PERMANENT PACEMAKER IMPLANTATION

The South African SHARE-TAVI registry: incidence and risk factors leading to conduction disturbances requiring permanent pacemaker implantation

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ABSTRACT

Background: One of the most common complications post transcatheter aortic valve implantation (TAVI) is the development of heart block requiring permanent pacemaker implantation (PPM). The incidence of PPM in international registries ranges from 13% - 17.5%.

Methods: The aim of this observational study was to report the PPM rate in the SHARE-TAVI registry and determine the clinical, electrocardiographic and procedural predictors of PPM as well as the effect of PPM on clinical outcomes.

Results: Three hundred and five subjects were analysed. The PPM rate was 9%. Third degree atrioventricular block at the time of implant was the most common indication for PPM. Self-expanding valves (PPM rate 14% vs. 6% for balloon-expandable valves, p=0.02) were correlated with the need for PPM. Baseline ECG predictors of PPM were axis deviation, QRS duration and conduction delay, most notably a pre-existing right bundle branch block (OR 15.88, p<0.01). PPM influenced functional class at 30 days, but not the need for repeat hospitalisation or mortality at 30-day and 1-year follow-up.

Conclusions: A PPM rate lower than that reported in large international registries was found. Predictors of PPM and the influence of PPM on outcomes were similar to those reported in the international data.

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INTRODUCTION

The first in vivo transcatheter aortic valve implantation (TAVI) was performed by Alain Cribier in Rouen in 2002.[1] Initially TAVI was indicated for patients with symptomatic severe aortic stenosis (AS) with an absolute contraindication to surgical aortic valve replacement and high surgical risk assessment. In the interim data in intermediate risk patients have influenced the current guidelines.[2,3] In the 2017 ESC guidelines TAVI carries a class IB recommendation for patients with an increased surgical risk assessment.[3] In the 2017 ACC/AHA guidelines TAVI carries a class IA recommendation for high risk patients and a Class IIa recommendation for intermediate surgical risk patients.[4]

TAVI has successfully been implemented in South Africa, with the first TAVI procedure performed in October 2009[5] and local guidelines were published by the South African Society of Cardiovascular Intervention and the Society of Cardiothoracic Surgeons of South Africa.[6] The South African SHARE-TAVI registry was established in October 2014. This registry is a first of its kind in South Africa and aims to include all patients referred for TAVI. Eleven centres in South Africa are recruiting patients. Outcomes reported are as per the VARC-2 (Valve Academic Research Consortium-2) consensus document published in 2012.[7] One of these end points is the development of conduction defects post TAVI. This is currently the most

common complication of the procedure, occurring in as much as 34.6% of patients at discharge.[8] Furthermore, improvements in TAVI technology, together with the increasing experience of operators/centres, have resulted in a major reduction in peri-procedural complications, yet the incidence of conduction disturbances leading to permanent pacemaker implantation (PPM) has remained relatively high.[9] It is therefore important to understand and limit such TAVI-related complications because TAVI is set to expand to patients at intermediate and low surgical risk among whom the detrimental consequences of conduction disturbances and long-term right ventricular pacing may be even more pronounced.[10]

METHODS

Study Rationale

The aim of this observational study was to report the PPM rate in the SHARE-TAVI registry and determine the clinical, electrocardiographic and procedural predictors of PPM as well as the clinical outcomes of the development of a conduction disturbance.

Study Population

The SHARE-TAVI registry prospectively collected detailed data on more than 96% of all TAVI implants in South Africa from November 2014 until the present. The registry has ethics approval from both the ethics committees of the University of Stellenbosch (HREC Ref No: N14/06/073) and the University of Cape Town. Data is entered by the treating physician into a protected and de-identified database.

To ensure accuracy, the investigators reviewed all case notes and electrocardiograms and verified all parameters entered into the database. For logistical reasons, only data from centres performing more than 10 procedures per year were analysed. Three hundred and five patients were analysed for this study of which 197 had follow up data available up to 1 year. Patients with pre-existing pacemaker implants were excluded.

