When Is Open Surgery Required To Treat ALI
When Is Mechanical Thrombectomy And Thrombo-Aspiration The Best Treatment:
When Should Lytics Be Used
Based On A Systematic Review And Meta-Analysis

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Disclosures

Y. Gouëffic reports:

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In France, 76.7% of Acute Limb Ischemia were Treated with an Open Approach

Table 1. **Demographic characteristics and medical history of French patients referred with acute limb ischaemia in 2015-2020 at the index hospital stay, and index hospital stay characteristics by approach**

Characteristics	All patients (n = 51 390)	Surgical approach (n = 39 411)	Endovascular approach (n = 11 979)	p value

The surgery group had a higher risk of death (hazard ratio [HR] 1.17, 95% CI 1.12 - 1.21), a higher risk of major amputation (sub-distribution HR 1.20, 95% CI 1.10 -1.30) than the endovascular group

Espitia, Eur J Vasc Endovasc Surg, 2024

Cochrane Library
Cochrane Database of Systematic Reviews

Surgery versus thrombolysis for initial management of acute limb ischaemia (Review)

Major amputations rate at 30 days	
- Open surgery:	6.9%
- CDT:	6.8%

Mortality rate at 30 days	
- Open surgery:	8.2%
- CDT:	5%

Darwood R, Cochrane, 2018

Mechanical Thrombectomy and Thrombus Aspiration

Recommendation 33

For patients with acute limb ischaemia, aspiration and mechanical thrombectomy should be considered.

Class	Level	References
IIa	C	Kwok *et al.* (2018),[141] Zehnder *et al.* (2000),[147] Byrne *et al.* (2014),[148] Kronlage *et al.* (2017)[152]

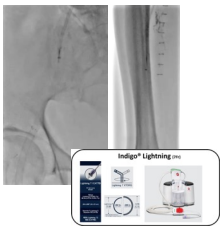
Table 3. **Clinical categories of acute limb ischaemia according to Rutherford[1]**

Grade	Category	Sensory loss	Motor deficit	Prognosis	Doppler signals: Arterial	Doppler signals: Venous
I	Viable	None	None	No immediate threat	Audible	Audible
IIA	Marginally threatened	None or minimal (toes)	None	Salvageable if promptly treated	Inaudible*	Audible
IIB	Immediately threatened	More than toes	Mild/moderate	Salvageable if promptly revascularized	Inaudible	Audible
III	Irreversible	Profound, anaesthetic	Profound, paralysis (rigor*)	Major tissue loss amputation. Permanent nerve damage inevitable	Inaudible	Inaudible

This is an identical replica of the table in the 1997 publication by Rutherford *et al.*, * with the exception of the asterisks (*).
† In the original 1997 classification it was stated that arterial Doppler signals are never present in Stage IIA, and that rigor (mortis) is always present in Stage III. However, it is the opinion of the Writing Committee that exceptions to these rules do exist, and a slight modification of the Rutherford classification from 1997 may be appropriate in the future.

Björck, Eur J Vasc Endovasc Surg, 2021

Thrombo-spiration



Mechanical Thrombectomy

To date, no meta-analysis has assessed these techniques.
The aim of this study is to assess the efficacy and safety of these techniques for ALI.

Meta-Analysis Methodology

in accordance with the PRISMA

Eligible criteria: RCT, cohort studies and case series (prospective and retrospective) that evaluated the safety and efficiency of thrombo-aspiration or mechanical thrombectomy for ALI

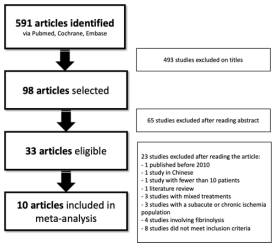
Exclusion criteria: <10 patients, editorials, literature reviews, animal studies, studies involving CDT, ultrasound-accelerated fibrinolysis, Angiojet® combined with fibrinolytics, studies combining several thrombo-aspiration or mechanical thrombectomy devices without the possibility of individualizing effect of either device, type B dissection or popliteal aneurysms or those including patients with subacute or chronic ischemia.

Search from 2010 to 2023 (PubMed/Medline and Cochrane Central)

Primary outcomes: Perioperative major amputation rate

10 Included Articles

Published between 2015 to 2022



10 articles

-No RCT - 8 retrospective - 2 prospective

-5 studies focused on the mechanical thrombectomy with Rotarex® system

-5 studies focused on thrombo-aspiration (3 with Penumbra® and 2 with other devices)

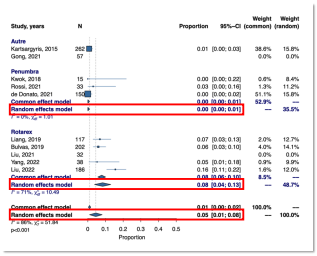
1083 included patients

Patients Demographic and Lesions Data

PARAMETERS	
MEAN AGE (Y)	69.54
MEN (%)	65.40
DIABETES (%)	30.40
KIDNEY FAILURE (DFG < 60)(%)	17.88
HYPERCHOLESTEROLEMIA (%)	61.17
SMOKER (%)	35.83
RUTHERFORD I (%)	26.50
RUTHERFORD IIA (%)	31.44
RUTHERFORD IIB (%)	41.78
RUTHERFORD III (%)	2.60

