Reversing the Miniaturization Trend: Why Going Bigger Is Better for Treating VTE

Design concept and case experiences—how the large-bore Triever24 catheter can extract large volumes of venous clot to optimize procedural success in different VTE settings.

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Arterial interventional devices have become smaller over time, primarily to reduce rates of access site complications. With arterial lesions representing relatively small treatment targets, technical success has been maintained despite the miniaturization trend. Venous thromboembolism (VTE), however, represents a different problem and requires a different solution. These clots are much larger, frequently chronic, and wall adherent. Additionally, large-bore venous access has been demonstrated to be safe in multiple interventional, structural, and electrophysiologic procedures.[1]

Accordingly, Inari Medical purposely developed the FlowTriever Mechanical Thrombectomy System for VTE. The system that included a 20-F Triever20 (T20) aspiration guide catheter was validated in the FLARE trial[2] and used in approximately 3,500 cases. The current system introduces the 24-F Triever24 (T24) aspiration guide catheter to increase the venous clot extraction effectiveness. Although other thrombectomy devices commonly used for pulmonary embolism (PE) have been repurposed from devices initially intended for the narrow vessels of the arterial system, the FlowTriever System's large-bore design targets the specific characteristics of VTE, including large amounts of thrombus of varying age and consistencies within the large vessels of the venous system and pulmonary arteries (PAs).[3]

So, why does the large-bore design play such a vital role in achieving successful VTE thrombectomy? The Hagen-Poiseuille equation of fluid dynamics states that flow rate is directly proportional to radius to the fourth

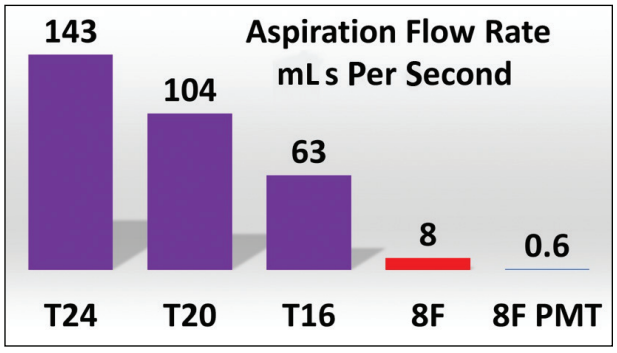


Figure 1. Aspirational flow rates of Inari Medical's T24, T20, and T16 aspiration guide catheters compared with two small-bore, 8-F competitive devices. PMT, pharmacomechanical thrombectomy; T16, Triever16.

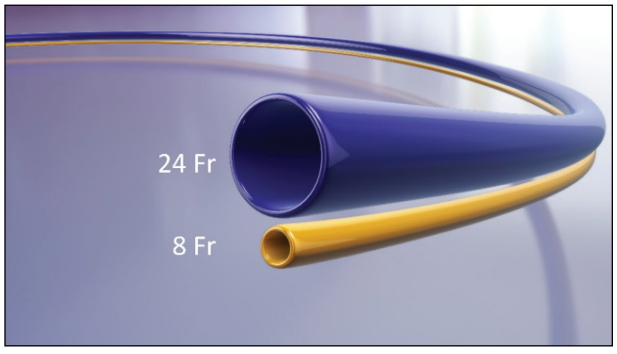
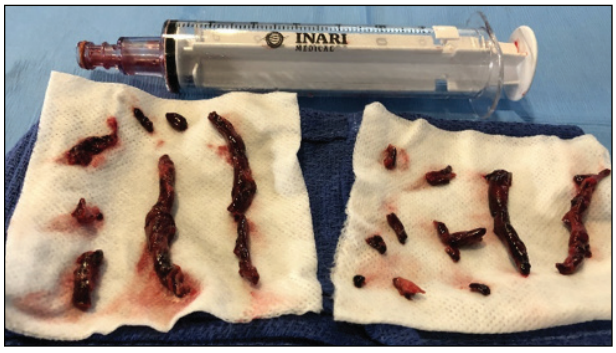


Figure 2. Lumen comparison of T24 aspiration guide catheter and 8-F competitive device.

