

# Simultaneous proximal embolic protection and inferior vena cava mechanical thrombectomy using the FlowTrier system

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## ABSTRACT

Interventional radiologists have the unique ability to apply their imaging knowledge, wide scope of technical skills, and use of innovative technologies to comprehensively address the percutaneous management of the thromboembolic disease processes. This report illustrates successful management of a thrombosed inferior vena cava (IVC), while protecting against possible pulmonary embolism. Here, we present a 49-year-old female with stage IIIB ovarian cancer who presented with severe bilateral lower extremity edema and anasarca in the setting of occlusive thrombus of IVC. The thrombus was the result of compression from a large hepatic hematoma which gradually developed after radical hysterectomy. A new mechanical thrombectomy device approved for use in pulmonary embolism, Inari FlowTrier catheter, was used off-label to remove the clot. The self-expanding mesh discs in the Inari FlowTrier catheter were utilized to protect against pulmonary embolism while percutaneously draining the hepatic hematoma and alleviating the IVC compression. The IVC was largely patent at the end of the procedure, and the patient experienced complete resolution of her symptoms. This case report demonstrates the successful and safe off-label use of a new mechanical thrombectomy device approved for pulmonary embolism thrombectomy in the IVC and illustrates a novel application of the nitinol mesh discs in the device as proximal embolic protection.

In the last 20 years, advances in endovascular techniques have enabled interventional radiologists to play a critical role in the management of patients with venous thromboembolic (VTE) disease, including deep vein thrombosis (DVT) and pulmonary embolism. Image-guided endovascular treatments include catheter-directed thrombolysis, placement of inferior vena cava (IVC) filters, and percutaneous mechanical thrombectomy. Interventional radiologists have the capability to perform all these interventions alongside any other necessary percutaneous treatment (1, 2). In May 2018, the Inari FlowTrier System (Inari Medical) was FDA approved for mechanical thrombectomy of pulmonary embolism. This device was approved based on the results of the FLARE study, a prospective multi-institutional study of 106 patients that demonstrated the Inari FlowTrier System is safe and effective at facilitating mechanical thrombectomy in patients with acute, intermediate-risk pulmonary embolism (3). The system consists of two main components: a 20 F 95 cm long, Trierer20 catheter (formerly known as the Aspiration Guide Catheter), used for clot aspiration and a separate FlowTrier catheter with three self-expanding nitinol mesh discs near the tip of the catheter for removal of adherent clots. While formally indicated for pulmonary arterial thrombectomy, the system can be utilized in any other large vessel. Here, we illustrate the safe and effective application of the FlowTrier system within the IVC. Additionally, we demonstrated the novel use of the system's nitinol mesh discs as an intraprocedural proximal embolic protection to reduce the risk of pulmonary embolism during IVC thrombectomy.

## Technique

A 49-year-old female with stage IIIB ovarian cancer was treated with total abdominal hysterectomy and bilateral oophorectomy and partial resection of the colon. Three weeks postoperatively, the patient developed a large subcapsular hepatic hematoma that expanded

