Original Article

Outcomes of rapid deployment aortic valve replacement with concomitant cardiac procedures

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Background: Rapid deployment aortic valve replacement (RD-AVR) has been recently introduced with encouraging results. Outcomes of isolated RD-AVR include good hemodynamic profile, facilitation of minimally invasive techniques, and reduction of surgical times. However, role of this prosthesis in concomitant surgery is not well known.

Methods: In 2016, we formed a registry to monitor the introduction of this prosthesis, RApid Deployment Aortic Replacement (RADAR). We aim to report mid-term outcomes focusing on patients who had RD-AVR combined with other surgical procedures.

Results: Between July 2012 and February 2021, 370 patients were included in this registry (mean age, 75.8±8.0 years; 64.32% male; mean EuroSCORE II, 3.5±2.8). Of these, 128 (34.59%) had concomitant procedures including myocardial revascularization surgery in 69 patients (53.91%), surgery on the ascending aorta in 34 (26.56%), and procedures on other valves in 10 patients (7.81%). There were no significant differences between the isolated AVR and concomitant AVR groups in postoperative complications, in-hospital mortality (4.72% *vs.* 3.32%, P=0.524), or hemodynamic behavior of these prostheses. Three-year survival was 83.73% and 89.89% in the isolated and concomitant AVR group respectively. There was no difference in survival between the two groups (log-rank test, P=0.4124).

Conclusions: Our results support the safety and efficacy of the Edwards INTUITY valve system even in complex aortic valve disease with additional cardiac procedures. RD-AVR could become a useful tool for concomitant surgeries where surgical times are expected to be prolonged.

Keywords: Rapid deployment (RD); aortic valve replacement (AVR); combined surgery

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Introduction

Rapid deployment valves (RDVs) are relatively new in clinical practice for aortic valve replacement (AVR) with encouraging results (1,2). Different studies have reported advantages of this new technology compared to conventional bioprosthesis, such as improved hemodynamic profile, significant decrease in surgical times, and facilitation of minimally invasive approaches (1-6). Conversely, these rapid deployment (RD) aortic valves present an increase in postoperative permanent pacemaker implantation (PPI) rate compared with conventional bioprosthesis (7,8).

Due to the increasing age of the population in Europe, the use of biological prostheses in aortic position has increased in recent decades (9). In addition, many older patients require additional cardiac surgical procedures, besides AVR (9). However, the role of RDV with concomitant procedures is not well studied. The objective of this study is to analyze the results of patients included in the RApid Deployment Aortic Replacement (RADAR) registry that received the Edwards INTUITY valve system (Edwards Lifesciences, Irvine, CA, USA) in combination with other cardiac surgical procedures. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-191/rc).

Highlight box

Key findings

- There was no difference in complications or hemodynamics between the isolated and combined cardiac surgery groups with INTUITY valve.

What is known and what is new?

- Rapid deployment (RD) valves reduce cross clamp times and myocardial ischemia in isolated aortic valve replacement (AVR).
- We analyze the RApid Deployment Aortic Replacement registry to show if outcomes of RD-AVR procedures are impacted by concomitant procedures.

What is the implication, and what should change now?

- Concomitant procedures do not impact the outcomes of RD-AVR procedures. It may safely improve outcomes and could have an important impact.

Methods

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The master Ethics Committee at the main center was the Official IRB of Galicia (Spain). The protocol was approved by all local institutional Ethics Committees on 1/16/2020 (Study No. Xunta de Galicia/Conselleria de Sanidade: 2016/018). Written informed consent was obtained from patients or patients' authorized representatives prior to study inclusion.

Study valve implantation

The Edwards INTUITY valve system is a stented bioprosthesis based on the Edwards Perimount valve design (Edwards Lifesciences). The main feature is the sub-annular balloon expandable stainless stent inflow frame and the cloth skirt that stabilizes the valve in the left ventricle outflow tract. The implant procedure of this prosthesis has been previously described (1-6). After a hockey stick aortotomy towards the non-coronary sinus, the native aortic valve is resected with the aortic annulus decalcified in a standard fashion. Three sutures are implanted at the nadir of the aortic sinuses and the valve is guided down until placed in a supra-annular position. The infra-annular frame is expanded with a balloon at a pressure between 3 and 5 atmospheres, depending on the size of the prosthesis for 10 seconds, and finally the three guide sutures are tied down.

