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Management of Conduction Disturbances Associated With Transcatheter Aortic Valve Replacement

JACC Scientific Expert Panel

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ABSTRACT

Despite major improvements in transcatheter aortic valve replacement (TAVR) periprocedural complications in recent years, the occurrence of conduction disturbances has not decreased over time and remains the most frequent complication of the procedure. Additionally, there has been an important lack of consensus on the management of these complications, which has indeed translated into a high degree of uncertainty regarding the most appropriate treatment of a large proportion of such patients along with major differences between centers and studies in pacemaker rates post-TAVR. There is therefore an urgent need for a uniform strategy regarding the management of conduction disturbances after TAVR. The present expert consensus scientific panel document has been formulated by a multidisciplinary group of interventional cardiologists, electrophysiologists, and cardiac surgeons as an initial attempt to provide a guide for the management of conduction disturbances after TAVR based on the best available data and group expertise. (J Am Coll Cardiol 2019;74:1086–106) © 2019 by the American College of Cardiology Foundation.

Transcatheter aortic valve replacement (TAVR) is a well-established alternative to surgery for the treatment of patients with severe aortic stenosis at increased surgical risk (1,2), and the results of 2 recent trials have established the basis for expanding this therapy towards a lower risk population (3,4). Although successive iterations in transcatheter heart valve (THV) systems along with increasing experience of the heart teams have translated into a reduction of the majority of periprocedural complications and death, the occurrence of conduction disturbances (i.e., high-degree

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HIGHLIGHTS

- A lack of consensus and large variability in the management of conduction disturbances post-TAVR exists.
- This paper provides an algorithm strategy proposal for managing conduction disturbances post-TAVR.
- Future studies need to validate the proposed algorithm and determine the role of EP studies, ambulatory continuous ECG monitoring, and prophylactic pacemaker in the management of conduction disturbance in post-TAVR patients.

atrioventricular block [HAVB] or complete heart block [CHB]) requiring permanent pacemaker implantation (PPM) and new-onset left bundle branch block [LBBB]) has not decreased over time and remains the most frequent shortcoming of the procedure (5,6), with some recent reports suggesting an increased risk associated with some newer-generation THVs (6,7). Additionally, there has been an important lack of consensus on the management of this complication (8), which has indeed translated into major differences between centers and studies in PPM rates post-TAVR, even with the use of similar THV systems (6,7). This heterogeneity partially relates to pre-procedural arrhythmic risk evaluation, management of new-onset LBBB, timing and indication for PPM in patients with periprocedural HAVB/CHB, and the management of patients with prior conduction disturbances such as right bundle branch block (RBBB). Differences in the management of conduction disturbances can have major consequences in the hospitalization length and costs of the TAVR procedure and may also affect clinical outcomes. These differences also prevent appropriate evaluation of the safety and efficacy of different strategies for managing conduction disturbances in a large cohort of patients from multiple centers. There is therefore a need for a uniform strategy regarding the management of conduction disturbances post-TAVR. The present expert scientific panel document has been formulated by a multidisciplinary group of interventional cardiologists, electrophysiologists, and cardiac surgeons as an attempt to provide a guide for the management of conduction disturbances post-TAVR based on the best available data and group expertise.

The definitions of conduction disturbances in the context of TAVR are summarized in **Table 1** (9,10).

MANAGEMENT OF CONDUCTION DISTURBANCES IN TAVR RECIPIENTS

PRE-PROCEDURAL RISK EVALUATION. An evaluation of the risk of conduction disturbances should be performed pre-procedure to facilitate procedural planning. The main pre-procedural factors associated with an increased risk of conduction disturbances post-TAVR are shown in Online Table 1. The presence of RBBB appears to be the strongest and most consistent risk factor, leading to an increased risk of PPM of at least 3 times and up to 47 times (Online Table 1). Also, a recent study showed that RBBB was associated with an increased risk of early and late mortality following TAVR (11). The presence of first-degree AVB has also been associated with an increased risk (4 to 11 times) of HAVB in some studies (Online Table 1); however, this has been much less consistent than RBBB, with multiple studies failing to demonstrate a significant association between first-degree AVB and an increased risk of conduction disturbances post-TAVR (12–14). The presence of pre-procedural LBBB or left anterior hemiblock have also been identified as risk factors for HAVB/CHB and PPM post-TAVR, but the data is restricted to 2 studies and lacks consistency (15,16). Interestingly, some studies have shown the potential utility of using anatomical factors determined by computed tomography (membranous septum length, calcium volume, noncoronary cusp device-landing zone calcium volume) in the risk evaluation of conduction disturbances (17–20). Data are still limited, however, and more studies are needed before the implementation of pre-procedural computed tomography for risk evaluation of conduction disturbances in TAVR candidates.

The pre-procedural risk, and particularly the presence of RBBB, should be acknowledged and patients properly informed of the (high) risk of PPM following TAVR in these cases. We also consider that the presence of RBBB may be included in the clinical decision-making process in those patients with a surgical option (i.e., low-to-intermediate surgical risk) (12). Although some studies have shown an increased risk of PPM in SAVR recipients with pre-existing RBBB, the rate of PPM in such cases has been <10% to 20% (21,22) compared with the nearly systematic >25% rate in RBBB-TAVR patients (11,19,23–28).

PRE-PROCEDURAL ELECTROCARDIOGRAM MONITORING. The advanced age of most TAVR candidates along with the presence of calcific aortic stenosis are

ABBREVIATIONS AND ACRONYMS

CHB = complete heart block
ECG = electrocardiography
EP = electrophysiologic
HAVB = high-degree atrioventricular block
ICD = implantable cardioverter-defibrillator
IVCD = intraventricular conduction delay
LBBB = left bundle branch block
LVEF = left ventricular ejection fraction
PPM = permanent pacemaker implantation
RBBB = right bundle branch block
TAVR = transcatheter aortic valve replacement
THV = transcatheter heart valve

TABLE 1 Conduction Disturbances After TAVR: Definitions

Conduction tissue abnormalities (infra nodal block) definitions (9,10)	
RBBB	• QRS duration ≥120 ms. • rsr′, rsR′, rSR′, or rarely a qR in leads V_1 or V_2. The R′ or r′ deflection is usually wider than the initial R-wave. • In a minority of patients, a wide and often notched R wave pattern may be seen in lead V_1 and/or V_2. • S-wave of greater duration than R-wave or >40 ms in leads I and V_6. • Normal R peak time in leads V_5 and V_6 but peak R-wave >50 ms in lead V_1.
LBBB	• QRS duration ≥120 ms. • Broad notched or slurred R-wave in leads I, aVL, V_5, and V_6 and an occasional RS pattern in V_5 and V_6 attributed to displaced transition of QRS complex. • Absent Q waves in leads I, V_5, and V_6, but in the lead aVL, a narrow Q-wave may be present in the absence of myocardial pathology. • R peak time >60 ms in leads V_5 and V_6 but normal in leads V_1, V_2, and V_3, when small initial R waves can be discerned in the precordial leads. • ST and T waves usually opposite in direction to QRS.
Left anterior hemiblock	• QRS duration <120 ms. • Frontal plane axis between −45° and −90°. • qR pattern in lead aVL. • R-peak time in lead aVL of ≥45 ms. • rS pattern in leads II, III, and aVF.
Left posterior hemiblock	• QRS duration <120 ms. • Frontal plane axis between 90° and 180°. • rS pattern in leads I and aVL. • qR pattern in leads III and aVF.
Nonspecific intraventricular conduction disturbance with QRS interval ≥120 ms	QRS interval duration ≥120 ms where morphology criteria for RBBB or LBBB are not present.
Atrioventricular block definitions (9,10)	
First-degree atrioventricular block	P waves associated with 1:1 atrioventricular conduction and a PR interval >200 ms.
HAVB	HAVB is defined as any of the following: • Second-degree AV block type 2 (Mobitz II) in the presence of a QRS ≥120 ms. • 2:1 AV block in the presence of a QRS ≥120 ms. • ≥2 consecutive P waves at a constant physiologic rate that do not conduct to the ventricles. • Transient third-degree AV block. • In the setting of AF, a prolonged pause (>3 s) or a fixed slow (<50 beats/min) ventricular response rate.
Third-degree atrioventricular block (CHB)	P waves with a constant rate with dissociated ventricular rhythm (no association between P waves and R waves) or fixed slow ventricular rhythm in the presence of atrial fibrillation.
Periprocedural conduction abnormalities according to time apparition	
Procedural HAVB/CHB	Any HAVB/CHB episode occurring during the TAVR procedure (before the patient leaves the procedure room).
Delayed HAVB/CHB	Any HAVB/CHB episode occurring after the TAVR procedure (any HAVB/CHB occurring after the patient has left the procedure room).
New-onset conduction disturbances post-TAVR	Any conduction disturbance that occurs in the periprocedural TAVR period (procedure + hospitalization period).
New-onset persistent conduction disturbances	Any conduction disturbance that occurs during the periprocedural TAVR period (procedure + hospitalization period) and persists at hospital discharge (or until day 7 post-TAVR in case of prolonged hospitalization).

CHB = complete heart block; HAVB = high-degree atrioventricular block; LBBB = left bundle branch block; RBBB = right bundle branch block; TAVR = transcatheter aortic valve replacement.

associated with an increased risk of conduction disturbances independent from TAVR (29). Thus, some relevant conduction issues may be present before TAVR but remain silent and are detected only after the procedure because of the systematic post-procedural electrocardiogram (ECG) monitoring. Urena et al. (30) showed that close to one-third of the patients requiring PPM post-TAVR exhibited episodes of HAVB/CHB or severe bradycardia diagnosed by 24-h continuous ECG monitoring pre-TAVR. Several studies are currently determining the usefulness of different systems allowing for longer periods (1 to 4 weeks) of ECG monitoring pre-TAVR. The detection of pre-procedural conduction abnormalities would permit implementation of the appropriate therapies (i.e., PPM or changes in medical therapy) before the procedure; this might reduce both the global rate of PPM post-TAVR and hospitalization length. While awaiting the results of ongoing studies, continuous ECG monitoring (minimum of 24 h) before TAVR may be considered to facilitate early diagnosis and treatment of conduction issues and improve the post-procedural management of TAVR recipients. In these cases, current guidelines should be followed for

implementing the most adequate treatment in the presence of significant bradyarrhythmias (10,31). The type and duration of continuous ECG monitoring pre-TAVR should be determined by the experience and available ECG monitoring systems in each center. In patients hospitalized ≥24 h pre-TAVR, the use of in-hospital telemetry may be an alternative to other ECG monitoring systems.

