu\text{mol/L}$); (2) coagulation dysfunction or intolerance to antiplatelet therapy; (3) lesions involving the aorta or common iliac artery; (4) hypersensitivity to paclitaxel or endovascular treatment-related devices or drugs; (5) advanced malignant tumors or an expected survival time of < 1 year; and (6) presence of infection at the lesion site. Patients were divided into the DCB and DES groups according to treatment modality.

This study adhered to the principles outlined in the Declaration of Helsinki and was approved by the Ethics Committee of Fuyang People's Hospital (Approval No.: 2025-21).

Since this was a retrospective study, no a priori sample size calculation was performed. The 1-year patency rates of the DES and DCB groups were 0.893 and 0.875, respectively. With sample sizes of 150 in the DES group and 152 in the DCB group, and $\alpha = 0.05$. The research flowchart is presented in Fig. 1. The overall data loss rate in this study was 2.32%, affecting only a small proportion of non-core baseline variables during data preparation and not affecting follow-up data or core prognostic variables. All 302 patients completed the 12-month evaluation and were included in the final analysis.

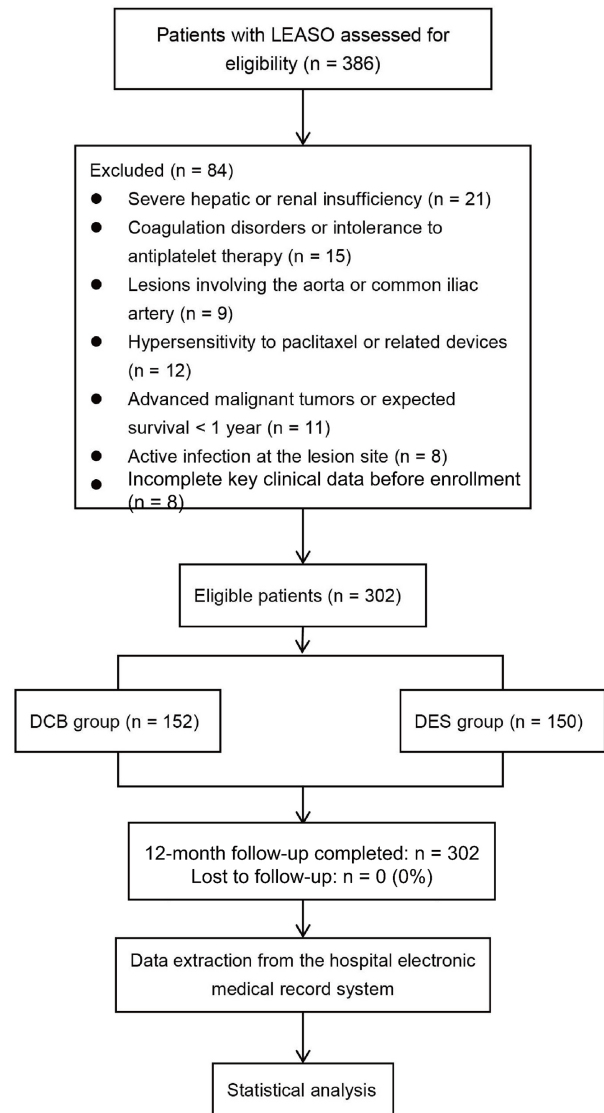


Fig. 1. Flow chart of patient enrollment, treatment allocation, follow-up, and final analysis in the study cohort. Missing data (2.32%) were limited to non-core baseline variables and did not represent loss to follow-up. LEASO, lower extremity arteriosclerosis obliterans; DCB, drug-coated balloon; DES, drug-eluting stent.

Data Collection

All data were obtained from the hospital's electronic medical record system. Data were collected across multiple domains, including demographic characteristics, past medical history (e.g., diabetes mellitus and hypertension), and clinical symptoms. Clinical assessments included Rutherford classification (Grades 0–6), claudication distance, and visual analog scale (VAS) scores. Imaging interventions recorded lesion location (e.g., iliac or femoral artery), lesion length, and degree of calcification. Severe calcification was defined as calcification involving >50% of the vessel circumference or extending >5 cm in length on preoperative CTA or DSA. Laboratory examinations included complete blood count, liver and renal function tests, blood lipid profile, and coagulation parameters. Vascular function was assessed using indices such as the ankle-brachial index (ABI) and toe-brachial index (TBI).