Data Collection

Multiple clinical echocardiographic baseline parameters were extracted from the registry [age, sex, site performed (state or private sector), baseline creatinine, aortic valve gradients and area, pulmonary pressures, valve type implanted, surgical risk scores and access site]. Electrocardiogram (ECG) parameters pre- and post-implant (rate, rhythm, PR interval, QRS width, QRS axis, evidence of conduction disturbance) were extracted from the registry and independently reviewed by the principal investigator by means of individual folder review. The aortic valve annulus diameter as determined by computed tomography (CT) was divided by the diameter of the implanted valve at the annulus as specified by the manufacturers to determine the degree of oversizing. It was ascertained whether a pacemaker was inserted and when it was inserted in temporal relation to the procedure. The indication for PPM in each case was assessed according to the ESC guideline.[11]

Statistical analysis

Comparisons of continuous measurements between groups were tested using one-way ANOVA. In all cases assumptions of normality were assessed by inspecting normal probability plots. In cases where the assumptions were suspect, Mann-Whitney U tests were also done, but were in all cases found to give the same results as the ANOVA F-tests. Thus, only the latter were reported.

For pre- post comparisons, mixed model ANOVAs were used with time (pre, post) as fixed effect, and the patients as random effect.

Categorical variables were compared using the cross tabulation and the Fisher exact test. For pre/post testing of categorical variables, the Stewart-Maxwell Chi-square test was used.

Receiver Operating Curve (ROC) analyses were conducted to investigate the predictive ability of continuous variables to predict PPM.

RESULTS

Baseline characteristics

Baseline characteristics and procedural information is displayed in Table I. The PPM rate was 9% in the cohort studied. All these parameters were correlated with the need for PPM. Predictors of PPM were baseline creatinine, dyspnoea grade and type of valve implanted [balloon-expandable (BE) vs. self-expanding (SE)] (Table II).

Procedural characteristics

The degree of oversizing was determined for those patients that had CT scan parameters entered into the registry. The degree of oversizing was determined as described in Methods. The degree of oversizing was higher for SE valves (1.22 vs. 1.11 for BE valves). The degree of oversizing was also associated with the need for PPM (Figure 1). The effect of valve type was also investigated, but did not influence the difference as seen in Figure 1 (interaction p=0.29) (Figure 2).

ECG Parameters pre- and post-TAVI

Baseline ECG parameters and immediate post TAVI parameters are described in Table III. The most notable changes were the development of heart block. There was a small but statistically significant prolongation of the average PR interval of the pre- and post-TAVI groups (from 184ms - 191ms), however only 19 patients (6%) progressed to a PR interval of more than 200ms.

TABLE I: Baseline and Procedural Characteristics (n=305).

Age (mean)	80 years	(SD 7.85 years)
Sex: Female	142	(47%)
Site performed (n)		
State	56	(18%)
Private	249	(82%)
NYHA Class		
I	5	(2%)
II	92	(33%)
III	163	(59%)
IV	15	(5%)
Creatinine (mean)	100mmol/L	(SD 38mmol/L)
Echocardiographic parameters (mean)		
Mean Gradient (mmHg)	53mmHg	(SD 19mmHg)
Peak Velocity (m/s)	4.31m/s	(SD 0.72m/s)
Aortic valve area (mean)	0.7cm^2	(SD 0.17cm^2)
Pulmonary artery pressure (mean)	49mmHg	(SD 14mmHg)
Risk Scores (mean)		
Log Euro Score % (mean)	23.5%	(SD 16.1%)
STS Score % (mean)	6.6%	(SD 7.1%)
Access Site (n)		
Transfemoral	280	(92%)
Transaortic	15	(5%)
Transapical	5	(2%)
Valve type (n)		
Balloon-expandable	189	(62%)
Self-expanding	116	(38%)

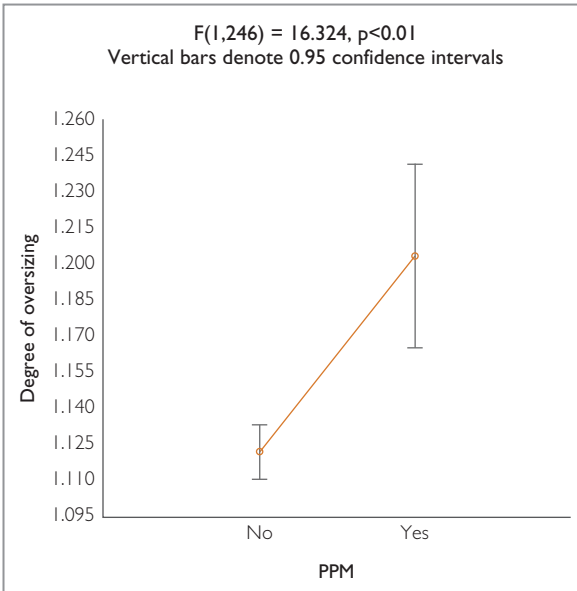

FIGURE 1: Degree of oversizing and need for PPM.

