Aspiration thrombectomy for acute iliofemoral or central deep venous thrombosis

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ABSTRACT

Objective: The use of catheter-directed thrombolysis (CDT) may provide clinical benefit in patients with acute deep venous thrombosis (DVT), but significant doubt remains about its indications and risks. We assessed technical success in resolution of acute iliofemoral or central DVT after single-session treatment with a novel mechanical aspiration thrombectomy device as an alternative to initiation of CDT.

Methods: This was a single-center retrospective review of patients with acute iliofemoral or central DVT treated with the Indigo continuous aspiration mechanical thrombectomy 8 system (Penumbra, Inc, Alameda, Calif) from 2016 to 2017. The primary outcome was technical success, defined as resolution of >70% of thrombus without need for postaspiration CDT, as an initial or adjunctive treatment. Secondary end points included DVT recurrence and treatment complications.

Results: There were 10 patients (50% male) with a median age of 44 years (range, 19-68 years). Indication for treatment was DVT (n = 4), recurrent DVT (n = 1), stent thrombosis (n = 3), high-grade extrinsic narrowing of the inferior vena cava (IVC) due to immunoglobulin G4-related disease (n = 1), and IVC obstruction from liver tumor invasion (n = 1). Five patients had underlying May-Thurner syndrome. Five patients had iliofemoral involvement, two iliocaval, and one iliac vein alone. Two patients had central DVT, one of them involving the IVC and one involving the superior vena cava with brachiocephalic extension. Aspiration thrombectomy was technically successful in a total of six patients. Success was achieved in five of eight patients as the initial or main treatment modality and as an adjunctive treatment in one of two patients. Of the four patients in whom aspiration thrombectomy was not successful, three underwent successful further treatment with CDT. Recurrence after successful aspiration was seen in two patients. One patient developed pulmonary embolism that required no additional treatment. One patient experienced severe headaches treated with oral analgesics.

Conclusions: We observed a technical success of 60% for acute iliofemoral and central DVT with an aspiration thrombectomy system that allowed definitive treatment in one setting. As a novel therapy, this avoided the need for thrombolysis in the majority of selected cases with no bleeding complications and is a promising technique for acute DVT management. (J Vasc Surg: Venous and Lym Dis 2019;7:162-8.)

Keywords: CDT; Catheter-directed thrombolysis; PMAT; Pharmacomechanical aspiration thrombectomy (ie, AngioJet); AMT; Aspiration mechanical thrombectomy; Indigo CAT; Continuous aspiration mechanical thrombectomy device

Acute deep venous thrombosis (DVT) is a common cause of morbidity and mortality, affecting approximately 1 in 1000 adults every year.[1,2] It commonly affects the lower extremities, involving the iliac veins, femoral veins, and occasionally the vena cava. Iliofemoral and central DVTs have a high risk of complications, such as life-threatening pulmonary embolism (PE), which can be seen in up to 10% to 25% of patients with DVT.[3,4] Mortality may occur in up to 6% of patients, and the risk is higher if DVT is complicated by PE.[1,4] DVT recurrence is common and can occur even if adequate treatment is given. Apart from the short-term morbidity, post-thrombotic syndrome, presenting with venous insufficiency, chronic leg pain, swelling, ulcers, and decreased quality of life, is a common long-term complication of lower extremity DVT.[4,5] Prompt treatment of iliofemoral and central DVT may avoid clinical deterioration and reduce the risk of complications, such as PE.[6]

Treatment of iliofemoral and central DVT can vary by clot burden and clinical condition. In addition to standard anticoagulation, percutaneous interventions including catheter-directed thrombolysis (CDT), pharmacomechanical aspiration thrombectomy (PMAT), and aspiration mechanical thrombectomy (AMT) have emerged as treatment options for patients in whom there is concern that anticoagulation alone may not resolve the DVT.[6-10] However, CDT and PMAT have risks of bleeding and hemolysis, respectively.[10-14] AMT devices aspirate acute thrombus without the need for administration of thrombolytic medication, thereby reducing the risk of bleeding.[7,15,16] One device, the AngioVac (AngioDynamics, Latham, NY) uses a large (26F) sheath

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and requires venovenous bypass and also requires an activated clotting time of >300 seconds.[15]

