Mini-sternotomy for aortic valve replacement reduces the length of stay in the cardiac intensive care unit: meta-analysis of randomised controlled trials

E Khoshbin, S Prayaga, J Kinsella, F W H Sutherland

ABSTRACT

Background: Mini-sternotomy for isolated aortic valve replacement aims to reduce operative trauma hastening recovery and improving the cosmetic outcome of cardiac surgery. The short-term clinical benefits from the mini-sternotomy are presumed to arise because the incision is less extensive and the lower half of the chest cage remains intact. The basic conduct of virtually all other aspects of the aortic valve replacement procedure remains the same. Therefore, similar long-term outcomes are to be expected.

Objectives: To conduct a meta-analysis of the only available randomised controlled trials (RCT) in the published English literature.

Data sources: Electronic search for relevant publications in MEDLINE, EMBASE and CENTRAL databases were performed. Four studies met the criteria.

Study eligibility criteria: RCT comparing minimally invasive (inverted C or L (J)-shaped) hemi-sternotomy versus conventional sternotomy for adults undergoing isolated aortic valve replacement using standard cardiopulmonary bypass technique.

Methods: Outcome measures were the length of positive pressure ventilation, blood loss, intensive care unit (ICU) and hospital stay.

Results: The length of ICU stay was significantly shorter by 0.57 days in favour of the mini-sternotomy group (CI −0.95 to −0.2; p=0.003). There was no advantage in terms of duration of ventilation (CI −3.48 to 0.36; p=0.11). However, there was some evidence to suggest a reduction in blood loss and the length of stay in hospital in the mini-sternotomy group. This did not prove to be statistically significant (154.17 ml reduction (CI −324.51 to 16.17; p=0.08) and 2.03 days less (CI −4.12 to 0.05; p=0.06), respectively).

Limitations: This study includes a relatively small number of subjects (n=220) and outcome variables. The risk of bias was not assessed during this meta-analysis.

Conclusion: Mini-sternotomy for isolated aortic valve replacement significantly reduces the length of stay in the cardiac ICU. Other short-term benefits may include a reduction in blood loss or the length of hospital stay.

Mini-sternotomy through an inverted C, L (or J)-shaped hemi-sternotomy is a technique that aims to reduce the operative trauma thereby hastening recovery and improving the cosmetic outcome of cardiac surgery. Some may be of the opinion that the latter has the potential to confer the greatest benefit. There have been numerous studies on this subject; some claim benefits in terms of postoperative outcomes, such as ventilation requirement, bleeding and intensive care unit (ICU) and hospital stay for isolated aortic valve replacement performed in this way, others have been equivocal. The two larger meta-analyses in the published literature included data from a spectrum of sources ranging from randomised controlled trials (RCT) to non-randomised studies. They addressed important broad questions of safety and efficacy and mortality and morbidity associated with this method. However, they failed to show any specific advantages in terms of the length of positive pressure ventilation, blood loss, ICU and hospital stay. We believe these outcomes are best assessed by way of RCT, and thus conducted a meta-analysis to address these.

ARTICLE SUMMARY

Article focus

- This article tests the null hypothesis that mini-sternotomy has no outcome benefit for aortic surgery.

Key message

- Mini-sternotomy for aortic valve replacement reduces the length of stay in the ICU.

Strengths and limitations of this study

- Use of the highest quality evidence-based medicine.

- This study is not a ‘gold standard’ systematic review in the sense of searching grey literature but a confirmatory study.
specific questions using only the available RCT3–6 published on this subject.

METHODS

Electronic search for relevant publications in the English language were conducted in MEDLINE, EMBASE and CENTRAL databases starting from 1996, when the first study of minimal invasive aortic valve replacement was conducted. The eligibility of each study was assessed by more than one author during the search of databases and references. We searched for the keywords ‘aortic valve surgery’, ‘controlled clinical trials’ and ‘minimally invasive surgery’. Reference lists of relevant articles were also searched. We only included RCT in our meta-analysis.

Of the 21 studies found in our search, four studies met our criteria. We selected the studies according to the following inclusion criteria: (1) the type of studies: RCT comparing minimally invasive versus conventional sternotomy; (2) participants: adult patients undergoing isolated aortic valve replacement using the standard cardiopulmonary bypass technique. The exclusion criteria were: (1) any other type of mini-sternotomy than hemi-sternotomy through the inverted C or L (J)-shaped approach; (2) the language of the article was limited to English (figure 1).

