

## Advances and Challenges in the Application of Wearable/Mobile Devices for Occult Atrial Fibrillation Management: Postprint

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### Abstract

Atrial fibrillation (AF) is one of the most common cardiac arrhythmias, which can lead to serious complications such as heart failure and stroke, resulting in increased mortality and morbidity in patients. Occult atrial fibrillation lacks obvious clinical manifestations and exhibits irregular episodes, leading to high rates of missed diagnosis and inability to receive timely standardized treatment, thereby predisposing to adverse clinical outcomes. Recent clinical studies have demonstrated significant advantages of wearable devices in the screening and management of occult atrial fibrillation. Based on a review of recent domestic and international literature, this article comprehensively examines the latest research status, clinical outcomes, cost-effectiveness, application challenges, and future prospects of wearable devices in occult atrial fibrillation screening and management, aiming to provide enhanced evidence-based support for their further implementation in occult atrial fibrillation care.

### Full Text

## Updated Progress and Challenges in the Application of Wearable/Mobile Devices in the Management of Silent Atrial Fibrillation

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## Abstract

Atrial fibrillation (AF) is among the most prevalent cardiac arrhythmias, leading to severe complications such as heart failure and stroke that significantly increase patient mortality and disability rates. Silent AF, characterized by the absence of clinical symptoms and irregular onset patterns, carries a high risk of missed diagnosis and delayed standardized treatment, resulting in poorer clinical outcomes. Recent clinical studies have demonstrated significant advantages of wearable devices in screening and managing silent AF. This review synthesizes current domestic and international literature to examine the latest research status, clinical outcomes, cost-effectiveness, application challenges, and future prospects of wearable devices in silent AF screening and management, aiming to provide enhanced evidence-based support for their broader implementation.

**Keywords:** Wearable electronic devices; Mobile; Silent atrial fibrillation; Management; Progress

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Atrial fibrillation is the most common cardiac arrhythmia, substantially increasing the risk of stroke and heart failure, with high prevalence, mortality, and disability rates [1-4]. Global AF cases were estimated at 59.7 million in 2019 [5]. The 2022 Chinese Cardiovascular Health and Diseases Report indicates approximately 4.87 million AF patients in China, with a prevalence of 1.6% among adults aged 18 and older [6]. A community-based survey of 47,841 Chinese adults (age  $\geq$  45 years) by Du et al. [7] reported a weighted AF prevalence of 1.8%. AF significantly elevates stroke risk; once stroke occurs, the one-year mortality rate reaches approximately 30%, with up to 30% of survivors experiencing permanent disability [8]. Additionally, AF represents a major cause of cognitive decline [9], making it a critical global public health concern [9].

Up to one-third of AF patients are asymptomatic, a condition termed silent or asymptomatic atrial fibrillation [10]. Silent AF may pose greater risks than symptomatic AF due to low patient awareness and delayed diagnosis and treatment [11]. Data show that silent AF patients face a threefold higher risk of cardiovascular events and mortality compared to symptomatic patients [11], underscoring the particular clinical importance of silent AF management.

Early accurate screening and standardized management of silent AF have become key challenges and research priorities in AF care [3,12]. Traditional screening methods have significant limitations. The ESC 2020 AF Management Guidelines recommend opportunistic screening via pulse palpation or ECG in individuals over 65 years, and systematic ECG screening for those  $\geq$  75 years or at high stroke risk [12]. The Canadian Cardiovascular Society/Canadian Heart

Rhythm Society (CCS) 2020 guidelines similarly suggest opportunistic screening by pulse palpation in those  $\geq 65$  [14]. However, the AHA/ACC/HRS 2019 guidelines [15] and US Preventive Services Task Force (USPSTF) 2022 report [3] conclude that evidence regarding benefits of silent AF screening using current technologies remains insufficient. The Chinese guidelines on “Atrial Fibrillation: Current Understanding and Treatment Recommendations (2021)” align with ESC recommendations.

In practice, few clinicians routinely perform opportunistic screening using pulse palpation or standard ECG [10]. Pulse palpation has low overall specificity (70-81%) [12] and accuracy is subject to clinicians’ subjective judgment and experience. Standard 12-lead ECG records only ~10 seconds, yielding high miss rates for intermittent silent AF. Holter monitoring improves detection but uses wired devices with poor patient compliance and lacks real-time response during AF episodes. Cardiac implantable electronic devices (CIEDs) enable continuous monitoring but are invasive, expensive, and carry perioperative complication risks, making them unsuitable for routine screening in general populations.

