Percutaneous Mechanical Thrombectomy Techniques and Options

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Cincinnati, Ohio
Disclosures

Speaker/Stock – Penumbra
Advisory Aboard – Boston Scientific
Speaker – EKOS/BTG
2000 Algorithm for Acute Limb Ischemia

Evidence-based

Rutherford Level

1

Angiogram
Semi elective

 +/- Rheolyic Thrombectomy
 +/- PTA/DES/DEB
 +/- USAT/Unifuse
 +/- CT Head rule out ICH

Cutdown Embolectomy
Thrombectomy/Bypass/
Cancel Dinner Plans/Wound
Care Consult/VAC

2A

2B

Emergent OR

Emergent Amputation

Next Morning

3

Ice

Amputation

Next Morning
## Peripheral Thrombectomy Devices (upper/lower extremity)

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Combination therapy used for:
- Fibrin-rich thrombus older thrombus
- Sub-acute to Chronic thrombus with high fibrin content
- Large thrombus volume
Rheolytic Pharmacomechanical Thrombectomy for the Management of Acute Limb Ischemia: Results From the PEARL Registry

Daniel A. Leung, MD\textsuperscript{1}, Lawrence R. Blitz, MD\textsuperscript{2}, Teresa Nelson, MS\textsuperscript{3}, Ali Amin, MD, RVT\textsuperscript{4}, Peter A. Soukas, MD\textsuperscript{5}, Aravinda Nanjundappa, MD, RVT\textsuperscript{6}, Mark J. Garcia, MD\textsuperscript{1}, Robert Lookstein, MD\textsuperscript{7}, and Eugene J. Simoni, MD\textsuperscript{8}

PEARL Registry

- Prospective, multicenter, observational study of patients undergoing PMT with AngioJet from Jan 2007-July 2013
  - 34 institutions (US and Europe)
  - Registry included patients treated for limb ischemia, as well as deep vein thrombosis and hemodialysis access
- 283 patients treated for acute limb ischemia (limb ischemia symptom onset ≤14 days)

PMT, pharmacomechanical thrombectomy
Risk of Acute Kidney Injury after Percutaneous Pharmacomechanical Thrombectomy Using AngioJet in Venous and Arterial Thrombosis

Guillermo A. Escobar, Dillon Burks, Matthew R. Abate, Mohammed F. Faramawi, Ahsan T. Ali, Lewis C. Lyons, Mohammed M. Moursi, and Matthew R. Smeds, Atlanta, Georgia and Little Rock, Arkansas

Increased risk of renal dysfunction with percutaneous mechanical thrombectomy compared with catheter-directed thrombolysis

Katherine L. Morrow, MS, Ann H. Kim, MD, Steven A. Plato II, MD, Andrew J. Shevitz, MS, Jerry Goldstone, MD, Henry Baele, MD, and Vikram S. Kashyap, MD, FACS, Cleveland, Ohio
JETi

- Aspiration
- &
- Internal disruption
EKOS

- Ultrasound enabled delivery of TPA

- Claims –
  - Localized delivery/reduces lytic dose 50-70%
  - Reduces distal emboli
  - Could be used after mechanical thrombectomy for TPA delivery, if needed

- Limitations
  - Neuro studies have shown no difference vs. lytic catheter
Lytic Disaster-How To Avoid?
MECHANICAL CLOT ENGAGEMENT
Proprietary Separator Technology

MAXIMIZED ASPIRATION POWER
Large Lumen Aspiration

TIP DIRECTIONALITY
For Circumferential Aspiration

ADVANCED TRACKING TECHNOLOGY
Multiple Materials Transitions
With more powerful tubing for maximum aspiration through entire system

Full Vacuum

- Continuous suction
- Simple setup with hands-free aspiration
- Maximized power

Flow Rate (cc/sec)

<table>
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<tr>
<th>Manual Aspiration Catheters</th>
<th>1.71°</th>
<th>3.25°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wall Suction</td>
<td>2.0°</td>
<td></td>
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- Up to 90% more suction with Indigo


b. Data on file at Penumbra, Inc. based on testing with CAT5.
The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT® is advanced through sheath over a wire.

The Indigo CAT® is placed just proximal to the face of the clot and wire is retracted.

Aspiration is applied to Indigo CAT® via Pump MAX until CAT® becomes occluded (recommend waiting at least 90 seconds).

