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EP & Arrhythmia

Comparison of Arrhythmia Detection by 24-Hour Holter and 14-Day Continuous Electrocardiography Patch Monitoring

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Background: Although 24-hour Holter monitoring is routinely used for patients with suspected paroxysmal arrhythmia, its sensitivity in detecting such arrhythmias is insufficient.

Methods: We compared a 14-day electrocardiography (ECG) monitor patch — a single-use, noninvasive, waterproof, continuous monitoring patch — with a 24-hour Holter monitor in 32 consecutive patients with suspected arrhythmia.

Results: The 14-day ECG patch was well tolerated, and its rates of detection of relevant arrhythmias on days 1, 3, 7, and 14 were 13%, 28%, 47%, and 66%, respectively. The detection rate of paroxysmal arrhythmias was significantly higher for the 14-day ECG patch than for the 24-hour Holter monitor (66% vs. 9%, $p < 0.001$). Among the 32 patients, 202 atrial fibrillation or atrial flutter episodes were detected in 6 patients (22%) with the 14-day ECG patch; however, only 1 atrial fibrillation episode was detected in a patient (3%, $p < 0.05$) with the 24-hour Holter monitor. Other clinically relevant arrhythmias recorded on the 14-day ECG patch included 21 (65.5%) episodes of supraventricular tachycardia, 2 (6.3%) long pause, and 2 (6.3%) ventricular arrhythmias. The mean dermal response score immediately after removal of the 14-day ECG patch from the patients was 0.64, which indicated minimal erythema.

Conclusions: The 14-day ECG patch was well tolerated and allowed for longer continuous monitoring than the 24-hour Holter monitor, thus resulting in improved clinical accuracy in the detection of paroxysmal arrhythmias. Future studies should examine the long-term effectiveness of 14-day ECG patches for managing selected patients.

Key Words: Arrhythmia • Atrial fibrillation • ECG monitoring patch • Holter monitor

INTRODUCTION

The prevalence of arrhythmia is increasing as societies age. Because of the low sensitivity of standard electrocardiography (ECG) in detecting paroxysmal arrhythmias, 24-hour Holter monitoring is often used for patients with palpitation, dizziness or presyncope, and syncope. However, 24-hour Holter ECG monitoring has low sensitivity and specificity in detecting relevant arrhythmias.[1,2] Extending the recording time from 24 to 72 hours can increase the prevalence of paroxysmal arrhythmias, so that the rate of arrhythmia detection can be increased with a longer duration of ECG monitoring.[3,4]

Atrial fibrillation (AF) is the most common sustained arrhythmia and affects at least 8% of the elderly population.[5] The prevalence of AF increases with age, and it has been estimated that the number of persons with AF

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will increase by 2.5 times over the next 50 years.[6] AF is an important clinical concern and imposes a heavy economic burden on healthcare systems.[7] Moreover, AF is associated with increased mortality and stroke.[8] Around 50% of cases of AF are asymptomatic,[9,10] and ischemic stroke or other complications are often the first clinical manifestation of asymptomatic AF.[11] A recent study reported that even a short AF episode can significantly increase the risk of ischemic stroke.[11] A large proportion of persons with AF are underdiagnosed.[12] Th early diagnosis of new AF can improve the cure rate by preventing progression to permanent AF. In addition, early diagnosis and treatment of AF can prevent AF-related complications (e.g., stroke).[1]

Previous studies have found that 24-hour Holter monitoring has a low diagnostic yield for paroxysmal AF and other arrythmias. Poor compliance and difficulties in long-term cardiac rhythm monitoring are usually mentioned when explaining the low diagnostic yield of 24-hour Holter monitoring.[13] To address this limitation of 24-hour Holter monitoring for paroxysmal arrhythmia and AF, a 14-day ECG patch monitor was developed and evaluated in this study. We hypothesized that the patch would improve compliance and the diagnostic rates of paroxysmal arrhythmias and AF. This prospective pilot study compared 24-hour Holter and 14-day ECG patch monitoring and analyzed variables including diagnostic yield for various arrhythmia types, compliance, and rates of adverse events.

