Easing the Burden of VTE Treatment

How single-session mechanical thrombectomy avoids thrombolytics, reduces ICU stays, and gets patients home sooner.

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No patient, physician, or hospital system wants an extended hospital stay. Aside from the obvious benefits of being sent home sooner, patients with shorter hospital stays experience lower rates of hospital-acquired infection, are less cost-intensive, and develop fewer venous thromboembolism (VTE) events.[1,2] In addition, approximately 18% of patients with VTE are readmitted to the hospital within 30 days, and 10% to 30% have recurrent VTE within 5 years. When including long-term VTE-related morbidities such as postthrombotic syndrome and chronic thromboembolic pulmonary hypertension, the projected annual cost of hospital-acquired VTE is $7 to $10 billion per year.[3]

In this new era of medicine after the COVID-19 outbreak, shortening hospital stays and freeing up intensive care unit (ICU) beds has become increasingly vital. ICU beds are the most resource-intensive beds in hospitals, costing approximately $4,300 per day and bringing in less revenue for the hospital than floor beds, which generates an estimated $5.8 billion loss for hospitals.[4-6] These beds should remain available for the patients who need them most, as well as to allow hospitals to avoid unnecessary ICU use, which is economically unviable.

What can be done to minimize VTE-related ICU stays and expedite hospital discharge? Inari Medical has developed the FlowTriever and ClotTriever Systems as single-session therapies for VTE that avoid the need for thrombolytics. The presentation of VTE often does not inherently necessitate an ICU stay; instead, it is the use of thrombolytics that requires the patient to be monitored in the ICU. Because of the associated bleeding risks, patients must spend upward of 1 to 2 days in the ICU when undergoing thrombolytic therapy.[7] Although the placement and removal of a thrombolytic catheter may be faster for an interventionalist than a typical mechanical thrombectomy procedure, the time and resources spent on caring for the patient can be tremendous. Furthermore, thrombolytic therapy enacts a physical and emotional toll on patients, who must endure 1 to 2 days of discomfort, lying flat in bed while connected to monitors and intravenous lines.

> "The presentation of VTE often does not inherently necessitate an ICU stay; instead, it is the use of thrombolytics that requires the patient to be monitored in the ICU."

The FlowTriever System is the first mechanical thrombectomy device to be FDA-cleared for the treatment of pulmonary embolism (PE). It takes advantage of its large-bore design and controlled aspiration to effectively extract large volumes of thrombus in a single session, without the need for thrombolytics. Patients experience immediate on-table improvements in hemodynamics and vital signs. In the FLARE trial using the first-generation system, all patients with PE were treated in one session, only 1.9% received adjunctive thrombolytics, and > 40% of patients did not require any time in the ICU.[8] Preliminary data from the ongoing FLASH registry using the current third-generation system show that nearly two-thirds of patients avoid the ICU after treatment.[9] Also, a recent single-center analysis demonstrated a significant decrease in ICU time for patients treated with FlowTriever as compared with conservative treatment with anticoagulation alone.[10]

The ClotTriever System, FDA-cleared for treatment of the peripheral vasculature and most often used for lower extremity deep vein thrombosis (DVT), consists of a nitinol coring element and integrated collection bag for effective thrombus removal. Data from the first 105 patients with DVT enrolled in the CLOUT registry show that 99% of patients were treated in a single session, none required thrombolytic drugs, only 4% were sent

TABLE 1. UTILITY MEASURES IN PATIENTS TREATED WITH FLOWTRIEVER AND CLOTTRIEVER

	PE Patients Treated With FlowTriever	DVT Patients Treated With ClotTriever
Single session	100%[8]	99%[11]
Patients receiving thrombolytics	1.9%[8]	0%[11]
ICU after treatment	36.4%[9]	4%[11]
Hospital LOS	4.1 days[8]	2 days[11]

Abbreviations: DVT, deep vein thrombosis; ICU, intensive care unit; LOS, length of stay; PE, pulmonary embolism.

to the ICU, and the median hospital stay was 2 days.[11] Furthermore, a multicenter study of 12 patients with DVT showed that all patients avoided the ICU and had an average hospital stay of 2 days.[12] Table 1 summarizes utility measures in patients treated with FlowTriever and ClotTriever.[8,9,11]

In this article, we present three cases demonstrating how a mechanical-based approach using the FlowTriever and ClotTriever Systems allows patients to avoid ICU stays and be quickly discharged home. We describe a recent lung transplant patient treated for an acute PE who did not require an ICU stay, a phlegmatic DVT patient who experienced immediate symptom improvement and was discharged less than 12 hours later, and a lower extremity DVT patient treated in an office-based laboratory (OBL) and discharged the same day.

