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EXPERT CONSENSUS DECISION PATHWAY

2020 ACC Expert Consensus Decision Pathway on Management of Conduction Disturbances in Patients Undergoing Transcatheter Aortic Valve Replacement

A Report of the American College of Cardiology Solution Set Oversight Committee

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ABSTRACT

Consensus regarding a reasonable strategy to manage cardiac conduction disturbances after transcatheter aortic valve replacement (TAVR) has been elusive. This is due to the absence of adequately powered, randomized controlled trials; the often transient nature of the conduction disturbances; evolving technologies; and the interplay of cardiology subspecialties involved. In the absence of high-quality trials, numerous practice styles have been developed, and prolonged observation, electrophysiological testing, and preemptive pacemaker implantation have been described. Although the 2013 European Society of Cardiology guidelines address pacing post-TAVR, they do not provide in-depth discussion of this topic. Furthermore, a summary and proposed strategy for this problem have not been published by cardiovascular societies in the United States, despite an interest in establishing best practices in TAVR, valvular heart disease, and cardiovascular implantable electrical devices.

This document reviews existing data and experience regarding the management of conduction disturbances after TAVR and proposes an evidence-based expert consensus decision pathway for their management. Where evidence is lacking or insufficient, the recommendations herein are based on expert opinion.

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PREFACE
The American College of Cardiology (ACC) has a long history of developing documents (e.g., decision path-

history of developing documents (e.g., decision pathways, health policy statements, appropriate use criteria) to provide members with guidance on both clinical and nonclinical topics relevant to cardiovascular care. In most circumstances, these documents have been created to complement clinical practice guidelines and to inform clinicians about areas where evidence may be new and

evolving or where sufficient data may be more limited. In spite of this, numerous care gaps continue to exist, highlighting the need for more streamlined and efficient processes to implement best practices in service to improved patient care.

Central to the ACC's strategic plan is the generation of "actionable knowledge"-a concept that places emphasis on making clinical information easier to consume, share, integrate, and update. To this end, the ACC has evolved from developing isolated documents to the development of integrated "solution sets." Solution sets are groups of closely related activities, policy, mobile applications, decision support, and other tools necessary to transform care and/or improve heart health. Solution sets address key questions facing care teams and attempt to provide practical guidance to be applied at the point of care. They use both established and emerging methods to disseminate information for cardiovascular conditions and their related management. The success of the solution sets rests firmly on their ability to have a measurable impact on the delivery of care. Because solution sets reflect current evidence and ongoing gaps in care, the associated content will be refined over time to best match changing evidence and member needs.

Expert consensus decision pathways (ECDPs) represent a key component of solution sets. The methodology for ECDPs is grounded in assembling a group of clinical experts to develop content that addresses key questions facing our members across a range of high-value clinical topics (1). This content is used to inform the development of various tools that accelerate real-time use of clinical policy at the point of care. They are not intended to provide a single correct answer; rather, they encourage clinicians to ask questions and consider important factors as they define a treatment plan for their patients. Whenever appropriate, ECDPs seek to provide unified articulation of clinical practice guidelines, appropriate use criteria, and other related ACC clinical policy. In some cases, covered topics will be addressed in subsequent clinical practice guidelines as the evidence base evolves. In other cases, these will serve as stand-alone policy.

> Ty J. Gluckman, MD, FACC Chair, ACC Solution Set Oversight Committee

1. INTRODUCTION

Complete heart block requiring a permanent pacemaker (PPM) occurs in roughly 15% of patients within 30 days after TAVR and is partly dependent on the depth of valve implantation, valve type, patient anatomy, and any pre-existing native cardiac conduction disturbance (2-4). The deployed valve can cause direct damage to the atrioventricular (AV) node and/or His bundle and infra-Hisian conduction system, leading to

transient or permanent AV and intraventricular conduction disturbances (5). The rates of in-hospital PPM implantation after TAVR have not changed significantly since commercialization in 2012 (4); however, there appears to be an increase in the rate of PPM utilization between discharge and 30 days postdischarge (**Figure 1**)—perhaps a reflection of early-discharge practices and/or surveillance strategies that detect delayed high-degree atrioventricular block (DH-AVB) (4).

Although sustained complete AV heart block is a clear indication for PPM, there is no consensus about the management of new bundle branch or transient complete AV heart block (6). Accordingly, practice patterns are heterogeneous, ranging from prolonged monitoring to electrophysiological testing or even pacemaker implantation for less stringent indications (7). In some cases, PPMs have been associated with increased short- and long-term mortality, possibly owing to the inherent conduction abnormality or a feature associated with the pacemaker implantation itself (7). These issues have ramifications for the aggregate cost and quality of life improvements ascribed to TAVR.

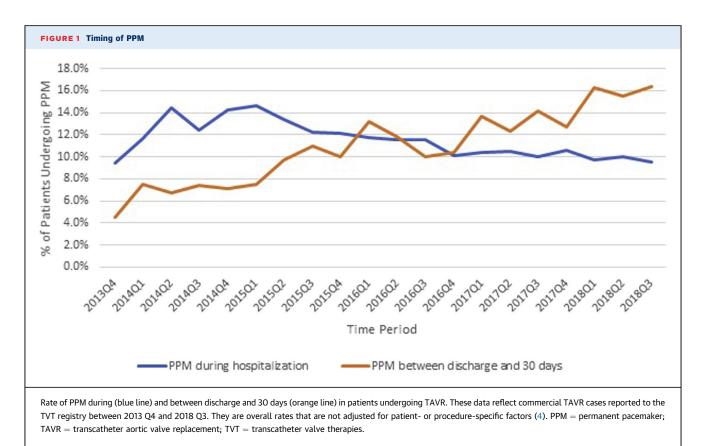
2. METHODS

The pathway described herein is the result of a proposal submitted to an oversight committee within the ACC's Science and Quality Division in September 2018 that called attention to the frequency, consequences, and heterogeneity of approaches to post-TAVR conduction disturbances. The proposal was approved as an ECDP, and the writing committee was formed in October 2018.

This document and associated tools were formulated on the basis of the writing committee's appraisal of current evidence since the beginning of committee formation through November 2019. An initial call was held to explain the goal and process of developing the ECDP, followed by biweekly teleconferences to incorporate panel feedback. Writing committee conference calls were confidential and attended only by committee members and ACC staff. Differences were resolved by consensus among the group. During the calls, the writing committee reviewed a scoping questionnaire developed by ACC's Quality Improvement Solutions team to help the authors determine the clinical content and optimal format for the tool. In consultation with the quality improvement team, the committee then identified a checklist decision guide as the best mechanism to support clinical decision making for managing post-TAVR conduction disturbances (see Appendix 1).

