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Preventing chronic heart failure and improving survival after transcatheter aortic valve implantation in patients with the need for permanent pacemaker implantation: Rationale and design of the physiologic cardiac pacing to prevent left ventricular dysfunction post transcatheter aortic valve implantation (PACE-4-TAVI) trial

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Introduction

Aortic stenosis (AS) is the most common primary valvular heart disease requiring surgical intervention [1]. At the same time, the aging of the population causes the prevalence of atherosclerotic AS to increase rapidly [2]. Originally, transcatheter aortic valve implantation (TAVI) was used in patients with AS whose risk of death from surgical aortic valve replacement (SAVR) was unacceptably

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high [3], high [4], or intermediate [5]. Nowadays, the percentage of TAVI in treating AS is increasing due to the possibility of using it in patients with a low risk of SAVR [6]. The 2021 Guidelines of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery for treating valvular heart disease [7] leave the decision regarding the choice of method (SARV vs. TAVI) to the Heart Team, depending on the patient's clinical, anatomical, and procedural conditions. Considering the advancements in percutaneous implantation techniques and implanted prostheses, we can expect an increased frequency of TAVI procedures and improved safety.

Unfortunately, anatomical proximity of the aortic valve and the cardiac conduction system favors the development of post-surgical atrioventricular (AV)/intraventricular conduction disorders due to direct pressure, developing inflammation, and ischemia of the conduction system [8, 9]. Conduction disturbances occur more often when self-expanding prostheses are used. They tend to exert higher mechanical stress on the surrounding cardiac tissues than balloon-expandable prostheses, especially when the valve is placed too deep in the left ventricular (LV) outflow tract and too close to the left bundle branch. This feature becomes particularly important in patients with right bundle branch block (BBB) before the procedure and those who have previously had aortic valvuloplasty [8, 9]. Thus, a significant percentage of patients after TAVI require permanent pacemaker implantation (PPMI), even when using a new generation of bioprostheses (a risk of 14.7–26.7% for Medtronic Core Valve/Evolut R and 4–24% for Edwards SAPIEN 3 valve) [9, 10].

PPMI worsens the prognosis of patients following TAVI due to the development of pacing-induced cardiomyopathy (PICM) [11, 12]. Therefore, despite 20 years of technological development and continuous improvement of team skills, conduction disturbances and the resulting need for PPMI in some patients remain fundamental problems to be solved using TAVI.

Objective of the study

A multicenter randomized control trial (RCT) was planned to compare survival free from hospitalization due to heart failure (HF) and death from any cause in patients after TAVI and PPMI using conduction system pacing (CSP; study intervention) versus currently standard therapy, that is, right ventricular pacing (RVP) or biventricular pacing (BVP; control group).

Methods

Study population

The study group (Caucasian, both sexes, aged ≥ ≥ 18 years) will be recruited from patients hospitalized after TAVI complicated with high-degree persistent AV block or newly developed complex AV and intraventricular conduction disturbances, qualified for PPMI within 30 days after surgery, following the 2021 ESC guidelines on cardiac pacing and cardiac resynchronization therapy [13]. The intended group size is 500 patients. The inclusion and exclusion criteria are presented in Table 1.

Study organization

The planned duration of the study is 60 months, including patient recruitment, which is 36 months, and the follow-up (F/U) period, which is 24 months. The intervention model is a parallel assignment. Masking is single (participant). The organization of the study is shown in the flowchart (Fig. 1). The study was registered in ClinicalTrials.gov (identifier: NCT05966675).

Randomization

Stratified block randomization will be used. Stratification factors were defined as sex (male or female and LVEF (≥ 40% or < 40% due to different pacing modalities recommended in [13] depending on this parameter). After assignment into one of the subgroups, subjects will be randomized into two arms (CSP vs. RVP/BVP) at a 1:1 ratio using an automatic algorithm with an internally generated randomization list.

Implantation procedures

Once all the inclusion criteria and none of the exclusion criteria of the PACE-4-TAVI trial are met, patients who have given written informed consent to participate in the study will be randomly assigned to the experimental group or the control group to achieve a 1:1 group size ratio.

Required cardiac implantable electronic devices (CIED)-related procedures will include the following:

— in the experimental group: CSP using His bundle/left bundle pacing lead;
— in the control group:
  - RVP using conventional right ventricular lead in case of left ventricular ejection fraction (LVEF) ≥ 40% or
  - BVP using both conventional right ventricular lead and a left ventricular (LV) lead inserted into the coronary sinus if LVEF is determined to be less than 40%.

