

# Deep Vein Thrombosis: Pharmacomechanical Therapy With/Without Catheter-Directed Thrombolysis

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## ABSTRACT

This study aimed to compare the early and mid-term outcomes of patients diagnosed with acute and subacute deep vein thrombosis (DVT) treated with pharmacomechanical thrombectomy (PMT) only versus combined pharmacomechanical thrombectomy and catheter-directed thrombolysis (PMT+CDT).

In this retrospective study conducted between January 2018 and January 2021, 60 patients diagnosed with acute or subacute iliofemoral DVT were included. Patients meeting the inclusion criteria underwent PMT alone or PMT combined with CDT. Thirty patients underwent PMT, while the other 30 received additional CDT following PMT. Demographic data, clinical findings, Doppler ultrasound results, Villalta scores, and complications were evaluated at 1, 6, and 12 months post-treatment.

The mean age was 61.2 years in the PMT group, comprising 14 males (46.6%) and 16 females (53.3%). At the 1-month follow-up, venous patency <70% was significantly more common in the PMT group (43.33%;  $p=0.032$ ). At 6 and 12 months, patency rates  $\geq 90\%$  were significantly higher in the PMT+CDT group (63.34% and 66.67%, respectively;  $p=0.033$ ). At 12 months, the rate of post-thrombotic syndrome (PTS) was significantly lower in the PMT+CDT group (33.33%;  $p=0.038$ ). Although minor complications such as bleeding and transient renal dysfunction were observed in both groups, no significant differences were found regarding major complications or pulmonary embolism.

The combination of PMT and CDT was more effective in maintaining venous patency and reducing the risk of PTS compared to PMT alone. Although minor bleeding risks were observed, the combined approach appears to offer superior clinical outcomes. Further multicenter, large-scale studies are warranted to validate these findings.

**Keywords:** Deep Vein Thrombosis, Thrombectomy, Thrombolytic Therapy, Postthrombotic Syndrome, Treatment Outcome

## Introduction

Deep vein thrombosis (DVT) is a clinical condition characterized by thrombus formation within deep venous structures and is associated with risk factors including endothelial injury, hypercoagulability, and venous stasis (1). If left untreated in the early stages, DVT may lead to complications such as pulmonary embolism, post-thrombotic syndrome, and chronic venous insufficiency. Early mechanical removal of the thrombus within the venous system reduces the risk of developing these complications. Oral anticoagulation therapy prevents thrombus progression and the formation of new thrombi but does not provide thrombolytic effects. Thrombolytic activity relies on the body's intrinsic fibrinolytic system, which is often insufficient, thereby failing to adequately prevent the development of post-thrombotic syndrome (2). Consequently, pharmacomechanical

thrombectomy and catheter-directed thrombolytic therapy have become increasingly widespread to expedite thrombus reduction. In mechanical thrombectomy, the thrombus located in the iliofemoral region is fragmented by thrombectomy catheters and aspirated for removal. The advantages of percutaneous endovascular procedures include rapid recovery, earlier achievement of sufficient venous patency, preservation of venous valve function by preventing thrombus-induced valve damage, and reduced venous reflux. Disadvantages of this procedure include its invasive nature, and limited applicability to selected patient groups (3). Thrombolytic therapy, by reducing thrombus burden in the venous system early, preserves valve function and reduces the risk of post-phlebotic syndrome (4). Unlike systemic thrombolytic therapy, catheter-directed thrombolysis (CDT) facilitates the administration of a high dose of thrombolytic agents directly into the thrombus

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material within the venous system using specialized catheters (5). Following percutaneous mechanical thrombectomy, CDT can be delivered directly into the thrombosed venous segment via catheter. In this method, the first stage involves creating a lumen within the thrombus via pharmacomechanical thrombectomy (PMT) (6). In this study, we aimed to compare early and mid-term outcomes of patients with acute and subacute DVT in iliofemoral venous structures, treated frequently in our clinic using the AngioJet® catheter for pharmacomechanical therapy alone and pharmacomechanical therapy followed by catheter-directed thrombolytic therapy.