PROCEDURAL CONSIDERATIONS. Certain modifiable aspects of the TAVR procedure have been implicated in the occurrence of conduction disturbances and PPM post-TAVR and should be taken into consideration when planning the procedure, particularly in patients with an intrinsic increased risk (Online Table 1).

Balloon valvuloplasty. Valve pre-dilation before the implantation of the THV (vs. direct THV implantation) may be associated with an increased risk of conduction disturbances (32–34). In fact, about one-half of conduction disturbances (including new-onset LBBB and HAVB/CHB) occur before valve implantation, particularly during valve pre-dilation (especially if the balloon is larger than the minor axis of the aortic annulus) (33,35,36). Also, Campelo-Parada et al. (36) have recently shown that balloon valvuloplasty was associated with an increased risk of persistence of the conduction abnormality. This has been described as a 2-hit model, in which the first hit is inflicted by the valvuloplasty balloon to the conduction system promoting the persistence of high-degree atrioventricular block followed by a second hit by the THV frame. However, this association may be confounded by a higher valve calcification burden among patients undergoing pre-dilation. Three ongoing randomized trials are comparing TAVR with and without balloon pre-dilation and should shed more light on this topic.

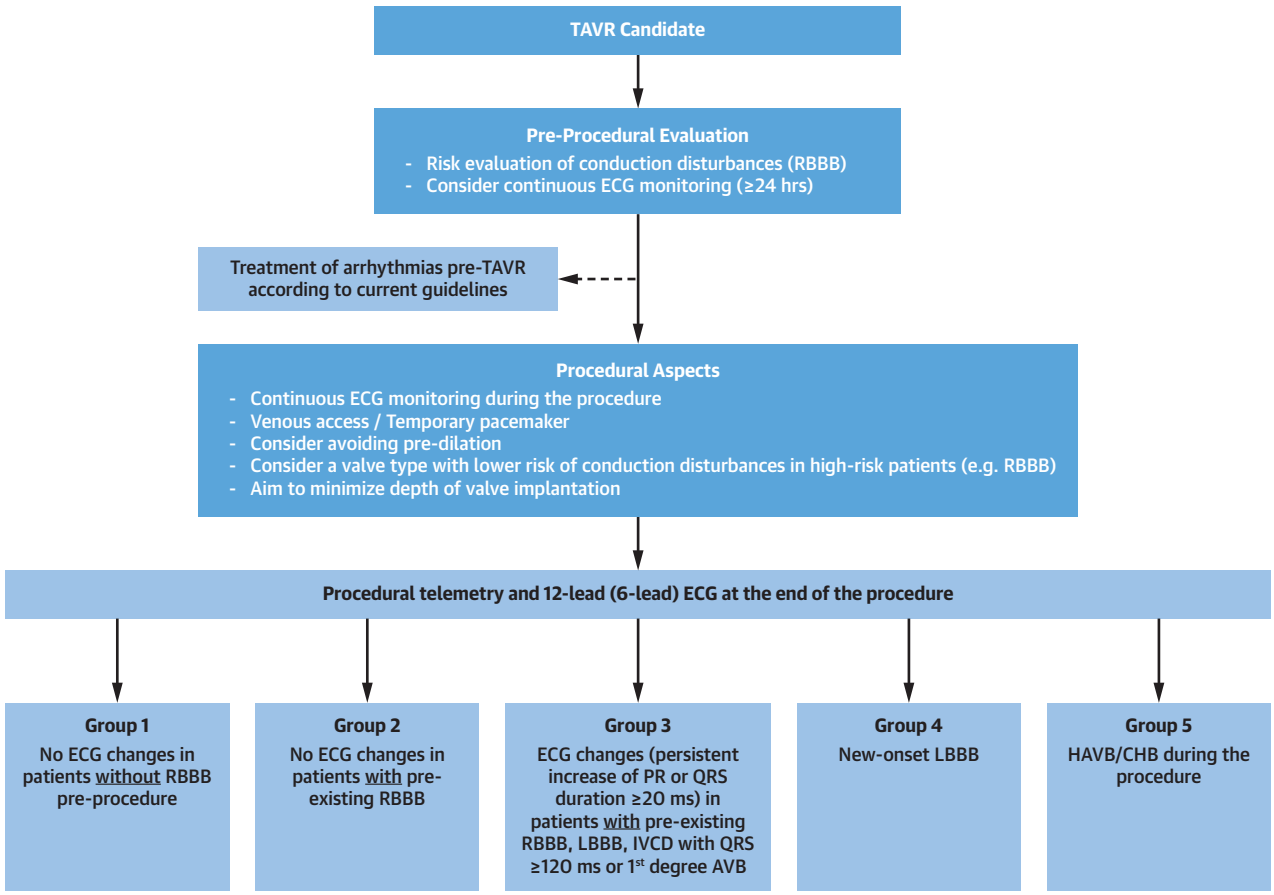
THV type. Although data on conduction disturbances and PPM with the use of newer-generation THV systems are scarce, some (a minority) newer devices have been associated with lower PPM rates (mean incidence <10%) post-TAVR (Online Figure 1A), and may be considered, particularly in the presence of increased risk features pre-TAVR (Online Table 1). There is, however, scarce randomized comparative evidence on which to base this recommendation. The recently reported SOLVE-TAVI (Second-generation Self-expandable Versus Balloon-expandable Valves and General Versus Local Anesthesia in TAVI) randomized trial showed a slightly higher PPM rate in Evolut R versus SAPIEN 3 recipients (37). Also, other characteristics of the THV and delivery system, valve performance, and experience of the heart team with each system should be included in the decision-making process regarding the selection of the THV type. Of note, no definite data exist to date on the potential differences among newer-generation transcatheter valves regarding the pattern of evolution (progression-regression) of conduction disturbances over time; thus, the recommendations provided in this document apply to all transcatheter valve types, with no specific differentiation according to valve type. However, local experience with post-TAVR conduction disturbances according to valve type may influence transcatheter valve selection.

Valve positioning. Multiple studies have shown that valve implantation depth is an important risk factor for conduction disturbances. Thus, a higher (more aortic) valve positioning is associated with a lower risk of conduction disturbances post-TAVR (Online Table 1). Whereas the implantation depth cutoff may vary among different valve systems, an implantation depth >5 to 7 mm below the aortic annulus has been nearly systematically associated with an increased risk of new-onset LBBB and need for PPM post-TAVR. This procedural aspect should be strongly considered by TAVR operators to reduce the risk of conduction disturbances post-TAVR.

Other procedural factors such as a higher degree of valve oversizing or the use of larger valves have also been associated with a higher risk of conduction disturbances in some studies (6). Although temporary discontinuation of the drugs with potential negative chronotropic effects has been suggested during the periprocedural TAVR period, no definite evidence supports this recommendation, and some studies have shown an increased risk of arrhythmias associated with beta blocker withdrawal pre-TAVR (38).

PROCEDURAL ECG MONITORING, TEMPORARY PACEMAKER. All patients should have continuous ECG monitoring during the TAVR procedure. A temporary pacing wire is usually implanted in the right ventricle at the beginning of the procedure. Alternatively, the wire placed in the left ventricle (mandatory for valve implantation with all current transcatheter valve systems) may be used for temporary pacing (39). In these cases, obtaining central venous access (femoral, jugular) at the beginning of the procedure may be recommended (even if no temporary pacing wire is placed in the right ventricle at the beginning of the procedure), considering that an urgent need for temporary pacing may occur any time during the procedure (including at delivery system/left ventricle wire retrieval). The recently reported results of the EASY-TAVI (Direct Left Ventricular Rapid Pacing Via the Valve Delivery Guide-wire in TAVI) trial, in which

FIGURE 1 **Pre-Procedural and Procedural Aspects Regarding Conduction Disturbances in TAVR Recipients**



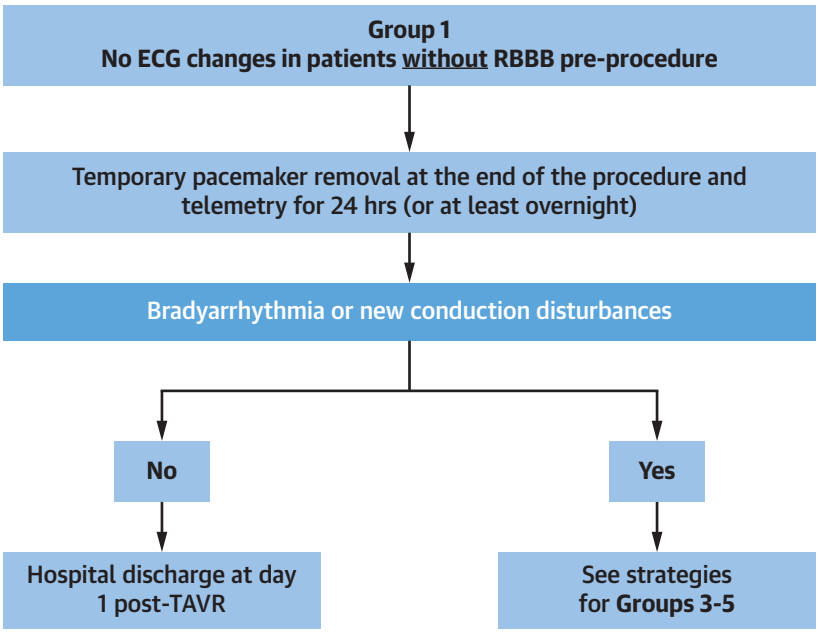
AVB = atrioventricular block; HAVB/CHB = high-degree atrioventricular block/complete heart block; IVCD = intraventricular conduction delay; LBBB = left bundle branch block; RBBB = right bundle branch block; TAVR = transcatheter aortic valve replacement.

