

Zenikor ECG Project

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1) INTRODUCTION & BACKGROUND

Atrial fibrillation (AF) is the most common serious arrhythmia in the adult population, affecting about 5% of the population over 65 years. AF is an independent risk factor for stroke and together with other cardiovascular risk factors significantly increases stroke risk¹.

Around 25% of brain infarctions are cardioembolic and AF is a major risk source.

Since AF is often paroxysmal (PAF) and asymptomatic, it often remains undiagnosed for a long time and in many patients AF is only discovered after suffering a stroke. The detection of PAF and its treatment is essential in reducing risk of strokes².

Zenikor ECG is an innovative way of detecting PAF developed and tried in Sweden and other Europe countries . Zenikor ECG is a handheld device (thumb-ECG) that the patient can use over an extended period of 3-4 weeks to record 30 sec. episodes of heart rhythm. ECG readings are then automatically transferred to a central secure database via the mobile network. The clinician can then at any time analyse the patient's ECG on-line. A study in Sweden showed that prolonged intermittent screening using the hand-held Zenikor ECG recorder is 3-4 fold better at detecting PAF after ischaemic stroke and transient ischaemic attack (TIA) compared to the standard continuous screening with a 24-48 hour Holter monitor³.

The Aim of this project was to determine the effectiveness of the prolonged intermittent screening for PAF using Zenikor ECG in the Portsmouth population.

2) METHODOLOGY

Patients were recruited from the stroke wards or TIA clinics. Patients included in the study were seen by at least one stroke physician and had a diagnosis of ischaemic stroke, TIA or amaurosis fugax.

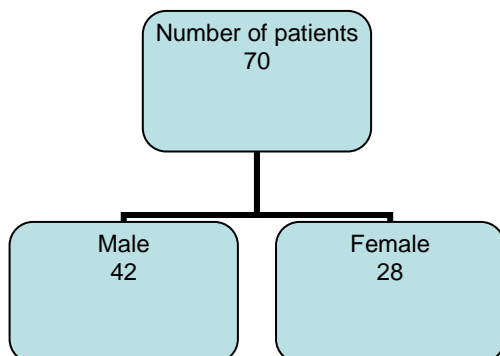
Inclusion criteria:

- Ischaemic stroke or TIA
- Satisfactory dexterity and adequate cognitive function to use the Zenicor device.

Exclusion criteria:

- Dense hemiplegia,
- History of PAF or AF on initial standard ECG
- Significant cognitive deficit or memory problems

Participants were recruited from 26th Nov 2014 to 30th May 2015. 71 patients in total agreed to participate. Each patient was taught how to use the device on the day of discharge from hospital or in the TIA clinic by a nurse specialist. Participants were advised to perform recordings twice daily and when having symptoms of palpitations for 21 days. The ECG recordings are sent to a secure server, accessible only by approved Portsmouth Hospital NHS trust staff. The ECG recordings were reviewed by a specialist cardiology technician competent at interpreting ECGs. Any positive results were directly communicated to a stroke physician for action. A patient feedback questionnaire was offered to participants at the end of their recording periods. 38 of the 70 participants responded to the feedback questionnaire. 9 participants ended recordings early for different reasons; 5 had unreadable recordings, 2 had very poor compliance and the other 2 ended early for personal reasons.



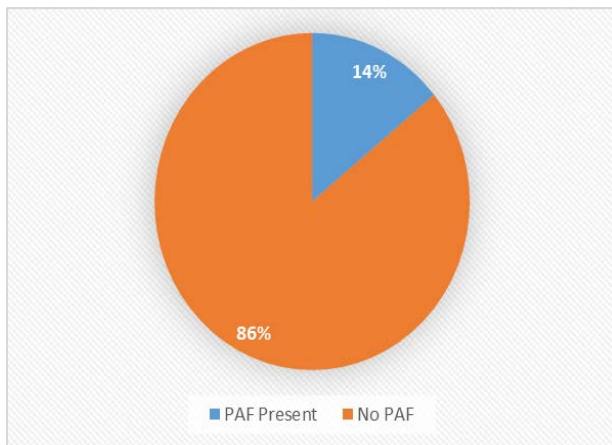
Mean age of participants was 66 years.

3) RESULTS

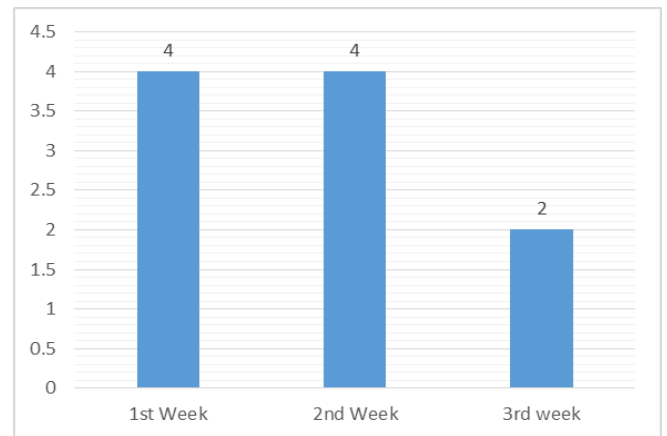
Most of the participants in the study 49 (70%) had a diagnosis of TIA, 21 patient 30% had a diagnosis of stroke.

PAF was detected in 10 of the 70 patients (14%).

