International Journal of Cardiology xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Correlation of tricuspid regurgitation and new pacemaker implantation in patients undergoing transcatheter aortic valve implantation

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ARTICLE INFO

Article history:
Received 10 October 2017
Received in revised form 6 February 2018
Accepted 6 March 2018
Available online xxxx

Keywords:
TAVI
Conduction abnormality
Tricuspid regurgitation
Aortic valve stenosis
Ventricular overload
Pacemaker

ABSTRACT

Aims: Conduction abnormalities (CA), in particular complete atrioventricular block (CAVB), requiring permanent pacemaker (PPM) implantation, are frequent complications after transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis (AS). However, the potential mechanisms are still incompletely understood. The objective of this retrospective study was to determine further predictors of CAVB after TAVI in patients without the known predictors.

Methods and results: This study included patients without prior CA/PPM who underwent TAVI of a balloon-expandable valve (Sapien or Sapien XT or Sapien 3). Of 563 patients (81.2 ± 6.9 years, 245 men [43.5%], logistic EuroSCORE 22.2 ± 14.1%, STS PROM 5.9 [3.4–8.0]) who were treated by TAVI at our institution between July 2008 and January 2016, 61 (10.8%) developed a permanent CAVB after the procedure. In a multivariable logistic regression analysis moderate/severe tricuspid regurgitation (TR) (OR 2.05; 95% CI 1.18–3.55; p = 0.010) was identified as an independent predictor for new CAVB after TAVI. Moreover, patients with more pronounced TR presented with increased left and right ventricular overload (left ventricular (LV) end-diastolic diameter, LV end-diastolic pressure), pulmonary pressures, NT-proBNP, and prevalence of mitral regurgitation ≥II, whereas LV ejection fraction, TAPSE and cardiac output were decreased.

Conclusions: PPM implantation is a frequent complication in patients undergoing TAVI. Increasing severity of TR seems to be a consequence of left and right ventricular overload caused by severe AS and is a significant predictor of new CAVB after TAVI.

Condensed abstract: Conduction abnormalities (CA) requiring permanent pacemaker (PPM) implantation, are frequent complications after transcatheter aortic valve implantation (TAVI). This study included patients without prior CA/PPM who underwent TAVI. Of 563 patients 61 (10.8%) developed a permanent CAVB after the procedure. In a multivariable logistic regression analysis moderate/severe tricuspid regurgitation (TR) (OR 2.05; 95% CI 1.18–3.55; p = 0.010) was identified as an independent predictor for new CAVB. Therefore, in patients with moderate/severe TR utmost care should be taken to avoid procedural factors conducive to mechanical irritation of the conduction system, resulting in pacemaker dependency.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is preferable recommended in high- and intermediate surgical risk patients with symptomatic severe aortic stenosis (AS) [1–6]. Injury of the conduction system is a known complication of TAVI procedures. As the atrioventricular (AV) conduction system is anatomically close to the aortic valve complex, any mechanical irritation could result in conduction abnormalities, particularly left bundle branch block (LBBB) or complete atrioventricular block (CAVB) requiring a permanent pacemaker (PPM) implantation [7–12]. The incidence of PPM implantations after TAVI has been reported to be 0–12% in balloon-expandable prostheses (e.g. Edwards Sapien) [11–13] and 18–49% in self-expanding prostheses (e.g. Medtronic CoreValve) [13]. Previous studies have shown that PPM implantation does not have an effect on survival after TAVI [14,15]. Nevertheless, it is associated with increased length of hospital stay and higher costs [8,16]. Furthermore, new PPM implantation could result in reduced left ventricular function recovery [7,17] due to impaired AV synchrony

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https://doi.org/10.1016/j.ijcard.2018.03.030
0167-5273/

by right ventricular pacing [18]. Previous studies have described different predictors for new PPM such as implantation depth [11,19], prosthesis oversizing [11], access route [12], device selection [12], and preexisting right bundle branch block (RBBB) [12]. The aim of this retrospective study was to analyze patients without the known predictors and to find additional independent prognostic factors for new PPM after TAVI of a balloon expandable valve.

