CTO Crossing Based on Cap Morphology

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Disclosure

- Abbott Vascular - Consultant, Speaker, Medical Advisory Board
- Bard Peripheral Vascular - Research, Consultant, Medical Advisory Board, Speaker, Trainer
- Bayer - Medical Advisory Board
- Biotronik - Research
- Boston Scientific - Speaker, Consultant
- Cardiovascular Systems, Inc. - Research, Consultant, Speaker, Trainer
- Cook Medical - Research, Consulting, Speaker, Trainer
- Cordis - Consultant, Trainer
- Medtronic - Consulting, Speaker, Trainer
- Terumo - Consulting, Speaker, Trainer
- Trireme – Research
- Spectranetics – Research, Consulting
Variation in the Use of Lower Extremity Vascular Procedures for Critical Limb Ischemia

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2,185 in 3 Years

Open Surgical Procedures

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>n*</th>
<th>percent of all CPTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>35656</td>
<td>Bypass graft, with other than vein;femoral-popliteal</td>
<td>854</td>
<td>3.3</td>
</tr>
<tr>
<td>35566</td>
<td>Bypass graft, with vein;femoral-anterior tibial, posterior tibial, peroneal artery</td>
<td>762</td>
<td>3.0</td>
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<tr>
<td>35666</td>
<td>Bypass graft, with other than vein;femoral-anterior tibial, posterior tibial, or peroneal artery</td>
<td>526</td>
<td>2.0</td>
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<tr>
<td>35571</td>
<td>Bypass graft, with vein;popliteal-tibial, -peroneal artery or other distal vessels</td>
<td>454</td>
<td>1.8</td>
</tr>
<tr>
<td>35585</td>
<td>In-situ vein bypass;femoral-anterior tibial, posterior tibial, or peroneal artery</td>
<td>443</td>
<td>1.7</td>
</tr>
<tr>
<td>35371</td>
<td>Thromboendarterectomy, including patch graft, if performed;common femoral</td>
<td>408</td>
<td>1.6</td>
</tr>
<tr>
<td>35556</td>
<td>Bypass graft, with vein;femoral-popliteal</td>
<td>405</td>
<td>1.6</td>
</tr>
<tr>
<td>35372</td>
<td>Thromboendarterectomy, including patch graft, if performed;deep (profunda) femoral</td>
<td>232</td>
<td>0.9</td>
</tr>
<tr>
<td>35661</td>
<td>Bypass graft, with other than vein;femoral-femoral</td>
<td>196</td>
<td>0.8</td>
</tr>
<tr>
<td>35681</td>
<td>Bypass graft; composite, prosthetic and vein</td>
<td>180</td>
<td>0.7</td>
</tr>
</tbody>
</table>
Current Evidence

• The Peripheral Registry of Endovascular Clinical Outcomes (PRIME Registry) is an ongoing multi-center CLI registry
• Started enrolling patients in 2013.
• Target to obtain data from 15 centers in the US and international, evaluating patients with advanced PVD and CLI
• The registry covers all aspects of patient care including patient evaluation, treatment modality and clinical follow up
Tibio-Pedal Access Outcomes

- N = 300 patients
- Ultrasound utilized 100% for access

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>AV Fistula</td>
<td>0/21 (0%)</td>
<td>0/65 (0%)</td>
<td>0/58 (0%)</td>
<td>1/33 (0.03%)</td>
<td>0/23 (0%)</td>
</tr>
<tr>
<td>Perforation</td>
<td>0/21 (0%)</td>
<td>0/65 (0%)</td>
<td>0/58 (0%)</td>
<td>0/33 (0%)</td>
<td>0/23 (0%)</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0/21 (0%)</td>
<td>2/65 (0.03%)</td>
<td>0/58 (0%)</td>
<td>0/33 (0%)</td>
<td>1/23 (0.04%)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>0/21 (0%)</td>
<td>1/65 (0.02%)</td>
<td>0/58 (0%)</td>
<td>0/33 (0%)</td>
<td>0/23 (0%)</td>
</tr>
<tr>
<td>Death</td>
<td>0/21 (0%)</td>
<td>0/65 (0%)</td>
<td>0/58 (0%)</td>
<td>0/33 (0%)</td>
<td>0/23 (0%)</td>
</tr>
</tbody>
</table>
Cook Tibio-Pedal Registry

