doi.org/10.36721/PJPS.2026.39.8.237.1

Long-term clinical outcomes of paclitaxel-coated balloon angioplasty in chronic deep vein thrombosis: A multicenter retrospective study

Orhan Rodoplu
Bahcesehir Cyprus University, Faculty of Health Sciences, Cyprus and Turkiye

Abstract: **Background**: Chronic deep vein thrombosis (DVT) is a persistent clinical condition that often results in venous obstruction, post-thrombotic syndrome and impaired quality of life. Conventional endovascular dilation is limited by elastic recoil and high rates of restenosis caused by neointimal hyperplasia. Paclitaxel-based localized venous therapy enables targeted delivery of antiproliferative agents directly to the venous wall, offering a pharmacological strategy to suppress pathological vascular remodeling and improve long-term outcomes. **Objectives**: To evaluate the efficacy and safety of paclitaxel-based localized venous therapy in improving long-term venous patency and reducing restenosis in patients with chronic DVT, compared with conventional angioplasty. **Methods**: This retrospective multicenter study analyzed patient records from three vascular centers between 2019 and 2024. A total of 245 patients with chronic DVT were included, of whom 127 received paclitaxel-based localized therapy and 118 underwent conventional angioplasty. Primary endpoints were venous patency and restenosis rates. Secondary endpoints included freedom from clinically driven reintervention and quality-of-life outcomes. Clinical and imaging follow-up was conducted at baseline and at 6, 12 and 24 months. Multivariate regression analysis was performed using SPSS version 28. **Results**: At 24-month follow-up, primary venous patency was significantly higher in the paclitaxel-based therapy group than in the conventional angioplasty group (82.7% vs. 61.9%), with lower restenosis rates (11.8% vs. 29.7%). Paclitaxel-based localized therapy was associated with greater freedom from reintervention (hazard ratio 0.42; 95% CI 0.29–0.61; $p < 0.001$). Quality-of-life scores improved significantly in the paclitaxel group (mean difference 14.3 points; $p = 0.002$). No significant differences were observed in major complications or thrombotic events between groups. **Conclusion**: Paclitaxel-based localized therapy provides superior long-term venous patency, reduced restenosis and improved quality of life without compromising safety. These findings highlight the pharmaceutical relevance of localized antiproliferative drug delivery in the management of chronic venous disease.

Keywords: Angioplasty; Deep vein thrombosis; Drug-coated balloons; Paclitaxel; Venous insufficiency; Vascular patency

Submitted on 19-01-2026 – Revised on 11-05-2026 – Accepted on 21-05-2026

INTRODUCTION

Chronic deep vein thrombosis (DVT) presents a difficult clinical challenge due to ongoing obstruction of the veins, continuous venous hypertension and the establishment of a post-thrombotic syndrome (PTS), leading to overall reduction of functional capacity and impaired quality of life (Lv *et al*., 2024). Many patients continue to experience long-term complications, including pain, edema, skin changes and venous ulceration despite advances in anticoagulation and endovascular therapies (Lei *et al*., 2024). While standard BA is the most common method for treating patients with DVT to restore patency of the venous lumen, its effectiveness is limited in duration. Persistent inflammatory activation and smooth muscle proliferation following endothelial injury contribute to elastic recoil and restenosis in chronic venous lesions (Lei *et al*., 2024). The biological events that cause neointimal hyperplasia place patients at increased risk of reocclusion and require multiple therapies.

The new therapeutic strategy of DCB angioplasty combines localized pharmacotherapy with mechanical dilation. Paclitaxel-coated balloons inhibit neointimal hyperplasia by suppressing smooth muscle cell proliferation and inflammatory vascular remodeling processes (Cui and Wu, 2024). Importantly, DCB technology allows for reduced systemic drug exposure, eliminates the need for permanent intravascular devices and provides for targeted, localized drug delivery to the vessel wall at the time of balloon inflation, achieving the highest local concentration.

Despite encouraging outcomes of drug-coated balloon (DCB) technology in arterial disease, evidence regarding its role in chronic venous obstruction remains limited. Chronic venous lesions differ biologically from arterial lesions because venous remodeling is characterized by thrombotic fibrosis, inflammatory activation, collateral formation and altered venous wall compliance. Therefore, extrapolation of arterial DCB data to venous disease remains uncertain. Advanced venous endovascular strategies are increasingly being explored for patients with complex occlusive vascular disease and limited

**Corresponding author:* e-mail: drauthour@gmail.com

conventional therapeutic options (Ilyas and Powell, 2022). Recent studies have highlighted the growing role of endovascular drug-delivery systems in improving venous patency and reducing recurrent thrombotic complications in chronic venous disease (Almeida *et al*., 2023; Chen *et al*., 2024). This study aimed to evaluate the long-term efficacy and safety of paclitaxel-coated BA compared with conventional BA in patients with DVT. Contemporary evidence suggests that localized antiproliferative therapy may provide durable venous remodeling and improved control of post-thrombotic symptoms compared with conventional angioplasty alone (Rodriguez *et al*., 2022).