The aim of this study was to compare the detection rates for arrhythmia events between a continuous 14-day ECG patch monitor and a 24-hour Holter monitor over the total wear time for each device. The study population included patients referred for evaluation of cardiac arrhythmias by ambulatory ECG monitoring.

METHODS

Study design

This open-label, prospective, observational pilot study enrolled outpatients at Shin Kong Memorial Wu Ho-Su Hospital. The inclusion criteria were (1) provision of signed written informed consent before study enrollment, (2) ability to communicate with the investigators and to understand and comply with the study requirements, (3) suitability for outpatient 12-lead ECG evaluation of suspected or asymptomatic arrhythmias, as judged by the investigators, (4) intent to wear 24-hour Holter monitors and the presence of arrhythmia-related signs and symptoms such as fatigue, palpitation, slow heartbeat, irregular heartbeat, feeling of pauses between heartbeats, lightheadedness, dizziness, syncope or near-syncope, sweating, and shortness of breath or chest tightness, as judged by the investigators; (5) age 18 years or older (men and women), and (6) willingness to comply with up to 14 days of continuous ECG monitoring.

The exclusion criteria were (1) poor tolerability, namely, severe skin allergies to the 24-hour Holter monitor or the investigational patch device, or a history of severe skin allergies, (2) any injury, eczema, dermatitis, chromatosis, or skin abnormalities at the site where the devices were to be applied, (3) history of allergic contact dermatitis to medical adhesive bandages, (4) confirmed persistent AF or permanent AF, as judged by the investigators, (5) current or planned use of pacing or external direct current cardioversion, (6) anticipated exposure to high-frequency surgical equipment, (7) use of any medication or treatment for arrhythmia, such as class Ia (quinidine, procainamide, disopyramide), Ib (lidocaine, mexiletine, phenytoin), Ic (flecainide, propafenone, moricizine), III (amiodarone, sotalol, ibutilide, dofetilide, dronedarone), or other antiarrhythmic drugs (digoxin, adenosine), as judged by the investigators, or (8) pregnancy. The study was approved by the Institutional Review Board (IRB) of Shin Kong Wu Ho-Su Memorial Hospital (IRB number 20170601D). All patients provided written informed consent before participation.

A 14-day ECG patch monitor (EZYPRO, UG01, Sigknow Biomedical Co., Ltd, Taipei, Taiwan) was developed and evaluated in this study. The EZYPRO is a lightweight, waterproof, single-lead ECG device with no external leads or wires and allows for continuous ECG monitoring for up to 14 days. Enrolled patients with suspected arrhythmias were asked to wear simultaneously a traditional 24-hour Holter monitor (AR4, Schiller AG, Baar, Switzerland) for up to 24 hours and a 14-day ECG patch monitor for up to 14 days. Both devices were started at the same time so that they did not interfere with each other. The event recorder on the 14-day ECG patch monitor was triggered when patients showed symptoms during the study. Data from the 2 devices were directly

compared for the initial 24-hour monitoring period. The 14-day ECG patch monitor allowed for up to 14 days of monitoring, while the Holter monitor only recorded 24 hours of data. We therefore assessed whether prolonged monitoring improved patient care or diagnosis.

Application procedures

On study day 1, the study devices were placed on the participants by clinical staff. After both devices had been set up, the 24-hour Holter monitor and 14-day ECG patch monitor were activated simultaneously. The 14-day ECG patch monitor was applied to a clean, dry, hair-free area over the left pectoral region of the participant's chest (Figure 1). The 24-hour Holter monitor was removed after 24 hours, and the 14-day ECG patch monitor was removed from the chest after application for up to 14 days.

