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Accuracy and reliability of wristband smartwatch-based estimation of circadian rhythm of heart rate in stroke patients

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Abstract

Background & Objective: Stroke has a high incidence, disability, and mortality rate, which has a serious impact on the patients' quality of life. Heart rate (HR) is valuable in the prognostic assessment of stroke patients. Continuous HR tracking helps to detect abnormal indicators and provide interventions timely to avoid disease progression. However, the cuff-based or electrode-based HR monitoring tools commonly used in clinic are not suitable for continuous monitoring in daily life. The aim of this study was to verify the accuracy and reliability of a wristband smartwatch in monitoring HR over 24-hour in stroke patients, including in terms of the circadian rhythm characteristics of HR. *Methods*: 25 stroke patients underwent 24-hour HR monitoring by wearing a smartwatch and a clinical monitor. We use ambulatory blood pressure monitors and bedside monitors as the gold standard for clinical HR monitoring. The degree of association between the two measurements was compared using Pearson's correlation coefficient. Bland-Altman analysis showed the accuracy of the smartwatch in HR monitoring. Intraclass correlation coefficients (ICC) and coefficients of variation (CV) were used to verify the reliability of the wristband smartwatch for repeated measurements. *Results*: A total of 625 heart rate pairs were acquired. The smartwatches had an average error of 0.816 bpm in 24-hour, with no difference from standard monitors ($P>0.05$), indicating good accuracy. The intraday repeated measures ICC was 0.969 and the interday repeated measures ICC was 0.788, indicating good reliability. *Conclusions*: The smartwatch is acceptable in detecting 24-hour ambulatory HR in stroke patients, and in the future, long-term HR monitoring with diurnal variations can be performed in daily life.

Keywords: Smartwatch; Stroke; Heart rate; Circadian rhythm; Accuracy; Reliability

INTRODUCTION

With an aging population, stroke is the leading cause of death and disability worldwide.[1] HR is a valid indicator of autonomic nervous system tone, and is vital in promoting stroke recovery and preventing recurrence.[2] It has been demonstrated that HR is an independent predictor of stroke recurrence and death.[3] Evidence suggests that abnormal heart rate accelerates the atherosclerotic process that leads to atherosclerosis and affects functional recovery in stroke patients. For example, Tang *et al*.[4] found that HR levels or the mean 24-hour HR on the first day of admission may have an inverse or U-shaped relationship with post-stroke outcome. Despite the important role of HR, most hospitals do not pay enough attention to HR in stroke patients.[3] The population of concern is mostly among stroke patients with heart disease such as atrial fibrillation, and sudden abnormal heart rate in stroke patients without concomitant heart disease. Moreover, most studies have addressed HR variability, the effect of individual HR values on stroke, and the lack of studies on trends in 24-hour ambulatory HR and circadian rhythm of HR in stroke patients. Circadian rhythms have a 24-hour cycle and different periods that maintain the main aspects of individual physiological processes, and disruption of circadian rhythms can affect the organism's health, leading to the development of many diseases.[5] For example, HR typically exhibits elevated levels during the day, with nocturnal decreases and localized peaks in the morning

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and late afternoon.[5] Durant *et al*.[6] noted that the HR during wakefulness is 25% higher than the resting HR. The 24-hour dynamics of HR affects physiological processes critical to the patient's health[7], so it is crucial to study the circadian rhythm of HR in stroke patients. At present, HR monitoring is primarily in the clinical setting and relies on chest straps and electrode-based HR monitors. However, these methods also have shortcomings. First, the inconvenience of wearing the device interferes with the patient's daily activities and sleep. Second, removing the device due to objective examinations or special activities makes continuous monitoring impossible. Finally, the methods are primarily performed in a clinical setting, so achieving HR monitoring of stroke patients in daily life. Dynamic monitoring and circadian rhythm analysis in stroke patients is challenging. Therefore, there is a need for HR detection devices that can overcome the shortcomings of traditional methods and be applied to everyday life.

