Anxiety, patient activation, and quality of life among stroke survivors prescribed smartwatches for atrial fibrillation monitoring

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BACKGROUND The detection of atrial fibrillation (AF) in stroke survivors is critical to decreasing the risk of recurrent stroke. Smartwatches have emerged as a convenient and accurate means of AF diagnosis; however, the impact on critical patient-reported outcomes, including anxiety, engagement, and quality of life, remains ill defined.

OBJECTIVES To examine the association between smartwatch prescription for AF detection and the patient-reported outcomes of anxiety, patient activation, and self-reported health.

METHODS We used data from the Pulsewatch trial, a 2-phase randomized controlled trial that included participants aged 50 years or older with a history of ischemic stroke. Participants were randomized to use either a proprietary smartphone-smartwatch app for 30 days of AF monitoring or no cardiac rhythm monitoring. Validated surveys were deployed before and after the 30-day study period to assess anxiety, patient activation, and self-rated physical and mental health. Logistic regression and generalized estimation equations were used to examine the association between smartwatch prescription for AF monitoring and changes in the patient-reported outcomes.

RESULTS A total of 110 participants (mean age 64 years, 41% female, 91% non-Hispanic White) were studied. Seventy percent of intervention participants were novice smartwatch users, as opposed to 84% of controls, and there was no significant difference in baseline rates of anxiety, activation, or self-rated health between the 2 groups. The incidence of new AF among smartwatch users was 6%. Participants who were prescribed smartwatches did not have a statistically significant change in anxiety, activation, or self-reported health as compared to those who were not prescribed smartwatches. The results held even after removing participants who received an AF alert on the watch.

CONCLUSION The prescription of smartwatches to stroke survivors for AF monitoring does not adversely affect key patient-reported outcomes. Further research is needed to better inform the successful deployment of smartwatches in clinical practice.

KEYWORDS Atrial fibrillation; Wearables; Smartwatches; Stroke; Elderly

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Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting 6 million patients in the United States and millions more worldwide.[1] AF is a major contributor to risk for ischemic stroke as well as heart failure, hospitalization, and death.[2,3] About 1 in 3 patients with a stroke of undetermined etiology are ultimately diagnosed with AF. The prompt detection and treatment of AF is critical to minimize the risk of stroke.[4] However, the early diagnosis of AF can be challenging owing to the fact that it can be paroxysmal and minimally symptomatic. By some estimates, at least 700,000 cases of AF remain undiagnosed.[5]

In recent years, consumer wearable devices, such as smartwatches, have gained popularity as convenient and accurate means of heart rhythm monitoring, with multiple companies gaining U.S Food and Drug Administration (FDA) clearance for devices designed to detect AF.[6,7] Compared with traditional heart rhythm monitors, smartwatches are

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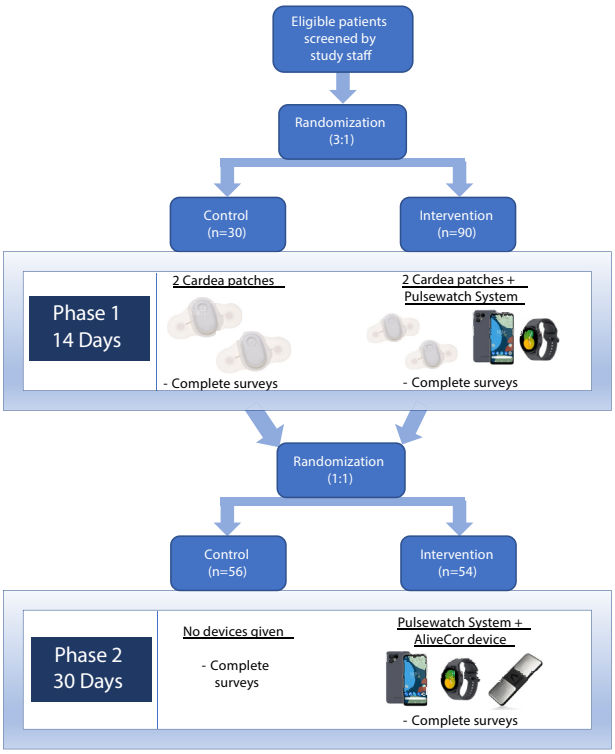

Figure 1 Process of participant randomization for phases 1 and 2, as well as the devices given to participants in each phase. The current study analyzes data from phase 2.

less invasive than implantable rhythm monitors and are designed to be convenient, comfortable, and engaging to use.[8] The prescription of these devices has the potential to provide noninvasive, long-term arrhythmia monitoring.[5,9]

Understanding the impact of smartwatch prescription for AF monitoring on critical patient-reported outcomes, including anxiety and quality of life, among stroke patients is vital to the meaningful integration of these devices into the clinical setting. Using data from a randomized controlled trial that enrolled older adults with a history of stroke, we examined the association between smartwatch prescription for AF detection and the patient-reported outcomes of anxiety, patient activation, and self-reported health.

