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RAPID COMMUNICATION

Practical Utility of the Postal Service in Delivering a Self-Fitted, Wearable, Long-Term Electrocardiogram Monitoring Device for Outpatient Care

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Background: Demand is growing for remote electrocardiogram (ECG) monitoring systems in the COVID-19 era in Japan. This study describes initial experiences with a small wireless ECG monitoring device and the utility of delivery via the postal service for outpatient care in Japan.

Methods and Results: Long-term ECG monitoring following postal delivery of the small ECG device was evaluated in 25 patients. The patients had no difficulties with either the postal delivery or self-fitting and wearing the devices. A median of 57 h monitoring per patient was performed. Arrhythmic events were detected in 8 patients. Most patients were satisfied with both the ECG devices and postal delivery.

Conclusions: Postal delivery of ECG devices could be used in clinical practice to achieve less or no in-person contact during the COVID-19 era.

Key Words: Coronavirus disease 2019 (COVID-19); Postal delivery; Remote ECG monitoring

The spread of coronavirus disease 2019 (COVID-19) has seriously affected medical systems worldwide. Some hospitals have temporarily closed their outpatient clinics because of COVID-19 clusters, and patients with chronic diseases have tended to avoid going to hospital for fear of contracting the disease. Avoiding regular consultations at hospitals or clinics may result in the worsening of chronic conditions. Currently, there is a growing demand on the part of patients and healthcare workers for remote monitoring systems that use digital technologies to collect medical data from individuals, thus eliminating the need to visit a medical facility in person.[1,2]

A patch-type wireless, real-time electrocardiogram (ECG) monitor (Duranta; ZAIKEN, Tokyo, Japan) has been approved and is already used as a Holter ECG device in Japan.[3,4] Conventionally, patients visit a hospital to have the Duranta attached. After ECG monitoring, the patients return to the hospital so the device can be removed. The Duranta device is small and attaches easily to the chest. Thus, we thought that patients would be able to attach the device themselves and that the device could be sent between the hospital and patients' homes via the postal service. This novel use of the Duranta would allow patients to share telemetry ECG data with their doctors without having to visit the hospital or visiting less often. Here, we report on our initial experience of using the small wireless ECG monitoring device and the utility of delivery via the postal service for outpatient care in Japan.

Methods

We retrospectively analyzed the data of patients who underwent long-term ECG monitoring at Kobe University Hospital between August and December 2020 with a Duranta device that was delivered via the postal service. The purpose of the long-term ECG was to investigate unknown palpitations or unknown syncope, and to follow-up tachy- or bradyarrhythmias after catheter ablation.

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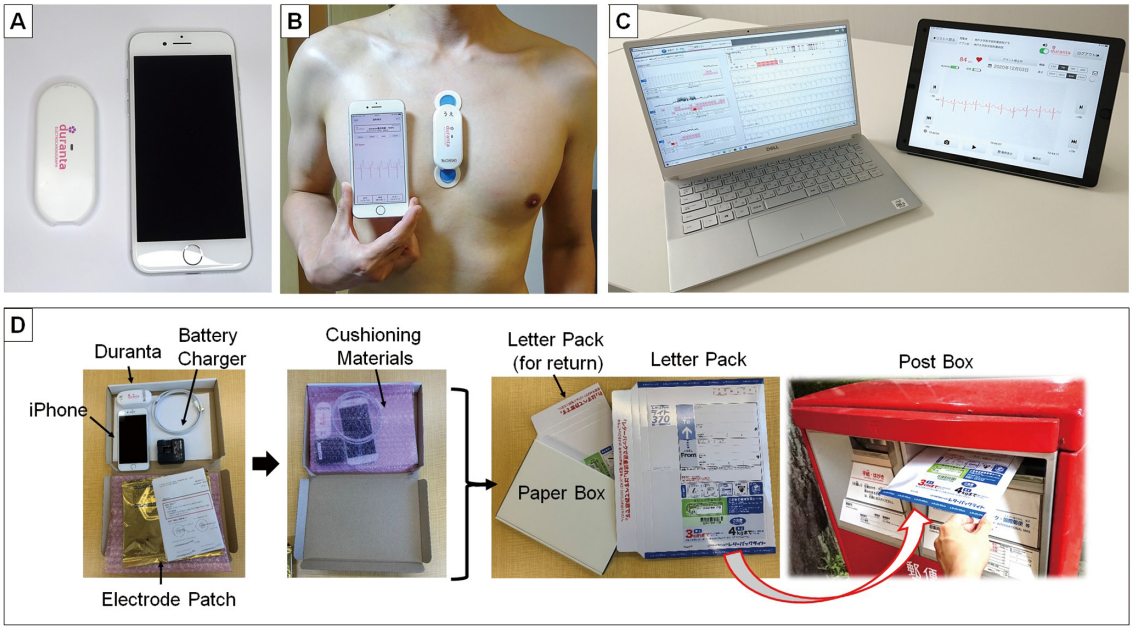

