

Rapid-deployment Valve versus Conventional Valves in Aortic Valve Replacement in Intermediate-risk Patients

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Abstract: Background: Aortic valve replacement (AVR) in intermediate-risk (IR) patients is particularly challenging when determining the type of prosthesis to use. Rapid-deployment valves (RD-V) are emerging as a potential alternative in this patient population. Objectives: To compare early mortality, postoperative complications, and transvalvular hemodynamic parameters between AVR with conventional valves and RD-V in IR patients. Methods: We conducted a retrospective observational study of consecutive IR patients (STS-PROM score 4-8) undergoing AVR with conventional prostheses and RD-V between 2007 and 2023. Results: A total of 205 patients were included (140 AVR vs. 65 RD-V). Surgical risk was similar in both groups (STS-PROM 5.07 % vs. 5.7 % respectively, $p = 0.210$). The minimally invasive approach was more common in the RD-V group (32.3% vs. 0.7%, $p < 0.001$). The cardiopulmonary bypass time and aortic cross-clamp time were significantly shorter in the RD-V group (134.5 vs. 100 min and 104 vs. 73 min, respectively, $p < 0.001$). There was a trend to lower incidence of pacemaker implantation in the conventional valve group (4.3% vs. 10.8%, $p = 0.075$). There were no significant differences in postoperative complications, and a strong trend to lower 30-day mortality with RD-V (0% vs. 5.7% for conventional valves, $p = 0.057$). The mean postoperative gradient across the prosthesis was significantly lower in the RD-V group (7.90 ± 3.3 mm Hg vs. 12.74 ± 6.07 mm Hg, $p < 0.001$). There were no differences in the incidence of valve thrombosis or prosthetic endocarditis. Conclusions: Rapid-deployment valves demonstrated trend to lower mortality, shorter cardiopulmonary bypass time and aortic cross-clamp time, improved hemodynamic profile, and were easier to implant via a minimally invasive approach.

Key words: biological valves; aortic valve replacement; intermediate risk; rapid deployment valves

1. Introduction

The number of patients with aortic valve disease requiring aortic valve replacement (AVR) has increased in recent decades as a result of higher life expectancy in the aging population. Most patients with severe aortic stenosis are elderly

patients with several comorbidities and, therefore, high preoperative risk. The development of new technologies and therapies has tried to solve this situation by reducing surgical risk. [1, 2] Minimally invasive surgery (MICS) with new prosthetic valve devices has reduced the invasiveness and trauma generated by conventional AVR. Transcatheter aortic valve replacement (TAVI) has revolutionized the course of treatment of aortic valve disease and has been established as the gold standard for patients with prohibitive or very high surgical risk, defined by a Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score ≥ 8 . This procedure is accepted and recommended worldwide with a class I indication for this population according to European and American guidelines. [3-5] For low risk patients (STS-PROM < 4), the indication is still conventional AVR according to these guidelines.

The current challenge is to define the best treatment for intermediate risk (IR) patients defined as those with a preoperative score between 4 to 8. This is the most interesting and difficult group to decide the best option when discussing patients in the Heart Team (a group made up of surgeons, cardiologists, interventional cardiologists and gerontologists).

Since the publication of controlled trials comparing the outcomes between AVR and TAVI in intermediate risk patients, [6, 7] the guidelines have begun to consider TAVI as an alternative to surgery. These results have not been widely applied in our country due to the high cost of TAVI, which despite being accepted in IR patients, is not considered as the first option. Currently, patients in this group may be candidates for both procedures. In this context, RD-Vs now play a role as one of the options that have been recently developed and have shown excellent results in terms of hemodynamic performance, versatility of use and safety. [8, 9]

Our center has already published results on IR patients undergoing conventional AVR, which were in line with expectations. [10] In 2018, we have started the RD-V program, and we observed satisfactory individual results that encouraged us to evaluate this technique as a possible better alternative to conventional valves in IR patients in terms of morbidity, mortality and hemodynamic performance.

The primary objective of this publication is to compare 30-day postoperative mortality in IR patients undergoing AVR with RD aortic valves (RD-V) versus conventional valves. The secondary objectives are to compare the incidence of intraoperative and postoperative complications within 30 days of surgery between both prostheses and the hemodynamic parameters of the device.

