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# Conduction disturbances and permanent cardiac pacing after transcatheter implantation of the CoreValve aortic bioprosthesis: initial single centre experience

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### Abstract

**Background:** The rate of significant conduction disturbances requiring permanent pacemaker implantation (PPI) following surgical aortic valve replacement (AVR) is 2–8%. Transcatheter aortic valve implantation (TAVI) is an alternative management approach in patients with severe aortic stenosis who are not considered candidates for AVR. The TAVI using the CoreValve (CV) bioprosthesis is associated with a nearly 30% rate of conduction disturbances requiring postprocedural PPI.

**Aim:** To provide an initial evaluation of the rate of conduction disturbances and the need for PPI, and to analyse factors that increase the risk of this complication in patients undergoing TAVI using CV bioprosthesis. In addition, we evaluated the rate of permanent conduction disturbances in patients who underwent PPI at one year after TAVI.

**Methods:** We studies 22 initial patients in a single centre who underwent CV bioprosthesis implantation in 2009–2010. After exclusion of 6 patients with preprocedural PPI, we ultimately evaluated 16 patients. Uni- and multivariate analyses were performed using  $\chi^2$ , Fisher, and Wilcoxon tests, and logistic regression analysis was performed using the SAS software.

Results: Overall, 8 (50%) patients in our study group required PPI after TAVI (TAVI + PPI), and the remaining 8 patients did not require PPI (TAVI). The most common indication for PPI was complete heart block. The decision to implant a pacemaker was made on average at 9 ± 7 days following TAVI (range 3 to 22 days). When we analysed risk factors for PPI that were unrelated to the TAVI procedure, we found that the TAVI + PPI group was characterised (vs the TAVI group) by a significantly larger diameter of the native a ortic valve (p = 0.03) and a larger left ventricular outflow tract (LVOT) dimension in the frontal (p = 0.02) and the corresponding frontal dimension in the transverse view (p = 0.01) by computed tomography angiography. Logistic regression analysis showed that the risk of PPI increased more than 2.5 times for each increase in the aortic annulus diameter by 1 mm (OR 2.64; 95% CI 0.90–7.74). None of the risk factors related to TAVI resulted in a significant increase in the rate of PPI. Among the patients who underwent PPI, we only noted a trend for a larger valvulotomy balloon diameter (p = 0.08), shorter procedure duration (p = 0.06), and deeper CV insertion within LVOT (p = 0.09). In addition, the bioprosthesis was inserted deeper in those patients who developed new LBBB after TAVI (p = 0.06). The ECG analysis at one day after the procedure showed a significant prolongation of PR, QRS, QT, and QTc intervals, and increased left axis deviation in the TAVI + + PPI group. In addition, the TAVI + PPI group showed increased QRS duration (p = 0.03) and increased left axis deviation (p = 0.049) compared to the TAVI group. Each increase in QRS duration by 10 ms was associated with 2.5-fold increase in the risk of PPI (OR 1.10; 95% CI 0.97–1.22), and each increase in PR interval duration by 10 ms with a 23% increase in risk (OR 1.02; 95% CI 0.99–1.05). New LBBB following CV implantation was noted significantly more frequently in the TAVI + PPI group vs the TAVI group (p < 0.0003). Pacemaker interrogation at one year after TAVI showed that the mean percentage of ventricular pacing in all patients with a pacemaker (DDD and VVI) pacing was 41%, and it was less than 10% in 2 patients.

**Conclusions:** 1. Transcatheter implantation of a CV bioprosthesis is associated with an increased risk of persistent conduction disturbances and subsequent PPI. 2. New LBBB after TAVI may predict the need for PPI. 3. Careful ECG monitoring is necessary for one week after CV bioprosthesis implantation due to a risk of atrioventricular conduction disturbances and the need for PPI. 4. Patients at an increased risk of postprocedural PPI may be those with deep bioprosthesis insertion in LVOT, larger LVOT diameter, and larger aortic annulus diameter in the frontal view. These observations require confirmation in a larger group of patients.

Key words: aortic stenosis, TAVI, CoreValve bioprosthesis, conduction disturbances, permanent cardiac pacing

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# **INTRODUCTION**

Degenerative aortic stenosis (AS) with calcifications is well known to be associated with cardiac conduction disturbances. Specifically, electrophysiological studies revealed that patients with severe AS are prone to prolongation of atrioventricular (AV) nodal conduction and nodoventricular conduction [1]. The rate of cardiac conduction disturbances in patients after conventional aortic valve replacement (AVR) is estimated at nearly 33%, and the rate of intermittent complete heart block may be up to 17% [1–3]. Permanent pacemaker implantation (PPI) following AVR is necessary in 3 to 8% of cases [1-4]. Cardiac conduction disturbances are associated with an increased risk of adverse cardiovascular events in the postoperative period [3]. Occurrence of AV conduction disturbances after AVR may be readily explained by anatomical proximity of the cardiac conduction system and aortic valve structures. The proposed aetiology includes calcifications, mechanical damage, and ischemia of the cardiac conduction system during the surgery [4, 5]. Established risk factors for PPI in patients undergoing AVR include female gender, impaired left ventricular systolic function, arterial and pulmonary hypertension, bileaflet aortic valve, concomitant aortic regurgitation, and bundle branch blocks [1, 2, 4, 5]. Koplan et al. [5] showed that right bundle branch block (RBBB) was the strongest predictor of pacemaker dependency after AVR [1, 6].

