Importance of Preoperative Computed Tomography Assessment of the Membranous Septal Anatomy in Patients Undergoing Transcatheter Aortic Valve Replacement With a Balloon-Expandable Valve

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Background: Cardiac conduction disturbance (CD) is the most frequent complication following transcatheter aortic valve replacement (TAVR). This study examined whether the anatomy of the membranous septum (MS) could provide useful information about the risk of CD following TAVR with a balloon-expandable valve (BEV).

Methods and Results: Among 132 consecutive patients, 106 (mean age, 85.6±5.1 years; 75 females) were included in the study. Using preoperative CT and angiography, MS length and implantation depth (ID) were assessed. The MS length minus the prosthesis ID was calculated (∆MSID). Correlation between CD, defined as new-onset left-bundle branch block (LBBB) or the need for permanent pacemaker (PPM) within 1 week after the procedure, and MS length were evaluated. A total of 19 patients (18%) developed CD following TAVR. MS length was significantly shorter in these patients than in those without CD (5.3±1.3 vs. 6.6±1.4; P<0.001), and was the important predictor of CD (odds ratio [OR]: 0.43, 95% confidence interval [CI]: 0.27–0.69, P<0.001). When considering the pre- and postprocedural parameters, the ∆MSID was smaller in patients with CD (−1.7±1.5 vs. 0.8±1.9, P<0.001), and emerged as the important predictor of CD (OR: 0.47, 95% CI: 0.33–0.69, P<0.001).

Conclusions: Short MS is associated with an increased risk of CD after TAVR with BEV.

Key Words: Conduction disturbance; Membranous septum; Multidetector computed tomography; Transcatheter aortic valve replacement
images (see Supplementary Figure 1); 7 had a previously implanted pacemaker; 3 had a previous CLBBB; and 3 died perioperatively after TAVR. Therefore, the final study population consisted of 106 patients (Figure 1). This study was approved by the institutional review board based on the ethical guidelines of the Declaration of Helsinki (IRB No. ERB-C-1425: A retrospective study on the predictor of the CD after TAVR in patients with severe aortic stenosis). Patient data were collected retrospectively via chart review without unique patient identifiers; hence, informed consent from individual patients was not required.

### Preprocedural Measurements

Surface 12-lead electrocardiography (ECG) results were evaluated twice during hospitalization: preprocedure and 1 week postprocedure. Transthoracic echocardiography was performed for all patients before TAVR to evaluate AS severity, LV function, left atrial dimension, and regurgitation severity. All patients underwent plain and contrast-enhanced CT before TAVR, using a 320-slice system (Canon Aquilion ONE Vision Edition; Canon Medical Systems, Tochigi, Japan). CT analysis of the aortic annulus was conducted in the systolic phase and other parameters were analyzed in the diastolic phase using ZioStation2 Plus version 2.9.3.3 (Ziosoft, Tokyo, Japan). MS length was measured as the distance from the aortic annulus to the His bundle. (B) Implantation depth (ID) defined as the distance from the native aortic annulus (on the side of the noncoronary or right coronary cusp) to the ventricular end of the implanted valve on the angiographic images. The ID minus the MS length=the difference between them (AMSID). Ao, aorta; LV, left ventricle; RA, right atrium.

### Postprocedural Measurements

Patients underwent TAVR with BEV (Edwards SAPIEN XT or SAPIEN 3; Edwards Lifesciences, Irvine, CA, USA). The ratio of the area of the prosthesis to the annulus and that of the perimeter of the prosthesis to the annulus were calculated. Implantation depth (ID) was defined as the distance from the native aortic annulus on the septal side (on the side of the noncoronary or right coronary cusp) to the ventricular end of the implanted valve using angiographic images and CT (perpendicular view) to verify orthogonality with regard to the aortic annulus (Figure 2B). Additionally, the difference between the MS length measured on the CT image and the ID measured on the angiography images was calculated using the following equation: ∆AMSID=MS−ID.

