Usefulness of membranous septum length in the prediction of major conduction disturbances in patients undergoing transcatheter aortic valve replacement with different devices

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Article type: Original article

Received: April 10, 2020.

Accepted: July 28, 2020.

Published online: July 29, 2020.

ISSN: 0022-9032
e-ISSN: 1897-4279
Usefulness of membranous septum length in the prediction of major conduction disturbances in patients undergoing transcatheter aortic valve replacement with different devices

**Short Title:** Usefulness of membranous septum length prior to TAVR

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This study includes no conflict of interest and no sources of any support for the work in the form of grants, equipment, drugs, or any combination of these.
What’s New?

The multidetector computed tomography assessment of membranous septum length prior to transcatheter aortic valve replacement can be a useful tool to guide appropriate device selection and subsequently reduce conduction disturbances. The risk of major conduction disturbances such as new-onset left bundle branch block and atrioventricular block requiring a permanent pacemaker implantation can be reduced by using a higher or more aortic implant height, not exceeding the length of the MS (ΔMSID > 0 mm), especially in self-expandable valves.
Abstract

**Background:** Conduction disturbances (CD) are one of the most common adverse events after transcatheter aortic valve replacement (TAVR), and seem to be dependent on the device used as well as anatomical factors.

**Aims:** The aim of this study was to evaluate whether the membranous septum (MS) length could provide useful information about the risk of CD and to examine the impact of MS on CD after TAVR using different devices.

**Methods:** This study included 140 patients undergoing TAVR with the balloon-expandable valve (BEV) or self-expanding valve (SEV). MS length was assessed using preoperative computed tomography. ΔMSID was calculated as MS length minus implantation depth.

**Results:** A total of 24 (17%) patients received a permanent pacemaker (PPM), 53 (38%) patients developed new-onset left-bundle branch block (LBBB) following TAVR. The MS length was shown to be the strongest independent predictor of new-onset LBBB (odds ratio [OR]: 3.05, 95% confidence interval [CI]: 1.96 to 4.77, \( P < 0.001 \)) and PPM implantation (OR: 3.76, 95% CI: 2.01 to 7.06, \( P < 0.001 \)). ΔMSID was also inversely associated with the development of LBBB and the need for PPM. In a head-to-head comparison, ΔMSID values were found to be statistically lower in the SEV group (-0.8 mm vs. 0.7 mm, \( P < 0.001 \)).

**Conclusions:** A short MS, and ΔMSID with negative value increase the risk of CD. Assessment of the MS length prior to TAVR might serve as an additional tool to guide clinical decision-making and appropriate device selection to reduce the risk of CD.

**Key words:** Conduction disturbance, left bundle branch block, membranous septum, permanent pacemaker implantation, transcatheter aortic valve replacement.
Introduction

Cardiac conduction disturbances (CD), which include the occurrence of left-bundle branch block (LBBB) and complete heart block (CHB) requiring permanent pacemaker implantation (PPM), are the most frequent complications following transcatheter aortic valve replacement (TAVR) [1-3]. The membranous septum (MS) is located at the base of the interleaflet triangle separating the non-coronary and right coronary leaflets of the aortic valve, which is closely related to the conduction pathways [4,5]. Thus, CD is thought to partly be due to the mechanical stress of deployment to the membranous septum, resulting in possible injury to the nearby AV node and left bundle branch.

Recent studies reported that assessment of the MS and left ventricular outflow tract (LVOT) anatomy with multidetector computed tomography (MDCT) prior to TAVR improves the ability to predict CD and our understanding of the mechanism by which it occurs [6-9]. A previous report showed that a short MS length predicted PPM implantation after TAVR with a self-expandable valve (SEV) [6]. The results of another study also indicated that a short MS length is a prominent risk factor for PPM implantation with a balloon-expandable valve (BEV) [7]. Conversely, two studies have shown conflicting results regarding whether there is an association between MS and CD in patients with BEV [8,9]. Although there is available information about the impact of MS on CD in patients receiving different transcatheter heart valve (THV) designs, inconsistencies and a lack of standardization lead to a lack of guidance for cardiac teams approaching a short MS. To date, no studies have summarized head-to-head trials comparing BEV and SEV.

