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Original Article

Clinical consequences of smartwatch implementation in a cardiology outpatient clinic

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ABSTRACT

INTRODUCTION. Long-term cardiac monitoring has become more accessible with the advent of consumer-oriented wearable devices. Smartwatches (SWs) hold promise for extended rhythm monitoring owing to their availability and direct electronic health record (EHR) integration. We studied the clinical consequences of SW implementation in patients with palpitations.

METHODS. Patients referred for palpitations or with inconclusive diagnostics were issued a SW for up to three months. They were instructed to take an SW-electrocardiogram (ECG) during symptoms and transfer it to the EHR. A cardiologist interpreted the ECGs, diagnosed the patient and initiated relevant clinical actions.

RESULTS. We included 50 patients with a median age of 57 years (IQR: 45-64), 56% women. The following ECG diagnoses were made: 20 (40%) had sinus rhythm, six (12%) had extrasystoles and 24 (48%) had clinically relevant arrhythmias. Consequently, 25 (50%) completed their arrhythmia evaluation, whereas clinical actions were taken in 25 (50%). Notably, more than 20% underwent an electrophysiology study and ablation. Patients found the SW to be user-friendly with minimal impact on their daily life.

CONCLUSIONS. SW use for symptom-based diagnosis had a high yield for both arrhythmia detection and completion of arrhythmia evaluation. Additional studies are needed to determine if SWs may replace traditional ECG monitoring.

FUNDING. The project was funded by internal funds at the Department of Cardiology, Herlev and Gentofte University Hospital (HGH), Denmark.

TRIAL REGISTRATION. As a quality assurance project, no ethical board approval was needed under Danish law. The study was approved by the HGH directors.

Long-term monitoring of physiological metrics has become easier with the advent of new wearable devices. This is relevant for the 10% of the population who experience palpitations at least once [1, 2]. Palpitations, the second most common reason for referral to a cardiologist, may impact quality of life and indicate underlying heart conditions [3, 4]. Approximately 40% of cases involving palpitations are attributed to arrhythmias. Traditional electrocardiogram (ECG) methods for detecting arrhythmias are challenging due to their episodic nature, high costs and limited benefits [5].

A common arrhythmia in patients with palpitations is atrial fibrillation (AF), which can cause stroke and heart

failure, making early diagnosis crucial [6-8]. Studies have shown that prolonged heart rhythm monitoring improves AF detection in high-risk populations [9, 10]. Even if no arrhythmia is found, evaluations reassure patients and complete their arrhythmia evaluation [11] .

Recent wearable technologies offer promising potential for long-term monitoring. Using integrated electrodes, smartwatches (SWs) can generate on-demand single-lead (SL) ECGs that can be transferred directly to electronic health records (EHRs) [12]. Unlike 12-lead ECGs and Holter monitors, SWs enable long-term monitoring and availability, and in contrast to implantable loop recorders (ILRs), a SW is non-invasive and reusable. With user-friendly SL-ECG availability and EHR integration, consumer-oriented ECG devices hold potential for a breakthrough in remote arrhythmia detection, adding new possibilities to the clinical workup toolbox and potentially improving patient outcomes.

This study aims to evaluate the clinical consequences of implementing SWs in a cardiology outpatient clinic by 1) describing patient characteristics and work-up indications, 2) investigating clinical SW-ECG diagnoses, 3) examining the consequences of detecting arrhythmias or normal rhythms and 4) assessing patients' experience using the SW.

Methods

Study design and population

This was a quality improvement, single-centre, prospective cohort study conducted at the Department of Cardiology, Herlev and Gentofte University Hospital, Denmark. At the physician's discretion, patients referred for palpitations or those with other inconclusive diagnostic evaluations were considered candidates for SW monitoring for up to three months.

