Background

The design of coronary stents continues to evolve to reduce short- and long-term adverse events.

BIOTRONIK, a medical device company, commissioned the present study to determine the likelihood of higher long-term myocardial infarction with a specific stent. We used a computer model to simulate the clinical and cost impact of using a new stent compared to an established one.

Methods

Better outcomes of BP-SES were a result of a lower rate of periprocedural myocardial infarction (ppMI), defined as elevation of CK-MB >3xULN, of 2.27% for BP-SES and 4.45% for DP-EES (p <0.05).

We used a Markov simulation to project the clinical and cost outcomes from a U.S. payer perspective over a 12-month horizon. All cost estimates were CPI-adjusted to 2018 US$.

Model parameters were derived from BIOTRONIK trial data, a systematic review of the literature and expert interviews (Table 1). Figure 1 shows a conceptual diagram of the model.

We conducted three types of sensitivity analyses:
1. Use of a more restrictive definition of ppMI with a CK-MB >5xULN elevation (0.79% for BP-SES and 2.45% for DP-EES [p <0.05]).
2. Univariate sensitivity analysis that varied each parameter individually by +/-10% from its midpoint estimate.
3. Probabilistic sensitivity analysis that varied all parameters simultaneously to reflect the overall uncertainty.

Table 1: Model parameters and sources

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Midpoint estimate</th>
<th>Range</th>
<th>Distribution</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>ppMI rate (CK-MB &gt;3xULN)</td>
<td>2.27%</td>
<td>1.25-2.10</td>
<td>Uniform</td>
<td>[1]</td>
</tr>
<tr>
<td>BP-SES</td>
<td>4.45%</td>
<td>4.01-4.95</td>
<td>Uniform</td>
<td>[1]</td>
</tr>
<tr>
<td>BP-SES</td>
<td>0.71%</td>
<td>0.71% - 0.75%</td>
<td>Uniform</td>
<td>[1]</td>
</tr>
<tr>
<td>DP-EES</td>
<td>2.45%</td>
<td>2.20-2.60</td>
<td>Uniform</td>
<td>[1]</td>
</tr>
<tr>
<td>BP-SES</td>
<td>0.79%</td>
<td>0.79% - 0.83%</td>
<td>Uniform</td>
<td>[1]</td>
</tr>
<tr>
<td>CK-MB &gt;5xULN</td>
<td>0.25%</td>
<td>0.20% - 0.30%</td>
<td>Uniform</td>
<td>[1]</td>
</tr>
<tr>
<td>Adjusted HR for mortality (PPMI)</td>
<td>1.25</td>
<td>1.10-1.40</td>
<td>Poisson</td>
<td>[3], [4], [5], [8]</td>
</tr>
<tr>
<td>Average initial cost</td>
<td>$5,563</td>
<td>$7,330 - $7,380</td>
<td>Uniform</td>
<td>[4], [1]</td>
</tr>
<tr>
<td>Average follow-up cost</td>
<td>$444</td>
<td>$7,310 - $7,360</td>
<td>Uniform</td>
<td>[4], [1]</td>
</tr>
</tbody>
</table>

Results

Based on the probabilistic sensitivity analysis, use of BP-SES compared to DP-EES is associated with an overall economic benefit of $124 (IQR $99-153) per patient for our base case definition of ppMI and $93 ($79-$109) for the more restrictive definition of ppMI (Figure 3).

Conclusions

- Lower ppMI rates of BP-SES translate into meaningful reductions in direct medical cost, amounting to about 10% of the cost of a drug-eluting stent, while improving patient outcomes.
- Most of the cost reduction is attributed to the initial admission with moderate savings up to 12 months post-discharge.

Limitations

- As with all simulation studies, our findings are suggestive and in need of confirmatory empirical research.
- Although we made several assumptions related to the structure and content of our model, we base all assumptions on empirical evidence augmented with expert opinion and our results are robust to different assumptions as demonstrated by our sensitivity analyses.

Implications

- Our findings suggest that the ultrathin, bioresorbable polymer sirolimus-eluting stent is an attractive option for patients undergoing percutaneous coronary intervention from a population health and economic perspective.
- The results should help clinicians, payers and purchasers in making future decisions about the choice of coronary stents. Additional research is needed to establish the improvement in cost and clinical outcomes past the 12 months covered by the current data.

Sensitivity analyses results

- In the univariate analysis, assumptions for differential ppMI rates have the largest effect on the predicted benefit, followed by the midpoint assumption for the attributed cost during the index admission.
- Based on the probabilistic sensitivity analysis, use of BP-SES compared to DP-EES is associated with an overall economic benefit of $124 (IQR $99-153) per patient for our base case definition of ppMI and $93 ($79-$109) for the more restrictive definition of ppMI (Figure 3).

Figure 2: Probabilistic sensitivity analyses

- $116 minimum cost
- $18 median cost
- $2 maximum cost

Overall economic benefit per patient