Right anterior minithoracotomy for aortic valve replacement: 10-year experience of a single center

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ABSTRACT

Objective: Minimally invasive aortic valve replacement (AVR) has been associated with several better outcomes over the standard full sternotomy approach. We revised our 10-year experience with right anterior minithoracotomy (RAMT) for AVR.

Methods: Between 2004 and 2014, a total of 593 patients (310 men; median age: 73.8 years) underwent AVR via RAMT. Preoperatively, a mixed valve lesion was diagnosed in 55 (9.3%) patients; and pure aortic regurgitation in 86 (14.5%). Mean logistic EuroSCORE I (European system for cardiac operative risk evaluation) was 7.4 (median: 5.76).

Results: In 302 (50.9%) patients, a sutureless or rapidly implantable biological prosthesis was used; in 23 (3.9%), a mechanical prosthesis; and in the remainder, a conventional biological prosthesis. A total of 113 (19.1%) patients had a small aortic annulus (≤ 21 mm). Operative times averaged 80 (median: 74) minutes of crossclamping time, and 117 (107) minutes of perfusion time; these were significantly shorter with a sutureless prostheses, compared with a sutured prostheses: perfusion 99 versus 134 minutes, $P < .0005$; aortic crossclamping time: 64 versus 97 minutes, $P < .0005$. The mean (median) assisted ventilation time was 9.8 (6) hours; intensive care unit stay was 1.5 (1) days; hospital length of stay was 6.6 (6) days. Overall in-hospital mortality was 9 deaths (1.5%). At 31.5 months mean follow-up time (1531 cumulative patient-years), 94.8% survival was observed.

Conclusions: Minimally invasive AVR is a safe procedure, with low perioperative morbidity, and low rates of reoperation and death at late follow-up. Excellent outcomes can be achieved with minimally invasive AVR via right anterior minithoracotomy. Sutureless prostheses facilitate minimally invasive AVR and are associated with reduced operative times. (*J Thorac Cardiovasc Surg* 2015;150:548-56)

Overall survival curve by Kaplan-Meier test for general cohort (593 patients).

Central Message

Aortic valve replacement through right anterior minithoracotomy provides excellent outcomes. Sutureless prostheses facilitate mini aortic valve replacement.

Perspective

Many patients with aortic valve disease still undergo conventional AVR or are directed to alternative treatment with transcatheter AVR. Mini-AVR, through RAMT, provides excellent short-term outcomes, with low mortality and perioperative morbidity, and comparable long-term survival. More surgeons should enrich their armamentarium by adding RAMT AVR. Sutureless prostheses can increase adoption of RAMT AVR.

See Editorial page 450.

Supplemental material is available online.

To reduce surgical trauma, several minimally invasive approaches (eg, right parasternal approach, upper and lower ministernotomy, V-shaped, inverse-T, J- and reverse-L partial ministernotomy, transverse sternotomy, and right

minithoracotomy) have been developed for aortic valve replacement¹⁻⁴ (AVR) since 1993 and have been associated with better outcomes and lower perioperative morbidity compared with full sternotomy.⁵⁻¹³

Partial sternotomy seems to be the most widely adopted option for minimally invasive AVR,^{3,6,14-17} whereas right anterior minithoracotomy (RAMT) has the potential to offer better outcomes—namely, lower incidence of

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Abbreviations and Acronyms

AVR	= aortic valve replacement
CABG	= coronary artery bypass grafting
CI	= confidence interval
CPB	= cardiopulmonary bypass
EuroSCORE	= European system for cardiac operative risk evaluation
ICU	= intensive care unit
IQR	= interquartile range
NYHA	= New York Heart Association
OR	= odds ratio
RAMT	= right anterior minithoracotomy

postoperative atrial fibrillation, and shorter ventilation time, intensive care unit stay, and hospital stay.^{4,8,9,12,18} However, with limited space to work, operative times are generally longer with minimally invasive approaches,^{4,8,12,18,19} although reduced aortic crossclamping times and cardiopulmonary bypass (CPB) times were reported with minimally invasive AVR as well.¹⁵

To overcome the technical challenges of AVR, and to shorten implantation time, a new generation of aortic valve prostheses have been introduced in clinical practice.²⁰ Sutureless AVR features shorter operative times, and probably, better outcomes compared with conventional surgery.²¹ Few studies have evaluated RAMT for AVR and its remote outcomes.⁹⁻¹² We aimed to analyze our 10-year experience with this approach and to compare early and midterm outcomes after conventional versus sutureless AVR.

METHODS

The clinical audit committee of the G. Pasquucci Heart Hospital institutional review board approved the study as meeting ethical and legal requirements. All patients gave written informed consent.

Patient Selection and Enrollment

A retrospective, observational cohort study was conducted with prospective data collection on 3313 consecutive patients who underwent an aortic valve procedure in our institution between August 2004 and May 2014. Patients, operated on with a right minithoracotomy or a small thoracotomy, were selected, and the final study population consisted of 593 patients. Thirteen patients with conversion to full sternotomy were analyzed as intent-to-treat.

Patient Morbidity and Survival

Overall mortality was defined as death for any reason, inclusive of events occurring <30 days from the procedure. Postoperative morbidity was defined according to information in the Society of Thoracic Surgeons database. Prolonged intensive care unit (ICU) stay was defined as ≥ 3 days in the ICU, immediately after surgery and afterward. New-onset atrial fibrillation was defined by documentation of atrial fibrillation of any duration at any point in the postoperative period, on a rhythm strip or 12-lead electrocardiogram.

