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Multi-center Registry For Vacuum-Assisted Thrombectomy of Acute Superior Mesenteric Artery Thrombosis

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Abstract

Objectives: *The aim of our study was to evaluate safety and efficacy of percutaneous vacuum-assisted thrombectomy (VAT) for treatment of acute thrombosis or thromboemboli of the superior mesenteric artery (SMA).*

Methods: *This study is a retrospective review of data from a multi-national registry, including consecutive patients with acute thrombosis or thromboemboli of the SMA who underwent VAT at 11 international study centers. Technical success was defined as successful removal of acute thrombus material without the need for alternative thrombectomy devices, systemic thrombolysis, or other revascularization strategies such as vascular surgery. Safety endpoints were in-hospital major adverse events e.g. intestinal gangrene or death. Mean follow-up period was 9.5 (3-16) months.*

Results: *A total of 98 patients (53 females; mean age 73 years; range 55-93 years) were included. Symptom onset defined as initial occurrence of abdominal pain to treatment time ranged from 8 hours to 7 days. Thromboemboli affected a native SMA vessel in all cases. Mean occlusion length was 20 mm (Range 18 to 22 mm). Technical success was achieved in 100% of cases. There was no relevant dissection, vessel rupture or peripheral embolization reported. Provisional stenting was required in 5 cases to treat underlying atherosclerotic stenosis. Mortality in the first 24 hours was 0%. Two deaths on day 27 and 28, following cardiac arrest from other co-morbidities were reported. Bowel resection was performed in 4 cases due to delayed intestinal gangrene.*

Conclusions: *Endovascular management using vacuum-assisted thrombectomy proved to be a safe and effective option for acute thrombotic SMA occlusion.*

Keywords: *Mesenteric Ischemia; Superior Mesenteric Artery; Thrombosis; Emboli; Thromboembolism; Percutaneous Aspiration; Thrombectomy; Mechanical Thrombectomy*

Introduction

Thromboembolic occlusion of the superior mesenteric artery (SMA) is a life-threatening condition requiring immediate diagnostic workup and therapeutic intervention [1, 2]. Acute mesenteric ischemia (AMI) is defined by a sudden interruption of the blood supply to a segment of the small intestine, leading to ischemia, intestinal necrosis, and patient death if untreated [3]. AMI may be classified as non-occlusive (NOMI) which preserves the patency of large mesenteric vessels, or occlusive [4]. AMI represents an infrequent reason for abdominal pain or discomfort, and emergency department admissions remain low (0.09

to 0.2%) [5]. Nevertheless, the prognosis for AMI is poor, with reported mortality rates of 60-80%, in part attributable to its unspecific nature of symptoms, the wide differential diagnosis, and need for extensive clinical workup[6].

Open surgical repair has traditionally been the standard care for SMA, however surgical intervention for AMI is related with a higher rate of both morbidity and mortality [6]. The emergence of minimally-invasive endovascular procedures over the last 15 years have enabled fast reestablishment of the blood supply with comparatively small consequential trauma or distress [7]. In both chronic and acute thromboembolic disease, endovascular techniques, such as stenting and percutaneous trans luminal angioplasty (PTA) are used to treat occlusions or stenosis [8]. Other endovascular techniques that may be beneficial for clinical outcomes in patients with AMI include aspiration thrombectomy, mechanical thrombectomy, vasodilator injection, and intra-arterial thrombolysis, but limited published data exist given the relative scarcity of this disease [9, 10]. While it has been reported that endovascular management of AMI is associated with lower risk of bowel resection, short bowel syndrome, and mortality than open surgical procedures, whether endovascular interventional should be considered a primary treatment mode for AMI is still unclear [11-13].

The objective of this study was to evaluate the safety and efficacy of firstline percutaneous vacuum-assisted thrombectomy (VAT) for thromboembolic occlusion of the SMA using the Indigo System.

Methods

Study Design and Patient Population

This was a retrospective analysis of multi-national registry data from 11 international centers (UK France, Spain, Italy, Germany, Greece, and Vietnam). Consecutive patients admitted from May 2016 to May 2018 for SMA associated to clinical signs of bowel ischemia, without biological and imaging suspicion of necrosis, and undergoing percutaneous VAT were included. All cases were reviewed by a multidisciplinary team of gastroenterologist, interventional radiologist and vascular surgeon.

