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Indigo® System for Thromboembolic Disease

Techniques for rapid evacuation of venous and arterial clot with vacuum-assisted thrombectomy.

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Acute arterial thromboembolism and venous thrombosis are limb-threatening and potentially life-threatening conditions. Acute arterial thrombus prohibits perfusion to affected limbs, resulting in emergent limb salvage situations. Acute lower extremity deep vein thrombosis (DVT) is a common condition that can cause substantial disability, with the most common feared complication being a life-threatening acute pulmonary embolus. In all of these situations, standard treatments—including anticoagulation, thrombolysis, and surgery—have significant limitations and potential complications. Therefore, continued innovation in this area is needed.

Many mechanical endovascular techniques for thrombus removal have been explored over the last two decades. Most have failed to be adequately efficacious or have been associated with unacceptable complication rates. Problems have included limited trackability, vessel injury, and incomplete revascularization. One of the main difficulties is designing a device that can remove adequate volumes of variable age thrombus while also maintaining an acceptably small size, flexibility, and ease of use. With the addition of larger 6- and 8-F systems and a venous indication, the Penumbra Indigo® System is designed to address many of these limitations by bringing more powerful, larger-bore aspiration catheters with greater trackability to the peripheral vasculature to evacuate greater thrombus burdens from large vessels.

Penumbra's Pump MAX™ and patented Separator™ technology help to maintain continuous aspiration, limiting clogging of the catheter's tip. This percutaneous system is available in four diameter options (CAT3, CAT5, CAT6, and CAT8), with lengths ranging from 85 to 150 cm, allowing smaller-diameter catheters to work coaxially through larger-diameter catheters to treat long lesions in tapering vessels. Smaller sizes can track into vessels as small as those in the foot, and larger sizes can be effective in vessels as large as the vena cava, allowing great flexibility.

Unlike thrombolysis, which often requires prolonged infusion times, Indigo is able to provide rapid restoration of flow to thrombosed vessels in settings in which there is inadequate time to allow thrombolysis to work. It can also be used for revascularization when thrombolytic therapy and surgery are contraindicated or prior to thrombolysis to decrease thrombus burden and potentially shorten lengthy infusion times (which can be quite costly). Finally, the Indigo System can be effective in removing more organized, subacute to chronic thrombus after thrombolytic therapy has failed.

We have found the Indigo System to be beneficial in removing clot related to a wide variety of thromboembolic conditions. The following cases highlight rapid revascularization with Indigo in both arterial and venous occlusions.

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An 11-year-old boy with a past medical history of hypoplastic left heart syndrome status after a fenestrated extracardiac Fontan procedure several years prior was admitted for worsening heart failure. In the course of his workup, cardiac catheterization was performed from a right common femoral artery access. The 6-F sheath was pulled at the conclusion of the procedure, and manual pressure was utilized for closure. The patient recovered normally and began anticoagula-

Figure 1. Digital subtraction angiography (DSA) image at the level of the right knee demonstrating high takeoff of the anterior tibial artery and occlusive embolus in the below-the-knee popliteal artery, with no flow in the peroneal or posterior tibial arteries.

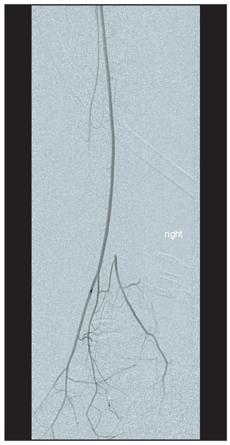

Figure 2. Oblique DSA image at the level of the right foot demonstrating single-vessel runoff via the anterior tibial artery.

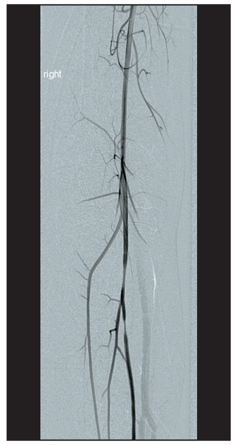

Figure 3. DSA image at the level of the right knee immediately after en bloc removal of embolus with the CAT3 catheter. The below-the-knee popliteal artery was patent, with mild arteriospasm. There was brisk flow in the peroneal and dominant posterior tibial arteries.

