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Original Research

Temporary-Permanent Pacemakers in the Management of Conduction Abnormalities in Patients Undergoing Transcatheter Aortic Valve Replacement

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ABSTRACT

Background: Injury to the cardiac conduction system requiring a permanent pacemaker (PPM) implantation is a known adverse outcome of transcatheter aortic valve replacement (TAVR). Temporary-permanent pacemakers (TPPM) have been used as a bridge to PPM implantation in patients with systemic infection; however, there are only a few reports of its routine use in patients undergoing TAVR. This study aimed to assess the utility of routine use of TPPM in patients undergoing TAVR with a high risk of needing a PPM or those who develop high-grade conduction abnormalities during/after TAVR.

Methods: Between April 2015 and December 2021, 978 patients underwent TAVR at our institution, of whom 111 patients had TPPM placed before or during/after TAVR during the study period. In total, 89 patients were included in the final analysis.

Results: The median age was 78 years (IQR, 71-84 years); 52 (58.4%) patients with preexisting native conduction disease were considered high risk for advanced heart block and had TPPM placed before TAVR. In addition, 37 (41.6%) patients had TPPM placed during/after TAVR. Of the 89 patients who received TPPM, 51 (57.3%) were treated with a balloon-expandable valve and 38 (42.7%) with a self-expandable valve. Of the patients who underwent TPPM placement, only 49 (55.1%) required a PPM, and TPPM was removed in 40 (44.9%) patients. TPPM was in place for a median of 6 days (IQR, 2-11 days). Only 1 of the 89 patients (1.1%) who received a TPPM had lead dislodgment. No other complications were noted. Median length of stay was 3 days (IQR, 2-4 days).

Conclusions: In patients with high-risk baseline conduction abnormalities before TAVR and those who develop new high-grade conduction abnormalities during/after TAVR, TPPM provides a feasible and safe method for pacing that could allow early ambulation, facilitate early discharge, and prevent unnecessary PPM implantations in some patients.

Background

Transcatheter aortic valve replacement (TAVR) numbers have grown significantly along with the aging population and expansion of indications to include intermediate-risk and lower-risk cohorts.[1,2] Given its anatomic proximity to the aortic valve, injury to the cardiac conduction system is frequently incurred during valve deployment.[3] Permanent pacemaker (PPM) implantation rates after TAVR have been reported to range from 6% to 28%.[4–7] The degree of conduction abnormalities sustained vary significantly, ranging from first-degree atrioventricular block to complete heart block (CHB).[5,7,8] Even in those with an obvious indication for PPM, a period of monitoring for spontaneous recovery is preferred, allowing avoidance of an unnecessary PPM use.[4,9] Several well-described risk factors are associated

Abbreviations: AVB, atrioventricular block; CHB, complete heart block; FDAVB, First-degree atrioventricular block; LAFB, left anterior fascicular block; LBBB, left bundle branch block; LPFB, left posterior fascicular block; PPM, permanent pacemaker; RBBB, right bundle branch block; TAVR, transcatheter aortic valve replacement; TPPM, temporary-permanent pacemaker.

Keywords: atrioventricular block; conduction abnormalities; temporary-permanent pacemaker; transcatheter aortic valve replacement.

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with a higher incidence of post-TAVR sustained conductive pathology necessitating PPM implantation, such as male sex, preexisting right bundle branch block (RBBB) or other conduction abnormalities, larger TAVR prosthesis to left ventricular outflow tract diameter ratio, length of membranous septum, type of TAVR prosthesis used (self-expanding vs balloon-expandable), and development of high-grade atrioventricular (AV) block during TAVR.[7,9–14]

When implementing temporary cardiac pacing, a temporary-permanent pacemaker (TPPM), which consists of an active fixation lead connected to an externalized generator, offers significant advantages over conventional temporary transvenous pacemakers whose leads are reliant on passive fixation mechanisms.[15] This stability affords more reliable pacing with lower incidence of lead dislodgment; enables early patient ambulation; facilitates management of patients on regular nursing floor, avoiding need for admission to cardiac intensive care unit; and allows potential early discharge despite a continued indication for temporary pacing. In this study, we report our institution's utilization of TPPMs in patients who underwent TAVR, including both preemptively in those deemed high risk for developing CHB and those needing a bridge to either recovery or PPM.