Thrombectomy Device

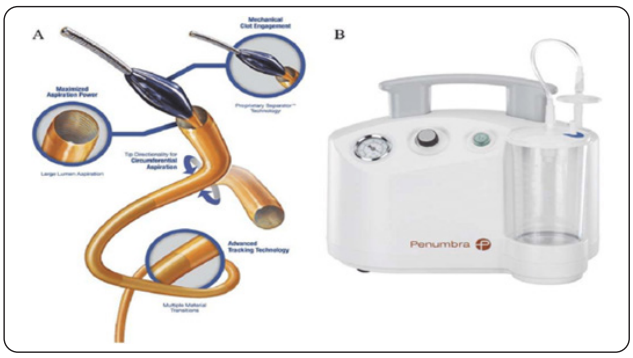

Figure 1: The Indigo thrombectomy system consists of an aspiration catheter (A), a vacuum pump (Pump MAX) that provides an aspiration power of almost −29-inch HG (B), and a separator (A), which facilitates fragmentation and aspiration of the thrombus. The separator ensures continuous aspiration throughout the system without clogging the catheter's tip.

The Indigo Aspiration System (Figure 1) consists of an aspiration catheter, pump, and separator. Aspiration catheters are available in 4 diameters (CAT3, CAT5, CAT6, and CAT8) with different profiles and lengths. For this study CAT3, CAT6, CAT8, and in some cases, ACE 6F (similar to CAT6), were used.

Diagnostic workup and indications for endovascular revascularization

When acute SMA occlusion was suspected, patients underwent computed tomography angiography (CTA) to confirm acute clot location within the SMA and exclude signs of bowel necrosis. Digital subtraction angiography (DSA) was then performed in patients who were considered candidates for endovascular intervention. Endovascular revascularization was indicated when there was CTA evidence of acute occlusion of the SMA and when there was no clinical or imaging evidence of advanced significant bowel infarction, free air or pneumatises intestinalis. CTA and DSA findings were used to assess the number and location of embolic occlusions.

Procedure

Conformist mesenteric arteriography was conducted before endovascular therapy. In most cases local anesthetic was applied to the puncture site and a 5-Fr sheath was introduced through a common femoral artery, radial or brachial approach with ultrasound guidance. Intraarterial heparin, was administered before the procedure. Once SMA occlusion was confirmed, the 5-Fr sheath was exchanged for a 6 or 8-Fr sheath depending on catheter choice and lesion location. The aspiration catheter was then advanced with the curved tip placed at the orifice of the SMA and at the origin of the clot. Clot was cleared from proximal to distal, with most operators avoiding crossing the clot with the catheter before the aspiration power was turned on. A separator was used at some centers per operator preference. The aspiration process was repeated as needed until a distal bowel perfusion was obtained.

Pharmacologic thrombolysis was indicated if persistent residual thromboemboli significantly reduced the bowel perfusion and included a bolus of urokinase slowly injected over 10 to 20 minutes or TPA per hospital policy. Direct intra-arterial prostaglandin E1 or Nitrates/ Glyceryl Trinitrate (GTN) was indicated if vascular spasm occurred and blood pressure allowed. If residual luminal narrowing was greater than 75% because of underlying atherosclerosis, an adjunctive stent was placed.

Post-Operative Care

After the endovascular procedure, patients were admitted to the intensive care unit. Patients were managed with bowel rest, nasogastric drainage, intravenous fluid therapy, and nutritional support. Laparotomy was indicated if abdominal pain worsened or if the patient developed new symptoms or signs suggestive of bowel perforation and/or gangrene. If bowel perforation or gangrene was reported during laparotomy, bowel resection was performed. Relook laparotomy was performed if there was further clinical deterioration after bowel resection. Subcutaneous low molecular weight heparin was administered for 3 days for most cases with residual thrombus or if known atrial fibrillation (AF).

Clinical follow-up

Outpatient clinic visits occurred at 1, 3, and 6 months and annually thereafter for follow-up of abdominal pain and other potential complications. Patients who exhibited abdominal pain underwent CTA of the SMA.

Study Outcomes and Definitions

The primary efficacy endpoint was technical success of endovascular revascularization, defined as residual stenosis of the previously occluded artery of less than 30% in diameter, without migration of small thromboemboli to branches, along with prompt flow and visible contrast reaching the entire bowel and without the need for lysis or alternative thrombectomy strategies (i.e., other endovascular technique or surgical repair) [12]. Primary safety endpoints were any in-hospital major adverse events, including death, re-interventions, stroke and myocardial infarctions.

Other outcomes assessed were procedure duration, volume of aspirated blood and contrast agent, acute reocclusion during the hospital stay, life-threatening major bleeding (LTMB), and the hemoglobin and hematocrit levels before and after the procedure. LTMB was defined according to the Bleeding Academic Research Consortium Definition for Bleeding.

