DOI: 10.4274/gulhane.galenos.2026.99997
Gulhane Med J 2026;68(2):127-131

Evaluation of the incidence and clinical outcomes of permanent pacemaker implantation after the Ozaki procedure: a retrospective cohort study

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Cite this article as: Yaşar S, Eravcı Ö, Fırtına S, Karpat MS, Yıldırım E, Özdem T, et al. Evaluation of the incidence and clinical outcomes of permanent pacemaker implantation after the Ozaki procedure: a retrospective cohort study. *Gulhane Med J.* 2026;68(2):127-131.

Date submitted:
07.08.2025
Date accepted:
03.03.2026
Epub:
10.06.2026
Publication Date:
16.06.2026

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Keywords: Ozaki procedure, aortic valve reconstruction, autologous pericardium, permanent pacemaker, echocardiography

ABSTRACT

Aims: Data on permanent pacemaker implantation (PPI) after the Ozaki procedure are limited. This study evaluates the incidence of PPI and compares echocardiographic and clinical outcomes between patients with PPI and without PPI.

Methods: We conducted a retrospective study to evaluate patients who underwent the Ozaki procedure between January 1, 2019, and September 1, 2022. Patients were divided into PPI and non-PPI groups after the procedure. Preoperative and postoperative echocardiographic parameters, surgical details, and clinical outcomes were compared.

Results: The study included 89 patients: two patients in the PPI group, aged 69 and 71 years, and 87 patients in the non-PPI group, with a mean age of 62.3±13.6 years. PPI was required in 2.2% of patients. While the numbers of men and women in the pacemaker group were equal, the number of men in the non-pacemaker group was higher (male/female: 49/38). The PPI group had cardiopulmonary bypass times of 135 and 100 minutes, respectively, compared with 100±30 minutes in the non-PPI group, and aortic cross-clamp times of 75 and 88 minutes, respectively, compared with 70±20 minutes in the non-PPI group. At discharge, peak gradients decreased from 78 and 74 mmHg to 22 and 29 mmHg in the PPI patients (non-PPI: 78±30 to 25±12 mmHg), and mean gradients decreased from 44 and 45 mmHg to 10 and 14 mmHg (non-PPI: 45±15 to 12±6 mmHg). No in-hospital mortality or paravalvular leak was observed.

Conclusions: In our experience, PPI after the Ozaki procedure was uncommon, while early echocardiographic and clinical outcomes remained favorable. Our findings are consistent with the available literature and highlight the need for vigilant postoperative conduction monitoring, especially in patients with baseline conduction disease or prolonged operative times.

Introduction

Aortic valve diseases remain a significant cause of morbidity and mortality worldwide, often necessitating surgical intervention (1,2). The Ozaki procedure, which involves aortic valve reconstruction using autologous pericardium, offers an alternative to prosthetic valve replacement, providing favorable hemodynamic profiles and potentially reducing the need for lifelong anticoagulation (3). Since its introduction, the procedure has been increasingly adopted, demonstrating promising early and mid-term outcomes (2,3). However, as with other valve surgeries, the Ozaki procedure carries a risk of conduction disturbances, particularly atrioventricular (AV) block, which may necessitate permanent pacemaker implantation (PPI) (4,5). While PPI after conventional aortic valve replacement has been well studied, limited data exist regarding the incidence, clinical predictors, and echocardiographic consequences of PPI following the Ozaki procedure (6). This study aims to assess the incidence of PPI after the Ozaki operation at our center and to compare echocardiographic parameters and clinical outcomes between patients requiring PPI and those who did not require PPI. Our goal is to provide insights that improve perioperative management and patient selection for this innovative surgical technique.

Methods

Study design, participants and ethics

We conducted a retrospective cohort study that included 89 consecutive patients who underwent the Ozaki procedure at University of Health Sciences Türkiye, Gülhane Training and Research Hospital between 2019 and 2022. Patients with incomplete data or concomitant procedures (for example, coronary artery bypass grafting, mitral valve surgery, or ascending aortic surgery) were excluded. The study was approved by the Ethics Committee of the University of Health Sciences Türkiye, Gülhane Training and Research Hospital (approval no: 2022/272, date: 12.09.2022). The study protocol conforms to the Declaration of Helsinki and good clinical practice guidelines.

Data collection and clinical variables

Demographic variables collected included age, sex, height, weight, and calculated body mass index. Preoperative risk was assessed using the EuroSCORE II. Comorbidities such as smoking status, chronic obstructive pulmonary disease, diabetes mellitus, renal insufficiency, peripheral vascular disease, and coronary artery disease were documented.

