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ORIGINAL ARTICLE

Predictors of permanent pacemaker implantation after transcatheter aortic valve implantation for aortic stenosis using Medtronic new generation self-expanding CoreValve Evolut R

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Abstract
Conduction disturbance requiring permanent pacemaker (PPM) implantation is a common complication after transcatheter aortic valve implantation (TAVI) using Medtronic self-expanding CoreValve, and has remained common following the introduction of the new generation CoreValve Evolut R device. The aim of this study was to identify the determinants of PPM implantation after TAVI with CoreValve Evolut R. We retrospectively examined 114 patients who underwent transfemoral TAVI using CoreValve Evolut R. We excluded 17 patients with preprocedural PPM, 1 patient requiring Edwards SAPIEN 3 implantation after CoreValve Evolut R implantation, and 4 patients who died during the hospital admission. Thus, 92 patients were finally included in the analysis. Seventeen patients (18%) underwent new PPM implantation after TAVI. Preprocedural electrocardiography showed a lower ventricular rate and more right bundle branch block (RBBB) in patients with new PPM implantation compared to those without. Quantitative multidetector computed tomography assessment revealed larger aortic valve calcification (AVC) and higher asymmetry (ΔAVC) in patients with new PPM implantation compared to those without. The univariate logistic regression analysis demonstrated that preprocedural ventricular rate ≤ 70 beats per minute, RBBB, AVC ≥ 110 mm^3, and ΔAVC ≥ 45 mm^3 were associated with new PPM implantation. Number of these factors clearly stratified the risk of new PPM implantation. In conclusion, PPM implantation occurs in 18% of patients undergoing TAVI with the new generation CoreValve Evolut R. Lower preprocedural ventricular rate, RBBB, larger AVC, and higher ΔAVC are associated with new PPM implantation after TAVI using the new generation CoreValve Evolut R.

Keywords Transcatheter aortic valve implantation · Permanent pacemaker implantation · Self-expanding CoreValve Evolut R · Right bundle branch block · Aortic valve calcification

Introduction

Transcatheter aortic valve implantation (TAVI) is a novel and less invasive therapeutic option for patients with severe aortic stenosis (AS) and a prohibitive or high conventional surgical risk [1–4]. Despite the continuous development of this procedure, high-grade conduction disturbance requiring subsequent permanent pacemaker (PPM) implantation is still a major complication of TAVI. The previous studies have shown that the rates of PPM implantation after TAVI with Medtronic self-expanding CoreValve (Medtronic, Inc., Minneapolis, MN, USA) was approximately 25–35%, and higher than other devices [5–7]. CoreValve Evolut R is a new generation self-expanding prosthesis, and is the most widely used prosthesis in the current TAVI procedure. However, PPM implantation still remains a common complication. Moreover, the risk factors for new PPM implantation after TAVI with this novel device have not yet been established. Currently, the further expansion of the indication of TAVI to surgical intermediate-risk or low-risk patients with AS is a subject of great debate. Given that CoreValve Evolut R is currently one of the most commonly used standard devices for TAVI, it is critical to identify the determinants of new

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PPM implantation at this timing. Therefore, we aimed to clarify the predictors of PPM implantation after TAVI with the new generation CoreValve Evolut R.

Patients and methods

Study population

We retrospectively examined 114 patients who underwent preprocedural cardiac computed tomographic angiography and transfemoral TAVI with a self-expanding CoreValve Evolut R at the Heart Center Brandenburg (Bernau bei Berlin, Germany) between February 2015 and April 2017. Seventeen patients who had a preprocedural PPM, 1 patient requiring Edwards SAPIEN 3 implantation due to the dislocation of the initial CoreValve Evolut R implantation, and 4 patients who died during the hospital admission after TAVI [due to myocardial infarction (2 patients), cardiac tamponade, and pneumonia] were excluded. Thus, 92 patients were finally included in the analysis. AS was diagnosed on the basis of the mean transvalvular pressure gradient and aortic valve area, calculated using the continuity equation. PPM implantation was performed according to the European guidelines for cardiac pacing and resynchronization therapy [8].

Ethics

The ethical committee of our institute approved the protocols of this study. All patients were informed of the specific risks and alternative treatments, and provided informed consent. This study was performed in accordance with the Declaration of Helsinki.