MATERIALS AND METHODS

Study design and ethical approval

Three tertiary referral vascular centers located in Istanbul, Ankara and Izmir, Türkiye, provided routinely collected clinical data for this retrospective multicenter observational study. A thorough review of patient records was conducted between January 2019 and December 2024. Ethical approval was obtained from the coordinating institutional review board under protocol number VAS-2019-045 and participating centers provided administrative approval for retrospective data sharing according to institutional policies. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki and the retrospective analysis of anonymized data eliminated the requirement for written informed consent.

Inclusion criteria of patients

Adults 18 years of age or older who had been diagnosed with DVT, which is characterized by the persistence of symptoms and/or imaging evidence of venous obstruction for a minimum of three months, were eligible to participate. As part of standard clinical care, patients with involvement of the iliofemoral, femoropopliteal, or infrapopliteal venous segments were treated with either standard BA or paclitaxel DCB angioplasty.

Patient exclusion criteria

Patients who were pregnant, had a life expectancy of less than two years, or were contraindicated for long-term anticoagulation therapy were not allowed to participate. Severe renal dysfunction, which is defined as an estimated glomerular filtration rate (eGFR) of less than 30 mL/min and recent catheter-directed thrombolysis within 30 days before the index procedure, was an additional exclusion criterion. These standards were used to reduce confounding variables that might affect clinical results and to guarantee patient safety.

A flow diagram illustrating study participant selection, eligibility assessment, treatment allocation and final analysis is provided in Fig. S1.

Data collection

Demographic and clinical data

Electronic medical records at each site were used to provide data in the form of demographics, comorbidities, history of DVT, previous treatments and baseline clinical characteristics. The severity of post-thrombotic syndrome was assessed using the validated Villalta scale and the VCSS was used to evaluate the clinical severity of chronic venous disease according to standardized clinical assessment criteria.

Quality of life assessment

Quality-of-life assessment was performed using the Chronic Venous Insufficiency Questionnaire (CIVIQ-20), a validated 20-item instrument specifically developed for chronic venous disorders. CIVIQ-20 measures pain, physical, social and psychological domains and a higher score indicate better quality of life (maximum score 100). Based on recorded clinical evaluations, CIVIQ-20 assessments were collected at baseline and during normal follow-up visits at roughly 6, 12 and 24 months.

Procedural and follow-up data collection tool

Medical documentation, such as notes of the operation, imaging and clinic visits, provided the procedural details and resulted in the subsequent information. The data collected included technical details of the intervention, peri-procedural drugs, complications and results at baseline, as well as at 6, 12 and 24 months after the intervention. Adverse drug reactions, including bleeding complications, allergic reactions, thrombotic complications and renal adverse events, were identified from follow-up clinical records. Potential drug-drug interactions involving anticoagulants and antiplatelet agents were reviewed using medication reconciliation records and were evaluated for their potential impact on clinical outcomes.

Anticoagulation and adjunctive medical therapy

All patients received therapeutic anticoagulation according to institutional protocols for the management of DVT. Direct oral anticoagulants or warfarin therapy was prescribed for at least six months unless contraindicated. Antiplatelet therapy with aspirin or clopidogrel was administered at the discretion of the treating physician, particularly in patients requiring adjunctive stenting. Compression therapy, smoking cessation counseling, early ambulation and lifestyle modification advice were routinely recommended during follow-up. Standardized compression therapy and structured post-procedural anticoagulation have been shown to improve venous hemodynamics and reduce the risk of recurrent thrombosis following endovascular intervention (Kim *et al*., 2023).

Interventional procedures

Experienced interventional radiologists or vascular surgeons carried out every procedure in accordance with

established institutional protocols. Using traditional guidewire procedures, venous access and lesion crossing were accomplished. A non-drug-coated balloon was routinely used in the DCB group for predilatation to prepare the lesion and maximize vascular compliance. A balloon coated with paclitaxel was then inflated and kept at nominal pressure for 180 seconds. The balloon was chosen in a 1:1 ratio to the reference vessel diameter. To optimize local drug absorption by the venous wall and effectively suppress smooth muscle cell proliferation and inflammatory pathways linked to restenosis, this inflation duration was selected based on previously reported endovascular drug-delivery protocols and on optimization of local venous wall drug absorption (Lei *et al*., 2024).