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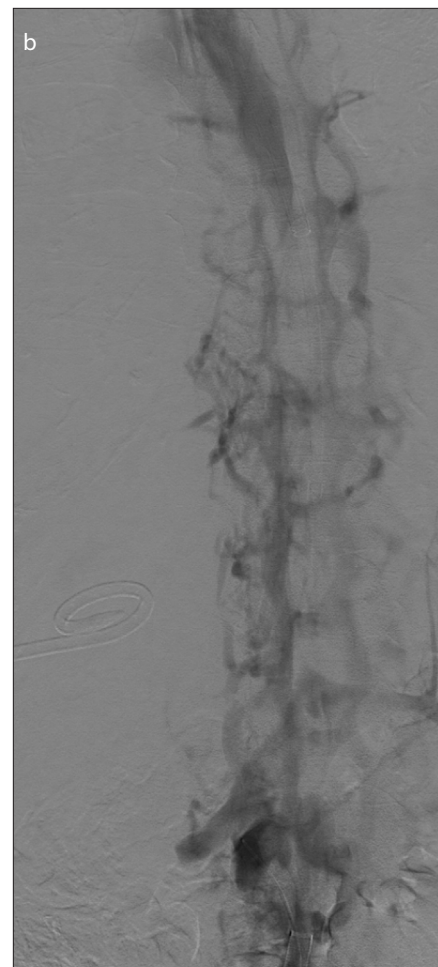
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over the following month. At this point, she acutely developed significant lower extremity anasarca and acute kidney injury, which was found on computed tomography (CT) of the abdomen and pelvis to be from an occlusive IVC thrombus (Fig. 1a). The etiology of the thrombus was presumed to be secondary to the mass effect of the hepatic hematoma over the proximal IVC. The patient had medical contraindications to anticoagulation, and most significantly a recent history of gastrointestinal bleeding. Interventional radiology was consulted for possible drainage of the liver hematoma and management of the IVC thrombosis. The patient was consented for hepatic drain placement, aspiration thrombectomy, and IVC filter placement.

First, a 12 F drainage catheter was placed into the hepatic hematoma under ultrasound and fluoroscopic guidance. The catheter was clamped to prevent decompression of the collection and IVC prior to thrombus removal. The right common femoral vein was accessed with a 6 F sheath under ultrasound and fluoroscopy. Venography demonstrated complete occlusion of the IVC just central to the iliac confluence extending to the level of hepatic IVC as well as proximal iliac veins, consistent with findings on a prior CT venogram (Fig. 1b).

In order to gain access superior to the occlusion, the right internal jugular (IJ) vein was then accessed. An Amplatz wire was advanced into the IJ, snared in the right atrium, and pulled down into the right common iliac vein. Subsequently, a 12 F 30 cm sheath was advanced into the superior aspect of the hepatic IVC through the IJ. The FlowTrievery catheter was then deployed to expose two discs, which would serve as a



**Figure 1. a, b.** Abdominopelvic CT image (a) reveals severe obstructive mass effect from the patient's large hepatic hematoma on the suprarenal IVC. The venogram (b) shows occlusion of the IVC.

proximal embolic protection during the aspiration thrombectomy (Fig. 2).

Returning to the groin, the Trierer20 catheter was advanced through the right common femoral vein sheath. Several aspirations were made with a marked reduction in clot burden and improved patency of the IVC observed on venograms. As flow within the IVC improved, the mass effect from the hepatic hematoma became apparent; the collection was compressing the suprarenal IVC. A small amount of eccentric clot, likely chronic, remained along the right wall of the IVC near the right renal vein. The remainder of the IVC was largely patent. After complete removal of the acute thrombus in the IVC, the hematoma was decompressed by unclamping the drainage catheter. The FlowTrievery disc was exchanged for a Gunter-Tulip IVC. The filter was deployed in patent suprarenal portion of IVC, but it was not detached from the delivery system. The hematoma was further drained, which allowed repositioning of the IVC filter to a more distal segment of the IVC. The unique

