Percutaneous-aspiration thrombectomy for acute and subacute lower-limb ischemia: feasibility and mid-term results

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Introduction
Thromboembolic occlusions of the peripheral arteries are an important cause of acute lower-limb ischemia (ALI). Different treatment strategies were implemented in management of this critical situation, including open surgery, percutaneous endovascular approaches, and hybrid techniques with variable outcomes.
Aim
To evaluate the feasibility and effectiveness of percutaneous vacuum-aspiration mechanical thrombectomy with Indigo system in cases presented with acute and sub-ALI due to thromboembolic occlusion of different arterial territories of lower limbs, including native arteries, in-stent thrombosis, and synthetic bypass grafts with assessment of early and mid-term results.
Patients and methods
A retrospective analysis was made that includes patients presented to vascular surgery units at our facilities diagnosed with ALI due to thromboembolic occlusion class I and IIA, from June 2019 to November 2020, and were treated by percutaneous-aspiration thrombectomy using penumbra vacuum-aspiration catheter. The data were collected from electronic patients' files, analyzed, and presented.
Results
A total of 19 patients (15 males and four females with mean age 57±9.5 years) have been identified during the period from June 2019 to November 2020. In total, nine (47.4%) patients were clinically diagnosed as having ALI of Rutherford stage I, while the other 10 (52.6%) patients were having acute ischemia Rutherford stage IIA. The average duration of limb ischemia from onset of pain till the time at hospital presentation was an average of 5.3±4 days. The level of arterial occlusion was at the iliac artery in eight (42.1%) cases, four cases with native-artery iliac occlusions, four cases of occluded common iliac artery (CIA) metal stents, femoral artery was occluded in three (15.8%) cases, popliteal artery in five (26.4%) cases, and femoropopliteal bypass synthetic grafts made of polytetrafluoroethylene in three (15.8%) cases. In most of the cases (12 patients, 63.3%) we have used CAT8 (115 cm, XTORQ tip) catheter, while in seven cases, we have used CAT6 (135 cm) catheter. Postaspiration, dilation balloon angioplasty was done in seven (36.7%) patients with 11 (68%) patients who needed stent insertion. Technical success was achieved in 18 (94.7%) patients out of 19 cases with only one (5.3%) patient with failure and the procedure was converted to open-surgical embolectomy. No major procedure-related complications were encountered, except for one (5.3%) case of access-site hematoma that was managed conservatively.
Conclusion
Indigo system can be a safe and effective alternative to surgery for treating acute nonthreatening lower-limb acute ischemia.

Keywords:
acute-limb ischemia, endovascular, thrombosis, aspiration

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Introduction

Thromboembolic occlusions of the peripheral arteries are an important cause of acute and subacute lower-limb ischemia (ALI). Different treatment strategies were implemented in management of this critical situation, including surgery, endovascular, and hybrid techniques with variable outcomes [1]. Although catheter-directed thrombolysis (CDT) has been effectively used to salvage the ischemic limb resulting from those problems, bleeding complications remain a major concern of this treatment modality [2]. Aspiration thrombectomy has been long used as an adjunct to CDT in acute

arterial occlusions, or as salvage therapy to remove distal emboli during iliac or femoropopliteal angioplasty [3].

Aim

We tried through this study to evaluate the feasibility and effectiveness of the modern technique of percutaneous vacuum-aspiration thrombectomy in management of stable patients presented with acute and sub-ALI due to thromboembolic pathology affecting different arterial segments, including native arteries, stent thrombosis, and bypass grafts, and assess the immediate technical success and mid-term results as regards the limb-salvage rate and patency of the treated arterial segments.

Patients and methods

We have reviewed the medical files of all patients with acute or sub-ALI who presented to the vascular surgery units at Saudi German Hospital – Dammam & Soliman Fakeeh Hospital – Jeddah (both units are operated by vascular surgery staff from Faculty of Medicine, Cairo University) from June 2019 to November 2020, and were treated by percutaneous-aspiration thrombectomy using penumbra vacuum-aspiration catheter. We collected data related to patients, the aspiration-thrombectomy procedures, and the follow-up assessment visits in the outpatient departments. An approval for that review and analysis was obtained from the hospital higher managements and quality team personnel in both hospitals, but no patient's special consents were taken for that analysis being a retrospective review of data.

Patient-related data include:

(1) Age and sex.
(2) Associated medical comorbidities (diabetes mellitus, hypertension, renal impairment, ischemic heart disease, or cardiac valve problems, etc.)
(3) Site and Rutherford clinical stage of the presenting limb ischemia.
(4) Duration of limb ischemia from onset of pain till the time at hospital presentation.
(5) The nature of the occluded limb vascular tree (native artery vs. synthetic grafts or occluded metal stents).
(6) The level of arterial occlusions and the state of collateral refilling of distal run-off vessels (as depicted from the preoperative radiological workup).
(7) The underlying etiology (as revealed from the postoperative diagnostic workups that were done).

Procedure-related data

(1) The arterial access that was used.
(2) Type of the aspiration catheter.
(3) The use of thrombolytic therapy.
(4) The need for adjunctive endovascular interventions (like balloon angioplasty with or without stent insertion).
(5) The need for conversions to open thrombectomy or surgical bypass procedures.
(6) The duration of the thrombectomy procedure.
(7) The technical success of the aspiration thrombectomy (both radiological and clinical success).
(8) Intraoperative as well as postoperative procedure-specific complications.

Follow-up data

(1) Patency of the treated arterial segments as depicted by clinical and radiological evidences.
(2) Clinical improvement of the target limb.
(3) The need for endovascular or surgical redo intervention.
(4) The need for a major (above the ankle) limb amputation.

