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STRUCTURAL

The Electrocardiogram After Transcatheter Aortic Valve Replacement Determines the Risk for Post-Procedural High-Degree AV Block and the Need for Telemetry Monitoring

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ABSTRACT

OBJECTIVES The study sought to identify predictors for delayed high-degree atrioventricular block (AVB) in patients undergoing transcatheter aortic valve replacement (TAVR) and determine the need and required duration of telemetry monitoring.

BACKGROUND Little is known about predictors and timing of high-degree AVB.

METHODS A total of 1,064 patients (52% women) without a permanent pacemaker undergoing TAVR at 3 centers in Switzerland were investigated. Electrocardiograms (ECGs) at baseline and post-TAVR were analyzed to identify atrioventricular and interventricular conduction disorders.

RESULTS Periprocedural high-degree AVB occurred in 92 (8.7%), delayed high-degree AVB in 71 (6.7%), up to 8 days post-procedure. In multivariate analysis, delayed high-degree AVB occurred more frequently in men (odds ratio: 2.4, 95% confidence interval: 1.3 to 4.5; $p < 0.01$), and in patients with conduction disorders post-TAVR (odds ratio: 10.8; 95% confidence interval: 4.6 to 25.5; $p < 0.01$). Patients in sinus rhythm without conduction disorders post-TAVR did not develop delayed high-degree AVB (0 of 250, 0%). Similarly, the risk in patients with atrial fibrillation but no other conduction disorders was very low (1 of 102, 1%). There was no patient developing delayed high-degree AVB who had a stable ECG for 2 days or more.

CONCLUSION Patients without conduction disorders post-TAVR did not develop delayed high-degree AVB. Such patients may not require telemetry monitoring. All other patients should be monitored until the ECG remains stable for at least 2 days. This algorithm should be validated in a separate patient population. (J Am Coll Cardiol Intv 2016;9:1269–76)
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ABBREVIATIONS AND ACRONYMS

AVB = atrioventricular block

BBB = bundle branch block

CI = confidence interval

ECG = electrocardiogram

LBBB = left bundle branch block

OR = odds ratio

RBBB = right bundle branch block

TAVR = transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has been performed with low mortality and complication rates in recent trials and registries (1-4). In light of these favorable results, early discharge after TAVR has been proposed to increase patient comfort and the cost effectiveness of the procedure (5-7). However, delayed high-degree atrioventricular block (AVB) after TAVR remains a feared complication (8). Thus, patients are usually monitored by telemetry for a few days, but there is currently no scientific evidence on the duration of telemetry. Furthermore, some patients may not require telemetry at all.

Previous studies have looked at baseline electrocardiograms (ECGs), and baseline and procedural characteristics to identify the risk for new conduction disorders (9-12). However, an ECG recorded immediately after TAVR may provide more accurate and clinically relevant prognostic information than baseline variables.

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In the present study, we investigated how the post-procedural ECG determines the risk for delayed high-degree AVB in patients undergoing TAVR with either a balloon-expandable or a self-expandable valve prosthesis. On the basis of data about the timing and frequency of high-degree AVB, we also evaluated the required duration of telemetry monitoring.

METHODS

STUDY POPULATION. Consecutive patients undergoing TAVR for the treatment of severe aortic stenosis between January 2009 and December 2014 at 3 centers in Switzerland, the University Hospital Berne, the University Hospital Zurich, and the Heart Center Lucerne, were analyzed. Patients undergoing TAVR with the self-expandable CoreValve (Medtronic Inc., Minneapolis, Minnesota) and the balloon-expandable SAPIEN XT or SAPIEN 3 (Edwards Lifesciences, Irvine, California) valves were included (n = 1,273). Patients were excluded, if they had a permanent pacemaker at baseline (n = 136, 11% of all patients), or if documentation was incomplete (early death or missing post-procedural ECGs; n = 73, 6% of all patients). The remaining 1,064 patients were analyzed in this study. All TAVR candidates were discussed by the interdisciplinary *HeartTeam* consisting of noninvasive cardiologists, interventional cardiologists, and cardiac surgeons. The study complies with the declaration of Helsinki. Prospective data acquisition after TAVR was approved by the local ethics committees of all 3 centers. All patients provided written informed consent for the TAVR procedure and for prospective data acquisition and follow-up examinations. Analysis of additional ECG data required for this study was performed retrospectively.