Apple Watch clinical workflow

Patients with an appointment at the Arrhythmia Outpatient Clinic received an Apple Watch (AW) Series 6 and an iPhone SE limited to transferring ECGs to the EHR. They were shown a video, received a ten-minute training session and were given an eight-page manual on recording and sharing AW-ECGs. A test ECG was sent to ensure that the patient was properly trained. AW-ECGs and self-reported symptoms were transferred to the EHR via the Health app on the iPhone, which sent the ECG to the "MinSP" app as a PDF. Patients were instructed to wear the AW continuously for up to three months, charge it regularly and record an ECG during symptoms. Patients were informed that recordings were not evaluated daily and told to contact acute healthcare services in case of severe symptoms.

AW-ECGs were evaluated weekly by a cardiologist specialised in arrhythmias. If a significant arrhythmia was detected, patients were scheduled for a telephone call or in-patient visit; otherwise, they were seen at the planned three-month follow-up. A clinical AW-ECG diagnosis was then made and shared with the patient, and relevant actions were taken. At the follow-up, patients were invited to complete two questionnaires. 1) The System Usability Scale, consisting of ten questions with five response options ranging from strongly disagree to strongly agree, evaluated the AW usability [13]. 2) The Impact Assessment Scale, originally coined the Follow-Up Questionnaire, assessed the impact of AW monitoring on daily life in terms of discomfort, sleep and physical activity. The scale has six questions with response options 1-10, ranging from minimal to maximal [14]. Questionnaires were translated from English to Danish and back to English, adopting a thorough process, and were then emailed to the patients.

Outcomes

The primary outcome was the clinical consequences, categorised as: 1) further ECG evaluations, 2) initiation of new medication (anticoagulants or rate-control therapy), 3) referral for electrophysiology study (EP study) and ablation, 4) clinical re-evaluation in the specialised arrhythmia outpatient clinic and 5) completion of arrhythmia evaluation. Secondary outcomes comprised clinical AW-ECG diagnoses: 1) arrhythmias: AF, atrioventricular nodal reentry tachycardia, supraventricular tachycardia (SVT), ectopic atrial tachycardia, and SVT induced by Wolff-Parkinson-White, 2) extrasystoles: supraventricular extrasystoles (SVES) and ventricular extrasystole and 3) normal sinus rhythm (SR). In addition, patients' experiences with the AW were measured.

Data collection

Patient data were extracted from EHRs. In case of uncertainty regarding outcomes, cardiologists reviewed medical records. After completing the trial, two questionnaires were distributed to the patients.

Statistical analysis

Baseline was defined as the day patients received their AW. Patients were grouped based on clinical consequences and AW-ECG diagnosis. Means and medians were calculated. Questionnaire responses were categorised by age, and descriptive statistics were performed.

Ethics

This quality assurance project was approved by the Herlev and Gentofte University Hospital directors; hence, no ethical board approval was necessary. Patients opting out of qualitative projects were excluded. Under Danish law, CSP was internally funded, and all data were anonymised in a REDCap database.

Trial registration: As a quality assurance project, no ethical board approval was needed. The study was approved by the Herlev and Gentofte University Hospital directors.

Results

Population selection

From 2021 to 2024, 64 patients received an AW and 14 were excluded: eight did not use the ECG function due to a lack of symptoms, five due to missing data in EHRs for AW-ECG diagnoses and consequences, and one declined participation in qualitative projects. Ultimately, 50 patients completed the study.

Baseline characteristics

Among the 50 patients, 28 (56%) were women, and the median age was 57 (IQR: 45-64) years. The most prevalent comorbidities were AF/atrial flutter (30%). Overall, 31 (62%) patients had prior arrhythmia diagnostics with either a Holter, event recording or loop recording. Baseline characteristics are summarised in **Table 1**.

TABLE 1 Characteristics of the study population at baseline (N = 50).

