

# Combined Aspiration–Maceration Thrombectomy with Catheter-Directed Thrombolysis for Proximal Lower Limb DVT: A Prospective Study

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## ABSTRACT

**Background:** Deep vein thrombosis (DVT) contributes significantly to morbidity and mortality despite standard anticoagulation. Endovascular therapies, including catheter-directed thrombolysis (CDT) and pharmacomechanical thrombectomy, aim to expedite thrombus clearance and reduce post-thrombotic syndrome (PTS). However, trials like CaVenT and ATTRACT have shown mixed efficacy.

**Aim:** To evaluate a hybrid technique combining aspiration–maceration thrombectomy with CDT in acute and subacute proximal lower limb DVT and to compare outcomes between the two groups.

**Methods:** In this single-centre prospective study, 67 patients with acute or subacute proximal lower limb DVT underwent aspiration–maceration thrombectomy with catheter-directed Tenecteplase infusion. IVC filters and venous stents were used when indicated. Recanalization was graded using Society of Interventional Radiology (SIR) criteria. Outcomes included pain, limb edema, PTS (Villalta score), and VEINES-QOL scores.

**Results:** Post-procedure, 98.5% of patients had SIR Grade II/III thrombus removal; 63% achieved complete (Grade III) lysis. At 3 months, 91% had full recanalization on ultrasound. Acute DVT patients had better outcomes than subacute: 81% vs 40% achieved initial complete lysis ( $p<0.01$ ), and all acute DVT cases vs 80% subacute achieved full recanalization at 3 months ( $p=0.006$ ). Mean VAS pain score reduced from 7.1 to 1.0 ( $p<0.001$ ). Limb edema resolved in 69% by 3 months. VEINES-QOL scores improved from 43 to 92. Only 7 patients (10.4%) had mild/moderate PTS.

**Conclusions:** This low-cost, combined aspiration–maceration thrombectomy with CDT achieved rapid and durable recanalization with significant symptom relief and low PTS incidence, especially in acute DVT. It offers a safe, effective alternative for early DVT intervention

**KEYWORDS:** Deep vein thrombosis, Catheter-directed thrombolysis, Aspiration thrombectomy, Mechanical maceration, Venous recanalization, Post-thrombotic syndrome, Tenecteplase, Endovascular intervention

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## INTRODUCTION

Deep vein thrombosis (DVT), a subset of venous thromboembolism (VTE) alongside pulmonary embolism (PE), remains a major global cause of morbidity and mortality. It is primarily driven by Virchow's triad: venous stasis, endothelial injury, and hypercoagulability [1–3]. DVT in the lower limbs may propagate or embolize to the lungs [2,4]. Even with anticoagulation, thrombus-related inflammation often damages venous valves, leading to chronic venous hypertension and post-thrombotic

syndrome (PTS), characterized by pain, swelling, and skin changes [5–7].

The annual incidence of VTE is 1–2 per 1000 persons, rising with age [1–3]. Indian hospital data suggest symptomatic VTE in ~0.2% of admissions, often in younger individuals than seen in Western populations [8]. Major risk factors include immobilization, surgery, trauma, cancer, pregnancy, hormonal therapy, age, obesity, and thrombophilias (e.g., factor V Leiden, APLA) [8,9]. Many proximal DVTs are asymptomatic; symptoms, when present, include unilateral limb swelling and pain, but are nonspecific [3,9,10]. Diagnosis relies on duplex ultrasonography, with ~97% sensitivity and ~98% specificity [11,12]. CT or MR venography may be needed for pelvic or IVC-level clots [10–13].

Anticoagulation remains the cornerstone of treatment [14–16], yet fails to remove thrombus directly, resulting in PTS in up to 60% of cases. Open thrombectomy is rarely used today due to high morbidity [16,17]. Catheter-directed thrombolysis (CDT) provides faster clot resolution and allows simultaneous venoplasty or stenting but carries a 3–5% risk of major bleeding [6,18].

Pharmacomechanical thrombectomy aims to reduce thrombus burden more rapidly [18–20]. However, major trials (CaVenT, ATTRACT) have shown inconsistent PTS reduction [21]. In India, high-cost thrombectomy devices are less accessible. We hypothesized that a low-cost hybrid technique manual aspiration, pigtail maceration, and Tenecteplase-based CDT using standard catheters could achieve effective clot removal. This study evaluated its efficacy and safety in acute and subacute proximal lower limb DVT.

## MATERIALS AND METHODS

**Study Design and Setting:** This was a single-center, prospective observational study conducted in the Department of Interventional Radiology, J. N. Medical College & KLES Dr. Prabhakar Kore Hospital, Belagavi, India, from January 2024 to May 2025. Ethical approval was obtained, and written informed consent was secured from all participants.

