

Early surgical outcomes of rapid deployment aortic valve replacement in bicuspid aortic valves

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Background: Biological valve prostheses in rapid-deployment aortic valve replacement (RD AVR) procedures have demonstrated excellent outcomes. However, previous studies indicate a lack of specific surgical outcomes for the bicuspid aortic valve (BAV) or recommend RD AVR implementation. The existing literature comparing the clinical and hemodynamic outcomes of patients with BAV and those with tricuspid aortic valves (TAVs) after RD AVR is limited. Therefore, this study evaluated the safety and feasibility of RD AVR in BAV, including Sievers type 0, and compared the early clinical and hemodynamic outcomes of patients who underwent RD AVR at a single center based on aortic valve type.

Methods: Our institution officially commenced performing RD AVR using Intuity valves in September 2022. The medical records of 80 patients who underwent aortic valve replacement (AVR) between September 1, 2022, and July 31, 2023 were retrospectively analyzed. In this set, 30 patients underwent RD AVR for aortic stenosis. Among the 30 RD AVR cases, groups A and B comprised 16 (53.3%) patients with TAV and 14 (46.7%) with BAV, respectively. The preoperative characteristics and postoperative echocardiographic data were compared between the two groups.

Results: No statistically significant differences in preoperative characteristics, including mean age and sex distribution, were found between groups A and B. Notably, no patient in both groups exhibited mild- or higher-grade aortic regurgitation. The postoperative transvalvular mean pressure gradients showed significantly lower values in group B than in group A (12.20 ± 4.64 vs. 16.26 ± 5.49 mmHg, $P=0.03$). The necessity to insert a permanent pacemaker was not found in any of the patients (0%) in group A but was found in one (7.1%) patient in group B ($P=0.46$). Among the BAV cases, six (20%) were categorized as Sievers type 0. Of the 14 patients in group B, six with Sievers type 0 and the remaining eight with other bicuspid valve types were designated as groups B0 and B1, respectively. Similarly, no significant difference in postoperative transvalvular mean pressure gradient was observed between the two groups (11.33 ± 4.49 vs. 12.86 ± 4.94 mmHg, $P=0.56$). No in-hospital mortality was observed among all 30 patients.

Conclusions: In this study, RD AVR was considered feasible in a small, carefully selected cohort of patients with aortic stenosis, even in BAV, including Sievers type 0, as observed from the standpoint of postoperative hemodynamic outcomes and the incidence of aortic regurgitation.

Keywords: Aortic stenosis; bicuspid aortic valve (BAV); rapid-deployment aortic valve replacement (RD AVR)

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Introduction

Sutureless and rapid-deployment valves have emerged over the past decade as viable treatment options for patients requiring surgical aortic valve replacement (AVR) due to aortic stenosis. The use of biological valve prostheses in sutureless, rapid-deployment AVR (RD AVR) procedures has yielded excellent outcomes, establishing it as a safe and effective treatment alternative for individuals with severe aortic valve stenosis (1).

A decrease in procedural times has been demonstrated with RD AVR using the Intuity Elite (Edwards Lifesciences, Irvine, CA, USA), making minimally invasive approaches easier and simplifying valve implantation under complex anatomical conditions when compared with conventional AVR (2). This prosthetic valve has also demonstrated superior hemodynamic performance to conventional aortic bioprostheses (2). Another study revealed that RD AVR leads to shorter aortic cross-clamp (ACC) and cardiopulmonary bypass (CPB) times than standard AVR, particularly in patients undergoing concurrent procedures (3). This enables the use of larger prostheses and results in reduced transvalvular gradients and an increased indexed

effective orifice area compared with standard AVR. Consequently, RD AVR may provide a solution to patient-prosthesis mismatch in certain cases.

However, these studies (2,3) did not provide specific surgical outcomes for bicuspid aortic valve (BAV) or recommend RD AVR implementation since they completely excluded Sievers (4) type 0 bicuspid cases. The implantation of a rapid-deployment valve is currently discouraged and not recommended in patients with BAV, particularly those with Sievers type 0 anatomy (5,6). BAV is more elliptical in an annular shape and exhibits asymmetry in the sinus of Valsalva. Furthermore, the positioning of the commissures and annulus height differs from that of the tricuspid aortic valve (TAV), and the raphe is present. Therefore, because the Intuity Elite valve for RD AVR is primarily designed based on TAV, performing RD AVR in patients with BAV may raise concerns and must be approached cautiously. A favorable review article (7) on RD AVR in BAV exists, although it did not specifically mention the Sievers type 0.