The writing committee included representatives from interventional cardiology, cardiac electrophysiology, and nursing specialties. The work of the writing committee was supported exclusively by the ACC without commercial support (i.e., committee members volunteered their time

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to this effort). A formal peer review process was completed, consistent with ACC policy, by expert reviewers nominated

by the ACC. A public comment period was also held to obtain additional feedback. Following reconciliation of all comments, this document was approved for publication by the ACC Clinical Policy Approval Committee.

The ACC and the Solution Set Oversight Committee (SSOC) recognize the importance of avoiding real or perceived relationships with industry (RWI) or other entities that may affect clinical policy. The ACC maintains a database that tracks all relevant relationships for ACC members and persons who participate in ACC activities, including those involved in the development of ECDPs. ECDPs follow ACC RWI policy in determining what constitutes a relevant relationship, with additional vetting by the SSOC.

ECDP writing groups must be chaired or co-chaired by an individual with no relevant RWI. While vice chairs and writing group members may have relevant RWI, this must constitute <50% of the writing group. Relevant disclosures for the writing group, external reviewers, and SSOC members can be found in Appendixes 2 and 3. To ensure complete transparency, a full list of disclosure information, including relationships not pertinent to this document, is available in an Online Appendix. Participants are discouraged from acquiring relevant RWI throughout the writing process.

3. ASSUMPTIONS AND DEFINITIONS

To enable understanding and application of the ECDP, certain assumptions were made by the writing committee. These assumptions are specified in the following text.

3.1. General Assumptions

- 1. The content of this pathway applies only to patients who are undergoing or have undergone TAVR.
- 2. The writing committee endorses the evidence-based approaches to conduction disturbances set forth in the 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay (6), 2017 ACC/AHA/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (8), 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease (9), and the 2017 AHA/ACC Focused Update of the 2014 AHA/ ACC Guideline for the Management of Patients With Valvular Heart Disease (10).
- 3. Care decisions ideally reflect a patient's values, preferences, and goals as well as the clinical considerations of the managing team.
- 4. This ECDP is intended to inform and complement good clinical judgement.

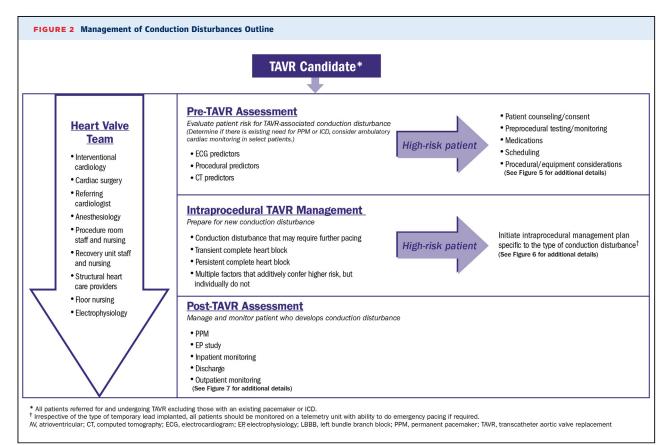
5. This ECDP is based on available data, and new information is being published rapidly. As new, relevant, and sound data become available, clinicians should incorporate them into their clinical practice and into the workflow described in this document.

3.2. Definitions

- 1. High-degree AV block: third-degree AV heart block or second-degree type II (Mobitz II) heart block. These suffice as indications for PPM even in the absence of symptoms (6).
- 2. Delayed high-grade atrioventricular block (DH-AVB): high-degree AV block that occurs >2 days after TAVR or after hospital discharge.
- 3. Sudden cardiac death (SCD): unexpected death from a presumptively cardiac cause that occurs in a short time period, generally within 1 hour of symptom onset or without prior symptoms. Sudden cardiac death events are often deemed arrhythmogenic (e.g., ventricular tachycardia, fibrillation). New-onset or paroxysmal complete AV heart block is a less frequent substrate for SCD, although it has been observed.

4. PATHWAY SUMMARY GRAPHIC

Figure 2 outlines the management of conduction disturbances in a TAVR candidate.



5. DESCRIPTION AND RATIONALE

5.1. Pre-TAVR Assessment

5.1.1. Identifying Patients at Risk for Conduction Disturbances

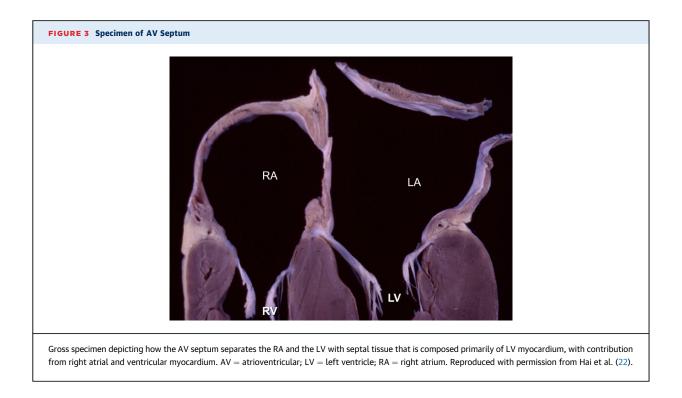
In an effort to anticipate the potential need for PPM, a pre-TAVR evaluation is important. The clinical presentation and symptoms of aortic stenosis and bradyarrhythmia overlap significantly. Especially common in both entities are fatigue, lightheadedness, and syncope. A careful history to assess if these symptoms are related to bradyarrhythmia needs to be obtained as part of the planning process for TAVR. A history suggestive of cardiac syncope, particularly exertional syncope, is concerning in patients with severe aortic stenosis; however, implicating the aortic valve or a bradyarrhythmia or tachyarrhythmia is often challenging (11).

The electrocardiogram (ECG) is a useful tool for evaluating baseline conduction abnormalities and can help predict need for post-TAVR PPM. There is no consensus for routine ambulatory monitoring prior to TAVR. However, if available, it is helpful to review any ambulatory

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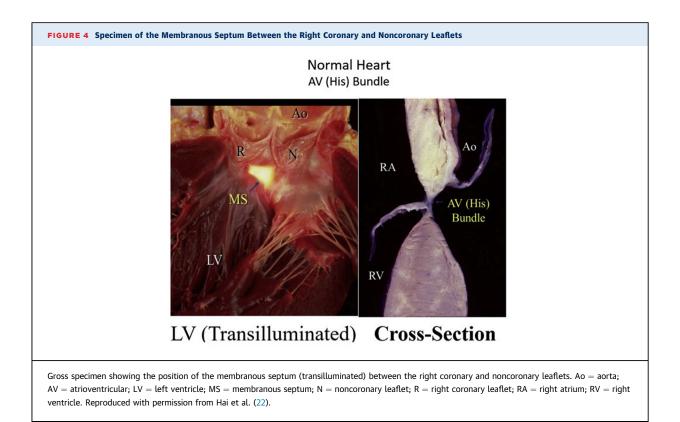
cardiac monitoring performed in the recent past. Twentyfour-hour continuous electrocardiographic monitoring can potentially identify episodes of transient AV block or severe bradycardia that are unlikely to resolve after TAVR without a PPM. These episodes may serve as evidence to support guideline-directed PPM implantation and lead to an overall reduction in the length of hospital stay (12). Beyond history and baseline conduction system disease, imaging characteristics, choice of device, and procedural factors can help to predict pacing needs (13-18).