**Inclusion/Exclusion Criteria:** Adults aged 18–75 years with imaging-confirmed acute ( $\leq 14$  days) or subacute (15–28 days) proximal lower limb DVT were enrolled. Exclusions included chronic DVT, contraindications to thrombolysis, prior DVT interventions in the same limb, contrast allergy, advanced renal failure, or inability to consent. A total of 67 patients were recruited using universal sampling.

**Endovascular Procedure:** Patients with ilio caval thrombus received temporary IVC filters before thrombectomy. Access was obtained via the popliteal vein under ultrasound guidance. Thrombosed segments (~10 cm each) were treated sequentially with:

Manual aspiration using an 8 Fr guiding catheter

Mechanical maceration using a 5 Fr pigtail catheter

Local Tenecteplase infusion (2 mg/segment)

Repeat aspiration after 10-minute dwell time

Balloon maceration was used for ilio-caval junction thrombus. A total of 10 mg Tenecteplase was given during lacing. Subsequently, a multi-side-hole infusion catheter delivered Tenecteplase at 0.5 mg/hour for 24 hours, alongside IV heparin.

**Post-Procedure Care:** Following thrombolysis, repeat aspiration and venogram were done. Venous stenting was performed for May–Thurner syndrome. Anticoagulation included vitamin K antagonists (for APLA) or DOACs (Rivaroxaban/Apixaban).

**Follow-Up and Outcomes:** Patients were assessed at discharge, 15 days, 1 month, and 3 months. Outcomes included:

Venous recanalization (SIR grade, Venous Registry Index)

Pain (VAS), edema (tape measurement), PTS (Villalta score), and VEINES-QOL

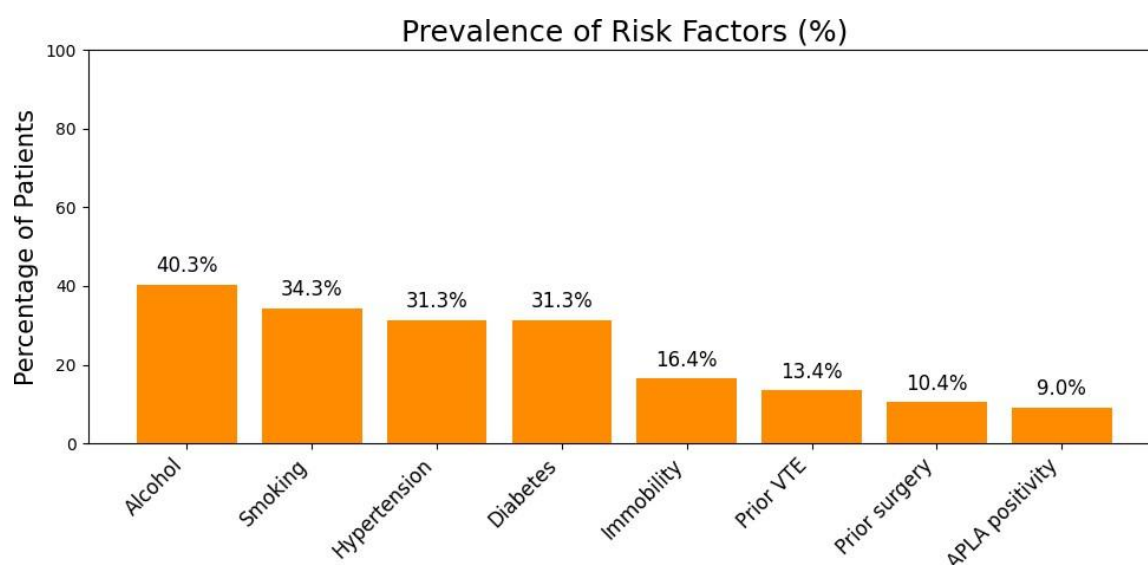
**Statistical Analysis:** Descriptive statistics were used. Comparative tests included t-tests, chi-square/Fisher's test, Wilcoxon/Mann–Whitney U test, and repeated-measures ANOVA. A p-value  $< 0.05$  was considered significant.

## RESULTS AND OBSERVATIONS

### Baseline Characteristics

A total of 67 patients with proximal lower-extremity DVT were included, with a mean age of  $46.9 \pm 16.5$  years (range 20–75), and a male predominance (64.2%). Over half of the cohort was under 50 years, indicating a younger affected population. The average BMI was  $27.5 \pm 4.8$  kg/m<sup>2</sup>, with about one-third classified as overweight or obese (BMI  $\geq 25$ ). Common risk factors included alcohol use (40.3%), smoking (34.3%), systemic hypertension (31.3%), and type 2 diabetes mellitus (31.3%). Less frequent but notable were histories of prolonged immobility (16.4%), recent surgery

within one month (10.4%), and previous VTE events (13.4%). Thrombophilia screening revealed antiphospholipid antibody positivity in 9% and hyperhomocysteinemia in 41.8% of patients. These findings reflect a diverse set of acquired and inherited risk factors contributing to thrombus formation in a relatively young Indian DVT population.



