ROUNDTABLE DISCUSSION

Current Insights on the AlphaVac F18[85] System and Future Directions of Mechanical Thrombectomy

How mechanical thrombectomy is reshaping pulmonary embolism treatment, from device selection and the role of AlphaVac, to blood loss mitigation, and future innovation.

With Sabah D. Butty, MD; F.A. (Erik) Klok, MD, PhD; Sameh Sayfo, MD, MBA, FSCAI, FACC; and Peter Monteleone, MD, FACC, FSCAI



Sabah D. Butty, MD
Interventional Radiologist
CHRISTUS Health
Alexandria, Louisiana



F.A. (Erik) Klok, MD, PhD
Department of Medicine–Thrombosis and Hemostasis
Leiden University Medical Center
Leiden, the Netherlands



Sameh Sayfo, MD, MBA, FSCAI, FACC
Program Director, Endovascular Fellowship Program
PERT Program Director
Baylor Scott & White The Heart Hospital
Plano, Texas



Peter Monteleone, MD, FACC, FSCAI
Interventional Cardiologist
Ascension Seton Medical Center
Austin, Texas

How have advances in pulmonary embolism (PE) management over the past 5 years accelerated the adoption of mechanical thrombectomy (MT), and what unmet needs with anticoagulation (AC) and catheter-directed thrombolysis (CDT) does MT address?

Dr. Butty: Success in other cardiovascular diseases, such as myocardial infarction and stroke intervention, has helped accelerate the adoption of MT for PE. The shortcomings with conventional treatment and CDT are more apparent with subacute and chronic embolic debris. Currently, this seems to be better suited for MT. However, both techniques still struggle with chronic PE patients. I believe additional limitations of medical-based therapies include a greater chance of prolonged recovery in returning to baseline functional status and an increased chance of post-PE syndrome.

Prof. Klok: Most influential has been the increasing availability of data from proper research and clinical studies that have provided a solid ground for accepting MT as a valuable treatment option. Of note, outcome studies comparing MT with standard of care are still lacking but are ongoing. Also, the increasing number of hospitals with EXPERT-PE care teams and PE response teams (PERTs) helps organize the best possible care for individual patients and acts as the gateway for novel interventional treatments. The accumulating evidence and experience have resulted in guidelines providing more grounds for MT and other interventional reperfusion treatments. MT addresses key limitations of AC and thrombolytic therapy by providing immediate mechanical reperfusion for patients with high-risk PE and hemodynamic compromise, and also avoiding the need for thrombolytics in patients at high risk of bleeding.

Dr. Sayfo: The biggest shift has been the agreement across specialties that some patients with PE need more than AC, together with a growing body of prospective data showing that MT can be done safely. The recent American Heart Association/American College of Cardiology guidelines move thrombectomy out of the "experimental" conversation and into a structured, guideline-referenced decision with a formal recommendation for PERTs to improve timeliness and coordination of care.[1] A recognized team, a common language for risk, and a payment pathway together have made it much easier for hospitals to build thrombectomy programs and for referring physicians to consult them early.

Unmet needs with AC and lytics remain, as AC prevents clot propagation but does not remove existing clot from the pulmonary arteries (PAs). In intermediate-high–risk patients, right ventricular (RV) strain may persist for days as the body breaks down the clot, and some patients decompensate or develop persistent symptoms. AC alone provides no immediate hemodynamic relief.

CDT still carries bleeding risk, making it unsuitable for many patients. MT fills these gaps by removing clot immediately without lytics, offering an option for lysis-ineligible patients, and often improving hemodynamics during the procedure. This may shorten intensive care unit stays and simplify recovery.

Dr. Monteleone: The biggest change has likely been awareness. The current generation of operators and clinicians were originally trained in an era where the treatment of PE was simple AC. "Massive PE" received systemic thrombolytics, and then everything else in the PE space was treated with AC alone. As novel technologies for PE treatment were developed, small pockets of advanced therapies emerged and took on the burden of demonstrating that these treatments were safe and important. We are now blessed with an absolute abundance of tools where we previously had none.

