scientific reports

Check for updates

OPEN

Randomized trial of smartphone application and bed sensor for atrial fibrillation detection in high-risk patients

Joonas Lehto[1], Joel Nuotio[1], Arto Relander[1], Jussi Jaakkola[1], Olli Lahdenoja[2], Tuija Vasankari[1], Arman Anzanpour[2], Ismail Elnaggar[2], Rami Rekola[2], Jonas Sandelin[2], Tero Hurnanen[2], Juhani KE Airaksinen[1], Tero Koivisto[2] & Tuomas O. Kiviniemi[1,3]✉

This two-arm single-center exploratory randomized controlled trial evaluated the efficacy of prolonged rhythm monitoring in atrial fibrillation (AF) detection after an invasive cardiac procedure. Altogether 150 patients were enrolled. In the intervention group (IG), a bed sensor (EMFIT QS) and twice-daily smartphone recordings (CardioSignal app) were used, followed by a 12-lead ECG and a continuous three-to-seven-day ECG monitoring if alerts occurred. The control group (CG) received usual care. Overall, 78 patients were assigned to the IG and 72 to CG. During the three-month follow-up, AF was detected in 6/78 (7.7%) patients in the IG and in 0/72 (0.0%) in the CG (absolute risk difference 7.7%, 95% CI 1.8–13.6%, $p = 0.029$). After exclusion of patients who withdrew before the 3-month follow-up, 33/68 (48.5%) patients had alarms not leading to ECG-verified AF diagnosis, indicating that the current approach, in its present form, is not suitable for routine clinical implementation. Future studies should concentrate on minimizing alarms not leading to AF diagnosis when developing these novel non-ECG-based technologies. ClinicalTrials.gov Identifier: NCT05351775, 2022/04/28.

Keywords Atrial fibrillation, Screening, Cardiac surgery, Gyrocardiography, Ballistocardiography

Abbreviations

AF	Atrial fibrillation
CABG	Coronary artery bypass graft surgery
CHA_2DS_2-VASc	Congestive heart failure, Hypertension, Age ≥ 75 years, Diabetes mellitus, Stroke, Vascular disease, Age 65–74 years, Female
CG	Control group
DOAC	Direct oral anticoagulant
ECG	Electrocardiogram
HAS-BLED	Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/alcohol usage
IG	Intervention group
NYHA	New York Heart Association functional classification
PCI	Percutaneous coronary intervention
SAVR	Surgical aortic valve replacement
SR	Sinus rhythm
TAVR	Transcatheter aortic valve replacement

It is estimated that over 10% of patients with atrial fibrillation (AF) remain undiagnosed[1,2]. Yet, primary prevention screening for AF in asymptomatic patients remains debatable[3]. Specifically, randomized clinical trials are lacking to determine which patients to screen and the best way to screen. Although intermittent and continuous cardiac monitoring have high diagnostic yield, they are resource-intensive, and their feasibility and clinical impact remain unclear. While current guidelines from the American Heart Association and the American College of Cardiology do not recommend AF screening for high-risk patients, the European Society

[1]Heart Center, Turku University Hospital and University of Turku, Turku, Finland. [2]Department of Computing, University of Turku, Turku, Finland. [3]Heart Center, Turku University Hospital and University of Turku T-hospital, TE6, Hämeentie 11, Turku 20521, Finland. ✉email: tuoski@utu.fi

of Cardiology guidelines recommend opportunistic screening for individuals aged 65 years or older and consideration of systematic ECG screening for those at high risk for stroke[4,5].

The randomized CARE-DETECT trial aimed to determine whether a combination of active screening using a smartphone application and passive screening with a bed sensor, compared to routine care, enhances the detection of new AF and is feasible for clinical use in patients at increased risk of stroke after cardiac interventions.

Results

Study cohort

In the Part II of the trial, between Oct 2022 and Jan 2024, altogether 273 patients were screened and 150 (median age 71.0 [interquartile range 66.0–76.0] years; 46 women [30.7%]) were randomly assigned to either the intervention group (IG) ($n=78$) or the control group (CG) ($n=72$) within a median of 1 day (range 0–9) after the index procedure during the index hospitalization (Fig. 1). The assigned interventions were initiated by all patients in both groups. Overall, 11 patients in the IG and one patient in the CG withdrew from the study; 11 withdrawals occurred within the first three months post-enrollment. In the IG, most withdrawals ($n=7$) were due to patients opting not to continue in the study, while withdrawals due to difficulties in the management of the study devices were rare ($n=2$). Other reasons included network connection problems and death due to ischemic heart disease. No device-related serious adverse events were reported. No patients were lost to follow-up.

Baseline characteristics

Baseline characteristics in both the IG and CG are detailed in Table 1. The proportion of patients undergoing PCI was 72.7%, TAVR 13.3%, CABG 11.3%, and SAVR with or without concomitant CABG 2.7% in the whole cohort, without significant differences between the groups (Table 2). Overall, 21 patients did not meet the original inclusion criteria but qualified under the extended enrichment criteria outlined in the protocol amendment. There were no significant differences between the groups in clinical variables, and the only difference in discharge medications was more common use of acetylsalicylic acid in the CG.

Primary outcome

The primary endpoint, the occurrence of new AF within the three-month follow-up period, was observed in 6 (7.7%) patients in the IG but in none of the patients in the CG (absolute risk difference 7.7%, 95% CI 1.8–13.6%, $p=0.029$). Of these episodes, five occurred after the index hospitalization, and median time to diagnosis was 34 (interquartile range 1.5–65) days (Fig. 2). Four (66.7%) of the episodes occurred after PCI and two (33.3%) after CABG. All the patients with new AF were male. The mobile phone app was the first device to indicate AF