All patients were seen 2 to 3 months after surgery, and thereafter were contacted for follow-up data. Patient survival was determined by telephone

calls, e-mail, surface mail, or out-patient interview. The median follow-up period was 31 months (interquartile range [IQR]: 10-49 months; cumulative follow-up: 1531 patient-years); follow-up data were 98% complete.

Anesthesia, Surgical Technique, and Postoperative Management

Anesthesia and surgical techniques were standardized according to institutional protocols for all patients, and have been described elsewhere.^{22,23} The choice of a specific, minimally invasive approach for AVR in our institution depends on the suitability of the patient's anatomy for RAMT, which is our first-line approach. The exclusion criteria for RAMT were: previous right-side chest surgery; a history of right pleurisy or previous right-side pleural effusion with adhesion formation; severe chest wall deformities; severe pulmonary bullous disease; and the presence of an ascending aorta aneurysm or the technical impossibility of obtaining peripheral percutaneous venous cannulation.

Furthermore, patients were considered suitable for RAMT if the following computed tomography scan criteria were met: (1) at the level of the main pulmonary artery, the ascending aorta was rightward (more than one-half located on the right in respect to the right sternal border); and (2) the distance from the ascending aorta to the sternum did not exceed 10 cm. However, in the sutureless era (since April 2011), these computed tomography criteria had only relative importance for the choice of surgical approach, and not every patient met them who underwent surgery for AVR through RAMT after May 2011. No specific selection criteria were applied for sutureless prostheses: since they became available, every patient considered for biological prosthesis implantation via RAMT was a potential candidate for sutureless AVR; however, type 1 and 2 bicuspid aortic valves without raphe and asymmetric aortic root were considered unfavorable anatomic conditions for sutureless AVR.

Statistical Analysis

The composite event score included the following complications: need for mechanical ventilation support for >24 hours, reoperation for any cause, perioperative acute myocardial infarction, stroke, transient ischemic attack, new-onset dialysis, multisystem failure, atrioventricular block that required permanent pacemaker implantation, cardiorespiratory arrest, need for percutaneous pericardial drainage, major arrhythmia, and death during the index hospitalization. A multivariable ordinal regression model based on preoperative and intraoperative variables ([Appendix E1](#)) was used for composite event score analysis.

Overall survival was evaluated using the Kaplan-Meier method, with an actuarial survival graph.

Factors found to trend toward significance by univariate testing ($P < .10$) were entered into a multivariable analysis (a total of 110 variables evaluated; [Appendix E1](#)). Binary logistic regression analysis of predictor variables for sutureless prosthesis receipt and perioperative short-term morbidity was performed with estimated odds ratios (ORs) and 95% confidence intervals (CIs) for each of the independent variables in the model displayed.

A propensity score, indicating the predicted probability of the patient receiving a sutureless prosthesis, was calculated using a nonparsimonious multiple logistic regression analysis ([Appendix E2](#) and [Figure E1](#)) from the logistic equation for each patient. All the preoperative variables listed in [Appendix E1](#) (first 63 on the list) were included in the analysis.

A Cox multivariate proportional hazards regression model, based on 110 preoperative and postoperative variables known to affect survival after AVR, was developed to describe the adjusted mortality risk for various prosthesis groups and to identify independent predictors of follow-up mortality in the studied population. The type of prosthesis variable was entered at the second step of the hazard model, thus showing the hazard ratio (HR) variance over and above the effects of covariates, and adjusted for any baseline differences between the compared groups. HRs with 95% CIs were

FIGURE 1. Proportion of aortic valve replacement cases performed via RAMT over time, year by year (numbers above the bars indicate % of the total number of isolated aortic valve replacement operations). Sternotomy approach (green bar) includes both full and partial sternotomy. Cases involving RAMT (blue bar) indicate that since 2011, the overall number of AVR cases has increased, owing to the RAMT component. RAMT, Right anterior minithoracotomy.

calculated for each of the significant risk factors. All reported probability tests are 2-tailed. All data analysis was performed with SPSS statistical software package, version 19.0 (SPSS Inc, Chicago, Ill).

RESULTS

Within the 10-year study period (2004–2014), 593 patients underwent AVR through RAMT (Figure 1). Baseline demographic and preoperative data of the study population are presented in Table 1. The sample was heterogeneous: for example, 93 (15.7%) patients were aged ≤ 60 years, and 144 (24.3%) were aged ≥ 80 years. Compared with the sutured prostheses cohort, the sutureless one was represented by older and sicker patients, with a higher prevalence of tricuspid aortic valve and aortic stenosis, but fewer smokers (Table 1).

The multivariable logistic regression model showed that older age ($P < .0001$), a higher logistic EuroSCORE (European system for cardiac operative risk evaluation) ($P = .036$), 4th quartile of logistic EuroSCORE ($P = .002$), being shorter in height ($P < .0001$), obesity ($P < .0001$), tricuspid aortic valve ($P < .0001$), preoperative atrial fibrillation ($P < .0001$), cerebrovascular disease ($P = .02$), aortic valve stenosis ($P < .0001$), and stenosis with incompetence ($P = .004$), previous heart surgery ($P = .001$), and operative priority ($P = .001$) were independently associated with the sutureless group, whereas first ($P = .0007$) and second ($P = .03$) quartiles of age, smoking history ($P = .0004$), 3rd/4th-grade chronic obstructive pulmonary disease ($P = .02$), prior cardiac arrhythmia ($P < .0001$), and III–IV functional class by NYHA ($P < .0001$) were linked to sutured prosthesis implantation

($-2 \log\text{-likelihood} = 425.0$; $P = .874$ for lack of fit by Hosmer–Lemeshow test).

