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The Journal of Cardiovascular Surgery 2023 June;64(3):233-9
DOI: 10.23736/S0021-9509.23.12696-6

REVIEW

ACUTE LIMB ISCHEMIA MANAGEMENT

Endovascular thrombectomy devices for acute limb ischemia management

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ABSTRACT

Acute limb ischemia still represents a challenge for the contemporary vascular surgeon, representing an immediate threat for patients' limb but potentially also for the proper patient life in some settings. Technology recently evolved and focused on the treatment of such complex situation. Several devices are available as of today allowing a complete acute limb ischemia endovascular management, aiming to remove intraluminal material while leaving the possibility for treating the underlying pathology when needed. In this review, proper specific device characteristics, indications and advantages are reported and discussed. Despite the broad spectrum of different available devices could appear as potentially confounding, each device has its own features, indications, weak and strength point. Ideally the modern endovascular surgeon should master every single tool, tailoring revascularization strategy and timing for the proper patient and arterial segment to be treated, maximizing the benefits coming from technological improvements.

(*Cite this article as*: Isernia G, Pasqui E, de Donato G, Fino G, Lenti M, Parlani G, *et al.* Endovascular thrombectomy devices for acute limb ischemia management. J Cardiovasc Surg 2023;64:233-9. DOI: 10.23736/S0021-9509.23.12696-6)

KEY WORDS: Extremities; Ischemia; Endovascular procedures; Thrombectomy; Equipment and supplies.

Acute limb ischemia (ALI) is defined as a sudden significant decrease in limb perfusion occurred within the last 14 days causing a threat to limb viability. To preserve viability and reduce mortality and morbidity, timely recognition and early blood flow restoration is crucial. In case left untreated, ALI could determine infection, necrosis, limb loss and ultimately, death.[1] Acute limb occlusion incidence is approximately 1.5 per 10,000 persons per year,[2] and clinical severity is commonly classified according to Rutherford scoring.[3] Despite treatment is generally provided in urgency, current estimates of 1-year amputation-free survival following an episode of ALI range from 50% to 65% due to the inherent underlying comorbidities of this patient population.[4] Treatment strategy depends on etiology (thrombus or embolus), location, type of conduit (artery of graft), Rutherford class, onset time, patients' comorbidities and therapy-related risks.

ALI is a challenging clinical entity placing patients at risk of both life and limb loss. Surgery has long been the paradigm for expedient revascularization. Contemporary experience, however, has demonstrated endovascular strategies to be safe and effective with success rates comparable to surgical experience. Recent data review seems to suggest perioperative morbidity and mortality reduction when ALI is managed via endovascular means. Based on available evidence and experience, an endovascular first approach to ALI is appropriate.[5] Nevertheless, the ideal treatment remains case dependent and should be tailored on the proper patient. A successful management requires a comprehensive understanding of the acute event and its

etiology, in addition to a deep knowlendge of available endovascular devices limitations and advantages.

Until the current decade, endovascular ALI management mostly consisted in catheter-directed thrombolysis (CDT). However, CDT is associated with prolonged infusion times, increased risk of major bleeding events, and the need for intensive patient monitoring. Moreover, frequent contraindications to lytic therapy hurdle this therapeutic strategy.

Nowadays percutaneous thrombectomy (PT) devices have further advanced endovascular possibilities. These tools overcome most of the CDT limitations and are emerging as effective tools for improved clot dissolution and removal, potentially averting the need for thrombolysis, or reducing thrombolytic drugs doses.

PT is defined as endovascular thrombus fragmentation and removal using dedicated devices and is currently wide-spreading as first-line therapy for ALI providing high technical success rates for primary re-opening when performed in peripheral arteries.[6, 7]

In patients with increased bleeding risk, thrombus mass debulking before local lysis aims to reduce the treatment length, thereby limiting the thrombolytic agent dose.[1] PT may also be used as an adjunctive procedure for incomplete thrombolysis or to treat distal embolic complications following CDT or surgical thrombo/embolectomy.

An endovascular first approach is especially useful in case of severe clinical symptoms, as in these cases time to reperfusion is of paramount importance for limb salvage.

