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Development of advanced conduction disturbances following balloon-expandable transcatheter aortic valve replacement leads to poorer clinical outcomes

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Abstract

Background: Transcatheter aortic valve replacement (TAVR) is a reliable method of treating patients with severe aortic stenosis, but is associated with postprocedure conduction defects.

Objective: The purpose of this study was to compare clinical outcomes in patients who developed advanced conduction defects post-TAVR to those who did not.

Methods: We conducted a retrospective chart review of 243 patients who underwent balloon-expandable TAVR with the Edwards Sapien valve to determine the incidence of advanced conduction defects in our cohort. We compared clinical outcomes including overall mortality, improvement in symptomatology, and improvement in left ventricular ejection fraction.

Results: Among the 243 patients included in the study, 9.1% (22/243) required permanent pacemaker (PPM); 19.8% (48/243) developed left bundle branch block (LBBB), and 71.2% (173/243) did not develop any permanent advanced conduction defects. Overall 1-year mortality was similar across all three groups. There was significant improvement in New York Heart Association functional capacity of all groups post-TAVR, but this was much less in the PPM group (45.5% vs 68.8%, $P = .04$). Postprocedure from TAVR, patients with LBBB or PM were less likely to have improvement in their ejection fraction (net loss of −0.7% for LBBB and −5.7% for PPM compared to a net gain of 2.3% for no-LBBB/PM ($P = .02$).

Conclusion: Patients who develop LBBB or require PM post-TAVR with Edwards Sapien valves are less likely to improve New York Heart Association functional capacity and more likely to have no improvement or deterioration of their pre-TAVR left ventricular ejection fraction.

KEYWORDS

clinical outcomes, left bundle branch block, pacemaker, right bundle branch block, TAVR

1 | INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has developed into a reliable method of treating patients with symptomatic severe aortic stenosis who have a low, moderate, and high surgical risk of surgical aortic valve replacement.[1] The continued evolution of the technology of TAVR along with increased clinical experience, has translated into improved patient outcomes and a decrease in peri-procedural complications. Nevertheless, multiple clinical studies on patients undergoing TAVR have demonstrated the increased incidence of new-onset conduction abnormalities, including left bundle branch block (LBBB) and advanced atrioventricular block requiring permanent pacemaker (PPM) implantation. Despite the advances in TAVR technology and procedural techniques, the incidence of postprocedure conduction defects still remains a concern.[2-5]

The clinical significance and clinical management of conduction abnormalities after TAVR remains unclear. There are limited data on clinical outcomes of conduction defects following TAVR with considerable variation among individual studies seeking to evaluate TAVR induced conduction defects. Similarly, the effects of conduction defects on symptom improvement and improvement in myocardial function after TAVR remain unclear. We accordingly performed a retrospective chart review comparing the postoperative clinical outcomes in patients who developed LBBB and/or require PPM implantation to patients who did not.

2 | METHODS

A retrospective chart review was conducted on all consecutive subjects who underwent TAVR for severe aortic stenosis at a single academic medical center between January 2012 and July 2018. In order to provide data analysis uniformity, for the purpose of this study, we included only patients who received balloon-expandable valves (Edwards SAPIEN, SAPIENT XT, or SAPIEN S3 valves), since they comprise 95% of the TAVR cases in our institution.

The decision to perform TAVR was based on Food and Drug Administration (FDA) approved indications at the time of the procedure. If deemed suitable for TAVR, the procedure was performed using either transfemoral, transaortic, or transapical approaches at the discretion of the structural heart team. All patients had a baseline electrocardiogram (ECG) and transthoracic echocardiogram (TTE). Follow-up ECG and TTE were performed within 5 days after the procedure. After hospital discharge, patients were followed according to STS/ACC TVT Registry[TM] recommendations at 30 days and at least annually thereafter.

The following patients were excluded from this study: those with (a) previously documented permanent or intermittent LBBB; (b) previously implanted PPM; (c) previous temporary third degree atrioventricular (AV) block that had not warranted a pacemaker; (d) previously documented second degree AV block; (e) missing echocardiogram or ECG date within 5 days after TAVR. Patients with previously documented first degree AV block and permanent or intermittent right bundle branch block (RBBB) were included within the study.