Moreover, the existing literature comparing the clinical and hemodynamic outcomes of patients with BAV and those with TAV after RD AVR is limited (8-13). Therefore, this single-center, retrospective observational cohort study aimed to describe the postoperative outcomes and complications of patients with BAV (including Sievers type 0) treated with RD AVR compared with those of patients with TAV. We present this article in accordance with the STROBE reporting checklist (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-1942/rc>).

Methods

Patients selection

RD AVR practice using Intuity valves was officially initiated at Seoul St. Mary's Hospital in September 2022. We retrospectively analyzed the medical records of 80 patients who underwent AVR between September 1, 2022, and July 31, 2023. Of the 80 patients who underwent AVR, 16 were excluded because they received mechanical prosthetic valves, leaving 64 patients. The choice between tissue and mechanical valves was made in consultation with the patient, taking into account their age and preferences. After

Highlight box

Key findings

- Rapid-deployment aortic valve replacement did not significantly affect postoperative paravalvular leakage occurrence and permanent pacemaker insertion in patients with bicuspid aortic valves accompanied by aortic stenosis.

What is known and what is new?

- Rapid-deployment aortic valve replacement was generally considered an inappropriate indication in cases of aortic stenosis with a concomitant bicuspid aortic valve.
- Bicuspid aortic valves, including Sievers type 0, did not significantly increase the risk of paravalvular leakage occurrence and permanent pacemaker insertion compared to tricuspid aortic valve, postoperatively.

What is the implication, and what should change now?

- The consideration of rapid-deployment aortic valve replacement is deemed feasible in cases of severe aortic stenosis, irrespective of the presence of a preoperative bicuspid aortic valve.

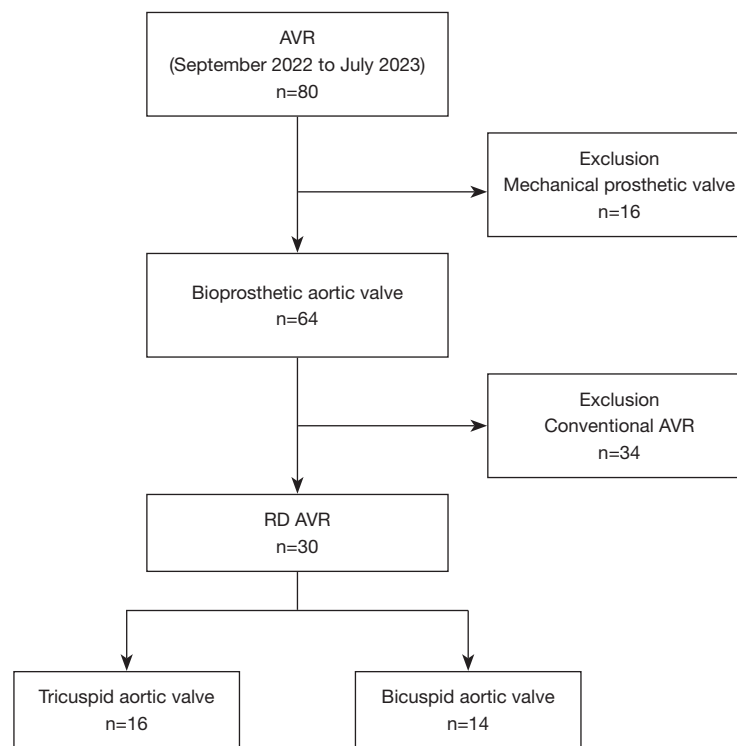


Figure 1 Patient selection diagram. AVR, aortic valve replacement; RD AVR, rapid-deployment aortic valve replacement.

excluding 34 conventional tissue valve cases, 30 RD AVR cases were analyzed (*Figure 1*). RD AVR was preferred for patients with aortic stenosis as the primary pathology, small aortic annulus (less than 21 mm on computed tomography), severe aortic annulus calcification, concomitant cardiac surgery, or other factors indicating high surgical risk (14). Individuals presenting with aortic regurgitation as the primary condition or exhibiting severe calcification in the left ventricular outflow tract (LVOT) were not considered candidates for RD AVR. Surgeon preference also played a role in this decision.

Surgical techniques

All RD AVR procedures were performed using an Edwards Intuity Elite (model 8300AB; Edwards Lifesciences) rapid-deployment valve system. All surgeries were performed using median sternotomy, given our initial experience with RD AVR. Depending on the need for concomitant surgery and the patient's characteristics, cavoatrial or bicaval CPB was initiated. Following aortotomy, we extracted the impaired aortic valve and performed complete decalcification, aiming to improve accommodation with

the implanted prosthesis, minimize the risk of paravalvular leakage, and establish a more accurate sizing standard.

