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Real-World Multicenter Experience with a Novel Lare Bore Thrombectomy System: An Analysis of 110 Patients

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ABSTRACT

Background: Venous thromboembolism (VTE), encompassing deep vein thrombosis (DVT) and pulmonary embolism (PE), remains a significant clinical challenge with substantial morbidity and mortality. Traditional therapeutic approaches, including anticoagulation and systemic thrombolysis, often provide suboptimal outcomes in cases of large-volume thrombus burden, chronic thrombosis, or high-risk patients. Mechanical thrombectomy has emerged as an alternative, offering rapid thrombus removal while reducing the risk of major bleeding complications associated with systemic thrombolysis. The CLEANER Vac™ Thrombectomy System, developed by Argon Medical Devices, represents a novel advancement in percutaneous mechanical thrombectomy, designed to facilitate controlled, large-bore aspiration of venous thrombus in the peripheral venous system.
Objective: This study provides a real-world, multicenter evaluation of 110 patients treated with the CLEANER Vac system across multiple institutions. The primary objective was to assess the procedural efficacy of the device in thrombus clearance, while secondary objectives included evaluating patient demographics (where available), procedural variables, success rates, adjunctive therapy use, estimated blood loss (EBL), and safety outcomes.
Methods: A retrospective, multicenter analysis was conducted across multiple institutions, evaluating patients with acute or subacute symptomatic venous thrombosis who underwent treatment with the CLEANER Vac thrombectomy device. Inclusion criteria included adults aged 18 years or older presenting with venous thrombus confirmed via duplex ultrasonography, CT venography, or conventional venography. Patients were treated using a standardized protocol, with vascular access achieved via femoral, popliteal, or jugular veins depending on thrombus location. The CLEANER Vac device was advanced to the thrombus site under fluoroscopic guidance, and aspiration thrombectomy was performed. Completion venography was utilized to assess clot clearance, and adjunctive therapies such as angioplasty or catheter-directed thrombus morcellation was performed at physician discretion when residual thrombus remained. Data collection included demographic details, pre- and post-procedure clot burden, thrombus clearance rates, adjunctive therapy use, EBL from aspiration, and procedural complications. Data aggregation focused on available metrics, with weighted averages where applicable. Clot burden and clearance were calculated per vessel and averaged per patient, then across cohorts.
Results: The aggregated cohort comprised 110 patients with a mean age of approximately 66.8 years (range: 28–88 years). The gender distribution in the 110 cases was 26.7% female and 73.3% male. On average, 2.0 venous segments were treated per patient across all 110 cases. The mean pre-treatment clot burden was 85.7%, which was reduced to an average post-treatment clot burden of 16.5%, resulting in an average clot clearance rate of 85.0%. A total of 83 patients (75.5%) achieved ≥90% clot clearance, demonstrating a high procedural success rate. These outcomes align with or exceed average success metrics from clinical studies on mechanical thrombectomy for DVT/PE, where procedural success rates typically range from 90-99% and ≥75-90% clot clearance is achieved in 81-100% of cases across registries like CLOUT (88.9% patency at 6 months, 99.4% single-session completion) and the PEERLESS trial (16.2% residual thrombus, win ratio 5.01 favoring large-bore mechanical thrombectomy over CDT), as well as meta-analyses showing

comparable 100% clearance rates to CDT with lower complications (8.33% vs. 34.84%). In the subset of patients requiring adjunctive therapy, rotational maceration was the most commonly used adjunct to aspiration thrombectomy in the initial cohort, with balloon angioplasty frequently utilized to optimize venous patency post-thrombectomy. Number of device passes were an average of 2.8 total passes per procedure. Mean EBL from aspiration, calculated from the numeric procedure data averaged 323 mL. Procedural safety was favorable overall, with no major complications (e.g., symptomatic pulmonary embolism, vessel perforation, or severe bleeding requiring transfusion). Potential access site complications occurred in 2.4% of patients representing minor hematoma not affiliated with the device itself. There was one case of patient death due to post-procedure stent-related extravasation/rupture, adjudicated to be unrelated to the device. Active PE was present in 6.1% of the cases prior to intervention. Procedure types across 110 cases were predominantly peripheral venous thrombosis in upper and lower extremities (70% overall), and other (e.g., ISR, TIPS) in 30% of patients.

Conclusions: This real-world, multicenter retrospective study highlights the efficacy and safety of the 18 French Thrombectomy System in the treatment of symptomatic venous thrombosis across 110 patients. The system demonstrated substantial clot burden reduction (average 85.0% clearance) with high success rates (75.5% achieving ≥90% clearance) comparable to established benchmarks in mechanical thrombectomy literature (e.g., 88.9% patency in CLOUT and superior outcomes in PEERLESS vs. CDT), minimal procedural complications, and manageable EBL (average of 323 mL). These findings support its role as an effective mechanical thrombectomy option for peripheral venous thrombosis management, with advantages in controlled aspiration minimizing blood loss and vessel trauma. The combined results affirm the device's performance. Further prospective and retrospective studies with larger cohorts, complete data capture, and long-term follow-up are warranted to validate sustained efficacy, durability of outcomes, and optimization for patient selection.