Preprocedural cardiac computed tomographic angiography

As previously described [9], patients underwent cardiac computed tomographic angiography using a 128-slice system (SOMATOM AS+, Siemens, Munich, Germany) with tube voltage of 100–120 kV and tube current based on patient size before TAVI. We performed a single-volume acquisition with a prospective electrocardiographic trigger during an inspiratory breath-hold. Nonionic contrast agent (iodixanol) was intravenously injected at a rate of 3.5 mL/s (100–120 mL). Images were reconstructed with a slice thickness of 0.75 mm.

Measurements by using 3mensio

We performed aortic annulus measurements using 3mensio Structural Heart software, version 7.2 (3mensio Medical Imaging BV, Bilthoven, The Netherlands) [10, 11]. Briefly, the three-dimensional multidetector computed tomography (MDCT) aortic annulus measurements included area, perimeter, and minimal and maximal diameters. Aortic root measurements were mainly performed in the mid-systole. All observers were blinded to the background characteristics.

Aortic valve calcium (AVC) was measured using 3mensio Structural Heart software with a threshold of 850 Hounsfield units [9, 12]. Calcium in left, right, and noncoronary cusp was quantified separately using the "Mercedes Benz" tool for localization (Fig. 1a). For calcium quantification, the total calcium volume in the aortic root was measured from 5 mm inferior to the annulus plane to the superior edge of the leaflets (Fig. 1b). Asymmetry (ΔAVC) was assessed using the maximum absolute difference in volume scores between any 2 leaflet sectors.

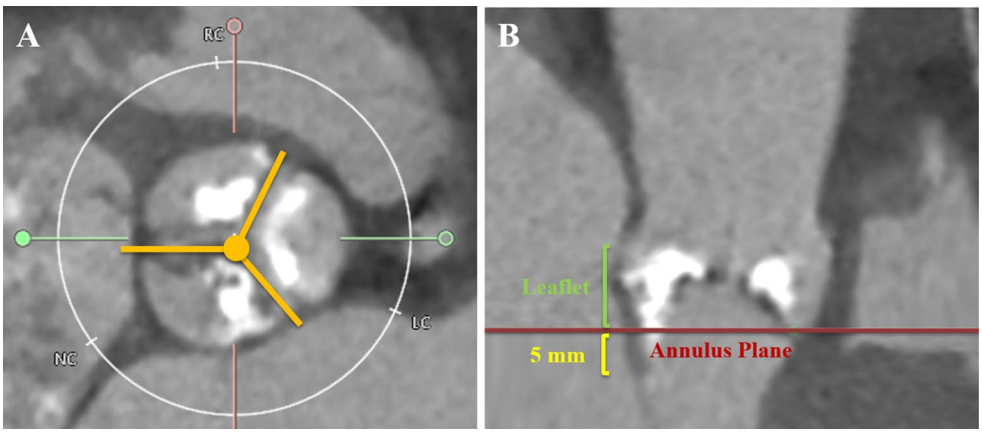

Fig. 1 Assessment of aortic valve calcium. **a** Calcium in left, right, and noncoronary cusp was quantified separately using the "Mercedes Benz" tool for localization. **b** Total calcium volume in the aortic root was measured from 5 mm inferior to the annulus plane to the superior edge of the leaflets

The CT_{area}-derived diameter was calculated using the following equation: $2 \times \sqrt{CT_{area}}$ $(mm^2)/\pi$. The $CT_{perimeter}$-derived diameter was determined as: perimeter (mm)/π. The percentage of oversizing was calculated using the following formula: % oversizing = (prosthesis diameter/annulus diameter − 1) × 100.

Statistical analysis

Categorical and continuous data regarding are presented as numbers (%) and mean ± standard deviation, respectively. The Chi-square test was used for comparisons between groups, and the unpaired *t* test was used for comparison of consecutive variables between patients with new PPM implantation and those without new PPM implantation. Receiver-operating characteristic (ROC) curves were generated using new PPM implantation rate and the area under the curve (AUC) was calculated. Cut-off values for ventricular rate, AVC, and ΔAVC were determined by the ROC analysis with the highest combination of sensitivity and specificity. We conducted a univariate logistic regression analysis to identify the predictors of PPM implantation. *p* value of < 0.05 was considered to indicate statistical significance. Analyses were performed using SPSS version 19.0 software (SPSS Inc., Chicago, IL, USA).