The placement of the conventional three guiding stitches (simple, double-armed, and braided 2-0 sutures) was determined using the valve sizers provided (*Figure 2*). Care was taken to position the three struts of the prosthetic valve away from the coronary orifices whenever possible. Additional stitches, usually about three, were applied between the three guiding stitches, spaced at 120° intervals, as required. In this process, the stitches may not necessarily pass through only the nadir but can vary in position, particularly in Sievers type 0 bicuspid cases, depending on the shape of the patient's aortic annulus (*Figure 3*). We aimed to equalize the heights of the annular planes and ensure uniform seating of the inflow ring of the Intuity valve across the entire annulus to prevent misplacement. Additional stitches were necessary to ensure annular circularity and uniform height along the annular plane. The needle that passed through the annulus was also removed. Once the guiding sutures were set, a valve sizer was used to verify uniform spacing, and the complementary needle of the suture was subsequently passed through the sewing cuff of the Intuity valve. Next, the valve was parachuted toward

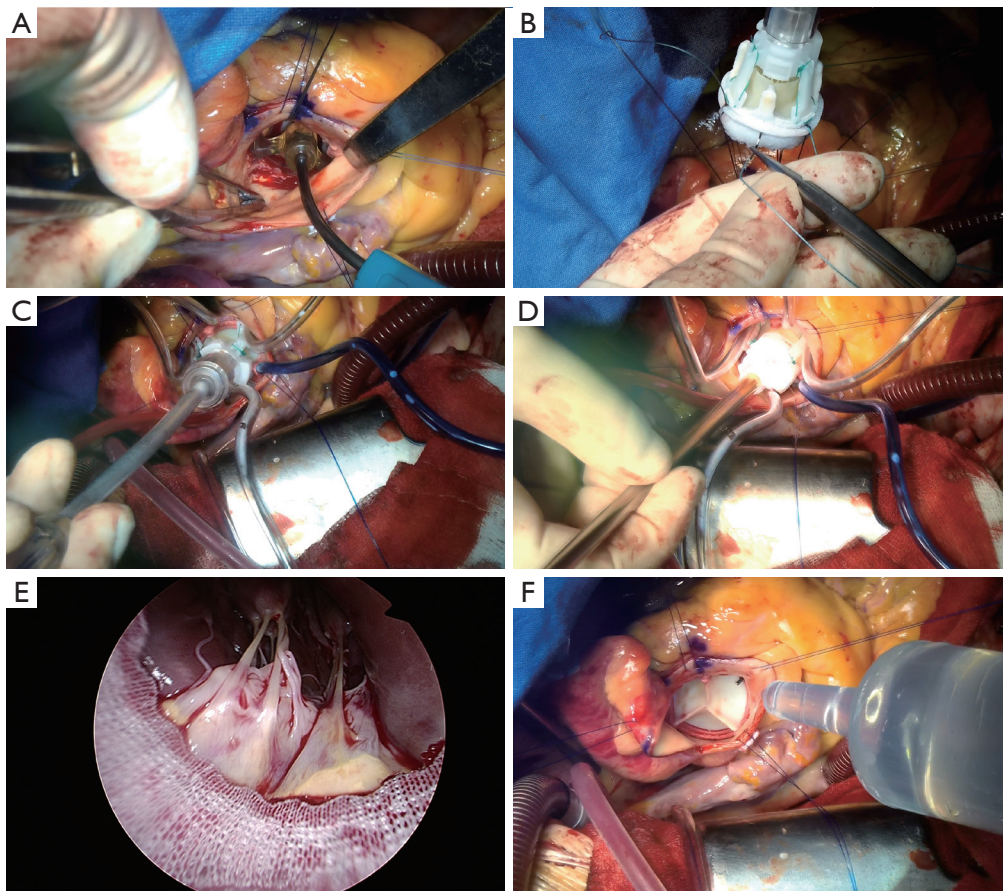


Figure 2 Rapid-deployment aortic valve replacement in a patient with a Sievers type 0 bicuspid aortic valve. (A) After marking the position of the coronary ostium, the decision regarding where to place the three guiding stitches is determined using a valve sizer. Additionally, three more stitches are added between the three guiding stitches, each separated by a 120° interval. (B) Conventional guiding sutures are placed at the sewing cuff of the Intuity valve, and the needles of these additional stitches are passed through the sewing cuff below the three struts. (C) After the Intuity valve is parachuted along the guide sutures down to the annulus, a total of six sutures are secured using stiff tourniquets. (D) The 5-mm scope is introduced through the center hole after the balloon catheter is detached from the valve holder. (E) The sealing frame is checked using the 5-mm scope before and after inflating the balloon. (F) Finally, normal saline was used to detect the presence of paravalvular leakage.

the annulus using suture guides. Several stiff tourniquets are used to secure the guiding sutures. While deploying a prosthetic valve, focusing on the orientation of the valve holder and guiding the stitch tension is important to ensure that the valve remains perpendicular to the annular plane. Before or after inflating the balloon to expand the sealing frame, if necessary, a 5-mm scope was inserted through the central hole to confirm the proper positioning of the balloon-expandable skirt within the LVOT. Finally, the holding sutures were tied using an automated suture-fastening device, and we confirmed the absence of paravalvular leakage using normal saline.

