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**Original Research** 

## Risk Stratification and Management of Advanced Conduction Disturbances Following TAVI in Patients With Pre-Existing RBBB

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## ABSTRACT

*Background:* Pre-existing right bundle branch block (RBBB) is a strong predictor of increased need for a permanent pacemaker (PPM) following transcatheter aortic valve implantation (TAVI). Yet, further risk stratification and management remain challenging in patients with pre-existing RBBB owing to limited data. Therefore, we sought to investigate the incidence, predictors, and management of advanced conduction disturbances after TAVI in patients with pre-existing RBBB.

*Methods*: We retrospectively reviewed 261 consecutive patients with pre-existing RBBB (median age 81 years; 28.0% female; 95.0% received a balloon-expandable valve) without a pre-existing PPM who underwent TAVI at our institution in 2015-2019. Outcomes were high-degree atrioventricular block/complete heart block (HAVB/ CHB) and PPM requirement.

*Results*: Overall, the 30-day HAVB/CHB rate was 28.0%, of which 76.7% occurred during the TAVI procedure. The delayed HAVB/CHB rate was 8.3%. Implantation depth below aortic annulus (per 1-mm increase) was significantly associated with increased risk of procedural HAVB/CHB (adjusted odds ratio = 1.25, 95% confidence interval = 1.07-1.46), delayed HAVB/CHB (1.34 [1.01-1.79]), and 30-day PPM (1.32 [1.11-1.55]). Predilation was associated with delayed HAVB/CHB (4.02 [1.22-13.23]). The combination of no predilation and implantation depth of  $\leq$ 2.0 mm had lower rates of procedural HAVB/CHB (11.2% vs. 26.7%-30.4%, *p* = 0.011), delayed HAVB/CHB (2.1% vs. 7.6%-28.1%, *p* < 0.001), and 30-day PPM (10.3% vs. 20.0%-43.5%, *p* < 0.001) than the other strategies of valve deployment. Complete HAVB/CHB recovery after PPM implantation was uncommon at 7.1%.

*Conclusions*: In patients with pre-existing RBBB, the majority of HAVB/CHB events occurred during the TAVI procedure. Avoidance of predilation coupled with high valve deployment may result in relatively low rates of procedural and delayed HAVB/CHB, along with 30-day PPM rates.

CHB, complete heart block; ECG, electrocardiogram; HAVB, high-degree atrioventricular block; ICD, implantable cardioverter defibrillator; LVOT, left ventricular outflow tract; MACE, major adverse cardiovascular events; NCC, noncoronary cusp; PPM, permanent pacemaker; RAO, right anterior oblique; RBBB, right bundle branch block; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve; TPM, temporary pacemaker.

## Introduction

ABBREVIATIONS

With technological advances and established clinical evidence during the last decade, transcatheter aortic valve implantation (TAVI) is now the

preferred intervention for the majority of patients with severe aortic stenosis.<sup>1</sup> Yet, the occurrence of advanced conduction disturbances following TAVI remains a major issue, owing to anatomical proximity of the positioned oversized transcatheter heart valve (THV) prosthesis and

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the atrioventricular node/His-Purkinje system.<sup>2-4</sup> Despite newer-generation THVs, average permanent pacemaker (PPM) rates remain around 10% or higher at 30 days after TAVI.<sup>5,6</sup> Importantly, pre-existing right bundle branch block (RBBB) is the most consistent patient factor that predicts PPM risk.<sup>7</sup> A recent meta-analysis revealed an increased 30-day PPM risk in patients with versus without pre-existing RBBB (38.1% vs. 11.4%; risk ratio = 3.56).<sup>8</sup> Furthermore, recent studies using ambulatory monitoring devices revealed pre-existing RBBB as a predictor of delayed conduction disorders after TAVI.<sup>9,10</sup>

The prevalence of RBBB is up to 3% in the general population<sup>11,12</sup> but increases with age.<sup>13</sup> Accordingly, pre-existing RBBB is more common (5%-20%) among patients undergoing aortic valve replacement.<sup>8,14</sup> Despite the high PPM risk after TAVI in patients with pre-existing RBBB, appropriate management has yet to be established owing to scarce data on detailed clinical course after TAVI.<sup>2,3</sup> Moreover, while numerous studies have demonstrated pre-existing RBBB *per se* as an overall strong predictor of PPM requirement after TAVI.<sup>7,8</sup> few data exist on additional predictors to further optimize risk stratification in this high PPM risk subpopulation. Therefore, the present study sought to evaluate the incidence, timing, predictors, and management of advanced conduction disturbances after TAVI in patients with pre-existing RBBB. A key aim of this analysis was to further identify secondary risk factors that consolidate advanced conduction disturbances and PPM risk in TAVI recipients with pre-existing RBBB.

## **Materials and Methods**

## Study Design and Data Collection

We undertook a retrospective analysis of consecutive patients aged  $\geq$ 18 years with pre-existing RBBB (QRS duration  $\geq$ 120 msec) who underwent TAVI at Cleveland Clinic between January 2015 and December 2019. Patients with pre-existing cardiac implantable electronic devices were excluded. Data on patient characteristics, electrocardiogram (ECG), imaging data, procedural characteristics, and in-hospital/postdischarge adverse events were extracted from our prospective institutional registries or were manually collected from electronic medical records. Adverse events were based on the Valve Academic Research Consortium-2 criteria.<sup>15</sup> The present study was approved by the Institutional Review Board of Cleveland Clinic with a waiver of informed consent owing to the retrospective nature of the study. The present research has adhered to the relevant ethical guidelines.

### Procedural Strategy and Postprocedure Management

In our institution, a high valve deployment technique has been introduced to decrease the post-TAVI PPM risk since April 2017.<sup>16</sup> Briefly, the right anterior oblique (RAO) caudal view that removes the parallax from the inflow of the valve stent frame was used to confirm that the radiographic lucent line of the Edwards Sapien 3 THV or inflow of the Medtronic Evolut THV was positioned at or just below the base of the noncoronary cusp (NCC) before deployment. The THV was deployed while the position was maintained during the valve expansion. This technique allowed us to deploy the valve at a higher position than conventional deployment technique using a 10:0 to 8.5:1.5 ratio of the valve frame in the aorta:left ventricular outflow tract (LVOT).

The temporary pacemaker (TPM) was removed at the end of the TAVI procedure irrespective of pre-existing conduction disturbances unless high-degree atrioventricular block (HAVB) or complete heart block (CHB) occurred periprocedurally or maintaining a TPM was deemed necessary by the operating physicians. When HAVB/CHB or bradyarrhythmia was observed during continuous telemetry monitoring after TAVI, TPM re-insertion was considered, and our electrophysiology team was consulted for PPM requirement. A Zio Patch (iRhythm San Francisco, CA) could be initiated upon hospital discharge for ambulatory ECG

monitoring at the discretion of operating physicians or as part of our prior prospective study.<sup>17</sup> In our institution, outpatient follow-up (typically with nurse practitioners or physician assistants) was routinely arranged within 3-7 days after discharge for all patients who underwent TAVI.

## ECG Assessment

Twelve-lead (or 6-lead) ECGs were routinely undertaken at least at 3 different time points (at baseline before TAVI, immediately after TAVI, and day 1 after TAVI). All ECG and telemetry data were evaluated according to the standard definitions and guidelines by the American Heart Association, American College of Cardiology Foundation, and Heart Rhythm Society recommendations.<sup>18,19</sup> HAVB/CHB was divided into procedural HAVB/CHB and delayed HAVB/CHB according to a recent expert panel document<sup>3</sup>: the former was defined as any HAVB/CHB episode occurring during the TAVI procedure, while the latter was defined as any HAVB/CHB episode occurring after the patient had left the procedure room and within 30 days after the procedure. Procedural HAVB/CHB (defined as HAVB/CHB that persisted until the end of the TAVI procedure) and procedural transient HAVB/CHB (defined as HAVB/CHB that recovered by the end of the procedure).

## **Imaging Assessment**

Data on aortic annulus were measured using ECG-gated computed tomography (CT) images with contrast before TAVI (or cardiac magnetic resonance imaging if contrast CT images were unavailable owing to poor renal function). The calcium score of aortic valve leaflets was quantified using ECG-gated contrast CT images before TAVI. A prespecified threshold was set to account for the hyperdensity of the applied contrast medium according to a previous report.<sup>20</sup> The presence or absence of LVOT calcification was also examined using available contrast-enhanced or noncontrast CT images before TAVI. These measurements were performed using Aquarius iNtuition (TeraRecon Inc, Foster City, CA). The eccentricity index and oversizing were calculated based upon the methods of a prior study.<sup>21</sup> Implantation depth of the THV relative to the base of the NCC was defined as the distance between the bottoms of the NCC and the valve stent frame in the final RAO caudal aortic root angiogram and was measured using SyngoDynamics imaging software (Siemens Healthcare, Malvern, PA).

## **Outcome Measures**

Outcomes of interest were the occurrence of procedural and delayed HAVB/CHB, TPM reinsertion, and the requirement of the PPM or implantable cardioverter defibrillator (ICD) within 30 days after TAVI. In-hospital adverse events and postdischarge outcomes were also assessed. Major adverse cardiovascular events (MACE) were defined as all-cause death, stroke/transient ischemic attack, and hospitalization for heart failure. In PPM/ICD recipients, the right ventricular (RV) pacing rate was assessed at 1-3 months after PPM/ICD implantation. Complete HAVB/CHB recovery was defined as an RV pacing rate of <1%, and PPM dependency was defined as an RV pacing rate of >40% according to a recent study.<sup>22</sup>

## Statistical Analysis

Categorical variables were presented as numbers and percentages and were compared using the chi-square test or Fisher exact test. Continuous variables were presented as median and interquartile range (IQR) or mean  $\pm$  standard deviation and were compared using the Mann-Whitney U test or Student *t*-test as appropriate. Multivariable logistic regression analyses were conducted to identify independent predictors of procedural HAVB/CHB, delayed HAVB/CHB, and 30-day PPM/ICD

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requirement. In each multivariable analysis, variables with clinical interest found to be p < 0.05 in univariable analyses were entered as covariates. Missing data were handled with multiple imputation, while complete case analyses were also conducted. We also performed a sensitivity analysis for those predictors using only patients who underwent TAVI with a balloon-expandable valve. The C-statistic, the area under the receiver operating characteristic curve, was calculated to determine the predictive ability for HAVB/CHB and 30-day PPM/ICD requirement. Kaplan–Meier curves were used to compare death and MACE between patients with or without the 30-day PPM/ICD with the use of the log-rank test. A 2-sided *p*-value of <0.05 was considered significant in all hypothesis tests. All statistical analyses were conducted using IBM SPSS Statistics, version 27 (IBM Corp, Armonk, NY).

## Results

## Study Patients

Among 2296 patients who underwent TAVI between January 2015 and December 2019, 261 patients (11.4%) with pre-existing RBBB without preexisting cardiac implantable electronic devices were identified, comprising the present study cohort (Supplemental Figure 1). The median age was 81.0 years; 28.0% were women; the median Society of Thoracic Surgeons (STS) risk score was 5.14%. Overall, 13.4% of the patients had atrial fibrillation (AF) at baseline before TAVI, 33.3% had first degree atrioventricular block, 26.8% had left anterior fascicular block, and 1.1% had left anterior fascicular block. As a result, 28.0% had bifascicular block, and 9.2% had trifascicular block (Table 1). A transfemoral approach was used in 93.5% of the patients (17 nontransfemoral: 7 subclavian, 7 apical, and 3 direct aortic). Balloon-expandable valves were used in 95.0% of the patients (237 Sapien 3; 11 Sapien XT: Edwards Lifesciences, Irvine, California), and selfexpanding THVs were used in 5.0% of the patients (1 Evolut PRO; 9 Evolut R; 3 CoreValve: Medtronic, Minneapolis, Minnesota).