Clinical Treatment Strategies

As this was a retrospective observational study, the specific decision-making process and detailed criteria for device selection (DCB or DES) could not be fully traced or verified from the medical records. Treatment allocation was determined by the attending vascular surgeons during routine clinical practice, based on the patient's general condition, lesion characteristics, and contemporary clinical guidelines. All procedures were performed by physicians certified in endovascular interventions. All patients received dual antiplatelet therapy before surgery, consisting of aspirin enteric-coated tablets (100 mg daily) combined with clopidogrel (75 mg daily) or ticagrelor (90 mg twice daily), for at least 3 days before the procedure; in urgent cases, a loading dose was administered. Postoperatively, dual antiplatelet therapy was continued for at least 3 months and, when tolerated, for 6 months in the DES group, followed by lifelong single antiplatelet therapy with aspirin 100 mg daily.

DCB group: appropriate DCB specifications were selected preoperatively based on lesion characteristics. All DCBs used in this study were paclitaxel-coated balloons. The devices available during the study period included IN.PACT Admiral (Medtronic; 3.5 $\mu\text{g}/\text{mm}^2$), Lutonix 035 (BD/Bard; 2.0 $\mu\text{g}/\text{mm}^2$), Stellarex (Philips/Spectranetics; 2.0 $\mu\text{g}/\text{mm}^2$), and Ranger (Boston Scientific; 2.0 $\mu\text{g}/\text{mm}^2$). The specific device was selected by the attending surgeon based on lesion characteristics and device availability and was used according to the manufacturer's instructions for use. Predilation was initially performed using a non-compliant balloon (pressure: 6–12 atm; duration: 30–120 s), followed by DCB dilation (pressure: 6–8 atm, duration: 60–120 s). The decision to perform post-dilation was based on the degree of residual stenosis. In cases of flow-limiting dissection or residual stenosis >50%, bailout implantation of a bare-metal stent was performed.

DES group: predilation or direct stent implantation was selected according to lesion characteristics. A DES matching the vascular diameter and lesion length was chosen and accurately deployed at the target lesion. All DESs used in this study were paclitaxel-eluting stents. The devices available during the study period included Eluvia (Boston Scientific; nitinol self-expanding platform, polymer-based coating, 0.167 $\mu\text{g}/\text{mm}^2$ paclitaxel), Zilver PTX (Cook Medical; nitinol self-expanding platform, polymer-free coating, 3.0 $\mu\text{g}/\text{mm}^2$ paclitaxel), and ZENFLEX Pro (Sino Medical Sciences Technology; nitinol self-expanding platform, polymer-based coating). The specific device was selected by the attending surgeon based on lesion characteristics, vessel diameter, and device availability. Post-dilation with a non-compliant balloon was subsequently performed to ensure optimal stent apposition. Technical success was defined as residual stenosis <30%.

Outcome Measures and Evaluation Criteria

The primary outcome measure was the 1-year primary patency rate, defined as freedom from clinically driven target lesion revascularization and restenosis, as determined by a duplex ultrasonography-derived peak systolic velocity ratio (PSVR) of ≤ 2.4 [16]. Restenosis and clinically driven target lesion revascularization were not mutually exclusive; loss of primary patency was defined by the first occurrence of either event, and the time to this first event was used in the Kaplan–Meier analysis. Thrombosis was recorded separately as an adverse event and could overlap with restenosis and/or clinically driven target lesion revascularization. Restenosis was formally diagnosed when PSVR >2.4 on duplex ultrasonography. All enrolled patients were followed up for 12 months (± 1 month) after surgery. Color Doppler ultrasonography of the lower extremity arteries was routinely performed as the primary evaluation method for vascular patency. An absolute peak systolic velocity (PSV) ≥ 3.5 m/s was used only as a screening threshold to raise suspicion of restenosis, while PSVR ≥ 2.4 served as the predefined formal criterion for restenosis and loss of primary patency. If ultrasonography suggested suspected stenosis or occlusion (triggered by PSV ≥ 3.5 m/s) or if recurrent ischemic symptoms occurred, lower extremity computed tomography angiography (CTA) was performed for further evaluation. CTA was performed in 37 patients (12.3%), including 18 in the DES group and 19 in the DCB group. When CTA findings remained inconclusive or before reintervention procedures, DSA was used as the reference standard for confirmation. DSA was performed in 11 patients (3.6%), including 5 in the DES group and 6 in the DCB group. The application of imaging modalities was balanced between the two groups.

When discrepancies occurred among imaging modalities, a standardized hierarchical adjudication strategy was applied: Clinical symptoms and ultrasonographic screening findings

(PSV ≥ 3.5 m/s) were initially evaluated; CTA was subsequently used to assess vascular patency; and DSA was considered the gold standard for final diagnosis. All patency evaluations were independently performed by two radiologists blinded to treatment allocation. Any disagreements were resolved through consensus with a third senior radiologist to ensure endpoint consistency and minimize measurement bias.

