

# Percutaneous Mechanical Thromboembolectomy in Acute Lower Limb Ischemia

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## Abstract

**Purpose** To analyze the immediate outcome of percutaneous mechanical thromboembolectomy in acute infrainguinal leg ischemia in a consecutive cohort of patients with acute lower limb ischemia.

**Material and Method** We retrospectively analyzed the data of 156 acute infrainguinal ischemic events in 148 patients. Patients presented with acute limb ischemia Rutherford category I in 68 cases (44%), Rutherford category II A in 64 instances (41%) and Rutherford II B in 24 instances (15%). In 62 cases (39.7%), the occlusion site started below the knee joint level, in 94 (60.3%) cases above. As a basic technique, an intervention was started by manual aspiration but if aspiration failed, an additional device was added. Most frequently, a rotational thrombectomy device (Rotarex, Straub Medical, Wangs, Switzerland) was used. An antegrade access to the femoral artery was the preferred access to the limb (154/156).

**Results** In 145 of 156 incidents, a technical success was achieved (93%). Aspiration was used in 153 cases (98%). Rotational thrombectomy by use of the Rotarex catheter was added in 60 cases (38%). Directional atherectomy was applied in a total of five patients. As main technical complications, a downward embolization occurred ( $n = 11$ ). There were four surgical groin revisions. Five patients died during the early follow-up with four not related to the

intervention. Clinically, 135 patients (86.5%) showed an improvement in their clinical situation.

**Conclusion** Acute lower limb ischemia can be successfully treated by mechanical thromboembolectomy only by combining aspiration embolectomy with rotational thrombectomy in most cases but manual aspiration alone will frequently fail especially above the knee joint level.

**Keywords** Arterial occlusion · Acute ischemia · Mechanical thrombectomy · Aspiration embolectomy · Rotational thrombectomy

## Introduction

Acute leg ischemia due to either emboli or local thrombosis remains a severe clinical problem endangering limb prevention and may also become life-threatening. Starck and Sniderman [1, 2] independently developed aspiration embolectomy as a mechanical thrombectomy approach. Aspiration embolectomy is a reliable low-budget approach especially below the knee joint and in smaller arteries. However, aspiration embolectomy of larger thrombi from larger arteries frequently results in failure or the need for large access diameters to remove thrombus material effectively [1–3].

As an alternative to surgical thrombectomy, local thrombolysis has been introduced decades ago but suffers from several limitations. It has a significant bleeding risk especially in the elderly. In severe ischemia, allotted treatment time is too long to become an alternative to

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surgery and there is a risk of developing compartment syndrome [1–5].

To improve this situation, several mechanical thrombectomy systems have been described with the last 3 decades but only few are still available.

This report describes the outcome of percutaneous mechanical thromboembolism in acute infrainguinal leg ischemia in an unselected consecutive cohort of patients. As a basic concept, a standardized technique of manual aspiration embolism first and if necessary combined with rotational thrombectomy (Rotarex, Straub Medical Inc., Wangs, Switzerland) but—if needed—also different additional tools were used. Thrombolysis was only regarded as a bailout addition.

## Materials and Methods

We retrospectively analyzed 156 treatments for lower limb ischemia by mechanical thrombectomy within a 10-year period from July 1, 2008, till June 30, 2018. Patient triage usually was done in the emergency unit by vascular surgery based on clinical and pulse status and duplex ultrasound. Patients of Rutherford classification III with irreversible ischemia were not included but underwent primary amputation. Patients of Rutherford classification for acute ischemia I to II B [3] and proven infrainguinal level of occlusion were referred to radiology for emergency treatment, which was performed on the same or next day after presentation. A primary angiographic approach was considered to be both diagnostic and therapeutic.

In all cases, an informed consent was obtained despite the emergent request for treatment if possible due to mental status. As this is a retrospective study based on anonymized data, an ethical board review was not required.

Patients with an iatrogenic embolic event such as due to peripheral interventions and patients with thrombectomy during an intervention for chronic peripheral arterial disease were primarily excluded from this analysis.