High-pressure, non-drug-coated balloons with inflation times similar to those in the DCB group were utilized for angioplasty in the normal BA group. In accordance with clinical practice, additional post-dilatation or bailout stenting was performed at the operator's discretion in cases of poor angiographic outcomes. Depending on institutional availability, commercially available paclitaxel-coated balloon platforms including IN.PACT Admiral™ (Medtronic, USA) and Lutonix™ DCB (BD Bard, USA) were used. These devices utilized paclitaxel dose densities ranging from 2.0 to 3.5 μg/mm² and employed similar antiproliferative coating technologies consistent with standard endovascular clinical practice.

Follow-up and outcome measures

Follow-up data were obtained from medical records at baseline and roughly 6, 12 and 24 months post-intervention, contingent upon available clinic visits, duplex ultrasonography reports and quality of life evaluations. Imaging assessments additionally evaluated fibrotic venous occlusions, collateral venous formation and venous wall remodeling whenever these findings were documented in procedural imaging reports. Advanced venous imaging plays an important role in evaluating chronic thrombotic remodeling and procedural success after venous intervention (Singh *et al*., 2024). The primary effectiveness outcome was primary venous patency at 24 months, defined as the absence of occlusion or significant stenosis (>50% diameter reduction) in the target vein as confirmed by imaging studies.

Secondary endpoints included:

- Freedom from clinically-driven target lesion revascularization (CD-TLR), defined as repeat intervention performed because of recurrent symptoms associated with imaging-confirmed restenosis.
- Changes in Villalta score and VCSS from baseline.
- Improvement in quality of life assessed using CIVIQ-20.
- Technical success is defined as residual stenosis <30%.
- Safety outcomes including thrombotic events, bleeding complications according to ISTH criteria, procedural complications and all-cause mortality.

The sample size was determined based on available data and set to 112 patients per group, which would provide 80 percent power to detect a 15 percent difference in 24-month primary patency rates at a significance level of 0.05, using a standard BA primary patency rate of 60 percent.

Statistical analysis

SPSS version 28.0 (IBM Corp., Armonk, NY) was used to analyze the results statistically. The continuous variables were given out as mean plus standard deviation or median (interquartile range) based on the normality of the distribution and were then compared using the Student t-test or the Mann-Whitney U test whenever necessary. Frequencies (percentages) were used to describe categorical variables and the chi-square or Fisher's exact test was used to analyze them. Missing follow-up data for variables including patency status, Villalta score, VCSS and CIVIQ-20 score were less than 5% and were addressed using multiple imputation with five imputations.

Kaplan-Meier curves were plotted to evaluate time-to-event results and log-rank tests were performed to compare intergroups. Hazard ratios and 95% confidence intervals were calculated using Cox proportional hazards regression. The dependent variables included in a multivariable analysis to determine primary patency independent determinants were the possible confounding factors. Selection bias was minimized using propensity score matching based on age, sex, comorbidities, DVT location and previous treatments. Observer bias was reduced through standardized imaging interpretation and predefined clinical outcome measures, while multivariable regression analysis was additionally performed to adjust for residual confounding variables. A p-value below 0.05 was considered significant. A graphical assessment of the proportional hazards assumption in Cox regression models indicated that it was acceptable for the main result.

RESULTS

Patient characteristics

Two hundred and forty-five patient records were reviewed: 127 with DCB and 118 with standard BA, obtained at three vascular centers between 2019 and 2024. Table 1 demonstrated that the baseline demographic and clinical features were similar between the two groups after propensity score matching. The average age was 57.3 ± 13.5 years, with a minor female majority (53.1%). The predominant location of DVT was iliofemoral (58.4%), followed by femoropopliteal (33.9%) and infrapopliteal (7.8%). Previous DVT episodes were documented in 39.2% of patients, while 42.9% presented

with established post-thrombotic syndrome at the time of enrolment.

Subgroup analysis demonstrated that patients with thrombophilia had lower primary patency rates than those without thrombophilia. However, DCB angioplasty maintained superior patency outcomes compared with standard BA in both thrombophilia and non-thrombophilia subgroups.