The technical aspects of the procedure:

Preprocedure preparation

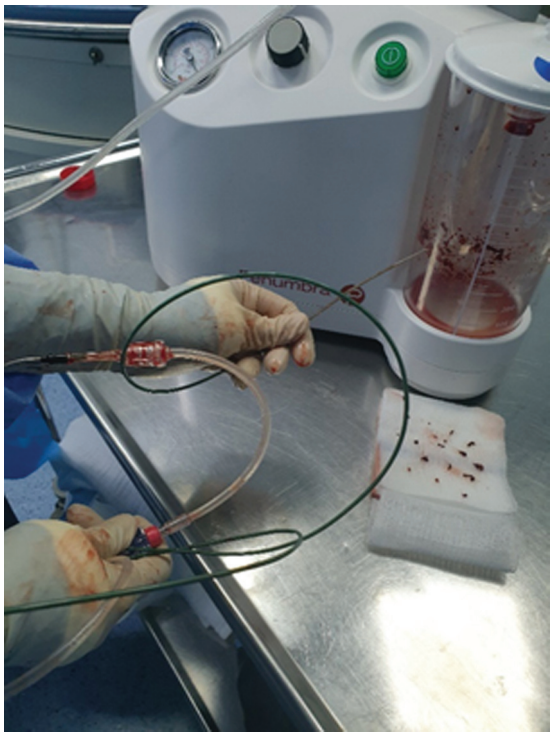
Arterial duplex scanning was done for all patients immediately after presentation to the Emergency Department to confirm diagnosis; some other patients have undergone computed tomography (CT) angiography to outline the arterial tree of the affected limb. All reviewed patients were diagnosed provisionally on the basis of clinical findings and arterial duplex as having ALI with nonimmediately threatened limbs (Rutherford stages: I and IIA) and were urgently admitted to undergo thrombectomy procedure on the next day. Therapeutic dose of parenteral anticoagulation (e.g. enoxaparin 1 mg/kg subcutaneous, twice daily or UFH infusion) was started immediately after admission, and a loading dose of clopidogrel (300 mg) was given the night before the procedure.

The procedure

All procedures were done in the angiography suite under deep (conscious sedation) with complete anesthesia monitoring. The patients were laid in the supine position, and both groins were prepared as usual using an antiseptic solution (povidone–iodine 10%), and then local anesthetic drug was given

(lidocaine 2%). Based on the preprocedural duplex or CT angiography findings, femoral access was either ipsilateral antegrade approach (in lesions involving the mid-to-distal femoropopliteal arteries) or contralateral retrograde or cross-over approach (in lesions of the iliac arteries, common femoral artery, or proximal superficial femoral artery and in obese patients). A 6-Fr sheath (11 cm) was advanced and then systemic heparin administration with initial dose of 80 IU/kg through the sheath was given with further 1000 IU for every 1 h guided by ACT. Initial diagnostic angiography of the target limb was done using an appropriate 4 or 5 Fr catheter (e.g. Bernstein Catheter; Cordis, Miami, Florida, USA). Delayed imaging up to 30 s with large contrast volumes was needed to opacity the tibial runoff vessels, which were classified based on angiographic findings into either cases with single run-off or cases with multiple run-offs. Once the occlusion was delineated, wire-traversal test was done by probing the occlusion with a soft floppy tip guide wire using a 0.035-inch 260-cm standard angled tip Terumo guide wire (Terumo Inc., Tokyo, Japan). If this standard workhorse guide wire traverses the thrombosed segment easily, then the clot is likely to respond well to thrombectomy. The guide wire was then advanced through the occluded part into a run-off. We have used the Indigo System aspiration catheters for the aspiration procedure. These catheters are available in a range of lengths and diameters that, when connected to the Penumbra ENGINE pump (Penumbra, Inc., headquartered in Alameda, California, USA) (Fig. 1), can remove the occlusive fresh thrombus present in various peripheral vascular beds without damaging the vessel wall. The catheters (CAT3, CAT RX, CAT5, CAT6, CAT8, and CATD) vary in diameters from 3.4 to 8 Fr and lengths of 50–150 cm to enable the operator to remove thrombus from small vessels, such as the pedal arch. We usually chose the largest no-occlusive catheter that would fit in the target vessel for aspiration (e.g. CAT6 for superficial femoral artery, popliteal, and tibial vessels, or CAT 8 Fr for iliac and bypass grafts). The catheter is advanced through the sheath over the wire and positioned 0.5–1 cm inside the occlusive clot or embolus, then the guide wire is retracted, and the catheter is connected via dynamic aspiration tubing with flow switch to Penumbra ENGINE pump that helps delivering and maintaining nearly pure vacuum (−29.2 mmHg) for at least 90 s. The suction is activated while the valve in the connection tube is closed to create enough suction power, then the valve is opened, and the catheter was slowly advanced through the thrombus till free blood is coming out. After that, suction is stopped and

Figure 1



Indigo (Penumbra) aspiration system.

