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Non-sutureless minimally invasive aortic valve replacement: mini-sternotomy versus mini-thoracotomy: a series of 1130 patients

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Abstract

OBJECTIVES: Aortic valve replacement through conventional sternotomy still represents the gold-standard surgical approach for aortic valve disease. However, given the increasing number of patients with comorbidities, strategies that can improve operative results are always sought. Minimally invasive aortic valve surgery, although related to a steep learning curve, might be associated with improved post-operative outcomes. The main aim of this study was to assess whether significant differences exist in terms of operative and early results between a mini-sternotomy and a right mini-thoracotomy approach for isolated aortic valve replacement without sutureless technologies.

METHODS: This is an observational retrospective multicentre study from nine Italian cardiac centres that analyses prospectively collected data of patients who underwent isolated minimally invasive aortic valve replacement between January 2010 and December 2014. Two approaches are considered (mini-sternotomy and mini-thoracotomy) and compared in terms of operative and early outcomes.

RESULTS: After interrogation of the centralized database, a total of 1130 patients were retrieved (854 mini-sternotomy and 276 mini-thoracotomy). Patients in the mini-sternotomy group had a higher risk profile. There was no difference in terms of early mortality; cardiopulmonary bypass and cross-clamp time did not differ significantly between the groups; and a significantly higher number of reoperations for bleeding was observed in the right mini-thoracotomy group.

CONCLUSIONS: Both mini-sternotomy and mini-thoracotomy could be performed safely, with low mortality and postoperative morbidity. The mini-thoracotomy approach was associated with a significantly higher rate of reoperation for bleeding. Uptake among cardiac centres was low. Sutureless technologies could potentially increase surgical volume by simplifying the mini-thoracotomy procedure.

Keywords: Aortic valve replacement • Exposure • Incision • Minimally invasive surgery • Surgery • Technique

INTRODUCTION

Aortic valve disease is a relatively common disorder in the elderly [1]. Aortic valve replacement via standard median sternotomy represents the gold-standard treatment for aortic disease and is related to excellent short- and long-term outcomes [2]. However, strategies that can improve surgical performance are always sought. Minimally invasive aortic valve replacement (MIAVR) can be performed using the following different approaches: right parasternal, upper and lower mini-sternotomy (MS), V-shaped, Z-shaped, inverse-T, J-shaped,

reverse-C and reverse-L partial MS, transverse sternotomy and right mini-thoracotomy [2]. These approaches might be associated with reduced bleeding, pain, infection, length of postoperative stay and improved patient satisfaction; also, some economic and survival benefits have been reported for MIAVR compared with aortic valve replacement via conventional sternotomy [3, 4].

The two most frequently used approaches for MIAVR are a 'J-shaped' upper mini-sternotomy with entry into the third or the fourth right intercostal space (MS) and right anterior mini-thoracotomy (RT), both of which have theoretical potential to be associated with certain improved outcomes. However, the superiority of one technique over the other has not yet been established.

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The relatively recent introduction of a sutureless/fast-release valve has been associated with improvement in certain outcomes, especially with the RT approach [5]; however, the adoption of such technologies remains limited to a few centres. The primary aims of this retrospective observational multicentre study were as follows: (i) to analyse operative and early postoperative outcomes of patients who underwent non-sutureless MIAVR in order to understand whether (ii) there are any significant differences between the MS and RT approach.

MATERIALS AND METHODS

Patients, data extraction, collection and distribution

GVM Care&Research (<http://www.gvmnet.it>) is a private group that runs, in partnership with the Italian National Health System, nine medium-volume cardiac units scattered, from North to South, in the Italian territory (Fig. 1) and performs ~10% of the Italian cardiac surgical workload. The aortic valve surgery minimally invasive programme started about 2009, with different uptake between centres (Fig. 1). Patients undergoing concomitant aortic procedures, such as aortic root replacement, ascending aorta replacement, valve-preserving aortic root replacement and aortic valve repair, were excluded. A limited number of sutureless valves were implanted; therefore, they were not considered in this study. Cardiac units are subjected to a centralized Clinical Governance Unit (CGU) that reviews on a monthly basis the data collected from

each cardiac unit and uploaded in a centralized database. The online centralized database became operative in January 2010. The demographics and characteristics of clinical patients are presented in Table 1.

Surgical techniques

All nine cardiac units adopted the surgical set-up described below.