### Patient Cohort

There were 148 individual patients with 156 ischemic events. Mean age was  $72 \pm 12$  years (median 75 years) ranging from 41 to 96 years. Seven of them suffered from multiple events (two events in 6 and three events in one). Treatment was performed on the left side in 85 cases and on the right side in 71 cases.

Patients with an acute onset of ischemia were included who showed either an embolic occlusion (102 events; 65.4%) or a thrombotic occlusion (35 events). In 19 patients, it was difficult to determine whether the event was clearly embolic or thrombotic; these were classified as

thromboembolic. Thrombotic and thromboembolic events counted for 34.6%.

Patients presented with acute limb ischemia Rutherford category I (viable limb) [3] in 68 cases (44%), Rutherford category II A (partial sensory loss but no muscle paralysis) in 64 instances (41%) and Rutherford II B (muscle paralysis and partial sensory loss present) in 24 instances (15%).

Although all patients experienced an acute onset of limb ischemia, not all patients were admitted early due to delayed presentation or admittance. Within 48 h after clinical onset, 95 patients were treated. In total, 138 were treated within the first week and 151 within the first 2 weeks after onset. Five patients underwent treatment later than 2 weeks after acute onset.

The patients were classified by the location of their occlusion (see Table 1). Sixty-two patients showed an occlusion of the crural arteries and/or the very distal popliteal artery (P3 segment). In 53 patients, the occlusion involved the P2 segment and below, in 29 the superficial femoral artery or P1 segment and below. In 12 cases, an isolated occlusion of the SFA or the P1 segment was present with no distal occlusion. In additional six patients, besides the distal occlusion, also an embolus within the profunda artery was found. So in 62 cases (39.7%), the occlusion site was below the knee joint level; in 94 (60.3%) cases, the occlusion site started at or above this level.

### Methods of Treatment

The approach to thromboembolic events in lower limb arteries included manual aspiration thrombectomy by appropriate end-hole catheters (Bard Medical, Covington GA, USA) from 5 to 8 French as the basic technique. Crural arteries were selectively catheterized by 4 F diagnostic catheters with a soft tip (vertebral configuration, Cordis Europe, Baar, Switzerland). Aspiration was performed by manual aspiration using syringes of 20–50 ml of volume.

Within the same study period, no other approach to infrainguinal ischemia was performed and no parallel cohort of patients with primary or secondary thrombolysis exists in the same institution.

Besides very few exemptions, an intervention was started by aspiration first but if aspiration failed to remove significant amounts of clot even by repeat aspiration runs or increased catheter diameter, an additional device was added. Most frequently, a rotational thrombectomy device (Rotarex 6 or 8 F, Straub Medical, Wangs, Switzerland) was used. In rare instances, other devices such as stents, stent grafts or atherectomy catheters were added (Fig. 1).

