Patient Specific Approaches for Femoro-popliteal Lesions: Stents, Atherectomy, & Drug-Eluting Devices

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Disclosures
- Symposium Honoraria and Course Proctor
  - Abbott, Medtronic, TriVascular
- Symposium Honoraria
  - Spectranetics, Cordis, Bard, Cardiovascular Research Foundation, Boston Scientific
- National PI
  - CANOPY, SAPPHIRE WW
- Stock, Research Grants, etc.
  - None

Which Device to Use?
(Lots of Options)

- PTA
- Atherectomy; Or Atherectomy + DCB/stent
- Drug Coated Balloons (DCB)
- Slotted Tube Nitinol Stents (STNS)
- Covered Stents
- Interwoven Nitinol Stents
- Drug-Eluting Nitinol Stents

Basic Concepts for Device Choices

- Claudication: ~ benign natural Hx of disease or restenosis, options “wide open”
- CLI: ANY method of revasc. saves limbs
- We should tailor/ individualize our treatment to patient’s anatomy & history
- Considerations: Lesion length, calcium, vessel size, thrombus, denovo vs. restenosis, results after initial therapy, etc.

Atherectomy

- Advantages:
  - No permanent implants in dynamic artery
  - “Deals with” calcium, thrombus, bulky plaque
  - 1 luminal gain, 1 dissection
  - Better preparation for DCB (esp. CA++; ISR)
- Disadvantages:
  - 1 cost, complications, procedure time
  - NO restenosis advantages ever shown
  - Distal embolization

Drug Coated Balloons

- Advantages:
  - Nothing left behind (future options open)
  - EASY to use, efficient procedure
  - Good data; “pass through” cost in US
  - Biologic anti-proliferative effect
  - Can be used in combination w other therapies
- Disadvantages:
  - No scaffolding of vessel
  - Vessel recoil
  - Uncertain results in CA++ or long lesions

Combinations atherectomy & DCB theoretically promising (esp. CA++, ISR)
**Slotted-Tube Nitinol Stents**

**Advantages:**
- Easy/quick, precise deployment, long lengths
- Well studied
- Good vessel scaffolding; early complications

**Disadvantages:**
- Poor radial strength; recoil
- Suboptimal flexibility in dynamic vessel
- Suboptimal in adductor canal, popliteal, CA++
- Poor results in long lesions
- Stent Fractures; challenging ISR interventions

**Drug-Eluting Stents**

**Advantages:**
- Combines scaffolding AND drug elution
- Excellent results in variety of lesions
- Durable results; easy

**Disadvantages:**
- It is a nitinol stent w/ those disadvantages
- 1st generation stent delivery issues
- Cost w/o reimbursement advantages

**Covered Nitinol Stents**

**Advantages:**
- Flexible, ~ No stent Fracture issues
- PTFE inhibits neointimal proliferation/long ISR
- Embolic risk; covers aneurysm, clot, etc.
- Good data for long lesions, some for ISR

**Disadvantages:**
- Covers collaterals/geniculates
- Poor radial strength; COST
- Removes drug elution options permanently
- May occlude acutely

**Interwoven Nitinol Stents**

**Advantages:**
- Conformable AND ~ “Fracture proof”
- High radial strength (>4XSTNS); no recoil
- Low chronic outward force (endoth irritation)
- Excellent results in complex lesions (long lesions, CA++, adductor canal/pop), etc.

**Disadvantages:**
- Imprecise length (not good for ostial SFA)
- Permanent implant; ISR issues

**Leipzig Database: Supera, BMS, and DCB**

- Propensity Score: Clinical, Lesion Characteristics
- 1:1 match “nearest neighbor”
- NON-randomized

**DCB - BMS - Supera**

- Institutional database comprising patients undergoing femoropopliteal treatment with
  - Drug coated balloon – DCB N=390
  - Conventional nitinol stent – BMS N=432
  - Intervenous nitinol stent – Supera N=470

- Assessment of primary patency up to 40 months (duplex ultrasound, angiography)

**Supera vs. BMS (STNS)**

- Matched cohort: 18 ± 10 vs. 19 ± 10.6 (p-value 0.6)
- Hazard ratio (HR): 0.36 (95% CI: 0.12-1.05)
Supera vs. DCB

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>Supera</th>
<th>DCB</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>Small vessels</td>
<td>143 ± 52</td>
<td>157 ± 102</td>
<td>0.09</td>
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<tr>
<td>Popliteal</td>
<td></td>
<td>DCB (esp. Trif) OR Supera stent</td>
<td></td>
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<tr>
<td>Ostial/prox SFA</td>
<td>atherecomy + DCB, OR DCB, or DES, or STNS (No Supera)</td>
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<tr>
<td>Heavily CA++ vessels</td>
<td>CSI&gt; Jetstream, TurboHawk + DCB OR Supera stent, OR Aggressive PTA and Supera</td>
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So, Which Device Do I Choose for Which Lesions?

- Small vessels: PTA/ atherotomy + DCB
- Popliteal: DCB (esp. Trif) OR Supera stent
- Ostial/prox SFA: atherecomy + DCB, OR DCB, or DES, or STNS (No Supera)
- Heavily CA++ vessels:
  - CSI> Jetstream, TurboHawk + DCB OR Supera stent, OR Aggressive PTA and Supera

Which Device? - 2

- Atherectomy- ONLY if specific need exists
- ISR- Jetstream or Laser + DCB (w/ DEPD)
  - “Reline” w/ Viabahn- IF clot or 2-3 failures
  - Treat underlying “failure mode”
- Long lesions-  
  - If heavy CA++ or dissection→ PTA + Superas
  - DCB alone, DES (Fx risk?), or Viabahn

80 yo male with severe IC @ 50'; ulcer L heel; ABI 0.13; CTA 99% mid SFA, 100% pop; 100% peroneal; 100% AT; 90% TPT/PT

4 X 80 VascuTrak at 14 atm

5 X 20 NC Trek @ 14 atm
Some dissection - Will need stent

High grade TPT lesion, peroneal CTO

More aggressive FF PTA

5.5 X 100 Supera

DCB Trial
Short nitinol stent mSFA, Supera stent popliteal, DCB alone for TPT and peroneal

R popliteal and TPT relatively sudden occlusions

Laser atherectomy R popliteal

Angio popliteal after laser

Prolonged DCB inflation R popliteal
Crossing TPT CTO

Focal force PTA TPT
Outside US or in clinical trial: consider DCB

ISR in long stented area

Distal EPD
Jetstream

4 overlapping DCB’s after PTA
Conclusions

- There are multiple devices available to treat femoro-popliteal lesions
- The strategy used should be individualized, matching the advantages of a device to the patient’s anatomy and clinical presentation
- Further data with head to head comparisons would likely be helpful

Thank You for Your Attention!