Predictors of pacemaker implantation in aortic regurgitation patients treated with a dedicated transcatheter heart valve

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BACKGROUND: The JenaValve Trilogy System (JVTS) is the only dedicated transcatheter heart valve system approved for treating patients with aortic regurgitation (AR). Recently, several studies have revealed high rates of permanent pacemaker implantation (PPI) exceeding 20% in patients with AR.

AIMS: The aim of this study was to evaluate the incidence and risk factors for new PPI after transcatheter aortic valve implantation (TAVI) with the JVTS.

METHODS: This retrospective multicentre registry included 141 patients without prior PPI who underwent transfemoral TAVI with the JVTS. Comparative analyses were performed regarding baseline and procedural parameters between patients with and without new PPI at discharge. Logistic regression models were fitted to identify predictors of PPI.

RESULTS: The median age of patients was 81 (interquartile range [IQR] 76-85) years, 41% were female, and the median European System for Cardiac Operative Risk Evaluation (EuroSCORE) II was 3.6% (IQR 2.0-6.4). All patients presented with \geq moderate AR. At discharge, 34 patients (24.1%) required a new PPI. Pre-existing first-degree atrioventricular block and right bundle branch block were identified as independent predictors of new PPI. Anatomical characteristics, including annular and left ventricular outflow tract perimeters, were not predictive. Procedural factors such as implantation depth and valve oversizing were also not statistically different between patients with or without new PPI.

CONCLUSIONS: Overall, 24.1% of patients undergoing TAVI with the JVTS required a new PPI. While rates of new PPI were strongly associated with pre-existing first-degree atrioventricular block and right bundle branch block using the JVTS, no modifiable risk factors were identified.

KEYWORDS: aortic regurgitation; permanent pacemaker implantation; transcatheter aortic valve implantation

Transcatheter aortic valve implantation (TAVI) is a treatment option for patients with aortic regurgitation $(AR)^{1,2}$. The JenaValve Trilogy System (JVTS; JenaValve Technology) is a transcatheter heart valve (THV) system designed for the transfemoral treatment of patients with AR. While non-dedicated TAVI systems have a high rate of procedural failure, treatment with this dedicated THV system has shown a high technical success rate, with recent studies demonstrating excellent haemodynamic performance, with notably low rates of paravalvular regurgitation (PVR) and low rates of valve embolisation¹⁻⁴.

However, these studies also report that cardiac conduction disturbances resulting in permanent pacemaker implantation (PPI) occurred in 19.6% to 24% of patients treated with the JVTS^{1,2}. Overall, these rates are comparable to those of new-generation non-dedicated THV systems when used off-label for AR treatment^{3,4}. Among aortic stenosis (AS) patients, anatomical, electrocardiographic, and procedural factors – including modifiable variables like lower implantation depth and degree of THV oversizing – influence the risk for postprocedural PPI⁵⁻⁷. However, the pathomechanism and anatomy of AR differ significantly from AS. Larger average annular diameters and minimal or even an absence of leaflet calcification to restrict THV expansion might affect the conduction system differently.

Whether the same predictors apply to patients with noncalcified AR as for AS is still unknown. Therefore, the purpose of the present study was to investigate potentially modifiable and non-modifiable predictors in patients undergoing TAVI with a dedicated THV for AR.

Methods

PATIENT POPULATION & DATA ACQUISITION

This registry included patients with AR and no prior history of PPI, treated at four experienced European centres (London, Bad Oeynhausen, Mainz, and Cologne). Patients undergoing transfemoral TAVI with the JVTS were retrospectively identified. Data were collected for cases performed between September 2021 and April 2024, plus one patient treated in April 2019. All patients referred for TAVI were discussed during multidisciplinary Heart Team meetings. AR was categorised as moderate, moderate-to-severe, and severe AR based on guideline recommendations⁸. For patients with mixed aetiology where AR was predominant, inclusion in the current analysis also required a mean aortic valve gradient of \leq 20 mmHg. Principal exclusion criteria for the JVTS have been previously reported². The study was conducted according to the Declaration of Helsinki and Good Clinical Practice guidelines.

