TITLE: Port-Access Versus Sternotomy For Mitral Valve Surgery: Comparative Clinical Effectiveness, Cost Effectiveness, And Safety

DATE: 26 November 2010

RESEARCH QUESTIONS:

1. What is the comparative clinical effectiveness of port-access versus sternotomy for mitral valve surgery?

2. What is the comparative safety of port-access versus sternotomy for mitral valve surgery?

3. What is the comparative cost-effectiveness of port-access versus sternotomy for mitral valve surgery?

KEY MESSAGE

One meta-analysis, one randomized controlled trial, and nine non-randomized studies suggest that the port-access technique may be a safe and effective alternative to the use of median sternotomy for mitral valve surgery. One study reported that port-access had a lower cost relative to median sternotomy. Port-access was consistently associated with longer cardiopulmonary bypass and cross-clamp times.

METHODS

A limited literature search was conducted using the following bibliographic databases: PubMed and the Cochrane Library (2010, Issue 11). Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, economic studies, and safety data. Where possible, retrieval was limited to the human population. The search was limited to English language documents published between January 1, 2005 and November 19, 2010. Grey literature was obtained through health technology agency websites and a focused Internet search. Internet links were provided, where available.
The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS

Rapid response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and economic evaluations.

The literature identified one relevant systematic review and meta-analysis, one relevant randomized controlled trial, one relevant economic evaluation, and seven relevant non-randomized studies. Four of the non-randomized studies provided a comparison of minimally-invasive surgery with sternotomy and the remaining three provided no comparison of techniques. There were no relevant health technology assessments identified. Additional references are presented in the appendix. These include studies that investigated minimally invasive mitral valve surgery but did not specifically state that a port-access (PA) approach was used, as well as rapid and narrative reviews.

OVERALL SUMMARY OF FINDINGS

Modi et al (2008)\(^1\) conducted a systematic review and meta-analysis to compare minimally invasive techniques with median sternotomy (MS) for mitral valve surgery. The meta-analysis showed no statistically significant differences in perioperative mortality \((p = 0.18)\), stroke \((p = 0.45)\), new onset atrial fibrillation \((p = 0.45)\), duration of stay in the intensive care unit \((p = 0.1)\), and length of stay in the hospital \((p = 0.07)\). Minimally invasive techniques were associated with a reduced need for re-operation for bleeding \((p = 0.02)\), longer time required for cardiopulmonary bypass \((p < 0.0001)\), and longer cross-clamp time \((p = 0.0007)\). Complete results from the meta-analysis are summarized in Table 1. Overall, the authors concluded that minimally invasive techniques are a safe alternative to a conventional MS for mitral valve surgery.

<table>
<thead>
<tr>
<th>Dichotomous outcomes</th>
<th>No. studies (n)</th>
<th>OR (95% CI)</th>
<th>Favours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>6 (n = 1641)</td>
<td>0.46 (0.15, 1.42)</td>
<td>No difference</td>
</tr>
<tr>
<td>Stroke</td>
<td>6 (n = 1801)</td>
<td>0.66 (0.23, 1.93)</td>
<td>No difference</td>
</tr>
<tr>
<td>Re-op for bleeding</td>
<td>5 (n = 1553)</td>
<td>0.56 (0.35, 0.90)</td>
<td>Minimally-invasive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Continuous outcomes</th>
<th>No. studies (n)</th>
<th>WMD (95% CI)</th>
<th>Favours</th>
</tr>
</thead>
<tbody>
<tr>
<td>cardiopulmonary bypass time</td>
<td>8 (n = 871)</td>
<td>25.81 (13.13, 38.50)</td>
<td>Sternotomy</td>
</tr>
<tr>
<td>cross-clamp time</td>
<td>7 (n = 671)</td>
<td>20.91 (8.79, 33.04)</td>
<td>Sternotomy</td>
</tr>
<tr>
<td>ICU stay</td>
<td>4 (n = 309)</td>
<td>−0.36 (−0.80, 0.08)</td>
<td>No difference</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>5 (n = 350)</td>
<td>−0.73 (−1.52, 0.05)</td>
<td>No difference</td>
</tr>
</tbody>
</table>

CI – confidence interval; ICU – intensive care unit; n – number of patients; OR – odds ratio; Re-op – re-operation required; WMD – weighted mean difference

There were a total of nine relevant primary studies included in this rapid review (summarized in Table 2). Dogan et al (2005)\(^2\) conducted a randomized controlled trial comparing port-access mitral valve surgery with a median sternotomy approach. Forty patients were enrolled in the trial. There were no significant differences with regard to markers of myocardial and cerebral
damage. Pulmonary and neuropsychological tests were also similar between the two groups. The authors concluded that the port access technique for mitral valve surgery is similar in safety to that performed with MS. This study was included in the review by Modi et al (2008).¹

Four non-randomized studies³⁻⁶ compared a PA approach with MS for mitral valve surgery (Raanani et al, 2010;³ Ryan et al, 2010;⁴ Suri et al, 2009;⁵ Antonic et al; 2007⁶). Sample sizes ranged from 143 to 1108. Statistically significant differences in the time spent on cardiopulmonary bypass and cross-clamp were consistently reported and favoured MS over PA. Results were inconsistent with regard to length of hospitalization with one study reporting no significant difference, one reporting a shorter duration with PA, and one reporting a longer duration with PA. Two studies reported that PA was associated with a statistically significant reduction in the requirements of postoperative ventilator support. An additional three retrospective, non-randomized studies were included that did not provide a comparison of the PA approach with MS (Meyer et al, 2009;⁷ Greco et al, 2008;⁸ Mishra et al, 2005⁹). These studies provided an overall summary of outcomes such as cardiopulmonary bypass time, aortic cross-clamp time, mean length of stay in the intensive care unit and hospital, mortality, stroke, and re-operations.