The mini-sternotomy is performed in a J-shaped fashion, up to the third/fourth intercostal space. Both arterial and venous cannulation are carried out centrally through the main surgical site (ascending aorta and right atrium with a double-stage cannula). If difficult exposure of the right atrium is encountered, venous drainage is achieved with percutaneous venous cannulas, such as BioMedicus multistages (Medtronic, Minneapolis, Minn), Quickdraw (Edwards LifeSciences) or RAP (Sorin), advanced through the right femoral vein into the right atrium. Accurate positioning is achieved using the Seldinger technique under transoesophageal echocardiographic guidance.

The right anterior mini-thoracotomy is performed through a 5–7 cm incision usually at the level of the second intercostal space, although some surgeons prefer the third intercostal space. No rib resection is performed. The choice between ascending aorta or femoral arterial cannulation is left to the surgeon's preference. Direct aortic cannulation is normally performed using low-profile cannulas, such as the Easyflow (Sorin, Sallugia, Italy). Venous drainage is achieved in the fashion described for MS. A preoperative computed tomography (CT) scan without contrast enhancement is obtained to evaluate the

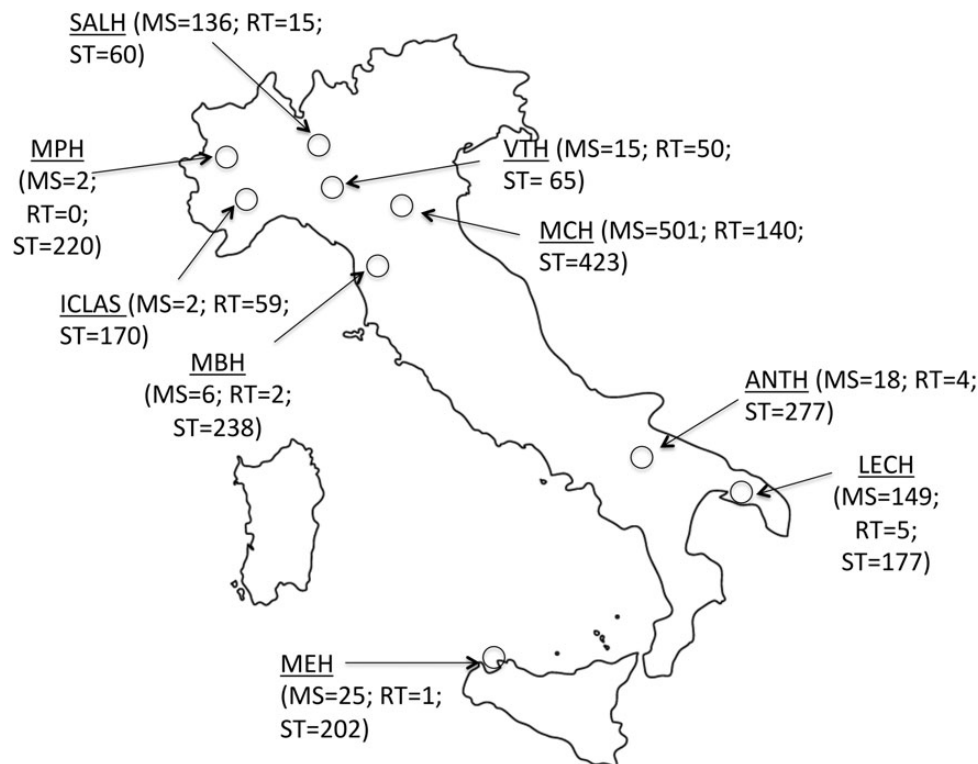


Figure 1: Geographical distribution of GVM Care and Research cardiac units. In parentheses is shown the number of non-sutureless minimally invasive aortic valve replacements performed since 2010 via mini-sternotomy (MS), right mini-thoracotomy (RT) and conventional sternotomy (ST). From North to South: SALH: Salus Hospital, Reggio Emilia, Emilia Romagna; MPH: Maria Pia Hospital, Torino, Piemonte; ICLAS: Istituto Clinico Ligure Alta Specialita', Rapallo, Liguria; VTH: Villa Torri, Bologna, Emilia Romagna; MCH: Maria Cecilia Hospital, Cotignola, Emilia Romagna; MBH: Maria Beatrice Hospital, Florence, Toscana; ANTH: Anthea Hospita, Bari, Puglia; LECH: Citta' di Lecce, Lecce, Puglia; MEH: Villa Maria Eleonora, Palermo, Sicily.

