

Diagnostic performance of a wearing dynamic ECG recorder for Atrial Fibrillation screening: The HUAMI heart study

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Research article

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Abstract

Background: Atrial fibrillation (AF) is the most prevalent cardiac dysrhythmia with a significant morbidity and mortality rate. Notably, one out of three patients with AF is asymptomatic. Given the asymptomatic and paroxysmal nature of AF, AF's timely detection with traditional instruments is somewhat unsatisfactory and delayed. Thus, wearing a dynamic electrocardiogram (ECG) recorder can help analyze, interpret, and distinguish AF from normal sinus rhythm accurately and safely, even in an upright position and after exercises, using an artificial intelligence (AI) algorithm.

Methods: A total of 114 participants in the outpatient registry of our institution from June 24, 2020 to July 24, 2020, were enrolled. Participants were tested with a wearable dynamic ECG recorder and 12-lead ECG in a supine, an upright position and after exercises for 60seconds.

Results: A total of 114 subjects (sixty-one with normal sinus rhythm, fifty-three with AF) were enrolled in the study. The number of cases unable to be determined by the dynamic ECG recorder wristband was two, one in each group. Case results not clinically objective were defined as false-negative or false-positive. The diagnostic accuracy, sensitivity and specificity using wearable dynamic ECG recorders in a supine position were 94.74% (95% CI% 88.76%-97.80%), 88.68% (95% CI 77.06%-95.07%) and 100% (95% CI 92.91%-100%), respectively. Meanwhile, the diagnostic accuracy, sensitivity and specificity in an upright position were 97.37% (95% CI% 92.21%-99.44%), 94.34% (95% CI 84.03%-98.65%), and 100% (95% CI 92.91%-100%), respectively. The result after exercise was the same as the result of the upright position.

Conclusion: AF can be detected using the widely accessible wearable dynamic ECG recorder with an AI algorithm after different postures and exercises. It may provide a useful and user-friendly screening tool, diagnosing AF early in at-risk individuals.

Background

Atrial fibrillation (AF) is the most common cardiac dysrhythmia, with an estimated prevalence rate of 2% and 4% in adults. ^[1]Notably, the incidence of AF substantially increases with age (6%; > 65-years of age and 8% ~15%; > 80-years of age). ^[2, 3] ATRIA study indicated that there would likely be almost three million individuals over 80-years of age with AF by the year 2050. ^[4] AF is related to significant morbidity and mortality and continues to be a major burden to public health. ^[5] The 2020 ESC guidelines suggested that AF's lifetime risk increased from one in four people of previous European descent to one in three by age 55. ^[6] AF primarily increases the risk of stroke and heart failure, significantly affecting people's quality of life and longevity. ^[7, 8] AF also increases the risk of stroke approximately five-times higher ^[5] and causes a two-fold risk of heart failure ^[9].

A study by Stewart, S. et al. showed that AF constituted a significant prevalent ratio in the global burden of disease and that AF accounts for 1% of Britain's National Health Service budget. ^[10] Another study by Kim, M.H. et al. showed that AF contributed significantly to the US Net spending of approximately \$16

billion and \$26 billion per annum.^[11] Presently, one out of three patients with AF is asymptomatic.^[12] Hence most people have heart failure or stroke as the first symptom of AF. Strikingly, compared with symptomatic AF, asymptomatic AF carries the same risks and sometimes even have adverse outcomes.^[13] Early detection of asymptomatic AF is challenging and becoming increasingly crucial. It is essential to detect asymptomatic AF in its early stages. Furthermore, the European guidelines recommend opportunistic screening for patients with AF over 65-years of age, including high-risk patients.^[14]

Given the asymptomatic and paroxysmal nature of AF, AF's timely detection with traditional instruments, such as the gold-standard 12-lead electrocardiogram (ECG),^[15] is somewhat unsatisfactory and delayed. Significantly, ECG is subject to testing space and time limitation and can only be examined in a hospital. Thus, Holter monitoring prolongs ECG monitoring time and makes up for the time limitation caused by 12-lead ECG. Although Holter improves paroxysmal AF's detection rate, long-term monitoring (24-hours and 72-hours) affects patients' daily routine, with some patients complaining of skin irritation.^[16]

Notwithstanding, considering cost and other factors, such as the inconvenience it causes patients, large-scale population screening would be nearly impossible. The present study focused on the patient's resting position without reflecting the state of the real world. Given these, we need more reasonable methods and user-friendly means for early screening and AF detection in different states. Wristbands have recently become a widely used health management tool, with several individuals wearing them daily. Hence, wearing dynamic ECG recorders will help distinguish AF from normal sinus rhythm accurately and safely in the Chinese population irrespective of postural states.