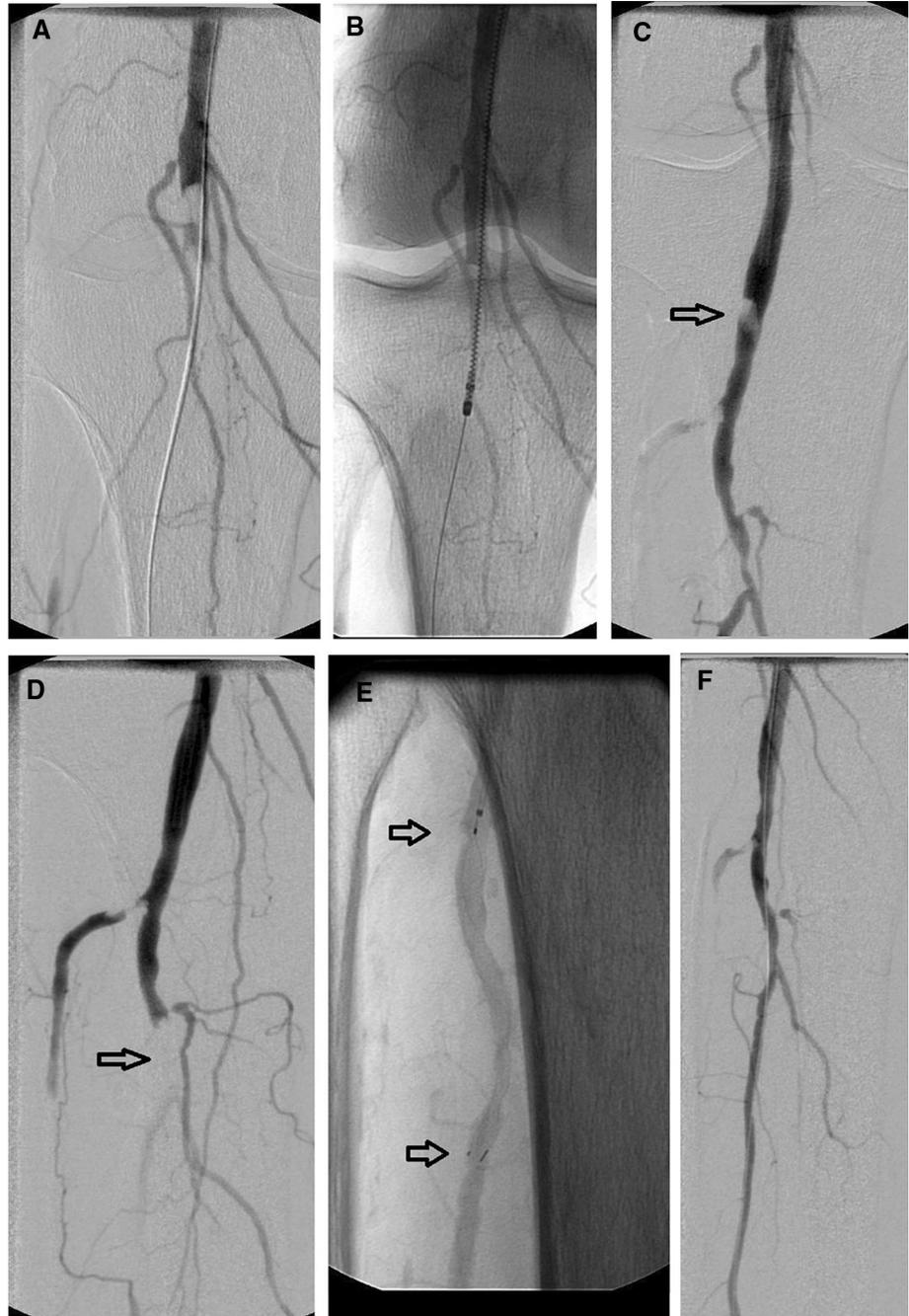
Directional atherectomy (Silver hawk or Turbohawk, Medtronic, EV 3 Inc., Plymouth, USA) was applied in

**Table 1** Thrombus location

Type	Location	N	%
1	Lower limb arteries including the tibiofibular trunk	25	16.0
2	Popliteal artery segment 3 and below	37	23.7
3	Popliteal segment 2 and below	53	34.0
4	Superficial artery or P1 segment and below	29	18.6
5	Isolated occlusions of the SFA and/or P1 segment	12	7.7

