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# Validation of the 2019 expert consensus algorithm for the management of conduction disturbances after transcatheter aortic valve replacement

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# Abstract

**Background:** The optimal management of patients with atrio-ventricular conduction disturbances after transcatheter aortic valve replacement (TAVR) is unknown. Guidance has been consolidated in an expert consensus algorithm in 2019.

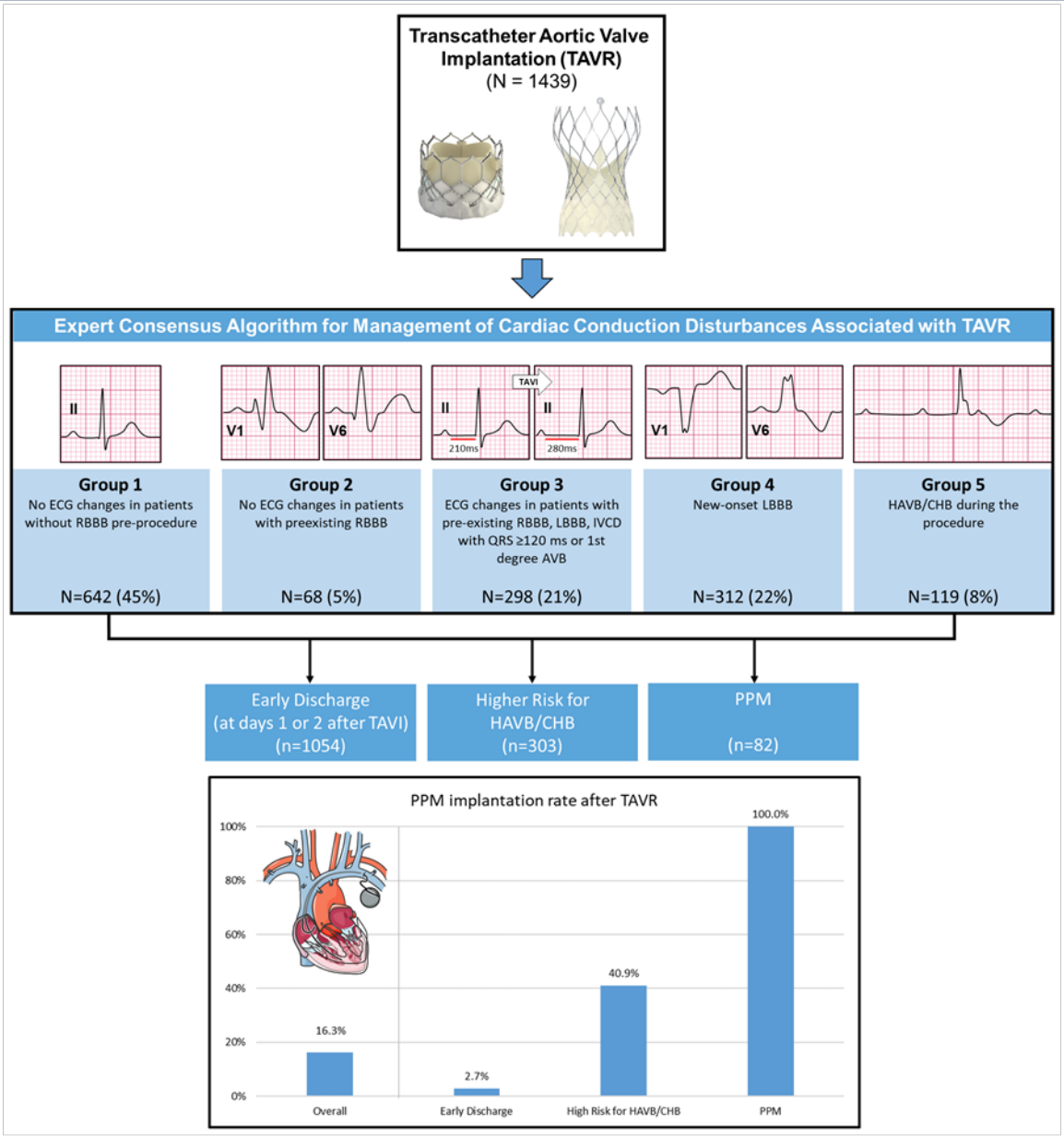
**Objectives:** To validate the 2019 consensus algorithm in a large cohort of contemporary TAVR patients.

**Methods:** In a retrospective analysis of a prospective registry, patients were classified according to the 2019 consensus algorithm as eligible for early discharge (days 1 or 2 after TAVR), higher risk for high degree AV block (HAVB)/complete heart block (CHB) or in need for a permanent pacemaker (PPM). The primary endpoint was the incidence of PPM implantations for HAVB/CHB within 30 days after TAVR. Patients with prior PPM/ICD implantation, valve-in-valve procedures or incomplete ECG data were excluded.

**Results:** Among 1439 patients undergoing TAVR between January 2014 and December 2019, the 2019 consensus algorithm classified 73% as eligible for early discharge, 21% as at higher risk for HAVB/CHB and 6% as in need for PPM. PPM implantation for HAVB/CHB occurred in 234 patients (16%) within 30 days after TAVR. The incidence of PPM implantation was 2.7% in the early discharge group, 41% in the higher risk for HAVB/CHB group and 100% in the PPM group.

**Conclusions:** The 2019 consensus algorithm safely identifies patients with no need for a PPM. This strategy allows a more uniform management of TAVR patients and early discharge of low-risk patients without prolonged monitoring in 3 out of 4 patients. The algorithm however is less precise in the identification of high risk patients.

**CENTRAL ILLUSTRATION:** Validation of the 2019 expert consensus algorithm for the management of conduction disturbances associated with TAVR




## Condensed Abstract:

The optimal management of patients with atrio-ventricular conduction disturbances after transcatheter aortic valve implantation (TAVI) remains unknown. Guidance has been consolidated in an expert consensus algorithm in 2019. This algorithm was clinically validated in a retrospective analysis of a prospective registry of 1439 patients undergoing TAVI. The algorithm identified patients with no need for a PPM with a negative predictive value of 97.3%. This strategy allows a more uniform management of TAVI patients and identifies 3 out of 4 TAVI patients eligible for a safe and early discharge without prolonged monitoring.