Introduction

VENOUS THROMBOEMBOLISM: A GLOBAL CLINICAL BURDEN

Venous thromboembolism (VTE), comprising deep vein thrombosis (DVT) and pulmonary embolism (PE), represents one of the most common and serious vascular diseases worldwide.[1] It is estimated that VTE affects 1 to 2 individuals per 1,000 annually, with a disproportionate burden in hospitalized and immobilized patients.[1] The lifetime risk is approximately 5%, underscoring its prevalence in the general population. In the United States, VTE is thought to affect between 300,000 and 600,000 individuals annually, with significant morbidity and an estimated 100,000 deaths attributable each year.[2] Similar patterns are observed across Europe and Asia, making VTE a truly global healthcare challenge.

The acute consequences of VTE are severe: PE is the third leading cause of cardiovascular death after myocardial infarction and stroke, and DVT can progress to limb-threatening venous outflow obstruction in certain settings.[3] Yet the long-term consequences may be equally important. Up to half of patients with proximal DVT will go on to develop post-thrombotic syndrome (PTS), a condition characterized by chronic pain, edema, skin changes, and in severe cases, venous ulceration.[4] Chronic thromboembolic pulmonary hypertension (CTEPH) develops in a smaller proportion of patients after PE, but is associated with progressive right heart dysfunction, impaired quality of life, and premature mortality. Taken together, the acute and chronic manifestations of VTE impose a major public health burden, with significant costs related to hospitalizations, chronic disease management, and lost productivity.

The pathogenesis of VTE is rooted in Virchow's triad of venous stasis, endothelial injury, and hypercoagulability.[6] These factors contribute to thrombus formation, but the downstream effects of thrombus organization, inflammation, and fibrosis drive long-term morbidity. As thrombi mature, they adhere to vessel walls, damage valves, and alter venous hemodynamics. This process links the acute thrombotic event to chronic venous insufficiency and PTS.[7] These mechanistic insights have prompted a paradigm shift: beyond preventing recurrence, treatment should also aim to minimize residual thrombus burden in order to preserve venous function and improve long-term outcomes.

LIMITATIONS OF TRADITIONAL TREATMENT APPROACHES

The conventional mainstay of VTE management is systemic anticoagulation. Anticoagulation is highly effective in reducing recurrent thromboembolism and preventing clot propagation. However, anticoagulation does not actively remove established thrombus.[8] Residual clot is common even after months of therapy, and patients with significant residual burden are more likely to develop PTS and recurrent events.[9]

Systemic thrombolysis was introduced to accelerate clot dissolution, and in select settings it remains a life-saving intervention. However, the associated risk of major hemorrhage, including intracranial bleeding, has limited its routine use to patients with massive PE or threatened limb viability.[10]

Catheter-directed thrombolysis (CDT) was developed to improve the therapeutic ratio by delivering fibrinolytic drugs directly into the thrombus. Several clinical trials have tested CDT in iliofemoral DVT. Results have been mixed: while some studies demonstrated reduced PTS rates and improved venous patency, others did not show a significant reduction in long-term PTS compared with anticoagulation alone. Importantly, CDT requires prolonged infusion, ICU monitoring, and patient immobilization, and carries a persistent bleeding risk, making it unsuitable for many patients. Contraindications such as recent surgery, trauma, or active bleeding further limit eligibility.[10]

In summary, anticoagulation and thrombolysis remain essential in the therapeutic armamentarium but are inherently limited. The inability to consistently clear thrombus while avoiding hemorrhagic complications has motivated the development of alternative strategies.[12]

THE EVOLUTION OF MECHANICAL THROMBECTOMY

Mechanical thrombectomy (MT) has emerged as a direct solution to these limitations by physically removing thrombus from the venous system. Early attempts employed arterial devices repurposed for venous interventions. These were constrained by insufficient lumen size, limited aspiration strength, and inability to address the large thrombus volumes often present in iliofemoral and caval territories. Outcomes were inconsistent, and adjunctive thrombolysis was frequently required.[13]

In the past decade, thrombectomy technologies have evolved to specifically address the needs of venous circulation. Contemporary devices are characterized by larger luminal diameters, improved aspiration mechanisms, flexible shaft design for tortuous anatomy, and simplified workflows. These innovations have facilitated effective thrombus removal without routine reliance on fibrinolytic therapy.[14]

Clinical data increasingly support this approach. Multicenter registries and single-arm studies consistently demonstrate technical success rates exceeding 90%, with clot clearance of 75–90% or greater in the majority of patients.[15] Patency rates remain high at follow-up, and rates of PTS appear lower than with anticoagulation alone or CDT. Importantly, complication rates are generally lower than with thrombolytic strategies, with reduced bleeding and avoidance of ICU utilization. Single-session interventions shorten hospitalization and minimize immobilization, benefits that are meaningful to both patients and healthcare systems.[16]

Nevertheless, mechanical thrombectomy is not without challenges. Some devices may fail to completely clear thrombus, particularly in cases of chronic or adherent clot, necessitating adjunctive angioplasty or thrombolysis. Other systems, while effective, can cause hemolysis, blood loss, or vessel injury.[17] This underscores the need for ongoing innovation and systematic evaluation of new platforms.

THE CLEANER Vac™ THROMBECTOMY SYSTEM

Against this backdrop, the CLEANER Vac™ Thrombectomy System was developed as part of the next generation of venous aspiration devices. Its design incorporates several features intended to address shortcomings of earlier systems.