However, well organized thrombi are still problematic for most of the available PT devices, moreover distal microembolization remains a concern when using these instruments. For this reason, devices with additional debries aspiration were developed such us the Rotarex (Straub Medical AG, Wangs, Switzerland), the AngioJet (Boston Scientific, Marlborough, MA, USA) and Penumbra Indigo Mechanical Thrombectomy System (Penumbra, Alameda, CA, USA).[8-10]

Various other devices designed for venous thrombosis were tested for mechanical thrombectomy in ALI, such as Aspirex® (Straub Medical AG, Wangs, Swiss), ThromCat XT® (Spectranetics International, Leusden, Netherlands), the Inari FlowTriever and ClotTriever devices (Inari Medical, Aliso Viejo, CA, USA), but applications in the peripheral arteries are limited.

Rheolytic thrombectomy devices

The AngioJet™ system is a rheolytic pharmaco-mechanical thrombectomy device. It has been approved by the Food and Drug Administration to treat acute thrombosis in venous grafts and native coronary arteries.

To date, the AngioJetTM Ultra device SOLENT platform is approved for the treatment of upper and lower extremity acute peripheral arterial occlusive disease in vessels with a diameter ≥1.5 mm.

The AngioJet system consists in three different units: a disposable catheter, a pump set and a reusable drive unit. The catheter is a sterile, single-use double-lumen over-the-wire channel in which one lumen allows the entry of high-velocity jets of saline and the other one the aspiration of thrombotic debris along with the placement of a 0.014-0.035' guidewire. The high-pressure system is contained within a stainless steel hypotube and receives fluid from the Pump Set at 7000 to 12,000 psi pressure, which is the pressure-limiting cut-off for the The Drive Unit.

Coming out from holes located in the catheter tip section, fluid jets exit at approximately 16,000 cm/sec (maximum instantaneous velocity) while pressure drops near to zero, creating a suction action according to the Bernoulli principle.[11] The high velocity jets are confined within the catheter outflow shaft and specifically designed to avoid any vessel wall injury. Precisely configured ports create a low velocity recirculation pattern around the catheter tip, taking advantage of the Cross Stream® technology. The pressurized saline jets not only generate a localized low-pressure zone resulting in thrombus fragmentation, but also provide the driving force through which particles are removed. Thrombotic debris are aspirated through the catheter and collected in an external non-sterile bag. An electronic air detector, located within the pump unit, inactivates the entire system in case of leakage. The system is designed for isovolumetric functioning: the volume of saline infused is approximately equal to the volume of evacuated material.[12]

An additional feature provided by the AngioJet system is the Ultra Power Pulse which allows pulsed spray delivery of thrombolytic agents (t-PA) or saline locally while aspirating thrombus thus improving basic catheter function and gaining up to 90% success rates.[13] The most used thrombolytic solution for this porpoise is obtained adding 20 mg of alteplase to 50 mL of saline. The power-pulsed spray delivers 0.6 mL of thrombolytic solution with every pulse. It is recommended to leave the solution within the occlusion for at least 20 minutes before completing the treatment.[14]

One of the most frequent Angiojet-related complications consists in red blood cell hemolysis: in fact, the rapid stream of fluid and hydrodynamic forces may cause

cellular damage resulting in hemoglobinemia and hemoglobinuria. Although these complications are frequently clinically non-relevant,[12] Shen *et al.* demonstrated that treatment with Angiojet is an independent risk factors for postoperative acute kidney injury with a 2,82 OR compared with CDT.

According to this evidence, renal protection strategies should be implemented when using the Angiojet. Increased clinician awareness and active vigilance for postprocedural renal failure signs could allow for early recognition and referral to nephrology services in case needed.[15]

Several studies demonstrated the effectiveness of the AngioJet system for the ALI treatment.[10, 12] The AngioJet catheter has been reported to aspirate most of the thrombus in patients presenting with ALI involving native vessels and grafts.[13, 16] A multicenter registry including 99 patients treated with rheolytic thrombectomy reported 70% substantial or complete revascularization (<50% residual defect) and <5% in-hospital and 30-day mortality related to limb ischemia.[12] Furthermore, primary patency rates of 74% and 69% have been reported at 3 months and 1 year respectively.[9]

