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Self-monitoring for recurrence of secondary atrial fibrillation following non-cardiac surgery or acute illness: A pilot study

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ABSTRACT

Background: Atrial fibrillation (AF) secondary to non-cardiac surgery and medical illness is common and, although often transient, is associated with an increased risk of stroke and mortality. This pilot study tested the feasibility of self-monitoring to detect recurrent AF in this setting and the frequency with which it occurred.

Methods: Patients with new secondary AF after non-cardiac surgery or medical illness that reverted to sinus rhythm before discharge were recruited in three tertiary hospitals in Australia. Participants performed self-monitoring for AF recurrence using a Handheld single-lead ECG device 3–4 times/day for 4-weeks.

Results: From 16,454 admissions, 224 (1.4%) secondary AF cases were identified. Of these, 94 were eligible, and 29 agreed to participate in self-monitoring (66% male; median age 67 years). Self-monitoring was feasible and acceptable to participants in this setting. Self-monitoring identified AF recurrence in 10 participants (34%; 95% CI, 18% −54%), with recurrence occurring ≤ 9 days following discharge in 9/10 participants. Only 4 participants (40%) reported associated palpitations with recurrence. Six participants (60%) with recurrence had a CHA_2DS_2-VA score ≥ 2, suggesting a potential indication for oral anticoagulation.

Conclusions: Approximately 1 in 3 patients with transient secondary AF will have recurrent AF within nine days of discharge. These recurrent episodes are often asymptomatic but can be detected promptly using patient self-monitoring, which was feasible and acceptable. Future research is warranted to further investigate the incidence of secondary AF, the rate of recurrence after discharge and its prognosis, and whether use of oral anticoagulation can reduce stroke in this setting.

1. Introduction

New-onset atrial fibrillation (AF) following hospitalisation for either acute medical illness or non-cardiac surgery, henceforth called secondary AF, is common and associated with poor prognosis [1]. Secondary AF occurs in 7.2% of medical ICU patients and up to 44% with septic shock [1,2]. Additionally, patients admitted with infections are up to 2.6 times more likely to develop secondary AF [3]. Secondary AF also occurs after ~1% of non-cardiac surgical procedures [4], equating to > 2 million cases of secondary AF per year given the large numbers of these procedures performed worldwide [5]. The incidence of secondary AF is higher following procedures such as abdominal surgery (11%)[6] or gastrectomy for cancer (8%)[7].

Secondary AF is often considered to be transient and provoked, because mostly it resolves spontaneously without need for car-

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dioversion, and subsequently there is uncertainty about the need for treatment [8–10]. However, retrospective registry data show patients with transient AF experience a recurrent AF episode in 42–44% of medical patients within 5 years [1,3,11] and a recurrence rate of 15% following non-cardiac surgery over ~2.5 years [12]. Despite this, surveillance for AF recurrence after hospital discharge is largely lacking, and detection of recurrence largely depends on symptomatic representation of the patient. However, palpitations occur in only a third of AF episodes [13], and atypical symptoms such as fatigue and dizziness may easily be attributed to recovery from hospitalisation. For these reasons, symptoms are likely an unreliable guide to AF recurrence.

Intuitively, early identification of secondary AF recurrence after discharge and subsequent anticoagulation could reduce the risk of stroke and its burden. Portable handheld ECG devices, including the AliveCor KardiaMobile ECG and Zenicor ECG, are suitable for patients to record their own ECG in the home environment [14,15]. However, there is little evidence assessing their value in identifying recurrent secondary AF after hospital discharge. Therefore, this study aimed to assess the feasibility of 1) identifying patients with a transient episode of secondary AF that reverted to sinus rhythm prior to discharge; and 2) patient self-monitoring for AF recurrence after discharge using a handheld ECG device.

