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Value of a Novel 7-Day Patch Electrocardiography on Monitoring Cardiac Arrhythmias

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Abstract

Objective: With the development of ECG monitoring systems, the diagnosis of cardiac arrhythmias is improved significantly. Here, we introduced our experience with another new long-term ECG patch device (Smartpatch II) for monitoring the cardiac arrhythmia.

Method: This device was applied to patients complained with a history of chest pain, palpitation or syncope and admitted to the 3 medical centers between April 13, 2017 and October 18, 2017. Patients wore both 24-hour Holter monitor and the Smartpatch II on the first day. On the second day, the 24-hour Holter monitor was removed and patients continued to wear the Smartpatch II up to 7 days. All ECGs were analyzed by 2 experienced independent observers.

Results: A total of 101 patients (mean age: 57.5 ± 15.4 years, 52.5% male patients, body mass index: 24.0 ± 2.9 kg/m^2) were included. Over the first 24 hours, Both the Smartpatch II and Holter monitor documented 36 events. The sensitivity and specificity of Smartpatch II was 100% (95% CI, 90.3%, 100.0%) and 100.0% (95% CI, 94.5%, 100.0%) respectively when compared with Holter monitor on the first day. Over the total 7 days of monitoring, Smartpatch II detected significantly more arrhythmic events than one day recording (59 (58.4%) versus 36 (35.6%), p<0.001).

Conclusion: Over a total wearing time of 7 days, the patch device detected more cardiac arrhythmia than 24-hour monitoring.

Keywords: Smartpatch II; Cardiac arrhythmia; 24-hour holter

Introduction

Ambulatory electrocardiographic (ECG) monitor and the Holter monitor are developed to evaluate suspected cardiac arrhythmias in in- and outpatients. The Holter monitor was first introduced by Norman J. Holter (1941-1983) in the 1940s and remains the most common used method for detecting cardiac arrhythmias in clinical practice [1,2]. It can record and store data from 2 to 3 ECG leads attached to the patient's chest and collected continuously over 24 to 48 hours [1]. However, the compliance of patients to Holter monitoring remains as an issue of consideration. When carrying Holter, the wires and equipment often constrain the physical activity and might affect the sleep of patients [3-5].

Many systems are currently available to monitor cardiac arrhythmia in patients [6,7]. Most of these tools are small, allowing ECG monitoring for longer time periods than Holter, and can provide nearly real-time data analysis when the patient transmits the recording data to remote analysis system in accordance to the symptomatic event [1]. However, some of them need interventional manipulation [8], some are one-time devices, which are associated with high cost and some devices have only limited ECG storage capacity. A smaller ECG recording instrument with longer recording capacity might fit the need to improve the compliance of the carriers and facilitate diagnosis of arrhythmia [9-14].

The Smartpatch II is a China Food and Drug Administration-Shanghai Medical Equipment Testing Center (CFDA-CMTC) proved, single-lead 7-day ambulatory ECG adhesive patch monitor. The size is small and there is no an external lead or wires. The objective of this study was to compare the value of Smartpatch II in detecting arrhythmia events compared with standard 24-hour Holter monitoring and to compare the detecting efficacy between 7 days monitoring versus 24 hours monitoring with Smartpatch II.

Research Methodology

Patient selection

Between April 13, 2017 and October 18, 2017, consecutive outpatients aged 18 to 80 years old were enrolled in the 3 medical centers. All these patients complained about a history of chest pain, palpitation or syncope. The consent forms and the protocol were approved by the local ethics committee. Patients with previous

arrhythmia were defined as having a history of arrhythmia detected by ECG monitoring in the past 12 months. Exclusion criteria were any previous allergic to hydrogels, pacemaker or ECG monitoring equipment implantation, anticipated to receive computed tomography and magnetic resonance during the planned monitoring period.

Devices and study protocol

The Smartpatch II (NS-SP-B-01, Ensense Biomedical Technologies Co., Ltd, Shanghai, China) is a CFDA-CMTC proved, single-lead ambulatory ECG adhesive patch monitor. Smartpatch II contains a main structure for monitoring as well as a charging cradle for repeated use and has no external wires and leads (Figures 1A and 1B). It can be adhered on plain precordial area (Figure 1C). It also has an integrated trigger button which can be pressed to make a marker when the patients suffer from any discomfort.

