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CLINICAL RESEARCH

Improving atrial fibrillation or flutter detection and management by smartphone-based photoplethysmography rhythm monitoring following cardiac surgery: a pragmatic randomized trial

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Aims

Atrial fibrillation (AF) and atrial flutter (AFL) after cardiac surgery are common and associated with adverse outcomes. The increased risk related to AF or AFL may extend beyond discharge. This study aims to determine whether photoplethysmography (PPG)-based smartphone monitoring to detect AF or AFL after hospital discharge following cardiac surgery improves AF management.

Methods and results

The intervention group performed 1 min rhythm checks three times daily using a smartphone-based PPG application during 6 weeks after hospitalization for cardiac surgery. The primary outcome involved AF management interventions by independent physicians, including initiation of oral anticoagulation (OAC), direct cardioversion, and up-titration or initiation of antiarrhythmic drugs. The study included 450 patients [mean (SD) age, 64.1 (9.2) years; 96 women (21.3%); 130 patients with AF history (28.9%); median (IQR) CHA2DS2-VASc score, 2 (1–3)], of whom 238 were randomized to PPG-based monitoring and 212 to usual care. AF/AFL was detected with PPG or electrocardiography in 44 patients (18.5%) in the monitoring group and 4 patients (1.9%) in the usual care group (OR 11.8; 95% CI, 4.2–33.3; $P < 0.001$); these were new detections in, respectively, 22 patients (9.2%) and 1 patient (0.5%) (OR 21.3; 95% CI, 2.9–166.7; $P = 0.003$). AF management interventions occurred in 24 patients (10.1%) in the monitoring group compared to 5 patients (2.4%) in the usual care group [odds ratio (OR), 5.1; 95% CI, 1.8–14.4; $P = 0.002$].

Conclusion

In unselected patients discharged home following cardiac surgery, PPG-based smartphone monitoring revealed significantly more AF/AFL which led to significantly more optimization of AF management.

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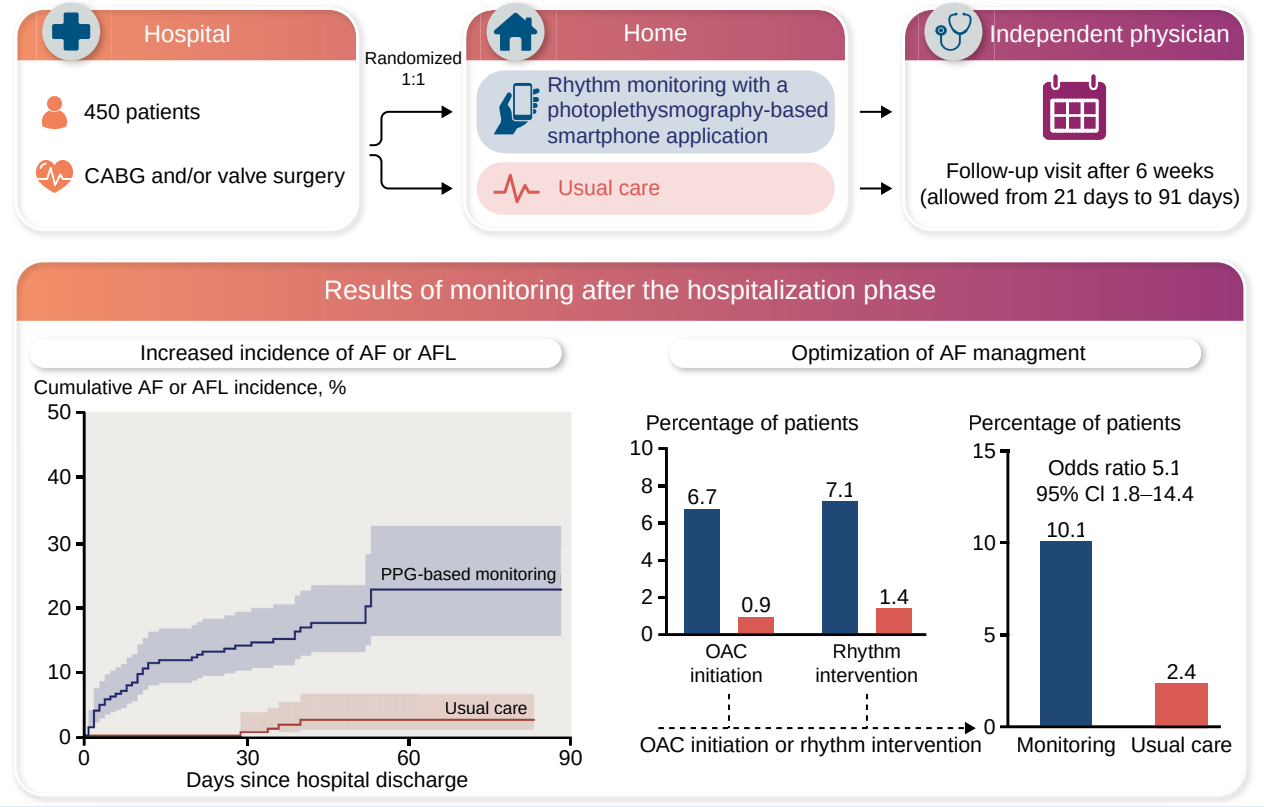
Graphical Abstract



AF, atrial fibrillation; AFL, atrial flutter; CABG, coronary artery bypass graft; OAC, oral anticoagulation

Keywords Atrial fibrillation • Digital health • Oral anticoagulation • Post-operative atrial fibrillation • Photoplethysmography • Stroke

What's new?

- Home-based self-monitoring of atrial fibrillation (AF) or atrial flutter (AFL) using a smartphone application is feasible after cardiac surgery, demonstrating good compliance in the majority of patients.
- Utilizing a photoplethysmography (PPG)-based smartphone application significantly increased the detection rate of AF or AFL in patients discharged after cardiac surgery.
- PPG-based smartphone monitoring led to a five-fold increase in AF management interventions, including the initiation of oral anticoagulation therapy and rhythm control therapy.
- A substantial proportion of AF or AFL detected after hospital discharge were subclinical, underscoring the importance of prolonged monitoring for early detection and management.