## Key words:

transcatheter aortic valve replacement, conduction disturbances, pacemaker implantation, ECG algorithm

## Abbreviations:

PPM = permanent pacemaker
TAVR = transcatheter aortic valve replacement
AVB = AV block
HAVB = high degree AV block
CHB = complete heart block
RBBB = right bundle branch block
LBBB = left bundle branch block

## Clinical Perspectives

**What is known?**
Conduction abnormalities post-TAVR are frequent, and optimal patient selection for permanent pacemaker implantations remains an unmet clinical need.

**What is new?**
A consensus algorithm for management of conductions abnormalities published in 2019 safely identifies post-TAVR patients with no need for a PPM. This strategy allows a more uniform management of TAVR patients and early discharge of low-risk patients without prolonged monitoring in 3 out of 4 patients. The algorithm however is less precise in the identification of high-risk patients.

**What is next?**
Additional external validation of the algorithm is needed. In particular, the ongoing prospective validation study (PROMOTE, ClinicalTrials.gov NCT04139616) will be important to further clarify on the value of the algorithm..

## Introduction

The introduction of transcatheter aortic valve replacement (TAVR) has profoundly changed the treatment of patients with severe, symptomatic aortic stenosis. Aggregate evidence from randomized clinical trials comparing TAVR and surgical aortic valve replacement (SAVR) in high, intermediate and low risk patients shows similar or superior clinical outcomes irrespective of baseline surgical risk and valve type.[1] As the TAVR procedure continues to expand to lower risk patients, the focus has shifted to the determinants of long-term effectiveness such as prosthetic valve durability, paravalvular regurgitation and atrioventricular conduction disturbances.

The prevalence of paravalvular regurgitation has decreased with time [2] owing to design iterations of transcatheter heart valves (THV) and improvements in multimodality imaging that in-turn optimize device selection, valve sizing and positioning.[2]

By contrast, atrioventricular conduction disturbances, particularly those that require the implantation of a permanent pacemaker (PPM) remain substantial and are in the range of 5-30% with contemporary THVs.[3-5] Although the long-term prognostic implications of PPM implantation post-TAVRI remain controversial,[3] the unpredictability of such rhythm disturbances can complicate the clinical pathway after TAVR and the associated cost. An increasing number of TAVR patients are being discharged within 24–48 hours after TAVR[6] and in select cases, they are discharged on the same day as the TAVR procedure.[7] As such, validated strategies that reliably and expeditiously triage patients as being safe for early discharge versus those who are at increased risk to require a PPM will be an important next step in streamlining post-procedural care pathways. At the same time, the occurrence of CHB as an outpatient event potentially leading to sudden cardiac death needs to be avoided.

Preprocedural factors (such as male gender or pre-existing right bundle branch block (RBBB)) as well as procedural factors (such as self-expanding valves (SEV) or implantation depth) have been consistently identified as major predictors of subsequent HAVB.[3,8] There is significant variability in management strategies and this translates to substantial differences in PPM implantation rates following TAVR even with the use of the same valve types.[3,9] While

some guidelines still recommend observation periods as long as 7 days,[10] procedural ECG changes as well as those in the subsequent 24 hours have emerged as important indicators.[11] Recently, the available evidence has been consolidated into an interdisciplinary expert consensus guideline with the aim to standardize the management of conduction disturbances associated with TAVR.[12]

The safety and efficacy of this algorithm has not been clinically validated to date. Therefore, the aim of the current investigation was to retrospectively validate this algorithm in a large prospective cohort of contemporary patients undergoing TAVR.

## Methods

### Study population

Consecutive patients undergoing TAVR for severe, symptomatic aortic stenosis at Bern University Hospital, Bern, Switzerland, were prospectively enrolled into an institutional registry, which is a part of the Swiss TAVR registry (NCT01368250)[13]. The registry was approved by the Bern cantonal ethics committee, and patients provided informed written consent for participation.

For the purpose of the present analysis, the following patients were excluded: those declining participation, patients in whom no transcatheter heart valve or a non-CE marked device was implanted, patients with alternative, non-transfemoral access, those requiring emergent conversion to open heart surgery, valve-in-valve procedures, pre-existing PPM or ICD, and those with incomplete ECG data pre- or post-TAVR.

### Collection of clinical, procedural and follow-up data

All baseline clinical, procedural, and follow-up data were prospectively entered into a dedicated web-based database, held and maintained at the Clinical Trials Unit of the University of Bern, Switzerland. Clinical follow-up data were obtained by standardized interviews, documentation from referring physicians, and hospital discharge summaries at 30 days and 1 year. All adverse events were systematically collected and adjudicated by a dedicated clinical event committee according to the Valve Academic Research Consortium (VARC-2) criteria.[14]

### Classification of patients according to the 2019 expert consensus document

12-lead ECGs were recorded and analysed at baseline, immediately post-procedure and daily thereafter during the in-hospital period. In addition, patients were monitored by continuous telemetry both during and after procedure until discharge. The information obtained from telemetry together with the relevant ECG recordings from the hospital stay were used to retrospectively categorize patients into one of five groups as described in the 2019 expert Consensus document[12] (group 1: no new changes without RBBB pre-procedure; group 2: no

new changes with RBBB pre-procedure; group 3: new ECG changes with pre-existing changes; group 4: new-onset LBBB; group 5: HAVB/CHB during the procedure). Patients were also classified into one of the following three algorithm management groups as described in the expert consensus document:[12] eligible for early discharge, higher risk for HAVB/CHB or need for PPM implantation

**Indications for PPM implantation**

A PPM was implanted at the discretion of the attending electrophysiologist for complete heart block (CHB), advanced high degree second-degree AVB (HAVB), left bundle branch block with progressive QRS widening after TAVR or in the presence of sinus node dysfunction and documented symptomatic bradycardia. For the purpose of this study, all indications leading to PPM implantation were reviewed and classified as either AV-node dysfunction (HAVB/CHB) or sinus node dysfunction (SND). For patients with a HAVB/CHB indication, those were further subclassified into (i) CHB, (ii) 2:1 AVB, (iii) alternating bundle branch block, (iv) AF with symptomatic pauses or (v) LBBB with increasing QRS and/or PR interval. Patients at risk of advanced conduction disturbances that did not undergo PPM implantation were followed-up with ECG monitoring. No EP studies were performed in this registry.