Planned Enrollment

– 200 patients at up to 12 US and European sites

Patient population

– Patient has an infrainguinal artery occlusion
– Previous attempts to cross the occlusion from an antegrade approach have been unsuccessful (unless institutional standard of care permits primary retrograde access)
– All techniques to be used for access, lesion crossing, lesion treatment, and vessel closure are at the investigator’s discretion according to institutional standard of care

Data collected include:

– Procedural information, access site and lesion characteristics, procedural times, treatments used, and closure methods
– Procedural complications and complications occurring within 30 days following the procedure

Walker et al. NCVH 2014
Cook Tibio-Pedal Registry

- Enrollment period May 2012 - July 2013
- Final enrollment: 199 patients from 8 US and 3 European sites

<table>
<thead>
<tr>
<th>PI (Site)</th>
<th>Patients Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jihad Mustapha (Metro Heart &amp; Vascular Institute)</td>
<td>50</td>
</tr>
<tr>
<td>George L. Adams (Rex Health)</td>
<td>31</td>
</tr>
<tr>
<td>Nelson Bernardo (Washington Hospital Center)</td>
<td>26</td>
</tr>
<tr>
<td>Andrej Schmidt (Park Hospital Leipzig)</td>
<td>24</td>
</tr>
<tr>
<td>Aravinda Nanjundappa (West Virginia University)</td>
<td>16</td>
</tr>
<tr>
<td>Robert Beasley (Mount Sinai)</td>
<td>11</td>
</tr>
<tr>
<td>Craig Walker (Cardiovascular Institute of the South)</td>
<td>11</td>
</tr>
<tr>
<td>Yazan Khatib (First Coast Cardiovascular Institute)</td>
<td>11</td>
</tr>
<tr>
<td>Thomas Zeller (Universitäts-Herzzentrum Bad Krozingen)</td>
<td>9</td>
</tr>
<tr>
<td>Marco Manzi (Casa Di Cura Abano Terme)</td>
<td>7</td>
</tr>
<tr>
<td>Luis Leon (Tucson Medical Center)</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>199</strong></td>
</tr>
</tbody>
</table>

Walker et al. NCVH 2014
Adverse Outcomes

- Low (< 3%) complication rate for all events associated with vascular access site

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local pain at access site</td>
<td>2.5% (5/199)</td>
</tr>
<tr>
<td>Infection at access site</td>
<td>1.0% (2/199)</td>
</tr>
<tr>
<td>Bruising at access site</td>
<td>1.0% (2/199)*</td>
</tr>
<tr>
<td>Bleeding at access site</td>
<td>1.0% (2/199)</td>
</tr>
<tr>
<td>Acute vessel dissection</td>
<td>0.5% (1/199)</td>
</tr>
<tr>
<td>Acute vessel thrombosis</td>
<td>0% (0/199)</td>
</tr>
<tr>
<td>Compartment syndrome</td>
<td>0% (0/199)</td>
</tr>
<tr>
<td>Urgent surgical revascularization</td>
<td>0% (0/199)</td>
</tr>
</tbody>
</table>

Walker et al.  NCVH 2014
Advantage of Retrograde Tibial Access

- Increase success rate of crossing
- Shorten treated segment
- Preserve options of therapy: surgery, atherectomy
- Utilize hibernating lumen
- Preserve tibial vessels flow
# Tibio-Pedal Access

## Clinical Consideration
- Critical Limb Ischemia patients
- Patients with Long CTOs
- Patients with CTO reconstitution with the P2/3 segment of the popliteal artery
- Patients with CTO reconstitution within the tibial vessels
- Patients with hostile groin access (fibrotic, obese, prior surgery)
- Patients unable to lay flat (back pain, COPD, CHF)

## Anatomical Consideration
- Adequate tibial reconstitution (usually distal third)
- Patients with adequate anterior and posterior communicating circulation
- Patients with distal CTO caps that are concave in retrograde fashion
### Tibio- Pedal Access

<table>
<thead>
<tr>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Claudication with single vessel runoff</td>
</tr>
<tr>
<td>• Patients with complete occlusion of tibial vessels. White stop sign</td>
</tr>
<tr>
<td>• Inability to insert a sheath</td>
</tr>
<tr>
<td>• Indolence to anticoagulation or vasodilators</td>
</tr>
</tbody>
</table>
CTO Cap Morphology PRIME Analysis