Sex, n (%)	
Women	28 (56)
Men	22 (44)
Age, median (IQR), yrs	57 (45-64)
BMI, median (IQR), kg/m²	24.4 (22-26)
Indications for AW, n (%)	
Arrhythmia diagnostics due to symptoms	48 (96)
Heart rate monitoring	2 (4)
Comorbidities, n (%)	
Atrial fibrilation/atrial flutter	15 (30)
Heart failure	1 (2)
Ischaemic heart disease	4 (8)
Diabetes	2 (4)
Metabolic disorders	3 (6)
Hypertension	4 (8)
Stroke	1 (2)
Sleep apnoea	1 (2)
Medication, n (%)	
Anticoagulant treatment	9 (18)
Platelet inhibitors	5 (10)
Antiarrhythmic drugs	2 (4)
β blockers	16 (32)
Non-dihydropyridine calcium channel blocker	4 (8)
Antidiabetic drugs	1 (2)
Methabolic therapy	2 (4)
Previous examinations/procedures, n (%)	
Holter monitoring	22 (44)
R-test/event recorder	16 (32)
Loop recorder	1 (2)
Any previous arrhythmia diagnostics[a]	31 (62)
Ablation	7 (14)
Pacemaker	0
Echocardiography	29 (58)
DC conversion	3 (6)
Electrophysiology study	0

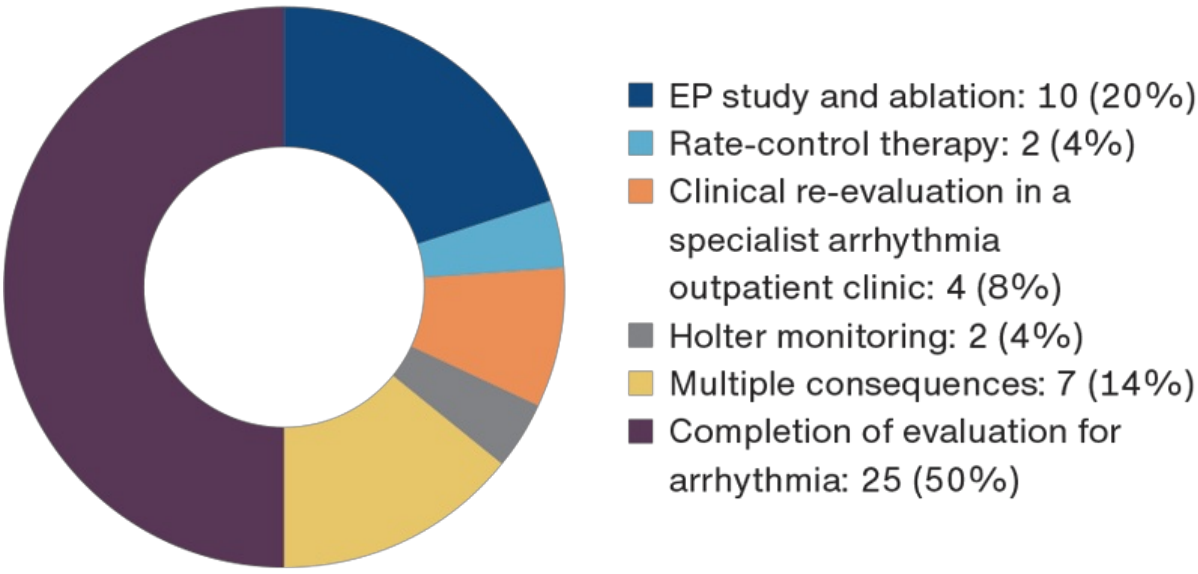
AW = Apple Watch.
a) Patients who have previously undergone evaluation with either Holter, event or loop recording.

