

ORIGINAL ARTICLE

INCIDENCE AND PREDICTORS OF PERMANENT PACEMAKER IMPLANTATION AFTER TRANS AORTIC VALVE IMPLANTATION (TAVI) – A SINGLE CENTER EXPERIENCE

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Objectives: The objective of the study is to evaluate the incidence and predictors of permanent pacemaker (PPM) implantation in patients undergoing transaortic valve implantation (TAVI).

Methodology: This study was conducted at the “National Institute of Cardiovascular Diseases (NICVD) Karachi, Pakistan”. All the consecutive patients who underwent TAVI between July 2015 and February 2020 were included in the study. Patient data were extracted from Hospital TAVI Registry. We included patients with severe symptomatic aortic stenosis (AS) with moderate to high surgical risk as per “society of thoracic surgeon score (STS)” and “EURO II score”, underwent TAVI. Patients were stratified into two groups based on the implantation of PPM, demographic characteristics, clinical characteristics, co-morbid conditions, valve pathology, and procedural characteristics were compared between both groups.

Results: Among 100 patients included only 22 patients (22%) underwent PPM implantation. The indication for implantation of PPM for all patients was complete heart block. Clinical characteristics which shows statistical significance for PPM implantation are preprocedural left ventricular dysfunction (p=0.015), right bundle branch block (RBBB) p<0.001, and left anterior hemiblock (p<0.001) noted on ECG and post-deployment valve area post-procedure (p<0.001). Multivariate analysis showed that pre-procedure RBBB and large post-deployment valve area are independent predictors for PPM implantation in Post TAVI patients.

Conclusion: The incidence of PPM implantation in patients who underwent TAVI at NICVD is 22%. Preprocedural left ventricular dysfunction, RBBB, and post-procedure large post-deployment valve area were noted to be significant predictors for PPM implantation.

Keywords: Trans Aortic valve implantation (TAVI), permanent pacemaker implantation (PPM)

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INTRODUCTION

Aortic stenosis (AS) is the most common form of valvular heart disease (VHD) in elderly.¹ One in eight people age above 75 has moderate to severe aortic stenosis.² For untreated symptomatic severe Aortic Stenosis, mortality is estimated around 25%.³ Trans catheter aortic valve implantation (TAVI) or Percutaneous aortic valve replacements has emerged preferred treatment modality not only for patients who have high surgical risk⁴ but also as a substitute for surgery in low risk patients as well.⁵ In spite of advancements and improvements in the efficacy and safety of TAVI procedures, compared to surgical counterparts, the conduction system abnormalities requiring implantation of permanent pacemaker (PPM) remains a common complication after the

procedure.⁶ There is a risk of injury to AV conduction system due to the close proximity to Aortic valve complex. A few predictors for AV block after TAVI have been defined.⁷⁻¹⁰ Some of the main predictors of permanent pacemaker implantation after TAVI are baseline right bundle branch block on ECG, depth of implantation, oversizing of aortic annulus, use of first generation aortic valve and first degree AV block. Identifying patient and procedure related risk factors has key importance in identifying patients who are at risk for subsequent AV block.¹¹

The “National Institute of Cardiovascular Diseases (NICVD)” is the pioneer institute to develop TAVI program in Pakistan, The objective of this study is to evaluate the incidence and predictors of PPM implantation in patients undergoing TAVI at National Institute of Cardiovascular Diseases.

METHODOLOGY

This was a retrospective study and a hospital based registry of patients undergone TAVI procedures at the “National Institute of Cardiovascular Diseases (NICVD) Karachi, Pakistan”. All the consecutive patients who underwent TAVI during July 2015 and February 2020 were included in the study, none of the included patients had prior PPM implantation. Patient data was extracted from Hospital Registry. Patients with severe symptomatic AS with moderate to high surgical risk as per the “society of thoracic surgeon (STS) score”¹² and “EURO II score”¹³ underwent TAVI. Few low risk patients as per STS and EURO II score also underwent TAVI who were otherwise inoperable due to comorbid conditions. Before procedure all patients underwent detailed evaluation including history, clinical examination, blood chemistry, complete blood count (CBC), Electrocardiography (ECG), X-Ray Chest, Trans-thoracic Echocardiography, Trans-esophageal Echocardiography (TEE) and “ECG gated Multi-detector computed Tomography (MDCT)” using 3 Mensio structural heart software (“Pie Medical Imaging, Maastricht, and the Netherland”). Patient’s selection for the procedure was made by the heart team approach and risk stratification of patients, as high, moderate, and low risk, was made with the help of EURO II score and STS score.

First and second-generation Core Valves were implanted in these patients. Post procedure at day one and on discharge ECG, TEE and labs were done and repeated if required during hospital stay and they were followed till one month of discharge from the hospital. All post procedure complications and implantation of PPM, if indicated during hospital stay were noted.

