Disclosure

Speaker name: VENITA CHANDRA

I have the following potential conflicts of interest to report:

- Consulting: Medtronic Inc, Cook Medical, Abbott Vascular, Alucent Medical, Shockwave Medical, Penumbra, Smith & Nephew

- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
1. Intimal Calcification
   • Luminal narrowing
2. Medial Calcification
   • Decreased artery wall elasticity and compliance

Vessel calcification adversely affects clinical outcomes after vascular interventions
Particularly a problem in BTK/BTA

Medial calcium is more prevalent in BTK arteries

* Credit: Pr Marianne Brodmann – CRT19
* Soor et al, Peripheral vascular disease: who gets it and why? , Pathology 2008
What can we do?

• **Plaque modification** followed by POBA, DCB and or stenting

• **How to modify plaque?**
  • Scoring/Cutting/Caged balloons- *primarily for Fibroelastic disease*
  • *PIERCE/PICKING techniques*
  • High pressure POBA with noncompliant balloon
  • Serration Angioplasty
  • Intravascular Lithoplasty (IVL)
  • Atherectomy
High pressure POBA with Noncompliant Balloons

• 620 patients
• 18 atm for at least 120 s.
• >90% with moderate/severe calcification
• Long lesions (335mm mean)
• 0 flow limiting dissections
• 13.5% BOS rate
Serration Angioplasty

Serrating Elements use “Point Force”
- Applies 1,000x the force compared to POBA
- Enables low pressure inflation (6 ATM*)

3 Linear Serrated Strips (120° apart)
- Symmetrical Stress Relief ensures equal pressure across treatment segment
- Opens resistant lesions

* Prelude BTK: Safety/efficacy study being presented at LINC2021 by Dr. Andrew Holden
Case Example: Serration Angioplasty

Pre-Procedure:
Multi-tibial occlusion with incomplete pedal arch

Procedure:
- 2.5 x 40mm Serranator in distal AT
- 3.0 x 120mm Serranator in mid/prox AT
- 2.0 POBA in pedal arch

Post:
AT patent but sluggish flow with minimal pedal arch perfusion
Case Example: Serration Angioplasty

**Procedure**

DP and Pedal arch Serration angioplasty with 2.5 mm Serranator

**Post**

Brisk AT perfusion with improvement in pedal arch flow
Intravascular Lithotripsy

Expanding and collapsing vapor bubble creates a short burst of sonic pressure waves.

Sonic pressure waves travel through the vessel with an effective pressure of ~50 atm.

A localized field effect within the vessel fractures both intimal and medial calcium.
Pre-Procedure

Calcified chronic TP trunk occlusion with single vessel peroneal runoff

Pre-Procedure

s/p 4mm IVL and DCB
Disrupt BTK IVL Data

- BTK study, n= 21
- All with moderate/severe calcification
- Majority Rutherford 5
- Mean lesion length 52.2mm

- 0 MAE
- Acute reduction of target lesions to 46.5%
- All patients achieved residual stenosis<50%
- 1 dissection, 2 stents place
Available Atherectomy Devices

Directional Atherectomy
- Hawk portfolio: Silver Hawk, TurboHawk, & HawkOne (Medtronic)
- Pantheris (Avinger)

Orbital Atherectomy
- Diamondback 360 (CSI)

Rotational Atherectomy
- JetStream (Boston Scientific)
- Phoenix (Volcano)

Photoablation Atherectomy
- Turbo-Elite & Turbo-Tandem (Spectranetics)
BTK Atherectomy in Calcified Vessels Data

<table>
<thead>
<tr>
<th></th>
<th>CALCIUM 360</th>
<th>DEFINITIVE LE (Infrapop)</th>
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<tbody>
<tr>
<td>OA+PTA v PTA</td>
<td></td>
<td>DA</td>
</tr>
<tr>
<td>Subjects</td>
<td>25 (OA+PTA)</td>
<td>145</td>
</tr>
<tr>
<td>Bail-out Stent</td>
<td>6.9% (2/29)</td>
<td>1.6% (3/189)</td>
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<tr>
<td>MAE (12-mo)</td>
<td>6.7% (1/15)†</td>
<td></td>
</tr>
<tr>
<td>FF MAE (12-mo)</td>
<td>93.1%</td>
<td>79.6%</td>
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<tr>
<td>1° Efficacy (12-mo)</td>
<td></td>
<td>84.0%</td>
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<tr>
<td>1° Efficacy Definition</td>
<td>Acute residual stenosis ≤ 30% w/o bail-out stenting or dissection (C through F)</td>
<td>Patency = PSVR &lt; 2.4</td>
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<tr>
<td>TLR (12-mo)</td>
<td>6.7% (1/15)</td>
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<tr>
<td>FF-TLR (12-mo)</td>
<td>91.2%</td>
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<td>Amputation (12-mo)</td>
<td>0%</td>
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<tr>
<td>Limb Salvage (12-mo)</td>
<td></td>
<td>97.1% (141/145)</td>
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- Studies differ in designs and endpoints (CALCIUM 360 = small, site-reported RCT v DEFINITIVE LE = large, core lab-adjudicated single-arm).
- Low bail-out stent and high limb salvage rates.

In Conclusion

• Heavily calcified BTK/BTA lesions are prevalent
• Some form of plaque modification likely necessary
• Growing armamentarium of tools
• BTA new frontier
• My algorithm:
  • Mild/Moderate intimal calcification:
    • High pressure POBA, and/or Serration angioplasty and/or IVL
  • Heavy bulky intimal calcium consider:
    • Atherectomy and/or Serration angioplasty
  • Significant medial and intimal calcification
    • IVL and/or Serration Angioplasty
Thank You!