Evolving Strategies and Economic Considerations In Treatment of Femoropopliteal Arterial Disease

Michael R. Jaff, DO
Paul and Phyllis Fireman Chair in Vascular Medicine
Massachusetts General Hospital
Professor of Medicine
Harvard Medical School
Boston, Massachusetts, USA
Michael R. Jaff, DO
Conflicts of Interest

- **Consultant**
  - Abbott Vascular (non-compensated)
  - Boston Scientific (non-compensated)
  - Cardinal Health
  - Cordis Corporation (non-compensated)
  - Covidien (non-compensated)
  - Ekos Corporation (DSMB)
  - Medtronic (non-compensated)
  - Micell, Inc
  - Primacea

- **Equity**
  - Access Closure, Inc
  - Icon Interventional, Inc
  - 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
    - CBSET

January 2015
Peripheral Artery Disease (PAD) is Still a Large Unmet Need

US Diagnosis and treatment of PAD Is underpenetrated¹

- 10MM¹ Prevalence
- 700k treated annually²
- 2.5MM Diagnosed¹

Treating PAD reduces burden of disease and increases Quality of Life³,⁴

- Lung Cancer: 84%
- Colon and Rectal Cancer: 36%
- PAD: 33%
- Hodgkin’s Disease: 16%
- Breast Cancer: 10%

1. Leerink Swann article, Sept 2012
4. American Cancer Society: Cancer Facts and Figures 2012, p. 1, 11, 12, 13, 16
There Are, After All, Other Options Which Work: Benefits of Exercise Training

- Cochrane review of 22 RCT
- Significant improvement in
  - Maximum walking time (5.12 minutes)
  - Pain-free walking distance (82.2 m)
  - Maximum walking distance (113 m)

Opportunity to reduce socio-economic burden, Improve mortality, patient outcomes

**PAD IS A HUGE ECONOMIC BURDEN**

$290B^*$  
Cost of PAD annually in the US

$25,400-$62,700* expenditure per patient

Total Medicare PAD Bill $67-$185B*

Above-the-Knee amputation third most Commonly Performed Procedure

*$160-294 B range. Total Costs Inpatient and Outpatient in 2010 $.

**AMPUTATION SocialLY DEVASTATING**

36%  
Mortality at 1 year**

$8.3B  
Short term healthcare cost for amputees

$500,000  
Per patient lifetime health care costs (nearly double estimated costs of average person)

54%  
of amputees attributed to vascular disease

**HIGHER MORTALITY RISK WITH PAD**

30 day mortality rates for ATK amputations is 13%³

“The coexistence of peripheral artery disease (PAD) and multilevel atherosclerosis increases death and stroke rates in patients with coronary artery disease (CAD)” ⁴

**HIGH PATIENT SATISFACTION**

Treatment for P.A.D. may slow or stop the progress of the disease, reduce symptoms, improve quality of life, and reduce the risk of complications.⁵

**For people age > 65**

---

5. [http://nihseniorhealth.gov/peripheralarterialdisease/livingwithandtreatingpad/01.html](http://nihseniorhealth.gov/peripheralarterialdisease/livingwithandtreatingpad/01.html)
Technology is Undoubtedly Improving Our Ability to Treat Patients with PAD....

BTK – Critical Limb Ischemia
- Reduce repeat revascularizations
- Improve quality of life and physical functioning
  - Walking capacity
  - Positive mental outlook
- Reduce amputations
- Improve wound healing
- Reduce repeat revascularizations

SFA – Intermittent Claudication
- Reduce hospital time
- Improve quality of life and physical function
  - Walking capacity

How Can We Pay For All Of This?
Lowering Cost to the Healthcare System: What Matters is TLR

“In economic terms, what matters is TLR. It is with repeat intervention that additional cost is incurred.” –Mark Burket, MD, Restenosis and the New Health Care Economy

Figure adapted from data in Burket, M., Restenosis and the New Health Care Economy. (Aug. 2013, Endovascular Today)

*Dollar amounts as referenced in above article. Initial Stent Placement cost of $798 assumes: 1 Balloon ($98 ea.), 1 Standard Nitinol Stent ($700), as noted in reference article. Restenosis Treatment Cost of $10,000 cited for center in reference article. Cost of equipment in treating restenosis with endovascular approach. Noted inclusions: embolic protection, PTFE-covered stent, atherectomy. Fem-Pop Bypass cost of $17,000 reported for this center within reference article.
Economic Analysis of Endovascular Interventions for Femoropopliteal Arterial Disease: A Systematic Review and Budget Impact Model for the United States and Germany