**Fig.2 – Bar chart showing prevalence of risk factors in the patients included in our study**

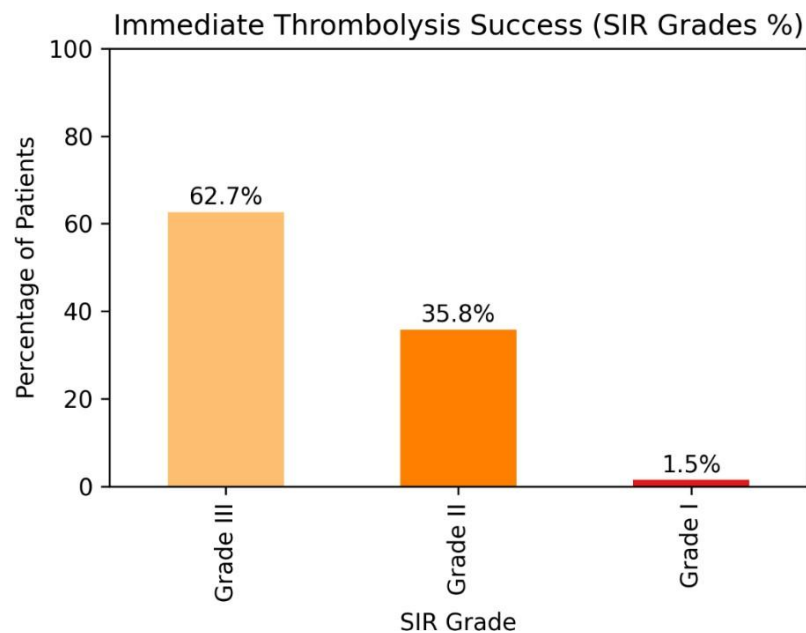
All 67 patients presented with classical features of proximal lower-limb DVT, including leg pain and swelling, with 100% reporting calf or thigh pain and significant limb edema. The mean baseline pain score was  $7.1 \pm 0.8$  on the VAS, indicating severe pain. Clinical signs such as calf tenderness, superficial vein distension, and a positive Homan's sign were common. Edema severity varied: 25.4% had swelling up to the knee, 56.7% up to the mid-thigh, and 17.9% up to the groin, consistent with iliofemoral involvement. A few patients with iliofemoral DVT had limb cyanosis, though none developed phlegmasia cerulea dolens.

Left-sided DVT was more prevalent (58.2%) than right-sided (41.8%), and May–Thurner syndrome was identified in 9 patients (13.4% overall). Four patients (6%) had concomitant pulmonary embolism at presentation. Based on symptom duration, 55% had acute DVT ( $\leq 14$  days), while 45% had subacute DVT (15–28 days). Ultrasound findings showed hypoechoic, non-compressible thrombi in acute cases, while older clots were more echogenic. A strong positive correlation (Spearman  $\rho \approx 0.87$ ,  $p < 0.001$ ) was observed between thrombus echogenicity and symptom duration.

Anatomically, 41.8% had femoropopliteal involvement, 44.8% had iliac extension, and 13.4% had IVC involvement. Routine ultrasound had limited sensitivity for proximal extension, missing ~21% of iliac and ~44% of IVC thromboses. CT venography showed 100% concordance with conventional venography. Baseline median Wells score was 3 (high probability), median HAS-BLED score was 0 (low bleeding risk), and median CHA<sub>2</sub>DS<sub>2</sub>VASc score was 3. All patients had preserved renal and hepatic function suitable for thrombolysis.

## TREATMENT OUTCOMES

All 67 patients underwent combined aspiration–maceration thrombectomy with catheter-directed thrombolysis (CDT), achieving high technical success. Immediate post-procedure venography showed  $\geq$  SIR Grade II recanalization in 98.5% of cases, with complete thrombus clearance (SIR Grade III) in 62.7% and partial clearance (Grade II) in 35.8%. Only one patient (1.5%) had limited clearance (Grade I). The mean luminal patency, as per the Venous Registry Index, was  $92.7\% \pm 8.7$ . In all cases, flow restoration was confirmed by duplex ultrasound, which showed previously non-compressible veins becoming compressible with restored Doppler signals, indicating effective early thrombus removal.