The Indigo continuous aspiration mechanical thrombectomy (CAT) system (Penumbra, Inc, Alameda, Calif) is a device approved by the U.S. Food and Drug Administration in 2015 for removal of arterial or venous thrombus without the requirement for concomitant use of thrombolytic medication. Early reports have shown that it may be a safe and promising tool for the treatment of PE and renovisceral thrombosis. To date, there are limited data about its efficacy and safety for the treatment of DVT.[7,17-19] Thus, we aimed to evaluate the outcomes of AMT with the Indigo device in patients with acute iliofemoral or central DVT as an alternative to initiation of CDT.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective cohort study
- **Key Findings:** Of 10 patients with iliofemoral or central deep venous thrombosis (DVT), treatment with aspiration thrombectomy using the Indigo CAT 8 system and Penumbra Pump was technically successful in six patients. Three of the remaining four were successfully treated with catheter-directed thrombolysis. There were no bleeding complications; one patient had minor pulmonary embolism and one developed severe headache. Two patients with successful aspiration thrombectomy had recurrent DVT.
- **Take Home Message:** Aspiration thrombectomy with the Indigo CAT 8 system can be considered for treatment of acute iliofemoral and central DVT with the potential advantage of definitive treatment in one setting.

METHODS

This minimal-risk study was approved by the Mayo Clinic (Rochester, Minn) Institutional Review Board, and no informed consent or authorization from patients was deemed necessary for inclusion. Per Minnesota statutes, all patients approved the use of their clinical data for research purposes.

We retrospectively reviewed patients treated with the Indigo device for iliofemoral or central DVT at Mayo Clinic (Rochester, Minn) from 2016 to 2017. No patients were excluded from the study, and no patients were treated for distal femoral or axillosubclavian DVT. The selected patients were identified from procedure case logs, and their medical records were subsequently reviewed for data collection. Charts were reviewed for demographics, hospitalization course, and complications. The types of treatment received before and after the procedure were also captured. Procedures were performed by interventional radiologists and vascular surgeons, usually with local anesthesia and moderate sedation during inpatient encounters.

Aspiration thrombectomy device. The Indigo CAT system (Fig 1) is a single-use device for aspiration of arterial or venous thrombus in any vessel except for the coronary vessels or neurovasculature.[7,17-19] It has three components: a catheter, a separator, and a vacuum pump. There are four different catheters available in 3.4F to 8F sizes. The CAT 8 (8F), which was used for all patients in this study, is indicated for larger vessels and can aspirate up to 160 mL/s. It has an angulated tip for rotational use to clear larger thrombus burdens. The separator allows thrombus fragmentation and mobilization as well as cleaning of the catheter when it is obstructed by thrombus. The vacuum pump provides continuous suction by applying and maintaining negative pressure of almost −29 mm Hg.

Procedure. Cases were performed under moderate sedation (or general anesthesia if the case was performed in the operating room) and with administration of intraoperative systemic anticoagulation through weight-based heparin infusion. Use of the device as a primary modality or as an adjunct was at the discretion of the proceduralist. Access was gained percutaneously under ultrasound guidance, and 9F to 10F access was established. Suction was applied intermittently while within the thrombus to minimize blood loss. Venography was used to assess adequacy of treatment. After the procedure, all patients were systemically anticoagulated for a minimum of 3 months; duration was determined on the basis of whether DVT was provoked or unprovoked. Outpatient follow-up was on a case to case basis, but patients were usually assigned a follow-up appointment around the 3-month mark with imaging by ultrasound or computed tomography (CT).

Outcomes and data analysis. Primary outcome was technical success, defined as resolution of >70% of thrombus without need for postaspiration initiation of overnight CDT. This measure was obtained by visual estimation of residual thrombus burden by multiplanar venography. Success could be achieved when the device was used as the main treatment or as an adjunctive after failure of another treatment modality. Secondary outcomes were DVT recurrence, treatment complications, and 30-day mortality. Types of treatment modalities used before and after the intervention were also included, as was intraprocedural vessel angioplasty or stenting. Iliac vein compression (May-Thurner syndrome) was recorded, if present, by intraprocedural multiplanar venography and preprocedural cross-sectional imaging, when available. Data were reported in a descriptive fashion as medians and frequencies. They were collected and analyzed using Excel (Microsoft Corp, Redmond, Wash) and Stata version 14 software (Stata Corp LP, College Station, Tex).

Fig 1. Aspiration mechanical thrombectomy (AMT) device. (Reproduced with permission of Penumbra, Inc, Alameda, Calif.)

