MECHANICAL ASPIRATION THROMBECTOMY IN PERIPHERAL ARTERIAL OCCLUSIONS: RESULTS FROM THE PENUMBRA INDIGO PRISM REGISTRY

Presenter: James F. Benenati, MD
1Miami Cardiac & Vascular Institute, Miami, Fl

Richard R. Saxon, MD, Corey Teigen, MD, George L. Adams, MD, Luke Sewall, MD
2San Diego Cardiac and Vascular Institute, San Diego Imaging Medical Group, San Diego, CA; 3Sanford Health, Fargo, ND; 4North Carolina Heart and Vascular Research, Raleigh, NC; 5Adventist Health Partners, Downers Grove, IL

TRIAL OVERVIEW
• Single arm, multi-center case review design
• Patients with evidence of peripheral or visceral arterial occlusion treated with the Penumbra/Indigo System were enrolled
• The primary outcomes included safety and vessel patency as measured by the TIMI scores
• Endovascular thrombectomy offers the advantage of reduced intraprocedural complications over surgical embolectomy and Catheter Directed Thrombolysis (CDT).
• The PRISM trial sought to evaluate the safety and efficacy of the Penumbra/Indigo System in treatment of peripheral and visceral arterial occlusion.

THE PENUMBRA/INDIGO SYSTEM
• Well established safety and effectiveness in ischemic stroke aspiration therapy
• Adopts similar principles of a highly trackable and effective aspiration system to reduce clot burden in the periphery
• Designed to reduce overall procedural time, improve outcomes and minimize complications

PATIENT SELECTION
• Inclusion Criteria
  • Presenting with evidence of peripheral or visceral arterial occlusion (TIMI 0-1)
  • Acute limb ischemia
  • Incomplete recanalization
  • Distal emboli from preceding intervention
  • Intervention performed using the XTRACT technique with components of the Penumbra/Indigo System
• Exclusion Criterion
  • Participation in another clinical investigation that may confound results of the present study

OUTCOME MEASURES
• Efficacy
  • The rate of TIMI 2-3 at post thrombectomy
  • TIMI scores assessed at:
    • Presentation
    • Prior to aspiration thrombectomy
    • Post aspiration thrombectomy
    • Post all interventions
• Safety
  • Incidence of procedure related serious adverse events (SAEs) within 24h of intervention

DISCLOSURES
• Consultant
  • Penumbra
  • Stock
  • Covidian
  • Cook
  • Xablecath
  • Bard
  • Royalties
  • Gore
  • Penumbra
  • Scientia
  • Editorial Compensation
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ENDOVASCULAR PROCEDURE

• Thrombectomy via the Penumbra/Indigo System using a power aspiration extraction (XTRACT) technique

• Adjunctive therapies (ie. angioplasty, stenting) were permitted to achieve complete revascularization

TRIAL OUTCOME

• Enrollment period for PRISM lasted from March 2014 to September 2015

• 85 patients were enrolled at 5 centers

BASELINE CHARACTERISTICS

Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>Number of patients, N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>85</td>
</tr>
<tr>
<td>Age (years), median [IQR]</td>
<td>69 [IQR 60-78]</td>
</tr>
<tr>
<td>Female, % (n/N)</td>
<td>41.2% (35/85)</td>
</tr>
</tbody>
</table>

Patient Medical History

<table>
<thead>
<tr>
<th>Disease</th>
<th>% (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Vascular Disease</td>
<td>81.2% (69/85)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>82.9% (68/82)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>31.3% (26/82)</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>15.9% (13/82)</td>
</tr>
<tr>
<td>Smoking</td>
<td>70.9% (56/79)</td>
</tr>
<tr>
<td>Stroke</td>
<td>15.0% (12/80)</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>37.0% (30/81)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>67.9% (55/81)</td>
</tr>
</tbody>
</table>

OCCLUSION SITES

<table>
<thead>
<tr>
<th>Vessel Location</th>
<th>% (n/N)</th>
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<tbody>
<tr>
<td>Popliteal</td>
<td>32.9% (28/85)</td>
</tr>
<tr>
<td>Profunda femoral</td>
<td>5.9% (5/85)</td>
</tr>
<tr>
<td>Common Femoral</td>
<td>1.2% (1/85)</td>
</tr>
<tr>
<td>Renal</td>
<td>2.4% (2/85)</td>
</tr>
<tr>
<td>External iliac</td>
<td>1.2% (1/85)</td>
</tr>
<tr>
<td>Common iliac</td>
<td>1.2% (1/85)</td>
</tr>
<tr>
<td>Sciatic</td>
<td>1.2% (1/85)</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>1.2% (1/85)</td>
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PROCEDURAL CHARACTERISTICS

Treatment Modality

<table>
<thead>
<tr>
<th>Modality</th>
<th>% (n/N)</th>
</tr>
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<tbody>
<tr>
<td>Study device used frontline</td>
<td>50.6% (43/85)</td>
</tr>
<tr>
<td>Study device after thrombolitics</td>
<td>16.5% (14/85)</td>
</tr>
<tr>
<td>Study device after other mechanical therapy</td>
<td>17.6% (15/85)</td>
</tr>
<tr>
<td>Study device after both thrombolitics and mechanical</td>
<td>15.3% (13/85)</td>
</tr>
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</table>