The Indigo CAT® is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.
Arterial Work

- 64 y/o with history of left Fem Pop with PTFE presents with ALI
- Stroke 3 weeks earlier
More Arterial Work
More Arterial Work
More Arterial Work
EVAR
EVAR w/ Renal Emboli
S/P CAT 6
PRISM Trial

- The PRISM trial\(^1\) and other studies\(^2,3\) have demonstrated the safety and efficacy of XTRACT (a power aspiration-based extraction technique) using Penumbra Indigo System as a frontline or secondary treatment for peripheral arterial occlusions.
- In this subset analysis, we present outcomes in patients with atrial fibrillation from the PRISM trial.

\(^1\) Saxon et al, 2018. JVRIR Jan;29(1):92-100
\(^3\) Kwok et al, 2018. JVRIR May;29(5):607-613

- 79 total
- 12 emboli mainly women
- 8% brachial(1)
## Revascularization Rate Post-XTRACT

<table>
<thead>
<tr>
<th>Treatment Modality</th>
<th>All Patients N=79</th>
<th>AFib N=12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall XTRACT Successful Revascularization TIMI 2-3</td>
<td>87.2% (68/78)*</td>
<td>83.3% (10/12)</td>
</tr>
<tr>
<td>XTRACT as frontline treatment</td>
<td>49.4% (39/79)</td>
<td>58.3% (7/12)</td>
</tr>
<tr>
<td>Successful Revascularization TIMI 2-3</td>
<td>79.5% (31/39)</td>
<td>1.4% (5/7)</td>
</tr>
<tr>
<td>XTRACT as secondary treatment</td>
<td>50.6% (40/79)</td>
<td>41.7% (5/12)</td>
</tr>
<tr>
<td>Successful Revascularization TIMI 2-3</td>
<td>92.5% (37/40)</td>
<td>100% (5/5)</td>
</tr>
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</table>
VACUUM ASSISTED THROMBECTOMY (INDIGO)

- Limited data exist on the use of novel vacuum assisted thrombectomy (VAT) devices for acute limb ischemia.

- Starting in 2014, our institution started using the Penumbra Indigo vacuum assisted thrombectomy device.
2000 Algorithm for Acute Limb Ischemia

**Evidence-based**

**Rutherford Level**

- 1
  - Angiogram
    - Semi elective
    - +/- Rheolyic Thrombectomy
    - +/- PTA/DES/DEB
    - +/- USAT/Unifuse
    - +/- CT Head rule out ICH
  - Cutdown Embolectomy
  - Thrombectomy/Bypass/
  - Cancel Dinner Plans/Wound
  - Care Consult/VAC

- 2A

- 2B
  - Emergent OR

- 3
  - Ice
  - Emergent Amputation
  - Amputation
  - Next Morning
2019 Algorithm for Acute Limb Ischemia

**Evidence-based**

**Rutherford Level**

1. **Angiogram**
   - Semi elective

2A. **Angiogram**
   - Semi Elective

2B. **Urgent Angiogram**
   - in Hybrid Room

3. **Amputation**
   - Next Morning

- **Aspiration Thrombectomy**
  - +/- Single Session with Turbo Pulse
  - +/- PTA/Supera
  - +/- USAT/Unifuse

  **FAILURE?**

  +/- Open Repair

- **Ice**
- **Emergent Amputation**
THANK YOU!
The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT8 is advanced through sheath over a wire.

The Indigo CAT8 is placed just proximal to the face of the clot and wire is retracted.

Aspiration is applied to Indigo CAT8 via Pump MAX until CAT8 becomes occluded (recommend waiting at least 90 seconds).

The Indigo CAT8 is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.
OBJECTIVE/METHODS

▪ OBJECTIVE: to evaluate outcomes of patients with ALI who have undergone VAT at our institution

▪ Retrospective review of patients who presented with ALI and underwent VAT (Penumbra, Alameda, California) between Jan. 2014 and Jan. 2018
STUDY ENDPOINTS

- **Primary**
  - Safety endpoints included estimated blood loss, distal embolization, need for transfusion, or other vessel pathologic occurrences
  - Efficacy was determined by presence of antegrade flow on angiography

- **Secondary**
  - Need for adjunctive intervention in addition to VAT
## PATIENT AND PROCEDURAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>PATIENTS WITH ALI (N=73)</th>
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<tbody>
<tr>
<td>Age, Mean ± SD</td>
<td>65.6 ± 12.3</td>
</tr>
<tr>
<td>Female, % (n/N)</td>
<td>34.2% (25/73)</td>
</tr>
<tr>
<td>Comorbidities, % (n/N)</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>46.6% (34/73)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>35.6% (26/73)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>26.0% (19/73)</td>
</tr>
<tr>
<td>History of tobacco use</td>
<td>86.3% (63/73)</td>
</tr>
<tr>
<td>Indication, % (n/N)</td>
<td></td>
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<tr>
<td>EVAR* limb occlusion</td>
<td>9.6% (7/73)</td>
</tr>
<tr>
<td>Lower extremity bypass occlusion</td>
<td>15.1% (11/73)</td>
</tr>
<tr>
<td>Lower extremity thromboembolism</td>
<td>50.7% (37/73)</td>
</tr>
<tr>
<td>Lower extremity stent occlusion</td>
<td>23.3% (17/73)</td>
</tr>
<tr>
<td>Upper extremity embolism</td>
<td>1.4% (1/73)</td>
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*EVAR: endovascular aneurysm repair*
## RESULTS

