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Yield and consistency of arrhythmia detection with patch electrocardiographic monitoring: The Multi-Ethnic Study of Atherosclerosis

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ABSTRACT

Background: Patch electrocardiographic (ECG) monitors permit extended noninvasive ambulatory monitoring. To guide use of these devices, information is needed about their performance. We sought to determine in a large general population sample the acceptability of patch ECG monitors, the yield of arrhythmia detection, and the consistency of findings in participants monitored twice.
Methods: In the Multi-Ethnic Study of Atherosclerosis, 1122 participants completed one or two monitoring episodes using the Zio Patch XT, a single-channel ECG patch monitor capable of recording for 14 days. Recordings were analyzed for atrial fibrillation (AF), atrial flutter, atrioventricular block, pauses, and supraventricular and ventricular ectopy.
Results: The mean(SD) age at the time of monitoring was 75(8) years, 52% were men, and 15% had a prior history of clinically-recognized AF/flutter. The median monitoring duration was 13.8 days. Among 804 participants with no prior clinical history of AF/flutter and at least 12 days of monitoring on a single device, AF/flutter was detected in 32 (4.0%); in 38% of these, AF/flutter was first detected during days 3 through 12 of monitoring. In participants monitored twice, findings from the two devices showed excellent agreement for supraventricular and ventricular ectopic beats per hour, but only fair agreement for high-grade atrioventricular block and pauses of >3 s duration.
Conclusions: In a general population of older individuals, new diagnoses of AF/flutter were made in 4.0% of participants without a prior history. A single monitoring episode accurately estimated rates of supraventricular and ventricular ectopy.

Introduction

Convenient electrocardiographic (ECG) patch monitors now make it practical to conduct extended noninvasive ambulatory monitoring for durations longer than conventional Holter monitors. The devices permit identification of atrial fibrillation (AF) and atrial flutter and estimation of AF burden, defined as the proportion of monitored time that the cardiac rhythm is AF. They also provide information on heart rate, pauses, high grade atrioventricular block, counts of isolated supraventricular and ventricular ectopic beats, and runs of supraventricular and ventricular tachycardia.

For both researchers and clinicians, it is of interest to understand the yield of AF detection for shorter versus longer monitoring periods. Studies in patients with major clinical indications for monitoring or indications for implanted devices have estimated the yield of AF detection for various monitoring durations and frequencies [1,2]. However, little information is available from a general population about yield and consistency of findings with various monitoring strategies, including ECG patch monitors. In the Multi-Ethnic Study of Atherosclerosis (MESA), we examined in a community-based sample of older individuals: 1) the yield of arrhythmia detection for various ECG monitoring periods up to 12 days, and 2) the consistency of results from two patch monitors worn one shortly after the other by the same person, to determine

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whether conducting two monitoring episodes of up to 14 days each adds important information beyond a single monitoring episode.

Material and methods

Setting

MESA is designed to investigate the pathogenesis of early cardiovascular disease and its progression. In 2000–2002, MESA enrolled 6814 participants 45–84 years of age and free of clinically-recognized cardiovascular disease from six US communities [3]. Participants self-identified with one of four race/ethnic groups: African-American (28%), white (38%), Hispanic (22%) and Asian, of Chinese descent (12%); 53% were women. After the initial baseline study visit, there have been five additional follow-up visits; the most recent study visit is in 2016–18. At study visits, height, waist circumference, and weight were measured, and smoking, current medications, and physician diagnoses of hypertension, diabetes, and AF were assessed by questionnaire [3]. Blood pressure was measured with the participant in a seated position; serum glucose was measured in a fasting blood sample.

Since baseline, participants have been contacted by telephone every 9–12 months to identify new hospitalizations and medical diagnoses during follow-up. Medical records were obtained for cardiovascular events; myocardial infarction and heart failure were adjudicated by the MESA Morbidity and Mortality Committee. Clinically-recognized AF and atrial flutter were identified by an International Classification of Disease (ICD) code for AF or atrial flutter (version 9: 427.31 or 427.32; version 10: I48) in any position assigned at hospital discharge; by 12 lead electrocardiogram at the 2010–2012 MESA exam; for those enrolled in fee-for-service Medicare, by an inpatient, outpatient, or physician claim with an AF or atrial flutter ICD diagnosis code in any position; or by a participant report of a physician diagnosis of AF. Details of the study protocol and procedures have been described [3].