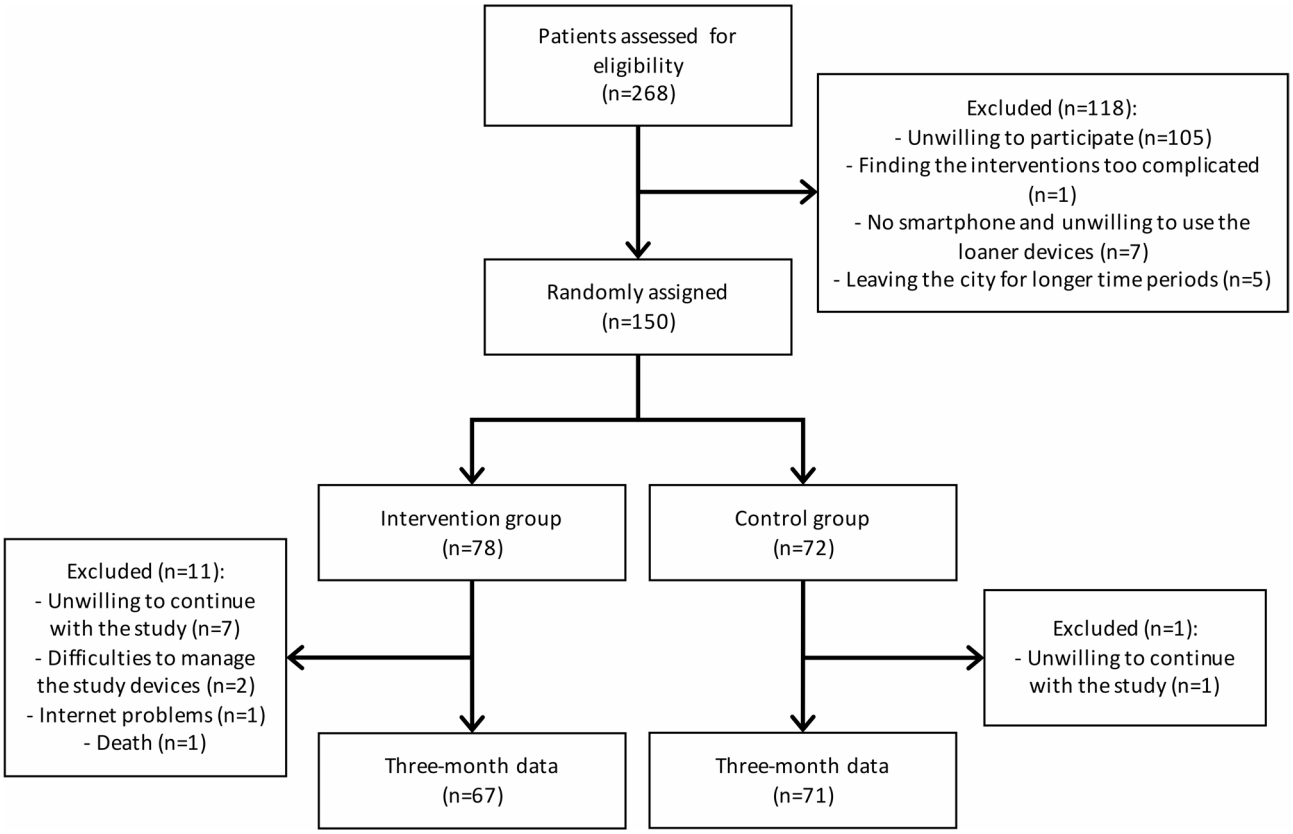

Fig. 1. Flow chart of Part II of the CARE-DETECT trial.

	Intervention $n=78$	Control $n=72$	p-value
Male sex	54 (69.2)	50 (69.4)	1.000
Age	72.0 (66.0–76.8)	70.0 (66.0–74.5)	0.352
Permanent anticoagulation therapy due to AF	0	0	NA
Pacemaker	1 (1.3)	0	1.000
Treatment for hypertension	63 (80.8)	59 (81.9)	1.000
Treatment for hypercholesterolemia	71 (91.0)	69 (95.8)	0.331
Diabetes	26 (33.3)	22 (30.6)	0.850
Previous stroke	9 (11.5)	2 (2.8)	0.081
Previous transient ischemic attack	4 (5.1)	2 (2.8)	0.683
Coronary artery disease	71 (91.0)	66 (91.7)	1.000
History of myocardial infarction	13 (16.7)	6 (8.3)	0.198
Extracardiac arteriopathy	4 (5.1)	1 (1.4)	0.369
Heart failure	5 (6.4)	8 (11.1)	0.464
Body mass index (kg/m^2)	29.1 (25.6–32.6)	28.7 (25.0–32.0)	0.478
Moderate or high-risk alcohol consumption[a]	2 (2.6)	3 (4.2)	0.927
Active smoking	13 (16.7)	11 (15.3)	0.993
NYHA class III or more	23 (29.9)	18 (25.0)	0.630
Canadian Cardiovascular Society angina grade III or more	36 (46.8)	31 (43.1)	0.773
CHA_2DS_2-VASc score	4.0 (3.0–5.0)	4.0 (3.0–4.0)	0.456
HAS-BLED score	2.0 (2.0–2.0)	2.0 (2.0–2.0)	0.434

Table 1. Demographic and clinical characteristics of the patients at baseline. Values denote n (%), mean ± standard deviation, or median (25th – 75th percentile), as appropriate. Abbreviations: AF, atrial fibrillation; CHA2DS2-VASc, Congestive heart failure, Hypertension, Age ≥ 75 years, Diabetes mellitus, Stroke, Vascular disease, Age 65–74 years, Female; HAS-BLED, Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/alcohol usage; NYHA, the New York Heart Association functional classification. [a]Men: ≥14 servings/week; women: ≥7 servings/week.

paroxysm in 3 (50.0%) of the detected episodes, and the diagnoses were confirmed with either ECG or three-to-seven-day ECG Holter patch. The remaining paroxysms were initially detected via ECG, telemetry during the index hospitalization, or pacemaker remote monitoring. Although the bed sensor was not the first device to generate an alert in any paroxysm, bed sensor alerts were present in 3 (50.0%) AF episodes, whereas mobile phone app alerts occurred in 4 (66.7%). Among the patients in the IG who completed the three-month follow-up, any device alert was detected in 39 (57.4%) patients leading to further investigations (ECG, ECG Holter) in 94.9% of cases. Mobile phone app alerts were detected in 29 (42.6%), and bed sensor alerts in 21 (30.9%) patients. In most cases, the alerts were repeated, with a median of 5 (interquartile range 3–10) alerts overall, 4 (interquartile range 2–9) mobile phone alerts, and 3 (interquartile range 2–5) bed sensor alerts. Altogether 47 (7.8 tests per true AF diagnosis) long-term ECG Holter tests were initiated due to these alerts, and they revealed sinus arrhythmia or either supraventricular or ventricular extrasystoles as the likely causes of the alerts in most of the cases. Among patients with at least one device alert, the patient-level positive predictive value was 15.4% (6/39). Due to the high number of alerts not leading to ECG-verified AF diagnosis, AF burden could not be reliably assessed.

Adverse events and quality of life

One death due to ischemic heart disease was observed in the IG during the follow-up period. No cerebrovascular events were detected. No significant differences were observed in the EQ-5D quality-of-life questionnaire before the operation or at three-month follow-up (Supplementary Table 2). Similarly, there were no significant differences in the Spielberger 6-item Anxiety Questionnaire before the operation, and only minor differences were detected at three-month follow-up.

Discussion

This randomized clinical feasibility trial demonstrated that, although prolonged rhythm monitoring using a bed sensor and a smartphone app increased AF detection compared to usual care in patients undergoing invasive cardiac procedures and at high risk for stroke and AF, the proposed multi-device approach is not suitable for routine clinical implementation because of the high number of alarms not leading to ECG-verified AF diagnosis. This population seems feasible for opportunistic AF screening, although the benefit of permanent anticoagulation in this population needs to be confirmed.

