Using Wearables to Manage Atrial Fibrillation: Pushing the Boundaries with Consumer Devices

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Abstract

The irregular pulse notification (IPN) algorithm on the Apple Watch (Apple Inc., Cupertino, CA) was not designed for use by atrial fibrillation (AF) patients. It is not FDA cleared for use in AF patients. Before this study by Dr. Wasserlauf and colleagues, there were no studies of its accuracy in AF patients. Yet, many AF patients could not resist the temptation to use the feature. In the Apple Heart Study1, even after making it clear that patients with AF were not eligible for the study, 174 (18%) of the participants who received an irregular pulse notification and connected with a study visit doctor confessed that they knew they already had AF and were excluded from the study. These participants were just too curious to pass up the opportunity to see what the new technology was all about.

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The irregular pulse notification (IPN) algorithm on the Apple Watch (Apple Inc., Cupertino, CA) was not designed for use by atrial fibrillation (AF) patients. It is not FDA cleared for use in AF patients. Before this study by Dr. Wasserlauf and colleagues, there were no studies of its accuracy in AF patients. Yet, many AF patients could not resist the temptation to use the feature. In the Apple Heart Study[1], even after making it clear that patients with AF were not eligible for the study, 174 (18%) of the participants who received an irregular pulse notification and connected with a study visit doctor confessed that they knew they already had AF and were excluded from the study. These participants were just too curious to pass up the opportunity to see what the new technology was all about.

Patients pushing boundaries of what "should" be done with consumer devices is not a novel concept. Patients with hypertension have been using home blood pressure monitors to optimize their own antihypertensive regimens for years. Clinical trials have shown that empowering patients to self-measure blood pressure

and to self-adjust their medications may even outperform traditional management strategies[2]. Similarly, diabetics who titrate their own insulin based on frequent or continuous glucose monitoring can do so safely and effectively[3]. More recently, as continuous glucose monitoring devices have become less expensive and easier to use, the number otherwise healthy people who are using them to optimize their diet is growing. While the devices have been studied in obese non-diabetic patients[4], their utility in the healthy population has not yet been validated.

It is natural that some AF patients will seek a similar sense of empowerment. Until recently, the only way an asymptomatic AF patient could confirm they were in AF was by going to a doctor's office to get an ECG. Savvy patients might measure their own pulse, or perhaps use a home blood pressure monitoring device that could measure pulse irregularity. However, most AF patients were in the dark until consumer ECG devices became available[5]. With the ability to measure ECGs at home and confirm AF, patients suddenly had opportunities to explore novel management strategies.

The Irregular Pulse Notification Algorithm on the Apple Watch was the first tool to use PPG on a smartwatch to detect AF. The technological leap here was that monitoring for AF became something that could be done passively and for prolonged periods. Shortly afterwards, other smartwatches followed with similarly designed algorithms[6, 7]. However, these tools were meant to detect AF in consumers who had never been diagnosed with AF. The algorithm was designed to be highly specific with very low false positive rates. To do this, the algorithm relied on multiple passive measurements of pulse irregularity, which was made practical by the wearable nature of the smartwatch. Although the false positive rate of the IPN algorithm was not measured in the Apple Heart Study, it had to be lower than the total positive rate, which was 0.52% over a median monitoring time of 117 days[1].

Despite these caveats, patients with AF saw an opportunity to push the boundaries of this screening tool. This could prove useful for patients who had asymptomatic AF, or who wanted more data around onset of paroxysms of AF. The potential to use AF notifications to manage rate and rhythm controlling medications was obvious to some patients. One of the challenges was that the IPN algorithm had never been validated in patients with known AF. Even clinicians who might want to help patients design personalized, albeit unvalidated, treatment strategies could not tell their patients how accurate the algorithm might be.

