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Clinical Research

Evaluation of the Diagnostic Performance and Efficacy of Wearable Electrocardiogram Monitoring for Arrhythmia Detection after Cardiac Surgery

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Background: Postoperative atrial fibrillation (A-fib) is a serious complication of cardiac surgery that is associated with increased mortality and morbidity. Traditional 24-hour Holter monitors have limitations, which have prompted the development of innovative wearable electrocardiogram (ECG) monitoring devices. This study assessed a patch-type wearable ECG device (MobiCARE-MC100) for monitoring A-fib in patients undergoing cardiac surgery and compared it with 24-hour Holter ECG monitoring.
Methods: This was a single-center, prospective, investigator-initiated cohort study that included 39 patients who underwent cardiac surgery between July 2021 and June 2022. Patients underwent simultaneous monitoring with both conventional Holter and patch-type ECG devices for 24 hours. The Holter device was then removed, and patch-type monitoring continued for an additional 48 hours, to determine whether extended monitoring provided benefits in the detection of A-fib.
Results: This 72-hour ECG monitoring study included 39 patients, with an average age of 62.2 years, comprising 29 men (74.4%) and 10 women (25.6%). In the initial 24 hours, both monitoring techniques identified the same number of paroxysmal A-fib in 7 out of 39 patients. After 24 hours of monitoring, during the additional 48-hour assessment using the patch-type ECG device, an increase in A-fib burden (9%→38%) was observed in 1 patient. Most patients reported no significant discomfort while using the MobiCARE device.
Conclusion: In patients who underwent cardiac surgery, the mobiCARE device demonstrated diagnostic accuracy comparable to that of the conventional Holter monitoring system.

Keywords: Thoracic surgery, Electrocardiography, Holter electrocardiography, Patch type single lead ECG, MobiCARE MC-100

Introduction

Atrial fibrillation (A-fib) is the most common complication of cardiac surgery, with incidence rates of 25%–30% after coronary artery surgery, 30% after valve surgery, and 40%–60% after combined coronary artery and valve surgery [1,2]. Postoperative A-fib is strongly associated with an increased risk of mortality and complications after cardiac surgery. It is a significant independent predictor of various complications, including elevated stroke risk by 2–4 times; the need for reoperation due to bleeding, infections, renal failure, respiratory failure, and cardiac arrest; and the need for permanent pacemaker insertion. Furthermore, A-fib is correlated with a doubled risk of 30-day and 6-month mortality [3-5]. Arrhythmias lead to substantial healthcare costs, and with increasing age, higher expenditures and utilization of healthcare resources due to arrhythmias have been reported [6].

To accurately diagnose arrhythmia, electrocardiograms (ECGs) corresponding to patients' symptoms are essential. The 24-hour Holter monitor has been widely used as the "gold standard" for diagnosing arrhythmias in both symptomatic and asymptomatic patients in clinical settings over extended periods [7]. However, the traditional Holter mon-

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itor ECG devices have several limitations, including the use of 12 leads, which can be cumbersome for patients; device weight; low sensitivity; wired data transmission; and challenges associated with prolonged use. To address these limitations, the development and commercialization of more user-friendly wearable ECG-monitoring devices has been focused upon. These innovative wearable/ambulatory ECG monitoring devices aim to overcome the drawbacks of existing systems. They offer an improved user experience, lighter weight, enhanced sensitivity, wireless data transmission capabilities, and seamless long-term usability. These wearable devices boast a lightweight and compact design for effortless portability while maintaining noise levels and signal quality, comparable to those of their conventional counterparts. They efficiently manage energy consumption, enable prolonged monitoring periods, and allow wireless data transmission. The combination of these advantages has the potential to significantly improve patients' quality of life [8].

In recent years, studies have aimed to utilize these wearable devices for preoperative and postoperative patient management [9]. The patch-type wearable ECG device (MobiCARE-MC100; Seers Technology, Pyeongtaek, Korea) used in this study was developed to diagnose arrhythmias using Holter monitoring. This device is lighter than the conventional Holter ECG devices and has a much smaller contact area using a single lead; therefore, it can be easily applied. Furthermore, it allows 72 hours of monitoring using a single battery. It also provides wireless data transmission without requiring a separate storage device. Additionally, this device is equipped with a built-in accelerometer and gyroscope sensors, enabling the measurement of patient's physical activity before and after surgery, which could potentially serve as an alternative to cardiopulmonary function assessments.

