An Examination of Arterial Closure Devices

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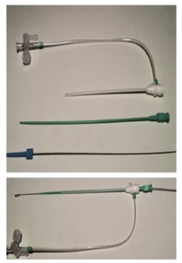
Introduction

- "Cardiac catheterization is the insertion and passage of small plastic tubes into arteries and veins to the heart to obtain x-ray images of coronary arteries and cardiac chambers and to measure pressures in the heart" (Sorajja et al., 2020, p. 1).
- There are several cardiac catheterization procedures that would require arterial access such as: left heart catheterizations, angioplasty, percutaneous coronary interventions, biopsies, intravascular ultrasound, transaortic valve replacement, etc.
- Blood pressure within the arterial system is higher than the pressure in the veinous system. Due to this fact, manual pressure or the use of vascular closure devices must be used to achieve hemostasis within these vessels (Moscucci, 2020).



Top: Vascular Sheath with dilator and guide wire. Creates arterial openings for catheters (Moscucci, 2020, p. 265)

- Additionally, the anticoagulant drug heparin is used regularly during catheterization procedures to slow the clotting time of the patient's blood. This reduces the likelihood of an embolism. However, heparin also increases the need for vascular pressure post procedurally while this medication is being filtered from the body (Sorajja et al., 2020).
- While manual compression is still considered the "gold standard" in achieving hemostasis, there are many vascular closure devices on the market that have shown to be a safe and reliable way to stop arterial bleeding after a catheterization has been performed. (Rao & Agasthi, 2023).
- Utilization of these closure devices have reduced the amount of time technologists must spend with patients, allowing cath labs to perform a greater number of cases per day while simultaneously decreasing the amount of bed rest required of patients following a procedure (Rao & Agasthi, 2023).
- Arterial closure devices may fall under one of two categories:
  - Active or passive

Radial Artery Closure Devices

- The radial artery is quickly becoming the most frequently chosen site for arterial access for a multitude of reasons:
  - Smaller vessels reduce the likelihood of major bleeding complications (Costa & Scalise, 2019)
  - The artery is more superficial allowing for quicker access and greater ease of post procedural compression (Costa & Scalise, 2019)
  - Although there are several benefits to using the radial artery as the chosen access site over the femoral artery, this is not without its risks.

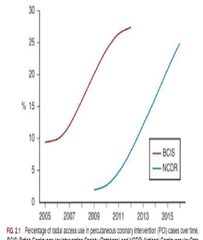


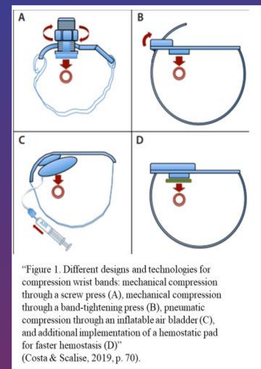
FIG 3.1 Percentage of radial access use in percutaneous coronary intervention (PCI) cases over time. BCIS: British Cardiovascular Intervention Society (Database) and NCDR: National Cardiovascular Data Registry

This graph demonstrates the increase in use of the radial artery for PCIs, a procedure in which a stent is placed within an occluded artery to allow for greater blood flow (Sorajja et. al, 2020, p. 20).

- "Despite being safe in most cases, radial artery catheterization has been shown to be almost invariantly associated with acute wall injuries, including radial artery acute dissection, pseudoaneurysm, and thrombus formation" (Costa & Scalise, 2019, p. 67).

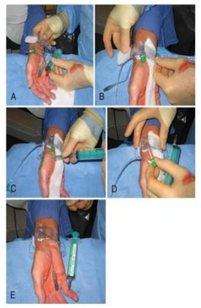
- Compression has proven to be the safest means by which to achieve hemostasis of the radial artery due to its small diameter. There is a plethora of radial bands available on the market. While these devices have different mechanisms of function, they all work by applying compression to the radial artery after a sheath has been removed (Costa & Scalise, 2019).

- "The main design of compression devices include (1) tourniquet, screw-based compression of a hard surface toward the radial artery; (2) mechanical compression obtained by the adjustable size of the wristband that closes up, which augments the local compression to the radial artery; or (3) localized compression of an air-inflatable bladder included in the wristband that can adjust the amount of pressure exerted on the radial artery by regulating the amount of air introduced in the system" (Costa & Scalise, 2019, p. 68).



"Figure 1. Different designs and technologies for compression wrist bands: mechanical compression through a screw press (A), mechanical compression through a band-tightening press (B), pneumatic compression through an inflatable air bladder (C), and additional implementation of a hemostatic pad for faster hemostasis (D)" (Costa & Scalise, 2019, p. 70).

