Device Choice for Femoropopliteal Therapy: Does This Predict Cost Effectiveness?

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Conflicts of Interest

- **Consultant**
  - Abbott Vascular (non-compensated)
  - AOPA
  - Boston Scientific (non-compensated)
  - Cardinal Health
  - Cordis Corporation (non-compensated)
  - Janacare, Inc
  - Medtronic (non-compensated)
  - Micell, Inc
  - Novella (DSMB)
  - Primacea
  - Valiant
  - Volcano

- **Equity**
  - Access Closure, Inc
  - Embolitech
  - I.C.Sciences, Inc
  - Janacare, Inc
  - MC10
  - Northwind Medical, Inc.
  - PQ Bypass, Inc
  - Primacea
  - Sano V, Inc.
  - Vascular Therapies, Inc

- **Board Member**
  - VIVA Physicians (Not For Profit 501(c) 3 Organization)
    - [www.vivapvd.com](http://www.vivapvd.com)
    - Intersocietal Accreditation Commission
    - CBSET

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Background

- TLR is impacted by the initial choice of endovascular strategy.
- The economic implications of procedure choice are affected by the initial procedure costs, the associated TLR risk, and the costs associated with repeat revascularization procedures.
- The long-term clinical effectiveness of Supera has been demonstrated in the SUPERB clinical trial where freedom from TLR is sustained over a 3-year period.
- Its economic impact compared to other endovascular strategies is not known.

TLR: target lesion revascularization
Objective

• To evaluate the 3-year economic impact of 5 different endovascular strategies for the treatment of femoropopliteal peripheral artery disease (PAD) from the perspectives of the United States (US) payer and provider

Methods

• 5 endovascular strategies included in the analysis:
  – Angioplasty (PTA)
  – Bare Metal Stent (BMS)
  – Drug Eluting Stent (DES)
  – Drug Coated Balloon (DCB)
  – Interwoven Nitinol Stent (Supera)

• Risk of TLR was used to estimate the expected number of re-interventions per patient for each strategy

This data analysis was funded by Abbott Vascular.
Model Concept

Index Procedure
- PTA
- BMS
- DES
- DCB
- Supera

3 possible outcomes for each modality

Maximum of 2 re-interventions after index procedure permitted in analysis

- No further re-intervention
- 2nd procedure (1st TLR)
- 3rd procedure (2nd TLR)

Determined by TLR rates

3-year time horizon
TLR Rates

• Rates were obtained from US investigational device exemption (IDE) studies published in peer-reviewed journals for PTA, BMS, DES, and DCB procedures

• The SUPERB trial provided the risk of TLR with Supera*

• Only IDE studies were chosen to ensure high quality and consistent clinical trial methodology

• When reported follow-up was less than 3 years, probabilities were extrapolated to estimate the TLR risk assuming an exponential distribution

IDE trials included in the analysis: DURABILITY II, RESILIENT, COMPLETE SE, STROLL, ZILVER PTX, LEVANT II, IN.PACT SFA, SUPERB

*Manuscript submitted for publication
# Pooled 3-Year TLR Risk From IDE Trials

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Pooled month TLR</th>
<th>Sources</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA(^1)</td>
<td>46.4%</td>
<td>RESILIENT, ZILVER PTX, LEVANT II, IN.PACT SFA</td>
<td></td>
</tr>
<tr>
<td>BMS(^1)</td>
<td>29.2%</td>
<td>DURABILITY II, RESILIENT, COMPLETE SE, STROLL</td>
<td></td>
</tr>
<tr>
<td>DES(^2)</td>
<td>19.4%</td>
<td>ZILVER PTX</td>
<td></td>
</tr>
<tr>
<td>DCB(^1)</td>
<td>24.6%</td>
<td>LEVANT II, IN.PACT SFA</td>
<td></td>
</tr>
<tr>
<td>Supera(^3)</td>
<td>6.0%</td>
<td>SUPERB</td>
<td></td>
</tr>
</tbody>
</table>