RESULTS

We identified 10 patients (50% male) who underwent AMT with the Indigo device for iliofemoral or central DVT. Median age was 44 years (range, 19-68 years; Table). The main indication for treatment was DVT in four, recurrent DVT in one, stent thrombosis in three, high-grade extrinsic narrowing of the inferior vena cava (IVC) due to immunoglobulin G4-related disease in one, and IVC obstruction from liver tumor invasion in one. In the patient with recurrent DVT, iliac vein occlusion was seen in the contralateral, nonstented iliac vein. In addition, five patients were noted to have superimposed iliac vein compression. Iliofemoral vessel involvement was seen in five patients, iliocaval in two patients, and iliac

Table. Patients' characteristics

Age, years, and sex	Vessel	Indication	Main vs adjunctive	Success	Stenting after treatment	Recurrence
57 F	Iliofemoral	DVT[a]	Main	Yes	Yes	3 months
57 F	Iliofemoral	DVT[a]	Main	Yes	Yes	
62 M	Iliofemoral	DVT	Main		Yes	
22 F	Iliofemoral	DVT[a]	Adjunctive	Yes	Yes	
19 F	Iliofemoral	Stent thrombosis[a]	Main			2 months
35 F	Iliac	Stent thrombosis[a]	Main	Yes		
36 M	Iliocaval	Recurrent DVT	Main	Yes	Yes	9 months
45 M	Iliocaval	IVC narrowing from IgG4 disease	Main		Yes	
68 M	IVC	IVC obstruction from liver tumor invasion	Adjunctive			–
36 M	SVC and left brachiocephalic vein	Stent thrombosis	Main	Yes		

DVT, Deep venous thrombosis; *IgG4,* immunoglobulin G4; *IVC,* inferior vena cava; *SVC,* superior vena cava.
[a]Underlying iliac vein compression (May-Thurner syndrome).

vein alone in one patient. Two patients had central DVT, one involving the IVC, and one had superior vena cava involvement with left brachiocephalic vein extension.

Technical success was achieved in a total of six patients treated with AMT. Success was achieved in five of eight patients who were treated with AMT as the initial or main treatment modality and in one of two patients treated adjunctively after failure of other modalities. AMT was not technically successful in four patients, three of whom subsequently underwent successful treatment with CDT followed by angioplasty or stenting. Intervention was aborted in one patient after the finding on frozen section analysis of the aspirated clot was positive for tumor.

AMT was used concomitantly with other treatment modalities, such as angioplasty, stenting, or limited use of thrombolytic medication. Angioplasty before aspiration was performed in three patients, and angioplasty afterward was performed in five patients. Concurrent angioplasty before AMT was performed in select cases to slightly macerate the thrombus to allow easier aspiration. Of the three patients who had angioplasty before AMT, two had narrowed pre-existing stents in the thrombosed vessel, and one patient had a narrowed segment of vessel immediately adjacent and proximal to the thrombosed area. Six patients were stented as part of their treatment; four patients were stented after successful same-session AMT, and two were stented after additional overnight CDT. One patient received adjunctive AMT after failure of CDT for 72 hours and PMAT with AngioJet (Boston Scientific, Natick, Mass). Full resolution was noted on day 3 after treatment with AMT. Subsequent angioplasty and stenting were also performed. Two of the three patients with stent thrombosis who had successful AMT underwent successful same-session angioplasty of in-stent stenosis. One patient underwent angioplasty of in-stent stenosis after overnight CDT.

Nine of 10 patients had clinical or imaging follow-up at or after 3 months. Eight of nine patients received standard ultrasound evaluation at 3-month follow-up or earlier if they were symptomatic. One patient underwent CT for unrelated oncologic reasons, and the stents were noted to be patent, but the patient has not followed up directly with the proceduralist. One patient was found to be occluded at 3-month follow-up, one presented with occlusion before standard follow-up (at 2 months), and one presented with occlusion 6 months after standard follow-up (at 9 months) showed stent patency. All others were patent at follow-up. The longest interval of follow-up is 22 months. There were three recurrences overall, one each with initial diagnosis of iliofemoral DVT (3 months), recurrent iliac DVT contralateral to a stent (9 months), and iliac stent thrombosis (2 months; nonsuccessful AMT). Recurrence after successful AMT was seen in two. The patient with iliofemoral DVT was found to have iliac stent thrombosis and no lower extremity DVT at routine follow-up 3 months after the treatment, but date of recurrence was uncertain; recurrence was treated with angioplasty and stenting. The patient with iliocaval DVT had recurrence at 9 months and was subsequently treated with PMAT and overnight CDT, followed by angioplasty and stenting. Notably, in-stent stenosis was uncovered after CDT, and international normalized ratio while the patient was taking warfarin was found to be subtherapeutic. The patient with iliac stent thrombosis had recurrence at 2 months after unsuccessful AMT but successful overnight CDT. The recurrence was treated with PMAT, CDT, angioplasty, and additional stenting.

