Next-Generation Wearable Devices for Atrial Fibrillation: Innovations in Detection, Monitoring, and Management

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ABSTRACT

Background: The most prevalent cardiac arrhythmia is atrial fibrillation (AF) which is linked to a higher risk of cardiovascular stroke and heart failure. It should be diagnosed and put under management early and closely monitored to ensure they are finally treated. The latest development of wearable technologies allows non-invasive and real-time recording of cardiac rhythm during the normal course of life.

Objective: This literature review assesses the role of wearable technologies in the detection and monitoring of atrial fibrillation with special emphasis on the type of devices, technologies of sensing, clinical uses, shortcomings, and outlook.

Methods: A literature review of wearable devices used to monitor atrial fibrillation on wearable devices, discussing the technologies presented in PPG, ECG, and AI in smartwatches, chest straps, ECG patches, and implantable loop recorders.

Results: Wearable devices facilitate real-time monitoring of the cardiac rhythms, which is continuous and helps in the early detection of AF. The technologies enhance patient interaction, self-management and early diagnosis. Nevertheless, there are still issues, such as battery capacity, false-positive and false-negative diagnoses, psychological impacts on users, and adverse incidences related to the devices. Adoption is also affected by ethical issues and regulations.

Conclusion: Wearable technologies have high potential of enhancing detection and management of atrial fibrillation. Further improvements in sensor technology, artificial intelligence, and regulatory measures can improve the accuracy of the devices and their clinical integration.

Keywords: smartwatches, wearable technology, electrocardiography, photoplethysmography, and chest straps.

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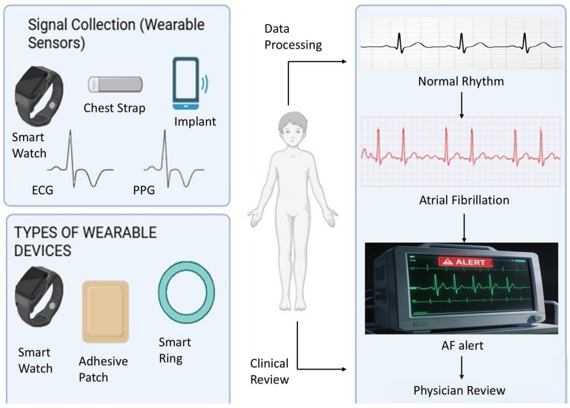
Introduction

CVD is the cause of death since it covers approximately 31 percent of the total mortality cases across the globe [1]. The CVD economic cost in the US alone is approximated to be staggering US$1.1 trillion by the year 2035 [2]. In the US, it is estimated that the present population with AF is approximately 2.3 million, which is set to grow to 5.6 million by 2050. Historically, ECG has been applied in the diagnosis of atrial fibrillation in the clinical setting; in the case of AF, the diagnosis method is not always adequate in the early stages due to its episodic, and asymptomatic nature. Recent technological progress in the field of wearable devices has enabled the creation of a new method of heart monitoring that allows to collect data in a non-invasive, continuous way, and in natural settings [3]. Some of the wearable technologies that have presented promise in the detection and treatment of atrial fibrillation are adhesive patches, smart watches and chest straps. The introduction of the advanced and sophisticated technology, including ECG, PPG, and AI, has significantly improved the diagnostic features of these wearable devices [4]. This article discusses the mechanism of AF, the type of wearable technology that is utilized to monitor AF, clinical use, side effects, challenges, and opportunities of the future.

The mechanism of action of atrial fibrillation

The atrial fibrillation is a kind of cardiac arrhythmia that is characterized by an irregular electric activity in the atria of the heart (Figure 1) leading to inappropriate supply of blood and flow and improper contraction of the atria. The first cause of atrial fibrillation (AF) is ectopic electrical impulses which are generated in the pulmonary veins and act as a catalyst to the chaotic atrial depolarization. Abnormal electric impulses may result because of changes in atrial tissue like fibrosis that disrupt normal impulses when a number of wavelets of electric activity circulate within the atria. These electric activities are even worsened by electrical and structural atrial remodelling. Structural remodelling encompasses atria dilatation and fibrosis caused by hypertension and chronic stress whereas the electric remodelling involves the shortening of atrial action potential and refractory period due to calcium influx via ion channels. ANS anomalies which scatter out atrial beat are high sympathetic tone. Another cause of AF is excessive calcium release by the sarcoplasmic reticulum which may also be delayed after the depolarization. Atrial abnormality has a genetic aspect as well as an oxidative stress aspect and leads to the irregular electrical signals that do not synchronize between the upper and lower chambers of the heart. It may lead to abnormal contraction of atria, abnormal ventricular contraction, and reduced cardiac output that may result in stroke complications [5].