There is controversy regarding the usefulness of population-level AF screening in asymptomatic patients[3,6]. Specifically, there is a clinical need to identify patients who may benefit from AF screening and to determine the optimal screening method and timing. CARE-DETECT trial provides evidence that patients at high risk for stroke undergoing invasive cardiac procedures are prone to AF paroxysms within three months after the

	Intervention $n=78$	Control $n=72$	p-value
Operation type			0.919
PCI	55 (70.5)	54 (75.0)	
TAVR	11 (14.1)	9 (12.5)	
CABG	10 (12.8)	7 (9.7)	
SAVR±CABG	2 (2.6)	2 (2.8)	
Acute coronary syndrome			0.694
No	43 (55.1)	39 (54.2)	
ST-elevation myocardial infarction	11 (14.1)	15 (20.8)	
Non-ST-elevation myocardial infarction	21 (26.9)	16 (22.2)	
Unstable angina pectoris	3 (3.8)	2 (2.8)	
Operation urgency			0.724
Elective	42 (54.5)	40 (55.6)	
Urgent	23 (29.9)	18 (25.0)	
Emergency	12 (15.6)	14 (19.4)	
Preoperative estimated glomerular filtration rate (ml/min/1.73 m^2)	87.0 (66.6–96.9)	79.5 (68.3–88.1)	0.293
Length of hospitalization (days)	2.0 (0.0–3.0)	2.0 (0.0–3.0)	0.647
Discharge medications			
Acetylsalicylic acid	66 (84.6)	69 (95.8)	0.044
P2Y12 inhibitor	56 (71.8)	55 (76.4)	0.649
DOAC	4 (5.1)	0 (0.0)	0.121
Warfarin	3 (3.8)	2 (2.8)	1.000
Low molecular weight heparin	3 (3.8)	1 (1.4)	0.621
Beta blocker	42 (53.8)	43 (59.7)	0.575
Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker	58 (74.4)	58 (80.6)	0.477
Calcium channel blocker	26 (33.3)	25 (34.7)	0.994
Statin	70 (89.7)	66 (91.7)	0.902
Metformin	22 (28.2)	17 (23.6)	0.649
Sodium-glucose cotransporter-2 inhibitor	11 (14.1)	18 (25.0)	0.138
Glucagon-like peptide-1 analog	6 (7.7)	4 (5.6)	0.747

Table 2. Periprocedural characteristics and discharge medications. Values denote n (%), mean ± standard deviation, or median (25th – 75th percentile), as appropriate. Abbreviations: CABG, coronary artery bypass graft surgery; DOAC, direct oral anticoagulant; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.

procedure, with a number needed to screen to diagnose one AF being 13. This finding has significant clinical implications, as many opportunistic screening methods have higher numbers needed to screen. For example, the widely used opportunistic ECG- or pulse-palpation-based screening methods yield a number needed to screen of 83 in people aged ≥ 65 years[7]. Also, the study population was enriched for AF and stroke risk using ECG (prolonged P wave criterion) and echocardiographic criteria (enlarged left atrial diameter) indicative of atrial cardiomyopathy. Although these markers have been previously recognized[8–10], this was the first time they were used in an AF screening setting within a randomized controlled trial. Markers of atrial cardiomyopathy are associated with a higher occurrence of AF in the general population[8] and higher AF burden in those with paroxysmal AF[11], and their utilization in AF screening studies is therefore encouraged[12].

Previous studies have reported various methods for successful AF screening, exploiting standard 12-lead ECG, pulse palpation, smartwatch, smartphone extensions, blood pressure monitor, implantable cardiac monitors, ambulatory ECG patch, and ECG Holter[3,6]. However, the clinical feasibility is often limited by high costs per detected AF driven by costly devices, high number needed to screen, or further investigations required for diagnosis validation. To achieve the feasibility, most of the previous studies have concentrated in patients at high AF and/or stroke risk, typically expressed by older age. Using cardiac procedures as a screening trigger may represent a sweet spot of timing, as these procedures can both unmask an underlying predisposition to AF and trigger previously undiagnosed AF[13]. It is well known that postoperative AF is a common clinical problem after cardiac surgery, with incidences ranging from 15% to 60%, depending on the type of procedure[14]. The SEARCH-AF study tested for the use of 30-day continuous cardiac rhythm monitoring with a wearable ECG patch in high AF and stroke-risk patients after cardiac surgery and found a notably high AF occurrence in the intervention arm (19.6% vs. 1.7%, $p< 0.001$)[15]. Although the results were promising, this is a relatively restricted population

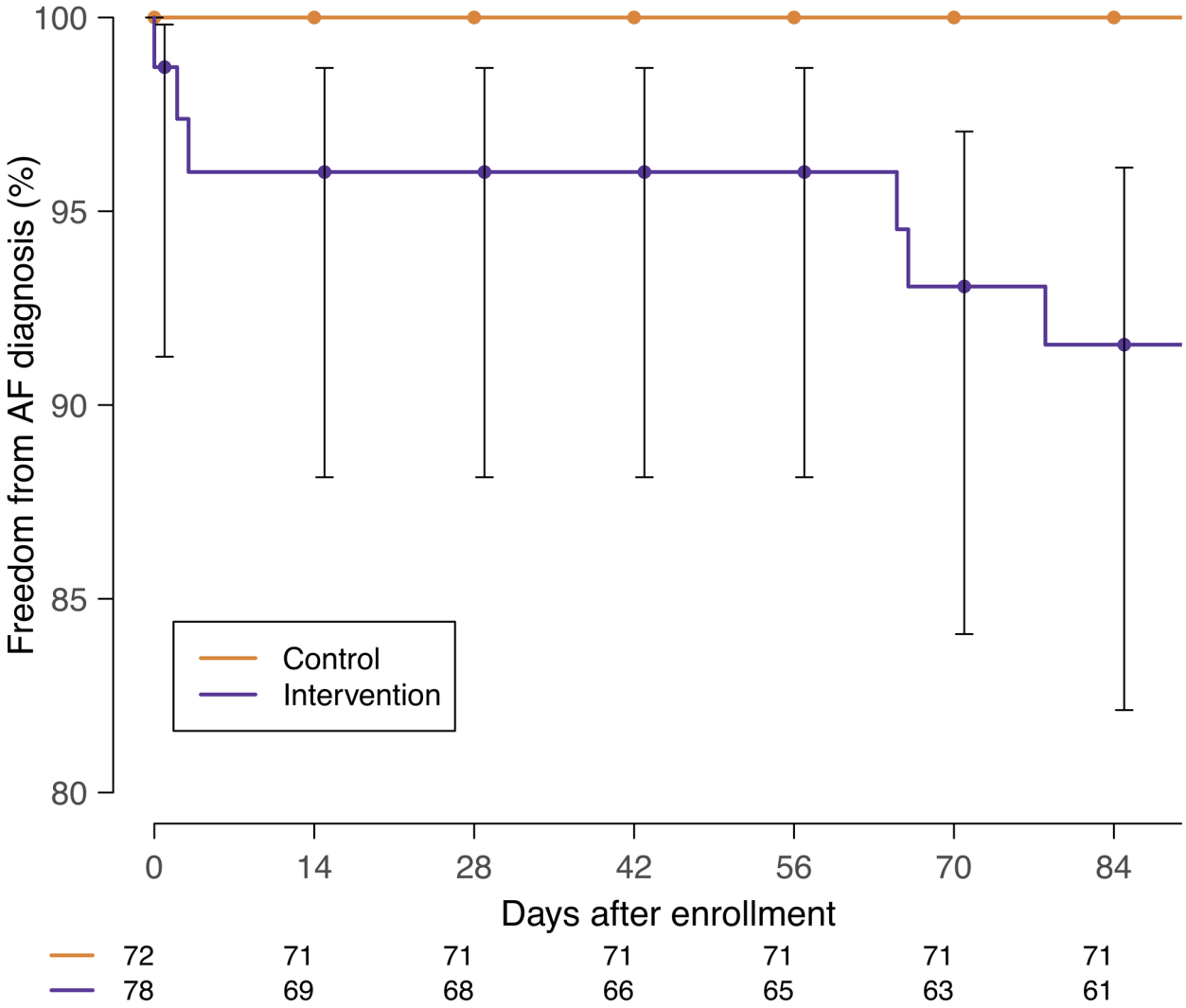

Fig. 2. New-onset atrial fibrillation (AF) at three months (primary outcome).

