

Minerva Access is the Institutional Repository of The University of Melbourne

Author/s:

Thuraisingam, A;Newcomb, AE

Title:

Rhythm disturbances following rapid-deployment aortic valve replacement

Date:

2021-12-01

Citation:

Thuraisingam, A. & Newcomb, A. E. (2021). Rhythm disturbances following rapid-deployment aortic valve replacement. *Jtcvs Techniques*, 10, pp.219-226. <https://doi.org/10.1016/j.xjtc.2021.10.029>.

Persistent Link:

<https://hdl.handle.net/11343/305129>

License:

[CC BY-NC-ND](#)

Rhythm disturbances following rapid-deployment aortic valve replacement



Amalan Thuraisingam, MD,^a and Andrew E. Newcomb, MBBS, FRACS^{a,b}

ABSTRACT

Objectives: There have been reports of postoperative conduction disturbances after rapid-deployment aortic valve replacement. Our objective was to assess electrocardiogram changes in patients undergoing this procedure and review the literature on this topic.

Methods: In this retrospective case series, clinical data were extracted from patient records at St Vincent's Hospital Melbourne and the Australia New Zealand Society of Cardiac and Thoracic Surgeons database. Electrocardiogram data were obtained at baseline and postoperatively on day 5 and at week 6 and reviewed for rhythm disturbances and intracardiac conduction problems. Pacemaker status was also recorded.

Results: From 2013 to 2017, 100 consecutive patients underwent rapid-deployment aortic valve replacement with 1 valve type at our institution. Three patients were excluded because of paced rhythm preoperatively, leaving 97 patients (mean age 74.7 ± 8.12 years; 56.7% male) for analysis. Some 18.6% of patients developed new left bundle branch block at 5 days postoperatively and only 4.1% of patients found with persistent left bundle branch block at 6-week follow-up compared with preoperatively. No significant changes were observed in the frequencies of atrial fibrillation, first-degree heart block, and right bundle branch block. However, there was evidence of increases in paced rhythm and subsequent need for a permanent pacemaker. A total of 14 patients (14.4%) had a permanent pacemaker implanted at an average of 11.1 ± 2.9 days postoperatively.

Conclusions: Rhythm disturbances and conduction abnormalities are noted with the rapid-deployment aortic valves used at our institution, but appear comparable to other rapid-deployment aortic valve replacement bioprostheses. These abnormalities may be related to the effect of the sub-annular stent frame of the valve system and implantation technique. (JTCVS Techniques 2021;10:219-26)



Complete deployment of the EIV (view from inside the left ventricle using the 5-mm 30-degree telescope).

CENTRAL MESSAGE

Rhythm disturbances and conduction abnormalities are noted with EIV RDAVR, but are comparable to other rapid-deployment aortic valve bioprostheses.

PERSPECTIVE

It appears that widened QRS complex may predispose to PPM implantation in the setting of RDAVR. Long-term follow-up is required to further assess whether new LBBB and widened QRS complex are transient or permanent beyond 6-week follow-up.

See Commentaries on pages 227 and 229.

Recent advancements in the technology of aortic valve design have led to new bioprosthetic valve designs that enable rapid deployment of aortic valve replacement (RDAVR). One of the RDAVR devices available is the

balloon-expandable, stented Edwards Intuity Elite (EIV) (Edwards Life Sciences LLC, Irvine, Calif).¹ RDAVR with the EIV is a safe procedure with shorter crossclamp time and cardiopulmonary bypass (CPB) time compared with conventional approaches and excellent early hemodynamic performance.²

Despite many clinical benefits of RDAVR with the EIV, there are some concerns over the effect of the subannular stent frame of the system with some evidence of subsequent postoperative conduction disturbances. The rate of permanent pacemaker (PPM) implantation for postoperative high-grade atrioventricular (AV) block ranges from 3.2% to 11.9% with the EIV.^{3,4} The recent US clinical trial by Barnhart and colleagues¹ showed the overall rate of new PPM implantation in patients with isolated aortic valve replacement (AVR) was 11.9%, in contrast to the previously reported rate of approximately 5% in the European EIV studies for isolated AVR.⁴ Because of the high

From the ^aDepartment of Cardiothoracic Surgery, and ^bUniversity of Melbourne Department of Surgery, St Vincent's Hospital Melbourne, Fitzroy, Australia.

The authors received no financial support for the research, authorship, or publication of this article. The study had the approval of the SVHM Ethics Committee (QA064/17), and as a de-identified, retrospective chart review study, the need for informed consent from patients was not deemed necessary.

Received for publication May 10, 2021; revisions received Sept 3, 2021; accepted for publication Sept 14, 2021; available ahead of print Oct 18, 2021.