DEVICE AND PROCEDURE

The JVTS is a low-profile, self-expanding, supra-annular porcine pericardial bioprosthetic valve with a nitinol frame,

Impact on daily practice

Despite excellent technical outcomes and favourable valve haemodynamics, permanent pacemaker implantation (PPI) remains a frequent complication after transcatheter aortic valve implantation for aortic regurgitation, even with a dedicated device. This study identified prior right bundle branch block and first-degree atrioventricular block as independent predictors of PPI with the JenaValve Trilogy System, while procedural factors such as implantation depth and valve oversizing were not associated with PPI. Careful baseline conduction assessment and further research on optimal timing, long-term outcomes, and tailored pacing strategies are essential to optimise patient care.

available in three sizes to cover aortic annular perimeters ranging from 66 mm to 90 mm. A key feature of this valve is its three locators, specifically designed for active anchoring by clipping onto the aortic leaflets. This mechanism ensures a secure seal between the native valve and the prosthesis while minimising protrusion into the left ventricular outflow tract (LVOT). Further design aspects of the JVTS and details of the implantation procedure have been described previously⁹. After TAVI, all patients were continuously monitored to assess clinical events and underwent postprocedural electrocardiography, echocardiography, and laboratory investigations.

DATA COLLECTION AND DEFINITIONS

Demographic data, clinical findings, and details of electrocardiographic and echocardiographic findings were collected as part of routine clinical care. Preprocedural multidetector computed tomography (CT) of the entire aorta and iliofemoral arteries was performed and analysed according to local standard methods by a blinded investigator (M. Stukenberg) using 3mensio Structural Heart software, version 10.3 (Pie Medical Imaging).

The standardised assessment included measuring the aortic annular dimensions, defined as the virtual basal plane encompassing the basal attachment of the three aortic cusps, with the area and perimeter primarily quantified in mid-systole. LVOT dimensions were assessed at 6 mm below the aortic annular plane. The "cover index" was calculated to assess the congruence between the aortic annulus and the device, defined as 100 × [(prosthesis diameter – CT-derived annulus diameter) / prosthesis diameter]. Valve oversizing at the level of the annulus and LVOT was calculated using multidetector CT: [(valve waist diameter/annulus perimeter) – 1] × 100 and [(device inflow diameter/LVOT perimeter) – 1] × 100. The length of the infra-annular portion of the membranous

Abbreviations AR aortic regurgitation

 AS
 aortic stenosis
 LVOT
 left ventricular outflow tract

 AV
 atrioventricular
 MS
 membranous septum

 ID
 implantation depth
 PPI
 permanent pacemaker implantation

JVTS

JenaValve Trilogy System

PVRparavalvular regurgitationRBBBright bundle branch blockTHVtranscatheter heart valveVARCValve Academic Research Consortium

Implantation depth, measured by aortography, was defined either as (1) the maximum distance (in millimetres) between the end of the intraventricular distal prosthesis and the aortic annulus at the level of the non-coronary and left coronary cusps, or (2) the deepest point of the distal prosthesis, regardless of the anatomical orientation. A pigtail catheter was used for calibration. The fluoroscopic projection for aortography was individualised to obtain a coplanar view for the patient's anatomy and the implanted THV.

STATISTICAL ANALYSIS

Continuous variables are expressed as median and interquartile range (IQR; 25th-75th percentile) and were

compared using the Wilcoxon rank-sum test. Categorical baseline characteristics were compared using the chi-square test or Fisher's exact test as appropriate. Univariable logistic regression was conducted to identify predictors for new PPI, with odds ratios (ORs) and 95% confidence intervals (CIs) reported. Factors with a p-value<0.10 and considered clinically relevant were included in the multivariable logistic regression model. P-values<0.05 were considered statistically significant. All statistical analyses were performed using R, version 4.4.2 (R Foundation for Statistical Computing).

Results

BASELINE CHARACTERISTICS

Baseline characteristics are summarised in **Table 1**. The median age of the cohort was 81.0 (IQR 76.0-84.8) years, with 41% being female. At discharge, 34 patients (24.1%) required

Table 1. Baseline characteristics.