Figure 4. Oblique DSA image at the level of the right foot demonstrating three-vessel runoff, with a widely patent and dominant posterior tibial artery.

tion with warfarin on postprocedure day 1 to help prevent cardiac thrombus formation. On postprocedure day 3, the patient reported acute onset of severe right calf and foot pain and was subsequently noted on examination to have numbness and weakness in the right foot. A bedside Doppler examination detected no pedal arterial signals. Formal arterial duplex examination demonstrated acute occlusion of the right mid to distal superficial femoral artery and anterior tibial artery.

The patient's numbness and weakness quickly subsided without intervention. Interestingly, on examination by the vascular team, his right common femoral and popliteal artery pulses were palpable. There was a strong Doppler signal in the right dorsalis pedis artery, but no pulse or Doppler signal in the right posterior tibial artery. The right foot was cool to the touch, and sensory and motor functions were intact. Initial concerns for limb-threatening ischemia subsided; however, there was clinical evidence of thrombus/embolus in transit in the right lower extremity arterial system.

Urgent arteriography was performed with a plan for single-setting intervention. The patient's tenuous underlying cardiac condition necessitated minimal to no sedation, because his baseline oxygen saturation hovered around 80%. Angiography from the right common femoral and superficial femoral arteries showed that they were widely patent. There were, however, occlusive emboli in the mid profunda femoris artery and below-the-knee popliteal artery. There was variant anatomy with a high takeoff of the anterior tibial artery, which was widely patent into the foot. The peroneal and posterior tibial arteries were not visualized (Figures 1 and 2).

We decided to intervene with the intent of restoring normal or near-normal blood flow to the right lower extremity. The patient was systemically heparinized, and a long up-and-over, 5-F sheath was placed in the above-the-knee popliteal artery. We administered 4 mg of tissue plasminogen activator (tPA) directly onto the embolus, which showed no change in appearance after several minutes. The Indigo System was quickly set up, and the CAT3 catheter was advanced to the level of the embolus in the popliteal artery. Aspiration was then turned on, and the embolus was engaged. Flow ceased in the system, and the catheter was held in position with active suction for 90 seconds. The CAT3 was withdrawn from the sheath with active suction. At the tip of the catheter, there was a soft, purplish clot that was a few centimeters in length. Angiography from the sheath demonstrated complete en bloc removal of the embolus from the popliteal artery, with brisk flow in the patent peroneal and posterior tibial arteries (Figure 3). There was mild arteriospasm that required no further treatment. The pedal arteries were widely patent, with no evidence of distal embolization (Figure 4).

DISCUSSION

In this young patient with a tenuous underlying cardiac condition, a quick and effective same-setting endovascular intervention was the safest option for treatment. This case highlights the strengths of the Indigo System, including en bloc removal of clot and the ability to safely navigate the catheter and track through small arteries.

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A 63-year-old woman presented to our facility with complaints of left lower extremity discomfort, which started 5 days prior to her presentation. The patient had previously undergone right knee surgery the same month. Her risk factors included hypertension and diabetes. There was no previous history of DVT. The patient was a nonsmoker and was not taking oral birth control medication.

The patient's left lower extremity was swollen and warm, and her arterial pulses were intact. There was a 1.5-inch difference in circumference between her left and right mid-calf regions, with her left being larger than the right. There was no evidence of any open wounds, but there was significant pain and discomfort.

Venous duplex ultrasound imaging showed evidence of DVT extending from all left tibial veins to the left common femoral vein (Figure 1). The distal posterior tibial vein appeared to be patent. The patient was started on anticoagulation and admitted to the hospital. Because of the patient's symptoms and acute presentation, a decision was made to proceed with endovascular therapy.

