Long-term ECG monitoring using an implantable loop recorder for the detection of atrial fibrillation after cavotricuspid isthmus ablation in patients with atrial flutter

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BACKGROUND In patients with atrial flutter who undergo cavotricuspid isthmus ablation, long-term electrocardiographic (ECG) monitoring may identify new onset of atrial fibrillation (AF).

OBJECTIVES To ascertain, through the use of an implantable loop recorder (ILR) with a dedicated AF detection algorithm, the incidence, duration, and burden of new AF in these patients and to develop an optimal postablation ECG monitoring strategy.

METHODS We enrolled 20 patients with flutter, a $CHADS_2$ score of 2–3, and no prior episode of AF. After cavotricuspid isthmus ablation, we implanted an ILR, which was interrogated routinely; all stored ECGs were adjudicated.

RESULTS During a mean follow-up of 382 ± 218 days, 3 patterns were observed. First, in 11 (55%) patients, stored ECGs confirmed AF at 62 ± 38 days after ablation. Second, in 4 (20%) patients, although the ILR suggested AF, episodes actually represented sinus rhythm with frequent premature atrial contractions and/or oversensing. Third, in 5 (25%) patients, no AF was observed. Episodes <4 hours were associated with low AF burden ($<1\%$) or false detections. The 1-year freedom from any episode of AF >4 and >12 hours was 52% and 83%, respectively.

CONCLUSIONS Our data show that many (but not all) patients develop new AF within the first 4 months of flutter ablation. Since external ECG monitoring for this duration is impractical, the ILR has an important role for long-term AF surveillance. Future research should be directed toward identifying the relationship between duration/burden of AF and stroke and improving existing ILR technology.

KEYWORDS Atrial fibrillation; Atrial flutter; Catheter ablation; Cavotricuspid isthmus; Implantable loop recorder

ABBREVIATIONS **AF** = atrial fibrillation; **CTI** = cavotricuspid isthmus; **ECG** = electrocardiographic; **ILR** = implantable loop recorder; **PPV** = positive predictive value

(Heart Rhythm 2013;10:1598–1604)

Introduction

The relationship between atrial fibrillation (AF) and stroke is now well established.[1] The risk of thromboembolism can be estimated by using schema such as the $CHADS_2$ scoring system; it is generally accepted that patients with a $CHADS_2$ score of ≥ 2 (annualized stroke risk of $\geq 4.0\%$) are at highest risk and are thus candidates for anticoagulation therapy.[2] Data obtained from patients with an implanted pacemaker or defibrillator suggest that silent episodes of AF may significantly increase the risk of thromboembolism.[3,4] Since most at-risk patients do not have an implanted pacemaker or defibrillator and are often entirely asymptomatic during AF episodes, there is great interest in alternative techniques that can capture electrocardiographic (ECG) recordings during these episodes.

A variety of ambulatory external ECG recording systems have been developed. These include 24–48-hour Holter monitoring, 7–14-day patch-type Holter monitoring, patient-activated event recorders, auto-triggered loop recorders, and mobile cardiovascular telemetry systems. However, the limited duration of monitoring inherent to all these systems confines their use for long-term AF monitoring in high-risk patients, in whom AF may occur with variable duration and burden.[5] As a result, an implantable loop

This study was funded by a research grant from Biosense Webster. Dr Mittal is a consultant to Biosense Webster and Medtronic; he has received research support from Biosense Webster and Medtronic. Dr Pokushalov is a consultant to Biosense Webster and Medtronic. Dr Romanov is a consultant to Biosense Webster and Medtronic. Dr Steinberg is a consultant to Biosense Webster, Medtronic, and St Jude Medical; he has received research support from Biosense Webster and Medtronic. **Address reprint requests and correspondence:** Dr Suneet Mittal, Valley Health System, The Valley Hospital, 223 N Van Dien Avenue, Ridgewood, NJ 07450. E-mail address: mittsu@valleyhealth.com.

recorder (ILR) with a dedicated AF detection algorithm may be a better alternative, since it can capture ECG data long-term (~3 years); the overall accuracy of the system has been suggested to be excellent.[6]

A particularly interesting cohort is a patient with typical atrial flutter but no documented episode of AF. Because of the high-risk recurrence rates of atrial flutter, catheter ablation of the cavotricuspid isthmus (CTI) has emerged as definitive and first-line treatment for these patients.[7,8] However, it is being increasingly recognized that in some of these patients, AF will be detected during long-term follow-up.[9,10] This is not a procedure-related proarrhythmia; rather, it reflects a common underlying substrate that predisposes some patients to both atrial flutter and AF. The exact incidence of AF in these patients is difficult to ascertain since most of these episodes are asymptomatic, the duration of follow-up has varied, and the methods for obtaining ECG follow-up has not been standardized. Nonetheless, a meta-analysis suggested that over a 2-year follow-up after CTI ablation, nearly one third of the patients can be expected to have AF.[11] Because there is no accepted post-CTI ablation ECG monitoring strategy, the optimal duration of anticoagulation after ablation is unknown. Most physicians prefer to maintain anticoagulation for 1 month after ablation and then hold further anticoagulation unless AF can be documented; on the other hand, some physicians advocate lifelong anticoagulation on the premise that all patients will eventually develop AF after CTI ablation.

