Aortic Valve Replacement via Mini-Sternotomy versus Full Sternotomy: A Single Centre Retrospective Cohort Study

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Abstract

BACKGROUND: The traditional method of aortic valve replacement (AVR) is via full sternotomy. However, this incision may not heal properly and cause significant pain. Minimally-invasive methods have been adopted, including mini-sternotomy, gaining popularity due to a smaller incision, reducing surgical trauma. The hypothesis is that AVR via mini-sternotomy is a safe alternative to full sternotomy.

METHODS: This retrospective study compares 2 groups; AVR via mini- and via full sternotomy. Inclusion criteria were all patients 18 and over who underwent AVR between September 2016 and December 2022 in Cork University Hospital. Patients who underwent concomitant cardiac procedures were excluded. Statistical analysis was performed using STATA software. Continuous data was analysed using the student t-test. Categorical data was analysed using the Pearson chi-squared test. A p value of <0.05 was deemed statistically significant.

RESULTS: 169 patients were included; 96 and 73 in the mini- and full sternotomy groups, respectively. Groups were well matched in terms of baseline characteristics including age, BMI, and co-morbidities. The mini-sternotomy group showed a statistically significantly shorter hospital length of stay ($t(166)=4.24$, $p=0.000$). There were no statistically significant differences in intra- ($t(167)=1.8$, $p=0.067$) and post-operative blood transfusion requirements ($t(167)=0.53$, $p=0.592$). The mini-sternotomy group had significantly longer cross-clamp ($t(167)=-2.1$, $p=0.039$) and cardio-pulmonary bypass times ($t(167)=-2.45$, $p=0.015$).

CONCLUSION:AVR via mini-sternotomy has been associated with shorter hospital stay, with the drawback of increased cross-clamp and cardio-pulmonary bypass times. This retrospective study demonstrates mini-sternotomy as a safe alternative to full sternotomy, in the cohort studied.

Introduction

The aortic valve is one of two semilunar valves, the other being the pulmonary valve, which lies between the left ventricle and aorta. It is composed of three leaflets and, by definition, allows blood flow in one direction only, from the left ventricle to the aorta [1]. The structure of the valve allows it to withstand various mechanical and haemodynamic forces throughout the cardiac cycle [1]. Although the aortic valve is quite robust, there are various factors which can contribute to its demise. These include age-related calcification, congenital heart defects and connective tissue disorders [1]. The valve can either become stenosed or insufficient. Aortic stenosis is a narrowing of the valve opening, reducing the valve area [1]. Aortic regurgitation (insufficiency) is the backflow of blood from the aorta to the left ventricle when the valve leaflets fail to close normally [1]. Both pathologies can be asymptomatic or can cause symptoms of syncope, dyspnoea or heart failure [1]. Pathologies of the aortic valve can have detrimental effects on bodily functions due to perfusion deficits [2]. These pathologies are managed by either aortic valve replacement or repair [2].

Aortic valve replacement (AVR) is the gold standard treatment for those patients suffering from severe or symptomatic aortic stenosis or aortic regurgitation [3]. The traditional method of AVR is via a median sternotomy incision, where a cut is made from the manubrium of the sternum to the xiphoid process and sometimes, as far as the umbilicus. While this remains the 'gold standard' approach, it may lead to poor sternal wound healing, severe pain and prolonged recovery, especially in patients suffering from conditions such as osteoporosis, osteopenia or diabetes mellitus [3]. Various minimally-invasive techniques with many different access routes have evolved, with the aim of reducing surgical trauma and ultimately improving patient outcomes [3].

The use of minimally-invasive surgical techniques in patient care is well documented in ancient history, however, it is only since 1990 that technological advancements have allowed surgeons to utilize the approach to its fullest extent [4]. The approach has transformed the surgical landscape, significantly reducing post-operative pain, recovery time, length of hospital stay and overall surgical costs [4]. Examples of such methods include laparoscopic abdominal surgery and endovascular aneurysmal repairs, but to name a few.

