Indigo System for Thromboembolic Disease

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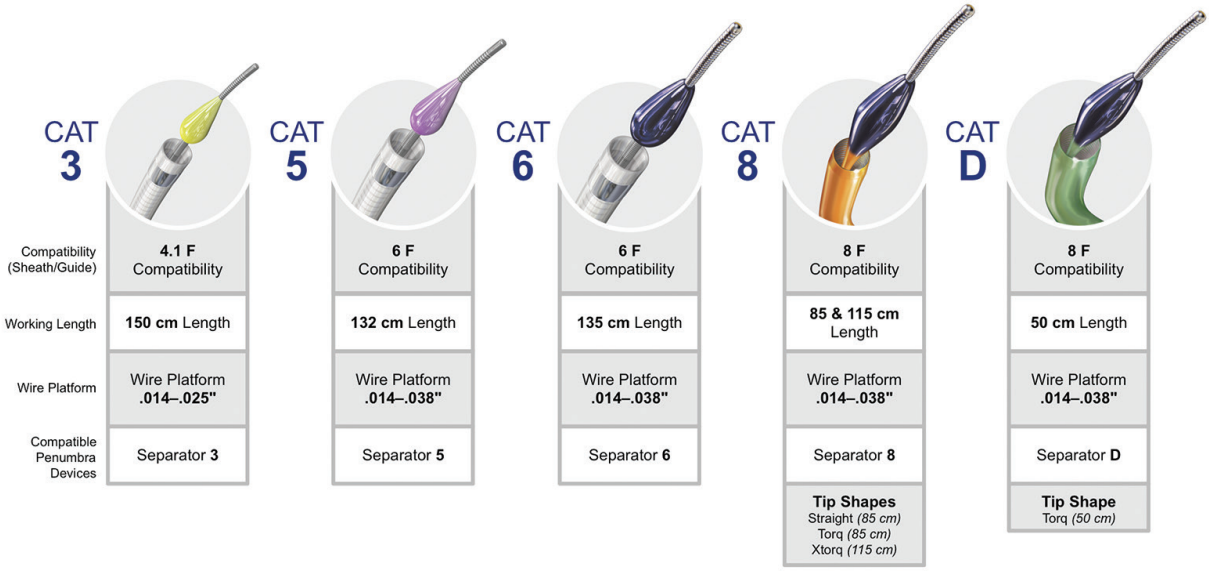
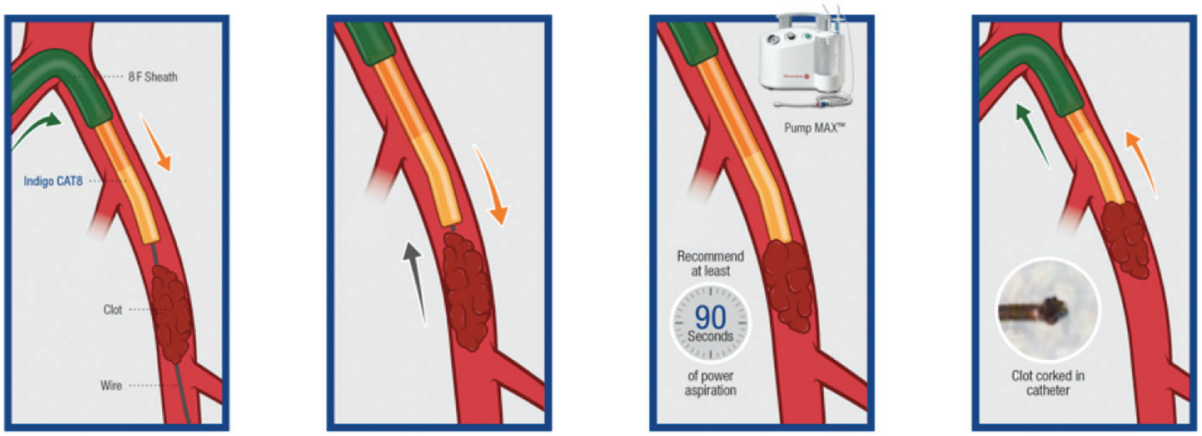
Thromboembolic disease comprises a group of disorders that crosses into the arterial and venous vascular beds and a combination of both vascular beds in hemodialysis arteriovenous fistulas. Arterial thrombus is typically a result of atherosclerotic plaque rupturing, launching the body into the clotting cascade, and resulting in platelet activation/aggregation, which then results in thrombus. Venous thrombus, which encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE), is typically the result of the following underlying sources: Virchow's triad of endothelial damage, hemostasis, and hypercoagulability—the occurrence of two of these three noted factors results in thrombus formation. Pulmonary thrombus typically involves the travel of a blood clot in the leg to the pulmonary artery, causing an acute occlusion. In the arterial vascular bed, the patient is symptomatic early on, and at the time of treatment, the thrombus is typically in the acute phase. In the venous vascular bed, the patient develops symptoms later, and at the time of treatment, the thrombus may be in the acute/subacute and/or chronic phase.

