Complications from Closure Devices

Zvonimir Krajcer, MD
Faculty Disclosures

Zvonimir Krajcer: Speakers’ Bureau – Abbott, BARD, Endologix, Teleflex, Medtronic

Dr. Zvonimir Krajcer has disclosed that the off-label use of Cross Seal, PerQseal, InClossure, Closer LB, Velox LB, Onyx will be discussed.

Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.
<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>Method of Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Vascular</td>
<td>Prostar™ XL</td>
<td>Braided suture</td>
</tr>
<tr>
<td></td>
<td>Perclose ProGlide®</td>
<td>Monofilament suture</td>
</tr>
<tr>
<td></td>
<td>StarClose™ SE</td>
<td>Nitinol clip</td>
</tr>
<tr>
<td>Cordis/Cardinal Health</td>
<td>ExoSeal®</td>
<td>Extravascular PGA plug</td>
</tr>
<tr>
<td></td>
<td>Mynx Control™</td>
<td>Extravascular PEG sealant</td>
</tr>
<tr>
<td></td>
<td>MynxGrip®</td>
<td>Extravascular PEG sealant</td>
</tr>
<tr>
<td>Cardiva Medical</td>
<td>Catalyst® II &amp; III</td>
<td>Kaolin, chitosan, &amp; protamine</td>
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<tr>
<td></td>
<td>Vascade®</td>
<td>Collagen</td>
</tr>
<tr>
<td>Morris Innovative</td>
<td>FISH™</td>
<td>SIS® arterial plug</td>
</tr>
<tr>
<td>Terumo</td>
<td>Angio-Seal™ VIP</td>
<td>Collagen plug &amp; anchor</td>
</tr>
<tr>
<td></td>
<td>Angio-Seal Evolution™</td>
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</table>

Current FDA-Approved Closure Devices (5-7Fr Sheaths)

Incidence of Vascular Complications: VCD vs Manual Compression (Studies in 10,000 or More Patients)

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th># Patients</th>
<th>Study Type</th>
<th>Complication Rates</th>
<th>VCD</th>
<th>MC</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tavris</td>
<td>2004</td>
<td>166,680</td>
<td>National Registry</td>
<td></td>
<td>1.1%</td>
<td>1.70%</td>
<td>&lt;0.001</td>
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<tr>
<td>Arora</td>
<td>2007</td>
<td>12,937</td>
<td>Single Center Registry</td>
<td></td>
<td>2.4%</td>
<td>4.90%</td>
<td>&lt;0.01</td>
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<tr>
<td>Applegate</td>
<td>2008</td>
<td>35,016</td>
<td>Single Center Registry</td>
<td></td>
<td>1.6%</td>
<td>2.1%</td>
<td>=0.03</td>
</tr>
<tr>
<td>Sanborn</td>
<td>2009</td>
<td>11,621</td>
<td>ACUITY post hoc</td>
<td></td>
<td>2.5%</td>
<td>3.3%</td>
<td>=0.01</td>
</tr>
</tbody>
</table>
RESPECT - Prospective, Randomized Clinical Trial

1810 FA procedures with 6Fr sheath

Device failure 8.34%
Minor complications 2.93%

Incidence of Access Site Vascular Complications that Require Surgery

Vascular Closure Devices¹,²
- Bleeding (~70%)
- Infection (~39%)
- Ischemia (~28%)
- Pseudoaneurysm (~20%)

Manual Compression¹,²
- Pseudoaneurysm (~71%)
- Hemorrhage (~32%)
- AV fistula (~15%)

Vessel thrombosis after the use of collagen-based closure device

- Know *how* and *when* to use the closure device!
- Each closure device has its potential problems!
- When complication occurs, be prepared to fix it!

Thrombolysis and mechanical thrombectomy
Learning Curve with VCDs

Fig. 5. Learning curve showing improvement of technical failure with increasing experience in system management.
Today’s Large Vessel Closure Devices (10-25Fr)

- Prostar XL® 10Fr braided SM VCD
  - Approved in EU for large-bore FA closure, but not in US
  - 1 device for 10-24Fr
  - Prolonged learning curve
  - Not extensively used

- ProGlide® 6Fr SM monofilament VCD
  - Approved in US for large-bore FA closure (12-21F)
  - Shorter learning curve
  - Commonly used
  - 2 devices

- MANTA® 14 & 18Fr
  - Approved in US for large-bore FA closure (12-25F)
  - Shorter learning curve
Causes of Complications with Prostar

• Device complexity (multiple steps, deployment angle, sliding knot technique)
• Anterior wall calcifications (needle deflection)
• Fibrosis (needle deflection)
• Morbid obesity (device too short)
• Poor marker lumen flow (laque, thrombus, tortuosity, narrow or diseased vessel, inadequate anticoagulation, low B)
• Operator inexperience with the device
• Faulty device (very rare)
Causes of Complications with ProGlide

- **Iliac tortuosity** (device is too short)
- **Anterior wall calcifications** (needle deflection)
- **Fibrosis** (needle deflection)
- **Obesity** (device is too short)
- **Poor marker lumen flow**
  - Plaque, thrombus, tortuosity, inadequate anticoagulation, low BP
- **Operator inexperience** with the device
  - Deployment angle, aggressive manipulation
- **Faulty device** (very rare)
Femoral Artery Complications with MANTA

- Iliac tortuosity
- Anterior wall calcifications
- Fibrosis
- Morbid obesity
- Operator inexperience with the device
  - Deployment angle, aggressive manipulation
- Faulty device (very rare)
Examples of Femoral Artery Complications with MANTA Closure Device

Dissection

Post-TAVR Thrombosis

Pseudoaneurysm
## Complications for LB VCD

<table>
<thead>
<tr>
<th>Studied Parameters</th>
<th>EU CE Mark Trial (N=50)</th>
<th>US IDE Pivotal Trial (N=263)</th>
<th>EU Post-Market Registry (N=719)</th>
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<tbody>
<tr>
<td>Technical Success</td>
<td>94%</td>
<td>97.7%</td>
<td>NA</td>
</tr>
<tr>
<td>VARC-2 Major Complications</td>
<td>2%</td>
<td>4.2%</td>
<td>1.9%</td>
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<tr>
<td>VARC-2 Minor Complications</td>
<td>0%</td>
<td>2.7%</td>
<td>2.4%</td>
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### Major Complications

<table>
<thead>
<tr>
<th>Type</th>
<th>Proglide</th>
<th>Prostar</th>
<th>Surgical</th>
<th>Composite</th>
<th>Manta</th>
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<tr>
<td>VARC-2</td>
<td></td>
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### Minor Complications

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Conclusions

• Proper patient selection, imaging and expertise are essential to avoid major access site complications

• When difficulty in advancing large-profile sheaths through iliac artery, anticipate complications (spasm, rupture, laceration, or avulsion)
  – Maintain wire access until hemostasis is achieved
  – Maintain contralateral FA access to inflate a compliant balloon in abd aorta or ipsilateral iliac artery
  – Identify the site and type of bleeding
  – Appropriate size endograft should be available for repair
  – Blood transfusion should be available
  – Surgical and anesthesia services should be available