Aspiration thrombectomy for acute limb ischemia. Is the era of Fogarty balloon over?

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Disclosure

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I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [x] I do not have any potential conflict of interest
Surgical arterial thromboembolectomy with Fogarty balloon catheter is an efficient treatment for acute arterial emboli of lower limbs when a single large vessel is involved.

In clinical practice, there is still a discrepancy between the immediate technical success of arterial TE that often seems adequate, and the early clinical outcome that still remains unsatisfactory in many cases:

- incomplete restoration of flow BTK arteries (36% to 82% of patients)
- distal embolization
- presence of underlying steno-occlusive lesions,
- vessel injuries secondary to balloon catheter passage may limit the clinical success rate

The results available document a persistently high medical need for patients presenting with ALLI:

- 30-day amputation rate of 5% to 12%
- mortality risk of 10% to 38%
- combined incidence of amputation and death of 25% to 37.5% at 6-month FU
The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia

Gianmarco de Donato, MD, Francesco Setacci, MD, Pasqualino Sirignano, MD, Giuseppe Galzerano, MD, Rosaria Massaroni, MD, and Carlo Setacci, MD, Siena, Italy

Objective: Surgical arterial thromboembolectomy (TE) is an efficient treatment for acute arterial thromboemboli of lower limbs, especially if a single large artery is involved. Unfortunately, residual thrombus, propagation of thrombi, chronic atherosclerotic disease, and vessel injuries secondary to balloons catheter passage may limit the clinical success rate. Intraoperative angiography can identify any arterial imperfection after TE, which may be corrected simultaneously by endovascular techniques (so-called “hybrid procedures,” HP). The aim of this study is to compare outcomes of surgical TE vs HP in patients with acute lower limb ischemia (ALLI).

Methods: From 2006 to 2012, 122 patients with ALLI were admitted to our department. Patients received urgent surgical treatment using only a Fogarty balloon catheter (TE group = 112) or in conjunction with endovascular completion (HP group = 210). In-hospital complications, 30-day mortality, primary and secondary patency, reintervention rate, limb salvage, and overall survival rates were calculated using the Kaplan-Meier method and compared by log-rank test.

Results: IHPs (n = 210) following surgical TE consisted of angioplasty (PTA) ± stenting in 90 cases, catheter-directed intra-arterial thrombolysis + PTA ± stenting in 24, thrombus fragmentation and aspiration by large guiding catheter + PTA ± stenting in 67, vacuum-based accelerated thromboaspiration by mechanical devices in 9, and primary covered stenting in 12. Estimated primary patency was 90.4% vs 70.4% at 2-year and 87.1% vs 66.3% at 5-year follow-up, respectively, for HP and TE patients (hazard ratio, 3.1; 95% confidence interval, 1.78-5.41; P < .01). A hazard ratio of 2.1 for limb salvage was noted for the HP group (95% confidence interval, 1.01-4.34; P = .03). Estimated freedom from reintervention at 1 year was 94.4% for HP vs 82.1% for TE patients, and 89% vs 73.7% at 5 years, respectively (P = .04).

Conclusions: HPs for ALLI may represent the tools that, when applied to specific clinical scenarios, hold the potential to reduce the morbidity previously associated with acute arterial occlusion. (J Vasc Surg 2014;59:729-36.)
Male, 77 yo
AF in therapy
PAOD – Rutherford 5
Nov 2019: left ATK fem-pop bypass (PTFE 7 mm)

17.01.2020: Cold and pale left lower limb with pain (since the last 3 days)

DUS: bypass occlusion, patency of the popliteal and the peroneal artery
Feb 2017 DUS:
SFA occlusion from the origin to the Hunter canal
out-flow: 3 vessels
no autologous saphenous vein

24.03.2017: PTA with distal embolization

Male, 70 yo
- Active smoker
- Hypertension
- 2000: bilateral SFA stenting
- 2014: right hip replacement
- 2016: left CEA
- 2017: right lower limb claudication <50 m (Ruth I, cat 3)
CASE 3
ACUTE LEFT POPLITEAL ARTERY OCCLUSION FOLLOWING ILIAC REVASCULARIZATION

Left popliteal artery obstruction
CASE 1

Male, 77 yo
AF in therapy
PAOD – Rutherford 5
Nov 2019: left ATK fem-pop bypass (PTFE 7 mm)
one run-off vessel: peroneal artery

17.01.2020: Cold and pale left lower limb with pain
(since the last 3 days)

DUS: bypass occlusion, patency of the popliteal and the peroneal artery

17.01.2020: embolectomy with Fogarty balloon

18.01.2020: bypass and popliteal patency;
5 cm obstruction of the peroneal artery
LEFT ANTEGRADE FEMORAL ACCESS:
- CAT 6 Indigo® System Penumbra InDIGO
- SEP 6 Separator Penumbra Inc.
CASE 2

Male, 70 yo

- Active smoker
- Hypertension
- 2000: bilateral SFA stenting
- 2014: right hip replacement
- 2016: left CEA
- 2017: right lower limb claudication <50 m (Ruth I, cat 3)

February 2017 DUS:
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ACUTE LEFT POPLITEAL ARTERY OCCLUSION FOLLOWING ILIAC REVASCULARIZATION

CASE 3
LEFT ANTEGRADE FEMORAL ACCESS:

- CAT 8 Indigo® System Penumbra Inc.
- SEP 8 Separator Penumbra Inc.
RIGHT ANTEGRADE FEMORAL ACCESS:

- CAT 3 Indigo® System
  Penumbra Inc.

