# Clinical Impact of Intraventricular Conduction Abnormalities After Transcatheter Aortic Valve Implantation With Balloon-Expandable Valves

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**Transcatheter aortic valve implantation (TAVI) often causes intraventricular conduction abnormalities (ICA), particularly left bundle branch block (LBBB) and advanced atrioventricular block, requiring pacemaker implantation (PMI). However, the relation between ICA and clinical outcomes after TAVI with balloon-expandable valves remains unclear, particularly in the Asian population. This retrospective study included all patients who underwent TAVI with balloon-expandable valves from October 2013 to September 2016. We defined ICA as new onset of complete LBBB (CLBBB) or PMI within 2 weeks after TAVI. We divided the patients into 2 groups: those with and without ICA (new-ICA and no-ICA groups) and we assessed 1-year outcome. Two hundred one consecutive patients underwent TAVI using balloon-expandable valves (mean age, 84.8 ± 5.7 years; women, 64%). ICA occurred in 47 patients (23%), 37 patients (18%) developed CLBBB, and 34 patients recovered from CLBBB within 1 year after TAVI. Ten patients (5%) who developed symptomatic bradycardia required PMI within 2 weeks after TAVI. At 30 days after PMI, 7 patients already had a very low ventricular pacing rate, and 6 patients who recovered from bradycardia needed pacing at 1 year. Patients with ICA tended to have high 1-year all-cause mortality, but there was no significant difference between the 2 groups (12% vs 7%, p = 0.15). In conclusion, ICA occurred in 23% of patients after TAVI with balloon-expandable valves, and approximately 90% of them recovered from ICA during the follow-up. There was no significant difference in 1-year all-cause mortality between the new-ICA and no-ICA groups.**  **(Am J Cardiol 2019;123:297−305)**

Recent studies have stated that transcatheter aortic valve implantation (TAVI) can cause intraventricular conduction abnormalities (ICA), particularly left bundle branch block (LBBB) and advanced atrioventricular block requiring pacemaker implantation (PMI).[1−2] Those are common and clinically important events, but the outcome of ICA after TAVI is controversial.[2−6] Moreover, there are few reports on the clinical impact of ICA in Asian patients. Asian TAVI candidates tend to have smaller bodies than European TAVI candidates.[7] The aim of the present study was to determine the impact of new onset of ICA after TAVI with balloon-expandable valves in an Asian population.

## Methods

Study subjects were a total of 229 consecutive patients with severe AS who underwent TAVI with balloon-expandable valves between October 2013 and September 2016 at Kokura Memorial Hospital. Inclusion criteria were the presence of symptomatic, degenerative AS with New York Heart Association functional class II or greater; an aortic valve area $< 1.0$ cm$^2$ or an effective orifice area index $< 0.6$ cm$^2$/m$^2$; a mean gradient $\geq 40$ mm Hg; or a jet velocity $\geq 4.0$ m/s. The final decision to perform TAVI was made by the consensus of the institutional heart team. Primary exclusion criteria were patients with congenital bicuspid valve, life expectancy $< 1$ year because of diseases other than AS, and failed surgical bioprosthesis implantation, as well as those who underwent dialysis. Furthermore, the following 28 patients were excluded: (1) those with previous complete or incomplete LBBB (n = 7), (2) those who previously underwent PMI (n = 19), (3) those who previously underwent implantable cardiac defibrillator implantation (n = 1), and (4) those who previously underwent cardiac resynchronization therapy defibrillator implantation (n = 1). A total of 201 patients were finally included (Figure 1). We defined ICA as new onset of complete LBBB (CLBBB) or PMI within 2 weeks after TAVI. We divided the patients into 2 groups: those with new onset of

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See page 304 for disclosure information.

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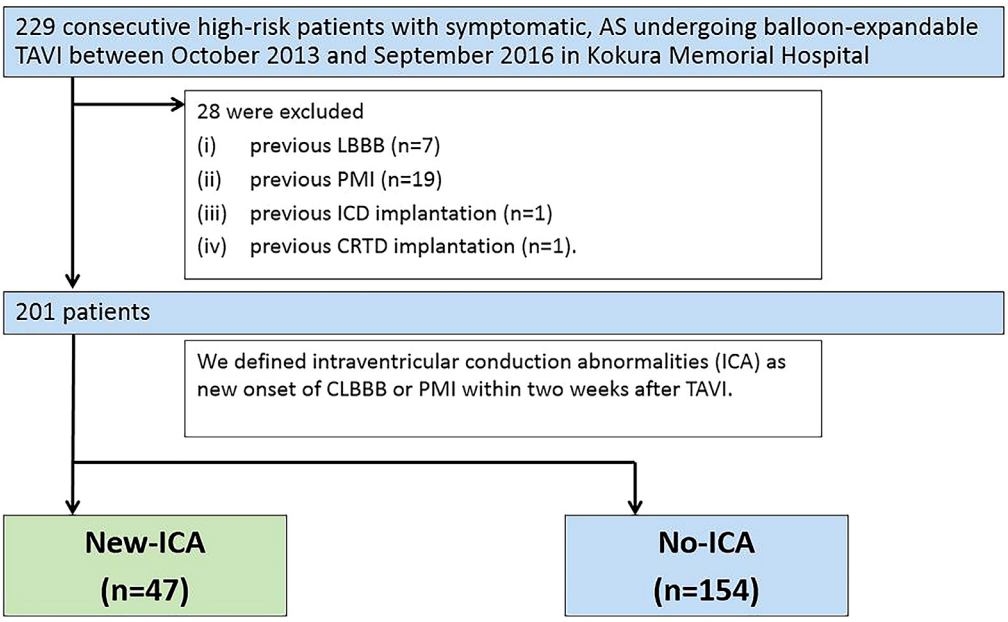