Table 1. Inclusion and exclusion criteria of the PACE-4-TAVI trial

Inclusion criteria
• TAVI in up to 30 days before qualification to PPMI
• Fulfilled criteria for permanent pacemaker implantation according to 2021 ESC guidelines:
a. Complete or high-degree AV block that persists for 24–48 hours after TAVI (class of recommendation IB)
b. New, variable bundle branch block after TAVI (class of recommendation IC)
c. Preexisting RBBB with progression of AV or intraventricular conduction disturbances after the procedure in the form of transient high-degree AV block or prolongation of the AV interval by > 20ms or a change in the axis of the QRS complex in the ECG (class of recommendation IIa B)
d. Persistent newly developed LBBB with QRS complex > 150ms or AV interval > 240 ms on ECG and HV interval confirmed by electrophysiological examination ≥ 70 ms (class of recommendation IIa C)
e. Preexisting conduction disturbances with periprocedural prolongation of QRS complex by > 20 ms or AV interval by > 20 ms in ECG and HV interval confirmed by electrophysiological examination ≥ 70 ms (class of recommendation IIb C)
• Written informed consent
• Age of at least 18 years
Exclusion criteria
• The occurrence of conduction disturbances more than 30 days after the TAVI procedure
• PPMI before the TAVI procedure
• Inability to obtain informed consent from the participant
• Predicted inability to obtain cooperation from the patient during the observation period

AV — atrioventricular; ECG — electrocardiogram; ESC — European Society of Cardiology; HV — His–ventricle; LBBB — left bundle branch block; PPMI — permanent pacemaker implantation; RBBB — right bundle branch block; TAVI — transcatheter aortic valve implantation

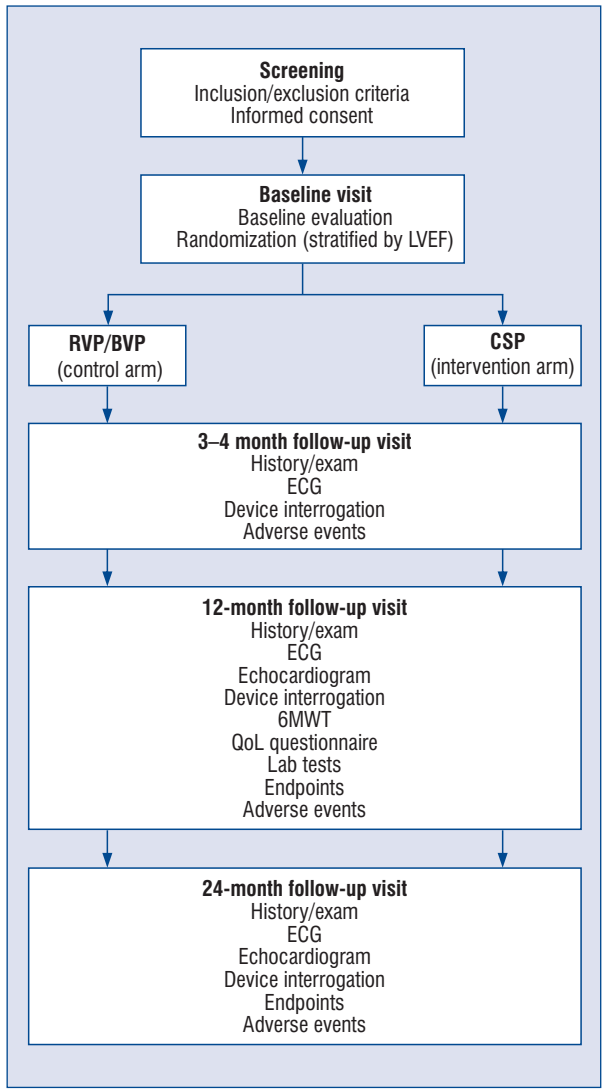

Figure 1. Flowchart of PACE-4-TAVI trial. 6MWT — 6-minute walk test; BVP — biventricular pacing; CSP — conduction system pacing; ECG — electrocardiogram; LVEF — left ventricular ejection fraction; QoL —quality of life; RVP — right ventricular pacing

In patients with LVEF ≤ 35%, cardiac resynchronization therapy (using BVP or CSP) with defibrillation function will be implemented.

