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Mid-term Outcomes of a Stent-free PMT-CDT Strategy for Acute Iliofemoral Deep Vein Thrombosis

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Abstract

Objectives: Acute iliofemoral deep vein thrombosis (DVT) is distinguished by a pronounced symptomatology and an increased risk of post-thrombotic syndrome. Various techniques of prompt thrombus removal are intended to improve venous patency and outcomes; however, controversy still surrounds the appropriate modality of endovascular treatment and the necessity of routine stenting. In this study, we aimed to evaluate the procedural safety, efficacy, and intermediate-term outcomes of a standard stent-free pharmacomechanical thrombectomy with catheter-directed thrombolysis (PMT-CDT) in acute iliofemoral DVT.

Materials and Methods: This was a retrospective single-center study of 50 consecutive patients undergoing treatment for acute iliofemoral DVT between January 2020 and December 2023. All patients underwent a standardized endovascular treatment protocol using PMT and low-dose CDT without the routine use of venous stenting. Technical success, periprocedural complications, and re-thrombosis were evaluated. Estimation of re-thrombosis-free survival was performed using Kaplan-Meier survival analysis at 3, 6, and 12 months.

Results: Technical success was obtained in 46 patients (92%). There were no deaths, pulmonary embolism, and major hemorrhage. Minor complications occurred in five patients (10%) and were managed conservatively. During the period of follow-up, five patients (10%) were lost to follow-up. Kaplan-Meier estimates showed that the probability of freedom from re-thrombosis at 3 months, 6 months, and 12 months was 97.5%, 92.5%, and 87.5%, respectively. Venous stent insertion was not necessary in any patient after thrombus clearance based on venographic assessment.

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Conclusion: In this study, a standard stent-free PMT-CDT approach was shown to be a feasible and safe option for selected patients with acute iliofemoral DVT, with good mid-term patency results. However, these results should be interpreted with caution, as this study was descriptive in nature, without any standard evaluation of outcome, such as post-thrombotic syndrome scoring. Further prospective studies are needed to clarify the role of stent-free techniques in managing acute iliofemoral DVT.

Keywords: Acute iliofemoral deep vein thrombosis, pharmacomechanical thrombectomy, catheter-directed thrombolysis, venous patency, stent-free endovascular strategy, venous thromboembolism

Introduction

Acute iliofemoral deep vein thrombosis (DVT) is considered one of the worst forms of venous thromboembolism, often resulting in significant morbidity, including limb edema, pain, and compromised venous outflow. Compared with DVT in the more distal veins, iliofemoral DVT tends to have a larger thrombus burden and a higher risk of long-term complications, including post-thrombotic syndrome (PTS)[1-3]. The development of PTS can result in chronic venous insufficiency, including venous hypertension, skin changes, and venous ulcers, thereby significantly impairing the quality of life and functional status of the patient[2,3]. Anticoagulation remains the mainstay of treatment for acute DVT, aiming to inhibit thrombus propagation and prevent pulmonary embolism. However, these agents are ineffective in thrombus dissolution and are often ineffective in the setting of extensive proximal thrombosis[4]. The presence of thrombus and compromised venous outflow are major factors in the development of PTS[1,5]. Therefore, thrombus removal techniques have been proposed as a means of hastening thrombus dissolution and restoration of venous outflow. Endovascular thrombus removal techniques, including catheter-directed thrombolysis (CDT) and pharmacomechanical thrombectomy (PMT), have been increasingly used in the treatment of acute iliofemoral DVT in carefully selected patients[6,7]. These modalities have the theoretical advantage of reducing thrombus burden while minimizing the use of thrombolytic agents. These modalities have been reported to result in improved early venous patency and symptom relief; however, the effect on long-term clinical outcomes remains a matter of ongoing debate[1,2,7]. The ATTRACT study also assessed the development of PTS using standardized clinical scoring systems and emphasized the difficulty in demonstrating clinical benefit from these endovascular modalities[1,2].

A further debated issue in the endovascular treatment of DVT is the role of venous stenting following thrombectomy. Although the placement of a stent can be beneficial for patients with fixed iliac vein obstruction or significant residual stenosis, the routine use of stenting remains a debated issue, and the use of an anatomy-based selective stenting approach has been advocated[8]. The PMT-CDT method is a hybrid endovascular treatment that combines the benefits of thrombectomy with the benefits of CDT, potentially improving thrombus removal while limiting the thrombolytic agent used and the time required for thrombolytic therapy when compared with CDT alone[6,7]. However, there is a lack of data supporting the use of standardized endovascular treatment protocols without stenting, and data on the mid-term results of such treatment are also lacking.

