Vacuum assisted catheter based thrombo-embolectomy for acute limb ischemia: how does it work and preliminary results from the INDIAN Registry

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Conflict of interest

Speaker’s name: Gianmarco de Donato

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
Acute Lower Limb Ischemia

BACKGROUND
Current treatment of acute limb ischemia
- possibility and limitations of Fogarty embolectomy
- from Fogarty to hybrid tx, to Indigo system

NEW SOLUTION
Indigo system in case of acute limb ischemia
- how it works
- cases in the box
- preliminary results from the INDIAN registry (ClinicalTrials.gov Identifier: NCT03386370)
Acute Lower Limb Ischemia

Background

Thrombo-embolectomy by Fogarty balloon catheter is an efficient treatment for acute arterial ischemia of lower limb, especially when ischemia occurs in healthy artery.
Fogarty embolectomy for acute on chronic ischemia

Possibility & limit of Fogarty embolectomy
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

(† Vasc Surg 2014;59:729–36.)
HYBRID TREATMENT

2 Steps

1. FOGARTY

2. ENDO

PTA ± Stenting

Covered stenting

Fibrinolysis through multiple side hole infusion catheter

thrombus fragmentation and aspiration by large guiding-catheter
Findings at intraoperative angiography
(HP group – n=210)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Native arterial lesions (stenosis underlying thrombosis)</td>
<td>90</td>
</tr>
<tr>
<td>II. Residual thrombus in SFA &amp; popliteal firmly adherent to the arterial wall</td>
<td>54</td>
</tr>
<tr>
<td>III. Residual thrombus in BTK vessels (not appropriately reached by the balloon catheter thromboembolectomy)</td>
<td>58</td>
</tr>
<tr>
<td>IV. Vessel injury after intraluminal Fogarty’s balloon catheter manipulation</td>
<td>8</td>
</tr>
</tbody>
</table>

(J Vasc Surg 2014;59:729-36.)
Vessel injury after Fogarty's balloon catheter manipulation

Hybrid treatment of ALI
Hybrid treatment of ALI
Limitations

1. Fogarty → Poor visual estimated outflow from distal vessels
   *(previous video)*

2. Completion angiography

3. Primary covered stenting

No adequate tool to remove this distal clot!

4. Distal embolization
The ideal thrombectomy catheter

- Safe
- Effective
- Atraumatic profile
- Simple setting
- Flexible
- No lytic agent
- No risk of hemolysis (hydrodynamic forces)
Endovascular solutions for Thrombectomy

**Syringe-based thrombosuction**

**Catheter direct thrombolysis**

**Rheolytic pharmaco-mechanical thrombectomy**

**Rotational mechanical thrombectomy**
The ideal thrombectomy catheter

- Safe
- Effective
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Rotational mechanical thrombectomy

- Rotational system & risk of small vessel injury
Background from cerebral stroke
Penumbra system has began the market leader in stroke

- dedicated design for intracranial navigation
- atraumatic tip
- trackability
- aspiration power
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
INDIGO CAT8 XTORQ with SEP
Place Catheter proximal to clot. If there is flow, advance Catheter until clot is engaged.
If flow is stopped, cycle the Separator to clear Indigo Catheter and restore flow through tubing. Repeat as needed until vessel is clear.
MECHANICAL CLOT ENGAGEMENT
Proprietary Separator Technology

MAXIMISED ASPIRATION POWER
Large Lumen Aspiration

TIP DIRECTIONALITY
For Circumferential Aspiration

ADVANCED TRACKING TECHNOLOGY
Multiple Materials Transitions
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.
Circumferential Aspiration

a. Data on file at Penumbra, Inc.
Competitor vs. Indigo

8 Transition Zones for Advanced Tracking

Photographs of Penumbra Indigo System and Competitor device taken from the first package opened.

