Femoral and Radial Artery Access

Arterial Closure Devices

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Director, Interventional Cardiology
UC Davis Medical Center
Overview

• Femoral Arterial Access and Complications

• Femoral Arterial Closure Devices

• Radial Artery Access, Angiography and Intervention
Solution to Femoral Arterial Access and Complications

Do the Case Radial

Thank you very much.

The End.
Background – Bleeding is Bad

• Despite marked advances in peripheral vascular and cardiac interventional procedures, complications of vascular access remain a major morbidity.
No good deed...
Goes unpunished...
Expert Access is not Blind Luck
Know Your Patient!!
Ideal Access
“Normal” Anatomy

Misconceptions despite 50 years experience
CFA Bifurcation Location

Number of patients

I: 111
II: 44
III: 34
IV: 8
V: 3

n=200

- Below inferior border: 55.5%
- At inferior border: 17%
- Below center of head: 22%
- At center of head: 4.0%
- Above center of head: 1.5%
Ideal: Mid Femoral Head
Fluoro
Skin Crease—Not A Reliable Landmark
Skin Crease

AP

Second Crease

18g Needle

RAO 20

First Crease
Modified Seldinger Technique
Ipsilateral View
Contralateral View

LAO
Femoral Access Complications
Complications of Femoral Access

- Hemorrhage (hematoma or retroperitoneal bleed)
- Thrombosis
- Peripheral Embolization
- Dissection
- Pseudoaneurysm, aneurysm, AV fistula
- Infection
- Injury to adjacent structures
- Acute lower extremity ischemia
Too Low a Stick
Too Low a Stick

Profunda or SFA puncture
- PSA – not compressible
- AV fistula
- Occlusion/Thrombosis
Too Low a Stick
Pseudoaneurysm: Ultrasound Assessment

Assessment:
- Origin Vessel
- Neck Width/Length
- Lobe (Sac) Size and Number
- Surrounding Hematoma
Left Femoral Artery PSA
After Cardiac Cath, Patient on Coumadin for Mechanical Valve

“Yin and Yang” Sign
Femoral Artery-Vein Relationship
Femoral AV Fistula
AV Fistula

- Associated with PSA in 13.9% of cases
- Incidence <1%
- Low puncture site and vein
- Large AVF may result in shunting and pain

Treatment
- Small: spontaneous closure
- Ultrasound guided compression
- Covered stent
- Balloon tamponade
- Surgical repair

Too High a Stick

“High Stick”

Note Circumflex Iliac Artery
Too High a Stick
High Puncture

“High” puncture of the femoral artery: Increases risk of retroperitoneal bleeding
Vascular Closure Devices
Why Use a Closure Device?

- Save Staff Time
- Patient Satisfaction
- Earlier Ambulation and Discharge
- Reduce Hospital Costs through decreasing length of stay

Global Vascular Closure Device Market to Exceed $900 Million by 2013
  - Reuters 2008
Before You Close

- Femoral angiography
- Choose your patient wisely
- Re-clean the groin
- Change your gloves?
- Consider antibiotics (no data)
- Choose the proper device to fit your needs
Vascular Closure Devices
Allow earlier ambulation but do not decrease vascular complications

- A meta-analysis of 31 prospective, randomized studies encompassing 7,528 patients randomized to VCDs or manual/mechanical compression

<table>
<thead>
<tr>
<th>Outcome Endpoints</th>
<th>No. of Studies</th>
<th>No. of Participants</th>
<th>Incidence VCDs vs Controls</th>
<th>Statistical Method and Effect Estimate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groin hematoma</td>
<td>14</td>
<td>2656</td>
<td>5.3% vs 5.2%</td>
<td>M-H; fixed RR, 1.01 (0.74-1.38)</td>
</tr>
<tr>
<td>Groin bleeding</td>
<td>8</td>
<td>2160</td>
<td>4.0% vs 0.9%</td>
<td>M-H; random RR, 3.49 (0.62-19.08)</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>16</td>
<td>4106</td>
<td>0.7% vs 1.1%</td>
<td>M-H; fixed RR, 0.69 (0.38-1.23)</td>
</tr>
<tr>
<td>Lower limb ischemia/arterial stenosis/device entrapment in the artery</td>
<td>11</td>
<td>2567</td>
<td>0.3% vs 0%</td>
<td>M-H; fixed RR, 3.07 (0.50-18.83)</td>
</tr>
<tr>
<td>Groin infection</td>
<td>11</td>
<td>3686</td>
<td>0.2% vs 0.06%</td>
<td>M-H; fixed RR, 2.56 (0.50-13.10)</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>12</td>
<td>2957</td>
<td>0.7% vs 0.8%</td>
<td>M-H; fixed RR, 0.78 (0.35-1.71)</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>17</td>
<td>4337</td>
<td>0.6% vs 0.3%</td>
<td>M-H; fixed RR, 1.76 (0.74-4.20)</td>
</tr>
<tr>
<td>Time to hemostasis</td>
<td>5</td>
<td>889</td>
<td>–</td>
<td>IV; random; mean difference –42.90 (–55.26 to –30.53)</td>
</tr>
</tbody>
</table>

Vascular Closure Devices

- VCDs reliably shorten the time to hemostasis after femoral arterial access. They may improve patient comfort.