Methods

Study population

As previously described, the Pulsewatch study is a randomized controlled trial developed to examine the accuracy, usability, and adherence of a smartwatch-based AF detection system in older stroke patients.[10] Participants were recruited from the cardiology and neurology clinics of a large academic tertiary care center in central Massachusetts. Participants were included if they (1) had a history of ischemic stroke or transient ischemic attack in the past 10 years, (2) were age 50 years or older, (3) were willing to use the Pulsewatch smartphone-smartwatch dyad, and (4) were proficient in English. Participants were excluded if they (1) had any contraindications to systemic anticoagulation, (2) had an allergy to medical-grade adhesives, or (3) had an implantable pacemaker.

Pulsewatch trial design

The trial was executed in 2 phases, a 14-day phase I and a 30-day phase II, and participants consented at baseline to participate in all phases of the study. Based on prespecified power calculations, a total of 120 participants were enrolled.[10] In phase I, participants underwent 3:1 randomization and were assigned to either a control group who received an FDA-approved Cardea SOLO patch monitor (Cardiac Insight, Seattle, WA) or an intervention group who were asked to use a Pulsewatch smartphone-smartwatch dyad daily as well as wear the Cardiac Insight Cardea SOLO patch monitor for 14 days, with the primary goal of assessing accuracy and usability of the Pulsewatch system. In phase II, participants underwent a 1:1 re-randomization to either a control group with no further heart rhythm monitoring or an intervention group who were asked to continue to use the Pulsewatch smartphone-smartwatch dyad daily for 30 days with the primary goal of assessing adherence to the dyad (Figure 1). Phase II intervention participants were also given a KardiaMobile single-lead electrocardiogram (ECG) (AliveCor, Mountain View, CA) to be used as needed for confirmation of AF if they received an alert from the Pulsewatch system.[10]

The present study focuses on data from phase II of the study, with the primary exposure of interest being randomization to the intervention group with prescription of a smartwatch for AF monitoring. The focus on phase II enabled us to study the largest possible study cohort and to examine possible relations between the exposure variable and psychological outcomes.

Pulsewatch wearable-smartphone app dyad for AF detection

The Pulsewatch system consisted of an Android OS smartwatch (Samsung Gear S3 or Samsung Galaxy Watch 3) paired to an Android smartphone. The system ran a proprietary application developed by co-investigators at the University of Connecticut in consultation with neurologists, cardiologists, stroke survivors, and their families using an iterative approach (Figure 2).[10]

The study application deployed on the Pulsewatch system used the Samsung smartwatches' photoplethysmography (PPG) sensor, running a program every 10 minutes, to monitor participants' R-R time as a function of the peak-to-peak interval between each cardiac cycle. Prior to AF detection, accelerometer data were used to eliminate highly motion artifact–contaminated PPG segments to minimize false AF detection. The sensor remained on for 5 minutes but could be extended based on PPG findings. During the "sensor-on" phase, a 1.5-minute event of AF triggered an alert for participants to "Hold still" for a further 1-minute analysis. An "Abnormality" alert appeared if AF was detected during the 1-minute monitoring period. If they received an AF alert,

Figure 2 Key screenshots of the Pulsewatch smartphone-smartwatch system given to intervention participants.

intervention participants could opt to confirm their rhythm on the provided AliveCor KardiaMobile single-lead ECG.

Intervention participants were asked to wear and charge the watch daily. The Pulsewatch app was designed to run in the background on the watch and phone and passively monitor for rhythm irregularities. At the end of the study period, all devices were mailed in for review.