Data collection

Data were collected and recorded twice: at 24 hours after the 24-hour Holter monitor was applied (visit 2, for the 24-hour Holter monitor), and on day 14, or at any time point before that if the patient removed and returned the 14-day continuous ECG patch (visit 3, for the 14-day ECG patch). The data were collected and recorded by the investigators and analyzed with the software provided by the manufacturer (EZYPRO, Sigknow Biomedical Co., Ltd., Taipei, Taiwan).

Arrhythmia events

Arrhythmia events recorded by the 14-day ECG patch (investigational device) were analyzed with the proprietary analytical software and qualified ECG technicians from Sigknow Biomedical Co., Ltd. and diagnosed by cardiologists (SKC and HML) at the study sites. In accordance with standard institutional practice, the 24-hour Holter monitor was fitted by a cardiac technician and returned after 24 hours to the study sites for analysis. The 24-hour Holter monitor data were independently analyzed by ECG technicians, and events were identified by physician investigators at the study sites. Reports from both the 14-day continuous ECG patch monitor and 24-hour Holter monitor were made available to physician investigators. Any ECG data from the 24-hour Holter monitor or the 14-day continuous ECG patch monitor that were of urgent clinical concern, as determined by the physician investigators, were relayed to the referring physician within 24 to 48 hours.

Arrhythmia events were defined as the detection of any of 6 types of arrhythmia, including (1) supraventricular tachycardia (> 4 beats, not including AF or flutter), (2) AF/atrial flutter (AFL) (> 4 beats), (3) a pause > 3 seconds, (4) atrioventricular block (second-degree, 2:1, or third-degree atrioventricular block; requiring advanced evaluation by the investigators), (5) ventricular tachycardia (VT) (> 4 beats), or (6) polymorphic ventricular tachycardia/ventricular fibrillation.[14]

Tolerability assessment

After patch removal, skin irritation was assessed using the dermal response score, an 8-point scale, as follows: 0 — no evidence of irritation; 1 — minimal erythema, barely perceptible; 2 — definite erythema, readily visible, minimal edema or minimal papular response; 3 — erythema and papules; 4 — definite edema; 5 — erythema, edema, and papules; 6 — vesicular eruption; and 7 — severe reaction spreading beyond the test site. After detachment, clear photos of the adhesion site were obtained for all participants. The participants were encouraged to return to the clinic for skin irritation assessment as soon as possible after the device had been completely detached.

Statistical analysis

Continuous variables are presented as mean and standard deviation, and categorical variables are presented as number and percentage. The McNemar test

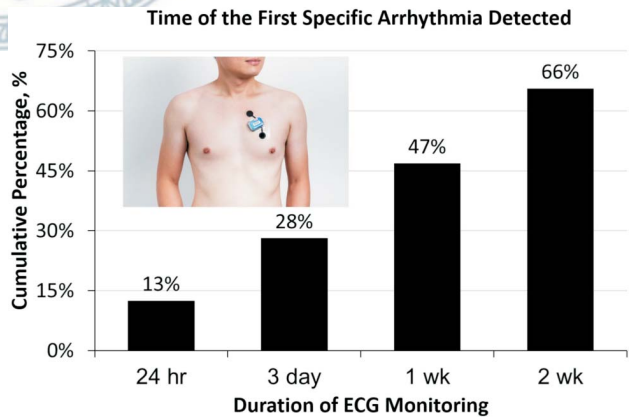

Figure 1. *The 14-day ECG (electrocardiography) patch was applied to a clean, dry, hair-free area over the left pectoral region of the participant's chest. The cumulative rate of arrhythmia detection by the 14-day ECG patch monitor.*

for paired proportions was used to test the hypothesis that there would be a significant difference between the 14-day ECG patch monitor and 24-hour Holter monitor in detecting relevant arrhythmias. A two-sided p value of less than 0.05 was considered to indicate statistical significance.