This study aimed to evaluate the mid-term results of a standardized, stent-free PMT-CDT method for the endovascular treatment of acute iliofemoral DVT.

Materials and Methods

Study Design and Patient Population

This retrospective study included consecutive adult patients treated for acute iliofemoral DVT at the

Trabzon Ahi Evren Thoracic and Cardiovascular Surgery Training and Research Hospital between January 2020 and December 2023. Acute DVT was defined as a DVT presenting for less than 14 days. The inclusion criteria for the study were patients aged 18 years and above presenting with imaging-confirmed acute iliofemoral DVT involving the common iliac, external iliac, and femoral veins. Exclusion criteria included patients who presented with contraindications to thrombolytic therapy, active bleeding, bleeding diathesis, pregnancy, isolated distal DVT without iliofemoral involvement, chronic and subacute thrombosis, and incomplete clinical and imaging data. Ethical approval for the study was obtained from the Ordu University Clinical Research Ethics Committee (approval no: 2020/225; date: 27.10.2020). Informed consent was not required for this retrospective study.

Endovascular Procedure

These were performed under local anesthesia in accordance with a standardized endovascular protocol. A temporary retrievable inferior vena cava (IVC) filter was placed pre-procedure according to institutional protocol, given the extensive thrombus burden and potential for embolization during pharmacomechanical manipulation. Venous access was achieved through the popliteal vein under ultrasound guidance. PMT-CDT was performed using a rotational thrombectomy device.

Alteplase was administered as an initial bolus of 5-10 mg via the thrombectomy catheter, followed by a continuous catheter-directed infusion at 0.5-1.0 mg/h, depending on thrombus burden and clinical response. The thrombolysis was continued for 12-24 hours, followed by venography to evaluate thrombus clearance.

An anatomic evaluation of the iliac venous segment was carried out using completion venography after thrombus removal. The extent of residual venous stenosis was evaluated visually and was considered significant when luminal narrowing of more than 30% was associated with impaired contrast flow or evidence of collateral circulation. Intravascular ultrasound was not routinely available during our study period and, hence, was not used to evaluate underlying iliac vein compression.

Balloon venoplasty was performed for residual venous stenosis. Venous stenting was not included in our protocol.

Postprocedural Management and Follow-up

Subsequent anticoagulant therapy was initiated with low-molecular-weight heparin, which was later replaced by a direct oral anticoagulant. The oral anticoagulant therapy was continued for at least 6 months for all patients, with long-term therapy considered for patients who continued to display thromboembolic risk factors. Compression stockings were recommended for all patients. Clinical assessment and ultrasound were planned at 3, 6, and 12 months.

Re-thrombosis was defined as the development of a new thrombus within a previously treated venous segment, as demonstrated by ultrasound assessment. The criteria for diagnosis were non-compressibility of the vein, visualization of echogenic material within the vein, and decreased or absent color flow on color Doppler assessment.

Study Endpoints

The primary endpoint was technical success, defined as restoration of inline venous flow with at least partial (≥50%) thrombus burden reduction on completion venography.

Secondary Endpoints Included:

- Periprocedural complications
- In-hospital outcomes
- Freedom from re-thrombosis during follow-up

PTS was not systematically evaluated using validated scoring systems during the study period.

Statistical Analysis

Continuous variables are expressed as means and standard deviations, whereas categorical variables are expressed as counts and percentages. Freedom from re-thrombosis was estimated by Kaplan-Meier analysis at

3, 6, and 12 months. The 95% confidence interval was calculated using Greenwood's formula with a log-log transformation. Because the sample was small, regression analysis was not performed to avoid overfitting. Statistical analysis was performed using SPSS software, version 22.0. Statistical significance was set at $p<0.05$ for two-tailed tests.

Results

Patient Characteristics

A total of 50 consecutive patients with acute iliofemoral DVT were enrolled in the study. The mean patient age was 55.0±13.8 years, with 28 patients (56.0%) being male. The mean duration of previous symptoms before presentation was 6.5±3.7 days. The most common presenting features were limb swelling and pain, occurring in 94.0% and 92.0% of patients, respectively. Phlegmasia was observed in 6.0% of the patients (three patients). Left iliofemoral DVT was observed in 60.0% of the patients. The thrombus was observed in the common iliac vein in 56.0% of patients, in the external iliac vein in 40.0%, and in the femoral vein in all patients. The involvement of the IVC was observed in 2.0% of the patients. The baseline patient demographics are presented in Table 1.

Procedural Outcomes

Technical success, as indicated by the restoration of venous flow with at least 50% thrombus removal on completion venography, was achieved in 46 patients (92.0%). Adjunctive balloon angioplasty for venous narrowing was needed in four patients (8.0%). Venous stenting was not required in any patient in accordance with the stent-free protocol. The mean duration of stay in the hospital was 3.5±1.0 days, and the mean duration of stay in the intensive care unit was 1.3±0.6 days. Table 2 shows detailed procedural and clinical results.

