Work in progress report - Valves

Permanent pacemaker implantation after transapical transcatheter aortic valve implantation

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Abstract

The aim of the study was to determine the incidence of permanent pacemaker implantation (PPMI) in a cohort of 358 patients undergoing transapical aortic valve implantation (TAVI) using a balloon-expandable prosthesis between April 2008 and March 2011. After excluding patients who had had a previous PPMI (n=36; 10%), the study group consisted of 322 patients. These were divided into two groups: patients who required PPMI (PPM group) and patients who did not require it (non-PPM group). Preoperative, perioperative and one-year follow-up data were collected prospectively. Twenty (6.2%) patients required PPMI. Previous implantation of an aortic prosthesis (P<non-significant), previous coronary artery bypass grafting (P=0.05) and coronary artery disease (P=0.005) were more common in the non-PPM group. On logistic regression, only patient age seemed to be correlated to PPMI (P=0.05, odds ratio 1.08; CI 0.9–1.1). There was no difference in survival rate between the groups after 30 days (PPM group 95%, non-PPM group 93.6%). Similarly, the survival rate did not differ after one year (PPM group 84%, non-PPM group 80.9%; P=0.3). The PPMI rate after transapical TAVI using a balloon-expandable prosthesis is thus low, and has no impact on early and follow-up mortality.

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Keywords: Aortic valve; Permanent pacemaker implantation; Transapical aortic valve implantation

1. Introduction

Aortic valve disease, both stenosis and regurgitation, is associated with a high rate of cardiac electrical conduction disorders, such as atrioventricular conduction delay [1, 2]. Surgical aortic valve replacement is further accompanied by heart block that may result in an increased rate of sudden death and postoperative permanent pacemaker implantation (PPMI) [3]. Furthermore, amelioration in the perioperative management of cardiac surgery candidates broadens the surgical indication to include elderly and sicker patients, who are often more prone to developing postoperative electrical conduction disturbances.

It has been speculated that the occurrence of atrioventricular conduction disturbances after transapical aortic valve implantation (TAVI) could be related to many factors including patients’ preoperative co-morbidities, the degree and bulkiness of aortic valve calcification, interventricular septal thickness, existing preoperative ECG abnormalities, the depth of implantation of the prosthesis, and the profile of the implanted prosthesis. The recent introduction and popularization of TAVI has led to the recruitment of further patients with even more complex co-morbidity profiles. This leads to a potentially higher rate of postoperative requirement for PPMI.

The aim of the present study was to establish the incidence and determinants of early postoperative permanent pacemaker requirements in a large single-center cohort of patients undergoing transapical TAVI with balloon-expandable prostheses.

2. Methods

Between April 2008 and March 2011, a total of 358 consecutive patients underwent transapical TAVI (83, 129, and 146 TAVI procedures in the first, second and third years, respectively). Thirty-six (10%) patients had a previously implanted permanent pacemaker and were for this reason excluded from this analysis. Therefore, the present study includes the remaining 322 patients. The study population was divided into two groups: the patients who required PPMI (PPM group) within 30 days after TAVI and patients who did not require pacemaker implantation (non-PPM group) during this period.

Our previous publications have described the training of our TAVI team with our learning curve, the criteria for patients and valve selection, indications and contraindications, technical considerations and our institutional procedural policies and results [4–6]. All TAVI procedures were performed in a hybrid operating room, under completely
sterile conditions as for standard cardiovascular surgery, and by a mixed team including surgeons, cardiologists and anesthesiologists. TAVI was performed through a mini left anterior thoracotomy using a left ventricular transapical route. Valve deployment was performed slowly and gradually, during simultaneous angiographic visualization of the aortic root. It enabled precise correction of the valve position and real-time visualization of the relationships among the prosthetic valve, aortic valve annulus, aortic cusps and coronary arteries [6].

In all patients, balloon-expandable transcatheter stent-prosthetic xenograft valves (Edwards Sapien THV; Edwards Lifesciences, Irvine, CA, USA) of 23 mm or 26 mm diameter were used. A 23 mm valve was chosen for the aortic valve annuli with a diameter <21 mm, and a 26 mm prosthesis for annuli ranging from 21 mm to 24 mm. As previously mentioned [4], in borderline cases the decision was made on an individual basis, taking into account additional factors, such as annulus-to-coronary artery ostia distance, annular shape (oval vs. circular), aortic leaflet anatomy and bulkiness of leaflet calcifications, diameters of the sinuses of Valsalva, sinotubular junction and ascending aorta, and the amount of calcification present in the left ventricular outflow tract (LVOT), including the anterior mitral valve and aortic valve leaflets. In patients with intraoperative transitory or permanent heart block, additional temporary epicardial pacemaker wires were placed for greater safety during the first postoperative days. In addition to the standard 12-lead ECG, all patients’ ECGs were continuously monitored during the procedure and postoperatively until discharge.