- VCDs have not consistently been shown to reduce (or increase) vascular complications.

- Numerous indications, contraindications and cautions for use. May not be cost effective.

- There are no large scale randomized clinical trials comparing outcomes with VCDs vs. manual compression.

Manual Compression

- Cheap, “simple”, and effective method of sheath management
- Allows close user monitoring of groin status at all times
Disadvantages of Manual Compression

- Discomfort
- Cost
  - Time
  - Patient returns to floor with sheath
  - Check ACTs before pulling
  - Staff returns to hospital
- Morbidity associated with prolonged bedrest and compression
Active Closure Devices

- Angioseal
- Perclose
- Starclose
Angioseal Device Closure

Mechanical and biochemical seal
PERCLOSE® PROGLIDE™

- Polypropylene monofilament suture
  - Gold standard for vessel repair
  - Enhanced knot delivery
  - Minimized tissue reaction
- Auto-Tie platform
- QuickCut™ mechanism
StarClose®

- Nitinol clip
- 4mm diameter
- 0.2mm thick
- Extravascular Closure
Passive Closure

- Mynx

Protamine is well known for its ability to neutralize heparin. The Cardiva Catalyst III has a protamine coating that is designed to enhance coagulation within the tissue tract at the puncture site.
Closure Begins with Access

- Arstasis Device
Summary

- Good access leads to good closure.
- Femoral angiography should be mandatory.
- Know advantages and disadvantages of each closure device.
- Keep a low threshold to re-evaluate entry sites – do not be lulled into false sense of security.
Transfemoral Access Will Endure

Transfemoral access will continue to have its place in PCI procedures, but efforts must focus on reducing access-site complications

- A need for larger sheaths
- More accurate access techniques such as real-time ultrasound guidance

<table>
<thead>
<tr>
<th>Complication</th>
<th>Fluoroscopy (N=501)</th>
<th>Ultrasound (N=503)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma ≥5 cm, n (%)</td>
<td>11 (2.2)</td>
<td>3 (0.6)</td>
<td>0.034</td>
</tr>
<tr>
<td>Pseudoaneurysm, n</td>
<td>0</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Dissection, n</td>
<td>3</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Hematoma with deep vein thrombosis, n</td>
<td>1</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Any complication, n (%)</td>
<td>17 (3.4)</td>
<td>7 (1.4)</td>
<td>0.041</td>
</tr>
</tbody>
</table>

Radial Artery Access, Angiography and Intervention
Why transradial?

- Patient comfort
- Ambulation time
- Bedrest duration
- Less Bleeding Complications
Why Do Radial – The Positives

• For the patients
  ▪ Increased comfort (ambulation, eating, no Foley, no groin issues)
• Decreased Bleeding Complications
• Decreased Length of Stay
• Economic Advantages – Future
• New techniques are enjoyable and make one a better operator
Radial – The Realities

- Increased procedure times, especially initially
  - Learning Curve
  - Technically more challenging
- Increased radiation dose
- Radial access not always possible
  - “Crossover” to femoral
God made the radial artery for a reason
Major Bleeding: Transradial Versus Transfemoral Access

Transradial access is associated with a 73% reduction in bleeding compared to transfemoral access.¹

Major Bleeding Comparison Between Transradial and Transfemoral Access

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Radial</th>
<th>Femoral</th>
<th>Peto OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCESS</td>
<td>0/300</td>
<td>4/300</td>
<td>0.13</td>
</tr>
<tr>
<td>Achenbach</td>
<td>0/152</td>
<td>4/155</td>
<td>0.14</td>
</tr>
<tr>
<td>Bodi</td>
<td>3/666</td>
<td>7/332</td>
<td>0.19</td>
</tr>
<tr>
<td>BRAFE</td>
<td>0/50</td>
<td>1/55</td>
<td>0.15</td>
</tr>
<tr>
<td>FARMI</td>
<td>3/57</td>
<td>3/57</td>
<td>1.00</td>
</tr>
<tr>
<td>Gorge</td>
<td>1/214</td>
<td>1/216</td>
<td>1.01</td>
</tr>
<tr>
<td>Mann 1998</td>
<td>0/68</td>
<td>2/77</td>
<td>0.15</td>
</tr>
<tr>
<td>OCTOPLUS</td>
<td>1/192</td>
<td>7/185</td>
<td>0.21</td>
</tr>
<tr>
<td>OUTCLAS</td>
<td>0/322</td>
<td>1/322</td>
<td>0.14</td>
</tr>
<tr>
<td>RADIAL AMI</td>
<td>1/25</td>
<td>4/25</td>
<td>0.27</td>
</tr>
<tr>
<td>RADIAMI</td>
<td>3/50</td>
<td>7/50</td>
<td>0.41</td>
</tr>
<tr>
<td>TEMPURA</td>
<td>0/77</td>
<td>2/72</td>
<td>0.12</td>
</tr>
<tr>
<td>Vazquez-Rodriguez</td>
<td>1/217</td>
<td>5/222</td>
<td>0.27</td>
</tr>
</tbody>
</table>