5.1.2. Anatomic Considerations

The risk factors for PPM after TAVR can be better appreciated by understanding the regional anatomy of the conduction system and the atrioventricular septum. When AV block occurs during TAVR, the risk is higher and the chance for recovery is lower than in other circumstances due to the proximity of the aortic valve (relative to the mitral valve) to the bundle of His. The penetrating bundle of His is a ventricular structure located within the membranous portion of the ventricular septum. The right bundle emerges at an obtuse angle to the bundle of His. It is a cord-like structure that runs superficially through the upper third of the right ventricular endocardium up to the level of the septal papillary muscle of the tricuspid valve, where it courses deeper into the interventricular septum. The AV component of the membranous septum is a consistent location at which the bundle of His penetrates the left ventricle (LV). The membranous septum is formed

between the 2 valve commissures. On the left side, it is the commissure between the right and noncoronary cusps, while on the right side, it is the commissure between the septal and anterior leaflets of the tricuspid valve (19). The tricuspid annulus is located more apical to the mitral annulus (See Figure 3). This AV septum separates the right atrium and the LV with septal tissue that is composed primarily of LV myocardium, with contribution from right atrial and ventricular myocardium (20). The AV septum is unique as it is part of neither the interatrial septum nor the interventricular septum. Therefore, valve implantation that overlaps with the distal AV septum may affect both the right and left bundles and lead to complete AV block (see Figure 4). Similarly, a relatively smaller LV outflow tract diameter or calcification below the noncoronary cusp may create an anatomic substrate for compression by the valve near the membranous septum or at the left bundle on the LV side of the muscular septum, leading to AV block or left bundle branch block (LBBB) (21).

These anatomic relationships are clinically relevant. In a retrospective review of 485 patients who underwent TAVR with a self-expanding prosthesis, 77 (16%) experienced high-degree AVB and underwent PPM implantation before discharge. A higher prosthesis-to-LV outflow tract diameter ratio and the utilization of aortic valvuloplasty during the procedure were significantly associated with PPM implantation (23). Similar findings have been reported with balloon-expandable valves (17). Although the



prosthesis to LV outflow tract diameters in these studies were statistically different, they did not vary by a considerable margin (<5%) between the PPM and no PPM groups. This, together with the lack of implantation depth conveyed in these reports, limits the utility of these observations for pre-TAVR planning.

Similarly, the length of the membranous septum has also been implicated in PPM rates. Specifically, the most inferior portion of the membranous septum serves as the exit point for the bundle of His, and compression of this area is associated with higher PPM implantation rates. In a retrospective review of patients undergoing TAVR, a strong predictor of the need for PPM before TAVR was the length of the membranous septum. After TAVR, the difference between membranous septum length and implant depth was the most powerful predictor of PPM implantation (24). Given these and other observations (16,25), lower PPM implantation rates may be realized by emphasizing higher implantation depths in patients in whom there is considerable tapering of the LV outflow tract just below the aortic annulus, a risk of juxtaposing the entire membranous septum with valve deployment, and/or considerable calcium under the noncoronary cusp (26).

5.1.3. The ECG as a Screening Tool

Multiple studies have noted that the presence of right bundle branch block (RBBB) is a strong independent

predictor for PPM after TAVR (17,27), and some have suggested that RBBB is a marker for all-cause mortality in this population (2,6,28). A report from a multicenter registry (n = 3,527) noted the presence of pre-existing RBBB in 362 TAVR patients (10.3%) and associated it with increased 30day rates of PPM (40.1% vs. 13.5%; p < 0.001) and death (10.2% vs. 6.9%; p = 0.024) (29). At a mean follow-up of 18 months, pre-existing RBBB was also independently associated with higher all-cause mortality (hazard ratio [HR]: 1.31, 95% confidence interval [CI]: 1.06 to 1.63; p = 0.014) and cardiovascular mortality (HR: 1.45; 95% CI: 1.11 to 1.89; p = 0.006). Patients with pre-existing RBBB and without a PPM at discharge from the index hospitalization had the highest 2-year risk for cardiovascular death (27.8%; 95% CI: 20.9% to 36.1%; p = 0.007) (28). In a subgroup analysis of 1,245 patients without a PPM at discharge from the index hospitalization and with complete follow-up regarding the need for a PPM, pre-existing RBBB was independently associated with the composite of sudden cardiac death and a PPM (HR: 2.68; 95% CI: 1.16 to 6.17; p = 0.023) (30). The OCEAN-TAVI (Optimized Transcatheter Valvular Intervention) registry from 8 Japanese centers (n = 749) reported a higher rate of pacing in the RBBB group (17.6% vs. 2.9%; p < 0.01). Mortality was greater in the early phase after discharge in the RBBB group without a PPM; however, having a PPM in RBBB increased cardiovascular mortality at midterm follow-up (31).

Pre-existing LBBB is present in about 10% to 13% of the population undergoing TAVR (32). Its presence has not been shown to predict PPM implantation consistently (13,27). Patients with LBBB were older (82.0 ± 7.1 years), had a higher Society of Thoracic Surgeons score (6.2 ± 4.0), and had a lower baseline left ventricular ejection fraction (LVEF) ($48.8 \pm 16.3\%$) (p <0.03 for all) than those without LBBB. In a multicenter study (n = 3,404), pre-existing LBBB was present in 398 patients (11.7%) and was associated with an increased risk of PPM need (21.1% vs. 14.8%; adjusted odds ratio [OR]: 1.51; 95% CI: 1.12 to 2.04) but not death (7.3% vs. 5.5%; OR: 1.33; 95% CI: 0.84 to 2.12) at 30 days (32).

The aggregate rate of PPM implantation was higher in the pre-existing LBBB group than in the non-LBBB group (22.9% vs. 16.5%; HR: 1.40; 95% CI: 1.11 to 1.78; p = 0.006); however, this was likely driven by the increased PPM implantation rate early after TAVR (median time before PPM 4 days; interquartile range: 1 to 7 days), and no differences were noted between groups in the PPM implantation rate after the first 30 days post-TAVR (pre-existing LBBB 2.2%; no pre-existing LBBB 1.9%; adjusted HR: 0.95; 95% CI: 0.45 to 2.03; p = 0.904) (32). It is proposed that the higher PPM rates observed represented preemptive pacing based on perceived, rather than actual, risk of high-grade AV block. There were no differences in overall mortality (adjusted HR: 0.94; 95% CI: 0.75 to 1.18; p = 0.596) and cardiovascular mortality (adjusted HR: 0.90; 95% CI: 0.68 to 1.21; p = 0.509) in patients with and without preexisting LBBB at mean follow-up of 22 ± 21 months (32).