Intraoperative characteristics are listed in Table 2. In 50 (8.4%) patients, femoral arterial cannulation was used to establish CPB. Nine percent of patients underwent associated procedures, mostly on the mitral valve and for atrial fibrillation; no differences were found ($P = .19$) between the sutured and sutureless groups. One patient underwent small subaortic ventricular septal defect closure with a direct suture, through enlarged aortotomy.

One hundred thirteen (19.1%) patients had a small aortic annulus (≤ 21 mm); 89% of patients received a 21-mm, 23-mm, or 25-mm prosthesis. Surgery duration was significantly shorter with sutureless prostheses compared with sutured ones: CPB duration was 99 ± 38 (median: 90) minutes versus 134 ± 47 (median: 126) minutes, $P < .0005$; and aortic crossclamping time was 64 ± 26 (median: 57) minutes versus 97 ± 29 (median: 89) minutes, $P < .0005$ (overall comparison; Table 3).

Thirteen (2.2%) patients needed conversion to full sternotomy, owing to: bleeding (5 of 13; 38.5%); unexpected right pleural cavity adhesions (2 of 13; 15.4%); difficult weaning from CPB and “stone heart syndrome” (1 of 13; 7.7%); technical impossibility of advancing the percutaneous venous cannula (2 of 13; 15.4%); perivalvular leakage (2 of 13; 15.4%) (both cases with sutured prosthesis); and arterial hypotension with hemodynamic instability (1 of 13; 7.7%). Hemodynamic instability upon aortic crossclamp removal led to intra-aortic counterpulsation balloon placement in 3 (0.51%) patients. Patient outcomes are presented in Table 4. Surgical mortality (death before discharge) was 6 (1.0%), and 30-day in-hospital mortality was 9 (1.5%). Assisted ventilation time was 9.8 hours (mean), with a median of 6 hours; the 25th to 75th percentiles (interquartile range [IQR]) was: 5 to 9 hours. The mean ICU stay was 1.5 days, with a median of 1 day (IQR: 1–1 day). Hospital length of stay averaged 6.6 days, with a median of 6 days (IQR: 6 to 7 days).

Because of having a higher preoperative risk profile, patients in the sutureless group had longer ICU and hospital stay duration, and a higher incidence of permanent pacemaker implantation; however, the assisted mechanical ventilation time was shorter. Mortality did not differ in the 2 groups ($P = .75$). For 2 postoperative outcome variables of particular interest, a multivariable logistic regression model was developed to assess the role of the type of implanted prosthesis in the occurrence of postoperative events/complications (Table 4, P values with asterisks).

Accordingly, a multivariable logistic regression model showed that a propensity score for a sutureless prosthesis (odds ratio [OR] 9.07; 95% CI: 2.40–34.24; $P = .001$); conversion to median sternotomy (OR 9.35; 95% CI: 1.76–49.51; $P = .009$); complex surgery (OR 3.77; 95% CI:

TABLE 1. Baseline preoperative data

Variable	Overall cohort (n = 593)	Sutureless subgroup (n = 302)	Sutured subgroup (n = 291)	P value
Age (y)	73.8 (66.1-79.4)	77.7 (72.4-81.7)	68.3 (58.9-76.0)	<.0005
Gender, female	283 (47.7)	190 (62.9)	93 (32.1)	<.0005
Height (cm)	166 (160-173)	163 (158-170)	170 (164-175)	<.0005
Weight (kg)	73.5 ± 13.8	72.5 ± 14.0	74.4 ± 13.6	.093
	74 (64-81.5)	72 (63-80.3)	74 (65-82.3)	.066
Body mass index (kg/m ²)	26.4 ± 4.1	27.0 ± 4.4	25.8 ± 3.7	<.0005
	26.0 (23.8-28.7)	26.8 (24.0-29.9)	25.4 (23.7-27.8)	<.0005
Obesity	114 (19.2)	81 (26.8)	33 (11.4)	<.0005
Arterial hypertension	412 (69.5)	227 (75.2)	185 (63.8)	.004
Hypercholesterolemia	348 (58.7)	188 (62.3)	160 (55.2)	.080
Diabetes mellitus type II	124 (20.9)	78 (25.8)	46 (15.9)	.003
Smoking history	183 (30.9)	63 (20.9)	120 (41.4)	<.0005
Family history of CAD	178 (30.0)	93 (30.8)	85 (29.3)	.69
Extracardiac arterial vascular disease	93 (15.7)	57 (18.9)	36 (12.4)	.031
Cerebral arterial vascular disease	34 (5.7)	28 (9.3)	6 (2.1)	<.0005
Previous TIA	4 (0.67)	4 (1.3)	0	.12
Previous stroke	10 (1.7)	6 (2.0)	4 (1.4)	.75
Previous cardiac arrhythmia	106 (17.9)	56 (18.5)	50 (17.2)	.60
Preoperative atrial fibrillation	46 (7.8)	43 (14.2)	3 (1.0)	<.0005
Previous pacemaker implantation	12 (2.0)	10 (3.3)	2 (0.7)	.037
Chronic renal failure	30 (5.1)	16 (5.3)	14 (4.8)	.79
Dialysis	6 (1.0)	4 (1.3)	2 (0.7)	.69
Infective endocarditis	8 (1.3)	0	8 (2.8)	.003
Chronic obstructive pulmonary disease	79 (13.3)	46 (15.2)	33 (11.4)	.17
With severe obstruction	29 (4.9)	13 (4.3)	16 (5.5)	.49
Chronic bronchodilator use	26 (4.4)	21 (7.0)	5 (1.7)	.002
Previous interventional cardiologic procedure	55 (9.3)	36 (11.9)	19 (6.6)	.024
Redo surgery	9 (1.5)	7 (2.3)	2 (0.7)	.18
Previous CABG	3 (0.51)	2 (0.7)	1 (0.3)	>.99
Previous valvular surgery	5 (0.84)	5 (1.7)	0	.062
Other cardiac surgery	3 (0.51)	1 (0.3)	2 (0.7)	.62
Previous myocardial infarction	20 (3.4)	13 (4.3)	7 (2.4)	.20
Angina pectoris	76 (12.8)	45 (14.9)	31 (10.7)	.13
Tumor	11 (1.9)	7 (2.3)	4 (1.4)	.40
Preoperative critical status*	2 (0.33)	1 (0.3)	1 (0.3)	>.99
Liver cirrhosis	5 (0.84)	3 (1.0)	2 (0.7)	>.99
Congestive heart failure	68 (11.5)	40 (13.2)	28 (9.7)	.17
Functional class III or IV by NYHA	171 (28.8)	79 (26.2)	92 (31.7)	.14
Aortic transvalvular gradient (mm Hg)	80 (62-97)	78 (62-94)	81 (65-99)	.15
Left ventricular ejection fraction (%)	60 (55-60)	60 (55-60)	60 (55-60)	.82
Left ventricular ejection fraction ≤0.5	61 (10.3)	31 (10.3)	30 (10.3)	.97
Left ventricular ejection fraction ≤0.3	8 (1.3)	6 (2.0)	2 (0.7)	.29
Aortic valve pathology				<.0005
Stenosis	452 (76.2)	274 (90.7)	178 (61.2)	
Mixed lesion	55 (9.3)	22 (7.3)	33 (11.3)	
Regurgitation	86 (14.5)	6 (2.0)	80 (27.5)	
Bicuspid aortic valve	127 (21.5)	33 (10.9)	94 (32.3)†	<.0005
Severe pulmonary hypertension	28 (4.7)	28 (9.3)	0	<.0005
Urgency or emergency	86 (14.5)	59 (19.5)	27 (9.3)	<.0005
EuroSCORE version I	6.00 (5.00-8.00)	7.00 (6.00-9.00)	5.00 (3.00-7.00)	<.0005
Logistic EuroSCORE version I	5.76 (3.28-9.52)	7.9 (4.8-11.4)	4.1 (2.1-6.3)	<.0005

Data are presented as mean ± SD, median (interquartile range), or n (%), as appropriate, unless otherwise indicated. CAD, Coronary artery disease; TIA, transient ischemic attack; CABG, coronary artery bypass grafting; NYHA, New York Heart Association; EuroSCORE, European System for Cardiac Operative Risk Evaluation. *For preoperative critical status, patients had ≥1 of the following: intubation and ventilation, counterpulsation, resuscitation, or oligoanuria. †Two patients with quadricuspid aortic valve, and 2 patients with monocuspid AV, in the sutured group.

TABLE 2. Intraoperative data

Variable	Overall cohort (n = 593)	Sutureless subgroup (n = 302)	Sutured subgroup (n = 291)	P value
Associated procedures	52 (8.8)	22/302 (7.3)	30/291 (10.3)	.19
Mitral valve procedure	33/52 (63.5)	17/22 (77.3)	16/30 (53.3)	.077
Repair	21/33 (63.6)			
Replacement	12/33 (36.4)			
Tricuspid valve procedure	6/52 (11.5)	2/22 (9.1)	4/30 (13.3)	>.99
Atrial fibrillation ablation	15/52 (28.8)	0	15/30 (50.0)	<.0005
Others (Morrow ventricular septal myectomy, left atrial appendage closure, VSD repair, aortic annulus reconstruction)	8/52 (15.4)	3/22 (13.6)	5/30 (16.7)	>.99
Other noncardiac procedure (quadrantectomy, iliac vein repair)	4/52 (7.7)	2/22 (9.1)	2/30 (6.7)	>.99
Implanted prosthesis size (mm)				.002
19	7 (1.2)	2 (0.7)	5 (1.7)	
21	83 (14.0)	38 (12.6)	45 (15.5)	
22	2 (0.34)	0	2 (0.7)	
23	191 (32.2)	96 (31.8)	96 (33.0)	
25	254 (42.8)	149 (49.3)	104 (35.7)	
27	53 (8.9)	17 (5.6)	36 (12.3)	
29	3 (0.51)	0	3 (1.0)	
Median (interquartile range) of implanted prosthesis size (mm)	25 (23-25)	25 (23-25)	23 (23-25)	.60
Sutureless prosthesis*	286 (48.2)	286 (94.7)		
Pericardial bioprosthesis†	245 (41.3)		245 (84.2)	
Porcine bioprosthesis‡	20 (3.4)		20 (6.9)	
Mechanical prosthesis§	18 (3.0)		18 (6.2)	
Mechanical prosthesis¶	3 (0.51)		3 (1.0)	
Mechanical prosthesis	2 (0.34)		2 (0.7)	
Aortic valve system#	10 (1.7)	10 (3.3)		
Sutureless bioprosthesis**	6 (1.0)	6 (2.0)		
Others	3 (0.51)		3 (1.0)	

Values are n (%), unless otherwise indicated. VSD, Ventricular septal defect. *Perceval S (Sorin, Saluggia, Italy). †Perimount (Carpentier-Edwards, Irvine, Calif). ‡Mosaic (Medtronic, Minneapolis, Minn). §CarboMedics, Austin, Tex). ¶(St Jude Medical, St Paul, Minn). ||Bicarbon Slimline (Sorin, Saluggia, Italy). #Edwards Intuity (Edwards Lifesciences, Irvine, Calif). **ATS 3F Enable (Medtronic, Minneapolis, Minn).