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**Figure 1.** Study population. CLBBB, complete left bundle-branch block.

**Figure 2.** Parameter measurements. (A) Length of the membranous septum (MS) measured in the coronal view: MS=distance between the aortic annulus and the His bundle. (B) Implantation depth (ID) defined as the distance from the native aortic annulus (on the side of the noncoronary or right coronary cusp) to the ventricular end of the implanted valve on the angiographic images. The ID minus the MS length=the difference between them (AMSID). Ao, aorta; LV, left ventricle; RA, right atrium.
Definition of Cardiac CD
Cardiac CD was assessed, defined as AVB requiring PPM implantation or CLBBB, because it is the most frequent complication after TAVR. New-onset CLBBB was defined as CLBBB that first appeared after TAVR and was maintained at 1 week after the procedure. Patients with improvement of CLBBB observed soon after TAVR were considered to not have CD. PPM implantation was indicated for the incidence of 3rd-degree or advanced 2nd-degree AVBs with symptomatic bradycardia within 7 days after TAVR.

Statistical Analysis
Continuous variables are presented as the mean±standard deviation. Categorical variables are shown as frequencies and percentages. Comparisons were performed using Student’s t-test, and P<0.05 was considered statistically significant. Box plot diagrams were used to assess MS deviation. Categorical variables are shown as frequencies and percentages. Comparisons were performed using Student’s t-test, and P<0.05 was considered statistically significant. Procedural data are shown in Table 2. The valve size and access were not significantly different between groups. However, other parameters, such as the ratio of 1st-degree AVB, right bundle branch block, and left anterior hemiblock were not significantly different between groups. Echocardiographic data were also not significantly different between groups (Table 2). According to the CT parameters, only MS length was significantly shorter in patients with CD than in patients without CD (5.3±1.3 vs. 6.6±1.4; P<0.001). The ratio of the valve perimeter, and the ratio of the valve annulus area were not statistically significant. Procedural data are shown in Table 3. The valve size and access were not significantly different between groups. However, ID was significantly deeper in patients with CD and ΔMSID was smaller in those with CD (−1.7±1.5 vs. 0.8±1.9; P<0.001).

We had 37 cases in which CD occurred immediately after the procedure and so we divided these patients into 2 groups: CD recovered, and CD not recovered (2 cases of delayed CD). MS was significantly longer in the CD recovered group than in the CD not recovered group (recovered vs. not recovered 6.1±1.2 vs. 5.2±1.2; P=0.03). Additionally, there was a significant difference in ΔMSID (recovered vs. not recovered 0.3±1.7 vs. −1.7±1.4; P<0.001) (Supplementary Figure 3). At 1 week after the procedure, 6 patients (6%) underwent PPM and 13 patients (12%) had new-onset CLBBB. The total incidence of CD was 19 (18%). Table 4 shows the univariate analyses of predictors for the incidence of CD, which revealed that MS

Results
Table 1 shows the characteristics of the study population. There were no significant differences in patients’ background, medical history, or medications. The average hospital stay was 18.7±11.1 days. Hospital stay tended to be longer in patients with CD than in patients without CD, but there was no significant difference between groups (22.4±20.9 vs. 17.8±7.3 days; P=0.10). Preoperative ECG data indicated that QRS duration was significantly longer in patients with CD; however, other parameters, such as the ratio of 1st-degree AVB, right bundle branch block, and left anterior hemiblock were not significantly different between groups. Echocardiographic data were also not significantly different between groups (Table 2). According to the CT parameters, only MS length was significantly shorter in patients with CD than in patients without CD (5.3±1.3 vs. 6.6±1.4; P<0.001). The ratio of the valve perimeter, and the ratio of the valve annulus area were not statistically significant. Procedural data are shown in Table 3. The valve size and access were not significantly different between groups. However, ID was significantly deeper in patients with CD and ΔMSID was smaller in those with CD (−1.7±1.5 vs. 0.8±1.9; P<0.001).

