

An Approach for the Management of Risk Factors for Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement in Severe Aortic Stenosis Patients

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ABSTRACT

Clinical Practice Guidelines have not yet been developed for the evaluation and management of risk factors associated with Permanent Pacemaker (PPM) implantation following Transcatheter Aortic Valve Replacement (TAVR) in patients with severe Aortic Stenosis (AS). Sufficient gaps in adequate data have resulted in a variety of valve center biases, small retrospective studies and consensus documents. TAVR is now more common in the US than Surgical Aortic Valve Replacement (SAVR) and the importance of establishing guideline therapy for this persistent major complication in FDA approved TAVR therapies is substantial. The thirty day PPM rate was 10.9% during the period of 2011-2013 and 10.8% in 2019 was highlighted in a recent publication tracking TAVR outcomes using FDA approved devices. Continued improvements in TAVR technology and technique along with the increasing experience in TAVR operators and valve team members have not changed this paradigm. We have gained some improvement in our understanding of Atrial Ventricular (AV) conduction abnormalities as it relates to segmental cardiac anatomy and procedural variables. Our approach to the management of post-TAVR patients at risk for PPM implantation nevertheless remains heterogenous. This review offers a proposed template for the evaluation and management of risk factors for PPM implantation following TAVR. Relevant risk factors are generally conduction defects that include High Grade AV Block or Complete Heart Block (HAVB/CHB).

Risk factors for PPM implantation can be categorized into pre, intra or post-procedural findings and generally detected as conduction defects on pre or post TAVR ElectroCardiogram (ECG), telemetry, Ambulatory ECG Monitoring (AEM), ElectroPhysiologic Studies (EPS) post-TAVR, anatomic characteristics by cardiac computerized tomography screening of the para aortic valve region and procedural characteristics.

A more homogenous approach needs to be driven by more definitive prospectively randomized data and less reliant on retrospective studies and anecdotal experiences. In the interim professional societies have suggested management pathways for patients at risk for post-TAVR PPM. Nevertheless in the absence of these data and formal Clinical Guidelines, the authors offer a tailored strategy described in this manuscript.

Keywords: Transcatheter aortic valve replacement; A-V Conduction defects; Surgical aortic valve replacement; Aortic stenosis; Electrocardiogram; Ambulatory ECG monitoring

INTRODUCTION

The Society of Thoracic Surgery-American College of Cardiology (STS-ACC) TransValvular Therapy (TVT) Registry is a large comprehensive data base populated with prospective data on 276,316 patients in the US extending from 2011-2019 that have undergone TAVR. It serves as a robust repository for well-defined

outcomes across a broad spectrum of demographics, clinical history, relevant anatomy/physiology, FDA valve type and ancillary devices, procedural techniques, operator and valve center experience. This data was recently analyzed and updated for publication as a State-of-the-Art Review in the Journal of American College of Cardiology [1]. The need for PPM implantation following TAVR was identified as one of three major complications with little improvement over time. The lack of thirty day PPM implantation rate improvement

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in combination with the significantly reduced length of stay to a median of 2 days (IQR: 1-3 days) leaves patients at an increased risk for outpatient HAVB/CHB complications such as sudden death. Trials should thus focus on earlier identification of these risk factors with a high degree of sensitivity and specificity providing for more appropriate use of PPM implantation following TAVR during index hospitalization.

LITERATURE REVIEW

It should be noted in the author's manuscript HAVB/CHB have been identified to represent a high risk segment of patients in need of PPM implantation. HAVB is a descriptor for second degree Mobitz Type II AV Block. In this manuscript Delayed-HAVB/CAHB (D-HAVB/CHB) is defined by time of occurrence i.e.; either two days post TAVR or following discharge whichever presents earliest. D-HAVB/CHB is generally detected by Ambulatory ECG Monitoring (AEM) in the outpatient setting.

DISCUSSION

Preprocedural risk factors

A patient's potential preprocedural risk factors for PPM should be identified and management strategies discussed at a TAVR centers valve team meetings [2]. Input from the spectrum of experts including structural heart interventionalists, cardiac surgeons, electrophysiologists, anesthesiologists, cardiac imaging experts and physician assistants should shape the appropriate strategy for patient treatment.

A) AV conduction disturbances Pre procedural 12 lead ECG is important in identifying abnormalities which carry an increased risk for PPM. Right Bundle Branch Block (RBBB) carries the highest and most consistent risk for PPM implantation [3]. A multi-center registry with 3527 patients including 362 (10.3%) having preprocedural RBBB demonstrated a 40.1% 30-day PPM rate vs 13.5% ($P<0.001$) and a 10.2% rate of mortality vs 6.9% ($P=0.024$) at a mean follow up of 18 months. Preexisting RBBB was also independently associated with higher all-cause mortality. (HR of 1.31; 95% CI: 1.06-1.31) ($p=0.014$) [4].

Ocean-Tavr (Optimized Transcatheter Valvular Intervention) registry carried out in 8 Japanese centers evaluated 749 patients undergoing TAVR using the Balloon Expandable (BE) Sapien XT (Edwards Lifesciences, Irvine, CA) was a prospectively trial with one hundred and two patients (13.6%) who had a pre-existing RBBB. The incidence of new PPM was significantly higher i.e.: 17.6% in the RBBB group vs. 2.9% in patients without baseline RBBB ($p<0.01$) [5].

Around 10-13% of a pre-TAVR population has Left Bundle Branch Block (LBBB) [6]. LBBB has not consistently predicted post-op PPM independently [7]. Patients with LBBB frequently have other risk factors for PPM such as age and low left ventricular ejection fraction. In a multi-center study with 3404 patients, 398 of which had pre-existing LBBB, there was an associated 21.1% risk of PPM in the LBBB group compared to 14.8% in the absence of LBBB (OR 1.51; 95% CI: 1.12-2.04) [6]. An association with pre-existing LBBB and PPM implantation post TAVR is nevertheless unclear and has perhaps been on the basis of preventive pacing based only on a perceived risk of HAVB/CHB. Prolonged QRS has not been significantly associated with subsequent PPM.