Table 1: Baseline characteristics and operative details

	Mini-sternotomy n (%) (n = 854)	Mini-thoracotomy n (%) (n = 276)	P-value
Age (years)	72.2 ± 11.4	72.2 ± 11.2	0.89
Sex (female)	396 (46.4)	115 (41.7)	0.17
BMI (kg/m ²)	27.6 ± 4.5	27.0 ± 4.2	0.03
Hypertension	622 (72.9)	195 (70.6)	0.48
Diabetes			0.94
Diet	20 (2.3)	6 (2.1)	
NIDDM	109 (12.8)	32 (11.6)	
IDDM	27 (3.2)	10 (3.6)	
NYHA III-IV	449 (52.6)	93 (33.7)	0.001
CCS 4	2 (0.2)	0	0.93
Recent MI	2 (0.2)	0	0.66
COPD	88 (10.3)	27 (9.8)	0.80
Preoperative AF	70 (0.9)	20 (7.2)	0.61
EuroSCORE (mean ± SD)	6.4 ± 2.5	6.1 ± 2.3	0.03
Prevalent aetiology ^a			
AS	601 (70.4)	200 (72.5)	0.99
AR	103 (11.7)	27 (9.8)	0.30
Mixed disease	147 (17.2)	49 (17.8)	0.99
XCT (min; mean ± SD)	62.4 ± 23.7	62.6 ± 24.8	0.11
CPB time (min; mean ± SD)	76.8 ± 31.7	78.7 ± 31.7	0.64
Valve type			
Mechanical	109 (12.8)	21 (7.6)	
Tissue	745 (87.2)	255 (92.4)	
Valve size ^b			
19	29 (3.4)	1	0.001
21	204 (23.9)	55 (19.9)	0.45
23	398 (46.6)	93 (33.7)	0.001
25	171 (20)	89 (32.2)	0.94
27	20 (2.3)	27 (9.8)	0.001
29	13 (1.5)	0	0.001

AF: atrial fibrillation; AR: aortic regurgitation; AS: aortic stenosis. BMI: body mass index; CCS: Canadian Class Score; COPD: chronic obstructive pulmonary disease; CPB: cardiopulmonary bypass; MI: myocardial infarction; (N)IDDM: (non)-insulin-dependent diabetes mellitus; NYHA: New York Heart Association; XCT: cross-clamping time.

^aThree missing data.

^b19 and 11 missing values (mini-sternotomy and right mini-thoracotomy, respectively).

anatomical relationship between the intercostal spaces, sternum, ascending aorta and aortic valve. Exclusion criteria for RT are considered for the following: completely retrosternal or relatively right lateral position of the ascending aorta or a deep chest (distance between the ascending aorta and the sternum 10 cm or more); however, the choice of approach depends on the surgeon's and team's experience.

In both approaches, after vacuum-assisted cardiopulmonary bypass (CPB; -40 to -60 mmHg) is established, a left ventricular vent is placed through the right superior pulmonary vein, and the patient is cooled to 34°C. The ascending aorta is clamped with the Cygnet cross-clamp (Novare Surgical Systems, Cupertino, CA, USA), and antegrade cardioplegic solution is given into the aortic root or selectively into the coronary ostia using warm blood cardioplegia or cold crystalloid solution (Custodiol Koehler Chemie, Alsbach-Haenlein, Germany). In all cases, the surgical field is flooded with carbon dioxide at a flow of 0.5 l/min.

Study design, ethics and end points

The study included patients from January 2010, and the search was concluded in December 2014. The study was approved by

our independent ethics committee, and patient informed consent was waived.

The main end point of the study was early mortality. Secondary end points were operative and relevant postoperative outcomes that are recorded in our database, such as aortic cross-clamp (XCT) and CPB time, incidence of postoperative atrial fibrillation (AF), transfusion of packed red blood cells (yes or no), reoperation for bleeding, stroke, wound infection, *de novo* dialysis, permanent pacemaker implantation and intensive care unit and postoperative length of stay. Data are presented in Tables 1 and 2.

