

Clinical Trial of Holter Monitor Versus Wireless Patient Monitor

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Recently, a new “wireless” patient monitoring device(Everguard 2000G, U-care Inc., Korea) has been developed for patient monitoring. The aim of this study was to compare a new “wireless” patient monitor with a standard Holter monitor in the evaluation of patient with ECG signals. Twenty consecutive patients (20 male, 21.4 ± 3.22 years) referred for evaluation of ECG signals were provided with both a standard Holter (GE) and a “wireless” patient monitor for 8 hours. The results of R-R interval show that Holter was 844.24 ± 95.29 ms and Everguard 2000G was 831.82 ± 103.27 ms. The average difference of the two systems was 12.41ms. The math rate of the two systems was 96.9%(p ≤ 0.001). The heart rate(beat/min) in Holter and Everguard 2000G were 71.71 ± 9.35 and 72.94 ± 10.67, respectively. The average difference of the two systems was 1.24. The math rate of the two systems was 96.4%(p ≤ 0.001). QRS duration time in Holter and Everguard 2000G were 59.59 ± 14.33 and 58.82 ± 13.71 ms, respectively. The average difference of the two systems was 0.76 ms. The math rate of the two systems was 99.7%(p ≤ 0.001). QT duration time in Holter and Everguard 2000G were 279.59 ± 22.7 and 281.94 ± 32.32 ms, respectively. The average difference of the two systems was 2.35 ms. The math rate of the two systems was 89%(p ≤ 0.001). The two systems showed the statistical validation. The “wireless” patient monitor has high patient compliance and results in high quality ECG recordings. Clinical trial results suggested that this monitoring system is equivalent to a standard Holter monitor.

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NOMENCLATURE

ECG = electrocardiography

IRB = Institutional Review Board

1. Introduction

A tendency of aging population is becoming more noticeable all over the world as the standard of living improves and a medical technology develops. The prevalence rate of chronic diseases is increasing due to population aging and another problem of the aged society is increasing numbers of elders who live alone according to declining of ability to support a family as being a nuclear family. Recently, a U-healthcare technology such as a telemedicine service is being developed to solve this[1]. The most basic factor of a U-healthcare technology is acquisition of medical information of patients and normal people through continuous monitoring[2].

ECG has been used most commonly as a method of obtaining

medical information of an individual. However, personal monitoring devices were connected with wire and limited activities of the surveillance target.

It is only in the last few years that the healthcare sector has embraced the concept of wireless communications and has started to follow the strong trend set previously by consumers and businesses. Wireless technologies allow enhanced freedom to access and exchange data, whether it is internally within a building or whether it expands across a wider community.

A new type of wireless patient surveillance device was developed lately. This device (Everguard 2000G(U-care INC., Korea; Fig.1)) can check ECG, temperature of epidermis, heart rate, and 3D movement status among body information of a patient, and it is operated with a coin type battery.

This study compared and analyzed form of ECG, RR interval, QRS duration time, QT duration time, and heart rate in order to secure credibility of data that were obtained by using wireless patient surveillance device(Everguard 2000G) and Holter(GE).



Fig. 1 System configuration of Everguard 2000G

2. Method

2.1 Study protocol

This clinical trial is an open-label study that selected healthy adult applicants who are considered to be suitable as a subject of this clinical trial by conducting screening examinations such as medical examination by interview and physical checkup within -28 days from the expected clinical trial date. The selected subjects were total 20 people (20 male, mean age 21.4 ± 3.22 years). And the test protocol was proceeded under the agreement of subjects after passing IRB of Chonbuk National University Hospital. Table 1 shows demographic information of subjects. Subjects had attached holter and wireless patient monitor device for the clinical trial, passed a process of checking if data is accurately measured, and measured ECG for 8 hours. Fig. 2 is a picture that shows a process of conducting the clinical trial.

Parameter	Value \pm SD
Number of patients	20
Age(years)	21.4 ± 3.22
Gender(male/female)	20/0
Height(cm)	174.24 ± 4.77
Weight(kg)	72.96 ± 15.4
Heart rate(beat/min)	74.25 ± 9.05