Figure 1: Wearable Technologies and AI-Based Workflow for Atrial Fibrillation Detection

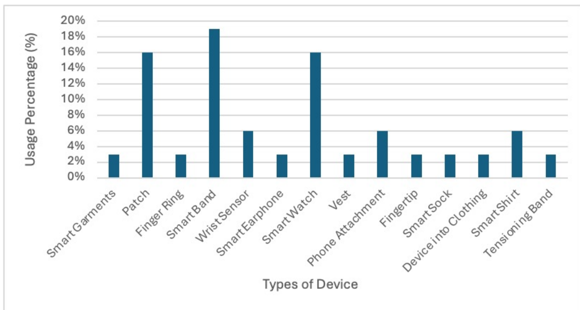


Atrial fibrillation detection workflow Workflow an ECG and PPG rhythm analysis and clinical alert generation workflow on wearable devices that collect and process signal data.

Wearable Devices type used to monitor Atrial Fibrillation (AF)

Development of wearable technologies has transformed the detection of atrial fibrillation (AF) to provide a wide range of options to use individual medication or customized treatment based on the needs of patients. These technologies have introduced a new and better method of detection of Atrial Fibrillation [6]. There are many devices used in monitoring AF which is shown in Figure 2.

Figure 2: Usage of Health Monitoring Wearable Devices



The physiological monitoring wearable devices and their comparative usage.

Wearable technology

The smartwatches have transformed the process of monitoring and detection of atrial fibrillation (AF) by providing a simple and convenient tool to monitor the heart rhythm in real-time [7]. As an example, Fitbit Sense, Samsung Galaxy Watch, and Apple watches (Series 4 and up) have advanced sensors and algorithms that are capable of detecting and diagnosing irregular heartbeats. Smartwatches have two contemporary sensors, which allow detection of AF in the form of photoplethysmography (PPG) and single-lead electrocardiography (ECG). PPG incorporates photodiodes and light-emitting diodes in the process of recording pulse waveforms off the wrist so as to measure the changes in blood volume [8]. These two passive sensors are designed to monitor cardiac rhythms and detect any abnormalities that are associated with atrial fibrillation. Conversely, users can record a single lead ECG by placing their fingers against the electrodes of the smartwatch. The trace recorded will be a complete and accurate representation of the electrical activity of the heart on which one is measuring AF. Apple Watch is the first wristwatch that is FDA approved to monitor and detect AF with a sensitivity of 98 and specificity of 90 to detect abnormal heart rhythms [9]. They have incorporated single-lead ECG, which gives medical quality information that consumers/patients can forward to healthcare providers to receive a diagnosis and treatment. Other devices such as the Samsung Galaxy Watch and Fitbit Sense have been provided with similar features; these have varying accuracy and regulatory standing. In addition to the detection of AF, smartwatches may also be utilized in other health monitoring tasks such as counting of steps, monitoring of oxygen saturation, and tracking of sleep. Thesis devices have numerous advantages yet they also possess disadvantages [10]. As an example, PPG-based monitoring may suffer the effect of motion aberrations, skin tone changes, and improperly placed devices, which could reduce accuracy. Also, to remain under constant control, ECG functionality requires active user interaction and limitations in detecting asymptomatic. Frequent charging is also a drawback because the battery life is required to be high. Along with constant AF monitoring, which makes smartwatches the most popular device to detect AF, around half to two-thirds of the wearable users with the preference to smartwatches are estimated to favor them because of simplicity and constant AF monitoring. Due to the presence of cardiac monitoring and cardiac care, smartwatches are trendy among the youth and those who seek vigorous health care [11].

