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Atrial fibrillation trial to evaluate real-world procedures for their utility in helping to lower stroke events (AFTER-PULSE): Study protocol for a randomized controlled trial

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ABSTRACT

Background: Enhancing detection of undiagnosed atrial fibrillation (AF) in hospitalized patients with a recent ischemic stroke is important because of the treatment implications; especially since presence of paroxysmal AF may not be picked up in a single 12-lead electrocardiogram (ECG) test. While several trials have shown improved detection of AF with prolonged ECG monitoring, this strategy is associated with relatively high cost, labor intensity, and patient inconvenience, thereby making it challenging to routinely implement in all hospitals. Fortunately, conventional 24-h Holter monitoring and repeated 12-lead ECGs are readily available to detect paroxysmal AF in all hospitals, but is unclear which is the better strategy for evaluating undiagnosed AF. The objective of his study is to conduct a randomized trial of serial 12-lead ECGs vs. 24-hour Holter monitoring in the detection of AF in ischemic stroke patients without known AF.

Methods and analysis: We plan to enroll 1200 participants from six hospitals in Taiwan. Patients will be eligible for enrollment if they are admitted for an acute ischemic stroke within 2 days, are ≥65 years of age, and have no known AF by history or on baseline ECG at admission. We will randomly assign participants in a 1:1 ratio to undergo daily 12-lead ECG once daily for 5 days (intervention group) or 24-h Holter monitoring (control group). Primary outcome is newly detected AF on a 12-lead ECG or AF lasting ≥30 s on Holter monitoring.

Trial registration number: ClinicalTrials.gov Identifier: NCT02578979.

1. Introduction

The prevention of stroke related to atrial fibrillation is a global public health priority. Atrial fibrillation is associated with 5-fold risk of future ischemic stroke in general population [1,2]. Among ischemic stroke patients, atrial fibrillation is associated with a high annual risk of stroke recurrence [3], and strategies to improve the detection and treatment of atrial fibrillation promise to reduce the burden of recurrent strokes. The early identification of underlying cardioembolic etiology is important, because the initiation of oral anticoagulation represents one of the most effective strategies in secondary stroke prevention [4]. In the absence of atrial fibrillation, the standard treatment for secondary

*List of abbreviations:*ECG, electrocardiogram

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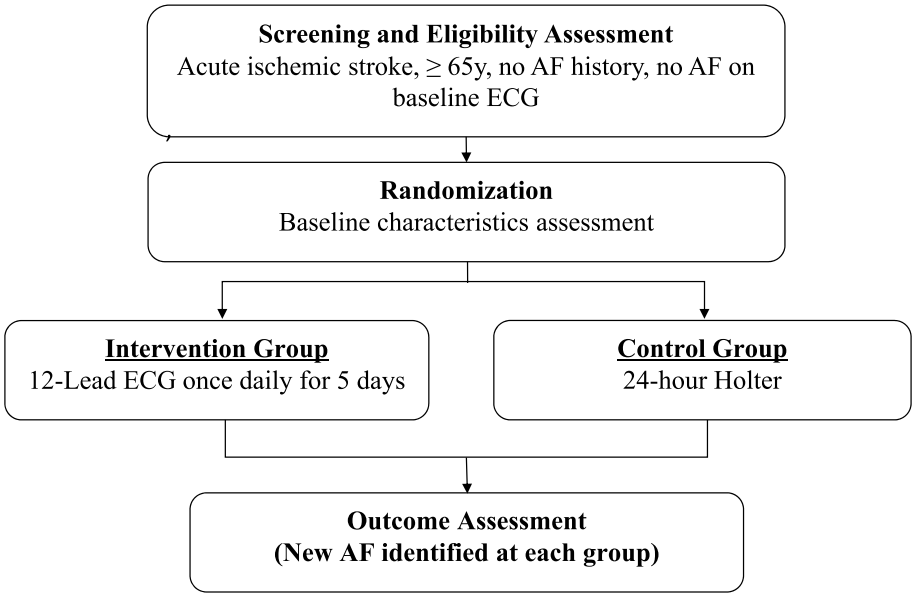

Fig. 1. Study design and study flow chart. AF: atrial fibrillation, ECG: electrocardiogram.