Recent rapid development of wearable/mobile devices offers new possibilities for early silent AF screening and intervention. These emerging technologies provide real-time, cost-effective, user-friendly solutions with high sensitivity and specificity, addressing limitations of traditional methods and demonstrating substantial potential for silent AF screening and management. Multiple international randomized controlled trials (RCTs) have confirmed the effectiveness of wearable devices in silent AF screening and early intervention [13], though studies on clinical outcome improvement and cost-effectiveness remain relatively limited. This review synthesizes the latest evidence on wearable devices in silent AF management to support their broader application.

## 1 Guideline Recommendations and Implementation Status for Silent Atrial Fibrillation Screening

The prerequisite for managing silent AF is successful detection. As silent AF patients lack obvious symptoms (palpitations, chest tightness, pain), they rarely seek medical care. Traditionally, silent AF is often discovered incidentally during physical examinations or ECGs performed for other conditions. To address this, guidelines recommend opportunistic screening. However, implementation remains suboptimal. KAASENBROOD et al. [16] (2020) and UITTENBOGAART et al. [17] (2020) conducted one-year opportunistic screening studies in Dutch general practices among patients  $\geq 65$  years without AF history, using intermittent MyDiagnostic ECG (30-second single-lead) devices during routine visits. With 35,083 participants in intention-to-screen analysis, handheld intermittent ECG devices did not significantly improve silent AF detection rates in general practice settings. LUBITZ et al. [18] (2022) performed one-year opportunistic screening in US primary care clinics among 15,393 patients  $\geq 65$  years, mostly without AF history, using handheld AliveCor KardiaMobile devices (30-second intermittent ECG). Compared to usual care ( $n=15,322$ ), the screening

group showed no significant increase in AF detection overall, though detection was significantly higher in those  $\geq 85$  years.

Current evidence indicates that continuous cECG patch monitoring significantly outperforms conventional methods in AF detection, while intermittent ECG devices show greater value for screening particularly high-risk populations.

## 2 Effectiveness of Wearable Devices for Silent Atrial Fibrillation Screening

A systematic review of RCTs using wearable devices for silent AF screening [13] demonstrated that continuous ECG (cECG) chest patches (5-30 days continuous monitoring) substantially improved AF detection compared to conventional methods. Handheld intermittent ECG devices showed more modest benefits.

## 3 Clinical Management Outcomes of Atrial Fibrillation with Wearable/Mobile Devices

Comprehensive AF management follows the “ABC” pathway: “A” (Anticoagulation/Avoid stroke), “B” (Better symptom control—rate or rhythm control oriented to patient symptoms), and “C” (Cardiovascular disease and comorbidity management, such as hypertension, sleep apnea, diabetes) [19]. Wearable/mobile technologies provide new support for implementing this approach, enabling early anticoagulation and comprehensive “ABC” management for screen-detected silent AF patients to improve outcomes (reduce stroke/thromboembolism or mortality).

### 3.1 Clinical Outcomes of Anticoagulation Therapy After Wearable/Mobile Device Screening

The STROKESTOP study represents the first international RCT using wearable/mobile devices for systematic silent AF screening to drive early anticoagulation and observe clinical outcomes. This multicenter, prospective Swedish trial randomized individuals aged 75-76 without prior AF to intervention ( $n=7,165$ ) or usual care ( $n=13,996$ ). The intervention group used handheld Zenicor intermittent ECG devices twice daily (30 seconds each) for two weeks, achieving a fourfold increase in new AF detection, with over 90% of detected patients receiving oral anticoagulation. After median 6.9 years follow-up (minimum 5 years), intention-to-treat analysis showed the intervention group had significantly lower composite outcome rates (ischemic/hemorrhagic stroke, systemic embolism, hospitalization for bleeding, all-cause mortality) (HR=0.96, 95%CI: 0.92-1.00) [20].