Using ultrasound guidance, we accessed the distal posterior vein. We then proceeded with the insertion of a Glidesheath™ (5-F outer diameter, 6-F inner diameter; Terumo Interventional Systems) into the posterior tibial vein. Retrograde venography showed evidence of layered thrombus in the popliteal and iliac veins (Figure 2). We traversed the length of the occlusion within the left lower extremity veins to the inferior vena cava (IVC) using a 0.018-inch V18™ wire (Boston Scientific Corporation) and

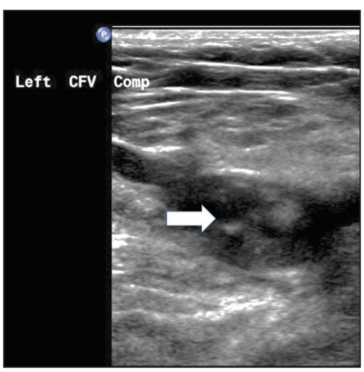

Figure 1. Ultrasound showing noncompressible acute thrombus in the left common femoral vein.

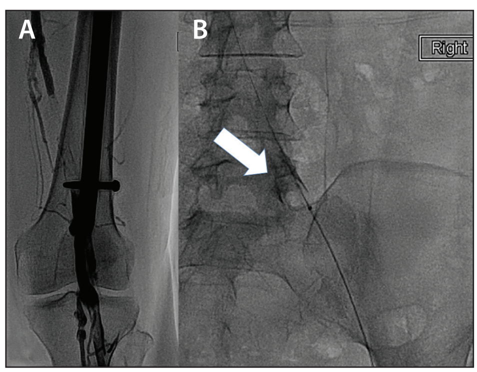

Figure 2. Acute thrombus in the left popliteal (A) and thrombus in the left iliac vein (B).

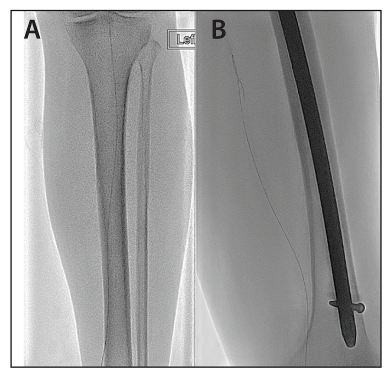

Figure 3. The 0.018-inch wire advanced through the posterior tibial vein (A) and femoral vein (B).

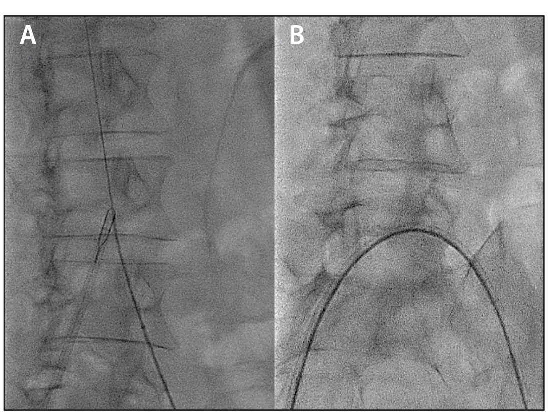

Figure 4. The V18 wire from the left iliac snared the right iliac vein sheath (A) and the 8-F sheath advanced into the left iliac vein (B).

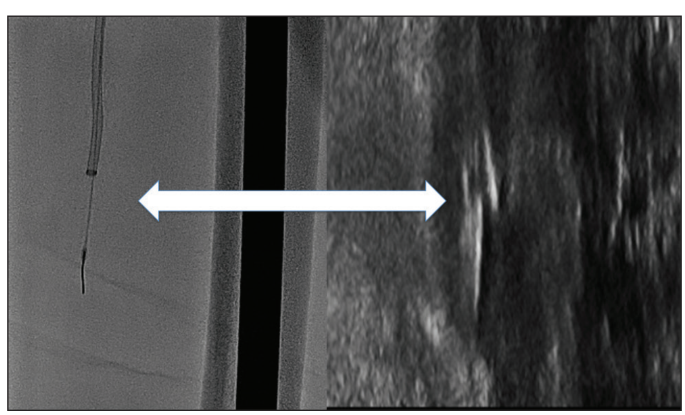

Figure 5. The CAT8 catheter advanced with the Separator SEP8, as directed under ultrasound.

