











REVIEW

Efficacy of wearable cardiac monitoring devices versus traditional methods in detecting atrial fibrillation: a systematic review and meta-analysis

Eficacia de los dispositivos portátiles de monitorización cardíaca frente a los métodos tradicionales en la detección de fibrilación auricular: una revisión sistemática y un metanálisis

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ABSTRACT

Introduction: atrial fibrillation (AF) is a prevalent arrhythmia with significant health and economic impacts. Traditional detection methods like 12-lead ECGs and Holter monitors are effective but limited by cost and patient compliance. Wearable devices, such as smartwatches and patches, offer a promising alternative for real-time AF detection.

Objective: this systematic review aims to evaluate the efficacy of wearable cardiac monitoring devices compared to traditional methods in detecting AF.

Method: a comprehensive literature search identified studies comparing wearable devices to traditional methods for AF detection. Data on sensitivity, specificity, and usability were extracted and analyzed. A pooled analysis using both fixed-effect and random-effects models assessed overall sensitivity and specificity.

Results: this systematic review analyzed data from 15 studies comparing wearable devices to traditional methods for AF detection. Wearable devices, including smartwatches, patch-type ECGs, and PPG-based technologies, showed high sensitivity and specificity, with the fixed-effect model estimating overall sensitivity at 91,59 % and specificity at 92,13 %. The random-effects model provided slightly higher sensitivity (94,03 %) and specificity (95,96 %). Smartwatches like the Apple Watch with KardiaBand demonstrated up to 97,5 % sensitivity, comparable to insertable cardiac monitors (ICMs). Patch-type ECGs, such as MobiCARE-MC100 and Zio XT, matched Holter monitors in accuracy, with extended monitoring enhancing AF detection. PPG-based technologies, exemplified by the WATCH AF trial, showed 93,7 % sensitivity and 98,2 % specificity. Despite high accuracy, significant heterogeneity among studies highlighted the need for standardized protocols.

Conclusion: wearable devices show high sensitivity and specificity for AF detection, comparable to traditional methods. However, substantial heterogeneity indicates the need for standardized protocols and further research to optimize these technologies for clinical use.

Keywords: Atrial Fibrillation; Electrocardiography; Wearable Electronic Devices; Diagnostic Techniques; Cardiovascular.

RESUMEN

Introducción: la fibrilación auricular (FA) es una arritmia prevalente con significativos impactos en la salud y la economía. Los métodos tradicionales de detección, como los ECG de 12 derivaciones y los monitores Holter, son efectivos pero limitados por su costo y la adherencia del paciente. Los dispositivos portátiles, como relojes inteligentes y parches, ofrecen una alternativa prometedora para la detección en tiempo real de la FA.

Objetivo: esta revisión sistemática tiene como objetivo evaluar la eficacia de los dispositivos portátiles de monitorización cardíaca en comparación con los métodos tradicionales para la detección de FA.

Método: se realizó una búsqueda exhaustiva de la literatura para identificar estudios que compararan dispositivos portátiles con métodos tradicionales para la detección de FA. Se extrajeron y analizaron datos sobre sensibilidad, especificidad y usabilidad. Un análisis conjunto utilizando modelos de efectos fijos y aleatorios evaluó la sensibilidad y especificidad globales.

Resultados: esta revisión sistemática analizó datos de 15 estudios que comparaban dispositivos portátiles con métodos tradicionales para la detección de FA. Los dispositivos portátiles, incluidos relojes inteligentes, ECG tipo parche y tecnologías basadas en PPG, mostraron alta sensibilidad y especificidad, con el modelo de efectos fijos estimando una sensibilidad global del 91,59 % y una especificidad del 92,13 %. El modelo de efectos aleatorios proporcionó una sensibilidad ligeramente mayor (94,03 %) y especificidad (95,96 %). Relojes inteligentes como el Apple Watch con KardiaBand demostraron hasta un 97,5 % de sensibilidad, comparable a los monitores cardíacos insertables (ICM). Los ECG tipo parche, como MobiCARE-MC100 y Zio XT, igualaron la precisión de los monitores Holter, con una monitorización extendida que mejora la detección de FA. Las tecnologías basadas en PPG, ejemplificadas por el ensayo WATCH AF, mostraron una sensibilidad del 93,7 % y una especificidad del 98,2 %. A pesar de la alta precisión, la heterogeneidad significativa entre los estudios destacó la necesidad de protocolos estandarizados.

Conclusión: los dispositivos portátiles muestran alta sensibilidad y especificidad para la detección de FA, comparables a los métodos tradicionales. Sin embargo, la heterogeneidad sustancial indica la necesidad de protocolos estandarizados y más investigación para optimizar estas tecnologías para uso clínico.

Palabras clave: Fibrilación Auricular; Electrocardiografía; Dispositivos Electrónicos Portátiles; Técnicas de Diagnóstico Cardiovascular.

