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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has become a valid option for treating severe symptomatic aortic stenosis (SASS) in high-risk patients or in patients with serious contraindications to aortic valve replacement.[1,2] Following TAVI, electrical conduction abnormalities are known to occur,[3-16] leading to the placement of a permanent pacemaker (PM) in 5–46% of cases [17-21].

The aim of the present study was to describe the post-procedural and 1-year follow-up incidence of heart conduction disturbances in patients with SASS undergoing TAVI using either the Edwards SAPIEN (Edwards Lifescience, Irvine, CA, USA) or the CoreValve ReValving System (Medtronic, Minneapolis, MN, USA) prosthesis.

MATERIALS AND METHODS

From May 2008–July 2011, all consecutive patients with SASS that underwent TAVI at the Città della Salute e della Scienza Hospital in Torino, Italy, were analyzed. All patients provided written informed consent before the procedure and acknowledged the follow-up period. The study was performed according to the principles of the latest updates of Declaration of Helsinki. Consecutive patients with SASS, diagnosed following the American Society of Echocardiography criteria, were considered at high or prohibitive surgical risk according to the position statement from the European Society of Cardiology based on a Logistic EuroSCORE ≥ 20%, the Society of Thoracic Surgeons predicted risk of mortality (STS-PROM) ≥ 10% or because they presented serious contraindications to aortic valve replacement.[22,23]

A multidisciplinary heart team evaluated each patient to identify either a retrograde or anterograde approach, depending on the presence of vascular disease or other comorbidities.[23,24 A] Edwards SAPIEN (Edwards Lifescience, Irvine, CA, USA) or CoreValve ReValving System (Medtronic, Minneapolis, MN, USA) prosthesis was selected and implanted as described elsewhere,[24] according to peripheral access conditions, aortic annulus diameter, aortic anatomy, and random prosthesis availability.

Reported clinical parameters, EuroSCORE, EuroSCORE II and STS-PROM scores were calculated the day before or on the same day as the procedure. Peri-procedural complications were assessed according to the Valve Academy Research Consortium (VARC).[25] In particular the "life threatening bleeding" was considered when patients experienced a drop of hemoglobin >5 g/dL or received packed red blood cells transfusions ≥4, regardless if considered "overt". This was decided to delete the subjectivity of the "overt" parameter. A 12-lead surface electrocardiogram (ECG) was recorded at 25 mm/s in our outpatient clinic at baseline, at discharge (6, interquartile range [IQ] 5–8 days), and at 3 (85, IQ 67–107 days), 6 (200 days, IQ 182–226 days) and 12 months (389 days, IQ 364–463 days) following TAVI. Four

patients (4.2 %) were unable to travel to the hospital and had their ECG sent by fax, mail or e-mail. Patients in whom a PM was implanted at discharge or during the follow-up, although followed regularly, progressively left the study.

The following parameters were analyzed on each ECG recording: cardiac rhythm, heart rate, PQ interval, QRS width, and QT interval corrected by heart rate using Bazett's formula. In addition, the presence of atrioventricular (AVB) or intraventricular block as complete right bundle branch block (RBBB), left bundle branch block (LBBB), left anterior fascicular block, and left posterior fascicular block were recorded.

Statistical analysis

Categorical variables are presented as counts and percentages and continuous variables as means ± standard deviation or as median and upper and lower IQ when a normal distribution had not been confirmed. Parametric distribution of included variables were tested and statistics performed according to it. Continuous variables were compared by a paired Student's t-test and repeated measures ANOVA when the degree of freedom was > 1. Dichotomic variables were analyzed by the Yates corrected χ^2 square or McNemar test, as appropriate. Statistical significance was set at $p < 0.05$. All analyses were performed using SPSS, version 13.0 (SPSS Inc., Chicago, IL).