Transcatheter aortic valve implantation (TAVI) is an alternative management approach in patients with severe AS in whom conventional AVR cannot be performed or is associated with an unacceptably high risk of perioperative mortality. By avoiding sternotomy and cardiopulmonary bypass, this new approach has reduced the perioperative complication rate, including mortality, in the elderly patients compared to conventional AVR [6-8]. Results of studies to evaluate effectiveness and safety of this new treatment are encouraging (PARTNER, SOURCE) [9, 10]. It is of concern, however, that these procedures are associated with a high incidence of conduction disturbances requiring PPI in the postprocedural period, particularly with the use of CoreValve (CV) bioprosthesis [1-4, 6, 11-14]. In contrast to AVR, calcifications associated with the aortic valve are not removed during TAVI, and thus is has been speculated that a heavily calcified native valve compressed by the expanded bioprosthesis damages the conduction system in the area of the membranous part of the ventricular septum [6, 13]. In addition, a longer CV bioprosthesis stent, which is inserted relatively deeply into the left ventricular outflow tract (LVOT), is probably responsible for a greater rate of postprocedural PPI compared to Edwards-Sapien and Sapien XT (ES) valves (20-30% vs 5-6%) [2, 3, 6, 12, 13].

The aim of the study was to provide an initial evaluation of the rate of conduction disturbances and the need for PPI, and to analyse factors that increase the risk of this complication in patients undergoing TAVI using CV bioprosthesis. In addition, we evaluated the rate of permanent conduction disturbances in patients who underwent PPI at one year after TAVI.

#### **METHODS**

We studied 22 initial patients who underwent CV bioprosthesis implantation in the Institute of Cardiology in Warsaw between January 2009 and December 2010. Six patients, in whom PPI was performed before TAVI, were excluded from this analysis, and thus we ultimately evaluated 16 patients, including 8 (50%) who required PPI after TAVI.

In all patients, electrocardiography (ECG) was performed within 24 h before TAVI. The procedure was performed under general anaesthesia or sedation under ECG control. Bioprosthesis implantation was always preceded by aortic valvuloplasty performed during rapid right ventricular pacing (160--200 bpm). Mean balloon size was adjusted to the aortic annulus diameter. A CV bioprosthesis was implanted during the baseline cardiac rhythm of the patient. A transvenous pacing lead was temporarily left in the right ventricular cavity for 48 h after the procedure to protect from possible cardiac conduction disturbances. Postprocedural ECG was performed directly upon return of the patient to the cardiac care unit and subsequently daily. The ECG parameters were measured electronically. Indications for PPI included complete heart block, persistent advanced AV blok, temporary bifascicular block with bradycardia, alternating bundle branch block with bradycardia, and symptomatic bradycardia.

The diameter of the native aortic valve annulus was estimated by transoesophageal echocardiography, depth of bioprosthesis insertion into LVOT was measured in angiographic images immediately after bioprosthesis implantation. In all cases, distances between the floor of the right and left coronary sinuses and the proximal margin of the bioprosthesis were measured and averaged.

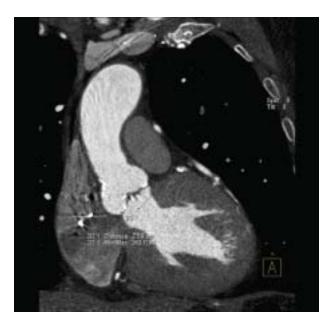
The LVOT diameter was evaluated using 64-row multidetector computed tomography images acquired routinely during patient selection for the procedure. In all cased, LVOT diameter was measured 6 mm below the aortic annular plane in frontal, sagittal and transverse views (Figs. 1, 2).

Coronary angiography was performed routinely during patient selection for the procedure, within 6 months before TAVI. If coronary angioplasty and stenting were necessary, these procedures had to be performed within 4 weeks before TAVI.

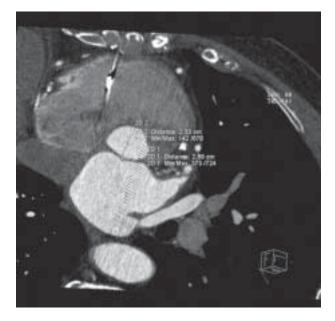
Uni- and multivariate analyses were performed using  $\chi^2$ , Fisher, and Wilcoxon tests, and logistic regression analysis was performed using the SAS software.