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### Table 1. Study Patients Characteristics

| Parameters | All patients (n=106) | CD yes (n=19) | CD no (n=87) | P value |
|------------|---------------------|--------------|-------------|--------|
| Patients’ characteristics | | | | |
| Age, years | 85.6±5.1 | 87.1±3.5 | 85.3±5.3 | 0.15 |
| Sex, female, n (%) | 75 (71) | 14 (74) | 61 (70) | 0.75 |
| BMI, kg/m² | 21.7±2.8 | 21.0±2.3 | 21.7±2.9 | 0.34 |
| Hypertension, n (%) | 77 (73) | 13 (68) | 64 (73) | 0.65 |
| Diabetes, n (%) | 21 (20) | 4 (21) | 17 (20) | 0.88 |
| CAD, n (%) | 30 (28) | 7 (37) | 23 (26) | 0.37 |
| Previous CABG, n (%) | 0 (0) | 0 (0) | 0 (0) | 1.00 |
| Previous PCI, n (%) | 28 (26) | 8 (42) | 20 (23) | 0.21 |
| CKD | 75 (71) | 13 (68) | 62 (71) | 0.81 |
| STS score, % | 7.0±3.4 | 7.1±2.1 | 7.0±3.6 | 0.85 |
| Logistic Euro score, % | 13.0±7.2 | 13.0±6.8 | 13.0±7.3 | 0.99 |
| Medications | | | | |
| β-blocker, n (%) | 46 (44) | 7 (37) | 39 (45) | 0.52 |
| ACEI/ARB, n (%) | 44 (42) | 10 (52) | 34 (39) | 0.28 |
| Diuretics, n (%) | 58 (55) | 8 (42) | 50 (57) | 0.22 |
| Aspirin, n (%) | 82 (77) | 16 (84) | 66 (76) | 0.41 |
| Thienopyridine, n (%) | 57 (54) | 11 (58) | 46 (53) | 0.69 |
| DOAC, n (%) | 25 (24) | 3 (16) | 22 (25) | 0.56 |
| Warfarin, n (%) | 3 (3) | 0 (0) | 3 (4) | 0.27 |
| Hospital stay, days | 18.7±11.1 | 22.4±20.9 | 17.8±7.3 | 0.10 |

ACEI, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; BMI, body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CD, conduction disturbance; CKD, chronic kidney disease; DOAC, direct oral anticoagulant; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons.
Discussion

The major findings of this study were as follows. First, new-onset CD occurred in 17.9% of patients after TAVR with BEV. Second, MS length and ΔMSID were useful predictive factors for the incidence of CD. Lastly, short MS length was associated with low BMI.

Incidence of CD in BEV Patients

Previous study reported the rate of CLBBB after TAVR with BEV as 12–22%,13,14 whereas it was 12.2% in the present study. The PPM implantation rate after TAVR with BEV was 4–12%;15–18 but 5.8% in the present study. Therefore, overall the rate of CD such as new-onset CLBBB or PPM implantation was comparable or relatively lower than in previous studies. The reasons for the relatively lower rate of CD in our cohort are dependent on the exact implantation characteristics (including depth and degree of length was an important preprocedural predictor of CD, with ΔMSID as an important postprocedural predictor of CD.

The shorter the MS and the smaller the ΔMSID, the more frequently CD appeared (Figure 3). As shown in Figure 4, the area under the curve (AUC) was 0.76 for MS length (cutoff value, 5.2 mm; sensitivity, 0.57; specificity, 0.88; P<0.001) and the AUC value was 0.85 for ΔMSID (cutoff value, −0.7 mm; sensitivity, 0.78; specificity, 0.82; P<0.001). The intraclass correlation coefficients for MS length were 0.96 and 0.92 for inter- and intraobserver measurements, respectively. Multivariate analyses found that lower body mass index (BMI) was an independent preprocedural factor of short MS length (odds ratio: 0.43, 95% confidence interval: 0.68–0.99, P=0.04).