'Minimally-invasive cardiac surgery' is defined as any procedure that is performed without a full sternotomy incision or cardiopulmonary bypass support [5]. Minimally-invasive AVR was first described by Cosgrove and Sabik in 1996, but the surgical uptake since then has been patchy at best [6]. This has been possibly due to inertia and perhaps, the need for additional training to perform a more technically challenging procedure [6]. Examples of minimally-invasive AVR techniques include a right parasternal approach, a right anterior mini-thoracotomy, a trans-sternal approach and a mini-sternotomy approach [5]. This paper focuses on the mini-sternotomy approach. In previous studies, the mini-sternotomy approach has been shown to lead to better cosmetic outcomes, shorter length of both ICU and hospital stay as well as lower amounts of blood loss [7].

However, research in the area has been limited and studies have had conflicting results. This paper is the first such study in an Irish hospital context. It will add to the existing body of knowledge and will further establish AVR mini-sternotomy as a safe alternative to the traditional approach. Mr. Kishore Doddakula and his colleagues have been performing this minimally-invasive procedure in Cork University Hospital (CUH) since 2011 [8].

The hypothesis of the study is that AVR via mini-sternotomy is a safe alternative to the full sternotomy approach. The objectives are to characterise the profile of the population who have undergone both procedures, to examine peri-operative outcomes for patients and to then compare results between the two cohorts.

Materials & Methods

This study is a retrospective database review conducted in the Department of Cardiothoracic Surgery, Cork University Hospital (CUH). The population studied was those who underwent aortic valve replacement (AVR) either via mini- or full sternotomy in CUH between September 2016 and December 2022. Data was obtained from the PATS (Patient Advocate Tracking System) and was input into a Excel file, which was encrypted on a password-protected computer in the Department of Cardiothoracic Surgery, CUH. This Excel file was the data collection sheet, which included parameters

such as operation time, cross-clamp time and length of hospital stay.

Inclusion criteria was all patients aged 18 years and older who underwent AVR either via mini- or full sternotomy in CUH between September 2016 and December 2022. Patients excluded were those aged less than 18 years and those who underwent concomitant cardiac procedures, such as a coronary artery bypass graft or an ascending aorta replacement.

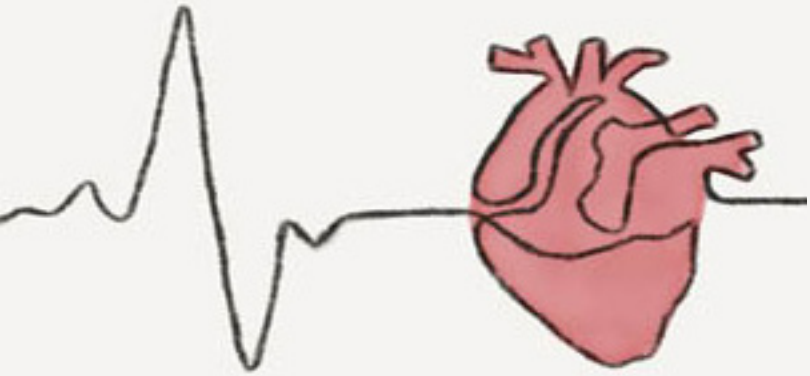
Statistical analysis was carried out using STATA software. Basic descriptive analysis was used to characterise the data, with results expressed as a mean and the absolute number (%). Continuous data was analysed using the student t-test and results were expressed as a mean and standard deviation. Categorical data was analysed using the Pearson chi-squared test, with results expressed as a number and percentage. A p-value of less than 0.05 was deemed as statistically significant. Ethical approval was obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC).

