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# Arrhythmic Burden as Determined by Ambulatory Continuous Cardiac Monitoring in Patients With New-Onset Persistent Left Bundle Branch Block Following Transcatheter Aortic Valve Replacement

## The MARE Study

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## ABSTRACT

**OBJECTIVES** The authors sought to determine: 1) the global arrhythmic burden; 2) the rate of arrhythmias leading to a treatment change; and 3) the incidence of high-degree atrioventricular block (HAVB) at 12-month follow-up in patients with new-onset persistent left bundle branch block (LBBB) following transcatheter aortic valve replacement (TAVR).

**BACKGROUND** Controversial data exist on the occurrence of significant arrhythmias in patients with LBBB post-TAVR.

**METHODS** This was a multicenter prospective study including 103 consecutive patients with new-onset persistent LBBB post-TAVR with the balloon-expandable SAPIEN XT/3 valve (n = 53), or the self-expanding CoreValve/Evolut R system (n = 50). An implantable cardiac monitor (Reveal XT, Reveal Linq) was implanted at 4 (3 to 6) days post-TAVR, and patients had continuous electrocardiogram monitoring for 12 months. All arrhythmic events were adjudicated in a central electrocardiography core lab. Primary endpoints were the incidence of arrhythmias leading to a treatment change, and the incidence of HAVB at 12-month follow-up.

**RESULTS** A total of 1,553 new arrhythmic events were detected in 44 patients (1,443 episodes of tachyarrhythmia in 26 patients [atrial fibrillation/flutter/atrial tachycardia: 1,427, ventricular tachycardia 16]; 110 episodes of bradyarrhythmia in 21 patients [HAVB 54, severe bradycardia 56]). All arrhythmic events were silent in 34 patients (77%), the arrhythmic event led to a treatment change in 19 patients (18%), and 11 patients (11%) required pacemaker or implantable cardioverter-defibrillator implantation (due to HAVB, severe bradycardia, or ventricular tachycardia episodes in 9, 1, and 1 patient, respectively). A total of 12 patients died at 1-year follow-up, 1 from sudden death.

**CONCLUSIONS** A high incidence of arrhythmic events was observed at 1-year follow-up in close to one-half of the patients with LBBB post-TAVR. Significant bradyarrhythmias occurred in one-fifth of the patients, and PPM was required in nearly one-half of them. These data support the use of a cardiac monitoring device for close follow-up and expediting the initiation of treatment in this challenging group of patients. (Ambulatory Electrocardiographic Monitoring for the Detection of High-Degree Atrio-Ventricular Block in Patients With New-onset PeRsistent LEft Bundle Branch Block After Transcatheter Aortic Valve Implantation [MARE study]: NCT02153307) (J Am Coll Cardiol Intv 2018;■:■-■) © 2018 by the American College of Cardiology Foundation.

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**ABBREVIATIONS AND ACRONYMS**

**ACC/AHA/HRS** = American College of Cardiology/American Heart Association/Heart Rhythm Society

**AF** = atrial fibrillation

**AFL** = atrial flutter

**ECG** = electrocardiogram

**HAVB** = high-degree atrioventricular block

**ICD** = implantable cardioverter-defibrillator

**ILR** = implantable loop recorders

**IQR** = interquartile range

**LBBB** = left bundle branch block

**PPM** = permanent pacemaker implantation

**TAVR** = transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has become a well-accepted option for treating patients with aortic stenosis at intermediate-to-high surgical risk. However, conduction disturbances, particularly new-onset left bundle branch block (LBBB), remain the most frequent complication of TAVR (1). New-onset LBBB has been reported in about one-fourth of TAVR procedures, with a varying incidence across different studies and valve types (1). Although the impact of LBBB post-TAVR on clinical outcomes remains controversial, some studies have suggested an increased risk of cardiovascular death and sudden death in patients with new-onset LBBB (2–4). Also, conflicting results have been reported regarding the risk of high-degree atrioventricular block (HAVB) and the need for permanent pacemaker implantation (PPM) at midterm follow-up in those patients leaving the hospital with a new LBBB after the TAVR procedure (1,5–7). In fact, the real incidence of late HAVB (silent, symptomatic) in these patients remains largely unknown.

Implantable loop recorders (ILR) with prolonged electrocardiogram (ECG) monitoring have recently emerged as valuable tools for the diagnosis of transient arrhythmic events with recognized advantages compared with traditional methods of external ECG monitoring (8,9). The use of ILR have also been demonstrated in patients with syncope and bundle branch block (10). However, the usefulness of ILR devices in the setting of TAVR, and particularly among patients with conduction disturbances following the procedure, has not been evaluated yet. The objectives of this study were to determine, with the use of ILR in patients with new-onset persistent LBBB post-TAVR: 1) the global arrhythmic burden; 2) the incidence of significant arrhythmias leading to a treatment change; and 2) the incidence of HAVB at 12-month follow-up.

## METHODS

**STUDY DESIGN AND PATIENTS.** This was a prospective multicenter study including patients undergoing TAVR with either self- or balloon-expandable valves (CoreValve or Evolut R [Medtronic, Minneapolis, Minnesota]; Edwards SAPIEN XT or SAPIEN 3 [Edwards Lifesciences, Irvine, California]). Patients receiving other transcatheter valve types were excluded. Following the procedure, patients were on continuous ECG monitoring during the hospitalization period (or at least during 72 h), and a 12-lead ECG was performed daily until hospital discharge in all patients. Patients with new-onset LBBB that persisted ≥3 days post-TAVR received a Reveal ICM XT or LINQ device as ILR before hospital discharge. LBBB was defined according to the American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) recommendations (11). The device was implanted subcutaneously in the most appropriate position to record adequate QRS and P complexes. Details on the Reveal XT and LINQ devices have been provided elsewhere (12,13). Patients with PPM or LBBB before TAVR and those who had PPM or died in the peri-procedural period post-TAVR were excluded.

Patients were followed during 12 months, and in-office visits and 12-lead ECG were performed at 1- and 12-month follow-up. Automatic wireless transmission of data (daily reports, alerts, monthly complete reports) was obtained in those patients with the Reveal LINQ device. Device interrogation at 1-, 3-,

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