Featured Article

Minimally invasive aortic valve replacement: 12-year single center experience

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Background: This study reports the single center experience on minimally invasive aortic valve replacement (MIAVR), performed through a right anterior minithoracotomy or ministernotomy (MS).

Methods: Eight hundred and fifty-three patients, who underwent MIAVR from 2002 to 2014, were retrospectively analyzed. Survival was evaluated using the Kaplan-Meier method. The Cox multivariable proportional hazards regression model was developed to identify independent predictors of follow-up mortality.

Results: Median age was 73.8, and 405 (47.5%) of patients were female. The overall 30-day mortality was 1.9%. Four hundred and forty-three (51.9%) and 368 (43.1%) patients received biological and sutureless prostheses, respectively. Median cardiopulmonary bypass time and aortic cross-clamping time were 108 and 75 minutes, respectively. Nineteen (2.2%) cases required conversion to full median sternotomy. Thirty-seven (4.3%) patients required re-exploration for bleeding. Perioperative stroke occurred in 15 (1.8%) patients, while transient ischemic attack occurred postoperative in 11 (1.3%). New onset atrial fibrillation was reported for 243 (28.5%) patients. After a median follow-up of 29.1 months (2,676.0 patient-years), survival rates at 1 and 5 years were 96%±1% and 80%±3%, respectively. Cox multivariable analysis showed that advanced age, history of cardiac arrhythmia, preoperative chronic renal failure, MS approach, prolonged mechanical ventilation and hospital stay as well as wound revision were associated with higher mortality.

Conclusions: MIAVR via both approaches is safe and feasible with excellent outcomes, and is associated with low conversion rate and low perioperative morbidity. Long term survival is at least comparable to that reported for conventional sternotomy AVR.

Keywords: Aortic valve replacement (AVR); minimally invasive heart surgery; heart valve prosthesis; outcomes

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Introduction

Aortic valve disease is a prevalent disorder that affects approximately 2% of the adult general population (1). Aortic stenosis is one of the most frequently acquired diseases of the cardiac valves, and most commonly affects the elderly (2). Surgical aortic valve replacement (AVR) via complete median sternotomy is a safe and time-tested technique associated with excellent short- and long-term outcome. It remains the gold standard treatment for symptomatic aortic valve disease and improves the life quality and life expectancy in the operated patients. To reduce surgical trauma, over the last two decades, different minimally-invasive approaches for AVR have been developed and are increasingly being utilized (3,4).

Several minimally invasive approaches (including the right parasternal approach, upper and lower ministernotomy (MS), V-shaped, Z-shaped, inverse-T, J-, reverse-C and

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reverse-L partial MS, transverse sternotomy and right minithoracotomy,) have been developed for AVR since 1993 (5-8) and have been associated with better outcomes and lower perioperative morbidity compared to full sternotomy (9-16). Minimally invasive approaches enable equally successful valve procedures, while reducing bleeding, pain, infection, and length of stay, as well as improving cosmesis, recovery, and patient satisfaction. Furthermore, economic (17) and survival (18) benefits have been reported for the minimally invasive against conventional sternotomy AVR. Subsequently, minimally invasive surgery for aortic valve disease has become a standard approach in several centers all over the world because of its proven advantages. Partial sternotomy seems to be the most widely adopted option for minimally invasive AVR (6,10,19-24). Although most surgeons that perform less invasive aortic valve surgery prefer a "J-shaped" partial upper sternotomy with entry into the third or the fourth right intercostal space (ICS) (25,26), the right anterior minithoracotomy (RAMT) has the potential to be associated with improved outcomes (7,12,14,16,27,28). The excellent results of minimally invasive valve surgery have been proposed as the reference standard to which emerging technologies should be compared (4,23,24,29-31).

This study reports the single centers experience on minimally invasive aortic valve replacement (MIAVR) through a RAMT or MS approach and describes the surgical technique, complication rates, and patient outcomes.

Methods

Study population and design

This was a retrospective, observational, cohort study of prospectively collected data from 853 consecutive patients (448 males, median age 73.8 years) with aortic valve disease who underwent minimally invasive AVR from September 2002 to May 2014. Patients who underwent aortic valve repair, aortic root replacement, ascending aorta replacement, valve-preserving aortic root replacement, or transcatheter aortic valve implantation were excluded. All patients were seen 2 to 3 months postoperatively and thereafter, were contacted for follow-up data. Follow-up information was obtained by telephone calls, e-mail, surface mail, or interview.