Our outcome measures included the length of positive pressure ventilation, blood loss, ICU and hospital stay.

Statistical analysis was performed using Review Manager (RevMan) V.5.0. As the data obtained were continuous, combined mean differences were measured using the random effects model on the presumption that individual studies had varied outcomes. Tests for heterogeneity were performed using the χ² test, I² test and degrees of freedom. In this meta-analysis the risk of bias was not assessed.

RESULTS

There were two meta-analyses on this subject,1 2 four of five RCT were subjected to our meta-analysis.3–6 One

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**Table 1** Study characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Moustafa et al, 2007³</th>
<th>Dogan et al, 2003⁴</th>
<th>Bonacchi et al, 2002⁵</th>
<th>Aris et al, 1999⁶</th>
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<tbody>
<tr>
<td>Methods</td>
<td>PRCT</td>
<td>PRCT</td>
<td>PRCT</td>
<td>PRCT</td>
</tr>
<tr>
<td>No of participants</td>
<td>30+30=60</td>
<td>20+20=40</td>
<td>40+40=80</td>
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<td>Mean age in years (full/min)</td>
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<td>64.3/65.7</td>
<td>62.6/64.0</td>
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<td>Sex M:F (full/min)</td>
<td>15:15/16:14</td>
<td>11:9:9:11</td>
<td>—</td>
<td>—</td>
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<td>Isolated AVR</td>
<td>Isolated AVR</td>
<td>Standard sternotomy</td>
<td>Isolated AVR</td>
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<td>Full sternotomy vs L-shaped mini-sternotomy</td>
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<td>Complete sternotomy vs L-shaped mini-sternotomy</td>
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<td>Pain management with tenoxicam</td>
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<td>mini-sternotomy</td>
<td>Pain management with metamizol</td>
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<tr>
<td>Outcomes</td>
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<td>Duration of ventilation</td>
<td>Duration of ventilation</td>
<td>Duration of ventilation</td>
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<tr>
<td>Postop blood loss</td>
<td>Postop blood loss</td>
<td>Postop blood loss</td>
<td>Postop blood loss</td>
<td>Postop blood loss</td>
</tr>
<tr>
<td>Length of ICU stay</td>
<td>Length of ICU stay</td>
<td>—</td>
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<td>—</td>
<td>pulmonary function.</td>
<td>—</td>
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<tr>
<td>Analgesic requirement</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Length of hospital stay</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cross-clamp time</td>
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<td>Survival to discharge</td>
<td>Survival to discharge</td>
<td>Survival to discharge</td>
<td>Survival to discharge</td>
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</table>

AVR, aortic valve replacement; ICU, intensive care unit; PRCT, prospective randomised controlled trial.

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*Figure 1* PRISMA flow diagram.
Mini-sternotomy for aortic valve replacement

Figure 2  Duration of ventilation in hours.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental Mean SD Total</th>
<th>Control Mean SD Total</th>
<th>Weight</th>
<th>Mean difference IV, Random, 95% CI</th>
<th>Mean difference IV, Random, 95% CI</th>
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<tr>
<td>03</td>
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<td>40</td>
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<tr>
<td>04</td>
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<td>20</td>
<td>9.9</td>
<td>4.50</td>
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</tr>
<tr>
<td>Total (95% CI)</td>
<td>110</td>
<td>110</td>
<td>100.0%</td>
<td></td>
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</table>

Heterogeneity: $\chi^2 = 3.11$, $d = 3$ ($p = 0.0001$); $F = 92%$

Test for overall effect: Z = 1.59 ($p = 0.08$)

Figure 3  Postoperative bleeding in the first 24 h measured in millilitres.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental Mean SD Total</th>
<th>Control Mean SD Total</th>
<th>Weight</th>
<th>Mean difference IV, Random, 95% CI</th>
<th>Mean difference IV, Random, 95% CI</th>
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<td>495</td>
<td>165</td>
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<td>479</td>
<td>274</td>
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<td>159</td>
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<tr>
<td>Total (95% CI)</td>
<td>110</td>
<td>110</td>
<td>100.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2 = 8.1296.09$, $d = 3$ ($p = 0.0001$); $F = 95%$