Device programming

The pacing parameters will be programmed according to current guidelines and recommendations [13, 14] in the control group. These will include:

— minimizing the unnecessary ventricular pacing with algorithms promoting spontaneous AV conduction in the RVP control group,
— ensuring BVP capture > 90% with adequate AV delay and/or base rate programming.

In the CSP experimental group, fixed AV delays will be used, warranting CSP capture and complete correction of intraventricular conduction disturbances.

Clinical follow-up

Assessment will occur at 3–4-month to 12-month intervals, with endpoints at 12 and 24 months. The observation will include the following:

— clinical assessment with determination of the functional class according to the New York Heart Association (NYHA) and exercise capacity in the 6-minute walk test (6MWT);

— electrocardiography (ECG) with an assessment of heart rhythm, the effectiveness of stimulation, and morphology and width of paced QRS complexes;
— echocardiography, including measurement of LV end-systolic volume (LVESV), LV end-diastolic volume (LVEDV), LVEF using the summation-of-disks method from two longitudinal planes, global longitudinal strain (GLS), the peak jet velocity/the maximum and average pressure gradient through the aortic prosthesis, and the assessment of the presence/severity of aortic regurgitation/paravalvular leak;
— control of the CIED parameters, including measurement of pacing thresholds, endocardial potentials, and leads resistance; assessment of ventricular and atrial pacing burden; evaluation of the percentage of the atrial high-rate episodes (AHRE); assessment of ventricular arrhythmic events and the type and effectiveness of antiarrhythmic therapy;
— laboratory tests, including assessing the concentration of N-terminal pro-brain natriuretic peptide (NT-proBNP);
— quality of life (QoL) assessment using the Short Form 36 Health Survey Questionnaire;
— evaluation of adverse events, including infectious and non-infectious complications related to the PPMI procedure.

Clinical data, ECG, device interrogation, and biochemical tests will be stored in a central electronic database. The detailed echocardiographic report will be submitted to the Echocardiography Core Laboratory for central assessment (Upper-Silesian Medical Center of the Silesian Medical University, Katowice, Poland).

Outcome parameters

The composite primary outcome of the PACE-4-TAVI trial is time to hospitalization due to HF or death from any cause over the 12-month F/U period. Secondary outcomes are as follows:
— change in exercise capacity over 12 months F/U, defined as a change of ≥ 1 NYHA functional class or a change in 6MWT distance by 55 m or more;
— response to cardiac resynchronization therapy (CRT) over 12 months F/U, defined as a decrease in LVESV by ≥ 15% or an increase in LVEF by ≥ 5% from the baseline value;
— change in GLS over 12 months F/U, defined as an increase in GLS value of 20 absolute percentage points from baseline or an increase above (–) 16%;
— development of PICM over 12/24 months F/U, defined as pacing-related HF with a decrease in LVEF by ≥ 10% to an absolute value of below 50%;
— occurrence of the first episode of atrial fibrillation (AF) over 24 months F/U in a patient with no previous history of AF;
— occurrence or change of AHRE burden in CIED recordings over 24 months F/U;
— change in the concentration of the NT-proBNP over 12 months F/U;
— change in QoL over 12 months F/U.

An independent HF and Death committee will be blinded to the treatment group or clinical characteristics of the patients and will review HF and death events. An event will be classified as an HF event if the patient:
— had symptoms and signs consistent with congestive HF and
— received intravenous diuretic or positive inotropic therapy for longer than 24 h or
— received an augmented oral or intravenous HF therapy during an in-hospital stay due to worsening of HF.

An independent, blinded Arrhythmia Adjudication Committee will review atrial and ventricular arrhythmia episodes.

Safety plan/study termination

A Data Safety Monitoring Board (DSMB) will perform pre-specified scheduled interim safety analysis following the enrollment of 30% and 60% of the study population. The statistical design will permit early termination of the trial if CSP efficacy is meaningfully more significant than that hypothesized for RVP/BVP or RVP/BVP efficacy is meaningfully more significant than that hypothesized for CSP. During the interim safety analysis, the study will terminate if the DSMB identifies a noticeable harm with an implanted CSP over an RVP/BVP.

Banking biological material for molecular diagnostics

The project involves collecting and banking biological material for molecular diagnostics, which may allow the identification of biochemical predictive factors related to treatment response and the expansion of medical knowledge about the mechanisms of cardiac remodeling due to the use of various types of ventricular pacing.