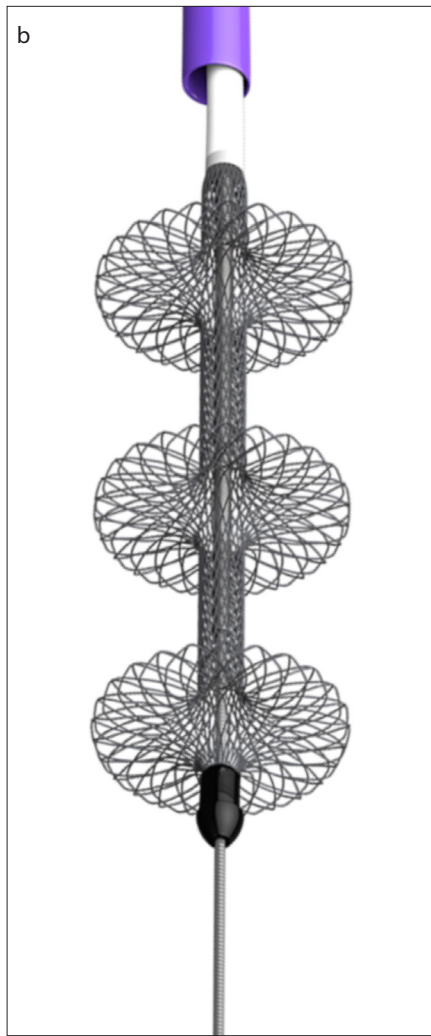
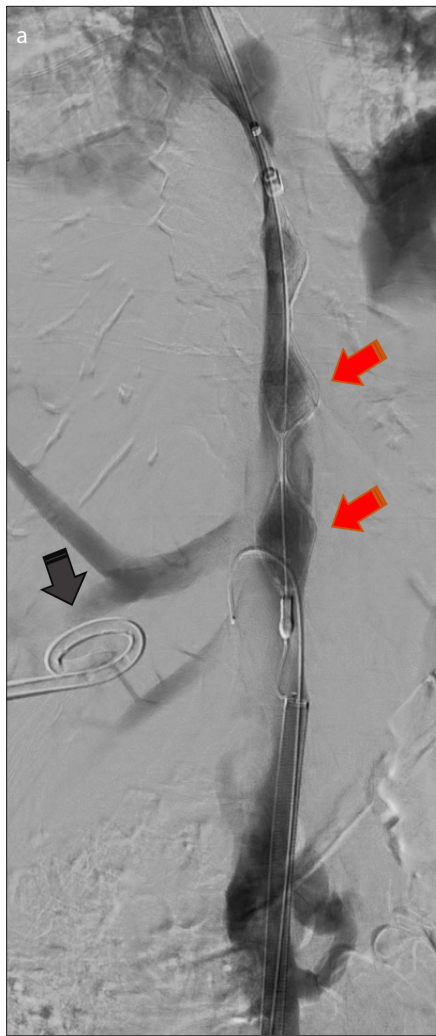
design of the Gunter Tulip filter allows temporary deployment, while keeping the filter attached to the delivery sheet (Fig. 3). The patient tolerated the procedure well and her edema improved post-procedurally within the next 48 hours, with complete restoration of renal function within three weeks. Multiple follow-up CT venograms showed patency of IVC with no recurrent thrombus without the need for anticoagulation.

## Discussion

Systemic anticoagulation therapy is still considered the mainstay treatment for an IVC thrombus. In patients with contraindications to anticoagulation such as bleeding risk as seen in this patient, interventional treatments may be considered. While catheter-directed thrombolysis is a safer alternative to systemic thrombolysis, mechanical thrombectomy is often favored relative to catheter-directed thrombolysis for thromboses in the IVC, as lysis times are often prolonged in the IVC given the higher

### Main points

- External compression from any mass in the liver could potentially result in IVC stenosis/occlusion, which could get complicated by thrombosis.
- Percutaneous mechanical thrombectomy is efficient for occlusive thrombosis.
- While the Trierer20 catheter of the recently FDA approved FlowTrievery system can be used for aspiration mechanical thrombectomy, concurrent deployment of the FlowTrievery catheter's mesh discs superior to the site of occlusion can serve as proximal embolic protection during aspiration until it is safe to place an IVC filter.



**Figure 3.** Final venogram demonstrates largely patent IVC with small burden of residual chronic clot in the distal IVC.

**Figure 2. a, b.** Fluoroscopy image (a) shows deployment of the FlowTrieve catheter discs (red arrows) proximal to thrombus as proximal embolic protection. Black arrow illustrates the drainage catheter placed in hepatic hematoma. The schematic figure (b) shows the FlowTrieve catheter discs in fully opened configuration. The FlowTrieve catheter comes in four sizes of a trio of self-expanding nitinol mesh discs near the tip of the catheter, which are used for mechanical clot capture and retrieval through the Trier20.

clot burden compared with femoral or popliteal veins (4). Interventional radiologists are uniquely positioned to manage these patients as they are able to retrieve clots, place IVC filters, and perform other necessary percutaneous interventions within a single session, as was done for this patient.

