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Accuracy of the Apple Watch in Detecting Atrial Fibrillation Among Patients Undergoing 24-Hour Holter Monitoring: A Prospective, Pragmatic Study

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The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

The authors declare that attempt to ask permission from Apple to conduct the study was tried, but there was no reply received. An inquiry was done to an author of a published article, which also assessed the accuracy of the Apple Watch, and the reply was that no approval from Apple was needed prior to conduct of their study.

The authors declare that this study was approved by the institutional ethics and review board of the hospital prior to the conduct of the study.

Abstract

BACKGROUND: As smartwatches with atrial fibrillation detection features gain popularity, it is important to assess the accuracy of these devices to guide decision-making.

OBJECTIVES: Our study aimed to assess the sensitivity and specificity of the irregular rhythm notification and the electrocardiogram (ECG)–based detection features of a commonly used smart wearable device (Apple Watch) in detecting atrial fibrillation.

METHODS: This was a prospective, pragmatic study conducted in Perpetual Succour Hospital–Cebu Heart Institute from August 2023 to January 2024. To assess the irregular rhythm notification feature, participants were asked to wear an Apple Watch alongside a 24-hour Holter monitor to verify notifications. For the ECG-based detection feature, participants had to tap the crown of the Apple Watch for 30 seconds to get a single-lead ECG similar to a lead I ECG tracing. They were instructed to get manual ECGs hourly, or more often while awake. Irregular rhythm notifications and ECG readings were then compared with that of the 24-hour Holter monitor. Sensitivity and specificity were then computed.

RESULTS: A total of 140 participants consented to join after full study disclosure. The irregular rhythm notification feature of the Apple Watch exhibited a low sensitivity of 21.4% but achieved a high specificity of 100% in detecting atrial fibrillation. Meanwhile, the ECG-based detection feature, analyzed from 1295 manually taken ECGs with interpretable sinus rhythm or atrial fibrillation, demonstrated a high level of agreement with the Holter monitor, with a sensitivity of 100% and a specificity of 99.1%.

CONCLUSION: The low sensitivity of the irregular rhythm notification feature of the Apple Watch in detecting atrial fibrillation cautions against relying on it as a primary screening tool. However, the high concordance of manually taken Apple Watch ECGs positions the device as a robust tool for detecting atrial fibrillation through manual ECG detection.

KEYWORDS: Apple Watch, atrial fibrillation, smartwatches

INTRODUCTION

Background of the Study

Atrial fibrillation (AFib) stands as the most prevalent cardiac arrhythmia globally, constituting a significant health concern responsible for 15% to 25% of strokes.[1,2,3] Its impact extends to substantial morbidity and mortality, elevating the risk of heart failure, major cardiovascular events, sudden cardiac death, chronic kidney disease, peripheral arterial disease, and all-cause mortality.[4,5] The criterion standard for AFib detection remains the 12-lead electrocardiogram.[6] However, detecting AFib proves challenging, given its often asymptomatic or paroxysmal nature, making a standard 12-lead ECG less accessible at its onset. Occasionally, a 24-hour Holter monitor is necessary to confirm paroxysmal AFib, but this, too, faces accessibility challenges and is cumbersome, hence the imperative to innovate new technologies for early AFib detection to mitigate associated morbidity and mortality.

Wearable devices, such as smartwatches, offer an innovative approach to screen for silent AFib within the general population.[2] These medical devices seamlessly integrate into daily life, opening avenues for real-time monitoring of personal health metrics, including cardiovascular measures.[3,7] Apple Inc (Cupertino, California) has introduced a groundbreaking feature on the Apple Watch, providing users with access to two optional features for detecting irregular heart rhythms: the irregular rhythm notification feature (available on Apple Watch Series 1 and later) and the ECG-based app, capable of AFib detection through a single-lead ECG (available on Apple Watch Series 4, Series 5, and Series 6).[8]

With the rising popularity of direct-to-consumer wearable devices in the general population, especially among patients seeking medical attention for irregular heart rate (HR) notifications and AFib detection, it becomes crucial to assess the reliability of these devices and their features for assisting in AFib diagnosis. Despite clinical validity studies confirming the performance of the Apple Watch in detecting AFib, further exploration is needed to understand its utility in real-world scenarios. The irregular rhythm notification feature of the Apple Watch has undergone testing in both the general population and among cardiac surgery patients, revealing a low sensitivity rate in both groups.[9-14] Notably, these assessments did not involve real-time comparison with e-patch or telemetry readings, potentially impacting the accuracy of arrhythmia detection.