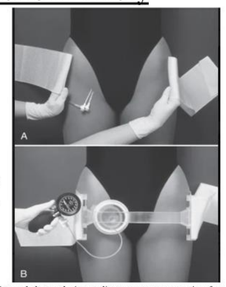
- Demonstration of the application of a radial band which utilizes pneumatic compression to achieve hemostasis of the radial artery
- (A & B) The band is wrapped tightly around the wrist and over the access sheath
- (C) A syringe is used to put air into the band to apply compression
- (D) The sheath is pulled from the patient's radial artery and the puncture site is examined for bleeding
- (E) The wrist is inspected for any signs of hematoma. The patient will be sent with the syringe and air will be taken from the device approximately 1.5-2 hours later (Sorajja et al., 2019)



(Sorajja et. al, 2019, p. 109)

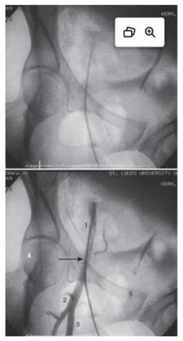
Compression Device for Femoral Artery

- Compression devices for the femoral artery work similarly to the compression devices used on the radial artery, just on a larger scale.
  - Femoral closure devices have a large band that wraps around the hips of the patient.
  - A large bubble presses into the puncture site where the sheaths were inserted.
  - An inflation bulb similar to one found on a sphygmomanometer connects to the bulb via a hose. This allows insertion of air into the bulb for the purpose of increasing or decreasing pressure within the bulb.
  - The gauge on the inflation bulb allows the technologists to precisely determine the psi within the bulb.



Femoral closure device applies pressure to access site after sheath removal (Sorajja et al., 2020. p. 95).

- The increase in diameter of the femoral artery correlates to a more diverse selection in arterial closure devices for this access site. Devices used to obtain hemostasis of the femoral artery include but are not limited to compression based, suture based, collagen based, patch based, and membrane based.
- While manual compression is largely considered the vascular closure devices achieve hemostasis of the femoral artery more quickly than manual compression, making them the premier choice when dealing with large bore arterial openings. (Rao & Agasthi, 2023).
- As with radial closure devices, arterial devices are not without risks. Some of these risks/complications include groin infection, ischemia, bleeding, hemorrhage, and the formation of pseudoaneurysms.



Angiogram image of sheath being inserted into the femoral artery (Moscucci, 2020, p. 84).

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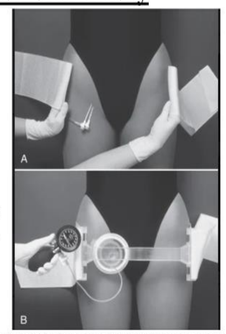
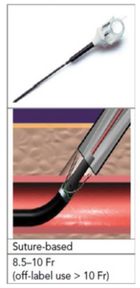


Femoral closure device applies pressure to access site after sheath removal (Sorajja et al., 2020. p. 95).

Suture Based Femoral Closure Devices

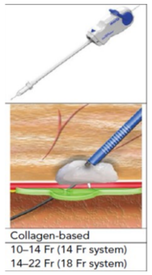
- According to van Weichen et al. (2019, p. 19), "The vast majority of large-bore vessel closure is performed by percutaneous suture- based techniques."
- Many of these devices utilize a pre-close technique. This means that the sutures are put in place around the arterial opening prior to the procedure, allowing the cardiologist to immediately tie the suture knots upon completion.
- "Suture devices are inserted directly into the site of the arteriotomy with the help of a guidewire. A marker with pulsatile blood flow ensures that the device is in the arterial lumen. Pressing a lever at the edge of the device deploys a footplate with suture cuffs on each side, which house the suture loops. Pushing the plunger deploys the needles from the device, which pierces through the artery wall on either side of the arteriotomy site and comes in contact with the suture cuffs. Upon retraction of the needles and the device, the suture ends follow, going through the artery wall on opposite sides of the artery access site. The sutures are retrieved, tied, and pushed toward the access site" (Rao & Agasthi, 2023, Active Femoral Vascular Closure Devices, para. 4).



Suture based closure device (van Wiechen, 2019, p. 19).

Collagen Based Femoral Closure Devices

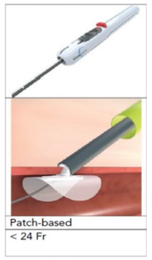
- Collagen based closure devices work by compressing a collagen plug on the exterior side of the artery.
- "The device is held in position for 30 to 45 seconds to allow for hydration of the collagen. After this, a push rod is required to separate the device from the collagen plug that is now deployed into the tissue. After applying pressure and deflating the disk, the device can now be removed. The collagen plug remains in place and offers appropriate tissue healing and hemostasis" (Rao & Agasthi, 2023, Active Femoral Vascular Closure Devices, para. 2).
- The collagen plug will eventually be broken down and absorbed by the body.
- The disadvantage of collagen plug devices when compared to suture devices is that the access site cannot be reopened once the device has been deployed.



Collagen based closure device (van Wiechen, 2019, p. 19).

