JACC: ASIA VOL. 3, NO. 6, 2023

ORIGINAL RESEARCH

Feasibility and Outcome of Transjugular Intracardiac Echocardiography–Guided Transcatheter Aortic Valve Replacement

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ABSTRACT

BACKGROUND There are limited data on the impact of intracardiac echocardiography (ICE)–guided transcatheter aortic valve replacement (TAVR) on the new permanent pacemaker implantation (PPMI) rate.

OBJECTIVES This study investigated the feasibility and outcome of transjugular ICE (TJ-ICE) –guided TAVR, by visualizing the relationship between the membranous septum (MS) and the transcatheter aortic valve (TAV).

METHODS Among patients with severe aortic stenosis who underwent TAVR between February 2017 and June 2020, this study enrolled a total of 163 patients with TJ-ICE–guided TAVR. MS length was measured by ICE. The primary endpoint of this study was the incidence of new PPMI at 30 days.

RESULTS The mean age of the patients in this study was 84.9 ± 4.6 years, and 71.2% of the patients were female. Device success was 96.3% with TJ-ICE guidance. A TJ-ICE–related complication occurred in 1 case (0.6%). The median length of the MS was 5.8 mm (IQR: 5.0-6.9 mm). Excellent intraobserver (intraclass correlation coefficient [ICC]: 0.94; 95% CI:0.79-0.98; $P < 0.001$) and interobserver (ICC: 0.93; 95% CI: −0.05 to 0.98; $P < 0.001$) agreements were shown. The new PPMI rate was 6.7% at 30 days without a significant difference between balloon-expandable valves and self-expandable valves (3.4% vs 8.7%; $P = 0.226$). Patients with a TAV implantation depth less than MS length had a significantly lower incidence of new PPMI compared with patients with a TAV implantation depth greater than MS length (2.1% vs 13.4%; $P = 0.005$), regardless of baseline right bundle branch block presence (6.7% vs 66.7%; $P = 0.004$) or absence (1.2% vs 8.2%; $P = 0.041$).

CONCLUSIONS TJ-ICE–guided TAVR demonstrated remarkable feasibility and safety. The TJ-ICE–guided final TAV position had a significant impact on the new PPMI rate. (Tokai Valve Registry; UMIN000036671) (JACC: Asia 2023;3:925-934) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received April 17, 2023; revised manuscript received July 18, 2023, accepted July 29, 2023.

ISSN 2772-3747 https://doi.org/10.1016/j.jacasi.2023.07.013

JACC: ASIA, VOL. 3, NO. 6, 2023
DECEMBER 2023:925–934

ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

CS = conscious sedation

CT = computed tomography

ICC = intraclass correlation coefficient

ICE = intracardiac echocardiography

LV = left ventricular

LVOT = left ventricular outflow tract

MS = membranous septum

MV = mitral valve

PPMI = permanent pacemaker implantation

PVL = paravalvular leakage

RBBB = right bundle branch block

TAV = transcatheter aortic valve

TAVR = transcatheter aortic valve replacement

TEE = transesophageal echocardiography

TJ-ICE = transjugular intracardiac echocardiography

TTE = transthoracic echocardiography

Transcatheter aortic valve replacement (TAVR) has become a viable option for patients with severe aortic stenosis (AS) regardless of their surgical risk.[1-6] In the most recent randomized controlled trials of TAVR in low-surgical risk patients, the outcomes of TAVR were comparable or favorable relative to surgical aortic valve replacement.[5-8] However, TAVR-related issues need to be further addressed among lower-risk and younger patients, particularly reducing the new permanent pacemaker implantation (PPMI) rate because of its potential impact on clinical outcomes.[9,10] The new PPMI rate has been consistently higher in patients receiving a self-expanding valves compared with patients receiving a balloon-expandable valve.[9,11] Lower implantation depth is an established procedural predictor of new PPMI, and this finding has led to technical improvements such as implanting self-expanding valves higher in the membranous septum (MS) or using a double S-curve or cusp-overlap technique.[12-14] However, these techniques are basically angiogram-guided procedures, and intraprocedural visualization of the MS is not possible.

ICE has been shown to be a viable choice of imaging modality during TAVR.[15,16] To facilitate implanting the valve at an optimal depth guided by direct visualization of the MS during the procedure, we developed transjugular ICE (TJ-ICE)-guided TAVR.[17,18] We hypothesized that the PPMI rate could be different whether the valve was deployed inside or beyond the MS. In this study, we evaluated the feasibility and outcome of TJ-ICE-guided TAVR and its potential impact on reducing the new PPMI rate.

