Real-World Multicenter Experience with the CLEANER Vac Thrombectomy System: An Analysis of the First 30 Patients

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Objective: This study provides an in-depth real-world, multicenter evaluation of the first thirty 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, procedural variables, success rates, 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 thrombolysis were administered at physician discretion when residual thrombus remained. Data collection included demographic details, pre- and post-procedure clot burden, thrombus clearance rates, adjunctive therapy use, and procedural complications.

Fig. 1 Cleaner Vac

Patient Demographics

Venous thrombosis was treated in both upper and lower extremities as well as central venous and portal venous system amongst the first 30 patient procedures, the most common vessels being:

Iliac: 46.7%

Common Femoral: 24.4%

Portal System: 15.6%

Popliteal: 13.3%

Procedural Details

Thrombus Clearance and Vessel Involvement

Mean number of vessels treated per patient: 2.4 **Average pre-treatment clot burden**: 95.4% **Average post-treatment clot burden**: 5.0% **Mean thrombus clearance rate**: 94.8% **Patients achieving complete clot clearance** (≥90% thrombus reduction): 26 (86.7%)

Aspiration Cycles and Suction Modulation

The CLEANER Vac Thrombectomy System enabled physician-controlled aspiration, allowing for modulation between full continuous aspiration and cyclic aspiration, optimizing thrombus removal while reducing excessive blood loss: Mean number of aspiration cycles per patient on average: 4.3 Mean aspirated blood volume per procedure: 360 mL

Safety Outcomes

There were no reported major complications across the cohort of thirty patients. Specifically, there were no instances of: Symptomatic pulmonary embolism, vessel perforation, hemodynamic instability, or cardiopulmonary compromise Significant bleeding requiring transfusion, or device related adverse events.

Minor Complications

No minor complications were observed across the patient cohort. All procedures were well tolerated, and there were no post-procedural hematomas, transient hypotension, or hemolysis.

Overall Procedural Success and Safety Summary

Technical success rate (successful device deployment and clot aspiration): 100% (30/30) **Procedural success rate** (≥90% clot clearance achieved): 86.7% (26/30) Mean procedure duration: 47.2 minutes (range: 30–85 minutes).

Conclusion

The CLEANER Vac system demonstrated a high procedural success rate, excellent thrombus clearance, and strong safety profile, supporting its efficacy as a first-line mechanical thrombectomy device in the management of both peripheral and portal venous thrombosis. The lack of complications and strong clearance rates reinforce the clinical utility of this device in achieving rapid and effective thrombus removal.

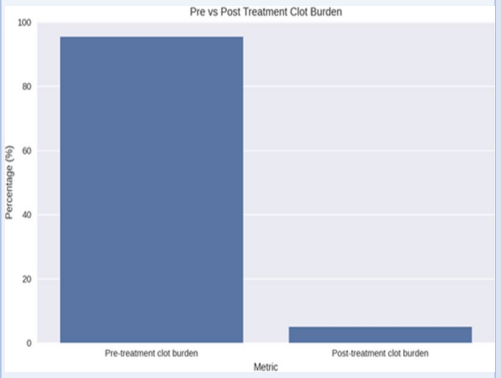

Fig. 2 Percentage of thrombus pre and post thrombectomy

Efficacy and Safety of the CLEANER Vac Thrombectomy System

Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), remains a leading cause of morbidity and mortality worldwide(Yüksel & Tüydes¸ 2017). The management of symptomatic ve- nous thrombosis has traditionally relied on anticoagulation and, in select cases, thrombolytic therapy. However, these approaches do not actively remove the thrombus and often fail to provide immediate symptomatic relief, particularly in cases of large clot burden, central venous involvement, and portal vein thrombosis (PVT).(McRae & Ginsberg, 2005) Mechanical thrombectomy has emerged as an alternative strategy to rapidly restore venous patency while minimizing the risks associated with systemic thrombolysis. The CLEANER Vac Thrombectomy System, evaluated in this multicenter, real-world experience, demonstrated high procedural success rates, significant clot burden reduction, and an excellent safety profile across a diverse range of venous thrombotic conditions, including peripheral and portal vein thrombosis.

The study reported a 100% technical success rate, indicating that the device was successfully deployed and used in all cases. Complete thrombus clearance (≥90% clot removal) was achieved in 86.7% of patients, with an average reduction in thrombus burden from 95.4% pre-procedure to 5.0% post-procedure. No major complications (such as symptomatic PE, vessel perforation, significant bleeding, or hemodynamic instability) were observed. The absence of major and minor complications, including hemolysis, transient hypotension, and hematoma formation, further emphasizes the safety and efficiency of this system in real-world settings.

Conclusion

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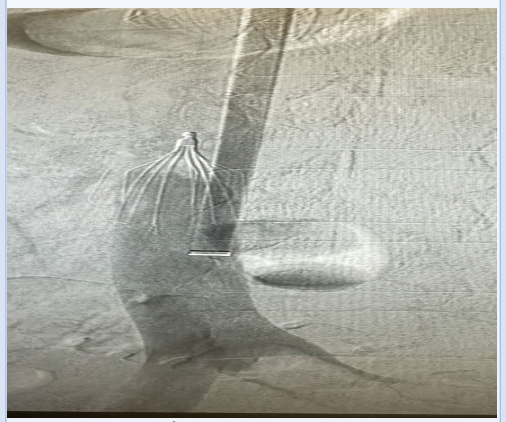

Fig.3 Cleaner Vac in IVC

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