Test for overall effect: Z = 1.77 ($p = 0.08$)

RCT was excluded due to lack of data. An attempt was made to contact the corresponding author for additional information with a view to include that study. This was unsuccessful. Other excluded studies were either prospective non-randomised (n = 5), case-control studies (n = 3), retrospective studies (n = 1), different types of incision (n = 2) or studies with outcome measures irrelevant to our study (n = 4). The total number of patients included in this meta-analysis was the sum of the patients recruited into the four RCT; that equals 220 patients. Table 1 illustrates each of these studies’ characteristics. The following results are presented as mean differences in outcomes between mini-sternotomy and conventional sternotomy groups in the random effects method.

Duration of mechanical ventilation in hours

There was a statistically insignificant reduction in the duration of ventilation (figure 2). This was 1.56 h less in the mini-sternotomy group (CI -3.48 to 0.36; p = 0.11).

Postoperative blood loss in the first 24 h

There was a statistically insignificant reduction in blood loss of 154.17 ml in the mini-sternotomy group compared with the full sternotomy (CI -324.51 to 16.17; p = 0.08), illustrated by figure 3.

Lengths of ICU stay in days

The combined mean difference of all the studies showed that the length of ICU stay was significantly shorter by 0.57 days in favour of the mini-sternotomy group (CI -0.95 to -0.2; p = 0.003). Figure 4 illustrates this primary outcome measure.

Lengths of hospital stay in days

As illustrated in figure 5, the duration of hospital stay was shorter by 2.03 days in favour of the mini-sternotomy group; however, the difference again failed to reach statistically significant levels (CI -4.12 to 0.05; p = 0.06).

DISCUSSION

We performed a meta-analysis to compare the short-term postoperative outcomes in four published studies, accounted for differences in their findings, and drew a consensus view on the potential benefits of a mini-sternotomy over a full median sternotomy for a standard aortic valve replacement. The following outcome measures were assessed: duration of ventilation; postoperative blood loss; length of stay in the ICU and the hospital stay.

Using only the best available level of evidence in this meta-analysis we have clearly illustrated the advantage of the mini-sternotomy approach in reducing the number


3
of days spent in the ICU ($p=0.003$) and a lack of advantage in terms of the number of hours ventilated ($p=0.11$). We failed to prove a clear superiority in favour of mini-sternotomy in terms of the reduction in blood loss ($p=0.08$) or the length of hospital stay ($p=0.06$). However, this shows a trend of significance. None of the previous meta-analyses showed such a trend. Our meta-analysis therefore highlights a much needed, larger and adequately powered RCT for these specific outcomes. The reduction in ICU stay by 0.57 days is a more than 50% reduction in the length of stay in ICU for a typical isolated aortic valve replacement with potential financial advantages.

This study is limited as it is not a ‘gold standard’ systematic review in the sense of searching grey literature but a confirmatory study. It only includes four RCT, with a relatively small number of subjects and outcome variables. The risk of bias was not assessed during this meta-analysis. A fifth RCT by Macheler 	extit{et al} was excluded due to the lack of data regarding ICU and the length of hospital stay; however, it should be noted that that trial supported our findings regarding the duration of ventilation and blood drainage per 24 h. It should also be mentioned that in the meta-analysis by Morgan 	extit{et al} three out of four of the above studies were analysed separately as a subgroup.4–6 They found a non-statistical advantage in terms of ventilation time, bleeding and ICU stay. In contrast, this meta-analysis excludes the RCT by Macheler 	extit{et al} but includes the most recent RCT by Moustafa 	extit{et al}.3 The lack of long-term data is not exclusive to this meta-analysis.

The total number of patients included in this study was 220. This is a small number considering that isolated aortic valve replacement constitutes a large proportion of our cardiac surgical work. There were two extensive well conducted meta-analyses comparing mini-sternotomy versus conventional sternotomy for aortic valve replacement.1 2 They improved the power of the study by including several comparative non-randomised studies, thus increasing the number of patients to 4586 and 4667, respectively. Those studies looked at a wide variety of non-sternotomy incisions. They excluded studies if more than 50% of reported cases were not a mini-sternotomy or operations were other than isolated aortic valve replacement. Their combined conclusion was that mini-sternotomy can be performed safely for aortic valve replacement without an increased risk of death or major complications1 but with no clinical benefits.2 In contrast, the rationale for our study was to focus on mini-sternotomy incisions and the commonest variations thereof, which included the inverted C and L or (J) mini-sternotomies. In this meta-analysis there are no non-mini-sternotomy cases and all cases underwent isolated aortic valve replacement.