In this study, we aimed to evaluate the efficacy, user-friendliness, and safety of a lightweight and compact wearable ECG device, the "MobiCARE-MC100," for monitoring arrhythmia (especially A-fib) in patients undergoing open cardiac surgery, and to compare its performance with the existing 24-hour Holter ECG monitor.

Methods

Study population

This is a single-center, prospective, investigator-initiated pilot study. We screened patients with preoperative sinus rhythm admitted to a single institution from July 2021 to June 2022 for cardiac surgery, such as on-pump or off-pump coronary artery bypass grafting, cardiac valve replacement or repair, thoracic aortic replacement, and other intracardiac interventions, all of which involved cardiopulmonary bypass and cardiac arrest. Patients with previous histories of A-fib, emergent surgery, concomitant surgical ablation, or a low left ventricular ejection fraction (<35%) were excluded from the study. Of the 42 patients, 3 were excluded because of consent withdrawal, recording errors due to device detachment, or severe skin irritability. Finally, 39 patients were included (Fig. 1).

This study was approved by the Institutional Review Board of Ajou University Hospital (AJIRB-MED-INT-21-265) and complied with the Declaration of Helsinki. Written informed consent was obtained from all patients.

Study protocol

On the second day after cardiac surgery, the patients underwent simultaneous conventional Holter monitoring (CardioMem 3-channel, 7 leads; GE Healthcare, Chicago, IL, USA) and patch-type ECG monitoring (MobiCARE-MC100; Seers Technology). After completing 24-hour ECG monitoring using both devices, the Holter device was removed, and the patients continued additional ECG moni-

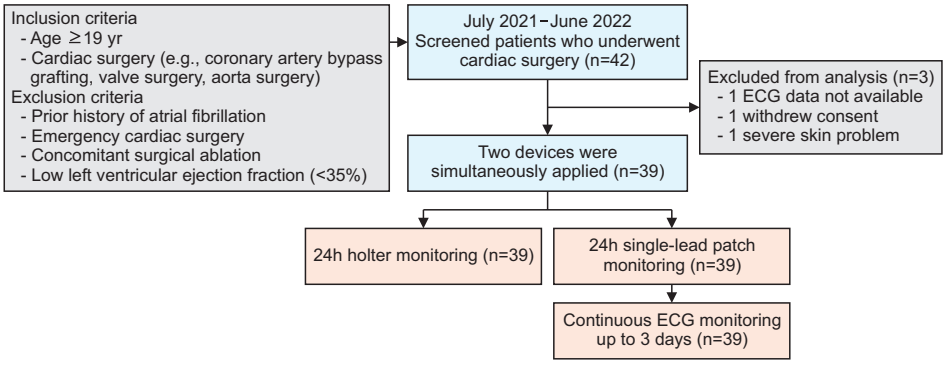

Fig. 1. study flow gram. ECG, electrocardiogram.

toring for 48 hours using a patch-type device. At the end of the monitoring period, the ECG data were reviewed by an experienced cardiologist. All patients were surveyed on the ease, satisfaction, and discomfort of the wearable patch-type monitoring device, and responses were reported on a 5-point scale.

Description of the patch-type single lead-ECG (MobiCARE-MC100)

MobiCARE detects potential differences generated on the body's surface due to cardiac activity, which occurs when the heart is in action. It achieves this by attaching electrodes to specific areas to capture signals, and it utilizes wireless transmission to display the ECG data.

The ECG measurement device consists of a main unit, application (app), and web software. The signals measured using the ECG measurement device are recorded, stored, and transmitted through an app installed on a smartphone or smartwatch. The transmitted ECG information of the user can be accessed and reviewed online using web-based software. As shown in Fig. 2, two 4-mm electrodes are connected by a single wire. The size of the device is 29 mm× 120 mm, and the weight of the device is 89.0 g.

Statistical analysis

The data obtained from the 2 devices are presented as paired data for each study subject. For continuous variables, the paired t-test was used for comparison, whereas the McNemar test was used for nominal variables. Holter examination results were used as the reference standard to calculate diagnostic agreement, sensitivity, specificity, and other metrics. Additionally, Bland-Altman plots were employed as statistical tools to assess the agreement between the measurements obtained from the conventional Holter monitoring device and the novel patch-type wearable ECG monitoring device. These plots provide a visual representation of the differences between the 2 methods for measuring variables, such as minimum, maximum, average heart rate (HR), and total QRS complex, allowing us to evaluate the level of agreement and identify any potential bias or systematic errors in the measurements. Furthermore, in the correlation graph analysis, we explored the relationships and associations between the 2 monitoring methods, specifically focusing on minimum, maximum, and average HRs, as well as the total QRS complex measurements. Statistical analyses were performed using the R software ver. 4.1.0 (R Development Core Team, Vienna, Austria).