300 patients were randomized to rapid pacing with the left ventricle wire versus standard right ventricle pacing, showed similar rates of successful pacing and a decrease in procedural time associated with left ventricular pacing (40). More studies are needed to confirm this technique as a definite alternative to the standard right ventricular temporary pacing.

At the end of the procedure and just before removing the temporary pacing wire/central venous access, a 12-lead ECG can be obtained. This ECG is important because it will determine the need for temporary pacing following the procedure. If a 12-lead ECG cannot be performed in the procedure room (cath laboratory, hybrid or operating room), at least a 6-lead ECG (with no precordial leads) can be obtained through the continuous ECG monitoring system to determine the presence of conduction disturbances before the patient leaves the procedure room. In such cases, a complete 12-lead ECG may be obtained as soon as possible once the patient has left the procedure room.

According to ECG changes/arrhythmias during the procedure and the analysis of the ECG at the end of the procedure, the patients may be categorized in 5 groups: 1) no ECG changes in patients without RBBB pre-procedure (irrespective of the presence of pre-existing conduction disturbances); 2) no ECG changes in patients with RBBB pre-procedure; 3) ECG changes (increase ≥20 ms in PR or QRS interval duration) in patients with conduction disturbances (RBBB, LBBB, intraventricular conduction delay [IVCD] with QRS ≥120 ms, or first-degree AVB) pre-procedure; 4) new-onset LBBB that persists at the end of the procedure; or 5) transient or persistent HAVB during the procedural period. Data on pre-procedural and procedural considerations regarding conduction disturbances in TAVR recipients are summarized in **Figure 1**.

FIGURE 2 Strategy Algorithm Proposal for the Management of Patients With no ECG Changes Post-TAVR in the Absence of Pre-Existing RBBB



RBBB = right bundle branch block.

Although the proposed treatment algorithm should cover the vast majority of conduction disturbances post-TAVR, it is not possible to anticipate all potential combinations of different types and timing of conduction disturbances post-procedure. Also, this document focuses on the management of conduction disturbances potentially related to the TAVR procedure; thus, patients with prior pacemaker are not included in this treatment algorithm proposal. Also, no specific recommendation is provided for those patients experiencing severe bradyarrhythmias secondary to sinus node dysfunction. In these cases, indications for PPM should follow current guidelines recommendations (10,31). The possibility of bradyarrhythmias likely secondary to a vasovagal mechanism should also be considered before establishing an indication for PPM. Finally, it has to be considered that the risk of conduction disturbances may significantly decrease in some circumstances such as TAVR for treating surgical bioprosthesis dysfunction (valve-in-valve TAVR) (41). Thus, the proposed algorithm may need to be adapted in such cases.

GROUP 1. No ECG changes in patients without pre-existing RBBB (Figure 2). Patients with no new conduction disturbances (first-degree AVB, RBBB, LBBB, QRS ≥120 ms with undefined IVCD) on the ECG performed immediately post-TAVR (and no episodes of HAVB/CHB during the procedure) have a very low risk of developing HAVB/CHB or any conduction disturbance within the hours and days following the procedure (13,42). In these cases, temporary pacing can be safely discontinued at the end of the procedure; however, continuous ECG monitoring until hospital discharge is recommended. Although the risk of any significant bradyarrhythmia is very low in these cases, in-hospital telemetry represents a low-cost measure that can be useful for the detection of any type of arrhythmias (including new-onset atrial fibrillation) (43). A 12-lead ECG is recommended 24 h after the procedure. If no arrhythmic episodes and no ECG changes occur within the 24 h post-procedure, the patient can be safely discharged (the day after TAVR) with no other monitoring measures in case of otherwise uneventful clinical course (absence of other TAVR-related adverse events). If the patient has to remain hospitalized because of other reasons or TAVR complications, telemetry would be recommended (but not strictly required) for the detection of post-TAVR tachyarrhythmias or late ECG changes. In the unlikely situation of significant ECG changes occurring within the 24 h post-procedure

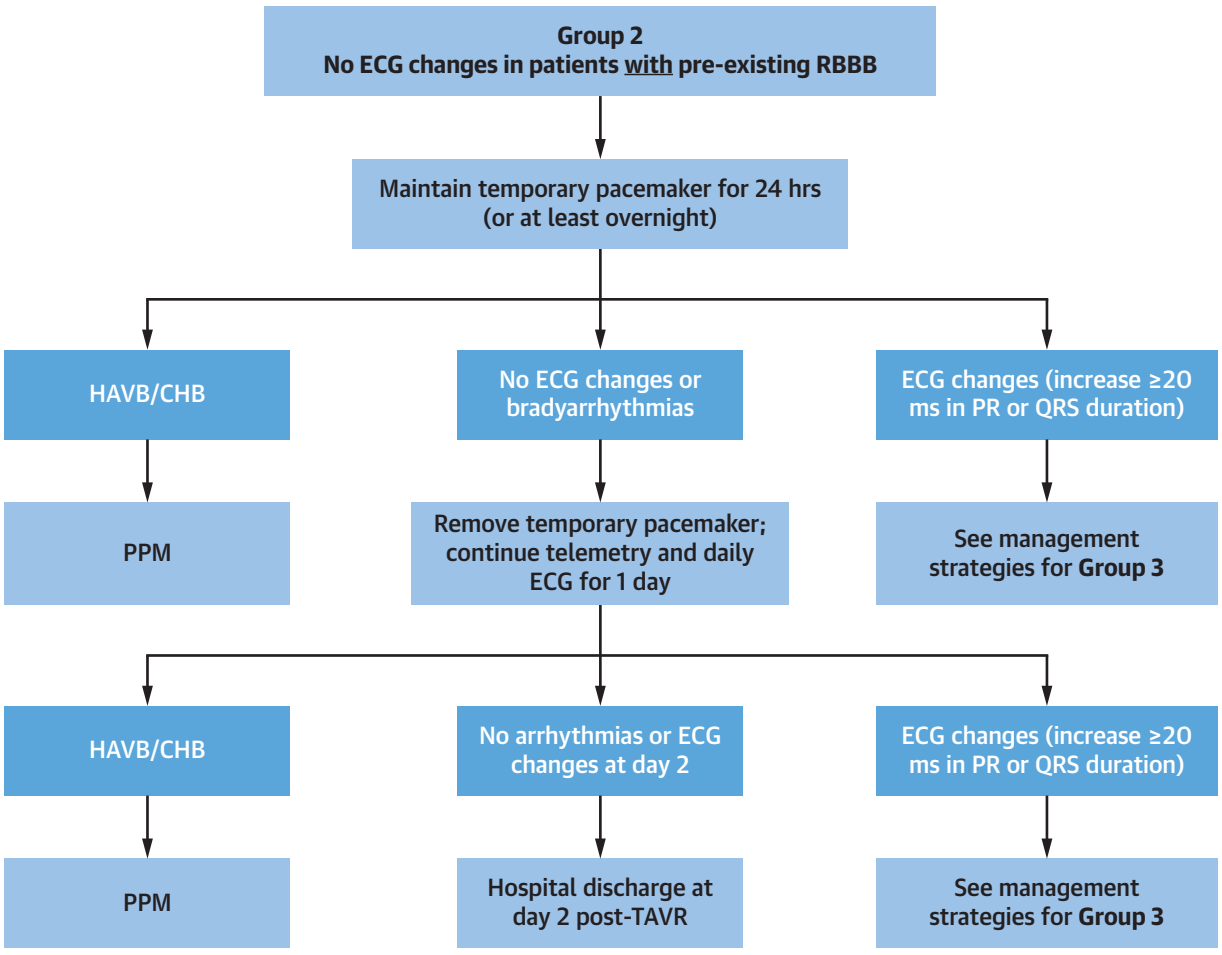
(new-onset LBBB, RBBB, first-degree AVB, HAVB/CHB), patients will be managed according to the ECG changes or arrhythmias algorithms (see management of groups 3 to 5).

Some studies have shown that patients with pre-existing LBBB and/or first-degree AVB with no ECG changes during the TAVR procedure exhibit a modest increase in the risk of further conduction abnormalities leading to the need of PPM post-TAVR (15,16,27,44). However, this increased risk has not been confirmed in other studies (12–14). In fact, in the absence of any significant changes in QRS or PR duration post-TAVR hospitalization, the risk of progression towards HAVB/CHB appears to be modest and, in such cases, the risks of prolonged temporary pacing may not overcome the potential benefits. Thus, we recommend the removal of the temporary pacing wire in these patients and maintaining continuous telemetry and daily ECG for at least 1 day. Several studies have shown that the risk of advanced conduction disturbances is very low beyond the initial 48 to 72 h post-TAVR (12,14,45). Patients can probably be safely discharged post-TAVR if no ECG changes occur at day 1 after the procedure, and hospital discharge at day 2 may also be considered in some cases. If ECG changes or significant bradyarrhythmias occur, the patients can be managed according to these changes (see management of groups 3 to 5). Following hospital discharge, no ECG monitoring is recommended, except for a repeat ECG at 1 and 12 months, and yearly thereafter (an additional ECG and echocardiography examination is also recommended at 3- to 6-month follow-up in those patients with LBBB and reduced ejection fraction to evaluate the need for defibrillator and/or resynchronization therapy).