Figure 1. Study design. CLBBB = complete left bundle branch block; CRTD = cardiac resynchronization therapy defibrillator; ICD = implantable cardiac defibrillator implantation; LBBB = left bundle branch block; PMI = pacemaker implantation.

ICA and those without ICA after TAVI. Before the procedure, all the patients underwent contrast-enhanced computed tomography (CT) for assessments of the anatomy and dimensions of the aortic valve, aorta, and iliofemoral arteries. CT data were analyzed for selection of the valve size and approach site. This study was approved by our institutional review board based on the ethical guidelines of the Declaration of Helsinki.

A balloon-expandable valve, namely, Edwards SAPIEN XT and SAPIEN 3 (Edwards Lifesciences, Irvine, CA), was used. The transfemoral approach was first chosen as an access route, but the transapical (TA) approach was considered in patients with aortic dissection, severe tortuosity, or small iliofemoral diameters. The femoral artery was punctured percutaneously and closed using a hemostatic device (PERCLOSE, Abbott, Chicago, IL) or surgically cut down and closed. TA was managed surgically.

Twelve-lead electrocardiogram (ECG) records were obtained from all the patients at baseline and immediately, 1 day, and at discharge in hospital after the procedure. ECG records were analyzed by cardiologists. The diagnosis of ICA was based on the American Heart Association (AHA), American College of Cardiology Foundation (ACCF), and Heart Rhythm Society (HRS) recommendations for the standardization and interpretation of ECG.[8] On the basis of ACCF/AHA/HRS practice guidelines for device-based therapy of cardiac rhythm abnormalities, permanent PMI was indicated for third-degree and advanced second-degree atrioventricular block at any anatomic level and sinus node dysfunction with documented symptomatic bradycardia.[9] All the patients who underwent PMI were implanted dual-chamber. We extracted medical histories from the hospital records of eligible patients. Data included patient characteristics, coronary angiography, CT, transthoracic echocardiography (TTE), procedural, and transfusion data. Information on prognosis was obtained from regular hospital visits at 30 days, 3 months, 6 months, and annually after the procedure or through direct calls to patients. All the definitions of clinical end points and adverse events were based on the Valve Academic Research Consortium 2 definitions.[10]

Categorical variables were compared between the groups using the chi-square test or Fisher's exact test, as appropriate. Continuous variables were assessed for normal distribution using the Student's *t* test or the Wilcoxon rank sum test, as appropriate, and were expressed as mean ± standard deviation or the median and interquartile range (IQR). All analyses were two-tailed with clinical significance defined as $p < 0.05$. Analysis of the survival rates between patients with new onset of ICA and those without ICA was performed using the Kaplan-Meier method. Differences in survival rates between the 2 groups were estimated by the log-rank test. Univariate logistic regression analysis was performed to obtain the odds ratio for new onset of ICA. Therefore, a Cox multivariate regression analysis was performed using the variables with $p < 0.10$ in the univariate analysis to identify the predictive values of new onset of ICA. To identify the predictive values of 1-year survival after TAVI, Cox multivariate regression analysis was performed. The multivariate model was adjusted for new onset of ICA or without ICA. The general risk factors for death for patients who underwent surgery for valvular heart disease or TAVI were age, gender, chronic heart failure, left ventricle ejection fraction, coronary artery disease, TA approach, Society of Thoracic Surgeons score, and diabetes mellitus. All statistical analyses were performed using SPSS version 25 (SPSS Inc., Chicago, IL).

## Results

In total, 47 patients (23%) had new onset of ICA after the procedure. No patients were lost to follow-up, and the

median follow-up period was 414.5 days (IQR, 305.5 to 752.8 days). The median follow-up period in the new-ICA group was 391.0 days (IQR 290.0 to 734.0 days), and the median follow-up period in the no-ICA group was 437.0 days (IQR, 313.0 to 759.0 days). Baseline patient characteristics are summarized in Table 1. The mean age of the patients was 84.8 ± 5.7 years, and 36% of the patients were men. The mean height was 150.5 ± 10.0 cm, the mean weight was 51.5 ± 10.8 kg, and the mean body surface area was 1.44 ± 0.19 $m^2$. Fewer male patients were observed in the new-ICA than in the no-ICA group. Other baseline characteristics were almost similar between the 2 groups.

