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Insights in a restricted temporary pacemaker strategy in a lean transcatheter aortic valve implantation program

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Abstract

Objectives: To study the safety and feasibility of a restrictive temporary-RV-pacemaker use and to evaluate the need for temporary pacemaker insertion for failed left ventricular (LV) pacing ability (no ventricular capture) or occurrence of high-degree AV-blocks mandating continuous pacing.

Background: Ventricular pacing remains an essential part of contemporary transcatheter aortic valve implantation (TAVI). A temporary-right-ventricle (RV)-pacemaker lead is the standard approach for transient pacing during TAVI but requires central venous access.

Methods: An observational registry including 672 patients who underwent TAVI between June 2018 and December 2020. Patients received pacing on the wire when necessary, unless there was a high-anticipated risk for conduction disturbances post-TAVI, based on the baseline-ECG. The follow-up period was 30 days.

Results: A temporary-RV-pacemaker lead (RVP-cohort) was inserted in 45 patients, pacing on the wire (LVP-cohort) in 488 patients, and no pacing (NoP-cohort) in 139 patients. A bailout temporary pacemaker was implanted in 14 patients (10.1%) in the NoP-cohort and in 24 patients (4.9%) in the LVP-cohort. One patient in the LVP-cohort needed an RV-pacemaker for incomplete ventricular capture. Procedure time was significantly longer in the RVP-cohort (68 min [IQR 52–88.] vs. 55 min [IQR 44–72] in NoP-cohort and 55 min [IQR 43–71] in the LVP-cohort [$p < 0.005$]). Procedural high-degree AV-block occurred most often in the RVP-cohort (45% vs. 14% in the LVP and 16% in the NoP-cohort [$p \leq 0.001$]). Need for new PPI occurred in 47% in the RVP-cohort, versus 20% in the NoP-cohort and 11% in the LVP-cohort ($p \leq 0.001$).

Abbreviations: AV-Block, atrioventricular block; BAV, balloon aortovalvuloplasty; LBBB, left bundle branch block; LV, left ventricular; LVP-cohort, pacing on the (LV) wire cohort; MSCT, multislice computed tomography; NoP-cohort, no rapid pacing cohort; RBBB, right bundle branch block; RV, right ventricular; RVP-cohort, temporary right ventricular pacemaker wire-cohort; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve; TTE, transthoracic echocardiography.

Conclusion: A restricted RV-pacemaker strategy is safe and shortens procedure time. The majority of TAVI-procedures do not require a temporary-RV-pacemaker.

KEYWORDS
conduction disturbances, pacing on the wire, rapid pacing, TAVI, temporary pacemaker

1 | INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a less invasive alternative to surgical aortic valve replacement (SAVR) for elderly patients across the entire operative risk spectrum.[1–3] Over the last two decades TAVI patient selection, pre-procedure planning, and refined device technologies have molted the procedure to a simplified intervention under local anesthesia with abbreviated hospital stay.[4] Ventricular pacing is often required for balloon dilatation or transcatheter heart valve deployment and high degree conduction blocks may mandate immediate (at least temporary) pacing. Conduction abnormalities are common surrounding a TAVI procedure. The incidence of new left bundle branch block (LBBB) is between 10% and 37%.[5] The need for a definite pacemaker varies between 5% and 35% and is associated with anatomical substrate (short membranous septum, left ventricular outflow tract calcification), conduction issues at baseline, and transcatheter heart valve (THV) design.[6,7]

A stiff wire in the left ventricle (LV) is essential to introduce, position, and deploy a THV. This LV wire can be connected to an external pacemaker for LV stimulation obviating the need for additional central venous access for a temporary transvenous pacemaker.[8] A French multi-center randomized controlled trial demonstrated safety and feasibility of LV pacing including shorter procedure and fluoroscopy time as compared with systematic use of a temporary right ventricular (RV) pacemaker.[6,9,10]

Pacing on the LV wire could complement simplified TAVI in order to reduce resources, time, and complications. Still, concerns remain about safety of more systematic use of LV pacing in TAVI with different THV designs. The aim of this study was to evaluate the safety and efficacy of more systematic LV pacing on the wire in terms of need for bailout temporary RV pacemaker insertion for failed pacing ability or occurrence of high-degree blocks mandating continuous pacing.

2 | MATERIALS AND METHODS

2.1 | Study population and study procedures

We included all patients undergoing TAVI in our center since the more systematic introduction of the pacing on the LV wire technique on June 7, 2018, until December 31, 2020. Patient eligibility for TAVI, access strategy and THV selection was per multidisciplinary heart team consensus. A dedicated prospective database captured relevant patient demographics, medical history and comorbidities, ECG, Transthoracic Echocardiography (TTE), Multislice computed tomography (MSCT), and procedural and clinical outcome data. All patients provided written consent for the TAVI procedure and use of anonymous individual data for research purposes. The study was conducted in accordance with the declaration of Helsinki and did not fall under the scope of the Medical Research Involving Human Subjects Act per Institutional Review Boards' review.

