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Original Research

Management of Postprocedural Conduction Disturbances Using a Prespecified Algorithm in the Optimize PRO Study

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ABSTRACT

Background: Lack of standardization in posttranscatheter aortic valve replacement (TAVR) conduction disturbance (CD) identification and treatment may affect permanent pacemaker implantation (PPI) rates and clinical outcomes. The safety and efficacy of a standardized TAVR CD algorithm has not been analyzed. This study analyzes the Optimize PRO post-TAVR CD management algorithm with Evolut PRO/PRO$^+$ valves.

Methods: Optimize PRO is a prospective, postmarket study implementing 2 strategies to reduce pacemaker rates: TAVR with cusp overlap technique and a post-TAVR CD algorithm. The 2-hour postprocedural electrocardiogram (ECG) stratified patients to early discharge in the absence of new ECG changes or to CD algorithms for (1) ECG changes with preexisting right or left bundle branch block (LBBB), interventricular conduction delay or first-degree atrioventricular block, (2) new LBBB, or (3) high-degree atrioventricular block (HAVB).

Results: The interim analysis of the CD cohort consisted of 125/400 TAVR recipients. In the CD cohort, the 30-day new PPI rate was higher (28.1% vs 1.5%; $P < .001$), and 60 (48%) patients were discharged with a 30-day continuous ECG monitor. At 30 days, 90% of patients discharged with a monitor did not require PPI. Clinical outcomes, including mortality, stroke, bleeding, and reintervention, were similar in patients with and without CDs. No patient experienced sudden cardiac death.

Conclusions: Effective management of CDs using a standard algorithm following Evolut TAVR provides similar 30-day safety outcomes to patients without CDs who undergo routine next day discharge. The CD algorithm may provide an effective strategy to recognize arrhythmias early, improve PPI utilization, and facilitate safe monitoring of patients after discharge.

Introduction

Transcatheter aortic valve replacement (TAVR) is now the primary mode of treatment for patients with severe symptomatic aortic stenosis.[1,2] Device iteration and refinements in technique have minimized the rates of complications; however, self-expanding valves have had significantly higher rates of conduction disturbances (CDs) and permanent pacemaker implantation (PPI). In the Evolut Low-Risk trial (Medtronic), the PPI rate at 30 days was 17.4% after TAVR, compared with 6.1% after surgical valve replacement.[3]

Abbreviations: AVB, atrioventricular block; CD, conduction disturbance; COT, cusp overlap technique; ECG, electrocardiogram; EP, electrophysiology; HAVB, high-degree atrioventricular block; IVCD, interventricular conduction delay; LBBB, left bundle branch block; PPI, permanent pacemaker implantation; RBBB, right bundle branch block; TAVR, transcatheter aortic valve replacement.

Keywords: conduction disturbance algorithm; left bundle branch block; permanent pacemaker implantation; transcatheter aortic valve replacement.

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Patients with conduction abnormalities often experience a longer length of hospital stay and are more likely to receive early PPI to expedite discharge. Assessing patients implanted with new pacemakers, studies have shown many are not pacer dependent at 6 months with less than a third of patients 100% paced at long-term follow-up in a large study.[4] Although standard post-TAVR management algorithms have been proposed,[5,6] the decision to proceed with PPI is frequently dependent on local practice of the heart team and cardiac electrophysiologist. Protocols for CD management have been proposed[5] but not universally adopted.

In the Optimize PRO study, participants underwent TAVR with Evolut PRO/PRO$^+$ valves, and intraprocedural and postprocedural strategies were used to reduce the occurrence of CDs and PPI rates. These included the use of the cusp overlap technique (COT) for valve implantation and implementation of a standardized pathway for management of CDs after TAVR. This prospective interim analysis aimed to characterize the safety and efficacy of the predetermined Optimize PRO postprocedural CD management algorithm after TAVR with the Evolut PRO/PRO$^+$ to provide clinicians data on patients with CDs that may change current practice.

Materials and methods

Trial design and oversight

Clinical and electrocardiographic outcomes from the Optimize PRO study (NCT04091048) were compared in patients with and without new or worsening conduction abnormalities after TAVR managed with a standardized algorithm. This interim analysis of the predetermined conduction management algorithm included 400 main cohort patients from North America for whom clinical outcomes were previously reported.[7] In brief, inclusion criteria included symptomatic severe aortic stenosis (aortic valve area < 1.0 cm^2 [or aortic valve area index of ≤ 0.6 cm^2/m^2] or mean gradient ≥ 40 mm Hg or maximal aortic valve velocity ≥ 4.0 m/s by transthoracic echocardiography at rest), New York Heart Association class II or greater, and suitable anatomy for transfemoral treatment with the Medtronic Evolut PRO or PRO$^+$ TAVR system. Patients with a left ventricular ejection fraction $<35\%$, previous aortic valve replacement, previous pacemaker or intracardiac defibrillator implantation, bicuspid aortic valve, life expectancy of <12 months, or prohibitive left ventricular outflow tract calcification (heart team determination) were excluded. A local institutional review committee approval was obtained, including written patient informed consent. The trial adhered to the principles of the Declaration of Helsinki.