Due to differing thrombus morphology, the traditional endovascular treatment options that have existed have been associated with high complication rates and intensive care unit stays. Complications have included bleeding risk, distal emboli, vessel damage, incomplete revascularization, and damage to patient's kidneys.

The Indigo System (Penumbra, Inc.) has been designed to address the limitations of the traditional treatment options.





The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT8 is advanced through sheath over a wire.

The Indigo CAT8 is placed just proximal to the face of the clot and wire is retracted.

Aspiration is applied to Indigo CAT8 via Pump MAX until CAT8 becomes occluded *(recommend waiting at least 90 seconds)*.

The Indigo CAT8 is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.

Figure 1. The XTRACT technique as described in the PRISM trial involves tracking the largest, nonocclusive Indigo System catheter to the face of the thrombus. Aspiration is applied to the catheter using the Pump MAX until the system becomes occluded, and 90 seconds of continuous aspiration is performed, allowing for the Indigo System to engulf the thrombus. After 90 seconds, the system is retracted out of the body under aspiration to ensure the clot is extracted from the body.

The Indigo System aspiration catheter is available in a range of lengths and diameters that, when connected to the proprietary Pump MAX, will atraumatically remove the thrombus present in all vascular beds. The catheters (CAT3, CAT5, CAT6, CAT8, and CATD) vary in diameter from 3.4 to 8 F and lengths from 50 to 150 cm to enable the operator to remove thrombus from small vessels, such as the pedal arch, to large vessels, such as the inferior vena cava (IVC).

Penumbra, Inc. released the CATD and SEPD, its latest addition of the Indigo System, in Europe. The 8-F CATD features multiple material transitions for optimal tracking. With a length of 50 cm, it is designed for situations in which the culprit thrombus lesion is close to the access site, such as fistula declots or thrombus in upper extremity arteries and veins.

THE PRISM STUDY

The PRISM study was a retrospective case analysis conducted to determine the utility of the power aspiration–based XTRACT technique (Figure 1) as an initial and secondary approach in the treatment of peripheral arterial thromboembolism. Prior to the use of the Indigo System, patients had TIMI (thrombolysis in myocardial infarction) scores of 0 or 1. The primary outcome was the rate of TIMI 2–3 revascularization after Indigo System intervention and at the end of the procedure after balloon and stenting of the underlying lesion (Table 1). TIMI 2–3 flow was achieved in 87.2% of patients immediately after Indigo System intervention and in 96.2% of patients at the end of the entire procedure (Table 2). In addition, there were no device-related adverse events. The study showed that the XTRACT technique was safe and effective for revascularization of acute or subacute peripheral arterial occlusions as primary therapy or as a secondary therapy after other endovascular techniques had failed.

TABLE 1. INDIGO SYSTEM TREATMENT MODALITY

Used frontline	49.4%
Used after thrombolytics	15.2%
Used after other mechanical therapy	19.0%
Used after both thrombolytics and mechanical therapy	16.5%

TABLE 2. PRISM TRIAL PRIMARY OUTCOMES

	TIMI 2-3 Revascularization (n/N)
After Indigo System use	87.2% (74/78)
At the end of the procedure	96.2% (76/79)

Abbreviations: TIMI, thrombolysis in myocardial infarction.

ENDOVASCULAR TREATMENT OF OCCLUDED DIALYSIS FISTULA

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SUMMARY OF CASE SERIES

The case series by Marcelin et al included a total of 35 patients with acutely thrombosed dialysis fistulas.[1] All procedures were performed within 48 hours of the occurrence of thrombosis. Technical success was 97.1% (34 of 35 patients), while clinical success was 91.4% (32 of 35 patients). There were no technical or device-related complications. The average procedure time was 38.1 minutes, and the average blood loss during the procedure was 122.5 mL. At a mean follow-up of 8.5 months, five patients underwent a second aspiration for recurrent thrombosis of the dialysis fistula, while two patients had a restenosis treated with balloon angioplasty. The 6-month primary patency, primary assisted patency, and secondary patency were 71%, 80%, and 88.5%, respectively.[1]