2. Methods

2.1. Study design

This was a prospective, feasibility study using a cross-sectional design at three tertiary hospital sites within Australia: Concord Repatriation General Hospital, Sydney (July 2016 to December 2016), Royal Perth Hospital, Perth (March 2017 to May 2018), and Gosford Hospital, Sydney (August 2017 to November 2018). Ethics approval was provided by Sydney Local Health District Human Research Ethics Committee – CRGH (CH62/6/2016-028) and South Metropolitan Health Service Human Research Ethics Committee (2016-099), and the study conforms to the ethical guidelines of the 1975 Declaration of Helsinki. The trial was prospectively registered with Australia New Zealand Clinical Trials Registry (ACTRN12616000904471).

2.2. Study population

The study recruited patients with an episode of new-onset AF secondary to hospitalisation for either non-cardiac surgery or non-cardiovascular acute medical illness. Patients were eligible if they were 1) admitted to hospital in sinus rhythm with no prior history of AF; 2) reverted to sinus rhythm prior to discharge (spontaneously or via cardioversion); 3) $\geq$ 18 years; and 4) able to provide informed consent. Patients were excluded if they were non-English speaking; or were unable to be contacted by phone following discharge.

2.3. Identification and recruitment of secondary AF cases

To identify patients with secondary AF, we used a progressively modified case finding strategy at each of the three hospital sites. We commenced with a strategy that most closely resembled standard practice at the first site, and then added additional nursing staff resources at the second two sites.

2.3.1. Case finding strategies

Site 1: Solely the cardiology registrars, identifying patients from those referred to the cardiology team from the surgical ward and ICU.

Site 2: A combination of the cardiology registrars, identifying patients from those referred to the cardiology team by the surgical and medical wards; and a research nurse who visited each ward (once per week) to review for secondary AF cases.

Site 3: A combination of the cardiology registrars, identifying patients from those referred to the cardiology team by the surgical and medical wards; and a research nurse who visited each ward (three times per week) to review for secondary AF cases.

Once a patient with secondary AF was identified, the research nurse assessed eligibility and approached eligible patients during the hospital stay. All participants received information about the study and provided written informed consent. No incentives were provided for participation. All participants received the intervention and the study was not blinded.

2.4. Baseline assessment

The baseline assessment was performed by the research nurse during the hospital stay. Socio-demographic and clinical data were collected from the medical record and participant. Socio-demographic data included age, gender, and education level. Clinical data included admission diagnosis/procedure; comorbidities including CHA_2DS_2-VA score (i.e. sexless CHA_2DS_2-VASc) [16], HAS-BLED score [16], thyroid function/status, obstructive sleep apnoea and pulmonary disease; and current medications. In addition, a 30-second lead-1 handheld ECG using the AliveCor KardiaMobile ECG was recorded to determine baseline heart rhythm.

2.5. Intervention

During the inpatient stay, all participants received education about AF, stroke risk, and the spectrum of AF symptoms (including palpitations, fatigue, dizziness and syncope). Each participant was provided with an AliveCor KardiaMobile ECG and Huawei Y560 smartphone for four-weeks and taught how to record their own 30-second ECG recording. Participants were asked to record their own ECG 3-times each day, for 4-weeks commencing after hospital discharge. Education was provided regarding the three possible results (i.e. normal; possible AF; or unclassified) determined by the automatic algorithm on the KardiaMobile ECG. If the device detected 'possible AF', participants were advised to immediately take additional ECG recordings, and to contact their treating doctor to discuss the results as soon as practicable. Additional ECG recordings were also advised if participants experienced any potential AF symptoms. Participants were provided with a diary to record and date any symptoms experienced.

Follow up occurred 4-weeks after hospital discharge, during which the research nurse reviewed all ECG readings and discussed the results with the participant. Participant's actions when 'possible AF' was identified by the device were noted, and any new diagnoses or treatment resulting from the screening intervention. The ECG results were also compared against the AF symptom diary. All participants were invited to participate in a semi-structured qualitative interview (Supplement 1). Interviews explored the participant's experience using the ECG, specifically, ease of use and any benefits and challenges they perceived from the program. Each interview was audio recorded and transcribed verbatim in a non-identifiable form. Once transcribed each recording was deleted. Interviews were analysed using content analysis.