With the rapid progress of mobile technology, wrist-worn HR monitors are becoming more and more popular among the public. They are portable, inexpensive, and real-time, and they help to develop personalized interventions by detecting HR abnormalities on time and following the dynamic trends of HR. However, such devices face quality issues, among which the accuracy of the collected HR values is particularly prominent. As its core function, data accuracy is a critical factor in assessing the quality of such devices, and it directly determines the usability and reliability of the device. Currently, the accuracy of wrist-worn HR monitors in measuring HR in stroke patients is uncertain, and there are no guidelines on what range of HR error is permissible. More significant errors in HR monitoring may prevent the development and implementation of medical interventions and delay the condition. Therefore, choosing a convenient and accurate HR testing device is vital to monitor the circadian rhythm of HR in stroke patients. Some investigators have examined the error profile of wristband wearable devices in monitoring HR.[8,9] Falter *et al*.[9] verified the accuracy of the Apple Watch in monitoring HR in patients with cardiovascular disease and found a HR deviation of 3.61 bpm in a seated position, 0.91 bpm in moderate-intensity activity, and -1.82 bpm in maximum-intensity activity. However, such studies have focused on single or multiple HR monitoring. They cannot validate continuous and ecologically valid HR accuracy over 24-hour in stroke patients. Nelson *et al*.[10] evaluated the accuracy of a wristband smartwatch monitoring 24-hour HR in a healthy population and found a good accuracy of -1.8 bpm. However, the study was conducted on only one subject, the sample size was small, and the findings needed to be more representative. Assessing the accuracy of monitors is essential for individuals who use monitors to guide their physical activity and for physicians to whom these monitors report HR readings. The HR monitoring device chosen for this study is a Chinese-made smartwatch based on the photoelectric volume pulse wave principle. The purpose of this study was to evaluate the accuracy and reliability of the smartwatch in monitoring HR over 24-hour in stroke patients, including in terms of the circadian rhythm characteristics of HR.

METHODS

Study design and participants

This study was approval by the Medical Ethics Committee of the First Affiliated Hospital of Soochow University. This study recruited inpatient stroke patients attending the hospital in August-September 2022. Patients were usually treated in the ward until their physical condition stabilized. A total of 33 stroke inpatients were recruited. All participants gave informed consent. Inclusion criteria were: (1) consistent with the diagnosis of ischaemic stroke and confirmed by cranial CT or MRI examination of the head; (2) age ≥18 years; (3) no recent involvement in thrombolysis; (4) the patient was conscious, had no previous cognitive impairment or psychiatric disease history, and could complete the questionnaire; (5) informed consent was obtained, and participation in the study was voluntary. Exclusion criteria were: (1) co-morbid diseases, such as malignant tumors and liver and kidney failure; (2) suffering from mental illness and unable to participate in the investigation; (3) history of heart disease (e.g., atrial fibrillation). Dropout criteria were: (1) data missing: wear devices <10 hours[11,12] during the day or night, due to activities, examinations, etc. (2) new-onset atrial fibrillation or other arrhythmias (SVT, atrial flutter, etc.) during the study.

Devices

The bracelet is made in Shenzhen, Guangdong Province, China, that is reasonably priced (about $100), lightweight, and easy to wear. It emits a photoelectric signal through the bracelet to the skin, and a sensor captures the pulse wave at

the wrist area to derive blood pressure data. This product has three features: long battery life, a HR monitoring function, and a large touch screen. In addition, it also has dynamic HR detection, sleep monitoring, and several reminders. In terms of appearance, the overall black tone is dominant. On the front of the dial is a touch screen; the main interface is the time and date; left and right sliding can view and monitor the current HR in real-time, with the intelligent health app can pay attention to the dynamic HR. The slightly raised design of the watch's sensor better fits the skin. It improves accuracy because the HR data is output by using the sensor to capture the pulse wave at the wrist area by emitting photoelectric signals to the skin through the watch.

24-hour ambulatory blood pressure monitors and bedside monitors are now commonly used in clinical practice for ambulatory heart rate monitoring and are therefore used as standard blood pressure devices. Compared to ambulatory electrocardiograms, these objective devices cannot diagnose diseases such as atrial fibrillation, but they can identify abnormal heart rate values easily and readily.[13] Therefore, we chose this type of device as the standard monitoring tool for this study. (1) The ambulatory blood pressure monitor, Ambulatory Blood Pressure Monitor, Model ABPM 6100, from Welch Allyn, lnc, USA. Studies have confirmed that the pulse rate measured by ABPM agrees with the heart rate measured by ECG, so ABPM can be used as an objective criterion. It was used to take measurements every 0.5 hour during the daytime from 8:00 to 20:00, and every 1 hour during the nighttime from 20:00 to 8:00. This study used it for standard heart rate monitoring in patients who are able to move independently out of bed. (2) Bedside monitor, model iM60, from Shenzhen Lippon Precision Instruments Company Limited, China. Set in advance to measure heart rate every 1 hour. This study used it for standard heart rate monitoring in bedridden patients.