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<td>Estimated blood loss $&lt; 300\text{mL}$</td>
<td>93.2% (68/73)</td>
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<td>6.8% (5/73)</td>
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<tr>
<td>Distal embolization</td>
<td>2.7% (2/73)</td>
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<tr>
<td>Need for transfusion</td>
<td>8.2% (6/73)</td>
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<td>Efficacy, % (n/N)</td>
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<tr>
<td>Established antegrade flow</td>
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<td>Adjunctive interventions, % (n/N)</td>
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<td>Lysis</td>
<td>67.1% (49/73)</td>
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<tr>
<td>Angioplasty</td>
<td>57.5% (42/73)</td>
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<td>Stent placement</td>
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## RESULTS

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*all 5 cases were associated with endovascular and open adjunctive interventions*

*all 6 cases included catheter directed thrombolysis as part of the intervention*
## EFFICACY ENDPOINTS

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<th>INTERVENTIONS</th>
<th>ESTABLISHED ANTEGRADE FLOW, % (n/N)</th>
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<tr>
<td>VAT only</td>
<td>62.5% (5/8)</td>
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<tr>
<td>VAT with adjunctive interventions</td>
<td>87.7% (57/65)</td>
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<tr>
<td>VAT with lysis</td>
<td>83.7% (41/49)</td>
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<tr>
<td>Timing of intervention</td>
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<tr>
<td>VAT performed first</td>
<td>82.5% (47/57)</td>
</tr>
<tr>
<td>VAT not performed first</td>
<td>93.8% (15/16)</td>
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CONCLUSION

▪ These initial results suggest that VAT is safe and can facilitate achieving antegrade flow in the management of ALI

▪ Further analysis is needed to evaluate VAT’s efficacy alone vs when it is combined with other adjunctive interventions

▪ Future studies should be performed focusing on endovascular management using VAT for Rutherford’s IIb ischemia
TRANSFUSION REQUIREMENT

INFORMATION

- Popliteal viabahn stent thrombosis. Hybrid approach with both open and vacuum assisted thrombectomy and lysis.
  - Transfused 5 units pRBC

- SFA-Popliteal thrombosis treated with VAT, lysis, angioplasty, and repeat lysis who developed compartment syndrome. Required fasciotomies and ultimately an above knee amputation
  - Transfused total of 7 units pRBC and 3 FFP

- CFA-DP bypass thrombosis treated with VAT, angioplasty, and lysis who developed a thigh hematoma requiring evacuation. Also developed compartment syndrome treated with fasciotomies
  - Transfused total of 3 units pRBC

- CFA-DP bypass thrombosis treated with VAT and lysis. Developed open bleeding from his graft. Ultimately lead to AKA
  - Transfused 2 units pRBC
TRANSFUSION REQUIREMENT INFORMATION

• Aortic thrombus with emboli to L popliteal and tibial arteries treated with VAT, lysis, repeat VAT and lysis. Developed large hematoma at access site
  • Transfused total of 2 units pRBC

• L CIA stenosis with embolism to L tibial arteries treated with VAT and lysis.
  • Transfused total of 1 unit pRBC
EMBOLIZING EVENTS

- L CIA emboli secondary to atrial fibrillation treated with VAT with subsequent emboli to tibial vessels. Treated successfully with CDT

- L CIA stent thrombosis treated with VAT with subsequent emboli to tibial vessels. Treated successfully with CDT
CONCLUSION

▪ These initial results suggest that SST is safe and can facilitate achieving antegrade flow in the management of Stent Graft Limb Occlusions

▪ Single Session Therapy is the Future of not only Stent Graft Limb Occlusions but Acute Limb Ischemia
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<td>16.7%</td>
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<td>XTRACT after other mechanical therapy</td>
<td>19.0%</td>
<td>8.3%</td>
</tr>
<tr>
<td>XTRACT after both thrombolitics and mechanical thrombectomy</td>
<td>16.5%</td>
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