Interventions

Computed tomography (CT) was used for surgical planning in 98% of patients. A 64-slice chest CT scan (Toshiba Aquilion ONE; Toshiba Medical System, Tokyo, Japan) without contrast enhancement was obtained to evaluate the anatomic relationship between the ICSs, sternum, ascending aorta, and aortic valve. Two CT-criteria of fundamental importance have been elaborated to choose between RAMT and MS: (I) completely retrosternal (*Figure 1A*) or relatively right lateral (*Figure 1B*) position of the ascending aorta, at the level of the pulmonary artery bifurcation; (II) a deeper chest (distance between the ascending aorta and the sternum 10 cm or more) (*Figure 1C,D*). The retrosternal position of the ascending aorta and the deep thorax were considered unfavourable anatomic conditions for the RAMT approach.

Upper MS through the 2nd (V-shaped), 3rd (J or inverted T) or 4th (J type) ICS was performed in the MS group, and the RAMT was done through the 2nd or the 3rd ICS, without rib resection. In the majority of patients, central aortic cannulation and standard (direct) clamping were achieved through the main surgical site, and venous cannulation was performed percutaneously through the groin. Standard implantation techniques for both sutured and sutureless prostheses were implemented. Intraoperative transoesophageal echocardiography was used routinely for the assessment of cardiac function, proper positioning of the percutaneous venous cannula, early surgical results and adequacy of air-removal. At the end of surgery, patients were transferred to the intensive care unit (ICU) and managed according to the unit protocol.

Data collection

The clinical audit committee of the G. Pasquinucci Heart Hospital institutional board approved the study to meet ethical and legal requirements, and written informed consent was waived. The completed data collection forms were entered in local databases and included several sections completed by the anaesthesiologists, cardiac surgeons, ICU personnel, and perfusionists involved in the care of the patients.

Statistical analysis

Patients' demographic and operative data are expressed as mean ± standard deviation, medians (interquartile range, IQR, 25th-75th percentiles) or as prevalence percentages, as appropriate. Survival was evaluated using the Kaplan-Meier method. The Cox multivariable proportional hazards regression model, based on 89 pre- and postoperative variables, was developed to identify independent predictors

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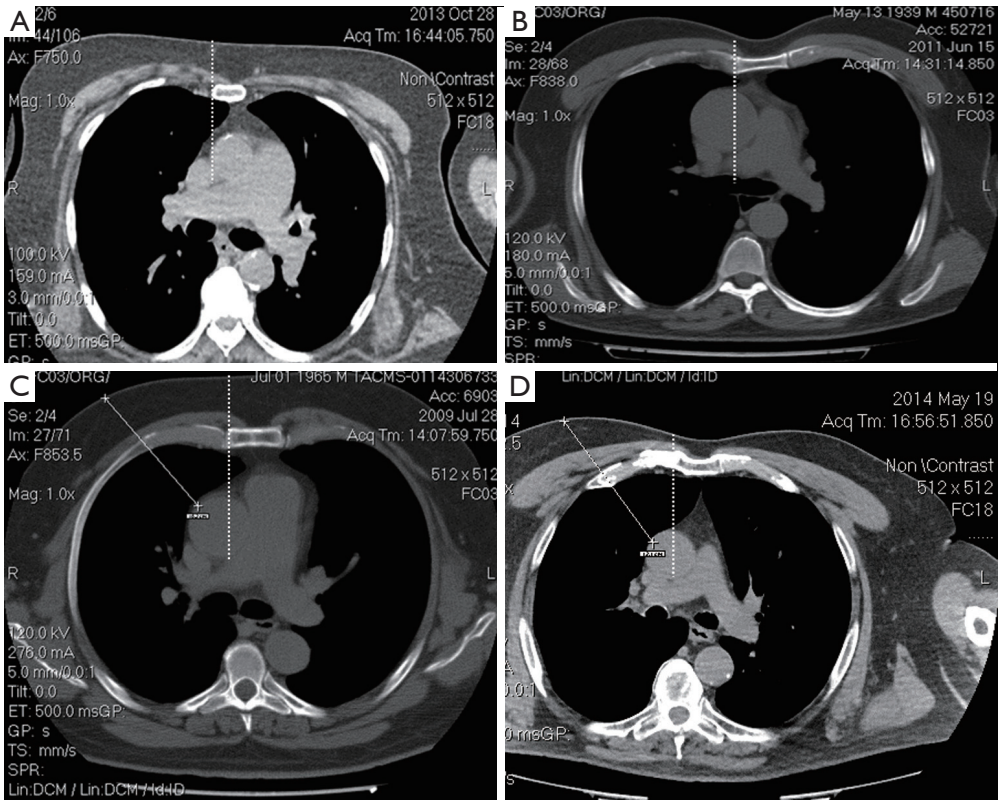

