REVIEW

Smartwatch Technology's Diagnostic Use in Atrial Fibrillation Detection – A Literature Review

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Abstract

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Introduction: An ECG is the gold standard for detecting various cardiology pathologies including AF. Current ambulatory heart rhythm monitoring technology include Holter monitoring and various implantable event monitors, which provide continuous monitoring but are invasive, uncomfortable and may lack in detecting intermittent arrhythmias, due to their periodic exploratory monitoring strategy.

Methods: A systematic search was conducted using the following databases: Cochrane Library, Embase, PubMed, and Google Scholar. The search was conducted using the keywords "atrial fibrillation," "smartwatch," "ECG," "stroke," and "PPG". Relevant sources between 2018 and 2023 were chosen, and data was analysed to establish clinical utility in early diagnosis of AF.

Results: Two studies assessing the diagnostic efficacy of smartwatch technology, two studies investigating the usability of new technology and one study assessing cost-effectiveness were included in our review. The diagnostic efficacy of smartwatches ranges from 93.5-98.25% accurate, 92.45-97.3% sensitive and 88.6-100% specific, with PPV ranging from 91.6-100%, and NPV ranging from 93.85-96.83%. Targeted audiences of AF detection includes a larger proportion of older adults with possible declined technological and/or cognitive function, and may find difficulty using current smartwatch technology. With a simplified user interface, novel software like Pulsewatch promotes user accessibility in smartwatch technology, making AF detection simple to identify, particularly in elderly people. 90 patients used the Pulsewatch system, and more than half reported having a positive experience with the system; only 13% considered it excessively stressful.

Discussion: Due to the low 65+ age group representation (6.6%) in studies like Fitbit, Huawei, and Apple heart studies, they overlook potential bias in older adults' adherence to pAF monitoring. Pulsewatch addresses this issue. Smartwatches, being user-friendly and cost-effective, offer real-time, reasonably accurate prospective data for patients. However, further research is required to gauge their clinical utility in early AF detection, diagnostic effectiveness during daily activities, and the heterogeneity of smartwatch devices remains to be fully explored.

Conclusion: User-friendly PPG-based smartwatch technology is a medically accurate alternative to standard AF detection techniques that may speed up the diagnosis and treatment of AF, lowering stroke and cardiovascular disease-related morbidity and mortality as well as AF-related healthcare costs.

Keywords: atrial fibrillation; smartwatch; ECG; stroke; photoplethysmography

Introduction

Physiology of the Contraction of the Heart

The contraction of the chambers of the heart relies on the electrical signals transmitted from the cardiac conduction system which consists of the sinoatrial (SA) node, atrioventricular (AV) node, Bundle of His and Purkinje fibres [1]. The SA node, located in the right atrium, auto-generates electrical impulses, stimulating the contraction of the atria, before travelling to the AV node, where the electrical signal is slowed to allow the ventricles to fill up with blood [2]. The Bundle of His, which extends from the AV node towards the centre of the heart, receives the electrical impulse, which then travels to the Purkinje fibres [3]. The ventricular muscles are then stimulated to contract, pumping oxygenated blood to the aorta and deoxygenated blood to the pulmonary arteries [1].

Pathophysiology and Complications of Atrial Fibrillation

Atrial fibrillation (AF) is a supraventricular arrhythmia which causes irregularly irregular ventricular contraction as a result of uncoordinated atrial activity [4]. The pathophysiological mechanism of AF is not fully comprehended; however, it may be initiated by the rapid firing of electrical signals from ectopic foci found in the muscular sleeves of the pulmonary veins [5]. It may also be caused by diseased, fibrotic atrial tissue as fibrosis alters

the conduction properties of the tissue, resulting in local conduction changes and conduction blockage; however, the precise mechanisms that cause these bursts are unknown [6].

The ineffective, rapid and uncoordinated contractions of the atria results in blood stasis in the atria [7,8]. Consequently, this will increase risk for thromboembolic events such as ischaemic stroke [9]. An almost fivefold increased risk of ischemic stroke was linked to AF [10]. Moreover, over 15% of all stroke patients in the US have a history of undetected AF [11]. Studies suggest that strokes caused by AF are more severe than strokes caused by other causes [12]. The association between undetected AF and stroke makes clear the importance of AF identification in lowering the morbidity, mortality, and financial burden caused by complications of AF.