Figure 1. Electrocardiogram (ECG) monitoring system (Duranta) and the delivery method. (**A**) The Duranta and iPhone for transmitting ECG data. (**B**) The Duranta is easy to attach to the chest via 2 electrode patches. Real-time ECG data can be seen on the iPhone. (**C**) The doctors and medical staff can see the real-time ECG on an iPad and analyze the data on a computer at the hospital. (**D**) Delivery method for the ECG devices. A Duranta, an iPhone, a battery charger, and electrode patches are surrounded by cushioning material and packed in a small cardboard box (225 mm wide × 160 mm deep × 22 mm thick). The box is put in a prepaid envelope (Letter Pack Light; Japan Post) and posted to patients. When the ECG devices are sent from the hospital to patients' homes, a return envelope is also included. The Letter Pack can be put in a postbox.

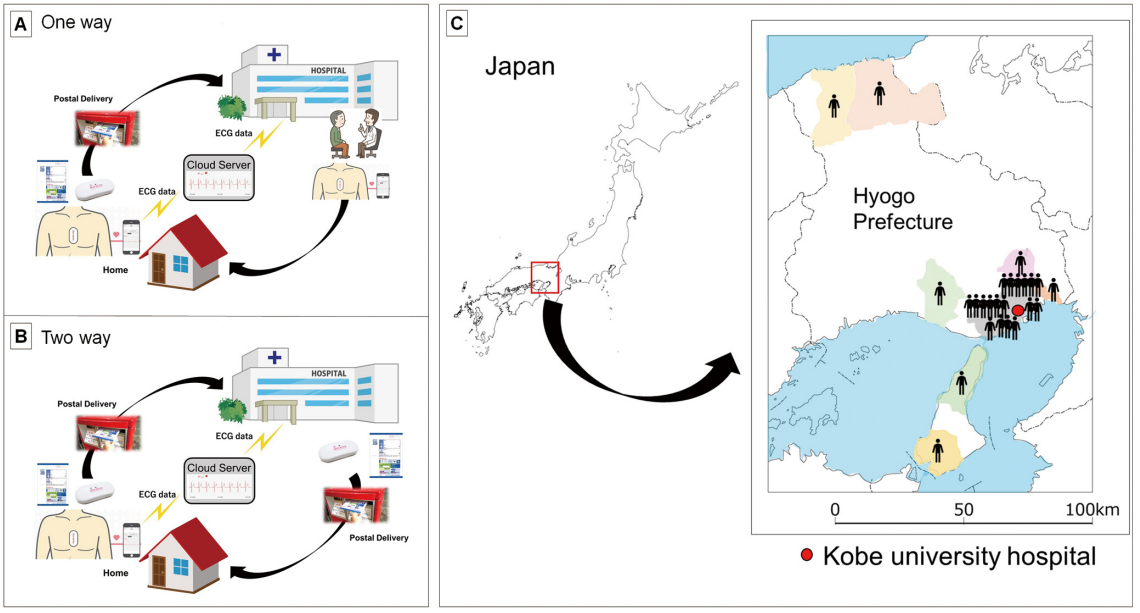

Figure 2. Delivery of electrocardiogram (ECG) devices. (**A**) "One-way" delivery: the device is attached to a patient at the outpatient clinic. ECG monitoring is performed for the scheduled period; after long-term ECG monitoring, the patients send the ECG device to the hospital by post. (**B**) "Two-way" delivery: the doctors or medical staff send the ECG devices to patients' homes by post on the scheduled day and patients put the device on at home. After long-term ECG monitoring, the patients send the devices back to the hospital by post. (**C**) Map showing the distribution of patients in the present study relative to Kobe University Hospital. The median distance to Kobe University Hospital from patients' homes was 10 km (range 1.1–183 km).

