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Electrophysiological Study-Guided Permanent Pacemaker Implantation In Patients With Conduction Disturbances Following Transcatheter Aortic Valve Implantation

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ABSTRACT

Conduction disturbances remain common following transcatheter aortic valve implantation (TAVI). Aside from high-degree atrioventricular block (HAVB), their optimal management remains elusive. Invasive electrophysiological studies (EPS) may help stratify patients at low or high risk of HAVB allowing for an early discharge or permanent pacemaker (PPM) implantation among patients with conduction disturbances. We evaluated the safety and diagnostic performances of an EPS-guided PPM implantation strategy among TAVI recipients with conduction disturbances not representing absolute indications for PPM. All patients who underwent TAVI at a single expert center from June 2017 to July 2020 who underwent an EPS during the index hospitalization were included in the present study. False negative outcomes were defined as patients discharged without PPM implantation who required PPM for HAVB within 6 months of the initial EPS. False positive outcomes were defined as patients discharged with a PPM with a ventricular pacing percentage $< 1\%$ at follow-up. A total of 78 patients were included (median age: 82.4 years, 38% female), among whom 35 patients (45%) received a PPM following EPS. The sensitivity, specificity, positive and negative predictive values of the EPS-guided PPM implantation strategy were 100%, 89.6%, 81.5%, and 100%, respectively. Six patients suffered a mechanical HAVB during EPS and received a PPM. These 6 patients showed PPM dependency at follow-up. In conclusion, an EPS-guided PPM implantation strategy for managing post-TAVI conduction disturbances appears effective to identify patients who can be safely discharged without PPM implantation.

Keywords: Transcatheter aortic valve replacement; Electrophysiological study, bundle branch block, atrioventricular block, pacemaker

A series of large prospective randomized trials established the superiority of transcatheter aortic valve implantation (TAVI) over surgical aortic valve replacement in treating patients with severe aortic stenosis with intermediate to high surgical risk¹ and more recently its short-term non-inferiority among low surgical risk patients^{2,3}. Unlike other periprocedural complications, conduction disturbances (*i.e.* mainly high-degree atrioventricular block [HAVB] requiring permanent pacemaker [PPM] implantation and new-onset left bundle-branch block [LBBB]) have remained stable with recent reports even suggesting an increased risk associated with the newer-generation transcatheter heart valves^{4,5}. While HAVB represents an unequivocal PPM indication in international guidelines⁶, the management of milder conduction disturbances such as worsening or new-onset first-degree atrioventricular block (FDAVB) or LBBB remains controversial. Experts have suggested the use of electrophysiological studies (EPS) may help stratify patients with post-TAVI new-onset or worsening conduction disturbances who would require PPM implantation^{5,7}. However, this suggestion relies on small retrospective studies, and, considering the evolving nature of post-TAVI conduction disturbances, the overall mid-term diagnostic performances of an in-hospital EPS-guided PPM implantation strategy remain unclear. The objective of this study was to evaluate the safety and diagnostic performances of such a strategy.

METHODS

The full version of the methods can be found in the supplemental appendix. A retrospective study of patients who underwent TAVI at a single center was performed. Patients with post-TAVI persistent new-onset or worsening conduction disturbances not representing absolute PPM indications who underwent EPS during the index hospitalization were included in the present study. All patients gave written informed consent for the procedures and anonymous collection of their data, which were prospectively gathered in an

electronic database as part of the FRANCE TAVI registry⁸. Details regarding the pre-procedural workup were previously described⁹. Post-procedural care consisted of heart rhythm monitoring for at least 48 hours after intervention, laboratory tests and a 12-lead electrocardiogram (ECG) on a daily basis. Clinical outcomes were defined according to Valve Academic Research Consortium 2 criteria¹⁰.

The surface ECGs before the TAVI procedure and at the time of the EPS, were employed to record rhythm, heart rate, PR interval, and QRS duration. Left anterior and posterior fascicular hemiblocks, LBBB, and right bundle branch block (RBBB) were defined according to the American Heart Association, American College of Cardiology Foundation, and Heart Rhythm Society recommendations for standardization and interpretation of the electrocardiogram⁶. HAVB was defined as type 2 second degree AVB or third degree AVB. Patients with persistent HAVB post-TAVI underwent PPM implantation in accordance with current European guidelines⁶. For patients with milder new-onset or worsening conduction disturbances persisting without improvement upon serial ECG at least 24h after the procedure, a local EPS-guided PPM implantation strategy was implemented in our center in June 2017. A senior electrophysiologist performed the EPS in the local electrophysiology laboratory, and all measurements were carried out on a General Electric electrophysiology workstation. PPM implantation was recommended for an infra-hisian significant conduction delay defined as HV interval > 70 ms, or second- or third-degree His-Purkinje block demonstrated during incremental atrial pacing with a rate ≤ 100 bpm. Final decision for PPM was at the discretion of the electrophysiologist taking into account the EPS findings but also the in-hospital ECG evolution and clinical data.