Address for reprints: Amalan Thuraisingam, MD, Department of Surgery, Barwon Health - University Hospital Geelong, Bellerine St, Geelong 3220, Australia (E-mail: dramalant@gmail.com).

2666-2507

Copyright © 2021 The Author(s). Published by Elsevier Inc. on behalf of The American Association for Thoracic Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.jtc.2021.10.029>

Abbreviations and Acronyms

AV	= atrioventricular
AVR	= aortic valve replacement
CABG	= coronary artery bypass grafting
CHB	= complete heart block
CPB	= cardiopulmonary bypass
ECG	= electrocardiogram
EIV	= Edwards Intuity Elite
HB	= heart block
LBBB	= left bundle branch block
PPM	= permanent pacemaker
RBBB	= right bundle branch block
RDAVR	= rapid deployment of aortic valve replacement
SR	= sinus rhythm
SVHM	= St Vincent's Hospital Melbourne
TAVI	= transcatheter aortic valve implantation

incidence of postoperative conduction disturbances and subsequent implantation of a PPM with RDAVR, we aimed to assess the electrocardiogram (ECG) changes in patients with EIV RDAVR over the postoperative period in comparison with their preoperative ECGs.

MATERIALS AND METHODS

This retrospective study included all consecutive patients who underwent RDAVR with EIV, with or without other concomitant procedures, from 2013 to 2017 at our institution by the same lead surgeon. Retrospective data collection, medical record review, and data analysis was undertaken to examine ECG changes. Data were extracted from patient records at the St Vincent's Hospital Melbourne (SVHM), Australia, and the Australia and New Zealand Society of Cardiac and Thoracic Surgeons database. Clinical data including preoperative characteristics, operative details, and early postoperative outcomes were obtained from the database. Patients' medical records were also reviewed to obtain ECGs. The study protocol was approved by the SVHM Human Research Ethics Committee approval (QA064/17).

Evaluation of Electrocardiogram Changes Associated With Rapid Deployment of Aortic Valve Replacement

All patients' 12-lead ECGs were analyzed at 3 time points: (1) baseline (before surgery); (2) day 5 postsurgery; and (3) approximately 6 weeks after surgery. ECGs were reviewed for rhythm disturbances and the presence of any conduction disturbances as per the standardized criteria by the World Health Organization and the International Society and Federation of Cardiology.⁵ Documentation of pacemaker status was also confirmed as appropriate.

Surgical Techniques: Rapid-Deployment Aortic Valve Replacement

Full sternotomy, normothermic CPB, and transesophageal echocardiography was used for all cases. Venting cannulation was placed via the right superior pulmonary vein. Blood cardioplegia was administered antegrade and retrograde. After cardioplegic arrest, a transverse aortotomy was performed above the sinotubular junction. The diseased aortic valve leaflets

were cautiously excised and the annulus decalcified, ensuring the aortic annulus was undamaged. The cleaned aortic annulus was sized to identify the appropriate EIV valve. Implantation and deployment of the EIV valve was performed as recommended (Figure 1 shows the view from inside the left ventricle after complete deployment of the valve). We used a 5-mm, 30 degree telescope into the valve to inspect the ventricular aspect and assess complete seating before deployment. The expandable balloon frame was deployed with a 10-second balloon inflation after confirmation of the valve position. Three guiding sutures were tied off, and the aortotomy was closed.

Postoperative Period and Follow-up

All patients were followed up at 6 weeks after surgery. The primary end point was ECG changes in RDAVR with EIV patients over the postoperative period. The development of intraventricular conduction delays was also evaluated. There were no postoperative complications such as endocarditis, tamponade, or perioperative myocardial infarction.

Statistical Analysis

Statistical analysis was performed using SPSS version 25.0 (IBM Corp, Armonk, NY). Preoperative and intraoperative characteristics were compared using chi-square (for categorical variables) and independent sample *t* tests (for continuous variables). Categories of ECG rhythms of patients were compared using McNemar's test. Intraventricular conduction delays were tested using repeated-measures analysis of variance. Sphericity was checked using Mauchly's test. If the data violated the assumption of sphericity, then the Huynh-Feldt correction was applied. Logistic regression analysis was performed to assess whether any baseline variables or intraoperative variables were associated with postoperative ECG changes/PPM implantation.

