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VALVULAR HEART DISEASE (TL KIEFER, SECTION EDITOR)

Electrophysiologic Implications of Transcatheter Aortic Valve Replacement: Incidence, Outcomes, and Current Management Strategies

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Abstract

Purpose of Review Transcatheter aortic valve replacement (TAVR) has changed the paradigm for management of severe aortic stenosis. Despite substantial procedural advancements, conduction system abnormalities remain a common complication following TAVR. In this review, we describe (1) incidence and risk factors for the development of conduction disturbances following TAVR, along with their prognostic significance, (2) the incidence and prognostic significance of new-onset arrhythmias following TAVR, (3) approach to management of perioperative and post-procedural conduction disturbances and arrhythmias, and (4) novel areas of research.

Recent Findings Conduction disturbances including left bundle branch block (LBBB) and high-grade atrioventricular block (HAVB) remain common issues post-TAVR despite advancements in valve technology and improvements in procedural technique. Despite data showing most conduction abnormalities resolve over time, rates of post-procedural permanent pacemaker implantation remain high. Similarly, rates of new-onset or newly detected arrhythmia, particularly atrial fibrillation, have been widely reported post-implantation of all types of TAVR valves.

Summary Recent consensus statements and decision pathway documents have been helpful in standardizing an approach to post-TAVR conduction disturbances. New areas of research show promise both for predicting which patients will develop conduction disturbances post-TAVR and for management of HAVB with novel pacing techniques. On the other hand, management of new-onset or newly detected atrial fibrillation after TAVR remains a significant challenge without standardized treatment strategy.

Keywords Transcatheter aortic valve replacement · Conduction disturbances · Electrophysiology study · Permanent pacemaker

Introduction

Transcatheter aortic valve replacement (TAVR) has become a viable alternative to surgical aortic valve replacement (AVR) for most patients with severe aortic stenosis. Initially studied for use in high-risk surgical populations [1, 2], TAVR has now gained approval for use in intermediate and low surgical risk patients, with randomized clinical trials demonstrating non-inferior safety and efficacy outcomes compared with traditional surgical AVR [3, 4, 5, 6]. As a result, TAVR procedural volume has dramatically increased over the past 10 years and an increasingly broad population of patients is now undergoing the transcatheter valve replacement rather than surgical AVR [7, 8•].

In the two decades since TAVR has been used in humans, substantial technological advancements have been made to improve safety and efficacy of the procedure. Despite rapid clinical uptake of this technology, new conduction disturbances and arrhythmias following TAVR continue to be common procedural complications [9–11]. In this chapter, we review (1) incidence and risk factors for the development of conduction disturbances following TAVR, along

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with their prognostic significance, (2) the incidence and prognostic significance of new-onset arrhythmias following TAVR, (3) approach to management of perioperative and post-procedural conduction disturbances and arrhythmias, and (4) novel areas of research.

New-Onset Conduction Disturbances Following TAVR: Incidence, Predictors, and Prognostic Implications

Damage to the atrioventricular and/or intraventricular conduction system remains the most common complication following TAVR. This is the result of close proximity between the aortic valve annulus and the membranous intraventricular septum, within which the proximal His-Purkinje system, especially the left bundle branch (LBB), is contained (Fig. 1). Catheter and valve-associated trauma, inflammation following valve deployment, valve positioning deeper within the left ventricular outflow tract (LVOT), compressive ischemia, and pacing-associated ischemia during valve deployment are all proposed mechanisms of conduction system injury caused by TAVR [12, 13]. Regardless of the specific etiology, damage to this region can result in delayed or blocked conduction at the level of the atrioventricular (AV) node, the bundle of His, or the LBB.

Conduction disturbances following TAVR most commonly occur in the acute periprocedural period or within 48 h of valve implantation [9]; however, delayed presentation of conduction disturbances including high-grade AV block has been reported to occur up to 24 days after TAVR [14]. Conduction abnormalities can be transient, occurring only during the intraoperative or periprocedural period, or permanent. Substantial differences have been noted between balloon-expandable and self-expanding valves with regard to risk of developing conduction system abnormalities following a TAVR procedure [15–17].