Baseline ECG findings before procedure were noted for all the patients which included pre-operative rhythm, degree AV block, QRS morphology {right bundle branch block (RBBB), left bundle branch block (LBBB), and interventricular conduction delay (IVCD)}, and left anterior Hemi block.

Patients were stratified into two groups based on implantation of PPM, demographic characteristics, clinical characteristics, co-morbid conditions, valve pathology, and procedural characteristics were compared between both groups.

Data were analyzed using IBM SPSS version 19. Data were summarized as frequency (%) and mean \pm standard deviation (SD) for categorical and continuous response variables respectively. Patients with and without permanent pacemaker implantation were compared by applying Chi-square and independent

sample t-test in univariate analysis. Clinical important and statistically significant variables from univariate analysis were taken as candidates for multivariate analysis. For multivariate analysis, multivariate logistic regression analysis was performed with requirement of permanent pacemaker as dependent variables and odds ratio (OR) along with 95% confidence interval (CI) were reported. All the statistical analysis were performed and 5% level of significance.

This study was approved by the ethical review committee of the “National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan”, approval reference number: ERC-53/2020. Consent for publication of data while maintaining confidentiality and anonymity of the subjects was obtained as a part of routine prior to procedure.

RESULTS

A total of 100 patients underwent TAVI (n=100), no patients were excluded as there were no prior PPM implantation before the TAVI. Among 100 patients included only 22 patients (22%) undergone permanent pacemaker implantation. Indication for implantation of PPM for all patients was complete heart block.

Baseline patient characteristics are shown Table 1, mean age of patients was 69.46 ± 10.25 years, among them 63% were males and 37% were females. The patients with high surgical risk as per STS score were 39% and with EURO score II were 36%. High prevalent co morbidities were hypertension 79%, coronary artery disease 62% and diabetes 51%. From total of 100 patients 18% of patients were in NYHA functional class IV.

Analysis of baseline characteristics showed significance in terms of PPM implantation among patients who had high surgical risk according to Euro score, $p=0.04$ but not with STS score $p=0.09$ and also patients who were in NYHA functional class IV, $p<0.001$. All other parameters shows no significance for PPM implantation.

Echocardiographic and procedural details are shown in Table 2. There were even distribution among the nature of the aortic valve morphology 50% were bicuspid and 50% were tricuspid. In 86% of them, Medtronic Core valve first generation was implanted while in 14% Evolute R (second generation) was used. Among all patients 22% of patients had left ventricular ejection fraction 30% or less which shows statistical significance for PPM implantation, p value=0.015.

Table 1: Clinical Characteristics

Characteristics	Total	Permanent Pacing		P-value
		Yes	No	
Total (N)	100	22	78	-
Gender				
Male	63 (63%)	11 (50%)	52 (66.7%)	0.153
Female	37 (37%)	11 (50%)	26 (33.3%)	0.153
Age (years)	69.46 ± 10.25	67.45 ± 10.72	70.03 ± 10.11	0.301
STS Score	6.79 ± 1.93	7.64 ± 1.46	6.55 ± 1.98	0.018*
Low risk (<4)	6 (6%)	0 (0%)	6 (7.7%)	0.180
Moderate risk (4 to 8)	55 (55%)	10 (45.5%)	45 (57.7%)	0.308
High risk (>8)	39 (39%)	12 (54.5%)	27 (34.6%)	0.091
EURO II Score	4.59 ± 1.28	5.26 ± 1.27	4.4 ± 1.23	0.005*
Low risk (<2)	3 (3%)	0 (0%)	3 (3.8%)	0.350
Moderate risk (2 to 5)	61 (61%)	10 (45.5%)	51 (65.4%)	0.091
High risk (>5)	36 (36%)	12 (54.5%)	24 (30.8%)	0.04*
Smokers				
Never smoked	65 (65%)	15 (68.2%)	50 (64.1%)	0.723
Ex-smoker	27 (27%)	6 (27.3%)	21 (26.9%)	0.974
Current smoker	8 (8%)	1 (4.5%)	7 (9%)	0.499
Co-morbid Condition				
Diabetes	51 (51%)	10 (45.5%)	41 (52.6%)	0.556
Hypertension	79 (79%)	17 (77.3%)	62 (79.5%)	0.822
Coronary artery disease	62 (62%)	14 (63.6%)	48 (61.5%)	0.858
Peripheral artery disease	2 (2%)	0 (0%)	2 (2.6%)	0.448
Renal disease (creatinine > 2)	4 (4%)	0 (0%)	4 (5.1%)	0.278
Previous Myocardial infarction	29 (29%)	7 (31.8%)	22 (28.2%)	0.742
Chronic obstructive pulmonary disease	23 (23%)	7 (31.8%)	16 (20.5%)	0.266
Severe liver disease	12 (12%)	5 (22.7%)	7 (9%)	0.08
Cerebrovascular disease	14 (14%)	4 (18.2%)	10 (12.8%)	0.522
Poor mobility	14 (14%)	2 (9.1%)	12 (15.4%)	0.452
Extensive calcification of ascending aorta	2 (2%)	0 (0%)	2 (2.6%)	0.448
Previous cardiac surgery	15 (15%)	5 (22.7%)	10 (12.8%)	0.25
Prior balloon aortic valvuloplasty	2 (2%)	1 (4.5%)	1 (1.3%)	0.334
Prior percutaneous coronary intervention	28 (28%)	6 (27.3%)	22 (28.2%)	0.931
NYHA dyspnea status (Pre-procedure; stable only)				
I	4 (4%)	1 (4.5%)	3 (3.8%)	0.882
II	7 (7%)	0 (0%)	7 (9%)	0.145
III	71 (71%)	10 (45.5%)	61 (78.2%)	0.003*
IV	18 (18%)	11 (50%)	7 (9%)	<0.001

