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J-ministernotomy for aortic valve replacement: a retrospective cohort study

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Abstract

Background: The advantage of minimally invasive sternotomy (MS) over full sternotomy (FS) for isolated aortic valve replacement (AVR) is still controversial. We aimed to examine if J-shaped MS is a safe alternative to FS in patients undergoing primary isolated AVR. This study is a retrospective and restricted cohort study that included 137 patients who had primary isolated AVR from February 2013 to June 2015. Patients with previous cardiac operations, low ejection fraction (< 40%), infective endocarditis, EuroSCORE II predicted mortality > 10%, and patients who had inverted *T* or inverted *C*-MS or right anterior thoracotomy were excluded. Patients were grouped into the FS group (n=65) and MS group (n=72). Preoperative variables were comparable in both groups. The outcome was studied, balancing the groups by propensity score matching.

Results: Seven (9%) patients in the MS group were converted to FS. Cardiopulmonary bypass (98.5 ± 29.3 vs. 82.1 ± 13.95 min; $p \leq 0.001$) and ischemic times (69.1 ± 23.8 vs. 59.6 ± 12.2 min; p = 0.001) were longer in MS. The MS group had a shorter duration of mechanical ventilation (10.1 ± 11.58 vs. 10.9 ± 6.43 h; $p = 0.045$), ICU stay (42.74 ± 40.5 vs. 44.9 ± 39.3; $p = 0.01$), less chest tube drainage (385.3 ± 248.6 vs. 635.9 ± 409.6 ml; $p = 0.001$), and lower narcotics use (25.14 ± 17.84 vs. 48.23 ± 125.68 mg; $p < 0.001$). No difference was found in postoperative heart block with permanent pacemaker insertion or atrial fibrillation between groups ($p = 0.16$ and 0.226, respectively). Stroke, renal failure, and mortality did not differ between the groups. Reintervention-free survival at 1, 3, and 4 years was not significantly different in both groups (p = 0.73).

Conclusion: J-ministernotomy could be a safe alternative to FS in isolated primary AVR. Besides the cosmetic advantage, it could have better clinical outcomes without added risk.

Keywords: Minimally invasive, Upper J-ministernotomy, Aortic valve replacement

Background

Several options are available for the management of aortic valve disease [1]. Despite the recent advances in transcatheter aortic valve interventions, conventional surgery remains the gold standard because of its well-established efficacy and durability [2]. It is still debated which approach is ideal for aortic valve replacement (AVR), median full sternotomy, or minimally invasive approaches. The minimally invasive techniques for AVR include right anterior thoracotomy [3], right parasternal incisions [4], right infra-axillary incisions [5], or ministernotomy.

Surgical exposure can be suboptimal with minimally invasive approaches compared to full sternotomy, and consequently, this could be associated with a longer cardiopulmonary bypass, ischemic, and operative times [6]. On the other hand, minimally invasive approaches provide better cosmetic results with less surgical trauma that keeps most of the cardiac surface untouched and hence facilitates redo operations [7]. However, their effects on the postoperative outcomes, including mechanical ventilation, intensive care unit (ICU) stay, pain, chest tube drainage, arrhythmias, stroke, renal failure, or mortality, are still being studied.

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This study aims to compare the outcome of minimally invasive aortic valve replacement through J-shaped upper ministernotomy with the conventional approach through full sternotomy for primary isolated aortic valve replacement.

Methods

Patients and study design

This retrospective study included 137 adult patients (older than 18 years) who had primary isolated aortic valve replacement from February 2013 to June 2015. The local Ethical Committee approved data collection for this study, and patient consent was waived due to the study's retrospective nature. The American Heart Association/American College of Cardiology (AHA/ACC) guidelines for aortic valve replacement in 2008 [8] and its update in 2014 [9] were followed.

Patients' demographics, preoperative, operative, and postoperative data were collected retrospectively from the cardiac surgery department database. The database captured detailed information on a wide range of preoperative, intraoperative, and postoperative variables for all patients undergoing cardiac surgery at the study center, in addition to the follow-up data. Morbidities were defined according to the Society of Thoracic Surgeons' national database [10].

