VASCULAR CLOSURE DEVICES AND THERAPY

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ABSTRACT: Technological advances in interventional angiography include covered stents that require large sheaths and increased use of adjunctive anticoagulation and antiplatelet therapy. Traditional methods of arterial closure require uncomfortable groin pressure and immobilization, and in the setting of anticoagulation, there is added prolonged arterial sheath time; all contribute to patient discomfort. Percutaneous arterial closure devices and patch adjuncts to manual compression promise more rapid achievement of hemostasis and shorter times to ambulation and discharge. These benefits come at a cost in terms of the price of the device. There is also an increased risk for limb-threatening complications. Thorough understanding of the mechanism and strict attention to sterile technique will improve success.

I. Manual Compression

i. 'gold standard' (1-3).
- a. Never rigorously tested
- b. Compression devices have equivalent success / complication rate (1,2,6)

ii. periprocedural anticoagulation and antiplatelet therapy have proven advantageous in coronary interventions, and are accepted as standard of care for complex or small vessel interventions (4,5).
- a. anticoagulation and access >6Fr increase the access site related complication rate from 0.5% to up to 3.4% (1-3,5-8)

iii. normal arterial wound healing
- a. digital compression confines local hematoma, forms thrombus in minutes.
- b. blood + exposed collagen in the arterial wall leads to platelet adhesion and trapping of red blood cells.
- c. Platelet aggregation and activation results in proliferation and migration of smooth muscle cells into the thrombus (30).
- d. inflammatory cells infiltrate thrombus, remove RBCs, platelets, and fibrin.
- e. Smooth muscle cells produce extracellular matrix, reconstitute wall (31).

iv. puncture site complication risk factors
- a. patient-related (2,6,8):
  - age over 65 years
  - obesity / decreased weight
  - female
  - diabetes
  - hypertension
  - steroid therapy
  - peripheral vascular disease
  - non-compliance with bed rest restriction
- b. procedure-related (8,10):
  - larger sheath sizes
  - delayed sheath removal
  - higher levels of anticoagulation
  - punctures below the CFA bifurcation
  - multiple punctures required
  - double wall puncture

II. Arterial Closure Devices

i. General

a. Ideal Closure device (35):
obtain complete hemostasis
complication < compression
not enlarge existing tract
no compromise of lumen
minimal periarterial sequelae
allow delayed repeat access

b. mid-1990's: initial closure devices: Vasoseal, Perclose, AngioSeal
reduced time to obtain hemostasis from 18 to 4 minutes (9-12)
reduced length of patient immobility from 18 down to 4 hrs (9,12,13)
no significant increase / decrease in complication rates (9-18)
small new risk of infected false aneurysm (11,13,19,20,23,25, 28)

ii. Existing devices (dates of FDA approval):

a. collagen-based

Vasoseal (9/95)

Mechanism: Wire guide localizes arteriotomy
Collagen plug unsheathed at arterial surface
2-5 minute manual compression

Benefit: Approved for peripheral vascular disease application

Unique complication: to 1.6% incidence of collagen distal embolization / occlusion (11,19,21,45,47), vs 0 in man comp cohorts.

Angio-Seal (9/96)

Mechanism: polylactic and polyglycolic acid anchor, attached to a collagen sponge by an absorbable Dexon traction suture
dilator 'locator' indicates when sheath tip is in artery.
locator removed, carrier is introduced, locks in, part of the handle is withdrawn and the anchor is unsheathed.
device is withdrawn to seat anchor against inner arterial wall, then further withdrawn, and collagen is deployed.
Unique complications: incorrect anchor to deployment correctly (1-9.4%) (10,22-24,49,50)
arterial embolism (0-0.5%), occlusion (0-1.4%) (10, 22-25,26,48) versus 0 in manual compression cohorts.

Duett (6/00)

Mechanism: compliant 3 Fr balloon for intra-arterial seal
procoagulant mixture of collagen / thrombin injected through sheath side arm, remove balloon
2-5 minutes manual compression
Unique complication: procoagulant leak into artery: 0.2% (51).
Avoid by: no blood return on aspiration sheath side port prior to injection + maintain tension on balloon during injection.

QuickSeal (3/02)

Mechanism: Gelfoam is cut and placed in Hydration Chamber.
Depth Marker to set the depth of the tract on the Introduction Catheter.
Gelfoam in Introduction Catheter and the Pusher deploys, holds gelfoam in place adjacent to the vessel wall.