RESULTS

Demographics

In total, 32 patients (15 men and 17 women; mean age, 62.4 years) completed the registration; of whom 19 (59.4%) had hypertension, 5 (15.6%) had diabetes mellitus, 5 (15.6%) had hyperlipidemia, 2 (6.3 %) had heart failure, 5 (15.6%) had a history of stroke or transient ischemic attack, and 5 (15.6%) had cardiovascular disease (Table 1). The mean $CHADS_2$ and CHA_2DS_2-VASc scores of the study patients were 1.5 ± 1.4 and 2.3 ± 1.6, respectively. Of the 32 patients, 17 (53.1%) were referred for palpitation, 3 (9.4%) for dizziness or presyncope, 8 (25.0%) for syncope, and 4 (12.5%) for ischemic stroke.

Detection of relevant arrhythmia

All 24-hour Holter monitor and 14-day ECG patch monitor recordings were of good quality. The detection rates of relevant arrhythmias on days 1, 3, 7, and 14 with the 14-day ECG patch monitor were 13%, 28%, 47%, and 66%, respectively (Figure 1). Analysis of the 24-hour Holter monitor recordings showed 1 AF episode in 1 patient and 3 supraventricular tachycardia (SVT) episodes in 2 patients. Analysis of the 14-day ECG patch monitor data showed 202 AF/AFL episodes (including one patient with 154 episodes of AF and 8 episodes of patient-triggered detection of AF) in 6 patients, 55 SVT episodes (including 2 episodes of patient-triggered detection of SVT) in 22 patients, 7 episodes of pause in 1 patient, and 4 episodes of VT in 2 patients. The rates of detection of relevant arrhythmias were 9% and 66% for the 24-hour Holter monitor and 14-day ECG patch monitor, respectively (Figure 2A). The 14-day ECG patch monitor was significantly better at detecting relevant arrhythmias ($p < 0.001$).

Table 1. Baseline characteristics of participants

Baseline characteristics	N = 32
Male	15 (46.9)
Age	62.4 ± 15.6
65-75 years	6 (18.8)
≥ 75 years	11 (34.4)
Hypertension	19 (59.4)
Diabetes	5 (15.6)
Hyperlipidemia	5 (15.6)
Heart failure	2 (6.3)
Stroke or transient ischemic attack	5 (15.6)
Cardiovascular disease	5 (15.6)
$CHADS_2$ score	1.5 ± 1.4
CHA_2DS_2-VASc score	2.3 ± 1.6
Indications of ECG monitor	
Palpitation	17 (53.1)
Dizziness or near syncope	3 (9.4)
Syncope	8 (25.0)
Ischemic stroke	4 (12.5)

Values presented as n (%) or mean ± standard deviation.
ECG, electrocardiography.