First-degree AV block has not been shown conclusively to be an independent predictor for PPM. However, change in PR interval, along with other factors, increases the risk of PPM implantation. A German report noted that in a multivariable analysis, postdilatation (OR: 2.219; 95% CI: 1.106 to 3.667; p = 0.007) and a PR interval >178 ms (OR 0.412; 95% CI: 1.058 to 5.134; p = 0.027) remained independent predictors for pacing following TAVR (33). In a retrospective analysis of 611 patients, Mangieri et al. (34) showed that baseline RBBB and the magnitude of increase in the PR interval post-TAVR were predictors of late (>48 h) development of advanced conduction abnormalities. Multivariable analysis revealed baseline RBBB (OR: 3.56; 95% CI: 1.07 to 11.77; p = 0.037) and change in PR interval (OR for each 10-ms increase: 1.31; 95% CI: 1.18 to 1.45; p = 0.0001) to be independent predictors of delayed advanced conduction disturbances (34). Prolonged QRS interval without a bundle branch block, however, has not been consistently noted as a marker for PPM (13).

5.1.4. Preparation and Patient Counseling

All patients undergoing TAVR should be consented for a temporary pacemaker. Options, including the use of a temporary active fixation lead, need to be discussed.

In patients with a high anticipated need for pacing, it is reasonable to prepare the anticipated site of access for employing an active fixation lead for safety considerations. Frequently, the right internal jugular vein is used. It is especially important to prepare the area *a priori* if the access site is going to be obscured by straps used for endotracheal tube stability or other forms of supportive ventilation. The hardware required—including vascular sheaths, pacing leads, connector cables, the pacing device itself (either a dedicated external pacemaker or implantable pacemaker used externally), and device programmers—should be immediately available. A physician proficient in placing and securing active fixation leads should be available. Allied health support for evaluating pacing parameters after lead placement and device programming should also be available (35).

If the patient is at high risk for needing a PPM, a detailed discussion with the performing physicians about the anticipated need should be undertaken before TAVR. Although the ultimate decision regarding pacing will occur post-TAVR, the patient should be prepared and, in some cases, consented before the procedure. Discussion regarding the choice of pacing device–pacemaker versus implantable cardioverter-defibrillator (ICD) versus cardiac resynchronization therapy–should be undertaken with the involved implanting physician and in agreement with recent guideline updates (8,36).

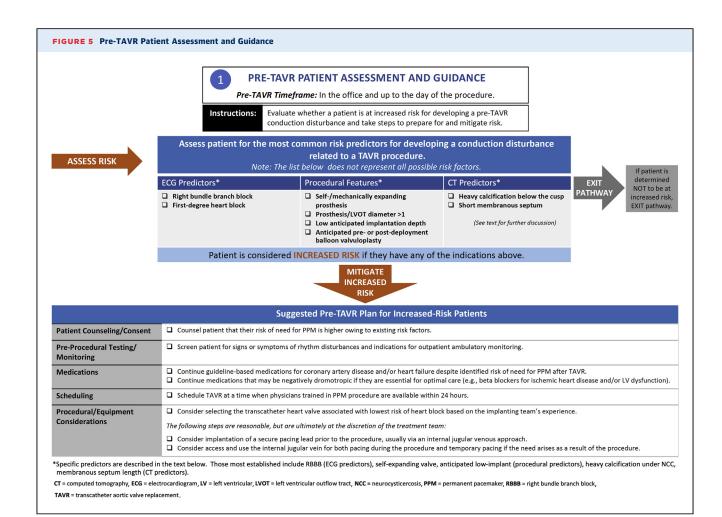
It is frequently noted that the LVEF in patients undergoing TAVR may not be normal (37). If the LVEF is severely reduced and the chance of incremental improvement is unclear or unlikely (due to factors such as prior extensive scarring and previous myocardial infarction), then a shared decision-making approach regarding the need for an ICD should be used (8). Similarly, if the patient is likely to have complete AV heart block after the procedure, especially in the setting of a reduced LVEF, then a discussion regarding cardiac resynchronization therapy or other physiological pacing needs to be held before the TAVR procedure (38). Due to the risks of reoperation, careful preprocedural evaluation, planning, and input from an electrophysiologist should be obtained to ensure that the correct type of cardiac implantable electronic device (CIED) is implanted for the patient's long-term needs. See Figure 5 for additional details.

5.2. Intraprocedural TAVR Management

Patients who are determined to have an elevated risk for complete AV heart block during pre-TAVR assessment require close perioperative electrocardiographic and hemodynamic monitoring. Aspects of the TAVR procedure itself that warrant consideration during the procedure in this group are listed in the following text (Figure 6).

5.2.1. Negative Dromotropic and Chronotropic Medications

Younis et al. (39) showed that discontinuation of chronic BB therapy in patients prior to TAVR was associated with



increased need for pacing. Beta-adrenergic or calcium channel blocking drugs that affect the AV node (not the bundle of His, which is at risk for injury by TAVR) may be continued for those with pre-existing LBBB, RBBB, or bifascicular block with no advanced AV heart block or symptoms. In keeping with the anatomic considerations discussed in the previous text, these drugs should not affect AV conduction changes related to TAVR itself, since the aortic valve lies near the bundle of His and not the AV node. If these agents are provided in an evidence-based manner for related conditions (e.g., heart failure, coronary artery disease, atrial fibrillation), they should be continued. The dose should be titrated to heart rate and blood pressure goals, and this titration should occur prior to the day of procedure (40,41).

5.2.2. Anesthesia

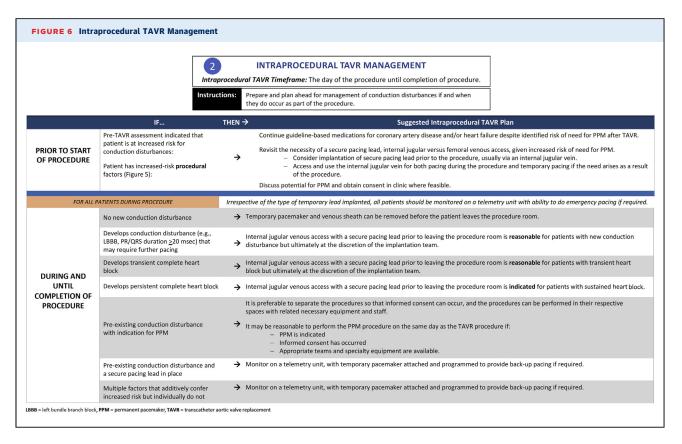
There are no instances in which the presence of baseline conduction abnormalities would dictate type and duration of anesthesia during the procedure. Accordingly, the anesthetic technique most suited for the individual patient's medical condition is best decided by the anesthesiologist in conjunction with the heart team.