Subjects were divided into three groups: (a) Patients with new LBBB on their post-TAVR ECG (n = 48 [19.8%]); (b) patients who required PPM (n = 22 [9.1%]) within 30 days post-TAVR, and (c) all other patients (No-LBBB/PM) (n = 173 (71.2%]). LBBB was defined based on standard electrocardiographic criteria. Patients who required temporary pacing without the need for PPM implantation were not included in the PPM group. The decision for PPM implantation was made based on the most recent American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) guidelines, and hence were dual chamber pacemakers that were programmed to DDD mode. No biventricular pacemakers were implanted. New LBBB was defined as any new LBBB occurring on the post-TAVR ECG.

Clinical and nonclinical parameters and outcomes were captured pre- and post-TAVR in patients with a minimum follow-up of 6 months postprocedure.

2.1 | Statistical analysis

Statistical analysis was performed between the three groups using analysis of variance (ANOVA) F-test for continuous variables, which are presented as a mean ± SD. Chi-square test and Fisher's exact test were used for categorical and ordinal variables, which are presented as numbers and percentages. Survival curves with time-to-event analysis were performed with Kaplan-Meier estimates and were compared with the log-rank (Mantel-Cox) test.

Multivariable logistic regression analysis was performed to detect independent predictors for the development of LBBB and indication for PPM. Univariate clinical variables were chosen for analysis based on clinical relevance. Univariate clinical variables with a $P < .05$ were then entered into a multivariable model. Results of the multivariable logistic regression analysis are presented as odds ratio with a 95% confidence interval. The C-statistic was used to verify the accuracy of the multivariable logistic regression model. A Hosmer-Lemeshow goodness-of-fit test was used to assess the fit of the model. Statistical analysis was performed using SAS software, version 9.4 (SAS Institute Inc). The study was approved by the Institution Review Board at Mayo Clinic.

3 | RESULTS

We identified 243 patients fitting study criteria. The baseline characteristics of the patient population are presented in Table 1.

The incidence of conduction defects that required PPM after TAVR in our cohort was 9.1% (22/243); 19.8% (48/243) patients developed LBBB, and 71.2% (173) did not require PM and did not develop LBBB. There was no difference in baseline characteristics among the groups in regards to age, body mass index, atrial fibrillation, hypertension, diabetes mellitus, coronary artery disease, and

TABLE 1 Patient demographics

	LBBB n = 48	PM n = 22	No-LBBB/PM n = 173	Total n = 243	P value
Age	81.3 ± 8.4	81.7 ± 6.9	82.0 ± 7.3	82.0 ± 7.4	.89
Male	22 (45.8)	17 (77.2)	101 (58.4)	140 (57.6)	.02
BMI	29.2 ± 7.4	27.8 ± 6.6	27.2 ± 5.7	27.9 ± 5.4	.36
NYHA FC pre-TAVR					
I/II	23 (47.9)	16 (72.3)	70 (40.4)	109 (44.9)	.03
III/IV	25 (52.1)	6 (27.3)	103 (59.5)	134 (55.1)	
Access					
Transfemoral	38	20	143	202	.77
Transapical	6	2	13	21	
Transaortic	4	0	17	20	
Echocardiography					
Ejection fraction % pre-TAVR	56.5 ± 4.2	59.1 ± 10.4	57.9 ± 11.8	57.3 ± 12.8	.67
Aortic valve area cm^2	0.8 ± 0.3	0.8 ± 0.3	0.8 ± 0.3	0.8 ± 0.3	.79
Mean aortic gradient mm Hg	41.9 ± 19.8	45.3 ± 17.8	41.8 ± 12.8	43.1 ± 14.3	.66
Hypertension	38 (79.2)	18 (81.8)	141 (81.5)	197 (81.1)	.68
Atrial fibrillation	19 (39.6)	4 (18.2)	52 (30.1)	75 (30.9)	.27
Diabetes	11 (22.9)	6 (27.3)	42 (24.3)	59 (24.3)	.82
History of stroke	6 (12.5)	7 (31.8)	13 (7.5)	26 (10.7)	.01
Coronary artery disease	19 (39.6)	12 (54.5)	73 (42.2)	104 (42.8)	.62
Previous myocardial infarction	3 (6.3)	2 (9.1)	13 (7.5)	18 (7.4)	.81
Vascular intervention (CABG or PCI)	10 (20.8)	9 (40.9)	56 (32.4)	75 (30.9)	.18
COPD	10 (20.8)	4 (18.2)	21 (12.1)	35 (14.4)	.51
CrCl	61.3 ± 29.7	52.7 ± 22.8	56.9 ± 26.2	57.4 ± 26.7	.39
Electrocardiogram					
First degree AV block	7 (14.6)	8 (34.8)	29 (16.8)	44 (18.1)	.09
RBBB/iRBBB	5 (9.4)	12 (52.2)	25 (14.4)	42 (17.3)	.0001
LAFB	1 (2.1)	5 (22.37)	12 (6.9)	18 (7.4)	.01
LPFB	0	0	0	0	