The most common conduction abnormality following TAVR is left bundle branch block (LBBB) [16, 18], though the incidence of new-onset LBBB has varied widely among cohorts (Fig. 2). Retrospective studies report that anywhere from 7 to 65% of patients develop new-onset LBBB following TAVR [15, 19]. Contemporary studies suggest an incidence of approximately 10–30%, with consistently higher incidence of new-onset LBBB in patients who receive self-expandable compared with balloon-expandable prostheses [19–22]. Persistence of LBBB also appears to be greater with the use of self-expanding valve, with only 10% resolution at 1-year follow-up compared with 39% resolution in the balloon-expandable valve cohort [16, 17]. Predictors of new-onset LBBB include baseline QRS duration, ventricular depth of prosthesis implantation, and the type of valve prosthesis implanted [23].

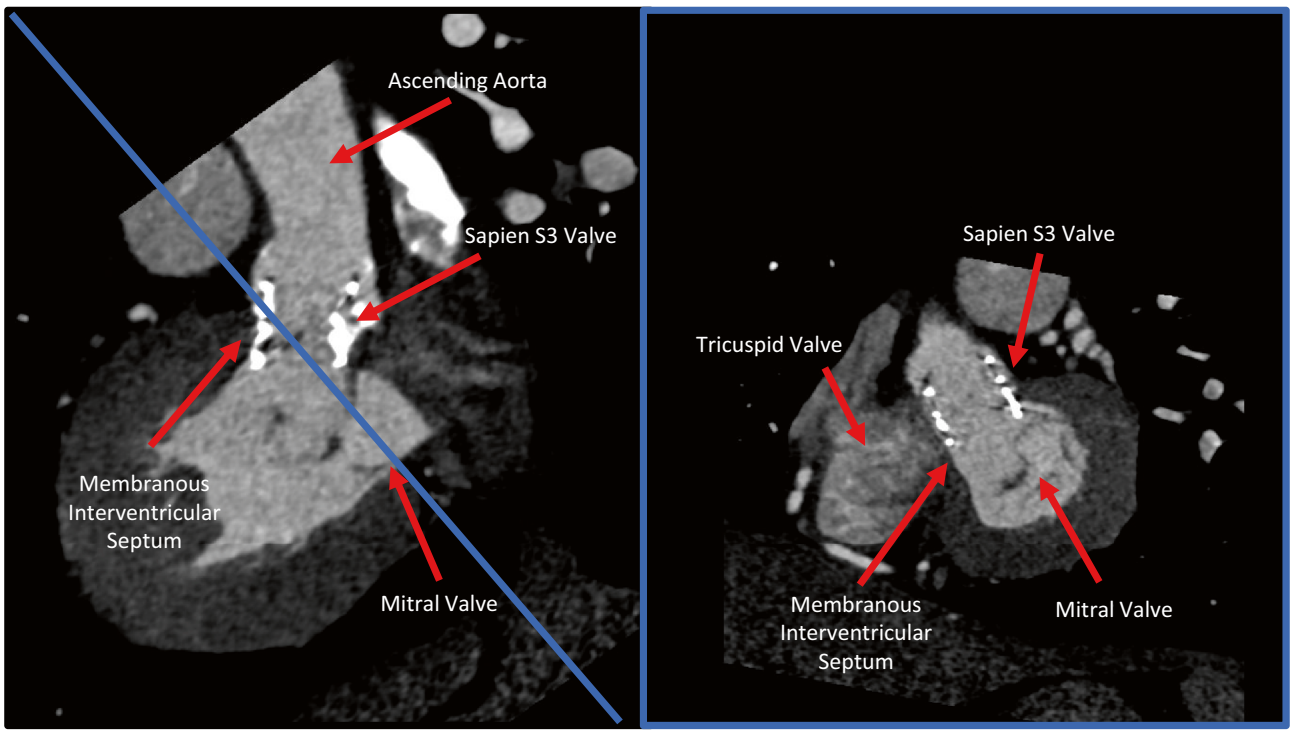

Fig. 1 Cardiac CT scan showing the position of a Sapien S3 TAVR valve relative to the ascending aorta, left ventricular outflow tract, and membranous interventricular septum in longitudinal (left panel) and shot axis (right panel) views. The proximal conduction system is encased in the membranous interventricular septum

