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Predictors for New-Onset Complete Heart Block After Transcatheter Aortic Valve Implantation

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Objectives The aim of this study was to identify risk factors for new-onset atrioventricular (AV) block requiring pacemaker (PM) implantation after transcatheter aortic valve implantation (TAVI).

Background High-grade AV block and consecutive PM implantation are frequent complications following TAVI.

Methods For logistic regression analysis, we included 159 patients (mean age: 81 ± 6 years, EuroSCORE: 22 ± 13%) who underwent TAVI (n = 116 transfemoral, n = 4 via subclavian artery, n = 37 transapical, n = 2 transaortic) between June 2007 and January 2009 and who had no previously implanted PM.

Results Thirty-five patients (22%) developed new-onset post-operative AV block with the need of PM implantation. Logistic regression revealed a 2-fold increased risk for new-onset AV block in patients in whom a large valve is implanted in a small annulus (32% pacemaker implantations, odds ratio [OR]: 2.378, p = NS), a 4-fold increased risk with the implantation of the CoreValve (Medtronic, Minneapolis, Minnesota) versus the Edwards Sapien valve (Edwards Lifesciences, Irvine, California) (27% pacemaker implantations, OR: 3.781, p = NS), and a 5-fold increased risk for patients who exhibit an AV block episode instantly during the implantation procedure (49% pacemaker implantations, OR: 4.819, p = 0.001). Pre-existing ECG alterations were not identified as risk factors for AV block after transcatheter aortic valve implantation.

Conclusions We assume that conduction tissue impairment is provoked by mechanical compression with large prostheses in smaller annuli or in the larger area of the CoreValve covering the outflow tract and may appear instantly during the implantation procedure. Continuous post-operative electrocardiogram monitoring should be performed for at least 3 days in all patients after TAVI procedures and until discharge in patients with increased risk for this complication. (J Am Coll Cardiol Intv 2010;3:524–30) © 2010 by the American College of Cardiology Foundation

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Transcatheter aortic valve implantation (TAVI) is a novel therapeutic option for high-risk patients with aortic stenosis. Avoiding sternotomy and cardiopulmonary bypass, this approach is assumed to reduce perioperative morbidity and mortality as compared to conventional surgical aortic valve replacement. However, results from randomized studies are not currently available. Technical feasibility has been proven by several groups (1–4), though the incidence and management of procedure-related complications remain fields of current investigation. As opposed to surgical valve replacement with excision of the native aortic valve, the calcified masses remain in situ during catheter-based aortic valve implantation. It is speculated that these masses affect the conduction system in the area of the membranous septum after prosthesis deployment. Based on our observation that pacemaker implantation is a frequent sequela after TAVI, the aim of the present study was to identify risk factors predicting post-operative atrioventricular (AV) block.

Methods

Patients. Between June 2007 and January 2009, 200 elderly patients >75 years of age underwent TAVI for symptomatic high-grade aortic stenosis at our institution. Those patients were refused for surgical aortic valve replacement due to high surgical risk. Surgical risk was assessed by the EuroSCORE (expected mortality >20%) and clinical judgment, if risk factors were present, which are not covered by the score (such as repeated previous cardiac surgery, liver cirrhosis, porcelain aorta, immobility due to orthopedic diseases, etc.). All patients signed an informed consent. Twenty-six patients who had a previously implanted permanent pacemaker and 3 patients in whom catheter valve implantation was unsuccessful were excluded from the study. Another 12 patients who died <14 days after implantation and did not undergo pacemaker implantation were excluded, because the end point of the present investigation was pacemaker implantation within 14 days. Of 159 patients, the valve prosthesis was implanted via the femoral artery in 116 patients (n = 112 CoreValve [Medtronic, Minneapolis, Minnesota], n = 4 Edwards Sapien [Edwards Lifesciences, Irvine, California]), via the left ventricular apex in 37 patients (n = 5 CoreValve, n = 32 Edwards Sapien), via the subclavian artery in 4 patients (CoreValve), and via the ascending aorta in 2 patients (CoreValve).

