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New Mechanical Thrombectomy Devices Designed to Treat Venous Thromboembolism

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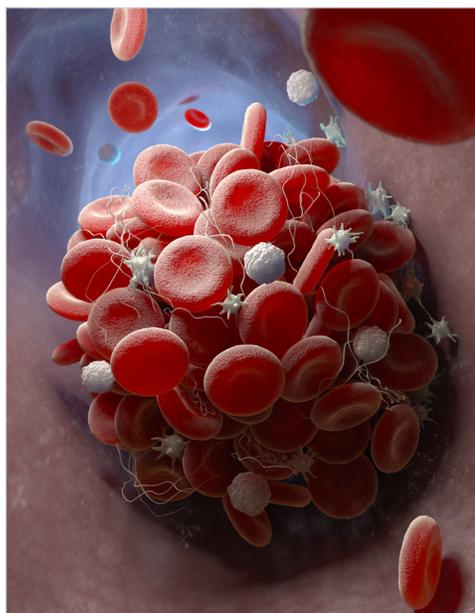
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iStock photo: Depiction of a blood clot forming inside a blood vessel – 3-D illustration

Mechanical thrombectomy devices may be a potential alternative to thrombolytic therapy to treat individuals with clotting conditions at high risk of hemorrhage.

How It Works

The FlowTrier System and the ClotTrier System (Inari Medical, Irvine, California) are two mechanical thrombectomy devices designed to treat blood clotting events such as pulmonary embolism and deep vein thrombosis.^{1,2} Specifically, the FlowTrier is a single-use mechanical thrombectomy device indicated for the percutaneous removal of emboli and thrombi from blood vessels and is intended to treat pulmonary embolism.³ The ClotTrier System is also a single-use endovascular device designed to remove thrombi and emboli from blood vessels but is only intended for use in the peripheral vasculature.⁴

The ClotTrier System is made up of the ClotTrier sheath and catheter. The sheath features a self-expanding funnel for clot removal and the catheter is made up of a coring mechanism and collection bag.¹ The ClotTrier System works by inserting the ClotTrier catheter into a vein and then deploying the coring mechanism and collection bag. The coring element is pulled through the blood vessel and collects thrombi as it goes. The catheter is then removed together with the thrombi. The process can be repeated several times in a single session in order to maximize clot removal.^{5,6}

The FlowTrier system is made up of the guiding catheter; the Trier20 – a large lumen catheter and syringe; as well as the FlowTrier catheter used for clot retrieval, which features three expanding mesh disks designed to capture clots from blood vessels and deliver them to the Trier20 for extraction.² The FlowTrier device works by inserting the guiding catheter into a vein in the groin area and threading it to the pulmonary arteries, and then deploying the retrieval catheter. Suction is then used to remove the clot.⁷

Who Might Benefit?

Deep vein thrombosis and pulmonary embolism are clotting conditions. Deep vein thrombosis affects about 200,000 Canadians each year.⁸ Venous thromboembolism occurs when a blood clot travels to the lungs and causes a pulmonary embolism; it affects about 100,000 Canadians and causes 10,000 deaths each year.⁹ There is some evidence emerging that COVID-19 – the disease associated with severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2 may be associated with an increased risk of these conditions.⁷

In some cases, such blood clotting conditions can be managed on an outpatient basis, however, more severe presentations often require more robust in-hospital treatment.^{10,11} There is some evidence that the FlowTrier device might be of greatest use in hospitalized patients with intermediate and high-risk pulmonary embolism (PE) for whom the risk associated with the use of thrombolysis might outweigh the benefits. These might be individuals who have experienced stroke or have recently undergone surgery and who are at increased risk of hemorrhage and pulmonary embolism, for example.¹²⁻¹⁴

Availability in Canada

The FlowTrier and ClotTrier devices have both received FDA clearance under the Premarket Notification 510(k) process.^{3,4} These devices are not currently approved for use in Canada and it is unclear at the time of publication whether the manufacturer plans to enter the Canadian market.

What Does It Cost?

A study that included the FlowTrier device and other devices currently used to remove blood clots estimated the cost of the FlowTrier device to be approximately US\$5,040; however, it was unclear how that cost estimate was ascertained.¹⁵

The FlowTrier and ClotTrier devices are both single-use technologies^{3,4} (i.e., they are not reusable), which may contribute to increased health care costs. However, there may be some cost savings if the devices lead to fewer complications related to use of thrombolysis. No cost impact is expected for patients assuming that the cost of the procedure would be covered under the public health care plan as for other endovascular interventions.

