

## TAVR Home Monitoring Pathway Clinical publications

Peer-reviewed clinical studies and articles demonstrating the need for mobile cardiac outpatient telemetry (MCOT) to monitor TAVR patients to improve outcomes

### Ambulatory rhythm monitoring to detect late high-grade atrioventricular block following transcatheter aortic valve replacement

#### Study characteristics:

- Participants: 150 participants; only 118 had 30-day ambulatory monitoring post-TAVR
- Inclusion criteria: patients undergoing TAVR
- Exclusion criteria: patients with prior permanent pacemaker (PPM) or implantable cardioverter defibrillator (ICD)
- Study design: prospective cohort
- Duration of mobile cardiac telemetry monitoring: 30-day

#### Author(s)

Ream K, Sandhu A, Valle J, et al.

#### Source

*Journal of the American College of Cardiology*. 2019;73(20):2538-2547.  
doi:10.1016/j.jacc.2019.02.068

#### Study results:

- Among 150 consecutive TAVR patients without a prior pacing device, 12% of the total cohort developed high grade atrioventricular block (H-AVB) necessitating PPM <2 days post-TAVR.
- Delayed high grade atrioventricular block (DH-AVB) occurred in 10% of ambulatory monitoring patients (or 8% of the total cohort), a median of 6 days (range 3 to 24 days) post-TAVR.
- DH-AVB versus non-AVB patients were more likely to have hypertension and right bundle branch block (RBBB).
- There was a greater prevalence RBBB among patients with H-AVB and DH-AVB (30.0% with H-AVB, 33.3% with DH-AVB compared with 1.9% in patients without H-AVB; all  $p < 0.001$ ).
- Left bundle branch block (LBBB) following TAVR increased from 11% pre-TAVR to 28.7% post-TAVR;  $p < 0.001$ .
- Development of LBBB was not associated with H-AVB or DH-AVB.

#### Overall summary:

- In this single-center analysis, ambulatory monitoring was helpful in expeditious identification and treatment of 10% of post-TAVR outpatients.
- RBBB occurred in approximately 1/3 of participants with H-AVB or DH-AVB.
- DH-AVB is an underappreciated complication of TAVR among patients without pre-procedure pacing devices.
- RBBB is a risk factor for DH-AVB but has poor sensitivity, and other predictors remain unclear.

# 2020 ACC expert consensus decision pathway on management of conduction disturbances in patients undergoing transcatheter aortic valve replacement: a report of the American College of Cardiology solution set oversight committee

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## Study characteristics:

- Participants: 742,168 with aortic stenosis, 96,259 included in analysis.
- Inclusion criteria: patients with aortic stenosis, with or without AF, undergoing transcatheter aortic valve implantation (TAVI) or surgical aortic valve implantation (SAVI)
- Exclusion criteria: 645,909 patients did not undergo TAVI or surgical aortic valve replacement (SAVR)
- Study design: retrospective database analysis

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## Author(s)

Lilly S, Deshmukh A, Epstein A, et al.

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## Source

*Journal of the American College of Cardiology*. 2020;76(20):2391-2411.  
doi:10.1016/j.jacc.2020.08.050

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## Study results:

- For those who are without clear pacemaker indications during their procedural hospitalization but are at risk for DH-AVB, prolonged monitoring is often employed.
- The length of inpatient telemetry monitoring varies, but reflects the timing of AVB after TAVR, clustering within the first 7 to 8 days post procedure (47,48,58). The cost and inherent risks of prolonged hospitalization for telemetry have prompted the evaluation of ambulatory ECG monitoring (AEM) strategies in three patient populations: 1) all patients without a pacemaker at the time of discharge after TAVR; 2) those with new LBBB; and 3) those with any new or progressive conduction abnormality after TAVR.
- Post-TAVR outpatient remote monitoring is recommended for at least 14 days in case of early hospital discharge within 48 hours post-TAVR, if the patient is found to have any of the following: no primary PPM indication, new first-degree or second-degree AV block, new bundle branch block (BBB), progression in baseline first-degree, second-degree AV block or prolongation of the QRS  $\geq 10\%$ .
- The monitoring device used must have the capability to provide timely notifications to physicians.
- Complete heart block (CHB) requiring PPM occurs in approximately 15% of patients within 30 days after TAVR.