DEFINITIONS AND ECG ANALYSES. Clinical endpoints were defined according to the updated definitions of the Valve Academic Research Consortium (13,14). ECGs were recorded and analyzed at baseline, and immediately post-procedure (the first ECG taken in the intensive care unit). In addition, patients were usually monitored by telemetry for 72 h after the procedure. Daily ECGs were analyzed in patients with delayed high-degree AVB. A first-degree AVB was defined as a PQ interval ≥200 ms. A complete bundle branch block (BBB) was defined as a QRS duration ≥120 ms and the typical pattern of either left bundle branch block (LBBB) or right bundle branch block (RBBB). QRS duration <120 ms was classified as no BBB. Periprocedural high-degree AVB was defined as a second- or third-degree AVB present on the first ECG taken post-TAVR. Delayed high-degree AVB was defined as high-degree AVB occurring later, on the same day, or during 30-day follow-up. All ECGs were analyzed by experienced cardiologists (Lucerne: Z.S., S.T., Zurich: E.H., R.S., R.B., Berne: K.Z., S.S.).

INDICATION FOR PACEMAKER IMPLANTATION. Generally, it was the operator's clinical decision to implant a permanent pacemaker. Reasons for implantation of a permanent pacemaker were high-degree AVB, marked first-degree AVB with a long PQ interval (>250 to 300 ms), or bradycardia.

STATISTICAL ANALYSIS. If not indicated otherwise, data are presented as mean ± SD for continuous and

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as number and frequency for categorical variables. Continuous parametric variables were compared using 1-way analysis of variance. Categorical variables were compared using the chi-square test and the Fisher exact test as appropriate. Variables with an univariate $p < 0.10$ were included in the logistic regression analysis to estimate odds ratio (OR) and 95% confidence interval (CI). Because data from 3 different centers was analyzed, center was included in the multivariate regression analysis as a categorical variable. Statistical analyses were conducted with STATA version 13 (StataCorp, College Station, Texas) and tested using 2-sided tests at a significance level of 0.05.

RESULTS

A total of 1,064 patients (52% female) with a mean age of 82 ± 7 years were investigated. Patients underwent TAVR with the self-expanding CoreValve (n = 508, 48%) or the second- or third-generation balloon-expandable Edwards SAPIEN valve (SAPIEN XT: n = 329, 31%; SAPIEN 3: n = 227, 21%). TAVR was performed via the transfemoral (n = 981, 92%), the transapical (n = 63, 6%), or direct aortic or transaxillary route (n = 20, 2%).

Table 1 summarizes baseline and procedural characteristics. For the purpose of this study, patients were grouped according to the occurrence of high-degree AVB. The majority of patients (n = 901, 85%) did not develop high-degree AVB. A total of 92 patients (9%) had periprocedural high-degree AVB. In addition, a total of 71 patients (7%) developed delayed high-degree AV block. As shown in Table 1, delayed high-degree AVB occurred more often in men—46 of 71 (65%) of patients with delayed high-degree AVB were male versus 416 of 901 (46%) without AVB ($p < 0.01$)—and diabetes was more frequently present—27 of 71 (38%) of patients with delayed high-degree AVB were diabetics versus 223 of 901 (25%) without AVB ($p = 0.02$). Periprocedural high-degree AVB occurred more frequently after implantation of a self-expanding CoreValve—63 of 92 (68%) of patients with periprocedural high-degree AVB received a CoreValve versus 405 of 901 (45%) without AVB ($p < 0.01$). A CoreValve was implanted in 40 of 71 (56%) of patients developing delayed high-degree AVB versus 405 of 901 (45%) without delayed high-degree AVB ($p = 0.06$).

A permanent pacemaker was implanted in 228 (21%), in most (209, 92% of patients receiving a pacemaker) during the first week after the procedure. The reason for implantation of a permanent pacemaker included high-degree AVB (n = 157, 15%), LBBB and AVB (n = 56, 5%), and bradycardia (n = 15, 1%). At 30 days, the rate of disabling strokes was 31 of 1,064 (2.9%), and all-cause mortality was 36 of 1,064 (3.4%).

