



## Original Article

# Rapid Deployment Valves Are Advantageous in the Redo Setting: A Single-Centre Retrospective Study

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### ABSTRACT

**Background:** The spectrum on how to manage aortic valve disease continues to widen. The purpose of this study is to add further clarification to the role of rapid deployment valves (RDVs) by comparing their outcomes with traditional sutured valves (TSVs) in the reoperative aortic valve replacement (AVR) setting.

**Methods:** This study was a retrospective review of all patients undergoing a second surgical reoperation for aortic valve disease. Patients were categorized into 2 groups: RDV and TSV. Cox proportional hazards regression models were used to determine the association between exposures of interest and the primary and secondary outcomes, after adjusting for all the baseline characteristics. The primary outcome was

### RÉSUMÉ

**Contexte :** Les nouvelles méthodes pour la prise en charge de la maladie de la valve aortique continuent de se multiplier. Cette étude vise à apporter d'autres précisions sur le rôle des valves à déploiement rapide (VDR) en comparant leurs résultats avec ceux des valves suturées traditionnelles (VST) dans le cadre d'un remplacement valvulaire aortique (RVA) réopératoire.

**Méthodologie :** Cette étude était une analyse rétrospective de tous les patients subissant une deuxième réopération chirurgicale pour la maladie valvulaire aortique. Les patients ont été classés en deux groupes : VDR et VST. Des modèles de régression des hasards proportionnels de Cox ont été utilisés pour déterminer l'association entre

Cardiac surgery continues to evolve, and there are now many approaches to the management of aortic valve disease. Research to date has demonstrated that rapid deployment valves (RDVs) are associated with reduced operative times but higher rates of permanent pacemaker insertion.<sup>1-6</sup> Overall, despite the reduction in cardiopulmonary bypass (CPB) times, clinical outcomes such as mortality and major morbidity do not differ.<sup>1-6</sup>

The question remains of where RDVs fit into the management of patients with aortic valve disease. Previous research has suggested benefit in minimally invasive cases; in patients with calcified, small aortic roots; and in the redo setting.<sup>2</sup> Evidence to support the use of RDVs in the redo setting

predominantly consists of case reports and case series.<sup>7-13</sup> An article using the Sutureless and Rapid-Deployment Aortic Valve International Registry (SURD-IR) looked at a series of 63 patients undergoing reoperation using a J-shaped mini-sternotomy and found favourable outcomes.<sup>14</sup> Redo surgical aortic valve replacement (surgical AVR [SAVR]) is considered a more complex procedure, and many of these patients will go for valve-in-valve (ViV) transcatheter aortic valve implantation (TAVI). However, ViV TAVI is not possible for everyone (eg, too-small implanted bioprosthesis, endocarditis), and this approach is not without complications.<sup>14</sup>

The purpose of this study is to add further clarification to the role of RDVs in the redo setting by comparing patients undergoing redo AVR through a full sternotomy with a RDV or a traditional sutured valve (TSV).

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**Ethics Statement:** Individual waiver for consent was granted by the local research ethics board. Approval for the study was achieved through the Health Research Ethics Board of the University of Alberta.

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See page 303 for disclosure information.

### Materials and Methods

#### Population

This study was a retrospective chart review that included all reoperative AVRs performed at the Mazankowski Alberta Heart Institute between January 1, 2010, and July 2, 2019. Patients were identified using the Alberta Provincial Project

major adverse cardiovascular events (MACE) within 3 years, which was the composite of all-cause death, readmission for myocardial infarct, readmission for stroke, and readmission for heart failure.

**Results:** A total of 307 patients made up the study population from 2010 to 2019. Of those, 254 patients received TSV, and 53 patients received RDV. RDV patients were significantly older than TSV patients by 10 years, on average. Shorter cardiopulmonary bypass (CPB) times were found with the RDV group. There was no significant difference in the primary outcome of MACE within 3 years.