INTRODUCCIÓN

In clinical practice, atrial fibrillation (AF) is the arrhythmia that is identified most often. In the United States, the projected number of people affected with AF is 2,3 million, and as the population ages, that number is predicted to rise to 5,6 million by 2050.⁽¹⁾ Heart failure, stroke, and thromboembolic events are among the well-known effects of AF. The substantial influence on morbidity, mortality, and healthcare expenditures may be attributed to these outcomes of disease development.⁽¹⁾ As a result, AF is not only a grave clinical issue but also a financial and public health burden. Although tiredness, dyspnea, palpitations, and chest discomfort are the usual symptoms of AF, 10-40 % of cases are thought to be asymptomatic.⁽²⁾ When subclinical or undetected AF first appears after an acute stroke, it has significant consequences and is associated with the same risks as symptomatic AF. It is unclear how arrhythmia and stroke are related, however the Framingham Study has shown that contemporaneous presentation of stroke and recently diagnosed AF raises the possibility that cardiac emboli are a significant cause of stroke.⁽³⁾ Prophylactic interventions are crucial for preventing strokes, as shown by the temporal link between AF and stroke. Early preventive actions may be taken to enhance health outcomes when clinical and subclinical AF are detected. The gold standard for diagnosing atrial fibrillation (AF) is interpretation of a 12-lead electrocardiogram (ECG) by a qualified cardiologist or heart rhythm expert.⁽⁴⁾ According to the American Heart Association/American Stroke Association's 2014 recommendations, patients who exhibit an irregular pulse should first have a 12-lead ECG before being screened for AF with pulse evaluations performed during routine clinical visits.⁽⁵⁾ The guidelines emphasize the benefits of active screening for individuals over 65, but they don't include advice for how often to do it. Comparably, the US Preventive Services Task Force (USPSTF) released a statement stating that there is not enough data at this time to assess the value of using an ECG to screen for AF.⁽⁶⁾ The issue is that there are just too many unknowns for all patients, particularly those who are not high-risk, to benefit from frequent ECG testing. According to recent studies, two major factors that contribute to these screening issues are the low prevalence and high prices.⁽⁷⁾ One issue is that since AF is erratic and intermittent, ambulatory ECG monitoring, which lasts anywhere from 12 hours to 14 days, is only tangentially indicative of a patient's experience.⁽⁸⁾

More comfort, convenience, and engagement are possible when it comes to real-time cardiac rhythm monitoring thanks to recent developments in wearable electronics and mobile health technologies. Smartwatches and other wearable technology have a lot of promise for diagnosing cardiac arrhythmias. In recent years, smartwatches have become more and more popular, particularly as a health tool for heart rhythm detection. With only one finger, patients using smartwatches may self-diagnose their cardiac rhythm in about 30 seconds.⁽⁹⁾ Early detection of AF reduces the burden on the health care system and guarantees that treatment begins early to avoid further episodes that might negatively affect quality of life. mHealth has provided a way to detect AF outside of the conventional cardiac monitoring system. Electrocardiographic (ECG) or photoplethysmography (PPG) data processing is now used in mHealth technology to identify atrial fibrillation (AF).⁽¹⁰⁾ Although ECG is still the most reliable method for detecting AF, these new technologies are interesting because they can handle near-continuous pulse data passively.⁽¹⁰⁾ PPG and related technologies provide a low-cost, non-invasive way to continuously monitor the heart cycle. Some of the problems with traditional screening techniques for AF detection may be resolved if wearable technology continues to improve in accuracy. Prior systematic evaluations provide insightful but constrained information about how well wearable technology detects atrial fibrillation (AF). Belani et al. assessed the sensitivity (96,83 %) and varied specificity (Apple: 99,61 %, Samsung: 81,13 %, KardiaBand: 97,98 %) of wrist-worn wearables (Apple Watch, Samsung, and KardiaBand) in detecting AF.⁽¹¹⁾ But this evaluation did not contrast these wearables with conventional techniques. In their 2020 study, Nazarian et al. examined the diagnostic performance of smartwatches in identifying several cardiac arrhythmias, with results showing 100 %, 95 %, and 97 % overall sensitivity, specificity, and accuracy, respectively.⁽⁹⁾ This evaluation just looks at smartwatches; it doesn't compare them to other conventional monitoring techniques. In light of these drawbacks and the paucity of available research, this systematic review attempts to provide current data about the superiority of a wider variety of wearable cardiac monitoring devices over more conventional techniques for the detection of atrial fibrillation.

METHOD

Study Design

This systematic review and meta-analysis evaluated the efficacy of wearable cardiac monitoring devices compared to traditional methods in detecting atrial fibrillation (AF). The review included studies that assessed the performance of wearable devices against established traditional diagnostic methods.

Sample Selection

The search strategy aimed to identify relevant studies comparing wearable cardiac monitoring devices with traditional methods for AF detection. Searches were conducted in databases including PubMed, Embase, and Cochrane Library using a combination of keywords and MeSH terms. The search terms included “wearable cardiac monitoring, traditional devices, “atrial fibrillation,” “smartwatch,” “ECG,” “Holter monitor,” and “PPG.”

Inclusion Criteria

- Studies comparing wearable cardiac monitoring devices (e.g., smartwatches, wristbands, adhesive ECG patches, patch-type ECG monitors, PPG-based mHealth devices, mobile telemetry, textile Holters) with traditional AF detection methods (e.g., 12-lead ECGs, Holter monitors, implantable cardiac monitors).
- Research articles published in English.
- Studies involving human participants.
- Studies published from January 2019 to July 2024.
- Peer-reviewed journals.
- Studies reporting on sensitivity and specificity for AF detection.

Exclusion Criteria

- Review articles, editorials, conference abstracts, and non-peer-reviewed publications.
- Studies not directly comparing wearable devices with traditional methods
- Studies focusing solely on wearable device validation without comparison to traditional methods.
- Studies with insufficient methodological detail or data on AF detection performance.