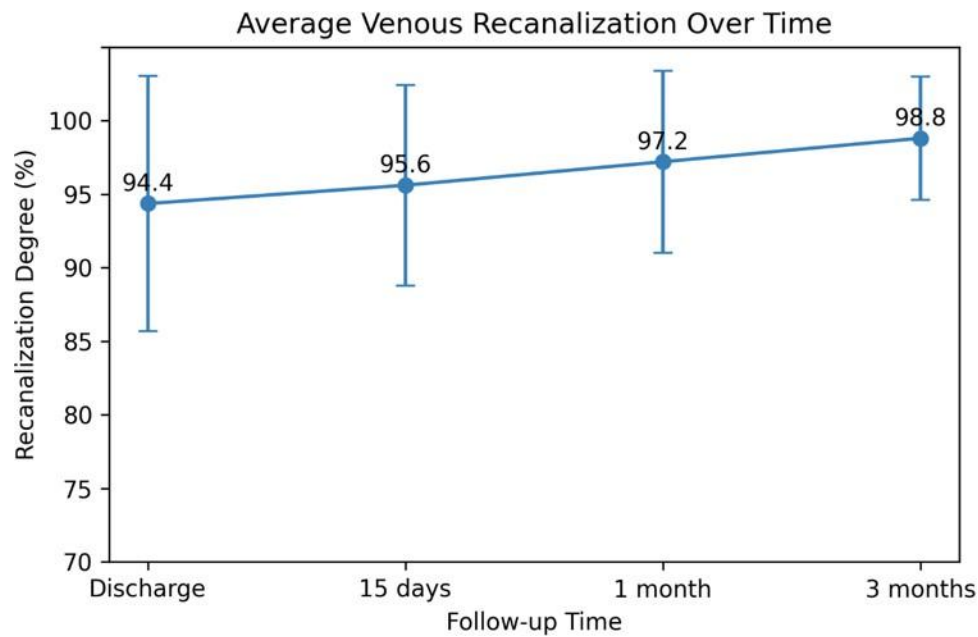


**Fig.3 – Bar chart showing immediate thrombus removal in terms of SIR grades of thrombolysis in the patients included in our study**

Clinically, patients showed rapid symptomatic relief following the intervention. By hospital discharge (typically on day 2), the mean VAS pain score had significantly reduced from 7.1 at baseline to  $4.8 \pm 0.4$ , indicating substantial pain improvement. Although all patients continued to have some residual edema, it was notably softer and less extensive compared to presentation. Importantly, no patient experienced worsening or new-onset swelling post-procedure.

#### **Venous Recanalization Over Time**

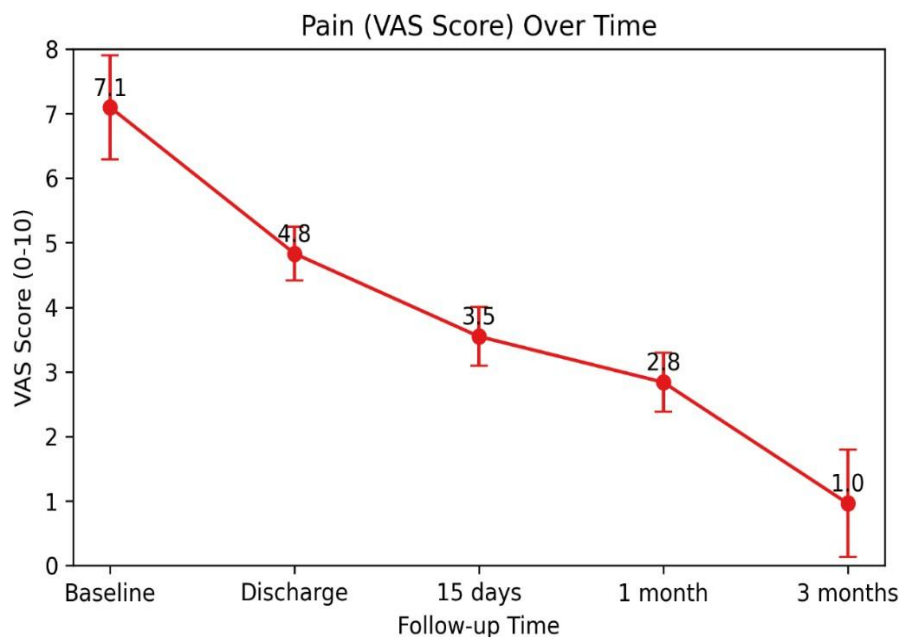
Duplex ultrasound follow-up demonstrated progressive and sustained improvement in venous patency over time. At discharge (day ~2), mean patency was approximately 93%, with complete recanalization in 61.2% of patients; the remainder showed minimal residual thrombus (SIR Grade II). By 15 days, mean lumen patency improved to  $95.6\% \pm 6.8$ , with 65.7% achieving full recanalization and no cases of re-occlusion. At one month, patency further increased to  $97.2\% \pm 6.2$ , and 79.1% of patients had 100% clearance. By three months, average patency reached  $98.8\% \pm 4.2$ , with 91% of patients showing complete recanalization and only 9% having minor residual thrombi (patency  $>80\%$ ). No instances of re-thrombosis were observed throughout follow-up. The improvement in patency from discharge to 3 months was statistically significant ( $p < 0.001$ ), confirming the durable effectiveness of the intervention.



