Emerging Evidence

Remote Ambulatory Cardiac Monitoring Before and After Transcatheter Aortic Valve Replacement

Jose L. Winter, MD, Jeffrey S. Healey, MD, Tej N. Sheth, MD, James L. Velianou, MD, Jon-David Schwalm, MD, Amanda Smith, RN, PhD, Seleman Reza, BSc, and Madhu K. Natarajan, MD

Hamilton Health Sciences, Population Health Research Institute, McMaster University, Hamilton, Ontario, Canada

ABSTRACT

Remote ambulatory cardiac monitoring (rACM) could identify high-grade atrioventricular block (AVB) before and after transcatheter aortic valve replacement (TAVR). Retrospective analysis of patients undergoing TAVR, with 14-day rACM before and after TAVR, was performed. Of 62 patients undergoing TAVR, 41 patients had rACM before TAVR. Three patients had asymptomatic AVB leading to planned pacemaker (PM) implant. After TAVR, 23 patients had rACM, with 1 patient requiring a PM implant for asymptomatic AVB. Five patients underwent unplanned PM after TAVR. Using rACM, almost half

RÉSUMÉ

La surveillance ambulatoire par télémétrie cardiaque pourrait permettre de détecter un bloc auriculoventriculaire (BAV) de haut grade avant et après le remplacement valvulaire aortique par cathéter (RVAC). Les données concernant des patients ayant subi un RVAC précédé ou suivi d'une période de surveillance ambulatoire de 14 jours ont été l'objet d'une analyse rétrospective. La surveillance ambulatoire a précédé le RVAC chez 41 patients sur 62 ayant subi l'intervention. Chez trois patients, un BAV asymptomatique a donné lieu à l'implantation planifiée d'un stimulateur cardiaque (SC). Le

Transcatheter aortic valve replacement (TAVR) has emerged as the preferred treatment of patients with aortic stenosis at high risk for cardiac surgery with expanding indication to lower risk patients.[1,2] Heart rhythm abnormalities, including high-grade atrioventricular block (AVB) and atrial fibrillation (AF), are currently the most common complications after TAVR.[3] The incidence and management of these complications varies between centres, particularly with respect to the rates of permanent pacemaker (PM) implantation and length of stay after TAVR.

Significant conduction abnormalities are present in up to one-sixth of patients undergoing TAVR when monitored for 24 hours before the procedure.[4] Remote ambulatory cardiac monitoring (rACM) of these patients could help identify patients who require a PM implant before the procedure, allowing the PM implant to be scheduled

electively. The use of rACM after TAVR could improve the detection of potentially serious conduction disturbances. The objective of this study is to describe the feasibility and initial clinical experience with rACM before and after TAVR.

Methods

Retrospective analysis of patients who received rACM with a mobile cardiac arrhythmia diagnostics monitoring system, before and after TAVR during a 1-year period in our institution, was undertaken. The monitor (Pocket-ECG; m-Health Solutions, Burlington, ON) provides remote continuous monitoring of patients outside of hospital, with the ability to identify potentially life-threatening arrhythmia and alert the patient to seek prompt medical attention.

Patients were assessed according to their baseline electrocardiogram (ECG) during their first clinic visit. If a high-risk ECG was present (bifascicular block plus either AF or first-, second-, or third-degree AVB), they were referred to the electrophysiology (EP) clinic for consideration of PM implantation before TAVR. Otherwise, if an rACM device was available, patients were instructed to wear the device for 14 days. Inpatients and patients with previous PM were not included in this initial experience. After TAVR, if the rACM was available, patients were also monitored for 14 days after discharge. Active monitoring was performed with a

Winter et al.
Patient Determinants of Fitness after CR

417

of PM implants in TAVR recipients were identified electively. High-grade AVB requiring PM was identified in nearly 10% of patients before TAVR.