Clinical consequences

For 25 (50%) patients, the clinical AW-ECG diagnosis concluded arrhythmia evaluation due to symptoms not correlating with significant arrhythmias or extrasystoles. Among these, 15 (60%) had palpitations during AW-ECG recordings, two (8%) had shortness of breath, one (4%) had chest pain, one (4%) felt dizzy and three (12%) had multiple symptoms (one experienced palpitations and chest pain, another had palpitations, chest pain and dizziness, while the third reported palpitations, chest pain and hot flashes). Among the 25 patients with completed arrhythmia evaluation, 19 (76%) had SR as AW-ECG diagnosis, four had SVES (16%), one had SVT (4%) and one had AF (4%). The second most common consequence was referral to an EP study and ablation, which

occurred in ten (20%) patients as the only consequence. Finally, seven patients (14%) had multiple consequences, detailed in the figure legend (**Figure 1**). At baseline, 15 (30%) patients already had a diagnosis of AF or atrial flutter. Most were given AWs to document arrhythmias or correlate known or newly emerged symptoms with arrhythmias before treatment.

FIGURE 1 The clinical consequences of Apple Watch. Values are counts (%). "Multiple consequences" consists of electrophysiology (EP) study and ablation + anticoagulant treatment (two patients), rate-control therapy + clinical re-evaluation in a specialised arrhythmia outpatient clinic (three patients), rate-control therapy + anticoagulant treatment + clinical re-evaluation in a specialised arrhythmia outpatient clinic (one patient) and rate-control therapy + Holter monitoring (one patient).



Clinical Apple Watch electrocardiogram diagnoses

The 50 patients collectively sent 499 AW ECGs, with a median of three (IQR: 2-7) per patient. Palpitations were the most common symptom reported (58%). A total of 20 (40%) patients had a normal SR, 24 (48%) had an arrhythmia and six (12%) had extrasystoles. AF was the most frequent clinical AW-ECG arrhythmia diagnosis, identified in 12 (24%) patients, with a median time to AF diagnosis of 18 days (IQR: 6-36). Among these, nine (18%) were newly diagnosed with AF. Among the 20 patients solely detected with SR, 19 (95%) completed their arrhythmia evaluation (**Table 2**).

TABLE 2 Demographic and clinical characteristics of the study population categorised by clinical Apple Watch-electrocardiogram diagnosis.