Figure 1 Chest computed tomography scan as a tool for minimally invasive approach choice. White vertical dotted line is a virtual reference, corresponding to the right margin of the sternal bone, and determines the position of the ascending aorta in relation to the sternum. (A) Retrosternal position of the ascending aorta (not favorable for RAMT); (B) quite dextrapositioned ascending aorta (favorable for RAMT); (C) an example of a deep thorax (the distance to ascending aorta from anterior chest measures 10.2 cm); (D) another example of a deep thorax (the distance to ascending aorta from anterior chest measures 12.1 cm).

of follow-up mortality in the studied population and to assess the weight of surgical approach in the late survival rate. Hazard ratios (HRs) with 95% CIs were calculated for each of the significant risk factors.

All reported probability values are two-tailed, and probability values of less than 0.05 were considered statistically significant. All statistical analysis was performed with SPSS software, version 19.0 (SPSS Inc, Chicago, IL, USA).

Results

Demographic and baseline data

Patients' preoperative variables, demographics, risk factors, and comorbidities are summarized in *Table 1*. The study cohort included 592 (309 males; median age 73.8) procedures performed through RAMT and 261 (139 males; median age 73.7) through MS. The median follow-up period was 29.1 months (interquartile range, 16.8-55.0 months; cumulated follow-up 2,676.0 patient-years), and the follow-up data were 98.2% complete. Redo surgery was performed in 12 (1.4%) patients.

Intraoperative data

The distribution of the received prosthesis type, operative times and other intraoperative data are shown in *Table 2*. A total of 443 (51.9%) and 368 (43.1%) patients received biological and sutureless prostheses, respectively. Median size of implanted prostheses was 23 (interquartile range, 23-25) mm. Median cardiopulmonary bypass (CPB) time and aortic cross-clamping time were 108 and 75 min, respectively. In 50 (8.4%) patients in the RAMT group, *vs.* 3 (1.1%) patients in the MS group, femoral arterial cannulation was used to establish CPB (P<0.0001).

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Table 1 Baseline preoperative data

Variable	Overall cohort (n=853)
Age, years	73.8 [66.1-79.1]
Female gender	405 (47.5%)
Height, cm	166 [160-173]
Weight, kg	74 [65-83]
Body mass index, kg/sq m	26.3 [23.9-29.2]
Obesity	207 (24.3%)
Arterial hypertension	591 (69.3%)
Hypercholesterolemia	483 (56.6%)
Diabetes mellitus type II	179 (21.0%)
Smoke history	271 (31.8%)
Family history of CAD	265 (31.1%)
Extracardiac arterial vascular disease	134 (15.7%)
Cerebral arterial vascular disease	39 (4.6%)
Previous TIA	5 (0.6%)
Previous stroke	17 (2.0%)
Previous cardiac arrhythmia	125 (14.7%)
Preoperative atrial fibrillation	53 (6.2%)
Pacemaker dependent	14 (1.6%)
Chronic renal failure	33 (3.9%)
Dialysis	9 (1.1%)
Infective endocarditis	8 (0.9%)
Chronic obstructive pulmonary disease	124 (14.5%)
With severe obstruction	54 (6.3%)
Chronic bronchodilators use	49 (5.7%)
Previous interventional cardiologic procedure	68 (8.0%)
Redo surgery	12 (1.4%)
Previous CABG	3 (0.4%)
Previous valvular surgery	7 (0.8%)
Other cardiac surgery	4 (0.5%)
Previous myocardial infarction	29 (3.4%)
Angina pectoris	105 (12.3%)
Active neoplastic pathology	14 (1.6%)
Preoperative critical status[a]	7 (0.8%)
Liver cirrhosis	5 (0.6%)
Congestive heart failure	100 (11.7%)
NYHA classification	2 [2-3]
	2.25±0.67
Functional class ≥3 by NYHA	270 (31.7%)
Aortic transvalvular gradient, mm Hg	80 [63-95]
	80.8±25.6
Left ventricular ejection fraction, %	60 [55-60]
Left ventricular ejection fraction 0.5 and less	95 (11.1%)
Left ventricular ejection fraction 0.3 and less	16 (1.9%)
Aortic valve pathology	
Stenosis	655 (76.8%)
Mixed lesion	76 (8.9%)
Regurgitation	122 (14.3%)
Severe pulmonary hypertension	31 (3.6%)
Urgency or emergency	121 (14.2%)
EuroSCORE version I	6.0 [5.0-8.0]
Logistic EuroSCORE version I	5.58 [3.3-9.5]

