Review Article

Interventional Cardiology

Wearable devices in atrial fibrillation screening: A review

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Abstract

Atrial Fibrillation (AF) is a common cardiac arrhythmia that increases stroke risk, even in patients who are asymptomatic and previously undiagnosed. The US Preventive Services Task Force and the National Heart, Lung, and Blood Institute have highlighted AF screening as a priority topic for further research. Recently, wearable devices employing a variety of technologies have emerged as an accurate and cost-effective means for AF screening. Several contemporary large clinical trials have demonstrated the feasibility of AF screening using wearable devices, though these studies included mostly young individuals with a low likelihood of new onset atrial fibrillation and cardiovascular complications. Further studies are needed to better understand whether wearable device-based AF screening strategies can lead to improved clinical outcomes among largely asymptomatic participants.

Keywords: Atrial fibrillation • Heart • Lung • Electrocardiogram

Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and is associated with an increased risk of stroke, heart failure, hospitalizations, and death [1]. Globally, AF affects over 43 million individuals, with a lifetime risk as high as one in three individuals [1]. While appropriate treatment for AF can help mitigate the risk of these complications, diagnosis of AF can be challenging as patients are often asymptomatic [2]. Stroke may be the first clinical manifestation of AF in up to 20% of AF-related strokes [3]. Furthermore, Asymptomatic Subclinical AF (SCAF) may account for up to 30% of all AF and is also associated with risk of stroke [1]. Despite the known cardiovascular risks associated with SCAF, many questions remain around the utility of early detection and how to best approach routine screening for asymptomatic AF. Currently, no major medical societies recommend routine screening in asymptomatic patients due to the limited evidence supporting its efficacy. Thus far, randomized controlled trials evaluating AF screening with single-lead Electrocardiograms (ECGs) or implantable loop recorders have not yet been able to demonstrate a significant association between AF screening and reduction in ischemic stroke [4,5]. The reasons for this lack of association are not entirely clear, but may be due to the observation that shorter episodes of subclinical AF are associated with a lower stroke risk compared to longer episodes of AF, limited duration of follow-up and inadequate statistical power [6].

Literature Review

Atrial fibrillation (AF) knowledge gaps highlight significant opportunities for further research, emphasizing the need to determine the optimal AF screening strategy and understand the overall impact of early AF detection and management on patient outcomes and healthcare utilization. The US Preventive Services Task Force and the National Heart, Lung, and Blood Institute have recently recognized AF screening as

a priority topic for further investigation [7,8]. Ongoing studies are investigating whether anticoagulation therapy for SCAF can effectively reduce the occurrence of stroke and thromboembolic events [9,10]. Furthermore, additional research is needed to clarify how the duration and overall burden of SCAF should guide anticoagulation decisions.

In recent years, wearable devices have gained significant traction as health monitoring tools, driven in part by increased consumer adoption due to their growing availability and affordability [11]. The appeal of wearable devices lies in their potential to provide continuous long-term and non-invasive monitoring, real-time data capture, and remote monitoring capabilities. Typically designed as wrist-worn bands containing electronic sensors, these devices can detect various physiologic parameters of interest such as heart rate and activity. Photoplethysmographic (PPG) sensors estimate heart rate based on light absorption, which allows for the measurement of changes in tissue blood volume. Various algorithms have been developed for AF diagnosis using these wearable technologies. Accelerometers used in combination with PPG sensors can help detect inappropriate tachycardia and bradycardia. They can also be used to limit AF detection to periods of inactivity, thereby enhancing specificity. Some wearable devices have also integrated single lead ECG technology. For instance, the apple watch series 4 employs the back of the device and the watch bezel as the lead I ECG bipoles. While the technology may act as a screening tool, the single lead ECG could be read by a physician to be diagnostic of AF. It is important to note that misclassification of AF can occur due to factors such as ectopic beats, sinus arrhythmia, patient/device movement, or environmental conditions. The accuracy of AF detection varies based on the specific device and algorithms employed, and combining multiple available technologies can improve specificity.

Previous smaller-scale studies have demonstrated the feasibility of detecting AF using wearable devices such as ECG patches and PPG-based wristwatches. In the mSTOPs study, which included participants aged ≥ 75 (or women aged ≥ 65 and men aged ≥ 55 with comorbidities) without prior AF, ECG patch monitoring was associated with higher rates of AF diagnosis when compared to routine care [12]. Participants were randomized to immediate or delayed ECG patch monitoring with the iRhythm ZioXT patch and were compared to matched observational controls. The study enrolled 5,214 participants in the overall observational cohort with a mean age of 74 years and found that participants who underwent ECG patch monitoring had a new AF diagnosis at 1 year at a rate of 6.7 per 100 person-years, compared to 2.6 per 100 person-years in those who did not undergo patch monitoring (difference, 4.1 (95% CI, 3.9-4.2)). EKG patch monitoring was associated with increased initiation of systemic anticoagulation and outpatient cardiology visits. The WATCH AF study demonstrated that a PPG-based wristwatch was able to detect AF with high sensitivity and specificity [13]. The study included 672 hospitalized patients with a recent history of AF who underwent consecutive wristwatch PPG (Samsung Gear Fit2) and mobile single lead ECG (Kardia device) recordings [13]. The authors found that the PPG algorithm achieved a sensitivity of 93.7% (95% Confidence Interval (CI), 89.8%-96.4%) and a specificity of 98.2% (95% CI, 95.8%-99.4%) for detecting AF using a cardiologist's interpretation of the single lead ECG recording as the gold standard [13].These findings support the potential of wearable devices as valuable tools for AF screening and diagnosis.