Definitions

In-hospital mortality included all deaths within 30 days of operation irrespective of where the death occurred and all deaths in hospital after 30 days among patients who had not been discharged after the index operation. Postoperative stroke was defined as any new permanent major (type I) neurological deficit that occurred at any time during the postoperative hospitalization and/or new findings on CT or magnetic resonance imaging, persisting for more than 72 h. Diagnosis of stroke was also confirmed and documented by a consultant neurologist. New-onset AF was defined by the

Table 2: Hospital outcomes

	Mini-sternotomy <i>n</i> (%) (<i>n</i> = 854)	Mini-thoracotomy <i>n</i> (%) (<i>n</i> = 276)	<i>P</i> -value
Blood transfusion	324 (41.2)	106 (40.6)	0.87
Reoperation for bleeding	30 (3.8)	21 (8.0)	0.006
Postoperative AF	223 (32.8)	85 (32.2)	0.29
Stroke	3 (0.4)	0	0.32
Wound dehiscence	18 (3.1)	9 (3.3)	0.29
Permanent pacemaker	10 (1.3)	7 (2.7)	0.12
<i>De novo</i> dialysis	4 (0.5)	2 (0.8)	0.63
Re-intubation	16 (2.0)	11 (4.2)	0.05
ICU length of stay	2.5 ± 4.0	2.4 ± 4.1	0.07
In-hospital length of stay	11.4 ± 9.4	11.5 ± 11.5	0.91
Early mortality	18 (3.3)	3 (1.1)	0.28

AF: atrial fibrillation; ICU: intensive care unit.

Early mortality was defined as in-hospital mortality and all deaths within 30 days of operation irrespective of where the death occurred.

documentation of AF of any duration at any point in the post-operative period on a rhythm strip or 12-lead ECG. Renal complications were defined as the requirement for haemodialysis. Respiratory failure was defined as the need for re-intubation. Wound dehiscence was defined as deep MS or RT wound infection necessitating surgical intervention or vacuum assisted closure therapy. Blood transfusion was indicated if patients received packed red cells.

Statistical analysis

Patients' data were summarized as the mean ± standard deviation or median and interquartile range for asymmetrically distributed continuous variables. Categorical data were expressed as percentages or prevalence, as appropriate. The Shapiro–Wilk test was used to check for the normality of data in groups before further analysis. Continuous normally or non-normally distributed variables were compared between two groups using Student's unpaired *t*-test or the Mann–Whitney *U*-test, respectively; the latter test was also used to compare ordinal variables. The frequency ratios between two groups were compared using the χ^2 test. Values of $P < 0.05$ were considered statistically significant. Statistical analysis was performed using the Statistical Package for Social Sciences software (SPSS) version 22.0 for Windows (IBM Corporation, Armonk, NY, USA).

RESULTS

Baseline characteristics

After interrogation of the database, a total of 2962 patients were retrieved, of whom 854 underwent MS and 276 RT. Figure 1 shows the total volume and distribution of approaches in each centre. The baseline characteristics, burden of disease and type of valve implanted for the two groups are listed in Table 1. Patients in the MS group had a higher body mass index ($P = 0.03$), were more symptomatic ($P = 0.001$) and had a higher operative risk profile ($P = 0.03$).

Primary end point: early mortality

Early mortality was similar in both groups (MS $n = 18$, 3.3% vs RT $n = 3$, 1.1%, $P = 0.28$; Table 2).

Secondary end point: operative outcomes

The XCT and CPB time were similar in both groups (XCT: MS = 62.4 ± 23.7 vs RT = 62.6 ± 24.8 min, $P = 0.11$; CPB time: MS = 76.8 ± 31.7 vs RT = 78.7 ± 31.7 min, $P = 0.64$; Table 1).

Secondary end point: early postoperative outcomes

Early postoperative outcomes are reported in Table 2. A higher incidence of re-exploration for bleeding was observed in the RT group ($P = 0.006$).

DISCUSSION

Surgical aortic valve replacement, a well-established and safe technique, remains the gold-standard treatment for severe symptomatic aortic valve diseases [6]. However, the population is ageing, and a consistent number of patients with severe aortic stenosis are denied the surgical procedure owing to high surgical risk for multiple comorbidities [7]; therefore, strategies that can improve results are welcome. Minimally invasive aortic valve replacement is generally performed through an MS or RT approach [2], both of which might be related to certain better postoperative outcomes than standard sternotomy [8–10]. To date, there are different reports in the literature comparing sternotomy vs MS or RT, but there is a lack of understanding of whether there are significant differences between these two approaches [11]. A recent Bayesian meta-analysis comparing the two approaches showed that RT may be associated with longer CPB and cross-clamp durations, but has similar postoperative outcomes compared with MS [11]. Miceli *et al.* [5] reported that the RT approach was significantly

associated with improved postoperative outcomes compared with the MS approach; however, sutureless technologies were used in the series. In fact, recent reports have described a positive impact of sutureless and rapid-deployment aortic valve replacement on immediate postoperative outcomes [12], especially when MIAVRs were performed [13–16]; however, robust evidence is lacking on the long-term outcomes [17].