[a], at least one of the following: intubated and ventilated, counterpulsated, resuscitated, or oligoanuric patient. CABG, coronary artery bypass grafting; CAD, coronary artery disease; EuroSCORE, European System for Cardiac Operative Risk Evaluation; NYHA, New York Heart Association; TIA, transient ischemic attack.

Associated procedures [mainly mitral valve surgery and atrial fibrillation (AF) ablation] (P=0.001) and sutureless or fast deployment prostheses (P<0.001) were more frequent in the RAMT. Six (2.3%) conversions to median sternotomy were necessary in the MS group *vs.* thirteen (2.2%) (P=0.93) in the RAMT group (*Table 2*).

Perioperative outcomes

The main clinical outcomes of the two cohorts are presented in *Table 3*. Overall 30-day mortality was 1.9% (nine patients in the RAMT and seven patients in the MS group, P=0.28). Median ICU stay was one day, median mechanical ventilation time was 6 h, and median hospital stay was six days. Thirty-seven (4.3%) patients required re-exploration for bleeding. No blood products were used in 671 (78.7%) patients. Perioperative stroke was reported in 15 (1.8%) patients, while transient ischemic attack occurred postoperatively in 11 (1.3%) patients. In 243 (28.5%) patients, new onset AF was reported.

Survival outcomes

During the median follow-up period of 29.1 months

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Table 2 Intraoperative data

Variable	Overall cohort (n=853)
Associated procedures	59 (6.9%)
Mitral valve procedure	33 (3.9%)
Repair	21/33 (63.6%)
Replacement	12/33 (36.4%)
Tricuspid valve procedure	6 (0.70%)
AF ablation	15 (1.8%)
Other cardiac procedure (septal myectomy by Morrow, left atrial appendage closure, VSD repair, aortic annulus reconstruction)	13 (1.5%)
Other non-cardiac procedure (quadrantectomy, iliac vein repair)	7 (0.82%)
Implanted prosthesis size, mm [median (25th-75th percentile)]	23 [23-25]
19 mm	15 (1.8%)
21 mm	144 (16.9%)
22 mm	2 (0.2%)
23 mm	285 (33.4%)
25 mm	328 (38.5%)
27 mm	73 (8.6%)
29 mm	6 (0.7%)
Aortic valve prosthesis implanted	
Sorin Perceval sutureless prosthesis	322 (37.7%)
Carpentier-Edwards Perimount pericardial bioprosthesis	362 (42.4%)
Medtronic Mosaic porcine bioprosthesis	27 (3.2%)
Carbomedics mechanical prosthesis	31 (3.6%)
St Jude mechanical prosthesis	8 (0.9%)
Sorin Bicarbon Slimline mechanical prosthesis	2 (0.2%)
Edwards Intuity aortic valve system	38 (4.5%)
ATS 3F Enable sutureless bioprosthesis	23 (2.7%)
Sorin SOLO stentless prosthesis	36 (4.2%)
Others	4 (0.5%)
Type of aortic valve prosthesis implanted	
Stented or stentless biological prosthesis	443 (51.9%)
Mechanical prosthesis	42 (4.9%)
Sutureless or fast deployment prosthesis	368 (43.1%)
Cardiopulmonary bypass time, min	108 [87-137]
Aortic cross-clamping time, min	75 [57-97]
Cardiopulmonary bypass time over 100 min	498 (59.5%)
Cardiopulmonary bypass time over 90 min	594 (71.0%)
Aortic cross-clamping time over 60 min	577 (68.9%)
Aortic cross-clamping time over 70 min	466 (55.7%)
Conversion to full median sternotomy	19 (2.2%)

AF, atrial fibrillation; AVR, aortic valve replacement; VSD, ventricular septal defect.