5.2.3. Procedural Temporary Pacemaker

Currently, most centers implant a transvenous pacing wire electrode via the internal jugular or femoral vein to provide rapid ventricular pacing and thereby facilitate optimal valve implantation. For patients with ports, dialysis catheters, and/or hemodialysis fistulae, we recommend placement of temporary transvenous pacemaker via the femoral vein. Alternatively, recent data suggest that placing a guidewire directly into the LV can provide rapid ventricular pacing and overcome some of the complications arising from additional central venous access and right ventricular pacing (8,35,42). In a prospective multicenter randomized controlled trial, Faurie et al. (35) showed that LV pacing was associated with shorter procedure time (48.4 \pm 16.9 min vs. 55.6 \pm 26.9 min; p = 0.0013), shorter fluoroscopy time (13.48 \pm 5.98 min vs. 14.60 \pm 5.59 min; p = 0.02), and lower cost (\in 18,807 \pm 1,318 vs. \in 19,437 \pm 2,318; p = 0.001) compared with right ventricular pacing with similar efficacy and safety (35). This

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approach has been FDA approved and is in early utilization (43). Given that LV pacing wire cannot be left in place postprocedure it is a less attractive option in patients at high risk for conduction disturbances. Although existing experience does not currently inform the optimal pacing site for those at high risk of procedural heart block, it is reasonable to select temporary pacemaker placement via the right internal jugular vein over the femoral vein given ease of patient mobility should it be necessary to retain the temporary pacemaker postprocedure.

5.2.4. Immediate Postprocedure Transvenous Pacing

In patients deemed high risk for conduction disturbances, it is reasonable to either maintain the pre-existing temporary pacemaker in the right internal jugular vein or insert one into that vein if the femoral vein has been used for rapid pacing. Procedural conduction disturbances and postimplant 12-lead ECG will help determine the need for a temporary but durable pacing lead (e.g., active fixation lead from the right internal jugular vein). For the purposes of procedural management, the following are 3 possible clinical scenarios:

- No new conduction disturbances (<20 ms change in PR or QRS duration) (44-49);
- New-onset LBBB and/or increase in PR or QRS duration ≥20 ms; and

3. Development of transient or persistent complete heart block.

In patients with normal sinus rhythm and no new conduction disturbances on an ECG performed immediately postprocedure, the risk of developing delayed AV block is <1% (48-50). In these cases, the temporary pacemaker and central venous sheath can be removed immediately postprocedure, although continuous cardiac monitoring for 24 hours and a repeat 12-lead ECG the following day are recommended. This recommendation also applies to patients with pre-existing first-degree AV block and/or pre-existing LBBB (3,27,42,48), provided that PR or QRS intervals do not increase in duration after the procedure. Krishnaswamy et al. (51) recently reported the utility of using the temporary pacemaker electrode for rapid atrial pacing up to 120 beats per minute to predict the need for permanent pacing, finding a higher rate within 30 days of TAVR among the patients who developed second-degree Mobitz I (Wenckebach) AV block (13.1% vs. 1.3%; p < 0.001), with a negative predictive value for PPM implantation in the group without Wenckebach AV block of 98.7%. Patients receiving selfexpanding valves required permanent pacing more frequently than those receiving a balloon-expandable valve (15.9% vs. 3.7%; p = 0.001). For those who did not develop Wenckebach AV block, the rates of PPM were low

(2.9% and 0.8%, respectively). The authors concluded that patients who did not develop pacing-induced Wenckebach AV block have a very low need for of permanent pacing (51).

In patients with pre-existing RBBB, the risk of developing high-degree AV block during hospitalization is high (as much as 24%) and has been associated with all-cause and cardiovascular mortality post-TAVR (30). This risk of high-degree AV block exists for up to 7 days, and the latent risk is greater with self-expanding valves (52). Hence, in the population with pre-existing RBBB, it is reasonable to maintain transvenous pacing ability with continuous cardiac monitoring irrespective of new changes in PR or QRS duration for at least 24 hours. If the care team elects to remove the transvenous pacemaker in these cases, the ability to provide emergent pacing is critical. Recovery location (e.g., step-down unit, intensive care unit) and indwelling vascular access should be managed to accommodate this.

Patients without pre-existing RBBB who develop LBBB or an increase in PR/QRS duration of \geq 20 ms represent the most challenging group in terms of predicting progression to high-grade AV block and need for permanent pacing. Two meta-analyses, the first by Faroux et al. (53) and the second by Megaly et al. (54), showed that new-onset LBBB post-TAVR was associated with increased risk of PPM implantation (RR: 1.89; 95% CI: 1.58 to 2.27; p < 0.001) at 1-year follow-up and higher incidence of PPM (19.7% vs. 7.1%; OR: 2.4 [95% CI: 1.64 to 3.52]; p < 0.001) during a mean follow-up of 20.5 \pm 14 months, respectively, compared with those without a new-onset LBBB. In addition to the paucity of data, there is significant variation in the reported PR/QRS prolongation that confers risk of early and delayed high-grade AV block (34,44-47,55). We propose that the development of new LBBB or an increase in PR/QRS duration ≥20 ms in patients without pre-existing RBBB warrants continued transvenous pacing for at least 24 hours, in conjunction with continuous cardiac monitoring and daily ECGs during hospitalization. In the event that the transvenous pacemaker is removed after the procedure in these cases, recovery location and indwelling vascular access need to be appropriate for emergent pacing should it become necessary.

A recent study employed atrial pacing immediately post-TAVR to predict the need for permanent pacing within 30 days. If second degree Mobitz I (Wenckebach) AV block did not occur with right atrial pacing (up to 120 beats per minute), only 1.3% underwent PPM by 30 days. Conversely, if Wenckebach AV block did occur, the rate was 13.1% (p < 0.001). It is important to note that this group of patients included those with pre-existing and postimplant LBBB and RBBB (51). This is an interesting strategy and may ultimately inform routine length of monitoring in post-TAVR patients. During instances of transient high-grade AV block during valve deployment, it is reasonable to maintain the transvenous pacemaker in addition to continuous cardiac monitoring for at least 24 hours irrespective of the preexisting conduction disturbance.

For patients with transient or persistent high-grade AV block during or after TAVR, the temporary pacemaker should be left in place for at least 24 hours to assess for conduction recovery. If recurrent episodes of transient high-grade AV block occur in the intraoperative or postoperative period, PPM implantation should be considered prior to hospital discharge regardless of patient symptoms. Patients with persistent high-grade AV block should have PPM implanted.

In patients with prior RBBB, transient or persistent procedural high-grade AV block is an indication for permanent pacing in the vast majority of cases, with an anticipated high requirement for ventricular pacing at follow-up (56,57). In these cases, a durable transvenous pacing lead is recommended prior to leaving the procedure suite.