The purpose of this study is to further elucidate TAVR-related new-onset LBBB and PPM implantation rates in patients with short MS and determine the respective PPM rates for different THV designs in patients with short MS to help guide patient-tailored THV selection.
Methods

Study population

We retrospectively examined 156 patients who undergoing transfemoral TAVR between January 2017 and February 2020. Exclusion from this study was performed due to the following reasons: (n = 6) insufficient quality of MDCT images, (n = 6) previously implanted PPM, (n = 2) requiring a second valve implantation in the same procedure due to valve migration, (n = 2) to die perioperatively (within first 24 hours) after TAVR. Therefore, the remaining 140 patients were enrolled the final study group. The patients were divided into two groups according to whether the CD developed or not. The protocol was approved by the local ethics committee (Clinical Trial Registration: 2019 - 76), and conducted according to the principles of the Declaration of Helsinki.

MDCT data acquisition protocol

All patients were scanned using a second-generation 320-row MDCT scanner (Aquilion ONE Vision Edition, Toshiba Medical Systems, Otawara, Japan). The aortic root was scanned with volume mode using a retrospective ECG-gated acquisition mode and the following parameters: 16 cm width, 100 kV, gantry rotation time of 275 milliseconds (ms), auto-mA maxed at 300 ms, acquisition over 1 heartbeat. The scan was acquired within a single breath hold and after a single bolus injection of iohexol 350 mg/mL (Ultravist 370, Bayer Schering Pharma, Berlin, Germany) using an automatic power injector at a rate of 3.5 mL/s, followed by 30 mL of saline chaser at a rate of 3 mL/s. Patients with a Body Mass Index (BMI) lower than 23 kg/m² had a 40 - 50 mL bolus, patients with a BMI between 23 and 30 had a 60 - 70 mL bolus and patients with a BMI over 30 had a 70 - 80 mL bolus. The bolus-tracking technique was used which was triggered using Region of Interest positioned in the descending thoracic aorta and a 180 Hounsfield Units threshold. The MDCT acquisitions of the patients were reconstructed with a soft kernel and a third-generation iterative reconstruction algorithm.
The aortic root volume was reconstructed with 10% increments from 0 to 90%. No β-blockers were used. All MDCTs were assessed in a consensus interpretation by an experienced radiologist and interventional cardiologist, both blinded to the clinical data.

**TAVR procedure**

Patients underwent TAVR after a careful evaluation and discussion by the heart team. All TAVR procedures were performed through transfemoral approach and under conscious sedation in a fully equipped hybrid operating room. Predilatation of the native aortic valve was performed according to operator’s choice. The optimal position of the valve was checked by fluoroscopically and a rapid pacing (160 to 200 beats/min) was triggered during the implantation of BEV as previously described [10]. A final control was performed by aortography. THV choices were based on the operators’ preference with regard to the patient’s individual characteristics and valve size was selected according to manufacturer’s recommendation. Two main categories of transcatheter aortic valve prostheses were compared: balloon-expandable Edwards Sapien XT (Edwards Lifesciences, Irvine, CA, USA) or self-expandable devices such as the Medtronic CoreValve Evolut R (Medtronic, Minneapolis, MN, USA) and St. Jude Portico valve valve (St. Jude Medical, St. Paul, MN, USA).

**Definitions**

MS length was measured as the distance from the aortic annular plane to the superior portion of the muscular interventricular septum in the modified coronal view (Figure 1A), as previously described [6]. Implantation depth (ID) was determined fluoroscopically in the implantation projection determined by using MDCT prior to TAVR [11]. ID was defined as the length of the stent frame from the basal plane to the left ventricular outflow tract (LVOT), measured at the septal side of the LVOT (on the side of the non-coronary cusp) (Figure 1B). The difference between MS and ID length was calculated using the following equation:
ΔMSID = MS − ID. The eccentricity of the aortic annulus was calculated by 1 –
(Dmin/Dmax) [12]. Calcification of basal ventricular septum was determined by MDCT (0 = no calcification, 1 = presence of calcification), as previously described [6]. Baseline
demographics, MDCT data, and procedural parameters were collected for each patient from
medical records as well as information regarding the development of CD and the need for
PPM after TAVR. A twelve-lead-electrocardiography was documented for all patients before
and daily after the procedure until hospital discharge. The new-onset LBBB was defined as
complete LBBB (QRS > 120 ms) that appeared after TAVR and was maintained at one week.