Procedure

Data collection was carried out from August to September 2022. Researchers received training on smartwatches, monitoring methods, and data processing prior to data collection using smartwatches. Researchers collected patient information through paper questionnaires, ambulatory electrocardiograms, and smartwatches. The questionnaire included demographic information (gender, age, height, weight, occupation, education level, marital status, place of residence, medical payment method, per capita monthly household income, type of health insurance, etc.), disease-related information (history of smoking and alcohol abuse, muscle strength, type of stroke, duration of disease, presence of recurrence, comorbid chronic diseases, sleep status, etc.), and equipment use-related information (wearing side, etc.). ABPM and beside monitor collected standard HR values of patients. Measured HR values of patients were collected using a smartwatch. Before wearing the bracelet, the investigator entered the patient's age, gender, height, and weight on a smart health app and set the bracelet to monitor vital signs every 10 minutes. Study subjects identified according to the nadir criteria wear the watch for 24-hour starting at 1 pm that day and wear a 24-hour ABPM monitor or bedside monitor on the same arm) to facilitate comparison of the accuracy of the HR values measured by the watch. HR was measured again at 1 pm the next day to compare the reliability of the HR values measured by the watch.

Sample Size

Accounting for an efficacy of 0.5 and a 5% probability of type I error, the sample size (n=25) is by the findings of Wallen *et al*.[14] Sample sizes in similar studies range from 20-60.[9]

Statistical analysis

Statistical Analysis was conducted using Excel 2010 and SPSS 25.0. Plots were carried out using GraphPad Prism 9 and Origin 2021. Numerical variables were represented as mean ± standard deviation, while categorical variables were expressed as numbers and percentages. Comparison of the degree of error between the measured HR value measured by the smartwatch and the standard HR value measured by the standard devices using mean error (ME), mean absolute error (MAE) and mean absolute error percentage (MAPE).[15] ME= (measured value-standard value), MAE=|measured value-standard value|, MAPE=|measured value-standard value|/standard value. Correlation of watch-measured HR with standard devices-measured HR using Pearson's correlation coefficient. Analysis of the accuracy of HR measurements from watches using Bland-Altman.[16] The relative reliability of daytime internal rate measurements was analyzed using intraclass correlation coefficients (ICC): greater than 0.75 means high consistency, between 0.40

and 0.75 is good consistency, and below 0.4 means poor consistency. The absolute reliability of daytime rate measurements is analyzed using CV (%).

RESULTS

General characteristics

Thirty-three stroke patients were included in the study, eight of whom were excluded due to incomplete data resulting from the early removal of the watch due to uncomfortable wear or clinical examination. The remaining 25 patients were included in the analysis. Participants were 66.68±11.52 years old, 68% were male, 164.32±7.81 cm in height, 67.48±10.52 kg in weight, 76% had a history of chronic disease, and 72.7% wore their reference device and watched on their left side. Detailed information is shown in Table 1.