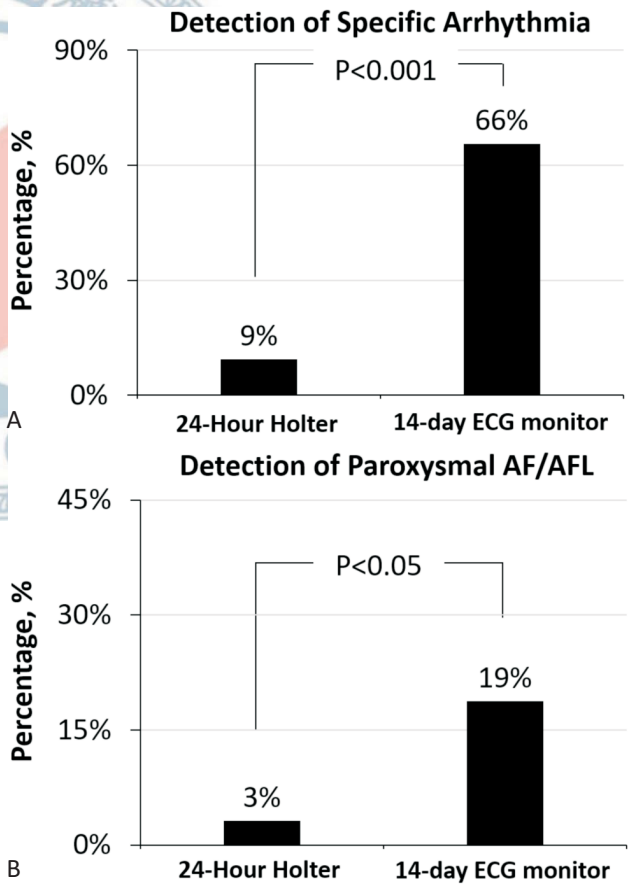

Figure 2. *The detection rate of relevant arrhythmias (A) and atrial fibrillation/flutter (B) by the 24-hour Holter monitor and 14-day ECG patch monitor. AF, atrial fibrillation; AFL, atrial flutter; ECG, electrocardiography.*

All patients underwent simultaneous 24-hour Holter and 14-day ECG patch monitoring on the first day. There was good agreement regarding the detection of specific arrhythmias between the 14-day ECG patch monitor and 24-hour Holter in the first days. Overall, of the 29 patients without relevant arrhythmias on 24-hour Holter monitoring, 18 had relevant arrhythmias on 14-day ECG patch monitoring. Among the 3 patients with relevant arrhythmias as detected by 24-hour Holter monitoring, none were reclassified as being arrhythmia-free by 14-day ECG patch monitoring. In addition, of the 31 patients without AF/AFL on 24-hour Holter monitoring, 5 had AF/AFL on 14-day ECG patch monitoring (Table 2).

Detection of paroxysmal AF/AFL

Among the 32 study patients, 202 AF/AFL episodes were detected in 6 patients (19%) by 14-day ECG patch monitoring, whereas only 1 AF episode was detected in 1 patient (3%, $p < 0.05$) by 24-hour Holter monitoring (Figure 2B). Among the 6 patients with AF/AFL episodes detected by 14-day ECG patch monitoring, 1, 6, 10, 12, 19, and 154 AF episodes were recorded, respectively. All 202 AF/AFL episodes were paroxysmal, and the longest was 16 hours and 17 minutes. Among 202 AF/AFL episodes, only 8 (3.9%) were patient-triggered AF/AFL and 194 (96.0%) AF/AFL episodes were asymptomatic. Patients with AF were slightly older than those without AF (age, 69.0 $\pm$ 6.8 vs. 60.9 $\pm$ 16.8 years, respectively) and had a slightly higher CHA_2DS_2-VASC score (2.7 $\pm$ 1.4 vs. 2.3 $\pm$ 1.6), however these differences were not statistically significant. All AF patients had a CHA_2DS_2-VASc score of 1 or higher and were potential candidates for oral anticoagulation therapy. An example of a 14-day ECG patch monitor recording of AF is shown in Figure 3A.

Detection of SVT, VT, and pause

A total of 55 episodes of SVT were detected by the 14-day ECG monitoring patch in 21 patients. The maximum heart rate was 167 beats per minute, and the longest duration was 49 minutes and 42 seconds. An example of a 14-day ECG showing patient-triggered detection of atrial tachycardia is shown in Figure 3B. The 14-day ECG monitoring patch detected non-sustained VT persisting for 2 seconds in 2 patients with ischemic heart disease. One patient with frequent syncope had 7 episodes of pause up to 6 seconds detected by 14-day ECG patch monitoring (Figure 3C), and therefore underwent permanent pacemaker implantation. The detection rates of all relevant arrhythmia by 24-hour Holter and 14-day ECG monitor are summarized in Table 3.

Dermal response scores

Of the 32 patients, 17 (53%) had a dermal response score of 0, 11 (34%) had a score of 1, 2 (6%) had a score of 2, and 2 (6%) had a score of 3; none had a score greater than 3 (Figure 4). The mean dermal response score immediately after removing the 14-day patch was 0.64, which indicated minimal erythema (barely perceptible). Figure 5 shows examples of patients with dermal response scores of 1 to 3.