1.16-12.25; $P = .027$); artificial ventilation time >12 hours (OR 3.61; 95% CI: 1.37-9.49, $P = .009$); and respiratory dysfunction (OR 7.25; 95% CI: 3.00-17.53; $P < .0005$) were independently associated with a ≥ 3 -day ICU stay ($P = .83$ for goodness of fit by Hosmer-Lemeshow; -2 log-likelihood = 180.4). Likewise, complete postoperative atrioventricular block with necessity of permanent pacemaker implantation was predicted ($P = .72$ for goodness of fit by Hosmer-Lemeshow, -2 log-likelihood = 128.5), by family history of CAD (OR 3.1; 95% CI: 1.14-8.47; $P = .03$); logistic EuroSCORE (OR 1.17; 95% CI: 1.06-1.29; $P = .002$); complex surgery (OR 9.99; 95% CI: 2.00-49.94; $P = .005$); and patient's height (OR 0.922; 95% CI: 0.865-0.983; $P = .014$).

In 98 (16.5%) patients, the composite event score was ≥ 1 (range: 1-5), resulting in a total sum of events equal to 148. By ordinal regression analysis, independent contributors were age quartiles (first age quartile 2.17; 95% CI: 0.02-4.31; $P = .047$, and second age quartile 1.52; 95% CI: 0.11-2.93; $P = .035$), extracardiac arterial vascular disease (1.81, 95% CI: 0.44-3.18; $P = .01$); previous CABG (13.7, 95% CI: 9.8-17.5; $P < .0005$); previous valvular surgery (11.4; 95% CI: 8.5-14.4; $P < .0005$), and CPB time (0.024; 95% CI: 0.012-0.037; $P < .0005$), whereas NYHA classification had only marginal significance (-1.98 ; 95% CI: -4.06 to 0.11; $P = .06$ for NYHA class I).

One (0.17%) patient, a woman aged 83 years, experienced acute aortic dissection on the third postoperative

TABLE 3. Operative times: overall data and comparison among subgroups

Variable	Overall study population (n = 593)	Isolated AVR (n = 541)	Isolated AVR with sutured prostheses (n = 258)	Isolated AVR with sutureless prostheses (n = 283)
CPB time (min)	107 (86-135)	104 (84-129)	121 (103.5-147.5)	88 (77-107)
ACC time (min)	74 (55-96)	71 (54-92)	87 (75-109)	55 (47-68)

For isolated AVR, $P < .0005$ (for both CPB and ACC times), compared with associated procedures (eg, AVR and/or mitral procedure and/or Morrow septal myectomy). For sutureless versus sutured comparison, $P < .0005$ (for both CPB and ACC times). AVR, Aortic valve replacement; CPB, cardiopulmonary bypass; ACC, aortic cross clamp.

TABLE 4. Overall patient outcomes

Variable	Overall cohort (n = 593)	Sutureless subgroup (n = 302)	Sutured subgroup (n = 291)	P value
ICU length of stay (d)	1 (1-1)	1 (1-1) (70 cases > median)	1 (1-1) (44 cases > median)	.011
Prolonged ICU stay	53 (8.9)	34 (11.3)	19 (6.6)	.046*
Assisted ventilation time (h)	6 (5-9)	6 (4-8)	7 (5-9)	.004
Prolonged ventilation support	22 (3.7)	9 (3.0)	13 (4.5)	.33
Hospital length of stay (d)	6 (6-7)	6 (6-8)	6 (6-7)	.027
In-hospital mortality	9 (1.5)	4 (1.3)	5 (1.7)	.75
Reopening for bleeding or cardiac tamponade	30 (5.1)	17 (5.6)	13 (4.5)	.53
Perioperative acute myocardial infarction	9 (1.5)	3 (1.0)	6 (2.1)	.33
Infective complications	19 (3.2)	9 (3.0)	10 (3.4)	.75
Sepsis	1 (0.17)	1 (0.3)	0	>.99
Wound dehiscence or infection	3 (0.51)	1 (0.3)	2 (0.7)	.62
Stroke	10 (1.7)	6 (2.0)	4 (1.4)	.75
Transient ischemic attack	6 (1.0)	3 (1.0)	3 (1.0)	>.99
Pulmonary complications/respiratory dysfunction	65 (11.0)	36 (11.9)	29 (10.0)	.46
Pneumonia	7 (1.2)	1 (0.3)	6 (2.1)	.064
	7/65 (10.8)	1/36 (2.8)	6/29 (20.7)	.039
Pleural effusion requiring puncture	16 (2.7)	11 (3.6)	5 (1.7)	.15
Perioperative acute kidney injury	23 (3.9)	13 (4.3)	10 (3.4)	.59
New-onset CVVH/hemofiltration support	2 (0.34)	1 (0.3)	1 (0.3)	>.99
Complete AV block; requested PM implant	19 (3.2)	14 (4.6)	5 (1.7)	.045*
New-onset atrial fibrillation or flutter	151 (25.5)	78 (25.8)	73 (25.2)	.86
Gastrointestinal complications	8 (1.3)	7 (2.3)	1 (0.3)	.069