Study Method

An initial search was conducted using electronic databases. Abstracts and titles were screened for relevance, and full texts of potentially eligible studies were reviewed in detail. Inclusion and exclusion criteria were applied to select studies for final analysis.

Sample Size

The review included a total of 17 studies meeting the inclusion criteria. Data extraction was performed from

these selected studies for analysis.

Quality Assessment

The quality of the included studies was assessed using appropriate tool of Newcastle-Ottawa Scale for observational studies. Quality assessment was conducted independently by two reviewers, with disagreements resolved through discussion or consultation with a third reviewer.

Data Extraction

Data were extracted using a standardized form, capturing key information such as study characteristics (author, year, population), types of wearable and traditional devices, duration of monitoring, sensitivity, specificity, and results.

Data Analysis

Meta-analysis was performed to synthesize quantitative data from the included studies. Sensitivity and specificity estimates were calculated for wearable devices and traditional methods. Statistical heterogeneity among studies was assessed using the I^2 statistic, with values above 50 % indicating significant heterogeneity. Random-effect models were used to account for variability between studies. Sensitivity analyses and subgroup analyses were conducted to explore sources of heterogeneity and evaluate the robustness of findings.

RESULTS

1722 publications in all were found during the first literature search. Following a meticulous assessment of abstracts and titles, 121 articles were deemed relevant, and their full texts were acquired for further examination. Excluded studies did not fulfill the inclusion criteria or did not explicitly investigate efficacy of wearable cardiac monitoring devices versus traditional methods in detecting atrial fibrillation. After a thorough screening procedure, ten papers were found to be appropriate for the systematic review and meta-analysis.

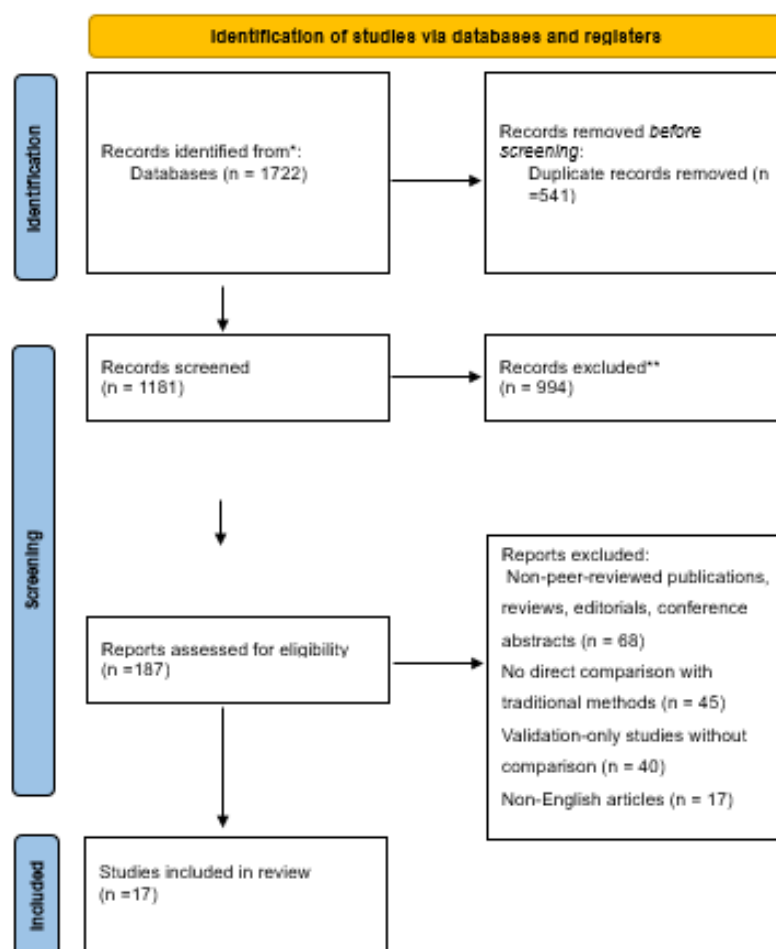


Figure 1. Prisma Flow Diagram

Study characteristics

The systematic review of wearable devices for atrial fibrillation (AF) detection included 17 studies. The bulk of the research ($n = 10$, 59 %) were prospective cohort studies, with a small number of cross-sectional observational studies ($n = 3$, 18 %). Case-control studies ($n = 1$, 6 %), randomized clinical trials ($n = 1$, 6 %), prospective pragmatic studies ($n = 1$, 6 %), siteless studies ($n = 1$, 6 %), and retrospective cohort assessments ($n = 1$, 6 %) made up a lesser percentage of the research. (table 1)

Patients recovering from heart surgery, older persons who had suffered a stroke, patients with TIA or cryptogenic stroke, patients with paroxysmal AF, and hospitalized participants were among the diverse demographics involved in the study. The number of participants varied across studies, with small cohorts ($n = 15$) and large cohorts ($n = 419,297$). The majority of research featured contrasts between wearable technology and conventional devices including ECG patches, Holter monitors, and implantable cardiac monitors (ICMs).

Numerous wearable devices were assessed during the trials, such as dyads of smartphone and wristwatch apps, adhesive ECG patches, patch-type ECG monitors, PPG-based mHealth devices, mobile telemetry, textile Holters, and standalone algorithms. While conventional equipment was usually used for continuous monitoring for 24 hours, wearable devices were utilized for monitoring for as little as 60 seconds and as long as 90 days.

