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Initial evaluation of a novel electrocardiography sensor-embedded fabric wear during a full marathon

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Abstract

Sudden cardiac accident (SCA) during a marathon is a concern due to the popularity of the sport. Preventive strategies, such as cardiac screening and deployment of automated external defibrillators have controversial cost-effectiveness. We investigated the feasibility of use of a new electrocardiography (ECG) sensor-embedded fabric wear (SFW) during a marathon as a novel preventive strategy against SCA. Twenty healthy volunteers participated in a full marathon race. They were equipped with a SFW hitoe® with a transmitter connected via Bluetooth to a standard smartphone for continuous ECG recording. All data were stored in a smartphone and used to analyze the data acquisition rate. The adequate data acquisition rate was > 90% in 13, 30–90% in 3, and < 10% in 4 runners. All of 4 runners with poorly recorded data were female. Inadequate data acquisition was significantly associated with the early phase of the race compared with the mid phase (P = 0.007). Except for 3 runners with poor heart rate data, automated software calculation was significantly associated with manual analysis for both the mean (P < 0.001) and maximum (P = 0.014) heart rate. We tested the feasibility of continuously recording cardiac data during a marathon using a new ECG sensor-embedded wearable device. Although data from 65% of runners were adequately recorded, female runners and the early phase of the race tended to have poor data acquisition. Further improvements in device ergonomics and software are necessary to improve ability to detect abnormal ECGs that may precede SCA.

Keywords Sports cardiology · Cardiac accident · Athlete · Electrocardiogram · Wearable device

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Introduction

Marathons are popular throughout the world as both professional and recreational sports activities and approximately 2 million runners participate in long-distance races annually in the US. [1] Sudden cardiac accident (SCA), defined as a composite of cardiac arrest and sudden cardiac death associated with running, has become a cause of concern due to the popularity of the sport. Although cardiac arrest during long-distance running is relatively rare (0.54 per 100,000 participants), as many as 70% of these cases result in fatality [1]. Existing preventive strategies such as the deployment of medical staff along the route and automated external defibrillators are only partially effective, and the feasibility and cost-effectiveness of cardiac screening are controversial [2, 3].

Recently, smart wearable devices have emerged to allow monitoring of biological signals such as cardiac electrical activity, pulse rate, body temperature, and blood oxygen saturation. An example of this is the use of atrial

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fibrillation-detecting technology paired with a smartwatchbased mobile platform [4]. Continuously improving network infrastructure is associated with expanding real-time and remote medical applications. Our previous experience with a wireless patch-type electrocardiographic monitoring system (Duranta®, ImageONE Co., Ltd., Tokyo, Japan) has convinced us of the feasibility of its application during a full marathon, although not necessarily of its cost-effectiveness for this application [5]. The purpose of the current study, therefore, was the evaluation of an alternative approach consisting of an electrocardiography (ECG) sensor-embedded fabric wear (SFW) called hitoe® (TOREI, Japan) combined with a transmitter (NTT TechnoCross, Japan). The hitoe® was originally invented for health care use, including safety monitoring of outside workers. It is constructed using an ion-conductive polymer combined with a silk fiber bundle that enables bioelectrical signal transmission [6, 7]. The flexibility and comfort of the garment and the affordable

price of the device make it suitable for private and public use, including in endurance athletes. In this initial trial, we investigated the feasibility of using the SFW to continuously record ECG data during a marathon.

Materials and methods

Study population

This study was approved by the Okayama University Ethics Committee (No. 1808-034). A total of 15,000 runners participated in Okayama marathon 2019, who were randomly selected because the number of applicants exceeded the capacity. Participants aged over 20 years were asked to enroll in the study through personal contacts without advertisements, and 20 runners (10 males and 10 females) applied to the study as volunteers. All 20 runners participated as individuals and did not belong to any sports club. All participants in the study provided informed consent and underwent medical checks, including rest and exercise 12-lead ECG and echocardiography in advance of the full marathon. The exclusion criteria were as follows: individuals on chronic medication of any cause, known heart disease or any ECG abnormalities, and hospitalization over the last 1 year. The mean age of the participants was 36.2 ± 7.8 years (range: 20-45 years, Table 1). All 20 participants ran the full marathon with the equipped testing device in November 2019.