DISCUSSION

The main finding of this pilot study was that 14-day continuous ECG monitoring was better than routine 24-hour Holter monitoring in detecting relevant arrhythmias, especially AF, in patients reporting symptoms of palpitation, dizziness, presyncope, or syncope. This find-

Table 2. Detection of relevant arrhythmias and atrial fibrillation/flutter by 24-hour Holter monitor versus 14-day ECG patch monitor

		14-day patch monitor		
Relevant arrhythmias		Positive	Negative	Results combined
24-hour Holter monitor	Positive	3	0	3
	Negative	18	11	29
	Results combined	21	11	Total: 32
Atrial fibrillation/flutter		Positive	Negative	Results combined
24-hour Holter monitor	Positive	1	0	1
	Negative	5	26	31
	Results combined	6	26	Total: 32

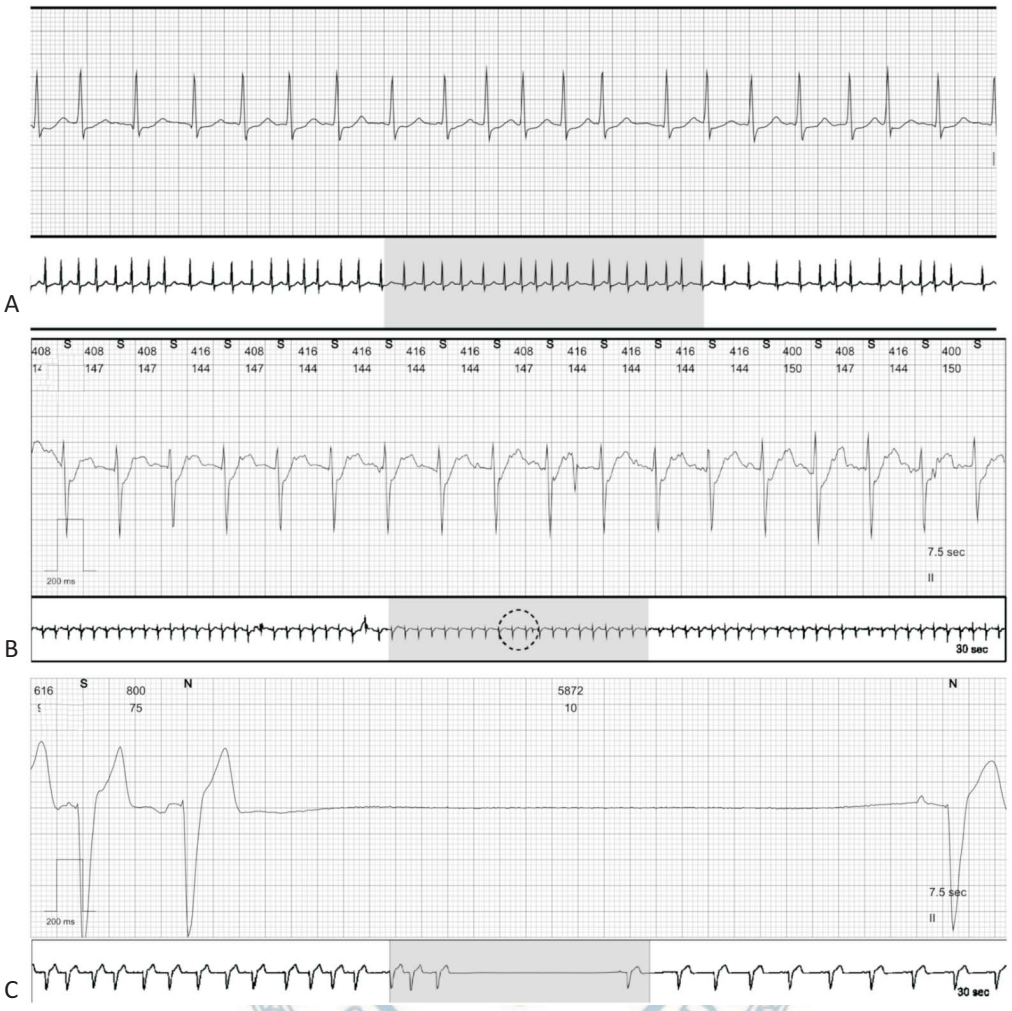

Figure 3. *Examples of 14-day electrocardiography patch monitor recordings. (A) A patient with asymptomatic atrial fibrillation; (B) An example of patient-triggered detection of atrial tachycardia; (C) A patient with a 10-second long sinus pause.*

Table 3. Summary of relevant arrhythmia detected by 24-hour Holter and 14-day ECG patch monitor (N = 32)

	24-hour Holter	14-day ECG monitor
Tachycardia		
Supraventricular tachycardia	2 (6.3%)	21 (65.6%)
Atrial fibrillation/Flutter	1 (3.1%)	6 (18.8%)