Complications during hospitalization were noted in two patients. One patient who developed bilateral PE presented with chest pain and mildly elevated troponins but no hemodynamic instability and no right-sided heart strain and did not require intensive care unit placement. No additional treatment was required in addition to ongoing anticoagulation for treatment of DVT. Repeated CT scan 3 months later showed resolution of PE. One patient developed severe headache and was treated with oral analgesics. This patient had a prior history of headaches; therefore, it was not thought to be a result of AMT. There were no bleeding complications.

Thirty-day mortality was observed in one patient in whom AMT was technically unsuccessful as an adjunctive treatment after failure of CDT. After 24 hours of CDT, AMT was attempted, and some thrombus was removed and sent for frozen section analysis, which demonstrated tumor thrombus. The intervention was subsequently aborted with no periprocedural complications related to AMT. Final diagnosis was metastatic unresectable intrahepatic cholangiocarcinoma with vascular invasion and a very poor prognosis. Comfort care was initiated, and the patient died 22 days after the attempt at AMT.

DISCUSSION

AMT with the Indigo CAT 8 device may be a viable treatment option in selected cases of acute iliofemoral or central DVT, and its use may avoid the need for initiation of CDT. In our review of all patients treated with Indigo CAT 8 for this condition at our institution, the device appears to be effective in clearing large burdens of thrombus in a single session, thus allowing definitive treatment with postaspiration angioplasty or stenting in most successful cases (Figs 2 and 3). The major benefit of this device in our study population was that 60% of patients were able to undergo definitive treatment of underlying stenosis without the need for thrombolysis owing to the fact that enough thrombus was cleared before that definitive treatment. This device may be a useful tool for those patients who cannot undergo thrombolysis. Other possible advantages to this device include lower cost of care by avoiding the need for