We created a restricted cohort study by applying strict exclusion criteria to make the surgical groups comparable regarding the preoperative variables. We excluded patients who had previous cardiac surgery, concomitant cardiac surgical procedures (e.g., other valve replacement or repair, coronary artery bypass grafting (CABG), root or ascending aorta replacements), patients with low ejection fraction (less than 40%), surgery for infective endocarditis, EuroSCORE II predicted mortality more than 10%, and those who were operated through inverted *T*, inverted *C* ministernotomy, or right anterior thoracotomy. Patients were grouped into a full sternotomy group (FS; n=65) and a ministernotomy group (MS; n=72).

Preoperative variables were comparable in both groups and included age, sex, body mass index, hypertension, hypercholesterolemia, diabetes mellitus, current smoking status, creatinine clearance, chronic obstructive pulmonary disease, preoperative dialysis, extracardiac arteriopathy, preoperative stroke, New York Heart Association class, preoperative angina, recent infarction, old infarction (more than 90 days), urgent surgery, EuroSCORE II, preoperative atrial fibrillation, complete heart block, preoperative hemoglobin, preoperative ejection fraction, aortic valve lesion, and valve pathology. (Tables 1 and 2).

The preoperative assessment included a detailed history taking and a thorough cardiac examination. All patients had a chest X-ray, electrocardiography, echocardiography, coronary angiography, and carotid artery ultrasonography as indicated. The choice of the surgical approach was based on the surgical team and patient preference.

Table 1 Preoperative patients' characteristics in both the full sternotomy (FS) group and the ministernotomy (MS) group. Continuous variables are presented as mean ± SD and categorical variables are number and (%)

Variables	FS (n=65)	MS (n=72)	P value
Age (years)	71.1 ± 10.3	70.6 ± 12.5	0.87
Male	34 (52.3%)	48 (66.7%)	0.09
Weight (kg)	77.8 ± 15.5	79.6 ± 17.02	0.54
Height (cm)	167.5 ± 8.5	170.2 ± 8.8	0.09
BMI (kg/m^2)	27.8 ± 5.3	27.3 ± 4.7	0.96
Hypertension	51 (78%)	51 (70%)	0.31
Hypercholesterolemia	50 (78%)	53 (74%)	0.65
Diabetes mellitus			0.38
Type 1	1 (1.5%)	1 (1.4%)	
Type 2	15 (23%)	10 (13.9%)	
Current smokers	7 (10.8%)	12 (16.7%)	0.31
Creatinine (mg/dl)	1.09 ± 0.43	1.07±0.37	0.69
Creatinine clearance (ml/min)	69.2 ± 22.63	77.72 ± 35.69	0.37
COPD	9 (13.8%)	5 (6.9%)	0.18
Preoperative dialysis	1 (1.5%)	0 (0%)	0.47
Extracardiac arteriopathy	3 (4.6%)	3 (4.1%)	0.9
Preoperative stroke	4 (6.2%)	1 (1.4%)	0.19
NYHA			0.35
I	7 (10.8%)	14 (19.4%)	
II	39 (60%)	36 (50%)	
III	19(29.2%)	21 (29.2%)	
IV	0	1 (1.3%)	
Preoperative angina	24 (36.9%)	20 (27.7%)	0.25
Recent infarction	1 (1.5%)	0	0.47
Old infarction	4 (6.15%)	1 (1.4%)	0.19
Urgent surgery	3 (4.6%)	1 (1.4%)	0.35
EuroSCORE (%)	1.99 ± 1.43	2.05 ± 1.77	0.64
Preop. AF	5 (7.6%)	6 (8.3%)	0.89
Preop. CHB	1 (1.5%)	2 (2.7%)	> 0.99
Preop. Hb (g/dl)	13.38 ± 1.41	13.35 ± 1.69	0.92

AF atrial fibrillation, *BMI* body mass index, *CHB* complete heart block, COPD chronic obstructive pulmonary disease, *Hb* hemoglobin, *NYHA* NewYork Heart Association, *SD* standard deviation

Surgical technique

General anesthesia was used in all patients with similar protocols in both groups. The aortic valve's approach was via either an oblique aortotomy carried into the non-coronary sinus of valsalva or a transverse aortotomy above the sinotubular junction, at the discretion of the surgeon.

