


Pacemaker dependency after transcatheter aortic valve replacement compared to surgical aortic valve replacement

You Mi Hwang, MD, PhD^a, Jun Kim, MD, PhD^b, Gi Byoung Nam, MD, PhD^b, Kee Joon Choi, MD, PhD^{b,*} , Duk-Woo Park, MD, PhD^b, Do-Yoon Kang, MD, PhD^b, Seung-Jung Park, MD, PhD^b, Seo Young Park, PhD^c

Abstract

Transcatheter aortic valve replacement (TAVR) is a standard treatment indicated for severe aortic stenosis in high-risk patients. The objective of this study was to evaluate the incidence of pacemaker dependency after permanent pacemaker implantation (PPI) following TAVR or surgical aortic valve replacement (SAVR) and the risk of mortality at a tertiary center in Korea.

In this retrospective study conducted at a single tertiary center, clinical outcomes related to pacemaker dependency were evaluated for patients implanted with pacemakers after TAVR from January 2012 to November 2018 and post-SAVR from January 2005 to May 2015. Investigators reviewed patients' electrocardiograms and baseline rhythms as well as conduction abnormalities. Pacemaker dependency was defined as a ventricular pacing rate > 90% with an intrinsic rate of <40bpm during interrogation.

Of 511 patients who underwent TAVR for severe AS, 37(7.3%) underwent PPI after a median duration of 6 (3–7) days, whereas pacemakers were implanted after a median interval of 13 (8–28) days post-SAVR in 10 of 663 patients ($P < .001$). Pacemaker dependency was observed in 36 (97.3%) patients during 7 days immediately post-TAVR and in 25 (64.9%) patients between 8 and 180 days post-TAVR. Pacemaker dependency occurred after 180 days in 17 (50%) patients with TAVR and in 4 (44.4%) patients with SAVR. Twelve (41.4%) patients were pacemaker-dependent after 365 days post-TAVR.

Pacemaker dependency did not differ at 6 months after TAVR vs SAVR. In patients undergoing post-TAVR PPI, 58.6% were not pacemaker-dependent at 1 year after the TAVR procedure.

Abbreviations: AF = atrial fibrillation, AVB = atrioventricular block, ECG = electrocardiogram, EPS = electrophysiology study, LBBB = left bundle branch block, PM = pacemaker, PPI = permanent pacemaker implantation, RBBB = right bundle branch block, SAVR = group, patients treated with PPI post-SAVR, SAVR = surgical aortic valve replacement, TAVR = group, patients treated with PPI post-TAVR, TAVR = transcatheter aortic valve replacement.

Keywords: aortic valve stenosis, artificial, heart conduction system, pacemaker, transcatheter aortic valve replacement

1. Introduction

Compared with surgical aortic valve replacement (SAVR),^[1] transcatheter aortic valve replacement (TAVR) is associated with

Editor: Simone Gulletta.

The authors have no funding and conflicts of interests to disclose.

Supplemental Digital Content is available for this article.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

^a Department of Cardiology, St. Vincent's Hospital, The Catholic University of Korea, ^b Department of Cardiology, ^c Department of Clinical Epidemiology and Biostatistics, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea.

* Correspondence: Kee Joon Choi, Division of Cardiology, Asan Medical Center, University of Ulsan College of Medicine, Seung-Jung Park, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 05505, Korea (e-mail: kjchoi@amc.seoul.kr, sjpark@amc.seoul.kr).

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How to cite this article: Hwang YM, Kim J, Nam GB, Choi KJ, Park DW, Kang DY, Park SJ, Park SY. Pacemaker dependency after transcatheter aortic valve replacement compared to surgical aortic valve replacement. *Medicine* 2021;100:22(e26123).

Received: 19 January 2021 / Received in final form: 8 April 2021 / Accepted: 10 May 2021

<http://dx.doi.org/10.1097/MD.00000000000026123>

a substantially higher risk of developing conduction disorders or undergoing permanent pacemaker implantation (PPI), especially with early versions of valves.^[2–6] A few studies have predicted the risk of PPI after TAVR. A high calcium burden in the aortic valve and pre-existing right bundle branch block (RBBB) can predict the use of a permanent pacemaker after TAVR,^[7] along with valve type and the use of an oversized valve.^[8] Recent studies have reported that post-TAVR de novo atrioventricular block (AVB) and left bundle branch block (LBBB)^[3,7,9] are strong risk factors for PPI. However, the significance of PPI dependency and recovery of atrioventricular conduction during long-term follow-up is unknown. In previous studies, pacemaker dependency was monitored for about 1 year and the dependency rate varied.^[10,11] The objective of this study was to evaluate pacemaker dependency and recovery of atrioventricular conduction in PPI patients post-TAVR and post-SAVR and their clinical significance for the risk of death after a long-term follow-up.