2. Methods

We conducted an analytical retrospective cohort study of consecutive IR patients undergoing AVR at the institution between January 1, 2007, and November 1, 2023.

Patients were eligible if they presented severe aortic stenosis (with or without associated insufficiency) or aortic infective endocarditis (off-label indication for RD-V), with diagnostic criteria defined by practice guidelines and intermediate surgical risk according to STS-PROM (4% - 8%). Patients with double valve replacement or associated surgeries (except myocardial revascularization surgery), ascending aorta replacement, tricuspid plastic surgery, septal myectomy or widening of the aortic annulus were excluded. The prosthesis used for the rapid implant group was only Intuity (INTUITY Elite, Edwards Lifesciences, Irvine, CA, USA) with diameters from 19 mm to 27 mm. For the traditional prostheses group, we used both biological prostheses: Hancock II and Mosaic (Medtronic, Minneapolis, MN), Perimount and Magna Ease (Edwards Lifesciences, Irvine, CA, USA), Epic (SJM; St. Jude Medical Inc.; Minneapolis, Minn), and Mitroflow (Sorin Group Inc, Arvada, USA), as mechanical prostheses: St. Jude Regent (SJM; St. Jude Medical Inc.; Minneapolis, Minn.), Carbomedics (CarboMedics Inc., Austin, TX), On-X (Artivion, Austin, TX, USA), and Open Pivot (Medtronic, Minneapolis, MN) in all diameters. The following variables were evaluated: a) clinical variables: age, sex, body mass index (BMI), cardiovascular history, chronic obstructive pulmonary disease (COPD), previous dialysis,

presence of bicuspid aortic valve, left ventricular systolic function, usual functional class (NYHA) and STS-PROM score; b) operative variables: preoperative status, incidence, approach, valve size, prosthesis explantation, associated surgical procedures, cardiopulmonary bypass time, aortic cross-clamp time, and presence of paravalvular leak; c) perioperative complications: prolonged mechanical ventilation (MV), requirement for intra-aortic balloon pump (IABP), myocardial infarction (MI), ischemic stroke, bleeding volume within 24 hours, units of red blood cells transfused, need for reoperation due to bleeding, cardiac arrhythmias, mediastinitis, length of hospital stay and early mortality defined as death from any cause within 30 days after surgery. Finally, the values of pre- and post-implantation gradients were considered, as well as the incidence of valvular thrombosis and prosthetic endocarditis within 30 days.

Data were retrieved from the electronic medical records of the institution and administrative databases of the Department of Cardiovascular Surgery.

2.1 Statistical considerations

Continuous variables are expressed as mean and standard deviation or median and interquartile range according to their distribution. Categorical variables are expressed as absolute and relative frequencies. Continuous variables were compared using the Student's t test or Mann-Whitney test, as appropriate. Categorical variables were compared using the chi-square test or the Fisher's exact test, as appropriate. A two-tailed value < 0.05 was considered statistically significant. All the statistical calculations were performed using STATA 13.1 software package (StataCorp LP, College Station, TX).

2.2 Ethical considerations

The study protocol was approved by the institutional review board (PRIISA Protocol N° 11721).

3. Results

Of a total of 1437 patients, 205 (14.26%) met the eligibility criteria; with 140 patients in the conventional AVR group and 65 in the RD-V group.

The demographic and preoperative characteristics are shown in Table 1. Median age was 80.8 (76.3-84) years, and 56% were men. There were no significant differences between conventional AVR and RD-V in terms of history of cardiovascular disease except for history of MI prior to surgery (16.4% vs. 3.1%, respectively, $p = 0.007$) and peripheral vascular disease (34.3% vs. 7.7%, respectively; $p < 0.001$). Patients with active endocarditis were treated only with conventional valves (8.6%). Three patients with bicuspid aortic valve underwent AVR in both groups (2.1% vs. 4.6% respectively, $p = 0.383$). Patients in the conventional AVR group had worse preoperative NYHA functional class (34.3% vs. 16.9% respectively, $p = 0.011$). The STS-PROM score was 5.07 (4.4-6.01) in the conventional AVR group vs. 5.7 (4.2-6.4) in the RD-V group ($p = 0.210$).