In this study by Dr. Wasserlauf and colleagues, questions around the accuracy of the IPN algorithm in AF patients are addressed [Wasserlauf et al., *JCE*]. They provided patients who already had insertable cardiac monitors or cardiac implanted electronic devices and a history of non-permanent AF with Apple Watches running the IPN application. Over the course of 6 months, 11 patients had an episode of AF lasting at least one hour while the watch was worn. Eight of these subjects had successfully-detected AF episodes lasting $>$ 1 hour with the smartwatch, resulting in a sensitivity of 72% and specificity of 100%. This was a relatively small study and therefore the caveats of small sample size and number of events apply. In addition, the gold standards in this study (insertable cardiac monitors and cardiac implanted electronic devices) are also prone to some degree of misclassification[8]. That said, the strength of this study is in its novelty: while many others had looked at the sensitivity and specificity of smartwatch and stand-alone ECG applications, no other study had looked at the accuracy of a PPG-based irregular pulse algorithm on a wearable device in AF patients.

To understand the limitations that the existing algorithm has for use in AF patients, one needs to delve into details of the design of the IPN algorithm[9]. The smartwatch makes one-minute-long pulse measurements once every two hours, as long as the user is not moving. However, if the device detects motion, a pulse check may not occur for prolonged periods of time. The algorithm then classifies the pulse as regular or irregular and if the latter is detected, the frequency of pulse checks increase to once every 15 minutes. A total of 5 out of 6 pulse checks must then be classified as irregular before a notification is delivered. Again, with motion detected by the smartwatch, this could prolong the verification process and extend the time-to-notification even further. This means that short episodes of AF are less likely to result in a notification. For large-scale screening, the low sensitivity of detecting short episodes may be acceptable, opting instead for high levels of specificity. However, for an AF patient who might want to consider waiting for episodes of AF before

taking medications, the IPN algorithm is not ideal. Finally, a wearable device can't detect AF if it is not being worn. In this study, about half of the AF episodes occurred while the participant was not wearing the smartwatch. Currently, limitations in battery life and charging habits limit wear times and sampling frequency, though these may improve in future generation devices.

Another limitation to the existing irregular pulse algorithms is that they can be triggered by long periods of frequent premature atrial or ventricular contractions[10]. In the Apple Heart Study, in participants who received a notification and subsequently wore an ECG patch, approximately 16% of the patients who received an irregular pulse notification had a rhythm other than AF. This number in theory could be higher in patients with a known history of AF, since high burden of PACs are associated with AF, though this did not appear to be an issue in this small sample.

Whether we as a clinical providers want our patients using wearables or not, patients with AF are already using these devices to monitor their AF. Apple released the AF History feature in 2022 (https://www.apple.com/legal/ifu/afhf/1-0/afhf-1-0-en_EN.pdf), which is designed for AF patients to measure AF burden, defined as the proportion of time that a patient has an irregular pulse. The History algorithm is based on frequent sampling and artificial intelligence distinguishing AF from other rhythms. The major limitation of this feature is that the burden measurement is reported only on a weekly basis. The algorithm was likely intentionally designed this way precisely to prevent patients from using the feature to make immediately reactive decisions about medication use.

Patients with AF who want to empower themselves to manage their disease with more granular detail will need to look for algorithms that are more sensitive to short periods of AF with more frequent sampling and lower thresholds for AF classification. These ideal algorithms will also need to provide passive and near-real-time monitoring of AF, and distinguish AF from frequent ectopy. There is currently no such device with this algorithm, much less one that has been validated, but the technologic limitations can be overcome.

The onus will be on the medical community to help our patients figure out the best ways to optimize their AF management in a safe and effective manner. Dr. Passman, senior author of this study, is leading a team to conduct REACT-AF, an NIH-sponsored, open-label, randomized clinical trial testing the safety of using a modified irregular pulse notification algorithm to guide anticoagulation use in patients with AF. Patients randomized to the intervention arm will only take their previously prescribed DOAC therapy for a limited period if their smartwatch alerts them to an episode of AF. The hope is that this strategy will not only be noninferior to standard management, but that there will be fewer bleeds.

REACT-AF is pushing existing boundaries of wearable devices. However, this is the direction the next generation of patients, who are technologically savvy and who demand empowered self-care, want to go. Our job as a clinical community is to help our patients push these boundaries safely.

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