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Minimally invasive access type related to outcomes of sutureless and rapid deployment valves

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Abstract

OBJECTIVES: Minimally invasive surgical techniques with optimal outcomes are of paramount importance. Sutureless and rapid deployment aortic valves are increasingly implanted via minimally invasive approaches. We aimed to analyse the procedural outcomes of a full sternotomy (FS) compared with those of minimally invasive cardiac surgery (MICS) and further assess MICS, namely ministernotomy (MS) and anterior right thoracotomy (ART).

METHODS: We selected all isolated aortic valve replacements in the Sutureless and Rapid Deployment Aortic Valve Replacement International Registry (SURD-IR, $n = 2257$) and performed propensity score matching to compare aortic valve replacement through FS or MICS ($n = 508$ /group) as well as through MS and ART accesses ($n = 569$ /group).

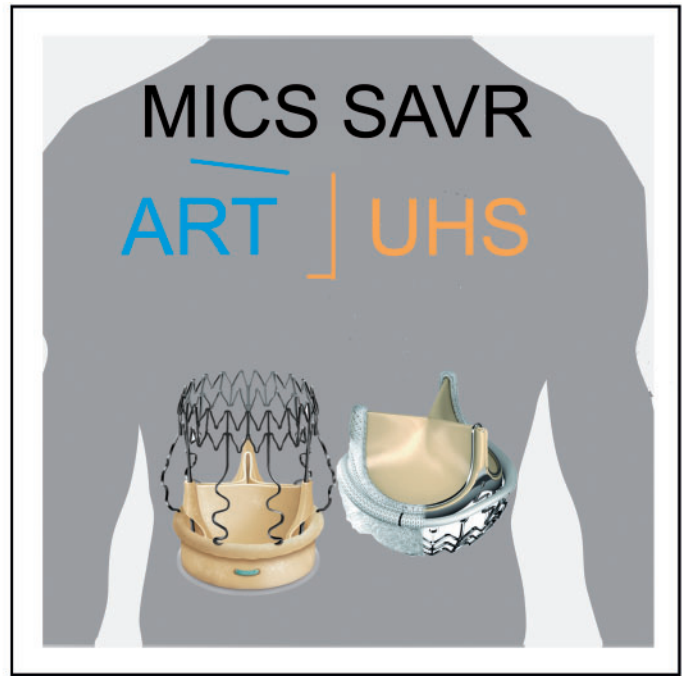
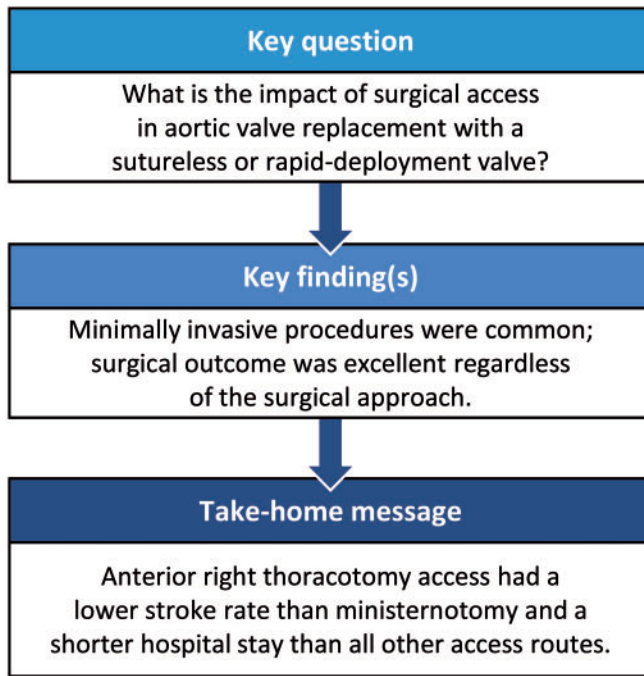
RESULTS: Postoperative mortality was 1.6% in FS and MICS patients who had a mean logistic EuroSCORE of 11%. Cross-clamp and cardiopulmonary bypass (CPB) times were shorter in the FS group than in the MICS group (mean difference 3.2 and 9.2 min; $P < 0.001$). Patients undergoing FS had a higher rate of acute kidney injury (5.6% vs 2.8%; $P = 0.012$). Direct comparison of MS and ART revealed longer mean cross-clamp and CPB times (12 and 16.7 min) in the ART group ($P < 0.001$). The postoperative outcome revealed a higher stroke rate (3.2% vs 1.2%; $P = 0.043$) as well as a longer postoperative intensive care unit [2 (1–3) vs 1 (1–3) days; $P = 0.009$] and hospital stay [11 (8–16) vs 8 (7–12) days; $P < 0.001$] in the MS group than in the ART group.

CONCLUSIONS: According to this non-randomized international registry, FS resulted in a higher rate of acute kidney injury. The ART access showed a lower stroke rate than MS and a shorter hospital stay than all other accesses. All these findings may be related to underlying patient risk factors.