Results

Ninety-eight cases (53 females; Age range: 55-93 years) diagnosed with acute thromboembolic SMA occlusion/acute SMA thrombosis were identified for the analysis. Baseline characteristic are reported in Table 1.

Baseline Characteristic	SMA Patients (N=98)
Female, % (n/N)	53% (53/98)
Age, Median [IQR]	
Symptom onset to treatment time, Range	8 hr to 7 days
SMA occlusion, % (n/N)	
Complete	64% (63/98)
Partial	36% (35/98)
Length of lesion (mm), Mean (range)	20 (18-22)

Table 1: Baseline Characteristics

Symptom onset to treatment time ranged from 8 hours to 7 days. None of the patients had signs of intestinal necrosis on CT. Preprocedural angiography showed complete SMA occlusion in 63 patients (64%) and partial SMA occlusion in 35 (36%) patients. All 98 cases were of native SMA vessel (i.e. not in stent thrombosis). Mean length of lesion was 20 mm (Range 18 to 22 mm).

Study outcomes are reported in Table 2. Technical success was achieved in all patients. Fibrinolysis was found to be associated with aspiration thrombectomy to improve the result. No periprocedural mortality was reported within 24 hours. Two deaths occurred over a mean follow-up of 9.5 (range 3-16) months.

Outcome	SMA Patients (N=98)
Technical success, % (n/N)	100% (98/98)
Mortality at 24 hours, % (n/N)	0% (0/98)
Mortality at follow-up, % (n/N)	2% (2/98)
Intraprocedural complications, % (n/N)	
Vessel dissection	0% (0/98)
Rupture	0% (0/98)
Distal embolization	0% (0/98)
Fibroylsis, % (n/N)	
Procedure time (minutes), Median [IQR]	
Acute reocclusion during the hospital stay, % (n/N)	
Volume of aspirated blood (mL), Mean ± SD	
Change in hemoglobin and hematocrit levels	
Volume of contrast agent (mL), Mean ± SD	
LTMB Score, % (n/N)	
Type 0 (no bleeding)	0% (0/98)
Type 1	
Type 2	
Type 3	
Type 4	
Type 5	

For intraprocedural complications, there were no cases of target vessel dissection, rupture, or distal embolization. Stenting was required in 5 cases (5%) to treat underlying stenosis in patients that presented an associated chronic atherosclerotic lesion. Example cases are presented in Figures 2and 3.

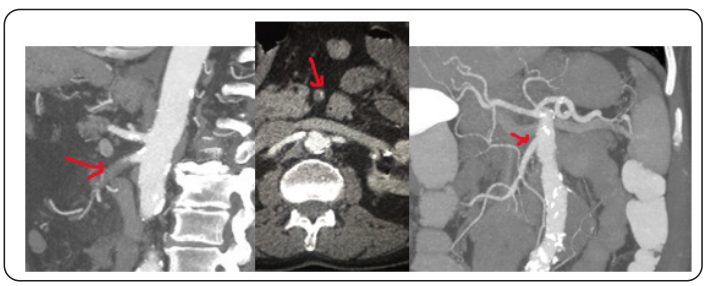

Figure 2: Image 1, 2: Starting point, occluded proximal SMA. Image 3: SMA following a single pass with the CAT6 indigo

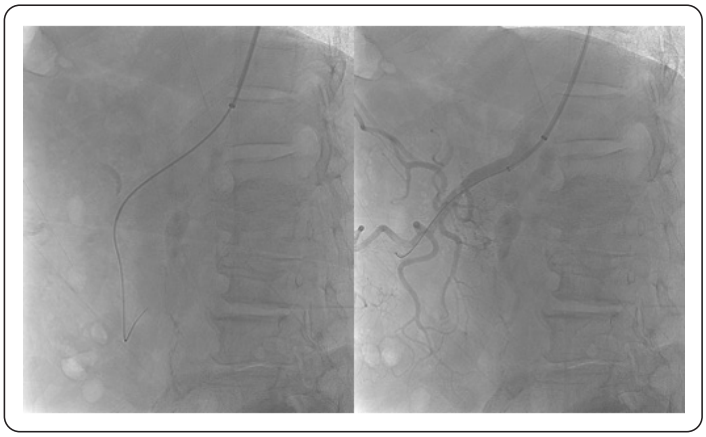

Figure 3: Image 4: 6Fr destination sheath with 0.018 wire and microcatheter. Brachial Approach.

Image 5: 6Fr destination sheath, CAT6 Indigo catheter, 0.018 wire in situ. GI surgical resection was required in 4 cases following this procedure for suspicious segments on CTA that were identified prior to VAT procedure as unlikely to resolve by improving blood flow alone. No abdominal compartment syndrome or bleeding was recorded Figure 5.

