Electrophysiological Evaluation of Atrioventricular Conduction Disturbances in Transcatheter Aortic Valve Implantation With Edwards SAPIEN Prosthesis

Abdurrahman Eksik, MD¹, Mehmet Gul, MD¹, Huseyin Uyarel, MD², Ozgur Surgit, MD¹, Aydin Yildirim, MD¹, Nevzat Uslu, MD¹, Huseyin Aksu, MD³, Selahatrin Turen, MD¹, Fazih Uzun, MD¹, Hulusi Satilmisoglu, MD¹, Mustafa Kemal Erol, MD¹, Ihsan Bakir, MD¹

ABSTRACT: Aims. Permanent pacemaker requirement is a known complication after transcatheter aortic valve implantation (TAVI). The aim of the present study was to analyze the effects of Edwards SAPIEN prosthesis implantation on atrioventricular conduction. Methods. The study included 28 patients who underwent TAVI due to severe aortic valve stenosis. An electrophysiological study was performed in the catheterization room immediately before the initial balloon valvuloplasty and immediately after Edwards SAPIEN prosthesis implantation. Results. His-ventricle interval was significantly prolonged postprocedure (55.9 ± 11.5 ms) vs preprocedure (47.3 ± 7.8 ms) (P < .001). The atrial Wenckebach point was observed to be significantly prolonged postprocedure (354.4 ± 41.3 ms) vs preprocedure (333.7 ± 45.4 ms) (P < .001). Despite atrial-His interval prolongation, it was not statistically significant. After the procedure, we observed significant conduction disturbances in 3 patients (10.7%). These conduction problems recovered before discharge. One of the patients (3.6%) with right bundle branch block + left anterior fascicular block required permanent pacemaker implantation. At postprocedure electrocardiogram, QRS duration increased, QRS axis shifted to the left, and both of the values became normal before discharge. The patient's echocardiographic and clinical parameters were improved during follow-up. Conclusion. The effect of Edwards SAPIEN on the conduction system was mostly infra-nodal and temporary. The physical properties of the Edwards SAPIEN prosthesis may explain this observation. This complication may be lessened if the frame height characteristics can be improved.

Key words: electrophysiological study, conduction disturbances, TAVI, Edwards SAPIEN prosthesis

Transcatheter aortic valve implantation (TAVI) has become an alternative therapy for patients who have severe aortic stenosis (AS) and are at high risk for surgery.¹ Despite continuous improvements in operator expertise and device technology, complications associated with TAVI are common.²³ Atrioventricular (AV) block is a known complication of surgical aortic valve replacement. Not surprisingly, AV conduction disturbance can also occur with TAVI, presumably as a consequence of the pressure applied on the conducting tissues located subendocardially in the left ventricular (LV) outflow tract and interventricular septum.⁴ Some clinical and electrocardiographic (ECG) predictors of AV block have already been reported. It’s well known that AV conduction disturbances and permanent pacemaker (PPM) requirement are more frequent after CoreValve versus Edwards SAPIEN implantation. There are a lot of studies about the electrophysiological changes of AV conduction in CoreValve prosthesis.⁵⁶ However, there is no available information regarding EPS changes on AV conduction with the Edwards SAPIEN prosthesis. The aim of this study was to analyze the effects of Edwards SAPIEN implantation on AV conduction.

Methods

This study included 28 patients (11 males, 17 females; mean age, 77.5 ± 4.8 years) undergoing TAVI between October 2010 and February 2012. Patients received new-generation balloon-expandable Edwards SAPIEN XT by the transfemoral (n = 27) and transapical (n = 1) approaches. After TAVI, the mean follow-up time was 9.9 months. All patients had severe AS and New York Heart Association (NYHA) class III or IV symptoms and were at high risk for surgery due to comorbidities such as chronic obstructive pulmonary disease, pulmonary hypertension, peripheral artery disease, and low ejection fraction. The decision to do TAVI was rendered by a consensus at the heart team meeting. Preoperative risk was assessed on the basis of either the European System for Cardiac Operative Risk Evaluation (EuroSCORE) or the Society of Thoracic Surgeons (STS) risk calculator system.⁷⁸ In the absence of other contraindications to surgical valve replacement, high-risk status was defined as a logistic EuroSCORE of >20% or an STS score of >10%.

Hypertension was defined as the use of antihypertensive medications, or the detection of systolic blood pressure >140 mm Hg, or diastolic blood pressure >90 mm Hg in at least two separate measurements. Diabetes mellitus was defined based on a previous diagnosis requiring the use of diet or antidiabetic drugs, or by a fasting venous blood glucose level of 126 mg/dL on two occasions in previously untreated patients. Body mass index was calculated as weight in kilograms divided by the square of the height in meters. Contrast-induced nephropathy was defined as an increase in serum creatinine level...
≥0.5 mg/dL or ≥25% from baseline (admission) within 72 hours of radiocontrast administration.