Procedural characteristics and technical success

Technical success was achieved in 125 of 127 (98.4%) patients in the DCB group and 110 of 118 (93.2%) in the standard BA group (p=0.042). Procedural specifics are delineated in table 2. The average lesion length was similar between the groups (DCB: 8.7 ± 4.9 cm *vs.* standard BA: 8.3 ± 5.1 cm, p=0.53). Pre-dilation was conducted in all DCB cases and in 84.7% of standard BA cases. Post-dilation was necessary in 12.6% of DCB cases and 28.0% of standard BA cases (p=0.002).

Primary and secondary efficacy outcomes

The 24-month primary patency rate was significantly higher in the DCB group compared with the standard BA group (82.7% *vs.* 61.9%, p<0.001) (Fig. 1). Kaplan-Meier analysis showed that the DCB group had much better freedom from loss of primary patency (log-rank p<0.001), with a hazard ratio of 0.38 (95% CI 0.24-0.59, p<0.001). The DCB group demonstrated significantly greater freedom from CD-TLR at 24 months (87.4% *vs.* 69.5%, p<0.001). The CD-TLR rate of the DCB group was 12.6% as compared to 30.5% in the standard BA group (p<0.001).

Clinical outcomes and quality of life

The results showed that both treatment groups showed substantial improvements in quality-of-life measures and clinical severity change scores at baseline and 24 months, although the improvements were more significant in the DCB group (Table 3). The mean reduction in Villalta score was significantly greater in the DCB group compared with the standard BA group (-6.9 ± 4.2 vs. -4.3 ± 3.8, p<0.001) and the VCSS (-5.1 ± 3.3 and -3.4 ± 2.9, p<0.001) was also significantly higher.

Improvement in quality of life was significantly greater in the DCB group compared with the standard BA group, as demonstrated by higher CIVIQ-20 score improvement (+23.7 ± 15.2 vs. +9.4 ± 13.8, p<0.001). The quality-of-life improvement was consistent across pain, physical, social and psychological domains and remained statistically significant after adjustment for baseline characteristics. Similar improvements in venous symptom burden and functional recovery following DCB therapy have recently been reported in studies of chronic venous obstruction (Garcia *et al*., 2023).

Safety outcomes

Safety outcomes were comparable between groups (Table 3). Thrombotic events were similar (DCB: 6.3% *vs.* standard BA: 5.9%, p=0.89) as well as the major bleeding (3.1% *vs.* 2.5%, p=0.77). In the 24-month follow-up, the DCB group showed 3 deaths (2.4%), the standard BA group 2 deaths (1.7%) and none of the deaths were under the category of procedure-related. No clinically significant contrast-induced nephropathy or radiation-related adverse events were observed during the follow-up period in either treatment group.

Multivariable analysis

Multivariable Cox regression analysis identified multiple independent predictors of primary patency at 24 months (Table 4). DCB angioplasty was significantly associated with improved primary patency after adjusting for potential confounders (adjusted HR 0.42, 95% CI 0.29-0.61, p<0.001).

Other independent predictors of loss of primary patency included diabetes (adjusted HR 1.58, 95% CI 1.11-2.24, p=0.01), active smoking (adjusted HR 1.76, 95% CI 1.24-2.49, p=0.002), previous deep vein thrombosis (DVT) (adjusted HR 1.48, 95% CI 1.05-2.09, p=0.03), total occlusion (adjusted HR 1.65, 95% CI 1.15-2.36, p=0.006) and lesion length greater than 10 centimeters (adjusted HR 1.93, 95% CI 1.32-2.83, p<0.001).

DISCUSSION

This multicenter retrospective study demonstrated that DCB angioplasty provided superior long-term venous patency, lower restenosis rates, reduced need for reintervention and greater improvement in quality-of-life outcomes compared with conventional BA in patients with DVT. The findings support the therapeutic role of localized paclitaxel delivery in suppressing venous restenosis and improving long-term vascular remodeling outcomes. Although propensity score matching was used to balance baseline clinical characteristics between groups, the possibility of residual confounding cannot be completely excluded.

Compared with traditional BA, this retrospective analysis shows that DCB angioplasty for DVT is associated with considerably better long-term outcomes. The therapeutic benefit of localized antiproliferative drug delivery in the treatment of complex chronic venous lesions is highlighted by the significantly higher primary patency rate (82.7% *vs.* 61.9%, p < 0.001) and the decreased need for reintervention (hazard ratio [HR] 0.42, 95% confidence interval [CI] 0.29–0.61, p < 0.001).

Table 1: Baseline demographic and clinical characteristics.