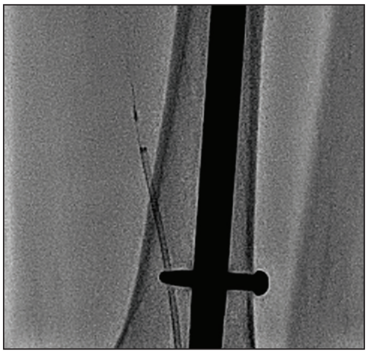

Figure 6. The CAT6 catheter advanced from the posterior tibial vein access site.

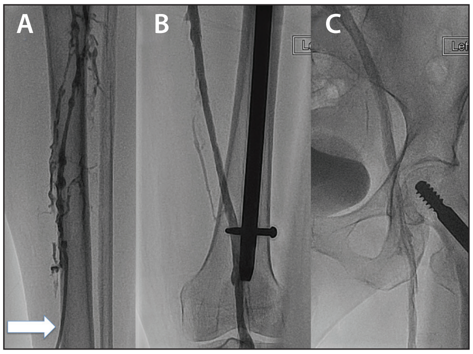

Figure 7. Final venogram showing restored flow through the posterior tibial vein (A), popliteal/femoral veins (B), and iliac vein (C). The arrow indicates the location of the posterior tibial vein sheath.

0.035-inch NaviCross® catheter (Terumo Interventional Systems) (Figure 3). After crossing into the IVC, we placed a lytic catheter and delivered 2 mg of rtPA over the course of 6 hours. After the 6 hours, we decided to proceed with mechanical thrombectomy using the Indigo CAT8 system through an 8-F sheath using an "up-and-over" approach via the right common femoral vein.

Using ultrasound guidance, we accessed the right common femoral vein. An 8-F, 45-cm Pinnacle® Destination® sheath (Terumo Interventional Systems) was advanced from the right common femoral vein into the IVC. Using a 10-mm snare, we were able to snare the 0.018-inch V18 wire from the left iliac vein to the right 8-F sheath (Figure 4). After snaring the wire, we were able to advance the 8-F sheath from the right iliac vein to the left iliac vein. We then advanced the CAT8 catheter over the wire and through the right 8-F sheath and proceeded with aspiration from the left femoral vein to the iliac veins. The Separator was utilized to facilitate clot aspiration by preventing the catheter from clogging in the extensive thrombus (Figure 5).

In addition to treating the left femoral and the iliac veins, we decided to treat the posterior tibial and popliteal veins. An Indigo CAT6 catheter was advanced in a retrograde fashion through the Glidesheath in the posterior tibial vein (Figure 6), and further clot was extracted. Final venography showed restoration of blood flow from the left posterior tibial vein to the IVC venous conduits (Figure 7).

The patient was started on oral anticoagulation and discharged home the next day. Thirty-day venous duplex ultrasound imaging showed no evidence of venous thrombosis and complete resolution of the patient's symptoms.

DISCUSSION

DVT is a debilitating disease with significant consequences to the patient and health care system. Tibial vein access offers an alternative method of crossing DVTs and allows for improved visualization of thrombus. The use of mechanical thrombectomy with the Indigo System offers a fast and effective modality to treat this disease.

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Disclosures: None.

An 83-year-old woman with a past medical history of atrial fibrillation, coronary artery disease, hyperlipidemia, and hypertension presented to the emergency department with acute onset of severe left leg pain for the past 2 hours. She had recently stopped taking her anticoagulation medication due to a life-threatening gastrointestinal bleed. Vascular ultrasound of the lower extremities revealed no blood flow in her left leg. On physical examination, the patient had acute critical limb ischemia of the left leg, which was notably cold, mottled, and had delayed capillary refill. The patient had motor and sensory deficits from her left toes to the knee and no palpable or Doppler detectable left pedal pulses.