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Keywords: Sutureless valve • Rapid deployment valve • Aortic valve replacement • Sutureless and Rapid Deployment Aortic Valve Replacement International Registry • The International Valvular Surgery Study Group

ABBREVIATIONS

ART	Anterior right thoracotomy
AVR	Aortic valve replacement
CPB	Cardiopulmonary bypass
FS	Full sternotomy
ICU	Intensive care unit
IVSSG	International Valvular Surgery Study Group
MICS	Minimally invasive cardiac surgery
MS	Ministernotomy
PS	Propensity score
SURD-IR	Sutureless and Rapid Deployment Aortic Valve Replacement International Registry
TAVI	Transcatheter aortic valve implantation

INTRODUCTION

Rapid deployment and sutureless valves were developed to facilitate and increase the speed of surgical aortic valve replacement (AVR) [1]. These valves are also well suited to facilitate minimally invasive procedures [2–4]. Currently, 2 main minimally invasive approaches are performed. Ministernotomy (MS) and anterior right thoracotomy (ART) are increasingly applied to reduce the trauma of isolated AVR. MS involves splitting the upper half of the sternum while leaving the caudal part intact [5]. This technique is easily adapted from full sternotomy (FS) and allows central cannulation. The surgical steps for AVR are very similar to those performed through FS. ART accesses the aortic valve via the 2nd or 3rd intercostal space [6]. This approach leaves the

sternum intact and thereby considerably reduces surgical trauma. However, cannulation and aortic valve implantation with sutures are more demanding. Previous reports and meta-analyses have compared FS to MS and ART with reassuring results for minimally invasive procedures [7, 8]. However, most of the procedures reported in previous analyses were performed with conventional aortic valves. Outcome data of minimally invasive procedures with sutureless and rapid deployment valves in a large patient population targeting the comparison of types of surgical access have not been reported thus far. Specifically, differences regarding MS and ART have not been intensively discussed. While several centres have reported excellent results with the ART procedure, 1 centre reported an increased rate of complications with ART compared to FS [9–12]. Therefore, we compared the outcome of surgical AVR through these 2 minimally invasive approaches with data from the currently largest registry for sutureless and rapid deployment valves, the Sutureless and Rapid Deployment Aortic Valve Replacement International Registry (SURD-IR) [13]. This analysis includes all minimally invasive AVRs that were performed and reported in this registry.

PATIENTS AND METHODS

Patients

The International Valvular Surgery Study Group (IVSSG) consists of 18 clinical centres in Europe, Australia and Canada, and it established the SURD-IR in 2015 [13]. All patients included in the registry were from one of the participating centres of the IVSSG. The SURD-IR aims to evaluate the current management

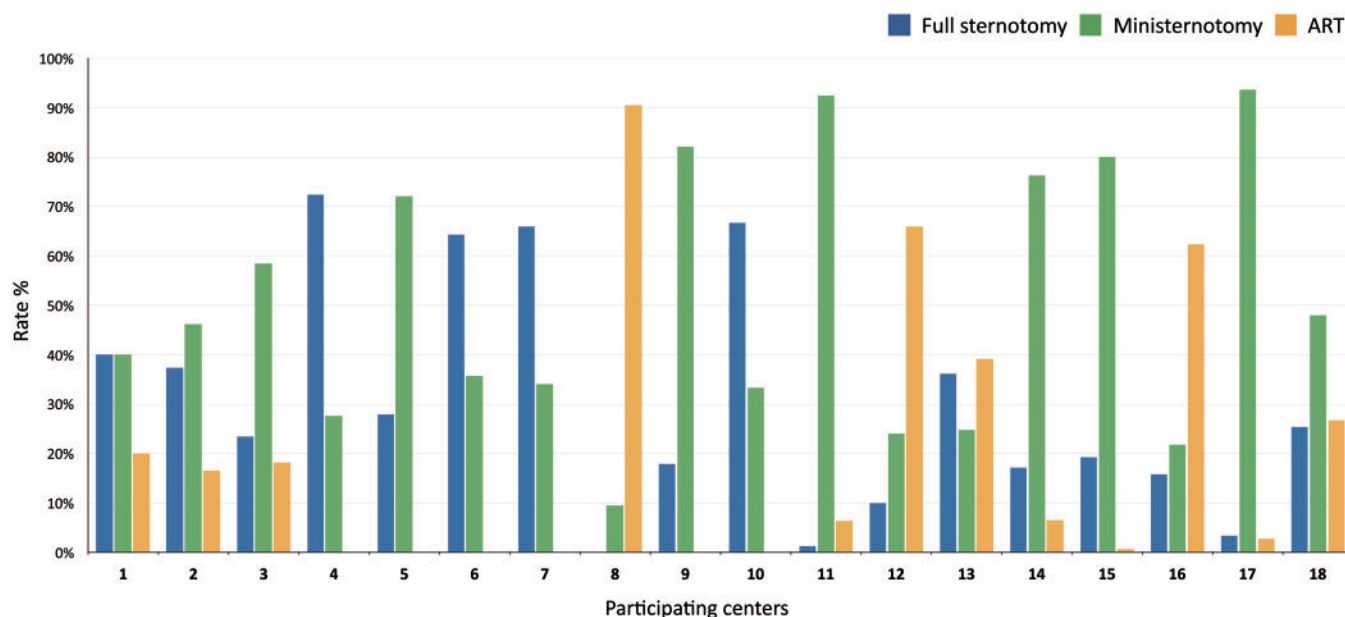


Figure 1: Surgical access distribution per centre. ART: anterior right thoracotomy.

and outcomes of surgery with sutureless and rapid deployment valves.