Jan B. Pietzsch,¹ PhD, Benjamin P. Geisler,¹ MD, MPH, Abigail M. Garner,¹ MS, Thomas Zeller,² MD, and Michael R. Jaff,³ DO
Cost Effectiveness in Femoropopliteal Intervention

**Objective**

Develop budget impact model to estimate 24-month costs to payers for four SFA index procedure modalities: PTA, BMS, DEB, DES

**Methods**

- Systematic Pubmed and EMBASE search for published trials and registries reporting TLR rates in femoral and/or popliteal artery disease
- Pooling of TLR rates, weighting by sample size
- Decision-analytic modeling to estimate total costs over 24-months;

**KEY ASSUMPTIONS:**

- 24-month period; constant TLR hazard rates assumed
- Up to 1 revascularization post index procedure (modality distribution based on expert opinion)
- Surgical bypass not considered as a revascularization technique; atherectomy only considered for TLR
- Typical patient: 70 yo WM with PAD, Rutherford 3 Symptoms
These Are The Clinical Trials We Identified in the Literature...

<table>
<thead>
<tr>
<th>Trial</th>
<th>Year</th>
<th>Comparators/Arms (n)</th>
<th>Age</th>
<th>Lesion (cm)</th>
<th>PTA</th>
<th>DEB</th>
<th>BMS</th>
<th>DES</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIROCCO</td>
<td>2006</td>
<td>46 BMS / 47 DES</td>
<td>66</td>
<td>8.3</td>
<td>13% (3%)</td>
<td>6% (2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FAST</td>
<td>2007</td>
<td>121 PTA / BMS</td>
<td>67</td>
<td>4.5</td>
<td>18% (10%)</td>
<td>15% (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>THUNDER</td>
<td>2008</td>
<td>54 PTA / 48 DEB</td>
<td>68</td>
<td>7.4</td>
<td>37%</td>
<td>4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEM-PAC</td>
<td>2008</td>
<td>42 PTA / DEB</td>
<td>68</td>
<td>5.9</td>
<td>33%</td>
<td>7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZILVER PTX SAS *†</td>
<td>2011</td>
<td>DES: 787</td>
<td>68</td>
<td>6.4</td>
<td>17% (5%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZILVER PTX RCT *†</td>
<td>2011</td>
<td>DES: 236</td>
<td>68</td>
<td>6.4</td>
<td>13% (4%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZILVER PTX (published)</td>
<td>2011</td>
<td>125 PTA / 62 DES</td>
<td>67</td>
<td>6.5</td>
<td>18% (2%)</td>
<td>10% (5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shammas et al.</td>
<td>2011</td>
<td>48 PTA / atherect.</td>
<td>69</td>
<td>9.1</td>
<td>17% (9%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STRIDES</td>
<td>2011</td>
<td>104 DES</td>
<td>69</td>
<td>9.0</td>
<td></td>
<td></td>
<td></td>
<td>20% (11%)</td>
</tr>
<tr>
<td>PACIFIER *</td>
<td>2012</td>
<td>44 PTA / 47 DEB</td>
<td>71</td>
<td>6.8</td>
<td>28%</td>
<td></td>
<td>7% (3.6%)</td>
<td></td>
</tr>
<tr>
<td>RESILIENT</td>
<td>2012</td>
<td>53 PTA / BMS</td>
<td>67</td>
<td>6.7</td>
<td>58% (14%)</td>
<td></td>
<td></td>
<td>25% (5%)</td>
</tr>
<tr>
<td>Micari et al. registry</td>
<td>2012</td>
<td>105 DES</td>
<td>68</td>
<td>7.3</td>
<td>8% (4%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

† only TLR for DES arm available – we combined TLR rates for randomized controlled trial and single arm study; * Conference publication only

SIROCCO and STRIDES included in base case, excluded in scenario analysis
Clinical Model Results:
Freedom from TLR over 24 Months (pooled)

Pooled results suggest clear patient benefit for DEB, DES, BMS vs. PTA, with potential non-inferiority between DEB and stents. DEB shows a 43% reduction in TLR rates compared to PTA.
Structure of Decision-Analytic Model