Follow-up was performed by on-site clinical visit and/or telephone at 1-month post-TAVI, at 1 year and yearly thereafter. Records from referring cardiologists, general

practitioners, and other hospitals were retrieved for further information. Ventricular pacing (VP) percentage was recorded among patients who underwent PPM implantation.

The primary objective of the study was to evaluate the diagnostic performances (sensitivity, specificity, positive and negative predictive value) of the local EPS-guided PPM implantation strategy. False negative outcomes were defined as patients discharged without PPM implantation who required PPM for HAVB within 6 months of the initial EPS procedure. False positive outcomes were defined as patients discharged with a PPM with a ventricular pacing (VP) percentage $< 1\%$ at follow-up. Patients who received a pacemaker due to mechanically-induced HAVB during EPS (bump of the right bundle branch in patients with an LBBB) were not included in the calculation of these diagnostic performances as they do not represent patients among whom conduction disturbances were solely TAVI-related.

Continuous variables were presented as mean \pm standard deviation or median (interquartile range) depending on their distribution, which was assessed using the Kolmogorov-Smirnov test, and were compared using t-tests or the Mann-Whitney U test as appropriate. Categorical variables were summarized as numbers (percentages), and compared using chi-square tests or the Fisher exact test. A multivariable backward stepwise logistic regression was performed to identify prolonged HV predictors. Variables with a p-value < 0.1 in univariable analysis were included in the model. Results were reported as adjusted odds-ratio (OR) with the corresponding 95% confidence interval (CI). All tests were 2-sided at the 0.05 significance level. Statistical analyses were conducted using the Statistical Package for Social Sciences version 25 (SPSS Inc., IBM, Armonk, New York).

RESULTS

Figure 1 provides the flow-chart of the study population. Baseline characteristics of the population are detailed in **Table 1**. There was no statistically significant difference

between the PPM and no PPM groups except for a higher body mass index and a more frequent history of pulmonary edema in the former group. **Table 2** summarizes ECG findings before and after TAVI. There was no significant difference in procedural characteristics and in-hospital complications between the two groups (**Table 3**).

Post-TAVI ECG changes leading to the performance of the EPS are detailed in **Figure 2**. EPS was performed at a median of 3 days (2-5) following TAVI. There was no difference in EPS indication or timing between the PPM and no PPM groups ($p= 0.62$ and 0.57 , respectively). Median HV interval was 65ms (56-79) in the total population, 80ms (73-92) in the PPM group, and 60 ms (50-65) in the no PPM group ($p<0.001$). Thirty patients had a HV interval > 70 ms. Six mechanically induced AVB by direct injury to the right bundle branch in patients with LBBB occurred and led to PPM implantation. No other complication of the EPS occurred. Multivariable predictors of a prolonged HV interval (>70 ms) were the pre-TAVI PR interval (OR = 1.02, 95%CI: 1.003-1.03; $p=0.02$), and the post-TAVI aortic valve area (OR = 0.09, 95%CI: 0.02-0.49; $p=0.005$).

PPM implantation was deemed necessary by the operator and performed in 35 patients following EPS. Among them, HV interval > 70 ms was the sole indication for PPM for 26 patients. Mechanical HAVB during EPS led to PPM implantation in 6 patients, among whom 3 had a HV interval ≤ 70 ms. In one of these patients, right bundle branch block injury precluded any HV interval measurement and required prompt PPM implantation. PPM implantation was decided by the operator despite HV intervals ≤ 70 ms in 3 cases: one for a long antegrade effective refractory period of the atrioventricular node (700ms), one for a 160ms RBBB with supra-hisian AV block, and one for junctional rhythm and sinus node dysfunction associated with a 160ms LBBB and a HV interval of 70ms. On the contrary, 2 patients with a HV interval > 70 ms did not receive PPM: one with a HV interval of 78ms who