The clinical centres were selected according to their experience with sutureless and rapid deployment aortic valves, defined by more than 50 cases or specific recommendations by the IVSSG Research Steering Committee [14]. The project was submitted and approved by the local ethics committees. Data were sent for centralized reporting. The requested data consisted of 155 variables, including demographics, patient comorbidities, functional status, imaging studies, surgical data, postoperative course and clinical and haemodynamic outcomes. Valve-related adverse events were collected and reported according to the current guidelines [15]. Clinically important absent data were queried with the submitting centre. Submitted clinical data were analysed for validity and compared to previously published data.

All patients in this registry undergoing isolated AVR via a minimally invasive (either via MS or ART) or FS approach and who received a currently available sutureless or rapid deployment valve [Perceval S (Livanova PLC, London, UK) or the EDWARDS INTUITY/INTUITY Elite (Edwards Lifesciences, Irvine, CA, USA)] were included in the present analysis. Databank closure occurred in November 2018.

Statistical analysis

Continuous variables were expressed as the mean \pm standard deviation, and categorical variables were expressed as percentages. When continuous variables did not follow a normal distribution (tested using the Kolmogorov-Smirnov test for normality and Q-Q plots), the median and interquartile range were reported. Percentages were calculated with the available data as the denominator.

Categorical variables were compared with the χ^2 test. Normally distributed continuous data were compared with unpaired *t*-tests or one-way analysis of variance as appropriate. Further specifications regarding missing data and propensity matching are provided in the [Supplementary Material](#). A *P*-value of 0.05 was considered significant. The SPSS 25.0 statistical

software package (SPSS, Chicago, IL, USA) was used for statistical calculations.

RESULTS

A total of 1111 patients underwent MS (37% male), 627 patients underwent ART (39% male), and 529 patients underwent surgery via FS (21% male). Surgical access varied significantly between centres according to institutional practice, and the surgeon's experience and preference (Fig. 1). After propensity score (PS) matching, 508 patients undergoing minimally invasive surgery were compared to 508 patients undergoing FS, and 569 patients undergoing ART were compared to 569 patients undergoing MS.

Full sternotomy versus minimally invasive aortic valve replacement

The baseline patient characteristics before and after PS are reported in Table 1. The surgical access in the minimally invasive cohort was MS in 69% and ART in 31%. The valve types were not different between the groups. Cross-clamp and cardiopulmonary bypass (CPB) times were significantly shorter in the FS group than in the minimally invasive cardiac surgery (MICS) group, with a mean difference of 3.2 min for cross-clamp time and 9.2 min for CPB time (Table 2). In-hospital mortality was 1.6% for both groups. Pacemaker implantation was required in 10% (MICS) and 9.1% (FS), which was not different between the groups. Other in-hospital outcomes were also similar, but patients undergoing FS had a higher rate of acute kidney injury and dialysis than patients undergoing MICS (Table 3).

Anterior right thoracotomy versus ministernotomy surgical access

Before PS matching, patients in the MS group were in a higher New York Heart Association functional class, had a higher body

Table 1: Patient characteristics (MICS vs FS)

Characteristics	Overall cohort			Propensity-matched cohort		
	MICS (n = 1738)	FS (n = 529)	Standardized difference ^a	MICS (n = 508)	FS (n = 508)	Standardized difference ^a
Male gender	37.9	33.6	8.4	35.6	34.1	3.2
Age (years), mean (SD)	76 (6.7)	77.7 (7.3)	-26	77.4 (6.7)	77.5 (7.3)	-2.1
NYHA class						
I	6.2	4.5	8.5	3.5	4.9	-4.6
II	46.3	30.7	32.6	36	31.3	9.1
III	44.6	57.7	-29.3	54.4	57.4	-7.9
IV	2.9	7.1	-20.7	6.1	6.4	-2.3
Hypertension	81.1	82.4	-2.7	83.3	82.5	3
Obesity	27.3	25.1	3.6	25.2	26	2.6
BMI (kg/m ²), mean (SD)	27.5 (4.9)	27.2 (4.9)	3.2	27.1 (4.9)	27.3 (5)	-2.1
Diabetes	28.4	28.9	-2.9	27.8	29.3	-3.5
Atrial fibrillation	12.4	17.5	-13.8	16.3	16.9	-1.6
PM	2.8	6	-18.8	2.8	5.5	-18.4
Surgical indications			-7			0
Aortic valve stenosis	62.6	75.8	-27.1	71.6	75.4	-4.2
Aortic valve regurgitation	1.3	0.4	7.6	0.8	0.4	3.6
Mixed aortic valve disease	36.1	23.8	26.5	27.6	24.2	7.1
Pulmonary hypertension	22.8	39.5	-32.1	32.5	34.8	-1.4
Cerebrovascular disease	10.9	9.3	4.6	10	9.4	0.6
Renal insufficiency	42.6	51.4	-14.8	48.3	51.7	-6.8
Chronic lung disease	15.1	14.9	2.1	15	15.4	-4.2
LVEF%, mean (SD)	58.6 (9.3)	58.3 (12.2)	4.9	59.1 (10)	58.5 (11.9)	8.3
LVEF >50	83.6	78.8		83.2	79.3	
LVEF 30–50	15.5	17.7		15.2	17.1	
LVEF <30	0.9	3.5		1.6	3.5	
Logistic EuroSCORE (%), mean (SD)	8.9 (6.4)	11.8 (9.7)	-46.3	10.7 (8.5)	11 (8.6)	-7.4

