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ORIGINAL ARTICLE

Electrophysiological evaluation following development of new and persistent left bundle branch block after transcatheter aortic valve replacement: A single center pilot study

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Abstract

Introduction: New and persistent left bundle branch block (NP-LBBB) following Transcatheter Aortic Valve Replacement (TAVR) is an ongoing concern with incidence ranging from as low as 4% to up to 65% (varying for different types of valves). Such patients are at risk of developing high-grade atrioventricular block (HAVB) warranting permanent pacemaker (PPM) implantation. However, currently, there are no consensus guidelines or large prospective studies to risk stratify these patients for safer discharge after TAVR.

Objectives: To provide insight from a single center study on using modified electrophysiology (EP) study to risk stratify post-TAVR patients to outpatient monitoring for low-risk versus pacemaker implantation for high-risk patients.

Methods and Results: Between June 2020 and March 2023, all patients who underwent a TAVR procedure (324 patients) at our institution were screened for development of NP-LBBB post-operatively. Out of 26 patients who developed NP-LBBB, after a pre-specified period of observation, 18 patients were deemed eligible for a modified EP study to assess His-Ventricular (HV) interval. 11 out of 18 patients (61.1%) had normal HV interval (HV < 55 ms). Three out of 18 patients (16.7%) had HV prolongation (55 ms < HV < 70 ms) without significant HV prolongation (defined as an increase in HV interval > 30%) with intra-procedural procainamide challenge. Four out of 18 patients (22.2%) had significant HV prolongation (HV > 70 ms) warranting PPM implantation based on a multidisciplinary approach and shared decision-making with the patients. Total of 50% of patients discharged with PPM (two out of four patients) were noted to be pacemaker dependent based on serial device interrogations. All patients who

Abbreviations: BEV, balloon expanding valve; CHF, congestive heart failure; CIED, cardiac implantable electronic device; ECG, electrocardiogram; HAVB, high grade Atrioventricular Block; HV, his-ventricular; LOS, length of stay; NP-LBBB, new persistent left bundle branch block; PPM, permanent pacemaker; SEV, self expanding valve; TAVI, transcatheter aortic valve intervention; TAVR, transcatheter aortic valve replacement.

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did not receive PPM were discharged with ambulatory monitoring with 30-day event monitor and did not develop HAVB on serial follow-up.

Conclusion: Normal HV interval up to 55 ms on modified EP study after TAVR and development of NP-LBBB can be utilized as a threshold for risk stratification to facilitate safe discharge. The optimal upper limit of HV interval threshold remains unclear in determining appropriate candidacy for PPM.

KEYWORDS
LBBB, permanent pacemaker, TAVR

1 | INTRODUCTION

The development of new and persistent LBBB (NP-LBBB) following transcatheter aortic valve replacement (TAVR) is common and ranges between 18%–65% for self-expandable valves (SEV) and 4%–30% for balloon-expandable valves (BEV).[1] Patients who develop NP-LBBB are at very high risk of developing high-degree AV block (HAVB) and requiring permanent pacemaker implantation (PPM).[2] Moreover, those that receive a PPM following TAVR eventually experience more rehospitalizations for congestive heart failure (CHF) compared to those that do not receive PPM.[3] Guidelines currently suggest implantation of PPM for patients with NP-LBBB, but only a minority of patients (17.5%) with NP-LBBB following TAVR require PPM implantation.[4,5] In recent years, several studies assessing the His-ventricular (HV) interval post-TAVR to help risk-stratify patients with NP-LBBB who may require PPM implantation have been published.[6–9] However, the optimal HV interval threshold and management strategy for dictating PPM implantation following electrophysiological (EP) study is still unclear. Additionally, the optimal timing for assessment of the HV interval is unclear, and we postulate that HAVB after discharge occurs due to worsening inflammation, edema, and/or mechanical stress, as evidenced by higher rates of HAVB following SEV than BEV because the SEV can continue to expand.[1,10] We have undertaken a pilot study to risk-stratify patients with NP-LBBB following TAVR by performing a modified EP study at least 24 or 48 h after TAVR to assess the intracardiac conduction system prior to discharge.

2 | MATERIALS AND METHODS

Between June 2020 and March 2023, all patients who underwent a TAVR procedure at our institution were screened for the development of NP-LBBB post-operatively. NP-LBBB was defined as new-onset widening of QRS complex to >120 ms with a typical LBBB morphology (lead V1 with QS complex or small r wave with large S wave and V6 with a notched R wave and no Q wave) from a baseline QRS complex <100 ms without any evidence of a conduction abnormality that persists until the time of modified EP study. Patients with a baseline LBBB or previous cardiac implantable electronic device (CIED) were excluded from the study. Modified EP study were performed at 24 h following development of NP-LBBB following BEV TAVR procedures, and at 48 h for SEV. The Saint Louis University institutional review board approved data analysis of this study and each subject gave his or her written informed consent for participation.