Kasirajan *et al.* investigated PT outcomes using the Angiojet in acute and subacute limb ischemia and divided technical success into three categories: failure (<50% luminal restoration), partial success (50-95% luminal restoration) and complete success (>95% luminal restoration). In their experience, the authors reported a 61.4% complete success rate.[17]

Byrne *et al.* compared rheolytic thrombectomy with adjunctive CDT (N.=71) to primary CDT (N.=83) in a retrospective single-center analysis and identified Angiojet use as significant predictor of procedural success (P=0.046), as with this approach a 90.1% success rate was obtained in the published series.[18]

In 2015, The PEARL (PEripheral Use of AngioJet Rheolytic Thrombectomy with a variety of catheter Lengths) registry data demonstrated safety and efficacy of rheolytic PT using the AngioJet system for ALI treatment in the "real-world" setting: procedural success was achieved in 235 out of 283 (83%) patients enrolled. The 12-month overall survival and amputation-free survival rates were 91% and 81%.[18-20] Subgroup analysis revealed better outcomes in patients without infrapopliteal arterial occlusion and in those undergoing rheolytic thrombectomy and not needing adjunctive CDT.

However, PEARL registry was intrinsically limited by heterogenous data for the Angiojet + CDT group. Indeed, for these patients, treatment sequence was not considered, and 25% were treated with CDT prior to rheolytic thrombectomy. This methodological issue significantly affects relevance of the study results.

More recently, Muli Jogi *et al.* in a single center review compared the efficacy and safety profile of CDT and PT in the management of acute limb ischemia, demonstrating how PT is associated with higher technical success and significantly shorter length of stay compared to CDT. However, clinical success is similar with a comparable safety profile.[21]

Similarly, Acosta *et al.* demonstrated that both rheolytic thrombectomy and CDT first have high technical success rates and concluded that a PT first appears could represent a reasonable treatment alternative also in Rutherford IIb patients.[14]

In conclusion, Veenstra *et al.* in a systematic review and meta-analysis of endovascular and surgical revascularization techniques for acute limb ischemia confirmed that AngioJet showed more limb salvage at 6 months compared with CDT (OR, 2.21; 95% CI) but also, that there are insufficient data to prefer endovascular rheolytic thrombectomy systems. Further studies are needed to effectively compare this approach with surgical techniques and establish the best clinical guidelines in the management of ALI.[22]

Atherothrombectomy devices

The Rotarex S is a rotational and mechanical thromboatherectomy endovascular device indicated for acute, subacute and chronic arterial occlusion treatment. Its catheter has a single lumen, inside which a steel helix rotates between 40,000 and 60,000 revolutions per minute, with a central lumen for the guidewire, based on Archimedes' endless screw concept allowing for the aspiration and transportation of thrombotic material outside the body. The metallic catheter tip rotates along with the internal screw, and its peculiar chisel-like design plays an active role for thrombus fragmentation and atheromatic plaque removal.

The system includes four different components: an external electronic handle, the proper electric engine, the active intravascular catheter and a collecting bag for aspirated material.

Depending on the anatomical district to be treated three different catheter sizes are available (6 Fr, 8 Fr and 10 Fr).

The Rotarex S catheter is advanced over a dedicated nitinol non-hydrophilic guidewire specifically built for athero-thrombectomy support.

Before starting a mechanical thrombectomy procedure

it is mandatory to administer full heparinization with 100UI/kg and, when technically viable, to maintain activated clotting time above 250 seconds.

Indication for use suggest to employ the largest available catheter fitting in the artery to be treated, ideally reaching a 1:1 ratio. In case of iliac artery thrombosis a 10 Fr catheter is generally preferred, while with infra-inguinal occlusion 8 Fr or 6 Fr catheters could be used.

The Rotarex S system is intended to be used only intraluminally or inside a surgical prosthetic graft, this to minimize the risks for vascular injuries.

The mechanical athero-thrombectomy (MTH) technique requires detection of the occluded segment through diagnostic angiography, lesion crossing, and dedicated guidewire positioning inside the patent distal vessel reconstitution. The Rotarex catheter is therefore advanced either from antegrade or retrograde approach, and activated just before approaching the obstruction.

MTH is hence performed with slow back-and-forth movements aiming to obtain maximum detachment and thrombotic material removal (Figure 1).