Methods

The study was reviewed and approved by the institutional review board at the University of Iowa Hospitals and Clinics (UIHC). All patients who received TPPM before or after TAVR at UIHC between April 1, 2015, and December 31, 2021, were included. All patients presented with severe aortic stenosis and underwent TAVR with either a self-expanding valve (CoreValve; Medtronic) or balloon-expandable valve (SAPIEN; Edwards LifeSciences). Patients with a preexisting PPM or implantable cardioverter defibrillator before TAVR were excluded from the study. Baseline demographics, comorbidities, type, and size of the valve were reviewed for each patient (Table 1). Pre-TAVR electrocardiogram findings and incidence of perioperative high-grade or complete AV block leading to placement of a TPPM are listed in Table 2. Baseline demographics and clinical and procedural data were obtained from the STS/ACC TVT registry or through a review of medical records where appropriate.

Statistical analysis

Continuous variables were reported as mean ± SD or median with IQR and compared using the 2-tailed Student *t* test or Mann-Whitney test, respectively, whereas categorical variable results were compared using the Fisher exact test. A *P* value of $\leq$.05 was considered statistically significant. Data were analyzed using Stata version 18 BE (StataCorp LLC) statistical package.

TPPM placement technique and follow-up

Right or left axillary venous access was obtained using micropuncture technique with ultrasound and fluoroscopic guidance, and a 7F peel-away sheath was inserted in the vein. In patients with challenging venous anatomy, right internal jugular venous access was obtained. Under fluoroscopic guidance, an active-fixation permanent-type, single-chamber pacemaker lead was advanced to the right ventricle and fixed at the apical septal location. Appropriate sensing and pacing thresholds were obtained. Then, the peel-away sheath was removed. The lead's suture sleeve was sutured to the skin, and a standard single-chamber pulse generator was connected to the lead. This was secured over the patient's skin using an adhesive dressing as depicted in Figure 1. In addition, pacemaker generators could be resterilized for multiple uses because these devices were used externally, but the leads were not sterilized or reused. Owing to the retrospective nature of this study, the device programming and decision to implant a PPM in the patient at follow-up was deferred to the consultant cardiac electrophysiologist. A chlorhexidine gluconate dressing was applied to the temporary-permanent insertion site to maintain sterility. Patients were asked to visit the structural clinic weekly for a review and dressing change. Decisions regarding TPPM removal or whether to proceed with a PPM placement were taken in consultation with the electrophysiology team. PPM was placed by the electrophysiology team where appropriate; otherwise, TPPM was removed at bed side in the clinic on follow-up.

Results

A total of 978 patients underwent TAVR at our institution between April 1, 2015, and December 31, 2021. Patients who had a preexisting PPM/implantable cardioverter defibrillator in place were excluded from the study; 111 patients had TPPM placed during the study period. However, 14 patients were lost to follow-up, and 8 died from non-cardiovascular causes during follow-up and, thus, were excluded from the final analysis. In total, 89 patients were included in the final analysis (Central Illustration).

Baseline demographics of patients who received TPPM before or after TAVR, including the implanted valve type and size, are noted in Table 1. The median age was 78 years, with an IQR of 71-84 years, and 49 (55%) patients were male. Of the 89 patients, 52 (58.4%) patients with preexisting native conduction disease were considered high risk for high-grade AV block or CHB. These patients had TPPM placed before TAVR, and 37 (41.6%) patients had TPPM placed during/after TAVR, of which 35 patients (39.3%) developed CHB or high-grade AV block periprocedurally, leading to placement of a TPPM (Table 2).