#### RESULTS

Eight (50%) patients in the analysed population required PPI after TAVI. Overall, mortality among the 22 patients was 13.63% (3 patients): one patient died due to a haemorrhagic complication on the first day after the procedure, another patient died after many days of hospitalisation due to decompensated he-



**Figure 1.** Computed tomography angiography, left ventricular outflow tract diameter measured 6 mm below the aortic annulus plane in the frontal view



**Figure 2.** Computed tomography angiography, left ventricular outflow tract diameter measured 6 mm below the aortic annulus plane in the transverse view (frontal and sagittal dimensions)

art failure, and the third patient, who required valve in valve implantation, died two months after hospital discharge, and the cause of death has not been clearly established.

Sinus rhythm was present before the procedure in 81.25% of patient, and permanent atrial fibrillation (AF) was found in the remaining patients. Table 1 shows characteristics of the study group.

 Table 1. Characteristics of 22 patients who underwent CoreValve bioprosthesis implantation

Bioprostheses: CV 29 mm/CV 26 mm	14 (63.63%)/8 (36.36%)
Implantation route: TF/Tsc.	19 (86.36%/3 (13.63%)
EuroSCORE [%]	$26.33\pm14.48$
Age [years]:	$80.27\pm7.19$
≥ 75	20 (90.9%)
Body mass index [kg/m <sup>2</sup> ]	$26.37\pm4.09$
Female gender	13 (59.09%)
Left ventricular dysfunction:	
$EF \leq 50\%$	11 (50%)
EF ≤ 35%	5 (22.72%)
NYHA class before the procedure:	
II	1 (4.54%)
III	16 (72.72%)
IV	5 (22.72%)
Chronic obstructive pulmonary disease	8 (36.36%)
Porcelain aorta	1 (4.55%)
Advanced osteoporosis	3 (13.64%)
Renal failure (creatinine level $\geq$ 200 mm GFR < 60 mL/min/1.73 m <sup>2</sup> )	ol/L; 15 (68.18%)
Coronary artery disease	19 (86.36%)
Previous CABG	4 (18.18%)
Previous PTCA	7 (31.82%)
Previous myocardial infarction	5 (22.73%)
Arterial hypertension	18 (81.82%)
Pulmonary hypertension	12 (54.55%)
Diabetes type 2	11 (50%)
History of stroke/TIA	5 (22.73%)
History of anaemia	12 (54.55%)
Duration of hospital stay [days]	18.95 ± 13.77

EF — ejection fraction; TF — transfemoral; Tsc. — transsubclavian; CABG — coronary artery bypass grafting; PTCA — percutaneous transluminal coronary angioplasty; TIA — transient ischaemic attack

### Risk factors for permanent pacing

Risk factors for permanent pacing that were unrelated to the procedure are shown in Table 2. Patient who underwent CV bioprosthesis implantation followed by PPI (TAVI + PPI gro-up) were older than patients who did not require PPI (TAVI group) but this difference in age was not significant. Mean estimated surgical risk was insignificantly higher in the TAVI + PPI group. Of the analysed anatomical parameters, LVOT diameter in the TAVI + PPI group was significantly greater in two of the four evaluated computed tomography angiography views: frontal (LVOT1; p = 0.02) and the corresponding frontal dimension in transverse view (LVOT3; p = 0.01). The diameter of the native aortic annulus measured in the frontal view was also higher in the TAVI + PPI group (p = 0.03). In multivariate analysis, the risk of PPI increased more than

Risk factor	TAVI	TAVI + PPI	Р
Age [years]	77.12 ± 9.99	80.25 ± 3.53	0.6
EuroSCORE [%]	$15.79\pm6.58$	$24.33 \pm 9.78$	0.07
LVOT1 [mm]	$26.50\pm2.20$	$29.12 \pm 1.24$	0.02
LVOT2 [mm]	$20.00\pm2.07$	$20.87 \pm 1.55$	0.46
LVOT3 [mm]	$25.87\pm2.79$	$30.5 \pm 1.85$	0.01
LVOT4 [mm]	$22.37\pm4.40$	$22.0 \pm 1.51$	0.95
Aortic annulus [mm]	$22.75 \pm 1.16$	$24.37 \pm 1.59$	0.03
Coronary artery disease	6/8 (75%)	8/8 (100%)]	0.07
Previous myocardial infarction	3/8 (37.5%)	1/8 (12.5%)	0.23
Diabetes type 2	4/8 (50%)	5/8 (62.5%)	0.51
Heart failure	4/8 (50%)	4/8 (50%)	1.0
Pulmonary hypertension	4/8 (50%)	6/8 (75%)	0.29

 Table 2. Risk factors for permanent pacemaker implantation unrelated to TAVI

LVOT1 — left ventricular outflow tract width in the frontal view by computed tomography (CT) angiography; LVOT2 — LVOT width in the sagittal view by CT angiography; LVOT3 — LVOT width, frontal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal dimension in the transverse view by CT angiography; LVOT4 — LVOT width, sagittal view by CT angiography; LVOT4 — LVOT4 — LVOT4 → LVO