**Fig.4 – Line graph (with range) showing venous recanalization (based on Venous Registry Index) achieved over time in our study**

#### Symptom Relief and Clinical Outcomes

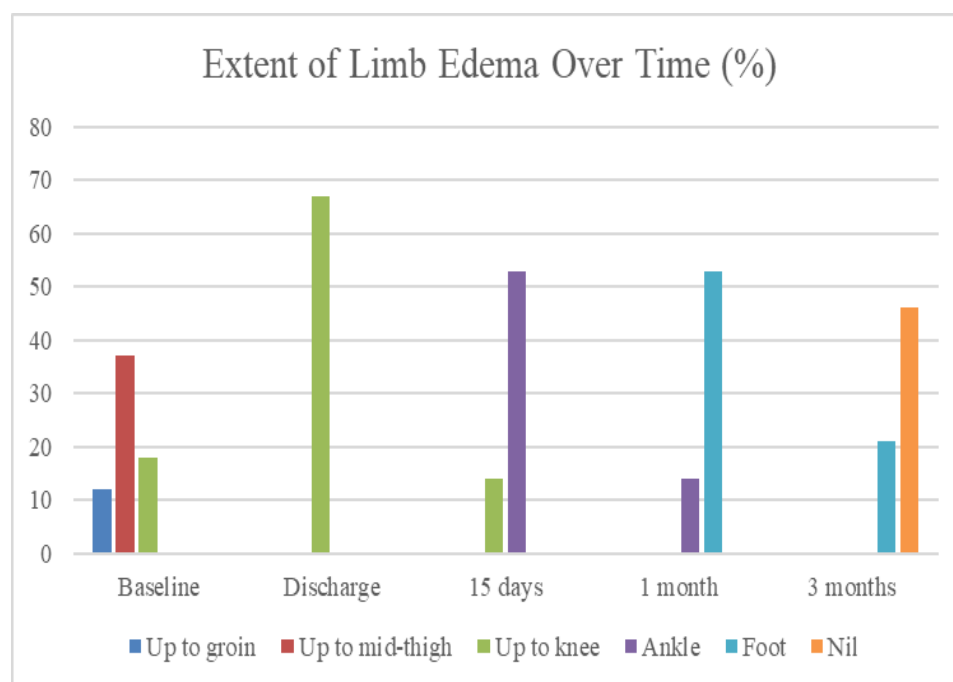
Pain levels showed a marked and sustained reduction following the intervention. The mean VAS score decreased from 7.1 at baseline to 4.8 at discharge,  $3.5 \pm 0.5$  at 15 days,  $2.8 \pm 0.5$  at 1 month, and reached  $1.0 \pm 0.8$  by 3 months. This trend was statistically significant ( $p < 0.001$ , repeated-measures ANOVA). By the 3-month follow-up, 93% of patients reported minimal or no pain ( $VAS \leq 1$ ). The average reduction in VAS exceeded 6 points (95% CI: 5.8–6.4;  $p < 0.001$ , paired t-test). Most patients who initially required analgesics were no longer on pain medication by the end of follow-up.