demonstrated a complete resolution of his conduction disturbances after the EPS, and one with a borderline HV of 71ms and a supra-hisian block with an antegrade effective refractory period of the atrioventricular node of 470ms. PPM brand were Microport CRM-Sorin in 12 patients (33%), St-Jude Medical in 9 patients (25%), Medtronic in 8 patients (22%), Biotronik in 4 patients (11%), and Boston scientific in 3 patients (8%). Programmed modes were VVI/VVIR in 17 patients (47%), DDD/DDDR in 13 (36%), and DDD-ADIR, AAI-DDD, or AAI-SafeR in 6 (17%). Among patients with a VVI/VVIR pacemaker, the basal pacing rate or hysteresis was ≤ 45 bpm in 7, ≤ 55 bpm in 7 and 60/min in the remaining 3 patients.

The median follow-up was 147 (71-465) days. There was no significant difference between the two groups regarding all-cause death, heart failure hospitalizations or new-onset AF. No SCD occurred (**Table 3**). Among patients without PPM at discharge, one patient reported episodes of faintness, which were not associated with high-degree conduction disturbances. Two patients received a PPM. The first received CRT at a follow-up of 386 days for heart failure associated with reduced left ventricular ejection fraction and a new-onset persistent LBBB of 180ms (160ms at discharge), the second received CRT for faintness, type 1 second-degree AVB, LBBB and reduced left ventricular ejection fraction at a follow-up of 617 days. Among the PPM group, one lead fracture requiring PPM extraction without reimplantation in a patient with a VP percentage $<1\%$ was reported. One upgrading to CRT was required 527 days after PPM implantation for heart failure and left ventricular dysfunction in a patient with a VP percentage of 90%.

Figure 3 illustrates the repartition of VP percentage among PPM patients at a median follow-up of 137 days (68-406 days). VP percentage was retrieved for 33 out of 35 PPM patients (94.3%). One patient died from a non-cardiovascular cause before the first device assessment. For the second patient, we were unable to obtain data regarding VP percentage

despite completing the clinical follow-up. After exclusion of the 6 patients implanted for a mechanically-induced AVB, the diagnostic performances of the EPS-guided PPM implantation strategy were evaluated among 27 PPM recipients and 43 of their no-PPM counterparts. The rate of false negative outcomes was 0%. False positive outcomes occurred in 5 (18.5%) patients without differences between patients with a VVI/VVIR pacemaker and patients with other modes (3 vs. 2 patients, $p=0.20$). The underlying rhythm pathologies requiring pacing in these subjects are summarized in **supplemental table 1**. The sensitivity, specificity, positive and negative predictive values of the EPS-guided PPM implantation strategy were 100%, 89.6%, 81.5%, and 100%, respectively. Of note, among the 6 PPM patients with a mechanical AVB, 3 had a VP percentage between 1 and 25% while 3 had a VP percentage $> 50\%$.

DISCUSSION

The natural history of post-TAVI conduction disturbances and their most appropriate management remain unclear due to the scarcity of prospective studies addressing this issue. The multicenter prospective LBBB-TAVI study focusing on post-TAVI new-onset LBBB will hopefully shed some light on this area¹¹. The Ambulatory Electrocardiographic Monitoring for the Detection of High-Degree Atrio-Ventricular Block in Patients With New-onset Persistent Left Bundle Branch Block After Transcatheter Aortic Valve Implantation (MARE) study elegantly provided insights into the natural history of TAVI-induced new-onset LBBB by implanting a cardiac monitor in 103 TAVI recipients¹². PPM implantation was required for HAVB or severe bradycardia in 10% of these patients at a mean delay of 42 days following TAVI. Therefore, allowing such patients to be discharged without PPM implantation based solely on routine ECG and continuous rhythm monitoring data may subject a significant proportion of them to the risk of a life-threatening bradyarrhythmia. On

the other hand, a recent meta-analysis suggested an increased risk of long-term mortality and heart failure hospitalization associated with PPM implantation post-TAVI⁴.

EPS appears as a potential candidate to help select patients who will benefit from PPM implantation or conversely who can be safely discharged without PPM implantation. An expert panel recently suggested that EPS may play a significant role in selecting PPM implantation candidates in two specific groups of patients: patients with ECG changes (increase in PR or QRS duration ≥ 20 ms) in the presence of pre-TAVI conduction disturbances, and patients with new-onset LBBB⁷.