METHODS

STUDY GROUP AND DESIGN. The ongoing, prospective, and single-center Tokai Valve Registry was approved by the Institutional Review Board for Clinical Research, Tokai University and conforms to the Declaration of Helsinki. The presence of severe AS was diagnosed according to the guidelines (ie, aortic valve area <1.0 cm^2 [or effective orifice area index <0.6 cm^2/m^2]), mean gradient of >40 mm Hg, or jet velocity of >4.0 m/s.[19] All enrolled patients underwent TAVR using the Edwards Sapien XT or Sapien 3 (Edwards Lifesciences) transcatheter aortic valve (TAV) or the Medtronic CoreValve, Evolut R, Evolut PRO, or Evolut PRO+ (Medtronic) TAV. This registry was registered in the University Hospital Medical Information Network Clinical Trial Registry, as accepted by the International Committee of Medical Journals (UMIN000036671). All patients gave informed consent to the use of their data for scientific purposes before participating in this prospective registry. Between February 2017 and June 2020, a total of 266 patients with severe AS who were undergoing TAVR were prospectively enrolled in the Tokai Valve Registry. A flowchart of this single-center, retrospective, observational study is shown in **Figure 1**. We excluded 86 cases in patients who underwent transesophageal echocardiography (TEE)-guided or transfemoral ICE-guided TAVR. The choice of intraprocedural imaging modality was decided by the heart team. After excluding patients with previous PPMI (n = 8), missing detailed ICE data (n = 6), conversion to TEE or transthoracic echocardiography (TTE) (n = 3), and TAVR performed using general anesthesia, 163 patients who underwent TJ-ICE-guided TAVR finally met study inclusion criteria.

TRANSJUGULAR ICE-GUIDED TAVR. All participants underwent imaging by 2 highly experienced and board-certified interventional echocardiographers (T.M., H.H.). A 9-F sheath (Cardinal Health Japan) was initially placed in the right jugular vein. Then, AcuNav (Biosense Webster) was inserted with the protective sleeve.[17] The procedural setting for TJ-ICE-guided TAVR is shown in **Figure 2**. The protocol for TJ-ICE-guided TAVR was as follows:

1. The tricuspid view was obtained by advancing ICE from the jugular vein to the right atrium (**Central Illustration**, step 1). This view enabled the assessment of tricuspid regurgitation and its velocity to estimate pulmonary artery systolic pressure.
2. The left ventricular outflow tract (LVOT) view was acquired by 30° to 60° of counterclockwise rotation from the tricuspid view (**Central Illustration**, step 2). Assessment of AS severity, baseline aortic regurgitation and postprocedural paravalvular leakage (PVL), and, importantly, length of the MS was feasible.
3. The left ventricular (LV) view was obtained by advancing ICE and turning the A (anterior) dial from the tricuspid view (**Central Illustration**, step 3). This view was useful for assessing the position of the wire inside the left ventricle and the length of the MS pre- and postvalve implantation. The length of the MS could be better assessed in this view because it seemed to be foreshortened in the LVOT view.

4. The mitral valve (MV) view was obtained by 30° to 60° of counterclockwise rotation from the LV view (Central Illustration, step 4). Assessment of the MV and pericardial effusion was feasible. Most of the images could be obtained from the right atrium. We sometimes needed to advance ICE into the right ventricle to obtain the LV and MV views.

MEMBRANOUS SEPTUM MEASUREMENT. The methods of MS measurement are shown in Figures 3A to 3F. The MS was detected on the LVOT view or the LV view and measured where it was observed longest at diastolic phase of the cardiac cycle before deploying the device. We analyzed whether the final position of the device was inside the MS (less ventricular; implantation depth less than MS length) (Figures 3B and 3C) or beyond the MS (more ventricular; implantation depth greater than MS length) (Figures 3E and 3F). MS measurements were separately analyzed by a team of 2 expert echocardiographers and were reviewed by a third reader for consensus when there was disagreement. To determine reproducibility of MS length assessments, 20 randomly selected data were analyzed by 2 independent analysts, and this analysis was repeated 1 month after the initial analysis.

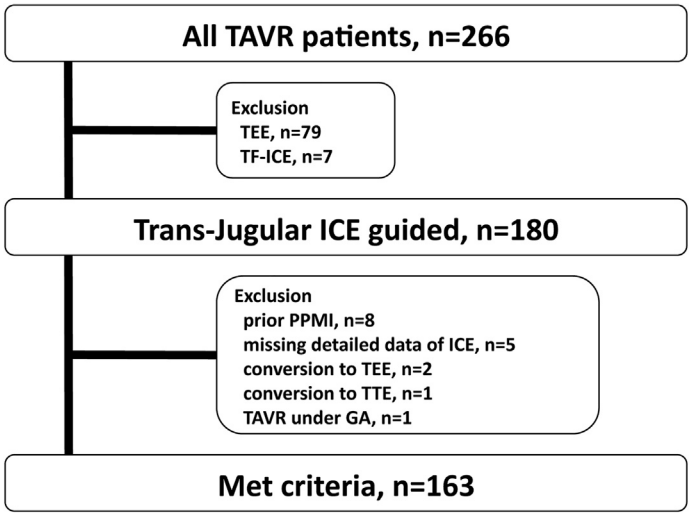
ENDPOINT DEFINITIONS. Clinical endpoints and definitions were in accordance with the Valve Academic Research Consortium 3 criteria.[20] The primary endpoint of this study was the incidence of new PPMI at 30 days. Secondary endpoints were the feasibility and safety of TJ-ICE-guided TAVR. The following safety events were collected: complications related to TJ-ICE, frequency of puncture site change or longer sheath requirement, conversion to other imaging modalities (TEE or TTE), or incidence of suboptimal rapid pacing.

