Indigo Catheter Thrombectomy System From Penumbra: A Novel Endovascular Way To Remove Clot From Medium-Sized And Small Arteries: What Makes It Different And Better And Multicenter Clinical Results From The PRISM Trial

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INDIGO SYSTEM
• Reinforced but flexible Catheter Technology – Highly trackable
• Maximum Aspiration Potential; doesn’t compress
• Concept of Continuous Vacuum
• Circumferential Aspiration with larger sizes

Purpose
• The PRISM REGISTRY is the first multicenter study designed to obtain:
  • Safety and efficacy data on the Indigo® System in patients with peripheral & visceral artery occlusion
  • Why?
    • Current treatments of arterial thrombo-embolism are associated with incomplete revascularization, significant morbidity, long treatment times, and rare but serious bleeding complications

Disclosures
Consultant and MAB:
Penumbra
Gore
Endoshape
Scientia
Cordis
Abbott
MC 10

Royalties:
Penumbra

Stock:
Reverse Medical
Xablecath
Bridgewater

Aspiration Efficiency

Methods
• 83 patients were enrolled in this retrospective, single-arm, multicenter registry
• Mechanical thrombo-embolectomy using the Penumbra Indigo® System was performed in cases of:
  • Acute peripheral and visceral arterial ischemia requiring rapid revascularization
  • Distal emboli as a complication of an endovascular intervention
  • Failed thrombolysis

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Aspiration Efficiency

Aspiration Volume (mL in 20 sec)

AngioJet CAT3 CAT5 CAT6 CAT8

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**Patient baseline Characteristics**

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>83</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) [mean ± SD]</td>
<td>68.7 ± 12.8</td>
</tr>
<tr>
<td>Female</td>
<td>40.2%</td>
</tr>
<tr>
<td>Target vessel location</td>
<td></td>
</tr>
<tr>
<td>Popliteal</td>
<td>33.7%</td>
</tr>
<tr>
<td>Peroneal</td>
<td>7.2%</td>
</tr>
<tr>
<td>Posterior tibial</td>
<td>4.8%</td>
</tr>
<tr>
<td>Anterior tibial</td>
<td>6.0%</td>
</tr>
<tr>
<td>Superficial femoral</td>
<td>27.7%</td>
</tr>
<tr>
<td>Profunda femoris</td>
<td>4.8%</td>
</tr>
<tr>
<td>Superior mesenteric</td>
<td>3.6%</td>
</tr>
<tr>
<td>Renal</td>
<td>2.4%</td>
</tr>
<tr>
<td>Brachial</td>
<td>1.2%</td>
</tr>
</tbody>
</table>

**Study METRICS**

<table>
<thead>
<tr>
<th>Treatment modality</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Penumbra used frontline</td>
<td>50.6% (41/81)</td>
</tr>
<tr>
<td>Penumbra after thrombolytics</td>
<td>27.2% (22/81)</td>
</tr>
<tr>
<td>Penumbra after other mechanical therapy</td>
<td>13.6% (11/81)</td>
</tr>
<tr>
<td>Penumbra after both thrombolytics + mechanical</td>
<td>8.6% (7/81)</td>
</tr>
</tbody>
</table>

**Distal Emboli During Intervention**

- 57 y/o male former heavy smoker, non-compliant with statin therapy.
- Presented with 6 months of progressive right calf claudication.

**Post Recanalization**

Post 24 hour thrombolysis with 10 cm UniFuse catheter

**Successful revascularization with Penumbra**

**History**

- 66 y/o M status post cardiac catheterization per right radial artery approach.
- The patient had severe ischemic cardiomyopathy with 15-20% LVEF and 3 vessel coronary artery disease.
- The right leg was found to be cold and pulseless shortly post-procedure.
The initial results of the PRISM study show that the Penumbra Indigo® System is safe and effective:
- 96.3% Successful revascularization (TIMI 2-3) post all interventions
- 89.9% post Indigo alone
- Wide range of clinical applications
  - Intra-procedural emboli
  - Frontline (50.6% of patients)
  - Acute mesenteric and renal ischemia
  - After failed thrombolysis (27.2% of patients)

**Results: Effectiveness**

Primary Endpoint = TIMI 2-3 Revascularization (N=81)

<table>
<thead>
<tr>
<th></th>
<th>Pre-procedure</th>
<th>Post Penumbra/Indigo System alone</th>
<th>Final angiographic outcome*</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIMI 0-1</td>
<td>94.9%</td>
<td>10.9%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Successful Revascularization (TIMI 2-3)</td>
<td>5.1%</td>
<td>89.0%</td>
<td>96.3%</td>
</tr>
<tr>
<td>Complete reperfusion (TIMI 3)</td>
<td>0%</td>
<td>52.4%</td>
<td>76.5%</td>
</tr>
</tbody>
</table>

**Results: Safety**

Type of adverse event  N of patients (%)  
Serious adverse event*  10 (12.0%)  
Device-related adverse event within 24 h  1 (1.2%)  

*5 SAEs were observed in 2 patients. These 5 events included myocardial infarction, anemia, renal insufficiency, metabolic acidosis/shock, and mesenteric ischemia. None were classified as related to the study device.

**Early Experience AT MCVI**

Arterial Thrombus
- Firstline therapy
  - Below the knee
  - Popliteal
  - Short segments of clot
  - Distal emboli
  - Mesenteric acute occlusions
  - Upper Extremity emboli
  - Great option post lytics for residual clot
  - With larger catheters; Cat 6 and Cat 8 SFA and larger vessels can be treated

Also used in venous and pulmonary interventions