A final phone call was made to each participant at 3-months post discharge to determine if any further changes were made to the person's medical treatment because of the intervention.

3. Outcomes

3.1. Primary outcome

Feasibility and efficacy of patient self-monitoring for AF recurrence after discharge, using a handheld ECG. Assessed using:

- acceptability and patient willingness to participate in the program (measured using recruitment data and qualitative process evaluation)
- compliance of participants to the intervention (measured by number of actual ECG recordings compared to requested protocol; and if participants actioned a review with their treating doctors if 'possible AF' was diagnosed by the on-device automated algorithm)
- incidence of AF recurrence identified through self-monitoring after discharge

3.2. Secondary outcomes

1. The relative effectiveness of case finding strategies to identify new onset secondary AF patients, and incidence of new onset secondary AF.
2. Thromboembolic and bleeding risk profile of patients with new onset secondary AF; measured using CHA_2DS_2-VA (i.e. sexless CHA_2DS_2-VASc) and HAS-BLED scores [16].

3.3. Statistics

Continuous variables are reported as medians and interquartile range (IQR), and categorical variables as numbers and percentages. Incidence of AF recurrence is presented as rates (true positives divided by total number screened) with accompanying binomial 95% CI calculated using Clopper–Pearson methodology. Pearson's chi-square test was used to compare case finding between recruitment sites. Due to the small sample size we did not statistically compare the groups with- and without AF recurrence. As the primary outcome was feasibility and acceptability, a power calculation was not performed.

4. Results

4.1. Case finding

The period of recruitment was 6-months at site one, and 13-months at site two and three (Fig. 1). In total, 16,454 patients were screened (range per site: 1050 to 12,970), identifying 224 (1.4%) secondary AF cases (range per site: 5 to 202 cases), (Fig. 1) with significant differences noted between the sites ($p < 0.001$). The site relying solely on the cardiology registrar to identify secondary AF cases, via ward referrals to the cardiology team, identified only 5 cases from 1050 patients screened (0.5%). The site with a nurse reviewing the ward lists three-times per week, in addition to the cardiology registrar, identified 202 cases from 12,970 patients screened (1.6%).

Ninety-four of the 224 secondary AF patients (42%) were eligible for recruitment, the main reason for exclusion being failure to revert to sinus rhythm before discharge (Fig. 1). Of the eligible patients, 32 were recruited (34%) and 29 (66% male; median age 67 years [IQR 57-74]) went on to complete the self-monitoring intervention (table 1). Nineteen (66%) were reviewed by a cardiologist on the ward, and just over half (52%) spontaneously reverted to sinus rhythm, without intervention, prior to discharge (table 1). Of note, over one third (38%) of participant were on rhythm-control medication on discharge. Primary admission diagnoses were varied (table 1) but pneumonia (n = 5) was most common.