limiting the clinical implication of the results. The incidence of AF after PCI is less well-known, but the risk is significantly lower compared to surgery and is more dependent on patient characteristics[16–18]. Furthermore, a large meta-analysis indicates that new-onset AF occurs in approximately 10% of patients after TAVR[19]. Whether TAVR is a causal factor or an indicator of patients with more comorbidities remains unclear. In our study, 7.7% of the patients in the IG experienced new-onset AF during the three-month follow-up. The relatively low incidence rate is likely driven by the high proportion of patients (> 70%) that underwent PCI, which is associated with a lower risk of postoperative AF compared to cardiac surgery or TAVR. No AF was observed in the CG during the follow-up period, but this is expected to change with extended follow-up. Similarly, in the CRYSTAL AF study, only 1.7% of control patients were diagnosed with AF during a six-month follow-up[20].

One of the key findings of the presents study was that both the bed sensor algorithm and the smartphone app generated a high number of alarms that did not lead to ECG-verified AF diagnosis. This finding underscores a problem that clinicians frequently face with novel AF detection devices and software: the lack of correlation with clinical AF. Although sensitivity and specificity are often high, especially repeated measurements using non-ECG-based methods can produce 'AF alerts' that cannot be verified using the gold standard ECG. This discrepancy is likely explained by rhythm disturbances other than AF causing pulse irregularity, such as atrial or ventricular ectopy, sinus arrhythmia, or ectopic atrial tachycardia. Although it is also possible that some of the paroxysms are so brief that they cannot be subsequently confirmed with ECG or ECG Holter monitoring, some studies have called similar cases 'subclinical AF'[21], which is at least questionable and should be avoided. The high number of alerts not leading to ECG-verified AF diagnosis is particularly important due to substantial resources required for ECG-based follow-up investigations. In the present study, these patients received a standard ECG and a three-to-seven-day ECG Holter recording, repeated up to three times in the presence of recurrent alarms, resulting in a substantial diagnostic workload despite the use of modern analysis software. The requirement for ECG-verification represents a major limitation of all non-ECG-based devices, and the resulting overall workload – including the need for further diagnostic investigations – must be considered when these devices are used in

a clinical practice. Nevertheless, the patient-level positive predictive value for ECG-verified AF in the present study was 15.4%, which is substantially lower than that reported in partially comparable settings in the Apple Heart Study (34%)[22] and the MAFA II study (87%)[23]; however, pre-existing AF was not excluded in the latter study. Minimizing alarms that do not lead to AF diagnosis should be a high priority in future trials to reduce diagnostic workload and associated costs. Furthermore, it has been stated that we should consider refocusing digital health interventions on *screening out* rather than *screening in* AF[24]. Besides diagnostic workload, the potential psychological impact of frequent alerts not leading to a confirmed diagnosis must be considered. Although no relevant differences in quality-of-life or anxiety scores were observed between IG and CG at three-months, device alerts are nonetheless likely to provoke anxiety. In theory, the alert-induced sympathetic activation could even contribute to tachyarrhythmias or facilitate AF paroxysms in susceptible individuals.

It also remains unclear how long paroxysms of AF are relevant for the initiation of permanent oral anticoagulation therapy. The NOAH-AFNET 6 and ARTESiA trials assessed the efficacy and safety of oral anticoagulation treatment in device-detected AF[25,26]. A meta-analysis of the two trials showed that anticoagulation for subclinical AF lasting 6 min or longer resulted in a 32% reduction in stroke risk[27]. However, the incidence of stroke was also low in the placebo group, and the stroke reduction came at the expense of a 62% higher risk of major bleeding. Although clinical AF (NOAH-AFNET 6: surface-ECG-verified; ARTESiA: surface-ECG-verified or device-detected AF > 24 h) developed in 6.3–8.7% of patients per year, the clinical AF diagnosis was not required for the treatment initiation. Similarly, the LOOP study screened for > 6-minute AF episodes with an implantable loop recorder and was not able to demonstrate a significant reduction in the primary endpoint of stroke and systemic embolism[28]. Therefore, based on the current literature, the optimal threshold of subclinical AF burden for initiation of oral anticoagulation likely lies between 6 min and several hours, but individual thromboembolic risk and transient triggers such as cardiothoracic surgery substantially influence the risk-benefit ratio. However, the requirement for 12-lead ECG or ECG Holter verification, as employed in the present trial, is likely to correlate with a higher incidence of stroke among individuals diagnosed with AF, while potentially yielding more significant health benefits from anticoagulation treatment. Nevertheless, the risk-benefit ratio of permanent anticoagulation in this patient population remains to be elucidated. In the present study, only one additional AF diagnosis was made using the ECG Holter monitoring. Therefore, conventional 12-lead ECG alone may be the preferred method for AF verification to mitigate the high diagnostic workload and costs associated with long-term ECG Holter monitoring.

This trial has limitations that need to be considered when interpreting the findings. It was a single-center trial with a limited number of patients. Without continuous rhythm monitoring, short AF paroxysms may have gone unrecognized. Additionally, preoperative cardiac monitoring to rule out the presence of subclinical AF before the operation was not performed. Moreover, the CG received only standard clinical monitoring, and no comparisons were made with other available AF screening methods. Consequently, the higher AF detection rate in the IG may reflect increased surveillance rather than a higher true incidence. The number of patients was also too low to analyze subgroups that might be more prone to AF. The sample size was reduced due to the high number of alarms not leading to AF diagnosis, leading to an underpowered analysis of clinical endpoints; this reduction was driven by pragmatic rather than statistical considerations. In addition, the enrichment criteria were broadened during the study, which may have affected the homogeneity of the population and study comparability. The high number of alarms not leading to AF diagnosis also precluded the analysis of AF burden, one of the primary endpoints of the study. Furthermore, the sample size and primary endpoint follow-up duration were not powered to detect differences in major adverse cardiovascular outcomes, stroke rates in comparison with the presence of AF, or the risk-benefit assessment of anticoagulation treatment in this postoperative patient group. Therefore, the benefit of permanent anticoagulation as well as the cost-effectiveness of the screening procedures should be carefully evaluated before widespread screening of this patient population. Although the bed sensor algorithm alerted in half of the patients diagnosed with AF, none of the paroxysms were initially detected by it. Therefore, the added value of the bed sensor algorithm appears to be low in this two-device screening setting. These devices cannot be used without proper smartphones or an internet connection at home, though these commodities are widely available globally. However, we provided a loaner smartphone to participants who might not have otherwise been able to participate, in order to improve the generalizability of the methods used. In accordance with the guidelines in place at the time of study design, the CHA_2DS_2-VASc score was used as an inclusion criterion instead of the currently recommended CHA_2DS_2-VA score[4]. However, overall 99.3% of the patients would have fulfilled the inclusion criteria had the CHA_2DS_2-VA score been applied. Notably, the exclusion rate was relatively high (44%, Fig. 1), primarily due to patients' unwillingness to participate. Unwillingness to continue with the study was also the most frequent reason for withdrawal in the IG. Combined with difficulties managing the study devices, this led to nine withdrawals in the IG, compared to only one in the CG. Although the intervention burden appeared relatively low – comprising bed sensor installation, a few minutes of daily smartphone app measurements, and ECG and three-to-seven-day ECG-monitoring when alerts occurred, the patients still perceived the monitoring burdensome. This lack of commitment and motivation is an important practical limitation in digital health interventions that limits the real-world applicability of the methods.