Preprocedural pathway standardization included a screening checklist, 12-lead electrocardiogram (ECG), and early discharge plan with a multidisciplinary team. Periprocedurally, Evolut implantation was performed using the COT (8). Postprocedurally, ECGs were performed at baseline, 2-hour postprocedure, 24-hour postprocedure (as-needed), 48-hour postprocedure (as-needed), discharge, and 30 days. New CD and ECG interpretation were site reported to provide continuity in the application of the clinical management pathway. A diagram of patient disposition is provided in Figure 1. Adverse events, such as mortality, were adjudicated by an independent Clinical Events Committee.

Study end points

The study primary end point was all-cause mortality or all-stroke at 30 days. Secondary end points included the rate of new PPI at 30 days, percentage of participants with moderate or greater aortic regurgitation at discharge, and median days from index procedure to discharge.[8] Clinical events were defined according to VARC-2 recommendations.[9] CD included right bundle branch block (RBBB), left bundle branch block (LBBB), interventricular conduction delay (IVCD), atrioventricular block (AVB), high-degree atrioventricular block (HAVB), or left anterior fascicular block.

Postprocedural care algorithm

The 2-hour post-TAVR ECG stratified patients into the following 5 categories (Central Illustration): (1) no ECG changes in patients without preexisting RBBB and eligible for routine early discharge; (2) no ECG changes in patients with preexisting RBBB and eligible for discharge 2 days postprocedure; (3) new-onset LBBB; (4) ECG changes (increase ≥ 20 ms in PR or QRS) and preexisting RBBB, LBBB, IVCD, or first-degree AVB; and (5) peri-procedural HAVB. Patients in categories 3 through 5 followed a prespecified CD algorithm. ECG changes directed treatment using the standardized CD algorithm, provided in the Supplemental Methods.

The CD algorithm proceeded with the maintenance of a temporary pacemaker and 24-hour ECG assessment for CD resolution. Monitoring continued for up to 48 hours with management according to the specific algorithm. If the QRS was >150 ms or PR was >240 ms, the CD algorithm recommended maintenance of the temporary pacemaker for an additional 24 hours. If the CD persisted, the algorithm allowed the

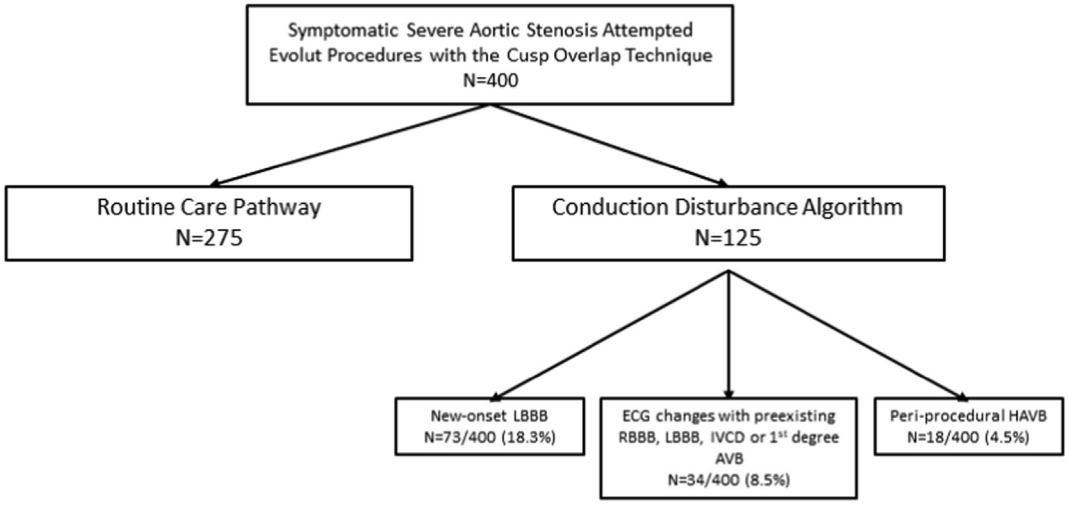
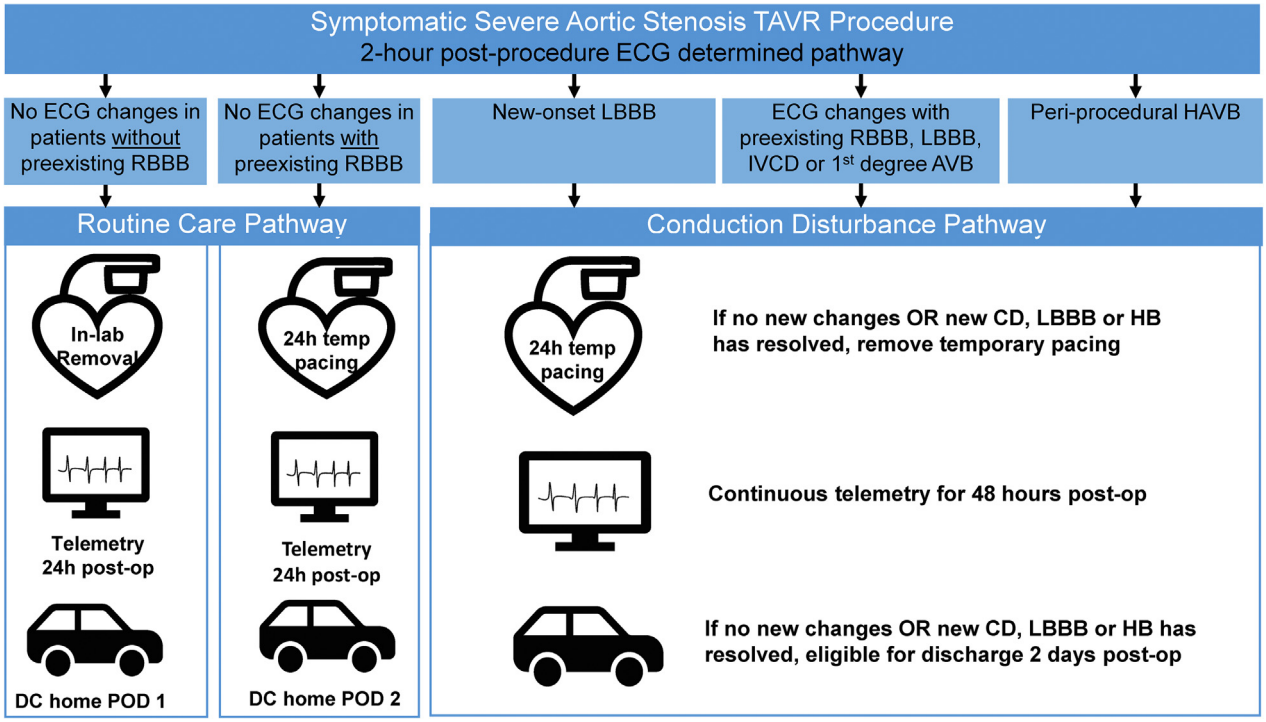