The REHEARSE-AF prospective multicenter UK study enrolled patients  $\geq 65$  years without AF history and CHA<sub>2</sub>DS<sub>2</sub>-VASc  $\geq 2$ . The intervention group ( $n=500$ ) performed twice-weekly 30-second ECGs using AliveCor KardiaMobile for one year, achieving 3.80-fold higher detection than control ( $n=501$ ) ( $P<0.05$ ), with all detected patients receiving timely anticoagulation

[21]. However, 2023 long-term follow-up data (median 4.2 years) showed similar AF detection rates between groups (HR=1.37, 95%CI: 0.86-2.19). Secondary outcomes including anticoagulation rates (HR=1.28, 95%CI: 0.83-1.96), stroke/systemic embolism (HR=0.92, 95%CI: 0.54-1.54), and long-term mortality (HR=1.07, 95%CI: 0.66-1.73) showed no significant differences [22].

The SCREEN-AF study enrolled primary care patients  $\geq 75$  years with hypertension but no AF history. The control group (n=422) received usual care, while the intervention group (n=434) underwent two 2-week cECG chest patch screenings (at baseline and 3 months), achieving ~10-fold higher detection (P<0.05). During 6-month follow-up, anticoagulation rates were 4.1% vs 0.9% (OR=4.4, 95%CI: 1.5-12.8, P=0.007). Clinical outcomes were secondary endpoints, with no significant differences in ischemic stroke, TIA, or cardiovascular mortality [23].

Thus, aside from STROKESTOP, these RCTs did not demonstrate significant clinical outcome improvements, possibly due to secondary outcome status, small sample sizes, or short follow-up durations.

### 3.2 Clinical Outcomes of Comprehensive Atrial Fibrillation Management Using Wearable/Mobile Devices

Poor anticoagulation adherence among Chinese AF patients may increase stroke risk [24]. Chen et al. [25] studied 210 anticoagulated AF patients across 6 institutions, examining smartwatch reminders' impact on medication adherence over 12 months. In usual follow-up, good adherence declined from 82.9% at month 1 to 27.8% at month 12, while the smartwatch group increased from 75.2% to 86.3%, with significantly better adherence from month 7 onward.

GUO et al. [19] evaluated the mAFA mobile app for comprehensive AF management in 1,646 intervention patients (mean age 67). After ~9 months, the intervention group showed significantly lower composite outcomes (ischemic stroke/systemic embolism, death, rehospitalization) (HR=0.39; 95%CI: 0.22-0.67; P<0.001). The mAFA-II long-term extension study followed 1,261 intervention patients for >1 year, maintaining significantly lower composite outcomes versus usual care (n=1,212) (HR=0.18, 95%CI: 0.13-0.25, P<0.001) [26].

YAO et al. [27] analyzed multimorbid AF patients in mAFA-II, comparing "ABC" comprehensive management to usual care. After >1 year, intervention patients had significantly lower composite outcomes (HR=0.37, 95%CI: 0.26-0.53) and uncontrolled blood pressure (HR=0.29, 95%CI: 0.19-0.45).

These findings demonstrate that mobile device/app-based comprehensive AF management—including anticoagulation, rate/rhythm control, and active self-management—effectively reduces cardiovascular risk.

## 4 Cost-Effectiveness Analysis of Wearable/Mobile Devices in Silent Atrial Fibrillation Screening and Management

Cost-effectiveness evaluation is crucial for clinical practice. In health economics, incremental cost-effectiveness ratio (ICER) measures incremental cost per unit health outcome gained, expressed as cost per stroke prevented or quality-adjusted life year (QALY) gained.

STROKESTOP' s real-world cost-effectiveness analysis showed a 7.8% stroke rate reduction in the screening group, yielding 65 incremental QALYs per 1,000 screened individuals. The ICER was €27,156/QALY versus usual care, demonstrating significant cost-effectiveness [28].

Based on STROKESTOP results, US cost-effectiveness modeling for 75-76 year-olds using handheld devices twice daily for two weeks showed an ICER of \$47,949/QALY, superior to single 12-lead ECG screening (\$58,728/QALY). Both were cost-effective at a \$100,000/QALY willingness-to-pay threshold [29].

CHEN et al. [30] simulated US populations 65, finding systematic AF screening using wearable devices cost-effective. The preferred strategy used PPG-based wristbands for initial screening followed by cECG patch confirmation, with ICER of \$57,894/QALY.

ANDRADE et al. [31] estimated Canadian opportunistic screening cost-effectiveness using AliveCor KardiaMobile in \$ \$65 year-olds, showing overwhelming cost-effectiveness with ICER reduced by ~1,100 CAD/QALY versus no screening.

