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Original Article

Access closure innovations

Ramesh K. Adiraju

RENU-CA Research Institute, Bristol, Pennsylvania USA

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ABSTRACT

Vascular access management is an important aspect of endovascular procedures. Optimal access closure not only prevents immediate complications but has long term implications for mortality and morbidity. Early ambulation and decreased length of hospital stay benefit patient comfort and decrease overall cost of the procedures.

Vascular access closure and hemostasis after percutaneous endovascular interventions is a constant problem. While industry evolution of downsizing guide catheters has helped reduce vascular complications, parallel evolution of interventional devices with their limitations to sheath and guide catheter size and newer anticoagulation protocols have kept the problem alive.[1] Complex peripheral vascular disease, older patients and high dose anticoagulation compound the problem. Increasingly, endovascular procedures are performed in older patients with diffuse peripheral vascular disease. Manual compression is the good old gold standard but is laborious and high risk for bleeding complications in anticoagulated patients. Manual compression also has many limitations such as the interruption of anticoagulation, prolonged bed rest, patient discomfort, and time demands from healthcare providers and delayed hospital discharge.

Immediate access site hemostasis and early ambulation have been of prime importance post percutaneous interventions.[2] These goals, while achieving patient comfort, also have cost benefits with reduced hospital stay and less complications. Evolution of technology with regards to access closure solutions has been predominantly on three fronts:

(1) Smaller access catheters
(2) Vascular closure devices
(3) Alternate access sites predominantly radial access Smaller access catheters have the benefit of less bleeding risk; however, anticoagulation during PCI predisposes to bleeding complications even with smaller access catheters. With peripheral interventions and device usage, larger access catheters cannot be avoided. Peripheral arterial disease also predisposes to increased bleeding complications. Radial access is convenient for the patient and has less bleeding complications. Radial access has several limitations: device selection, size limitation when doing complex interventions, patient eligibility, vasospasm and vascular thrombosis. Vascular access closure devices have therefore been developed to address the problems of bleeding after percutaneous interventions in anticoagulated patients to improve patient comfort and safety along with early ambulation and decreased length of hospital stay.

Vascular closure devices (VCD) are mainly passive and active types.

Passive closure devices are external. There are predominantly two kinds of devices that have been used:

(1) Compression devices: Femstop, ClampEase, Safe guard. They are not reliable. Failure rate is 5–19%. They are adjunct devices that can be used with manual compression.
(2) Hemostasis pads: Chito-seal, Clo-sur pad, Syvek patch, Neptune pad, D-stat dry. Not reliable in anticoagulated patients.

Active closure devices

In early 1990s, the vascular complication rate after percutaneous interventions was around 6% with 25% incidence of blood transfusions and 20–38% need for surgical repair. Since the early 1990s to current times, the evolution of vascular closure devices has been from suture devices to intravascular devices to extravascular closure devices. With the usage of VCDs, vascular complications from PCIs has dropped to 2%. The importance of vascular complications is evident by the fact that the 1 year mortality in patients post PCI with vascular complications is 7.5% compared to 1.1% in patients without vascular complications. The economic burden of vascular complications is also

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very steep. The cost of hospital stay after vascular complication doubles, 9500 to over 18,000/case. Active closure device usage according to a 995 hospital registry between 2004 and 2008 was 42% over 1.5 million PCIs. There have been reports in literature showing declining complications with usage of VCDs but in select groups of patients (Northern New England Cardio Vascular Disease Study group 3.7% to 1.96%, 2002 to 2006). J. Popma and Resnic in 2001 demonstrated a (5.53 to 3.03%) decline in vascular complications in anticoagulated patients undergoing PCI; however only 1485 out of 3151 patients qualified for VCDs. D.J. Maenka and Piper (2007) demonstrated 42% reduction in vascular complications with VCDs, but again, only in select group of patients. These studies highlight the fact that VCDs are not for all comers. Virtually all studies of VCDs specifically exclude patients with small or diseased arteries. Therefore most interventionists tend to avoid using VCDs in these patients.[3]