In this study, we implanted an ILR with a dedicated AF detection algorithm after CTI ablation in patients with atrial flutter but no documented AF. Our aims were to ascertain the actual incidence of AF in these patients, to characterize AF in terms of duration and burden, and to determine whether this information could be used to develop an optimal post-flutter ablation ECG monitoring strategy.

Methods

Study population

In this pilot registry, we included 20 consecutive patients with typical paroxysmal or persistent atrial flutter who were referred for CTI ablation. All patients were aged ≥18 years, had ECG documented paroxysmal or persistent typical atrial flutter, and had *no* previous documented evidence of AF. Investigators carefully reviewed all available ECG documentation to exclude the presence of prior AF. In addition, we included only patients with a $CHADS_2$ score ≥2 because this is a cohort at high risk for stroke in whom it was essential to know with certainty whether they had any AF after CTI ablation, as it could have a material effect on the decision regarding ongoing anticoagulation.

No patient had an indication for anticoagulation other than atrial flutter. In addition, no patient had an existing pacemaker, defibrillator, or cardiac resynchronization therapy device. All patients provided written informed consent. The institutional review boards of all 3 contributing institutions—St. Luke's-Roosevelt Hospital, New York, NY; The Valley Hospital, Ridgewood, NJ; State Research Institute of Circulatory Pathology, Novosibirsk, Russia—approved the study protocol.

Catheter ablation

The patient's echocardiogram was reviewed to assess left atrial size and left ventricular function. All patients underwent CTI ablation by using the CARTO electroanatomic mapping system (Biosense Webster, Diamond Bar, CA) in conjunction with an open-irrigated ablation catheter (THERMOCOOL irrigated tip catheter and integrated ablation system, Biosense Webster). The end point of ablation was the demonstration of bidirectional block across the CTI by using differential pacing. No patient was treated with an antiarrhythmic drug after ablation.

Implantable loop recorder

Immediately after ablation, all patients underwent implantation of a loop recorder (Reveal XT, Model 9529, Medtronic Inc, Minneapolis, MN). This device, which has a battery life of ~3 years, has an AF detection algorithm that can detect the presence of AF episodes (>2 minutes in duration) and quantify the burden of AF. The device can store up to 49.5 minutes of ECG data; storage is allocated to 27 minutes of automatically activated events and 22.5 minutes of patient-activated events. Patients were advised to undergo removal of their ILR if (1) a bradyarrhythmia was documented that necessitated implantation of a pacemaker, (2) a decision was made to pursue lifelong anticoagulation on the basis of the documentation of AF, or (3) no episodes of AF were documented within 2 years of device implantation.

The ILR stores information regarding the presence of AF in various ways. First, it reports the number of AF events since the last device interrogation along with the percentage of time spent in AF (Figure 1A). Since each and every episode cannot be adjudicated by review of a stored ECG, the percentage of time spent in AF reported by the device represents the "worst-case scenario." In other words, this would be the percentage if the device exhibited 100% specificity. (Given the high sensitivity of the device, it is unlikely that the device would have failed to identify true AF episodes.[6]) Second, the device records an Arrhythmia Episode List, which contains information about the date, time, duration, median, and maximal ventricular rate of the 30 most recent episodes of AF (Figure 1B). This list includes all ILR-detected episodes lasting ≥2 minutes. It is not possible to alter this detection duration parameter. Third, the device "bins" all individual AF episodes into 1 of 8 distinct time frames: 2–10 minutes, 10 minutes to 1 hour, 1–4 hours, 4–12 hours, 12–24 hours, 24–48 hours, 48–72 hours, and >72 hours (Figure 1C).

The storage and availability of ECG data depend on device programming. At the time of implant, the implanter has to program the "Record ECG of" detection period. The nominal option is "All episodes"; alternatively, one can restrict ECG storage to events "≥6 minutes," "≥10 minutes," "≥20 minutes," "≥30 minutes," or "≥60 minutes" (Figure 2). The ILR will then store ECG data for the first 2 minutes of the most recent 13 episodes that meet the "Record ECG of" criteria (Figure 3). However, these 13 episodes have to be within the