Introduction

Post-operative atrial fibrillation (POAF) is the most common type of secondary atrial fibrillation (AF) and the most common complication after cardiac surgery.[1] AF or atrial flutter (AFL) after cardiac surgery occurs in 30–50% of patients during their hospital stay.[2] However, there is paucity of data on AF or AFL after the hospitalization phase. Data from continuous electrocardiography (ECG) monitoring during the first 30 days after discharge from cardiac surgery found a recurrence of AF or AFL in 33% of patients who suffered AF or AFL during hospitalization and found new-onset AF or AFL in 19.6% of patients during the first 30 days after discharge from cardiac surgery.[3,4] While POAF is generally defined as newly occurring AF or AFL immediately after surgery, there is no consensus on the details of its definition. The guidelines of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) do not define a minimal duration of the arrhythmia nor a maximal time limit after surgery.[5] To specify the time relationship between surgery and AF or AFL, the term 'early POAF' is used to describe AF or AFL during the hospitalization phase as opposed to 'late POAF' which describes AF or AFL after the hospitalization phase.[6,7]

Early POAF is known to be associated with a two-fold increase in early adverse outcomes such as stroke and mortality, both early and long-term.[2,8–10] It is unknown whether these outcomes could be generalized to late POAF. Moreover, the evidence on oral anticoagulation (OAC) effects in patients with early POAF to mitigate the stroke risk is not very robust. Hence, the ESC/EACTS guidelines recommend that long-term OAC therapy may be considered following early POAF in subjects at risk for stroke.[5] Whereas, the American College of Cardiology (ACC) guidelines state that OAC should be considered in this situation, however for a restricted period of 60 days.[11] The treatment of late POAF is not described by the guidelines. However, from a temporal perspective, late POAF is more closely related to non-surgically related AF or AFL, for which there is a body of evidence for OAC therapy and rhythm

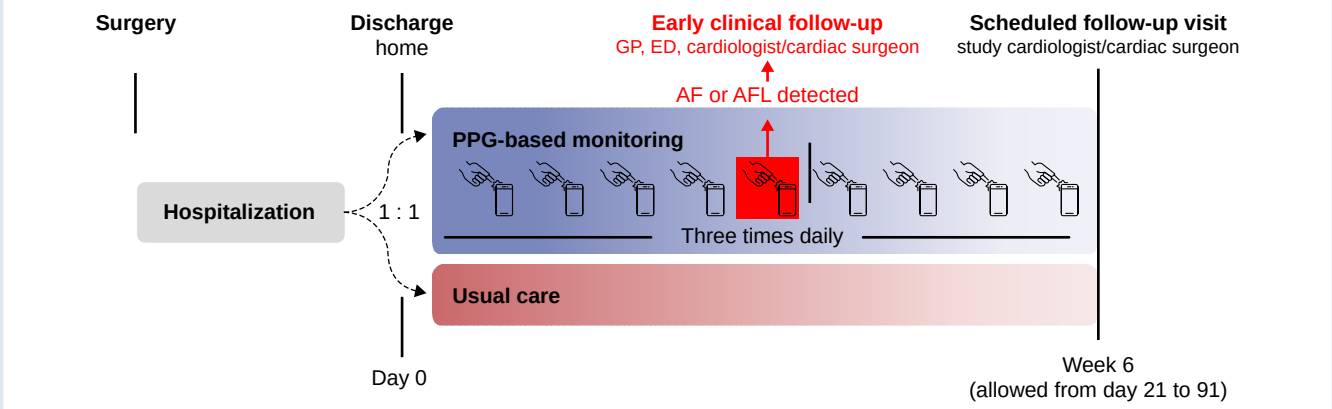


Figure 1 Study protocol. Patients were randomly assigned in a 1:1 ratio to the monitoring group (PPG measurements three times daily and while perceiving symptoms of AF) or to usual care with no mandated monitoring. Patients randomized to the monitoring group were instructed to commence the PPG measurements on the day of discharge from the hospital and to continue until the follow-up visit with their cardiologist or cardiac surgeon, scheduled at 6 weeks after discharge (allowed from 21 to 91 days after discharge). In case of AF or AFL detection with PPG, the patient was instructed to visit a physician. Early follow-up was either performed by the patient's general practitioner, cardiologist, or cardiac surgeon or at the emergency department. Patients randomized to the usual care group did not undergo any protocol-mandated rhythm monitoring after randomization. AF, atrial fibrillation; AFL, atrial flutter; ED, emergency department, GP, general practitioner; PPG, photoplethysmography.

control.[12,13] It is recommended that stroke prevention strategies in patients with solitary AFL follow the same principles as in patients with AF and the ABC ('A' Avoid stroke; 'B' Better symptom control; and 'C' Cardiovascular and Comorbidity) pathway for integrated AF management largely applies to patients with AFL.[5] Therefore, the management of both arrhythmias is concisely referred to as 'AF management' in this paper.

The problem, until recently, was that rhythm monitoring after the hospitalization phase was cumbersome with either short-duration ECG monitoring or invasive ECG devices.[3,4,6] Nowadays, digital devices increasingly permit intensified heart rhythm monitoring at home with ECG or photoplethysmography (PPG) technology.[14] Whereas the 2020 ESC guidelines still require an ECG to make the diagnosis of AF, PPG-based smartphone applications can detect AF with high accuracy based on either manual reading of the PPG recording or algorithm interpretation.[5,15,16] However, the effect of home-based POAF monitoring with digital devices has not been studied. Accordingly, we conducted a randomized clinical trial comparing intermittent PPG-based smartphone monitoring with usual care for the detection and management of AF or AFL after hospitalization for cardiac surgery.

Methods

Study design

The SURGICAL-AF 2 trial was an investigator-initiated, prospective, open-label, multicentre, randomized, pragmatic clinical trial at three tertiary care cardiac surgical centres in Belgium. The trial protocol (registered at ClinicalTrials.gov, identifier number NCT05509517) was approved by the central ethical review board and local ethical review boards of all participating centres. All participants provided written informed consent. The study complies with the Declaration of Helsinki, and the report was prepared in accordance with the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline for randomized trials.

Study population

Patients were eligible if they were aged 18 years or older, underwent cardiac surgery [coronary artery bypass grafting (CABG) or valve repair or replacement with or without CABG], and were able to perform PPG-based smartphone measurements three times daily at home during the study period. Patients were excluded if they had a pacemaker, were in AF or AFL at the time of randomization, or were incapable to participate in the trial due to language or cognitive barriers that incapacitated the patient to follow the study protocol. Detailed inclusion and exclusion criteria were listed in the Supplementary material online, *Table S1* and *Table S2*.

Study procedure

Patients were randomly assigned in a 1:1 ratio to the monitoring group (PPG measurements three times daily and while perceiving symptoms of AF) or to usual care with no mandated monitoring. Randomization was performed by the electronic case report from the software REDCap using a random allocation with 1:1 odds.[17,18] Randomization was performed at the latest possible day before the discharge date from the hospital, contingent upon the availability of the study personnel.