Note: Values are mean ± SD or n (%)

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; FC, functional class; iRBBB, incomplete right bundle branch block; LAFB, left anterior fascicular block; LPFB, left posterior fascicular block; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RBBB, right bundle branch block.

ejection fraction (EF). The post-TAVR PM group had more males and more history of stroke (Table 1).

Patients in the PM group had better preprocedure New York Heart Association Functional Class (NYHA FC) and higher number of FC I-II patients when compared to III-IV (Table 1). Only 27.3% of patients in the PM group had NYHA FC III/IV symptoms prior to TAVR, although 55.1% of the rest of the patients had NYHA III/IV symptoms. RBBB and incomplete RBBB were present in over half of the patients who eventually required pacemakers post-TAVR, but was present in only 9.4% of patients who developed LBBB and 14.4% of patients who developed no other conduction defects.

Postprocedure, the overall 1-year mortality, total follow-up mortality, and time-to-die were not statistically different among the groups (Table 2). There was a numerically higher mortality in the PM

group (hazard ratio 2.09) at 1 year, but this was not statistically significant (HR CI 0.69-6.35, log-rank P = .18) (Figures S1 and S2):

Postprocedure from TAVR, patients with LBBB or PM were less likely to have improvement in their EF (net loss of −0.7% for LBBB and −5.7% for PPM compared to a net gain of 2.3% for no-LBBB/PM (P = .02) (Table 2). When comparing mortality between the PM and LBBB groups, further risk stratification by decrease in left ventricular ejection fraction (LVEF) still failed to demonstrate difference in mortality. It is noted that the PM group had a trend toward increased mortality (HR 2.89) that almost reached statistical significance (HR CI 0.83-10.08, log-rank P = .081) (Figure S2).

There was a significant improvement in the functional capacity of the overall population post-TAVR. 65.5% of the total population had improvement of their NYHA functional class from III or IV to I or

TABLE 2 Outcomes post-TAVR

	LBBB n = 48	PM n = 22	No-LBBB/PM n = 173	Total n = 243	P value
1-y mortality	4 (8.3)	4 (18.2)	13 (7.5)	21 (8.6)	.29
Overall mortality	10 (20.8)	7 (30.4)	36 (20.8)	53 (21.8)	.67
Days until death	466.5 ± 289.2	345.0 ± 233.6	563.6 ± 382.7	517.9 ± 350.7	.27
Echocardiography					
Valve area change (%)	59.7 ± 20.5	65.5 ± 13.2	58.6 ± 27.1	59.4 ± 24.8	.45
Mean gradient change (mm Hg)	−30.1 ± 17.4	−35.7 ± 17.0	−32.4 ± 12.6	−32.2 ± 14.2	.27
Change in LVEF%	−0.7 ± 12.0	−5.7 ± 14.7	+2.3 ± 14.1	+1.0 ± 13.9	.02
NYHA FC					
I/II	42 (87.5)	17 (73.9)	149 (86.1)	208 (85.6)	.23
III/IV	10 (20.8)	6 (27.3)	25 (14.4)	41 (16.8)	
Improvement in NYHA FC	33 (68.8)	10 (45.5)	123 (71.0)	165 (67.9)	.043
No change or worsening NYHA FC	20 (41.7)	13 (59.1)	55 (31.8)	88 (36.2)	.043

Note: Values are mean ± SD or n (%)

Abbreviations: FC, functional class; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

II. In patients who did not develop any conduction defects, 69.3% of them had improved functional capacity, compared to only 62.3% in the LBBB group and 43.5% in the PM group (P = .04) (Table 2).

Multivariate analysis demonstrated that RBBB and incomplete RBBB on preprocedure ECG were independent predictors of PPM implantation post-TAVR with an odds ratio of 6.54 (95% CI 2.63-16.29, P < .0001). First degree AV block had an odds ratio of 2.24 for the development of PPM indication (95% CI 0.83-5.98), but this did not achieve statistical significance. We did not identify any independent predictors of LBBB postprocedure (Table 3).