## Materials and Methods

This retrospective study was conducted on patients diagnosed with deep vein thrombosis (DVT) who presented to Eskisehir Osmangazi University Health Practice and Research Hospital between January 2018 and January 2021. Patients meeting the inclusion criteria during the study period were retrospectively identified from institutional records. Ethical approval was obtained from the Eskisehir Osmangazi University Faculty of Medicine Non-Interventional Clinical Research Ethics Committee (dated 26.04.2022; approval no: E-25403353-050.99-326996). A priori power analysis using G\*Power 3.1 software indicated that, with a type I error ( $\alpha$ ) of 0.05, power ( $1-\beta$ ) of 0.90, and an effect size of 0.80, at least 28 patients were required in each group.

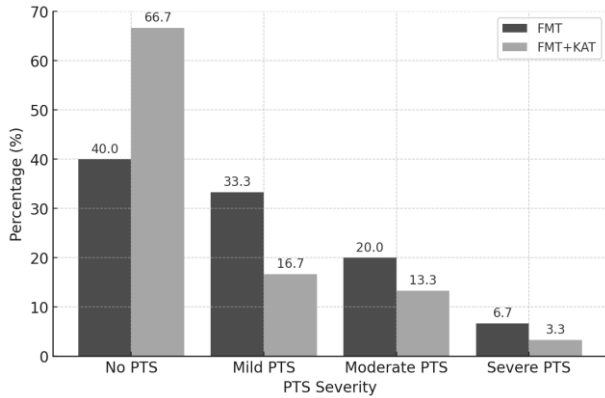
During the study period, 72 patients were evaluated for eligibility. Of these, 12 were excluded due to incomplete medical records or predefined exclusion criteria. A total of 60 patients were included in the final analysis. These patients were divided into two groups: 30 underwent pharmacomechanical thrombectomy (PMT) alone, and 30 received pharmacomechanical thrombectomy combined with catheter-directed thrombolysis (PMT+CDT) to compare early and mid-term outcomes in acute and subacute deep vein thrombosis. The decision to perform additional catheter-directed thrombolysis following pharmacomechanical thrombectomy was based on residual thrombus burden, incomplete venous recanalization on intraoperative venography, and the treating physician's clinical judgment. Patients included in the study had been diagnosed with acute-subacute iliofemoral-popliteal (proximal) deep vein thrombosis by Doppler ultrasound and underwent

percutaneous angioplasty between January 2018 and January 2021. Exclusion criteria were isolated iliac vein thrombosis without inferior vena cava involvement, preoperative pulmonary embolism diagnosis, isolated femoral or popliteal vein thrombosis without iliac vein involvement, and incomplete patient records. Patients with incomplete baseline or follow-up data were excluded from the study; therefore, no data imputation was required.

Collected data included age, gender, lower-extremity circumference difference at presentation, presence of Homans sign, hyperemia, history of cancer, recent surgical history, oral contraceptive (OC) use, recanalized flow detected by postoperative venous Doppler ultrasound, and presence of recurrence. Patient data were obtained through postoperative follow-up examinations at 1, 6, and 12 months, patient record systems, and phone interviews. Clinical severity was assessed using the Villalta scoring system at the 12-month outpatient follow-up visit. The Villalta score includes five patient-reported symptoms (pain, cramps, heaviness, pruritus, and paresthesia) and six clinical signs (edema, skin induration, hyperpigmentation, redness, venous ectasia, and pain on calf compression), each graded from 0 to 3. A total score  $\geq 5$  was considered diagnostic for post-thrombotic syndrome (PTS), and severity was categorized as mild (5–9), moderate (10–14), and severe ( $\geq 15$ ) (7). In addition, data regarding Doppler ultrasound follow-up, complications, pulmonary embolism rates, and recurrence were analyzed.

Statistical analyses were performed using SPSS for Windows, version 15.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean  $\pm$  standard deviation or median (interquartile range), depending on distribution. Categorical variables were presented as numbers and percentages. Categorical data were analyzed using chi-square or Fisher's exact test, as appropriate. A p-value  $< 0.05$  was considered statistically significant.