Table 1 Patients Characteristics

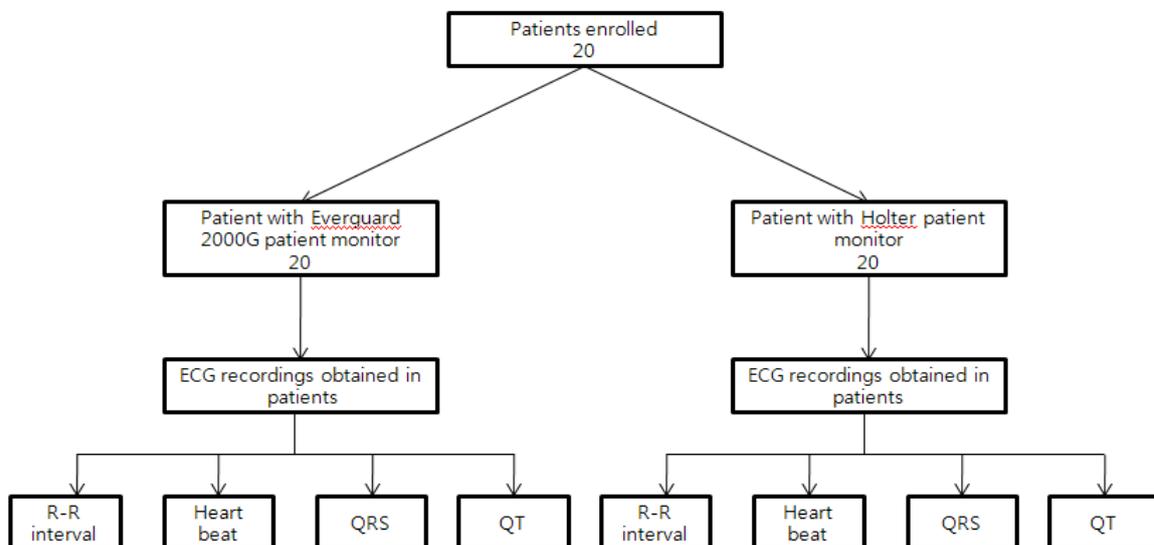


Fig. 2 Measurement process of the two monitoring devices

2.2 Everguard 2000G Wireless Monitor

The sensor of “wireless” ECG monitoring device of U-care company has a size of about 48mm X 42mm X 11mm, weight is 20g, and it operates with a coin type 3V lithium battery. The bandwidth of device is conducted between 0.05 and 40 Hz, and 204.8Hz was used as the sampling frequency. This sensor is attached to the body of patient, checks body information such as ECG, body temperature, heart rate, and 3D movement in real time, and transmits it wirelessly. This data is transmitted to the network server through a gateway.

3. Results and discussion

Data obtained from Holter and wireless patient monitor device were all downloaded with a computer and analyzed after the clinical trial. Continual variables were shown as mean value ± standard deviation, and interclass correlation analysis was conducted to compare two systems. A p value less than 0.05 was considered statistically significant. All statistical processes were performed using SPSS (IBM, Version 17, USA). Data analysis of two systems had analyzed data of the simultaneous time zone. Data could be obtained from 17 subjects from the total 20, and data of other 3 could not be obtained because the attached electrode was taken off during the test.

Fig. 3 shows the R-R interval time of Holter monitoring system and Everguard 2000G (R-R interval time, 844.24 ± 95.29 v/s 831.82 ± 103.27 ms).

The heart rate in Everguard 2000G and Holter were 71.71 ± 9.35 and 72.94 ± 10.67, respectively, and the average difference of two systems is 1.24 ms which confirms statistical significance with the match rate of 96.4% (P≤0.001).

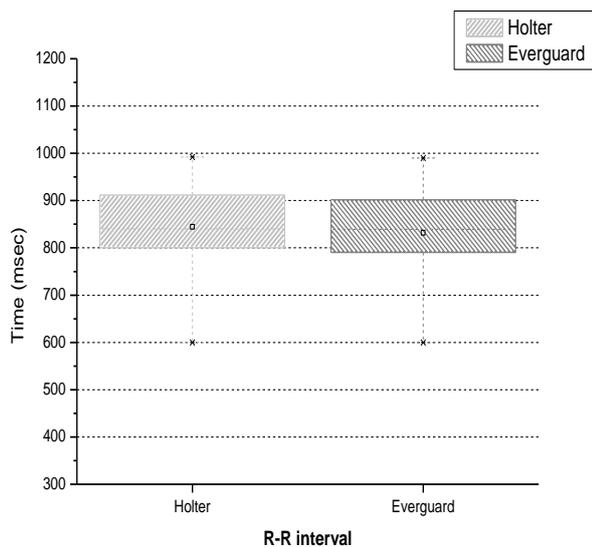


Fig. 3 Comparison of a R-R interval time of Holter monitor and Everguard 2000G monitor.

Fig. 5 shows the QRS duration time of Everguard 2000G and Holter (59.59 ± 14.33 v/s 58.82 ± 13 ms), and the average difference of two systems is 0.76 ms which confirms statistical significance with the match rate of 99.7% (P≤0.001).