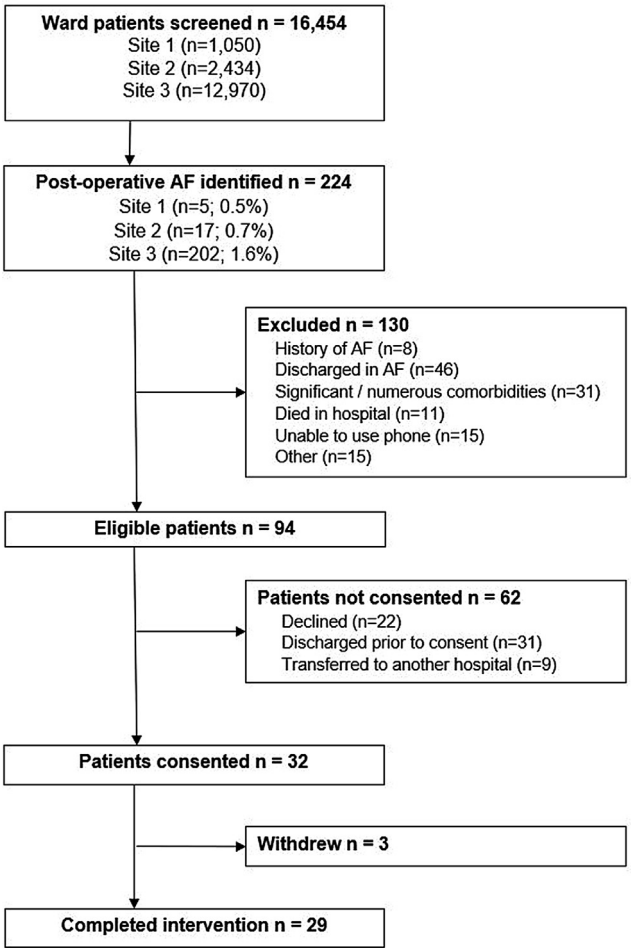

Fig. 1. Study Flow.

4.2. Participant self-monitoring

17/29 (59%) participants completed 4-weeks of self-monitoring, 3/29 (10%) completed between 3 and 4 weeks, 2/29 (7%) completed between 1 and 3 weeks, and 6 individuals (21%) completed < 1 week (of these 3 were readmitted to hospital within 1-week; and 2 withdrew due to dislike of the pop-up advertisements, google games requests, and app update requests that we were unable to disable on the study phone). Participants recorded an ECG a median of 28 days (IQR 10-31), with a median of 3.5 (IQR 1.5-4.5) recordings per day. Compliance with the screening intervention is illustrated for a sub-set of participants in Fig. 2.

Sixteen people, who completed the screening intervention, participated in semi-structured interviews at 4-weeks (Supplement 1). All 16 reported the ECG device was easy to use, and time taken to record ECGs was not onerous. The majority (11/16) also reported a sense of security from being able to self-monitor at home, reporting it was "reassuring" and gave them "a sense of control".

4.3. Atrial fibrillation recurrence

Self-monitoring resulted in 12/29 participants diagnosed with 'possible AF' by the device algorithm. Ten of the 12 participants followed instructions and sought medical review prior to the 4-week follow-up, and all were confirmed with AF recurrence: recurrence

Table 1
Participant characteristics.

