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

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Abstract

Introduction: In the COVID-19 era, demand is growing for remote ECG monitoring systems with less or no in-person contact. However, the practical usage of wearable ECG devices has been little studied in Japan. This study aimed to report our initial experience of using the postal system in the delivery of the self-wearable ECG device (Duranta) and long-term ECG monitoring in outpatient care. Methods: The Duranta is small, light (35 g), and easy to attach to the chest with two patch electrodes. Real-time ECG data were automatically transmitted to a cloud server via iPhones. The devices were packed in prepaid envelopes that could be put in any postbox for delivery between the hospital and patients' homes. Results: Twenty-five patients (61 ± 17 years) were enrolled. The median distance to the hospital from the patients' homes was 10 km (range: 1.1–183). The patients had no difficulties with either the postal delivery or wearing the ECG devices. A total of 57 hours (range: 20–179) of ECG monitoring per patient was performed, and the data were successfully transmitted to the hospital. The median percentage of noise/artifact burden during the ECG monitoring was 0.9%. Arrhythmic events were observed in 8 patients. Most patients were satisfied with the ECG system and delivery via the postal service. Conclusion: The use of a postal delivery of a wearable ECG device could work in clinical practice with to achieve less or no in-person contact. This system can be applicable for telehealth, home care, and arrhythmia screening.

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Key Words

remote ECG monitoring, Holter ECG, postal delivery service, COVID-19

Introduction

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

A patch-type wireless, real-time electrocardiogram (ECG) monitor (Duranta; ZAIKEN Co., Ltd. Tokyo, Japan) has been approved and already used as a Holter ECG device in Japan.[3, 4] Conventionally, patients visit the hospital to have the Duranta attached. After the ECG monitoring, the patients return to the hospital to remove the device. The device is small (35 g) and attaches easily to the chest using two electrode patches. We therefore thought that patients could attach the device themselves and that the device could be sent via the postal service between the hospital and the patients' homes. This novel usage of the Duranta would allow patients to share the telemetry ECG data with their doctors without visiting the hospital or visiting less often. Here, we report the initial experience of using the small wireless ECG monitoring device and the utility of delivery via the postal service in 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 the Duranta device that was delivered via the postal service. The data including patient characteristics, the method of delivery, ECG monitoring duration, detection of arrhythmia, and any noises or signal interruption during the ECG monitoring were analyzed. In addition, we surveyed the patients to quantify their satisfaction regarding the self-wearable ECG monitoring device delivered via the postal service. The protocol for this research project was approved by the Ethics Committee of Kobe University Hospital (Approval no. B200276).

ECG devices

The details of the wireless, patch-type ECG monitoring device (Duranta; medical device certificate number in Japan: 226AIBZX00055000) were previously reported.[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 two patch electrodes (**Figures 1A, 1B**). The battery lasts up to seven consecutive days without charging. The patients detach the device to bathe and reattach it afterwards. The ECG data is automatically transmitted to the cloud server via a dedicated iPhone. The patients can see their own ECG on the iPhone. Medical staff can access the cloud server using a personal ID/password and can see the real-time ECG of the patients on an iPad and download the ECG data to a computer in the hospital (**Figure 1C**). The patients' personal information was not input in the ECG devices (the Duranta and the iPhone); therefore, there was no risk of personal date leakage during delivery of the ECG devices.

Postal Delivery Method

Figure 1D shows how the ECG devices are delivered. The Duranta, iPhone, battery charger, and electrode patches were surrounded by cushioning materials and packed in a small paper box. The box and written instructions for the ECG device were put in a pre-paid envelope (Letter Pack Light, Japan Post). The Letter Pack Light format can be used to send items that weigh up to 4 kg with thickness up to 3 cm. The price is 370 yen ([?]$3.50) throughout Japan, including tracking and confirmation of delivery. When the ECG devices were sent from the hospital to patients' homes, the package included a return envelope. The Letter Pack can be put in any postbox in Japan. Usually, the Letter Pack arrived at their destinations in 1–2 days.