4 | DISCUSSION

The incidence PPM implantation after TAVR in our cohort was 9.1% (22/243), which is similar to the 13.1% incidence that was found in a meta-analysis of 49 studies analyzing data from 16 063 patients.[6] Our cohort included exclusively patients who underwent balloon-expandable valves with the Edwards Sapein valves, as opposed to the self-expanding Medtronic CoreValve which has a higher incidence of PPM implantation. New LBBB developed in 19.8% (48/243) of patients. Similar to the PM cohort, this incidence of new-onset LBBB falls within the range of 10%-22% that has been cited in prospective studies.[2,4,7-11] It is likely that the anatomic proximity between the aortic valve and the location of the transcatheter valve and the native conduction system with resultant tissue edema and mechanical stress postdeployment of the transcatheter valve is thought to play a major role in the progression of these conduction abnormalities (Figure 1; Figure S3).[7] This is supported by studies that demonstrate that greater amounts of calcification and a greater prosthesis to left ventricular outflow tract ratio are both risk factors for the development of conduction disease.[12,13]

There was no statistical significance between improvement in mean gradient nor in aortic valve area among the various cohorts, negating the possibility that the aortic stenosis itself, or lack of improvement thereof could contribute to differences in mortality, heart failure functional class, or change in echocardiographic parameters such as LVEF.

Neither new-onset of LBBB nor indication for PPM with implantation was associated with increased mortality at 1 year, although there was a trend toward increased mortality in the PM group (HR 2.09, 95% CI 0.69-6.35, log-rank P = .18; Figure 2; Figure S1). One-year all cause mortality in the entire cohort was 8.6%, and was 8.3% in the LBBB group. This is less than the 1-year all-cause mortality in the PARTNER registry in which 1-year all-cause mortality was 20.8%, and the 1-year cardiovascular mortality was 9.0%.[10] Our findings are consistent with a large meta-analysis of 4756 patients that demonstrated that neither new-onset LBBB post-TAVR nor PPM implantation are associated with increased 1 year all-cause mortality.[10,11,14] In our study, we speculate that the observed trend toward increased mortality not reaching significance may be because of the small number of patients requiring PPM. However, other studies have interestingly suggested a trend toward protection in the PPM cohort. This may be true in the immediate post-TAVR phase, when conduction defects primarily occur and can lead to hemodynamic compromise, but do not take long-term mortality into account.[15,16] Nevertheless, given the lack of improvement of LVEF in the LBBB and PPM populations, longer term data are needed with regards to these patients.

Although there was no statistical difference among the various cohorts and NYHA functional class post-TAVR, there was a difference *pre-TAVR*, with the patients who eventually developed LBBB and pacemaker having a lower NYHA functional class prior to TAVR. The change in the NYHA functional class also was statistically

TABLE 3 Predictors of delayed conduction disturbances: Univariate and multivariate analysis

	Univariate analysis		Multivariate analysis	
	Odds ratio (95% confidence interval)	P value	Odds ratio (95% confidence interval)	P value
LBBB				
Pre-TAVR LVEF	0.99 (0.97-1.01)	.39		
Mean aortic gradient	1.0 (0.98-1.02)	.80		
Mean aortic valve area cm^2	0.70 (0.24-2.07)	.52		
LAFB	0.21 (0.03-1.61)	.13		
RBBB/iRBBB	0.45 (0.17-1.20)	.11		
First degree AV block	0.77 (0.33-1.76)	.53		
Atrial fibrillation	1.65 (0.74-3.69)	.23		
Hypertension	0.77 (0.37-1.60)	.48		
Coronary artery disease	0.87 (0.47-1.60)	.64		
Diabetes	0.81 (0.40-1.62)	.55		
Stroke	1.18 (0.48-2.93)	.71		
PM				
Pre-TAVR LVEF	1.0 (0.97-1.03)	.88		
Mean aortic gradient	1.01 (0.99-1.04)	.35		
Mean aortic valve area cm^2	1.25 (0.40-3.96)	.71		
LAFB	4.68 (1.50-14.60)	.008	2.54 (0.73-8.83)	.14
RBBB/iRBBB	7.07 (2.87-17.42)	.0001	6.54 (2.63-16.29)	<.0001
First degree AV block	2.72 (1.08-6.87)	.03	2.24 (0.83-5.98)	.11
Atrial fibrillation	0.57 (0.13-2.57)	.47		
Hypertension	1.14 (0.37-3.53)	.82		
Coronary artery disease	1.72 (0.72-4.07)	.22		
Diabetes	1.43 (0.58-3.54)	.44		
Stroke	3.98 (1.48-10.67)	.006		