2.1 | Electrophysiology study evaluation

During the modified EP study, the HV was determined by the average of 5 consecutive HV intervals. If the average HV interval was >70 ms, then a PPM was implanted (Medtronic Azure or Cobalt, Medtronic Inc, Minneapolis, MN) with an algorithm to promote intrinsic conduction (Managed Ventricular Pacing™) enabled. If the HV interval was ≤55 ms, then no PPM was implanted. If the HV interval was >55 ms but ≤70 ms, then a procainamide challenge infusion of 10 mg/kg was infused over 30 min to further risk-stratify these patients.[11] At the end of the 30-min infusion, the HV interval was measured again, using the average of five consecutive HV intervals. A procainamide challenge infusion was considered positive if HAVB was provoked or if HV interval prolonged by greater than 30% from baseline, and a PPM was implanted at that time.

2.2 | Follow-up

All patients who did not receive a PPM were discharged from the hospital with a 30-day event monitor. All patients were seen in the office at 1-, 3-, and 6-month post-TAVR. Patients who developed HAVB on 30-day event monitor or at follow-up received a PPM. Pacemaker interrogations were performed after the implant and at 1-, 3-, and 6-months after implantation. In patients who received a PPM, HAVB was defined as pacing percentage >1% on device interrogation during office follow-up.

2.3 | Statistical analyses

Patients were dichotomized into two groups and deemed PPM-necessary if they developed HAVB (received PPM and required >1% ventricular pacing or developed HAVB anytime during follow-up if

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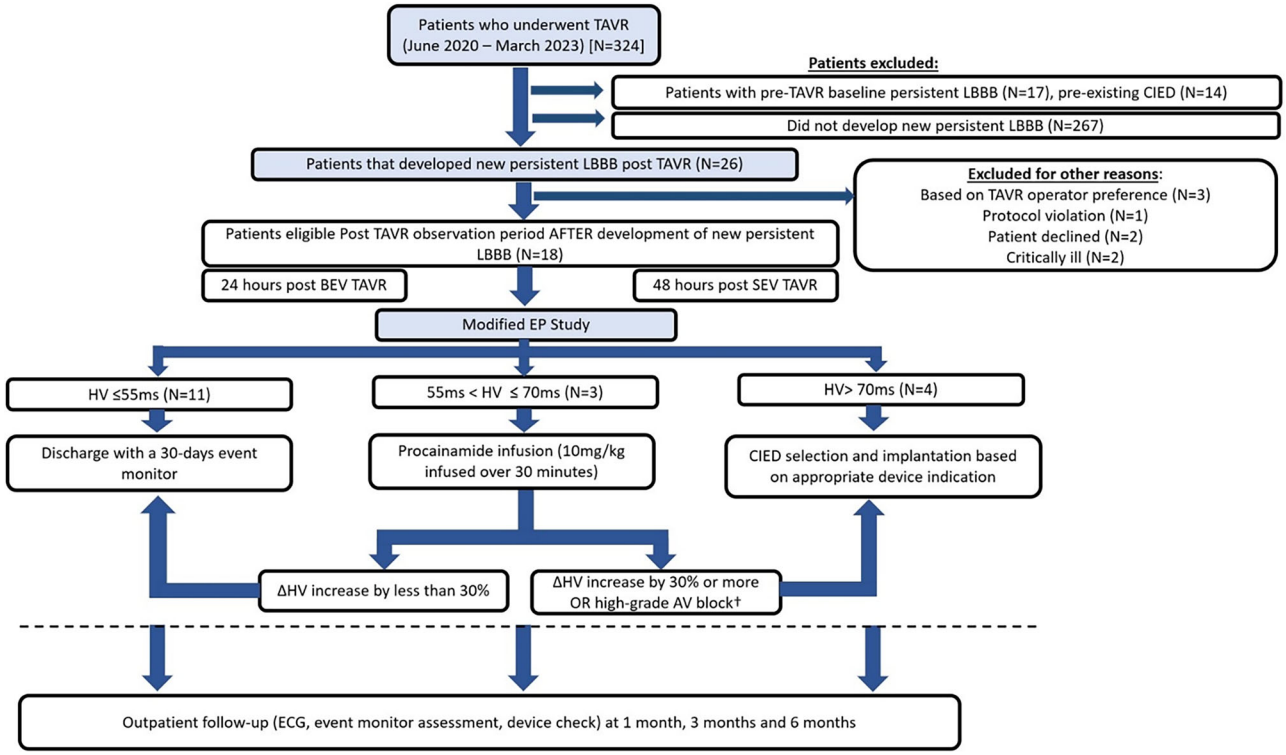