TABLE 1 Baseline and Procedural Characteristics

	No High-Degree AVB (n = 901)	Periprocedural High-Degree AVB (n = 92)	Delayed High-Degree AVB (n = 71)	p Value
Age, yrs	82 ± 7	83 ± 6	82 ± 5	0.32
Female	485 (54)	47 (51)	25 (35)	0.01
Hypertension	725 (80)	79 (86)	59 (83)	0.41
Diabetes	223 (25)	17 (18)	27 (38)	0.01
Coronary artery disease	517 (57)	56 (61)	43 (61)	0.73
Prior stroke	115 (13)	9 (10)	11 (15)	0.55
STS PROM, %	6.2 ± 4.8	6.4 ± 3.6	6.3 ± 3.9	0.93
Aortic valve area, cm^2	0.67 ± 0.26	0.65 ± 0.27	0.73 ± 0.24	0.09
Ejection fraction, %	53 ± 16	51 ± 20	52 ± 17	0.14
Valve type				<0.01
CoreValve	405 (45)	63 (68)	40 (56)	
SAPIEN XT or 3	496 (55)	29 (32)	31 (44)	

Values are mean ± SD or n (%).

AVB = atrioventricular block; ECG = electrocardiogram; LBBB = left bundle branch block; RBBB = right bundle branch block; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

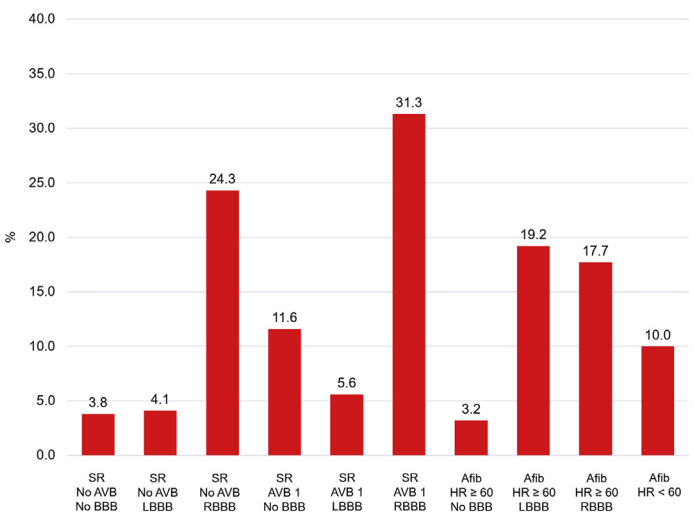
TABLE 2 ECG Findings Before and After TAVR

	No High-Degree AVB (n = 901)	Periprocedural High-Degree AVB (n = 92)	Delayed High-Degree AVB (n = 71)	p Value
QRS duration at baseline				<0.01
No BBB	744 (83)	49 (53)	45 (63)	
LBBB	104 (12)	9 (10)	9 (13)	
RBBB	53 (6)	34 (37)	17 (24)	
First-degree AVB at baseline*				<0.01
Absent	486 (69)	32 (48)	27 (47)	
Present	220 (31)	35 (52)	30 (53)	
Atrial fibrillation at baseline				0.42
Absent	706 (78)	67 (73)	57 (80)	
Present	195 (22)	25 (27)	14 (20)	
QRS duration post-TAVR				<0.01
No BBB	523 (58)	N/A†	9 (13)	
LBBB	320 (36)	N/A†	41 (58)	
RBBB	58 (6)	N/A†	21 (30)	
First-degree AVB post-TAVR‡				<0.01
Absent	403 (57)	N/A†	17 (30)	
Present	305 (43)	N/A†	39 (70)	
Atrial fibrillation post-TAVR				0.05
Absent	708 (79)	62 (67)	56 (79)	
Present	193 (21)	30 (33)	15 (21)	

Values are n (%). *In patients without atrial fibrillation at baseline. †In patients with high-degree AVB, QRS duration was not measured and analysis of PQ interval was not possible. ‡In patients without atrial fibrillation post-transcatheter aortic valve replacement (TAVR).