ECG, TTE, and CT findings are presented in Table 2. A smaller annular area tended to be observed in the new-ICA compared with that in the no-ICA group, but there was no significant difference. And the rate of baseline complete right bundle branch block did not differ between the 2 groups. Other baseline ECG and TTE parameters were also comparable, and the severity of AS was the same between the 2 groups. Procedural data are summarized in Table 2. Transfemoral and TA approaches were performed in 137 patients (68%) and 54 patients (27%), respectively. There was no significant difference in approach site between the new-ICA and no-ICA groups. Moreover, 86% of the implanted valves were SAPIEN XT and 14% of those were SAPIEN 3. Most implanted valve sizes were 23 mm (n = 123, 61%), followed by 26 mm (n = 64, 32%). The new-ICA group tended to be implanted with 23 mm valves, but there was no significant difference in implanted valve size, and the area oversizing ratio and postdilatation did not differ between the 2 groups.

We used a Cox proportional hazards regression model to identify the predictive values of new onset of ICA. The covariates included female sex, previous balloon aortic valvuloplasty, stroke volume, and annulus area, but no variable differed significantly between the 2 groups.

Postprocedural outcomes and follow-up are summarized in Table 3. The incidences of major postprocedural complications were similar in the 2 groups. After the procedure, between the new-ICA and no-ICA groups, the echocardiographic parameters and the incidence of new atrial fibrillation were similar. This study revealed that the 30-day survival rate and early safety end point did not differ between the 2 groups.

Overall, 37 patients (18%) developed CLBBB after TAVI, and 34 patients recovered from CLBBB within 1 year after TAVI. The changes in QRS duration are shown in Figure 2. On the first postoperative day, patients tended to recover from wide QRS, and they recovered from wide QRS at 30 days after TAVI compared with baseline (99.5 ± 20.0 msec vs 91.2 ± 16.1 msec, respectively, p = 0.07).

Table 1
Clinical characteristics of study population

| Characteristic | Overall (n = 201) | Intraventricular conduction abnormalities | | p Value |
|---|---|---|---|---|
| | | No (n = 154) | Yes (n = 47) | |
| Age (years) | 84.8 ± 5.7 | 84.6 ± 5.8 | 85.2 ± 5.3 | 0.57 |
| Men | 72 (36%) | 62 (40%) | 10 (21%) | 0.02 |
| Height (cm) | 150.5 ± 10.0 | 151.1 ± 10.5 | 148.7 ± 7.6 | 0.09 |
| Weight (kg) | 51.5 ± 10.8 | 51.5 ± 11.2 | 49.0 ± 9.0 | 0.17 |
| BSA ($m^2$) | 1.44 ± 0.19 | 1.45 ± 0.20 | 1.41 ± 0.14 | 0.08 |
| BMI ($kg/m^2$) | 22.3 ± 3.3 | 22.4 ± 3.3 | 22.1 ± 3.5 | 0.69 |
| NYHA class III or IV | 97 (48%) | 76 (49%) | 21 (42%) | 0.58 |
| Logistic EuroSCORE (%) | 15.3 (11.4–22.7) | 15.1 (11.4–21.6) | 17.2 (11.4–26.0) | 0.27 |
| Euro II score (%) | 4.3 (3.2–6.5) | 4.3 (3.1–6.1) | 4.6 (3.3–8.7) | 0.13 |
| STS score (%) | 6.4 (4.3–8.9) | 6.3 (4.1–8.8) | 7.5 (5.1–9.4) | 0.15 |
| Hypertension | 161 (80%) | 123 (80%) | 38 (81%) | 0.88 |
| Hyperlipidemia | 84 (42%) | 62 (40%) | 22 (47%) | 0.43 |
| Diabetes mellitus | 52 (26%) | 40 (26%) | 12 (26%) | 0.95 |
| Peripheral artery disease | 17 (9%) | 13 (8%) | 4 (9%) | 0.99 |
| Cerebral vascular disease | 38 (19%) | 31 (20%) | 7 (15%) | 0.42 |
| Chronic obstructive pulmonary disease | 36 (18%) | 29 (19%) | 7 (15%) | 0.54 |
| Cardiac history | | | | |
| CAD | 85 (42%) | 65 (42%) | 20 (43%) | 0.97 |
| Prior coronary bypass | 23 (11%) | 20 (13%) | 3 (6%) | 0.21 |
| Prior PCI | 49 (24%) | 38 (25%) | 11 (23%) | 0.86 |
| Prior BAV | 81 (40%) | 57 (37%) | 24 (51%) | 0.09 |
| Old MI | 6 (3%) | 5 (3%) | 1 (2%) | 0.69 |
| eGFR ($ml/min/1.73m^2$) | 52.3 (38.4–66.8) | 52.5 (38.5–67.3) | 47.9 (35.5–62.5) | 0.24 |
| BNP (pg/ml) | 199.9 (90.6–441.8) | 203.9 (90.0–441.1) | 192.0 (91.5–458.3) | 0.92 |

BAV = balloon aortic valvuloplasty; BMI = body mass index; BNP = brain natriuretic peptide; BSA = body surface are; CAD = coronary artery disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; GFR = glomerular filtration rate; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STS = Society of Thoracic Surgeons.

Data given as n (%), mean ± standard deviation, or median (interquartile range).