Further significant changes were the development of a new left bundle branch block (LBBB) and a prolongation of the QRS duration post-TAVI.

Indications and timing of PPM

The incidence of PPM was 9%. This equated to 27 pacemaker implantations, 26 of which had a Class I indication for PPM according to the ESC guidelines.[11] The patient with no Class I indication for PPM had a pacemaker implanted because of progressive PR interval prolongation, from 210ms prior to

TABLE II: Clinical and Procedural Predictors of PPM.

Parameters at implant of the TAVI valve (mean)	PPM	No PPM	p-value (ANOVA F-test
Age (years)	78.9	80.4	0.32
Creatinine (umol/L)	119	99	0.02
Mean Aortic Valve Gradient (mmHg)	49	53	0.22
Peak Aortic Valve Velocity (m/s)	4.34	4.30	0.88
Aortic Valve Area (cm^2)	0.7	0.75	0.19
Aortic Valve Annulus Diameter (mm)	23.2	22.6	0.38
Pulmonary Artery Systolic Pressure (mmHg)	41.7	49.8	0.08
Log Euro score (%)	27.6	23.3	0.26
STS score (%)	4.7	6.8	0.20
NYHA grade dyspnoea	2.95	2.66	0.03
History of Syncope (%)	31	25	0.56
Frailty (%)	71	72	1.00
Porcelain Aorta (%)	17	21	1.00

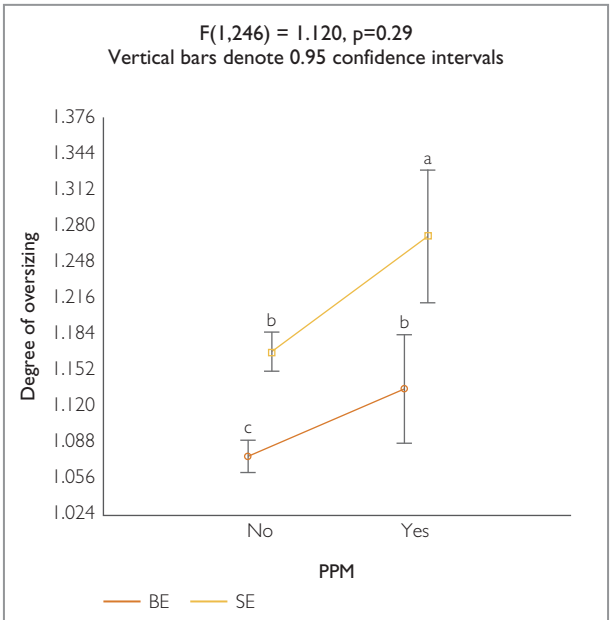

FIGURE 2: Degree of oversizing and need for PPM for individual valve types (BE: balloon-expandable/ SE: self expanding).

TAVI, to 320ms immediately post TAVI, and 360ms at day 3 post implant. 17 of the patients developed the indication for PPM immediately post TAVI. For the remaining 10 patients there was an average delay of 5.8 days until the indication for PPM occurred. In these patients an average of prolongation in QRS duration of 20ms was demonstrated. Seven of these patients had variable changes in an ECG parameter from their baseline ECG. Interestingly 2 cases developed their indication for PPM on days 10 and 11 respectively.

ECG predictors of PPM

Pre-existing arrhythmia, pre-TAVI heart rate and presence of a first degree heart block did not predict the development of an indication for PPM. The parameters that were statistically significant predictors for the development of indications for PPM were a prolonged QRS duration, and pre-existing right bundle branch block (RBBB).

A QRS of less than 103ms provided a negative predictive value of 96%, with a ROC curve AUC of 0.70 (Figure 3). The positive predictive value however was only 20%. The mean delta QRS

TABLE III: ECG parameters.

	Pre-TAVI (n = 292)	Post–TAVI (n =271) (immediately post TAVI)	p-value
Sinus Rhythm (%)	83%	80%	<0.01
Arrhythmias (%)	17%	20%	0.03
Atrial fibrillation	17%	13%	
Atrial flutter	0%	1%	
Other	0%	0%	
Heart Block (AV)	0%	6%	
Rate mean (bpm)	72 (SD 14)	72 (SD 16)	0.64
PR Interval (ms)	184 (SD 44)	191 (SD 49)	<0.01
Axis			0.07
Normal	80%	76%	
Left	16%	19%	
Right	4%	4%	
North West	1%	1%	
QRS duration mean (ms)	104 (SD 24)	110 (SD 27)	<0.01
Conduction delays (incidence)			0.01
LBBB	10%	24%	
RBBB	5%	7%	
Left Anterior Hemiblock (LAHB)	9%	8%	
Left Posterior Hemiblock (LPHB)	0%	1%	
Non-specific intraventricular (NSIVC)	0%	0%	

