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ORIGINAL ARTICLE

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CONVENTIONAL VALVE OPERATIONS

Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR): early results from 3343 patients†

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Abstract

OBJECTIVES: The Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR) was established by a consortium of 18 research centres—the International Valvular Surgery Study Group (IVSSG)—to overcome limitations of the literature and provide adequately powered evidence on sutureless and rapid-deployment aortic valves replacement (SURD-AVR).

METHODS: Data from 3343 patients undergoing SURD-AVR over a 10-year period (2007–2017) were collected in the registry. The mean age of the patients was 76.8 ± 6.7 years, with 36.4% being 80 years or older. The average logistic EuroSCORE was 11.3 ± 9.7%.

RESULTS: Isolated SURD-AVR was performed in 70.7% ($n = 2362$) of patients using full sternotomy (35.3%) or less invasive approaches (64.8%). Overall hospital mortality was 2.1%, being 1.4% in patients who had isolated SURD-AVR and 3.5% in those who had concomitant procedures ($P < 0.001$). When considering baseline risk profile, mortality rate was 0.8% and 1.9% in low risk (logistic EuroSCORE <10%) isolated SURD-AVR and combined SURD-AVR, respectively, and 2.2% and 3.7% in higher risk patients (logistic EuroSCORE ≥10%). Postoperative neurological complications included stroke (2.8%) and transient ischaemic attack (1.1%). New atrioventricular block requiring pacemaker occurred in 10.4% of the patients. The rate of pacemaker implantation significantly decreased over time [from 17.2% (2007–2008) to 5.4% (2016); $P = 0.02$].

CONCLUSIONS: Our findings showed that SURD-AVR is a safe and effective alternative to conventional aortic valve replacement and is associated with excellent clinical outcomes. Further adequately powered statistical analyses from the retrospective and prospective SURD-IR will allow for the development of high-quality evidence-based clinical guidelines for SURD-AVR.

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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

INTRODUCTION

The sutureless concept of aortic valve implantation was developed in the early 60s. However, this approach was abandoned due to frequent valve-related thromboembolic complications and severe paravalvular leakage [1]. More recently, new sutureless, rapid-deployment aortic valve prostheses have been reintroduced based on modern experience with transcatheter aortic valve implantation (TAVI) and with the advent of bovine pericardial material for tissue valves. However, because of the limited number of cases and the short observational interval, the current literature on sutureless and rapid-deployment aortic valve replacement (SURD-AVR) is still scarce because the majority of the publications are retrospective and based on observational nature. In addition, heterogeneous definitions of clinical variables, insufficient reporting of postoperative outcomes and lack of robust follow-up data make the actual knowledge weak. To overcome these limitations and provide convincing evidence for SURD-AVR surgery, the Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR) was established by a consortium of 18 research centres—the International Valvular Surgery Study Group (IVSSG)—with the aim to evaluate the current management and outcomes of valvular surgery [2].

In this article, we report characteristics and hospital outcomes of the patients enrolled in the SURD-AVR Registry.

METHODS

Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry

The Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry was established in 2015 enrolling patients at 18 large referral centres in Europe, Australia and Canada (Supplementary Material, Fig. S1).

The study population was defined as patients undergoing SURD-AVR intervention using any available sutureless and rapid-deployment valve prosthesis either by conventional sternotomy or less invasive approach. Valve prosthesis types included Perceval S (Livanova PLC, London, UK) EDWARDS INTUITY/INTUITY Elite (Edwards Lifesciences, Irvine, CA, USA) and Enable 3F (Medtronic, MN, USA). Less invasive approaches involved ministernotomy and minithoracotomy.

Details of the site selection and invitation have been previously published [2]. Briefly, centres that had published reports on more than 50 SURD-AVR cases were initially invited to participate in the present database, as this was hypothesized to represent experienced centres with quality data collection. Further institutions recommended by the IVSSG Research Steering Committee were also invited to participate in the retrospective registry. Ethics approval was obtained at each of the participating centres, and datasets were submitted according to predefined spreadsheet format. Participating SURD-IR centres enrolled between 40 and 735 patients and collected information on demographics, patient comorbidities, functional status, imaging studies, surgical data, postoperative course, clinical and haemodynamic outcomes. Following electronic data submission, each dataset was evaluated to ensure that all patients were older than 18 years. All variables between datasets were assessed with identical variables collated into a centralized database. Isolated variables reported by less than 25% of centres were excluded from analysis. Individually missing data and centre-specific non-reported data were coded separately. Clinically important absent data were queried with the submitting centre. Data were analysed for clinical face validity and internal validity. Submitted clinical data were compared against published data for inconsistencies.