Study outcomes

The primary outcome was postoperative paravalvular regurgitation, while the secondary outcomes were transvalvular pressure gradients and pre-discharge pacemaker implants. Overall clinical outcomes, including surgical time, valve size, hospital stay, stroke, and 30-day mortality, were also analyzed.

The risk of early postoperative mortality was assessed using the European System for Cardiac Operative Risk Evaluation (EuroSCORE) II (15) and the Society of Thoracic Surgeons 30-day Predicted Risk of Mortality

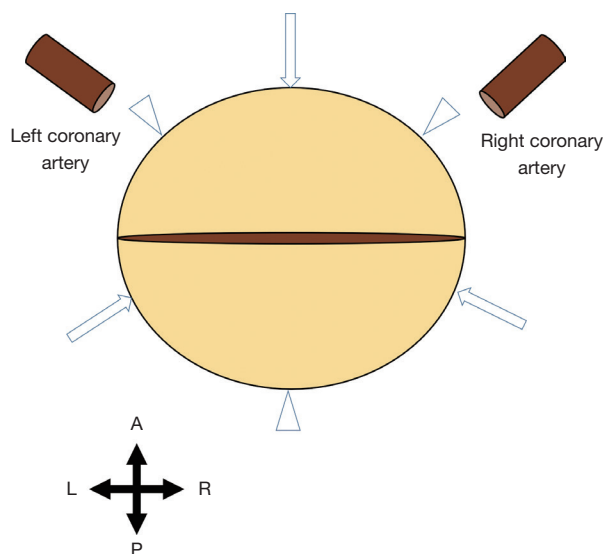


Figure 3 Schematic representation of a rapid-deployment aortic valve replacement in a patient with a Sievers type 0 bicuspid aortic valve. Traditional three guiding stitches (indicated by white arrowheads) are positioned 120° apart from each other. Two stitches are positioned below each coronary ostium, and one suture is applied at the lowest point of another sinus. Additional three stitches (indicated by white arrows) are necessary to ensure the annular circularity and uniform heights along the annular plane. A, anterior; P, posterior; R, right; L, left.

score (STS PROM) (16). Transthoracic echocardiography was performed in all patients before discharge from the hospital. Postoperative paravalvular leakage was defined as reaching a grade of mild or higher on postoperative echocardiography (17).

This study was conducted in accordance with the principle of the Declaration of Helsinki (as revised in 2013). The Institutional Review Board (IRB) of Seoul St. Mary's Hospital reviewed and approved this study's protocol (IRB No. KC23RISI0665), and the requirement for informed consent was waived due to its retrospective nature.

Statistical analysis

Continuous variables were expressed as means and standard deviations, while categorical variables were presented as counts and percentages. Group comparisons involved the use of independent-sample *t*-tests or Mann-Whitney *U* tests for continuous variables and Chi-squared or Fisher's exact tests for categorical variables. All statistical analyses

were performed using R (R 4.3.2; The R Foundation for Statistical Computing, Vienna, Austria), with statistical significance set at a two-sided *P* value of <0.05.

Results

Baseline characteristics

No patient had undergone previous cardiac surgery. Among the 30 patients, 16 and 14 were diagnosed with TAV (group A) and BAV (group B), respectively (Figure 1). No statistically significant differences were observed between the groups regarding sex, age, or baseline conditions (Table 1). However, the mean body surface area value was significantly higher in group B than in group A (1.59 ± 0.10 vs. 1.69 ± 0.12 m², *P*=0.02). Although EuroSCORE II did not significantly differ between both groups, STS PROM was higher in group A than in group B (2.08 ± 1.49 vs. 2.36 ± 1.67 , *P*=0.62 and 2.24 ± 1.29 vs. 1.27 ± 0.56 , *P*=0.01, respectively).