Ventricular tachycardia	0 (0%)	2 (6.3%)
Bradycardia		
Atrioventricular block	0 (0%)	0 (0%)
Pause	0 (0%)	2 (6.3%)
Total	3 (9.4%)	21 (65.6%)

Values presented as N (%). ECG, electrocardiography.

ing indicates that larger studies of arrhythmia detection with the 14-day continuous ECG monitoring patch are warranted. Moreover, several additional findings of this pilot study of continuous monitoring of arrhythmias using the 14-day ECG patch are of interest.

Previous studies have reported that the sensitivity of 24-hour Holter monitoring for detecting paroxysmal arrhythmias is low, however such monitoring is still widely used in primary care.[15-17] In the present study, 14-day ECG patch monitoring revealed several clinically important arrhythmias, including long sinus pause in 1 patient and ventricular tachycardia in 2 patients, which were not detected by 24-hour Holter monitoring. The 14-day ECG patch, as with the 24-hour Holter monitor, has a trigger button for use when symptoms such as palpitation, dizziness, or near-syncope develop, and the patients were instructed to press the 14-day ECG patch trigger button when they felt such symptoms. The pa-

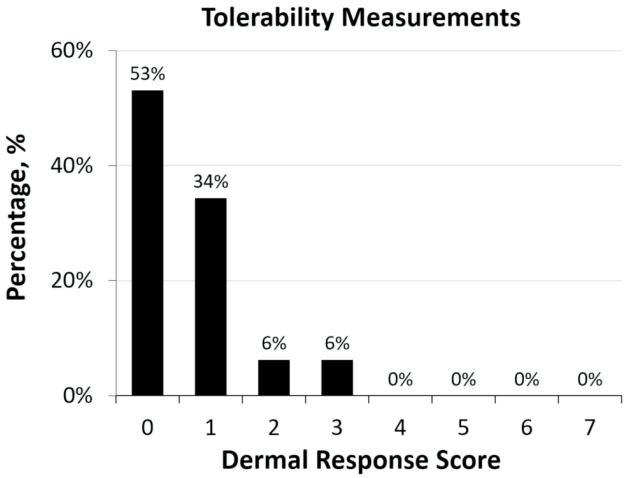

Figure 4. *Dermal response score among study patients wearing the 14-day electrocardiography patch monitor.*

