SHORT COMMUNICATION

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Electrocardiographic and further predictors for permanent pacemaker requirement after transcatheter aortic valve implantation

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The objective of this study was to identify electrocardiographic (ECG) and further predictors for atrioventricular (AV) block with a need for pacemaker (PM) implantation after transcatheter aortic valve implantation (TAVI). Pre- and post-procedural ECGs of patients with severe aortic stenosis and ongoing TAVI were investigated in a prospective study. From 50 consecutive patients enrolled in the study (mean age 80 $\pm$ 6 years, 46% men), 17 (34%) experienced an AV block with subsequent requirement of a permanent PM [16 of 36 (44.4%) with CoreValve System and 1 of 14 (7.1%) with Edwards Sapiens System]. In patients with right bundle branch block (RBBB), PM implantation had to be performed more frequently [6 of 6 (100%) with CoreValve System and none with Edwards Sapiens System], $P = 0.005$. An AV block (Mobitz II second degree and third degree) occurred mostly within the first 24 h (range: Days 0–13) after the index procedure. No recovery of AV conduction with a change in PM indication occurred in a mean follow-up time of 13 $\pm$ 6 days. Our data demonstrate that patients with pre-operative RBBB and those receiving CoreValve prosthesis are at a significantly higher risk for PM implantation after TAVI. Therefore, patients with the presence of RBBB before TAVI may be at lower risk for PM implantation using the Edwards Sapiens System.

Background

Atrioventricular (AV) block with a need for pacemaker (PM) implantation is a possible complication after transcatheter aortic valve implantation (TAVI), which is considered as an alternative therapy to conventional open aortic valve replacement when too high risk for surgery is present in patients with severe aortic stenosis. However, the occurrence of AV block with a need for PM implantation is up to five times higher in TAVI than in the conventional open aortic valve replacement.[1–4] The objective of our prospective study was to identify a possible risk predictor for this event.

Methods

Fifty consecutive patients were included in the study. All patients had continuous electrocardiographic (ECG) monitoring after the procedure until discharge (13 $\pm$ 6 days). Last routine pre- and post-procedure 12-channel ECGs were used for analysis. PR and QT intervals, QRS axis, and heart rate were measured. QRS axis was classified into normal (-30° to 105°), right (105° to 180°), and left (-90° to -30°) axis deviation. Bundle brunch blocks (BBB), defined as QRS $\geq$120 ms, were categorized into either left BBB (LBBB), right BBB (RBBB), left anterior hemiblock (LAHB), left posterior hemiblock (LPHB), combinations of them, or left or only right ventricular delay. LAHB was defined as QRS axis less than -30° with rS morphology in leads II, III, and aVF. LPHB was defined as new onset of QRS axis $>120^\circ$ looking to prior ECGs with no evidence of right ventricular hypertrophy or anterior infarction. Further tested parameters were: age, gender, Euroscore, prosthesis type, ejection fraction, pulmonary disease, coronary artery disease, hypertension, New York Heart Association class, diabetes mellitus, and negative dromotrope or chronotrope medications.

Statistical analysis

Fisher' exact test or the Man–Whitney *U*-test was used as appropriate. The incidence of BBB pre- and post-procedural was compared using the McNemar test. Further multivariate logistic regression analysis was used to define independent predictors for AV block occurrence during or immediately after the index procedure with a need for PM implantation. The difference was considered significant at $P < 0.05$.

Results

Between October 2008 and December 2009, 56 patients underwent TAVI in our centre. Six patients were excluded from our analysis due to pre-existing permanent PM. Baseline clinical and ECG data of the 50 study patients and the numbers of different procedural approaches are summarized in *Table 1*. Thirty-six patients had a transfemoral approach [CoreValve prosthesis (CVP), sizes 23–29 mm, CoreValve Inc., Irvine, CA, USA] and 14 patients had a transapical approach (Edwards Sapiens prosthesis, sizes 23 or 26 mm, Edwards Lifesciences Corporation, Irvine, CA, USA).