Results

A total of 169 patients were included in the study, after inclusion and exclusion criteria were applied. Among them, 96 patients underwent AVR via mini-sternotomy and 73 patients underwent AVR via full sternotomy. Table 1 presents the demographics of the cohorts studied, Table 2 summarises the peri-operative outcomes for patients with results expressed as a mean, Table 3 presents the post-operative outcomes and complications and Table 4 presents the peri- and post-operative mortality of patients at various times following surgery.

Table 1: Demographic Data

Demographic Parameter	Mini-Sternotomy (n=96)	Full Sternotomy (n=73)	P-value
Age (years)	68 (+/- 1.3)	69 (+/- 1.2)	0.800
Male	54 (56%)	54 (74%)	0.170
Body Mass Index (kg/m^2)	29 (+/- 0.5)	31 (+/- 0.8)	0.003
Diabetes	12 (13%)	18 (25%)	0.040
Hypertension	64 (66%)	53 (73%)	0.408
Hyperlipidaemia	68 (71%)	55 (75%)	0.514
Coronary Artery Disease	18 (19%)	18 (25%)	0.353
Smoking History	43 (45%)	55 (75%)	0.000
COPD	18 (19%)	14 (19%)	0.944
Creatinine Clearance (ml/min)	84 (+/- 2.9)	86 (+/- 4.9)	0.660



The demographic data (Table 1) shows that both groups (AVR via mini-sternotomy and AVR via full sternotomy) were generally well-matched in terms of baseline characteristics, including age, sex, creatinine clearance and prevalence of co-morbidities, such as hypertension, hyperlipidaemia and coronary artery disease. However, the full sternotomy group showed a significantly lower mean BMI [p=0.003] and a higher prevalence of diabetes mellitus [p=0.04] and patients with a smoking history [p=0.000] (either past or current).

Table 2: Peri-Operative Outcomes

Peri-Operative Outcome Parameter	Mini-Sternotomy (n=96)	Full Sternotomy (n=73)	P-value
Operative time (mins.)	242 (+/- 48)	257.93 (+/- 58.94)	0.063
Cardio-pulmonary bypass time (mins.)	92.1 (+/- 16)	85.2 (+/- 19.66)	0.015
Cross-clamp time (mins.)	72.8 (+/- 14)	68.4 (+/- 13.35)	0.039
Ventilation time (hours)	15.29 (+/- 15)	19.29 (+/- 10.9)	0.002
Length of hospital stay (days)	11 (+/- 10.67)	19 (+/- 15.61)	0.000
Length of ICU stay (days)	3.09 (+/- 7.02)	2.93 (+/- 4.32)	0.995
Intra-operative blood transfusions (units)	0.26 (+/- 1)	0.57 (+/- 1.43)	0.067
Post-operative blood transfusions (units)	0.7 (+/- 1)	0.8 (+/- 1.29)	0.592

The mini-sternotomy group showed a statistically significantly reduced overall length of hospital stay and ventilation time. Although both intra- and post- operative transfusion requirements were lower in the mini-sternotomy group, this was not statistically significant. However, cross-clamp and cardio-pulmonary bypass time were significantly longer in the mini-sternotomy group versus the full sternotomy cohort. This is likely due to the initial technical challenges with the introduction of a new, more intricate procedure and has been demonstrated in the literature [9]. AVR via mini-sternotomy is associated with a steep learning curve due to the initial technical challenges of the procedure [10]. Although these prolonged times have been associated with increased numbers of complications in previous studies [11], they did not appear to increase the incidence of major post-operative adverse events in the cohort studied. Interestingly, overall operative time was longer in the full sternotomy group compared to the mini-sternotomy group, even with longer cross-clamp and cardio-pulmonary bypass times in the latter.