FIGURE 1 Flowchart of TAVR patients enrolled in study. BEV, balloon expanding valve; CIED, cardiac implantable electronic device; ECG, electrocardiogram; EP, electrophysiologic; HV, his-ventricular; LBBB, left bundle branch block; SEV, self expanding valve; TAVR, transcatheter aortic valve replacement. [Color figure can be viewed at wileyonlinelibrary.com]

no PPM was implanted) or PPM-unnecessary if they did not develop HAVB during the follow-up period or received a PPM without ventricular pacing exceeding 1% on any interrogation during the follow-up period. Independent 2-tailed Student's *t*-tests were used to compare continuous variables between PPM-necessary and PPM-unnecessary groups. Fisher's exact test was used to compare categorical variables. Numerical data are presented as mean ± standard deviation and categorical variables as number and percentages. A *p*-value of <.05 was considered to be statistically significant. SPSS version 22 for Windows (IBM Corp., Armonk, NY) was used for statistical analysis.

3 | RESULTS

3.1 | Patient population

A total of 324 TAVRs were performed between June 2020 and March 2023. There were 17 patients who had baseline LBBB and 14 patients who had a CIED prior to TAVR (Figure 1). Twenty six patients developed NP-LBBB of which 18 patients underwent modified EP study. Two patients declined to participate in the pilot study, two patients were deemed too critically ill to undergo EP study, and three patients did not undergo study due to TAVR operator preference. One patient was excluded due to deviation from the pre-specified period of observation prior to EP study (Figure 1).

Out of those who underwent modified EP study, 50% were male, and 56% (10/18) received BEV. Other baseline clinical characteristics are detailed in Table 1A-E. All patients had findings of severe aortic stenosis based on echocardiographic and/or invasive hemodynamic evaluation (Table 1B). None of the patients in the study were on any antiarrhythmics.

3.2 | Electrocardiographic (ECG) characteristics

All patients were in sinus rhythm except for one patient that was in atrial fibrillation. No baseline bundle branch block or interventricular conduction delay were noted on the ECGs. Other ECG characteristics are detailed in Table 1C.

3.3 | Modified electrophysiologic study findings (Figure 2)

Out of 18 patients who underwent modified EP study (Table 2), 11 patients (61.1%) had HV interval less than 55 ms and hence were discharged home with a 30-day event monitor after modified EP study. During this follow-up monitoring period, none of these patients developed advanced conduction abnormalities or arrhythmias needing pacemaker or other device therapy.

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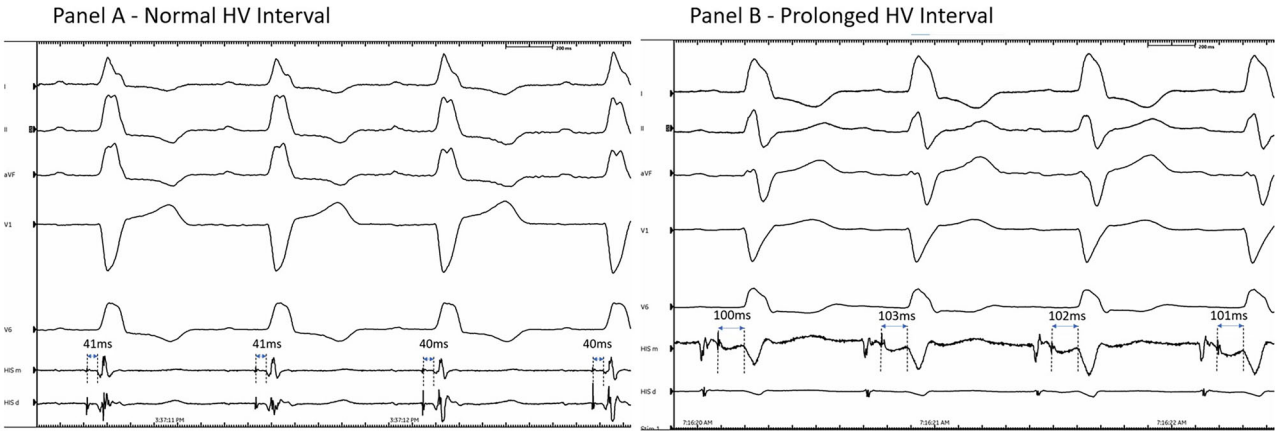


FIGURE 2 Figure of HV intervals, normal HV interval versus prolonged HV interval, His Ventricular (HV) interval from modified electrophysiologic (EP) study from patients comparing normal HV interval (Panel A) and prolonged HV interval (Panel B). [Color figure can be viewed at wileyonlinelibrary.com]