GROUP 2. Patients with pre-existing RBBB (**Figure 3**). The presence of RBBB remains the most important risk factor for HAVB/CHB and need for PPM following TAVR, and multiple studies in the field have systematically recognized this conduction abnormality as the 1 determining the highest risk for PPM post-TAVR (Online Table 1). Also, a recent study showed that RBBB was associated with an increased risk of early and late mortality following TAVR (11). The increased risk of HAVB in such patients starts at the time of the procedure but persists afterwards, particularly within the initial 2 to 3 days post-procedure (with a peak risk within the first 24 h). Thus, a temporary pacing wire is recommended to be maintained for 24 h (or at least overnight) in all patients with prior RBBB, along with telemetry and daily ECG during the entire hospitalization period (minimum of 2 days). The risks of prolonging temporary pacing beyond the first 24 h may overcome the potential benefits. If any ECG changes occur during the initial 2 to 3 days, patients can be managed according to the proposed strategy (see management strategies for groups 3 and 5). If no ECG changes or significant bradyarrhythmias occur within the 2 to 3 days following the procedure, the patient can probably be safely discharged. Considering that the increased risk of life-threatening bradyarrhythmias in these patients may extend beyond the hospitalization period, continuous ECG monitoring systems (minimum of 48 h, up to 4 weeks) may be considered, but no data exist on its safety/efficacy in this subgroup of patients (11,14,42). Despite the increased risk of HAVB/CHB, Auffret et al. (11) showed, in the largest series evaluating the impact of RBBB in TAVR, that about 60% of TAVR candidates with prior RBBB did not require PPM during the hospitalization period, and about one-half of them were free from PPM at 2-year follow-up. Thus, in the absence of randomized data, "prophylactic" PPM in TAVR candidates with RBBB is not recommended. Importantly, the (acute and chronic) morbidity and risks associated with PPM should be taken into account (46), and may not be overcome by its potential benefits in these patients. Further studies are needed to determine the optimal management of this high-risk group of TAVR candidates, as well as the safety of earlier hospital discharge (within 24 h post-TAVR) in such cases.

GROUP 3. ECG changes (persistent increase in PR or QRS duration ≥20 ms) in patients with prior conduction disturbances (pre-existing RBBB, LBBB, nonspecific IVCD with QRS ≥120 ms or 1st degree AVB) (**Figure 4**). Those TAVR candidates with prior conduction disturbances exhibiting ECG changes (but not HAVB/CHB) post-procedure represent the most challenging group regarding temporary and permanent pacemaker recommendations. Apart from the paucity of data, the large variation and degree of ECG changes over time make it very difficult to establish a simple strategy in such patients. Based on the scarce data available, we consider that both the degree of the changes and the final ECG manifestation (PR, QRS duration) may be taken into account. Mangieri et al. (14) showed that a mean increase in PR and QRS interval duration of 40 or 22 ms, respectively, were associated with an increased risk of delayed (>48 h) HAVB/CHB and PPM (however, only the increase in PR duration was retained in the multivariable analysis). On the other hand, Jørgensen et al. (42) showed that patients with a post-procedural PR

FIGURE 3 Strategy Algorithm Proposal for the Management of Patients With Pre-Existing RBBB



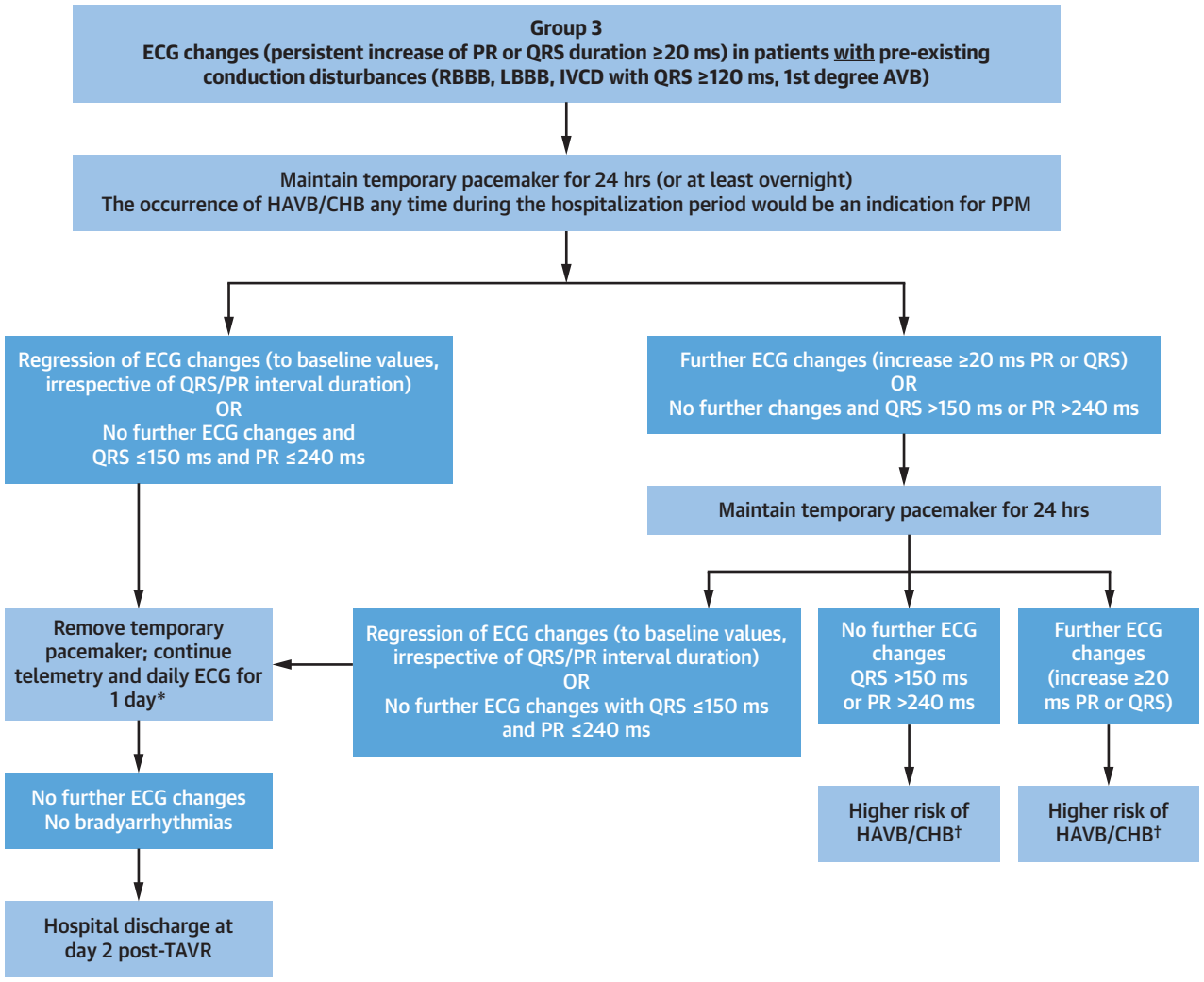
PPM = permanent pacemaker implantation; other abbreviations as in Figure 1.

interval ≥240 ms and/or QRS duration ≥150 ms (140 ms in patients with AF) had a higher risk of delayed HAVB/CHB post-TAVR.

We propose that any significant increase in PR or QRS interval duration (at least 20 ms) with respect to the ECG pre-TAVR may lead to continuing the temporary pacing wire for 24 h (or at least overnight), along with daily ECG and telemetry for a minimum of 1 to 2 days. If the ECG changes regress in <24 h, an earlier removal of the temporary pacing wire may be considered. Also, a strategy of multiple ECGs during the first 24 h to better determine the progressive changes (peak, plateau, regression) of PR and QRS intervals may be considered to facilitate both the clinical decision-making process and early discharge (i.e., 1 day post-TAVR). If ECG changes regress or no further changes occur and the PR and QRS intervals remain ≤240 ms and ≤150 ms, respectively (or >240 ms or >150 ms, respectively, but similar to the baseline ECG), the patient can be discharged with no PPM at 1 to 2 days post-TAVR.

If 24 h post-TAVR, the PR and QRS interval remain stable but >240 or >150 ms, respectively, and ≥20 ms longer than baseline, we recommend maintaining the temporary pacing wire for another 24 h. If no decrease in the PR or QRS duration occurs at day 2, the patient can be considered at risk for more advanced conduction disturbances requiring PPM (HAVB/CHB). No studies have evaluated the best management strategy in these patients. Although the utility of electrophysiologic (EP) studies post-TAVR has been limited to a few and controversial studies, mainly focusing on patients with new-onset conduction disturbances (particularly LBBB) rather than patients suffering

FIGURE 4 Strategy Algorithm Proposal for the Management of Patients With ECG Changes (Increase in PR or QRS Interval Duration ≥20 ms) in the Presence of Conduction Disturbances Pre-TAVR