Characteristic	DCB angioplasty (n=127)	Standard BA (n=118)	p-value
Age, years	58.1 ± 12.9	56.4 ± 14.1	0.32
Female sex	69 (54.3%)	61 (51.7%)	0.68
BMI, kg/m²	28.9 ± 5.7	29.3 ± 6.1	0.57
Comorbidities			
Hypertension	63 (49.6%)	57 (48.3%)	0.83
Diabetes	31 (24.4%)	28 (23.7%)	0.90
Dyslipidemia	49 (38.6%)	45 (38.1%)	0.94
Active smoking	36 (28.3%)	39 (33.1%)	0.42
Thrombophilia	18 (14.2%)	15 (12.7%)	0.73
DVT location			
Iliofemoral	76 (59.8%)	67 (56.8%)	0.62
Femoropopliteal	42 (33.1%)	41 (34.7%)	0.78
Infrapopliteal	9 (7.1%)	10 (8.5%)	0.69
Previous DVT	48 (37.8%)	48 (40.7%)	0.64
Established PTS	53 (41.7%)	52 (44.1%)	0.71
Baseline Villalta score	12.3 ± 6.1	11.9 ± 5.8	0.59
Baseline VCSS	10.7 ± 4.3	10.5 ± 4.1	0.71
Baseline CIVIQ-20 score	51.3 ± 17.6	53.8 ± 16.9	0.25

Values are presented as mean ± SD or n (%). BMI = body mass index; DCB = drug-coated balloon; DVT = deep vein thrombosis; PTS = post-thrombotic syndrome; VCSS = Venous Clinical Severity Score; CIVIQ-20 = Chronic Venous Insufficiency Questionnaire.

Table 2: Procedural characteristics and technical success.

Characteristic	DCB angioplasty (n=127)	Standard BA (n=118)	p-value
Target vessel			
Common iliac vein	48 (37.8%)	42 (35.6%)	0.72
External iliac vein	28 (22.0%)	25 (21.2%)	0.87
Common femoral vein	27 (21.3%)	24 (20.3%)	0.86
Femoral/popliteal vein	24 (18.9%)	27 (22.9%)	0.44
Lesion length (cm)	8.7 ± 4.9	8.3 ± 5.1	0.53
Degree of stenosis (%)	72.8 ± 15.3	70.6 ± 16.9	0.27
Occlusion (*vs.* stenosis)	38 (29.9%)	36 (30.5%)	0.92
Pre-dilation	127 (100%)	100 (84.7%)	<0.001
Post-dilation	16 (12.6%)	33 (28.0%)	0.002
Additional stenting	5 (3.9%)	14 (11.9%)	0.02
Technical success	125 (98.4%)	110 (93.2%)	0.042
Residual stenosis (%)	13.7 ± 9.5	19.3 ± 12.8	<0.001
Procedure time (min)	68.9 ± 23.7	63.2 ± 25.1	0.07
Radiation dose (mGy)	421.3 ± 304.7	401.8 ± 312.5	0.62
Contrast volume (mL)	102.5 ± 48.9	97.3 ± 46.2	0.39

Values are presented as mean ± SD or n (%). DCB = drug-coated balloon; BA = balloon angioplasty. Pre-dilation refers to initial balloon expansion before drug-coated balloon deployment. Post-dilation refers to additional balloon expansion after primary angioplasty. Technical success was defined as residual stenosis less than 30% on venography.

Recent vascular intervention studies have similarly demonstrated improved endothelial stabilization and reduced restenosis rates with localized paclitaxel delivery systems (Wang *et al*., 2022). Localized paclitaxel delivery suppresses venous restenosis and neointimal hyperplasia, thereby improving long-term vascular patency. Previous experimental vascular studies have demonstrated that paclitaxel inhibits smooth muscle proliferation, inflammatory signaling pathways and extracellular matrix remodeling associated with restenosis development (Anderson *et al*., 2023; Miller *et al*., 2024). These findings support the mechanistic rationale for DCB technology, which enables targeted therapeutic drug delivery without the complications associated with permanent intravascular stent implantation.

Previous endovascular studies involving DCB technology provide indirect mechanistic support for the present findings, although important biological differences exist between arterial and venous disease.

