Prospective evaluation of the CELT arterial closure device in an outpatient based catheterization laboratory

Syed M Hussain MD

Director of Vascular & Endovascular Surgery

Vein & Vascular Center at Christie Clinic

Clinical Asst Professor of Surgery

University of Illinois Carle College of Medicine

Champaign, Illinois

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Disclosure

- ❑ I have NO potential conflicts of interest to report:

Background

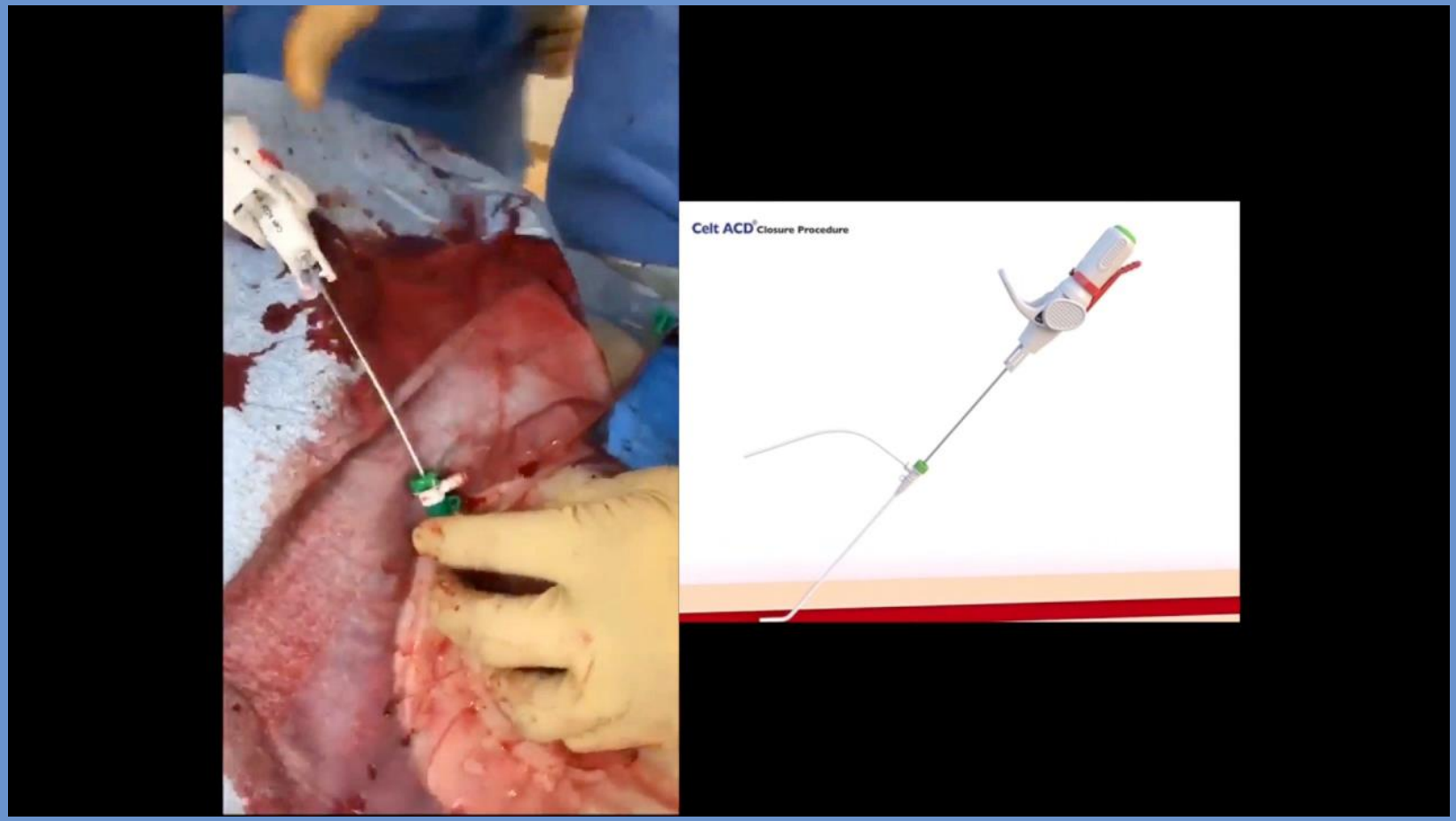
Vascular closure devices (VCD) have been in use for more than 20 years