To date, studies assessing the role of EPS in the post-TAVI setting have been scarce and each included less than 100 patients¹³. In four studies assessing the value of a post-TAVI EPS in predicting PPM implantation, with a HV interval cut-off ranging from 65 to 100ms, and reported a long-term follow-up and the need for PPM, no SCD occurred and no patients needed a PPM during at least 1 year of follow-up¹³. Only two prior studies, including 121 patients undergoing EPS, truly reported the results of predefined EPS-guided strategies¹³. Tovia-Brodie et al. presented the results of 81 patients with conduction abnormalities after TAVI, showing an improved event-free survival (mortality or PPM implantation) among the 26 EPS-assessed patients with a 75ms HV interval cut-off prompting PPM implantation (9% vs. 0%, $p = 0.04$)¹⁴. In another study including 95 patients who developed conduction disturbances without an absolute indication for PPM, Rogers et al. showed the safety of their EPS-guided strategy regarding the risk of PPM implantation without significant mortality difference at 1-year of follow-up between patients who received a PPM and those who did not based on the EPS findings¹⁵. However, the HV interval threshold prompting PPM implantation was 100ms with a pharmacological test involving IV procainamide, which is not available worldwide, limiting the reproducibility of the study. In addition to this two previous

studies, the present analysis provides valuable data regarding the mid-term diagnostic performances of an EPS-guided strategy by evaluating the ability of a post-TAVI EPS to predict PPM dependency at follow-up. We demonstrated an acceptable 18.5% rate of false positive patients, with VP percentage <1% at follow-up, using a single, widely accepted, 70ms HV interval cut-off.

A theoretical limitation of the use of EPS in the post-TAVI conduction disturbances setting is the “screenshot” characteristic of EPS, which captures AV conduction properties at a specific time. Indeed, it is well described that post-TAVI conduction disturbances may worsen or improve over time⁵. Therefore, the prognostic value of an EPS performed during the index hospitalization regarding the prediction of late HAVB or PPM dependency remains largely elusive. To circumvent this limitation, experts recommend that EPS is realized at least 24h after TAVI and after stabilization of ECG findings. Using a strategy essentially aligned with this recommendation, with a HV interval cut-off of 70ms prompting PPM implantation, which falls in the range proposed by Tovia-Brodie et al¹³, we demonstrated a reassuring 100% NPV regarding PPM requirement within the first 6 months of follow-up among patients with a negative EPS.

Importantly, the EPS-guided PPM implantation strategy was associated with a significant number of HAVB induced by a direct injury to the right bundle branch as 7.6% of patients were implanted because of a mechanical HAVB. None of these patients were considered PPM independent at follow-up. Nonetheless, this observation stresses the need to reduce EPS-related implantation to further increase the safety of EPS-guided PPM implantation strategies.

In the three EPS-guided PPM implantation studies, which assessed PPM dependency post-TAVI, one used a dependency definition of VP >50% while the others defined PPM

dependency as underlying permanent AV block¹⁶⁻¹⁸. In the present study, we aimed at “penalizing” the negative predictive value estimation to increase the confidence regarding the long-term safety of our strategy. Therefore, we chose a conservative definition of VP>1% for PM dependency, since even rare paroxysmal HAVB, which would translate in a low VP percentage, may cause SCD or serious bradyarrhythmia-related events.

Several limitations of the present analysis should be considered. First, this was a single-center study of limited size, which may limit the generalizability of our results. Second, most patients received a balloon-expandable valve, the magnitude and timing of effect of which upon the conduction system may differ from other transcatheter heart valve designs. However, in a recent study including 2804 patients, 82% and 94% of conduction disturbances occurred within 48h and 4 days of TAVI, respectively, without difference between valve type¹⁹. The MARE study demonstrated no difference in the timing of bradyarrhythmic events post-TAVI according to valve type, and self-expandable valves were not a significant predictor of delayed HAVB in a study by Toggweiler et al. including 1064 TAVI recipients²⁰. On the contrary, a small study encompassing 133 patients demonstrated a delayed occurrence of PR prolongation among self-expandable valve recipients compared with their balloon-expandable counterparts²¹. However, PR prolongation occurred within 48h of the procedure after self-expandable valves’ implantation. Thus, it is unlikely that the indications and diagnostic performances of our strategy would be vastly different in a population including a greater proportion of self-expandable valves given the 3 days median delay between TAVI and EPS in the present study. Finally, the choice of pacemaker brand, programmed modes and frequencies were not protocolled but left to the operator discretion. Thus, although programs preserving spontaneous conduction were systematically preferred, the interpretation of pacing data from device interrogations may be challenging.

