Early and Mid-Term Results of Rapid Deployment Valves: The Intuity Italian Registry (INTU-ITA)

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Background. **Rapid deployment bioprostheses (RDBs) have been recently introduced into clinical practice for the treatment of severe aortic valve stenosis. The aim of this retrospective multicenter study was to assess early and mid-term clinical and hemodynamic outcomes of patients undergoing RDB implantation.**

Methods. **Data from a national registry that included patients who underwent isolated or combined aortic valve replacement with RDB in Italy were analyzed. Definitions of the European System for Cardiac Operative Risk Evaluation were used for preoperative variables and updated definitions from the Valve Academic Research Consortium were used for postoperative outcomes assessment. Univariable and multivariable analyses were performed to identify independent predictors of mortality. Follow-up was performed with clinical and echocardiographic examinations at each study site and, if this was not possible, through telephonic interviews. The Kaplan-Meier method was used for survival analysis.**

Results. **A total of 902 patients (December 2012 through November 2017) from 20 national centers were included in the registry. Device success was 95.9%, and 30-day all-cause mortality was 2.8%. Postoperative pacemaker implantation was needed in 63 patients (6.9%). At discharge, peak and mean transaortic gradients were 19 ± 7 mm Hg and 11 ± 4 mm Hg, respectively. Mild and moderate aortic regurgitation were found in 71 patients (8.2%) and in 10 patients (1.2%), respectively. Median follow-up time was 357 days (interquartile range: 103 to 638 days). Survival at 4 years was 86% ± 1%. Preoperative conduction disturbances and history of previous myocardial infarction were independently associated with mortality.**

Conclusions. **Aortic RDBs provide good early and mid-term clinical and hemodynamic outcomes. These devices may be considered as a reasonable alternative to conventional bioprostheses, especially in minimally invasive and combined operations.**

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Although transcatheter aortic valve replacement (TAVR) is rapidly growing and is now approved also in intermediate-risk patients [1], surgical aortic valve replacement (SAVR) is still the procedure of choice in low-risk patients and in patients who need concomitant procedures [2, 3]. Among the several aortic valve substitutes available for SAVR, rapid deployment (RDBs) and sutureless (SLBs) bioprostheses have been recently introduced into clinical practice [4, 5] for the treatment of patients with severe aortic valve stenosis. The aim was to reduce aortic cross-clamp and cardiopulmonary bypass times and to facilitate minimally invasive procedures because they do not require the typical set of annular sutures to be implanted but three guiding sutures at the nadir of each sinus for correct annular placement [6]. After RDB implantation, the three guiding sutures are tied down, and for this reason they cannot be truly defined as sutureless devices. The only commercially available rapid deployment device is the Intuity (and its evolution Intuity Elite) valve system (Edwards Lifesciences, Irvine, CA). The aim of this multicenter retrospective study was to evaluate early and mid-term clinical and hemodynamic outcomes of patients undergoing rapid deployment aortic valve replacement (RDAVR).

Patients and Methods

The INTU-ITA Registry

In this study, we analyzed data from the Italian Registry of the Intuity Valve (INTU-ITA). The INTU-ITA is a real-world, all-comers independent multicenter registry that includes all patients who underwent isolated or combined RDAVR with the Edwards Intuity (and its evolution Intuity Elite) at participating centers. In particular, the INTU-ITA registry includes 902 patients from 20 Italian cardiac surgical institutions from October 2012 through November 2017. The list of participating centers, the number of patients enrolled in each center, and the enrollment period is shown in the Supplemental Table. Because the Intuity valve is not approved for aortic insufficiency, all patients included in the registry underwent SAVR for severe aortic valve stenosis. Data were collected at each study site and then anonymously sent to the University of Padova (coordinating center) for storage and analysis. The study was approved by the ethic committee, and patients' informed consent for the procedure and for data collection for scientific purposes was always collected.