Statistical Analysis

All statistical analyses were performed using SPSS version 27.0 software (SPSS Inc., Chicago, IL, USA). Missing values in non-core baseline variables were imputed using the median. No missing data were present for core prognostic variables or the primary outcome. Continuous variables were first tested for normality using the Shapiro-Wilk test. A p -value > 0.05 indicated that the data conformed to a normal distribution. Continuous variables with normal distributions were expressed as mean $\pm$ standard deviation (SD) and compared between groups using the independent-samples t -test. Homogeneity of variance was evaluated using Levene's test, with $p > 0.05$ indicating equal variances. Paired t -tests were used for intra-group comparisons. Non-normally distributed data were expressed as median (interquartile range, IQR) and compared between groups using the Mann-Whitney U test, while the Wilcoxon signed-rank test was used for intra-group comparisons. Categorical variables are expressed as counts (percentages) and were compared using the chi-square test or Fisher's exact test, as appropriate. Kaplan-Meier survival curves were generated to analyze patency rates, and differences between groups were evaluated using the log-rank test. For the time-to-event analysis, the event was defined as the first occurrence of restenosis (PSVR ≥ 2.4) or clinically driven target lesion revascularization. Time was calculated from the index procedure to the first event or the last follow-up. Patients without an event were censored at their last follow-up visit (12 months $\pm$ 1 month). As all patients completed the 12-month follow-up, no censoring due to loss to follow-up occurred. A Cox proportional hazards regression model was used to identify independent risk factors affecting patency, with results reported as hazard ratios (HRs) and 95% confidence intervals (CIs). The proportional hazards assumption was formally assessed using the Schoenfeld residual test. For each covariate included in the model, $p > 0.05$ indicated that the proportional hazards assumption was satisfied. A two-sided $p < 0.05$ was considered statistically significant. To control the overall type I error rate at the predefined 0.05 level and to reduce type I error accumulation from repeated hypothesis testing, the Bonferroni correction was applied. After correction, the significance threshold for a single secondary outcome test was adjusted to $\alpha' = 0.05/9 \approx 0.0056$. For secondary outcomes, including Rutherford classification, intermittent claudication distance, VAS score, ABI, TBI, and individual adverse events, Bonferroni correction

was applied to control for type I error inflation due to multiple comparisons.

Results

Comparison of Baseline Characteristics Between the Two Groups

A total of 302 patients with LEASO were enrolled in this study, including 150 patients in the DES group and 152 patients in the DCB group. Among them, 180 patients (59.6%) were male, and 122 patients (40.4%) were female. No statistically significant differences were observed between the DES and DCB groups in baseline characteristics, including age, gender, and medical history (all $p > 0.05$) (Table 1).

Comparison of Patency Rates Between the Two Groups

The 1-year primary patency rate was 87.5% (133/152) in the DCB group and 89.3% (134/150) in the DES group. No statistically significant difference in the 1-year primary patency rates was observed between the two groups ($\chi^2 = 0.248$, $p = 0.619$). Kaplan-Meier survival curve analysis further demonstrated no statistically significant difference in 1-year primary patency duration between the DCB and DES groups (log-rank test, $p = 0.310$) (Fig. 2).

Comparison of Symptom Improvement Between the Two Groups

Rutherford classification, intermittent claudication distance, and resting pain VAS score were used as primary indicators of clinical symptoms to compare symptom improvement between the DES and DCB groups. The results showed that at 1 year postoperatively, both groups exhibited significant improvements in Rutherford classification, intermittent claudication distance, and VAS score compared with preoperative values ($p < 0.05$). After Bonferroni correction, except for Rutherford classification, in which the difference between the DCB group and the DES group was statistically significant, no statistically significant differences were observed between the two groups in VAS score and intermittent claudication distance ($p > 0.0056$) (Table 2).

Comparison of Changes in Vascular Functional Parameters Between the Two Groups

Comparison of vascular functional parameters between baseline and 1 year postoperatively showed that both the DES and DCB groups exhibited significant increases in ABI and TBI from baseline (all p -values < 0.05). After Bonferroni correction, no statistically significant differences in ABI or TBI were observed between the DCB and DES groups at 1 year postoperatively ($p > 0.0056$), indicating comparable restoration of vascular function in both groups (Table 3).

Table 1. Comparison of baseline characteristics between the two groups.