RESULTS**Patient Characteristics**

A total of 100 patients underwent RDAVR with EIV. Three patients were excluded because of paced rhythm preoperatively, leaving 97 patients for analysis. Preoperative characteristics and valve pathologies are shown in Table 1. There were no significant differences in preoperative variables between patients who subsequently needed PPM implantation and those who did not (Table 1). Prevalent comorbidities, including coronary artery disease, hypertension, diabetes, respiratory disease, and arrhythmias diagnosed before the valve replacement, were comparable in

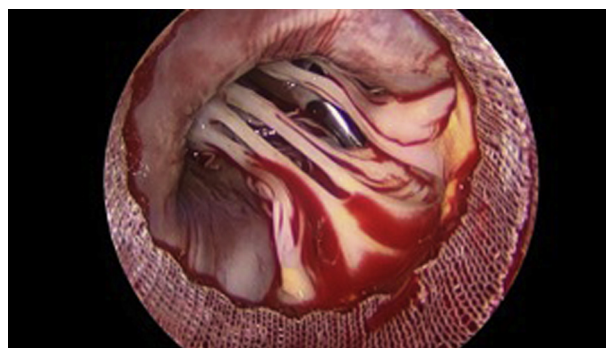


FIGURE 1. Complete deployment of the EIV (view from inside the left ventricle using the 5-mm 30-degree telescope).

TABLE 1. Preoperative characteristics (n = 97)

	All patients (n = 97)	No PPM (n = 83)	PPM (n = 14)	P value
Age, y	74.7 ± 8.12	74.6 ± 8.20	75.4 ± 7.93	.750
Male sex	55	48	7	.584
Height (cm)	164.61 ± 9.50	165.02 ± 9.73	162.14 ± 7.89	.296
Weight (kg)	77.46 ± 16.89	76.58 ± 16.67	82.71 ± 17.88	.210
Aortic valve stenosis	89	75	14	.225
Aortic valve regurgitation				
None	8	7	1	.312
Trivial	34	27	7	
Mild	26	24	2	
Moderate	18	14	4	
Severe	11	11	0	
Aortic valve pathology				
Idiopathic calcification	79	69	10	.078
Rheumatic	1	1	0	
Myxomatous degeneration	1	0	1	
Other degenerative disease	4	4	0	
Active infection	1	1	0	
Congenital bicuspid valve	6	3	3	
Prosthetic valve failure	3	3	0	
Trauma	1	1	0	
Other	1	1	0	
Preoperative ECG rhythm				.096
SR	58	52	6	
SR and LBBB	6	4	2	
AF	14	14	0	
SR and first-degree HB	6	6	0	
SR and RBBB	4	1	3	
SR and LAFB	1	1	0	
AF and RBBB	2	1	1	
AF and LBBB	6	4	2	
Previous CABG surgery	7	5	2	.269
Previous valve surgery	6	6	0	.299
Previous PCI stent	15	12	3	.505
Previous valvuloplasty	2	0	2	.001
Diabetes	35	29	6	.568
Hypertension	81	69	12	.810

Values are given as mean ± standard deviation and percentage. PPM, Permanent pacemaker; ECG, electrocardiogram; SR, sinus rhythm; LBBB, left bundle branch block; AF, atrial fibrillation; HB, heart block; RBBB, right bundle branch block; LAFB, left anterior fascicular block; CABG, coronary artery bypass grafting; PCI, percutaneous intervention.

patients with and without PPM. The study had the approval of the SVHM Ethics Committee (QA064/17), and as a de-identified, retrospective chart review study, the need for informed consent from patients was not deemed necessary.

Intraoperative Characteristics

Intraoperative characteristics are shown in Table 2. In all, 56 of 97 patients (57.7%) underwent isolated RDAVR. Coronary artery bypass grafting (CABG) surgery (42.3%) was the most common concomitant procedure performed with RDAVR. The most prevalent reason for AVR was isolated

severe aortic valve stenosis (91.8%) or combined with a variable degree of regurgitation. The most prevalent aortic valve pathology was idiopathic calcification (81.4%). The mean bioprosthetic aortic valve size did not differ between patients who needed PPM implantation postoperatively and those who did not (23.2 ± 2.6 vs 22.9 ± 2.1 , respectively, $P = .087$). There was no statistically significant difference in total crossclamp time ($P = .462$) and CPB time ($P = .195$) between patients who needed PPM implantation and those who did not (Table 2). Hospital mortality was 1.03%, and 30-day mortality was 4.12%.