First degree AV block has not been definitively shown to place TAVR patients at risk for PPM post procedure. Of note though a PR interval progressive in length that has been associated with

RBBB by preop ECG is associated with a higher risk of D-HAVB/CHB [8].

B) Peri-Aortic Valve Anatomy by Screening Cardiac Computerized Tomography has highlighted anatomic associations with post-TAVR HAVB/CHB. Aortic valve regional anatomy needs to be considered along with baseline AV conduction abnormalities in determining a procedural strategy which may even include TAVR vs. alternatively Surgical Aortic Valve Replacement (SAVR). It's important to understand the relationships of the AV conduction system with adjacent cardiac landmarks (Figure 1). The bundle of HIS penetrates the membranous septum at the commissure between the non-coronary and right coronary cusp in the adjacent sub annular region. The Left Bundle Branch (LBB) further penetrates near the membranous septum and muscular interventricular junction. This component of the AV conduction system is susceptible to compression when the prosthetic valve is positioned more distally in the Left Ventricular Outflow Tract (LVOT), generally greater than 5 mm. It is also more susceptible to compression in the presence of a heavily calcified Non Coronary Cusp (NCC) along with adjacent basal segment of the annulus.

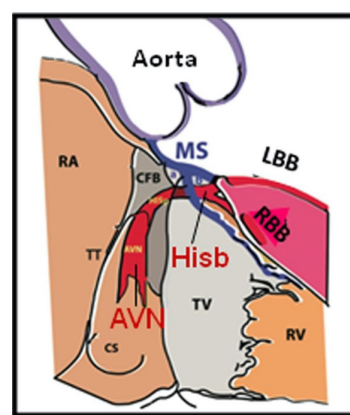


Figure 1: Schematic of the AV conduction system superimposed on relevant anatomic landmarks. RA: Right Atrium; TT: Tendon of Todazo; CS: Coronary Sinus; AVN: Atrioventricular Node; CFB: Central Fibrous Body; MS: Membranous Septum; Hisb: His Bundle Penetrating Membranous Septum; TV: Tricuspid Valve; LBB: Left Bundle Branch; RBB: Right Bundle Branch; RV: Right Ventricle.

A Membranous Septum (MS) length has been used as a surrogate for the distance between the AV annulus and distal bundle of HIS. This is generally measured on the TAVR pre-screening CT and this has been shown to be inversely related to significant AV conduction abnormalities and risk for post procedure PPM. In one study with 73 consecutive patients and severe AS who underwent pre-TAVR CT the MS length, calcium volume in all three coronary cusps and annulus perimeter were measured [9]. Multivariate logistic regression as a pre-procedural prediction model demonstrated MS length to be the strongest predictor of need for PPM (OR:1.43, 95% CI:1.1-1.8) ($p=0.002$). In addition pre and post-procedural predictors included calcification in the basal septum and difference in the basal septum length and valve prosthesis implantation depth (MSID) (OR:4.9, 95% CI:1.2-2.05) ($p=0.0031$) and (OR: 1.39,95%CI:1.2-1.7) ($p<0.001$) respectively. Optimal cutoffs were an implantation depth of 7.4 mm and a MSID difference of 0.04 mm for predicting PPM implantation. No PPM occurred beyond day 8 post procedure. Indications for PPM

were: 1) CHB in 9 patients,

2) Mobitz type II AV Block in 4 patients; 3) LBBB prolongation in 3 patients; 4) New LBBB and atrial fibrillation with slow ventricular response <100 beats/min; 5) Intra-procedure temporary asystole in 2 patients. Need for PPM was higher in patients with pre-procedural RBBB, calcification in the basilar septum and larger valve prosthesis perimeter.

In a single center trial a total of 240 consecutive patients obtained from a prospective database (Nov. 2013-Dec 2015) with adequate quality cardiac CT's were used to develop a predictive model for post procedure PPM following use of the BE Sapien 3 valve. Membranous Septum length was a significant pre-procedural multivariate predictor of PPM implantation (OR: 0.63-95% CI: 0.48-0.82) (p=0.001) [10].

In addition Non Coronary Cusp Device Landing Zone (NCC-DLZ) calcium was also a significant pre-procedural predictor of subsequent PPM (OR: 1.04, 95% CI 1.02-1.06). (p<0.001). Median values for the calcium volume of the NCC was 110.2 (IQ: 44.2-226.3) mm³, DLZ (all) was 39. (IQ: 16.2-86.9) mm³ and a mean MS length of 6.4 mm +/-SD 1.7 for those requiring a PPM. For those not requiring a PPM the mean MS length was 7.7 mm +/-SD 1.9, median calcium volume of 66.5 (IQ range: 26.0-150.5) mm³ and DLZ (all) calcium value of 14.1 (IQ range: 2.5-40.3)mm³. RBBB incorporated into the predictive model was also a multi-variant predictor as was MSID difference. The risk model has not yet been validated by prospective multi-center trials. Non randomized data sets however have set forth similar pre TAVR anatomic risk factors for post procedure PPM in severe AS patients [11,12].

Finally as small subannular LVOT diameter and in particular higher prosthetic valve diameter to subannular LVOT diameter ratio and recently suggested presence of congenital bicuspid aortic valve predicts post TAVR PPM. In a recent prospective, multi-center study with low risk bicuspid severe AS patients undergoing TAVR with either a self-expanding SE or BE valve prosthesis, post procedure PPM was evaluated [13]. Sixty one patients from 2016-2019 having a mean age of 68.6 +/-7.4 years congenital bicuspid valve (82.5% Sievers Type I) was associated with an overall 30 day PPM implant rate in 8 of 61 patients (13.1%). Seventy four percent of the sixty one patients received a Sapien 3 BE valve and 26% received an Evolute R or Evolute Pro SE valve (Medtronic, Minneapolis, MN.). The Sapien 3 valve resulted in a 6.5% thirty day PPM rate and the SE valves in a 31.3% PPM rate. The PPM risk appeared to be associated predominantly with the SE valve prosthesis. This is a small non-randomized study and therefore inconclusive. The higher PPM rate in these generally younger, lower risk patients that frequently have bicuspid aortic valves should give pause to the routine use of TAVR in this patient group who are good candidates for SAVR.