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## Overall summary:

- Post-operative monitoring with a mobile cardiac telemetry device for 14-30 days is recommended to identify critical arrhythmias in a timely manner, decrease health care utilization, decrease hospital length of stay or rehospitalization, and decrease patient health care related costs.

# Ambulatory electrocardiogram monitoring in patients undergoing transcatheter aortic valve replacement: JACC state-of-the-art review

## Study characteristics:

- Targeted literature review
- This review provides an overview of the current status, clinical implications and future perspectives of ambulatory electrocardiogram (AECG) monitoring in the TAVR setting

## Author(s)

Muntane-Carol G, Philippon F, Nault I, et al.

## Source

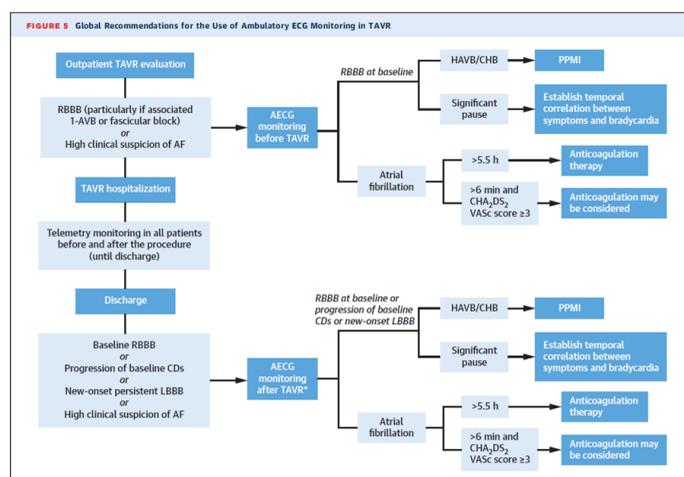
*Journal of the American College of Cardiology*. 2021;77(10):1344-1356.  
doi:10.1016/j.jacc.2020.12.062

## Study results:

- To date, three pre-TAVR studies with different types and duration of AECG monitoring (from 24 hours to 14 days) have been published, including a total of 582 patients. Overall, pre-TAVR AECG monitoring H-AVB showed the presence of arrhythmic events in ~15% of patients (60% bradyarrhythmia, severe bradycardia or H-AVB; 40% new onset AF), most of them (95%) asymptomatic.
- To date, six studies have evaluated the use of AECG monitoring after TAVR.
- Current available data regarding electrocardiogram (ECG) monitoring before the TAVR procedure revealed potential clinical benefits because it would identify significant arrhythmic events (severe bradyarrhythmia or AF) in around 10% of TAVR candidates.
- A post TAVR monitoring strategy may help with an approach to early discharge strategy and the risk of missing delayed significant arrhythmic events.
- While the cost-effectiveness of using AECG monitoring before the procedure in all TAVR patients remains questionable, the incidence of H-AVB/severe bradycardia (up to 47%) in patients with previous ECG abnormalities such as first-degree aortic valve replacement (AVR) or RBBB suggest that AECG monitoring would be highly sensitive and of particular value in this group.

## Overall summary:

- AECG monitoring has recently emerged as a tool to unravel the complex issue of arrhythmic disorders (bradyarrhythmias and tachyarrhythmias) before and after TAVR. To date, the preliminary results from the initial experience using AECG monitoring systems showed the safety, usefulness, and potential clinical implications of this diagnostic tool in TAVR recipients. Refer to monitoring recommendations in image below.