CRediT Author statement

Hamed Bourenane : Data curation, Writing original draft, review. Vincent Galand : Data curation, review. Dominique Boulmier : Data curation, review. Christophe Leclercq : Data curation, review. Guillaume Leurent : Data curation, review. Marc Bedossa : Data curation, review. Nathalie Behar : Data curation, review. Camille Pichard : Data curation, review. Baptiste Polin : Data curation, review. Jacques Tomasi : Data curation, review. Jean-Philippe Verhoye : Data curation, review. Sam Sharobeem : Data curation. Marielle Le Guellec : Data curation. Erwan Donal : Data curation, review. Dominique Pavin : Data curation, review. Raphael P. Martins : Data curation, review. Hervé Le Breton : Data curation, review, validation and Vincent Auffret : Conceptualization, Data curation, Formal analysis, supervision, writing original draft, review, editing, validation.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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FIGURES LEGENDS

Figure 1- Flow chart of the study population

EPS: electrophysiological study; ESC: European Society of Cardiology; PPM: permanent pacemaker; TAVI: transcatheter aortic valve implantation.

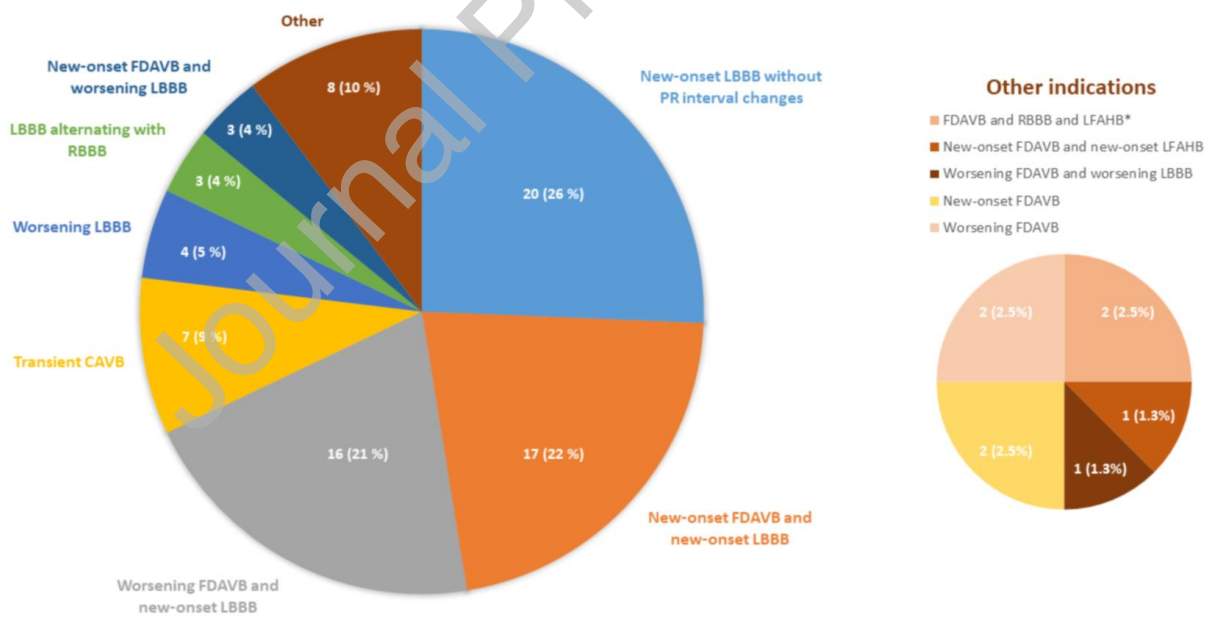
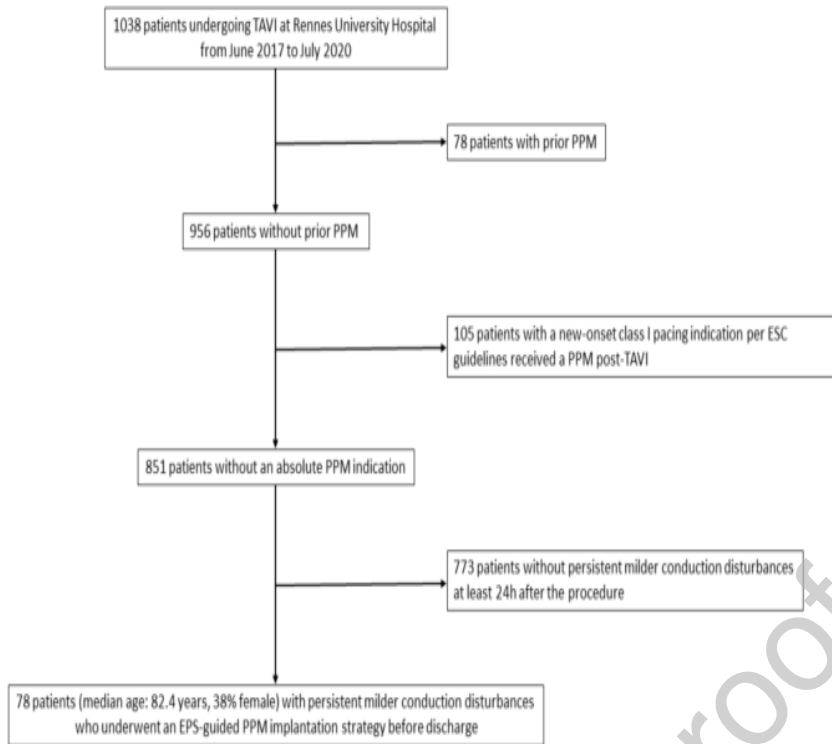
Figure 2 –Indications for the electrophysiological study

