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

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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.

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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 man-

Ambulatory electrocardiographic (ECG) monitoring is the most widely used method to detect cardiac arrhythmias in the outpatient ambulatory setting. Conventional 24-hour

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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.

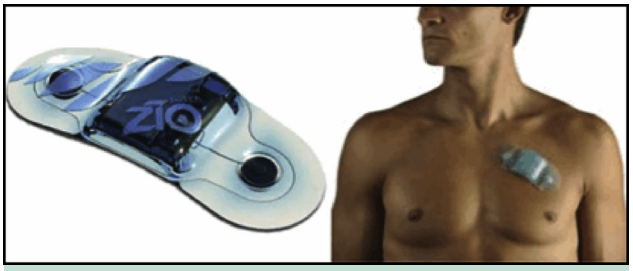

Figure 1 The Zio Patch (iRhythm Technologies, Inc, San Francisco, Calif) is an FDA-cleared, single-use, noninvasive, water-resistant, 14-day, ambulatory ECG monitoring adhesive patch.

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.

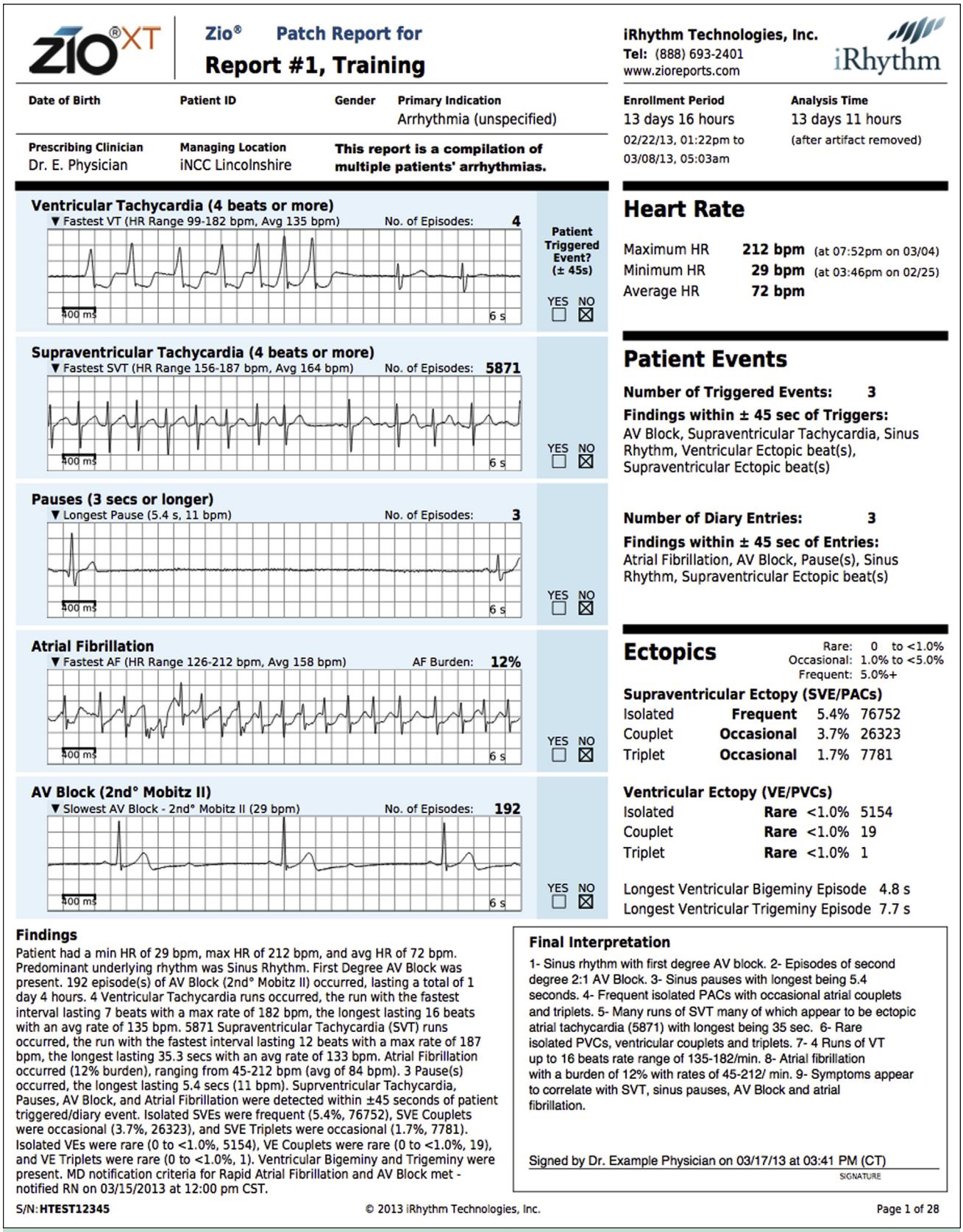

Figure 2 iRhythm Technologies Inc, sample Zio Patch report format.

The data then underwent technical review for report generation and quality assurance (Figure 2). This report was then uploaded to a secure website for independent review by physician investigators at the Scripps Translational Science Institute.

Per standard institutional practice, the Holter monitor was fitted by a cardiac technician and returned at 24 hours to the cardiac investigation laboratory for interrogation. Holter monitor data were independently analyzed by physician investigators at the Scripps Translational Science Institute. Reports from both the adhesive patch monitor and the Holter monitor were made available to the referring physician. Any ECG data that were thought to be of urgent clinical concern from the Holter monitor or adhesive patch monitor, as determined by the physician investigators, were relayed to the referring physician within 24 to 48 hours.

Arrhythmia events were defined as detection of any 1 of 6 arrhythmias, including supraventricular tachycardia (>4 beats, not including atrial fibrillation or flutter), atrial fibrillation/flutter (>4 beats), pause >3 seconds, atrioventricular block (Mobitz type II or third-degree atrioventricular block), ventricular tachycardia (>4 beats), or polymorphic ventricular tachycardia/ventricular fibrillation. Arrhythmias were categorized into 2 groups. The first consisted of all 6 arrhythmias. The second consisted of the 5 most clinically significant arrhythmias, which excluded supraventricular tachycardia.

