Z natančnim načrtovanjem implantacije lahko vplivamo na potrebo po srčnem spodbujevalniku po TAVI, to pa lahko predvidimo z vrednostjo troponina po posegu

The Need for a Pacemaker after TAVI can be Influenced by Careful Planning and Predicted by Higher Troponin Values after Implantation Study

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Izvleček

Namen: *Transkatetrsko implantacijo aortne zaklopke (TAVI) spremljajo prevodne motnje, ki lahko zahtevajo vstavitev trajnega srčnega spodbujevalnika (PM). Obstajajo nekatere specifične značilnosti, ki so povezane z večjo potrebo po implantaciji srčnega spodbujevalnika. Te so odvisne od bolnika in povezane s postopkom implantacije.*

Metode: *Analizirali smo retrospektivne podatke za en sam center, kar vključuje 150 bolnikov s TAVI v letu 2023, od katerih je 14 bolnikov še imelo vstavljen PM. Dva sta bila izključena zaradi operacije in ponovne TAVI v istem mesecu.*

Rezultati: *Na podlagi CT (angl. Computer Tomography) analize so operaterji izbirali med dvema vrstama transkatetrskih srčnih zaklopk*

Abstract

Aim: *Conduction abnormalities that require the implantation of a permanent pacemaker (PM) are known to accompany transcatheter aortic valve implantation (TAVI). Specific patient-dependent and procedure-related features are known to correlate with higher pacemaker implantation rates.*

Methods: *We analysed retrospective data from a single centre with 150 TAVI cases in 2023. Fourteen cases had a PM already implanted and two were excluded due to a change to surgery and repeated TAVI in the same month.*

Results: *Two types of transcatheter heart valves (THVs) were implanted and chosen based on computer tomography scans. Nineteen patients (14%) required PM after TAVI*

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(THV). 19 bolnikov (14 %) je po TAVI potrebovalo PM in vsi so bili vstavljeni v isti hospitalizaciji. Vrsta vstavljene THV ni bila povezana s potrebo po PM. Bolniki, ki so potrebovali PM, so pogosteje imeli predhodnji desnokračni blok (20 % v primerjavi z 9 %, p = 0,355), vendar ta ni bil statistično značilen. Imeli so višje vrednosti troponina (p = 0,012) in potrebovali daljšo hospitalizacijo (p = 0,007). Na prvem ambulantnem pregledu so imeli tisti z vstavljenim PM v povprečju 95 % ventrikularnega stimuliranja, ni prišlo do upada iztisnega deleža levega prekata in ni bilo razlike v trimesečnem preživetju v primerjavi z bolniki brez vstavljenega PM.

Zaključki: *Potrebo po PM po TAVI je mogoče predvideti in se ji do neke mere izogniti. Vsak postopek TAVI je treba skrbno načrtovati. Ustrezno vstavljen PM ne predstavlja tveganja za kratkoročno preživetje.*

and all underwent implantation in the same hospital. There was no difference in the type of THV implanted. Patients that required PM had preexisting right bundle branch block more frequently (20% vs. 9%, p = 0.355), but this was not significantly different. They had however, have significantly higher values of troponin (p = 0.012) and required longer hospitalisations (p = 0.007). On first outpatient control, patients with PM implants had an average of 95% of ventricular pacing, no difference in ejection fraction, and no difference in three month survival compared to patients without a PM implanted.

Conclusions: *The need for a PM after TAVI can be predicted and avoided to some point. Every TAVI procedure should be carefully planned. Well implanted PMs carry no risks for short term survival.*

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is an established therapeutic method for the treatment of aortic stenosis (1). Due to transcatheter heart valve (THV) interactions with tissue under the aortic anulus and in the left ventricular outflow tract (LVOT), it is possible to damage conduction tissue in the bundle of His and bundle branches, thus, causing infranodal aortic valve (AV) block. Left bundle is especially vulnerable to infranodal AV block as it lies just beneath the membranous septum and is relatively shallow in the myocardium. Some anatomical features (2), preexisting diseases, and TAVI technology (3) (4) are linked to higher rates of conduction abnormalities after TAVI. THV design and implantation depth was also shown to influence conduction abnormalities (CAs) (5). Due to stent frame compression and oedema, THV can cause AV block or left bundle branch block (LBBB). LBBB is often self-resolving and patients can be dismissed without PM (6). Although new LBBB occurs frequently, it is not linked to progression to AVB and the need for early PM implantation (7). The latest guidelines recommend PM implantation in persistent AVB with the same recommendations as in the non-TAVI population (8). The only difference is the time interval from detection to implantation. Some studies implied that PM implantation is linked to worse outcomes after TAVI (9), making need for PM a complication. Time is crucial to lower the PM rate and avoid PM implantations that do not need pacing on further follow up (10).