Straps across the chest

Chest straps are an unpopular yet a very reliable wearable device that is used to monitor cardiac rhythms particularly during physical activity and exercise [12]. Examples of these devices include Garmin HRM-Pro and Polar H10 which utilize an electric sensor strapped around the chest region in order to capture the electric signal of the heart. They are designed to provide accurate ECG measurements even in environment that typically hamper the functioning of wrist-based monitors such as high activity or any physiological condition such as sweating [13]. Unlike smartwatches, chest straps are unique devices to measure heart rate and heart rhythm. The electrical impulses generated by the heart are diagnosed or detected by skin contact with the electrodes on the strap through skin contact. This advancement allows one to constantly observe the real-time ECG registration, and it can be used to diagnose cardiac arrhythmias such as AF. Whilst the studies also indicate a high-degree of accuracy of such chest straps, greater than 95 percent in the overall measurement of heart rates during high-intensity exercises, the device is not completely FDA-approved to monitor and detect AF [14]. They are the instruments of preference of athletes, sport and fitness enthusiasts and other active people who require accurate monitoring of their heart rates. Polar H10 is easy to combine with activity trackers and comparison applications because of its advanced sensor and Bluetooth connection. The Garmin HRM-Pro also provides similar features and is able to track heart rate as well as tracking running aspects such as stride length [15]. These are chest straps, which means that they have a larger battery life, thanks to not having to be charged regularly like wrist-based wearables and can last weeks on a single charge. But since the strap must be tightened on the chest in order to guarantee a correct reading, there are several disadvantages to chest straps, such as being not so comfortable as the other wearables [16]. This might not be convenient when used in the long run. Moreover, these chest straps do not provide automated AF diagnosis or detection. The data recorded have to be manually analysed by the user or by using specialist software in order to detect any potential abnormalities [17].

Sticky Patches

An example of such devices is the BardyDx Carnation Ambulatory Monitor (CAM) and Zio XT Patches made by iRhythm since they offer long-term ECG recording and as such are ideal when it comes to diagnosing the asymptomatic cases of atrial fibrillation [18]. Non-invasive, though highly efficient in continuous cardiac monitoring, are adhesive patches. During a maximum of 14 days, these patches (which are attached directly to the chest) enable undistributed monitoring [19]. The adhesive patches are very convenient and comfortable to the patient due to its wirelessly powered nature, light weight, and small size as compared to the traditional holter monitors. Zio XT Patch is able to capture ECG data and this is analyzed by various algorithms and reviewed by medical experts to identify arrhythmias, including AF [20]. The BardyDx CAM P-wave centred design helps to detect irregular or aberrant heart rhythms including atrial fibrillation accurately. Both approved devices have demonstrated approximately 80% accuracy of diagnosis of arrhythmias in clinical trials [21]. The first strength of these patches is that they have the ability to record a rare episode of AF which may go unnoticed by short term monitoring hence this gives it an advantage over patients with paroxysmal AF. Nevertheless, they possess some disadvantages although they have the advantages. As an example, they are single-use devices, which may be prohibitively costly to monitor repeatedly and they need expert supervision to interpret data, which restricts their accessibility to direct client use. Although this device has several disadvantages, it is a significant solution of AF to fill the gap between implanted devices and short-term Holter monitors [22].

Table 1: Atrial fibrillation wearable device comparative summary

Device Type	**Examples**	**Mechanism**	**FDA Status**	**Monitoring Duration**	**Target Users**	**Accuracy**
Implantable Recorders	Medtronic LINQ II	Multi-lead ECG	FDA-approved	Up to 3 years	High-risk patients	Sensitivity: >98%
Adhesive Patches	Zio XT Patch	Continuous ECG	FDA-approved	Up to 14 days	Clinical patients	80% diagnostic yield
Chest Straps	Polar H10, Garmin HRM	Electrical Sensors	Not FDA-cleared	Continuous (during use)	Athletes, fitness users	>95%
Smartwatches	Apple Watch, Fitbit	ECG, PPG	FDA-cleared	Continuous (during use)	General population	Sensitivity: 98%

Electrocardiogram (ECG), PPG (photoplethysmography), and FDA (Food and Drug Administration)

The implantable loop recorders (ILRs)

Implantable loop recorders are modern medical equipment which is utilized to monitor the heart rhythm on a long-term basis. Such devices as Abbott Confirm Rx and Medtronic LINQ II are installed subcutaneously and the procedure is simple [23]. This implant can also be considered as one of the most efficient devices to monitor the AF as it utilizes the multi-lead ECG data, and it helps to perpetrate the constant surveillance and identification of all the arrhythmias, including AF. Its sensitivity is over 98% [24]. An example is that the Medtronic LINQ II has remote monitoring features and provides doctors with real-time data and alerts regarding AF. On the same note, the Abbott Confirm Rx, is based on Bluetooth technology, which is constantly connecting with patient smartphones, through which data can be transmitted and the symptoms monitored in real-time [25]. ILRs are advantageous to patients who have high-risk paroxysmal AF and cryptogenic stroke. The implantation of the device serves to constantly trace the heart rhythms in the period of up to three years. ILRs have certain disadvantages In as much as it is a minimally invasive therapeutic option, it is associated with risks such as local pain, migrations, and infections [26]. Moreover, they are applied exclusively to essential patients that require a thorough rhythmology; they are not applied to regular customers. A comparative summary of these wearable devices is shown in Table 1.