Sample Size Calculations and Statistics

The primary aim of the study was to compare the detection of arrhythmia events between the adhesive patch monitor and the Holter monitor over the total wear time of both devices. Secondary end points included comparison of detection of arrhythmia events over a simultaneous initial 24-hour period and survey data examining patient preference to both devices. Arrhythmia events were analyzed for 2 arrhythmia groupings including all 6 arrhythmias and the 5 more clinically significant arrhythmias as previously described. McNemar's test was used to compare if any 1 of the 6 arrhythmias or any 1 of 5 more clinically significant arrhythmias were detected by the adhesive patch monitor versus the Holter monitor for (1a) 24 hours for the Holter monitor and up to 14 days for adhesive patch monitor and then for (1b) the first 24 hours of observation for both devices. Descriptive statistics were provided for age, total wear time, and survey results.

A sample size of at least 120 after attrition achieves 80% power for a 2-tailed McNemar's test. Because a planned interim analysis was performed for (1a) when 50% of patients were enrolled, the alpha for the interim analysis was 0.005 and an alpha of 0.048 was used for the final analysis. The interim analysis requirement was met ($P < .001$), and the study was completed.

The study was designed and data were collected by the Scripps Translational Science Institute. Fought Statistical Consulting (Chicago, Ill) independently analyzed the data. SAS 9.3 (SAS Institute Inc, Cary, NC) was used to perform the statistical analyses.

RESULTS

Of the 238 patients screened, 88 declined enrollment. A total of 150 patients were enrolled, and 4 were lost to follow-up, 3 in the adhesive monitoring patch group and 1 in the Holter monitoring group. A total of 146 patients with data on both the 24-hour Holter monitor and the adhesive patch monitor were included in the final analysis. The median age for patients enrolled was 64 years (range, 22-94 years), and 41.8% of patients were male. The median wear time in days for the Holter monitor and adhesive patch monitor was 1.0 (range, 0.9-1.0) and 11.1 (range, 0.9-14.0), respectively.

