Cost-effectiveness of drug-coated balloons for femoropopliteal chronic limb-threatening ischemia

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Disclosure

Speaker name:
Michel Reijnen

I have the following potential conflicts of interest to report:

✓ Consulting

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

☐ I do not have any potential conflict of interest
Background

• Chronic limb-threatening ischemia (CLTI) is associated with a high risk of lower limb loss.¹

• Drug-coated balloons (DCB) play an increasing role in the treatment of CLTI, caused by femoropopliteal occlusive disease, with a reported 82% patency rate and a 7% major amputation rate to 12-months in one meta-analysis.²

• The objective of the current study was to assess the potential cost effectiveness of DCB use versus standard-of-care interventions in the Dutch and German healthcare systems.

**United States**

Total National Health Expenditures, $ per Capita

**The Netherlands**

Total National Health Expenditures, € per Capita

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Study Design

**Method**

Decision-analytic Markov model using Dutch and German reimbursement data

**Groups**

- DCB with Bailout Stenting (IN.PACT Admiral DCB)
- "Status Quo" Standard PTA and Primary or Bailout Stenting

**Clinical Data**

- IN.PACT Global Study
  - Prospective, multicenter, international, single-arm
  - N=156 Rutherford 4-5 Subjects with femoropopliteal lesions

**Systematic Literature Search**

- PTA, DCB, BMS, or DES in cohorts with close to 100% CLTI symptoms (Rutherford 4-6) and primary femoropopliteal lesions

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QALY Analysis

• The incremental cost-effectiveness ratio of DCB versus Status Quo was evaluated as the cost per quality-adjusted life year (QALY) gained.¹

• The decision-analytic Markov model was applied separately for each country.

• Strategy-specific QALY gains were calculated from survival and health state-specific utilities.¹

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Clinical Inputs and Additional Details

<table>
<thead>
<tr>
<th></th>
<th>DCB 2 (N=156)</th>
<th>Status Quo 3-7 (N=192)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Year</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLR</td>
<td>14.1%</td>
<td>18.0%</td>
</tr>
<tr>
<td>Major amputation</td>
<td>1.4%</td>
<td>6.1%</td>
</tr>
<tr>
<td><strong>2 Years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(projected event rates using 12-month data)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLR</td>
<td>26.2%</td>
<td>32.8%</td>
</tr>
<tr>
<td>Major amputation</td>
<td>2.8%</td>
<td>11.9%</td>
</tr>
</tbody>
</table>

• Three health states:
  • Post-endovascular intervention
  • Post-major amputation
  • Death

• TLR: One-time 0.059 QALY decrement
• Amputation: 0.68 QALY decrement applied to post-amputation period
• The base case used a 2-year horizon
• Willingness-to-pay threshold was set at €50,000 per QALY gained
• Sensitivity analyses were carried out to evaluate variations in clinical input and device use parameters

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DCB and Status Quo Treatment Costs over Two Years


### Netherlands
- **Status Quo:** €10,791
  - Index Cost: €7,063
  - TLR Cost: €1,714
  - Amputation Cost: €2,152
- **DCB:** €9,761
  - Index Cost: €7,678
  - TLR Cost: €1,714
  - Amputation Cost: €2,152

### Germany
- **Status Quo:** €5,175
  - Index Cost: €1,030
  - TLR Cost: €810
  - Amputation Cost: €3,256
- **DCB:** €4,662
  - Index Cost: €883
  - TLR Cost: €1,109
  - Amputation Cost: €3,588

**DCB cost savings:** €1,030 in the Dutch analysis and €513 in the German analysis
Two-year Calculated QALYs for Status Quo and DCB

**24-Month Costs**

<table>
<thead>
<tr>
<th></th>
<th>Netherlands</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status Quo</td>
<td>1.479</td>
<td>1.456</td>
</tr>
<tr>
<td>DCB</td>
<td>1.496</td>
<td>1.473</td>
</tr>
</tbody>
</table>

**DCB QALY advantage:**
+0.017 in both analyses

Sensitivity Analyses
DCB Dominant or Cost-effective Across a Wide Range of Assumptions

Cost Difference
DCB vs. Status Quo (Netherlands)

Cost Difference
DCB vs. Status Quo (Germany)

High Input
Low Input

Base Cost Difference
(€1030)

Base Cost Difference
(€513)

Summary

• In this analysis of the IN.PACT Admiral DCB, DCB treatment was associated with favorable health economic value in Germany and the Netherlands.¹

• DCB use was associated with lower total costs (€1030 Dutch and €513 German) and higher QALYs (0.017 in both) and is therefore likely the dominant treatment strategy in both the Dutch and German settings.¹

• Higher DCB index procedure costs are offset over 24 months by reduced reintervention rates and avoided amputation events.¹

• Because this study evaluated only one type of DCB compared to a literature-based comparator, future studies are needed to confirm these results.¹

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