The preliminary study on the clinical application of the WHAM (Wearable Heart Activity Monitor)

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Abstract— **In this paper, we investigated the validity of the WHAM (Wearable Heart Activity Monitor) in the clinical applications, which has been implemented as a wearable ambulatory device for continuously and long-term monitoring user's cardiac conditions. To this end, using the WHAM and the conventional Holter monitor the ECG signals over 24 hours were recorded during daily activities. The signal from the WHAM was compared with that from the conventional Holter monitor in terms of the readability of the signal, the quality of the signal, and the accuracy of arrhythmia detection. The performance of the WHAM was a little lower as compared with the conventional Holter monitor, although showing no significant difference (the readability of the signal: 97.2% vs 99.3%; the quality of the signal: 0.97 vs 0.98; the accuracy of arrhythmia detection: 96.2% vs 98.1%). From these results, it is likely that the WHAM shows the performance enough to be used in the clinical application as a wearable ambulatory monitoring device.**

I. INTRODUCTION

The ECG has been extensively utilized as a non-invasive tool that provides a variety of information on patient's cardiac conditions, such as arrhythmias and heart blocks etc. In general, even in the patients with cardiovascular diseases, most of arrhythmias are very difficult to be identified from a short-term recording of the ECG during a routinely performed examination in hospitals. Up to now, a Holter monitor or an event recorder has been broadly used for a long-term monitoring of ECG over a 24-hour period during daily activities. One of important hindrances to wider acceptance of those monitors is the unwieldy wires between electrodes and a processing unit.

To overcome the drawback of the conventional devices, we proposed the WHAM, showing its effectiveness, which can provide physicians with the useful data to opportunely detect the abnormal conditions of the heart via continuous and online monitoring of a user's cardiac conditions [1]. The WHAM can operate in two different modes: the Holter mode, in which it records the ECG tracing over a period of more than 24 hours; the event telemetry mode, in which it records and transmits two one-minute segments of a real-time ECG signals before and after an event via a radio frequency link. In fact, the WHAM has the capability to continuously record the ECG signals for a maximum of up to seven days, which are sampled at the rate of 250 Hz, with the resolution of 12 bits.

In this paper, we performed a clinical test to evaluate the validity of the WHAM as a wearable ambulatory monitor in the clinical area via the comparison of ECG signals from the WHAM and the conventional Holter monitor (Seer Light Digital Holter Recorder from GE Medical Systems) [2].

II. METHODS

A. Subjects

Thirty patients with cardiovascular diseases (13 males, 17 females; aged 53.2 12.6) participated in this study that was approved by the Institutional Review Board for human research of Samsung Medical Center in Korea. All of them gave informed written consent after being fully aware of the study protocol and its purpose. And then, a technical staff gave an account of how to use the WHAM and the conventional Holter monitor. Each patient will need to make two visits to hospital: once to have the devices fitted and once to return it.

B. ECG signal acquisition

To obtain a standard ECG from the conventional Holter monitor, first, the surface electrodes were placed in standard

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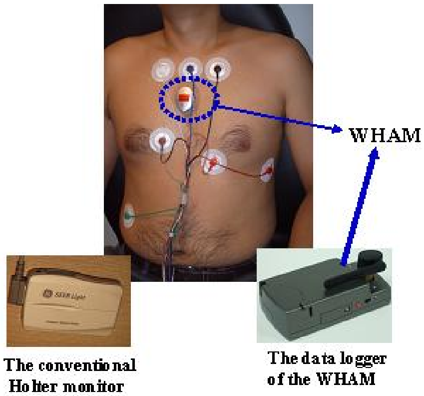

Fig. 1 The configuration of devices for the acquisition of ECG signals

locations on the chest of each patient, and then were connected to the recorder, worn on a belt around his waist, through wires. Next, the WHAM was attached to him via a disposable patch electrode. ECG signal from the WHAM was wirelessly transmitted and stored to its data logger, which was also worn on a belt around his waist (refer to Fig. 1). Patients were asked to press the button to mark the onset of an event whenever they feel an abnormal symptom (e.g., heart palpations, shortness of breath, and chest pain etc.). Finally, he left the hospital to record ECG signals over a 24-hour period while doing daily activities.