Accuracy

A smartwatch and a standard device were used to monitor stroke patients' 24-hour HR. The trends of 24-hour HRs, daytime HR, and nighttime HR measured by the two devices are shown in Figure 1. Overall, the smartwatch had an average error of 0.816 bpm, a mean absolute error of 6.1152 bpm, and a mean absolute percentage error of 8.99% over the 24-hour of testing. Under daytime conditions, the smartwatch measured HR with an average error of -0.2167 bpm, an average absolute error of 5.7233 bpm, and an absolute percentage error of 7.79%. Under nighttime conditions, the average error of the smartwatch in measuring HR was 1.7692 bpm, the absolute average error was 6.4769 bpm, and the absolute percentage error was 10.10%. Details are shown in Table 2. The results of this study showed that there was no statistically significant difference between the 24-hour HR measured by the smartwatch and the standard devices ($P > 0.05$) (Table 2). The smartwatch recognized fewer abnormal heart rates than the standard device in the presence of heart rates greater than 100 and less than 60. However, there was no difference between smartwatches and standard devices in recognizing abnormal heart rates(Table 3). There was a moderate correlation between the smartwatch and the standard devices device in the 24-hour HR(r=0.6852), daytime HR(r=0.7223), and nighttime HR(r=0.6547) (Table 2, Figure 2. (A-C)). Bland-Altman analysis of the HR monitored by the smartwatch and the standard devices revealed a range of deviations from -17.89 to 19.52 bpm for 24-hour, -17.44 to 17.01 bpm for daytime, and -18.05 to 21.58 bpm for nighttime HR (Table 2, Figure 2. (D-F)).

Table 1: Characteristics of the study participants

Characteristics	n=25
Sex(male), n	17(68%)
Age, years	66.68±11.52
Height, cm	164.32±7.81
Weight, kg	67.48±10.52
Muscle strength(≤3), n	3(12%)
Stroke severity (severe)	11(44%)
Stroke staging	
Acute, n	14(56%)
Recovery, n	4(16%)
Sequelae, n	7(28%)
Disease duration (≤1 month), n	14(56%)
Presence of recurrence, n	4(18.2%)
Wearing side (left side), n	20(80%)
History of chronic disease, n	19(76%)
Sleep duration, minutes	569.52±184.43
number of nocturnal awakening, n	2.02±0.94

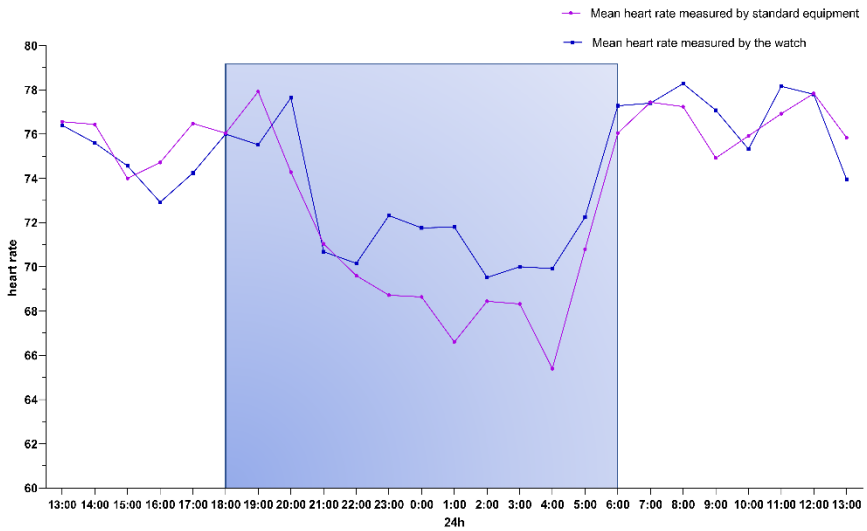

Figure 1. Standard and measured values of mean hourly heart rate during 24-hour: The blue line indicates the 24-hour heart rate variation curve measured by the smartwatch, and the purple line indicates the 24-hour heart rate variation curve measured by the electrocardiogram.

Reliability

HR measurement device reliability was verified by repeated measurements, including intraday and inter-day reliability. Hourly HR assessments demonstrated intraday reliability during the day, and inter-day reliability was represented by HR assessments simultaneously on two consecutive days. Comparison of intra-day retest reliability indicated absolute percentage errors of 0.07531 ± 0.08336 and 0.0522 ± 0.6686 for daytime and nighttime HR, respectively (Table 4, **Error! Reference source not found**.ure 3. (A)). We found that the intraclass correlation coefficient between the percentage error of daytime HR measured by the smartwatch and the percentage error of nighttime HR was 0.969, showing a high correlation, and the difference between the percentage error of daytime and nighttime HRs was statistically significant(p<0.05) (**Error! Reference source not found**.ure 3. (A)). The coefficient of variation (CV) between daytime and nighttime HRs was 17.66%. Verification of the daytime retest reliability revealed that the absolute percentage errors of the HR measured by the smartwatch at 13:00. on the first day and at 13:00. on the second day were 0.07786 ± 0.10398 and 0.10103 ± 0.15101, correspondingly (Table 4, **Error! Reference source not found**.ure 3. (B)). We found that the intraclass correlation coefficient between the percentage error of the HR measured by the smartwatch on the first day and the HR on the second day was 0.788, showing a high correlation, and the difference between the percentage error of the two HR measurements was not statistically significant (**Error! Reference source not found**.ure 3. (B)). The two HR measurements' coefficient of variation (CV) was 15.14%.