1. Weighted average taken based on sample size and extrapolation carried out assuming exponential survival function.
2. Extrapolation carried out assuming exponential survival function.
3. SUPERB nominal deployment

Kaplan-Meier point estimates for TLR rates

## Baseline Characteristics From Pooled Studies

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PTA</th>
<th>BMS</th>
<th>DCB</th>
<th>DES</th>
<th>Supera</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age (yrs)</td>
<td>67.9</td>
<td>68.0</td>
<td>67.7</td>
<td>67.9</td>
<td>68.7</td>
</tr>
<tr>
<td>Male sex</td>
<td>66%</td>
<td>65%</td>
<td>63%</td>
<td>66%</td>
<td>64%</td>
</tr>
<tr>
<td>Claudication (Rutherford 2–3)</td>
<td>92%</td>
<td>96%</td>
<td>93%</td>
<td>90%</td>
<td>95%</td>
</tr>
<tr>
<td>CLI (Rutherford 4–6)</td>
<td>7%</td>
<td>3%</td>
<td>7%</td>
<td>9%</td>
<td>5%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>43%</td>
<td>44%</td>
<td>42%</td>
<td>50%</td>
<td>44%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>86%</td>
<td>88%</td>
<td>90%</td>
<td>89%</td>
<td>94%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>77%</td>
<td>84%</td>
<td>88%</td>
<td>76%</td>
<td>87%</td>
</tr>
<tr>
<td>History of smoking</td>
<td>83%</td>
<td>80%</td>
<td>79%</td>
<td>86%</td>
<td>80%</td>
</tr>
<tr>
<td>ABI pre-treatment</td>
<td>0.71</td>
<td>0.69</td>
<td>0.75</td>
<td>0.67</td>
<td>0.73</td>
</tr>
<tr>
<td><strong>Lesion characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>68</td>
<td>76</td>
<td>74</td>
<td>66</td>
<td>83</td>
</tr>
<tr>
<td>Percent diameter stenosis</td>
<td>79%</td>
<td>80%</td>
<td>81%</td>
<td>80%</td>
<td>78%</td>
</tr>
<tr>
<td>Severe calcification</td>
<td>20%</td>
<td>31%</td>
<td>9%</td>
<td>37%</td>
<td>45%</td>
</tr>
</tbody>
</table>
Methods – Costs

• Costs evaluated from the US payer and provider perspectives
• **US payer perspective:** Medicare facility and physician reimbursement
• **Provider perspective:** hospital *remaining payment*, defined as the facility reimbursement payment minus the cost of the device(s) used in the procedure

<table>
<thead>
<tr>
<th>Input</th>
<th>Amount</th>
<th>Sources / Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting of care: hospital inpatient/outpatient</td>
<td>40%/60%</td>
<td>CMS, 2013 MEDPAR file</td>
</tr>
<tr>
<td>Number of devices used per procedure</td>
<td>1</td>
<td>Assumption</td>
</tr>
<tr>
<td>Incremental reimbursement for DCBs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New technology add-on payment (NTAP, hospital inpatient setting)</td>
<td>$1,036</td>
<td>CMS, full NTAP for all inpatient DCB procedures</td>
</tr>
<tr>
<td>Transitional pass-through payment (hospital outpatient setting)</td>
<td>$1,403</td>
<td>CMS, payment covers full cost of DCB(s) for outpatient procedures</td>
</tr>
</tbody>
</table>

Device costs: PTA - $187, BMS - $1,293, DES - $2,021, DCB - $1,403, Atherectomy - $2,859, ViaBahn - $2,807 (Pietzsch 2014, 2013 dollars converted to 2015 dollars); Supera - $1,500
Results: Total Number Of Procedures Per 100 Patients Over 3-Years