Table 2 Preoperative echocardiographic and valve data in both the FS and MS groups. Continuous variables are presented as mean ± SD and categorical variables are number and (%)

Variables	FS (n=65)	MS (n=72)	P value
Preoperative EF	59.5 ± 9.72 %	59.5 ± 10.29 %	0.99
Aortic stenosis	61 (93.8%)	69 (95.8%)	0.6
Aortic valve area (cm^2)	0.84 ± 0.27	0.82 ± 0.22	0.77
Peak aortic gradient (mmHg)	72 ± 19.7	75.7 ± 23.7	0.38
Mean gradient (mean ± SD)	45.14 ± 14.9	45.8 ± 16.4	0.82
AR degree			0.76
1	32 (49.2%)	35 (48.6%)	
2	18 (27.7%)	21 (29.2%)	
3	12 (18.5%)	15 (20.8%)	
4	3 (4.6%)	1 (1.4%)	
Valve pathology			0.93
Congenital (bicuspid aortic valve)	1 (1.5%)	1 (1.4%)	
Calcific	59 (90.8%)	67 (93%)	
Degenerative	4 (6.15%)	4 (5.6%)	
Rheumatic	1 (1.5%)	0	

AR aortic regurge, *EF* ejection fraction, *FS* full sternotomy, *MS* ministernotomy

Aortic valve replacement was performed in the full sternotomy group through conventional sternotomy with aortic and right atrial cannulation. Cardiac arrest was achieved by using either antegrade cardioplegia or retrograde cardioplegia in patients with aortic regurgitation. In MS, a 6- to 10-cm vertical midline skin incision over the upper part of the sternum, starting just above the level of the manubriosternal angle down to the level of the 3rd intercostals space, was done. The sternotomy was then performed, with the narrow blade oscillating saw, starting at the sternal notch level down to the 3rd or 4th intercostal space level. The sternotomy was then extended into the right 3rd or 4th intercostal space depending on the anatomic structures' topographic relationships. We aimed to preserve the internal mammary vessels, and we flooded the field routinely with CO_2. The aorta was cannulated high in the ascending aorta, with venous drainage either through the right atrial appendage or through the femoral vein. According to the valve lesion, cardioplegia was administered either through an antegrade cannula inserted in the aortic root or selectively in the coronary ostia after cross-clamping, induction of fibrillation, and aortotomy.

Study outcomes

Study endpoints included duration of cardiopulmonary bypass and ischemic times, ICU and hospital stay, mechanical ventilation, postoperative drainage, postoperative transfusion of packed RBCs, atrial fibrillation, heart block with permanent pacemaker insertion, renal failure, stroke, and operative mortality. Long-term outcomes included reintervention-free survival.

The pain was assessed using the total dose of analgesics. Narcotics were used till the moment of extubation and then replaced with tramadol infusion that was mostly continued till the patient was discharged from ICU to the ward and stopped mostly in the first postoperative day. Thereafter, paracetamol was used according to the patient's need with a maximum of 4 g per 24 h. Tramadol can be added to paracetamol if needed.

Statistical analysis

Continuous variables were expressed as mean and standard deviation and categorical variables as number and percent. Continuous variables were compared using Student's t test for normally distributed variables and Wilcoxon test for non-normally distributed variables. Chi-squared was used to compare categorical variables, and Fisher's exact test was used if the expected frequency was less than 5. The treatment effect of the surgical access was calculated using propensity score matching (based on the standard logistical treatment model [logit]) after adjusting for possible confounders, including preoperative EuroSCORE, operator, implant type, and size. Similarly, preoperative hemoglobin level was adjusted when comparing the postoperative blood transfusion between both groups. Moreover, the converted patients from ministernotomy to full sternotomy were analyzed in their original group (intention to treat analysis).

Reintervention-free survival was assessed non-parametrically using the Kaplan-Meier curve, and the log-rank test was used to test the equality of the survival distributions for unstratified and stratified analysis using EuroSCORE. A p value less than 0.05 was considered significant. All statistical analyses were done using STATA 14 (Stata Corp. College Station, TX, USA).