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Table 3 Overall patient outcomes

Variable	Overall cohort (n=853)
30-day mortality	16 (1.9%)
ICU length of stay, days	1 [1-1]
Prolonged ICU stay (3 days or more)	89 (10.4%)
Assisted ventilation time, h	6 [5-9]
Need for ventilation support <12 h	709 (83.2%)
Prolonged ventilation support (>24 h)	37 (4.3%)
Hospital length of stay, days	6 [6-8]
Discharge by 6th postoperative day	450 (52.8%)
Discharge after 9th postoperative day	157 (18.4%)
Prolonged length of stay (>12 days)	67 (7.9%)
Reopening for bleeding or cardiac tamponade	37 (4.3%)
Blood products transfusion*	182 (21.3%)
Blood transfusion pack per patient, unit*	0 [0-0]
Perioperative acute myocardial infarction	12 (1.4%)
Infective complications	29 (3.4%)
Sepsis	2 (0.2%)
Wound dehiscence or infection	7 (0.82%)
Stroke	15 (1.8%)
Transient ischemic attack	11 (1.3%)
Pulmonary complications/respiratory dysfunction	89 (10.4%)
Pneumonia	11 (1.3%)
Pleural effusion requiring puncture	32 (3.8%)
Perioperative acute kidney injury	40 (4.7%)
New onset CVVH/hemofiltration support	5 (0.6%)
Complete AV block requiring PM implant	23 (2.7%)
New onset atrial fibrillation or flutter	243 (28.5%)
Gastrointestinal complications	11 (1.3%)
Composite event score**	0 [0-0]
0	715 (83.8%)
1	91 (10.7%)
2	31 (3.6%)
3	10 (1.2%)
4	5 (0.6%)
5	1 (0.1%)

*, during the surgery and ICU stay. **, composite event score included following complications: necessity for prolonged (over 24 h) mechanical ventilation support, reoperation for any cause, perioperative acute myocardial infarction, stroke, transient ischemic attack, new onset dialysis, multisystem failure, atrioventricular block with need of pacemaker implantation, cardiorespiratory arrest, need for percutaneous pericardial drainage, major arrhythmia, and death during the index hospitalization. AV, atrioventricular; CVVH, continuous veno-venous hemofiltration/hemodialysis; ICU, intensive care unit; PM, pacemaker.

(interquartile range, 16.8-55.0 months; cumulated follow-up 2,676.0 patient-years), 66 deaths were registered, with 33 occurring in the RAMT group. In the general cohort, leading causes were cardiac (32 patients, including 5 valve-related deaths), followed by pulmonary (14 patients), oncological (8 patients), neurological (6 patients), and infection-related (4 patients). Survival in the overall cohort was 96%±1% at 1 year, and 80%±3% at 5 years (*Figure 2*). Actuarial freedom from reoperation at 5 years was 97.5%±2%.

Univariate and multivariate analysis

Forty-three factors have been associated with follow-up mortality by univariate analysis (P≤0.10 criterion), and subsequently have been included in multivariable regression model. Using the Cox multivariable proportional hazards regression model, which demonstrated good overall fit (–2 Log likelihood =691.2; Chi-squared statistic =214.1; P<0.001 for overall model fit), seven factors have been independently associated with the long-term survival: advanced age, history of cardiac arrhythmia, preoperative chronic renal failure, MS approach, prolonged mechanical ventilation and hospital stay, and wound revision (*Table 4*). A Cox multivariate-adjusted survival curve is demonstrated in *Figure 3*.

Learning curve

To better assess the effect of growing experience, we compared the perfusion times in the patients operated on before or after February 2012 (median of the study time-frame). For both CPB [119 (98-147) *vs*. 98 (80-125) min, P<0.0001] and aortic cross clamping [84 (69-105) *vs*. 61 (50-85) min, P<0.0001], there was a significant time reduction in the second half of the study. This effect remained statistically significant when comparing the quartiles of patients by date of surgery (*Table 5*).