Intra-procedural risk factors

1) Negative chronotropic medications have not been demonstrated to be risks for procedural AV block with TAVR. They should be continued periprocedurally in the absence of HAVB/CHB which should have been treated by standard clinical guideline recommendations for PPM implantation preoperatively. In fact holding B-blockers at the time if TAVR may increase the risk of morbidity.

2) A decision regarding whether to use conscious sedation or general anesthesia should not be influenced by the presence of

AV conduction risk factors. A progressive shift toward conscious sedation has taken place over the last four years. Conscious sedation is now being used more frequently than general anesthesia in the TAVR setting, utilized in 33% of U.S. cases in 2016 and increased to 64% in 2019 [1].

3) SE valves have generally been associated with a higher incidence of intra and post-TAVR procedure HAVB/CHB leading to a higher thirty day PPM rate than BE valves, especially in the presence of AV conduction defects. Multiple studies have reported a higher incidence of subsequent PPM following SE valve implantation than BE valves. In an early trial using meta-analysis evaluating 11,210 TAVR patients obtained from 41 studies extending from 2005-2011 evaluated the PPM rate out to one year [14]. Both the SE CoreValve and early generation BE Sapien Valves were used. The overall incidence of post-TAVR PPM was 17%. The Sapien BE valve PPM rate was 6% and the SE CoreValve had a median PPM rate of 28%.

New generation repositionable Medtronic SE Valves have now been associated with a significant decrease in PPM rates contributed to by operator experience and understanding the relevance in maintaining an SE valve implantation depth of less than 5 mm below the annulus achieving rates of less than 20% at 30 days.

Of note post TAVR PPM rates as a major complication has not changed significantly throughout the duration of the U.S. STS-ACC TVT Registry evaluating a total of 276,316 patients. The initial 2011-2013 PPM rate was 10.9% and the 2019 rate was 10.8% [1]. Implantation of the Sapien 3 BE valve has been associated with higher rates of PPM implantation than earlier Sapien generations, likely related to the distal valve expanded cuff. However, in a large single center study with 1266 severe AS patients, multivariate analysis was performed on a retrospective derivation cohort who had undergone TAVR with a Sapien 3 valve that included 778 patients to determine a risk score model. The risk model was tested in a validation cohort of 367 patients. Of relevance was the need for one year post procedure PPM following Sapien 3 implantation in the 367 patients of 8.2%, (7.3% in the 788 patients from the derivation cohort) [7].

A surprising reduction in post-TAVR PPM was demonstrated in a single center 248 consecutive patient study using repositionable SE Evolute R, Evolute Pro or Evolute 34 XL (Medtronic, Minneapolis, MN) with the understanding that the predictor in this trial for post procedure PPM was MS length-implant depth (mm) [15]. In 24 of the 248 patients (9.7%) with a 30 day post TAVR PPM implantation rate, the mean MS length minus valve implant depth (mm) was minus 1.6 +/-2.4 mm. In the 224 of 248 patients (3.0%) with a PPM rate at thirty days, the mean MS length minus valve implant depth was 0.9 +/-3.0 mm. (p<0.001). Using this retrospective data, in an anatomically directed approach to device positioning based on the CT determined MS length was used to minimize post-TAVR PPM rate. This MIDAS (Minimizing Depth According to the Membranous Septum) approach set a new target for positioning/repositioning the prosthesis at a prerelease depth shorter than the MS length at the NCC. The 100 patient prospective MIDAS depth was 2.3 +/-1.2 mm vs. 3.3 +/-1.8 mm (p<.0001) in the retrospective non-MIDAS group.