Efficacy of Wearable Devices

Sensitivity and Specificity

The sensitivity and specificity of wearable devices to detect atrial fibrillation (AF) varied. For example, Wasserlauf et al. (2019) found that the Apple Watch with KardiaBand has a high sensitivity (97,5 %) for identifying bouts of AF. In a similar vein, Väliäho et al. (2019) discovered that a wristband PPG for AF detection had a 91,7 % sensitivity and a 98,1 % specificity. The Amazfit Health Band 1S was reported by Chen et al. (2020) to have specificities of 96,41 % and 99,20 %, respectively, with a sensitivity of 88,00 % (PPG) and 87,33 % (ECG). Furthermore, a wavelet PPG wristband was shown to be as accurate in identifying AF as the AliveCor KardiaBand ECG, with sensitivity and specificity of 100 % and 96 %, respectively, by Selder et al. (2020). According to this research, the accuracy of wearable technology—such as the Apple Watch, wristband PPG, and Amazfit Health Band 1S—often equals or surpasses that of conventional techniques, such as Holter monitors and ECG patches.

Comparison of Wearable vs. Traditional Devices

When compared to conventional technologies, wearables often had detection capabilities that were either equal to or better. Hyun et al. (2024) discovered that while the MobiCARE-MC100 recognized an increasing AF load over a prolonged length of time, the patch-type ECG (MobiCARE-MC100) and 24-hour Holter ECG originally indicated AF in the same individuals. When compared to the 24-hour Holter ECG, Lang et al. (2021) showed that the Zio XT patch shortened the time needed for fitting and hospital visits. In contrast to wearable solutions, conventional devices such as 12-lead ECGs and insertable cardiac monitors (ICM) provided continuous monitoring but had drawbacks such as greater dropout rates and false positives (Wouters et al., 2023; Rajakariar et al., 2023). (table 1)

Usability and Patient Compliance

Patient Preferences and Usability

Wearable technology is often thought to be very useful by people with chronic diseases and older persons who have had a stroke. According to Ding et al. (2022), 46 % of older persons who had had strokes thought the Samsung wristwatch and smartphone app pair was very useful. Although there were some difficulties, such as individuals who were already anxious or who were using assistance equipment, wearable technology was generally preferred over more conventional techniques. Additionally, Wouters et al. (2023) observed that mHealth and wristwatch technologies had better usability ratings because they were less invasive and more user-friendly. (table 1)

Compliance and Dropout Rates

The trials' compliance rates varied, and several wearables had problems with prolonged usage. Due to signal quality problems, Dörr et al. (2019) reported a 21,8 % dropout rate for a wristwatch with PPG algorithm, while Pagola et al. (2021) found a 7 % dropout rate over 90 days for the textile Holter (Nuubo®). Notwithstanding these difficulties, wearable technology often outperformed conventional techniques in terms of compliance, particularly when it came to real-time feedback and ease of use. (table 1)

Extended Monitoring Benefits

Extended monitoring with wearable devices showed significant benefits in detecting AF. Hyun et al. (2024) reported that the MobiCARE-MC100 detected an increase in AF burden over 48 hours, which was not possible with the 24-hour Holter ECG.

Table 1. Characteristics and results of the studies reviewed

Author	Year	Population Type and Number	Study Design	Wearable Device	Traditional Device	Duration of Monitoring (Wearable & Traditional)	Sensitivity	Specificity	Results with Stats	Conclusion	
Seungji Hyun et al. ⁽¹²⁾	2024	Post-cardiac surgery patients, 39	prospective cohort study	Patch-type ECG (MobiCARE-MC100)	24-hour ECG	Holter ECG	MobiCARE - MC100: 72 hours, Holter ECG: 24 hours	Not specified	Not specified	Both methods identified A-fib in 7 out of 39 patients in the initial 24 hours. An increase in A-fib burden (9 %→38 %) was observed in 1 patient during the extended 48 hours.	The MobiCARE device demonstrated comparable accuracy to Holter monitoring, and extended monitoring showed potential benefits for A-fib detection.
Eric Y. Ding et al. ⁽¹³⁾	2022	Older adults' post-stroke, 90	randomized clinical trial	Smartwatch-smartphone app dyad (Samsung / Android)	Patch monitor (Cardea SOLO™ ECG System)		Samsung / Android: 14 days, Cardea SOLO™: 14 days	Not specified	Not specified	46 % of participants found the smartwatch highly usable (SUS ≥68). Participants with assistive devices or anxiety reported higher anxiety with watch use.	Older adults found the smartwatch usable and preferred it over traditional methods, but improvements in device interface and battery life are needed for better usability.
Alex Lang et al. ⁽¹⁴⁾	2021	Cryptogenic stroke/TIA patients, 93	prospective cohort study	Adhesive ECG patch (Zio XT)	24-hour ECG	Holter ECG	Zio XT: 14 days, Holter ECG: 24 hours	Not specified	Not specified	The median time to fitting the monitor was significantly reduced with the Zio XT patch, and hospital visits were reduced by a median of two.	The use of the Zio XT patch is feasible in routine clinical care, with a positive impact on patient care pathways by reducing time to fitting and hospital visits.
Femke Wouters et al. ⁽¹⁵⁾	2023	Cryptogenic stroke/TIA patients, 39	Prospective cohort study	PPG-based mHealth (smartphone/smartwatch)	Insertable cardiac monitor (ICM)		mHealth: 6 months, ICM: Continuous	Not specified	Not specified	10 patients had AF detected by ICM, but only 1 confirmed. PPG-based mHealth also detected the confirmed AF. High false positives were observed in ICM readings.	mHealth and ICM have potential for AF detection but require physician revision. mHealth compliance is a challenge without direct feedback, highlighting device limitations.
Jorge Pagola et al. ⁽¹⁶⁾	2021	Cryptogenic stroke patients, 254	Prospective cohort	Textile Holter (Nuubo®)	traditional Holter monitoring		Nuubo®: 90 days, N/A	Not specified	Not specified	Cumulative incidence of AF detection at 90 days was 34,84 %. Monitoring time was similar across the 3 months. 7 % of patients abandoned monitoring.	Intensive 90-day Holter monitoring with a textile Holter was feasible and detected a high percentage of AF. Enlarged left atrial volume predicted AF beyond the first week.