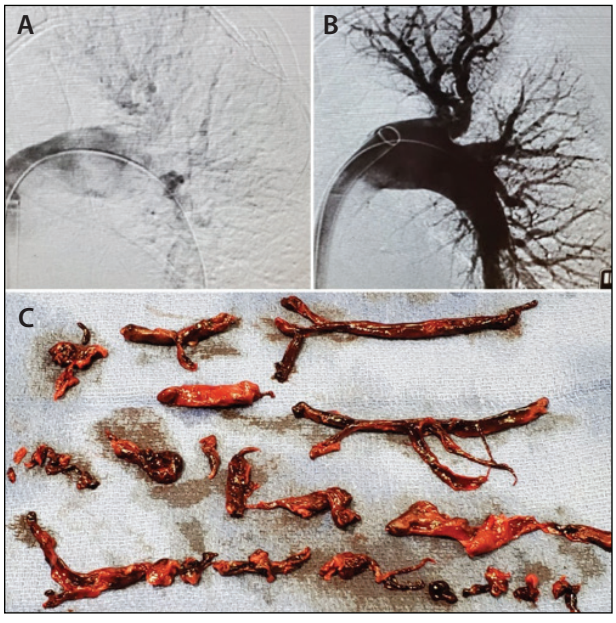
power. In other words, size is the most critical factor influencing suction efficiency. With this in mind, Inari Medical bucked the trend of smaller interventional devices and developed the T24 aspiration guide catheter, a 24-F system that boasts even stronger aspirational force with the trackability to successfully navigate the tortuosity of the right heart. The T20 catheter already possesses an aspirational flow rate of 104 mL/s, which is an order of magnitude larger than the 0.6 to 8 mL/s that can be achieved by smaller 8-F devices (Figure 1). The T24 increases the aspirational flow rate up to 143 mL/s, while still limiting blood loss to 60 mL per aspiration with its controlled aspiration design. Furthermore, the T24 catheter has the potential to require fewer aspirations to achieve successful thrombectomy with more efficient thrombus capture, resulting in shorter procedure times. Lastly, a larger lumen should minimize instances of catheter clogs that occur in smaller devices due to the sheer size of venous clot (Figure 2).

The T24 represents the next frontier in achieving surgical thrombectomy-like results via a percutaneous



Courtesy of Dr. Christopher M. Huff, OhioHealth Vascular Institute.

Figure 3. Thrombus removed from the right main PA using the T24 aspiration guide catheter, resulting in an on-table mean PA pressure decrease of 7 mm Hg.



Courtesy of Dr. Weems Pennington, Aiken Regional Medical Centers.

Figure 4. Pre- (A) and postthrombectomy (B) angiograms showing reperfusion of the left lung after use of the T24 aspiration guide catheter. Extracted thrombus shows casting of the PAs (C).

approach (Figures 3 and 4). This article presents three cases in which the T24 FlowTriever System was used to successfully extract markedly large thrombus, including a massive PE, a submassive PE, and an inferior vena cava (IVC) thrombus.

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2. Tu T, Toma C, Tapson VF, et al. A prospective, single-arm, multicenter trial of catheter-directed mechanical thrombectomy for intermediate-risk acute pulmonary embolism: the FLARE study. JACC Cardiovasc Interv. 2019;12:859-869.
3. Bozlar U, Ors F, Deniz O, et al. Pulmonary artery diameters measured by multidetector-row computed tomography in healthy adults. Acta Radiol. 2007;48:1086-1091.

T24 in Massive PE

By Christopher M. Huff, MD, FACC, RPVI; Michael A. Jolly, MD, FACC, RPVI; and Mitchell J. Silver, DO, FACC, FSVM, RPVI

PATIENT PRESENTATION

A 72-year-old man with hypertension and lumbar disk disease underwent routine spinal decompression and fusion at an outlying hospital. The next morning, he experienced syncope on attempted ambulation with physical therapy. Urgent bedside evaluation found the patient pale and diaphoretic, with 82% SpO_2 and a systolic blood pressure (SBP) of 70 mm Hg. The patient reported burning chest pain and an impending sense of doom. Supplemental oxygen and 5 µg/min norepinephrine increased his SpO_2 to 87% and his SBP to 95 mm Hg. Laboratory analysis revealed moderately elevated troponin levels, and an electrocardiogram showed sinus tachycardia. CT of the PAs demonstrated extensive bilateral PEs in the right and left main PAs and beyond (Figure 1). His right ventricle (RV) was abnormally large, with an RV/left ventricle (LV) ratio of 2, indicating severe right heart strain. Neurosurgery approved a heparin infusion. Due to continued hemodynamic compromise and his absolute contraindication to thrombolytic therapy, he was transferred to our facility for catheter-directed intervention.