Surgical Operation

All procedures were performed under general anesthesia through full sternotomy, mini-sternotomy (inverted T or J-shape), or right anterior thoracotomy according to the preference of implanting surgeons and to the policy of each single center. The Edwards Intuity aortic valve system is built on the Carpentier-Edwards Perimount platform (three bovine pericardial leaflets) with a subanular balloon-expandable skirt, similar to a transcatheter valve stent, that serves both for anchoring and sealing. The implanting technique has already been extensively described [6]. Briefly, after aortic cross-clamp and aortotomy the degenerated aortic valve was excised and the aortic annulus was decalcified. Then three guiding sutures (generally 2-0, braided) are passed at the nadir of each sinus and subsequently on the valve sewing ring. The valve is parachuted into the aortic annulus and stabilized with three tourniquets. Then the balloon is inflated for 10 seconds by using the manometer as a reference. The delivery system is then removed, and the three guiding sutures are tied before closing the aortotomy.

Definitions and Follow-Up

Preoperative variables were defined according to the European System for Cardiac Operative Risk Evaluation (EuroSCORE) definitions [7], and postoperative outcomes were defined according to the updated Valve Academic Research Consortium (VARC-2) definitions [8]. We decided to use VARC definitions to allow easy comparison between these data and those of TAVR. Patients underwent clinical and echocardiographic assessment at the study site before the operation, at hospital discharge, and then according to each center's protocol (that usually included a clinical and echocardiographic assessment at the study site on a yearly basis), mainly with follow-up visits at the study site or by using telephone interviews. The last census date was December 31, 2017.

Statistical Analysis

For continuous variables, data are reported as mean with SD or as median and first and third quartile. For categorical variables, data are reported as frequency and percentage. A univariable analysis was performed to test which covariates would be considered in a further multivariable analysis. Comparison between groups for continuous variables was performed with t test or Wilcoxon-Mann-Whitney test according to type of distribution; comparison between groups for categorical variables was performed with χ^2 or Fisher exact test as appropriate; for paired categorical variables we used McNemar test. Clinically significant variables were then entered in the model; we chose the variables with a 0.2 significance level. Cox proportional hazard regression analysis was performed to identify independent predictors of mortality at follow-up, which are reported as hazard ratios (HRs), 95% confidence intervals (CIs), and p values. Cumulative survival was estimated with the Kaplan-Meier method. All statistical tests were two-sided, and p values of 0.05 or less were considered statistically significant. Statistical analyses were conducted with IBM SPSS Statistics, version 19 (SPSS, Inc, Chicago, IL).

Results

Study Population

The study population included 902 patients enrolled in the INTU-ITA registry from October 2012 through November 2017. Preoperative variables are shown in Table 1. Mean age was 74 ± 7.7 years; mean Logistic EuroSCORE, EuroSCORE II, and The Society of Thoracic

Table 1. Preoperative Variables (n = 902 patients)

Variable	Value
Sex	
Female	454 (50.3)
Male	448 (49.7)
Age, years	74 ± 7.7
Arterial hypertension	717 (79.5)
Dyslipidemia	450 (49.9)
Diabetes mellitus	202 (22.3)
Insulin dependent	56 (6.2)
Serum creatinine, mg/dL	1.04 ± 0.72
Serum creatinine ≥ 2 mg/dL	16 (1.8)
Glomerular filtration rate, $mL \cdot min^{-1} \cdot 1.73^{-2}$	68.4 ± 25.4
Glomerular filtration rate ≤ 50 $mL \cdot min^{-1} \cdot 1.73^{-2}$	168 (18.6)
Long-term dialysis	4 (0.4)
Peripheral vascular disease	143 (15.9)
Chronic obstructive pulmonary disease	115 (12.8)
Neurologic dysfunction	24 (2.7)
Previous cardiac operation	47 (5.2)
Aortic valve replacement	21 (2.3)
CABG	9 (1.0)
Mitral replacement/repair	(0.8)
Aortic valve and root replacement	3 (0.3)
Valve-sparing	2 (0.2)
Ascending aortic replacement	1 (0.1)
Subaortic membrane resection	1 (0.1)
Aortic valve and ascending aortic replacement	1 (0.1)
Aortic valve replacement and CABG	1 (0.1)
Balloon aortic valvuloplasty	1 (0.1)
Previous acute myocardial infarction	
<90 days	28 (3.1)
≥90 days	49 (5.4)
History of coronary artery disease	315 (34.9)
Cardiac rhythm	
Sinus rhythm	757 (83.9)
Permanent atrial fibrillation	88 (9.8)
Paroxysmal atrial fibrillation	27 (3.0)
Pacemaker	30 (3.3)
New York Heart Association functional class	
Class I	69 (7.6)
Class II	400 (44.4)
Class III	395 (43.8)
Class IV	38 (4.2)
Logistic EuroSCORE	8.0 ± 8.1
EuroSCORE II	3.0 ± 3.1
STS-PROM	2.4 ± 1.8

Values are n (%) or mean ± SD.