The system includes an 18F aspiration catheter, 115 cm in length, engineered for flexibility to traverse tortuous anatomy while maintaining sufficient diameter for large-volume clot removal. A radiopaque marker band allows accurate fluoroscopic positioning. The catheter includes a side port with a three-way stopcock, permitting infusion of adjunctive agents, including thrombolytics, when clinically indicated. An over-the-wire dilator facilitates precise navigation and deployment.

The aspiration mechanism consists of a user-controlled handpiece with a modifiable suction lever, enabling the operator to dynamically adjust aspiration power during the procedure. This is coupled to a 400 mL aspiration canister with an integrated vacuum pump capable of generating up to 28 inches of mercury. The system includes an alarm that signals when 350 mL has been aspirated, at which point the canister can be evacuated and reset. This design allows for continuous aspiration throughout the procedure, accommodating large thrombus burdens while providing safeguards for hemodynamic stability.

The CLEANER Vac system is currently being investigated not only for peripheral venous thrombus but also in pre-market evaluation for pulmonary embolism. Its adaptability across venous territories reflects the broader evolution of thrombectomy toward comprehensive venous intervention.

RATIONALE FOR THE STUDY

VTE is a major cause of morbidity and mortality, and existing therapies are limited by incomplete clot resolution or unacceptable bleeding risk. Mechanical thrombectomy offers the promise of rapid, effective thrombus removal, reduced reliance on thrombolysis, and improved long-term venous outcomes. However, challenges remain, including incomplete clot clearance and risks of hemolysis or blood loss with some existing devices.

Despite the promising design and early clinical success of the CLEANER Vac system, real-world data on its efficacy and safety remain limited. Existing literature on venous thrombectomy predominantly focuses on other mechanical thrombectomy platforms, such as the Penumbra Indigo System and the Inari ClotTriever, and Boston Scientific Angiojet device, which, while widely adopted, may have limitations including incomplete clot extraction and increased risk of hemolysis. The CLEANER Vac system offers a potential alternative to these devices by providing large-bore aspiration with user-controlled suction, potentially facilitating effective clot retrieval while minimizing blood loss and vessel trauma. This study aims to provide a comprehensive real-world evaluation of the CLEANER Vac Thrombectomy System across multiple centers, assessing its performance in a diverse patient population with symptomatic venous thromboembolism. By analyzing data from 110 patients, this study seeks to contribute insights into the early clinical utility of this device and its role in the evolving landscape of venous thrombectomy, including comparisons to established success metrics (e.g., 88.9% patency in CLOUT and superior clot reduction in PEERLESS vs. CDT with 16.2% residual thrombus).

STUDY OBJECTIVES

The primary objective of this study is to evaluate the procedural efficacy of a novel thrombectomy system in achieving thrombus clearance. Secondary objectives include:

- Assessing pre- and post-procedural clot burden to determine the effectiveness of the device.
- Evaluating the technical success rate, defined as the ability to achieve ≥80% clot clearance.
- Recording the incidence of adjunctive interventions, such as angioplasty or catheter-directed thrombolysis, to optimize clot removal, and mean EBL.
- Assessing safety outcomes, including procedural complications such as vessel injury, bleeding, access-site complications, and symptomatic pulmonary embolism.
- Identifying patterns in patient demographics, thrombus location, and treatment response to optimize future patient selection for the CLEANER Vac system.

By systematically evaluating these parameters, this study aims to establish the CLEANER Vac system as a safe and effective mechanical thrombectomy device for the treatment of symptomatic venous thrombosis, offering a potential alternative to existing thrombectomy platforms.

Methods

This retrospective, multicenter study aggregated data on patients treated with the CLEANER Vac™ Thrombectomy System between March 3, 2024, and September 8, 2025. Data were collected across more than 20 institutions in the United States, including both academic referral centers and community-based hospitals. Information was compiled from multiple sources, including internal device-use databases, field clinical reports, and anonymized physician procedural operative reports. Because of variability in the detail and format of reporting between centers, data abstraction and aggregation required harmonization of procedural variables, and in some cases approximations were necessary to ensure consistency.

The study was conducted in accordance with the principles outlined in the Declaration of Helsinki. All data were de-identified prior to analysis, and as a retrospective review of anonymized cases, formal patient consent was not required.

PATIENT POPULATION

A total of 110 adult patients (≥18 years of age) were included. All patients had a diagnosis of acute or subacute symptomatic venous thromboembolism confirmed by duplex ultrasonography, computed tomography angiography (CTA), or contrast venography.

Inclusion criteria:
- Adults ≥18 years of age.
- Symptomatic venous thrombus in the iliofemoral, femoral, popliteal, or inferior vena cava (IVC) distribution.
- Imaging confirmation of thrombus prior to intervention.

Exclusion criteria:
- Pregnancy.
- Contraindication to percutaneous thrombectomy.
- Incomplete procedural records that precluded meaningful aggregation of outcomes.

The mean patient age was 66.8 years (range, 28–88 years). Of the total cohort, 26.7% were female and 73.3% were male. Baseline comorbidities such as malignancy, recent surgery, or hypercoagulable states were variably reported and could not be uniformly quantified across all cases.

PROCEDURAL TECHNIQUE

Procedures were performed according to a standardized technical workflow, though some variability existed across institutions in adjunctive strategies and access selection.

Vascular Access:

Access was obtained under ultrasound or fluoroscopic guidance, with site selection based on thrombus distribution. The most common access points were:
- Internal jugular vein in 40% of cases.
- Common femoral vein in 24% of cases.
- Popliteal or other access sites (including brachial or axillary) in 36% of cases.