Discussion

Different minimally invasive approaches have been developed for AVR over the years, including partial upper sternotomy, right parasternal thoracotomy or transverse sternotomy, with common goals of reducing invasiveness and surgical trauma. With developments in perfusion technology that accommodate CPB through smaller incisions, and the institution of carbon dioxide insufflation and intraoperative transesophageal echocardiography,

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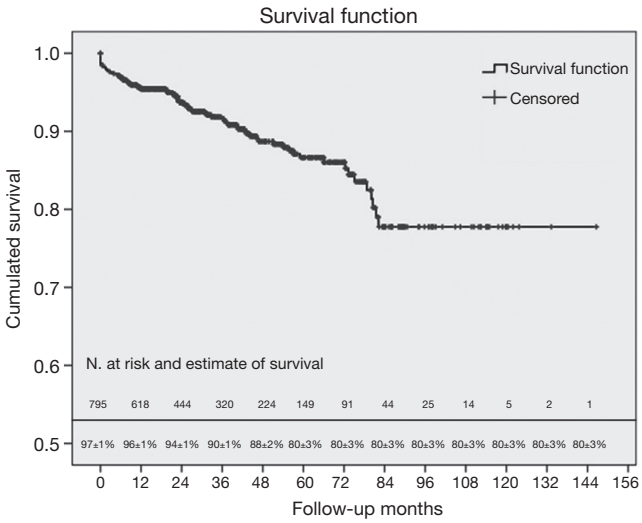

Figure 2 Survival function curve in the overall cohort.

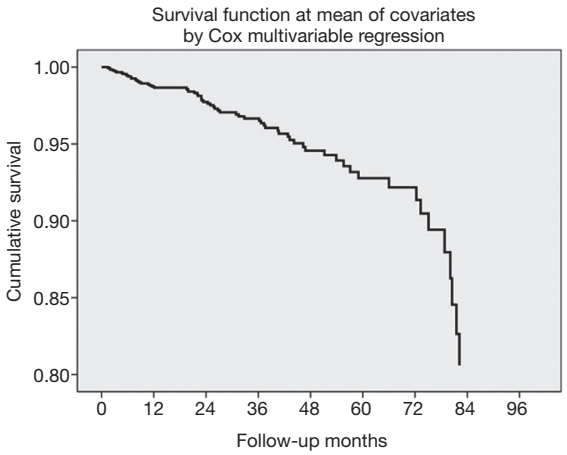

Figure 3 Survival function at mean of covariates by Cox multivariable proportional hazards regression model. Overall study population data on 853 patients.

Table 4 Long-term mortality analysis by the Cox multivariable proportional hazards regression model: independent predictors of mortality

Variable	Hazard ratio [Exp (B)]	95% confidence interval for hazard ratio		P value
		Lower	Upper	
Age quartiles	2.14	1.64	2.79	<0.0001
History of cardiac arrhythmia	3.18	1.81	5.59	0.0001
Preoperative chronic renal failure	3.80	1.84	7.83	0.0003
Surgical approach (ministernotomy)	2.47	1.48	4.14	0.0005
Mechanical ventilation duration (h)	1.013	1.004	1.021	0.0031
Hospital length of stay 7 days or more	1.78	1.04	3.06	0.0366
Wound revision	7.67	1.80	32.63	0.0058

–2 Log likelihood =691.2; Chi-squared statistic =214.1; P<0.001 for overall model fit.

Table 5 Changes in operative time for minimally invasive aortic valve surgery during the study. Data presented as n [interquartile range]

Variable	Quartiles by date of surgery				P value
	I	II	III	IV	
Cardiopulmonary bypass time, min	120 [101-151]	117 [95-144]	94 [79-126]	100 [81-125]	<0.00001
Aortic cross clamping time, min	85 [72-106]	83 [66-104]	60 [49-84]	62 [50-85]	<0.00001

minimally invasive aortic valve surgery has evolved into a routinely performed operation with excellent results (9,10,18,24).

Currently, the upper partial sternotomy with unilateral J-shaped extension to the right through the fourth ICS seems the most popular minimal access approach (10,19-26). Despite widespread adoption of limited sternotomy approaches for MIAVR and its outstanding achievements in terms of life quality and duration, several studies reported only marginal benefits (10,32) or did not find at all significant difference between mini-access and conventional AVR (19,21,33-36).