- Concave
- Convex
- Acoustic shadowing
- Branching and collaterals
Chronic Total Occlusion Crossing Approach based on the Plaque Cap Appearance. The C-TOP Trial

- Retrospective analysis evaluating CTO CAP morphology.
- Interim analysis of patients enrolled in the PRIME registry with CTOs
- Prevalence of different CTO caps
- Access selection, technique and success rate of crossing
Proposed C-TOP Classification

Type I: 0%
Type II: 39%
Type III: 39%
Type IV: 21.7%
26%
Planned Antegrade & Retrograde
34%

Retrograde Crossing

60% of cases required pedal access
CTO

CTO Length

Intermed late 5-10 cm
- Start with CTO crossing device
  - Type I
    - CFA access
    - High likelihood of crossing
    - Start CTO crossing Device
    - Change to catheter / wire if difficult to cross
    - Catheter/Wire if failed, re-entry device

- Consider catheter and wire
  - Type II
    - SFA Reconstitution . proximal P1
    - CFA access
    - Consider Popliteal/Tibial
    - less likely to cross in antegrade or retrograde fashion
    - CTO Crossing device

- CTO Cap analysis
  - Type III
    - Popliteal/Tibial reconstitution
    - Combined antegrade/retrograde access
    - CTO crossing device from antegrade and retrograde (Tunneling)
    - Catheter and wire, antegrade/retrograde (Tunneling)

- Catheter and wire technique
  - Type IV
    - Antegrad/retrograde access
    - Consider starting with Tibial/popliteal access
    - CFA access
    - Consider Popliteal/Tibial
    - low profile CTO crossing device
    - Catheter/Wire technique (0.018 catheter)

Short <5 cm
- Catheter and wire technique

Long > 10 cm
- CTO Cap analysis
- Catheter and wire technique

Pending publication
CTO Crossing tools....
Clinical Scenario

• 67 year old male presented with a 2 week hx rest pain. Ulcer involving the tip of R toe.
• Risk factors include HTN, DM, HLP and smoking
• Non compressible ABIs
Cap Analysis – Planning an Intervention
C-TOP Classification
Proximal Cap Analysis
Distal CTO Cap
Options of Therapy

1. Retrograde or Antegrade Access, attempt Crossing to the tibials
2. Antegrade and Retrograde Access?
3. Retrograde Access Only?

Antegrade and Retrograde
Antegrade US Guided Access
Antegrade Crossing Attempt
• Operator must understand the limitation of CTO devices and wires with catheters
• Low profile CTO crossing device, less risk of clinically significant complications
US Guided Pedal Access
Retrograde Access
Clinical Scenario

- 53 year old male that presented with a non healing ulcer of the Left foot, involves AT and PT distribution
- Applying the C-TOP algorithm.....
Retrograde Access
Distal CTO Cap
Choose Appropriate access

Low profile CTO crossing device

Mechanical activation, less operator dependency

Less concern with retrograde dissection and perforation

Microcaviatation Phenomenon
Confirm Position After Crossing
Final Result
Advanced Techniques

• Re-constitution of the CTO within the popliteal artery will require the operator experience in guiding re-entry
• Retrograde access in long CTO will guarantee no loss of relatively healthy conduits
Re-Back Technique

• Re-entry using ante grade outback and retrograde balloon
• Utilized if antegrade and retrograde wires/catheters are in two different sub-intimal planes
Case Demonstration

- 72 year old male
- Rutherford Class III - advanced claudication
- 2 attempts for revascularization 1 year prior
- Hx CABG
- No adequate venous conduits
Superior control with antegrade access
- Type III CTO
- Longer than 10 cm
- High likelihood of subintimal crossing
- Re-entry may occur beyond re-constitution
- Retrograde access will preserve relatively normal segments
Two Sub-intimal Planes
Wire advanced into the balloon

Balloon pulled distally

Wire advanced from one sub-intimal space to another

Deliver treatment from true lumen to true lumen
Define CTO Caps
- CTO length

Determine Access Points

CTO Crossing Device if CTO cap is favorable

CTO crossing device for antegrade access, low profile

Wire and catheter technique in experienced hands

Operator can switch from CTO device to wire and catheter, but not the opposite
Conclusion

• CTOs remain a challenging and difficult arena to treat
• Operators should be comfortable with a device to utilize in crossing CTOs especially with tibial disease
• Crossing a CTO requires a detailed analysis to determine access point, strategy and device required
Thank You

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