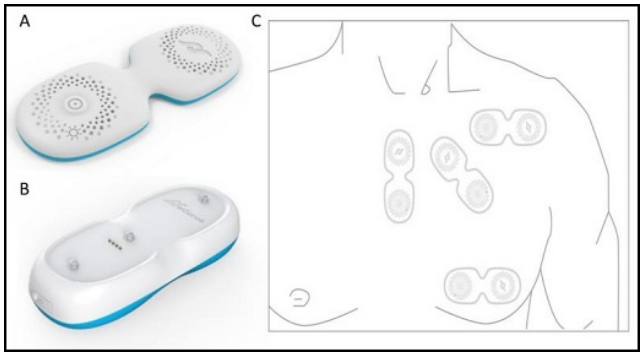

Figure 1: The Smartpatch II System, it contains a main structure for monitoring (A) as well as a base for recharging (B) and can be adhered on plain parts of the precordial area (C).

All enrolled patients were introduced to wear both the 24-hour Holter monitor (DigiTrak XT, Philips (China) investment co. LTD) and the Smartpatch II device simultaneously on the first day. On the second day, the 24-hour Holter monitor was removed and the patients continued to wear the Smartpatch II up to 7 days. On the study end or at any time point prior the study end due to any reason, the device was removed and returned to the clinic center. All data were collected and uploaded to a secure website. Technical review for both Smartpatch II and Holter records were performed by both an electrocardiologist and a cardiologist for report creation and quality assurance. Investigators analyzing the Smartpatch II recordings were blinded to the baseline characteristics and reports of the 24-hour Holter monitor.

Arrhythmia events were defined as detection of any of the following arrhythmias including: (1) supraventricular tachycardia (>4 beats, not including atrial fibrillation or flutter); (2) atrial fibrillation and atrial flutter (>30 seconds; (3) sinus bradycardia (<55 beats/min; (4) sinus arrest >3 seconds; (5) complete or Mobitz type 2 second-degree atrioventricular block; (6) ventricular tachycardia (>4 beats). Positive was defined as detection of any of the six arrhythmias and negative was none of the six arrhythmias.

Outcomes

The primary aim of the study was to compare the arrhythmia events detection between the Smartpatch II and the Holter monitor after 24 hours. The second end point was the comparison on the detection of arrhythmia events of Smartpatch II between 24 hours and after 7 days as well as the compliance of carrying Smartpatch II among enrolled patients.

Statistical Analysis

Continuous variables are shown as mean ± SD and categorical variables are given as frequencies and percentages. Comparisons were performed with the Chi-square test or Fisher's exact test for categorical variables (depending on field values). By using the arrhythmia history as standard, the sensitivity, specificity and 95% confidence interval of Holter, Smartpatch II in detecting cardiac arrhythmias were calculated. By using the Holter result as the standard, the sensitivity, specificity and 95% confidence interval of Smartpatch II in detecting cardiac arrhythmias on the first day were calculated. Concordances among different standards (history of arrhythmia, Holter and Smartpatch II) in diagnosing arrhythmia were calculated using McNemar's test and Cohen's kappa. A good level of agreement was defined as $\kappa \geq 0.6$ with $\kappa=1$ being the perfect agreement [15]. All tests were 2-sided, and a p-value <0.05 was considered statistically significant. The Statistical Package for the Social Sciences for Windows (version 18.0, SPSS Inc., Chicago, IL, USA) was used for analysis.

Results and Discussion

Study population

A total of 108 patients were included in this study, 101 patients (mean age: 57.5 ±15.4 years, 52.5% male patients, body mass index: 24.0 ± 2.9 kg/m^2) with available data on both the 24-hour Holter monitor and the Smartpatch II monitor at 24 hours and 7 days were included in the final analysis. Among the seven patients excluded, four were excluded because of the machinery malfunctions, two due to improper wear-resulted data lost and one due to recording stopped before 7 days because of skin allergy.