Patch Based Femoral Closure Device

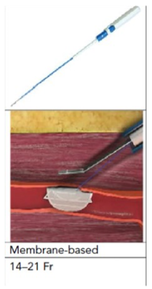
- Some vascular closure devices work with a simple patch system that is deployed within the vessel and adheres to the arteriotomy from both the internal and external surfaces of the artery.
- One such device "uses a combined procedural sheath and bioabsorbable extracellular matrix 'patch' made from porcine small intestinal submucosa, which is inserted through the arteriotomy so that it straddles the arterial wall. After insertion, a wire is pulled to release the 'patch' from the device, leaving a reabsorbable plug in the artery wall" (Moscucci, 2020, p. 289).
- Manufacturers of these patch-based devices boast faster deployment times, a product that is completely absorbable leaving the access site usable for future procedures, and a lower rate of post procedural complications.
- Similarly to collagen plug systems, the patches are typically made of tissue harvested from pigs.



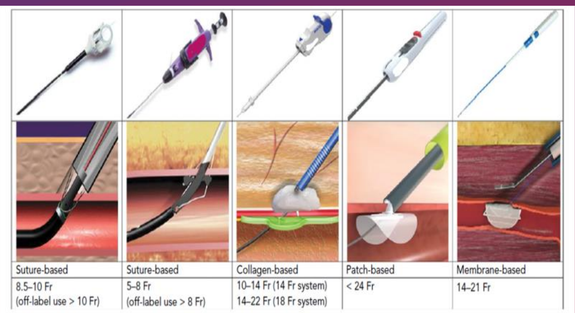
Patch based closure device (van Wiechen, 2019, p. 19).

Membrane Based Femoral Closure Devices

- Membrane based femoral closure devices consist of "a self-expanding nitinol frame, a biodegradable membrane and a bioresorbable polyglycolic acid (PGA) tether. The … device is introduced with the membrane in a collapsed configuration. The sheath is then pulled back and the release wire is pulled to deploy the VCD. The membrane is pushed against the arteriotomy site by the nitinol frame and traction is kept by keeping the tether fixed to the skin using a steristrip or suture. The flexible membrane should compensate for arterial wall irregularities and calcifications" (van Wiechen et al. 2019, p. 20).
- These devices allow for reaccess to the artery within 26 weeks after deployment.



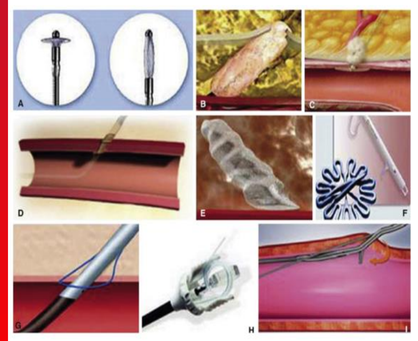
Membrane based vascular closure device (van Wiechen, 2019, p. 19)



Vascular closure devices: suture, collagen, patch, and membrane-based (van Wiechen et al., 2019, p. 19)

Safety Statistics

- A 2019 study collected data from 24 previously conducted studies on the use of femoral vascular closure devices and the rates of post procedural bleeding complications.
  - CFA = common femoral artery
  - SFA = superficial femoral artery
- "Pooled occurrence of all complications across closure devices used in the CFA ranged from 0.9% to 7.4%. These included access site bleeding/hematoma (3%), retroperitoneal bleed (0.03%), vessel occlusion (0.4%), pseudoaneurysm (0.7%), and arteriovenous fistula (0.03%). Pooled occurrence of all complications across closure devices used in the SFA ranged from 0% to 10.1%. These included access site bleeding/hematoma (4.7%), vessel occlusion (0.5%), and pseudoaneurysm (1.6%)" (Kennedy et al., 2021, p 722).
  - Bleeding complication results for this pooled study were as follows:
  - Collagen = 0.4%
  - Disk = 7.2%
  - Clips = 6.4%
  - Sutures = 0%



Additional arterial closure device illustrations (Moscucci, 2019, p. 287).

A) Nitinol Disk
B) Polyglycolic Acid Plug
C) Collagen Plug
D) Reabsorbable Porcine Biomaterial Plug
E) Polyethylene Glycol Plug
F) Nitinol Clip
G) Suture Closure
H) Suture Closure
I) Intravascular Hemodynamic Pressure Device

Conclusion

- "VCDs have demonstrated comparable overall safety compared with the gold standard of manual compression after CFA access, while reducing time to hemostasis. However, VCDs do carry unique risks including inappropriate deployment leading to vascular occlusion/stenosis" (Kennedy et al., 2021, p. 722).
- There are a wide variety of vascular closure devices available on the market today. While the current literature demonstrates that some of these pose a lower risk of complications, no device or procedure will likely ever be one hundred percent risk free.
- Patients cooperating with the post procedural instructions is as important to reducing bleeding complications as proper application of the devices themselves.
  - Premature physical activity can inevitably disrupt the hemostasis process.
  - Patients recovering from radial access procedures must avoid bending or putting weight on their wrist until it is safe to release the pressure from the band.
  - Patients who have undergone a procedure where femoral access was required must avoid hip flexion for up to several hours after a procedure.

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