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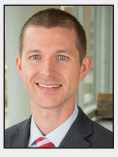
Successful FlowTriever Pulmonary Embolectomy in the Setting of a Recent Single Lung Transplant



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A 69-year-old man with interstitial lung disease presented to the hospital for his regularly scheduled pulmonary rehabilitation after a single lung transplant 10 weeks before. He reported not feeling well earlier that day when working on his car, followed by acute exertional dyspnea and difficulty walking into the hospital. His oxygen saturation was in the 80% range, and CTA revealed a large thrombus burden in the transplanted left pulmonary arteries (PAs; Figure 1). Consolidation in the lower lobe of the transplanted left lung was present, which is suspicious for early or impending pulmonary infarct. There was no sign of right heart strain. The patient was initiated on therapeutic enoxaparin, and due to concerns with the transplanted lung and a lack of pulmonary reserve, our interventional radiology group was consulted for consideration of catheter-directed therapy for the PE.

PROCEDURAL OVERVIEW

Right common femoral vein (CFV) access was achieved via ultrasound-guided micropuncture. A pigtail catheter was used to traverse the right heart and gain access to the main PA. Pulmonary angiography confirmed a large embolus in the main left PA, extending into the lower lobe (Figure 2A). PA pressures (PAPs)

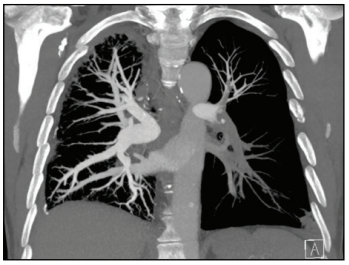

Figure 1. CTA showing extensive thrombus throughout the PAs of the recently transplanted left lung.

were relatively normal, with a mean PAP of 25 mm Hg, and there was no involvement of the native right lung. Due to the extensive thrombus burden, the decision was made to pursue large-bore mechanical thrombectomy via the FlowTriever System. A 24-F DrySeal sheath (Gore & Associates) was placed, and the 24-F Triever24 (T24) aspiration catheter (Inari Medical) was tracked over an Amplatz Super Stiff guidewire (Boston Scientific Corporation) into the main left PA (Figure 3). Initial aspirations yielded small fragments of organized thrombus. The T24 was then repositioned into the left lower lobe, and an additional aspiration yielded the remainder of the embolus in one large, highly organized, fibrous piece (Figure 2C). Immediate improvements in heart rate (from 73 to 64 bpm) and blood pressure (from 100/56 to 115/61 mm Hg) were noted. Postprocedure angiography revealed restored perfusion to the entire left lung (Figure 2B). An inferior vena cava (IVC) filter was placed due to a small amount of thrombus on lower extremity Doppler ultrasound, and hemostasis was achieved via manual compression. The procedure took 69 minutes in total. The patient was sent to a step-down unit for observation and was prepared to be discharged the next day, but a complication unrelated to the PE led to an extension of his hospital stay. A follow-up ventilation/perfusion (V/Q) scan 3 weeks later revealed normal perfusion of the treated left lung (Figure 4).

DISCUSSION

Lung transplant recipients are at particularly high risk for PE, with one autopsy study showing a 27% PE rate after transplant.[1] PE in lung transplant recipients is associated with increased risk of pulmonary infarction, occurring in 37.5% of patients,[1] as well as potential graft complications including bronchial stenosis and restrictive chronic lung allograft dysfunction, which has a median survival of < 1 year from time of diagnosis.[2] Therefore, even though this patient presented without signs of right heart strain and had normal PAPs, the extent of thrombus burden and the lack of pulmonary reserve led us to aggressively treat the PE. The patient avoided the high likelihood of an impending pulmonary infarct, and the transplant graft was preserved.