Clinical outcomes

Table 2 presents the operative data. A tendency for more concomitant aortic surgeries was found in patients from group B than in those from group A, without a significant difference (6.3% vs. 35.7%, *P*=0.07). A significant difference was found between group A and group B in the insertion of larger-sized valves (20.62 ± 1.82 vs. 22.86 ± 2.28 mm, *P*=0.006). Additionally, the CPB and ACC times were significantly longer in group B than in group A (151.64 ± 21.97 vs. 126.81 ± 22.49 min, *P*=0.005 and 111.21 ± 20.33 vs. 90.75 ± 16.32 min, *P*=0.005, respectively).

The postoperative results are outlined in Table 3. No paravalvular leakage was observed in any patient on postoperative transthoracic echocardiography performed before discharge. Patients with TAV exhibited higher mean and peak pressure gradients than those with BAV (16.26 ± 5.49 vs. 12.20 ± 4.64 mmHg, *P*=0.03 and 28.65 ± 8.31 vs. 22.05 ± 8.35 mmHg, *P*=0.03, respectively). Regarding permanent pacemaker implantation (PPI) during hospitalization, only one (7.1%) case occurred in group B (*P*=0.46). However, stroke and 30-day mortality were not found in any of the patients. The mean intensive care unit stay was 3.50 and 1.44 days in groups B and A, respectively (*P*=0.09). No significant difference was found between the two groups in the length of hospital stay (9.94 ± 4.81 vs. 11.86 ± 9.71 days, *P*=0.49).

Table 1 Preoperative clinical characteristics

Variables	Group A (n=16)	Group B (n=14)	P value
Sex, female	11 (68.8)	5 (35.7)	0.14
Age, years	71.06±4.99	64.86±12.83	0.08
BMI, kg/m ²	23.46±2.13	25.14±3.24	0.10
BSA, m ²	1.59±0.10	1.69±0.12	0.02
Atrial fibrillation	1 (6.3)	0	>0.99
Chronic kidney disease	2 (12.5)	1 (7.1)	>0.99
Cerebrovascular disease	2 (12.5)	1 (7.1)	>0.99
Chronic obstructive lung disease	0	2 (14.3)	0.20
Diabetes mellitus	6 (37.5)	5 (35.7)	>0.99
Hypertension	10 (62.5)	6 (42.9)	0.46
PCI	2 (12.5)	3 (21.4)	0.64
NYHA class, III–IV	9 (56.3)	10 (71.4)	0.46
Ejection fraction, %	62.84±6.01	60.29±9.90	0.39
Previous cardiac surgery	0	0	–
EuroSCORE II, %	2.08±1.49	2.36±1.67	0.62
STS PROM, %	2.24±1.29	1.27±0.56	0.01

Group A, patients diagnosed with TAV; group B, patients diagnosed with BAV. Categorical variables are shown as numbers with percentages, and continuous variables are shown as mean ± standard deviation. BMI, body mass index; BSA, body surface area; PCI, percutaneous coronary intervention; NYHA, New York Heart Association; EuroSCORE, European System for Cardiac Operative Risk Evaluation; STS PROM, Society of Thoracic Surgeons 30-day Predicted Risk of Mortality; TAV, tricuspid aortic valve; BAV, bicuspid aortic valve.

Table 2 Operative data

Variables	Group A (n=16)	Group B (n=14)	P value
Concomitant procedures			
Aortic aneurysm repair	1 (6.3)	5 (35.7)	0.07
CABG	1 (6.3)	1 (7.1)	>0.99
Mitral valve replacement	2 (12.5)	0	0.48
Maze procedure (left side)	1 (6.3)	1 (7.1)	>0.99
Valve size, mm	20.62±1.82	22.86±2.28	0.006
Aortic cross-clamp time, min	90.75±16.32	111.21±20.33	0.005
Cardiopulmonary bypass time, min	126.81±22.49	151.64±21.97	0.005

Group A, patients diagnosed with TAV; group B, patients diagnosed with BAV. Categorical variables are shown as numbers with percentages, and continuous variables are shown as mean ± standard deviation. CABG, coronary artery bypass grafting; TAV, tricuspid aortic valve; BAV, bicuspid aortic valve.

Table 3 Postoperative outcomes

Variables	Group A (n=16)	Group B (n=14)	P value
Stroke	0	0	–
Postoperative bleeding	1 (6.3)	0	>0.99
ICU stay, days	1.44±0.63	3.50±4.75	0.09
Hospital stay, days	9.94±4.81	11.86±9.71	0.49
30 days mortality	0	0	–
Paravalvular leakage	0	0	–
Mean pressure gradient, mmHg	16.26±5.49	12.20±4.64	0.03
Peak pressure gradient, mmHg	28.65±8.31	22.05±8.35	0.03
Peak aortic velocity, m/s	2.69±0.37	2.31±0.45	0.01
Permanent pacemaker implantation	0	1 (7.1)	0.46

Group A, patients diagnosed with TAV; group B, patients diagnosed with BAV. Categorical variables are shown as numbers with percentages, and continuous variables are shown as mean ± standard deviation. ICU, intensive care unit; TAV, tricuspid aortic valve; BAV, bicuspid aortic valve.