Table	<ol><li>Risk</li></ol>	factors	for permanent	pacemaker	<sup>.</sup> implantation	directly	related	to	TAVI
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Risk factor	TAVI	TAVI + PPI	Р
Bioprosthesis diameter [mm]	27.5 ± 1.6	$28.62 \pm 1.06$	0.15
Balloon [mm]	$23.5\pm1.6$	$25.0\pm1.6$	0.08
Duration of the procedure:	$183.57 \pm 49.47$	$136.42 \pm 37.04$	0.06
$\Delta$ valve/annulus [mm]	$4.75\pm1.48$	$4.25\pm1.58$	0.56
$\Delta$ balloon/annulus [mm]	$0.75\pm1.48$	$0.62\pm2.26$	0.71
Mean CoreValve depth within LVOT [cm]	$5.39 \pm 2.69$	$9.70\pm4.74$	0.09
TF/Tsc.	6/8 (75%)	7/8 (87.5%)	1.0
Mean CoreValve depth within LVOT in patients with new LBBB [cm]	$5.38\pm2.38$	9.7 ± 4.73	0.06

LVOT — left ventricular outflow tract; TF — transfemoral route; Tsc. — transsubclavian route; LBBB — left bundle branch block

2.5 times for each increase in the aortic annulus diameter by 1 mm (OR 2.64; 95% CI 0.90–7.74).

Risk factors for PPI related to TAVI are shown in Table 3. In the TAVI + PPI group, a 29 mm bioprosthesis was implanted in 7 patients, and a 26 mm bioprosthesis in one patient. In the TAVI group, a 26 mm bioprosthesis was implanted in 4 patients, and a 29 mm bioprosthesis in 4 patients. The difference in bioprosthesis size had no significant effect on whether PPI was needed. None of the analysed potential risk factors related to the procedure significantly affected the need for PPI. Among the patients who underwent PPI, we only noted a trend for a larger value value balloon diameter (p = 0.08), shorter procedure duration (p = 0.06), and deeper CV insertion within LVOT (p = 0.09). In addition, when assessing the depth of bioprosthesis insertion within LVOT, we analysed whether it was related to the occurrence of left bundle branch block (LBBB) after the procedure. We found that the bioprosthesis was inserted deeper in those patients who developed

new LBBB after TAVI (p = 0.06). Differences in the analysed parameters were not significant, likely due to a low number of the studied subjects.

#### ECG analysis

The ECG parameters obtained in the two groups before and on the first day after the procedure are shown in Table 4. No significant differences in baseline parameters were seen between the groups.

Comparison of ECG parameters on the first day after the procedure showed significantly increased QRS duration (p = 0.03) and left axis deviation (p = 0.049) in the TAVI + PPI group compared to the TAVI group (Table 4). In the TAVI group, CV bioprosthesis implantation was associated with significant left axis deviation (p = 0.01; significantly more commonly in those patients who underwent PPI) and prolongation of corrected QT (QTc) interval (p = 0.01). In the TAVI + PPI group, all ECG parameters increased significantly on the first day after the proce-

	PQ [ms]	QRS [ms]	QT [ms]	QTc [ms]	Electrical axis [°]	HR [bpm]		
ECG parame	ters in TAVI and TA	VI + PPI groups o	n the day before TA	.VI				
TAVI	$178.85\pm38.46$	$107.5\pm20.21$	$424.25\pm39.76$	$435.62 \pm 13.89$	$13.25\pm34.96$	$68.12\pm21.41$		
TAVI + PPI	$180.85\pm33.68$	$112.0\pm33.96$	$431.75\pm33.42$	$427.75 \pm 54.74$	$4.42\pm39.26$	$64.28\pm8.03$		
Р	0.53	0.95	0.53	0.41	0.77	0.86		
ECG parame	ECG parameters in TAVI and TAVI + PPI groups on the first day after TAVI							
TAVI	$173.57 \pm 37.91$	$122.0\pm29.81$	$439.12\pm50.40$	$492.25\pm61.06$	$-4.75\pm32.48$	$78.87 \pm 13.97$		
TAVI + PPI	$210.5\pm39.56$	$158.0 \pm 11.22$	$463.37 \pm 44.89$	$496.87\pm37.47$	$-35.75 \pm 24.17$	$70.62\pm11.46$		
Р	0.11	0.03	0.38	1.0	0.049	0.5		

Table 4. ECG parameters in TAVI and TAVI + PPI groups before and on the first day after TAVI

PPI — permanent pacemaker implantation; TAVI — transcatheter aortic valve implantation; HR — heart rate