	Overall N=141	No PPI N=107	New PPI N=34	<i>p</i> -value
Age, years	81.0 (76.0-84.8)	80.7 (74.0-84.2)	82.0 (79.7-85.0)	0.12
Female sex	58 (41)	46 (43)	12 (35)	0.43
Body mass index, kg/m ²	24.8 (21.9-27.8)	24.7 (21.3-27.8)	25.1 (23.0-28.7)	0.24
New York Heart Association Functional Class				0.80
1	5 (3.5)	3 (2.8)	2 (5.9)	
II	37 (26)	28 (26)	9 (26)	
III	88 (62)	68 (64)	20 (59)	
IV	11 (7.8)	8 (7.5)	3 (8.8)	
EuroSCORE II, %	3.6 (2.0-6.4)	3.4 (1.8-6.5)	3.8 (2.3-5.1)	0.95
Diabetes mellitus	21 (15)	15 (14)	6 (18)	0.60
Hypertension	118 (84)	86 (80)	32 (94)	0.059
Previous stroke	15 (11)	11 (10)	4 (12)	0.76
Chronic obstructive pulmonary disease	17 (12)	12 (11)	5 (15)	0.56
Extracardiac arteriopathy	12 (8.5)	9 (8.4)	3 (8.8)	>0.99
Coronary artery disease	58 (41)	47 (44)	11 (32)	0.23
Previous cardiac surgery	12 (8.5)	12 (11)	0 (0)	0.070
Glomerular filtration rate, ml/min/1.73 m ²	56.4 (39.0-79.0)	59.0 (42.0-80.0)	48.5 (36.0-71.0)	0.076
Chronic renal replacement therapy	2 (1.6)	1 (1.0)	1 (3.2)	0.42
Sinus rhythm at baseline	107 (76)	82 (77)	25 (74)	0.71
History of atrial fibrillation	55 (39)	42 (39)	13 (38)	0.92
PR duration, ms; N missing	184.0 (167.0-218.0); 36	181.0 (166.0-212.0); 26	215.5 (182.5-236.0); 10	0.010*
QRS duration, ms	105.0 (94.0-128.0)	104.0 (94.0-118.0)	114.0 (96.0-152.0)	0.081
Prior right bundle branch block	8 (5.7)	2 (1.9)	6 (18)	0.003*
Prior left bundle branch block	22 (16)	17 (16)	5 (15)	0.87
First-degree AV block	37 (26)	23 (21)	14 (41)	0.023*
Left ventricular ejection fraction				0.57
>50%	71 (50)	57 (53)	14 (41)	
41-50%	44 (31)	31 (29)	13 (38)	
31-40%	17 (12)	13 (12)	4 (12)	
<31%	9 (6.4)	6 (5.6)	3 (8.8)	
Aortic regurgitation				0.17
Moderate	15 (11)	14 (13)	1 (2.9)	
Moderate-severe	53 (38)	37 (35)	16 (47)	
Severe	73 (52)	56 (52)	17 (50)	

Data are presented as median (IQR) or frequency (%). *Indicates statistical significance. AV: atrioventricular; EuroSCORE: European System for Cardiac Operative Risk Evaluation; IQR: interquartile range; PPI: permanent pacemaker implantation

a new PPI (**Central illustration**). The primary indication for PPI was complete heart block, which accounted for 74.0% (n=25) of all patients.

Baseline characteristics were generally similar between groups, except for a trend towards reduced renal function in patients requiring PPI (estimated glomerular filtration rate: 48.5 [IQR 36.0-71.0] ml/min/1.73 m² vs 59.0 [IQR 42.0-80.0] ml/min/1.73 m²; p=0.076). Pre-existing right bundle branch block (RBBB) and first-degree atrioventricular (AV)

block were significantly more prevalent among patients requiring PPI, while no significant difference was observed in the incidence of left bundle branch block (Figure 1).

The unadjusted and body surface area-adjusted diameters of the sinus of Valsalva, sinotubular junction, and ascending aorta were larger in patients requiring PPI. Aortic annular and LVOT perimeters were similar between groups. The MS length was also comparable in both groups (**Table 2**). In the subgroup of patients with prior RBBB and first-degree AV



A) Study details. B) Predictors of PPI after TAVI. Reproduced with permission from Jena Valve Technology for providing the valve image of the Jena Valve Trilogy System. AR: aortic regurgitation; AV: atrioventricular; BSA: body surface area; CI: confidence interval; OR: odds ratio; PPI: permanent pacemaker implantation; TAVI: transcatheter aortic valve implantation; THV: transcatheter heart valve



Figure 1. Rates of PPI in non-pacemaker-dependent patients following transcatheter aortic valve implantation with prior conduction abnormalities. New PPI in patients with prior right bundle branch block (A), prior left bundle branch block (B) and prior first-degree AV block (C). AV: atrioventricular; PPI: permanent pacemaker implantation block, the median MS length was similar between patients requiring PPI and those who did not (new PPI: 2.2 [IQR 0.8-2.8] mm vs no PPI: 1.4 [IQR 0.7-2.3] mm; p=0.43).