Importantly, treating this patient with the FlowTriever System enabled us to forego the use of thrombolytics. The option to quickly extract large amounts of thrombus with the T24 catheter allowed the patient to avoid an ICU stay and instead recover in a step-down bed. Thrombolytics not only carry a risk of major bleeding,[3,4] but their use also likely would not have been successful in treating this thrombus, which was organized and fibrous despite the patient's acute symptoms. It is probable that this thrombus was

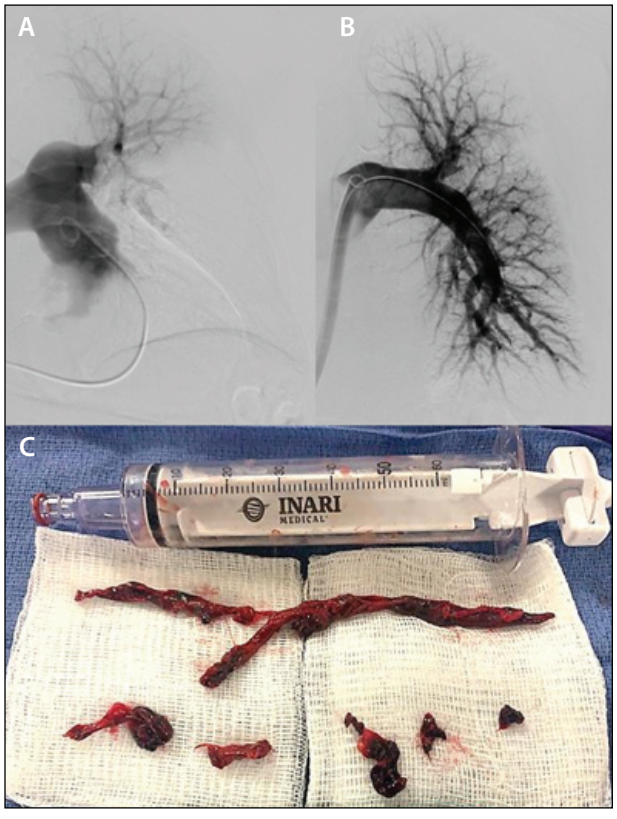

Figure 2. Preprocedure pulmonary angiogram demonstrating large filling defect in the left main PA (A) and postprocedure angiogram (B) showing restored perfusion of the recently transplanted left lung after extraction of extensive and highly organized thrombus (C).

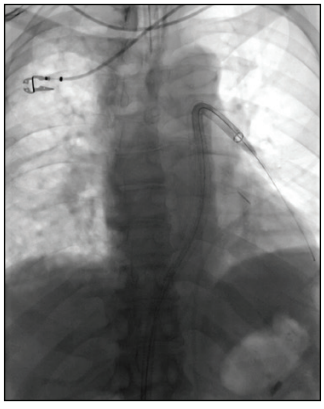

Figure 3. The T24 catheter traversed through the right heart and positioned in the left main PA for aspiration.

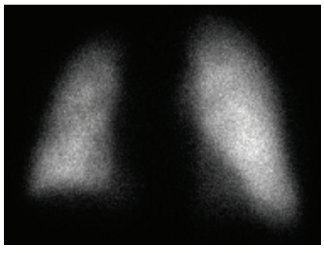

Figure 4. V/Q scan taken at 3-week follow-up showing normal perfusion of the transplanted left lung, while the untreated right lung remains diseased.

present for an extended period of time before the acute event exacerbated the patient's symptomology.

We were prepared to discharge the patient from the hospital 1 day after the procedure. However, the patient developed upper extremity compartment syndrome related to bleeding from an arterial line, which unfortunately required additional time in the hospital. After his eventual discharge, a follow-up V/Q scan at 3 weeks revealed continued restoration of pulmonary perfusion to the transplanted left lung.

In conclusion, percutaneous pulmonary thrombectomy via the FlowTriever System allowed us to quickly and efficiently extract a fibrinous embolus, restore lung perfusion, normalize the patient's hemodynamics, and avoid thrombolytics in a recent lung transplant patient.