Of the 261 eligible patients, 56 (21.5%) patients developed procedural HAVB/CHB (39 patients developed procedural persistent, and 17 patients developed procedural transient); of the remaining 205 patients, 17 (8.3%) patients developed delayed HAVB/CHB (Figure 1a). Overall, 73 (28.0%) patients developed HAVB/CHB (70 CHBs and 3 HAVBs). The 30-day PPM/ICD rate was 21.8% (57/261) in patients with pre-existing RBBB, which was significantly higher than that in patients without pre-existing RBBB (6.4% [108/1692], p < 0.001), driven by the higher in-hospital PPM/ICD rate (20.7% vs. 5.3%, p <0.001), with a similar postdischarge PPM/ICD rate (1.1% vs. 1.1%, p =0.75). The incidence of 30-day HAVB/CHB and PPM requirement both declined over the 5 years from 2015 to 2019 in patients with preexisting RBBB, to coincide in 2017 with the regular adoption of the NCC-guided valve implant from the RAO caudal view with subsequent high valve deployment technique (30-day HAVB/CHB, from 48.3% to 14.7%; 30-day PPM/ICD, from 44.8% to 9.3%; Figure 1b).<sup>16</sup> The indications for the 30-day PPM/ICD were HAVB/CHB (n = 50), HAVB/CHB + low left ventricular ejection fraction (n = 4), left bundle branch block + low left ventricular ejection fraction (n = 1), bifascicular block and AF bradycardia with syncope (n = 1), and trifascicular block (prophylactic, n = 1). The types of implanted device were dual-chamber PPM (n = 49), single-chamber (RV lead) PPM (n = 2), leadless PPM (n = 1), and cardiac resynchronization therapy with a pacemaker (CRT-P, n = 1) or defibrillator (CRT-D, n = 4). A total of 27 patients were discharged with Zio Patch, which detected delayed HAVB/CHB in 2 patients. One patient was an 82-year-old man who underwent transfemoral TAVI with Sapien 3 (29 mm) with an implantation depth of 2.7 mm and developed symptomatic persistent CHB on day 4. The other patient was a 77-year-old man who underwent transfemoral TAVI with Sapien 3 (26 mm) with an implantation depth of 2.6 mm and developed symptomatic 5.5 sec pause owing to advanced atrioventricular block with permanent AF on day 13. Both HAVB/CHB events resulted in dual-chamber PPM implantation.

### Timing of 30-Day HAVB/CHB Occurrence and TPM Reinsertion

The timing of HAVB/CHB occurrence ranged from procedural period to post-TAVI day 13 (Figure 2); the most frequent timing was the procedural period (76.7%), followed by the same day of TAVI (8.2%); 94.5% occurred within 3 days after TAVI. Two HAVB/CHB events occurred after discharge (day 4 and day 13).

In 205 patients without procedural HAVB/CHB, the TPM was removed at the end of the TAVI procedure in 199 (97.0%) patients, of whom 9 (4.5%) required TPM reinsertion. Details on these 9 patients are summarized in Supplemental Table 1. The reasons for TPM reinsertion in all patients were delayed HAVB/CHB events, including 8 CHBs and 1 Mobitz type II 2:1 atrioventricular block. When delayed HAVB/CHB was detected, 3 patients were symptomatic, and 6 patients were asymptomatic. No patient experienced cardiac arrest.

## Characteristics of Patients With HAVB/CHB and 30-Day PPM Requirement

Patients with procedural HAVB/CHB, as compared to those without, had a higher STS risk score, a smaller aortic valve area, and a greater implantation depth relative to the base of the NCC (Table 1). In a subgroup comparison between procedural persistent vs. procedural transient HAVB/CHB, although the age and the prevalence of the bicuspid aortic valve and first degree atrioventricular block appeared numerically different, the differences did not reach statistical significance (Supplemental Table 2). The 30-day PPM/ICD rate was significantly higher after procedural persistent HAVB/CHB than that after procedural transient HAVB/CHB (82.1% vs. 41.2%; p < 0.001).

Patients with delayed HAVB/CHB, as compared to those without, received general anesthesia and predilation more frequently and had a greater implantation depth (Table 2). Patients with 30-day PPM/ICD requirement, as compared to those without, had a greater prevalence of LVOT calcification and received a self-expanding valve and predilation more frequently, along with a greater implantation depth (Supplemental Table 3).

## In-Hospital Adverse Events

No patient died during the index hospitalization. A second valve deployment was needed in 5 patients for significant paravalvular leak (none of the second valve deployments were due to valve migration or embolization) after the first valve deployment, all of whom developed procedural HAVB/CHB. Overall, the median length of hospital stay was 3 (IQR = 2-5) days. The length of hospital stay was significantly longer in patients with than without HAVB/CHB. There were no significant differences in other in-hospital adverse events regardless of the occurrence of HAVB/CHB (Table 3).

## Predictors for HAVB/CHB Occurrence and PPM Requirement

In multivariable analyses, greater implantation depth was independently associated with a higher risk of procedural HAVB/CHB, delayed HAVB/CHB, and 30-day PPM (Table 4 and Supplemental Table 4). The STS risk score and aortic valve area were also associated with a higher risk of procedural HAVB/CHB, while predilation was associated with a higher risk of delayed HAVB/CHB. These results with multiple imputations were consistent with those with complete case analyses (Supplemental Table 5). Moreover, those results were also consistent in the sensitivity analysis using only 248 patients who underwent TAVI with a balloon-expandable valve (Supplemental Figure 2 and Supplemental Tables 6 and 7).

# Predictive Values of Implantation Depth and Predilation for HAVB/CHB and PPM Requirement

The C-statistics of implantation depth for procedural HAVB/CHB, delayed HAVB/CHB, and 30-day PPM/ICD requirement were 0.63, 0.74,

#### Table 1

Baseline and procedural characteristics of patients who did and did not develop procedural HAVB/CHB

	All	Procedural I	p value	
	(N = 261)	No (n = 205)	Yes (n = 56)	
Age, y	81.0 (76.0-86.0)	81.0 (76.0-85.0)	84 (77.5-88.0)	0.086
Female	73 (28.0)	52 (25.4)	21 (37.5)	0.092
Caucasian	251 (96.2)	197 (96.1)	54 (96.4)	1.00
Body mass index, kg/m <sup>2</sup>	29.1 (25.4-33.3)	29.4 (25.4-33.6)	27.5 (25.4-32.7)	0.36
STS risk score, %	5.14 (3.50-8.06)	4.62 (3.32-7.97)	5.85 (4.35-10.84)	0.006
Prior CABG	83 (31.8)	69 (33.7)	14 (25.0)	0.26
Prior myocardial infarction	63 (24.1)	47 (22.9)	16 (28.6)	0.38
ESRD on dialysis	12 (4.6)	7 (3.4)	5 (8.9)	0.14
Chronic lung disease	132 (50.6)	101 (49.3)	31 (55.4)	0.45
History of syncope	18 (6.9)	13 (6.3)	5 (8.9)	0.55
History of atrial fibrillation/flutter	101 (38.7)	74 (36.1)	27 (48.2)	0.12
NYHA functional class III or IV	210 (80.5)	163 (79.5)	47 (83.9)	0.57
LVEF, %	59 (54-63)	59 (55-64)	56 (50-63)	0.074
Aortic valve area, cm <sup>2</sup>	0.71 (0.58 - 0.84) [N = 245]	0.72 (0.61 - 0.85) [n = 189]	0.64 (0.52 - 0.79) [n = 56]	0.007
Aortic valve mean gradient, mmHg	41 (34-52)	41 (34-51)	46 (35.5-56)	0.30
Aortic valve peak gradient, mmHg	70 (58-86)	70 (58-85)	71 (58-89)	0.71
Bicuspid aortic valve	14 (5.4)	10 (4.9)	4 (7.1)	0.51
Failed bioprosthetic valve	18 (6.9)	17 (8.3)	1 (1.8)	0.13
Moderate or severe AB	48 (18.4)	39 (19.0)	9 (16.1)	0.70
Data on aortic annulus*	[N = 253]	[n = 197]	[n = 56]	
Maximum annular diameter mm	28 (26-30)	28 (26-30)	28 (26-30 5)	0.85
Minimum annular diameter, mm	23 (21-25)	23 (21-24 9)	22.5 (20.5-25)	0.62
Eccentricity index	0.18 (0.14-0.23)	0 18 (0 14-0 23)	0.19 (0.15-0.25)	0.28
Annular area $mm^2$	493 (416-560)	500 (420-560)	476 (411-560)	0.67
Calcium score of aortic valve leaflets HII	2118(1310-3261) [N - 197]	2168 (1321-3240) [n - 149]	2051 (1263-3345) [n - 48]	0.80
LVOT calcification <sup>‡</sup>	135/241(56.0)	98/186 (52 7)	2001 (1200 00 10) [n = 10]	0.064
Pre-TAVI baseline FCG findings	155/211 (55.5)	56/100 (52.7)	577 55 (07.5)	0.001
Bhythm				0.87
Sinus rhythm	218 (83 5)	173 (84 4)	45 (80.4)	0.07
Atrial fibrillation	35 (13.4)	26 (12 7)	9 (16 1)	
Atrial flutter	5 (19)	4 (2 0)	1 (1.8)	
Junctional rhythm	3 (1.1)	(2.0)	1 (1.8)	
PR interval ms	190(170.220) [N - 220]	190(168.219) [n - 175]	190(172-226) [n - 45]	0.56
OPS duration ms	1/6 (126 156)	146(126156)	1/5(1/2-220)[n = +5]	0.30
Eirst degree AVP	97 (22.2)	49 (22 2)	10 (22 0)	1.00
OPS duration $>150$ ms	07 (33.3)	00 (33.2) 87 (42.4)	19 (33.9)	0.76
$V_{\rm rest}$	70 (26.9)	67 (42.4) E7 (27.9)	12 (22 2)	0.70
Left anterior faccicular block	2 (1 1)	2 (1 5)	0 (0 0)	1.00
Diference black	3 (1.1)	3 (1.3) (0 (20 2)	0 (0.0)	1.00
Bilascicular block	/3 (28.0)	10 (29.3)	13 (23.2)	0.41
Presedural details	24 (9.2)	19 (9.3)	5 (8.9)	1.00
Nonelective procedure	12 (4 6)	10 (4 0)	2 (2 ()	1.00
Nonference procedure	12 (4.0)	10 (4.9)	2 (3.6)	1.00
Nomemoral approach	17 (6.5)	12 (5.9)	5 (8.9)	0.37
Anestnesia type	015 (00 4)	170 (02.0)	42 (7( 0)	0.24
Conscious sedation	215 (82.4)	172 (83.9)	43 (76.8)	
General anestnesia	46 (17.6)	33 (16.1)	13 (23.2)	0.40
Valve type	242 (25 2)	100 (05 0)	50 (00 0)	0.49
Balloon-expandable	248 (95.0)	196 (95.6)	52 (92.9)	
Self-expanding	13 (5.0)	9 (4.4)	4 (7.1)	0.00
Valve size				0.38
≤23 mm	73 (28.0)	55 (26.8)	18 (32.1)	
26 mm	100 (38.3)	83 (40.5)	17 (30.4)	
≥29 mm	88 (33.7)	67 (32.7)	21 (37.5)	
Predilation	62 (23.8)	44 (21.5)	18 (32.1)	0.11
Postdilation	118 (45.2)	91 (44.4)	27 (48.2)	0.65
Oversizing, %	5.0 (0.8-8.6) [N = 253]	4.8 (0.9-8.6) [n = 197]	5.7 (0.5-9.7) $[n = 56]$	0.40
Implantation depth relative to the NCC, $mm^{\delta}$	2.3 (1.0-4.0) [N = 259]	2.0 (0.9-3.6) [n = 204]	3.1 (1.6-5.0) [n = 55]	< 0.001

Notes. Values are n (%), n/total n (%), or median (interquartile range).

AR = aortic regurgitation, AV = aortic valve, AVB = atrioventricular block, CABG = coronary artery bypass grafting, CHB = complete heart block, CT = computed tomography, ECG = electrocardiogram, ESRD = end-stage renal disease, HAVB = high-degree atrioventricular block, HU = Hounsfield unit, LVEF = left ventricular ejection fraction, LVOT = left ventricular outflow tract, NCC = noncoronary cusp, NYHA = New York Heart Association, STS = Society of Thoracic Surgeons, TAVI = transcatheter aortic valve implantation.

\* Data on aortic annulus were unavailable in 8 patients because neither contrast CT images nor cardiac magnetic resonance images were performed.

<sup>†</sup> The calcium score of aortic valve leaflets was unavailable in 64 patients owing to a lack of contrast CT images before TAVI or a prior bioprosthetic valve.

<sup>‡</sup> Data on LVOT calcification were unavailable in 20 patients owing to a lack of appropriate CT images before TAVI or a prior bioprosthetic valve.