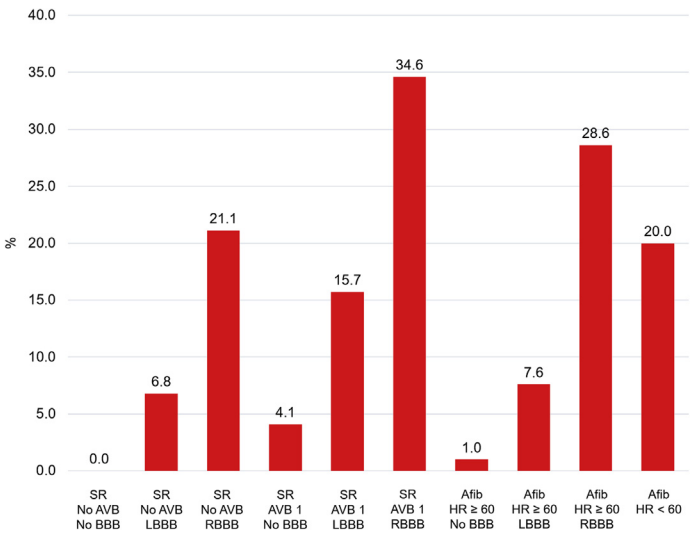
BBB = bundle branch block; ECG = electrocardiogram; LBBB = left bundle branch block; RBBB = right bundle branch block; other abbreviations as in Table 1.

FIGURE 1 Proportion of Patients With Delayed High-Degree AVB According to the Electrocardiogram at Baseline



Generally, patients with a right bundle branch block (RBBB) had the highest risk of delayed high-degree atrioventricular block (AVB). However, a small proportion of patients without any conduction disorders developed high-degree AVB after transcatheter aortic valve replacement (TAVR). SR = sinus rhythm.

FIGURE 2 Proportion of Patients With Delayed High-Degree Atrioventricular Block According to the Electrocardiogram Post-TAVR



Patients in sinus rhythm without conduction disorders after TAVR did not develop delayed high-degree AVB. Similarly, the risk in patients with atrial fibrillation but no other conduction disorders was very low. Afib = atrial fibrillation; BBB = bundle branch block; LBBB = left bundle branch block; HR = heart rate; other abbreviations as in Figure 1.

PREDICTIVE VALUE OF THE ECG AT BASELINE. As shown in Table 2, a complete LBBB was present in 122 (11%), a RBBB in 104 (10%) and the remaining 838 (79%) had no BBB. Patients with a RBBB at baseline were more likely to develop periprocedural or delayed high-degree AVB. Also, periprocedural and delayed high-degree AVB was more frequent in patients with a first-degree AVB at baseline. The proportion of patients with delayed high-degree AVB according to the baseline ECG is summarized in Figure 1.

PREDICTIVE VALUE OF THE ECG POST-TAVR. Similar to the ECG at baseline, patients with a complete RBBB post-TAVR had a high rate of delayed high-degree AVB (21 of 79, 27%). The rate of delayed high-degree AVB was 41 of 361 (11%) in patients with a LBBB and only 9 of 532 (2%) in patients without a BBB (Table 2). Also, a first-degree AVB post-TAVR was associated with a higher probability of subsequent high-degree AVB. As shown in Figure 2, 0 of 250 (0%) patients without a BBB and without first-degree AVB developed high-degree AVB. One patient (0.4%) required implantation of a permanent pacemaker for reasons other than high-degree AVB. Similarly, the rate of high-degree AVB was very low in patients with atrial fibrillation, no BBB, and no bradycardia (1 of 103, 1%). Such an ECG was found in 352 of 1,064 (33%) of patients after TAVR: 140 of 508 (28%) after CoreValve, 133 of 329 (40%) after SAPIEN XT, and 79 of 227 (35%) after SAPIEN 3.

Overall, the presence of conduction disorders (BBB, first-degree AVB in patients with sinus rhythm, bradycardia in patients with atrial fibrillation) on the ECG post-TAVR had a sensitivity of 99%, a specificity of 39%, a positive predictive value of 11%, and a negative predictive value of 99.7% for delayed high-degree AVB.

UNIVARIATE AND MULTIVARIATE PREDICTORS OF DELAYED HIGH-DEGREE AVB. Table 3 lists univariate and multivariate predictors for delayed high-degree AVB. In multivariate analysis, male sex (OR: 2.41; 95% CI: 1.28 to 4.53; $p < 0.01$), and the presence of a LBBB or RBBB post-TAVR (OR: 10.83 vs. no BBB; 95% CI: 4.58 to 25.5; $p < 0.01$) were associated with higher risk for delayed high-degree AVB.