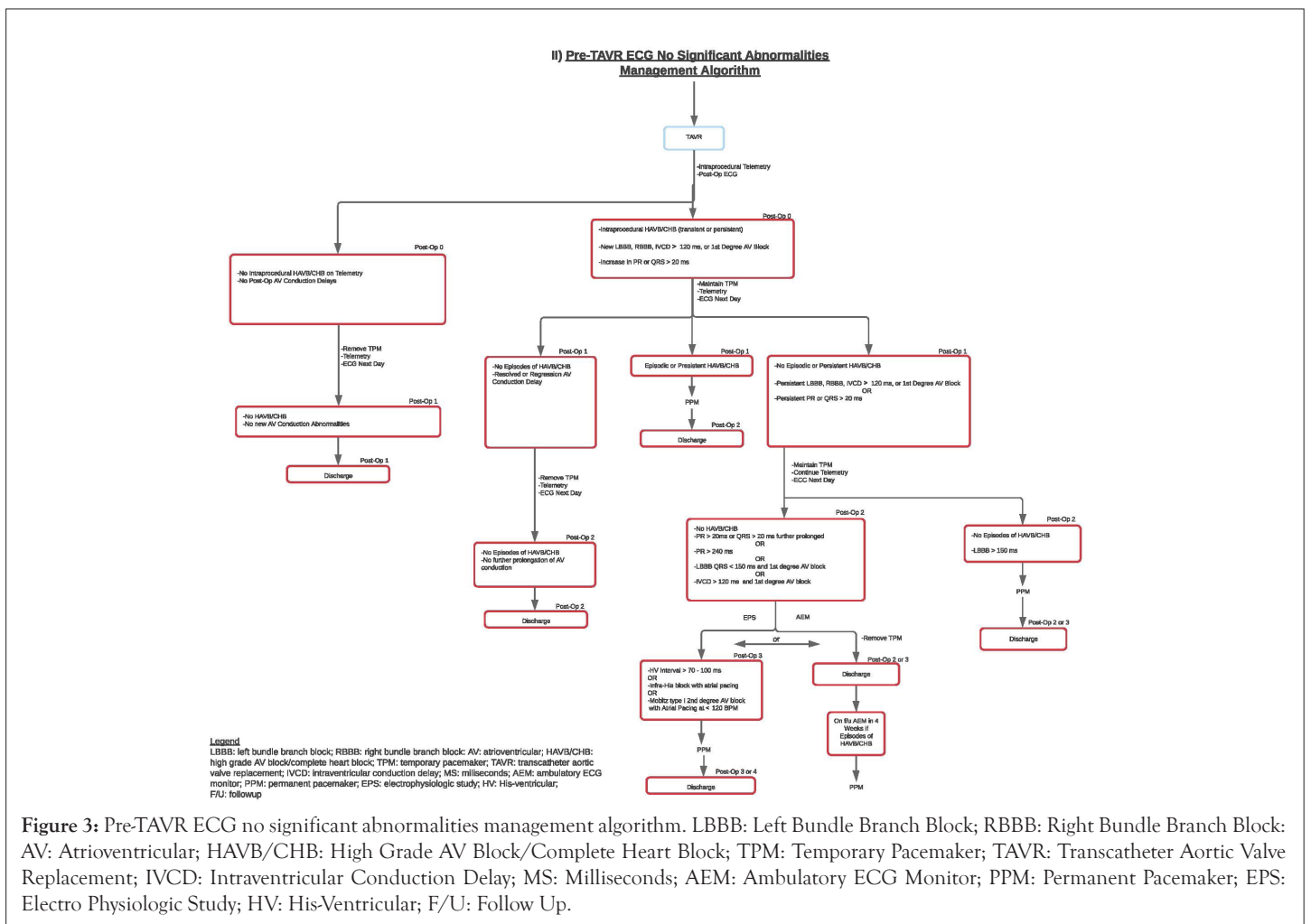
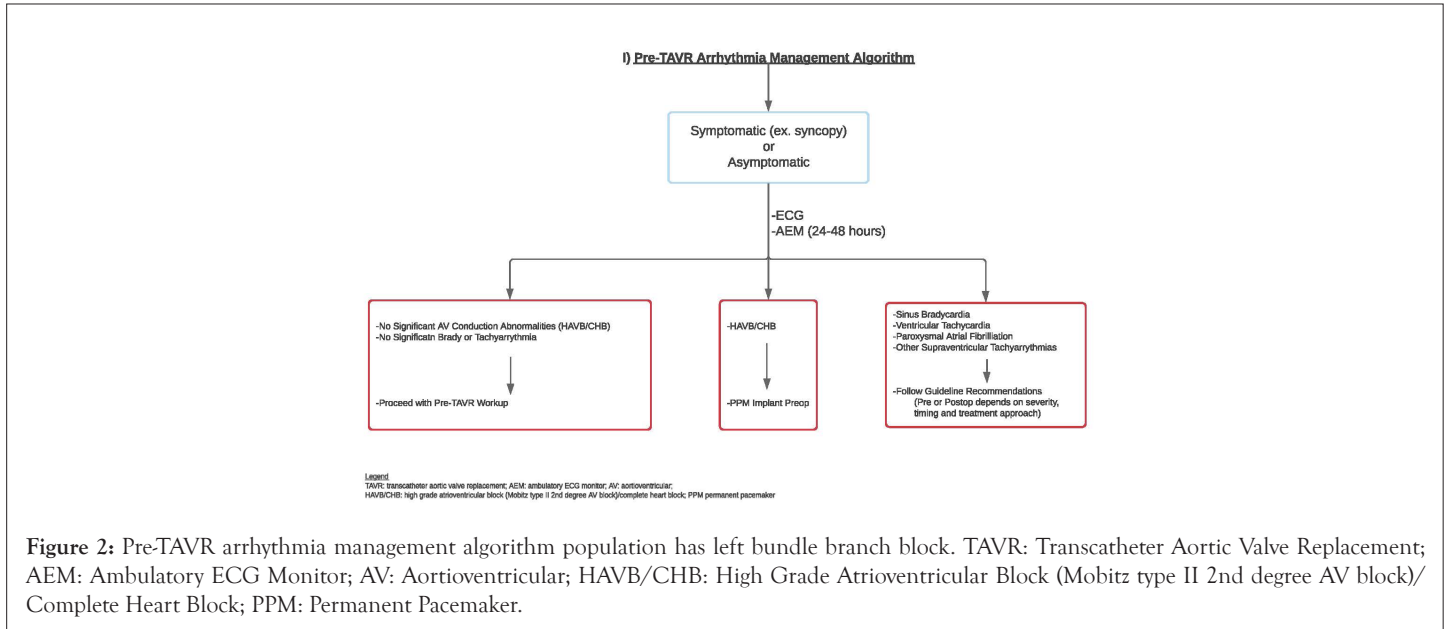
4) Balloon Aortic Valvuloplasty (BAV) pre and/or post TAVR has inconsistently suggested that BAV during TAVR was associated with new significant AV conduction defects and PPM especially in the presence of balloon diameter to annulus diameter of greater

than 1.0 [16-18]. This has been a concern predominantly in the setting of SE valves relevant especially for its use in the treatment of associated paravalvular leaks. The association may be enhanced by combining pre and post TAVR BAV especially in heavily calcified aortic valves. Of significance however are the findings in the only prospectively randomized trial designed to compare pre-TAVR BAV with non TAVR BAV patients in the setting of SE valve implantation in severe AS [19]. This trial consisted of only 100 patients and demonstrated no difference between the two groups.

New PPM was implanted in 27.5% of the pre-BAV and 32.8% of the non-pre non BAV patients (p=0.54).