Results

Patients' characteristics

Baseline clinical characteristics of the study patients are summarized in Table 1. The mean age was 82 ± 7 years and 67% of the patients were female. The mean logistic euroSCORE was 17 ± 13%. Approximately eighty percent of patients had severe heart failure symptoms (≥ NYNA class III). There were no significant differences in clinical characteristics between patients with and without new PPM implantation. The following sizes of CoreValve Evolut R were successfully implanted: 23 mm in 1 patient (1%); 26 mm in 19 patients (21%); 29 mm in 56 patients (61%), and 34 mm in 16 patients (17%). The peak and mean pressure gradients after CoreValve Evolut R implantation were 16 ± 8 and 9 ± 5 mmHg, respectively. Only one patient (1%) had moderate paravalvular regurgitation. Severe paravalvular regurgitation was not observed. A total of 17 patients (18%) required PPM implantation after TAVI with a CoreValve Evolut R [due to advanced atrioventricular (AV) block third degree in 15 patients and atrial fibrillation with long pause in 2 patients]. Among 17 patients required PPM implantation, 10 patients (59%) underwent PPM implantation on or after post-operative day 3 (Fig. 2).

Preprocedural electrocardiography

There were also no significant group differences in preprocedural rhythm, PR duration, QRS duration, prevalence of AV block, and left bundle brunch block (LBBB). However, the preprocedural ventricular rate was lower (70 ± 10 vs. 79 ± 13 beats per minute (bpm), $p = 0.001$), and prevalence of right bundle brunch block (RBBB) was higher (24% vs. 7%, $p = 0.035$) in patients with new PPM implantation compared to that in patients without PPM implantation (Table 1).

Preprocedural echocardiography

Preprocedural echocardiographic findings are shown in Table 1. All patients had severe AS. The average aortic valve area was 0.7 ± 0.2 cm^2. The peak and mean pressure gradients were 71 ± 25 and 47 ± 18 mmHg, respectively. There were no significant group differences in the severity of AS, preprocedural left ventricular ejection fraction, and prevalence of other valvular diseases.

Aortic valve calcification

The average AVC and ΔAVC were 242 ± 270 and 90 ± 102 mm^3, respectively. Based on the ROC curves, the cut-off values for AVC and ΔAVC were determined as 110 and 45 mm^3, respectively. AVC ≥ 110 mm^3 and ΔAVC ≥ 45 mm^3 were both more commonly observed in patients with new PPM implantation than in those without PPM implantation (88% vs. 56%, $p = 0.013$; 82% vs. 52%, $p = 0.022$, respectively) (Table 2).

Size of CoreValve Evolut R and rate of post-dilatation

The size of CoreValve Evolut R was not different between patients with and without PPM implantation. Patients with and without PPM implantation did not significantly differ in area-derived and perimeter-derived oversizing (26.9 ± 5.2% vs. 25.6 ± 6.8%, $p = 0.464$, 24.1 ± 4.9% vs. 23.1 ± 6.6%, $p = 0.591$, respectively). The rate of post-dilatation was comparable between patients with and without PPM implantation (29.4% vs. 25.3%, $p = 0.730$, respectively).

Predictors of PPM implantation

The univariate logistic regression analysis showed that ventricular rate ≤ 70 bpm, RBBB, AVC ≥ 110 mm^3, and ΔAVC ≥ 45 mm^3 were associated with subsequent conduction disturbance requiring PPM implantation (Table 3). The number of risk factors including ventricular rate ≤ 70 bpm, RBBB, AVC ≥ 110 mm^3, and ΔAVC ≥ 45 mm^3 was clearly correlated with new PPM implantation rate (Fig. 3).