Patient-reported outcomes

Participants completed 3 questionnaires at the start and end of phase II: Generalized Anxiety Disorder-7 (GAD7), Consumer Health Activation Index (CHAI), and the Health Survey SF-12 for physical and mental health (PCS and MCS, respectively). GAD7 is a widely used clinical assessment tool validated for the diagnosis and characterization of severity of anxiety. GAD7 score ranges from 0 to 21, with cut points of 5, 10, and 15 representing mild, moderate, and severe anxiety, respectively. Scores less than 4 indicate no anxiety.[11] CHAI is a measure of patient activation, or the ability or willingness to engage in one's health management. CHAI is a 10-item survey with scores from 0 to 100, with a higher score associated with greater physical functioning and fewer depressive symptoms.[12] The Health Survey SF-12 PCS and MCS are short-form health surveys designed to examine quality of life as it relates to both physical and mental health. Scores range from 0 to 100, with higher scores indicating higher quality of life.[13]

Outcomes of anxiety, patient activation, and self-reported health were measured as a change in respective scores at the start of phase II ("baseline") and after the 30-day study period. The outcome of anxiety was also measured as a binary outcome at 30 days, with positive anxiety defined as GAD7 >4.

Statistical analysis

Participants' baseline characteristics were compared between intervention group, who were prescribed smartwatches for AF monitoring, and control group, who were not given the smartwatch-smartphone dyad for AF monitoring, using Student t tests for continuous variables and χ^2 tests for categorical variables (Table 1). A logistic regression model was used to assess the association between smartwatch prescription and anxiety as a binary outcome (defined as GAD7 >4) after the 30-day study period. This model was adjusted for baseline anxiety, baseline patient activation, valvular disease, diabetes, anticoagulation use, and prior exposure to smartwatches. General estimating equations were also used to examine the association between smartwatch prescription for AF monitoring and anxiety as the change in GAD7, CHAI, and SF-12 scores before and after the study period. Favorable outcomes were indicated by lower GAD7 scores

Table 1 Baseline characteristics of participants based on randomized assignment to intervention (smartwatch-smartphone for atrial fibrillation monitoring) vs control (usual care) in phase II of the Pulsewatch study

Characteristics	Participants randomized to usual care (n = 56)	Participants randomized to use a smartwatch-smartphone (n = 54)	*P* value
Sociodemographic			
Age, mean (SD) years	66.2 (9.1)	63.7 (8.8)	.15
Female sex, n (%)	24 (42.8)	22 (40.7)	.82
Non-Hispanic White race, n (%)	49 (87.5)	49 (90.7)	.2
Body mass index, mean (SD)	31.9 (24.8)	29.9 (10.5)	.59
Patient-reported characteristics			
Anxiety, n (%)	15 (27.8)	20 (37.0)	.3
Consumer health activation index (high CHAI score vs not), n (%)	12 (21.8)	10 (18.9)	.70
Chronic disease self-efficacy			
Manage disease in general, mean (SD)	41.0 (7.7)	40.3 (8.1)	.65
Manage symptoms, mean (SD)	40.2 (9.6)	38.4 (10.5)	.36
SF-12 (self-reported health status)			
Physical component score, mean (SD)	47.6 (9.3)	48.3 (8.9)	.70
Mental component score, mean (SD)	51.6 (7.9)	50.1 (9.1)	.43
Medical history			
Congestive heart failure, n (%)	3 (5.4)	4 (7.4)	.66
Prior cardiac arrhythmia (not atrial fibrillation), n (%)	6 (10.7)	7 (13.0)	.71
Valvular disease, n (%)	1 (1.8)	9 (16.7)	<.05[†]
Vascular disease, n (%)	17 (30.4)	12 (22.2)	.33
Hypertension, n (%)	44 (78.6)	39 (72.2)	.44
Diabetes, n (%)	19 (33.9)	7 (13.0)	<.05[†]
Chronic pulmonary disease, n (%)	5 (8.9)	7 (13.0)	.50
Major bleeding event or predisposition to bleeding, n (%)	3 (5.4)	4 (7.4)	.66
Prior myocardial infarction, n (%)	8 (14.3)	9 (16.7)	.73
Antiarrhythmic medication, n (%)	1 (1.8)	1 (1.9)	.98
Medications			
Beta-blocker, n (%)	29 (51.8)	18 (33.3)	.05
Calcium channel blocker, n (%)	15 (26.8)	10 (18.5)	.30
Oral anticoagulant, n (%)	2 (3.4)	11 (20.4)	<.05[†]
Physiologic parameters			
Systolic BP, mean (SD) mm Hg	133.2 (17.7)	130.0 (14.9)	.31
Diastolic BP, mean (SD) mm Hg	76.1 (8.4)	76.3 (8.9)	.91
Heart rate, mean (SD) beats/min	71.4 (14.0)	75.1 (14.2)	.18

BP = blood pressure; CHAI = Consumer Health Activation Index.