End points

More than 190 variables were collected for each patient. Variables of interest for the SURD-IR involved (i) 'clinical data' including age, sex, New York Heart Association (NYHA) class, CCS class, comorbidities, indications for surgery, baseline echocardiographic and haemodynamic data and patient history; (ii) 'risk assessment variables' including logistic EuroSCORE, EuroSCORE II, STS PROM risk and major organ system compromises; (iii) 'operative details' including surgical approach (full sternotomy, ministernotomy or minithoracotomy), concomitant procedures, type of prostheses, prostheses size, operative times [cardiopulmonary bypass (CPB) duration, cross-clamp time]; (iv) 'technical outcomes' including immediate procedural success (defined as successful first implant of the valve not requiring repeated cross-clamping), occurrence of first implant failure, valve migration/embolization, conversion to sutured aortic valve replacement (AVR), postimplantation aortic valve regurgitation, pressure valve gradients and (v) 'hospital outcomes' including mortality and cause of death, echocardiography and haemodynamic parameters, perioperative blood transfusion, postoperative complications (cardiac, renal, respiratory, neurological, infective, gastrointestinal and wound complications), cardiac and aortic valve reinterventions and duration of intensive care unit (ICU) and hospital stay. The definitions of the main variables are described in the Supplementary material, Appendix.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation and categorical variables as percentages. Where 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 using the χ^2 test. Normally distributed continuous data were compared using the unpaired *t*-test or 1-way analysis of variance as appropriate. The linear-by-linear association was used to evaluate linear trends across time groups. No imputation techniques were performed in this analysis as this is an explorative study. No formal adjustments were made for the multiple tests of significance. The level of significance, α, was set at 5% for this study.

Table 1: Patient demographics

	Frequency	Percentage
Male	1371/3338	41.1
Age (n = 3336), mean ± SD	76.8 ± 6.7	
NYHA class (n = 3072)		
I	201	6.5
II	1162	37.8
III	1540	50.1
IV	169	5.5
Hypertension	2219/2796	79.4
Diabetes	910/3060	29.7
Smoke	452/1818	24.9
BMI, mean ± SD	27.4 ± 4.8	
COPD	475/2891	16.4
Renal insufficiency	561/3032	18.5
Cerebrovascular disease	325/2524	12.9
Atrial fibrillation	392/2396	16.4
Previous pacemaker implantation	135/3121	4.3
Bicuspid aortic valve	115/2020	5.7
Pulmonary hypertension	634/1921	33
Cardiac reoperation	372/3343	11.1
CABG	38	1.1
AVR	136	4.1
Surgical indications		
Aortic valve stenosis	2233/3343	66.8
Aortic valve regurgitation	36/3343	1.1
Mixed aortic valve disease	1074/3343	32.1
Endocarditis	21/2680	0.8
Logistic EuroSCORE (%) (n = 2745), mean ± SD	11.3 ± 9.7	

AVR: aortic valve replacement; BMI: body mass index; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; NYHA: New York Heart Association; SD: standard deviation.

Table 2: Echocardiographic data

	Frequency	Percentage
LVEF (%), mean ± SD	57.7 ± 10.8	
>50	2471/3123	79.1
30–50	548/3123	17.5
<30	104/3123	3.3
Aortic valve area (cm^2) (n = 1150), median (IQR)	0.7 (0.6–0.8)	
Peak aortic valve gradient (mmHg) (n = 2105), mean ± SD	73.9 ± 31.3	
Mean aortic valve gradient (mmHg) (n = 2278), mean ± SD	46.3 ± 20.2	

IQR: interquartile range; LVEF: left ventricle ejection fraction; SD: standard deviation.