Table 2
Baseline electrocardiographic, echocardiographic, computed tomography parameters and procedural data

| Characteristic | Overall (n = 201) | Intraventricular conduction abnormalities | | p Value |
|---|---|---|---|---|
| | | No (n = 154) | Yes (n = 47) | |
| Electrocardiogram | | | | |
| Sinus rhythm | 171 (85%) | 131 (85%) | 40 (85%) | 0.99 |
| PQ duration (msec) | 188.1 ± 35.0 | 186.1 ± 33.9 | 195.3 ± 38.0 | 0.15 |
| QRS duration (msec) | 97.0 ± 21.0 | 97.7 ± 21.3 | 94.8 ± 20.0 | 0.41 |
| CRBBB | 24 (12%) | 19 (12%) | 5 (11%) | 0.75 |
| Echocardiogram | | | | |
| AVA ($cm^2$) | 0.63 ± 0.14 | 0.64 ± 0.15 | 0.62 ± 0.10 | 0.30 |
| AVA index ($cm^2/m^2$) | 0.44 ± 0.09 | 0.44 ± 0.09 | 0.44 ± 0.07 | 0.97 |
| Peak gradient (mm Hg) | 92.4 ± 28.3 | 93.7 ± 28.5 | 87.9 ± 27.3 | 0.22 |
| Mean gradient (mm Hg) | 54.0 ± 17.7 | 54.3 ± 17.2 | 52.9 ± 19.5 | 0.64 |
| LVEF (%) | 60.6 ± 9.1 | 60.3 ± 9.1 | 61.6 ± 9.1 | 0.43 |
| LVDd (mm) | 44.1 ± 5.6 | 44.4 ± 5.7 | 43.3 ± 5.2 | 0.22 |
| LVDs (mm) | 29.6 ± 5.6 | 29.8 ± 5.7 | 28.9 ± 5.5 | 0.36 |
| IVS (mm) | 10.9 (10.1−12.0) | 10.9 (10.1−12.0) | 10.6 (10.0−12.0) | 0.58 |
| Moderate-to-severe AR | 32 (15.9) | 23 (14.9) | 9 (19.1) | 0.49 |
| E/A | 0.71 (0.59−0.90) | 0.70 (0.59−0.87) | 0.76 (0.59−0.96) | 0.33 |
| E/e′ | 20.9 (16.7−25.6) | 20.8 (16.4−25.5) | 21.6 (17.1−26.1) | 0.38 |
| DcT (msec) | 242.0 (196.0−307.8) | 240.0 (196.0−311.3) | 242.0 (197.7−307.4) | 0.96 |
| CT | | | | |
| CAA diameter (mm) | 21.7 (20.7−23.1) | 21.9 (20.7−23.4) | 21.2 (20.1−22.6) | 0.060 |
| CAA area ($mm^2$) | 366.7 (337.1−419.5) | 375.0 (337.5−431.9) | 351.1 (316.8−402.0) | 0.060 |
| Left coronary height (mm) | 13.0 (11.3−14.4) | 13.1 (11.3−14.4) | 12.4 (11.3−14.1) | 0.29 |
| Right coronary height (mm) | 14.3 (12.8−16.8) | 14.5 (12.9−16.8) | 13.9 (12.3−16.8) | 0.58 |
| SOV (RCC) diameter (mm) | 28.7 (26.9−31.0) | 28.8 (27.0−31.3) | 28.2 (25.9−30.1) | 0.18 |
| SOV (NCC) diameter (mm) | 29.7 (28.0−32.1) | 29.8 (28.2−32.6) | 29.6 (27.3−31.3) | 0.15 |
| SOV (LCC) diameter (mm) | 29.7 (27.4−32.3) | 30.0 (27.5−32.6) | 29.4 (27.3−30.9) | 0.12 |
| Procedural data | | | | |
| Approach | | | | 0.96 |
| Transfemoral | 137 (68%) | 105 (68%) | 32 (68%) | |
| Transapical | 54 (27%) | 41 (27%) | 13 (28%) | |
| Transiliac | 10 (5%) | 8 (5%) | 2 (4%) | |
| Kind of valve | | | | 0.46 |
| SAPIEN XT | 173 (86%) | 131 (85%) | 42 (89%) | |
| SAPIEN 3 | 28 (14%) | 23 (15%) | 5 (11%) | |
| Valve size | | | | 0.18 |
| 20 mm | 4 (2%) | 3 (2%) | 1 (2%) | |
| 23 mm | 123 (61%) | 88 (57%) | 35 (75%) | |
| 26 mm | 64 (32%) | 54 (35%) | 10 (21%) | |
| 29 mm | 10 (5%) | 9 (6%) | 1 (2%) | |
| Area oversizing ratio | 1.11 (1.07−1.17) | 1.11 (1.07−1.17) | 1.10 (1.08−1.16) | 0.78 |
| Postdilatation value | 47 (23%) | 36 (23%) | 11 (23%) | 0.44 |

AR = aortic regurgitation; AVA = aortic valve area; CAA = calculated average annulus; CRBBB = complete right bundle branch block; CT = computed tomography; DcT = deceleration time; E/A = the ratio of peak early to peak late mitral inflow velocity; E/e′ = the ratio of early diastolic transmitral flow velocity to early diastolic mitral annual velocity; ICA = intraventricular conduction abnormalities; IVS = interventricular septum thickness; LCC = left coronary cusp; LVDd = left ventricular end-diastolic dimension; LVDs = left ventricular internal dimension in systole; LVEF = left ventricular ejection fraction; NCC = noncoronary cusp; RCC = right coronary cusp; SOV = sinus of Valsalva.