RVAC a été suivi d'une surveillance ambulatoire par télémétrie cardiaque chez 23 patients. La présence d'un BAV asymptomatique a nécessité l'implantation d'un SC chez un patient. L'implantation non planifiée d'un SC a été effectuée chez cinq patients après le RVAC. Grâce à la surveillance ambulatoire par télémétrie cardiaque, près de la moitié des cas nécessitant l'implantation d'un SC ont été dépistés accessoirement parmi les patients ayant subi un RVAC. Un BAV de haut grade nécessitant l'implantation d'un SC a été détecté chez près de 10 % des patients avant le RVAC.

technologist routinely reviewing the transmitted strips on a twice-daily basis. When a significant conduction abnormality (pauses > 3 seconds, second- or third-degree AVB) was detected, a report was generated and the cardiologist on call was contacted immediately to review; otherwise the recordings were evaluated when the monitoring period was completed. Based on the interpretation, a simple closed-loop notification system that incorporated the TAVR team, the clinical cardiologist, and the electrophysiology service was used. The appropriate course of action for the patient was determined (eg, semiurgent clinic visit, call to patient to present to nearest emergency department, and activate ambulance dispatch).

The arrhythmia service was consulted for all patients in whom a PM was contemplated. Patients were followed up to 30 days after TAVR.

Results

In the period between July 2017 and June 2018, 151 patients underwent TAVR. Ten patients had a prior PM, 10 had their TAVR conducted as an inpatient, and 4 refused cardiac monitoring. Of the 127 remaining patients, 62 were fitted with rACM (39 before, 21 after, and 2 both before and after TAVR) (Fig. 1). Their mean age was 84 ± 5.3 years, 29 (46.8%) were female, baseline AF was present in 14 (22.5%), and their mean Society Thoracic Surgery score was 8.9 ± 6.5. All patients received an Edwards Sapien-3 (n = 59) or Sapien-XT (n = 3) valve via transfemoral access.

The mean recording time for the 41 patients with pre-TAVR monitoring was 12.9 ± 4.2 days. Their baseline ECG findings are shown in Table 1. Two patients in this group had baseline bifascicular (right bundle branch block and left anterior hemiblock) block and 1 patient had
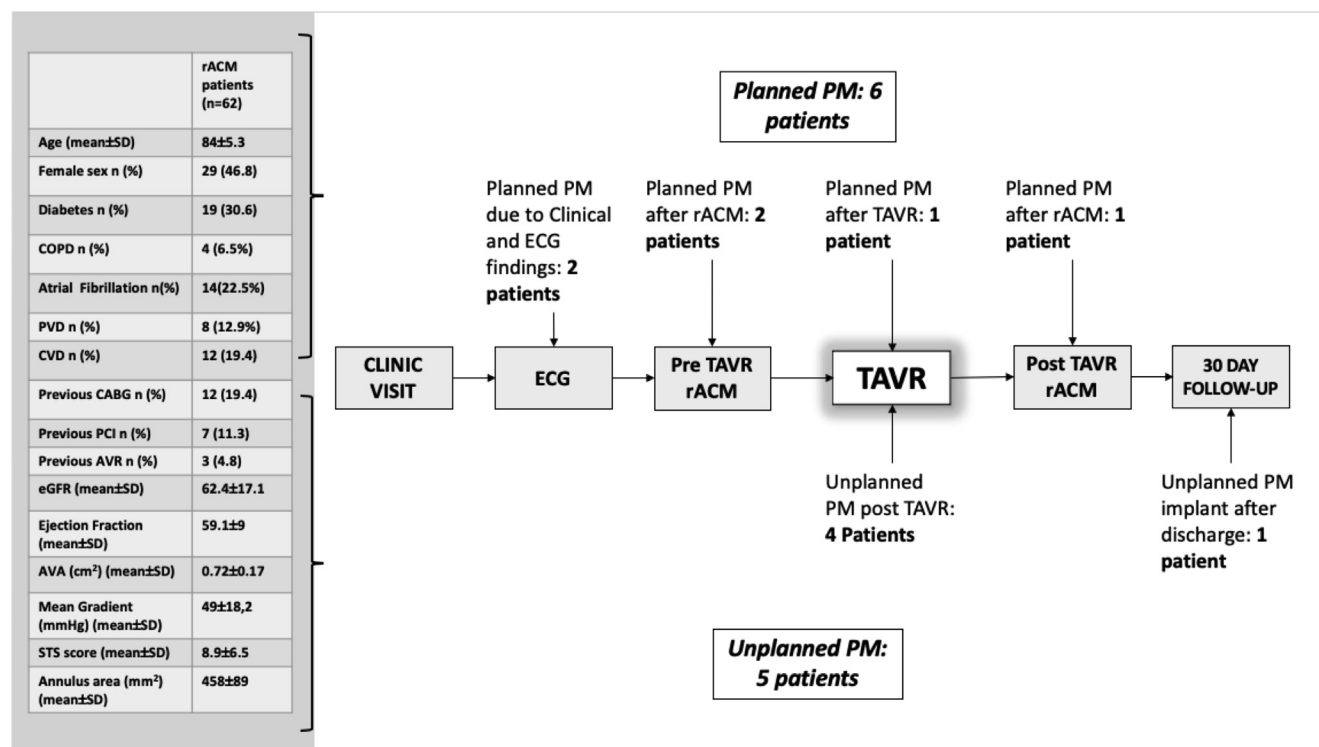
Figure 1. Clinical, electrocardiographical, and rACM details of patients receiving permanent pacemakers. Patient timeline from initial clinic visit to post-TAVR. Strategy for permanent pacemaker distributed as planned or unplanned. AF, atrial fibrillation; AVA, aortic valve area; AVB, high-grade atrioventricular block; AVR, aortic valve replacement; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram; eGFR, estimated glomerular filtration rate; EP, electrophysiologist; LAFB, left anterior fascicular block; LBBB, left bundle branch block; PCI, percutaneous coronary intervention; PM, permanent pacemaker; PVD, peripheral vascular disease; rACM, remote ambulatory cardiac monitoring; RBBB, right bundle branch block; STS, Society Thoracic Surgery; TAVR, transcatheter aortic valve replacement.