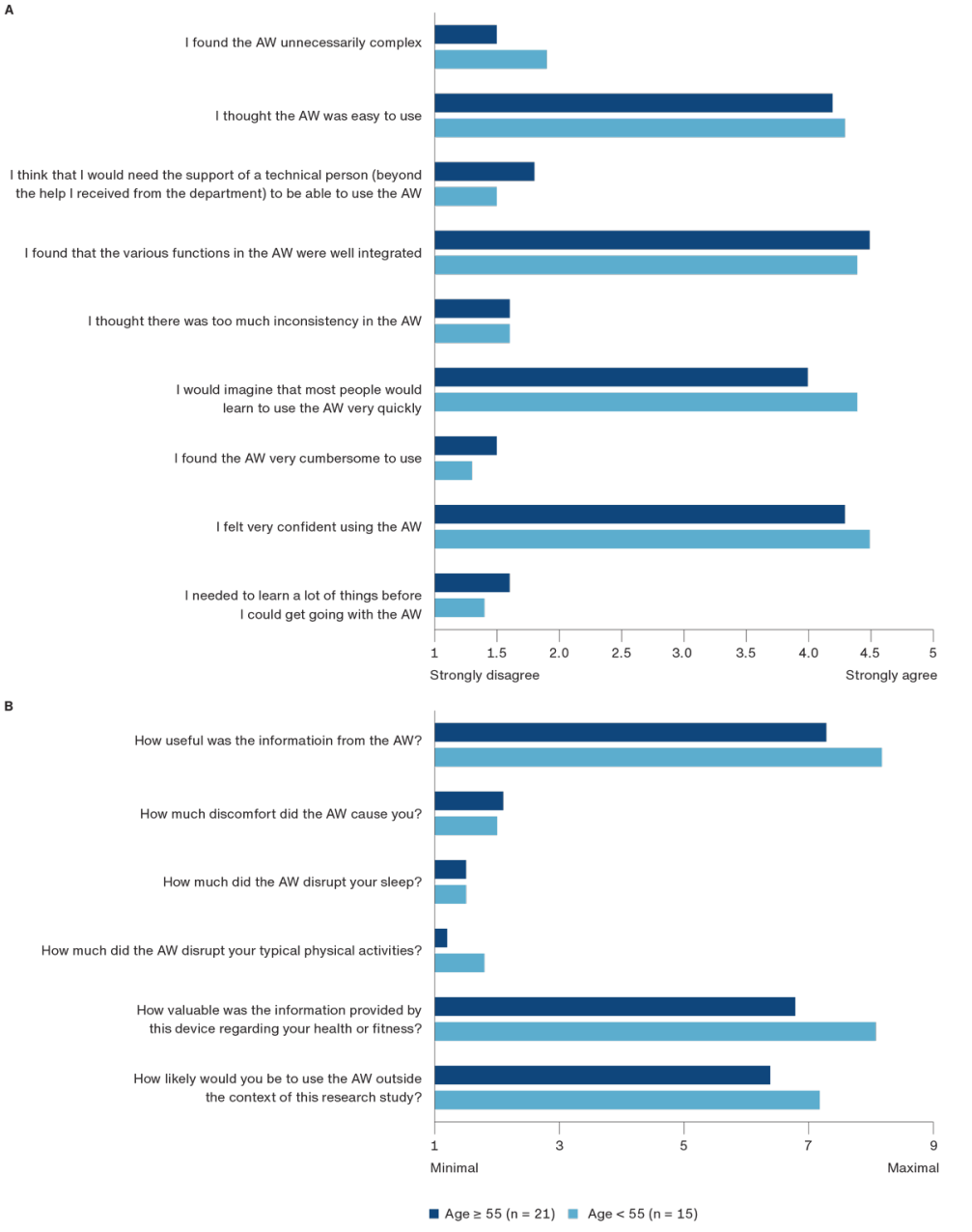
	AW-ECG diagnosis								
	AF (n = 12 (24%))	AVNRT (n = 5 (10%))	SVT (n = 2 (4%))	EAT (n = 2 (4%))	WPW (n = 1 (2%))	SVES (n = 5 (10%))	multiple diagnoses[a] (n = 3 (6%))	SR (n = 20 (40%))	Total (N = 50 (100%))
Sex, n (%)									
Women	4 (33.3)	2 (40)	0	1 (50)	1 (100)	5 (100)	1 (33.3)	14 (70)	28 (56)
Men	8 (66.7)	3 (60)	2 (100)	1 (50)	0	0	2 (66.7)	6 (30)	22 (44)
Age, median (IQR), yrs	57 (54-67)	45 (44-61)	49.5 (46-53)	25.5 (23-28)	59	60 (42-63)	66 (66-70)	57.5 (44-61)	57 (45-64)
Indications for AW, n (%)									
Arrhythmia diagnostics due to symptoms	10 (83.3)	5 (100)	2 (100)	2 (100)	1 (100)	5 (100)	3 (100)	20 (100)	48 (96)
Heart rate monitoring	2 (16.7)	0	0	0	0	0	0	0	2 (4)
Time to diagnosis[b], median (IQR), days	18 (6-36)	24 (16-38)	67 (41-93)	44 (24-64)	215	97 (95-97)	66 (66-70)	104 (91-133)	73.5 (21-99.5)
Symptoms[c], n (%)									
Palpitations	7 (58.3)	4 (80)	1 (50)	1 (50)	0	4 (80)	1 (33.3)	11 (55)	29 (58)
Dizziness	0	0	0	0	0	0	0	1 (5)	1 (2)
Shortness of breath	2 (16.7)	0	0	0	0	0	1 (33.3)	2 (10)	5 (10)
Chest pain	0	0	0	0	0	0	1 (33.3)	1 (5)	2 (4)
Multiple symptoms	3 (25)	1 (20)	1 (50)	1 (50)	1 (100)	0	0	3 (15)	10 (20)
Unknown	0	0	0	0	0	1 (20)	0	2 (10)	3 (6)
Consequences, n (%)									
EP study and ablation	5 (41.7)	3 (60)	1 (50)	0	1 (100)	0	0	0	10 (20)
Rate-control therapy	1 (8.3)	0	0	0	0	0	1 (33.3)	0	2 (4)
Clinical re-evaluation in a specialized arrhythmia outpatient clinic	2 (16.7)	1 (20)	0	0	0	1 (20)	0	0	4 (8)
Holter monitoring	0	0	0	0	0	0	1 (33.3)	1 (5)	2 (4)
EP study and ablation + anticoagulant treatment	2 (16.7)	0	0	0	0	0	0	0	2 (4)
Rate-control therapy + clinical re-evaluation in a specialised arrhythmia outpatient clinic	0	1 (20)	0	2 (100)	0	0	0	0	3 (6)
Rate-control therapy + anticoagulant treatment + clinical re-evaluation in a specialised arrhythmia outpatient clinic	1 (8.3)	0	0	0	0	0	0	0	1 (2)
Rate-control therapy + Holter	0	0	0	0	0	0	1 (33.3)	0	1 (2)
Completion of evaluation for arrhythmia	1 (8.3)	0	1 (50)	0	0	4 (80)	0	19 (95)	25 (50)
Medication[d], n (%)									
Anticoagulant treatment	3 (25)	0	0	0	0	0	0	0	3 (6)
β blockers	2 (16.7)	1 (20)	0	1 (50)	0	0	1 (33.3)	0	5 (10)
Non-dihydropyridine calcium channel blocker	0	0	0	1 (50)	0	0	1 (33.3)	0	2 (4)