TABLE 2. Intraoperative characteristics (n = 97)

	All patients (n = 97)	No PPM (n = 83)	PPM (n = 14)	P value
Isolated RDAVR	56	49	7	.527
Other concomitant cardiac surgery				
CABG	41	34	7	.527
Mitral valve replacement	4	4	0	.402
Tricuspid valve repair	3	2	1	.344
LV rupture repair	1	1	0	
Cardiac tumor	1	1	0	
Permanent epicardial lead placement	1	1	0	
Atrial arrhythmia surgery	2	2	0	
ASD closure	1	0	1	
Trauma	1	1	0	
Mean bioprosthesis aortic valve size (mm)	23.0 ± 2.2	22.9 ± 2.1	23.2 ± 2.6	.087
Total crossclamp time (min)	81.1 ± 33.50	81.0 ± 34.5	81.2 ± 28.3	.462
Total CPB time (min)	112.7 ± 44.40	112.0 ± 46.3	117.1 ± 31.8	.195

Values are given as mean ± standard deviation and percentage. PPM, Permanent pacemaker; RDAVR, rapid deployment of aortic valve replacement; CABG, coronary artery bypass grafting; LV, left ventricular; ASD, atrial septal defect; CPB, cardiopulmonary bypass.

Electrocardiogram Rhythm Analysis

Mean heart rate did not vary significantly between the preoperative and the follow-up measures ($P = .481$). Table 3 shows ECG rhythms between the 97 patients across the 3 repeated measures (preoperative, day 5 postoperatively, and at follow-up). No significant changes in the frequencies of atrial fibrillation were noted over time.

Descriptive statistics for the PR interval, QRS interval, and cQT interval are shown in Tables 4-6, respectively. The mean PR interval did not vary significantly across the 3 repeated measures. The mean QRS interval and mean cQT interval increased between the preoperative and postoperative measures and then decreased at follow-up

and varied significantly between the preoperative, 5-day postoperative, and 6-week follow-up.

Analysis of variance results are shown in the bottom of Tables 4-6. The within-subject effect was significant for QRS interval and cQT interval. Logistic regression analysis showed that there were no recorded variables that were significantly associated with subsequent PPM implantation.

Incidence of Permanent Pacemaker Implantation

A total of 14 patients (14.4%) had PPM implanted postoperatively. Only 7 of these patients had isolated RDAVR, and the remaining 7 patients had other concomitant procedures, most commonly CABG. The mean time of PPM

TABLE 3. Frequencies of repeated measures of electrocardiogram rhythms (n = 97)

ECG rhythm	(1) Preoperative	(2) Five d postoperative	(3) Follow-up	McNemar's test	
				Z	P
SR	58	24	26	12.19	<.001
SR and LBBB	6	25	16	11.65	.006
AF	14	12	10	0.67	1.00
SR and first-degree HB	6	4	6	0.40	1.00
SR and RBBB	4	7	2	0.82	1.00
SR, first-degree HB, and LBBB	1	5	1	2.67	1.00
SR and LAFB	1	0	0		
SR, first-degree HB, and RBBB	3	0	0		
AF and RBBB	2	1	0		
Paced rhythm	0	11	0		
AF and LBBB	6	1	0		
PPM	0	0	14		
SR, second-degree HB (Mobitz type 2), and RBBB	0	1	0		

Values are given as percentages. ECG, Electrocardiogram; SR, sinus rhythm; LBBB, left bundle branch block; AF, atrial fibrillation; HB, heart block; RBBB, right bundle branch block; LAFB, left anterior fascicular block; PPM, permanent pacemaker.

TABLE 4. Descriptive statistics for PR interval classified for 97 patients

	Repeated measures	Mean (ms)	95% CI	
			Lower bound	Upper bound
1	Preoperative	176.59	163.21	188.77
2	5 d postoperative	180.69	168.08	193.32
3	6-wk follow-up	177.35	164.17	190.53
Repeated-measures analysis of variance for PR interval classified by patient group				
Effect	Factor	df	F	P
Within-subject	Time	2	.231	.795

CI, Confidence interval.

implantation was 11.1 ± 2.9 days postoperatively. The main indication for needing PPM was complete heart block (CHB). Nine of these patients were in CHB, 2 patients were in bradyarrhythmia, 1 patient was in transient asystole, and 2 patients were pacing dependent.

We analyzed heart rate, PR, QRS, and cQT conduction intervals for PPM recipients ($n = 14$) compared with nonrecipients ($n = 83$). Baseline PR, QRS, and cQT intervals were slightly increased for PPM recipients compared with nonrecipients. At day 5 postsurgery, QRS and cQT intervals were significantly prolonged in PPM recipients compared with nonrecipients ($P = .001$ and $P = .027$, respectively). At day 5 and 6 weeks postsurgery, PR intervals were slightly longer in PPM recipients compared with nonrecipients; however, this difference was not statistically significant ($P = .303$ and $P = .632$, respectively). At 6 weeks follow-up, QRS and cQT intervals were significantly prolonged in PPM recipients compared with nonrecipients ($P = .014$ and $P = .023$, respectively).