NeoMend

Mechanism: catheter with distal mesh disc 'locator', deploy in artery and retract to seal. Sheath with side-holes for deposition of polyethylene glycol-albumin bioadhesive. Disk collapses, catheter removed.

b. suture

Perclose (4/97)

Mechanism: sheath-catheter device advanced, bleed identifies level of arteriotomy.
Needles driven through the artery wall into 'foot' plates that engage ends of single suture.
Needles with suture brought out, slip knot advanced as device removed
Improvements: Braided suture → monofilament
Fisherman's knot→ knot making device→ auto tie in device
Suture trimmer with knot pusher, can cut at knot.
Advantage: guidewire may be replaced prior to sheath removal
Preclose (see below)
Unique complications: (% of all failures): (14,27);
breakage of suture (15%)
inability to advance the knot (8%)
failure to obtain bleedback to confirm intraarterial position (6%)
failure of the needle to engage tissue (3%)
non-capture of suture needles (1%)
sutures stuck, need surgical removal (rare) (25,28).

Prostar Plus

Mechanism: Catheter holds 4 needles and 2 sutures
Brought through arterial wall and into hub of device
Needles cut, sutures tied sequentially as device removed

Sutura (9/01)

Mechanism: device advances through existing sheath
footplates are deployed, sheath is withdrawn, the needles are driven through the arterial wall to engage the suture held by the footplates. Needles are withdrawn, tied with modified fisherman's knot, and advanced with a pusher through sheath to arteriotomy.
Advantage: Devices for 12-18 Fr access sites incorporate four to six needles

XPress

Mechanism: notch between the sheath and catheter reaches the artery, back bleeds
suture needle is loaded at the proximal end and driven through the shaft, across a distal gap positioned across the arterial wall, into the distal catheter shaft.
device rotated 180 degrees, needle on opposite end of the suture is placed.
Retraction of the catheter; the sutures have passed into the artery and out through the puncture site. Device removed as knot slides down
Advantage: May place additional sutures.

c. staple

EVS (11/04)

Mechanism: introducer / dilator indicates sheath at arteriotomy via back bleed.
dilator removal extends two plastic 'stabilizers', form T-anchors
stabilize device and spread the arterial wall defect slightly to approximate edges
preloaded titanium staple device placed into sheath
staple expands to 13 Fr and "tissue stops" on limit penetration to the depth of the adventitia and media
staple deployment simultaneously straightens the stabilizers, and they are removed with the sheath.

StarClose (spring 06)

Mechanism: Vessel locator wings deploy within artery. Star-shaped nitinol clip on applier, advanced through sheath. On deployment tines pucker and spring inward, apposing tissue in circumferential fashion

d. high frequency ultrasound

Therus Acoustic Hemostasis System

Mechanism: diagnostic US to target; .seals by deposition of high intensity US energy (76).

heat-mediated alteration in the medial and adventitial collagen.

Advantage: independent of blood, no foreign bodies

e. other

Boomerang (10/04 510k)

Mechanism: Through sheath elastomeric membrane covered braided nitinol 13 F mesh disc is placed in artery. Retracted to seal. Sheath retracted, wire secured. Tissue closes around wire. Wire removed, 2-5 min manual compression closes.

iii. Clinical performance:

	Technical Success (%)	Hemostasis (%)	Device Fail (%)	Min to stasis	Hrs to Ambulation
Vasoseal	97.0	90.5	1.8	7.2	6.3
Angio-Seal	94.8	94.6	5.0	4.4	4.0
Duett	92.6	95.0	1.5	5.9	3.8
Perclose	93.4	93.6	6.1	13.4	4.3
QuickSeal	96.7	97.9		18.5	5.1

iv. Complications

(%)	major	surgery	transfus	hem	fa	infxn	embo
Vasoseal	4.9 (1.5-13)	2.1 (5)	1.1 (1.9)	1 (2.5)	1.5 (3.2)	1.7 (6.5)	0.6 (1.4)
AngoSeal	2.0 (0.5-3.7)	0.6 (1.6)	0.6 (1.4)	1.8 (5)	0.6 (3.2)	0 (0.3)	0.4 (1.4)
Duett	3.0 (2.4-4.1)	1.0 (1.9)	1.3 (1.8)	1.1 (1.8)	1.2 (2.1)	0 (1.8)	0.6 (0.8)
Perclose	3.0 (0.5-8.8)	0.9 (2)	1.6 (8)	0.9 (2.8)	1.0 (2.7)	0.6 (1.6)	0.2 (0.5)