Data given as n (%), mean ± standard deviation, or median (interquartile range).

Echo parameters in patients with new onset of CLBBB at 1 year after TAVI are summarized in Supplementary Table 1. Left ventricle ejection fraction did not differ between patients with transient CLBBB and those with persistent CLBBB, but patients with persistent CLBBB had a longer left ventricular diameter than those with transient CLBBB. In addition, patients with persistent CLBBB had higher E/e′ values and longer deceleration time (DcT), but it did not significantly differ from those in patients with transient CLBBB.

The incidence, cause, and timing of new permanent PMI are summarized in Table 4. Ten patients (5.0%) who developed symptomatic bradycardia required PMI within 2 weeks after TAVI. Most patients were women, and the main reason for PMI was complete atrioventricular block. At 30 days after PMI, 7 patients had a very low ventricular pacing rate, and 60% of the patients who recovered from bradycardia needed pacing (ventricular pacing rate $\leq$1.0%) at 6 months and 1 year after PMI.

Table 3
Postprocedural outcomes and follow-up

| Characteristic | Overall (n = 201) | Intraventricular conduction abnormalities | | p Value |
|---|---|---|---|---|
| | | No (n = 154) | Yes (n = 47) | |
| Major vascular complication | 5 (3%) | 5 (3%) | 0 (0%) | 0.21 |
| Minor vascular complication | 11 (6%) | 8 (5%) | 3 (6%) | 0.75 |
| Life-threatening bleeding | 12 (6%) | 10[7] | 2 (4%) | 0.57 |
| Major bleeding | 55 (27%) | 38 (25%) | 17 (36%) | 0.12 |
| Minor bleeding | 15 (8%) | 12 (8%) | 3 (6%) | 0.75 |
| Myocardial infarction | 2 (1%) | 2 (1%) | 0 (0%) | 0.43 |
| Coronary obstruction | 2 (1%) | 1 (1%) | 1 (2%) | 0.41 |
| Cardiac tamponade | 1 (1%) | 1 (1%) | 0 (0%) | 0.58 |
| Valve migration | 0 (0%) | 0 (0%) | 0 (0%) | 1.00 |
| Conversion to open surgery | 1 (1%) | 1 (1%) | 0 (0%) | 0.58 |
| Stroke | 6 (3%) | 6 (4%) | 0 (0%) | 0.34 |
| Transfusion | 63 (32%) | 46 (31%) | 17 (37%) | 0.44 |
| Postimplantation | | | | |
| Mean pressure gradient (mm Hg) | 11.3 ± 5.0 | 11.5 ± 5.3 | 10.5 ± 3.9 | 0.24 |
| LVEF (%) | 60.6 ± 9.1 | 60.4 ± 9.1 | 61.3 ± 9.2 | 0.56 |
| Moderate-to-severe AR | 4 (2%) | 4 (3%) | 0 (0%) | 0.58 |
| Moderate-to-severe MR | 8 (4%) | 6 (4%) | 2 (4%) | 0.91 |
| New atrial fibrillation | 6 (3%) | 6 (4%) | 0 (0%) | 0.34 |
| Early safety end point (30 days) | 27 (13%) | 22 (14%) | 5 (11%) | 0.52 |
| 30-day survival | 200 (99%) | 153 (99%) | 47 (100%) | 0.58 |
| 1-year all-cause mortality* | 14 (8%) | 9 (7%) | 5 (12%) | 0.15 |
| 1-year cardiovascular mortality* | 4 (2%) | 4 (3%) | 0 (0%) | 0.18 |
| 1-year rate of admission for HF* | 6 (4%) | 5 (4%) | 1 (2%) | 0.49 |

AR = aortic regurgitation; HF = heart failure; ICA = intraventricular conduction abnormalities; LVEF = left ventricular ejection fraction; MR = mitral regurgitation.

Data given as n (%), mean ± standard deviation, or median (interquartile range).

* Cumulative Kaplan-Meier estimates at 1 year.

Between the new-ICA and no-ICA groups, there was a trend toward higher 1-year all-cause mortality in the new-ICA group (12% vs 7%, n = 5 vs 9, respectively), but the Kaplan-Meier analysis revealed that new onset of ICA is not associated with 1-year all-cause mortality (p = 0.15; Table 3, Figure 3). Both groups had low cardiovascular mortality (0% vs 3%, p = 0.18; Table 3), and there was no significant difference in the rate of admission for heart failure (2% vs 4%, p = 0.49; Table 3, Figure 4). In the Cox regression analysis, new onset of ICA was not significantly related to 1-year all-cause mortality (hazard ratio, 1.71; 95% confidence interval, 0.52 to 5.66; p = 0.38; Supplementary Table2). After the acute phase, 3 patients required permanent PMI (322, 393, and 571 days after TAVI), and all were patients without new onset of ICA.

