Journal of Clinical Case Studies and Reviews

Research Article Open Access

Initial Experience of Aspiration Thrombectomy using the Indigo Aspiration System for Acute Iliofemoral Deep Vein Thrombosis

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Received: 20 February 2021; **Accepted:** 18 March 2021; **Published:** 25 March 2021

Abstract

Objective: *The objective of this study was to report initial experience using aspiration thrombectomy with the Indigo Aspiration System, as the first line treatment for acute iliofemoral deep vein thrombosis (DVT).*

Methods: *This study is a retrospective case review of patients with acute symptomatic iliofemoral DVT who underwent aspiration thrombectomy using the Indigo Aspiration System between December 2015 and January 2018 at three centres. Data on patient demographics, adjunctive treatments, and intraprocedural complications were collected from electronic patient records. Technical success was defined as antegrade flow and maximal luminal stenosis of 30% assessed following the use of Indigo System. Clinical and imaging follow-up was conducted at 30 days and 12-months.*

Results: *A total of 35 patients (20 females; median age 43 years) met study criteria. Technical success was achieved in 80% (28/35) of patients, with the Indigo System alone. There were no intra-procedure or immediate post-procedure complications. Adjunctive interventions included venous stents (with post-dilatation) in 97.1% of patients, thrombolytics in 37.1% of patients, and caval filters in 14.2% of patients. No DVT recurrence, pulmonary embolism, or deaths occurred over 12 months of follow-up except for one patient with active neo-plastic disease. Moderate to severe post-thrombotic syndrome occurred in two patients.*

Conclusion: *This study provides evidence that aspiration thrombectomy using the Indigo System is an effective treatment for acute iliofemoral DVT. There were no procedural complications and complication rates over the 12-month follow-up period were low.*

Keywords: Iliofemoral; Deep Vein Thrombosis; Thrombectomy; Aspiration Thrombectomy

Introduction

Acute deep venous thrombosis (DVT) carries serious complications, including pulmonary embolism (PE) in 10-25% and may lead to mortality, or a subsequent post-thrombotic syndrome (PTS). It is more common in the lower extremities, in the iliac and femoral veins [1,2]. The estimated incidence of DVT is 1 per 1000 individuals per year.1 However, its true incidence can be difficult to estimate due to non-specific signs and symptoms, misdiagnosis, and the occurrence of a DVT in the setting of critical illnesses. Therefore, early recognition and prompt treatment of DVT can help prevent the associated morbidity and poor long-term outcomes [3].

Management of acute DVT is dependent on clot burden, location of the clot, and symptom severity. After diagnosis, standard anticoagulant therapy is initiated unless there is a specific contraindication. More aggressive treatment using systemic pharmacological thrombolysis may be given to those who are clinically unstable, have extensive embolic burden, saddle embolism, or patent foramen ovale, and for more proximally located DVT. Further treatment include percutaneous interventions, such as catheter directed thrombolysis (CDT), pharmaco-mechanical thrombectomy (PMT), aspiration thrombectomy or vacuum-assisted thrombectomy, with adjunctive procedures like IVC filters, venous angioplasty and/or stenting[4-12]. Surgical venous thrombectomy is rarely performed from the past decade [1].

Unlike CDT and PMT, aspiration thrombectomy does not require the concomitant use of thrombolytics and is not as complicated by bleeding or haemolysis. An additional benefit is a potentially shorter length of hospital stay given the shorter procedure times. Evidence from retrospective case reviews has reported successful use of aspiration

thrombectomy using the Indigo Aspiration System (Penumbra, Inc., Alameda CA) in acute pulmonary embolism and reno-visceral thrombosis, but there is limited data regarding its efficacy in the treatment of acute DVT [9-15].

The objective of this study was to evaluate the safety and efficacy of aspiration thrombectomy, using the Indigo System with power aspiration, as the first line of treatment, in patients with acute iliofemoral DVT.

Materials and Methods

Study Design:

We conducted a retrospective review of the data collected between December 2015 and January 2018, for patients who were treated with aspiration thrombectomy using the Indigo Aspiration System for symptomatic acute iliofemoral DVT, from three European centres. Data were obtained from electronic patient records (EPR), with review of clinical presentation, time of symptom onset, demographics, procedure report and follow up outcome over 12 months.