Values are percentages unless otherwise indicated.

^aStandardized difference is the mean difference divided by the pooled SD, expressed as a percentage.

BMI: body mass index; FS: full sternotomy; LVEF: left ventricular ejection fraction; MICS: minimally invasive cardiac surgery; NYHA: New York Heart Association; PM: pacemaker; SD: standard deviation.

mass index, and had a higher rate of atrial fibrillation, pulmonary hypertension and renal insufficiency than those of patients in the ART group ($P < 0.01$). The patient baseline characteristics after matching are reported in Table 4. Patients undergoing the ART procedure were significantly more likely to receive a Perceval S valve than patients undergoing MS (87.7 vs 67.6%; $P < 0.001$). No differences were found regarding valve malpositioning or conversion to FS (Table 5). However, the mean cross-clamp time was 12 min longer and the mean CBP time was 16.7 min longer in the ART group than those in the MS group ($P < 0.001$, Table 5). Postoperative outcomes revealed a higher stroke rate and a longer postoperative intensive care unit (ICU) and hospital stay in the MS group than those in the ART group (Table 6). Pacemaker implantation was required in 8.5% (ART) and 9.9% (MS), and mild postoperative aortic regurgitation occurred in 6% (ART) and 8.2% (MS); both were not different between the groups.

DISCUSSION

This analysis of SURD-IR data reports the access-specific outcomes for isolated AVR with sutureless and rapid deployment aortic valves. While the outcomes for all access types were comparable regarding low perioperative mortality, patients undergoing FS had a higher rate of acute kidney injury than those undergoing MICS, and patients undergoing MS had a higher

stroke rate than those undergoing ART. ART patients had a shorter hospital stay than MS patients.

Minimally invasive AVR has previously been described to be associated with reduced postoperative complications, reduced hospital stay and increased patient satisfaction [7, 8, 11]. This procedure may improve patient satisfaction and acceptance. A potential drawback of minimally invasive access is the inability to treat concomitant pathologies such as atrial fibrillation. The access should therefore be discussed in detail with the patient prior to surgery if the patient is an eligible candidate for a maze procedure. Furthermore, the observed increased rate of postoperative kidney injury was not seen in other reports and cannot be attributed to the surgical access alone due to the non-randomized study design [10].

We report on the largest contemporary cohort comparing the 2 most relevant minimally invasive techniques for AVR with rapid deployment or sutureless prostheses [13]. The present results reflect the real-world experience with these valves in expert and high-volume centres as well as the learning curve with these new valves. The percentage of patients receiving either MS or ART was different between study centres, which may also account for some of the observed differences (Fig. 1). Overall mortality was low compared to the preoperative surgical risk (1.6% for a logistical EuroSCORE of 11%). As expected, CPB and cross-clamp times were prolonged in patients who underwent a minimally invasive access compared with patients who underwent FS, and within this group, ART patients had the longest perfusion times

Table 2: Operative data (MICS vs FS)

	Overall cohort			Propensity-matched cohort		
	MICS (n = 1738)	FS (n = 529)	P-value	MICS (n = 508)	FS (n = 508)	P-value
Valve type			0.16			0.12
Perceval S	75.9	79		74.4	78.7	
Intuity/Intuity Elite	24.1	21		25.6	21.3	
Valve malpositioning	1	0.3	0.37	0.6	0.3	0.91
ART	36.1			31.1		
MS	63.9			68.9		
Conversion to FS	1			0.6		
CPB time (min), mean (SD)	79.4 (30)	69.2 (33.4)	<0.001	78.0 (27.4)	68.8 (33.4)	<0.001
Clamp time (min), mean (SD)	50.2 (21.1)	45.7 (23)	<0.001	48.8 (18.9)	45.6 (22.8)	<0.001

Values are percentages unless otherwise indicated.

ART: anterior right thoracotomy; CPB: cardiopulmonary bypass; FS: full sternotomy; MICS: minimally invasive cardiac surgery; MS: ministernotomy; SD: standard deviation.