**Interventional Procedures:** All procedures were performed under fluoroscopic guidance in either the operating room or angiography laboratory, depending on availability. Patients were positioned prone and monitored for heart rhythm and oxygen saturation. Under ultrasound guidance, the ipsilateral popliteal vein was accessed using the Seldinger technique, and an 8F sheath was inserted. A bolus of 5000 IU heparin was administered at the beginning of the procedure.



**Fig. 1.** The distribution of post-thrombotic syndrome (PTS) severity based on the Villalta score at 12-month follow-up after FMT or FMT-CAT in patients

Pharmacomechanical thrombectomy was performed using a rheolytic thrombectomy catheter. Alteplase was added to saline solution during the procedure to enhance thrombus dissolution, allowing simultaneous thrombolytic infusion and aspiration.

In patients with a high residual thrombus burden following thrombectomy, catheter-directed thrombolysis was continued via an infusion catheter positioned within the thrombus. Alteplase infusion was administered at 1 mg/h, with fibrinogen levels monitored periodically to guide dose adjustment or discontinuation.

Inferior vena cava filter placement was not routinely performed, as no patient had an absolute indication such as contraindication to anticoagulation or active pulmonary embolism. Postoperatively, systemic anticoagulation was continued, and patients were followed clinically and with Doppler ultrasonography at 1, 6, and 12 months.

## Results

Patients were categorized into two groups: those undergoing pharmacomechanical thrombectomy alone (PMT) and those undergoing pharmacomechanical thrombectomy combined with catheter-directed thrombolysis (PMT+CDT) for acute deep vein thrombosis extending into the iliac vein. A total of 60 patients were included in the study. The overall mean age was 60.6 years, and 31 patients (51.7%) were male. The mean age was 59.9 years in the PMT group and 61.2 years in the PMT+CDT group. Male patients comprised 46.7% of the PMT group and 56.7% of the PMT+CDT group. No statistically significant differences were observed between the groups in

terms of age or sex distribution. Left extremity involvement was observed in 17 patients (56.67%) in the PMT group and 18 patients (60.00%) in the PMT+CDT group, while right extremity involvement was observed in 13 patients (43.33%) and 12 patients (40.00%), respectively (Table 1). Although no statistically significant difference was found between the two groups in terms of extremity involvement distribution, left extremity involvement was more common in both groups. In the PMT group, hospitalization duration was  $\leq 5$  days for 27 patients (90%) and  $> 5$  days for 3 patients (10%). In the PMT+CDT group, hospitalization duration was  $\leq 5$  days for 24 patients (80%) and  $> 5$  days for 6 patients (20%).

Predisposing factors evaluated collectively for both groups included immobility in 22 patients (73.33%), malignancy in 10 patients (16.67%), recent surgical history in 11 patients (36.67%), recent trauma in 2 patients (6.6%), femoral vein hemodialysis/central venous catheter placement in 2 patients (6.6%), and oral contraceptive use in 3 patients (10.00%) (Table 2).

Venous patency rates assessed by Doppler ultrasound at the 1st, 6th, and 12th-month follow-ups were analyzed in both groups. At the 1-month Doppler ultrasound follow-up, venous patency  $< 70\%$  was significantly more frequent in the PMT group compared to the PMT+CDT group (43.33%;  $p=0.032$ ). At the 6-month Doppler ultrasound follow-up, venous patency  $\geq 90\%$  was significantly more frequent in the PMT+CDT group compared to the PMT group (63.34%;  $p=0.033$ ). At the 12-month Doppler ultrasound follow-up, venous patency  $\geq 90\%$  remained significantly more frequent in the PMT+CDT group compared to the PMT group (66.67%;  $p=0.034$ ) (Table 3).

Villalta scores were evaluated at 12-month outpatient follow-up visits in both groups to assess the incidence and severity of post-thrombotic syndrome (PTS). In the PMT+CDT group at 12-month follow-up, Villalta scoring showed no PTS in 20 patients (66.67%), mild PTS in 5 patients (16.67%), moderate PTS in 4 patients (13.33%), and severe PTS in 1 patient (3.33%). According to the 12-month Villalta scores, the rate of PTS development was significantly lower in the PMT+CDT treatment group (33.33%;  $p=0.038$ ) (Table 4, Figure 1).