STATISTICAL ANALYSIS. Continuous variables with normal distribution are expressed as mean ± SD. Numeric factors with skewed distribution are shown as median (IQR). Continuous variables were compared using Student's *t*-test or the Mann-Whitney *U* test depending on the variable's distribution. Categorical variables were compared by the chi-square or the Fisher exact test. Interobserver and intraobserver agreements were calculated using intraclass correlation coefficient (ICC), with excellent agreement defined as ICC >0.8. All *P* values reported are 2-sided, and *P* values <0.05 were considered significant. All statistical calculations were performed using JMP software version 10 (SAS Institute, Inc).

RESULTS

BASELINE CHARACTERISTICS. Overall, 163 patients were enrolled in this study. Baseline characteristics are summarized in Table 1. The mean age was 84.9 ± 4.6 years, 71.2% of the patients were women, and the mean body surface area was 1.4 ± 0.2 m^2. The median Society of Thoracic Surgeons (STS) score was 6.3% (IQR: 4.7%-8.5%). Among electrocardiographic findings, complete left bundle branch block and complete right bundle branch block (RBBB) were observed in 4 cases (2.5%) and 21 cases (12.9%), respectively. In 3 patients, baseline RBBB was complicated with left anterior hemiblock (1.8%). First-degree atrioventricular block was observed in 23 cases (14.1%). The mean PR interval was 176 ± 32 ms, and the mean QRS duration was 98 ± 23 ms.

FIGURE 1 Study Flowchart



The flow of the retrospective cohort study is described. GA = general anesthesia; ICE = intracardiac echocardiography; PPMI = permanent pacemaker implantation; TAVR = transcatheter aortic valve replacement; TEE = transesophageal echocardiography; TF = transfemoral; TTE = transthoracic echocardiography.

TAVR PROCEDURE OUTCOME UNDER TJ-ICE GUIDANCE. The procedural outcome is shown in Table 2. All patients underwent valve placement in the proper anatomical location; however, moderate PVL was observed in 4 patients, and a second valve was required in 2 patients, thus leading to device success of 96.3%. All cases were performed using conscious sedation (CS).

A self-expandable Evolut PRO or Evolut R valve was implanted in 104 cases (63.8%). The decision to recapture or not was based on the initial position of the device as observed by ICE, thereby resulting in recapture in 35 cases (33.7%). Severity of PVL was also evaluated by ICE. Postdilatation was required in

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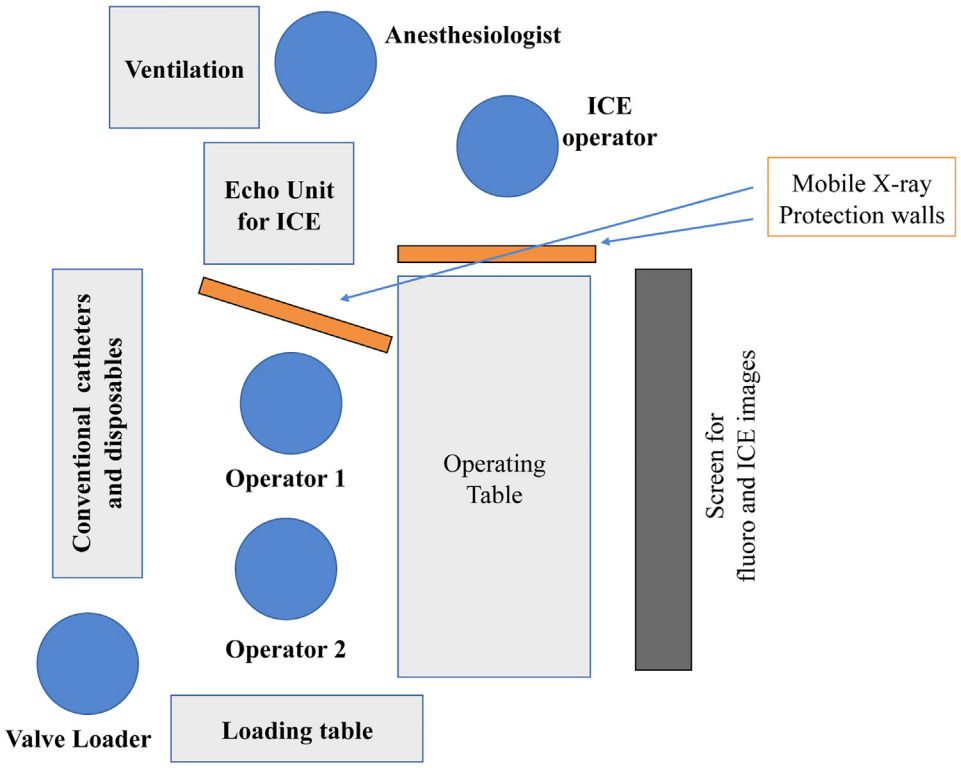
FIGURE 2 Procedural Setting for Transjugular ICE-Guided Transcatheter Aortic Valve Replacement



The intracardiac echocardiography (ICE) operator manipulates the intracardiac echocardiography catheter from the head side of the patient using mobile x-ray protection walls in the setting of transjugular intracardiac echocardiography guidance. Echo = echocardiography.