Three out of 18 patients (16.7%) had HV intervals between 55 and 70 ms and hence underwent procainamide challenge during the modified EP study. These patients did not develop advanced conduction blocks or significant prolongation of HV interval (defined as 30% increase in HV interval from baseline) with procainamide infusion. Similar to patients with normal HV interval, these patients did not develop any advanced conduction abnormalities during the 30-day monitoring period and did subsequently not require PPM. Four out of 18 patients (22.2%) were noted to have prolonged HV interval with modified EP study without procainamide infusion (HV interval >70 ms) and received PPM after multidisciplinary and shared decision-making discussions between the electrophysiologist, interventional cardiologist, and the patient or their family if applicable. One patient received a leadless pacemaker due to patient and operator preference.

3.4 | Follow-up monitoring

Amongst patients with normal HV conduction (11 patients) and those without significant HV prolongation with procainamide challenge (three patients), no patients developed advanced conduction abnormalities or symptoms suggestive of bradyarrhythmia during or beyond the 30-day event monitor period, based on outpatient follow-up visit assessment of ECGs and clinic encounters. A total of three patients (two patients from the normal HV interval group and one patient from the procainamide challenge group) had resolution of their previously noted post-procedural LBBB on follow-up ECG in 1 month.

Device monitoring and pacing needs for the four patients with prolonged HV interval (>70 ms on post-TAVR modified EP study) who received PPM were also assessed. Their device settings at the time of implant and follow-up-device interrogation data for underlying pacing needs are outlined in Table 3. Only two of the four patients who received PPM required ventricular pacing >1% during follow-up (subject #9 and subject #13).

3.5 | PPM-necessary versus PPM-unnecessary patients

There was no difference in age, BMI, LVEF, or aortic valve stenosis characteristics between PPM-necessary or PPM-unnecessary patients (Table 4). PPM-necessary patients had prolonged PR intervals pre-TAVR (215.0 ± 9.9 ms vs. 166.4 ± 24.6 ms, $p = .016$), prolonged PR intervals immediately post-TAVR (261.0 ± 21.2 ms vs. 202.7 ± 29.7 ms, $p = .018$), prolonged PR intervals Day 1 post-TAVR (242.0 ± 25.5 ms vs. 179.0 ± 33.6 ms, $p = .023$), and longer HV intervals (85.0 ± 1.4 ms vs. 57.4 ± 14.6 ms, $p = .019$) during modified EP study when compared to the PPM-unnecessary group. PPM-necessary patients were also more likely to have positive modified EP study assessments (100% vs. 12.5%, $p = .039$) compared to PPM-unnecessary patients.

4 | DISCUSSION

We assessed the HV interval 48 h post-TAVR after a SEV and 24 h post-TAVR after a BEV in patients who developed NP-LBBB. Patients with a normal HV interval at baseline (<55 ms) or had a negative procainamide challenge infusion (<30% increase in HV interval) if baseline HV interval was >55 ms but ≤70 ms during the modified EP study did not require a PPM post-TAVR during the monitoring period.

4.1 | Optimal timing of modified EP study

The bundle of His, and particularly the fascicles of the left bundle, lie in close proximity to the base of the aortic leaflets as they exit the membranous septum, and make them particularly vulnerable to injury during TAVR implantation.[12] Inflammation, edema, ischemia, and/or mechanical stress have all been mechanisms proposed to cause LBBB after TAVR implantation.[10] Worsening inflammation, edema, and/or

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TABLE 1 Baseline characteristics of patients that received EP study after developing NP-LBBB after TAVR [$N = 18$].[a]