Table 5. Complete heart block after	r TAVI and left bundle branch block before an	d after TAVI in TAVI and TAVI + PPI groups
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Group	Complete heart block after TAVI	LBBB before TAVI	LBBB after TAVI	u	Р
TAVI	1/8 (12.5%)	0/8 (0%)	3/8 (37.5%)	2.64	0.008
TAVI + PPI	5/8 (62.5%)	1/8 (12.5%)	8/8 (100%)	4.84	< 0.0001
u	2.20	1.45	3.65		
Р	< 0.03	0.15	< 0.0003		

PPI — permanent pacemaker implantation; TAVI — transcatheter aortic valve implantation; LBBB — left bundle branch block

dure, including PQ (p = 0.01), QRS (p = 0.01), QT (p = 0.04), and QTc (p = 0.01) intervals, and left axis deviation (p = 0.04). We found that each increase in QRS duration by 10 ms was associated with 2.5-fold increase in the risk of PPI (OR 1.10; 95% CI 0.97–1.22), and each increase in PR interval duration by 10 ms with a 23% increase in the risk of PPI (OR 1.02; 95% CI 0.99–1.05) in the study group.

Before the procedure, no difference in the prevalence of LBBB was noted between the groups. Bundle branch blocks related to the procedure developed within minutes to hours after bioprosthesis implantation. New LBBB after CV bioprosthesis implantation was significantly more common in those patients who subsequently required PPI (it occurred in all patients in this group;  $p \le 0.0001$ ) (Table 5). The most common indication for PPI was complete heart block which developed in 5 patients within several hours to 3 days after the procedure. In addition, in one patient with complete heart block on the third day after the procedure, successfully resuscitated cardiac arrest occurred previously during CV bioprosthesis implantation. Among patients in the TAVI group, one case of advanced AV block with intermittent complete heart block was diagnosed. For this reason, temporary pacing was used for the first two days after the procedure but the block turned out to be short-term and self-limiting. In the TAVI + + PPI group, advanced AV block was an indication for PPI in two patients. Symptomatic bradycardia was an indication for PPI in one patient in whom the procedure was associated with a first-in-life AF episode with alternating bundle branch blocks and symptomatic bradycardia.

### Follow-up pacemaker interrogation

Eight permanent pacemakers were implanted, including 7 AV pacemakers and one ventricular pacemaker. The decision to implant a pacemaker was made on average at  $9 \pm 7$  days following TAVI (range 3 to 22 days). Pacemaker interrogation at one year after TAVI showed that the mean percentage of ventricular pacing in all patients with a pacemaker (DDD and VVI) pacing was 41%, and it was less than 10% in 2 patients. In the only patient with a ventricular pacemaker, percentage of ventricular pacing at the basic rate of 70 bpm was 85%. In 5 patients with AV pacemakers, Auto Mode Switch episodes (automatic switch from DDD to DDI pacing with the occurrence of supraventricular arrhythmia) were detected, most likely due to AF episodes, although this arrhythmia was not seen before bioprosthesis implantation in any of the patients. The analysed parameters are summarised in Table 6.

## DISCUSSION

Anatomical proximity of the aortic valve complex to the AV node, His bundle and its branches may explain the observed increase in conduction disturbances after TAVI [12, 13]. The depth of insertion of the proximal end of CV bioprosthesis stent seems to be the major aetiologic factor of new LBBB following the procedure, and the occurrence of the latter within several hours after bioprosthesis implantation precedes the need for PPI [11–13]. A high incidence of new LBBB suggests that previously diagnosed RBBB should be considered a risk factor for complete heart block and such patients require careful monitoring [12, 13].

Table 6.	Follow-up	pacemaker	interrogation	parameters
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Parameter	Results	
Basic rate [bpm]	$65.0 \pm 5.5$	
SAVD [ms]	204.2 ± 31.4	
PAVD [ms]	221.7 ± 35.6	
Search AV [ms]	$66.7 \pm 30.8$	
A pacing [%]	58 ± 22	
V pacing [%]	41 ± 39	
AVD native [ms]	$229.8 \pm 61.7$	

SAVD — programmed atrioventricular (AV) delay for sensed atrial impulses; PAVD — programmed AV delay for paced atrial impulses; Search AV — programmed AV delay prolongation to promote native impulse conduction; A pacing — percentage of atrial pacing; V pacing — percentage of ventricular pacing; AVD native — native AV conduction delay (maximum delay between sensed atrial impulse and sensed ventricular impulse)

Koplan et al. [5] analysed baseline ECG parameters in patients undergoing AVR and found that LBBB, RBBB, and first degree AV block are independent risk factors for postprocedural need for PPI, and RBBB diagnosed before AVR was the strongest predictor of PPI. This is related to more frequent damage of the left bundle branch during AVR or mitral valve replacement, which results in complete heart block when combined with preexisting RBBB. Similar conclusions were drawn by Piazza et al. [1] who analysed complications related to TAVI.

Khawaja et al. [13] analysed 243 patients from 10 centres in the United Kingdom and identified the following risk factors of conduction disturbances requiring PPI after TAVI: AV block, LBBB, RBBB, and preprocedural QRS widening. Predictors of postprocedural high-degree AV block included preprocedural PR interval prolongation, QRS widening, and the degree of left axis deviation.