Prostheses. Both the CoreValve prosthesis and the Edwards Sapien prosthesis were implanted in our series. Both received the CE mark in 2007 for transarterial implantation. In addition, the Edwards Sapien prosthesis received the CE mark for transapical implantation in December 2007. The CoreValve prosthesis is a porcine pericardial valve mounted in a self-expandable nitinol stent. Transapical implantation of the CoreValve prosthesis was performed within the context of the approval study (n = 5, approved by the institutional ethics committee). The Edwards Sapien prosthesis is a bovine pericardial valve in a balloon-expandable steel stent. It is suitable for native annulus sizes of 17 to 25 mm, whereas the CoreValve prosthesis can be implanted in annuli of 19 to 27 mm.

Implantation techniques. All patients were operated on in a surgical hybrid suite. We opted to perform the procedures under general anesthesia to ensure stable hemodynamics and avoid patient movements during valve implantation. Transfemoral valve implantation was performed by percutaneous punctuation and device closure (ProStar XL, Abbott Vascular, Illinois) or by surgical dissection of the femoral artery. For the subclavian access, the vessel was dissected through a 5-cm subclavicular skin incision (5). Antegrade transapical aortic valve implantation was performed through a left anterolateral minithoracotomy. In 2 no-access patients, the prosthesis was implanted through the ascending aorta with an upper ministernotomy (6). A transient pacemaker wire was placed transvenously for transarterial retrograde implantation and epicardially for transapical antegrade valve implantation. A balloon valvuloplasty of the stenotic aortic valve was performed under rapid ventricular pacing with 160 to 180 beats/min in all patients. Under fluoroscopy control, the prosthesis, crimped on the delivery catheter, was placed in the aortic annulus. The CoreValve prosthesis was then released stepwise on the beating heart, whereas the Edwards Sapien prosthesis was deployed by balloon inflation under rapid ventricular pacing. Details of the implantation procedures have previously been described (1,3,5–8). Prosthesis function was assessed by angiography and intraoperative transesophageal echocardiographic investigation. After the procedure, the patients were transferred to the intensive care unit and usually extubated within 2 to 4 h. The transient pacemaker wire was left in place for at least 3 days in all patients.

Abbreviations and Acronyms

AV = atrioventricular
ECG = electrocardiogram
TAVI = transcatheter aortic valve implantation

Data collection and statistical analysis. The end point of the present study was a newly developed AV block after TAVI requiring pacemaker implantation within 14 days after the procedure, according to the guidelines for reporting morbidity and mortality after cardiac valve interventions (9). Bradyarrhythmia and sick sinus syndrome represent preexisting indications for pacemaker implantation that might not have been noticed before aortic valve implantation and are not related to the transcatheter valve procedure. Therefore, our analysis targets only the patients who exhibited new-onset AV block requiring pacemaker implantation within 14 days. An institutional database for transcatheter valve procedures was instituted to record patients' demographics and pre-, intra-, and post-operative data.

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Annulus diameter measurements were averaged from computed tomography and transthoracic and transesophageal echocardiographic data, where annulus dimensions were measured at the level of the leaflet hinges as described by Roman et al. (10). A borderline annulus size for valve size was defined as an annulus of <19.5 mm for the 26-mm CoreValve, <23.5 mm for the 29-mm CoreValve, <17.5 mm for the 23-mm Edwards Sapien, and <21.5 mm for the 26-mm Edwards Sapien prosthesis. The presence of bulky calcifications was assessed by echocardiography. The preoperative valve orifice area was obtained echocardiographically by using the continuity equation (11). Any intraoperative episode of transient or persistent AV block requiring pacemaker stimulation with the transient pacemaker wires was recorded.

The implantation height of the final prostheses placement was measured in 82 patients in a fluoroscopic aortogram with the deployed catheter valve in a right anterior oblique projection that displayed the aortic valve in optimal alignment with all 3 leaflets visible en face. The depth of delivery was defined as the distance from the native aortic annular margin on the side of the noncoronary cusp (leftward on the described projection) and on the side of the left coronary cusp (rightward on the described projection) to the most proximal edge (deepest in the left ventricle) of the deployed prosthesis stent frame. To compensate for projection errors, the depth of the prosthesis is presented in relation to full prosthesis length. Implantation height measurement is depicted in Figure 1. Due to the different designs, the CoreValve and the Edwards Sapien implantation heights were analyzed separately.