Exclusion criteria were as follows: a narrow or too wide anulus of the aortic valve (≤18 mm or ≥25 mm) on echocardiography, an aortic valve area of more than 0.8 cm², a short distance between the main coronary artery and aortic valve (for Edwards SAPIEN prosthesis <8 mm), severe left ventricular systolic dysfunction (ejection fraction <20%), acute coronary syndrome, a history of renal or liver disease, malignancy, hematologic disorders, acute or chronic infection, and a life expectancy of <12 months due to non-cardiac causes. The study was approved by the local ethics committee, and all patients gave informed consent.

Severity of AS, aortic valve structure, and the aortic root were evaluated by transthoracic and transesophageal echocardiography (General Electric Vivid 7 GE Vingmed Ultrasound AS). Echocardiographic measurements were performed in the left lateral decubitus position according to the criteria of the American Society of Echocardiography. Multislice computed tomography and angiography were performed to assess the aortic root-arch calcification, diameters of the femoral and iliac arteries, and calcifications and tortuities. The procedure was accomplished under general anesthesia in 17 patients and under mild sedation in 11 patients. Access was gained by a surgical cutdown in 16 patients, and a percutaneous closure device (Prostar XL) was used in 12 patients.

Procedure. The TAVI procedure was performed in a sterile environment (catheterization laboratory) under general or local anesthesia. The femoral artery with a greater diameter and less tortuosity was selected. Two sheaths were placed in the contralateral femoral artery and femoral vein for placement of a pigtail catheter in the aorta and a pacemaker lead in the right ventricle, respectively. Balloon predilation was performed in all of the patients. For a proper procedure, the balloon was predilated after passing the native valve with a straight-tip guidewire and an Amplatz left guide catheter. During balloon predilatation, ventricular tachycardia was induced by rapid ventricular pacing, providing an optimal reduction in cardiac output by creating a transient cardiac standstill. This was usually achieved at a heart rate of 200 bpm. The Edwards SAPIEN prosthesis was then passed through the delivery systems and expanded at the level of the native valve. Rapid ventricular pacing was repeated at that stage in patients receiving the prosthesis. The aortic root and peripheral arteries were evaluated after the intervention by contrast injection into the aortic root and by peripheral angiography.

Electrophysiological study. A 7 Fr sheath was placed into the femoral vein for electrophysiological study (EPS), which was implemented in the catheterization room immediately before the initial balloon valvuloplasty and immediately after Edwards SAPIEN prosthesis implantation. Atrial and ventricular refractory periods were not measured because of the risk for arrhythmia induction, nor did we appraise sinus node functions in order not to prolong the procedure. No patients received medications likely to have potential effect on the conduction system. The patients were hemodynamically stable before and after the procedure and during the measurements, and no patients took positive inotropic agent. The portable EP Tracer system (CardioTek) was utilized for the procedure, and 1-quadrupole catheters were placed across the tricuspid annulus to record His bundle activation. Atrial-His (AH) and His-ventricle (HV) were measured on records before balloon valvuloplasty from intracardiac catheter in His region and after placement of the valve. Antegrade AV node function was assessed with atrial pacing and extra stimuli. The following parameters were considered to be normal: an AH interval of <125 ms; an HV interval of ≤55 ms; and a Wenckebach AV block point of <450 ms. All patients were followed for at least 2 days with temporary transvenous pacemakers.

Statistical analysis. Statistical analysis was performed using the statistical software SPSS 17.0 for Windows (SPSS Inc). Data were expressed as mean ± standard deviation for continuous variables, and as numbers with corresponding percentages for categorical variables. The paired sample test was used to compare the pre- and postprocedural results. A P-value <.05 was considered significant.

Results

Baseline demographic and clinical parameters are given in Table 1. The mean age was 77.5 ± 4.8 years, and 17 patients (60.7%) were female. Procedural complications of the patients are given in Table 2. All devices were properly positioned and valves were found to be properly functioning on postprocedural angiographic and echocardiographic evaluations. PPM implantation was required in 1 patient due to atrioventricular conduction abnormalities. Peripheral arterial injuries occurred in 4 patients. Coronary artery occlusion occurred in 1 patient. No paravalvular aortic regurgitation of greater than grade +3-4 was observed. Five patients developed contrast nephropathy. One patient developed a clinical stroke. At the 1-month echocardiographic follow-up, both the aortic valve area and the left ventricular ejection fraction significantly increased, with significant decreases in the transvalvular (peak systolic and mean) gradients. At the 4-month follow-up, the overall mean NYHA functional class score decreased significantly.