**Fig. 1** 77-year-old male patient with acute onset of symptoms and treatment on the same day. Rutherford stage II a.

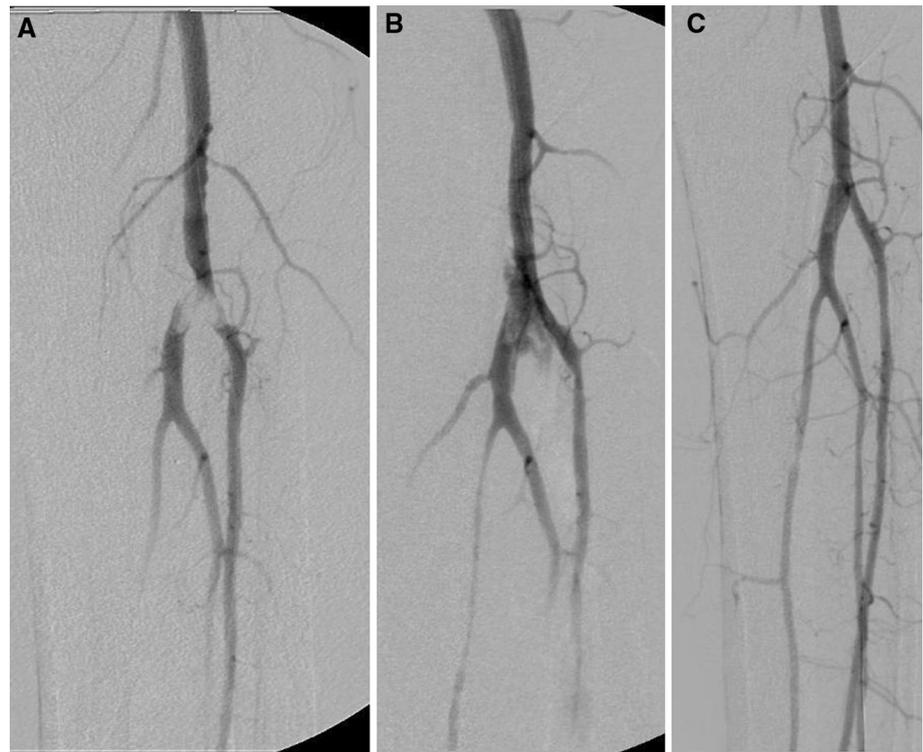
**A** Embolic occlusion of the popliteal artery from the P2 level downwards including the calf arteries. An 0.035 inch guidewire already placed in the fibular artery. **B** After exchange for an 0.018 in guidewire the 6 F rotational thrombectomy catheter is advanced into the distal popliteal artery. **C** After rotational thrombectomy some clot remains in the proximal P3 segment (arrow) that was dilated by plain balloon angioplasty. **D** After PTA, some material dislodged into the tibiofibular trunk (arrow) but was difficult to be aspirated. **E** A stent retriever (arrows) was placed within the embolic occlusion via a microcatheter and released. **F** After removal of the stent retriever, patency to the fibular artery could be restored



localized wall-adherent clot material mainly in small arteries or in curved locations (Fig. 2).

In case of very distal embolization and when 4 F aspiration failed, special devices such as dedicated small-sized

**Fig. 2** 55-year-old male patient with acute onset of calf pain 6 weeks earlier and very short walking distance. Clinical stage Rutherford I. **A** 6-week-old embolus riding on the trifurcation with occlusion of both anterior tibial orifice as the proximal tibioperoneal trunk. Rotational thrombectomy appeared risky due to the curved and small anatomy. **B** The orifice of the anterior tibial artery could be successfully reopened by use of an atherectomy catheter (Silverhawk, Medtronic) but after atherectomy of the tibioperoneal trunk, extravasation is visible. **C** After prolonged balloon angioplasty, the leakage was sealed and patency restored



aspiration catheters (Max 4, Penumbra Inc, Alameda, USA) or retriever systems (Preset, Phenox Inc, Bochum, Germany or Solitaire, EV 3, Plymouth, USA) were also infrequently used (Figs. 1, 3).

An antegrade access to the femoral artery was the preferred access to the limb. Only in two cases, a cross-over approach from right to left femoral artery using a 6 or 7 F cross-over sheath was used. In all other events, an antegrade puncture was performed using a maximum diameter of 6 F sheath in 45 cases, a 7 F sheath in 14 cases and an 8 F sheath in 95 cases.

In all cases, an appropriate closure device (6–7 F Exoseal, Cordis or 6 or 8 F Angioseal, Terumo) was applied. In case of use of the Exoseal device, an additional compression bandage was applied, in case of use of an Angioseal device, no additional bandage was routinely used.

Rotational thrombectomy was performed when aspiration embolectomy was not sufficient to remove enough clot material from the artery despite repeat runs of manual aspiration and eventual upsizing of catheter diameters. 8 F and 6 F rotational catheters were used depending on the size of the underlying vessel. An appropriate 0.018 in guidewire was inserted via a 4–5 F catheter into a distal part of a crural artery. The catheter was advanced over the wire and activated at the level of the proximal thrombus. A couple of back and forth passages was performed until the thrombotic mass was removed or no improvement was achieved despite several passages.