Of the 89 patients who received TPPM, 51 (57.3%) patients had a balloon-expandable valve implanted, and 38 (42.7%) patients underwent implantation of a self-expandable valve (Table 1). Among the patients who had TPPM placed, 49 (55.1%) required a PPM, and TPPM was removed in the remaining 40 (44.9%) patients. Of the 49 patients who had a PPM eventually placed, 3 had their TPPM removed initially after TAVR but, ultimately, required a PPM. Two of these patients had evidence of intermittent CHB on event monitor after discharge. One of these 3 patients was noted to have sick sinus syndrome 5 months later and treated with a pacemaker.

Of the 40 patients who had their TPPM removed, 1 patient required AV nodal ablation and placement of biventricular pacemaker several months after TAVR for uncontrolled atrial fibrillation with rapid ventricular rate and, thus, was included in the TPPM removal group because no abnormalities in the conduction system were noted post-TAVR. Of the 52 patients who had TPPM placed before TAVR, 29 (55.8%) had their TPPM eventually removed, and 23 (44.23%) had a PPM. Of the 37 patients who had TPPM placed after TAVR, 26 (70.3%) patients had PPM placement and 11 (29.7%) patients had their TPPM removed at follow-up.

There was an instance of lead dislodgment of the 89 patients who underwent TPPM placement. This patient had a TPPM placed preemptively as an outpatient 1 day before TAVR. He had a history of sinus bradycardia with RBBB and left anterior fascicular block (LAFB) on resting electrocardiogram, thus considered to have a high risk of significant conduction abnormalities after TAVR. He was discharged but readmitted the same day with presyncope. There was concern for lead dislodgment on chest X-ray, and the patient underwent a new TPPM placement the following day, after which TAVR was performed successfully. He was discharged with a TPPM and underwent a PPM placement 2 weeks later after his device interrogation revealed evidence of sick sinus syndrome and intermittent high-grade AV block.

No other pacemaker-related complications, such as infection, bleeding, pneumothorax, or perforation, were noted in the 89 patients included in the analysis. Indications for TPPM placement are listed in

Table 1. Baseline characteristics of the study population.

