Diagnostic Utility of a Novel Leadless Arrhythmia Monitoring Device

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Although extending the duration of ambulatory electrocardiographic monitoring beyond 24 to 48 hours can improve the detection of arrhythmias, lead-based (Holter) monitors might be limited by patient compliance and other factors. We, therefore, evaluated compliance, analyzable signal time, interval to arrhythmia detection, and diagnostic yield of the Zio Patch, a novel leadless, electrocardiographic monitoring device in 26,751 consecutive patients. The mean wear time was 7.6 ± 3.6 days, and the median analyzable time was 99% of the total wear time. Among the patients with detected arrhythmias (60.3% of all patients), 29.9% had their first arrhythmia and 51.1% had their first symptom-triggered arrhythmia occur after the initial 48-hour period. Compared with the first 48 hours of monitoring, the overall diagnostic yield was greater when data from the entire Zio Patch wear duration were included for any arrhythmia (62.2% vs 43.9%, p <0.0001) and for any symptomatic arrhythmia (9.7% vs 4.4%, p <0.0001). For paroxysmal atrial fibrillation (AF), the mean interval to the first detection of AF was inversely proportional to the total AF burden, with an increasing proportion occurring after 48 hours (11.2%, 10.5%, 20.8%, and 38.0% for an AF burden of 51% to 75%, 26% to 50%, 1% to 25%, and <1%, respectively). In conclusion, extended monitoring with the Zio Patch for ≤14 days is feasible, with high patient compliance, a high analyzable signal time, and an incremental diagnostic yield beyond 48 hours for all arrhythmia types. These findings could have significant implications for device selection, monitoring duration, and care pathways for arrhythmia evaluation and AF surveillance.

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Ambulatory electrocardiography is a widely used diagnostic tool to detect arrhythmias for a variety of symptoms and conditions.[1−3] Because of memory and technical limitations, ambulatory electrocardiographic (ECG) monitors have historically provided either short-term (24 to 48 hour) continuous monitoring (Holter) or longer term intermittent (triggered) monitoring (event or loop recorder).[3,4] Continuous ECG monitoring longer than the traditional 24- to 48-hour duration might improve the diagnostic yield of infrequent arrhythmias. However, such technologies have generally been limited by patient compliance, the analyzable wear time, and electrode skin irritation.[3−9] We, therefore, investigated the patient compliance, device analyzable time, and diagnostic yield of a novel, leadless, wearable monitor for extended ambulatory ECG monitoring.

Methods

We performed a cross-sectional study of patients receiving a single-use, long-term, continuous, cardiac monitoring patch for clinical indications. The Zio Patch monitor (iRhythm Technologies, San Francisco, California) is a compact (123 × 53 × 10.7 mm), lightweight (34 g), and water-resistant, cutaneous single-lead ECG monitor that provides ≤14 days of continuous ECG data obtained from a single vector. The single-use device is placed over the patient's left pectoral region with skin adhesive and is typically applied by trained technicians at the ordering ambulatory clinic. A button can be pressed by the patient to annotate symptoms (Figure 1). After completion of the monitoring period, the patient mails the device and diary to the data processing center, where the data are analyzed, and a report is generated and sent to the ordering physician.

We obtained de-identified data from the device manufacturer and servicer (iRhythm Technologies) for all patients who had completed Zio Patch monitoring for clinical indications from January 1, 2011 to December 31, 2011. These data were transferred to us after removal of all patient-, physician-, and site-level identifiers. We included all Zio Patch data from consecutive patients receiving first-time patches at the enrolling site. We excluded data for repeated or subsequent Zio Patch monitoring to minimize confounding by indication. A local institutional review board and the Veterans Affairs Palo Alto Health Care System

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See page 524 for disclosure information.