Values are n (%), or median (range), unless otherwise indicated. ICU, Intensive care unit; CVVH, continuous veno-venous hemofiltration/hemodialysis; AV, atrioventricular; PM, pacemaker. *Statistically insignificant P values for the type of valvular prosthesis variable in multivariable model predicting this event/complication.

day and underwent reoperation to replace the aortic root and ascending aorta.

Nine (1.5%) patients were lost to follow-up. At 31.5 months, the mean follow-up time (median: 20.1; IQR: 11.1-51.5 months), with 1531 accumulated patient-years, 94.8% (562 of 593) survival was observed. Patients in the sutureless group had a shorter follow-up time: 12.6 (5.4-19.0) months versus 51.5 (26.5-66.6) months, $P < .0005$.

Twenty-two late deaths have been observed during follow-up, 3 of them due to cardiac pathology. Eleven (11 of 584; 1.9%) failed prostheses necessitated reoperation: 2 patients from the sutureless subgroup, and 5 patients from the conventional subgroup have undergone reoperation for infective endocarditis, and 4 patients from the conventional subgroup underwent redo AVR for a degenerated bioprosthesis. Overall actuarial survival by Kaplan-Meier at 1, 3, 5, and 8 years was $96.5\% \pm 1\%$, $94.1\% \pm 1\%$, $93.3\% \pm 2\%$, and $93.3\% \pm 2\%$, respectively (Figure 2). Actuarial survival was similar in the sutureless versus conventional prostheses groups ($P = .11$ by log-rank), but it was limited with a shorter follow-up time in the sutureless group (Figure 3). Actuarial freedom from reoperation at 5 years was $97.2\% \pm 2\%$.

Late survival by a Cox multivariable proportional hazards regression model was associated with 3 independent predictors: preoperative cardiac arrhythmia (hazard ratio [HR] 2.58; 95% CI: 1.06-6.28; $P = .036$), logistic EuroSCORE (HR 1.067; 95% CI: 1.007-1.131; $P = .029$), and

artificial ventilation time (HR 1.014; 95% CI: 1.006-1.022, $P < .0005$), but it was not affected by the sutureless/sutured variable (HR 1.02; 95% CI: 0.33-3.14, $P = .97$) (Figure 4).

DISCUSSION

Many centers have reported their midterm and remote results after mitral valve surgery via right anterior minithoracotomy (RAMT), but only a few have published articles

FIGURE 2. Overall survival function by Kaplan-Meier test.

FIGURE 3. Comparison of survival by Kaplan-Meier between sutured and sutureless cohort. Green line and green numbers refer to sutureless prostheses; blue line and blue numbers refer to sutured prostheses. Shorter follow-up in the sutureless group, with information lacking over 24 months, is evident by “block” shape of green line.

regarding AVR.⁹⁻¹² To our knowledge, this is the largest single-center experience to date on the minimally invasive AVR via RAMT. Our data, along with earlier reports, confirm that minimally invasive AVR via RAMT is safe and reproducible. It is associated with low perioperative mortality and morbidity.

We began our clinical experience with RAMT AVR in mid-2004, based on the minimally invasive mitral valve surgery setting. Physiologic antegrade perfusion should be preferred, to avoid cerebral and splanchnic embolic complications. Surgical exposure of femoral vessels is additionally associated with groin complications.⁴ The standardized

FIGURE 4. Follow-up survival by Cox multivariable proportional hazards regression model at mean of covariates, stratified by the type of aortic valve prosthesis (hazard ratio 1.02; 95% CI: 0.33-3.14; $P = .97$). Shorter follow-up in the sutureless group, with information lacking over 24 months, is evident by “block” shape of green line.

surgical technique used by all attending surgeons in our department may be the reason for success.²⁴ Teamwork and patient care continuity, from operating room to ICU and ordinary ward, are of essential importance. Figure 1 shows the substantial increase in the number of patients operated on with RAMT since 2011, which is the year that clinical application of sutureless technology began to increase in our institution.

Since our very early experience with RAMT, through interim analysis, we have been gaining clear confidence that reduced surgical trauma, compared with sternotomy, is transformed into improved perioperative outcomes. Subsequently, we tried to recruit more patients who were operable via RAMT; however, patients' individual anatomy and CT selection criteria created natural limits on the number. Nonetheless, increased experience with RAMT allowed us to make definite progress, and between 2005 and 2010, we steadily increased the number of RAMT procedures (Figure 1).

The population in Italy is rapidly gaining a larger proportion of elderly people, and this trend is common in the post-industrial world. This increasing proportion consists of people who are older and sicker, are affected by the substantial impact of associated comorbidities and frailty, and need a biological prosthesis rather than a mechanical one. These factors, along with the necessity of maintaining at least the same outcome rate after AVR, despite a worse baseline risk profile, were the impetus for entering the sutureless era at our institution.