The postal delivery of the ECG devices was performed in two different ways called the "One way" and the "Two way" (**Figure 2**). "One way" indicates that the patients attached the ECG devices when they visited a outpatient clinic. After long-term ECG monitoring at home, they sent the devices back to the hospital by post. "Two way" indicates that medical staff sent the ECG devices to patients' homes by post on a prearranged day and the patients attached the device at home. After long-term ECG monitoring, the patients sent the devices back to the hospital by post. All ECG devices and iPhones were sterilized with an 80% ethyl alcohol swab after they were returned to the hospital. The electrode patches were disposable.

Statistical Analysis

Continuous variables were examined using the Shapiro–Wilk test for normality. For continuous variables of normal distribution, the data were presented as means +- standard deviation (SD). For the non-normal distribution, the data were presented as medians (ranges). Spearman's rank correlation was used to investigate the relationship between the percentage of noise duration and the actual monitoring time. The p-values are two-sided. A p-value of < 0.05 was considered to indicate statistical significance. All statistics were calculated using R statistical software (version 2.13.0, R Foundation for Statistical Computing, Vienna, Austria).

Results

Patients characteristics and the postal delivery

A total of 25 patients (63+-16 years, 17 male) underwent long-term ECG monitoring using the Duranta delivered via the postal service.**Table 1** shows the patient characteristics. The purpose of the long-term ECG monitoring was to investigate unknown palpitations (n = 3) and unknown syncope (n = 3), to follow up the tachyarrhythmias after the catheter ablation (n = 18), and to follow up the bradycardia (n = 1). Three of the 25 patients (12%) needed assistance in daily life. **Figure 3** shows the distribution map of the patients enrolled in the study. The median distance to the Kobe University Hospital from patients' homes was 10 km (range: 1.1–183 km).

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

ECG monitoring duration and arrhythmia detection

The patients or their families had no difficulty attaching the ECG device. A median 57 hours (range: 20–179 hours) of ECG monitoring per patient was performed. **Figure 4** shows the relationship between the prescheduled ECG monitoring duration and the actual ECG monitoring duration for each patient. Monitoring the ECG was performed as planned in most cases. **Figure 5** shows a representative case of ECG monitoring. By utilizing the postal delivery service, this patient did not need to visit the hospital to undergo the long-term ECG examination. Arrhythmic events were detected in 8 of the 25 patients (32%), atrial fibrillation (AF) in 5 patients, atrial tachycardia in 2 patients, and frequent premature ventricular contractions in 1 patient.

Noises and interruption during ECG monitoring

The electromyographic noise, the electrode motion artifacts, and the temporary interruption of ECG signals were observed (**Figure 6A**). The median percentage of the total duration of noise signals and temporary interruption during the whole monitoring duration was 0.9% (range 0.1–4.5%). **Figure 6B** shows the relationship between the monitoring duration and the percentage of the noises/interruption of the monitoring. The monitoring duration did not have a significant correlation with the duration of the noises and the ECG signal interruption.

Patient survey

Figure 7 shows the results of the patient survey regarding the long-term ECG monitoring and the 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. Most patients thought the postal delivery of ECG devices could reduce patient burden in terms of going to the hospital.

Of the patients, 12 (48%) felt itchiness or irritation at the sites of the electrode patches during the ECG monitoring but could continue to undergo 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 the self-wearable ECG monitoring and the postal delivery service over the 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 to the hospital (n = 7).

Discussion

There has been 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 invented.[5] However, Ferguson et al.[6] state there are disadvantages regarding the adoption of wearable devices for older patients; these relate to the design of the devices, appropriate and timely feedback, user-friendliness, and cost. In the present study, we provide evidence of high patient acceptance of self-wearing an ECG device and sending the device by post. The Japanese postal service is known for its reliable, fast, and high-quality service that is 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 to put on or take off the ECG device. Instead, the patients just put the ECG devices in the nearest postbox to return them to the hospital, thus reducing patient burden. In terms of the cost, patients did not need to pay an additional charge for postal delivery. The cost of postal delivery was only around $3.50 everywhere in Japan. All ECG devices were sterilized and could be used for the next examination. The medical cost performance of the self-wearable ECG monitoring device delivered via the postal service would be high for both patients and medical facilities.