This study aimed to determine the accuracy of the two optional features of the Apple Watch in detecting AFib among patients undergoing 24-hour Holter monitoring in a tertiary care hospital in Cebu City, Philippines. Our study stands out for its unique approach, as it will directly compare real-time ECGs, leveraging timestamps reflected on notifications and aligning with the 24-hour Holter monitor. This methodological distinction allows for a more accurate assessment of arrhythmias during their occurrence, enhancing the reliability of our findings. Meanwhile, the ECG-based detection feature of the Apple Watch demonstrates higher sensitivity and specificity compared with the irregular notification feature. Unlike clinical validation studies, our research mirrors real-world scenarios or pragmatic nature, akin to standard 24-hour Holter monitoring procedures, thus presenting a methodologically distinct approach.

METHODOLOGY

Research Design

This study used a prospective, pragmatic approach, aimed at evaluating the real-life effectiveness of the Apple Watch. Pragmatic studies assess interventions in authentic, everyday settings, mirroring the conditions in which they are typically utilized. In our research, we assessed the accuracy of the Apple Watch in a manner consistent with its real-world usage by individuals in their daily lives, ensuring the findings reflect practical scenarios encountered by Apple Watch users.

Research Locale

This study was conducted in Perpetual Succour Hospital–Cebu Heart Institute, a tertiary care hospital owned and operated by the Sisters of St Paul of Chartres. The Perpetual Succour Hospital–Cebu Heart Institute is a Catholic, private, not-for-profit, nonstock corporation, categorized as a level III general training and education health care facility, with a capacity of 372 beds. Equipped with a state-of-the-art cardiovascular laboratory, the hospital provides comprehensive care to its patients, including 24-hour Holter monitoring services. On average, the cardiovascular laboratory serves 40 to 50 patients per month for 24-hour Holter monitoring, demonstrating its commitment to delivering high-quality cardiovascular care to the community.

Research Participants

All patients who were ordered with a 24-Hour Holter monitoring from August 1, 2023, to January 31, 2024, were asked to participate in the study after full disclosure and informed consent. The following were the inclusion and exclusion criteria:

Inclusion Criteria

- Twenty-two years and older with a request for 24-hour Holter monitoring
- Able to comprehend the nature of the study and give consent to participate
- Able to follow instructions after careful evaluation by the researcher

Exclusion Criteria

- Presence of physical disabilities that will prohibit patients from taking their ECG using the Apple Watch, such as paralysis
- Patients with pacemakers with paced rhythms and intracardiac defibrillators

Sample Size

Using Open Epi 3, the computed sample size was a minimum of 139 participants with 95% CI.

Sampling Design
Patients were selected through convenience sampling. Convenience sampling is a nonprobability sampling technique where subjects are selected based on their easy accessibility and proximity to the researcher.

Research Instruments
A researcher-made data-gathering tool was devised to get the data on the demographic profile and medical history of the participants (Appendix D).

Data Gathering Procedure
Before the actual data gathering, the researchers sought approval from the section of adult cardiology and the hospital administration. Ethical approval of the study was secured from the institutional review board of the hospital.

During the actual data gathering, patients with indications to undergo 24-hour Holter monitoring in the cardiovascular laboratory were invited to participate in the study. After complete disclosure of the study details, signed informed consent was obtained. If the patient had an accompanying relative, the relative also received an explanation to assist the patient in using the Apple ECG. Instructions on operating the Apple Watch to obtain an ECG were provided to the patients.

Once the Holter monitor (BTL) was attached, the Apple Watch was worn on the patient's left hand. The Apple Watch ECGs used were Apple Watch Series 6 and Apple Watch Series 8, which were the devices available from the researchers. The Apple ECG feature version 2.0 (updated version 2.2OU73), released in 2023, was used for the Apple Watch. The initial ECG was taken by the patient under the researcher's supervision to ensure proper understanding. Patients were advised to sit properly, with their left hand resting comfortably, placing their index finger on the Apple Watch crown. Although clicking the crown was not necessary, it could be done to steady the hands on the crown. After 30 seconds, the patient pressed "Done," and the ECG file was sent to the Health app on the iPhone.

After the initial ECG, patients were instructed to take one ECG every hour or more frequently while awake throughout the entire 24 hours. In addition, patients were advised to record an ECG if they experienced symptoms suggestive of AFib, such as palpitations, irregular heartbeat, or dizziness. They were also instructed to capture an ECG if a rhythm notification appeared on the Watch.

Patients were equipped with a diary to document activities and report symptoms during the 24-Hour Holter monitoring. In addition, they were instructed to wear the Apple Watch continuously for the entire 24-hour period. Clear guidance was given regarding when to return for the removal of both the Holter monitor and Apple Watch. After the designated time frame, patients returned to the cardiovascular laboratory for the removal of the Holter monitor and Apple Watch. Subsequently, the researchers synchronized the ECG with the Health app on the iPhone and exported the PDF of the ECG for printing. The corresponding ECG from the Holter monitor, matched accurately to the time the patient took their ECG, was also printed.