# Evaluating out-of-hospital 30-day mortality after transfemoral TAVR

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## Study characteristics:

- Participants: 106,749 (98,578 with transfemoral approach TAVR)
- Inclusion criteria: patients undergoing TAVR without concomitant procedures.
- Exclusion criteria: patients were excluded for missing status for in-hospital or 30-day mortality, missing cause of death for in-hospital or 30-day mortality, undergoing open heart surgery as part of index hospitalization, missing data for valve sheath access site, being discharged to other acute care hospitals, or being discharged alive but beyond 30-day of procedure. Also excluded if TAVR was performed for off-label indications
- Study design: retrospective database analysis
- Duration of observation: 30-day

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## Author(s)

Anwaruddin S, Desai N, Vemulapalli S, Reardon M. Reply

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## Source

*JACC Cardiovascular interventions*. 2021;14(9):1040-1041. doi:10.1016/j.jcin.2021.03.037

## Study results:

- Transfemoral TAVR was performed in 92.3% of patients.
- A total of 2,137 (2.2%) transfemoral patients died within 30 days of the procedure, and 623 (29%) of these patients experienced out-of-hospital 30-day mortality.
- Cardiovascular and pulmonary etiologies accounted for most of the observed mortality.
- Multivariable regression analysis identified older age, gender, lower body surface area, lower left ventricular ejection fraction, lower hemoglobin, atrial fibrillation or flutter, severe lung disease, home oxygen use, lack of moderate-to-severe aortic insufficiency, urgent TAVR, lower Kansas City Cardiomyopathy Questionnaire score, longer hospital length of stay, and in hospital complications as being independently associated with the primary endpoint.
- New onset or pre-existent atrial fibrillation or flutter was also independently associated with 30-day out-of-hospital cardiovascular mortality in the transfemoral population.

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## Overall summary:

- 2% of patients had all-cause mortality within 30 days, which ~1/3 occurred out-of-hospital.
- Those who died within 30 days and were discharged home (instead of to assisted care facility) were likely healthier than those who were discharged to nursing facilities.
- Further work is needed to understand how best to improve out-of-hospital mortality following TAVR, which provides good indication that mobile telemetry monitoring may help reduce all-cause mortality post-TAVR.

# Permanent pacemaker implantation after TAVR: reviewing the current landscape of permanent pacemaker implantation post-TAVR and a look at the road ahead

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## Study characteristics:

- Participants: variable between included studies
- Inclusion criteria: variable between included studies
- Exclusion criteria: variable between included studies
- Study design: targeted literature review

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## Author(s)

R. Sharma, RP. Sharma

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## Source

*Cardiac Interventions Today.*  
2019;13(2):79-83.e

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## Study results:

- In a study examining the balloon-expandable Sapien valve, researchers performed an as-treated analysis of 1,973 patients who underwent TAVR in the randomized PARTNER trial and continued access registry. Multivariate analysis, the strongest electrocardiographic predictors for post-TAVR PPM included pre-existing RBBB and left anterior fascicular hemiblock (LAFB;  $P < .001$ ).
- A separate meta-analysis of 41 studies, which included 11,210 TAVR patients, showed a 17% post-TAVR PPM rate and an increased risk of PPM in men (risk ratio [RR], 1.23;  $P < .01$ ), as well as those with baseline first-degree AVB (RR, 1.52;  $P < .01$ ), LAFB (RR, 1.62;  $P < .01$ ), and RBBB (RR, 2.89;  $P < .01$ ).
- In a study by Hamdan et al, multidetector CT (MDCT) was used to assess membranous septum (MS) length in 73 patients who underwent TAVR with the CoreValve self-expanding prosthesis. The reported post-TAVR PPM rate was 28%. MS length was the strongest preprocedural predictor of H-AVB (odds ratio [OR], 1.35;  $P = .01$ ) and PPM implantation (OR, 1.43;  $P = .002$ ). Thus, a shorter MS length was associated with increased PPM rates after TAVR. Patients who required a new PPM after TAVR tended to have shorter MS length ( $6.4 \pm 1.7$  mm vs  $7.7 \pm 1.9$  mm;  $P < .001$ ) and a larger valve implantation depth ( $0.60 \pm 2.9$  mm vs  $2.5 \pm 2.4$  mm;  $P < .001$ ).
- A retrospective analysis of 240 patients who received the Sapien transcatheter heart valve between 2013 and 2015 demonstrated a 14.6% PPM rate.
- In a report on 867 patients treated with the Sapien transcatheter heart valve, valve implantation depth  $> 6$  mm was associated with a significant increase in new PPM (OR, 2.03;  $P = .0092$ ).