AC alone left a huge void, and we are still learning which pathologies are best treated with CDT versus MT. That said, in certain clinical situations there are clear benefits to the availability of MT. It provides a more immediate treatment and thus is likely better suited to patients who have either hemodynamically collapsed and been rescued by ECMO (extracorporeal membrane oxygenation) or who have impending hemodynamic collapse and may require stabilization with vasopressors (category E1 or E2). Although low doses of infused thrombolytic have been increasingly demonstrated to be extremely safe, there are also patients for whom any thrombolytic or even any AC is contraindicated. In certain clinical circumstances, MT has even been performed without AC with placement of an inferior vena cava filter at case conclusion. MT therefore provides a remarkable variety of options for treatment of the sickest of the sick and the most complex venous thromboembolism (VTE) patients.

What are the most important factors when selecting a thrombectomy device?

Dr. Butty: Focusing only on catheter size and aspiration power is somewhat short-sighted. An important criteria in device selection is a strong understanding of the pathophysiology of a PE patient. Although the end goals of each thrombectomy catheter are similar (ie, rapid removal of large amounts of embolic debris), how we get there can be very different from one catheter to another. Understanding the mechanical forces exerted by each catheter, importance of selectivity, and nuances of thrombus engagement and ingestion on cardiopulmonary physiology allows one to better evaluate the unique strengths, deficiencies, and efficiency of each device; ultimately, this will allow for a more informed and safer option for clinical success.

Prof. Klok: Aspiration size, blood loss mitigation, navigability/selectability, or procedural simplicity matter but mostly: What does the evidence tell us regarding efficacy, safety, and costs? Moreover, teams should learn to work with one device for optimal delivery of quality of care; only teams with high exposure should use multiple devices.

Dr. Sayfo: Navigability and selectability come first. A large-bore catheter is useless if you can't get it safely through the dilated dysfunctional right heart and into the PA tree. The ability to steer into the target artery is dictated by clot burden and location. Blood loss mitigation comes next. These patients often have little physiologic reserve, and aggressive aspiration can turn a successful clot extraction into a transfusion or a hemodynamic problem.

Aspiration size and procedural simplicity come next. More bore generally means more effective clot removal per pass, but only if it can be delivered and controlled. Simplicity matters more than people admit, especially at night and on weekends at centers where the PERT case volume is spread across several operators and among teams that don't do these procedures every day. The simplicity of the procedure does matter if we are looking to have this technology adopted across the country regardless of physician or hospital level of expertise. In practice, the best device is one that the whole team can set up and run reliably with predictable blood loss, while still having enough bore to clear central clot efficiently.

Dr. Monteleone: We are learning a lot about the benefits of the various MT tools at our disposal. We know that critically ill patients do not tolerate prolonged sedation or prolonged periods with the RV outflow obstructed by a large cannula. As such, the ease of use and the efficiency provided by a particular MT device go far beyond operator

preference and are mandated for patient safety. It has also been apparent since the early days of MT that refractory clot is large, bulky organized clot, which some catheters cannot engulf and remove. This type of clot leads to the dreaded "lollipopping" of clot at the end of a catheter, which can prohibit extraction or lead to recurrent embolization. As with every technology, we look forward to a future of smaller catheters; but catheter size in the current era does seem to help mitigate the occurrence of "lollipopping." Finally, we know that the large-bore catheters used in anticoagulated patients can result in bleeding. We also know that PE patients with their recurrent hypoxia and hemodynamic challenge are uniquely vulnerable to the challenges of acute anemia. Therefore, mitigation of blood loss with these devices is extremely important—likely more important than we fully understand. Therefore, optimization of blood loss mitigation is at the absolute forefront of the field currently.

In which cases do you feel the AlphaVac system (AngioDynamics, Inc.) offers the greatest advantage compared with other available technologies?

Dr. Butty: The AlphaVac system can be used in all acute and subacute embolic events. Its unique technique for ingestion of embolic debris emphasizes selectivity, enhanced thrombus/embolus engagement, wireless navigation, and localized thrombectomy. This concept of localized thrombectomy offers physiologic advantages; specifically, clot ingestion without the rapid pressure changes or large-volume changes we see with other technologies, which can exaggerate the obstructive pathophysiology and cardiogenic shock that occurs during an embolic event.

