“The vacuum-assisted thromboaspiration in patients with acute lower limb ischaemia: safety and efficacy results from the INDIAN registry”

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x I have the following potential conflicts of interest to report:

- Research contracts
- Consulting (Endologix, Penumbra)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

☑ I do not have any potential conflict of interest
The aspiration thrombectomy system designed for peripheral intervention

The Indigo catheters:
- dedicated, last generation system
- designed specifically to address the limitations of conventional technology:
  - trackability,
  - risk of vessel injury,
  - incomplete revascularization
The Indian registry
(The Indigo system in acute lower limb malperfusion)

First investigator meeting on Sept 25, 2017

Vascular and Endovascular Surgery
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

Recruiting (enrollment started in Oct 2017)
The Indian registry
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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 primary endpoint of the study
- the technical success of the thromboaspiration with the Indigo system.
- **TIMI** (Thrombolysis In Myocardial Infarction)

- **TICI** (Thrombolysis In Cerebral Infarction)

- **TIPI** (Thromboaspiration in Peripheral Ischemia)

<table>
<thead>
<tr>
<th>Description</th>
<th>TIPI score</th>
</tr>
</thead>
<tbody>
<tr>
<td>No recanalization of the thrombotic occlusion</td>
<td>0</td>
</tr>
<tr>
<td>Incomplete or partial recanalization of the thrombotic occlusion with no distal flow</td>
<td>1</td>
</tr>
<tr>
<td>Incomplete or partial recanalization of the thrombotic occlusion with any distal flow</td>
<td>2</td>
</tr>
<tr>
<td>Complete recanalization of the thrombotic occlusion with normal distal flow</td>
<td>3</td>
</tr>
</tbody>
</table>
Data first 150 patients

ARTERIAL OCCLUSION LOCALIZATION

- Aorta: 8 (4.1%)
- Common Iliac: 18 (9.3%)
- External Iliac: 9 (4.7%)
- Common Femoral: 17 (8.8%)
- Profunda: 4 (2.1%)
- Superficial Femoral: 73 (37.8%)
- Popliteal: 111 (57.5%)
- Below the Knee: 72 (37.3%)
- Below the Ankle: 5 (2.6%)

European Journal of Vascular & Endovascular Surgery

In press
Efficacy data

In case of chronic lesion or residual thrombus after Indigo:
- additional PTA or stents
- additional lysis

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

<table>
<thead>
<tr>
<th>Reason for adjuvant procedure</th>
<th>Underlying Chronic Lesion</th>
<th>Residual Thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures performed (n)</td>
<td>39</td>
<td>52</td>
</tr>
<tr>
<td>Endovascular procedures (PTA±Stenting or covered stenting) (n, %)</td>
<td>39, 100%</td>
<td>15, 28.8%</td>
</tr>
<tr>
<td>Intra-arterial thrombolysis (n, %)</td>
<td>0</td>
<td>21, 40.4%</td>
</tr>
<tr>
<td>Intra-arterial thrombolysis followed by PTA±Stenting (n, %)</td>
<td>0</td>
<td>10, 19.3%</td>
</tr>
<tr>
<td>Fogarty’s embolectomy (n, %)</td>
<td>0</td>
<td>6, 11.5%</td>
</tr>
</tbody>
</table>

Use of lysis as adjuvant therapy after Indigo (31/150, 20.7%)
amount of drug (mean 10.5 mg rtPA, 1.1 million unit urokinase)
& duration (mean 13 hrs)  
**typically lower than that when lysis is the only treatment**
The Indian registry
(The **Indigo** system in acute lower limb **malperfusion**)

Subgroup analysis

<table>
<thead>
<tr>
<th>Classification Groups</th>
<th>TIPI 2/3 after Indigo procedure</th>
<th>TIPI 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>

**Indigo as intraprocedural bail-out solution or after open embolectomy works particularly well!!**
Acute results

• No vessel injuries or clinically significant distal embolization attributable to the Indigo procedures.
• No Major bleeding complications
• Mean blood loss 220 cc (range 20-600 cc)
• One device-related adverse events occurred
## Results at 1 month (first 150 pts)

<table>
<thead>
<tr>
<th>ADVERSE EVENT</th>
<th>6 (4%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SERIOUS ADVERSE EVENT</td>
<td>2 (1.33%)</td>
</tr>
<tr>
<td></td>
<td>1 death</td>
</tr>
<tr>
<td></td>
<td>1 amputation</td>
</tr>
<tr>
<td>ADVERSE EVENTS</td>
<td>4 (2.66%)</td>
</tr>
<tr>
<td></td>
<td>1 acute renal failure</td>
</tr>
<tr>
<td></td>
<td>3 re-intervention (2 lysis, 1 lysis + Indigo)</td>
</tr>
<tr>
<td>ADVERSE DEVICE-RELATED EVENT</td>
<td>1 (0.66%)</td>
</tr>
<tr>
<td></td>
<td>sep tip lost / re-captured</td>
</tr>
</tbody>
</table>
The Indian registry
(The Indigo system in acute lower limb malperfusion)

Results

- Mean hospitalization stay was 3 ± 2.7 days (range 1-10 d).
- Additional fasciotomy was needed in 8 cases (5.3%).
- AEs as bleeding and hemolysis are not reported.
- Primary patency at 1 month of 92% (138/150).
- Secondary patency at 1 month of 99.33%.

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What we have learned from the Indian registry up to now....
Tips & tricks

1. Choose the most appropriate Indigo CAT (the larger the better)
Post-EVAR limb occlusion – case
Embolus at risk of migration in the only patent hypogastric artery

- Clot engaged
- Clot removal

CAT 8 Xtorq

XTRACT techn
1:1 sizing of Indigo

CAT 8 Xtorq (till P3 & ostium of tibials)
1:1 sizing of Indigo

CAT 6 or 5 till BTA vessel
Conclusions

• Results from this on-going prospective multicenter registry reveal the safety and technical effectiveness of the Indigo mechanical thrombectomy system as initial treatment in patients with different settings of arterial occlusions (TIPI 2/3 flow in 88.7%, increasing up to 95.3% after adjuvant procedures).

• Continuing the enrollment of patients in a further phase of the registry (Indian UP) will allow a further better definition of the optimal technique and of the ideal candidates for this technology.

150 pts -> 500 pts