Post procedure risk factors

Post-TAVR AV Conduction Defects Relevant to Pre-operative A-V Conduction Abnormalities are relevant but integration and quantitative aspects remain in part controversial. The authors have proposed a strategy supported by preliminary data and valve center experience [see branching diagrams 2-5] (Figures 2-5).



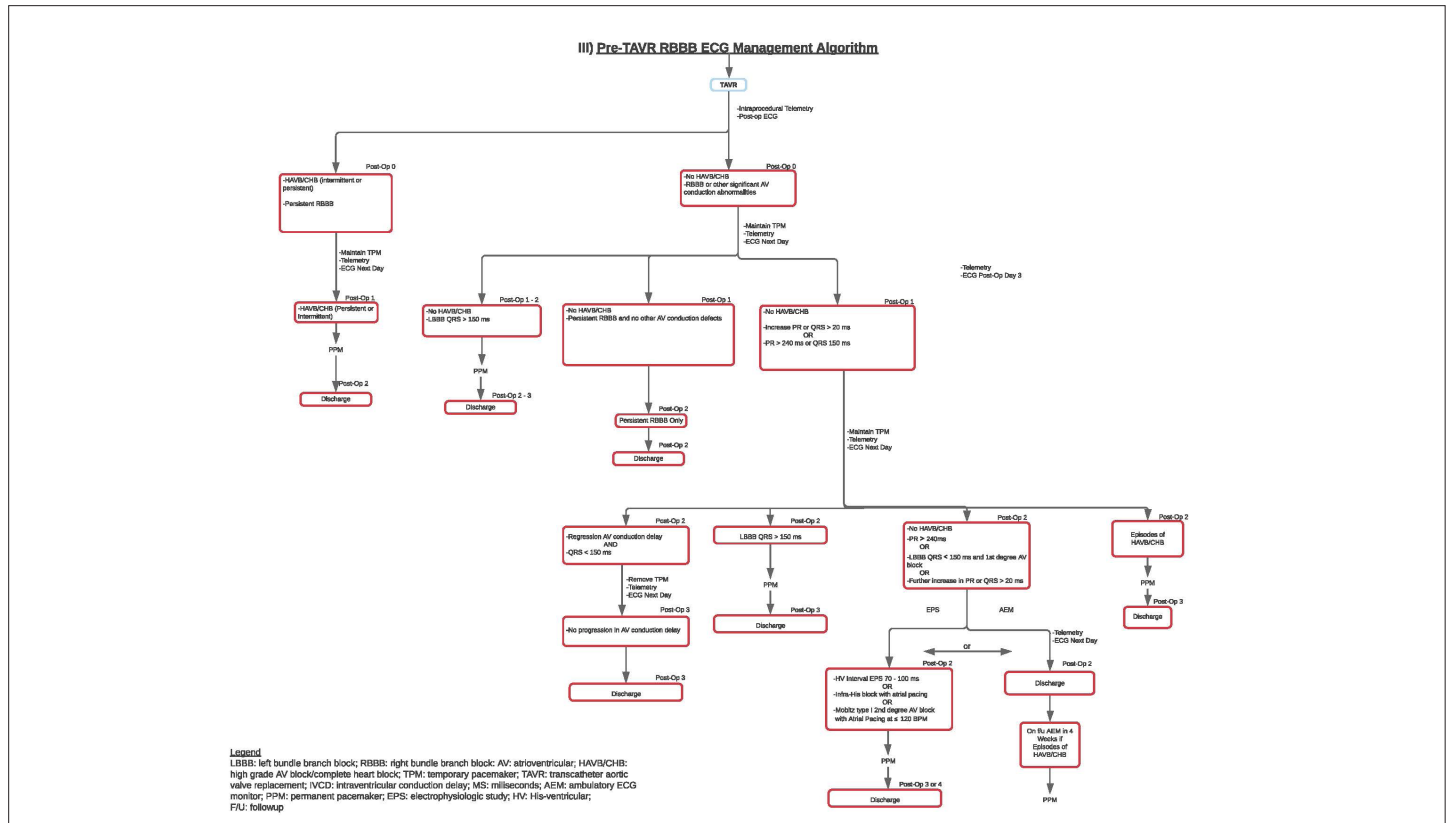


Figure 4: Pre-TAVR RBBB ECG Management Algorithm. LBBB: Left Bundle Branch Block; RBBB: Right Bundle Branch Block; AV: Atrioventricular; HAVB/CHB: High Grade AV Block/Complete Heart Block; TPM: Temporary Pacemaker; TAVR: Transcatheter Aortic Valve Replacement; IVCD: Intraventricular Conduction Delay; MS: Milliseconds; AEM: Ambulatory ECG Monitor; PPM: Permanent Pacemaker; EPS: Electro Physiologic Study; HV: His-Ventricular; F/U: Follow Up.