Table 3: Post-Operative Outcomes

Post-Operative Outcome Parameter	Mini-Sternotomy (n=96)	Full Sternotomy (n=73)	P-value
Stroke	1	1	0.845
Myocardial Infarction	0	1	0.432
Re-do Sternotomy	5	4	0.938
Sternal Wound Infection	2	0	0.506
Paravalvular leak	1	2	0.408
Acute Kidney Injury	0	2	0.185
Arrhythmias	25	23	0.435
Pulmonary Embolism	0	0	1
Deep Vein Thrombosis	0	1	0.432
Prolonged Use of Inotropes	18	15	0.77

Similar numbers of post-operative complications were observed between the two groups (Table 3). There was a higher number of patients suffering from arrythmias, prolonged use of inotropes and sternal wound infection in the mini-sternotomy group. However, none of these differences were determined to be statistically significant. There was a small number of patients in the full sternotomy group who experienced acute kidney injuries and deep vein thromboses, while there was no such complications in the mini-sternotomy group, but this again was not statistically significant.

Table 4: Post-Operative Outcomes

Mortality Parameter	Mini-Sternotomy (n=96)	Full Sternotomy (n=73)	P-value
Peri-operative mortality	0	0	1
30-day mortality	0	3	0.787
90-day mortality	0	0	1
1-year mortality	2	0	0.554
3-year mortality	3	2	0.811

No statistically significant differences were found when examining peri-operative, 30-day and 90-day mortality between the two groups (Table 4). The difference between 1-year and 3-year mortality between the two cohorts was also not determined to be statistically significant.

Discussion

SUMMARY OF MAIN FINDINGS

- Patients were very well matched in terms of baseline characteristics. These include age and sex, along with the prevalence of co-morbidities, such as hypertension, hyperlipidaemia and coronary artery disease. However, the mini-sternotomy group showed a significantly higher mean BMI [p=0.003] compared to the full sternotomy cohort and there was a much higher prevalence of diabetes mellitus [p=0.04] and a smoking history [p=0.00] in the mini-sternotomy group.
- There were some interesting findings noted on comparison of peri-operative outcomes. The mini-sternotomy group showed a significantly shorter ventilation time [p=0.022] and length of overall hospital stay [p=0.000]. This group also demonstrated a shorter operative time, but this was not statistically significant [p=0.063]. Although these are some positive results, the mini-sternotomy cohort did show statistically significantly longer cross-clamp [p=0.039] and cardio-pulmonary bypass times [p=0.015]. However, these prolonged times have been shown in the literature [7], and also did not appear to increase the incidence of post-operative complications.
- There were similar numbers of post-operative outcomes and complications between the two groups, such as stroke, myocardial infarctions and arrhythmias. None of these differences were determined to be statistically significant.
- There were no in-hospital mortalities in either group and there were similar numbers of deaths between both cohorts at 30 days, 90 days, 1 year and 3 years.

STRENGTHS AND LIMITATIONS OF THE STUDY

- Strengths:
- All data collected was readily accessible in the PATS centralised database. This allowed quick and efficient data collection without the need to review old patient charts individually.
- This study, and retrospective reviews generally are often much more cost- and time- effective compared to other study designs as the data already exists. Patients did not need to be recruited for participation and questionnaires did not need to be distributed. No follow-up was required in this study either.
- This study allowed for the analysis of a multitude of different variables. This meant that the relationship between a wide range of exposures and outcomes could be measured.
- There were no ethical concerns with this study. Consent was not required as this was a retrospective review that did not necessitate communication with patients. The study did not require an intervention either, again avoiding ethical concerns.
- Weaknesses:
- This study was performed in a single centre only (Cork University Hospital), which means that there is limited generalizability as it is difficult to determine if the population studied is representative of all patients both nationally and internationally undergoing AVR via mini- or full sternotomy.
- Selection bias is a weakness of a retrospective review like this. Since the data collected was from pre-existing records, the study population may not be representative of the general population.
- Inability to perform propensity-matching is a potential weakness. It was not performed as there was an insufficient sample size. However, both cohorts were already well matched in terms of baseline characteristics, decreasing the possibility of confounding.
- Missing data may be an issue with retrospective reviews. Existing databases, like the PATS database, occasionally have missing or incomplete data within individual patient records, which can lead to inaccurate results or false conclusions. Only a small number of patients in our study were missing some data.