Observed conduction disturbances may partially result from inflammation and repair processes within ventricular septal myocardium adjacent to the bioprosthesis stent [3, 11]. This is confirmed by regression of prolonged PR and QRS intervals seen in subsequent days after TAVI [2]. Compared to the literature data, we observed a high rate of early postprocedural PPI (50%). This discrepancy is likely related to a small number of patients in our study and required further studies. Our findings do not confirm previous suggestions [1-6, 11-13] that preprocedural RBBB is a risk factor for PPI following CV bioprosthesis implantation. We were also unable to identify other arrhythmias and conduction disturbances occurring before TAVI that would be associated with a subsequent need for permanent pacing. We found, however, that CV bioprosthesis implantation induces changes in the cardiac conduction system already in the first postprocedural day, as indicated by a significant increase in the rate of new LBBB after the procedure in both study groups.

The American National Heart, Lung, and Blood Institute Balloon Valvuloplasty Registry of 1991 and a 2002 study reported the need for PPI in 4% and 3.5% patients undergoing aortic valve valvulotomy, respectively. Mechanical and ischaemic damage related to prior valvulotomy, the use of a larger bioprosthesis (29 mm), and a mismatch between bioprosthesis size and aortic annulus diameter are established risk factors for PPI [12, 13]. Similarly, our findings show a trend for worse outcomes regarding postprocedural PPI with the use of larger predilatation balloons and larger bioprostheses, and deeper bioprosthesis insertion within LVOT. When we assessed changes in ECG parameters in the 16 patients included in the present analysis, significant QRS widening was noted on the first postprocedural day in all patients, while the TAVI + PPI group was characterised by a significant increase in all analysed ECG parameters. Khawaja et al. [13] highlighted the importance of QRS width as a predictor of PPI and suggested that lack of postprocedural QRS widening and/or new bundle branch block eliminates the need for prolonged ECG monitoring [14].

In a multivariate analysis, Khawaja et al. [13] found that QRS width after TAVI showed the strongest positive correlation with preprocedural QRS widening and the depth of bioprosthesis insertion within LVOT. They also showed that interventricular septal thickness correlated positively with the need for PPI, and aortic annulus diameter correlated positively with the occurrence of a high-degree AV block. Thus, LVOT and native aortic annulus anatomy and width may also be associated with postprocedural PPI. When we analysed these parameters, the 8 patients in the TAVI + PPI group were characterised by a significantly wider LVOT in the frontal view and corresponding transverse view in computed tomography angiography, and a significantly larger native aortic annulus diameter in these views. Native aortic valve and LVOT dilatation may be considered an indicator of an advanced disease of the aortic valve complex, and cardiac conduction system damage may be directly induced by forcible rapid dilation of the predilatation balloon and the bioprosthesis within a larger aortic valve orifice [2].

Both LVOT and aortic annulus are ellipsoid-shaped structures in a cross-sectional view. Significantly larger LVOT dimensions in the frontal plane in patients in the TAVI + PPI group may indicate an effect of LVOT asymmetry, i.e. increased bioprosthesis compression of the cardiac conduction system within the interventricular septum along the sagittal dimension, leading to significant postprocedural AV conduction disturbances [13]. However, reliable interpretation of these findings is precluded by a small number of patients in our study.

Overall, PPI following AVR is necessary in 6–6.5% of the elderly patients [1, 2]. Patients undergoing TAVI are usually elderly subjects with multiple comorbidities. Recent studies show that patient age correlates significantly with QRS widening and the occurrence of high-degree AV blocks [13]. In our analysis, the mean age of patients in the TAVI + + PPI group was increased compared to the TAVI group but this difference did not reach statistical significance. It has been found, however, that the risk of PPI after TAVI increases by 6.6% with each year of life.

Piazza et al. [1] showed that the depth of bioprosthesis insertion within LVOT is an aetiologic factor contributing to conduction disturbances following TAVI [1–6, 11, 12] and suggested that insertion of the proximal end of CV bioprosthesis by < 6.7 mm within LVOT does not result in an increased risk of PPI. In our study, we only observed a trend for an increased need for PPI and increased incidence of new LBBB with deeper bioprosthesis insertion.

An unexpected observation is an inverse association between the duration of implantation procedure and the risk of PPI: every increase in TAVI procedure duration by one minute reduced the need for PPI by 2.7%. Evaluation whether it has been a chance finding will be possible upon examining a larger group of patients. Regarding appropriateness of the decision to implant a pacemaker and indications for pacing, follow-up pacemaker interrogation showed that the percentage of ventricular pacing was less than 10% in 2 patients which, as suggested by Jilaihawi et al. [11] may indicate an improvement of native AV conduction or a premature decision to implant a pacemaker in these patients. In such situations it is, however, difficult to exclude that appropriate ventricular pacing actually occurs whenever an advanced AV block develops. Atrioventricular delay for sensed atrial impulses and paced atrial impulses and algorithms promoting native AV conduction have been programmed so as to reduce the percentage of ventricular pacing. Thus, the reported percentage of ventricular pacing seems approximate to the values that are both necessary and safe for the patients. In addition, the programmed basic rate (60-70 bpm in our patients) may also affect pacemaker parameters read upon follow-up pacemaker interrogation.