In conclusion, this trial demonstrated that patients at high risk of stroke and AF who have recently undergone a cardiac procedure seem a feasible target population for AF screening, although the benefit of permanent anticoagulation needs to be confirmed before widespread screening of the population. However, both the bed sensor algorithm developed in this trial and the smartphone app demonstrated a high number of alarms that did not lead to ECG-verified AF diagnosis, consequently causing extensive resource consumption. Therefore, the current approach, in its present form, is not suitable for routine clinical implementation. Future studies should concentrate on minimizing alarms not leading to AF diagnosis when developing novel non-ECG-based technologies.

Methods

Study design and participants

Cardiovascular Research Consortium - a Randomized Prospective Trial to Assess Low Workload Concept for the Detection of Silent Atrial Fibrillation (AF) and Atrial Fibrillation Burden in Patients at High Risk of AF and Stroke (CARE-DETECT trial) was an investigator-initiated, prospective, randomized, open-label, single-center trial conducted at Heart Center, Turku University Hospital. The study consisted of two parts: Part I, which is detailed in a previous publication[29], and the randomized Part II, which is presented here.

In Part I of the trial, a bed sensor algorithm was developed for the randomized part (Part II) of the trial. Patients aged ≥ 18 years hospitalized at the Heart Center were screened for the study. Overall, 62 patients in AF and 62 in sinus rhythm (SR) were enrolled. All study subjects were monitored with an ECG Holter patch, a bed sensor, and a smartphone application twice daily for 12 to 48 h during the hospital stay. The first 72 patients formed the cohort for the development of the bed sensor algorithm (Fig. 3). The remaining Part I patients were included for further validation, while the bed sensor algorithm used in Part II was solely designed based on the initial 72 patients. Baseline characteristics of the patients included in the Part I are detailed in Supplementary Table 1. In addition, the reliability of the devices and applications in AF detection was tested before the randomized Part II of the trial.

The development of the bed sensor algorithm is described in greater detail in a separate publication[29]. Briefly, the bed sensor algorithm used in Part II always recorded a whole night's ballistocardiogram signal. Motion artifacts and absences from the bed sensor measurements were first removed from the signal. Subsequently, a bandpass filter and envelope detection were applied for signal enhancement. The signal was then divided

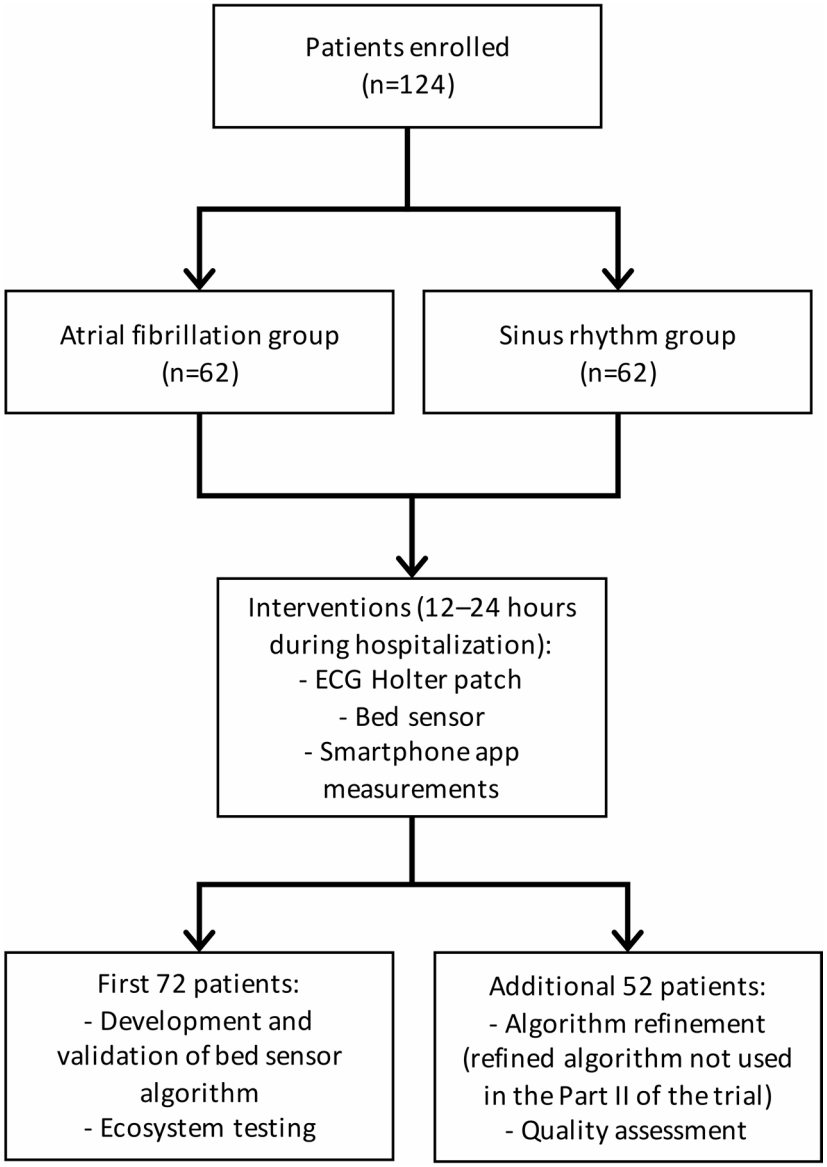

Fig. 3. Flow chart of Part I of the CARE-DETECT trial.

into short segments (5 s each), and each segment was classified as either periodic or non-periodic based on autocorrelation analysis (MODE-AF study[30]. A visual presentation of ballistocardiogram signal is shown in the Fig. 4. If the number of periodic segments divided by the overall number of valid segments within the overnight signal recording was less than 0.1 (i.e., 10%), an alert for suspected AF was triggered. The method yielded a sensitivity of 85.7% and a specificity of 95.2% in the Part I of the study.