Statistical Analysis
Statistical analysis of the study was done with SPSS Version 24.0 program (SPSS Inc.,
Chicago, Illinois, USA). Whether variables show normal distribution were evaluated using
graphical (histograms, probability curves) and numerical methods (Kolmogorov-Smirnov’s
and Shapiro-Wilk). Continuous variables are expressed as mean (SD) or as median
(interquartile range) if not normally distributed. Categorical variables are presented as
frequency and percentage. The patients were divided into groups according to whether
developed LBBB and requiring PPM. For comparison of continuous variables, the Student t
test or Mann Whitney U test were used, as appropriate. Categorical variables were analyzed
with Chi-Square or Fisher's exact test. Logistic regression analysis was performed to
determine the predictors of PPM and LBBB. Univariate analysis included parameters with $P$
< 0.10 in binary comparisons. Multivariate analysis was performed to identify independent
predictors and seperated into two models: ante-factum prediction model (only pre-procedural
predictors) and post-factum prediction model (pre-procedural and post-procedural predictors).
In order to calculate the cut off values of independent predictors, receiver operator
characteristic (ROC) analysis was performed and the value with the highest sensitivity and
specificity value was considered as cut off. In more than 2 groups, statistical analysis of
numerical variables was done with Kruskal Wallis test and Tamhane's T2 test was used for post hoc analysis. If $P$ value $< 0.05$, it was considered statistically significant.

Results

Patients’ characteristics

Comparison of baseline demographic, clinical, imaging, and procedural parameters between patients who were performed PPM or developed new-onset LBBB is reported in Table 1. Mean age was 78 (8) years, the majority was female 63%, and the median predicted risk of mortality ‘Society of Thoracic Surgeons (STS) score was 7.0. Main baseline characteristics did not significantly different between the two groups except for chronic renal failure. In total, 24 (17%) patients received a PPM and 53 (38%) patients developed a new-onset LBBB following TAVR. Indications for PPM implantation included complete heart block ($n = 15$), Mobitz type II second-degree AV block ($n = 4$), development of LBBB with a prolonged PR interval and atrial fibrillation with slow ventricular response resulting in hemodynamic instability ($n = 5$).

MDCT and Procedural Characteristics

As seen in Table 1, the ratio of the valve perimeter, the mean dimensions and area of the native aortic valve annulus were not statistically significant. The eccentricity of the aortic annulus was not different between the groups. According to the MDCT parameters, the mean MS length in the study was 7.6 (1.1) mm. MS length was significantly shorter in patients with developed new-onset LBBB (6.9 [1.1] mm in its favor when compared to without LBBB 8.1 [0.9] mm, $P < 0.001$) and required PPM implantation (6.5 [0.9] mm in its favor when compared to without PPM 7.9 [1.0] mm, $P < 0.001$). We found that calcium in the basal septum was present in 18% patients undergoing TAVR and is predictive of new CD.

The rate of post-dilatation was comparable between patients with BEV and SEV. Greater ID into the LVOT was more likely to cause the development of LBBB (9.2 [1.8] mm vs. 6.8 [1.7]...
mm, \( P < 0.001 \) and PPM implantation (9.2 [1.7] mm vs. 7.4 [2.1] mm, \( P < 0.001 \)). Additionally, the mean \( \Delta \text{MSID} \) was 0.3 mm (IQR -2.1 - 1.8). The new-onset LBBB and PPM implantation were significantly higher in patients with lower \( \Delta \text{MSID} \) than in those without.