Angiography was performed through a right common femoral artery approach, showing sluggish flow down the left common iliac artery and external iliac artery with occlusive embolus at the mid left common femoral artery, extending into the proximal superficial femoral artery (SFA) and profunda femoris artery (profunda). There was poorly filled and delayed reconstitution of the SFA and profunda (Figure 1). An 8-F, 45-cm vascular sheath was placed in the left external iliac artery, and the Indigo CAT8 catheter was advanced into the proximal cap of the embolus. The aspiration catheter engaged the embolus and effectively removed the embolus in a single pass using the "ADAPT"[1,2] technique developed with the neurovascular system. This technique involves placing the Indigo catheter just proximal to the thrombus and then turning on the aspiration pump. This allows the Indigo System's aspiration power to either ingest the clot en bloc through the catheter or latch onto it so it is "corked" in the catheter tip. The intact thrombus can then be safely removed from the body by withdrawing the Indigo catheter under aspiration.

Subsequent angiography showed complete removal of emboli in the common femoral artery and SFA. Further profunda embolus was noted (Figure 2). The Indigo CAT8 catheter was next readvanced to the proximal profunda to engage the embolus. A single pass was made to completely remove the embolus (Figure 3).

Imaging was performed lower in her leg and showed a patent SFA and popliteal artery with an occlusive embolus at the tibioperoneal trunk without significant reconstitution (Figure 4). In a coaxial fashion, the smaller 5-F Indigo CAT5 catheter was advanced through the Indigo CAT8 catheter into the tibioperoneal trunk. A single pass was made in the peroneal artery and in the posterior tibial artery to successfully aspirate the emboli (Figure 5).

The patient had immediate clinical improvement, regaining her motor and sensory function in her left leg. Her foot was noticeably warmer, with palpable pedal pulses. She was placed on a heparin drip and was discharged 1 day later on anticoagulation.

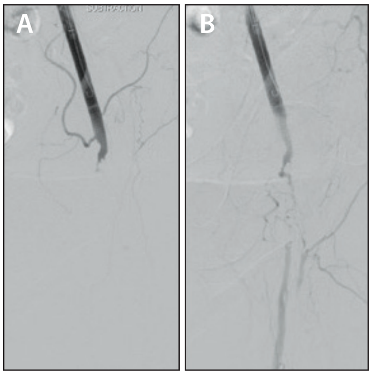

Figure 1. Initial angiogram demonstrating sluggish flow down the common iliac artery and external iliac artery with occlusive embolus at the mid left common femoral artery, extending into the proximal SFA and profunda (A). Poor filling and delayed reconstitution of the SFA and profunda (B).

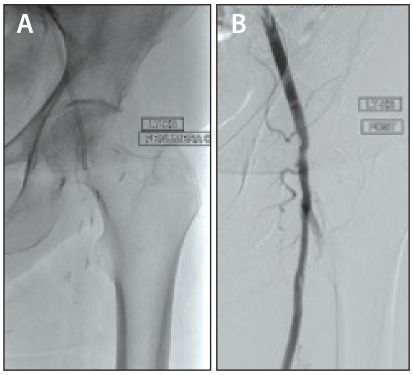

Figure 2. The CAT8 was advanced into the proximal cap of the embolus (A). Subsequent angiography after the first pass with the CAT8 showed complete removal of emboli in the common femoral artery and SFA. The CAT8 was then advanced to the profunda (B).

Figure 3. Angiogram after emboli extraction with the CAT8 in the profunda.

Figure 4. Angiogram showing tibioperoneal trunk occlusion.

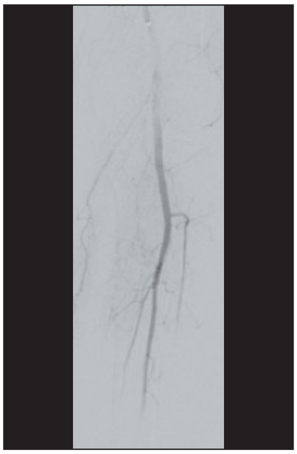

Figure 5. Angiogram after the CAT5 aspiration in the peroneal and posterior tibial arteries, showing successful aspiration of emboli and complete revascularization.