Generally, PPMI was performed in patients with postoperative complete heart block (with ventricular replacement rhythm) or symptomatic bradycardia on the fifth postoperative day, and usually on the third postoperative day in patients without ventricular replacement rhythm. This policy was taken from the institutional policy for PPMI in patients undergoing conventional aortic valve replacement.

2.1. Data collection and statistical analysis

All data concerning patients’ co-morbidities, morbidity and mortality were prospectively collected in an electronic database and analyzed together with anatomical data from the aortic unit (root and valve), ECG findings (heart rate and rhythm) and prosthesis characteristics. The preoperative and the perioperative differences between the PPM group and the non-PPM group were investigated using univariate analysis. Normality of continuous variables was tested with the Wilk-Shapiro test. Differences between the two groups were tested using the unpaired Student’s t-test, Mann–Whitney test, χ²-test and Fisher exact test whenever appropriate. Multivariable analysis by means of logistic regression was performed to identify independent determinants for the occurrence of PPMI. A multivariate analysis model was built including all variables that at univariate analysis had a P<0.1. Kaplan–Meier survival was determined, and equality of survival distribution between the two groups was tested using the Mantel–Cox, Breslow and Tarone–Ware tests. Data were analyzed using SPSS Version (SPSS Inc, Chicago, IL, USA) 17.0 for Windows.

3. Results

During the first 30 postoperative days, PPMI was performed in 20 (6.2%) patients (PPM group), and 302 patients did not require it (non-PPM group). No patient required pacemaker implantation after discharge, except for one on the 61st postoperative day. The pacemaker implantation rate for the first year of our institutional experience was 7.4% (five of 68 patients), 6.7% (eight of 120 patients) for the second year, and 5.2% (seven of 134 patients) for the third year.

The demographic data and co-morbidities for the two groups are presented in Tables 1 and 2. There were no significant differences between the two subgroups regarding the logistic EuroSCORE (non-PPM group 37.3±20.5%, PPM group 39.6±22.2%; P=0.6). However, a higher STS (Society of Thoracic Surgeons) score was found in the non-PPM group (18.8±16.3%) in comparison to the PPM group (13.4±8.2%; P<0.01). There was a trend towards a higher age in the PPM group (82.4±5.8 years) than in the non-PPM group (79±8.4 years; P=0.09). Previous implantation of a stented aortic prosthesis (P=non-significant), previous coronary artery bypass grafting (P=0.05) and preoperative diagnosis of coronary artery disease (P=0.005) were more frequently encountered in the non-PPM group than in the PPM group. It was also found that TAVI combined with simultaneous elective percutaneous coronary intervention (PCI) was more commonly performed in the non-PPM group than in the PPM group (12% and 0%, respectively; P=0.1).

Table 1. Univariate analysis: comparison between continuous variables

<table>
<thead>
<tr>
<th>Variables</th>
<th>Non-PPM group (mean±S.D.)</th>
<th>PPM group (mean±S.D.)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>37.3±20.5</td>
<td>39.6±22.2</td>
<td>0.6</td>
</tr>
<tr>
<td>STS score (%)</td>
<td>18.8±16.3</td>
<td>13.4±8.2</td>
<td>0.01</td>
</tr>
<tr>
<td>Age (years)</td>
<td>79.1±8.4</td>
<td>82.4±5.8</td>
<td>0.09</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>27.2±5.4</td>
<td>25.7±4.5</td>
<td>0.2</td>
</tr>
<tr>
<td>Left ventricular ejection fraction (%)</td>
<td>50.5±14.9</td>
<td>50.5±14.7</td>
<td>0.9</td>
</tr>
<tr>
<td>FEV₁ (%)</td>
<td>74.6±23.2</td>
<td>75.0±29.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Creatinine (µmol/l)</td>
<td>91.5±45.7</td>
<td>83.8±30.5</td>
<td>0.5</td>
</tr>
<tr>
<td>pro-BNP (ng/l)</td>
<td>5559±9042</td>
<td>5211±5335</td>
<td>0.8</td>
</tr>
<tr>
<td>Troponin I (µg/l)</td>
<td>0.3±0.2</td>
<td>0.0±0.02</td>
<td>0.6</td>
</tr>
<tr>
<td>Left ventricular end-diastolic diameter (mm)</td>
<td>47.6±6.3</td>
<td>47.6±6.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Aortic valve area (cm²)</td>
<td>0.6±0.1</td>
<td>0.6±0.01</td>
<td>0.3</td>
</tr>
<tr>
<td>Aortic annulus (mm)</td>
<td>21.9±1.5</td>
<td>22.1±1.1</td>
<td>0.6</td>
</tr>
</tbody>
</table>

BNP, brain natriuretic peptide; FEV₁, forced expiratory volume in one second; PPM, permanent pacemaker; STS, Society of Thoracic Surgeons.
The 30-day mortality was similar in both groups, being 5% (one of 20 patients) in the PPM group and 6.4% (19 of 302 patients) in the non-PPM group (P = 0.4). (Accordingly, there was no difference in the survival rates between the groups after 30 days: PPM group 95%, non-PPM group 93.6%.) Similarly, the survival rates did not differ after one year [PPM group 84% (in total, three patients died), non-PPM group 80.9% (in total, 51 patients died); P = 0.3] (Fig. 1).