Characteristic	Secondary AF (n = 29) Number (%)	AF recurrence (n = 10) Number (%)	No recurrence (n = 19) Number (%)
Gender, male	19 (66)	6 (60)	13 (68)
Primary admission diagnosis			
Medical (n = 15)			
Pneumonia	5 (17)	1 (10)	4 (21)
Acute pulmonary oedema	2 (7)	1 (10)	1 (5)
Sepsis	2 (7)	0	2 (11)
Cellulitis	1 (3)	0	1 (5)
Infected diabetic foot ulcer	1 (3)	0	1 (5)
Myopericarditis	1 (3)	1 (10)	0
Pancreatitis	1 (3)	1 (10)	0
Gastro virus	1 (3)	0	1 (5)
Spasmodic dysphonia	1 (3)	0	1 (5)
Surgical (n = 14)			
Orthopaedic (lower limb)	4 (14)	2 (20)	2 (11)
Bowel	4 (14)	3 (30)	1 (5)
Cancer	2 (7)	0	2 (11)
Vascular	2 (7)	0	2 (11)
Ureteroscopy / stent insertion	1 (3)	1 (10)	0
Thyroid	1 (3)	0	1 (5)
Comorbidities			
Hypertension	17 (59)	7 (70)	10 (53)
Diabetes	8 (28)	4 (40)	4 (21)
Vascular disease	3 (10)	0	3 (16)
Previous stroke or TIA	2 (7)	0	2 (11)
Congestive heart failure	1 (3)	0	1 (5)
COPD	3 (10)	0	3 (16)
Respiratory failure	3 (10)	0	3 (16)
Renal dysfunction	3 (10)	2 (20)	1 (5)
Obstructive sleep apnoea	0	0	0
Cardiologist review during hospitalisation	19 (66)	5 (50)	14 (74)
Reversion to sinus rhythm			
Spontaneous	15 (52)	6 (60)	9 (47)
Cardioversion / Amiodarone	14 (48)	4 (40)	10 (53)
CHA_2DS_2-VA score ≥ 2	16 (55)	6 (60)	10 (53)
Medication on discharge			
Anticoagulant (warfarin / NOAC)	18 (62)	6 (60)	12 (63)
Rhythm control (amiodarone/ sotalol)	11 (38)	3 (30)	8 (42)
Rate control (digoxin / β-blocker/ calcium channel blocker)	12 (41)	4 (40)	8 (42)
None of above	6 (21)	2 (20)	4 (21)
	Median (IQR)	**Median (IQR)**	**Median (IQR)**
Age, years	67 (57–74)	65 (56–73)	68 (57–75)
Length of hospitalisation, days	8 (6–18)	6 (4–10)	9 (6–25)
Maximum AF rate during admission, bpm	140 (113–160)	130 (118–145)	140 (110–160)
Stroke risk, CHA_2DS_2-VA score	2 (1–3)	2 (1–3)	2 (1–3)
Bleeding risk, HASBLED score	1 (0–2)	1 (0–1)	1 (1–2)
BMI	27 (22–37)	29 (23–30)	27 (21–38)

AF = atrial fibrillation; TIA = transient ischaemic attack; COPD = chronic obstructive pulmonary disease; NOAC = non-vitamin K oral anticoagulant; CHA_2DS_2-VA = (C: congestive heart failure/left ventricular dysfunction, H for high blood pressure, A_2: age > 75 years, D: diabetes, S_2: stroke/transient ischemic attack/thromboembolism, V: vascular disease [coronary artery disease, myocardial infarction, peripheral artery disease, aortic plaque], A: age 65 – 74 years); HASBLED = (H: Hypertension, A: Abnormal renal/liver function, S: stroke, B: Bleeding tendency, L: Labile INR, E: Elderly > 65 years, D: Drugs Concomitant aspirin NSAIDS or alcohol); bpm = beats per minute; IQR = interquartile range; BMI = body mass index.

incidence 34% (95% CI, 18%-54%) (10/29) (Table 1). This resulted in a change in clinical management in 9/10 cases: hospitalisation for reversion (n = 3), cardiology referral (n = 3), commencement of oral anticoagulation (n = 2), insertion of permanent pacemaker (n = 1); and 1 case had no change in management as they were discharged home on anticoagulants. The ECG recordings for the remaining 2 participants with 'possible AF' were reviewed by the research team cardiologists and were determined to be sinus rhythm with atrial ectopic beats and artefact.

AF recurrence was first identified at a median of 6 days (range 2–23 days) post discharge with 9/10 recurrences occurring in $\leq$ 9 days. Five of the 10 participants with recurrent AF experienced associated symptoms: palpitations alone (n = 2), combination of palpitations plus fatigue or dizziness (n = 2), and fatigue only (n = 1).

In addition to the above-mentioned participants, an additional patient was identified with previously undetected AF recurrence by the research nurse whilst being screened for recruitment with the handheld ECG. As the patient was found to be in AF, the patient was not recruited to the study (Fig. 1).

4.4. Thromboembolic and bleeding risk

More than half (55%, 16/29) of participants with secondary AF, and 60% (6/10) of participants in the AF recurrence subgroup, had a CHA_2DS_2-VA score ≥ 2 and therefore a class-1 guideline recommendation for oral anticoagulation (Table 1). The median CHA_2DS_2-VA score for all participants was 2 (IQR: 1–3) not differing across subgroups (Table 1). The median HASBLED (bleeding risk) score was 1 (IQR: 0–2) for the 29 secondary AF participants, and 1 (IQR: 0–1) for the AF recurrence subgroup (Table 1).