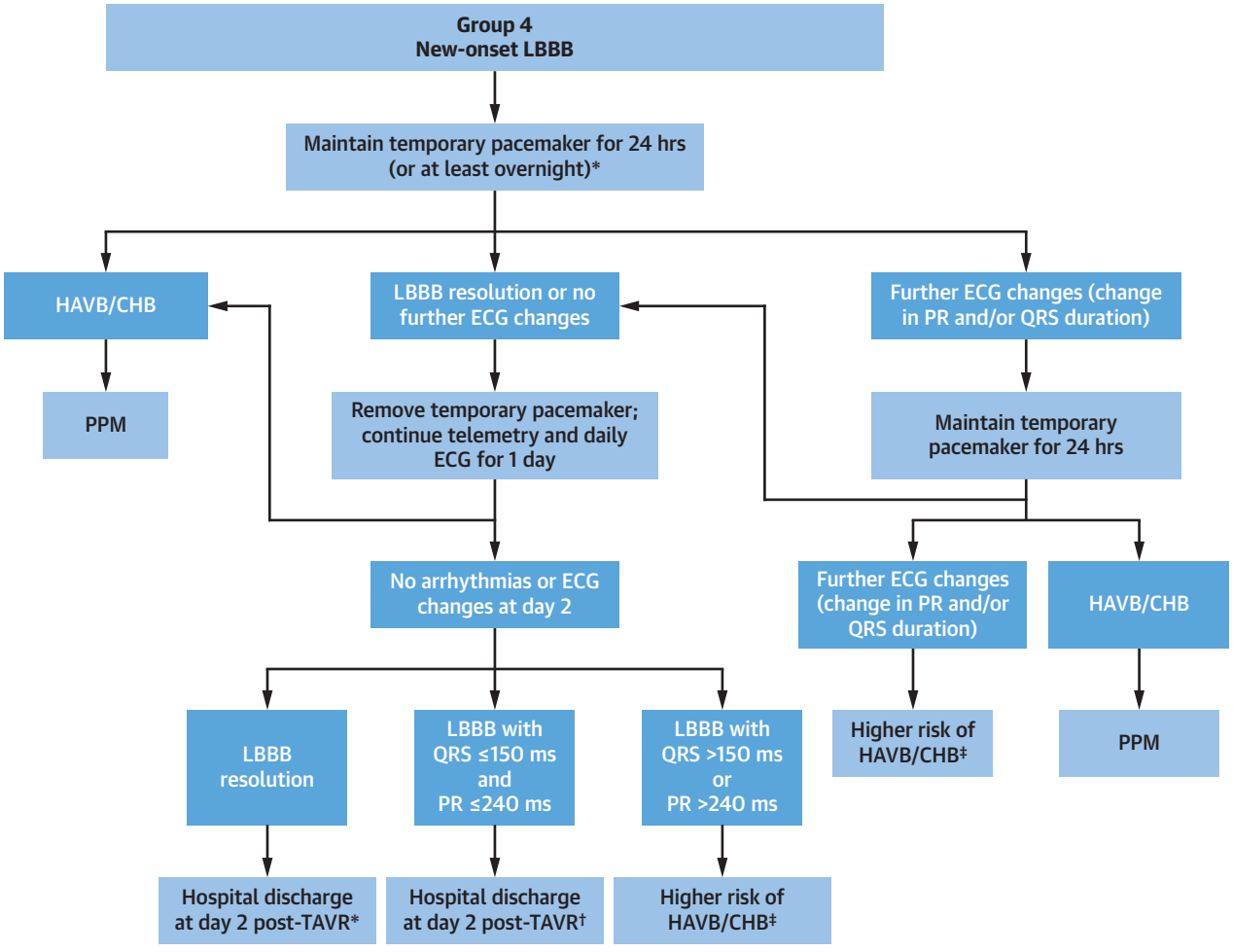


*Consider earlier discontinuation of temporary pacing and discharge at day 1 post-TAVR if regression of ECG changes in <24 h (except for RBBB).
†Consider: 1) invasive EPS to guide the decision about PPM; 2) continuous ECG monitoring; 3) PPM (not in patients with PR >240 ms but QRS <120 ms).

EPS = electrophysiologic study; other abbreviations as in Figures 1 and 3.

from worsening of a prior conduction disturbance (47-50), the use of an EP study may be a reasonable option for deciding PPM in those patients with prior conduction disturbances with worsening of ECG changes post-TAVR. Infra-Hisian block during atrial pacing or a spontaneous HV interval >100 ms may be considered as the cutoff to prompt PPM (51). Also, continuous ECG monitoring at hospital discharge may be considered. Finally, PPM before hospital discharge may also be an option, particularly in those patients combining a QRS interval >150 ms (≥20 ms larger than baseline) and first-degree AVB. No PPM is recommended in those patients with long PR interval (irrespective of the PR interval duration) as the only abnormality (QRS <120 ms). A PPM would also be advised if further increase in the PR or QRS interval occurs within the 2 days following the procedure (with a total increase of ≥30 to 40 ms with respect to prior ECG), irrespective of the final PR or QRS duration. A 48-h delay between the increase in PR or QRS interval

FIGURE 5 Strategy Algorithm Proposal for the Management of Patients With New-Onset LBBB Post-TAVR



*Consider earlier discontinuation of temporary pacing along with hospital discharge at day 1 if partial/complete resolution of LBBB in <24 h.
†Consider continuous ECG monitoring at hospital discharge.
‡Consider: 1) invasive EPS to guide the decision about PPM; 2) continuous ECG monitoring at hospital discharge; 3) PPM.

Abbreviations as in Figures 1, 3, and 4.

duration and PPM is recommended to rule out the possibility of partial or complete regression of the ECG changes. In those patients with first-degree AVB (with stable PR duration for at least 48 h) as the only conduction abnormality and a QRS duration <120 ms, continuous ECG monitoring at hospital discharge would be the preferred option (instead of PPM).

The recommendations provided for this complex group of patients are based on little evidence. No data exist on pacing percentage or pacemaker dependency in patients with prior conduction disturbances and ongoing ECG changes (but not HAVB/CHB) post-TAVR. That a significant proportion of these patients may not require pacing at follow-up cannot be excluded. However, we consider that, despite the limited data available, the risk of advanced conduction disturbances in some of these patients (with iatrogenic aggravation of a prior conduction abnormality) may justify additional measures (including PPM before hospital discharge) to prevent life-threatening arrhythmias and sudden cardiac death. Future studies are needed to confirm the safety and clinical efficacy of the proposed strategy.

GROUP 4. New-onset LBBB (Figure 5). The occurrence of new-onset LBBB post-TAVR remains the most frequent complication of the procedure with an

incidence of about 25% (4% to 65%) overall, and an increased rate associated with the use of the first-generation CoreValve system (6). Data on the occurrence of new-onset LBBB with the use of newer-generation THV systems are scarce, with a reported incidence ranging from 10% to 70% (Online Figure 1B). New-onset LBBB appears in the procedural period in most (>80%) cases, and the presence of new-onset LBBB has been identified as a risk factor for periprocedural PPM (6). Although some patients with new-onset LBBB will develop HAVB/CHB within the few days following the procedure, a significant proportion (about 50%) will partially or completely normalize their ECG during the post-TAVR hospitalization period (6). Following hospital discharge, new-onset persistent LBBB has been associated with an increased risk for PPM during the 12 months following the procedure. Thus, patients with new-onset LBBB that persists at hospital discharge exhibit a PPM rate of 10% to 15% at 1-year follow-up, compared with 2% to 3% among patients without LBBB (6,52–54). Although the impact of new-onset LBBB on major cardiovascular events (including cardiac death, sudden death) remains controversial (52,54–59), several studies have shown a negative effect of LBBB post-TAVR on left ventricular function (53,60).

The recently published MARE (Ambulatory Electrocardiographic Monitoring for the Detection of High-Degree Atrio-Ventricular Block in Patients With New-onset Persistent Left Bundle Branch Block After Transcatheter Aortic Valve Implantation) study provided novel and important data to the field (61). The study included a total of 103 consecutive patients with new-onset LBBB that persisted at day 3 post-TAVR. A newer-generation THV (SAPIEN 3, Evolut R) was used in more than one-half of the patients. All patients had an ICM implanted at hospital discharge. The results at 1-year follow-up showed that: 1) close to 10% of the patients presented at least 1 HAVB/CHB episode requiring PPM; 2) about one-third of the patients had first-degree AVB at hospital discharge, with a mean PR duration of 228 ms, and this was not associated with an increase in the risk of HAVB/CHB; 3) about one-half of the events occurred within the first 4 weeks following the procedure; 4) the rate of sudden death was very low (1%), with only 1 sudden death occurring 8 months post-TAVR, likely secondary to a coronary event; and 5) the ECG partially or completely normalized in about one-third of the patients at 1-year follow-up (with LBBB partial/complete resolution occurring mainly within the initial 30 days post-TAVR). In summary, the results of the MARE study showed that continuous ECG monitoring is a safe alternative in patients with new-onset persistent LBBB post-TAVR. That most events occurred within the weeks following hospital discharge suggests that a shorter-term ECG monitoring (4 weeks) may be a reasonable option in these patients. Also, that most (>85%) patients remained stable with no major bradyarrhythmic events along with the resolution of conduction abnormalities in about one-third of them strongly suggests that no "prophylactic" PPM is required in patients with this conduction abnormality. Based on all these data, the following management strategy is suggested in patients with new-onset LBBB (**Figure 5**).

We recommend maintaining the temporary pacing wire for 24 h, along with daily ECG and telemetry for at least 1 to 2 days in all patients with new-onset LBBB post-TAVR. Earlier removal of the temporary pacing wire can be considered if LBBB resolves in <24 h, and the patient can be discharged at day 1 post-TAVR.

If LBBB persists but no further progression of the duration of the QRS or PR interval is observed at day 1, temporary pacing can be discontinued. If no further ECG changes are observed up to day 2 to 3 post-TAVR, the patient can be discharged. These patients, however, are at increased risk of delayed HAVB/CHB requiring PPM, and the implementation of measures like continuous ECG monitoring (minimum of 2 to 4 weeks) and/or EP studies may be considered. Infra-Hisian block during atrial pacing or a spontaneous HV interval >100 ms can be considered as the cutoff to prompt PPM (51); however, scarce data exist on the safety and efficacy of any of these measures in patients with new-onset LBBB, and further validation is required.

If further prolongation of the QRS or PR interval (of at least 20 ms) is observed at day 1, the temporary pacing wire is recommended to be maintained for an additional 24 h. If the prolongation of the QRS or PR intervals continues at day 2, additional evaluation with EP studies (followed by continuous ECG monitoring if no PPM implantation) or direct PPM implantation may be considered. If no further prolongation of the QRS or PR interval is observed at day 2, temporary pacing can be discontinued and the patient remain hospitalized for 1 additional day (with daily ECG and telemetry). If no further changes are observed, the patient can be discharged at day 3 post-TAVR. These patients, however, are at increased risk of delayed HAVB/CHB requiring PPM, and the implementation of measures such as continuous ECG monitoring (minimum of 2 to 4 weeks) and/or EP studies may be considered.