Statistical analysis

Both primary and secondary endpoints will be analyzed for the entire cohort and compared between:

— the study intervention group (experimental) vs. the control group (active comparator) and
— in predetermined subgroups depending on the value of LVEF ≥ 40% vs. < 40%.

Data analysis will be performed on an intention-to-treat basis.

The planned statistical analysis includes the following:

— comparison of the time to the occurrence of the composite primary endpoint in the intervention group vs. the control group will use the Kaplan–Meier survival function estimator and the log-rank test (Subgroup analysis is also planned.);
— comparison of the mean/median value of secondary endpoint variables in the intervention group vs. the control group will use the paired Student t-test or the Wilcoxon matched-pairs signed-ranks test according to the distribution of the variables (Subgroup analysis is also planned);
— the odds ratio of occurrence of the secondary endpoints in the intervention group vs. the control group using logistic regression analysis (Subgroup analysis is also planned);
— determination of independent predictors of clinical outcome in terms of primary and secondary endpoints using multivariate Cox regression analysis.

In multivariate analysis, the following candidate variables will be used: input and output parameters related to both TAVI and PPMI procedures, such as functional NYHA class, distance in 6MWT, LVEF, GLS, NT-pro-BNP concentration, type of transcatheter implanted prosthetic valve (self-expanding vs. balloon-expandable), presence and type of intraventricular conduction disturbances after TAVI, width of the paced QRS after PPMI, baseline pacing parameters and baseline functional parameters of the implanted prosthesis. The sample size is estimated for the primary composite endpoint at 500 patients.

The survival rate in patients with PPMI will be calculated based on the results of two groups of studies. The first one concerns the development of PICM in the general population with a high RVP burden [15–17] and includes one study comparing the group with a high RVP burden with a group with a high CSP burden [18]. The second group consists of reports comparing survival free from hospitalization due to HF and death from any cause in patients after TAVI requiring or not requiring PPMI [11, 19–22].

The following assumptions will be made:

— null hypothesis: survival time free from the primary endpoint does not differ between the study group (CSP) and the reference group (RVP or BVP);
— type I error alpha (significance) is 0.05;
— type II error beta (1-power test) is 0.2;
— the predicted primary endpoint-free survival rate for the RVP group is 0.7284;
— as a result of using an alternative stimulation site, i.e., CSP, the survival rate will increase by 15% to 0.8367;
— randomized assignment to study groups will be 1:1.

Additionally, it will be assumed that the analysis would be performed in pre-specified groups, i.e., with LVEF < 40% and LVEF ≥ 40%. Based on data from a documented TAVI implantation database from 2014–2018 covering 344 patients [23], it was shown that the percentage of patients with LVEF < 40% is 10.1%.

Statistical calculations will be performed using MedCalc® Statistical Software version 20.115 (MedCalc Software Ltd, Ostend, Belgium).

Discussion

The percentage of severe conduction defects and pacemaker implantation after TAVI remains high. There appears to be insufficient evidence to support the thesis that currently used techniques and technologies can bring the risk of periprocedural PPMI after TAVI to near-zero levels [8, 24].

Due to the type of conduction defects presented, most patients qualified for PPMI after TAVI are expected to have a high ventricular pacing burden. In 79% of them, the reason for qualification for PPMI is a complete AV block requiring permanent ventricular pacing [11]. However, almost half of the patients who received PPMI have other preexisting evidence of conduction defects on ECG before TAVI, including first-degree AV block (18.8%), right bundle branch block (RBBB) (47.6%), and left bundle branch block (LBBB) (7.1%), [19]. Additional patients develop atrioventricular and intraventricular conduction disorders after TAVI, with the rate of new-onset LBBB in up to 65% of patients, depending on the valve type [8, 9]. Yet, only about 33–36% of patients are pacemaker-dependent after 1-year follow-up [25]. Resolution of AV conduction disturbances

and programming algorithms promoting spontaneous AV conduction in the RVP control group may affect the expected RV pacing burden and clinical outcomes. However, prolonged AV conduction time or RBBB/LBBB correctable with CSP, apart from RV pacing burden, potentially will impact the outcomes.