TIMING OF HIGH-DEGREE AVB. As shown in Figure 3, periprocedural high-degree AVB occurred in 92 of 1,064 (8.7%) of patients, whereas delayed high-degree AVB occurred in 71 of 1,064 (6.7%). Most delayed heart blocks occurred within the first 48 h, but 24 patients (2.3%) had developed high-degree AVB at 3 to 8 days post-TAVR. Of these 24 patients,

21 were in sinus rhythm and 3 in atrial fibrillation. In these 21 patients with sinus rhythm, PQ interval (the interval between the beginning of the atrial contraction and the beginning of the ventricular contraction) generally increased over time and there were no patients developing high-degree AVB with a stable ECG of at least 48 h. Of the 3 patients with atrial fibrillation and high-degree AVB at 3 to 8 days post-TAVR, heart rate decreased and there was no patient with stable heart rate for more than 48 h.

NEW ONSET VERSUS PRE-EXISTING CONDUCTION DISORDERS. The risk for delayed high-degree AVB did not differ between patients with new onset and pre-existing conduction disorders. Delayed high-degree AVB occurred in 9 of 113 (8%) patients with pre-existing LBBB and 33 of 248 (13%) with new onset LBBB (p = 0.14), and in 28 of 219 (13%) and 11 of 116 (9%) of patients with a pre-existing and new onset first-degree AVB, respectively (p = 0.47).

TABLE 3 Univariate and Multivariate Predictors of Delayed High-Degree AVB

	Univariate OR (95% CI)	p Value	Multivariate OR (95% CI)	p Value
Male	2.15 (1.30–3.55)	<0.01	2.41 (1.28–4.53)	<0.01
Diabetes	1.87 (1.13–3.08)	0.02	1.68 (0.90–3.12)	0.10
CoreValve implantation	1.58 (0.97–2.57)	0.07	1.22 (0.62–2.04)	0.71
LBBB or RBBB at baseline	2.74 (1.64–4.57)	<0.01	1.42 (0.73–2.76)	0.30
First-degree AVB at baseline	2.45 (1.42–4.22)	<0.01	1.12 (0.73–3.14)	0.27
LBBB or RBBB post-TAVR	9.53 (4.68–19.4)	<0.01	10.83 (4.58–25.5)	<0.01
First-degree AVB post-TAVR	3.02 (1.68–5.43)	<0.01	1.84 (0.84–4.03)	0.13

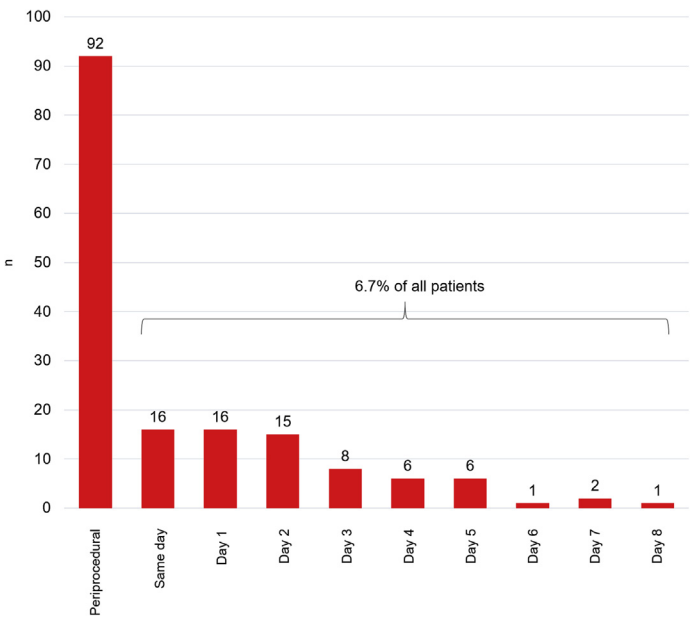
Patients with periprocedural high-degree AVB were excluded.
CI = confidence interval; OR = odds ratio; other abbreviations as in Tables 1 and 2.