Patients randomized to the monitoring group were instructed to perform intermittent rhythm checks using a PPG-based smartphone application three times daily and while perceiving symptoms of AF (*Figure 1*). Patients were instructed to commence the PPG measurements on the day of discharge from the hospital and to continue until the follow-up visit with their cardiologist or cardiac surgeon, scheduled 6 weeks after discharge (allowed from 21 to 91 days after discharge). Patients performed the measurements using their personal smartphone and the FibriCheck (FC) application (Qompium NV, Belgium). The FC app is a CE-certified (Class 2a, European Union Directive 93/42/EEC) and FDA-approved medical device for the detection of AF. The FC algorithm has a sensitivity of 98.3% and a specificity of 99.9% to detect AF.[15] Manual reading of the PPG recordings has a sensitivity of 97.7 and 99.4% to detect AF or AFL, respectively.[16] Both the algorithm and manual reading were combined in this study. The FC app reminded participants to take self-measurements through push notifications. To perform PPG measurements, patients were instructed to place their index finger over the smartphone camera while the FC application was activated. The smartphone LED flashlight automatically turns on during the procedure and the camera captures the changes in reflected light intensity, generating a pulse waveform, as described elsewhere.[19] The PPG signal acquisition time was set at 1 min, during which a visible countdown timer was displayed on the smartphone screen. At the end of the recording, patients were questioned for symptoms and were subsequently provided with feedback on the quality of the measurement and the heart rhythm. In case of insufficient quality, the patient was instructed to repeat the procedure until a measurement of sufficient quality for analysis was recorded. Measurements categorized as AF

or AFL were subsequently reviewed by a medical technician within one business day (example in Supplementary material online, *Figure S1*). In case of a confirmed abnormal PPG finding, the local study personnel contacted the participants by phone and instructed the patient to visit a physician (general practitioner, cardiologist, cardiac surgeon, or emergency department) who examined the patient and verified the current heart rhythm with ECG. If necessary, patients were offered assistance in scheduling the appointment. The PPG recordings demonstrating AF or AFL were made available to the physician conducting the (early or scheduled) follow-up visit. Therapeutic decisions, such as initiation of OAC therapy or antiarrhythmic drugs (AAD), were left to the treating physician's discretion, who was not involved in the study. All therapeutic actions performed between hospital discharge and the scheduled follow-up visit were registered.

Patients randomized to the usual care group did not undergo any protocol-mandated rhythm monitoring after randomization. This practice is consistent with current guidelines, which make no recommendations for routine monitoring.[5,11] However, if clinically indicated, patients in the usual care group could undergo standard ECG or Holter monitoring prior to the follow-up visit with their cardiologist or cardiac surgeon. Any AF or AFL detected by an ECG, Holter, or any other type of monitoring performed in the usual care group was included in the outcome assessment. In parallel to the monitoring group, therapeutic decisions, such as initiation of OAC therapy or initiation of AAD, were left to the treating physician's discretion, who was not involved in the study, and recorded at the follow-up visit.

Outcomes

Outcome events were monitored and documented during the follow-up period, spanning from the patient's discharge from the hospital until their scheduled follow-up visit. The primary outcome was defined as a composite of initiation of OAC, direct cardioversion, up-titration or initiation of AAD (Vaughan Williams Class I or III), and implantation of a cardiac implantable electronic device (CIED). The secondary outcome was incidence of AF or AFL detected with either PPG or ECG technology. Subgroups were predefined based on the history of AF or AFL (including both presurgical AF or AFL and post-operative AF or AFL during hospitalization) and based on OAC prescription at discharge. A sensitivity analysis was conducted, excluding patients with active OAC or AAD treatment at the time of enrolment.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate. Comparisons were made using the student *t*-test, the Wilcoxon rank sum test, or the Kruskal–Wallis tests where appropriate. Categorical data are summarized with the use of frequencies and proportions and were compared using the χ^2 test.

The trial was designed to test the hypothesis of the superiority of PPG-based monitoring over usual care in the detection of the primary outcome within the follow-up period after discharge from the hospital. Based on the results of previous rhythm monitoring trials after cardiac surgery, the rate of the primary outcome was estimated to be 2% in the usual care group and 9% in the monitoring group.[4] To detect significant differences between the monitoring group and the usual care group, a total of 442 patients (221 in each group) would be necessary to provide the trial with 90% power at a two-sided $\alpha = 0.05$. Assuming some attrition, the final sample size was 450 patients.

Outcome analyses were performed on the intention-to-treat population, which analysed patients according to their randomization status. The primary outcome was a composite of four endpoints. Accumulation of multiple events across these four components within individual patients was allowed and accounted for in the analysis. However, accumulation of recurrences of events in a single component was not accounted for in the analysis. Hence, the maximum number of events in the primary outcome of a single patient was four. A logistic regression model with repeated measures was constructed using generalized estimating equations (GEE) to account for the accumulation of events in the four components of the primary outcome. The comparison in the primary outcome between the two study groups was reported as odds ratios (OR) with associated 95% CIs. Binary logistic regression was used to compare the groups for individual components of the primary outcome and secondary outcomes. A subgroup analysis was performed involving prespecified subgroups based on AF history, OAC use, and CHA_2DS_2-VASc risk score. Kaplan–Meier curves of the primary and secondary outcomes were generated for illustrative purposes. They were compared between the monitoring group and usual care group using a log-rank test. A two-sided *P*-value of <0.05 was considered statistically significant. Statistical analyses were performed with SAS Enterprise Guide 8.2 (SAS Institute Inc., Cary, NC, USA), IBM SPSS Statistics (version 29, Chicago, IL, USA), and Prism 8 (GraphPad Software; San Diego, CA, USA).

Results

Study population

Between December 2021 and June 2023, 450 patients [mean (SD) age, 64.1 (9.2) years; 96 women (21.3%)] were randomized to PPG-based rhythm monitoring (238 patients) or usual care (212 patients) at three Belgian sites (*Figure 2*). The median (IQR) time from surgery to randomization was 6 (4–8) days, and the median (IQR) time from randomization to discharge was 1 (0–2) days.

Baseline characteristics of the two assigned groups are listed in *Table 1*. The median (IQR) CHA2DS2-VASc score was 2 points (1–3); the median EuroSCORE II was 1.2% (0.8–2.1%); 266 patients

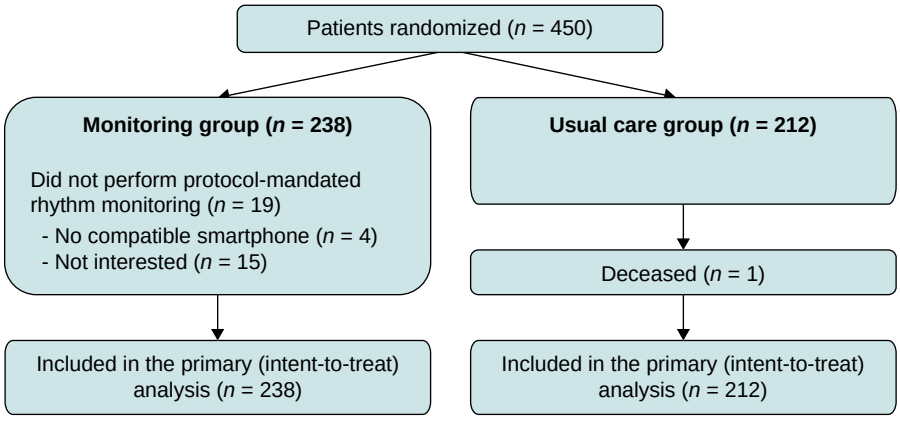


Figure 2 Study flowchart.