Gersak et al (2005)¹⁰ conducted a non-randomized study comparing PA with MS for mitral valve surgery (n = 215). In addition to a number of clinical and safety outcomes, the authors also reported a comparison of costs for the two procedures. On average, PA procedures were reported to be less costly than those involving MS (P < 0.0005). Similar to the other studies, PA was associated with a statistically significant increase in cardiopulmonary bypass time and aortic cross-clamp time compared with MS. The authors also reported statistically significant differences favouring PA for the duration of time spent in the intensive care unit and overall stay in the hospital, postoperative thoracic bleeding, and extubation time. There were no statistically significant differences in mortality and stroke between the two groups. Overall, the authors concluded that the cost of the PA approach for mitral valve surgery is 20% lower than the MS approach.

**Table 2: Summary of primary randomized and non-randomized primary studies**

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study design</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Randomized controlled trials</strong></td>
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</table>
| Dogan, 2005² | • RCT (n = 40)  
• PA vs. MS | • No statistically significant differences in markers of myocardial damage, cerebral damage, pulmonary tests, and neuropsychological tests |
| **Non-randomized studies (comparisons with sternotomy)** |
| Raanani, 2010³ | • Non-randomized  
(n = 143)  
• PA vs. MS | • Operative, bypass, and cross-clamp times were significantly longer in the PA group  
• No statistically significant difference in hospital stay, NYHA class, moderate or severe mitral regurgitation |
| Ryan, 2010⁴ | • Retrospective,  
non-randomized  
(n = 1108)  
• PA vs. MS | • PA for MV repair had a shorter LOS, less postoperative ventilator usage, and shorter ICU stay; fewer patients requiring postoperative ventilation or reoperation for bleeding, fewer patients compared to MS  
• PA for MV replacement had reductions in mortality, ventilation time, ICU stay, and LOS  
• Cross-clamp time was longer with PA for MV repair and replacement |
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</tr>
</thead>
<tbody>
<tr>
<td>Suri, 2009</td>
<td>Retrospective, non-randomized (n = 715) PA vs. MS</td>
<td>Statistically significant difference favouring MS for cross-clamp time and bypass time. Univariate analysis: PA group had a shorter duration of postoperative ventilator support and a greater LOS. Multivariate analysis: PA independently predicted a lower duration of postoperative ventilator support; no significant differences in other outcomes.</td>
</tr>
<tr>
<td>Antonic, 2007</td>
<td>Retrospective, non-randomized (n = 198) PA vs. MS</td>
<td>No statistically significant difference in any creatinine-based renal function markers. Minimal postoperative creatinine clearance was significantly lower with MS. Multivariate analysis: MS was an independent renal risk factor.</td>
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**Non-randomized studies (retrospective studies without comparison)**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Meyer, 2009</td>
<td>Retrospective, non-randomized (n = 107) PA in patients with previous MS</td>
<td>Outcomes: mean cardiopulmonary bypass time (140.8 ± 43.7 min), aortic cross-clamp time (77.0 ± 49.7 min), mean LOS was 9.6 days, 30-day mortality (4.7%). Complications: reoperations for bleeding (5.6%), stroke (0.9%), and wound infections (1.9%).</td>
</tr>
<tr>
<td>Greco, 2008</td>
<td>Retrospective, non-randomized (n = 100) PA</td>
<td>Median ICU stay (20.0 ± 30.8 h); hospital LOS (7.0 ± 5.9 days); hospital mortality (4%); no patient required conversion to sternotomy. Minimally invasive surgical revision for bleeding (5%), and reoperation due to failure of a mitral valve repair (1%).</td>
</tr>
<tr>
<td>Mishra, 2005</td>
<td>Retrospective, non-randomized (n = 430) PA</td>
<td>Outcomes: mean cardiopulmonary bypass time (90 ± 48 min); mean cross-clamp time (51 ± 29 min); mean intubation time (14.8 h); mean LOS ICU (26 h), mean LOS (7 days); hospital mortality (0.46%).</td>
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</table>

**Economic evaluations**

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study design</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gersak, 2005</td>
<td>Retrospective, non-randomized (n = 215) PA vs. MS</td>
<td>The average total patient cost was less for PA compared to MS (P &lt; .0005). PA was associated with a statistically significant increase in cardiopulmonary bypass time and aortic cross-clamp time compared with MS. There were no statistically significant differences in mortality and stroke. Statistically significant differences favouring PA were also reported for: ICU stay, LOS, blood transfusion, postoperative thoracic bleeding, and extubation time.</td>
</tr>
</tbody>
</table>

ICU – intensive care unit; LOS – length of stay; MS – median sternotomy; MV – mitral valve; n – number of patients; NYHA – New York Heart Association; PA – port access; RCT – randomized controlled trial.
REFERENCES SUMMARIZED

Health technology assessments
No literature identified.

Systematic reviews and meta-analyses

Randomized controlled trials

Non-randomized studies
Comparisons with sternotomy

Retrospective studies without comparison

Economic evaluations


PREPARED BY:
Canadian Agency for Drugs and Technologies in Health
Tel: 1-866-898-8439
www.cadth.ca
APPENDIX – FURTHER INFORMATION:

Randomized controlled trials not specific to port-access


Non-randomized studies not specific to port-access

Comparisons with sternotomy


Retrospective studies without comparison


Rapid Review


Review articles