If permanent pacing is deemed necessary after TAVR, it is preferable to separate the procedures so that informed consent can occur and the procedures can be performed in their respective spaces with related necessary equipment and staff. When clinical and logistical circumstances warrant it, there are instances in which PPM implantation may be reasonable the same day as the TAVR (e.g., persistent complete heart block in patients with a pre-existing RBBB). When this has been anticipated, consent for PPM implantation may be obtained prior to TAVR. Otherwise, it is preferable that the patient is awake and able to provide consent before permanent device implantation.

5.3. Conduction Disturbances After TAVR: Monitoring and Management

DH-AVB has been reported in ~10% of patients (47) and is conventionally defined as DH-AVB occurring >2 days after the procedure or after hospital discharge, the latter representing the larger proportion of this group. Whether this is a substrate for the observed rates of sudden cardiac death remains unclear, although syncope has been reported in tandem with devastating consequence (47). Although pre-existing RBBB and, in some reports, new LBBB are risk factors for DH-AVB (47,58), they do not reach sufficient sensitivity to identify those appropriate for preemptive pacing devices. Accordingly, different management strategies are often employed, ranging from electrophysiological studies (EPS) to prolonged inpatient monitoring and/or outpatient ambulatory event monitoring (AEM) (see Figure 7).

The role of EPS after TAVR to guide PPM has not been studied in a randomized prospective clinical trial. Although there are nonrandomized studies that describe

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Post-TAVR Conduction Disturbances Decision Pathway

	3 POST-TAVR MA Post-TAVR Timeframe: From completion of p Instructions: Manage and monitor patients wh	rocedure thro	ugh 30 days post-discharge.
	IF the Patient Aligns with Any of These Scenarios	THEN \rightarrow	Suggested Post-TAVR Plan
	Symptomatic bradycardia or persistent, complete heart block	÷	PPM.
PPM/ EP STUDY	New, progressive, or pre-existing conduction disturbance that changes post-procedure	÷	Monitor, consider EP study and PPM.
	Narrow QRS before and after TAVR	÷	EP study and PPM are not indicated.
DISCHARGE	 All of the following: No primary PPM indication No new 1st degree or 2nd degree AV block No new bundle branch block No progression in baseline 1st, 2nd degree AV block or prolongation of the QRS ≥10% 	→	Patient can be considered for early discharge.
	If any of the above are present	÷	Telemetry until conduction is stable for \geq 48 hours; discharge with an outpatier monitor for \geq 14 days.
OUTPATIENT MONITORING	New rhythm disturbance (e.g., atrial fibrillation) OR Progression of baseline conduction disturbance OR For whom the provider feels that monitoring is warranted	÷	 Discharge with a monitor for a minimum of 14 days. Care teams should be resourced to manage outpatient monitoring to idea progressive rhythm issues in a timely manner. Use monitoring system that is accurate, enables adherence, notifies care in a timely manner.*

metrics associated with PPM decisions, these metrics were determined retrospectively and without prospective randomization to PPM or no PPM on the basis of such measurements. In general, EPS is not needed for patients with a pre-existing or new indication for pacing, especially when the ECG finding is covered in the bradycardia pacing guidelines (6). In this setting, implantation can proceed without further study.

At the other end of the spectrum are scenarios in which neither pacing nor EPS need be considered, such as for patients with sinus rhythm, chronotropic competence, no bradycardia, normal conduction, and no new conduction disturbance. Similarly, if there is first-degree AV block, second-degree Mobitz I (Wenckebach) AV block, a hemiblock by itself, or unchanged LBBB, neither a PPM nor EPS is indicated (27,48,55). Notably, Toggweiler et al. (48) reported that from a cohort of 1,064 patients who underwent TAVR, none of the 250 patients in sinus rhythm without conduction disorders developed DH-AVB; only 1 of 102 patients with atrial fibrillation developed DH-AVB; and no patient with a stable ECG for ≥ 2 days developed DH-AVB. The authors suggested that since such patients without conduction disorders post-TAVR did not develop DH-AVB, they may not even require telemetry monitoring and that all others should be monitored until the ECG is stable for at least 2 days (48).

Patients in the middle of the spectrum described in the previous text are those best suited for EPS because for

them, the appropriateness of pacing is unclear. Predictors of need for pacing include new LBBB, new RBBB, old or new LBBB with an increase in PR duration >20 ms, an isolated increase in PR duration \geq 40 ms, an increase in QRS duration ≥22 ms in sinus rhythm, and atrial fibrillation with a ventricular response <100 beats per minute in the presence of old or new LBBB (34,56,59,60). These individuals have, in some cases, been risk-stratified by EPS. Rivard et al. (61) found that a \geq 13-ms increase in Hisventricular (HV) interval between pre- and post-TAVR measurements correlated with TAVR-associated AVB, and, especially for those with new LBBB, a post-TAVR HV interval ≥ 65 ms predicted subsequent AVB. Therefore, when these changes are identified on EPS, Rivard et al. (61) suggest that pacing is necessary or appropriate. A limitation of this study is that EPS is required pre-TAVR (61). Tovia-Brodie et al. (59) implanted PPM in post-TAVR patients with an HV interval \geq 75 ms, but there was no control group with patients who did not receive a device. Rogers et al. (62) justified PPM in situations in which an HV interval ≥100 ms was recorded at post-TAVR EPS either without or after procainamide challenge, but the study was neither randomized nor controlled, and the 100-ms interval chosen was based on old electrophysiology data related to predicting heart block not associated with TAVR. In this study, intra- or infra-His block also led to PPM implantation (62). Finally, second-degree AV block provoked by atrial pacing at a rate <150 beats per

minute (cycle length >400 ms) predicted PPM implantation (59). Limitations of these studies include their lack of a control group for comparison, meaning that outcomes without pacing are unknown.

In the study by Makki et al. (63), 24 patients received a PPM in-hospital (14% of the total cohort) and 7 (29%) as the result of an abnormal EPS. The indications for EPS were new LBBB, second-degree AV block, and transient thirddegree AV block. With a mean follow-up of 22 months and assessment of nonpaced rhythms in those with a PPM who both had and did not have EPS, the authors concluded that pacemaker dependency after TAVR is common among those who had demonstrated third-degree AV block pre-PPM but not among those with a prolonged HV delay during EPS. Limitations of this study are its small size and the fact that new LBBB was the primary indication for EPS. The observation that a minority of post-TAVR patients are pacemaker-dependent upon follow-up underscores the often transient nature of the myocardial injury and the complexity of identifying those who will benefit from a long-term indwelling device (64).

Although algorithms for PPM implantation have been proposed that are based on ECG criteria without EPS (65) and with EPS (59,61,62), all are based on opinion and observational rather than prospective data. Provided one recognizes the limitations of the studies reviewed earlier, EPS can be used for decision making when a definitive finding is identified that warrants pacing, such as infra-His block during atrial pacing, a prolonged HV interval with split His potentials (intra-Hisian conduction disturbance with 2 distinct, separated electrogram potentials), or an extremely long HV interval with either RBBB or LBBB (6). Although studies are forthcoming, the currently available data do not support PPM indications specific to the TAVR population.