Table 1 Baseline characteristics

Baseline characteristics	Intervention group ($n = 238$)	Usual care group ($n = 212$)
Age, y	63.7 ± 9.4	64.5 ± 9.1
Sex, female	50 (21.0)	46 (21.7)
BMI, kg/m^2	26.9 ± 3.9	28.0 ± 4.6
Euroscore II (IQR)	1.2 (0.8–2.1)	1.3 (0.8–2.2)
CHA_2DS_2-VASc score		
0	22 (9.2)	22 (10.4)
1	52 (21.8)	47 (22.0)
2	67 (28.2)	71 (33.5)
3	59 (24.8)	35 (16.5)
≥4	38 (16.0)	36 (15.6)
Congestive heart failure	22 (9.4)	18 (8.5)
Ischaemic	13 (5.5)	11 (5.2)
Non-ischaemic	6 (2.5)	6 (2.8)
Arterial hypertension	153 (64.3)	132 (62.3)
Diabetes mellitus	55 (23.1)	33 (15.6)
Stroke, TIA, or systemic embolism	22 (9.2)	12 (5.7)
Peripheral vascular disease	53 (22.5)	49 (23.2)
Chronic pulmonary disease	22 (9.2)	16 (7.5)
COPD	11 (4.6)	7 (3.3)
Sleep apnoea syndrome	11 (4.6)	8 (3.8)
LVEF		
>50%	184 (79.0)	167 (79.9)
40–50%	38 (16.3)	39 (18.7)
<40%	11 (4.7)	3 (1.4)
AF history	70 (29.4)	60 (28.3)
Prior to surgery	20 (8.4)	17 (8.0)
Early POAF	56 (23.5)	49 (23.1)
Surgical Procedure		
Isolated CABG	146 (61.3)	120 (56.6)
Isolated valve surgery	77 (32.4)	75 (35.4)
Combined CABG and valve surgery	15 (6.3)	16 (7.5)
Drug therapy at discharge		
Anticoagulation	54 (22.8)	49 (23.1)
NOAC	23 (9.7)	26 (12.3)
VKA	31 (13.0)	22 (10.4)
LMWH	0 (0)	1 (0.5)
Antiarrhythmic drugs		
Class I	4 (1.7)	2 (1.0)
Class III	31 (13.0)	28 (13.2)

The Vaughan Williams classification was used to classify antiarrhythmic drugs. AF, atrial fibrillation; BMI, body mass index; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; LMWH, low molecular weight heparin; LVEF, left ventricular ejection fraction; NOAC, non-vitamin K oral anticoagulants; POAF, post-operative AF; PVI, pulmonary vein isolation; SD, standard deviation; TIA, transient ischaemic attack; VKA, vitamin-K antagonist

(59.1%) underwent CABG alone, 152 patients (33.8%) underwent valve repair or replacement alone, and 31 patients (6.9%) underwent both CABG and valve repair or replacement. A presurgical history of AF was documented in 37 patients (8.2%). A presurgical history of AFL was documented in only three patients (0.7%); these patients also had a presurgical history of AF. Early POAF (more than 30 s) was documented in 105 patients (23.3%) during hospitalization. At hospital discharge, anticoagulation was prescribed for 103 patients (22.9%), and AAD (Class I or III) was prescribed for 59 patients (14.4%).

All study-related follow-up visits were attended by 449 patients (99.8%). The median (IQR) time between hospital discharge and follow-up consultation was 42 (37–48) days. Among the 238 patients in the monitoring group, 19 patients (8.0%) did not perform any PPG measurements during the follow-up period. The remaining 219 patients in the monitoring group cumulatively performed 23 099 PPG measurements (see Supplementary material online, *Figure S2*). Among these patients, the median number of measurements was 102 (64–135). During the follow-up period, at least one PPG measurement was performed every single day by 74 patients (33.7%), and a least one PPG measurement was performed every 2 days by 194 patients (88.6%). The overall compliance (number of PPG measurements performed / number of PPG measurements requested) was 77.0% (23 099 / 29 988).

Atrial fibrillation or atrial flutter detection

AF or AFL was detected with a PPG-based smartphone application or clinical ECG in 44 patients (18.5%) in the monitoring group during the follow-up period vs. 4 patients (1.9%) in the usual care group [OR (95% CI) 11.8, (4.2–33.3); $P < 0.001$]. The number needed to monitor to detect one additional patient with AF or AFL was six patients (95% CI, 5–9 patients). The time to AF or AFL detection was significantly lower in the monitoring group compared to the usual care group ($P < 0.001$) as illustrated by the Kaplan–Meier curves with non-overlapping CIs in *Figure 3B*.

AF or AFL detected with PPG or ECG technology was a new detection in 22 patients in the monitoring group (9.2%) and in 1 patient in the usual care group (0.5%) (OR 21.3; 95% CI, 2.9–166.7; $P = 0.003$). AF or AFL detected during the follow-up period was first detected during hospitalization for cardiac surgery in 13 patients (5.5% of the monitoring group) and 1 patient (0.5% of the usual care group) and was already known before surgery in 9 patients (3.8% of the monitoring group) and 2 patients (0.9% of the usual care group). Among all 44 patients with AF or AFL in the monitoring group, 20 patients (45.5%) perceived symptoms during the arrhythmia. The technology used to detect patients with AF or AFL is detailed in *Table 2*. Of the 37 patients with PPG-detected AF or AFL, 22 patients had sequential measurements indicating the arrhythmia. The other seven patients with AF or AFL detection in the monitoring group were detected with a clinical ECG only. The overall compliance (number of PPG measurements performed / number of PPG measurements requested) of these seven patients was only 20.7% (176 / 852). The number of PPG measurements indicating AF or AFL is displayed for individual patients in the