RESULTS

Patient demographics and risk profile

A total of 3343 patients undergoing SURD-AVR over a 10-year period between 2007 and 2017 were enrolled in the registry. The mean age was 76.8 ± 6.7 (range 25–94) years, with 36.4% being 80 years or older. Overall, 1371 of 3338 (41.1%) of cases were men and more than 50% of patients presented with advanced NYHA class symptoms (NYHA III 1540 of 3072, 50.1%; NYHA IV 169 of 3072, 5.5%). The indications for SURD-AVR were degenerative aortic stenosis in 2233 (66.8%) patients, aortic regurgitation in 36 (1.1%) patients and mixed aortic valve pathology (stenosis + regurgitation) in 1074 (32.1%) patients . Twenty-one of 2680 (0.8%) patients presented with active aortic valve endocarditis and 115 of 2020 (5.7%) presented with a bicuspid aortic valve. Three hundred and seventy-two (11.1%) patients had prior cardiac surgery [coronary artery bypass grafting (CABG) n = 38, 1.1%; AVR n = 136, 4.1%]. Demographics and baseline characteristics are listed in Table 1. Echocardiographic data revealed a reduced left ventricular function [left ventricular ejection fraction (LVEF) < 50%] in 652 of 3123 (20.9%) patients; mean aortic valve area was 0.76 cm^2 with peak and mean aortic valve gradient of 73.9 mmHg and 46.3 mmHg, respectively (Table 2).

The average logistic EuroSCORE of the study cohort was 11.3 ± 9.7%. When stratified by risk profile, nearly half of patients presented with increased surgical risk (n = 1169/2745, 42.6%) (logistic EuroSCORE ≥10%), when compared with 57.4% (1576 of 2745) of low risk (logistic EuroSCORE <10%).

Operative data and procedural outcomes

Isolated SURD-AVR was performed in 70.7% (2362 of 3340) of patients through full sternotomy (704 of 1993, 35.3%) or less invasive approaches (1289 of 1993, 64.7%). Of those who underwent minimally invasive AVR (MIAVR) upper ministernotomy was used in 55.4% (714 of 1288) and right anterior minithoracotomy in 44.6% (574 of 1288) of patients.

Concomitant procedures included CABG (712 of 3197, 22.3%), mitral and/or tricuspid valve surgery (160 of 2784, 5.7%), septal myectomy (67 of 2615, 2.6%), maze procedure (56 of 2730, 2.1%) and ascending aorta or root surgery (53 of 2666, 2%). Mean CPB and cross-clamp time were 87.3 ± 38.5 and 57.2 ± 28.7 min, respectively. For isolated SURD-AVR, mean cross-clamp time was 47.5 ± 22.9 min for full sternotomy approach, 49.9 ± 17.1 min for ministernotomy and 62.9 ± 23.1 min for minithoracotomy. Among 3343 patients in the study cohort, Perceval S was implanted in 2461 (73.7%) patients, EDWARDS INTUITY or INTUITY Elite in 757 (22.7%) patients and Enable 3F in 123 (3.7%) patients. Devices implantation was successful in 98.9% of patients. Valve migration/embolization and the intraoperative use of a different prosthesis occurred in 0.8% and 0.9% of cases, respectively. Prosthesis sizes and operative data are summarized in Tables 3 and 4, respectively.

Hospital outcomes

Overall hospital mortality was 2.1% (67 of 3222). It was 1.4% in patients who had isolated SURD-AVR and 3.5% in those who had concomitant procedures (P < 0.001). When considering the baseline risk profile, mortality rate was 1.1% in low-risk patients (logistic EuroSCORE <10%) when compared with 2.7% in patients at increased surgical risk (logistic EuroSCORE ≥10%) (Fig. 1). Moreover, in very low-risk patients (logistic EuroSCORE <5%), early mortality was 0.4% (n = 2 of 511) (Supplementary Material, Fig. S2). The main postoperative complications included bleeding requiring revision (97 of 2198, 4.4%), acute kidney injury (>Stage 1) (78 of 2169, 3.6%), respiratory failure (111 of 3343, 3.3%) and neurological dysfunction (99 of 2636, 3.8%) involving

Table 3: Valve prostheses: sizes and postoperative haemodynamics

	Frequency (%)	Peak gradient (mmHg), mean ± SD	Mean gradient (mmHg), mean ± SD
Perceval S	2461/3341 (73.7)	26.4 ± 10.5	14.1 ± 5.8
Small	317/2356 (13.5)	28.4 ± 10.3	15.1 ± 5.9
Medium	876/2356 (37.2)	27.6 ± 10.9	15 ± 6.1
Large	906/2356 (38.5)	25.5 ± 10.2	13.4 ± 5.4
Extra large	257/2356 (10.9)	23.5 ± 10.2	12.2 ± 5.3
EDWARS INTUITY/ INTUITY Elite	757/3341 (22.7)	21.9 ± 8.7	11.3 ± 4.9
19	74/748 (9.9)	34.3 ± 10.1	17.2 ± 5.2
21	210/748 (28.1)	22.7 ± 7	11.8 ± 4
23	242/748 (32.4)	20.9 ± 7.4	11 ± 4.9
25	163/748 (21.8)	19.6 ± 8.7	9.8 ± 4.4
27	59/748 (7.9)	17 ± 6.7	8.3 ± 3.4

SD: standard deviation.