## Discussion

The major findings of the present study are as follows: (1) New onset of ICA occurred in 23% of the patients after TAVI using balloon-expandable valves, and new onset of ICA was not associated with worse outcomes after 1-year follow-up in Asian populations. (2) The rate of reversibility of new onset of ICA was high. The peak QRS length was observed at cardiac care unit, and 93% of the patients with new onset of CLBBB recovered from CLBBB during the first year after TAVI. In addition, 60% of the patients who recovered from bradycardia needed pacing at 6 months and 1 year after PMI.

Previous evidence has shown that new onset of ICA is an independent risk factor for mortality[5,6]. Other studies have reported that new onset of ICA does not increase the risk of global or cardiovascular mortality or rehospitalizations at 1-year follow-up[3,4]; hence, new onset of ICA is a common and clinically important event, but the outcome is controversial. Our study demonstrated that new onset of ICA occurred in 23% of patients in an Asian population after TAVI using balloon-expandable valves, and new onset of ICA was not associated with all-cause or cardiovascular mortality or repeat hospitalizations for heart failure at 1-year follow-up. To the best of our knowledge, this is the first clinical study on the relation between new onset of ICA after TAVI and mid-term prognosis in an Asian population. Nishiyama et al showed that new onset of ICA was observed in 22.2% of patients after TAVI in an Asian population,[11] which was almost the same as that reported in the present study. Unlike the report by Nishiyama et al, the sample size in our study was larger, and we could follow 1-year prognosis.

Previous studies have also shown that a larger size of valve implantation, lower position of valve implantation, longer baseline QRS duration, or smaller left ventricular outflow tract can cause direct trauma or mechanical damage to the His bundle at the region of the membranous septum

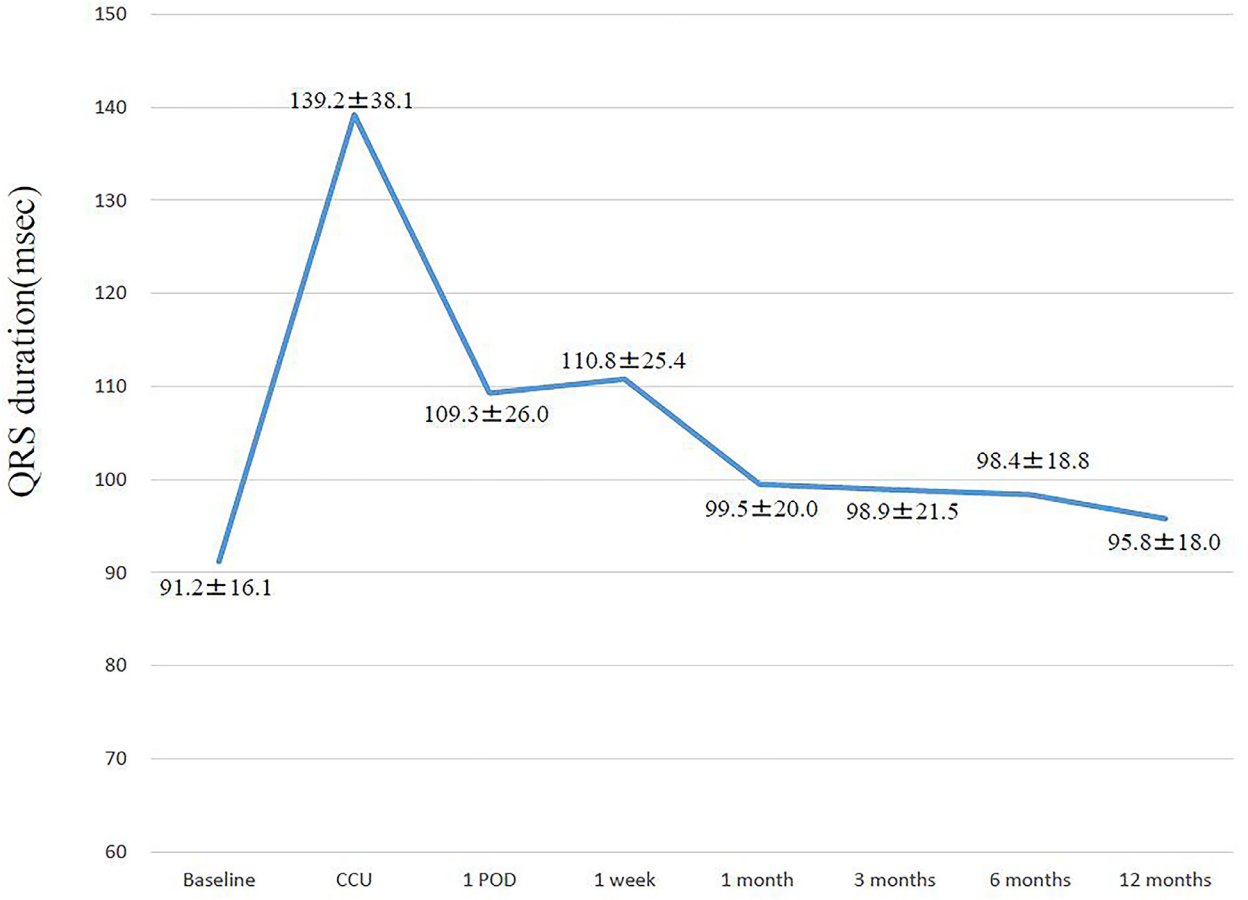



Figure 2. Change in the QRS duration after transcatheter aortic valve implantation in the case of new onset of complete left bundle branch block. CCU = cardiac care unit; POD = postoperative day.