**Predictors of new-onset LBBB and PPM implantation**

Univariate and multivariate analyses examining the occurrence of new-onset LBBB and subsequent CD requiring PPM implantation are summarized in Table 2. Multivariable logistic regression of the antefactum prediction model indicated that MS length was the most strong independent predictor of new-onset LBBB (odds ratio [OR]: 3.05, 95% confidence interval (CI): 1.96 to 4.77, \( P < 0.001 \)). In the postfactum prediction model, \( \Delta \text{MSID} \) was the strongest independent predictor of new-onset LBBB (OR: 2.24, 95% CI: 1.71 to 2.94, \( P < 0.001 \)). Cover index\textsubscript{LVOT} and calcification in the basal septum were the other independent predictors. The univariate analysis showed that chronic kidney disease, eccentricity, calcification in the basal septum, cover index\textsubscript{LVOT}, MS, ID, and \( \Delta \text{MSID} \) were associated with PPM implantation (Table 3). According to the multivariate analysis, calcification in the basal septum significantly increased the odds of post-procedural PPM implantation \( (P = 0.007) \). MS length (OR: 3.76, 95% CI: 2.01 to 7.06, \( P < 0.001 \)) and \( \Delta \text{MSID} \) (OR: 1.68, 95% CI: 1.32 to 2.15, \( P < 0.001 \)) were powerful pre- and postprocedural predictors of PPM, respectively. The distributions of MS length and \( \Delta \text{MSID} \) in patients with and without new-onset LBBB or PPM are shown in a box plot format (Supplementary Figure S1).

As shown in Figure 2A and 2B, for predicting PPM implantation, an area under the curve (AUC) of 0.821 for MS length 6.95 mm and an AUC of 0.857 for \( \Delta \text{MSID} < 0.0 \) mm indicated very good accuracy in discriminating PPM from non-PPM. In the ROC analysis, cut-off values of MS < 7.35 mm and \( \Delta \text{MSID} < 0.0 \) mm were strongly associated with the occurrence of new-onset LBBB (AUC: 0.778 95% CI, 0.694 to 0.862; AUC: 0.902 95% CI, 0.844 to 0.960; \( P < 0.001 \) for both, respectively) (Figure 2C and 2D). Moreover, a smaller MS length
and decreasing ΔMSID increases the probability of PPM implantation. According to the cut-off values, the OR of PPM was 10.7 for MS length (95% CI: 3.4 to 32.9) and 34.7 for the ΔMSID (95% CI: 4.4 to 271.3). Likewise, the OR of new-onset LBBB was 8.8 and 45.7 for these cut-off values, respectively (Supplementary Figure S2).

Figure 3 summarizes the comparison of the MS, ID, ΔMSID length, and PPM ratio in the BEV and SEV groups. In a head-to-head comparisons, there was a significantly higher incidence of PPM implantation (20.3% in its favor when compared to BEV %13.6) and the development of new-onset LBBB (31.1% in its favor when compared to BEV %21.1) in the SEV group. However, these results did not reach statistical significance in this study. When the THV designs (BEV vs. SEV) were compared, the mean MS length was not significantly different between groups (BEV; 7.5 [1.2] mm vs. SEV; 7.7 [1.0] mm, P = 0.25), while ΔMSID values were found to be statistically lower in the SEV group (BEV; 0.7 [2.5] mm vs. SEV; -0.8 [2.5] mm, P < 0.001). It was observed that this difference was due to the longer ID in the SEV group (BEV; 6.81 [1.9] mm vs. SEV; 8.56 [1.9] mm, P < 0.001). Patients who were implanted with Evolut R and Portico had similar ID and MS length.

**Discussion**

The main findings of our study were as follows: (1) a shorter MS length and the consequent high chance of a ΔMSID with negative value is associated with an increased risk of new-onset LBBB and PPM in patients with TAVR. (2) the length of the ΔMSID, which was inversely associated with CD, was significantly lower in the SEV group.