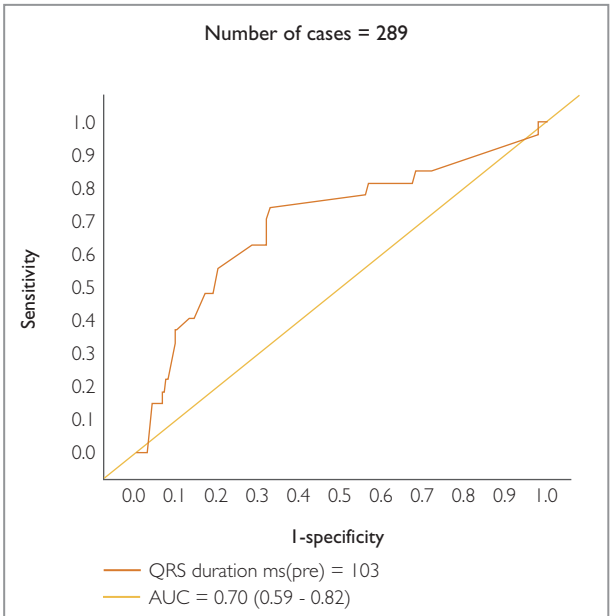

FIGURE 3: ROC curve pre-existing QRS duration as predictor of PPM.

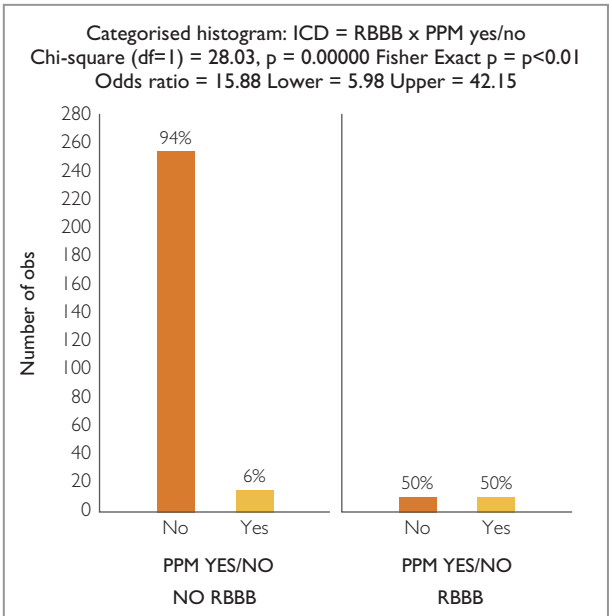

FIGURE 4: Incidence of PPM in presence and absence of pre-procedural RBBB.

(difference between pre- and post-TAVI QRS duration) was 20 milliseconds for the 10 patients who required PPM and did not develop an immediate third degree AV block post TAVI, compared to 11ms mean delta QRS for those that did not require PPM (p=0.06).

The strongest predictor was the presence of a pre-existing RBBB (Odds Ratio 15.88) (Figure 4).

Post procedural predictors were interpreted speculatively as only 10 of the 27 patients who did have a PPM did not develop their heart block immediately post TAVI. Of these 10 patients, 7 had a change in their ECG parameters, prior to developing heart block. These changes included a prolongation in PR interval, the development of a new axis deviation or a new bundle branch block.

PPM and clinical outcomes

At 30 days of follow up there was no statistically significant difference in mortality or rehospitalisation in the PPM vs. non PPM groups. A larger proportion of patients had NYHA III dyspnoea in the PPM group vs. the non-PPM group (27% vs. 5%, p=0.05) At 1 year there was no difference in mortality or rehospitalisation between the groups. The difference in functional class was no longer significant PPM prolonged the procedure as expected. PPM had no significant difference on the duration of time spent in the ICU or in hospital (Table IV).

TABLE IV: Duration of ICU and ward stay for the PPM and no PPM groups.

	No PPM group	No PPM group	p-value (ANOVA F-test)
Duration of ICU stay (days)	1.87	2.62	0.07
Duration of ward stay (days)	1.52	1.92	0.58

DISCUSSION

We report from the SHARE-TAVI Registry, the first data on pacemaker implantation post TAVI in a resource limited environment and could show lower rates of PPM implantation than in other international studies.