**Primary and Secondary endpoints**

The pre-specified primary endpoint of the present analysis was the incidence of PPM implantation for HAVB/CHB within 30 days after TAVR as a function of the 3 algorithm management recommendations: eligible for early discharge, higher risk for HAVB/CHB or need for PPM implantation. Secondary endpoints included the aforementioned incidence according to 1) the 5 proposed groups as described in the consensus document, 2) type of trans-catheter heart valve and 3) the timing of the occurrence of HAVB/CHB. The pre-specified primary prognostic endpoint was all-cause mortality at 1 year after TAVR.

**Statistical analysis**

Categorical data are represented as frequencies and percentages and the differences between groups were evaluated with the Chi-square test. Continuous variables are expressed as median values and interquartile range (IQR) and compared between groups using the Mann-Whitney-U test or the Kruskal-Wallis test. Event-free survival curves were constructed using the Kaplan-Meier method, and the log-rank test was used to assess differences between groups. Throughout the present study, a *p*-value of $<0.05$ was considered significant. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0. IBM, Armonk, NY, USA.

## Results

### Study population

Among 1851 consecutive patients undergoing TAVR between January 2014 and December 2019, 1439 individuals met the inclusion criteria (see supplemental Figure 1 for details). Baseline clinical, ECG and procedural characteristics of the study population are summarized in Table 1. The median age was 83 years (IQR 79-86) and 737 patients (51%) were female. Balloon expandable valves (BEV) were used in 738 patients (51%), self-expanding valves (SEV) in 597 patients (42%) and mechanically expandable valves (MEV) in 104 patients (7%). Details on the valve types used in the study are presented in Supplemental Table 1. The median length of hospital stay was 7 days (IQR 6-8).

### Incidence of PPM implantation for HAVB/CHB within 30 days after TAVR

234 patients (16.2%) underwent permanent pacemaker (PPM) implantation for HAVB/CHB within the first 30 days after the TAVR procedure. The rate of PPM for HAVB/CHB was 12.6% for balloon expandable valves, 17.3% for self-expanding valves and 36.5% for mechanically expandable valves.

Baseline characteristics of patients with and without implantation of a PPM for HAVB/CHB within the first 30 days after TAVR are presented in Table 1. PPM recipients were more often male, had evidence of pre-existing conduction system disease (AVB I, RBBB, LAHB) and more often underwent implantation of a self-expanding or mechanically expandable valve. The timing of PPM implant after TAVR is shown in Figure 1. Of all PPM's, 32% were implanted on days 0 and 1; up to day 4, 66% were implanted, reaching 95% on day 9. Of the 234 PPM implants, 225 (96%) occurred during the in-patient stay, and 9 (4%) following hospital discharge. Details regarding the type of AV-conduction abnormality leading to PPM implatation are shown in Supplemental Table 2.

An additional 15 patients (1.0%) underwent PPM implantation for isolated symptomatic sinus node dysfunction within 30 days of the TAVR procedure.

**Group assignments and management recommendations according to the expert consensus Algorithm**

Group assignments immediately following the TAVR procedure based on presence or absence of pre-existing and new ECG changes according to the expert consensus algorithm was as follows: 642 patients (45%) were classified in group 1, 68 patients (5%) in group 2, 298 patients (21%) in group 3, 312 patients (22%) in group 4 and 119 patients (8%) in group 5.

The resulting management recommendation of the consensus algorithm was early discharge in 1054 patients (73%), while 303 patients (21%) were assigned to the higher risk of HAVB/CHB group. PPM implantation was recommended in 82 patients (6%). The baseline characteristics of the patients according to the 3 management recommendation groups are shown in Table 2. The association of the post-procedural algorithm groups within the management recommendation groups is shown in Table 3.

**Incidence of PPM implantation according to the post-procedural algorithm groups**

The PPM rate for HAVB/CHB within 30 days as a function of algorithm group assignment immediately after the TAVR procedure is shown in Figure 2. PPM rates were highest in group 5 (intraprocedural HAVB/CHB) followed by group 2 (pre-existing RBBB without new ECG changes immediately after the procedure). A sensitivity analysis focusing exclusively on patients with a 2$^{nd}$ or 3$^{rd}$ degree AVB indication for PPM implantation yielded similar results (supplemental table 3A).

**Incidence of PPM implantation according to the algorithm's management recommendation**

The overall PPM rate for HAVB/CHB within 30 days after TAVR according to the algorithm's management recommendation is shown in Figure 3A. Among patients who were classified as "eligible for early discharge", 28 patients (2.7%) underwent PPM implantation for HAVB/CHB within 30 days of the TAVR procedure, which corresponds to a negative predictive

value of 97.3%. Patients classified by the algorithm as being “higher risk for HAVB/CHB” had a 30-day PPM rate of 40.9%.

30-day PPM implantation rates according to device type are shown in Figure 3B. In patients classified as eligible for early discharge, those were 2.6%, 2.1% and 8.3% in patients with BEV, SEV and MEV respectively. In patients classified as higher risk for HAVB/CHB, PPM implantation rates within 30 days were 35.1%, 42.5% and 51.1% in patients with BEV, SEV and MEV respectively.

A sensitivity analysis focusing exclusively on patients with a 2$^{nd}$ or 3$^{rd}$ degree AVB indication for PPM implantation yielded similar results (supplemental table 3B).

**Detailed analysis of patients “eligible for early discharge” with subsequent PPM implantation**

The rate of subsequent PPM implantation for HAVB/CHB in patients assigned “eligible for early discharge” was 2.1% in group 1, 6.8% in group 2, 3.4% in group 3 and 3.5% in group 4. Detailed clinical characteristics of patients “eligible for early discharge” with subsequent PPM implantation are presented in Supplemental Table 4.