2. Materials and methods

2.1. Patients

This study was a retrospective analysis of patients with PPI for severe aortic stenosis post-TAVR and post-SAVR at a single tertiary center in South Korea. Patients undergoing PPI after TAVR from January 2012 to November 2018 and patients with PPI post-SAVR between January 2005 and May 2015 were included in the present study. Investigators reviewed patients'

baseline clinical demographics and electrocardiograms (ECGs) based on hospital records. This study was approved by the Institutional Review Board (IRB) of Asan Medical Center, Seoul, South Korea (IRB No.2016–1147).

2.2. ECG parameters

Investigators reviewed baseline rhythms and conduction disturbances (LBBB, RBBB, degree of AVB, and fascicular block). Investigators also reviewed perioperative and postoperative ECGs.

2.3. Evaluation of pacemaker dependency and clinical profile

In the present study, post-TAVR or post-SAVR pacemaker dependency was defined by >90% pacing rate during interrogation. Investigators interrogated the pacemaker every 3 to 6 months and analyzed atrial and ventricular pacing rates. We induced an atrial pacing rate >100 to 150 bpm in patients with dual-chamber pacemakers to test the recovery of atrioventricular conduction. Atrioventricular conduction recovery was defined by higher atrial pacing followed by intrinsic narrow QRS complex. However, a few patients with pre-operative intraventricular conduction delay leading to recovery of baseline QRS were also categorized as patients with atrioventricular conduction recovery. In patients with atrial fibrillation (AF) or implanted with single VVI pacemakers, the ventricular pacing rate was analyzed if the intrinsic rate was less than 40 bpm.

2.4. Statistical analysis

Continuous variables were analyzed with *t* test when appropriate. Results are expressed as mean ± standard deviation. Continuous variables that were not normally distributed were interpreted as median [interquartile range] and analyzed using the Mann–Whitney *U* test. Categorical variables were described as frequencies and compared using the Chi-Squared test or Fisher exact test as appropriate. The Cochran–Armitage trend test was performed to analyze differences in PM dependency during follow-up. Predictors of PM dependency were analyzed via univariate analysis (*P* < .2). Kaplan–Meier survival analysis based on PM dependency was performed. RV pacing rate higher than 40%, atrioventricular conduction recovery and new onset conduction disorders were analyzed. All statistical analyses were performed using R 4.0 statistical software (R Foundation for Statistical Computing, Vienna, Austria, 2018).

3. Results

3.1. Patient characteristics

Of 511 patients who underwent TAVR for severe AS, 37 (7.3%) underwent PPI after a median duration of 6 (3–7) days, whereas 10 of 663 patients who were treated with SAVR underwent PPI [1]. Patients, valves, and baseline ECG and indications for PPI in both groups are described in Table 1. The mean age of PPI patients post-TAVR (TAVR group) was 81.4 ± 4.5 years, while the mean age of PPI patients post-SAVR (SAVR group) was 67.5 ± 8.6 years. The median follow-up duration was 807 (105–2336) days in the TAVR group and 1058 (286–3528) days in the SAVR group. Balloon-expandable (Edwards Sapien 3) trans-catheter heart valves were implanted in 14 (37.8%) patients, while self-

Table 1

Patient, valve, ECG characteristics, and pacemaker dependency of the study population.

	SAVR (N=10)	TAVR (N=37)	P value
Age (yrs)	67.5 ± 8.6	81.4 ± 4.5	<.001
Sex (male, %)	5 (50%)	20 (54.1%)	.665
POD to PPI (days)	13 [8–28]	6 [3–7]	<.001
Valve size	21.0[19–27]	27 [23–31]	<.001
Valve type			.008
Mechanical valve	6 (60%)	14 (37.8%)	
Tissue valve	4 (40%)	23 (62.2%)	
Balloon expandable valve (Edwards Sapien)		21 (56.8%)	
Self expandable valve		1 (2.7%)	
Corevalve		1 (2.7%)	
Lotus			
Evolut R			
Baseline rhythm			
RBBB	3 (30%)	17 (45.9%)	
LBBB	3 (30%)	0	
AF	2 (20%)	8 (21.6%)	
First-degree AVB	0	4 (10.8%)	
Sinus	3 (30%)	8 (21.6%)	
Rhythm before PPI (Indication for PPI)			.013
New onset LBBB	0	17 (45.9%)	
High degree or complete AVB	5 (50%)	34 (91.9%)	
Bifascicular or Trifascicular block	5 (50%)	3 (8.1%)	

AF = atrial fibrillation, AVB = atrioventricular block, LBBB = left bundle branch block, POD = postoperative day, PPI = permanent pacemaker implantation, RBBB = right bundle branch block, SAVR = surgical aortic valve replacement, TAVR = transcatheter aortic valve implantation.

expandable valves were implanted in 23 (62.2%) patients (21 Core valves (56.8%), 1 Evolut R (2.7%), and 1 Lotus (2.7%) valve) in the TAVR group. Six (60%) patients in the SAVR group underwent tissue valve implantation, while 4 (40%) patients were treated with mechanical valves. The median valve size was 27 mm (23–31 mm) in the TAVR group and 21 mm (19–27 mm) in the SAVR group.