CASE REPORT

A 61-year-old woman presented to our center with an acute occlusion of an arteriovenous fistula in the left antecubital fossa. Two days earlier, dialysis was uneventful, although recirculation was noted, with a suspicion of a stenosis of the postanastomotic area. Physical examination revealed absence of a thrill over the shunt. Dialysis was attempted but was not possible. Phlebography through a 4-F sheath confirmed occlusion of the fistula (Figure 1A). An exchange was made for an 8-F sheath with a detachable valve and thromboaspiration using the Indigo System CAT8 XTORQ catheter (Penumbra, Inc.) was performed. After the initial passage, partial reconstitution of flow was seen (Figure 1B). After additional passages with the same aspiration catheter, full restoration of the lumen was observed and an underlying high-grade stenosis was revealed (Figure 1C). This stenosis was dilated with a 5- X 40-mm standard angioplasty balloon, with good angiographic outcome (Figure 1D). The patient underwent dialysis immediately after the procedure and was able to continue dialysis in the months thereafter.

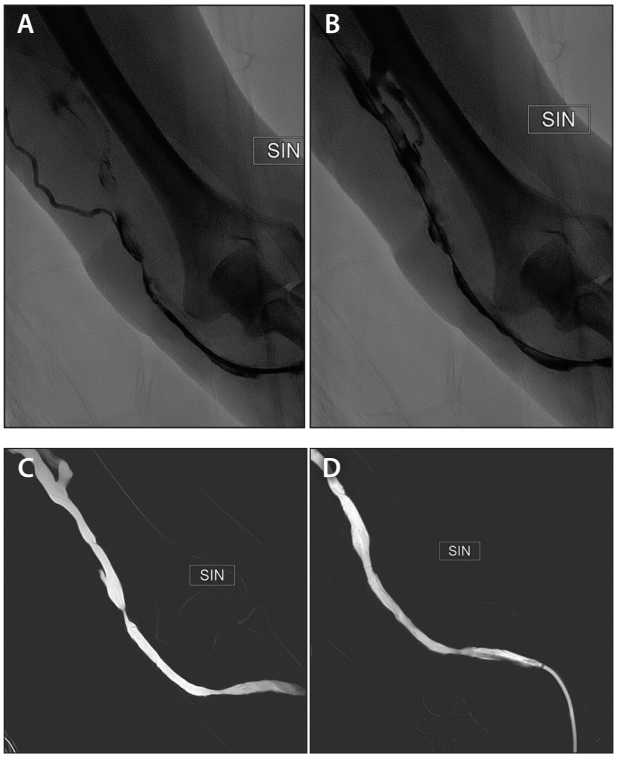

Figure 1. Phlebogram showing the occluded fistula (A). Partial reconstitution of flow after initial passage thrombus aspiration (B). Full restoration of the lumen and the underlying high-grade stenosis (C). Angiographic results after stenosis dilation (D).

DISCUSSION

The Indigo System is a useful adjunct for the treatment of acute dialysis fistula occlusion, with a high technical success rate and low complication rate.[1]

1. Marcelin C, D'Souza S, Le Bras Y, et al. Mechanical thrombectomy in acute thrombosis of dialysis arteriovenous fistulae and grafts using a vacuum-assisted thrombectomy catheter: a multicenter study. J Vasc Interv Radiol. 2018;29:993-997.

ENDOVASCULAR THROMBECTOMY OF ACUTE DISTAL EMBOLIZATION AFTER POSTTRAUMATIC TEVAR

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Lower extremity arterial thromboembolism is a significant medical problem that needs sophisticated interventional tools. The Indigo System was an effective tool to rapidly remove acute emboli after thoracic endovascular aortic repair (TEVAR) in a young man.

CASE REPORT

A 30-year-old man was involved in a motor vehicle accident and developed an acute thoracic dissection. The patient underwent TEVAR. Postprocedure, the vascular surgeon noticed the patient's lower extremity developed a pallor appearance, was cold, and had pulselessness. A Doppler ultrasound was performed, identifying a bilateral occlusion starting at the tibioperoneal arterial trifurcation and extending down to the pedal arteries.