CABG = coronary artery bypass grafting; EuroSCORE = European System for Cardiac Operative Risk Evaluation; STS-PROM = The Society of Thoracic Surgeons-Predicted Risk of Operative Mortality.

Surgeons (STS) Predicted Risk of Operative Mortality scores were 8.0% ± 8.1%, 3.0% ± 3.1%, and 2.4% ± 1.8%, respectively. The New York Heart Association (NYHA) functional class was III or IV in 433 patients (48%).

Table 2. Preoperative Echocardiographic Data (n = 902 patients)

Variable	Value
Peak aortic gradient, mm Hg	78 ± 24
Mean aortic gradient, mm Hg	49 ± 15
Indexed aortic valve area, cm^2/m^2	0.43 ± 0.12
Aortic regurgitation	
Mild	276 (30.6)
Moderate	134 (14.9)
Severe	60 (6.7)
Left ventricular ejection fraction, %	59 ± 10

Values are mean ± SD or n (%).

Baseline echocardiographic data are shown in Table 2; mean transaortic gradient was 49 ± 15 mm Hg.

Operative Data

Operative data are listed in Table 3. The second-generation Intuity Elite was implanted in the majority of patients (70.6%). A minimally invasive operation was performed in 40% of patients, mainly mini-sternotomy (37.9%). Combined procedures were done in 310 patients (34.4%), and of these most were coronary artery bypass grafting. In isolated AVR, median cardiopulmonary bypass (CPB) and aortic cross-clamp (ACC) times were 83 and 64 minutes, respectively. Interestingly, median CPB and ACC durations were similar between full sternotomy (CPB: 81 minutes, ACC: 56 minutes) and mini-sternotomy (CPB: 82 minutes, ACC: 58 minutes), whereas patients undergoing mini-thoracotomy had longer median operative times (CPB: 116 minutes, ACC: 80 minutes). Intraoperative complications are listed in Table 4. Device success was 95.9% (865 patients). Causes of no device success in 37 patients are listed in Table 4. Severe aortic regurgitation after Intuity deployment occurred in 18 patients (2%); in 12 patients, the RD valve was removed, and a standard stented bioprosthesis was implanted; in 4 patients the Intuity valve was successfully repositioned, and in 2 patients extra stitches were positioned to close the leak. Immediate procedural mortality, defined according to VARC-2 definitions [8] as mortality occurring within 72 hours from the procedure, occurred in 8 patients (0.9%). Causes of immediate procedural mortality were sudden cardiac death in 4 patients, multiple organ failure in 2 patients (1 with acute myocardial infarction, life-threatening bleeding, and acute kidney injury (AKI) in the immediate postoperative period; the other with stroke, bleeding, and vascular complications), pneumonia in 1 patient, and septic shock in 1 patient Of 362 minimally invasive approaches, 10 patients (2.8%) were converted to full sternotomy due to the occurrence of an intraoperative complication.

Early Postoperative Clinical and Hemodynamic Outcomes

Early postoperative outcomes are shown in Table 5. VARC all-cause mortality (within 30 days or during index

Table 3. Operative Variables (n = 902 patients)

Variable	Value
Prosthesis type	
Intuity	265 (29.4)
Intuity Elite	637 (70.6)
Prosthesis diameter	
19 mm	127 (14.1)
21 mm	283 (31.4)
23 mm	271 (30.0)
25 mm	169 (18.7)
27 mm	52 (5.8)
Surgical access	
Full sternotomy	540 (59.9)
Mini-sternotomy	342 (37.9)
Mini-thoracotomy	20 (2.2)
Combined procedures	310 (34.4)
CABG	208 (23.1)
Mitral replacement/repair	32 (3.5)
Ascending aortic replacement	15 (1.7)
Others	55 (6.1)
Cardiopulmonary bypass time, minutes	90 (70–120)
Isolated AVR	83 (65–103)
Full sternotomy	81 (65–100)
Mini-sternotomy	82 (64-–102)
Mini-thoracotomy	116 (90–158)
Combined procedures	120 (90–145)
Aortic cross-clamping time, minutes	64 (50–95)
Isolated AVR	57 (45–73)
Full sternotomy	56 (45–71)
Mini-sternotomy	58 (45–73)
Mini-thoracotomy	80 (68–112)
Combined procedures	86 (67–108)

Values are n (%) or mean (interquartile range).

