Adopting New DVT Tools: What Are the Key Questions to Ask Beforehand?

An assessment of essential considerations for clinicians adopting new DVT tools, focusing on efficacy, safety, and integration into existing protocols to ensure effective and safe adoption.

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Deep vein thrombosis (DVT) remains a significant global health issue, with acute cases potentially leading to severe long-term complications, such as postthrombotic syndrome (PTS).[1] Current standard treatment predominantly relies on anticoagulation (AC), aimed at preventing thrombus extension and recurrence, but it often falls short in addressing residual thrombus burden, which can lead to PTS and chronic venous insufficiency in up to 50% of patients.[1,2] Over the past 2 decades, technologic advancements have led to the development of various interventional therapies, including catheter-directed thrombolysis (CDT),[3,4] pharmacomechanical CDT (PCDT),[5] mechanical thrombectomy (MT), or aspiration-assisted thrombectomy,[6] each aiming to mitigate the risk of PTS by enhancing thrombus clearance.

Numerous large-scale trials have contributed to the understanding and management of DVT, highlighting the potential benefits and challenges of various interventional approaches.[7] Trials such as CaVenT,[3] CAVA,[4,8] and ATTRACT[5,9] have played crucial roles in assessing CDT and PCDT, offering valuable insights into how these therapies compare with traditional AC. Additionally, real-world registries like CLOUT have provided essential data on newer MT devices, helping clinicians understand their application across different patient settings.[6,10] Current ongoing trials, like BOLT and DEFIANCE,[11,12] aim to advance aspiration-assisted and MT techniques by evaluating the safety and efficacy of the Indigo aspiration system (Penumbra, Inc.) in acute iliac and femoral DVT or comparing the ClotTriever system (Inari Medical) to standard AC, focusing on PTS severity. The insights from these studies will emphasize the importance of ongoing research and clinical trials to refine patient selection, optimize treatment protocols, and ultimately improve long-term outcomes for DVT patients.

Given the evolving landscape of DVT management, this article aims to outline key considerations for clinicians before adopting new DVT tools, focusing on safety, integration, cost-effectiveness, and regulatory approval to guide informed and effective decision-making.

EFFICACY AND EVIDENCE

The efficacy of various DVT treatment systems has been evaluated extensively through several key clinical trials and registries, each highlighting different approaches to thrombus removal and symptom management. The CaVenT trial demonstrated that CDT led to a 14.4% absolute reduction in PTS incidence over 2 years compared to AC alone. The trial also supported early intervention in first-time acute femoral or iliofemoral DVT, especially if initiated within 3 weeks of onset. These findings suggest that timely CDT can play a crucial role in reducing long-term complications for selected patients.[3] The ATTRACT and CAVA trials evaluated PCDT for patients with acute proximal DVT lasting < 2 weeks and ultrasound-accelerated CDT for DVT cases < 2 weeks, respectively.[4,5,8,9] ATTRACT enrolled both iliofemoral and femoropopliteal DVT and reported decreased PTS severity; venous disease–specific quality of life (QOL) improved in the iliofemoral subgroup, although the QOL analysis in the overall proximal DVT study population found no

benefit. CAVA enrolled patients with iliofemoral DVT; although a reduction in PTS occurrence or severity was not reported among the results at 1 and 3 years, subsequent analyses suggested improvement in those patients who had successful recanalization.

More recent data from the CLOUT registry demonstrated favorable clinical changes over time after use of AC and MT with the ClotTriever system, showing restoration of vein patency and improvement in symptoms and QOL in both short- and long-term follow-up.[6,10,13,14]

The efficacy of DVT treatment systems varies across techniques, with MT showing robust outcomes in real-world settings, while CDT techniques provide targeted benefits depending on patient selection and thrombus characteristics. Overall, these findings suggest that personalized approaches are essential, where treatment selection considers not only the efficacy but also patient-specific risk factors and clinical scenarios.

EVALUATING NEW DVT DEVICES

To determine the effectiveness and safety of a new device, clinicians should review evidence from clinical trials, registries, and real-world outcomes, focusing on key characteristics such as efficacy in thrombus clearance, safety profiles, and measurable improvements in patient outcomes, including symptom relief and reduced PTS rates. For example, in cases of acute thrombosis, where the clot is fibrin-rich and appears expansile and hypoechoic on ultrasound, tissue plasminogen activator–based techniques or aspiration may be equally effective and carry a lower theoretical risk of valve or intimal damage compared to CDT or MT. However, if the clot is more chronic or collagen-rich, MT or aspiration-assisted methods often become the preferred choice. Another factor to consider is the presence of an inferior vena cava filter, which may necessitate more complex techniques and require clinicians who are experienced and familiar with catheter-based or mechanical interventions. Additional support from societies, early adoption studies, and experienced peers can help guide decisions on incorporating new devices into clinical practice.