Results

Baseline data

There was no significant difference between both groups regarding the preoperative patients' characteristics (Table 1) and preoperative echocardiographic and valve data. (Table 2)

Study outcomes

After adjustment of the operator, EuroSCORE, implant type, and size, we observed that total cardiopulmonary bypass and cross-clamp times were significantly longer in the ministernotomy group compared to the full sternotomy group (98.5 ± 29.3 versus 82.1 ± 13.95 min with p < 0.001 and 69.1 ± 23.8 vs. 59.6 ± 12.2 min with p = 0.001, respectively). (Table 3)

The ministernotomy group (MS) had shorter duration of mechanical ventilation (10.1 ± 11.58 vs 10.9 ± 6.43 h with p = 0.045), ICU stay (42.74 ± 40.5 vs 44.9 ± 39.3 h with p = 0.01), less postoperative drainage (385.3 ± 248.6 vs 635.9 ± 409.6 ml with p = 0.001), and lower doses of narcotics (25.14 ± 17.84 vs 48.23 ± 125.68 mg with p < 0.001). Regarding the postoperative complete heart block with the need for permanent pacemaker insertion, MS was not significantly associated with new-onset complete heart block after AVR (8.3% vs. 3.1% in the FS group, p = 0.16) (Tables 4 and 5).

Seven patients in the MS group (9.7%) were converted to full sternotomy for several reasons including adhesions between the aorta and the pericardium (n= 1), obesity with a body mass index (BMI) of 38.34 kg/m^2 (n=1), difficult access to the aortic root and right atrial appendage which were either lying deep in the chest or rotated to the right side (n=4), and paravalvular leakage detected with transesophageal echocardiography (TEE) intraoperatively (n=1) that needed conversion to full sternotomy and resizing of the annulus and implantation of smaller aortic valve sized 23 mm instead of the 25 mm.

Reintervention-free survival

The median follow-up duration was 3.55 years. Reintervention-free survival at 1, 3, and 4 years in MS was 97%, 89.7%, and 80.27%, respectively. At the same time, it was 95.3%, 83.15%, and 72.72% in FS with no significant difference between both groups either before (p = 0.45) and after adjustment of EuroSCORE (p = 0.73). (Figs. 1 and 2). Reintervention was performed in one patient of the MS group for aortic valve re-replacement because of structural valve deterioration of the aortic bioprosthesis 3.5 years after the first replacement. Two patients in the FS group required reintervention because of mitral valve procedures (one for mitral valve replacement and the other for Mitraclip).

Discussion

The best surgical approach for aortic valve replacement is still debated, and several factors can affect the outcomes when comparing minimally invasive approaches to full sternotomy. The results of minimally invasive approaches could be affected by the surgeon's experience. Adjustment of the operators' and patients' specific factors are essential when comparing both approaches. In this study, we created a restricted cohort study by applying strict inclusion criteria to make comparable groups; in addition, we adjusted for EuroSCORE, operator, implant size, and type. Other factors that affect the outcomes were also adjusted in the model, e.g., preoperative hemoglobin level was adjusted for postoperative blood transfusion. Moreover, patients who were converted to full sternotomy were analyzed in their original group (intention to treat analysis) to simulate a clinical trial.

Cardiopulmonary bypass (CPB) and ischemic times were significantly longer in the MS approach, although the intervention was adjusted for the operator, and the learning curve did not affect these results. Similar results were previously reported in a meta-analysis [11]. On the other hand, CPB and ischemic times were shorter in the MS group in more recent studies [12–14]. Our results could be explained by the intention to treat analysis used in our patients in which patients who were converted to full sternotomy were analyzed in their original group. Two patients in the MS group needed intraoperative revision of valve placement because of paravalvular leakage. One of them was converted to FS with the placement of a smaller size (23 instead of 25), which could affect the CPB and ischemic time.

Table 3 Mean intraoperative timing data in both the FS and MS groups

Variables	FS (n=65)	MS (n=72)	P value
Cardiopulmonary Bypass time (min), (mean ± SD)	82.1 ± 13.95	98.5 ± 29.3	< 0.001*
Cross clamp time (min), (mean ± SD)	59.6 ± 12.2	69.1 ± 23.8	0.001*

FS full sternotomy, *MS* ministernotomy, *SD* standard deviation
*Statistically significant

Table 4 Postoperative data in both the FS and MS groups. Continuous variables are presented as mean ± SD and categorical variables are number and (%)