Table 1. Demographic and preoperative characteristics

	Total (n = 205)	Conventional AVR (n = 140)	RD-V (n = 65)	P
Age, years, median (IQR)	80.8 (76.32-84)	80 (75-84)	81.3 (78.6-84)	0.072
Male sex, n (%)	115 (56.1)	82 (58.6)	33 (50.8)	0.364
BMI (Kg/m ²), mean (SD)	27.66 (4.68)	27.56 (4.70)	27.87 (4.66)	0.660
Smoking habits, n (%)				
Never	139 (67.8)	90 (64.3)	49 (75.4)	0.323
Active smoker	11 (5.4)	9 (6.4)	2 (3.1)	
Former smoker	55 (26.8)	41 (29.3)	14 (21.5)	
Hypertension, n (%)	181 (88.3)	123 (87.9)	58 (89.2)	0.775

	Total (n = 205)	Conventional AVR (n = 140)	RD-V (n = 65)	p
Diabetes, n (%)	53 (25.9)	39 (27.9)	14 (21.5)	0.336
Atrial fibrillation, n (%)	43 (21)	31 (22.1)	12 (18.5)	0.546
Previous MI, n (%)	25 (12.2)	23 (16.4)	2 (3.1)	0.005
Previous CABG, n (%)	29 (14.1)	19 (13.6)	10 (15.4)	0.728
Peripheral vascular disease, n (%)	53 (25.9)	48 (34.3)	5 (7.7)	< 0.001
Previous stroke, n (%)	21 (10.2)	14 (10)	7 (10.8)	0.865
TIA	5 (2.4)	5 (3.6)	0 (0)	0.181
Ischemic stroke	3 (1.5)	3 (2.1)	0 (0)	0.553
COPD, n (%)	14 (6.8)	11 (7.9)	3 (4.6)	0.555
Previous dialysis, n (%)	12 (5.9)	8 (5.7)	4 (6.2)	1
Active aortic endocarditis, n (%)	12 (5.9)	12 (8.6)	0 (0)	0.010
Bicuspid aortic valve, n (%)	6 (2.9)	3 (2.1)	3 (4.6)	0.383
Moderate/severe LV dysfunction, n (%)	28 (13.7)	21 (15)	7 (10.8)	0.411
NYHA FC III/IV, n (%)	59 (28.8)	48 (34.3)	11 (16.9)	0.010
STS-PROM, median (IQR)	5.1 (4.3-6.3)	5.07 (4.4-6.01)	5.7 (4.2-6.41)	0.210

Note: AVR: aortic valve replacement; BMI: body mass index; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; FC: functional class; IQR: interquartile range; LV: left ventricular; MI: myocardial infarction; NYHA: New York Heart Association; RD-V: rapid deployment aortic valve replacement; SD: standard deviation; STS-PROM: Society of Thoracic Surgeons predicted risk of mortality; TIA: transient ischemic attack.

The intraoperative characteristics are shown in Table 2. A minimally invasive approach was more common in the RD-V group compared with the conventional AVR group (32.3% vs. 0.7%, $p < 0.001$). Conversion to sternotomy was not necessary in none of the groups. There were no relevant differences regarding prosthetic valve sizes. Only one patient in the RD-V required prosthesis explantation followed by implantation of a conventional prosthetic valve (1.5%). Aortic annulus enlargement was more common in the conventional AVR group (12.9% vs. 4.6%, $p = 0.084$). Cardiopulmonary bypass time (CPB) and aortic crossclamp time were lower in the RD-V group (134.5 vs. 100 min, $p < 0.001$, and 104 vs. 73 min, $p < 0.001$, respectively).