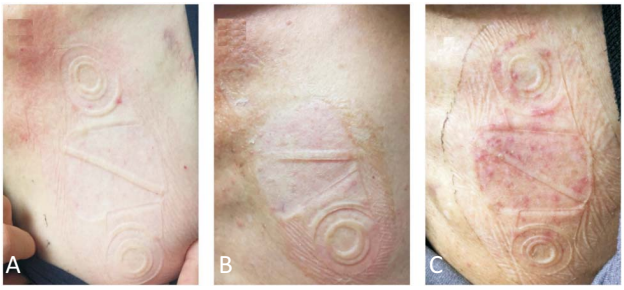

Figure 5. *Patients with dermal response scores of 1 (A), 2 (B), and 3 (C).*

tients could press the trigger button on the 14-day ECG patch to make a mark in the continuously recorded data stream, which allowed for accurate correlations with symptoms. These patients were referred for appropriate management, including the patient with frequent pause who was admitted for permanent pacemaker implantation, and both patients with ventricular tachycardia who were admitted for a cardiac electrophysiology studies.

Because AF is becoming more prevalent, the need for convenient, longer, and well-tolerated rhythm monitoring for AF is likely to increase. In this pilot study, the 14-day ECG patch monitor yielded several insights regarding AF. Because of the frequency of paroxysmal AF, the duration of monitoring should be inversely proportional to AF burden. Long monitoring periods may be necessary in order to detect infrequent but clinically important paroxysmal AF.[4,18] In the present study, the rate of detection of AF was significantly higher with longer monitoring.

Second, asymptomatic or subclinical AF is increasingly common in aging populations and has been identified as a risk factor for ischemic stroke. The early identification of AF and appropriate anticoagulation therapy may therefore decrease stroke morbidity and mortality.[19] Previous studies have reported that most AF episodes are asymptomatic, which underscores the unreliability of using symptoms to diagnose AF.[18,20] In this pilot study, 96% of the AF episodes were asymptomatic. In addition, the ability to identify asymptomatic AF is particularly important for patients who have undergone ablation for AF, as AF recurrence is often asymptomatic in such patients.[21]

AF recurrence was detected by 14-day ECG patch monitoring in all 6 AF patients. The data from 14-day ECG patch monitoring were in good agreement with respect to capturing the recurrence pattern of paroxysmal or persistent AF. This finding has important implications for determining AF burden, which is correlated with stroke risk.[22] In addition, it provides important information regarding the rate and rhythm control in such patients. Finally, the decision to start anticoagulant therapy after the detection of AF was made according to current guidelines.[23] In the present study, all patients with AF detected by 14-day ECG patch monitoring received anticoagulant therapy.

Although continuous 14-day ECG patch monitoring has been studied with the Zio Patch (iRhythm Technologies Inc, San Francisco, CA),[14,24] all of the related studies have been performed in the United States but not Asia. Moreover, the dermal irritation and tolerability of the Zio Patch has not been tested in Asia, especially in Taiwan where the climate is humid. In the present study, the mean dermal response of the 14-day ECG patch was very minimal after removing it from the participants, which indicates that the 14-day ECG patch may be well tolerated for continuous 14-day monitoring in Taiwan.

Clinical implications

Patch-based appliances capable of long-term continuous recording are more likely to capture arrhythmia episodes during physical exertion, sleep, and syncope. In addition, 14-day ECG patch monitoring was better than 24-hour Holter monitoring in detecting AF episodes, quantifying AF burden, and identifying the pattern of AF recurrence, and in detecting other arrhythmias such as pause and ventricular arrhythmia in this study. The 14-

day ECG patch was well tolerated by most participants over the 14-day follow-up period. The number of study patients was limited. However, the promising data from this pilot study suggest that a 14-day ECG patch may be more convenient and efficient than 24-hour Holter monitoring for detecting arrhythmias among outpatients. Larger studies are needed to confirm the efficacy of a 14-day ECG patch in detecting paroxysmal arrhythmias.

CONCLUSIONS

In this single-center pilot study, we found that a 14-day continuous ECG monitoring patch was more effective than routine 24-hour Holter monitoring in detecting paroxysmal arrhythmia, especially AF. This device might offer new diagnostic options for patients with suspected arrhythmia.

DISCLOSURES

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All the authors declare no conflict of interest.

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