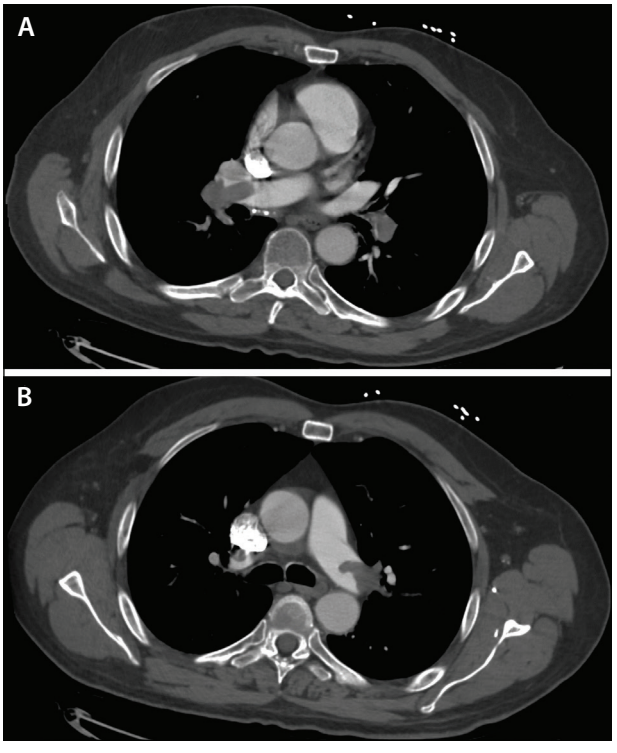

Figure 1. CT scan revealing clot in the right (A) and left (B) PAs.

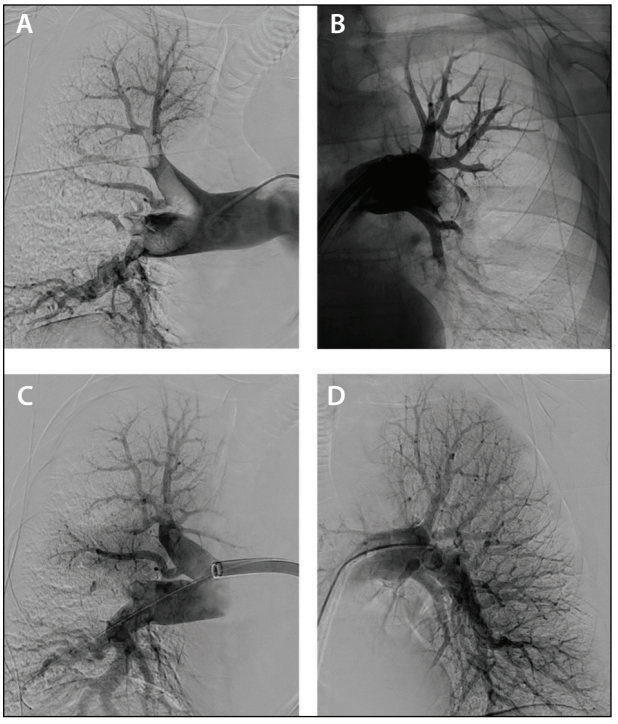

Figure 2. Preprocedural right (A) and left (B) pulmonary angiography shows compromised perfusion. After clot extraction with the T24 catheter, there was improved perfusion in the right (C) and left (D) lungs.

PROCEDURAL OVERVIEW

The patient was transferred directly to our cardiac catheterization laboratory, where heparin infusion was continued. Because of his tenuous respiratory status, we elected against sedation. We achieved right common femoral vein (CFV) access using ultrasound guidance. Venography ruled out right-sided iliofemoral deep vein thrombosis (DVT) before large-bore sheath insertion. The right CFV was preclosed (Perclose ProGlide, Abbott) and dilated to accept a 24-F DrySeal sheath (Gore & Associates). A Swan-Ganz balloon catheter was then used to safely navigate the tricuspid valve to access the main PA. Initial PA pressure was 54/21 mm Hg and mixed venous oxygen saturation (MVO_2) was 53.2%.