<sup>§</sup> Implantation depth was unavailable in 2 patients owing to a lack of an appropriate fluoroscopy image.

and 0.69, respectively (Supplemental Figure 3). Predilation and categorized implantation depth (>1.0 mm, >2.0 mm, or >3.0 mm) each showed a relatively high negative predictive value (>80%) in predicting these outcomes (particularly high at >95% for delayed HAVB/CHB; Supplemental Table 8). When predilation and categorized implantation depth were combined, the combination of predilation and implantation depth of >2.0 mm had a higher C-statistic for all the outcomes (procedural HAVB/CHB, delayed HAVB/CHB, and 30-day PPM) than the other combinations (Supplemental Figure 4). Therefore, for risk stratification, eligible patients were categorized into 4 groups according to predilation

## a 30-day HAVB/CHB occurrence and PPM requirement



## b Temporal trend of 30-day HAVB/CHB occurrence and PPM requirement



Figure 1. Incidence and trend of 30-day HAVB/CHB and PPM requirement after TAVI in patients with pre-existing RBBB. (a) The incidence of 30-day HAVB/CHB and PPM requirement after TAVI in patients with pre-existing RBBB. (b) The temporal trend of 30-day HAVB/CHB and PPM requirement after TAVI in patients with pre-existing RBBB between 2015 and 2019. Abbreviations: AF, atrial fibrillation; CHB, complete heart block; HAVB, high-degree atrioventricular block; ICD, implantable cardioverter defibrillator; LBBB, left bundle branch block; PPM, permanent pacemaker; RBBB, right bundle branch block; TAVI, transcatheter aortic valve implantation.

and implantation depth (>2.0 or  $\leq$ 2.0 mm). Patients with no predilation and implantation depth of  $\leq$ 2.0 mm had the lowest risk of HAVB/CHB and 30-day PPM/ICD requirement (Figure 3). Notably, delayed HAVB/ CHB occurred in only 2.1% (2/95) of the patients with no predilation and implantation depth of  $\leq$ 2.0 mm.

# Follow-Up Outcomes of Patients With or Without 30-Day PPM/ICD Requirement

In the early phase (within 30 days after TAVI), no sudden death was observed; one patient died from TAVI-related stroke at a skilled nursing facility on day 25. During the median follow-up of 20.4 (IQR = 12.2-34.3) months, there was no significant difference between patients with or without the 30-day PPM/ICD with respect to death (26.3% vs. 18.6%; log-rank p = 0.32) and MACE (38.6% vs. 27.9%; log-rank p = 0.11) (Figure 4).

## Ventricular Pacing Rate After PPM/ICD Implantation

In 57 patients with the 30-day PPM/ICD, data on pacing rate at follow-up (median = 45 [IQR, 37, 61] days after PPM/ICD implantation) were available in 47 patients (40 dual-chamber PPMs; 1 single-chamber PPM; 1 leadless PPM; 5 CRT-P or CRT-D). In 42 patients with the PPM





(excluding 5 patients with CRT-P or CRT-D), the median RV pacing rate was 78.5% (IQR = 18.0%-99.0%). Complete HAVB/CHB recovery (RV pacing < 1%) was observed in 3 (7.1%) patients, while PPM dependency (RV pacing > 40%) was observed in 28 (66.7%) patients.

## Discussion

The present study has several key findings: (1) the overall 30-day HAVB/CHB rate in pre-existing RBBB TAVI recipients was 28.0%, of which 76.7% occurred during TAVI procedure, followed by the same day of TAVI in 8.2% of individuals; (2) the delayed HAVB/CHB rate was 8.3% among patients without procedural HAVB/CHB, with a TPM reinsertion rate of 4.5%; (3) implantation depth independently predicted HAVB/CHB or/and 30-day PPM/ICD requirement; (4) a combination of no predilation and implantation depth of  $\leq$ 2.0 mm harbored a relatively low risk of procedural HAVB/CHB (11.2%), delayed HAVB/CHB (2.1%), and PPM/ICD requirement (10.3%) at 30 days; (5) complete HAVB/CHB recovery after PPM implantation was uncommon.

## Incidence and Timing of HAVB/CHB Occurrence After TAVI

To date, many studies have examined the PPM risk in the overall TAVI population.<sup>7</sup> However, only the present study and a recent Canadian study  $[n = 110]^{22}$  investigated the details of HAVB/CHB occurrence and subsequent need of the PPM among patients with pre-existing RBBB. Although the present study demonstrated a much lower HAVB/CHB rate than the Canadian study (28.0% vs. 55.5%), these 2 studies have several findings in common. First, the majority of HAVB/CHB events occurred during TAVI procedure (76.7% vs. 86.4%). Second, delayed HAVB/CHB occurred in an early period after TAVI (within 13 days vs. within 7 days) with a similar incidence (6.5% vs. 7.2%). These findings may suggest that despite different HAVB/CHB risks across clinical settings, HAVB/CHB mostly occurs periprocedurally, whereas delayed HAVB/CHB typically occurs in a very early phase with an incidence of ~7%.

Timing of TPM removal remains controversial in patients with preexisting RBBB. Recent expert consensus documents recommend maintaining the TPM for 24 h (or at least overnight) following TAVI in all patients with pre-existing RBBB.<sup>2,3</sup> The present study revealed that the need for TPM reinsertion is relatively uncommon (4.5%) after TPM removal at the end of the TAVI procedure. This finding suggests that TPM removal immediately after TAVI followed by close telemetry monitoring with availability of rapid TPM reinsertion may be a reasonable strategy in many patients with pre-existing RBBB except for procedural HAVB/CHB cases.

## Additional Predictors of HAVB/CHB Among Patients With Pre-Existing RBBB

The prevalence of pre-existing RBBB in our TAVI recipients was 11.4%, comparable to other studies (5%-20%).<sup>8</sup> Given the non-negligible prevalence and high post-TAVI PPM risk of pre-existing RBBB, additional factors for increased HAVB/CHB risk should be explored to help further risk stratification and facilitate safe yet timely discharge in patients with pre-existing RBBB. The aforementioned Canadian study investigated such factors in patients with pre-existing RBBB, reporting older age and pre-existing first degree atrioventricular block as predictors of increased PPM risk.<sup>22</sup> However, implantation depth was not reported in that analysis. Recent studies reported implantation depth as a strong independent predictor of post-TAVI PPM risk,7,23,24 which has a sound anatomical basis.<sup>4</sup> The present study revealed implantation depth as an independent predictor of procedural and delayed HAVB/CHB and 30-day PPM requirement among patients with pre-existing RBBB. In addition, predilation was a predictor of delayed HAVB/CHB. Importantly, unlike anatomical and electrical predisposing factors, these 2 procedural factors are potentially modifiable by operators to reduce the HAVB/CHB and PPM risks.

## Procedural Strategy and Risk Stratification

Minimizing the procedural HAVB/CHB risk and detecting delayed HAVB/CHB appropriately are essential goals in the conduction disorder management of TAVI recipients with pre-existing RBBB. The present results suggest that avoiding predilation and deploying THV at a higher position are important procedural strategies in this high PPM risk group. While procedural HAVB/CHB is easily detected by procedural monitoring, identification of delayed HAVB/CHB remains challenging. Delayed HAVB/CHB can potentially cause sudden death after discharge. Thus, risk stratification to identify the subpopulation at higher risk of

#### Table 2

Baseline and procedural characteristics of patients without procedural HAVB/CHB who did and did not develop delayed HAVB/CHB

