Predictors of Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement

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Objective: **Determine predictors of permanent pacemaker (PPM) implantation after transcatheter aortic valve replacement (TAVR).**

Design: **A retrospective chart review of patients undergoing TAVR at the authors' institution. Extracted data included patient demographics, electrocardiogram, procedural, and echocardiographic data. Multivariate regression was performed to identify associations with PPM implantation.**

Setting: **Single-center academic hospital.**

Participants: **Patients undergoing TAVR.**

Interventions: **This study was retrospective. No interventions were performed on patients.**

Measurements and Main Results: **Baseline electrocardiogram, Society of Thoracic Surgeons score, age, and echocardiographic parameters were not predictors of PPM implantation. However, multiple deployments was a risk factor, and degree of paravalvular leak trended toward significance. Ten patients required placement of a 2nd valve, or valve-in-valve (VIV). Of the 10 patients with VIV, 5 (50%) required a PPM, compared with 8 (14%) of 56 patients with a single valve (OR 6.0, $p = 0.02$). PPM implantation occurred in 5 (42%) patients with no leak, 8 (19%) patients with trace leak, and no patients with mild or moderate leak ($p = 0.085$). In patients with no or trace leak, VIV increased the likelihood of PPM from 17.4% to 62.5% (OR 7.9, $p = 0.006$). For the 42 patients with trace leak, VIV increased the likelihood of PPM from 11.4% to 57.1% (OR 10.33, $p = 0.005$).**

Conclusions: **The authors found VIV placement, and likely degree of paravalvular leak, to be predictors of PPM placement. VIV and the degree of leak may be useful markers for postoperative prophylactic pacemaker placement.**

KEY WORDS: Transcatheter aortic valve replacement, ECG, ECHO, paravalvular leak, pacemaker

TRANSCATHETER AORTIC VALVE replacement (TAVR) is an increasingly common procedure for replacement of the aortic valve in patients with aortic stenosis (AS). In patients older than 65, the overall prevalence of AS is 2%, increasing to 4% by the age of 85.[1] Patients with severe aortic stenosis or symptomatic disease are considered for valve replacement. TAVR has found a niche in improving symptoms in patients deemed to be high-risk surgical candidates, with lower overall mortality.[2,3,4]

Injury to the conduction system that requires permanent pacemaker (PPM) placement is a known complication in both surgical aortic valve replacement and TAVR. This risk is believed generally to result from the proximity of the conducting system to the aortic valve.[4–6] It is likely that the risk of PPM placement is secondary to mechanical trauma, inflammation, and tissue edema to the conduction system.[7] Previous studies have used pre-procedural electrocardiogram (ECG) data to determine characteristics of patients who required PPM implantation, assuming that patients with pre-existing conduction disturbances would be at higher risk for more severe injury. In these studies, right bundle-branch block (RBBB) was identified most consistently as a risk factor for PPM implantation.[8] Other studies have stratified risk by patient comorbidities such as diabetes mellitus, peripheral vascular disease, septal wall thickness, and male gender.[8–10] Few studies have examined the effect of procedural characteristics in the prediction of need for PPM, although there is evidence that balloon predilation, using the self-expandable CoreValve device and significant valve oversizing may contribute to PPM requirement.[11,12] An additional cofactor that has been shown to increase the risk of PPM placement following TAVR is low implantation of the valve and valve-in-valve procedures.[4]

This study combined ECG, procedural, and echocardiographic characteristics to predict PPM implantation. The authors hypothesized that if the need for a PPM is related to conduction system injury, then procedural characteristics may influence the rate of conduction abnormality following the procedure. Many of the previous studies that have compared ECG findings and PPM implantation rate have not been evaluating solely the balloon expandable SAPIEN XT valve, whereas the authors' study included only patients with SAPIEN XT implantation.

METHODS

This study was approved by the Dartmouth-Hitchcock Medical Center Committee for the Protection of Human Subjects and the Institutional Review Board for Dartmouth College. Written informed consent was waived due to the retrospective nature of the study.