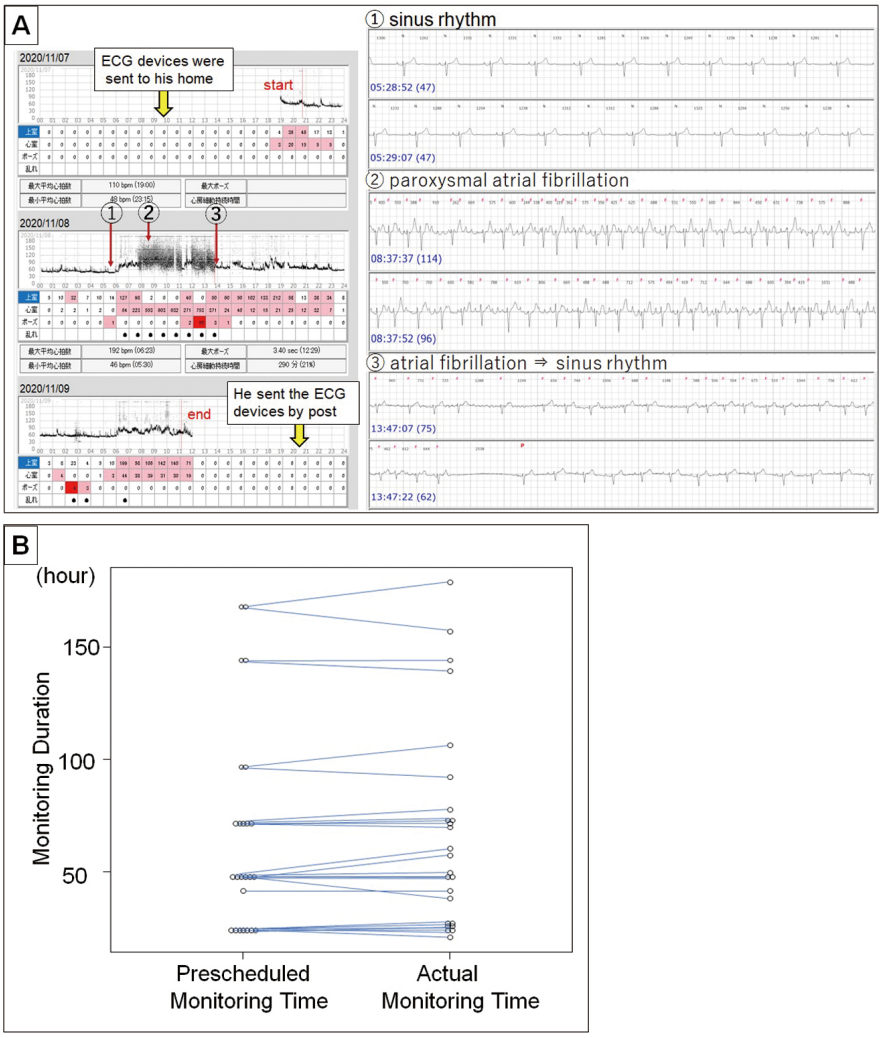

Figure 3. Long-term electrocardiogram (ECG) monitoring. (**A**) Representative case. The patient was a 73-year-old man who had undergone atrial fibrillation catheter ablation 3 months previously. The patient sometimes suffered palpitations. ECG monitoring was performed using a Duranta device delivered by the postal service. The ECG device arrived at the patient's home on the scheduled day. He put the device on himself, and ECG monitoring started. The next day, the patient felt palpitations, and paroxysmal atrial fibrillation was recorded by the Duranta. On the third day, the ECG monitoring ended. The patient sent the ECG device back to the hospital by post. By using this postal delivery service, the patient did not need to visit the hospital to undergo long-term ECG examination. (**B**) Relationship between the prescheduled and actual monitoring time. The doctors and patients decided on the duration of ECG monitoring before the examination. ECG monitoring using the self-fitted wearable devices could be performed as planned in most patients.

This study was conducted in accordance with the Declaration of Helsinki and the Ethical Guidelines for Medical and Health Research Involving Human Subjects. The protocol for this research project was approved by the Ethics Committee of Kobe University Hospital (Approval no. B200276). The patients consented to the use of their anonymized clinical data for research purposes by the opt-out method.

ECG Devices

The details of the Duranta wireless, patch-type ECG monitoring device have been reported elsewhere.[3,4] The Duranta device is small (78.4 mm wide×35.1 mm deep×14.7 mm thick), light (35 g), and easy to attach to the chest via 2 patch electrodes (**Figure 1A**,**B**). The battery lasts up to 7 consecutive days without charging. ECG data are automatically transmitted to a cloud server via a dedicated iPhone. Medical staff can access the cloud server using a personal ID and password and can see the ECG of patients on an iPad in real time and can download the ECG data to a computer in the hospital (**Figure 1C**). Patients' personal information was not input into the ECG devices; therefore, there was no risk of personal data leakage during delivery of the ECG devices.

Postal Delivery Method

Figure 1D shows how the ECG devices were delivered. The ECG devices were put in a prepaid envelope (Letter Pack