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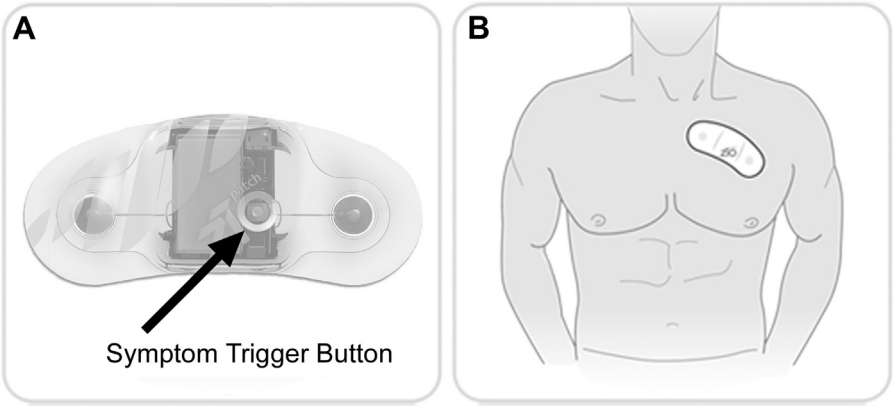

Figure 1. Zio Patch button and placement. *(A)* Patients can press a button on the Zio Patch to mark a symptomatic episode. *(B)* The device is placed over the patient's left pectoral region. (Images courtesy of iRhythm Technologies, Inc., San Francisco, California.)

Table 1
Provider-reported clinical indications

Variable	Patients (n)
Palpitations	10,786 (40.3)
AF	6,493 (24.3)
Syncope or presyncope	4,029 (15.1)
Bradycardia	964 (3.6)
SVT	570 (2.1)
Unspecified tachycardia	547 (2.1)
VT	187 (0.7)
Pause	48 (0.2)
AV block*	44 (0.2)
Polymorphic VT, torsade de pointes, VF	6 (0.0)
Other indications†	3,557 (13.4)

Data in parentheses are percentages.

Clinical indications for ambulatory electrocardiography monitoring were ascertained from a free-text variable provided by the ordering provider; patients could have >1 clinical indication for cardiac monitoring.

AV = atrioventricular; VF = ventricular fibrillation.

* Second-degree Mobitz II or third-degree AV block.

† Providers reported unspecified arrhythmias, nonarrhythmic cardiovascular indications, or no indication, exclusive of indications listed.

Table 2
Detected arrhythmias

Variable	Patients (n)	All Patients With Arrhythmia (%)	Women (%)
Detected arrhythmias (excluding chronic AF)	16,142 (60.3)	100.0	52.0
Single arrhythmias (excluding chronic AF)	12,298 (46.0)	76.2	56.5
Multiple arrhythmias (excluding chronic AF)	3,083 (11.5)	19.1	39.7
Chronic AF	2,003 (7.5)	—	39.4
No other arrhythmias	1,242 (4.6)	—	45.2
≥1 Other arrhythmias	761 (2.8)	4.7	30.0
No arrhythmia	10,609 (39.7)	—	58.3

Data in parentheses are percentages.

Arrhythmias, excluding chronic AF, were detected in 60.3% of patients; men were more likely than women to have chronic AF, ≥1 arrhythmias in addition to chronic AF, or multiple arrhythmias (excluding chronic AF).

research and development committee approved the present study.

The clinical indication for monitoring was ascertained from a free-text variable that was entered by the ordering provider. Trained research staff aggregated the indications into 11 categories: palpitations, AF, syncope or presyncope, bradycardia, supraventricular tachycardia (SVT), unspecified tachycardia, ventricular tachycardia (VT), pause, second degree Mobitz II or third degree (complete) atrioventricular block, polymorphic VT (including torsade de pointes and ventricular fibrillation), and other indications. If a patient had >1 clinical indication, all indications were retained for analysis.

Arrhythmia adjudication was performed and coded using a 2-step process. First, the servicer applied a digital signal processing algorithm to continuously recorded ECG data to identify potential arrhythmia episodes. The algorithm, cleared using the 510(k) method by the Food and Drug Administration for clinical use, detects potential arrhythmias by detection of the heart rate, irregularity, and morphology. The algorithm then uses the heart rate increase from the preceding portion of heart rate regularity (sinus rhythm) to confirm a candidate episode. Next, trained and certified cardiovascular technicians employed by the servicer re-examined the detected arrhythmia episodes to confirm the diagnoses and to classify the arrhythmia where appropriate. Because the algorithm assigns an arrhythmia classification to every portion of the continuous recording, a second detected rhythm (including artifact) occurring in the middle of an arrhythmia event can cause the event to be classified as multiple discrete episodes. These episodes are reclassified on review by technicians to a single arrhythmia event, when appropriate. Arrhythmia adjudication was performed for clinical findings by technicians with no knowledge of the present study.