Variable	DES group (n = 150)	DCB group (n = 152)	t/χ^2 value	p-value
Age (years)	68.45 ± 7.25	69.25 ± 6.76	0.988	0.324
Gender, n (%)			0.371	0.543
Male	92 (61.3)	88 (57.9)		
Female	58 (38.7)	64 (42.1)		
BMI (kg/m ²)	24.26 ± 3.05	24.55 ± 3.89	0.713	0.476
Diabetes mellitus, n (%)	63 (42.0)	65 (42.8)	0.018	0.893
Hypertension, n (%)	98 (65.3)	102 (67.1)	0.106	0.745
WBC (×10 ⁹ /L)	6.52 ± 1.34	6.47 ± 1.29	0.263	0.793
ALT (U/L)	32.55 ± 8.15	33.15 ± 9.05	0.606	0.545
Creatinine (μmol/L)	89.65 ± 15.35	90.45 ± 14.75	0.462	0.645
Total cholesterol (mmol/L)	5.23 ± 0.87	5.31 ± 0.92	0.774	0.439
INR	1.05 ± 0.12	1.07 ± 0.11	1.188	0.236
Lesion location, n (%)			1.264	0.867
External iliac artery	28 (18.7)	30 (19.7)		
Common femoral artery	10 (6.7)	12 (7.9)		
Superficial femoral artery	51 (34.0)	55 (36.2)		
Popliteal artery	53 (35.3)	45 (29.6)		
Infrapopliteal arteries	8 (5.3)	10 (6.6)		
Severe calcification, n (%)	38 (25.3)	41 (27.0)	0.105	0.746
Lesion length (cm)	16.25 ± 2.54	16.39 ± 2.41	0.492	0.623

Note: BMI, body mass index; DCB, drug-coated balloon; DES, drug-eluting stent; WBC, white blood cell count; ALT, alanine aminotransferase; INR, international normalized ratio.

Table 2. Comparison of clinical symptom improvement between the two groups.

Variable	Time point	DES group	DCB group	t/U value	p-value
Intermittent claudication distance (m)	Preoperative	175.85 ± 21.19	173.18 ± 23.43	1.040	0.299
	1 year postoperative	831.98 ± 95.51*	835.96 ± 86.57*	0.379	0.705
Rutherford classification	Preoperative	4.00 (4.00, 4.00)	4.00 (4.00, 4.00)	0.136	0.712
	1 year postoperative	1.00 (1.00, 1.00)***	1.00 (1.00, 1.00)***	7.767	0.005
VAS score	Preoperative	6.35 ± 1.56	6.48 ± 1.62	0.694	0.488
	1 year postoperative	3.25 ± 0.79*	3.13 ± 0.82*	1.240	0.216

Note: VAS, visual analog scale. * $p < 0.05$ and *** $p < 0.001$ versus preoperative values within the same group.

Table 3. Comparison of changes in vascular functional parameters between the two groups.

Variable	Time point	DES group	DCB group	t/Z -value	p-value
ABI	Preoperative	0.58 ± 0.16	0.56 ± 0.18	1.207	0.228
	1 year postoperative	0.70 (0.42, 1.08)*	0.78 (0.46, 1.19)*	-0.930	0.354
TBI	Preoperative	0.32 ± 0.09	0.31 ± 0.11	0.502	0.616
	1 year postoperative	0.62 ± 0.13*	0.64 ± 0.12*	1.664	0.097

Note: ABI, ankle-brachial index; TBI, toe-brachial index. * $p < 0.05$ versus preoperative values within the same group.

Univariate Analysis of Factors Influencing Patency Rates

Using “occurrence of restenosis” as the dependent variable, univariate analysis was performed with baseline patient characteristics, lesion features, and procedure-related variables as independent variables. The results indicated that diabetes mellitus, lesion length, and severe calcification were associated with reduced patency rates after intervention (all $p < 0.10$). In contrast, variables such as age, gender, hypertension, and lesion location showed no sig-

nificant association with patency rates (all $p > 0.05$) (Table 4).

Multivariable Cox Regression Analysis of Factors Influencing Patency Rates

Variables with p -value < 0.1 in the univariate analysis (lesion length, severe calcification, and diabetes mellitus) were entered into a multivariable Cox proportional hazards regression model. The results demonstrated that diabetes mellitus (HR = 3.16, 95% CI: 1.53–6.54, $p = 0.002$), lesion