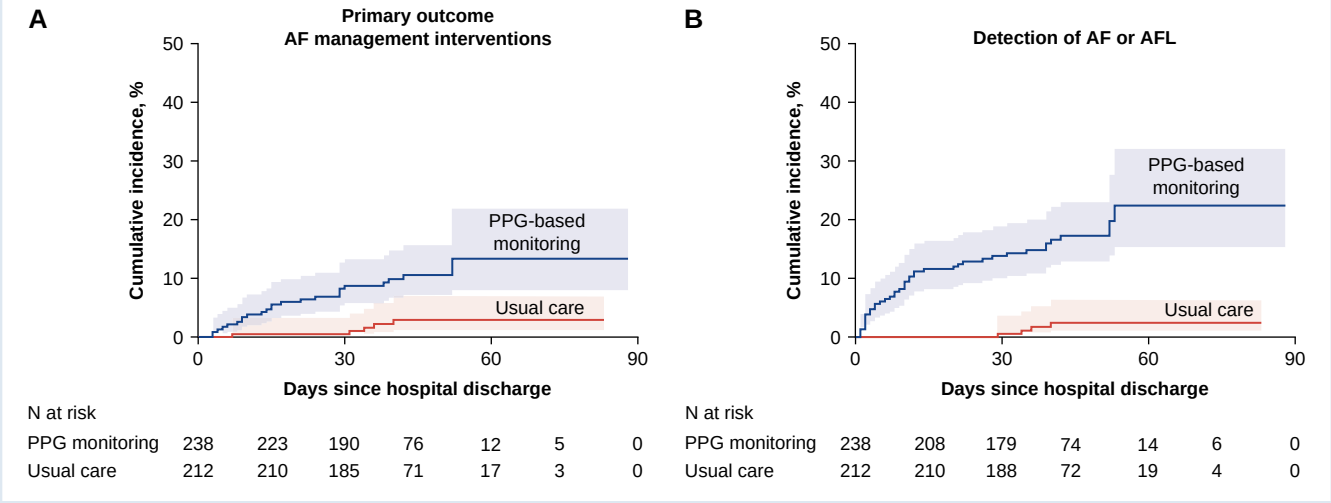


Figure 3 Kaplan–Meier curves showing the cumulative incidence of the primary and secondary outcome for the monitoring and usual care groups. Kaplan–Meier estimates for the cumulative incidence of (*A*) the primary outcome, which is a composite endpoint driven by initiation of OAF therapy and rhythm control intervention, and (*B*) AF or AFL detection in the monitoring group (blue) and in the usual care group (red). AF, atrial fibrillation; AFL, atrial flutter.

Table 2 Primary and secondary outcomes by measurement technology

***n* patients (%)**	**Intervention group (*n* = 238)**			**Usual care (*n* = 212)**
AF or AFL detected	**PPG-detected (*n* = 37)**		**ECG-detected (*n* = 7)**	**ECG-detected (*n* = 4)**
	With ECG confirmation	**Without ECG confirmation**		
AF only	13 (5.5)	17 (7.1)	6 (2.5)	2 (0.9)
AFL only	0 (0)	3 (1.3)	1 (0.4)	2 (0.9)
AF and AFL	1 (0.4)	3 (1.3)	0 (0)	0 (0)
AF intervention	12 (5.0)	7 (2.9)	4 (1.7)	4 (1.9)
OAC therapy	8 (3.4)	6 (2.5)	2 (0.8)	2 (0.9)
Cardioversion	10 (4.2)	0 (0)	2 (0.8)	4 (1.9)
AAD therapy	6 (2.5)	1 (0.4)	2 (0.8)	0 (0)

AAD, antiarrhythmic drug; AF, atrial fibrillation; AFL, atrial flutter; ECG, electrocardiography; OAC, oral anticoagulation

Supplementary material online, *Figure S3*. The AF or AFL episode duration was calculated for patients with sequential PPG measurements indicating the arrhythmia, using the methods displayed in the Supplementary material online, *Figure S4*. The longest episode duration of individual patients is displayed in Supplementary material online, *Figure S5*. The median (IQR) episode duration was 13.8 h (1.5–33.0).

Atrial fibrillation management interventions

In the monitoring group, the AF management interventions occurred in 24 of 238 patients (10.1%) compared with 5 of 212 patients (2.4%) in the usual care group (OR 5.1; 95% CI, 1.8–14.4; $P = 0.002$). The number needed to monitor for one additional AF management intervention was 13 patients (95% CI, 8–30 patients). The time to an intervention was significantly lower in the monitoring group compared with the usual care group ($P < 0.001$) as illustrated by the Kaplan–Meier curves with non-overlapping CIs in *Figure 3A*.

The endpoints constituting the primary outcome 'AF management interventions' were compared between both groups and presented in *Figure 4*. The outcome was driven by initiation of OAC therapy [documented in 17 patients (7.1%) in the monitoring group vs. 3 patients (1.4%) in the usual care group (OR 5.4; 95% CI, 1.5–18.5)] and interventions to restore or maintain sinus rhythm [in 16 patients (6.7%) in the monitoring group vs. 2 patients (0.9%) in the usual care group (OR 7.6; 95% CI, 1.7–33.3)]. The latter included cardioversion and initiation or

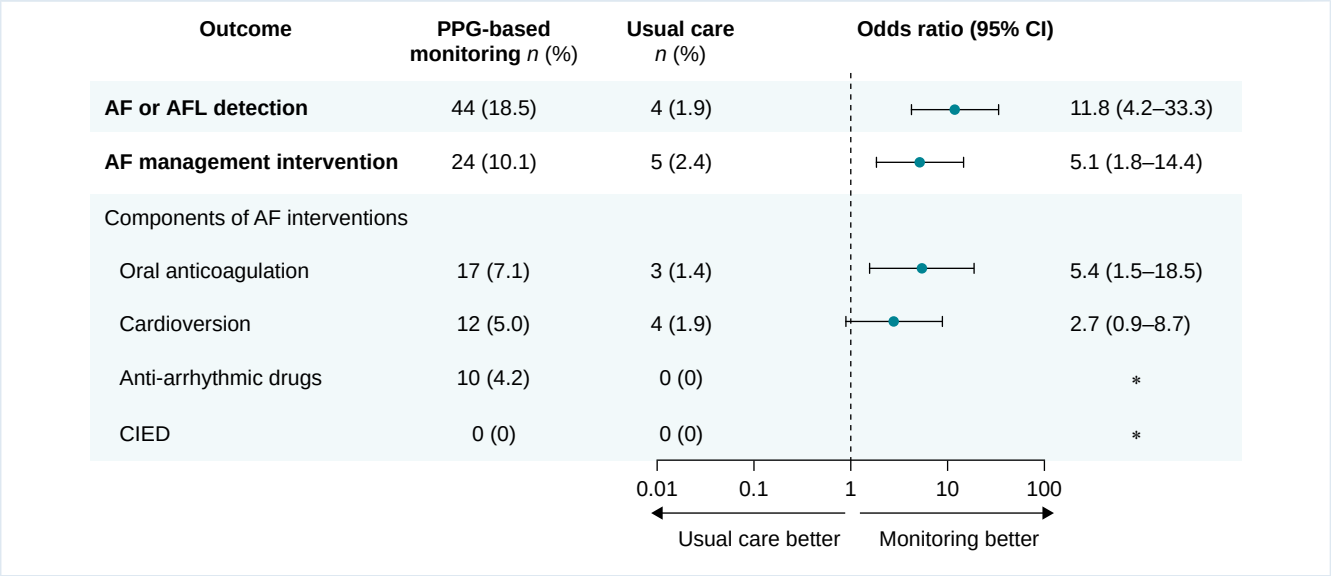


Figure 4 Primary and secondary outcomes by intent-to-treat analysis. Odds ratio for the primary outcome was calculated with GEE logistic regression. Odds ratios of components of the primary outcome and secondary outcomes were calculated with binary logistic regression. AF or AFL were detected with PPG or ECG technology. *Odds ratios could not be calculated because 0 events occurred in one group or both groups. AF, atrial fibrillation; AFL, atrial flutter.

up-titration of AAD (*Figure 4*). Implantation of a CIED was not observed during the follow-up period. The accumulation of endpoints in individual patients is presented in Supplementary material online, *Table S3*.