Echocardiographic evaluation

Comprehensive transthoracic echocardiograms were performed preoperatively and before discharge. Recorded parameters were left ventricular ejection fraction (LVEF), aortic valve area (AVA), peak and mean aortic valve gradients (pressure gradient and mean gradient), and the presence of paravalvular leaks.

Surgical details

Cardiopulmonary bypass (CPB) and aortic cross-clamp (ACC) times were noted separately.

Postoperative outcomes

Recorded postoperative complications included acute renal failure, myocardial infarction, cerebrovascular events, new-onset arrhythmias (including atrial fibrillation), AV block, and PPI. Length of stay in the intensive care unit, total hospital stay, and hospital mortality were documented.

Statistical Analysis

Patients were categorized into two groups according to whether PPI was required postoperatively. Continuous variables were summarized as mean ± standard deviation or median with interquartile range, as appropriate. Categorical variables were summarized as counts and percentages. Given the very small number of PPI events (n=2), the analyses were restricted to descriptive statistics and no inferential statistical testing was performed.

Results

Among 89 patients undergoing the Ozaki procedure, two (2.2%; 1 male, 1 female) required PPI due to AV block. In the non-PPI group (n=87), 49 patients (56.3%) were male and 38 (43.7%) were female.

The PPI group consisted of two patients with EuroSCORE II values of 6.22% and 9.1%, whereas the non-PPI group had a mean EuroSCORE II of 7.2±3.5%. Cardiopulmonary bypass time was 135 and 100 minutes in the PPI group and 100±30 minutes in the non-PPI group. Similarly, aortic cross-clamp times were 75 and 88 minutes in the PPI group, compared with 70±20 minutes in the non-PPI group (Table 1). Preoperative LVEF was 60% and 65% in the PPI group, with a mean of 56±10% in the non-PPI group. The mean AVA preoperatively was 0.85 cm^2 and 1.2 cm^2 in the PPI group, and 0.75±0.2 cm^2 in the non-PPI group. Peak and mean aortic valve gradients were elevated preoperatively in both groups. At discharge, the PPI group showed sustained LVEF values (60% and 65%) and significant reductions in peak gradients (22 and 29 mmHg) and mean gradients (10 and 14 mmHg), consistent with the average reductions observed in the non-PPI group (Figures 1 and 2, Table 2). Mortality was not observed in either group. No paravalvular leaks were observed.

Discussion

In our cohort of 89 patients who underwent the Ozaki procedure, PPI was required in 2 (2.2%) patients. The first

patient requiring PPI was a 71-year-old man with preoperative sinus rhythm, incomplete right bundle branch block (iRBBB), QRS 118 ms, and severe periaortic tissue calcification. Postoperatively, he developed complete AV block. He received temporary epicardial pacing; because of persistent complete AV block, a dual-chamber permanent pacemaker was implanted on postoperative day 5 (DDD mode; lower rate limit of 55 bpm). The second patient requiring PPI was a 69-year-old woman with first-degree AV block (PR 232 ms) and non-specific intraventricular conduction delay (nsIVCD), QRS 112 ms, on baseline ECG, along with periaortic tissue calcification. Postoperatively, she exhibited persistent 2:1 AV block with intermittent episodes of complete AV block. A dual-chamber permanent pacemaker was implanted on postoperative day 7 (DDD mode; lower rate limit 50 bpm). At the 1 month device interrogation, the first patient was fully pacemaker-dependent (ventricular pacing 100% with no intrinsic rhythm during VVI 30 bpm testing), whereas the second patient had a ventricular pacing burden of 52%. PPI after the Ozaki procedure is infrequent and comparable to rates after conventional valve replacement. When the literature is reviewed, in the Ozaki procedure, the need for a permanent pacemaker is very low (0.25-2.9%), significantly less than the rates in traditional AVR or TAVR (4-6).

In a multicenter study conducted by Chernov et al. (7), the incidence of PPI following the Ozaki procedure was 1.8%. Conversely, in a study by Ozaki et al. (8), complete heart block necessitating a pacemaker was reported at 1.5% overall, with reduced rates observed after isolated Ozaki procedures compared to concomitant operations. Notably, our patients who required PPI had preoperative conduction abnormalities (iRBBB and prolonged PR/nsIVCD) and marked periaortic calcification; these features that have been repeatedly associated with postoperative high-grade AV block in the aortic valve literature. Extensive annular/periaortic calcification may necessitate deeper or more extensive suture placement and increased traction during leaflet fixation, thereby increasing mechanical stress and edema near the membranous septum and His bundle. Technical factors (stitch depth and proximity to the right-non-coronary commissure) and postoperative inflammation/ischemia represent plausible mechanisms for conduction system injury in this setting. Consistent with this concept, our