Data are presented as n (%). CAVB: complete atrioventricular block; FDAVB: first degree atrioventricular block; LBBB: left bundle branch block; LFAHB: left fascicular anterior hemiblock; RBBB: right bundle branch block.

* FDAVB and LFAHB were new-onset whereas RBBB was pre-existing in both patients

Figure 3 – Ventricular pacing percentage at follow-up

Data are presented as n (%) in each category. VP: ventricular pacing



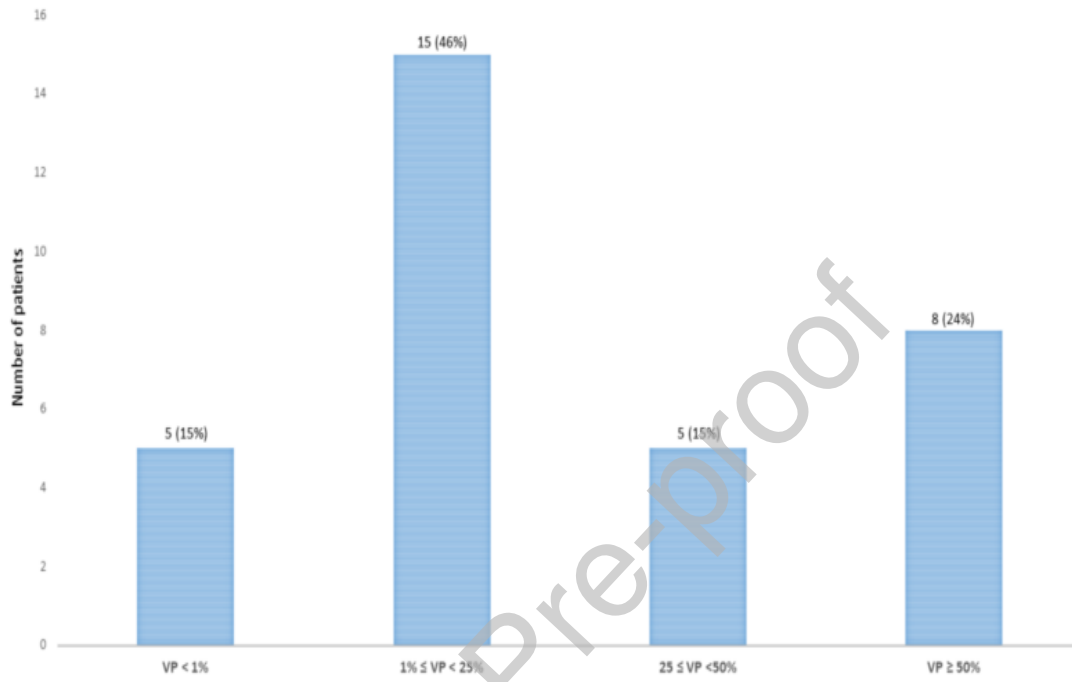


Table 1 : Baseline characteristics according to in-hospital permanent pacemaker implantation