Postoperative AV block requiring PM implantation occurred in 17 of 50 (34%) patients. Of those, 16 of 17 patients with CVP ($P = 0.018$) and the remaining one with Edwards Sapiens prosthesis. The incidence of LBBB increased statistically significant after the procedure from 10% (5 of 50 patients) to 40% (20 of 50) ($P < 0.001$). In nine patients, the indication for PM occurred within the first 24 h (AV block Mobitz II second degree in one case and third degree in eight cases), and in eight patients, it occurred in >24 h (two on Day

Table 1 Baseline characteristics of the 50 study patients

Age (years)	80 ± 6
Men [*n* (%)]	23 (46)
Euroscore (mean ± SD)	20 ± 15
Aortic valve area (cm^2) (mean ± SD)	0.7 ± 0.1
New York Heart Association class [*n* (%)]	
II	2 (4)
III	34 (68)
IV	14 (28)
Ejection fraction (mean ± SD)	51 ± 13
Diabetes [*n* (%)]	15 (30)
Hypertension [*n* (%)]	41 (82)
Pulmonary disease [*n* (%)]	23 (46)
Coronary artery disease [*n* (%)]	28 (56)
Atrial fibrillation [*n* (%)]	17 (34)
Heart rate (bpm) (mean ± SD)	78 ± 15
PQ ≥ 200 ms [*n* (%)]	10 (20)
QTc interval (ms) (mean ± SD)	446 ± 30
Bundle branch block [*n* (%)]	12 (24)
Left bundle branch block	5 (10)
Right bundle branch block	7 (14)
Left anterior hemiblock	8 (16)
Left posterior hemiblock	0 (0)
Electrical axis deviation [*n* (%)]	
Left axis deviation	13 (26)
Right axis deviation	1 (2)
Normal axis deviation	36 (72)
Negative dromotrope or chronotrope medications [*n* (%)]	
Beta-blocker	32 (64)
Digitalis	4 (8)
Non-dihydropyridine calcium blocker	7 (14)
Antiarrhythmic class I or III	0 (0)
Transfemoral approach (CoreVavle prosthesis 23–29 mm) [*n* (%)]	36 (72)
Transapical approach (Edwards Sapiens prosthesis 23 or 26 mm) [*n* (%)]	14 (28)

1 after procedure, two on Day 2 and one on Days 4, 6, 9, and 13, respectively). Six of these eight patients developed intermittent AV block third degree and two AV block Mobitz II second degree. During the follow-up (Days 3 and 19 after procedure), further two patients with transfemoral approach received a PM, indicated by a symptomatic sick sinus syndrome. These two additional PM implantations were unrelated to the index procedure; accordingly they were not included in our analysis of AV block-related permanent PM requirement after TAVI (*Table 2*).

Pacemaker implantation in TAVI had to be performed more frequently in patients with pre-operative RBBB. Six of seven patients with RBBB (85.7%) developed within 24 h an AV block third degree ($P = 0.005$). All six patients received a CVP (26–29 mm). The patients with pre-operative RBBB and without AV block received an Edwards Sapiens prosthesis (26 mm). Using multivariate logistic regression analysis, AV block with subsequent PM requirement correlated with RBBB ($P = 0.019$) and CVP ($P = 0.044$). Age, gender, Euroscore, and further non-ECG potential predictors had no significant influence for later PM implantation (*Table 3*). During the follow-up of 13 ± 6 days after the index procedure, there was no recovery of AV conduction and change in PM indication.