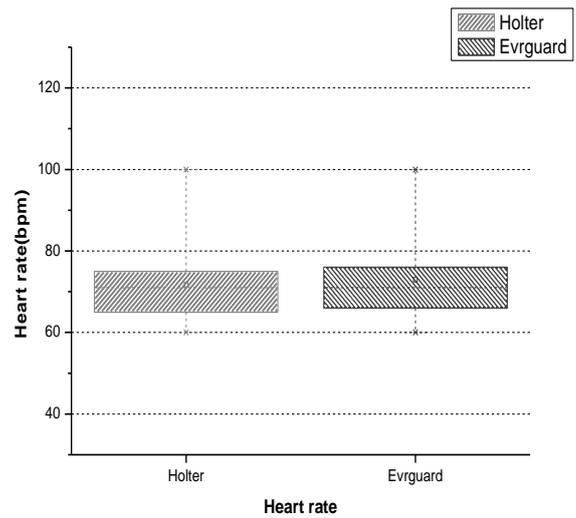


Fig. 4 Comparison of a Heart rate of Holter monitor and Everguard 2000G monitor.

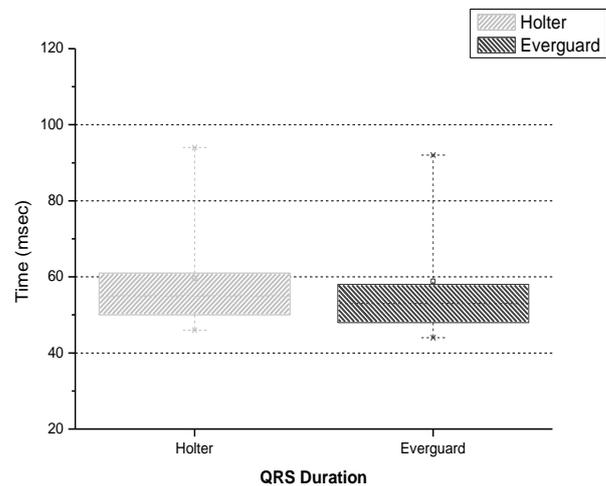


Fig. 5 Comparison of QRS duration time of Holter monitor and Everguard 2000G monitor.

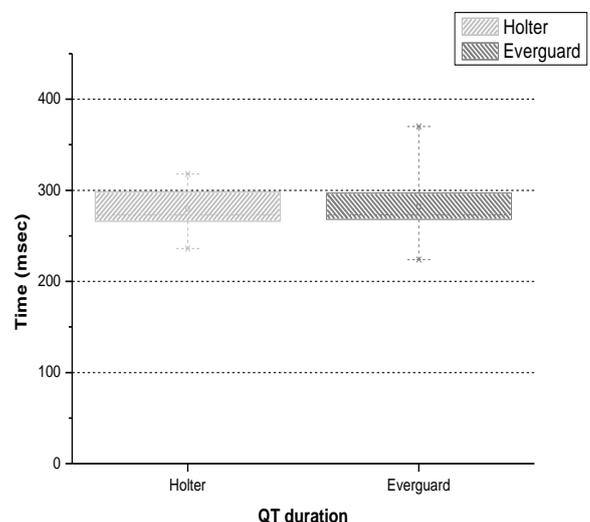


Fig. 6 Comparison of QT duration time of Holter monitor and Everguard 2000G monitor.

Fig. 6 shows QT duration time of Everguard 2000G and Holter (279.59 ± 22.7 and 281.94±32.32 ms), and the average difference of two systems is 2.35ms which confirms statistical significance with the match rate of 89% (P<0.001).

This study is the report on the use of a new “wireless” ECG monitor for evaluation of patients ECG signals. The results of this study reveal that the acceptability of the “wireless” ECG monitor is high, and its use results in high quality ECG recordings and is associated with high compliance. No difference was observed in the quality of the tracings obtained with the “wireless” ECG monitor as compared with the standard Holter monitor. Sixteen of 20 individuals found the “wireless” ECG monitor easier to operate and more user friendly than the standard Holter monitor.

4. Conclusions

This clinical research conducted a non-inferiority clinical trial of the newly developed wireless patient monitoring device and the standardized holter monitoring device. Through the results of this trial, the newly developed wireless patient monitoring device could give more even data than the standardized holter monitoring device and most of subjects expressed the convenience than the standardized holter in wear ability. Holter can only obtain ECG signal, however, the newly developed wireless patient monitoring system can obtain ECG signal, temperature of epidermis, and 3D activity detection signal and therefore it can also acquire safety of patients as it detects emergency signals such as sudden falling down.

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