In the evaluation of the ECG at day 2 post-TAVR, the QRS duration and PR intervals may be taken into account. Current data do not support the systematic implantation of PPM in patients with new-onset LBBB and first-degree AVB. Also, the small number of patients with PR >240 ms included in the MARE study limits insight from the analysis of this specific group (61). However, some data suggest that the presence of a very long PR interval (particularly >240 ms) in these patients significantly increases the risk of delayed HAVB/CHB (13,42), and some studies have shown high pacing rates in about one-half of the patients with new-onset LBBB and a more prolonged PR interval (62). Also, some studies showed that, in the presence of new-onset LBBB, a long QRS duration (>150 to 160 ms, irrespective of the PR interval) was associated with an increased risk of delayed HAVB/CHB and sudden death (42,56). Although no specific measures have proven to be safe and effective in these patients yet, the authors consider that the implementation of additional measures for either preventing or facilitating the early detection of potentially life-threatening arrhythmias may be important in these patients. Thus, performing an EP study before and/or using continuous ECG monitoring at hospital discharge may be considered. Also, while waiting for additional data, it may be an option to implant a PPM in those patients with new-onset LBBB and a PR interval >240 ms or those with new-onset LBBB with QRS interval duration >150 to 160 ms to prevent life-threatening arrhythmias at follow-up. Further studies, particularly evaluating pacing percentage and pacemaker dependency over time in these patients, are warranted.

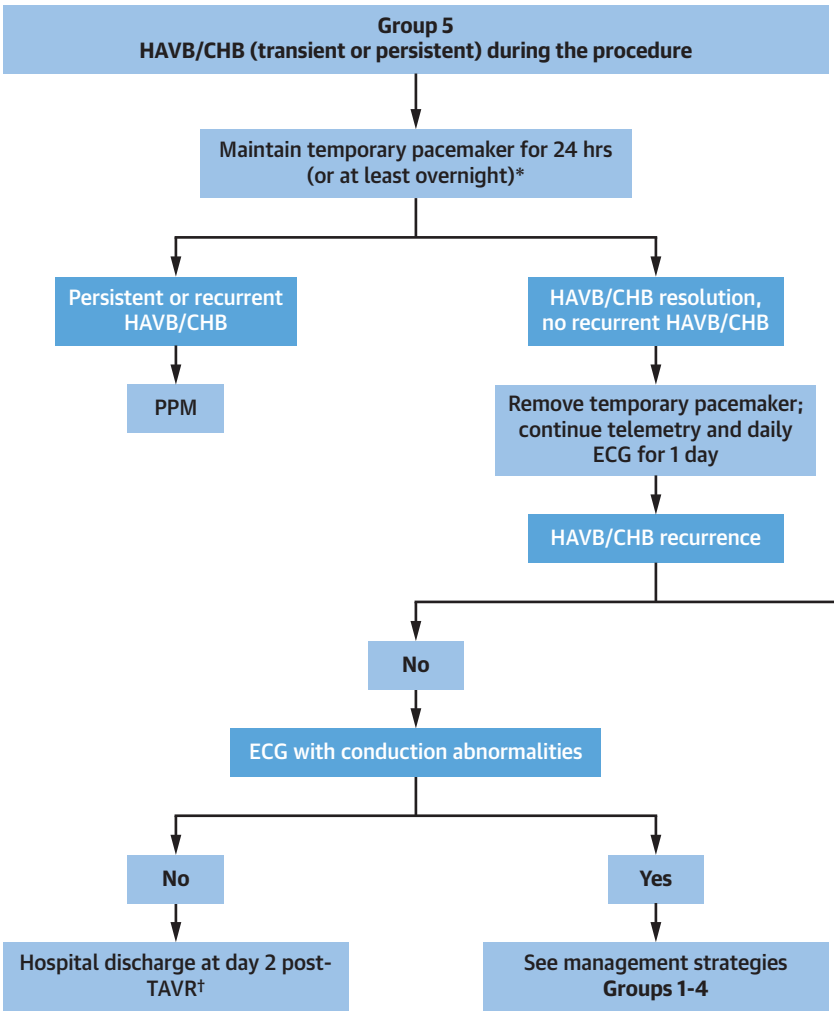
The occurrence of any episode of HAVB/CHB during the days following TAVR in a patient with new-onset LBBB can be considered an indication for PPM. No studies have yet determined the safety of delaying PPM in patients with progressive conduction disturbances leading to HAVB/CHB post-TAVR. The expert panel considers that, even if some of these severe conduction abnormalities may be transient and resolve over time, the risk of life-threatening arrhythmias or sudden death may remain high (or at least unpredictable) in these cases within the weeks to months following TAVR.

No or very scarce data exist on the occurrence, evolution, and clinical effect of new-onset RBBB, nonspecific IVCD (with QRS ≥120 ms) or first-degree AVB post-TAVR (14,42,63). While waiting for further data, we recommend following the algorithm proposed for group 3 in such patients.

GROUP 5. HAVB/CHB during the periprocedural period (**Figure 6**). The vast majority of episodes of HAVB/CHB occur during the TAVR procedure, and only a minority (<20%) during the initial post-procedural days, typically within the 2 to 3 days following the procedure (6,12,45). This information provides the rationale for avoiding an excessive hospitalization length post-TAVR based on the possible occurrence of delayed HAVB/CHB. Importantly, the vast majority of delayed (post-procedural) HAVB/CHB episodes occur in patients with either prior or new-onset conduction disturbances (RBBB, LBBB, first-degree AVB), for which specific recommendations have already been provided (see groups 2 to 4).

Procedural HAVB/CHB that persists at the end of the procedure. This is defined as any episode of HAVB that occurs during the procedural time and persists at the end of the procedure (after obtaining access hemostasis, at least 15 min after the initial diagnosis of the HAVB/CHB episode). The occurrence of procedural HAVB/CHB has been identified as a major risk factor of PPM post-TAVR (16). In patients with prior RBBB, persistent procedural HAVB determines an indication for PPM in the vast majority of cases, and high pacing rates and pacemaker dependency have been shown at follow-up in these cases (64). Also, Junquera et al. (65) evaluated the occurrence of persistent procedural HAVB/CHB in a series of 676 consecutive patients with no prior conduction disturbances undergoing TAVR. A balloon-expandable Edwards valve was implanted in 409 patients and a CoreValve system in 238 patients. Persistent procedural HAVB/CHB occurred in 5% of patients and persisted 24 h after the procedure in the vast majority. A PPM was implanted in 97% of patients and the mean pacing percentage was >95% at 1- and 12-month follow-up. Overall, these data should help to determine the optimal time for maintaining the temporary pacing wire in such patients. In fact, data on procedural persistent HAVB/CHB suggest that the likelihood of these persistent conduction disturbances resolving over time is very low. Thus, we believe that maintaining the temporary pacing wire in place for several days (up to 7 according to the most recent European guidelines) (31) would not be a cost-effective strategy. In addition to the low ECG recovery rate after the initial 24 h, a prolonged observation period often implies bed rest with the use of a temporary pacemaker and its inherent risks (thromboembolism, cardiac perforation, infection) (66). Thus, the safety, efficacy, cost-effectiveness, and the impact on functional recovery among elderly patients following such a strategy remain largely unknown.

FIGURE 6 Strategy Algorithm Proposal for the Management of Patients With HAVB (Transient or Persistent) During the TAVR Procedure



*Consider earlier discontinuation of temporary pacing if very brief procedural episode of HAVB/CHB and normal ECG (no conduction disturbances).
†Consider hospital discharge at day 1 if very brief procedural episode of HAVB/CHB and normal ECG.

Abbreviations as in Figures 1 and 3.

Furthermore, it should be highlighted that this prolonged observation period competes with the current trends toward shortened length of stay. Performing PPM after a short observation period may be a safe option allowing rapid patient mobilization. We consider that an observation period of 24 h following the HAVB/CHB episode appears to be a reasonable compromise, especially in the case of procedural persistent HAVB/CHB, which is much less likely to recover >24 h after its onset. We thus recommend maintaining the temporary pacing in patients with procedural persistent HAVB/CHB, and monitoring the patients in an intensive care unit. If HAVB/CHB persists at 24 h post-TAVR, PPM is recommended to be implanted with no further observational period. If HAVB/CHB recovers the day after TAVR, the temporary pacing wire can be removed and the patient can remain hospitalized for 1 additional day, with telemetry and daily ECG. If another episode of HAVB/CHB occurs, PPM is recommended. If no other episode of HAVB/CHB occurs, and no other features potentially justifying PPM or other additional measures (EP

TABLE 2 Ambulatory ECG Monitoring Modalities and Technology

Type of Recorder	Duration of Recording	Modality of Recording	Potential Advantages	Potential Disadvantages
Standard Holter monitor	24–48 h	Continuous single and multilead external recorders.	• Ability to record and document 3- to 12- lead ECG signal simultaneously.	• Frequent noncompliance with symptom logs and event markers. • Frequent electrode detachments. • Signal quality issues. • Absence of real-time analysis.
External event recorders/ smartphone-based recorder	<1 min	Intermittent external patient- or auto-trigger activated post-event recorders.	• Records only selected ECG segments of fixed duration after an event is detected by the patient. • Immediate alarm generation upon the event detection. • Well-tolerated for the patient.	• Single-lead devices. • Noncontinuous cardiac recording. • Diagnostic capacity dependent on patient's ability to recognize symptoms.
Patch ECG recorders	Up to 4 weeks	Continuous single- or 2-lead external recorders without and with wireless data transmission.	• Long-term recorder of 14 days or longer. • Excellent patient acceptance.	• Records a limited ECG from closely spaced electrodes (lack of localization ability of arrhythmia origin). • Inconsistent optimal ECG signal quality resulting from varying body types.
External loop recorders	4–8 weeks	Intermittent external patient- or event-activated (auto-triggered) recorders.	• Records only selected ECG segments of fixed duration marked as events either automatically or manually by the patient. • Immediate alarm generation on event detection.	• Records a single-lead ECG sequence. • P waves may not be visible. • Requires patients to wear electrodes continuously.
Mobile cardiac outpatient telemetry	Real-time streaming to call centers	External real-time continuous cardiac tele-monitoring systems.	• Multilead ECG detection. • Immediate alarm generation.	• Frequent electrode changes.
Implantable cardiac monitor	Up to 3 yrs	Intermittent implantable or insertable patient- or auto-trigger activated post-event recorders.	• Very long-term recording. • Well-tolerated.	• Single-lead devices. • Risk of infection. • Cost.