[†]These variables were statistically significant. Adjusted analysis controlled for these factors.

correlating to less anxiety, and higher CHAI and SF-12 scores correlating to higher activation and quality of life, respectively. The longitudinal general estimating equations were adjusted for valvular disease, diabetes, anticoagulation use, and prior exposure to smartwatches. All statistical analyses were completed using SAS 9.3. The study protocol was approved by the University of Massachusetts Medical School Institutional Review Board (H00016067).

Results

Overall population

Of the initial 120 participants from phase I, a total of 110 underwent randomization in phase II of the Pulsewatch study. Of the 10 who left the study, 3 were lost to follow-up, and the remaining 7 withdrew owing to illness, privacy concerns, or an inability to continue wearing the patch monitor. In phase II, 54 participants were randomized to receive the smartwatch-smartphone dyad (intervention group) and 56 were randomized to receive no device for AF monitoring (control group). The intervention group had an average age of 64 ± 9 years; 41% were female and 91% White. The control group had an average age of 66 ± 9 years; 43% were female and 88% White. Seventy percent of intervention participants were novice smartwatch users, as opposed to 84% of controls. There were no significant differences in baseline characteristics between these groups (Table 1).

Baseline levels of anxiety, patient activation and self-reported health status

At baseline, rates of anxiety—measured using the GAD7—were similar between intervention and control participants (37% vs 28%, respectively, $P = .3$) and are comparable to anxiety rates among stroke survivors in the general population—commonly cited as 30%.[14] At baseline, the percentage of participants who scored in the "high" range of the CHAI, suggesting high levels of patient activation, were comparable

Table 2 Changes in anxiety, patient activation, and self-reported physical and mental health among smartwatch users (intervention group) and non-users (control group) over the course of the 30-day study period

	Anxiety (vs no anxiety)[†]	Change in anxiety level (GAD7 score)[‡§]		Change in patient activation (CHAI score)[‡§]		Change in self-reported physical health (SF-12 PCS)[‡§]		Change in self-reported mental health (SF-12 MCS)[‡§]	
	aOR (95% CI)	Estimate (standard error)	*P* value	Estimate (standard error)	*P* value	Estimate (standard error)	*P* value	Estimate (standard error)	*P* value
Smartwatch users (vs no smartwatch use)	1.90 (0.84–4.32)	1.41 (0.81)	.08	1.27 (2.48)	.61	1.74 (1.89)	.36	-1.90 (1.52)	.21

CHAI = Consumer Health Activation Index; GAD7 = Generalized Anxiety Disorder-7; SF-12 MCS = short-form survey, mental component score; PCS = short-form survey, physical component score.
[†]Adjusted for baseline anxiety, baseline patient activation, valvular disease, diabetes, anticoagulant use, and exposure to prior smartwatch use in "phase 1" of study.
[‡]Adjusted for valvular disease, diabetes, anticoagulant use, and exposure to prior smartwatch use in "phase 1" of study.
[§]A higher GAD7 indicates poorer psychosocial outcome (anxiety), while higher CHAI or SF-12 indicates better psychosocial outcomes (patient activation and self-reported health, respectively).

between intervention and control participants (19% vs 22% respectively, $P = .7$). Self-reported health was measured as both physical (PCS) and mental health component scores (MCS). There were no significant differences between PCS or MCS among intervention and control participants at baseline (PCS, 47.6 vs 48.3, respectively, $P = .7$; MCS, 51.6 vs 50.1, respectively, $P = .4$).

Changes in patient-reported outcomes over the 30-day follow-up period

Participants who were prescribed a smartwatch for AF monitoring did not have a statistically significant change in GAD7 score (β 1.41, $P = .08$, Table 2), nor was the prescription of a smartwatch associated with anxiety at 30-day follow-up (GAD7 score >4, adjusted odds ratio 1.90, 95% CI 0.84–4.32, Table 2) compared to those who were not prescribed smartwatches. Of note, the unadjusted model did show a statistically significant change in GAD7 score, but did not show a significant change in prevalence of anxiety (Table 3). Similarly, after adjusting for confounders, participants who were prescribed smartwatches did not have a statistically significant change in patient activation (CHAI, β 1.27, $P = .61$, Table 2), self-reported physical health (PCS, β 1.74, $P = .36$, Table 2), or self-reported mental health (MCS, β -1.90, $P = .21$, Table 2) as compared with those who were not prescribed any digital health tools for AF monitoring.