As the system is meant to be used with a continuous blood flow through the catheter to avoid rotating head overheating, it is crucial to repeatedly check whether proper aspiration is being provided during athero-thrombectomy maneuvers. This can be easily done pinching the sterile collecting tube and ensuring blood flow.[23]

Freitas *et al.* in 2016 reported their experience treating acute and subacute native arterial occlusions in 525 consecutive patients. In the treated cohort mean lesion length was 159 mm with moderate and severe calcifications in 23.3% of the cases. Technical success rate, defined as the absence of residual stenosis >50% was 97.7%. Device-related embolic events were identified in 11 (2.1%) of the cases, while major amputation was needed only for 6 patients (1.1%).

In this single-center experience rotational athero-thrombectomy was used as a stand-alone therapy in 143 (27.2%) of the cases, while additional arterial angioplasty or stenting were needed in 39.2% and 28.6% procedures. Target lesion revascularization at 12 months was 10.1%.[24]

Aspiration thrombectomy devices

Aspiration thrombectomy represents an alternative for thrombus removal in patients with ALI. It is especially useful in those considered at high risk for bleeding or when thrombolysis is contraindicated (*i.e.* patients with hepatic failure, recent surgery, trauma or neurovascular accident). This option aims to allow for flow restoration in few minutes instead of hours as required by thrombolysis. Moreover, the risk for hemolysis is reported to be negligible compared to rheolytic thrombectomy.

Three different devices taking advantage of this mechanism are available on the market up to now: in two of them, the Aspirex® thrombectomy system (Straub Medical AG, Wangs,Switzerland) and The ThromCat XT® (Spectranetics International, Leusden, the Netherlands) aspiration is

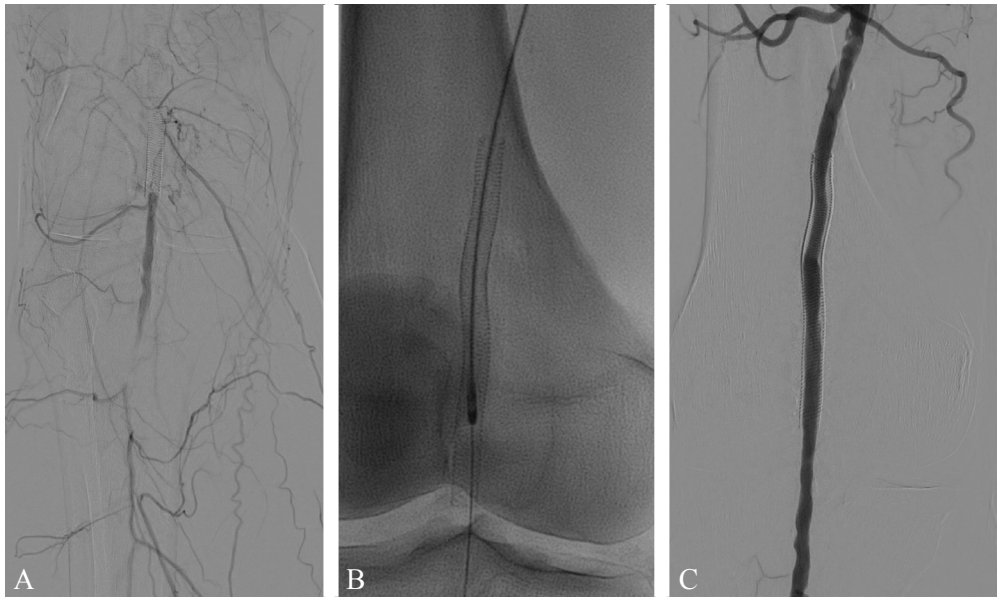

Figure 1.—A) Diagnostic digital substraction angiography performed in a patient with acute popliteal stent occlusion; B) Rotarex 6 Fr intrastent passage; C) final control.

associated with a rotational mechanism; in the other, the Indigo® System (Penumbra, Alameda, CA, USA), aspiration is the only mechanism of action.