No. 1n - 188)Ye. 1n - 758)Ye. 1n - 758)Ye. 1n - 770Ror, Y81 (758)31 (754)0.05Body mask (sky m²254 (25.33.5)253 (32.53.5)0.03Body mask (sky m²254 (25.33.6)455 (32.53.53.5)0.03Por or No. 61 (abs (sky m²61 (3.3.5)61 (3.3.5)0.03Por or No. 61 (abs (sky m²61 (3.3.5)0.030.03Por or No. 61 (abs (sky m²61 (3.5.1)10.120.04Body of synche91 (16.5.1)10.12,5)0.04Basky of synche10 (7.0)10 (7.0)0.03History of actual fibrillation (future66 (35.1)8 (47.1)0.06With Americal actual III or IV10.079,8)11 (7.0,5)0.02With Americal III or IV10.079,8)72 (4.4.1)0.04With Americal Cast III or IV10.079,810.12,7,5)0.02Decision actual ac		Delayed H	HAVB/CHB	<i>p</i> value
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Body musick, ky and STN rick score, %229, (223,323, 0)239, 227, 273,33, 00.30Prior AbG63 (33.3)6 (53.3)100Prior myocatikal infraction44 (23,4)3 (17.6)0.60Prior myocatikal infraction44 (23,4)3 (17.6)0.60Chronic tung disease93 (49.5)8 (47.1)0.60Chronic tung disease93 (49.5)8 (47.1)0.63History of priope10 (5.3)13 (76.5)0.76VIPK in factional dises III or IV150 (75.60,4)0.76 (64.1)0.67VIPK in factional dises III or IV150 (75.60,4)0.76 (64.1)0.67Acric vive are, car <sup>3</sup> 0.72 (0.64.6) (5.5)17.75 (0.64.64.0)0.71Acric vive are, car <sup>3</sup> 0.72 (0.64.65.5)17.75 (0.64.64.0)0.71Acric vive are, car <sup>3</sup> 0.72 (0.64.65.5)17.75 (0.64.64.0)0.75Acric vive are, car <sup>3</sup> 0.72 (0.64.65.5)17.75 (0.64.64.0)0.75Acric vive are, car <sup>3</sup> 0.72 (0.61.65.5)17.750.75Marine annual and antered, numlig16.101.750.75Acric vive are, car <sup>3</sup> 0.72 (0.77)3.77,630.83Minimu annual diameter, num2.22 (2.34)0.23 (2.77,63)0.23Annual area, num10.16 (25.6)12.70 (0.17,62.5)1.00Arrial fibrillation2.11 (1.74,73)1.000.70Arrial fibrillation2.12 (1.77,74.23.5)1.00Arrial fibrillation2.12 (1.77,75.(2.94.1)0.80Arrial fibrillation <td< td=""><td>Caucasian</td><td>180 (95.7)</td><td>17 (100.0)</td><td>1.00</td></td<>	Caucasian	180 (95.7)	17 (100.0)	1.00
ST inde score, %4.75 (3.324.84)4.83 (3.5.5)6.300.30Prior CM663 (33.5.7)6 (15.5.3)1.100Prior CM663 (32.5.7)1.15.910.46SEDI on dikpiso6 (3.5.1)1.15.910.46SEDI on dikpiso6 (6.5.1)1.15.910.46Ibisory of stronger10 (5.3)8 (47.1)0.43NTHA functional class III or V150 (79.8)13 (76.5)0.76Netwer area, on <sup>2</sup> 0.72 (0.61.45.5) (n - 172)0.75 (0.61.46.8) (n - 17.1)0.87Acrit: walve area gradient, muRity17 (16.95.5)7.2 (24.85.1)0.99Bacagid corti: valve0.64.8)1.6.300.37Acrit: walve area gradient, muRity7.0 (58.85)7.2 (24.85.1)0.99Bacagid corti: valve0.14 (3.5.1)0.100.100.37Maximum annuiter diameter, num22 (25.24)23 (27.27)0.43Maximum annuiter diameter, num22 (25.24)23 (27.27)0.43Maximum annuiter diameter, num22 (25.24)23 (27.27)0.43Maximum annuiter diameter, num22 (25.24)23 (27.7)0.20Cachein ascer of acrit: walve leaders, HU219 (13.13.340) [n = 134]2096 (131.500)1.00Cachein ascer of acrit: walve leaders, HU219 (13.13.340) [n = 134]206 (13.17)0.00Cachein ascer of acrit: walve leaders, HU210 (13.7)1.001.00Cachein ascer of acrit: walve leaders, HU210 (13.7)1.001.00Cachein ascer of acrit: walve leaders, HU210 (13.0) <td>Body mass index, kg/m<sup>2</sup></td> <td>29.4 (25.3-33.6)</td> <td>29.7 (27.5-33.3)</td> <td>0.39</td>	Body mass index, kg/m <sup>2</sup>	29.4 (25.3-33.6)	29.7 (27.5-33.3)	0.39
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Chronic Intrg disease96 (49.5)8 (47.1)1.00History of aridal fibrillation/Inter66 (35.1)8 (47.1)0.081History of aridal fibrillation/Inter66 (35.1)13 (74.5)0.75Mark Instance and assili or IV15 (74.5)0.750.75Mark Instance and assili or IV0.72 (0.01 085) [b = 17.2]0.75 (0.01 046) [n = 17]0.75Arris vulve peak gradien, mmitg70 (58.85)72 (45.45)0.99Biccapid oriti vulve9 (4.8)15 (5.5)1.00Arris vulve peak gradien, mmitg70 (58.85)2.92 (72.53)0.43Macinum annulur diameter, mm28 (23.30)2.92 (72.53)0.43Macinum annulur diameter, mm28 (23.30)2.021 (0.17.0.25)0.32Andical area, mm <sup>3</sup> 4.95 (410.570)3.02 (0.07.0.25)0.32Annul area, mm <sup>3</sup> 4.94.55 (410.570)2.00 (40.540)0.85Calcium store of ordit vulve leafets, HU2.93 (1.01.43.340) (n - 1.34)2.06 (0.31.5.3000) (n - 1.5]0.77MOR and Calcibar atom8.97.1691.001.001.00PETAVI baseline ECG finding1.61 (65.6)1.42 (70.6)1.00PR taread, na1.66 (1.56.155)1.44 (1.28.155)0.44Fint dispres A/86.2 (3.30)6.(3.5.3)1.00QK sharaton, na1.66 (1.36.155)1.44 (1.28.155)0.44Fint dispres A/86.2 (3.7)5.(2.9.4)1.00Marine manifer finance1.16 (3.9)1.001.00Pretavit baseline ECG finding1.16 (3.9) <td< td=""><td>ESRD on dialysis</td><td>6 (3.2)</td><td>1 (5.9)</td><td>0.46</td></td<>	ESRD on dialysis	6 (3.2)	1 (5.9)	0.46
History of avenetic density of avenetic de	Chronic lung disease	93 (49.5)	8 (47.1)	1.00
lationy of atrial iben/lation/lation?         60 (3.1)         8 (4/1)         0.43           NHA fanctical data SII or IV         50 (58.6)         57 (54.1)         0.66           NHA fanctical data SII or IV         0.72 (0.01 (49.4) = 17)         0.75 (0.01 (49.4) (49.4) (49.4)         0.75 (7)         0.75 (7)	History of syncope	10 (5.3)	3 (17.6)	0.081
N11A interconit class in or iv         150 (948)         13 (948)         13 (948)         0.66           Artic view cres, cn <sup>2</sup> 072 (0.01 0.85) [n - 172]         0.75 (0.61 0.46) [n - 17]         0.87           Artic view cres, cn <sup>2</sup> 072 (0.01 0.85) [n - 172]         0.75 (0.61 0.46) [n - 17]         0.87           Morite view cress         70 (58.48)         71 (90)         0.00         0.37           Morite view cress         71 (90)         0.00         0.37           Morite view cress         3 (0.19.1)         3 (0.76.)         1.00           Data on actic annulas         [n = 180]         [n = 17]         Maximum annular diameter, nm         28 (25-90)         29 (27.6.30)         0.43           Minitrum annular diameter, nm         28 (25-90)         500 (46-540)         0.85         Calcium score of acric view leaflest, HU         2193 (131.33400 [n = 134]         2996 (16-540)         0.85           Calcium score of acric view leaflest, HU         2193 (131.53400 [n = 14]         201 (0.70.6)         1.00           Pre-TM baseline ECG findings         12 (10.17         4 (23.5)         1.00           Sins rhythin         161 (16.5.6)         14 (12.9156)         0.41           Max reso, na         20 (0.00         6 (29.1)         1.00           Find brinitrit	History of atrial fibrillation/flutter	66 (35.1)	8 (47.1)	0.43
L/L*, **         59 (3940)         59 (3940)         59 (3940)         00           Antic valve mear, cm <sup>3</sup> 02 (2014.055) ln = 172]         0.75 (0.61.045) ln = 170]         0.87           Antic valve mear, gradiem, mmlig         41 (335.51)         40 (34.46)         0.87           Antic valve mear, gradiem, mmlig         70 (59.455)         72 (54.456)         0.89           Brougel ordic valve         9 (19.45)         10 (00)         0.37           Antic valve pack gradiem, mmlig         70 (59.45)         10 (00)         0.37           Minimum anudar diameter, mm         28 (27.40)         20 (27.70.0)         0.43           Minimum anudar diameter, mm         23 (21.24)         23.8 (22.24)         0.85           Calcium score of arric valve leades, HU         219 (131.33.340) (n = 134]         2096 (133.15.300) (n = 150)         0.77           LVOT calcification         89 /49 (52.7)         9 /17 (52.9)         1.00           Calcium score of arric valve leades, HU         29 (131.33.340) (n = 134]         2096 (133.15.300) (n = 150)         0.77           LVOT calcification         89 /49 (52.7)         9 /17 (52.9)         1.00         0.77           LVOT calcification         89 /49 (52.7)         9 /17 (52.9)         1.00           Artial fibrililation         12 (17	NYHA functional class III or IV	150 (79.8)	13 (76.5)	0.76
Antic vice ands, thi         0.72 (0.01 (03) [1 = 1.72]         0.01 (0.01 (04) [1 = 1.7])         0.03           Antic vice and gradient, multig         70 (56 885)         72 (54 85)         0.99           Antic vice peak gradient, multig         70 (56 885)         72 (54 85)         0.99           Bicupid antic view         9 (4 8)         1 (5.9)         0.59           Pailed bioprosthetic valve         17 (9)         0 (0.0)         0.37           Matinum annual diameter, mm         2 (24 20)         22 (27 20)         0.43           Matinum annual diameter, mm         2 (24 20)         22 (27 20)         0.43           Matinum annual diameter, mm         2 (24 20)         22 (01 7 0.25)         0.85           Calcium arore of artic valve leaflest, HU         2193 (131 3340) [n = 134]         2066 (133 1.5 3000) [n = 15]         0.77           More Table         50 (16 (55 0)         12 (70 6)         1.00         0.00           Word         16 (85 6)         12 (70 6)         1.00         0.00         0.00           Word         16 (16 56)         14 (12 2 15 (5)         0.01         0.00         0.01         0.00         0.01           Word         2 (21 1.7)         4 23 5.         4 (23 5.)         1.00         0.00         0.01	LVEF, %	59 (55-64)	57 (54-61)	0.66
	Aortic valve area, cili	0.72(0.01-0.85)[II = 172]	(0.75(0.01-0.84) [11 = 17])	0.87
	Aortic valve mean gradient, mmHg	70 (59 95)	72 (54 85)	0.71
bill         17 (9)         1 (0.0)         0.07           Moderate are severed as evere as as a field bioproduction is vere and as a field bioproduction is vere as a field bis vere as a field bis vere as a field bis vere as	Bicuspid aortic valve	9 (4 8)	1 (5 9)	0.59
Intervent $1/2$ $0/2$ $0/2$ $0/2$ $0/2$ Date on actic annulus $[n = 180]$ $[n = 17]$ Maximum annular diameter, mm $28$ (25-30) $29$ (27,5-30) $0.35$ Eccentricity index $0.18$ (0.14-0.23) $0.21$ (0.17-0.25) $0.35$ Eccentricity index $0.18$ (0.14-0.23) $0.21$ (0.17-0.25) $0.35$ Annular area, mm <sup>2</sup> 496.5 (410-570)         500 (460-540) $0.85$ Calcium score or actic valve leafles, HU $2193$ (33) 3340 (n = 134) $206$ (123) 15-3000 (n = 15) $0.77$ EVAT Moseline ECG findings         Territy Min         161 (85.6) $12$ (70.6) $12$ Mythm         2 (11.7)         4 (23.5) $44$ $445$ $15.9$ $146$ Junctional rhythm         2 (11.7)         4 (23.5) $144$ $145$ $15.9$ $146$ $16.9$ $12$ Junctional rhythm         2 (11.1)         0 (0.0) $16$ $98.0$ $98.0$ $16.0$ $16.0$ $16.0$ $16.0$ $16.0$ $16.0$ $16.0$ $16.0$ $16.0$ </td <td>Failed hipprosthetic valve</td> <td>17 (0)</td> <td>0 (0 0)</td> <td>0.39</td>	Failed hipprosthetic valve	17 (0)	0 (0 0)	0.39