Conduction Disturbances after TAVI

The Atrioventricular (AV) node and the left bundle are in close relation with the aortic valve. This may explain the development of conduction abnormalities post TAVI implant (Figure 5). Necropsy studies have found that interaction between the newly implanted TAVI valve and the conduction system may lead to a direct mechanical insult to the conduction system associated with various degrees of oedema, haematoma, and ischaemia.[12]

New LBBB is the most commonly described conduction disturbance due to TAVI.[13] The aforementioned was also found

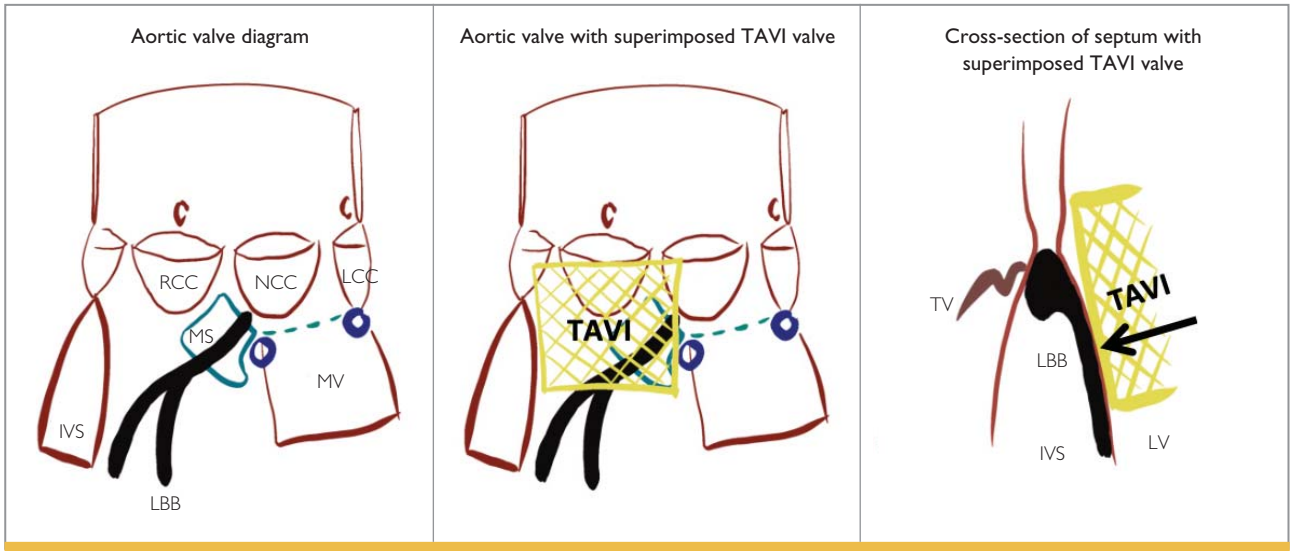

FIGURE 5: Graphic representation of the relationship of the TAVI valve to the aortic valve and conduction system.
*nIVS = interventricular septum, NCC = non-coronary leaflet, RCC = right coronary leaflet, LCC = left coronary leaflet, TV = tricuspid value, MS = membranous septum, LBB = left bundle branch, TAVI = superimposed TAVI value, MV = mitral valve, LV = left ventricle.

in this study with the incidence of LBBB increasing from 10% pre-procedurally to 24% post-procedurally. A statistically significant prolongation of the QRS duration was found in the cohort.

High degree AV block and PPM after TAVI

A meta-analysis published in 2013 of 49 studies and registries comprising 16 063 patients demonstrated a pooled PPM rate of 13%.[14] A more recent meta-analysis published in 2016 showed a PPM rate of 13% in 20 287 patients [15]. The German Aortic Valve Registry (GARY) published data in 2015 of 15 964 patients who received TAVI between 2011 and 2013 and reported a PPM rate of 17.5%.[16] A significantly lower PPM rate of 9% was found in this study. The exact explanation for this low rate is not known, but 2 important factors should be noted: because of the small number of cases, every patient's data and ECG could be verified by the principal investigator, making our data very robust. Secondly, we could show that operators adhered strictly to established indications for pacing.[11]

It is well described that PPM rates vary according to valve type. The PPM rate has been shown to be 5 times more frequent in patients receiving a SE valve (25% - 28%) compared to those who received a BE valve (5% - 7%).[17] This correlates with our findings in which self-expanding valves had a 14% incidence of PPM vs. a 6% incidence of PPM for balloon expanding valves.

