Cost-utility analysis of Intravascular Ultrasound (IVUS) guided Percutaneous Transluminal Angioplasty (PTA) in patients with Peripheral Arterial Disease (PAD)

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Disclosure

Speaker name:
Michael Lichtenberg

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
Adjunctive IVUS during peripheral interventions remains under-utilized despite proven clinical benefits

Current state of endovascular interventions

Endovascular interventions are the treatment of choice in symptomatic patients with femoropopliteal (FP) peripheral artery disease (PAD).

Conventionally, PTA is guided by angiography, but limitations to lesion visualization and image interpretation remain.¹

IVUS use in PTA

There has been growing interest in using IVUS during PTA as it may aid in higher efficiency and accuracy in device deployment.²

Observational data suggests that use of IVUS can improve long-term outcomes. However, its use remains limited due to lack of large-scale, prospective data.

IVUS reimbursement and challenges

In Germany, current diagnostic-related group (DRG) codes may not sufficiently cover costs associated with IVUS.

Economic evaluations have been used to quantify value of health technologies, but there is a paucity of such studies for IVUS guidance in PTA for PAD patients.

Aim

Investigate the cost-effectiveness of IVUS-guided PTA over angiography-guided PTA in patients with PAD in Germany

Aid decision making by clinicians, hospital administrators and/or policy makers

A cost-effectiveness model was constructed inline with recommendations by IQWiG\(^1\) and ISPOR\(^2\)

<table>
<thead>
<tr>
<th>PICO</th>
<th>PATIENTS</th>
<th>INTERVENTION</th>
<th>COMPARATOR</th>
<th>OUTCOMES</th>
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</table>
|      | PAD Patients with femoropopliteal (FP) lesions eligible for PTA | IVUS-guided PTA | Angiography-guided PTA | • Target lesion revascularization (TLR)  
• Amputation  
• Mortality  
• HRQoL (EQ-5D)  
• Costs |

**Model Structure**
- Perspective: German payer perspective
- Time Horizon: 1 year and lifetime
- Discount Rate: 3% for both costs and outcomes
- Willingness-to-pay (WTP) Threshold: No set threshold by IQWiG\(^1\). Adopted a €50,000 / QALY threshold to facilitate discussions

\(^1\) Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, \(^2\) The Professional Society for Health Economics and Outcomes Research
The model consists of a decision tree to model events 1 year post index PTA, followed by a lifetime Markov model.

Transition to Markov model based on health state at end of the decision tree.
Model inputs were derived from literature and national sources

### Clinical Parameters

1. Probabilities of TLR, amputation, and all-cause mortality for 1-year decision tree
   
   Derived from Allan et al 2022, a prospective, single-center randomized controlled trial (RCT) investigating effect of IVUS imaging during endovascular interventions for patients with FP occlusive disease.

2. Probabilities of TLR and amputation for Markov model
   
   Derived from Iida et al 2014, a retrospective, propensity score analysis on the effect on IVUS use among patients with (TASC II) class A to C FP lesion.

3. Probability of all-cause mortality for Markov model
   
   Applied hazard ratio (HR) of all-cause mortality of symptomatic PAD patients against those with no PAD reported by Diehm et al 2009 onto German life tables.

### Utility Parameters

1. Quality of life of patients pre- and post-PTA
   
   Derived from Petersohn et al. 2019, where health related quality of life (HRQoL) in PAD patients was reported using EQ-5D.

2. Quality of life of patients post-amputation
   
   Derived from Barshes et al. 2011, where HRQoL for patients after major amputation across studies (EQ-5D) were weighted.

### Cost Parameters

1. Cost of PTA, TLR, and amputation
   
   Derived from German DRG codes. Cost of TLR assumed to be higher than the cost of PTA to reflect a higher clinical severity warranting revascularization after an index PTA.

2. Cost of IVUS
   
   Assumed to be a once-off cost on top of existing cost of PTA, obtained from internal sources.
Incremental cost-effectiveness ratio (ICER) as the primary outcome of this economic evaluation

\[
\text{ICER} = \frac{\text{Cost}_{\text{IVUS-guided PTA}} - \text{Cost}_{\text{angiography-guided PTA}}}{\text{QALY}_{\text{IVUS-guided PTA}} - \text{QALY}_{\text{angiography-guided PTA}}}
\]

All relevant costs are aggregated for each arm and discounted when appropriate. The difference in cost between the IVUS-guided arm and the angiography-guided arm is known as the **incremental cost**.