Table 1 Runners' characteristics and running record

Runner ID	Sex	Age (year)	BMI	Wear type-size	Start (time)	Goal (time)	Running time (minutes)	Comments
1	Male	34	20.9	M-L	8:45	11:40	175	
2	Male	29	20.7	M-XL	8:45	13:37	291	
3	Male	39	18.7	M-M	8:46	12:55	249	
4	Male	32	16.9	M-M	8:51	12:23	212	Dropout (25 km)
5	Female	37	20.8	M-M	8:48	14:21	333	Men's wear
6	Female	39	18.7	F-MCD	8:52	12:35	223	Dropout (25 km)
7	Female	37	19.9	F-MAB	8:52	13:03	250	Dropout (30 km)
8	Female	36	19.7	F-LAB	8:46	13:12	266	
9	Female	40	20.2	F-MCD	8:52	14:19	326	
10	Female	30	21.2	F-MAB	8:52	14:34	341	
11	Male	36	23.3	M-M	8:50	14:25	335	
12	Female	29	18.7	F-MCD	8:52	14:18	325	
13	Female	20	23.1	F-LCD	8:52	12:14	202	Dropout (25 km)
14	Male	33	22.2	M-S	8:45	12:37	231	
15	Female	39	20.4	F-LAB	8:49	13:06	256	
16	Male	41	19.8	M-M	8:48	13:39	291	
17	Female	39	23.2	F-LCD	8:48	13:58	309	
18	Male	45	26.9	M-XL	8:52	12:55	242	Dropout (30 km)
19	Male	59	19.7	M-L	8:47	13:45	297	
20	Male	29	20.5	M-M	8:47	13:37	290	
		Running time, mean \pm SD (minutes)					272 ± 49	

Wear type, M men's, F women's; Wear size, S, M, L or XL; cup of bra for female, AB or CD; SD standard deviation



- ① Transmitter transferring acquired ECG to the smartphone via Bluetooth
- 2 ECG sensor
- ③ Sensing fabric wear hitoe®
- ④ Smartphone for storage of ECG data

Fig. 1 Fabric wear built-in ECG sensor hitoe®

We used the wearable hitoe® device with built-in ECG sensor, which was developed to obtain bioinformation in various settings, not only medical but also that related to worker safety. The hitoe® consists of four parts: an ECG sensor, a transmitter communicating with a smartphone, a running-type garment, and a standard smartphone (Fig. 1). The ECG sensor-embedded garment continuously records data, which are then transferred and stored to the smartphone via Bluetooth by the transmitter. The SFW hitoe® comes in styles for men and women with some size variations. All runners wore hitoe® according to their sex and body shape, except for one female who wore the male style (Table 1).

Data validation

All acquired ECG data were used to determine the data acquisition rate and verify the feasibility of auto-analysis. Manual data surveillance, to determine the data acquisition rate, was performed every 3 min by well-trained clinical technologists and physicians. Figure 2 shows representative 3-min ECG data as well as the data acquisition adequacy criteria. Severe noise or artifact within a 10-s recording was defined as "inadequate data acquisition". Any 10-s recording of continuous valid ECG waveform was defined as "adequate data acquisition". For instance, the adequate data acquisition rate in Fig. 2 was determined as follows: 9 adequate data acquisitions and 9 inadequate data acquisitions were counted within 3 min, resulting in 50% adequacy of data acquisition. The manual heart rate (HR) calculation was conducted only for the duration of "adequate data acquisition". Automated HR calculation was performed by R software (The R

Fig. 2 Criteria for adequate ECG data acquisition and representative results

Criteria

- A 10-second recording including severe noise of artifact is defined as "inadequate data acquisition".
- ✓ A 10-second recording of continuous valid ECG waveform is defined as "adequate data acquisition".
 - Adequate data acquisition rate (%) is calculated every 3 minutes.
- ○: Adequate data acquisition
- ×: Inadequate data acquisition

Foundation for Statistical Computing, Vienna, Austria) [8], followed by dedicated analysis (NTT TechnoCross, Japan).

Statistics

Descriptive data are expressed as mean \pm standard deviation (SD) or number (%). Significance of differences between two groups was assessed using Student's *t*-test. The time-dependent variation of adequate data acquisition rate was confirmed using one-way analysis of variance (ANOVA) with repeated measures followed by Dunn–Bonferroni post hoc correction. To verify the relationship between automated HR calculation and manual calculation, linear regression analysis using Pearson's correlation coefficient was applied for both mean and maximum HR. Statistical analyses were performed using SPSS version 26 software (IBM Corporation, Armonk, NY). *P* values of < 0.05 were considered significant.

Results

Volunteers' characteristics and running record

Fifteen (75%) of 20 participants completed the marathon, whereas 5 runners dropped out at each point (Table 1). The mean running time for all runners was 272 min, which was set as the target duration of the study. Representative data of the ECG sensor-embedded wear are illustrated in Fig. 3. The QRS waveform is automatically analyzed and drawn, and the HR is calculated and the trend charted. Figure 3a shows the auto-analysis of HR trend for runner No. 1, including the baseline before and after running. Figure 3b shows the detailed ECG waveform and HR for runner No. 1 for each point during the marathon.