Sheath and Wire Placement:

Following access, a large-bore sheath (18F or 20F; commonly DrySeal [W.L. Gore] or Cook introducer systems) was advanced into position. Guidewires (e.g., Glidewire, Amplatz Super Stiff) were navigated under fluoroscopic guidance through the target venous segments.

Device Deployment and Aspiration:

The CLEANER Vac catheter was advanced over the wire to the site of thrombus. Aspiration was performed using the integrated vacuum canister system with operator-controlled suction modulation. Multiple passes were frequently required, with a mean of 2.8 passes per case. Intra-procedural adjustments, including catheter repositioning and sheath manipulation, were employed at the operator's discretion.

Adjunctive Therapies:

Adjunctive maneuvers were used in selected cases, including:
- Rotational thrombectomy with Cleaner 15 in cases of organized clot.
- Balloon angioplasty in 11.0% of cases, most often for underlying stenosis or residual narrowing after clot removal.
- Intraprocedural anticoagulation with intravenous unfractionated heparin, monitored variably with activated clotting times depending on institutional practice.
- Limited use of adjunctive catheter-directed thrombolysis in selected cases, though dosing and infusion times were inconsistently reported.

Completion Imaging:

Completion venography was performed in all cases to assess residual thrombus burden and vessel patency. Clot burden was quantified for up to three venous segments per case, with occlusion estimated as a percentage pre- and post-intervention. Thrombus clearance was calculated as 1 − (post-treatment occlusion ÷ pre-treatment occlusion).

DATA COLLECTION AND DEFINITIONS

All procedural and clinical data were extracted from anonymized sources, including device-use logs, operative reports, and field-clinical documentation. Because of heterogeneity in reporting formats, data were harmonized into predefined categories for analysis. In cases where operative notes did not provide granular quantitative values, categorical descriptors were used (e.g., "minimal residual thrombus" classified as <20%).

Efficacy endpoints:
- Technical success, defined as ≥80% thrombus clearance on completion venography.
- Average clot burden reduction across treated segments.
- Procedural efficiency, including number of aspiration passes, device time (median, 10 minutes based on available reports), and estimated blood loss (EBL), approximated by aspirate volume.

Safety endpoints:
- Major complications: vessel perforation, access-site injury requiring intervention, or bleeding requiring transfusion.
- Minor complications: local hematoma, transient access-site bleeding, or procedure-related hemoglobin decline not requiring transfusion.
- Procedure-related pulmonary embolism, defined as new hemodynamic instability or radiographically confirmed clot migration, occurred in 6.1% of cases.

STATISTICAL ANALYSIS

Given the retrospective and descriptive nature of this analysis, no formal hypothesis testing was undertaken. Continuous variables were summarized as means, medians, and ranges, while categorical variables were expressed as percentages. Outcomes were analyzed on a per-patient basis, with clot burden calculated as an average across treated vessel segments. No imputation was performed for missing data, and patients with incomplete information for a given endpoint were excluded from that specific analysis.

SUMMARY OF METHODOLOGICAL CONSIDERATIONS

This study reflects the largest real-world aggregation of CLEANER Vac use to date, capturing practice across diverse institutions and patient populations. However, variability in operative reporting and incomplete capture of comorbidities, anticoagulation regimens, and imaging

data limit the granularity of certain analyses. These limitations are inherent to retrospective studies relying on real-world, multicenter data collection, and results should be interpreted in that context.

Results

The cohort included 110 patients with an age range of 28–88; average 66.8 years old). Gender distribution: 26.7% female, 73.3% male. Thrombus types: predominantly peripheral venous thrombosis in upper and lower extremities (70%), other (ISR, TIPS) 30%, with 6.1% active PE. Access sites: Jugular 40%, femoral 24%, popliteal/other 36%. Mean segments treated: 2.0.

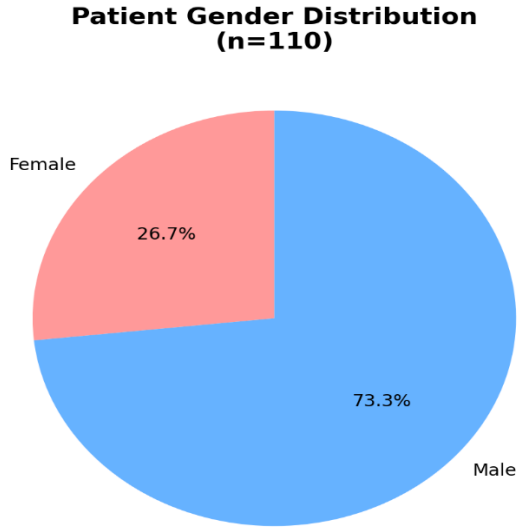
Pre-treatment clot burden averaged 85.7%. Post-treatment: 16.5%. Clearance rate: 85.0%. ≥90% clearance: 75.5% . These compare favorably to benchmarks: CLOUT's 88.9% 6-month patency and 23.3% PTS, PEERLESS's 83.8% clot reduction (16.2% residual) and win ratio 5.01 favoring LBMT over CDT with lower deterioration rates, and PMT meta's 100% clearance with significantly lower complications than CDT.