**Conclusions:** This single-centre large cohort study of patients with reoperative AVR found that RDVs facilitate smoother operations by saving 1 hour of cross-clamp time and CPB time. Furthermore, RDVs have comparable outcomes with TSVs, despite the significantly older patient population.

for Outcome Assessment in Coronary Heart Disease (APPROACH) and the Alberta Strategy for Patient-Oriented Research Support Unit Discharge Abstract Database. An additional chart review of perfusion records was performed to identify patients undergoing reoperation. This patient list was cross-referenced with the APPROACH database to ensure that a complete patient list as possible. Patients were included if they were older than or equal to 18 years of age and had previously undergone aortic valve surgery through a median sternotomy and were now receiving reoperative AVR. Patients were excluded if they received aortic root replacement, any other concomitant procedure, or if their original operations were not aortic valve replacements. Patients were categorized into 2 groups based on valve type: RDV and TSV.

The primary outcome of this study was major adverse cardiovascular events (MACE) within 3 years, which was the composite of all-cause death, readmission for myocardial infarct (MI), readmission for stroke, and readmission for heart failure. Secondary outcomes included incidences of pacemaker insertion, rehospitalization, aortic insufficiency, and paravalvular leak within 3 years. The average follow-up for the entire cohort was 2.4 years; for the RDV group: 1.8 years; and for the TSV group: 2.5 years. There were no biases in follow-up toward any group. There was none lost to follow-up. The last date of follow-up was September 9, 2019.

Baseline characteristics, procedural data, and in-hospital outcomes were collected and analyzed for both valve groups. Echocardiographic data were collected by looking at the data upward to 3 years of follow-up. There were 250 echocardiograms available for analysis. The average echocardiogram follow-up interval was 74 days. The Perceval S (LivaNova, London, UK) and Intuity Elite (Carpentier-Edwards, Irvine, CA) were the 2 RDVs included in the study. The bio-prosthetic TSVs were predominantly Perimount Magna Ease (Carpentier-Edwards) and Trifecta (St Jude Medical, St Paul, MN). The predominant mechanical TSV used was On-X (CryoLife Inc, Kennesaw, GA).

les expositions d'intérêt et les critères d'évaluation principal et secondaires, après ajustement pour toutes les caractéristiques initiales. Le paramètre principal était les événements cardiovasculaires indésirables majeurs (ECIM) dans les trois ans, soit un critère composite incluant le décès toutes causes confondues, la réadmission pour un infarctus du myocarde, la réadmission pour un accident vasculaire cérébral et la réadmission pour une insuffisance cardiaque.

**Résultats :** Au total, 307 patients faisaient partie de la population de l'étude de 2010 à 2019. Parmi ceux-ci, 254 patients ont reçu une VST, et 53 patients ont reçu une VDR. Les patients porteurs d'une VDR étaient significativement plus âgés que ceux porteurs d'une VST, soit de 10 ans en moyenne. Des temps plus courts sous circulation extracorporelle (CEC) ont été constatés dans le groupe VDR. Aucune différence significative n'a été observée en ce qui concerne le critère d'évaluation principal des ECIM dans les trois ans.

**Conclusions :** Cette importante étude de cohortes menée à un seul centre auprès de patients subissant un RVA réopératoire a permis de constater que les VDR facilitaient les interventions en réduisant d'une heure le temps de clampage et le temps de CEC. De plus, les VDR ont procuré des résultats comparables à ceux obtenus avec les VST, malgré une population de patients significativement plus âgée.

## Statistical analysis

Continuous variables were described as means with standard deviations or as medians with their respective interquartile ranges (IQRs) if not normally distributed. Categorical variables were described as the total number with the corresponding percentage they represented in each category. Continuous variables were compared using Student's *t*-test or Mann-Whitney U test in cases of non-normal distribution. Categorical variables were compared with the  $\chi^2$  test or Fisher's exact test, as appropriate.