34 cases (20.9%). One case of cardiac tamponade after balloon aortic valvuloplasty was immediately detected by ICE imaging. In this case, we decided to deploy the device quickly before hemodynamic collapse. After successful implantation, pericardial drainage was safely performed, and the patient was managed conservatively.

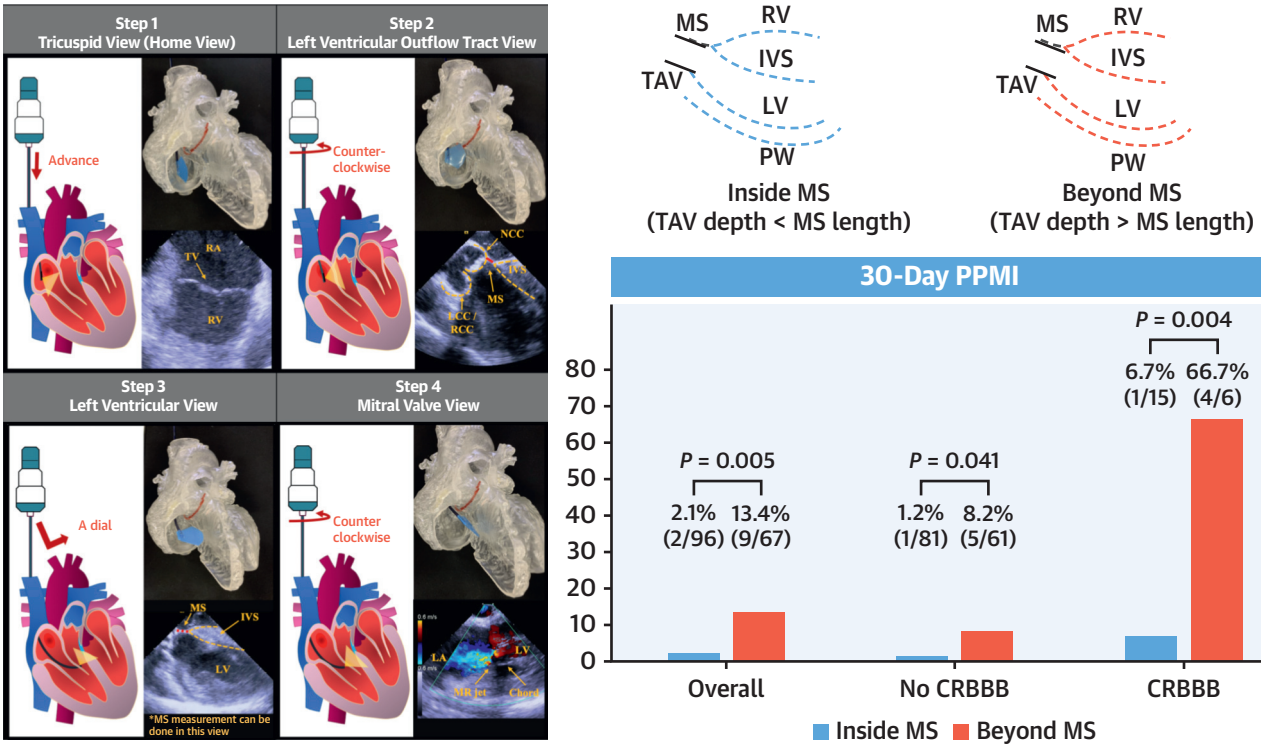
TJ-ICE PROCEDURE OUTCOME. Among 180 patients who underwent TJ-ICE-guided TAVR, 2 patients (1.1%) required a long sheath to reach into the right atrium as a result of vein anomaly. Six patients (3.3%) required a change of puncture site to the left jugular vein because of puncture failure secondary to a hypoplastic right jugular vein.

The LVOT and LV views were obtained in all cases (100%). The median length of the MS was 5.8 mm (IQR: 5.0-6.9mm). Interobserver and intraobserver agreements were both excellent for MS length measurements: the ICC for interobserver measurements was 0.93 (95% CI: −0.05 to 0.98; $P < 0.001$), and the ICC for intraobserver measurements was 0.94 (95% CI: 0.79-0.98; $P < 0.001$), respectively.

TJ-ICE-related complication occurred in 1 case (0.6%). This case was converted to TTE. After sheath insertion to the right jugular vein, the ICE catheter could not be advanced to the right atrium, and this eventually led to mediastinal hematoma. Fortunately, no further clinical event was observed while the patient received antibiotic therapy, and the patient was discharged home safely. Suboptimal rapid pacing was noted in 1 case (0.6%) during balloon-expandable valve implantation with no adverse consequence.