The episodes were classified into 3 categories according to the type of arrhythmia: first occurrence, first symptomatic occurrence (if occurring 45 seconds before or after patient triggering), and longest duration. The arrhythmias were classified into the following independent, but not mutually exclusive, categories: atrial fibrillation (AF), pause >3 seconds, second-degree Mobitz II or complete atrioventricular

Table 3
Prevalence of detected arrhythmias

Variable	All Patients (%)	All Patients With Arrhythmia (%)	Women (%)	Time to First Arrhythmia			Time to First Symptomatic Arrhythmia		
				Mean ± SD (days)	Median (IQR)	Occurring After 48 hrs (%)	Mean ± SD (days)	Median (IQR)	Occurring After 48 hrs (%)
Any arrhythmia	60.3	100.0	52.0	1.7 ± 2.2	0.8 (0.2–2.4)	29.9	3.0 ± 2.9	2.1 (0.8–4.4)	51.1
Atrial fibrillation burden (%)	17.3	28.7	41.0	1.4 ± 2.1	0.4 (0.1–1.8)	23.4	2.7 ± 2.8	1.8 (0.6–4.0)	47.2
<1	2.9	4.8	46.2	2.2 ± 2.7	1.2 (0.3–3.3)	38.0	3.8 ± 3.6	2.7 (0.9–5.7)	57.4
1–25	4.8	7.9	41.1	1.2 ± 1.8	0.4 (0.1–1.5)	20.8	3.2 ± 2.9	2.3 (0.9–4.7)	56.5
26–50	1.3	2.1	40.4	0.7 ± 1.3	0.1 (0–0.6)	10.5	2.6 ± 2.8	1.5 (0.4–3.9)	40.4
51–75	0.6	1.0	35.4	0.6 ± 1.2	<0.1 (0–0.6)	11.2	2.2 ± 2.2	1.6 (0.6–3.3)	39.3
76–99	0.3	0.4	43.0	0.2 ± 0.4	<0.1 (0–0.3)	1.4	1.8 ± 2.9	0.7 (0.2–1.7)	23.1
100 (chronic AF)	7.5	—	39.4	—	—	—	—	—	—
Pause >3 s	3.7	6.1	38.9	2.8 ± 2.9	1.7 (0.6–4.0)	46.6	3.0 ± 3.1	1.8 (0.8–5.1)	42.9
Mobitz II or complete AV block	1.4	2.3	37.3	2.2 ± 2.9	1.0 (0.3–2.7)	34.1	2.3 ± 2.8	1.0 (0.6–3.1)	36.6
SVT (beats)									
≥4	45.9	76.1	56.1	1.9 ± 2.3	1.0 (0.3–2.6)	32.3	3.4 ± 3.0	2.5 (1.1–5.1)	59.1
≥8	30.8	51.1	57.1	1.4 ± 1.9	0.6 (0.2–1.8)	23.3	3.3 ± 2.9	2.3 (1.0–4.9)	58.0
VT (beats)									
≥4	12.3	20.4	36.1	3.4 ± 3.2	2.6 (0.9–5.2)	58.3	3.7 ± 3.1	3.0 (1.1–5.6)	63.3
≥8	4.7	7.8	34.7	3.0 ± 3.0	2.1 (0.5–4.6)	51.2	3.6 ± 3.2	2.7 (1.0–5.6)	61.0

Excluding chronic AF, the mean time to first arrhythmia and first symptom-triggered arrhythmia was 1.7 ± 2.2 days and 3.0 ± 2.9 days, respectively; the median time to first arrhythmia and first symptom-triggered arrhythmia was 0.8 day (IQR 0.2–2.4) and 2.1 days (IQR 0.8–4.4), respectively; 29.9% of first arrhythmias and 51.1% of first symptom-triggered arrhythmias occurred >48 hours after the start of monitoring; patients with a low AF burden had a longer time to detection; 27.4% of patients with an AF burden ≤25% had their first AF episode beyond 48 hours, and 56.8% of patients with an AF burden of ≤25% had their first symptomatic AF episode beyond 48 hours.