DISCUSSION

Electrocardiogram Changes After Rapid Deployment of Aortic Valve Replacement

In this study, we have compared frequencies of ECG rhythms in 97 patients with RDAVR with EIV across 3 repeated measures (preoperative, 5 days postoperatively, and follow-up at 6 weeks). We found that sinus rhythm (SR) decreased in frequency over time ($P < .001$) and left bundle branch block (LBBB) increased in frequency over

time ($P = .006$). A study by Herry and colleagues⁶ had similar findings from a single-center experience where they compared EIV with conventional aortic valve bioprosthesis. No significant changes in the frequencies of atrial fibrillation, first-degree heart block (HB), and right bundle branch block (RBBB) were noted over time. However, there was evidence to indicate a likely increase in paced rhythm and subsequent implantation of PPM between the preoperative and follow-up measures. Only 59.8% of patients were in SR and without any conduction disturbance on ECGs preoperatively.

In terms of rhythm disturbances, only 24.7% of patients remained in SR, and 18.6% of patients developed new LBBB at 5 days postoperatively. However, at 6-week follow-up, only 4.1% of patients were found with persistent LBBB compared with preoperatively. Therefore, new onset of LBBB at 5 days postoperative was transient, with some completely resolved at 6-week follow-up. Previous studies have reported up to 20% incidence of new LBBB after Edwards Intuity valves.⁷ One recent large study by Coti and colleagues⁸ reported 31.1% of patients developed LBBB and 25.6% remained in LBBB at discharge. Likewise, a small sample size study ($n = 58$) reported 28% of new onset of LBBB in patients who had isolated RDAVR with the Edwards Intuity valve.⁹ Regeer and colleagues¹⁰ found 23% new-onset of LBBB with other RDAVR prostheses (Perceval S valve and 3f Enable valve) and 25% with transcatheter aortic valve implantation (TAVI) at hospital discharge.¹⁰ Persistent LBBB with TAVI was reported

TABLE 5. Descriptive statistics for QRS interval classified for 97 patients

	Repeated measures	Mean (ms)	95% CI	
			Lower bound	Upper bound
1	Preoperative	106.38	98.64	114.12
2	5 d postoperatively	129.51	121.33	137.68
3	6-wk follow-up	112.81	102.72	122.92
Repeated measures analysis of variance for QRS interval in 97 patients				
Effect	Factor	df	F	P
Within-subject	Time	2	12.29	<.001

CI, Confidence interval.

TABLE 6. Descriptive statistics for cQT interval classified for 97 patients

	Repeated measures	Mean (ms)	95% CI	
			Lower bound	Upper bound
1	Preoperative	407.22	387.57	425.86
2	5 d postoperative	439.93	430.98	448.87
3	6-wk follow-up	402.66	378.23	427.08
Repeated measures analysis of variance for cQT interval in 97 patients				
Effect	Factor	df	F	P
Within-subject	Time	2	4.86	.015

CI, Confidence interval.

approximately 9% at long term follow-up¹¹ and only 2% with conventional AVR, which had been the gold standard treatment for AVR.⁷ In comparison with other studies, the new incidence of LBBB after EIV RDAVR in our study was good.¹⁰ We had 18.6% of new LBBB at 5 days postoperatively and only 4.1% of patients remained in LBBB at 6 weeks follow-up.

Changes in Conduction Intervals

We analyzed changes in conduction intervals across the 3 repeated measures (preoperative, 5 days postoperative, and 6-week follow-up) for each patient. Our study found that the mean PR interval did not vary across the 3 repeated measures ($P = .795$). This was consistent with no changes in the frequencies of AV conduction rhythm disturbances: first-degree HB and second-degree HB (Mobitz type 2). D'Onofrio and colleagues⁹ reported approximately one-third of new onset of conduction disturbance and significant increase of QRS duration. It should be noted that this study had a small population ($n = 58$) and only included patients who had isolated RDAVR. A study by Coti and colleagues⁸ associated a higher incidence of new-onset LBBB in patients with widened QRS complex after RDAVR in follow-up periods. We have observed significant transient reduction in frequencies of new LBBB, widened QRS complex, and prolonged cQT conduction interval at 6-week follow-up compared with 5 days postoperatively. This could be related to the resolution of local inflammation, edema, and ischemia of the surrounding tissue after the valve replacement. However, there were patients with persistent new LBBB, widened QRS complex, and prolonged cQT interval at 6-week follow-up and remained asymptomatic. It seems that persistent new LBBB, widened QRS complex, and prolonged cQT interval are related to RDAVR itself. Previous studies have shown 2% of patients remained in new LBBB with conventional AVR and 9% of patients remained in new LBBB with TAVI.^{8,12} Our study showed only 4.1% of patients remained in new LBBB. Therefore, it appears that risk of developing new LBBB, wide QRS complex, and prolonged cQT interval is directly associated with complications with AVR regardless of valve choice. Conventional aortic valves are placed supra-annularly,