Two independent authors (K.T.K. and A.T.J.) were tasked with reading the ECG based on the Apple Watch and the ECGs from the Holter monitor. They checked for concordance using the result notification format of the Apple Watch, categorizing it as either SR, low/high HR, AFib, inconclusive, or poor recording. A third author (M.G.O.C.) served as an arbiter in case of any discordance in the readings between the two authors.

Statistical Tools
Descriptive analyses of the demographic and clinical characteristics of the participants were determined using frequency and percentage for categorical variables. The continuous data were described using mean. The sensitivity and specificity were computed using the MedCalc diagnostic calculator. SPSS software version 20 (IBM Corp, Armonk, New York) was used in the analysis.

RESULTS, DISCUSSION, CONCLUSION, AND RECOMMENDATIONS

Results
Profile of the Respondents
The study enrolled a total of 140 participants, including both inpatients and outpatients, prescribed with a 24-hour Holter monitor by their attending physicians. Table 1 outlines the demographic characteristics of the study population. The mean age of the participants was 54.7 years, with the majority being male (n = 83 [59.3%]), and 40.7% (n = 57) were females. Hypertension (n = 80 [57.1%]), diabetes mellitus (n = 34 [24.3%]), and prior cardiac surgeries due to coronary artery disease or arrhythmias (n = 25 [17.9%]) emerged as the most prevalent comorbidities. Many patients were on maintenance medications such as statins, antiplatelets, antihypertensive drugs, and antidiabetic drugs. The primary reason for ordering a 24-hour Holter monitor was the presence of symptoms, with palpitation (n = 59 [42.1%]) being the most common indication, followed by irregular rhythm (n = 15 [10.7%]) on physical examination, syncope/near-syncope (n = 12 [8.6%]), shortness of breath (n = 11 [7.9%]), chest pain (n = 10 [7.1%]), and screening for AFib due to stroke (n = 9 [6.4%]).

Sensitivity and Specificity of the Irregular Notification Feature of the Apple Watch in Detecting AFib
The irregular rhythm notification feature of the Apple Watch demonstrated low sensitivity of 21.4% but with a high specificity of 100% in detecting AFib (Table 2). Among the 140 participants, 14 participants (10%) had AFib based on the 24-hour Holter monitor readings. However, only 3 of the 14 participants received an irregular rhythm notification. It missed detecting AFib in 11 participants with short episodes of paroxysmal AFib. The longest duration of AFib in the Holter monitor was 4 minutes but was not captured by the Apple

Table 1. Profile of the Participants (n = 140)

Profile	f	**%**
Age, mean (SD), y	54.7	
Gender		
Male	83	59.3
Female	57	40.7
Comorbidities		
Hypertension	80	57.1
Diabetes mellitus	34	24.3
Prior cardiac surgeries or procedures	25	17.9
Present stroke	9	6.4
Thyroid disorders	6	4.3
Valvular heart disease	4	2.9
Chronic kidney disease	2	1.4
Medications taken		
Statin	52	37.1
Antiplatelet	46	32.9
β-Blockers	47	33.6
ACEI/ARB	42	30.0
CCB	22	15.7
Amiodarone	12	8.6
NOACs	14	10.0
Metformin	16	11.4
DDP4 inhibitors	13	9.3
Insulin	5	3.6
SGLT2 inhibitors	9	6.4
Prior valve surgery	2	1.4
Reason for getting a 24-Apple ECG Holter monitor		
Part of an annual physical examination	6	4.3
Presence of any of these symptoms		
Palpitation	59	42.1
Shortness of breath	11	7.9
Stroke	9	6.4
Irregular rhythm	15	10.7
Syncope/near-syncope	12	8.6
Chest pain	10	7.1
Dizziness	8	5.7
Bradycardia	6	4.3
Others (hypotension, seizure)	3	2.1

Abbreviations: ACEI/ARB, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker; CCB, calcium-channel blocker; ECG, electrocardiogram; NOAC, novel oral anticoagulant.