Variable	All patients (n=78)	PPM (n=35)	No PPM (n=43)	p value
Age (years)	83.5 (80.0-86.3)	84.0 (79.0-87.0)	83.0 (80.0-86.0)	0.84
Women	30 (39%)	12 (34%)	18 (42%)	0.64
Body-mass index (kg/m ²)	25.9 (23.3-29.1)	28.0 (24.8-29.4)	25.1 (22.3-28.4)	0.03
Prior myocardial infarction	1 (1%)	1 (3%)	0 (0%)	0.45
Prior CABG	4 (5%)	2 (6%)	2 (5%)	1.00
Prior PCI	16 (21%)	8 (23%)	8 (19%)	0.78
Prior stroke or TIA	9 (12%)	3 (9%)	6 (14%)	0.50
Peripheral vascular disease	19 (24%)	10 (29%)	9 (21%)	0.60
History of atrial fibrillation	27 (35%)	15 (43%)	12 (28%)	0.23
Diabetes mellitus	15 (19%)	8 (23%)	7 (16%)	0.57
Hypertension	49 (63%)	23 (66%)	26 (61%)	0.65
NYHA class III or IV	32 (41%)	16 (46%)	16 (37%)	0.49
Prior pulmonary oedema	20 (26%)	13 (37%)	7 (16%)	0.04
Prior syncope	6 (8%)	3 (9%)	3 (7%)	1.00
eGFR < 60 ml/min/m ²	30 (40%)	16 (49%)	14 (33%)	0.24
Logistic EuroScore I	10.0 (7.0-17.3)	14.0 (6.2-22.0)	9.0 (7.0-15.0)	0.17
Logistic EuroScore II	2.1 (1.5-3.3)	2.7 (1.7-4.8)	1.9 (1.4-3.1)	0.11
<i>Treatment at the time of procedure</i>				
Amiodarone	10 (13%)	6 (17%)	4 (9%)	0.33
Calcium channel blocker	7 (9%)	3 (9%)	4 (9%)	1.00
Beta blockers	35 (45%)	13 (37%)	22 (51%)	0.26
Coronary artery disease	36 (46%)	14 (40%)	22 (51%)	0.37
<i>Number of narrowed coronary arteries</i>				
1	21 (27%)	10 (29%)	11 (26%)	
2	11 (14%)	2 (6%)	9 (21%)	
3	4 (5%)	2 (6%)	2 (5%)	
Pre-TAVI Echocardiography				
LVEF(%)	60.0 (55.0-67.0)	60.0 (48.0-68.0)	60.0 (57.3-67.0)	0.55
Aortic valve area (cm ²)	0.73 (0.62-0.81)	0.75 (0.62- 0.83)	0.71 (0.61-0.80)	0.77
Mean gradient (mmHg)	50.6 (42.0-61.9)	51.0 (42.0-66.0)	50.3 (42.0-61.0)	0.98
Computed tomography				
Perimeter-derived annulus diameter (mm)	25.0 (22.8-26.5)	25.1 (23.0-26.1)	24.3 (22.8-26.7)	0.98

Values are median (interquartile range) and number (%). CABG = coronary artery bypass graft ; eGFR= glomerular filtration rate; NYHA = New York Heart Association ; PCI = percutaneous coronary intervention ; LVEF = left ventricular ejection fraction ; PPM = Permanent pacemaker ; TAVI = Transcatheter aortic valve replacement ; TIA = transient ischaemic attack