PROCEDURAL CHARACTERISTICS AND CLINICAL OUTCOMES

Procedural characteristics, as displayed in **Table 3**, showed no significant differences between groups. Implantation depths at the non-coronary cusp, left coronary cusp, and the deepest implantation point did not differ significantly between the groups. Oversizing at the annular level was 11.5% (IQR 8.3-14.1%), and at the LVOT level, 14.9% (IQR 10.3-20.9%); there were no significant differences between groups. An analysis of various degrees of valve oversizing at the annular (**Figure 2A**) and LVOT (**Figure 2B**) levels did not reveal a trend towards increased PPI rates in patients with greater valve oversizing.

Other procedural parameters, including contrast usage, fluoroscopy time, and type of anaesthesia, were comparable between groups. Complication rates – including stroke, valve implantation success, and the need for a second valve – showed no significant differences. However, patients requiring PPI had a significantly longer hospital stay (new PPI: 8 [IQR 6.5-12] days vs no PPI: 7 [IQR 5-9] days; p=0.012).

Table 2. Computed tomographic characteristics.

	Overall N=141	No PPI N=107	New PPI N=34	<i>p</i> -value
Annular perimeter, mm	83.8 (76.4-86.7)	83.3 (76.4-86.9)	84.3 (74.7-86.1)	0.81
Minimum annular perimeter, mm	22.9 (21.4-24.3)	23.1 (21.4-24.4)	22.6 (21.2-23.9)	0.35
Maximum annular perimeter, mm	29.4 (26.8-30.8)	29.0 (26.8-30.7)	29.9 (26.8-31.3)	0.23
Annular area, mm ²	534.1 (446.0-578.1)	533.8 (446.0-578.1)	540.9 (438.4-571.4)	0.97
LVOT perimeter, mm	85.8 (80.7-91.0)	85.6 (81.3-91.0)	87.4 (78.7-91.4)	0.88
Minimum LVOT perimeter, mm	21.6 (19.6-23.0)	21.6 (19.5-23.2)	21.3 (19.7-22.5)	0.45
Maximum LVOT perimeter, mm	31.1 (29.2-33.3)	31.1 (29.3-33.1)	31.4 (28.6-33.8)	0.78
Sinus of Valsalva diameter, mm	37.2 (33.2-39.3)	36.7 (32.9-38.4)	38.5 (36.4-41.8)	0.005*
Sinus of Valsalva diameter/BSA, mm/m ²	20.0 (18.4-21.8)	19.7 (17.9-21.7)	20.9 (19.2-22.4)	0.044*
Sinotubular junction diameter, mm	35.3 (32.2-39.9)	34.4 (30.9-38.7)	38.8 (35.2-41.9)	0.001*
Sinotubular junction diameter/BSA, mm/m ²	19.0 (17.3-21.8)	18.7 (17.0-21.2)	21.1 (18.4-23.1)	0.007*
Sinotubular junction height, mm	29.6 (26.1-33.8)	29.2 (25.9-33.2)	31.6 (28.3-35.3)	0.027*
Sinotubular junction height/BSA, mm/m ²	16.2 (14.6-18.3)	15.9 (14.2-18.2)	17.0 (15.8-18.7)	0.057
Maximum ascending aorta diameter, mm	40.3 (37.0-44.7)	38.8 (36.5-42.7)	43.0 (39.9-46.9)	0.003*
Maximum ascending aorta diameter/BSA, mm/m ²	21.9 (19.4-24.7)	21.2 (19.0-24.7)	23.4 (21.0-24.5)	0.062*
Aortic annulus-to-left coronary artery distance, mm	15.3 (13.0-18.1)	15.6 (13.4-18.2)	14.7 (12.7-16.8)	0.24
Aortic annulus-to-right coronary artery distance, mm	20.3 (18.2-22.9)	20.4 (18.0-22.8)	20.2 (18.3-22.9)	0.98
Morphology of the LVOT				0.46
Tubular	19 (13)	16 (15)	3 (8.8)	
Tapered	93 (66)	71 (66)	22 (65)	
Flared	29 (21)	20 (19)	9 (26)	
Aortic root angle, °	55.0 (49.0-63.0)	54.0 (49.0-63.0)	57.0 (51.0-62.0)	0.30
LVOT calcification	6 (4.3)	5 (4.7)	1 (2.9)	>0.99
Annular calcification				0.76
No calcification	126 (89)	96 (90)	30 (88)	
Mildly calcified (small, isolated spots)	15 (11)	11 (10)	4 (12)	
Membranous septum length, mm	2.1 (1.2-3.0)	2.1 (1.2-3.0)	2.3 (1.1-3.0)	0.70
Membranous septum length <2 mm	63 (45)	49 (46)	14 (41)	0.64

