Importance of Vessel Prep Before Stenting and DCBs: How to Best Do It and Proof of Its Value

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Disclosures
• Symposia Honoraria & Proctor Fees:
  — Abbott, Endologix/ TriVascular
• Symposia Honoraria:
  — Boston Scientific, Bard, Gore, CSI, Medtronic
• VIVA Board Member
• National PI/Co-PI: Confidence, SAPPHIRE WW, CANOPY
• Research Grants, Stocks, Equity
  — None

Chris: “Evidence for Vessel Prep”?
• “Vessel prep” makes sense, especially before DCB alone Rx
• There are a lot of devices designed for vessel preparation
• Many of these devices offer theoretic advantages, particularly in complex lesion subsets
• Some of these prep devices are relatively expensive
• Let’s pay attention to the amount of “evidence” we have that demonstrates superiority of individual vessel prep strategies...

What do We Mean by “Vessel Prep”??
• We want to “pre-treat” the lesion safely such that we leave definitive therapy options wide open AND increase their effectiveness
• BTK our Vessel prep may be “stand alone” therapy
• For femoro-popliteal lesions we want to maximize drug delivery to the vessel wall, while minimizing dissection and maximizing lumen (IF DCB is strategy, help it work best)

What Does “Vessel Prep” before DCB Mean?- 2
• In my opinion, it does NOT necessarily mean atherectomy
• Vessel Prep Goals:
  — Pretreat such that ≥ 1:1 DCB doesn’t dissect or that stent delivery and expansion are optimized
  — Remove impediments to drug delivery
  — Avoid drug loss on way to lesion
  — Maximize DCB expansion & vessel contact
  — Minimize dissections & issues w/ Prep, Rx

Limitations of Endovascular Therapy

1. Flow Limiting Dissection
2. Lesion Length
3. Calcium
4. Provisional Stenting

One goal: Maximize luminal gain while minimizing dissection
Are There Effective Strategies in these Scenarios to Get Luminal Gain While Minizing Dissection??

Vessel Preparation: GOOD PTA or Specialty Balloons

**Chocolate™ PTA Balloon Catheter**

- **Nitinol Constraining Structure:** Creates PILLOWS and GROOVES in balloon that provide predictable, uniform and atraumatic dilatation.
- **Braided Catheter Shaft:** Provides robust pushability to reach and cross lesions.
- **Nylon, Semi Compliant Balloon:** Allows for optimal balloon pillow formation
- **Distal and Proximal Marker Bands:** Provides visibility and accuracy of placement under fluoroscopy.
- **Tapered Tip:** Enables lower entry profile for optimal lesion access.

Chocolate Bar Study: Overview

**LARGE, PROSPECTIVE, POST MARKET STUDY**

<table>
<thead>
<tr>
<th>Study Overview</th>
<th>133 Patients (1-22/17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>Jihad Mustapha, MD</td>
</tr>
<tr>
<td>Number of Sites</td>
<td>33</td>
</tr>
<tr>
<td>Patients Enrolled</td>
<td>488</td>
</tr>
<tr>
<td>BTK</td>
<td>262</td>
</tr>
<tr>
<td>With planned follow-up through 6 months</td>
<td>226</td>
</tr>
<tr>
<td>AKI</td>
<td>226</td>
</tr>
<tr>
<td>With planned follow-up through 12 months</td>
<td>262</td>
</tr>
</tbody>
</table>

Inclusion Criteria:
- Any ATK or BTK lesion with at least 1 vessel runoff successfully crossed with a guidewire
- Use of atherectomy/re-entry devices accepted

Exclusion Criteria:
- Presence of a flow-limiting dissection at the target lesion prior to use of the Chocolate™* PTA balloon (secondary to the use of another device)
- Patients with Rutherford 6
- Chocolate™* PTA balloon not used in accordance with study protocol (2 min inflation to at least nominal pressure)

**Outcomes**

**Procedural Success**

| | BTK (n = 226) | ATK (n = 222) |
|------------------|----------------|
| Freedom from Flow Limiting Dissections* (Site Reported) | 97.7% | 99% |
| Freedom from Flow Limiting Dissections* (Adjudicated) | 100% | 100% |
| Achieved <30% Diameter Stenosis (Adjudicated) | 85.1% | 84.6% |
| Freedom from Bail-Out Stenting | 98.4% | 99.1% |