**Transfusions Predict Mortality**

*Through the reduction of bleeding complications, radial access may reduce the need for transfusions, and therefore, may potentially save lives*

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### Adjusted Odds Ratios for Variables as Independent Predictors of 1-Year Mortality

*From the MORTAL Study*

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;75</td>
<td>2.75 (2.45 to 3.09)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Low BMI</td>
<td>2.40 (1.79 to 3.24)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male sex</td>
<td>1.01 (0.89 to 1.14)</td>
<td>NS</td>
</tr>
<tr>
<td>Previous CVD</td>
<td>1.71 (0.46 to 2.01)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.42 (1.26 to 1.60)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>1.35 (1.16 to 1.57)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous MI</td>
<td>1.52 (1.35 to 1.71)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Urgent PCI</td>
<td>3.15 (2.77 to 3.58)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stable angina</td>
<td>0.42 (0.33 to 0.55)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Increased creatinine</td>
<td>2.04 (1.82 to 2.28)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Radial access</td>
<td>0.83 (0.71 to 0.98)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Transfusion</td>
<td>3.58 (2.94 to 4.36)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous pulmonary disease</td>
<td>2.01 (1.73 to 2.33)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous malignancy</td>
<td>1.64 (1.38 to 1.96)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

BMI=body mass index; CABG=coronary artery bypass graft; CI=confidence interval; CVD=cardiovascular disease; MI=myocardial infarction; NS=not specified; OR=odds ratio.

In patients who have had both transradial and transfemoral procedures, quality of life improvements offered by transradial access directly affect preference.


Patient Preference for Type of Access
N=200

Patient Preference for Radial

Number of Patients

Strongly Prefer Radial

No Preference

Strongly Prefer Femoral

$P<0.0001$
Radial May Not Be for Everyone

However the patients demand it now. Payors and guidelines may demand it in the future.
Transradial Approach

Anatomy and Assessment
Normal Aortic Arch

- The left subclavian comes directly off the arch of aorta
- The right subclavian originates from the innominate artery

Normal Brachial to Subclavian Anatomy

• The brachial artery connects the radial and ulnar arteries to the axillary artery, which in turn joins the subclavian.

Normal Radial Anatomy

- The radial artery originates at the bifurcation of the brachial artery just below the bend of the elbow, passing along the radial side of the forearm to the wrist.

Anatomy

Schematic cross section proximal to flexor retinaculum

- Median duo
  - Palmaris longus tendon
  - Median nerve
- Flexor carpi radialis tendon
- Flexor pollicis longus tendon in radial bursa
- Radial artery
- Palmar carpal ligament
- Flexor digitorum superficialis tendons and Flexor digitorum profundus tendons
- Ulnar bursa
- Ulnar artery
- Ulnar nerve
- Flexor carpi ulnaris tendon
- Pronator quadratus muscle
- Radius
- Ulna

Simple method of demonstrating arrangement of flexor digitorum superficialis tendons at wrist

© Novartis
Modified Allen’s Test
Modified Allen’s test

**Baseline**

**Occlusion**

**Ulnar Release**

*Delay of >15 seconds = abnormal*
Barbeau Classification
A, B or C: OK to proceed

- **A**: No damping of pulse tracing immediately after radial artery compression
- **B**: Damping of pulse tracing
- **C**: Loss of pulse tracing followed by recovery of pulse tracing within 2 minutes
- **D**: Loss of pulse tracing without recovery within 2 minutes

Transradial Approach

Gaining Access
- Too distal
  - inadvertent puncture of superficial branches
  - Perforation of reticular ligament of wrist
- Too proximal
  - Difficult to compress
  - Preserve for repeat puncture

Styloid process

Patel’s Atlas 2007
Radial Access: Proximal to Styloid Process: Not Really the Wrist!!