whereas the RDAVR and TAVI prosthesis are placed intra-annularly, close to the left bundle branch.¹⁰ Size of the bioprosthesis and annulus is paramount to avoid any disturbances to the conduction system.¹⁰ It should be noted that conventional prosthesis is sutured to the annulus; therefore, the prosthesis does not generate a radial force that compresses the conduction system. On the other hand, RDAVR prosthesis and TAVI prosthesis are placed intra-annularly and generate a radial force with expandable property, increasing the risk of compressing the conduction system compared with the conventional prosthesis. This would lead to permanent new LBBB, widened QRS complex, prolonged cQT interval, and perhaps the need for PPM implantation with RDAVR bioprosthesis.

Permanent Pacemaker Rates After Rapid Deployment of Aortic Valve Replacement

At 5 days postoperatively, 11 patients (11.3%) were found in paced rhythm (ie, complete AV block) and subsequently required implantation of PPM before hospital discharge. Three patients re-presented to hospital with symptomatic CHB and had PPM implanted postoperatively on days 23, 40, and 54, respectively, resulting in a total of 14 patients (14.4%) with a PPM implanted postoperatively. At 5 days postoperatively, these patients were in SR with LBBB, first-degree HB with LBBB, and atrial fibrillation with LBBB, respectively.

Literature review. A 2011 literature review reported a PPM implantation rate after RDAVR with EIV in patients who had isolated AVR of 3.0% to 11.8%.¹² We updated this literature review with 17 more recent studies, and PPM ranged from 4.5% to 14.5%. At 14.4%, the overall rate of PPM implantation in our study is at the higher end of the range reported in the literature. This can largely be explained by the fact that our patients had a higher rate of other concomitant procedures. Only 7 of our patients who required PPM had isolated RDAVR (57.7%), and the remainder had other concomitant procedures, most commonly CABG (42.3%). Other authors have also identified that postoperative pacemaker rates vary depending on these variables, for example, Rahmanian and colleagues¹³ reported rates of 3.5% for isolated RDAVR compared

with 12.5% for RDAVR/CABG. Evidence suggests that the EIV valve has slightly lower rates of PPM compared with the Perceval prosthesis with rates of 5% to 30%.¹⁴ The reported PPM rate in those undergoing TAVI is significantly higher with values up to 36%.¹⁵

Predictors of Permanent Pacemaker

Matthews and colleagues¹² concluded that first-degree AV block, left anterior hemiblock, RBBB, and LBBB are the most powerful independent predictors of PPM after AVR. The TRANSFORM trial study¹ associated preoperative rhythm disturbances with the occurrence of PPM implantation. Rahmanian and colleagues¹³ reported that preoperative RBBB was a strong independent predictor for PPM.

In contrast, no significant association between preoperative rhythm disturbance and postoperative risk of PPM implantation was observed in our study ($P = .096$). We analyzed whether preoperative conduction abnormalities, including prolonged PR interval (PR >200 ms), pre-excitation short PR interval, widened QRS complex (QRS interval >100 ms) and prolonged cQT interval (cQT >440 ms), increased the risk of PPM implantation. We did not find any significant differences in preoperative conduction between patients with and without PPM implanted postoperatively ($P = .494$). Other studies have also reported no association.¹³ In contrast, at 5 days postoperatively, there was a significant increase in the number of widened QRS complexes found in patients with PPM compared with patients without PPM implanted postoperatively ($P = .047$). There were no significant changes in prolonged PR interval or cQT interval between the 2 groups. Previous studies have reported widened QRS complex as a predictive marker for PPM implantation in TAVI patients.^{16,17} Therefore, one could argue that postoperative widened QRS complex may predispose patients to PPM implantation. We also compared baseline preoperative characteristics (Table 1) and intraoperative characteristics (Table 2) of the patients who did and did not have PPM postoperatively. We observed that patients who had previous aortic valvuloplasty had permanent PPM implanted postoperatively. Aortic valvuloplasty is a known risk factor for developing rhythm disturbances and subsequent need for PPM, which had been evidenced in previous trials. No other significant differences were seen in preoperative characteristics between the 2 patient groups. Rahmanian and colleagues¹³ reported a high rate of PPM implantation in patients who had combined AVR and CABG surgery. However, we did not observe any concomitant procedures, including CABG, that increased PPM implantation rates. Aortic valve pathology, including bicuspid aortic valve, was not identified as a risk factor.

