Drug-coated balloon use in the SFA: Budget impact analysis and reimbursement in Austria

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Disclosure

Speaker name: Marianna Brodmann, MD

I have the following potential conflicts of interest to report:

- Consulting: Medtronic, Spectranetics
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Clinical Evidence to support Austria DCB reimbursement

- As concluded in the Health Technology Assessment (HTA) by the Ludwig Boltzmann Institut, the available evidence indicates that DCB for patients with PAD (Rutherford ≥3) in femoropopliteal arteries is more effective and not less safe than PTA with uncoated balloons.

Objective

However, the cost-effectiveness of drug-coated balloons compared to other reimbursed therapies is unknown in Austria.
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Our objective was to study the economic impact of the four main endovascular treatment strategies for femoropopliteal arterial disease in Austria, using latest clinical evidence and 2016 reimbursement rates and device costs.
Methodology & Assumptions

- A previously published decision-analytic Markov model[1] was adapted to the Austrian setting taking into account country-specific therapy utilization and 2016 costs.

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- We estimated clinical performance of PTA, BMS, DCB, and DES using information from a recent systematic search of studies of femoropopliteal lesions reporting TLR as an endpoint.\(^2\)


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- For the four index procedure strategies (PTA, DCB, BMS, and DES), we computed budget impact to payers, considering up to one reintervention. Assumptions about therapy use in any applicable secondary revascularization were based on physician experience in the Austrian setting.

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Clinical Model Results: Freedom from TLR over 24 Months (pooled)

- 28 studies were included, reporting on n = 5,167 primarily de-novo TASC A or B lesions.
- Pooled 24-month probabilities of Freedom from TLR were 82.4% (DCB), 80.6% (DES), 73.1% (BMS), and 61.5% (PTA).
- A subset analysis of urea-excipient based DCB (3.5 μg/mm² — Medtronic IN.PACT) vs. other DCB yielded Freedom from TLRs of 88.8% (IN.PACT) vs. 78.1% (other DCB).

*IN.PACT DCB DCB only, pooled: 88.8%

Proportions of patients without TLR, by therapy, at 12 and 24 months, based on weighted pooling of identified trial data.
Over 24 months, DCB had the lowest budget impact to payers of €4,100,
followed by PTA (€5,010), DES (€5,478), and BMS (€5,747).
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- Considering only the urea excipient-based DCB (IN.PACT DCB), DCB budget impact was further reduced to €3,839 because of lower TLR cost.

24-month budget impact for all modalities including all DCB devices, and using urea-excipient-based DCB (IN.PACT DCB) only (right column).
Numbers Need to Treat to avoid One Re-intervention

• Comparing DCB (all types) to the least effective therapy (PTA), we found a NNT of 4.8, suggesting that for every five patients treated with DCB, one TLR could be avoided over 24 months.¹

• In comparison, NNT of the IN.PACT DCB to PTA was 3.7, and that of “all other DCBs” to PTA 6.0
  – It would take 1.5 times as many patients treated with another DCB to avoid 1 TLR, compared to IN.PACT DCB

¹ NNT to avoid 1 TLR over 24 months (compared to PTA): BMS: 8.6; DES: 5.2; DCB: 4.8; IN.PACT DCB: 3.7; Other DCB: 6.0
Clinical Evidence to support Austria DCB reimbursement

- Ludwig Boltzmann Institut HTA: the available evidence indicates that DCB for patients with PAD (Rutherford ≥3) in femoropopliteal arteries is more effective and not less safe than PTA with uncoated balloons.
- Reimbursement in Austria supported in large part by quality of IN.PACT DCB clinical results

<table>
<thead>
<tr>
<th>Randomized Controlled</th>
<th>Randomized Controlled</th>
<th>Uncontrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheinert 2015</td>
<td>Fanelli 2012 (IN.PACT DCB)</td>
<td>Micari 2012 (IN.PACT DCB)</td>
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<tr>
<td>Tepe 2015 (IN.PACT DCB)</td>
<td>Fanelli 2014 (IN.PACT DCB)</td>
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<tr>
<td>Scheinert 2014</td>
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<tr>
<td>Liistro 2013 (IN.PACT DCB)</td>
<td>Tepe 2008</td>
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From January 1st 2017, DCB used in lower extremities procedures is officially reimbursed in Austria.

The new DRG points/tariff for the DCB (code EF031) will be >65% greater in 2017 in comparison to 2016 and in line with reimbursement in other European countries.

With this new reimbursement, the efficacy and impact on patient outcomes, rather than cost, should be the primary consideration in use of DCB in patients with femoropopliteal disease.

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**Austria DRG 2017 vs. 2016 for Drug-Coated Balloon in Use of Lower Extremities Procedures**

<table>
<thead>
<tr>
<th>Year</th>
<th>MEL Group</th>
<th>DRG Code *</th>
<th>DRG Points (€) **</th>
<th>LOS Component (€)</th>
<th>Operation Component (€)</th>
<th>Operation Supplement (€) ^</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>MEL20.01</td>
<td>EF031</td>
<td>5,590</td>
<td>2,924</td>
<td>2,666</td>
<td>1,084</td>
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<tr>
<td>2016</td>
<td>MEL20.01</td>
<td>EF031</td>
<td>3,383</td>
<td>1,949</td>
<td>1,434</td>
<td>795</td>
</tr>
</tbody>
</table>

* EF031 = Percutaneous transluminal angioplasty (PTA) with drug-coated balloon (DCB) in the lower extremities.

** 1 DRG/LKF point is approximately 1 € as calculated from the Ministry of Health. The tariff (DRG points) covers the total cost of operation including costs for hospital admission (LOS = length of stay). There are some differences in LKF point values between 9 Federal states. Nevertheless a differential settlement in all public hospitals should be covered with additional federal state budget.

^ Operational supplement is applicable when the contralateral limb is treated during the same procedure.
Conclusion

• DCB is shown to be the most cost-effective therapy in comparison to other SFA technologies
  • DCB with urea-based excipient (IN.PACT) shown to be more cost-effective than other DCB due to difference in efficacy level
• DCB technology is now reimbursed in Austria
  • New code, new DRG (LKF) points
• IN.PACT DCB’s robust clinical evidence (Freedom from TLR >90%) led to new DCB reimbursement in Austria
My personal experience with procedures including DCB in Graz

- A procedure with standard endovascular modalities (PTA, BMS) is coded ~4,300 DRG/LKF points

- With the addition of DCB, reimbursement for the procedure is raised by 2,000 DRG/LKF points
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