After 25 years of collective experience with VCDs, the safety and efficacy of VCDs still remains controversial. Some VCDs have been shown to increase the risk of abrupt vascular complications and limb ischemia. Surgical intervention and increased risk for infections have also been reported with some devices. The analysis by Tavris et al. is the best available data which shows both IVCDs and EVCDs decreased the incidence of vascular complications when compared to manual compression. There are no large scales clinical trial data with long term follow up to demonstrate the efficacy of VCDs. Neither are there clinical studies demonstrating the usability of VCDs in all comers without patient selection bias. This begs the questions – do the benefits outweigh the risks? Are all devices created equal? Is there a device that can be used universally in all cases? There is no conclusive literature on the efficacy of VCDs nor is there clear comparison of different VCDs. It is also important to note that the efficacy and success of VCDs is dependent on various factors such as:

Patient population characteristics – age, DM, PAD, other co-morbidities.

Procedural characteristics – device type, disease complexity.

Anticoagulation.

Operator experience – learning curve.

Active closure devices are predominantly three types:

(1) Suture closure devices.
(2) Intravascular closure devices.
(3) Extravascular closure devices.

An ideal vascular closure device can be defined as one that is:

(a) Easy to use, simple design, safe
(b) Extravascular with no disruption of the endothelial lining (Peace of mind with no piece left behind). This is particularly important for patients with peripheral vascular disease.
(c) Safe to re-access the site immediately[12]
(d) No device related complications
(e) Can be used in all types of patients
(f) Inexpensive Vascular access site hemostasis after percutaneous endovascular interventions is a very essential requirement for successful completion of the procedure for several reasons.

1. Minor access site bleeding:

- Prolonged hospital stay
- Hinder optimal anticoagulation post intervention
- Distress and discomfort for the patient
- Increased cost for the procedure

1. Major bleeding:

- Risk for abrupt life threatening complications such as uncontrolled blood loss, stent thrombosis from reversal of anticoagulation
- Surgical intervention
- Increased morbidity and mortality with increased patient distress
- Increased costs and prolonged hospital stay

1. Benefits:

- Early ambulation
- Patient comfort
- Early discharge and decreased hospital length of stay
- Preserving the access site for future re-access

Suture closure devices: Perclose, Prostar

- Advantages:
  Standard vascular technique
  Wide range usage 6–10 French. However increased break through bleeding with larger French access
- Disadvantages:
  Operator learning curve
  Device failure particularly in PAD patients, calcified vessels and deep vascular access
  Vessel and endothelial damage

Intravascular closure devices:

Absorbable plug devices. Cardiva catalyst (boomerang), Angioseal (collagen plug with absorbable anchor pad)

Metal clips: Star-close, Angiolink.

- Advantages:
  Ease of deployment
  Early ambulation, patient comfort
- Disadvantages:
  Intra-vascular foreign body
  Local reaction with patient discomfort
  Infection
  Thrombosis with abrupt vessel closure. 33% increase incidence of urgent surgical exploration with increased morbidity and cost.
  Embolization
  Endothelial disruption and delayed scarring
  Device failure. Not suitable for all comers. Patient selection limitations. Some experience on use of two simultaneous angioseals for larger French access sheaths reported.
  Learning curve. High failure rate in peripheral vascular disease patients.
  Immediate re-access of the site not safe.

Extra-vascular closure devices: Mynx – Collagen plug, Vaso-seal (obsolete).[4]

- Advantages:
  Ease of deployment. Requires less skill. Practically no learning curve.
  Extra-vascular device with disruption of the endothelium and foreign body left behind
  Early ambulation
  No risk for abrupt vascular complications such as embolization and thrombosis requiring surgical exploration.
  Can be used in all types of patients. No contraindication in PAD patients

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