Health Economic Analysis of Drug-Coated Balloon Use in Belgium: Implications for Practice

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Disclosure

Speaker name: Frank Vermassen, MD

I have the following potential conflicts of interest to report:

X Consulting: Medtronic, Abbott Vascular, Bard, W.L. Gore, Terumo, Boston Scientific

☐ 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

• Drug-coated balloons (DCBs) have emerged as an effective treatment for atherosclerotic disease in the femoropopliteal segment

• Results from randomized trials have demonstrate superiority of DCBs versus angioplasty at 1 and 2 years \(^{1-7}\), with IN.PACT DCB showing sustained and durable benefit through 4 years \(^{8,9}\)

• Previous economic analyses from a German, Austria, United Kingdom, and United States health system perspective have shown IN.PACT DCB to be cost-effective in all these countries

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Objective

• The Belgian reimbursement system is based on an all-in reimbursement for the materials used during a procedure.

• The cost-effectiveness of drug-coated balloons compared to other reimbursed therapies is unknown in Belgium.

• The objective was to study the economic impact of three main endovascular treatment strategies for femoropopliteal arterial disease in Belgium, 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 Belgian setting taking into account country-specific therapy utilization and 2016 costs

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Methodology & Assumptions

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

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

Clinical Model Results

Freedom from TLR over 24 Months (Pooled)

• Pooled 24-month probabilities of Freedom from TLR were 83.5% (DCB), 73.2% (BMS), and 60.5% (PTA)

Proportions of patients without TLR, by therapy, at 12 and 24 months, based on weighted pooling of identified trial data.
Budget impact of 3 revascularization strategies over 24 months

- Based on this model, over 24 months, DCB had the lowest budget impact to payers of €7,676, followed by PTA (€9,250), and BMS (€9,291)
Budget impact of IN.PACT DCB

- A subset analysis of the Medtronic IN.PACT balloon vs. other DCB showed freedom from TLR of 91.5% (IN.PACT) vs. 78.1% (other DCB)
- Considering the results with the IN.PACT DCB, DCB budget impact per patient was further reduced to €7,089
DCB Reimbursement In Belgium

- Based on the results of this analysis from **April 1st 2017**
  IN.PACT DCB used in SFA and/or popliteal procedures is officially reimbursed in Belgium.
- Value of reimbursement:
  - PTA + DCB(‘s) for SFA and/or popliteal.: €1,524.00
  - PTA + DCB(‘s) and stent(‘s) for SFA and/or popliteal.: €1,524.00
  - Contralateral: €1,143.62

Reference:
- PTA (POBA) without stent: €464.93
- PTA with stent (BMS): €1401.42

- Clinical criteria required for Reimbursement:
  - Probability of revascularisation superior vs POBA or not inferior vs already reimbursed device – prospective RCT – 12m FU – 80% per protocol statistical power
  - Acceptable safety profile ≥ 200 pts
Conclusion

• DCB was shown to be the most cost-effective therapy in comparison to other SFA technologies. Freedom from TLR is the most important driver.

• Value-based healthcare is gaining importance, guiding health insurance institutions in their reimbursement policy.

• Thanks to this new reimbursement, the efficacy and impact on patient outcomes, rather than cost, became the primary consideration in use of DCB in patients with femoropopliteal disease.