Current Practice

According to 2017 guidance from Thrombosis Canada, current practice for treating both pulmonary embolism and deep vein thrombosis involves the use of anticoagulation drugs, or in some more severe cases intravenous thrombolysis or catheter-directed thrombolysis.^{10,11} The choice of treatment for pulmonary embolism is based on the Pulmonary Embolism Severity Index (PESI) and the treatment of deep vein thrombosis (DVT) also varies according to the risk of complications.^{10,11} Hemorrhage is the main risk of both anticoagulation drugs and thrombolysis.

What Is the Evidence?

Two published studies,^{13,16} one substudy,¹⁷ as well as an ongoing clinical trial¹⁸ on the FlowTrier device, were identified. The FLARE study was a manufacturer-sponsored prospective, single-arm, multi-centre trial of the FlowTrier device that enrolled 106 individuals experiencing pulmonary embolism and found a significant right-to-left ventricle diameter ratio reduction 48 hours after the device was used.¹³ The second study was a single, retrospective case review study of 46 cases of pulmonary embolism treated with the FlowTrier device, which reported an 88% clinical success defined as an intraprocedural decrease in mean pulmonary artery pressure.¹⁶ The sub-study reported the use of the FlowTrier device to treat patients for pulmonary embolism who were diagnosed in the emergency department.¹⁷ The authors of these studies concluded that the FlowTrier device can successfully remove blood clots, but that additional evidence about the long-term outcomes of these patients would be useful. In addition to these two studies, several abstracts¹⁹⁻²⁹ and case reports describe the successful use of the device.^{28,30-37}

One clinical registry for the ClotTrier device was identified.³⁸ An abstract that describes how the preliminary results of the registry will be reported was also identified,³⁹ as well as several case reports.^{5,6,40-45} These case reports generally indicate that the device can be used successfully in the treatment of DVT of both the arms and legs.

Ideally, robust clinical trials on the optimal treatment of DVT and pulmonary embolism would be conducted to help determine the appropriate use of the FlowTrier and ClotTrier devices. For example, a study that compared thrombectomy to standard treatments like systemic anticoagulation, intravenous thrombolysis, and catheter-directed thrombolysis in terms of clinical outcomes, safety, and long-term outcomes would be very useful.

Safety

For the FlowTrier device, the FLARE study reported that 3.8% of patients suffered a major adverse event.¹³ According to the study, these events were the result of the procedural process and not the device itself.¹³ A retrospective case review study reported two major adverse events (4.6%) including hemoptysis requiring intubation, and intraprocedural blood loss requiring transfusion.¹⁶ Thus, the risk posed by the FlowTrier device regarding bleeding events and pulmonary artery injury remains unclear.

No evidence on the safety of the ClotTrier System was identified in the literature search.

Issues to Consider

Access to Care

Mechanical thrombectomy is a procedure that requires not only specific tools but also special training for clinicians.⁴⁶ In Canada, mechanical thrombectomy is used for other indications such as stroke. However, it is only available in tertiary care centres, whereas thrombolysis can be offered in a wider variety of hospitals and care centres.^{47,48} As a result, the availability of this procedure may depend on where an individual experiencing symptoms resides.

Related Developments

There is considerable innovation happening in the treatment of clotting conditions such as pulmonary embolism and venous thromboembolism. In addition to the FlowTrier and ClotTrier devices, there are other mechanical thrombectomy devices coming to market, including the Aspirex catheter (Straub Medical AG, Wangs, Switzerland), the Indigo System (Penumbra, Inc., Alameda, California), Aspire Max 7 mechanical thrombectomy system (Control Medical Technology, Salt Lake City, Utah), and the AngioVac Cannula (AngioDynamics, New York).¹²

Looking Ahead

The FlowTrier and ClotTrier devices appear to have promising safety and effectiveness outcomes; however, more information is needed regarding when best to employ these devices so that they can be used to the greatest benefit. Additional information about the cost of these single-use devices would also help to position them in real-world practice. Robust studies comparing these new treatments to other emerging and standard treatments for venous thromboembolism are needed.

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