Table 3: In-hospital outcomes (MICS vs FS)

	Overall cohort			Propensity-matched cohort		
	MICS (n = 1738)	FS (n = 529)	P-value	MICS (n = 508)	FS (n = 508)	P-value
In-hospital mortality	1.4	1.6	0.84	1.6	1.6	1
Stroke	2.4	1.2	0.21	2.1	1.2	0.41
Low cardiac output	0.9	0.5	0.86	1.1	0.5	0.66
Ventilatory support >72 h	3	3	1	3.1	3.1	1
New-onset AF	27.7	28.4	0.76	26.6	28.3	0.59
PM implantation	9.4	8.4	0.78	10	9.1	0.71
Aortic regurgitation			0.007			0.11
Mild	7.1	12.7		7.8	12.4	
Moderate	1	1.4		1.2	1.4	
Severe	0.2			0.6		
Bleeding	4.1	3.5	0.86	3.9	3.2	0.83
AKI (>stage 1)	3	5.4	0.029	2.8	5.6	0.012
Dialysis	1.3	4.2	0.006	1.5	4.3	0.04
Wound complications	3.5	3.1	0.97	3.1	3.2	0.99
Peak gradient (mmHg), mean (SD)	25.9 (10.3)	24.1 (9)	0.005	25.2 (9.7)	24.1 (8.9)	0.17
Mean gradient (mmHg), mean (SD)	13.7 (5.8)	13.1 (5.4)	0.052	13.6 (5.9)	13.1 (5.4)	0.27
ICU stay (days), median (IQR)	1 (1–3)	1 (1–3)	0.16	1 (1–3)	1 (1–3)	0.10
Hospital stay (days), median (IQR)	8 (7–12)	9 (7–13)	0.76	8 (7–12)	9 (7–14)	0.65

Values are percentages unless otherwise indicated.

AF: atrial fibrillation; AKI: acute kidney injury; FS: full sternotomy; ICU: intensive care unit; IQR: interquartile range; MICS: minimally invasive cardiac surgery; PM: pacemaker; SD: standard deviation.

[10, 11]. However, cross-clamp times were expected to be significantly shorter with these valves compared to conventional valves with the same access. Berger *et al.* [16] showed reduced cross-clamp times for rapid deployment valves in a randomized trial. Furthermore, studies analysing ART access with conventional valves showed higher cross-clamp times compared to the data from our registry [12, 17]. MS patients had a higher rate of post-operative stroke than that of ART patients. In addition, ART patients had a shorter postoperative ICU and hospital stay than MS patients, which has been previously described [17]. The observed differences between the access groups can be partially explained by the access itself but may also be related to a higher level of experience of the operating surgeons or specific patient selection not adjusted by PS matching. We additionally analysed the stroke rate for the complete matched cohort according to valve type to exclude an effect of unequally distributed valve

types in the ART and MS groups, but valve type was not associated with a significantly different stroke rate (stroke rate: Perceval 2.5%, Intuity 1.1%; $P=0.23$). Although this was not a randomized study, ART access appeared to be at least as safe as MS and FS. However, specialized centres performed the procedures in this registry, and outcome data may vary according to the centre's experience.

Chang *et al.* [10] recently performed a meta-analysis of 19 studies including >10 000 patients to evaluate the outcomes of MS and ART compared to each other and to conventional AVR. However, no information regarding the use of sutureless or rapid deployment aortic valves was provided. Minimally invasive aortic valve surgery led to a reduced postoperative stay, which was more pronounced after the ART procedure than after MS. This finding was confirmed by our results for sutureless and rapid deployment aortic valves and is in line with

Table 4: Patient characteristics (ART vs MS)

Characteristics	Overall cohort			Propensity-matched cohort		
	ART (n = 627)	MS (n = 1111)	Standardized difference ^a	ART (n = 569)	MS (n = 569)	Standardized difference ^a
Male gender	39.1	37.3	3.7	38.5	38.3	0.4
Age (years), mean (SD)	75.5 (7.1)	76.3 (6.5)	-10.5	75.8 (6.8)	75.9 (6.5)	-1.5
NYHA class						
I	4.2	7.1	-6.5	5.1	6	-2.1
II	55	41	32.5	51.3	48.7	5.3
III	39.4	48	-21.8	40.6	41.8	-2.5
IV	1.3	3.9	-18.8	1.2	1.8	-5
Hypertension	79.5	82.3	-7	79.3	79.4	-0.4
Obesity	23.4	29.7	-15.6	25	24.8	0.4
BMI (kg/m ²), mean (SD)	27 (4.5)	27.7 (5.1)	-11.2	27.2 (4.6)	27.3 (4.7)	-1.1
Diabetes	25.7	29.6	-10.3	26.7	27.4	-1.6
Atrial fibrillation	7.2	14.4	-24.2	8.3	9.5	-4.6
PM	2.8	2.8	0.0	2.8	2.1	6.4
Surgical indications						
Aortic valve stenosis	45.4	71.4	-49.7	50.5	54.1	-6.3
Aortic valve regurgitation	0.6	1.4	-11.2	0.7	0.7	0
Mixed aortic valve disease	53.8	27.3	53.5	48.9	45.2	7.7
Pulmonary hypertension	19.4	25.3	-12.9	19.7	21.1	-3.6
Cerebrovascular disease	10	10.8	-2.5	11.7	10.5	6.5
Renal insufficiency	36.1	45	-22.4	38.1	41.3	-4.4
Chronic lung disease	17.2	13.8	9.8	16.2	14.1	6.4
LVEF%, mean (SD)	57.9 (8.3)	59 (9.8)	-14.7	58 (8.4)	57.9 (9.7)	1.1
LVEF >50	84.8	83.2		85.2	82.3	
LVEF 30–50	14.4	15.8		14.1	17	
LVEF <30	0.6	1		0.7	0.7	
Logistic EuroSCORE (%), mean (SD)	8.6 (6.1)	9.1 (6.6)	-10.6	8.7 (6.3)	9 (6.3)	-3.9

Values are percentages unless otherwise indicated.