The study was approved by the participating hospitals' ethical review boards and consent was obtained from each patient to use their data.

Eligibility Criteria:

Inclusion criteria were patients who presented with acute symptomatic venous thrombosis at iliofemoral site under 14 days and were treated with the Indigo System. Exclusion criteria were previous diagnosis of DVT in the same limb (with acute DVT on admission), or known medical predisposition, such as recurrent DVTs and thrombophilia (ruled out by haematological screening), patients lost to follow up, and treatment of the DVT with CDT prior to aspiration thrombectomy during admission. All, but one patient, received Rivaroxaban for 1 year and compression stockings for at least 6 months, post-procedure. Authors have decided to exclude patients with confirmed previous active neoplastic disease in order to have unbiased outcomes. One of the included patients was diagnosed to have para-neoplastic syndrome after histological analysis of the clot. Only one of the patients included in the study had mild chronic kidney disease. Four of the included patients had previous history of DVT in limbs other than the one with acute presentation.

Procedure

The procedures were performed by an interventional radiologist or endovascular surgeon under local anaesthetic with sedation or general anaesthetic.

The aspiration thrombectomy device used in this study was the Indigo Aspiration System (Figure 1).

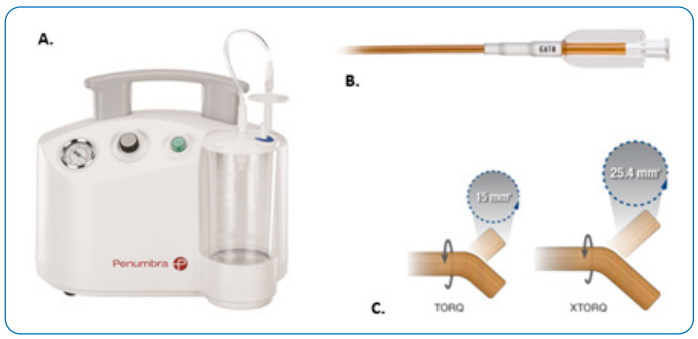

Figure 1: Indigo Aspiration System. A: Aspiration pump with canister. B: CAT8 aspiration catheter. C: TORQ (85 cm) and XTORQ (115 cm) catheters with directional tip

The Indigo System was indicated for the removal of fresh, soft emboli and thrombi from the venous systems of these patients. It consists of an aspiration catheter, a separator and a vacuum pump for suction (Pump MAX). A continuous mechanical aspiration via the catheter is generated by the pump system that forms a vacuum at -29mmHg pressure.

The CAT (continuous aspiration thrombectomy) 8 catheter, which requires an 8.0 French Sheath (outer diameter 2.67 mm and a 6.7 French aspiration lumen), was used in all patients included in the study. The 2 types of CAT8 catheters used were TORQ (85 cm) and XTORQ (115 cm), with directional tip to assist in clearing a large thrombus. The 8Fr catheter size was chosen due to larger size of the iliac and femoral veins. A popliteal vein approach, with patient in prone position, was used as access site in all but 3 patients, who instead had a CFV access in supine position. The operators at all centres are experienced in the use of the Indigo System.

5000 units of heparin were administered intravenously via the access sheath to all patients during the procedure. Use of adjunctive procedures to assist removing the thrombus, such as CDT, and deploying venous specific stent (optimed or Veniti®) with post-dilatation, was operator and site dependant, but more likely in circumstances when AMT alone was not sufficient due to the presence of a more organized clot. Stent choice was per operator preference and sizes available. Pre- and post-stent angioplasty were performed and common endovascular DVT stent management was used and within the Instructions for Use (IFU) for each stent. In addition, a caval filter was used in patients with a high risk of developing PE, as they had extensive DVT. All the caval filters were removed though, directly at the end of the procedure, and were not left for long-term in any patient. All the patients had blood tests post-procedure, to monitor renal function and electrolytes, for signs of mechanical haemolysis and acute kidney injury (AKI).

Study Outcomes:

Technical success was defined as antegrade flow and maximal luminal stenosis of 30%, post-aspiration thrombectomy with Indigo System, assessed on intra-vascular ultrasound (IVUS) and the final procedural venography, and with evidence of a spontaneous Doppler signal in the treated vein segment. Intra- and post-procedure complications were identified from the EPR. All patients had follow-up at 30 days and 12 months post-procedure. Recurrence of DVT and stent occlusion at treatment site were identified using ultrasound or CT scan, at the 12-month follow-up.