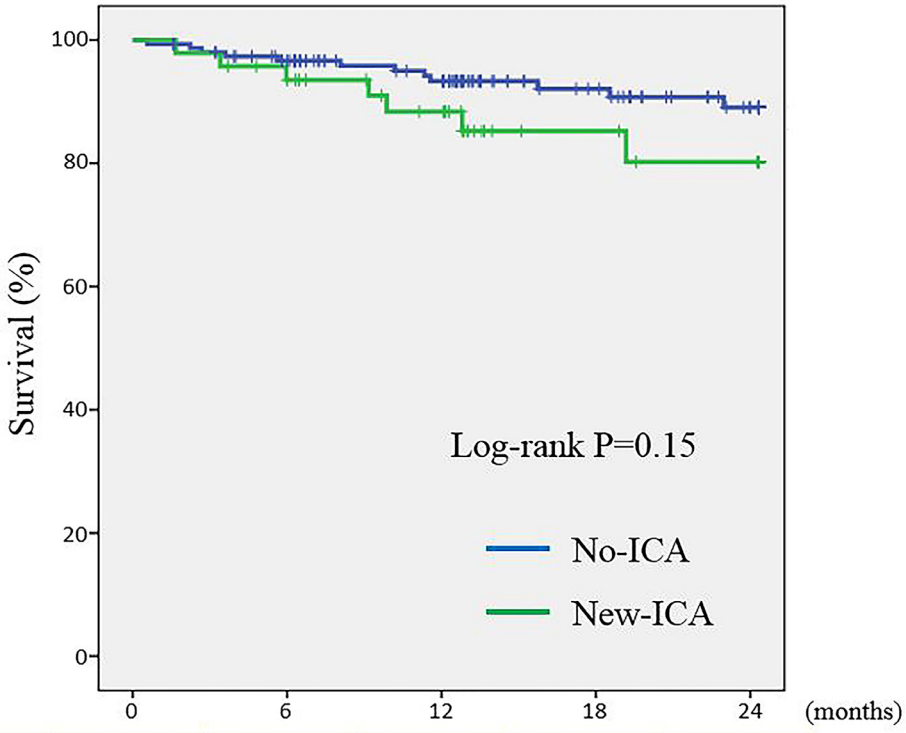
and right trigone beneath the noncoronary and right coronary cusps, leading to new onset of ICA after TAVI.[2,11–14] In Asian populations wherein people have smaller bodies, aortic annulus areas, and other heart structures than those of people in Europe,[7] the present study demonstrated that the rate of new onset of ICA is the same as those in Europe and the United States (10.5% to 36.8%),[2–6] and new onset of ICA did not influence worse outcomes after 1-year follow-up.

A previous study reported that female patients were associated with lower risk of pacemaker implantation compared with male patients,[15] whereas fewer male

Table 4
Summary of cases with permanent pacemaker implantation after transcatheter aortic valve implantation

| No | Age (years) | Gender | Valve type | Time from TAVI (days) | Reason of PMI | VP rate 30 days after PMI (%) | VP rate 6 months after PMI (%) | VP rate 1 year after PMI (%) |
|---|---|---|---|---|---|---|---|---|
| 1 | 87 | Female | SAPIEN XT 23 mm | 13 | SSS | 0.2 | 0.2 | 0.2 |
| 2 | 92 | Female | SAPIEN XT 23 mm | 8 | CAVB | 100.0 | 0.2 | 0.2 |
| 3 | 94 | Male | SAPIEN XT 26 mm | 11 | CAVB | 0.3 | 0.3 | 1.0 |
| 4 | 81 | Female | SAPIEN XT 23 mm | 12 | CAVB | 1.7 | 0.4 | 0.5 |
| 5 | 87 | Female | SAPIEN XT 26 mm | 8 | CAVB | 14.0 | 66.0 | 58.0 |
| 6 | 89 | Male | SAPIEN XT 26 mm | 7 | CAVB | 99.9 | 99.9 | 99.9 |
| 7 | 80 | Female | SAPIEN XT 26 mm | 13 | CAVB | 0.0 | 0.0 | 0.0 |
| 8 | 84 | Female | SAPIEN 3 23 mm | 6 | CAVB | 30.0 | 30.0 | 54.0 |
| 9 | 87 | Female | SAPIEN 3 23 mm | 12 | CAVB | 0.0 | 0.0 | 0.0 |
| 10 | 85 | Female | SAPIEN 3 23 mm | 13 | CAVB | 100.0 | 99.0 | 100.0 |

CAVB = complete atrioventricular block; PMI = pacemaker implantation; SSS = sick sinus syndrome; TAVI = transcatheter aortic valve implantation; VP = ventricular pacing.