Manual compression still considered gold standard

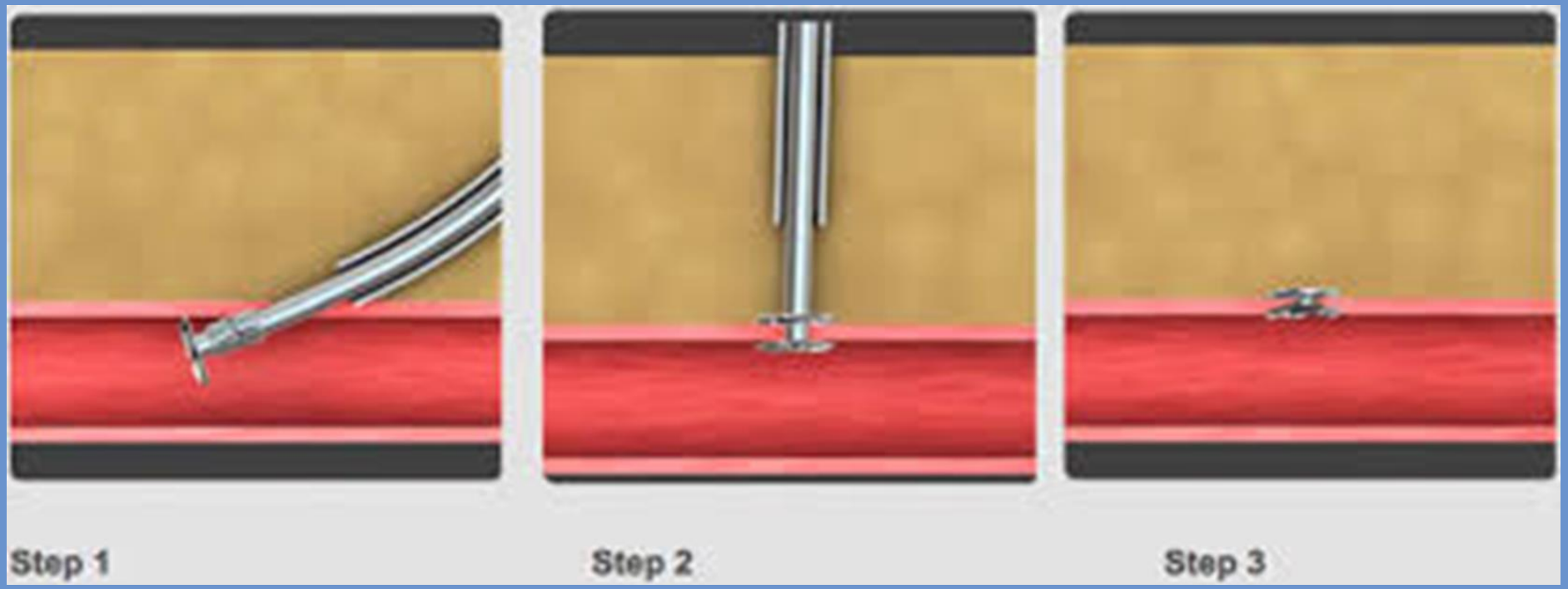
VCD associated with higher complication rates than manual compression in closure device trials

NO ideal device present to handle all types of morphologies (calcified vessels, soft plaque, scarred groins)

Deployment Video



CELT Closure Steps



CELT device details

- Extravascular
- Stainless steel internal and External disc
- Post in between to “cork” the arteriotomy
- Manual pressure for 2-3 minutes to stop tract ooze
- Ambulation time: immediate -20 minutes

Pros and Cons of CELT

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 is extravascular over time (endothelialization)
- 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

Data for CELT in a hospital setting

- 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%

Out-Patient Office Based Catheterization Laboratory (OBL)

- Rapidly expanding concept in the USA
- Approximately 800 OBL are operational in the USA
- Patient safety, satisfaction, efficiency, and excellent outcomes are paramount
- Closure technique of arterial puncture is vital for optimum patient satisfaction and throughput in the OBL

Christie Clinic CELT Experience

- Methods:
  - Prospective non-randomized single center single arm trial
  - Retrograde and Antegrade Common femoral and superficial femoral artery access
  - Evaluated Time to Hemostasis (TTh), Time to Ambulation (TTa), Time to Discharge (TTd), device success, minor and major complications
  - All patients were assessed at 7 days post procedure

RESULTS

- 400 consecutive patients enrolled (263 males/ 137 females)
- 232 retrograde CFA, 168 antegrade access (91 CFA, 68 prox SFA, 9 mid-distal SFA)
- Heparin utilized in 96% (384)cases (avg dose 4200 units)
- 6F sheaths used in all cases
- TTh: .1 min (0-10 seconds)
- Tta: 17 min (5-25 min)
- TTd: 33min (22-48 min)
- Device success 99.75% (399/400)
- Minor complications: 0%
- Major complication 0.25% (1/400)- embolization of device on 2nd case successfully retrieved percutaneously with snare
- Retrograde access of CFA in complication

Conclusion

- CELT ACD is a safe and effective alternative to current closure modalities
- It facilitates conventional as well as non-conventional access approaches (e.g. direct SFA antegrade) to address a larger patient population
- Care should be taken during positioning to minimize risk
- Immediate ambulation is evolutionary leap forward in patient care/satisfaction as well as patient care economics