The cost economic value of DCB

Konstantinos Katsanos, MSc, MD, PhD, EBIR
Consultant Interventional Radiologist
Guy's and St.Thomas' Hospitals
King's Health Partners
London, UK
Traditional business model

- Company
- Customers

Healthcare business model

- Payers
- Providers
- Patients
Incremental Cost-effectiveness (ICER = $\Delta$ cost / $\Delta$ effect)

Trade-off between incremental costs and benefits
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
ALL ITT, 12-month Clinically-driven TLR

<table>
<thead>
<tr>
<th>IN.PACT DCB</th>
<th>PTA</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically-driven TLR [1]</td>
<td>2.4%</td>
<td>20.6%</td>
</tr>
</tbody>
</table>

1. Clinically-driven TLR defined as any re-intervention due to symptoms or drop of ABI/TBI of >20% or >0.15 compared to post-procedure ABI/TBI
2. Actual event rate by frequency ratio algorithm calculation

(p<0.001 by log-rank test)
Methods

• Prospective economic analysis alongside the IN.PACT SFA II trial

• Analytic perspective
  – US healthcare system

• Patient population
  – US patients - all intention-to-treat participants were included

• Primary 2-year endpoint
  – Total PAD related costs for the target limb
  – The current results are an interim 1-year analysis
### Index Resource Use

<table>
<thead>
<tr>
<th></th>
<th>DCB n=121</th>
<th>Standard PTA n=60</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard PTA balloons</td>
<td>1.3 ± 0.5</td>
<td>2.3 ± 0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Drug-coated balloons</td>
<td>1.4 ± 0.6</td>
<td>0.0 ± 0.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stents</td>
<td>0.1 ± 0.3</td>
<td>0.2 ± 0.5</td>
<td>0.067</td>
</tr>
<tr>
<td>Index procedure costs</td>
<td>$5918 ± 2425</td>
<td>$4604 ± 2331</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Index hospitalization costs</td>
<td>$8258 ± 3223</td>
<td>$7164 ± 3325</td>
<td>0.002</td>
</tr>
</tbody>
</table>

**Initial hospitalization cost excess = $1,094/pt treated with DCB**
## Follow-up Resource Use and Costs

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Target Vessel Revascularization (TVR) events (per 100 pts)</td>
<td>11.6 ± 76.6</td>
<td>23.3 ± 62.1</td>
<td>0.005</td>
</tr>
<tr>
<td>Proportion with at least 1 TVR</td>
<td>6 (5.0%)</td>
<td>11 (18.3%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Target limb hospitalization costs</td>
<td>$1324 ± 9148</td>
<td>$1975 ± 5260</td>
<td>0.002</td>
</tr>
<tr>
<td>Medication costs</td>
<td>$348 ± 440</td>
<td>$344 ± 277</td>
<td>0.378</td>
</tr>
<tr>
<td>Physician fees</td>
<td>$104 ± 574</td>
<td>$211 ± 522</td>
<td>0.002</td>
</tr>
<tr>
<td>Total follow-up costs</td>
<td>$1777 ± 9699</td>
<td>$2530 ± 5823</td>
<td>0.067</td>
</tr>
</tbody>
</table>

Follow-up Costs offsets = -$753/pt treated with DCB
Total ∆ in 1-year costs = $341

Higher initial costs for DCB arm are largely offset by lower 1 year follow-up costs.
Cost per Target Vessel Revascularization Avoided

Δ cost = $341/pt
Δ TVR = 0.117

ICER = ~$2,910 per TVR avoided
Summary

- Index hospitalization costs were \( \approx $1000 \) per patient higher in patients treated with DCB, driven primarily by the cost of the DCB itself.

- Fewer target vessel revascularizations over 1-year follow-up in patients treated with DCB, with average cost offsets of \( \sim $750 \) per patient \( \rightarrow \) net 1-year cost increase of $340/patient.

- The incremental cost-effectiveness ratio for the DCB was \( \sim $2,910 \) per repeat revascularization avoided.
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