Figure 1.
Summary of patient disposition. Patient flow stratified into routine care pathway vs conduction disturbance algorithm. AVB, atrioventricular block; ECG, electrocardiogram; HAVB, hemi-atrioventricular block; IVCD, interventricular conduction delay; LBBB, left bundle branch block.



Central Illustration.

Treatment algorithm for patients with and without conduction disturbances. Patients were stratified into the following 5 categories based on the 2-hour post-TAVR ECG: (1) no ECG changes in patients without preexisting RBBB and eligible for routine early discharge, (2) no ECG changes in patients with preexisting RBBB and eligible for discharge 2 days after procedure, (3) new-onset LBBB, (4) ECG changes (or PR or QRS increase $\geq$ 20 ms) and preexisting RBBB, LBBB, IVCD, or first-degree AVB, and (5) peri-procedural HAVB. Patients proceeded to pacemaker implantation with an occurrence of HAVB/CHB at any time during the post-TAVR period. If new CD continued or worsened or QRS > 150 ms or PR > 240 ms, continuous monitoring was suggested with consideration of an invasive electrophysiology study and continuous ECG monitoring until the 30-day follow-up visit or PPI. AVB, atrioventricular block; ECG, electrocardiogram; HAVB, hemi-atrioventricular block; IVCD, interventricular conduction delay; LBBB, left bundle branch block; RBBB, right bundle branch block; PPI, permanent pacemaker implantation.

following 3 options based on site preference: (1) perform an invasive electrophysiology (EP) study, (2) discharge with continuous ECG monitoring until the 30-day follow-up visit, or (3) implant a permanent pacemaker. Patients in the CD algorithm were discharged at 48 hours if there were no new changes compared with those of the 24-hour ECG or if there was resolution of the new ECG change (Central Illustration).

Per the CD algorithm, follow-up ECGs were assessed for progression or resolution of the CD. Resolved was defined as a new CD ECG change that was no longer present. Persistent was defined as a new CD ECG finding that continued to be present and unchanged. Evolved was defined as a change from a new CD ECG to a different CD ECG feature.

Statistical analysis

Continuous variables are presented as mean ± SD or median (first quartile [Q1]-third quartile [Q3]) and compared between pathways using the Student *t* test. Categorical variables are reported as counts and percentages and compared between groups using the Fisher exact test or χ^2 test. Clinical outcomes at 30 days were summarized as Kaplan-Meier estimates and compared between the groups using log-rank test. No adjustments were made for multiplicity. Statistical analyses were performed using SAS version 9.4 (SAS Institute).

Results

Patient characteristics

Evolut implantation was attempted in 400 patients between September 2019 and October 2021. The proportion of patients assigned to the CD algorithm due to a CD detected at 2 hours was 125 (31.3%) of the 400. Baseline characteristics stratified by CD care algorithm are summarized in Table 1. The mean age of the patients was 78.7 ± 6.6 years, 54.0% were male, and 6.5% presented with a preexisting RBBB. Patients in the CD algorithm showed higher Society of Thoracic Surgeons Predictive Risk of Mortality (3.3 ± 2.6 vs 2.9 ± 2.2; P =.010), more peripheral arterial disease (15.2% vs 5.1%; P =.001), and more cerebrovascular disease (22.4% vs 14.2%; P =.041) but less frequent previous myocardial infarction (4.8% vs 13.0%; P =.014).