The aim of this retrospective study was to compare data on implantation rates, potential preexisting factors, and implantation outcomes relative to the existing literature.

MATERIALS AND METHODS

This retrospective study analysed 134 consecutive patients without previously implanted PMs that underwent TAVI in the University Medical Centre Maribor in 2023. Patients with PM implanted more than one month after TAVI were deemed to be not TAVI related. All data were collected form patient reports form TAVI centre or hub hospitals, and no

additional tests were performed out of daily clinical practice for the purpose of this observational study. All patients underwent pre- and post-procedural 12-lead ECG, pre- or post-dilatation, and implanted THV. There were two types of THV used, including balloon expandable (BEV) Sapien 3 by Edwards, and the self-expandable (SEV) Navitor by Abbott. We recorded indications for PM implantation on the day of PM implantation after TAVI. All implant patients had scheduled outpatient visits with PM assessments to collect data on the percentage of ventricular pacing. Three-month survival was recorded by TAVI outpatient clinics. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research.

CONDUCTION ABNORMALITY

Bundle branch block (BBB) was defined as a QRS > 120 ms and further defined as right bundle branch block (RBBB) or LBBB according to QRS morphology. High degree AVB was considered first degree AVB with a PQ > 280 ms, second degree AVB Mobitz II when awake, and complete AV block or bradycardic atrial fibrillation (AF) with pauses longer than 6 s.

TAVI

Preprocedural computer tomography (CT) scans were carefully examined for the degree of aortic valve leaflet calcination, LVOT morphology, and calcination and aortic root. Two types of THV were implanted: SEV Abbot Navitor and BEV Edwards Sapien 3. The operators chose the THV type based on CT measurements, but the exact reason was not written in majority of case reports. Annuli sized 430 mm2 are most often considered as small annuli. We did not have systematic measurements of annulus size or the extent of valve calcification before TAVI. However, because the Sapien 3 23 mm and Navitor 25 mm can accommodate a maximal area of 430 mm2, we used those sizes as cut-offs. Predilation was performed in cases of heavily calcified valves, based on the operators' preferences. A pre-dilation balloon was used based on the minimum anulus diameter. In cases of frame compression after implantation, THV was post-dilated with a balloon chosen according to the average anulus diameter.

PM IMPLANTATION AND FOLLOW-UP

PM was implanted in cases of complete AVB lasting longer than 24 hours. In cases of first degree AVB with a PQ > 280 ms, second degree AVB Mobitz II, or pauses longer than 6 s in AF when awake, patients were observed closely. The number of days from TAVI to PM implantation were recorded. PM follow-up was performed on average two months after implantation.

LABORATORY TESTS

We recorded serum troponin I with a Siemens Dimension Vista system 12–24 h after TAVI. Serum troponin I is measured routinely after all invasive procedures to determine mortality risk. Other laboratory parameters and baseline troponin values were not collected.

STATISTICAL ANALYSIS

Jamovi 2.5 was used for statistical analysis. The Mann–Whitney U test and χ^2 test were used for contingent tables. P-values < 0.05 were considered statistically significant.

RESULTS

We collected data from TAVI patients at the University Medical Centre Maribor in 2023. One-hundred fifty patients were screened, and 14 were excluded because they had a PM already implanted before procedure. One patient was later excluded due to acute complication that resulted in THV explant and surgical aortic valve replacement. A second patient was excluded due to repeated TAVI due to a severe paravalvular leak. Retrospective data for 134 consecutive patients were used for statistical analysis.

Nineteen patients (14%) required PM implantation after TAVI.