3.2. Pre-existing conduction disturbances and arrhythmias in patients undergoing PPI

In the TAVR group (n = 37), 17 (45.9%) patients had pre-existing RBBB, 8 (21.6%) patients had AF (paroxysmal AF in 5 cases and persistent AF in 3 patients) and 4 (10.8%) patients had first-degree AVB. For 8 (21.6%) patients, there was no documented arrhythmia before TAVR. In the SAVR group (n = 10), 3 (30%) patients had pre-existing RBBB and 3 (30%) patients had LBBB. Two (20%) patients showed AF while 3 (30%) patients had no arrhythmia diagnosis before SAVR.

3.3. Newly developed conduction disturbances

De novo conduction disturbances were detected in 115 (22.5%) of 511 TAVR patients. These 115 cases included 37 patients who underwent PPI (30 with complete AVB, 4 with a high degree of AVB, 3 with symptomatic trifascicular block). A total of 78 patients with new onset conduction disorders without PPI included 53 cases of LBBB, 7 cases of RBBB, 14 manifesting first-degree AVB, 2 cases of bifascicular block, and 2 cases involving trifascicular block (Figure S1, Supplemental Digital Content, <http://links.lww.com/MD2/A193>). In the TAVR group, 17

(45.9%) patients manifested new-onset LBBB and 35 (94.6%) patients had high-degree and complete AVB as an indication for PPI. A comparison of post-TAVR changes in QRS duration between PPI and non-PPI patients revealed significantly longer QRS duration in PPI patients (31 ms vs 4 ms, $P = .001$). Before pacemaker implantation in the TAVR group, we performed electrophysiology studies (EPS) in 12 (32.4%) patients who were diagnosed with an intra-Hisian block (1 patient) or an infra-Hisian block (11 patients) with HV prolongation (79.2 ± 4.3 ms).

De novo conduction disorders were detected in 68 (10.3%) of 663 patients post-SAVR. These 68 cases included 10 patients with complete AVB and 58 patients with newly developed first-degree AVB. Five patients with complete AVB recovered from

within 1 week. They were discharged without PPI. Overall, 10 patients in the SAVR group underwent PPI (5 cases of complete AVB and 5 cases of symptomatic trifascicular/bifascicular block) due to de novo conduction disturbances.

3.4. Pacemaker dependency during the follow-up period

Pacemaker dependency was observed in 36 (97.3%) patients in the TAVR group during the first 7 days, 25 patients (64.9%) between days 8 and 180, and 17 patients (50%) after 180 days (Fig. 1; Table 2). In patients with balloon-expandable valves, 7 of 14 patients were pacemaker-dependent, whereas 10 of 23 patients undergoing self-expandable valve implantation were