Table 2: Accuracy of HR measurement by smartwatch at different times

Time	Error analysis			Differences	Relevant analysis	Bland-Altman analysis	
	Mean Error	Mean Absolute Error	Mean Absolute Percent Error (%)	p	r	Lower LoA	Upper LoA
24h	0.816	6.1152	8.99	0.302	0.6852	-17.89	19.52
Daytime	-0.2167	5.7233	7.79	0.848	0.7223	-17.44	17.01
Nighttime	1.7692	6.4769	10.10	0.102	0.6547	-18.05	21.58

Table 3: Comparison of smartwatches and standard devices for identifying abnormal HR values

HR	Abnormal HR counts		χ^2	p
	>100	<60		
Standard device	32	103	0.892	0.345
Smartwatch	30	73		

DISCUSSION

This study evaluated the accuracy and reliability of a non-invasive wristband smartwatch in clinical stroke patients by comparing standard HRs measured by ambulatory electrocardiographic monitors. This study found that a wristband HR monitoring device, exemplified by a smartwatch, could provide the equivalent of continuous 24-hour ambulatory HR values for 75.8% (25 of 33) of stroke patients in an inpatient setting, indicating better adherence to smartwatches use among stroke patients. This study validated the accuracy and reliability of smartwatches with standard devices and found that the smartwatches were good accurate reliable in monitoring 24-hour ambulatory HR in stroke patients. In particular, the smartwatch was more accurate in monitoring daytime HR than nighttime.

Our study found that the mean bias of the smartwatch in monitoring 24-hour HR in stroke patients was 0.816. It is inconsistent with Bunn *et al*.[17] who found that wearable devices tend to underestimate HR. This study verified that the smartwatch has good accuracy, with an acceptable margin of error, and can be applied to long-term wear in daily life so that abnormal heart rate values can be detected and diagnosed promptly. However, this smartwatch reflects the heart rate by monitoring the pulse. The study also noted that the standard deviation of the pulse measured by such a device is ≤5 beats per minute before it can be used to assess the heart rate in patients with atrial fibrillation.[18] If heart rate monitoring of these individuals is to be performed, it will need to be re-validated to recognize atrial fibrillation. Therefore, it is not recommended as a diagnostic criterion for atrial fibrillation. We should choose a more reliable method of diagnosing the disease. Due to the advantages of portability, intelligence, and low error of this smartwatch, we can choose this device for daily continuous heart rate monitoring to detect abnormal heart rates in time and provide early intervention. In