Patients of different ages (range: 15–82 years old) were enrolled in the present study. Some had dementia and needed partial assistance in daily life. However, there was no difficulty with wearing the ECG devices or sending them back to the hospital by post, which suggests that this method would be applicable in other clinical practices.

1) 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.

2) Screening and early detection of atrial fibrillation

Asymptomatic AF has been independently associated with an increased risk of stroke and mortality compared with symptomatic AF.[8] A recent study shows 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 pulse taking or ECG rhythm strip in patients $>\_65$.[10] The postal delivery of the ECG devices and the long-term ECG screening would be applicable as a tool for AF screening in medical checkups in high-risk populations.

3) 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 activity 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 would share the ECG data with a cardiologist and ask them how to deal with the arrythmia. This would be particularly useful in areas in Japan where there is poor access to medical facilities.

Points to be improved

The actual monitoring duration did not reach the prescheduled duration in some patients. The percentage of noises or interruption during ECG monitoring and actual monitoring time did not show any significant correlation, which suggests that the ECG monitoring quality largely differed among the patients. To improve the monitoring quality, precise oral and written instructions for patients on how to use the self-wearing ECG device should be provided for patients depending on 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 of the electrode patches should be improved.

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 other patient populations.

Conclusion

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 were highly satisfied with the system, as it reduced the patient burden of visiting the hospital. This system would be applicable in other patient care, such as telehealth, home care, and arrhythmia screening.

Acknowledgement

None

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Table 1. Patient characteristics

Age* [range] (year)	63 $\pm$ 16 [15-82]
Male sex^{+}	17 (77)
BMI*	25 $\pm$ 4
Distance to the hospital [range] (km)	10 [1.1-183]
LVEF* (%)	60 $\pm$ 8
NYHA $^{+}$ I	20 (80)
II	4 (16)
III	1 (4)
IV	0 (0)
Dementia^{+}	3 (12)
Hypertension^{+}	12 (48)
Diabetes $^{+}$	4 (16)
Stroke^{+}	3 (12)
Coronary artery disease^{+}	4 (16)
Chronic kidney disease^{+}	4 (16)
Activities of Daily Living:	
Autonomous^{+}	22 (88)
Needs partial assistance^{+}	3 (12)
Needs assistance, bedridden^{+}	0 (0)
Style of Living:	
Living alone^{+}	5 (20)
Living together with family^{+}	20 (80)
Purpose for the long-term ECG	
Unknown palpitations^{+}	3 (12)
Unknown presyncope^{+}	3 (12)
Follow-up the tachyarrhythmia after catheter ablation^{+}	18 (72)
Follow-up the bradycardia^{+}	1 (4)

*, mean±SD; $^{+}$, n (%); BMI, body mass index; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association functional classification; ECG, electrocardiogram.