The patient was referred to our interventional radiology department and was taken to the angiography suite for immediate intervention. An angiogram was performed, which confirmed the bilateral below-the-knee occlusion. At this point, the decision was made to remove the embolic event (Figure 1A) with continuous aspiration using the Indigo System to quickly remove the thrombotic material. Due to the patient's vessel size, the largest, nonocclusive catheter was chosen (the CAT5), and it was tracked distally to the face of the thrombus in the left leg to start. It was decided that the SEP5 would be used in conjunction to aid in the aspiration of the large volume of thrombus present. The Indigo System Separator is an adjunctive device that is advanced and retracted through the Indigo System catheter at the proximal margin of the primary occlusion to facilitate clearing of thrombus from the catheter tip. After a few minutes of continuous aspiration, the thrombus present down to the pedal arch was removed. At this point, the CAT5 was deemed too large for the vessel, and the 150-cm CAT3 was selected and tracked with ease to the distal segment of the patient's leg. The catheter was connected to the continuous aspiration Pump MAX and recanalization of the artery was obtained (Figure 1B).

Next, the right leg was selected, and the Indigo System CAT5/SEP5 were used in the same way to remove the embolic debris, resulting in bilateral three-vessel runoff all the way distal into the patient's pedal arch (Figure 2). Postprocedure, the patient's symptoms were resolved.

CONCLUSION

The Indigo System allowed for safe and rapid removal of distal emboli, restoring normal three-vessel flow in a severe acute bilateral lower limb ischemia. There

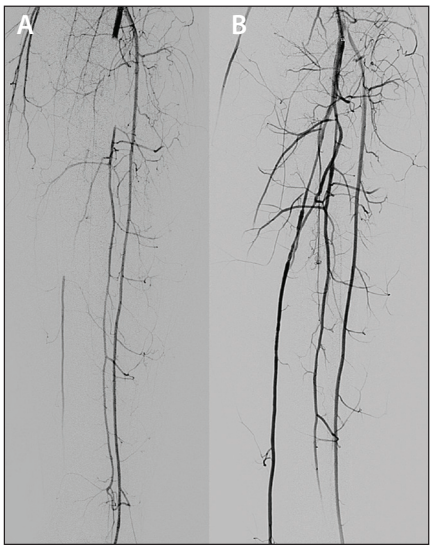


Figure 1. Angiogram of the left leg before (A) and after (B) successful thrombus removal.

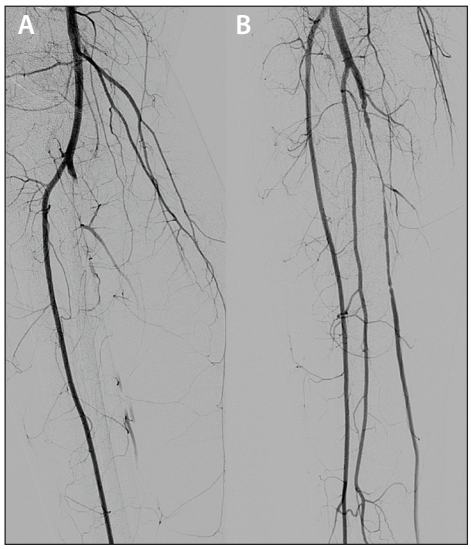
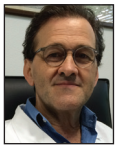


Figure 2. Angiogram of the right leg before (A) and after (B) successful thrombus removal.

are numerous circumstances and thrombus disease states in which the Indigo System can be used, including when thrombolytic therapy or surgery are contraindicated, and, in my opinion, it may replace surgical embolectomy in certain cases, such as in below-the-knee vessels, due to its trackability and the catheter's atraumatic distal tip. Furthermore, the Indigo System Separator helps to engage and break up the thrombus and limits catheter clogging, thus increasing the efficiency of the suction.

ACUTE THROMBOEMBOLIC OCCLUSION OF THE SUPERIOR MESENTERIC ARTERY



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CASE REPORT

An 87-year-old woman was admitted to our hospital for acute abdominal pain. Her clinical history was significant for chronic heart disease, chronic atrial fibrillation, and hypertension (blood pressure, 155/90 mm Hg). On physical examination, her abdomen was painful to palpation.

The patient underwent urgent abdominal contrast-enhanced multidetector CT that showed a focal and segmental thromboembolic occlusion of the superior mesenteric artery (SMA) at its middle third as well as occlusion of two jejunal artery branches (Figure 1). No air distension of the bowel was noted. After multidisciplinary discussion, the patient was deemed a candidate for endovascular recanalization. The patient was urgently transferred to the hybrid angiographic room for the procedure.