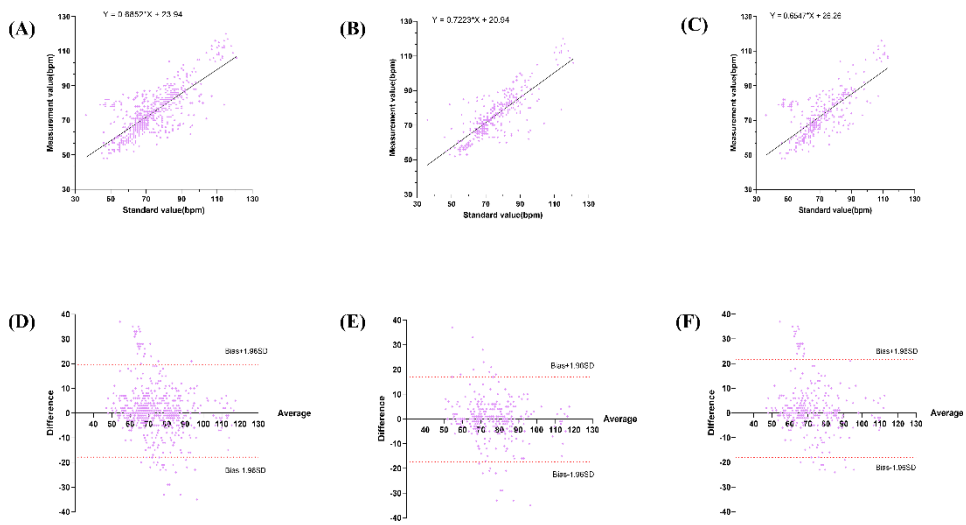

Figure 2. Accuracy of smartwatch measuring heart rate:(A-C) Correlation between heart rate values measured by smartwatch and the standard devices at different time periods. (A) Correlation of 24-hour heart rate. (B) Correlation of daytime heart rate. (C) Correlation of nighttime heart rate. (D-F) Bland-Altman plots between heart rate values measured by smartwatch and standard devices at different time periods. (D) Error plots of 24-hour heart rate. (E) Error plots of daytime heart rate. (F) Error plots of nighttime heart rate.

Table 4: Reliability of the smartwatch for repeated HR measurements

Reliability index	First data	Second data	ICC	95%CI	CV(%)
intraday	0.07531(0.08336)	0.0522(0.6686)	0.969	0.948-0.984	17.66
interday	0.07786(0.10398)	0.1010(0.1510)	0.788	0.520-0.907	15.14

addition, 24-hour ambulatory heart rates measured by both smartwatches and standard devices showed a significant decrease in nighttime heart rate, which was lower than daytime heart rate, in line with the findings of Durant *et al*.[6] The possible reason is that the organism is in a state of rest at night, and the vagus nerve division is excited, so there will be a decrease in heart rate performance, which is a normal neural regulation of the body. It is also possible that stroke patients often suffer from autonomic dysfunction, resulting in an imbalance in the control of the sympathetic and parasympathetic nerves that innervate the heart. As a result, at night, parasympathetic excitability increases, leading to a decrease in heart rate. However, this study's mean deviation from daytime HR was -0.2167 bpm, and the mean deviation from nighttime HR was 1.7692 bpm. The wristband HR detector tended to underestimate daytime HR, consistent with the findings of Bunn *et al*.[17] It may be because daytime activity tends to cause higher HR values in individuals, and wristband devices do not readily recognize higher HR values through the sensor, resulting in lower measured values than the traditional values. Benedetti *et al*.[19] monitored HR during sleep and found that HR measurements from the FBCHR tended to be more accurate during sleep than wakefulness. It has been noted that higher rates of wrist motion during wakefulness and lower stability associated with sensor-skin contact make wristband HR monitoring devices less accurate for monitoring daytime HR compared to nighttime HR.[20] However, the results of the present study could have been more consistent with the studies mentioned above. This study found that the mean absolute error of the wristband HR detector in monitoring daytime HR was lower than that of nighttime HR, the correlation coefficient of daytime HR was higher than that of nighttime HR, and the protocol-limited range of daytime HR was smaller than that of nighttime HR. Overall, the smartwatch in this study measured daytime HR more accurately than nighttime HR. Possible reasons for this are the reduced daily activities caused by operations such as infusions during the daytime while hospitalized, so that daytime measurements are more accurate, and the nighttime sleep environment is different from that at home, causing lower sleep quality, which leads to individual HR instability and high HR variability. At present, the specific causes of such

