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Mini-sternotomy for aortic valve replacement reduces the length of stay in the cardiac intensive care unit: metaanalysis 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.

ARTICLE SUMMARY

Article focus

 This article tests the null hypothesis that ministernotomy 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.

A 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^{1 2} 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 efficacy1 and mortality and morbidity² 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

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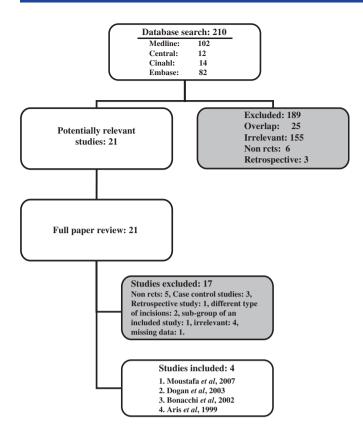


Figure 1 PRISMA flow diagram.

specific questions using only the available RCT^{3-6} 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 metaanalysis.

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 χ^2 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

Table 1 Study characteristics									
Study	Moustafa <i>et al</i> , 2007 ³	Dogan <i>et al</i> , 2003 ⁴	Bonacchi <i>et al</i> , 2002 ⁵	Aris <i>et al</i> , 1999 ⁶					
Methods	PRCT	PRCT	PRCT	PRCT					
No of participants	30+30=60	20+20=40	40+40=80	20+20=40					
Mean age in years (full/mini)	23.8/22.9	64.3/65.7	62.6/64.0	62.2/66.5					
Sex M:F (full/mini)	15:15/16:14	11:9/9:11	_	_					
Operation	Isolated AVR	Isolated AVR	Isolated AVR	Isolated AVR					
Interventions	Full sternotomy	Complete sternotomy	Standard sternotomy	Median sternotomy					
	vs L-shaped	vs L-shaped	vs C or L-shaped	vs C or L-shaped					
	mini-sternotomy	mini-sternotomy	mini-sternotomy	mini-sternotomy					
	Pain management			Pain management					
	with tenoxicam			with metamizol					
Outcomes	Duration of ventilation	Duration of ventilation	Duration of ventilation	Duration of ventilation					
	Postop blood loss	Postop blood loss	Postop blood loss	Postop blood loss					
	Length of ICU stay	Length of ICU stay	Length of ICU stay	Length of ICU stay					
	Pulmonary function	Pulmonary function.	Pulmonary function	Pulmonary function					
	Analgesic requirement	_	Analgesic requirement	_					
	Length of hospital stay	Length of hospital stay	Length of hospital stay	Length of hospital stay					
	Cross-clamp time	Cross-clamp time	Cross-clamp time	Cross-clamp time					
	Bypass time	Bypass time	Bypass time	Bypass time					
	Operation time	Operation time	Operation time	Operation time					
	Survival to discharge	Survival to discharge	Survival to discharge	Survival to discharge					
AVR, aortic valve replacement; ICU, intensive care unit; PRCT, prospective randomised controlled trial.									

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

Mean difference

Mean difference

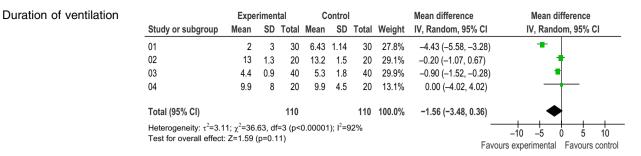


Figure 3 Postoperative bleeding in the first 24 h measured in millilitres.

Figure 2

in hours.

	EAPC		ui		001101			mount annoi onioo	incut a		
Study or subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% (CI IV, Rando	om, 95% Cl	
01	233.33	47.95	30	590	164.74	30	25.9%	-356.67 (-418.07, -295.2	7) ◀		
02	240	69	20	495	165	20	25.4%	-255.00 (-333.38, -176.6	2)		
03	183	89	40	280	189	40	25.9%	-97.00 (-161.74, -32.26) —		
04	479	274	20	355	159	20	22.8%	124.00 (-14.84, 262.84)	-		\rightarrow
Total (95% CI)			110			110	100.0%	-154.17 (-324.51, 16.1	7)	+	
Heterogeneity: τ^2 =281	26.90; χ ²	=57.10,	df=3 (p	o<0.000	01); I ² =9	5%			-200 -100	0 100 2	200
Test for overall effect:	Z=1.77 (p	=0.08)							Favours experimental		

Control

Experimental

RCT was excluded due to lack of data.⁷ An attempt was made to contact the corresponding author for additional information with a view to include that study. This was unsuccessful. Other excluded studies⁸⁻²⁴ were either non-randomised (n=5), case-control prospective 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 in to 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

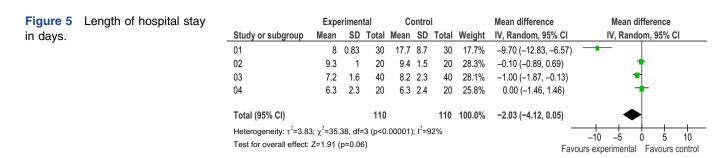
As illustrated in figure 5, the duration of hospital stay was shorter by 2.03 days in favour of the mini-sternotomy group; however, the difference again failed to reach statistically significant levels (CI -4.12 to 0.05; p=0.06).

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 ministernotomy 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

Figure 4 Length of intensive		Experimental Control			Mean difference		Mean difference			
care unit stay in days.	Study or subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
	01	0.28	0.16	30	1.15	0.6	30	29.1%	-0.87 (-1.09, -0.65)	
	02	1.2	0.1	20	2.1	0.9	20	23.8%	-0.90 (-1.30, -0.50)	
	03	1.1	0.4	40	1.4	0.8	40	27.6%	-0.30 (-0.58, -0.02)	•
	04	1.83	0.7	20	1.94	1	20	19.5%	-0.11 (-0.64, 0.42)	+
	Total (95% CI)			110			110	100.0%	-0.57 (-0.95, -0.20)	•
	Heterogeneity: τ^2 =0.11; χ^2 =15.31, df=3 (p=0.002); l ² =80%								-	-10 -5 0 5 10
	Test for overall effect:	Test for overall effect: Z=2.99 (p=0.003)							Fav	ours experimental Favours control



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 metaanalysis 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 metaanalysis. A fifth RCT by Macheler et al was excluded due to the lack of data regarding ICU and the length of hospital stay; however, it should be noted 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 *et al*¹ 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 et al but includes the most recent RCT by Moustafa 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 ministernotomy 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 ministernotomy 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 population³ (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.

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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.

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