prevention of stroke is antiplatelet therapy; however, when atrial fibrillation is present, antiplatelet therapy is only modestly effective (22% reduction in risk, as compared with placebo) [5], and anticoagulation is strongly recommended instead (39% [5] to 63% [6] reduction in the risk of stroke as compared with antiplatelet therapy). It is likely that a proportion of strokes labeled as cryptogenic are cardioembolic in origin because of occult atrial fibrillation [7]. Undiagnosed atrial fibrillation is often suspected as the cause of many cryptogenic strokes, but anticoagulation is not recommended unless atrial fibrillation has been documented. Even stroke patients found to be associated with a certain mechanism, such as lacunar infarct or large artery atherosclerosis, atrial fibrillation may still exists. Once atrial fibrillation is found, anticoagulant therapy, rather than antiplatelet therapy, is recommended for secondary stroke prevention.

The incidence of atrial fibrillation increases exponentially with age [8]. Atrial fibrillation may occur in paroxysmal, persistent, or permanent forms [1]. Paroxysmal atrial fibrillation is often undetected because characteristics such as short duration, episodic, and frequently asymptomatic nature make it challenging to diagnose at the bedside, leading to suboptimal secondary prevention [9]. It is not uncommon for paroxysmal atrial fibrillation to be undetected in a single electrocardiogram (ECG) on admission [10]. Detection rate of new atrial fibrillation from a standard 12-lead ECG after ischemic stroke/transient ischemic attack is 2%–5% [11] and from 24-h Holter monitoring is 2%–6% [12,13]. The American Heart Association/American Stroke Associations recommend that conventional 24-h Holter monitoring be used to detect occult atrial fibrillation/paroxysmal atrial fibrillation when suspected, and no other cause for stroke is found [14]. Systematic review suggests Holter monitoring will identify atrial fibrillation in only an additional 4.6% of patients [11], no better than detection rates observed in groups lacking routine monitoring [15]. Shafqat et al. observed that Holter monitoring does not always detect atrial fibrillation in patients atrial fibrillation-positive on 12-lead ECG [16], suggesting an inadequacy of Holter monitoring in the detection of atrial fibrillation and the potential for underestimation of atrial fibrillation in this setting.

Randomized controlled trials have shown that there is improved detection of atrial fibrillation with prolonged ECG monitoring [17,18]. However, such a strategy has implies a high up-front cost, is labor intensive and even invasive, thereby limiting widespread use in clinical practice [18]. A standard 12-lead ECG is a basic mandatory device in all hospital and is the gold standard tool for the diagnosis of atrial fibrillation [19]. It is convenient, straightforward, and inexpensive to perform a 12-lead ECG on each acute ischemic stroke patient and the interpretation of atrial fibrillation on a 12-lead ECG is generally not difficult for a physician. Also if a patient has documented atrial fibrillation on 12lead ECG, this would be known during or immediately after the exam. If atrial fibrillation is indeed identified, doctors may be able to shift from antiplatelet therapy to anticoagulant therapy promptly. For ischemic stroke patients with sinus rhythm at baseline, but suspected paroxysmal atrial fibrillation, no recommendation beyond repeated 12-lead ECGs is made in the UK guideline [20,21]. Serial 12-lead ECGs have been used to detect possible paroxysmal atrial fibrillation among acute ischemic stroke patients without atrial fibrillation at baseline, with the finding of 15 new cases of atrial fibrillation in 133 acute ischemic stroke patients (11.3%) [22]. There are several advantages of serial 12-lead ECGs to detect paroxysmal atrial fibrillation among acute ischemic stroke patients, and so it appears generally easier to apply serial 12-lead ECG vs. Holter monitoring in each potential patient.

The optimal investigation strategy, including modality, duration of investigation, and patient subgroup remains undefined, not only for efficacy in the detection of atrial fibrillation, but also cost-effectiveness in healthcare systems. A prior study found the fact that all episodes of atrial fibrillation were detected in individuals older than 65 years indicates that age is important when selecting patients for screening [23]. As to our knowledge, there is no randomized controlled trial comparing the efficacy of serial ECGs and 24-h Holter monitoring to detect new cases of atrial fibrillation in elderly patients with acute ischemic stroke. The objective of this project is to conduct a pragmatic multicenter randomized controlled trial for the comparison of serial 12-lead ECGs once daily for 5 days and 24-h Holter monitoring to detect paroxysmal atrial fibrillation in acute ischemic stroke patients without atrial fibrillation identified by baseline ECG or history.