Patch-Integrated Flexible Sensors and Smart Rings

One of the most promising innovations in the field of atrial fibrillation monitoring is becoming smart rings, which are compact in size and are much more convenient to wear by patients compared to other wearables [27]. They operate their devices on high-tech photoplethysmography (PPG) sensors, temperature, and motion analytics to record pulse waveforms and beat-to-beat variability. Smart rings are very lightweight, non-obtrusive, and comfortable, which allows a long-term rhythm monitoring with an unusually high user compliance, which is particularly beneficial in the detection of paroxysmal and asymptomatic AF attacks [28]. Coupled with the AI-based rhythm analysis, such rings can detect irregular pulses, low heart rate variability, and patterns possibly indicative of early onset of AF and, therefore, can be applied in screening high-risk individuals in non-clinical settings. Even though the existing models are primarily based on PPG (subject to motion artifact and under perfusion at the periphery), recent advances to micro-ECG measurements and FDA approval are quickly relegating the smart rings to the realm of reliable instruments in remote cardiac monitoring and population-based AF detection programs [29].

Patch-integrated flexible sensors are the future of wearable biosensing technology and is engineered to conform smoothly to the skin and to give continuous and high-fidelity cardiac recordings [30]. This is a type of ultra-thin (2mm) stretchable patches which contain flexible electrodes, nanomaterial-based sensors and wireless communication modules to record multi-lead ECG signals, pulse wave dynamics and mechano-cardio graphic signals with an almost clinical accuracy. These patches have been especially useful in the management of A-fibrillation to detect small disturbances in rhythm, to monitor the burden of atrial ectopy, and to detect paroxysmal AF signals that are frequently overlooked by short-term devices [31]. Others include more sophisticated versions with microfluidic sweat sensors that have the ability to detect biomarkers associated with stress and inflammation, which can further give physiological insight into the triggers of AF [32]. They are also easy to wear, biocompatible, and have the capability to record continuously over days to weeks, thus being the best to use in post-ablation follow-up, outpatient rhythm assessment, and remote patient monitoring using the telemedicine system. Though still with some challenges, like cost and the need to handle large data volumes, the future of the personalized and predictive management of AF is being formed by these versatile biosensors at an alarming rate [33].

Atrial Fibrillation Digital Biomarkers

Wearables provide continuous physiological data which when converted into a digital biomarker can provide more information on atrial fibrillation than a mere detection. The quantitative indicators of arrhythmia severity and progression are digital biomarkers which include AF burden, heart rate variability (HRV), P-wave morphology and beat-to-beat irregularity patterns [34]. The percentage of time that a patient is in AF is now regarded as a powerful predictor of the risk of stroke and heart failure, so-called AF burden. The wearable ECG or PPG-derived HRV indices indicate the activity of the autonomic nervous system and can indicate the onset of AF many hours before the episode. Advanced ECG-based parameters, such as the duration and variability of P-wave, are digital signatures of atrial remodelling [35]. These AI-generated biomarkers are useful in assisting clinicians to categorize the risk of patients, customize the therapy, and track the progress in treatment. One of the biggest steps towards precision cardiology is to incorporate digital biomarkers into wearables [36].

Ethical and Regulatory Implications of AF Wearable monitoring

With the evolution of wearable devices as a means of consumer wellness to use to clinical-grade diagnostic technologies, regulatory and ethical issues become paramount. The FDA of the U.S. regulates AF-detecting wearables within the Software as a Medical Device (SaMD) framework and mandates proof of the accuracy of software algorithms, clinical efficacy, and safety [37]. The devices can take 510(k) route, De novo or PMA routes depending on the risk level. On the same note, the EU Medical Device Regulation (MDR) requires stringent conformity testing of digital cardiac devices. Ethical issues are that of data privacy, since constant surveillance produces sensitive ECG/PPD data, which can be easily hacked in the air [38]. Another problem is algorithmic bias, the accuracy of PPG can depend on skin color, age, motion, and so on, and it can provide people with different levels of diagnostic accuracy. Patient trust requires the presence of transparency in AI decision-making and safe data management. A solution to these regulatory and ethical considerations makes the use of wearable AF technologies safer and fairer.