Jonathan Krathen et al. ⁽¹⁷⁾	2021	Cryptogenic stroke patients, 15	Prospective cohort study	Mobile telemetry (MT)	Implantable loop recorders (ILR)	MT: 4 weeks, ILR: Continuous	Not specified	Not specified	AF was detected in 13 % of patients within the first 4 weeks on both MT and ILR. AF was detected in 1 patient at 92 days on the ILR.	Early results showed MT was non-inferior to ILR in detecting early AF. Initial use of MT may be considered, reserving ILR for after an uneventful four-week period.
Martin E. Matsumura et al. ⁽¹⁸⁾	2020	Cryptogenic stroke or TIA patients, 196	Retrospective cohort assessment	Wearable ambulatory ECG (AECG)	Inpatient Telemetry	AECG: 14 days, N/A	Not specified	Not specified	AF was detected in 12,8 % of patients. CHA2DS2Vasc ≤ 3 had a negative predictive value of 97,3 % for AF. Additional 5,3 % diagnosed with AF on long-term follow-up.	Fourteen-day AECG diagnosed the majority of AF cases within 24 months following the event. CHA2DS2Vasc may help identify patients unlikely to show AF with 14-day AECG.
Jeremiah Wasserlauf et al. ⁽¹⁹⁾	2019	Patients with paroxysmal AF, 24	Prospective cohort study	Apple Watch with KardiaBand	Insertable cardiac monitor (ICM)	Apple Watch: Mean 11,3 hours/day, ICM: Continuous	97,5 %	Not specified	The AFSW detected 80 out of 82 AF episodes ≥ 1 hour detected by the ICM. Episode sensitivity was 97,5 %, duration sensitivity was 97,7 %.	The AFSW is highly sensitive for AF detection and assessment of AF duration when compared with an ICM. It represents an inexpensive, noninvasive approach for long-term AF surveillance.
Rajakariar et al. ⁽²⁰⁾	2020	200 patients	Prospective cohort	AliveCor KardiaBand (KB)	12-lead ECG	AliveCor KardiaBand: Immediate after iECG tracing, 12-lead ECG: Immediate after iECG tracing	94,4 %	81,9 %	Moderate agreement between 12-lead ECG and KB ($\kappa=0,60$). PPV: 54,8 %; NPV: 98,4 %. EP interpretation improved accuracy (EP1: $\kappa=0,76$; EP2: $\kappa=0,74$).	KB shows moderate accuracy; combining automated diagnosis with EP interpretation improves results. Physician involvement remains crucial.
Dörr et al. (WATCH AF Trial) ⁽²¹⁾	2019	6 7 2 hospitalized subjects	case-control	Smartwatch with PPG algorithm	Internet-enabled mobile ECG	Not specified for both	93,7 %	98,2 %	High accuracy (96,1 %). Dropout rate due to signal quality issues (21,8 %).	Smartwatch detects AF with high accuracy, but signal quality issues limit applicability. Real-time checks needed for improvement.
Ding et al. ⁽²²⁾	2020	40 older adults	prospective cohort study	Smartwatch with novel algorithm	Holter monitor	Smartwatch: 42 minutes, Holter monitor: Simultaneous	98,2 %	98,1 %	High accuracy (98,1 %) in identifying pulse irregularities.	Algorithm shows high accuracy. Participants found the smartwatch highly acceptable despite age and comorbidities.

