TITLE: Real-time Smartphone Alerts During Atrial Fibrillation Episodes with Implantable Cardiac Monitors and Wearable Devices: SMART-ALERT study

SHORT-TITLE: SMART-ALERT study

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Funding: The study was funded by a Heart Research UK Novel and Emerging Technology Grant (RG2689/20/22) and the Oxford Hospital Charity (2020/1352). AB is supported by the Royal Society University Research Fellowship (Grant No. URF\R1\221314).

Conflict of Interest: ABG, AJS, MTBP, ML, RV, AB, and TRB have no CI for this study. NC reports grant funding from Haemonetics, HeartFlow, Boston Scientific & beckman Coulter; speaker fees/consultancy from Abbott, HeartFlow, Edwards.

Acknowledgements: We thank Mrs. Trudie Lobban MBE, founder and president of the Atrial Fibrillation Association, for her advice during the design of this study. Her input on patient perspectives helped guide our research approach and methodology

Authorship: All authors have made substantial contributions to the conception, design, data acquisition, analysis, or interpretation of the work. All authors participated in drafting or critically revising the manuscript and have given final approval.

Key words: Anticoagulation; Apple Watch; Atrial Fibrillation; CART Ring; Wearable Devices.

Word Count: 6000

ABBREVIATIONS

AF – Atrial Fibrillation

DNR – Did Not Reply

DNS – Did Not Send

DOAC – Direct Oral Anticoagulant

ECG – Electrocardiogram

EF – Ejection Fraction

ICM – Implantable Cardiac Monitor

IQR – Interquartile Range

OAC – Oral Anticoagulation

PPG – Photoplethysmography

PPV – Positive Predictive Value

SD – Standard Deviation

SMS – Short Message Service

TIA – Transient Ischaemic Attack

Abstract

Background: Atrial fibrillation (AF) is a major cause of stroke, with dynamic thromboembolic risk during and shortly after episodes. Implantable cardiac monitors (ICMs) and wearable devices have emerged as tools for real-time AF detection, yet their comparative performance in supporting anticoagulation strategies remains underexplored.

Methods: This single-centre feasibility study investigated the performance of real-time AF detection and notification for episodes >30 minutes. Phase 1 evaluated the integration of ICM and bespoke cloud-based software (SMART-ALERT) in sending automated SMS notifications (n=50) for episodes uploaded within 24 hours. Phase 2 evaluated an Apple Watch (n=23) and CART Ring (n=23) detecting and notifying participants of AF episodes. Primary outcome was the successful AF notification rates via (i) SMART-ALERT software and (ii) wearable devices. Secondary outcomes included acknowledgement rates, notification times, and adherence.

Result: Among 4,943 AF episodes detected in 31 participants, the SMART-ALERT software successfully notified 511/691 eligible AF episodes (74%), with a 99.6% acknowledgment. In contrast, wearable devices showed poor notification performance: Apple Watch identified 76/389 episodes (19.5%) and the CART Ring 72/474 (15.1%). This performance difference was partly explained by suboptimal device adherence (Apple Watch: 66.3%; CART Ring: 23.9%), with 24.6% and 55.7% of AF episodes missed due to devices not being worn.

Conclusion: The SMART-ALERT system demonstrated the feasibility of real-time AF detection and automated notifications, achieving a 74% notification success but facing important connectivity challenges. Wearable devices showed poor notification rates (<20%) and adherence, highlighting significant technical barriers for their current use in clinical AF monitoring.

INTRODUCTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, affecting millions worldwide and associated with a five-fold increase in stroke risk.[1,2] Lifelong oral anticoagulation (OAC) is the cornerstone of AF management, reducing stroke risk by two-thirds but at the expense of 5% annual risk of major bleeding. Bleeding complications often impact anticoagulation adherence and overall quality of life.[3-5] International guidelines recommend risk scores, such as the CHA_2DS_2-VASc, to guide anticoagulation decisions, but these do not take into account different AF patterns and burden.[1]

New evidence suggests that thromboembolic stroke risk is dynamic, increasing during and shortly after AF episodes and then decreasing during periods of sinus rhythm.[6, 7] In patients with low stroke risk profiles, brief episodes of AF, lasting minutes to hours, are associated with lower thromboembolic event rates compared to prolonged AF episodes lasting days.[8] This temporal relationship has driven interest in a "pill-in-the-pocket" OAC strategy, which limits anticoagulation only to periods of high thromboembolic risk in patients during AF episodes. This approach could provide comparable stroke prevention to continuous OAC while reducing bleeding risk and healthcare costs.[9] Early studies, such as REACT.COM[10] and TACTIC-AF[11], demonstrated that this approach is feasible in carefully selected patients on continuous rhythm monitoring. However, widespread adoption requires adherence to minimally- or non-invasive, accurate, and scalable monitoring solutions.

There is a significant technological barrier to a "pill-in-the-pocket" anticoagulation strategy: the need for reliable real-time AF detection and prompt patient notifications. Current technologies have limitations. Implantable cardiac monitors (ICMs) offer continuous monitoring with high sensitivity for AF detection but rely on manual adjudication of detected episodes, limiting their scalability. Wearable devices, such as smartwatches and rings, provide accessible near-continuous monitoring, but face challenges with adherence and AF detection accuracy. While both technologies are promising, their ability to support real-time AF detection and automated patient notifications remains uncertain, with limited data on their practical implementation in clinical settings.

The SMART-ALERT study aimed to evaluate two approaches for detecting and notifying patients of AF episodes >30 minutes: (i) an ICM integrated with a bespoke software (SMART-ALERT), and (ii) two wearable devices (Apple Watch and CART ring). There is no consensus on the AF duration threshold that warrants oral anticoagulation, with studies suggesting cutoffs from 5 minutes to 24 hours due to an observed increase in thromboembolic risk.[12] While REACT.COM and TACTIC-AF trials used a 1-hour threshold, we selected 30 minutes as a pragmatic balance — long enough to capture episodes for a robust evaluation of the study devices without generating excessive alerts from shorter, potentially less clinically relevant episodes that could compromise patient engagement.

METHODOLOGY

The SMART-ALERT study was a single-centre, investigator-initiated feasibility study which recruited participants from Oxford University Hospitals between December 2021 and August 2022. Eligible participants included adults (≥18 years old) with paroxysmal AF who experienced frequent episodes, defined as at least one but fewer than 15 episodes per month, or persistent AF requiring recurrent cardioversions. This cohort was selected to ensure sufficient AF episodes to evaluate detection and alerting performance. All participants were required to have an Apple iOS or Android smartphone compatible with the Medtronic MyCareLink app, which enabled communicates with the LINQ II ICM.

We excluded patients with permanent AF, contraindications for an ICM, or visual or physical impairments that would prevent them from interacting with smartphone notifications.

Written informed consent was obtained from all participants prior to enrolment. The SMART-ALERT Study adhered to the principles of the Declaration of Helsinki and CONSORT guidelines. Ethical approval was granted by the Health Research Authority (ref: 294367), and the study was registered on ClinicalTrials.gov (NCT05207150).