| Table 2. Preprocedural Measurements                                      | All patients (n=106) | CD yes (n=19) | CD no (n=87) | P value |
|------------------------------------------------------------------------|----------------------|---------------|--------------|---------|
| **ECG data**                                                           |                      |               |              |         |
| HR, beats/min                                                          | 70±13                | 66±9          | 71±13        | 0.12    |
| PQ duration, ms                                                        | 173±52               | 156±67        | 176±48       | 0.12    |
| QRS duration, ms                                                       | 106±21               | 115±24        | 104±20       | 0.04    |
| QT duration, ms                                                        | 416±41               | 420±45        | 416±40       | 0.66    |
| 1st-degree AVB, n (%)                                                 | 24 (23)              | 3 (16)        | 21 (24)      | 0.57    |
| Atrial fibrillation, n (%)                                             | 10 (9)               | 2 (11)        | 8 (9)        | 0.85    |
| Right bundle branch block, n (%)                                       | 15 (14)              | 4 (21)        | 11 (13)      | 0.36    |
| Left anterior hemiblock, n (%)                                         | 2 (2)                | 1 (5)         | 1 (1)        | 0.29    |
| **Laboratory data**                                                    |                      |               |              |         |
| Hb, g/dL                                                               | 11.1±1.8             | 11.4±1.9      | 11.1±1.8     | 0.48    |
| TP, g/dL                                                               | 6.7±0.6              | 6.6±0.65      | 6.8±0.6      | 0.32    |
| Alb, g/dL                                                              | 3.7±0.5              | 3.7±0.58      | 3.7±0.53     | 0.53    |
| eGFR, mL/min/1.73 m²                                                   | 50.7±21.1            | 55.6±16.9     | 49.6±21.8    | 0.26    |
| BNP, pg/mL                                                             | 36.37±472.3          | 263.7±267.7   | 385.2±504.7  | 0.31    |
| CRP, mg/dL                                                             | 0.4±1.2              | 0.64±2.0      | 0.38±0.98    | 0.38    |
| **Echocardiography data**                                             |                      |               |              |         |
| LVdD, mm                                                               | 41.1±5.7             | 41.7±5.6      | 41.0±5.8     | 0.59    |
| LVds, mm                                                               | 28.0±6.1             | 28.3±4.2      | 27.9±6.5     | 0.79    |
| LVEDV, mL                                                              | 76.9±25.7            | 81.1±24.3     | 76.0±26.0    | 0.43    |
| LVESV, mL                                                              | 31.7±18.5            | 32.7±12.2     | 31.5±19.6    | 0.82    |
| LVEF, %                                                                | 60.6±11.1            | 59.4±8.7      | 60.9±11.5    | 0.58    |
| LAD, mm                                                                | 41.2±7.1             | 40.9±8.2      | 41.2±6.9     | 0.86    |
| Aortic valve peak velocity, m/s                                        | 4.5±0.7              | 4.5±0.77      | 4.5±0.70     | 0.90    |
| Aortic valve mean pressure gradient, mmHg                              | 50.7±17.3            | 50.9±18.4     | 50.6±17.2    | 0.94    |
| **CT data**                                                            |                      |               |              |         |
| Aortic valve perimeter, mm                                            | 73.3±6.4             | 73.7±6.7      | 73.2±6.4     | 0.73    |
| Aortic valve annulus area, mm²                                        | 303.6±68.6           | 303.8±68.4    | 303.5±69.1   | 0.98    |
| Left coronary height, mm                                              | 13.5±2.3             | 13.2±1.8      | 13.5±2.4     | 0.60    |
| Right coronary height, mm                                             | 14.9±3.1             | 15.4±3.6      | 14.8±2.9     | 0.48    |
| Ratio of the prosthesis area to the native valve area                  | 1.18±0.18            | 1.20±0.11     | 1.18±0.19    | 0.57    |
| Ratio of the prosthesis perimeter to the native valve perimeter        | 1.05±0.06            | 1.05±0.04     | 1.05±0.06    | 0.87    |
| MS length, mm                                                          | 6.4±1.5              | 5.3±1.3       | 6.6±1.4      | <0.001  |