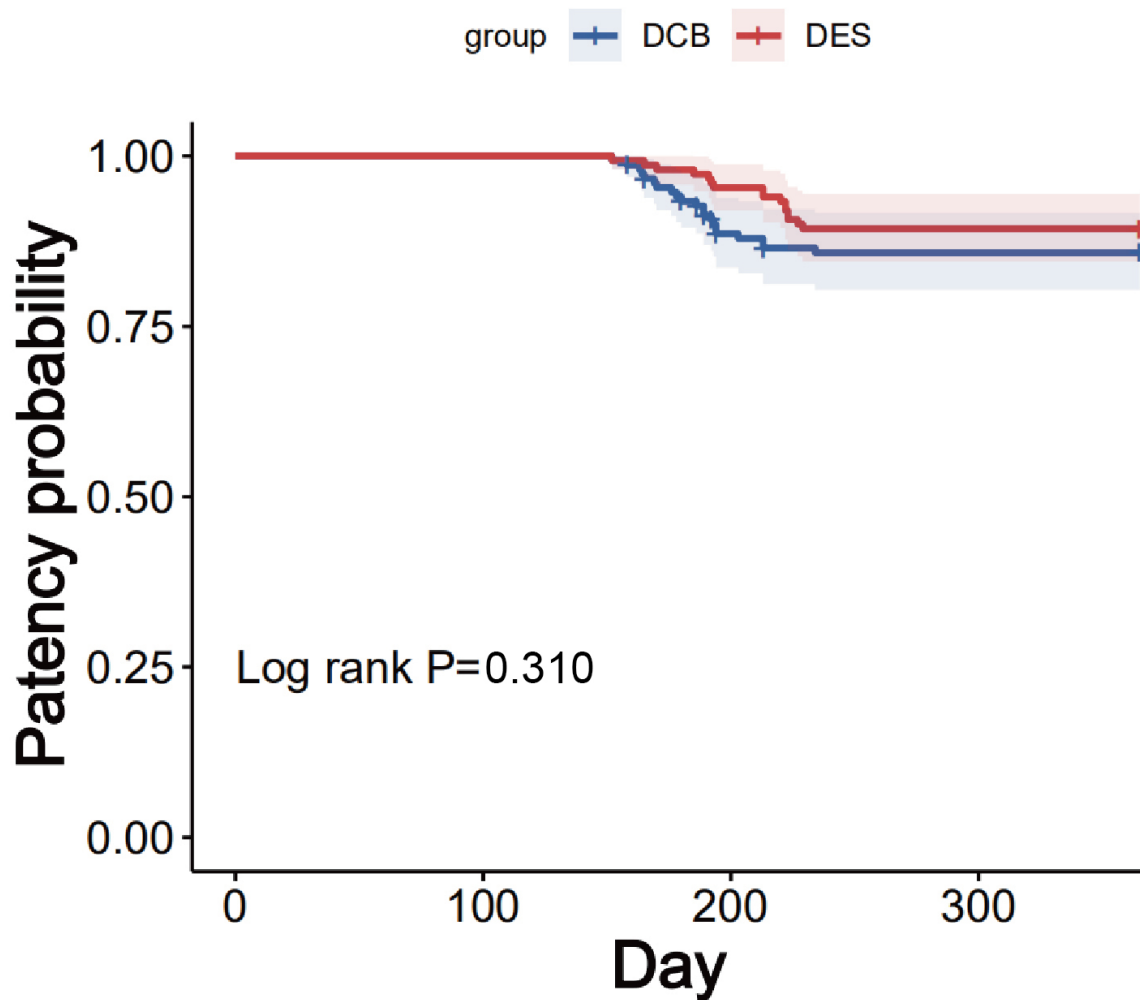


Fig. 2. Kaplan-Meier curves comparing patency time between the DCB and DES groups.

length (HR = 1.42, 95% CI: 1.21–1.66, $p < 0.001$), and severe lesion calcification (HR = 3.73, 95% CI: 1.81–7.71, $p < 0.001$) remained independent risk factors for reduced patency rates after intervention (Table 5, Fig. 3).

Incidence of Adverse Events in the Two Groups

During the follow-up period, a total of 19 adverse events occurred in the DCB group (12.5%), including 13 cases of target vessel revascularization, 1 case of amputation, 2 cases of thrombosis, and 3 cases of aneurysms. In the DES group, 28 adverse events were recorded (18.7%), including 15 cases of target vessel revascularization, 2 cases of amputations, 9 cases of thrombosis, and 2 cases of aneurysm. No statistically significant difference was observed in the overall incidence of adverse events between the two groups ($p > 0.05$) (Table 6). Although the incidence of thrombosis was numerically higher in the DES group than in the DCB group (6.0% vs 1.3%), this difference did not reach statistical significance after Bonferroni correction ($p = 0.034 > \alpha' = 0.0056$).