Under local anesthesia, from the right femoral artery with an 8-F, 80-cm Neuron MAX (Penumbra, Inc.), the patient underwent emergency selective angiography of the SMA that confirmed the diagnosis of focal and segmental thromboembolic occlusion of the SMA at its middle third with occlusion of two jejunal artery branches (Figure 2A). The Neuron MAX is an extremely trackable neuro-developed sheath that was selected due to its ability to deliver additional catheters distal into the peripheral anatomy. Then, coaxially, an Indigo System CAT6/SEP6 was advanced into the first jejunal artery branch and connected to the continuous aspiration Pump MAX (Figure 2B). First, a 20-second aspiration pass was completed removing the proximal occlusion of the SMA. A secondary 30-second pass into the second jejunal artery branch was performed with suc-

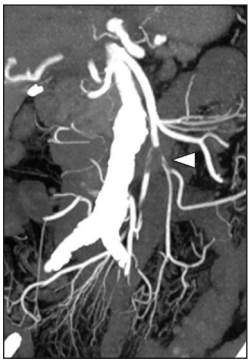

Figure 1. Abdominal contrast-enhanced multidetector CT coronal maximum intensity projection (MIP) reconstruction showing a focal and segmental occlusion of the middle third SMA (arrowhead).

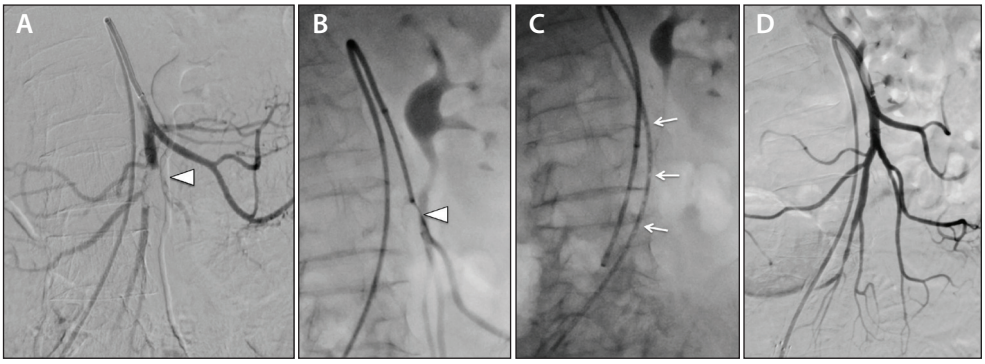

Figure 2. Selective angiography of the SMA confirming focal and segmental occlusion of the middle third SMA and occlusion of two jejunal artery branches (arrowhead) (A). Advancement of the CAT6/SEP6 into the first jejunal artery branch before clot aspiration (arrowhead) (B). Advancement of the CAT6 system into the second jejunal artery branch after clot aspiration. Note thrombus pieces as filling defects in the catheter (arrows) (C). Final angiographic control of the SMA demonstrating total patency of the artery without clots (D).

cessful aspiration of the embolic material (Figure 2C). The final angiogram of the SMA demonstrated complete patency of the artery and its jejunal branches, distal arcades, and vasa rectae (Figure 2D). Intravenous heparin (1,000 IU/hr) was administered for 48 hours. The patient did not need a bowel resection. The patient underwent abdominal contrast-enhanced multidetector CT control that demonstrated patency of the SMA and its branches with no bowel wall alterations (Figure 3).

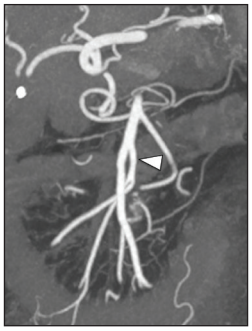

Figure 3. Abdominal contrast-enhanced multidetector CT coronal MIP reconstruction demonstrating patency of the SMA, specifically at its middle third (arrowhead).

DISCUSSION

Acute SMA thromboembolic occlusion is a rare and potentially fatal vascular emergency that requires rapid diagnosis as well as early restoration of mesenteric blood flow.[1] This vascular emergency, if not treated promptly, can have a high mortality rate.[1,2] Conventional treatment options, such as open embolectomy or catheter-directed thrombolysis, are not viable options due to the deep anatomic position of the SMA and the need for rapid recanalization. Percutaneous endovascular aspiration with the Indigo System is a simple, rapid, and effective solution to remove the thrombus in such difficult anatomy. In a single-center registry, Bisdas et al demonstrated safe and effective results with restoration of antegrade blood flow in 100% of patients without the need for thrombolysis when utilizing the Indigo System to treat renovisceral occlusion.[3] The 6-F Indigo System can be used for prompt endovascular intervention with vascular flow restoration in seconds, which is necessary to safeguard the possible ischemic damage of the distal organs.