Data are presented as median (IQR) or frequency (%). *Indicates statistical significance. BSA: body surface area; IQR: interquartile range; LVOT: left ventricular outflow tract; PPI: permanent pacemaker implantation

Table 3. Procedural/in-hospital characteristics.

	Overall N=141	No PPI N=107	New PPI N=34	<i>p</i> -value
Implantation date				0.89
≤2022	74 (52)	57 (53)	17 (50)	
2023/2024	67 (48)	50 (47)	17 (50)	
Valve size				0.61
23 mm	23 (16)	19 (18)	4 (12)	
25 mm	28 (20)	22 (21)	6 (18)	
27 mm	90 (64)	66 (62)	24 (71)	
Anaesthesia				0.28
General anaesthesia	39/140 (28)	32/106 (30)	7/34 (21)	
Conscious sedation	101/140 (72)	74/106 (70)	27/34 (79)	
Procedure duration, min; N missing	66.0 (57.0-84.0); 12	68.5 (54.0-86.0); 9	66.0 (59.0-78.0); 3	0.98
Contrast, ml; N missing	155.0 (120.0-209.0); 16	157.0 (120.0-209.0); 10	143.0 (122.5-207.5); 6	0.81
Fluoroscopy time, min; N missing	16.0 (12.4-21.8); 17	16.0 (13.0-22.0); 10.0	16.0 (11.1-21.5); 7	0.65
Post-dilatation performed	1 (0.7)	0 (0)	1 (2.9)	0.24
LVOT oversizing, %	14.9 (10.3-20.9)	14.5 (9.9-20.4)	15.7 (11.3-24.0)	0.55
Annular oversizing, %	11.5 (8.3-14.1)	11.5 (8.3-14.1)	11.5 (9.2-13.4)	0.89
Annular minimal perimeter/valve size	0.9 (0.8-0.9)	0.9 (0.8-0.9)	0.9 (0.8-0.9)	0.11
Eccentricity index	0.2 (0.2-0.2)	0.2 (0.2-0.2)	0.2 (0.2-0.3)	0.10
Cover index	0.0 (-3.0 to 2.2)	0.0 (-3.0 to 2.2)	0.4 (-2.2 to 2.6)	0.55
Non-coronary cusp ID, mm; N missing	6.6 (5.7-7.4); 40	6.5 (5.8-7.4); 32	6.6 (5.2-7.7); 8	0.95
Left coronary cusp ID, mm; N missing	6.6 (6.0-7.4); 40	6.6 (6.0-7.4); 32	6.7 (5.9-7.4); 8	0.76
Deepest ID, mm; N missing	7.2 (6.6-7.9); 40	7.1 (6.7-7.9); 32	7.3 (6.4-7.9); 8	0.77
New stroke	2 (1.4)	1 (0.9)	1 (2.9)	0.43
Acute kidney injury stage	120 (04)	101 (04)	21 (01)	0.45
None	132 (94)	101 (94)	31 (91)	
Stage 1	6 (4.3)	3 (2.8)	3 (8.8)	
Stage 2	2(1.4)	2(1.9)	0 (0)	
Stage 5	1 (0.7)	1 (0.9)	0(0)	0.70
Nene	122 (04)	101 (04)	22 (04)	0.79
None Minor vascular complication	6 (4 3)	101 (94)	32 (94) 2 (5 9)	
Major vascular complication	0(4.3)	4(3.7)	2 (3.9)	
Reading complication	2 (1.4)	2 (1.9)	0 (0)	0.64
None	128 (91)	98 (92)	30 (88)	0.04
	120(51) 10(7.1)	7 (6 5)	3 (8 8)	
Type 2	3 (2 1)	2 (1.9)	1 (2 9)	
Type 3/4	0 (0)	0 (0)	0(0)	
Second valve implanted	2 (1.4)	1 (0.9)	1 (2.9)	0.43
Conversion to open surgery	1 (0.7)	1 (0.9)	0 (0)	>0.99
Total length of hospital stay, days	7.0 (6.0-9.0)	7.0 (5.0-9.0)	8.0 (7.0-11.0)	0.012*
Mean aortic valve gradient at discharge, mmHg; N missing	4.0 (3.0-5.0); 8	4.0 (3.0-5.0); 7	5.0 (4.0-6.0); 1	0.006*
Aortic valve area at discharge, cm ² ; N missing	2.4 (2.0-2.9); 58	2.4 (2.0-2.9); 43	2.5 (2.0-2.9); 15	0.54
Paravalvular regurgitation				>0.99
None-trace	127/138 (92)	96/105 (91)	31/33 (94)	
Mild	11/138 (8.0)	9/105 (8.6)	2/33 (6.1)	
Moderate-severe	0/138 (0)	0/105 (0)	0/33 (0)	
Technical success	139 (99)	106 (99)	33 (97)	0.43
Indication for PPI AV block III°	-	_	25 (74)	
Bradyarrhythmia absoluta	-	-	0 (0)	
AV block I°+left bundle branch block	-	-	4 (12)	
Sinus arrest/sick sinus syndrome	-	-	0 (0)	
AV block II°+left bundle branch block	-	-	3 (8.8)	
Other indication	-	-	2 (5.9)	