Relation between atrial fibrillation or atrial flutter detection and atrial fibrillation management interventions and subgroup analyses

Of the 24 patients in the monitoring group in whom the primary outcome occurred, 23 patients (95.8%) had at least one episode of detected AF or AFL. Of the five patients with a primary outcome event in the usual care group, AF or AFL was detected in four patients (80%).

The predefined subgroups were analysed by the intention-to-treat group allocation. The effect of PPG-based monitoring on AF or AFL detection by subgroup is presented in Supplementary material online, *Table S4*. There was significantly more AF or AFL detection in the monitoring group compared to the usual care group in all subgroups. The effect of PPG-based monitoring on AF management interventions by subgroup is presented in Supplementary material online, *Table S5*. There were more AF interventions in the monitoring group compared to the usual care group in all subgroups. This was statistically significant in the subgroup without a history of AF or AFL prior to randomization and in the subgroup without OAC prescription at discharge. In the sensitivity analysis, patients with OAC or AAD treatment at the time of enrolment were excluded. Still, there were significantly more AF management interventions in the intervention group (13 out of 166 patients, 7.8%) compared to the usual care group (2 out of 149 patients, 1.3%) (OR 8.4; 95% CI, 1.7–40.6; $P = 0.008$), confirming the results of the primary analysis. In the subgroup with an elevated CHA_2DS_2-VASc score (1 or more for men, 2 or more women), OAC initiation occurred significantly more frequently in the intervention group (15 out of 209 patients, 92.8%) compared to the control group (3 out of 186 patients, 1.6%) (OR 4.7; 95% CI, 1.3–16.7; $P = 0.015$).

Discussion

The SURGICAL-AF 2 study was a randomized trial that compared enhanced rhythm monitoring after discharge from the hospital following cardiac surgery with usual care. Enhanced rhythm monitoring was performed during 6 weeks with twice daily rhythm checks using a PPG-based smartphone application. PPG-based monitoring led to an increased detection of AF or AFL, resulting in more AF management interventions.

In this study, PPG-based monitoring was essential to uncover the ongoing risk of AF and AFL after the hospitalization phase. AF or AFL after the hospitalization phase is referred to as 'late POAF', as opposed to 'early POAF', which occurs during the hospitalization phase and is considered to be an early, transient phenomenon because of pericardial effusion and inflammation, cardiac ischaemia, haemodynamic fluctuations, and high adrenergic state, which is assumed to resolve in days.[20,21] Late POAF occurs when acute stressors have waned; therefore, late POAF is more closely related to non-surgically related AF or AFL. However, the incidence of late POAF occurring weeks to months after surgery is not well-defined; apart from the SEARCH-AF trial, prior studies are few, retrospective, or non-randomized.[4,22,23] This represents an important unknown for clinicians managing these patients. In this study, PPG-based rhythm monitoring detected AF or AFL with PPG or ECG technology within 6 weeks after discharge in one out of three patients with a history of AF and one out of eight patients without a history of AF. This indicates that a substantial proportion of AF or AFL after hospitalization is subclinical and would not be diagnosed without the use of PPG-based rhythm monitoring. Remarkably, only half of the patients with AF or AFL were asymptomatic and qualify as truly subclinical. However, symptoms after surgery are common and may not solely be related to AF or AFL. Compared to the SEARCH-AF trial that studied screening for post-operative AF or AFL during a similar window of the post-hospitalization phase, the detection rate of new-onset AF or AFL was slightly higher in the SEARCH-AF trial (one of five patients).[4] This higher detection rate may be attributed to continuous monitoring with ECG and the inclusion of patients with a higher CHA_2DS_2-VASc score (median 4 points), which is associated with the development of

AF.[4,24,25] Compared to the eBRAVE trial that used smartphone-PPG to screen for AF in a non-surgical population with similar age and CHA_2DS_2-VASc score to that of this study (median age = 65, CHA_2DS_2-VASc = 3), the detection rate of new-onset AF was much lower in the eBRAVE trial (1.6% after 6 months follow-up with intermittent PPG measurements).[26] This demonstrates that the increased incidence of AF or AFL after the hospitalization phase for cardiac surgery was much higher than in a general, matched population. There is accumulating evidence from other studies that the increased risk for AF persists for years after POAF detection.[3,6,27,28]

To detect AF or AFL, this study utilized PPG technology in the intervention group. This technology is promising and has rapidly advanced over the last decade,[29,30] particularly in combination with artificial intelligence.[31] Its use is increasing both in clinical trials and real-world applications.[31–33] However, the ESC guidelines for the diagnosis and management of AF are not updated as frequently as PPG technology advances. Recent validation studies have demonstrated that PPG-based smartphone applications can detect AF or AFL with high accuracy, using either manual reading of the PPG recording or algorithm interpretation.[15,16] This has led to conflicting situations where AF management interventions were performed based on PPG measurements without ECG confirmation, contrary to the guidelines. Given these validation studies, cases where AF or AFL episodes were detected with multiple sequential high-quality PPG measurements using the FC algorithm and confirmed by manual reading, yet terminated prior to ECG confirmation, had a high likelihood of being true AF or AFL episodes. This was particularly evident if subsequent PPG measurements following the AF or AFL episode demonstrated sinus rhythm, indicating the episode had terminated. The study shows that this was convincing enough for the independent physician, not involved in the study protocol, to guide AF management despite being aware that this approach is not yet supported by the guidelines. This is increasingly relevant as PPG is already being used to detect AF or AFL in clinical trials and in clinical practice.[14,34,35] Interestingly, the intervention group exhibited a higher number of patients diagnosed with AF or AFL by ECG alone compared to the usual care group (seven vs. four patients). This observation is assumed to be due to a heightened awareness of AF and AFL among patients induced by the study intervention. These patients were all diagnosed with clinical ECGs. The main reason why these arrhythmias were not detected with PPG in the intervention group was non-compliance with PPG monitoring.

The ABC pathway for integrated AF management also applies to patients with AFL and includes: (i) stroke prevention with OAC, (ii) symptom reduction with rate or rhythm control, and (iii) evaluation of risk factors.[5] In patients with non-surgical AF or AFL at risk for stroke, OAC therapy is strongly recommended.[5,11,13] In patients with early POAF, OAC therapy should be considered (at least for a limited duration).[5,11] Patients identified with AF or AFL during the post-hospitalization phase occupy an intermediate position within this spectrum for which data from randomized studies are lacking. Hence, initiation of long-term OAC therapy remains a case-based decision. In this study, OAC therapy was initiated five times more often in the monitoring group compared to the usual care group. However, not all patients with AF or AFL who were eligible for OAC therapy based on the CHA_2DS_2-VASc score were started on OAC. This reflects the case-based assessment by independent physicians opting not to initiate OAC in some patients with a detection of AF or AFL despite an elevated CHA_2DS_2-VASc score.