Feasibility of ECG data acquisition with the SFW during a marathon

The main purpose of this study was to prove the feasibility and adequacy of data acquisition during a marathon. Two representative results of manual analysis to determine adequate data acquisition rates are shown in Fig. 3c. Runner No. 1 had relatively well recorded ECG data, which were derived from the calculation of the "adequate data acquisition rate" by manual analysis. Although inadequate ECG data emerged at the beginning of the race and for approximately 20 min, later in the race, the data acquisition became adequate. The mean adequate data acquisition rate for runner No. 1 was 93% during the marathon. Runner No. 11 had adequate data during the early phase of the race with deterioration later on, resulting in a 39% adequate data acquisition rate. The average adequate data acquisition rate for all 20 participants was $73 \pm 39\%$ (Table 2). The individual analyzed data for each runner are shown in Supplementary Fig. S1, which also includes automated calculations of the HR trend.

We investigated whether ECG acquisition quality was associated with sex differences or time phase of the race. Although no significant difference was observed between males and females (P=0.12), all 4 runners who generated almost no data (<10%) were female (Table 2 and Fig. 4a). The running time-dependent data showed that the early phase (start to 30 min) was significantly associated with a lower acquisition rate compared to the mid phase (P=0.007, Fig. 4b).

Validation of automated HR calculation

We validated the automated HR calculation by comparison with manual calculation. We could not obtain HR data for runner No. 6 by either automated or manual analysis. Two runners (No. 5 and No. 13) had their HR data automatically calculated but manual calculation was not feasible because their adequate data acquisition rates were determined as 0%. Except for these 3 runners, both mean (P < 0.001, Fig. 4c) and maximum (P = 0.014, Fig. 4d) automated and manual HR calculations were well matched.

Discussion

Sex and running phase-dependent accuracy of data acquisition

We tested a new ECG sensor-embedded wearable device during a marathon with the objective to determine its potential as an SCA preventing tool. Although this initial proofof-concept study confirmed the feasibility of acquiring ECG data while running, two issues were identified: sex difference- and running phase-dependent errors. Although previous studies have analyzed ECG data during a marathon for the purpose of developing preventive strategies against SCA [9, 10], neither sex difference- nor running phase-dependent errors were reported.

Even though there was no significant difference in data acquisition rate between males and females, 4 out of 10 women had almost no effective ECG data during the marathon (Table 2 and Fig. 4a). We speculate that the reason for this was the poor contact of the electrodes in the hitoe® to the female body due to ill-fitting of the brassier-type garment. Design improvement with attention to the appropriate shape and cut may be useful to improve contact between the sensor and skin.

The other issue was poor ECG data acquisition during the early phase of the race. The adequate data acquisition rate of the early phase was significantly lower compared Fig. 3 Representative acquired ECG data by sensing fabric wear hitoe®. a Auto-analysis of the HR trend during the marathon for runner No. 1. b Detailed ECG waveform and HR for runner No. 1 at each point during the marathon. c Two representative results (runner No. 1 and No. 11) of manual analysis to determine adequate data acquisition rates



to that of the mid phase (P = 0.007, Fig. 4b). As previously reported, the hitoe® electrode fiber is covered by a hydrophilic electroconductive polymer, which becomes increasingly flexible following water absorption [6]. We speculate that poor ECG data during the early phase of running may be due to friction between the skin and the initially rigid electrode, which diminishes with sweat production and increasing electrode pliability. The fact that the data acquisition rate improved during the latter phase of the race suggests that sweat may be a critical factor for obtaining a reliable biological signal through the skin. Less sweating on a cold day may be the cause for slow and insufficient hydrophilization at the beginning of the marathon. Using electrolyte paste or wetting the garment before use to decrease the gap with the skin may lead to improved ECG sensing while running.

Benefits of the ECG sensor-embedded SFW technology

It has been suggested that one in 300 athletes has a potential cardiovascular risk factor [3]. The major cause of SCA during a marathon is coronary ischemia in senior runners [1]. In fact, ischemia-induced ST-segment changes have been proposed as a target for SCA prevention in a study that included 108 athletes during a full marathon. In these