angiography is performed to assess the results, the process can be repeated as required. A separator wire that came with the aspiration kit can be used to assess dislodging thrombus that clogged inside the catheter. After retrieval of all thromboembolic material, a final angiography is performed and any significant residual lesion is dealt with via balloon angioplasty with or without stenting as needed. Vessel recanalization was considered successful when direct noninterrupted contrast flow was obtained angiographically in the treated vessel. Patients were transferred to the in-patient wards after the end of the procedure where the arterial sheath was routinely removed 2–6 h after the last heparin dose, and digital compression was held proximal to the skin puncture site for 15–20 min. Patient mobilization from bed was delayed for 6–12 h after the procedure. On the next day, auxiliary procedures for foot care were done in the form of ulcer debridement, toe amputations, or foot wound dressings as needed with administration of systemic culture-based antibiotic therapy as dictated by the clinical condition of each patient. Patients were discharged only after clinical improvements as evidenced by resolution of the limb ischemic symptoms with regain of pulse, local limb warmness, distal limb edema, disappearance of rest pain, and improvement of capillary refill with absence of any complication from the interventional procedure like major bleeding requiring blood transfusion or surgery,

intracranial hemorrhage, lower-limb compartment syndrome, distal embolization, access-site complications (bleeding orhematoma), or contrast-induced nephropathy. Follow-up duplex ultrasound assessment was routinely done before discharge to objectively document the arterial patency and improvements in ankle peak systolic velocities. Medications were prescribed to the patients, including aspirin 100 mg/day for life, clopidogrel 75 mg/day for at least 6 weeks, and atorvastatin 20 mg once daily (for cases with acute on top of chronic limb ischemia). Oral anticoagulation with vitamin-K antagonists followed the short course of low-molecular-weight heparin therapy and continued for a minimum of 6 months after discharge with necessary dose titration made to obtain international normalized ratio values of 2–3; some other cases were given new oral anticoagulation therapy.

Statistical analysis

The statistical methods that were used in this study included the range, the mean, and P level for statistical significance. Statistical workup was performed using MedCalc, version 15.8 (Medcalc Software, Ostend, Belgium).

Results

A total of 19 patients (15 males and four females with mean age 57±9.5 years) have undergone percutaneous-aspiration thrombectomy in the vascular surgery units at both hospitals during the period from June 2019 to November 2020. In total, nine (47.4%) patients were clinically diagnosed as having ALI of Rutherford stage I, while the other 10 (52.6%) patients were having acute ischemia Rutherford stage IIA. In 11 (57.9%) patients, the underlying cause of ALI was due to thrombosis that affected native limb arteries in four cases, bare metal stents in four cases, and synthetic vascular grafts in three cases, while arterial embolism was the cause of limb ischemia in seven (36.7%) patients only. In only one (5.26%) critically ill patient, the cause of limb ischemia was thought due to peripheral circulatory hypoperfusion (low flow state) on top of chronic limb ischemia. Patients' demographic data, associated medical morbidities, and limb ischemia clinical characteristics are outlined in Table 1.

In the 19 patients, the average duration of limb ischemia from onset of pain till time at hospital presentation was in the average of 5.3±4 days. All cases have been given a therapeutic dose of low-molecular-weight heparin once diagnosis was made on clinical basis, and in all except two patients, the diagnosis was confirmed by CT angiography. In the two patients with renal impairment, diagnosis was further confirmed by arterial duplex scanning. The level of arterial occlusion as revealed from the preoperative diagnostic workup was at the iliac artery in eight (42.1%) cases, four cases with native artery iliac occlusions and four cases of occluded CIA metal stents, femoral artery was occluded in three (15.8%) cases, popliteal artery in five (26.3%) cases, and femoropopliteal bypass synthetic grafts made of polytetrafluoroethylene in three (15.8%) cases. All data regarding the level of arterial occlusions and the state of distal run-off vessels are shown in Table 2.

The contralateral femoral artery access with up- and overbifurcation technique to cross to the other CIA was used in seven (36.8%) cases with occlusions at the

Table 1 Patients' clinical and demographic data

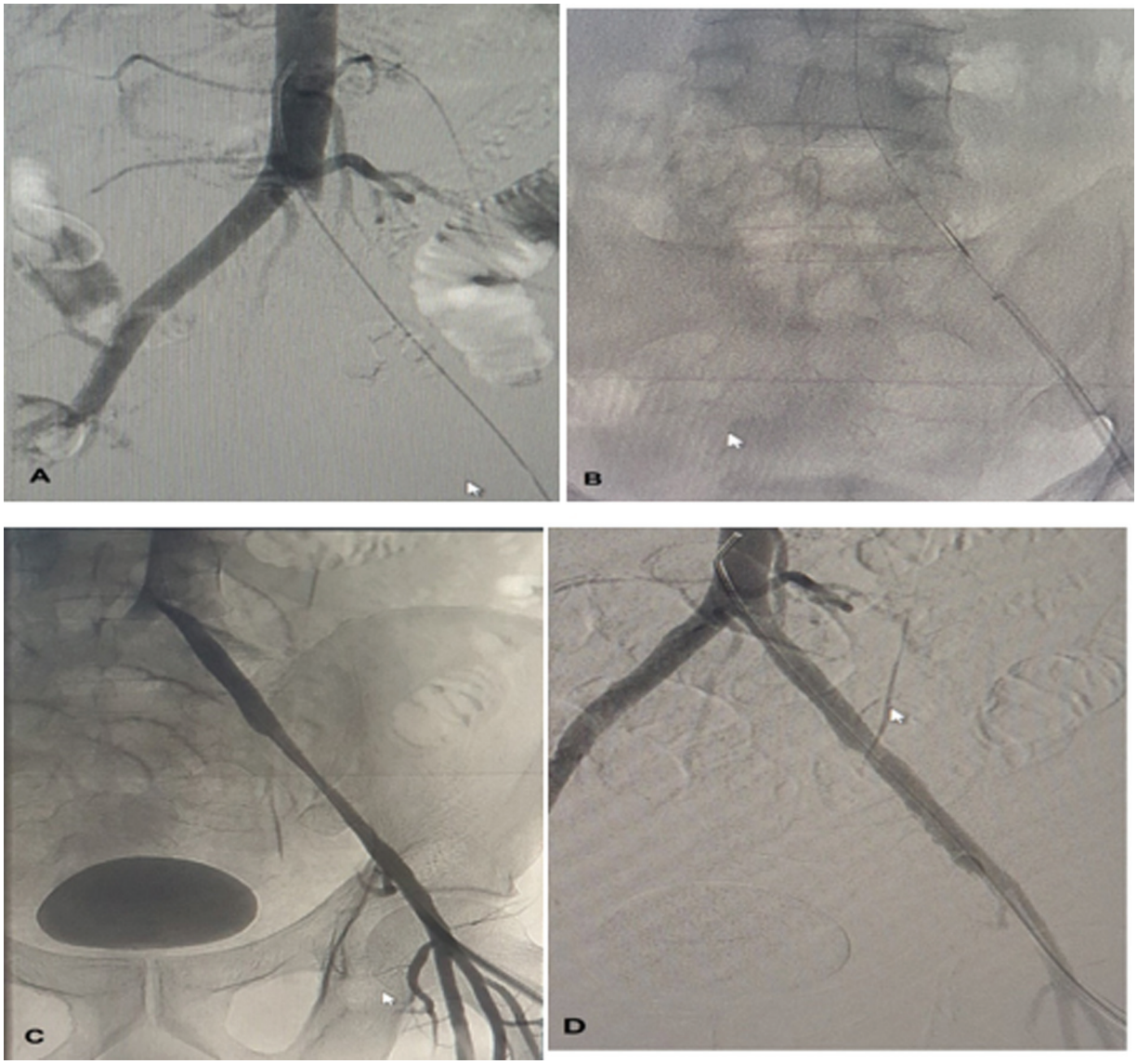
	n (%)
Sex	
Male	15 (78.9)
Female	4 (21.1)
Comorbidities	
Hypertension	17 (89.5)
Ischemic heart disease	11 (57.9)
Valvular heart disease	6 (31.6)
Renal impairment	2 (10.5)
Diabetes mellitus	15 (78.9)
Rutherford ischemia class	
Class I	9 (47.4)
Class II A	10 (52.6)
Causes of acute limb ischemia	
Acute arterial thrombosis	11 (57.9)
Arterial embolism	7 (36.7)
Others	1 (5.3)