Table 2. Intraoperative characteristics

	Total (n = 205)	Conventional AVR (n = 140)	RD-V (n = 65)	p
Preoperative status, n (%)				
Elective	144 (70.2)	93 (66.4)	51 (78.5)	0.210
Urgent	57 (27.8)	44 (31.4)	13 (20)	
Emergency	4 (2)	3 (2.1)	1 (1.5)	
Incidence first surgery, n (%)	190 (92.7)	129 (92.1)	61 (93.8)	0.778
Ministernotomy, n (%)	22 (10.7)	1 (0.7)	21 (32.3)	< 0.001
Mini-to-full conversion, n (%)	0 (0)	0 (0)	0 (0)	
Valve size, n (%)				

Total (n = 205)		Conventional AVR (n = 140)	RD-V (n = 65)	p
19	16 (7.8)	12 (8.6)	4 (6.2)	0.260
21	81 (39.5)	58 (41.4)	23 (35.4)	
23	69 (33.7)	49 (35)	20 (30.8)	
24	1 (0.5)	1 (0.7)	0 (0)	
25	35 (17.1)	19 (13.6)	16 (24.6)	
27	3 (1.5)	1 (0.7)	2 (3.1)	
Associated procedures, n (%)	112 (54.6)	83 (59.3)	29 (44.6)	0.049
CABG, n (%)	107 (52.2)	80 (57.1)	27 (41.5)	0.038
Aortic annulus enlargement	21 (10.2)	18 (12.9)	3 (4.6)	0.084
Number of grafts, median (IQR)	1 (1-2)	1 (0-2)	2 (1-2)	0.035
CPB time, median (IQR)	125 (103-165)	134.5 (111-172)	100 (80-129)	< 0.001
Aortic cross-clamp time, median (IQR)	93 (75-121)	104 (85-135)	73 (61-103)	< 0.001
Paravalvular leak $\geq$ mild, n (%)	10 (4.9)	7 (5.0)	3 (4.6)	1

Note: AVR: aortic valve replacement; CABG: coronary artery bypass grafting; CPB: cardiopulmonary bypass; IQR: interquartile range; RD-V: rapid deployment valve.

Table 3 shows the postoperative results. More patients in the conventional AVR group required prolonged mechanical ventilation (20.7% vs. 12.3%), although this difference was not statistically significant ($p = 0.174$). There were no relevant differences in terms of postoperative complications, bleeding and reoperations, with a non-significant trend toward need for permanent pacemaker implantation (PPI) due to atrioventricular block in the RD-V group (10.8% vs. 4.3%).

Table 3. Postoperative results

Total (n = 205)		Conventional AVR (n = 140)	RD-V (n = 65)	p
Prolonged MV, n (%)	37 (18.8)	29 (20.7)	8 (12.3)	0.145
IABP, n (%)	10 (4.9)	8 (5.7)	2 (3.1)	0.508
Postoperative MI, n (%)	2 (1)	1 (0.7)	1 (1.5)	0.534
Ischemic stroke, n (%)	13 (6.3)	9 (6.4)	4 (6.2)	1
Bleeding in ml/24 hours, median (IQR)	230 (160-340)	240 (160-365)	220 (175-315)	0.640
RBCU/48 hours, median (IQR)	2 (0-2)	2 (0-3)	2 (1-2)	0.480
Reoperation due to bleeding, n (%)	9 (4.4)	7 (5)	2 (3.1)	0.722
Postoperative atrial fibrillation, n (%)	88 (42.9)	60 (42.9)	28 (43.1)	0.976
AV block with PPI, n (%)	13 (6.3)	6 (4.3)	7 (10.8)	0.076
Mediastinitis, n (%)	4 (2)	3 (2.1)	1 (1.5)	1
LOS, median (IQR)	7 (6-13)	7.5 (6-14)	7 (5-13)	0.530
Death < 30 days, n (%)	8 (3.9)	8 (5.7)	0 (0)	0.057

Note: AV: atrioventricular; AVR: aortic valve replacement; IABP: intra-aortic balloon pump; IQR: interquartile range; LOS: hospital length of stay; MI: myocardial infarction; MV: mechanical ventilation; PPI: permanent pacemaker implantation; RBCU: red blood cell units; RD-V: rapid deployment valve.