30-DAY OUTCOME. The 30-day outcome is shown in Table 3. One case (0.6%) of in-hospital or 30-day death was identified as a result of type 4 bleeding, which occurred in a patient with liver cirrhosis after a successful TAVR procedure. Four patients (2.5%) experienced disabling strokes. Vascular complications developed in 16 patients (9.8%): 15 cases of

CENTRAL ILLUSTRATION **Method of Transjugular Intracardiac Echocardiography-Guided Transcatheter Aortic Valve Replacement and 30-Day New Permanent Pacemaker Implantation Rate**



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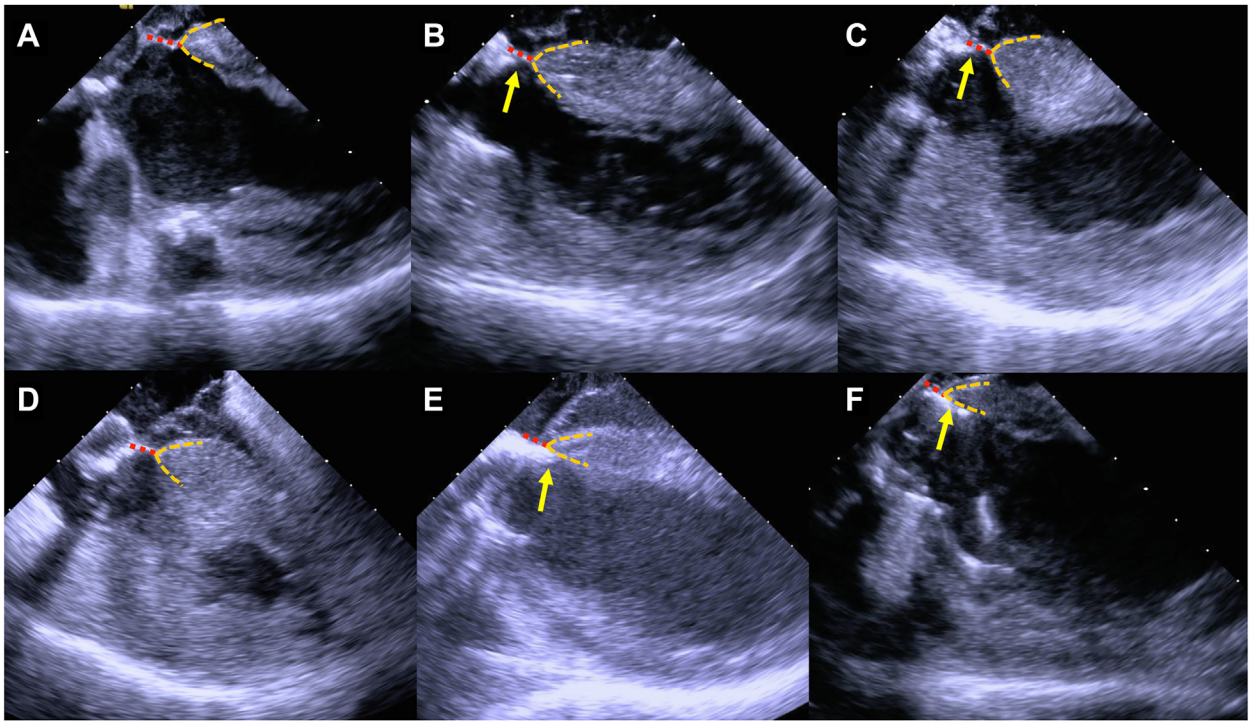
Comparison of an illustration, a 3-dimensional printing model, and the actual image of transjugular intracardiac echocardiography in the tricuspid view *(Step 1)*, the left ventricular outflow tract view *(Step 2)*, the left ventricular view *(Step 3)*, and the mitral valve view *(Step 4)*. In the 3-dimensional printing model, the red line demonstrates the aortic annulus, whereas the blue fan shape shows the range of visualization by intracardiac echocardiography. The 30-day permanent pacemaker implantation (PPMI) rate on the basis of the transjugular intracardiac echocardiography–guided final position of the device relative to the membranous septum (MS). CRBBB = complete right bundle branch block; IVS = interventricular septum; LA = left atrium; LCC = left coronary cusp; LV = left ventricle; MR = mitral regurgitation; NCC = noncoronary cusp; PW = posterior wall; RA = right atrium; RCC = right coronary cusp; RV = right ventricle; TAV = transcatheter aortic valve; TV = tricuspid valve.

access site-related complications and 1 case of descending aortic dissection. Among these patients, unplanned surgical (n = 6) and endovascular (n = 5) interventions were necessary as a result of difficult hemostasis. There were 2 cases of pseudoaneurysm that required surgical repair and 2 cases of endovascular therapy caused by closure device failure. Type 2 bleeding was identified in 15 patients (9.2%), and 1 patient developed type 4 bleeding according to Valve Academic Research Consortium 3 criteria, as mentioned earlier.