Wasserlauf et al. ⁽¹⁹⁾	2018	24 patients	Prospective cohort	A p p l e Watch with KardiaBand	Insertable cardiac monitor (ICM)	Apple Watch: 11,3 (4,4) hours/day, ICM: 31,348,9 hours simultaneous monitoring	97,5 %	Not reported	High sensitivity (97,5 %) for AF detection. PPV: 39,9 %.	AFSW is highly sensitive for detecting AF and duration. Represents a cost-effective, noninvasive option for long-term AF monitoring.	
Perez et al. ⁽²³⁾	2019	4 1 9 , 2 9 7 participants	Prospective Pragmatic, siteless	Apple with app	Watch iPhone	ECG patch	Apple Watch: Median 117 days, ECG patch: Up to 7 days	84 %	Not reported	34 % had AF on subsequent ECG patch readings. PPV for AF on ECG was 0,84.	Low notification probability; 34 % with AF on ECG. Foundation for large-scale studies with user-owned devices.
Väliaho et al. ⁽²⁴⁾	2019	213 patients	c r o s s - s e c t i o n a l observational study	Wristband PPG	Electrocardiogram (ECG)	Wristband PPG: 5 minutes, ECG: Simultaneous	91,7 % (pulse)	98,1 % (AF)	PPG sensitivity: 91,7 %; PPV: 97,5 % for AF. Sensitivities for AF detection algorithms: 96,2 % and 95,3 %.	PPG wristband enables accurate AF detection; algorithms show high accuracy. Suitable for AF screening.	
Selder et al. ⁽²⁵⁾	2020	60 subjects (mean age 70±17)	c r o s s - s e c t i o n a l observational study	Wavelet PPG wristband	A l i v e c o r KardiaBand	Wavelet PPG wristband: 60 seconds, Alivecor KardiaBand: 30 seconds	100 %	96 %	Sensitivity/specificity/PPV/NPV/accuracy: 100/96/75/100,97 % for PPG, 100/98/86/100/98 % for ECG.	PPG wristband accurately detects AF, comparable to one-lead ECG. Suitable for long-term AF screening and monitoring.	
Rajakariar et al. ⁽²⁶⁾	2019	200 patients (56,5 % male, age 67 ± 16)	Prospective cohort study	A l i v e C o r KardiaBand	12-lead ECG	Not specified for both	Not specified	Not specified	Manual interpretation of unclassified traces concurred with 12-lead ECG in 89 % of cases. Strong inter-observer agreement ($\kappa = 0,98$, $p < 0,001$).	High accuracy of clinician interpretation of unclassified iECGs. Efficient and cost-effective solution for arrhythmia screening.	
Chen et al. ⁽²⁷⁾	2020	401 patients (251 normal, 150 AF)	C r o s s - s e c t i o n a l Observational study	A m a z f i t Health Band 1S	Not specified	Not specified for both	88,00 % (P P G) , 87,33 % (ECG)	96,41 % (P P G) , 99,20 % (ECG)	Sensitivity/specificity/accuracy: 88,00 %/96,41 %/93,27 % for PPG; 87,33 %/99,20 %/94,76 % for ECG. Physician-judged ECG: 96,67 %/98,01 %/97,51 %.	Combination of PPG, ECG, and AI algorithm facilitates AF detection. Potential for long-term monitoring.	

Table 2. Quality assessment of the reviewed studies by New Castle Ottawa Scale

Study	Representativeness of the exposed cohort (1)	Selection of the non-exposed cohort(1)	Ascertainment of exposure (1)	Demonstration that outcome of interest was not present at start of study(1)	Compare ability of cohorts on the basis of the design or analysis (2)	Assessment of outcome (1)	Was long enough for follow-up to occur(1)	Adequacy of follow up of cohorts (1)	Representativeness of of the exposed cohort (1)
Seungji Hyun et al. ⁽¹²⁾	1	1	1		2	1	1	1	1
Alex Lang et al. ⁽¹⁴⁾	1	1	1	1	2	1	1	1	1
Femke Wouters et al. ⁽¹⁵⁾	1	1	1		2	1	1	1	1
Jorge Pagola et al. ⁽¹⁶⁾	1		1		1	1	1	1	1
J o n a t h a n Krathen et al. ⁽¹⁷⁾	1		1		1	1	1	1	1
Martin E. Matsumura et al. ⁽¹⁸⁾	1	1	1		2	1	1	1	1
J e r e m i a h Wasserlauf et al. ⁽¹⁹⁾	1	1	1	1	2	1	1	1	1
Rajakariar et al. ⁽²⁰⁾	1	1	1		2	1	1	1	1
Ding et al. ⁽²²⁾	1	1	1	1	1	1	1	1	1
Wasserlauf et al. ⁽¹⁹⁾	1		1	1	1	1	1	1	1
Rajakariar et al. ⁽²⁶⁾	1	1	1	1	2	1	1	1	1

Similarly, Lang et al. (2021) found that the Zio XT patch, with its 14-day monitoring period, detected AF cases more effectively than the 24-hour Holter ECG. Extended monitoring also proved beneficial in studies using the Apple Watch (Wasserlauf et al., 2019) and textile Holter (Pagola et al., 2021), with higher AF detection rates reported over longer periods.

Clinical Implications and Impact on Patient Care:

The use of wearable devices significantly impacted clinical pathways by reducing time to diagnosis and improving patient outcomes. Lang et al. (2021) demonstrated that the Zio XT patch facilitated quicker fitting and reduced hospital visits, streamlining the care pathway for stroke and TIA patients. Wasserlauf et al. (2019) found that the Apple Watch with KardiaBand provided a non-invasive and cost-effective approach for long-term AF surveillance, potentially reducing the need for more invasive procedures. Overall, wearable devices contributed to more efficient patient management, earlier detection of conditions, and improved long-term monitoring, thereby enhancing the overall quality of patient care. (table 1)

Quality assessment

The quality assessment of the cohort studies was conducted using the Newcastle-Ottawa Scale (NOS), which evaluates studies based on criteria such as the representativeness of the exposed cohort, selection of the non-exposed cohort, ascertainment of exposure, and demonstration that the outcome of interest was not present at the start. The studies generally scored well across most categories, with several achieving maximum points in areas like comparability of cohorts, adequacy of follow-up, and assessment of outcomes. For example, studies by Alex Lang et al., Jeremiah Wasserlauf et al., and Rajakariar et al. received high scores across all categories, including representativeness of the exposed cohort, comparability of cohorts, and adequacy of follow-up. Studies by Jorge Pagola et al. and Jonathan Krathen et al., while generally strong, had some gaps, particularly in demonstrating that the outcome of interest was not present at the start and in the selection of non-exposed cohorts. (table 2)