We then used a 0.035-inch guidewire and a standard support catheter to navigate into a subsegmental branch of the right PA and exchanged the guidewire for an Amplatz Super Stiff guidewire (Boston Scientific Corporation). With the Amplatz guidewire in a stable position, we inserted the 24-F T24 thrombectomy catheter into the distal right main PA. After two aspirations in the right PA and removal of a large volume of thrombus, repeat angiography was performed (Figure 2A and 2C). Satisfied with the results, the process was repeated in

the left PA. Because of moderate distal thrombus in the left interlobar branch, we used the small (6–10 mm) FlowTriever disks to assist in thrombus removal. The disks were deployed in the interlobar branch, left in place for 2 minutes, and then retracted into the FlowTriever catheter. Repeat aspiration removed more thrombus, and final angiography demonstrated marked improvement in lung perfusion (Figure 2B and 2D). A total of five aspirations were performed in the right and left PAs, with an estimated blood loss of 250 mL. We then reassessed the PA pressure, which measured 26/7 mm Hg, and the repeat MVO_2 was 68.2%. Hemostasis was achieved using the Perclose ProGlide device and a figure-of-eight skin suture. Procedure duration was 68 minutes. The norepinephrine infusion was discontinued in the catheterization lab. The patient was transferred to the medical intensive care unit hemodynamically stable with 98% SpO_2 on a 2-L nasal cannula. The next morning, transthoracic echocardiography revealed normal RV size and function. The patient was transitioned to apixaban therapy and discharged home 48 hours later.

DISCUSSION

PE is the third leading cause of cardiovascular death behind myocardial infarction and stroke, and the number one cause of in-hospital mortality.[1] In the area of PE, current thrombolytic-based strategies leave a significant treatment void for the management of patients with absolute contraindications to thrombolysis, such as our patient who presented with a massive PE 24 hours after spinal surgery.

The FlowTriever thrombectomy catheter has significantly impacted our institution's approach to patients with high-risk submassive and massive PE. These patients are triaged similarly to patients with ST-segment elevation myocardial infarction and are rapidly transferred to the cardiac catheterization lab, where PA thrombectomy using the FlowTriever catheter can be performed quicker than the time it takes to order, mix, and administer a systemic thrombolytic. Also, many patients present with subacute PE, which is resistant to thrombolysis. In this setting, a pure mechanical thrombectomy approach may, theoretically, be advantageous in treating this older, more fibrin-deficient thrombus.

Although we initially selected it for cases with high clot burden, the T24 thrombectomy catheter is now our device of choice for all pulmonary thrombectomy cases. The efficiency with which the T24 removes thrombus results in fewer aspirations within the PA. As a result, our cases with the larger device have been highlighted by a reduction in blood loss and procedure time. Fortunately, the increased size of the T24 catheter does not reduce its trackability through the RV outflow tract and into the PA. Overall, based on our early experience, the T24 appears to be more effective at treating submassive and massive PE, without a reduction in safety.

1. Raskob GE, Angchaisuksiri P, Blanco AN, et al. Thrombosis: a major contributor to global disease burden. Arterioscler Thromb Vasc Biol. 2014;34:2363-2371.

T24 in Submassive PE

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PATIENT PRESENTATION

A 71-year-old woman presented to the emergency department with shortness of breath and chest tightness. Two weeks earlier, she underwent external beam radiation therapy followed by intracavity brachytherapy for stage III squamous cell carcinoma of the cervix. Despite 5-L supplemental oxygen, the patient had a reduced SpO_2 of 90%. CTA revealed extensive bilateral PEs mostly proximal at the right PA, with an enlarged RV (RV/LV ratio = 2) (Figure 1). After 12 hours of bilateral catheter-directed thrombolysis, the patient's attempts to ambulate resulted in dyspnea and drops in SpO_2. After discussing the risk/benefit tradeoff, mechanical thrombectomy with the FlowTriever System was selected as the next treatment.

PROCEDURAL OVERVIEW

The patient was placed under moderate conscious sedation. Right CFV access was achieved under ultrasound guidance. The right heart was traversed with the back end of a Bentson wire (Cook Medical) inside an angled pigtail catheter maintained as a loop to avoid chordae entanglement. The backward Bentson wire was carefully maintained

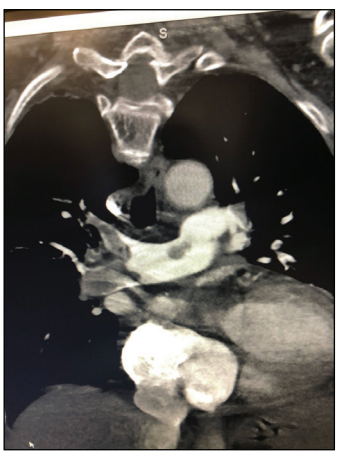

Figure 1. CT scan revealing extensive clot in the right PA.