DISCUSSION

In the present study, delayed high-degree AVB occurred in about 7%, as late as 8 days after TAVR. In clinical routine, it is not practicable to monitor all patients for more than a week, and there is no consensus and insufficient scientific evidence on the optimal duration of telemetry. As some patients may not require telemetry at all, the present study showed that the ECG recorded immediately after TAVR was able to identify such patients. Furthermore, on the basis of follow-up ECGs, we were able to determine the required duration of telemetry. On the basis of our findings, we proposed a simple algorithm determining the need and duration of telemetry, as summarized in Figure 4. However, implementation of this algorithm should be taken with caution, and the criteria should be validated in a separate population. Also, a daily 12-lead ECGs in each patient during the time of hospitalization should be recorded, regardless of telemetry monitoring.

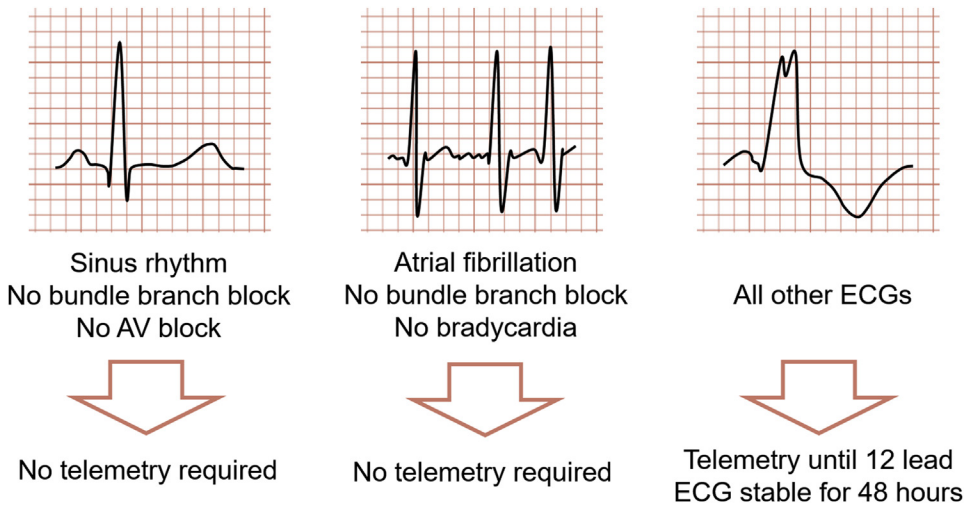
MANAGEMENT OF PATIENTS WITHOUT CONDUCTION DISORDERS POST-TAVR. The most important finding of this study is that patients without a left- or right bundle branch block and without first-degree AVB post-TAVR did not develop high-degree AVB during the first 30 days post-procedure. Similarly, patients with atrial fibrillation but no bundle branch block and no bradycardia post-TAVR had a very low risk of delayed high-degree AVB. Such an ECG was found in 33% of patients after TAVR (28% after CoreValve, 40% after SAPIEN XT, 35% after SAPIEN 3). Accordingly, the provisional pacemaker can be safely removed immediately after the procedure in this group of patients. Furthermore, there is no need for telemetry monitoring, which facilitates early ambulation. In the absence of other complications, these patients may be candidates for early discharge, which may help to improve patient comfort and cost effectiveness of the procedure. However, as noted previously, we would still recommend to record a daily 12-lead ECG, as long as the patient remains hospitalized.

FIGURE 3 Timing and Frequency of High-Degree AVB



Periprocedural high-degree AVB occurred in 92 of 1,064 (8.7%) of patients. Delayed high-degree AVB occurred in 71 of 1,064 (6.7%), up to 8 days post-TAVR. Abbreviations as in Figure 1.

FIGURE 4 Recommendation on the Use and Duration of Telemetry



About one-third of patients do not require telemetry after transcatheter aortic valve replacement. ECG = electrocardiogram.

MANAGEMENT OF PATIENTS WITH A LEFT- OR RIGHT BUNDLE BRANCH BLOCK OR FIRST-DEGREE AVB POST-TAVR. In all other patients, there was a certain risk for delayed high-degree AVB. Patients with a RBBB post-TAVR generally had the highest risk (about 20% to 35%), whereas the risk was lower if a LBBB was observed (7% to 16%). Therefore, such patients should be monitored and daily 12-lead ECG should be written to monitor the PQ interval and QRS duration until the ECG remains stable for at least 2 days. This is sufficient, as the PQ interval generally increased in patients developing high-degree AVB more than 2 days after the procedure, and there were no patients developing high-degree AVB with a stable ECG of 2 or more days. In patients at very high risk (patients with a RBBB or patients who already have a very long PQ interval), the provisional pacemaker should be left in place during telemetry monitoring, or the decision to implant a definitive pacemaker should be made. Again, if the PQ interval remains stable for at least 2 days, telemetry monitoring can be stopped. In patients with atrial fibrillation, the heart rate should be monitored and followed as there is no PQ interval.