Causes, Prevalence, Symptoms and Classification of AF

AF can be caused by a number of pre-existing disorders such as pulmonary embolism, myocardial ischemia or infarction, myocarditis, pericarditis and excessive alcohol intake (13). However, the most common cause of AF is increasing age [14]. An estimated 2.2 million people in the United States have AF, with the median age being 75 years of age, and 70% people above 65 [15]. In addition, AF has relatively equal prevalence in both males and females [16]. Other risk factors are obesity, European ancestry, heart defects, a family history of AF and hypertension [17,18]. AF usually presents asymptomatically as one in three patients are asymptomatic. However, when an AF patient does exhibit symptoms, they are frequently nonspecific (palpitations, chest pain, dyspnoea, etc.) [19].

AF is organised into classifications depending on how long an episode lasts. Within the first seven days, it is referred to as paroxysmal AF (pAF). Episodes lasting for more than 7 days and ending spontaneously or with treatment, are referred to as persistent AF. Episodes of AF that last for longer than a year are known as long-standing AF. Permanent AF is when the AF does not respond to treatment [20].

Traditional AF Diagnostic Tools

An electrocardiogram (ECG) is the gold standard for detecting various cardiology pathologies including arrhythmias [21]. Recommendations from the 2014 American Heart Association/American Stroke Association suggest routine ECG screening in older adults \geq 65, but do not provide guidelines on the frequency at which screening should occur [22,23]. The United States Preventive Services Task Force found inadequate evidence for the benefit of ECG screening in asymptomatic older adults, opposed to lifestyle modifications including diet management, and regular exercise [24]. Unnecessary ECG screening can cause patient anxiety from inaccurate results or misdiagnosis, and treatments such as anticoagulants can increase adverse event risk, such as major bleeds [24]. Current ambulatory heart rhythm monitoring technology include Holter monitoring and various implantable event monitors, which provide continuous monitoring [25]. Holter monitoring requires skin patches, electrodes, and wires which are uncomfortable and only provide periodic exploratory monitoring for 12-48 hours at a time in which intermittent AF may go undetected [26]. While implantable cardiac monitors avoid these disadvantages, they are invasive and unnecessary in patients without current AF [26]. Smartwatch technology offers a unique, potentially inexpensive method for continuous heart rhythm monitoring as a screening tool, especially in individuals who are not currently susceptible to thromboembolic events.

Smartwatch Technology and How It Works

Smartwatches are being increasingly used by people across the US as around 13% of Americans own smartwatches, an additional 40% of Americans have expressed interest in purchasing a smart watch and 77% of Americans own smartphones [27]. Smartwatches on the market, such as the Apple Watches series 7, 8 and the Ultra, were able to detect AF with 98.3% sensitivity and 99.6% specificity and were granted FDA-approval [28,29]. These watches all include photoplethysmography (PPG) technology which is used to determine the users heart rate [28]. PPG technology uses measurements of the volumetric differences in blood circulation using an infrared light on the surface of the skin [30]. This measurement provides information about irregularities of the cardiovascular system, such as alerting the user if there is an increased, skipped, low, or irregular heartbeat [30]. The users' heart rhythm is periodically monitored, and weekly alerts are delivered with an estimated percentage of the time their heart showed signs of AF [31]. This may provide a more accurate picture of present cardiac abnormalities if the results are consistent over time. However, PPG-based watches may not track PPG signals accurately while the user is performing daily tasks and light physical activity [32].

Cost-effectiveness of Smartwatch Usage for AF detection

Primary admissions due to AF account for between 0.9% and 1.6% of NHS spending, potentially rising to 1.35-4.27% of NHS spending in the next two decades [33]. The cost-effectiveness of smartwatch devices was compared to that of conventional methods, which included manual pulse palpation and 12-lead ECG, for the identification of AF in symptomatic primary care patients in a 2019 study [34]. Smartwatches produce an incremental cost-effectiveness ratio for each quality adjusted life year (QALY) gained below the £20,000–£30,000 mark [34].

Diagnostic Efficacy of Smartwatch Detection of AF: Sensitivity, Specificity, Accuracy, Positive Predictive Value and Negative Predictive Value

Most published data regarding the diagnostic efficacy of smartwatches to detect cardiac arrhythmias (primarily detection of AF) was summarised by a meta-analysis by Nazarian et.al in 2021. In the study, smartwatch's diagnostic efficacy in identifying cardiac arrhythmias revealed pooled sensitivity of 100% in 17 trials with 5074 patients and pooled specificity of 95% in 16 studies with 5050 subjects [35]. Furthermore, the combined accuracy for arrhythmia detection among the 1769 individuals under study was 97% [35]. A total of 421,267 patient instances were analysed to examine the positive predictive value (PPV) for cardiac arrhythmia detection, which resulted in a PPV of 85%. In six trials, the pooled negative predictive value (NPV) was reported to be 100% when 3323 participants were considered [35]. Overall, these studies suggest that smartwatches have a relatively high sensitivity and specificity in diagnosing AF.

<u>Clinical Usefulness of Smartwatch Usage for Early</u> <u>Detection of AF</u>

The difficulty in detecting AF is that it might be intermittent or asymptomatic for a long period before manifesting clinically, presenting a significant financial burden [36]. Using smartwatches, it is possible to identify asymptomatic AF quickly and start treatment in at riskpopulations [37]. The periodic exploratory strategy used by current AF detection techniques, during which an irregular pulse might not be present, is challenged as AF can often be intermittent [26]. A simple, non-invasive, and user-friendly alternative to existing ECG monitoring methods, such as 24hour Holter monitoring, could be a smartwatch device that detects AF. Due to their simplicity, patients have preferred these devices over traditional monitoring systems [38]. In a study published by Ding et al. discussing usability of smartwatches among the elderly, two-thirds of participants deemed the smartwatch to be extremely acceptable despite their advanced age, lack of knowledge with smartwatches, and significant load of comorbidities [39].

Limitations of Smartwatch Devices for AF Detection

In geriatric communities, the use of wearable technology may have limitations of concern. In a study of 445 hospitalised patients in cardiology and geriatric departments, the use of wearable electronics failed in 7% of cardiology and 21.4% of geriatric patients due to difficulty in correctly managing the equipment [34]. Patients may also go to the emergency department after receiving a false-positive result, which raises questions about wearable device-related anxiety, healthcare expenditure, and the dangerous side-effects of unnecessary anticoagulants. Furthermore, this relatively new technology has caused issues with patient privacy as the usage of smartwatches provides opportunity for data brokers to access patient data [34]. This review will focus on the clinical usefulness of the usage of smartwatches for the early detection of AF including diagnostic efficacy, usability, and cost-effectiveness.

Methods

Search Strategy and Selection Criteria

This literature review took a systematic approach to find relevant literature. All studies pertaining to smartwatchdetected AF, regardless of publication type or language, were identified using the online databases of PubMed, Google Scholar, Cochrane Library and EMBASE. MeSH headings were used in PubMed and Cochrane, and EMTREE headings were used in Embase. All databases were searched from January 1, 2018 to February 20, 2023 and relevant sources were selected, and data was analysed to determine a potential clinical usefulness in early detection of AF. The search strategy was limited to papers published after 2018 as the field of smartwatch technology is rapidly developing and articles published before 2018 most likely investigated smartwatch technology no longer widely used today. The search terms used were: ("atrial fibrillation" OR "arrhythmia" OR "cardiac arrhythmia" OR "supraventricular arrhythmia") AND ("smartwatch" OR "Apple Watch" OR "Samsung Gear" OR "photoplethysmography" OR "PPG") AND ("ECG" OR "electrocardiogram" OR "Holter monitor") AND ("stroke" OR "thromboembolic events"). In order to increase sensitivity, all search terms were combined with Boolean operators and searched using both key words and MeSH terms. The search was modified using EMTREE phrases when searching the Embase database. To further obtain articles that are suitable for inclusion, reference lists of papers found in the literature search were manually searched.

Based on their titles and abstracts, articles were initially assessed by two reviewers (J.M. and D.T.). All identified articles were systematically evaluated. An independent reviewer (R.S.) settled disputes regarding inclusion.

Results

Search Results and Characteristics

The database searches yielded 231 studies that met the criteria. After duplicates were eliminated, 223 studies qualified for title and abstract screening. The following step was to conduct a full-text review, which included a total of 5 studies. Studies that didn't meet the criteria for inclusion were disregarded, and the reasons for this included unsuitable interventions (such as not using a smartwatch) or unsuitable outcomes (such as studies that didn't involve the detection of cardiac arrhythmias or reports on diagnostic accuracy).

The studies included in this literature review were all published between 2018 and 2023. In terms of diagnostic efficacy, the outcome measure in the studies was primarily AF detection. The Huawei smartwatch was used in one study, while the Garmin smartwatch was used in another. In

all studies, an ECG in the form of a 12-lead ECG or a Holter monitor was used as the reference standard. The Samsung Tizen Watch OS was used in the Pulsewatch study.

Diagnostic Efficacy of Smartwatches in AF Detection

In the Huami heart study in Shanghai in 2020, 114 patients were placed in supine position for 60 seconds producing diagnostic accuracy, sensitivity, and specificity using wearable dynamic ECG recorders of 96.49%, 92.45% and 100%, respectively. The PPV was 100%, while NPV was 93.85%. The same 114 patients placed in an upright position yielded a diagnostic accuracy, sensitivity, and specificity of 98.25%, 96.23%, and 100%, respectively. The PPV was 90%, while NPV was 90%, while NPV was 96.83% [40].

In a study by Chung et al, 109 of the 112 people diagnosed with AF had instances of AF detectable by Garmin smartwatch PPG technology when compared to the gold standard Holter ECG. The accuracy was 93.5%; the PPV was 91.6%; the NPV was 96.3%; the specificity was 88.6%; and the sensitivity was 97.3% [41]. Results also showed that rapid ventricular rate in AF was the most common cause of false negative AF detection and premature beats were the most common reason for false positive AF detection [41].

Though heterogeneous in regards to patient's position while being measured and in regards to which devices were used, new studies regarding diagnostic efficacy of smartwatches range in accuracy from 93.5%-98.25%, sensitivity from 92.45%-97.3%, specificity from 88.6%-100%, PPV from 91.6%-100%, and NPV from 93.85%-96.83% [40,41].

Usability of Smartwatches in the Elderly Population

Typically, smartwatches are catered towards a younger, busier population, subsequently encouraging productivity and efficiency with which day-to-day tasks are carried out. The disparity in lifestyle and technological intuition between the young and old results in a steep learning curve and poor user adherence in older adults. Pulsewatch is a novel smartwach program which provides continuous monitoring through the same PPG detection of the smartwatch, and the smartphone app serves as a data transfer hub between the watch and cloud [42]. Pulsewatch increases user accessibility in smartwatch technology with a streamlined user interface, in which the smartwatch face includes the time, heart rate, normal/abnormal rhythm, and a corresponding colour whether the rhythm is normal or abnormal, making AF detection easy to understand and recognize in older adults with cognitive impairment [42]. Monitoring occurs every 10 minutes for about 1.5 minutes, is processed in near real time (<1s), with a corresponding result, and is uploaded to the phone's local storage and cloud through the dyad; if abnormal rhythm is detected, the watch notifies the patient to hold still for around 1 minute to confirm the result (Figure 1) [42]. Pulsewatch swaps the

busy and potentially confusing user interface of most smartwatches, with a simple and easy to understand format while simultaneously using the same smartwatch technology, without the need for any added devices. However, it is also important to note that the clinical trial was conducted using the Samsung Tizen Watch OS and it is unknown whether the app would be made available on other smartwatch models.

There were 90 patients using the Pulsewatch system which were surveyed with an average age of 65 years. 39% found the system to be highly usable, 64% strongly agreed or agreed the watch app was easy to use and 52% in response to the phone app. Overall over half enjoyed their experience using the system, while only 13% found the system stressful to use [42]. In an analysis on the Pulsewatch study done by Ding et al, 90 patients with assistive devices (ie. walker) and a history of anxiety or depression were more likely to express hesitancy regarding smartwatch usage [38]. Participants in the research expressed a desire for a simplified system that was more centred on rhythm monitoring and a wristwatch with a longer battery life. The participants' experiences were significantly improved by in-person instruction and assistance, and they overwhelmingly favoured using a smartwatch over conventional cardiac monitoring because of its comfort, aesthetics, and ease [38].

Cost-Effectiveness

In a study assessing the cost-effectiveness of wearable technology in screening for atrial fibrillation, findings indicate an increase in QALY and an increase in positive cost-effective ratio when compared with multiple treatment options across multiple scenarios including sex, and earlier screening ages [43]. The study consisted of 30 million individuals aged ≥ 65 and 6 different screening strategies including wrist-worn PPG technology were analysed (43). All 6 strategies proved to be more effective than no screening (range of QALYs gained, 226-957 per 100,000 individuals), as well as more effective than traditional screening methods (range of QALYs gained, -116 to 93 per 100,000 individuals) including in-person visits, wearable monitors, and telehealth [43]. The preferred screening method involved wrist-worn PPG screening followed conditionally by a wearable ECG patch monitor in which the total cost-effectiveness ratio was calculated to be US\$57,894 per QALY, meeting the acceptability threshold of US\$100,000 [43].

Discussion

Current mobile applications and software used to detect AF are designed for intermittent AF detection and are catered toward a young consumer market [42]. Smartwatches have emerged as a viable, non-invasive method of automated pulse and ECG generation [44]. Initial iterations required an individual to place the back of the smartwatch across various points of the body in sync with

an ECG unit, which does not provide the continuous, passive monitoring required to detect pAF, the most common type of AF in patients prone to a thromboembolic event [42]. PPG sensors provide a near-continuous and a more user-friendly method in detecting pAF. Recent studies including the Apple heart study, Huawei heart study, and Fitbit heart study all use PPG in smartwatch technology to monitor pAF [27,45,46]. However, these studies include, on

average, only 6.6% of participants \geq 65 years old, and target participants who already own each respective smartwatch, resulting in consumer bias [27,45,46]. Furthermore, these studies fail to provide adequate insight on patient adherence for pAF monitoring in older adults [27,45,46]. Implementation of a novel smartwatch smartphone application dyad such as Pulsewatch makes an effort to solve this limitation.

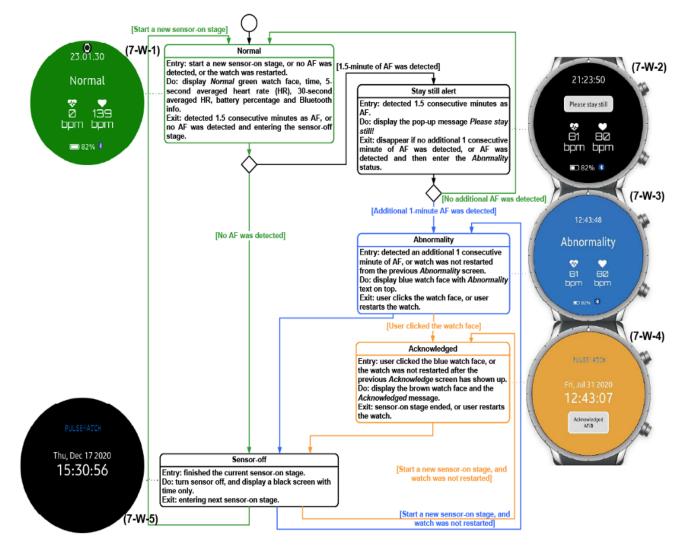


Figure 1. Pulsewatch provides a simplistic interface with continuous heart rhythm monitoring. Monitoring occurs every 10 minutes and a corresponding, colour-coded result is displayed along with time, and heart rate. If the rhythm is normal, a green screen is displayed. If an abnormality is suspected, the patient is directed to remain still for further monitoring for an additional 1.5 minutes. If an abnormality is detected, a blue screen appears which consequently turns yellow after acknowledgement from the user. Following each result, the screen returns to its resting face with a black colour and the current time. Figure was taken from (Han D, Ding EY, Cho C, Jung H, Dickson EL, Mohagheghian F, Peitzsch AG, DiMezza D, Tran KV, McManus DD, Chon KH. A Smartwatch System for Continuous Monitoring of Atrial Fibrillation in Older Adults After Stroke or Transient Ischemic Attack: Application Design Study. JMIR cardio. 2023 Feb 13;7:e41691. https://cardio.jmir.org/2023/1/e41691} with copyright permission from Dong, Han.

Further studies are required to assess the clinical usefulness of smartwatch usage for early detection of AF;

diagnostic efficacy of the devices during daily activities and the heterogeneity between smartwatch devices is yet to be

thoroughly studied. Though current data on diagnostic efficacy of smartwatches is promising, the external validity is a potential source of error (i.e. accuracy during walking, sleeping, etc.). Attempts to address the difference in the diagnostic efficacy of smartwatch devices in a 2020 study by placing patients in a supine position versus an upright position is an advancement in the field as it has proven a decrease in both sensitivity (-1.76%) and specificity (-3.76%) while in the supine position [40]. However, further studies addressing diagnostic efficacy during daily activities are required.

Smartwatch technology is a user-friendly and costeffective method that has shown significant potential in morbidity caused by undetected reducing AF. Hospitalizations, strokes, and lost productivity are the three main cost-contributors for AF, which is known to have a considerable influence on health care expenditures [47]. While conventional diagnostic techniques like ECGs are successful in identifying cardiac arrhythmias, any episodes that take place outside the testing window may go undetected [26]. Continuous monitoring is a feature that wearable ECG devices provide, which may influence clinical diagnosis and guide treatment decisions. Other continuous methods such as cardiac implantable electronic devices are invasive and often carry procedure-related complications [26]. Smartwatches may not only serve a function in reducing morbidity due to undetected AF, but they may also be more cost-effective relative to the goldstandard ECG counterpart. Smartwatches are a potential strategy to test for AF, which will lessen the financial burden, particularly for nations with a strained healthcare system [34]. However, further research for all types of smartwatch devices is required to determine their true economic potential in the context of AF screening. Furthermore, the reported patient approval of these devices and patient compliance have ultimately led to improved health outcomes [38]. Further studies investigating the heterogeneity among the different smartwatches and diagnostic efficacy during daily activities are required to assess if they have clinical usefulness. According to previous investigations, smartwatches are user-friendly, cost-effective and offer patients prospective information in real time with a fair amount of sensitivity and specificity [35,38,40,41,43].

Conclusions

While standard AF detection devices include 12-lead ECG, Holter monitor or implantable devices, user-friendly PPG-based smartwatch technology is a medically accurate alternative that may speed up the identification and treatment of AF, reducing stroke and cardiovascular disease-related morbidity and mortality, while also reducing healthcare costs associated with AF [35,38,43].

List of Abbreviations Used

SA: sinoatrial AV: atrioventricular AF: atrial fibrillation pAF: paroxysmal atrial fibrillation ECG: electrocardiogram PPG: photoplethysmography QALY: quality-adjusted life-year PPV: positive predictive value NPV: negative predictive value

Conflicts of Interest

The authors have no conflict of interest to declare.

Ethics Approval and/or Participant Consent

This literature review did not require ethics approval or participant consent.

Authors' Contributions

JM: made contributions to the design of the study, collected and analysed data, drafted the manuscript, and gave final approval of the version to be published. DT: made contributions to the design of the study, collected and analysed data, drafted the manuscript, and gave final approval of the version to be published. RS: made contributions to the design of the study, collected and analysed data, drafted the manuscript, and gave final approval of the version to be published.

Acknowledgements

The authors would like to first and foremost acknowledge the contributions of our mentor Miriam Basta, without whom this project would not have been possible. She has continually offered guidance and indispensable advice throughout this project.

Funding

This study was not funded.

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Article Information

Managing Editor: Jeremy Y. Ng Peer Reviewers: Miriam Basta, Jala Rizq, Jeremy Ng Article Dates: Received Mar 30 23; Accepted Jul 21 23; Published Oct 03 23

Citation

Please cite this article as follows: Mikhail JA, Tadros D, Shehata R. Smartwatch technology's diagnostic use in atrial fibrillation detection – A literature review. URNCST Journal. 2023 Oct 03: 7(10). <u>https://urncst.com/index.php/urncst/article/view/475</u> DOI Link: <u>https://doi.org/10.26685/urncst.475</u>

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