30-DAY NEW PPMI RATE. New PPMI within 30 days was required in 11 patients (6.7%), all because of complete atrioventricular block. Patients with baseline RBBB had a higher incidence of new PPMI than did patients without RBBB (23.8% vs. 4.2%; $P < 0.001$). There was a significant difference in the incidence of new PPMI on the basis of the final position of the device (ie, whether the final device position was inside the MS or beyond the MS). There was no significant difference in the length of the MS between patients who required new PPMI and those who did not (6.0 mm [IQR: 4.8-7.9 mm] vs 5.8 mm [IQR: 5.0-6.9 mm]; $P = 0.966$). Patients whose device was implanted inside the MS had a significantly lower incidence of new PPMI (overall 2.1% vs13.4%; $P = 0.005$). This finding was consistent in patients with baseline RBBB (6.7% vs 66.7%; $P = 0.004$) or without RBBB (1.2% vs 8.2%; $P = 0.041$) (Central Illustration). There was no significant difference in

FIGURE 3 Methods of Membranous Septum Measurement and Postprocedural Assessment by Transjugular Intracardiac Echocardiography



(A to F) The membranous septum is depicted by the red dotted line in the left ventricular view. The yellow dotted line indicates the muscular part of the interventricular septum. (B) A Sapien 3 valve (Edwards Lifesciences) was implanted inside (less ventricular) the membranous septum (arrow shows the distal edge of the transcatheter aortic valve). (C) An Evolut PRO valve (Medtronic) was implanted inside (less ventricular) the membranous septum (yellow arrow shows the distal edge of the transcatheter aortic valve). (E) A Sapien 3 valve was implanted beyond (more ventricular) the membranous septum (arrow shows the distal edge of the device). (F) An Evolut PRO valve was implanted beyond (more ventricular) the membranous septum (arrow shows the distal edge of the device).

new PPMI between patients with balloon-expandable valves and those with self-expandable valves (3.4% vs 8.7%; $P = 0.226$).

DISCUSSION

The present study on the largest dataset on TJ-ICE-guided TAVR thus far demonstrated remarkable feasibility and safety. The main findings of this study are as follows: 1) adequate image acquisition was possible in all cases; 2) the TJ-ICE procedure showed excellent safety with CS use, with minimal complications; 3) real-time visualization of the MS was feasible in all cases, with excellent intraobserver and interobserver agreements; and 4) patients whose TAV was implanted inside the MS under ICE guidance had a significantly lower incidence of new PPMI regardless of the presence or absence of baseline RBBB.

RATIONALE FOR TJ-ICE-guided TAVR. Intraprocedural imaging during TAVR is important to guide positioning of the valve accurately and identify complications quickly. Although TEE has been used as the default imaging modality during general anesthesia because it provides high-quality real-time imaging, there is a recent trend toward a minimalistic approach using TTE in patients who are under CS.[21] The major drawbacks of TTE guidance are as follows: difficult imaging acquisition in the supine position, especially in patients with obesity or lung disease; and interruption of the procedure while obtaining the images. The rationale for developing user-friendly TJ-ICE-guided TAVR is that it facilitates TAVR without interrupting the procedure while ensuring high-quality real-time continuous monitoring, including the MS, and maintaining the advantages of CS (ie, shorter hospital stay and potential short-term survival benefit).[17,18] Moreover, the MS could be visualized with TEE. However, given that the MS is anatomically more anterior in comparison with aortic valve, it could be visualized at baseline but in the phase of valve deployment, because of the shadow of the stent frame of the valve, it is no longer possible to

TABLE 1 Patient Characteristics (N = 163)

Age, y	84.9 ± 4.6
Female	116 (71.1)
Height, cm	150.7 ± 9.3
Weight, kg	50.6 ± 10.7
Body surface area, m^2	1.4 ± 0.2
Body mass index, kg/m^2	22.2 ± 3.7
Hypertension	132 (81.0)
Diabetes mellitus	44 (27.0)
Hyperlipidemia	103 (63.2)
Atrial fibrillation	35 (21.5)
Chronic kidney disease	84 (51.5)
Previous cerebral infarction	21 (12.9)
Post PCI	27 (16.6)
Post CABG	4 (2.5)
Previous myocardial infarction, n (%)	4 (2.5)
Current or past smoking	26 (16.0)
Chronic lung disease	26 (16.0)
NYHA functional class at admission	
I	1 (0.6)
II	110 (67.5)
III	50 (30.7)
IV	2 (1.2)
EuroSCORE II	3.1 (2.1-4.3)
STS score	6.3 (4.7-8.5)
Clinical Frailty Scale	
2	2 (1.2)
3	97 (59.5)
4	58 (35.6)
5	1 (0.6)
6	2 (1.2)
7	3 (1.8)
Laboratory data	
Hemoglobin, g/dL	11.4 ± 1.8
Albumin, g/dL	3.8 ± 0.4
Creatinine, mg/dL	0.89 (0.73-1.11)
eGFR, mL/min/1.73 m^2	51 (40-61)
BNP, pg/mL	200 (90-454)
HbA_{1c}, %	6.0 (5.7-6.5)
Baseline echocardiographic data	
Left ventricular ejection fraction, %	65.6 ± 11.9
Aortic valve	
Peak velocity, m/s	4.6 ± 0.8
Mean pressure gradient, mm Hg	46.2 ± 17.1
Aortic valve area, cm^2	0.6 ± 0.2
Bicuspid valve	4 (2.5)
Mitral regurgitation moderate or greater	22 (13.5)
Aortic regurgitation moderate or greater	18 (11.0)
Baseline electrocardiographic data	
LBBB	4 (2.5)
RBBB	18 (11.1)
RBBB with LAHB	3 (1.8)
First-degree atrioventricular block	23 (14.1)
PR interval, ms	176 ± 32
QRS duration, ms	98 ± 23

Values are mean ± SD, n (%), or median (IQR).