Discussion

As one of the most common peripheral arterial diseases [17], LEASO is a chronic ischemic disorder that poses a substantial threat to human health, with lesions frequently involving critical vascular segments such as the femoral artery, popliteal artery, and distal arteries [17,18]. Arterial stenosis, occlusion, and aneurysmal lesions primarily arise from systemic arteriosclerotic processes involving medium- and large-sized arteries, including the distal abdominal aorta, iliac arteries, and femoral arteries. This pathological process is characterized by arterial wall thickening, reduced vascular elasticity, and luminal stenosis. The principal mechanisms include atherosclerotic plaque formation, medial degeneration, and secondary thrombus adhesion, which ultimately lead to progressive vascular occlusion and lower extremity ischemia. The resulting ischemia further induces hemodynamic disturbances manifested by reduced blood flow velocity, decreased vessel diameter, and impaired microcirculation, which collectively trigger a series of clinical ischemic symptoms [19,20].

Table 4. Univariate Cox regression analysis of factors associated with primary patency rates.

Variable	β	SE	Z value	p-value	HR (95% CI)
Group					
DCB					1.00 (Reference)
DES	-0.34	0.33	-1.02	0.309	0.71 (0.37–1.37)
Gender					
Male					1.00 (Reference)
Female	0.14	0.33	0.42	0.676	1.15 (0.60–2.20)
Diabetes mellitus					
No					1.00 (Reference)
Yes	1.09	0.35	3.11	0.002	2.98 (1.50–5.92)
Hypertension					
No					1.00 (Reference)
Yes	-0.21	0.34	-0.63	0.529	0.81 (0.42–1.57)
Severe calcification					
No					1.00 (Reference)
Yes	1.47	0.33	4.43	<0.001	4.36 (2.27–8.37)
Lesion location					
External iliac artery					1.00 (Reference)
Common femoral artery	0.17	0.69	0.25	0.803	1.19 (0.31–4.59)
Superficial femoral artery	0.04	0.47	0.08	0.938	1.04 (0.41–2.60)
Popliteal artery	-0.05	0.48	-0.10	0.924	0.96 (0.37–2.46)
Infrapopliteal arteries	0.37	0.69	0.54	0.590	1.45 (0.38–5.61)
Age	-0.01	0.02	-0.59	0.554	0.99 (0.94–1.03)
BMI	-0.04	0.05	-0.87	0.385	0.96 (0.87–1.05)
WBC	-0.20	0.12	-1.57	0.116	0.82 (0.65–1.05)
ALT	0.02	0.02	1.24	0.213	1.02 (0.99–1.06)
Creatinine	-0.02	0.01	-1.41	0.159	0.98 (0.96–1.01)
Total cholesterol	-0.15	0.18	-0.79	0.427	0.86 (0.60–1.24)
INR	2.28	1.42	1.61	0.107	9.78 (0.61–156.65)
Lesion length	0.35	0.07	5.00	<0.001	1.42 (1.24–1.64)

Note: HR, hazard ratio.

Table 5. Multivariable Cox regression analysis of factors associated with primary patency rates.

Variable	β	SE	Z value	p-value	HR (95% CI)
Diabetes mellitus					
No					1.00 (Reference)
Yes	1.15	0.37	3.11	0.002	3.16 (1.53–6.54)
Severe calcification					
No					1.00 (Reference)
Yes	1.32	0.37	3.56	<0.001	3.73 (1.81–7.71)
Lesion length	0.35	0.08	4.38	<0.001	1.42 (1.21–1.66)

Table 6. Comparison of adverse events between the two groups.

	DES group, n (%)	DCB group, n (%)	Statistical test	p-value
Target vessel revascularization	15 (10.0)	13 (8.6)	0.188	0.665
Amputation	2 (1.3)	1 (0.7)	-	0.621
Thrombosis	9 (6.0)	2 (1.3)	-	0.034
Aneurysm	2 (1.3)	3 (2.0)	-	1.000
Total	28 (18.7)	19 (12.5)	2.185	0.139

Note: Individual adverse events were compared between groups using the χ^2 test or Fisher's exact test, as appropriate. “–” indicates that Fisher's exact test was used.