Meta-analysis

There is a significant amount of variation in the sensitivity of wearable devices for detecting atrial fibrillation, according to a pooled analysis of 9 studies. Assuming homogeneity across studies, the fixed-effect model estimates an overall sensitivity of 91,59 % with a narrow confidence interval (95 % CI: 89,22 % to 93,48 %), indicating high sensitivity. The heterogeneity-accounting random-effects model provides a slightly higher estimate of 94,03 % (95 % CI: 90,05 % to 96,49 %). A τ^2 of 0,4480, an I^2 value of 70,2 %, and an H value of 1,83 (95 % CI: 1,30 to 2,58) suggest considerable variance beyond sampling error, indicating substantial heterogeneity among the studies. The test of heterogeneity ($Q = 26,88$, $p = 0,0007$) further supports this significant discrepancy.

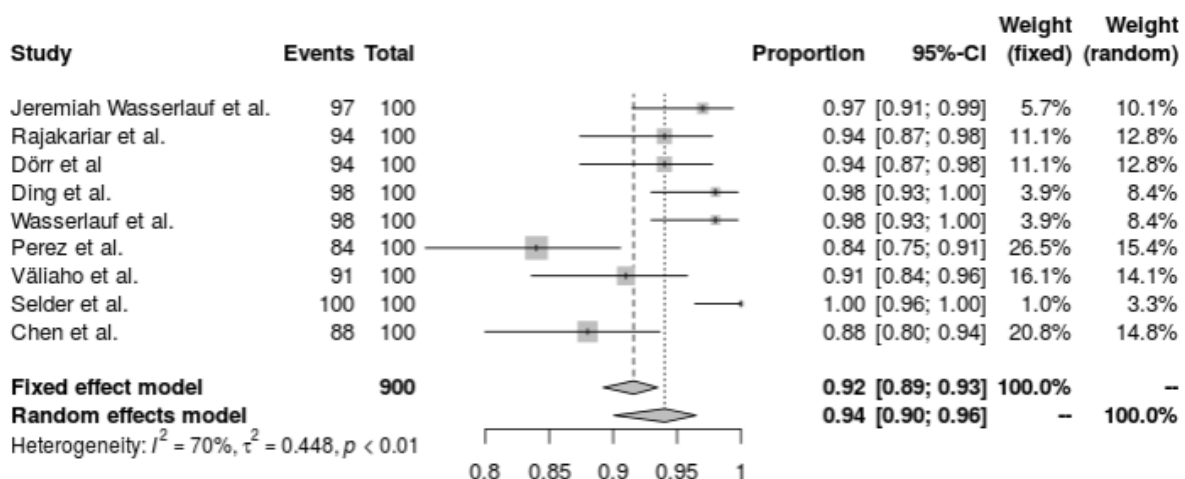


Figure 2. Forest plot regarding the sensitivity of the wearable devices

There is a significant amount of variation in the specificity of wearable devices for detecting atrial fibrillation (AF), according to a pooled analysis of 6 studies. Assuming homogeneity across studies, the fixed-effect model estimates an overall specificity of 92,13 % with a narrow confidence interval (95 % CI: 89,01 % to 94,42 %), indicating high specificity. The heterogeneity-accounting random-effects model provides a slightly higher estimate of 95,96 % (95 % CI: 89,63 % to 98,49 %). A τ^2 of 1,2596, an I^2 value of 82,9 %, and an H value

of 2,41 (95 % CI: 1,66 to 3,51) suggest considerable variance beyond sampling error, indicating substantial heterogeneity among the studies. The test of heterogeneity ($Q = 29,16$, $p < 0,0001$) further supports this significant discrepancy.

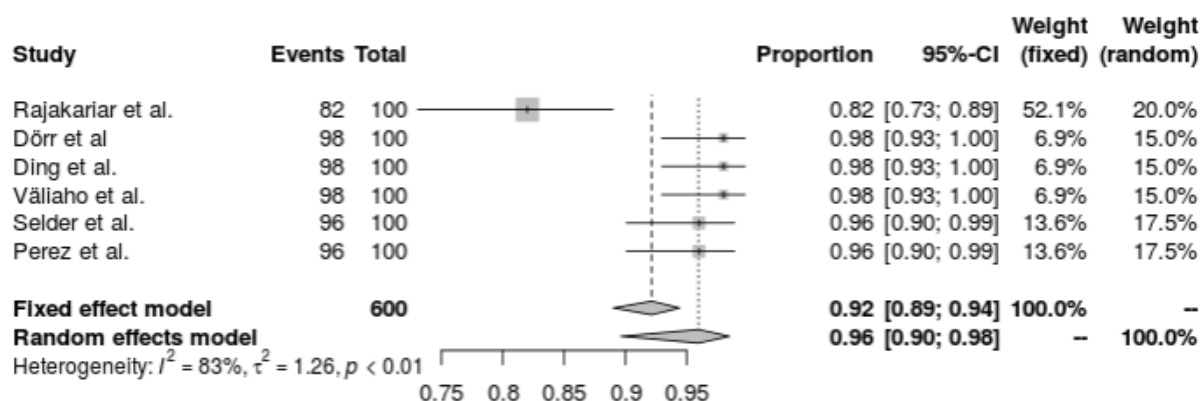


Figure 2. Forest plot regarding the specificity of the wearable devices

DISCUSSION

This review and meta-analysis reveal that wearable cardiac monitoring devices show considerable variation in their efficacy compared to traditional methods for detecting atrial fibrillation. The pooled analysis from various studies demonstrates that wearable devices generally possess high sensitivity and specificity, although significant variability exists across different devices and study designs.