2.2 | Ventricular pacing strategy during TAVI

We identified three cohorts: cohort 1 represents the patients with planned LV wire Pacing (= LVP-cohort). Cohort 2 features the patients

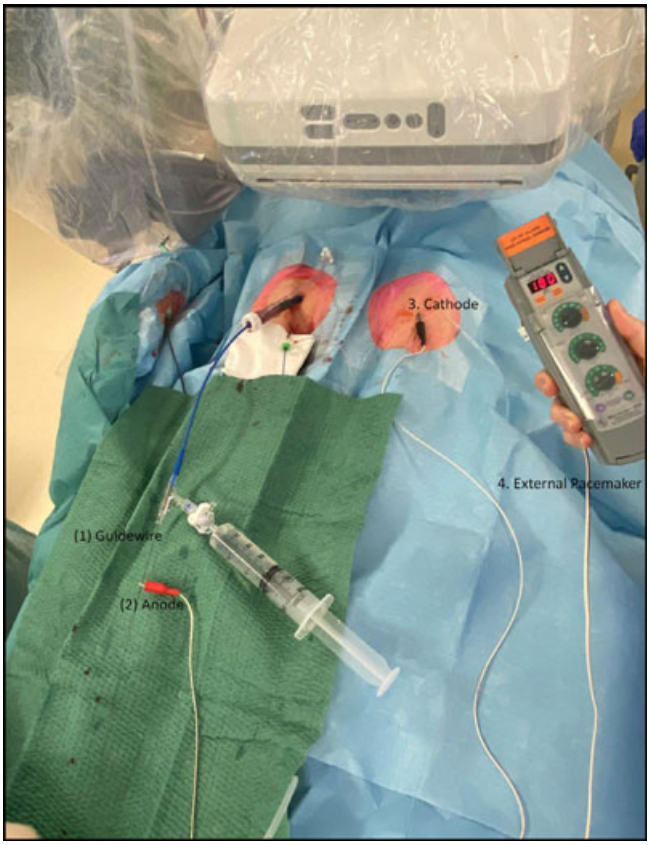

FIGURE 1 Pacing on the wire set-up. (1) A guidewire was inserted in the right femoral artery. (2) The (red) anode of an external pacemaker was connected to the distal end of the wire. (3) The (black) cathode to a 15- or 18-gauge needle that partially pierced the skin. (4) Ventricular sensing and electrical capture with the external pacemaker was checked prior to the valve intervention [Color figure can be viewed at wileyonlinelibrary.com]

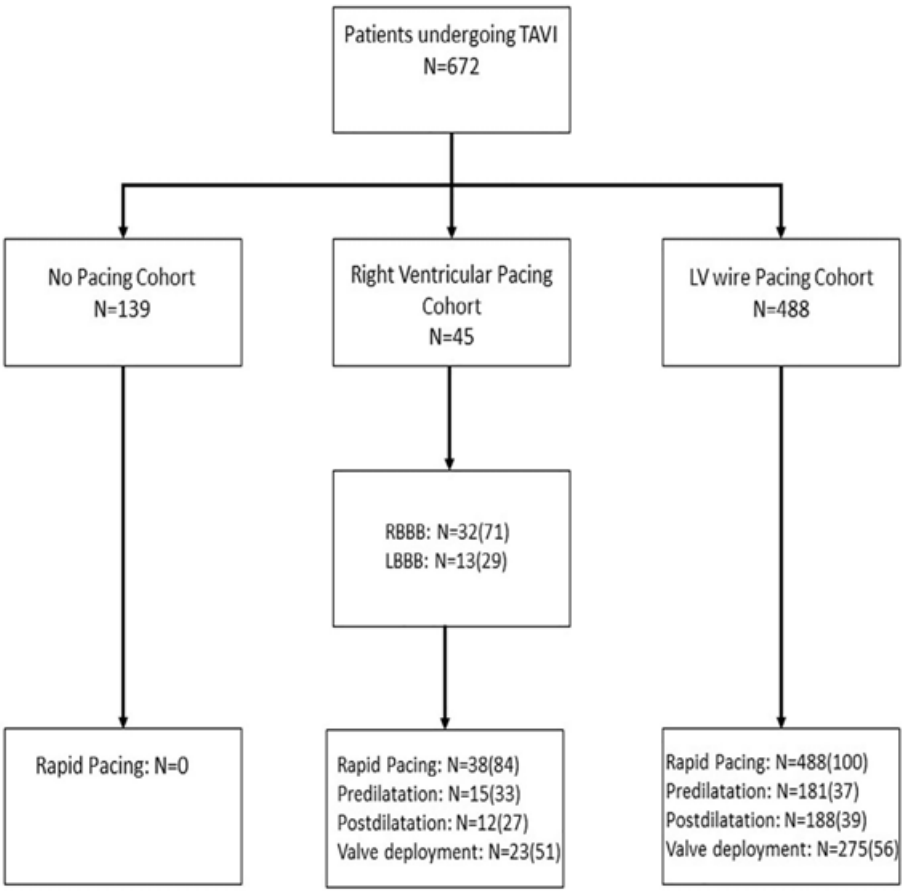

FIGURE 2 flow chart of patient selection and distribution. LV, left ventricular; RBBB, right bundle branch block; LBBB, left bundle branch block