Up to 21× the Aspiration Power

Penumbra Indigo System
Aspiration Catheter

195 cc/min

Competitor
Aspiration Catheter

9 cc/min

a. Data on file at Penumbra, Inc.
Trackability of the Indigo System – CAT 3 into pedal arch
MY FIRST CASE
1. Some conflicting results with other mechanical thrombectomy system

2. Very positive feedback from neuroradiologists (Stroke Unit @ University of Siena)

3. Possibility to borrow ACE 64 (neuro catheter from Penumbra)
SFA DES Occlusion
ACE 64

- CLI (ABI 0.36), CABG, previous intracranial hemorrhage
- SFA recanalization and 3 DES implantation
- ABI 0.95

- Acute pain at 1 month
- Stent thrombosis
- Conservative treatment for 10 days
- Increasing pain
- Aspiration thrombectomy by ACE 64
LONG SFA DES OCCLUSION

- Zilver PTX thrombosis
- Tibial embolization
- ALI Rutherford IIb
- Crossover approach
- ACE 64 + 4 MAX (coaxially)
CLOT ENGAGED

Temporary stent collapse
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
- tibial & plantar thrombosis in dialysis-dep patient
Indigo – Siena experience

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Popliteal & BTK acute on-chronic occlusion
Popliteal & BTK acute on-chronic occlusion
Popliteal embolism

P1-P2 embolism

INDIGO SYSTEM:
CAT 8 XTORQ + SEP 8

Final result
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
- tibial & plantar thrombosis in dialysis-dep patient

Indigo – Siena experience
Tibial & plantar thrombosis in dialysis dependent patient
Tibial & plantar thrombosis in dialysis dependent patient
Tibial & plantar thrombosis in dialysis dependent patient
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
Preliminary data

- 28 centers (VS, IR, IC)
- 16 centers active
- 146 pts enrolled
Preliminary data

Ethiological hypothesis of acute limb ischemia

- Embolic: 75.9%
- Thrombotic: 22.2%
- I don't know: 1.9%
Preliminary data

Thrombus location

<table>
<thead>
<tr>
<th>Location</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aorta</td>
<td>7</td>
<td>6.8%</td>
</tr>
<tr>
<td>Common Iliac</td>
<td>11</td>
<td>10.7%</td>
</tr>
<tr>
<td>External Iliac</td>
<td>6</td>
<td>5.8%</td>
</tr>
<tr>
<td>Common Femoral</td>
<td>8</td>
<td>7.8%</td>
</tr>
<tr>
<td>Profunda</td>
<td>2</td>
<td>1.9%</td>
</tr>
<tr>
<td>Superficial Femoral</td>
<td>37</td>
<td>35.9%</td>
</tr>
<tr>
<td>Popliteal</td>
<td>57</td>
<td>55.3%</td>
</tr>
<tr>
<td>Below the Knee</td>
<td>44</td>
<td>42.7%</td>
</tr>
<tr>
<td>Below the Ankle</td>
<td>4</td>
<td>3.9%</td>
</tr>
</tbody>
</table>
Preliminary results
124 patients

**TIMI FLOW BEFORE TREATMENT**

- TIMI 0: 73%
- TIMI 1: 23%
- TIMI 2: 2%
- TIMI 3: 2%

**After Indigo**

**TIMI FLOW GRADE AFTER INDIGO PROCEDURE**

- TIMI 0: 2%
- TIMI 1: 6%
- TIMI 2: 36%
- TIMI 3: 56%

**TIMI FLOW AT THE END OF THE ENTIRE PROCEDURE**

- TIMI 0: 2%
- TIMI 1: 2%
- TIMI 2: 24%
- TIMI 3: 73%

- TIMI 2-3: 96.8%

In case of chronic lesion or residual thrombus after Indigo:
- additional PTA or stents
- additional lysis
The Indian registry
(The Indigo system in acute lower limb malperfusion)

Further data
Indigo first option

- All acute on chronic limb ischemia
- Embolism is popliteal and tibial arteries
- Embolism with particular anatomical localization
89 y old female

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

Procedural time 15 min, fluoroscopy 6’30”
Embolus at risk of migration in the only patent hypogastric artery

- Clot engaged

- Clot removal
See the clot
The catheter-tracking technology allows the device to reach the foot even from a contralateral approach.

The system is not provided of any rotational components.

No rapid stream of fluid / no hydrodynamic forces.

Flexible, atraumatic tip (born for cerebral navigation), large-bore catheter.

Access to any located peripheral arterial or venous thrombosis.

INDIGO SYSTEM FOR THE PERIPHERY

The risk of vessel injury is truly minimized.

No risk of intravascular haemolysis and acute renal insufficiency.
PENUMBRA INDIGO SYSTEM FOR THE PERIPHERY
The Indian registry
(The **Indigo** system in acute lower limb malperfusion)
INDIGO SYSTEM FOR THE PERIPHERY

• Provide endovascular option for clot management
• Safe and simple procedure
• Reduce risk of bleeding complications
• Reduce the need for lytics
• Reduce overnight ICU stay
• Visualize the clot