Table 1. Baseline and surgical characteristics by permanent pacemaker implantation status

Characteristic	PPI group (n=2)	Non-PPI group (n=87)
Continuous variables		
Age (years)	69; 71	62.3±13.6
Height (cm)	165; 171	165.0±9.8
Weight (kg)	75; 85	77.5±12.9
BMI (kg/m²)	27.5; 29.1	28.7±4.9
EuroSCORE II (%)	6.22; 9.1	7.2±3.5
Categorical variables		
Sex (male)	1 (50.0)	49 (56.3)
Sex (female)	1 (50.0)	38 (43.7)
Smoking	1 (50.0)	19 (21.8)
COPD	1 (50.0)	13 (14.9)
Diabetes mellitus	0 (0.0)	18 (20.7)
Renal insufficiency	1 (50.0)	16 (18.4)
Peripheral vascular disease	1 (50.0)	3 (3.4)
Coronary artery disease	1 (50.0)	37 (42.5)
Operative Times		
Cardiopulmonary bypass time (min)	135; 100	100±30
Aortic cross-clamp time (min)	75; 88	70±20

Data presentation: For the PPI group (n=2), continuous variables are presented as individual values for patient 1 and patient 2. For the non-PPI group (n=87), continuous variables are presented as mean ± SD; categorical variables are presented as n (%)
COPD: Chronic obstructive pulmonary disease, SD: Standard deviation, PPI: Permanent pacemaker implantation, min: Minute, BMI: Body mass index

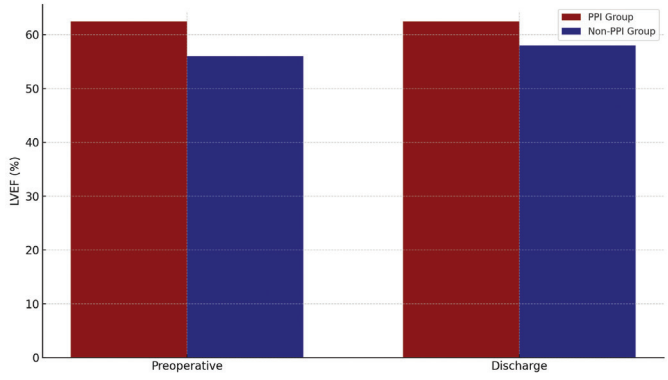

Figure 1. Preoperative and postoperative LVEF in patients with and without permanent pacemaker implantation after the Ozaki procedure

LVEF: Left ventricular ejection fraction, PPI: Permanent pacemaker implantation

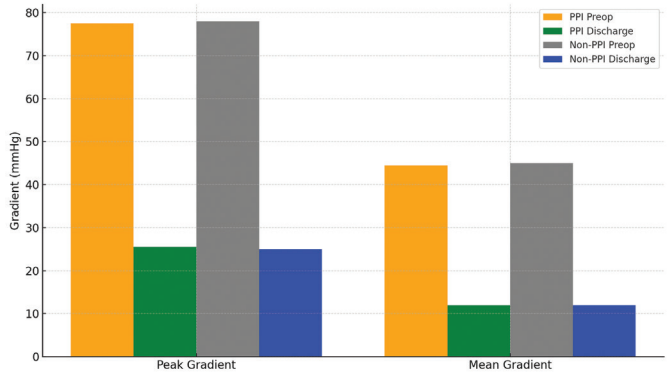

Figure 2. Changes in peak and mean aortic valve gradients preoperatively and at discharge between PPI and non-PPI groups

PPI: Permanent pacemaker implantation

Table 2. Echocardiographic parameters by permanent pacemaker implantation status

Parameter	Timepoint	PPI group (n=2)	Non-PPI group (n=87)
LVEF (%)	Preoperative	60; 65	56±10
	Discharge	60; 65	58±9
Aortic valve area (cm^2)	Preoperative	0.85; 1.2	0.75±0.2
Peak gradient (mmHg)	Preoperative	78; 74	78±30
	Discharge	22; 29	25±12
Mean gradient (mmHg)	Preoperative	44.5	45±15
	Discharge	10; 14	12±6

Data presentation: PPI group values are reported as individual values, whereas non-PPI values are presented as mean ± SD
PPI: Permanent pacemaker implantation, LVEF: Left ventricular ejection fraction, SD: Standard deviation

PPI patients also had longer CPB/ACC times, which may reflect more complex anatomy and prolonged manipulation-both linked to higher pacing rates in prior surgical series (4).