A logistic regression model was built including age, STS score, coronary artery disease, previous coronary artery bypass grafting, and concomitant TAVI with elective PCI. It showed that only patient age was independently correlated to postoperative PPMI, with borderline significance (P = 0.05, OR = 1.08; CI 0.91–1.1).

### 4. Discussion

Our experience with a large cohort of patients demonstrates that PPMI after TAVI has no influence (either positive or negative) on survival, either early after the procedure or later, up to one year after it. It may be that these specific patients have pejorative morbidity factors that may impact survival much more than a single PPMI. Our results demonstrated that the PPMI rate after TAVI with a balloon-expandable prosthesis is low, being comparable to the reported rates of between 1% and 10% after conventional aortic valve replacement [3].

Pre-existing conduction abnormalities were not accounted for in this analysis. It has already been demonstrated that preoperative ECG data (i.e. QRS duration, preoperative presence of bundle branch blocks and pre-existing atrioventricular conduction delays) have an influence on the new onset of conduction abnormalities and the PPMI rate after TAVI [7–10]. In our TAVI patient population, elderly patients were at higher risk for PPMI after TAVI, similar to the increased pacemaker implantation rate in the elderly after conventional valve replacement [3]. Interestingly, our results indicate that our TAVI patients with coronary artery disease, including those who had previous coronary artery bypass grafting and also those who underwent simultaneous TAVI and elective PCI, were somehow protected from the occurrence of high-grade heart block.

Furthermore, we noticed a trend (without statistical significance) toward a reduced PPMI rate in patients who underwent TAVI after previous biological aortic valve replacement. None of these 16 patients developed conduction abnormalities. It could be hypothesized that the previously implanted bioprosthetic valve protects the conduction system from the crushing forces of the calcified leaflets and from the stent of the newly implanted valve.

Conduction disorders after conventional aortic valve replacement result from localized trauma secondary to aggressive decalcification of the annulus and/or suture placement in proximity to the sinoatrial or atrioventricular nodes or the bundle. Furthermore, inadequate myocardial protection together with coronary artery disease may induce tissue trauma, resulting in the new onset

![Fig. 1. Kaplan–Meier survival of the patients with and without postoperative permanent pacemaker implantation.](https://academic.oup.com/icvts/article-abstract/13/4/373/763841)
of conduction disturbances. In TAVI patients, the localized surgical trauma and global myocardial ischemia are avoided. However, impingement of the remaining calcified native valvular leaflets and less accurate positioning of the prosthesis (a lower position) may cause conduction abnormalities after TAVI. The SOURCE registry [11] showed a similar rate of PPMI after transfemoral and transapical implantation of Edwards Sapien valves (6.7% and 7.3%, respectively) [11].

The incidence of new left bundle branch block and permanent postoperative pacemaker implantation is higher after TAVI with the Medtronic valve (CoreValve ReValving prosthesis; Medtronic Inc, MN, USA) than with the Edwards Sapien valve. It seems that the latter is less invasive for the LVOT than the CoreValve, as reported by Koos et al. [7]. Several studies with smaller cohorts have confirmed a higher PPMI rate after TAVI with the CoreValve compared with the Edwards Sapien valve [7, 8]. Recent larger multicenter studies showed that CoreValve implantation was combined with a PPMI rate after transfemoral and transaxillary implantation of between 16% and 42.5% [12, 13]. This seems to be the result of too low an implantation of the valve rather than of the valve design.

Piazza et al. [14] were the first to suggest that the occurrence of conduction abnormalities is related to the prosthesis implantation position during TAVI with the CoreValve [14]. In a more recent and larger ECG analysis, the same authors found the following to be predictors for new left bundle branch block: male gender, previous myocardial infarction, pre-existing right bundle branch block, diameter of the inflow portion of the prosthesis frame post-implantation, and level of implantation. The sole predictors for PPMI were QRS duration and septal wall thickness before TAVI [15].

In the current study, it could not be shown how TAVI with a balloon-expandable valve decreases the incidence of PPMI. We did not investigate the relationship between PPMI rate and level of valve implantation within the aortic annulus or LVOT. The reason was that, almost from the beginning of our experience with TAVI, we have adopted a higher implantation position of the valve than we were taught. We believe that, in the future, increased experience with TAVI will identify the precise pathological mechanism or mechanisms of the conductive disturbances after TAVI, and that the PPMI rate will therefore be lower than today.

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References