Variables	FS (n=65)	MS (n=72)	P value
Postoperative ventilation time (h)	10.9 ± 6.43	10.1 ± 11.58	0.045
ICU stay (h)	44.9 ± 39.3	42.74 ± 40.5	0.01
Hospital stay (days)	11.2 ± 4.9	10.8 ± 4.8	0.22
Postop. drainage (ml)	635.9 ± 409.6	385.3 ± 248.6	0.001
PRBCs transfusion (units)	1.01 ± 1.26	0.93 ± 1.35	0.78
Postoperative new AF	25 (38.5%)	30 (41.7%)	0.23
Postop. new CHB	2 (3.1%)	6 (8.3%)	0.16
Delayed pleurocentesis	1 (1.5%)	4 (5.6%)	0.37
New postop. stroke	0 (0%)	2 (2.8%)	0.498
Dipidolor (mg)	48.23 ± 125.68	25.14 ± 17.84	< 0.001
Paracetamol (g)	13.08 ± 2.49	12.87 ± 2.75	0.75
Tramadol (mg)	246.51 ± 298.54	337.29 ± 345.3	0.73

AF atrial fibrillation, *CHB* complete heart block, *FS* full sternotomy, *g* gram, *Gr.* gradient, *Hb* hemoglobin, *ICU* intensive care unit, *mg* milligram, *ml* milliliter, *MS* ministernotomy, *PRBCs* packed red blood cells

Despite the longer operative time, a significantly shorter postoperative mechanical ventilation duration was observed in the MS group (p = 0.045). The maintained thoracic cage's integrity could help preserve the respiratory mechanics, and smaller incisions can be accompanied by less surgical pain and easier respiratory movement. MS patients required significantly lower doses of narcotics. Better pain control was reflected in the ICU and hospital stay duration, and the MS group had a significantly shorter ICU stay (p = 0.01). The duration of ICU and hospital stay varied widely in the published series [13–16], which could be attributed to the difference in ICU protocols in different centers. In our study, the same ICU protocol was used for both groups.

MS group had significantly lower drainage that may be explained by the smaller incision and less tissue dissection with smaller surface area amenable for bleeding. A meta-analysis published in 2017 confirmed less blood loss in the limited sternotomy approach in comparison to the full sternotomy approach [15]. Although the postoperative blood loss was significantly lower in the MS approach, we did not find a significant difference in postoperative tamponade or re-exploration for bleeding and the number of the perioperatively transfused PRBCs between both groups.

Pain score or the total analgesics dose within a fixed number of days were used as indicators of the degree of the postoperative pain. We used the total cumulative amount of narcotics (fentanyl and piritramide) and other analgesics used postoperatively until the end of the 4th postoperative day to indicate the pain severity. We did not observe a significant difference in the total dose of paracetamol, or tramadol, used until the end of the 4th postoperative day between both groups (p = 0.75 and 0.73, respectively). However, the total dose of narcotics used was significantly diminished in the MS group (p < 0.001).

Heart block with the need for permanent pacemaker insertion is a complication that may follow aortic valve replacement. Its incidence after AVR in the literature is ranging from 3 to 6.5% [17]. In our study, MS was not significantly associated with new-onset complete heart

Table 5 The treatment effect of the surgical access calculated using propensity score matching

Absolute effect of ministernotomy	Coef. (95% conf. interval)	P value
Cardiopulmonary bypass time	21.69(12.56–30.83)	< 0.001
Ischemic time	13.08(5.64–20.52)	0.001
Ventilation time (log transformation)	− 0.33(− 0.66 to − 0.008)	0.045
ICU stay "inverse transformation"	0.01 (0.002–0.016)	0.01
Hospital stay "inverse transformation"	0.008 (− 0.005–0.02)	0.22
Postoperative drainage "log transformation"	− 0.53 (− 0.85 to − 0.21)	0.001
Heart block	0.08 (− 0.03 to − 0.2)	0.16
Dipidolor dose (log transformation)	− 0.59 (− 0.88 to − 0.297)	< 0.001