Log-rank test was used to compare the unadjusted primary and secondary outcomes between the RDV group and the TSV group. Cox proportional hazards regression models were used to determine the association between exposures of interest and the primary and secondary outcomes, after adjusting for all the variables included in Table 1. The proportional hazard assumption was tested by adding an interaction term of grouping variable and time to the full model, for which *P* values less than 0.05 indicate violation of assumption. No violations were found in all the Cox regression models. Multivariable logistic regression was performed for in-hospital outcomes, and the *P* values of testing statistical significance between the RDV and TSV groups were reported. Statistical analysis was performed using the SAS 9.4. (SAS Institute, Cary NC). Hazard ratios (HRs) describe the ratio of the hazard rate in the RDV group vs the TSV group. HR > 1 favours the TSV group. A *P* value < 0.05 was considered to be of statistical significance.

## Results

### Study population

A total of 307 patients underwent a reoperation AVR between January 1, 2010, and July 2, 2019. The majority of patients received TSV (*n* = 254), and the remainder received RDV (*n* = 53).

### Baseline demographics

Overall, the 2 groups were well balanced, with an average Society of Thoracic Surgeons (STS) score of 1.1% in the RDV group and 0.9% in the TSV group (Table 1). There were no statistically significant differences between the 2 groups, with the exception of age ( $P < 0.001$ ). Patients receiving RDVs were, on average, 11 years older than patients receiving TSVs ( $68 \pm 9.8$  vs  $57 \pm 15.7$ , respectively) (Table 1).

### Intraoperative details

There was a statistically significant difference in CPB time ( $P < 0.001$ ) and cross-clamp time ( $P < 0.001$ ) favouring the RDV group. On average, a total of 78.5 minutes were saved in CPB time and 70.6 minutes in cross-clamp time (Table 1). The breakdown of valve choices can be found in Figure 1.

### Postoperative outcomes

The perioperative mortality was 0 patients (0%) and 1 patient (0.4%) for the RDV group and TSV group, respectively. In years 2 to 3, 5 deaths (2%) occurred in the TSV group. There was no statistically significant difference with or without adjustment in the primary outcome of MACE within 3 years ( $P = 0.761$ ) (Tables 2 and 3). There was no statistically significant difference in the secondary outcomes with or without adjustment except for rehospitalization within 3 years ( $P = 0.042$ ) (Tables 2 and 3). There were 26 patients (61.9%) rehospitalized from all causes within 3 years in the RDV group compared with 100 (41.7%) in the TSV group. Of note, pacemaker insertion rate, although not statistically significantly different, was in favour of the RDV group (2.2% vs 3.1%,  $P = 0.487$ ). Other in-hospital outcomes are listed in Table 4. There was statistically significant difference in post-operative mean and peak gradient ( $P < 0.001$ ), favouring better gradients for the TSV (Table 4).

### Discussion

This study demonstrated 2 main findings. First, the RDV facilitated a much smoother reoperation, with more than 1 hour of CPB and cross-clamp time saved. This is a larger reduction in time than seen in previous studies that have reported ~18 to 30 minutes of time saved in primary AVR. We speculate that, in the reoperative setting, the time saved was mostly from debridement at the aortic root. In addition, a large number of our primary valves were Freestyle (Medtronic, Dublin, Ireland) and in the context of reoperative AVR with RDVs, we could simply cut out the leaflets and deploy the new RDV instead of having to take out the whole valve. This approach likely saves us operative time as well. Second, there was no statistically significant difference in the primary outcome of MACE at 3 years despite the significant age difference between the 2 groups.

The results should be interpreted carefully given the small sample size. MACE within 3 years was not significantly different between RDVs and TSVs. This is important because there was a 10-year age gap between the 2 groups. Despite being older, the patients in the RDV group had comparable outcomes. In the most recent American College of Cardiology/American Heart Association (ACC/AHA) guidelines, TAVI has become a class I indication for patients aged 65-80,