AVR = aortic valve replacement; CABG = coronary artery bypass grafting.

Table 4. Intraoperative Complications (n = 902 patients)

Intraoperative Complications	No. (%)
VARC device success	865 (95.9)
No device success	37 (4.1)
Immediate procedural mortality (≤72 hours from the procedure)	8 (0.9)
Not correct positioning of a single prosthesis (without death)	16 (1.8)
Not intended performance of the prosthetic valve	13 (1.4)
Moderate PVL	10 (1.1)
Mean gradient > 20 mm Hg	3 (0.3)
Substantial paravalvular regurgitation	18 (2.0)
PVL closure with extra annular stitches	2 (0.2)
Prosthesis repositioning	4 (0.5)
Prosthesis replacement	12 (1.3)
New Intuity prosthesis	2 (0.2)
Stented prosthesis	10 (1.1)
Full sternotomy conversion	10 (2.8)
362 minimally invasive approaches	
Intra-aortic balloon pump	3 (0.3)
Extracorporeal membrane oxygenation	1 (0.1)
Aorto-ventricular junction rupture	1 (0.1)
Brachiocephalic artery lesion	1 (0.1)
Aortic root injury and urgency right coronary CABG	1 (0.1)
Left atrial lesion	1 (0.1)

CABG = coronary artery bypass grafting; PVL = paravalvular leak; VARC = Valve Academic Research Consortium.

procedure hospitalization if the postoperative length of stay was longer than 30 days) was 2.8% (25 patients) and cardiovascular mortality was 2.2% (20 patients). Causes of VARC mortality were immediate procedural mortality in 8 patients (see "Operative Data" section), multiple organ failure in 9 patients, respiratory insufficiency (including pneumonia) in 4 patients, low-output syndrome due to postoperative cardiac failure in 2 patients, stroke in 1 patient, and sudden cardiac death in 1 patient. The incidence of acute myocardial infarction, stroke, life-threatening bleeding, and severe AKI (stage 3) was 0.6%, 0.8%, 6%, and 3.3%, respectively. A permanent pacemaker implantation for new-onset conduction disturbances was needed in 63 patients (6.9%). At discharge, peak and mean transaortic gradients were 19 ± 7 mm Hg and 11 ± 4 mm Hg, respectively. Mild and moderate aortic regurgitation were found in 71 patients (8.2%) and in 10 patients (1.2%), respectively. Echocardiographic data at discharge are depicted in Table 6, and echocardiographic data according to valve size are shown in Table 7.

Clinical and Echocardiographic Outcomes at Follow-Up

Median follow-up time was 357 days (IQR: 103 to 638 days). We observed a low incidence (approximately 1%) of valve-related complications, as shown in Table 8. In particular, we recorded four prosthetic endocarditis (0.5%) with one reoperation and three reoperations for severe aortic regurgitation (0.3%). Kaplan-Meier survival at 4 years was 86% ± 1% (Fig 1). We observed a statistically significant and stable reduction of mean aortic gradients and an increase of aortic valve area at follow-up, if compared with preoperative values (Fig 2). Of the 71 patients with mild aortic regurgitation at discharge, 39 patients (54.9%) underwent echocardiographic control at 1 year that showed no changes in 20 patients (51.3%), no more aortic regurgitation in 18 patients (46.2%), and progression to moderate aortic regurgitation in 1 patient (2.5%). Of the 10 patients with moderate aortic regurgitation at discharge, 3 patients underwent echocardiographic control at 1 year (30%) that showed no changes in 1 patient (33.3%), mild aortic regurgitation in 1 patient (33.3%), and progression to severe aortic regurgitation in 1 patient (33.3%). Furthermore, we observed a statistically significant improvement in NYHA functional class at follow-up compared with the preoperative period (Fig 3). The multivariable analysis identified as independent predictors of mortality at follow-up were the following variables: preoperative conduction disturbances (HR 2.9,

Table 5. Postoperative Outcomes (n = 902 patients)

Variable	Value
ICU stay, hours	48 (24–72)
Hospital stay, days	8 (7–11)
VARC all-cause mortality	25 (2.8)
VARC cardiovascular mortality	20 (2.2)
VARC acute myocardial infarction	5 (0.6)
VARC major stroke	7 (0.8)
VARC life-threatening bleeding	54 (6.0)
Pacemaker implantation	63 (6.9)
New onset atrial fibrillation	268 (29.7)
VARC acute kidney injury	58 (6.4)
Stage 1	10 (1.1)
Stage 2	18 (2.0)
Stage 3	30 (3.3)

Values are median (interquartile range) or n (%).

