Real-World Multicenter Experience with the CLEANER Vac™ Thrombectomy System: An Analysis of 110 Patients

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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 as- sociated 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.

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 re- mained. 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 62 years (range: 28–88 years) with an average of 66.8 years old. The gender distribution in the 110 cases was 26.7% female and 73.3% male. On average, 2.0 ve- nous segments were treated per patient across all 110 cases. The mean pre-treatment clot burden was 85.7%, which was re- duced to an average post-treatment clot burden of 16.5%, re- sulting in an average clot clearance rate of 85.0%. A total of 83 patients (75.5%) achieved ≥90% clot clearance, demonstrat- ing a high procedural success rate. These outcomes align with or exceed average success metrics from clinical studies on me- chanical 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, rota- tional maceration was the most commonly used adjunct to as- piration thrombectomy in the initial cohort, with balloon an- gioplasty 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, cal- culated from the numeric procedure data averaged 323 mL. Pro- cedural safety was favorable overall, with no major complica- tions (e.g., symptomatic pulmonary embolism, vessel perfora- tion, or severe bleeding requiring transfusion). Potential access site complications occurred in 2.4% of patients representing mi- nor hematoma not affiliated with the device itself. There was one case of patient death due to post-procedure stent-related ex- travasation/rupture, adjudicated to be unrelated to the device. Active PE was present in 6.1% of the cases. Procedure types across 110 cases were predominantly peripheral venous thrombosis in upper and lower extremities (70% overall.

Conclusions

This real-world, multicenter retrospective study highlights the efficacy and safety of the CLEANER Vac 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 estab- lished benchmarks in mechanical thrombectomy literature (e.g., 88.9% patency in CLOUT and superior outcomes in PEER- LESS vs. CDT), minimal procedural complications, and man- ageable EBL (average of 323 mL). These findings support its role as an effective mechanical thrombectomy option for pe- ripheral venous thrombosis management, with advantages in controlled aspiration minimizing blood loss and vessel trauma. The combined results affirm the device's performance. Fur- ther 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 opti- mization for patient selection.

Metric	Aggregated 110 Patients
Mean Age (years)	68 (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. Outcomes Table

Figure 2. Cleaner Vac, Argon Medical, Plano, TX. USA

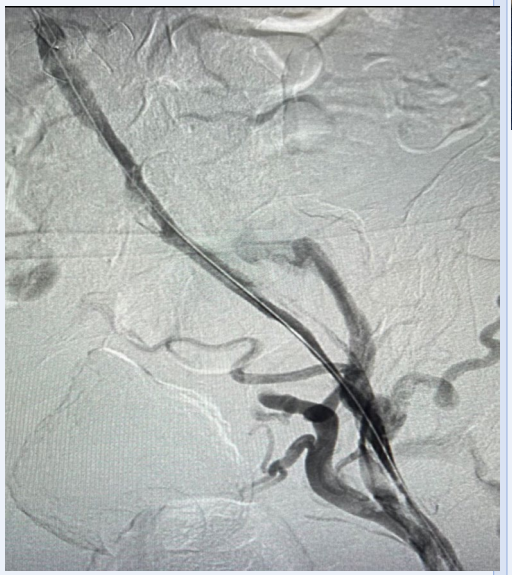

Figure 3. May-Thurner With Thrombosis

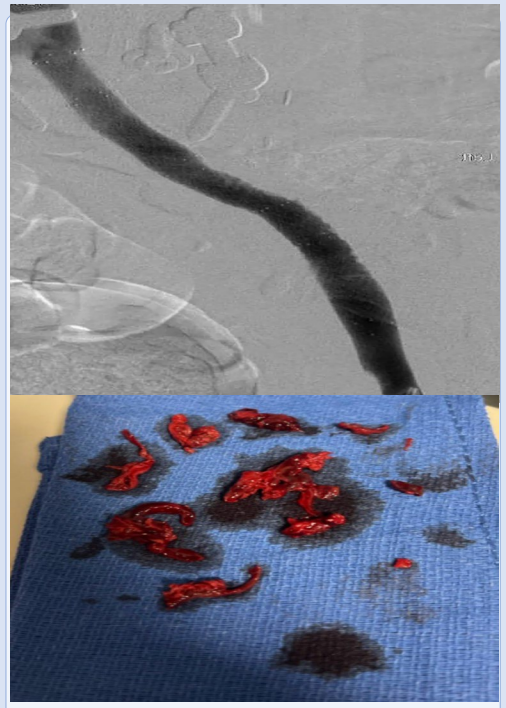

Figure 4. and 5. Post Thrombectomy

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