Registry design

In 2016, the RADAR registry began to collect the experience with the Edwards INTUITY valve system in 8 Spanish centers. The study protocol of the RADAR registry was previously published (10). This registry is a real-world multicenter, observational, prospective, single-arm, non-randomized study; its main objective is to obtain information about this relatively novel type of prosthesis and to facilitate its use in current clinical practice.

The aim of the present study is to analyze the results of patients included in the RADAR registry for having

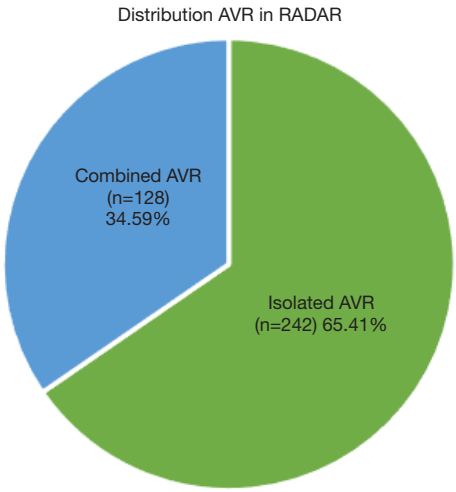

Figure 1 Patient distribution in the RADAR registry. AVR, aortic valve replacement; RADAR, RApid Deployment Aortic Replacement.

received the Edwards INTUITY RD aortic prosthesis with other concomitant cardiac surgical procedures.

Statistical analysis

A descriptive analysis of all the variables included in the study was undertaken. A normality assessment of the quantitative variables was performed with the Shapiro-Wilk test. The quantitative variables were expressed as median (interquartile range) or mean ± standard deviation (SD) as appropriate. The qualitative variables were expressed as n (%). The comparison of means was made by Student's *t*-test or Mann-Whitney *U* test, as appropriate. The difference between group variables was analyzed using the Student's *t*-test for independent data. The association of qualitative variables was estimated using either the chi-square statistic or Fisher's test. A value of $P<0.05$ was considered statistically significant. Overall survival analysis was performed using Kaplan-Meier analysis with in- or out-of-hospital mortality established as a terminal event. Survival was compared using the log-rank test. The lost values were treated statistically as unknown values. StataCorp 2015 software package was used (Stata Statistical Software: Release 14, College Station, TX, USA; StataCorp LP for statistical analysis).

Results

Between July 2012 and February 2021, 370 patients were included in the RADAR registry [mean age 75.8±8.0 years; 64.32% male; mean EuroSCORE II, 3.5±2.8; 92.70% were New York Heart Association (NYHA) functional grade II or III]. Of these, 128 (34.59%) had other cardiac surgery associated with AVR (combined surgery) (*Figure 1*). This population constitutes the objective of this study (*Table 1*).

The most common concomitant procedures were coronary artery bypass grafting (CABG) surgery in 69 patients (53.91% of the concomitant group and 18.65% of the total registry), ascending aorta surgery in 34 (26.56% and 9.19%, respectively), followed at a distance by procedures on other valves in 10 patients (1 case associating CABG corresponding to the 0.27% of the total RADAR registry and 0.78% of the concomitant group and 9 cases with exclusively multi-valve surgery corresponding to 2.43% and 7.03%, respectively). Two cases of atrial fibrillation surgery (1.56% and 0.54% respectively) and 3 left atrial appendage (LAA) ligation (2.34% and 0.81% respectively). In the combined procedures on other valves, 8 mitral prostheses were implanted (2 mechanical prostheses and 6 biological prostheses), 2 mitral rings, and 1 tricuspid ring (*Table 2*).

The number of grafts in the cases of concomitant CABG: 26 patients (38%) received one graft, another 26 (38%) received two grafts, 13 patients (19%) received three grafts, and 4 patients (6%) received four grafts. Considering the sizes of the implanted prostheses in the combined surgery group (n=139), the most frequently implanted sizes were 23 mm in 45 patients (35%), 25 mm in 38 patients (30%), 21 mm in 30 patients (24%), 27 mm in 8 patients (6%), and 19 mm in 6 patients (5%). In isolated AVR, the mean times of myocardial ischemia and cardiopulmonary bypass (CPB) were 45±18 and 63±25 min, respectively. For concomitant surgery, mean times of myocardial ischemia and CPB rose to 87±28 and 118±41 min, respectively. The stay in the intensive care unit (ICU) was shorter for the isolated valve surgery population (isolated *vs.* concomitant: 3.32±4.70 *vs.* 4.24±7.09 days, P=0.203), while the hospital stay was slightly shorter in patients with concomitant procedure (concomitant *vs.* isolated: 6.00±4.75 *vs.* 7.00±5.00 days, P=0.265) but without statistical significance in both cases. Regarding perioperative complications, no significant differences were found between the two groups for in-hospital mortality (4.72% *vs.* 3.32%, P=0.524) (*Table 3*).