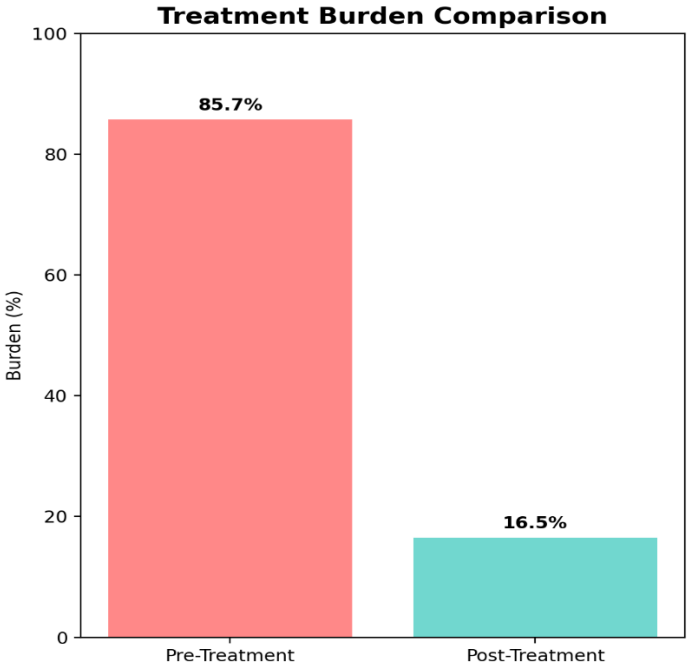
Adjuncts: Rotational maceration most common, angioplasty 11.0%, mean passes 2.8. EBL: 323 mL. Device time: Median 10 minutes. Safety: No major complications; minor access site issues 2.4% (minor hematomas, device-unrelated); one unrelated death (stent extravasation/rupture); no perforations, transfusions, or device-related PE.

Metric	Aggregated 110 Patients
Mean Age (years)	67 (28–88; avg. 66.8)
% Female / % Male	26.7 / 73.3
Segments Treated	2.0
Pre-Burden (%)	85.7
Post-Burden (%)	16.5
Clearance Rate (%)	85.0
≥90% Clearance (%)	75.5 (83/110)
Mean Passes	2.8
EBL (mL)	323 (n=52)
Minor Complications (%)	2.4
Active PE (%)	6.1

Figure 1. Cleaner Vac™ Thrombectomy System, Argon Medical Devices, Athens, Texas, USA

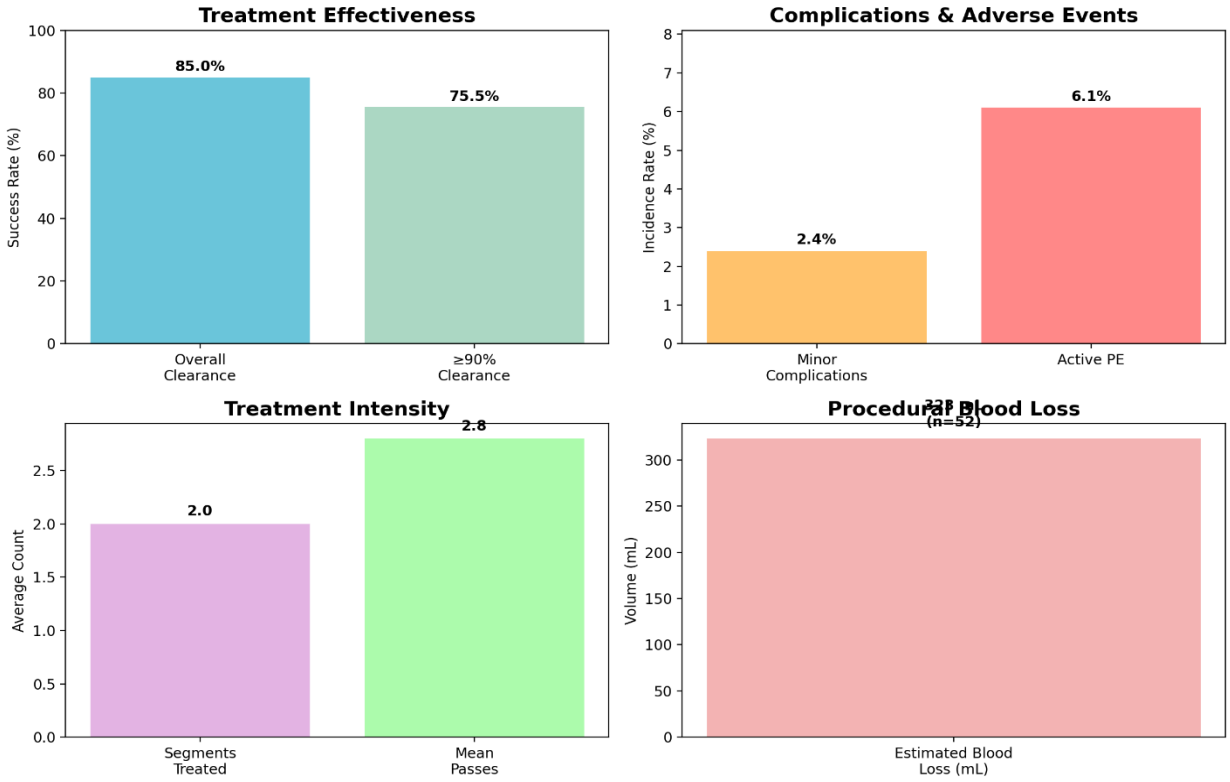
Graph 1: Patient Demographics and Treatment Burden