Regarding intraoperative complications, shortness of breath or respiratory distress was observed in 1 patient from the PMT group and 2 patients from the PMT+CDT group; all patients recovered fully with oxygen support without requiring intubation.

**Table 1:** Baseline Characteristics of the Study Population

Variable	PMT (n=30)	PMT+CDT (n=30)	p value
Age (years)	59.9	61.2	0.624
Gender			
Female	16 (53.3)	13 (43.3)	0.605
Male	14 (46.7)	17 (56.7)	
Extremity side			
Right	13 (43.3)	12 (40.0)	0.793
Left	17 (56.7)	18 (60.0)	
Length of hospital stay			
≤5 days	27 (90.0)	24 (80.0)	0.278
>5 days	3 (10.0)	6 (20.0)	

Categorical variables were analyzed using the chi-square test

**Table 2:** Predisposing Factors in PMT Versus PMT+CDT Groups

	PMT n (%)	PMT+CDT n (%)
Immobility	10 (33.33)	12 (40.00)
Malignancy	4 (13.33)	6 (20.00)
Hypertension	10 (33.33)	9 (30.00)
Diabetes mellitus	12 (40.00)	7 (23.33)
Dyslipidemia	13 (43.33)	8 (26.67)
History of surgery	6 (20.00)	5 (16.67)
History of DVT	2 (6.67)	2 (6.67)
History of trauma	1 (3.33)	1 (3.33)
History of stroke	1 (3.33)	1 (3.33)
Hemodialysis/central venous catheterization	1 (3.33)	1 (3.33)
OCP use	2 (6.67)	1 (3.33)

PMT: Pharmacomechanical Therapy, CDT: Catheter-Directed Thrombolysis, DVT: Deep Vein Thrombosis, OCP: Oral Contraceptive Pills

Extravasation was not observed in any patient from either group. Postoperative complications included transient elevation in renal function tests in 1 patient from each group, both recovering without hemodialysis within one month following nephrology consultation. While no major bleeding was observed in the PMT group, gastrointestinal bleeding occurred in 1 patient, alveolar bleeding in 1 patient, and retroperitoneal bleeding in 1 patient within the PMT+CDT group. As minor bleeding, nosebleed was observed in 1 patient in the PMT group, whereas in the PMT+CDT group, nosebleed occurred in 3 patients and hematoma at the operative site was noted in 2 patients. No postoperative pulmonary embolism or deaths related to the operation occurred in either group.

## Discussion

The present study demonstrated that combined pharmacomechanical thrombectomy and catheter-directed thrombolysis was associated with significantly higher venous patency rates at 6 and 12 months, as well as a lower incidence of post-thrombotic syndrome at 12-month follow-up compared to pharmacomechanical thrombectomy alone. These findings suggest that the addition of catheter-directed thrombolysis may enhance mid-term venous recanalization and reduce the risk of post-thrombotic complications in patients with acute and subacute iliofemoral deep vein thrombosis.

Previous studies have reported favorable recanalization rates with pharmacomechanical

**Table 3:** Venous Patency Rates at 1, 6, and 12 Months: PMT vs PMT+CDT

	PMT n (%)	PMT-CDT n (%)	Total n (%)	X2 p value
1st Month Venous Patency Percentage				
>%90a	8 (26.67)	17 (56.67)	25 (41.67)	0.032
%70-90a,b	9 (30.00)	8 (26.67)	17 (28.33)	
<%70b	13 (43.33)	5 (16.66)	18 (30)	
6th Month Venous Patency Percentage				
>%90a	9 (30.00)	19 (63.34)	28 (46.67)	0.033
%70-90b	12 (40.00)	7 (23.33)	19 (31.67)	
<%70b	9 (30.00)	4 (13.33)	13 (21.66)	
12th Month Venous Patency Percentage				
>%90a	10 (33.33)	20 (66.67)	30 (50.00)	0.034
%70-90b	13 (43.34)	7 (23.33)	20 (33.33)	
<%70b	7 (23.33)	3 (10.00)	10 (16.67)	
Total	30 (100)	30 (100)	60 (100)	

Column percentages; a,b: groups not sharing the same letter are significantly different.