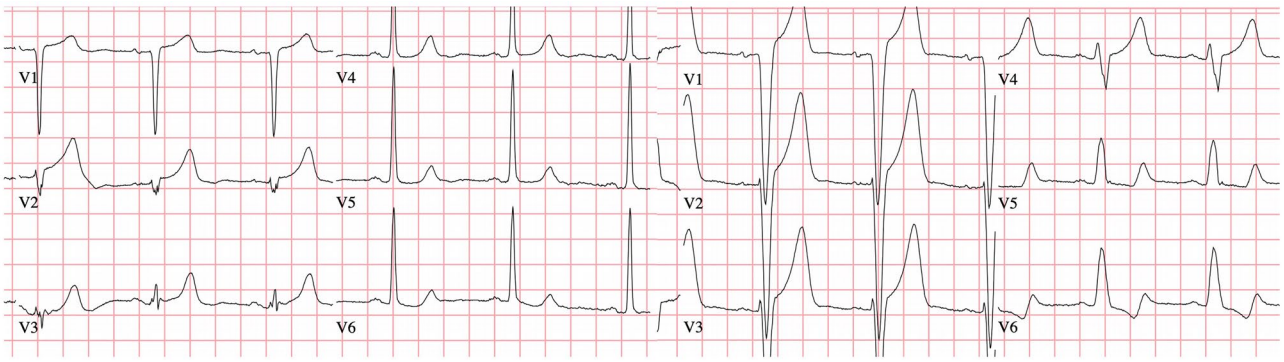

Fig. 2 Precordial leads on ECGs before and after TAVR in a patient who developed intra-procedural left bundle branch block

Development of new-onset LBBB following TAVR has been associated with poorer long-term outcomes such as decline in left ventricular ejection fraction, development of syncope, and need for permanent pacemaker implantation [16, 19, 23, 24, 25]. The effect of new-onset LBBB following TAVR on cardiovascular and all-cause mortality remains a subject of debate, with the majority of early studies suggesting no increased risk of mortality [20]. However, retrospective studies [19, 21] and pooled data from a meta-analysis [22] demonstrate concern for new-onset LBBB post-TAVR and increased risk of cardiovascular or all-cause mortality.

Second, high-grade atrioventricular block (HAVB) is a common complication following TAVR. The incidence of HAVB requiring permanent pacemaker (PP) implantation in early-generation prostheses has been reported to range from 3.8 to 17.3% for balloon-expandable and 19.8 to 37.6% for self-expandable valves [2, 26]. Despite improvements in procedural technique and rapid advancements in prosthesis technology, HAVB has remained quite common with contemporary valves. Recent analyses show rates of new pacemaker implantation following TAVR to range from 6.5 to 20.5% and 17.4 to 25.9% for modern balloon-expandable (Sapien 3, Edwards Lifesciences, Irvine, CA, USA) and self-expandable (Evolut R, Medtronic Inc. Minneapolis, MN, USA) valves, respectively (Fig. 3) [5, 6, 10, 11]. Accordingly, the real-world rate of PP implantation for all patients undergoing TAVR among all valve types reported to the STS registry in 2019 was 8.3% in-hospital and 10.8% within 30 days [8]. While the incidence of HAVB requiring PP implantation has declined over time for self-expandable prostheses, the opposite is true for balloon-expandable prosthesis. This may be related to features of the Sapien 3 design intended to minimize the risk of paravalvular leak, which likely result in greater mechanical pressure on the conduction system compared with earlier Sapien models [27, 28].