The incidence of postoperative atrial fibrillation was 26.02%, and the early rate (in-hospital) PPI was 7.86%. When analyzing the hemodynamic behavior of the RD prosthesis in the aortic position, no significant differences were observed between both populations for the peak

Table 1 Demographics and characteristics

Parameters	Isolated AVR (n=242)	Combined AVR (n=128)
Age (years)	76.13±0.39	75.28±0.52
Gender (male)	148 (61.16)	90 (70.21)
Weight (kg)	76.36±0.85	76.30±1.05
Height (cm)	161.94±0.57	163.48±0.84
EuroSCORE II	2.59±0.16	5.36±0.36
Smoker	67 (27.69)	31 (24.41)
AHT	169 (70.12)	104 (81.89)
DM	91 (37.60)	47 (36.72)
Dyslipidemia	144 (59.75)	85 (66.41)
Previous CVA	12 (4.96)	6 (4.69)
Arteriopathy	18 (7.44)	11 (8.59)
COPD	34 (14.05)	16 (12.50)
PHT	14 (5.79)	11 (8.59)
Previous cardiac insufficiency	35 (14.46)	70 (54.69)
NYHA functional grade		
I	5 (2.10)	4 (3.20)
II	115 (48.32)	60 (48.00)
III	111 (46.64)	57 (45.60)
IV	5 (2.10)	3 (2.40)
Creatinine (mg/dL)	1.09±0.05	1.13±0.05

Data were expressed as mean ± SD or n (%). AVR, aortic valve replacement; AHT, arterial hypertension; DM, diabetes mellitus; CVA, cerebrovascular accident; COPD, chronic obstructive pulmonary disease; PHT, pulmonary hypertension; NYHA, New York Heart Association; SD, standard deviation.

Table 2 Concomitant procedures

AVR procedure distribution	N	Total RADAR registry (n=370), %	Combined AVR group (n=128), %
Isolated AVR	242	65.41	NA
AVR & ascending aortic surgery	34	9.19	26.56
AVR & maze	2	0.54	1.56
AVR & LAA ligation	3	0.81	2.34
AVR & CABG	69	18.65	53.91
AVR & another valve procedure	9	2.43	7.03
AVR & CABG & ascending aortic surgery	3	0.81	2.34
AVR & CABG & another valvular procedure	1	0.27	0.78
AVR & other procedures	7	1.89	5.47

AVR, aortic valve replacement; RADAR, RApid Deployment Aortic Replacement; LAA, left atrial appendage; CABG, coronary artery bypass grafting.

Table 3 Perioperative complications

Complication	Isolated AVR (n=242)	Combined AVR (n=128)	Total (n=370)	P value
Bleeding reintervention	12 (4.96)	11 (8.66)	23 (6.23)	0.162
Atrial fibrillation	59 (24.38)	37 (29.13)	96 (26.02)	0.482
Postoperative PPI	19 (7.85)	10 (7.87)	29 (7.86)	0.769
CVA	6 (2.48)	2 (1.57)	8 (2.21)	0.571
Perioperative AMI	2 (0.83)	1 (0.79)	3 (0.81)	0.968
AKI requiring hemofiltration	10 (4.15)	10 (7.94)	20 (5.45)	0.129
Intrahospitalary death	9 (3.32)	7 (4.72)	16 (3.70)	0.524

Data were expressed as n (%). AVR, aortic valve replacement; PPI, permanent pacemaker implantation; CVA, cerebrovascular accident; AMI, acute myocardial infarction; AKI, acute kidney injury.

Table 4 Hemodynamic results of isolated AVR *vs*. AVR with concomitant procedure

Hemodynamic behavior in follow up	Isolated AVR		Combined AVR		Test Wilcoxon P value
	N	Mean (SD)	N	Mean (SD)	
Peak to peak gradient (mmHg)	142	17.70 (8.62)	54	15.77 (9.76)	0.163
Mean gradient (mmHg)	135	9.33 (5.23)	47	10.03 (4.76)	0.389
Effective valvular area (cm^2)	57	1.76 (0.45)	10	1.84 (0.51)	0.608

AVR, aortic valve replacement; SD, standard deviation.