A rhythm control strategy includes interventions to restore and maintain sinus rhythm with direct cardioversion and/or AAD. In patients with new-onset non-surgically related AF and cardiovascular conditions, early rhythm control decreases the risk of important adverse cardiovascular events.[12] In patients with early POAF, the determination to pursue rhythm control, is a clinical decision primarily based on factors such as haemodynamic instability, symptoms, or difficult rate control.[5] The evidence in early POAF is limited and fails to establish clear benefits of rhythm control for early POAF in terms of hospital length of stay, recurrence of AF, or mortality.[36] Again, patients with AF or AFL detected in the post-hospitalization phase are situated in the middle of this spectrum. Therefore, the effect of early rhythm control to decrease the risk of cardiovascular events is more likely to apply for AF or AFL in the post-hospitalization phase than for early POAF during the hospitalization phase. This study observed a seven-fold increase in rhythm control interventions due to PPG-based monitoring. Hence, considering the presumed effects of OAC initiation and early rhythm control in this population, we hypothesize that enhanced cardiac monitoring can play a role in optimizing outcome following cardiac surgery.

The primary outcome measure extends the beneficial effect of PPG-based rhythm monitoring after the hospitalization phase from increasing the detection rate of AF or AFL to optimizing AF management. A larger trial with longer follow-up is needed to determine whether the optimization of AF management will lead to improved patient outcomes.

Limitations

This study monitored patients during 6 weeks after hospital discharge. The study did not monitor the long-term, ongoing risk of AF or AFL. The study used a smartphone-based monitoring technique. Patients without access to a smartphone were not included in this trial. Even with this patient-centred monitoring technique, some patients did not complete the digital monitoring. Lack of adherence by these patients led to underestimation of AF or AFL. With intermittent monitoring, short asymptomatic AF episodes remained undetected. However, the importance of short asymptomatic AF episodes remains questionable,[37–40] and there was no improvement in clinical outcomes with continuous monitoring over intermittent monitoring for early POAF in a recent meta-analysis.[41] By design, this study was not powered to detect differences in major adverse cardiovascular outcomes and stroke rates. As a consequence, the study's scope did not extend to the potential modification of ischaemic risk by OAC therapy.

Conclusion

In unselected patients discharged home following cardiac surgery, PPG-based smartphone monitoring revealed significantly more AF and AFL detection with PPG or ECG technology which led to optimization of AF management, including OAC therapy and rhythm control therapy.

Supplementary material

Supplementary material is available at *Europace* online.

Author contributions

H.G., P.H., and F.R. conceptualized and designed the study. H.G. and P.H. had full access to the data, supervised the project, and take responsibility for the integrity of the data and the accuracy of the data analysis. H.G. and L.V.L. analysed the data. H.G. drafted the first version of the manuscript. H.G., N.D.M., L.D., and P.Ve. contributed to data acquisition. H.H., L.P., and P.Va. contributed to conceptual thinking and data interpretation. All authors took part in the revision of the manuscript and approved the submitted version.

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Conflict of interest: H.H. received personal lecture and consultancy fees from Bayer, Biotronik, Bristol Myers Squibb, Centrix Healthcare Ltd, Daiichi Sankyo, Downtown Europe, Pfizer-BMS, ESC, Medscape, Springer Healthcare Ltd, and Viatris Pharmaceuticals Inc. He received unconditional research grants through the University of Antwerp and/or the University of Hasselt from Abbott, Bayer, Biosense Webster, Boston Scientific, Daiichi Sankyo, FibriCheck/Qompium, Medtronic, and Pfizer-BMS, all outside the scope of this work. P.V. holds stock in Qompium NV. The other authors have nothing to declare.

Data availability

Data will be shared upon reasonable request to the corresponding author.

