Hemostasis of Antegrade Femoral Artery Access Using an Extravascular, Bioabsorbable Closure Device

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Disclosures

Speaker’s Bureau:
• None

Honorarium:
• None

Consultant:
• None

Stockholder:
• None

Grant/Research Support:
No Personal Financial Support
Clinical Trial Investigator for:
• W.L Gore & Associates, Inc
• C.R. Bard, Inc.
• Boston Scientific
• Juventas Therapeutics
• Boehringer Ingelheim
• Intelligent Delivery Systems, LLC

Medical/Scientific Boards:
• None
Antegrade Access Adoption is Growing

• Driven by growth in CLI procedures in patients with distal vessel disease

• Advantages of antegrade approach:
  • Steerability / pushability
    - Only one vector force
  • Equipment length
    - Can reach the distal pedal vessels
  • ↓Radiation, contrast
  • Patient comfort
Why Antegrade Access?

Kissing aorto-iliac stents

EVAR

Aorto-bifem grafts

Extreme angulation
Disadvantages with Antegrade Access?

• ↑ Risk of complications
  → Stick too high retroperitoneal bleed
  → Stick too low AV fistulas, pseudoaneurysms
• Steep learning curve
• More challenging to achieve hemostasis with manual compression or vascular closure devices

Bleeding complications increase healthcare costs
\[ \approx 5400 \]

Antegrade PVD Study

• A Multi-Center, Prospective, Post-Market Registry to Evaluate Procedural Outcomes Data Using the Cardiva VASCADe Vascular Closure System (VCS) for the Management of the Femoral Arteriotomy After Percutaneous Endovascular Procedures Via Antegrade Access

• ANTEGRADE PVD is the first prospective, multi-center study to evaluate a vascular closure technology with antegrade access in peripheral arterial interventions.
VASCADE – Vascular Closure System

Current Labeling
- 5-7 french arterial closure

Extravascular Design
- Nothing left behind in the vessel

Collagen Plug
- Thrombogenic material
- Soft, expands to fill tissue tract

Simple deployement
- Single operator
- No sutures, no material in the vessel

FDA approved
Over 120,000 Devices Distributed
RESPECT Study
Published in Journal of Invasive Cardiology

Study Design
• Multi-center – 420 patients, 20 sites
• Randomized, controlled
• Both interventional and diagnostic procedures

Study Outcome
• Statistical superiority on reduced bleeding complications
  • VASCADE: 1.1%
  • Manual compression: 7.0%
Only closure device to ever demonstrate reduced complications
VASCADE Deployment
Vascade Antegrade Deployment
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<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Mehdi Shishehbor, MD</td>
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ANTEGRADE PVD Registry

• Prospective, single arm registry – 100 patients
• Multi-Center – 5 enrolling US sites

• Entry criteria
  • Non-emergent ipsilateral peripheral interventional endovascular procedure
  • Antegrade access
  • 5, 6 or 7 French introducer sheath
  • Acceptable candidate for post-procedural manual compression
  • Able and willing to complete follow-up office visit and telephone assessments
  • Able to ambulate at least 20 feet, with or without assistance
ANTEGRADE PVD Registry

- Primary procedural outcome – performance
  - Time to hemostasis

- Secondary procedural outcomes – performance
  - Time to ambulation
  - Time to hospital discharge
  - Device success
  - Procedure success
ANTEGRADE PVD Registry

• Primary procedural outcome – safety
  ➢ Major Complications
    • Access site closure-related bleeding requiring transfusion
    • Vascular injury requiring repair
    • Others

• Secondary procedural outcomes – safety
  ➢ Minor Complication
    • Access site-related bleeding requiring > 30 minutes to hemostasis
    • Access site-related hematoma > 6 cm
    • Other defined complications not meeting the definition of primary
Study Status

• All 5 centers enrolling
• 33 patients enrolled to date
• 97% device success rate to date
• Full enrollment expected in 2017
Personal Experience with Antegrade Vascade Closure

- Closure has been successful on a wide spectrum of patients
  - Obese
  - Calcified vessels
  - 6Fr and 7Fr access
  - Fully anticoagulated – including GP IIb/IIIa inhibitors and thrombolytics

- In calcified vessels, we recommend brief fluoroscopic visualization to ensure proper deployment

- Among our most experienced Vascade operators (Cardiovascular Institute of the South, Houma, Louisiana) successful antegrade closure rates approach 100%

Practice Makes Perfect!!!
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