EPS study parameters before and after the procedure are given in Table 3. The HV interval significantly increased after the procedure (55.9 ± 11.5 ms) compared to the interval before the procedure (47.3 ± 7.8 ms; P < .001). The antegrade Wenckebach point was also observed to be significantly more elongated after the procedure (354.4 ± 41.3 ms) than before (333.7 ± 45.4 ms; P < .001). We were unable to measure the AH interval in 5 of our patients because they had atrial fibrillation. We performed statistical analysis of the AH interval in the remaining 23 patients. AH interval was prolonged, but it was not statistically significant. AH interval, HV interval, and antegrade Wenckebach points of patients before and after the procedure are illustrated explicitly in Figures 1, 2, and 3.

The baseline ECG cardiac conduction parameters of the 28 patients and the postprocedural changes in cardiac conduction following the procedure and at discharge are shown in Table 4. Preprocedurally, 5 patients were in atrial fibrillation. Eleven patients had one or more AV conduction disturbances, with left bundle branch block (LBBB; 3 patients) and right bundle branch block (RBBB; 4 patients) being the most
frequent conduction problem, followed by first-degree AV block (2 patients), left anterior fascicular block (LAFB; 1 patient), and RBBB + LAFB (1 patient). These conduction problems recovered before discharge. One patient with RBBB + LAFB required PPM implantation because of symptomatic bradycardia. Immediately after the procedure, QRS duration increased, and the QRS axis shifted to the left; both of these values normalized before discharge.

Discussion

This is the first study to examine EPS and ECG changes in TAVI procedures with the Edwards SAPIEN prosthesis. Despite the conduction disturbances observed in EPS and ECG immediately after the procedure (10.7%), patients recovered before discharge. Moreover, the conduction defects were chiefly infranodal and temporary. Only 1 patient required PPM implantation (3.6%).

There are currently two percutaneous heart valves in clinical trials: the balloon-expandable Cribier-Edwards and Edwards SAPIEN prosthesis (Edwards Lifesciences), and the self-expanding CoreValve (Medtronic). PPM implantation has been reported in 3%-9% of patients undergoing surgical aortic valve replacement.10-12 PPM implantation among patients undergoing TAVI is not uncommon. Previous studies have reported PPM implantation rates ranging from 5%-43%, with an increased incidence among patients receiving the CoreValve prosthesis (18%-43%), as compared with patients treated with the Edwards SAPIEN prosthesis (5%-22%).13-19 At our center, we determined that the patients with CoreValve prostheses more frequently required PPM implantation.20

The atrioventricular conduction system passes superficially through the interventricular septum immediately below the aortic valve. Injury during valve implantation may result in partial or complete AV heart block. Several predictors of AV conduction disturbances necessitating PPM implantation after TAVI have been described, including advanced age, RBBB at baseline, prosthesis oversizing, increased septal wall thickness, deep valve implantation (>6 mm below the annular plane), non-coronary cusp thickness, and the degree of calcification.13,21,22

In our study, 1 patient with RBBB + LAFB required PPM implantation. Similar to our study, Rubin et al evaluated EPS and ECG findings before and after TAVI in 18 patients who received
CoreValve prosthesis implantation. They evaluated AH and HV intervals from EPS and QRS, and PR intervals and the QRS axis from ECG. They found significantly prolonged AH, HV, QRS, and PR intervals, and the QRS axis shifted to the left. Following the procedure, 78% of patients had conduction problems and most of them were permanent. CoreValve implantation worsens AV conduction in most patients, either transiently or permanently. This is the result of direct damage either to the His bundle or the AV node. In their study, no differences were found in hemodynamic parameters, such as arterial pressure and heart rate before and after the procedure, or in sinus function parameters. Therefore, an autonomic effect is unlikely to be responsible for the changes. The QRS axis shift was thought to be associated with edema and the implanted valve's proximity to the left conduction system.

In our study, mean HV intervals were 47.3 ± 7.8 ms and 55.9 ± 11.5 ms (P < .001) before and after the procedure, respectively. HV interval was significantly prolonged after the procedure. The PPM implanted patients had a significantly prolonged HV interval (from 45 ms to 75 ms). At ECG after the procedure, a significantly prolonged QRS interval and a QRS axis shift to the left were noted. Despite prolongation of AH, there was no significant difference noted in the PR interval. The 3 patients (10.7%) with conduction defects regressed during follow-up. Our study revealed that Edwards SAPIEN prosthesis had less effect on conduction system than the CoreValve. These effects on the conduction system as a result of Edwards SAPIEN prosthesis may be due to indirect mechanisms such as edema or local inflammation, rather than direct pressure (as in the case of the CoreValve). The mean length of the CoreValve was 53-55 mm; however, the mean Edwards SAPIEN length was 15-17 mm. Differences in device design may explain this finding, as deeper extension of the tent frame in the left ventricular outflow tract and the self-expanding properties of the CoreValve prosthesis lead to the maintenance of a steady radial force on the annular and subendocardial tissue.23 Most changes occur as direct effects on the infra-Hisian conduction system, probably caused by direct pressure on the lower area of the prosthesis on the basal portion of the ventricular septum and the area involving the His bundle. The procedure also affects the compact AV node, probably due to the length of the prosthesis, which is consistent with the lower rate of AV block in the shorter Edwards SAPIEN prosthesis. AV blocks typically manifest immediately after valvuloplasty or valve implantation; therefore, placement of a temporary pacemaker is desirable during the procedure. There are different heterogenous implantation techniques for the TAVI procedure, which may influence the PPM implantation ratio.24,25 In the TAVI procedure, PPM requirements may be lowered by decreasing the frame height.