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## Overall summary:

- Receiving a new PPM after TAVR has been reported to significantly increase per-patient costs and hospital length of stay, particularly when the PPM is implanted more than 24 hours after TAVR.
- This analysis suggests that while many of these factors are not able to be modified pre-TAVR, there should be an emphasis on preoperative testing (including MDCT), Left Ventricular Outflow Tract (LVOT), electrocardiography, and in recent years, assessment of MS length on the MDCT.
- Given that health cost per-patient and hospital length of stay increase, there is evidence for pre-TAVR cardiac monitoring as well as post-TAVR monitoring.

# Impact of atrial fibrillation on outcomes of aortic valve implantation

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## Study characteristics:

- Participants: 742,168 with aortic stenosis, 96,259 included in analysis
- Inclusion criteria: patients with aortic stenosis, with or without AF, undergoing TAVI or SAVR
- Exclusion criteria: 645,909 patients did not undergo TAVI or SAVR
- Study design: retrospective database analysis

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## Author(s)

Ahmed R, Sawatari H, Deshpande S, et al.

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## Source

*The American Journal of Cardiology.*  
Published online November 2021.  
doi:10.1016/j.amjcard.2021.09.036

## Study results:

- The median length of stay in the patients with AF increased by 33.3% as compared with those without AF undergoing TAVI and SAVR (5 [3 to 8] days vs 3 [2 to 6] days,  $p < 0.0001$  and 8 [6 to 12] days vs 6 [5 to 10] days,  $p < 0.0001$ , respectively).
- AF increased the median value of adjusted healthcare associated costs of both TAVI (\$46,754 [36,613 to 59,442] vs \$49,960 [38,932 to 64,201],  $p < 0.0001$ ) and SAVR (\$40,948 [31,762 to 55,854] vs \$45,683 [35,154 to 63,026],  $p < 0.0001$ ).
- The patients with AF were older (76 [68-82] vs 72 [64-81] years,  $p < 0.0001$ ) and more likely to be males (with AF: 64.2%, without AF: 60.8%;  $p < 0.001$ ) than those without AF.
- Patients in SAVR and AF group had the highest length of stay as compared with other groups ( $p < 0.0001$ ).
- Inpatient mortality was found to be significantly higher with increasing age and female gender ( $p < 0.0001$ ).

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## Overall summary:

- The presence of AF did not independently increase the in-hospital mortality.
- Inpatients undergoing SAVR or TAVI, AF significantly increased the length of stay and adjusted healthcare adjusted costs, but did not independently increase the in-hospital mortality.
- This could be mitigated by initiating pre-TAVR and post-TAVR cardiac monitoring, which could lead to changes in clinical management of patients prior to the TAVR procedure, or more timely treatment changes post-procedurally. This could also lead to decreased all-cause mortality in the out-of-hospital setting and decreased mortality due to cerebrovascular events.
- Timely initiation of treatment changes will also likely have implications for hospital length of stay, healthcare costs per-patient, reduce readmissions, and optimize utilization of emergent and non-emergent health services.

# Shifting trends in timing of pacemaker implantation after TAVR

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## Study characteristics:

- Participants: 62,083
- Inclusion criteria: patients undergoing TAVR
- Exclusion criteria: patients with prior PPM or ICD
- Study design: retrospective database analysis
- Duration of observation: 30-day

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## Author(s)

Mazzella AJ, Hendrickson MJ, Arora S, et al.

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## Source

*JACC Cardiovascular interventions.* 2021;14(2):232-234. doi:10.1016/j.jcin.2020.09.034

## Study results:

- 6,817 (11.0%) underwent PPM implantation after TAVR with 6,137 (9.9%) occurring during the same hospitalization as TAVR and 680 (1.1%) occurring during a subsequent hospitalization.
- Rates of PPM implantation after TAVR ranged between 8% and 12.5% from 2012 to 2017.
- However, as overall length of stay for index TAVR hospitalization trended down from 2012 to 2017 ( $P < 0.0001$ ), there was an increase in proportion of PPM implants during subsequent hospitalization after discharge from TAVR.

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## Overall summary:

- Decreasing TAVR hospitalization length of stay in combination with similar rates of PPM implantation after TAVR has increased the proportion of patients requiring readmission for PPM after discharge from TAVR.
- Decreased length of stay may have clinical implications for rehospitalization.

