Drug Eluting Devices: Facts or Concerns

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Drug Elution for Peripheral Applications: Intended Clinical Benefit of DES & DCB

Anti-proliferative drugs (e.g., paclitaxel) counteract neointimal response to intervention\(^1\)

Prolong vessel patency
Reduce need for reintervention

**DES**
- Inhibit restenotic cascade
- Scaffolding prevents vessel shrinkage (recoil)

**DCB**
- Inhibit restenotic cascade
- Prevent lumen loss

Meta-analyses have shown improved patency and TLR rates for DES and DCB treatment, compared with bare-metal stents and PTA, in the femoropopliteal segment\(^1,2\)

DCB, drug-coated balloon; DES, drug-eluting stent; PTA, percutaneous transluminal angioplasty; TLR, target lesion revascularization.

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only. The Ranger Drug Coated balloon is an investigational device, not available for sale in the United States.
Limits of DCB Treatment Durability: *Long Lesion*
Limits of DCB Treatment Durability

Lesion Length

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

- **1 year**: no association between increasing mean lesion length and worsening primary patency or TLR rates
Limits of DCB Treatment Durability
Lesion Length

• 2 years: patency and reintervention rates appear to be worse for cohorts with longer lesions

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In Studies Assessing DCB Outcomes: Primary Therapy Stents Were Commonly used

- Longer mean lesion length correlates with higher provisional stenting rate
Pilot study results suggest increased benefit of DES (vs DCB) in lesions >10cm in length (greater separation between patency curves)

![Graph showing survival probability over time with Kaplan-Meier estimates for Zilver PTX and DCB]

<table>
<thead>
<tr>
<th>Lesion Length</th>
<th>DCB</th>
<th>ZILVER PTX</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>&gt;10 cm</td>
<td>0.26±0.07</td>
<td>0.45±0.08</td>
<td>0.1892</td>
</tr>
<tr>
<td>&lt;10 cm</td>
<td>0.64±0.11</td>
<td>0.77±0.09</td>
<td>0.4524</td>
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</tbody>
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- Intent-to-treat; DCB group includes patients who received bailout stents.
Limits of DCB Treatment Durability: Calcium
Lesion Calcification May Affect Drug-Coated Balloon Efficacy

- 60 patients with SFA stenosis or occlusion treated with DCB
- 50% primary patency rates in heavily calcified SFA lesions, regardless of lesion length
- Greater calcification was associated with poorer outcomes at 1 year:
  - Greater TLR rate
  - Lower ankle-brachial index
  - Greater late lumen loss

DCB, drug-coated balloon; SFA, superficial femoral artery; TLR, target lesion revascularization.

Calcium burden quantified with computed tomography angiography (CTA), digital subtraction angiography (DSA), and intravascular ultrasound (IVUS).
Severe Calcification Is More Prevalent In Stenting Studies

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.
Limits of DCB
Treatment Durability:
Occlusions
• 1 year: no association between occlusions and worsening primary patency or TLR rates
Limits of DCB Treatment Durability

Occlusions

- 2 years: patency and reintervention rates appear to be worse for cohorts with greater proportions of patients with occlusions

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Limitations of Stent Technology on the Market
SFA Stenting Clinical Trials at 12M

- Historically, stenting studies show TLR rates near double digits and higher

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.
SFA Stenting Clinical Trials at 12M

- What vessel beds are we most comfortable stenting in?
- What is an acceptable SFA TLR rate?

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.
Mortality Rates from Literature

### 3-Year Mortality

- **Cook PTX**: 10, 11, 16
- **Cook BMS**: 5, 10, 15
- **PAD Mortality Literature Review**: 9, 10, 12

### 5-Year Mortality

- **Cook PTX**: 14, 19, 24, 51
- **Cook BMS**: 15, 18, 23, 23
- **PAD Mortality Literature Review**: 9, 16, 25, 25, 26, 27
No Increased Long-term Mortality with DES

- Medicare CMS population
- 51,456 patients
  - 47,351 BMS
  - 4,105 DES (Zilver PTX)
- Similar mortality for BMS and DES through 4.1 years
  - Overall adjusted $p=0.53$
  - Without CLI adjusted $p=0.95$
  - With CLI adjusted $p=0.32$

Conclusions

- Data show lesion complexity and characteristics (lesion length, calcium and occlusions) may negatively impact DCB treatment durability from year one to year two.

- Data suggests provisional stenting becomes more prevalent as mean lesion length increase, exceeding 30% in some DCB trials.

- SFA stenting clinical trials continue to achieve lower TLR rates as next generation technology become available.
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