PHILIPS

BioTel HEART

Peri-TAVR Home Monitoring Pathway Clinical publications

Peer-reviewed published clinical studies demonstrating the value of Mobile Cardiac Outpatient Telemetry to monitor peri-TAVR patients

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 PPM or ICD
- Study design: prospective cohort
- Duration of monitoring: 30 Days

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 H-AVB necessitating permanent pacemaker <2 days post-TAVR.**
- **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). This is statistically significant.**
- LBBB following TAVR **increased from 11% pre-TAVR to 28.7% post-TAVR; p < 0.001. This is statistically significant.**
- **Development of LBBB was not associated with H-AVB or DH-AVB.**

Overall summary:

- **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.
- In this single-center analysis, **ambulatory monitoring was helpful in expeditious identification and treatment of 10% of post-TAVR outpatients.**

Shifting trends in timing of pacemaker implantation after TAVR

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 monitoring: 30 Days

Author(s)

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

Source

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. This is statistically significant.**

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.

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

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 days of procedure. Also excluded if TAVR was performed for off-label indications
- Study design: retrospective database analysis
- Duration of monitoring: 30 Days

Author(s)

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

Source

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.

Overall summary:

- **2% had all-cause mortality within 30 days of procedure. Of these, ~1/3 occurred out-of-hospital.**
- Those who died within 30 days and were discharged home (instead of to 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 again 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

Study characteristics:

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

Author(s)

R. Sharma, RP. Sharma

Source

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

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 preexisting right bundle branch block (RBBB) and left anterior fascicular hemiblock (LAFB; P < .001). This is statistically significant.**
- 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 atrioventricular block (AVB) (RR, 1.52; P < .01), LAFB (RR, 1.62; P < .01), and RBBB (RR, 2.89; P < .01). This is statistically significant.**
- In a study by Hamdan et al, **MDCT was used to assess 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 high-degree AVB (odds ratio [OR], 1.35; P = .01) and PPM implantation (OR, 1.43; P = .002). **This is statistically significant.**
  - Thus, **a shorter MS length was associated with increased PPM rates after TAVR.**
- A retrospective analysis of 240 patients who received the Sapien transcatheter heart valve between 2013 and 2015 demonstrated a **14.6% PPM rate.**
  - Patients who required a new PPM after TAVR tended to have **shorter MS length** (6.4 ± 1.7 mm vs 7.7 ± 1.9 mm; P < .001) and a **larger valve implanta¬tion depth** (0.60 ± 2.9 mm vs 2.5 ± 2.4 mm; P < .001). **This is statistically significant.**
- 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). This is statistically**

Overall summary:

- Regarding health care costs, 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 multidetector CT (MDCT), Left Ventricular Outflow Tract (LVOT), electrocardiography, and in recent years, assessment of Membranous Septum (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. The cost per-patient receiving PPM more than 24hrs after TAVR increasing is supported by internal BioTelemetry Health Economics Data.**

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

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

Author(s)

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

Source

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 AEM strategies in 3 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 1st degree or 2nd degree AV block, new bundle branch block (BBB), progression in baseline 1st, 2nd degree AV block or prolongation of the QRS ≥10%.**
- **The monitoring device used must have the capability to provide timely notifications to physicians.**
- **Complete heart block (CHB) requiring a permanent pacemaker (PPM) occurs in approximately 15% of patients within 30 days after TAVR**

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.**
- **Similarly, in the recent JACC State of the Art Review, new global recommendations suggest utilizing Pre-TAVR ambulatory monitoring AND post-TAVR monitoring6. Refer to image under the Muntane-Carol JACC article.**
  - **iRhythm currently uses this clinical approach per their TAVR webpage (https://www.irhythmtech.com/providers/use-cases/tavr).**

Impact of atrial fibrillation on outcomes of aortic valve implantation

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

Author(s)

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

Source

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). **This is statistically significant.**
- **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). **This is statistically significant.**
- **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. **This is statistically significant.**
- Patients in SAVR and AF group had the highest length of stay as compared with other groups (p<0.0001). **This is statistically significant.**
- Inpatient mortality was found to be significantly higher with increasing age and female gender (p<0.0001). **This is statistically significant.**

Overall summary:

- **The presence of AF did not independently increase the in-hospital mortality.**
- In patients 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 potentially be mitigated by initiating pre-TAVR AND post-TAVR cardiac monitoring which could potentially lead to changes in clinical management of patients prior to the TAVR procedure, or more timely treatment changes post-procedurally[6,8–10]. 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.

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 AECG monitoring in the TAVR setting.

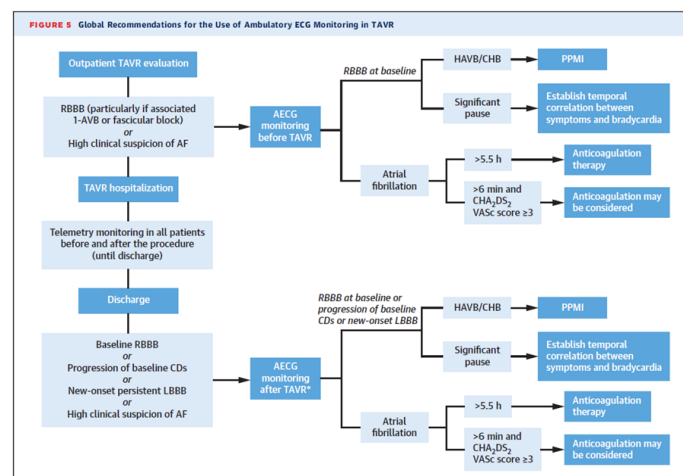## Author(s)

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

Source

Study results:

- To date, 3 pre-TAVR studies with different types and duration of AECG monitoring (from 24 h to 14 days) have been published, including a total of 582 patients.
  - Overall, pre-TAVR AECG monitoring showed the presence of arrhythmic events in ~15% of patients (60% bradyarrhythmia, severe bradycardia or HAVB; 40% new onset AF), most of them (95%) asymptomatic.
- To date, 6 studies have evaluated the use of AECG monitoring after TAVR.
- Current available data regarding 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 HAVB/severe bradycardia (up to 47%) in patients with previous ECG abnormalities such as first-degree AVR or RBBB suggest that AECG monitoring would be highly sensitive and of particular value in this group.**

Overall summary:

- **Ambulatory electrocardiogram (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.**

FIGURE 5 Global Recommendations for the Use of Ambulatory ECG Monitoring in TAVR