Inari CloTriever Device for acute DVT

VEITH 2018

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Disclosures

- Inari Medical
  - Co- PI for national registry

Venous Clot is Different and Requires a Different Solution

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Arterial System</th>
<th>Venous System</th>
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<tbody>
<tr>
<td>Hemodynamics</td>
<td>High flow, high pressure</td>
<td>Low flow, low pressure</td>
</tr>
<tr>
<td>Vessel morphology</td>
<td>Vessels taper in direction of flow</td>
<td>Vessels enlarge in direction of flow</td>
</tr>
<tr>
<td>Presentation</td>
<td>Ischemic insult (MI, AIS, CLI, sudden, severe symptoms, treatment sought quickly)</td>
<td>DVT, swelling, pain, symptoms emerge over days/weeks, treatment delayed</td>
</tr>
<tr>
<td>Clot morphology</td>
<td>Small amounts of soft clot in small vessels, &quot;floating&quot; in the vessel</td>
<td>Large amounts of firm/hard clot in large vessels, adhered to vessel wall</td>
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</tbody>
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Case Presentation:

- 53 yo male w/ hx of spondylolisthesis L5-S1
  - Lumbar interbody fusion via anterior approach
  - Corpectomy with application of interbody cage
    - Application of local bone graft and bone powder

- 7 days post op significant left leg swelling
  - Venous duplex – acute obstruction Left CFV, FV, PV, PTV, external ilac vein
  - CT-venogram – acute obs L CIV→CFV, no thrombus in IVC
Goals of intervention for acute DVT

• Maximize clot removal to re-establish normal outflow
• Minimize bleeding risk
• Reduce treatment or infusion time
• Single-session therapy
  – Reduce need for ICU utilization
  – Reduce hospital time

CloTriever: Mechanical thrombectomy without lytic

CloTriever procedure

• Access popliteal
• Cross thrombosed segments with standard techniques
  – Exchange wire to SVC
• 13 or 16F sheath with funnel tip inserted through pop

• Insert sheathed CloTriever catheter with coring element just above thrombus
• Unsheath and expand coring element and collection bag
• Withdraw capturing clot into collection bag and down into distal funnel and sheath

Elected Mechanical Thrombectomy with TPA avoidance
Case Presentation: procedure details

- Percutaneous mechanical thrombectomy
  - ClotTriever
    • Clot extracted with removal of device through sheath

18 x 90 wallstent placed across iliac obstruction

Hospital course:

- Discharge post procedure day #1
  - Compression
  - Anti-coagulation

- 3 month follow up
  - No swelling or pain of left leg
  - Venous duplex: L CFV partial compressible w/phasic flow

CLOUT (ClotTriever Outcomes) Registry

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Summary</th>
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<tbody>
<tr>
<td>Primary Objective</td>
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<tr>
<td>Technical success: complete or near-complete (≥75% removal Marder score with venography)</td>
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<tr>
<td>Composite: MAE at 30 days: all-cause mortality, major bleeding, PE, re-thrombosis of treated vein segment(s)</td>
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<tr>
<td>Secondary Objectives</td>
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<tr>
<td>Bleeding: access site complications; death; recurrent DVT</td>
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<tr>
<td>AVCS: Pain scale; Villalta; patency by duplex at discharge; 30 days, 6 mo, 1 and 2 years</td>
<td></td>
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<tr>
<td>Patients</td>
<td></td>
</tr>
<tr>
<td>Up to 500 patients total</td>
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<tr>
<td>Key Inclusion / Exclusion Criteria</td>
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<tr>
<td>Includes: Ages 18-75; lower extremity DVT in one or more vein segments from the IVC through popliteal vein</td>
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