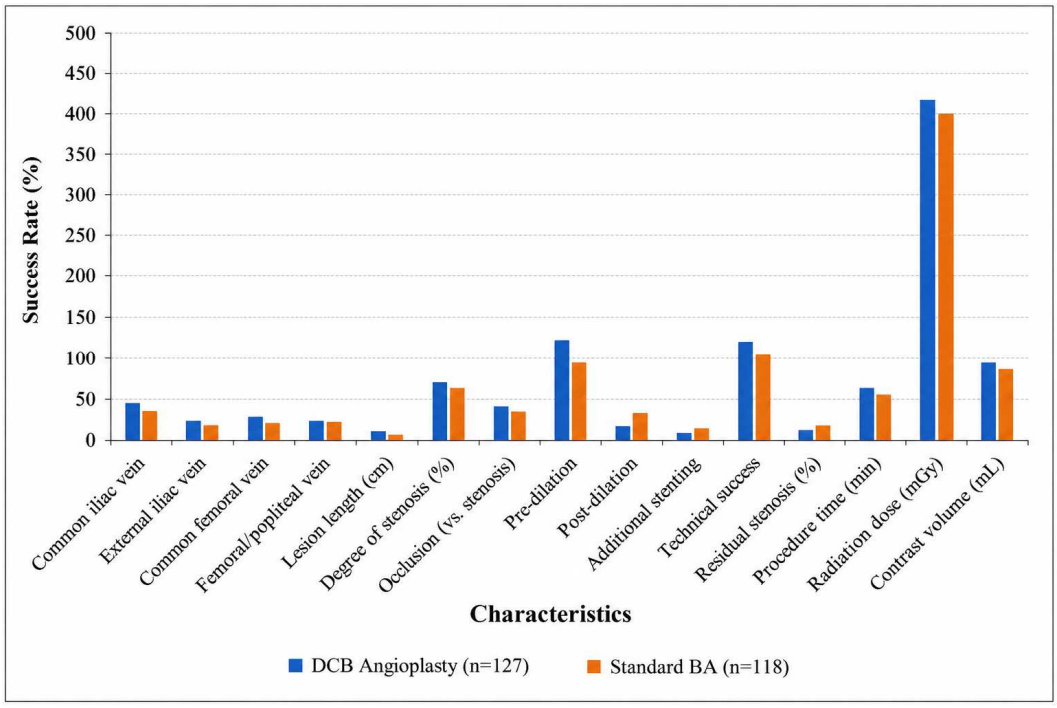

Fig. 1: Procedural characteristics and technical success rate.

Table 3: Primary and secondary efficacy outcomes at 24 months follow-up.

Outcome	DCB Angioplasty (n=127)	Standard BA (n=118)	p-value
Primary patency	105 (82.7%)	73 (61.9%)	<0.001
Freedom from CD-TLR	111 (87.4%)	82 (69.5%)	<0.001
Restenosis	15 (11.8%)	35 (29.7%)	<0.001
Reocclusion	7 (5.5%)	10 (8.5%)	0.35
Change in Villalta score	-6.9 ± 4.2	-4.3 ± 3.8	<0.001
Change in VCSS	-5.1 ± 3.3	-3.4 ± 2.9	<0.001
Change in CIVIQ-20 score	+23.7 ± 15.2	+9.4 ± 13.8	<0.001
Major bleeding	4 (3.1%)	3 (2.5%)	0.77
Thrombotic events	8 (6.3%)	7 (5.9%)	0.89
All-cause mortality	3 (2.4%)	2 (1.7%)	0.71

Values are presented as mean ± SD or n (%). CD-TLR = clinically-driven target lesion revascularization; DCB = drug-coated balloon; BA = balloon angioplasty; VCSS = Venous Clinical Severity Score; CIVIQ-20 = Chronic Venous Insufficiency Questionnaire.

Table 4: Multivariable Cox regression analysis for loss of primary patency.

Variable	Adjusted HR	95% CI	p-value
DCB *vs.* standard BA	0.42	0.29 - 0.61	<0.001
Age (per 10-year increase)	1.16	0.98 - 1.37	0.09
Female sex	0.87	0.61 - 1.24	0.44
Diabetes	1.58	1.11 - 2.24	0.01
Active smoking	1.76	1.24 - 2.49	0.002
Previous DVT	1.48	1.05 - 2.09	0.03
Thrombophilia	1.39	0.91 - 2.12	0.13
Iliofemoral location	1.27	0.89 - 1.81	0.19
Occlusion vs. stenosis	1.65	1.15 - 2.36	0.006
Lesion length >10 cm	1.93	1.32 - 2.83	<0.001
Technical success	0.54	0.32 - 0.91	0.02

HR = hazard ratio; CI = confidence interval; DCB = drug-coated balloon; BA = balloon angioplasty; DVT = deep vein thrombosis.