Abb: albumin; AVB: atrioventricular block; BNP: B-type natriuretic peptide; CRP: C-reactive protein; CT: computed tomography; ECG: electrocardiography; eGFR: estimated glomerular filtration rate; Hb: hemoglobin; HR: heart rate; LAD, left atrial dimension; LCC, left coronary cusp; MS, membranous septum; NCC, noncoronary cusp; LVdD, left ventricular diastolic dimension; LVds, left ventricular systolic dimension; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; RCC, right coronary cusp; TP, total protein.
distance from the annulus to the His bundle, may allow more space for device penetration without causing CD. Moreover, the anatomical length difference in the MS between our study (6.6 mm) and previous studies (7.5 mm in both) is generally derived from features of the patient such as lower BMI and smaller LV size. The Japanese population with a small body size has been reported to have a small LV diameter compared with Westerners. Actually, the mean BMI was 28.0 in the American study population, which is much larger than that of our cohort (mean BMI 21.7). Thus, patients with a small body size such as Asians, who may also have a small LV and short MS, may need more careful assessment of MS length by preoperative CT. A recent study by Jilaihawi et al examined the effect of PPM with self-expandable TAVR in relation to MS length, and achieved low and predictable rates of PPM in their Western patients. We are the first to provide data on BEV that accounts for the small body size of the Asian population. Moreover, our results indicate that a low BMI is a risk factor for shorter MS.

Importance of Preprocedural MS Assessment in the Era of TAVR Application for Intermediate-Risk Patients

Based on excellent long-term transcatheter aortic valve function, lower rates of bioprosthetic valve failure, and fewer deaths and reduced stroke rates, TAVR is expected to be adapted for younger patients. However, the oversizing). A higher position and greater foreshortening of the frame, especially, are potential reasons for the lower incidence of PPM in our cohort.

MS Length as Risk Factor for CD in BEV Patients

Previous studies have stated that cardiac CD is associated with longer QRS, SEV implantation, diabetes mellitus, post dilatation, and ID. However, the relationship between MS length and the incidence of PPM implantation following TAVR with BEV is still controversial. Oestreich et al showed that mean MS length was 7.5 mm in all their study subjects and no difference was observed between those with (7.9 mm) and without CD (7.2 mm); however, Maeno et al indicated that a significant difference was seen in the mean MS length in patients requiring PPM (6.4 mm) and in those who did not require PPM (7.7 mm). Our study also showed significant differences in mean MS length among patients requiring PPM (5.3 mm) and those who did not (6.6 mm).

Our study showed that a shorter MS length and the consequent high chance of a small ∆MSID led to a higher risk of CD. The development of CD immediately after TAVR is related to the proximity of the atrioventricular node and left-bundle branch to the aortic valve. Therefore, the deeper the penetration of the prosthesis into the LV outflow tract, the more frequent the occurrence of CD. On the other hand, a longer MS length, indicating a longer distance from the annulus to the His bundle, may allow more space for device penetration without causing CD.

Moreover, the anatomical length difference in the MS between our study (6.6 mm) and previous studies (7.5 mm in both) is generally derived from features of the patient such as lower BMI and smaller LV size. The Japanese population with a small body size has been reported to have a small LV diameter compared with Westerners. Actually, the mean BMI was 28.0 in the American study population, which is much larger than that of our cohort (mean BMI 21.7). Thus, patients with a small body size such as Asians, who may also have a small LV and short MS, may need more careful assessment of MS length by preoperative CT.