ICU = intensive care unit; VARC = Valve Academic Research Consortium.

Table 6. Echocardiographic Data at Discharge

Variable	Patients Discharged With Intuity Prosthesis (n = 869)
Peak aortic gradient, mm Hg[a]	19 ± 7
Mean aortic gradient, mm Hg[b]	11 ± 4
Indexed aortic valve area, cm^2/m^{2c}	1.12 ± 0.34
Patient–prosthesis mismatch (EOAi ≤ 0.85)[c]	57 (18.4)
Severe patient–prosthesis mismatch (EOAi < 0.65)[c]	7 (2.3)
Aortic regurgitation	
Mild	71 (8.2)
Moderate	10 (1.2)
Severe	0 (0)
Left ventricular ejection fraction, %	59 ± 10

[a] n = 745 patients. [b] n = 789 patients. [c] n = 310 patients.

Values are mean ± SD or n (%).

EOAi = effective orifice area index.

95% CI: 1.027 to 8.002, $p = 0.0444$) and history of previous myocardial infarction (HR 5.129, 95% CI: 1.487 to 17.895, $p = 0.0097$).

Comment

After the introduction into clinical practice of SLBs and of RDBs, the portfolio of aortic valve substitutes available for the treatment of patients with severe aortic valve stenosis has now a new option that enables surgeons to implant an aortic valve prosthesis through a surgical access but with no need for annular sutures. The two available prostheses are the SLB Perceval (Livanova, London, UK) and the RDB Intuity (Edwards Lifesciences). The former is made of a self-expanding nitinol stent with bovine pericardial leaflets, the latter is built on the Perimount Magna Ease valve platform with a subanular balloon-expandable stent derived from the Sapien TAVR device. Although these two prostheses have a different design and a slightly different implantation technique, the ultimate goal of both devices is to reduce surgical time (especially during combined operations) and to facilitate minimally invasive procedures. This study is based on data from the INTUITA and, to the best of our knowledge, to date is the study with the highest number of enrolled patients undergoing Edwards Intuity RDB implantation worldwide. When talking about RDB there are mainly three aspects that are worth discussing: (1) surgical times, (2) hemodynamic performance (gradients and paravalvular leaks [PVLs]), and (3) pacemaker implantation rate. Durability of course is another crucial aspect, but it is definitely too early because longer follow-up times are needed to obtain reliable data about the Intuity valve. In our study population, 40% of patients underwent minimally invasive AVR due to the rapidity and ease of valve deployment; of these most (37.9%) were done through mini-sternotomy and just a few through right anterior thoracotomy. Surgical times were similar between the full and mini-sternotomy but they were substantially longer in the mini-thoracotomy. In our analysis, median ACC time and CPB times for isolated RDAVR through full sternotomy were 56 and 81 minutes, respectively. These values are shorter than those reported in the STS database [9] for conventional surgical AVR (78 and 106 minutes, respectively) but are longer than those reported in other studies with the Intuity valve. In fact, in the Efficacy and Safety of Initial Triple Versus Dual Oral Combination Therapy in Patients With Newly Diagnosed Pulmonary Arterial Hypertension (TRITON) trial [6] cross-clamp and CPB times were 41 and 66 minutes, respectively, and in the Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement (TRANSFORM) trial [10] they were 44 and 69 minutes, respectively. This difference, approximately 10 to 15 minutes, may be due to the real world all comers and observational nature of this study and to the variability of the number of patients enrolled in each center. Another possible explanation is that 40% of the participating centers of our registry are teaching institutions with residents and fellows. Under the hemodynamic point of view our data show a good performance of all sizes of RDB (see Supplemental Table). Overall mean transvalvular gradient at discharge was 11 mm Hg with an indexed aortic valve area of 1.12 cm^2/m^2. Looking at small valve sizes, 19 and 21 mm, we found at discharge a mean gradient of 14 and 11 mm Hg, respectively. These values are consistent with those reported in the TRITON trial [6] and also by Theron and colleagues [11] who reported mean gradients at 30 days for the 19- and the 21-mm RDB of 15 and 12 mm Hg, respectively. We also found a good stability of hemodynamic variables during follow-up, confirming the 5-year data analysis from the TRITON trial [12] that, although no splitting according to valve size was done, showed no variance of hemodynamic behavior of the Intuity valve over time. Furthermore, Andreas and colleagues [13] found significant