In case of residual prominent thrombus or an underlying severe stenosis, balloon angioplasty (PTA) or stent implantation was added.

Periinterventionally, 5000 IU of intraarterial heparin were added. Post-treatment anticoagulation protocol included i.v. heparinization for at least 72 h while searching for embolic sources and cardiac arrhythmia. In cases with embolism, an oral anticoagulation regimen was started in an overlapping fashion; in patients with thrombotic events, a double-platelet regimen was started for at least 3 months.

#### Definition of Success

A technical success was defined if complete thrombus removal from the main axis and at least one crural artery patent down to the foot arteries or to sufficient preexisting collaterals to the foot arteries was achieved.

Clinical success was defined as the absence of clinical symptoms of acute ischemia with limb salvage at the date of hospital discharge.

#### Data Collection

Retrospectively, the radiological information system (RIS) was searched for cases of mechanical thrombectomy within the period mentioned above. Only patients meeting the inclusion criteria (see above) were selected and further

**Fig. 3** 77-year-old male with acute onset of symptoms on the same day of treatment. Rutherford II a. **A** Angiography proves peripheral embolization into the distal fibular artery (arrow) with variant connection to the plantar artery. No further calf artery present. Aspiration by a 4 F catheter (in place) fails. **B** A 3 F flexible aspiration catheter (Penumbra Inc) in place (arrow) proximal to the embolus was advanced across the embolus and suction applied. **C** After successful aspiration patency was restored



analyzed. All radiological reports, clinical data from the hospital information system (HIS) and all relevant imaging were reevaluated by the use of a standardized questionnaire. Only patients with a complete data set were included in the analysis.

## Results

### Technical Success

In 145 of 156 incidents, a technical success was achieved (93%) with at least one patent crural artery or sufficient collateral flow to the foot arteries.

In 11 incidents (7%), the treatment failed to achieve the definition of technical success. But in four of them, at least partial success was obtained. Failure rate was higher for thrombotic (three cases, 9%) and thromboembolic (two cases; 11%) than for embolic events (6%). With regard to the outflow status, the intervention remained technically insufficient in seven patients with no patent outflow vessel,

in two patients with one outflow vessel and in two patients with two patent outflow vessels but remaining distal arterial occlusion.

Further reasons to fail were early termination of the intervention before a complete technical success was achieved because the patient became hemodynamically instable due to hypotension caused by additional intraarterial application of nitroglycerine ( $n = 3$ ).

### Methods Applied

Aspiration was used in 153 incidents (98%). In the majority of cases (> 70%), larger sizes up to 7 and 8 F were applied (Table 2). Rotational thrombectomy by use of the Rotarex catheter was added in 60 cases (38%). In 25 cases, a 6 F device was applied, and in 35 cases, an 8 F device was applied. Frequency of rotational thrombectomy depended on the type of occlusion (Table 3).

When rotational thrombectomy was applied, failure to achieve a technical success occurred in three cases (3/60, i.e., 5%).

**Table 2** Aspiration catheters used (153/156)

Size (F)	Incidents	%
4 only	3	1.9
6 only	30	19.2
7 only	6	3.8
8 only	39	25.0
Combined up to 8	44	28.2
Combined up to 7	31	20.0
None	3	1.9

**Table 3** Rotational thrombectomy and thrombus location

Type	Total	Rotational ThX added	%
1	25	3	12
2	37	7	19
3	53	24	45
4	29	22	76
5	12	4	33

Directional atherectomy was applied in a total of five patients (3.2%) with occlusion type 3 in 4 patients and type 2 in one patient. Atherectomy only was used in one patient and combined with other methods in four incidents. Technically, all five cases were successful.

In seven cases, a retriever system was used to remove clot material from the distal crural or pedal arteries; in one case, 10 mg rTPA was locally applied to foot arteries.

Additional PTA was performed in 74 patients (47%) either to flatten residual clot to the wall or to treat underlying stenoses. For the same purpose, self-expanding stents ( $n = 17$ ) or stent grafts ( $n = 1$ ) were implanted in 18 patients (11.5%). In all, the intervention was successfully terminated.