In Part II of the study, patients hospitalized for coronary artery disease or valvular heart disease who underwent an invasive cardiac intervention were identified and screened. Only patients at high risk of AF and stroke were included, defined by a CHA_2DS_2-VASc score ≥ 4 or a CHA_2DS_2-VASc score ≥ 2 with at least one enrichment criterion. Initially, the only enrichment criterion was an ECG P wave duration ≥ 120 ms. Due to slow enrollment, the protocol was amended to include the following enrichment criteria: CHA_2DS_2-VASc score ≥ 2 and at least one of the following: ECG P wave duration ≥ 120 ms, left atrial diameter > 38 mm in women or > 40 mm in men, renal impairment (estimated glomerular filtration rate < 50 ml/min), age ≥ 70 years, or active smoking. Patients were also required to have an anticipated life expectancy of 12 months or more and the ability to use the smartphone application and bed sensor. A complete list of the inclusion and exclusion criteria is provided in the Supplement. Patients were randomized in a 1:1 allocation ratio into one of two groups: the IG, which used a smartphone application (CardioSignal by Precordior) for measurements twice daily and a bed sensor (EMFIT QS by Emfit Ltd) for three months following index hospitalization, along with an ECG Holter patch during index hospitalization; or the CG receiving usual care. Both the CardioSignal application (Precordior) and EMFIT QS (Emfit Ltd) are CE-marked devices. The gyrocardiography-based assessment of signs of AF through the smartphone application (CardioSignal) has been described before, and according to the original study, the method demonstrated a sensitivity of 95.3% and a specificity of 96.0% for distinguishing AF from SR[30]. Although the EMFIT QS bed sensor was originally developed for the tracking of heart rate variability, heart and breathing rates, and sleep quality, in the present study, we analyzed the ballistocardiogram signal with the algorithm developed in the Part I of the trial. In the IG, if the bed sensor algorithm detected rhythm irregularities or if two consecutive recordings from the smartphone application indicated possible signs of AF, an ECG was performed. Patients were informed of the smartphone application results immediately after each

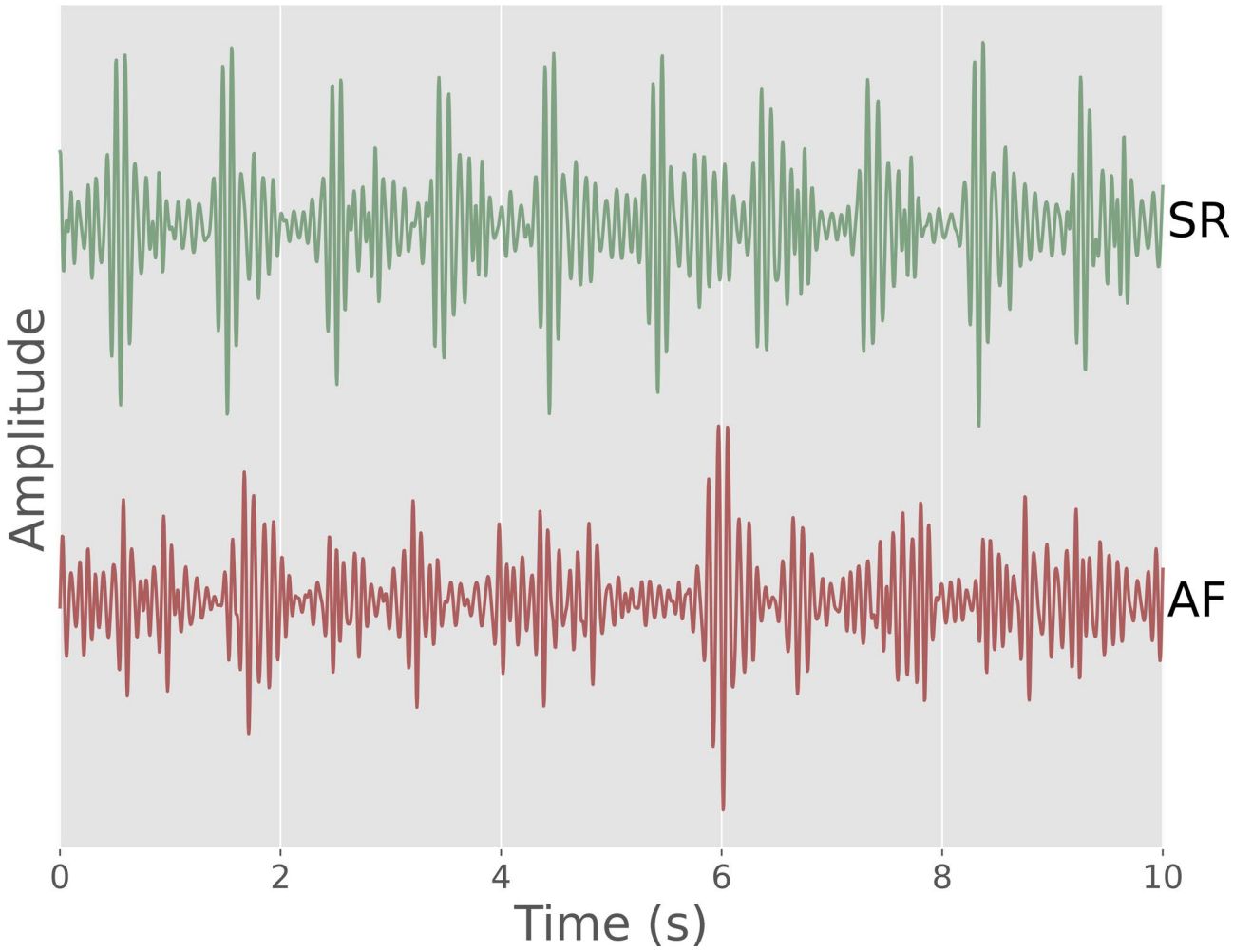

Fig. 4. Visual presentation of bandpass-filtered ballistocardiogram signal in atrial fibrillation (AF) and sinus rhythm (SR).