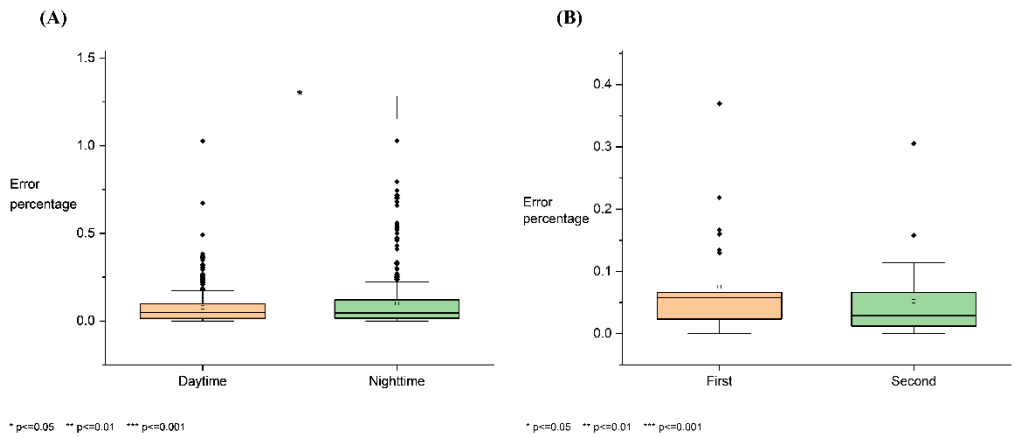

Figure 3. (A) Intraday repeat measurement reliability. Yellow represents box plots of percent error in daytime heart rate measurements. Green represents box plots of the percentage error of nighttime heart rate measurements. p indicates comparison of the percentage error of daytime and nighttime repeated measurements, and $p<0.05$ indicates a statistically significant difference. (B) Daytime repeated measurement reliability. Yellow represents box plots of the percentage error of heart rate measurement on the first day. Green represents box plots of the percentage error of heart rate measurements on the second day.

results are unclear, and there are few relevant studies, and further investigations are needed to analyze the influencing factors causing the errors.[21] In brief, compared to heart rate measurement devices commonly used in hospitals, the smaller the error of the watch-measured heart rate, the relatively more accurate it is, and it cannot be shown to be more professional than standard monitoring devices. Considering the lower error, the watch-measured heart rate value can still be referred to and has some professional value. At the same time, given that smartwatches are comfortable, portable, and inexpensive, they are more cost-effective for heart rate monitoring. However, for disease diagnosis, there is still a need to use more accurate medical monitoring equipment. The choice of such watches in the future is essential for the continuous monitoring of heart rate in the daily life of patients after discharge from the hospital.

Previous studies on HR retest reliability have focused on verifying intra-device and inter-device reliability.[22] The present study focuses on intra-device reliability, mainly because the reference gold standard is cuff-based monitor, which requires a wristband HR detector to be worn on the same side as the cuff to reduce errors. Repeatability of intra-HR (ICC=0.969) and inter-day HR (ICC=0.788) measurements was found to be high in studies of smartwatch reliability metrics for HR monitoring. Consistent with previous HR reliability studies, our study resulted in higher intra-day reliability of HR measurements than inter-day reliability.[23] It may be related to the fact that the intra-day environment is more uniform and has a more consistent physiological and psychological state than the daytime. More importantly, this study is a 24-hour continuous monitoring of stroke patients in a clinical setting and therefore has a high level of ecological validity. In brief, the device is highly reliable in measuring the HR of stroke patients. Given that hospitalized patients are easier for healthcare professionals to operate reliably and realistically in a controlled environment, compared to outpatients and post-discharge patients. Therefore, the smartwatch was verified for accuracy in monitoring the heart rate of hospitalized stroke patients to provide a comfortable, portable, and accurate heart rate monitoring and management tool for outpatient and post-discharge patients to enable long-term dynamic heart rate tracking. This is of great significance for improving stroke patients' awareness of self-health management, controlling disease progression, and improving patient prognosis.

The advantages of this study are that the smartwatch can be used directly without calibration and can give remote long-term dynamic HR monitoring and data storage, enabling participants to monitor their health status and change bad habits dynamically, as well as enabling remote health management at the back end for timely health risk detection. The limitations of this study are the relatively small sample size, the relatively homogeneous nature of the disease and the need for future validation with large samples and patients with different diseases.

In conclusion, the smartwatch had good accuracy and reliability in overall 24-hour HR measurements. Although it slightly overestimated HR, which is acceptable. Notably, smartwatches measured daytime HR with higher accuracy than nighttime HR, suggesting that circadian rhythm differences in HR can affect the accuracy and reliability of the measurements. Given the importance and convenience of the smartwatch in monitoring the dynamic HR of stroke patients, the use of such devices for long-term continuous HR tracking in the future can help patients pay attention to their health status and avoid health risks, and also help doctors to monitor the patient's status remotely and give relevant examination and treatment in a timely manner.

DISCLOSURE

Data availability: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Conflict of interest: None

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