A. Baseline characteristics	
Male (%)	9/18 (50%)
Body Mass Index (kg/m^2)	32.54 ± 5.72
Hypertension	18/18 (100%)
Diabetes Mellitus	4/18 (22.22%)
Hyperlipidemia	18/18 (100%)
Chronic Kidney Disease	6/18 (33.33%)
End Stage Renal Disease on Hemodialysis	0/18 (0%)
Coronary Artery Disease	11/18 (61.11%)
Prior Revascularization:	7/18 (38.89%)
Percutaneous Coronary Intervention	7/7 (100%)
Coronary Artery Graft Bypass	1/7 (14.29%)
Atrial Fibrillation	3/18 (16.67%)
Prior cardiac arrest	0/18 (0%)
Prior Ventricular Tachycardia	1/18 (5.56%)
Heart Failure:	9/18 (50%)
Heart failure with reduced Ejection fraction (HFrEF)	1/9 (11.11%)
Heart failure with reduced Ejection fraction (HFpEF)	7/9 (77.78%)
Heart failure with mid-range Ejection fraction (HFmidEF)	1/9 (11.11%)
Left ventricular ejection fraction (%) (pre TAVR)	60 ± 15
Obstructive Sleep Apnea	4/18 (22.22%)
Chronic Obstructive Pulmonary Disease	5/18 (27.78%)
Smoker	5/18 (27.78%)
B. Pre-TAVR echocardiographic characteristics	
Peak Velocity on Echocardiogram (m/s)	3.91 ± 0.6
Mean Gradient on Echocardiogram (mmHg)	38 ± 13
Aortic valve area on Echocardiogram (cm^2)	0.82 ± 0.18
Left ventricular hypertrophy on echocardiogram:	10/18 (56%)
Concentric	9/10 (90%)
Eccentric	1/10 (10%)
Mean Gradient on Invasive hemodynamic valve study (mmHg)	43 ± 5.4
Aortic valve area on Invasive hemodynamic valve study (cm^2)	0.77 ± 0.19
Aortic valve calcification present	17/18 (94%)
C. Baseline ECG characteristics:	
Pre-TAVR ECG:	
Heart Rate (bpm)	77 ± 14
Normal Sinus rhythm	17/18 (94.44%)
Atrial fibrillation	1/18 (5.56%)
PR interval (ms)	172 ± 28
QRS duration (ms)	97 ± 14
QTc interval (ms)	441 ± 28
Post TAVR ECG (Day 0):	
Heart Rate (bpm)	64 ± 13
Normal Sinus rhythm	17/18 (94.44%)
Atrial fibrillation	1/18 (5.56%)
PR interval (ms)	194 ± 72
QRS duration (ms)	151 ± 22
QTc interval (ms)	514 ± 45
Post TAVR ECG (Day 1):	
Heart Rate (bpm)	80 ± 11
Normal Sinus rhythm	17/18 (94.44%)
Atrial fibrillation	1/18 (5.56%)
PR interval (ms)	186 ± 38
QRS duration (ms)	146 ± 21
QTc interval (ms)	495 ± 41
D. Medications	
Pre-TAVR Medications:	
Aspirin	14/18 (77%)
Beta-blockers	11/18 (61%)
Calcium Channel blockers:	6/18 (33%)
Dihydropyridine	6/6 (100%)
Non- Dihydropyridine	0/6 (0%)
Anti-arrhythmic drug therapy (AAD)[b]	0/18 (0%)
Digoxin/Digitalis	0/18 (0%)
Discharge Medications:	
Aspirin	15/18 (83%)
Beta-blockers	9/18 (50%)
Calcium Channel blockers:	7/18 (39%)
Dihydropyridine	7/7 (100%)
Non- Dihydropyridine	0/7 (0%)
Anti-arrhythmic drug therapy (AAD)[b]	0/18 (0%)
Digoxin/Digitalis	0/18 (0%)
E. TAVR valve characteristics	
Type of TAVR valve[c]	
Balloon expanding (BEV)	10/18 (56%)
Self-expanding (SEV)	8/18 (44%)
Approach	Femoral (100%)
Post dilatation post deployment	1/18 (CoreValve)[d]
Valve-in-valve (ViV)	0/18 (0%)

[a]Expressed as mean with standard deviations: Body Mass Index, left ventricular ejection fraction, peak velocity, mean gradient and aortic valve area on echocardiogram, peak velocity, mean gradient and aortic valve area on invasive hemodynamics (valve study), ECG characteristics (Heart Rate, PR interval, QRS duration, QTc interval).

[b]Anti-arrhythmic drug therapy (AAD) [Amiodarone/Dronederone/Sotalol/Dofetilide/Flecainide/Propafenone].

[c]Self-expanding valves used were Medtronic CoreValve (26, 29, and 34 mm) and Evolut FX (29 and 34 mm) and balloon expanding valves used were Edwards Sapien 3 Ultra (23, 26, and 29 mm).

[d]TAVR required post deployment balloon dilatation to improve valve apposition with the underlying heavily calcified valve.

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TABLE 2 Modified EP study results and outcomes.