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Rapid Extraction With ClotTriever of DVT Causing Phlegmasia Cerulea Dolens

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Disclosures: None.

A 21-year-old woman reported to the emergency department (ED) complaining of severe pain and swelling of her left lower extremity. Her symptoms began 3 days prior, originating with back pain that had progressed to her left hip. She visited a chiropractor earlier in the week with no resolution of symptoms. The day of presentation, she developed severe pain and swelling, as well as a bluish discoloration in her leg. She reported no recent long-haul travel and no family history of VTE, but she did take oral contraceptive pills. On examination, the patient's left lower extremity showed cyanotic changes at the toes and was tender to the touch (Figure 1). Bedside ultrasound revealed extensive thrombosis of the left leg, and she was diagnosed with acute DVT causing phlegmasia cerulea dolens, a limb-threatening condition without rapid treatment. Due to her severe symptoms and after we discussed different therapeutic options with the patient, we decided to pursue mechanical thrombectomy with the ClotTriever System.

PROCEDURAL OVERVIEW

Left popliteal vein access was achieved via ultrasound-guided micropuncture. Prethrombectomy venography revealed extensive thrombus extending from the popliteal vein to the common iliac vein (CIV; Figure 2). The access sheath was exchanged for the specialty 13-F ClotTriever sheath. The ClotTriever

Figure 1. The left lower extremity diagnosed with phlegmasia cerulea dolens prior to mechanical thrombectomy with the ClotTriever System.

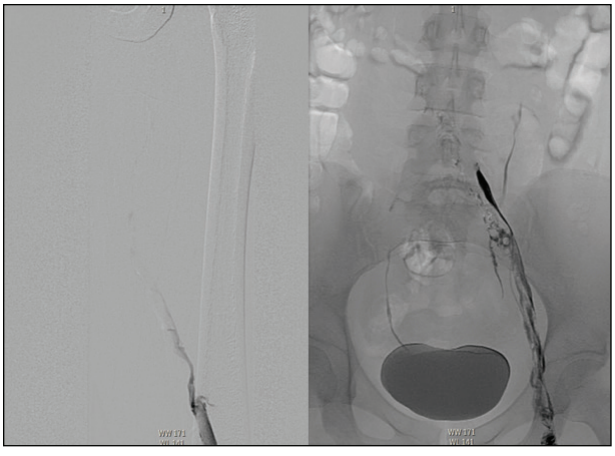

Figure 2. Prethrombectomy venograms showing occlusive DVT.

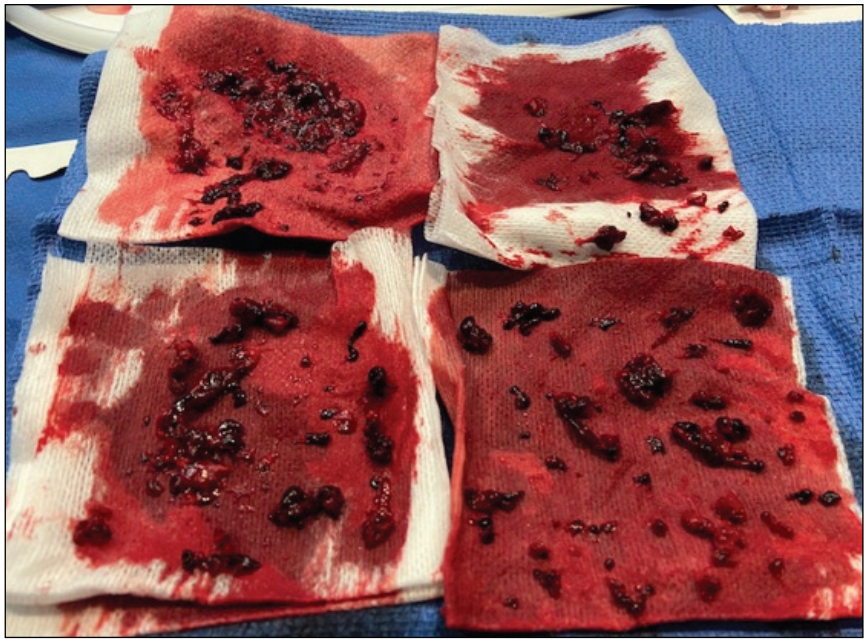

Figure 3. Extensive thrombus extracted from the left lower extremity in four passes.