Alerts and incident AF

Among the intervention group, there were 6 (12%) participants who received alerts prompting them to "Hold still," indicating possible AF. Subsequent rhythm analysis by the Pulsewatch system revealed 3 participants (6%) to have incident AF. In a sensitivity analysis, removing participants who received alerts, there was no observed statistically significant change in the outcomes.

Discussion

In this randomized controlled trial examining the accuracy and usability of smartwatch prescription for AF monitoring in stroke survivors, we did not observe adverse sequelae of smartwatch use on anxiety, self-activation, or self-reported physical or mental health. Our study stands in contrast with smaller, nonrandomized studies that suggest that use of commercial wearables may cause harm to patients.[5,15] Our study is unique in that we were able to examine changes in key patient-reported outcomes among older adults with stroke randomized to smartwatch use for AF monitoring. Furthermore, our targeted assessment of key, patient-reported outcomes adds more knowledge of patients' subjective experience to the current literature.

The unknown effects that the use of smartwatches for AF monitoring may have on anxiety, depression, and other psychological factors remains a potential barrier to their prescription. Stroke survivors are known to be at increased risk of anxiety, depression, and apathy compared to the general population, suggesting that the impact of AF detection in the

Table 3 Unadjusted changes in anxiety, patient activation, and self-reported physical and mental health among smartwatch users (intervention group) and non-users (control group) over the course of the 30-day study period

	Anxiety (vs no anxiety)	Change in anxiety level (GAD7 score)		Change in patient activation (CHAI score)		Change in self-reported physical health (SF-12 PCS)		Change in self-reported mental health (SF-12 MCS)	
	OR (95% CI)	Estimate (standard error)	*P* value	Estimate (standard error)	*P* value	Estimate (standard error)	*P* value	Estimate (standard error)	*P* value
Smartwatch users (vs no smartwatch use)	1.89 (0.92–3.87)	1.55 (0.70)	.03	-0.55 (2.36)	.82	0.63 (1.89)	.74	-2.20 (1.36)	.10

CHAI = Consumer Health Activation Index; GAD7 = Generalized Anxiety Disorder-7; SF-12 MCS = short-form survey, mental component score; PCS = short-form survey, physical component score.
Note: A higher GAD7 indicates poorer psychosocial outcome (anxiety), while higher CHAI or SF-12 indicates better psychosocial outcomes (patient activation and self-reported health, respectively).

general population may not be generalizable to stroke patients.[14] Furthermore, despite increasing technology use among older adults, there remains a significant lack of confidence in stroke survivors' ability to use wearable devices.[16] Being prescribed medical devices that one does not feel confident operating can be a potential source of stress and anxiety.

At baseline, 30% of participants in our study had anxiety. The burden of anxiety in our study is higher than observed in general populations but is similar to prior studies including stroke survivors.[1,14] A recent randomized trial included participants who were asked to self-monitor for AF after catheter ablation using KardiaMobile's single-lead ECG and its associated smartphone app. As was observed in our study, there was no association between self-monitoring for AF and increased anxiety levels among participants over the study period.[17] Notably, the participant demographics and indications for AF monitoring among postablation and poststroke patients are different; however, the lack of a strong signal toward increased anxiety with AF monitoring is consistent.

Similarly, we did not observe that smartwatch-smartphone use for AF monitoring impacted patient engagement over the 30-day follow-up. Despite the concerns that increased use of technology has the potential to overwhelm older adults, our findings suggest that even with the prescription of multiple digital health tools, stroke survivors do not disengage from their health care. This may be explained by the fact that the smartwatch-smartphone dyad was not onerous to use, a finding supported by a mixed-methods study of Pulsewatch participants describing that the smartwatch was "highly usable."[8] Considering that the design of the smartwatch-smartphone dyad was not intended to promote engagement, but instead was intended to promote adherence to passive monitoring for AF, our findings are expected.