BNP = B-type natriuretic peptide; CABG = coronary artery bypass grafting; CLBBB = complete left bundle branch block; COPD = chronic obstructive pulmonary disease; CRBBB = complete right bundle branch block; eGFR = estimated glomerular filtration rate; EuroSCORE II = European System for Cardiac Operative Risk Evaluation II; HbA_{1c} = glycosylated hemoglobin; IVST = interventricular septal thickness; LAD = left atrial diameter; LHAB = left anterior hemiblock; LVDd = left ventricular diastolic diameter; LVDs = left ventricular systolic diameter; PCI = percutaneous coronary intervention; PWT = posterior wall thickness; RBBB = right bundle branch block; STS = Society of Thoracic Surgeons; TTE = transthoracic echocardiography.

Continued in the next column

visualize it, thus making real-time valve navigation difficult. However, there is an increased risk of radiation exposure to the ICE operator; therefore, x-ray protection walls could be extremely important (**Figure 2**).[22]

IMAGING QUALITY AND SAFETY OF TJ-ICE. In this study, we were able to acquire adequate images in all patients with TJ-ICE. By establishing the TJ-ICE protocol (**Central Illustration**), key images to guide TAVR procedures were obtained systematically. All cases that required either a long sheath or use of the contralateral side of the jugular vein were the result of vein anomaly or hypoplasia. Although not frequent, anatomical variations of the internal jugular vein were found in 2% according to the previous report.[23] TJ-ICE-related complication occurred in 1 case (0.6%). One case of suboptimal rapid pacing (pacing failure) occurred during implantation of a balloon-expandable valve, although the valve was implanted in the proper position. Interference between the ICE catheter and the pacing catheter, which was placed through the femoral vein, was considered to be the cause; therefore, the position of the pacing catheter or the pacing threshold should be confirmed before rapid pacing is undertaken. Local anesthesia with CS was possible in all cases.

Previous publications on ICE-guided TAVR were limited to review articles or single case reports.[15-18,24] Thus, the current study represents the largest dataset on TJ-ICE-guided TAVR, and it demonstrated notable feasibility and safety.

MEMBRANOUS SEPTUM MEASUREMENT. The MS was clearly visualized in all patients in this study. The median length of MS was 5.8 mm (IQR: 5.0-6.9 mm), which was significantly longer compared with previously reported computed tomography (CT)-based MS measurements.[12,25,26] Jilaihawi et al[12] reported a mean MS length of 3.9 ± 2.3 mm in their study, whereas Nai Fovino et al[25] and Hokken et al[26] described median MS lengths of 3.3 mm (IQR: 1.8-4.0 mm) and 4.1 mm (IQR: 2.7-6.0 mm), respectively.

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TABLE 2 Procedure Outcome (N = 163)

TAVR procedure outcome	
Device success	157 (96.3)
Device	
Evolut PRO (Medtronic) 23 mm/26 mm/29 mm	6/20/16
Evolut R 23 mm/26 mm/29 mm	9/39/14
Sapien 3 (Edwards Lifesciences) 20 mm/23 mm/26 mm/29 mm	2/34/17/6
Approach	
Transfemoral/trans-subclavian	161/2
Conscious sedation	162 (99.4)
Number of recaptures (Evolut PRO and Evolut R only)	(N = 104)
0	69 (66.3)
1	26 (25.0)
2	8 (7.7)
3	1 (1.0)
Postdilation	34 (20.9)
Paravalvular leakage moderate or greater	4 (2.5)
Required second valve	2 (1.2)
Conversion to open heart surgery	0 (0)
Coronary obstruction	0 (0)
Cardiac tamponade	1 (0.6)
TJ-ICE procedure outcome	
Adequate image acquisition	163/163 (100)
Conversion to TEE	2/180 (1.1)
Conversion to TTE	1/180 (0.6)
Required longer sheath	2/180 (1.1)
Required change to left jugular vein	6/180 (3.3)
Suboptimal rapid pacing	1/180 (0.6)
Complications	1/180 (0.6)

Values are n (%), n, or n/N (%).
TAVR = transcatheter aortic valve replacement; TEE = transesophageal echocardiography; TJ-ICE = transjugular intracardiac echocardiography; TTE = transthoracic echocardiography.

The major difference between ICE-based and CT-based measurements could be explained as follows: ICE measures the distance from the nadir of the noncoronary cusp to the transition of the MS and the muscular part of the interventricular septum, as depicted in Figures 3A to 3F, whereas CT measures the distance from the basal aortic annulus at the level of the intersection of the right and noncoronary cusps with the transition of the MS and the muscular part of the interventricular septum. Therefore, CT-based measurement provides a shorter MS length. Whether ICE-based MS length correlates with CT-based MS length warrants further investigation.