Several large trials have subsequently explored the effectiveness of wrist-worn wearable devices for AF screening in large populations without a known AF diagnosis. The apple heart study demonstrated strong concordance between irregular pulse notifications and AF in a large, pragmatic study [14]. The study included 419,297 participants aged ≥ 22 who wore a Smart Watch for rhythm monitoring. If an irregular pulse notification was triggered, participants underwent a telemedicine visit and were provided with a wearable ECG patch. Over a median monitoring period of 117 days, 2,161 participants (0.52%) received irregular pulse notifications. Of these, 945 (43.7%) underwent the first telemedicine visit and 450 (20.8%) returned analyzable ECG patches. Among those who underwent ECG patch monitoring, there was an 84% concordance (95% CI, 0.76-0.92) between subsequent irregular pulse notifications and AF detection on ECG [14]. The Huawei study also found that PPG-based devices determined suspected AF with high positive predictive value [15]. Study participants were monitored with PPG-based devices for at least 14 days, and if suspected AF was detected they were referred to a telecare team or hospital. The study included 187,912 participants with a mean age of 54 years. A total of 424 participants (0.23%) received suspected AF notifications, and among those who underwent clinical follow-up there was a 92% concordance (95% CI: 91.5%-91.8%) between suspected AF notifications and clinical diagnosis of AF [15]. Finally, the Fitbit study also demonstrated that an irregular heart rate detection algorithm correlated well with diagnosis of AF in a large study population [16]. The study included 455,699 participants who underwent rhythm monitoring, and those with irregular pulse notifications were referred for a telehealth appointment and sent a wearable ECG patch. During a median monitoring period of 122 days, 4728 (1%) participants received suspected AF notifications. Among those who underwent ECG patch monitoring there was 98.2% (95% CI, 95.5%–99.5%) concordance between subsequent irregular pulse notifications and AF on ECG [16]. Overall, these studies demonstrated that wrist-worn wearable devices were able to identify AF with high positive predictive value, though notably enrolled participants tended to be younger and had relatively low

CHA2DS2-VASc scores. This may explain the lower incidence of AF detected in these studies compared to prior studies that enrolled older participants, such as the mSTOPs study, which reported an incidence of AF of 6.7% in the intervention arm [12].

AF screening with wearable devices has additionally been shown to be cost-effective. A recent study conducted by Chen, et al. utilized a microsimulation decision analytic model to evaluate 8 screening strategies in a simulated population of 30 million individuals aged ≥ 65.17 the authors found that all screening strategies involving wrist-worn devices were more cost-effective than no screening. Among the tested strategies, wearable PPG followed by wearable ECG with patch confirmation was identified as the most cost-effective, with an Incremental Cost-Effectiveness Ratio (ICER) of $57,894 per quality-adjusted life year [17]. While wearable devices are likely cost-effective, a potential limitation to the widespread utility of these devices is patient adoption. In a recent JAMA Network Open article, Dhingra et al. examined the usage patterns of wearable devices among individuals with or at risk for cardiovascular disease [18]. The authors found that only 18% of individuals with established cardiovascular disease and 26% of those at risk for cardiovascular disease reported using wearable devices, in comparison to 29% of the general population [18]. Furthermore, less than half of individuals with or at risk for cardiovascular disease reported consistent daily use, and factors such as older age, lower educational attainment, and lower income were associated with decreased usage. These findings raise concerns around the low uptake of wearable devices, particularly among certain patient populations who are at a higher risk for adverse cardiovascular outcomes. In summary, while AF screening with wearable devices is likely cost-effective, a challenge lies in ensuring widespread adoption and consistent usage among patients, especially in high-risk populations.

Several ongoing trials are currently underway to address remaining clinical questions regarding AF screening. The PATCH-AF study, a cluster-randomized controlled trial, aims to expand upon previous literature by collecting longitudinal data from a higher-risk study population [19].The study will enroll participants in the Netherlands who were free of AF at baseline aged ≥ 65 with a high CHA2DS2VASc score. Those randomized to the intervention arm will undergo 7-day continuous ECG monitoring. Participants will be followed for a study period of 3 years to determine the diagnostic yield of ECG monitoring, with outcomes determined from national electronic health records. The apple heartline study is a large, pragmatic, randomized trial designed to investigate whether the smart watch with single-lead ECG capabilities in addition to a digital engagement application (the Heartline iPhone application) can improve cardiovascular outcomes in a real-world setting [20]. The trial will enroll participants aged ≥ 65 both with and without a prior diagnosis of AF. Participants will be randomized to either use of an apple watch with the Heartline application or use of the Heartline application alone. Claims data will be used to evaluate clinical outcomes of interest, including time from randomization to clinical diagnosis of AF. Secondary endpoints will include incidence of a composite cardiovascular/systemic embolism/mortality events, oral anticoagulant medication use and adherence, costs and health resource utilization, and bleeding-related hospitalizations [20]. The results from these ongoing studies may help guide future strategies for AF screening and management.

Conclusion

In conclusion, wearable devices equipped with continuous and non-invasive rhythm monitoring capabilities have emerged as promising tools for AF screening, offering the potential for enhanced early detection. Findings from several large clinical trials have consistently demonstrated the feasibility and effectiveness of various wearable devices in accurately detecting AF with high sensitivity and specificity. These promising findings, coupled with favorable cost-effectiveness analyses, support the use of wearable devices as viable options for population-wide AF screening strategies. However, challenges remain, such as ensuring widespread adoption and consistent usage of wearable devices among patients, particularly in high-risk populations. Additionally, further research is necessary to address existing knowledge gaps and to clarify whether early AF detection can lead to improved patient outcomes. Ongoing trials, such as the Apple Heartline study, hold promise in providing valuable insights into these areas of interest.

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