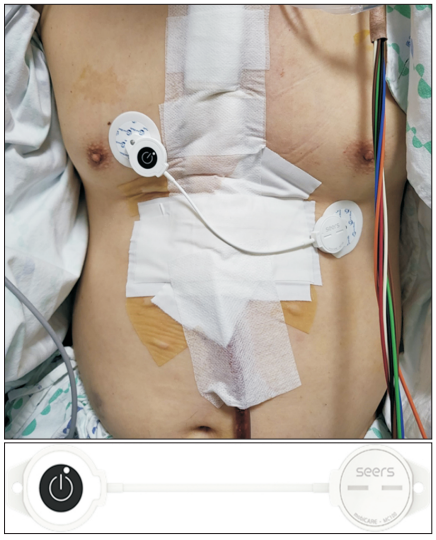

Fig. 2. MobiCARE MC-100. Written informed consent for the publication of this image was obtained from the patient.

Results

Baseline characteristics

The baseline patient characteristics are shown in Table 1. The mean age of the patients was 62.2 years, and 74.4% were men. The most prevalent comorbidity was hypertension, followed by coronary artery disease. The most common type of surgery was isolated coronary artery bypass grafting, accounting for 66.7% of cases.

Comparison between the conventional Holter monitor and the MobiCARE-MC100 device

The conventional Holter monitor and the MobiCARE device were compared over a 24-hour period after device attachment, and the results are presented in Table 2. Similar levels were recorded for HR, ventricular ectopic beat, supraventricular ectopic beat, and A-fib occurrences between Holter and MobiCARE, with no statistically significant differences. Overall, MC100 exhibited a lower noise burden, although no significant differences were observed. The ability of the MobiCARE device to detect arrhythmias in postoperative patients is likely comparable to that of Holter monitoring.

Comparison of the hourly analysis of the Holter monitor and the MobiCARE-MC100 device

To assess the reliability of the ECG data, a correlation

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analysis was conducted between the mean, minimum, and maximum HRs and the QRS count recorded from the Holter monitor, along with the HR and QRS count measured using MobiCARE (Fig. 3). Even without removing outliers, a high level of correlation was observed (r=0.98 or 0.99), confirming the reliability of the ECG data.

Table 1. Patients' characteristics (N=39)

Characteristic	Value
Age (yr)	62.2±9.3
Female (%)	10 (25.6)
Body surface area (m^2)	1.74±0.20
Comorbidities (%)	
Smoking	21 (53.8)
Current	13 (33.3)
Ex-smoker	8 (20.5)
Hypertension	29 (74.4)
Diabetes mellitus	16 (41.0)
Chronic renal failure	8 (20.5)
Cerebrovascular accidents	2 (5.1)
Coronary arterial disease	28 (71.8)
Previous PCI	9 (23.1)
Heart failure	3 (7.7)
Heart rate (beats/min)	65.4±10.5
Systolic BP (mm Hg)	132.5±15.1
Diastolic BP (mm Hg)	79.2±10.4
Left ventricular ejection fraction (%)	58.9±10.5
Surgical procedure (%)	
CABG	26 (66.7)
Valve	3 (7.7)
Valve+CABG	1 (2.6)
Aortic surgery+valve	3 (7.7)
Others[a]	6 (15.4)

Values are presented as mean±standard deviation or number (%).
PCI, percutaneous coronary intervention; BP, blood pressure; CABG, coronary artery bypass grafting.
[a]1 Cardiac mass removal, 3 atrial septal defect repair, 2 ventricular septal defect removal, respectively.

Changes in A-fib burden over 3 days using MobiCARE

A-fib burden refers to the extent, frequency, or duration of A-fib episodes over a specific period. This concept helps in understanding the severity and impact of A-fib on a patient's heart's function. Among the 39 patients, 7 patients with A-fib were detected, and the A-fib burden showed a 2% difference between 24-hour Holter and MobiCARE MC-100 monitoring. In most cases, patients were initiated on medication following A-fib detection, resulting in a decrease in the burden (Table 3). One patient (patient #35) exhibited a 9% burden in 24-hour monitoring, which increased to 38% over the 72-hour period (Fig. 4).