Data are presented as median (IQR) or frequency (%). *Indicates statistical significance. AV: atrioventricular; ID: implantation depth; IQR: interquartile range; LVOT: left ventricular outflow tract; N: number; PPI: permanent pacemaker implantation

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PPIs were performed at a median of 3 (IQR 1-6) days after the TAVI procedure. Pacing data beyond 30 days were available for 21 patients, with device interrogation conducted at a median of 111 (IQR 93-360) days, revealing a median right ventricular pacing rate of 92% (IQR 30-99%).

Haemodynamic performance was excellent in both groups, characterised by low valve gradients, large orifice areas, and over 90% of patients showing no or trace PVR. At follow-up, 29 patients (85%) in the PPI group were alive (median follow-up: 342 [IQR 100-534.5] days), compared to 95 patients (89%) in the non-PPI group (median follow-up: 363 [IQR 122.5-716] days; p=0.55).

PREDICTORS FOR PPI

Table 4 presents the univariable and multivariable analyses for predictors of PPI. In the univariable analyses, the diameter of the sinus of Valsalva and the sinotubular junction exhibited statistically significant trends with p-values<0.10, but these did not reach statistical significance in the multivariable analysis. RBBB and first-degree AV block were statistically significant predictors of PPI in the multivariable analysis (**Central illustration**). Notably, valve oversizing at the annular or LVOT level and implantation depth were not significant predictors of PPI.

Discussion

In this study, the PPI rate with the dedicated TAVI device (JVTS) was 24.1%. The main findings can be summarised as follows (**Central illustration**): (1) patients with prior RBBB had a significantly increased risk of new PPI; (2) a similar trend towards new PPI was observed for patients with first-degree AV block, whereas left bundle branch block showed no such association; and (3) modifiable risk factors such as implantation depth and valve oversizing did not differ between the groups with or without new PPI.

Cardiac conduction disturbances requiring PPI are frequently observed in patients undergoing TAVI for AS¹¹⁻¹³. PPI following TAVI may yield limited benefits due to the impact on AV synchrony and right ventricular pacing¹⁴. While rates are lower with contemporary valves used in the treatment of AS (ACURATE neo2 [Boston Scientific]: 8.0%, SAPIEN 3 Ultra [Edwards Lifesciences]: 9.9%, Evolut FX [Medtronic]: 11.9%, Navitor [Abbott]: 19.0%), they remain clinically significant^{12,13,15}. Similarly, low-risk patients undergoing surgical aortic valve replacement for AS have reported PPI rates of 4.0-6.1% in the Evolut Low Risk and PARTNER 3 trials^{11,16}. However, studies also indicate that surgical aortic valve replacement in AR patients is associated with PPI rates exceeding 10%^{17,18}, suggesting a potentially more vulnerable interaction with the conduction system when treating AR compared to AS; this might be due to anatomical and pathophysiological differences between these two aortic valve diseases. In patients with AR, the aortic annulus and LVOT tract are rarely calcified, which means there is less restriction on THV expansion and greater interaction between the THV and the conduction system.