SAFETY PROFILE

The safety of various DVT treatment tools has been a key focus across multiple trials, with particular emphasis on bleeding risks and procedural complications. For catheter-based thrombolysis, CaVenT reported 20 bleeding complications, including three major bleeds and five clinically relevant incidents. Despite these risks, the safety profile was deemed acceptable for carefully selected patients, particularly those with extensive proximal DVT who were at lower risk for bleeding complications.[3]

Similarly, the ATTRACT trial found a higher incidence of major bleeding events in the PCDT group (1.7%) at 10 days compared to the AC group (0.3%), with a non-significant trend toward a higher rethrombosis rate in the PCDT arm.[5] A subanalysis found recurrent DVT to be more frequent after AngioJet PCDT (Boston Scientific Corporation) than no PCDT.[9,15]

The CAVA trial also reported increased bleeding risks, with 5% of patients in the intervention group experiencing major bleeding at a median of 5.5 days, while no major complications were observed in the AC group. This trial showed benefits in symptom severity with successful recanalization, and no major bleeding was observed in long-term follow-up.[4,8]

These trials highlighted the association of CDT systems with higher bleeding risks and raised concerns about their safety, particularly for patients with elevated bleeding risks. This has limited the broader application of CDT, despite its ability to provide some symptomatic relief.

The CLOUT registry has reported a favorable safety profile with a low rate of reported bleeding using MT.[6,13] A retrospective study compared MT and PCDT and found that MT achieved higher rates of single-session treatment (97.7% vs 26.9%), shorter hospital stays, reduced intensive care unit use, and greater thrombus reduction after 1 year of follow-up.[16] A recent meta-analysis suggested that using an adjuvant MT or aspiration-assisted thrombectomy system with CDT for selected patients leads to better clinical outcomes, with a lower rate of PTS and fewer major bleeding complications.[17,18] The CLOUT registry reported that nearly all MT procedures were performed without major complications or vessel/valve damage, low device-related serious adverse events (0.2%), with 1% (5 cases) rethrombosis rate noted in follow-up. However, ultrasound valvular reflux studies were not included in the registry, limiting confirmation of vein or valvular damage. Still, overall findings suggest favorable short-term outcomes and highlight the safety of the ClotTriever system.[6,13] Further, a cohort study recently reported a low rate of partial or complete rethrombosis after percutaneous thrombectomy using the Lightning Flash aspiration system (Penumbra, Inc.).[19]

Another retrospective study compared the clinical efficacy and safety of MT versus aspiration-assisted thrombectomy and found that venous damage was 4.6% with MT compared to 0% with aspiration thrombectomy, although this was not statistically significant.[20] The primary mechanism of action in clot retriever MT is the coring element, which traps and collects the clot in a basket. Aspiration techniques, on the other hand, rely on a vacuum effect manually exerted through a syringe, a handle, or a computer-assisted device, to preserve femoral vein valves and reduce the risk of venous injury and bleeding.

Overall, these findings highlight the potential benefits of MT or aspiration-assisted thrombectomy in providing effective treatment with fewer complications for a broader range of patients, particularly those for whom traditional thrombolytic therapy is less suitable. As the field progresses, there is a need for more comprehensive safety data, including larger multicenter trials that focus on long-term outcomes and rare adverse events associated with these thrombectomy devices.

INTEGRATION WITH CURRENT PROTOCOLS

The effective integration of new DVT treatment tools into clinical practice requires actionable steps for individual practitioners. Current guidelines, such as those from the American College of Chest Physicians,[21] the Society of Interventional Radiology,[22] and the European Society for Vascular Surgery,[23] address standard AC and CDT and also support the use of MT for selected patients with symptomatic DVT. They include clear recommendations on when to escalate to more invasive treatments.

To align with recent advancements, individual practices should focus on clear patient selection based on thrombus location/characteristics, symptom duration, and postthrombotic risk factors. For device selection, prioritize tools supported by clinical evidence that are suited to patient needs and available resources. Factors to consider include the extent and location of the clot (proximal or distal), the need for distal embolic protection, and whether a Protrieve sheath (Inari Medical) can be used to accommodate other CDT tools. Additional considerations are patient positioning (supine vs prone), the need for anesthesia, whether the patient must be prone, the accessibility of a suitable proximal access vessel, and whether the vessel meets the size criteria as specified by the device's instructions for use. Implement training programs to ensure clinicians and staff are proficient in device use, procedural steps, and complication management. Establish structured follow-up by imaging and symptom monitoring to detect any postprocedure complications early and optimize patient outcomes. Ongoing input from clinical trial studies and real-world data will be vital for maintaining high standards of care, guiding clinical decisions, and smoothly integrating innovative approaches into daily practice.