The outcomes of the patient satisfaction survey

Of the participants, 62% experienced no discomfort while using the MobiCARE device (Fig. 5). Furthermore, 10% of patients indicated slight discomfort, 10% described their experiences as moderate, and 18% reported feeling uncomfortable. None of the patients experienced discomfort. Regarding skin irritability, 82% of all patients responded with "none," while only 5% each responded with "very much so" or "somewhat."

Discussion

According to our study, the patch-type wearable ECG monitoring device, MobiCARE, demonstrated an equivalent ability to detect A-fib in patients following cardiac surgery, compared with the conventional Holter ECG monitoring. Additionally, when monitoring only using the MobiCARE device after 24 hours of Holter ECG monitoring, the A-fib burden increased in 1 of 39 patients. Most

Table 2. Comparisons of ECG monitoring parameters

Variable	Holter (n=39)	MobiCARE-MC100 (n=39)	p-value
Minimum HR (beats/min)	68.2±13.5	68.2±14.7	0.990
Maximum HR (beats/min)	129.9±29.1	131.6±29.1	0.794
Average HR (beats/min)	92.1±12.3	92.9±12.9	0.782
Maximum RR interval (ms)	1,100 (840–1,230)	1,101(893–1,237)	0.964
No. of total QRS complexes	131,271±17,602	130,395±19,380	0.835
No. of total VEBs	5 (1–18)	4 (1–34)	0.896
Burden of VEBs (%)	0.005 (0.001–0.012)	0.004 (0.001–0.023)	0.956
No. of total SVEBs	19 (5–152)	21 (7–108)	0.826
Burden of SVEBs (%)	0.013 (0.004–0.105)	0.018 (0.006–0.090)	0.822
No. of atrial fibrillation detection	7 (17.9)	7 (17.9)	>0.999

Values are presented as mean±standard deviation, median (interquartile range), or number (%).
ECG, electrocardiogram; HR, heart rate; VEB, ventricular ectopic beat; SVEB, supraventricular ectopic beat.