who received a transvenous RV pacemaker (= RVP-cohort) prior to TAVI because of pre-existing high likelihood for procedure related high degree atrioventricular block that could make the patient pacemaker dependent including (1) right bundle branch block (RBBB) with a QRS duration > 140 ms, (2) LBBB > 150 ms, (3) bifascicular or trifascicular block. A third cohort of patients was scheduled for TAVI with no rapid pacing (= NoP-cohort); the external pacemaker was connected to the LV wire to provide temporary pacing only when needed.

A Safari wire (Boston Scientific, Marlborough, MA) was the LV wire of first choice. The (red) anode of an external pacemaker was connected to the distal end of the wire and the (black) cathode to a 15- or 18-gauge needle that partially pierced the skin (Figure 1). Ventricular sensing and electrical capture were checked prior to any valve intervention (balloon aortic-valvuloplasty [BAV] or THV implantation). Anode and cathode could be exchanged in case of insufficient ventricular sensing or electrical capture. Central venous access was obtained prior to TAVI if the operator decided to proceed with a balloon tipped RV temporary pacemaker lead (St. Jude Medical, Saint Paul, MN) (RVP-cohort) or during TAVI if the patient developed high-degree AV-block with inadequate escape rhythm.

2.3 | Outcomes and definitions

The primary endpoint for the LVP and NoP-cohorts was the need for bailout temporary RV pacemaker insertion for failed pacing ability (no ventricular capture) or occurrence of high degree blocks mandating continuous pacing. Secondary endpoints included relevant clinical endpoints at 30 days follow-up and "unnecessary" RV-pacemakers (i.e., a transvenous pacemaker that was inserted prior to TAVI but not used for BAV, THV implantation, or high-degree AV-block). Relevant clinical endpoints at 30 days follow-up were reported according to the VARC definitions and included the need for permanent pacemaker.[11]

2.4 | Statistical analysis

Distribution of continuous variables were tested for normality with the Shapiro–Wilk test. Continuous variables were reported as mean ± *SEM* (interquartile range) and analyzed with a student's *t* test, Mann–Whitney U- or Kruskal-Wallis-test as appropriate. Categorical variables were reported as percentage and compared with Chi-Square or Fishers Exact test. A two-sided *p*-value <0.05 was considered statistically significant. All statistics were performed with SPSS software version 25.0 (SPSS, Chicago IL).

3 | RESULTS

3.1 | Study population

A total of 672 patients were included in the study and 365 (54.3%) were male. Median age was 80 (IQR 74–84) and the median BMI

TABLE 1 Baseline characteristics

	Total	NoP-cohort	RVP-cohort	LVP-cohort	*p*-value
N	672	139	45	488	
Age	80 (74–84)	79 (73–84)	81 (78–86)	79 (73–84)	0.07
Male	365 (54.3)	62 (44.6)	32 (71.1)	271 (55.5)	0.005
BMI	26.5 (23.6–30.3)	25.9 (22.5–29.7)	26.3 (23.4–29.6)	26.8 (24.0–30.5)	0.07
Medical history					
Hypertension	482 (71.7)	107 (77.0)	33 (73.3)	342 (70.1)	0.27
Hypercholesterolemia	372 (55.4)	90 (64.7)	26 (57.8)	256 (52.5)	0.035
Diabetes	201 (29.9)	41 (29.5)	16 (35.6)	144 (29.5)	0.92
Peripheral vascular disease	183 (27.2)	50 (36.0)	19 (42.2)	114 (23.4)	0.001
History of myocardial infarction	101 (15.0)	25 (18.0)	13 (28.9)	63 (12.9)	0.009
History of PCI	175 (26.0)	36 (25.9)	15 (33.3)	124 (25.4)	0.51
History of CABG	79 (11.8)	21 (15.1)	7 (15.6)	51 (10.5)	0.24
Stroke	146 (21.7)	38 (27.3)	9 (20.0)	99 (20.4)	0.20
COPD	101 (15.1)	27 (19.4)	5 (11.1)	69 (14.1)	0.23
Renal failure	211 (31.4)	48 (34.5)	16 (35.6)	146 (30.1)	0.51
Pacemaker at baseline	109 (16.2)	25 (18.0)	0	84 (17.2)	0.009
Indication TAVI					0.61
Aortic stenosis	647 (96.4)	132 (94.9)	44 (97.8)	471 (96.5)	
Aortic regurgitation	5 (0.7)	3 (2.2)	0	2 (0.4)	
Mixed aortic disease	9 (1.3)	2 (1.4)	0	7 (1.4)	
Failed bioprosthesis	11 (1.6)	2 (1.4)	1 (2.2)	8 (1.6)	