Table 2 Level of arterial occlusions and state of run off arteries

	n (%)
Occluded segment	
Common iliac artery	4 (21)
Common femoral artery and superficial femoral artery	3 (15.8)
Popliteal artery	5 (26.3)
Iliac artery stent	4 (21)
Synthetic bypass graft	3 (15.8)
Distal arterial refill segment (run off)	
External iliac artery	7 (36.8)
Common femoral artery	1 (5.26)
superficial femoral artery	3 (15.8)
Popliteal artery	P1 segment (1) (–5.26)
	P2 segment (2) (–10.5)
Tibial arteries	5 (26.3)

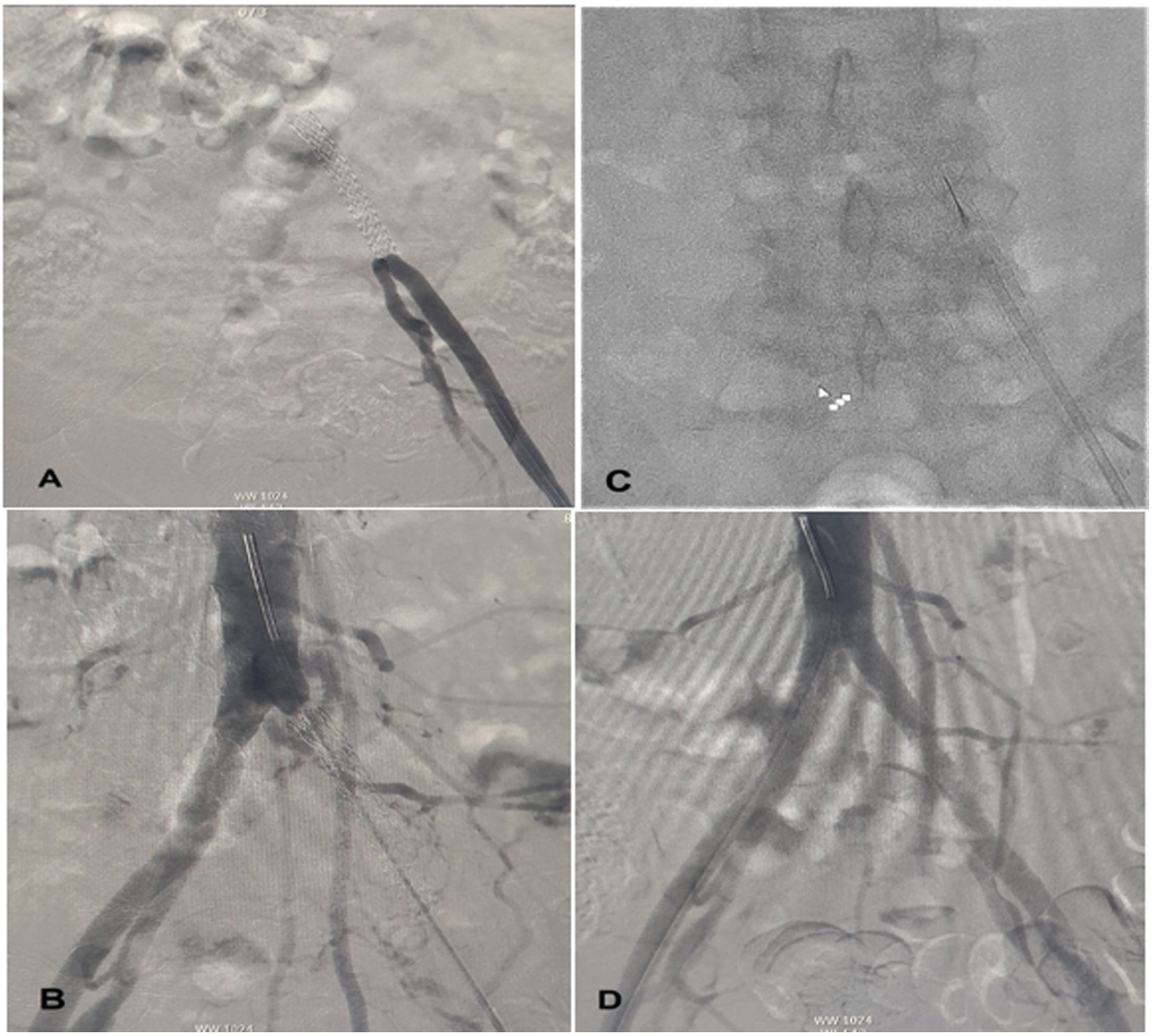
common femoral artery, superficial femoral artery levels, or thrombosed femoropopliteal bypass grafts (Figs 4 and 5), while in six (31.6%) cases with occlusions at the CIA level, the ipsilateral retrograde femoral artery access was utilized (Figs 2 and 3). Only in one (5.26%) case of CIA/external iliac artery occlusion, the left brachial artery access was used due to inability to use either the ipsilateral retrograde or the contralateral and cross-over femoral access. In the five (26.3%) cases of popliteal artery thrombosis, the ipsilateral antegrade femoral access was used. Based on intraoperative angiographic measurements, the largest nonocclusive catheter that would fit in the vessel for aspiration was chosen, in most of the cases (12 patients, 63.15%), we have used CAT8 (115 cm, XTORQ tip) catheter connected to the Penumbra ENGINE pump, while in seven cases, we have used CAT6 (135 cm) catheter. The median duration of thrombectomy procedure was 87±35.3 min with average number of catheter passes (3–5 pass/segment). No thrombolytic therapy was used in any of those patients as we have kept a window for possible immediate surgical intervention should the thrombectomy procedure has failed or serious complications developed, also, not to have bias between the effect of thrombolysis and the individual efficiency of the aspiration procedure. Postaspiration, dilation balloon angioplasty was done in seven (36.8%) patients with 11 (57.8%) patients who needed self-expandable nitinol stent or balloon-mounted stent insertion to scaffold the treated arterial segments. Only in one patient, the aspiration