Of the patients with complete survey data, 93.7% (134/143) found the adhesive monitoring patch comfortable to wear as opposed to 51.7% (74/143) for the Holter monitor. The adhesive patch monitor affected 10.5% (15/143) of patients' activities of daily living as opposed to 76.2% (109/143) of patients in the Holter group. When asked whether they would prefer to wear the adhesive patch monitor or the Holter monitor, 81% (111/137) chose the adhesive patch monitor. Of the 102 physicians surveyed, 90% (92/102) thought a definitive diagnosis was achieved using data from the adhesive patch monitor, as opposed to 64% (65/102) using data from the Holter monitor.

Device Performance Over Total Wear Time

When device data were compared over the total wear time, the adhesive patch monitor detected significantly more events than the Holter monitor. For all 6 arrhythmias, the Holter monitor detected 61 arrhythmia events compared with 96 arrhythmia events by the adhesive patch monitor ($P < .001$) (Table 1). Of these events, 60 were detected by both the Holter monitor and the adhesive patch monitor. The adhesive patch monitor detected 36 events that went undetected by the Holter monitor primarily as a function of prolonged monitoring (Table 1). There was only 1 instance when the Holter monitor detected at least 1 event and the adhesive patch monitor did not.

Because the substantially increased performance of the adhesive patch monitor may be a function of detecting less clinically meaningful supraventricular tachycardias over an extended monitoring period, supraventricular tachycardia

Table 1 Total Wear Time for Both Devices (Holter 24 Hours, Zio Patch [iRhythm Technologies, Inc, San Francisco, Calif] Up to 14 Days)

		Holter Any 6 (24 h)	
		No	At least 1
Patch any 6 (total wear time)	No	49	1
	Yes	36	60

Any arrhythmias (of the 6 types → atrioventricular block, pause, polymorphic ventricular tachycardia, supraventricular tachycardia, ventricular tachycardia, or atrial fibrillation) (McNemar's $P < .001$).

Table 2 Total Wear Time for Both Devices

		Holter Any 5 (24 h)	
		No	At least 1
Patch any 5 (total wear time)	No	105	0
	Yes	14	27

Any of the 5 clinically relevant arrhythmias (atrioventricular block, pause, polymorphic ventricular tachycardia, supraventricular tachycardia, ventricular tachycardia, or atrial fibrillation) (McNemar's $P < .001$).

events were removed from the total wear time analysis. The total number of arrhythmia events detected diminished for both devices, but the adhesive patch monitor still detected significantly more arrhythmia events than the Holter monitor, 41 and 27, respectively ($P < .001$). Of these events, 27 were detected by both the Holter monitor and the adhesive patch monitor. Of note, 14 clinically significant arrhythmia events were detected by the adhesive patch monitor but went undetected by the Holter monitor (Table 2). Over the total wear time of both devices, the adhesive patch monitor detected significantly more arrhythmia events when both arrhythmia groups were assessed.

Device Performance Over Simultaneous Initial 24-hour Monitoring Period

As a secondary outcome measure, the adhesive patch monitor was compared with the Holter monitor for detection of arrhythmia events over a simultaneous 24-hour period. In this period, the Holter monitor detected significantly more of the 6 types of arrhythmia events than the adhesive patch monitor. The Holter monitor detected 61 arrhythmia events compared with 52 arrhythmia events by the adhesive patch monitor ($P = .013$) (Table 3). Of these events, 50 were detected by both the Holter monitor and the adhesive patch monitor. Of the arrhythmia events detected by 1 device but not the other, the Holter monitor detected 11 arrhythmia events that were undetected by the adhesive patch monitor in the simultaneous 24-hour period and the adhesive patch monitor detected 2 arrhythmia events that were undetected by the Holter monitor. Of the 11 events undetected by the adhesive patch monitor in the first 24 hours, 10 arrhythmia events were subsequently detected by the adhesive patch monitor beyond 24 hours. Of these 11 events, 8 were the same arrhythmia type as initially detected by the Holter monitor, with 7 being supraventricular tachycardias and 1 being short runs of ventricular tachycardia. Of the 3 arrhythmia events that were different, 2 were episodes of supraventricular tachycardia initially detected by the Holter monitor, but the adhesive monitoring patch detected paroxysmal atrial fibrillation at greater than 24 hours. The other was a single episode of supraventricular tachycardia detected by the Holter monitor and with no arrhythmia events detected by the adhesive patch monitor beyond 24 hours.