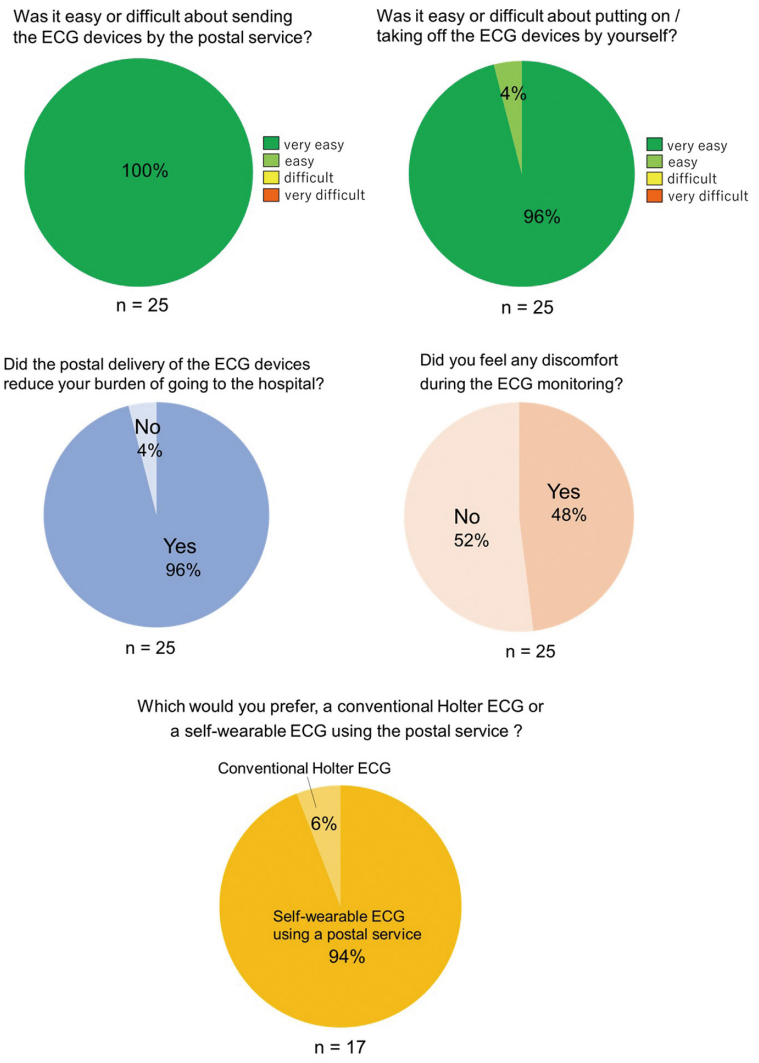

Figure 4. Results of the patient survey regarding patient acceptance of the postal delivery and use of self-fitted wearable electrocardiogram (ECG) monitoring devices.

Light; Japan Post). The Letter Pack Light format can be used to send items that are up to 3 cm thick. The cost of postage price throughout Japan is 370 yen (~US$3.50), including tracking and confirmation of delivery. The Letter Pack Light can be put in any postbox in Japan. Usually, the Letter Pack Light arrives at its destinations within 1–2 days.

There were two methods of postal delivery of ECG devices: "one way" and "two way" (**Figure 2A,B**). All ECG devices and iPhones were sterilized using an 80% ethyl alcohol swab after they were returned to the hospital. The electrode patches were disposable.

Statistical Analysis

The distribution of continuous variables was examined using the Shapiro-Wilk test for normality. For continuous variables with a normal distribution, data are presented as the mean±SD, whereas those that were not normally distributed are presented as the median and range. Two-sided $P<0.05$ was considered to indicate significant differences and all statistical analyses were conducted using R version 2.13.0 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient Characteristics and Postal Delivery

In all, 25 patients (age 63±16 years [range 15–82 years]; 17 male) underwent long-term ECG monitoring using a Duranta device delivered via the postal service. The purpose of the long-term ECG monitoring was to investigate unknown palpitations (n=3) and unknown syncope (n=3), to follow-up tachyarrhythmias after catheter ablation (n=18), and to follow-up bradycardias (n=1). Three of the 25 patients (12%) had dementia and needed assistance in daily life. **Figure 2C** shows the distribution of patient throughout Hyogo Prefecture. The median distance to Kobe University Hospital from the patients' homes was 10 km (range 1.1–183 km).