Outcomes, in terms of quality-adjusted life-years (QALYs) are aggregated for each arm and discounted when appropriate. The difference in QALYs between the IVUS-guided arm and the angiography-guided arm is known as the **incremental QALY**.

**If ICER > WTP threshold**, IVUS is **not** cost-effective.

**If ICER < WTP threshold**, IVUS is cost-effective.

\[€50,000 / \text{QALY gained}\]

Predefined WTP threshold
IVUS-guided PTA was shown to be cost-effective over angiography-guided PTA in the 1-year horizon, and dominant* in the lifetime horizon

### Table 1: Outcomes and Incremental Results

<table>
<thead>
<tr>
<th></th>
<th>One year horizon</th>
<th>Lifetime horizon</th>
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<tbody>
<tr>
<td></td>
<td>IVUS-guided</td>
<td>Angiography-guided</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total QALYs</td>
<td>0.65</td>
<td>0.63</td>
</tr>
<tr>
<td>Total Costs, €</td>
<td>5,897</td>
<td>4,977</td>
</tr>
<tr>
<td><strong>Incremental results</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incremental costs, €</td>
<td>919</td>
<td>-</td>
</tr>
<tr>
<td>Incremental QALYs</td>
<td>0.02</td>
<td>-</td>
</tr>
<tr>
<td><strong>ICER (€/QALY)</strong></td>
<td>45,195</td>
<td>-</td>
</tr>
</tbody>
</table>

*Dominant refers to being cost saving and having better outcomes
Utility post-TLR and probabilities of death and TLR were the main drivers for the ICER observed in the 1-year horizon.
Cost and probabilities of TLR and amputation were the main drivers for the ICER observed in the lifetime horizon.
IVUS-guided PTA was found to be 50.4% cost-effective in the probabilistic sensitivity analysis using a 1-year horizon.
Probability of IVUS-guided PTA being cost-effective increased to 85.9% in the lifetime horizon
The following limitations were acknowledged during the conduct of this study

1. The model was populated based on current available evidence, and we acknowledge that there is a general lack of long-term data. Nevertheless, the clinical parameters from Allan et al. and Iida et al. were regarded to be sufficiently robust, and the current proposed model can thus be replicated should other sources of data be available in the future.

2. The results may not be directly transferable to similar interventions for PAD patients with lesions at a different site. This is largely due to a lack of robust data for PAD patients with ex-FP lesions.

3. As per all model-based studies, inherent uncertainty exists due to the need for assumptions and data extrapolations. As such, expert opinion was sought to confirm model assumptions. In addition, when the more conservative bound of the point estimates were used in the OWSAs, IVUS-guided PTA was still cost-effective compared against angiography-guided PTA.
Value of IVUS was investigated using a model-based approach

**IVUS-guided PTA is cost-effective**

At a €50,000/QALY gained threshold, use of adjunctive IVUS during PTA was cost-effective at a 1-year horizon. However, in the long-term, IVUS use was associated with cost savings and better outcome.

The results remained robust to various sensitivity analyses, and adds to the growing body of evidence recommending the use of IVUS in endovascular interventions.

**Results were driven by lower TLR events**

The findings were largely attributed to lower number of TLRs in the IVUS group.

Revascularizations are a major contributor to overall healthcare costs for patients with PAD, as it often necessitates hospitalization considerable length of stay that may drive overall healthcare utilization.

This may be a result of better device placement and hence long-term patency afforded by IVUS use.

**First model to investigate economic implications**

A lack of studies investigating the cost-effectiveness of IVUS may have contributed to its current underutilization.

Panaich et al. 2016⁴ initially suggested higher cost was partially offset by the lower healthcare utilization due to averted revascularizations associated with IVUS-guided interventions.

Our model further confirms that the cost savings from averted TLRs need to be taken into consideration when ascertaining the potential economic value of IVUS.

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