Table 3. Procedural Data

| Parameters                  | All patients (n=106) | CD yes (n=19) | CD no (n=87) | P value |
|-----------------------------|----------------------|---------------|--------------|---------|
| Device and procedure        |                      |               |              |         |
| Access site                 |                      |               |              |         |
| Direct aorta, n (%)         | 1 (1)                | 0 (0)         | 1 (1)        | 0.52    |
| Transfemoral, n (%)         | 105 (99)             | 19 (100)      | 86 (99)      |         |
| Valve size                  |                      |               |              |         |
| 20 mm, n (%)                | 4 (4)                | 1 (5)         | 3 (3)        |         |
| 23 mm, n (%)                | 52 (49)              | 8 (42)        | 44 (51)      | 0.88    |
| 26 mm, n (%)                | 42 (40)              | 8 (42)        | 34 (39)      |         |
| 29 mm, n (%)                | 8 (7)                | 2 (11)        | 6 (7)        |         |
| Post dilatation, n (%)      | 52 (49)              | 9 (47)        | 43 (49)      | 0.87    |
| Cineangiographic data after implantation | | | | |
| ID, mm                      | 6.1±1.8              | 7.0±1.9       | 5.8±1.7      | 0.008   |
| ∆MSID, mm                   | 0.3±2.1              | −1.7±1.5      | 0.8±1.9      | <0.001  |

∆MSID, difference between the membranous septum (MS) length and the implantation depth (ID).

Table 4. Univariate Analysis of Predictors of Conduction Disturbance Before and After TAVR

| Parameters                                      | OR   | 95% CI          | P value |
|------------------------------------------------|------|-----------------|---------|
| Age                                            | 1.08 | 0.97–1.2        | 0.13    |
| Female                                         | 1.19 | 0.38–3.66       | 0.76    |
| QRS duration                                   | 1.02 | 1.00–1.04       | 0.04    |
| CRBBB                                          | 1.8  | 0.46–6.3        | 0.35    |
| MS                                             | 0.46 | 0.30–0.71       | <0.001  |
| Post dilatation                                | 0.92 | 0.34–2.5        | 0.87    |
| Ratio of the prosthesis area to the native valve area | 2.3  | 0.13–40.5       | 0.56    |
| ∆MSID                                          | 0.46 | 0.32–0.66       | <0.001  |

CI confidence interval; CRBBB, complete right bundle branch block; MS, membranous septum; OR, odds ratio; TAVR, transcatheter aortic valve replacement. Other abbreviations as in Tables 1, 3.
Therefore, especially for younger patients, an assessment of the MS length should be performed, because having this information will be helpful when discussing with the patient the individual risks of CD, instead of solely relying on the reported CD rate.

Study Limitations
This study was a non-randomized, retrospective, and single-center observational study. Because of the retrospective design, some patients were excluded for insufficient CT image quality. Moreover, MS length and ID were mea-
sured by different modalities, although the measurement method used in this study was similar to that used in previous studies.8,9 The patients who underwent TAVI were older and most of them had chronic kidney disease. There was a risk of kidney function deterioration postoperatively. Therefore, contrast-enhanced CT was not performed after the procedure and evaluation of ID with CT was not possible. Furthermore, because ID was measured not by post-valve-oriented perpendicular view but by native valve-oriented perpendicular view, there may be slight deviations. However, considering that the difference between these views confirmed in all cases is small (left anterior oblique $0.46 \pm 3.8^{\circ}$, caudal $5.3^{\circ}\pm 7.0^{\circ}$), there seems to be no significant effect. This study discussed the occurrence of CD during hospitalization after TAVR; therefore, the pacing rate and restoration of CLBBB during long-term follow-up were not observed.

Conclusions

New-onset CD occurred in 18% of patients after TAVR with BEV. Short MS landing zone is associated with an increased risk of conduction disturbance after TAVR with BEV. A preoperative CT assessment of MS anatomy may aid in procedural planning before TAVR.

Acknowledgments

None.

Disclosures

The authors declare no conflicts of interest.

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Supplementary Files
Please find supplementary file(s):
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