Figure 2



Left common iliac artery (CIA) thromboembolic occlusion (a). Retrograde approach percutaneous-aspiration thrombectomy using CAT eight and separator wire (b). Balloon angioplasty with the final angiogram showing opening of the occluded parts (c, d).

Figure 3



Left common iliac artery (CIA) stent occlusion treated by percutaneous-aspiration thrombectomy and angioplasty with restenting. (a) Left femoral retrograde access with diagnostic angiography showing total occlusion of CIA stent. (b) Crossing the occluded stent. (c) Using CAT eight aspiration catheter and separator wire to declot the stent. (d) Final angiography after relining the stent.

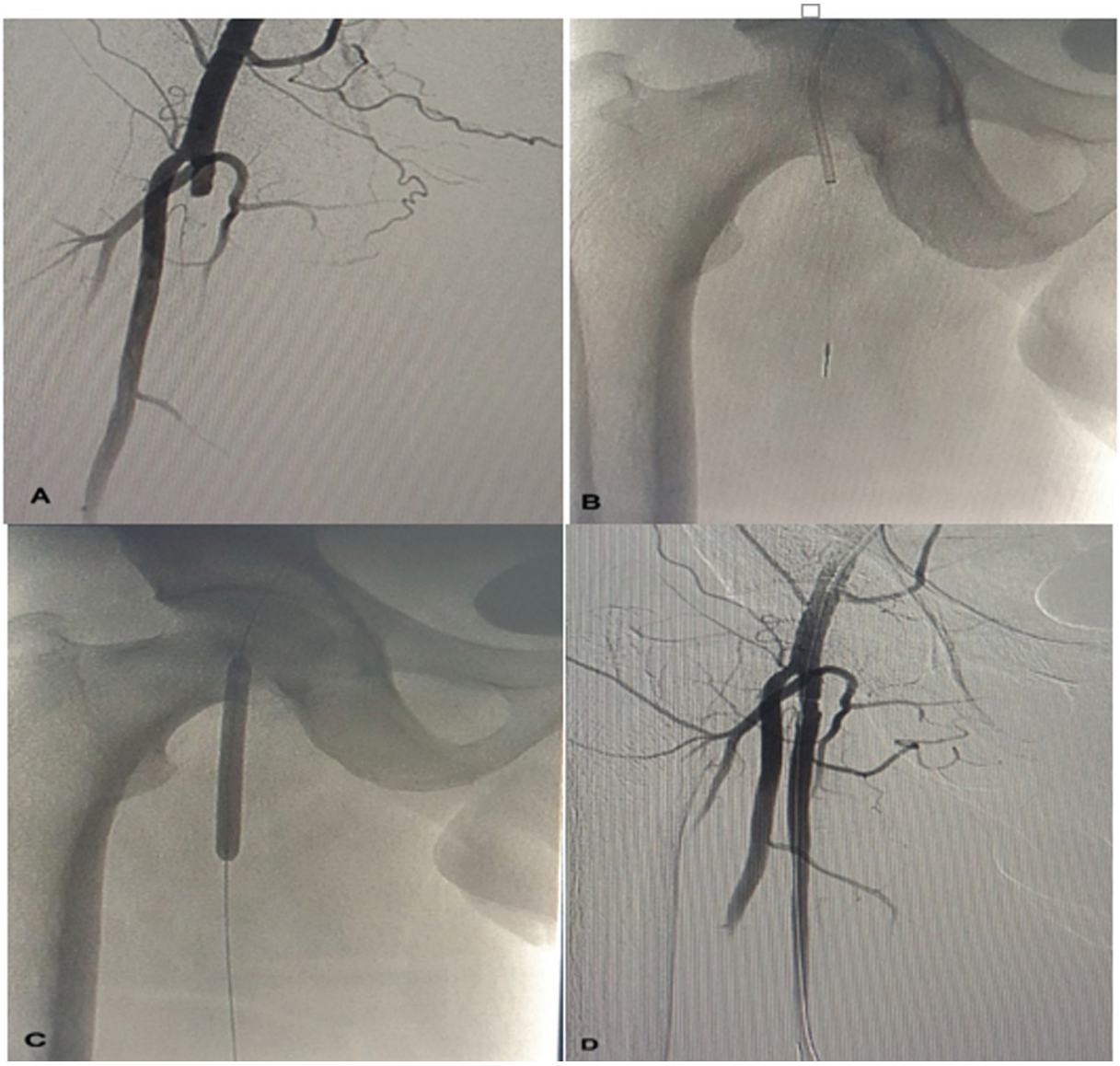
procedure failed and surgical embolectomy from femoral approach was needed. All procedural data are listed in Table 3.