**Fig.5 – Line graph (with range) showing reduction in pain scores (VAS) achieved over time in our study**

## Limb Edema:

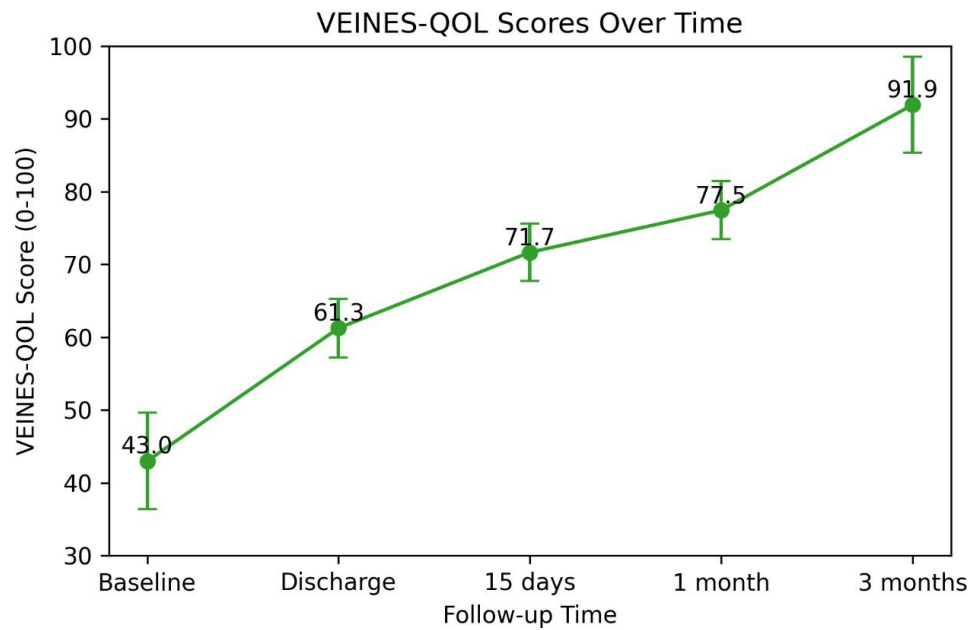
Edema showed gradual but consistent improvement following intervention. At discharge and through the first two weeks, all patients had residual swelling, though it was noticeably softer and less extensive. By 15 days, the severity had regressed, with previously groin-level edema typically limited to the calf. At 1 month, edema persisted in all patients but was confined to the distal leg (foot or ankle), with no cases of thigh or groin swelling. By 3 months, 46 patients (68.7%) had complete resolution of edema, and the remaining 21 (31.3%) had only mild residual swelling at the ankle or foot, without functional limitation. The overall reduction in edema from 100% at baseline to 31% at 3 months was statistically significant ( $p < 0.001$ , McNemar's test). Additionally, calf tenderness, present in all patients initially, resolved completely by day 15 in all cases.



**Fig.6 – Clustered column chart showing extent of limb edema over time in our study**

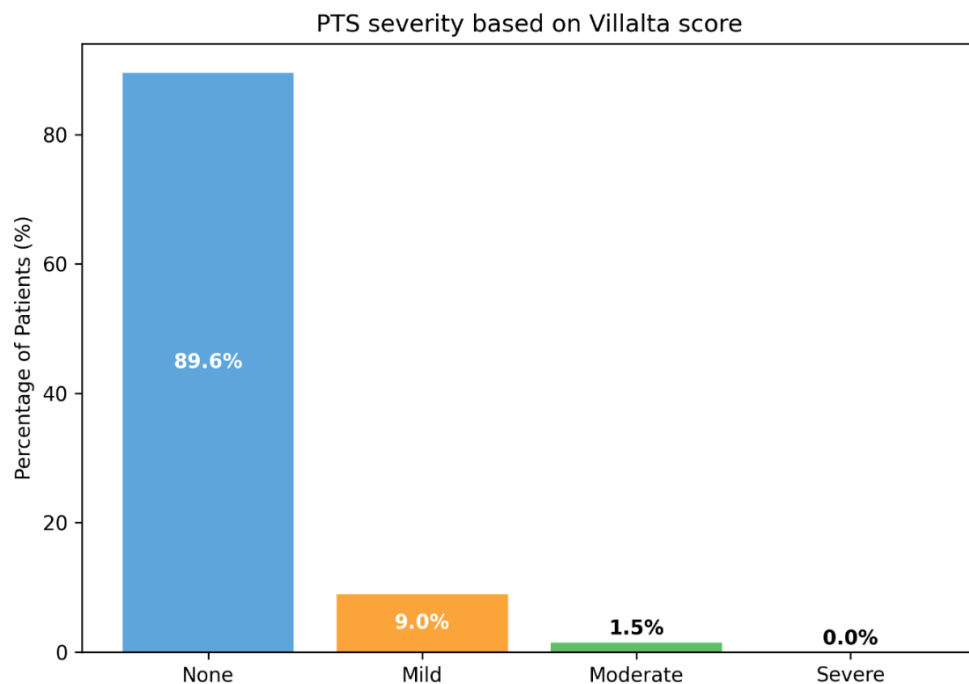
Objective measurements confirmed a significant reduction in limb edema over time. At baseline, the mean mid-calf circumference was  $36.5 \pm 0.6$  cm and mid-thigh circumference was  $56.7 \pm 2.0$  cm. By 3 months, these reduced to  $34.0 \pm 0.5$  cm and  $51.8 \pm 1.5$  cm respectively. This corresponds to a mean decrease of 2.6 cm at the calf and 4.9 cm at the thigh (both  $p < 0.001$ ), with statistically significant reductions observed at every follow-up point (pairwise  $p < 0.001$ ).