catheter, consisting of a laser-cut coring element and integrated woven nitinol collection bag, was introduced over a 0.035-inch guidewire, advanced beyond the thrombus burden, and unsheathed to deploy the coring element. Four passes of the ClotTriever catheter were made toward the sheath, extracting a large volume of acute, subacute, and chronic thrombus with each pass (Figure 3). Postthrombectomy venography showed restored blood flow and no residual thrombus (Figure 4). No thrombolytics were required, and the total procedure time was approximately 80 minutes. There were no procedural complications, and the patient was sent to the medical floor for monitoring.

The next morning, the patient's leg was warm with normal color. Her pain and edema had improved, and she did not require narcotic pain medication. She was discharged from the hospital < 12 hours after the procedure and resumed normal activities and exercise later that week. At 1- and 3-month follow-up, she remained symptom-free and had no evidence of post-thrombotic syndrome.

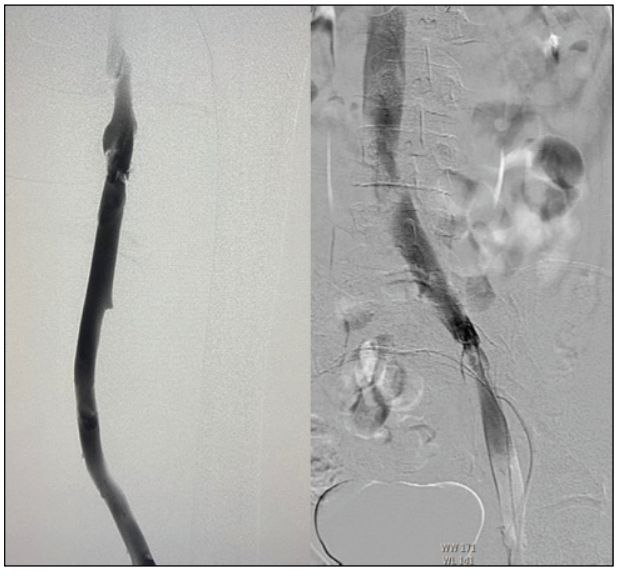

Figure 4. Postthrombectomy venograms showing restored blood flow, lack of residual thrombus, and underlying compression that was not stented due to the patient's young age.

DISCUSSION

Phlegmasia cerulea dolens is a potentially limb-threatening complication of severe DVT. If left untreated, it carries a 25% to 40% mortality rate and an amputation rate of 20% to 50%.[1,2] Due to the severity of this young patient's symptoms, we sought to rapidly extract the DVT via mechanical thrombectomy with the ClotTriever System, restoring blood flow and potentially saving her left lower limb.

Because the patient did not require thrombolytics, ICU admission was avoided, and she was admitted directly to the medical floor to recover. This approach offered multiple advantages, including avoiding the risk of bleeding from thrombolytic therapy, saving the hospital money and resources related to an ICU admission, and making an ICU bed available for another patient, which was particularly important because this patient presented during the initial COVID-19 outbreak.

In conclusion, single-session mechanical thrombectomy via the ClotTriever System allowed us to rapidly extract the limb-threatening DVT, avoid thrombolytic drugs and the subsequent need for ICU monitoring, and discharge the patient shortly after the procedure.

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Treating Acute DVT in an OBL in the COVID-19 Era

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A 30-year-old woman presented to the ED complaining of progressive swelling and worsening stiffness in her left leg, which had started 4 days prior. She had deferred going to the ED to avoid exposure to COVID-19 in the midst of surging hospitalizations in the region.

The patient had no history of shortness of breath or chest pain. She was on birth control pills, and her mother had a history of DVT. She had no recent surgery, trauma, or travel. The patient denied any history of leg swelling, leg heaviness, varicose veins, or varicose vein therapy. She had no history of superficial thrombophlebitis or DVT, and there was no other significant medical history or signs and symptoms of COVID-19, pneumonia, or flu. Her physical exam revealed notable swelling of the left leg from the foot to the upper thigh, and the leg was mildly cyanotic in the calf. The skin was distended but not threatened.