1. Rossi UG, Rigamonti P, Dahmane M, Cariati M. Endovascular manual aspiration thrombectomy of acute superior mesenteric artery thromboembolic occlusion: the good, the bad, and the ugly. Diagn Interv Radiol. 2013;19:518-520.
2. Gagnière J, Favrolt G, Alfidja A, et al. Acute thrombotic mesenteric ischemia: primary endovascular treatment in eight patients. Cardiovasc Intervent Radiol. 2011;34:942-948.
3. Bisdas T, Stavroulakis K, Beropoulis E, et al. Initial experience with the 6-F and 8-F Indigo Thrombectomy Systems for acute renovisceral occlusive events. J Endovasc Surg. 2017;24:604-610.

STENT GRAFT OCCLUSION AFTER ENDOVASCULAR ANEURYSM REPAIR

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CASE REPORT

A 60-year-old woman underwent emergency endovascular aneurysm repair in 2016 with preservation of the right renal artery using a periscope technique. At the time, malperfusion led to a dysfunctional left kidney, which was sacrificed.

The patient presented in our ambulatory unit experiencing several days of anuria. Laboratory testing revealed an elevated serum creatinine level (8.6 mg/dL), and duplex ultrasound showed an occlusion of the stent graft (Viabahn 6 X 100 mm, Gore & Associates) feeding the right renal artery.

The time of occurrence of the occlusion was unclear, but it was suspected to have occurred at least 4 to 7 days prior to presentation. The dialysis/nephrology colleagues only saw a small chance of adequate renal function restoration, even in the case of a successful recanalization.

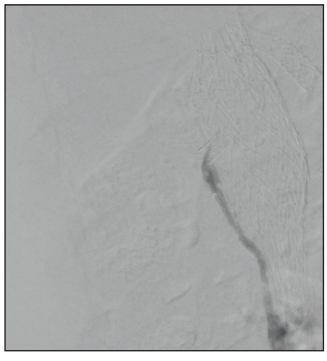

Figure 1. Angiogram after the occluded passage of the bridging stent graft was crossed.

Figure 2. Angiogram after removal of thrombotic material from the occluded renal artery.

PROCEDURE

The procedure was performed through the right femoral artery. A 7-F, 45-cm sheath was used to stabilize the support catheter and the wire. Using a 4-F multipurpose catheter and a 0.035-inch Glidewire (Terumo Interventional Systems), the occluded passage of the bridging stent graft was crossed, and we were able to perform diagnostic angiography (Figure 1). The Indigo System CAT6 was selected and tracked to the face of the thrombus in the bridging stent graft. The guidewire was exchanged for the Indigo System SEP6 to maintain continuous aspiration while aspirating the large volume

of clot present. The 6-F Indigo System was connected to the continuous vacuum Pump MAX, allowing for gentle percutaneous removal of the thrombotic material from the renal artery. A final angiogram was performed, which demonstrated widely patent flow (Figure 2).

DISCUSSION

The highly trackable Indigo System has the potential to remove thrombus from these challenging visceral occlusions with a rapid, minimally invasive endovascular approach. In this case, the Indigo System helped avoid the need for long-term dialysis.

VENOUS THROMBOSIS MECHANICAL THROMBECTOMY AND THROMBOLYSIS

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CASE REPORT

A 30-year-old woman was referred to our hospital, the Hospital Regional Universitario de Málaga, from a district hospital. The patient presented with edema of the lower limbs, back pain, and evening fever for 2 weeks. A Doppler ultrasound was performed, showing a deep vein thrombosis of the right limb extending into the IVC and down into the left common iliac vein. The patient had a recent history of spontaneous birth 3 weeks prior and was currently in the postnatal period.

A CT venogram performed upon arrival confirmed the ultrasound findings (Figure 1). An endovascular approach was chosen by the treating physicians, which was performed in two sessions over 2 days while the patient was under conscious sedation. The first session was performed with a right jugular vein access to implant an IVC filter (Celect Platinum, Cook Medical) to prevent a pulmonary embolism.

It was then decided to utilize the Penumbra Indigo System to attempt to aspirate the extensive bilateral venous thrombus. A short, 8-F destination sheath (Terumo Interventional Systems) was placed in the femoral vein (Figure 2). The Indigo System CAT8 XTORQ and SEP8 were selected, and multiple passes were completed under continuous vacuum. The 8-F Indigo System was able to remove the thrombus and create a channel through the occlusion (Figure 3). Because residual clot was present, bilateral catheter-directed thrombolysis was performed for 12 hours.