AV = atrioventricular; IQR = interquartile range.

block, SVT, VT, and symptomatic bradycardia. The AF burden was further calculated as the percentage of analyzable time. We segmented the AF burden into the following categories of paroxysmal AF (<1%, 1% to 25%, 26% to 50%, 51% to 75%, and 76% to 99%) and chronic AF (100%). For analytical purposes, we did not count chronic AF as an arrhythmia event or toward the diagnostic yield. This method has been shown to have excellent agreement with simultaneously acquired Holter recordings for the detection of AF ($\kappa = 1.0$) and quantification of AF burden ($r = 0.96$).[10]

The total wear time was calculated from the point of activation to the point of the last recorded analyzable signal. Wear time end points of 2, ≥6, and ≥13 days were used to mark the comparison points of the typical 48 hours (Holter), 1 week, and 2 weeks of ECG monitoring. The device analyzable time fraction was defined as the proportion of the total wear time that the ECG signal is interpretable (sufficiently free of noise) by the arrhythmia detection algorithm.

Descriptive statistics were performed using STATA, version 11 (StataCorp, College Station, Texas) for analysis. Continuous variables and proportions were compared using the *t* test and chi-square test, respectively, and $p < 0.05$ was considered significant. All analyses were performed by 2 of us (D.D.H., M.P.T.) and were independently verified and reproduced by a second statistician (X.X.).

Results

Of the 28,038 consecutive Zio Patch studies from January 2011 to December 2011, we included 26,751 first-time studies (95.4%) of unique patients and excluded 1,287 repeat studies from the present analysis.

The mean age was 60.2 ± 18.7 years, and 54.5% of the patients were women. The mean wear time was 7.6 ± 3.6 days. The median wear time was 7.0 days (25th to 75th percentile interquartile range 5.9 to 9.3); 95.9% wore the device >48 hours, 74.3% wore the device ≥6 days, and 16.1% wore the device ≥13 days. The median analyzable time, expressed as a percentage of the total wear time, was 99% (interquartile range 94% to 99%); 87.1% of the patients had an analyzable time the equivalent of ≥22 hr/day. No significant difference was found in age or wear time between the genders.

The provider-reported clinical indications are listed in Table 1; the most prevalent indications were palpitations, atrial fibrillation, and syncope or presyncope.

The overall prevalence of single and multiple arrhythmias is listed in Table 2. Arrhythmias, not counting chronic AF, were detected in 16,142 patients (60.3%). Of all the patients, 12,298 (46.0%) had a single arrhythmia and 3,083 (11.5%) had multiple arrhythmias (not including chronic AF). Chronic AF was present in 2,003 patients (7.5%), and 761 of these patients (2.8%) had other arrhythmias, in addition to chronic AF.

The distribution and time to the detection of each category of asymptomatic arrhythmias are listed in Table 3. Overall, the mean and median time to the first arrhythmia was 1.7 ± 2.2 days and 0.8 day (interquartile range 0.2 to 2.4), and the mean and median time to the first symptom-triggered arrhythmia was 3.0 ± 2.9 days and 2.1 days (interquartile range 0.8 to 4.4), respectively. Among the patients with arrhythmias, the most common was SVT.