Statistical Analysis:

Baseline and follow-up clinical and imaging data were summarized using standard descriptive statistics, which included the number of observations, mean, median, standard deviation, minimum and maximum for continuous variables, and counts and percentages for discrete variables.

Results

A total of 35 patients (15 male and 20 female) who underwent aspiration thrombectomy using the Indigo System with CAT 8 device

were identified that met study criteria. Baseline patient characteristics are reported in Table 1.

Characteristics	All Patients
Number of patients Germany centre UK centre Greece centre	35 18 12 5
Median age, years (IQR)	43 (24.75)
Gender Male, n (%) Female, n (%)	 15 (42.9%) 20 (57.1%)
Side of DVT Right, n (%) Left, n (%)	 7 (25.9%) 20 (74.1%)
Median interval between symptoms and treatment, days (range)	8 (2-10)
Involvement of CFV, n (%)	29 (82.9%)
Involvement of popliteal vein, n (%)	3 (8.6%)
Paraneoplastic syndrome (diagnosed post-procedure), n (%)	1 (2.8%)
Previous DVT in other limbs, n (%)	4 (11.4%)
Previous symptomatic pulmonary embolism, n (%)	2 (5.7%)

Table 1: Baseline characteristics

Median age was 43 years (range 25-89 years). The indication for aspiration thrombectomy in these patients was symptomatic acute iliofemoral DVT, presenting with a swollen, painful lower limb impacting daily life activities. None of the patients identified had DVT involving inferior vena cava (IVC). Median time from onset of symptoms and treatment was 8 days (range 2 to 10 days). The mean length of hospital stay was 1.5 days (range 1 to 7 days). The average length of hospital stays for patients with aspiration alone versus aspiration and CDT was 2 versus 5 days.

The aspiration thrombectomy procedure was completed in all 35 patients. Procedural characteristics are reported in Table 2.

Procedural Characteristic	All Patients
Median lesion length of clot, mm (IQR)	190 (122.5)
Median aspirated volume, mL (range)	645 (250 - 1240)
Adjunctive treatments, % (n/N)	-
Venous stenting (with post-dilatation)	97.1% (34/35)
Caval filter	14.2% (5/35)
CDT	37.1% (13/35)
Mean procedure duration, minutes (range)	116 (93 - 138)
Technical success (post-aspiration thrombectomy with Indigo System)	80.0% (28/35)
Complication rate (intra- and immediate post-procedure)	0%

Table 2: Procedural characteristics

Technical success with the Indigo System alone was achieved in 80% (28/35) of the patients while the remaining patients required adjunct procedures to achieve a luminal patency of > 70%. Figure 2a and Figure 2b illustrate two technically successful case examples. The median lesion length of clot amounted to 190mm, ranging between 60mm and 300mm.

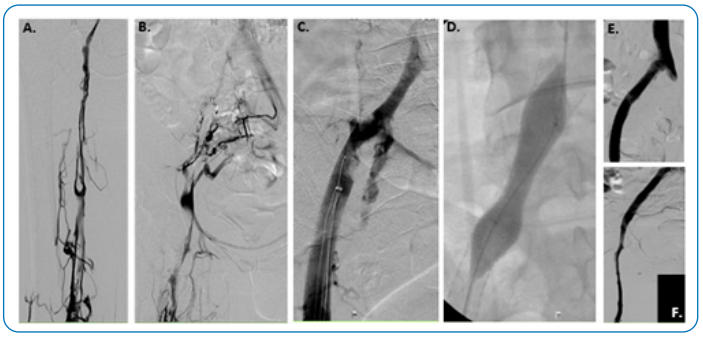

Figure 2(a): Case Example 1.

Images A, B at the start of procedure: thrombosis involving the right common femoral vein and iliac veins.

C-F: using the CAT8 Indigo system to aspirate the clot followed by balloon venoplasty of the right common iliac vein. Flow is restored.