Patient no.	EP Study findings						Disposition (Event monitor,[a] PPM implantation or none)
	Underlying rhythm (QRS duration)	AH Interval (ms) [Normal 60-125 ms]	HV Interval (ms) [Normal 40-55 ms]	HIS potential width (ms) [Normal 10-20 ms]	Rhythm during study	Procainamide challenge required? [If yes, HV interval post infusion (ms)]	
1	Normal sinus rhythm (148 ms)	65	53	18	Sinus rhythm	No	Discharged with 30-day event monitor
2	Normal sinus rhythm (176 ms)	144	51	13	Sinus rhythm	No	Discharged with 30-day event monitor
3	Normal sinus rhythm (88 ms)[b]	78	52	13	Sinus rhythm	No	Discharged with 30-day event monitor
4	Normal sinus rhythm (146 ms)	101	58	15	Sinus rhythm	Yes, 73 (25.9% increase in HV interval)	Discharged with 30-day event monitor
5	Normal sinus rhythm (136 ms)	71	101	12	Sinus rhythm	No	Dual chamber pacemaker implantation
6	Normal sinus rhythm (122 ms)	129	45	11	Sinus rhythm	No	Discharged with 30-day event monitor
7	Normal sinus rhythm (168 ms)	82	78	29	Sinus rhythm	No	Dual chamber pacemaker implantation
8	Atrial fibrillation (152 ms)	N/A	52	12	Atrial fibrillation	No	Discharged with 30-day event monitor
9	Normal sinus rhythm with intermittent Junctional rhythm (158 ms)	N/A	84	14	Sinus rhythm with intermittent junctional rhythm	No	Dual chamber pacemaker implantation
10	Normal sinus rhythm (138 ms)	114	52	18	Sinus rhythm	No	Discharged with 30-day event monitor
11	Normal sinus rhythm (146 ms)	88	54	18	Sinus rhythm	No	Discharged with 30-day event monitor
12	Normal sinus rhythm (181 ms)	128	49	10	Sinus rhythm	No	Discharged with 30-day event monitor
13	Normal sinus rhythm (108 ms)[b]	120	86	35	Sinus rhythm	No	Leadless pacemaker implantation
14	Normal sinus rhythm (172 ms)	110	69	14	Sinus rhythm	Yes, 77.7 (12.6% increase in HV interval)	Discharged with 30-day event monitor
15	Normal sinus rhythm (133 ms)	129	42	14	Sinus rhythm	No	Discharged with 30-day event monitor
16	Normal sinus rhythm (146 ms)	133	53	10	Sinus rhythm	No	Discharged with 30-day event monitor
17	Normal sinus rhythm (166 ms)	163	48	9	Sinus rhythm	No	Discharged with 30-day event monitor
18	Normal sinus rhythm (138 ms)	119	61	22	Sinus rhythm and junctional rhythm	Yes, 66.2 (8.5% increase in HV interval)	Discharged with 30-day event monitor

[a] 30-day event monitor performed for all patients discharged without a device. No clinically significant tachyarrhythmia (including atrial fibrillation), bradyarrhythmia (including clinically significant pauses) noted on outpatient monitoring.

[b] ECG prior to study with persistent LBBB but with improvement or resolution in QRS duration during EP study.

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TABLE 3 Cardiac implantable electronic device (CIED) follow-up data.

		EP study findings			Pacemaker outcomes									
Patient no.	Type of TAVR valve	HV Interval (ms) [Normal 40–55 ms]	HIS potential width (ms) [Normal 10–20 ms]	Procainamide challenge performed?	Device Mode (LRL/URL)	Pacemaker Dependency	Sensed AV delay	Paced AV delay	%ventricular pacing 1 month	%atrial pacing 1 month	%ventricular pacing 3 months	%atrial pacing 3 months	%ventricular pacing 6 months	%atrial pacing 6 months
5	SEV	101	12	No	AAIR-DDDR (60/130)	No	150	180	0.1	0.1	<0.1	77.9	0.1	98.2
7	BEV	78	29	No	AAIR-DDDR (60/130)	No	100	130	0.1	0.1	<0.1	<0.1	0.04	0
9	BEV	84	14	No	AAIR-DDDR (60/130)	Yes	150	180	0.56	0.06	0.06	26.97	47.67	0.18
13	SEV	86	35	No	VDD (60/120)	Yes	N/A (leadless pacemaker)	N/A (leadless pacemaker)	Unavailable	N/A (leadless pacemaker)	Unavailable	N/A (leadless pacemaker)	4.7	N/A (leadless pacemaker)

Abbreviations: AV, atrioventricular; BEV, balloon expanding valve; HV, his ventricular; LRL, lower rate limit; PPM, permanent pacemaker; SEV, self expanding valve; URL, upper rate limit.

mechanical stress after initial TAVR may account for the development of HAVB following discharge. Therefore, the precise time interval to wait before performing a modified EP study to assess the conduction system is critical. Ream et al. found that most patients who are discharged without PPM and develop HAVB do so within the first 30 days, but it is not feasible to observe patients for this long after TAVR.[13] Rivard et al. performed their EP study immediately before and a median 4 days after TAVR implantation while Knechet et al. performed their EP study within 24 h if NP-LBBB occurred.[6,7] More recently, Massouillie et al. performed EP study 2–4 days after TAVI.[8] A longer interval of 48 h post-TAVR was chosen in our study to assess the HV interval for SEV due to a theoretically higher chance of continued expansion and increasing mechanical stress beyond the 24-h interval that was used for BEV. Increasing the length of stay (LOS) post-TAVR to perform these modified EP studies will naturally increase the use of healthcare resources. However, based on our results, a modified EP study performed within 24–48 h minimizes the additional LOS and still appears to rule out future development of HAVB as long as the HV interval is less than 55 ms or a procainamide challenge test is negative.