Table 2. Sensitivity and Specificity of the Irregular Rhythm Notification Feature of the Apple Watch in Detecting Atrial Fibrillation When Compared With the 24-Hour Holter Monitor

Apple Watch	24-h Holter Monitor		Sensitivity	Specificity
	Atrial Fibrillation	No Atrial Fibrillation		
Irregular rhythm notifications	3	0	21.4%	100%
No irregular rhythm notifications	11	126		

Table 3. Sensitivity and Specificity of the ECG-Based Detection Feature of the Apple Watch in Detecting Atrial Fibrillation When Compared With the 24-Hour Holter Monitor

Apple Watch	24-h Holter Monitor		Sensitivity	Specificity
	Atrial Fibrillation	No Atrial Fibrillation		
Atrial fibrillation	140	11	100%	99.1%
No atrial fibrillation	0	1144		

Watch. This was probably because the device collects and analyzes tachograms only if the user remains still enough to obtain a reading. The algorithm was not always monitoring the user, but rather is doing so opportunistically when adequate signal was available for collection and analysis.[8] The findings of this study reflected that of Seshadri et al[11] and the Apple Heart study, which also reported a low sensitivity of 41% and 34%, respectively, in detecting AFib.

Sensitivity and Specificity of the ECG-Based Detection Feature of the Apple Watch in Detecting AFib

Among 1660 Apple Watch ECGs, 1295 were interpretable as SR (n = 1144 [69%]) and AFib (n = 151 [12%]). One hundred thirty-two (8%) were inconclusive readings, 88 (5.3%) were poor recordings, 41 (2.5%) were high rates, and 104 (6.3%) were low HRs. The Apple Watch incorrectly interpreted 11 ECGs as AFib when they were actually in SR (Table 3). Among the common observations of getting a false-positive AFib reading were the presence of frequent premature beats and inability to be still when getting the ECG. Moreover, there was notable concordance in readings other than SR or AFib. The ECG-based detection feature has a high sensitivity and specificity of 100% and specificity of 99.1%, respectively. These findings were consistent with the high accuracy of the ECG-based detection feature in the Clinical Validation Study 2.0, where its sensitivity was estimated to be 98.5% and specificity was 99.3%. Rhythms presenting with frequent premature atrial complexes and premature ventricular complexes were often categorized as inconclusive.

Discussion

The Apple Watch's irregular rhythm notification feature, with its sensitivity at 21.4%, presents a notable limitation in its ability to reliably detect AFib. A low sensitivity implies that a substantial proportion of cases may go unnoticed, which could hinder its effectiveness as a primary screening tool for this cardiac arrhythmia. However, the high specificity of 100% suggests that when the notification feature does identify irregularities, it does so with a high degree of accuracy, reducing the risk of false positives. This trade-off between sensitivity and specificity underscores the importance of using the Apple Watch in conjunction with other diagnostic methods for a comprehensive evaluation.

Meanwhile, the ECG-based detection feature tell a different story as it demonstrated impressive sensitivity and specificity figures of 100% and 99%, respectively. This performance indicates a high level of accuracy in identifying both the presence and absence of AFib. The high concordance with the Holter monitor readings further emphasizes the reliability of the Apple Watch when users intentionally capture ECG data. The user-initiated ECGs emerge as a valuable component, providing users with a tool that not only detects AFib effectively but also aligns closely with established diagnostic methods.

Although the irregular rhythm notification feature may serve as an automatic surveillance mechanism, the user-initiated ECGs become pivotal for those actively participating in their cardiac health management. This duality in the Apple Watch's functionality suggests that its role in AFib detection depends significantly on user engagement and intent. Understanding these nuanced aspects can guide both users and health care professionals in optimizing the use of Apple Watch features based on individual needs, promoting a more personalized and effective approach to cardiac monitoring.

Conclusion

The irregular rhythm notification of the Apple Watch has a low sensitivity but has a high specificity for detecting AFib. Meanwhile, the ECG-based detection feature has high sensitivity and specificity for detecting AFib.

Recommendations

The following are the recommendations of this study:

Caution in Sole Reliance: Relying solely on the irregular rhythm notification feature of the Apple Watch for detecting AFib is advised due to its observed low sensitivity of 21.4%. This feature, although valuable, should not be the exclusive diagnostic tool for ruling out AFib, especially in symptomatic patients.

Enhanced User Education: Health care providers should focus on educating Apple Watch users about the limitations of the irregular notification feature and the potential benefits of actively engaging in user-initiated ECGs. Increased awareness will empower users to make informed decisions about their cardiac health monitoring.

Integration of Multiple Data Sources: In clinical settings, considering a multifaceted approach to AFib detection is advisable. Integrating data from both automatic irregular notifications and user-initiated ECGs can provide a more comprehensive understanding of a patient's cardiac rhythm, leading to improved diagnostic outcomes.

Continuous Technological Advancements: As wearable technology evolves, continuous advancements in the irregular notification feature should be pursued to enhance its sensitivity. Future updates could potentially address the observed limitations, making it a more reliable tool for automatic detection of AFib in diverse patient populations.

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