Methods

Study Population

One hundred sixteen outpatients were recruited from the Shanghai Chest Hospital from June 24, 2020 to July 24, 2020. In two cases, the participants withdrew informed consent halfway through the study. Finally, 114 participants met the inclusion criteria for participation in the study. Participants older than 18-years of age were involved in the study. We excluded participants who were unable to hold both devices, severe arterial occlusion or ischemia of the upper limbs, patients with a pacemaker or implantable cardioverter-defibrillator, and patients who registered for other clinical studies that may affect the purpose of the study. Patients diagnosed as "AF" by 12-lead ECG were selected as AF positive and AF negative patients as AF control groups. Standardized in-person interviews for baseline characteristics, which were collected, included demographics, medical history, and medications. Figure 1 shows a flowchart of the study.

The study is a prospective, registration only, single-center study whose overall goal is to assess the effectiveness and safety for the detection of AF and provide a reliable non-invasive method for the screening and management of AF during daily routines (ClinicalTrials.gov NCT04462653). The study was approved by the Shanghai Chest Hospital's local ethics committee (No.LS2035), and all participants gave

written informed consent before the study. The study was approved following the Helsinki Declaration. The wearable dynamic ECG recorder had been approved by the China Food and Drug Administration (Anhui Device Registration Approval No. 20182210012).

Signal acquisition and processing

Each participant was asked to lie down in a supine position. The choice of an individual's left-or right-hand wristband is pre-set in the wristband's application. Participants held the wearable dynamic ECG recorder on the left wrist on the bed in the ECG room to ensure the results' consistency. Notably, when participants were tested, the attending physician made sure each participant touched the button attached to the 6 o'clock side of the wearable dynamic ECG recorder. After participants were tested with a 12-lead ECG for 60 seconds, subjects actively triggered the wearable dynamic ECG recorder to record the ECG signal for 60 seconds. Then, participants were asked to wear the wristband in an upright position for 60 seconds. After that, participants climbed the third floor and were measured again for 60 seconds. Finally, a full 15 seconds 12-lead ECG recording was performed immediately to confirm ECG's diagnosis at this point.

The participants were asked to rest their right forefinger on the touch button and press their right forefinger with enough force to ensure that the electrode sensors are in contact with their left wrist's skin for the entire duration of the recording. When the participant wore the wristband on his or her left hand with the right thumb on the touch button, it was seen to be equivalent to limb Lead I. The ECG data is transmitted to the Amazfit CardiDoc application and Cloud servers in real-time and analyzed by artificial intelligence (AI) algorithm.

The device consists of a wristband, ECG recorder, the embedded software (installed on the ECG recorder), mobile phone application (Amazfit CardiDoc application installed on the mobile phone, which transmits the ECG data over the network to the cloud servers), and charging cable, designed to capture a user's ECG data and transmit the data via Bluetooth to an iOS or Android mobile phone. The AmazfitCardiDoc application can store thousands of recordings on the mobile phone, and these recordings are also accessible to authorize users on cloud servers. The application determines the presence or absence of a classified waveform for AF or sinus rhythm, which is not recommended for other users with known arrhythmias. Figure1 shows a prototype for AF detection using the wearable dynamic ECG recorder and 12-lead ECG.

Rhythm analysis

12-lead ECG recordings were used as the reference standard for heart rhythm classification. The 12-lead ECG were reviewed by two independent electrophysiologists who were blinded to analyze the results. Possible disagreements will be solved by consensus. Immediately after the wearable dynamic ECG recorder recordings were complete, the software would automatically save the ECG data. It delivered a diagnosis citing by an AI algorithm either as "non-AF," "AF," and "unclassified." If the signal quality was

too poor, unstable, or the requirements were not met, the output was "unclassified." If the contact with the electrode was disconnected during the acquisition, the recording stopped and was restarted.

Study outcomes

The study's primary outcome was the wearable dynamic ECG recorder's accuracy compared with the 12-lead ECG in detecting AF. In contrast, the secondary outcomes were the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the wearable dynamic ECG recorder to detect AF. Safety evaluation criteria included the occurrence of adverse events (AE) and device defects. AE and serious adverse events (SAE) that occurred during the clinical study were recorded, and if the AE and SAE were related to the test device were determined. Device defects included problems arising from the use of test devices, such as failure to wear, no result output, and signal interference.

Statistical methods

A sample size of 108 outpatients would be required with an 80% power and an α of 0.05. Therefore, considering a roughly 5% dropout rate, six outpatients were needed to ensure complete data. Continuous variables with a normal distribution were presented as mean \pm standard deviation (SD), and dates with discrete variables were presented as percentages. On the other hand, dates with non-normal distribution were presented as medians and interquartile ranges. The estimated 30% of patients with AF, fifty-four positive AF samples, and sixty non-AF samples were selected.

Data were analyzed using t-test, Chi-square, or Fisher's exact tests, and the Wilcoxon tests were appropriate. A four-fold table was established to diagnose "AF" or "non-AF" using a 12-lead ECG and "AF" or "non-AF" using a wristband algorithm. When diagnosing AF, the matching rate of the difference between the AI algorithm of wristband judgment and human judgment is a means to evaluate the positive result's consistency. The number of True Positives (TP), True Negatives (TN), False Positives (FP), and False Negative (FN) from the AF and typical sinus rhythm databases were counted.

Subsequently, we calculated the sensitivity $TP/(TP+FN)$, specificity $TN/(TN+FP)$, positive predictive value $TP/(TP+FP)$, negative predictive value $TN/(FN+TN)$, and accuracy $(TP+TN)/(TP+TN+FP+FN)$. The "unclassified" cases were defined as true positive and true negative or false positive and false negative, and then counted and described separately. Statistical analysis was performed using SPSS 22.0 software for Windows (IBM Corp., Armonk, NY, USA). A P -value of < 0.05 was considered statistically significant.

Results

Study population and baseline characteristics

A total of 114 subjects (61 with normal sinus rhythm and 53 with AF), sixty-five males and forty-nine females, mean age 59 ± 11.16 years (range: 25–80 years), were included in the study. Table 1 provided the demographic characteristics of the study population. The age of the AF group was significantly older

than the non-AF group ($P < 0.001$). Also, the proportion of participants with coronary heart disease was higher than the non-AF group ($P = 0.014$). The thromboembolic risk was also higher in participants with AF based on the CHA₂DS₂VASc ($P = 0.001$). Notably, the use of oral anticoagulants, antiplatelet agents, calcium channel blockers (CCB), diuretics, digoxin, and β -blockers was significantly higher in participants with AF (All $P < 0.05$) (Table 2).

Table 1
Baseline characteristics of participants included in the analysis (N = 114)

Characteristics	Mean \pm SD	Min	Max
Age(years)	59 \pm 11.16	25	80
Height(m)	1.66 \pm 0.08	1.5	1.8
Weight (Kg)	66.1 \pm 11.96	40	105
BMI(Kg/m ²)	23.87 \pm 3.28	16.65	33.75
Note: SD, standard deviation.			

Table 2
Baseline demographic of in Non-AF and AF group (N = 114).

Variable	Non-AF (n = 61)	AF (n = 53)	P-value
Demographics			
Age(years)	55.15 ± 11.01	64.00 ± 9.38	∞0.001
Females (n, %)	25(41.0)	24(45.3)	0.644
Height(m)	1.66 ± 0.08	1.66 ± 0.08	0.619
Weight (Kg)	66.16 ± 11.89	66.07 ± 12.15	0.965
BMI(Kg/m ²)	23.97 ± 3.21	23.74 ± 3.38	0.711
Medical history (n, %)			
Hypertension	21(34.4)	24(45.3)	0.237
Diabetes mellitus	6(9.8)	9(17.0)	0.260
Heart failure	14(23.0)	13(24.5)	0.843
Stroke	2(3.3)	1(1.9)	0.643
Coronary artery disease	0(0.0)	5(9.4)	0.014
Vascular disease	3(4.9)	5(9.4)	0.346
Pulmonary embolism	0(0.0)	1(1.9)	0.285
Hyperthyroidism	0(0.0)	1(1.9)	0.285
Renal dysfunction	0(0.0)	1(1.9)	0.285
Hepatic dysfunction	1(1.8)	5(9.4)	0.076
Current drinking	17(27.9)	13(24.5)	0.686
Current smoking	1(1.6)	2(3.8)	0.090
CHA2DS2-VASc score	1(1-2.5)	2(1-3)	0.001
Medication, n (%)			
Oral anticoagulant	1(1.6)	21(39.6)	∞0.001
Antiplatelet drug	1(1.6)	11(20.8)	0.001
ACEI/ARBs	14(23.0)	14(26.4)	0.668

Note: AF, atrial fibrillation; BMI, body mass index; CHA2DS2-VASc, congestive heart failure, hypertension, age ≥ 75, diabetes, stroke, vascular disease, age 65–74 and sex category(female);ACEI/ARBs,angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers∞CCB∞calcium channel blocker.

Variable	Non-AF (n = 61)	AF (n = 53)	P-value
CCB	7(11.7)	18(34.0)	0.004
Diuretic	0(0.0)	8(15.1)	0.002
Digoxin	0(0.0)	10(19.2)	0.001
Beta-blocker	3(4.9)	28(52.8)	0.001
Amiodarone	1(1.6)	5(9.4)	0.063

Note: AF, atrial fibrillation; BMI, body mass index; CHA2DS2-VASc, congestive heart failure, hypertension, age \geq 75, diabetes, stroke, vascular disease, age 65–74 and sex category (female); ACEI/ARBs, angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers; CCB, calcium channel blocker.

Accuracy and safety evaluation of wearable dynamic ECG recorders in 60 seconds in a supine position

The algorithm automatically determined the 60 seconds detection of the wearable dynamic ECG recorder for forty-seven cases of AF, sixty-five cases of non-AF, and two cases that could be judged. The number of cases that were "unable to classify" was defined as "TPTN." The diagnostic accuracy, sensitivity, and specificity using wearable dynamic ECG recorders were 96.49% (95% CI 91.03%-98.92%), 92.45% (95% CI 81.64%-97.52%), and 100% (95% CI 92.91%-100%), respectively. The PPV was 100% (95% CI 91.32%-100%), while NPV was 93.85% (95% CI 84.78%-98.02%).

For cases like "unable to classify," which were defined as "FPFN," the diagnostic accuracy, sensitivity, and specificity using wearable dynamic ECG recorders were 94.74% (95% CI 88.76%-97.80%), 88.68% (95% CI 77.06%-95.07%), and 100% (95% CI 92.91%-100%), respectively. The PPV was 100% (95% CI 90.98%-100%), and NPV was 91.04% (95% CI 81.48%-96.16%).

The medical devices tested in the study belong to category II medical devices with low-risk management level. No adverse events or obvious device defects occurred from beginning to the end.

Accuracy and safety evaluation of wearable dynamic ECG recorders in 60 seconds in an upright position

The algorithm automatically determined the 60 seconds detection of the wearable dynamic ECG recorder for fifty cases of AF, sixty-three cases of non-AF, and one case that could not be judged. The number of cases that were "unable to classify" was defined as "TPTN." The diagnostic accuracy, sensitivity, and specificity were 98.25% (95% CI 93.43%-99.91%), 96.23% (95% CI 86.51%-99.69%), and 100% (95% CI 92.91%-100%), respectively. The PPV was 100% (95% CI 91.63%-100%), while NPV was 96.83% (95% CI 88.50%-99.77%).

For cases like "unable to classify," which were defined as "FPFN," the diagnostic accuracy, sensitivity, and specificity were 97.37% (95% CI 92.21%-99.44%), 94.34% (95% CI 84.03%-98.65%), and 100% (95% CI

92.91%-100%), respectively. The PPV was 100% (95% CI 91.48%-100%), while NPV was 95.31% (95% CI 86.57%-98.92%). There were no adverse events or obvious device defects that occurred from beginning to end.

Accuracy and safety evaluation of wearable dynamic ECG recorders in 60 seconds after climbed the third floor

The result was consistent with the upright position measurement. There were fifty cases of AF, sixty-three cases of non-AF, and one case that could not be judged. No adverse events or obvious device defects occurred from beginning to the end.

Discussion

The study has shown the accuracy of wearable dynamic ECG recorder for AF detection from sinus rhythm in a small population trial setting. It provided a non-invasive, easy-to-use, and affordable tool to detect and discriminate AF in different positions and after exercises. The instrument used in the research is the first domestic instrument that applies an AI algorithm, and a single-lead ECG applied a wristband, which is convenient user-friendly to operate and convenient to wear. The wearable dynamic ECG recorder with an AI algorithm can accurately detect AF in different postures. As such, the specificity and positive predictive value reached 100%. When the position was changed to stand and measured after exercise, it was easier to detect the signal and make the correct diagnosis. The AI algorithm (Huami Technology) evaluated in the study has been fully trained and tested via large-scale real user data to make the algorithm reliable. AI is developed using deep convolutional neural networks. The test set's official data's sensitivity and specificity were 93.36% and 99.75%, respectively.

The single-lead ECG provided physicians with higher specificity and a clear review of the ECG records. Furthermore, the wearable dynamic ECG recorder did not affect daily activities and was waterproof, safe, battery-powered, and electrically safe. The wristband tested in the study did not require frequent communication with smartphones, thus decreasing power consumption and increasing the time of continuous data recording. It could also stand on standby for seven days on a fully charged battery.

The study provided the results of lying position, standing position and exercise to simulate the tool's test results in different states. Moreover, when the application detects AF, it promptly sends text messages to the wearer, related relatives, and a designated doctor assigned by Huami. The designated doctor would then provide patients with further diagnosis and treatment.

Early intervention and qualifiable risk factor control could reduce the incidence of AF. Hence, provide patients with or at risk an essential tool to detect AF at a particular time or over a long period, thus promoting the detection and management of silent AF early before adverse health consequences such as ischemic stroke or heart failure occur.

Nowadays, there are several studies on the detection of AF using ECG signals. It is easy to detect irregular pulse beats by palpation of the pulse. Based on simple training of 173 subjects aged ≥ 75 -years, the elderly subjects were able to identify the sinus rhythm better after been educated, compared with the healthcare control group. The study showed that the proportion of slow (81.8% vs. 56.1%) and fast AF (91.9% vs. 80.7%) were significantly better than the control group. ^[17] Also, older adults could adequately identify normal rhythms by self-palpation of the pulse after been educated, although for most individuals, it is more challenging to find irregular pulse without adequate training. Nonetheless, the dynamic ECG armband recorder proves a useful low-cost method for screening asymptomatic AF patients.

Presently, the 12-lead ECG remains the gold standard for the diagnosis of AF. In a study by Jonas D.E. et al., ECG screening detected more new AF cases than no screening (absolute increase from 0.6% [95% CI, 0.1%-0.9%] to 2.8% [95% CI, 0.9%-4.7%] over 12-months). ^[18] The study also showed that ECG detected no more cases than an approach using pulse palpation. ^[18] Due to the time constraint of recording, AF findings with ECGs are significantly limited. Holter makes up for the missed detection due to the time constraint and the prolonged ECG monitoring duration. In other study with 105 enrolled patients ≤ 50 years, 95 patients (90%) were cryptogenic. ^[19]

In the study, paroxysmal AF was detected in nine patients (two during 24-hour ECG Holter and seven during 3-weeks Holter monitoring). The results showed that prolonged ECG monitoring could improve the detection rate of paroxysmal AF. The implantable circulation recorder is an invasive screening method for AF, which can further improve paroxysmal AF screening with a longer monitoring time. Deshmukh et al. ^[20] conducted a study to evaluate the performance of a single-chamber implanted cardioverter-defibrillator (ICD) in detecting AF, and the research results showed that its sensitivity and specificity in the diagnosis of AF were 95.0% and 99.6%, respectively. However, its high cost, invasive, and difficulty in promotion seriously limit the possibility of its large-scale use, making it impossible to achieve universal screening in a large-scale target population.

Screening AF using traditional methods is challenging. As technology advances, the present research has confirmed that smart devices, such as mobile phones, handing devices, and wearable devices, can be used for AF detection. McManus et al. ^[21] provided an algorithm connecting the root mean square of successive RR difference (RMSSD/mean) and Shannon entropy (ShE). The pulse of seventy-six adults with persistent AF were recorded before and after cardioversion using an iPhone 4S camera. The algorithm demonstrated excellent sensitivity of 96.2%, a specificity of 97.5%, and an accuracy of 96.8% for the beat-to-beat distinction of an irregular pulse during AF from sinus rhythm.

Svennberget et al. ^[22] described a handheld ECG recorder for intermittent ECG recordings with an integrated mobile transmitter that sends 30-second ECG strip data to a database. Participants placed their thumbs on the device twice daily, and whenever they noticed palpitation. Finally, 118 cases (3.0%) were diagnosed with AF, among which only thirty-seven cases (0.5%) were detected with the first handheld ECG, and eighty-one cases (2.5%) were detected with repeated tests. The study showed that

repeated routine ECG examination over a long period could improve AF detection sensitivity, which was four times higher than the number of cases diagnosed by routine ECG examination at a single time point.

In 2017, the AF-SCREEN international collaboration ^[23] confirmed that concerning the method of mass screening, handheld ECG devices have the advantage of providing a confirmable ECG trace, which is required by the diagnostic guidelines for AF, and thus it is preferred as a screening tool. Steinhubl et al. ^[24] conducted a mSToPS randomized clinical trial to confirm the impact of a self-applied wearable ECG patch in detecting AF. The results showed that the new diagnosis rate of AF in the immediate group at four months was higher than the delayed group (3.9% vs. 0.9%, the absolute difference was 3.0%, 95% CI 1.8% ~ 4.1%).

A recent technology of photo-plethysmography (PPG) application was mentioned for the detection of AF. The PPG algorithm's sensitivity and specificity for AF detection were 97–100% and 92–94%, respectively. ^[25] The Apple-Heart Study ^[26] is a mobile application that screens participants by measuring blood flow change flow through the wristband to generate a PPG. The study showed that if periodic signals are detected with PPG technology, participants will receive notifications on the Apple Watch and Apple-Heart study application. After the participant contacts the physician in charge, the physician would decide if they should wear the ECG monitoring patch.

The study demonstrated the positive role of smart wearable devices in AF screening. HUAWEI Heart-Study-MAFA II ^[27] concluded higher sensitivity and specificity of the PPG method in AF screening and achieved a sensitivity of 100%, specificity of 99%, and a positive predictive value of 91.6%. Nevertheless, their data was collected in a supine position. Nonetheless, the supine position does not reflect the actual situation for home screening, where the movement has a more significant influence on the PPG signal. Interference caused by movement should be avoided between single-lead ECG and the PPG technology to improve accuracy. Since single-lead ECG recordings with mobile phones or wristbands for AF detection are clinically superior to PPG signals, they tended to use single-lead ECG recordings in several patients with paroxysmal AF.

With the increase of health awareness, wearable health monitoring is gaining attention, allowing patients to manage symptoms from their own homes comfortably. The wearable dynamic ECG recorder is a feasibility and accurate way for people in need to monitor and track their ECG recordings and share them with their attending physicians.

There are a few limitations to the study. Firstly, the ECG monitoring was collected in no symptoms, not in participants with symptoms. Secondly, our instruments were only used for discriminating between AF and sinus rhythm. The wearable dynamic ECG recorder cannot detect other arrhythmias, such as premature beats, atrial tachyarrhythmias, and atrial flutter. In our future study, new algorithms will be added to help identify and distinguish sinus arrhythmias and various arrhythmia forms. Thirdly, the participants were not followed up. We do not know if people with a normal ECG will develop AF later, and keep the

physicians recommended AF guidance. Finally, the sample size was relatively small, and more extensive testing will be needed to be performed in the future.

Conclusions

AF can be detected using the widely accessible wearable dynamic ECG recorder after different postures and exercises in patients with prior history of AF or at-risk for AF. It may provide a useful and user-friendly tool in screening and diagnosing AF early. More extensive clinical trials are needed to assess the technique's effectiveness in monitoring and early diagnosis of AF recurrence.

Abbreviations

AF, Atrial fibrillation; ECG, electrocardiogram; AI, artificial intelligence; PPV, positive predictive value; NPV, negative predictive value; AE, adverse events; SAE, serious adverse events; SD, standard deviation; TP, true positives; TN, true negatives; FP, false positives; FN, false negative; CCB, calcium channel blockers; ICD, implanted cardioverter-defibrillator; She, Shannon entropy; PPG, photo-plethysmography.

Declarations

Ethics approval and consent to participate The study was approved by the Shanghai Chest Hospital's local ethics committee.

Written informed consent from all participants was obtained.

Consent to publish

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributions

WXF took responsibility for all aspects of the reliability and freedom from bias of the data presented and was a major contributor in writing the manuscript. RGL took responsibility for research design. All authors read and approved the final manuscript.

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Figures

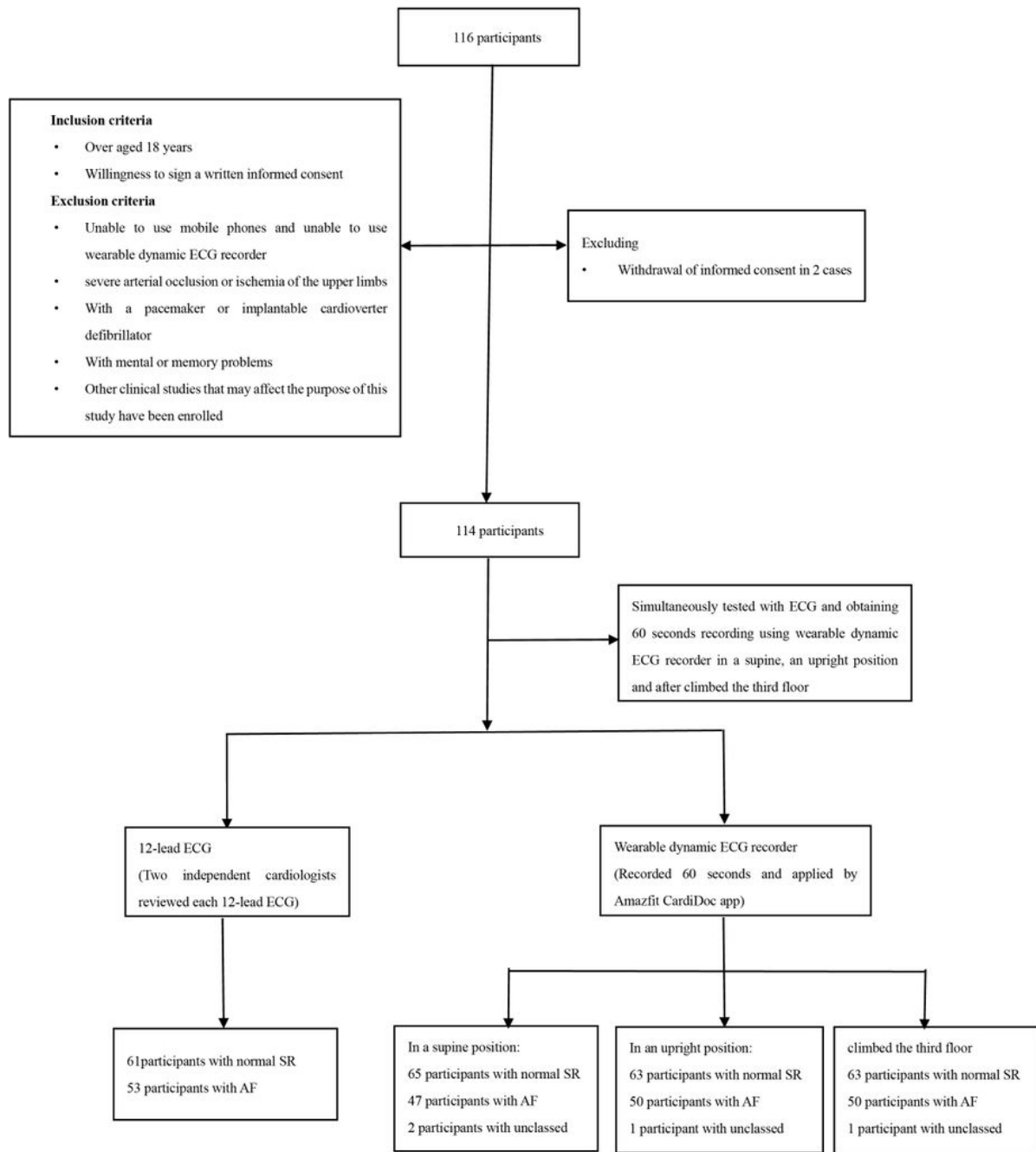


Figure 1

A flowchart of the study. AF: atrial fibrillation; ECG, electrocardiogram; SR: sinus rhythm

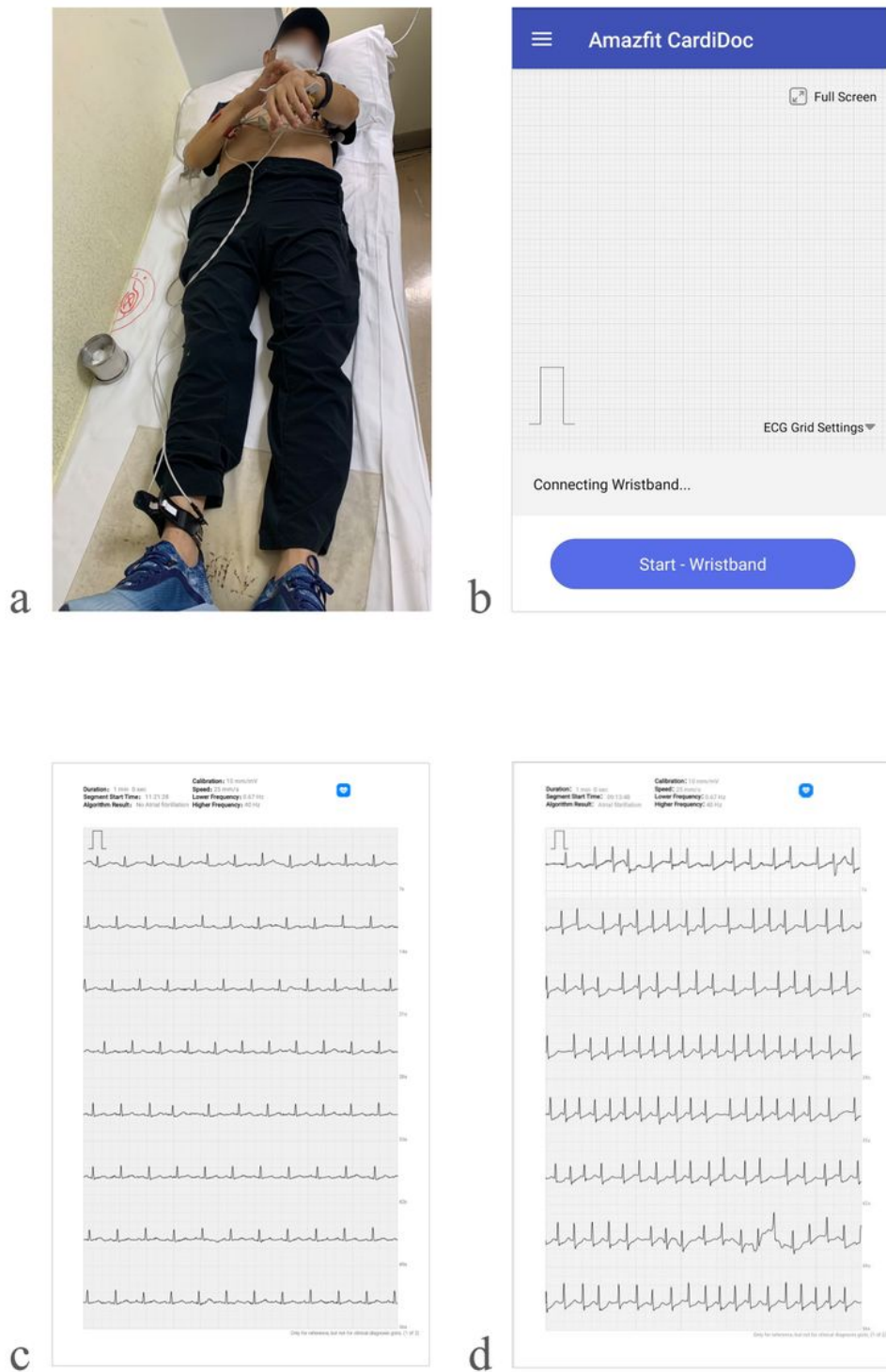


Figure 2

A prototype for AF detection using wearable dynamic ECG recorder and 12-lead ECG. A: A patient is simultaneously tested with wearable dynamic ECG recorder and 12-lead ECG. B: A screenshot of Amazfit CardiDoc app installed on the mobile phone. C: Representative pulse waveform recording a participant with normal sinus rhythm. D: Representative pulse waveform recording a participant with AF. AF: atrial fibrillation; ECG, electrocardiogram.