We have already demonstrated the feasibility and safety of non-sutureless MIAVR performed through the RT approach [18].

In this study, we wanted to carry out a retrospective comparison of the early operative and postoperative results of patients who underwent non-sutureless MIAVR, both MS and RT, among the nine Italian cardiac units of the entire GVM Care and Research group in order to investigate safety in terms of mortality and morbidity and to ascertain whether differences exist between these two surgical approaches. The analysis of 1130 patients showed that only reoperation for bleeding was significantly higher in the RT group, although the highest incidence was observed during the first period of the learning curve in some cases; moreover, that was in relationship to chest wall bleeding [18]. Both of the approaches were also associated with limited postoperative complications, similar to sutureless or fast-release series reported in the literature [15–17]. However, this finding should be set in the context of the reduced RT group risk profile, whereby there was a propensity to select ‘easier’ patients for the RT approach, with lower body mass index, fewer symptoms and lower EuroSCORE.

Although MIAVR is more technically demanding, our recorded surgical times for both MS and RT were lower than those reported in the last STS database in the full sternotomy stented group (mean XCT 78 min, mean CPB time 106 min) [19]. In our series, there were no differences in terms of CPB time and XCT between the MS and RT group; this was attributable to the running sutures surgical implantation technique used in the two centres accounting for the largest number of RT approaches (Fig. 1). In the RT series, however, a lower incidence of small annulus was found (Table 1).

An important finding is that the general uptake of MIAVR in centres was low, with only one cardiac unit accounting for a medium volume of both approaches, but with a preference for the MS approach (Fig. 1). This might well be related to the greater technical complexity of the RT approach as a result of its less conventional access. Another finding is that the incidence of wound infection was relatively high (>3% in both groups), which may be seen in relationship to the learning curve and/or to groin dehiscence.

Notably, the median length of stay was 11 days, but after minimally invasive surgery the patients were usually discharged home rather than being referred to rehabilitation centres.

A strength of this study is that it reports real-world data from a real-world population and merges a relatively large number of patients. Results from different centres and different surgeons in diverse phases of the training for minimally invasive surgery are reported in a single scenario.

This study has several limitations. Firstly, this is a retrospectively observational study, with all the limitations that may entail; however, data were collected prospectively. Secondly, surgeon-related skills and preferences might have affected the results; some surgeons preferred RT and others MS. Although MS could theoretically have been performed in all cases, the RT approach was dependent upon the anatomical position of the ascending aorta and, ultimately, upon surgeon preferences. That resulted in a bias of selection; in fact, the RT group accounted for a lower risk

profile. Moreover, there were different set-ups, specifically with regard to RT in terms of the cannulation site. However, the incidence of stroke was low in both groups, indicating that antero-grade or retrograde perfusion had no impact on neurological events. Preoperative left ventricular function and pulmonary hypertension were not retrieved from the aortic database because the completeness of the echocardiographic database was <80%; therefore, they could not be incorporated into the binary logistic regression model. This study remains confined to the early outcomes; no long-term events were considered in the analysis and no quality-of-life-related issues or cost-effectiveness analysis/rehabilitation resources. Also, this was not an intention-to-treat analysis, hence the number of patients converted to a full sternotomy could not be reported. A prospective analysis comparing the two approaches would be of interest, with an arm including sutureless and fast-release valves. Lastly, no comparison with conventional sternotomy was made and no propensity score analysis could be performed given the limited number of patients in the RT group.

In conclusion, in this retrospective observational multicentre study both MS and RT were safe approaches for isolated non-sutureless aortic valve replacement, with low mortality and favourable intraoperative and early postoperative outcomes, similar to certain sutureless series reported in literature [15–17]. However, the RT approach was associated with a significantly higher incidence of reoperation for bleeding. The volume of MIAVR among centres was low, with a larger number of MS approaches performed. Potentially, the use of sutureless technologies with adequate training may increase the adoption of minimally invasive approaches, but that requires further investigation.

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