## 5 Future Challenges

Wearable/mobile devices and mHealth solutions have achieved remarkable progress in AF screening and management, particularly demonstrating unique advantages in systematic silent AF screening to promote early standardized care. However, controversies remain regarding clinical outcome improvements, and widespread healthcare system implementation faces multiple challenges.

### 5.1 Limited Effectiveness Evidence for Opportunistic Screening Using Wearable Devices

Current international and Chinese guidelines recommend opportunistic screening for silent AF in \$ \$65 year-olds. However, clinical studies on wearable device effectiveness remain insufficient, preventing specific device recommendations, though their potential is recognized.

**Screening protocol issues:** Three major RCTs on opportunistic AF screening [16-18] used handheld intermittent ECG devices for single 30-second recordings in general practice patients \$ \$65, failing to achieve statistically significant detection improvements over usual care. Given silent AF' s intermittent nature, many cases are missed during brief 30-second recordings [13].

*Optimization approach:* Improve opportunistic screening protocols by increasing cumulative monitoring duration through more frequent, repeated testing.

**RCT design issues:** In reported opportunistic screening RCTs, actual screening completion rates among patients pre-randomized to intervention groups fell far below expectations [16-17], affecting results.

*Optimization approach:* Strengthen health education, enhance privacy protection, improve awareness among primary care providers and patients, and consider randomizing only consenting patients to improve completion rates.

## 5.2 Insufficient Evidence for Clinical Outcome Improvement After Silent Atrial Fibrillation Screening

The Lancet-published STROKESTOP study made important contributions, but the USPSTF identified critical design limitations: while screened AF patients receiving anticoagulation had reduced stroke/embolism rates, they also faced increased bleeding risk. STROKESTOP' s composite endpoint combined beneficial and harmful outcomes (ischemic stroke, hemorrhagic stroke, systemic embolism, hospitalization for bleeding, all-cause mortality), precluding clear conclusions about net health benefits [4].

Furthermore, whether all screen-detected silent AF patients require anticoagulation remains unclear. The Lancet-published LOOP RCT enrolled Danish patients aged 70-90 with stroke risk factors but no prior AF, comparing implantable loop recorder continuous ECG monitoring (n=1,501) to usual care (n=4,503). Despite threefold higher AF detection (HR=3.17, 95%CI: 2.81-3.59, P<0.0001) and higher anticoagulation rates (HR=2.72, 95%CI: 2.41-3.08, P<0.0001), stroke/systemic embolism rates did not differ significantly (HR=0.80, 95%CI: 0.61-1.05, P=0.11). However, the subgroup with poorest blood pressure control showed significantly lower stroke/embolism rates. This suggests not all continuously-detected silent AF patients need anticoagulation, while high-risk subgroups may derive substantial benefit [32]. Though LOOP used implantable rather than wearable devices, findings have important implications. Future studies should separately analyze screening benefits and harms to identify patients with maximal net benefit. Several ongoing RCTs addressing silent AF screening outcomes [4] will provide valuable evidence.

## 5.3 Need for Strengthened Cost-Effectiveness Evidence

Overall, wearable/mobile devices appear cost-effective for AF screening and management. However, beyond STROKESTOP and REHEARSE-AF analyses, other estimates derive from STROKESTOP outcomes or assumed health benefits based on prior studies. More clinical research is needed for validation.

#### 5.4 Need for Further Validation of mHealth-Based Comprehensive Management Strategies

GUO et al.'s [25] mAFA App studies consistently showed significantly lower composite outcomes (ischemic stroke, systemic embolism, death, rehospitalization) in intervention groups. mAFA supports improved anticoagulation adherence, better risk factor control (hypertension, diabetes), and lifestyle management. However, REHEARSE-AF's 2023 long-term results showed that without "ABC" comprehensive management, screened silent AF patients had suboptimal sustained anticoagulation and clinical outcomes, suggesting screening tools alone may not guarantee benefit. The ultimate clinical outcomes of mHealth-supported "ABC" management require independent validation by other research groups.

In summary, China faces a large AF burden that will worsen with population aging. Currently, reliable, targeted silent AF screening and management strategies are lacking. Traditional ECG and pulse palpation have limited effectiveness. While wearable/mobile devices offer advantages, domestic application remains preliminary, particularly regarding long-term outcomes and cost-effectiveness. Future research must explore more efficient, reliable screening protocols based on clinical evidence to achieve comprehensive patient benefits.

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