2. Methods

2.1. Study design and setting

We plan to conduct a multicenter randomized trial at 6 hospitals (Chang Gung Hospital Chiayi branch, Keelung branch and Linkou branch, National Taiwan University Hospital, Chiayi Christian Hospital, Buddhist Tzu General Hospital Chiayi branch) in Taiwan. This protocol follows CONSORT guidelines for reporting clinical trial protocols [24]. The Study Design and Study Flow Chart was presented

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
1. Cerebral ischemia defined as stroke (sudden focal neurologic deficit lasting > 24 h consistent with the territory of a major cerebral artery and categorized as ischemic) and/or a corresponding lesion on brain imaging
2. Stroke symptoms within 2 days
3. Age ≥65 years
Exclusion criteria
1. History of atrial fibrillation or documented atrial fibrillation prior to randomization
2. Indication for oral anticoagulation at randomization
3. Absolute contraindication for oral anticoagulation at randomization
4. Intracerebral hemorrhage in medical history
5. Implanted pacemaker device or cardioverter/defibrillator
6. End stage renal disease

in Fig. 1. The study was approved by the local Institutional Review Board of Chang Gung Memorial Hospital, Chiayi Branch, Taiwan (103-7597B and 104-9611C).

2.2. Study population

The study population will be elderly patients admitted to a hospital for an ischemic stroke. Participants will be recruited between August 2015 and July 2018. Inclusion and exclusion criteria are shown in Table 1. Patients will be included in the study only if they fulfill all of the following criteria: (1) clinical diagnosis of acute ischemic stroke; (2) stroke symptoms started less than 2 days; (3) aged 65 years or older. Exclusion criteria will be: patients with (1) atrial fibrillation on history or baseline ECG at admission; (2) indication for oral anticoagulation at randomization; (3) intracerebral hemorrhage in medical history; (4) pacemaker or implantable cardioverter-defibrillator device; (5) end stage renal disease. We will exclude patients with end stage renal disease because a recent meta-analysis suggested warfarin use in these patients increased hemorrhagic stroke and did not decrease ischemic stroke [25] and novel oral anticoagulants are not indicated in these patients.

2.3. Randomization procedure

Participants will be randomly assigned to one of two groups: 12-lead ECGs daily for 5 days (intervention group) or 24-h Holter monitoring (control group). The research assistants will screen newly admitted ischemic stroke patients Monday through Friday. Allocation occurs when a study participant meets the inclusion criteria and does not meet any exclusion criterion, and signs the informed consent forms. Randomization will be done once patients are eligible and agree to participate in this study. Study participants will be randomized in blocks of random sizes of 4 and 6 at each site by using of a web-based randomization service. Site-specific randomization lists will be computer-generated. Investigators and patients will be aware of study group allocation.

2.4. Trial intervention

If a participant is randomly assigned to a serial ECG group, he or she will receive first 12-lead ECG within 2 days of stroke onset. The participants in the intervention group will be given a 12-lead ECG once daily for 5 days during the hospitalization. Participants randomly assigned in a 24-h Holter group will receive such exam as routine schedule in each hospital during hospitalization. This is a pragmatic study, which will reflect real world clinical practice patterns, and so we chose to plan for situations in which all ECGs might not necessarily be obtained during the index hospitalization. We are not aware that there are data to suggest that atrial fibrillation is more likely to be detected by ECGs conducted on a daily basis vs. on a more varied schedule within a short term period after a given stroke (i.e. within 3 months). We will endeavor to make sure that all if not a substantial majority of participants complete their 5 ECGs during the index hospitalization. Those that do not which we expect to be a substantial minority will be completed when they return to the outpatient clinic. However, we will also conduct a separate analysis to assess whether not having all 5 ECGs completed during the index hospitalization had a differential effect on the study endpoints. The trial intervention requires no specific medical treatment. Thus, all secondary stroke prevention therapies and rehabilitation treatments will be at the discretion of the patients' treating physicians.