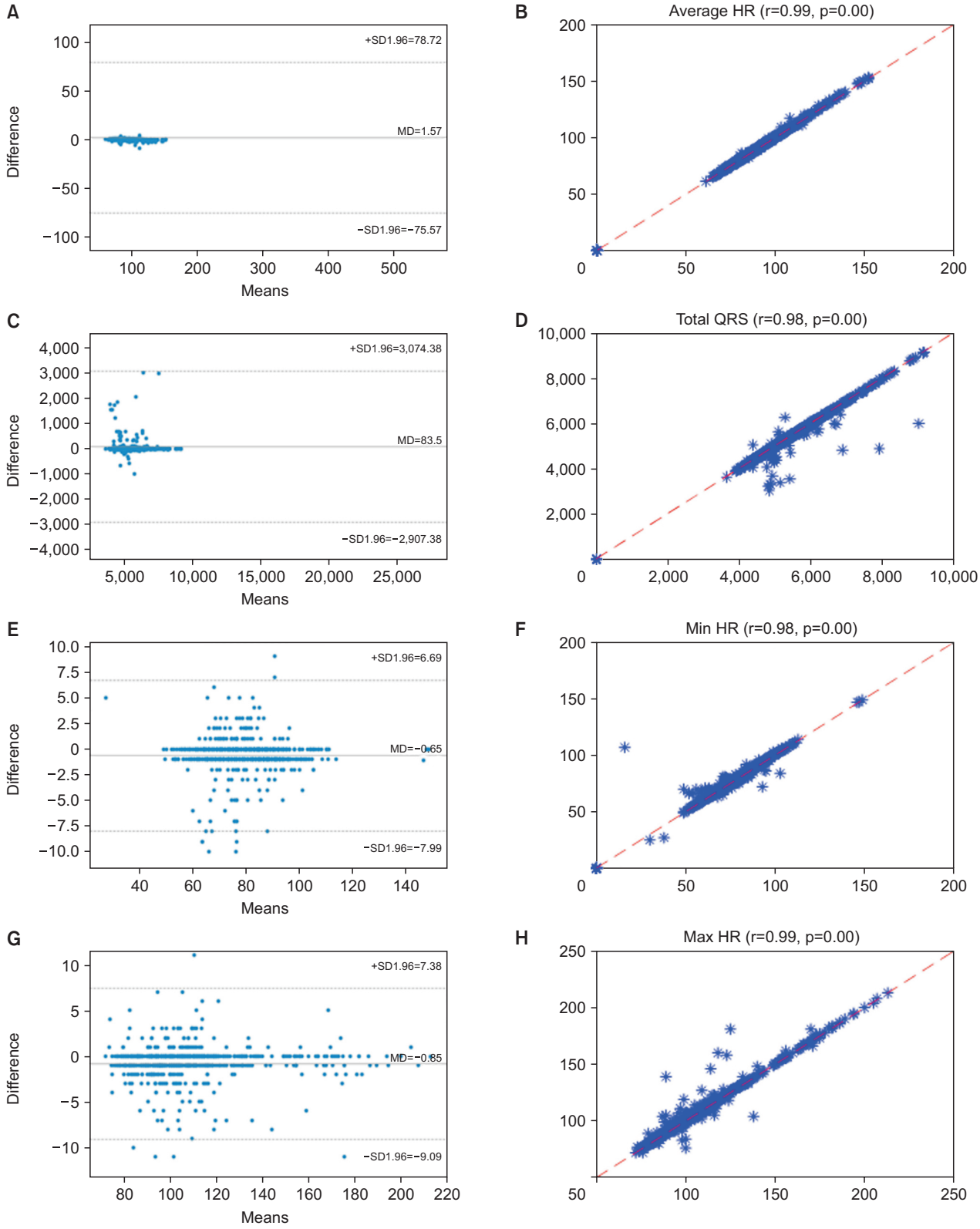

Fig. 3. Comparison of hourly analyses of Holter and MobiCARE MC-100. (A) Bland-Altman plot of the average heart rate (HR). (B) Correlation plot of the average HR. (C) Bland-Altman plot of the total QRS complex. (D) Correlation plot of the total QRS complex. (E) Bland-Altman plot of the minimum HR. (F) Correlation plot of the minimum HR. (G) Bland-Altman plot of the maximum HR. (H) Correlation plot of the maximum HR. SD, standard deviation; MD, mean difference.

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Table 3. Burden of atrial fibrillation (%)

Patient no.	Holter	MobiCARE-MC100	
	24H	24H	72H
Patient 02	42	42	28
Patient 03	85	83	91
Patient 09	92	92	91
Patient 21	6	5	3
Patient 22	64	63	28
Patient 26	3	3	1
Patient 35	9	9	38

patients reported no significant discomfort while using the MobiCARE device.

In a prospective observational study focusing on patients undergoing coronary artery surgery, A-fib primarily occurred 2–3 days after surgery, with >60% of cases occurring within 2 days postoperatively [10].

A recent trend has emerged regarding the use of wearable devices for ECG monitoring. Wearable patch-type ECG monitoring devices offer several advantages over traditional Holter ECG machines. Specifically, they are lightweight, have a small contact area, are easy to attach, support wireless data transmission, and enable monitoring for >24 hours.

In South Korea, domestically used devices include S-Patch Cardio (Wellysis Co. Ltd., Seoul, Korea), Hicardi (Mezoo Co. Ltd., Seoul, Korea), and the MobiCARE-MC100 (Seers Technology) device used in this study.

In 2022, Kwon et al. [11] compared the mobiCARE device to conventional Holter monitoring in patients in a cardiology outpatient department. They reviewed 200 patients who had previously been diagnosed with paroxysmal A-fib or were indicated for 24-hour Holter testing for A-fib monitoring at cardiology outpatient clinics. During the initial 24 hours when both devices were simultaneously applied, no significant difference was observed in A-fib detection between the 2 devices. However, when MobiCARE was applied for an additional 48 hours after the conclusion of Holter monitoring, the A-fib detection rate increased by 1.6 times [11].

Our results are similar to those of a previous study. In our study, no significant difference was identified in the A-fib detection rate between the conventional Holter test and MobiCARE during the initial 24-hour monitoring period. However, this study differs from previous research because it targeted patients after cardiac surgery, a stage that has not been previously investigated.

The importance of conducting 72-hour ECG monitoring after cardiac surgery lies in the fact that postoperative

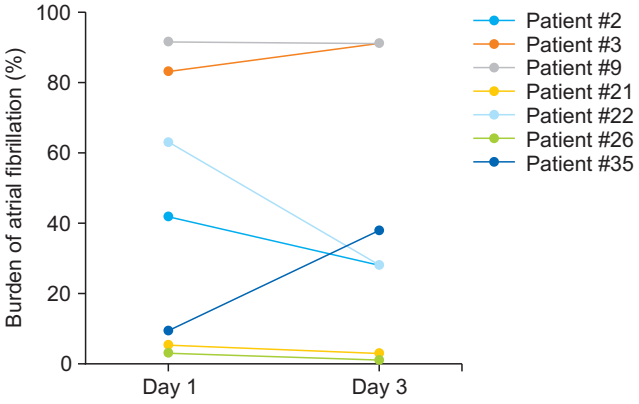

Fig. 4. Changes in the atrial fibrillation burden over 3 days of monitoring using MobiCARE.