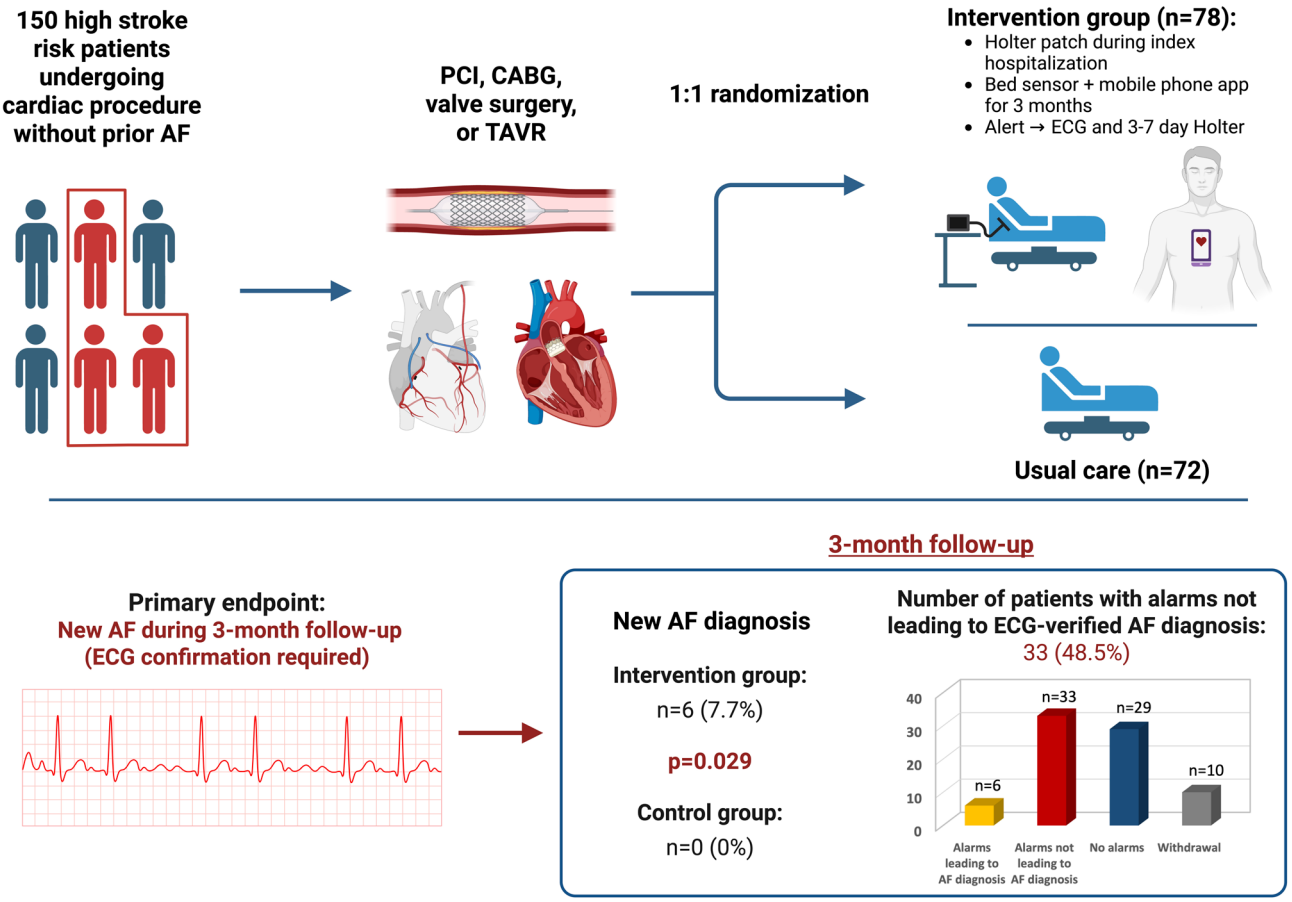

Fig. 5. Atrial fibrillation screening using a bed sensor and a mobile phone application in patients at high stroke risk after cardiac procedures. AF: atrial fibrillation; CABG: coronary artery bypass graft surgery; ECG: electrocardiogram; PCI: percutaneous coronary intervention; TAVR: transcatheter aortic valve replacement. Created with BioRender.com.

measurement, and any potential bed sensor alarms were communicated by the study nurses. If the ECG was normal, a three-to-seven-day ECG Holter monitoring was conducted. The ECG and ECG Holter were initiated within a few days after the device alerts. In the CG, the follow-up was performed according to the treating physician's discretion. This typically involved continuous ECG telemetry during hospitalization, as well as 12-lead ECGs on the morning of the first postoperative day (if the patient remained hospitalized), on subsequent in-hospital days as required, and during outpatient clinical follow-ups after discharge. AF diagnoses identified through these conventional methods were also considered endpoints in the IG. The study protocol is summarized in the Fig. 5.

The trial was approved by the Ethics Committee of Southwestern Finland Hospital District (approval ID 49/1801/202021 and later VARHA/446/13.02.02/2023, referred by the National Committee on Medical Research and Ethics, Tukija) and the Finnish Medicines Agency (FiMEA) (approval ID 2021/006081). This study was registered at ClinicalTrials.gov (NCT05351775) on April 28, 2022. The trial was conducted in accordance with the Declaration of Helsinki.

Consent

In both parts of the trial, written informed consent was obtained from all eligible participants.

Endpoints

The primary clinical medical endpoints were the incidence of new AF during the index hospitalization and at the three-month follow-up post-discharge. The AF diagnoses were validated with either 12-lead ECG or ECG Holter adjudicated by two independent cardiologists. If AF diagnosis was confirmed, patients were asked to continue the interventional recordings in order to reveal the AF burden during the three-month follow-up period. The primary technical endpoints included algorithm development, and the security and reliability of the concept and interface.

Randomization and blinding
Randomization envelopes were produced by an independent statistician using a randomization algorithm from http://www.sealedenvelope.com. Stratified block randomization was employed based on procedure type (coronary artery bypass graft surgery [CABG], surgical aortic valve replacement [SAVR] with or without concomitant CABG, percutaneous coronary intervention [PCI], transcatheter aortic valve replacement [TAVR]) and sex. Patients were considered randomized as soon as the envelope was opened and the intervention allocation revealed.

Post-randomization procedures and follow-up
Following randomization, the IG received the devices and education on their use prior to hospital discharge. Post-discharge, patients were monitored through a user interface that notified study personnel if a rhythm disorder meeting the criteria was detected. The CG received usual care, typically including ECG telemetry during the index hospitalization and 12-lead ECGs as clinically indicated. Both groups were monitored for adverse outcomes and events during the initial hospitalization, and patient records were reviewed to identify outcomes up to three months post-discharge. At the three-month mark, patients were reassessed either during a routine follow-up phone call or a study site visit.

Sample size calculation
The inclusion criteria of the trial have not been used in prior studies, making the AF incidence in the study population unknown and the nature of sample size calculation exploratory. In the SEARCH-AF study, the incidence of AF following cardiac surgery was approximately 20% in the active intervention arm and less than 2% in the control arm at 30-days follow-up[15]. We anticipated an AF incidence of 20% in the active treatment arm and 8% in the control arm due to longer follow-up time. Assuming 80% power and a 5% alpha level, with a 1:1 enrollment ratio, the required sample size was calculated to be 130 patients per group. Accounting for anticipated dropouts, a total of 300 patients were initially planned for enrollment. A prespecified interim analysis was scheduled as per the original plan after the enrollment of 100 patients to assess the observed rate of AF (efficacy) and potential technical challenges or harm (safety). Based on the interim analysis results after 100 patients, the target enrollment was reduced in a protocol amendment to 150 patients due to the high number of alarms not leading to ECG-verified AF diagnosis.

Adjudication
Data was monitored by a third party. Primary outcomes were adjudicated by two independent cardiologists after study completion.

Statistical analysis
Data were analyzed using R statistics software version 4.1.3 (R Foundation for Statistical Computing, Vienna Austria). Graphs were drawn using R and Biorender. Continuous variables were reported as mean ± standard deviation if normally distributed and as median (25th – 75th percentiles) if skewed. The data were tested for normal distribution using the Shapiro-Wilk test. Categorical variables were described as counts and percentages. Pearson $\chi 2$ and Fisher's exact test, unpaired t test, and Mann-Whitney test were used for univariable analysis.

Data availability
The data that support the findings of this study can be shared by the corresponding author upon reasonable request.

Code availability
The underlying code for this study is not publicly available but may be made available to qualified researchers on reasonable request from the corresponding author.