The PPI rates exceeding 20% in our study are consistent with previous findings for this device as well as for non-dedicated devices used in the treatment of AR¹⁻⁴. The underlying mechanism for conduction system disorders may be attributed to the proximity of the aortic valve complex to the cardiac conduction system. Interaction between the stent frame of the THV and the conduction system can lead to compression, haemorrhage, ischaemia, trauma, and infarction¹⁹.

Over recent years, intensive research has focused on identifying predictors for PPI in AS patients. Baseline conduction disturbances are recognised as the most significant predictors of PPI following TAVI^{5,20}. Consistent with recent studies in patients with severe AS, RBBB emerged as the strongest predictor^{5,21,22}, while first-degree AV block also demonstrated an impact, aligning with the current literature²³.

Several studies have demonstrated that a shallower implantation depth for self-expanding valves is associated with fewer conduction disturbances and lower rates of PPI in AS patients^{5,21}. However, our analysis found no difference in implantation depth between groups, which may be related to technical factors inherent to the JVTS, where the locators are positioned at the nadir of the annulus^{1,2,9} and thereby might predefine the implant depth to a relevant extent. In addition, the MS length was not associated with new PPI following TAVI with the JVTS, whereas a relationship between the MS length and new PPI has been identified in patients with AS^{10,24}. Notably, in our study, we observed a shorter MS length in both groups compared to these prior studies^{10,24}, which might help to identify a high-risk population for new PPI.

Moreover, we observed no differences in valve oversizing between the groups, a factor with a controversial role regarding PPI in patients with severe AS^{25,26}. Furthermore, we did not find any difference in LVOT morphology related to PPI. In contrast, Zhang et al reported higher rates of PPI in patients with non-tubular LVOT shapes undergoing TAVI with the VitaFlow Liberty device (MicroPort)²⁷.

Surprisingly, we identified a difference in anatomical characteristics related to the diameters of the sinus of Valsalva and the sinotubular junction, which appeared to have a relevant impact; however, this effect did not persist in the multivariable model.

A historical electrophysiological study indicated that patients with aortic valve disease have a high incidence of

Table 4. Univariable and multivariable analysis for new PPI.

	Univariable model		Multivariable model	
	OR (95% CI)	<i>p</i> -value	OR (95% CI)	<i>p</i> -value
Age, years	1.03 (0.98-1.09)	0.31		
Female sex	0.72 (0.32-1.59)	0.43		
Body mass index, kg/m ²	1.04 (0.96-1.13)	0.33		
New York Heart Association Functional Class III/IV vs I/II	0.85 (0.38-2.01)	0.71		
EuroSCORE II, %	0.95 (0.85-1.02)	0.25		
Left ventricular ejection fraction <50% vs \geq 50%	1.63 (0.75-3.61)	0.22		
Diabetes mellitus	1.31 (0.43-3.58)	0.61		
Atrial fibrillation	0.96 (0.43-2.10)	0.92		
Prior right bundle branch block	11.3 (2.44-79.7)	0.004*	13.6 (2.69-102)	0.001*
Prior left bundle branch block	0.91 (0.28-2.54)	0.87		
AV block I°	2.56 (1.11-5.84)	0.026*	3.60 (1.45-9.13)	0.006*
Annular perimeter, mm	1.01 (0.96-1.07)	0.65		
Annular area, mm ²	1.00 (1.00-1.01)	0.80		
Cover index	1.02 (0.93-1.10)	0.71		
Left ventricular outflow tract oversizing, %	1.01 (0.97-1.05)	0.62		
Annular oversizing, %	1.00 (0.93-1.06)	0.95		
Minimum annular perimeter/valve size	0.01 (0.00-2.94)	0.12		
Sinus of Valsalva diameter/BSA, mm/m ²	1.14 (0.99-1.31)	0.074*	1.07 (0.86-1.34)	0.53
Sinotubular junction diameter/BSA, mm/m ²	1.10 (0.99-1.21)	0.065*	1.07 (0.92-1.24)	0.37
Sinotubular junction height/BSA, mm/m ²	1.08 (0.97-1.21)	0.17		
Maximum ascending aorta diameter/BSA, mm/m ²	1.05 (0.97-1.14)	0.21		
Membranous septum length, mm	1.02 (0.77-1.32)	0.90		
Morphology of the left ventricular outflow tract				
Tubular	—			
Tapered	1.65 (0.49-7.57)	0.46		
Flared	2.40 (0.60-12.2)	0.24		
Aortic root angle	1.02 (0.98-1.06)	0.38		
Left ventricular outflow tract calcification	0.62 (0.03-4.02)	0.67		
Annular calcification: no vs mild	1.16 (0.30-3.69)	0.81		
Implantation date: ≤2022 vs 2023/2024	1.14 (0.52-2.48)	0.74		
Valve size				
23 mm	—			
25 mm	1.30 (0.32-5.72)	0.72		
27 mm	1.73 (0.58-6.41)	0.36		
Non-coronary cusp ID, mm (N=101)	0.98 (0.68-1.42)	0.93		
Left coronary cusp ID, mm (N=101)	0.86 (0.54-1.34)	0.51		
Deepest ID, mm (N=101)	0.93 (0.63-1.34)	0.70		