Characteristics	All
Age, mean (SD), year	57.5 (15.4)
Male No. (%)	53 (52.5)
BMI, mean (SD), kg/m^2	24.0 (2.9)
Previous Arrhythmia, No. (%)	51 (50.5)
Hypertension, No. (%)	30 (29.7)
Diabetes, No. (%)	8 (7.9)
Coronary Heart Disease, No. (%)	10 (9.9)
Heart Rate, mean (SD), bpm	75.1 (9.7)
SBP, mean (SD), mmHg	122.9 ± 13.1
DBP, mean (SD), mmHg	78.6 ± 9.8
Taking AAD, No. (%)	32 (31.7)
Note: BMI- body mass index (calculated as weight in kilograms divided by height in meters squared); AAD- antiarrhythmic drugs	

Table 1: Baseline characteristics of the study population.

Baseline characteristics of all 101 patients analyzed were summarized in Table 1, with 51 (50.5%) of them had a cardiac arrhythmic history, 30 (29.7%) had hypertension, 10 (9.9%) have history of coronary heart disease and 32 (31.7%) are taking antiarrhythmic drugs.

Performance in arrhythmia detection

Over the first 24 hours, Both the Smartpatch II and Holter monitor documented 36 events. The sensitivity and specificity of Smartpatch II was 100% (95% CI, 90.3%, 100.0%) and 100.0% (95% CI, 94.5%, 100.0%) respectively when compared with Holter monitor on the first day.

As a second outcome analysis, the results of 1st day recording and 7 days recording of Smartpatch II were compared. Over the total wear time, Smartpatch II after 7 days detected significantly more arrhythmic events than after 24 hours (59 (58.4%) versus 36 (35.6%), κ=0.57, p<0.001) (Tables 2 and 3, Figure 2). Among the 51 events had a history of cardiac arrhythmia at baseline, 40 (78.4%) were documented by Smartpatch II over the total time. The difference between them reached no statistic difference (p=0.2) but with a low consistency (κ =0.41p<0.001).

Smartpatch	p-value		Holter		Total
			Positive	Negative	
1st day	1	Positive	36	0	36
		Negative	0	65	65
7 days*	<0.001	Positive	36	23	59
		Negative	0	42	42
		Total	36	65	101
Note: * κ=0.57p<0.001					

Table 2: Comparison of Holter and Smartpatch in detecting cardiac arrhythmia.

Variables	p-value		Arrhythmic History		Total
			Positive	Negative	
Holter*	0.006	Positive	30	6	36
		Negative	21	44	65
Smartpatch 1st day	0.006	Positive	30	6	36
		Negative	21	44	65
Smartpatch 7 days**	0.2	Positive	40	19	59
		Negative	11	31	42
		Total	51	50	101
Note: * κ=0.47p<0.001 ** κ=0.41p<0.001					

Table 3: Comparison of Holter and Smartpatch II versus arrhythmic history.

Using patients' arrhythmic history as the standard, the sensitivity and specificity of Smartpatch II on detecting arrhythmias is 78.4% (95% CI, 64.7%, 88.7%) and 62.0% (95% CI, 47.2%, 75.4%) respectively. 24 hours monitoring by Holter or Smartpatch II detected less arrhythmic events (30 (58.8%), p=0.006). Comparing with arrhythmic history, the sensitivity and specificity of 24 hours Holter or Smartpatch II is 58.8% (95% CI, 44.2%, 72.4%) and 88.0% (95% CI, 75.7%, 95.5%) respectively.

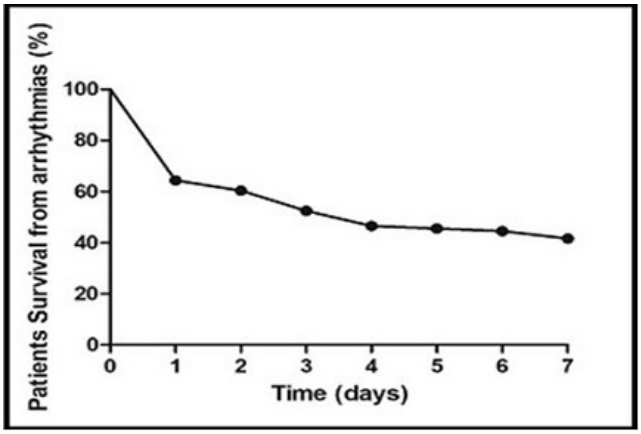

Figure 2: Detection of cardiac arrhythmia of the Smartpatch II over the total monitoring time.