The Aspirex is provided with a steel helix rotating inside a single-lumen catheter with a speed of 40,000-60,000 rpm, producing negative pressure at the catheter tip. The thrombus is first aspirated, then fragmented by the spinning helix and transported to a collection bag. Since the spinning helix is located inside the catheter, unintentional contact with the vessel wall is avoided, limiting injury risks. This device encloses therefore three different actions: aspiration, fragmentation and transportation. As this is preferentially utilized in the venous system or in occluded venous grafts, data on the application of this device in ALI patients are quite poor. Teymen *et al.* reported a technical success of 75% and a clinical success of 100% in a cohort of 24 cases.[25] The authors advocated major caution regarding the use of this device in small arteries due to possible complications.

The ThromCat XT® is a rotational thrombectomy catheter primarily developed for coronary interventions. Its flexible and atraumatic tip consists of a stainless-steel helix with a kink-resistant covering. The catheter neck encases the distal end of the helix, avoiding any direct contact with the vessel wall. At the catheter tip, the rotating helix creates a negative pressure by using the principle of Archimedes' screw determining aspiration power. Due to increased flexibility, it is suitable for crossover accesses. Application of the ThromCat XT system is limited to vessels with diameters ranging from 2.5 to 7 mm. Although it received CE mark approval in 2009, data on its efficacy are still limited. The technical success with a restoration of flow is reported in 70% of patients in a single center experience of 10 patients. The preliminary analysis revealed that thrombus age (especially if greater than five days) could be considered a major predictor of failure.[26]

The Indigo/Penumbra system was originally designed for acute ischemic stroke treatment and therefore it provides some unique features as its smooth atraumatic tip combined to noticeable trackability and effective suction pressure. The technology beneath Penumbra/Indigo system[27] became available in 2005 in Europe and the USA, and was then translated into the peripheral artery district for ALI treatment.

Even though ALI and cerebral ischemic events are similar in terms of etiology, several differences ought to be disclosed. In patients with ALI the blood-clot constitution and longevity could be quite tougher and longer. Clot is generally much more organized and adhered to the vessel wall or even to chronic atherosclerotic lesions resulting in a more challenging revascularization procedure. A thrombectomy device providing and intense vacuum force is therefore needed in such settings (Figure 2).

Nowadays, the catheters available sizes range between 3 Fr and 12 Fr. Their design is characterized by a flexible, atraumatic large-bore channel which is delivered to the site of occlusion, and aspiration is directly applied to the lesion itself. An additional option component, the so-called

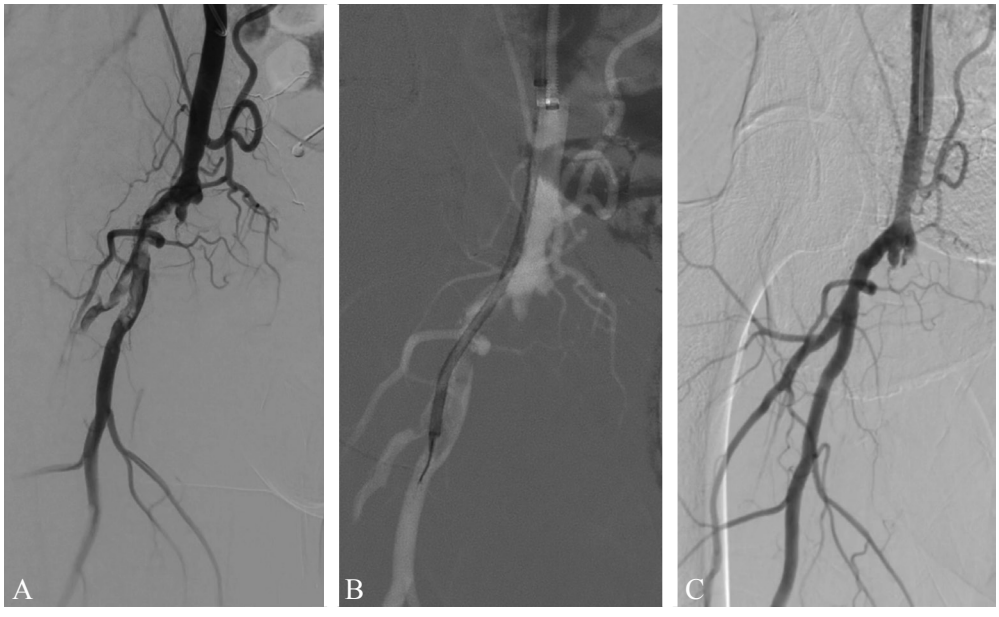

Figure 2.—A) Diagnostic digital substraction angiography performed in patient with chronic femoro-popliteal by pass occlusion treated in urgent setting because of cardioembolic material in the profunda femoris artery; B) Indigo 8 Fr + separator performing thrombus aspiration; C) final control showing complete resolution.