Table 1. Baseline ECG characteristics

	rACM pre-TAVR group (n = 41)	rACM post-TAVR group (n = 23)
Normal ECG	13 (31.7)	9 (39.1)
Atrial fibrillation	9 (21.9)	5 (21.7)
1 HB	9 (21.9)	7 (30.4)
LAHB	6 (14.6)	2 (8.6)
RBBB	7 (17)	2 (8.6)
LBBB	3 (7.3)	1 (4.3)

1 HB, first degree AV block; ECG, electrocardiogram; LAHB, left anterior hemiblock, LBBB, complete left bundle branch block; rACM, remote ambulatory cardiac monitoring; RBBB, complete right bundle branch block; TAVR, transcatheter aortic valve replacement.

bifascicular block with a prolonged PR interval. Pre-TAVR monitoring revealed intermittent high-degree AVB in 4 patients (9.8%) (Table 2), with a mean time to detection of 2.6 days. Asymptomatic AF was detected in 1 additional patient (2.4%).

Among the 41 patients undergoing pre-TAVR rACM, 5 patients (12.1%) received a planned PM: 3 patients due to the presence of AVB on rACM (1 of them had a planned PM implant immediately after TAVR) and 2 without AVB on rACM, but with bifascicular block on their ECG (including 1 patient with syncope before TAVR). A fourth patient with AF with asymptomatic pauses of up to 3.5 seconds on pre-TAVR rACM did not receive a PM as he was asymptomatic; apical access was planned and felt to pose a greater risk of dislodging newly implanted pacer wires.

Another 5 patients developed AVB after TAVR that required an "unplanned" PM implant, 4 of them before discharge and 1 with readmission for symptomatic AVB at day 12 after TAVR.

Post-TAVR monitoring was performed in 23 patients with a mean recording time of 12.5 ± 3.4 days. Episodes of asymptomatic complete AVB were found by rACM in 1 patient on the third day of monitoring after discharge. This was a patient with previous first-degree AVB who developed both an increase in PR interval (>20 ms) and new left bundle branch block persistent for 24 hours after TAVR, but both resolved before discharge on day 4. Patient was immediately contacted for readmission and PM was implanted successfully. No patients in the post-TAVR rACM group experienced syncope or cardiac arrest after discharge. No patients required a PM implant 30 days after TAVR.