^aStandardized difference is the mean difference divided by the pooled SD, expressed as a percentage.

ART: anterior right thoracotomy; BMI: body mass index; LVEF: left ventricular ejection fraction; MS: ministernotomy; NYHA: New York Heart Association; PM: pacemaker; SD: standard deviation.

Table 5: Operative data (ART vs MS)

	Overall cohort			Propensity-matched cohort		
	ART (n = 627)	MS (n = 1111)	P-value	ART (n = 569)	MS (n = 569)	P-value
Valve type			<0.001			<0.001
Perceval S	87.6	69.3		87.7	67.6	
Intuity/Intuity Elite	12.4	30.7		12.3	32.4	
Valve malpositioning	1.9	0.9	0.23	2	0.8	0.35
Conversion to FS	1	0.9	0.99	0.8	1.2	0.49
CPB time (min), mean (SD)	90.9 (33)	72.8 (26)	<0.001	90.3 (34)	73.6 (25.7)	<0.001
Clamp time (min), mean (SD)	58.7 (23.7)	45.4 (17.5)	<0.001	58.1 (23.9)	46.1 (17.5)	<0.001

Values are percentages unless otherwise indicated.

ART: anterior right thoracotomy; CPB: cardiopulmonary bypass; FS: full sternotomy; MS: ministernotomy; SD: standard deviation.

other reports [18]. Balmforth *et al.* showed a comparable mortality and stroke rate between MS and ART, but ART had a reduced rate of postoperative atrial fibrillation. We were able to confirm similar mortality between groups and a trend towards a reduced rate of postoperative atrial fibrillation, but we observed a higher stroke rate in the MS group than in the ART group. This worrying observation is unlikely to be related to surgical access but needs further investigation. The rate of atrial fibrillation and the number of patients with aortic stenosis were

numerically higher in the MS group than in the ART group after propensity matching, which might also have contributed to these findings.

Recent results of the Partner 3 and the EvolutR Low-Risk trials suggest the extension of transcatheter aortic valve implantation (TAVI) to low-risk patients [19, 20]. However, this option should be considered carefully due to the associated risks, the selective inclusion criteria for these trials and the currently unknown long-term durability. Nevertheless, surgical programmes have to adapt

Table 6: In-hospital outcomes (ART vs MS)

	Overall cohort			Propensity-matched cohort		
	ART (n = 627)	MS (n = 1111)	P-value	ART (n = 569)	MS (n = 569)	P-value
In-hospital mortality	0.7	1.8	0.19	0.9	1.4	0.58
Stroke	1.1	3.1	0.023	1.2	3.2	0.043
Low cardiac output	0.2	1.4	0.041	0.4	1.4	0.11
Ventilatory support >72 h	1.9	3.6	0.14	1.8	3.2	0.18
New-onset AF	25.9	28.6	0.52	25.1	30.2	0.088
PM implantation	7.3	9.9	0.31	8.5	9.9	0.67
Aortic regurgitation			0.41			0.41
Mild	5.7	7.3		6	8.2	
Moderate		1.2			0.7	
Severe		0.2				
Bleeding	3.8	4.2	0.83	3	4.4	0.27
AKI (>stage 1)	2.1	3.5	0.049	2.1	2.8	0.57
Dialysis	0.9	1.5	0.006	0.7	1.5	0.033
Wound complications	3.9	3.3	0.83	4.4	4	0.86
Peak gradient (mmHg), mean (SD)	24.6 (8.1)	26.3 (10.8)	0.061	24.1 (9.3)	25.2 (10.7)	0.063
Mean gradient (mmHg), mean (SD)	13.9 (5.3)	13.7 (5.9)	0.13	13.5 (5.5)	13.4 (5.8)	0.89
ICU stay (days), median (IQR)	1 (1-2)	2 (1-3)	<0.001	1 (1-3)	2 (1-3)	0.009
Hospital stay (days), median (IQR)	8 (7-12)	10 (8-15)	0.001	8 (7-12)	11 (8-16)	<0.001

Values are percentages unless otherwise indicated.