2. Methods

2.1. Patient population and study design

A total of 1328 patients with severe AS underwent TAVI at our hospital between July 2008 and January 2016. Patients with pre-existed PPM (n = 155) or RBBB (n = 65), patients who underwent emergency TAVI (n = 44), and those with degenerated biological aortic prosthesis (n = 59) were excluded from this analysis. Additionally, only patients who received an Edwards Sapien (n = 25, 4.4%), Sapien XT (n = 251, 44.6%) or Sapien 3 (n = 287, 51%) prosthesis were included. Thereby, 563 patients treated with a balloon-expandable valve were included in the final retrospective analysis. These patients were divided into two groups according to the need for a new PPM after TAVI (no PPM vs. new PPM: 502 (89.2%) vs. 61 (10.8%); Fig. 1A).

2.2. TAVI procedure

Indication for aortic valve replacement was the presence of severe, symptomatic AS with an aortic valve area ≤ 1.0 cm^2 (≤0.6 cm^2/m^2) as determined by echocardiography. The patients' operative risk was assessed by calculation of the logistic EuroSCORE and the Society of Thoracic Surgeons predicted risk of mortality (STS PROM). A "Heart Team" consisting of an interventional cardiologist, a cardiac surgeon, and an anesthesiologist evaluated candidates and did the final decision for TAVI procedures. Pre-procedural screening was done by transthoracic and transesophageal echocardiography (annulus diameter, annular morphology, amount of valvular calcification), left heart catheterization, aortic root angiography, and peripheral vascular angiography for evaluation of the aortic annulus (diameter) and the access route. Written informed consent was obtained from all patients. TAVI procedures have been described previously [20,21]. Outcome parameters were assessed according to the Valve Academic Research Consortium (VARC)-2 criteria [22]. Follow-up was scheduled at 30 days and 12 months after discharge.

2.3. Data collection and definitions

The patients' functional capacity, as defined by the New York Heart Association (NYHA), was documented before TAVI and at each follow-up visit. Laboratory parameters (N-terminal pro-brain natriuretic peptide [NT-proBNP], creatinine, glomerular filtration rate [GFR], and blood urea nitrogen [BUN]) were collected at baseline. NT-proBNP was measured by a chemoluminescence immunoassay (e411, Roche Diagnostics GmbH, Grenzach-Wyhlen, Germany). The estimated GFR was calculated via the CKD-EPI formula [23].

All patients underwent an extended transthoracic echocardiographic examination by different operators including assessment of aortic valve with mean transvalvular pressure gradient (Pmean), aortic peak velocity (Aortic Vmax) and aortic valve area (AVA) via the continuity equation, severity of regurgitation (AR), left ventricular ejection fraction (LVEF), and severity of mitral regurgitation (MR) and tricuspid regurgitation (TR). Grading of MR and TR was based on an integrated approach of the current European guidelines [24–26] and graded as 0 (none), I (mild), II (moderate), and III (severe). Furthermore, left atrial diameter (LA), left ventricular end-systolic (LVESD) and end-diastolic diameters (LVEDD), thickness of the interventricular septum (IVS) and left ventricular posterior wall (PW), as well as the ratio of mitral peak velocity of early filling (E) to early diastolic mitral annular velocity (E') as a parameter of diastolic function (E/E' ratio), and tricuspid annular plane systolic excursion (TAPSE) were documented.

A 7Fr Swan-Ganz catheter (Edwards Lifesciences, Irvine, CA, USA) was routinely used for hemodynamic measurements during the procedure before and after deployment of the prosthesis. Right atrial pressure (RAP), pulmonary capillary wedge pressure (PCWP), systolic (PASP), diastolic (PADP), and mean pulmonary artery pressures (PAMP) were recorded. Cardiac output (CO) was determined using the thermodilution method. Additionally, valvulo-arterial impedance (Zva), cardiac index (CI), and left ventricular stroke work index (LVSWI) were calculated. Aortic valve area (AVA) was calculated using the Gorlin formula.