One could argue that increased risk of permanent conduction disturbances and inevitably AV block and

subsequent need for PPM implantation with RDAVR bioprosthesis would be related to excessive oversizing in addition to intra-annular placement and expandable property with radial force. In addition, anatomy of the cardiac conduction system should be kept in mind. The bundle of His penetrates the interventricular septum between the right and noncoronary aortic leaflets, giving rise to the left bundle branch; this is where the skirt frame of EIV is anchored. Certainly, surgical trauma associated with excising the native valve and debriding the annulus may also increase the risk of developing conduction abnormalities and subsequent need for PPM implantation.¹⁸ It is important to note that patients with new conduction abnormalities, mainly LBBB postsurgical AVR, have a high risk of developing syncope or cardiac death compared with patients who did not have any new conduction abnormalities postsurgical AVR within 1-year follow-up.¹⁹ PPM implantation has its complications, such as lead or device infection, risk of HB after treatment of infection or replacement of the generator or leads, and malfunction of the device.¹⁸ Therefore, it is vital to take extra precautions intraoperatively to reduce the incidence of postoperative conduction disturbances and subsequent need for PPM implantation with EIV valve system.

Timing of Permanent Pacemaker Implantation

In our study, on average PPM implantation was performed 11.1 ± 2.9 days postoperatively and 3 of 14 (21.4%) were implanted in patients after hospital discharge. There are limited data on the timing of PPM implantation, if required, after RDAVR. The current European Society of Cardiology guidelines recommend a period of 7 days of persistent first-degree AV block after valve replacement before PPM implantation. Romano and colleagues²⁰ reported that the median time to pacemaker implantation was 6 days, 22% were required within the first 48 hours after surgery, and 20 of 107 (18.7%) underwent implantation after the initial hospitalization. Matthews and colleagues¹² reviewed 4 studies and reported that the mean time to PPM was 6 to 13 days after AVR. In comparison, after TAVI, one study reported that 25% of patients required PPM implantation within the first 72 hours.¹⁶ We have observed transient reduction in conduction abnormalities mainly in new LBBB and widened QRS complexes at 6 weeks follow-up compared with 5 days postoperatively. Thus, there appears to be a causal relationship between RDAVR and conduction abnormalities. In addition, after discharge, 3 patients presented with symptomatic CHB and had PPM implanted postoperatively on days 23, 40, and 54, respectively. This warrants further studies to establish a possible time limit before PPM implantation in some patients because of the transient nature of some conduction abnormalities.

Study Limitations

Limitations of this study include the retrospective design and only a small cohort of patients from a single center were included. Our analysis focused on ECG changes, and we did not provide information on echocardiography results at 6-week follow-up or on quality of life parameters. In addition, only short-term follow-up was included and longer-term follow-up would be required to investigate whether transient nature of observed ECG changes resolves over time. However, longer-term follow-up was not possible because many patients were from rural or regional areas and follow-up was not at our institution. In addition, the small study size may have resulted in a lack of power to detect differences between groups, such as the comparison between patients who did and did not need subsequent PM implantation.

CONCLUSIONS

In our case series, rhythm disturbances and conduction abnormalities comparable to other RDAVR bioprostheses are noted with EIV RDAVR. The most frequently observed abnormalities were new LBBB and widened QRS complex. Our study also found that there was a reduction in the number of new LBBB and widened QRS complex at 6-week follow-up compared with postoperative day 5. However, it appears that widened QRS complex may predispose to PPM implantation in the setting of RDAVR. Long-term follow-up is required to further assess whether new LBBB and widened QRS complex are transient or permanent beyond 6-week follow-up.

Conflict of Interest Statement

A.E.N. is a paid consultant for Edwards LifeSciences and Johnson & Johnson. A.T. reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