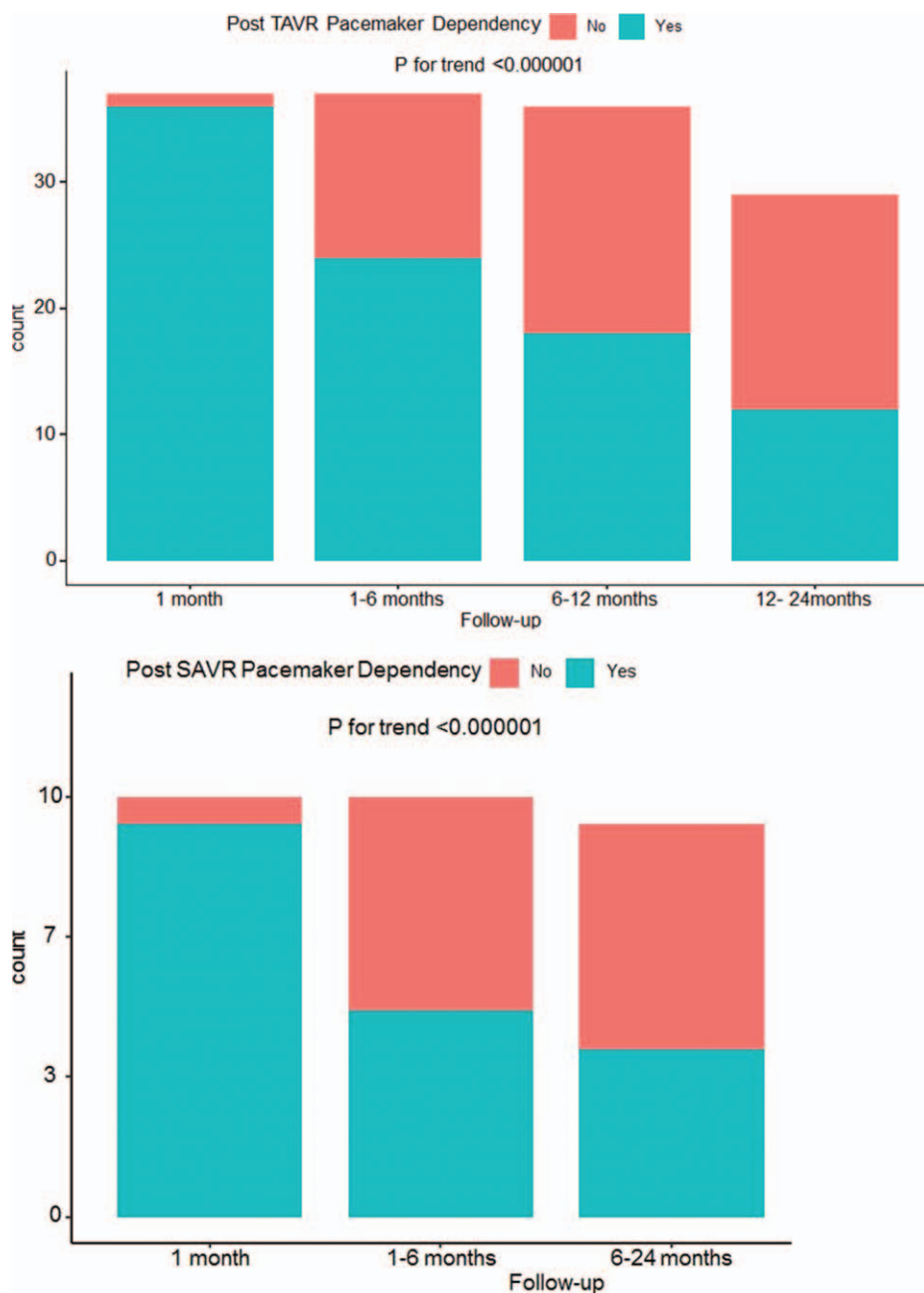


Figure 1. Changes in pacemaker dependency rate in TAVR and SAVR patients during the follow-up period.

Table 2
Pacemaker dependency and mortality during follow up.

	SAVR (N = 10)	TAVR (N = 37)	P value
Pacemaker mode			.594
DDD(R)	8 (80%)	33 (89.2%)	
VI(R)	2 (20%)	4 (10.8%)	
Pacemaker dependent patients within 6 months	5 (50%)	25 (64.9%)	.456
Pacemaker dependent patients after 6 months	4 (44.4%)	17 (50%)	.872
RV pacing rate >40% at 2 year	5 (55.5%)	25 (67.6%)	.153
Atrioventricular conduction recovery <6 months	2 (20%)	7 (18.9%)	>.999
Atrioventricular conduction recovery >6 months	3 (33.3%)	10 (27.0%)	>.999
Death (%)	0 (0%)	13 (35.1%)	.043

PM-dependent after 180 days. There was no significant difference in pacemaker dependency between balloon-expandable and self-expandable valves after 180 days ($P = .07$). Even in patients who underwent EPS before pacemaker implantation, 8 of 12 patients with infra-Hisian blocks at the time of PPI were not dependent on the pacemaker after 180 days (Fig. 2). After 365 days, 12 (41.4%) patients were pacemaker-dependent. In the SAVR group, pacemaker dependency was observed in 9 (90%) patients within 30 days and 4 (44.4%) patients even after 180 days (Fig. 1; Table 2).

An RV pacing rate higher than 40% was observed in 67.6% and 55.5% of patients in the TAVR group and the SAVR group, respectively. Pre-existing arrhythmia was not related to pacemaker dependency in our study population based on logistic regression analysis (pre-existing RBBB (OR = 1.786 [0.47–7.07], $P = .397$); first AVB (OR = 0.94 [0.10–8.64], $P = .95$; AF (OR = 0.7 [0.12–3.73], $P = .675$).