Study Design

This feasibility study was designed to be conducted in two sequential phases, with a target follow-up of approximately three months (Figure 1). In Phase 1, all 50 participants had an ICM (LINQ II, Medtronic, Minneapolis, USA) implanted and programmed to detect and record AF episodes lasting longer than 30 minutes. Data from the ICMs were transmitted via Bluetooth to Medtronic MyCareLink smartphone app, which used an internet connection to transfer the episodes to their cloud-based remote monitoring platform (CareLink). This action occurred at least once an hour if the device was within range. Episodes could only be transmitted if the smartphone app was running in the background.

The bespoke SMART-ALERT software system monitored all transmissions in CareLink every five minutes for new episodes. Upon detection, it automatically triggered an SMS notification to participants based on predefined criteria: (i) AF episodes >30 minutes, (ii) first episode within a 24 hours-period, and (iii) episode uploaded to CareLink within 24 hours of its onset (Figure S1).

To prevent excessive notifications, if multiple AF >30 minutes occurred within the same 24 hours-period, only the first would trigger an automated notification. Episodes were not uploaded to CareLink when there was no Bluetooth connection between the ICM and the smartphone, no network connection to upload the episode, the smartphone was turned off, or scheduled maintenance was taking place on the CareLink platform. Participants were instructed to acknowledge receipt of the SMS

notifications by replying to a designated study telephone number, and all interaction timestamps were recorded in the software database.

In Phase 2, participants continued to have the ICM implanted, but the SMART-ALERT software did not trigger SMS notifications. Instead, the ICM served as the reference standard for evaluating the AF detection performance of both wearable devices. Participants were allocated an Apple Watch series 7 (Apple Inc., Cupertino, USA) or a CART Ring (Skylabs, Seongnam-si, South Korea), depending on their smartphone's operating system, as the Apple Watch required an iPhone.

Once AF was detected by wearable devices, AF notifications were sent directly to the participants' smartphones. Unlike Phase 1, there were no restrictions on the number of alerts per day, as AF detection settings were defined by the manufacturers and could not be altered. The CART Ring triggered AF notifications for episodes lasting longer than 30 minutes, while the Apple Watch's detection criteria were less explicitly defined. Apple documentation stated that if the device detected an irregular rhythm during a pulse check, it would initiate more frequent sampling, typically multiple times per hour. In optimal conditions, the watch should have been able to identify and notify users of AF episodes lasting at least 30 minutes.

Participants were instructed to confirm receipt of these notifications by replying via SMS to a designated study telephone number. All participants continued their standard of care medications, including OAC where prescribed. No treatment decisions were influenced by study participation.

Study Devices

The LINQ II ICM continuously monitors heart rhythm and rate. AF detection relies on identifying irregular R-R intervals, the absence of P-waves, and sustained episodes lasting at least 2 minutes. The AccuRhythm™ AI algorithm further enhances diagnostic accuracy by validating detected episodes against an extensive database of AF and non-AF rhythms, significantly reducing false positive detections (FP).[13]

The Apple Watch and CART Ring (Figure S2) use photoplethysmography (PPG) to measure heart rate semi-continuously and detect irregular patterns, which in turn trigger AF notifications. However, PPG measurements during ambulatory conditions are challenging due to motion artefacts from arm movement, improper device position and poor skin contact, ambient light interference, and variability in peripheral circulation. To mitigate false positives, both devices perform multiple confirmatory readings, particularly during rest periods, where motion artefacts are minimal.

Both wearable devices rely on Bluetooth to communicate with their respective companion app. Apple Watch AF notifications appear on both the watch and smartphone screens, accompanied by sound or

vibration, depending on user preferences, with summaries accessible in the iPhone's Health app. The CART Ring delivers AF alerts exclusively through its smartphone app via pop-up notifications, and no alerts are sent directly to the ring.

Outcomes

The primary outcome for Phase 1 was the performance of the SMART-ALERT software in delivering automated real-time SMS notifications to participants for AF episodes detected by the ICM and transmitted to CareLink that met predefined criteria. Performance was defined as the percentage of study-defined AF episodes that were associated with a successful SMS notification. In Phase 2, the primary outcome was the performance of wearable devices—the Apple Watch and CART Ring—in detecting AF episodes lasting longer than 30 minutes and sending notifications to participants. Performance was defined as the percentage of ICM-detected AF episodes ≥30 minutes that resulted in a notification from the wearable device. While the CART Ring was programmed to notify users of AF episodes longer than 30 minutes, Apple's detection criteria were less explicitly defined, but its performance was evaluated against the same 30-minutes threshold.

Secondary outcomes included percentage of notifications that were acknowledged, the time from AF detection to acknowledgment in both phases, and wearable device adherence. We evaluated the diagnostic performance metrics for the wearable devices using ICM as the reference standard. A false positive was defined as an AF notification generated by a wearable device when no AF episode ≥ 30 minutes was detected by the ICM within the same time frame. A false negative was defined as an ICM detected AF episode ≥ 30 minutes without a corresponding AF notification from the wearable device. We also calculated the positive predictive value (PPV) of wearable device notifications, which represents the proportion of all wearable-triggered AF alerts that corresponded to true AF episodes as confirmed by the ICM.

Wearable device adherence was assessed by analysing heart rate data recordings. Data were reviewed in rolling 10-minutes windows. If heart rate data were recorded within a window, the device was considered to be in use. To account for potential transient data gaps due to movement, signal dropout or other interruptions when the device was still in use, a gap of at least three consecutive 10-minutes windows without heart rate recordings was used as a surrogate for non-use. Adherence was calculated separately for daytime and night-time periods, expressed as a percentage of total available time. It was further evaluated to determine whether any AF episodes were missed due to non-use of the wearable device. All interactions, including timestamps of detected episodes and participant acknowledgments, were logged in the software database for subsequent analyses.

We provided a structured questionnaire to all participants that completed follow-up to assess their experience and satisfaction with each monitoring approach. We also asked for open-ended feedback suggestions for improvements and barriers to adherence of the devices and alert systems.

Adjudication and Statistical Analysis

Adjudication of all available ECGs in CareLink for AF episodes >30 minutes was performed by two cardiologists (A.B.G) and (A.S) blinded to participants' data. Any disagreements in adjudication were resolved by a third cardiologist.

The SMART-ALERT software created a database in Excel format, logging timestamps of when SMS alerts were sent to study participants and when subsequent acknowledgements were received. Wearable device data were exported to retrieve AF alert notification logs, heart rate data, and single-lead ECGs.

Statistical analyses were conducted using R version 4.0.3, with support from a trained statistician (A.B). Categorical data were summarised as frequencies and percentages, while continuous data were reported as means with standard deviations or medians with interquartile ranges, depending on whether it followed a Gaussian distribution. Comparative analyses of adherence and performance metrics, both within and between devices, were performed using paired *t*-tests for continuous variables and chi-square tests for categorical variables, as appropriate.

RESULTS

A total of 50 participants were enrolled in the study and underwent implantation of an ICM. The median age was 62 years, 30% were female, and 76% had paroxysmal AF. The median CHA_2DS_2-VASc and HAS-BLED scores were both 1 (Table 1).

The study was designed with a target follow-up duration of three months per phase but due to logistical constraints, including scheduling challenges and device allocation, some participants remained in Phase 1 for slightly longer before transitioning to Phase 2. As a result, the overall follow-up was slightly longer than planned, with a mean follow up of 6.8 ± 1.2 months, with a total study period from December 2021 to March 2023.