Study limitations. This is a single-center study with a small sample size. TAVI is a complex and time-consuming procedure. Because of this, we did not assess sinus node functions. Other studies have revealed that there was no change in sinus node functions.3 Predictors of AV conduction problems cannot be analyzed because of the small sample size and low PPM ratio. We need further studies comparing Edwards SAPIEN and CoreValve implantation procedures.

Figure 1. Atrial-His (AH) intervals of 23 patients without atrial fibrillation pre- and postprocedure indicated as preAH and postAH. There was no statistically significant difference between mean AH intervals pre- and postprocedure (81.8 ± 16.9 ms and 119.1 ± 32.9 ms, respectively; P = .25).

Figure 2. His-ventricle (HV) intervals of all patients pre- and postprocedure indicated as preHV and postHV. The HV interval was significantly prolonged postprocedure (55.9 ± 11.5 ms) compared to preprocedure (47.3 ± 7.8 ms; P < .001).

Figure 3. Antegrade Wenckebach point intervals of 23 patients without atrial fibrillation pre- and postprocedure indicated as preWB vs postWB. Mean antegrade Wenckebach point was significantly prolonged postprocedure compared to preprocedure (354.4 ± 41.3 ms and 333.7 ± 45.4 ms, respectively; P = .001).
Table 4. Electrocardiogram parameters before and after the procedure.

<table>
<thead>
<tr>
<th></th>
<th>Before Procedure</th>
<th>After Procedure</th>
<th>Discharge</th>
<th>P1</th>
<th>P2</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR interval (ms)</td>
<td>162 ± 33.4</td>
<td>180.6 ± 53.7</td>
<td>165.9 ± 31.4</td>
<td>.08</td>
<td>.41</td>
</tr>
<tr>
<td>QRS duration (ms)</td>
<td>108.9 ± 26.9</td>
<td>117.1 ± 29.5</td>
<td>109.6 ± 27.9</td>
<td>.007</td>
<td>.36</td>
</tr>
<tr>
<td>QRS axis (degree)</td>
<td>17.6 ± 42.6</td>
<td>4.7 ± 16.1</td>
<td>9.4 ± 42.4</td>
<td>.064</td>
<td>.13</td>
</tr>
<tr>
<td>Normal conduction</td>
<td>17 (60.7%)</td>
<td>15 (53.6%)</td>
<td>18 (64.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraventricular conduction defect</td>
<td>0 (0%)</td>
<td>1 (3.6%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st atrioventricular block</td>
<td>2 (7.1%)</td>
<td>2 (7.1%)</td>
<td>1 (3.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd atrioventricular block</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd atrioventricular block</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left bundle branch block</td>
<td>3 (10.7%)</td>
<td>3 (10.7%)</td>
<td>3 (10.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAFB</td>
<td>1 (3.6%)</td>
<td>1 (3.6%)</td>
<td>1 (3.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right bundle branch block</td>
<td>4 (14.3%)</td>
<td>3 (10.7%)</td>
<td>4 (14.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right bundle branch + LAFB</td>
<td>1 (3.6%)</td>
<td>1 (3.6%)</td>
<td>1 (3.6%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are given as mean ± standard deviation or as number (%); LAFB = left anterior fascicular block.

P1 = comparison of preprocedural and postprocedural values; P2 = comparison of preprocedural and discharge values.

Conclusion

In this study, EPS and ECG findings during the procedure revealed fewer conduction problems with Edwards SAPIEN prosthesis compared to CoreValve prosthesis similar to previous studies. In addition, the effect of Edwards SAPIEN on the conduction system was mostly temporary and infranodal. The physical properties of the Edwards SAPIEN prosthesis may explain this observation. This complication may be lessened if the frame height characteristics can be improved.

References

9. Lang RM, Bierig M, Devereux RB, et al. Recommendations for chamber quantification: a report from the American Society of Echocardiography’s Guidelines and Standards Committee and the Chamber Quantification Writing Group, developed in conjunction with the European Association of Echocardiography, a branch of the European Society of Cardiology. *J Am Soc Echocardiogr*. 2005;18(12):1440-1463.