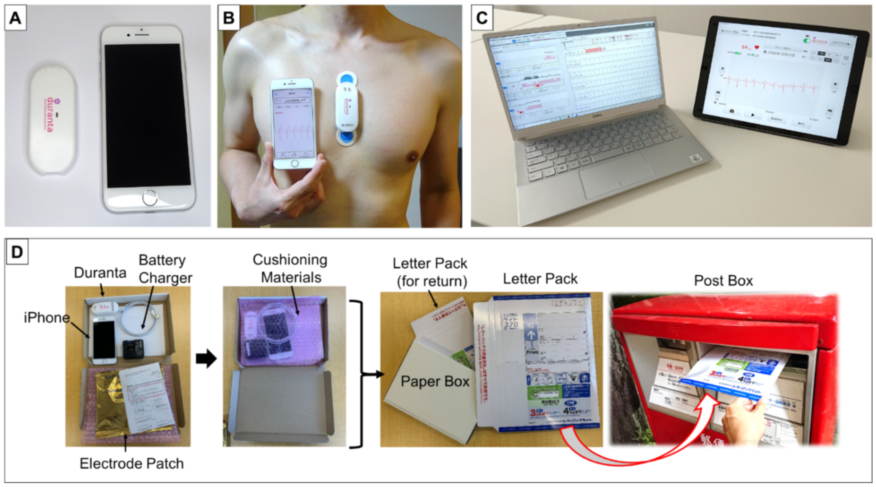

Figure 1. ECG monitoring system (Duranta) and the delivery method. (A) The Duranta and the iPhone for transmitting ECG data. (B) The Duranta is easy to attach to the chest via two electrode patches. The real-time ECG data can be seen on the iPhone. (C) The doctors and medical staff can see the ECG on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