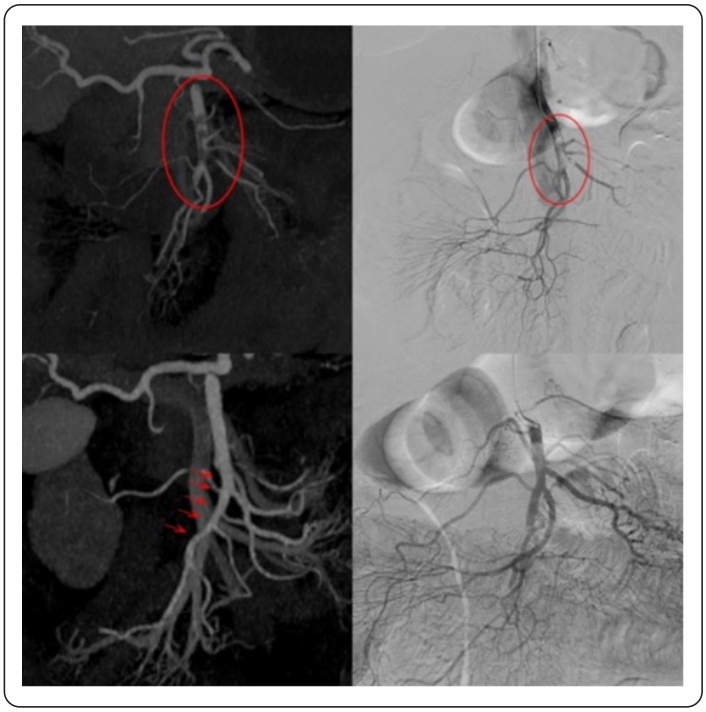

Figure 5: Images 8-11: Before and after the Indigo system CAT6, radial approach.

Out of these four cases, 2 patients died at day 27 and 28 because of myocardial infarction. As to LTMB score, none of the patients was classified as type 0 (no bleeding), since some amount of blood was aspirated in all cases.

Discussion

Acute thromboembolic occlusion of SMA is associated with high rates of morbidity and mortality [1]. Early diagnosis and immediate treatment are crucial to reversing bowel ischemia [2]. Acute SMA thromboembolic disease is associated with age, severe atherosclerotic disease, or AF. The occlusion can be caused by single or multiple emboli consisting of simple thrombosis, organized clot, or atherosclerotic plaque. In this study, we report high rates of technical success, low mortality rate, and few complications with firstline VAT using the Indigo System in AMI patients. Based these results, we believe that aspiration should be attempted first to remove the embolus and re-establish vital flow to the small bowel, regardless of embolus composition. Pharmacologic thrombolysis can assist when mechanical embolectomy is incomplete or if emboli result predominantly from fresh thrombotic emboli.

For AMI patients in our study, VAT was an effective and safe standalone management option, though our experience is limited. Alternative endovascular devices may be equally effective in restoring blood flow, with reported technical success rates of up to 100% in other studies, but a number of limitations deserve mention [10, 14]. Compared traditional surgical therapy with primary endovascular therapy, including fibrinolysis, mechanical thrombectomy and/or angioplasty, for the treatment of AMI [11]. Successful endovascular treatment was achieved in 87%, and the authors reported lower rates of required laparotomy, acute renal failure, and pulmonary failure in patients receiving primary endovascular therapy compared with traditional therapy. Manual aspiration of the thrombus through a sheath and a 60-mL syringe has been reported with an 88% technical success rate [15]. The main drawback of manual aspiration is the reduced aspiration power compared to the Penumbra pump, which provides a continuous negative pressure (−29-inHg) that is much higher than could achieve with a manually controlled syringe. Moreover, the Indigo catheter is more flexible than a sheath and conventional aspiration catheter, allowing catheter advancement while potentially reducing the risk of vessel dissection.

Rotational thrombectomy is an alternative approach that could be especially effective for old thrombi. Recently, several small studies have demonstrated the feasibility of rotational thrombectomy to treat SMA occlusions, with no post-surgical PMT-related complications, and no patient's deaths resulting from complications related to the use of rotational thrombectomy [16-17]. In our study, the majority of Reno visceral artery ischemia were acute events, making this approach comparatively traumatic for the tortuous and small Reno visceral vessels, especially if the occlusion was due to thrombosis of an atherosclerotic lesion. Rheolytic Pharmaco-mechanical thrombectomy is another alternative therapeutic option for AMI that was formerly used in our institutions in bridging stent-graft occlusions after branched endo-grafting before large Indigo thrombectomy catheters became available[18, 19]. However, notwithstanding the risk of major bleeding and the unknown extent of bowel or kidney ischemia, rheolytic pharmaco-mechanical thrombectomy has been related to an increased rate of postoperative renal dysfunction due to the hemolysis and hemoglobinuria [20].

