Optimal Treatment For Crural Artery Lesions In 2018 In The US And Elsewhere: Value Of Coronary Drug Eluting Stents (DESs): When And How To Use Them

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Disclosures:
In the past 12 months, my spouse or myself have engaged in financial relationships as follows:

- Consultant:
  - Boston Scientific, Medtronic
- Advisory Panel:
  - The Medicines Company
- Speakers Bureau:
  - Medtronic, Abbott, Endologix
- Research Support
  - Philips Healthcare, Venite, Bard, BTG, Boston Scientific, Penumbra, Angiodynamics
- Clinical Events Committee
  - Shockwave (Drug eluting), Intact Vascular (TOBA-2)

Infrapopliteal---BTK

Randomized trials for DES-BTK

- Achilles
  - Sirolimus eluting (Cypher) stent vs. PDBA
- Yukon
  - Sirolimus eluting (Yukon/no polymer) stent vs. BMS
- Destiny
  - Euvrolimus eluting stent (Xience) vs. BMS (Multilink Vision)

Summary of DES-BTK randomized trials
12 month Patency

<table>
<thead>
<tr>
<th>Trial</th>
<th>DES</th>
<th>PTA/BMS</th>
<th>Lesion length</th>
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<tr>
<td>Achilles</td>
<td>80.6%</td>
<td>58.1%</td>
<td>25-27mm</td>
</tr>
<tr>
<td>Yukon</td>
<td>80.6%</td>
<td>55.6%</td>
<td>31mm</td>
</tr>
<tr>
<td>Destiny</td>
<td>85.2%</td>
<td>54.4%</td>
<td>16-19mm</td>
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In a purely CLI cohort

- Statistically better Amputation free survival
- Statistically better freedom from MALE
- These divergent results occurred between 12-24 months
**DESTINY 2 study:**
12 Month Primary Patency

75.4%

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**Updated Mt. Sinai DES-BTK long lesion registry**

- 10 yr Single Center Experience
- EES-BTK (Xience)
- 214 pt cohort
- 70 pts “Long Lesions” (>2stents)
- Mean lesion length 10.4cm (3 Stents) (45-150mm)
- Rutherford 4,5

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**Summary of DES-BTK randomized trials**

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<tr>
<td>PADI</td>
<td>65.1%</td>
<td>42%</td>
<td>23mm</td>
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<tr>
<td>Destiny 2</td>
<td>75.4%</td>
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<td>45mm</td>
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Whats on the Horizon??

SAVAL™ Trial DES BTK stent
- Nitinol Self-Expanding Stent
  - Flexible crush resistant scaffold
  - Diameter compliant
- PTx drug coating (PBMA/PVDF)

Experience With the Absorb Everolimus-Eluting Biodegradable Vascular Scaffold in Arteries Below the Knee 12-Month Clinical and Imaging Outcomes

The SAVAL™ Pivotal Trial
A Randomized Trial comparing the Drug-Eluting Stent (DES) Below-the-Knee Vascular Stent System vs Percutaneous Transluminal Angioplasty (PTA) Treating Infrapopliteal Lesions in Subjects With Critical Limb Ischemia
- Planned Global Pivotal Trial
- Randomized DES vs PTA
- 6 Month Primary Patency Endpoint
- FDA EAP - Breakthrough Pathway
- First Ever EAP in Peripheral Branch of FDA
- Enrollment Started Mid-2018

In summary
- Four randomized trials demonstrate the superiority of BX-DES over POBA and BMS for short below knee lesions at improving primary patency
- The patency benefit does not translate into limb salvage or survival benefit at 1 year follow up
- 2 year follow up appears to demonstrate clinical benefit
- Below knee stent trials in the US are years away.
- There will likely be a need for both BX and SX BTK implants given the complexity of the lesions being treated

In my practice
- Long lesion POBA based on the evidence from the randomized trials
- Balloon expandable drug eluting stents for short lesions or bailout in the setting of recoil or dissection
- Reserve atherectomy for dense/severe calcification
- Eagerly awaiting dedicated labeled implants for BTK in the US.