Femoral Closure Devices: Good, Bad and Ugly

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Disclosure Statement of Financial Interest

<table>
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<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>Grant/Research Support</td>
<td>Abbott Vascular</td>
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<td>Arstasis</td>
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<td>Cordis/Johnson and Johnson</td>
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<td>Vasorum</td>
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<td>Consulting Fees/Honoraria</td>
<td>AccessClosure</td>
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<td>Cordis/Johnson and Johnson</td>
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<td>St. Jude Medical</td>
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Manual Compression

- Discomfort
- Cost?
- Morbidity associated with prolonged bedrest and compression
Mechanical Compression
The mechanical fellow

A fellow is cheaper – Bill Grossman
The Promise of Vascular Closure Devices

- Patient comfort and convenience
  - Early ambulation
  - Early hemostasis
- Decrease complication rate
Categories of closure devices

- Anchored plugs
- Unanchored plugs
- Suture closure
- Clip/staple closure
- Topical patches
- “No footprint” devices
- Closure begins with access
Anchored Plugs

Active Approximation

Angio-Seal

Thrombosing agent

+ High success rate, short learning curve, short deployment time
- Vascular occlusion, infection
Suture or Staple/Clip Devices

Active Approximation

Perclose
StarClose

No thrombosing agent
Preclosure

12F

18 - 24 F

12 – 24 F

15 – 18 F
Preclosure Success Rates


French Size

Surgery n = 258
Success = 93.8%

Percutaneous Endovascular Aortic Aneurysm Repair (PEVAR): Results from the First Prospective Multicenter Randomized Trial

Peter R. Nelson, MD, MS
Unanchored Plugs

- Passive approximation

Thrombosing agent
Unanchored Plugs

1994-2006

VasoSeal and Duett no longer marketed
Return of the Unanchored Plugs?

- Passive approximation

+ Through procedure sheath, simplified, resorption
- Passive approximation

- Sealing agent
No footprint devices

- Passive approximation

Boomerang Closurewire/Catalyst

- Mix of thrombosing materials

no foreign body
Vascade

- Passive approximation
- Collagen plug

Apply Gentle Compression
Remove Device
Continue Compression to Achieve Final Hemostasis

- Thrombosing agent
Arstaotomy Procedure

Micropuncture access

Heel deployed

Heel secured against vessel wall

Arstaotomy Needle Port
Procedure sheath is then inserted and cath performed.
Tissue Track Seals with Hydrostatic Pressure

No footprint device
FISH
Femoral Introducer Sheath and Hemostasis

Small Intestinal Submucosa
A Few Novel Technologies

Closer™
Vascular Sealing System
Topical Patches

- Passive approximation

NONINVASIVE

Chito-Seal, Clo-Sur P.A.D., V+PAD, D-Stat, Neptune, Stasys, Syvek

Thrombosing agents
Complication Rates


**OR (95% CI)**

- **Dx studies**
  - 1.44 [0.43, 4.82]†
  - 0.66 [0.18/, 2.38]*

- **PCI studies**
  - 1.11 [0.94, 1.33]*
  - 1.35 [0.87, 2.11]*

- **Both Dx+PCI studies**
  - 1.83[1.15,2.90]†
  - 1.15 [0.67, 1.98]*

- **All studies**
  - 1.34 [1.01, 1.79]†
  - 1.30 [0.90,1.87]*

**Heterogeneity test**

- P-value
  - 0.0003
  - 0.16
  - 0.22
  - 0.15
  - 0.001
  - <0.0001
  - 0.19

**Favors VCD**

**Favors Manual Compression**

*If VasoSeal was excluded, no difference*
Vascular Closure Devices

Early hemostasis, early ambulation

ACUITY

Sanborn Circ CI 2009

Class III indication – VCD use to lower complication rates
Some complications – infection, RPH - clearly ↑
Where I think twice -

- Diabetes, immune suppressed, poor hygiene
- Too thin, too fat
- ≤ 5F
- Low stick, high stick
- Significant vascular disease
Why Femoral Infections

- Bacteria friendly region
- Failure to maintain good sterile technique
- Insertion of foreign body in tissue track
- Sheath left indwelling
- Blood in deep track is great culture medium
Infections

- 0.3%
- Median incubation – 8 days
- Staph aureus 75%
- BC + 86%
- Diabetics 80%
- PSA 42%
- 6% mortality

Sohail Mayo Clinic Proceedings

Courtesy Dr. John Eidt, UAMS.
Which Device to Use?

- Patient and vessel specific:
  - Fully anticoagulated
    - Active approximation?
  - Diseased vessel
    - Passive approximation?
    - No intraluminal foreign body
  - Oozing
    - Thrombosing or sealing agent, patch
- Perhaps more important than above:
  - Operator competence

Between device evidence base is poor
The Evidence Base

• Complication rate manual compression = vascular closure device, but some complications (infection, RPH are additive)
• Patient preference
• Relative cost savings with shorter length of stay and less management outside cath lab
Complications of Vascular Closure Devices—Not Yet Evidence Based

The interesting publication by Dias et al. [1] claims to compare arteriotomy closure devices with various reentry coronary intervention. Unfortunately, the “evidence” that can be extracted from this article is not very compelling.

The Road to Perfect Closure—Still Unpaid

Pitfalls Everywhere: 60 Years and Still Poking Blindly

Sixty years after Seldinger’s original publication (for angiography was performed. It is puzzling that this is still routinely shipped by many institutions and remains unsolved [1]. The current series of 8 cases includes 1 closure when sheaths were placed in the superficial femoral and external iliac arteries. The former is all labeled so that occasionally makes clinical sense. The operators close angiography after angioplasty of the SFA to avoid compression and transient closure across a small angio-link site. However, the SFA is frequently small, and the Proctor device is not designed to be used in arteries that are <5