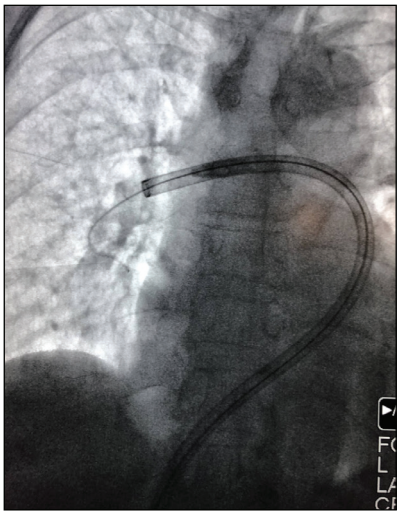

Figure 2. The FlowTriever T24 deep in the right PA, just proximal to the embolism.

Figure 3. Total extracted clot haul consisting of acute and chronic pieces.

inside the pigtail catheter for this maneuver. PA pressures measured 45/16/28 mm Hg. Given the large clot burden, the T24 aspiration guide catheter was selected for thrombectomy.

The pigtail was directed to the right PA, where an Amplatz Super Stiff wire with a 1-cm tip was placed in a stable location. The femoral vein access was dilated to accommodate a 24-F DrySeal sheath. After a bolus of 8,000 heparin units, the T24 was advanced through the right heart into the right PA (Figure 2). A controlled aspiration extracted large amounts of hard, chronic clot into the syringe. Next, a FlowTriever catheter (medium disks) was maneuvered to dislodge and extract clot, followed by an additional aspiration to extract remnant thrombus. A buddy wire was then placed to guide the T24 into the truncus anterior branch, which was cleared in a single aspiration. A large volume of clot was extracted (Figure 3), resulting in significant restoration of lung perfusion (Figure 4).

After mechanical thrombectomy, PA pressure measured 27/6/13 mm Hg, representing a systolic drop of 18 mm Hg, a diastolic drop of 10 mm Hg, and a mean drop of 15 mm Hg. Venous access was closed with a purse-string suture and manual pressure without complication. The patient's heart rate dropped from 115 bpm before thrombectomy to 89 bpm after the procedure. The skin-to-skin procedure time was 55 minutes, with blood loss estimated to be 150 to 200 mL. The patient was placed in a step-down bed and discharged after 48 hours.

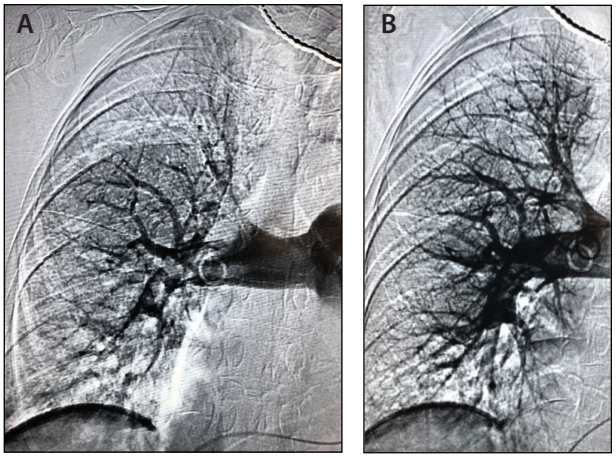

Figure 4. Contrast before (A) and after (B) thrombectomy indicates increased blood flow through the right lung after clot extraction.

DISCUSSION

Inari Medical's T24 catheter was safely maneuvered through the right heart and positioned for PA thrombectomy in this submassive PE patient. To cross the right heart with a large catheter, it is imperative to use a blunt-tip catheter (such as a pigtail catheter with the full loop expanded or a balloon catheter) to place the guidewire in the PA. This prevents entangling or dissecting the chordae tendineae of the tricuspid valve once the large-bore catheter is introduced. The T24's large profile did not provoke any cardiac, pulmonary, or access site complications in this patient.

In just three aspirations, the T24 catheter extracted a large volume of acute and chronic thrombus, significantly improving right lung perfusion. Due to the efficiency of each aspiration, blood loss was minimal. The submassive PE was resolved in a single intervention lasting < 1 hour. The patient did not require intensive care unit admission and was discharged from the hospital in only 2 days.