Received: 8 October 2025; Accepted: 29 January 2026
Published online: 03 February 2026

References
1. Davidson, K. W. et al. Screening for atrial fibrillation. *JAMA* **327**, 360 (2022).
2. Turakhia, M. P. et al. Contemporary prevalence estimates of undiagnosed and diagnosed atrial fibrillation in the united States. *Clin. Cardiol.* **46**, 484–493 (2023).
3. Khurshid, S., Healey, J. S., McIntyre, W. F. & Lubitz, S. A. Population-Based screening for atrial fibrillation. *Circ. Res.* **127**, 143–154 (2020).
4. Van Gelder, I. C. et al. 2024 ESC guidelines for the management of atrial fibrillation developed in collaboration with the European association for Cardio-Thoracic surgery (EACTS). *Eur. Heart J.* **45**, 3314–3414 (2024).
5. Joglar, J. A. et al. 2023 ACC/AHA/ACCP/HRS guideline for the diagnosis and management of atrial fibrillation: A report of the American college of Cardiology/American heart association joint committee on clinical practice guidelines. *Circulation.* **149**, e1–e156 (2024).
6. Corica, B. et al. Yield of diagnosis and risk of stroke with screening strategies for atrial fibrillation: a comprehensive review of current evidence. *Eur. Heart J. Open.* **3**, 1–13 (2023).
7. Lowres, N. et al. Estimated stroke risk, yield, and number needed to screen for atrial fibrillation detected through single time screening: a multicountry patient-level meta-analysis of 141,220 screened individuals. *PLoS Med.* **16**, e1002903 (2019).
8. Eranti, A. et al. Orthogonal P-wave morphology, conventional P-wave indices, and the risk of atrial fibrillation in the general population using data from the Finnish hospital discharge register. *EP Europace*. **22**, 1173–1181 (2020).
9. Liantinioti, C. et al. Potential utility of neurosonology in paroxysmal atrial fibrillation detection in patients with cryptogenic stroke. *J. Clin. Med.* **8**, 2002 (2019).

10. Martínez-Sellés, M. et al. Advanced interatrial block and P-wave duration are associated with atrial fibrillation and stroke in older adults with heart disease: the BAYES registry. *EP Europace*. **22**, 1001–1008 (2020).
11. Relander, A. et al. Novel electrocardiographic classification for stroke prediction in atrial fibrillation patients undergoing cardioversion. *Heart Rhythm*. **21**, 2407–2418 (2024).
12. Schnabel, R. B. et al. Early diagnosis and better rhythm management to improve outcomes in patients with atrial fibrillation: the 8th AFNET/EHRA consensus conference. *EP Europace* **25**, 6–27 (2023).
13. Chyou, J. Y. et al. Atrial Fibrillation Occurring During Acute Hospitalization: A Scientific Statement From the American Heart Association. *Circulation* **147**, (2023).
14. van de Kar, M. R. D. et al. Anticoagulation for post-operative atrial fibrillation after isolated coronary artery bypass grafting: a meta-analysis. *Eur. Heart J.* **45**, 2620–2630 (2024).
15. Ha, A. C. T. et al. Effect of continuous electrocardiogram monitoring on detection of undiagnosed atrial fibrillation after hospitalization for cardiac surgery. *JAMA Netw. Open.* **4**, e2121867 (2021).
16. Lin, C. F., Chang, Y. H., Su, C. H., Liu, H. Y. & Chien, L. N. Risk of new-onset atrial fibrillation after drug-eluting stent implantation in patients with stable coronary artery disease. *Int. J. Cardiol.* **291**, 63–68 (2019).
17. Kosmidou, I. et al. New-Onset atrial fibrillation after PCI or CABG for left main disease. *J. Am. Coll. Cardiol.* **71**, 739–748 (2018).
18. Mrdovic, I. et al. Incidence, predictors, and 30-day outcomes of new-onset atrial fibrillation after primary percutaneous coronary intervention. *Coron. Artery Dis.* **23**, 1–8 (2012).
19. Ryan, T. et al. New-Onset atrial fibrillation after transcatheter aortic valve replacement. *JACC Cardiovasc. Interv*. **15**, 603–613 (2022).
20. Sanna, T. et al. Cryptogenic stroke and underlying atrial fibrillation. *N. Engl. J. Med.* **370**, 2478–2486 (2014).
21. Gruwez, H. et al. Smartphone-based atrial fibrillation screening in the general population: feasibility and impact on medical treatment. *Eur. Heart J. - Digit. Health*. **4**, 464–472 (2023).
22. Perez, M. V. et al. Large-Scale assessment of a smartwatch to identify atrial fibrillation. *N. Engl. J. Med.* **381**, 1909–1917 (2019).
23. Guo, Y. et al. Mobile photoplethysmographic technology to detect atrial fibrillation. *J. Am. Coll. Cardiol.* **74**, 2365–2375 (2019).
24. Reading Turchioe, M. & Slotwiner, D. Screening for atrial fibrillation using digital health. *JACC: Adv.* **2**, 100621 (2023).
25. Kirchhof, P. et al. Anticoagulation with Edoxaban in patients with atrial High-Rate episodes. *N. Engl. J. Med.* **389**, 1167–1179 (2023).
26. Healey, J. S. et al. Apixaban for stroke prevention in subclinical atrial fibrillation. *N. Engl. J. Med.* **390**, 107–117 (2024).
27. McIntyre, W. F. et al. Direct oral anticoagulants for stroke prevention in patients with Device-Detected atrial fibrillation: A Study-Level Meta-Analysis of the NOAH-AFNET 6 and artesia trials. *Circulation* **149**, 981–988 (2024).
28. Svendsen, J. H. et al. Implantable loop recorder detection of atrial fibrillation to prevent stroke (The LOOP Study): a randomised controlled trial. *Lancet* **398**, 1507–1516 (2021).
29. Sandelin, J. et al. Bed sensor ballistocardiogram for non-invasive detection of atrial fibrillation: a comprehensive clinical study. *Physiol. Meas.* **46**, 035003 (2025).
30. Jaakkola, J. et al. Mobile phone detection of atrial fibrillation with mechanocardiography. *Circulation* **137**, 1524–1527 (2018).

Author contributions

T.O.K., T.K., J.K.E.A., T.V., O.L., A.A., I.E., R.R., J.S., and T.H. participated in the trial design. O.L., A.A., I.E., R.R., J.S., T.H., and T.K. participated in the software design. J.L., J.N., A.R., J.J., T.V., and T.O.K. coordinated patient recruitment and data collection. J.L., J.N., T.O.K., J.K.E.A., and O.L. wrote the main manuscript text, and all authors substantively revised the manuscript. J.L. prepared the analyses of the manuscript and Figs. 1, 2 and 3, and 5. J.S. prepared figure 4.

Funding

The study received funding within the Electronic Components and Systems for European Leadership Joint Undertaking (ECSEL JU) in collaboration with the European Union's H2020 Framework Programme (H2020/2014–2020) and National Authorities, under grant agreement H2020-ECSEL-2019-IA-876190, as well as Business Finland. The sponsors had no involvement in the study design, protocol amendments, collection, analysis, or interpretation of the data, report writing, or the decision to submit the paper for publication. The authors had full access to all study data and held final responsibility for the decision to submit the manuscript for publication.

Declarations

Competing interests

Olli Lahdenoja reports part-time work at Precordior ltd. Juhani Airaksinen reports research grants from the Finnish Foundation for Cardiovascular Research and Clinical Research Fund of Turku University Hospital, Turku, Finland and lecture fees from Astra Zeneca, Bayer, and Boehringer Ingelheim. Tero Koivisto is a shareholder of Precordior ltd. Tuomas Kiviniemi reports grants from EU and Business Finland (Moore4Medical), and outside this work EU/EIC Pathfinder, Finnish Medical Foundation, Finnish Foundation for Cardiovascular Research, and State Research Funding, Vifor Pharma, and Atricure. Other authors report no conflicts of interest.

Additional information

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1038/s41598-026-38273-5.

Correspondence and requests for materials should be addressed to T.O.K.