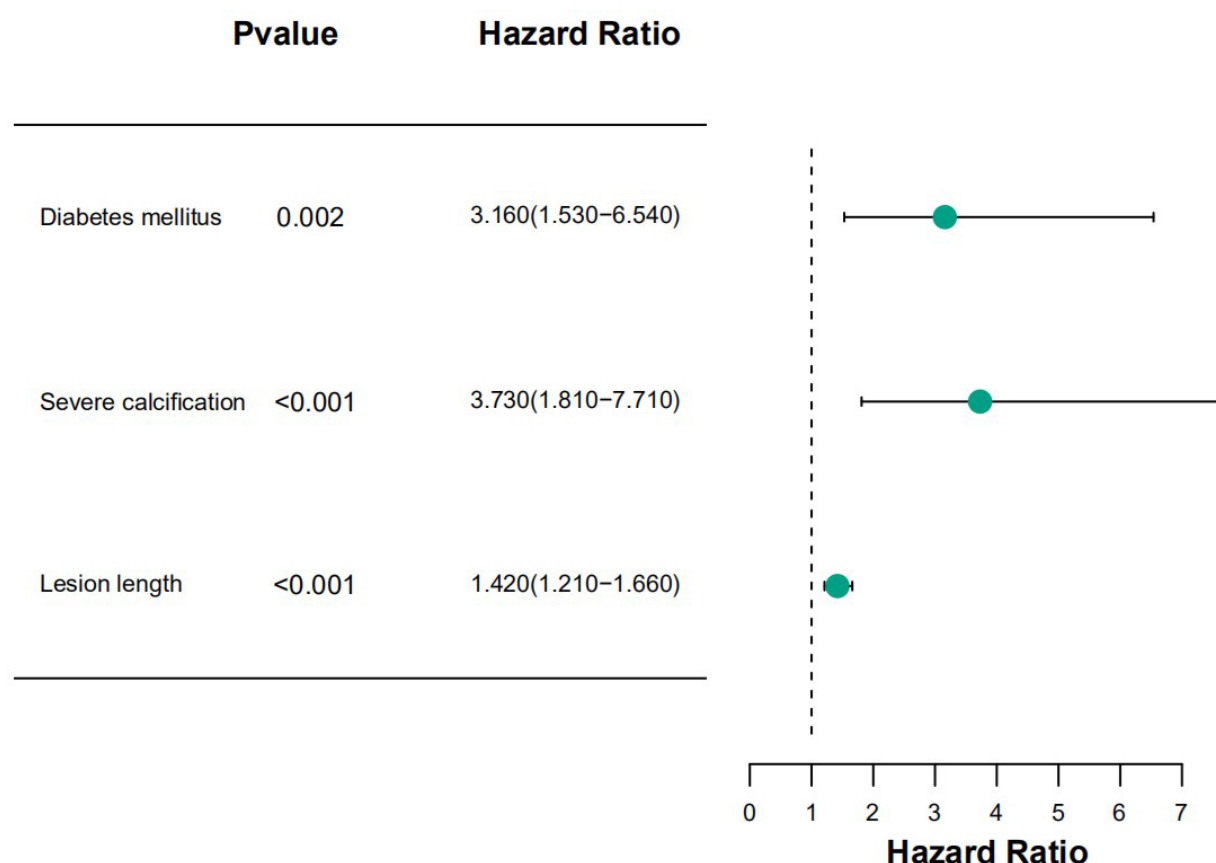


Fig. 3. Forest plot of the multivariable Cox proportional hazards regression analysis.

Endovascular therapy has become an established standard strategy for achieving revascularization. Procedural success largely depends on the operator's technical expertise, particularly the ability to achieve smooth guidewire recanalization or to successfully re-enter the true lumen following subintimal angioplasty. DCBs inhibit luminal intimal hyperplasia by locally releasing antiproliferative agents from the balloon surface. DESs maintain vascular lumen patency and use drugs to inhibit tissue overgrowth, thereby providing better patency and efficacy compared with bare-metal stents [21,22]. However, the indications for the primary use of DESs and DCBs in LEASO remain inconclusive due to limited definitive clinical evidence. Therefore, the present retrospective study compared key outcome indicators, including postoperative patency rates, clinical symptom improvement, and vascular functional recovery, between the two treatment modalities. Additionally, major prognostic factors influencing treatment outcomes were systematically analyzed to provide a more comprehensive reference for clinical decision-making.

Our study demonstrated no statistically significant difference in the 1-year primary patency rates between the DCB group (87.5%) and the DES group (89.3%). This finding is consistent with previous reports [23]. Regarding the onset of restenosis, the DES group showed a trend toward a

longer time to restenosis than the DCB group; however, the difference was not statistically significant ($p > 0.05$). A previous meta-analysis reported that DES implantation confers better 1-year primary patency outcomes than DCB alone [24]. In terms of symptom relief and vascular functional improvement, both the DCB and DES groups showed significant postoperative improvements in Rutherford classification, intermittent claudication distance, VAS score, ABI, and TBI compared with baseline values. Notably, the DCB group achieved greater improvement in Rutherford classification than the DES group. Although most previous studies have reported no significant differences in efficacy between DCBs and DESs [24,25,26], these studies generally focused on a single disease subtype or a specific lesion location. Since the present study was not limited to specific lesion locations, the more favorable improvement in Rutherford classification observed in the DCB group may indicate broader clinical applicability. Overall, no significant difference in therapeutic efficacy was observed between the DCB and DES groups for the treatment of LEASO.