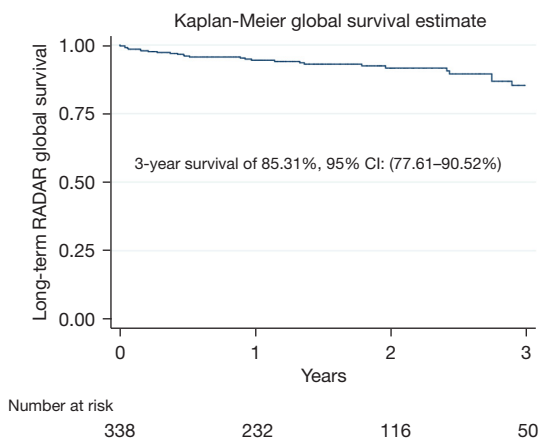

Figure 2 Global survival. RADAR, RApid Deployment Aortic Replacement; CI, confidence interval.

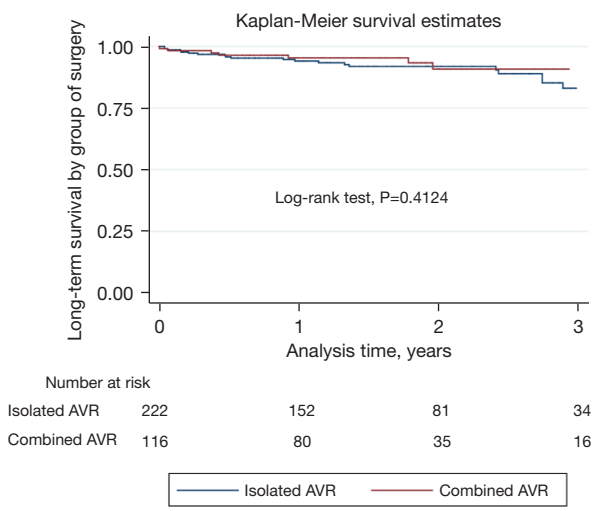

Figure 3 Isolated AVR *vs*. AVR with concomitant procedure. AVR, aortic valve replacement.

gradient, mean gradient, or effective valve area (*Table 4*).

During the in-hospital stay, no cases of prosthetic endocarditis, thrombosis, early structural failure, or hemolysis were reported. During follow-up, 27 patients (7.6%) died. All-cause mortality of 11%. The mean follow-up was 1.48 years, with 564.36 patient-years of time at risk. The 3-year survival of the entire population was 85.31% (*Figure 2*). No difference in survival between the two groups at 3 years was found (log-rank test, P=0.4124) (*Figure 3*). There were no cases of reoperation during follow-up due to significant periprosthetic leak, structural valve deterioration, or endocarditis. We did not find any case of endocarditis, valve thrombosis, prosthesis displacement or migration, or hemolysis during follow-up.

Discussion

Our results show that the implantation of an Edwards INTUITY valve system in the context of AVR with concomitant procedures is a feasible, reproducible, and safe procedure with good clinical and hemodynamic results observed. Due to both the progressive aging of the population in the Western world and technological advances in cardiac surgery and anesthesia, patients who benefit from cardiac surgery are getting older, more fragile with greater comorbidities, which is why they face increasingly complex interventions (9). Previous studies have linked the longer duration of myocardial ischemia and CPB times with higher perioperative mortality and morbidity; paradoxically, this does not happen in our series (11,12).

RD aortic prostheses first appeared in the 1960s (13) and re-emerged in the second decade of the 21st century within the group of biological prostheses (1-6). These prostheses make it possible to shorten surgical times, reduce myocardial ischemia and CPB times, and favors less invasive approaches (1-6). Previous studies with this technology have focused mainly on the isolated AVR procedure (1-6,14). In 2016, the RADAR registry began with the aim of bringing together the experience with the Edwards INTUITY RD aortic prosthesis in 8 Spanish centers (10). Around 35% of the cases included in this registry had concomitant surgery added to AVR. This percentage is similar to that of other previous series of RD and sutureless aortic prostheses (15,16). In our series, CABG was also the most frequently associated procedure (53.91%), followed by surgery on the ascending aorta (26.56%), and surgery on other heart valves, mainly the mitral valve (7.81%).