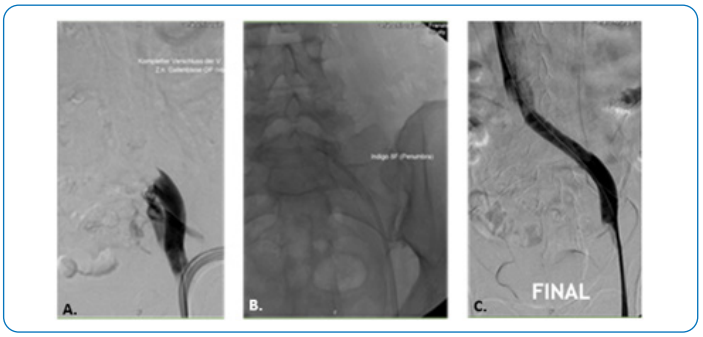

Figure 2(b): Case Example 2.

A: Occluded left common and external iliac veins with DVT.

B: Intra-procedure aspiration using CAT8.

C: flow restored with mechanical aspiration alone

There were no intra-procedural or immediate post-procedural complications, including any significant drop in haemoglobin (2 unit drop), clinically relevant pulmonary embolism, or thrombotic events. No dissection, ruptures, or vascular or adjacent structural damage were reported. AKI or increased potassium levels were not observed immediately post-procedure or after 24 hours, in any of the patients, and none of them required any aggressive hydration. There were no bleeding complications as a result of aspiration thrombectomy in any of the patients up to 30 days. The median aspirated volume was 645 ml

(range, 250-1240). A clinical improvement was documented in all cases – from direct patient feedback, pain reduction, reduction in analgesia requirements, reduction in limb swelling, and return to normal mobility. No mortality was observed in any patients at 30 days post-procedure.

Adjunctive treatment modalities (angioplasty, stenting, CDT, and IVC filters) were used in all 35 patients. Venous-specific stents, with post-dilatation, were required in 34 (97.1%) patients after aspiration thrombectomy due to underlying pathology (mostly due to a diagnosis of May Thurner syndrome, in 32 cases). Of those requiring stents, 24 cases used Veniti®/BSC stents, and 10 used sinus-Obliquus (optimed). About 1-4 stents were used on average per patient. Two of the stents were implanted across the CFV/inguinal ligament. Intra-procedural thrombolytic agent was used in 37.1% (13/35) of patients during or after aspiration via direct infusion through the sheath or catheter (CDT) or after via infusion pump set up (6 cases intra-operative, and 7 cases post-operative). Caval filter (Capturex®, Straub Medical) was used prior to aspiration thrombectomy in five (14.2%) patients who had increased risk of PE due to longer hospital stay and immobility. All of them were removed immediately after the thrombectomy.

The primary patency rate was 96% on imaging at the 12-month follow-up. A standard ultrasound evaluation was performed in 51.4% (18/35) of patients at follow-up, while 48.6% (17/35) of patients underwent a CT scan due to the complexity of their case and to further assess stent wire form and integrity. Patency on follow-up was defined as <30% residual disease/clot burden. Stent occlusions (confirmed on CT and US) were observed in two patients on the 12-month follow-up, who were both asymptomatic. Both these patients were treated with aspiration thrombectomy (with prior caval filters) and venous stenting, and both patients refused further intervention due to lack of symptoms and the wish to continue normal life activity.

None of the patients presented during the 12-month follow-up period as being symptomatic, and none of the patients were reported to have a recurrence of DVT. At the 12-month follow-up, the median Villalta score (done for all the patients for PTS) was 2 points (IQR 2.5). The main clinical signs were skin induration and venous ectasia. There was moderate to severe PTS (Villalta scale ≥ 10) in 2 patients (6%). Symptomatic pulmonary embolism was present in 1 patient (3%) who unfortunately passed away leading to one long term death (3%). This patient suffered from an active neoplastic disease.

Discussion

This study provides evidence that endovenous aspiration mechanical thrombectomy using the Indigo Aspiration System is safe and effective for acute iliofemoral DVT. Clot removal with this system alone was successful in 80% of patients. The remaining patients had either a difficult-to-remove more organized thrombus or aspiration of more than 2L of bloods, and required use of adjunct procedures. Moreover, no incidence of PE or a significant drop in haemoglobin level or renal function post-procedure were documented. Patients were largely free from any major or minor complications over 12 months of follow-up except for the one patient who died with active neoplastic disease, and 2 patients with moderate to severe PTS. On the 12-month follow-up, there were 2 cases of asymptomatic stent occlusions.