Discussion

Recent published data for predictors of PM requirement after TAVI are limited. Whereas one group reported that pre-operative ECG findings have no influence for later PM implantation,[3] another described pre-existing LBBB with left axis deviation as a significant predictor.[2] Piazza

Table 2 Electrocardiographic predictors for atrioventricular block with need for pacemaker implantation after transcatheter aortic valve implantation

	CVP (23–29 mm) [*n* (%)]	ESP (23–26 mm) [*n* (%)]	CVP + ESP [*n* (%)]	*P*-value
PMR	16/36 (44.4)	1/14 (7.1)	17/50 (34)	
HR				0.07
AF	5/13 (3.4)	0/4 (0)	5/17 (29.4)	0.75
PR > 200 ms	4/10 (40)	0/0 (0)	4/10 (40)	0.71
BBB	6/11 (54.5)	0/1 (0)	6/12 (50)	0.29
RBBB	6/6 (100)	0/1 (0)	6/7 (85.7)	0.005
LBBB	0/5 (0)	0/0 (0)	0/5 (0)	0.14
LAHB	4/7 (57.1)	0/1 (0)	4/8 (50)	0.41
LPHB	0/0 (0)	0/0 (0)	0/0 (0)	
EAD				0.17
QTc				0.29

CVP, CoreValve prosthesis; ESP, Edwards Sapiens prosthesis; PMR, pacemaker requirement; HR, heart rate; AF, atrial fibrillation; BBB, bundle branch block; RBBB, right bundle branch block; LBBB, left bundle branch block; LAHB, left anterior hemiblock; LPHB, left posterior hemiblock; EAD, electrical axis deviation.

Table 3 Non-electrocardiographic predictors for atrioventricular block with need for pacemaker implantation after transcatheter aortic valve implantation

	P-value
Age	0.10
Gender	0.56
Euroscore	0.23
NYHA	0.99
Ejection Fraction	0.56
CoreValve System	0.018
Diabetes	0.74
Hypertension	0.24
Pulmonary disease	0.99
Coronary artery disease	0.38
Digitalis	0.59
Beta-blocker	0.35
Calcium blocker	0.39

et al.[5] described in a retrospective study with 40 patients that pre-existing RBBB may be at risk for development of complete heart block with subsequent need for PM. Two patients with pre-existing RBBB and CoreValve System required PM in their study. Our ECG analysis supports and compounds this observation. We identified a pre-existing RBBB as a statistically significant predictor for AV block occurrence with a need for PM implantation after TAVI. Only one patient with RBBB required no PM implantation. This patient received an Edwards Sapiens prosthesis (26 mm) via the transapical approach. All patients with RBBB and implantation of a CVP developed AV block with PM requirement. Compared with the Edwards Sapiens prosthesis, the CVP seems to be more compressive to the subvalvular septum. The CoreValve stent frame can dilate the surrounding structures in the left ventricular outflow tract with destruction of the left bundle branch (LBB). After the index procedure, the incidence of destruction of the LBB increased significantly, comparably with previously reported data.[4–6] The combination of pre-existing RBBB and additional traumatic destruction of the LBB can explain our result. No significant recovery of an intra- or peri-procedural AV block was reported with subsequent no requirement of permanent PM.[4–7] Therefore, we implanted the PM immediately after occurrence within the first 24–48 h. Sinhal *et al.*[7] reported a total AV block only in 1 of 10 patients with pre-existing RBBB, and Gutierrez *et al.*[6] reported no occurrence of AV bock. However, in these studies, only Edwards Sapiens prosthesis implantation had been reported. The low incidence of AV block is in accordance with our experience with the Edwards Sapiens System.

Conclusion

Our data demonstrate that patients with pre-operative RBBB and those receiving CVP are at a significantly higher risk for PM implantation after TAVI. These findings strongly argue in favour of discussing the risk of AV block with patients before the procedure (34% in total vs. 44% in CVP and 100% in RBBB/CVP). In this small series, 100% of patients with RBBB and a CVP got a PM. Despite the fact that PM implantation in most major centres represents a minor procedure with minimal risk, one could try to reduce the risk for PM indication by selecting the Edwards Sapiens System instead of the CoreValve System, especially in the presence of RBBB.

Study limitations

We report from a single centre experience. There was no randomization between the two types of prostheses and the number of patients may be too small to be evidentiary on associated risks for AV block. Nevertheless, our findings strongly argue for randomized studies needed between the various types of implantable valves to adequately assess the risk for permanent pacemaker requirement.

Conflict of interest: none declared.

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