5. Discussion

To our knowledge, this is the first study to use self-monitoring to detect AF recurrence after hospital discharge in non-cardiac surgical and medical patients. Our results indicate self-monitoring with a hand-held ECG is feasible, that patients can easily manage the technology, and they experience a sense of security using it. Self-monitoring detects a high rate of recurrent AF, most of which occurs within 9 days of discharge. Most recurrences were asymptomatic and many individuals with recurrence were at high risk of stroke. Self-monitoring after hospital discharge is worth exploring further in this population, especially as ways of self-monitoring for AF are expanding and emerging technology is becoming more readily available.

5.1. Screening for recurrent AF after discharge

Our detection rate of 34% over 30 days of self-monitoring, is similar to the detection rate of 30% noted in a recent study that used an event recorder for ~14-days during months 1-, 6-, and 12 following discharge after surgery for malignancy [17]. To date, we are not aware of any other prospective studies that have reported on secondary AF recurrence after discharge, although a Canadian study is in progress [18]. Our previous study that employed similar methodology to the current study using a hand-held ECG following cardiac surgery, identified an AF recurrence rate of 24% within 17-days of discharge [14]. Similarly, a systematic review of monitoring for postoperative AF after cardiac surgery discharge, identified approximately 28% recurrence within 30-days, with various monitoring methods used [19]. Regardless of the patient group and method of monitoring, all studies have reported 50–93% of AF recurrences were asymptomatic, and palpitations occurred in only 7–30% of all recurrences [14,17,19]. Thus, our results appear to be consistent with the limited studies available, and it is likely that most AF recurrences will go undetected and not brought to the attention of the patients' physician without explicit monitoring.