Procedural characteristics and outcomes

Conscious sedation or monitored anesthesia care was predominant in each group (Table 2). The median procedure time was significantly longer for patients in the CD algorithm (115.0 min [92.0-145.00]) than that of those in the routine care pathway (101.0 min [84.0-128.0]; P = .001). Postimplant balloon dilatation was higher in patients in the CD algorithm group (18.4% vs 9.5%; P = .011). Resheathing (31.2% vs 15.3%; P < .001) and full recapture (37.6% vs 23.3%; P = .003) were used more frequently in patients in the CD algorithm group. The depth of implant was significantly deeper in the patients in the CD algorithm group; mean noncoronary cusp implant depth was 4.1 ± 3.2 mm compared with 2.6 ± 2.8 mm in those following the routine care pathway (P < .001). The median length of stay was 2 days (1.0-2.0 days) in the CD algorithm group, compared with 1 day in the routine care cohort.

Clinical outcomes

The primary end point of all-cause mortality or all-stroke at 30 days occurred in 2.4% of patients following the CD algorithm versus 4.4% of

Table 1. Baseline characteristics.

	Conduction disturbance algorithm (n = 125)	Routine care pathway (n = 275)	*P*
Age, y	79.0 ± 6.9	78.5 ± 6.5	.479
Male sex	69 (55.2)	147 (53.5)	.745
Body mass index, kg/m^2	30.7 ± 6.1	30.2 ± 6.3	.492
New York Heart Association			.304
II	70 (56.0)	167 (60.7)	
III	50 (40.0)	103 (37.5)	
IV	5 (4.0)	5 (1.8)	
STS predicted risk of mortality: isolated AVR[a]	3.3 ± 2.6	2.9 ± 2.2	.010
Diabetes	48 (38.4)	84 (30.5)	.122
Dialysis	2 (1.6)	3 (1.1)	.650
Hypertension	108 (86.4)	228 (82.9)	.377
Chronic lung disease	13 (11.6)	47 (17.8)	.134
Peripheral arterial disease	19 (15.2)	14/273 (5.1)	.001
Cerebrovascular disease	28 (22.4)	39 (14.2)	.041
Previous coronary artery bypass graft	18 (14.4)	31 (11.3)	.377
Previous percutaneous coronary intervention	36 (28.8)	61 (22.5)	.176
Previous myocardial infarction	6 (4.8)	35 (13.0)	.014
Arrhythmia history	36 (28.8)	61 (22.2)	.152
Previous atrial fibrillation/ atrial flutter	31 (24.8)	50 (18.2)	.127
History of RBBB	12 (9.8)	13 (5.0)	.075
Left ventricular ejection fraction, %	59.8 ± 8.2	59.5 ± 7.0	.734

Continuous variables are means ± standard deviation. Categorical data are n (%).
AVR, aortic valve replacement; RBBB, right bundle branch block.
[a] The Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) provides an estimate of the risk of death at 30 days among patients undergoing surgical aortic valve replacement based on several demographic and procedural variables.

Table 2. Procedural characteristics.

	Conduction disturbance algorithm (n = 125)	Routine care pathway (n = 275)	*P*
Total time in the procedure room, min	115.0 (92.0-145.0)	101.0 (84.0-128.0)	.001
Anesthesia type			.684
Conscious sedation or monitored anesthesia care	106 (84.8)	231 (84.0)	
General anesthesia	18 (14.4)	44 (16.0)	
Preimplant balloon valvuloplasty performed	74 (59.2)	164 (59.6)	.934
Postimplant dilatation	23 (18.4)	26 (9.5)	.011
Membranous septum measurements used to determine depth of implant during the TAVR procedure[a]	54 (43.5)	109 (41.9)	.763
Resheathing	39 (31.2)	42 (15.3)	<.001
Full recapture used	47 (37.6)	64 (23.3)	.003
Valve migration	3 (2.4)	1 (0.4)	.058
Valve embolization	0 (0.0)	1 (0.4)	.500
Ectopic valve deployment	0 (0.0)	0 (0.0)	NA
TAV in TAV deployment	1 (0.8)	1 (0.4)	.567
Noncoronary implant depth, mm (core laboratory)	4.1 ± 3.2	2.6 ± 2.8	<.001
Embolic protection device used	44 (35.2)	91 (33.1)	.679
EP study completed before discharge	5 (4.0)	0/274 (0.0)	.003
Discharged with an external continuous ECG monitoring system	60 (48.0)	24/274 (8.8%)	<.001
Time from index procedure to discharge, d	2.0 (1.0-2.0)	1.0 (1.0-1.0)	<.001

Continuous variables are means ± SD or median (Q1-Q3). Categorical data are n (%).
EP, electrophysiology; TAV, transcatheter aortic valve; TAVR, transcatheter aortic valve replacement.
[a] Site reported the use of the sponsor provided membranous septum length to decide on the depth of implant.

patients in the routine care pathway ($P = .334$). Patients in the CD algorithm experienced similar 30-day all-cause mortality, all-stroke, reintervention, and bleeding complications compared with patients in the routine care pathway (Table 3). PPI for new-onset or worsening CD was higher in the CD algorithm cohort (28.1% vs 1.5%; $P < .001$). Hospital readmission rates were also higher in the CD group (14.5% vs 8.1%; $P = .047$). Of the 399 patients discharged, none experienced sudden cardiac death by 30 days.