Table 2 : ECG intervals before and following TAVI

	ECG pre-TAVI				ECG post-TAVI				Difference between pre and post TAVI			
	All patients (N=78)	PPM (N=35)	No PPM (N=43)	p value	All patients (N=78)	PPM (N=35)	No PPM (N=43)	p value	All patients (N=78)	PPM (N=35)	No PPM (N=43)	p value
AF	11 (14%)	4 (11%)	7 (17%)	0.75	12 (16%)	5 (14%)	7 (17%)	1.00	-	-	-	-
Heart rate (bpm)	68 (61-77)	72 (59 - 76)	68 (61 - 78)	0.72	71 (63-82)	70 (62-81)	71 (63-82)	0.41	3 (-5 - 10)	1 (-8 - 9)	5 (-3 - 11)	0.26
PR length (ms)	197 (178-230)	211 (184-242)	192 (169-214)	0.06	236 (200-258)	233 (200-272)	236 (199-250)	0.50	29 (4 - 48)	23 (8 - 47)	32 (3 - 54)	0.80
FDAVB	30 (46%)	18 (58%)	12 (34%)	0.08	47 (73%)	21 (72%)	26 (74%)	1.00				
QRS duration (ms)	100 (90-117)	99 (90-119)	101 (91-115)	0.85	155 (139-165)	157 (142-167)	152 (136-161)	0.61	51 (28-67)	54 (35-67)	49 (19-65)	0.61
QRS type				0.75				0.89	-	-	-	-
Narrow QRS < 100ms	48 (62%)	24 (66%)	25 (60%)		2 (3%)	1 (3%)	1 (2%)					
LBBB	9 (12%)	3 (9%)	6 (14%)		64 (83%)	29 (83%)	35 (83%)					
RBBB	5 (7%)	2 (6%)	3 (7%)		6 (8%)	2 (6%)	4 (10%)					
UICD	1 (1%)	1 (3%)	0 (0%)		1 (1%)	1 (3%)	0 (0%)					
Incomplete LBBB	13 (17%)	5 (14%)	8 (19%)		4 (5%)	2 (6%)	2 (5%)					
Incomplete RBBB	1 (1%)	1 (3%)	0 (0%)		0 (0%)	0 (0%)	0 (0%)					

Values are median (interquartile range) or n (%)

AF = atrial fibrillation ; LBBB = left bundle branch block ; PPM = Permanent pacemaker ; RBBB = right bundle branch block ; UICD = unspecified intraventricular conduction disturbance ; TAVI = Transcatheter aortic valve replacement

Table 3: Procedural, in-hospital and follow-up characteristics

Variable	All patients (N=78)	PPM (N =35)	No PPM (N = 43)	p value
Procedural characteristics				
<i>Valve type</i>				0.09
Balloon-expandable	62 (80%)	31 (89%)	31 (72%)	
Self-expandable	16 (21%)	4 (11%)	12 (28%)	
Femoral approach	72 (92%)	33 (94%)	39 (91%)	0.26
<i>Prosthesis size (mm)</i>				0.88
23	19 (24%)	9 (26%)	10 (23%)	
26	32 (41%)	15 (43%)	17 (40%)	
29	27 (35%)	12 (31%)	16 (37%)	
Procedural transient CAVB	10 (13%)	7 (20%)	3 (7%)	0.10
In-hospital outcomes				
Stroke	3 (4%)	3 (9%)	0 (0%)	0.09
New onset AF	3 (4%)	2 (6%)	1 (2%)	0.59
Vascular complication†	4 (5%)	1 (3%)	3 (7%)	0.62
Major bleeding	4 (5%)	2 (6%)	2 (5%)	1.00
<i>Post-TAVI echocardiography</i>				
LVEF (%)	60.0 (51.0–65.0)	62.0 (51.0–67.0)	60.0 (50.0–65.0)	0.84
Aortic valve area (cm ²)	1.81 (1.54–2.11)	1.70 (1.40–1.95)	1.92 (1.60–2.30)	0.04
Mean gradient (mmHg)	11.0 (8.0–15.0)	11.0 (9.0–15.0)	11.0 (7.0–16.0)	0.57
Aortic regurgitation degree				0.85
None (grade 0/4)	25 (34%)	11 (32%)	14 (35%)	
Trace (grade 1/4)	39 (53%)	19 (56%)	20 (50%)	
Mild (grade 2/4)	10 (14%)	4 (12%)	6 (15%)	
Hospital length of stay	6 (5–8)	7 (5–9)	4 (4–7)	0.01
Follow-up				
New onset AF	6 (8%)	4 (13%)	2 (5%)	0.39
Heart failure hospitalization	4 (5%)	3 (9%)	1 (2%)	0.31
Sudden death	0 (0%)	0 (0%)	0 (0%)	
All-cause mortality	3 (4%)	2 (6%)	1 (2%)	0.59
<i>Among No PPM patients</i>				
Syncope/faintness			1 (2%)	
PPM implantation			2 (5%)	

Values are median (interquartile range). n (%). or mean ± standard deviation

AF = atrial fibrillation ; CAVB = complete atrioventricular block ; PPM = Permanent pacemaker.

† All vascular complications were minor.