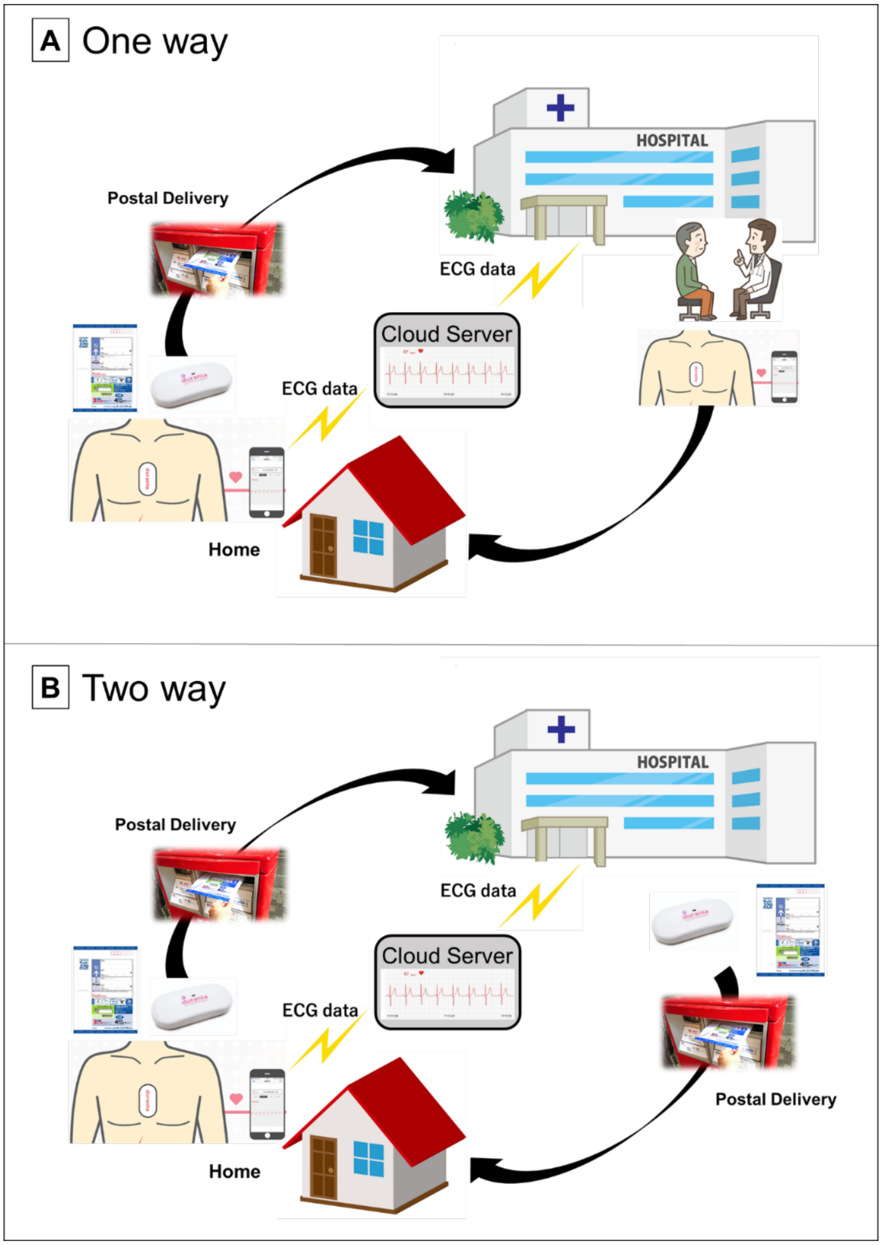

Figure 2. ECG delivery system between the hospital and patient's home. (A) "One way": The patient attached the device at the outpatient clinic. The ECG monitoring was performed during the scheduled period. After the long-term ECG monitoring, the patients sent the ECG device to the hospital by post. (B) "Two way": The doctors or medical staff sent the ECG devices to the patients' homes by post on the scheduled day. The patients put the device on at home. After the long-term ECG, the patients sent the devices back to the hospital by post. ECG, electrocardiogram.

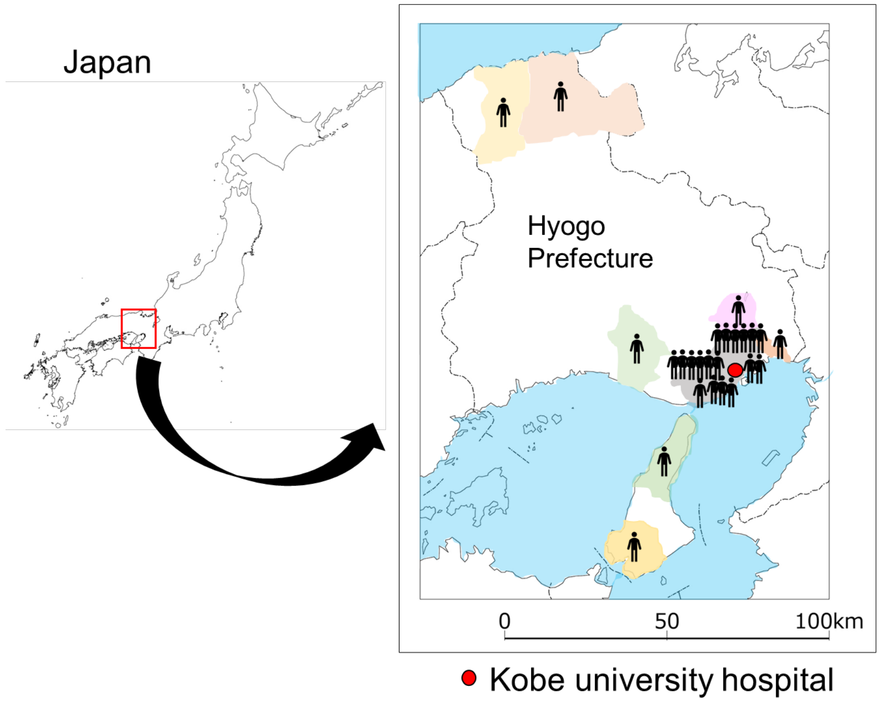

Figure 3. Patients distribution map in the present study. Kobe University Hospital is located in Kobe, the prefectural capital of Hyogo, Japan. Most patients live in Kobe City, but some live in the rural area of Hyogo Prefecture. The median distance to Kobe University Hospital from patients' homes is 10 km (range: 1.1–183 km).