Abbreviations: iRBBB, incomplete right bundle branch block; LAFB, left anterior fascicular block; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; PM, pacemaker; RBBB, right bundle branch block; TAVR, transcatheter aortic valve replacement.

significant, as patients who developed conduction abnormalities were less likely to improve post-TAVR NYHA functional class (67.9% for the total population, 68.8% for patients with LBBB, 45.5% for patients with PPM and 71.2% of all the no-LBBB/PM (P = .043). The statistical difference pre-TAVR explains why there was not a difference in NYHA post-TAVR but there was a difference in the change in NYHA functional status. Once again, the pacemaker group had worse outcomes than the LBBB group, and both had worse clinical improvement in functional status compared to the No-LBBB/PM group.

Both the LBBB and PM cohorts failed to have improvement in their LVEF compared to the cohort without conduction abnormalities who did improve in LVEF (Figure 3). Particularly in the cohort

requiring pacemakers, there was a 5.7% drop in LVEF during post-TAVR follow-up, which is an 8.0% absolute decrease from those who did not have any conduction disease after TAVR; 4/22 or 18.1% of the post-TAVR patients requiring pacemakers had a drop in LVEF to less than 40%. Right ventricular pacing is independently associated with cardiomyopathy and depressed LVEF, with an incidence of 12.3% of pacemaker-induced cardiomyopathy at 4 years. [17] In the post-TAVR population, the decrease in LVEF with right ventriculular (RV) pacing was seen very early after PPM implantation, in an unusual behavior for pacemaker-induced cardiomyopathy. The mechanisms underlying this remain unclear and need to be further investigated. The larger decrease in LVEF in the PM group as compared to the LBBB cohort may additionally explain the trend toward increased mortality
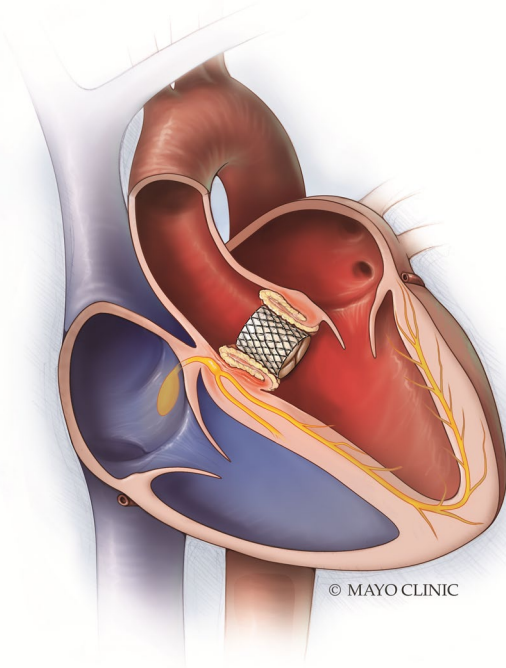
FIGURE 1 Anatomy of the distal conduction system post-transcatheter aortic valve replacement. Note that the calcified aortic valve has been crushed by the prosthetic valve which can lead to compression of the atrioventricular node and His bundle

FIGURE 2 Kaplan-Meier Curve demonstrating 3-y overall mortality. Subjects with left bundle branch block (LBBB) (blue curve) and those without LBBB who did not require permanent pacemaker (red curve) had similar mortality over 3 y

in the PM group. This decrease in LVEF in the PM also correlated to worse NYHA class suggesting that these are clinically relevant differences. Although we did not evaluate for hospitalizations in our study, a recent study did demonstrate an increase in hospitalizations in the post-TAVR patients who receive pacemakers.[18]