Sutureless prostheses came to cover a vast slice of patients, who were eligible, on the one hand, for biological prosthesis implantation; on the other hand, they requested less-invasive technique implementation because of their poorer baseline conditions. Sutureless aortic valve prostheses may enhance the minimal invasiveness of surgical incision, especially with right minithoracotomy, in which the chest bone structure is not divided at any point to reach pericardium. The complementary character of a sutureless prosthesis implanted with a really minimally invasive technique—RAMT—forsaged an important paradigm shift. Today, our first-line option for an average patient with degenerative aortic valve stenosis is sutureless AVR via right minithoracotomy, unless it is contraindicated by some exclusion criteria (eg, regarding right chest abnormality or venous anatomy). We feel that sutureless technology, facilitating the surgical technique and rendering it step-by-step standardizable, could contribute to a wider adoption of minimally invasive AVR.

In our case series, a single patient underwent stentless AVR in the RAMT approach. In contrast to Sansone and colleagues,²⁵ we were not satisfied with aortic root exposure with a stentless prosthesis inside, with the limited space to work and reduced angle of instrument movement that resulted in cumbersome suture placement. Thus, we thereafter

reserved a partial sternotomy for minimally invasive stentless AVR, in which a lower border of surgical incision of the thoracic wall allows better amplitude of surgical maneuvers. However, even Sansone and colleagues²⁵ had to enlarge the initial incision to transverse sternotomy in 2 of 7 patients.

Minimally invasive AVR has been associated by most authors with better perioperative outcomes,^{5,6,8,10,13} but constantly longer operative times, compared to full sternotomy. Extremely variable perfusion times with RAMT AVR have been reported.^{4,8,18} Our data, observed with conventional prostheses, are in line with previous reports, but they are much improved with use of sutureless prostheses.

As in previous reports,^{20,21} we showed that sutureless prostheses significantly reduce operative times and provide at least comparable clinical outcomes. Indeed, direct univariate comparison favored the sutured group with regard to early postoperative outcomes (Table 4), but more-robust multivariable regression model analysis did not indicate that conventional prostheses had better general performance. Several confounders (eg, age, female gender, obesity), revealed by multivariable logistic regression analysis to be independently associated with the sutureless group, were underlying factors.

Although it was projected as a tool for isolated AVR, RAMT does not preclude use of various associated procedures, and even triple-valve surgery is possible in selected patients. Five patients underwent triple-valve surgery in this series,²⁶ and we agree with Elmahdy et al.²⁷ on the technical feasibility of this approach. In addition, some patients undergoing a reoperation can be treated for AVR via RAMT, when preoperative computed tomography evaluation does not exclude this surgical approach.

The issue of limited space during AVR via RAMT is handled easily with the choice of sutureless prosthesis. However, our experience shows that not every type of sutureless aortic valve prosthesis can be implanted through RAMT. The most useful and effective concept in such circumstances seems to be a collapsible device. A collapsible profile of the prosthesis enhances visualization in a reduced surgical exposure site and allows a surgeon to secure its correct position under direct visual control before deployment. Wider use of sutureless prostheses may increase adoption of minimally invasive AVR, especially with RAMT.

Multivariable logistic analysis failed to indicate independent predictors of in-hospital mortality in the present study, whereas Sharony and colleagues¹¹ linked hospital mortality to congestive heart failure, urgent surgery, depressed left ventricular function, and age. We may suppose that in our population, hospital mortality was rare (only 9 patients) and was casually associated with various factors, probably not those considered in the database, that precluded confident statistical identification of them. However, 3 independent predictors of late mortality have been demonstrated by Cox multivariable regression analysis.

Permanent pacemaker implantation after sutureless AVR is still a topic of intense debate. In the present study, complete postoperative atrioventricular block was linked to a family history of CAD, a higher logistic EuroSCORE, and patient's height, and not to sutureless treatment, even though the latter seemed to affect atrioventricular block incidence, as assessed by univariate analysis. This empirical analysis, however, lacked more-specific data (eg, degree of aortic annulus decalcification, preoperative electrocardiogram abnormalities, and electrophysiologic evaluation of the block), which might have more-precise prognostic significance. Experience on the subject is growing, and we will continue our research.

Limitations

Several limitations of our study have to be noted. It is based on a retrospective analysis of our large, institutional, observational, prospectively collected database; thus, it reflects 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. In addition, this study reflects our initial experience with the RAMT approach and encompasses the “learning curve.”

Given that ours is a retrospective study without a control group, unadjusted biases may have confounded our findings. We might have been unable to account for the influence of residual unmeasured factors that could affect adverse outcomes. On the other hand, this experience with “all comers” shows real-world data.

We fully recognize that our case series is extremely heterogeneous, and comprises various clinical scenarios. An extremely heterogeneous study population may account for the skewness of continuous data, and the abnormal distribution of dichotomous data. However, with a multivariable regression model-based propensity score adjustment, we attempted to smooth the differences between the 2 main groups—sutured and sutureless. For outcome incidence, which differed in the 2 groups, specific multivariable regression models were created to adjust for confounders. Despite a Cox regression model that identified several independent predictors of late mortality, this analysis is limited by the low number of events that could have affected the result, as shown by a wide CI.

Further, statistics cited earlier were based on a median follow-up time of approximately 1 year for sutureless prostheses, accounting for clearly unequal follow-up duration, compared with conventional prostheses. Thus, a longer duration is needed to confirm durability and hemodynamic performance of the sutureless prostheses. We have utilized all-cause mortality data, although they were 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, comprehensive analysis was performed on the whole study population, without any selection; thus, it is a real-world study on the largest, to our knowledge, single-center experience to date with RAMT AVR.