**Association of PPM implantation and the Algorithm Classification on clinical outcomes**

In the first 30 days following TAVI, 21 patients died (1.5%). In 2 of the 25 (0.14% overall), asystole due to AVB was the suspected cause of death (both patients were assigned to early discharge by the algorithm and died on days 8 resp. 16 after TAVR). An additional 3 patients died unexpectedly on days 4, 6 and 22, but no additional information was available regarding the circumstances and causes of death.

After 1 year, no significant differences in all-cause mortality were observed when TAVR patients without PPM implantation (8.7%) were compared to those requiring a PPM within 30 days (12.1%; p=0.11, Figure 4A).

When stratified according to the 5 post-procedural algorithm groups, all-cause mortality was 8.7% in group 1, 5.0% in group 2, 11.0% in group 3, 9.6% in group 4 and 9.5% in group 5 (p=0.63, Figure 4B).

When stratified according to the 3 management recommendations of the algorithm, all-cause mortality was 8.4% in patients classified as safe for early discharge, 11.1% in patients classified as higher risk of HAVB/CHB and 12.7% in patients with an immediate recommendation for PPM implantation (p=0.21, Figure 4C). For the subgroup of patients classified as higher risk of HAVB/CHB, no difference in 1 year mortality was observed in patients undergoing and those not undergoing PPM implantation (9.7% vs. 12.2%, p=0.48).

Similar results were observed for cardiovascular mortality (supplemental figure 2).

## Discussion

The optimal management of conduction disturbances after TAVR remains a key challenge. After consolidation of the available evidence into an expert consensus algorithm in 2019,[12] this is the first comprehensive clinical validation of the proposed algorithm in a large cohort of consecutive TAVR patients. Our principal findings can be summarized as follows:

First, the algorithm classified 73% of patients as eligible for early discharge, 21% were categorized as at higher risk of HAVB/CHB and direct PPM implantation was recommended in 6% of the patients. Second, only 2.7% of patients deemed eligible for early discharge subsequently underwent PPM implantation for HAVB/CHB within 30 days of the TAVR procedure. The PPM rates were similarly low for patients in the early discharge group with BEV (2.6%) and SEV (2.1%), but significantly higher for patients with MEV (8.3%). Third, patients categorized as higher risk for HAVB/CHB subsequently required PPM implantation for HAVB/CHB in 41% of cases within 30 days.

The expert consensus algorithm proposed in 2019 by a multidisciplinary group of interventional cardiologists, electrophysiologists, and cardiac surgeons attempted to provide a guide for the management of atrio-ventricular conduction disturbances after TAVR based on the available evidence.[12] Patients are assigned to one of 5 groups based on the presence and type of conduction disturbances on the 12-lead ECG pre- and post-TAVR. This group assignment in combination with 1) the occurrence of episodes of HAVB/CHB on telemetry and 2) the evolution of the conduction disturbances on the 12-lead ECG's in the subsequent 24-72 hrs results in one of three management recommendations (eligible for early discharge, higher risk for HAVB/CHB, direct PPM implantation).

This current validation of the algorithm has two clinical implications: First, with a classification of nearly 3 out of 4 TAVR patients as eligible for early discharge and with a negative predictive value of 97.3% for the subsequent need for a PPM, the algorithm appears both safe and effective. This might indeed allow a more uniform identification of low risk patients. It is an important step forward, will obviate unnecessary prolonged telemetry monitoring and could help to further shorten hospital stays after TAVR without compromising safety.[6,7] Second, the performance is less precise with regards to the identification of high risk

patients. Of the 21% of patients assigned as higher risk for HAVB/CHB, 41% finally required a PPM implantation for HAVB/CHB within 30 days. The consensus document vaguely suggests 3 options for the further assessment of these patients: 1) continuous ECG monitoring after hospital discharge; 2) invasive EPS to guide decision about a PPM; 3) PPM implantation. Our data show that HAVB/CHB can occur with significant delay to the TAVR procedure. Cumulative frequency of PPM implants reached 66% on day 4 and 95% on day 9. Accordingly, continuous ECG monitoring in-hospital or after hospital discharge would be needed for at least 7 days. A potential downside of this strategy however is the uncertainty about the clinical presentation during the delayed occurrence of HAVB/CHB as an outpatient with the worst case scenario of a sudden cardiac death. It is reassuring in that regard that two recent studies using 30-day ambulatory rhythm monitors in an overall TAVR population[15] or implantable loop recorders in high-risk groups with new-onset LBBB [16] did not find sudden death episodes within the first weeks following TAVR, with the majority of initial episodes of advanced conduction disturbances following hospital discharge being either asymptomatic or associated with mild symptoms. The second option is an electrophysiological study (EPS). The potential of EPS for the identification of patients that need or do not need a PPM following TAVR however is unclear. The HV-interval as a static marker for disease in the conduction system has been studied pre- and post-procedure.[17,18] More recently, the value of a functional assessment of the conduction system by means of dynamic atrial pacing was assessed.[19] To date, neither of the two strategies has been implemented into routine clinical practice. Several studies assessing the value of electrophysiological testing after TAVR are currently ongoing and those certainly have the potential to improve discrimination in patients assigned to higher risk of HAVB/CHB. Due to the limitations of both prolonged continuous ECG monitoring and EPS, the third option, a direct PPM implantation should for the time being probably indeed be considered, also when taking into account the overall PPM rate of 41% in this group. Accordingly, clinical judgment remains important when evaluating patients classified as higher risk for HAVB/CHB for pacemaker implantation post TAVR. Additional strategies for refining the risk assessment in this group of patients are needed.