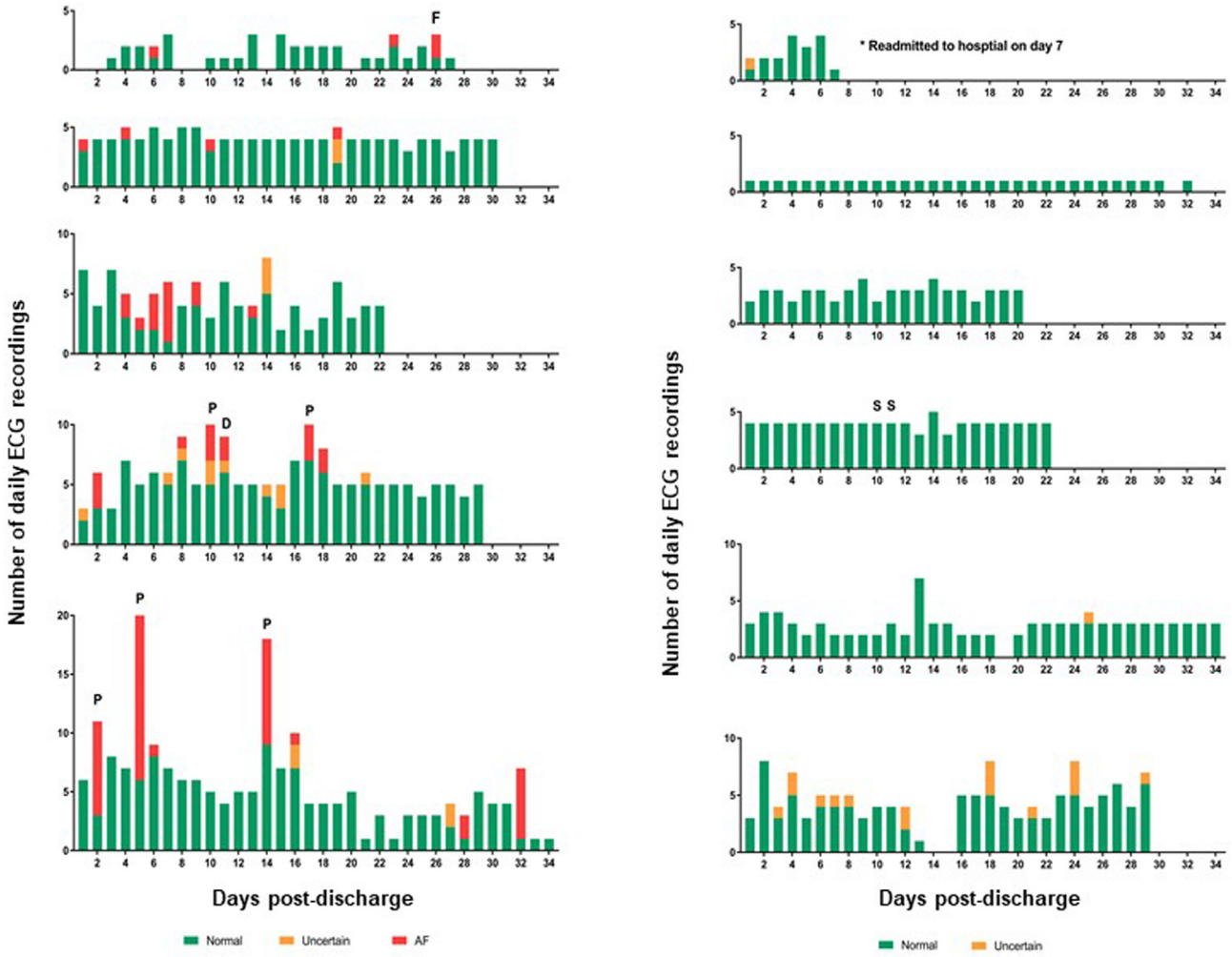

Fig. 2. Patterns of compliance with screening intervention and symptoms, Legend: AF = atrial fibrillation; ECG = electrocardiogram; P = palpitations; D = dizziness; F = fatigue; S = shortness of breath.

5.2. Secondary AF: Risk profile and consequences

Patients with secondary AF after non-cardiac surgery have an approximately 5-fold increased risk of ischaemic stroke and myocardial infarction, with approximately 2.5 fold increase in death within 1-year of surgery [4,7,10]. In fact, stroke risk is significantly higher for people with AF after non-cardiac compared to cardiac surgery (HR 2.0 vs 1.3 $p < 0.001$) [4]. Similarly, stroke and mortality rates for secondary AF following acute medical illness parallel those reported for clinically detected AF [1]. Infection-related secondary AF is also associated with higher risk of stroke (HR 1.91) and death (HR 1.52) compared to those without AF [3]. Despite this, there are no guidelines to direct management of secondary AF attributed to non-cardiac surgery and medical admissions, and in many cases, secondary AF is untreated with thromboprophylaxis because it is felt to be transient, provoked and hence less likely to recur.

The decision as to whether to treat patients with secondary AF with oral anticoagulation is not clear, especially as the majority of episodes revert to sinus rhythm before discharge [20], and our findings suggest half the reversions are spontaneously. As such, many patients are presumed to be in stable sinus rhythm at and after discharge. This presumption is clearly incorrect, and it is possible that recurrent AF following discharge portends a greater risk of stroke or systemic thrombo-embolism. Recent trials have shown oral anticoagulation after discharge can reduce thromboembolic events in patients with post-operative AF after valve surgery (HR 0.45) [21], and for secondary AF following infection [3]. This highlights the potential use of oral anticoagulation in patients with secondary AF, to reduce risk of stroke and premature death, presuming that AF episodes are identified during hospitalisation.