The ICM detected 4,943 AF episodes lasting longer than 30 minutes in 31 participants (Table 2). This figure includes all episodes stored on the ICM, irrespective of time of upload to CareLink. Forty-six participants progressed to Phase 2 (Figure 2) and were assigned a wearable device (Apple Watch or CART Ring).

AF Notification Rates

In Phase 1, the bespoke SMART-ALERT software successfully triggered automated SMS notifications for 511 of the 691 AF episodes (74%) that met the three predefined rules. In Phase 2, using the ICM as the reference, the Apple Watch notified participants of 76 of 389 AF episodes (19.5%) lasting ≥30 minutes compared to 72 of 474 episodes (15.1%) from the CART Ring (Figure 3). At a per-patient level, successful AF alerts were recorded in 65.7% of participants using the SMART-ALERT software, 27.9% with the CART Ring, and 25.0% with the Apple Watch (Table S1)

The Apple Watch generated 109 AF notifications in total, of which 76 were true positives, yielding a PPV of 69.7%. In contrast, the CART Ring produced 349 AF notifications, of which only 72 were true positives, resulting in a lower PPV of 20.6% ($p < 0.001$; Figure 3B). The CART Ring had a significantly higher rate of false positive detection compared to the Apple Watch (79.4% vs. 30.3%, $p<0.0001$).

Wearable Devices Adherence and Impact on Detection

Participants given the Apple Watch demonstrated higher adherence, with an average time worn of 66.3% (Figure 4A) and a mean daily wear time of 16.0±6.8 hours (Table S2). Compliance was consistent across daytime (67.3%) and nighttime (63.5%) periods. In comparison, participants using the CART Ring had a lower compliance rate of 23.9%, with a mean daily wear time of 5.73 ± 7.96 hours. Adherence was significantly higher at night than during the day (32.1% vs 19.0%; $p = 0.008$). Device reliability further impacted compliance, as 9 CART Rings ceased functioning after 4 to 6 weeks, necessitating replacements.

Wearable device adherence significantly influenced AF notification rates in Phase 2. The Apple Watch was not worn during 24.6% of AF episodes, while the CART Ring was not worn during 55.7% of episodes. Restricting the AF notification performance to episodes during which the devices were worn, notification rate was 25.5% of 293 episodes for the Apple Watch and 34.6% of 210 episodes for the CART Ring (Figure 3A).

Acknowledgement Rates and Responses Times

The acknowledgment rate of notifications varied between technologies. In Phase 1, the median time from ICM AF detection to SMS notification transmission was 2.4 hours, and 287 notifications (41.5%) were sent within 3 hours. Participants acknowledged 509 of 511 SMS notifications (99.6%) generated by the SMART-ALERT software, with a median response time of 4.5 minutes. The complete alert cycle—comprising AF detection, notification, and acknowledgment—was achieved for 73.7% of episodes, with a median completion time of 4.2 hours (Figure 4A-C).

In Phase 2, the Apple Watch cohort demonstrated a median notification time of 1.9 hours from AF onset. Participant engagement was lower than in Phase 1, with only 21 of 76 notifications (27.7%) acknowledged. 368 of 389 episodes (94.6%) failed to complete the detection-notification-acknowledgement alert cycle. Among those episodes that did complete the cycle, the overall median time from AF onset to acknowledgment was 4.6 hours (Figure 4D-F). The CART Ring cohort had a median notification time of 38 minutes; however, none of the 72 notifications sent (15.1% of total episodes) were acknowledged, resulting in no episodes completing the alert cycle (Figure 4G-I).

Wearable Device Detection Rates by Episode Duration

We examined detection rates for AF episodes separately for instances when the Apple Watch (293 AF episodes) and the CART Ring (210 AF episodes) were worn (Table 3). The Apple Watch demonstrated a significant trend of improved detection rates with longer episode durations, increasing from 6.4% for episodes lasting less than 3 hours to 58.7% for episodes exceeding 3 hours ($p < 0.001$). In contrast, CART Ring showed consistency across episode durations with only a small increase in episodes longer than 3 hours, suggesting that its performance was less influenced by episode length.

Participants' Perspectives

A total of 30 out of 41 patients (73.2%) completed our questionnaire. Most participants (93.1%) reported no impact of AF alerts on daily activities, with 82.2% experiencing no change or reduced anxiety from monitoring (Figures S3-S5). Three-quarters never had connectivity issues with the ICM app, and 81.9% acknowledged alerts "most of the time" or "always". For wearable devices, 92.3% of Apple Watch users never had connection problems; however, only 55.2% felt very confident using the app and just 42.9% found it comfortable overnight. In contrast, 87.5% of CART Ring users wore their device overnight, but had a lower daily wear and nearly half experienced connectivity difficulties, with 20% reporting daily issues. Participants expressed concerns that the apps drained the smartphones' battery, and wearables had poor battery life (Table S3). When asked about "pill-in-the-pocket" anticoagulation, 86.7% (26/30) were willing to use an ICM-based system, compared to 68.8% (11/16) for the CART Ring and only 50% (7/14) for the Apple Watch (p=0.46).

DISCUSSION

The SMART-ALERT study revealed a stark contrast between ICM-based notification and wearable devices real-time AF notifications. The integration of the SMART-ALERT software with an ICM successfully triggered SMS notifications in 74% of eligible episodes, whilst wearable devices performed poorly, notifying participants of only 19.5% (Apple Watch) and 15.1% (CART Ring) of ICM-detected AF episodes.

The SMART-ALERT software's 74% notification rate should be interpreted with caution, as it reflects the intentional trade-offs in our decision tree: suppressing alerts beyond the first episode in a 24-hours period and those uploaded more than 24 hours after onset. This design suited to our high-burden AF cohort (4,080 AF episodes in 31 patients) as a more aggressive notification algorithm would risk notification fatigue and affect patient engagement. SMS failures were primarily due to connectivity issues, not software performance. Of the 26% (180/691) of eligible AF episodes that did not trigger SMS alert, we estimate 44% (80/180) in 23 patients were due to failure to upload an AF episode to CareLink within 24 hours. Episodes uploaded depend on three factors: Blueetooth connectivity, CareLink app running, and an active internet connection. If the app was closed, participants are only reminded to reopen the app after four consecutive days of data transmission failure. The SMART-ALERT software successfully alerted other participants during the same period, confirming these failures stemmed from app connectivity issues (Figure S6).

Wearable devices showed marked disparity between their real-world performance and previous validation studies of spot-check ECGs, which reported high sensitivity (>90%). [14-16] Those studies were conducted in controlled settings with minimal motion artefacts and optimal device positioning. The comparison between continuous (ICM) and intermittent (wearable devices) monitoring introduces an inherent detection bias. The Apple Watch's low AF notification rate of 19.5% likely stemmed from limitations of PPG monitoring during daily activities — motion artefacts, variable skin contact, and intermittent sampling all reduce detection accuracy. Notably, even when worn, the detection rate remained low at 25.5%, suggesting technical limitations beyond simple non-wear time. Apple Watch performance improved with longer episodes (9.3% for 1–3-hours vs 63.7% for >24 hours) suggesting that the algorithm favours longer episodes and that the intrinsic sampling frequency creates a systematic bias against detecting shorter episodes. Similarly, CART Rings' irregular rhythm notifications were poor, missing approximately two-thirds of AF episodes and generating a higher rate (74%) of false positive notifications.