3.5. Post-TAVR vs post-SAVR pacemaker patients

Compared with SAVR patients, patients undergoing TAVR were older, had a larger valve size, and a higher prevalence of newly developed atrioventricular conduction disorders. The duration of PPI was significantly shorter in the TAVR patients than in the SAVR patients (6 days vs 13 days). Temporal variation in pacemaker dependency was not statistically significant between the 2 groups (Table 2). There were no significant differences in PM dependency during the 7-day follow-up period after PPI. In TAVR patients with PPI within 7 days, 14 of 28 cases (50%) were PM-dependent. For those with PPI after 7 days (10 SAVR patients + 9 TAVR patients), 8 of 19 cases (42.1%) were PM-dependent after 180 days.

Until 180 days, AVB recovery was observed in 7 (18.9%) patients with TAVR and 2 (20%) patients with SAVR after atrioventricular conduction with atrial pacing at a higher rate (100–150 bpm). AVB recovery after 180 days was seen in 8 (21.6%) patients undergoing TAVR and 2 (22.2%) patients treated with SAVR. There were no significant differences in mortality according to AVB recovery (Figure S2, Supplemental Digital Content, <http://links.lww.com/MD2/A194>).

Thirteen (35.1%) deaths occurred in the TAVR group during the follow-up period. However, no death was found in the SAVR group during the follow-up period. Mortality was significantly higher in PM-dependent patients during <180 days of follow-up.

However, it showed no difference after 180 days (Fig. 3). In the TAVR group, patients with an RV pacing rate >40% had a lower survival during more than 2 years of follow-up (Fig. 4). Additionally, there were no statistically significant differences in mortality due to newly developed conduction disturbances (Figure S3, Supplemental Digital Content, <http://links.lww.com/MD2/A195>).

4. Discussion

In this study, we demonstrated temporal variation in pacemaker dependency. Goldenberg et al have found a decreased rate of pacemaker dependency compared with the rate immediately post-PPI during the 52-week follow-up of patients after PPI following TAVR.^[11] Previous studies investigating pacemaker dependency in patients who underwent PPI after TAVR had limited durations of follow-up.^[10,12] In our study, at the end of 12-month follow-up, the rate of pacemaker dependency decreased from 97.4% to 41.4%. A similar reduction in pacing dependency was also found in SAVR patients (44.4% of patients were pacemaker-dependent after 6 months).^[11] Although no factors predicting PM dependency over time were identified (Table S1, Supplemental Digital Content, <http://links.lww.com/MD2/A196>), this study demonstrated a changing pattern of pacemaker dependency over time. It was unclear whether conduction disorders resolved after TAVR. Although a decreasing trend in pacemaker dependency was observed, it did not obviate the need for a pacemaker.

We did not identify any predictive factors in multivariable analysis of PM dependency, although our data were analyzed based on valve characteristics (self-expandable, balloon-expandable, or surgical valves), baseline rhythm, and post-TAVR arrhythmias. The timing of PPI did not predict PM dependency in the current study population either. We performed EPS in a small number of patients before PPI. During our early experience with TAVR, EPS was performed for patients with newly developed high-degree AVB to determine whether AVB grade was related to recovery from injuries associated with the conduction system. However, all EPS results consistently showed intra-Hisian and infra-Hisian blocks with prolonged HV intervals, indicating PPI at the time of EPS. Performing EPS prior to pacemaker insertion was not pragmatic. However, atrioventricular conduction recovery after pacemaker implantation was determined by conducting pacing for >100 to 150 bpm in all patients implanted with dual-chamber pacemaker (33 patients) during pacemaker interrogation, which was an effective indirect way to replace EPS after PPI. In patients with atrioventricular conduction recovery or pacemaker-independent patients, we actively minimized RV pacing during the interrogation.

The decrease in PM dependency during the follow-up was most likely due to partial or complete recovery from acute injury to the conduction tissue after the procedure. Since aortic valve and the atrioventricular conduction system are anatomically adjacent to each other, a direct injury or acute/subacute edema and ischemia after AVR could lead to transient or permanent conduction disturbances. We failed to establish any parameter to distinguish temporary from permanent damage in early stages.