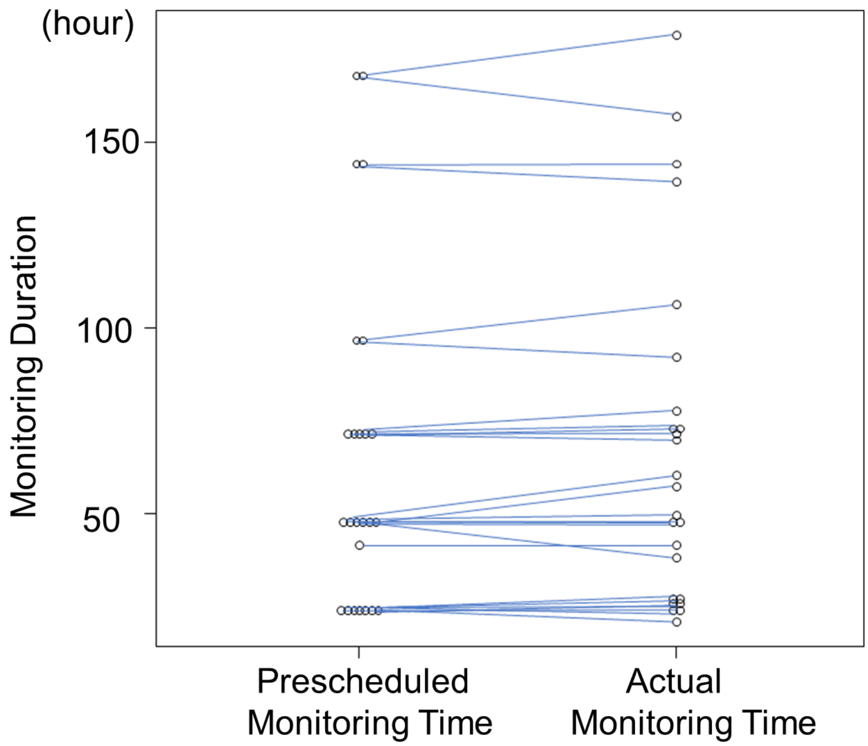

Figure 4. Relationship between the prescheduled monitoring time and the actual monitoring time

The doctors and the patients decided the duration of the ECG monitoring before the examination. The dots on the left indicate the prescheduled monitoring time. The dots on the right indicate the actual monitoring time. The ECG monitoring by self-wearing devices could be performed as planned in most of the patients. ECG, electrocardiogram.

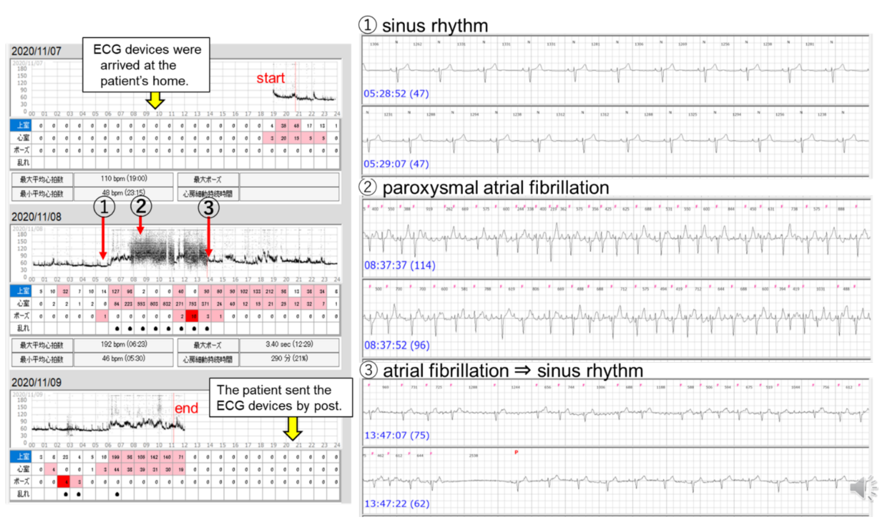

Figure 5. Representative case. The patient was a 73-year-old man who underwent atrial fibrillation

catheter ablation 3 months ago. He sometimes suffered palpitation. We performed the ECG monitoring using the Duranta delivered by the postal service. The ECG device arrived at the patient's home on the scheduled day. He put the device on by himself, and ECG monitoring started. On 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. ECG, electrocardiogram.