The study population was elderly with an average age of 80 years. Female patients were represented at 41% and they required a PM at a frequency of 19% compared to 13% in males. Age, height, and weight did not predispose the group to PM (Figure 1). Preexisting RBBB was observed in 13 patients (10%) and did not predispose to PM implantation after TAVI (p = 0.355). BEV was implanted more frequently (Sapien 3, in 66%) than SEV, but PM was implanted with similar frequencies, irrespective of the THV type used (p = 0.187). Coronary disease with previously implanted stent, status of post-surgical revascularisation, or known chronic total occlusion of coronary artery (CTO) were present in 25% of cases. Flow limiting stenosis was used during TAVI in three cases. Thirty-one patients (23%) had a small anulus assumed by the size of the valve implanted (Sapien 3 size 23 mm, Navitor 25 mm or smaller). A small anulus size and coronary artery disease did not predispose for PM (p = 0.335 and p = 0.215). Accessible demographic data are represented in Table 1.

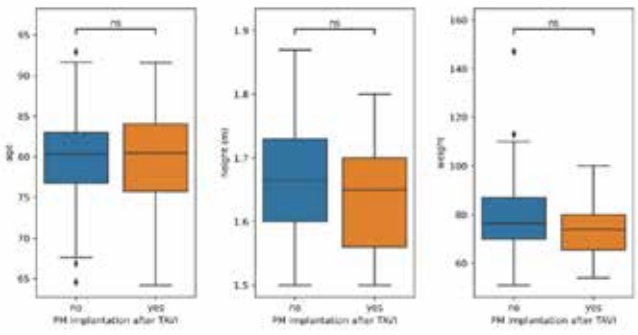

Figure 1. *Age, height, and weight - PM vs. no PM*
Age, height, and weight - PM vs. no PM. There was a slight trend towards smaller and shorter patients in the group with fewer PM patients.
PM, pacemaker; TAVI, transcatheter aortic valve implantation; ns, not significant

Nineteen out of 134 patients had PM implants due to symptomatic high-degree AVB (14%). On average, PM was implanted on day 5 after TAVI (Figure 2). Patients that had PM implants more than one month

Table 1: *Demographics*

		Total	No PM implantated post TAVI	PM implantated post TAVI	p-value
All		134	115 (85.8%)	19 (14.2%)	
Weight (average kg)		78	79	73	0.217
Height (average cm)		167	163	166	0.211
BMI (average)		28	28	27	0.754
Sex	Male	78	68	10	0.574
	Female	56	47	9	
CAD	Yes	34	27	7	0.215
	No	100	88	12	
RBBB	Yes	13	10	3	0.355
	No	121	105	16	
Small annulus	Yes	31	25	6	0.335
	No	103	90	13	
SEV	Yes	46	37	9	0.187
	No	88	78	10	

Demographic data of patients undergoing TAVI in 2023 did not predict the need for PM.
BMI, body mass index; CAD, coronary artery disease; RBBB, right bundle branch block; SEV, self expandable valve; PM, pacemaker; TAVI, transcatheter aortic valve implantation

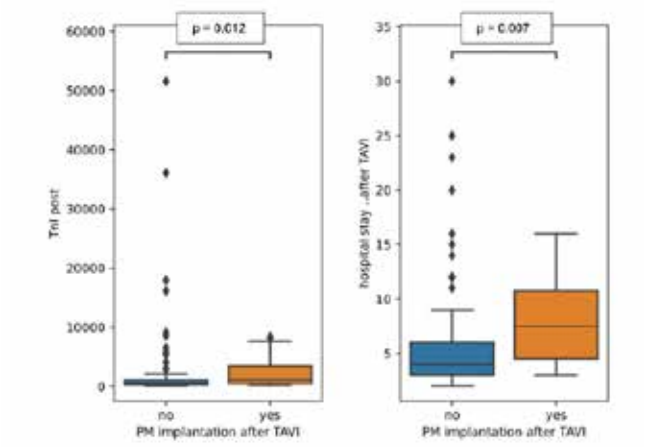

Figure 2. *Troponin I and hospitalisation - PM vs. no PM TnI and hospitalisation - PM vs. no PM. Patients that required PM implantation after TAVI had higher TnI levels and required prolonged hospital stays.*
PM, pacemaker; TAVI, transcatheter aortic valve implantation; TnI, troponin I

after TVI were considered as not being TAVI related. Periprocedural and in-hospital data were available for all 134 patients. Eleven patients were transferred to local hub hospitals one day after procedure and we did not include their length of hospital stay due to different local policies. The length of hospital stay in Maribor was significantly longer in cases where patients required a PM (p = 0.007), lasting 6 days on average. On average, TAVI patient were discharged after 5 days (Figure 2).