T24 in an IVC Filter

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PATIENT PRESENTATION

A 43-year-old woman presented to an outlying hospital with chest pain, mild shortness of breath, leg pain, and chronic bilateral leg edema that was more pronounced in the right leg. The patient was on apixaban at admission because her medical history included factor V Leiden deficiency, PE, and DVT. CT revealed subsegmental PE, and duplex ultrasound showed an IVC filter originally implanted in 2010 that migrated to the right iliac vein near the IVC confluence. After 4 days of anticoagulation treatment for the PE and DVT, she was transferred to our facility for an intervention to clear the IVC filter.

PROCEDURAL OVERVIEW

Bilateral CFV access was achieved under ultrasound guidance. Venography demonstrated large clot burden in and above the IVC filter (Figure 1A). A 15,000-unit bolus of heparin was administered, and two Glidewire Advantage guidewires (Terumo Interventional Systems) were placed centrally. A FlowTriever catheter was advanced through a 12-F sheath in the left access, and the XL disks were deployed above the IVC filter for distal protection. The right access was dilated to accommodate a 24-F DrySeal sheath, and the 24-F T24 aspiration guide catheter was advanced into the IVC (Figure 1B). Double-suction aspiration (vacuum applied from two consecutive syringe pulls) with the catheter landing in the middle IVC extracted a large amount of chronic clot (Figure 2). An additional double-suction aspiration was applied with the T24 positioned at the iliocaval confluence. Repeat venography demonstrated restored flow in the IVC (Figure 1C). The old filter was not retrieved in this setting. A Celect filter (Cook Medical) was placed in the IVC just caudal to the renal veins. The sheaths were removed, and the skin was closed with a figure-of-eight suture plus 30 minutes of manual compression. The estimated blood loss was 300 mL, and the skin-to-skin procedure time was 87 minutes. The patient was awoken from anesthesia, transferred to the postanesthesia care unit in stable condition, and discharged 48 hours later on therapeutic enoxaparin. Leg edema was significantly reduced at discharge, and continued overall PE and DVT symptom improvement was noted at 2 weeks and at 2 months postprocedure.

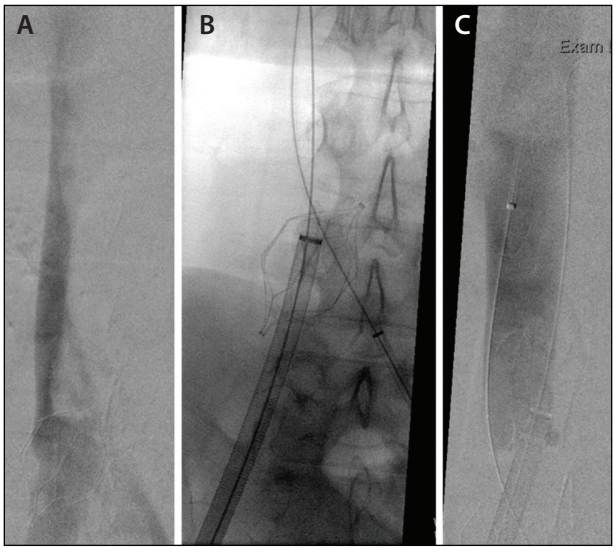

Figure 1. Venography showing evidence of clot at and above the filter (A). T24 placed within the IVC filter for aspiration alongside a 12-F sheath from contralateral access (B). Venography after thrombectomy shows flow through the IVC (C).

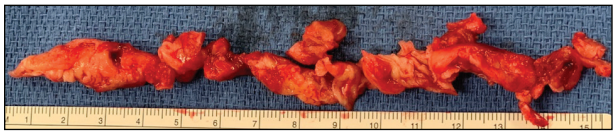

Figure 2. Large chronic clot extracted from the IVC filter with a single aspiration.

DISCUSSION

Thrombosed IVC filters can result in severe morbidity for patients, and effective treatment options are limited due to embolism concerns. Protection distal to the filter is essential to prevent an iatrogenic PE, particularly in a patient with a history of PE and a thrombus protruding past the filter into the IVC. Given the large size of the typical infrarenal IVC (23 mm in diameter)[1] and the fact that the filter was implanted nearly a decade previously, we expected a substantial amount of mixed acute and chronic thrombus. For these reasons, the T24 was chosen to treat this patient. The T24 effectively removed the large volume of organized thrombus in a single session without complications. Notably, the large venous access was well tolerated with careful dilation. The T24 is a valuable new option to remove extensive VTE burden, as can commonly be found in thrombosed IVC filters. ■

1. Doe C, Ryu RK. Anatomic and technical considerations: inferior vena cava filter placement. Semin Intervent Radiol. 2016;33:88-92.