RESULTS

Among the 102 consecutive patients undergoing TAVI, 95 were prospectively enrolled in the study. (Figure 1) We excluded five (4.9%) patients who received a previously implanted PM and two (1.9%) patients in whom the chosen Edwards trans-femoral approach failed. Baseline characteristics of the study population are shown in Table 1, stratified by procedural approach. The mean age was 81.8 ± 7.2 years and 60 (63.1%) patients were female. The logistic EuroSCORE was 19.9 ± 11.6 and 75 (78.9%) patients were in NYHA class III or IV. Fifty-seven (60%) patients received an Edwards SAPIEN prosthesis with 31 (32.6 %) by a trans-apical (ES-TA) and 26 (27.4 %) by a trans-femoral (ES-TF) approach, while 38 (40%) patients received a CoreValve (CV) prosthesis with one by a trans-subclavian approach. The procedural success rate was 95%, according to the VARC definition. Two (2.1%) patients, both in the ES-TF group, died during the procedure due to left main coronary artery obstruction or prosthesis embolization in the left ventricle. Intra- and peri-procedural bleeding occurred in 65 (68.4%) patients. Among these, 43 (66.2%) were considered life threatening, 21 (32.3%) considered major and 1 (1.5%) considered minor. Twenty-eight (29.5%) and five (5.3%) patients suffered from major and minor vascular complications, respectively.

ECG characteristics at admission and discharge, stratified by procedural approach, are shown in Table 2. At baseline, the PQ interval ($p = 0.45$), QRS width ($p = 0.15$) or atrioventricular or interventricular conduction disturbances did not differ among the patients. Following TAVI prior to discharge, 11 (11.6%) patients were implanted with a PM (7 CV, 3 ES-TA, 1 ES-TF; $p = 0.18$) due to abrupt high grade AVB, which emerged in 10 patients within the first week and in one case 13 days after the procedure. Among the 82 survivors not receiving a PM, TAVI increased the PQ interval (176 ± 29 vs. 188 ± 36 msec; $p = 0.001$), QRS width (90 ± 15 vs. 108 ± 26 msec; $p < 0.001$) and first grade AVB (17 vs. 29%; $p < 0.001$). Post-procedural LBBB was reported more frequently in the ES-TA (from 10–36 %, $p = 0.01$) and CV (from 8–64 %, $p < 0.001$) groups compared to the ES-TF group (from 0–13%, $p = 0.19$).

Follow-up

During the 1-year follow-up, 24 (25.3%) patients died, including 4 patients implanted a PM before discharge excluded from the study. Among the remaining 20 patients, 8 died due to sepsis, 3 to heart failure, 3 to acute renal failure, 2 to stroke, and one each due to respiratory insufficiency and cancer. Two patients died of sudden cardiac death at home, both 86-year old females that received a CV prosthesis. The first patient died on post-operative day 57, 10 days following rehabilitation clinic discharge where a stable ECG was recorded. The second patient died 5 months after the procedure. In this case, the ECG at rehabilitation clinic discharge showed an increased QT interval (520 vs. 460 msec at discharge). Unfortunately, this patient unfortunately did not attend the 3-month follow-up visit.

Four patients (2 CV, 2 ES-TA) required late PM implantation. One patient in the CV group received a PM on post-operative day 27 due to progressive high-degree AVB that occurred during the stay at the rehabilitation clinic. The

second patient in the CV group received a bicameral PM 8 months following the procedure due to dizziness related to atrial flutter episodes with variable atrioventricular conduction (maximum pause 2.8 s detected by a 24-h ECG recording). Two patients in the ES-TA group received a PM 6 months after TAVI; the first due to an acute episode of third degree AVB and the second due to mild symptomatic chronotrope incompetence that was present at baseline.

Figure 2 shows the PQ interval and QRS width trends during 1 year of follow-up among survivors not receiving a PM. From discharge to the 3-month follow-up, the PQ interval (186 ± 37 vs. 177 ± 24 msec, p = 0.01) and QRS (108 ± 26 vs. 100 ± 22 msec, p = 0.001) decreased, the latter driven principally by patients in the ES-TA (110 ± 24 msec vs. 102 ± 18, p = 0.01) and CV (QRS 115 ± 26 vs. 107 ± 25 msec, p = 0.02) groups. No significant differences were noted concerning AVB and intraventricular conduction disturbances. ECG recordings at the 6-month follow-up were superimposable to those at the 3-month follow-up (data not shown). ECG characteristics at discharge and 12-month follow-up, stratified by procedural approach, are reported in Table 3. The PQ interval (178 ± 27 vs. 188 ± 36 msec, p = 0.39) remained stable, while the QRS width (100 ± 22 vs. 108 ± 26 msec, p = 0.008) decreased, particularly among patients in the CV group (118 ± 26 vs. 107 ± 26, p = 0.04). In addition, the QT interval (431 ± 29 vs. 417 ± 27 msec, p = 0.01) decreased, particularly among patients in the ES-TA group (415 ± 30 vs. 444 ± 33, p = 0.006).