Of the 25 patients, 13 used the "one-way" service and 12 used the "two-way" service. All ECG devices arrived at the patients' homes or the hospital on the scheduled day. There were no mechanical issues with the ECG devices during postal delivery or during monitoring.

Duration of ECG Monitoring and Detection of Arrhythmia

Patients underwent a median of 57 h (range 20–179 h) of ECG monitoring. **Figure 3A** shows a representative case of ECG monitoring. **Figure 3B** shows the relationship between the prescheduled and actual ECG monitoring duration for each patient. ECG monitoring was performed as planned in most cases. Arrhythmic events were detected in 8 of 25 patients (32%), atrial fibrillation (AF) was detected in 5 patients, atrial tachycardia was detected in 2 patients, and frequent premature ventricular contractions was detected in 1 patient.

Noises and Interruption During ECG Monitoring

Electromyographic noise, electrode motion artifacts, and temporary interruption of ECG signals were observed. The median percentage of the total duration of noise signals and temporary interruption during the entire duration of monitoring was 0.9% (range 0.1–4.5%).

Patient Survey

Figure 4 shows the results of the patient survey regarding the long-term ECG monitoring and postal delivery service. Most patients had no difficulty sending the devices by post and no difficulty putting on or taking off the ECG device by themselves.

Of the patients, 12 (48%) felt itchiness or irritation at the sites of the electrode patches during the ECG monitoring but were able to continue with ECG monitoring by slightly changing the location of the patches on the chest. Seventeen of the 25 patients had experienced conventional Holter ECG monitoring before. Sixteen of these 17 patients (94%) preferred self-fitting wearable ECG monitoring and the postal delivery service over conventional Holter ECG monitoring because the Duranta device is wireless, smaller, and lighter than the conventional Holter ECG device (n=9), and it was extremely convenient to use the postal service to return the devices rather than having to go into the hospital (n=7).