Predictors of the development of high degree AV block and PPM

Clinical Predictors

Clinical characteristics described in the literature to be associated with a higher rate of PPM are age greater than 75 years,[18] male sex[19] and a higher surgical risk stratification score (EuroSCORE).[20] These factors did not correlate with PPM in our cohort, however baseline creatinine and dyspnoea grade did. It is hard to explain this other than the chance and variable reporting by operators.

ECG Predictors

Pre- and post-procedural evidence of conduction abnormalities on the electrocardiogram (ECG) have been associated with PPM. The most commonly described association with PPM in the literature is the presence of pre-procedural RBBB.[21–26] Furthermore a first degree atrioventricular block,[22,23] a left axis deviation,[27] prolonged QRS duration[20] and atrial fibrillation[25,28] are ECG abnormalities associated with PPM. Our study revealed that a prolonged QRS duration and a pre-existing RBBB were predictors of PPM. The longer QRS duration may be indicative of pre-existing infra-nodal conduction disease and a RBBB would leave the patient dependent on the at-risk left bundle. Our findings therefore correlate well with the proposed pathophysiology of heart block post TAVI (see Figure 5). First degree AV block, QRS axis deviation and pre-procedural arrhythmia did not correlate with PPM.

Procedural Predictors

Degree of oversizing has been associated with a higher PPM rate.[28] This correlated with the need for PPM in our study but was no longer significant when assessed within individual valve types (BE and SE) (Figure 2). Height of implantation may have been a better parameter to evaluate but this analysis was not possible in the current study.

Post Procedural Predictors

Reported post procedural ECG changes associated with PPM are the development of a new left bundle branch block (LBBB),[27,29] and an increase in QRS duration from baseline.[30] It has further been shown that delta QRS duration (i.e., QRS duration after TAVI minus QRS duration before TAVI) of 38 milliseconds or more is predictive of PPM.[28] In this study a small number of patients [10] did not develop heart block immediately. A mean delta QRS of 20ms was found in these patients. Of these, 7 did have a change from their baseline ECG. These changes were variable in each of the 7 patients. Because of the small numbers, we cannot make meaningful recommendations on a cut-off value that can be used in clinical practise.

Timing of PPM

TAVI-induced high degree AV block occurs mainly in the peri-procedural setting, 60% - 96% of these events were recorded within 24 hours of TAVI[31] Approximately 2% - 7% of patients (representing up to 30% of all patients with high degree AV block) experienced delayed high degree AV block more than 48 hours after TAVI [31,32]. PPM is mainly performed within 7 days of the procedure (85% - 90% of cases), with a median time from TAVI to PPM of 3 days.[33] In this study the majority of patients (63%) developed an immediate indication for PPM. The remainder developed their indication an average of 5.8 days after TAVI. One patient developed an indication for PPM 11 days after TAVI.

The ESC pacing guidelines recommend a period of clinical observation and electrocardiographic monitoring for up to 7 days before PPM in patients with high degree AV block to determine whether rhythm disturbances after TAVI are transient or permanent (Class I, Level of Evidence C).[11] This is however not what is practised as more than 50% of pacemakers are implanted in the first 3 days post TAVI.[33] The prolonged waiting period may incur risk associated with prolonged temporary pacing and its resultant immobility. As the indications for TAVI implantation expand this will no doubt become a difficult clinical management question.

Impact of PPM on outcomes

Reporting on the impact of PPM on morbidity and mortality has shown variable results. There is evidence that PPM after TAVI has been linked to and increased risk of recurrent hospitalisations for cardiovascular reasons.[34] Fadahunsi, et al., in a cohort of 9 785 patients, demonstrated that PPM negatively affected survival (31% higher relative risk for 1-year mortality) and heart failure admissions (33% increased relative risk).[33] A cohort of 1 973 patients in the PARTNER trial showed a trend toward a reduction in 1-year survival after PPM, this was, however not statistically significant.[35]

In a meta-analysis published by Regueiro, et al., the authors demonstrated a trend toward a reduction of cardiovascular deaths in those who received PPM post TAV.I[36]

In our study no difference in mortality or rehospitalisation was seen at 30-days and 1-year of follow-up. The UK TAVI registry analysed 6 420 patients and found a 1-year survival of 83.4%, compared to our cohort, where the 1-year survival was 89.5%.[37] Lower PPM rate may in theory predispose to increased sudden cardiac death in those who develop heart block late. Our mortality data suggests that our significantly lower PPM rate had no deleterious impact on long term survival. There was a trend towards a reduction in functional class at 30-days, but not at 1-year (although 1-year follow-up numbers were low).