Index Procedure

- **PTA**
- **DEB**
- **BMS**
- **DES**

2 possible Outcomes for each modality (based on TLR rate)

- **No Revascularization**
  - Fewer revascularizations = Lower costs

- **Revascularization**

Budget impact

MASSACHUSETTS GENERAL HOSPITAL
INSTITUTE FOR HEART, VASCULAR AND STROKE CARE
German Healthcare System Perspective

**24-month Payer Cost by Index Procedure**

Total G-DRG payments per patient over 24 months, index-procedure and possible revascularization

- DES and DEB least costly index procedure strategies over 24 months
- Per patient savings:
  - €561 for DEB vs. PTA index procedure
- Potential total savings/yr.:
  - For hypothetically assumed 25,000 cases per year treated with DEB instead of PTA in German healthcare system
  - ~ €14 M savings

Based on 2013 German DRG schedule.
Results: U.S. Budget Impact, 100% Outpatient

Medicare Perspective
Total charges* for 24 months post index-procedure

Facility Provider Perspective
Total headroom (APC – device price) for 24 mths

Assumption: DEB reimbursed at PTA rate; DES at BMS rate. * Charges= 2012 Medicare APC Schedule
Results: U.S. Budget Impact, 100% Outpatient

Medicare Perspective
Total charges* for 24 months post index-procedure

Facility Provider Perspective
Total headroom (APC – device price) for 24 mths

---

<table>
<thead>
<tr>
<th>Rank</th>
<th>Strategy</th>
<th>24-month total Cost</th>
<th>Incremental Costs (to lowest-cost strategy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DEB</td>
<td>$6,317</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>PTA</td>
<td>$9,241</td>
<td>$2,924</td>
</tr>
<tr>
<td>3</td>
<td>DES</td>
<td>$9,616</td>
<td>$3,299</td>
</tr>
<tr>
<td>4</td>
<td>BMS</td>
<td>$10,113</td>
<td>$3,797</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Rank</th>
<th>Strategy</th>
<th>24-month total headroom</th>
<th>Incremental (to highest-profit strategy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BMS</td>
<td>$8,211</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>PTA</td>
<td>$7,739</td>
<td>($472)</td>
</tr>
<tr>
<td>3</td>
<td>DES</td>
<td>$7,298</td>
<td>($913)</td>
</tr>
<tr>
<td>4</td>
<td>DEB</td>
<td>$4,417</td>
<td>($3,793)</td>
</tr>
</tbody>
</table>

* Charges=2012 Medicare APC Schedule

---

STRIDES and SIROCCO excluded
Numbers Needed to Treat (NNT) to Avoid 1 TLR Over 24 Months

**DEB vs. PTA**
- Freedom from TLR at 24 months: 85.6% for DEB vs. 60.0% for PTA
- Absolute difference: 25.6%
- NNT: 4

**DEB vs. BMS**
- Freedom from TLR at 24 months: 85.6% for DEB vs. 72.0% for BMS
- Absolute difference: 13.6%
- NNT: ~7
Limitations

- **Clinical Data**
  - Comparative data still limited, especially RCTs
  - TLR rates vary highly between trials
  - For some trials, only 6-month TLR rates available
  - Study designs and populations vary

- **Budget Impact Model**
  - Constant TLR hazard rates assumed
  - Only includes up to one potential TLR post index procedure
  - Distribution of reintervention modalities based on expert opinion
  - Reintervention strategies assumed constant over time
  - Quality of life/ functional health status impact not considered
How Do We Think About Costs of Fem-Pop Revascularization Strategies?

- Pooling analysis suggests clear patient benefit for DEB, BMS, DES vs. PTA, with potential non-inferiority between BMS, DES, and DEB

- From the payer perspective, DEB is financially attractive in Germany and represents significant savings potential vs. PTA

- If reimbursed at current PTA rate in markets like the US, DEB will be financially attractive to payers, but access may be impacted because of financial constraints of providers

- DEB combines clinical benefits with economic value. Future reimbursement should consider the value proposition of DEB and balance it with provider incentives for adoption
Evolving Strategies and Economic Considerations In Treatment of Femoropopliteal Arterial Disease

Michael R. Jaff, DO
Paul and Phyllis Fireman Chair in Vascular Medicine
Massachusetts General Hospital
Professor of Medicine
Harvard Medical School
Boston, Massachusetts, USA