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Timeliness of Single-Patch 12-Lead Electrocardiography for Patients with Chest Pain at the Emergency Department

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Abstract. A 12-lead ECG is used in emergency departments to diagnose and treat patients with chest discomfort. Performing ECGs at the proper time has been found to increase treatment outcomes. A timer on a wearable ECG ensures proper recording. We compared the timing accuracy of single-patch 12-lead ECG to conventional ECG, expecting the former to be more accurate. Adult patients with chest pain but not in shock were randomized into two groups: SP-ECG and C-ECG. The final analysis included 33 of the 36 recruited patients. The key result was the time taken to record the ECG in both groups. The two groups' average ages were 63.7 and 58.1 years. The SP-ECG group was 87.5 percent timely, while the C-ECG group was 47.0 percent (P.74). At the second follow-up, it was 75.0 percent and 35.2%. Continuous ECG without interfering with other exams is feasible in complex ER circumstances. But the accuracy of single-patch ECG has not been verified. The device also had some minor difficulties. The use of SP-ECG may help alleviate overcrowding or staffing issues in EDs, although more research is required.

Keywords. Electrocardiogram, Wireless Technology, emergency department

1. Introduction

Twelve-lead electrocardiography (ECG) is an essential process in the emergency department (ED) for patients with complaints of chest pain. The most important step in a patient who complains of chest pain is to identify the location of the pain. ECG should be performed to determine if the pain is caused by cardiovascular disease. Timely ECG is associated with improved clinical outcomes in patients with cardiovascular disease. Therefore, delayed ECG in the ED, which can be aggravated when the ED is overcrowded or short-staffed, can result in poor outcomes. [1-2] Complex and unstable circumstances in the ED are challenging for current monitoring systems. Patients are often moved from one place to another for various tests and procedures. In addition, long

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physical lines, large sizes, and multiple patches of current ECG devices are not suitable for long-term use and require a long preparation time. A single-patch wireless 12-lead ECG (SP-ECG) with a timer could be beneficial in cases of pre-decided follow-up ECG. A single patch would make it possible for patients to move outside the bed and could be used in complex emergency room situations requiring many tests. However, to our knowledge, there have been no studies on such devices in the ED setting. This study aimed to evaluate the effect of a SP-ECG with a timer on the timeliness of follow-up ECG for chest pain patients in the clinical setting.

2. Methods

The study was conducted in an academic tertiary hospital's ED. Participants were divided into two groups: C-ECG and SP-ECG. The key comparative variable was the timing of the two ECG types. The hospital's institutional review board accepted the study protocol (#2019-01-046-008).

The study took place in an academic tertiary hospital in Seoul with 2,000 inpatient beds and 2 million outpatient visits each year. Annually, 78,000 people visit the ED. The study began on July 30, 2020, and ended on October 8, 2020. The trial lasted about 70 days. The study comprised patients who came to the hospital's ED with chest pain. The inclusion criteria were: admissions to the ER with chest pain or discomfort, age over 19, and consent to participate. Shock or cardiac arrest state, refusal to provide consent to participate, and ST-segment elevation myocardial infarction (STEMI) detected in the initial ECG test were all exclusion criteria. After screening, all patients were randomly separated into the intervention and control groups. Both groups had to get ECGs every 15 minutes starting at baseline. The SP-ECG group used the device's time setting, while the control group did not. It was the doctor's order after the patient was allotted a bed (Figure 1).