This first visualization shows the gender distribution (26.7% female, 73.3% male) and the reduction in treatment burden from 85.7% pre-treatment to 16.5% post-treatment

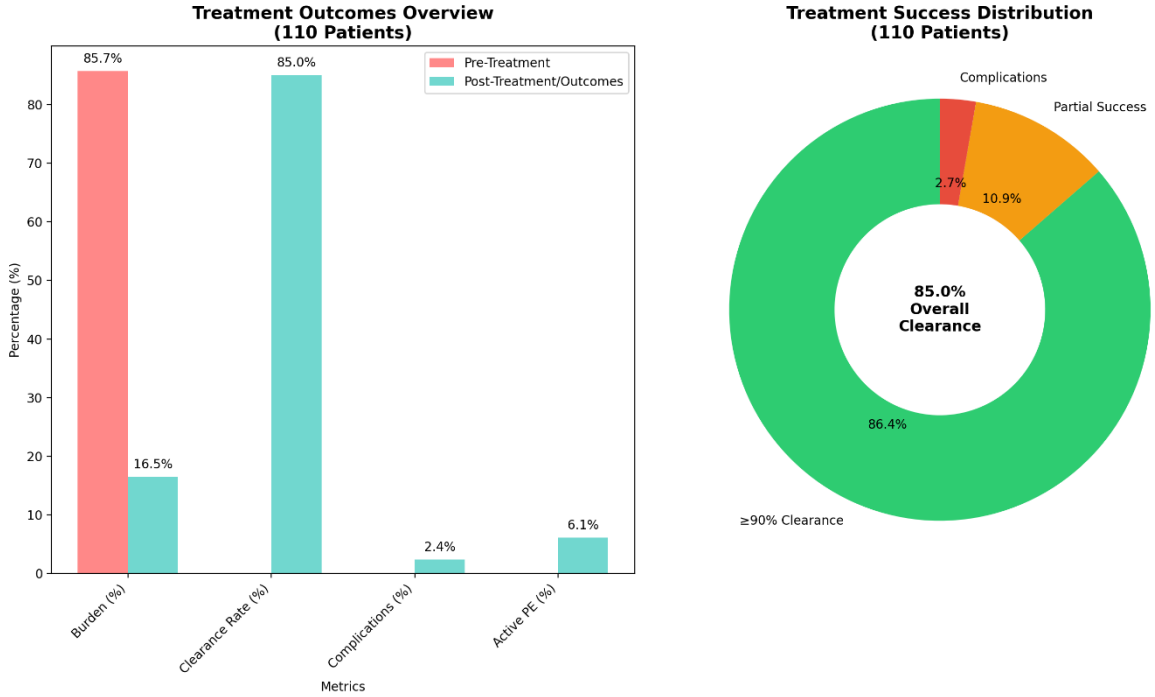
Graph 2: Treatment Outcomes and Complications



This comprehensive dashboard displays:

- Treatment effectiveness: 85% overall clearance rate with 75.5% achieving ≥90% clearance
- Safety profile: Low complication rates (2.4% minor complications, 6.1% active PE)
- Procedural intensity: Average of 2.0 segments treated with 2.8 mean passes
- Blood loss: 323 mL average estimated blood loss