In the analysis of factors influencing patency rates, diabetes mellitus, lesion length, and severe calcification were identified as independent risk factors for poor patency outcomes. In patients with diabetes mellitus, poor glycemic control often induces microvascular injury and a chronic pro-

inflammatory milieu, exacerbating intimal thickening and atherosclerotic plaque formation and subsequently compromising vascular patency [27]. One study comparing the two-year clinical outcomes of DCB therapy for long (>15 cm) versus short (≤ 15 cm) femoropopliteal lesions demonstrated that the primary patency rate was significantly lower in the long-lesion group [28]. This finding may be attributed to the fact that long lesions generally involve more extensive vascular wall injury, preventing the drugs from fully covering the entire lesion segment. Additionally, more pronounced postoperative hemodynamic changes may promote intimal hyperplasia and thrombosis, ultimately resulting in lower patency rates. Furthermore, severe calcification increases vascular stiffness and impairs paclitaxel delivery into the arterial wall, thereby increasing the incidence of postoperative in-stent restenosis [29]. Our findings are consistent with the results of a previous study [30].

In terms of safety, this study observed no statistically significant difference in complication rates between the DES and DCB groups. However, it should be noted that although DESs are gradually replacing bare-metal stents, the gradual decline in drug concentration inevitably causes DESs to revert to simple stent structures over time. Consequently, DESs cannot fundamentally overcome the inherent limitations associated with permanent metallic implants. In the long term, they remain susceptible to complications such as in-stent restenosis, stent fracture, and restricted options for repeated revascularization procedures. Persistent mechanical stimulation of the vascular endothelium by residual metallic stents may lead to endothelial dysfunction. Additionally, mechanical factors, including incomplete stent expansion, overlapping stent layers, and long stent length (>40 mm), may further increase the risk of thrombosis. Due to its “potential to avoid permanent metallic implantation” characteristic, DCB therapy may therefore be more suitable for patients who are not ideal candidates for repeat stent implantation.

This study has several limitations. First, this was a retrospective single-center study with non-randomized treatment allocation, which may have introduced indication bias and potential confounding factors. In addition, only patients with technical success and complete follow-up were included, potentially introducing selection bias. Multiple imaging modalities were used to evaluate patency which may have introduced potential variability in assessment, potentially affecting the interpretation of outcomes. Furthermore, some patients in the DCB group required emergent stent implantation, which may have influenced clinical outcomes and between-group comparisons. Moreover, the follow-up duration was limited to 1 year and therefore could not adequately evaluate long-term patency outcomes. In particular, late lumen loss after DES implantation, in-stent restenosis, and long-term restenosis risk associated with DCB therapy require further long-term follow-up val-

idation. The long-term patency rates and sustained clinical benefits of both treatment modalities remain to be clarified. In addition, due to the relatively small sample size in certain lesion-location subgroups (e.g., only 18 cases of infrapopliteal artery lesions) and the presence of multisegment lesions in some patients, subgroup analyses stratified by lesion type (e.g., femoropopliteal or infrapopliteal lesions) were not performed. Therefore, differences in efficacy between the two devices for specific lesion types could not be fully determined.

Given these limitations, the clinical implications of this study should be interpreted cautiously. Given the retrospective observational design, the current evidence is insufficient to support definitive clinical recommendations. The present findings should therefore be considered exploratory and hypothesis-generating, requiring further validation through future multicenter, prospective, randomized controlled trials.

Conclusions

No statistically significant difference in the 1-year primary patency rates was observed between DCB and DES for the interventional treatment of LEASO. However, the DCB group showed significantly superior outcomes in the Rutherford classification than the DES group. No significant difference in vascular function recovery was identified between the two treatment groups. In addition, diabetes mellitus, long lesion length, and severe calcification were identified as primary factors associated with reduced patency rates.

Availability of Data and Materials

The data analyzed are available from the corresponding author upon reasonable request.

Author Contributions

XL conceived and designed the research. JH contributed to the study design and data analysis and drafted the manuscript. MW collected and analyzed the data. All authors have been involved in revising the manuscript critically for important intellectual content. All authors gave final approval of the version to be published. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study adhered to the principles outlined in the Declaration of Helsinki and was approved by the Ethics Committee of Fuyang People's Hospital (Ethical Approval No.: 2025-21). All patients provided signed informed consent after understanding the research objectives.

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Conflict of Interest

The authors declare no conflict of interest.

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