### Limitations of the study

One limitation of our study was a small number of the analysed patients. In addition, this was a single-centre experience, with all procedures performed by the same team. Thus, our findings should be considered preliminary and require confirmation in a larger sample.

#### CONCLUSIONS

- 1. Transcatheter implantation of a CV bioprosthesis is associated with an increased risk of persistent conduction disturbances and subsequent PPI.
- 2. New LBBB after transcatheter CV bioprosthesis implantation may predict the need for PPI.
- 3. Careful ECG monitoring is necessary for one week after CV bioprosthesis implantation due to a risk of AV conduction disturbances and the need for PPI.

4. Patients at an increased risk of postprocedural PPI may be those with deep bioprosthesis insertion in LVOT, larger LVOT diameter, and larger aortic annulus diameter in the frontal view. These observations require confirmation in a larger group of patients.

#### Conflict of interest: none declared

#### References

- 1. Piazza N, Onuma Y, Jesserun E et al. Early and persistent intraventricular conduction abnormalities and requirements for pacemaking after percutaneous replacement of the aortic valve. J Am Coll Cardiol Intv, 2008; 1: 310–316.
- Haworth P, Behan M, Khawaja M et al. Predictors for permanent pacing after transcatheter aortic valve implantation. Catheter Cardiovasc Interv, 2010; 76: 751–756.
- Baan J, Yong ZY, Koch KT et al. Factors associated with cardiac conduction disorders and permanent pacemaker implantation after percutaneous aortic valve implantation with the CoreValve prosthesis. Am Heart J, 2010; 159: 497–503.
- Sinhal A, Altwegg L, Pasupati S et al. Atrioventricular block after transcatheter balloon expandable aortic valve implantation. J Am Coll Cardiol Cardiovasc Intervent, 2008; 1: 305–309.
- Koplan BA, Stevenson WG, Epstein LM, Aranki SF, Maisel WH. Development and validation of a simple risk score to predict the need for permanent pacing after cardiac valve surgery. J Am Coll Cardiol, 2003; 41: 795–801.
- Bleiziffer S, Ruge H, Hörer J et al. Predictors for new-onset complete heart block after transcatheter aortic valve implantation. J Am Coll Cardiol Cardiovasc Intervent, 2010; 3: 524–530.
- Vassiliades TA, Block PC, Cohn LH et al. The clinical development of percutaneous heart valve technology: a position statement of the society of thoracic surgeons (STS), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography and Interventions (SCAI) Endorsed by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA). J Am Coll Cardiol, 2005; 45: 1554–1560.
- Vahanian A, Alfieri OR, Al-Attar N et al. Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur J Cardiothorac Surg, 2008; 34: 1–8.
- Leon MB, Smith CR, Mack M et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. NEJM, org. 2010; 10:1056/NEJMoa1008232.
- Thomas M, Schymik G, Walther T et al. Thirty-Day Results of the SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry: a European Registry of Transcatheter Aortic Valve Implantation Using the Edwards SAPIEN Valve. Circulation, 2010; 122: 62–69.
- Jilaihawi H, Chin D, Vasa-Nicotera M et al. Predictors for permanent pacemaker requirement after transcatheter aortic valve implantation with the CoreValve bioprosthesis. Am Heart J, 2009; 157: 860–866.
- Godin M, Eltchaninoff H, Furuta A et al. Frequency of conduction disturbances after transcatheter implantation of an Edwards Sapien aortic valve prosthesis. Am J Cardiol, 2010; 106: 707–712.
- Khawaja M, Rajani R, Cook A et al. Permanent pacemaker insertion after CoreValve transcatheter aortic valve implantation. Incidence and contributing factors (the UK CoreValve Collaborative). Circulation, 2011; 123: 951–960.
- Eltchaninoff H, Prat A, Gilard M et al. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry. Eur Heart J, 2011; 32: 191–197.

# Zaburzenia przewodzenia i stała stymulacja serca po przezcewnikowej implantacji bioprotezy aortalnej CoreValve: wstępne doświadczenia jednego ośrodka

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# Streszczenie

**Wstęp:** Odsetek poważnych zaburzeń rytmu i przewodzenia wymagających implantacji układu stymulującego (PPI) po kardiochirurgicznej wymianie zastawki aortalnej (AVR) sięga 2–8%. Przezcewnikowa implantacja zastawki aortalnej (TAVI) stanowi alternatywną metodę leczenia dla chorych z ciasną stenozą aortalną wyłączonych z AVR; TAVI z zastosowaniem bioprotezy CoreValve (CV) wiąże się z ok. 30-procentowym odsetkiem zaburzeń przewodzenia wymagających PPI w okresie pozabiegowym.