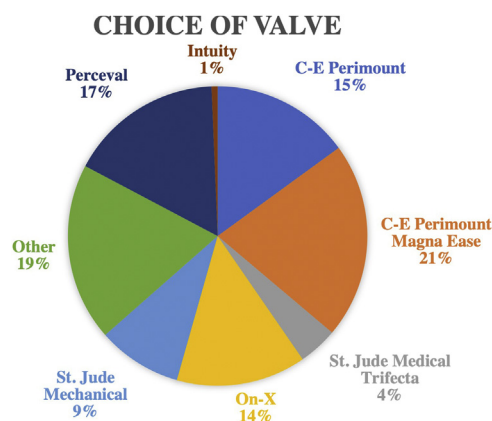
**Table 1. Baseline characteristics (N = 307)**

Baseline characteristics	RDV (n = 53)	TSV (n = 254)	P value
Age, years	68 ± 9.8	57 ± 15.7	< 0.001
BMI, kg/m <sup>2</sup>	29.1 ± 6.4	28.6 ± 5.9	0.576
Female	33 (62.3)	182 (71.7)	0.175
Hypertension	35 (66)	151 (59.4)	0.372
Dyslipidemia	34 (64.2)	147 (57.9)	0.398
Diabetes mellitus	7 (13.2)	37 (14.6)	0.797
Heart failure	19 (35.8)	75 (29.5)	0.364
COPD	17 (32.1)	90 (35.4)	0.641
Liver disease	0 (0)	8 (3.1)	0.191
GI disease	2 (3.8)	20 (7.9)	0.293
Malignancy	4 (7.5)	9 (3.5)	0.188
Peripheral vascular disease	2 (3.8)	3 (1.2)	0.175
Cerebrovascular disease	1 (1.9)	22 (8.7)	0.088
Current smoker	10 (18.9)	50 (19.7)	0.892
Past smoker	25 (47.2)	103 (40.6)	0.374
Chronic kidney disease	3 (5.7)	12 (4.7)	0.774
Dialysis	0 (0)	5 (2)	0.303
Previous MI	5 (9.4)	18 (7.1)	0.555
Previous CABG	10 (18.9)	35 (13.8)	0.341
Previous PCI	2 (3.8)	15 (5.9)	0.537
STS score	1.1 ± 0.5	0.9 ± 0.6	0.153
Pump time	118.5 ± 61.9	197.1 ± 98.5	< 0.001
Clamp time	85.8 ± 48.7	156.4 ± 76.4	< 0.001

Malignancy is defined as a history of solid organ malignancy or leukemia/lymphoma requiring treatment within the past 5 years.

BMI, body mass index; CABG, cardiopulmonary bypass graft; COPD, chronic obstructive pulmonary disease; GI, gastrointestinal; MI, myocardial infarction; PCI, percutaneous coronary intervention; RDV, rapid deployment valve; STS, Society of Thoracic Surgeons; TSV, traditional sutured valve.

whereas, previously, TAVI was only to be considered in high-risk surgical patients.<sup>15</sup> As a result, the challenge is to continue to improve the early outcomes of SAVR.<sup>16</sup> The results of our study suggest a clear role for RDVs in the setting of reoperation, with comparable outcomes with TSVs despite having a significantly older patient population. To the best of our knowledge, the long-term outcomes of RDVs are still limited, although early degeneration has not been reported so far. In principle, RDVs are based on similar technology to transcatheter valves. Previous studies have linked the crimping process of transcatheter valves with reduced prosthetic durability.<sup>17</sup> Crimped valves have structural damage caused by



**Figure 1.** Breakdown of valve choices. “Other” denotes Inspiris Resilia (Edwards Lifesciences, Irvine, CA), Mitroflow (Sorin Group, Milan, Italy), and Carbomedics (LivaNova, London, UK).

**Table 2. Unadjusted primary and secondary outcomes**

Outcome variables	RDV (n = 53)	TSV (n = 254)	P value
MACE	6 (12.6%)	27 (11.8%)	0.422
Death at 3 years	0 (0.0%)	12 (5.2%)	0.175
Rehospitalization for non-fatal MI at 3 years	1 (2.8%)	2 (1.4%)	0.415
Rehospitalization for stroke at 3 years	0 (0.0%)	3 (2.2%)	0.522
Rehospitalization for HF at 3 years	5 (9.8%)	14 (6.2%)	0.107
Pacemaker insertion at 3 years	1 (2.2%)	7 (3.1%)	0.948
Redo aortic valve replacement at 3 years	2 (3.8%)	6 (1.7%)	0.257
Rehospitalization at 3 years	26 (61.9%)	100 (41.7%)	0.014

MACE is defined as the composite of all-cause mortality, rehospitalization for MI, stroke, or HF at 3 years.