PMT: Pharmacomechanical Therapy, CDT: Catheter-Directed Thrombolysis. Statistical analysis was performed using the chi-square test

**Table 4:** Post-Thrombotic Syndrome at 12 Months (Villalta Score): PMT vs PMT+CDT

	PMT n(%)	PMT+CDT n(%)	X2 p value
No PTS	12 (40.00)	20 (66.67)	0.038
PTS	18 (60.00)	10 (33.33)	
Total	30 (100)	30 (100)	

PMT: Pharmacomechanical Therapy, CDT: Catheter-Directed Thrombolysis, PTS: post-thrombotic syndrome. Statistical analysis was performed using the chi-square test.

thrombectomy in patients with iliofemoral DVT, generally ranging between 74% and 100%, with low rates of pulmonary embolism and major bleeding (8-10). These findings support the role of mechanical thrombus removal in achieving early venous patency and preventing long-term venous complications. In our study, the 12-month patency rate in the PMT group was 76.67%, which is consistent with previously published data. Furthermore, postoperative Villalta scores were comparable to those reported in earlier studies and no major bleeding events or pulmonary embolism were observed. Minor bleeding complications were infrequent and clinically manageable (11).

Despite these favorable outcomes, concerns have been raised regarding mechanical thrombectomy, particularly related to potential risks such as pulmonary embolism, extravasation, and major bleeding (12). However, Holt et al. reported no major bleeding events, with transfusion rates

ranging between 4.2% and 14% and pulmonary embolism rates remaining below 1% (9). In our cohort, no pulmonary embolism, major bleeding, or extravasation was observed during the 12-month follow-up period.

Although systemic thrombolysis has been shown to improve venous recanalization compared to anticoagulation alone, its use is limited by bleeding risk and inadequate thrombus penetration within occluded venous segments (13). Catheter-directed thrombolysis enables targeted delivery of thrombolytic agents directly into the thrombus, potentially enhancing clot dissolution while minimizing systemic exposure and bleeding complications (14). This localized approach provides a mechanistic rationale for combining thrombolysis with pharmacomechanical thrombectomy in selected patients.

There is limited evidence evaluating the combined use of pharmacomechanical thrombectomy and catheter-directed thrombolysis in acute iliofemoral

DVT. The potential superiority of this approach may be explained by complementary mechanisms: pharmacomechanical thrombectomy reduces thrombus burden and creates intraluminal channels, thereby enhancing thrombolytic penetration and accelerating fibrinolysis. Rabuffi et al. reported a 12-month success rate of 95.5% in patients treated with combined therapy (15). PEARL multicenter study demonstrated improved mid-term outcomes with combined interventional strategies compared to single-modality treatment (16). In the present study, using  $\geq 70\%$  venous patency as the threshold for success, the 12-month patency rate was 76.67% in the PMT-only group and 90.00% in the combined therapy group. While Shen et al. reported a 22.8% rate of acute kidney injury (AKI) following combined therapy (17). In our study, this rate was found to be 3.33% among patients receiving combined therapy, and renal function parameters returned to normal within three months without the need for hemodialysis.

This study has several limitations. Its retrospective, single-center design and relatively small sample size may limit the generalizability of the findings. In addition, treatment allocation was not randomized and was based on clinical judgment, which may introduce selection bias. Finally, the follow-up period was limited to 12 months, and longer-term outcomes remain to be clarified.

In conclusion, combined pharmacomechanical thrombectomy and catheter-directed thrombolysis was associated with improved mid-term venous patency and a lower incidence of post-thrombotic syndrome compared to pharmacomechanical thrombectomy alone. These findings suggest that a combined interventional strategy may provide clinical benefit in appropriately selected patients with acute and subacute iliofemoral DVT.

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