## Limitations

The findings of this study should be viewed in light of some limitations. First, this was a retrospective analysis of a prospective study. It is important to note that the patients were not treated as recommended by the algorithm, which was only implemented after the study period. Furthermore, 6% of the patients were excluded due to incomplete ECG data. Even though our study represents the first comprehensive clinical validation of the algorithm, the ongoing prospective validation study (PROMOTE, ClinicalTrials.gov NCT04139616) implementing the algorithm for patient management will further clarify on the value of the algorithm. Second, indications for PPM implantation after TAVR in patients with HAVB/CHB are not always clear cut, which is one of the reasons for the large variation of PPM implantation rates across studies.[3-5] The decision to proceed to PPM implantation in particular in patients with LBBB and increasing QRS and/or PR interval (15% of the PPM indications in our study) is often based on clinical judgement. This subjectivity however affects the performance of any criteria/algorithm attempting to identify patients in need for a pacemaker and has the potential to introduce some form of incorporation bias. Given that the expert consensus algorithm was only published in 2019, this should not have affected the assessment of its' performance over the time period of 2014-2019 in our study. Third, in line with previous studies, mechanically expandable valves had by far the highest rate of PPM implantations (36.5%). The rate of 8.3% PPM even in the early discharge group (compared to 2.6% and 2.1% in patients with balloon expandable and self expanding valves) indicates that further validation is needed before the use of the algorithm can be recommended in these patients.

## Conclusions

The 2019 consensus algorithm identifies patients with no need for a PPM with a negative predictive value of 97.3%. This strategy allows for a more uniform management of TAVR patients and identifies 3 out of 4 TAVR patients that are eligible for safe and early discharge without prolonged monitoring. The algorithm however is less precise in the identification of high risk patients.

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## Figure titles and captions

| Central Illustration | Validation of the 2019 expert consensus algorithm for the management of conduction disturbances associated with TAVR |
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| Figure 1 | Timing of PPM implantation for HAVB/CHB after TAVR |
|---|---|

The number of PPM implantations for HAVB/CHB after TAVR is indicated by the blue bars for every day. The cumulative percentage of all PPM implanted within 30 days is indicated by the red line

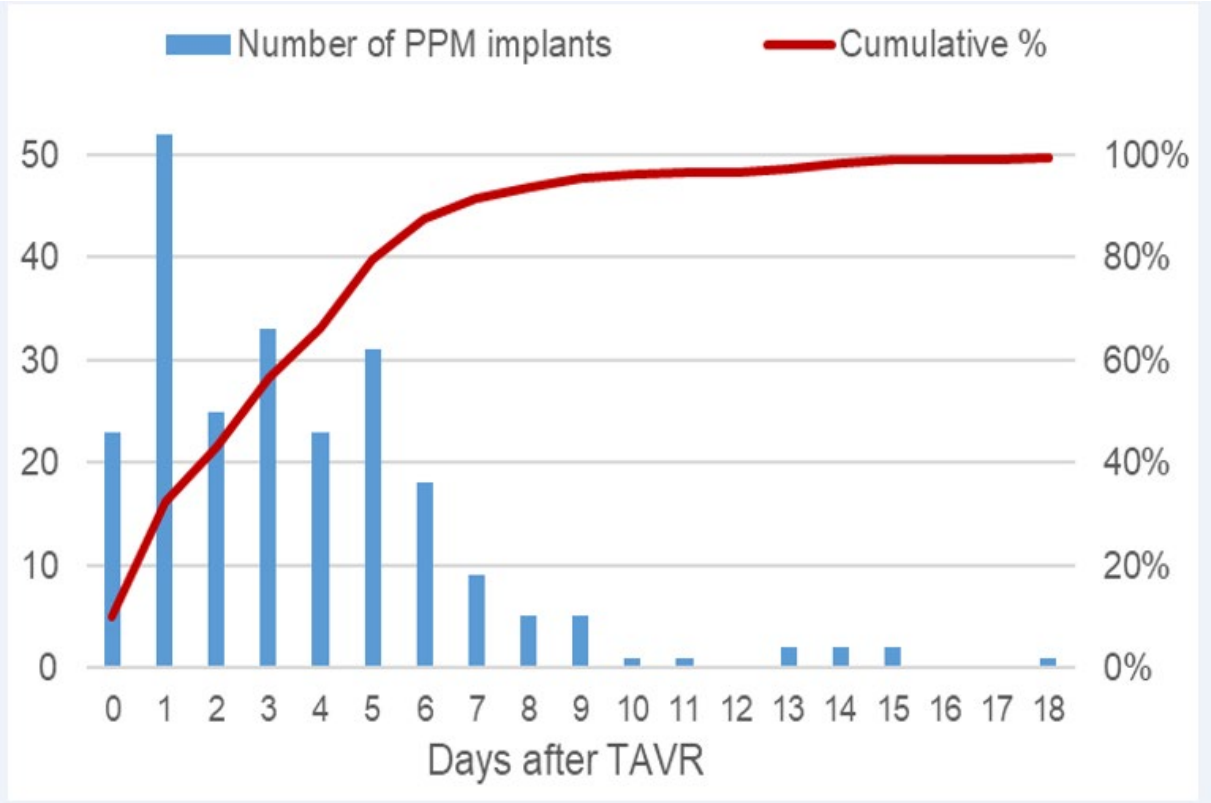


**Figure 2** **Incidence of PPM implantation for HAVB/CHB within 30 days after TAVR according to the Algorithm group classification**

The PPM implantation rate for HAVB/CHB after TAVR according to the algorithm group classification is presented for the overall population in Panel A and further stratified according to the device type in Panel B.