Table 1 Baseline clinical characteristics

Variable	No PPM ($n=75$)	PPM ($n=17$)	p value
Age (years)	82 ± 7	80 ± 9	0.204
Female gender	53 (71%)	9 (53%)	0.159
Body mass index (kg/m^2)	24 ± 11	25 ± 6	0.671
Hypertension	58 (77%)	13 (77%)	0.939
Diabetes	49 (65%)	13 (77%)	0.376
Hyperlipidemia	26 (35%)	3 (18%)	0.173
eGFR (mL/min/1.73 m^2)	63 ± 22	58 ± 25	0.494
CKD	36 (48%)	9 (53%)	0.713
Prior history of MI	8 (11%)	2 (12%)	0.896
Logistic euroSCORE (%)	17 ± 14	17 ± 13	0.888
NYHA Class			0.180
II	18 (24%)	1 (6%)	
III	55 (73%)	16 (94%)	
IV	2 (3%)	0 (0%)	
Preprocedural electrocardiography			
Ventricular rate (bpm)	79 ± 13	70 ± 9	0.001
Ventricular rate ≤ 70 bpm	20 (27%)	11 (65%)	0.003
Sinus rhythm	48 (64%)	13 (77%)	0.326
Atrial fibrillation	27 (36%)	4 (24%)	0.326
PQ duration (ms)	186 ± 56	188 ± 60	0.922
QRS duration (ms)	103 ± 21	111 ± 22	0.218
First-degree AV block	13/48 (27%)	4/13 (31%)	0.793
LBBB	7 (9%)	0 (0%)	0.190
RBBB	5 (7%)	4 (24%)	0.035
Preprocedural echocardiography			
Aortic valve area (cm^2)	0.7 ± 0.2	0.7 ± 0.2	0.655
Peak pressure gradient (mmHg)	73 ± 26	63 ± 23	0.155
Mean pressure gradient (mmHg)	48 ± 18	42 ± 16	0.176
LVEF (%)	54 ± 9	51 ± 10	0.233
LVEF ≤ 40%	11 (15%)	3 (18%)	0.757
AR ≥ moderate	18/73 (25%)	6/16 (38%)	0.294
MR ≥ moderate	24/73 (33%)	5/16 (31%)	0.900
TR ≥ moderate	19/67 (28%)	4/13 (31%)	0.860

Data are expressed as mean ± standard deviation or number (percentage)

PPM permanent pacemaker, *eGFR* estimated glomerular filtration rate, *CKD* chronic kidney disease, *MI* myocardial infarction, *NYHA* New York Heart Association, *bpm* beats per minute, *AV* atrioventricular, *LBBB* left bundle branch block, *RBBB* right bundle branch block, *LVEF* left ventricular ejection fraction, *AR* aortic regurgitation, *MR* mitral regurgitation, *TR* tricuspid regurgitation

Discussion

The principal findings of our study are the following: (1) new PPM implantation was required in 18% of patients undergoing transfemoral TAVI using CoreValve Evolut R prosthesis; (2) the preprocedural ventricular rate was lower and RBBB was more frequently observed in patients requiring PPM implantation; (3) a larger AVC and ΔAVC was more commonly observed in patients requiring PPM implantation.

Cardiac conduction disturbances requiring subsequent PPM implantation frequently occurs after both TAVI and conventional surgical aortic valve replacement (SAVR) due to the close anatomical proximity of the atrioventricular conduction system to the aortic valvular complex and the high prevalence of comorbid conduction system disease in patients with advanced AS [13, 14]. The PPM implantation rate of the Medtronic self-expanding CoreValve ranges from 25 to 35% [5–7], and is substantially higher compared to that of SAVR (around 5%) and TAVI using Edwards balloon-expandable SAPIEN valve (Edwards Lifesciences, Irvine, CA, USA) (5–10%). The higher rate of PPM implantation with CoreValve is attributed to the different device structures and self-expanding device character, which could influence

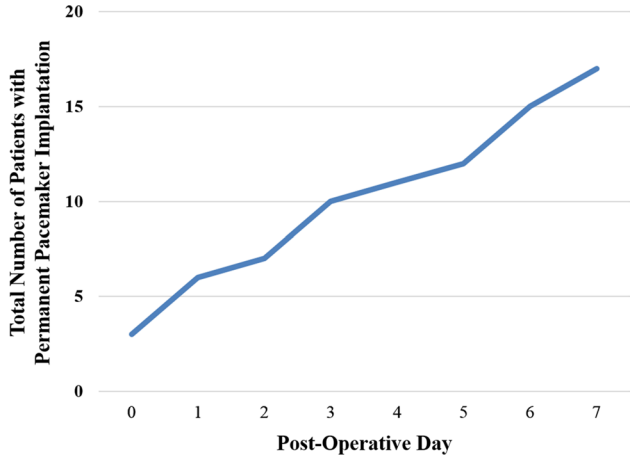

Fig. 2 Timing of permanent pacemaker implantation. Permanent pacemaker implantation continues to occur without attenuation during 7 days after transcatheter aortic valve implantation with the new generation CoreValve Evolut R