No deaths were reported in the RD-V group while 8 patients died in the conventional AVR group (0% vs. 5.7%, $p = 0.057$). In a sensitivity analysis of the postoperative outcomes excluding 12 patients with infective endocarditis (all in the conventional AVR group), there were no significant variations; mortality remained lower in the RD-V group (0% vs. 6.3%, $p = 0.053$). The valvular and prosthetic hemodynamic results are detailed in Table 4. The RD-V had better hemodynamic performance after the intervention, with lower peak and mean gradients.

Table 4. Valvular and prosthetic hemodynamic results

Total (n = 205)		Conventional AVR (n = 140)	RD-V (n = 65)	p
Peak preop aortic valve gradient (mm Hg), mean (SD)	67.04 (28.19)	63.51 (30.77)	74.26 (20.35)	0.011
Mean preop aortic valve gradient (mm Hg), mean (SD)	40.99 (17.07)	39.99 (18.77)	42.96 (12.97)	0.250
Preop aortic valve area (cm ²), mean (SD)	0.75 (0.43)	0.71 (0.46)	0.83 (0.35)	0.077
Peak postop aortic valve gradient (mm Hg), mean (SD)	20.93 (9.71)	23.53 (9.89)	15.81 (6.97)	<0.001
Mean postop aortic valve gradient (mm Hg), mean (SD)	11.06 (5.76)	12.74 (6.07)	7.90 (3.35)	<0.001
Valvular thrombosis, n (%)	1 (0.5)	1 (0.7)	0 (0)	1
Prosthetic endocarditis, n (%)	5 (2.4)	4 (2.9)	1 (1.5)	1

Note: AVR: aortic valve replacement; preop: preoperative; postop: postoperative; RD-V: rapid deployment valve; SD: standard deviation.

4. Discussion

So far, a paucity of information exists in both the local and international literature regarding the comparison of the use of both prostheses in intermediate-risk patients. [11] Our institution has considerable experience in the use of RD-V prostheses, with 200 implants to date and favorable outcomes, which we will examine in further detail below.

4.1 Cardiopulmonary bypass time, aortic cross-clamp and minimally invasive approach

As expected, due to the technique, the RD-V group exhibited a significant decrease in CPB time (134.5 vs. 100 min; $p < 0.001$) and aortic cross-clamp time (104 vs. 73 min; $p < 0.001$) and a greater trend towards the use of a minimally invasive approach (32.3% vs. 0.7%; $p < 0.001$). All these factors can explain the lower morbidity and mortality rates observed in this group. [12, 13] It is notable that there were no conversions to sternotomy in patients undergoing MICS, and although the total length of hospital stay did not decrease, the improved comfort and postoperative cosmetic results in patients who underwent this approach are well known benefits. The only case of RD-V explantation was due to paravalvular leak.

4.2 Pacemaker implantation

Undoubtedly, an unfavorable aspect reported for RD-V is the higher incidence of PPI. This was not the exception in our study (10.8% vs. 4.3%, $p = 0.076$). The incidence of PPI after RD-V reported in the literature ranges from 5% to approximately 13%. [14, 15] Of the patients in the RD-V group who required PPI, two had first-degree atrioventricular block, one had left bundle branch block, and four had sinus rhythm. Although there are many factors related to the procedure that increase the risk of atrioventricular block, such as previous bundle branch block, hypertrophic

cardiomyopathy and excessive decalcification of the annulus, [16] some are inherent to the prosthesis implant. This implantation system, requiring balloon deployment with infra-annular extension, generates direct compression of the conduction system, similar to the mechanism produced during TAVI. In a series of 700 patients, Coti et al. demonstrated that preoperative right bundle branch block (RBBB) was the only independent predictor of PPI (9.5%). [17] Therefore, we believe that candidates for RD-V implantation should be selected, and those with RBBB should be excluded. We also recommend avoiding prosthesis oversizing, and in case of uncertainty whether to implant a larger or a smaller prosthesis, the smaller size should be chosen.

4.3 Mortality

The lower postoperative mortality was one of the most outstanding findings of this study, with a strong trend favoring the RD-V (0% vs. 5.7%; $p = 0.057$). This result is slightly lower than that of the SURD-IR registry, [18] which analyzed mortality in all preoperative risk categories and reported a mortality rate of 0.8% in the IR group. It is noteworthy that the baseline STS-PROM score was similar in both groups.