Table 4: Operative data

	Frequency	Percentage
Isolated SURD-AVR	2362/3340	70.7
Full sternotomy	704/1993	35.3
Ministernotomy	714/1991	35.9
Minithoracotomy	574/1991	28.9
Concomitant procedures	978/3340	29.3
CABG	712/3197	22.3
Valve surgery (mitral/tricuspid)	160/2784	5.7
Septal myectomy	67/2615	2.6
Maze procedure	56/2730	2.1
Thoracic aorta surgery	53/2666	2
Valve type		
Perceval S	2461/3341	73.7
Intuity	757/3341	22.7
Enable 3F	123/3341	3.7
CPB time (min) (n = 3212), mean ± SD	87.3 ± 38.5	
Aortic cross-clamp time (min) (n = 3218), mean ± SD	57.2 ± 28.7	
Isolated AVR full sternotomy	47.5 ± 22.9	
Isolated AVR ministernotomy	49.9 ± 17.1	
Isolated AVR minithoracotomy	62.9 ± 23.1	
Combined AVR	75.6 ± 37.5	

AVR: aortic valve replacement; CABG: coronary artery bypass grafting; CPB: cardiopulmonary bypass; SD: standard deviation; SURD-AVR: sutureless and rapid-deployment aortic valve replacement.

stroke (75 of 2636, 2.8%) and transient ischaemic attack (24 of 2133, 1.1%) (Table 5). New atrioventricular block requiring pacemaker (PM) occurred in 10.4% (281 of 2710) of patients (Perceval 10.7%, INTUITY 8.4% and Enable 3F 17.1%). As time passed, the rate of PM implantation decreased from 17.2% to 5.4% (P = 0.02) (Fig. 2). Significant postoperative aortic regurgitation was observed in 26 of 1997 cases (1.3%), being moderate in 23 (1.2%) and severe in 3 (0.2%) cases. Over the study period, the overall aortic regurgitation rate (≥1+) significantly decreased from 17.2% to 6% (P < 0.001) (Fig. 3). Postoperative mean peak valve gradient was 25.3 ± 10.5 mmHg, and mean gradient was 13.3 ± 5.7 mmHg (Table 3).

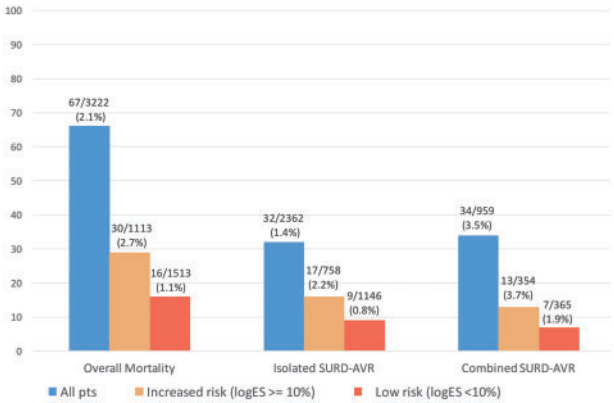

Figure 1: In-hospital mortality according to patient risk profile. logES: logistic EuroSCORE; pts: patients; SURD-AVR: sutureless and rapid-deployment aortic valves replacement.

Table 5: Postoperative morbidity

	Frequency	Percentage
Ventilatory support >72 h	111/3343	3.3
New onset atrial fibrillation	723/2648	27.3
New AV block requiring pacemaker	281/2710	10.4
Bleeding requiring revision	97/2198	4.4
Acute kidney injury (>Stage 1)	78/2169	3.6
Dialysis	33/1811	2.2
Neurological dysfunction	99/2636	3.8
Transient ischaemic attack	24/2133	1.1
Stroke	75/2636	2.8
Wound complications	49/1804	2.7
ICU stay (days) (n = 2235), median (IQR)	1 (1–3)	
Hospital stay (days) (n = 2818), median (IQR)	9 (7–14)	

AV: atrioventricular; ICU: intensive care unit; IQR: interquartile range.