PPI and CD resolution

In the CD group, 29 of the 125 patients received PPI by discharge. PPI rates varied by the CD subgroup: 2 (2.7%) of the 73 patients with new-onset LBBB; 13 (38.2%) of the 34 patients with ECG changes in the setting of preexisting RBBB, LBBB, IVCD, or first-degree AVB; and 14 (77.8%) of the 18 patients with periprocedural HAVB. Five of the patients who received a pacemaker had undergone an EP study.

At 30 days, 35 (28.0%) of the 125 patients in the CD algorithm cohort had undergone PPI compared with 4 (1.5%) of the 275 in the routine care pathway cohort (Figure 2). At discharge, 23 (82.1%) of the 28 patients in the CD algorithm group were reported to show a paced rhythm and sites reported 23 (71.9%) of the 32 patients were paced at 30 days. Approximately half of new ECG changes identified on the 2-hour ECG had resolved (Table 4), and the most common rhythm abnormality was LBBB (Figure 3). Of the 6 patients with PPI after discharge, at 2 hours, 3 patients showed new-onset LBBB, 2 new first-degree AVB, and 1 new RBBB. At discharge, 3 patients demonstrated LBBB and 3 first-degree AVB. All patients were discharged to home with telemetry. PPI was implanted on days 3 (2), 4, 6, 8, and 14. All patients underwent implantation owing to AVB.

There were 4 (1.5%) of the 275 PPI events in the routine care pathway cohort. Two occurred before discharge: both patients presented with baseline first-degree AVB with no change at the 2-hour ECG but subsequent progression to second-degree AVB. In the 2 PPI cases after discharge, 1 patient was with baseline RBBB and 1 patient with fascicular block; no new ECG changes were present at 2 hours after TAVR. Both patients experienced syncope after discharge and underwent PPI before the 30-day follow-up visit.

Patients discharged with continuous ECG monitoring

Of the 125 patients in the CD algorithm group, 60 (48.0%) were discharged with a continuous ECG monitor (Figure 4). In these patients, at 2 hours, the ECG showed the following rhythms: 46 new-onset LBBB; 11 ECG changes in the setting of preexisting RBBB, LBBB, IVCD, or first-degree AVB; and 3 periprocedural HAVB. The persistent CD rhythms on discharge ECG were as follows: 30 LBBB, 1 RBBB, 2 AVB, 10 combined bundle and block, and 2 IVCD; 15 patients were discharged with a continuous ECG monitor despite new rhythm abnormalities that subsequently resolved. Within 30 days of discharge, 6 patients (10.0%) with a continuous ECG monitor underwent PPI; at discharge, 3 of these patients showed new LBBB, 2 combined bundle branch block with first-

Table 3. 30-Day clinical outcomes.

	Conduction disturbance algorithm (n = 125)	Routine care pathway (n = 275)	*P*
All-cause mortality or all-stroke	3 (2.4)	12 (4.4)	.334
All-cause mortality	1 (0.8)	2 (0.7)	.940
Stroke	2 (1.6)	10 (3.6)	.266
Disabling stroke	0 (0.0)	3 (1.1)	.242
Reintervention	1 (0.8)	0 (0.0)	.139
Bleeding complications	6 (4.8)	15 (5.5)	.783
Life threatening or disabling	1 (0.8)	6 (2.2)	.330
Major	5 (4.0)	7 (2.6)	.436
Minor	1 (0.8)	3 (1.1)	.786
Acute kidney injury	5 (4.0)	2 (0.7)	.020
Myocardial infarction	0 (0.0)	4 (1.5)	.176
Valve thrombosis (clinical)	0 (0.0)	1 (0.4)	.500
PPI (for new-onset or worsening conduction disturbance)[a]	35 (28.1)	4 (1.5)	<.001
New-onset LBBB[b]	79 (65.3)	3 (1.1)	<.001
Hospital readmission[b]	18 (14.5)	22 (8.1)	.047
Cardiovascular hospitalizations	11 (8.9)	13 (4.8)	.110

Discharge values presented as n (%). The 30-day events are Kaplan-Meier rates presented as no. of participants (%). Patients with baseline permanent pacemaker implant (PPI) were excluded from the study.
LBBB, left bundle branch block.
[a] Of 39 total new PPI in both groups, 8 occurred after discharge and before 30 days. Seven of the 8 were discharged with continuous ECG monitor; no deaths occurred. [b] Site reported.

Table 4. ECG changes by conduction disturbance subgroup at discharge.