Patients with endocarditis were also included in this series despite there were no IR patients in the RD-V group, because we have used this prosthesis in selected cases. The benefits of RD-V remained in the sensitivity analysis performed to evaluate the postoperative outcomes excluding this subgroup. Of the patients who died, the first patient underwent endarterectomy of the left anterior descending coronary artery and required extracorporeal membrane oxygenation (ECMO) after weaning from CPB. The second case was an 86-year-old patient with a history of chronic kidney failure who underwent AVR + triple bypass surgery and died of acute kidney failure and metabolic cardiopulmonary arrest. The third patient was 78 years old, had severe preoperative left ventricular dysfunction (AVR + triple bypass surgery) and presented bleeding and MI in the immediate postoperative period. The fourth case was an 82-year-old patient (AVR + single bypass surgery) who died of low cardiac output syndrome and cardiogenic shock. Finally, the fifth patient, aged 75 years (AVR + double bypass surgery) required ECMO + IABP after weaning from CPB. All of them died between postoperative days 1 and 5.

Of the remaining three patients undergoing isolated AVR, a 58-year-old patient with severe ventricular dysfunction required ECMO after weaning from CPB and died on postoperative day 5; an 88-year-old patient died on postoperative day 22 due ischemic stroke and mediastinitis, and an 82-year-old patient with cardiac tamponade who required reoperation died on postoperative day 25 due to sepsis.

4.4 Transvalvular prosthetic gradient

This analysis shows that lower postoperative gradients were obtained with the use of RD-V. This has already been published by other groups. [19, 20] Although the mean diameter of the implanted prostheses was slightly larger in conventional prostheses (Table 2), the mean postoperative transvalvular gradient was statistically lower in RD-V prostheses, which demonstrates that their hemodynamic performance is better: 12.74 (6.07) mm Hg vs. 7.90 (3.35) mm Hg ($p < 0.001$). Instead, Andreas et al. [21] described the transvalvular gradients comparing both prostheses but they did not obtain a clinically relevant difference.

This would be related to the stent-based fixation system of RD-V which reshapes the left ventricular outflow tract, reduces turbulent flow and optimizes the hemodynamic performance of the valve prosthesis. Subclinical obstruction at the valve inlet may be induced by protrusion of bulky pledget material used to fixate the conventional valve. The negative effect of pledgeted mattress sutures on transvalvular gradients compared with single interrupted sutures has already been demonstrated. [22]

The RD-V used in this study (INTUITY Elite, Edwards Lifesciences, Irvine, CA, USA) is a trileaflet valve comprised

of bovine pericardium based on the Carpentier-Edwards Perimount prosthesis (Edwards Lifesciences, Irvine, CA) with a balloon expandable stainless-steel frame and requires only three sutures in the annulus. This prosthesis has exceptional long term results (freedom from reoperation due to structural damage at 15 years in patients > 70 years of $98.1\% \pm 0.8\%$), so the durability of the RD-V is also expected to be prolonged. [23] Regarding costs, they are higher than those of conventional valves, although significantly lower than those of a TAVI. This makes RD-Vs an attractive option in non-high-income countries. Although a cost-benefit analysis would be necessary to determine which prosthesis is more convenient in different scenarios.

4.5 Study limitations

The limitations of this study are those inherent to its observational and retrospective design. There may be selection bias and confusion by indication that contribute to explaining the better evolution, beyond the benefits of the valve. Furthermore, it represents to patients from a single center.

5. Conclusions

Our study provides relevant information on the effectiveness of rapid deployment valves compared to conventional valves in intermediate-risk patients requiring AVR. These patients benefit from shorter operative times and more favorable postoperative transvalvular gradients, with a trend towards lower mortality. Further multicenter randomized studies are needed to validate our findings.

Conflicts of Interest

Dr. VK, discloses conflicts of interest with Medtronic, Edwards Lifescience, and Johnson & Johnson. The remaining authors have no conflicts of interest to declare.

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