COST-EFFECTIVENESS

When assessing the cost-effectiveness of different DVT treatments, several key factors must be considered, including initial treatment costs, hospital stays, maintenance, and potential savings from avoiding long-term complications, such as PTS. The CaVenT and ATTRACT trials found that CDT/PCDT had higher costs than standard AC, with an increased incremental cost-effectiveness ratio per quality-adjusted life-year gained, making it generally less economically favorable compared to AC.[24,25] A recent cost-effectiveness study comparing three DVT treatments (AC, CDT, and MT) observed that AC had the lowest up-front costs per 1% improvement in therapeutic effect but was less effective in reducing PTS. CDT provided moderate effectiveness but led to higher expenses due to thrombolytics and longer hospital stays. Although MT had higher initial costs, under the assumptions made by the investigators, it emerged as the most cost-effective in the long term via the reduction in hospital stays and complications.[26] Of note, incremental effectiveness of MT has not been firmly established in prospective studies with control groups, which would be needed to truly determine its true cost-effectiveness.

If MT is indeed proven clinically effective/proficient and cost-effective, it might be particularly beneficial in resource-limited settings, where managing long-term costs is crucial for sustainable health care options. Further research should evaluate various CDT, PCDT, and MT or aspiration-assisted-thrombectomy devices for cost-effectiveness and health care resource utilization to better understand these hypotheses.

REGULATORY APPROVAL

Regulatory approval plays a vital role in establishing the safety and efficacy of DVT treatment devices, setting a benchmark that promotes clinical trust, influences adoption, and facilitates insurance reimbursement. There are > 60 FDA-approved peripheral/venous MT or thrombolysis devices offering distinct benefits,[27] with some having both FDA and CE Mark approval, permitting their use across the United States and Europe in treating DVT. However, such approvals often come with conditions. Given the risks involved with smaller veins, certain devices are approved specifically for iliofemoral DVT and require specialized clinician training. Patient-specific factors, such as age, comorbidities, and clot characteristics, are also critical in selecting the appropriate DVT tool, emphasizing the importance of personalized treatment planning and risk stratification. Ongoing postmarket surveillance further ensures safety, enabling adjustments based on real-world data to support evidence-based practice tailored to individual needs.

PATIENT AND DEVICE SELECTION

The ATTRACT trial suggests PCDT is most beneficial for patients with extensive iliofemoral DVT, especially when applied early in those with low bleeding risk.[3,5,9] MT, as shown in the CLOUT registry, is valuable for patients contraindicated for thrombolysis, emphasizing

the need for individualized treatment planning and risk assessment to optimize outcomes.[6,10] The ClotTriever system, a nonthrombolytic device, is ideal for single-session removal of clots in iliofemoral DVT patients at high bleeding risk without requiring thrombolytics.[14] MT with AngioJet combined with CDT has demonstrated effectiveness in accelerating thrombolysis and rapidly opening the vessel passage, making it suitable for acute DVT cases but carrying a higher bleeding risk.[18] The Indigo system catheters provide versatility for central and peripheral DVT cases with real-time monitoring without bleeding complications, but further ongoing studies are necessary to evaluate long-term outcomes and patency rates.[11,28] Therefore, each device is designed to fit specific patient profiles and clinical needs, highlighting the importance of thorough patient assessment and consideration of device efficacy and safety to ensure the treatment choice aligns with individual risk factors and DVT characteristics. Although other devices are available on the market, further discussion is pending the publication of prospective data analyses to provide more robust comparisons.

SUMMARY AND FUTURE DIRECTIONS

This review highlights essential considerations for clinicians when adopting new DVT treatment tools. Key factors include evaluating the efficacy and safety of each device, understanding integration with existing protocols, and assessing cost-effectiveness and regulatory compliance. Clinical trials have provided valuable insights, showing that although CDT and PCDT are effective for specific patient groups, MT offers advantages in terms of safety and potentially cost-effectiveness, particularly for patients with contraindications to thrombolysis.

This patient-centered approach highlights the importance of customizing treatment plans to match each tool's strengths with individual patient risks and clinical needs. Future directions in DVT treatment focus on advancing MT or aspiration-assisted thrombectomy device precision, reducing complications, and exploring CDT as a complementary option. Ongoing research and clinical trials are essential to refine guidelines and effectively implement new innovations. Collaboration across specialties will also be crucial for developing comprehensive, evidence-based guidelines and supporting clinicians in delivering personalized, data-driven care that evolves with emerging technology. ■

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