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; N, number; PCI, percutaneous coronary intervention.

was 26.5 (IQR 23.6–30.3). LVP was initiated in 488 patients (73%) and a "no-pacing" strategy was applied in 139 patients. (Figure 2) An RVP was inserted a priori in 45 patients (6.7%) because of LBBB in 13 (29%) and RBBB in 32 patients (71%). Baseline characteristics are summarized in Table 1. There were no differences in medical history, except for peripheral vascular disease (36.0% in the NoP-cohort vs. 42.2% in the RVP-cohort and 23.4% in the LVP-cohort, $p = < 0.001$) and history of myocardial Infarction (18.0% in the NoP-cohort, 28.9% in the RVP-cohort and 12.9% in the LVP-cohort, $p = 0.009$). A permanent pacemaker was present prior to TAVI in 18.0% and 17.2% of the NoP and LVP-cohorts respectively and in no patient in the RVP-cohort.

3.2 | Procedural characteristics and outcomes

Table 2 displays the procedural characteristics. The majority of patients received TAVI under local anesthesia for symptomatic severe aortic stenosis. Overall, a transfemoral access was applied in 94%. Transaxillary approach was used in 15% of the patients with NoP versus 6.7% in the RVP and 3.3% in the LVP-cohort ($p \leq 0.001$). The Sapien3-valve (Edwards Lifesciences, Irvine, CA) was used in 12.3% of the patients, Evolut R and Pro (Medtronic, Minneapolis, MN) was respectively used in 18.3% and 20.4%, Lotus Edge and Acurate (Neo) (Boston Scientific, Marlborough, MA) in 10.4% and 8.3% and JenaValve (JenaValve Technology, Irvine, CA) in 0.3% of the patients.

Predilatation was performed in 33.3% of the RVP-cohort and 37.1% in the LVP-cohort and postdilatation in 26.7% in the RVP-cohort versus 38.5% in the LVP-cohort and 0% in the NoP-cohort. There were no significant differences in complications during the TAVI-procedure, except for the need for a second valve (0% in the NoP-cohort vs. 6.7% in the RVP-cohort and 2.5% in the LVP-cohort, $p = 0.025$). A bailout temporary pacemaker during the TAVI procedure was implanted in 14 patients (10.1%) in the NoP-cohort and in 24 patients (4.9%) in the LVP-cohort. Reasons for bailout temporary pacemaker were (transient or permanent) high-degree AV-block in the majority of these patients (23 patients, 95.8%). One patient in the LVP-cohort required a temporary RV pacemaker lead for inadequate electrical ventricular capture during LV pacing. Rapid Pacing for pre- or postdilatation or valve deployment was performed in 84.4% in the RVP-cohort and a high-degree AV-block occurred in 45% of the patient in the RVP-cohort. In four patients (8.9%), a temporary pacemaker was not necessary for rapid pacing or as bail-out during the procedure. Procedure time was significantly longer in the RV pacing cohort (68 min [IQR 52–88.] vs. 55 min [IQR 44–72] in NoP-cohort and 55 min [IQR 43–71] in the LVP-cohort [$p = 0.005$]).

The 30-day outcomes are tabulated in Table 3. There were no significant differences in vascular or bleeding complications between