Discussion

Wearable atrial fibrillation devices clinical studies

Many clinical trials related to clinical application of wearable technology to CVD monitoring were published. One of the popular studies is the Apple Heart Study which discovered that more than 419,000 individuals had atrial fibrillation (AF). Consequently, this trial established that in 34 percent of the total cases, those who were alerted to abnormal pulse use such watches to identify AFs and 84 percent of all cases indicated that the use of ECG patches was associated with AFs [39]. Yet another notable research was the mSToPS Trial (Monitoring Study to Prevent Stroke) that tested the capability of the Zio Patch, a continuously worn ECG monitor, offered by iRhythm, to detect atrial fibrillation (AF) in individuals at risk of it. Therefore, 3.9% of AF cases were diagnosed within the immediate monitoring group, and 0.9% in the delayed monitoring group [40]. This indicated that continuous monitoring works well in early diagnosis. The wearable device has been extensively tested and has enhanced its success as a cardiopulmonary health monitoring device. In particular, the Apple Heart Study showed that PPG sensors built into wrist-worn devices had high specificity and sensitivity rates in the detection of AF [41]. The sensitivity and specificity of the wrist-worn device were found to be 98.0 and 90.2% in the detection of AF in such patients. The KardiaBand, a wrist ECG device, was also evaluated in a study that was published in the journal JAMA Cardiology to determine its capability to detect atrial fibrillation. Based on the findings, the device is capable of more accurately diagnosing AF thus it is an effective tool in monitoring cardiac rhythm over a long period [42]. These studies therefore bring out the significance of wearable technology in cardiovascular diseases early detection and continuous treatment. Table 2 presents the clinical research on wearable technology on AF.

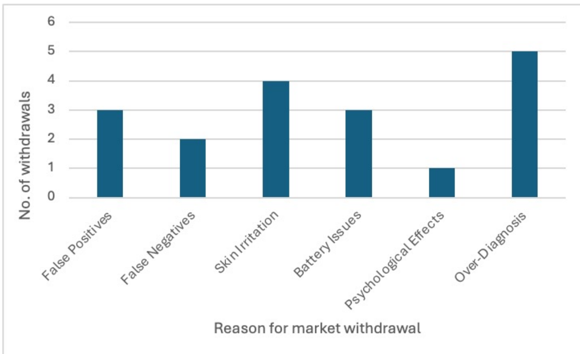
Table 2: Wearable Atrial Fibrillation Monitoring Clinical Trials

Study Name	Sample Size	Efficacy (%)	Device Used	Condition Monitored
mSToPS Trial	2,659	3.9	iRhythm Zio Patch	Atrial Fibrillation
Health Heart Study	1,617	98	Apple Watch	Atrial Fibrillation
Apple Heart Study	419,000	84	Apple Watch	Atrial Fibrillation
KardiaBand Study	520	95	KardiaBand	Atrial Fibrillation

Adverse Events in Wearable Technology to detect Atrial Fibrillation (AF)

The advantage of wearable devices that monitor atrial fibrillation through the use of PPG and ECG sensors is that it can offer a non-invasive monitoring of heart rate, which is, likely, the greatest positive outcome. Notwithstanding, there are several adverse effects of employing such devices, especially in in-clinic or household care [43]. Accuracy is one of the primary concerns; despite the use of wearable technology in continuous monitoring, both false positives and false negatives are a possibility, particularly with patients with irregular heartbeats or misplaced sensors [44]. The presence of false negatives may also cause a late diagnosis of AF which may cause many side effects such as heart failure or stroke whereas false positives may lead to unnecessary medical tests, doctor visits and stress. Moreover, there is often a skin irritation following prolonged use of such electrodes and sensors by the users. Patients exposed to the substance repetitively may develop skin rashes. As a study indicated, these wearables failed to detect AF reliably, poor signal quality during workouts, and irregular heartbeats, all of which led to the unnoticed cases of AF [45]. Another problem is the battery life of these devices as it can intervene with long-term monitoring and lead to a gap in AF episode monitoring. The anxiety and other psychological effect caused an increased reliance on wearable medical technology. case studies of non-AF that was over diagnosed as AF. In another research, a patient who had information about AF episodes on a frequent basis and turned to unnecessary hospitalization, went through a range of examinations, including an ECG, a traditional diagnostic tool, and the findings indicated that the patient had no AF [46]. As Figure 3 illustrates, these adverse occurrences resulted in wearable AF detection devices being removed off the market.