Date matrix manular         In         100         In         100           Maximum numblar diameter, mm         32 (21-24)         23 8 (22-24)         0.485           Beccentricity index         0.18 (0.14-0.23)         0.21 (0.17-0.25)         0.355           Calcium score of aortic valve leaflets, HU         2193 (13.3340) [n = 134]         2096 (13.1.53000) [n = 15]         0.77           LVOT calcification         89/169 (22.7)         9.71 (52.9)         100           Pre-TAU baseline ECG findings         0.22 (11.7)         4 (23.5)         10           Khytim         16 (85.6)         12 (70.6)         12           Atrial finditari         21 (1.7)         4 (23.5)         10           Junctional rhythm         16 (85.6)         12 (70.6)         10           Junctional rhythm         22 (11.7)         4 (23.5)         10           Junctional rhythm         21 (11)         0 (0.0)         10           Pre-Harrings         188 (67-219) [n = 164]         202 (19-42.0) [n = 11]         0.16           QRS duration, ms         146 (136-156)         144 (128-156)         0.41           First degree AVB         6 (23.0)         6 (35.3)         1.00           Left noterior fasciular block         5 (29.3)         5 (29.4)	Moderate or severe AB	36 (19 1)	3 (17 6)	1.00
Image         B3 (26-30)         P2 (27.6-30)         0.43           Minimum annular diameter, mm         23 (21-24)         23 8 (22-30)         0.45           Excentricly index         0.18 (0.14-0.23)         0.21 (0.17-0.25)         0.32           Annular area, mm <sup>2</sup> 490.65 (410-370)         500 (460-640)         0.85           Galciman score of arcit valve leaflets, HU         219 (1.13-330 00) [n = 134]         206 (133.15-3000) [n = 15]         0.77           PVCT calcification         89/169 (52.7)         9/17 (52.9)         1.00           PVETAV Ibaseline ECG findings         7         8         0.29           Rhythm         161 (85.6)         12 (70.6)         1           Atrial finditaria         21 (1.1)         0 (0.0)         1           PK interval, ms         188 (167-219) [n = 164)         202 (19-220) [n = 11]         0.16           QK duration, ms         146 (136-156)         144 (128-156)         0.44           First degree AVB         62 (33.0)         6 (35.3)         1.00           QK duration ≥ 150 ms         79 (42.0)         8 (47.1)         0.806           Left anterior fascicular block         52 (29.3)         5 (29.4)         1.00           Left anterior fascicular block         52 (29.3)         5 (29	Data on aortic annulus	[n - 180]	[n - 17]	1.00
Minimum annular diameter, and         23 (21-24)         2.8.8 (22-24)         0.85           Executicity index         0.18 (0.14.0.23)         0.21 (0.17-0.25)         0.35           Calcum score of acrite valve leafles, HU         2193 (131-33.340) [n = 134]         2096 (1331.5-3000) [n = 15]         0.77           VOT calcification         89/169 (5.7)         9/17 (5.2)         0.10           Pre-Tvi baseline ECG findings           Rhythm         161 (85.6)         12 (70.6)         1           Atrial fibrillation         22 (11.7)         4 (22.5)         4           Atrial fibrillation         22 (11.7)         4 (22.5)         0.41           Atrial fibrillation         22 (11.1)         0 (0.0)         0           PR interval, ns         188 (167-219) [n = 164]         202 (194-226) [n = 11]         0.16           QRS duration >50         79 (42.0)         8 (47.1)         0.80           Left materior fascicular block         52 (27.7)         5 (29.4)         1.00           Infisionation >150 ms         79 (42.0)         8 (47.1)         0.80           Left materior fascicular block         52 (27.7)         5 (29.4)         1.00           Infision >150 ms         79 (42.0)         8 (47.1)         0.20 <td< td=""><td>Maximum annular diameter mm</td><td>28 (26-30)</td><td>29(276-30)</td><td>0.43</td></td<>	Maximum annular diameter mm	28 (26-30)	29(276-30)	0.43
Eccuricity index $0.18 (0.14.0.23)$ $0.21 (0.17.0.25)$ $0.32$ Annular area, mm <sup>2</sup> 496.5 (10.570)         500 (460.540)         0.85           Calcium score of acrit valve leaflets, HU         2193 (131.3340) [n = 134]         2096 (131.5-3000) [n = 15]         0.77           LVOT calcification         89.169 (52.7)         9.17 (52.9)         1.00           PreTAVI baseline ECG findings         0.22         0.21 (0.17.0.25)         0.29           Atrial fibrillation         22 (1.17)         4 (23.5)         0.21 (0.0)           Atrial fibrillation         21 (1.1)         0 (0.0)         0.16           PR interval, ns         146 (136.156)         144 (128.156)         0.41           First degree AVB         62 (33.0)         6 (35.3)         1.00           QRS duration, ms         146 (136.156)         144 (128.156)         0.41           First degree AVB         62 (33.0)         6 (35.3)         1.00           Left posterior fascicular block         3 (1.6)         0.00.0)         1.00           Infinitorial block         3 (1.6)         0.00.0)         1.00           Infinitorial block         3 (1.6)         0.00.0)         1.00           Infinitori Staccular block         3 (1.6)         0.00 </td <td>Minimum annular diameter, mm</td> <td>23 (21-24)</td> <td>23.8 (22-24)</td> <td>0.85</td>	Minimum annular diameter, mm	23 (21-24)	23.8 (22-24)	0.85
Annalize arise, mm2 $996$ ( $4(0.570$ ) $500$ ( $460.540$ ) $0.87$ Calcium score of aortic valve leaflets, HU $2193$ ( $133.33409$ [n = 134] $2096$ ( $331.53000$ [n = 15] $0.77$ LVOT calcification $89/169$ ( $52.7$ ) $9/17$ ( $52.9$ ) $1.00$ <b>Pre-TVU baseline ECG findings</b> $161$ ( $85.6$ ) $12$ ( $70.6$ )Riythm $161$ ( $85.6$ ) $12$ ( $70.6$ )Arrial fibrillation $22$ ( $11.7$ ) $4$ ( $23.5$ )Arrial fibrillation $22$ ( $11.7$ ) $4$ ( $23.5$ )Arrial fibrillation, ans $186$ ( $167.219$ ) [n = 164] $202$ ( $994.226$ ) [n = 11] $0.66$ QRS duration, ans $186$ ( $167.219$ ) [n = 164] $202$ ( $994.226$ ) [n = 11] $0.61$ Fint degree AVB $62$ ( $33.0$ ) $6$ ( $35.3$ ) $1.00$ QRS duration, ans $79$ ( $42.0$ ) $8$ ( $47.1$ ) $0.80$ Left posterior fascicular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $11$ ( $5.9$ ) $1.00$ $1.00$ Difficacular block $52$ ( $27.7$ ) $5$ ( $29.4$ ) $1.00$ Difficacular block $16$ ( $55.9$ $1.0$ ( $4.7$ )	Eccentricity index	0.18 (0.14-0.23)	0.21 (0.17-0.25)	0.32
	Annular area, mm <sup>2</sup>	496.5 (410-570)	500 (460-540)	0.85
LVOT calcification89/169 (52.7)9/17 (52.9)100Pre-TAVI baseline EGG findings0.29Khythm161 (85.6)12 (70.6)Artial fibrillation22 (11.7)4 (23.5)Artial fibrillation22 (11.7)4 (23.5)Artial fibrillation21 (1.1)0 (0.0)PR interval, ms188 (167-219) [n = 164]202 (194-226) [n = 11]0.16QRS duration, ms188 (167-219) [n = 164]202 (194-226) [n = 11]0.16QRS duration, ms188 (167-219) [n = 164]202 (194-226) [n = 11]0.16QRS duration, ms188 (167-219) [n = 164]202 (194-226) [n = 11]0.10QRS duration, ms188 (167-219) [n = 164]202 (194-226) [n = 11]0.10QRS duration, ms188 (167-219) [n = 164]202 (194-226) [n = 11]0.10QRS duration, ms197 (42.0)8 (47.1)0.80DRS duration ≥ 150 ms79 (42.0)8 (47.1)0.80Defisecicular block52 (23.3)5 (29.4)1.00Diffascicular block17 (9.0)2 (11.8)0.20Nonfemoral approach11 (5.9)1.001.00Drederad details27 (14.9)6 (35.3)0.20Nonfemoral approach16 (95.7)16 (94.1)5Self-expanding8 (4.3)1 (5.9)0.00Valve size0.101.590.10Self-expanding8 (4.3)1 (5.9)0.21Valve size0.101.590.21Valve size0.101.590.21Valve	Calcium score of aortic valve leaflets, HU	2193 (1313-3340) $[n = 134]$	2096 (1331.5-3000) $[n = 15]$	0.77
Pre-TAV baseline ECG findingsRbythm161 (85.6)12 (70.6)Sinus rhythm161 (85.6)12 (70.6)Artial fibrillation2 (11.7)4 (23.5)Junctional rhythm2 (1.1)0 (0.0)PR interval, ms148 (156.7249) [n = 164]202 (2194.226) [n = 11]0.16QBS duration, ms146 (136.156)144 (128.156)0.41First degree AVB62 (23.0)6 (35.3)1.00QBS duration $\geq$ 150 ms79 (42.0)8 (47.1)0.80Left anterior fascicular block52 (27.7)5 (29.4)1.00Left anterior fascicular block3 (1.6)0 (0.0)1.00Infrascicular block53 (29.3)5 (29.4)1.00Drinfrascicular block17 (9.0)2 (11.8)0.20Nonelective procedure8 (4.3)2 (11.8)0.20Nonelective procedure8 (4.3)1 (5.9)1.00Nonelective procedure8 (4.3)1 (5.9)1.00Nonelective procedure8 (4.3)1 (5.9)1.00Conscious sedation16 (85.6)11 (64.7)0.01Self-expanding8 (4.3)1 (5.9)1.011.02Valve type6 (35.3)1 (5.9)1.012.23Self-expanding54 (28.7)1 (5.9)1.012.23Valve type6 (35.3)1 (5.9)2.011.02Valve type6 (35.3)1 (5.9)2.011.02Valve type73 (38.8)10 (58.8)0.01Self-expanding8 (4.57	LVOT calcification	89/169 (52.7)	9/17 (52.9)	1.00
Rhythm       0.29         Sinus rhythm       161 (85.6)       12 (70.6)         Atrial flutter       3 (1.6)       1 (29.)         Atrial flutter       3 (1.6)       1 (59)         Junctional rhythm       2 (1.1)       0 (0.0)         PR interval, ns       188 (157.219) [n = 164]       202 (194.226) [n = 11]       0.16         QRS duration, ms       62 (33.0)       6 (35.3)       0.00         QRS duration, ms       79 (42.0)       8 (47.1)       0.80         QRS duration, ms       79 (42.0)       8 (47.1)       0.80         QRS duration block       52 (27.7)       5 (29.4)       1.00         Left anterior fascicular block       52 (27.3)       5 (29.4)       1.00         Bifascicular block       52 (29.3)       1.00       0.60         Drecedural detaib       71 (9.0)       2 (11.8)       0.20         Nonfmoral approach       11 (5.9)       1 (5.9)       1.00         Ansethesia type       0.036       0.05       0.00         Conscious sedation       161 (85.6)       11 (64.7)       1.00         Self-expanding       8 (4.3)       1 (5.9)       0.00         Avet type       6 (35.3)       (0.01       0.01 <tr< td=""><td>Pre-TAVI baseline ECG findings</td><td></td><td></td><td></td></tr<>	Pre-TAVI baseline ECG findings			
Sinus rhythm       161 (85.6)       12 (70.6)         Arrial fibrillation       22 (11.7)       4 (23.5)         Arrial fibrillation       2 (1.1)       0 (0.0)         Junctional rhythm       2 (1.1)       0 (0.0)         PR interval, ms       188 (672-19) [n = 164]       202 (194-286) [n = 11]       0.16         QRS duration, ms       146 (136-156)       144 (128-156)       0.41         First degree AVB       62 (33.0)       6 (35.3)       0.00         QRS duration ≥150 ms       79 (42.0)       8 (47.1)       0.80         Left posterior fascicular block       32 (1.6)       0 (0.00)       1.00         Bifascicular block       31 (1.6)       0 (0.00)       1.00         Diffascicular block       31 (1.6)       0.20       0.20         Nonelective procedure       8 (4.3)       2 (11.8)       0.60         Procedural details       27 (14.4)       6 (35.3)       0.00         Valve type       057       3 (3.8)       0.01         Self-expanding       8 (4.3)       1 (5.9)       0.20         Valve type       1 (5.9)       .010       2.23       .010         23 mm       54 (28.7)       1 (5.9)       .010       2.23       .010 <t< td=""><td>Rhythm</td><td></td><td></td><td>0.29</td></t<>	Rhythm			0.29