HF, heart failure; MACE, major adverse cardiovascular events; MI, myocardial infarction; RDV, rapid deployment valve; TSV, traditional sutured valve.

altered collagen arrangement, which might predispose the valves to thrombus formation and accelerated calcification. Despite the similar technology, RDVs are mounted on a dedicated delivery device, and their diameters are reduced to the desired sizes by collapsing rather than crimping. Although the collapsing process, in theory, have could damage the leaflets and result in early prosthetic failure, the extent of this in reality remains to be determined.

Again, the purpose of this study was to add further clarification to the role of the RDV in the management of patients with aortic valve diseases. This single-centre study had more than 300 patients undergo reoperation AVR, which is 1 of the largest reported data. As mentioned previously, evidence has predominantly consisted of case reports and case series that have supported the use of RDVs in the redo setting. In none of the reported series was there significant postoperative complication with the use of the RDV.<sup>7-11</sup> One of the advantages of the RDVs in the redo setting is in the context of a previous homograft. There have been case reports supporting the technique of cutting out the leaflets of the previous homograft and implanting the RDV directly into the root of the homograft.<sup>12,13</sup> A redo AVR in the context of a previous homograft would normally result in a total replacement of the aortic root: a much more complex operation than essentially replacing the leaflets of the valve.

**Table 3. Adjusted primary and secondary outcomes**

Outcome	Hazard ratio	95% CI		P value
		Lower	Upper	
MACE at 3 years	1.21	0.36	4.11	0.761
Death at 3 years	NA	NA	NA	NA
Rehospitalization for MI at 3 years	NA	NA	NA	NA
Rehospitalization for stroke at 3 years	NA	NA	NA	NA
Rehospitalization for HF at 3 years	2.66	0.32	21.88	0.364
Pacemaker insertion at 3 years	2.48	0.19	32.33	0.487
Redo aortic valve replacement at 3 years	NA	NA	NA	NA
Rehospitalization at 3 years	1.84	1.02	3.32	0.042
Aortic insufficiency at 3 years	0.46	0.06	3.28	0.438
Paravalvular leak at 3 years	3.29	0.13	85.8	0.474

Hazard ratios describe the ratio of the hazard rate in the RDV group vs the TSV group. Hazard ratio > 1 favours the TSV group.

CI, confidence interval; HF, heart failure; MACE, major adverse cardiovascular events; MI, myocardial infarction RDV, rapid deployment valve; TSV, traditional sutured valve.

White et al. recently published a paper on RDVs vs TSVs in isolated AVR patients.<sup>1</sup> Despite finding no significant differences in overall survival, there was a statistically significant difference in pacemaker insertion rate, with a 7% pacemaker rate in the RDV group, which was lower compared with previous studies.<sup>1</sup> The conclusion was that RDVs should not be used in the setting of an isolated AVR, as it poses more harm than benefit. TAVI valves are associated with a 20% pacemaker insertion rates (although likely lower with new valve technology), and traditional SAVRs generally have a 3% rate of pacemaker insertion.<sup>18</sup> In this study, pacemaker insertion rates were lower in the RDV group than the TSV group, which is an interesting finding. A possible explanation, as no data exist for the reoperative setting, would be less debriement and manipulation required at the level of the atrioventricular node to allow implantation of a RDV than a TSV. An anecdotal explanation is in the patients in whom previous Freestyle root bioprosthesis (Medtronic) was used; the RDV would sit within the root of the previous prosthesis.