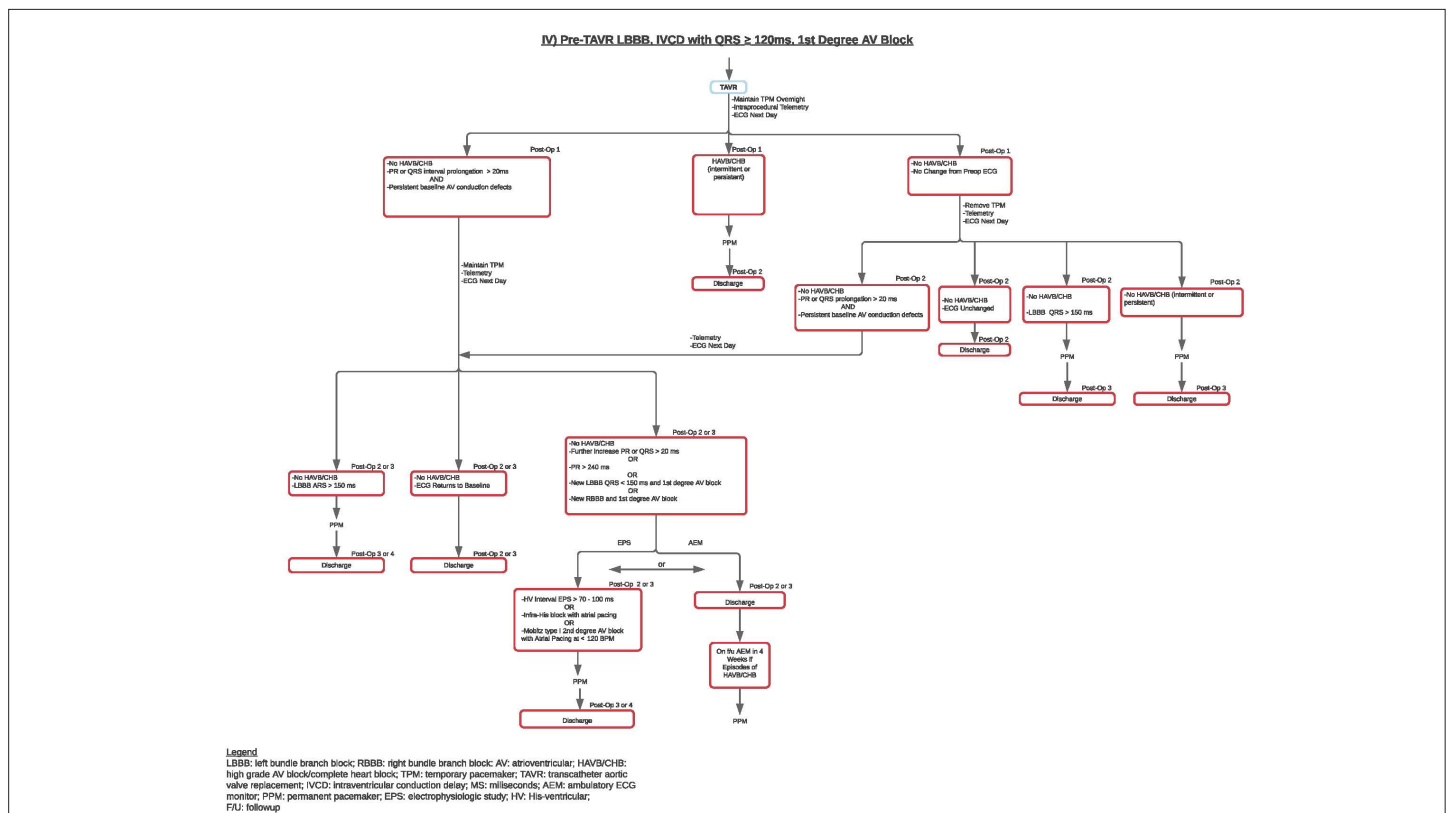


Figure 5: Pre-TAVR LBBB, IVCD with QRS ≥ 120 ms, 1st Degree AV Block. LBBB: Left Bundle Branch Block; RBBB: Right Bundle Branch Block; AV: Atrioventricular; HAVB/CHB: High Grade AV Block/Complete Heart Block; TPM: Temporary Pacemaker; TAVR: Transcatheter Aortic Valve Replacement; IVCD: Intraventricular Conduction Delay; MS: Milliseconds; AEM: Ambulatory ECG Monitor; PPM: Permanent Pacemaker; EPS: Electro Physiologic Study; HV: His-Ventricular; F/U: Follow Up.

Post-TAVR risks for PPM implantation are drawn from post procedure 12-lead ECG, hospital telemetry pre-discharge, invasive ElectroPhysiologic Studies (EPS) and post discharge Ambulatory ECG Monitor (AEM) to identify high risk AV conduction defects. Delayed HAVB/CHB (D-HAVB/CHB) is defined as occurring >2 days post-TAVR or following discharge whichever comes first. Given a median index hospitalization Length of Stay (LOS), now at two days (IQR: 1-3 days). It has become more important to discharge patients with intermediate risk AV conduction defects post-TAVR to undergo pre-discharge EPS or AEM for 2-4 weeks assessing for D-HAVB/CHB who may require PPM. Although unclear, pre-discharge invasive EPS data [see EPS finding under definitions] has been used by some to re-stratify patients an intermediate risk for PPM implantation. At this point there is no significant data to support such an approach but ongoing prospective trials may support such an approach. Electrophysiologic Study followed by findings which have been used to influence the post-TAVR decision process are predominantly arbitrary but in part drawn from what has been learned in other settings in determining PPM implantation need. AEM was useful in this regard for expeditious PPM intervention in 10% of those appropriately monitored [20]. Our preferred AEM system has been patch ECG recorders having 2-4 weeks duration and capable of wireless data transmission. They have excellent patient acceptance.

In reality, decisions for managing these patients require an integrated and experienced approach. Baseline ECG defined conduction abnormalities, anatomical choice of TAVR device, procedural technique along with post procedure AV conduction risk management of post TAVR patients is critical. Currently there is a great deal of heterogeneity in the incorporation of these risk factors when arriving at a decision for appropriate PPM implantation.

In an excellent paper put forth by The American College of Cardiology, Scientific Expert Panel a useful template was proposed outlining post-TAVR conduction disturbances as a framework for their management [21]. A post-procedural ECG with respect to the pre-procedural ECG and procedural brady arrhythmias were used to place patients into 5 risk groups [22].

Definitions

Post-Operative ECG: obtained within 15-30 minutes of TAVR procedure.

New Significant ECT Changes: (NSCE);

- increase in PR or QRS >20 ms in patients with preexisting RBBB LBBB, IVCD >120 ms or First Degree AVB
- PR duration >240 ms or QRS >150 ms.