The reduction in wearable PPG-based AF detection has been consistently demonstrated in ambulatory studies. Wasserlauf *et al.*[17] reported that only half of AF episodes occurred while smartwatches were worn, with a patient-level sensitivity for these episodes of 72% against ICMs and cardiac implantable electronic devices. Episode level detection with the Apple Watch was only 21.4% when compared to a 24-hour Holter monitor.[18] The Fitbit Heart Study showed similar limitations with participant-level and episode-level sensitivities of 70.9% and 67.6%, respectively, using a 7-day Holter as reference.[19] The Verily wrist-worn device has a different approach and samples heart rate at all levels of activity

but only analyses adequate-quality PPG tracings. The overall sensitivity in ambulatory patients was 75.5%, increasing to 96.1% when poor-quality samples (22.8%) were excluded.[20]

These findings provide a sobering reality: despite significant advancements in consumer wearable technologies, substantial barriers remain in using these tools as reliable clinical monitoring systems. While spot-check ECGs are useful for AF screening, PPG-based monitoring capabilities face fundamental limitations in both sampling frequency and signal quality, falling short for continuous monitoring in ambulatory patients.

The median delay from AF episode detection to SMS notification was longer for the ICM and SMART-ALERT software (2.6 hours) than with the wearable devices (1.9 hours for the Apple Watch and 38 minutes for the CART Ring). This mostly reflects the design of each monitoring system. The ICM typically uploads episodes after termination, so that a final duration can be assigned. For long or ongoing episodes, transmission can be postponed until termination or occur without a duration field. Uploads only occur if the smartphone app is running with an internet connection and Bluetooth is enabled. We designed the SMART-ALERT software to check episode start time and determine if 30 minutes had passed, even without a duration provided. The software reviews transmissions every 5 minutes and sends the SMS within seconds. In contrast, wearables are app-integrated and can trigger alerts more rapidly once AF is detected.

We observed striking differences in notification acknowledgment: 99.6% for SMS notifications versus 27.7% for Apple Watch and none for CART Ring. Several factors likely contributed to this discrepancy. SMS messages are prioritised by smartphone operating systems and are harder to miss than app-based alerts, which can be muted or buried among other notifications limiting visibility. Some participants acknowledged CART Ring notifications from false positive episodes, while others used single-lead ECGs to document acknowledgment of a notification rather than adhering to study protocol and sending a SMS to the research team. SMS alerts during Phase 1 explicitly asked for an acknowledgment, which may have led to more consistent replies.

Participants wearing the Apple Watch had a mean daily wear time of 16 hours, compared to 5.7 hours for the CART Ring, which was influenced by device malfunction. Non-adherence had an impact on AF detection performance, with the Apple Watch missing 24.6% of AF episodes due to non-wear, while the CART Ring missed 55.7% of episodes. These adherence challenges align with previous wearable devices studies.[21,22] For example, a study using the Oura Ring found wear times ranging from 15 to 19 hours across 30-day periods, with users attributing non-adherence to battery limitations, discomfort, and inconvenience.[23] Similarly, Ding et al.[24] reported a progressive decline in smartwatch adherence

from 73% at the initial phase of the study to 63% by day 30, with half of participants wearing the device for less than five hours daily.

The implications for "pill-in-the-pocket" anticoagulation strategies are significant. A meta-analysis of studies using ICMs highlighted delays in OAC initiation due to the need for manual adjudication and patient contact. This approach was resource-intensive; for example, in REACT.COM, 59 patients generated 24,000 ICM transmissions.[10] The SMART-ALERT software improved efficiency by integrating ICM detection with near real-time automated patient notifications, achieving a 74% success rate in delivering alerts. Our ICM data showed high PPV for AF, correctly identifying 1043 out of 1048, aligning with Mittal *et al*. [25] findings of 91.3% PPV for AF episodes longer than 30 minutes in 1,049 patients using the Reveal LINQ ICM. Despite a small risk of false positives—potentially leading to unwarranted initiation of OAC in about 1 in 20 patients—closed-loop systems with direct patient notifications could significantly reduce delays in starting OAC. Subsequent adjudication by clinical teams could ensure safety, bridging the gap between accurate detection and timely anticoagulation. Patient perspectives also support exploring ICM-based approaches for pill-in-the-pocket OAC. In our previous survey of 321 AF patients conducted in collaboration with the AF Association, 54% expressed willingness to use ICM-guided OAC if proven to be as safe as continuous OAC, whilst only 48% would consider using a wearable device.[26] This preference was confirmed in our post-study questionnaires, with 86.7% of participants choosing the ICM, compared to 68.8% for the CART Ring and 50% for the Apple Watch.

Building on the findings from this study, we have refined the SMART-ALERT software. The updated version addresses earlier connectivity issues by triggering SMS reminders when no data upload is received for over 24 hours and automatic alerts to the research team during scheduled CareLink maintenance. In recent testing, the revised system achieved a 100% alert success rate for eligible episodes (abstract to be presented at Heart Rhythm Session 2025). These improvements have informed the design of the ongoing RESPOND-AF study, which is a single-centre study evaluating a real-world PIP-OAC pathway guided by the SMART-ALERT platform and LINQ II ICMs and is currently recruiting.

Intermittent use, low detection rates, and unreliable notifications with wearable devices are particularly problematic for a “pill-in-the-pocket” OAC strategy; it can result in failed AF detection, delayed anticoagulation, and increased stroke risk. Innovations should focus on three key areas. First, to improve adherence, it requires maximising battery life to reduce charging frequency and design improvements to enhance comfort. Second, PPG sampling frequency needs to be increased including during periods of activity. To mitigate the likely reduced quality of PPG tracings, artificial intelligence (AI)-based algorithm can compensate by improving the signal-to noise ratio, filtering artefacts, and

overall enhancing arrhythmia detection[27, 28]. The final key direction should be shifting analysis from device to cloud-based systems with larger processing power and with continuous updates to AI training sets as new patterns emerge.

Limitations

This study has several limitations. The small sample size and short follow-up time limit generalisability of our findings, particularly for populations with different AF burdens. Variability in participants' familiarity with wearable technology and adherence to monitoring protocols are important sources of potential bias in evaluating these devices. Technical challenges with the CART Ring, including frequent device malfunctions requiring replacement, further complicate interpretation of adherence and overall effectiveness as a monitoring tool. Our analysis included all AF episodes stored on the LINQ II ICMs, but there remains a potential for ascertainment bias. The LINQ II ICM has a reported sensitivity for AF episodes >30 seconds of over 98%, but it may occasionally miss AF episodes. Therefore, a small number of True-AF episodes may have gone undetected and excluded from the analysis, potentially affecting comparison with the wearable devices. However, given that we used a >30 minutes threshold, the likelihood and impact of bias are expected to be small.

Finally, another important limitation is the deliberate design of our software to censor notifications uploaded to CareLink more than 24 hours after initiation, which may have underestimated the software's notification performance in patients with low AF burden, such as those eligible for a "pill-in-the-pocket" strategy. Larger studies with longer follow-up time with a diverse population are needed to validate these results and evaluate the feasibility of wearable devices for AF monitoring and anticoagulation management.