STS score= Society of thoracic surgeon risk score, EURO II Score= European System for Cardiac Operative Risk Evaluation, NYHA = New York Heart Association.

Table 2: Valve pathology and procedure characteristics

Characteristics	Total	Permanent Pacing		P-value
		Yes	No	
N	100	22	78	-
Valve assessment				
Pulmonary artery systolic pressure (mmHg)	34.57 ± 9.9	35.09 ± 11.31	34.42 ± 9.55	0.782
Aortic valve mean gradient (mmHg)	51.28 ± 10.26	52.36 ± 11.12	50.97 ± 10.06	0.577
Aortic valve peak gradient (mmHg)	81.42 ± 14.98	81.91 ± 18.16	81.28 ± 14.09	0.863
Aortic valve area (Sqr. cm)	0.82 ± 0.18	0.79 ± 0.15	0.83 ± 0.19	0.336
Aortic annular diameter (mm)	24.76 ± 2.87	25.5 ± 3.04	24.55 ± 2.81	0.169
Valve size (mm)	28.04 ± 2.92	27.5 ± 2.79	28.19 ± 2.95	0.328
Valve Nature				
Bicuspid	50 (50%)	9 (40.9%)	41 (52.6%)	0.334
Tricuspid	50 (50%)	13 (59.1%)	37 (47.4%)	0.334
Implanted Valve				
Core Valve	86 (86%)	18 (81.8%)	68 (87.2%)	0.522
Evolut R	14 (14%)	4 (18.2%)	10 (12.8%)	0.522
Mitral regurgitation				
None	49 (49.5%)	9 (42.9%)	40 (51.3%)	0.390
Mild	36 (36.4%)	7 (33.3%)	29 (37.2%)	0.644
Moderate	14 (14.1%)	5 (23.8%)	9 (11.5%)	0.182
Severe	0 (0%)	0 (0%)	0 (0%)	-

Left ventricular function				
Good (LVEF >=50%)	48 (48%)	5 (22.7%)	43 (55.1%)	0.007*
Fair (LVEF = 30-49%)	30 (30%)	8 (36.4%)	22 (28.2%)	0.461
Poor (LVEF <30%)	22 (22%)	9 (40.9%)	13 (16.7%)	0.015*
Aortic balloon valvuloplasty before valve deployment				
Not done	96 (96%)	22 (100%)	74 (94.9%)	0.278
Completed	4 (4%)	0 (0%)	4 (5.1%)	0.278
Valve successfully deployed	94 (94%)	22 (100%)	72 (92.3%)	0.18
Post deployment valve assessment				
Aortic valve peak gradient (mmHg)	8.84 ± 4	8.27 ± 4.43	9 ± 3.89	0.454
Aortic valve mean gradient (mmHg)	5.33 ± 4.13	6 ± 6.44	5.14 ± 3.2	0.388
Aortic valve area (Sqr. cm)	2.75 ± 1.02	3.59 ± 0.75	2.51 ± 0.97	<0.001*

LVEF= left ventricular ejection fraction..

Post deployment valve area among patients who underwent PPM implantation was 3.59 ± 0.75 sq.cm and without PPM implantation was 2.51 ± 0.97 sq.cm, showing significance p<0.001, with sensitivity 77.27% and specificity 75.64%. All other parameters like pre and post valve gradients, annular diameter showed no significance.

Electrocardiographic characteristics are shown in Table 3. Most of the patients (92%) were in sinus rhythm, Patients with RBBB at baseline were 19 among them 14(63.6%) were implanted pacemaker, p<0.001. Out of 22 patients who were implanted pacemaker 6 (27.3%) had Left anterior hemiblock documented preprocedure, p<0.001. No other electrocardiographic feature turned out to be significant.