Mitro-aortic surgery using an Edwards INTUITY RD prosthesis poses a certain challenge since the presence of the infra-annular stent, by which the prosthesis is attached to the left ventricular outflow tract, could deform the outflow tract and interfere with the previously implanted mitral prosthesis. The length of the infra-annular stent varies between 6 and 8 mm depending on the size of the Edwards INTUITY prosthesis (1,8,9), so we do not recommend implanting the Edwards INTUITY prosthesis if the aortic-mitral distance does not measure 8 mm. If 8 mm distance is maintained, no interference with the mitral prosthesis has been reported (17,18). Although, no problems were seen in our series for combined aortic and mitral valve replacements. Regarding the number of grafts in the cases of concomitant coronary surgery, it should be noted that 75% of the patients received one or two grafts and the remaining 25% received three or more grafts.

Considering the size of the implanted RD prosthesis, it should be noted that 30% of the patients analyzed received a small prosthesis (19–21 mm) and the remaining 70% received 23 mm or larger valve similar to the previous series (19). As expected, the myocardial ischemia and CPB times were higher in the combined surgery group. When analyzing the perioperative complications of both groups, we did not find significant differences in any variable. The incidence of postoperative atrial fibrillation was 26%, similar to that reported by other groups (14,15). The early rate of PPI was 7.8%, which is lower than that reported by other groups with this type of prosthesis (7,20). Unlike other studies, we found no differences in the incidence of postoperative pacemakers between isolated AVR with RD prosthesis and cases of concomitant or combined surgery (6). We have previously reported that low preoperative weight (as a surrogate for small aortic valve annulus) and preoperative arrhythmias were related to the need for postoperative PPI. Moreover, we recommend not to oversize the valve and carefully consider the implantation of this technology in patients with pre-existing arrhythmia to minimize the risk for postoperative PPI (21).

Hospital mortality was 3.7%, which is slightly higher than that calculated by preoperative EuroSCORE II (3.5%) but lower than the published registry of the Spanish Society of Cardiovascular and Endovascular Surgery (SECCE) in 2019 than was 5.75% for this type of intervention (22). The stay both in the ICU and in the hospital for both the groups was short, especially in the case of the concomitant surgery group given their complexity. Shorter surgical times for AVR surgery have been related to shorter intensive care and intubation times, outcomes, and in-hospital stay; thus, utilization of the Edwards INTUITY valve system could be of benefit in terms of recovery after cardiac surgery for this challenging subset of patients (23). Regarding hemodynamic profile, the mean trans-prosthetic gradients at discharge were low in both groups, and the mean valve effective area upon leaving the hospital was 1.8 cm^2. Our results align with other publications for this RD aortic valve and confirm the good hemodynamics of the Edwards INTUITY valve system (1,14,15,19,24). Survival of the entire series at 3 years was 85.31%, and we found no difference in terms of survival between the two groups. These values are in line with previous studies for both combined surgery with sutureless prostheses (16) and surgery with the Edwards INTUITY system (14,25). This could especially be interesting for patients undergoing AVR with concomitant

procedures because of their increased perioperative surgical risk.

Limitations

There are some limitations to this study in relation to its retrospective nature, the number of patients per center was not homogeneous. First, follow-up was not available for all patients due to the continuous actualization of the data and its corresponding center. Echocardiographic examinations were performed by different teams and technicians, and adverse events were not reviewed by an external committee. Second, there is no control group with conventional biological prostheses and concomitant surgery, but we believe that this study is a good reflection of the daily clinical practice.

Conclusions

In a "real-world" setting, data from the RADAR registry show 237 excellent outcomes of both isolated- AVR and AVR with concomitant procedures using an RDV. Our results support the safety of the Edwards INTUITY valve system even for complex aortic valve disease with additional cardiac procedures. RD-AVR could become a useful tool for combined and complex surgeries where surgical times are expected to be prolonged.

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Footnote

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Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-191/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-191/coif). All authors report that this registry was supported by a research grant provided by Edwards Lifesciences. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The master Ethics Committee at the main center was the Official IRB of Galicia (Spain). The protocol was approved by all local institutional Ethics Committees on 1/16/2020 (Study No. Xunta de Galicia/ Conselleria de Sanidade: 2016/018). Written informed consent was obtained from patients or patients' authorized representatives prior to study inclusion.

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