Although the needing for PPM implantation has decreased after TAVR in recent years due to advances in valve technology [13], the CD is still a problematic issue in this patient population. A high incidence of CD occurs following TAVR mainly because of the close anatomical relationship between conduction pathways lying under the MS and the aortic annulus [4,5]. The clinical significance of easy measurement and evaluation of MS with
MDCT in patients undergoing TAVR has been shown in previous studies [6,7]. However, the relationship between MS length and the incidence of PPM implantation following TAVR is still controversial [8,9].

In a prior study, Hamdan et al. found that a shorter MS and ΔMSID length were associated with an increased risk of AV block and the need for PPM implantation with self-expanding prostheses, inversely related to these risks [6]. They revealed that patients with an MS length < 6.8 mm and ΔMSID < -1 mm had the highest likelihood of high-degree AV block. The OR was 4.7 for MS length (95% CI: 1.3 to 16.4), and 11.3 (95% CI: 2.9 to 43.8) for the ΔMSID, respectively. The findings of our analysis also reinforced the importance of short MS length as a risk of CD. According to the ΔMSID, our study exhibited a higher risk of CD when compared to Hamdan. This might be explained by the fact that the ID was longer in our study (7.7 [2.1] mm in favor when compared to Hamdan 6.4 [4.4] mm).

Miki et al. recently reported that patients who required new PPM had a significantly shorter MS and ΔMSID length (MS length 5.3 [1.3] mm vs. 6.6 [1.4] mm; ΔMSID, -1.7 [1.5] mm vs. 0.8 [1.9] mm; P < 0.001 for both). When considering the pre- and postprocedural parameters, both MS and ΔMSID length were independent predictors of CD [7]. Likewise, Maeno et al. recently showed that shorter MS length was an important predictor of PPM implantation following TAVR with the SAPIEN 3 valve (OR: 0.63, 95% CI: 0.48 to 0.82, P = 0.001) [8].

In our study, we used the Sapien XT prosthesis, unlike the previous two studies, which used the Sapien 3 prosthesis. The frame heights of the Sapien XT and Sapien 3 valves are similar, and the same prosthesis material is used for the scaffold. Furthermore, there are studies in which the PPM rates of the two prostheses have been found to be similar [14].

On the contrary, Oestreich et al. found no significant differences among patients who developed a new LBBB or requiring PPM versus those who did not in terms of MS length (7.9 [2.0] mm vs. 7.2 [2.0] mm, P = 0.20, respectively) [9]. The reasons for the relatively
lower rate of CD in their cohort, which differed from previously published literature and our study, are based on anatomical and procedural characteristics. First, the median ID in their study was more aortic than in previous studies (4.9 mm of stent frame in the LVOT). Thus, the higher implant frame may have decreased the interaction between the valve and the conduction system and reduced the effects of short MS length on the risk of PPM implantation. Second, the bundle of His and its branch, which are the continuation of the AV node, continues under the MS. The variations in this relationship determine how susceptible these structures are to injury during TAVR. The left-sided AV bundle variant may expose patients to a higher risk of TAVI-induced CD, especially in patients with a short MS [4]. According to this information, we surmised that patients in that study might have more right-sided AV bundles.

Technical aspects of TAVR procedures, especially the valve design and the potential of deeper implantation into the LVOT, may expose patients to a higher risk of TAVI-induced CD, especially those with a short MS. It is well known that self-expanding prostheses are a predictor of PPM because of their higher frame height, as the frame protrudes into the LVOT [6, 15-18]. Additionally, implantation of BEV with increased ID is associated with high rates of PPM implantation [19]. Therefore, we aimed to determine which type of valve we should choose in the presence of a short MS. In our head-to-head comparison, self-expandable prostheses appeared to be associated with higher rates of PPM implantation and development of LBBB. However, these results did not reach statistical significance. We would expect to reach statistical significance and demonstrate a true association between valve types and CD with an increased number of patients. In this research, self-expandable prostheses were associated with shorter ΔMSID ($P < 0.001$). This difference was due to the longer ID in the SEV group. Accumulating data have suggested that the CoreValve prosthesis ID is a predictor for PPM and LBBB. Another study revealed that the PPM rate was reduced to 13.3% at 1-
month follow-up when Evolut R was implanted according to the recommended practice (ID < 6 mm) [20].