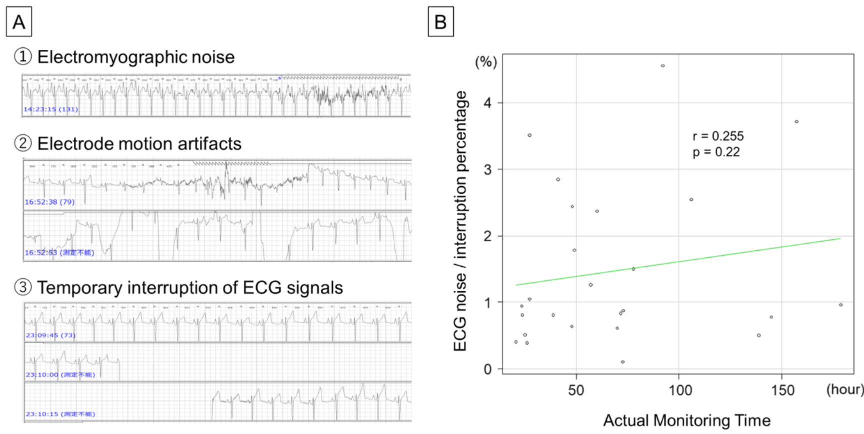

Figure 6. Noises or temporary interruption of ECG signals during the monitoring. (A) Noises or temporary interruption of ECG signals were observed during the ECG monitoring:1) electromyographic noise; 2) electrode motion artifacts; 3) temporary interruption of ECG signals due to longer distance (over 3–5 m) between the Duranta and the iPhone. (B) The graph shows the relationship between the actual monitoring time and ECG noises/interruption percentage. ECG, electrocardiogram. r, correlation coefficient.

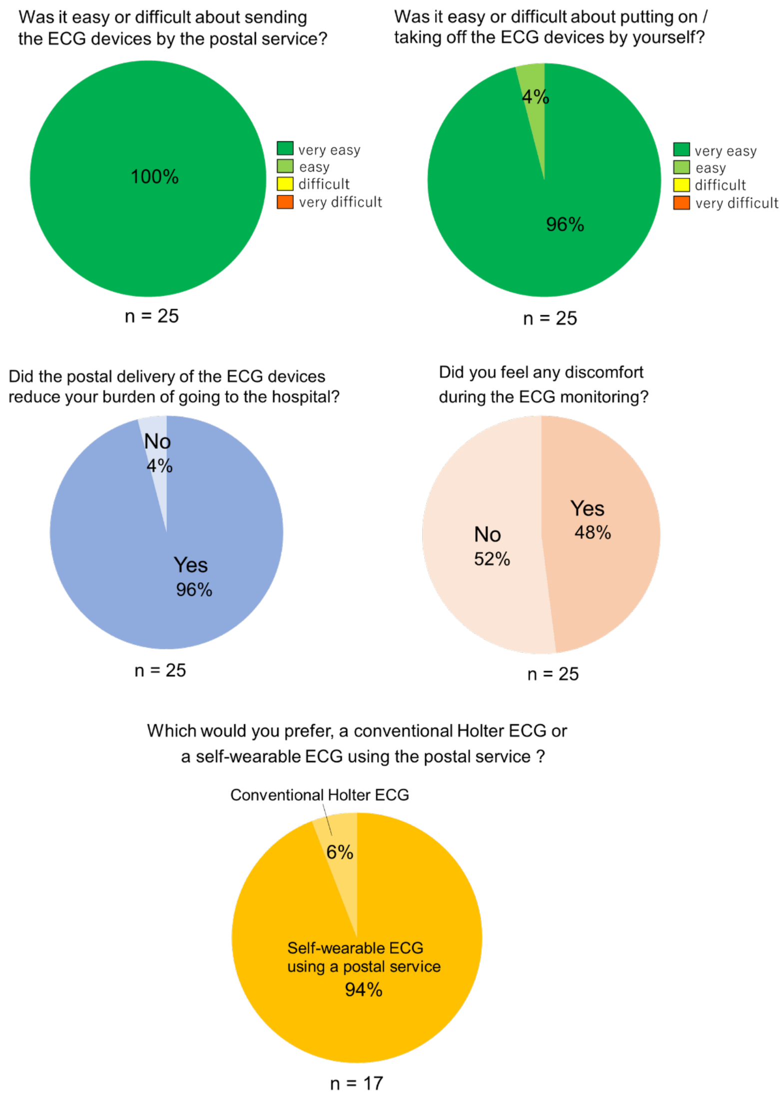

Figure 7. Results of the patient survey

ECG, electrocardiogram.