AF = atrial fibrillation; AVNRT = atrioventricular nodal reentry tachycardia; AW = Apple Watch; EAT = ectopic atrial tachycardia; ECG = electrocardiogram; EP = electrophysiology; SR = sinus rhythm; SVES = supraventricular extrasystole; SVT = supraventricular tachycardia; VES = ventricular extrasystole; WPW = Wolff-Parkinson-White.
a) Consists of SVT + VES, SVES + VES, and EAT + SVES.
b) Indicates the number of days from when the patient received the AW to the clinician gave a clinical AW-ECG diagnosis.
c) Indicate the experienced symptoms at the time of the AW-ECG recording.
d) Indicates the pharmaceutical treatment initiated following the AW-ECG.

Questionnaires

A total of 36 (72%) patients completed the questionnaires. Answers with mean values are shown in **Figure 2.** Patients reported wearing the AW for an average of 17 hours daily (IQR: 15-23). Overall, patients found that the AW was user-friendly. The AW had minimal impact on daily life in terms of discomfort, sleep and physical activity. Responses did not differ between patients over or under 55 years of age.

FIGURE 2 The System Usability Scale (SUS) (**A**) and the Impact Assessment Scale (IAS) (**B**) categorised by age ≥ 55 and < 55 years. Values are presented as means. In SUS, the scale ranges from 1 (strongly disagree) to 5 (strongly agree). In the IAS, the scale ranges from 1 (minimal) to 10 (maximal). The question/statement "I think I would like to use the Apple Watch (AW) frequently" from the original SUS was omitted due to its lack of relevance in this study (N = 36).



Discussion

Our findings show that clinical actions were taken in every second patient. Notably, more than 20% underwent EP study and ablation. This may seem like a high proportion, but this is likely due to patient selection by experienced arrhythmologists. Nine (18%) patients were first-time diagnosed with AF. Importantly, 50% completed their arrhythmia evaluation.

The AW is a potential alternative to continuous monitoring, e.g. using a Holter. Extended monitoring is crucial for detecting paroxysmal arrhythmias; in one study, 72-hour monitoring of AF patients significantly improved

AF detection [15]. Compared to a study using a seven-day Holter on a population similar to ours without known AF, our study found new AF in 18% of patients versus 9% in their study [16], indicating that prolonged AW monitoring better detects paroxysmal arrhythmias. Our median monitoring period was 2.5 months, but longer durations may potentially be more beneficial. A study found higher AF detection rates with increasing monitoring durations up to 18 months, using insertable cardiac monitors [10].