Overall, wearable devices exhibit varying degrees of sensitivity and specificity in AF detection. For instance, devices like the Apple Watch with KardiaBand and the AliveCor KardiaBand show high sensitivity for AF detection, closely matching or even surpassing traditional methods such as Holter monitors and ILRs in some cases.^(19,20) Devices such as the Apple Watch with KardiaBand and the Wavelet PPG Wristband achieved particularly high sensitivity, with figures of 97,5 % and 100 %, respectively.^(19,25) The high sensitivity indicates that these wearable devices are effective at identifying episodes of AF, which is crucial for early detection and management. This is consistent with previous studies of literature, such as a systematic review of 208 studies on the use of mobile health solutions for the detection of AF, which found that the sensitivity and specificity of ECG-based devices were as follows: The percentages for belts, patches, portable devices, and belt-mounted devices are 95,6 %-98,5 %, 76,0 %-95,0 %, and 93,4 %-97,0 %, respectively.⁽²⁸⁾ High sensitivity (94 %, 95 % CI 92-25) and specificity (97 %, 95 % CI 96-98) were seen for AF identification in a meta-analysis of 28 trials comparing smartphone PPG against ECG for AF detection.⁽²⁹⁾ Nevertheless, there was significant inter-study variability in the low-quality studies, which also carried a high risk of selection and publication bias.

Conversely, the specificity of these wearable devices varies. For example, wearable devices like the PPG-based mHealth system and the Zio XT patch demonstrate a high detection rate but also exhibit challenges such as high false positives.^(14,15) However, some devices, such as the insertable cardiac monitor (ICM), exhibited lower specificity due to higher false-positive rates.⁽¹⁵⁾ This discrepancy underscores the importance of combining wearable technology with physician oversight to minimize false positives and ensure accurate diagnosis. The Amazfit Health Band 1S, for example, showed high specificity of 99,20 % for ECG readings.⁽²⁷⁾

When comparing wearable devices to traditional methods like Holter monitors and 12-lead ECGs, several important observations emerge. Wearable devices offer the advantage of extended monitoring durations compared to traditional methods. For instance, the Nuubo® textile Holter provided continuous monitoring for up to 90 days, leading to a 34,84 % cumulative incidence of AF detection.⁽¹⁶⁾ This extended monitoring can enhance AF detection rates compared to the typical 24-hour duration of traditional Holter monitors.^(12,14) Thirty-day smartphone ECG monitoring with KardiaMobile (AliveCor) revealed an absolute difference of 7,5 % in AF detection ($P = 0,024$) compared to 24-hour Holter monitoring, according to a multicenter, open-label RCT on patients aged ≥ 55 having ischemic stroke or TIA in the previous 12 months.⁽³⁰⁾

Wearable technology adoption has been increasing year on year, and is estimated to reach more than 1 billion users in 2022, which may increase the acceptability and cost-effectiveness of wearable devices for cardiac monitoring of patients. Usability and patient preference also play significant roles. Wearable devices often present improved usability and higher patient acceptance. The smartwatch with a novel algorithm was preferred by older adults over traditional patch monitors, despite issues related to interface and battery life.⁽²²⁾ The high usability of devices like the Apple Watch further supports their potential for better patient adherence to long-term monitoring.⁽¹⁹⁾

While wearable devices show high accuracy, they are not always equivalent to traditional methods. For

instance, the AliveCor KardiaBand demonstrated moderate agreement with 12-lead ECGs, indicating that while wearable devices can be highly effective, they may not completely replace traditional diagnostic methods.⁽²⁰⁾ Additionally, mobile telemetry (MT) has been found to be non-inferior to implantable loop recorders (ILR) for early AF detection, suggesting that wearable devices can be a viable alternative in specific scenarios.⁽¹⁷⁾

The meta-analysis revealed substantial heterogeneity among the included studies. For sensitivity, the fixed-effect model estimated an overall proportion of 91,59 % (95 % CI: 89,22 % to 93,48 %), while the random-effects model provided an estimate of 94,03 % (95 % CI: 90,05 % to 96,49 %). The heterogeneity measures ($I^2 = 70,2$ %) indicate significant variance beyond sampling error. For specificity, the fixed-effect model estimated a proportion of 92,13 % (95 % CI: 89,01 % to 94,42 %), and the random-effects model estimated 95,96 % (95 % CI: 89,63 % to 98,49 %), with an I^2 value of 82,9 %. These findings suggest substantial variability in study outcomes, necessitating caution in interpreting pooled results.

CONCLUSIONS

Wearable cardiac monitoring devices have demonstrated considerable potential in detecting AF with high sensitivity and specificity. However, their performance varies widely, and they may not yet completely replace traditional methods like Holter monitors or 12-lead ECGs. The review highlights the benefits of extended monitoring durations and improved patient compliance associated with wearable devices. Still, it also points out the need for continued advancements in device accuracy, usability, and integration into clinical workflows. Future research should focus on refining algorithms, reducing false-positive rates, and exploring the most effective use cases for wearable devices in AF detection.

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CONFLICT OF INTEREST

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