Descriptive data for continuous variables are presented as mean ± SD or as medians with ranges. Categorical variables are presented as relative frequencies. Fisher exact test was performed to detect significant differences between groups. For comparison of continuous variables between 2 groups, the *t* test was used (2-tailed tests were used for all analyses).

Sixteen pre-operative and intraoperative factors were tested for a potential impact on post-operative AV block: gender, age, logistic EuroSCORE value, pre-operative rhythm, pre-operative AV block or right or left bundle branch block, pre-operative valve orifice area, aortic annulus diameter, implanted valve type and size, borderline annulus size for valve size, size of valvuloplasty balloon, the difference between annulus size and valve size, the difference between annulus size and balloon size, the presence of bulky calcifications, and the occurrence of intraoperative AV block. Variables with p values <0.1 in univariate analysis were entered into the multivariate model. Multivariate analyses were performed by means of a logistic regression model. Analyses were performed with SPSS version 16.0 for Windows (SPSS Inc., Chicago, Illinois).

Due to an inadequate number of measurements, the implantation height was analyzed separately from the multivariate analysis.

Results

Of 159 patients who had no previously implanted pacemaker, 44 required permanent pacemaker implantation within 14 days after transcatheter aortic valve implantation (mean time to implantation was 4.2 ± 3.5 days, range 0 to 11 days). Indications for pacemaker implantation were new-onset high-grade AV block (n = 35), sick sinus syndrome (n = 1), and bradyarrhythmia (n = 8). Univariate findings of potential influencing factors for post-operative

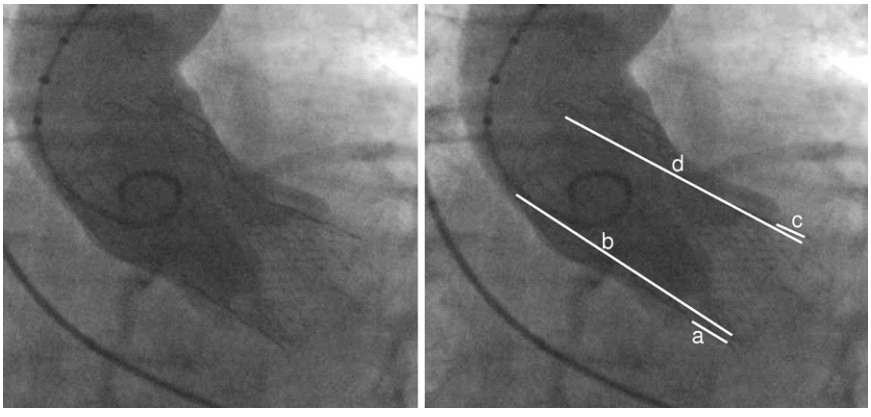

Figure 1. Implantation Height Measurement

The depth of delivery of the catheter valve was defined as the distance from the native aortic annular margin on the side of the noncoronary cusp (**a:** leftward on the described projection) and on the side of the left coronary cusp (**c:** rightward on the described projection) to the most proximal edge (deepest in the left ventricle) of the deployed prosthesis stent frame. To compensate for projection errors, the depth of the prosthesis is presented in relation to full prosthesis length **(b and d)**. Mean implantation height was defined as: (a/b + c/d)/2.