Dr. Sayfo: The AlphaVac system's design suits patients where control matters most. The system consists of an ergonomic handle that acts as the vacuum source; a large, 18-F cannula with a funnel tip that expands to 33 F; and a waste bag that can hold up to 250 mL of blood and clot material. Because the operator controls aspiration with the handle, suction is applied only during engagement. I find this most useful in intermediate-high–risk patients who can't receive lytics, in smaller or anemic patients where every 100 mL counts, and for central or proximal lobar clot that the funnel tip can take in effectively. The 85° angled cannula is designed to make right heart navigation and vessel selection easier, as well as for cases of right side clot in transit, a very dangerous clinical scenario where torqueability and ability to suction large clot is needed.

APEX-AV, an investigational device exemption study, has shown impressive clinical outcomes with an excellent safety margin.[2] Because the device needs no capital console, I'd also highlight it for smaller programs or off-hours settings where a simple, self-contained system is a practical advantage.

Dr. Monteleone: The AlphaVac system has a lot of advantages: The technology is simple and obvious to the user. The enhanced ability to easily navigate the catheter makes its use extremely efficient, which is important for patient safety, particularly in the sickest of patients or in patients with tortuous PA anatomies. The funneled end of the catheter also provides an enhanced ability to engulf bulky, organized thrombus. The funnel creates a unique ability to visualize on fluoroscopy when the catheter end is abutting the vessel wall secondary to visualizing deformation of the funnel. The funnel is also uniquely visible on ultrasound imaging, including transesophageal echocardiography, which can optimize the performance of intracardiac thrombus removal with the AlphaVac system when necessary.

What is your blood loss mitigation strategy, and how does a blood return system change your approach to a case?

Dr. Butty: Speaking to the concept of blood return is somewhat premature, as I believe blood loss mitigation strategies are far more important. The AlphaVac system is unique in that it allows for active and complete control of blood loss rather than being dependent on a vacuum, algorithm, or a high-volume syringe. Also, the amount of blood loss is predictable and consistent with each thrombectomy attempt. These opportunities for minimizing blood loss are achieved through unparalleled selectivity and maximized thrombus engagement. Thus, the AlphaVac system's unique features offer a more efficient procedure, making blood return an enhancement rather than a necessity of the procedure.

Dr. Sayfo: My strategy starts before access. I check baseline hemoglobin and hemodynamics, set a working blood loss budget for that patient, and make sure blood products are available for higher-risk patients. During the case, I aspirate only when the catheter is engaged with clot and avoid sustained aspiration in free-flowing blood. I confirm position angiographically before each pass and track cumulative aspirate continuously. With the AlphaVac system, the handle-driven, operator-controlled aspiration is the main tool for this: Suction starts and stops with the operator. Repetitive angiography between suction will prevent unnecessary suction and blood loss.

A filtered blood return system changes the math. It lets the operator take more aggressive or numerous passes, because aspirated blood can be sent back to the patient instead of being lost. That loosens the blood loss budget in large-burden cases. We are participating in APEX-RETURN, which is evaluating whether the investigational AlphaReturn Blood management system (AngioDynamics, Inc.) can support more complete thrombectomy while limiting net blood loss.

Dr. Monteleone: We know that persistent AC without interruption is one of the most important parts of the treatment of VTE. Therefore, blood loss mitigation has to be extremely thorough because patients are fully anticoagulated before, during, and after their procedures. Meticulous venous access technique, operator comfort with large-bore devices, and availability of percutaneous vessel closure are mandatory to prevent the benefits of MT from being outweighed by the dangers of bleeding. Blood return is also mandatory with large-volume aspiration. As blood return techniques have developed, our ability to achieve more successful and robust clot evacuation has grown and will no doubt enhance patient outcomes. However, we have an absolute obligation and responsibility to not simply assume that blood return is safe and effective. We must prove the safety of these blood return techniques, particularly because the availability of blood return has led to more extensive aspiration and thus more blood being removed during a MT procedure. That is why we are so proud of the work we are doing in the APEX-RETURN clinical trial.