	New-onset LBBB (n = 73)	ECG changes with preexisting RBBB, LBBB, IVCD, or first-degree AVB (n = 34)	Periprocedural HAVB (n = 18)	Total (N = 125)
PPI	2	13	14	29
Resolved	31	10	2	43
Persistent	38	10	2	50
Evolved	2	1	0	3

Resolved was defined as a new CD ECG change that was no longer present. Persistent was defined as a new CD ECG finding that continued to be present or unchanged. Evolved was defined as a change from a new CD ECG change to a different CD ECG feature.
AVB, atrioventricular block; CD, conduction disturbance; ECG, electrocardiogram; HAVB, hemi-atrioventricular block; IVCD, interventricular conduction delay; LBBB, left bundle branch block; RBBB, right bundle branch block; PPI, permanent pacemaker implantation.

degree AVB, and 1 first-degree AVB. By contrast, 54 (90.0%) of the 60 patients discharged with a monitor did not require PPI, and through 30 days, 21 (39.6%) of the 53 conduction abnormalities resolved, 31 (58.5%) of the 53 persisted, 1 (1.9%) of the 53 evolved to a different rhythm, and 1 patient had missing ECG data.

Discussion

The Optimize PRO study is among the first to prospectively implement a CD algorithm to stratify patients who may be at high risk for new PPI versus those without CD who can be safely discharged the next day. Among 400 patients who underwent TAVR with Evolut PRO/PRO+ valves in North America, approximately a third of patients were assigned to the CD algorithm based on the 2-hour postprocedural ECG, with most having new-onset LBBB. Patients in the CD algorithm group more frequently underwent PPI before discharge (23.2% vs 0.7%) with most being paced at 30-day follow-up. Patients stratified to the CD algorithm but not meeting criteria for new PPI were safely discharged with a monitor, and 90% of these patients did not require a pacemaker by the 30-day follow-up. Resheathing and recapture use and postimplant dilatation were higher in the group with CDs, which may reflect more complex patient anatomy. Procedure time for patients in the CD group was higher than procedure time for those in the routine care pathway group and might be consistent with higher acute kidney injury at 30 days. Outcomes were similar at 30 days for mortality, stroke, and reintervention in both cohorts, and no patient experienced sudden cardiac death.

The Optimize PRO study used 2 strategies to decrease PPI after TAVR: the intraprocedural use of the COT to achieve shallow implantation depth and the postprocedural implementation of the CD algorithm. As previously reported, the combined strategy resulted in a 9.8% PPI rate at 30 days, which was further reduced to 5.4% if the 4 key steps of the COT were followed. This represents the lowest PPI rate demonstrated in a large, multicenter, prospective study of TAVR with the self-expanding Evolut platform.[8] By comparison, recent TVT registry data report that 10.8% of the patients without PPI at baseline who underwent TAVR with Evolut were implanted with a new pacemaker by 30-day follow-up.[10] Certainly, the transition to the COT that was published in 2018 contributed to the

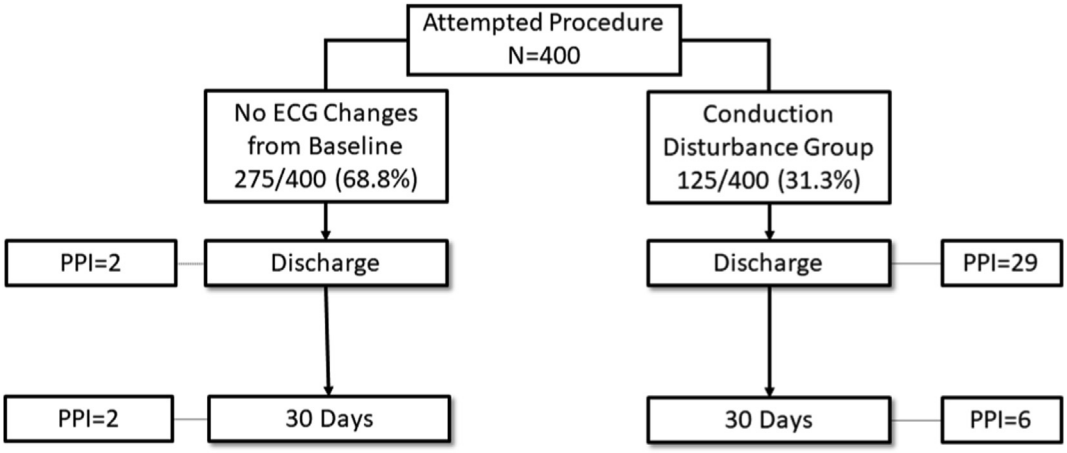


Figure 2.
Permanent pacemaker implantation in groups with and without 2-hour ECG changes. Permanent pacemaker implantation at 30 days reflects additional PPI to those implanted before discharge. AVB, atrioventricular block; ECG, electrocardiogram; PPI, permanent pacemaker implantation.

