New Developments In Access Site Closure For Small Sheaths; For Large Sheaths

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Disclosures
• NONE

Background
• Vascular closure devices (VCD) have been in use for more than 20 years
• Manual compression still considered gold standard
• VCD associated with higher complication rates than manual compression in closure device trials
• No ideal device present to handle all types of morphologies (calcified vessels, soft plaque, scar)

Vascade VCD and CELT Arterial Closure Device (ACD)

Vascade VCD Steps

CELT ACD Steps
Are the 2 devices comparable?

**Vascade VCD**
- Extravascular
- Nitinol Disc mediated internally
- Collagen material - swells creating plug
- Apply gently manual pressure for 5-7 minutes for tract ooze
- Ambulation time: 2 hours

**CELT ACD**
- Extravascular
- Stainless Steel internal disc
- External clip cinching adventitia closed
- Apply gentle pressure for 2-3 minutes for tract ooze
- Ambulation time: immediate-20 minutes

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**Data for Vascade**
- RESPECT Trial
  - Randomized 420 patients to Vascade or Manual Compression (MC) at 21 centers
  - 278 Vascade and 142 Manual compression
  - Time to Hemostasis: 3 min vs 21 min
  - 30 day outcomes assessed
  - No Major complications
  - Minor Complications: 1.1% vs 7%
  - First trial to show better results with a VCD vs MC
  - Limitations: patient’s with complex femoral anatomy and/or renal insufficiency were excluded

**Data for CELT ACD**
- CELT ACD Trial:
  - Randomized 207 patients to CELT and Manual Compression at 5 centers
  - 148 CELT and 59 MC
  - Time to Hemostasis: 0 min vs 8 min
  - 30 day outcomes assessed
  - 1 complication in CELT arm: embolization of device successfully retrieved percutaneously
  - 0 complications in MC
  - Complication rate: 0.7% vs 0%

**Pros and Cons: Vascade VCD**

**Pros**
- Extravascular
- Easy visualization on US imaging
- Utilize antegrade and retrograde
- Absorbable
- Versatile - can be used in moderate calcification
- Safe
- Low Pain
- Immediate restick possible

**Cons**
- Conventional Bedrest Time (at least 2 hours)
- Passive Closure may require additional compression time
- Can create scarring of the artery making surgical dissection challenging
- Can be difficult to manipulate through densely calcified vessels
- Some discomfort with deployment of device

**Pros and Cons of CELT ACD**

**PROS**
- Instant Definitive Closure in ALL Patient Types, notably calcified arteries
- Easily visible with US imaging
- Can visualize device after deployment
- 2 discs connected by a spindle - extravascular
- Immediate Ambulation
- Can be used in antegrade/retrograde approach and calcified arteries
- Safe
- Immediate Restick Possible
- Minimal scarring limited to disc area only

**CONS**
- Permanent implant - not absorbable
- There is a learning curve with the device
- Care in manipulation required through densely calcified vessels
- Some discomfort with deployment of device

**Christie Clinic Experience with VASCADE**

- Non-randomized prospective single center and single arm trial
  - Retrograde and antegrade femoral artery access
  - TTh, TTa, TTd, device success, minor/major complications
  - Vascade use assessed at 7 days post deployment
  - Results:
    - 300 Consecutive patients (204 males and 96 females) enrolled and all followed up at 7 days
    - 213 retrograde and 87 antegrade access
    - Heparin utilized in 96% cases (avg 3700 units) and 100% 6F sheath use
    - TTh 4.7 minutes, TTa 2.1 hrs, TTd 2.4 hrs, device success 99.3%, Minor complications 0.25% (6/300), NO major complications
    - 4 hematomas noted and 2 devices failures due to technical error in deployment
Christie Clinic Experience with CELT ACD

- Non-randomized prospective single center and single arm trial
- Retrograde and antegrade femoral artery access
- TTh, TTa, TTd, device success, minor/major complications
- All patients assessed at 7 days post deployment

Results

- 400 consecutive patients enrolled (263 males/137 females)
- 232 retrograde CFA, 168 antegrade (91 CFA, 68 prox SFA, 9 mid-distal SFA)
- Heparin utilized in 96% cases (avg dose 4200 units) and 100% 6F sheath use
- TTh: 3.8 min, TTa 18.3 min, TTd 38.4 min, device success 99.25%, minor complications 0.5% (2/400)
- Major complication 0.25% (1/400)- embolization of device successfully retrieved percutaneously with snare
- Access was retrograde CFA in all 3 cases

Conclusions

- Both devices are safe and effective in use for both retrograde and antegrade access
- These devices clearly are comparable to manual compression and some instances superior to MC
- They are cost effective devices and increase throughput in the cath lab or the OBL setting