A significantly higher level of troponin I (TnI) was observed after TAVI in patients that required PM implantation (p = 0.012). Three months survival data were available for 128 patients. PM implantation did not affect survival rate (p = 0.678).
Despite low numbers, pre-dilatation or post-dilatation did not predispose patients to for PM implantation (Table 2).

DISCUSSION

The need for PM after TAVI varies among studies and has changed with the technical advancements of THVs. The need for PM after TAVI was traditionally considered as a failure of TAVI based on comparisons to surgical aortic valve replacement. The latest guidelines on pacing (8) with special consideration of pacing after TAVI suggest that PM is needed in 3.4% to 25.9% of cases. Some patient characteristics, THV design, and implantation depth are linked to higher PM implantation rates. Therefore, to achieve lower PM rates, we must understand patient characteristics during planning and adjust the implantation strategy to achieve optimal TAVI results.
Our one-year registry data represent real-life situations in clinical practice. Since the number of implanted PMs also depends on the type of THV used, our data are representative of approximately 50% BEV and 50% SEV implants. The data are from a retrospective registry, and one should consider the significant bias as THV was chosen based on patient characteristics.

Table 2: *Pre- and post-dilatation*

Total			No PM implantated post TAVI	PM implantated post TAVI	p-value
Predialtation	Yes	38	30	8	0.144
	No	96	85	11	
Postdilatation	Yes	8	6	2	0.360
	No	127	110	17	

Pre- and post-dilatation. Patients that had pre-dilatation or post-dilatation during TAVI implantation did not have higher PM implantation rates.
PM, pacemaker; TAVI, transcatheter aortic valve implantation

To date male sex, RBBB (11), calcinations in LVOT at the level of the non-coronary cusp (12), and membranous septum morphology (2) are predictors of a higher need for PM implantation. One of the strongest predictors of PM implantation after TAVI is preexisting RBBB (3). Interestingly, we did not observe the same correlation in our registry. Thirteen patients (10%) had a preexisting RBBB, but only three required PM after TAVI. Therefore, RBBB did not predispose to PM implantation after TAVI in our group. Most patients with preexisting RBBB had a BEV implanted (in 85% of cases) and the valve type was selected by the operators. BEVs are known to cause less CA compared to SEV (13). Thus, operators may have chosen BEV in RBBB patients, which resulted in a lower number of PM implantation in this specific population.

Our study patients had an average age of 80 years and were reffered for TAVI based on the 2021 guidelines on age, surgical risk score, and comorbidities. They were predominantly males (58%), but sex did not predict the need for PM after TAVI.

Aortic valve calcifications are linked to CA abnormalities after TAVI (6) and several studies have stressed the importance of calcium volume and distribution on aortic valves, annulus, and LVOT (14). A short length of membranous septum is also linked to higher PM implantation rates. (2) Those measurements demand special imaging protocols that are not routinely used in our environment, and therefore, we routinely assess the degree of calcification only visually during pre-TAVI planning. Thus, we were unable to gather numerical data on the amount of calcium in valves in the study population.

Pre-dilatation is linked to higher PM implantation rates. It is used to open the native valve to allow easier crossing and deployment of THV. Therefore, pre-dilatation is a marker of a high degree of aortic valve calcination. The more calcified the valve, the more often is it predilated, and the higher the chances of conduction abnormalities that require PM implantation in case of SEV implants (15). In our study, predilation was performed at the operator's discretion in 38 cases, but was not correlated with the need for PM ($p = 0.144$). Pre-dilatation was performed less frequently in cases of BEV implantation compared to SEV (BEV 14% vs. in SEV 48%). Nevertheless, the SEV used in our centre is known for its lower radial force, and we tend not to use it in heavily calcified valves, which may have influenced our results.