Conclusion

The SMART-ALERT study revealed a stark contrast between ICM-based and wearable device real-time AF notifications. The integration of the SMART-ALERT software with the ICM showed promising efficacy in AF notifications (74% success rate) within 24 hours, yet it faced important connectivity problems: 44% of missed notifications stemmed from data transmission failure between ICM and CareLink platform. The current generation of wearable devices showed poor AF detection rates in ambulatory patients (19.5% for the Apple Watch and 15.1% for CART Tings), compounded by adherence challenges and unreliable smartphone notifications. These findings highlight that significant technical hurdles must be surmounted before digital health technologies can be safely integrated into AF management strategies.

REFERENCES

1. Van Gelder IC, Rienstra M, Bunting KV, et al. 2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): Developed by the task force for the management of atrial fibrillation of the European Society of Cardiology (ESC), with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. Endorsed by the European Stroke Organisation (ESO). Eur Heart J 2024;45:3314-3414.

2. Lin H-J, Wolf PA, Kelly-Hayes M, et al. Stroke severity in atrial fibrillation: the Framingham Study. Stroke 1996;27:1760-1764.

3. Ruff CT, Giugliano RP, Braunwald E, et al. Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with atrial fibrillation: a meta-analysis of randomised trials. Lancet Mar 15 2014;383:955-962.

4. Lamberts M, Staerk L, Olesen JB, et al. Major Bleeding Complications and Persistence With Oral Anticoagulation in Non-Valvular Atrial Fibrillation: Contemporary Findings in Real-Life Danish Patients. J Am Heart Assoc Feb 14 2017;6.

5. Salmasi S, Loewen PS, Tandun R, et al. Adherence to oral anticoagulants among patients with atrial fibrillation: a systematic review and meta-analysis of observational studies. BMJ Open 2020;10:e034778.

6. Singer DE, Ziegler PD, Koehler JL, et al. Temporal Association Between Episodes of Atrial Fibrillation and Risk of Ischemic Stroke. JAMA Cardiology;6:1364-1369.

7. Turakhia MP, Ziegler PD, Schmitt SK, et al. Atrial Fibrillation Burden and Short-Term Risk of Stroke: Case-Crossover Analysis of Continuously Recorded Heart Rhythm From Cardiac Electronic Implanted Devices. Circ Arrhythm Electrophysiol Oct 2015;8:1040-1047.

8. Kaplan RM, Koehler J, Ziegler PD, et al. Stroke Risk as a Function of Atrial Fibrillation Duration and CHA2DS2-VASc Score. Circulation Nov 12 2019;140:1639-1646.

9. Passman R. “Pill-in-Pocket” Anticoagulation for Atrial Fibrillation: Fiction, Fact, or Foolish? Circulation 2021;143:2211-2213.

10. Passman R, Leong-Sit P, Andrei AC, et al. Targeted Anticoagulation for Atrial Fibrillation Guided by Continuous Rhythm Assessment With an Insertable Cardiac Monitor: The Rhythm Evaluation for Anticoagulation With Continuous Monitoring (REACT.COM) Pilot Study. J Cardiovasc Electrophysiol Mar 2016;27:264-270.

11. Waks JW, Passman RS, Matos J, et al. Intermittent anticoagulation guided by continuous atrial fibrillation burden monitoring using dual-chamber pacemakers and implantable cardioverter-defibrillators: Results from the Tailored Anticoagulation for Non-Continuous Atrial Fibrillation (TACTIC-AF) pilot study. Heart Rhythm;15:1601-1607.

12. Chen L, He Y. Identification of atrial fibrillation from electrocardiogram signals based on deep neural network. Journal of Medical Imaging and Health Informatics May 2019;9(4):838-846.

13. Singh J, Radtke A, Rosemas S, et al. Abstract 18672: Impact of Enhanced Artificial Intelligence on Clinic Burden From False Alerts of Insertable Cardiac Monitors. Circulation 2023;148:A18672-A18672.

14. Pepplinkhuizen S, Hoeksema WF, van der Stuijt W, et al. Accuracy and clinical relevance of the single-lead Apple Watch electrocardiogram to identify atrial fibrillation. Cardiovasc Digit Health J Dec 2022;3:S17-s22.

15. Lopez Perales CR, Van Spall HGC, Maeda S, et al. Mobile health applications for the detection of atrial fibrillation: a systematic review. EP Europace 2020;23:11-28.

16. Shahid S, Iqbal M, Saeed H, et al. Diagnostic Accuracy of Apple Watch Electrocardiogram for Atrial Fibrillation. JACC: Advances 2025;4:101538.

17. Wasserlauf J, Vogel K, Whisler C, et al. Accuracy of the Apple watch for detection of AF: A multicenter experience. J Cardiovasc Electrophysiol May 2023;34:1103-1107.

18. Inocian E, Junia A, Cordovez MG, et al. Accuracy of the Apple Watch in detecting atrial fibrillation among patients undergoing 24-hour Holter monitoring. Eur Heart J 2024;45.
19. Lubitz SA, Faranesh AZ, Selvaggi C, et al. Detection of Atrial Fibrillation in a Large Population Using Wearable Devices: The Fitbit Heart Study. Circulation 2022;146:1415-1424.
20. Poh MZ, Battisti AJ, Cheng LF, et al. Validation of a Deep Learning Algorithm for Continuous, Real-Time Detection of Atrial Fibrillation Using a Wrist-Worn Device in an Ambulatory Environment. Journal of the American Heart Association 2023;12:e030543.
21. Galarnyk M, Quer G, McLaughlin K, et al. Usability of a Wrist-Worn Smartwatch in a Direct-to-Participant Randomized Pragmatic Clinical Trial. Digital Biomarkers 2019;3:176-184.
22. Golbus JR, Pescatore NA, Nallamothu BK, et al. Wearable device signals and home blood pressure data across age, sex, race, ethnicity, and clinical phenotypes in the Michigan Predictive Activity & Clinical Trajectories in Health (MIPACT) study: a prospective, community-based observational study. The Lancet Digital Health 2021;3:e707-e715.
23. Nolasco HR, Vargo A, Bohley N, et al. Examining Participant Adherence with Wearables in an In-the-Wild Setting. Sensors 2023;23:6479.
24. Ding EY, Tran KV. Accuracy, Usability, and Adherence of Smartwatches for Atrial Fibrillation Detection in Older Adults After Stroke: Randomized Controlled Trial. Nov 28 2023;7:e45137.
25. Mittal S, Rogers J, Sarkar S, et al. Real-world performance of an enhanced atrial fibrillation detection algorithm in an insertable cardiac monitor. Heart Rhythm Aug 2016;13:1624-1630.
26. Briosa E Gala A, Pope MT, Leo M, et al. P353Anticoagulation profile if an as required oral anticoagulation strategy is used in patients with complex cardiac devices. EP Europace 2020;22.
27. Kwon S, Hong J, Choi E-K, et al. Deep Learning Approaches to Detect Atrial Fibrillation Using Photoplethysmographic Signals: Algorithms Development Study. JMIR Mhealth Uhealth 2019;7:e12770.
28. Antiperovitch P, Mortara D, Barrios J, et al. Continuous Atrial Fibrillation Monitoring From Photoplethysmography. JACC: Clinical Electrophysiology 2024;10:334-345.

