CLINICAL RESEARCH STUDY

THE AMERICAN JOURNAL of MEDICINE®

# Comparison of 24-hour Holter Monitoring with 14-day Novel Adhesive Patch Electrocardiographic Monitoring☆

**Paddy M. Barrett, MB, BCh, BAO,[a] Ravi Komatireddy, MD,[a] Sharon Haaser, RN, BSN, CCRC,[a] Sarah Topol, RN, BSN, BA,[a] Judith Sheard, MPH,[a] Jackie Encinas, MS,[a] Angela J. Fought, MS,[b] Eric J. Topol, MD[a,c]**

*[a]Scripps Translational Science Institute, La Jolla, Calif; [b]Fought Statistical Consulting, Chicago, Ill; [c]Scripps Health, La Jolla, Calif.*

## ABSTRACT

**BACKGROUND:** Cardiac arrhythmias are remarkably common and routinely go undiagnosed because they are often transient and asymptomatic. Effective diagnosis and treatment can substantially reduce the morbidity and mortality associated with cardiac arrhythmias. The Zio Patch (iRhythm Technologies, Inc, San Francisco, Calif) is a novel, single-lead electrocardiographic (ECG), lightweight, Food and Drug Administration–cleared, continuously recording ambulatory adhesive patch monitor suitable for detecting cardiac arrhythmias in patients referred for ambulatory ECG monitoring.

**METHODS:** A total of 146 patients referred for evaluation of cardiac arrhythmia underwent simultaneous ambulatory ECG recording with a conventional 24-hour Holter monitor and a 14-day adhesive patch monitor. The primary outcome of the study was to compare the detection arrhythmia events over total wear time for both devices. Arrhythmia events were defined as detection of any 1 of 6 arrhythmias, including supraventricular tachycardia, atrial fibrillation/flutter, pause greater than 3 seconds, atrioventricular block, ventricular tachycardia, or polymorphic ventricular tachycardia/ventricular fibrillation. McNemar's tests were used to compare the matched pairs of data from the Holter and the adhesive patch monitor.

**RESULTS:** Over the total wear time of both devices, the adhesive patch monitor detected 96 arrhythmia events compared with 61 arrhythmia events by the Holter monitor ($P < .001$).

**CONCLUSIONS:** Over the total wear time of both devices, the adhesive patch monitor detected more events than the Holter monitor. Prolonged duration monitoring for detection of arrhythmia events using single-lead, less-obtrusive, adhesive-patch monitoring platforms could replace conventional Holter monitoring in patients referred for ambulatory ECG monitoring.

 *• The American Journal of Medicine (2014) 127, 95.e11-95.e17*

**KEYWORDS:** Atrial fibrillation; Cardiac arrhythmias; Electrocardiographic; Holter monitor; iRhythm; Zio Patch

Cardiac arrhythmias, such as atrial fibrillation, are often asymptomatic yet are associated with critical adverse outcomes, such as embolic stroke.[1,2] Furthermore, their management is expensive, with atrial fibrillation alone costing approximately $26 billion annually in the United States.[3,4] Ambulatory electrocardiographic (ECG) monitoring is the most widely used method to detect cardiac arrhythmias in the outpatient ambulatory setting. Conventional 24-hour monitoring often fails to detect the culprit arrhythmia in patients with symptomatic arrhythmia.[5] Beyond detection



**Funding:** This study was supported in part by Clinical and Translational Science Award funding to the Scripps Translational Science Institute (National Institutes of Health/National Center for Advancing Translational Sciences UL1 TR000109) and iRhythm Technologies Inc, San Francisco, Calif. ClinicalTrials.gov identifier: NCT01559246.

**Conflict of Interest:** None.

**Authorship:** All authors had access to the data and played a role in writing this manuscript.

Requests for reprints should be addressed to Eric J. Topol, MD, Scripps Translational Science Institute, 3344 North Torrey Pines Court, La Jolla, CA 92037.

E-mail address: etopol@scripps.edu

0002-9343/$ -see front matter 
http://dx.doi.org/10.1016/j.amjmed.2013.10.003

of symptomatic arrhythmia events, there is a growing body of evidence related to the morbidity and mortality associated with subclinical arrhythmias often missed by conventional 24-hour monitoring.[6]

The Holter monitor, first introduced in the late 1940s, remains the most commonly used method for investigating patients in the ambulatory setting with suspected arrhythmias.[7] For the investigation of patients with palpitations, 24-hour Holter monitoring is reported to have a diagnostic yield of 15% to 39%.[8-10] Although extended event recorder monitoring can increase this yield, their cumbersome form factor often limits patient activities. Their utility is further eroded by the fact that approximately 1 in 4 patients are unable to activate their event recorder during a symptomatic period.[8,11] Because many clinically significant arrhythmias are often asymptomatic, their appropriate identification and treatment are critical to reducing mortality and morbidity.