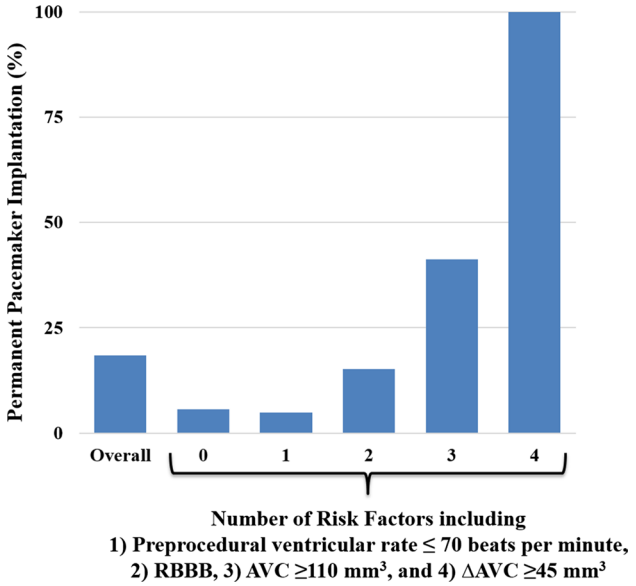

Fig. 3 Rate of permanent pacemaker implantation. The rate of permanent pacemaker implantation after transcatheter aortic valve implantation with the new generation CoreValve Evolut R increases with the number of risk factors including preprocedural ventricular rate ≤ 70 bpm, right bundle brunch block, AVC ≥ 110 mm^3, and ΔAVC ≥ 45 mm^3

Table 2 Aortic valve calcification

Variable	No PPM ($n=75$)	PPM ($n=17$)	p value
AVC ≥ 110 mm^3	42 (56%)	15 (88%)	0.013
ΔAVC ≥ 45 mm^3	39 (52%)	14 (82%)	0.022

Data are expressed as number (percentage)

AVC aortic valve calcification

Table 3 Predictors of PPM implantation

Variable	p value	OR	95% CI
Ventricular rate ≤ 70 bpm	0.005	5.0	1.6–15.4
RBBB	0.047	4.3	1.0–18.2
AVC ≥ 110 mm^3	0.024	5.9	1.3–27.6
ΔAVC ≥ 45 mm^3	0.031	4.3	1.1–16.2

PPM permanent pacemaker, *OR* odds ratio, *CI* confidence interval, *bpm* beats per minute, *RBBB* right bundle branch block, *AVC* aortic valve calcification

the radial force exerted on the conduction system [15, 16]. This complication is considered an "Achilles' tendon" of CoreValve prosthesis.

After the introduction of the new generation self-expanding CoreValve Evolut R, the rate of PPM implantation became relatively decreased; however, the rate still remains relatively high [17]. Since the new generation CoreValve Evolut R is the most widely used TAVI device, along with Edwards SAPIEN 3, it is necessary to identify the predictors of post-procedural PPM implantation after TAVI with CoreValve Evolut R. In the present study, 18% of patients undergoing TAVI with CoreValve Evolut R required PPM implantation due to subsequent conduction disturbance, which is similar to that reported in preceding studies on TAVI with CoreValve Evolut R [18–20]. Thus, we believe that our study provides a snapshot of the real-world clinical demographic data for the CoreValve Evolut R.

Furthermore, it should be noted that approximately 60% of patients underwent PPM implantation on or after post-operative day 3. In the latest guideline, the close heart rhythm observation including ECG monitoring is strongly observed up to 7 days after TAVI (Class I) [21]. In addition, CoreValve Evolut R is a self-expanding prosthesis, and therefore, the persistent and progressive damage in conduction system could occur. Hence, we believe that our result emphasizes the importance of the guideline adherence.