Demographic	Total (N = 89)	PPM (n = 49)	No PPM (n = 40)	*P* for difference between groups
Age, y	78 [71-84]	79 [70-84]	78 [72-86]	.96
Male	49 (55.06)	27 (55.10)	22 (55.00)	.99
White	87 (97.80)	48 (97.96)	39 (97.50)	.88
BMI, kg/m^2	30.2 ± 7.10	29.9 ± 7.50	30.6 ± 6.80	.63
Hypertension	83 (3.30)	45 (91.80)	38 (95.00)	.55
Diabetes mellitus	39 (43.82)	23 (46.94)	16 (40.00)	.51
Coronary artery disease	63 (70.80)	32 (65.31)	31 (77.50)	.2
Previous CABG	18 (220.22)	9 (18.37)	9 (22.50)	.63
Previous PCI	30 (33.70)	19 (38.80)	11 (27.50)	.263
Peripheral artery disease	21 (23.60)	10 (20.41)	11 (27.50)	.43
HFrEF	59 (66.30)	37 (75.51)	22 (55.00)	.04
Atrial fibrillation/flutter	34 (38.20)	20 (40.82)	14 (35.00)	.57
Previous stroke	9 (10.11)	3 (6.12)	6 (15.00)	.17
Chronic lung disease	35 (39.33)	19 (38.78)	16 (40.00)	.09
Chronic renal failure	36 (40.50)	20 (40.80)	16 (40.00)	.93
Pre-TAVR aortic valve morphology				
Bicuspid native valve	10 (11.24)	4 (8.16)	6 (15.00)	.16
Previous tissue aortic valve replacement	2 (2.25)	0 (0.00)	2 (5.00)	.16
Trileaflet native valve	77 (86.52)	45 (91.84)	32 (80.00)	.16
Pre-TAVR atrioventricular node blocker use				
Pre-TAVR β-blocker use	62 (69.70)	32 (65.31)	30 (75.00)	.32
Pre-TAVR calcium channel blocker use	6 (6.74)	3 (6.12)	3 (7.50)	.80
Pre-TAVR digoxin use	2 (2.25)	0 (0.00)	2 (5.00)	.22
Pre-TAVR sotalol use	1 (1.12)	0 (0.00)	1 (2.5)	.22
Pre-TAVR amiodarone use	7 (7.87)	5 (10.20)	2 (5.00)	.22
Access used for TAVR				
Transfemoral access	86 (96.63)	48 (97.96)	38 (95)	.44
Alternate access (transcarotid/transaortic)	3 (3.37)	1 (2.04)	2 (5.00)	.44
Type of TAVR valve placed				
Balloon-expandable valve	51 (57.30)	23 (46.94)	28 (70.00)	.07
SAPIEN 3 (23.0 mm)	8 (8.99)	2 (4.08)	6 (15)	
SAPIEN 3 (26.0 mm)	18 (20.22)	10(20.41)	8 (20)	
SAPIEN 3 (29.0 mm)	12 (13.48)	7 (14.29)	5 (12.50)	
SAPIEN 3 Ultra (23.0 mm)	4 (4.49)	1 (2.04)	3 (7.5)	
SAPIEN 3 Ultra (26.0 mm)	9 (10.11)	3 (6.12)	6 (15.00)	
Self-expandable valve	38 (42.70)	26 (53.06)	12 (30)	.07
Evolut R (34.0 mm)	5 (5.62)	3 (6.12)	2 (5.00)	
Evolut Pro/Pro+ (23.0 mm)	2 (2.25)	0 (0.00)	2 (5.00)	
Evolut Pro/Pro+ (26.0 mm)	11 (12.36)	8 (16.33)	3 (7.50)	
Evolut Pro/Pro+ (29.0 mm)	11 (12.36)	10 (20.41)	1 (2.50)	
Evolut Pro/Pro+ (34.0 mm)	9 (10.11)	5 (10.20)	4 (10)	

Values are median [IQR], n (%), or median ± SD. The study population was further divided into those who eventually received a PPM after insertion of a temporary-permanent pacemaker (PPM group) and those who did not eventually receive a PPM (no PPM group).
BMI, body mass index; CABG, coronary artery bypass graft; HFrEF, heart failure with reduced ejection fraction; PCI, percutaneous coronary intervention; PPM, permanent pacemaker; TAVR, transcatheter aortic valve replacement.

Table 2. The most common indications for TPPM placement before TAVR were as follows: (1) preexisting RBBB, (2) RBBB with LAFB, and (3) RBBB with concomitant LAFB or left posterior fascicular block along with first-degree AV block (Table 2). All patients who received TPPM during/post-TAVR exhibited high-grade AV block or CHB anywhere from the same day of the procedure (interprocedurally after valve deployment) to 10 days after procedure. TPPM was in place for a median of 6 days (IQR, 2-11 days). However, patients were discharged as soon as they were otherwise ready for discharge after the TPPM was placed, thus facilitating early discharge. The median length of stay in patients who received a TPPM before or after TAVR was 3 (IQR, 2-4) days.

Discussion

In this article, we described our experience with the use of TPPMs either implanted before TAVR in patients with preexisting native conduction disease and were considered high risk for high-grade AV block or CHB, or after TAVR in patients who developed new high-risk conduction abnormalities during/after valve deployment. Our results showed that TPPM devices are safe and effective in achieving temporary pacing while awaiting recovery of post-TAVR conduction abnormalities. The complication rates were low with the use of TPPMs with only 1 patient experiencing lead dislodgment (1.1% overall complication rate). There were no other TPPM-related complications. In

Table 2. Indications for TPPM such as preprocedural EKG findings used for risk stratification and incidence of CHB and high-grade atrioventricular block noted perioperatively in the study population leading to TPPM placement.