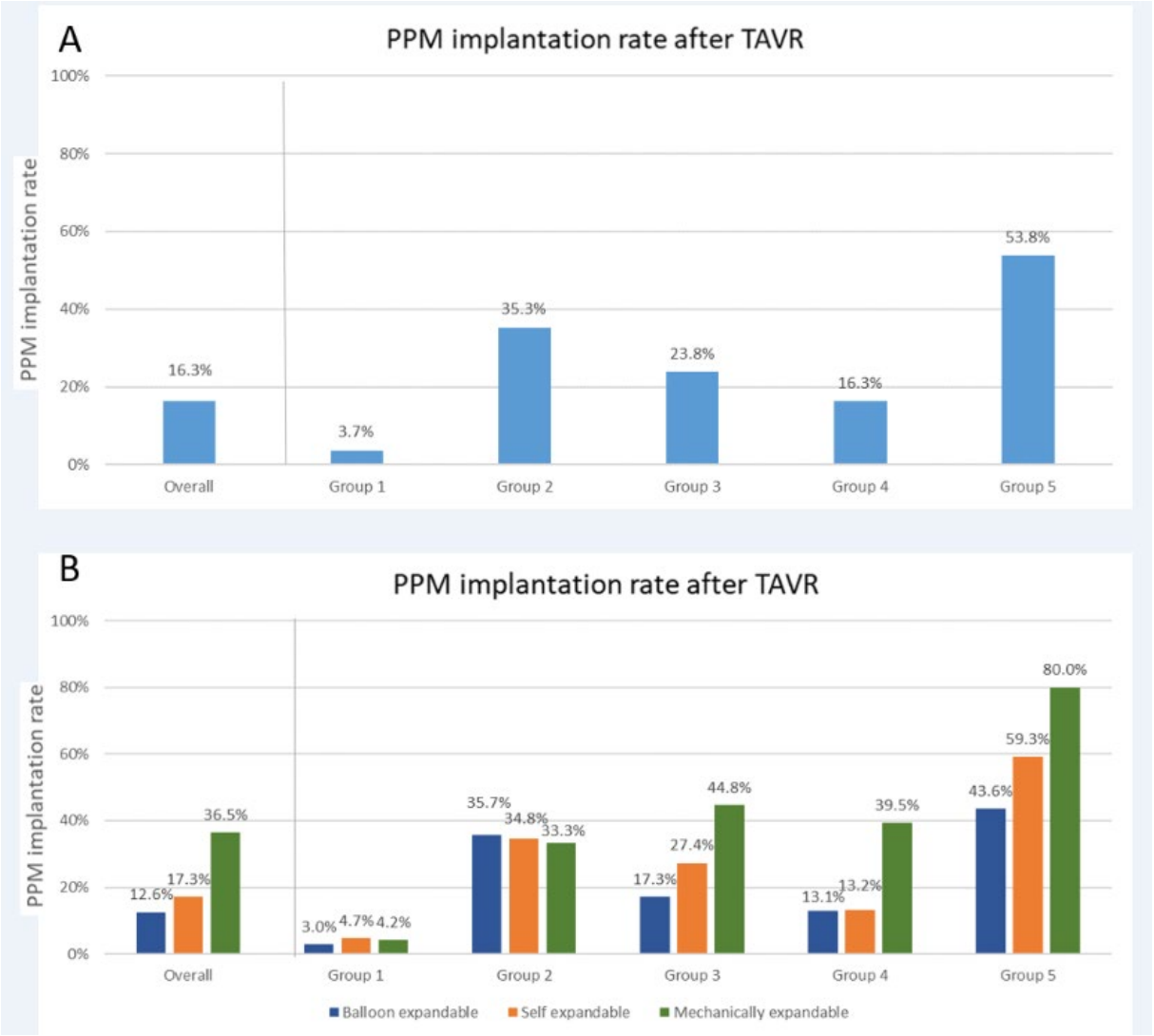



**Figure 3** **Incidence of PPM implantation for HAVB/CHB within 30 days after TAVR according to the Algorithm recommendation**

The PPM implantation rate for HAVB/CHB after TAVR according to the algorithm recommendation is presented for the overall population in Panel A and further stratified according to the device type in Panel B.