Prosthesis sub-study analysis

Conduction abnormalities following TAVI were stratified by prosthesis type and size (Appendix, Table A and B). Twenty-one patients were implanted with a 23-mm ES and 32 patients with a 26-mm ES prosthesis, while 15 and 16 patients were implanted with a 26- and 29-mm CV, respectively. The conduction abnormalities described following TAVI in the general population were stratified by prosthesis type and size in each subgroup; the results suggested no clear association with these parameters. However, a multivariate analysis of the relationship between these parameters was not performed due to the poor statistical power due to the small sample size.

DISCUSSION

The different incidence of conduction disturbances following various TAVI procedures suggested to analyze three subgroups of patients. Indeed the CoreValve ReValving System has been demonstrated to have higher incidence of PM.[26] Depth has been demonstrated to be the most important predictor factor for the onset of conduction disturbances.[27] Thus the more reliable deployment of transapical compared to transfemoral prosthesis, because of the short distance to the target and the direct feedback from the rigid but steerable catheter, lead us to the assumption that also the approach could affect the rhythm conduction.

Following TAVI, electrical conduction abnormalities of the heart are known to occur.[3-21] In this study, patients undergoing TAVI suffered a significant increase in atrio-ventricular (PQ interval) and intra-ventricular (QRS width) conduction times. Patients who were implanted with a CV prosthesis have the highest incidence of first-degree AVB and LBBB. Nevertheless, during 1 year of follow-up, conduction abnormalities within survivors not receiving a PM stabilized and an overall significant decrease in QRS width was recorded. In addition, 11 (11.6%) patients required PM implantation following TAVI, which was seemingly not influenced by the procedural approach allocated (p = 0.18). These data correlate with a recent review by Bates *et al.*, which reported that the incidence of PM implantation was 14.2% overall, reaching 20% in patients who received a CV prosthesis.[18] Despite recent evidence of the association between conduction disturbances and baseline ECG and procedural parameters, such as LBBB with left axis deviation and inter-ventricular septum >17 mm, RBBB and paroxysmal AVB episodes during the procedure, preoperative bradycardia, over-sizing prosthesis, a confirmatory multivariate analysis was not performed in the present study due to the limited sample size.[13-21] Moreover, the finding that first grade AVB and QRS width increased more in patients approached by CV confirms previous reports that the self-expandable characteristic of this prosthesis may have a greater effect on the nearby electrical structures. [9,13,16,17,18]

Compared to its own baseline the ES-TA surprisingly reported higher rate of post-procedural LBBB compared to the other two groups. Probably the more accurate deployment of the prosthesis affected the atrio-ventricular conduction as a consequence of a major pressure applied on the conducting tissues. Only a higher sample size could reveal if this theory is realiable.

The most original finding of our study is the long-term follow-up of conduction disturbances following TAVI, which partially addresses a point raised by Bates *et al.*, regarding the follow-up required.[18] The observation of a progressive reduction in QRS width after 12 months of follow-up compared to discharge (108 ± 26 vs. 100 ± 22 msec, p = 0.008), particularly in the CV group (p=0.04), was surprising. This trend was evident in patients treated by CV at 3 months after the procedure with a reduction in the QRS from 115 ± 6 to 107 ± 25 msec (p =0.02). Based on these results, we hypothesize that a progressive stabilization of the auto-expandable process may increase the risk of conduction disturbances only during the acute phase, which occurs in-hospital and the rehabilitation clinic.

The mortality due to sudden cardiac death and the fact that some patients required late PM implantation deserves attention. Among these patients, in three cases late conduction disturbances could not be excluded as causative (one patient due to sudden cardiac death, having exhibited an increased QT interval in the last available ECG, and two patients due to abrupt AVB at 1 and 6 months following the procedure). Despite the increased QT interval in one case, unfortunately, the retrospective analysis of both clinical and ECG features of these patients resulted in identification of no predictive factors.

Conclusions

Patients undergoing TAVI, particularly those receiving a CV prosthesis, can suffer post-procedural atrioventricular and intraventricular conduction disturbances. In our population, 11% of patients required a PM, irrespective of the procedural approach, although following hospital discharge the conduction disturbances stabilize over time. However, the small percentage of patients suffering late sudden death and PM implantation requires special attention by physicians.

Study limitations

This was a single-center prospective observational study further limited by the fact that neither patient randomization nor prosthesis selection was performed. In addition, the small number of enrolled patients was not sufficient for additional analysis and the data were self-reported with no adjudication.

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Conflicts of interest

None declared.

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