In a pilot study, self-application by MESA participants of a patch monitor capable of recording for 14 days was found to be feasible and to result in wear time and analyzable time nearly equal to those from devices applied by MESA staff. For self-applied monitors, median wear time was 13.9 days and median analyzable time was 98% of total wear time; for staff-applied monitors; corresponding figures were 13.9 days and 99% [4].

Participants

During the 2016–2018 study visit, we enrolled a subset of MESA participants in an ancillary study designed to determine the prevalence of AF, atrial flutter, and other arrhythmias, and to study these arrhythmias in relation to cardiac and brain structure and function. The present analysis reports on the yield and consistency of arrhythmia detection from ECG monitoring of the first 1122 MESA participants enrolled in the ancillary study between September 6, 2016 and October 12, 2017; the target enrollment is 1500. Participants both with and without a prior history of heart disease or clinically-recognized AF were included in the ancillary study; those with a history of clinically-recognized AF were oversampled. Participants were not queried about or selected on the basis of symptoms suggestive of arrhythmia. Individuals with a history of skin allergy to tape or adhesives were excluded. At the 2016–2018 study visit, study staff at each field center applied an ECG patch monitor and asked the participant to wear it for the full 14 days. Study staff made one or more follow-up phone calls during the monitoring period to check on progress and answer participant questions. Participants removed the device at the end of the monitoring period and mailed it to the manufacturer (iRhythm Technologies, Inc., San Francisco, CA) for interpretation. By phone, participants were questioned about their willingness to complete a second monitoring period shortly after the first. A second monitor was mailed to those who agreed and they were asked to self-apply it. Processing and analysis of the ECG data was done by certified technicians at iRhythm and all reported arrhythmias were verified by the Epidemiological Cardiology Reading Center at Wake Forest University School of Medicine, Winston-Salem, NC. Approval for the study was obtained from the institutional review board on human research at each participating institution (University of Washington, Wake Forest University, Columbia University, Johns Hopkins University, University of Minnesota, Northwestern University, and University of California, Los Angeles) and all participants provided written informed consent. The ECG monitoring devices were purchased for the study and the device manufacturer had no role in the study design or statistical analysis. Dr. Heckbert had full access to all the data in the study and takes responsibility for its integrity and the data analysis.

ECG patch monitors

For cardiac rhythm monitoring, we used the Zio Patch XT (iRhythm Technologies, Inc., San Francisco, CA). This device is an FDA-approved single-channel ECG patch monitor with a battery and memory capable of detecting and storing up to 14 days of cardiac rhythm. It does not communicate in real time with anyone; rather, at the end of the recording period, the participant mails the device back to the company, which processes and analyzes the ECG data. Wear time was defined as the interval from activation of the device until removal of the device. Analyzable time was defined as the total time during which the monitor provided a tracing adequate to determine cardiac rhythm. AF was defined as an irregularly irregular rhythm with absent P waves lasting at least 30 s. AF burden was quantified as the proportion of the analyzable time that the rhythm was AF. Isolated supraventricular ectopic beats, isolated ventricular ectopic beats, number of runs of ≥4 supraventricular ectopic beats (supraventricular tachycardia), and number of runs of ≥4 ventricular ectopic beats (ventricular tachycardia) were counted.

Measurement of arrhythmia

The total number of isolated supraventricular ectopic beats during the monitoring period was divided by the total analyzable time, and was expressed as the average rate of supraventricular ectopic beats per hour. The average rate of isolated ventricular ectopic beats was calculated similarly. The total number of runs of supraventricular tachycardia during the monitoring period was divided by the total analyzable time, and was expressed as the average rate of runs of supraventricular tachycardia per 24 h; the average rate of runs of ventricular tachycardia was calculated similarly. The presence of high grade atrioventricular block (2nd degree Mobitz II and 3rd degree block) and pauses of 3 s or longer were also reported.

Assessment of participant characteristics

Participant age and history of past clinically-recognized AF were determined at the date the first ECG monitor was activated. For the present analysis, all other participant characteristics were assessed at the 2010–2012 MESA exam. Treated hypertension was defined as use of an antihypertensive medication in combination with self-report of a physician diagnosis of hypertension. Diabetes was defined by use of a diabetes medication or fasting glucose ≥126 mg/dL.

Statistical analysis

In analyses of the yield of arrhythmia diagnoses for various lengths of monitoring on a single device (Analysis 1), we included all participants with at least one monitoring period with analyzable time of at least 12 days. In analyses that examined the consistency of findings in participants monitored twice (Analysis 2), we limited consideration to participants who wore two devices with analyzable time of at least 2 days on each device and with an interval between monitoring periods