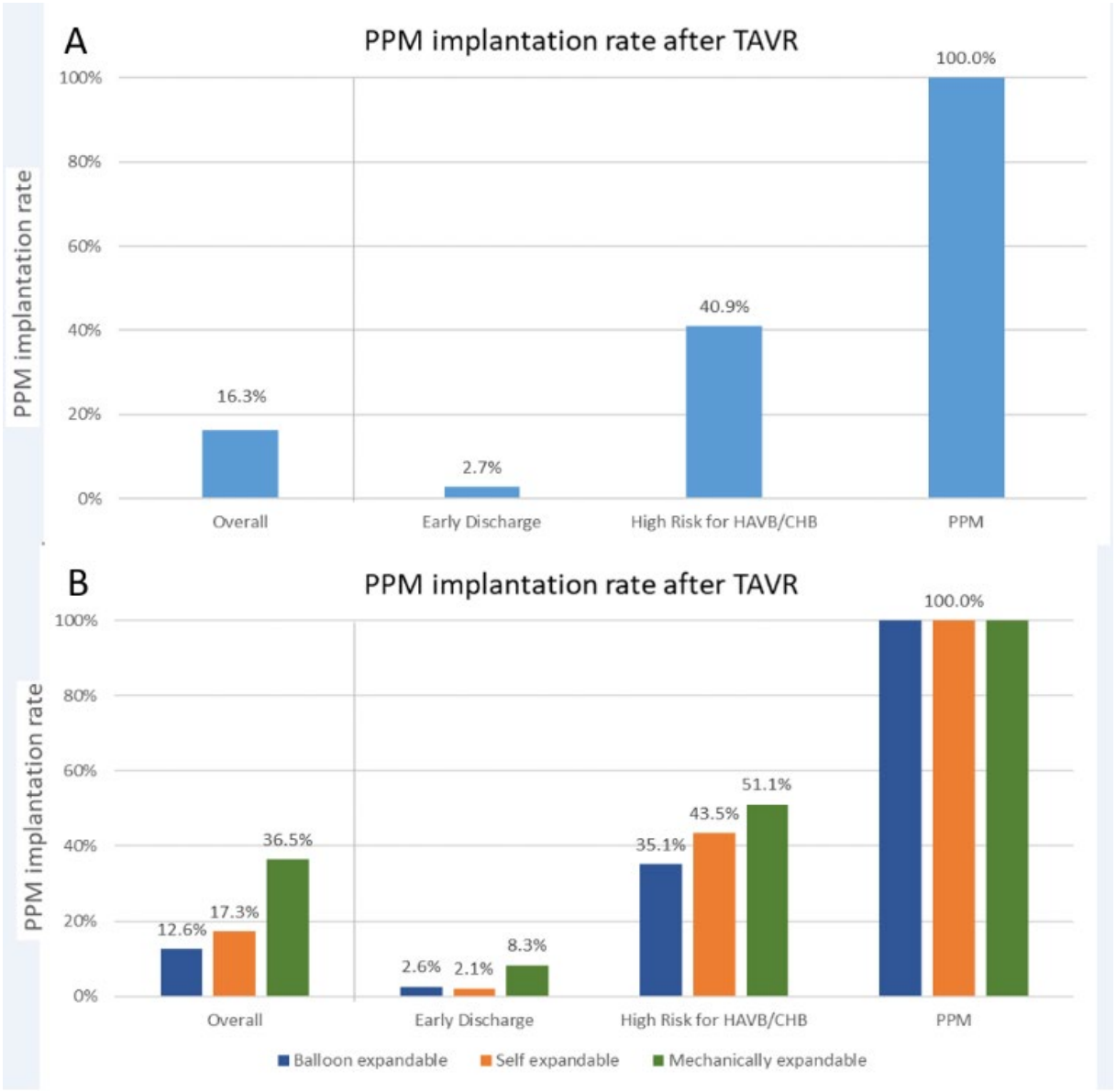
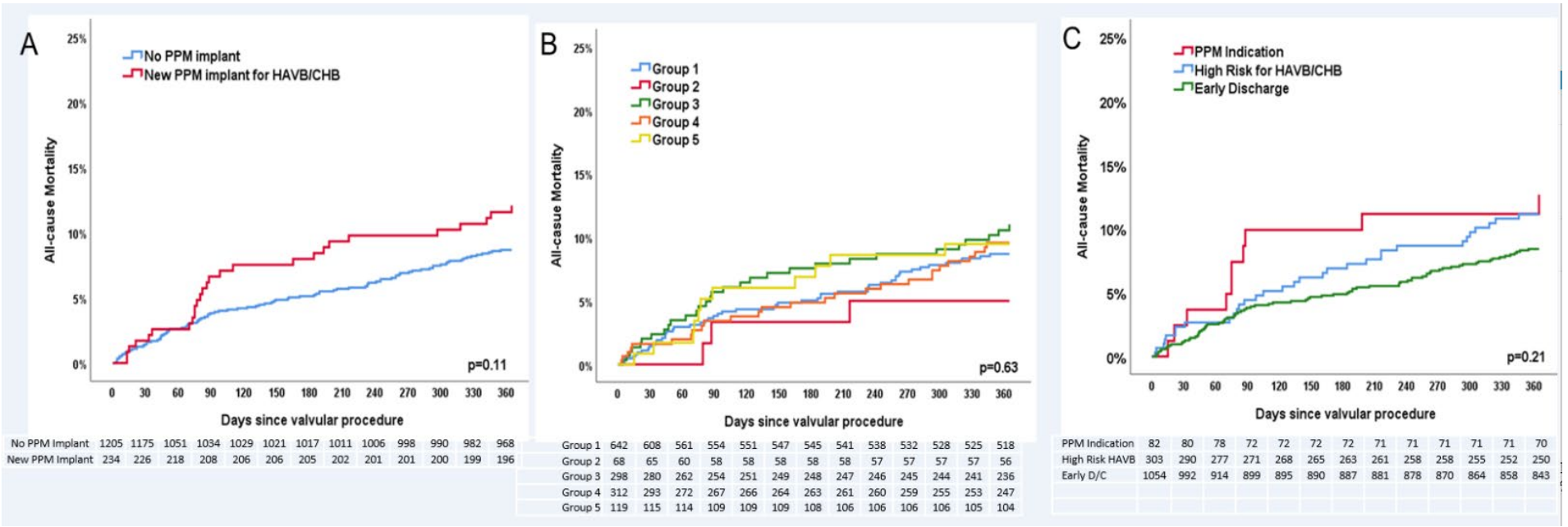



**Figure 4** **All-cause mortality after TAVR**

All-cause mortality after TAVR in Kaplan Meier analysis is shown according to the need for a PPM implantation for HAVB/CHB within the first 30 days (Panel A), the recommendation of the Algorithm (Panel B) and according to the initial group assignment (Panel C). Differences in all-cause mortality were assessed using log-rank test.




| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| No PPM Implant | 1205 | 1175 | 1051 | 1034 | 1029 | 1021 | 1017 | 1011 | 1006 | 998 | 990 | 982 | 968 |
| New PPM Implant | 234 | 226 | 218 | 208 | 206 | 206 | 205 | 202 | 201 | 201 | 200 | 199 | 196 |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Group 1 | 642 | 608 | 561 | 554 | 551 | 547 | 545 | 541 | 538 | 532 | 528 | 525 | 518 |
| Group 2 | 68 | 65 | 60 | 58 | 58 | 58 | 58 | 58 | 57 | 57 | 57 | 57 | 56 |
| Group 3 | 298 | 280 | 262 | 254 | 251 | 249 | 248 | 247 | 246 | 245 | 244 | 241 | 236 |
| Group 4 | 312 | 293 | 272 | 267 | 266 | 264 | 263 | 261 | 260 | 259 | 255 | 253 | 247 |
| Group 5 | 119 | 115 | 114 | 109 | 109 | 109 | 108 | 106 | 106 | 106 | 106 | 105 | 104 |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PPM Indication | 82 | 80 | 78 | 72 | 72 | 72 | 72 | 71 | 71 | 71 | 71 | 71 | 70 |
| High Risk HAVB | 303 | 290 | 277 | 271 | 268 | 265 | 263 | 261 | 258 | 258 | 255 | 252 | 250 |
| Early D/C | 1054 | 992 | 914 | 899 | 895 | 890 | 887 | 881 | 878 | 870 | 864 | 858 | 843 |