Discussion

In this experience, a 2-week rACM strategy, incorporating a clinical feedback system for notification of the

Table 2. Device findings

	ACM pre-TAVR group (n = 41)	ACM post-TAVR group (n = 23)
High-degree AV block	4 (9.7)	1 (4.3)
Nonsustained VT	6 (14.6)	4 (17.3)
New AF	1 (2.4)	0 (0)
Other SVT	17 (41.4)	12 (52.1)
Normal	11 (26.8)	6 (26)

ACM, ambulatory cardiac monitoring; AF, atrial fibrillation; SVT, supraventricular tachycardia; TAVR, transcatheter aortic valve replacement; VT, ventricular tachycardia.

patient and TAVR team, had high patient compliance to this device. In combination with pre-TAVR ECG screening, approximately half of all patients requiring PM were implanted electively and post-TAVR rACM helped with the rapid identification of 1 patient with third-degree AVB after discharge. Successful screening and management with rACM before TAVR may help reduce the number of patients requiring an urgent, unplanned PM implant that could be wrongly attributed as a complication of the procedure and could increase hospital length of stay. Using this novel real-time technology allows rapid identification of conduction disturbances and activation of the clinical team to make real-time decision-making processes, potentially reducing further serious clinical events.

Patients with aortic stenosis have a higher disposition to conduction disturbances, due to shared risk factors such as age and shared pathophysiology (ie, calcification of the aortic valve and conduction system).[5] Our series has shown that systematic screening identifies advanced conduction disease in many individuals before TAVR is even performed, suggesting that we may overestimate how much advanced AVB is "caused" by TAVR.

Heart block after TAVR continues to be a significant contributor to morbidity and length of stay after the procedure.[6] This phenomenon is thought to be multifactorial and related to device-specific issues, deployment technique, anatomic changes such as calcification in left ventricle outflow tract, and annulus and pre-existing conduction disturbances. Baseline ECG abnormalities such as first-degree AVB, left anterior hemiblock, and right bundle branch block as well as intraprocedural AVB are predictors for implantation of PM after TAVR.[7,8]

The optimal preprocedural screening for patients at risk of developing AVB after TAVR is still an unanswered question that is not specifically addressed in clinical guidelines, with significant variability in practice patterns and PM rates observed between centres.[9,10] There is limited reported experience of preprocedural heart rhythm monitoring of patients undergoing TAVR. Urena et al.[4] first reported observations of 24-hour continuous monitoring in patients immediately before TAVR. Even with this brief period of monitoring, they observed newly diagnosed arrhythmias in 16.1% of patients including advanced AVB, severe bradycardia, and paroxysmal AF. We considered a 14-day period of observation, which was readily available with our monitoring technology and performed remotely with daily review, as a more effective screening tool for conduction disturbances in TAVR patients. The mean time from rACM recording to AVB detection in our study was less than 3 days, suggesting that the time of monitoring could be shortened significantly improving patient comfort, adherence to monitor, and costs. In combination with baseline ECG abnormalities, there might be an opportunity to incorporate rACM to enhance clinical management of patients before TAVR.[11]

Ongoing observations are needed for promoting early discharge of patients with confidence that those at risk of developing delayed high-grade AVB after TAVR can be identified appropriately. The predictive value of the resting ECG after TAVR has been evaluated by Wood et al.,[12] showing that early discharge 1 day after TAVR is feasible in

Winter et al.
Patient Determinants of Fitness after CR

419

patients who develop intraventricular conduction delay without advanced conduction abnormalities if the QRS after TAVR was stable or decreasing after 24 hours. With this approach, the rate of delayed AVB requiring a PM implant was only 0.28%.[12] Another study showed that patients with sinus rhythm without any conduction disorders after TAVR did not develop AVB on follow-up. Also, patients with AF without any other conduction abnormalities had a very low incidence of AVB (1%).[13] In our cohort, AVB was found with rACM in 1 patient with pre-existing AVB who developed new left bundle branch block persistent for 24 hours after TAVR before returning to baseline. This heart block was found on the third day of rACM. This is a complex clinical situation where current practice is variable and further evidence for appropriate management is needed.[11] Longer periods of monitoring could be useful in the post-TAVR setting. A recent publication by Ream et al.,[8] using a 30-day loop monitoring device in 150 post-TAVI patients, demonstrated delayed AVB in 12 of them with a median of 6 days (range, 3-24 days). Also, in a more recent experience by Tian et al.,[14] remote monitoring for 30 days after TAVR allowed detection of AVB that required a PM implant in an additional 8.6% of patients after discharge. The optimal duration of monitoring after TAVR is unclear and needs to balance the detection of high-risk arrhythmias vs the limitations of patient comfort and costs.