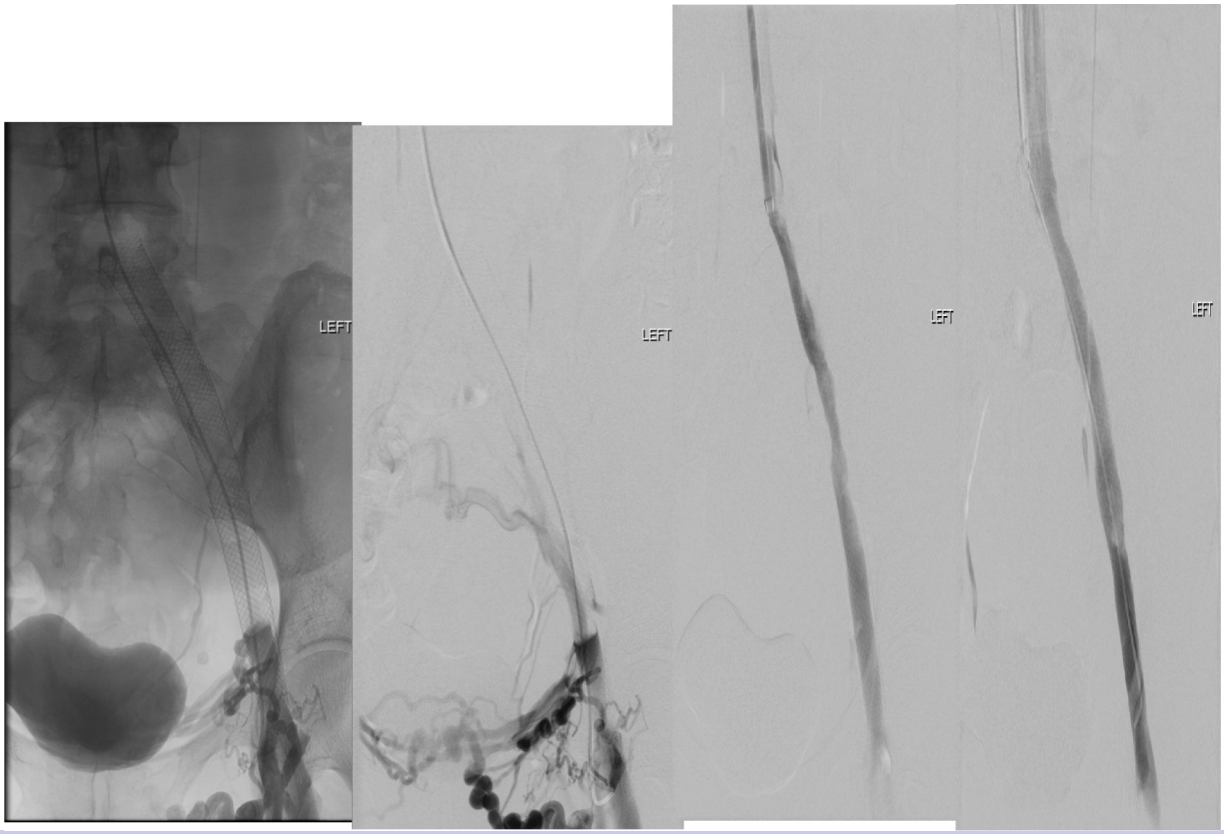

Fig 2. A 35-year-old woman with iliac vein stent thrombosis before and after successful aspiration mechanical thrombectomy (AMT). From *left to right*, the *first two images* show the initial pelvic venogram through the right internal jugular vein, demonstrating acute thrombosis of left iliofemoral stents with collateral filling from left to right. The *third image*, the venogram after Indigo continuous aspiration mechanical thrombectomy 8 system (CAT 8) aspiration and before angioplasty, shows resolution of acute thrombus and presence of underlying stenosis of midstent complex. The *fourth image* shows venogram after 16-mm angioplasty of midstent complex stenosis with resolution of stenosis and brisk in-line outflow.

intensive care unit admission. One potential technical issue is difficulty in advancing the device without a wire. In our experience, we found that the device can be advanced without a wire in long, straight segments of vein. In veins that are tortuous, the device may be advanced over a guiding catheter and wire to its desired location. Also, the wire can be left in place during the aspiration.

There are several other modalities in current practice for treatment of this condition, each having its own benefits and limitations. CDT is one of the most commonly used modalities for the treatment of acute iliofemoral or central DVT as it is highly effective, but it has a well-known risk of bleeding complications.[11,12] In the Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT) trial, the rate of major bleeding in the pharmacomechanical lysis group was 1.7%.[11] Patients undergoing thrombolysis require intensive care monitoring, which also possibly increases the immediate cost of care.[20,21] In our general practice, patients are typically considered for initial treatment with CDT when indicated, but each case requires thorough individual planning by the proceduralist. Although there is no formal algorithm for use of this device in our institution, its selection was influenced heavily in the setting of a patient who cannot undergo thrombolysis or in whom there was a desire to attempt to treat in one session. A low threshold was maintained to switch to CDT when AMT was attempted as the initial or main treatment modality. In three patients, AMT cleared large amounts of thrombus, but significant residual thrombus remained after multiple passes, thus requiring initiation of CDT. It is possible that these patients may have presented with acute-on-chronic thrombosis; therefore, further thrombolysis was required before definitive treatment.

The Indigo CAT 8 device seems to be a safe option with minimal risk of bleeding or complications. Of the 10 reviewed cases, the procedure was completely aborted in a single case because of tumor invasion of the vessel, and this patient died within the 30-mortality window from progression of the tumor as detailed before. Use