Table 7. Echocardiographic Data According to Valve Size

Variable	19 mm (n = 127)	21 mm (n = 276)	23 mm (n = 268)	25 mm (n = 169)	27 mm (n = 52)
Indexed aortic valve area, cm^2/m^2					
Baseline (n = 621)	0.43 ± 0.12	0.43 ± 0.11	0.43 ± 0.11	0.43 ± 0.12	0.43 ± 0.12
Discharge (n = 310)	0.83 ± 0.14	0.98 ± 0.27	1.16 ± 0.36	1.20 ± 0.33	1.32 ± 0.33
1-year follow-up (n = 146)	0.84 ± 0.20	0.96 ± 0.22	1.10 ± 0.31	1.27 ± 0.36	1.24 ± 0.26
2-year follow-up (n = 25)	1.00 ± 0.05	1.09 ± 0.23	1.29 ± 0.48	1.27 ± 0.45	1.21 ± 0.23
3-year follow-up (n = 59)	1.00 ± 0.16	1.07 ± 0.26	1.10 ± 0.22	1.20 ± 0.24	1.10 ± 0.25
4-year follow-up (n = 40)	1.01 ± 0.21	1.11 ± 0.19	1.05 ± 0.25	1.23 ± 0.12	…
Mean transvalvular gradient, mm Hg					
Baseline (n = 853)	50 ± 15	50 ± 16	48 ± 16	46 ± 13	45 ± 16
Discharge (n = 789)	14 ± 5	11 ± 4	10 ± 4	9 ± 3	9 ± 3
1-year follow-up (n = 323)	13 ± 4	10 ± 4	10 ± 4	8 ± 3	8 ± 3
2-year follow-up (n = 74)	11 ± 5	9 ± 3	9 ± 5	9 ± 3	6 ± 1
3-year follow-up (n = 74)	11 ± 4	8 ± 4	7 ± 2	8 ± 3	8 ± 4
4-year follow-up (n = 45)	9 ± 4	9 ± 5	6 ± 2	5 ± 2	…
Peak transvalvular gradient, mm Hg					
Baseline (n = 820)	83 ± 25	82 ± 25	76 ± 22	74 ± 21	70 ± 26
Discharge (n = 745)	24 ± 8	20 ± 7	18 ± 7	16 ± 6	16 ± 5
1-year follow-up (n = 308)	22 ± 7	19 ± 6	18 ± 6	15 ± 5	15 ± 6
2- year follow-up (n = 72)	20 ± 9	15 ± 5	17 ± 8	17 ± 5	11 ± 3
3-year follow-up (n = 73)	19 ± 5	14 ± 5	12 ± 4	16 ± 6	17 ± 5
4-year follow-up (n = 40)	16 ± 5	13 ± 4	12 ± 4	12 ± 5	…

Values are mean ± SD.

lower gradients in the Intuity valve if compared with its stented version, the Magna Ease valve (16 mm Hg versus 14 mm Hg, $p = 0.025$). A possible explanation of the improved hemodynamics with the rapid deployment valves is the lack of pledget material obstructing the left ventricular outflow tract (LVOT) together with the LVOT expansion due to the balloon-expandable skirt. Because the Intuity valve has an anchoring and sealing system similar to that of the balloon-expandable transcatheter aortic valve, one of the main concerns about the incidence of PVL. In fact, PVL has been demonstrated to have a significant impact on patients' survival in TAVR populations [14]. In our analysis, we observed substantial intraoperative PVLs that required repositioning of the RDB in 4 patients and implantation of a new device in 12 patients. In our experience, one of the most common causes of severe PVLs after Intuity implantation is wrong valve sizing; a smaller valve will not provide a proper annular sealing, a bigger valve will not fit into the annulus and consequently pop-up toward the ascending aorta with the three tied guiding sutures that prevent it from true embolization. At discharge, we observed mild and moderate PVLs in 8.2% and 1.2% of patients, respectively. These PVL rates are lower than those reported for TAVR. In the Sapien-3 high-risk cohort of the Placement of AoRTic TraNscathetER Valves (PARTNER 2) trial researchers reported mild and moderate PVL rates of 29.1% and 2.7%, respectively [15], whereas data from the