Safety Outcomes

No procedure-related deaths or symptomatic pulmonary embolisms occurred during hospitalization. No major bleeding complications were encountered. Minor complications were encountered in five patients (10.0%), including hematuria in three patients (6.0%) and access-site hematoma in two patients (4.0%). All minor complications were managed conservatively without further intervention.

Follow-up and Re-thrombosis

Of the total patients, 5 (10.0%) were lost to follow-up. The Kaplan-Meier method was used to estimate freedom from re-thrombosis, yielding rates of 97.5% at 3 months, 92.5% at 6 months, and 87.5% at 12 months. The Kaplan-Meier survival curve for the rate of freedom from re-thrombosis during the 12-month follow-up period is presented in Figure 1.

Discussion

The current study aimed to evaluate the procedural feasibility, safety, and mid-term results of a standardized stent-free PMT-CDT approach for patients with acute

Table 1. Baseline demographic and clinical characteristics of patients with acute iliofemoral DVT (n=50)

Variable	Value
Age, years	55.0±13.8
Male sex	28 (56.0%)
Symptom duration, days	6.5±3.7
Hypertension	19 (38.0%)
Diabetes mellitus	15 (30.0%)
Smoking	15 (30.0%)
Recent major surgery	8 (16.0%)
Malignancy	5 (10.0%)
Hypercoagulable state	4 (8.0%)
Limb swelling	47 (94.0%)
Limb pain	46 (92.0%)
Phlegmasia	3 (6.0%)
Left-sided DVT	30 (60.0%)
Right-sided DVT	19 (38.0%)
Bilateral DVT	1 (2.0%)
Common iliac vein involvement	28 (56.0%)
External iliac vein involvement	20 (40.0%)
Femoral vein involvement	50 (100%)
Inferior vena cava involvement	1 (2.0%)

DVT: Deep vein thrombosis

iliofemoral DVT. The key results of this study show that it has a high success rate, low rates of bleeding complications, and favorable midterm outcomes in carefully selected patients.

One of the most debated issues in the management of iliofemoral DVT with endovascular techniques is the role of venous stenting after removal of thrombi. Although stenting is generally recommended in situations with fixed iliac vein obstruction or with significant residual stenosis, the routine use of stenting still remains debatable[9-11]. Various concerns have been raised about the long-term patency of stents, in-stent restenosis, and the need for further interventions. In the present study, stenting of the veins was not performed because the completion venogram did not show any hemodynamically significant iliac vein obstruction after removal of the thrombi. These findings suggest that a stent-free strategy may also be possible in selected patients after proper removal of thrombus.

Table 2. Procedural and clinical outcomes of stent-free PMT-CDT strategy (n=50)

Variable	Value
Hospital stay, days	3.5±1.0
ICU stay, days	1.3±0.6
Technical success	46 (92.0%)
Adjunctive balloon angioplasty	4 (8.0%)
Venous stent implantation	0 (0%)
Minor bleeding complications	5 (10.0%)
Hematuria	3 (6.0%)
Access-site hematoma	2 (4.0%)
Major bleeding	0 (0%)
Loss to follow-up	5 (10.0%)
Freedom from re-thrombosis at 3 months*	97.5%
Freedom from re-thrombosis at 6 months*	92.5%
Freedom from re-thrombosis at 12 months*	87.5%

**Estimated using Kaplan-Meier analysis*
ICU: Intensive care unit, PMT-CDT: Pharmacomechanical thrombectomy with catheter-directed thrombolysis

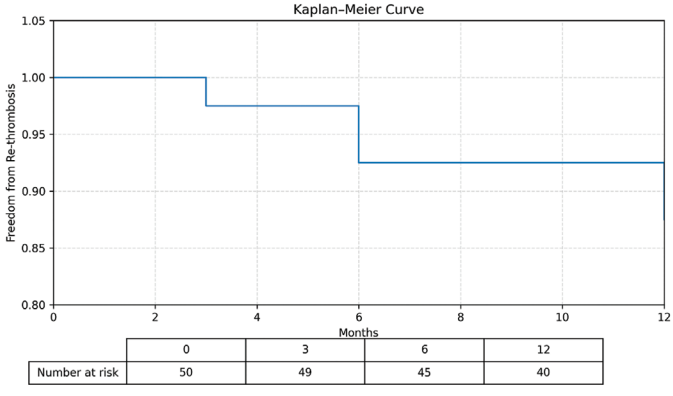

Figure 1. Kaplan-Meier curve of freedom from re-thrombosis at 12 months following stent-free PMT-CDT for acute iliofemoral DVT. Numbers at risk are displayed at 0, 3, 6, and 12 months
DVT: Deep vein thrombosis, PMT-CDT: Pharmacomechanical thrombectomy with catheter-directed thrombolysis

Increasing data suggest that a selective, anatomy-based method of venous stenting may be more advisable than the routine use of stenting following thrombus removal[12]. The rationale for the selective method is to avoid unnecessary stenting in patients without significant underlying obstruction of the iliac veins. In the current series, the restoration of venous flow was considered sufficient following PMT and CDT.