Our present study shows that both RAMT and MS are technically feasible and safe approaches, with low perioperative mortality and complications, and result in acceptable surgical results. In the majority of prior

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reports, MIAVR was associated with longer operative times compared with conventional sternotomy (10,19), but shorter duration of surgery with minimal access was also reported (20). Physically limited exposure and little space to operate are intrinsic drawbacks of minimally invasive approaches. With less room to manipulate, the use of HeartPort instruments is frequently required. However, operative duration can be reduced over time with growing experience as surgeons traverse the learning curve. This may at least in part explain the dynamics of CPB and aortic cross clamping times, which have shortened over time. Similar trends have been demonstrated in other, large centers experienced in MIAVR (9). Another important factor was the introduction of sutureless or rapid deployment prostheses in our clinical practice in 2011. Sutureless prostheses drastically reduce the implantation time, and contribute to the reduction of CPB, cross clamping, and overall operation time. As much as 43.1% of subjects enrolled in the present study received sutureless or rapid deployment prostheses.

Shorter ventilation times (16,35,37) and ICU/hospital stays (11-13,15,20,28) have been reported for MIAVR by high volume centers, but were less evident in pooled studies (10,19,24).

Numerous studies have addressed the incidence of new onset AF—the most frequent arrhythmia in cardiac surgery—after mini-access and conventional AVR. Notable controversy exists in available literature on the matter: while new onset AF reduction (12,16) has been reported in several studies, no difference between minimally invasive and full sternotomy approaches was found by other authors (10,19,20,28,33,35,38,39).

MS and RAMT approaches allow a smaller pericardial incision and exposed area, as well as anatomical and electrical integrity of the percutaneously cannulated right atrium, which reduces the inflammatory response. In addition, an intact sternum (for RAMT) would result in less postoperative pain, reducing the likelihood of AF. RAMT is known to be most often performed using peripheral CPB (40). The relatively higher rate of femoral arterial cannulation in the RAMT cohort in the current study may result from a learning curve effect (six attending surgeons have been in training since 2005); nowadays femoral perfusion is quite unusual in our practice, being reserved only for particular cases. The retrograde perfusion is not a physiological one, and may increase the incidence of perioperative cerebrovascular accident and groin vascular complications.

Although there is still a role for conventional sternotomy for AVR, minimally invasive techniques will continue to increase in popularity and may benefit the patient with shorter postoperative course, less morbidity, and decreased overall cost. Furthermore, minimally invasive approaches may be further facilitated by the development of sutureless or rapid deployment prostheses (41), which may reduce the CPB and cross-clamp durations. The results of the current study should be considered when commencing a minimally invasive AVR program by a single surgeon or entire department. New emerging technologies in the field of AVR should also be compared with the excellent results of minimally invasive approaches, before being widely adopted as a benchmark procedure.

Limitations

The present study is constrained by several limitations. It is based on a retrospective analysis of our large, institutional, observational, prospectively collected database, and thus it reflects a single center experience only and carries all the limits that a retrospective analysis design implies. Our internal institutional electronic database contains EuroSCORE I based records, instead of the newly introduced and more efficient EuroSCORE II. This study also reflects our initial experience with the two minimally invasive approaches and encompasses the 'learning curve'.

There may be biases that could confound our findings, which were not adjusted for (e.g., personal performance of each surgeon). We might have been unable to account for the influence of any residual unmeasured factors that could affect the adverse outcomes. We fully recognize that our case series is widely variegated and comprises different clinical scenarios. The extremely heterogeneous study population may account for the skewedness of continuous data and abnormal distribution of dichotomous data.

We have utilized all-cause mortality data, though reliably obtained from our database, rather than the more specific cardiac-related mortalities and we did not address the relative incidence of nonfatal cardiac-related events. At the same time however, comprehensive analysis was performed on the whole study population, without any selection. Thus, to the best of our knowledge, this study comprises the largest contemporary single center experience with right minithoracotomy and ministernotomy AVR.

Conclusions

MIAVR via both approaches is safe and feasible with

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excellent outcomes, and is associated with low conversion rates and low perioperative morbidity. Long term survival is at least comparable to that reported for conventional sternotomy AVR.

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