The downside of vascular closure devices

George S. Chrysant, M.D. FACC, FSCAI, FSCCT  
Chief Medical Officer  
INTEGRIS Cardiovascular Physicians
Disclosures

Consultant:
• Abbott Vascular
• Boston Scientific
• Medtronic
• Philips

Medical Advisory Boards:
• Abbott Vascular
• Boston Scientific
• Medtronic
Femoral Arteriotomy Anatomy

- Anterior superior iliac spine
- Common iliac artery
- Inguinal ligament
- Os pubis
- Femoral artery
- Profunda
- Deep iliac circumflex
- Inferior epigastric
- SFA
Ideal Femoral Arteriotomy

- Stick location just inferior to midline of medial femoral head
- At least 2cm inferior to inguinal ligament (utilizing the inguinal crease is outdated)
- Fluoroscopic verification or ultrasound recommended
# Vascular Closure Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Type</th>
<th>Fr Range</th>
<th>CE Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostar® XL</td>
<td>Suture-based</td>
<td>8.5–10 Fr (off-label use &gt; 10 Fr)</td>
<td>Yes</td>
</tr>
<tr>
<td>ProGlide®</td>
<td>Suture-based</td>
<td>5–8 Fr (off-label use &gt; 8 Fr)</td>
<td>Yes</td>
</tr>
<tr>
<td>MANTA™</td>
<td>Collagen-based</td>
<td>10–14 Fr (14 Fr system)</td>
<td>Yes</td>
</tr>
<tr>
<td>PerQseal®</td>
<td>Patch-based</td>
<td>&lt; 24 Fr</td>
<td>Yes</td>
</tr>
<tr>
<td>InSeal</td>
<td>Membrane-based</td>
<td>14–21 Fr</td>
<td>Yes</td>
</tr>
</tbody>
</table>
ISAR-CLOSURE Trial

6289 Patients assessed for eligibility

1765 Excluded
833 Refused participation
677 Had a puncture below the common femoral artery
31 Vessel size of common femoral artery <5 mm
224 Other reasons

4524 Randomized

1509 Randomized to receive intravascular VCD
1493 Received intravascular VCD
16 Did not receive intravascular VCD

1506 Randomized to receive extravascular VCD
1491 Received extravascular VCD
15 Did not receive extravascular VCD

1509 Randomized to receive manual compression
1509 Received manual compression

1401 Completed 30-day follow-up
1393 Completed 30-day follow-up
1398 Completed 30-day follow-up

3015 Included in intention-to-treat analysis
2984 Included in per-protocol analysis

1509 Included in intention-to-treat analysis
1509 Included in per-protocol analysis

## ISAR-CLOSURE Results

<table>
<thead>
<tr>
<th>Vascular access site complications (primary end point)(^a)</th>
<th>No. (%) of Patients</th>
<th>Difference in Proportions, % (95% CI)</th>
<th>(P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular Closure Device (n = 3015)</td>
<td>208 (6.9)</td>
<td>-1 (-2.7 to 0.7)</td>
<td>&lt;.001(^b)</td>
</tr>
<tr>
<td>Manual Compression (n = 1509)</td>
<td>119 (7.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematoma ≥5 cm</td>
<td>145 (4.8)</td>
<td>-2 (-3.4 to -0.4)</td>
<td>.006</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>53 (1.8)</td>
<td>0.3 (-0.5 to 1.1)</td>
<td>.56</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>12 (0.4)</td>
<td>0.3 (-0.1 to 0.6)</td>
<td>.13</td>
</tr>
<tr>
<td>Access site-related major bleeding(^c)</td>
<td>3 (0.1)</td>
<td>-0.1 (-0.4 to 0.2)</td>
<td>.39</td>
</tr>
<tr>
<td>Acute ipsilateral leg ischemia</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Need for vascular surgical or interventional treatment</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local infection</td>
<td>1</td>
<td></td>
<td>.48</td>
</tr>
</tbody>
</table>

### Secondary end points

- **Time to hemostasis, median (IQR), min**
  - Vascular Closure Device: 1 (0.5 to 2.0)
  - Manual Compression: 10 (10 to 15)
  - \(P\) Value: <.001

- **Repeat manual compression**
  - Vascular Closure Device: 53 (1.8)
  - Manual Compression: 10 (0.7)
  - \(P\) Value: .003

---

# ISAR-CLOSURE: Female Subgroup


<table>
<thead>
<tr>
<th></th>
<th>Vascular Closure Device n=917</th>
<th>Manual Compression n=478</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary end point of vascular access-site complications*</td>
<td>79 (8.6)</td>
<td>47 (9.8)</td>
<td>0.451</td>
</tr>
<tr>
<td>Hematoma ≥5 cm</td>
<td>56 (6.1)</td>
<td>41 (8.6)</td>
<td>0.085</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>20 (2.2)</td>
<td>8 (1.7)</td>
<td>0.521</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>4 (0.4)</td>
<td>1 (0.2)</td>
<td>0.501</td>
</tr>
<tr>
<td>Access site–related major bleeding†</td>
<td>2 (0.2)</td>
<td>2 (0.4)</td>
<td>0.507</td>
</tr>
<tr>
<td>Acute ipsilateral leg ischemia</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Need for vascular surgical or interventional treatment</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Local infection</td>
<td>1 (0.1)</td>
<td>0</td>
<td>0.608</td>
</tr>
</tbody>
</table>

**Secondary end points**

<table>
<thead>
<tr>
<th></th>
<th>Vascular Closure Device n=917</th>
<th>Manual Compression n=478</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to hemostasis, min</td>
<td>1 (0.5–2.0)</td>
<td>11 (10–15)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Repeat manual compression</td>
<td>22 (2.4)</td>
<td>3 (0.6)</td>
<td>0.018</td>
</tr>
</tbody>
</table>
Issues with VCDs

- Recognize mechanism of complication
- Endovascular therapy
- Surgical therapy
Case 1: Perclose Used

Initial Procedure

2 Months Later
PTA and Provisional Stenting
Case 2

Angioseal used
“Cold leg”

6 hours after PCI
PTA and post- PTA angiogram
Final Angiogram
Conclusions

- VCDs are safe and effective
- When they fail, understand the mechanism of failure
- Some are appropriate for endovascular therapy
- Some are not...
The downside of vascular closure devices

George S. Chrysant, M.D. FACC, FSCAI, FSCCT
Chief Medical Officer
INTEGRIS Cardiovascular Physicians