References

- Barnhart GR, Accola KD, Grossi EA, Woo YJ, Mumtaz MA, Sabik JF, et al. TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: performance of a rapid deployment aortic valve. *J Thorac Cardiovasc Surg.* 2017; 153:241-51.e2.
- Kocher AA, Laufer G, Haverich A, Shrestha M, Walther T, Misfeld M, et al. One-year outcomes of the surgical treatment of aortic stenosis with a next generation surgical aortic valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY valve system. *J Thorac Cardiovasc Surg.* 2013;145:110-6.
- Fischlein T, Meuris B, Hakim-Meibodi K, Misfeld M, Carrel T, Zembala M, et al. The sutureless aortic valve at 1 year: a large multicenter cohort study. *J Thorac Cardiovasc Surg.* 2016;151:1617-26.e4.
- Borger MA, Dohmen PM, Knosalla C, Hammerschmidt R, Merk DR, Richter M, et al. Haemodynamic benefits of rapid deployment aortic valve replacement via a minimally invasive approach: 1-year results of a prospective multicentre randomized controlled trial. *Eur J Cardiothorac Surg.* 2016;50:713-20.
- Willems JL, Robles de Medina EO, Bernard R, Coumel P, Fisch C, Krikler D, et al. Criteria for intraventricular conduction disturbances and pre-excitation. World Health Organization/International Society and Federation for Cardiology task force ad hoc. *J Am Coll Cardiol.* 1985;5:1261-75.
- Herry M, Laghnam D, Touboul O, Nguyen LS, Estagnasie P, Brusset A, et al. Pacemaker implantation after aortic valve replacement: rapid-deployment IntuityVR compared to conventional bioprostheses. *Eur J Cardiothorac Surg.* 2020; 58:335-42.
- Poels TT, Houthuizen P, Van Garsse LA, Soliman Hamad MA, Maessen JG, Prinzen FW, et al. Frequency and prognosis of new bundle branch block induced by surgical aortic valve replacement. *Eur J Cardiothorac Surg.* 2015;47:e47-53.
- Coti I, Haberl T, Scherzer S, Werner P, Shabanian S, Kocher A, et al. Outcome of rapid deployment aortic valves: long-term experience after 700 implants. *Ann Cardiothorac Surg.* 2020;9:314-21.
- D'Onofrio A, Bagozzi L, Tessari C, Francescato A, Cibir G, Besola L, et al. Evaluation of conduction disorders after aortic valve replacement with rapid deployment bioprostheses. *Innovations (Phila).* 2018;13:356-60.
- Regeer MV, Merckestein LR, de Weger A, Kamperidis V, van der Kleij F, van Rosendaal PJ, et al. Left bundle branch block after sutureless, transcatheter, and stented biological aortic valve replacement for aortic stenosis. *EuroIntervention.* 2017;12:1660-6.
- Nazif TM, Williams MR, Hahn RT, Kapadia S, Babaliaros V, Rodés-Cabau J, et al. Clinical implications of new-onset left bundle branch block after transcatheter aortic valve replacement: analysis of the PARTNER experience. *Eur Heart J.* 2014;35:1599-607.
- Matthews IG, Fazal IA, Bates MG, Turley AJ. In patients undergoing aortic valve replacement, what factors predict the requirement for permanent pacemaker implantation? *Interact Cardiovasc Thorac Surg.* 2011;12:475-9.
- Rahmanian PB, Kaya S, Eghbalzadeh K, Menghesha H, Madershahian N, Wahlers T. Rapid deployment aortic valve replacement: excellent results and increased effective orifice areas. *Ann Thorac Surg.* 2018;105:24-30.
- Bouhout I, Mazine A, Rivard L, Ghoneim A, El-Hamamsy I, Lamarche Y, et al. Conduction disorders after sutureless aortic valve replacement. *Ann Thorac Surg.* 2017;103:1254-60.
- Schroeter T, Linke A, Haensig M, Merk DR, Borger MA, Mohr FW, et al. Predictors of permanent pacemaker implantation after Medtronic CoreValve bioprosthesis implantation. *Europace.* 2012;14:1759-63.
- López-Aguilera J, Segura Saint-Gerons JM, Mazuelos Bellido F, Suárez de Lezo J, Ojeda Pineda S, Pan Álvarez-Ossorio M, et al. Atrioventricular conduction changes after CoreValve transcatheter aortic valve implantation. *Rev Esp Cardiol (Engl Ed).* 2016;69:28-36.
- Urena M, Mok M, Serra V, Dumont E, Nombela-Franco L, DeLarochellière R, et al. Predictive factors and long-term clinical consequences of persistent left bundle branch block following transcatheter aortic valve implantation with a balloon-expandable valve. *J Am Coll Cardiol.* 2012;60:1743-52.
- Levack MM, Kapadia SR, Soltesz EG, Gillinov AM, Houghtaling PL, Navia JL, et al. Prevalence of and risk factors for permanent pacemaker implantation after aortic valve replacement. *Ann Thorac Surg.* 2019;108:700-7.
- El-Khalily Z, Thibault B, Staniloae C, Theroux P, Dubuc M, Roy D, et al. Prognostic significance of newly acquired bundle branch block after aortic valve replacement. *Am J Cardiol.* 2004;94:1008-11.
- Romano MA, Koeckert M, Mumtaz MA, Slachman FN, Patel HJ, Chitwood WR Jr, et al. Permanent pacemaker implantation after rapid deployment aortic valve replacement. *Ann Thorac Surg.* 2018;106:685-90.

Key Words: aortic valve replacement, Edwards Intuity Elite valve, electrocardiogram, RDAVR