DORSALIS PEDIS ARTERY EMBOLIZATION DURING SFA PTA
The Indian registry
(The Indigo system in acute lower limb malperfusion)

To evaluate, in a controlled setting, the early safety and effectiveness of the Penumbra/Indigo aspiration thrombectomy Systems in patients with acute limb ischemia

ClinicalTrials.gov Identifier: NCT03386370
PI: prof GM de Donato, prof C. Setacci

- Prospective
- Multicenter (Italy)
- 150 patients
The Indian registry
(The Indigo system in acute lower limb malperfusion)

**Indications:**
- Any acute lower limb ischemia
  - embolism
  - thrombosis
  - graft or endograft thrombosis
  - distal emboli secondary to preceding intervention
  - incomplete reperfusion after Fogarty or lysis

**Exclusion:**
- ALI longer 14 days
- ALI Rutherford class III

Vessel patency, evaluated by TIMI score

Any further treatment of the target vessel/s after thrombus removal is according the physician’s discretion

- 28 centers (VS, IR, IC)
- 18 centers active
- 256 pts. enrolled
Secondary Endpoints

- **Safety rate at discharge**, defined as absence of any serious adverse events (SAE). A SAE is defined as any clinical event that is fatal, life-threatening, or judged to be severe by the investigator; resulted in persistent or significant disability.

- **Primary patency at 1 month**. Primary patency is defined as a target lesion without a hemodynamically significant stenosis/reocclusion on duplex ultrasound (>50%).

- **Limb salvage at 1 month**. Any amputation above the ankle is considered as major and impacts negatively the limb salvage rate.

- **Clinical success at follow-up** is defined as an improvement of Rutherford classification at 1-month follow-up of one class or more as compared to the pre-procedure Rutherford classification, without amputation and without target limb reintervention (TLR).

The Indian registry (The Indigo system in acute lower limb malperfusion)
PRELIMINARY RESULTS ON THE FIRST 150 PATIENTS

LESION SITE

AORTO-ILIAC DISTRICT: 12% (18)

POPL. A. + BTK: 39.4% (59)

BTA: 1.3% (2)

SFA: 18% (27)

SFA + POPL. A. + BTK: 29.3% (44)
PRELIMINARY RESULTS ON THE FIRST 150 PATIENTS

ETIOLOGY

THROMBOSIS 43%
UNKNOWN 40%
EMBOLIC 17%
AF 41%
NO AF 59%
PRELIMINARY RESULTS ON THE FIRST 150 PATIENTS

- **Pre-intervention (PRE-INTERVENTO):**
  - TIMI 0: 79%
  - TIMI 1: 15%
  - TIMI 2: 4.50%
  - TIMI 3: 1.50%

- **Post-Indigo (POST-INDIGO):**
  - TIMI 0: 95.4%
  - TIMI 1: 89.6%
  - TIMI 2: 5.90%
  - TIMI 3: 34.60%

- **Post-procedure adiuvanti (POST-PROCEDURE ADIUVANTI):**
  - TIMI 0: 74.20%
  - TIMI 1: 21.20%
  - TIMI 2: 3.80%
  - TIMI 3: 0.80%
### PRELIMINARY RESULTS ON THE FIRST 150 PATIENTS

#### GROUP ANALYSIS

<table>
<thead>
<tr>
<th>Classification Groups</th>
<th>TIMI 2/3 after Indigo procedure</th>
<th>TIMI 2/3 after all interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native Arteries</td>
<td>89/102 (87.3%)</td>
<td>95/102 (93.1%)</td>
</tr>
<tr>
<td>Post Endovascular Procedures</td>
<td>22/26 (84.6%)</td>
<td>26/26 (100%)</td>
</tr>
<tr>
<td>Post By-Pass</td>
<td>12/12 (100%)</td>
<td>12/12 (100%)</td>
</tr>
<tr>
<td>Post By-Pass and Fogarty Embolectomy</td>
<td>4/4 (100%)</td>
<td>4/4 (100%)</td>
</tr>
<tr>
<td>Post Fogarty Embolectomy</td>
<td>6/6 (100%)</td>
<td>6/6 (100%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>133/150 (88.7%)</td>
<td>143/150 (95.3%)</td>
</tr>
</tbody>
</table>
PRELIMINARY RESULTS ON THE FIRST 150 PATIENTS

ASPIRATION PROCEDURE DETAILS

- Blood loss: 240 ml (range 20-600)
- Mean procedure time: 86 min
- Mean fluoroscopy time: 24.4 min
- Medium contrast: 107.5 ml
- No vessel injuries or clinically significant distal embolization attributable to the Indigo procedures
- No patients required surgical revascularization
PRELIMINARY RESULTS ON THE FIRST 150 PATIENTS

1 month follow up

<table>
<thead>
<tr>
<th>ADVERSE EVENT</th>
<th>9 (6.6%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEATH</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td>AMPUTATION</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>ARI</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>RE-INTERVENTION</td>
<td>5 (3.7%)</td>
</tr>
<tr>
<td>SERIOUS ADVERSE EVENT</td>
<td>3 (2.4%)</td>
</tr>
<tr>
<td>ADVERSE DEVICE EFFECT</td>
<td>0</td>
</tr>
<tr>
<td>SERIOUS ADVERSE DEVICE EFFECT</td>
<td>0</td>
</tr>
</tbody>
</table>

- 3 THROMBOLYSIS,
- 1 RELINING WITH STENTGRAFT
- 1 RE-DO WITH INDIGO
Clinical results of TE with Fogarty balloon are still limited by arterial imperfection frequently detected at angio post-procedure.

TE amputation rate, mortality rate and combined amputation/mortality rate are still high.

Aspiration thrombectomy with Penumbra Indigo System is a safe and effective alternative option to TE not only in native arteries (small and large vessels), but also in the treatment of distal embolization during endovascular procedure.

In our registry of 150 patients, the amputation rate was <1% and serious adverse events <3%, with no adverse events related to the device.
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