Although there is no definite consensus regarding the ideal timing for PPI after TAVR,^[13] ESC guidelines recommend waiting for 5 to 7 days after the TAVR procedure before PPI. A recent expert consensus^[14] recommends PPI within 2 to 3 days depending on the new-onset, persistent conduction disorder. In

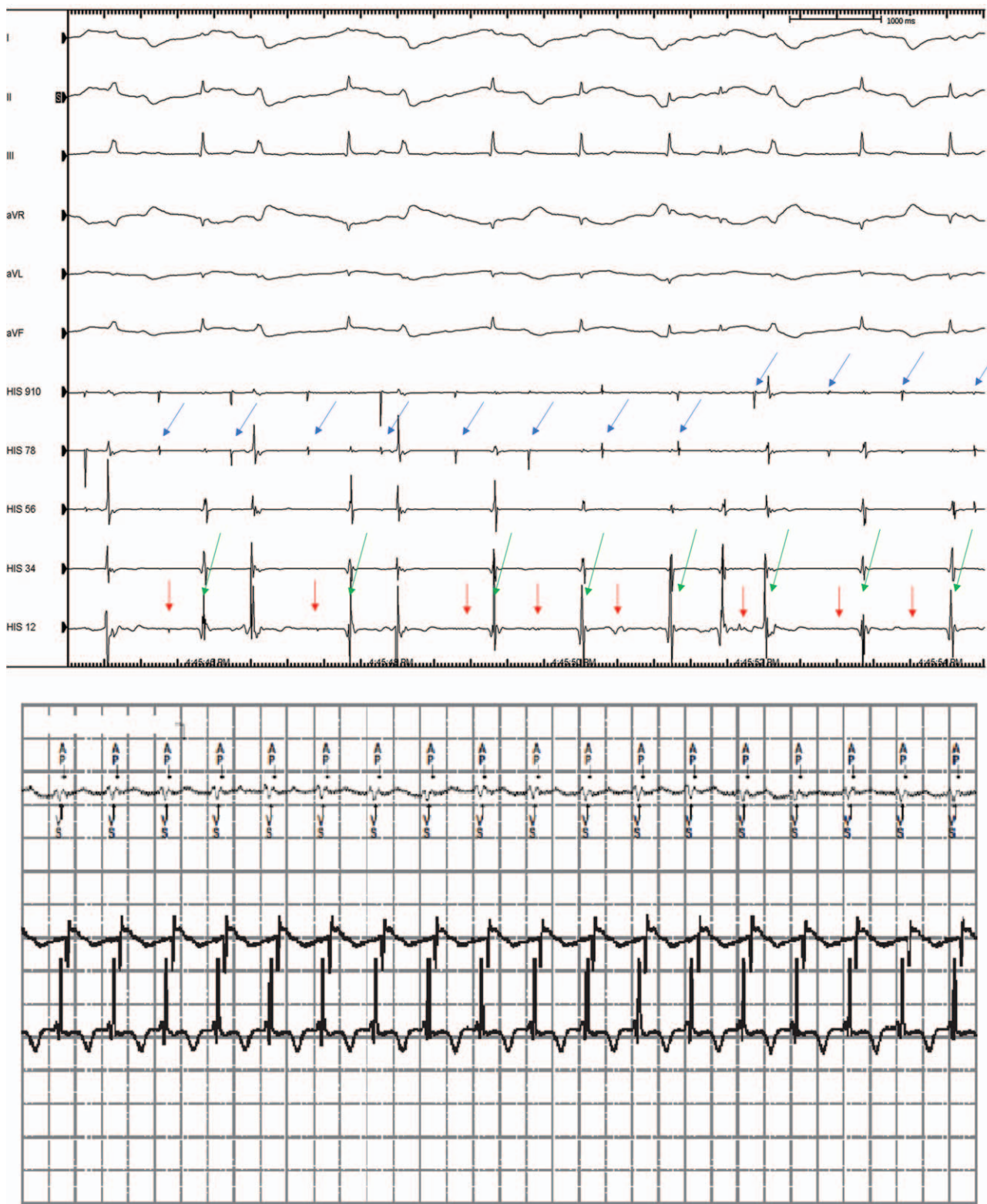


Figure 2. A case of PPI demonstrating HV block due to HV prolongation during EPS (5 days post-TAVR for complete AVB; blue arrows: atrial signal; red arrows: His signal; green arrows: ventricular signal) and recovery of 1:1 AV conduction during the follow-up period (AAI pacing tested at 150bpm 125 days post-TAVR).

the present study, PPI was performed after a median duration of 6 (3.0–7.0) days. Compared with SAVR, PPI lasted fewer days after TAVR (median 13 days), consistent with another study.^[15] Shorter PPI duration after TAVR was attributed to the greater

impact of conduction disorders on hemodynamic recovery after TAVR since most TAVR patients were older with higher comorbidities compared with SAVR patients. Thus, acute management with temporary pacing was indicated in most