Safety and applicability of the device

Overall, 96.3% (4/101) Smartpatch II ran normally over the study period. Among the 7 patients excluded at the baseline, the machine was replaced in four patients due to machine failure and two patients shut down the machine by mistake when marking their symptom. Another patient developed allergic rash on the fourth day of wearing Smartpatch II and dropped out from the study.

Over the wearing time, cutaneous pruritus in the wearing area happened in 15 (14.9%) patients. Fourteen patients' pruritus remitted after changing the patch to another place and cream was used in one patient to reduce the itching. Broken skin or skin infection was not documented. Full charged Smartpatch II was used in this study and there was no need to re-charge the patch during the 7 days wearing.

Main findings

In this prospective, multicenter study, we introduced the experience of using Smartpatch II, a CFDA-proved, noninvasive, rechargeable and single-lead ECG monitoring system for cardiac arrhythmic identification. The detecting efficacy is similar as Holter. After monitoring for 7 days, we demonstrated Smartpatch II is viewed as a safe and effective tool as an initial diagnostic strategy in arrhythmia evaluation.

Performance in arrhythmic detection

The diagnosis of arrhythmia often requires ECG monitoring longer than 24 hours. Holter monitoring. Turakhia et al. showed that 51.1% patients had their first symptom-triggered arrhythmia after the initial 48-hour period [16] and others suggested the highest diagnostic yield for arrhythmia detection is usually the first 7 days of ECG monitoring [17]. In our study, the Smartpatch II reported significantly more cardiac arrhythmias after a 7-day monitoring compared with 24-hour

monitoring (59 versus 36, p<0.001), consistently with previous arrhythmic history (59 versus 51, p=0.2). Arrhythmia was documented in 19 patients with no arrhythmia history but with palpitation or chest pain at baseline by the 7-days patch. This result demonstrated that 7-days ECG monitoring is helpful to clarify the complaint driving by arrhythmias.

Moreover, there were eleven cases with history of arrhythmia and negative monitoring results even with the 7 days monitoring, indicating the need to monitor the arrhythmias for more than 7 days. However, a longer monitoring time maybe associated with higher medical costs and lower compliance. Zimetbaum et al. suggested ambulatory ECG monitoring beyond 7 days provided only an additional 3.9% diagnosis rate for patients while the medical cost was likely to be more than 5 times over a 14-day period [17]. Paddy et al. showed that an average wear time of 11.1 days was usually enough to achieve an adequate diagnostic efficacy [18]. In our study, all patients wore the fully charged Smartpatch II and there was no need to recharge the Smartpatch II during the 7 days wearing period. If a longer monitoring is needed, patients can recharge it by using the charging base themselves. This enabled one patch device to be used for monitoring in a longer time period.

The Smartpatch II

Compared with other monitoring systems, this novel patch also has some other advantages. Some device can only upload real-time data and some are of limited storage volume [19]. The Smartpatch II can store up to 45 days ECG data and a marker can be made when the patient feel sick and facilitate the analysis between symptom-arrhythmias interaction. Moreover, real-time monitoring can be achieved by connecting the device to an APP through Bluetooth. Patients are allowed to view their real-time ECG after connected to the APP and send them to their doctors for consulting if necessary. These advantages affirmed its application value in clinical practice.

To our knowledge, this is the first multi-center study reporting results of using the Smartpatch II for arrhythmia detecting. Over the total monitoring time, this new patch device has similar detection efficacy as the traditional 24-hour Holter. As expected, 7 days monitoring with Smartpatch II detected more patients with arrhythmias.

Limitations

This study had an inherent major limitation of only enrolled patients with chest pain, palpitation or syncope history. Arrhythmias such as atrial fibrillation may be asymptomatic are also associated with potentially adverse outcomes, such as embolic stroke [20]. Further studies including these asymptomatic patients are needed. Limitations about this new patch device including non-continuous real-time uploading, skin allergy caused by gel and electrocardiogram quality et al.

Conclusion

The Smartpatch II is a CFDA-proved, leadless, water-resistant and rechargeable small patch device, does not limit the mobility of the patients. In the diagnosis of patients with symptoms of a potential cardiac arrhythmia, it provides a similar detecting efficacy as the 24-hour Holter monitor and this system is suitable for long-term arrhythmia monitoring.

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Conflict of Interests

The authors declare no conflicts of interest. Zhimin Xu and Yan Zhao contributed equally to this work.

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