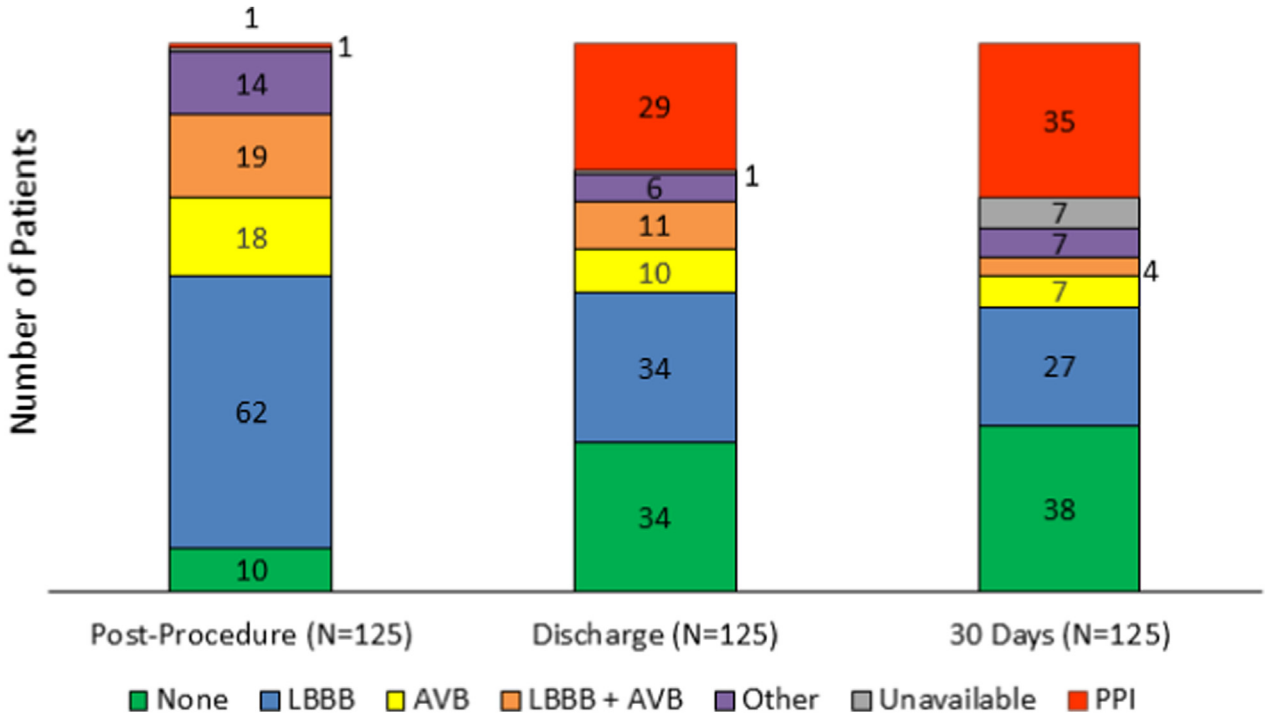


Figure 3.
Summary of patients in the conduction disturbances algorithm after TAVR with Evolut. Rhythm changes in the conduction disturbance cohort by 30 days. Other includes interventricular conduction delay, right bundle branch block, or left ventricular fascicular block. AVB, atrioventricular block; LBBB, left bundle branch block; PPI, permanent pacemaker implantation.

decreased PPI rates[11] but does not solely explain the improvements demonstrated in this study.

The impetus to institute the CD algorithm in the Optimize PRO study stemmed from a perception that self-expanding valves would have higher rates of late CDs that could result in sudden death. Before the study, some heart teams used a strategy of early PPI to expedite discharge and alleviate the concern for late heart block; this concern has been shown by this study to be largely unfounded. In this context, the 2-hour postprocedural ECG identified patients with concerning new conduction disorders promptly after valve implantation, but at a time point at which any transient procedure–related conduction abnormality would likely have resolved. This allowed for close monitoring and planning for a safe and timely discharge, whereas reserving PPI for cases where truly required. In the routine care pathway, patients with preexisting CD (except RBBB) and no ECG change at 2 hours post-procedure could be safely discharged the next day. Only 2 of these patients ultimately required PPI, thus demonstrating the effectiveness of the algorithm. A third of the patients in the study met CD algorithm criteria and were monitored for up to 48 hours, and most were successfully discharged without PPI with a median length of stay of 2 days.

It is worth mentioning that only 8 patients in the study required PPI from the time of discharge to 30-day follow-up, 7 of whom were