How do you envision thrombectomy devices evolving over the next decade?

Dr. Butty: The feasibility of MT for the treatment of PE has been validated. This will evolve into new and refined treatment strategies that will allow for a more inclusive procedure treating all types of PE patients. I believe we will see a new classification approach to thrombectomy catheters. We are already seeing early glimpses of this evolution with the introduction of the AlphaVac system; specifically, the importance of selectivity, wireless navigation, thrombus engagement, procedural ease, and procedural efficiency. I consider AlphaVac to be the first truly selective pulmonary thrombectomy catheter. Also, devices that provide widespread, real-time physiologic data will bring greater uniformity in the treatment of these patients. Consequently, these benefits will allow for a more efficient and fluid procedure, greater set of data points for research, and improved outcomes with fewer patient complications.

Prof. Klok: Demonstration that the devices are safe and effective, further development to increase sustainability, and lower costs would be welcome steps toward implementation across the globe.

Dr. Sayfo: I expect devices to become smarter, safer, and more integrated. Closed-loop aspiration is the clearest trend: sensing technology that tells the system whether the catheter tip is in clot or in free-flowing blood and adjusts suction automatically, together with routine filtered blood return. Together, this should make blood loss a minor consideration instead of a limiting one. We will also likely see better navigation and steerability, catheters that can reach segmental branches without compromising bore, and real-time feedback such as integrated pressure monitoring, so we can measure hemodynamic improvement during the case instead of guessing.

I expect to see platforms that work across vascular beds, covering PE, deep vein thrombosis, and right heart masses. This way, one inventory serves the entire program. Imaging and artificial intelligence tools will help quantify clot burden and select patients.

Dr. Monteleone: My biggest hope is that we will start targeting therapies more effectively. I hope that someday soon we will look at clot on a CT scan and have a better understanding of what thrombus types will respond to which interventions. I also hope that the devices themselves will become smaller, safer, and more effective. I have been impressed with the rapid growth in the field, and I am excited for what the next decade holds in the treatment of PE. ■

1. Writing Committee Members; Creager MA, Barnes GD, Giri J, et al. 2026 AHA/ACC/ACCP/ACEP/CHEST/SCAI/SHM/SIR/SVM/SVN guideline for the evaluation and management of acute pulmonary embolism in adults: a report of the American College of Cardiology/American Heart Association joint committee on clinical practice guidelines. Circulation. 2026;153:e977-e1051. Published correction appears in Circulation. 2026;154:e24. doi: 10.1161/CIR.0000000000001415
2. Ranade M, Foster MT 3rd, Brady PS, et al. Novel mechanical aspiration thrombectomy in patients with acute pulmonary embolism: results from the prospective APEX-AV trial. J Soc Cardiovasc Angiogr Interv. 2024;4:102463. doi: 10.1016/j.jscai.2024.102463

Disclosures

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Dr. Sayfo: Consultant to AngioDynamics, Penumbra, Inari, BSCI; investigator, APEX-RETURN (AngioDynamics); National PI, Jupiter Medical; Vice Chair of the Education Committee, The PERT Consortium.

Dr. Monteleone: National PI, APEX-RETURN (AngioDynamics); consultant to AngioDynamics, Boston Scientific, FlowPhysix, Medtronic, and RapidAI; on scientific advisory boards for Abbott, Boston Scientific and Medtronic.

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Only the AlphaVac F18[85] is indicated for the treatment of pulmonary embolism. The AlphaVac F22[20] and F22[180] are not indicated for the treatment of pulmonary embolism.

Indications for Use:
The Cannula is indicated for:
- the non-surgical removal of thrombi or emboli from the vasculature
- aspiration and injection of contrast media and other fluids from and into the vasculature

The Cannula is intended for use in the venous system and for the treatment of pulmonary embolism. The Handle is indicated as a vacuum source for the AlphaVac Multipurpose Mechanical Aspiration System. The Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of the AlphaVac. Cannula/Obturator and other endovascular devices while minimizing blood loss associated with such insertions.

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