Quality of life, assessed using the VEINES-QOL questionnaire, also improved markedly. The mean score increased from  $43.0 \pm 6.6$  at baseline to 61.3 at discharge, 71.7 at 15 days, 77.5 at 1 month, and  $91.9 \pm 6.6$  by 3 months. The total mean improvement of nearly 49 points was highly significant ( $p < 0.001$ ), indicating substantial recovery in patient-reported wellbeing. The greatest gain occurred within the first two weeks post-procedure, with continued improvement thereafter, reflecting both symptomatic and functional recovery.



**Fig.7 – Line graph (with range) showing quality of life (VEINES-QOL score) over time in our patients**

At 3 months, the incidence of post-thrombotic syndrome (PTS) was low. The mean Villalta score was  $1.5 \pm 2.1$ , with a median of 1 (range 0–12). Only 7 patients (10.4%) met the criteria for PTS (Villalta  $\geq 5$ ), of whom 6 had mild symptoms and 1 had moderate PTS (score of 12). No patient developed severe PTS ( $\geq 15$ ) or venous ulcers. A significant inverse correlation was observed between the extent of vein recanalization and Villalta scores (Spearman  $\rho = -0.394$ ,  $p = 0.001$ ), indicating that patients with incomplete recanalization tended to have higher PTS scores, while those with complete thrombus clearance reported minimal or no PTS symptoms.



**Fig.8 – Bar chart showing PTS severity at the end of 3 months in our study**

#### Subgroup Analysis: Acute vs. Subacute DVT

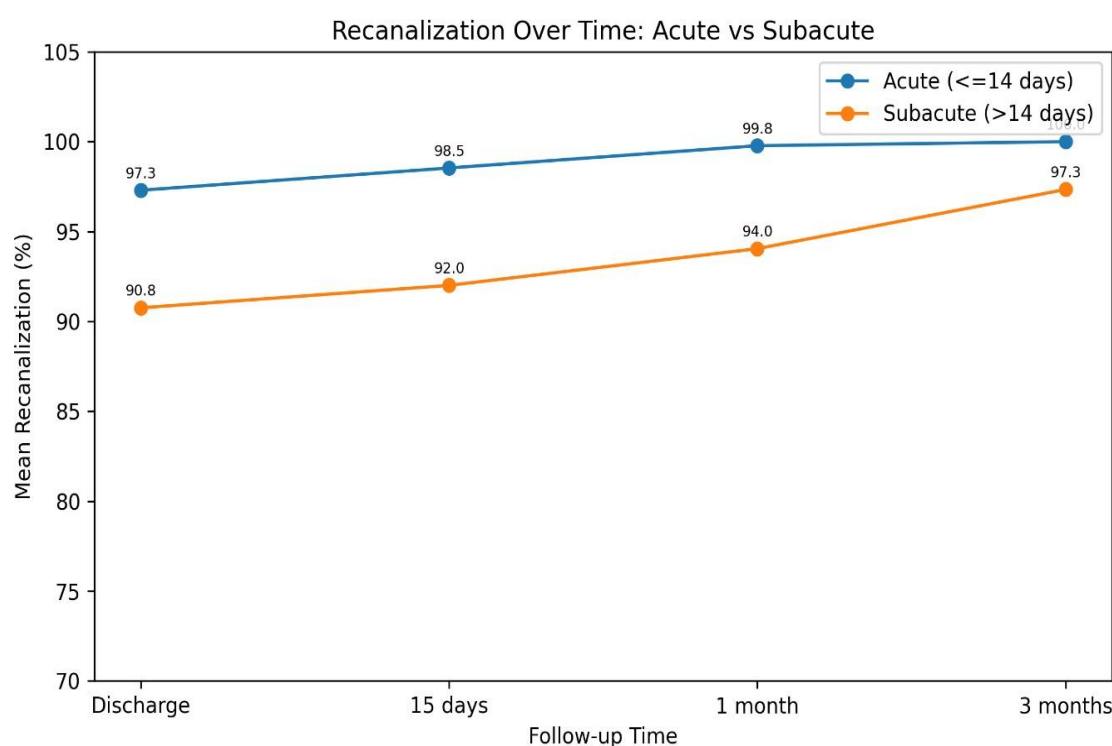
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Patients with acute DVT ( $n = 37$ ) demonstrated significantly better immediate thrombus clearance than those with

subacute DVT (n = 30). On post-procedure venography, 81% of acute cases achieved complete thrombolysis (SIR Grade III) compared to only 40% of subacute cases (p = 0.002). Subacute patients more frequently had residual clot, with 60% achieving only Grade I or II, versus 19% in the acute group. The median immediate luminal patency was 100% in acute DVT (mean ~96.6%) versus 87.5% in subacute DVT (mean ~87.9%, p =  $2 \times 10^{-4}$ ).