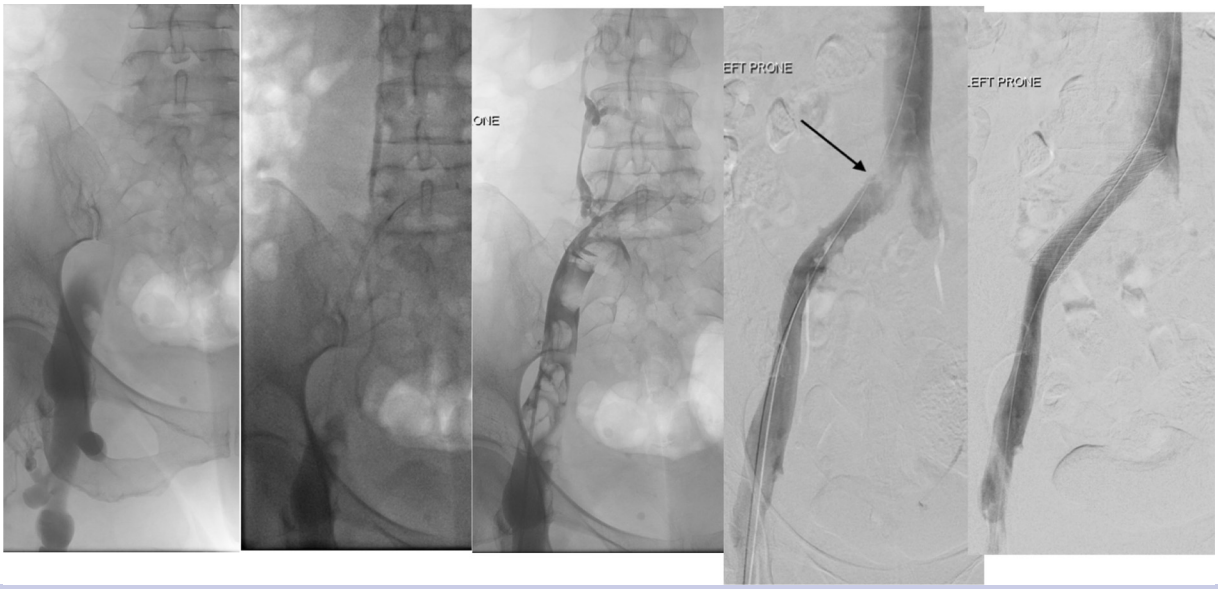

Fig 3. A 57-year-old woman with acute deep venous thrombus (DVT) in the left iliac, common femoral, femoral, popliteal, and upper peroneal veins before and after aspiration mechanical thrombectomy (AMT) with primary iliac vein stenting. From *left to right*, the *first image* demonstrates the initial venogram with catheter in the left common femoral vein and acute thrombotic occlusion of the left external and common iliac veins. The *next image* shows the Indigo continuous aspiration mechanical thrombectomy 8 system (CAT 8) catheter at the level of the iliac confluence. The *next two images* show improvement in the thrombus burden after AMT, with underlying stenosis (*arrow*) at the left iliac vein confluence with inferior vena cava (IVC). The *last image* shows robust outflow from the left common femoral vein through the IVC after common iliac vein stent placement.

of the device was never halted because of intraprocedural bleeding or complications related to the device. Only one patient developed bilateral PE that did not require treatment in addition to standard anticoagulation and fully resolved by the 3-month follow-up appointment. This does raise the need for caution because fragmentation of the thrombus may result in PE. Blood transfusions were not required in any of the cases, even in patients receiving postaspiration CDT.

Our study has several notable limitations. Although our sample was small, our findings suggest that the device may be a viable initial option with possible high reward and low risk. In addition, long-term outcomes are limited. Although all of the surviving nine patients have been seen for at least one follow-up, the longest interval of follow-up is only 22 months. Although the device seems to be effective in the short term, recurrence was observed in two cases after successful AMT. Thus, we cannot objectively comment on long-term results of this modality. Finally, technical success for our study was defined as resolution of >70% of clot without need for postaspiration CDT. This measure was obtained by visual estimate of residual thrombus burden by multiplanar venography. One limitation of our study is that vessel blood flow measurements were not obtained or reported in all cases; therefore, the authors determined technical success using procedure logs, review of multiplanar venography, and data documented by proceduralists on the basis of their clinical experience and judgment. Intravascular ultrasound quantitation of residual thrombus was not obtained as this was not standard practice at the time of these procedures. Another possible limitation of our study is that we did not evaluate outcomes of other devices such as CDT and pharmacomechanical thrombolysis, but this may represent another avenue for potential future research. Further studies are needed to confirm our findings as well as to evaluate long-term outcomes and recurrence rates before effective comparisons can be made with other modalities.

CONCLUSIONS

AMT with the Indigo CAT 8 device may be an effective treatment modality for patients with acute iliofemoral or central DVT. It allowed definitive treatment with angioplasty or stenting in one setting for most patients while avoiding the need to initiate thrombolysis. As a novel device, it seems like a safe option that allowed definitive treatment without bleeding complications. Further studies are necessary to confirm our findings and to evaluate long-term outcomes and patency rates.

AUTHOR CONTRIBUTIONS

Conception and design: RL, RD, MN
Analysis and interpretation: RL, RD, MN
Data collection: RL, RD, MF, HB, MN
Writing the article: RL, RD, MN
Critical revision of the article: RL, RD, MF, HB, MN

Final approval of the article: RL, RD, MF, HB, MN
Statistical analysis: RD
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Overall responsibility: MN

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