Percentage of PAF detected



Week of recording during which PAF detected

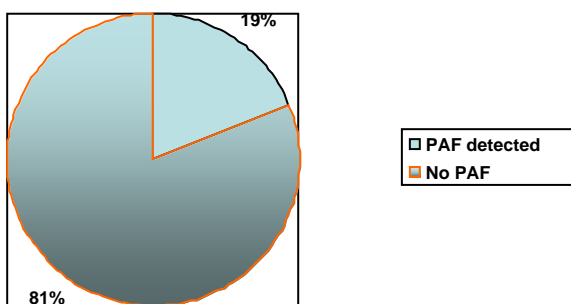


In the stroke patients subgroup PAF was detected in 4 of 21 patients (19 %). In TIA patients subgroup PAF was diagnosed in 6 of 49 patients (12 %).

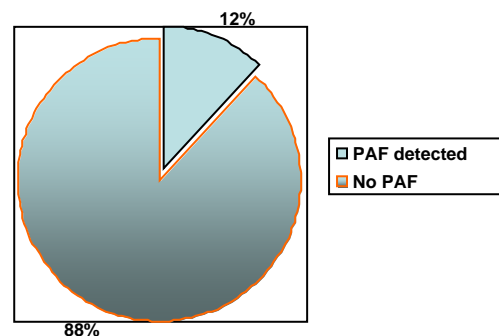
This is a higher rate than in the Swedish stroke study which found PAF in 11.4% of patients³.

Most of the PAF were detected within the first two weeks of recording, the earliest on day 1 and latest on day 17. The average number of recording days to detection was 9 days. .

PAF detection rate in Stroke subgroup



PAF detection rate in TIA subgroup



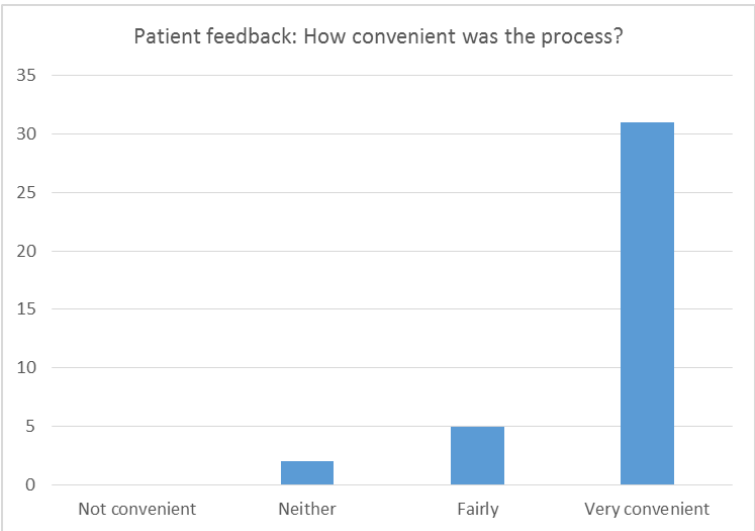
One patient had a recording of PAF for 10 sec., the rest patients had PAF throughout the 30 sec. recording.

All participants with PAF detected attended TIA clinic within 48 hours, was seen by a stroke physician and anticoagulation options discussed. All 10 with PAF patients agreed to anticoagulation for stroke prevention.

5 of 10 patients with PAF on Zenicor also have had 24 hour Holter fitted at some time. Only 2 of these 5 patients had PAF detected on the Holter monitor. 3 patients of all 5 would have had their PAF missed if not for the Zenicor.

The patient satisfaction questionnaire showed that the overwhelming majority (81.6%) of the participants felt the device was very convenient to use.

Patients satisfaction with the device use



4) DISCUSSION

The practice in cardiac monitoring varies from institution to institution. The duration of monitoring, time after stroke and method of monitoring all may play a role in detection rate of PAF. There is upcoming evidence that longer duration of cardiac monitoring increases the likelihood of PAF diagnosis for patients after stroke or TIA. even with a snapshot ECG recording device like the Zenicor monitor^{3,4,5,6}. The Crystal-AF trial showed that 30% of cryptogenic strokes would eventually be

diagnosed with PAF after 3 years with implantable cardiac monitor. However such a monitors are expensive, involves intervention and is not readily available.

It is estimated that with 24 hour Holter PAF detection rate for stroke patient is only about 6%⁴. It is vital to provide patients with the good quality diagnostics at rational cost. Zenicor handheld ECG monitoring proved to be more effective than 24 Holter in PAF detection in multiple studies and is cheaper than implantable monitors^{3,5}. Our pilot project in Queen Alexandra Hospital has confirmed the results of research with up to 19% PAF detection rate in stroke patients comparing with 11% of PAF detection on 24 hour Holter in the same hospital.

There are some weakness of the Zenicor method. Patients with significant paresis, tremor or cognitive impairment would not be suitable to use the device on their own due to tremor artefacts and complexity of use. However the majority of appropriate candidates in our study described the method as very convenient and simple to use. The quality of recording generally was very good. It appears that for minor stroke or TIA patients the prolonged non-intervention cardiac monitor for up to 4 weeks with Zenicor may improve detection of PAF and help in cardioembolic stroke prevention...

5) ACTION PLAN

The business plan is being prepared to acquire 10 Zenicor ECG machines to improve PAF diagnostic service for stroke patients at QAH.

6) REFERENCES

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