Median time from symptom onset to intervention → 6.0 days [IQR 2.0-24.0]

PRIMARY OUTCOME

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<tr>
<th>Time Period</th>
<th>TIMI 0-1</th>
<th>TIMI 2-3</th>
</tr>
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<tbody>
<tr>
<td>Baseline</td>
<td>31.7%</td>
<td>88.1%</td>
</tr>
<tr>
<td>Plus Indigo aspiration thrombectomy</td>
<td>55.3%</td>
<td>43.5%</td>
</tr>
<tr>
<td>Post all interventions</td>
<td>1.2%</td>
<td>39.3%</td>
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Procedure Timeline

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Post (TIMI 2-3)
**REVASCULARIZATION BY TREATMENT MODE**

<table>
<thead>
<tr>
<th>Treatment Mode</th>
<th>N</th>
<th>TIMI 2-3 Post XTRACT</th>
<th>TIMI 2-3 Post All Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTRACT Frontline</td>
<td>43</td>
<td>81.4% (35/43)</td>
<td>95.3% (41/43)</td>
</tr>
<tr>
<td>tPA prior to XTRACT</td>
<td>14</td>
<td>92.9% (13/14)</td>
<td>No Change</td>
</tr>
<tr>
<td>Mechanical Thrombectomy (MT)</td>
<td>15</td>
<td>92.9% (13/14)*</td>
<td>100% (15/15)</td>
</tr>
<tr>
<td>tPA + MT prior XTRACT</td>
<td>13</td>
<td>100% (13/13)</td>
<td>No Change</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>85</strong></td>
<td><strong>88.1% (74/85)</strong></td>
<td><strong>96.5% (82/85)</strong></td>
</tr>
</tbody>
</table>

*TIMI score was unable to be assessed for 1 patient

TIMI 3 was achieved in 77.6% (66/85) post all intervention
Median procedure time from puncture to aspiration off: 67.5 mins [IQR 50 – 81]

**SAFETY OUTCOME**

<table>
<thead>
<tr>
<th>Safety Outcome</th>
<th>% (n/N) of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure related serious adverse events (SAE) within 24h</td>
<td>7.1% (6/85)</td>
</tr>
<tr>
<td>Device related adverse events (AE)</td>
<td>0 (0/85)</td>
</tr>
<tr>
<td>Device related SAE</td>
<td>0 (0/85)</td>
</tr>
</tbody>
</table>

9 SAEs occurred within 24 h of intervention in 6 patients

**DISCUSSION**

- The Penumbra/Indigo System is an atraumatic, versatile system that is **safe** and **effective** against peripheral and vascular arterial occlusions
- **Efficacy**
  - TIMI 2-3 post all intervention → 96.5%
  - TIMI 3 post all intervention → 77.6%
  - As frontline therapy, TIMI 2-3 was achieved in
    - 81.4% from XTRACT alone
    - 95.3% with adjunctive therapy
- **Safety**
  - No device related serious adverse events

**BENEFITS OF XTRACT**

- Offers faster time to revascularization compared to surgical embolectomy
- Wide clinical application - intra-procedural emboli, acute mesenteric and renal ischemia, salvage therapy, and as first intention
- The highly trackable study device reduces adverse sequelae and vessel injuries associated with surgical Fogarty embolectomy
- Reduced risk of morbidity
- Promising results in utility as frontline device
- Potential to reduce or eliminate lytic therapy → reduce cost and complications
**CONCLUSION**

- Promising results - XTRACT using the Penumbra/Indigo System is effective in treatment of peripheral/visceral occlusions.
- Effective as a frontline device
- Equally effective as salvage therapy

- The improvements in post procedure TIMI scores support the potential use of the Penumbra/Indigo system as frontline, in cases both with and without lytic therapy.

**ALI AND ACUTE VISCERAL OCCLUSIONS**

- Need for emergent of immediate revascularization
- Options for treatment
  - Lysis—maybe time consuming and require long sessions or even overnight treatment
  - Surgery—Patient co morbidities are high
  - Mechanical—Risks of distal embolization
- Xtract method—Vacuum Assisted Thrombectomy
  - Indigo System: Penumbra
  - Allows for quick therapeutic option
  - Distal embolization is rare
  - Immediate restoration of blood flow

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**78 YR, ACUTE EMBOLIC OCCLUSION OF SMA; ABDOMEN TENSE, LACTIC ACID 2.0 (0.5-2.2), CR 1.9**

**SELECTIVE SMA ANGIOGRAM**

**EXPLORATORY LAPAROTOMY**

**67 YR MALE WITH RUTHERFORD III CLAUDICAITON**
**CONCLUSION**

- Penumbra Indigo System is a game changer
- Quick, safe, reproducible results
- Ideal for ALI and acute mesenteric occlusions