(range) (upper limits of range)

b. intervention for occlusive complications: transcatheter, open approaches

embolized or obstructing AngioSeal or Vasoseal have been removed percutaneously with a snare or cut-down and fogarty embolectomy

embolized Duett procoagulant has been treated with thrombolytics

stenoses may be balloon dilated

v. indications for use where “efficacy not proven”

a. include most IR indications

clinical evidence of peripheral arterial disease

thrombolytic therapy

known coagulation abnormalities

uncontrolled hypertension (blood pressure >180/100)

puncture below the common femoral artery

arterial diameter less than 5 mm

groin hematoma

two-wall arterial puncture

b. VIR studies that document efficacy where "unproven" criteria exist.
Morris, Braden (59): Perclose: double-wall puncture, anticoagulation.
Balzer and colleagues (55), anticoagulated, PVD
Duda and colleagues (54) : PVD
Beyer-Enke and colleagues (58): Angio-Seal, PVD

iv. PREclose

a. to close larger arteriotomy than perclose/prostar was built for
Mechanism: deployment of the device at the nominal arteriotomy diameter. further dilation, performance of procedure. tie knot(s) to close larger arteriotomy

b. efficacy:
8, 10 Fr devices for 16-22 Fr arterial access (70,72).
Success 85% for 16 Fr, 65% for 22 Fr
6 Fr device for 7-8 Fr sheath access sites (71)

v. Infection

a. Organism: gram-positive cocci (28) usually Staphylococcal
→ bacteremia, abscess, endocarditis, and endarteritis

b. Risk factors for endarteritis include hematoma formation and the presence of foreign material within the arterial lumen (65).

c. Prophylactic measures:
prophylactic antibiotics
changing of gloves
repreparation of the site
use of a fresh table
irrigation of the tract with antibiotic (Bacitracin)

III. Patch 'technology'

i.. Manual compression *augmentation*

a. All are pads that are placed on wound, and pressure held.
Advantage: require 4-10 minutes of compression
reduce time to hemostasis in the anticoagulated patient
permit safe early ambulation

c. question of real effect versus manual compression better than we thought

d. mystery: how contact effect on blood is transmitted from skin surface to level of arteriotomy

ii. Existing Patches

a. Syvek Patch (Marine Polymer Technologies)
Active: poly-n-acetyl glucosamine microalgae
Source: microalgae

b. Clo-Sur PAD (Scion Cardio-Vascular, Medtronic)
Active: polyprolate acetate

c. Neptune disc / pad (TZ Medical)
Active: calcium alginate
Source: seaweed

d. Stasys Patch (aka Hemaderm) (St. Jude Medical)
Active: microporous polysaccharide spheres
Source: potato

e. ChitoSeal (Abbott)
Active: chitosan gel
Source: sea shells

IV. Conclusion

i. Available arterial closure devices are particularly useful in the anticoagulated patient, where 4-6 hours of sheath time may be eliminated. In some studies there has been a significant decrease in the length of stay (9,56,58,61).

ii. Some risk factors for increased complications remain significant despite the use of closure devices; after multivariate analysis, increased risk was found with age over 65 years, female sex, diabetes, and smaller body size (9,50,53)

iii. No device consistently demonstrated a better hemostasis success rate or complication rate.

iv. Infectious complications were seen with Vasoseal, Angio-Seal, and Perclose. Although rare, this is a potentially fatal complication (28), and adds significantly to the cost of patient care. With manual compression, infectious complications were unheard of, with an incidence of less than one tenth of 1% of cases (.06%)(3).

v. Cost-Effectiveness

a. Vasoseal and Angio-Seal meta-analysis was done from the perspective of the health-care system (66):

The incremental cost of averting one complication exceeded $9000 for device versus manual compression.

In standard cost-effectiveness quality adjusted life years (QUALY) this was $60,000 / QUALY, (where over $50,000 is considered excessive).

b. The assumptions for the analysis have been supported by large population studies where the success rates and incidence of complications for those devices is roughly unchanged; however, the potential decreased length of stay has now been demonstrated. Calculations based on a one day reduction in hospitalization found device-mediated closure to be superior both in effectiveness and cost (66).

vi. Recommendations

Cost-effectiveness calculations do not, however, take into account the full costs of the rare infected false aneurysm that results in an amputation or death. A conservative approach may be warranted. The manual method has stood the test of time, and may be indicated for a routine diagnostic study, where an overnight stay is not an issue. In the higher risk therapeutic study where there is a definite benefit for continued anticoagulation, and increased risk for a prolonged sheath dwell time, closure devices may be unequivocally indicated. The decreased morbidity of percutaneous access can be extended to patients that require larger diameter access sheaths (>9 Fr) for interventions such as stent grafts through the use of the ‘Preclose technique’. .

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