Technical success in terms of radiological improvement of the treated arterial segments was achieved in 18 (94.7%) patients out of 19 cases with only one (5.26%) patient in which the aspiration thrombectomy has failed and the procedure was converted to open-surgical embolectomy. No major procedure-related complications were encountered, except for one (5.26%) case of access-site hematoma that was managed conservatively. During the follow-up period, one patient that was critically ill and referred from the intensive care unit had died 3 weeks after intervention from causes not related to the thrombectomy procedure, another patient had experienced symptom recurrence during the fifth month after thrombectomy for whom a redo endovascular-aspiration thrombectomy was done again with resolution of symptoms and regain of distal limb perfusion. Patency rates during the follow up period are shown in Table 4. All patients reviewed in this analysis had a well-perfused limb at the maximum follow-up period (18 months after intervention) with no major (above-ankle) amputation done for any case and limb-salvage rate of 19/19 (100%) was achieved.

Discussion

ALI, defined as acute (<2 weeks) severe hypoperfusion of a limb that results in pain, pallor, absent distal pulses, poikilothermia, paresthesias, and paralysis, is one of the most common vascular emergencies [4]. ALI can result from many underlying causes such as a sudden

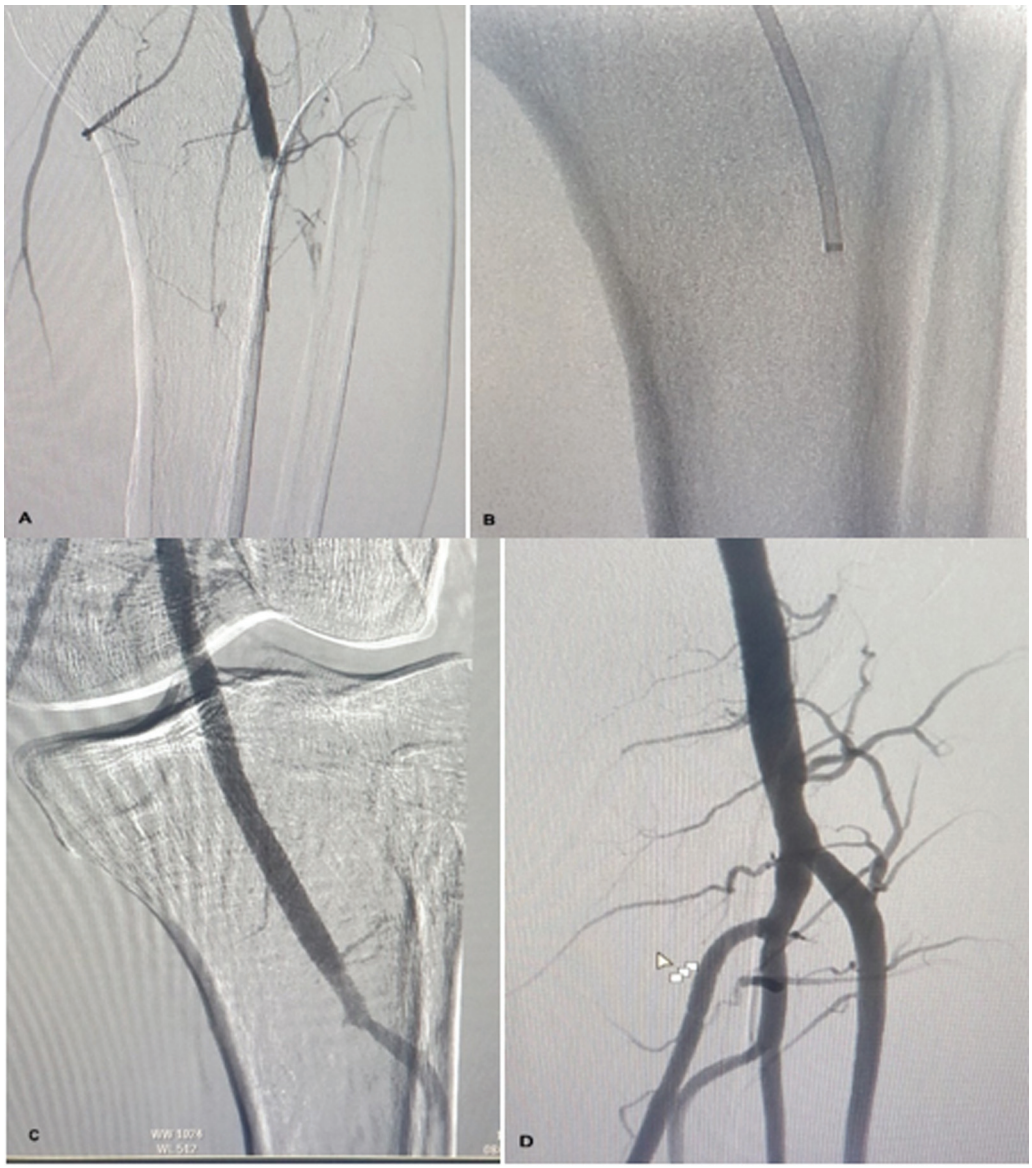
Figure 4



Right proximal SFA embolic occlusion treated by percutaneous-aspiration thrombectomy and balloon angioplasty. (a) Crossover diagnostic angiography showing total occlusion of proximal SFA (b). Using CAT eight and separator wire to aspirate the thrombus (c). Balloon angioplasty for residual stenosis (c). Final angiogram. SFA, superficial femoral artery.

obstruction in the arterial flow to the extremity owing to arterial embolism or in situ intra-arterial thrombosis, bypass graft thrombosis, acute aortic dissection, popliteal artery entrapment syndrome, cystic adventitial disease, lower-limb vascular trauma, phlegmasia cerulea dolens, ergotism, hypercoagulable states, and iatrogenic complications related to cardiac catheterization, or other endovascular procedures [5]. Embolic events result in a greater degree of ischemia than acute thrombosis. The embolus usually lodges in the affected limb that is previously healthy with no prior collateral circulation; on the contrary, an in situ thrombosis occurs in vessels with prior, gradual atherosclerotic stenosis that has stimulated the formation of collateral vessels. The presence of these collateral channels helps to reduce the severity of acute ischemia symptoms when the atherosclerotic stenosis progresses to sudden total occlusion of the arterial segment [6]. Systemic anticoagulation with full therapeutic dose of heparin followed by urgent/emergent revascularization has been recently reemphasized as class-I recommendations in all patients with ALI and a viable or threatened limb [7]. However, the optimal revascularization method for management of ALI is still remaining unclear, and contemporary comparative data on the effectiveness of endovascular versus surgical revascularization are lacking since five randomized controlled trials from the 1990s comparing the effectiveness of endovascular CDT versus surgical revascularization for ALI have