Recent narrative reviews have also emphasized the expanding role of DCB angioplasty in managing complex vascular lesions and maintaining long-term vessel patency (DePietro and Trerotola, 2023). Lei *et al*. (2024) showed that the 12-Month Primary Patency Rate for DCB Angioplasty for In-Stent Restenosis in Iliofemoral DVT was 76.5%. Comparable findings were also reported in multicenter venous intervention registries that evaluated long-term patency outcomes following DCB-based treatment strategies (Patel *et al*., 2023). Similar benefits of DCB angioplasty in maintaining vascular access patency have also been demonstrated in multicenter randomized studies involving hemodialysis-related venous lesions (Moreno-Sánchez *et al*., 2024). The 24-month primary patency observed in the present study was higher than the 12-month outcomes reported by Lei *et al*. (2024), possibly because of differences in lesion complexity, follow-up duration and patient selection.

Primary patency and restenosis outcomes

The significantly higher 24-month primary patency observed in the DCB group suggests that localized antiproliferative therapy may effectively reduce venous neointimal hyperplasia and pathological vascular remodelling. Reduced restenosis rates and lower target lesion revascularization further support the long-term efficacy of paclitaxel-coated balloon technology in chronic venous obstruction. Similar findings have been reported in previous venous intervention studies evaluating DCB therapy in iliofemoral venous disease and post-thrombotic lesions (Lei *et al*., 2024; Patel *et al*., 2023).

Clinical implications

Patients treated with DCB angioplasty demonstrated significantly greater improvements in Villalta score, VCSS and CIVIQ-20 quality-of-life scores compared with conventional BA. Similar improvements in functional recovery and vascular outcomes following DCB therapy have also been reported in peripheral vascular intervention studies (Barco *et al*., 2022). These findings suggest that localized paclitaxel delivery may improve both anatomical venous patency and patient-reported functional outcomes in the management of chronic DVT. Recent translational vascular studies have emphasized the importance of combining pharmacological drug delivery with mechanical venous recanalization to optimize long-term outcomes (Nakamura *et al*., 2024).

Study strengths

The study's strengths include its multicenter design, which reflects clinical practice and the relatively high sample size (n = 245) across three centers. Additionally, a propensity score matching process was conducted, which strengthened the comparison of treatment groups by reducing baseline differences. Additionally, thorough examination of both objective and patient-centered outcomes was guaranteed using validated clinical and quality-of-life assessment instruments, such as the Villalta score, VCSS and CIVIQ-20 questionnaire.

CONCLUSION

In this multicenter retrospective study, DCB BA yielded superior long-term outcomes in patients with DVT compared with conventional BA. In addition, DCB BA maintained a safety profile comparable to traditional BA but demonstrated improved 24-month primary patency rates, lower rates of target lesion revascularization and restenosis and improved clinical severity and quality of life scores for DCB-treated patients. From both clinical and pharmacological perspectives, DCB angioplasty appears to be a promising localized drug-delivery strategy for selected patients with DVT, especially those who are more likely to develop restenosis. However, these results should be interpreted with caution due to the retrospective design and the lack of direct comparison with venous stenting. To further define the optimal role of paclitaxel DCBs in the management of chronic venous disease, prospective randomized controlled trials with longer follow-up periods and head-to-head comparisons with other endovascular techniques are necessary.

Limitations and future recommendations

Several limitations should be considered while interpreting the present findings. The retrospective multicenter design may introduce selection bias and variability in procedural and follow-up practices between centers. In addition, the study was conducted in tertiary referral centers within a single country, which may limit the generalizability of the findings to other healthcare settings. Although the 24-month follow-up provided meaningful mid-term clinical outcomes, longer follow-up studies are still needed to evaluate late adverse events and long-term durability of DCB therapy. Another limitation is the absence of a venous stenting comparison group, which limits direct comparison with other established endovascular treatment strategies for DVT. Future prospective randomized multicenter trials with standardized imaging protocols and direct comparisons between DCB angioplasty and venous stenting are recommended to further define the optimal management strategy for chronic venous disease (Thompson *et al*., 2025; Lopez *et al*., 2024).

Acknowledgement

None.

Author's contributions

O.R. contributed to study conceptualization, study design, data collection, statistical analysis, manuscript drafting, critical revision of the manuscript and final approval of the submitted version.

Funding
There was no funding.

Data availability statement
The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethical approval
The study was approved by the Institutional Review Board of Bahcesehir Cyprus University, Faculty of Health Sciences, Türkiye, under protocol number VAS-2019-045. This study was performed in adherence with the RECORD guidelines. See supplementary file for the RECORD checklist.