Figure 3: The quantity of market withdrawals brought on by adverse events



Typical reasons that prompt the withdrawal of wearable devices to the market, such as detection errors, battery problems and effects of users.

Atrial fibrillation detection AL and ML Wearable Technology.

Wearables are becoming more and more AI and ML-enabled to enhance their accuracy of predictive analytics and health monitoring. As an illustration, AI can detect such diseases as atrial fibrillation or irregular cardiac rhythms, which could be indicative of an impending cardiovascular disease, using real-time wearable data. The algorithms can be trained using user data and they can also learn as time goes on. Wearable technology and artificial intelligence could constantly keep track of the ECGs and detect AF events. In particular, CNNs are much more correct and sensitive in comparison to the conventional rule-based methods in respect of AF detection. Upon recognizing that AF is seeking, such patients can use such wearables as AI-powered devices to be proactively notified [47]. The recent technological progress has seen AI models such as DeepECG that are capable of learning on the basis of large ECG samples and achieving the skill to recognize atrial fibrillation. The models apply the deep learning technique to identify even the minutest changes in the heart activity to detect them over time. Automated AF detection based on AI has been built into mobile health devices such as Fitbit and Apple wearables too, and its performance has been shown to be effective in clinical use.

Limitations on wearable devices

Due to this, wearable technology has a lot of unrealized potential in spite of its potential. To begin with, smart watches, such as Apple Watch and Zio Patch, are effective in the recognition of some arrhythmias, including atrial fibrillation (AF) [48]. In spite of this, these devices have not been established to detect other cardiac diseases, including coronary artery disease and heart failure. There is also severe limitation in seeking generalization with many populations. Studies often apply homogeneous and high-risk samples common to the industrialized economies, which is a fairly narrow range of the global population. As an example, although Apple Heart study produced valuable data, the sample of participants was restricted to middle-aged and technologically inclined individuals, and it also brings up the issue of the study applicability to the elderly who are not technologically advanced [49]. Moreover, nowadays, there is the lack of long-term data regarding patient outcomes, compliance and quality of life improvement due to the use of wearable monitoring. The other problem is that of patient compliance since some patients are not comfortable with the idea of having the devices with them all the time and this leads to either non-data or inadequate data [50]. The reason is that wearables need to be able to operate in the real world, the concerns over the safety of the data stored in devices and the government regulations on the subject matter by the relevant authorities are the greatest impediments to the widespread use of these gadgets. Security of the personal patient information, especially the information that is stored on the cloud or accessible on numerous networks, remains one of the central anxieties. Thus, there is need to introduce and reform existing laws in a manner that guarantees high safety of confidential data.

Conclusion

Wearable technology is being embraced with a paradigm shift in a bid to diagnose and treat atrial fibrillation more precisely during the initial stages. It is a transition between actual informal ongoing observation and conventional clinical testing. Since they allow non-invasive, real-time monitoring of heart rhythm, a number of devices, such as smartwatches, adhesive patches, and implantable loop recorders, is a wonderful contribution to any type of medical use, as well as personalized healthcare. The implication of such devices in the individualized healthcare procedures would have to be modified in response to various limitations such as the problem of inaccuracy, skin irritation, diminished battery capacity and sometimes even psychological effects. These have increased the clinical application of wearable technology based on artificial intelligence and machine learning, although issues of data privacy security, regulatory compliance, and internationally are yet to be addressed. Innovative design, stricter regulation and global harmonization of wearables would be required before these restrictions can be fully beneficial. All these wearables, within their limitations, would be created in the future to relieve the load of the atrial fibrillation and improve the outcome of the cardiovascular care.

Abbreviations:

Abbreviation	Definition
AF	Atrial Fibrillation
ILR	Implantable Loop Recorder
ML	Machine Learning
AI	Artificial Intelligence
CVD	Cardiovascular Diseases
US	United States
ANS	Autonomic Nervous System
FDA	Food Drug Administration

CAM	Carnation Ambulatory Monitor
PPG	Photoplethysmography
ECG	Electrocardiography
CNN	Convolutional Neural Network

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All authors declare that there is no conflict of interest.

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