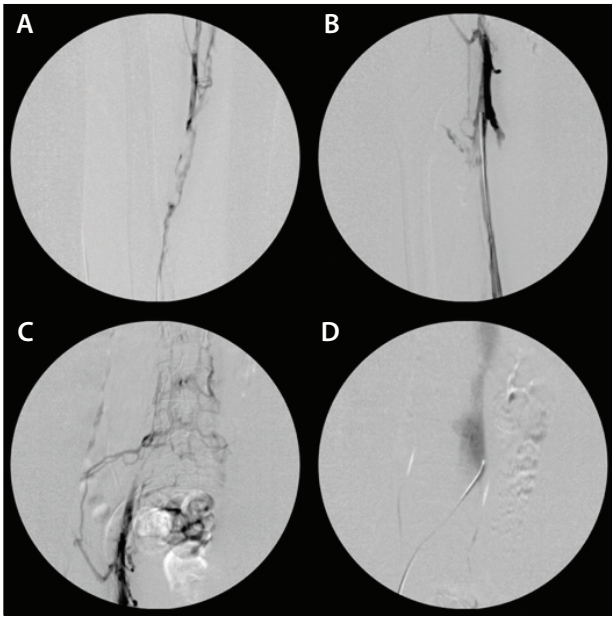

Figure 1. Prethrombectomy venography showing acute DVT of the left FV, CFV, EIV, and CIV (A-C). Collateral flow to the IVC was present via paravertebral collaterals. The IVC was free of thrombus (D).

A left leg venous duplex ultrasound revealed partial thrombosis of the posterior tibial, peroneal, gastrocnemius, and soleus veins. The popliteal vein, femoral vein (FV), and caudal CFVs were fully thrombosed. The cranial CFV, external iliac vein (EIV), and CIV were also partially thrombosed. The deep femoral vein (DFV) was patent. The CFV waveform was monophasic. DVT or occlusive disease were not present in the deep veins of the right leg from the calf to the iliac veins.

The patient was started on 10 mg of apixaban every 12 hours and compression therapy. She was discharged and scheduled for outpatient follow-up. On reexamination 3 days later, the patient noted decreased swelling, but on physical examination, the left leg was twice the size of the right to the level of the upper thigh. The cyanosis had resolved.

Our concern was that this young, otherwise healthy woman would be at significant risk of long-term post-thrombotic syndrome without prompt removal of the acute thrombus from her left leg. Due to her concern about potential COVID-19 exposure and the hospital's COVID-19 guidelines limiting interventional procedures to patients with life- or limb-threatening conditions, we sought a therapeutic option that could be accomplished in the OBL. Having experience with the ClotTriever System, I scheduled a percutaneous thrombectomy procedure to treat this acute occlusive DVT in a single session in our OBL.

PROCEDURAL OVERVIEW

The patient was positioned prone and administered conscious sedation with fentanyl and midazolam. The caudal segment of the left popliteal vein was accessed under ultrasound guidance. An ascending left leg venogram confirmed the acute occlusive DVT findings that were predicted by duplex imaging (Figure 1). A catheter placed at the CFV confirmed the duplex ultrasound findings of CIV and EIV occlusion. The IVC was free of thrombus. A 260-cm Rosen guidewire was introduced and advanced into the right internal jugular vein. The access site was then upsized to the 13-F ClotTriever sheath, the ClotTriever catheter was introduced over the guidewire, and the coring element was deployed above the left CIV thrombus. The ClotTriever catheter was brought back to the access site, extracting mostly red and some salmon-colored thrombus from the left CIV, EIV, CFV, and FV (Figure 2). Two passes in total were made with the device. Some resistance was noted at the cranial portion of the left CIV, suggesting a May-Thurner compression lesion.

Figure 2. Thrombus extracted from the left CIV, EIV, CFV, and FV.

