Acute lower limb malperfusion treated by endovascular thrombectomy: the INDIAN Registry

Gianmarco de Donato, MD, PhD
Associate Professor Vascular Surgery
University of Siena - Italy
Disclosure

Speaker name:

...Gianmarco de Donato........................................

I have the following potential conflicts of interest to report:

☑  Consulting: Endologix, Penumbra, Gore
☐  Employment in industry
☐  Stockholder of a healthcare company
☐  Owner of a healthcare company
☐  Other(s)

☐  I do not have any potential conflict of interest
Thrombo-embolectomy by Fogarty balloon catheter is an efficient treatment for acute arterial ischemia of lower limb, especially when ischemia occurs in healthy artery.
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

(J Vasc Surg 2014;59:729-36.)

From Fogarty to hybrid treatment

Fogarty group vs. Hybrid group (Fogarty + endo)
From Fogarty to hybrid treatment

2 Steps

1. FOGARTY

2. ENDO

PTA ± Stenting

Covered stenting

thrombus fragmentation and aspiration by large guiding-catheter

Fibrinolysis through multiple side hole infusion catheter
The ideal thrombectomy catheter

- Safe
- Effective
- Atraumatic profile
- Simple setting
- Flexible
- No risk on hemorrhage
- No risk of hemolysis (hydrodynamic forces)

Syringe-based thrombosuction
From Fogarty to total endovascular solution – The aspiration thrombectomy system

Background from cerebral stroke
Penumbra system has began the market leader in stroke

- dedicated design for intracranial navigation
- atraumatic tip
- trackability
- aspiration power
The Indigo catheters from Penumbra:
- dedicated, last generation system
- designed specifically to address the limitations of conventional technology:
  - trackability,
  - risk of vessel injury,
  - incomplete revascularization
INDIGO CAT8 XTORQ with SEP
Indigo System

Simple and Effective

• Pure continuous vacuum
• Single operator design
• No warm up or time limit
• Hands free aspiration
• Simple setup


b. Data on file at Penumbra, Inc. based on testing with CAT5.

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Indigo – Siena experience

**Acute ischemia**

Level of application:
- Aorto-iliac occlusion
- **post-EVAR iliac limb occlusion**
- in-stent SFA thrombosis
- cardiac embolization in diseased SFA
- popliteal & BTK acute on-plaque occlusion
- Below the ankle (BTA) vessels
5 year after EVAR
Acute ischemia

Mechanical thrombectomy by Indigo within 24 hours from symptoms onset

Post-EVAR limb occlusion
Post-EVAR limb occlusion
Post-EVAR limb occlusion
Indigo – Siena experience

Acute on chronic ischemia

Level of application:
- iliac occlusion
- post-EVAR iliac limb occlusion
- in-stent SFA thrombosis
- cardiac embolization in diseased SFA
- femoro-popliteal bypass graft (PTFE)
- popliteal & BTK acute on-chronic occlusion
- Below the ankle (BTA) vessels
Pooleiteal embolism

P1-P2 embolism

INDIGO SYSTEM:
CAT 8 XTORQ + SEP 8

Final result
ALI at 4 am, Jan 1\textsuperscript{st} 2019

Procedural time 15 min, fluoroscopy 6’30”
Indigo – Siena experience

Acute on chronic ischemia

Level of application:
- iliac occlusion
- post-EVAR iliac limb occlusion
- in-stent SFA thrombosis
- cardiac embolization in diseased SFA
- popliteal & BTK acute on-plaque occlusion
- Below the ankle (BTA) vessels
Blue toe syndrome in patient with popliteal aneurysm
Blue toe syndrome in patient with popliteal aneurysm

CAT 3 over a 0.014” gw

Plantar loop by Indigo CAT 3
Mechanical thrombectomy aspiration of distal emboli
Indigo & Blue toe syndrome

a) Clinical presentation of acute forefoot occlusion (good pulsation of anterior and posterior tibial artery at the ankle)
b) Angiography shows acute below-the-ankle (BTA) vessel occlusion
c) Indigo CAT 3 advancing through the BTA vessels with the plantar loop technique
d) Macroscopic aspect of thrombi aspirated
e) Angiography after Indigo tromboaspiration revealing nice patency of plantar arch
f) Clinical appearance on day 1 post-op
To evaluate, in a controlled setting, the early safety and effectiveness of the Penumbra/Indigo aspiration thrombectomy Systems in patients with acute limb ischemia.

- Prospective
- Multicenter (Italy)
- 150 patients
- Estimated primary completion date: March 2019

ClinicalTrials.gov Identifier: NCT03386370
The Indian registry
(The Indigo system in acute lower limb malperfusion)

Protocol presentation: 25 September 2017

**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
The Indian registry
(The Indigo system in acute lower limb malperfusion)

Preliminary data

• 28 centers (VS, IR, IC)
• 18 centers active
• 256 pts enrolled
### Preliminary data

150 patients

#### Arterial Occlusion Localization

<table>
<thead>
<tr>
<th>Location</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aorta</td>
<td>8</td>
<td>4.1%</td>
</tr>
<tr>
<td>Common Iliac</td>
<td>18</td>
<td>9.3%</td>
</tr>
<tr>
<td>External Iliac</td>
<td>9</td>
<td>4.7%</td>
</tr>
<tr>
<td>Common Femoral</td>
<td>17</td>
<td>8.8%</td>
</tr>
<tr>
<td>Profunda</td>
<td>4</td>
<td>2.1%</td>
</tr>
<tr>
<td>Superficial Femoral</td>
<td>73</td>
<td>37.8%</td>
</tr>
<tr>
<td>Popliteal</td>
<td>111</td>
<td>57.5%</td>
</tr>
<tr>
<td>Below the Knee</td>
<td>72</td>
<td>37.3%</td>
</tr>
<tr>
<td>Below the Ankle</td>
<td>5</td>
<td>2.6%</td>
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</tbody>
</table>
In case of chronic lesion or residual thrombus after Indigo:
- additional PTA or stents
- additional lysis

Preliminary data
Revascularization rate

<table>
<thead>
<tr>
<th>AT PRESENTATION</th>
<th>TIMI 0</th>
<th>TIMI 1</th>
<th>TIMI 2</th>
<th>TIMI 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>80,7</td>
<td>13,3</td>
<td>4,0</td>
<td>2,0</td>
<td>0,0</td>
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</tbody>
</table>
Acute results

- No vessel injuries or clinically significant distal embolization attributable to the Indigo procedures.
- No patients required surgical revascularization.
- No device-related adverse events occurred.
- No Major bleeding complications.
- Mean blood loss 220 cc (range 20-600 cc)
The Indian registry
(The Indigo system in acute lower limb malperfusion)

Preliminary results

• Indigo is safe and effective in acute lower limb ischemia

• Technical success is high even in very small arteries (BTK & BTA)

• Low risk of blood loss (mean blood loss 220 cc)

• AEs as bleeding and hemolysis are not reported

• No device-related AE
CONCLUSION

Mechanical Percutaneous Aspiration Thrombectomy With The Indigo System

When Indigo first option

- All acute on chronic limb ischemia
- Embolism is popliteal and tibial arteries
- Distal Embolism after open or endo procedures
Piazza del Campo, Siena – Italy