AF: atrial fibrillation; AKI: acute kidney injury; ART: anterior right thoracotomy; ICU: intensive care unit; IQR: interquartile range; MS: ministernotomy; PM: pacemaker; SD: standard deviation.

and offer minimally invasive alternatives to FS with excellent results. However, this strategy is still slowly developing, and several centres do not offer these techniques [21]. Rapid deployment and sutureless aortic valves have the ability to facilitate minimally invasive surgery and are therefore an excellent adjunct to support the required changes in surgical practice [2, 22, 23]. We were able to show improved laminar flow for the Edwards Intuity valve, which opens the left ventricular outflow tract with the stent part of the valve [24]. This reduces transvalvular gradients and may be a relevant factor contributing to the excellent long-term survival in this patient population [3, 23, 25, 26]. This is also a very important argument in the current discussion regarding the low-risk patient population, as the recent Partner 3 trial revealed higher gradients in the TAVI cohort than that in the surgical comparator [19]. Lower gradients are essential to reduce the risk of prosthesis-patient mismatch, which may adversely influence long-term survival. Long-term durability data are currently not available for sutureless and rapid deployment valves, but no increased rate of reoperation has been observed so far. Therefore, it seems appropriate to also discuss the prospect of valve-in-valve procedures for sutureless and rapid deployment aortic valves. These valves are well-suited targets for potential valve-in-valve procedures, which is not true for every other currently available standard surgical prosthesis [27]. Postoperative conduction disturbances are still a matter of concern following sutureless and rapid deployment AVR [13, 25]. This may also present a potential issue for younger patients, who would require a permanent pacemaker. However, we reported a relevant risk reduction of 5.6% in the most recent cohort due to growing surgical experience, which was also shown in the current report for minimally invasive approaches [3]. Furthermore, a recent analysis of conduction disturbances after rapid deployment aortic valves revealed preoperative right bundle branch block as a strong risk factor for pacemaker implantation [28]. Therefore, improved

patient selection for these specific valves may further reduce the pacemaker implantation rate.

Limitations

This study has the limitations of any observational registry involving no adjudication of patient inclusion and data collection. Because of the retrospective nature of the registry, there was no core laboratory to review images, and the investigators were responsible for data reporting from their own institutions. A majority of the participating institutions might have a potential bias as the surgeons participated in first-in-man and CE market studies. Propensity analysis is a powerful statistical technique, but it is limited by the number and accuracy of the assessed variables. However, it is worth noting that in our analysis, a considerable number of plausible preoperative and intraoperative covariates were used to compute the PS, and the post-matching covariate balance was excellent. Long-term survival is currently not sufficiently recorded to include these data in the article.

CONCLUSIONS

According to this non-randomized international registry, FS resulted in a higher rate of acute kidney injury. Patient with an ART access had a lower stroke rate than those with MS, and a shorter hospital stay than those with all other accesses. All these findings may be related to underlying patient risk factors.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

Conflict of interest: Martin Andreas is a proctor (Edwards, Abbott) and advisory board member (Medtronic), Emmanuel Villa is a proctor (LivaNova) and Theodor Fischlein is a consultant (LivaNova and BioStable). All other authors declared no conflict of interest.