Due to the THV design and the nature of implantation, THV itself can cause infranodal AV block due to His bundle compression or LBBB in cases of isolated left bundle compression. The occurrence rate depends on the THV design; the bigger the stent frame, the more tissue it interferes with and more it compresses delicate structures. SEV platforms with large stent frames extend low in the LVOT and are more prone to causing conduction abnormalities than BEV platforms (16). Therefore, we suggest to implant SEVs high in the native anulus to reduce the contact of the stent frame with LVOT tissue. Our data showed no differences between the THV type implanted in patients with conduction disturbances requiring PM, and thus, we can conclude that we implanted our THVs high.

Comparing literature to time, indication for PM implantation varies. In the current study, we adhered to current guidelines on PM implantation (8). In most patients with first degree AV block and LBBB, conduction abnormalities disappeared during prolonged observation and they did not meet the indications for PM implantation (17). All patients were examined two months after PM. After implantation, pacing frequency was set to 50 beats per minute (bpm) or lower. PM patients had an average of 78% of ventricular pacing, only two had no or 1% pacing, and one had 14% pacing two months after PM implantation.

In our practice, we do not routinely record the frequency of escape or intrinsic rhythm during back-up pacing at 30 bpm on follow-up examination. Majority of patients had high percentage of ventricular pacing. However, three patients with low pacing rates had low values of < 10% and we conclude those patients may be overtreated.

Elevated troponin levels after invasive procedures is linked to a higher risk for adverse events (18). The same is true for elevated preprocedural levels of high sensitivity troponin before TAVI (19). Koifman et al. found that patients with elevated troponin levels after TAVI have more frequent CA (20). We

also made similar findings in this study. Elevated troponin can be explained by direct tissue damage during implantation, because of hypoperfusion durnig rapid pacing for THV deployment or due to possible calcium embolisation and direct ischemia. because of hypoperfusion during rapid pacing or slow THV deployment, and direct ischemia due to calcium embolization.

The sample size in this study was too small for subgroup analyses of different THV types, preexisting heart failure, or concomitant coronary artery disease. Much larger studies managed to prove that troponin is a good marker for mortality and adverse events, but its levels are influenced by many factors, and therefore, inappropriate to make conclusions.

During a 1 year follow-up of 19 patients with PM implanted after TAVI, none were hospitalised for heart failure. However, we did not observed a worsening of ejection fraction on control echocardiography compared to patients who did not need PM. However, data on ejection fraction before and after PM implantation were only available for PM patients. Data on QRS duration after PM implantation were not available, but based on implantation reports, all ventricular leads were implanted in the septal position. That could also be the reason for less pacemaker induced cardiomyopathy and heart failure. Since there is a strong trend of physiological pacing worldwide, we still miss data on septal pacing or LBBB pacing after TAVI.

Predicting CA after TAVI is challenging. Some centres prefer early or prophylactic PM implantation to facilitate mobilisation and discharge. Every device implanted without a benefit is a risk for the patient. Consequently, the latest guidelines on pacing recommend prolonged observation (8). In our experience, complete recovery is possible, even in some cases with complete AV block immediately after TAVI. Prolonged observation resulted in significantly longer hospitalisations in patients with CA. In our cohort, patients were observed for an average of 5 days before implanting a PM. Therefore, we suggest additional tests and decision models that predict irreversible CA within a short observation time.

We revealed that maximum adaptation of an implantation strategy and THV selection based on patient characteristics can lower the PM rate, however, high levels of troponin can predict PM implantation and may shorten hospitalization duration due to earlier PM implantation without the fear of overtreatment. The main limitation of this study is the relatively small number of pacemaker implantations after TAVI as the main event. Our data were observatory and it lacks long term follow up. The use of two different THV types rendered the results complex, and this should be taken into account when analysing real word data.

CONCLUSION

The need for PM after TAVI is relatively common. This retrospective study showed that the consideration of factors such as preexisting RBBB when contemplating THV selection and high THV implantation can lower the PM implantation rate. More data are needed for additional parameters, such as troponin elevation after TAVI, to facilitate a final decision on PM implantation and shorten the time from TAVI to discharge. In patients that require PM after TAVI, a properly implanted device had a high percentage of ventricular pacing and low rate of PM cardiomyopathy.

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