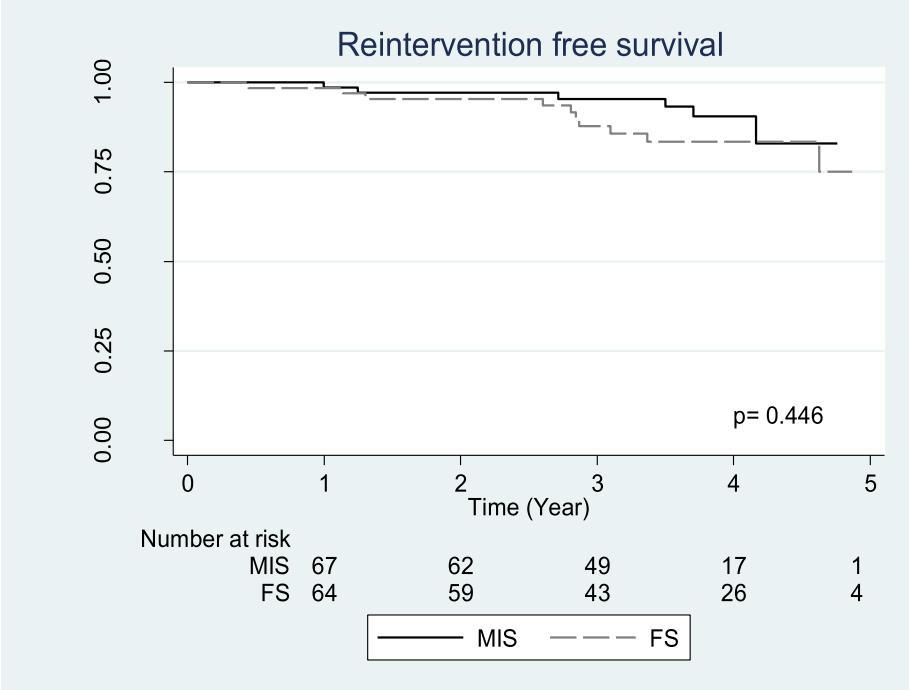

Fig. 1 Reintervention-free survival in FS and MS groups. FS, full sternotomy; MS, ministernotomy

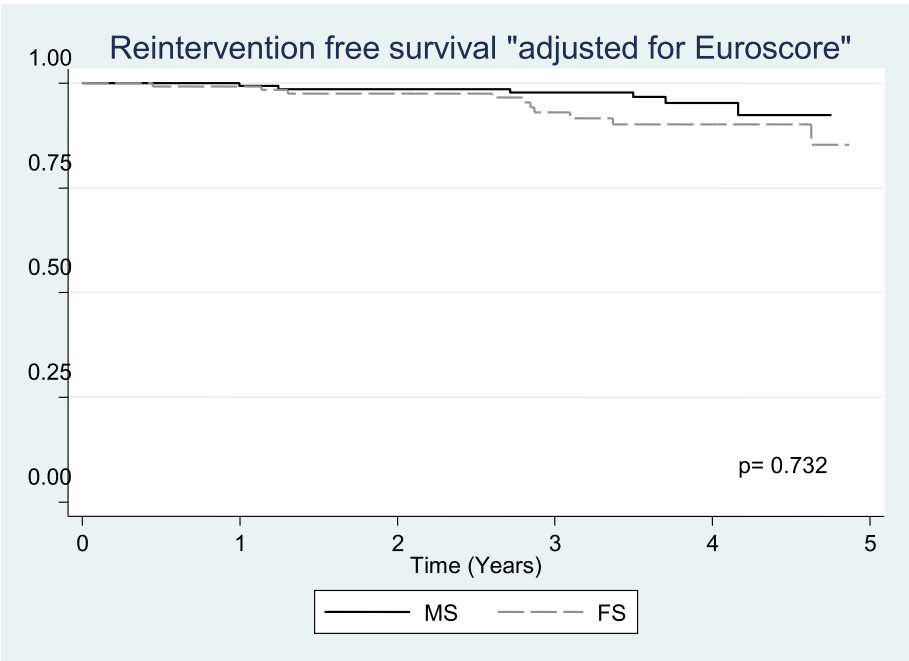

Fig. 2 Reintervention-free survival adjusted for EuroSCORE. FS, full sternotomy; MS, ministernotomy

block after AVR (8.3% vs. 3.1% in the FS group, p = 0.16). Preoperatively, two patients (2.8%) in the MS group had preoperative right bundle branch block, one patient (1.4%) had preoperative first-degree heart block, and one patient (1.4%) had left bundle branch block; however, no patients in the FS group had preoperative conduction defects. However, no significant difference in postoperative AF was noticed.

Seven patients in the MS group (9.7%) were converted to full sternotomy. This conversion rate from MS to FS was relatively high compared to that published by other researchers, ranging from 0 to 4% [11, 14, 18, 19]. Chest CT scan was not routinely performed for all patients who were candidates for minimally invasive approaches, which may explain the higher rate of conversion in such patients as most of the conversion was due to anatomical causes, and patients with high BMI were not excluded from the study.