In the last decade, more bioprosthetic valves have been used in comparison with mechanical prostheses. As bioprosthesis durability is limited over time, and the general population is getting older, managing degenerating bioprosthetic valves is becoming more common. Redo SAVR and ViV TAVI represent the 2 current treatment options for aortic bioprosthesis failure. Successful ViV TAVI requires careful evaluation of the implanted prosthetic valve and patient-specific anatomy to pick the most appropriate transcatheter valve as well as implantation position for the existing valve prosthesis. Failure to do so can result in procedure failure and poor patient outcomes. Potential complications of ViV TAVI include coronary obstruction, transcatheter valve migration and embolization, and high residual transvalvular gradients. There are limited comparative data for ViV TAVI and redo SAVR. Multiple previous studies have shown ViV TAVI to be a less invasive approach with noninferior to superior outcomes compared with redo SAVR, despite generally higher risk patient populations.<sup>19-23</sup> The caveat to this is that most of these studies were retrospective with limited data on long-term outcomes. Clinical trials are needed to evaluate the safety and efficacy profile of each treatment modality thoroughly. Regardless, in the era when ViV TAVI is becoming more and more popular, redo SAVR using RDVs may be a good option for patients with higher surgical risks who are not candidates for the ViV approach. As the field continues to evolve, various treatment modalities become available, which allows for a patient-oriented approach to the management of aortic valve

**Table 4. Other postoperative outcomes**

Outcome	RDV (n = 53)	TSV (n = 254)	OR (95% CI)	P value
New-onset AF	5 (9.4%)	41 (16.1%)	1.83 (0.6-6.1)	0.325
Acute kidney injury	1 (1.9%)	8 (3.2%)	2.16 (0.2-21.3)	0.601
Postop mean gradient	15.2 ± 6.2	11.1 ± 5.3	NA	< 0.001
Postop peak gradient	28.3 ± 11.4	21.3 ± 10.1	NA	< 0.001
ICU LOS	3 (3.0)	2.8 (3.8)	NA	0.461
Hospital LOS	9.9 (7.8)	9.9 (10.6)	NA	0.510

AF, atrial fibrillation; CI, confidence interval; ICU, intensive care unit; LOS, length of stay; OR, odds ratio; RDV, rapid deployment valve; TSV, traditional sutured valve.

disease. The decision-making process should take into account multiple factors such as the type of prosthesis failure, the risks and benefits of each approach, anatomic factors, local expertise, and patient preference.<sup>24</sup>

### Limitations and strengths

There are many limitations to this study. First, The retrospective nature of the study limits the ability to control for potential confounders. In this study, age is a major confounder with the 2 groups of patients having a 10-year age difference. There is likely an inherent surgeon bias toward choosing a RDV in older patients to decrease CPB and cross-clamp times. Second, the sample size of the study is small, and it may be difficult to generate statistically significant differences. Despite the small sample size, our study is among the larger studies reported for patients receiving RDV in the redo setting. Third, as in many studies, follow-up of 3 years may be too short to generate significant differences in the primary and secondary outcomes. Finally, combining multiple valve types, each with different durability into RDV and TSV groups, may be another potential source of bias in the study.

Overall, our study demonstrated that there was no difference in primary or major secondary outcomes for patients receiving RDVs or TSVs, despite an older patient population in the RDV group. In the era in which TAVI is now a class I recommendation for patients aged 65 to 80, we are likely to see more and more patients requiring a reoperation for their aortic valves, and not every patient is going to qualify for ViV TAVI. Future study should focus on comparing reoperative AVR via sternotomy and reoperative TAVI outcomes. The results of this study would suggest that RDVs might be a suitable and advantageous alternative to TSVs, especially in older patients, even if it is to save 1 hour of operating time.

### Conclusions

This study demonstrated that there were comparable short- and medium-term outcomes in patients who received RDVs or TSVs. Furthermore, RDV is a suitable option for older patients undergoing SAVR. In the context of reoperation, a reduction of 1 hour of CPB and cross-clamp times may be favourable not only for the patient but for the surgeon performing an already difficult procedure.

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### Disclosures

The authors have no conflicts of interest to disclose.

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