The effectiveness of aspiration thrombectomy is well-recognized in acute cerebral infarctions, with a high rates of revascularization and an established safety profile [21]. This technique is also considered in the

management of vascular territories in the periphery [22-24]. Notably, the PRISM study was a retrospective multicenter study evaluating use of the Indigo System in peripheral arteries [22]. Complete or near-complete revascularization was achieved in 87.2% (68/78) of patients and no device-related adverse events occurred. Of these patients, only 5 cases had acute renovisceral ischemia (2 renal arteries and 3 SMAs) but no separate analysis of the renovisceral arteries was performed. Of note, the Indigo System was implemented as front-line therapy without any adjuncts in 51% of the patients [22].

In the current study, percutaneous VAT was implemented successfully as standalone treatment option with immediate improvement of symptoms in all 98 patients. The high rate of technical success was likely related with the age of the thrombus given that most occlusions in this vascular bed lead to early symptom onset. No significant post-procedural complications were reported, likely due to the absence of any additional pharmacologic lysis. In particular, the reduced need for lysis decreases potential bleeding risks. The quantity of aspirated blood and the decline in hemoglobin level and hematocrit were not significant issues. The chief advantages of this technique are rapid and efficient removal of large thrombus without the need for local thrombolysis and its minimal invasiveness, which avoids complications linked with surgery.

All of the centers involved in this study were experienced using the Indigo System prior to this study. In our experience, blood loss with this technique is reduced as the learning curve proceeds and technical expertise are developed. Blood loss from the aortic lumen can be minimized by only aspirating once the sheath is embedded into the proximal segment of the clot inside the target vessel. Having two physicians perform the intervention with well-defined roles (e.g. one operator advances the catheter into the thrombus and a second controls the back bleeding into the canister by steering the switch of the vacuum) can also minimize blood loss. Using this strategy, physicians were able to reduce the blood loss to less than 100 mL. However, in cases of aortic occlusion, deep vein thrombosis, or in long lesions, the issue of blood loss could be considered as an important limitation of the technique. In those patients we recommend anaesthesiology monitoring throughout the process. Patients in our study were mostly treated with the larger CAT8 catheter to order to increase aspiration capacity, prevent fragmentation through the separator, and to easily advance the catheter through the angulated lumen. If further thrombus aspiration of distal branches is necessary, a smaller catheter can be brought through the CAT8 in a coaxial technique. However, this was not always necessary, and the utility of size-matched, large-bore catheters was highlighted in a recent report on Indigo thrombectomy in the peripheral vasculature before the launch of large-bore catheters [23]. Although the profile of the CAT8 catheter aspiration tip is small compared to the visceral arteries (2.24 mm), the circumference of aspiration can reach 15 mm if an angled tip is used. The highly flexible tip also adapts to the diameter and shape of the vessel, and in our study, no adverse events such as dissection or perforation were reported.

The gravity of potential vessel damage, particularly in smaller vessels, should not be overlooked, and such complications can be managed by procedures such as endovascular coiling. Strict patient selection, based on clinic and CTA with early and late acquisition should be done before initiating treatment, since SMA recanalization in patients with necrosed bowel could have poor consequences [6]. The location of the embolus should also be considered, as the recanalization of entirely occluded SMA ostium might be technically challenging and potentially dangerous due to the risk of distal rupture of small peripheral branches. The main drawback of percutaneous revascularization is that the viability of the bowel structure cannot be assessed, and delayed diagnosis of bowel necrosis may increase the morbidity and mortality [6]. In our study, a multidisciplinary approach with a strict follow-up of the patient allowed the prompt evaluation of bowel necrosis that required surgical resection. We believe that the presence of abdominal pain is an important indicator of ongoing bowel ischemia, suggesting that the patient may require surgery.

The major limitation of our study was its retrospective nature, which prevented direct comparisons with other treatment strategies. Most of the patients who presented with advanced signs and symptoms of bowel ischemia were excluded from our study because of concerns over delaying treatment. Finally, a significant proportion of patients (36%) had partial SMA occlusion, which may have contributed to the positive outcomes.

Conclusion

Endovascular vacuum-assisted thrombectomy offers a safe and effective therapeutic option for percutaneous recanalization of acute thrombotic SMA occlusion, which can be performed under local anesthesia alone. Further collaborative research work to improve our understanding and management of the SMA, with long term follow-up is needed.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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