A reassuring addition to the literature from Ream et al. (47) reported that although AV block developed ≥ 2 days post-TAVR in 18 (12%) of 150 consecutive patients, it occurred in only 1 patient between days 14 and 30. Importantly, of those with DH-AVB, only 5 had symptoms (dizziness in 3, syncope in 2) and there were no deaths. The greatest risk factor for developing DH-AVB was baseline RBBB (risk 26-fold). The PR interval and even the development of LBBB were not predictors of DH-AVB. The authors recommended electrophysiology consultation for EPS and/or PPM implantation for patients with high-risk pre-TAVR ECGs (e.g., with a finding of RBBB), those with intraprocedure high-degree AV block, and for those who, on monitoring, have high-degree AV block (47). Thus, for patients not receiving an early PPM, follow-up without EPS but with short-term monitoring is reasonable when there is not a clear indication for pacing immediately after TAVR.

For those who are without clear pacemaker indications during their procedural hospitalization but are at risk for DH-AVB, prolonged monitoring is often employed. The length of inpatient telemetry monitoring varies but reflects the timing of AVB after TAVR, clustering within the first 7 to 8 days postprocedure (47,48,58). The cost and inherent risks of prolonged hospitalization for telemetry have prompted the evaluation of AEM strategies in 3 patient populations: 1) all patients without a pacemaker at the time of discharge after TAVR; 2) those with new LBBB; and 3) those with any new or progressive conduction abnormality after TAVR.

The largest post-TAVR AEM study to date observed 118 patients after discharge for 30 days. Twelve of these (10%) had DH-AVB at a median of 6 days (range 3 to 24 days), with 10 of the 12 events occurring within 8 days. One of these patients with an event had no pre- or post-TAVR conduction abnormalities, and new LBBB was not identified as a risk factor for subsequent DH-AVB. The AEM and surveillance infrastructure employed in this study enabled the prompt identification of DH-AVB, and no serious adverse events occurred in the group that experienced it (47). However, in the observational experience preceding this study, the same group reported 4 patients (of 158 without a PPM at discharge) who experienced DH-AVB necessitating readmission, all within 10 days of the procedure (range 8 to 10 days). Three underwent uncomplicated PPM implantation, although 1 sustained syncope and fatal intracranial hemorrhage. Importantly, for this group, routine AEM was not in place, and none of these patients had baseline or postprocedure conduction disturbances (46). While others have observed no DH-AVB in those without pre-existing or post-TAVR conduction disturbances, or with a stable ECG 2 days after TAVR (0 of 250 patients), AEM postdischarge was not employed, raising the possibility of under-reporting (48).

The 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) trial enrolled patients (n = 103) with new-onset and persistent LBBB after TAVR, a common conduction abnormality post-TAVR and one associated with DH-AVB and sudden death in some observations (6,27,34,48,55,58,59). Patients meeting these criteria had a loop recorder implanted at discharge. Ten patients (10%) underwent permanent pacing due to DH-AVB (n =9) or bradycardia (n = 1) at a median of 30 days post-TAVR (range 5 to 281 days). Although the rate of PPM implantation was relatively consistent throughout the observational period, it is important to note that the median length of stay in this cohort was 7 days, whereas the current median in the United States is approximately 2 days (66). There was a single sudden cardiac death 10 months after discharge, and presence or absence of an arrhythmogenic origin was not determined

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as the patient's implantable loop recorder was not interrogated (58).

A third prospective observational study enrolled patients with new conduction disturbances (first- or seconddegree heart block, or new bundle branch block) after TAVR that did not progress to conventional pacemaker indications during hospitalization. These patients were offered AEM for 30 days after discharge. Among the 54 patients, 3 (6%) underwent PPM within 30 days. Two of the patients had asymptomatic DH-AVB, and 1 had elected not to wear the AEM and suffered a syncopal event in the context of DH-AVB. No sudden cardiac death or other sequelae of DH-AVB were observed (47).

Given these results, in patients with new or worsened conduction disturbance after TAVR (PR or QRS interval increase $\geq 10\%$), early discharge after TAVR is less likely to be safe. We recommend inpatient monitoring with telemetry for at least 2 days if the rhythm disturbance does not progress, and up to 7 days if AEM is not going to be employed. We suggest that it is appropriate to provide AEM to any patient with a PR or QRS interval that is new or extended by $\geq 10\%$, and that this monitoring should occur for at least 14 days postdischarge. The heart team and the AEM monitor employed should have the capacity to receive and respond to DH-AVB within an hour and to dispatch appropriate emergency medical services.

We also acknowledge the shortcomings of existing observational experience. These include that DH-AVB has been identified in patients with normal ECGs pre- and post-TAVR, and that 14 or even 30 days of monitoring is unlikely to be sufficient to capture all occurrences of DH-AVB. Ongoing and forthcoming studies and technology will enable the development of more sophisticated protocols and of device systems that facilitate adherence, real-time monitoring, and effective response times in an economically viable manner.

6. DISCUSSION AND IMPLICATION OF PATHWAY

This tool is intended to be employed in the clinic during the initial evaluation of patients, in planning meetings, and in preprocedural areas prior to TAVR. It is also intended to assist in decisions regarding length of stay and safe discharge planning. All members of the structural heart team should be knowledgeable about the incidence and management of rhythm disturbances in patients undergoing TAVR, and this tool can permit uniformity across providers and systems in the care of these patients.

The goal of this document is to provide a framework for the risk assessment and management of rhythm disturbances after TAVR. As TAVR becomes more common than surgical aortic valve replacement, the risk and consequences of conduction disturbances are important discussion points in the structural heart clinic. The management of these disturbances involves a number of physicians and care providers from different medical specialties working through transitions of care from the inpatient to outpatient setting. Decisions regarding PPM have implications for length of stay, aggregate procedural risks, and likely intermediate-term quality of life and mortality. In many cases, however, there remains uncertainty regarding the manner in which conduction block should be managed after TAVR, and clinical judgment is foundational. Additionally, most studies cited herein involved patients who are elderly and high-risk populations; whether the observations are also apparent in younger, lower-risk patients remains to be determined. As more data become available, the appropriate management of patients with transient and/or new conduction disturbances will likely be clarified. As we await these trials, it is our hope that this document will assist care teams in the management of patients.