CAUSES AND LOCATIONS	
EMBOLIC	35.50
THROMBOTIC	71.37
POPLITEAL ANEURYSM	0.50
DISSECTION OR TRAUMATIC	0.00
AORTO-ILIAQUE	30.50
FEMORAL	55.00
POPLITE	46.67
BELLOW THE KNEE	19.50

Major Amputations Rate @ 30 Days: 5% [95% CI: 0.01 – 0.08]



According to the type of device

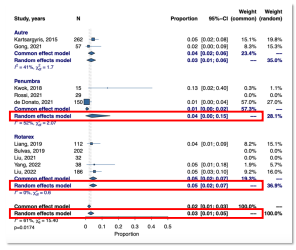
- Penumbra: **0** [95% CI: 0.00 – 0.01]
- Rotarex: **0.08** [95% CI: 0.04 – 0.13]

According to the ALI severity

>10% Rutherford I: **0.04** [95% CI: 0.00 - 0.10]

<10% Rutherford I: **0.06** [95% CI: 0.04 - 0.09]

Mortality Rate @ 30 Days: 3% [95% CI: 0.01 – 0.05]



According to the device

- Penumbra®: **0.04** [95% CI: 0.00 – 0.15]
- Rotarex®: **0.05** [95% CI: 0.02 – 0.07]

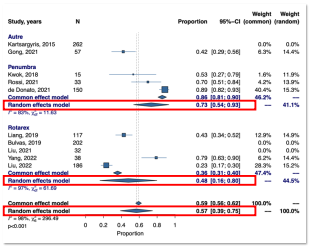
According to the ALI severity

>10% Rutherford I: **0.04** [95% CI: 0.01 - 0.07]

<10% Rutherford I: **0.03** [95% CI: 0.01 - 0.05]

Technical Success: 57% [95% CI: 0.39 – 0.75]

Near complete or complete revascularisation of the occluded artery).



According to the device

- Penumbra®: **0.73** [95% CI: 0.54 – 0.93]
- Rotarex®: **0.48** [95% CI: 0.16 – 0.80]

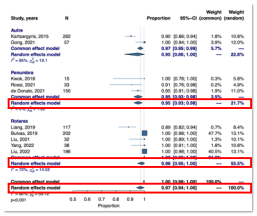
According to the ALI severity

>10% Rutherford I: **0.59** [95% CI: 0.30 - 0.88]

<10% Rutherford I: **0.54** [95% CI: 0.31 - 0.78]

Assisted Technical Success: 97% [95% CI: 0.94 – 1]

Technical success with additional endovascular interventions



According to the device

- Penumbra®: **0.95** [95% CI: 0.93 – 0.98]
- Rotarex®: **0.98** [95% CI: 0.95 – 0.1]

According to the ALI severity

>10% Rutherford I: **0.96** [95% CI: 0.91 - 1]
<10% Rutherford I: **0.98** [95% CI: 0.95 - 1]

Combined CDT was used in 33% of cases, and angioplasty in 45%. A stent was implanted in 32% of cases

Take Home Message

- Our meta-analysis reports a slightly lower rate of major amputations at 30 days of 5% compared to 6.9% and 6.8% in the surgery and CDT groups of the Cochrane review

- Our meta-analysis reports a lower rate of mortality rate at 30 days of 3% compared to 8.2% and 5% in the surgery and CDT groups of the Cochrane review.

These results seem to confirm that mechanical thrombectomy and thrombo-aspiration are less morbid than open surgery and CDT, with better technical success.

- Peroperative major amputation rates appears to favor the Penumbra® device **BUT**, Penumbra® device is used in less severe patients. Indeed, in the Penumbra® studies, the rate of Rutherford I patients varies from 16 to 33%, compared with 0 to 15% in the Rotarex®

Darwood R, Cochrane Database Syst Rev., 2018

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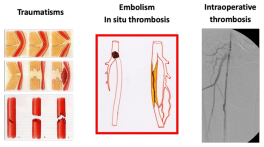
Acute Limb Ischemia (ALI) is a medical emergency (<14 days)



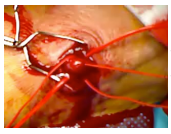
...and it is important that the diagnosis is confirmed promptly, and proper treatment is started in order to prevent limb loss and other severe complications

Revascularization options

-Open surgery
(Fogarty thrombectomy, bypass)

-Catheter direct thrombolysis

-Endovascular thrombectomy
(aspiration or mechanical)



Fogarty thrombectomy

The strategy employed will depend on a number of factors, including the expertise and facilities of the treating team, and patient factors such as the duration and severity of ALI, the location and cause of the occlusion, comorbidities, and therapy related risks.

Björck, Eur J Vasc Endovasc Surg, 2021