4.2 | Optimal HV interval threshold to implant PPM and procainamide infusion

The optimal HV interval threshold to implant PPM following the development of NP-LBBB post-TAVR is currently unclear. Rivard et al. found a post-TAVR threshold of >65 ms predicted subsequent HAVB with a sensitivity of 83% and a specificity of 82%. Knecht et al. found the HV interval of 55 ms predicted subsequent HAVB with a sensitivity of 67% and a specificity of 84%.[7] Massouille et al. utilized a HV interval threshold of ≥70 ms to implant a PPM.[8] They found using an HV interval threshold yielded a sensitivity of 44% and a specificity of 83% for subsequent HAVB and an HV interval ≥70 ms increased the risk of HAVB by 2.4 times. These studies also demonstrate that the 12-month risk of developing HAVB after an HV interval of <55 ms was low (10%–19%),[7,8] and consistent with our results (0% with HV <55 ms or negative procainamide challenge infusion) given our shorter follow-up at 6 months.

A significant proportion of our patients had an HV interval that was >55 ms but ≤70 ms (16.7%). This is similar to the percentage of patients with an HV interval between 55 and 70 ms (69/183) seen in the study by Massouille et al.[8] They showed that a significant proportion (18/69) of this subset of patients develop subsequent HAVB. To help risk-stratify this group of patients in our study, we utilized an infusion of procainamide. Procainamide infusion has had a long history of being used to assess the conduction system, including the post-TAVR setting.[11,14] The provocation of HAVB with procainamide infusion has been shown to predict subsequent HAVB.[11,14] However, there is no clear consensus on the extent of HV interval change that will predict subsequent HAVB if no HAVB is immediately provoked by procainamide infusion. While Twidale et al. defined a positive response as >15 ms increase in HV interval with procainamide infusion, this was not predictive of subsequent HAVB.[11] Rogers et al. defined a positive

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TABLE 4 Comparison of baseline characteristics between permanent pacemaker (PPM) necessary and PPM unnecessary groups.

	PPM necessary ($n = 2$)	PPM unnecessary ($n = 16$)	*p*-value
Age (in years)	81.5 ± 3.5	78.0 ± 8.4	.578
Gender (Male)	1/2 (50%)	12/16 (75%)	.49
Diabetes	0/2 (0.0%)	4/16 (25.0%)	1.00
Chronic Kidney Disease (CKD)	0/2 (0.0%)	6/16 (37.5%)	.53
Coronary Artery Disease (CAD)	1/2 (50.0%)	10/16 (62.5%)	1.00
Prior Revascularization	0/2 (0.0%)	1/16 (6.3%)	1.00
Atrial fibrillation	0/2 (0.0%)	3/16 (18.8%)	1.00
Body Mass Index (kg/m^2)	31.5 ± 9.3	31.2 ± 4.6	.957
Left ventricular ejection fraction (LVEF) (%)	57.5 ± 10.6	62.2 ± 14.5	.664
Mean gradient across the aortic valve (mmHg)	59 ± 26.8	34 ± 7.9	.412
Aortic valve area (cm^2)	0.7 ± 0.2	0.8 ± 0.1	.337
Pre-TAVR			
PR interval (ms)	215.0 ± 9.9	166.4 ± 24.6	.016*
QRS duration (ms)	100.0 ± 2.8	96.8 ± 15.1	.779
Post-TAVR Day 0			
PR interval (ms)	261.0 ± 21.2	202.7 ± 29.7	.018*
QRS duration (ms)	156.0 ± 25.4	151.3 ± 22.9	.788
Post-TAVR Day 1			
PR interval (ms)	242.0 ± 25.5	179.0 ± 33.6	.023*
QRS duration (ms)	148.0 ± 16.9	145.6 ± 22.6	.889
Baseline HV interval during EP study (ms)	85.0 ± 1.4	57.4 ± 14.6	.019*
Baseline Medications			
Beta-blockers	1/2 (50.0%)	8/16 (50.0%)	1.00
Calcium Channel Blockers (CCB)	1/2 (50.0%)	6/16 (37.5%)	1.00
Self-Expanding valve	0/2 (0.0%)	8/16 (50%)	.48
Positive EP study[a]	2/2 (100%)	2/16 (12.5%)	.04*

[a]Positive EP study was defined as HV interval between 55 to 70 ms and positive procainamide challenge test or HV interval more than 70 ms.
*Statistically significant.

response when the HV interval increased to >100 ms, but the authors conceded this threshold was not sensitive enough to predict subsequent HAVB.[14] Therefore, we defined an abnormal response in our procainamide challenge infusion to be >30% increase in HV interval from baseline, which is more specific than a >15 ms increase in HV interval and more sensitive than an HV interval increase to >100 ms. Finally, a threshold >70 ms to automatically implant a PPM may be excessively conservative since only 50% of our patients who received CIED were noted to have evidence of HAVB on device interrogation (see below).