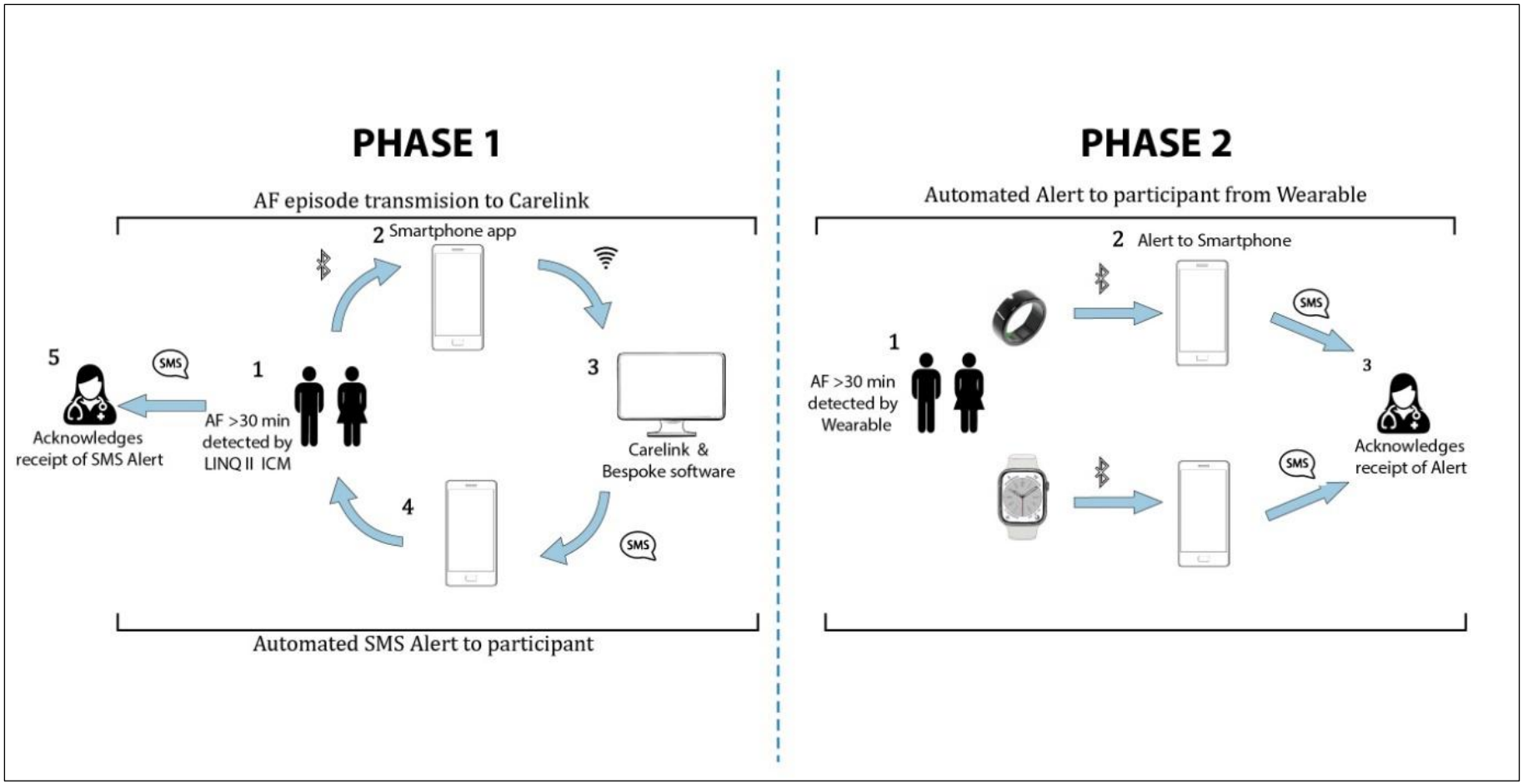


Figure 1. SMART-ALERT study workflow.

Table 1. Demographics and characteristics of patients at baseline and at the beginning of phase 2.

Characteristics	**Total (N = 50)**	**Apple Watch (N=23)**	**CART Ring (N=23)**
Age — yr	62 (57—69)	62 (60—70)	62 (54—68)
Female sex — no. (%)	15 (30%)	8 (35%)	6(26%)
BMI — median (IQR)	26.8 (24.9- 30.2)	26.8 (24.9- 30.2)	26.8 (24.9- 30.2)
Paroxysmal AF — no. (%)	38 (76%)	19 (83%)	17 (74%)
AF duration (months) — median (IQR)	42 (24-68)	48 (24-96)	27 (26-30)
AF symptoms frequency — no. (%)			
• No symptoms	1 (2.0%)	1 (4.3%)	—
• Most days	9 (18%)	4(17%)	5 (23%)
• Most weeks	32 (64%)	8 (35%)	9(41%)
• Most months	8 (16%)	10 (43%)	8 (53%)
CHA2DS2-VASc — median (IQR)	1 (0—3)	1 (1—3)	1 (0—2)
HAS-BLED — median (IQR)	1 (0–1)	1 (0–1)	1 (0–1)
Hypertension — no. (%)	13 (26%)	6 (26%)	6 (26%)
Ischaemic Heart Disease — no. (%)	5 (10%)	3 (13%)	1 (4.3%)
Vascular Heart Disease — no. (%)	1 (2%)	1 (4.3%)	—
Heart Failure — no. (%)	10 (20%)	2 (8.7%)	7 (30%)
Cardiac Surgery — no. (%)	1 (2%)	1 (4.3%)	—
Previous Stroke/TIA — no. (%)	6 (12%)	3 (13%)	3 (13%)
Previous Ablation — no. (%)		12 (52%)	12 (52%)
Previous Cardioversion — no. (%)		7 (30%)	4 (17%)
Rate control drugs — no. (%)	33 (64%)	12 (51.6%)	18 (78.3%)
• Beta-blocker	30 (60%)	10 (43%)	17 (74%)
• Calcium-channel blockers	1 (2%)	—	1 (4.3%)
• Digoxin	1 (2%)	1 (4.3%)	—
• Others	1 (2%)	1 (4.3%)	—
Anti-arrhythmic drugs — no. (%)	26 (52%)	13 (57%)	15 (65.7%)
• Class Ic	17 (34%)	8 (35%)	12 (35%)
• Amiodarone	3 (6%)	—	2 (8.7%)
• Sotalol	6 (12%)	5 (22%)	1 (4.3 %)
Oral anticoagulation — no. (%)	34 (68%)	16 (70%)	14 (61%)
• DOAC	15 (30%)	15 (65.7%)	14 (61%)
• Warfarin	1 (2%)	1 (4.3%)	—
Normal EF — no. (%)	44 (88%)	21 (91%)	19 (83%)
Sinus rhythm — no. (%)	46 (92%)	22 (96%)	21 (91%)

AF, atrial fibrillation. BMI, body mass index. DOAC, direct oral anticoagulants. EF, ejection fraction. TIA, transient ischaemic attack.