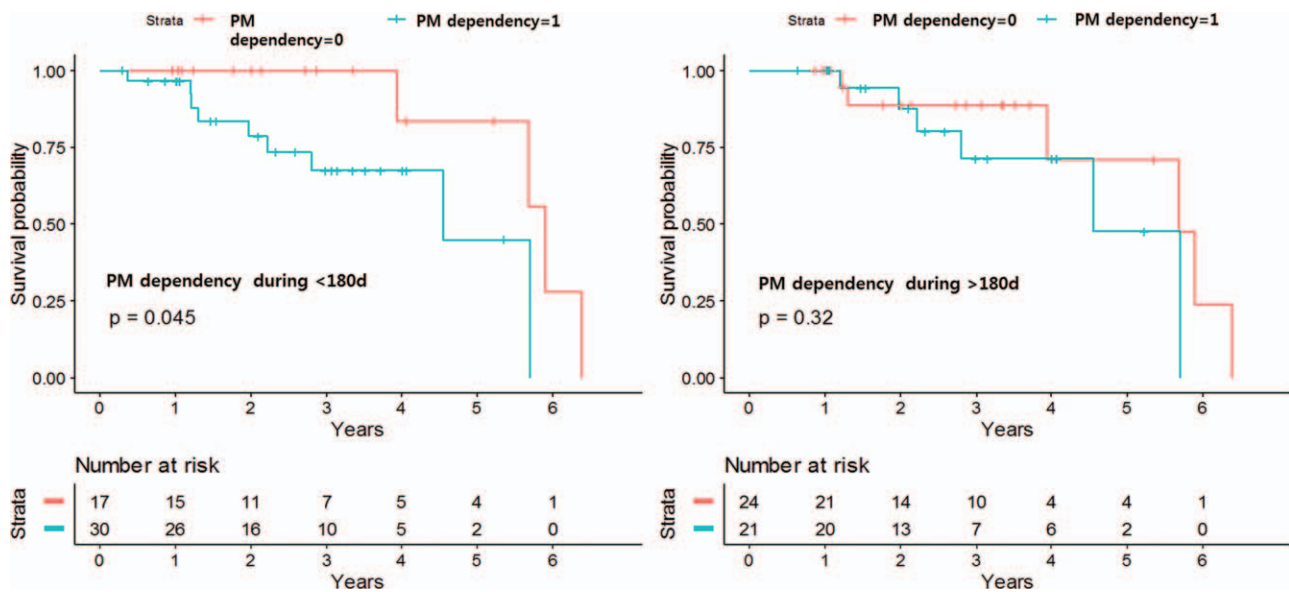


Figure 3. Kaplan-Meier survival curve according to PM dependency showing higher mortality in post-TAVR PM-dependent patients within 180 days.

cases. A temporary pacemaker lead can only be used for a limited duration due to the risk of infection. Therefore, a semi-permanent pacemaker lead insertion^[16] or a leadless pacemaker may be an option for patients who develop acute conduction disorders post-TAVR. This can prevent complications related to the pacemaker pocket. However, delayed PPI timing in both groups in this study was attributed mostly to the inclusion of patients exposed to TAVR a decade earlier than SAVR.

In this study, the rate of PPI after TAVR (7.3%) was lower than in previous reports.^[2,6] It is partly attributed to the frequent use of balloon-expandable valves and accurate valve sizing based on computed tomography (CT) evaluation. The low pacemaker

implantation rates and delayed PPI after aortic valve intervention in Korea could also be attributed to strict reimbursement criteria.^[17,18] Furthermore, low in-patient costs might have contributed to prolonged in-hospital telemetry observations, which delayed PPI.

Patients with AS are prone to mechanical injuries and inflammation during and after TAVR. Pre-existing factors such as aging, myocardial fibrosis, atherosclerosis and calcification nearby aortic valve can aggravate cardiac conduction defects after aortic valve replacement.^[10,19,20] Procedure-related factors, more with TAVR than SAVR, and larger valve size appear to be related to conduction disturbances, which can increase the risk of

