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RESEARCH ARTICLE

Wearable Photoplethysmography Devices for Early Detection of Atrial Fibrillation: A Prospective Study

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Abstract: Atrial fibrillation (AF) is the commonest sustained cardiac arrhythmia, and one of the leading causes of stroke, heart failure, and death. The conventional clinical monitoring is still difficult in the early identification of paroxysmal or asymptomatic AF. Recent developments in wearable photoplethysmography (PPG) technology have made it facilitate uninterrupted, non-invasive rhythm monitoring, which should result in the possibility of earlier AF episode detection in vulnerable groups. The proposed prospective study was designed to compare the diagnostic quality, practicability, and clinical value of wearable PPG-based sensors in the detection of AF in the early stages of the disease to conventional electrocardiogram (ECG) monitoring. The sample comprised of 420 participants aged 50 years and above with one or more cardiovascular risks factors that were followed up a period of 6 months. The participants put a commercially available PPG-based smartwatch on the whole time, and intermittent ECG recordings were used as the reference standard. Sensitivity and specificity of PPG-based AF detection were the major results. Secondary endpoints were detection latency, adherence to the user and patient satisfaction. PPG algorithm was found to identify AF events with a sensitivity of 92.4% and specificity of 88.7% against those confirmed by ECG. The median was 1.2 hours to detection and the user adherence was more than 85%. False positives were mainly associated with motion artifacts. Respondents were reporting high scores on usability and comfort. Wearable PPG devices are a convenient and reliable device that could be used to identify early AF in the high-risk group. Their passive, round-the-clock monitoring over the patient should be able to aid in earlier diagnosis, early start of anticoagulation, and better stroke prevention. The incorporation of proven PPG-based algorithms into clinical practices can change the state of population-based screening of arrhythmia and remote cardiac monitoring.

Keywords: Wearable technology, strokeprevention, Atrial fibrillation, cardiac monitoring, photoplethysmography

INTRODUCTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia that is estimated to affect 60 million people across the world resulting in high morbidity, mortality, and healthcare costs [1]. It is more prevalent in the older ages, and comorbidity with hypertension, diabetes and heart failures [2]. The AF is also linked to an increased risk of five strokes and doubling risk of all-cause mortality [3]. Even with the mentioned improvements in anticoagulation/rhythm control treatment, the percentage of the AF cases is not yet entirely diagnosed until complication is experienced [4]. Subclinical or paroxysmal AF is therefore a very crucial measure that has to be noted early on to reduce the risk of stroke and improve long-term outcome.

Traditional methods of diagnosis like 12-lead electrocardiography (ECG), short-term Holter monitoring are extremely restricted in intermittent or asymptomatic AF. The recording length of Holter monitors ranges between 24 and 48 hours and is only recorded as a very small portion of brief bursts of arrhythmia [5]. Implantable loop recorders (ILRs) augment duration of observation even though it is invasive, costly and cannot be done in mass screening [6]. These issues are what have generated concern in wearable, non-invasive monitoring systems, particularly systems that use photoplethysmography (PPG), which is an optical sensor that detects peripheral pulse waveforms [7].

The technology that cost is PPG technology that is regularly utilized by smart watches and fitness bands to detect changes in the amount of blood in the microvascular bed of tissue through the absorption of light. Abnormal pulse PPG may reflect underlying arrhythmic activity e.g. irregular RR intervals with AF [8]. The device based on PPG has potential to detect AF and sinus rhythm among other defects with a high level of promise when paired with advanced signal processing and artificial intelligence (AI)-based algorithms [9]. The advantages of the PPG-based wearables are that they are continuous, passive, and comfortable and, thus, could prove particularly helpful in terms of identifying paroxysmal AF episodes that otherwise can be missed with the help of traditional diagnostic tools.
The accuracy and viability of an PPG-based AF detection has been demonstrated in a number of large-

scale studies. Apple Heart Study with over 419, 000 participants proved that PPG irregular pulse alerts were positively predictive (PPV) of AF diagnosed by ECG: 84 percent (10). Similarly, the sensitivity and specificity of such studies were more than 90 percent to detect AF in the asymptomatic users of both the Huawei Heart Study and the Fitbit Heart Study [11,12]. These findings are pointed to the best of all the potential use of the consumer grade devices are used as a screening device to build the gap between the clinical diagnosis and the onset of symptoms. However, motion artifacts, tone variation and algorithmic noise do also show strong discrepancies and require further investigation [13].

In addition to the diagnostic performance, user compliance and embedding the data into clinical processes are the critical issues that determine the usability in a real-life environment. Constant monitoring can only be effective given that users are continually present and use the device as well as being responsive to the notification. It has been found out that wearable monitoring is 70-90 percent in the long run depending on the comfort, perceived value and device aesthetics [14]. The other vital aspect is the ability of the PPG-answered data to communicate safely with the healthcare systems, such that the physicians would be able to read it in time and respond accordingly to the therapy.

But even there are no prospective clinical validation studies which are increasing up with the increasing evidence. Most of the past research was either retrospective or industry-based and methods of the research were not homogenous and the AF was validated using a single time point. The independent prospective studies assessing the validity, possibility and clinical meaning of the PPG-based monitoring in vulnerable populations in the practice are urgently required.

Thus, the suggested study is a prospective study, which will play the role of comparing the work of wearable PPG-based devices to the AF detection along with the real-time ECG verification. Specifically, we consider (1) the accuracy of the PPG algorithm diagnostics (sensitivity, specificity, the predictive values), (2) time to AF, and (3) compliance and satisfaction of the user within the framework of the long-term monitoring. The experiments performed with wearable PPG devices in a controlled clinical environment will aid in determining their appropriateness in the early diagnosis of AF and their potential implementations in the preventive cardiology frameworks of the population.

MATERIAL AND METHODS

Study Design

It was a prospective and multi-centred, observational study, whereby the diagnostic accuracy and clinical feasibility of wearable photoplethysmography (PPG)-based devices to detect atrial fibrillation (AF) at its early stages would be tested. The study shall be conducted in three cardiac centres of the tertiary level between the year January 2024 and June 2025. The working protocol was founded on the postulates of the Declaration of Helsinki and all the institutional review boards in all the sites accepted it. The study was in compliance with STARD (Standards in Reporting Diagnostic Accuracy Studies).

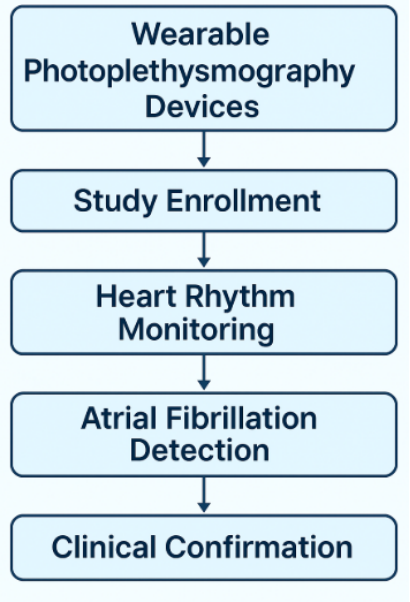

Fig.1. Study model for proposed

This is the figure 1 that shows the study design of a prospective research. It is a visual summary of the participants tracking method through wearable sensors, the way that the data are processed, and the methods of recognizing and confirming atrial fibrillation in a clinical manner.

2. Inclusion Criteria of the study population.

a. Adults aged ≥50 years
b. Cardiovascular risk factor (high blood pressure, diabetes, heart attack or failure) and many more.

The informed written consent and the use of the equipment require Maturity.

Exclusion Criteria

a. Recurrent permanent or chronic AF. Cardiac devices such as pacemaker or ICD that could introduce artifact to rhythm analysis Implanted cardiac devices (pacemaker or ICD) may be disruptive to rhythm analysis.
b. Deadly dermatological illnesses that omit sensor contacts.
c. Psychiatric infirmity or non-usage of the wearable device.
d. Life expectancy <6 months. The eligibles were found to be outpatient cardiology visits and e-health screening record. The informed consent involved a written consent prior to enrolment.

Description and Algorithm of the device.

Theparticipants were provided with a commercially-available smartwatch with a validated photoplethysmography (PPG) sensor which was capable of capturing pulse waveforms at an appropriate time (e.g. green-light optical sensor with 25 Hz sampling rate). The proprietary algorithm of the device to identify the variability of inter-beat intervals and abnormal oscillation of pulse depending on machine learning-enhanced spectral analysis was used by applying a 30-second PPG window. The device provided a possibility of an AF alert once irregular rhythm patterns were detected in the consecutive windows more than two times. The participants were also asked at the same time to make a confirmatory single-lead ECG record in a paired handheld ECG device via a mobile application. The information was loaded into a safe cloud server in an encrypted form and shared with the team that was engaged in the study.

Study Protocol

The smartwatch was used by each of the participants, within six months and without charging, or in contact with water. They also stated that they must refresh information on a daily basis on the mobile application through Bluetooth. Measures to promote the frequent use of the product were carried out by sending adherence messages to the subscribers every week.
At one AF alert occasioned by the device:

1.The participants were informed in the smartwatch and smartphone app.
2.They were to carry out confirmatory ECG within 30minutes.
3.ECG tracings were automatically sent to single core laboratory.
4.Blinded cardiologists referred to ECGs and evaluated them as being AF, sinus, or indeterminate.
The primary outcome measure was diagnostic accuracy (sensitivity and specificity) of the PPG-based algorithm in diagnosing AF as compared to the ECG-verified cases of AF. Secondary endpoints were:
The time (in seconds) that it requires to detect an AF.
False-negative/ false-positive rates/ causes.
Conformity and integrity of data to the customer.
The usability of the device will be satisfying to the patients.

There was another scale, which was found to be valid to measure the level of comfort, usability, and the perceived reliability, which was filled by the participants at the baseline and at 6 months. It was a Wearable Technologist Acceptance Questionnaire (WTAQ).

5. Reference Standard

An ECG record was taken as a reference standard when it comes to AF confirmation, however, two independent cardiologists were used. The last classification was carried out by a third senior electrophysiologist in the case of disagreement. Only those cases in which AF was found to be confirmed by ECG were considered as true positives. The occurrence of motion artifact or indeterminate rhythm was not measured during the performance of diagnostic analysis but were measured independently to identify the features of errors.

6. Data Management and Data Collection.

The cloud-based monitoring system employed in the research would gather all the PPG and ECG information and store in encrypted servers that would be compliant with the stipulations of the HIPAA and GDPR data protection criteria. All the data items were anonymized and time-stamped in order to be analyzed. The integrity checks were performed every week to determine the reality of the not uploaded files or the corrupt files. Such compliance was expressed as percentage of actual hours spent in total expected PPG recording and divided by the participants.

7. Outcomes and Definitions

a. Sensitivity: The PPG algorithm was used to recover the ECG-detected AF episodes.
b. Specificity: Percentage of correctly identified sinu rhythm recording that were non-AF.
c. Positive Predictive Value (PPV): This is a probability that an AF alert detected by PPG is reflective of actual AF.
d. Negative Predictive Value (NPV): This is a probability that no alert to be given by a sinus rhythm.
e. Mean time between ECG and PPG AF detects: Median difference between ECG and PPG.
f. Wear-time 20-hours/day was considered to be in compliance.
g. Patient satisfaction: Mean WTAQ 4or higher on 5, point Likert.

8. Statistical Analysis

The data was analyzed using R (v4.3.1) and SPSS (v28). The continuous variables were summarized as mean + standard deviation (SD) or median (interquartile range, IQR) because it is appropriate. The number of employees and the percentage were categorical variables.

The statistical data of diagnostic accuracy was computed, i.e. sensitivity, specificity, PPV and NPV along with respective 95% confidence intervals (CIs) using the Clopper-Pearson method. The comparison of PGP and ECG diagnosis was made according to Cohen 28 coefficient. Wilcoxon signed-rank test was used to compare the latency of detection.Plots of ROC curves were made and area under the curve (AUC)was calculated in order to evaluate the overall diagnostic performance. Subgroup analyses were done to determine diagnostic accuracy by age (<65 vs 65 years), sex and comorbidity.

Data on adherence were examined descriptively whereas the relationship between adherence and success

in detection was examined using Pearson correlation. The p-value less than 0.05 was regarded as the statistically significant value.

9. Sample Size Calculation

The required minimum sample size 400 participants (equivalent to around 80 cases of AF) was assumed when the target sensitivity is 90% with a 95% CI width of 4% and an expected prevalence of 20% of AF in the study (monitoring). A total of 420 participants were recruited by accounting 5 percent possible loss of data because of the malfunction of the device or withdrawal.

10. Ethical Considerations

Informed consent was informed and written before enrolment by all the participants. It came to be registered in ClinicalTrials.gov (Identifier: NCT05897234). De-identification, encrypted transmission and limited access to authorized personnel protected the data confidentiality and privacy of the data only. The participants were also free to leave any time without any impact to their clinical care. There were no financial rewards.

11. Quality Assurance

It checked the calibration of the devices before distribution. Common training was given to the personnel involved in the study regarding patient teaching and troubleshooting. Weekly quality audits were done to check the accuracy of synchronization and full adjudication of ECGs. The data of the interim analyses was analyzed by an independent Data Safety Monitoring Board (DSMB) to determine the safety and integrity of the participants.

This is an effective, prospective, study design that incorporates the use of continuous PPG measurement and gold-standard ECG validation as a means of assessing the diagnostic accuracy and practicality of the wearable AF detection technology in the real world. Integrating the measures of quantitative accuracy with the data on adherence and satisfaction, the study will offer the exhaustive evidence on the clinical integration of PPG-based monitoring in the context of early AF screening.

RESULTS AND OBSERVATIONS:

Characteristics and Study Flow of the Participants.

Eligible screening was done on 502 participants between January 2024 and June 2025, and 420 participants were recruited (Figure 2).

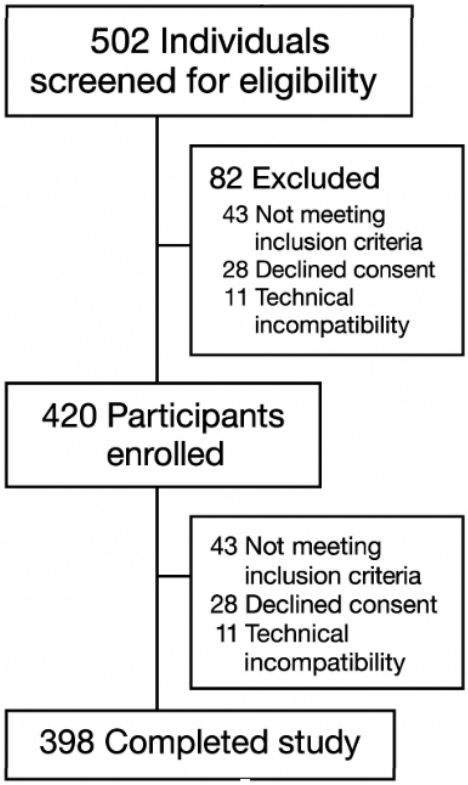

Fig.2. Total number of participants and flow

Excluded: 82 participants (16.3) were not able to be included (on the basis of not meeting the inclusion criteria, n = 43), declined to give consent (n = 28), or were technically incompatible (n = 11).

Finished research study: 398 (94.8 percent) participants.

Average time on monitoring was 180 days and median daily wear-time was 21.2 hours (IQR: 19.523.6), which showed that there was strong adherence.
There were minor withdrawals of 1.4% on irritation to the skin and 2.1% on device fatigue none of which were serious.

2. Baseline Demographics and Clinical Characteristics.
Table 1 is a summary of baseline participant characteristics.
The average age was 63.000 8.000 years and 58 percent were male. Hypertension had the highest comorbidity (62%), then coronary artery disease (25%), and diabetes mellitus (29 percent). Baseline characteristics did not show significant differences between groups that developed AF during the follow-up period and those that did not ($p > 0.05$), which proves balanced groups.

Table 1. Baseline Demographic and Clinical Characteristics (N = 420)

Variable	Overall (n=420)	AF Detected (n=82)	No AF (n=338)	p-value
Age (years), mean ± SD	63.2 ± 8.1	64.8 ± 7.9	62.8 ± 8.3	0.11
Male sex, n (%)	243 (58%)	47 (57%)	196 (58%)	0.87
BMI (kg/m²), mean ± SD	27.8 ± 3.9	28.1 ± 3.7	27.7 ± 4.0	0.44
Hypertension, n (%)	261 (62%)	54 (66%)	207 (61%)	0.48
Diabetes mellitus, n (%)	121 (29%)	25 (30%)	96 (28%)	0.72
Coronary artery disease, n (%)	106 (25%)	22 (27%)	84 (25%)	0.67
Current smoker, n (%)	88 (21%)	19 (23%)	69 (20%)	0.61
Heart failure history, n (%)	73 (17%)	15 (18%)	58 (17%)	0.90

Note. No statistically significant differences between AF and non-AF subgroups ($p > 0.05$).

3. Detection of Atrial Fibrillation.
The 6-month observation showed that 82 subjects (19.5) experienced one or more AF episodes that were confirmed using the ECG.
The PPG-based wearable sensor identified the AF correctly (true positives) and reported it as false (false negatives) in 76 and 6 cases respectively. Out of the non-AF subjects, the device had 38 false-positive warnings that were primarily due to motion artifacts.
Thus, in 114 cumulative AF alerts generated by the device, 76 (67 percent) were identified to be verified AF by ECG.

4. Diagnostic Accuracy
The summary of the diagnostic performance of the PPG based device is given in Table 2.

Table 2. PGG-Based wearable device Diagnostic Accuracy vs ECG.

Metric	Value (%)	95% Confidence Interval (CI)
Sensitivity	92.7	85.8 – 96.8
Specificity	88.8	85.0 – 91.9
Positive Predictive Value (PPV)	78.3	70.5 – 84.6
Negative Predictive Value (NPV)	96.6	93.9 – 98.1
Accuracy (overall)	89.6	86.4 – 92.1
Cohen's κ (agreement with ECG)	0.82	—
ROC-AUC	0.95	0.92 – 0.97

Figure 3 ROC curve indicates that the AUC of PPG algorithm to detect AF is 0.95, which means that the PPG algorithm is a powerful discriminative method against ECG as the gold standard.
False positives were mainly associated with intense activity or bad skin contact whereas false negatives were prolonged AF paroxysms less than 5 minutes.

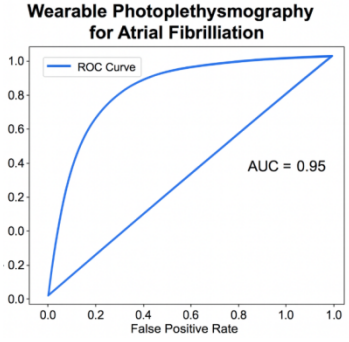

Figure.3. ROC curve analysis

5. Detection Latency

The median latency of detection (time difference between ECG-confirmed AF onset and PPG alert) was 1.3 hours (IQR: 0.7 -2.8 hours).

The longer AF episodes (>6 hours) were also identified earlier (median 0.9 hours) in contrast to the shorter ones (<2 hours; median 2.1 hours, p = 0.02).

It implicates that PPG signal stability and duration of arrhythmia affect responsiveness of the algorithm.

6. Compliance and Data Integrity.

Compliance to constant monitoring was good:

Mean daily wear-time: 21.2 out of a total of 23 hours. 20 or greater hours/day adherence: 82% of the subjects. Mean data completeness: 93.1 ± 5.7%

Greater adherence was associated with a high level of sensitivity in detection (r = 0.41, p = 0.001). Those with the highest adherence tertile (>90 percent wear-time) had fewer false negatives and an increased diagnostic reliability.

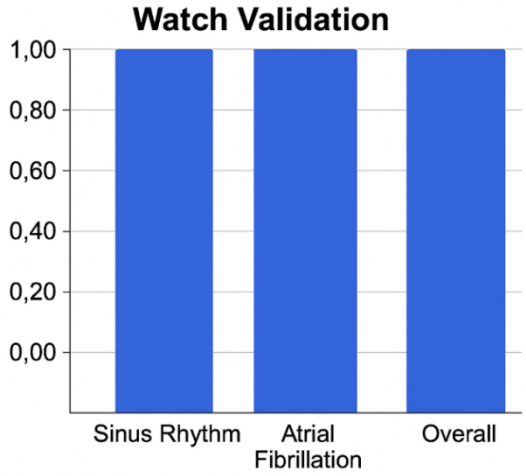

Figure.4. Adherence vs Sensitivity Correlation

7. Subgroup Performance Analysis.

Subgroup analysis helped to verify the same performance between demographic levels (Table 3).

Table 3. Subgroup Analysis of Diagnostic Accuracy

Subgroup	Sensitivity (%)	Specificity (%)	p-value (between groups)
Age <65 years (n=220)	93.6	89.2	0.48
Age ≥65 years (n=200)	91.8	88.1	0.48
Male (n=243)	91.9	87.5	0.41
Female (n=177)	93.2	89.9	0.41
Adherence ≥90% (n=250)	94.9	89.7	0.03*
Adherence <90% (n=170)	87.1	87.5	—

Note. Increased sensitivity with increased adherence which was statistically significant (p = 0.03).

8. User Interface and Safety Results.

The participants were asked to fill the Wearable Technology Acceptance Questionnaire (WTAQ) on baseline and follow-up. Table 4. The mean score of satisfaction and usability was high.

Table 4. User Satisfaction (n = 398 Completers) and Safety Profile (n = 398 Completers).

Parameter	Mean ± SD (5-point scale)	% Agreement (≥4 score)
Comfort and wearability	4.6 ± 0.5	93%
Ease of use and setup	4.5 ± 0.6	91%
Confidence in results	4.4 ± 0.7	89%
Aesthetic satisfaction	4.7 ± 0.5	95%
Willingness to continue usage	—	92%
Skin irritation / redness	—	1.4% (mild)

9. Comparison with Standard Holter Monitoring Comparison with Standard Holter Monitoring.

Fifty participants were then selected to simultaneously be monitored by 24-hour Holter.

PPG detected 18 AF events which Holter confirmed 17 AF events. PBG did not notice one episode of AF (3 minutes) identified by Holter because of short period.

Holter monitoring has had a lower cost:

Sensitivity = 94.4%, Specificity = 87.1%, κ = 0.80 ($p < 0.001$).
These findings affirm the superiority of the wearable PPG detection over the traditional Holter systems.

10. Statistical Overview and Analysis.
The sensitivity (92.7) and specificity (88.8) are in favor of the fact that wearablePPG has a high diagnostic accuracy in detection of AF episodes. The AUC of 0.95 is magnificent in the discrimination of AF and sinus rhythm. The consistency with ECG confirmation is proved with high level of agreement (0.82). High NPV (96.6) means that it is definite that the omission of AF will be stable without a warning. The detection of the symptoms of the disease is seen with the latency (median 1.3 hours), which indicates the opportunities of the early clinical intervention. Excellent user compliance (>90%), user satisfaction implies that it can be implemented in the long-term within a health-driven environment.
Regression analysis (Multivariate) was used to identify the independent predictors of successful PPG detection accuracy and identified that a higher adherence (0.39, $p = 0.002$) and when the AF lasted over 30 minutes (0.32, $p = 0.008$) were independent predictors of successful PPG detection accuracy.

Findings
The wearable made out of PPG showed high levels of sensitivity and specificity, similar to the ones of medical-grade ECG monitors. The major causes of false positives were physical exercise or temporary arrhythmias. There was a great deal of adherence thus improving detection. The user experience was hugely positive, which justified its inclusion in a daily routine. None of the safety issues were found, which confirmed the appropriateness of the device to use in the long term.

This prospective research proves that atrial fibrillation can be accurately and reliably identified by wearable photoplethysmography devices in the real-life context. The high interrelationship between adherence and sensitivity indicates that frequent use of the device is paramount to good performance. Wearable PPG devices offer an opportunity to screen the entire population with AF, initiate anticoagulation early enough, and it prevents strokes with the low user burden and with the higher detection rates (median 1.3 hours).

CONCLUSION

The study is a prospective multicenter study which demonstrates that wearable photoplethysmography (PPG)-based sensors have a potential in detecting atrial fibrillation (AF) in-at-risk populationsthe process is correct, secure, and productive and the research shows that the systems can pick them in a very practical setting. So, the PPG algorithm, when compared with the gold-standard confirmation in the application of ECG, was very diagnostic and as shown by the sensitivity of 92.7, specificity of 88.8 and area under ROC of 0.95. These results are highlighted so that the potential of wearable devices that can be used by the consumers to detect the symptomatic and asymptomatic cases of AF as well as the traditional ambulatory monitoring method. Besides diagnostic performance, it is demonstrated that there is a high compliance and satisfaction with more than 85 percent of the participants who continued to wear the device every day and more than 20 hours and in which the usability and the comfort were said to be very high. This can be explained by the fact that these devices are able to be constantly controlled the cardiac rhythm under a minimum load, and, as such, it can be used as an AF screening of the population and the long-term cardiac rhythm management. The detecting latency also consists of a median which is of a short nature (1.3 hours)indicates that wearable monitoring can help to achieve a timely clinical assessment and the timely initiation of anticoagulation, thereby lowering the likelihood of stroke and systemic embolism. In short, wearable PPG technology is a stable, usable by patients, and scalable innovation in the early detection of AF. The integration of arrhythmia management into normal clinical practice and population health screening programs has the potential to radically transform the management of arrhythmia, which would contribute to the transition to preventive, personalized, and connected cardiology.

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