After 12 hours of tissue plasminogen activator (tPA), venography was performed, which showed residual clot in the left iliac vein (Figures 4 and 5). To reduce the dose and duration of tPA in this patient, the Indigo System was employed again using CAT8/SEP8. After two passes on the left side, the clot burden was removed.

A post-clot removal venogram uncovered an area of compression in the left iliac vein; therefore, a

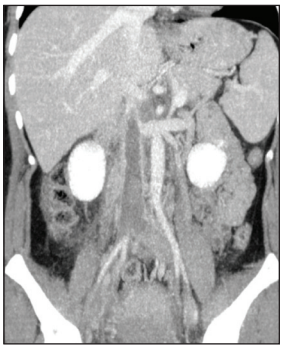

Figure 1. Coronal CT venogram showing thrombus extending through both iliac vein sector and upper renal veins of the IVC.

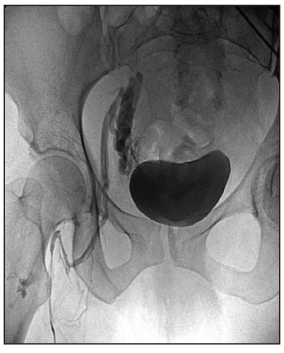

Figure 2. Angiogram of the first session showing a completed occlusion of iliac vein sector with presence of collateral.

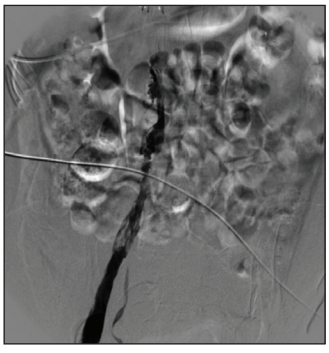

Figure 3. Recanalization of iliac left sector was successful.

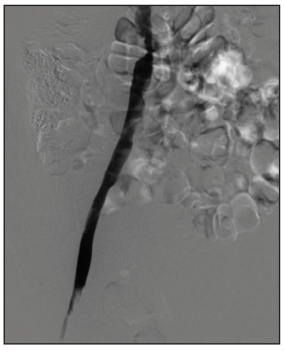

Figure 4. Venogram of the right side showing an almost complete revascularization of iliac veins and IVC with some residual thrombus.

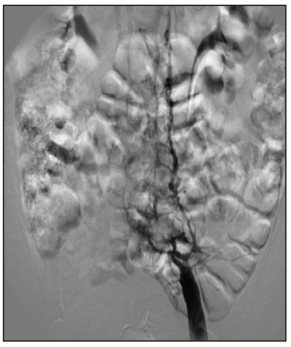

Figure 5. Venogram of the left side before treatment.

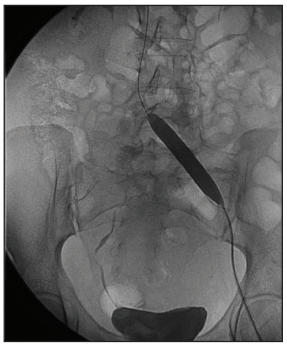

Figure 6. Venoplasty of the left iliac sector.

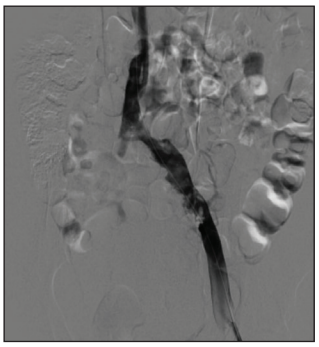

Figure 7. After recanalization, aspiration and venoplasty were performed. An isolated stenosis persisted in the left common iliac vein, so a venous stent was implanted.

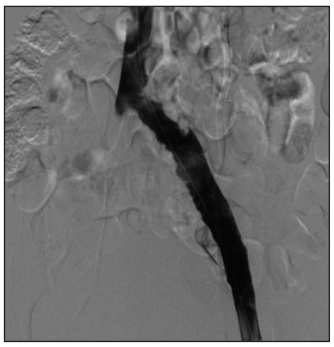

Figure 8. Venogram showing a good result.

12- X 80-mm balloon and 14- X 80-mm venous stent were utilized to resolve the compression (Figures 6 and 7). The final venogram showed patent flow through both legs (Figure 8).

DISCUSSION

In patients such as this, a young postnatal woman, it is imperative to resolve the deep vein thrombosis endovascularly while reducing the dose duration of tPA to mitigate potential complications. The Indigo System and its reliance on continuous high-powered aspiration alone to remove the thrombus enables the operator to have an endovascular approach that limits the patient's exposure to clot-dissolving drugs.