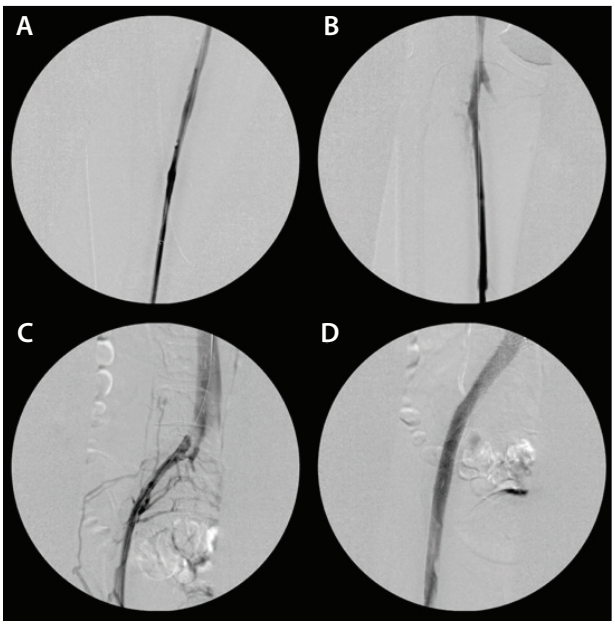

Figure 3. Postthrombectomy venography showing the FV and CFV free of thrombus and the EIV and CIV with minimal residual thrombus (A-C). Collateral transpelvic and paravertebral flow remained due to May-Thurner compression of the CIV. After iliac stenting, there was no collateral flow and the lumen was widely patent, with rapid and spontaneous contrast evacuation (D).

Completion venography and intravascular ultrasound (IVUS) imaging revealed a patent FV, stagnant flow with significant CIV and EIV stenosis, and a small amount of residual acute clot in the EIV (Figure 3). Cross-pelvic collaterals were prominent, suggesting long-standing chronic outflow stenosis of the left CIV. IVUS further revealed that the CIV and EIV had diffuse intramural wall thickening and sclerotic contraction. The CFV was free of scar, and the confluence of the DFV and FV was widely patent. The FV was free of thrombus, with no evidence of wall thickening or postthrombotic intramural or intraluminal scar.

To treat the underlying stenosis, the CIV and EIV were dilated with a balloon to 14 mm and the CFV was dilated to 12 mm. A 14- X 140-mm Venovo venous stent (BD Interventional) was placed at the confluence of the IVC and left CIV (avoiding jailing of the right CIV) and extended to the EIV. This was postdilated with a 14-mm balloon. The caudal CFV was then stented, preserving inflow from the FV and DFV, with a 14- X 90-mm Wallstent (Boston Scientific Corporation), which overlapped by 2 to 3 cm into the Venovo stent. The Wallstent was then postdilated to 12 mm in the CFV and 14 mm in the EIV. On completion, the iliofemoral vein outflow tract was widely patent with brisk and spontaneous drainage of contrast on venography (Figure 3D). The FV was also patent and free of thrombus, although contrast drainage was slow.

The patient was anticoagulated with therapeutic unfractionated heparin during the procedure. She was given a 1-mg/kg subcutaneous dose of enoxaparin before leaving the interventional suite, which was continued for 4 weeks. Oral anticoagulation with apixaban was planned for continued anticoagulation thereafter. She was also given 81 mg of aspirin in the recovery room to be continued for 3 months.

One month after the procedure, the patient has no leg swelling, cyanosis, erythema, or stiffness. She has no pain or problems walking and has resumed jogging. Her FV has rethrombosed, likely due to inadequate inflow, but her DFV and stents are widely patent, and she is clinically asymptomatic.

DISCUSSION

We treated a young female patient with extensive lower extremity DVT in an OBL in the midst of the COVID-19 outbreak, allowing her to avoid the risk of infection at the hospital and freeing up scarce hospital resources. Two passes with the ClotTriever catheter extracted a majority of the thrombus, followed by balloon angioplasty and stenting to treat the underlying chronic stenosis in the CIV and EIV. The patient was pleased with her improvement, especially given the circumstances of an extensive and major leg DVT occurring in the middle of a frightening and surging pandemic characterized by capacity overload of our local hospitals. ■