Fig. 3 Aggregate risk of pacemaker implantation in older and latest-generation TAVR valves

Incidence of New Pacemaker Placement within 30 Days after TAVR				
	Older Generation Valves		Latest Generation Valves	
	Edwards Sapien® Valves	Medtronic CoreValve®	Edwards Sapien 3®	Medtronic CoreValve Evolut-R®
Valve Image				
STS/ACC Registry	4.3%	25.1%	10.8%	
Range Reported from Worldwide Clinical Trials	3.8-17.3%	19.8-37.6%	6.5-20.5%	17.4-25.9%

The variable incidence of HAVB noted above is evidence that a multitude of risk factors contribute to conduction disturbances following TAVR, such as patient age, comorbid conditions, pre-existing conduction system disease, valve prosthesis size and positioning, operator technique, and prosthesis type. Established pre-procedural predictors of HAVB following TAVR are right bundle branch block, first-degree AV block, left anterior fascicular block, history of syncope, and short membranous intraventricular septum [29, 30, 31, 32, 33, 34, 35, 36]. Intra-procedural risk factors include self-expandable prosthesis, new-generation balloon-expandable prosthesis (Sapien 3), prosthesis/LVOT diameter ratio (i.e., valve oversizing), depth of valve implantation, and transient complete heart block with valve deployment [10, 29–34, 37, 38].

HAVB and subsequent PP implantation is of significant consequence to patients and healthcare systems. Studies evaluating short- and long-term outcomes have demonstrated longer duration of intensive care unit and hospital admission, higher costs associated with hospitalization, higher rates of hospital readmission, less robust improvement in left ventricular ejection fraction, and higher rates of 1-year mortality in patients who require PP implantation following TAVR compared with those who do not [9, 29, 30, 39, 40, 41].

New-Onset Arrhythmia Following TAVR

New-onset arrhythmias unrelated to atrioventricular and intraventricular conduction disturbances have been widely reported following TAVR. The most common new-onset arrhythmia is atrial fibrillation; however, sinus node dysfunction, supraventricular tachycardia, and ventricular arrhythmias have all been described [42]. In many cases, arrhythmias are detected through periprocedural monitoring, either during the procedure or through inpatient telemetry during the post-procedure hospitalization. In addition, a significant number of arrhythmias are also detected after hospital discharge on ambulatory cardiac monitors or during routine clinical follow-up.

The incidence of new-onset atrial fibrillation (NOAF) within 30 days following TAVR ranges from 5 to 13% across landmark randomized controlled trials in which the TAVR procedure was most rigorously studied [1–6]. Aggregated estimates suggest a prevalence of 11% NOAF before hospital discharge and up to 25% at 2-year follow-up [42]. While other new-onset supraventricular and ventricular arrhythmias have also been reported following TAVR, their incidence is consistently much lower than that of NOAF. As a result, the clinical impact and true incidences of these arrhythmias remain less certain.

Unlike intraventricular conduction disturbances, new-onset arrhythmias are not thought to be directly attributable to the TAVR valve deployment. In the case of NOAF, however, the prevalence of previously diagnosed atrial fibrillation in patients undergoing TAVR has been reported at 16–41% [1, 3, 5], suggesting that the disease processes of aortic stenosis and atrial fibrillation occur in parallel. Therefore, the high prevalence of NOAF diagnosed following TAVR may simply reflect an incidental finding in a patient population already highly predisposed to developing atrial fibrillation.

As with conduction disturbances following TAVR, NOAF also has important prognostic implications. Data have consistently demonstrated that TAVR patients who develop NOAF are at increased risk of cerebrovascular accident and death compared with patients who do not develop atrial fibrillation [42, 43, 44, 45]. To limit the adverse clinical impact, the identification of NOAF requires early attention and a shift in management strategy.