Limitations

For logistical reasons, this study includes the results from the higher volume centres only. Although it represents the vast majority of cases done in this time period, it may not be representative of the whole country. The total number of cases included is modest relative to international registries but still enabled us to make significant deductions on a number of parameters.

CONCLUSION

This is the first data from a resource limited setting describing the incidence and predictors of PPM after TAVI. The data was generated from a combination of state and private healthcare patients.

The clinical and ECG predictors for PPM were similar to those that have been well described in large studies, with self-expanding valves and a pre-existing RBBB being the strongest predictors of PPM.

For the local TAVI operator this study shows that extra care should be taken in those with pre-existing QRS prolongation or a RBBB and those who develop ECG changes post TAVI should be observed vigilantly for an indication for PPM. QRS duration of less than 103ms also provides a fair negative predictive value for PPM.

Reassuringly the PPM rate was significantly lower than that described in larger trials and registries from the developed world, without a negative effect on outcomes. The reasons for this may be multifactorial, it must be noted that TAVIs are implanted in a resource limited environment with strict adherence to guidelines.

Conflict of interest: none declared.

REFERENCES

1. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: First human case description. Circulation. 2002;106(1524-4539; 24):3006-8.
2. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic valve replacement in intermediate-risk patients. N Engl J Med. 2016;374:1609-20.
3. Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012). Eur Heart J. 2012;33(19):2451-96.
4. Nishimura RA, Otto CM, Bonow RO, et al. 3rd TJAC of CHATF on PG. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: Executive summary: A report of the American College of Cardiology/American Heart. J Am Coll Cardiol. 2014;63(22):2438-88.
5. Weich H, Mabin T, Van Wyk J, et al. First experience with the Edwards SAPIEN transcatheter aortic valve implantation (TAVI). Data from the Western Cape, South Africa. South African Hear J. 2012;9(1).
6. Scherman J, Weich H. SASCI/SCTSSA joint consensus statement and guidelines on transcatheter aortic valve implantation (TAVI) in South Africa. Cardiovasc J Afr. 2016;27(6).
7. Kappetein AP, Head SJ, Généreux P, et al. Updated standardised endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document. EuroIntervention. 2012;8(7):782-95.
8. Nazif TM, Williams MR, Hahn RT, et al. Clinical implications of new-onset left bundle branch block after transcatheter aortic valve replacement: analysis of the PARTNER experience. Eur Heart J. 2014;(35):1599-607.
9. Auffret V, Puri R, Urena M, et al. Conduction disturbances after transcatheter aortic valve replacement: Current status and future perspectives. Circulation. 2017;136(11):1049-69.
10. Urena M R-CJ. Conduction abnormalities: the true Achilles' heel of transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2016;(9):2217-2219.
11. Brignole M, Bordachar P, Germany OB, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. Eur Heart Journal. 2013;34(29):2281-329.
12. Moreno R, Dobarro D, López de Sá E, et al. Cause of complete atrioventricular block after percutaneous aortic valve implantation: Insights from a necropsy study. Circulation. 2009;120:29-30.
13. Urena M, Mok M, Serra V, et al. Predictive factors and long-term clinical consequences of persistent left bundle branch block following transcatheter aortic valve implantation with a balloon-expandable valve. J Am Coll Cardiol. 2012;60:128-36.
14. Khatri PJ, Webb JG, Rodés-Cabau J, et al. Adverse effects associated with transcatheter aortic valve implantation: A meta-analysis of contemporary studies. Ann Intern Med. 2012;158:35-46.
15. Mohananey D, Jobanputra Y, Kumar A, et al. Clinical and echocardiographic outcomes following permanent pacemaker implantation after transcatheter aortic valve replacement. Circ. Cardiovascular Interv. 2017;10(7).
16. Walther T, Hamm CW, Schuler G, et al. Perioperative results and complications in 15 964 transcatheter aortic valve replacements prospective data from the GARY Registry. J Am Coll Cardiol. 2015;65(20):2173-80.