Our study has limitations. This is a nonrandomized experience with a small number of patients and using convenience sample. All patients received balloon expandable Sapien valves. Risks of heart block observed after TAVR may have been higher with other valve types. Because of logistical issues, the patients undergoing pre- and post-TAVR rACM were not the same and should be considered more as a feasibility cohort. Also, there was a higher incidence of baseline conduction abnormalities compared with other experiences. This could be explained by selection bias due to the absence of randomization. Accordingly, the results should be interpreted as exploratory. However, on the basis of these findings, we planned a prospective study of consecutive patients of routine pre- and post-TAVR rACM (ReDireCT TAVI NCT03810820) to address these limitations.

Conclusion

rACM before and after TAVR is feasible and identifies around half of the individuals requiring a PM implant, allowing the PM to be implanted electively, thereby reducing the need for unplanned, urgent procedure and delayed hospital discharge. Pre-TAVR rACM also demonstrates that a large proportion of patients who would have undergone a post-TAVR PM implant actually had an indication for PM before TAVR. Finally, post-TAVR rACM can allow early point-of-care identification of potentially lethal arrhythmias after hospital discharge, thereby improving patient outcomes.

Funding Sources

Disclosures

The authors have no conflicts of interest to disclose.

References

1. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med 2019;380:1695-705.

2. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med 2019;380:1706-15.

3. Khatri PJ, Webb JG, Rodes-Cabau J, et al. Adverse effects associated with transcatheter aortic valve implantation: a meta-analysis of contemporary studies. Ann Intern Med 2013;158:35-46.

4. Urena M, Hayek S, Cheema AN, et al. Arrhythmia burden in elderly patients with severe aortic stenosis as determined by continuous electrocardiographic recording: toward a better understanding of arrhythmic events after transcatheter aortic valve replacement. Circulation 2015;131:469-77.

5. Young Lee M, Chilakamarri YS, Chava S, Lawrence LD. Mechanisms of heart block after transcatheter aortic valve replacement—cardiac anatomy, clinical predictors and mechanical factors that contribute to permanent pacemaker implantation. Arrhythm Electrophysiol Rev 2015;4:81-5.

6. Aljabbary T, Qiu F, Masih S, et al. Association of clinical and economic outcomes with permanent pacemaker implantation after transcatheter aortic valve replacement. JAMA Network Open 2018;1:e180088.

7. Siontis GC, Juni P, Pilgrim T, et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: a meta-analysis. J Am Coll Cardiol 2014;64:129-40.

8. Ream K, Sandhu A, Valle J, et al. Ambulatory rhythm monitoring to detect late high-grade atrioventricular block following transcatheter aortic valve replacement. J Am Coll Cardiol 2019;73:2538-47.

9. Toggweiler S, Leipsic J, Binder RK, et al. Management of vascular access in transcatheter aortic valve replacement: part 2: Vascular complications. JACC Cardiovasc Interv 2013;6:767-76.

10. Massoullie G, Bordachar P, Irles D, et al. Prognosis assessment of persistent left bundle branch block after TAVI by an electrophysiological and remote monitoring risk-adapted algorithm: rationale and design of the multicentre LBBB-TAVI Study. BMJ Open 2016;6:e010485.

11. Rodes-Cabau J, Ellenbogen KA, Krahn AD, et al. Management of conduction disturbances associated with transcatheter aortic valve replacement—JACC Scientific Expert Panel. J Am Coll Cardiol 2019;74: 1086-106.

12. Wood DA, Lauck SB, Cairns JA, et al. The Vancouver 3M (multidisciplinary, multimodality, but minimalist) clinical pathway facilitates safe next-day discharge home at low-, medium-, and high-volume transfemoral transcatheter aortic valve replacement centers: the 3M TAVR study. JACC Cardiovasc Interv 2019;12:459-69.

13. Toggweiler S, Stortecky S, Holy E, et al. The electrocardiogram after transcatheter aortic valve replacement determines the risk for postprocedural high-degree AV block and the need for telemetry monitoring. JACC Cardiovasc Interv 2016;9:1269-76.

14. Tian Y, Padmanabhan D, McLeod CJ, et al. Utility of 30-day continuous ambulatory monitoring to identify patients with delayed occurrence of atrioventricular block after transcatheter aortic valve replacement. Circ Cardiovasc Interv 2019;12:e007635.