In this study, aspiration thrombectomy was used as the primary technique to treat acute DVT in all the patients. Underlying pathology was then treated with appropriate methods such as angioplasty and stenting. In all but one patient, venous-specific stents were deployed to treat the underlying pathology. The Indigo System is designed to aspirate acute clot only, therefore lytic agent was required in 13 patients with more organized fibrin-rich thrombi, which were unresponsive to aspiration alone. The use of aspiration thrombectomy at our centres prevented the need for CDT in 62.9% of patients. Given that CDT typically involves a 24 to 48-hour infusion on specialised wards, the use of aspiration thrombectomy decreased the length of hospital stay in our patients. Furthermore, the availability of aspiration thrombectomy is highly beneficial to patients with contraindications to thrombolysis, such as high risk of bleeding and pregnancy. No pregnant patients were present during this study.

The findings from this study are consistent with the only identified published study reporting the use of power aspiration thrombectomy for acute DVT, with the Indigo System [10]. In this study, Lopez et al treated 10 patients with acute iliofemoral or central DVT and found that resolution of >70% of thrombus was achieved in 90% of patients after aspiration thrombectomy; 60% without the need for CDT. Other studies have described the use of manual aspiration thrombectomy using a syringe and have reported >50% clot removal in 89-100% of patients with CDT required in 8-27% of patients with older clot [16-18]. In a small randomised trial including 42 patients with acute iliofemoral DVT, the safety and efficacy of anticoagulation alone was compared with anticoagulation combined with manual aspiration thrombectomy using a 9Fr guide catheter [8]. Compared with anticoagulation only, venous patency rates were significantly higher (12 month follow-up 57.1% vs 4.76%) and clinical symptoms scores were significantly more improved with manual aspiration thrombectomy (p<.0001). Over follow-up, recurrent DVT and PE occurred in 19.0% (4/21) patients in the anticoagulation only group and 4.8% (1/21) patients in the aspiration thrombectomy group [6]. Despite the technical limitations of manual aspiration, such as decreasing vacuum pressure as aspiration is performed, these findings provide evidence for the benefit of manual aspiration thrombectomy for clot removal and long-term clinical outcomes.

Aspiration thrombectomy was not an intervention investigated in the ATTRACT trial (Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis) [5, 19]. The ATTRACT trial investigated the use of pharmaco-mechanical CDT (PCDT) devices in patients with proximal DVT and found that the addition of PCDT to anticoagulation did not result in a lower risk of the PTS, but did result in a higher risk of major bleeding (1.7% with PCDT vs 0.3% with anticoagulation alone, p=.049). Given these findings, a risk comparison should be made between using PCDT and aspiration thrombectomy, particularly in patients with increased risk of bleeding. One disadvantage in the current technology for aspiration thrombectomy is that clot removal for large volume clot burden can be time-consuming with available catheter sizes. Allowing for the fact that vein diameters

tend to be large (average 16mm), a larger diameter aspiration catheter for large volume clot burden would likely improve procedure times. Through observation and fluoroscopy procedural time, the larger the vein size and the greater the clot burden, longer time was required by the operators. This is most evident in lesion lengths >150mm and vessel diameter equal to or greater than 14mm. On average procedure length increased by 31 minutes in those cases.

The main limitations of this study were the use of retrospective data and the small sample size. We included data from 35 patients treated at three institutions, which does not provide sufficient statistical power to generalise to larger populations. Furthermore, we did not include a comparison with patients treated with anticoagulation alone, or other thrombectomy devices. Longer follow-up than 1 year may also be useful to establish any long-term complications and to exclude the occurrence of PTS. The results of this study can be generalized to those patients only, who are decided for first-line treatment of acute DVT with the Indigo Aspiration System.

Conclusions

Overall, our study provides evidence that aspiration thrombectomy using the Indigo Aspiration System is an effective treatment for removing clot in patients with acute iliofemoral DVT. There were no immediate or 30-day post procedural complications. Furthermore, treatment with thrombolytics was required in only 37.1% of patients, thus reducing the length of hospital stay.

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Citation: Huasen B, Khan A , Suwathep P , Beropoulis E , Bisdas T "Initial Experience of Aspiration Thrombectomy using the Indigo Aspiration System for Acute Iliofemoral Deep Vein Thrombosis." J Clin Case Stud (2021): 002 doi: 10.47755/2766-9556.100107