17. Erkapic D, De Rosa S, Kelava A, et a. Risk for permanent pacemaker after transcatheter aortic valve implantation: A comprehensive analysis of the literature. J Cardiovasc Electrophysiol. 2012;23:3917.
18. Schroeter T, Linke A, Haensig M, et al. Predictors of permanent pacemaker implantation after Medtronic CoreValve bioprosthesis implantation. Europace. 2012;14(12):1759-63.
19. Siontis GCM, Jüni P, Pilgrim T, et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVI: A meta-analysis. J Am Coll Cardiol. 2014;64:129-40.
20. Villa E, Clerici A, Messina A, et al. Risk factors for permanent pacemaker after implantation of surgical or percutaneous self-expanding aortic prostheses. J Hear Valve Dis. 2016;25(6):663-71.
21. Abramowitz Y, Kazuno Y, Chakravarty T, et al. Concomitant mitral annular calcification and severe aortic stenosis: Prevalence, characteristics and outcome following transcatheter aortic valve replacement. Eur Heart J. 2016;ehw594.
22. Gonska B, Seeger J, Keßler M, et al. Predictors for permanent pacemaker implantation in patients undergoing transfemoral aortic valve implantation with the Edwards Sapien 3 valve. Clin Res Cardiol. 2017;106:590-7.
23. Naveh S, Perlman GY, Elitsur Y, et al. Electrocardiographic predictors of long-term cardiac pacing dependency following transcatheter aortic valve implantation. J Cardiovasc Electrophysiol. 2017;28(2):216-23.
24. Schymik G, Tzamalis P, Bramlage P, et al. Clinical impact of a new left bundle branch block following TAVI implantation: 1-year results of the TAVIK cohort. Clin Res Cardiol. 2015;104(4):351-62.
25. Calvi V, Conti S, Pruiti GP, et al. Incidence rate and predictors of permanent pacemaker implantation after transcatheter aortic valve implantation with self-expanding CoreValve prosthesis. J Interv Card Electrophysiol. 2012;34(2):189-95.
26. Koos R, Mahnken A, Aktug O, et al. Electrocardiographic and imaging predictors for permanent pacemaker requirement after transcatheter aortic valve implantation. J Heart Valve Dis. 2011;20(1):83-90.
27. Nijenhuis VJ, Van Dijk VF, Chaldoupi SM, et al. Severe conduction defects requiring permanent pacemaker implantation in patients with a new-onset left bundle branch block after transcatheter aortic valve implantation. Europace. 2017;19(6):1015-21.
28. Rivard L, Schram G, Asgar A, et al. Electrocardiographic and electrophysiological predictors of atrioventricular block after transcatheter aortic valve replacement. Hear Rhythm. 2015;(12):321-9.
29. Massoullié G, Bordachar P, Ellenbogen K, et al. New-onset left bundle branch block induced by transcutaneous aortic valve implantation. Am J Cardiol. 2016;117(5):867-73.
30. Maeno Y1, Abramowitz Y, Israr S, et al. Prognostic impact of permanent pacemaker implantation in patients with low left ventricular ejection fraction following transcatheter aortic valve replacement. J Invasive Cardiol. 2019;31(2):E15-22.
31. Toggweiler S, Stortecky S, Holy E, et al. The electrocardiogram after transcatheter aortic valve replacement determines the risk for post-procedural high-degree AV block and the need for telemetry monitoring. JACC Cardiovasc Interv. 2016;(9):1269-1276.
32. Chorianopoulos E, Krumsdorf U, Pleger ST, et al. Incidence of late occurring bradyarrhythmias after TAVI with the self-expanding CoreValve® aortic bioprosthesis. Clin Res Cardiol. 2012;(101):349-355.
33. Fadahunsi OO, Olowoyeye A, Ukaigwe A, et al. Incidence, predictors, and outcomes of permanent pacemaker implantation following transcatheter aortic valve replacement: analysis from the U.S. Society of Thoracic Surgeons/American College of Cardiology TVT Registry. JACC Cardiovasc Interv. 2016;(9):2189-99.
34. Chamandi C, Barbanti M, Munoz-Garcia A, et al. Long-term outcomes in patients with new permanent pacemaker implantation following transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2018;(11):301-10.
35. Nazif TM, Dizon JM, Hahn RT, et al. PARTNER publications office. predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2015;(8):60-9.
36. Regueiro A, Abdul-Jawad Altisent O, Del Trigo M, et al. Impact of new-onset left bundle branch block and periprocedural permanent pacemaker implantation on clinical outcomes in patients undergoing transcatheter aortic valve replacement: A systematic review and meta-analysis. Circ Cardiovascular Interv. 2016;9(5).
37. Martin, G. Sperrin, M. Hulme, W. et al. Relative survival after transcatheter aortic valve implantation: How do patients undergoing transcatheter aortic valve implantation fare relative to the general population.