In one case, the primary thrombectomy approach was to apply a stent graft on a fresh thrombotic occlusion of the proximal superficial femoral artery but after post-dilatation, thrombus material dislodged proximally into the SFA requiring additional rotational thrombectomy, which was successful.

### Acute Complications

There were a number of acute complications. Most frequently, a downward embolization ( $n = 11$ ) and one upward embolization occurred. Further aspiration was successful to clear this complication in 8 (CIRSE

complication grade 1), but remained unsuccessful in 4 (CIRSE grade 2) [6].

In two incidents, severe arterial spasm of the crural arteries occurred but remained without clinical sequelae (CIRSE grade 1).

Arterial perforation occurred in two cases, one due to rotational thrombectomy and one due to directional atherectomy. Prolonged balloon dilatation was sufficient to seal the vessel in both cases (CIRSE grade 1).

In five cases, the patients suffered from limited severe hypotension caused by additional arterial application of nitroglycerine (0.1–0.2 mg) ( $n = 3$ ) or unknown reason ( $n = 2$ ) that required termination of the procedure in three (CIRSE grade 3). In one patient, the intervention had to be terminated due to severe ischemic pain.

In one patient, the closure system could not be delivered properly leading to development of a severe groin hematoma that required immediate surgical revision. There were three additional hematomas that required surgical revision (CIRSE grade 3) ( $n = 4$ , i.e., 2.6%). In two cases, a larger hematoma was treated conservatively (CIRSE grade 2).

### Clinical Success

Clinically, 135 patients (86.5%) showed a profound improvement of their clinical situation with the absence of clinical signs of acute ischemia. Partial minor amputation (toe, foot) was performed in four cases following thrombectomy but with no further signs of acute ischemia.

In 21 patients, the clinical results remained insufficient (13.5%). Early reocclusion despite primary technical success occurred in four cases (2.7%). Surgical bypass was performed in three patients but failed early in one. Surgical thrombectomy was further applied in two patients. Five patients underwent amputation of the ipsilateral thigh. Five patients underwent conservative treatment.

Three patients developed lower leg compartment syndrome despite successful thrombectomy (1.9%) requiring surgical intervention.

### Mortality

Five patients (3.2%) died within the early phase < 30 days post-intervention. Two patients died suddenly for unknown reasons, no autopsy was performed. Two patients died from their underlying disease (bronchial and breast carcinoma) and one patient died from septic complications of a gangrenous limb after failed recanalization.

## Follow-Up Events

Most of the patients were dismissed from hospital without clinical signs of acute ischemia (see above). Three patients were handicapped by the sequelae of a synchronous stroke.

In the follow-up period, seven patients experienced a recurrent embolization to the lower limbs. Five patients experienced a stroke (at 6 weeks, 3, 6, 11 and 36 months), and in two patients, it was fatal. One patient experienced a fatal mesenteric infarction 24 months after peripheral embolectomy. One patient died from pneumonia 7 months and one patient from cardiac insufficiency 4 months later.

One patient became symptomatic from an ipsilateral popliteal arterial stenosis within 12 months after thrombectomy that was treated percutaneously.

## Discussion

Acute lower leg ischemia is a relatively frequent problem in current practice and may be either caused by embolic events preferentially from the heart, local thrombosis on the bottom of severe atherosclerosis or paraneoplastic in patients with advanced tumors.

There are significant morbidity and mortality with acute lower limb ischemia. In 1987, Dregelid et al. [4] analyzed 202 patients with acute leg ischemia and surgical embolectomy. They found a 30-day mortality of 26% and an amputation rate of 18.5%.

Thrombolysis has been tested to treat acute limb ischemia [5, 7, 8] and may have a role in Rutherford 1 cases. But in patients with threatened limbs, time to reestablish perfusion usually is regarded as too long for these cases [5]. Furthermore, development of compartment syndrome in up to 10% was reported with thrombolysis in acute limb ischemia [7].