ECG = electrocardiogram.

study, continuous ECG monitoring) exist (see management of groups 2 to 4), the patient can probably be safely discharged.

Transient HAVB during the procedure. This is defined as any episode of HAVB/CHB occurring during the procedure that is transitory (irrespective of the timing of HAVB/CHB, the conduction abnormality has resolved at the end of the procedure, when the patient is ready to leave the implant room). Temporary pacing is recommended to be maintained in these patients for 24 h, along with telemetry and daily ECG for 2 days. However, discontinuing temporary pacing post-procedure may be considered in those cases with extremely brief episodes of HAVB/CHB during the procedure and normal ECG (no conduction disturbances pre- or post-procedure). If no recurrent episodes of HAVB/CHB occur, and the patient has no other potential indications for PPM or other additional measures (EP study, continuous ECG monitoring) based on the presence of other conduction abnormalities (see management of groups 2 to 4), the patient can be discharged at day 2 post-TAVR with no continuous ECG monitoring (hospital discharge at day 1 may be considered in the absence of conduction disturbances). PPM would be indicated if any recurrent episode of HAVB/CHB occurs during the hospitalization period.

Delayed HAVB/CHB. This is defined as any HAVB/CHB episode occurring after the procedure. The vast majority of these episodes (all episodes in multiple studies) occur in patients with prior or new-onset conduction disturbances (RBBB, LBBB, first-degree AVB). Thus, the occurrence of any episode of HAVB/CHB during the hospitalization period represents a further progression of the conduction disturbance, and this would constitute an indication for PPM with no further delay. To the best of our knowledge, no studies to date have evaluated the application of a watchful waiting period (with temporary pacing) in these patients. In future studies, it would be important to properly collect the timing of delayed HAVB/CHB (in-hospital and at follow-up).

CHOICE OF PACEMAKER, CONTINUOUS ECG MONITORING SYSTEM.

Temporary pacing. The use of standard temporary pacing wires requires strict bed rest to avoid the potential displacement of the pacemaker wire. Although this is a reasonable option for a 24-h surveillance, keeping the temporary pacing wire in place for longer periods increases the risk

TABLE 3 Ongoing Studies in the Field of TAVR and Conduction Disturbances

Study Acronym	NCT #	Study Design	Intervention	n	Target TAVR Population	Transcatheter Valve System	Main Outcomes
PAMIT	NCT02768064	Randomized Prospective	Temporary pacemaker using a flexible screwed electrode vs. conventional temporary pacemaker with stiff standard electrode	120	All patients	Edwards Sapien and Medtronic CoreValve	• Pericardial effusion with or without tamponade. Time frame: 1 week. • Number of participants with Electrode Dislocation. Time frame: 1 week.
Comparison of transcatheter valve types (or evaluation of a valve type)							
Conduct	NCT03497611	Observational Retrospective	Transcatheter valve implantation	1,000	All patients	Edwards Sapien 3	• Occurrence of PPM. • Timing of PPM. • Indications for PPM.
Conduct-pro	NCT03715894	Observational Prospective	Edwards Sapien 3	300	Patients undergoing transfemoral SAPIEN 3 implantation with at least 1 identified risk factor for PPM	Edwards Sapien 3	• Occurrence of permanent pacemaker implantation after TAVR in high risk patients. Time frame: 1 year.
SCOPE II	NCT03192813	Randomized Prospective	Boston ACURATE neo TF vs. Medtronic Evolut R	764	All TAVR patients	Boston ACURATE neo TF and Medtronic Evolut R	• Composite of all-cause mortality or stroke rates. Time frame 1 year. • New permanent pacemaker rate. Time frame: 30 days.
REBOOT	NCT02668484	Randomized Prospective	Edwards Sapien 3 vs. Boston Lotus valve	116	All TAVR patients	Edwards Sapien 3 and Boston Lotus valve	• Incidence of new permanent pacemaker implantation.
Electrophysiology studies							
HESITATE	NCT02659137	Observational Prospective	HV measurement during TAVI procedure	100	New-onset LBBB patients	NS	• Presence of a conduction disturbance in the His bundle on occurrence of a LBBB on surface ECG by registering the HV-time in milliseconds during the TAVR procedure.
LBBB-TAVI*	NCT02482844	Nonrandomized Prospective	Electrophysiologic study with pacemaker Implantation if HV >70 ms and implantable Holter monitoring if <70 ms	200	New-onset LBBB	NS	• To assess the appearance (rate and deadline time after TAVR) of AV high-grade conductive disorders (complete AV block and AV block II Mobitz 2) in patients with de novo LBBB induced by TAVR. Time frame: 12 mo.
Clinical Monitoring Strategy vs. EP-Guided Algorithmic in LBBB Patients Post-TAVI*	NCT03303612	Randomized Prospective	Group 1: electrophysiology-based algorithmic approach. Group 2: standard clinical follow-up with transcutaneous cardiac monitoring.	134	New-onset LBBB	NS	• Number of patients with cardiovascular hospitalization, and/or syncope, and/or death after TAVR. Time frame: 12 mo.
Continuous ECG recording studies							
PARE	NCT03561805	Observational Prospective	ECG continuous monitoring pre-TAVR (CardioSTAT device)	100	All TAVR outpatient patients	NS	• Incidence of arrhythmic events.
Remote ECG Monitoring of TAVI Patients	NCT03810820	Nonrandomized Prospective	Wearable cardiac monitor with real time data transmission (m-CARDS) pre- and post-TAVR.	240	All outpatient TAVR patients	NS	• Feasibility. • New-onset conduction disturbances.
Reveal	NCT02559011	Observational Prospective	Medtronic Reveal implantation.	100	All TAVR patients	NS	• Number of patients with incidence of new onset atrial fibrillation and complete AVB. Time frame: up to 12 months.
Brady-TAVR Study	NCT03180073	Observational Prospective	Ziopatch (ECG recording) pre- and post-TAVR.	100	All patients	NS	• Need for pacemaker.

Continued on the next page

TABLE 3 Continued

Study Acronym	NCT #	Study Design	Intervention	n	Target TAVR Population	Transcatheter Valve System	Main Outcomes
Pacemaker evaluation							
STIMTAVI	NCT03338582	Observational Prospective	Transcatheter valve implantation Pacemaker implantation	275	Pacemaker recipients	NS	• To look for 1 or several high-level AV block episodes beyond 7 d after a TAVI procedure, by the analysis of the ECG and of the pacemaker memories during the follow-up visits. Follow up at 1–3 months at a 1 year.
PPM in TAVR	NCT02994667	Observational Prospective	Permanent pacemaker implantation	50	PPM recipients	NS	• Incidence of ventricular pacing. Time frame: 7–90 days.

*Studies with also ECG continuous recording.

AVB = atrioventricular block; ECG = electrocardiograph; LBBB = left bundle branch block; NCT = number of clinical trials; NS = not specified; PPM = permanent pacemaker implantation; TAVR = transcatheter aortic valve replacement.

of complications and may significantly influence patient's recovery. The proposed algorithm minimizes the potential complications of long periods of temporary pacing, but the use of temporary pacing for periods >24 h cannot be excluded in some cases. Thus, the use of a permanent pacemaker lead from the internal jugular vein, connected to an external generator as temporary pacemaker (67) may be considered in those cases where an extended period of temporary pacing is expected. This strategy has been widely and safely used post-lead extraction and would facilitate early mobilization, which may indeed improve patients' recovery and reduce hospitalization length. Also, the use of temporary pacing wires with active fixation (e.g., BioTrace Tempo) (68) may be considered. Groups 3 and 4 of the present consensus document (i.e., ECG changes in patients with prior conduction disturbances and new-onset conduction disturbances) can be considered at risk for prolonged (>24 h) temporary pacing and may benefit more from this strategy. Also, some logistic factors (e.g., center availability for PPM implant on weekends or holidays) should be taken into account.

Permanent pacemaker. Dual-chamber pacemakers programmed with algorithms promoting spontaneous atrioventricular conduction should be implanted in patients with HAVB/CHB and sinus rhythm to minimize chronic right ventricular pacing. Single ventricular lead pacemakers may be considered as a potential cost-effective strategy in those cases with expected low pacing rates at follow-up. Currently, scarce data exist regarding the potential benefits of leadless pacemakers in TAVR recipients; however, leadless pacemakers may be considered in patients requiring single-chamber pacing only (atrial fibrillation) or in those with severe or very severe tricuspid regurgitation that may require a transcatheter interventional therapy at the tricuspid level within the months to years following TAVR (69). One of the most important challenges of the TAVR field is the paucity of data regarding the detection of arrhythmic events during the follow-up period. Although some studies have evaluated (using different definitions) the pacing percentage and pace dependency at different follow-up time points post-TAVR, even very low (<1%) pacing percentages may be important in this population because of the potential occurrence of paroxysmal and potentially life-threatening HAVB/CHB.

The presence of reduced left ventricular ejection fraction (LVEF) may lead to consideration of enhanced therapies such as implantable cardioverter-defibrillator (ICD) or resynchronization therapy at the time of PPM post-TAVR. However, LVEF can improve after the resolution of aortic stenosis, and some conduction disturbances may resolve over time leading to low pacing percentage at follow-up. Thus, we do not recommend these therapies to be implemented in the TAVR periprocedural period but rather being further evaluated during the follow-up period (see follow-up section). Further studies are needed.

Continuous ECG monitoring systems. The use of continuous monitoring systems at the time of hospital discharge has emerged as an interesting tool for the management of patients with conduction disturbances post-TAVR. Although the use of standard Holter monitoring for 24 to 48 h may be a simple and widely available option, it may be insufficient to cover the potential period of increased risk for arrhythmic events post-TAVR, which extends up to 1 month post-procedure. Thus, systems allowing for a

more prolonged period (minimum of 2 weeks) of ECG monitoring should be favored. Also, those with an alarm system incorporated allowing for a rapid intervention in case of life-threatening arrhythmias may be preferred thought not universally available. However, systems requiring the intervention of patients in order to activate the alarm system may exhibit a reduced efficacy in the current TAVR population (elderly patients with potentially more difficulties for using such systems). A summary of the currently available systems for continuous ECG monitoring is shown in **Table 2** and Online Table 2.