Table 8. Clinical Outcomes at Follow-Up (n = 877 patients)

Variable	No. (%)
All-cause late mortality	50 (5.7)
Cardiovascular mortality	31 (3.5)
Hemorrhage	3 (0.3)
Thromboembolism	7 (0.8)
Stroke	5 (0.6)
Acute myocardial infarction	5 (0.6)
Heart failure	13 (1.5)
Arrhythmia	10 (1.1)
Endocarditis	4 (0.5)
Reoperation for endocarditis	1 (0.1)
Reoperation for aortic regurgitation	3 (0.3)
Late pacemaker implantation	11 (1.3)

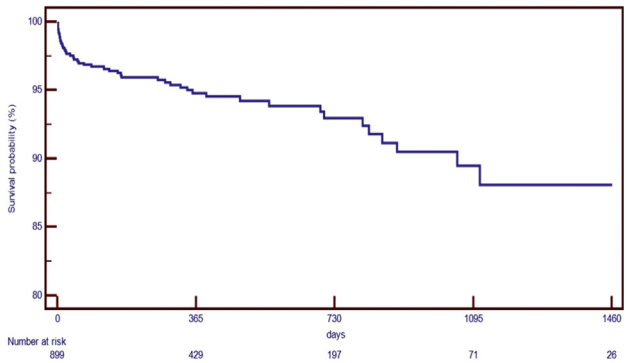

Fig 1. Kaplan-Meier survival of the Italian Registry of the Intuity Valve population.

Distribution of patients according to valve size and follow-up time

	1 year	2 years	3 years	4 years
19 mm	71	40	17	3
21 mm	135	65	23	10
23 mm	125	57	22	6
25 mm	77	28	8	7
27 mm	21	7	1	1

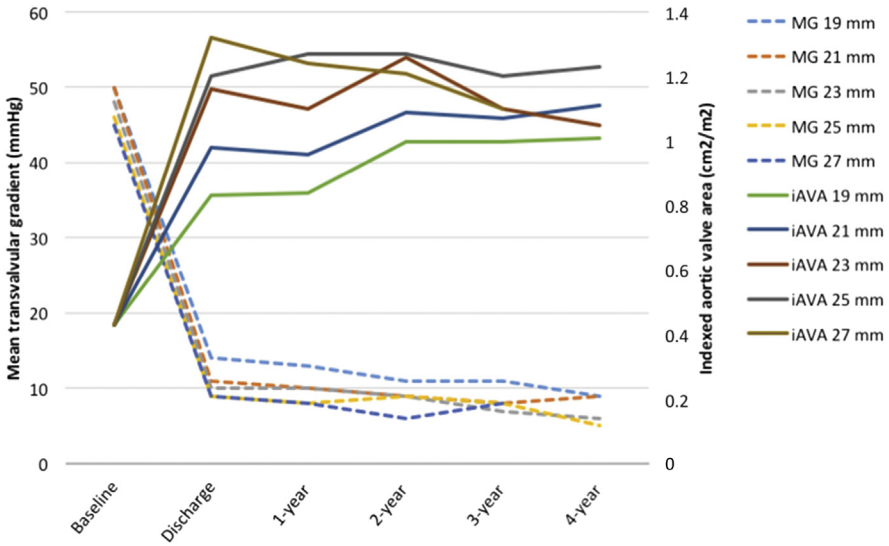

Fig 2. Indexed aortic valve area (iAVA) and mean gradient (MG) trends according to valve size.

