Economic Consequences of Drug-coated Balloon Usage for AV Access Based on 12-Month Data from the IN.PACT AV Access Study

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On behalf of the economic analysis author group
Faculty Disclosure
Robert Lookstein MD MHCDL

For the 12 months preceding this CME activity, I or my spouse/partner disclose the following types of financial relationships:

- **Honoraria received from**: Medtronic, Boston Scientific, Penumbra
- **Consulted for**: Medtronic, Boston Scientific, Penumbra
- **Held common stock in**: None
- **Research, clinical trial, or drug study funds received from**: Medtronic, Boston Scientific, Vesper, BlackSwan, Terumo, BD Bard, Penumbra, Inari, Ethicon

I will not be discussing products that are investigational or not labeled for use under discussion.
The recent IN.PACT AV Access Trial evaluated the safety and clinical benefit of the IN.PACT AV drug-coated balloon (DCB) compared to percutaneous transluminal angioplasty (PTA) for treatment of obstructive lesions of native AVFs

Objectives:
- Assess the economic implications of drug-coated balloon (DCB) versus standard balloon angioplasty (PTA) in the US healthcare system based on 12-month Data from the IN.PACT AV Access Trial
Methods and Materials

**Analytic Approach 1 (Primary Analysis): Index and Reintervention Based Costs**

- Decision-analytic Markov model to capture index costs and reinterventions
- **Clinical inputs:** Access circuit reintervention rates (12M, from IN.PACT AV Access Trial)
- **Cost Inputs:** US Medicare FY 2020 facility and physician fees per reintervention
- **Analysis horizons:**
  - 12M (trial-observed), and
  - 36M (projected from 12M data)

**Approach 2 (Secondary Analysis): Comprehensive Vascular Access Costs**

- Calculation based on cost data of n=2,704 Medicare patients with *maintained vs. not maintained primary patency* (Thamer et al., 2018*)
- **Clinical inputs:** Access circuit primary patency rates (12M, from IN.PACT AV Access Trial)
- **Cost Inputs:** Annualized vascular access costs per patient per year from Thamer et al, 2018
- **Analysis horizon:**
  - 30M (Thamer et al. study follow-up)

### Methods and Materials

**Clinical Effectiveness (IN.PACT AV Access Trial)**

<table>
<thead>
<tr>
<th></th>
<th>IN.PACT AV DCB</th>
<th>Standard PTA</th>
<th>Difference (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean number of interventions required to maintain access circuit patency (12M)</td>
<td>0.65</td>
<td>1.05</td>
<td>-0.4 [-0.6, -0.2]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Other Inputs and Assumptions**

- 1.23 DCBs per procedure
- Mortality HR of ESRD population: 6.75 (IN.PACT AV Access Trial relative to general US population mortality)
- Discount rate for health care costs: 3% p.a.

### Cost Data – US

<table>
<thead>
<tr>
<th></th>
<th>Cost</th>
<th>Source/Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA Procedure Cost</td>
<td>$3,142</td>
<td>Weighted average CY 2020 payment (51% OBL, 26% hospital outpt., 19% ASC, 4% inpt.)</td>
</tr>
<tr>
<td>DCB Procedure Cost</td>
<td>$3,142</td>
<td>Same as PTA, plus incremental DCB therapy cost (exploratory analysis in absence of established therapy cost)</td>
</tr>
<tr>
<td>Reintervention cost</td>
<td>$3,475</td>
<td>Weighted average payments, assuming 85% PTA, 10% stent placement, 5% thrombectomies and surgical interventions as observed in trial</td>
</tr>
</tbody>
</table>

**Approach 1 (Primary Analysis): Reintervention Event Based Costs**
## Methods and Materials

### Approach 2 (Secondary Analysis): Comprehensive Vascular Access Costs

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Access circuit primary patency (12M)</td>
<td>53.8%</td>
<td>32.4%</td>
<td>21.4% [10.2%, 32.6%]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### Costs: Per-Patient Per-Year Vascular Access Related Costs Based on AVF Outcomes in Year 1 post AVF Creation*

<table>
<thead>
<tr>
<th>Medicare Cohort: Patients initiating HD with a mature AVF</th>
<th>Costs in Patients who Maintained Primary Patency</th>
<th>Costs in Patients who Experienced Loss of Primary Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>$6,442 ± $8,882</td>
<td>$15,009 ± $16,896</td>
</tr>
<tr>
<td>Year 2</td>
<td>$4,279 ± $11,378</td>
<td>$7,403 ± $14,179</td>
</tr>
<tr>
<td>Average Per-Patient-Per-Year Costs</td>
<td>$5,560 ± $8,368</td>
<td>$11,761 ± $15,871</td>
</tr>
</tbody>
</table>

Results: Primary Analysis

Reintervention Rates & Follow-up Cost Difference, IN.PACT AV DCB vs PTA, Years 1-3
(Analysis considers no add-on DCB reimbursement)

- Meaningful reductions in projected reintervention cost
- If DCB cost is $1,800 or less, DCB strategy would break-even at 2 years horizon and achieve savings of ~$1,400 at 3 years horizon
Results: Primary Analysis, by Site of Service

Follow-up Cost Difference for DCB vs. PTA at 1 and 3 years, by Site of Service
Results: Secondary Analysis

12M Primary Patency and Corresponding 12M and 30M Estimated Costs
PTA vs. DCB

- Notable cost reductions at one and 2.5 years
- For DCB cost of $1,800, cost-neutrality at 12M and savings >$1,650 at 2.5 yrs.
Additional Results & Implications at Healthcare System level

• Number needed to treat (NNT) to avoid one reintervention: 2.48

• Over a one-year horizon, cost per reintervention avoided:
  • $1,680 for assumed incremental DCB therapy cost of $2,000
  • $3,050 for assumed incremental DCB therapy cost of $2,500

• Potential savings to Medicare if 50% of current 233,000 annual procedures performed with DCB instead of PTA:
  • $160-250M over one year
  • >$420M over three years

• If incremental DCB device reimbursement is implemented, the improved clinical outcomes could be achieved at overall cost savings at 2.5 years as long as device reimbursement is <$2,380*

*Using the more conservative calculation (Approach 1); based on Approach 2, amount would increase to $3,165.
Conclusions

• Using two independent calculation approaches, treatment with the IN.PACT AV DCB can be expected to lead to substantive per-patient and health system savings.

• Savings increase with longer analysis horizon, and vary by site of service.

• Reductions in reinterventions can help reduce patient morbidity and improve quality of life.

• Findings are based on data from the IN.PACT AV ACCESS Trial and may not apply to other DCB devices.