Table 1. Univariate Analysis

Parameter	All Patients (n = 159)	Patients Without AV Block (n = 124)	Patients With New-Onset AV Block (n = 35)	p Value
Female sex	91 (57%)	69 (56%)	22 (63%)	0.446
Mean age, yrs	80.8 ± 6.2	80.7 ± 6.4	81.2 ± 5.8	0.648
Mean logistic EuroSCORE, %	21.6 ± 13.0	21.6 ± 13.1	21.7 ± 12.9	0.967
Pre- and intraoperative ECG findings				
Pre-operative heart rhythm				0.869
Sinusal	114 (73%)	89 (72%)	25 (71%)	
Atrial fibrillation	41 (26%)	32 (26%)	9 (26%)	
Supraventricular rhythm	1 (1%)	1 (1%)	0	
Pre-operative AV block °I	22 (14%)	15 (12%)	7 (20%)	0.232
Pre-operative right bundle branch block	6 (4%)	3 (2%)	3 (9%)	0.078
Pre-operative left bundle branch block	27 (17%)	20 (16%)	7 (20%)	0.504
Intraoperative AV block	37 (23%)	19 (15%)	18 (51%)	0.000
Prosthesis and balloon-specific parameters				
Valve type				
CoreValve	124 (78%)	91 (73%)	33 (94%)	0.008
Edwards Sapien	35 (22%)	33 (27%)	2 (6%)	
Labeled valve size				
23 mm	13 (8%)	12 (10%)	1 (3%)	0.297
26 mm	65 (41%)	52 (42%)	13 (37%)	
29 mm	81 (51%)	60 (48%)	21 (60%)	
Valvuloplasty balloon size, mm	23.0 ± 2.1	22.8 ± 2.1	23.7 ± 1.8	0.019
Anatomic parameters				
Pre-operative valve orifice area	0.65 ± 0.2	0.65 ± 0.2	0.65 ± 0.2	0.928
Annulus diameter, mm	22.8 ± 2.0	22.8 ± 2.1	22.9 ± 1.8	0.841
Borderline annulus size for valve size	41 (26%)	28 (23%)	13 (37%)	0.069
Annulus-to-valve size difference (annulus diameter minus labeled valve size), mm	–4.5 ± 1.4	–4.4 ± 1.4	–4.8 ± 1.5	0.133
Annulus-to-balloon size difference, mm	–0.13 ± 1.6	–0.01 ± 1.5	–0.65 ± 1.6	0.045
Bulky calcifications	25 (16%)	22 (18%)	3 (9%)	0.188

AV = atrioventricular; ECG = electrocardiogram.

AV block and consecutive pacemaker requirement are summarized in Table 1.

Six parameters with $p < 0.1$ (intraoperative AV block, valve type, borderline annulus size, pre-procedural right bundle branch block, annulus-to-balloon size difference, and valvuloplasty balloon size) were included into the multivariate analysis. Logistic regression revealed intraoperative episodes of AV block requiring transient or permanent stimulation as the only highly significant parameter to predict later requirement for permanent pacemaker implantation for AV block with an odds ratio of 4.8. The implantation of a CoreValve versus an Edwards Sapien prosthesis and a borderline annulus size for prosthesis size had a considerable effect on new-onset AV block, though not statistically significant on a 5% level. The results of the logistic regression are displayed in Table 2.

Implantation height. Due to the differing designs of the CoreValve and the Edwards Sapien prosthesis, implantation height was analyzed separately for the 2 groups. The mean depth of the CoreValve prosthesis in the left ventricular outflow tract was 23 ± 11% of full prosthesis length in 70 investigated angiograms, that is, 12 ± 6 mm of the stent frame are localized below the native aortic annulus. There was a tendency for deeper prosthesis implantation in patients who needed post-procedural pacemaker implantation. Implantation depth was 20 ± 9% (n = 41, no AV block) versus 24 ± 13% (n = 29, new-onset AV block) at the

Table 2. Results of the Logistic Regression

Parameter	Univariate p Value	Multivariate p Value	Odds Ratio	95% CI
Intraoperative AV block	0.000	0.001	4.819	2.0–11.9
Valve type = CoreValve	0.008	0.090	3.781	0.8–17.6
Borderline annulus size for valve size	0.069	0.063	2.378	1.0–5.9
Valvuloplasty balloon size	0.019			
Right bundle branch block	0.078			
Annulus-to-balloon size difference	0.045			

CI = confidence interval; other abbreviation as in Table 1.

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noncoronary cusp (p = 0.150), 22 ± 11% versus 27 ± 19% at the left-coronary cusp (p = 0.169), and mean implantation depth was 21 ± 9% versus 26 ± 13% (p = 0.104), respectively. Edwards Sapien mean implantation height was 27 ± 17%, 27 ± 18% at the noncoronary cusp, and 26 ± 17% at the left coronary cusp (n = 12). As only 1 of 12 patients required post-procedural pacemaker implantation, no statistics were performed for this group.