There exists a degree of geographical variation that should be taken in to consideration; for example, the benefits due to the incision. Cosmesis does not appear to be a priority for patients in the western world.8 A more cosmetic scar may be more of an issue in Asia due to the younger patient population9 (table 1). This was a limitation in this study for which there were insufficient data for comparisons to be made. However, minimally invasive valve surgery is already known to improve patient satisfaction while reducing the costs of cardiac valve replacement.25 26

**CONCLUSION**

There is a significant reduction in the length of stay in the cardiac ICU and an overall benefit in short-term outcomes from mini-sternotomy for isolated aortic valve replacement. This meta-analysis would no doubt prove useful when designing a much needed, larger and adequately powered RCT on this subject.

**Acknowledgements** The authors would like to thank the Department of Biostatistics at the Robertson Centre, University of Glasgow, for their help with the statistical methods, the library staff at Glasgow Royal Infirmary and the audit office staff at the Golden Jubilee National Hospital for their help with the literature search.

**Funding** The authors would like to thank Mark Woolley from Cardiosolutions for providing funding to present this work at the International Society of Minimally Invasive Cardiothoracic Surgery in Washington, DC, USA, in June 2011.

**Competing interest** None.

**Contributors** All authors contributed equally in the design, review of the literature, analysis and intellectual discussion of this manuscript. All authors critically revised the manuscript and approved the final version. The primary author, EK, presented this work at the International Society of Minimally Invasive Cardiothoracic Surgery in Washington, DC, USA, in June 2011.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** No additional data available.

**REFERENCES**


## PRISMA 2009 Checklist

<table>
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<tr>
<th>Section/topic</th>
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<th>Mini-sternotomy for Aortic Valve Replacement Reduces the Length of Stay in the Cardiac Intensive Care: Meta-analysis of randomised controlled trials. Khoshbin E, Prayaga S, Kinsella J, Sutherland FWH.</th>
<th>Reported on page #</th>
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</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td><strong>Identify the report as a systematic review, meta-analysis, or both.</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td><strong>Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</strong></td>
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<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td><strong>Describe the rationale for the review in the context of what is already known.</strong></td>
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<tr>
<td><strong>Objectives</strong></td>
<td></td>
<td><strong>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</strong></td>
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<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td><strong>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Protocol and registration</strong></td>
<td>5</td>
<td><strong>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</strong></td>
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<tr>
<td><strong>Eligibility criteria</strong></td>
<td>6</td>
<td><strong>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</strong></td>
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<tr>
<td><strong>Search</strong></td>
<td>7</td>
<td><strong>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</strong></td>
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<tr>
<td><strong>Study selection</strong></td>
<td>9</td>
<td><strong>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</strong></td>
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<td><strong>Data collection process</strong></td>
<td>10</td>
<td><strong>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</strong></td>
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<tr>
<td><strong>Risk of bias in individual studies</strong></td>
<td>12</td>
<td><strong>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</strong></td>
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<tr>
<td><strong>Summary measures</strong></td>
<td>13</td>
<td><strong>State the principal summary measures (e.g., risk ratio, difference in means).</strong></td>
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</table>
**Synthesis of results**

Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$) for each meta-analysis.

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**RESULTS**

**Study selection**

Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.

**Study characteristics**

For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.

**Risk of bias within studies**

Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).

**Results of individual studies**

For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.

**Synthesis of results**

Present results of each meta-analysis done, including confidence intervals and measures of consistency.

**Risk of bias across studies**

Present results of any assessment of risk of bias across studies (see Item 15).

**Additional analysis**

Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).

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**DISCUSSION**

**Summary of evidence**

Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).

**Limitations**

Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).

**Conclusions**

Provide a general interpretation of the results in the context of other evidence, and implications for future research.

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**FUNDING**

**Funding**

Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.

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