PORTAL VEIN THROMBOSIS TREATED WITH THROMBOLYSIS AND MECHANICAL THROMBECTOMY

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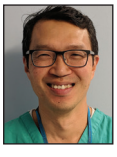

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CASE PRESENTATION

A 28-year-old man with a long history of inflammatory bowel disease and previous bowel resections presented to the local hospital with abdominal pain. Results of CT demonstrated inflammation of the distal ileum with subacute portal vein thrombosis. Management with oral anticoagulation was initiated but his pain progressed. A second CT scan demonstrated complete occlusion of the portal vein with thrombus extending into the superior mesenteric vein (SMV) (Figure 1). The patient was subsequently transferred to our center for consideration of further treatment options.

Intravenous heparin therapy was initiated; however, the patient was developing bowel ischemia as shown on repeat imaging, and therefore more aggressive intervention was required. A transjugular intrahepatic portosystemic shunt (TIPS) procedure was undertaken to gain access to the clot and enable thrombolysis and thrombectomy (Figure 2).

COURSE OF TREATMENT AND RESULTS

With access to the portal vein and SMV and due to the chronic morphology of the thrombus, a lysis catheter was placed, and tPA was administered for 12 hours. After 12 hours of lysis, a repeat venogram was performed, which showed a suboptimal result with thrombus still present within the SMV and poor flow into the TIPS

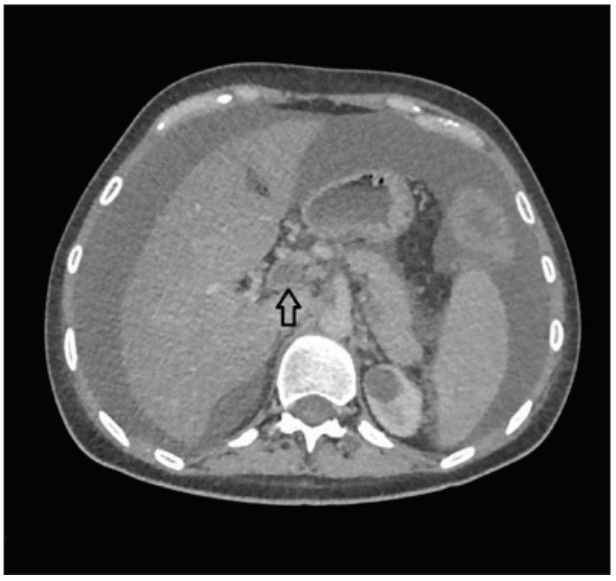

Figure 1. Selected slice from portal phase CT with arrow demonstrating complete occlusion of portal vein with thrombus.

(Figure 3). To resolve the thrombus and not utilize tPA for another period, the Indigo System was introduced.

The Indigo System CAT8 was selected and connected to the proprietary Pump MAX for continuous aspiration, and the catheter was passed through the occlusion. The postprocedure venogram showed patent flow throughout the SMV and through the TIPS (Figure 4).

DISCUSSION

Portal vein thrombosis is a relatively rare manifestation of inflammatory bowel disease, with a prevalence of 0.17%.[1] This case demonstrates successful management of this rare pathology using mechanical aspiration thrombectomy with a low dose of tPA when conservative treatment options failed. ■

1. Maconi G, Bolzacchini E, Dell'Era A, et al. Portal vein thrombosis in inflammatory bowel diseases: a single-center case series. J Crohns Colitis. 2012;6:362-367.

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

Figure 2. Successful cannulation of the portal vein and SMV from hepatic vein during the TIPS procedure. Multiple filling defects are demonstrated within the SMV and portal vein consistent with thrombus.

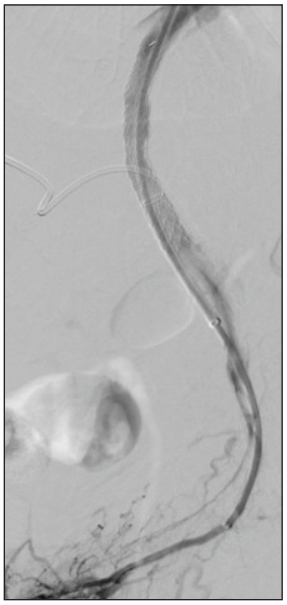

Figure 3. Postlysis venogram demonstrates residual thrombus within the SMV and poor flow within the TIPS.

Figure 4. Postthrombectomy venogram with CAT8 catheter in situ demonstrating improved flow in SMV, iliac branches, and TIPS.