4.3 | Pacing percentage as a marker for HAVB

Development of HAVB and adjudication of PPM appropriateness was difficult since not all of the patients developed PPM dependency during follow-up, which would inconclusively prove PPM appropriateness. This is important since Massouillie et al. found that almost a third of their patients that received PPM were never ventricularly paced.[8] In the absence of PPM dependency, prior studies have utilized a wide range of pacing burden to define HAVB in patients with PPM.[6,7] Rivard et al. used a pacing percentage of >90%.[6] However, Knecht et al. used a pacing percentage threshold of >1% to define PPM appropriateness following PPM implantation in their study since 1% corresponds to roughly 15 min of pacing per 24-h period.[7] In the absence of confirmed PPM dependency during interrogation, it is difficult to ascertain PPM appropriateness using pacing percentage as even pacing percentage <1% could conceivably miss episodes of intermittent HAVB. Ultimately, we settled with the more conservative definition of PPM appropriateness since paroxysmal AV block for even a few minutes can be catastrophic.[15] Based on this criterion for HAVB in patients who received a CIED, only 50% (2/4) of these patients in our study were deemed to have HAVB, which suggests that a HV interval threshold of 70 ms to implant a device may be too short. However, in the

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CIED patients who were not deemed to have HAVB—subjects #5 and #7 – their HV intervals were 101 and 78 ms, respectively. Raising the HV interval threshold to implant a PPM to >80 ms could be considered in the future to reduce the rate of "unnecessary" PPM implantation, which would be, in our study, PPM implanted in patients who do not exhibit obvious signs of HAVB on their subsequent device interrogation.

Additionally, there is uncertainty about how the LRL of the device should be programmed when determining PPM appropriateness since a LRL set to 60 bpm is more likely to increase ventricular pacing than a LRL of 50 bpm, especially at night when the parasympathetic tone is high, resulting in longer AV conduction times that could potentially exceed the paced AV delay threshold.

5 | LIMITATIONS

There was only a limited number of study subjects enrolled, which is not unusual for a single-center pilot study. Another reason for the relatively small number of study subjects was the rather low incidence of NP-LBBB following TAVR at our center. We also excluded patients with transient LBBB as these patients were shown to have similar outcomes in terms of mortality and PPM requirement compared to patients who did not develop a LBBB.[16] It is also unclear if a prolonged PR interval before or immediately after TAVR is predictive of HAVB development. The PR interval is more prolonged in the PPM-necessary group, but this may simply be related to how the PPM-necessary group was defined, which was by the percentage of ventricular pacing and would be expected to be higher in patients with a longer PR. Nevertheless, our results are consistent with previous reports that a HV interval <55 ms following TAVR is associated with a low incidence of developing subsequent HAVB.[7,8] Large-scale, multicenter prospective studies are required to fully elucidate the prognostic significance of a normal HV interval following TAVR.

6 | CONCLUSION

No patients with a HV interval <55 ms as obtained on modified EP study 24 h after BEV or 48 h after SEV in our study developed HAVB up to 6 months after TAVR implantation. The results from our study add to the growing body of evidence that a normal HV interval following TAVR can be helpful in terms of risk-stratifying patients who develop NP-LBBB and identifying patients who may not need prophylactic PPM implantation. At the same time, we hopefully elucidate a potential role of procainamide challenge during EP study as an adjunctive testing tool for patients with HV interval in the intermediate zone (HV > 55 ms but ≤70 ms) post-TAVR.

AUTHOR CONTRIBUTIONS

Hiren Patel, Christina Tsai: Concept/design, data collection, analysis/interpretation, drafting article. Issam Atallah, Ali Ahmad, Rohil Bedi, Lolita Golemi, Salwa Mikhail, Jissmaria Karickal: data collection, analysis/interpretation, drafting article. Elie Azrak, Sam Bishara, Kishore Harjai, Christopher Bauer, Ahmed Hussein, Rakesh Gopinathannair: Critical revision and approval of the article. Philip Mar: Concept/design, analysis/interpretation, drafting article, critical revision, and approval of the article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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