TABLE 3 30-Day Outcome (N = 163)

In-hospital death	1 (0.6)
30-d mortality	1 (0.6)
New pacemaker implantation	11 (6.7)
Disabling stoke	4 (2.5)
Major vascular complications	16 (9.8)
Type 3 or 4 bleeding	1 (0.6)
Type 2 bleeding	15 (9.2)
Periprocedural myocardial infarction	0 (0)

Values are n (%).

Importantly, we demonstrated excellent intraobserver and interobserver agreements for MS length measurement. Ease of use is one of the advantages of using ICE, which does not require complex measurements.

TAV POSITION RELATIVE TO THE MEMBRANOUS SEPTUM. The main contribution of the present study to current knowledge is the strong association of TAV position with new PPMI rate, which was clearly visualized by ICE during the procedure. Patients with a TAV implantation depth less than the MS length had a significantly lower incidence of new PPMI (2.1% vs 13.4%; $P = 0.005$) regardless of the presence or absence of baseline RBBB. It is well established that a lower implantation depth is a strong procedural predictor of new PPMI.[27] More importantly, recent studies demonstrated that TAV depth in relation to MS length was highly predictive of PPMI in both balloon- and self-expandable TAVR procedures, findings that are in line with present study.[12,25-27] However, all of these previous studies have compared the relationship between TAV implantation depth and MS length by using different modalities (ie, measuring MS length by CT while assessing implantation depth by angiography, which could be inaccurate).[28]

In contrast, we were able to compare the depth and MS length by using the same modality during the procedure. The greatest advantage of our TJ-ICE guided TAVR is that this approach enables direct visualization of the MS during implantation, and this allows us to adjust the landing point inside the MS as intended.[18,29] This is extremely relevant in the low-risk TAVR era in which we also need to consider coronary access after TAVR and potential TAV-in-TAV interventions in the future. In these circumstances, we can aim to implant a TAV intentionally deeper yet still inside the MS using this approach, thereby balancing the risk of conduction disturbance and securing future intervention.

Although this approach is most likely to avoid new PPMI after TAVR, as shown in this study, there are some patients who require new PPMI even after implantation of the valve inside the MS. It is known that new conduction disturbance can occur not only at the time of valve implantation but also when the stiff wire is placed in the left ventricle or when pre-dilatation is performed. Indeed, in 2 patients who required new PPMI in our series and whose valves were appropriately implanted inside the MS,

complete atrioventricular block developed immediately after pre-dilatation.

Recent randomized controlled studies of TAVR in low-surgical risk patients showed a new PPMI rate of 17.4% with self-expandable valves and 6.6% with balloon-expandable valves.[5,6] We were able to achieve lower PPMI rates of 8.7% and 3.4%, respectively. Whether TJ-ICE-guided TAVR can further decrease the new PPMI rate warrants further investigation.

STUDY LIMITATIONS. The present study has the limitations inherent in its retrospective, nonrandomized design, although the data were collected prospectively. The choice of intraprocedural imaging modality was decided on the basis of heart team discussion, which may introduce selection bias. We designed this study as a single-arm study of TJ-ICE-guided TAVR and did not include the outcomes related to TEE-guided TAVR because the aim of this study was to investigate the feasibility and outcome of TJ-ICE-guided TAVR, and we were not trying to demonstrate the superiority of TJ-ICE in comparison with other imaging modalities. Moreover, operators' implantation skills could have influenced the results; however, most of the cases in this study were performed by highly experienced board-certified operators. Because the LVOT view tends to foreshorten the MS, we measured the length of the MS using the LV view in all cases; nonetheless, the MS and the valve could be foreshortened as a result of limited spatial resolution of 2-dimensional ICE used in this study. Finally, the limited number of patients included and the relatively low event rates observed in this study preclude definitive conclusions, and future investigation is warranted with larger groups of patients.

CONCLUSIONS

TJ-ICE-guided TAVR demonstrated remarkable feasibility and safety. Real-time visualization of the MS was feasible in all cases with excellent intraobserver and interobserver agreements. Patients whose TAV was implanted inside the MS had a significantly lower incidence of new PPMI that was consistent regardless of baseline RBBB.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

Dr Kamioka has served as a proctor for Edwards Lifescience. Dr Ohno has served as a proctor for Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: The new PPMI rate after TAVR has been decreasing but remains considerable even after device evolution. Real-time visualization of membranous septum during TAVR procedures with TJ-ICE guidance was feasible and safe, thus achieving a low rate of new PPMI.

TRANSLATIONAL OUTLOOK: On the basis of the findings demonstrated in this relatively small single-center study, whether TJ-ICE-guided TAVR can further decrease the new PPMI rate warrants further investigation.

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KEY WORDS **aortic stenosis, membranous septum, permanent pacemaker implantation, transcatheter aortic valve replacement, transjugular intracardiac echocardiography**