Management of Post-Procedure Conduction Disturbances and Arrhythmias

There has historically been a lack of consensus and heterogeneity of practice with regard to management of post-procedural conduction disturbances. This has led to substantial differences in observed rates of PP implantation between studies and clinical centers, despite the use of similar valve types [46, 47]. Heterogeneity in practice with regard to PP implantation largely relates to differences in management of new-onset LBBB, timing of PP implantation in patients with intraoperative or periprocedural HAVB, differences in multidisciplinary approach to management of conduction disturbances, and different approaches to pre-procedural risk assessment for determining who is likely to need PP implantation following TAVR. With an increasing volume of procedures, lack of decline in rates of postoperative PP implantation, and substantial practice variability among centers, the American College of Cardiology (ACC) provided expert panel recommendations and consensus guidelines in an attempt to help standardize management of post-TAVR conduction disturbances [48••, 49].

In 2019, the American College of Cardiology published a scientific expert panel statement for guiding management of conduction disturbances associated with TAVR. That document attempted to outline a near-universal strategy for pre-procedural risk stratification, intra-procedural management, and post-procedural care for patients who develop TAVR-associated conduction disturbances. Notably, they stratified patients into 5 groups representing different risk categories for the development of post-procedural HAVB or complete heart block.

Group 1 includes patients without conduction disturbances on electrocardiogram (ECG) before or after TAVR. It is recommended that those patients be monitored overnight on telemetry with post-procedure removal of a temporary pacemaker

if one was used to support valve implantation. Groups 2 and 3 include patients who are found to have conduction system disease prior to undergoing TAVR (Group 2: right bundle branch block; Group 3: QRS duration > 120 ms or first-degree atrioventricular block who then develop PR or QRS prolongation post-procedure). Group 2 has emerged as the highest risk for development of HAVB within 48 h requiring PP implantation. Accordingly, that group should be monitored on telemetry for 48 h with a temporary pacing wire left in place overnight. Group 3 is somewhat lower risk but should also be monitored overnight on telemetry with a temporary pacing wire. The wire can be removed, and discharge considered if there is regression of PR interval and QRS duration back to baseline. If further increase is seen in these parameters, an invasive electrophysiology study (EPS) could be considered to guide decision regarding PP implantation.

Group 4 consists of those who develop new-onset LBBB after TAVR. In these patients, it is recommended that a temporary pacing wire be retained overnight, then removed if there is no progression of LBBB, QRS, or PR intervals. If further conduction disturbances occur, EPS, ambulatory monitoring on discharge, or PP implantation should be considered. Lastly, group 5 consists of those who have transient intra- or post-procedure high-grade AVB. Expert panel recommendations recommend that a temporary pacing wire be retained in these patients overnight and PP implanted if abnormalities persist.

The 2019 Expert Panel Statement was supplemented in 2020 with an ACC Expert Consensus Decision Pathway in Management of Conduction Disturbances in Patients Undergoing TAVR [48••]. That document sets criteria for early discharge following TAVR in patients with low risk for development of HAVB, defined as patients with no primary PP indication, no new first- or second-degree atrioventricular block (AVB), no new bundle branch block, no progression of pre-existing first- or second-degree AVB, and no QRS prolongation > 10% for patients with pre-existing bundle branch block. The 2020 decision pathway also adds explicit recommendations regarding the use of ambulatory cardiac monitoring in patients with increased risk for delayed HAVB. It suggests using an ambulatory monitor with real-time rhythm alerts for at least 14 days in all patients who develop arrhythmia or conduction disturbances after TAVR. Like the 2019 Expert Panel Statement, the 2020 decision pathway includes the consideration of electrophysiology (EP) study for risk stratification in patients with new, progressive, or pre-existing conduction disturbances, and especially for dynamic post-TAVR changes, although data is insufficient to support the use of EP studies in all patients with conduction disturbances.