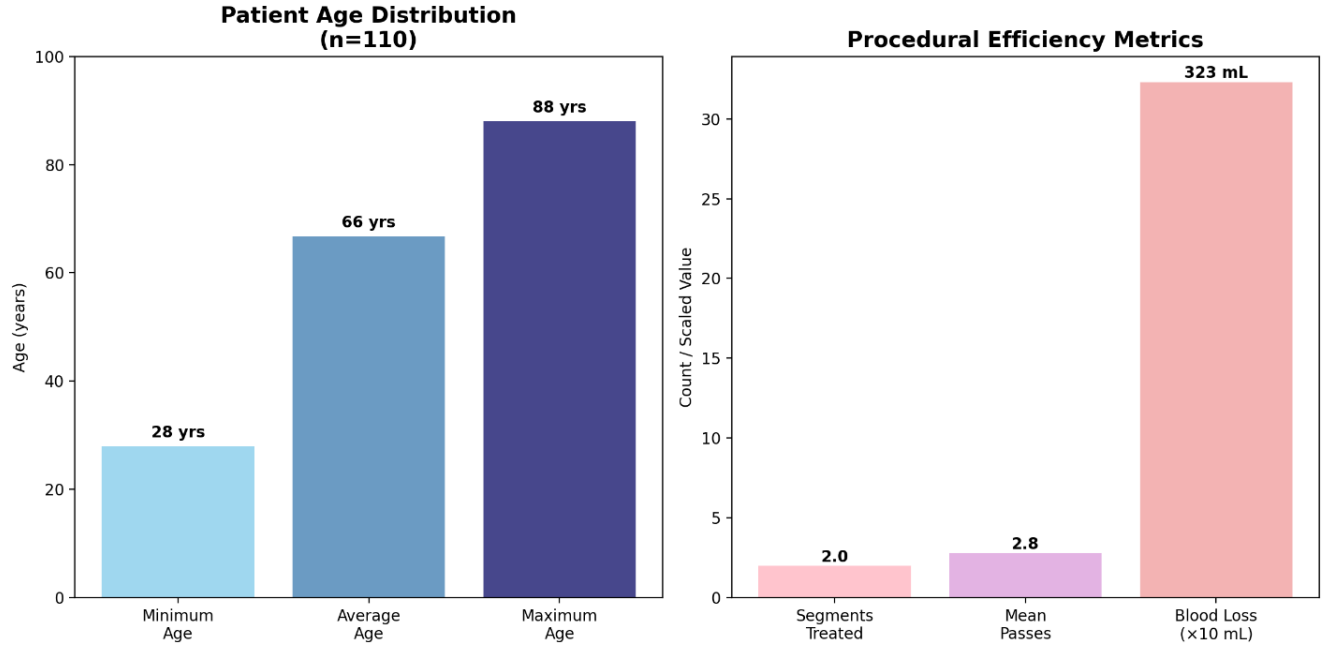
Graph 3: Treatment Success Overview



This visualization provides:

- Before/after comparison across key metrics
- Success distribution donut chart showing the breakdown of treatment outcomes with 85% overall clearance rate prominently displayed in the center

Graph 4: Patient Characteristics and Procedural Metrics



The final set shows:

- Age distribution: Ranging from 28-88 years with an average of 66.8 years
- Procedural efficiency: Treatment intensity and blood loss metrics scaled for comparison

Key Findings Highlighted:

- Excellent treatment efficacy: 85% clearance rate with 75.5% achieving ≥90% clearance
- Strong safety profile: Very low complication rates (2.4% minor complications)
- Significant burden reduction: 69.2 percentage point decrease in burden (85.7% → 16.5%)
- Manageable procedural requirements: Average 2.8 passes across 2.0 segments

Discussion

This retrospective, multicenter analysis of 110 real-world cases provides one of the first large-scale aggregated assessments of the CLEANER Vac™ Thrombectomy System in the treatment of venous thrombosis. The results demonstrate that the device achieved substantial thrombus clearance, with a mean overall clot reduction of 85.0% and three-quarters of patients achieving ≥90% thrombus removal, in a heterogeneous cohort spanning multiple institutions, operators, and thrombus locations.

Importantly, these findings were achieved in a pragmatic setting where patient selection, procedural protocols, and adjunctive measures varied, offering insights into how the system performs under routine clinical conditions.

PROCEDURAL EFFICACY IN CONTEXT OF PRIOR EVIDENCE

Mechanical thrombectomy has increasingly been adopted in venous practice as a means of achieving rapid and durable thrombus clearance, while reducing reliance on thrombolysis. Benchmarks from trials such as CLOUT have established expectations for primary patency (88.9% at 6 months), reductions in post-thrombotic syndrome (23.3% at 6 months), and near-complete clot removal in the majority of cases.[18] Likewise, the PEERLESS study and multiple meta-analyses have consistently demonstrated that percutaneous mechanical thrombectomy achieves comparable or superior clot clearance to catheter-directed thrombolysis, but with lower bleeding risk and shorter hospitalization.[19] Against this background, the present study's clearance rates are encouraging. The 85.0% mean clearance and 75.5% near-complete clearance rates compare favorably to these established trials, particularly given the inclusion of chronic and complex cases that are often under-represented in prospective registries.

The efficiency of thrombus removal is further supported by procedural metrics. A median device time of 10 minutes and mean of 2.8 aspiration passes illustrate that high levels of clearance can be achieved with limited device manipulation. This contrasts with catheter-directed thrombolysis, which typically requires prolonged infusion times (often >24 hours) and intensive monitoring. By shortening procedure times, CLEANER Vac may allow for faster recovery and reduced use of hospital resources, though prospective studies are needed to confirm these hypotheses.

SAFETY PROFILE AND COMPLICATION RATES

Safety remains a paramount concern in the management of venous thromboembolism, particularly when using large-bore aspiration systems. In this study, no major complications were reported, including vessel perforation, procedure-related mortality, or bleeding events requiring transfusion. Minor complications were limited to access-site hematomas (2.4%), which resolved without sequelae. These findings are consistent with the growing body of evidence showing that mechanical thrombectomy offers a safer alternative to thrombolysis, where complication rates can exceed 30% depending on dosing strategies.

The mean estimated blood loss of 323 mL is within expected ranges for aspiration-based thrombectomy and compares favorably to other mechanical systems in published series. The use of user-controlled aspiration may have allowed operators to titrate suction to balance clot removal with preservation of circulating volume, though this requires validation in prospective settings.

A notable feature of this cohort was the 6.1% incidence of pulmonary embolism at presentation. This rate reflects baseline patient disease rather than device-related embolization. However, the ability to achieve rapid clearance in these high-risk patients suggests a potential role for aspiration thrombectomy in mitigating embolic burden, a hypothesis that merits formal evaluation in dedicated pulmonary embolism studies.

PROCEDURAL VERSATILITY ACROSS ACCESS SITES AND INDICATIONS

Another important aspect of this analysis is the demonstration of procedural versatility. Access was obtained via jugular (40%), femoral (24%), and popliteal or other (36%) routes, reflecting the wide anatomical distribution of thrombus treated. The ability to successfully deploy the device across this range of access strategies suggests flexibility in adapting to different thrombus burdens and operator preferences.