Discussion

The TAVI procedure is a novel treatment option for nonsurgical patients with severe symptomatic aortic stenosis. The nature and incidence of complications after transcatheter treatment of aortic stenosis are different than those after conventional surgical aortic valve replacement. A high incidence of post-procedural pacemaker implantation is 1 of the sequelae requiring particular consideration in this context.

Few series of 10 to 102 patients describe new pacemaker implantation in 27% to 33% of the patients after CoreValve implantation (12–14), and in 4% to 12% after Edwards Sapien implantation (15,16). In our series of 200 patients, the overall incidence of new pacemaker implantation within 14 days was 22% (n = 44). However, it was crucial to eliminate patients from the analysis who died <14 days after prosthesis implantation (n = 12), patients in whom the prosthesis implantation procedure was not successful (n = 3), and patients who had a previously implanted pacemaker (n = 26) to report the factual pacemaker implantation rate of 28% (44 of 159) only in patients who are at risk for this complication. The overall new pacemaker implantation rate of the series described might under-report the actual rate of pacemaker requirement. We additionally separated the patients who developed new-onset AV block, which is a procedure associated complication, from those who apparently had pre-existing indications for pacemaker implantation, such as bradyarrhythmia or sick sinus syndrome. Therefore, we state that the rate of procedure-associated pacemaker requirement was 22% (35 of 159) in our series, which is significantly higher than the reported rates of up to 6% after conventional surgical aortic valve replacement (17–19).

Pacemaker implantation was performed according to the European Society of Cardiology guidelines for cardiac pacing and cardiac resynchronization therapy (20). When the bradyarrhythmias were diagnosed during the post-operative monitoring, pacemaker implantation was performed without further hesitation even in cases of intermittent bradyarrhythmias. This approach might be called a somewhat liberal indication, but in this population of elderly patients all with underlying organic heart disease, we opted for patients' safety.

As sudden post-operative AV block can be a life-threatening complication, we aimed to detect risk factors predicting this complication to identify patients with the need for prolonged electrocardiogram (ECG) monitoring. Two patients in our series with sudden unexplained in-hospital death might have developed an unrecognized AV block. One of those had a borderline annulus size for valve size, which has been identified as a risk factor for AV block by multivariate analysis.

Reasons for post-operative AV block after surgical aortic valve replacement are injury to the cardiac conduction system during surgical excision of the adjacent diseased valve and annular tissue. It is speculated that conduction tissue injury during TAVI is induced by mechanical pressure to the conduction system by the prosthesis and the native valve calcium that remains in situ. Subsequently edema, ischemia, and necrosis may develop. Therefore, we looked at parameters associated with the induced dilating pressure, which may affect the conduction system during TAVI. The valvuloplasty balloon size used and the difference between the balloon size and the aortic annulus were found to be significantly larger in patients who developed AV block (p = 0.019 and p = 0.045, respectively). However, both parameters were not found to influence pacemaker requirement by multivariate analysis.

The presence of bulky calcifications assessed echocardiographically did not predict the development of AV block. Additionally, preliminary results from 3-dimensional measurements of the native valve calcium volume in 27 pre-operative computed tomography scans revealed no association between native valve calcium volume and the occurrence of AV block. However, a recent study demonstrated the noncoronary cusp thickness measured by transesophageal echocardiography as being a predictive parameter for the need for pacemaker implantation, indicating that an AV block may be predicted by pre-operative imaging (21).

Concerning the size of the implanted prosthesis in relation to the native annulus size, we found that patients with an annulus at the lower edge of the recommended size for a specific prosthesis size (an annulus of <19.5 mm for the 26-mm CoreValve, <23.5 mm for the 29-mm CoreValve, <17.5 mm for the 23-mm Edwards Sapien, and <21.5 mm for the 26-mm Edwards Sapien prosthesis) exhibited an increased risk for pacemaker implantation (32% [13 of 41] pacemaker implantation, p = 0.069). Such a borderline relation between annulus size and prosthesis size was detected to more than double the risk for pacemaker requirement in the logistic regression analysis (odds ratio [OR]: 2.378, not significant on the 5% level, p = 0.063). However, we opted for the larger valve size when the size of the aortic annulus was in between 2 valve sizes to minimize the risk of valve migration and paravalvular leak. In summary, these data support the hypothesis that in-

creased pressure to the conduction system by relatively larger valvuloplasty balloons or larger prostheses in a smaller annulus increases the risk of new-onset AV block.