Sapien-3 European approval study reported mild and moderate PVLs in 17.2% and 1.1% of patients, respectively [16]. The implantation technique of RDB includes leaflet removal and complete decalcification of the aortic annulus, together with annular sizing under direct vision, exactly as for a conventional stented aortic bioprosthesis. Therefore, this is a possible explanation for the low rate of PVLs detected after Intuity implantation. Furthermore, the possibility to intraoperatively check valve function and positioning with transesophageal echocardiography and to intervene in case a substantial PVL is found, as demonstrated by our registry, is a potential advantage of RDB over TAVR. The Intuity balloon-expandable stent that inflates into the LVOT generates high radial forces that may interfere with the conduction tissue generating rhythm disturbances after operation. Our data show the need for a permanent pacemaker implantation in 6.9% of patients. This rate is consistent with the 7% found in the TRITON trial [6] but lower than the 11% reported in the TRANSFORM trial [10]. In patients undergoing SAVR the pacemaker rate ranges between 3% and 11% [17]; in the surgical cohort of the PARTNER 2A trial, in patients at intermediate risk of undergoing SAVR, the incidence of postoperative pacemaker implantation was 7.9% [18]. Therefore, the real impact of RDB on postoperative conduction disturbances requiring the implantation of a pacemaker should be still assessed. However, the postoperative need for a pacemaker after Intuity implantation compares favorably with TAVR that has a reported rate that ranges between 6% and 30% [19–21]. This can be easily explained by the complete decalcification of the aortic annulus with consequent no dislodgment of bulky calcification during stent expansion (that happens during TAVR) and also because there is no need for valve oversizing in RDB implantation with consequently less compression on the LVOT.

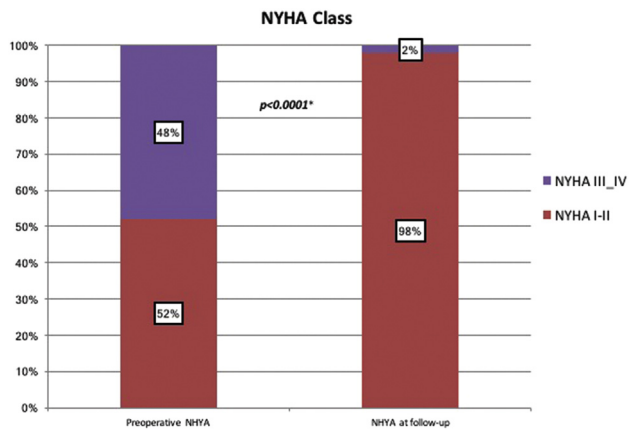

Fig 3. New York Heart Association (NYHA) class before operation and at follow-up.

Limitations

The limitations of this study are mainly related to its retrospective nature. The number of patients undergoing an operation at each center was heterogeneous, ranging from 4 to 189. There is no Adverse Event Adjudication Committee nor echocardiographic core laboratory; therefore, adverse events were self-adjudicated. Echocardiographic examinations were done by different physicians using different machines.

Conclusion

RDBs are a useful tool in the already rich portfolio of devices available for the treatment of patients with severe symptomatic aortic valve stenosis. According to the INTU-ITA data, the Intuity valve provides good early and mid-term outcomes in terms of survival, device success, valve-related adverse events, and hemodynamic performance. Preoperative conduction disturbances and a

history of previous myocardial infarction were identified as independent predictors of mortality.

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INVITED COMMENTARY

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Aortic valve replacement (AVR), performed by conventional surgery or by transvascular or transapical access (TAVR), is the treatment of choice in patients with severe aortic valve stenosis. Conventional AVR has advantages compared with TAVR, including controlled decalcification of the aortic annulus and safe valve positioning under direct vision. A new generation of bioprostheses based on expendable stents and designed to be placed without extensive suturing allows rapid-deployment (RD) AVR (RD-AVR), potentially reducing procedure times and thus rates of complications. So far, results from clinical trials have been published, showing the feasibility and safety of RD-AVR with the Intuity valve system [1]. Moreover, larger series from single centers have reported improved results compared with conventional AVR [2]. Furthermore, the use of larger valve sizes may be possible because of an implantation technique that avoids pledges in the outflow tract, and the radial forces of the expendable stents may reshape and widen the left ventricular outflow tract, thereby potentially leading to better hemodynamics compared with standard AVR [3].

In this issue of *The Annals of Thoracic Surgery*, D'Onofrio and colleagues [4] report results from the Italian Intuity Registry, including 902 RD-AVR–treated patients, comprising one of the largest series of what these investigators call "real life" patients. D'Onofrio and colleagues [4] can be congratulated for their effort to constitute a nationwide database including a large number of patients undergoing this relatively new procedure.

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