C. Performance Evaluation

When the patient returned back to the hospital the next day, ECG signals recorded were downloaded into the dedicated Holter review system and the PC from the Holter monitor and the data logger via USB interface, respectively. To evaluate the effectiveness of the WHAM in a clinical application, two experienced ECG technicians visually scored 10 one-minute ECG epochs from the conventional Holter monitor and the WHAM in terms of the following criteria:

i) The readability of signal defined as

$$Det(\%) = \frac{Number(Yes\_events)}{Total(events)} \times 100$$

where *Number (Yes_events)*: the number of epochs that an ECG interpreter judges he can identify any arrhythmia or heart disease in.

ii) The quality of signal (QoS)

Good: R < 50 (%)

Normal: 50 ≤ R < 75 (%)

Bad: R ≥ 75 (%)

where R is defined as the ratio of the noisy segment to one-minute epoch. The epoch scored as more than normal was considered as effective. That is, QoS can be defined as:

$$QoS = \frac{Number(Good + Normal)}{Total}$$

iii) The accuracy of arrhythmia detection

$$Acc = \frac{\sum correctly\ identified\ arrhythmia}{Total\ Number\ of\ arrhythmia} \times 100$$

which reflects how accurate an ECG interpreter can visually detect the arrhythmia existing in any epoch.

III. RESULTS AND DISCUSSIONS

Figure 2 depicted the representative example of ECG epochs recorded with the conventional Holter monitor and the WHAM, which was used to assess the performance of the WHAM as a clinical device. In figure 2(a), the upper, middle, and bottom tracings represented lead V1, V2, and V3, respectively. From figure 4, it is indicated that the ECG signal recorded with the WHAM showed the very similar morphology to the V3 of Wilson's unipolar chest leads. Also, in both of ECG tracings, we can easily identify the existence of arrhythmias with the naked eye, which indicates that the WHAM can be sufficiently used as a Holter monitor.

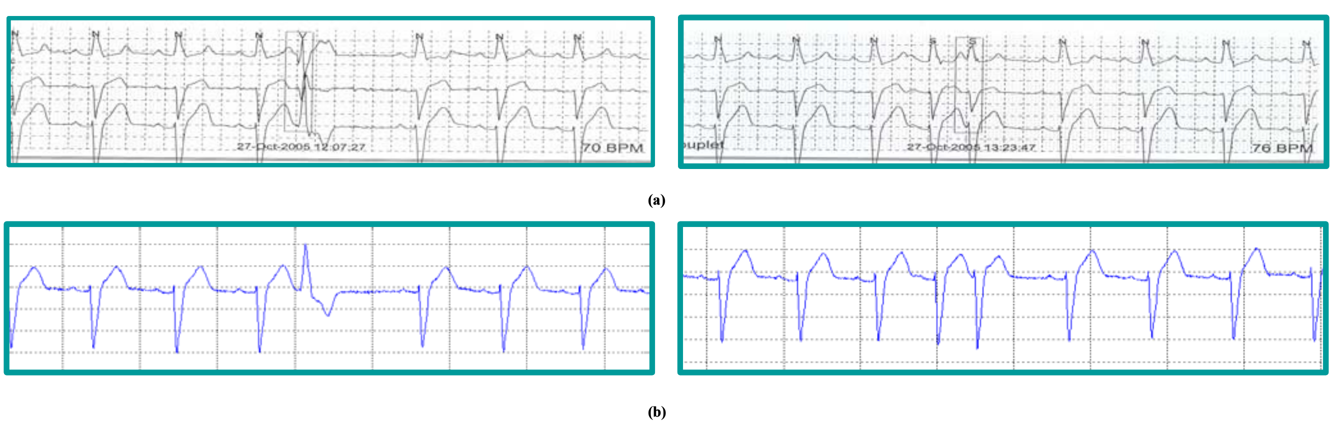

Fig. 2 The typical example of ECG epochs. (a) from the conventional Holter monitor and (b) from the WHAM