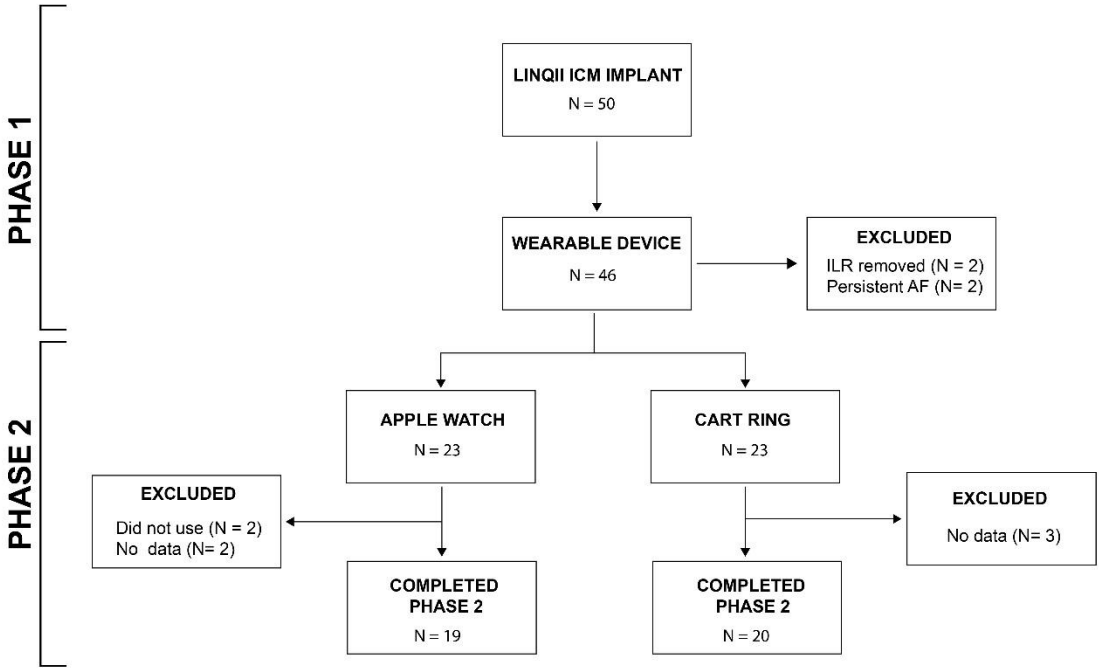


Figure 2. Study workflow diagram.

Table 2. Characteristics of AF episodes detected by the LINQ II ICM.

	Phase 1	Phase 2†	
	LINQ II ICM (N=50)	**Apple Watch (N=19)**	**CART Ring (N=20)**
AF episodes detected by ICM	4080	389	474
AF episodes meeting criteria for Notification	691‡	389	474
AF episodes with ECG	460	293	295
True AF episodes	458 (99.5%)	293(100%)	292 (99.0%)
Number of Patients with at least one AF episode	31	13 (68.4%)	9 (45%)
Episode duration (minutes), median (IQR)	80 (180)	82 (390)	66 (62)
Follow-up (months), mean±SD	4.3±1.7	5.3±1.7	3.5±2.5

AF, Atrial fibrillation. **ECG,** electrocardiogram. **IQR**, interquartile range. **SD**, standard deviation.
† Includes only participants who completed Phase 2. Of the 46 participants allocated a wearable device, two did not use it, and five had no analysable data.
‡ Number of AF episodes meeting the criteria for the bespoke software alert (first episode within a 24-hours period).

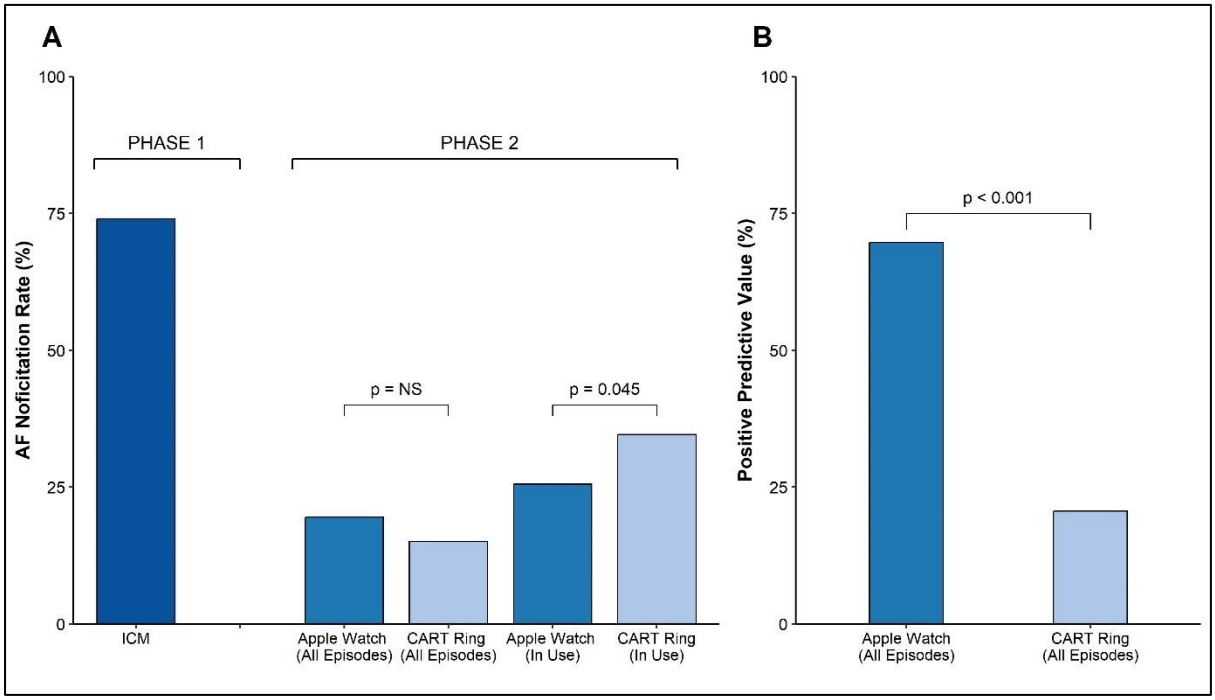


Figure 3. (A) Percentage of successful AF notifications sent in the ICM cohort (Phase 1) and in the Apple Watch and CART Ring cohorts (Phase 2). **(B)** Positive predictive value of AF notifications by the wearable devices during Phase 2.