Because supraventricular tachycardia is often of lesser clinical consequence, the analysis was repeated over the same initial 24-hour period excluding supraventricular tachycardias and including only the more clinically significant arrhythmias of atrial fibrillation/flutter (>4 beats), pause >3 seconds, atrioventricular block (Mobitz type II or third-degree atrioventricular block), ventricular tachycardia (>4 beats), and polymorphic ventricular tachycardia/ventricular fibrillation. Again, the Holter monitor detected more events than the adhesive patch monitor, 27 and 24, respectively, but this did not reach statistical significance ($P = .083$). Of these events, 24 were detected by both the Holter monitor and the adhesive patch monitor (Table 4).

Three clinically more significant arrhythmia events were detected by the Holter monitor and not by the adhesive patch monitor, whereas the adhesive patch monitor did not detect any events that also were not detected by the Holter monitor.

The benefit of prolonged monitoring is demonstrated by the fact that of the 3 clinically significant arrhythmia events initially undetected by the adhesive patch monitor in the first day of monitoring, all 3 were subsequently detected with extended monitoring beyond 24 hours, 2 of which were short runs of atrial fibrillation and the other a single short run of ventricular tachycardia. Although the Holter monitor detected significantly more events than the adhesive patch monitor over the initial 24-hour monitoring period, when limited to more clinically significant events, 3 events went undetected but were subsequently detected with monitoring beyond 24 hours.

DISCUSSION

The Zio Patch is an FDA-cleared, noninvasive continuous ambulatory ECG adhesive monitoring patch that is less cumbersome to wear than a conventional 24-hour Holter monitor. With 93.7% of patients finding the adhesive patch monitor comfortable to wear and 81% indicating they would prefer it over the Holter monitor, it is clearly a less-obtrusive and more patient-friendly monitoring platform.

Table 3 Twenty-four—hour Wear Time for Both Devices

		Holter Any 6 (24 h)	
		No	At least 1
Patch any 6 (24 h)	No	83	11
	Yes	2	50

Any arrhythmias (of the 6 types → atrioventricular block, pause, polymorphic ventricular tachycardia, supraventricular tachycardia, ventricular tachycardia, or atrial fibrillation) (McNemar's $P = .013$).

Table 4 Twenty-four—hour Wear Time for Both Devices

		Holter Any 5 (24 h)	
		No	At least 1
Patch any 5 (24 h)	No	119	3
	Yes	0	24

Any of the 5 clinically relevant arrhythmias (atrioventricular block, pause, polymorphic ventricular tachycardia, supraventricular tachycardia, ventricular tachycardia, or atrial fibrillation) (McNemar's $P = .083$).

Furthermore, physicians thought a definitive diagnosis was achieved more often using the adhesive patch monitor as opposed to the Holter monitor. The convenience of sending and returning the adhesive patch by mail and the durable capture of ECG rhythm data over the substantially longer monitoring period of up to 14 days offer some distinct theoretic advantages. However, the reference standard is the 3-lead, 24-hour Holter monitor, and the value of a single-lead, 14-day adhesive patch monitor needs to be assessed in comparison with this standard. Our study demonstrated increased arrhythmia diagnostic yield using the prolonged adhesive patch monitor compared with conventional 24-hour Holter monitoring.

Although short of the approved 14-day wear time, the median adhesive patch monitor wear time of 11.1 days in this study is likely a sufficient diagnostic window to capture arrhythmia events, because the highest diagnostic yield for arrhythmia detection is usually the first 7 days of ambulatory ECG monitoring.[12] Ambulatory ECG monitoring beyond 7 days often provides only an additional 3.9% of patients with a diagnosis.[12] Furthermore, the cost of extended monitoring periods beyond 2 weeks using older technologic platforms can range up to $5832 per new diagnosis with a disappointing 0.01 diagnosis per patient per week after 2 weeks. This compares with a per patient diagnosis cost of $98 over an initial 7 days and $576 over a 14-day period, again based on older, often more expensive platforms.[12] An average wear time of 11.1 days is then likely to achieve a reasonable balance of adequate diagnostic yield at a reasonable cost per new diagnosis using newer, potentially cheaper technology. Furthermore, the adhesive patch monitor can achieve monitoring periods equal to older event recorder platforms but using less cumbersome technology.