Table I The performance of the WHAM in terms of DEC and QoS

Criteria	Device	Interpreter	Value	Average
DEC	WHAM	1	97.0	97.2
		2	97.3	
	Holter	1	99.3	99.3
		2	99.3	
QoS	WHAM	1	0.97	0.97
		2	0.96	
	Holter	1	0.98	0.98
		2	0.98	

Table I summarizes the performance of the WHAM, which has been evaluated in terms of the readability of signal and the quality of signal as mentioned above. In Table I, the readability of signal was a little lower in the WHAM (97.2%: Interpreter 1 = 97.0 %; Interpreter 2 = 97.3%) than the conventional Holter monitor (99.3%: Interpreter 1 = 99.3 %; Interpreter 2 = 99.3%), although showing no significant difference in both devices. Similarly, in case of the QoS, there were no significant difference between the WHAM (0.97: Interpreter 1 = 0.97; Interpreter 2 = 0.96) and the conventional Holter monitor (0.98: Interpreter 1 = 0.98; Interpreter 2 = 0.98). These results may indicate that the WHAM is by no means inferior to the conventional Holter monitor as an ambulatory, long-term ECG monitor.

The resultant performance of the WHAM assessed in terms of the accuracy of arrhythmia detection is summarized in Table II.

Table II The accuracy of arrhythmia detection for the WHAM

	Subj.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total		SR APC	SR APC	SR PAF PAPL Pause APC	AF	SR APC VPC	SR APC	AF	AF	SR LBBB 1st AV Blck	SR VPC	SR	SR APC	SB JR AV Diss Pause	SR VPC	SR VPC 1st AV Blck
WHAM		2	2	5	1	3	2	1	1	2	2	1	2	4	2	3
Holter		2	2	5	1	3	2	1	1	3	2	1	**2**	**4**	**2**	**3**
	Subj.	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**
Total		SR	SR	AF	SR	SR APC	SR APC	SR VPC	SR	SR VPC	SR	SR	SR	SB VPC	SR	SR
WHAM		1	1	1	1	2	2	2	1	1	1	1	1	**2**	**1**	**1**
Holter		1	1	1	1	2	1	2	1	2	1	1	**1**	**2**	**1**	**1**

There are a variety of arrhythmias in ECG tracings, including SR (Sinus Rhythm), APC (Atrial Premature Complex), PAF (Paroxysmal Atrial Fibrillation), PAFL (Paroxysmal Atrial Flutter), VPC (Ventricular Premature Complex), LBBB (Left Bundle Branch Block), 1st AV BLCK (1st degree atrioventricular block), JR (Junctional Rhythm), and AV DISS (Atrioventricular dissociation). For the ECG epochs extracted from a 24-hour ECG recording of the WHAM, both of ECG technicians could detect those arrhythmias with the accuracy of 96.2 %. Meanwhile, they showed the accuracy of 98.1% with respect to the ECG epochs from the conventional Holter monitor. As a result, it seems to imply that there is no problem in the identification of any arrhythmia by a cardiologist using the WHAM.

IV. Conclusion

This paper addressed the results of the first medical trial, of which purpose is to confirm the possibility of the WHAM as a wearable, ambulatory Holter monitor. As mentioned above, the WHAM allows the continuous and on-line monitoring of a user's cardiac condition with the capability of recording ECG signals over a period of seven days. Our results indicated that the WHAM shows enough potential as a wearable, ambulatory monitoring device as compared with the conventional Holter monitor. Therefore, it is expected that the WHAM can empower a user to cope with cardiovascular diseases by the early detection of abnormal cardiac events via the continuous, long-term monitoring, which is attributable to the improvements of user's facility owing to its small size and no wire leads.

Future works include preparing an approach for the reduction of motion artifacts, improving the interface between a disposable electrode and the controller, and developing an automatic detection of arrhythmia.

References

[1] Kunsoo Shin, "WHAM: A novel, wearable heart activity monitor based on Laplacian potential mapping," 27th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC'05), 2005.

[2] The Seer Light Digital Holter Recorder from GE Medical Information Technologies, http://www.gehealthcare.com/usen/cardiology/diagnostic_ecg/products/amb_centerpg.html.