There is an ongoing discussion to which extent pre-existing ECG alterations influence the occurrence of new-onset AV block after TAVI (21–23). In our series, a pre-existing AV block grade I and a pre-existing left bundle branch block were not risk factors for new-onset high-grade AV block after the transcatheter valve procedures. Jilaihawi et al. (21) identified left axis deviation and left bundle branch block with left axis deviation as strong predictors for permanent pacemaker requirement, but not left bundle branch block alone. In contrast, of the patients with pre-existing right bundle branch block, 50% (3 of 6, p = 0.078) experienced procedure-related high-grade AV block. However, right bundle branch block was rare in our series, and this parameter was not relevant by multivariate analysis. In concordance with our findings, Sinhal et al. (23) found no statistically significant association between pre-existing ECG alterations and new-onset AV block. Piazza et al. (22) speculate that a pre-existing right bundle branch block might be a strong predictor for later pacemaker requirement, as both (2 of 2) patients with right bundle branch block in their series of 40 patients developed AV block. According to Koplan et al. (24), right bundle branch block is a strong predictor of pacemaker requirement in patients undergoing conventional valve surgery. As right bundle branch block is an infrequent phenomenon, very large populations have to be investigated to reveal a potentially significant effect.

Our data give evidence that patients who undergo catheter valve implantation with the CoreValve prosthesis are at higher risk for post-operative AV block. Among 124 patients receiving a CoreValve prosthesis, 27% underwent pacemaker implantation for valve-related AV block, compared with 6% of 35 patients who received an Edwards Sapien prosthesis (p = 0.008). Multivariate analysis revealed an almost 4-fold increased risk for AV block with the CoreValve prosthesis (not significant on the 5% level, p = 0.090). This is the first description of this phenomenon, as most of the other centers implant either the CoreValve or the Sapien prosthesis. There was a tendency toward lower CoreValve position within the left ventricular outflow tract in patients developing post-operative AV block, though this tendency was not significant. In the study by Piazza et al. (22), a low CoreValve position was associated with the development of new-onset left bundle branch block. It is speculated that with a low CoreValve position in the left ventricular outflow tract there is a larger stent frame area that potentially compresses the conduction system.

The most evident finding from this study is that patients who experience an AV block instantly in the operating room after balloon valvuloplasty or after valve deployment exhibit an almost 5-fold risk to develop permanent AV block with the need for pacemaker implantation by logistic regression analysis. This finding was highly significant (p = 0.001). Among patients with intraoperative AV block, 49% (18 of 37) required later pacemaker implantation as opposed to only 14% (17 of 122) in patients without intraoperative AV block. We assume that conduction tissue injury may immediately be caused by compression from the balloon or the prosthesis. In those patients, post-procedural ECG monitoring should be extended to at least 5 days.

In summary, valve-related AV block requiring pacemaker implantation is a frequent finding after TAVI that occurred in 22% in our series. Our data demonstrate a 2-fold increased risk for new-onset AV block in patients in whom a large valve is implanted in a small annulus (OR: 2.378, p = NS), a 4-fold increased risk with the implantation of the CoreValve versus the Edwards Sapien valve (OR: 3.781, p = NS), and a 5-fold increased risk for patients who exhibit an AV block episode instantly during the implantation procedure (p = 0.001). We assume that conduction tissue impairment is provoked by mechanical compression with relatively large balloons and prostheses in smaller annuli and may appear instantly during the implantation procedure. However, the implantation of large prostheses in smaller annuli cannot be avoided without increasing the risk for paravalvular leakage. Continuous post-operative ECG monitoring should be performed for at least 3 days in all patients, and until discharge in patients with increased risk for this complication. In this population of elderly patients, all with underlying organic heart disease, we opted for patients' safety and did not hesitate to implant a pacemaker, if episodes of high-grade AV block were diagnosed during the post-operative course.

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