**Clinical Outcomes (Kaplan Meier)**

| | BTK (n = 226) | ATK (n = 222) |
|------------------|----------------|
| Freedom from Target Lesion Revascularization | 78.3% | 69.9% |
| Freedom from Major Unplanned Amputation | 92.3% | 96.7% |
| Freedom from All-Cause Mortality | 93.3% | 97.1% |

*Flow Limiting Dissections defined as: Type E - Persistent luminal filling defect with delayed run off of the contrast material in the distal lumen and Type F - Filling defect accompanied by total occlusion

**DEFINITIVE LE**

**Study Overview**

Prospective Multinational, Single Arm Study

Core-Lab Adjudicated*

Objective: Evaluate the effectiveness of standalone SilverHawk™/TurboHawk™ plaque excision systems for endovascular treatment of peripheral arterial disease in the femoropopliteal and tibioperoneal arteries

**Primary Outcomes**

- Claudicant: Primary Patency by Duplex Ultrasound at 12 months
- (PSVR ≤2.4 with no clinically-driven reintervention)
- CLI: Freedom From Major Unplanned Amputation at 12 months

**800 Patients**

- **47 Sites**
- US and Europe

**Follow up:** 1 year
DEFINITIVE LE

Results

<table>
<thead>
<tr>
<th>Classification</th>
<th>CLI</th>
<th>P-value</th>
<th>All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 598</td>
<td>n = 201</td>
<td>n/a</td>
<td>n = 799</td>
</tr>
<tr>
<td>Number of Lesions</td>
<td>763</td>
<td>279</td>
<td>1022</td>
</tr>
<tr>
<td>Mean Length (cm ± SD)</td>
<td>7.5 ± 5.3</td>
<td>7.2 ± 5.5</td>
<td>7.4 ± 5.3</td>
</tr>
<tr>
<td>Flow-Limiting Dissection Rate</td>
<td>2.2% (13)</td>
<td>2.1% (3)</td>
<td>2.3% (18)</td>
</tr>
<tr>
<td>Bailout Stenting</td>
<td>-</td>
<td>-</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

SO, We Do Have Data to Support Achieving Luminal Gain with Low Rates of Dissection and Bail-out Stenting for Some Vessel Prep Devices

What About Evidence to Support that Vessel Prep Devices are Superior to POBA Prep?

DEFINITIVE AR

Study Overview
Pilot Study to assess the effect of treating a lesion with directional atherectomy followed by drug-coated balloon vs. drug-coated balloon alone

DA: SilverHawk™/TurboHawk™ plaque excision systems
DCB: Cotavance™ drug eluting balloon

Primary Outcome: Target Lesion Percent Lesion Stenosis at 1 year (Angiographic Core Lab)

221 Patients
10 Centers in Europe
Follow up: 1 year

DEF AR and DA-ART: 12-Mo. DUS Patency
A Potential Advantage in Long, Severely Calcified Lesions?

12-Month Patency: DA-ART RCT Patients
Minimizing residual stenosis with directional atherectomy may be important

Directional Atherectomy + Drug Coated Balloon To Treat Long Calcified Femoropopliteal Artery Lesions

Ongoing; Overall very little completed RCT data!
POBA as Vessel Prep for DCB’s did Well!

12 mo. Primary Patency:
- Good PP w/ POBA Prep
  - 79.5%
  - 82.3%
  - 87.6%
  - 89.0%
- Bail Out Stenting %
  - Low stent rates w/ POBA prep

My “Vessel Prep” Algorithm
- Does the lesion look like it “needs” or would benefit from atherectomy before DCB?
  - If yes, individualized atherectomy w/ dEPD
- If not, perform PTA OR specialty PTA 1mm ≤ DCB, on roadmap
  - LONG, slow inflations; no “geographic miss”
- ≥1:1 DCB, with good technique
- Accept less than perfect results; only stent prn
  - If stenting, still need vessel prep (interwoven or nitinol)

Conclusions
- Vessel preparation, with increasing luminal gain, limiting dissection, preserving options, and maximizing drug delivery is essential for optimizing endovascular intervention outcomes
- There are several specialized tools to potentially improve vessel preparation
- There is very limited evidence for superiority of one vessel prep technique over another
- While awaiting data, use an individualized tailored approach

Thank You Very Much for Your Attention!