In real-world practice, monitoring for conduction disturbances and HAVB after discharge remains an area of significant practice variability among providers. Locally, our approach to post-procedural management closely resembles the recommendations summarized above; however, it differs somewhat with regard to patient follow-up. Specifically, after recognizing that a small but significant number of patients developed delayed (> 2 days) HAVB post-TAVR, we have been routinely discharging all patients who do not have a pacing device with 30-day ambulatory ECG monitor. In addition to 12% rate of acute HAVB within 2 days of TAVR among 150 consecutive patients, this approach has led to the detection and expedient treatment of HAVB in an additional 10% of patients wearing cardiac monitors after discharge, all of whom were readmitted for PP implantation (Fig. 4).

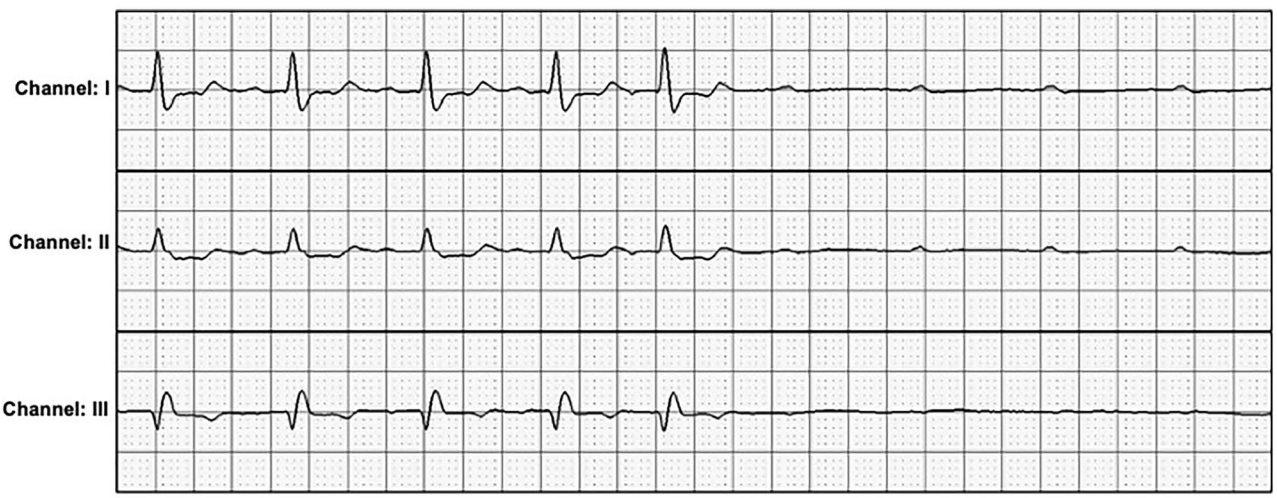

Fig. 4 Event monitor for patient in whom TAVR was performed, and no evidence of AV block was noted prior to hospital discharge. Note a premature atrial contraction followed by the development of transient complete heart block associated with syncope. This patient was instructed to return to the hospital immediately for permanent pacemaker implantation

While most of these patients were symptomatic, none developed syncope or sudden death and none had adverse events related to hospital readmission or PP implantation [14, 50].

Novel Areas of Research

Recent expert panels recommend preoperative risk stratification and interdisciplinary communication regarding patients who are at high risk of developing HAVB following TAVR. However, the preoperative determination of which patients will require PP implantation remains an inexact science. As outlined above, prior studies have identified a variety of clinical, electrocardiography, echocardiographic, and CT or MRI imaging characteristics that portend increased risk. Ongoing work is currently being done to produce a simple and highly predictive risk model based on pre-TAVR clinical features to determine which patients will be most likely to require PP implantation after TAVR. Multiple additional studies are currently ongoing to assess the value of preoperative ambulatory ECG for early determination of patients with undiagnosed arrhythmias and/or conduction disturbances which may require adjustments to management or planned PP at the time of a TAVR procedure.