To the best our knowledge, this is the first study to compare CD between a self-expanding Portico/Evolut R prosthesis and the balloon-expanded Sapien XT prosthesis according to variability in the length of the MS. We recommend selecting one of these two strategies in the presence of a short MS length: 1) Given that balloon-expandable devices have less TAVR-related CD due to a smaller ID and shorter frame height, operators may prefer this THV for patients with a shorter MS and avoid mechanically expanded valves; 2) If an SEV is planned, the risk of PPM implantation could be reduced by using a higher or more aortic implant height (ΔMSID > 0 mm).

There are some limitations that must be acknowledged in the present. Although the frame height is similar in Sapien XT and Sapien 3 valves and the same prosthesis material is used for the scaffold, it may be inappropriate to compare our results. The decision to implant a PPM was made at the discretion of the attending physician, but it was most often for a high-degree AV block and thus conforms to current international guidelines.

In conclusion, a short MS length and decreasing ΔMSID increases the risk of new-onset LBBB and PPM implantation in patients undergoing TAVR. Assessment of the MS anatomy prior to TAVR can help to guide appropriate device selection and subsequently reduce CD. The risk of new-onset LBBB and PPM implantation can be reduced by using a higher or more aortic implant height, not exceeding the length of the MS (ΔMSID > 0 mm), especially with self-expandable prostheses.

**Acknowledgements**

None
References:


**Table 1. Baseline characteristics of study population**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Total (N = 140)</th>
<th>LBBB (-) (n = 87)</th>
<th>LBBB (+) (n = 53)</th>
<th>P value</th>
<th>PPM (-) (n = 116)</th>
<th>PPM (+) (n = 24)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>78.8 (7.5)</td>
<td>78.2 (8.2)</td>
<td>79.7 (6.0)</td>
<td>0.26</td>
<td>78.5 (7.5)</td>
<td>79.9 (7.6)</td>
<td>0.40</td>
</tr>
<tr>
<td>Female</td>
<td>89 (63.6)</td>
<td>54 (62.1)</td>
<td>35 (66.0)</td>
<td>0.63</td>
<td>74 (63.7)</td>
<td>15 (62.5)</td>
<td>0.90</td>
</tr>
<tr>
<td>Hypertension</td>
<td>86 (61.4)</td>
<td>52 (59.8)</td>
<td>34 (64.2)</td>
<td>0.60</td>
<td>69 (59.5)</td>
<td>17 (70.8)</td>
<td>0.29</td>
</tr>
<tr>
<td>Diabetes</td>
<td>50 (35.7)</td>
<td>31 (35.6)</td>
<td>19 (35.8)</td>
<td>0.97</td>
<td>42 (36.2)</td>
<td>8 (33.3)</td>
<td>0.78</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>90 (64.3)</td>
<td>56 (64.4)</td>
<td>34 (64.2)</td>
<td>0.97</td>
<td>72 (62.1)</td>
<td>18 (75.0)</td>
<td>0.22</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>30 (21.4)</td>
<td>21 (24.1)</td>
<td>9 (17.0)</td>
<td>0.31</td>
<td>25 (21.6)</td>
<td>5 (20.8)</td>
<td>0.93</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>39 (27.9)</td>
<td>20 (23.0)</td>
<td>19 (35.8)</td>
<td>0.10</td>
<td>28 (24.1)</td>
<td>11 (45.8)</td>
<td>0.03</td>
</tr>
<tr>
<td>STS score</td>
<td>7.0 (4.8 - 9.1)</td>
<td>6.8 (4.8 - 9.0)</td>
<td>7.4 (4.8 - 10.0)</td>
<td>0.32</td>
<td>7.0 (4.8 - 9.1)</td>
<td>7.5 (5.0 - 10.0)</td>
<td>0.48</td>
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<tr>
<td>Atrial fibrillation</td>
<td>29 (20.7)</td>
<td>16 (18.4)</td>
<td>13 (24.5)</td>
<td>0.38</td>
<td>23 (19.8)</td>
<td>6 (25.0)</td>
<td>0.58</td>
</tr>
<tr>
<td>BEV</td>
<td>66 (47.1)</td>
<td>45 (51.7)</td>
<td>21 (39.6)</td>
<td>0.16</td>
<td>57 (49.1)</td>
<td>9 (37.5)</td>
<td>0.29</td>
</tr>
<tr>
<td>MDCT parameters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MS length, mm</td>
<td>7.6 (1.1)</td>
<td>8.1 (0.9)</td>
<td>6.9 (1.1)</td>
<td>&lt; 0.001</td>
<td>7.9 (1.0)</td>
<td>6.54 (0.9)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>ID, mm</td>
<td>7.7 (2.1)</td>
<td>6.8 (1.7)</td>
<td>9.2 (1.8)</td>
<td>&lt; 0.001</td>
<td>7.4 (2.1)</td>
<td>9.2 (1.7)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>ΔMSID, mm</td>
<td>0.3 (-2.1 - 1.8)</td>
<td>1.2 (0.4 - 2.5)</td>
<td>-2.6 (-4.0 - -0.8)</td>
<td>&lt; 0.001</td>
<td>0.8 (-0.9 - 2.1)</td>
<td>-2.6 (-4.3 - -1.2)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Annulus perimeter, mm</td>
<td>78.1 (7.0)</td>
<td>78.5 (7.1)</td>
<td>77.4 (6.8)</td>
<td>0.35</td>
<td>78.2 (7.0)</td>
<td>77.5 (7.4)</td>
<td>0.67</td>
</tr>
<tr>
<td>Anulus mean, mm</td>
<td>24.3 (2.1)</td>
<td>24.5 (2.1)</td>
<td>24.1 (2.1)</td>
<td>0.26</td>
<td>24.4 (2.1)</td>
<td>23.9 (2.2)</td>
<td>0.31</td>
</tr>
<tr>
<td>Anulus area, mm²</td>
<td>472 (8)</td>
<td>477 (9)</td>
<td>464 (8)</td>
<td>0.38</td>
<td>474 (8)</td>
<td>464 (8)</td>
<td>0.62</td>
</tr>
<tr>
<td>LVOT area</td>
<td>452 (8)</td>
<td>461 (9)</td>
<td>439 (8)</td>
<td>0.14</td>
<td>456 (8)</td>
<td>435 (8)</td>
<td>0.27</td>
</tr>
<tr>
<td>Eccentricity index</td>
<td>0.21 (0.06)</td>
<td>0.20 (0.06)</td>
<td>0.21 (0.07)</td>
<td>0.59</td>
<td>0.20 (0.06)</td>
<td>0.23 (0.05)</td>
<td>0.07</td>
</tr>
<tr>
<td>Calcification in basal septum</td>
<td>26 (18.5)</td>
<td>11 (12.6)</td>
<td>15 (28.3)</td>
<td>0.01</td>
<td>17 (14.7)</td>
<td>9 (37.5)</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>Cover index&lt;sub&gt;A&lt;/sub&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---------------------------</td>
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<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>21.1 (9.0 - 27.2)</td>
<td>17.3 (5.8 - 27.0)</td>
<td>22.8 (15.6 - 27.5)</td>
<td>0.03</td>
<td>21.5 (6.9 - 27.2)</td>
<td>19.3 (13.6 - 27.9)</td>
<td>0.59</td>
</tr>
<tr>
<td>b</td>
<td>Cover index&lt;sub&gt;LVOT&lt;/sub&gt;</td>
<td>23.3 (15.6 - 28.7)</td>
<td>22.1 (10.2 - 26.9)</td>
<td>25.2 (22.2 - 30.6)</td>
<td>0.001</td>
<td>23.0 (14.1 - 28.5)</td>
<td>25.5 (21.7 - 29.1)</td>
</tr>
</tbody>
</table>

Note: Values are mean (SD), n (%) or median (interquartile range).