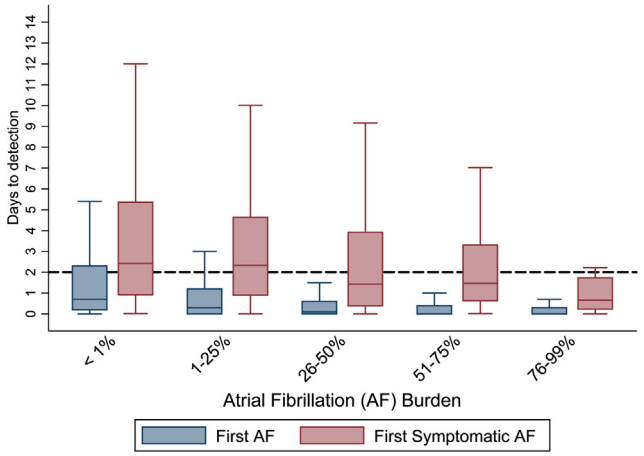

Figure 2. Time to first AF and first symptomatic AF stratified by AF burden. The *bottom*, *middle*, and *top lines* of each box correspond to the 25th, 50th (median), and 75th percentile, respectively. The *whisker caps* mark 1.5 times the interquartile range below the 25th percentile and 1.5 times the interquartile range above the 75th percentile. For all nonchronic AF, the time to first detection was 2.7 ± 2.8 days. The smaller the AF burden, the longer the mean time to first detection. The mean time to the first diagnosis of AF ranged from 0.2 ± 0.4 day for an AF burden of 76% to 99% (1.4% after 48 hours) to 2.2 ± 2.7 days for an AF burden <1% (38.0% after 48 hours). Likewise, a longer time to the first symptomatic episode of AF was associated with a decreased AF burden. The mean time to the first diagnosis of symptomatic AF ranged from 1.8 ± 2.9 days for an AF burden of 76% to 99% (23.1% after 48 hours) to 3.8 ± 3.6 days for an AF burden <1% (57.4% after 48 hours).

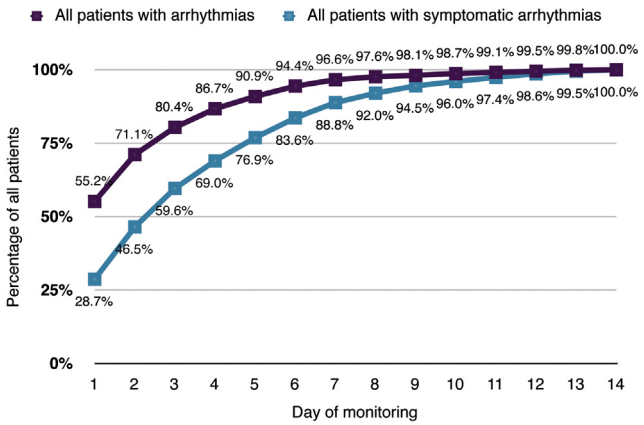

Figure 3. Cumulative yield of arrhythmia detection over time. Among patients with arrhythmias, regardless of symptoms, 90% had arrhythmia identified by the fifth day of monitoring; only 71% did so in the first 2 days of monitoring. The trends were similar for symptom-triggered arrhythmias, with a 90% yield by 8 days of monitoring.

The distribution of the time to the first arrhythmia and first symptom-triggered arrhythmia is listed in Table 3. Overall, the variation in the time to the first event for all arrhythmias types was wide. Among the patients with arrhythmias, 29.9% had their first arrhythmia occur >48 hours from the start of monitoring. Among the patients with symptom-triggered arrhythmias (Table 3), 51.1% occurred >48 hours from the start of monitoring (Table 3). The diagnostic yield of pauses, Mobitz II or complete atrioventricular block, SVT, and VT all improved with extended monitoring (Table 3).

Excluding chronic AF, the time to the detection of the first AF was 2.7 ± 2.8 days. The time to AF detection was inversely proportional to the total AF burden. As the burden of AF decreased, the mean time to the first detection increased, with an increasing proportion occurring after 48 hours, ranging from 0.2 ± 0.4 days for an AF burden of 76% to 99% (1.4% after 48 hours) to 2.2 ± 2.7 days for an AF burden <1% (38.0% after 48 hours; Figure 2). The findings were similar for the time to the first symptom-triggered AF episode.