DISCUSSION

SURD-IR is the first international independent registry enrolling patients undergoing SURD-AVR using any available sutureless and rapid-deployment valve prosthesis at large referral centres. It is currently the largest worldwide registry for sutureless and rapid-deployment valves and represents a unique opportunity to analyse contemporary data on the characteristics, haemodynamic profiles and safety and efficacy outcomes of patients undergoing SURD-AVR by minimizing the inherent biases observed in small surgical registries or single-centre series.

The SURD-IR study cohort consisted of near octogenarians (mean age 77 years, 36.4% of patients older than 80 years) with a considerable burden of comorbidities that translated into a mean logistic EuroSCORE of 11.3%, which was consistent with an increased surgical risk [3]. Despite this high-risk profile, SURD-AVR was associated with excellent operative and clinical outcomes. Overall hospital mortality was 2.1%, being 1.4% and 3.5% in patients undergoing isolated and combined SURD-AVR, respectively. Our results compare favourably with those reported in conventional AVR and TAVI registries both in low- and increased-risk patients [4–6]. When stratified according to risk profile, early

mortality was 0.8% and 1.9% in low risk (logistic EuroSCORE <10%) isolated SURD-AVR and combined SURD-AVR and 2.2% and 3.7% in increased risk patients (logistic EuroSCORE ≥10%), respectively. Moreover, in very low-risk patients (logistic EuroSCORE <5%), the mortality rate was outstandingly low (0.4%). In this setting, the German Aortic Valve Registry (GARY) showed comparable 30-day mortality in low-risk patients undergoing isolated (1.5%) or combined AVR (2.7%) [4]. However, reported early mortality was considerably higher in low-risk TAVI patients (3.7%) and in patients at increased risk (logistic EuroSCORE 10–20%) undergoing isolated AVR (3.7%), combined AVR (5.1%) and TAVI (4.1%) [4].

During heart valve surgery, prolonged CPB and cross-clamp times are strong predictors for early mortality and major postoperative complications. This harmful effect further increases when surgery is performed in elderly or high-risk patients [7]. Sutureless and rapid-deployment prostheses, which do not require placement and tying of sutures, have been associated with considerably reduced procedural times and improved surgical outcomes [8–13]. In SURD-IR, CPB and cross-clamp times were significantly shorter than those reported in the Society of Thoracic Surgeons (STS) database, both in overall isolated AVR (79 and 51 min vs. 106 and 78 min) and combined AVR + CABG (106 and 72 min vs 147 and 112 min).

Because of the simplified handling and the quicker deployment, SURD-AVR remarkably facilitates minimally invasive approaches [10]. This finding is confirmed by the observation possible with the present registry, with almost two-thirds of isolated AVRs performed through a less invasive approach. As reported by others [11, 12, 14], the high rate of minimally invasive approaches did not significantly impact the overall CPB and cross-clamp times, which were 80 and 50 min, for ministernotomy and 97 and 64 min for minithoracotomy, respectively.

SURD-AVR has been associated with better haemodynamic performances when compared with conventional valves [12, 14–20]. In SURD-IR, the mean and peak valve gradients were 13 and 25 mmHg, respectively. These gradients may still appear a bit higher than expected, but this has to do with the predominantly small to medium-sized annular diameter (19–23 mm) of our patients.

Concern exists regarding the increased incidence of conduction disorders following SURD-AVR [14, 21, 22]. In the population of the registry, the overall PM implantation rate was 10.4%. This may be related in part to the high-risk profile of the patients and with subclinical preoperative conduction disorders [23, 24]. Unfortunately, data on preoperative conduction abnormalities collected in the registry were insufficient, precluding adequately powered conclusions. In addition, the threshold for postoperative PM implantation may have been different between the centres. However, it has been suggested that the principal cause may be the 'learning curve effect' in terms of procedural implanting steps and mainly sizing. In this setting, several authors have proposed simple technical modifications of valve implantation technique to prevent conduction disorders [25, 26]. In the SURD-IR study cohort, indeed, the rate of PM implantation diminished significantly over the study period, from 17.2% to 5.4% ($P = 0.002$), (Fig. 2). This compares satisfactorily with the rates reported for sutured AVR and TAVI [27]. Finally, the 'learning curve effect' significantly influenced the incidence of aortic regurgitation as well. Indeed, the rate and the severity of postoperative aortic insufficiency decreased significantly over time (Fig. 3).