Figure 5



Left popliteal artery embolism (a). Percutaneous antegrade approach aspiration thrombectomy using CAT six catheter (b). Selective catheter passage using a guide to direct the catheter in each of the infrapopliteal vessels (c). Excellent result without need for angioplasty (d).

Table 3 Technical and procedural characteristics

	n (%)
Access site	
Contralateral femoral access with cross-over	7 (36.8)
Ipsilateral antegrade femoral access	5 (26.3)
Ipsilateral retrograde femoral access	6 (31.6)
Left brachial artery access	1 (5.26)
Catheter size	
CAT 6	7 (36.8)
CAT 8	12 (63.15)
Adjuvant procedure	
Balloon angioplasty	7 (36.8)
Stent insertion	11 (57.89)
Thrombolytic therapy	0
Conversion to surgical embolectomy	1 (5.26)

produced conflicting results [8–12]. In the absence of a convincing evidence favoring one revascularization method over another, the choice of revascularization approach (endovascular or surgical) in the setting of ALI is often influenced by patient factors, cause of ischemia, local resources, and clinical expertise. Recently, a number of new endovascular modalities have emerged, including aspiration thrombectomy, rheolytic thrombectomy, and ultrasound-assisted catheter-directed low-dose thrombolysis [13]. Catheter-directed aspiration thrombectomy, traditionally done by large-bore catheter and manual (50 ml) syringe aspiration, is an established method for removal of distal thromboemboli during the conventional peripheral vascular interventions [14].

Table 4 Patency and limb salvage rates

	n (%)
Outcome	
Radiological success	18 (94.7)
Conversion to open embolectomy	1 (5.26)
Limb salvage	19 (100)
Major amputation	0
Access complications	1 (5.3)
Patency at 1–3 months	19 (100)
Patency at 6–18 months	18 (94.7)
Need for re-interventions	1 (5.26)

But recently, new automated devices such as the Indigo System CAT-series catheters (Penumbra Inc., Alameda, California, USA) have begun to be widely used as adjuncts to other therapies [15].

The Penumbra system enables the removal of emboli and thrombi from vessels of the peripheral arterial system by using vacuum aspiration as its primary mechanism of action. A flexible, large-bore over-the-wire catheter was delivered to the site of arterial occlusion, and aspiration was directly applied to the thrombotic/embolic lesion itself. A Penumbra Separator was used at the tip of the catheter to continually break up the clot once ingested under aspiration to maintain lumen patency of the aspiration catheter, thus allowing continuous thrombectomy under constant aspiration supplied by the external vacuum pump. Unlike CDT, which often requires prolonged infusion times in an intermediate care unit, Indigo is able to provide rapid restoration of flow to thrombosed vessels in a short-time procedure at the angiography suite. It can also be used for limb reperfusion when thrombolytic therapy and surgery are contraindicated as in old critically ill patients. The Penumbra system not only successfully removes macroemboli at the site of obstruction, but the mechanism of continuous automated suction may also prevent further escape of microemboli to distal vascular beds [16], for that reason no distal filter protection was needed during the procedures.