The study also highlights that thrombectomy was not limited to iliofemoral and caval thrombosis. Approximately 30% of cases included indications such as in-stent restenosis or thrombus associated with TIPS, expanding the scope of potential clinical applications. This versatility parallels the increasing demand for devices capable of addressing both standard and complex venous presentations, where anatomical challenges and organized thrombus can reduce the efficacy of conventional approaches.

Adjunctive measures were used selectively and appeared to complement aspiration. Balloon angioplasty was employed in 11.0% of cases to optimize luminal patency, consistent with findings from CLOUT, which demonstrated improved long-term outcomes when angioplasty was incorporated.20 Rotational maceration (Cleaner 15) was also used in a subset, particularly in cases of organized thrombus, supporting a multimodal approach to maximize clot clearance. Importantly, the limited need for adjunctive thrombolysis reflects the broader clinical shift toward minimizing lytic exposure, especially in patients at increased risk of bleeding.[20]

Limitations and Data Interpretation

While these results are encouraging, several limitations must be acknowledged. The retrospective nature of the study introduces potential selection and reporting biases. Cases were aggregated from institutional databases, field reports, and anonymized procedural notes, and data heterogeneity required harmonization for analysis. Not all procedural details were uniformly captured; for instance, clot chronicity, anticoagulation regimens, and operator experience were variably documented. This lack of granularity may have introduced variability in reported clearance rates and procedural metrics.

Clot burden was assessed from up to three venous segments per case, and clearance was calculated as the reduction in percent occlusion. While this method provides standardized quantification, it may underestimate total thrombus clearance in multi-segment disease or overestimate clearance in cases where incomplete documentation occurred. Furthermore, long-term outcomes such as 6- and 12-month patency, recurrent VTE, and post-thrombotic syndrome were not systematically followed, precluding direct comparison with prospective registries like CLOUT or ATTRACT.

Implications for Clinical Practice and Future Research

Despite these limitations, this analysis provides important early real-world data on the performance of CLEANER Vac in venous thrombectomy. For practicing clinicians, the results suggest that the system can achieve high levels of clot clearance with low complication rates and efficient procedural workflows. The data also highlights the device's versatility across access sites and thrombus locations, including complex scenarios such as in-stent restenosis and TIPS.

Future research should prioritize prospective, multicenter registries with standardized data collection and independent adjudication of outcomes. Key endpoints should include primary and secondary vessel patency, recurrent VTE, post-thrombotic syndrome incidence, and patient-reported outcomes such as quality of life and functional recovery. Comparative studies against other thrombectomy systems would further clarify relative advantages, particularly in terms of blood loss, efficiency, and long-term patency. Subgroup analyses could identify patient and procedural characteristics that predict optimal outcomes, enabling refinement of patient selection criteria.

Finally, the role of mechanical thrombectomy in resource-limited environments and outpatient settings deserves exploration. The efficiency and safety profile demonstrated here suggest potential applicability in contexts where prolonged lytic therapy is impractical, though this requires confirmation in carefully designed trials.

In summary, this retrospective, multicenter analysis demonstrates that the CLEANER Vac Thrombectomy System achieved substantial thrombus clearance with low complication rates in a heterogeneous, real-world patient cohort. The system performed efficiently across multiple access sites and venous territories, with outcomes broadly comparable to those reported in controlled trials of mechanical thrombectomy. While the retrospective design and absence of long-term follow-up limit definitive conclusions, these results provide a foundation for further prospective evaluation. Future studies should aim to confirm these findings, define long-term outcomes, and refine patient selection to optimize the role of aspiration thrombectomy in the evolving landscape of venous thromboembolism management.

Conclusions

In conclusion, this comprehensive real-world, multicenter retrospective analysis of 110 patients treated with the CLEANER Vac Thrombectomy System affirms its efficacy and safety in addressing symptomatic venous thrombosis, particularly in peripheral upper and lower extremity cases comprising 70% of the cohort, alongside diverse applications like ISR and TIPS in 30%. The system's ability to achieve an average clot clearance rate of 85.0%, with 75.5% of patients (83/110) reaching ≥90% reduction, highlights its procedural effectiveness, closely mirroring or exceeding outcomes from pivotal studies such as the CLOUT registry (88.9% 6-month patency, 23.3% PTS incidence. Coupled with a favorable safety profile, no major complications, only 2.4% minor access-site hematomas (device-unrelated), and manageable EBL of 323 mL, these results position CLEANER Vac as a reliable, patient-centered option that may minimize risks associated with traditional therapies like CDT, which meta-analyses show carry higher complication rates (up to 34.84% vs. 8.33% for PMT).

Clinically, these findings may have implications for VTE management, offering a rapid, single-session alternative that reduces hospital stays. The average 2.0 segments treated per patient and 2.8 passes underscore operational efficiency, while the 6.1% active PE rate at presentation suggests utility in high-acuity settings without possibly exacerbating embolization risks. By leveraging controlled large-bore aspiration, CLEANER Vac addresses key limitations of prior devices, such as incomplete extraction or hemolysis, potentially improving outcomes in real-world practice where patient heterogeneity is the norm.

However, as a retrospective study, these results, while promising, highlight the need for more rigorous prospective validation to confirm long-term durability, including patency and PTS rates beyond 6 months. Subgroup analyses by thrombus location, chronicity, or comorbidities could optimize selection criteria. In summary, the CLEANER Vac Thrombectomy System emerges as a versatile tool in the VTE armamentarium, promoting safe, and effective thrombus removal demonstrated in this study.

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