DISCUSSION

In the past, this type of patient had only one option, surgical embolectomy. The Indigo System provides a highly effective endovascular alternative to surgery. Over time, the technique and technology may evolve to where endovascular embolectomy may be preferred over surgery, mirroring trends seen with other vascular diseases, such as abdominal aortic repair.

1. Turk AS, Spiotta A, Frei D, et al. Initial clinical experience with the ADAPT technique: a direct aspiration first pass technique for stroke thrombectomy. J Neurointerv Surg. 2014;6:231-237.
2. Turk AS, Frei D, Fiorella D, et al. ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy. J Neurointerv Surg. 2014;6:260-264.

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A 65-year-old man with known right lung cancer and a prior history of deep vein thrombosis (DVT) presented to the emergency department with acute left leg swelling and pain. He had been on warfarin until approximately 3 weeks prior to presentation. He also had a fall approximately 1 week prior to presentation, which resulted in facial and nasal bone fractures and scalp lacerations.

Physical examination revealed a markedly swollen, tender, and tense left leg with bluish discoloration and diminished but Dopplerable distal pulses compatible with phlegmasia cerulea dolens (PCD). His right leg was normal with palpable pulses. Duplex evaluation confirmed extensive left lower extremity DVT extending into the external iliac vein with pandiastolic flow reversal in the left lower extremity arteries (Figure 1). He was started on heparin drip, and following clinical evaluation and discussion, the decision was made to pursue rapid endovenous thrombectomy with mainly mechanical thrombectomy rather than thrombolysis, given his worrisome examination, as well as his recent facial/head trauma.

From a left small saphenous vein approach, an 8-F sheath was placed. Venography was performed and confirmed extensive occlusive DVT throughout the left lower extremity through the iliac veins (Figure 2). An Indigo CAT8TORQ catheter (85 cm with an angled tip) with Separator SEP8 was introduced, and aspiration thrombectomy was successfully performed with large-volume thrombus extraction. Venography performed after the procedure demonstrated excellent complete iliofemoral thrombectomy (Figure 3) and confirmed an underlying critical left common iliac vein stenosis, which was treated with a 14-mm stent and angioplasty (Figure 4). The patient had immediate clinical improvement of his left leg prior to leaving the angiography suite. He was continued on heparin, with no bleeding from his prior facial injuries, and was discharged on warfarin. Clinical follow-up at 1 and 3 months revealed no recurrent symptoms, DVT, or evidence of postthrombotic syndrome.

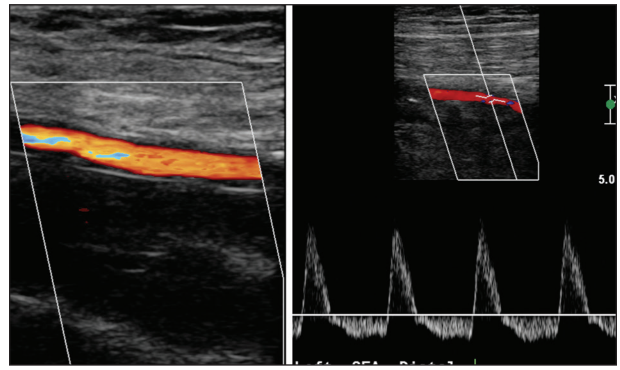

Figure 1. Extensive DVT in the left lower extremity (femoral veins) with pandiastolic flow reversal in the adjacent arteries.

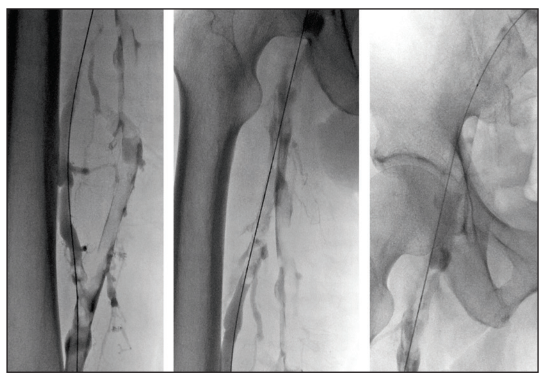

Figure 2. Venography confirming extensive acute DVT in the left lower extremity.