TABLE 2 Procedural characteristics

	Total	NoP-cohort	RVP-cohort	LVP-cohort	*p*-value
Procedure					
Anesthesia					0.11
Local	659 (98.1)	138 (99.3)	42 (93.3)	479 (98.2)	
General	13 (1.9)	1 (0.7)	3 (6.7)	9 (1.9)	
Access					<0.001
Femoral	633 (94.2)	119 (85.6)	42 (93.3)	472 (96.7)	
Subclavian/axillary	39 (5.8)	20 (14.4)	3 (6.7)	16 (3.3)	
Cerebral protection	303 (45.1)	54 (38.8)	24 (53.3)	225 (46.1)	0.16
Rapid pacing total	526 (78.3)	0	38 (84.4)	488 (100)	<0.001
Predilatation	196 (29.2)	0	15 (33.3)	181 (37.1)	<0.001
Postdilatation	200 (29.8)	0	12 (26.7)	188 (38.5)	<0.001
Valve deployment	298 (44.3)	0	23 (51.1)	275 (56.4)	<0.001
Implantation depth NCC	6.4 [4.6–8.6]	7.7 [4.7–10.2]	5.9 [4.8–8.1]	6.3 [4.6–8.0]	0.04
Implantation depth LCC	6.2 [4.5–8.6]	8.1 [5.3–10.8]	5.5 [4.8–6.6]	5.9 [4.4–7.7]	<0.001
Transcatheter heart valve					<0.001
Sapien3	284 (42.3)	0	22 (48.9)	262 (53.7)	
Evolut (R and Pro)	260 (38.7)	96 (69.1)	14 (31.1)	150 (30.7)	
Lotus	70 (10.4)	41 (29.5)	4 (8.9)	25 (5.1)	
Acurate	56 (8.3)	0	5 (11.1)	51 (10.5)	
Jenavalve	2 (0.3)	2 (1.4)	0	0	
Procedural complications					
Procedural death	3 (0.4)	2 (1.4)	0	1 (0.2)	0.14
Need second valve	15 (2.2)	0	3 (6.7)	12 (2.5)	0.025
Valve embolization	10 (1.5)	1 (0.7)	1 (2.2)	8 (1.6)	0.67
Conversion AVR	2 (0.3)	0	0	2 (0.4)	0.69
Coronary obstruction	3 (0.4)	2 (1.4)	0	1 (0.2)	0.14
Need temporary PM during procedure	83 (12.4)	14 (10.1)	45 (100)	24 (4.9)	<0.001
Need temporary PM due to no capture	1 (0.1)	0	0	1 (0.2)	
New high-degree AV-block	76 (13.6)	18 (16.1)	20 (44.5)	38 (9.4)	<0.001
New LBBB	255 (45.5)	56 (50.0)	6 (13.3)	193 (47.9)	<0.001
Temporary PM left in	72 (10.7)	13 (9.4)	36 (80.0)	23 (4.7)	<0.001
Procedure time	56 (44–74)	55 (44–72)	68 (52–88)	55 (43–71)	0.005

Abbreviations: AV, atrioventricular; AVR, aortic valve replacement; LBBB, left bundle branch block; LCC, left-coronary cusp; NCC, non-coronary cusp; PM, pacemaker.

the three groups. Any neurological events occurred more in the RVP-cohort (8.9% in RVP vs. 5.0% in NoP vs. 1.6% in LVP, $p = 0.004$). However, there was no significant difference in disabling stroke (4.4% in RVP vs. 1.4% in NoP vs. 1.0% in LVP, p = 0.16). Twenty-one patients (46.7%) received a definite pacemaker in the RVP-cohort versus 27 (19.7%) in the NoP and 53 (10.9%) in the LVP-cohorts ($p \leq 0.001$).

3.3 | Conduction disturbances

Subgroup analysis excluding procedural deaths and patients with a pacemaker at baseline showed high degree AV-block during the procedure occurred most often in the RVP-cohort (45% vs. 14% in the LVP-cohort and 16% in NoP-cohort [$p \leq 0.001$]) (Figure 3). In the RVP-cohort, 50% of the RBBB-patients developed a high-degree AV-block, compared with 31% of the LBBB patients ($p = 0.33$). In 23(4.7%) patients in the LVP-cohort, the temporary pacemaker was left in, compared with 13 (9.7%) in the NoP-cohort and 36 (80%) in the RVP-cohort. Of these 36 patients from the RVP-cohort, 20 patients (56%) had a temporary pacemaker due to procedural high-degree AV-block and in 16 (44%) patients the temporary pacemaker was left in due to their high pre-procedural risk factors for conduction disturbances.

In total, 101 patients (18%) received a new PPI. Indications for a definitive PPI were high-degree AV-block (82%), Brady-Tachy

TABLE 3 Thirty-day outcomes

30-day outcomes	Total	NoP-cohort	RVP-cohort	LVP-cohort	P-value
Death	15 (2.2)	2 (1.4)	2 (4.4)	11 (2.3)	0.49
Any neurological event	19 (2.8)	7 (5.0)	4 (8.9)	8 (1.6)	0.004
Disabling stroke	9 (1.3)	2 (1.4)	2 (4.4)	5 (1.0)	0.16
Vascular complication (overall)					0.43
Major	43 (6.4)	13 (9.4)	1 (2.2)	29 (5.9)	
Minor	56 (8.3)	12 (8.6)	3 (6.7)	41 (8.4)	
Bleeding (overall)					0.56
life-threatening	18 (2.7)	5 (3.6)	1 (2.2)	12 (2.5)	
Major	22 (3.3)	7 (5.1)	0	15 (3.1)	
Minor	41 (6.1)	6 (4.3)	2 (4.4)	33 (6.8)	
Vascular complication heart	11 (1.6)	3 (2.2)	1 (2.2)	7 (1.4)	0.80
Bleeding heart	10 (1.4)	3 (2.1)	1 (2.2)	6 (1.2)	0.38
Conduction					
New LBBB	156 (27.9)	41 (36.6)	1 (2.2)	114 (28.3)	<0.001
New pacemaker	101 (15.1)	27 (19.7)	21 (46.7)	53 (10.9)	<0.001
New pacemaker in pacemaker naïve patients	101 (18.0)	27 (24.1)	21 (46.7)	53 (13.2)	<0.001
Indication pacemaker					0.068
High-degree AV-block	83 (82.2)	24 (88.9)	20 (95.2)	39 (73.6)	
Brady-Tachy syndrome	12 (11.9)	1 (3.7)	0	11 (20.8)	
First degree AV-block + LBBB with prolonged conduction times	6 (5.9)	2 (7.4)	1 (4.8)	3 (5.7)	
Length of stay (days)	4 (3–7)	5 (4–7)	6 (4–7)	4 (3–7)	0.004
Rehospitalizations	75 (11.2)	19 (13.9)	9 (20.0)	47 (9.7)	0.060

