Why My Stent Usage is Increasing

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Why My Stent Usage is Increasing Not Decreasing

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Disclosure

Speaker name:
Andrew Holden

I have the following potential conflicts of interest to report:

☒ Consulting – Clinical Researcher for Cook Medical
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)
Is a Stent or Scaffold Necessary in The SFA?

- Stents were developed to optimize acute results after angioplasty.
- Specifically, stents are universally accepted to manage flow-limiting dissections and hemodynamically significant residual stenoses.
Is a Stent or Scaffold Necessary in The SFA?

- Stents were developed to optimize acute results after angioplasty.
- Specifically, stents are universally accepted to manage flow limiting dissections and hemodynamically significant residual stenoses.
- In the era of DCBs, should the incidence of primary stenting or bail-out stenting be reduced?
IN.PACT SFA: A Prospective Randomized Trial of a Drug-Coated Balloon for Femoro-popliteal Lesions

Log-rank $P < 0.001$

Primary Patency

Number at risk

DCB

PTA

Time after Index Procedure (Months)

<table>
<thead>
<tr>
<th>Time</th>
<th>DCB</th>
<th>PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>220</td>
<td>111</td>
</tr>
<tr>
<td>6</td>
<td>209</td>
<td>103</td>
</tr>
<tr>
<td>12</td>
<td>185</td>
<td>66</td>
</tr>
<tr>
<td>18</td>
<td>153</td>
<td>51</td>
</tr>
<tr>
<td>24</td>
<td>143</td>
<td>50</td>
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</table>
In the randomized DCB trials, patients with sub-optimal angioplasty that would normally require stenting were excluded from the trial!
1. With symptoms of claudication and/or rest pain and angiographic evidence of SFA/PPA stenosis
2. Pre-dilatation mandatory for all subjects in IN.PACT SFA II phase only

Charing Cross 2014

**Trial Design**

Pre-screening

Screening

Randomization

**Screen Failure**
(treat per std practice)

**RC 2-3-4**

Clinical and Anatomic Inclusion / Exclusion Criteria

SUCCESSFUL PRE-DILATATION

331 Randomized 2:1

IN.PACT (220)

PTA (111)

Provisional Stenting?

**Secondary Analysis**
(331 ITT ALL Subjects)

**Primary Analysis**
(301 ITT NON-Stented Subjects)
LEVANT 2 Clinical Trial

PTA Pre-Dilatation
With 1mm undersized Uncoated Balloon

Randomize 2:1

Successful Pre-Dilation

Test Arm:
Dilatation with Drug Coated Balloon

Control Arm:
Dilatation with Uncoated Balloon

Suboptimal PTA:
Major flow limiting dissection OR >70% residual stenosis

Treat per standard practice
30 day follow-up for safety

12 Month Follow-up

CAUTION: Investigational Device - Limited by Federal (USA) Law to Investigational Use
What Can We Conclude from the DCB Trials?

- Treatment of short and medium length lesions (8.9cm In.PACT SFA; 6.3cm Levante 2)
- Relatively simple lesions
- Evaluates a sub-group of patients who have a good result after plain balloon angioplasty
- These patients have better 1 and 2 year patency if they are subsequently treated with a DCB
Challenges for Nitinol Stents in the SFA last Decade

- Stent fractures
- Ongoing chronic outward force and vessel irritation leading to re-stenosis
- Patency excellent at 12 months but declining after this
- “Leave nothing behind”

Absolute Trial, Circulation 2007
Scheinert et al. JACC; 45(2): 312-315
Stents in the SFA in 2016

- Significant stent fractures are rare:
  - Cook Zilver PTX RCT 1.9% @ 5 years
  - Abbott Supera SUPERB IDE 0.5% @ 2 years
  - Cordis SMARTFlex FIM 0% @ 18 months
Stents in the SFA in 2016

Long term patency concerns of stents addressed by two technologies:

- Drug elution
- Stent design
24-Month Effectiveness
Primary Patency (PSVR < 2.0): Zilver PTX vs. PTA

- Zilver PTX: 83.1% (Successful PTA 116 Lesions)
- All PTA: 74.8% (All PTA 241 Lesions)
- Zilver PTX: 53.4%
- Substudy PTA: 26.5%
At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care.
Boston Scientific Eluvia™ Drug-Eluting Stent for the SFA: Majestic Clinical Trial

- Innova stent platform, Paclitaxel eluting
- 6F Tri-axial SDS, 0.035” guidewire compatible
- Controlled drug release
Boston Scientific Eluvia™ Drug-Eluting Stent for the SFA: Majestic Clinical Trial

- 12 month primary patency 96.1% (49/51)
- Kaplan-Meier estimate 96.4%

<table>
<thead>
<tr>
<th>Length (mm)</th>
<th>70.8±28.1</th>
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<tbody>
<tr>
<td>Calcification</td>
<td></td>
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<tr>
<td>None/Mild</td>
<td>21.1%</td>
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<tr>
<td>Moderate</td>
<td>14.0%</td>
</tr>
<tr>
<td>Severe</td>
<td>64.9%</td>
</tr>
<tr>
<td>Percent Diameter Stenosis</td>
<td>86.3±16.2%</td>
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<tr>
<td>Occlusions</td>
<td>46%</td>
</tr>
</tbody>
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![Graph showing primary patency rate over 12 months]
Stent Design – Biomimetic Stent

• Abbott Supera interwoven nitinol design provides high radial compressive resistance, low chronic outward force and flexibility
• Need for thorough vessel preparation, accurate sizing and careful deployment
• Impressive Registry data but a relative lack of randomised data
• Excellent clinical results in challenging anatomic location
At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care.
At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care.
Only patient group evaluated in DCB RCTs
DES shows a clear long term patency benefit

Only patient group evaluated in DCB RCTs
Primary Stenting in Intermediate/Complex Lesions?

- Even in the era of conventional nitinol SE stents, there was evidence that primary stenting in selected patient anatomies did better than angioplasty/provisional stenting.
Primary Stenting in Intermediate/Complex Lesions?

- The ability to perform propensity scoring, has allowed matching of data sets and valid comparisons between competitive technologies – SUPERA, BMS, DEB

<table>
<thead>
<tr>
<th></th>
<th>SUPERA (n=470)</th>
<th>BMS (n=432)</th>
<th>DEB (n=390)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length (mm)</td>
<td>126 +/- 82</td>
<td>148 +/- 108</td>
<td>199+/116</td>
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- Zilver PTX not included in the analysis
- Loss of patency based on PSVR > 2.4

Steiner et al, University Hospital Leipzig, LINC 2015
Primary stenting in complex CTOs optimizes the result and minimizes the risk of complications including distal embolization.
Current Approach to Claudicants with SFA Disease

The vast majority of lesions are initially managed with plain balloon angioplasty (for at least 2 minutes) dilated to NOMINAL...
Current Approach to Claudicants with SFA Disease

- Short lesions (≤ 8cm) that respond well to POBA are then treated with DCB as an anti-restenosis strategy
- Sub-optimal post-angioplasty lesions are treated with DES. Very calcified and popliteal lesions – biomimetic stent
Current Approach to Claudicants with SFA Disease

- Intermediate lesions (8-20cm) are treated with either DCB with spot stenting OR direct DES
- The more complex the lesion (CTO length etc) or poorer result after POBA, the lower the threshold for 1° Stenting
Roger’s Bell Curve – Technology Adaptation Lifecycle
Conclusions

- Plain balloon angioplasty to nominal diameter allows all treatment strategies to be utilized.
- Bail out stenting after sub-optimal angioplasty (POBA and DCB) is still frequently required when treating complex SFA lesions.
- There is some evidence that a primary stenting approach for complex SFA disease is associated with improved patency.
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