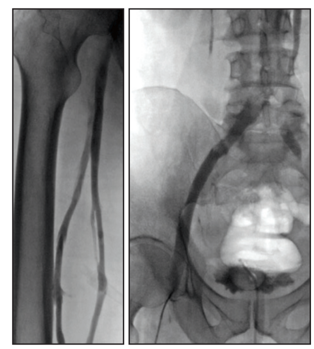

Figure 3. Venography confirming successful aspiration thrombectomy with Indigo.

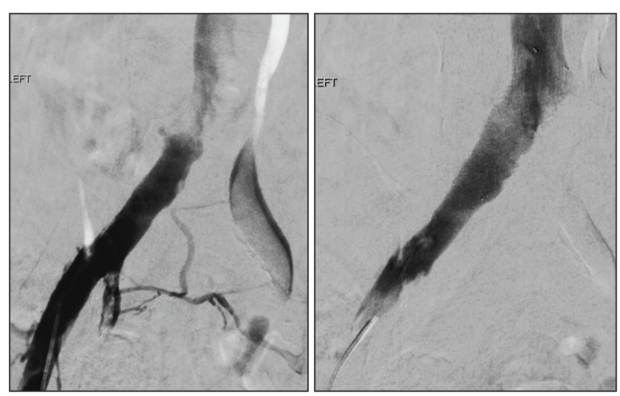

Figure 4. Left common iliac vein stenosis treated with stenting and angioplasty.

DISCUSSION

PCD is a rare condition caused by complete venous outflow occlusion, leading to significant pain, swelling, and impaired arterial perfusion. PCD is an emergency, given amputation rates approaching 50% and mortality rates of 25% to 40% if not treated promptly. In cases of DVT, when rapid debulking of thrombus burden is necessary and thrombolysis may not be feasible, thrombectomy with the Indigo System provides an efficient solution utilizing a trackable large-bore aspiration catheter and continuous vacuum technology.

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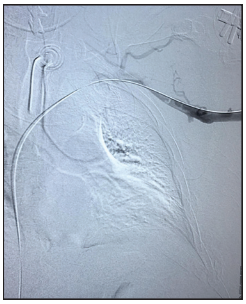

Figure 1. Venogram revealing multiple filling defects within the left jugular vein and total occlusion of the left subclavian and collaterals filling into the superior vena cava.

Figure 2. Venography performed after Indigo thrombectomy showing excellent flow throughout the left axillary and subclavian veins with normal passage of contrast into the superior vena cava and no persistent filling defects.

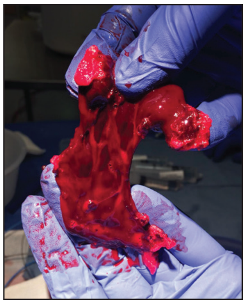

Figure 3. Clot removed with Indigo.

A 47-year-old man who was involved in a motor vehicle accident sustained severe traumatic injuries. The patient had multiple fractures involving the face and skull base. He sustained a ruptured globe in the right eye, bilateral hemopneumothoraces with bilateral open rib fractures, a severely comminuted left humerus, and left radius and ulnar fractures. The patient was treated in the intensive care unit for his multiple injuries. After 1 month in the intensive care unit, the patient developed severe edema in his left upper extremity, with erythema and tenderness. Duplex Doppler ultrasound of the left upper extremity was performed, which demonstrated significant DVT in the left upper extremity, with no color flow and a lack of compressibility of the left subclavian, axillary, and brachial veins.

The left basilic vein was accessed using an 8-F sheath system. A venogram revealed multiple filling defects within the left jugular vein, total occlusion of the left subclavian, and collaterals filling into the superior vena cava. The Indigo CAT8 thrombectomy device was utilized for multiple passes of suction thrombectomy. A significant amount of clot was removed. Another venogram revealed persistent filling defects within the left axillary vein and a high-grade stenosis in the mid left subclavian vein. Suction thrombectomy was then performed again in these persistent areas. Subsequently, balloon angioplasty of the area of stenosis was performed. Venography after the thrombectomy procedure showed excellent flow throughout the left axillary and subclavian veins, with normal passage of contrast into the superior vena cava and no persistent filling defects. The sheath was then removed, and manual pressure was applied to achieve hemostasis. The patient was then started on anticoagulation therapy.