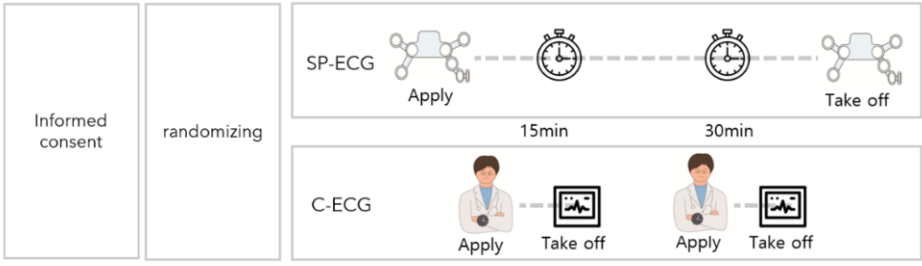

Figure 1. Construction of the study

Patients were randomly divided into two groups after screening. Both groups were instructed to perform ECGs 15 minutes and 30 minutes after the first ECG. The C-ECG group's patients used standard ECG equipment, while the SP-ECG patients had their ECGs recorded automatically using the device's timer. The SP-ECG was authorized as a Holter ECG by the Korean Ministry of Food and Drug Administration (Figure 2). The main body fits into the patch's socket. The tablet and main body are connected through Bluetooth to perform 12-lead ECG exams. The device's main board is a context-m4 DSP board. Analog front-end receives ECG signal from patch via analog-to-digital converter.[4] By clicking the tablet's “upload” button, researchers can transfer ECG exam results in real-time to their dashboards through LTE networks [5].

Follow-up timeliness When an ECG is taken within 3 minutes of the predetermined time. An ECG recorded 14 minutes after the initial ECG is considered timely. Based on initial triage information, age, gender, KTAS, heart rate, body temperature, respiration rate, and blood pressure were recorded.

A paired t-test was used to compare each patient's scores. P .05. The two groups were compared using two-way repeated-measures analysis. Neither group showed statistically significant differences over time, hence no post-analysis was undertaken.

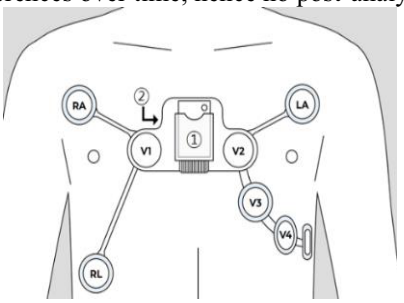

Figure 2. Configuration of the device

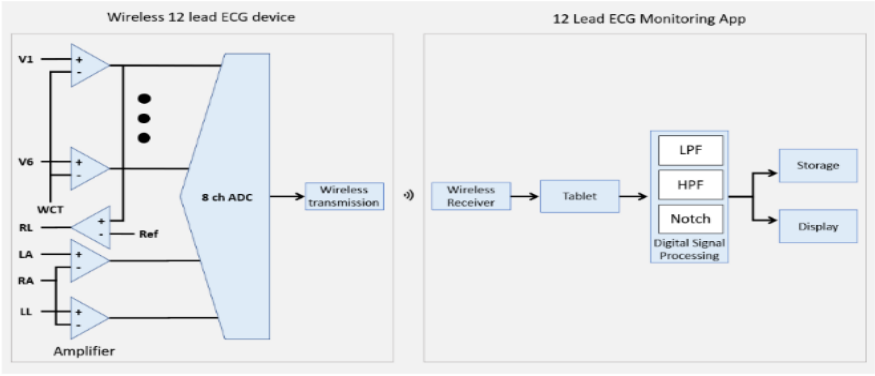

Figure 3. System architecture of Simple patch 12 lead ECG

Amplifier: Amplify analog voltage obtained from Electrode, 8ch ADC(8-channel analog-to-digital converter): Converting an amplified analog signal into a digital signal, Wireless transmission: Wireless transmission of converted digital signals, Wireless Receiver: Receive digital signals wirelessly, Digital signal processing: Compute received digital signals as ECG signals through digital operation, LPF (Low pass filter): Eliminates high frequency noise, HPF (High pass filter) : Eliminates low frequency noise, Notch (Notch filter): Eliminate noise at a certain frequency, eliminate 60 Hz noise used for commercial power sources, Storage: Store processed ECG data, Display: Output processed ECG data into a visualization graph

3. Results

The study included 36 people. The SP-ECG and C-ECG groups had median ages of 63.8 and 58.8 years. The study includes 33 patients out of 36 enrolled. One of the excluded patients requested out due to disorientation. A research breach caused time measurement problems in one person from each group. The final 33 participants averaged 61.06 years (SD: 15.8 years). 14 (42.4%) patients were female, with a KTAS of 3. Other traits showed no significant intergroup variations (Table 1).