5.3. Identification of patients with secondary AF

The incidence of secondary AF during medical admissions ranges from 1% to 44%, according to a recent systematic review, and the rate is highly influenced by duration of ECG monitoring [22]. The incidence of AF post non-cardiac surgery is also highly variable, ranging from 0.5% to 15% [23]. ECG monitoring for 48–72 h is guideline recommended for detection of postoperative AF after thoracic surgery [24]. However, surveillance for AF is not routine after non-cardiothoracic surgery, nor during many acute medical illnesses, and thus considerable numbers of transient secondary AF episodes will go undetected, particularly when a high proportion are asymptomatic or subclinical [25,26]. Further work is required to clarify the true incidence of secondary AF, and if necessary, develop strategies to better detect these during hospitalisation.

5.4. Strengths and limitations

Our study is unique as it investigates use of self-monitoring following discharge in a population potentially at high risk of stroke: i.e. new-onset AF during non-cardiac surgery or medical admission. In addition, our study was prospective and multicentre. This was a pilot study with a small sample size and the study results should be interpreted in this context. Furthermore, the study population may be biased, through self-selection, towards a sample more familiar with using a smartphone. The incidence of secondary AF identified on the wards is likely underestimated due to probable under-reporting of secondary AF episodes and a lack of routine comprehensive screening, thus the sample may be biased towards patients with symptomatic AF. Nursing review of ward lists identified significantly greater numbers with a secondary AF episode than reliance on the ward referring secondary AF episodes to the cardiology team. Nevertheless, the main aim of this study was to not to report the incidence of secondary AF but to determine the feasibility and utility of patient self-monitoring for AF recurrence after discharge.

5.5. Clinical implications

Currently, multiple methods exist for self-monitoring, including simple methods such as pulse palpation, which could be encouraged on discharge. Daily ECG self-monitoring, as used in our study, is likely to identify a high number of paroxysmal AF episodes. Importantly, the strategy used in the current study identifies recurrence soon after discharge facilitating early intervention and potentially reducing the likelihood of adverse consequences. Further studies looking at recurrence after discharge are warranted, to better understand the prognosis of AF recurrence versus non-recurrence, and to develop optimal treatment pathways for these patients.

6. Conclusions

Secondary AF is likely underdiagnosed during hospital admissions, especially on non-cardiac surgical and medical wards, and such patients appear to be at increased risk of thromboembolic stroke. The current data suggest approximately 1-in-3 patients who experience transient secondary AF in this setting and who are discharged in sinus rhythm, will have recurrent AF early after discharge. These recurrent episodes are often asymptomatic but can be detected promptly and easily using patient self-monitoring. Our data suggest most patients with recurrent AF have a risk of thromboembolic complications sufficient to consider prophylactic anticoagulation. Future research is required to further investigate the incidence of secondary AF, rate of recurrence after discharge, prognostic implications of AF recurrence, and to inform guidelines in this setting.

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CRediT authorship contribution statement

Nicole Lowres: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing - original draft. **Graham S. Hillis:** Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Supervision, Writing - review & editing. **Marc A. Gladman:** Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Supervision, Writing - review & editing. **Mark Kol:** Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Supervision, Writing - review & editing. **Jim Rogers:** Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Supervision, Writing - review & editing. **Vincent Chow:** Investigation, Methodology, Project administration, Resources, Supervision, Writing - review & editing. **Ferris Touma:** Investigation, Methodology, Project administration, Resources, Supervision, Writing - review & editing. **Cara Barnes:** Investigation, Project administration, Resources, Supervision, Writing - review & editing. **Joanne Auston:** Investigation, Project administration, Resources, Supervision, Writing - review & editing. **Ben Freedman:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing - review & editing.

Declaration of Competing Interest

BF reports prior fees and advisory board honoraria from Bayer Pharma AG, Boehringer Ingelheim, Daiichi-Sankyo, Omron and Pfizer/BMS, and grants to the institution for investigator-initiated studies from BMS and Pfizer. All other authors have no conflicts to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2020.100566.

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