Arial fbuillation       22 (1.7)       4 (23.5)         Arial fbuilter       3 (1.6)       1 (5.9)         Junctional rhythm       2 (1.1)       0 (0.0)         PR interval, ms       188 (157-219) [n = 164]       202 (194-226) [n = 11]       0.16         QR5 duration, ms       146 (136-155)       1444 (128-156)       0.41         First degree AVB       62 (33.0)       6 (35.3)       1.00         QR5 duration ≥150 ms       79 (42.0)       8 (47.1)       0.80         Left anterior fascicular block       3 (1.6)       0 (0.0)       1.00         Bifascicular block       3 (1.6)       0 (0.0)       1.00         Diffascicular block       17 (9.0)       2 (11.8)       0.60         Procedural details	Sinus rhythm	161 (85.6)	12 (70.6)	
Arial flutter3 (1.6)1 (5.9)Junctional rhythm2 (1.1)0 (0.0)PR interval, ms188 (167-219) [n = 164]202 (194-226) [n = 11]0.16QRS duration, ms146 (136-156)144 (128-156)0.41QRS duration ≥150 ms79 (42.0)8 (47.1)0.80QRS duration ≥150 ms79 (42.0)8 (47.1)0.80Left anterior fascicular block52 (22.7)5 (29.4)1.00Left anterior fascicular block3 (1.6)0 (0.0)1.00Bifascicular block5 (29.3)5 (29.4)1.00Triffascicular block17 (9.0)2 (11.8)0.20Nonelective procedure8 (4.3)2 (11.8)0.20Nonelective procedure8 (4.3)1 (5.9)1.00Conscious sedation161 (85.6)11 (64.7)2.01General anesthesia27 (14.4)6 (35.3)1.00Self-expanding8 (95.7)1 (694.1)5.05Self-expandiable180 (95.7)1 (5.9).00Self-expanding54 (28.7)1 (5.9).00Valve tse0.105 (29.4).0125 mm53 (38.8)10 (58.8).0026 mm53 (28.7)5 (29.4).0127 mm64 (32.4)6 (35.3).0126 mm63 (68.7)5 (29.4).0126 mm63 (68.7)5 (29.4).0127 mm66 (48.7.9) [n = 180]7.4 (3.0-9.0) [n = 17].01226 mm66 (45.7)5 (29.4).0110 m	Atrial fibrillation	22 (11.7)	4 (23.5)	
Junctional rhythm $2(1.1)$ $0(0.0)$ PR interval, ns $168(167.219)$ [n = 164] $202(194.205)$ [n = 11] $0.16$ QR5 duration, ms $166(136.156)$ $1144(128.156)$ $0.41$ First degree AVB $62(33.0)$ $6(35.3)$ $1.00$ QR5 duratio ≥150 ms $79(42.0)$ $8(47.1)$ $0.80$ Lefn anterior fascicular block $52(27.7)$ $5(29.4)$ $1.00$ Lefn posterior fascicular block $55(29.3)$ $5(29.4)$ $1.00$ Bifascicular block $77(9.0)$ $2(11.8)$ $0.66$ Procedural details $0$ $0.00$ $1.00$ Trifascicular block $17(9.0)$ $2(11.8)$ $0.20$ Nonelective procedure $8(4.3)$ $1(5.9)$ $0.20$ Valve type $0(714.4)$ $6(35.3)$ $0(55.8)$ $0.00$ Self-expanding $4(62.7)$ $5(29.4)$ $0.12$ Valve size $1(5.9)$ $7.4(3.0.9.0)$ [n = 17] $0.21$ $20$ mn $6(45.7)$ $5(29.4)$ $0.20$ $20$ mn $8(45.7)$ $5(29.4)$ $0.001$ </td <td>Atrial flutter</td> <td>3 (1.6)</td> <td>1 (5.9)</td> <td></td>	Atrial flutter	3 (1.6)	1 (5.9)	
PR interval, ms       188 (167.219) [n = 164]       202 (194-226) [n = 11]       0.16         QRS duration, ms       146 (136-156)       144 (128-156)       0.41         First degree AVB       62 (33.0)       6 (35.3)       1.00         QRS duration ≥150 ms       79 (42.0)       8 (47.1)       0.80         Left anterior fascicular block       52 (27.7)       5 (29.4)       1.00         Diffascicular block       55 (29.3)       5 (29.4)       1.00         Trifascicular block       17 (9.0)       2 (11.8)       0.66         Procedural details       7       1.00       1.00         Nonelective procedure       8 (4.3)       2 (11.8)       0.20         Nonelective procedure       8 (4.3)       2 (11.8)       0.06         Conscious sedation       161 (85.6)       11 (64.7)       0.036         Conscious sedation       161 (85.6)       11 (64.7)       0.010         Self-expanding       8 (4.3)       1 (5.9)       0.10         Valve type       54 (28.7)       1 (5.9)       0.10         Self-expanding       8 (4.3)       1 (5.9)       0.10         Valve size       6 (35.3)       7       1 (5.9)       2.2         Self-expanding       8 (4.8)	Junctional rhythm	2 (1.1)	0 (0.0)	
QRS duration, ms         146 (136-156)         144 (128-156)         0.41           First degree AVB         62 (33.0)         6 (35.3)         1.00           QRS duratio ≥150 ms         79 (42.0)         8 (47.1)         0.80           Left posterior fascicular block         52 (27.7)         5 (29.4)         1.00           Bifascicular block         55 (29.3)         5 (29.4)         1.00           Bifascicular block         55 (29.3)         5 (29.4)         1.00           Trifascicular block         55 (29.3)         5 (29.4)         1.00           Romelective procedure         8 (4.3)         2 (11.8)         0.20           Nonfemoral approach         11 (5.9)         1.00         0.036           Conscious sedation         161 (85.6)         11 (64.7)         0.036           Conscious sedation         161 (85.6)         11 (64.7)         0.036           Valve type         0.35         54 (28.7)         16 (94.1)         0.55           Balbon-expanding         8 (4.3)         1 (5.9)         0.01         52 (24.1)         0.10           Self-spanding         54 (28.7)         1 (5.9)         0.01         52 (24.1)         0.01         52 (24.1)         0.010           Self-spanding	PR interval, ms	188 (167-219) [n = 164]	202 (194-226) [n = 11]	0.16
First degree AVB       62 (33.0)       6 (35.3)       1.00         QRS duration ≥150 ms       79 (42.0)       8 (47.1)       0.80         Left anterior fascicular block       52 (27.7)       5 (29.4)       1.00         Bifascicular block       3 (1.6)       0 (0.0)       1.00         Bifascicular block       5 (29.3)       5 (29.4)       1.00         Trifascicular block       17 (9.0)       2 (11.8)       0.66         Procedural details       0       0.00       1.00         Nonlective procedure       8 (4.3)       2 (11.8)       0.20         Nonfemoral approach       11 (5.9)       1 (5.9)       1.00         Conscious sedation       161 (85.6)       11 (64.7)       0.006         General anesthesia       27 (14.4)       6 (35.3)       0.001         Self-expanding       8 (4.3)       1 (5.9)       0.10         Valve type       0.10       0.58.8)       0.102         Self-expanding       8 (4.3)       1 (5.9)       0.10         Valve size       0.10       15.9       0.10         Self-expanding       8 (4.3)       1 (5.9)       0.10         Self-expanding       8 (4.3)       1 (5.9)       0.10 <t< td=""><td>QRS duration, ms</td><td>146 (136-156)</td><td>144 (128-156)</td><td>0.41</td></t<>	QRS duration, ms	146 (136-156)	144 (128-156)	0.41
QRS duration ≥150 ms         79 (42.0)         8 (47.1)         0.80           Left anterior fascicular block         52 (27.7)         5 (29.4)         1.00           Eff posterior fascicular block         3 (1.6)         0 (0.0)         1.00           Bifascicular block         55 (29.3)         5 (29.4)         1.00           Trifascicular block         17 (9.0)         2 (11.8)         0.66           Procedural details	First degree AVB	62 (33.0)	6 (35.3)	1.00
Left anterior fascicular block         52 (27.7)         5 (29.4)         1.00           Left posterior fascicular block         3 (1.6)         0 (0.0)         1.00           Bifascicular block         55 (29.3)         5 (29.4)         1.00           Trifascicular block         17 (9.0)         2 (11.8)         0.66           Procedural details         0         0.00         1.00           Nonelective procedure         8 (4.3)         2 (11.8)         0.20           Nonefmoral approach         11 (5.9)         1.05         1.00           Anesthesia type         0.036         0.053         0.006           Conscious sedation         161 (85.6)         11 (64.7)         0.036           General anesthesia         27 (14.4)         6 (35.3)         0.00           Valve type         0.55         5         0.10         0.55           Balloon-expandable         180 (95.7)         16 (94.1)         0.00           ≤23 mm         54 (28.7)         1 (5.9)         0.10           26 mm         73 (38.8)         10 (58.8)         <0.001	QRS duration $\geq 150 \text{ ms}$	79 (42.0)	8 (47.1)	0.80
Left posterior fascicular block         3 (1.6)         0 (0.0)         1.00           Bifascicular block         55 (29.3)         5 (29.4)         1.00           Trifascicular block         17 (9.0)         2 (11.8)         0.66           Procedural details           0.20           Nonelective procedure         8 (4.3)         2 (11.8)         0.20           Anesthesia type         1 (5.9)         1.00           Conscious sedation         161 (85.6)         11 (64.7)           General anesthesia         27 (14.4)         6 (35.3)           Valve type         0.55           Balloon-expandable         180 (95.7)         16 (94.1)           Self-expanding         8 (4.3)         1 (5.9)           Valve type         0.10         54 (28.7)           223 nm         54 (28.7)         1 (5.9)           26 mm         73 (38.8)         10 (58.8)           ≥29 mm         61 (32.4)         6 (35.3)           Predilation         34 (18.1)         10 (58.8)           ≥29 nm         64 (6.57.7)         5 (29.4)         0.21           Oversizing, %         4.6 (0.87.9) [n = 180]         7.4 (3.0.9.0) [n = 17]         0.12           Implantation depth rela	Left anterior fascicular block	52 (27.7)	5 (29.4)	1.00
Bifacciular block55 (29.3)5 (29.4)1.00Trifasciular block17 (9.0)2 (11.8)0.66Procedural detailsNonelective procedure8 (4.3)2 (11.8)0.20Nonfemoral approach11 (5.9)1.000.36Anesthesia type0.360.360.36Conscious sedation161 (85.6)11 (64.7)0.36General anesthesia27 (14.4)6 (35.3)0.55Balloon-expandable180 (95.7)16 (94.1)0.55Self-expanding8 (4.3)1 (5.9)0.10Valve size0.100.55≤ 23 mm54 (28.7)1 (5.9)0.10≤ 23 mm54 (28.7)1 (5.9)0.21Over size0.100.58.8)0.001≥ 29 mm61 (32.4)6 (35.3)0.001Predilation34 (18.1)10 (58.8)<0.001Postdilation66 (45.7)5 (29.4)0.21Over sizing, %4.6 (0.87.9) [n = 180]7.4 (3.0-9.0) [n = 17]0.12LEG changes: end of TAVI - pre-TAVIImage: Self (40.0) [n = 155]10 (-2 to 52) [n = 10]0.92ΔPR interval, ms16 (2-31) [n = 155]10 (-2 to 52) [n = 10]0.92ΔQRS duration, ms0 (-4 to 6)-2 (-6 to 4)0.80ΔQRS duration ≥20 ms2 (1.1)1 (5.9)0.23	Left posterior fascicular block	3 (1.6)	0 (0.0)	1.00
Triascicular block17 (9.0)2 (11.8)0.66Procedural detailsNonelective procedure8 (4.3)2 (11.8)0.20Nonfemoral approach11 (5.9)1 (5.9)1.00Anesthesia type0.036Conscious sedation161 (85.6)11 (64.7)0.55General anesthesia27 (14.4)6 (35.3)0.55Valve type0.55Balloon-expandable180 (95.7)16 (94.1)0.10≤elf-expanding8 (4.3)1 (5.9)0.10Valve size0.100.100.10≤23 mm54 (28.7)1 (5.9)0.10≥29 mm61 (32.4)6 (35.3)0.001Postdilation36 (45.7)5 (29.4)0.21Oversizing, %4.6 (0.8-7.9) [n = 180]7.4 (3.0-9.0) [n = 17]0.12Implantation dept relative to th NCC, mm1.9 (0.8-3.5) [n = 187]4.1 (2.6-5.8) [n = 17]0.12 <i>L</i> CG changes: end of TAVI - pre-TAVIImplantation dept relative to th NCC, mm1.6 (2-31) [n = 155]10 (−2 to 52) [n = 10]0.92ΔPR interval, ms62 (40.0) [n = 155]4 (40.0) [n = 10]1.0020R8 duration $20$ ms0.2 (41.0)1.60ΔQRS duration $20$ ms2 (1.1)1 (5.9)0.230.230.23	Bifascicular block	55 (29.3)	5 (29.4)	1.00