Table 1. Demographic information of study participants

	SP-ECG group (N = 17)	C-ECG group (N = 16)	P-value
Age (Yr), mean ± SD	63.7 ± 18.4	58.1 ± 12.5	0.32
Gender			
Female, N (%)	6 (35.2)	8 (50.0)	
Male, N (%)	11 (64.8)	8 (50.0)	
KTAS, N (%)			0.80
-1	0	0	
-2	3 (17.6)	6 (37.5)	
-3	12 (70.6)	5 (31.2)	
-4	2 (11.8)	5 (31.2)	
-5	0	0	
Heart rate (bpm ± SD)	79.4 ± 17.9	79.3 ± 12.6	0.99
Body temperature (°C ± SD)	36.7 ± 0.5	36.7 ± 0.4	0.82
Respiratory rate (Breath/min ± SD)	18.5 ± 2.7	18.1 ± 1.7	0.61
SBP (mmHg ± SD)	133.4 ± 18.4	129.8 ± 18.2	0.57
DBP (mmHg ± SD)	79.7 ± 14.3	81.3± 14.6	0.75

a KTAS : Korean Triage and Acuity Scale b SBP : systolic blood pressure c DBP: diastolic blood pressure

3.1. Main Outcome

Figure 4 compares the time of the two research groups. The first follow-up ECG recording was timely in 87.5 percent of SP-ECG and 47.0 percent of C-ECG groups (P.74). At the second follow-up, it was 75.0% and 35.2% (P.71). Overall, 81.2 percent and 41.1 percent accuracy (P.62). The chart also shows that the C-ECG group's timing was not only outside the specified time window but was also severely delayed. Notably, four C-ECG subjects (4/16) had ECGs recorded more than an hour. Despite of the results, the minor issues have been detected with SP-accuracy. ECG's The device setup and study had four human errors in the test group. The provider should be adequately trained to avoid possible problems during the application. Later, more correction methods will be required. But more research is needed [4].

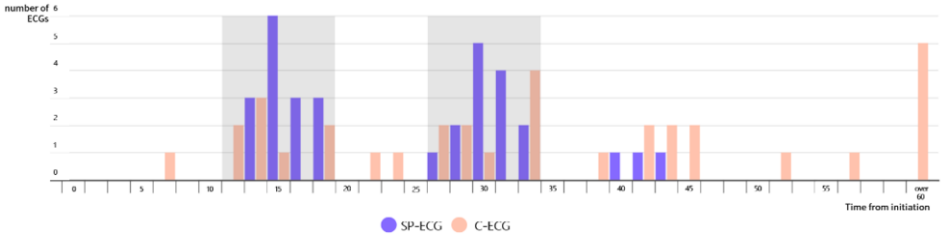

Figure 4. Patients' numbers on time accuracy
SP-ECG: Single Patch 12lead Electrocardiogram C-ECG: Conventional Electrocardiogram

4. Discussion

In addition to identifying substantial results and condensing the difficult process in the emergency room, this study is the first RCT using wireless and single patch ECG in Korea. The device could perform other procedures such as chest X-rays and lab testing without disrupting the emergency department's protocol. No patients had to leave the

study to follow the protocols, and no patients or medical staff had to miss other appointments.
Its correctness has yet to be verified, and small issues were discovered throughout the test. The supplier will need to be properly trained and compensated for future blunders. Human mistake occurred in setting up equipment and conducting research among four subjects in the test group, and to prevent future errors, the provider should be well trained before usage. Human resources will be needed to detect Single patch wireless 12lead ECG [6].

5. Limitations

The study has certain limitations. To begin, the study's patient cohort is not demographically representative. So, we should cross-validate our data with other institutions before drawing broad conclusions. Second, the trial was short-lived, therefore the procedure's impact in the ED couldn't be properly assessed. Finally, just time accuracy was compared and evaluated, leaving out the impact on the test provider's satisfaction, patient outcome, or diagnosis.

6. Conclusions

The ECG is the most significant and commonly done test in the ED to diagnose chest discomfort. The EKG's ST elevation helps distinguish STEMI patients from non-STEMI patients who require rapid treatment. However, about 40% of STEMI patients do not have ST elevation soon after symptom start. So, not only once, but frequently [7]. However, due to ED congestion and staffing shortages, some patients may not receive ECG results on time. To increase ECG timeliness, medical devices must be developed and used to autonomously capture patient ECGs without disrupting ED activities. The patient's examination and treatment processes were significantly faster with minimal disruption.

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