| Table 1 | Baseline and procedural characteristics | | | |
|---|---|---|---|---|
| | **All patients** (n=1439) | **Patients without PPM implantation for HAVB/CHB** (n=1205) | **Patients with PPM implantation for HAVB/CHB** (n=234) | **p-value** |
| Age, years | 83 (79-86) | 83 (79-86) | 83 (79-87) | 0.12 |
| Female, % | 737 (51) | 633 (53) | 104 (44) | 0.02 |
| STS PROM | 3.72 (2.49-5.58) | 3.69 (2.47-5.44) | 3.99 (2.58-6.55) | 0.03 |
| Concomitant diseases/history, % | | | | |
| Hypertension, % | 1247 (87) | 1043 (87) | 204 (87) | 0.80 |
| Diabetes, % | 373 (26) | 308 (26) | 65 (28) | 0.48 |
| CKD (eGFR <60ml/min/1.73 $m^2$) , % | 956 (66) | 407 (34) | 73 (31) | 0.55 |
| Coronary artery disease, % | 853 (59) | 704 (58) | 149 (64) | 0.14 |
| Cerebrovascular accident, % | 150 (10) | 129 (11) | 21 (9) | 0.43 |
| Atrial fibrillation, % | 459 (32) | 372 (31) | 87 (37) | 0.06 |
| Echocardiographic data | | | | |
| LVEF, % | 60 (46-65) | 60 (50-65) | 60 (45-65) | 0.26 |
| Aortic valve area, $cm^2$ | 0.63 (0.50-0.80) | 0.63 (0.50-0.80) | 0.66 (0.50-0.80) | 0.50 |
| Baseline Electrocardiographic data | | | | |
| AVB I, % | 295 (21) | 223 (19) | 72 (31) | <0.001 |
| RBBB, % | 138 (10) | 75 (6) | 63 (27) | <0.001 |
| LBBB, % | 164 (11) | 137 (11) | 27 (12) | 0.94 |
| LAHB, % | 108 (8) | 81 (7) | 27 (12) | 0.01 |
| Valve Type | | | | |
| Balloon expandable valve, % | 738 (51) | 645 (54) | 93 (40) | |
| Self expandable valve, % | 597 (42) | 494 (41) | 103 (44) | <0.001 |
| Mechanically expandable valve, % | 104 (7) | 66 (6) | 38 (16) | |

Data are presented as n (%) or median (IQR).
HAVB = high degree AV block; CHB = complete heart block; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; CKD = chronic kidney diseades; eGFR = estimated glomerular filtration rate; TIA = transient ischemic attack; LVEF = left ventricular ejection fraction; AVB I = 1$^{st}$ degree AV block; RBBB = right bundle branch block; LBBB = left bundle branch block; LAHB = left anterior hemi block

| Table 2 | Baseline and procedural characteristics according to Algorithm assignment | | | |
|---|---|---|---|---|
| | **Eligible for early discharge** (n=1054) | **Higher Risk for HAVB/CHB** (n=303) | **Recommendation for PPM** (n=82) | **p-value** |
| Age, years | 83 (79-86) | 82 (78-86) | 84 (80-88) | 0.08 |
| Female, % | 569 (54) | 127 (42) | 41 (50) | 0.001 |
| STS PROM | 3.70 (2.49-5.43) | 3.72 (2.40-6.03) | 3.91 (2.78-5.73) | 0.28 |
| Concomitant diseases/history, % | | | | |
| Hypertension, % | 908 (86) | 265 (88) | 74 (90) | 0.52 |
| Diabetes, % | 267 (25) | 87 (29) | 19 (23) | 0.42 |
| CKD (eGFR <60ml/min/1.73 $m^2$) , % | 702 (67) | 192 (63) | 62 (76) | 0.24 |
| Coronary artery disease, % | 610 (58) | 194 (64) | 49 (60) | 0.16 |
| Cerebrovascular accident, % | 107 (10) | 37 (12) | 6 (7) | 0.37 |
| Atrial fibrillation, % | 334 (32) | 88 (29) | 37 (45) | 0.02 |
| Echocardiographic data | | | | |
| LVEF, % | 60 (50-65) | 60 (40-65) | 60 (45-65) | 0.006 |
| Aortic valve area, $cm^2$ | 0.62 (0.50-0.80) | 0.70 (0.50-0.85) | 0.65 (0.48-0.82) | 0.03 |
| Electrocardiographic data | | | | |
| AVB I, % | 163 (15) | 115 (38) | 17 (21) | <0.001 |
| RBBB, % | 59 (6) | 44 (15) | 35 (43) | <0.001 |
| LBBB, % | 111 (11) | 44 (15) | 9 (11) | 0.16 |
| LAHB, % | 72 (7) | 24 (8) | 12 (15) | 0.04 |
| Valve Type | | | | |
| Balloon expandable valve, % | 573 (54) | 134 (44) | 31 (38) | |
| Self expandable valve, % | 433 (41) | 124 (41) | 40 (49)) | <0.001 |
| Mechanically expandable valve, % | 48 (5) | 45 (15) | 11 (13) | |

Data are presented as n (%) or median (IQR).
HAVB = high degree AV block; CHB = complete heart block; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; CKD = chronic kidney diseades; eGFR = estimated glomerular filtration rate; TIA = transient ischemic attack; LVEF = left ventricular ejection fraction; AVB I = 1$^{st}$ degree AV block; RBBB = right bundle branch block; LBBB = left bundle branch block; LAHB = left anterior hemi block

| Table 3 | Association of post-procedural group assignment and final management recommendation provided by the algorithm | | | | |
|---|---|---|---|---|---|
| **Group Assignment** | **All patients** (n=1439) | **Eligible for early discharge** (n=1054) | **Higher Risk for HAVB/CHB** (n=303) | **Recommendation for PPM** (n=82) | **p-value** |
| Group 1: no new changes without RBBB pre-procedure | 642 (45) | 618 (59) | 19 (6) | 5 (6) | <0.001 |
| Group 2: no new changes with RBBB pre-procedure | 68 (5) | 44 (4) | 13 (4) | 11 (13) | 0.001 |
| Group 3: new ECG changes with pre-existing changes | 298 (21) | 148 (14) | 135 (45) | 15 (18) | <0.001 |
| Group 4: new-onset LBBB | 312 (22) | 200 (19) | 106 (35) | 6 (7) | <0.001 |
| Group 5: HAVB/CHB during the procedure | 119 (8) | 44 (4) | 30 (10) | 45 (55) | <0.001 |

Data are presented as n (%) or median (IQR).
RBBB = right bundle branch block; LBBB = left bundle branch block; HAVB = high degree AV block; CHB = complete heart block