Overview of Vascular Closure Device Complication Management

• Roger Gammon, M.D.
• Director of Research
• Austin Heart
Disclosures

Consultant:
• Covidien

Stockholder:
• TissueGen

Medical/Scientific Boards:
• Texans For Stem Cell Research
Access Site Issues

• Access site management is the primary event the patient can assess and remember from the encounter.

• Access site complications are the number one source of lawsuits following interventions.

• Bleeding consistently linked to mortality.

• Make a great entrance and a triumphant exit!
Transfemoral Access – Risk Factors for Complications

Patient Related

- Advanced Age
- Female Gender
- Small Vessel Size
- Low or very high BMI
- Renal failure
- Diabetes
- Vascular disease

Procedure Related

- Increased Sheath size
- High or Low Puncture Site
- Prior procedures
- Anticoagulation
- GPIIb/IIIa infusion
- Lytic Use
Potential Benefits of Closure Devices

Early ambulation – decreased bed rest

Patient (and nurse’s) comfort

Secure “closure”

But – Does not decrease overall complications rates

And may cause their own specific complications
Complication Rates: Meta analysis 30 studies


|                  | OR (95% CI)                  | Heterogeneity test
|------------------|------------------------------|----------------------
|                  |                              | P-value              |
| **Dx studies**   | 1.44 [0.43, 4.82]†           | 0.0003               |
|                  | 0.66 [0.18/, 2.38]*          | 0.16                 |
| **PCI studies**  | 1.11 [0.94, 1.33]*           | 0.22                 |
|                  | 1.35 [0.87, 2.11]*           | 0.15                 |
| **Both Dx+PCI studies** | 1.83[1.15,2.90]†        | 0.001                |
|                  | 1.15 [0.67, 1.98]*           | 0.43                 |
| **All studies**  | 1.34 [1.01, 1.79]†           | <0.0001              |
|                  | 1.30 [0.90,1.87]*            | 0.19                 |

Favors VCD

Favors Manual Compression
Closure Device Complications

Early Diagnosis
- Document pre-VCD deployment vascular exam
- Have staff evaluate distal pulse after deployment
- Evaluate the foot for temperature difference, pallor

Management
- Endovascular approach
- Surgery often best approach
Closure Device Complications

- **Infection**

- **Bleeding**
  - Device failure (or operator failure)
  - Exacerbated if anticoagulated
  - Hematomas, retroperitoneal hemorrhage, AV fistula, pseudoaneurysm

- **Vessel obstruction**
  - Direct mechanical – foot plates, plaque disruption, intimal dissection, thrombus development
  - Embolization of plugs, plaque, thrombus
• Surprising not more common after placing foreign body mixed with blood down in puncture wound in one of the most unsanitary places in the body.

• Practice good sterile technique

• Consider prophylactic antibiotics

• Major problem when it occurs and must be treated aggressively:
  • Surgical exploration and debridement
  • IV antibiotics
Bleeding--Prevention

- Take care with initial access
  - Fluoroscopy
  - Ultrasound
  - Micropuncture?

- Anticoagulation strategy

- Blood pressure control

- Patient and device selection
  - Femoral angiogram
Vascular Closure Devices

No footprint devices

Boomerang Closurewire/Catalyst
# Retroperitoneal Hematoma

## Table II: Independent Correlates of Retroperitoneal Bleeding

<table>
<thead>
<tr>
<th>Correlation</th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath placement superior to inferior epigastric artery\textsuperscript{a}</td>
<td>17.6</td>
<td>2.21–141.63</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female sex</td>
<td>3.73</td>
<td>2.55–5.43</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Angioseal\textsuperscript{TM}</td>
<td>2.80</td>
<td>1.95–4.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>GP IIb/IIIa inhibitor</td>
<td>1.92</td>
<td>1.31–2.82</td>
<td>0.001</td>
</tr>
<tr>
<td>Weight (per kg)</td>
<td>0.987</td>
<td>0.976–0.997</td>
<td>0.014</td>
</tr>
<tr>
<td>Acute MI</td>
<td>1.82</td>
<td>1.05–3.17</td>
<td>0.035</td>
</tr>
</tbody>
</table>
Transfemoral Access – Basics

Femoral Crease
Where is the Crease?

Perhaps This

Is this the Crease?

Courtesy
Dr Z Turi
Fluoroscopy Shows Impact of Pannus on Femoral Crease
Transfemoral Access – Basics

1. Inguinal Ligament - Demarcated by imaginary Line drawn from Anterior Superior Iliac Spine to the Pubic Symphysis

2. Inferior Border of the Femoral Head

“The Target” – Mid Femoral Head
Transfemoral Access – Ultrasound Assisted

A

B

C

SFA

PFA

FV

CFA

FV

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 3, NO. 7, 2010
JULY 2010:751-8
Transfemoral Access – Ultrasound Assisted

### Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Fluoroscopy (n = 501)</th>
<th>Ultrasound (n = 503)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma ≥5 cm</td>
<td>11 (2.2%)</td>
<td>3 (0.6%)</td>
<td>0.034</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Dissection</td>
<td>3</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Access bleeding, transfusion</td>
<td>2</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Hematoma with DVT</td>
<td>1</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Any complication</td>
<td>17 (3.4%)</td>
<td>7 (1.4%)</td>
<td>0.041</td>
</tr>
</tbody>
</table>

### Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Fluoroscopy (n = 500)</th>
<th>Ultrasound (n = 502)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of attempts</td>
<td>3.0 ± 3.2</td>
<td>1.3 ± 0.9</td>
<td>&lt;0.000001</td>
</tr>
<tr>
<td>First pass success</td>
<td>232 (46.4%)</td>
<td>415 (82.7%)</td>
<td>&lt;0.000001</td>
</tr>
<tr>
<td>Venipuncture</td>
<td>79 (15.8%)</td>
<td>12 (2.4%)</td>
<td>&lt;0.000001</td>
</tr>
<tr>
<td>Number of arterial punctures</td>
<td>1.14 ± 0.43</td>
<td>1.09 ± 0.36</td>
<td>0.076</td>
</tr>
<tr>
<td>Mean time to insertion, s</td>
<td>213 ± 194</td>
<td>185 ± 175</td>
<td>0.016</td>
</tr>
<tr>
<td>Median time to insertion, s</td>
<td>148 (102–242)</td>
<td>136 (90–212)</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Micropuncture Technique

A Novel, Minimally Invasive Access Technique Versus Standard 18-Gauge Needle Set for Femoral Access

Catheterization and Cardiovascular Interventions 79:1180-1185 (2012)
Femoral Angiogram

- Femoral angiogram at end of case may reveal dissection of iliac caused by catheter passage; may be easy to repair now.

- Be sure the sheath free of wall (or leave wire in for injection) or the injection itself may cause dissection.
Inferior Epigastric Artery Perforation

- Femoral angio at end of case may reveal branch perforation which may be easy to fix now and won’t be fixed by any closure device.
Management

Manual Compression (not compression device)
Analgesics
Volume resuscitation

If unable to control --- > Cath Lab or Surgery

Any significant hematoma should be evaluated for a pseudo-aneurysm
Active Bleeding from Puncture Site: Endovascular Repair

Contra-lateral access
Immediate balloon tamponade
Reverse or limit anticoagulation
Stent or covered stent (hopefully self-expanding)
Try to respect side branches
Options may be limited
Arteriovenous Fistula

• Rarely close spontaneously but may be asymptomatic

• Indications for repair:
  • Persistent tenderness
  • Leg edema
  • High output heart failure
  • Ischemia (vascular steal)

• Repair
  • Covered stent
  • Surgery
Pseudoaneurysm

- Symptoms: pain, swelling
- Signs: pulsatile mass, hematoma, bruit
Management of Pseudoaneurysm

• Groin US
• Small (<2cm) may spontaneously close (especially if no anticoag.)
• Prolonged compression may promote thrombosis and resolution of PA (must have pain control)
• Larger PA
  • Narrow neck → thrombin injection with US guidance
  • Wide neck → Surgery
• Repeat US
  • 2 wks if small, asymptomatic
  • Following day if injected
Closure Devices—Well that worked!
Treatment options

- Surgery
- Endovascular repair
  - Angioplasty
  - Atherectomy
  - Try to avoid stenting
  - No lytics
Closing Remarks
The Boomerang Wire is a novel device designed to assist in arteriotomy closure by providing temporary arterial tamponade through the use of a low-profile, nitinol disk deployed opposing the inner vessel wall through the existing arterial sheath. The disk is anchored to a 2 French wire and stabilized by a tension clip placed on the skin surface. After adequate dwell time to allow for physiological vessel wall constriction and reduction in anticoagulation, the disk is collapsed and removed leaving no foreign material behind.
Antegrade sheath removal with the Boomerang device following peripheral intervention

- Forty consecutive patients with antegrade sheath (6F or 7F) for peripheral intervention.
- All patients had severe PAD and were anti-coagulated.
- Sheath was removed with Boomerang device at end of intervention to allow antegrade blood flow and minimize compression force subsequently needed for hemostasis.

<table>
<thead>
<tr>
<th>Procedural challenges in addition to antegrade access</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients receiving ASA/Clopidogrel</td>
<td>100% (n=40)</td>
</tr>
<tr>
<td>Patients receiving periprocedural Heparin</td>
<td>82.5% (n=33)</td>
</tr>
<tr>
<td>Patients receiving periprocedural Bivalirudin</td>
<td>15% (n=6)</td>
</tr>
<tr>
<td>Patients receiving periprocedural Tirofiban</td>
<td>2.5% (n=1)</td>
</tr>
<tr>
<td>7 Fr. Femoral Access</td>
<td>77.5% (n=31)</td>
</tr>
</tbody>
</table>
Results:

- The Boomerang Wire was deployed at the end of the procedure and removed following a predetermined time interval (mean 139 minutes) to allow for the activated clotting time to fall below 180 seconds, followed by brief manual pressure (mean 16 minutes) and bedrest (mean 4 hours and 9 minutes).

*Data source: Randomized manual compression arm of Boomerang Vascular Management Trial II Results, 2008*
• Using this approach, 37 patients (92.5%) had successful sheath removal without complication. Two patients developed small hematomas (less than 4 cm). One device was removed early and that patient developed a large hematoma and pseudoaneurysm.
Thank You
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