Various electrocardiographic factors are thought to influence the incidence of subsequent conduction disturbance after TAVI and are suggested as predictors of PPM implantation, such as bradycardia, atrial fibrillation (AF), PR interval, AV block, LBBB, and RBBB. In the present study, patients with and without new PPM implantation did not significantly differ in the baseline rhythm, AF, PR interval, or the prevalence of AV block and LBBB. Lower ventricular rate (≤ 70 bpm) and RBBB was associated with an increased risk of PPM implantation. These results are concordant with the previous studies including CoreValve [15, 22]. Therefore, the close heart rhythm observation would be required in patients with ventricular rate ≤ 70 bpm and RBBB as

high-risk subsets for PPM implantation after TAVI using CoreValve Evolut R.

AVC is associated with various complications of TAVI. Latsios et al. reported that AVC increased the need for PPM implantation after TAVI with a CoreValve [23]. However, the association between AVC and PPM implantation after TAVI with the new generation CoreValve Evolut R was not addressed in the previous studies. In addition, AVC was assessed based on the semi-quantitative Agston score in the study by Latsios et al. [23] and there are no relevant data assessing AVC quantitatively. Thus, we examined AVC using a quantitative evaluation in the present study. Furthermore, we measured AVC separately in each coronary cusp in order to evaluate asymmetry (ΔAVC). A larger volume of AVC (≥ 110 mm^3) and ΔAVC (≥ 45 mm^3) were both associated with new PPM implantation. This result suggests that not only the total volume of AVC but also asymmetric calcification patterns might increase the interaction of the implanted CoreValve Evolut R with the conduction system, damaging the conduction system and resulting in a higher new PPM implantation rate.

The mechanisms of subsequent conduction disturbance after TAVI are multifactorial, and other factors could be associated with this complication. For example, oversizing could also lead to subsequent damage to the conduction system [15, 24]. However, there was no significant different in oversizing percentage between patients with and without PPM implantation after TAVI with CoreValve Evolut R. Although post-dilatation might also affect the rate of PPM implantation, the rate of post-dilatation was not difference between patients with and without new PPM implantation, suggesting that a short period of high-pressure compression to the aortic annulus through the post-dilatation of CoreValve Evolut R device might not cause irreversible damage against the conduction system.

The present study has important clinical implications. Currently, the number of patients undergoing TAVI is rapidly increasing worldwide. Given the favorable result of recent randomized trials focusing on TAVI for intermediate-risk patients with AS [25, 26], the indication of TAVI could be further expanded. Hence, it is critical to minimize the risk of life-threatening complications of TAVI. Subsequent conduction disturbance requiring PPM implantation is the most frequent adverse event [27] and could limit the clinical benefits of TAVI. This complication is associated with a prolonged hospital stay and increased procedural cost [28]. Nazif et al. reported that PPM implantation was associated with a longer duration of hospitalization and higher rates of repeat hospitalization and mortality or repeat hospitalization [29]. Furthermore, our data clarifies the incidence and the timing of new PPM implantation and emphasizes the importance of ECG monitoring based on the latest guidelines [21]. Using the simple candidate predictors suggested in this study, the risk of PPM implantation after TAVI with CoreValve Evolut R could be simply evaluated. Therefore, we believe that our data provide further information regarding clinical decision-making, risk stratifying, and device selection for future patients undergoing TAVI.

Study limitations

There are several limitations in the present study to acknowledge. The presented data are from a single center experience and the sample size is limited. Therefore, the statistical power might not be sufficient for any negative data to be conclusive and the multivariable logistic regression analysis was not performed. Further studies with larger sample size are required. In addition, we could quantitatively measure the implantation depth in a limited number of patients due to a low contrast volume for aortography after CoreValve Evolut R implantation. Hence, we did not include this parameter, which might have affected the results [30]. The indication for PPM implantation and its timing might influenced by various factors. For example, a relatively aggressive PPM implantation was opted for patients with severe comorbidities to avoid hemodynamic instability due to conduction disturbance. AVC and ΔAVC are possible confounding factors. We have no data regarding medications including β blockers prior to TAVI.

Conclusion

Permanent pacemaker implantation remains a common complication of TAVI with new generation self-expanding CoreValve Evolut R implantation. A lower preprocedural ventricular rate (≤ 70 bpm), RBBB, larger AVC (≥ 110 mm^3) and higher ΔAVC (≥ 45 mm^3) are associated with the development of subsequent conduction disturbance requiring PPM implantation after TAVI using the new generation CoreValve Evolut R.

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Compliance with ethical standards

Conflict of interest We have no conflict of interest for this study.

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