Procedural details           Nonelective procedure         8 (4.3)         2 (11.8)         0.00           Nonelective procedure         8 (4.3)         1 (5.9)         1.00           Anesthesia type         0.036           Conscious sedation         16 (85.6)         11 (64.7)         0.036           Conscious sedation         16 (85.6)         11 (64.7)         0.036           General anesthesia         27 (14.4)         6 (35.3)         0.55           Balloon-expandable         180 (95.7)         16 (94.1)         0.55           Self-expanding         8 (4.3)         1 (5.9)         0.10           ✓23 mm         54 (28.7)         1 (5.9)         0.10           ≤ 23 mm         54 (28.7)         1 (5.9)         0.10           2 de man         73 (38.8)         10 (58.8)         <0.01           Predilation         34 (18.1)         10 (58.8)         <0.01           Postdilation         86 (45.7)         5 (29.4)         0.12           Oversizing, %         4.6 (0.8-7.9) [n = 180]         7.4 (3.0-9.0) [n = 17]         0.12           Implantation depth relative to the NCC, mm         1.9 (0.8-3.5) [n = 187]         10 (-2 to 52) [n = 10]         0.92           APR interval, ms	Trifascicular block	17 (9.0)	2 (11.8)	0.66
Nonelective procedure         8 (4.3)         2 (11.8)         0.20           Nonfemoral approach         11 (5.9)         1 (5.9)         0.00           Anesthesia type         0.36         0.36           Conscious sedation         161 (85.6)         11 (64.7)         0.36           General anesthesia         27 (14.4)         6 (35.3)         0.55           Valve type         0.55         0.55         0.55           Balloon-expandable         180 (95.7)         16 (94.1)         0.10           ≤23 mm         54 (28.7)         1 (5.9)         0.10           ≤23 mm         54 (28.7)         1 (5.9)         0.10           ≤23 mm         54 (28.7)         1 (5.9)         0.20           26 mm         73 (38.8)         10 (58.8)         29           ≥29 mm         61 (32.4)         6 (35.3)         0.21           Predilation         86 (45.7)         5 (29.4)         0.21           Oversizing, %         4.6 (0.8-7.9) [n = 180]         7.4 (3.0-9.0) [n = 17]         0.12           Implantation depth relative to the NCC, mm         1.9 (0.8-3.5) [n = 187]         4.1 (2.6-5.8) [n = 17]         0.001           EGC changes: end of TAVI - pre-TAVI         16 (2-31) [n = 155]         10 (-2 to 52) [n = 10]<	Procedural details	0 (1 0)	0 (11 0)	0.00
Nonemoral approach11 (5.9)1 (5.9)1 (5.9)1.00Anesthesia type0.036Conscious sedation161 (85.6)11 (64.7)General anesthesia27 (14.4)6 (35.3)Valve type0.55Balloon-expandable180 (95.7)16 (94.1)Self-expanding8 (4.3)1 (5.9)Valve size0.10≤23 mm54 (28.7)1 (5.9)26 mm73 (38.8)10 (58.8)≥29 mm61 (32.4)6 (35.3)Predilation34 (18.1)10 (58.8)≥29 mm61 (32.4)5 (29.4)Oversizing, %4.6 (0.87.9) [n = 180]7.4 (3.0-9.0) [n = 17]Oversizing, %4.6 (0.87.9) [n = 180]7.4 (3.0-9.0) [n = 17]Destiliation depth relative to the NCC, mm1.9 (0.8-3.5) [n = 187]4.1 (2.6-5.8) [n = 17]ΔPR interval, ms16 (2.31) [n = 155]10 (-2 to 52) [n = 10]0.92ΔPR interval, ms0 (-4 to 6)-2 (-6 to 4)0.80ΔQRS duration, ms0 (-4 to 6)-2 (-6 to 4)0.83ΔQRS duration , ms2 (1.1)1 (5.9)0.23	Nonelective procedure	8 (4.3)	2 (11.8)	0.20
Anisetine Star Type       0.036         Conscious sedation       161 (85.6)       11 (64.7)         General an esthesia       27 (14.4)       6 (35.3)         Valve type       0.55         Balloon-expandable       180 (95.7)       16 (94.1)         Self-expanding       8 (4.3)       1 (5.9)         Valve size       0.100         ≤ 23 mm       54 (28.7)       1 (5.9)         26 mm       73 (38.8)       10 (58.8)         ≥ 29 mm       61 (32.4)       6 (35.3)         Predilation       34 (18.1)       10 (58.8)       <0.01	Nonremoral approach	11 (5.9)	1 (5.9)	1.00
Construits setation161 (85.6)11 (64.7)General anesthesia27 (14.4)6 (35.3)Valve type0.55Balloon-expandable180 (95.7)16 (94.1)Self-expanding8 (4.3)1 (5.9)Valve size0.10 $\leq 23$ mm54 (28.7)1 (5.9)26 mm73 (38.8)10 (58.8) $\geq 29$ mm61 (32.4)6 (35.3)Predilation34 (18.1)10 (58.8) $\geq 29$ mm61 (32.4)6 (35.3)Predilation86 (45.7)5 (29.4)Oversizing, %4.6 (0.8.7.9) [n = 180]7.4 (3.0-9.0) [n = 17]Oversizing, %1.9 (0.8-3.5) [n = 187]4.1 (2.6-5.8) [n = 17]ECG changes: end of TAVI - pre-TAVI $4$ (2.31) [n = 155]10 (-2 to 52) [n = 10] $\Delta$ PR interval, ms16 (2-31) [n = 155]10 (-2 to 52) [n = 10]0.92 $\Delta$ PR interval $\geq 20$ ms62 (40.0) [n = 155]4 (40.0) [n = 10]1.00 $\Delta$ QRS duration, ms0 (-4 to 6)-2 (-6 to 4)0.80 $\Delta$ QRS duration $\geq 20$ ms2 (1.1)1 (5.9)0.23		161 (05 6)	11 (647)	0.036
Valve type0.53.3Valve type180 (95.7)16 (94.1)Self-expanding8 (4.3)1 (5.9)Valve size0.10 $\leq 23 \text{ mm}$ 54 (28.7)1 (5.9)26 mm73 (38.8)10 (58.8) $\geq 29 \text{ mm}$ 61 (32.4)6 (35.3)Predilation34 (18.1)10 (58.8)Predilation86 (45.7)5 (29.4)Oversizing, %4.6 (0.8-7.9) [n = 180]7.4 (3.0-9.0) [n = 17]Oversizing, %4.6 (0.8-7.9) [n = 187]4.1 (2.6-5.8) [n = 17]ECG changes: end of TAVI - pre-TAVI10 (-2 to 52) [n = 10]0.92 $\Delta PR$ interval, ms16 (2-31) [n = 155]10 (-2 to 52) [n = 10]0.92 $\Delta PR$ interval >20 ms62 (40.0) [n = 155]4 (40.0) [n = 10]0.92 $\Delta QRS$ duration, ms0 (-4 to 6)-2 (-6 to 4)0.80 $\Delta QRS$ duration >20 ms2 (1.1)1 (5.9)0.23	Conscious sedation	101(83.0)	11 (04.7) 6 (25.2)	
Value type0.53Balloon-expandable180 (95.7)16 (94.1)Self-expanding8 (4.3)1 (5.9)Valve size0.10 $\leq 23 \text{ mm}$ 54 (28.7)1 (5.9)26 mm73 (38.8)10 (58.8) $\geq 29 \text{ mm}$ 61 (32.4)6 (35.3)Predilation34 (18.1)10 (58.8)Predilation86 (45.7)5 (29.4)Oversizing, %4.6 (0.8-7.9) [n = 180]7.4 (3.0-9.0) [n = 17]Oversizing, %4.6 (0.8-7.9) [n = 187]4.1 (2.6-5.8) [n = 17]ECG changes: end of TAVI - pre-TAVI $10 (-2 \text{ to } 52) [n = 10]$ 0.92 $\Delta PR$ interval, ms16 (2-31) [n = 155]10 (-2 to 52) [n = 10]0.92 $\Delta PR$ interval >20 ms62 (40.0) [n = 155]4 (40.0) [n = 10]0.92 $\Delta QRS$ duration >20 ms2 (1.1)1 (5.9)0.23	Velve trac	27 (14.4)	0 (33.3)	0.55
ballot fexpanding100 (9.7.7)10 (9.7.1)Self-expanding8 (4.3)1 (5.9)Valve size0.10 $\leq 23 \text{ mm}$ 54 (28.7)1 (5.9)26 mm73 (38.8)10 (58.8) $\geq 29 \text{ mm}$ 61 (32.4)6 (35.3)Predilation34 (18.1)10 (58.8)Postdilation86 (45.7)5 (29.4)Oversizing, %4.6 (0.8-7.9) [n = 180]7.4 (3.0-9.0) [n = 17]Oversizing, %4.6 (0.8-7.9) [n = 187]4.1 (2.6-5.8) [n = 17]ECG changes: end of TAVI - pre-TAVI $M$ $M$ $\Delta PR$ interval, ms16 (2-31) [n = 155] $10 (-2 \text{ to } 52) [n = 10]$ $0.92$ $\Delta PR$ interval $\geq 20 \text{ ms}$ 62 (40.0) [n = 155] $4 (40.0) [n = 10]$ $0.92$ $\Delta QRS$ duration, $20 \text{ ms}$ 2 (1.1) $1 (5.9)$ $0.23$	Ralloon expandable	180 (05 7)	16 (04.1)	0.55
Value size       0.10 $\leq 23 \text{ mm}$ $54 (28.7)$ 1 (5.9) $26 \text{ mm}$ $73 (38.8)$ $10 (58.8)$ $\geq 29 \text{ mm}$ $61 (32.4)$ $6 (35.3)$ Predilation $34 (18.1)$ $10 (58.8)$ $0.10$ $86 (45.7)$ $5 (29.4)$ Oversizing, % $4.6 (0.87.9) [n = 180]$ $7.4 (3.0-9.0) [n = 17]$ $0.12$ Implantation depth relative to the NCC, mm $1.9 (0.8-3.5) [n = 187]$ $4.1 (2.6-5.8) [n = 17]$ $<0.001$ ECG changes: end of TAVI - pre-TAVI $I0 (-2 \text{ to } 52) [n = 10]$ $0.92$ $\Delta PR$ interval, ms $16 (2-31) [n = 155]$ $10 (-2 \text{ to } 52) [n = 10]$ $0.92$ $\Delta PR$ interval >20 ms $62 (40.0) [n = 155]$ $4 (40.0) [n = 10]$ $0.92$ $\Delta QRS$ duration >20 ms $0 (-4 \text{ to } 6)$ $-2 (-6 \text{ to } 4)$ $0.80$ $\Delta QRS$ duration >20 ms $2 (1.1)$ $1 (5.9)$ $0.23$	Self-expanding	8 (4 3)	1 (5 9)	
$ \begin{array}{c c c c c c c } & & & & & & & & & & & & & & & & & & &$	Valve size	0 (4.3)	1 (3.9)	0.10
260 mm73 (38.8)10 (58.8) $\geq 29 \text{ mm}$ 61 (32.4)6 (35.3)Predilation34 (18.1)10 (58.8)<0.001	<23 mm	54 (28 7)	1 (5.9)	0.10
$\begin{array}{c c c c c c c } \hline \begin{tabular}{ c c c c c } \hline \begin{tabular}{ c c c c c c } \hline \begin{tabular}{ c c c c c c } \hline \begin{tabular}{ c c c c c c c } \hline \begin{tabular}{ c c c c c c c c c c c c c c c c c c c$	26 mm	73 (38.8)	10 (58.8)	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	>29 mm	61 (32.4)	6 (35.3)	
Postiliation         b (45.7)         5 (29.4)         0.21           Oversizing, %         4.6 (0.8-7.9) [n = 180]         7.4 (3.0-9.0) [n = 17]         0.12           Implantation depth relative to the NCC, mm         1.9 (0.8-3.5) [n = 187]         4.1 (2.6-5.8) [n = 17]         <0.001	Predilation	34 (18 1)	10 (58.8)	< 0.001
$\begin{array}{c c} Oversizing, \% & 4.6 \ (0.8-7.9) \ [n = 180] & 7.4 \ (3.0-9.0) \ [n = 17] & 0.12 \\ Implantation depth relative to the NCC, mm & 1.9 \ (0.8-3.5) \ [n = 187] & 4.1 \ (2.6-5.8) \ [n = 17] & <0.001 \\ \hline \textbf{ECG changes: end of TAVI - pre-TAVI} & & & & \\ \Delta PR \ interval, ms & 16 \ (2-31) \ [n = 155] & 10 \ (-2 \ to 52) \ [n = 10] & 0.92 \\ \Delta PR \ interval \geq 20 \ ms & 62 \ (40.0) \ [n = 155] & 4 \ (40.0) \ [n = 10] & 1.00 \\ \Delta QRS \ duration, ms & 0 \ (-4 \ to 6) & -2 \ (-6 \ to 4) & 0.80 \\ \Delta QRS \ duration \geq 20 \ ms & 2 \ (1.1) & 1 \ (5.9) & 0.23 \end{array}$	Postdilation	86 (45.7)	5 (29.4)	0.21
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $	Oversizing. %	4.6 (0.8-7.9) [n = 180]	7.4(3.0-9.0) [n = 17]	0.12
ECG changes: end of TAVI - pre-TAVI $16 (2-31) [n = 155]$ $10 (-2 \text{ to } 52) [n = 10]$ $0.92$ $\Delta PR$ interval $\geq 20 \text{ ms}$ $62 (40.0) [n = 155]$ $4 (40.0) [n = 10]$ $1.00$ $\Delta QRS$ duration, ms $0 (-4 \text{ to } 6)$ $-2 (-6 \text{ to } 4)$ $0.80$ $\Delta QRS$ duration $\geq 20 \text{ ms}$ $2 (1.1)$ $1 (5.9)$ $0.23$	Implantation depth relative to the NCC. mm	1.9 (0.8-3.5) [n = 187]	4.1 (2.6-5.8) [n = 17]	< 0.001
$ \begin{array}{c c} \Delta PR \text{ interval, ms} & 16 (2-31) [n = 155] & 10 (-2 \text{ to } 52) [n = 10] & 0.92 \\ \Delta PR \text{ interval} \geq 20 \text{ ms} & 62 (40.0) [n = 155] & 4 (40.0) [n = 10] & 1.00 \\ \Delta QRS \text{ duration, ms} & 0 (-4 \text{ to } 6) & -2 (-6 \text{ to } 4) & 0.80 \\ \Delta QRS \text{ duration} \geq 20 \text{ ms} & 2 (1.1) & 1 (5.9) & 0.23 \\ \end{array} $	ECG changes: end of TAVI - pre-TAVI			
$ \begin{array}{c c} \Delta PR \text{ interval} \geq 20 \text{ ms} & 62 (40.0) [n = 155] & 4 (40.0) [n = 10] & 1.00 \\ \Delta QRS \text{ duration, ms} & 0 (-4 \text{ to } 6) & -2 (-6 \text{ to } 4) & 0.80 \\ \Delta QRS \text{ duration} \geq 20 \text{ ms} & 2 (1.1) & 1 (5.9) & 0.23 \end{array} $	$\Delta PR$ interval, ms	16 (2-31) [n = 155]	10 (-2 to 52) [n = 10]	0.92
$\Delta QRS$ duration, ms       0 (-4 to 6)       -2 (-6 to 4)       0.80 $\Delta QRS$ duration $\geq 20$ ms       2 (1.1)       1 (5.9)       0.23	$\Delta PR$ interval $\geq 20$ ms	62 (40.0) [n = 155]	4 (40.0) [n = 10]	1.00
$\Delta QRS \ duration \ge 20 \ ms$ 2 (1.1) 1 (5.9) 0.23	$\Delta QRS$ duration, ms	0 (-4 to 6)	-2 (-6 to 4)	0.80
	$\Delta QRS \text{ duration} \geq 20 \text{ ms}$	2 (1.1)	1 (5.9)	0.23