Secondary analysis

The outcomes of the patients in group B were analyzed and stratified into two subgroups based on the bicuspid anatomy. Among the 14 patients with BAV in group B, six classified as having true BAV (Sievers type 0) and eight classified as Sievers type 1 were categorized into groups B0 and B1, respectively. The clinical outcomes of the six participants in group B0 were assessed and compared with those of the eight individuals in group B1. [Table S1](#) presents the baseline characteristics of the patients.

No significant difference was found in the prosthetic valve size between the two groups (22.75±1.98 *vs.* 23.00±2.83 mm, *P*=0.84) ([Table S2](#)). However, the CPB and ACC times were significantly longer in group B0 than in group B1 (169.50±20.92 *vs.* 138.25±10.28 min, *P*=0.003 and 129.83±15.84 *vs.* 97.25±8.28 min, *P*<0.001, respectively). Concomitant aortic surgery was performed in four (66.7%) and one (12.5%) case in groups B0 and B1, respectively (*P*=0.09).

Furthermore, no significant differences were observed in the echocardiographic findings, including transvalvular pressure gradients, between the two groups ([Table S3](#)). None among the six patients with Sievers type 0 BAV required PPI.

Discussion

Surgical AVR procedures have become easier with the

Intuity valve system, leading to significantly shorter ACC and CPB times while ensuring excellent survival rates and improved valvular hemodynamic function (8,9). RD AVR, which has a balloon-expandable frame positioned in the subvalvular area of the LVOT, helps reduce blood flow turbulence (18). Consequently, it is considered advantageous in terms of hemodynamic performance even in patients with a small aortic root (19).

Patients who underwent RD AVR received larger prostheses despite sharing similar characteristics with those who underwent conventional AVR, leading to reduced pressure gradients and an improved indexed effective orifice area (3). This is particularly crucial for patients with smaller aortic roots. Compared to conventional AVR, which typically requires smaller prostheses, RD AVR does not require pledgeted sutures, which causes surgeons to select larger prostheses in borderline cases.

Although mortality and paravalvular regurgitation rates are similar when comparing sutureless or rapid-deployment valves for AVR to conventionally stented bioprosthetic valves, advantages and disadvantages might exist due to a higher PPI incidence (12). Typically, the reported PPI rates range from 3% to 8% for conventional surgical AVR (20). In transcatheter AVR cases, the reported PPI rate ranges from approximately 6.5% to 17.4% (21,22), and for bicuspid cases specifically, it is known to be in the range of 6.1% to 15.1% (23,24). This elevated occurrence of PPI in transcatheter AVR cases is reportedly believed to result from

the conduction system's compression due to expanding the bioprosthetic valve device without removing the calcified native valve (25). Sutureless AVR using the Perceval valve (LivaNova PLC, London, United Kingdom) reportedly has a high PPI rate of up to 23% (26). The PPI incidence ranged from approximately 5% to 13.6% following RD AVR using the Intuity valve system (9-11,13). In this study, among a total of 30 patients who underwent RD AVR, there was one case of PPI (3.3%).

However, most of the abovementioned study outcomes (8-13) did not encompass or acknowledge patients with BAV, and bicuspid valves were not referenced. The application of sutureless and rapid-deployment prostheses may be avoided in individuals with BAV because of anatomical concerns and the increased risk of paravalvular leaks. Additionally, the application of an extra guiding suture to a larger sinus, such as the noncoronary sinus, has been documented (5). However, according to Coti *et al.* (5) performing this procedure in high-volume centers is advisable for BAV cases. In cases of Sievers 0 BAV, where an abnormal origin of both coronary arteries from a single cusp is observed, an increased risk of coronary obstruction exists, leading to the avoidance of using the Intuity valve.

Some studies (5,6) involving patients with BAV for RD AVR have shown that moderate-to-severe paravalvular regurgitation occurs in >3% of cases, with a reported PPI incidence exceeding 9%. However, the number of patients with Sievers type 0 is minimal, and RD AVR is not recommended for patients with Sievers type 0 BAV. Additionally, a favorably inclined review article (7) on RD AVR in BAV did not specifically mention Sievers type 0.