**CLINICAL SIGNIFICANCE**

- Extended iRhythm Zio patch monitoring detected more arrhythmia events than 24-hour Holter monitoring in those referred for ambulatory electrocardiographic monitoring.
- Extending arrhythmia monitoring periods results in a greater number of arrhythmia events to be detected.
- Detection of more arrhythmia events should result in the prompt recognition and treatment of clinically significant arrhythmias.
- The iRhythm Zio patch was tolerated better by patients than the Holter monitor.

The Zio Patch (iRhythm Technologies, Inc, San Francisco, Calif) is a Food and Drug Administration (FDA)–cleared, single-lead, lightweight, 14-day ambulatory ECG adhesive patch monitor (**Figure 1**). The device does not have external leads or wires. Unlike the Holter monitor, its low-profile design and water-resistant properties allow patients to participate in almost all activities of daily living with minimal disruption. It can be mailed directly to the patient and self-applied. Once monitoring is completed, the patch is mailed to a facility that analyzes the recorded data, and a report is made available to the ordering physician.

The Comparison of 24 Hour Holter Monitoring Versus 14 Day Novel Adhesive Patch Electrocardiographic Monitoring study is a prospective analysis of patients referred for evaluation of cardiac arrhythmias by ambulatory ECG monitoring. We aimed to evaluate the diagnostic utility of a novel adhesive patch monitor for up to 14 days compared with standard 24-hour Holter monitoring.

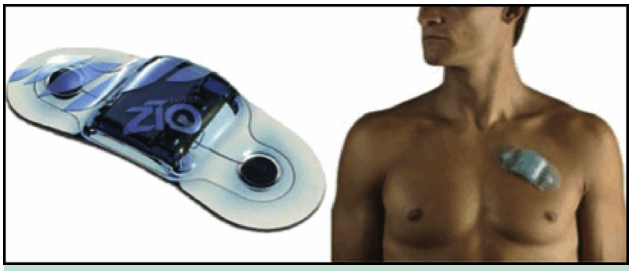


**Figure 1** The Zio Patch (iRhythm Technologies, Inc, San Francisco, Calif) is an FDA-cleared, single-use, noninvasive, water-resistant, 14-day, ambulatory ECG monitoring adhesive patch.

## MATERIALS AND METHODS

### Patient Selection and Data Collection

The Scripps Institutional Review Board approved the protocol, and all patients enrolled gave informed consent to participate. Between April 2012 and July 2012, patients referred to the cardiac investigations laboratory at Scripps Green Hospital (La Jolla, Calif) for ambulatory ECG monitoring were fitted with an adhesive patch monitor and a 24-hour Holter monitor. Both devices were activated simultaneously. Patients were enrolled prospectively in a consecutive fashion on the basis of appropriate eligibility criteria. Inclusion criteria included an age of 18 years or older and being under evaluation for cardiac arrhythmia, capable of providing informed consent, and able to comply with continuous ECG monitoring for up to 14 days. Exclusion criteria were any known skin allergies, conditions, or sensitivities to any of the components of the adhesive patch monitor, receiving or anticipated to receive pacing or external direct current cardioversion during the monitoring period, or the anticipation of being exposed to high-frequency surgical equipment during the monitoring period.

### Devices and Study Protocols

The Zio Patch is an FDA-cleared, single-use, noninvasive, water-resistant, 14-day, ambulatory ECG monitoring adhesive patch. A study coordinator applied the device over the left pectoral region of the patient's chest (**Figure 1**). A trigger button, integrated into the monitor's design, can be activated to create a digital time stamp on the continuously recorded data stream to synchronize the recorded ECG rhythm with symptoms. Patients were instructed to activate the trigger should they experience any suspected symptom of arrhythmia. Patients also were instructed to wear the adhesive patch monitor for as long as possible, with the goal of obtaining up to 14 days of ECG data recording. On day 14 or at any time point prior, the patient removed and returned the adhesive patch monitor by means of a prepaid mail package to iRhythm Technologies, Inc. ECG data were collected and interrogation was performed using the manufacturer's FDA-cleared, proprietary algorithm.