Abbreviations: AV, atrioventricular; LBBB, left bundle branch block.

syndrome (12%), and first-degree AV-block with LBBB with excessive QRS duration (6%). Need for new PPI occurred in 47% in the RVP-cohort compared with 20% in the NoP-cohort and 11% in the LVP-cohort, $p \leq 0.001$. In the RVP-cohort, 59% of the patients with a RBBB received a new PPI compared with 15.4% of patients with LBBB. Patients who developed a per-procedural high-degree AV-block received a new PPI in 57% of cases compared with 12% in the patients without a per-procedural high-degree AV-block ($p < 0.001$). Of the patients with a procedural transient high-degree AV-block, 42% needed a definitive PPI, compared with 84.6% of the patients with a persistent high-degree AV-block ($p < 0.001$).

4 | DISCUSSION

Our experience with a restricted RV pacing strategy during TAVI highlighted the following: (1) majority of TAVI procedures can be safely performed without a temporary RV pacemaker and a no-RV pacemaker strategy contributes to a lean procedure by reducing overall procedure time. (2) Pacing on the LV wire is reliable and safe and a bail-out temporary RV pacemaker was required in only 5% of cases because of the occurrence of permanent high-degree AV-block. (3) TAVI induced conduction disorders require observation but most often no temporary RV pacemaker. (4) RV pacing remains reasonable in patients at high-risk for permanent high-degree AV-block (e.g., selected RBBB and LBBB phenotypes).

TAVI transformed into a simplified procedure characterized by local anesthesia or conscious sedation and minimized instrumentation. A temporary RV pacemaker through central venous access was originally deemed a prerequisite to abate new conduction disorders and to deliver rapid RV pacing for balloon- pre- or postdilatation and transcatheter valve deployment. Our restricted RV pacing practice refuted this paradigm demonstrating that the vast majority of TAVI cases could be executed without temporary RV pacemaker lead: a temporary pacemaker was deemed necessary at the start of the TAVI procedure because of extensive conduction issues at baseline at high likelihood for a high-degree AV-block in only 6.7% of cases. Pacing on the LV wire was safely used in 72.6% of patients and no pacing was delivered in 20.7% of patients. Strategy was determined by THV design selection and patient characteristics. Any kind of pacing is essential for the deployment of balloon-expandable THV and in selected cases of self-expanding THVs or when balloon dilatation is required. Importantly, new conduction disorders were not rare but did not require pacing in the vast majority of events. Indeed, a bail-out