The interventional management of a patient with an occlusive IVC thrombus poses a challenging dilemma of balancing risks of embolism versus benefits of thrombectomy. Aspiration of the thrombus without proximal protection poses the risk of causing a pulmonary or renal vein embolism (5). However, deployment of an IVC filter upstream of a known occlusive thrombus is not ideal, as a thrombosed IVC filter can produce similar symptoms to the occlusive

clot itself and can be difficult to retrieve. An ideal solution would be to deploy a temporary embolic protection device upstream of the occlusion to protect the lungs, which can be replaced with a traditional IVC filter after aspiration thrombectomy is complete. In this case, the Inari FlowTrieve system discs were repurposed to serve as such proximal embolic protection. The mesh discs are designed to engage clot and are designed to be safely removed through the sheath with clot in place, as opposed to a thrombosed IVC filter. In the event that the FlowTrieve mesh discs are not available, partial deployment of a large Amplatz vascular plug or WALLSTENT as well as partial deployment of a Gunther-Tulip filter without complete release could be considered

as an alternative option. The plug could be unsheathed without being released and re-sheathed after thrombectomy. However, the additional cost of a plug or WALLSTENT and the specific design of the FlowTrieve discs to effectively engage with clot make the built-in device nitinol mesh discs a favorable alternative.

The Inari FlowTrieve system consists of a 20 F 95 cm long Trier20 catheter used for clot aspiration through a 60 cc self-locking syringe and the FlowTrieve catheter (6). The FlowTrieve catheter comes in four sizes of a trio of self-expanding nitinol mesh discs near the tip of the catheter, which are used for mechanical clot capture and retrieval through the Trier20. Typically, the Trier20 is advanced over a wire just proximal to the site of the thrombus. The FlowTrieve catheter is then advanced through the Trier20. In this case, the Trier20 catheter was used to aspirate clot while the FlowTrieve catheter discs were



deployed superior to the clot. Since the nitinol mesh discs are engineered to expand to fill the lumen of the vessel and engage with clots, we posited that they would serve as an effective failsafe in the event of unintended embolism during thrombectomy. The highest risk for embolism was when the hepatic hematoma was decompressed, relieving compression of the IVC filter and rapidly altering flow resistance. Once a significant clot burden was removed, the FlowTrieve catheter was removed from the internal jugular access and reintroduced through the Trieve20 at the groin. The discs were deployed again, this time within the remaining thrombus.

Aside from the off-label application of the FlowTrieve system, several other mechanical thrombectomy devices can be used to treat caval thromboses. To be effectively applied within the IVC, thrombectomy systems must be large enough to fit within a large diameter vessel (the IVC averages 15–17 mm) and maneuver well within the IVC's distensible vessel walls. Each system has its advantages and limitations; the FlowTrieve system is primarily limited by its large size which requires access through femoral vein. The CleanerXT/Cleaner15 (Argon Medical Devices) is comprised of a rotating S-wire and the drive motor with a side port which allows infusion of thrombolytics or contrast media. While effective at clearing thrombus,

this device can potentially cause emboli (7). Similarly, the AngioJet Rheolytic Thrombectomy system (Boston Scientific) may be less effective in the IVC due to the large vessel size (8). The AngioVac system (AngioDynamics) creates a suction vortex, facilitating the removal of large amounts of thrombus. However, the stiffness of the cannula may cause difficulty when advancing the device into the IVC and it requires perfusion setup (9).

In conclusion, percutaneous mechanical thrombectomy is a useful intervention for occlusive thromboses performed by interventional radiologists and other interventional physicians. The FlowTrieve is a new FDA approved device for pulmonary embolism aspiration mechanical thrombectomy that is also effective in the IVC. Deployment of the catheter mesh discs superior to the site of occlusion intraprocedurally can serve as proximal embolic protection during aspiration until it is safe to place an IVC filter.

#### Conflict of interest disclosure

The authors declared no conflicts of interest.

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