From February 6, 2012 to May 28, 2014, consecutive patients undergoing TAVR with the SAPIEN XT valve device for severe aortic stenosis formed the study population. This included the authors' entire experience with the TAVR procedure at their institution at the time the investigation began. Exclusion criteria included perioperative mortality, previous pacemaker placement, and aborted procedure.

For the procedure, patients were taken to the catheterization laboratory where standard American Society of Anesthesiologists monitors were applied and an arterial catheter was placed, most commonly in the radial artery. General anesthesia was induced in a controlled fashion followed by endotracheal intubation, transesophageal echocardiography (TEE) probe placement, central venous cannulation, and pulmonary artery catheter placement. The femoral veins and femoral arteries were cannulated by the surgical team. A pacemaker lead was placed in the right ventricle for rapid pacing during valvuloplasty, placement of the valve, and further dilations or deployments. If the approach was transapical, an incision was made in the fourth interspace on the left. Patients were heparinized prior to balloon valvuloplasty. Following this, a pacing run was performed, and the valve was deployed. Final valve placement was confirmed

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Table 1. Pre-Procedure Characteristics

	Combined			No Pacemaker			Pacemaker			Comparison		
	Mean or %	N	SD or N	Mean or %	N	SD or N	Mean or %	N	SD or N	Difference or OR	95% CI	p
Pre-procedure RBBB	24.24	66	16	24.53	53	13	23.08	13	3	0.92	(0.14, 4.38)	0.91
Pre-procedure LBBB	10.61	66	7	9.43	53	5	15.38	13	2	1.75	(0.15, 12.42)	0.53
Pre-procedure left axis deviation	16.67	66	11	15.09	53	8	23.08	13	3	1.69	(0.24, 8.76)	0.49
Pre-procedure right axis deviation	4.55	66	3	3.77	53	2	7.69	13	1	2.12	(0.03, 43.44)	0.54
Pre-procedure intraventricular conduction delay	9.09	66	6	9.43	53	5	7.69	13	1	0.80	(0.02, 8.22)	0.84
Pre-procedure fascicular hemiblock	13.64	66	9	11.32	53	6	23.08	13	3	2.35	(0.32, 13.29)	0.27
Pre-procedure rhythm												0.36
Sinus	65.15	66	43	66.04	53	35	61.54	13	8	0.82	(0.20, 3.69)	0.76
First-degree block	4.55	66	3	5.66	53	3	0.00	13	0	0.00	(0.00, 5.38)	0.38
Atrial fibrillation	25.76	66	17	24.53	53	13	30.77	13	4	1.37	(0.26, 5.98)	0.64
Atrial flutter	1.52	66	1	1.89	53	1	0.00	13	0	0.00	(0.00, .)	0.62
Second-degree block	1.52	66	1	0.00	53	0	7.69	13	1	.*	(0.00, .)	.042
Junctional	1.52	66	1	1.89	53	1	0.00	13	0	0.00	(0.00, .)	0.62
LVH on ECG	24.24	66	16	24.53	53	13	23.08	13	3	0.92	(0.14, 4.38)	0.91
LVH on ECHO	13.64	66	9	11.32	53	6	23.08	13	3	2.35	(0.32, 13.29)	0.27
Annular calcification												0.57
1	41.54	65	27	44.23	52	23	30.77	13	4	0.56	(0.11, 2.36)	0.38
2	43.08	65	28	42.31	52	22	46.15	13	6	1.17	(0.28, 4.71)	0.80
3	15.38	65	10	13.46	52	7	23.08	13	3	1.93	(0.27, 10.39)	0.39
STS Scores	8.77	60	5.23	8.33	48	4.82	10.50	12	6.60	-2.17	(-6.50, 2.17)	0.30
Age	83.50	66	8.46	83.06	53	8.97	85.31	13	5.85	-2.25	(-6.41, 1.91)	0.28
Pre PR length	192.17	46	55.81	183.74	38	49.85	232.25	8	68.31	-48.51	(-106.04, 9.01)	0.089
Pre-procedure heart rate	69.79	66	13.86	70.53	53	13.85	66.77	13	13.99	3.76	(-5.28, 12.80)	0.40
Pre-procedure QRS length	111.85	66	25.46	109.40	53	23.30	121.85	13	32.00	-12.45	(-32.47, 7.57)	0.21
Pre-procedure QT Interval	432.12	66	44.94	428.94	53	43.86	445.08	13	48.73	-16.13	(-47.24, 14.97)	0.29
Pre-procedure QTc	462.09	66	41.82	461.00	53	41.60	466.54	13	44.11	-5.54	(-33.85, 22.77)	0.69
Pre-procedure calculated T-axis	42.73	66	84.91	40.02	53	82.69	53.77	13	96.23	-13.75	(-74.85, 47.35)	0.64
Pre-procedure calculated R-axis	1.92	63	49.87	3.96	50	48.32	-5.92	13	56.86	9.88	(-26.29, 46.05)	0.57
Pre-procedure calculated P-axis	37.47	45	34.60	34.61	36	35.36	48.89	9	30.53	-14.28	(-39.30, 10.74)	0.24
Pre-procedure ejection fraction	56.59	66	14.29	56.81	53	14.31	55.69	13	14.74	1.12	(-8.38, 10.62)	0.81