*Indicates statistical significance. AV: atrioventricular; BSA: body surface area; CI: confidence interval; EuroSCORE: European System for Cardiac Operative Risk Evaluation; ID: implantation depth; OR: odds ratio; PPI: permanent pacemaker implantation

atrioventricular and intraventricular conduction disorders, which may occur without a clear pattern on the surface electrocardiogram in some cases²⁸. Therefore, one could hypothesise that in AR patients with a large aortic root, sinotubular junction, and ascending aorta, the increase in wall stress with more pronounced dilatation might render the conduction system increasingly vulnerable to mechanical stress during valve implantation.

PPI was associated with a longer in-hospital stay, and the high right ventricular pacing burden suggests that earlier PPI may be warranted in clinical practice. During follow-up, most patients exhibited high percentages of right ventricular pacing rates, indicating a potential and ongoing requirement for PPI. However, due to limited data on pacing modes, we could not precisely define pacemaker dependency. Furthermore, higher rates of right ventricular pacing might be associated with poorer long-term outcomes¹⁴.

Recently, Chang et al introduced a novel system utilising a temporary-permanent pacemaker as a 1-month bridge therapy to differentiate between reversible and persistent conduction disturbances. In their study of 688 patients with severe AS, 70 patients received a temporary-permanent pacemaker, and at 1 month, 17 required a PPI. This resulted in a PPI rate of 2.5% in this cohort²⁹.

In light of these developments, future investigations are needed to further understand the requirement for PPI in this vulnerable group of patients and to better identify those who may persistently need PPI.

Limitations

The findings of our study must be interpreted considering several limitations inherent to its retrospective design and the relatively small sample size compared to contemporary studies involving patients with AS. This limited cohort may result in statistical underpowering, thereby affecting the generalisability of our results. Additionally, the outcomes reported are specific to a single device type, which limits the applicability of our findings to other THV systems. The decision regarding PPI was at the physician's discretion, in accordance with European guidelines, thereby introducing the potential for unmeasured confounding factors that may have influenced the PPI rates³⁰. Moreover, the lack of a standardised assessment protocol for implantation depth could have resulted in inaccuracies in the estimation of procedural parameters. The evaluation of PPI rates was limited to in-hospital outcomes, raising concerns that rates at follow-up, such as at 30 days or 1 year, may be underestimated. Finally, the JVTS is currently not indicated for use in patients with bicuspid valves, which further restricts the broader applicability of our findings.

Conclusions

In this multicentre study, 24.1% of patients without prior PPI who underwent TAVI with the JVTS required new PPI. Baseline RBBB and first-degree AV block were independent predictors of PPI requirement, and no modifiable risk factors for PPI were identified in this analysis. Our findings highlight a higher incidence of conduction disturbances and new PPI in AR patients compared to those with AS, underscoring the importance of further research on the optimal timing of AR interventions, PPI outcomes, and tailored management strategies.

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Conflict of interest statement

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