EXISTING LITERATURE

Previous retrospective studies published support the findings of this study. A 2022 study entitled "Comparison Between Mini-Sternotomy and Full Sternotomy for Aortic Valve Replacement: A 10-Year Retrospective Study" found that AVR via mini-sternotomy was a safe alternative to full sternotomy, in the cohort studied, with a reduction in length of both hospital and ICU stay observed

[12]. Although, a prolonged ICU stay was not found in our study, prolonged cardio-pulmonary bypass and cross-clamp times were seen in both studies and were an expected result. A randomized controlled trial published in 2021 compared the two approaches and used the proportion of patients who received post-operative red blood cell transfusions as the primary outcome [13]. While it was found that mini-sternotomy reduced chest drain losses, it did not reduce red-cell transfusions [13]. This is in line with our study as although post-operative transfusion requirements were lower in the mini-sternotomy group, this was not statistically significant. This paper also demonstrated longer cardio-pulmonary bypass and cross-clamp times [13]. "Efficacy of Aortic Valve Replacement through Full Sternotomy and Minimal Invasion (Ministernotomy)" displayed some interesting results [14]. It found significantly longer bypass and cross-clamp times in the mini-sternotomy group, however it demonstrated shorter ventilation, shorter length of hospital stay and also better cosmetic results [14]. The conclusion then proposed AVR via mini-sternotomy as perhaps a better approach than full sternotomy [14]. Further investigation would be required to make this claim in our study. A comparative study published in 2015 further supported the results of our study. It found a shorter ventilation time, shorter length of hospital stay and reduced blood transfusions in the mini-sternotomy group [15]. Although, interestingly, it found shorter bypass and cross-clamp times in the mini-sternotomy group [15]. Perhaps, this was due to a high level of surgical skill and a substantial amount of time spent performing the procedure. Again, this study confirmed clinical benefits of the technique, similar to our study, without an increased incidence of post-operative complications [15].

IMPLICATIONS FOR FUTURE RESEARCH OR CLINICAL PRACTICE

This study is a follow-on from the paper entitled titled "Aortic Valve Replacement via Mini-Sternotomy: Results of a Single Centre Analysis", which was published in the 4th Edition of the UCC Student Medical Journal [8]. Like this paper, this is the first such study in an Irish hospital context and increases both the national and also international knowledge database surrounding this under-utilized minimally-invasive surgical technique. It is hoped that publication of this paper will further highlight and strengthen AVR via mini-sternotomy as a safe alternative to the 'gold standard' approach and prompt surgeons to learn the procedure and ultimately, perform on their own patients. It is also hoped that this study will act as a catalyst for others to research not just mini-sternotomy, but other minimally-invasive approaches to AVR both nationally and internationally.

Conclusions

The aim of the study was to demonstrate AVR via mini-sternotomy as a safe alternative to the full sternotomy approach, in the cohort studied. This was achieved through a retrospective database review of patients who underwent both procedures, in Cork University Hospital, between September 2016 and December 2022. Data for the 169 patients included in the study was analysed using STATA software. The results are presented in this paper and provide information surrounding patient demographics, such as the prevalence of co-morbidities, along with peri- and post-operative outcomes for patients, such as length of hospital stay and incidence of major adverse events. We demonstrated similar numbers of complications between the two groups. The mini-sternotomy group showed a significantly shorter length of hospital stay and also significantly shorter ventilation times. However, the mini-sternotomy technique requires greater surgical expertise as demonstrated by prolonged cross-clamp and cardio-pulmonary bypass times. The findings provide additional information surrounding this poorly-researched minimally-invasive surgical technique and increase both the national and international knowledge database. This is the first study of its kind in an Irish hospital context.

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