Multivariate analysis revealed that RBBB and intermittent RBBB were independent predictors of PPM implantation post-TAVR with an odds ratio of 6.54 (95% CI 2.63-16.29, $P < .0001$) and these patients should be screened prior to TAVR and extra caution taken given their increased odds of developing advanced conduction defect. Other factors, such as first degree AV block (OR 2.24, 95% CI 0.83-5.98) and left anterior fascicular block (LAFB; OR 2.54, 95% CI 0.73-8.83) also had a trend toward prediction of PPM implantation post-TAVR. Likely the cohort of PPM patients did not achieve
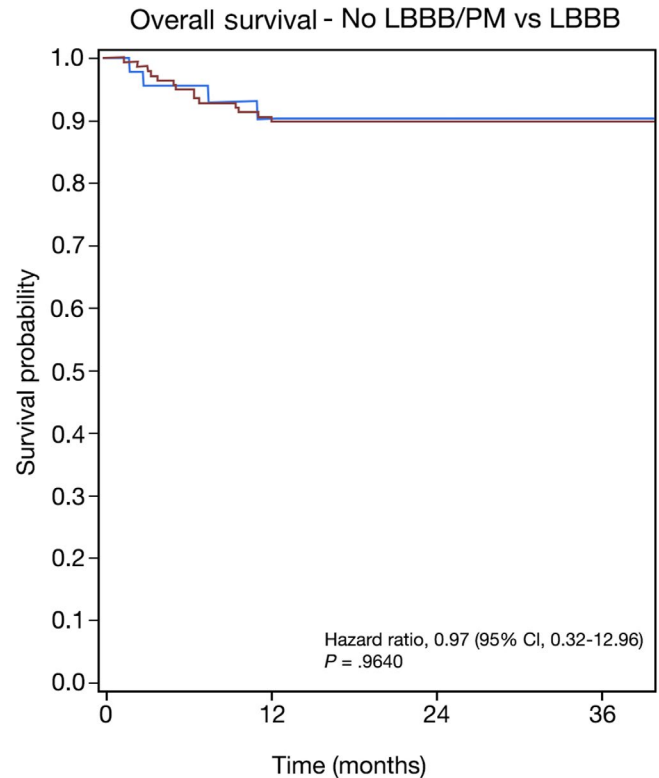
significant power to demonstrate this, and for this reason, we recommend similar caution in these patients. Contrary to other studies have found that PR prolongation *after* TAVR predicted PPM implantation, we did not find such relationship in our population.[18]

Mean aortic gradient, mean aortic valve area, LVEF, and LAFB did not achieve statistical significance as independent predictors of LBBB post-TAVR.

Interestingly, there was a statistically significant increase in patients who required PPM post-TAVR who had a history of stroke prior to TAVR (31.8%). This increase was not seen in the patients who developed LBBB only. The reasons for this finding are unclear and require further studies.
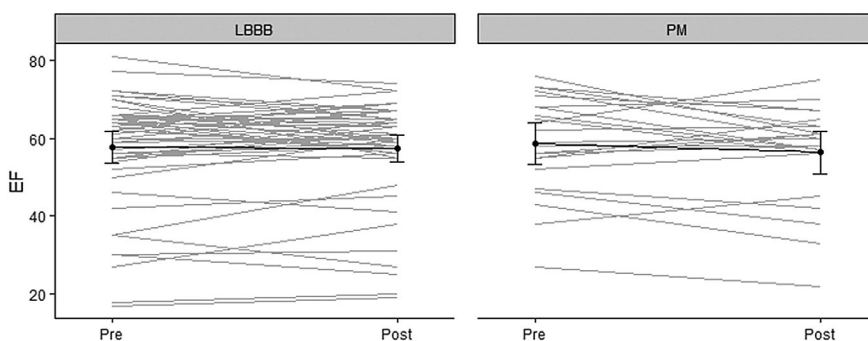

FIGURE 3 Ejection fraction percentage pre- and post-transcatheter aortic valve replacement in patients who had left bundle branch block (LBBB) and permanent pacemaker (PPM). Gray lines indicate individual patients

The limitations of this study include its retrospective nature and that fact that it is a single center study from a high volume tertiary care hospital whose results may not be generalizable to a wider population. Nevertheless, the prevalence of new-onset conduction defects was very much within the ranges that have been reported by other authors. There was a statistically predominance of males in our study population, which can raise questions on its validity for women.

5 | CONCLUSION

Patients who develop LBBB post-TAVR or require PPM with RV pacing are less likely to have improvement of NYHA functional capacity and in their post-TAVR EF as measured by echocardiography. RBBB is an independent risk factor for PPM implantation post-TAVR. Patients who developed a LBBB or require a PM should have more vigilant observation and follow-up. Advancements in technology and techniques to reduce post-TAVR conduction abnormalities are highly desirable and the hypothesis that cardiac resynchronization therapy or His-bundle pacing in this population with preserved LV systolic function will lead to better outcomes must be tested in the future.

CONFLICT OF INTEREST

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.