MANAGEMENT OF PATIENTS WITH POST-PROCEDURAL HIGH-DEGREE AVB. In our study, almost all patients with a post-procedural high-degree AVB underwent permanent pacemaker implantation. This probably reflects clinical practice of many centers, but the optimal duration of "watchful waiting" in such patients has not yet been defined (15). However, evidence indicates that at least a subset of these conduction disorders may resolve over time (12,16).

COMPARISON WITH PREVIOUS STUDIES. TAVR is now the treatment of choice for patients with symptomatic aortic stenosis and prohibitive surgical risk, and an established alternative for those at high surgical risk (17,18). However, some issues remain to be solved. Indeed, the occurrence of new conduction disturbances after TAVR, particularly high-degree AVB and new LBBB, are causing concern. These complications occur at a high frequency and may have a negative impact on late outcomes, although study results are conflicting (19–21). Several studies have identified risk factors for the occurrence of conduction disorders and need for pacemaker implantation including pre-existing RBBB, use of a self-expanding valve, male sex, implantation depth, anatomical features, or the occurrence of intraprocedural AVB (9–12,22). However, for in-hospital management of an individual patient, the value of these baseline measures is limited. To our knowledge, only 1 previous study has evaluated the predictive value of the ECG after TAVR. Mouillet et al. (23) investigated 79 patients undergoing TAVR with the CoreValve. They found that all 21 patients with a QRS duration ≤128 ms did

not develop high-grade AVB during follow-up. However, this study was likely underpowered. In our study, the rate of delayed high-degree AVB in patients with a QRS duration ≤128 ms was 2.7% (16 of 582). It was 4.2% (10 of 228) after implantation of the CoreValve, and 1.7% (6 of 354) after implantation of a balloon-expandable valve. In our study, only patients with a QRS duration <120 ms *and* absence of first-degree AVB did not develop high-degree AVB.

STUDY LIMITATIONS. This study is observational and, is therefore, subject to the limitation of the study design. ECGs were analyzed by experienced cardiologists, but there was no Core Lab analysis performed. A total of 68 patients (6%) required implantation of a permanent pacemaker for other reasons than high-degree AVB. Therefore, we were unable to detect delayed high-degree AVB in such patients. The number of patients in some of the ECG subgroups was relatively low (e.g., only 102 patients with atrial fibrillation, no bradycardia, and no BBB after TAVR). Therefore, our recommendations should be validated in a separate population. Finally, next-generation self-expanding valves were not included in this study because the number of patients was too low to draw meaningful conclusions. Further studies are required to determine if our results hold true for these newer self-expanding valves.

CONCLUSIONS

Delayed high-degree AVB occurred in 7% of patients undergoing TAVR, up to 8 days post-procedure, and more frequently in men and in patients with conduction disorders in the ECG recorded post-TAVR. Patients in which the ECG after TAVR showed sinus rhythm, no BBB, and no first-degree AVB (24% of all patients) had no delayed high-degree AVB. Similarly, patients with atrial fibrillation, no bradycardia, and no BBB immediately post-TAVR (10% of all patients) had a very low risk for delayed high-degree AVB. Such patients may not require telemetry at all, facilitating early ambulation and discharge. In all other patients, monitoring until 12 lead ECG is stable for at least 48 h should be considered. However, we recommend to perform a daily 12-lead ECG in all patients during the time of hospitalization, regardless of telemetry monitoring. This algorithm should be validated in a separate patient population.

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PERSPECTIVES

WHAT IS KNOWN? Delayed high-degree AVB is a feared complication after TAVR. Thus, patients are usually monitored by telemetry for a few days.

WHAT IS NEW? According to the results of our study, patients without conduction disorders after TAVR do not require telemetry monitoring. All other patients should be monitored until the ECG remains stable for at least 2 days.

WHAT IS NEXT? Our conclusions should be validated in a separate population including next-generation self-expanding valves.

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