Smartwatch use for AF monitoring among older stroke survivors did not relate to participants' perception of their own physical or mental health in this study. Notably, we previously showed that receipt of a smartwatch alert (n = 16, 17% of participants) was associated with lower self-reported mental well-being among Pulsewatch participants but was not associated with increased anxiety.[18] Taken in aggregate, these findings suggest that use of the smartwatch per se does not adversely affect mental or physical well-being, but receipt of a possible AF alert may introduce stress or reduce perceived well-being.[14]

Implications for broader use of commercial wearables for rhythm monitoring

Despite the absence of robust evidence demonstrating a clinical benefit from their use, an increasing proportion of cardiologists and heart rhythm specialists are recommending the use of commercial wearables for AF monitoring.[19] Our findings suggest that older adults with prior stroke or transient ischemic attacks are able to use a smartwatch-smartphone dyad without adverse effects on engagement, anxiety, or quality of life, reinforcing findings from prior studies

demonstrating that older adults find digital health tools useful and acceptable, particularly when they are involved with determining how the technology is incorporated into their care.[20] It is important to note that all Pulsewatch study participants received significant training at baseline on the proper use of the smartwatch and smartphone. This may not occur routinely in clinical practice, and may lead to technology being used inappropriately by older patients. In a survey of 1601 heart rhythm health care providers examining perspectives on commercially available devices for detecting AF, 36.4% noted that patients struggle to use these devices as the provider intended.[19] These providers' concerns highlight the need for the thoughtful integration of technology into AF management, rooted in patient education and shared decision making. Large, real-world studies are needed to validate our findings, but our results suggest that thoughtful training-supported technology deployment enables stroke survivors to successfully use wearables for AF monitoring.

Strengths and limitations

Our study has strengths and limitations. The Pulsewatch Study was a multiphase randomized controlled trial that examined older stroke survivors. With a mean age of 65 and a significant burden of comorbidity, our cohort represents a significantly sicker population than was included in studies such as the Huawei Heart Study, Apple Heart Study, or Fitbit Heart Study.[5,16,21] Our study and analyses were conducted on participants randomly assigned to use a smartwatch-smartphone irrespective of their prior experiences with technology, thereby enhancing the generalizability of our findings to clinical practice.

Several limitations should be considered when interpreting our findings. PPG signals do not exhibit p waves, which are used to further validate the presence of AF on traditional ECG systems. However, for wearable ECG applications, typically, reliance on the observance of p waves would require data with minimal motion. Although the Pulsewatch system only uses pulse-to-pulse intervals for AF detection, PPG data can provide highly accurate AF detection when a motion artifact algorithm is used to detect and remove noisy segments so that only noise-free data segments are analyzed.[22,23] When motion artifacts are minimal, random pulse-to-pulse interval characteristics are preserved in PPG signals. This is similar to irregular R-R intervals—that suggest AF—being preserved in the ECG when motion artifacts are minimal. Our embedded motion artifact detection algorithm in the Pulsewatch system was based on threshold and statistical features that were derived using training data that were collected in a controlled environment from only 37 subjects.[23] The inaccuracy in AF detection from the embedded algorithm during our long-term monitoring in this real-life setting clinical trial can be overcome when we further train the artificial intelligence algorithms using a much larger dataset.

Although we were powered for our primary outcome of AF detection, the current analysis was conducted post hoc, and our moderate sample size may have impacted our ability to detect statistically significant differences between groups. Additionally, 30 days may be a limited time period in which to see drastic, subjective changes. We had a relatively low incidence of alerts, but longer use of wearables may reveal larger changes in patient-reported outcomes should a larger proportion of participants receive alerts. However, it is also possible that as participants gain greater familiarity with the use of the wearable, they would be less adversely affected by their use. Also of note, this was a voluntary study using surveys. Although the surveys are standardized, validated, and widely accepted clinical and research tools, there is subjectivity in interpretation, recall, and preconceived notions that are inherent in this type of analysis.

Finally, our cohort was composed largely of non-Hispanic White stroke survivors, and findings may not generalize to individuals from other racial or ethnic groups.

Conclusion

Our study findings suggest that the use of smartwatches by stroke survivors for AF monitoring does not adversely affect key patient-reported outcomes. Further real-world studies are needed to evaluate the impact of longer-term use of cardiac wearables on patient engagement and well-being in cohorts of patients at high risk for AF.

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Authorship

All authors attest that they meet the current ICMJE criteria for authorship.

Patient Consent

All patients provided written informed consent.

Ethics Statement

The authors designed the study and gathered and analyzed the data according to the Helsinki Declaration guidelines on human research and CONSORT guidelines for clinical research. The research protocol used in this study was reviewed and approved by the institutional review board.

Disclaimer

Given his role as Editor-in-Chief, Dr David McManus had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Dr David Duncker. Given his role as Associate Editor, Dr Ki Chon had no involvement in the peer review of this article and has no access to information regarding its peer review.

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