Number of revascularization procedures calculated using economic model
Risk of a second TLR is assumed to be the same as the risk of the first TLR for a given therapy
Results: Payer Perspective, Cost To Medicare Per Patient Over 3-Years

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Cost to Medicare Per Patient Over 3-Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bare Metal Stent (BMS)</td>
<td>$16,158</td>
</tr>
<tr>
<td>Angioplasty (PTA)</td>
<td>$15,166</td>
</tr>
<tr>
<td>Drug Eluting Stent (DES)</td>
<td>$14,845</td>
</tr>
<tr>
<td>Drug Coated Balloon (DCB)</td>
<td>$13,421</td>
</tr>
<tr>
<td>Interwoven Nitinol Stent (Supera)</td>
<td>$13,036</td>
</tr>
</tbody>
</table>

*Analysis based on 2015 Medicare national average payment rates*
Results: Supera Is Cost-Saving Compared To PTA, BMS, DES, And DCB

<table>
<thead>
<tr>
<th>Supera Compared to:</th>
<th>PTA</th>
<th>BMS</th>
<th>DES</th>
<th>DCB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number needed to treat to avoid one TLR with Supera</td>
<td>2</td>
<td>4</td>
<td>7</td>
<td>6</td>
</tr>
</tbody>
</table>

**Δ Cost (per 100 patients)**

- **Supera vs. PTA**
  - Δ Cost: $500,000
- **Supera vs. BMS**
  - Δ Cost: $300,000
- **Supera vs. DES**
  - Δ Cost: $100,000
- **Supera vs. DCB**
  - Δ Cost: -$100,000

**Δ Effectiveness**

- **Number of TLRs Avoided per 100 patients**
- **Value Threshold (Cost per TLR avoided <$10,000)**
- **Cost-Effective**

- **Supera vs. DCB**
- **Supera vs. DES**
- **Supera vs. PTA**
- **Supera vs. BMS**

**Cost Saving**
### Results: Provider Perspective, Hospital Remaining Payment Over 3-Years

| Treatment | Total Hospital Remaining Payment*  
(per 100 patients over 3 years) | Total Number of Procedures  
(per 100 patients over 3 years) | Average Hospital Remaining Payment* per Procedure  
(over 3 years) |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Supera</td>
<td>$1.06M</td>
<td>107</td>
<td>$9,926</td>
</tr>
<tr>
<td>BMS</td>
<td>$1.31M</td>
<td>133</td>
<td>$9,885</td>
</tr>
<tr>
<td>DES</td>
<td>$1.14M</td>
<td>122</td>
<td>$9,375</td>
</tr>
<tr>
<td>PTA</td>
<td>$1.31M</td>
<td>153</td>
<td>$8,588</td>
</tr>
<tr>
<td>DCB</td>
<td>$1.05M</td>
<td>125</td>
<td>$8,442</td>
</tr>
</tbody>
</table>

* Remaining payment = facility reimbursement – device costs  
Analysis based on 100 index procedures per treatment strategy
Limitations

• TLR risk was based on statistical model using published TLR rates from IDE trials
  – TLR risk may not reflect real world patient outcomes
  – Heterogeneity between trials was not formally incorporated into pooling estimates, although the choice of using only IDE trials helped to mitigate this heterogeneity and sensitivity analysis was conducted to determine the impact of different TLR rates on economic outcomes.

• This model did not consider events such as death, amputation, and atherothrombotic complications (MI, stroke, bleeding), which may have cost implications and affect the subsequent risk of clinical events
Conclusions

In this 3-year economic analysis of various treatment modalities:

• From the patient perspective, Supera has the lowest risk of repeat procedures (TLR)

• From the payer perspective (Medicare), Supera is an economically attractive (i.e., cost-saving) strategy compared to PTA, BMS, DES, and DCB

• From the provider perspective, Supera results in the greatest remaining payment per procedure compared to PTA, BMS, DES, and DCB
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