The primary objective of this retrospective analysis was to compare in-hospital outcomes of aspiration thrombectomy revascularization in a cohort of patients hospitalized with ALI to examine the feasibility, short-term and intermediate-term outcomes of such new modality to be able to incorporate this type of revascularization in our new cases based on solid data, and an evidence-based background. Aspiration mechanical thrombectomy (AMT) devices are an alternative approach to remove thrombus in the peripheral arterial system and to restore limb perfusion, but data regarding effectiveness of this approach of limb revascularization among vascular surgeons are limited.

In the most recently similar study done by Lopez *et al.* [17], there were 41 patients (68% male, 32% female; mean age, 67 years; range, 27–90 years) with total of 43 AMT procedures. Technical success of AMT was 52% (15/29) as main treatment and 50% (7/14) as adjunctive treatment. Thrombolysis was avoided in 53% of patients (23/43). There were no 30-day deaths. Five patients required amputations, but only one after successful AMT. Complications included intraoperative distal embolization (two), access-site hematoma (one), pseudoaneurysm (one), acute kidney injury (one), and spontaneous calf hematoma (one).

Another recently published results from the multicenter PRISM study assessing the Indigo system (utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: results of the multicenter PRISM trial XTRACT study) have shown that total or near-total revascularization was achieved in 87.2% of patients immediately after the procedure. A total of 79 patients were enrolled: 39 (49.4%) underwent XTRACT as the initial therapy and 40 (50.6%) underwent XTRACT after failed CDT or other mechanical intervention. Successful revascularization was achieved in 79.5% of patients (31 of 39) as an initial treatment and in 92.5% (37 of 40) as salvage or secondary therapy. The study has concluded that XTRACT was safe and effective for revascularization of acute or subacute peripheral arterial occlusions as a primary therapy or as a secondary therapy after other endovascular techniques had failed [18].

Regarding complications, we did not realize any complications specific to this type of intervention apart from access-site hematoma that occurred in one patient and was managed conservatively. Otherwise, no other complications had occurred epically vessel wall dissection or embolism showering to distal vessels. No major amputation (above the ankle) was done with limb salvage rate of 100% achieved. All patients during the follow-up visits showed clinically viable limbs with audible Doppler signals at the pedal vessels with no major procedure-related complications. The case that showed failure of AMT was a 48-year man with ischemic cardiomyopathy and was presented with acute embolic ischemia due to right iliac artery occlusion, a trial was done using CAT eight catheter through retrograde femoral access, after an easy passage of the wire, the catheter was introduced and positioned and

then multiple passes were performed with failure to retrieve the embolus and angiography showed failure to regain an adequate vessel lumen. A trial of thrombolysis for 2–6 h was discussed with the patient versus conversion to open surgical thromboembolectomy but he refused the thrombolysis option. So, after multiple trials, the aspiration process aborted and a femoral cut down was done and the procedure was completed as standard surgical embolectomy using Fogarty's balloon thrombectomy catheter that resulted in retrieval of multiple embolic materials and return of femoral pulse. The postoperative transesophageal echocardiography showed intracardiac thrombus, and life-long anticoagulation was the management plan. This may explain that the nature of the occluding material may greatly affect the results of the aspiration thrombectomy procedure, with high success rate expected in fresh thrombus and soft emboli, versus low rate of procedure success in hard fibrotic embolic material or old thrombotic occlusion. Another case of right iliac artery stent thrombosis with initial primary successful aspiration thrombectomy and iliac artery restenting, presented 3 months later with chronic limb pain and absent femoral pulse on the previously treated limb. A follow-up CT angiography showed stent reocclusion. Redo percutaneous-aspiration thrombectomy was done followed by relining the common iliac stent with a new covered stent and return of femoral and distal pulses. This may reflect the ability to easily repeat AMT in case of recurrence, which adds more to its advantages versus standard surgery, especially in old fragile patients with multiple morbidities. The patient was then kept on clopidogrel 75 and apixaban 5 mg twice daily with covered stent that remained patent on 6 months of follow-up.Embolic-protection devices could be used during endovascular revascularization of ALI to reduce this risk and minimize the amount of dislodged material that reaches distal vessels. In our study, no embolic protection device was used in any case, one study showed that the incidence of significant distal embolization, despite the use of an embolic protection device, was around 12% [19].

It is important to realize that, in our practice, considering the high cost of this technique, we only offered percutaneous-aspiration thrombectomy to selected embolic ischemia patients with anticipated difficulty during surgical embolectomy (morbid obese, previous groin surgery) or anticipated need for adjuvant procedure (e.g. CDT or balloon angioplasty with or without stenting).

This study faced several important limitations: first, the sample size was small, and second, the follow-up period was relatively short, as a result of difficulty in conducting longer periods of follow-up owing to lack of patient compliance. The relatively small sample size is attributed to many reasons like the high costs of the procedure that basically has limited the number included in the study in view of the limited available resources and absence of external funding; and last, the study was targeting primarily the patients with early-stage ALI, whereas most patients who presented to emergency department at our institution were actually in late stages (being tertiary care and referral centers) mostly owing to delay in timely diagnosis at the outside primary care centers.

We believe that in the future studies, long-term follow-up for at least 24 months will be necessary to determine the real durability of this type of intervention, but at that stage, we wanted only to emphasize the feasibility of this technique in management of early stages of ALI, to be taken later on into consideration as an additional technique at our therapeutic armamentarium.

Conclusion

The results of this analysis reconfirmed the recent concept that vacuum-aspiration thrombectomy using Indigo system can be a safe and effective alternative to surgery for treating ALI. It did not lead to a high rate of major complications. Moreover, failure of this revascularization modality does not necessarily prevent a successful surgical intervention nor lead to amputation.

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Conflicts of interest

There are no conflicts of interest.

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