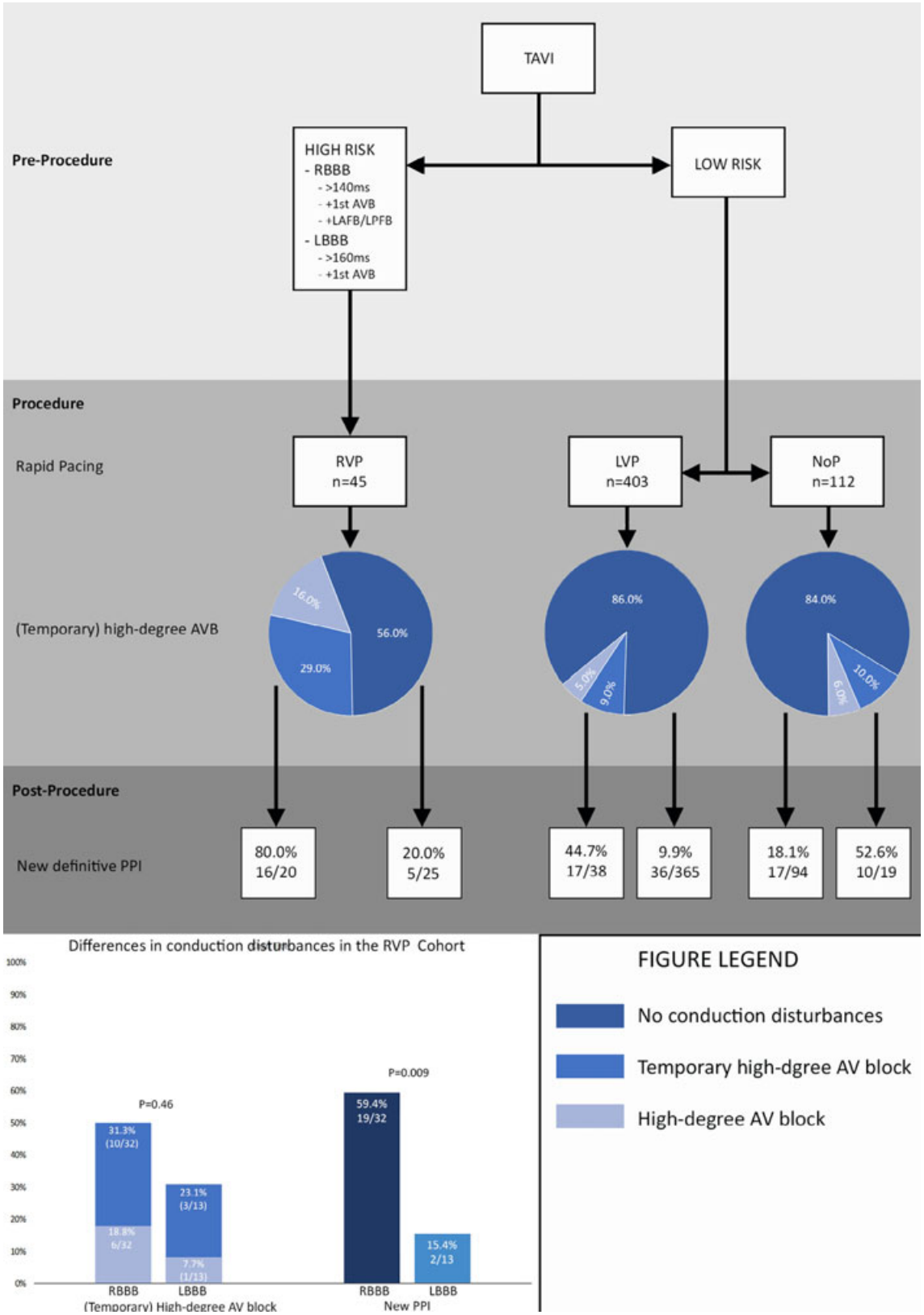

FIGURE 3 overview of conduction disturbances in a subgroup of patients without a pacemaker at baseline or procedural death. RBBB, right bundle branch block; LBBB, left bundle branch block; RVP, right ventricular temporary pacemaker; LVP, left ventricular rapid pacing; NoP, no rapid pacing; AVB, atrioventricular block; PPI, permanent pacemaker implantation [Color figure can be viewed at wileyonlinelibrary.com]

temporary pacemaker was required for permanent high-degree AV-block in 5% of the LVP-cohort and in 10% of patients with an initial no-pacing strategy. Only one patient in the LVP-cohort needed a temporary pacemaker because of insufficient electrical ventricular capture during LV pacing. The EASY TAVI randomized trial demonstrated similar pacing safety and efficacy and shorter procedure times with LV pacing as compared with RV pacing in 307 patients undergoing TAVI with a balloon-expandable THV. Our experience extend these findings to a clinical practice that included various THV designs and also demonstrated no need for any pacing in a significant portion of patients (undergoing TAVI with a self-expanding THV and without any need for balloon dilatation).[9] We confirmed that this restricted RV pacing strategy may complement a lean TAVI program by further curtailing overall procedure time by >10 min. As expected need for permanent pacemaker was higher in the RVP-cohort because of the risk profile of patients. In this cohort new permanent pacemakers were required particularly in patients with RBBB at baseline (59%). RBBB is an established risk factor with new pacemaker rates of up to 40%.[12] In the RVP-cohort, the risk for a permanent pacemaker was even higher as we only included RBBB-patients with a prolonged QRS-duration (>140 ms) or bi- or trifascular block. A procedural temporary pacemaker remains reasonable in these patients.