AWs have been used in arrhythmia studies before. In the Apple Heart Study, non-selected individuals were screened for AF using photoplethysmography [17]. Irregular pulse notifications led to ECG monitoring, detecting AF in < 0.2% of the population. This shows that AWs yield higher detection rates in symptomatic patients, reducing unnecessary evaluations in healthy individuals and minimising anxiety and resource use, as argued by Mandrola et al. [18]. Furthermore, the LOOP Study found that AF screening and subsequent anticoagulant treatment did not significantly reduce stroke risk [19]. Both studies highlight the benefits of clinician-guided indications over broad population screening. As technology advances and the use of AWs increases, this approach is crucial to avoid overwhelming healthcare providers while preventing overdiagnosis and overtreatment.

A study found that external loop recorders detected arrhythmias in 39% of patients with unexplained palpitations, compared to 17% with conventional methods at a cost of 375 € versus 5,185 € per diagnosis, respectively [20]. Thus, non-invasive monitors offer potential cost savings. An AW set costs around 1,000 € and is reusable, potentially offering savings. Detecting previously undiagnosed arrhythmias allows for prompt treatment, reducing complications and improving quality of life. Wearing an AW for months comes with the convenience of capturing an ECG during symptoms, enabling a more confident confirmation of arrhythmia absence. This allows for confident discharge of healthy patients, avoiding the allocation of resources to unnecessary evaluations and providing reassurance to patients that their symptoms are not arrhythmia-related. However, 22% of our patients were referred for further evaluations, which may lead to additional costs in some cases. This project focused on SW evaluation of monosymptomatic palpitations only, with the agreement of the involved physicians. Fifty per cent completed the evaluation without further work-up. Future studies should investigate safety concerns, such as a final diagnosis of coronary heart disease or heart failure, if applied to broader populations. In our study, the median number of ECGs sent was three, totalling 1.5 minutes of recording time. In contrast, a study reported a median recording time of 128 hours with a Holter, leading to more material to review and therefore higher costs [17]. The benefit of using a cardiologist is the accurate diagnosis with an ECG and symptoms. However, receiving multiple ECGs from some patients increases the time spent per diagnosis, reducing the benefit of our approach.

Study limitations

The generalisability of our study was limited by including patients from only one hospital and lacking information on those referred for AW monitoring who did not ultimately receive one, potentially introducing selection bias. Administering questionnaires over two years after the first AWs were issued may also have introduced recall bias. The small population size complicates drawing conclusions when comparing subgroups like patients with different AW-ECG diagnoses.

Clinical implications

Our study illustrates the use of consumer-oriented ECG devices for remote arrhythmia detection. AW-ECGs integrated into existing EHRs and interpretation by cardiologists ensure a streamlined clinical workflow. The AW-ECGs are interpreted clinically by cardiologists, meaning that diagnoses and consequences rely on an overall assessment. AW's advantage over a Holter lies in longer wearing time, improving ECG capture during symptoms. This aids in diagnosing previously undetected arrhythmias and facilitates confident discharge of

healthy patients, avoiding unnecessary evaluations. Compared with ILRs, AW is a non-invasive, reusable and cost-saving alternative, which is well-received by patients owing to its usability and limited impact on daily life.

Conclusions

Our study found that AW monitoring led to clinical actions in 50% of cases, with more than 20% undergoing EP study and ablation, whereas 50% completed their arrhythmia evaluation. The AW detected arrhythmias in 48%, including first-time AF in 18%. The AW's extended wearability enhances arrhythmia detection and confirmation of their absence compared to conventional ECG methods, to the benefit of patients and the healthcare system alike. Our study highlights consumer-oriented SL-ECG devices' potential for remote arrhythmia detection, offering a user-friendly, non-invasive, accessible and cost-effective alternative to traditional monitoring.

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