CONCLUSIONS

Minimally invasive AVR is a safe procedure, with low perioperative morbidity, and low rates of reoperation and death at late follow-up. Excellent outcomes can be achieved with minimally invasive AVR through RAMT. Sutureless prostheses facilitate minimally invasive AVR and are associated with reduced operative times.

Conflict of Interest Statement

Dr Glauber and Dr Solinas have a commercial/financial relationship with Sorin Group. The other authors have nothing to disclose regarding commercial support.

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Key Words: aortic valve replacement, minimally invasive aortic valve replacement, right anterior minithoracotomy, sutureless aortic valve prosthesis

APPENDIX E1. List of variables used for multivariable tests

1. Age*
2. Quartile of age
3. Height
4. Weight
5. Body mass index
6. Obesity
7. Smoking history
8. Hypercholesterolemia
9. Diabetes mellitus
10. Family history of coronary artery disease
11. Preoperative cardiac arrhythmia history
12. Atrial fibrillation history
13. Arterial hypertension
14. Preoperative glycemia
15. Chronic renal insufficiency (anamnestic data)
16. Preoperative serum creatinine (mg/dL)
17. Preoperative dialysis
18. Extracardiac arterial vascular disease
19. Cerebrovascular disease
20. Previous transient ischemic attack
21. Previous stroke
22. Residual neurologic dysfunction
23. Acute stroke (<30 d from onset)
24. Carotid artery echo color Doppler abnormality
25. Infective endocarditis
26. Chronic lung disease
27. Chronic obstructive pulmonary disease
28. Grade 3-4 chronic bronchial obstruction
29. Chronic bronchodilator use
30. Prior percutaneous vascular procedure
31. Prior cardiovascular surgery
32. Prior coronary artery bypass grafting
33. Prior heart valve surgery
34. Prior other cardiac surgery
35. Acute myocardial infarction
36. Remoteness of acute myocardial infarction
37. Angina pectoris
38. Unstable angina pectoris
39. Active neoplastic process
40. Critical preoperative status
41. Prior pacemaker implantation
42. Intravenous antibiotics
43. Intravenous nitrates
44. Liver failure
45. Congestive heart failure
46. Cardiogenic shock
47. NYHA functional class†
48. Functional class III or IV by NYHA
49. Left ventricular ejection fraction* (%)
50. Coronary artery disease
51. Left common trunk lesion
52. Number of diseased coronary arteries
53. Transvalvular aortic gradient (echocardiography measurement) (mm Hg)

(Continued)

APPENDIX E1. Continued

54. Aortic valve pathology (stenosis, stenosis and incompetence, pure incompetence)
55. Bicuspid aortic valve
56. Mitral valve disease
57. Tricuspid valve disease
58. Pulmonary hypertension
59. Additive EuroSCORE I
60. Logistic EuroSCORE I
61. Quartile of logistic EuroSCORE I
62. Surgery priority
63. Isolated aortic valve replacement
64. Mitral valve surgery
65. Tricuspid valve surgery
66. Atrial fibrillation ablation
67. Other surgical heart procedures
68. Type of implanted prosthesis (sutureless/conventional; biological/mechanical)
69. Commercial (trade) name of the implanted prosthesis
70. Size of the implanted prosthesis† (mm)
71. Conversion to full sternotomy
72. Cardioplegia type
73. CPB duration* (min)
74. Aortic crossclamp duration* (min)
75. Intra-aortic balloon pump use
76. Arterial cannulation site
77. Venous cannulation site
78. Assisted mechanical ventilation duration* (h)
79. Intensive care unit stay* (d)
80. Revision for bleeding or tamponade
81. Revision for any reason
82. Perioperative myocardial infarction
83. Wound dehiscence or infection
84. Groin cannulation site complications
85. Urinary tract infection
86. Postoperative sepsis
87. Infective complications
88. Confusion/delirium postoperatively
89. Postoperative transient ischemic attack
90. Postoperative stroke
91. Pulmonary distress
92. Pulmonary embolism
93. Pneumonia
94. Pleural effusion requiring drainage
95. Acute kidney injury
96. New-onset renal replacement therapy
97. Acute limb ischemia
98. Atrioventricular block requiring permanent pacemaker implantation
99. Postoperative cardiac arrest
100. Pericarditis
101. Relevant pericardial effusion treated conservatively
102. Gastrointestinal complications
103. Multiorgan failure
104. Postoperative new-onset atrial fibrillation

(Continued)

APPENDIX E1. Continued

- 105. Acute postoperative aortic dissection
- 106. Major cardiac arrhythmia
- 107. Acute liver failure
- 108. Composite event score
- 109. Discharge destination (home, rehabilitation facility, other hospital)
- 110. Hospital length of stay*

NYHA, New York Heart Association; *EuroSCORE*, European system for cardiac operative risk evaluation. *Variable tested as continuous, ordinal, and binary. †Variable tested as ordinal.

APPENDIX E2.

Propensity-score model for sutureless prosthesis implantation: Receiver operating characteristic curve and model fit by C-statistic and Hosmer-Lemeshow criteria.

FIGURE E1. Area under the curve = 0.929; SE = 0.010. 95% CI: 0.909-0.948. Overall model fit by Hosmer-Lemeshow: $-2 \log\text{-likelihood} = 398.4$; χ^2 statistic = 6.84; $P = .554$. *ROC*, Receiver operating characteristic.