Similarly to previous studies, in our studuy echocardiographic parameters improved significantly in all patients, indicating effective restoration of valve function (9,10). As previous studies, longer operative times in the PPI group may contribute to conduction disturbances, though clinical outcomes remained similar (11). In this retrospective cohort of 89 patients undergoing the Ozaki procedure, PPI was required in 2.2% of cases, indicating a relatively low incidence of conduction disturbances requiring pacing. This rate is comparable to or slightly lower than those reported after conventional aortic valve replacement procedures, suggesting that the Ozaki procedure may not increase the risk of AV conduction system injury despite its technical nuances (12). Our findings demonstrate significant improvements in echocardiographic parameters postoperatively in both groups. Patients requiring PPI exhibited stable LVEF and substantial reductions in peak and mean aortic valve gradients, similar to those who did not require pacing (9,10,13). These results confirm the efficacy of the Ozaki procedure in restoring favorable hemodynamics and preserving ventricular function, even in patients who develop conduction abnormalities (14). The PPI group had longer CPB and ACC times compared to the non-PPI group, which may reflect more complex intraoperative courses or anatomical challenges potentially contributing to conduction system injury (6,11). However, given the small number of PPI cases, definitive conclusions about procedural risk factors are limited (15). No significant differences in early clinical outcomes, including mortality were observed between groups, suggesting that pacing does not adversely affect short-term recovery after the Ozaki procedure (16).

Our study supports the relative safety of the Ozaki procedure in terms of conduction system preservation, with a low rate of permanent pacing comparable to that observed after traditional valve replacement. Surgeons should remain vigilant for conduction disturbances, especially in cases with prolonged CPB or ACC times. Postoperative echocardiographic monitoring is essential for evaluating valve function and detecting potential complications early. Echocardiographic outcomes demonstrate significant and sustained improvement in valve function, regardless of pacing status. Overall, this series demonstrates that the Ozaki procedure can be performed successfully with favorable early echocardiographic and clinical outcomes at our center.

Study Limitations

The primary limitation of this study is the very small number of patients requiring PPI (n=2). This sample size precludes formal comparative statistical inference between PPI and non-PPI groups and precludes reliable identification of predictors; therefore, the findings should be interpreted as exploratory and descriptive. Consistent with this limitation, post hoc power analysis (G*Power) demonstrated low statistical power for between-group comparisons, with an achieved power of approximately 0.12 for cardiopulmonary bypass and cross-clamp time differences, primarily driven by the extremely small PPI group. Although patients requiring PPI were older than those without PPI, and age could confound associations with operative times, robust age-adjusted multivariable modeling (e.g., logistic regression/ANCOVA) was not feasible because of the high risk of overfitting with only two events. The retrospective design may introduce selection bias, and the single-center nature of the cohort may limit generalizability. Longer-term follow-up and larger, multicenter cohorts are needed to evaluate durability and validate potential predictors using appropriately powered and adjusted analyses.

Conclusion

The Ozaki procedure provides excellent echocardiographic and clinical outcomes with a low incidence of PPI. Although patients requiring pacing had longer operative times, short-term clinical outcomes were comparable to those without pacing. These findings support the safety and effectiveness of the Ozaki procedure in aortic valve reconstruction, with minimal risk of conduction disturbances.

Ethics

Ethics Committee Approval: The study was approved by the Ethics Committee of the University of Health Sciences Türkiye, Gülhane Training and Research Hospital (approval no: 2022/272, date: 12.09.2022).

Informed Consent: Retrospective study.

Declaration on the Use of Artificial Intelligence (AI): For transparency, the authors note that an artificial intelligence-assisted language model (ChatGPT, OpenAI) was utilized to support text editing and language correction. This assistance was limited to linguistic refinement; all scientific content, critical analysis, and final editorial decisions were made exclusively by the authors.

Footnotes

Authorship Contributions

Surgical and Medical Practices: T.Ö., E.K., K.K., Concept: S.Y., Ö.E., H.K.K., Design: S.Y., Ö.E., K.K., H.K.K., Data Collection or Processing: S.Y., Ö.E., S.F., Analysis or Interpretation: S.Y., Ö.E., M.S.K., T.Ö., H.K.K., Literature Search: Ö.E., S.F., M.S.K., E.K., K.K., Writing: S.Y., Ö.E., E.Y., H.K.K.

Conflict of Interest: The authors declare that they have no conflict of interest regarding this study.

Financial Disclosure: The authors declared that this study received no financial support.

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