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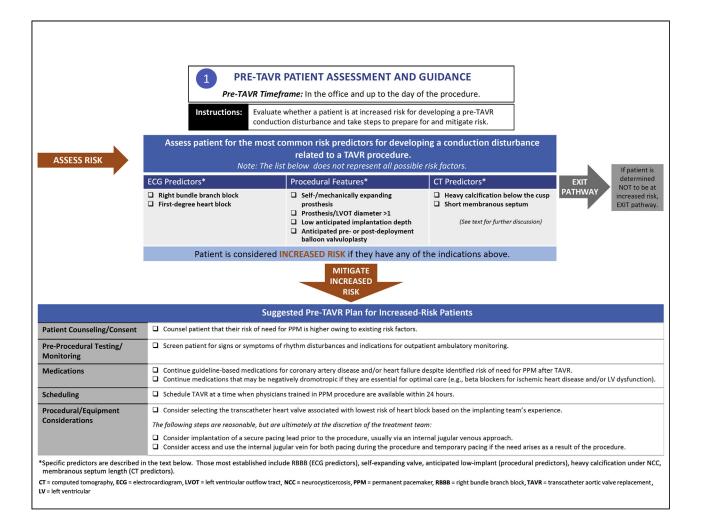
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KEY WORDS ACC Expert Consensus Decision Pathway, delayed high grade atrioventricular block, permanent pacemaker, transcatheter aortic valve replacement

APPENDIX 1. DECISION GUIDE FOR MANAGING CONDUCTION DISTURBANCES AFTER TAVR



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Post-TAVR Conduction Disturbances Decision Pathway

2 INTRAPROCEDURAL TAVR MANAGEMENT Intraprocedural TAVR Timeframe: The day of the procedure until completion of procedure.				
	Instruc			
	IF	THEN → Suggested Intraprocedural TAVR Plan		
PRIOR TO START OF PROCEDURE	Pre-TAVR assessment indicated that patient is at increased risk for conduction disturbances: Patient has increased-risk procedural factors (Figure 5):	 Continue guideline-based medications for coronary artery disease and/or heart failure despite identified risk of need for PPM after TAVF Revisit the necessity of a secure pacing lead, internal jugular versus femoral venous access, given increased risk of need for PPM. Consider implantation of secure pacing lead prior to the procedure, usually via an internal jugular vein. Access and use the internal jugular vein for both pacing during the procedure and temporary pacing if the need arises as a n of the procedure. Discuss potential for PPM and obtain consent in clinic where feasible. 		
FOR ALL F	PATIENTS DURING PROCEDURE	Irrespective of the type of temporary lead implanted, all patients should be monitored on a telemetry unit with ability to do emergency pacing if required		
	No new conduction disturbance	➔ Temporary pacemaker and venous sheath can be removed before the patient leaves the procedure room.		
	Develops conduction disturbance (e.g., LBBB, PR/QRS duration ≥20 msec) that may require further pacing	Internal jugular venous access with a secure pacing lead prior to leaving the procedure room is reasonable for patients with new conduct disturbance but ultimately at the discretion of the implantation team.		
DURING AND	Develops transient complete heart block	Internal jugular venous access with a secure pacing lead prior to leaving the procedure room is reasonable for patients with transient heart block but ultimately at the discretion of the implantation team.		
UNTIL	Develops persistent complete heart block	> Internal jugular venous access with a secure pacing lead prior to leaving the procedure room is indicated for patients with sustained heart block.		
COMPLETION OF PROCEDURE	Pre-existing conduction disturbance with indication for PPM	It is preferable to separate the procedures so that informed consent can occur, and the procedures can be performed in their respective spaces with related necessary equipment and staff. It may be reasonable to perform the PPM procedure on the same day as the TAVR procedure if: PPM is indicated Informed consent has occurred Appropriate teams and specialty equipment are available.		
	Pre-existing conduction disturbance and a secure pacing lead in place	→ Monitor on a telemetry unit, with temporary pacemaker attached and programmed to provide back-up pacing if required.		
	Multiple factors that additively confer increased risk but individually do not	→ Monitor on a telemetry unit, with temporary pacemaker attached and programmed to provide back-up pacing if required.		

	3 POST-TAVR MANAGEMENT Post-TAVR Timeframe: From completion of procedure through 30 days post-discharge.			
	Instructions: Manage and monitor patients wh	o do develop a	a conduction disturbance.	
	IF the Patient Aligns with Any of These Scenarios	THEN \rightarrow	Suggested Post-TAVR Plan	
	Symptomatic bradycardia or persistent, complete heart block	>	PPM.	
PPM/ EP STUDY	New, progressive, or pre-existing conduction disturbance that changes post-procedure	>	Monitor, consider EP study and PPM.	
	Narrow QRS before and after TAVR	→	EP study and PPM are not indicated.	
DISCHARGE	All of the following: All of the following: No primary PPM indication No new 1 st degree or 2 rd degree AV block No new bundle branch block No progression in baseline 1 st , 2 rd degree AV block or prolongation of the QRS≥10%	÷	Patient can be considered for early discharge.	
	If any of the above are present	<i>→</i>	Telemetry until conduction is stable for ≥48 hours; discharge with an outpatien monitor for ≥14 days.	
♦ OUTPATIENT MONITORING	New rhythm disturbance (e.g., atrial fibrillation) OR Progression of baseline conduction disturbance OR For whom the provider feels that monitoring is warranted	→	 Discharge with a monitor for a minimum of 14 days. Care teams should be resourced to manage outpatient monitoring to iden progressive rhythm issues in a timely manner. Use monitoring system that is accurate, enables adherence, notifies care t in a timely manner.* 	

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APPENDIX 2. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT) – 2020 ACC EXPERT CONSENSUS DECISION PATHWAY ON MANAGEMENT OF CONDUCTION DISTURBANCES IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE REPLACEMENT

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACC Solution Set Oversight Committee reviews these disclosures to determine which companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no relevant relationships with industry (RWI), led by a chair with no relevant RWI. RWI is reviewed on all conference calls and updated as changes occur. Author RWI pertinent to this document is disclosed in the table below and peer reviewer RWI is disclosed in Appendix 3. Additionally, to ensure complete transparency, authors' *comprehensive disclosure information*–including RWI not pertinent to this document–is available online. Disclosure information for the ACC Solution Set Oversight Committee is also available online, as well as the ACC disclosure policy for document development.

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ACC=American College of Cardiology.

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APPENDIX 3. PEER REVIEWER INFORMATION-2020 ACC EXPERT CONSENSUS DECISION PATHWAY ON MANAGEMENT OF CONDUCTION DISTURBANCES IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE REPLACEMENT

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ACC=American College of Cardiology; EP=electrophysiology; HCMC=Hennepin County Medical Center; UT=University of Texas; VCU=Virginia Commonwealth University.

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APPENDIX 4. ABBREVIATIONS

ACC = American College of Cardiology

- $AEM = ambulatory \ event \ monitoring$
- $AVB = atrioventricular \ block$
- $DH\text{-}AVB = delayed \ high \ grade \ atrioventricular \ block$
- $ECDP = Expert \ Consensus \ Decision \ Pathway$
- ECG = electrocardiogram

 $\label{eq:eps} EPS = electrophysiological studies$

HV = His-ventricular

LBBB = left bundle branch block

PPM = permanent pacemaker

- $RBBB = right \ bundle \ branch \ block$
- TAVR = transcatheter aortic valve replacement