Kiemeneij F, unpublished.
Techniques

• Cannulation
  - Single wall puncture
    • With needle
  - “Through and through”
    • For Jelco (catheter over needle) or 22 gauge Angiocath
Local Anesthesia
Needle Access
Sheath Insertion
The use of a Hydrophilic Sheath will promote smooth insertion, help prevent vessel spasm, and decrease the chance of vessel damage upon removal.
Use a “cocktail” of Nitro, Heparin and Verapamil, to help prevent vessel spasm.
Radial Artery Spasm

• How to prevent:
  - Use hydrophilic sheath to minimize friction
  - Adequate sedation
  - Give cocktail flush (200-400 ug Nitroglycerin, 2.5 mg Verapamil)
  - Additional cocktail if needed
Factors Affecting Radial Artery Occlusion

Radial Occlusion v Heparin Dose

Radial Occlusion v Sheath Size

Comparison of the Effect of Intra-Arterial Versus Intravenous Heparin on Radial Artery Occlusion After Transradial Catheterization

Samir B. Pancholy, MD*

- 500 subjects
  - 250 IA, 250 IV (50 U/kg or 5000 U max)

- 30 day RA occlusion (Barbeau’s test)
  3.2% (IV) vs. 4% (IA); p=NS
Transradial

Patient Selection and Setup
Guitar Board
Plexiglass Board
After access is gained this is the optimal position for the patient's arm. This will be more comfortable for the patient, and allow the technician/physician to pan the table in the same manner as the femoral approach.
Catheterization Lab Setup

- Position the arm so that the wrist is hyperextended
- Support it using a rolled towel or one of several available arm devices
- Radiation exposure may be significantly reduced by positioning the arm beside the body, thereby approximating the location of the femoral artery

Hyperextended wrist held in position with tape

An example of several available arm devices

Recommendations on this slide are not intended to replace patient-specific clinical judgment.

Cohen MG, Alfonso C. J Invasive Cardiol. 2009;21(Suppl A):11A-17A.

Photos used with permission from Mauricio G. Cohen, MD.
Using a radial/brachial drape position the radial artery in the middle of the circle.
Have all the equipment within easy reach.
Right Arm

• More conventional side for operator

• More tortuosity in right subclavian, especially in elderly, short stature

• Vertically downward approach to the ascending aorta, completely excluding the aortic arch

• Specialty diagnostic catheters work best
Left Arm

- Left radial approach is similar to the femoral approach because it involves aortic arch

- Conventional catheters work well

- Substantial adduction of the arm to accommodate positioning of the operator on the patient’s right side

- Left arm is common in patients with CABG grafts because of easy access to the left internal mammary artery
Randomized Comparison of Transradial Coronary Angiography Via Right or Left Radial Artery Approaches

Yumiko Kanei, MD*, Navin C. Nakra, MD, Michael Liou, MD, Lori L. Vales, MD, Ramesh Gowda, MD, Hugo Rosero, DO, Tak Kwan, MD, and John T. Fox, MD

Figure 1. For the left radial approach, (1) access was obtained from the left side (left), and (2) the patient’s left forearm was pulled to the right side and secured to the catheterization table using a sling (right).

Am J Cardiol 2011;107:195–197)
Transradial

Equipment and Procedure
Catheters

- Left: JL 3.5 or 4.0, Tiger, Jacky
- Right: JR4, Tiger, MPA
- SVG-LCA: JR4, AL, LCB, MPA
- SVG-RCA: JR4, MPA, AL, RCB

Catheter shapes commonly used for aorto-coronary bypass grafts
When not to use radial approach

- Indequate radial/ulnar pulses
  - Abnormal Allen’s test
- Scleroderma, Radical Mastectomy, Raynaud’s
- Possible Dialysis candidate
- Ipsilateral AV shunt
- Need for larger guides than artery can handle
Causes of Failure

Dehghani et al, JACC Interv 2009
Post-Procedural Management
Once the procedure ends the use of a hemostasis device is recommended for access site management. The radial sheath will be removed in the cath lab.
Fill the TR Band with 13-15 cc of air and then proceed to remove the sheath. In the majority of patients this should be adequate pressure to control bleeding. If more is needed you can instill a maximum of 18 cc’s of air into the device.
Once hemostasis is achieved transport the patient with the inflation syringe attached either to the patients chart or taped to the patient.
RadStat or D-Stat

- Direct Pressure
- No wrist flexion
- No Ulnar artery obstruction
- Universal – left or right hand
Protocols

• The band remains on for 60-90 minutes as long as there is a good ulnar pulse and the hand is warm
• Check capillary refill every 15 min
• Gradually release 2-3 ccs of air every 15 minutes after that
  ▪ Diagnostic- 90 minutes for hemostasis
  ▪ PCI- 120-180 minutes
Discharge

- No lifting anything over 10 lbs for 24 hours
- No heavy lifting for 1 week
- Take the 2 x 2 off the next morning
- If bleeding recurs hold pressure and contact your physician
Conclusions

• Femoral access a mainstay but has limitations with regards to vascular access complications

• Radial artery access and intervention will increasingly be utilized

• Knowledge of both techniques should be standard for high volume cath labs