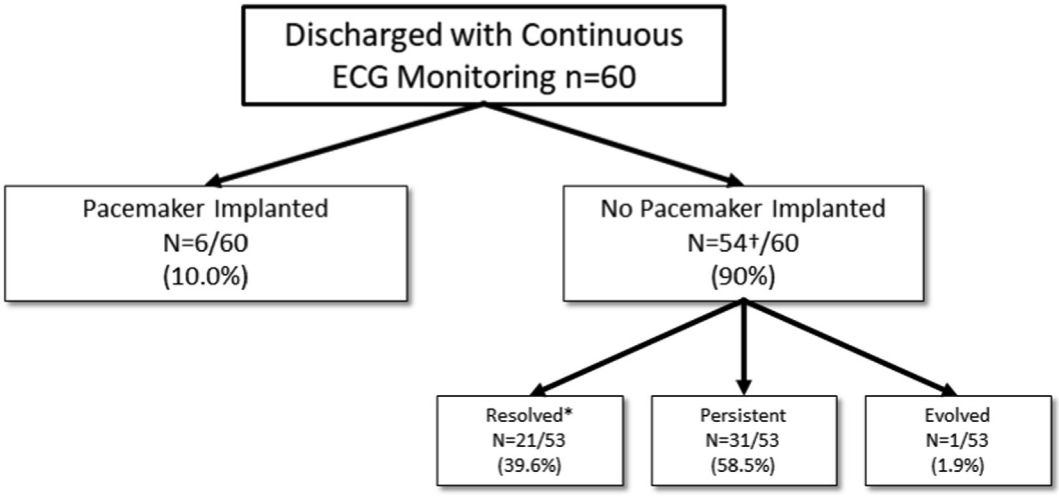


Figure 4.
Patients in the conduction disturbance algorithm with continuous ECG monitoring after discharge. ECG rhythm changes at 30 days after discharge with continuous ECG monitoring. Resolved was defined as a new CD ECG change that was no longer present. Persistent was defined as a new CD ECG finding that continued to be present and unchanged. Evolved was defined as a change from a new CD ECG to a different CD ECG feature. *One patient partially resolved from LBBB to IVCD between 2 hours and discharge. †One patient with ECG missing. CD, conduction disturbance; ECG, electrocardiogram; IVCD, interventricular conduction delay; LBBB, left bundle branch block.

discharged with a continuous ECG monitor. Per the algorithm, patients with new LBBB (73/125) followed the CD algorithm; however, only 2 patients showed a progressive arrhythmia requiring PPI before discharge and 3 more who were monitored underwent PPI for third-degree AVB before 30 days. For patients with new LBBB after Evolut, many (43.7% in this study) will resolve uneventfully. Moreover, 24 patients in the routine care pathway group, at the discretion of the local heart team, were discharged with a continuous ECG monitor and only 1 ultimately required PPI. Routine monitoring in patients with preexisting or new CD post-TAVR has been discussed extensively, with recommendations for the use of ambulatory ECG monitoring, particularly in patients with preexisting RBBB or progression of a baseline CD.[12] However, there is little in the way of randomized controlled data supporting current practices.

It is possible that the option to perform an EP study to determine the necessity for a PPI was underused in this North American cohort of patients. Only 5 patients underwent an EP study, and all 5 underwent PPI before discharge. We hope to understand the utility of the EP study on a global scale when the study completes enrollment of all 650 patients.

We believe that the data from this North American analysis of the Optimize PRO study are important to disseminate to implanters because the study reinforced the need for a thoughtful approach to PPI after Evolut implantation. Using a prespecified CD algorithm simplifies the periprocedural care of patients and could facilitate early discharge of appropriate patients and decrease unnecessary PPI in patients with CD.

Limitations

This interim analysis included the first 400 main cohort patients in the Optimize PRO study implanted in North America. The complete data set will represent a global assessment of the standardized CD algorithms in a much broader patient population. Results may vary depending on regional expertise and compliance with the algorithm. Other limitations to note include, first, the STS Predicted Risk of Mortality was collected rather than heart team surgical risk score. Second, the study excluded patients with bicuspid aortic valves, low ejection fraction, or significant calcification extending into the left ventricular outflow tract; thus, the results may not be generalizable to these patient populations. Third, the 2-hour postprocedure ECG interpretation was site reported with no additional core laboratory analysis on the confirmation of appropriate CD algorithm or compliance to the algorithm, thus may introduce bias. Fourth, owing to variability in types of devices implanted, we are unable to provide the amount of pacing for patients during the 30 days of follow-up. Detailed per-patient cost data were unavailable, limiting an economic analysis and additional related discussion. Finally, because study enrollment primarily occurred during the early phase of the COVID-19 pandemic, patient selection could have been biased, but follow-up was routinely completed.

Conclusions

Use of a standardized algorithm for management of CDs after TAVR with Evolut provides similar 30-day safety outcomes compared with patients without CDs who underwent routine next day discharge. The CD algorithm may provide an effective strategy to recognize CDs early, improve PPI utilization in patients with persistent CDs, and maintain safe monitoring of patients after discharge.

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Declaration of competing interest

Kendra Grubb is a proctor, a principal investigator, and on the advisory board for Medtronic and serves on the advisory board of or is a consultant for Ancora Heart, Boston Scientific, Abbott, 4C Medical, and Edwards Lifesciences. Steven Yakubov has received institutional research grants from Medtronic and serves on an advisory board for Medtronic and Boston Scientific. Tamim Nazif is consultant for and has received institutional grants from Edwards Lifesciences, Medtronic, and Boston Scientific. Suneet Mittal has received honoraria/consultant fees from Abbott, Boston Scientific, and Medtronic. Hemal Gada has served as a consultant to Abbott, Bard Medical Corporation, Boston Scientific, Edwards Lifesciences, and Medtronic. Douglas Fraser is a proctor for Medtronic and receives speaker fees from Edwards Lifesciences and Medtronic. Joshua Rovin is a physician proctor with and a consultant for Medtronic and Abbott. Samin Sharma has received speakers bureau fees from Abbott Vascular, Boston Scientific, and Cardiovascular Systems. Jian Huang is an employee and shareholder of Medtronic. Josep Rodes-Cabau has received institutional research grants and consultant/speaker fees from Edwards Lifesciences and Medtronic. All other authors have reported that they have no relationships relevant to the contents of this article to disclose.

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Ethics statement and patient consent

Local institutional review committee approval was obtained, including written patient informed consent. The trial adhered to the principles of the Declaration of Helsinki.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2023.101066.

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