Significant EPS findings

- HIS bundle minus Ventricular (HV) interval 70-100 ms.
- Infra-Hisian block with atrial pacing.
- Mobitz type 1 second degree AV block with atrial pacing at less than or equal to 120 Beats per Minutes (BPM)

Electrocardiographic criteria can be used to stratify post-TAVR risk for the consideration of post-TAVR PPM implantation. The authors have used such criteria to empirically divide these patients into 5 groups.

Group 1: This group consists of patients in the absence of both pre and post-operative ECG changes and absence of intraprocedural episodes of HACB/CHB. Relevant to this group is a single center study with 467 consecutive patients undergoing TAVR using either a BE or SE valve. Zero of seventy patients in sinus rhythm, PR interval <200 ms and QRS interval <120 ms developed HAVB/CHB [23].

Group 2: This group included patients with preoperative RBBB with no postoperative ECG changes or intra procedural HAVB/CHB. Preoperative risk for HAVB/CHB in baseline RBBB patients is high as previously described but in the absence of postoperative changes remains low in this group [24].

Group 3: In this group, patients include those with preoperative ECG changes but importantly demonstrate on postoperative ECG further increase in the PR or QRS interval. More specifically it includes an "intermediate" risk group with preexisting RBBB, LBBB, IVCD with a QRS interval >120 ms or First degree AVB and no intra procedural HAVB/CHB. This represents a challenging group divided into those who may require PPM implantation vs. those who PPM implantation can be avoided. Decision making often requires further testing and data integration [24].

Group 4: In this group, patients consist of post-TAVR ECG demonstrating new LBBB. This is a common occurrence following TAVR with an incidence often >25% (4%-65%) overall [25]. Some of these patients are at risk for PPM. Approximately 50% however will partially or completely normalize on repeat ECG prior to discharge. New onset LBBB are at risk for HAVB/CHB and subsequent PPM, but a cut off QRS duration for determining a more precise risk remains controversial and thus alternative management strategies have been recommended at different TAVR centers [25-27].

Group 5: This group constitutes patients with post procedural HAVB/CVB which may be intermittent or persistent and occur in the presence or absence of 12-lead ECG AV conduction defects pre and post TAVR. These episodes of HAVB/CHB can occur early within the index hospitalization or within a few days post discharge but may initially be documented weeks to months later [20,28,29].

Management of atrioventricular conduction, cardiac computerized tomography guided anatomy and procedural risk factors for permanent pacemaker implantation following transcatheter aortic valve replacement

Approaches in managing apparent risks for post TAVR PPM implantation are varied from one TAVR center to another and in addition operators within each center. Given the complex interaction of risk variables and lack of adequate multicenter randomized trials, significant data is unavailable to recommend formal Clinical Guidelines [see branching diagrams 2-7] (Figures 2-7). In this manuscript, suggestions for post-TAVR management are laid out in a diagrammatic format. Variables have been organized in groups the authors have found useful for managing risk of post procedural PPM implantation and potential sudden death. They are categorized in these severe AS patients using pre and post-TAVR ECG, preoperative cardiac CT for defining aortic valve complex anatomy, intra and postoperative telemetry, pre-discharge EPS and post discharge 2-4 weeks AEM when appropriate. Based on the expanded use of these variables they have now been integrated into a more encompassing approach displayed in diagrams I-IV.