"Separator" allows to apply direct mechanical action to the thrombous, being advanced back and forth, this action facilitates clearing of the clot from the catheter tip. Continuous aspiration is supplied by an external vacuum pump called Pump MAX™ which is capable of delivering and maintaining nearly pure vacuum (29 inHg or 98.2 kPa).

Recently two re-designed catheters (CAT 7fr and CAT 12fr) have been lunched on the market allowing the treatment of large arteries and/or venous thrombosis and pulmonary embolism, with a very contained blood loss.[28] In fact, these novel platforms are provided with a Lightning Intelligent Aspiration system that has dual pressure sensors for real-time blood flow monitoring. The built-in microprocessor features a proprietary thrombus removal algorithm that automatically controls a valve in the tubing to provide continuous or intermittent aspiration. With automatic valve control, Lightning can help the physician focus on optimizing thrombus removal procedures.

The very first data from a multicenter trial regarding thromboaspiration was published by Saxon RR *et al.* in 2018. Seventy-nine patients with ALI were enrolled. Primary technical success was 87.2%, assisted primary technical success was 96.2% with high safety rates (no device related adverse events).[29]

Lopez *et al.* provided data from 43 procedures in which technical success was reached in 52% as main treatment and 50% as adjunctive treatment.[30]

Up to now, the largest study evaluating safety and effectiveness for the Indigo system in the treatment of ALI is represented by INDIAN Trial,[31, 32] a national multicenter registry. In this experience technical success after thromboaspiration alone was reached in 88.7%, while it raised to 95.3% after adjunctive maneuvers when needed. The majority of patients was admitted with an acute occlusion located in the distal vessels (popliteal and below-the-knee arteries). Notably, operators were more prone to use this kind of device for the revascularization of BTK vessels. This trend could be related to the device's trackability and pushability features.

The usefulness of Penumbra/Indigo system has been demonstrated also in the treatment of ALI associated with popliteal artery aneurysms. It was used as a bridge therapy before performing a femoro-popliteal bypass this mitigating ALI complexity and allowing to definitely treat patients in non-urgent setting.[33]

Thromboaspiration has been used for the improvement of tibial and/or below-the ankle vessels occluded by embolic events reduced the rate of early major amputations (5.9%) in a single center experience.[34]

Moreover, challenging cases can occur due to distal embolic complications during other percutaneous procedures as also reported in 2015 by Gandini *et al.* in a case series of three patients who developed a below-the-ankle occlusion during proximal peripheral artery revascularizations.[35]

Conclusions

Recent development of dedicated devices expanded treatment possibilities for patients affected by acute limb ischemia, allowing for effective minimally invasive treatments and overcoming open surgical procedures and intravascular thrombolysis limitations, which represented for years the only viable alternatives for such condition.

Despite the broad spectrum of different available devices could appear as potentially confounding, each device has its own features, indications, weak and strength point.

Ideally the modern endovascular surgeon should master every single tool, tailoring revascularization strategy and timing for the proper patient and arterial segment to be treated, maximizing the benefits coming from technological improvements.

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Conflicts of interest

Gianmarco de Donato, Giacomo Isernia, Gioele Simonte received honoraria for lectures from Penumbra Inc., Gore, Terumo, Endologix, Artivion.

Authors' contributions

Conception and design, critical revision: Giacomo Isernia, Edoardo Pasqui, Gianmarco de Donato, Gianluigi Fino, Massimo Lenti, Gianbattista Parlani, Gioele Simonte; data collection: Giacomo Isernia, Edoardo Pasqui, Gioele Simonte; writing the manuscript: Giacomo Isernia, Edoardo Pasqui, Gianmarco de Donato, Gioele Simonte. All authors read and approved the final version of the manuscript.

History

Manuscript accepted: April 11, 2023. - Manuscript received: April 3, 2023.