References

1. Lubitz SA, Yin X, Rienstra M, Schnabel RB, Walkey AJ, Magnani JW *et al.* Long-term outcomes of secondary atrial fibrillation in the community the Framingham Heart Study. *Circulation* 2015;**131**:1648–55.
2. Lin MH, Kamel H, Singer DE, Wu YL, Lee M, Ovbiagele B. Perioperative/postoperative atrial fibrillation and risk of subsequent stroke and/or mortality: a meta-analysis. *Stroke* 2019;**50**:1364–71.
3. Abdelmoneim SS, Rosenberg E, Meykler M, Patel B, Reddy B, Ho J *et al.* The incidence and natural progression of new-onset postoperative atrial fibrillation. *JACC Clin Electrophysiol* 2021;**7**:1134–44.
4. Ha ACT, Verma S, Mazer CD, Quan A, Yanagawa B, Latter DA *et al.* Effect of continuous electrocardiogram monitoring on detection of undiagnosed atrial fibrillation after hospitalization for cardiac surgery: a randomized clinical trial. *JAMA Netw Open* 2021;**4**:e2121867–867.
5. Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomström-Lundqvist C *et al.* 2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J* 2021;**42**:373–498.
6. Bidar E, Zeemering S, Gilbers M, Isaacs A, Verheule S, Zink MD *et al.* Clinical and electrophysiological predictors of device-detected new-onset atrial fibrillation during 3 years after cardiac surgery. *Europace* 2021;**23**:1922–30.
7. Shahim B, Malaisrie SC, George I, Thourani VH, Biviano AB, Russo M *et al.* Postoperative atrial fibrillation or flutter following transcatheter or surgical aortic valve replacement: PARTNER 3 trial. *JACC Cardiovasc Interv* 2021;**14**:1565–74.
8. Kaw R, Hernandez AV, Masood I, Gillinov AM, Saliba W, Blackstone EH. Short- and long-term mortality associated with new-onset atrial fibrillation after coronary artery bypass grafting: a systematic review and meta-analysis. *J Thorac Cardiovasc Surg* 2011;**141**:1305–12.
9. Gillinov AM, Bagiella E, Moskowitz AJ, Raiten JM, Groh MA, Bowdish ME *et al.* Rate control versus rhythm control for atrial fibrillation after cardiac surgery. *N Engl J Med* 2016;**374**:1911–21.
10. Butt JH, Xian Y, Peterson ED, Olsen PS, Rørth R, Gundlund A *et al.* Long-term thromboembolic risk in patients with postoperative atrial fibrillation after coronary artery bypass graft surgery and patients with nonvalvular atrial fibrillation. *JAMA Cardiol* 2018;**3**:417–24.
11. Joglar JA, Chung MK, Armbruster AL, Benjamin EJ, Chyou JY, Cronin EM *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* 2024;**149**:109–279.
12. Kirchhof P, Camm AJ, Goette A, Brandes A, Eckardt L, Elvan A *et al.* Early rhythm-control therapy in patients with atrial fibrillation. *N Engl J Med* 2020;**383**:1305–16.
13. Hart RG, Pearce LA, Aguilar MI. Meta-analysis: antithrombotic therapy to prevent stroke in patients who have nonvalvular atrial fibrillation. *Ann Intern Med* 2007;**146**:857–67.
14. Svennberg E, Tjong F, Goette A, Akoum N, Di Biaise L, Bordachar P *et al.* How to use digital devices to detect and manage arrhythmias: an EHRA practical guide. *Europace* 2022;**10**:15.
15. Gruwez H, Ezzat D, Van Puyvelde T, Dhont S, Meekers E, Bruckers L *et al.* Real-world validation of smartphone-based photoplethysmography for rate and rhythm monitoring in atrial fibrillation. *Europace* 2024;**26**:5–8.
16. Fernstad J, Svennberg E, Åberg P, Kemp Gudmundsdottir K, Jansson A, Engdahl J. Validation of a novel smartphone-based photoplethysmographic method for ambulatory heart rhythm diagnostics: the SMARTBEATS study. *Europace* 2024;**26**:euae079.
17. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L *et al.* The REDCap consortium: building an international community of software platform partners. *J Biomed Inform* 2019;**95**:103208.
18. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;**42**:377–81.
19. Proesmans T, Mortelmans C, Van Haelst R, Verbrugge F, Vandervoort P, Vaes B. Mobile phone–based use of the photoplethysmography technique to detect atrial fibrillation in primary care: diagnostic accuracy study of the FibriCheck app. *JMIR Mhealth Uhealth* 2019;**7**:e12284.
20. Maesen B, Nijs J, Maessen J, Allessie M, Schotten U. Post-operative atrial fibrillation: a maze of mechanisms. *Europace* 2012;**14**:159–74.
21. Gaudino M, Di Franco A, Rong LQ, Piccini J, Mack M. Postoperative atrial fibrillation: from mechanisms to treatment. *Eur Heart J* 2023;**44**:1020–39.
22. Ayoub K, Habash F, Almomani A, Xu J, Marji M, Shaw-Devine A *et al.* Long term risk of recurrent atrial fibrillation and ischemic stroke after post-operative atrial fibrillation complicating cardiac and non-cardiac surgeries. *J Atr Fibrillation* 2018;**10**:1–5.
23. Lowres N, Mulcahy G, Gallagher R, Ben Freedman S, Marshman D, Kirkness A *et al.* Self-monitoring for atrial fibrillation recurrence in the discharge period post-cardiac surgery using an iPhone electrocardiogram. *Eur J Cardiothorac Surg* 2016;**50**:44–51.
24. Saliba W, Gronich N, Barnett-Griness O, Rennert G. Usefulness of CHADS2 and CHA2DS2-VASc scores in the prediction of new-onset atrial fibrillation: a population-based study. *Am J Med* 2016;**129**:843–9.
25. Chao TF, Liu CJ, Chen SJ, Wang KL, Lin YJ, Chang SL *et al.* CHADS2 score and risk of new-onset atrial fibrillation: a nationwide cohort study in Taiwan. *Int J Cardiol* 2013;**168**:1360–3.
26. Rizas KD, Freyer L, Sappler N, von Stülpnagel L, Spielbichler P, Krasniqi A *et al.* Smartphone-based screening for atrial fibrillation: a pragmatic randomized clinical trial. *Nat Med* 2022;**28**:1823–30.
27. Kaur H, Healey JS, Belley-Cote EP, Bidar E, Kawczynski M, Ayala-Paredes FA *et al.* Long-term recurrence of new-onset post-operative AF in cardiac surgery patients as detected by an implantable loop recorder: a systematic review and individual participant data meta-analysis. *Eur Heart J* 2023;**404**:131930.
28. Thorén E, Wernroth ML, Christersson C, Grinnemo KH, Jidéus L, Ståhle E. Compared with matched controls, patients with postoperative atrial fibrillation (POAF) have increased long-term AF after CABG, and POAF is further associated with increased ischemic stroke, heart failure and mortality even after adjustment for AF. *Clin Res Cardiol* 2020;**109**:1232–42.
29. Svennberg E, Caiani EG, Bruining N, Desteghe L, Han JK, Narayan SM *et al.* The digital journey: 25 years of digital development in electrophysiology from an Europace perspective. *Europace* 2023;**25**:1–2.
30. Chen W, Khurshid S, Singer DE, Atlas SJ, Ashburner JM, Ellinor PT *et al.* Cost-effectiveness of screening for atrial fibrillation using wearable devices. *JAMA Health Forum* 2022;**3**:e222419–19.
31. Schnabel RB, Marinelli EA, Arbelo E, Boriani G, Boveda S, Buckley CM *et al.* Early diagnosis and better rhythm management to improve outcomes in patients with atrial fibrillation: the 8th AFNET/EHRA consensus conference. *Europace* 2023;**25**:6–27.
32. Brandes A, Stavrakis S, Freedman B, Antoniou S, Boriani G, Camm AJ *et al.* Consumer-Led screening for atrial fibrillation: frontier review of the AF-SCREEN international collaboration. *Circulation* 2022;**146**:1461–74.
33. Hermans ANL, Isaksen JL, Gawalko M, Pluymaekers NAHA, van der Velden RMJ, Snippe H *et al.* Accuracy of continuous photoplethysmography-based 1 min mean heart rate assessment during atrial fibrillation. *Europace* 2023;**25**:835–44.
34. Linz D, Pluymaekers NAHA, Hendriks JM. TeleCheck-AF for COVID-19. *Eur Heart J* 2020;**41**:1954–5.
35. Manninger M, Kosiuk J, Zweiker D, Njeim M, Antolic B, Kircanski B *et al.* Role of wearable rhythm recordings in clinical decision making—the wEHRAbles project. *Clin Cardiol* 2020;**43**:1032–9.
36. Ahmed M, Belley-Coté EP, Qiu Y, Belesiotis P, Tao B, Wolf A *et al.* Rhythm vs. Rate control in patients with postoperative atrial fibrillation after cardiac surgery: a systematic review and meta-analysis. *J Clin Med* 2023;**12**:4534.
37. Kirchhof P, Toennis T, Goette A, Camm AJ, Diener HC, Becher N *et al.* NOAH-AFNET 6 investigators. Anticoagulation with edoxaban in patients with atrial high-rate episodes. *N Engl J Med* 2023;**389**:1167–79.
38. Healey JS, Lopes RD, Granger CB, Alings M, Rivard L, McIntyre WF *et al.* Apixaban for stroke prevention in subclinical atrial fibrillation. *N Engl J Med* 2023;**390**:107–17.
39. Svendsen JH, Diederichsen SZ, Højberg S, Krieger DW, Graff C, Kronborg C *et al.* Implantable loop recorder detection of atrial fibrillation to prevent stroke (the LOOP study): a randomised controlled trial. *The Lancet* 2021;**398**:1507–16.
40. Van Gelder IC, Healey JS, Crijns HJGM, Wang J, Hohnloser SH, Gold MR *et al.* Duration of device-detected subclinical atrial fibrillation and occurrence of stroke in ASSERT. *Eur Heart J* 2017;**38**:1339–44.
41. Perezgrovas-Olaria R, Alzghari T, Rahouma M, Dimagli A, Harik L, Soletti GJ *et al.* Differences in postoperative atrial fibrillation incidence and outcomes after cardiac surgery according to assessment method and definition: a systematic review and meta-analysis. *J Am Heart Assoc* 2023;**12**:30907.