However, also the LVP and no-pacing cohorts demonstrated relevant permanent pacemaker needs despite no temporary pacemakers were used. This seems to illustrate that TAVI related high-degree AV-blocks are often transient or with sufficient escape rhythms that allow to bridge to a permanent pacemaker implantation without the need of a temporary pacemaker. We believe this is clinically relevant because central venous access and insertion of a temporary pacemaker in the RV apex may not be harmless and could result in clinically relevant bleeding or access site complications (including pericardial effusion and tamponade). In fact, data from Milan suggested that more than half of the pericardial tamponade cases after TAVI were related to RV perforation by a temporary pacemaker.[13]

The 2020 American College of Cardiology expert consensus document recommended (1) a temporary RV pacemaker lead, preferably inserted through the right internal jugular vein over LVP in patients at high-risk for conduction disturbances, which included a RBBB or first-degree AV-block, a heavily calcified aortic valve or a short membranous septum and (2) to keep a central venous access and preferably transvenous pacemaker in situ for at least 24 h also in patients who developed new LBBB or an increase in PR/QRS duration ≥20 ms.[14] A Journal of the American College of Cardiology Scientific Expert Panel also recommended to keep a transveous temporary pacemaker lead in situ for 24 h after TAVI (or at least overnight) in all patients except those with no new conduction disorders and no RBBB.[15] Our data tone down the formal requirement for an indwelling transvenous pacemaker for 24 h because only 10% of the patients had a temporary pacemaker in situ after the procedure with no additional conduction issues requiring bail-out temporary pacemaker in the remaining patients.

4.1 | Study limitations

Our study is a single center registry analysis with inherent limitations. Valve selection and choice of (pacing) wire was per operators discretion, with innate selection bias. In addition, 10% of patients received a mechanically expanded THV that was associated with the highest need for permanent pacemaker implantation, but is no longer commercially available.

Our study aimed to demonstrate the safety of a restricted temporary pacemaker use in every-day practice. Patient selection for RVP was predominantly based on ECG criteria. Other known risk factors for conduction disorders post-TAVI, such as membranous septum length and LVOT calcifications, were not used as a specific criterion. These factors could further refine conduction management after TAVI.

5 | CONCLUSIONS

A restricted RV pacemaker strategy is safe and shortens procedure time. The majority of TAVI procedures do not require a temporary RV pacemaker lead.

CONFLICT OF INTEREST

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Nicolas M. Van Mieghem received research grants from Abbott, Boston Scientific Corporation, Edwards Lifesciences, Medtronic, Teleflex, Daiichi Sankyo; Pie Medical. All other authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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REFERENCES

1. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380:1695-1705.
2. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017;376:1321-1331.
3. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380:1706-1715.

4. Cahill TJ, Chen M, Hayashida K, et al. Transcatheter aortic valve implantation: current status and future perspectives. Eur Heart J. 2018;39:2625-2634.
5. Regueiro A, Abdul-Jawad Altisent O, Del Trigo M, et al. Impact of new-onset left bundle branch block and periprocedural permanent pacemaker implantation on clinical outcomes in patients undergoing transcatheter aortic valve replacement: a systematic review and meta-analysis. Circ Cardiovasc Interv. 2016;9:e003635.
6. Siontis GC, Juni P, Pilgrim T, et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: a meta-analysis. J Am Coll Cardiol. 2014;64:129-140.
7. Mahajan S, Gupta R, Malik AH, et al. Predictors of permanent pacemaker insertion after TAVR: a systematic review and updated meta-analysis. J Cardiovasc Electrophysiol. 2021;32:1411-1420.
8. Faurie B, Abdellaoui M, Wautot F, et al. Rapid pacing using the left ventricular guidewire: reviving an old technique to simplify BAV and TAVI procedures. Catheter Cardiovasc Interv. 2016;88:988-993.
9. Faurie B, Souteyrand G, Staat P, et al. Left ventricular rapid pacing via the valve delivery guidewire in transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2019;12:2449-2459.
10. Li YM, Tsauo JY, Liao YB, Zhao ZG, Chen M. Comparison of third generation balloon-expandable Edwards Sapien 3 versus self-expandable Evolut R in transcatheter aortic valve implantation: a meta-analysis. Ann Palliat Med. 2020;9:700-708.
11. Kappetein AP, Head SJ, Genereux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the valve academic research Consortium-2 consensus document. Eur Heart J. 2012;33:2403-2418.
12. Auffret V, Webb JG, Eltchaninoff H, et al. Clinical impact of baseline right bundle branch block in patients undergoing Transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2017;10(15):1564-1574.
13. Rezq A, Basavarajaiah S, Latib A, et al. Incidence, management, and outcomes of cardiac tamponade during transcatheter aortic valve implantation: a single-center study. JACC Cardiovasc Interv. 2012;5:1264-1272.
14. Lilly SM, Deshmukh AJ, Epstein AE, et al. 2020 ACC expert consensus decision pathway on Management of Conduction Disturbances in patients undergoing Transcatheter aortic valve replacement: a report of the American College of Cardiology Solution set Oversight Committee. J Am Coll Cardiol. 2020;76:2391-2411.
15. Rodes-Cabau J, Ellenbogen KA, Krahn AD, et al. Management of Conduction Disturbances Associated with Transcatheter Aortic Valve Replacement: JACC scientific expert panel. J Am Coll Cardiol. 2019;74:1086-1106.

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