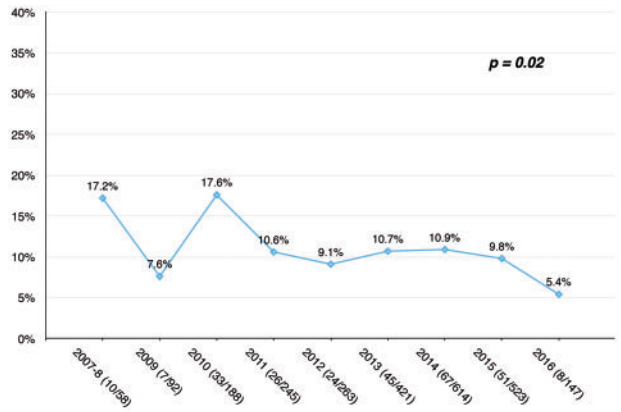

Figure 2: Pacemaker implantation rate over the years.

Limitations

This study has limitations of any observational registry involving no adjudication of patient inclusion and data collection and the lack of comparative arms, which does not allow powerful conclusions on the risk–benefit regarding the different prostheses used and the surgical approaches. Because of the retrospective nature of the registry, no VARC II criteria [28] were used for events adjudication. Moreover, there is no core laboratory to review images yet, and the investigators are responsible for data reporting from their own institutions. However, the SURD-IR is the largest and the only

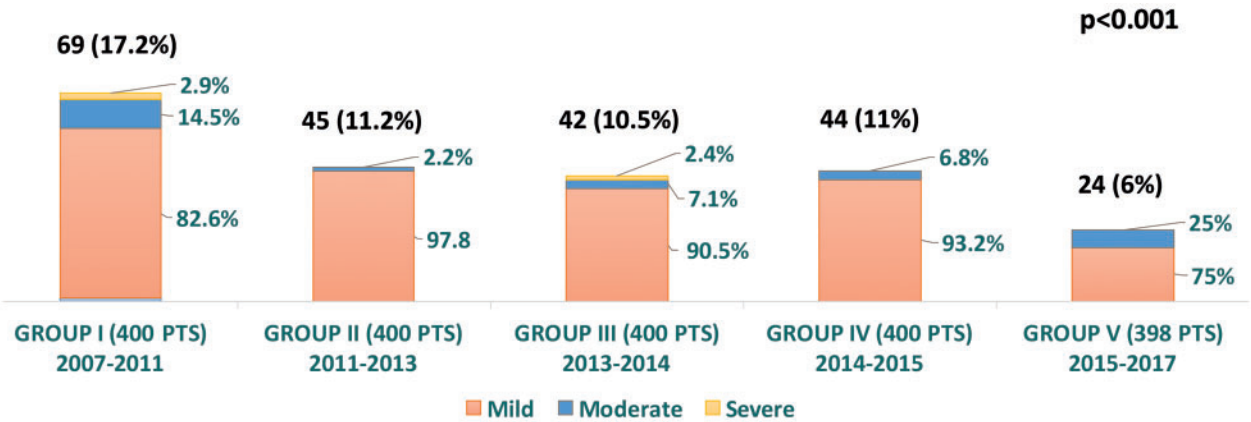

Figure 3: Aortic regurgitation rate over the study period. PTS: patients.

independent SURD-AVR registry, including all available sutureless and rapid-deployment valves. Thus, it reflects a 'real-world' scenario and gives a valuable opportunity to assess this new technology.

CONCLUSIONS

With more than 3300 patients enrolled, the SURD-AVR International Registry is currently the largest worldwide registry on sutureless, rapid-deployment aortic valves that provides a real-world picture of SURD-AVR surgery. This article confirms that SURD-AVR is a safe and efficacious alternative to conventional AVR with excellent clinical outcomes. SURD-AVR may have the potential to become the new gold standard treatment for aortic valve surgery: when compared with conventional AVR, SURD-AVR may facilitate less invasive approaches, allow shorter operative times and provide satisfactory haemodynamic results. We believe that more powered statistical analyses will give more and better evidence with this type of prostheses and may help to find a place for SURD-AVR in the valvular guidelines.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

Conflict of interest: Martin Andreas is a proctor for Edwards Lifesciences and Advisory Board Member for Medtronic, Inc. Thierry A. Folliguet is in charge of "PERSIST-AVR" Trial as investigator. Carmelo Mignosa is a consultant/proctor for LivaNova. Alberto Albertini receives consulting and lecture fees from LivaNova.

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