| New ICA | 0 | 6 months | 12 months | 18 months | 24 months |
|---|---|---|---|---|---|
| No at risk | 47 | 42 | 34 | 27 | 16 |
| Incidence | 0.0 % | 6.5 % | 11.6 % | 14.8 % | 19.8 % |

| No ICA | 0 | 6 months | 12 months | 18 months | 24 months |
|---|---|---|---|---|---|
| No at risk | 154 | 139 | 112 | 73 | 53 |
| Incidence | 0.0 % | 3.3 % | 6.7 % | 7.9 % | 10.9 % |

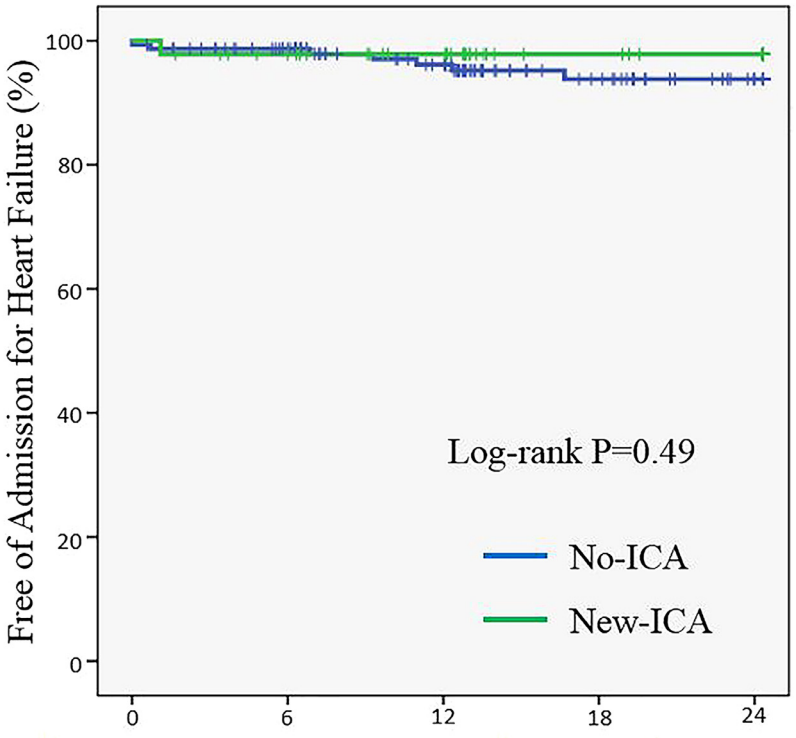
Figure 3. Kaplan-Meier curves of overall survival probability in patients with new-ICA and no-ICA. ICA = intraventricular conduction abnormalities.

patients were in the new onset of ICA group compared with the no-ICA group in the present study. In addition, the majority of patients who received pacemaker were also female. This difference is difficult to explain based on gender, but in previous report, more self-expandable valves were implanted in male compared with female.[15] Previous studies have shown a significant higher risk of pacemaker implantation with self- versus balloon-expandable valves.[16]

A previous study reported approximately 85% of patients with new onset of LBBB who recovered from LBBB during the first year following TAVI with a SAPIEN valve.[2] In the present study, the peak QRS length was observed at cardiac care unit, and 93% of the patients with new onset of CLBBB recovered from CLBBB during the first year after TAVI. Moreover, there are few reports regarding recovery from CAVB, but our study showed that the ventricular pacing rate was low during the first year following permanent PMI. In the present study, the patients with persistent CLBBB had a longer left ventricular diameter and a tendency of high E/e′ values and long DcTs at 1 year after TAVI. Furthermore, CLBBB is known to cause an asynchrony of ventricular contraction. These factors may influence left ventricular function and the onset of heart failure; thus, careful follow-up of patients with new onset of ICA is necessary.

This study has some limitations. First, it is a single-center, observational study. Second, the sample size was relatively small. Third, only balloon-expandable valves were studied. Fourth, left ventricular outflow tract area and implantation depth were not assessed. Fifth, the follow-up period was quite short. Hence, future multicenter studies with larger samples and longer follow-up periods are warranted.

In conclusion, new onset of ICA after TAVI with balloon-expandable valves was observed in 23% of the patients in an Asian population, and approximately 90% of them recovered from ICA during the follow-up. New onset of ICA was not associated with worse outcomes after 1-year follow-up.




| New ICA | 0 | 6 months | 12 months | 18 months | 24 months |
|---|---|---|---|---|---|
| No at risk | 47 | 45 | 45 | 45 | 45 |
| Incidence | 0.0 % | 2.2 % | 2.2 % | 2.2 % | 2.2 % |

| No ICA | 0 | 6 months | 12 months | 18 months | 24 months |
|---|---|---|---|---|---|
| No at risk | 154 | 150 | 110 | 68 | 68 |
| Incidence | 0.0 % | 1.3 % | 3.8 % | 6.2 % | 6.2 % |

Figure 4. Kaplan-Meier curves of admission for heart failure in patients with new-ICA and no-ICA. ICA = intraventricular conduction abnormalities.

## Disclosures

Miura is a consultant for Japan Lifeline. All other authors declare no conflict of interest.

## Supplementary Data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.amjcard.2018.10.005.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