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REFERENCES

- Miceli A, Santarpino G, Pfeiffer S, Murzi M, Gilmanov D, Concistre G *et al.* Minimally invasive aortic valve replacement with Perceval S sutureless valve: early outcomes and one-year survival from two European centers. *J Thorac Cardiovasc Surg* 2014;148:2838–43.
- Andreas M, Wallner S, Haberbauer A, Rath C, Schauperl M, Binder T *et al.* Conventional versus rapid-deployment aortic valve replacement: a single-centre comparison between the Edwards Magna valve and its rapid-deployment successor. *Interact CardioVasc Thorac Surg* 2016;22:799–805.
- Berretta P, Andreas M, Carrel TP, Solinas M, Teoh K, Fischlein T *et al.* Minimally invasive aortic valve replacement with sutureless and rapid deployment valves: a report from an international registry (Sutureless and Rapid Deployment International Registry). *Eur J Cardiothorac Surg* 2019;56:793–9.
- Laborde F, Fischlein T, Hakim-Meibodi K, Misfeld M, Carrel T, Zembala M *et al.* Clinical and haemodynamic outcomes in 658 patients receiving the Perceval sutureless aortic valve: early results from a prospective European multicentre study (the Cavalier Trial). *Eur J Cardiothorac Surg* 2016;49:978–86.
- Kocher A, Coti I, Laufer G, Andreas M. Minimally invasive aortic valve replacement through an upper hemisternotomy: the Vienna technique. *Eur J Cardiothorac Surg* 2018;53:ii29–31.
- Andreas M, Mahr S, Kocher A, Laufer G. Minimalinvasiver Aortenklappenersatz über eine anteriore rechtsseitige Thorakotomie. *Z Herz- Thorax- Gefäßchir* 2017;31:241–6.
- Brown ML, McKellar SH, Sundt TM, Schaff HV. Ministernotomy versus conventional sternotomy for aortic valve replacement: a systematic review and meta-analysis. *J Thorac Cardiovasc Surg* 2009;137:670–9.e5.
- Phan K, Xie A, Di Eusanio M, Yan TA. Meta-analysis of minimally invasive versus conventional sternotomy for aortic valve replacement. *Ann Thorac Surg* 2014;98:1499–511.
- Lamelas J, Mawad M, Williams R, Weiss UK, Zhang Q, LaPietra A. Isolated and concomitant minimally invasive minithoracotomy aortic valve surgery. *J Thorac Cardiovasc Surg* 2018;155:926–36.e2.
- Chang C, Raza S, Altarabsheh SE, Delozier S, Sharma UM, Zia A *et al.* Minimally invasive approaches to surgical aortic valve replacement: a meta-analysis. *Ann Thorac Surg* 2018;106:1881–9.
- Phan K, Xie A, Tsai YC, Black D, Di Eusanio M, Td Y. Ministernotomy or minithoracotomy for minimally invasive aortic valve replacement: a Bayesian network meta-analysis. *Ann Cardiothorac Surg* 2015;4:3–14.
- Semsroth S, Matteucci-Gothe R, Heinz A, Dal Capello T, Kilo J, Muller L *et al.* Comparison of anterolateral minithoracotomy versus partial upper hemisternotomy in aortic valve replacement. *Ann Thorac Surg* 2015;100:868–73.
- Di Eusanio M, Phan K, Berretta P, Carrel TP, Andreas M, Santarpino G *et al.* Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR): early results from 3343 patients. *Eur J Cardiothorac Surg* 2018;54:768–73.
- Di Eusanio M, Phan K, Bouchard D, Carrel TP, Dapunt OE, Di Bartolomeo R *et al.* Sutureless Aortic Valve Replacement International Registry (SU-AVR-IR): design and rationale from the International Valvular Surgery Study Group (IVSSG). *Ann Cardiothorac Surg* 2015;4:131–9.
- Akins CW, Miller DC, Turina MI, Kouchoukos NT, Blackstone EH, Grunkemeier GL *et al.* Guidelines for reporting mortality and morbidity after cardiac valve interventions. *Eur J Cardiothorac Surg* 2008;33:523–8.
- Borger MA, Moustafine V, Conradi L, Knosalla C, Richter M, Merk DR *et al.* A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement. *Ann Thorac Surg* 2015;99:17–25.
- Miceli A, Murzi M, Gilmanov D, Fuga R, Ferrarini M, Solinas M *et al.* Minimally invasive aortic valve replacement using right minithoracotomy is associated with better outcomes than ministernotomy. *J Thorac Cardiovasc Surg* 2014;148:133–7.
- Balmforth D, Harky A, Lall K, Uppal R. Is ministernotomy superior to right anterior minithoracotomy in minimally invasive aortic valve replacement? *Interact CardioVasc Thorac Surg* 2017;25:818–21.
- Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M *et al.* Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019;380:1695–705.
- Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D *et al.* Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med* 2019;380:1706–15.
- Fujita B, Ensminger S, Bauer T, Mollmann H, Beckmann A, Bekeredjian R *et al.*; for the GARY Executive Board. Trends in practice and outcomes from 2011 to 2015 for surgical aortic valve replacement: an update from the German Aortic Valve Registry on 42 776 patients. *Eur J Cardiothorac Surg* 2018;53:552–9.

- [22] Wahlers TCW, Andreas M, Rahmanian P, Candolfi P, Zemanova B, Giot C *et al.* Outcomes of a rapid deployment aortic valve versus its conventional counterpart: a propensity-matched analysis. *Innovations (Phila)* 2018;13:177–83.
- [23] Borger MA, Dohmen PM, Knosalla C, Hammerschmidt R, Merk DR, Richter M *et al.* Haemodynamic benefits of rapid deployment aortic valve replacement via a minimally invasive approach: 1-year results of a prospective multicentre randomized controlled trial. *Eur J Cardiothorac Surg* 2016;50:713–20.
- [24] Capelli C, Corsini C, Biscarini D, Ruffini F, Migliavacca F, Kocher A *et al.* Pledget-armed sutures affect the haemodynamic performance of biologic aortic valve substitutes: a preliminary experimental and computational study. *Cardiovasc Eng Tech* 2017;8:17–29.
- [25] Andreas M, Coti I, Rosenhek R, Shabanian S, Mahr S, Uyanik-Uenal K *et al.* Intermediate-term outcome of 500 consecutive rapid-deployment surgical aortic valve procedures. *Eur J Cardiothorac Surg* 2019;55:527–33.
- [26] Laufer G, Haverich A, Andreas M, Mohr FW, Walther T, Shrestha M *et al.* Long-term outcomes of a rapid deployment aortic valve: data up to 5 years. *Eur J Cardiothorac Surg* 2017;52:281–7.
- [27] Andreas M, Coti I, Laufer G, Kastner J. Valve-in-valve transcatheter aortic valve implantation into a novel, sutureless bioprosthesis: technical considerations. *EuroIntervention* 2018;13:1902–3.
- [28] Coti I, Schukro C, Drevinja F, Haberl T, Kaider A, Kocher A *et al.* Conduction disturbances following surgical aortic valve replacement with a rapid-deployment bioprosthesis. *J Thorac Cardiovasc Surg* 2020; doi: 10.1016/j.jtcvs.2020.01.083.