Kashiap et al. [8] reported on 129 limbs treated with thrombolysis and partly additional pharmacomechanical means such as hydrodynamic thrombectomy (Angiojet, BSIC, Boston, USA) and spray lysis. Early amputation rate was 15%. Compartment syndrome was seen in 4%, and local hematoma (11%) and bleeding requiring transfusion (8%) were reported.

Starck and Sniderman independently developed aspiration embolectomy [1, 2], which quickly got acceptance as a rapid low-budget method offering quick recanalization especially for below-the-knee arteries. New atraumatic and flexible aspiration catheters as derivatives from stroke approach are now available that allow thrombosuction even from very small pedal arteries.

Surprisingly, there have not been too many publications about aspiration embolectomy over the years. Despite that, in many interventional institutions, thrombosuction

represents the working horse for managing acute limb ischemia. Nevertheless, still major problems remain unsolved. Suction will fail in large arteries, and also complete removal of wall-adherent material may remain incomplete with manual aspiration alone. Starck et al. [9] therefore developed additional tools to face these problems such as rotational nitinol baskets. In 1992, Wagner and Starck [9] published their results of this approach in 102 cases. They achieved a technical success in 93% with an additional use of rotational devices in 12%. This system, however, is no longer available.

Success of thrombosuction depends on the relation of diameter of the catheter used and the diameter of the artery treated. This is illustrated by the findings, that below the knee joint level, rotational thrombectomy was utilized in a maximum of 20%, but above the knee joint it was used in more than the half of cases up to 75% in emboli/thrombi starting at the SFA or P1 level.

The Rotarex rotational catheter has been introduced to interventional radiology around 18 years ago. There are several publications of its usefulness and efficacy [10, 11]; however, it did not experience widespread use until cost-effective reimbursement was introduced at least in Germany representing the largest market for IR products in Europe. Recently, Heller et al. [12] reported on their results with the Rotarex device in acute limb ischemia in 147 patients. They used the Rotarex device as a primary tool in 120 cases and as a bailout tool in 27. They reported on a technical success with Rotarex alone combined with aspiration in 68.7% but with additional thrombolysis in 90.5%. They experienced a rate of compartment syndrome of 4% and access site hematoma of 4%.

One of the potential drawbacks of aspiration embolectomy and large rotational catheters is its frequent need for large access sheaths. Although in the majority of patients, larger access diameters were applied, and the rate of access bleeding and pseudoaneurysm formation remained low in this cohort, in which closure devices were used systematically.

The limitation of this study is its retrospective nature. Nevertheless, the data describe a nonselected cohort of patients with acute infrainguinal leg ischemia that usually presents in emergency rooms. It does not focus on the use of a particular instrument in selected patients but illustrates a more or less standardized approach that consists of large access, antegrade puncture, aspiration first and rotational thrombectomy second.

Kwok et al. [13] compared thrombolysis with primary aspiration embolectomy and found a primary technical success rate of roughly 50% in their cohort of patients treated by primary aspiration embolectomy. This is quite consistent with our findings that in a nonselected setting of patients with acute leg ischemia, it can be expected that

more than half of the patients will show thrombosis exceeding above the knee joint level, where aspiration alone will have limited success.

For these patients, additional instruments will be needed to achieve a successful result. Although stents have been proven as an excellent tool to locally fix also fresh thrombus to the vascular wall [14], this is not a preferred option in the popliteal artery but should be limited to the superficial femoral artery alone.

Rotational thrombectomy using the Rotarex device has been proven as a reliable, safe and effective tool to remove clot from the SFA and the popliteal segments. Complications and device failure occurred infrequently. In particular, arterial perforation, which was more frequently with up to 10% described in early papers on the Rotarex device [10], has become rare.

Rotational thrombectomy, however, is no option in very distal crural arteries. The development of very flexible and atraumatic aspiration catheters certainly offer more options but stent retrievers—originally developed for stroke treatment—may be applicable in selected situations.

In conclusion, mechanical thrombectomy without thrombolysis combining thrombosuction and rotational thrombectomy—if needed—appears to be a technically successful approach in patients with infrainguinal acute leg ischemia and helps to overcome usual shortcomings of manual aspiration alone.

#### Compliance with Ethical Standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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