Figure 3 illustrates the cumulative yield of arrhythmias over time. Among patients with arrhythmias, regardless of symptoms, only 71.1% had arrhythmias identified in the first 2 days of monitoring (Figure 3). By the fifth day of monitoring, 90% of all patients with arrhythmias through the end of monitoring were identified. Among the patients with symptomatic arrhythmias, 92% of patients with arrhythmias through the end of follow-up were detected by the eighth day compared with only 46.5% in the first 2 days (Figure 3). Because patients might discontinue monitoring after the first symptomatic arrhythmia, we also evaluated the subgroup of patients who wore the patch for ≥13 days. In this subgroup, 12 days of monitoring were required to capture 90% of all patients with arrhythmias.

Discussion

In the present study of 26,751 patients with first-time, patch-based (leadless) ambulatory ECG monitoring for clinical indications, we found high patient compliance (wear time), a high analyzable time, and a large portion of arrhythmias identified beyond the first 48 hours of monitoring. These findings were consistent across all arrhythmia types and among the subset of symptom-triggered arrhythmias. These findings indicate that extended monitoring with the Zio Patch is feasible and identifies arrhythmias that could be missed with traditional 48-hour monitoring.

The relatively high wear time and analyzable time of the Zio Patch might have resulted from the practical benefits of patch-based monitoring compared with the traditional design of the "Holter" style monitors, with detachable leads, removable skin electrodes, and a recording unit. Previous studies have reported substantially reduced compliance with lead-based extended monitoring (Holter, event monitors, and mobile cardiac outpatient telemetry devices) because of the high rates of skin irritation, difficulty of use, and disruption to the patient's work, travel, or lifestyle.[5,11–13] Wired monitors with temporary electrodes are also susceptible to motion artifact, which can limit the interpretability during exercise and must be removed before showering or contact with water. In the present study, although 74% wore the device for ≥6 days, 16% wore the device for the maximum duration (>13 days). The reasons for this were multifactorial, including a shift in the manufacturer's recommendations from 7 days of monitoring to 14 days during the study period and variations in provider preferences or instructions. The mean wear time increased from 7 to 9 days during the study period. The Zio Patch's small size, absence of wired leads, and water resistance could have contributed to the patient compliance and signal quality.

For all arrhythmia types, the diagnostic yield increased with monitoring beyond 48 hours. Among patients with paroxysmal AF, the time to the detection of the first AF episode increased as the total AF burden decreased. Our findings are consistent with those from a small, single-center study of patients with known AF who concurrently wore Zio Patches and 24-hour Holter monitors.[10] They found that compared with 24-hour Holter monitoring, AF events were identified in 18 of 70 subjects after Zio Patch monitoring; 21 patients had a change in clinical management because of reclassification by the Zio results. Therefore, these findings could have significant implications for minimizing repeat testing, assessing treatment response, and expediting appropriate therapy, such as anticoagulation.

Previous studies have also shown that continuous monitoring with implantable loop recorders increase the diagnostic yield for AF recurrence after catheter ablation, cardioversion, or initiation of antiarrhythmic drug therapy.[14,15] However, our data have indicated that $\leq$14 days of monitoring can substantially improve AF detection in paroxysmal AF, even when the observed AF burden was $<$15%. Therefore, cutaneous patch-based monitoring should be investigated further as a potential alternative before implantation of an implantable loop recorder or mobile cardiac outpatient telemetry, particularly if real-time transmission, which is not available with the Zio Patch, is not required.

Our study had several limitations. First, our retrospective study of patients who received a Zio Patch for clinical indications might not reflect the epidemiology of all patients presenting for ECG monitoring, because clinical suspicion of arrhythmia frequency could have informed the device selection at certain sites. Second, arrhythmia episodes of relatively short duration were included in our SVT and VT categorizations. It is possible that the identification of some of these episodes, even if detected with extended monitoring, might not be clinically important. However, the findings for symptom-triggered arrhythmias of short duration were significant and consistent with the overall results. Finally, although previous studies have shown excellent agreement between simultaneous Zio and Holter recordings for AF,[10] differences in signal processing and detection algorithms could have led to variation in the agreement of arrhythmia detection and classification across the Zio Patch and other monitoring devices, although the variation would be expected to be low.

Disclosures

Dr. Kumar is the founder and former chief medical officer of iRhythm Technologies, Inc. (San Francisco) and retains a significant equity share in the company. The remaining authors have no conflicts of interest to disclose.

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