**Cost-Effectiveness Analysis of Drug Eluting Stents (DES) Compared with Bare Metal Stents (BMS) Based on an Ontario Field Evaluation**

Goeree R¹, Bowen J¹, Hopkins R¹, He Y², Blackhouse G¹, Lazzam C³, Tu J², Cohen E⁴,⁵, Tarride J-E¹

¹Program for Assessment of Technology in Health (PATH), St. Joseph’s Health Care & Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada; ²Institute of Clinical & Evaluative Sciences, Sunnybrook & Women’s College Health Sciences Centre, Toronto, ON, Canada; ³TriHill Health Centre, Mississauga, ON, Canada; ⁴Faculty of Medicine, University of Toronto, Toronto, ON, Canada; ⁵Sunnybrook & Women’s College Health Sciences Centre, Toronto, ON, Canada

**RATIONALITY**

- Stents cost province of Ontario $14 million in 2002/03
- Volume projected to increase by 37% over 5 years
- Health Canada approved DES in 2002/03
- Srinivas (University of Waterloo)
- Uptake of DES in US approximately 90%
- Therefore, DES represent a major cost concern due to higher cost and volume projections
- However, RCTs indicate DES have a lower rate of restenosis (offsetting ‘re-do’ procedure costs)
- Treatment effect may be greater for specific subgroups
- ‘Real world’ effectiveness of DES uncertain
- ‘Real world’ cost-effectiveness of DES uncertain

**OBJECTIVES**

1. Conduct a systematic literature review of effectiveness of DES vs. BMS.
2. Conduct a field evaluation to collect ‘real world’ rates of revascularization in the province.
3. Conduct an interim analysis on a subset of patients with at least 9 months of follow-up recruited into the field evaluation.
4. Construct a decision analytic model to evaluate the cost-effectiveness of DES versus BMS.
5. Estimate the budget impact for Ontario.

**METHODS**

**Literature Search**

- Databases searched:
  - MEDLINE, EMBASE, Cumulative index to nursing & allied health literature (CINAHL), Cochrane Database of Systematic Reviews (CDSR), ACP Journal Club, Database of Abstracts of Reviews of Effects (DARE) and Cochrane Central Register of Controlled Trials (CTR)
  - 1st search to December 2004, updated in 2005
- Clinical studies comparing BMS and DES
- Randomized trials only
- English language studies only since 1990

**Data Sources for Model**

- Field evaluation for:
  - Revascularization rates (TVR)
  - Types of Revascularization
  - Stent utilization patterns
  - Waiting times
- OHTAC, Ontario Schedule of Benefits, Stent manufacturers for costing
- DES utilization-weighted average cost: $1,899
- BMS average cost: $600
- Costs will be updated for final report (moving target)
- Literature for Quality of Life values

**RESULTS**

**Data Sources for Model**

- Field evaluation for:
  - Revascularization rates (TVR)
  - Types of Revascularization
  - Stent utilization patterns
  - Waiting times
- OHTAC, Ontario Schedule of Benefits, Stent manufacturers for costing
- DES utilization-weighted average cost: $1,899
- BMS average cost: $600
- Costs will be updated for final report (moving target)
- Literature for Quality of Life values

**Outcomes**

- By cohort and by stent type, 5 endpoints
  - Target lesion revascularization (TLR) - PCI with stent
  - Target vessel revascularization (TVR) - PCI with stent
  - Target vessel revascularization adjusted (TVRadj) - TVR with stent, all PCI without stent, CABG
  - All revascularization procedures
  - CABG, PCI with stent, PCI without stent
- Mortality (all causes)

**Unadjusted vs Adjusted Rates**

- The event rates in patients receiving DES are similar to the rates reported in the RCTs.
- The event rates for patients receiving BMS are substantially lower than that reported in RCTs.
- Therefore the difference in revascularization rates between DES and BMS were lower in field evaluation than reported in clinical trials.
- Can be due to imbalances (observational bias)
- Multivariate regression analysis used to adjust for differences in baseline characteristics
  - Age, gender, LAD, stent length, stent size, lesion severity, multiple vessel disease, angina severity

**Immediate and Post-MI DIEs**

<table>
<thead>
<tr>
<th>Type of Revascularization</th>
<th>Immediate</th>
<th>Post-MI DIEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI with stent</td>
<td>11.5%</td>
<td>7.9%</td>
</tr>
<tr>
<td>PCI without stent</td>
<td>7.9%</td>
<td>5.7%</td>
</tr>
<tr>
<td>All PCI</td>
<td>9.2%</td>
<td>6.3%</td>
</tr>
<tr>
<td>CABG</td>
<td>6.7%</td>
<td>4.9%</td>
</tr>
</tbody>
</table>

**Economic Evaluation**

- Determine cost-effectiveness of DES vs. BMS from field evaluation data and literature
- Model structure
  - 1 year timeframe
  - Decision analytic model
  - Costs
  - Initial stent costs
  - Revascularization costs – stent and procedure
- Outcomes
  - Revascularizations averted
  - QALY’s gained
- Perspective: Ontario MOH

**DISCUSSION**

- Results from the field evaluation did not demonstrate the same relative difference in revascularization rates as seen in the RCT literature.
- There are a number of possible explanations:
  - ‘Real-world’ patients’ vs. clinical trial patients (all Ontario patients (diverse) & all lesion types)
  - Newer generation of BMS than in earlier trials
- Differences in use of post PCI pharmacotherapy
- Protocol-driven revascularizations
- Selection bias for BMS & DES use. Analyses may not control for all of this (uncontrolled nature of registry data)
- Final report with even larger sample (n > 20,000) and longer follow-up period due out Q4/06

Support: This study was funded by a grant from the Ontario Ministry of Health & Long-term Care. Report presented on October 21, 2005 to the Ontario Health Technology Advisory Committee (OHTAC). Interim report available at [http://www.path-hta.ca/report.htm](http://www.path-hta.ca/report.htm)