Consistent with our findings, there is substantial evidence to suggest that extending the ECG monitoring period beyond 24 hours increases the diagnostic yield of arrhythmia diagnosis. To date, however, this could only be achieved using bulky, activity-limiting technology requiring multiple chest leads.[13] Although previous studies have demonstrated the incremental diagnostic yield of prolonging the monitoring period, in this study the extended monitoring was achieved with a more lightweight, unobtrusive, adhesive, patch device.[14-16] Primarily as a function of extended monitoring, the adhesive patch monitor detected 36 events that went undetected by the Holter monitor. Using the incremental diagnostic yield of an extended monitoring period as opposed to relying on data acquisition during brief, often asymptomatic periods is critical, because even prolonged pauses of up to 9.7 seconds can be asymptomatic.[17]

Over a simultaneous 24-hour monitoring period, the Holter monitor detected more arrhythmia events than the adhesive patch monitor for both groups of arrhythmias used in this study. The Holter monitor's performance advantage in this timeframe, with detection of 11 arrhythmia events not detected by the adhesive patch monitor, was unexpected and warranted explanation. A root cause analysis was performed to determine the reason for these discrepancies, and each of these cases was then run for a second time through the iRhythm Technologies algorithm and Quality Assurance Tool and reviewed in the page view format, which allowed full visual review of the continuously running ECG data. Of the 11 discrepant arrhythmia events, 2 can be explained by an algorithm misclassification and 7 by a processing error by the initial iRhythm Technologies Inc, physician reviewer. With respect to the algorithm misclassifications, in one instance the algorithm did not detect the arrhythmia event possibly because of transiently reduced signal quality and in the other instance classified a brief run of supraventricular tachycardia as a sinus tachycardia, because it fell into a rate range just outside of the set supraventricular tachycardia zone. In light of this, the adhesive patch monitor supraventricular tachycardia zones have been adjusted. As part of the report generation, an iRhythm physician performs an initial overview of all detected potential arrhythmia events and classifies them accordingly. In 7 of the discrepant arrhythmia event cases, short runs of mostly supraventricular tachycardia were not classified as such and therefore were never surfaced to the report viewed by the ordering physicians or investigators. In-house iRhythm staff training has been implemented to correct this issue.

In general, the information provided by the Holter monitors additional 2 ECG leads are an obvious advantage for both automatic algorithm analysis and physician interpretation. Specifically, 3-lead recordings allow for the detection of arrhythmia events characterized by a shift in electrical axis that can be missed by single-lead recordings. Multi-lead recordings also allow for improved detection of aberrant/broader QRS complexes where a single-lead recording may not detect the altered QRS complex width because the leading edge or trailing edge of the QRS complex may be relatively isoelectric to the single-lead recording vector.

These differences may then apply more so to broad complex tachycardia arrhythmia detection rather than narrow complex arrhythmia detection. Evidence from our study supports this, with no episode of atrial fibrillation/flutter detected by the Holter monitor going undetected by the adhesive.

Of the more clinically meaningful arrhythmia events initially undetected by the adhesive patch monitor, in the simultaneous 24-hour monitoring period, all subsequently had a clinically meaningful arrhythmia event detected with prolonged monitoring by the adhesive patch monitor. These arrhythmia events were the same in all 3 cases, with 2 episodes of paroxysmal atrial fibrillation and 1 episode of a brief run of ventricular tachycardia being detected with extended monitoring by the adhesive patch monitor.

Study Limitations

The patients enrolled included all those referred for ambulatory ECG monitoring rather than for determination of a

previously undocumented arrhythmia. Although the majority had no previously documented arrhythmia, several had preexisting arrhythmias and were referred for reasons other than symptomatic arrhythmia. In practice, the adhesive patch monitor is mailed to and self-applied by the patient, whereas in this study it was applied by a study research coordinator.

CONCLUSIONS

Over the total wear time of both devices, the adhesive monitoring patch detects significantly more arrhythmia events than the Holter monitor. On the basis of these findings, novel, single-lead, prolonged-duration, low-profile devices may soon replace conventional Holter monitoring platforms for the detection of arrhythmia events in patients referred for ambulatory ECG monitoring.

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