Table 3: ECG characteristics and Outcomes

	Total	Permanent Pacing		P-value
		Yes	No	
N	100	22	78	-
Pre-operative heart rhythm				
Sinus rhythm	92 (92%)	21 (95.5%)	71 (91%)	0.499
Atrial fibrillation/ flutter	7 (7%)	1 (4.5%)	6 (7.7%)	0.609
1st degree heart block	1 (1%)	0 (0%)	1 (1.3%)	0.594
QRS Morphology				
LBBB	12 (12%)	3 (13.6%)	9 (11.5%)	0.789
RBBB	19 (19%)	14 (63.6%)	5 (6.4%)	<0.001
IVCD	5 (5%)	2 (9.1%)	3 (3.8%)	0.319
Normal	64 (64%)	3 (13.6%)	61 (78.2%)	<0.001
Left anterior hemiblock	7 (7%)	6 (27.3%)	1 (1.3%)	<0.001

LBBB=left bundle branch block, RBBB=right bundle branch block, IVCD=interventricular conduction delay

The multivariable logistic regression analysis for predictors of PPM is shown in Table 4. The RBBB at

baseline (OR: 155.85, 95% CI: 9.48 - 2563.18, p<0.001) and post deployment valve area (OR: 5.68, 95% CI: 1.5 - 21.51, p<0.011) were found to be independent predictors of PPM.

Table 4: Multivariate logistic regression analysis

Factors	Odds Ratio (OR)	95% CI	P-value
STS Score >5	6.25	0.55 - 70.51	0.138
EURO II Score >5	0.65	0.06 - 6.52	0.710
NYHA IV	5.49	0.61 - 49.52	0.129
Poor LVEF (<30%)	0.84	0.09 - 7.46	0.872
RBBB	155.85	9.48 - 2563.18	<0.001*
Left anterior hemiblock	0.52	0.01 - 21.73	0.731
Post deployment valve area	5.68	1.5 - 21.51	0.011*

STS score= Society of thoracic surgeon risk score, EURO II Score= European System for Cardiac Operative Risk Evaluation, NYHA = New York Heart Association, LVEF= left ventricular ejection fraction, RBBB, right bundle branch block

DISCUSSION

It is the first study from Pakistan regarding the subject of PPM implantation incidence and the most likely characteristics (patients and procedural) which lead to PPM implantation in patients who underwent TAVI. The principal findings are: incidence of PPM implantation within 30 days is 22%, clinical characteristics which shows statistical significance for PPM implantation are pre-procedural left ventricular dysfunction, RBBB and Left anterior hemiblock noted on ECG and post deployment valve area post procedure. Multivariable analysis showed, pre-procedure RBBB and large post deployment valve area are independent predictors for PPM implantation in post TAVI patient.

Cardiac conduction abnormalities are common with both surgical replacement and TAVI procedures. This possibly related to close anatomic proximity to the conduction tissue. Data regarding the mechanism of conduction tissue injury shows different mechanism include compression, direct trauma, hemorrhage, and infarction or ischemia of the conduction system tissues.¹⁴⁻¹⁵ After the isolated surgical valve replacement, the incidence of PPM implantation is 3.2% to 7.1%.¹⁶⁻¹⁷ Incidence of PPM implantation in Edward Sapein Valve averages 5.9% to 6.5%.¹⁸ Overall rate of new PPM implantation in TAVI using Core valve is reportedly higher 25% and 29%.¹⁸ In our study 86% of the patients were implanted with Core Valve which possibly reflects high (22%) pacemaker implantation rate as already described in literature Core valve.

A very limited literature are available regarding various aspects of post-procedure PPM implantation including indication, timing, and type of the PPM, Nazif, et al.¹⁹, showed the indication for PPM was high-degree atrioventricular block in approximately 80% of cases same as our study in which all patients who have PPM implantation had complete heart block.

Among data regarding the predictors of PPM implantation after TAVI preexisting RBBB is the most commonly reported predictor,²⁰ same as our study although with limited number of patients. Other predictors include the use of core valve, lack of prior valve surgery, porcelain aorta, degree of calcification of the mitral annulus, aortic annulus, aorta or LVOT, and depth of implantation below the aortic valve annulus.²¹⁻²³

Limitations of our study are, it is a small study and consist of limited number of patients of which high number of patients received first generation valve which has already high risk of conduction abnormality. Any prediction regarding the risk factor for PPM implantation post TAVI cannot be done with high confidence.

CONCLUSION

Among patients who underwent TAVI at our center, 22% of them implanted with permanent pacemaker. Clinical characteristics which shows significance in terms of PPM implantation post procedure are reduced left ventricular function, preexisting RBBB, left anterior hemiblock, post deployment valve area.

AUTHORS' CONTRIBUTION

MA and GI: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be

accountable for all aspects of the work. AA, PA, KA, and TS: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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