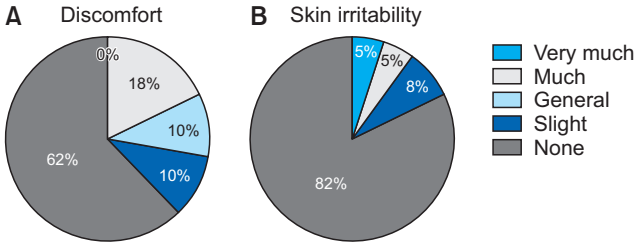

Fig. 5. (A, B) The outcomes of the patient satisfaction survey.

A-fib tends to occur at specific times. According to prior research, the highest risk of A-fib occurrence is immediately after surgery, and the risk substantially decreases within the first 18 hours post-surgery, almost reaching zero. A second peak in risk emerges around 48 hours after surgery and gradually diminishes over the following 4–7 days [4].

Conventional Holter monitoring, which is limited to 24 hours, has difficulty capturing the occurrence of A-fib beyond the initial peak. In contrast, it is feasible to conduct monitoring using the MobiCARE device for 72 hours; thus, it is able to detect both peaks in postoperative A-fib occurrence. This is important because, as mentioned previously, the occurrence of postoperative paroxysmal A-fib can impact patients' outcomes, emphasizing the importance of early detection, because it serves as an independent predictive marker of late A-fib, which is independently associated with long-term mortality [12].

Extended ECG monitoring has also been proven useful for monitoring medication efficacy and facilitating dosage adjustments based on burden levels. For example, if A-fib occurs after cardiac surgery, medical treatment, such as beta-blockers or other anti-arrhythmic agents, is initially considered. If there is no improvement in the patient's

A-fib burden during ECG monitoring, clinicians may consider increasing the medication dosage, switching to alternative medications, or performing an additional intervention such as cardioversion. Monitoring plays a pivotal role in the formulation of treatment plans and strategies for patients undergoing cardiac surgery.

Previous studies have established that the A-fib detection rate increases with longer monitoring periods. In a recent prospective study conducted in 2022 by Okubo et al. [13] comparing a patch-type ECG monitoring device called MYBEAT with conventional Holter monitoring (the MYBEAT trial), the silent A-fib detection rate of MYBEAT was significantly higher. In addition, Sandberg et al. revealed that prolonged continuous ECG monitoring, with an average monitoring duration of >6 days, led to a higher rate of detecting previously undiagnosed A-fib than intermittent ECG recording methods [14]. In this study, 1 participant experienced an increase in the A-fib burden after the initial 24-hour monitoring period had ended.

Most patients who underwent cardiac surgery had a median sternotomy wound, and during conventional Holter monitoring, wound dressing was challenging because conventional Holter monitoring consists of 12 leads with a larger skin contact area. In contrast, mobiCARE has a smaller contact area, making it more convenient for wound dressings. This characteristic not only highlights the user-friendliness of the device, but also makes it advantageous for healthcare professionals. Additionally, real-time patient ECG information can be readily accessed through Wi-Fi connectivity; therefore, treatment plans, including medication changes, can be adjusted based on the data obtained during examinations.

Limitations

This study had several limitations. First, this was a single-center study with a relatively small sample size. Therefore, future large-scale, multicenter, prospective studies in patients after cardiac surgery are necessary. Moreover, a significant proportion of patients undergoing cardiac surgery are elderly; however, this study primarily included patients who were capable of operating smartphones, leading to a relatively lower average age. Consequently, this limits the applicability of the findings to the elderly population.

Conclusion

In patients who underwent cardiac surgery, a single-lead patch-type ECG monitoring device provided diagnostic accuracy similar to that of the traditional 24-hour Holter monitors. Additionally, extended ECG monitoring beyond 24 hours improved the detection rate of previously undiagnosed arrhythmias. Further large-scale studies are required to validate this device in various clinical settings.

Article information

Correction

This article was corrected on March 27, 2024, to include the correct ORCID of the corresponding author.

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Conceptualization: DJK. Data curation, Funding acquisition: SWL, SHL, YSH. Formal analysis, methodology, project administration, and visualization: DJK. Writing–original draft: SJH. Writing–review & editing: SJH, DJK. Final approval of the manuscript: all authors.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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