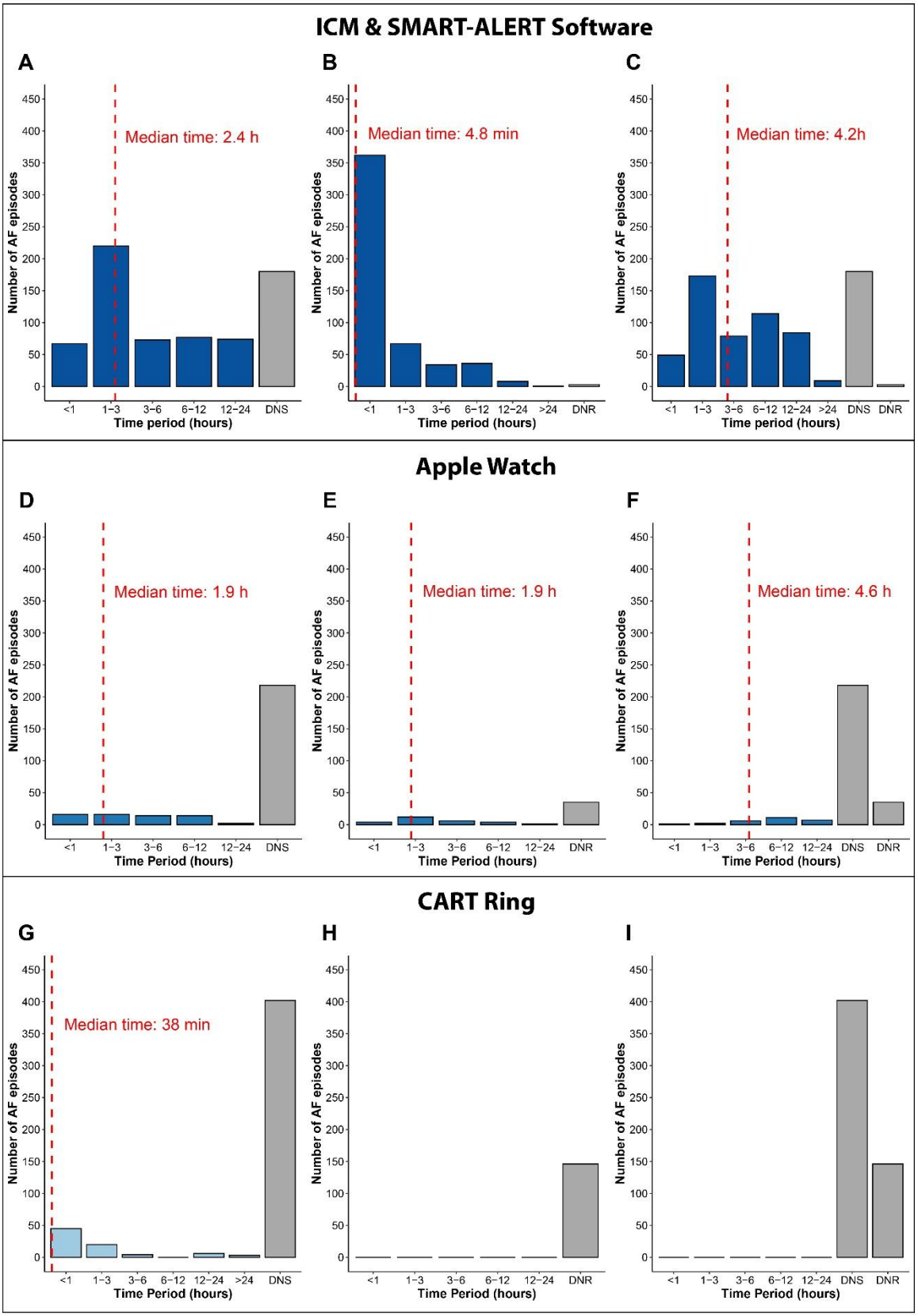


Figure 4. Time intervals for AF detection, notification, and acknowledgement. Rows represent detection method: **ICM (SMART-ALERT)**, **Apple Watch**, and **CART Ring**. Columns represent: (1) Time from AF detection to notification, (2) Time from notification to participant acknowledgement, (3) Total time from AF onset to acknowledgement. **DNS** – did not send; **DNR** – did not reply.

Table 3. Detection rates of AF episodes by duration category for the Apple Watch and CART Ring.

Episode duration	Apple Watch		CART Ring	
	Episodes Detected	Detection Rate	Episodes Detected	Detection Rate
<1 hour	3/93	3.1%	28/89	31.5%
1-3 hours	8/86	9.3%	34/70	32.7%
3-6 hours	15/27	55.6%	5/11	45.45%
6-12 hours	18/32	56.25%	2/3	66.6%
12-24 hours	18/30	60%	1/1	100%
>24 hours	14/22	63.7%	—	—

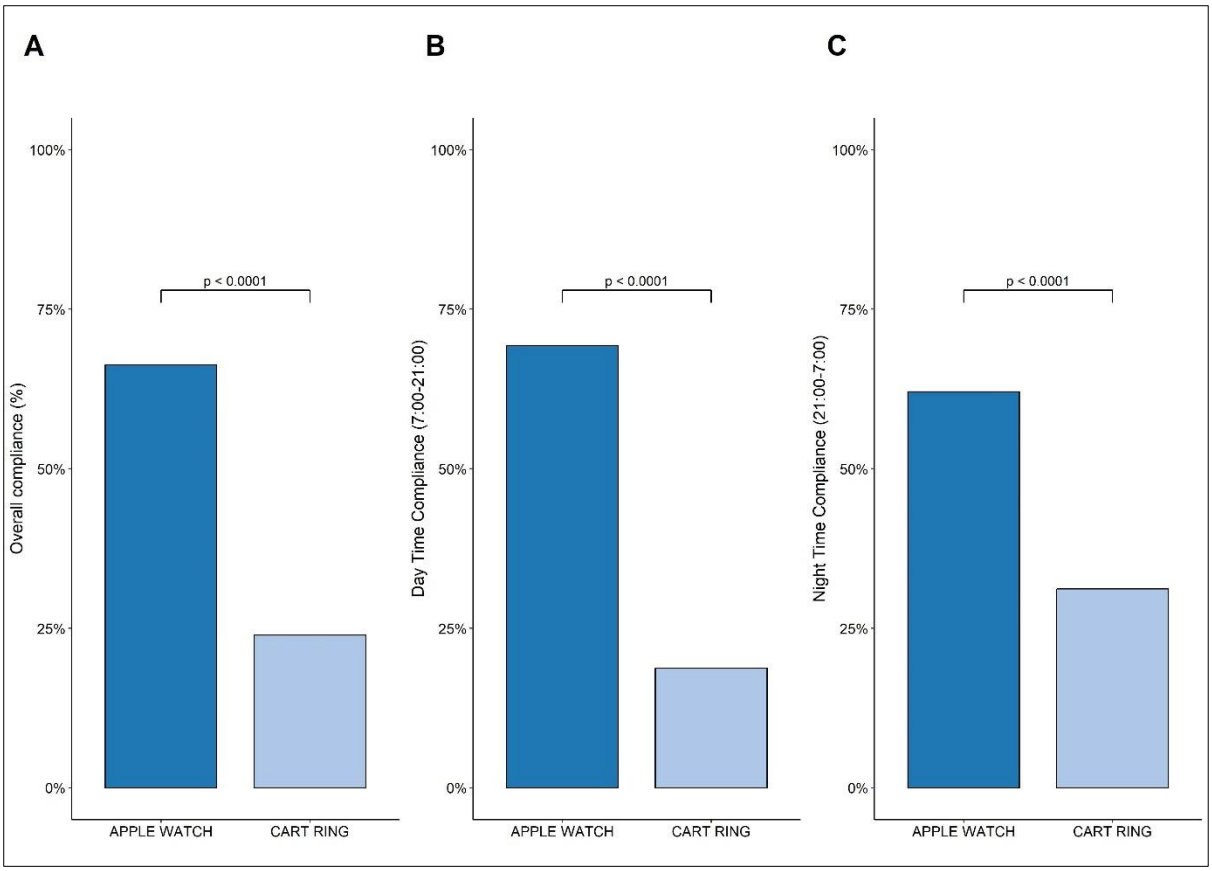


Figure 5. (A) Overall compliance rates for the Apple Watch and CART Ring. **(B)** Compliance during daytime hours (7 am–9 pm). **(C)** Compliance during nighttime hours (9 pm–7 am).