PMT in combination with CDT has also been postulated as a novel hybrid technique that may help in the acceleration of thrombus removal and reduction in the overall thrombolytic use and treatment time when compared to CDT alone[13]. PMT in combination with CDT may help accelerate thrombus removal and improve venous patency in a select group of patients with acute iliofemoral DVT. Notably, PTS may develop in patients even in the absence of recurrent thromboembolic events; hence, the lack of assessment of PTS in the current study makes it difficult to evaluate overall patient benefits.

In addition, previous studies of PMT systems have indicated satisfactory safety of the procedure and low rates of major bleeding complications[14]. Similar to the findings of this study, no major bleeding complications were noted. The minor bleeding complications were conservatively managed without the need for further intervention. Another factor which might have an effect on the long-term results of endovascular treatment of DVT is the anticoagulant therapy used during follow-up[15]. Similar to the results of this study, in which patients

received guideline-concordant anticoagulant therapy, the therapy may have contributed to the satisfactory mid-term rates of freedom from re-thrombosis.

Some limitations of the current study need to be acknowledged. First, the single-center retrospective design of the current study may limit the external validity of the data. Second, the relatively small number of patients limited the ability to perform multivariable modeling to identify independent predictors of re-thrombosis. During the study period, intravascular ultrasound was not commonly used; thus, underlying iliac vein compression syndromes, such as May-Thurner syndrome, may have been undertreated based on venography alone. Temporary IVC filters were commonly used during the study period because of the high thrombus burden and risk of embolization associated with PMT. However, the use of IVC filters is a contentious issue.

On the one hand, loss to follow-up was observed in a minority of patients observed in a minority of patients, which may have affected the Kaplan-Meier estimates of freedom from re-thrombosis. On the other hand, PTS was not evaluated using established clinical scoring tools, which may have influenced the evaluation of long-term functional outcomes. Despite these limitations, the present study provides valuable insights into the effectiveness of a standardized, stent-free strategy combining PMT and CDT in patients with acute iliofemoral DVT. The study results suggest that stent-free PMT combined with CDT may lead to satisfactory outcomes in terms of thrombus removal and mid-term patency rates in carefully selected patients. However, these results must be interpreted with caution, as they may not provide concrete evidence of the effectiveness of stent-free PMT-CDT in patients with acute iliofemoral DVT; rather, they may generate a hypothesis that can be tested in prospective studies.

Future prospective studies, including a standardized imaging evaluation, assessment of PTS, and a higher number of patients, are needed to clearly delineate the role of stent-free PMT-CDT.

Study Limitations

This study has several noteworthy limitations. Included among these is the fact that the study was performed retrospectively at a single center, which increases the risk of selection bias. The relatively low number of patients limited the capacity for risk analysis of re-thrombosis. Because intravascular ultrasound was not performed, venography alone carried a risk of failing to detect mild forms of iliac vein compression, such as May-Thurner syndrome. Because temporary IVC filters were used routinely during the study, the results may not be universally applicable. Because a minority of patients were lost to follow-up, there was a risk that Kaplan-Meier estimates of time to re-thrombosis were influenced by attrition bias. The PTS was not formally assessed using a validated clinical score (such as the Villalta score), which limited the capacity to assess the long-term functional outcomes of the research.

Conclusion

In this study, a standardized, stent-free PMT combined with CDT was used and found to be feasible and safe for the treatment of selected patients with acute iliofemoral in this study, a standardized, stent-free PMT combined with CDT was used and found to be feasible and safe for the treatment of selected patients with acute iliofemoral DVT. However, the study should be viewed with caution due to its descriptive nature, small sample size, and lack of a standardized method for assessing patient outcomes. Further studies are recommended to fully establish the role of PMT in the treatment of iliofemoral DVT.

Ethics

Ethics Committee Approval: Ethical approval for the study was obtained from the Ordu University Clinical Research Ethics Committee (approval no: 2020/225; date: 27.10.2020).

Informed Consent: Informed consent was not required for this retrospective study.

Footnotes

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