**Cel:** Celem pracy była wstępna ocena częstości występowania zaburzeń przewodzenia i konieczności PPI oraz analiza czynników zwiększających ryzyko takiego powikłania u chorych poddawanych przezcewnikowej implantacji CV w ujście aortalne. Ponadto oszacowano odsetek utrzymujących się zaburzeń przewodzenia u chorych z PPI podczas kontroli urządzenia do roku po TAVI.

**Metody:** Badaniem objęto 22 pierwszych chorych z jednego ośrodka poddanych implantacji CV w latach 2009–2010. Ostatecznej analizie poddano grupę 16 osób po wykluczeniu 6 pacjentów z PPI przed zabiegiem. Analizę statystyczną jednoi wieloczynnikową przeprowadzono przy użyciu testu  $\chi^2$ , Fishera, Wilcoxona i analizy logistycznej za pomocą systemu SAS.

Wyniki: W badanej grupie 8 (50%) chorych wymagało PPI po TAVI (TAVI + PPI) v. 8 badanych bez konieczności PPI (TAVI). Blok całkowity był najczęstszą przyczyną kwalifikacji do PPI. Decyzję o implantacji stymulatora podjęto średnio w dobie 9 ± 7 (3–22) po zabiegu. Analizując czynniki ryzyka PPI niezwiązane z zabiegiem, wykazano, że grupę TAVI + PPI v. TAVI charakteryzuje istotnie większa średnica pierścienia natywnej zastawki aortalnej (p = 0.03) i szerszy wymiar drogi odpływu lewej komory (LVOT) w projekcji czołowej (p = 0,02) oraz projekcji poprzecznej (p = 0,01), obliczany na podstawie badania angio-CT. Analiza logistyczna wykazała ponad 2,5-krotny wzrost ryzyka PPI przy zwiększeniu o 1 mm średnicy pierścienia aortalnego (OR 2,64; 95% CI 0,90–7,74). Żaden z czynników ryzyka związanych z TAVI nie wpływał istotnie na zwiększenie odsetka PPI. Natomiast zaobserwowano trend w kierunku większej średnicy balonu do walwulotomii (p = 0,08), krótszego czasu zabiegu (p = 0,06) i głębszego osadzenia CV w LVOT (p = 0,09) u chorych z PPI. Ponadto proteza była osadzona głębiej u osób, u których po TAVI rozwinął się nowy blok lewej odnogi pęczka Hisa (LBBB) (p = 0,06). Analiza EKG w 1. dobie po zabiegu wykazała, że w grupie TAVI + PPI wszystkie oceniane parametry istotnie się wydłużyły: PQ, QRS, QT, QTc i nasiliło się odchylenie osi elektrycznej serca w lewo. Ponadto grupa TAVI + PPI v. grupa TAVI charakteryzowała się istotnie poszerzonymi zespołami QRS (p = 0,03) i większym odchyleniem osi elektrycznej serca w lewo (p = 0,049). Wykazano, że wydłużenie się czasu trwania QRS o każde 10 ms wiązało się z 2,5-krotnym wzrostem ryzyka (OR 1,10; 95% Cl 0,97–1,22), a wydłużenie się czasu trwania PQ o każde 10 ms z 23-procentowym zwiększeniem ryzyka konieczności PPI (OR 1,02; 95% CI 0,99–1,05). Nowy LBBB po implantacji CV obserwowano znamiennie częściej w grupie TAVI + PPI v. TAVI (p < 0,0003). Podczas kontroli układu stymulującego do roku po TAVI odsetek stymulacji komorowej u wszystkich chorych z implantowanym układem stymulującym (DDD i VVI) był równy średnio 41%, a u 2 pacjentów wynosił on mniej niż 10%.

Wnioski: 1. Przezcewnikowa implantacja bioprotezy CV wiąże się ze zwiększonym ryzykiem pojawienia się trwałych zaburzeń przewodzenia i następowej PPI. 2. Nowy LBBB po TAVI może zapowiadać konieczność PPI. 3. Uważna obserwacja elektrokardiograficzna powinna być prowadzona w ciągu tygodnia po implantacji protezy CV ze względu na możliwość pojawienia się zaburzeń przewodzenia przedsionkowo-komorowego i konieczność PPI. 4. Wydaje się, że na konieczność PPI po zabiegu mogą być narażeni chorzy z głębokim osadzeniem protezy w LVOT, większym LVOT i szerszym pierścieniem aortalnym w wymiarze czołowym. Obserwacja ta wymaga potwierdzenia w większej grupie chorych.

Słowa kluczowe: stenoza aortalna, bioproteza CoreValve, zaburzenia przewodzenia, stała stymulacja serca

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