Discussion

There has been a strong demand for remote monitoring devices to gather data with no or less in-person contact.[1] Various types of wearable monitoring devices with higher accuracy, specificity, and sensitivity have been developed.[5] However, there are disadvantages regarding the use of wearable devices for older patients that relate to the design of the devices, appropriate and timely feedback, user-friendliness, and cost.[6] In the present study, we provide evidence of high patient acceptance of a self-fitted wearable ECG device and sending the device by post. The Japanese postal service is known for its reliable, fast, and high-quality service, and it was able to deliver the ECG devices in 1 or 2 days with no difficulty. There are approximately 180,000 postboxes in Japan; therefore, there was no need for patients to visit the hospital for the device to be put on or taken off. Instead, patients were able to put the device on and take it off themselves and, after taking it off, simply put the ECG device in the nearest postbox to return it to the hospital, thus reducing patient burden. Patients of different ages (range 15–82 years) were enrolled in the present study. Some had dementia and needed partial assistance in daily life. However, none had any difficulty wearing the ECG devices or sending them back to the hospital by post, which suggests that this method could also be used in other clinical settings.

Telehealth

Since the emergence of the COVID-19 pandemic, telehealth and online consultations have been gaining attention worldwide. The market for telehealth continues to grow rapidly.[7] However, one of the shortcomings of telehealth is the lack of information about the body during the online appointment. With the postal delivery of ECG devices before the online consultation, the doctor could see the real-time ECG during the online consultation.

Screening and Early Detection of AF

Asymptomatic AF has been independently associated with an increased risk of stroke and mortality compared with symptomatic AF.[8] A recent study showed that early rhythm control therapy for AF is associated with a lower risk of cardiovascular outcomes than the usual rate control therapy.[9] Therefore, a recent guideline has recommended opportunistic screening for AF by taking the pulse or an ECG rhythm strip in patients aged ≥65 years.[10] The postal delivery of ECG devices and long-term ECG screening can be used as a tool for AF screening as part of the medical checkup in high-risk populations.

Home Care of Elderly Patients

Japan is the world's most aged country. The long-term care insurance system in Japan was started in 2000, and many elderly patients have since received home care services. Some elderly patients have difficulty visiting medical facilities on a regular basis due to low activities of daily living. In such cases, the family doctor can send an ECG device by post, and the family or home care worker can attach the device to the patient's chest. If the ECG shows any abnormalities, the family doctor can share the ECG data with a cardiologist and ask them how best to deal with the arrhythmia. This would be particularly useful in areas in Japan where there is poor access to medical facilities.

Areas for Improvement

The actual monitoring duration did not reach the prescheduled duration in some patients. In addition, the quality of ECG monitoring differed considerably among the patients. To improve monitoring quality, precise oral and written instructions for patients on how to use the self-fitting, wearable ECG device should be provided for patients depending on their age and level of understanding. Approximately 48% of patients felt itchiness or irritation at the sites of the electrode patches during the long-term ECG monitoring. The adhesive material for the electrode patches should be improved.

Study Limitations

First, this study was a retrospective study, and the number of the patients was small. A further prospective study will be needed to establish the convenience and efficacy of the ECG monitoring system delivered via the postal service compared with conventional ECG monitoring methods. Second, patients with severe dementia and bedridden patients were not enrolled in the present study. Therefore, the results may not be generalizable to some patient populations.

Conclusions

Wearable ECG devices delivered via the postal service can

safely monitor and record long-term ECG data in patients with no or less in-person contact. The patients in this study were highly satisfied with the system because it reduced their burden of having to visit the hospital. This system could be used for other types of patient care, such as telehealth, home care, and arrhythmia screening.

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Disclosures

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IRB Information

The research protocol was approved by the Ethics Committee of Kobe University Hospital (Approval no. B200276).

Data Availability

Individual deidentified participant data will not be shared.

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