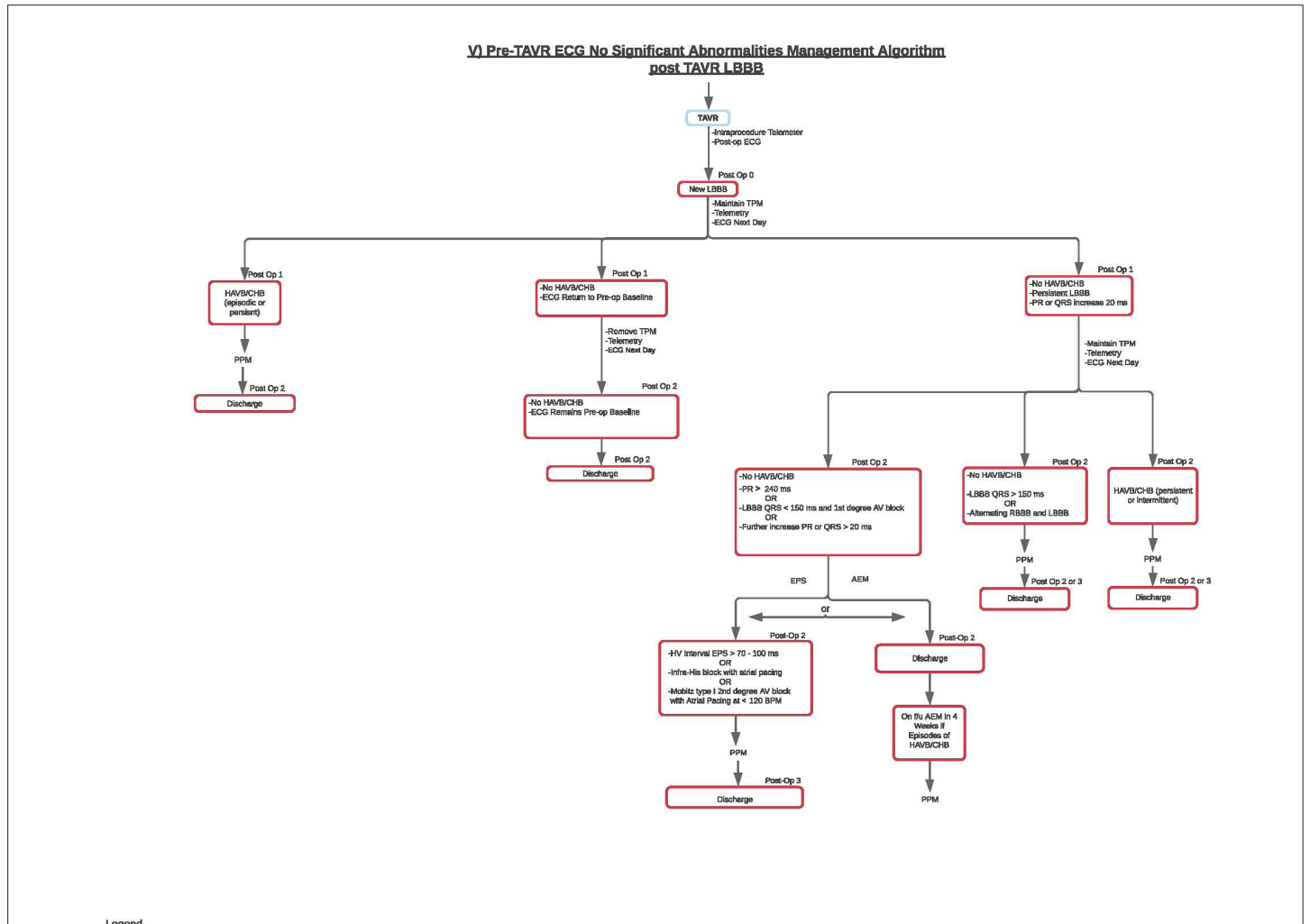


Figure 6: Pre-TAVR ECG No Significant Abnormalities Management Algorithm. LBBB: Left Bundle Branch Block; RBBB: Right Bundle Branch Block; AV: Atrioventricular; HAVB/CHB: High Grade AV Block/Complete Heart Block; TPM: Temporary Pacemaker; TAVR: Transcatheter Aortic Valve Replacement; IVCD: Intraventricular Conduction Delay; MS: Milliseconds; AEM: Ambulatory ECG Monitor; PPM: Permanent Pacemaker; EPS: Electro Physiologic Study; HV: His-Ventricular; F/U: Follow Up.

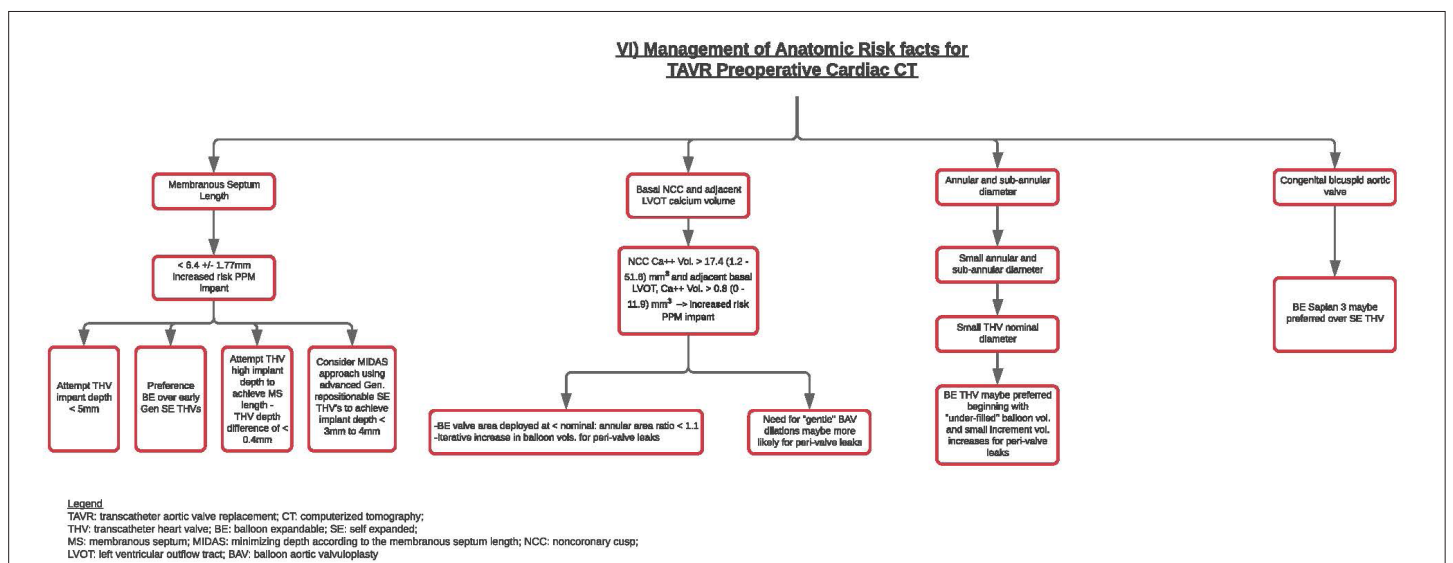


Figure 7: Management of Anatomic Risk factors for TAVR Preoperative Cardiac CT. TAVR: Transcatheter Aortic Valve Replacement; CT: Computerized Tomography; THV: Transcatheter Heart Valve; BE: Balloon Expandable; SE: Self-Expanded; MS: Membranous Septum; MIDAS: Minimizing Depth according to the Membranous Septum Length; NCC: Non-Coronary Cusp; LVOT: Left Ventricular Outflow Tract; BAV: Balloon Aortic Valvuloplasty.

CONCLUSION

Post-TAVR 30 day PPM rate in severe AS patients has remained a major complication with little improvement over the past decade as documented in the most recent STS-ACC TVT Registry analysis published this year, remaining 10.8% in 2019. In spite of increasing annual case numbers documenting 72,991 TAVR procedures in 2019 at 669 U.S. TAVR centers, improving valve technology and techniques, lower risk patient groups and improving valve team and operator experience, outcomes with regard to PPM implantation have not changed. Of further relevance is the progressively early hospital discharge post TAVR and thus the need for defining patients at risk for post discharge PPM. The authors have put forth in this paper an approach for the evaluation and management of pre and post procedural AV conduction abnormalities, anatomic and procedural risk factors in this clinical setting. It is clear that there is a need for more robust prospective, randomized, multi centered trial data to develop a more uniform consensus and ultimately formal Clinical Guidelines.

CONFLICT OF INTEREST

None.

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