2.5. Outcome measures

Primary outcome will be newly detected atrial fibrillation on a 12-lead ECG vs. atrial fibrillation lasting 30 s or longer on Holter monitoring after randomization. Sustained paroxysmal atrial fibrillation will be diagnosed where atrial fibrillation is recorded for the complete 30-s rhythm strip after event triggering based on the current atrial fibrillation consensus statements and guidelines [1,26,27]. Secondary outcomes will include episodes of atrial fibrillation on 12-lead ECG vs. any duration of atrial fibrillation on Holter monitoring. Stroke mechanism (e.g. lacunar, large artery atherosclerosis, cardioembolic, cryptogenic) will be recorded and tracked. Cost of serial 12-lead ECGs during hospitalization and outpatient setting as well as 24-h Holter monitoring during hospitalization will be recorded, respectively and compared between active and control groups False diagnostic rate in serial 12-lead ECG and 24-h Holter monitoring, respectively will also be assessed. For 12-lead ECG, atrial fibrillation noticed by research assistants who perform ECGs will be compared to a final report from an attending cardiologist. For 24-h Holter monitoring, reports from automatic interpretation by machine will be compared to a final report from an attending cardiologist. Also, oral anticoagulant therapy in each group will be recorded by 90 days.

2.6. Sample size calculation

We will calculate the sample size based on the results from our preliminary data preceding this trial. In our preliminary study, we evaluated 193 patients comprising 96 patients in a serial 12-lead ECG group and 97 patients a Holter monitoring group. Atrial fibrillation was detected in 5 patients in the serial ECG group and in 2 patients in the Holter monitoring group. For a two-tailed *t*-test at the 5% level and with 80% power, 576 patients would be required per group. To allow for drop outs, we plan to recruit 600 patients per group. Sample size calculation will be performed using G Power software.

2.7. Statistical analysis

The analysis will be on an intention-to-treat basis. Data will be collected till in the end of intervention, and participants choosing to withdraw from either intervention arm. Reasons for withdrawal, if elicited, will be recorded. Baseline characteristics will be compared using student *t*-test for continuous variables or chi-square test for categorical variables, as appropriate. Percentage of anticoagulant prescribed by 90 days among atrial fibrillation patients will also be recorded.

3. Discussion

This will be the first trial to evaluate the effectiveness of serial 12-lead ECGs and Holter monitoring to detect paroxysmal atrial fibrillation in stroke patients without known atrial fibrillation at baseline. Although longer monitoring with certain novel devices is associated with higher detection rate of paroxysmal atrial fibrillation, ordinary

tools, such as 12-lead ECGs and 24-h Holter monitoring, are likely to be available at all levels of hospitals, considering of cost and noninvasive characteristics. Therefore it is crucial to know which tool is optimal to detect paroxysmal atrial fibrillation in ischemic stroke patients.

Observed absolute stroke rates for non-anticoagulated AF patients with single independent risk factors are about 8% per year for prior stroke [3]. As modern oral anticoagulation treatment can reduce the risk for stroke with 70%, it is reasonable to survey paroxysmal atrial fibrillation in ischemic stroke patients regardless of their age. However, an observational study showed a low rate of paroxysmal AF among young patients (< 60 years) presenting with stroke on the basis of 21-day cardiac monitoring [28]. In this study, investigators will focus on elderly stroke patients since these patients have substantial high risks of paroxysmal atrial fibrillation as suggested in a prior study [29].

Our primary outcome of atrial fibrillation lasting 30 s or longer is consistent with guidelines and is a potentially clinically important and actionable finding in this population [1,26,27]. However, it has been shown that patients with short atrial fibrillation bursts also have an increased risk of ischemic stroke [30]. Therefore we will report paroxysmal atrial fibrillation in any duration on Holter monitoring as a secondary endpoint. On the other hand, any atrial fibrillation noted on 12-lead ECG will be the evidence of having paroxysmal atrial fibrillation.

Trial status

Recruitment commenced in August 2015 and is ongoing.

Competing interests

We declared no competing interests.

Authors' contributions

Research idea and study design: TTH, ML, BO; data acquisition: TTH, ML, WYH, SCT, SFS, KHC, JDL, YSH, JSJ, THL, YLW, CMC; supervision or mentorship: BO. Each author have given final approval of the version to be published; and 4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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