For patients who are determined preoperatively to be high risk for HAVB, management strategies differ substantially between centers. Consensus recommendations suggest that a secure pacing lead be placed at the beginning of the procedure, regardless of whether it will be required for valve deployment. Throughout many centers, placement of a tined, balloon-tip pace-sense lead has been introduced to facilitate valve deployment and early management of post-procedure conduction disturbances [51]. Compared with traditional balloon-tipped, pace-sense leads, tined leads allow for increased stability and short-term retention with more reliable backup pacing capability. Many clinical questions remain unanswered about the use of transvenous pacemakers postoperatively, particularly with regard to newer tined leads. Optimal transvenous pacemaker settings, the effect of tined leads on postoperative conduction disturbances, the ideal timing of transvenous pacemaker removal, and the effect of tined leads on PP implantation rates are all questions that have not been adequately studied.

Determining which patients will be at high risk for developing HAVB > 2 days after TAVR also continues to be a challenge in the field. Consensus guidelines recommend the consideration of EP study to help in assisting with that determination in patients with postoperative conduction disturbances and unclear clinical trajectory. Measurements of His-ventricular conduction intervals as well as the concept of "stress testing" the conduction system with rapid atrial pacing have been described as methods of risk-stratifying post-TAVR patients and determining who is appropriate for PP implantation. These efforts have been complicated by lack of baseline preoperative conduction interval data and lack of control groups in whom EP study was not used to determine the need for PP implantation [52, 53, 54, 55]. Despite lack of consensus regarding a standardized approach to EP study and appropriate conduction interval thresholds for proceeding with PP implantation, this method shows promise as a potentially reliable means of postoperative risk stratification.

In patients who do require PP implantation, it has been demonstrated that long-term outcomes such as hospital readmission, improvement of LVEF, and all-cause mortality are compromised [9, 29, 30]. Poor outcomes in patients undergoing PP implantation may be related to high burden of right ventricular pacing following single or dual chamber PP implantation. Therefore, attention must be paid to anticipated burden of pacing in patients with HAVB following TAVR. Recent data have shown feasibility of pacing the proximal conduction system (His bundle or left bundle area) in this cohort of patients [56, 57, 58]. This technique of pacing may be particularly useful in the post-TAVR population because it can target ventricular pacing immediately distal to the region of conduction system block caused by the procedure, most commonly in the left bundle branch, and potentially decrease risk of pacing-induced cardiomyopathy. Further studies evaluating health outcomes in patients undergoing conduction system pacing compared with traditional right ventricular pacing post-TAVR are needed.

Leadless pacemakers have also emerged as a viable pacing option for patients with permanent atrial fibrillation who develop HAVB after TAVR. In those patients, the benefits of dual chamber pacemakers are limited, and the percutaneous implantation of a leadless device may be desirable. While no clinical trials or rigorous analyses have been done evaluating the safety and efficacy of leadless pacemaker implantation in this population, many case reports have demonstrated that this can be a reasonable option in select patient populations. Locally, our approach has been to consider leadless pacemaker implantation in post-TAVR patients with HAVB, permanent atrial fibrillation, limited mobility who do not need robust rate-responsiveness, and in whom standard subcutaneous pacemaker implantation is anticipated to result in high risk of postoperative complications such as hematoma, infection, poor wound healing, or lead dislodgement. Further studies evaluating the safety and efficacy of leadless pacemaker implantation in patients undergoing TAVR are warranted.

Conclusions

Transcatheter aortic valve replacement has revolutionized the field of cardiology and changed the paradigm for management of severe aortic stenosis. Although rapid advancements have been made in valve technology and procedural

techniques, postoperative arrhythmias and conduction system disturbances continue to be common complications that place patients at increased long-term morbidity and mortality. In particular, minimizing damage to the proximal conduction system, which is anatomically adjacent to the aortic valve annulus, is an issue that remains unresolved. Interdisciplinary collaboration and clinical investigation into reliable methods of accurately predicting, preventing, and appropriately managing postoperative conduction system disturbances following TAVR should remain a high priority as the field of transcatheter valve therapy continues to advance.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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•• Of major importance

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