Abbreviations: BEV, balloon-expandable valve; CABG, coronary artery bypass grafting; ID, implantation depth; LBBB, left bundle branch block; LVOT, left ventricular outflow tract; MDCT, multidetector computed tomography; MS, membranous septum; ΔMSID, membranous septum length – implantation depth; PPM, permanent pacemaker; STS, Society of Thoracic Surgeons.

The cover index<sub>A</sub> was calculated as (THV nominal area/MDCT annulus area – 1)*100.

The cover index<sub>LVOT</sub> was calculated as (THV nominal area/MDCT LVOT area – 1)*100.
Table 2. Predictors of new-onset LBBB on univariate and multivariate analysis

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Univariate Analysis</th>
<th></th>
<th></th>
<th>Multivariate Analysis</th>
<th>Pre-Procedural</th>
<th></th>
<th></th>
<th>Pre- and Post-Procedural</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
<td></td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>1.87</td>
<td>0.88 - 3.97</td>
<td>0.10</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Calcification in basal septum</td>
<td>3.64</td>
<td>1.77 - 7.50</td>
<td>&lt; 0.001</td>
<td>3.33</td>
<td>1.40 - 7.93</td>
<td>0.006</td>
<td>3.65</td>
<td>1.25 - 10.7</td>
<td>0.01</td>
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</tr>
<tr>
<td>SEV</td>
<td>1.79</td>
<td>0.89 - 3.57</td>
<td>0.10</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Cover index$_A$</td>
<td>1.04</td>
<td>1.01 - 1.07</td>
<td>0.02</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Cover index$_{LVOT}$</td>
<td>1.06</td>
<td>1.02 - 1.09</td>
<td>0.002</td>
<td>1.09</td>
<td>1.04 - 1.14</td>
<td>0.001</td>
<td>1.10</td>
<td>1.03 - 1.17</td>
<td>0.003</td>
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</tr>
<tr>
<td>Membranous septum length</td>
<td>2.80</td>
<td>1.87 - 4.19</td>
<td>&lt; 0.001</td>
<td>3.05</td>
<td>1.96 - 4.77</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implantation depth</td>
<td>2.11</td>
<td>1.61 - 2.77</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>ΔMSID</td>
<td>2.22</td>
<td>1.71 - 2.89</td>
<td>&lt; 0.001</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; OR, odds ratio; SEV, self-expandable valve; others, see Table 1.
Table 3. Predictors of PPM implantation on univariate and multivariate analysis.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Univariate Analysis</th>
<th>Multivariate Analysis</th>
<th>Pre-Procedural</th>
<th>Pre- and Post-Procedural</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
<td>OR</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>2.66</td>
<td>1.07 - 6.60</td>
<td>0.03</td>
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</tr>
<tr>
<td>Eccentricity</td>
<td>856</td>
<td>0.46 - &gt; 1000</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>Calcification in basal septum</td>
<td>7.08</td>
<td>2.28 - 22.0</td>
<td>0.001</td>
<td>5.17</td>
</tr>
<tr>
<td>Cover index_{LVOT}</td>
<td>1.03</td>
<td>0.99 - 1.08</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>Membranous septum length</td>
<td>3.62</td>
<td>2.05 - 6.38</td>
<td>&lt; 0.001</td>
<td>3.76</td>
</tr>
<tr>
<td>Implantation depth</td>
<td>1.48</td>
<td>1.18 - 1.85</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>ΔMSID</td>
<td>1.67</td>
<td>1.35 - 2.06</td>
<td>&lt; 0.001</td>
<td>1.68</td>
</tr>
</tbody>
</table>

Abbreviations: See Table 1 and 2
Figure 1.

A) Membranous septum length.

B) Implantation depth.

Source: authors’ own material.

Abbreviations: ID, implantation depth; MS, membranous septum.
Figure 2. Receiver-operating characteristic curves of the membranous septum length and ΔMSID for the new-onset left bundle branch block and permanent pacemaker.

Abbreviations: AUC, area under the curve; others, see Table 1 and 2.
Figure 3. Membranous septum, implantation dept, ΔMSID and percentage of permanent pacemaker according to the type of prosthesis.

Abbreviations: See Table 1 and 2.