There was no difference in stroke, renal failure, or operative mortality between groups. During the follow up no difference was found between groups in reintervention freedom survival before and after adjusting for the preoperative EuroSCORE, which is similar to other reports [14, 20–22]. These results indicate that MS could be a safe approach for AVR and with good short- and long-term outcomes. However, the conversion rate is a potential complication of the MS approach affecting perioperative morbidity. Proper preoperative planning is essential to avoid this complication. A careful analysis of chest X-ray or even routine CT scan is recommended for patients assigned to the MS approach.

Study limitations and strength

The study's main limitation is the retrospective non-randomized design, in which selection bias may play a role. To overcome this drawback, we created a strict cohort study group. We used propensity score analysis and intention to treat analysis to simulate clinical trials and balance the groups as good as possible. Nevertheless, unmeasured variables could have affected the outcomes. Another limitation is the absence of pain score; however, the dose of analgesics is considered an objective proxy for pain. In this study, patients converted to FS were included in the MS group as it is a complication of MS, which was not considered for many of the published series.

Conclusion

The ministernotomy approach could be a feasible, applicable, and reproducible option for primary isolated AVR. Beyond the cosmetic aspect, the MS approach could have better outcomes compared to FS. Intraoperative conversion is a complication of MS, and preoperative CT chest scanning is recommended to avoid unexpected intraoperative conversion to FS. MS might be as effective as FS as regard to the long-term outcomes.

Abbreviations

ACC: American College of Cardiology; AF: Atrial fibrillation; AHA: American Heart Association; AR: Aortic regurge; AS : Aortic stenosis; AV: Aortic valve; AVR: Aortic valve replacement; Bl.: Blood; BMI: Body mass index; CABG: Coronary artery bypass grafting; CAVR: Conventional aortic valve replacement; CC: Cross clamp; CHB: Complete heart block; Coef.: Coefficiency; COPD: Chronic obstructive pulmonary disease; CPB: Cardiopulmonary bypass; CT: Computed tomography; CXR: Chest X-ray; Dis.: Disease; DM: Diabetes mellitus; EF: Ejection fraction; EOA: Effective orifice area; EuroSCORE: European System for Cardiac Operative Risk Evaluation; F: Female; FFP: Fresh frozen plasma; FS: Full sternotomy; Hb: Hemoglobin; HS: Hospital stay; HTN: Hypertension; IABP: Intraaortic balloon pump; ICU: Intensive care unit; ICUS: Intensive care unit stay; IVC: Inferior vena cava; LBBB: Left bundle branch block; LV: Left ventricle; M: Male; MG: Mean gradient; MI: Myocardial infarction; MIAVR: Minimally invasive aortic valve replacement; MICS: Minimally invasive cardiac surgery; MS: Ministernotomy; MV: Mechanical ventilation; N.: Number; PA: Pulmonary artery; PG.: Peak gradient; PPM: Permanent pace maker; RBBB: Right bundle branch block; PRBCs: Packed red blood cells; PRS: Prospective randomized study; PSM: Propensity score matched; Pt.: Patient; Pts.: Patients; RA: Right atrium; RAT: Right anterior thoracotomy; RCTs: Randomized controlled trials; RF: Renal failure; RNS: Retrospective non-randomized study; Std. Err.: Standard error; SD: Standard deviation; STS: Society of Thoracic Surgeons; SVC: Superior vena cava; TAVI: Transcatheter aortic valve implantation; TEE: Trans-esophageal echocardiography; TTE: Trans-thoracic echocardiography; vs: Versus

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Authors' contributions

MT: Data collection and interpretation of statistical analysis, drafting the manuscript, and writing and approval of the final version of the manuscript. AA: Statistical analysis and its interpretation, drafting the manuscript, and writing and approval of the final version of the manuscript. HF: Study design, revision of the draft of the manuscript and approval of the final version of the manuscript. AT: Study design, revision of the draft of the manuscript, and approval of the final version of the manuscript. EW: Study design, supervision of the study, revision of the draft of the manuscript, and approval of the final version of the manuscript. PH: Study design, supervision of the study, revision of the draft of the manuscript, and writing and approval of the final version of the manuscript.

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Availability of data and materials

Upon reasonable requests.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of Leuven University, Belgium. The study is retrospective, and consent to participate was waived by the IRB. The committee's reference number is not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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