Notes. Values are n (%), n/total n (%), or median (interquartile range).

AR = aortic regurgitation, AVB = atrioventricular block, CABG = coronary artery bypass grafting, CHB = complete heart block, ECG = electrocardiogram, ESRD = end-stage renal disease, HAVB = high-degree atrioventricular block, HU = Hounsfield unit, LVEF = left ventricular ejection fraction, LVOT = left ventricular outflow tract, NCC = noncoronary cusp, NYHA = New York Heart Association, STS = Society of Thoracic Surgeons, TAVI = transcatheter aortic valve implantation.

delayed HAVB/CHB is clinically essential for early safe TPM removal and discharge in patients with pre-existing RBBB. Our data suggest that both predilation and categorized implantation depth have high negative predictive values for delayed HAVB/CHB (>95.0%). The combination of no

predilation and implantation depth of  $\leq$ 2.0 mm had a low risk (2.1%) of delayed HAVB/CHB, which may be helpful to select patients eligible for early safe TPM removal and discharge in the context of the recent trend toward a shorter hospital stay after TAVI.<sup>5,25</sup> In the absence of procedural

#### Table 3

#### In-hospital adverse events

	All	Procedural HAVB/CHB			Delayed HAVB/CHB			
	(N = 261)	No (n = 205)	Yes (n = 56)	p value	No (n = 188)	Yes (n = 17)	p value	
Death	0 (0.0)	0 (0.0)	0 (0.0)	(-)	0 (0.0)	0 (0.0)	(-)	
Major vascular complication	1 (0.4)	0 (0.0)	1 (1.8)	0.21	0 (0.0)	0 (0.0)	(-)	
Conversion to open surgery	0 (0.0)	0 (0.0)	0 (0.0)	(-)	0 (0.0)	0 (0.0)	(-)	
Coronary obstruction	1 (0.4)	1 (0.5)	0 (0.0)	1.00	1 (0.5)	0 (0.0)	1.00	
Second valve deployment	5 (1.9)	0 (0.0)	5 (8.9)	< 0.001	0 (0.0)	0 (0.0)	(-)	
Valve migration or embolization	0 (0.0)	0 (0.0)	0 (0.0)	(-)	0 (0.0)	0 (0.0)	(-)	
New-onset atrial fibrillation	8 (3.1)	6 (2.9)	2 (3.6)	0.68	4 (2.1)	2 (11.8)	0.080	
Paravalvular leak $\geq 2+$	3 (1.1)	2 (1.0)	1 (1.8)	0.52	2 (1.1)	0 (0.0)	1.00	
Stroke/transient ischemic attack	5 (1.9)	3 (1.5)	2 (3.6)	0.29	2 (1.1)	1 (5.9)	0.23	
Overall length of stay, d	3 (2-5)	2 (1-4)	4 (3-8)	< 0.001	2 (1-3)	4 (3-6)	< 0.001	
Post-TAVI length of stay, d	2 (2-4)	2 (1-3)	4 (3-7.5)	< 0.001	2 (1-3)	3 (2-6)	< 0.001	

*Notes*. Values are n (%) or median (interquartile range).

CHB = complete heart block, HAVB = high-degree atrioventricular block, TAVI = transcatheter aortic valve implantation.

HAVB/CHB, TPM removal at the end of the TAVI procedure appears reasonable in patients with a balloon-expandable valve implanted at a higher position without predilation. Meanwhile, maintaining the TPM for 12-24 hours is also acceptable in inexperienced centers with less supportive infrastructure. In the other patients (especially those with both predilation and implantation depth of >2.0 mm), providing prolonged in-hospital observation and ambulatory ECG monitoring for at least 2 weeks should be considered in the early-phase management.<sup>26</sup> We propose a risk stratification and subsequent management algorithm using predilation and implantation depth among patients with pre-existing RBBB undergoing TAVI (Figure 5).

One possible concern regarding a high valve deployment technique is the potential risk of valve migration or embolization. However, no valve migration or embolization occurred in the present study. In addition, our prior research demonstrates that while a high valve deployment technique led to a significantly lower rate of PPM implantation than conventional development (5.5% vs. 13.1%), there was only one valve embolization (0.2%) among 406 patients who underwent Sapien 3 TAVI with our high deployment technique,<sup>16</sup> demonstrating the effectiveness and safety of the technique. Nonetheless, despite a wealth of experience in our center since the 2017 adoption of a higher valve deployment relative to the NCC isolated in the RAO caudal view as our standard TAVI technique for all types of THVs, a more formal replication across other centers of our technique would be helpful. The present study was mainly limited to the Sapien valve during which our implantation technique evolved toward an NCC-based high implantation technique. As such, few patients received a self-expanding THV such as Evolut or ACURATE neo (Boston Scientific, Marlborough, Massachusetts); the ACURATE neo recently has been shown to associate with a lower 30-day PPM rate than Sapien 3 (29.6% vs. 43.9%, respectively) as reported by the SELECT RBBB (Transcatheter heart valve SELECTion in Patients with Right Bundle Branch Block) multicenter registry study,<sup>27</sup> while the PPM rates in the study were globally much higher than in our cohort. Further studies are needed to better understand the impact of THV selection on the PPM risk in the context of high valve implantation.

## Follow-Up With or Without PPM Implantation

Our data found no significant difference in death during follow-up between patients with or without the 30-day PPM/ICD, which contradicts prior investigations reporting an increased cardiovascular mortality after TAVI in patients with pre-existing RBBB and without the PPM.<sup>28,29</sup> Our negative result could be attributable partly to a small sample size. Thus, we should await a prospective multicenter study to determine the impact of the PPM in post-TAVI patients with pre-existing RBBB. Among patients requiring the PPM, the median RV pacing rate was as high as ~80%, and complete HAVB/CHB recovery was uncommon (7.1%). These findings are consistent with prior observations<sup>22,30</sup> and underscore

#### Table 4

Predictors of HAVB/CHB and 30-d PPM/ICD requirement after TAVI in patients with pre-existing RBBB

	Univariable analyses			Multivariable analyses		
	OR	95% CI	p value	OR	95% CI	p value
Procedural HAVB/CHB ( $n = 261$ )						
STS risk score, per 1% increase	1.09	1.02-1.16	0.008	1.08	1.01-1.15	0.030
Aortic valve area, per 0.1-cm <sup>2</sup> decrease	1.27	1.07-1.52	0.008	1.23	1.03-1.48	0.024
Implantation depth relative to the NCC, per 1-mm increase	1.27	1.09-1.48	0.002	1.25	1.07-1.46	0.004
Delayed HAVB/CHB ( $n = 205$ )*						
General anesthesia (vs. conscious sedation)	3.25	1.11-9.53	0.032	1.03	0.29-3.68	0.96
Predilation	6.47	2.30-18.21	< 0.001	4.02	1.22-13.23	0.022
Implantation depth relative to the NCC, per 1-mm increase	1.53	1.18-1.99	0.001	1.34	1.01-1.79	0.044
30-d PPM/ICD requirement ( $n = 261$ )						
LVOT calcification	2.37	1.24-4.53	0.009	1.77	0.89-3.52	0.11
Self-expanding valve (vs. balloon-expandable valve)	3.31	1.07-10.28	0.038	1.72	0.48-6.19	0.41
Predilation	3.18	1.69-5.98	< 0.001	1.94	0.96-3.90	0.064
Implantation depth relative to the NCC, per 1-mm increase	1.42	1.21-1.66	< 0.001	1.32	1.11-1.55	0.001

*Notes.* Predictors were examined in multivariable logistic regression models including variables with a p value at <0.05 in univariable models (Supplemental Table 3). In multivariable models, missing data for aortic valve area, implantation depth, and LVOT calcification were handled with multiple imputation. CHB = complete heart block, CI = confidence interval, HAVB = high-degree atrioventricular block, ICD = implantable cardioverter defibrillator, LVOT = left ventricular outflow tract, NCC = noncoronary cusp, OR = odds ratio, PPM = permanent pacemaker, RBBB = right bundle branch block, TAVI = transcatheter aortic valve implantation.

Includes patients who did not develop procedural HAVB/CHB.

Pre-dilation (-) + Implantation depth ≤2.0 mm (n=107)
 Pre-dilation (+) + Implantation depth ≤2.0 mm (n=15)
 Pre-dilation (-) + Implantation depth >2.0 mm (n=91)

Pre-dilation (+) + Implantation depth >2.0 mm (n=46)



Figure 3. Risk of 30-day HAVB/CHB and PPM/ICD requirement according to predilation and implantation depth. This figure was made from the data of 259 patients with implantation depth available. \*Includes 204 patients without procedural HAVB/CHB.

Abbreviations: CHB, complete heart block; HAVB, high-degree atrioventricular block; ICD, implantable cardioverter defibrillator; PPM, permanent pacemaker.

the importance of PPM implantation in a timely fashion when necessary. Meanwhile, both the present and the Canadian studies<sup>22</sup> demonstrate that patients with procedural transient HAVB/CHB may have a chance (50%-60%) to avoid PPM implantation. Since the determinants of persistent or transient HAVB/CHB are currently unknown, close follow-up and discussion with the electrophysiology team are important to judge the indications for the PPM.

## Study Limitations

a Death

The present study has several limitations to be acknowledged. This study was conducted in a single very high-volume U.S. center with the predominant use of balloon-expandable THVs and a unique high deployment technique based on the NCC basal plane. Therefore, the present findings may not be generalizable directly to other centers, especially those where the self-expanding THV is more frequently used with a conventional coplanar view deployment technique or in less experienced hands where valve migration/embolization may pose an issue. The number of self-expanding THV recipients is too small to assess the impact of the self-expanding THV on HAVB/CHB occurrence. The study's retrospective design without routine ambulatory ECG monitoring may have precluded us from complete detection of asymptomatic arrhythmic events after discharge. The present study may be underpowered to examine the impact of PPM implantation on long-term outcomes owing to the small sample size of the PPM group. Finally, our risk stratification using predilation and implantation depth (Figure 5) requires validation in a prospective multicenter study.

## Conclusions

The present study found that 30-day HAVB/CHB occurred in 28.0% of patients with pre-existing RBBB (95% balloon-expandable THVs), with more than 3-quarters occurring during the TAVI procedure. Delayed HAVB/CHB was not rare, but TPM reinsertion was needed in only 4.5%, suggesting that early TPM removal may be possible in many patients. An absence of predilation coupled with an implantation depth of  $\leq$ 2 mm portended the lowest overall 30-day PPM rate of 10.3% in our study patients, indicative of the importance of the procedural strategy, valve choice, and meticulous high implantation technique to potentially optimize outcomes in pre-existing RBBB TAVI recipients. Further



## **b** MACE (death, stroke/TIA, or HF hospitalization)

**Figure 4.** Kaplan–Meier estimates of death and MACE of patients with or without **30-day PPM/ICD requirement**. This Figure shows the Kaplan–Meier curves with the log-rank test to compare (a) death and (b) MACE (death, stroke/TIA, or HF h)

This Figure shows the Kaplan–Meier curves with the log-rank test to compare (a) death and (b) MACE (death, stroke/TIA, or HF hospitalization) between patients with or without 30-day PPM/ICD among TAVI recipients with pre-existing RBBB. Abbreviations: HF, heart failure; ICD, implantable cardioverter defibrillator; MACE, major adverse cardiovascular events; PPM, permanent pacemaker; TIA, transient ischemic attack.



Figure 5. Proposal for risk stratification using predilation and implantation depth among patients with pre-existing RBBB undergoing TAVI. Abbreviations: CHB, complete heart block; ECG, electrocardiogram; HAVB, high-degree atrioventricular block; ICD, implantable cardioverter defibrillator; NCC, noncoronary cusp; RBBB, right bundle branch block; TAVI, transcatheter aortic valve implantation.

prospective multicenter studies are required to establish appropriate management strategies (THV selection and deployment technique) in TAVI recipients with pre-existing RBBB.

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## **Ethics statement**

The present study was approved by the Institutional Review Board of Cleveland Clinic with a waiver of informed consent owing to the retrospective nature of the study.

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## **Disclosure statement**

The authors declare no conflict of interest.

## **Supplementary Material**

Supplemental data for this article can be accessed on the publisher's website.

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