FOLLOW-UP. Patients with no conduction disturbances. The patients may have the standard follow-up post-TAVR recommended by current guidelines (70,71). A 12-lead ECG is recommended to be obtained at 1- and 12-month follow-up and yearly thereafter. Arrhythmic events are recommended to be managed according to current guidelines (American College of Cardiology/American Heart Association, European Society of Cardiology guidelines on bradyarrhythmias) (10,31). Those patients with low LVEF could also be evaluated at 3- to 6-month follow-up to determine whether or not there is an indication for an ICD. The indications for an ICD should also follow the current guidelines (72–74).

Patients with conduction disturbances and no PPM post-TAVR. These patients may have a 12-lead ECG at 1- and 12-month follow-up. Those patients with low left ventricular ejection fraction and LBBB post-TAVR (either chronic or new-onset LBBB) can also be evaluated at 3- to 6-month follow-up (with ECG and echocardiography examinations) to determine a potential indication for resynchronization therapy and/or implantable cardioverter defibrillator therapy (31,74–76). All arrhythmic events would be managed according to current guidelines (10,31).

Patients with PPM post-TAVR. These patients may be followed at 1-, 6-, and 12-month follow-up, and pacemaker interrogation performed and recorded, including parameters such as pacing percentage and pacemaker dependency. Pacemaker dependency is recommended to be evaluated by decreasing the paced rate below 40 beats/min to determine the presence of a spontaneous rhythm. It would be important to note all significant arrhythmic events detected by the pacemaker at the time of interrogation. Those patients with low LVEF at hospital discharge can also be evaluated (pacemaker interrogation and echocardiography examinations) at 3- to 6-month follow-up to determine the need for resynchronization therapy and/or ICD. The indications for an implantable defibrillator and resynchronization therapy would follow current guideline recommendations (31,72–76).

FUTURE PERSPECTIVES

Multiple gaps remain in the field of conduction disturbances post-TAVR and further research efforts are needed to optimize the management of these patients.

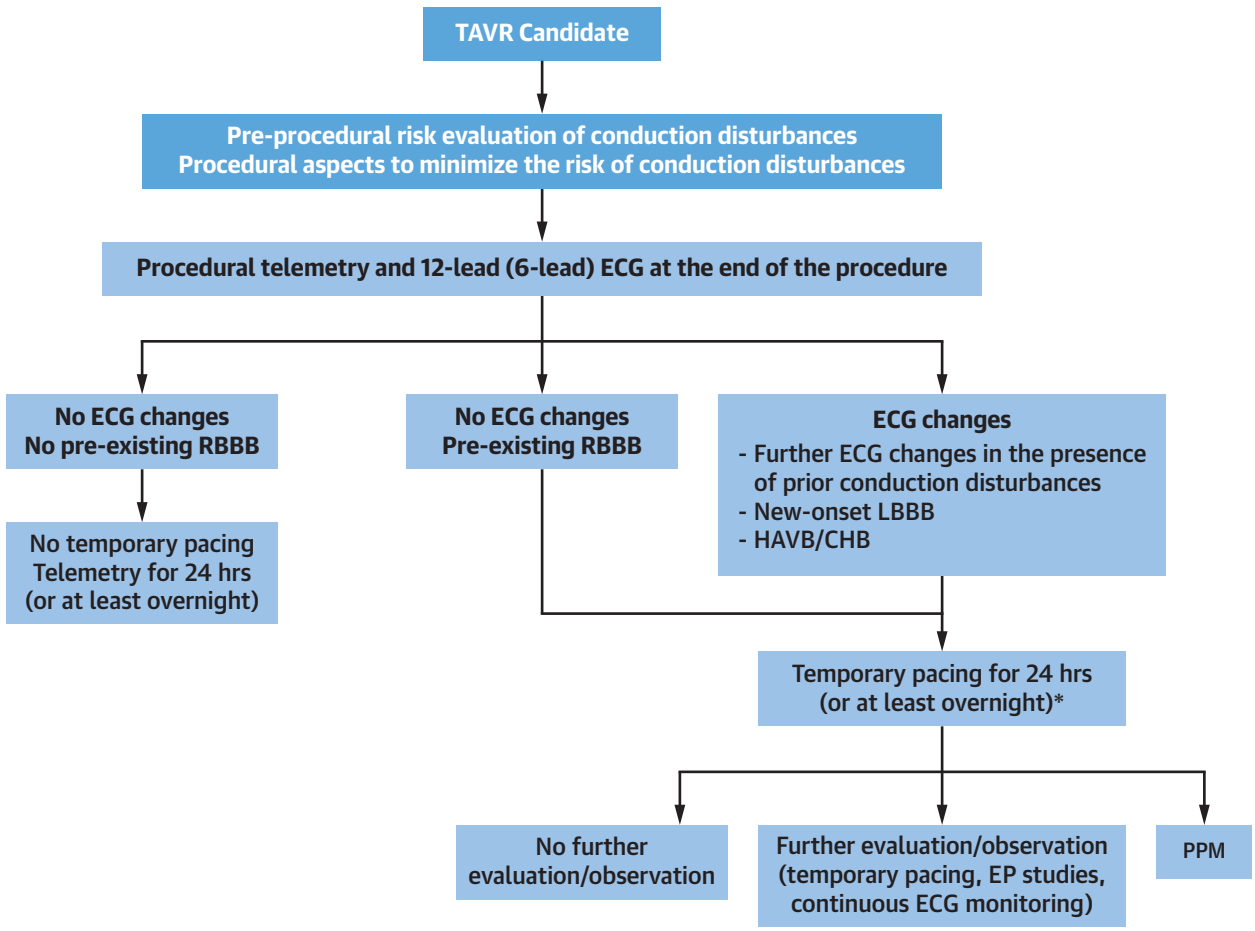
DETECTION OF ARRHYTHMIAS PRE-TAVR. Three ongoing studies are evaluating the usefulness of continuous ECG monitoring within the weeks pre-TAVR to detect and treat clinically relevant arrhythmias before the TAVR procedure (**Table 3**).

ACCURATE EVALUATION OF THE RISK AND TIMING OF LIFE-THREATENING ARRHYTHMIAS AND SUDDEN DEATH POST-TAVR. Studies with a much larger cohort of patients will be required to provide definite data on the risk of delayed life-threatening arrhythmias and sudden death post-TAVR, particularly among those patients exhibiting conduction disturbances following the procedure. Indeed, these risk scores may need to take into account the transcatheter valve type (a risk score for each valve may be needed). Importantly, applying a uniform strategy regarding the management of conduction disturbances in multiple centers seems to be key to create reliable arrhythmia risks scores. Some preliminary attempts in this direction are currently being evaluated (**Table 3**). The authors believe that patients at high to extreme risk may benefit from preventive PPM, whereas those at intermediate risk may be managed with EP studies or continuous ECG monitoring. Ultimately, randomized trials may be required to provide definite evidence on any specific risk-based treatment strategy.

DETERMINING THE ROLE OF EP STUDIES AND CONTINUOUS ECG MONITORING IN THE MANAGEMENT OF PATIENTS WITH CONDUCTION DISTURBANCES. Multiple observational studies are currently evaluating the usefulness of both EP studies and continuous ECG monitoring post-TAVR, particularly focusing on those patients with new-onset LBBB (**Table 3**). These studies should provide further data for both improving patient risk stratification and establishing specific indications and timing for these examinations. Ultimately, randomized trials may be needed to provide definite data on their cost-efficacy.

PACEMAKER EVALUATION. In addition to applying more uniform strategies regarding the management of conduction disturbances post-TAVR, further studies with a more accurate and systematic evaluation of PPM are needed to validate such treatment

CENTRAL ILLUSTRATION **Strategy Algorithm Proposal for the Management of Patients With Conduction Disturbances Post-Transcatheter Aortic Valve Replacement**



*Consider earlier discontinuation of temporary pacing if regression of ECG changes in <24 h (except for pre-existing RBBB).

Rodés-Cabau, J. et al. J Am Coll Cardiol. 2019;74(8):1086–106.

EPS = electrophysiologic study; HAVB/CHB = high-degree atrioventricular block/complete heart block; LBBB = left bundle branch block; PPM = permanent pacemaker implantation; RBBB = right bundle branch block.

strategies. Some ongoing studies are prospectively determining the parameters of PPM implanted in the TAVR periprocedural period (Table 3).

CONCLUSIONS

The high incidence and variety of conduction disturbances post-TAVR represents a major challenge in the periprocedural management of TAVR recipients. Despite the growing body of knowledge on this topic, the large variability in the management of these complications has translated into a high degree of uncertainty regarding the most appropriate treatment of a large proportion of such patients. This expert report document represents an initial effort to provide a comprehensive and structured guide for managing patients with conduction disturbances post-TAVR and a framework for future research (Central Illustration). As such, it should be considered a work in progress and the recommendations regarded as suggestions based on current evidence and consensus opinion of a group of experts in the field. A compromise between the increasing pressure toward a minimalist approach including early discharge of TAVR recipients and the potential risks associated with a too-precipitous clinical decision in

this context has been taken into consideration throughout the entire document. Despite the limitations, primarily related to the lack of definite data in many instances, a more uniform practice regarding the management of conduction disturbances post-TAVR applied to a large cohort of patients would permit to identify the benefits and drawbacks of each specific aspect of the treatment algorithm proposal. This may help to improve both the management and clinical outcomes of the complex group of patients with conduction disturbances associated with TAVR.

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KEY WORDS aortic stenosis, conduction disturbances, pacemaker, transcatheter aortic valve replacement

APPENDIX For a supplemental figure and tables, please see the online version of this paper.