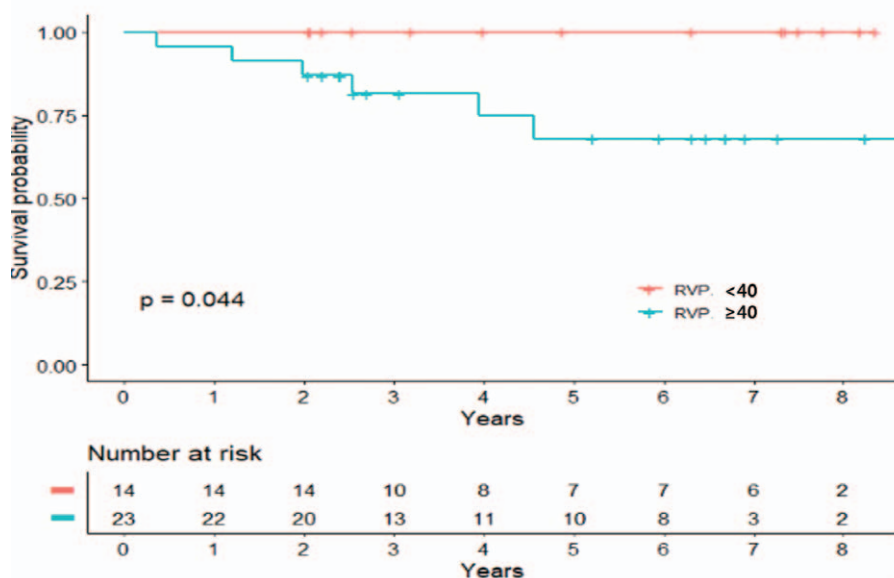


Figure 4. Kaplan-Meier survival curve based on RV pacing >40% revealing higher mortality in PM-dependent patients post-TAVR.

mortality and hospitalization due to heart failure.^[21] New-onset BBB and conduction abnormalities post-TAVR are associated with poor cardiovascular outcomes.^[22,23] Limited evidence supports the resolution of conduction disturbances in TAVR or SAVR patients since many patients already show conduction abnormalities before surgery.^[24] Conduction disturbances post-AVR, especially newly developed complexes with wide QRS, are attributed to infra-Hisian injuries during the procedure, while AVB can be explained by intra-Hisian injury. In the present study, although pacemaker dependency decreased with the passage of time, higher short-term mortality (<180 days) was found in pacemaker-dependent patients. During this period, pacemaker dependency was caused by acute and subacute regional inflammation or mechanical damage after AVR. Our results suggest that short-term close follow-up might be warranted, especially for pacemaker-dependent patients. In this study, RV pacing rate >40% after 2 years of follow-up was associated with increased mortality in TAVR patients. Despite investigators' efforts to minimize RV pacing strategy, RV pacing rate was higher than 40%, which was not negligible, suggesting the need of PM for these patients.

In addition, no reliable test for recovery of the conduction system is currently available. As demonstrated in our study, an in-office high-rate atrial pacing test during pacemaker programming can be a good alternative to EPS. However, in some patients with recovered atrioventricular conduction, paroxysmal AVB or sinus pause can occur during the follow-up, suggesting the need of pacemakers for long-term safety even with a lower pacing rate. During 2 years of follow-up in our study, more than 50% of patients required RV pacing >40%, which was not negligible. A few patients with newly developed conduction abnormalities who were contraindicated for PPI warranted prompt and careful observation via ECG monitoring during regular follow-up visits. Further studies are needed to investigate factors affecting the recovery of the conduction system after TAVR along with evaluation of the long-term clinical impact of PM dependency in TAVR patients. Lastly, intermittent high-grade or third-degree AV blocks can also occur.^[25] These events could only be detected with a specially programmed pacemaker, which was not available during the study period.

4.1. Limitations

This study had all limitations inherent to a retrospective study design. Another limitation was the variation in valve types used in the present study, which hindered the evaluation of impact of different valves on conduction disturbance. The lack of factors predicting pacemaker dependency in the present study might be attributed to the small number of patients enrolled. Further studies with a large number of post-AVR pacemaker patients are needed. The high rate of atrial pacing for AVB recovery test, which is not accurate for patients with paroxysmal AVB since infra-Hisian block is an all-or-none phenomenon, is 1 limitation. Another limitation was different follow-up duration between TAVR and SAVR patients because the majority of SAVR patients were transferred to regional medical clinics beyond 1 year postoperatively. Since follow-up data regarding de novo conduction disorder patients are limited in present study, further studies are warranted to evaluate long term clinical impact of de novo conduction disorder in patients without necessity of PPI.

5. Conclusion

Aortic valve management in AS patients carries a substantial risk of PPI. Although 58.6% and 55.6% of patients undergoing PPI after TAVR and SAVR were not pacemaker-dependent during a long-term follow-up (>365 days), PPI was still needed for more than 50% of patients, even AV conduction recovery was seen in about 20% of patients. RV pacing rate >40% had higher mortality. AV conduction recovery rate was low during the follow up. Thus, patients with de novo conduction disturbance after AVR need a close follow up.

Author contributions

Conceptualization: You Mi Hwang.

Data curation: You Mi Hwang, Do-Yoon Kang, Seo Young Park.

Formal analysis: Seo Young Park.

Investigation: You Mi Hwang, Seo Young Park.

Methodology: Jun Kim, Duk-Woo Park.

Resources: Duk-Woo Park, Do-Yoon Kang.

Supervision: Gi-Byoung Nam, Kee-Joon Choi, Seung-Jung Park.

Validation: Gi-Byoung Nam.

Writing – original draft: You Mi Hwang.

Writing – review & editing: Kee-Joon Choi, Seung-Jung Park.

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