Some reports (27,28) have suggested that patients with Sievers type 0 BAV are unsuitable candidates for RD AVR. A modified implant technique has been introduced in the case of a sutureless Perceval valve, focusing on Sievers type 0 BAV (29). Therefore, the significance lies in sharing our successful experience using RD AVR without any instances of paravalvular leakage, even in patients with type 0 BAV. However, short-term data on RD AVR technologies in patients with BAV, particularly Sievers type 0, are lacking, necessitating ongoing research.

Typically, the Intuity Elite valve requires three conventional guiding sutures to be placed at the nadir. However, in our study, we included additional stitches and used a scope pre- and post-balloon inflation to confirm the balloon-expandable frame and LVOT, potentially lengthening the surgical time. The meticulous choice of locations for additional sutures and the evaluation of diverse

anatomical factors, such as the coronary ostia, aimed to prevent complications, including valve malposition, leakage, and coronary obstruction. Furthermore, the attempt to use an oversized strategy to address the uneven or small annulus was avoided to prevent the potential risk of pacemaker insertion.

According to Barnhart *et al.* (11), the mean ACC and CPB times were reported as 49.3±26.9 and 69.2±34.7 min, respectively, for full sternotomy in isolated RDAVR procedures and 63.1±25.4 and 84.6±33.5 min, respectively, for minimally invasive approaches. Although they did not mention patients with BAV, our procedure took longer for AVR than that in the abovementioned study, given our initial experience, the higher number of patients with BAV, and the ratio of concomitant surgeries.

Given our institution's low volume of cardiac surgery and early experience, we focused more on achieving superior hemodynamic outcomes when performing RD AVR than on its advantages, such as reduced procedural times or enabling minimally invasive approaches. A report (30) indicated that although RD AVR shows low rates of postoperative regurgitation, the incidence remains higher than that of conventional AVR. However, our study did not find any cases of paravalvular regurgitation despite the higher proportion of patients with BAV. Therefore, we expect better surgical outcomes over time with increasing experience in our institution, akin to the findings in the report by Berretta *et al.* (31).

Reviewing the surgical risk profile of the patients in this study, the average value indicates a low-risk scenario. It is worth mentioning that in our institution's multidisciplinary discussions on the treatment strategy for aortic stenosis, patients predominantly classified as low surgical risk frequently choose surgical aortic valve replacement.

Coti *et al.* (5) reported that the rate of aortic surgery among patients with BAV was 22.4%, surpassing the 4.2% rate observed in the TAV group ($P<0.001$). Our data showed that aortic surgery was necessary in five (35.7%) patients in the BAV group. Since these cases involved concurrent aortic surgery, this emphasizes the continued requirement for careful consideration when surgically managing patients with BAV. Therefore, investigating the outcomes of surgical AVR in patients with Sievers type 0 BAV remains an ongoing and important issue.

This study had some limitations. Not being a prospective, randomized controlled clinical trial, there is a potential for selection bias in this study. When adopting a new procedure, the early experience involves some level

of surgeon preference in patient selection. The population size was limited, resulting in small sample sizes for the TAV and BAV groups, leading to heterogeneity. Therefore, conducting a statistical comparison between the two groups might substantially reduce statistical significance. This study's clinical significance lies in the experience of RD AVR in patients with BAV from a single institution perspective rather than categorizing its article as a comparative study. It also provides insights into the surgical techniques for patients with Sievers type 0 BAV. The purpose of performing subgroup analysis is not to discover additional statistical significance but to present the pre- and postoperative data separately for type 0 bicuspid patients and other bicuspid patients, aiming to demonstrate their distinct characteristics.

We focused on the early postoperative echocardiographic outcomes in our clinical analysis and did not include the details regarding late complications, quality of life, or long-term hemodynamic performance. According to Berretta *et al.* (13), the pressure gradient within the Intuity valve decreases as the valve size increases. Therefore, considering this characteristic of the valve size in our study results is necessary. Because larger prosthetic valve sizes were used in patients with BAV, a more extensive study involving a larger patient cohort is required.

Our study population has a limitation stemming from the limited number of patients with BAV, which was somewhat influenced by the prevalence of BAV. However, among the 30 RD AVR cases, 14 (46.67%) were BAV, indicating a substantially higher ratio. Although the general population has a relatively low BAV prevalence, ranging from approximately 1% to 2% (32), this pattern where a relatively greater number of patients with BAV are inclined toward surgical AVR rather than transcatheter AVR emerged from our multidisciplinary discussions involving patients with severe aortic stenosis.

