How Important Is Rapid Flow Restoration In DVT:

Single Session Pharmacomechanical Thrombectomy

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Why Pharmacomechanical Thrombectomy?
Why Single Session?

• Thrombolysis alone has drawbacks
  – Long infusion times (mean infusion time during the CAVENT trial was 57 hours (30-80 hours)
  – Bleeding risks
  – ICU costs (> $15,000/day)

Modern Thrombectomy Systems for Pharmacomechanical Thrombectomy

• AngioJet (Boston Scientific)
• Trellis (Covidien; Bacchus Medical)
• CAT8 (Penumbra)
• JETI (Walk Vascular)
• Combined pharmacological thrombolysis & mechanical thrombectomy

PHARMACOMECHANICAL THROMBECTOMY

• Likely Advantages
  • Enhance the delivery of thrombolytic agent
  • Reduce duration of thrombolytic agent
  • Enhance efficacy of thrombus removal with mechanical thrombectomy
  • Reduce/ Eliminate ICU stay

Benefits and Risks

Potential Advantages
• No ICU stay
• Lower cost to health system
• Less dose of thrombolytic
• Greater patient satisfaction

Potential Disadvantages
• Need for thrombectomy device
• Need for balloons and stents
• Larger sheath
• Rapid protocol may leave clot behind
• Poor outcomes
• More trauma to valvular system

Catheter-Directed Thrombolysis with Percutaneous Rheolytic Thrombectomy Versus Thrombolysis Alone in Upper and Lower Extremity Deep Vein Thrombosis

<table>
<thead>
<tr>
<th>Event</th>
<th>CDT alone (n = 40)</th>
<th>CDT and PMT (n = 27)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment duration (hr)</td>
<td>48.0 ± 27.1</td>
<td>28.3 ± 16.6</td>
<td>0.0064</td>
</tr>
<tr>
<td>CDT failure</td>
<td>7%</td>
<td>82%</td>
<td>0.395</td>
</tr>
<tr>
<td>Grade II</td>
<td>15%</td>
<td>19%</td>
<td>0.784</td>
</tr>
<tr>
<td>Grade I</td>
<td>13%</td>
<td>0</td>
<td>0.056</td>
</tr>
<tr>
<td>Stenosis area</td>
<td>16%</td>
<td>1%</td>
<td>0.772</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>5%</td>
<td>6%</td>
<td>0.880</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>3%</td>
<td>0</td>
<td>0.487</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>3%</td>
<td>4%</td>
<td>0.779</td>
</tr>
</tbody>
</table>
CDT vs Pharmacomechanical Thrombectomy

• Results:
  • Duration mean 48 hours vs. 26.3 hours
  • Mean dose 5.6 mill U vs. 2.7 mill U
  • Success 73% had >90% lysis vs. 82%
  • Cost was $10,127 vs $5,128
  • No difference in bleeding rates

CLINICAL STUDY
Mark J. Garcia, MD, MS, Robert Lockstein, MD, Rahul Malhotra, MD, Ali Amin, MD, RVT, Lawrence R. Blitz, MD, Daniel A. Leung, MD, Eugene J. Simon, MD, and Peter A. Soukas, MD

PEARL Comparison
Treatment of LE DVT

<table>
<thead>
<tr>
<th>Product Feature(s)</th>
<th>Solent™ Omni</th>
<th>Proxi</th>
<th>Zelante DVT™</th>
<th>AngioJet™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>Arterial and Venous</td>
<td>Venous Only</td>
<td>Venous Only</td>
<td>Venous Only</td>
</tr>
<tr>
<td>Minimum Vessel Diameter</td>
<td>3 mm</td>
<td>6 mm</td>
<td>6 mm</td>
<td>6 mm</td>
</tr>
<tr>
<td>Sheath Compatibility</td>
<td>GF</td>
<td>GF</td>
<td>GF</td>
<td>GF</td>
</tr>
<tr>
<td>Working Length</td>
<td>120 cm / 90 cm</td>
<td>105 cm</td>
<td>105 cm</td>
<td>105 cm</td>
</tr>
<tr>
<td>Power Pulse™ Enabled</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Guide Wire Swappable</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Wire Compatibility</td>
<td>0.035&quot; (0.89 mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Run Times (No Flow / Flow)</td>
<td>8 minutes / 4 minutes</td>
<td>8 minutes / 4 minutes</td>
<td>8 minutes / 4 minutes</td>
<td>8 minutes / 4 minutes</td>
</tr>
<tr>
<td>Power Pulse™ Delivery</td>
<td>0.6 mL / pump stroke</td>
<td>0.6 mL / pump stroke</td>
<td>0.6 mL / pump stroke</td>
<td>0.6 mL / pump stroke</td>
</tr>
</tbody>
</table>
Single Session Therapy: Iliofemoral DVT

60 minutes after the case has started
Conclusions

1. Single day PCDT is a technically feasible and a safe method of endovascular treatment of DVT
2. Results in shorter thrombolytic infusion times compared to standard CDT
   – Decreased bleeding risks due to lower duration of thrombolysis
   – Decreased costs due to reduction/elimination of monitoring in an intensive care setting
   – Improved patient satisfaction with faster recovery and less morbidity