DISCUSSION

In patients who have had recent traumatic injuries, thrombolytics can be risky. The Indigo System provides a safe and effective option to manage clot in patients with upper extremity DVT.

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The efficacy of vacuum-assisted thrombectomy has been proven with the Penumbra System®, which was developed to extract clot from the neurovasculature. Using this technology, Indigo was launched, bringing vacuum-assisted thrombectomy to the peripheral vasculature. The original Indigo catheters were smaller in caliber and were best suited for treating below-the-knee lesions. Now, with the addition of a venous indication and the launch of larger 6- and 8-F systems (CAT6 and CAT8), many more lesions are now quickly and easily treatable without surgery and with minimized need for lytics.

CASE REPORT

A 45-year old "veteran" hemodialysis patient returned with a report of "abnormal transconic values" and, finally, occlusion. Prior to the loss of the thrill in his loop graft, the patient reported decreased flow during dialysis. However, he denied prolonged bleeding, so venous outflow obstruction or a central lesion was less likely.

The venous outflow tract of the left arm loop graft was open, and the central venous evaluation was performed. As expected, the abnormality was not a part of

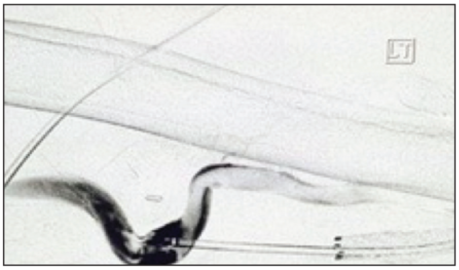

Figure 1. Venogram showing chronic thrombus at the native brachial artery.

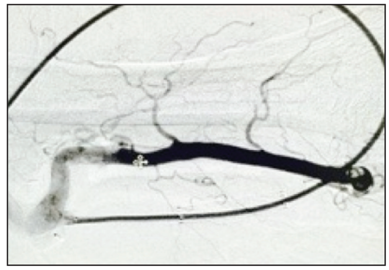

Figure 2. Postaspiration with the CAT8 aspiration catheter. Note filling of previously absent muscular branches and arterial anastamosis of a brachiocephalic loop graft.

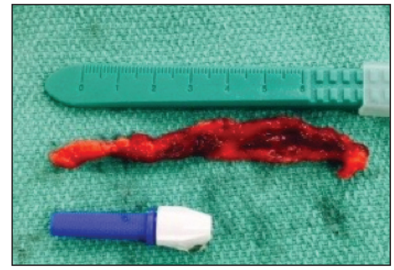

Figure 3. Chronic thrombus measuring 15 X 85 mm aspirated via the CAT8 catheter.

the venous outflow or central venous structures. Next, a retrograde venous evaluation was performed and demonstrated a prominent abnormality.

The Indigo CAT8 catheter was inserted and was able to traverse the loop graft in the subsequent switch back, which occurred at the arterial anastomosis. Under aspiration, the CAT8 catheter was used to engage the relatively long area of thrombus visualized within the native brachial artery. After multiple passes of aspiration, the thrombus was ingested through the CAT8. Follow-up angiography demonstrated clearing of the native brachial artery, and filling of smaller muscular branches was seen.

After checking the Penumbra vacuum canister, chronic thrombus was found (Figure 3). The 8-F CAT8 was able to remove a large thrombus measuring 15 mm at its widest point and 85 mm in length. Based on its chronic appearance, it did not appear to have refluxed across the arterial anastamosis.

DISCUSSION

For the average graft or fistula declotting procedure, there are several alternatives. However, when a powerful adjunct is required, it is good to have the Indigo System in our toolbox. To date, in our practice, the Indigo System has been used in venous structures of the arms, legs, inferior vena cava, as well as the lower extremity arteries with impressive results. ■

Disclaimer: The opinions and clinical experiences presented herein are for informational purposes only. The results may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes.