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The Use of Wearable ECG Devices in the Clinical Setting: a Review

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Abstract

Purpose of Review This review investigates the use of wearable electrocardiograms (ECGs) in the clinic and acute care setting, and their impact on patient care, particularly pertaining to the management of cardiac arrhythmias.

Recent Findings Wearable ECGs have consistently demonstrated their non-inferiority in detecting arrhythmias when compared to the current standard of care. Different studies have highlighted their ability to improve patient care and reduce healthcare costs, while more devices are being created to work as a screening tool at a larger scale or to fit the physical abilities of a variety of patients.

Summary The use of wearable cardiac monitoring devices demonstrated considerable symptom–rhythm correlation in various clinical settings, which often resulted in a reduction in time to diagnosis and lower rates of ED visits. However, this relatively new technology raised concerns for patient accessibility and privacy among others. Further research is needed to assess their sensitivity and specificity in the clinical setting, as well as their limitations.

Keywords Wearable ECG · Arrhythmia · Emergency department · AliveCor · Diagnostic

Introduction

In 2019, chest pain and similar cardiac-related complaints were the second most common reason (5.3%) for emergency department (ED) visits in the USA [1]. For females aged 65 and older, it was the number one chief complaint. Consequently, key diagnostic tests like cardiac monitors and electrocardiograms (ECGs) were, respectively, ordered approximately 13,428 and 33,903 times. This can be compared to national data from 2013, when cardiac monitors and electrocardiograms were used approximately 9163 and 23,764 times [2]. Chest pain and similar cardiac-related complaints were consistently the second most common reason (4.9%) for ED visits in 2013 as well.

Recommendations by the American College of Cardiology and the American Heart Association (ACC/AHA) include performing an ECG immediately for ED patients experiencing cardiac symptoms. The recommended period of time between patient arrival and ECG is 10 min [3, 4]. Among ED patients presenting with chest pain across eight hospitals in Canada and the USA, one study reports that only 34–40.9% of patients completed an ECG within the recommended 10-min window [5]. Furthermore, ST-elevation myocardial infarction (STEMI) patients who did not receive an ECG within 10 min had a greater likelihood of experiencing adverse clinical events. Another ED study aimed to improve their door-to-ECG time by registering and triaging chest pain patients after administering an ECG [6]. Although the study was successful in increasing the percentage of chest pain patients who received an ECG within 10 min of arrival from 16 to 64%, a more efficient approach is needed to improve clinical outcomes and provide effective patient care.

The door-to-ECG time in the ED could make a case for the need to revisit the current standard of care for arrhythmia detection. Considering the rapidly growing technology of wearable cardiac monitoring devices, this paper summarizes the existing literature on the use of wearable ECGs in clinical settings and their implementation in patient care.

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FDA-Approved Devices

AliveCor

The wireless FDA and Conformité Européenne-approved AliveCor Kardia Mobile (KM) device uses a smartphone case with two electrodes that transmit ECG rhythm strip data through the corresponding smartphone app. After patients press their fingers onto the case, a single-lead ECG recording is stored onto the smartphone app and online server, where it can be accessed by healthcare providers. A 2018 prospective cross-sectional study compared the effectiveness of the portable KM device to external loop recorders in 33 participants experiencing heart palpitations without a definitive diagnosis [7]. At 33.7%, more symptomatic arrhythmias were detected using the KM device than with the traditional external loop recorder (20.4%). Another study of 26 participants at the Columbia University Medical Center demonstrated that patients who used the AliveCor device had double the detection rate of atrial fibrillation and atrial flutter compared to patients who received standard periodic in-office cardiac monitoring care (61% vs 30%) [8]. In addition, these patients experienced better quality of life and reported being more health conscious after participating in the study. Overall, the diagnostic effectiveness of the KM device has proved to be non-inferior and it has been recommended as a diagnostic tool for assessing low-risk patients experiencing palpitations.

The KM device has also been examined in the acute care setting. A multicenter study conducted in emergency departments and acute medical units of ten UK hospitals revealed that when compared with standard care, the use of the KM device resulted in a fivefold increase in the number of diagnostic ECGs that were successfully recorded during symptoms and an 11-fold increase in the detection of symptomatic cardiac arrhythmias including sinus rhythm, sinus tachycardia as well as ectopic beats [9•]. Furthermore, it effectively decreased the mean time to symptomatic rhythm detection from 42.9 days to 9.5 days. Following this study, a Smartphone Palpitation and Pre-syncope Ambulatory Care Clinic was established at the Royal Infirmary Edinburgh (RIE) in 2019, where patients are often referred to after being evaluated in their emergency department and acute medical unit for palpitation or pre-syncope. In 2021, Cullen et al. were able to reproduce the previous findings at the RIE by reporting a 7.2% symptom–rhythm correlation compared to 8.8% in the previous study [10••]. This demonstrated that the widespread use of this device will result in reduced risk of adverse cardiovascular events from untreated cardiac arrhythmias, as well as reduced costs of avoidable hospital visits. Thus, it can effectively be used to alleviate the economic burden and ongoing health safety concerns of the COVID-19 pandemic.

Apple Watch

Over the past few years, electronic watches have increasingly expanded their focus from mere watches to wearable cardiac monitors. The Apple Watch specifically uses a photoplethysmography sensor to identify irregular pulses and subsequently detect atrial fibrillation and atrial flutter. When used as intended (worn on the left wrist), it can generate a single-lead ECG that will be recorded on a phone application from where it can subsequently be shared with a physician. In a 2019 study funded by Apple, 34% of the 450 participants who received an irregular pulse notification from the device, were ultimately diagnosed with atrial fibrillation [11•]. Although the study authors indicated the need for further testing, the article supported the use of a smartwatch to detect cardiac arrhythmias and improve digital health outcomes.

In addition to its intended use, several studies have reported that the Apple Watch 4 could be adjusted to the six positions required to record the classical Einthoven ECG leads I, II and III as well as leads V1, V4 and V6, with high accuracy and signal quality comparable to conventional 12-Lead ECGs [12, 13]. In a 2019 case series, Avila found that the 3-lead electrocardiogram rhythm reported by the Apple Watch 4 matched the reading obtained with traditional ECG demonstrating STEMI [14]. This finding implies that earlier detection of acute coronary artery disease is feasible using the Apple Watch 4, although sensitivity and specificity remain unknown.

ZioPatch

The ZioPatch is a 14-day ambulatory adhesive device that is worn over the left pectoral region. It is a water-resistant patch that records a 3-lead ECG strip and subsequently sends it to ZioPatch for analysis. A 2018 study demonstrated that the detection rate for this device was comparable to the one of the Holter monitor for atrial fibrillation [15]. Considering that the first signs of atrial fibrillation appear within 48 h of a stroke or a TIA in 15% of patients, early prolonged monitoring with the ZioPatch resulted in better diagnostic results than the Holter monitor, which could lead to 10.8 more strokes avoided per year with a projected budget impact of £113,63 [16, 17].

Another single-center study reported a diagnosis of symptomatically significant arrhythmia in 10.5% of emergency department patients with unexplained syncope that were fitted with a ZioPatch compared to 2% with standard

procedure [18]. This suggests early monitoring with patches may improve and speed up the diagnostic process, effectively reducing the requirement for outpatient ambulatory ECG monitoring.

ECG Check

The ECG Check device is an over-the-counter FDA-cleared ECG monitoring device that measures a single-lead electrical tracing and transmits it to a smartphone app. Arrhythmias are detected and recorded in 30-s rhythm strips and can be uploaded to a server for access by a healthcare provider. A single-center retrospective study of 90 post-ablation patients with atrial fibrillation found that the ECG check device had a sensitivity of 100% and a specificity of 97% for detection of atrial fibrillation and atrial flutter [19••]. When compared to conventional ambulatory monitoring techniques (event recorder, Holter monitor or mobile cardiac monitor), the use of the ECG check device reduced by half the number of non-scheduled outpatient (OP) visits and ED visits for atrial arrhythmias. Knowing that early symptom recurrence post-ablation correlates with an increased risk of cardiovascular complications such as stroke, the use of the ECG check device could not only improve healthcare usage, but also patients' health outcome and quality of life.

Non-FDA-Approved Devices

CardioSecur

CardioSecur (CS-ECG) is a mobile ECG device that has been approved by the Conformité Européenne as a class IIa product and is broadly used across Europe. It uses four electrodes to generate a 22-lead ECG that can be uploaded to a secure server and subsequently shared with healthcare providers. A 2020 study compared the use of CS-ECG to a conventional 12-lead ECG (c12L-ECG) in the ambulance setting for acute coronary disease management in Heidelberg, Germany [20]. It revealed that both devices were similarly proficient at detecting STEMI in participants with need for percutaneous coronary intervention, with a sensitivity and specificity of 0.63 and 0.87, respectively, for c12L-ECG, and 0.7 and 0.84, respectively, for CS-ECG. Moreover, time to diagnosis was significantly reduced with the use of CS-ECG (79%) and emergency healthcare providers deemed it a significant improvement over the c12L-ECG for 92% of all participants.

Zenicor-EKG 2

The Zenicor ECG is a single-lead handheld finger sensor. The device records the ECG readings and can transmit the data through a smartphone. Patients press their thumbs on the two sensors for 10 s after which they are visually and audibly notified to remove them by the device. The data is saved in an encrypted database that the physician can access for evaluation. A study by Doliwa PS et al. evaluated the device's ability to detect various arrhythmias on 100 patients in a cardiology outpatient clinic [21]. These patients had atrial fibrillation, atrial flutter or sinus rhythm. The device was able to give a correct diagnosis of atrial fibrillation with a sensitivity of 96% and a specificity of 92%. Another study by Usadel et al. used the Zenicor in the setting of pediatric outpatient departments and found it to detect or exclude heart rhythm disturbances with 77% sensitivity and 92% specificity [22].

MyDiagnostick

The MyDiagnostick is an easy to apply device that registers and analyzes single-lead rhythm strips after holding the device with both hands for a minute. The light signals if there are any rhythm irregularities (green for normal, red for suspicion for atrial fibrillation). The device can be used with a standalone application or Internet-based web portal to print and share ECG data. A study from 2016 analyzed the use of the device in the setting of primary care clinics during influenza vaccinations [23]. Of the sample of 3269 subjects, only those aged 60 years or over were considered because atrial fibrillation under that age is rare. 3.7% of the cases were found to be suspicious for atrial fibrillation (2.6% were already known cases of atrial fibrillation, 1.1% were new cases). The results of the study confirmed the MyDiagnostick as a feasible option for large-scale screening. Another validation study found that the device had 100% sensitivity and a 95.9% specificity for detection of atrial fibrillation [24].

T-Shirt-Type Wearable Electrocardiography Monitor

Different form factors for ECG devices have been explored as well. Such ideas can help adjust ECG monitoring to fit the lifestyles of different ages. One such device involves the use of an electrode embedded T-shirt made of a highly electrically conductive material called Hitoe. The entire device serves as a single-lead ECG, and the conductive material of the T-shirt functions as electrolyte patches and a transmitter [25]. The device was made to check for atrial fibrillation while fitting the lifestyle of physically active young adults. In a 2019 descriptive study, 100 participants were instructed to wear a T-shirt for at least 40 h a week (4 days a week for 10 h each time with a target of 320 h) over 2 months. The article showed that the T-shirt had similar effectiveness in detecting atrial fibrillation as other wearable devices. A 2022 prospective observational study monitored 18 patients who underwent atrial fibrillation ablation using the wearable

ECG and a Holter ECG device [26•]. Through simultaneous monitoring, the two devices were shown to have almost complete correlation in all clinically related testing except in R-wave amplitude ($r = 0.743$, $p < 0.001$). Further clinical studies are needed for long-term monitoring in ambulatory settings.

Strengths of Wearable ECG Devices

In addition to their clinical performance, wearable ECG devices have demonstrated economical advantages in various settings. A 2019 study compared the cost-effectiveness of single-time point lead-I handheld ECG devices with that of standard procedure including manual pulse palpation (MPP) and 12-lead ECG for the detection of atrial fibrillation in symptomatic primary care patients [27]. Lead-I ECG devices generate an incremental cost-effectiveness ratio (ICER) per quality adjusted life year (QALY) gained below the £20,000-£30,000 threshold, with Kardia Mobile appearing to be the most cost-effective. These devices may result in higher rates of atrial fibrillation detection yielding increased healthcare costs, but they ultimately improve mortality and quality of life for patients. Furthermore, current literature supports the use of mobile ECG technology in screening for AF in low-resource settings and its ability to detect a significant proportion of AF cases that will otherwise go undiagnosed [28].

Multiple studies have also reported patient preference for these devices compared to standard monitoring devices due to their ease of use and convenience, which resulted in greater compliance and ultimately better health outcomes [7]. Additionally, although standard diagnostic methods like the 12-lead ECG are effective in diagnosing cardiac arrhythmias, any events occurring after the testing period can be missed [29]. Many wearable ECG devices offer the benefit of continuous monitoring which may impact clinical diagnoses and help direct treatment options.

Limitations of Wearable ECG Devices

The use of wearable ECG devices is not without risks and limitations. In 2018, the US Preventive Services Task Force concluded that there is not sufficient evidence to assess the balance between the benefits and harms of using ECGs as a screening tool to prevent cardiovascular events in asymptomatic intermediate to high-risk individuals [30]. This could be for various reasons. When used as guides for the timing of arrhythmia in the decision to cardiovert, it is important to investigate how the patient uses a specific device. In the case of the Apple Watch for example, there is a higher probability for arrhythmia detection if it is worn continuously, as a tachogram is captured every 3–4 h. An alert for potential arrhythmia is only issued if five out of six sequential tachographs are classified as irregular within a 48-h period [31].

Furthermore, the utilization of wearable devices may be limited in some populations. In a study of 445 hospitalized patients in cardiology and geriatric departments, the use of handheld devices to record ECGs failed in 7% of cardiology and 21.4% of geriatric patients due to difficulties they had properly handling the devices [32]. Patients may also present to the emergency room after what turns out to be a false-positive, raising concerns for wearable device-induced anxiety and healthcare utilization, as well as the risks of unnecessary anticoagulation therapy.

Moreover, this new wave of multifunctional cardiac monitoring devices will undoubtedly be accompanied by a steady stream of new medical smartphone apps that might not be as reliable or accurate [33]. Concurrently, the use of digital technology to monitor individuals' health also raises concern for privacy. This presents a new lucrative market for data brokers who could collect geographical and behavioral information from the different devices and apps, and use it for marketing. Accessibility is also a concern for smartphone based event recorders, especially among older adults. In 2021, the Pew Research Center reported that only 61% of adults aged 65 and older owned a smartphone, compared to 80% of those aged 18–64 [34]. Nevertheless, this percentage has steadily increased from 2015 and 2016 (30% and 42%, respectively) [34, 35].

Conclusion

The steady prominence of cardiac-related presentations in the ED setting and the rise in the use of essential diagnostic tools indicates a need for faster and robust screening services for patients experiencing cardiac-related symptoms. Rapid advancements in the wearable ECG market have opened the discussion about their implementation in patient care. The use of FDA-approved devices such as the AliveCor Kardia Mobile (KM) device, Apple Watches, ZioPatch and the ECG Check has been investigated in various clinical settings across the USA and has demonstrated their non-inferiority when compared to standard procedure. Other devices such as CardioSecur (CS-ECG), Zenicor ECG 2, MyDiagnostick and the T-shirt wearable ECG have also proved their efficacy in the clinic and acute care setting internationally. Thus, wearable ECG devices may present a promising alternative as they are cost-effective and improve ECG access for low-resource settings. Their continuous monitoring abilities as well as ease of use and overall convenience may also improve patient compliance and provide a more comprehensive clinical picture. However, there are concerns about patient accessibility, wearable device-induced anxiety and protection of privacy which may impact healthcare

utilization. Therefore, further clinical studies are needed to assess the effectiveness and feasibility of wearable ECG device application in the clinic in general and in the ED in particular.

Compliance with Ethical Standards

Conflicts of Interests Paola Kamga, Rasik Mostafa and Saba Zafar declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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