Indication for TPPM	Total (N = 89)	PPM (n = 49)	No PPM (n = 40)
Preprocedural ECG changes			
No significant conduction abnormalities	21 (23.6)	15 (30.6)	6 (15.0)
RBBB, LAFB	22 (24.7)	11 (22.5)	11 (27.5)
LBBB	7 (7.9)	6 (12.2)	1 (2.5)
RBBB	21 (23.6)	9 (18.4)	12 (30.0)
RBBB with LAFB/LPFH and FDAVB	9 (10.1)	4 (8.2)	5 (12.5)
RBBB, FDAVB	7 (7.9)	3 (6.1)	4 (10.0)
LBBB, FDAVB	2 (2.3)	1 (2.0)	1 (2.5)
Periprocedural EKG changes			
CHB/high-grade AVB	35 (39.3)	25 (51.0)	10 (25.0)

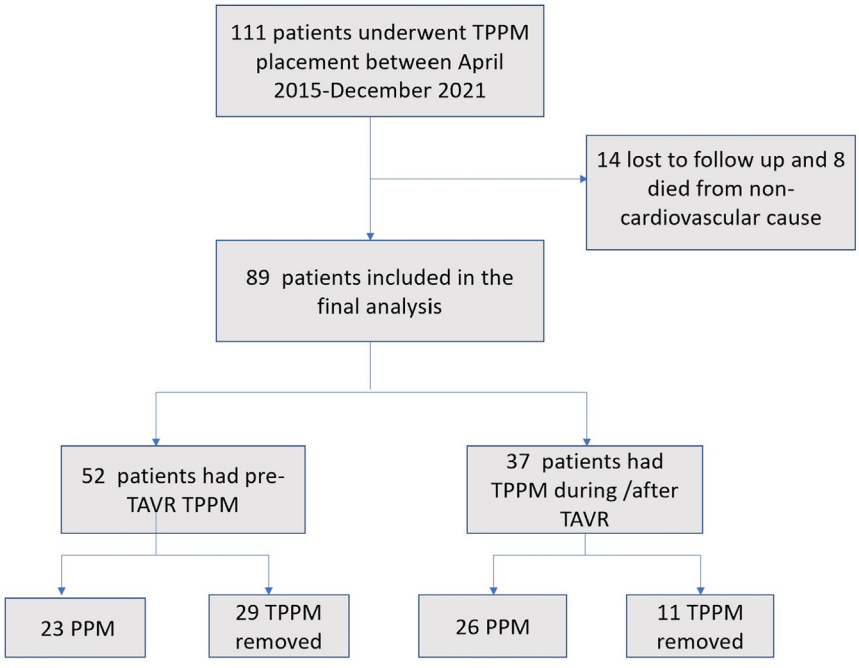
Values are n (%).
CHB, complete heart block; ECG, electrocardiogram; FDAVB, first-degree atrioventricular block; LAFB, left anterior fascicular block; LBBB, left bundle branch block; LPFB, left posterior fascicular block; RBBB, right bundle branch block; TPPM, temporary-permanent pacemaker.

Figure 1.
TPPM with an external pulse generator and active fixation lead. TPPM, temporary-permanent pacemaker.

our series of cases, TPPMs were in place for a median of 6 days, with the longest duration of TPPM after TAVR being 31 days. Placing a TPPM allowed early ambulation and discharge, with a median length of stay in the study patients being 3 days (IQR, 2-4). Patients were followed up on a weekly basis until a decision regarding either TPPM removal or PPM placement could be made. Among patients with TPPM, 49 (55%) ended up getting a PPM and TPPM was removed in the remaining 40 (45%) patients (Table 2). Thus, use of TPPM could have prevented the need for a PPM in at least some patients who had recovery of condition in the follow-up period, although this will need to be studied in larger randomized controlled trials.