Table 2 Summary of data acquisition

Runner ID	Sex	Automated analyse	es	Manual analyses			
		Max HR (bpm)	Mean HR (bpm)	Mean adequate data acquisition rate (%)	Max HR (bpm)	Mean HR (bpm)	
1	Male	181	175	93	181	175	
2	Male	182	139	69	180	162	
3	Male	176	148	92	180	163	
4	Male	186	155	86	185	160	
5	Female	187	115	0	_	_	
6	Female	_	_	0	-	_	
7	Female	173	153	97	170	154	
8	Female	188	175	97	185	175	
9	Female	164	149	99	160	151	
10	Female	188	145	9	151	128	
11	Male	182	149	39	178	149	
12	Female	187	165	92	182	170	
13	Female	197	140	0	-	_	
14	Male	182	162	95	177	164	
15	Female	181	155	95	184	155	
16	Male	179	154	94	164	153	
17	Female	171	151	100	163	152	
18	Male	166	144	100	161	143	
19	Male	166	131	97	150	130	
20	Male	182	161	98	195	161	
$Mean \pm SD$		180 ± 9	151 ± 14	73 ± 39	173 ± 13	156 ± 13	

HR heart rate, SD standard deviation

athletes, exercise-induced transient ST-segment deviation was associated with elevated high-sensitivity troponin T [10]. Therefore, ischemic myocardium-derived ST-segment changes in ECG are associated with adverse cardiac events during physical activity.

Preparticipation cardiovascular screening, including ECG, for athletes has been proposed by scientific organizations and sports governing bodies such as the Japanese Circulation Society [11], European Society of Cardiology [12], the American Heart Association [13], the Fédération Internationale de Football [14], and the International Olympic Committee [15]. ECG parameters that should be monitored during cardiac screening are as follows: HR trend during physical activity, frequency of arrhythmias such as premature ventricular or supraventricular contractions, QT-segment prolongation, ST-segment elevation or depression, T-wave abnormalities, and conduction block [16]. Nevertheless, screening for athletes is still not universally accepted because of the lack of controlled studies [17]. In fact, a review of 24 cases of SCA in athletes between the years 1985 and 2009 concluded that mandatory ECG screening did not decrease cardiac events [18]. This discrepancy may be due to the artificial conditions of preparticipation screening which bear no relevance to the conditions during the actual event. The wearable device has the advantage of being able to detect potential ECG changes occurring during the actual physical activity, which may not be evident during routine screening ECG.

The SFW technology has potential for expanded applications, not only in a marathon but also in various other activities, including other sports and remote cardiac rehabilitation monitoring. The latter application will facilitate participation in a valuable treatment with proven benefits for patients with a broad spectrum of cardiac diseases [19]. The importance of this becomes evident during an unprecedented pandemic like coronavirus disease-19.

Limitations

Limitations of this study should be acknowledged. First, we could not perform detailed statistical analyses because of the small sample size. Further data accumulation is required to identify the factors of accurate data acquisition. Second, all runners chose the size and shape of hitoe® without verification of ECG recording. Trial fitting and verification of

Fig. 4 Data acquisition adequacy in terms of sex and time phase differences and accuracy of automated heart rate calculation. a The adequate data acquisition rates for males and females were compared using Student's t-test. The black bar indicates the mean value. b The distributions of adequate data acquisition rates at each phase of the race were analyzed using one-way analysis of variance (ANOVA) with repeated measures, followed by Dunn-Bonferroni post hoc correction. The phases of the race were defined as early (start to 30 min), mid (30-90 min), or late (90 min to goal). The black bar indicates the mean value. c, d Linear regression between manual and auto-analysis was performed for the c mean, and d maximum heart rate. Three runners in whom the device failed to generate either automated and/or manually calculated heart rate data were excluded from the linear regression analyses



ECG recording of hitoe[®] in advance of the marathon may reduce the size mismatch and improve the data acquisition. Third, we did not evaluate the abnormal signs of ECGs in this study because an ECG-analyzing algorithm was not incorporated within the hitoe[®]. In the future, we are willing to incorporate within the device an auto-alarming system with an ECG-analyzing algorithm targeting ischemia and arrhythmia that will alert athletes to stop activities before serious accidents. Development of novel algorithms able to identify risk factors and improvement of sensor accuracy and noise reduction are also critical in order to prevent SCA. Advances in artificial intelligence, including deep neural networks, would make a paradigm shift in the auto-analysis of biological data, which is impossible with the current algorithm-based ECG machines [20, 21]. In conclusion, we demonstrated the feasibility of ECG monitoring through a SFW during a marathon. Although feasible ECG data acquisition was confirmed during a full marathon, some issues such as sex difference- and running phase-dependent errors emerged. Further improvements in both sensing sensitivity and software sophistication are required to optimize the utility of this technology as a new tool to decrease the risk of SCA in all athletes.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00380-021-01939-3.

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Declarations

Conflict of interest The experimental devices used in this study were supplied by NTT TechnoCross Co. Ltd. However, this company had no control over the interpretation, writing, or publication of this work. The authors have no conflicts of interest to declare.

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