Conflict of interest
The author declares no conflict of interest.

Supplementary data
https://www.pjps.pk/uploads/2026/06/SUP1780751304.pdf

REFERENCES

Almeida JF, Costa R, Pereira M and Santos L (2023). Endovascular drug delivery strategies in chronic venous disease management. *J. Vasc. Interv. Radiol*., **34**(6): 881–889.

Anderson P, Lewis J and Carter M (2023). Mechanisms of paclitaxel-mediated inhibition of venous neointimal hyperplasia. *J. Vasc. Res*., **60**(4): 211–219.

Barco S, Sebastian T, Voci D, Engelberger RP, Grigorean A, Holy E, Leeger C, Munger M, Periard D, Probst E and Spescha R (2022). Major adverse limb events in patients with femoro-popliteal and below-the-knee peripheral arterial disease treated with either sirolimus-coated balloon or standard uncoated balloon angioplasty: A structured protocol summary of the "SirPAD" randomized controlled trial. *Trials*., **23**(1): 334.

Chen Y, Zhao H, Liu X and Wang J (2024). Advances in paclitaxel-coated balloon therapy for chronic venous obstruction. *Front. Cardiovasc. Med*., **11**: 1452217.

Cui HJ and Wu YF (2024). The efficacy of drug-coated balloons and drug-eluting stents in infrapopliteal revascularization: A meta-analysis. *J. Endovasc. Ther*., **31**: 15266028231222385.

DePietro DM and Trerotola SO (2023). Choosing the right treatment for the right lesion, Part II: A narrative review of drug-coated balloon angioplasty and its evolving role in dialysis access maintenance. *Cardiovasc. Diagn. Ther*., **13**(1): 233–244.

Garcia M, Velasquez P, Rivera D and Torres J (2023). Functional recovery after drug-coated balloon angioplasty in chronic venous insufficiency. *Vasc. Endovascular Surg*., **57**(8): 741–748.

Ilyas S and Powell RJ (2022). Management of the no-option foot: Deep vein arterialization. *Semin. Vasc. Surg*., **35**(2): 210–218.

Kim SY, Park JK and Lee DH (2023). Post-procedural anticoagulation strategies following venous endovascular intervention. *Ann. Vasc. Surg*., **91**: 188–196.

Lei J, Pu H, Zhang L, Zeng C, Peng Z, Wu Z, Jiang Y, Wang R and Lu X (2024). Drug-coated balloon therapy for in-stent restenosis in patients with iliofemoral deep vein thrombosis: A single-arm observational study. *Catheter. Cardiovasc. Interv*., **103**(5): 752–757.

Lopez R, Martinez A and Cruz P (2024). Emerging pharmacological technologies in venous endovascular therapy. *Int. Angiol*., **43**(2): 120–128.

Lv S, Wei G, Shi X, Xu Q and Li X (2024). Efficacy and safety of drug-coated balloon in elderly patients with intrastent restenosis after lower extremity arteriosclerotic obliterans following Rotarex thrombus removal. *Altern. Ther. Health Med*., **30**(2): 178–182.

Miller R, Zhang Y and Thompson K (2024). Antiproliferative drug delivery systems in chronic venous intervention. *Vasc. Pharmacol*., **158**: 107312.

Moreno-Sánchez T, Moreno-Ramírez M and Machancoses FH (2024). Multicenter randomized controlled trial to assess the effectiveness of PASSEO-LUX DCB® drug-coated balloon compared to plain balloon angioplasty of arteriovenous fistulae for hemodialysis: Two-years results. *J. Vasc. Access*., **25**: 11297298241272259.

Nakamura T, Ishikawa H and Sato M (2024). Combined pharmacomechanical approaches in chronic venous obstruction treatment. *J. Endovasc. Ther*., **31**(3): 322–330.

Patel K, Sharma V and Mehta R (2023). Long-term patency outcomes following drug-coated balloon therapy in iliofemoral venous disease. *Phlebology*., **38**(7): 512–520.

Rodriguez A, Fernandez M and Ruiz C (2022). Localized antiproliferative therapy in chronic venous intervention: Current evidence and future perspectives. *Vascular*., **30**(5): 823–831.

Singh R, Verma P and Kulkarni S (2024). Imaging evaluation of chronic venous remodeling after endovascular therapy. *Diagn. Interv. Radiol*., **30**(1): 45–53.

Thompson L, Green D and Walker P (2025). Standardization of outcome reporting in chronic venous intervention trials. *J. Vasc. Surg. Venous Lymphat. Disord*., **13**(1): 66–74.