Concerns regarding RD AVR can stem from elliptical annuli rather than circular annuli, incomplete prosthesis expansion, asymmetric calcification, and suboptimal alignment in BAV, particularly in Sievers type 0. However, based on our experience, conducting RD AVR might face fewer difficulties in scenarios where bicuspid valve anatomies exhibit a round aortic annulus and uniform commissure height. Therefore, exercising caution is necessary when using a valve sizer to mark the placement of guiding stitches to prevent coronary obstruction by any of the prosthesis commissural posts. Furthermore, safely performing RD AVR was feasible even in cases of Sievers

type 0 BAV, ensuring no paravalvular leakage, albeit with a slightly extended surgical duration using additional stitches.

Conclusions

This study shows that RD AVR can be performed as safely and efficiently as RD AVR in patients with BAV with aortic stenosis, with or without concomitant cardiac surgery, even when compared with TAV outcomes. Although RD AVR in BAV can be technically demanding, BAV, including Sievers type 0, may not be a contraindication for RD AVR if the shape of the aortic annulus is carefully considered.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-1942/rc>

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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-23-1942/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of this work and ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was conducted in accordance with the principle of the Declaration of Helsinki (revised in 2013) and was approved by the Institutional Review Board (IRB) of Seoul St. Mary's Hospital (IRB No. KC23RISI0665). The requirement for informed consent was waived due to the retrospective nature.

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Table S1 Preoperative clinical characteristics of patients with bicuspid aortic valves

Variables	Group B1 (n=8)	Group B0 (n=6)	P value
Sex, female	3 (37.5)	2 (33.3)	>0.99
Age, years	61.00±16.14	70.00±2.76	0.206
BMI, kg/m ²	25.73±3.30	24.36±3.28	0.453
BSA, m ²	1.71±0.13	1.65±0.12	0.346
Atrial fibrillation	0	0	–
Chronic kidney disease	1 (12.5)	0	>0.99
Cerebrovascular disease	1 (12.5)	0	>0.99
Chronic obstructive lung disease	1 (12.5)	1 (16.7)	>0.99
Diabetes mellitus	3 (37.5)	2 (33.3)	>0.99
Hypertension	5 (62.5)	1 (16.7)	0.138
PCI	2 (25.0)	1 (16.7)	>0.99
NYHA class, III–IV	5 (62.5)	5 (83.3)	0.580
Ejection fraction, %	63.02±6.13	56.65±13.20	0.248
EuroSCORE II, %	1.48±1.01	3.53±1.72	0.016
STS PROM, %	1.14±0.51	1.44±0.63	0.339

Group B0, six participants classified as Sievers type 0; group B1, eight participants classified as Sievers type 1. Categorical variables are shown as numbers with percentages, and continuous variables are shown as mean ± standard deviation. BMI, body mass index; BSA, body surface area; PCI, percutaneous coronary intervention; NYHA, New York Heart Association; EuroSCORE, European System for Cardiac Operative Risk Evaluation; STS PROM, Society of Thoracic Surgeons 30-day Predicted Risk of Mortality.

Table S2 Operative data of patients with bicuspid aortic valve

Variables	Group B1 (n=8)	Group B0 (n=6)	P value
Concomitant procedures			
Aortic aneurysm repair	1 (12.5)	4 (66.7)	0.091
CABG	0	1 (16.7)	0.429
Mitral valve replacement	0	1 (16.7)	0.429
Maze procedure (left side)	0	0	–
Valve size, mm	22.75±1.98	23.00±2.83	0.849
Aortic cross-clamp time, minutes	97.25±8.28	129.83±15.84	<0.001
Cardiopulmonary bypass time, minutes	138.25±10.28	169.50±20.92	0.003

Group B0, six participants classified as Sievers type 0; group B1, eight participants classified as Sievers type 1. Categorical variables are shown as numbers with percentages, and continuous variables are shown as mean ± standard deviation. CABG, coronary artery bypass grafting.

Table S3 Postoperative outcomes in patients with bicuspid aortic valves

Variables	Group B1 (n=8)	Group B0 (n=6)	P value
Stroke	0	0	–
Postoperative bleeding	0	0	–
ICU stay, days	4.50±5.93	2.17±2.40	0.384
Hospital stay, days	13.88±12.43	9.17±3.71	0.391
30 days mortality	0	0	–
Paravalvular leakage	0	0	–
Mean pressure gradient, mmHg	12.86±4.94	11.33±4.49	0.563
Peak pressure gradient, mmHg	22.96±8.73	20.83±8.46	0.655
Peak aortic velocity, m/s	2.35±0.46	2.25±0.48	0.700
Permanent pacemaker implantation	1 (12.5)	0	>0.99

Group B0, six participants classified as Sievers type 0; group B1, eight participants classified as Sievers type 1. Categorical variables are shown as numbers with percentages, and continuous variables are shown as mean ± standard deviation. ICU, intensive care unit.