Currently, PPMI is most often performed by transvenous RVP, leading to asynchronous electrical activation of the myocardium with mechanical dyssynchrony of the ventricles [26] and, in the long-term F/U, to the development of PICM in 12% of patients [27]. The PICM is associated with LV remodeling, impaired systolic and diastolic function, decreased LVEF, functional mitral valve regurgitation, and increased atrial arrhythmia burden [28, 29]. It is assumed that RVP burden greater than 20–40% [28, 29] and preexisting HF [28] significantly increases the risk of developing PICM. Therefore, patients after TAVI, usually with a high-degree AV block or BBB, high RVP burden, electro-mechanical dyssynchrony, and LV systolic or diastolic dysfunction, are the population at risk [28–30]. PICM affects the long-term results of TAVI, including an increased risk of death and hospitalization due to HF in a one-year F/U [11, 12, 19] and death from any cause and hospitalization due to HF in a 2.5-year F/U [31].

The 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy [13] indicate the possibility of preventing PICM using CRT in the case of an expected high RVP burden. This strategy may apply to patients after TAVI. In recent years, the possibility of CSP, that is, His bundle pacing and left bundle branch area pacing, respectively (HBP/LBBAP), has emerged as an effective alternative to BVP using a left ventricular lead and an alternative to conventional RVP [32, 33] with successful CSP lead implantation at 90.4% [34]. CSP provides synchronous, close-to-physiological stimulation of the ventricles, as well as the correction of coexisting intraventricular conduction disturbances, either with the morphology of the left or right BBB, making it a viable option for CRT [32]. The value of CSP has been confirmed in HF patients with impaired LV systolic function regardless of etiology [35, 36] and in participants with preserved LVEF [37]. It has recently been demonstrated that CSP may be more practical than BVP in treating PICM [38].

Other authors [39, 40] confirmed the possibility and safety of CSP in patients requiring PPMI after TAVI. In a systematic review by Shah et al. [39] of seven studies that included 153 patients after TAVI in whom CSP was attempted for pacing indications, the overall success rate was 83.2%. However, HBP had a lower overall success rate (66.9% vs. 94.3%) and higher thresholds (1.35 ± 1 V/ /0.85 ms vs. 0.67 ± 0.4 V/0.44 ms) than LBBAP. The most common reason for LBBAP failure in post-TAVI patients was the inability to implant the His bundle pacing lead due to septal thickness or fibrosis. Niu et al. [40] enrolled 30 patients with CSP (10 were implanted with HBP and 20 with LBBAP) and 30 with RVP with high-degree/complete AV block after TAVI. Paced QRS duration was significantly longer in the RVP group (153.5 ± 6.8 ms) than in the HBP and LBBAP groups (121.8 ± 8.6 ms and 120.2 ± 10.6 ms), and the capture threshold was stable in F/U (1.7 ± 0.8 V/0.4 ms for the HBP group, 0.8 ± 0.1 V/0.4 ms for the LBBAP group, and 0.6 ± 0.2 V/0.4 ms for the RVP group). During a 15.0 ± 9.1 months F/U, the CSP group had higher LVEF (55.8 ± 3.9% in the HBP group and 54.9 ± 6.7% in the LBBAP group than the RVP group 48.9 ± 9.1%). However, no results from a large RCT evaluating CSP compared to RVP/BVP in post-TAVI patients are available.

The PACE-4-TAVI trial checks whether CSP, as an alternative to conventional RVP/BVP, prevents chronic HF due to PICM after TAVI. The present hypothesis herein is that patients with an iatrogenic AV block after TAVI, due to an expected high burden of ventricular pacing and high incidence of BBB, may benefit from CSP for the preservation or improvement of LV systolic function, reducing the frequency of HF hospitalizations, improving QoL, and reducing all-cause mortality. The study results could help formulate recommendations regarding permanent cardiac pacing in patients requiring surgical intervention due to AS.

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Conflict of interests: All authors declare no conflicts of interest.

Author contributions: DL, RG, RG, DH, DJ, JKW, JK, JL, PM, GS, WW and KSG developed the study concept; DL, RG, TS, and KSG prepared the study protocol; DL, RG, TS, KSG prepared the manuscript; RG, DH, DJ, JKW, JK, JL, PM, GS, and WW proofread the manuscript. All authors approved the final version to be published.

Ethics statement: The proposed study has received a positive opinion from the Bioethical Committee of the Medical University of Silesia in Katowice, Poland (Resolution No. PCN/0022/KB1/52/20 of Jun 2 2020 and PCN/CBN/0052/KB1/52/I/20/22 of Oct 4 2022).

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