2.4. Statistics

Continuous variables are described as means and standard deviations or medians and interquartile range (IQR), as appropriate, and compared by *t*-tests if the data were approximately normally distributed and Wilcoxon's rank-sum test otherwise. Categorical data are described with absolute and relative frequencies and compared by the Fisher's exact test. A stepwise binary logistic regression analysis, including all variables with a p-value <0.05 in the univariate analysis, was used to determine predictors of the occurrence of a new CAVB requiring PPM implantation after TAVI. The following three variables were included in the multivariable model: arterial hypertension, atrial fibrillation, and tricuspid regurgitation ≥II. All p-values are two-sided. A p-value <0.05 was considered statistically significant. Statistical analyses were performed with IBM Statistical Package for Social Sciences, version 20.0.0 (SPSS, Inc., Chicago, Illinois).

3. Results

3.1. Patients

Comorbidities and baseline characteristics are summarized in Table 1. The average patient age was 81.2 ± 6.9 years and mean logistic EuroSCORE was 22.2 ± 14.1%. 318 (56.5%) of the patients were female. 61 of 563 (10.8%) patients developed a new CAVB after TAVI and were in need in implantation of a PPM either during the TAVI procedure or a few days after. Similar prevalences of comorbidities were documented in all patients, except arterial hypertension, which occurred more often in patients without new PPM while atrial fibrillation was seen less often in that subgroup. Analysis of echocardiographic parameters showed a significant difference in the occurrence of baseline moderate to severe TR (No PPM vs. New PPM: 29.3% vs. 47.5%; p = 0.005). Also, the diameter of the left atrium (LA) was statistically increased in patients with new PPM (No PPM vs. New PPM: 46.3 ± 6.3 vs. 48.8 ± 6.7 mm; p = 0.009). There were no more differences in echocardiographic parameters and biomarkers at baseline between both groups (**sup. Table 1**).

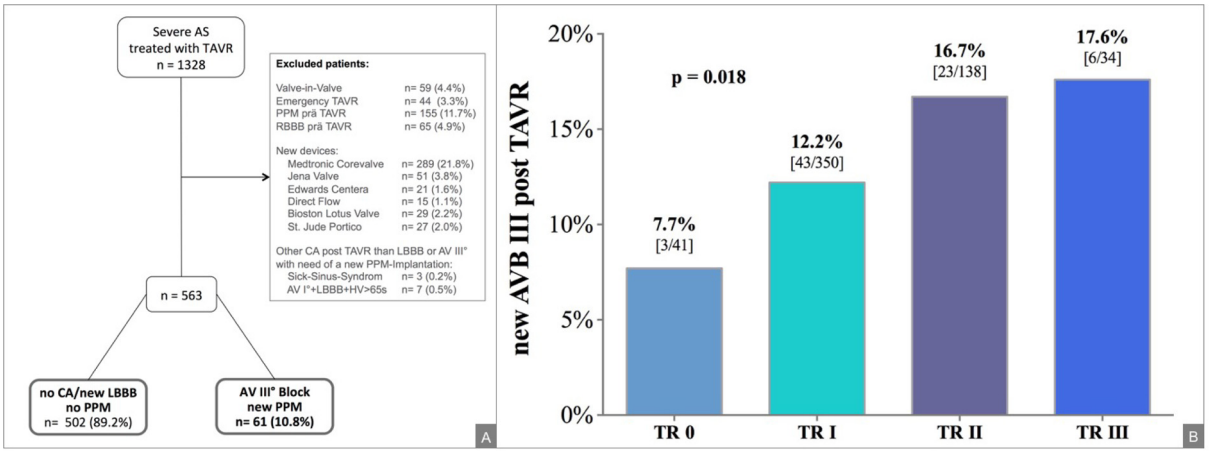

Fig. 1. A) Patient flow chart. Abbreviations: AS = aortic stenosis; AVB = atrioventricular block; CA = conduction abnormalities; LBBB = left bundle branch block; PPM = permanent pacemaker; RBBB = right bundle branch block; TAVI = transcatheter aortic valve replacement. B) Incidence of complete atrioventricular block (CAVB) after TAVI according to the severity of tricuspid regurgitation (TR).

Please cite this article as: D. Schewel, et al., Correlation of tricuspid regurgitation and new pacemaker implantation in patients undergoing transcatheter aortic valve implantati..., Int J Cardiol (2017), https://doi.org/10.1016/j.ijcard.2018.03.030