NOTE. For categorical variables, percent with the risk factor and count are shown. For continuous variables, mean and standard deviation are shown.

Abbreviations: CI, confidence interval; ECHO, echocardiogram; ECG, electrocardiogram; LBBB, left bundle-branch block; LVH, left ventricular hypertrophy; OR, odds ratio; RBBB, right bundle-branch block; SD, standard deviation; STS, Society of Thoracic Surgeons.

*Incalculable data point.

with fluoroscopy and TEE. Grading of the paravalvular leak was done at this time by cardiology. If placement of the valve was complicated by a significant paravalvular leak, a post-deployment re-inflation was performed. If the valve was seated poorly, a second valve was deployed.

Data were obtained retrospectively from chart review. Each patient underwent a pre- and post-procedure 12-lead ECG. These ECGs were examined for information, including PR length; QRS length; QT/QTc interval, calculated P, R, and T axes; right- or left-axis deviation; RBBB; left bundle-branch block; interventricular conduction delay; fascicular hemiblock; left ventricular hypertrophy (LVH); and rhythm. Postoperative surgical notes were reviewed for number of balloon valvuloplasties, valve-in-valve (VIV) technique, number of post-placement valve inflations, and balloon inflation volume (standard inflation *v* over- or under-inflation). Each echo report was reviewed for LVH, post-valve deployment leak, and annular calcification. Additionally, ejection fraction (EF) was obtained from the initial echocardiogram and when available at 24 hours and 30 days. For calcification, all valves were graded originally as having severe calcification on initial read. Consequently, the images were reviewed individually by a single researcher, who was board certified in echocardiography, and given a grade of 1-3 (an arbitrary scale denoting an increasing degree of annular calcification within this cohort). Valvular leak was graded using the following nomenclature: none, trace, mild, mild-moderate, moderate, moderate-severe, and severe. This was in agreement with the guidelines developed by the Valve Academic Research Consortium.[9] No patient had a degree of leak higher than moderate. A patient was determined to have required PPM placement if they had the procedure performed within 30 days of TAVR.

STATISTICAL ANALYSIS

The primary outcome was the requirement for permanent pacemaker after the procedure that the authors modeled as a dichotomous variable. Univariate statistical analyses included unadjusted chi-squared or t-test as appropriate for categorical and continuous data, respectively. Odds ratios (ORs) with 95% confidence intervals were reported. Multivariate exact logistic