Conduction disturbances after TAVR remain an important complication, which contribute significantly to increased morbidity and mortality and cost associated with TAVR. There exists a significant risk of sudden cardiac death in patients who develop high-grade AV block or CHB after TAVR.[1,16,17] In patients with preexisting RBBB, the risk of developing high-grade AV block or CHB during hospitalization is high (as much as 24%). This risk exists for up to 7 days or more and has been associated with all-cause and cardiovascular disease–related mortality after TAVR.[9,18] However, implantation of a PPM for conduction abnormalities after TAVR itself is not without risks. These risks include device infection, bleeding, hematoma formation, tricuspid regurgitation, and myocardial perforation. The deleterious effects of chronic, long-term right ventricular pacing on cardiac function are well known.[16] Despite the increased risk of high-grade AV block or CHB, Auffret et al[19] showed in an extensive series evaluating the impact of RBBB in TAVR that ~60% of TAVR candidates with previous RBBB did not require PPM during the hospitalization period, and about one-half of them were free from PPM at the 2-year follow-up.[9] Hence, it can be postulated that TPPMs can provide a safe and effective way to monitor patients regarding ultimate need for pacemaker and so, at least in some patients who recover native conduction after TAVR, a PPM could be avoided with their use.

The use of conventional temporary pacing wires with passive fixation requires strict bed rest to avoid the potential displacement of the pacemaker wire. In previous studies, the rate of lead dislodgment/loss of capture is reported to range from 10% to 30% with passive fixation leads in general, compared with a dislodgment rate of ~1.7% with TPPMs.[15] In this study, the rate of lead dislodgment was 1 of the 89 (1.1%), certainly lower than what would be expected with passive fixation leads. Although temporary pacing passive fixation leads may be a reasonable option for back-up pacing for brief periods, keeping the temporary pacing lead in place for more extended periods increases the risk of complications and may significantly hinder patient recovery. There is an increased risk of cardiac perforation with active fixation leads, although we did not encounter this complication in our study population. It is noteworthy that the active fixation leads used for TPPMs can be slightly more expensive than passive fixation leads upfront (difference was $326.8 in a previous study); however, the TPPM leads can actually save costs when pacing is needed for longer durations, particularly over 18 hours.[20] This is related to the cost saving from



Central Illustration.
Study design. PPM, permanent pacemaker; TAVR, transcatheter aortic valve replacement; TPPM, temporary-permanent pacemaker.

early ambulation and discharge and the ability to manage these patients on monitored telemetry floors rather than the need to monitor them in a cardiac intensive care unit with passive temporary pacing wires. Most importantly, however, early ambulation and early discharge are highly desirable outcomes from both patient and physician standpoint, which are facilitated with the use of TPPM devices. The cost of TPPM itself is an additional one time cost to the institution, although the TPPMs can be reused as needed within the institution.

The *JACC* scientific expert panel consensus document on the management of conduction disturbances associated with TAVR proposed a potential application of TPPMs in cases where an extended period of temporary pacing is anticipated.[9] However, short-term use, particularly when the patient is discharged from the hospital, is not well studied. There are only a few reports of TPPM's use in patients undergoing TAVR.[16,21–24] Our study supports the use of TPPM in high-risk patients with preexisting conduction abnormalities and those who develop CHB or high-grade AV block perioperatively in the setting of TAVR. However, randomized controlled studies are needed to confirm the abovementioned findings.

Conclusion

In patients with high-risk baseline conduction abnormalities and those who develop new high-grade conduction abnormalities in setting of TAVR, TPPM is a safe and effective method of providing cardiac pacing to patients to prevent adverse outcome due to advanced AV conduction block. TPPM also provides a safe approach to monitor and evaluate patients after TAVR and may prevent unnecessary PPM implantation in patients who eventually recover their AV conduction. Prospective studies are warranted to further investigate other predictive factors for PPM implantation and the progression or recovery of conduction abnormalities after TAVR.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics statement and patient consent

The research reported in this article has adhered to the relevant ethical guidelines. The study was reviewed and approved by the institutional review board at the University of Iowa Hospitals and Clinics.

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