At 3-month follow-up, complete recanalization was achieved in all acute DVT patients (100%), compared to 80% in subacute cases. The remaining 20% of subacute patients had minor residual thrombi (80–95% patency), with no such cases in the acute group (p = 0.006). Mean patency at 3 months was slightly higher in the acute group (virtually 100%) compared to subacute (~97.3%).

Clinically, 3-month PTS occurred in 5% of acute cases (2/37) and 17% of subacute cases (5/30). Mean Villalta scores were lower in acute (1.2) than subacute (1.9) patients. Though both groups showed improvement, subacute cases had slightly higher VAS pain scores and more residual edema in early follow-ups. Notably, all patients with residual thrombus or PTS at 3 months belonged to the subacute group.



**Fig.9 – Line graph showing the relation of DVT chronicity to recanalization over time in our study**

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## DISCUSSION

**Patient Profile** The mean age (~47 years) and male predominance (64%) are similar to the ATTRACT and CaVenT trials, though our cohort skewed slightly younger, consistent with Indian data. Notably, hyperhomocysteinemia was present in 42% far higher than the 10–15% seen in Western studies likely due to nutritional deficiencies. Comorbidities such as hypertension and diabetes were present in ~31%, suggesting a metabolic contribution to thrombosis. May–Thurner syndrome was found in 23% of left-sided DVTs, highlighting the importance of recognizing anatomical factors.

**Efficacy of Combined Therapy** The hybrid technique achieved excellent outcomes, with 63% complete lysis and >98% partial or better clearance immediately post-procedure. By 3 months, 91% achieved full recanalization. These rates surpass those in CaVenT and ATTRACT trials, likely due to our multimodal approach using aspiration, maceration, and Tenecteplase-based CDT. Symptom relief was rapid and sustained, and VEINES-QOL scores (~92) at 3 months were higher than those reported in other trials.

**PTS Prevention** Only 10% of patients developed mild-to-moderate PTS by 3 months, significantly lower than the 20–50% seen with anticoagulation alone. Mean Villalta score (~1.5) was also much lower than in historical controls. This supports the notion that near-complete thrombus clearance may attenuate venous hypertension and preserve valve function, thereby reducing early PTS.

**Safety** Our protocol, using moderate-dose Tenecteplase (0.5 mg/hr), resulted in one major bleed (1.5% ICH), comparable to ATTRACT (1.7%). No deaths or surgical interventions occurred. However, 10% required transfusion, underscoring the need for careful monitoring. Overall, the safety profile was acceptable, with meaningful clinical benefit outweighing the bleeding risk.

**Acute vs Subacute DVT** Outcomes were significantly better in acute cases. Complete lysis occurred in 81% of acute vs 40% of subacute patients. All acute cases had full recanalization by 3 months, compared to 80% in subacute. Subacute cases also had more residual thrombus, symptoms, and PTS. These findings emphasize the importance of early intervention within the first two weeks of symptom onset.

**Cost and Resource Considerations** This technique avoided costly thrombectomy devices and relied on standard, low-cost equipment and Tenecteplase. The average dose used (~22 mg) was lower than that for MI. Outcomes were comparable to device-based interventions but at significantly reduced cost and hospital stay (3–5 days), making it ideal for resource-limited settings.

**Limitations** The study was single-center and lacked a non-intervention control group, limiting generalizability and direct comparisons to anticoagulation-only treatment. Nevertheless, the high success rates and low PTS incidence suggest the approach is effective and worthy of broader evaluation.

## CONCLUSION

Combined aspiration–maceration thrombectomy with catheter-directed thrombolysis was found to be a safe, effective, and economical treatment for acute and subacute proximal lower limb DVT. The hybrid technique resulted in rapid and sustained venous recanalization, with significant relief of pain and edema, and a notably low short-term incidence of post-thrombotic syndrome. Importantly, the complication rate remained minimal. These outcomes highlight the value of early, aggressive intervention in preserving venous function and enhancing quality of life. Given its cost-effectiveness and accessibility, this approach is especially promising for use in resource-limited settings and in patients presenting within the early phase of DVT. Larger studies with extended follow-up are needed to validate these findings and support wider adoption of combined pharmaco-mechanical therapy as a standard treatment for proximal DVT.

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