Screening for atrial fibrillation: sensitivity and specificity of a new methodology

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ABSTRACT

There is no comprehensive screening programme for atrial fibrillation (AF) in either the UK or the US. This paper describes a simple new technology that could contribute to such a universal screening programme. The work analyses the utility of a new instrument that uses plethysmographic analysis of finger-tip pulse in the detection of AF. Comparative analysis of the instrument with the ‘gold-standard’ diagnostic method was undertaken in 594 patients. With the instrument set to detect all cases of AF (100% sensitivity), a specificity of 91.9% (8.1% false positives) was obtained. The authors conclude that the instrument described provides an accurate and reliable screening tool for AF, filling a gap in the current process of early detection in the community.

Keywords
atrial fibrillation; screening.

INTRODUCTION

Atrial fibrillation (AF) is the commonest arrhythmia seen in medical practice. It is associated with an increased morbidity and mortality, and its management, particularly that of associated adverse outcomes, is costly.1 The prevalence of AF increases with age (0.5% of those aged 50–59 years to 8.8% of those aged 80–89 years), as do the associated risks.2 It is implicated in the aetiology of 33% of strokes in older people.3 The risk of stroke can be significantly reduced by antiplatelet drugs or anticoagulants, but to benefit from such interventions, individuals with AF need to be identified before an adverse event. Given that AF may be asymptomatic or associated with mild, vague, and non-specific symptoms, many individuals remain undiagnosed until such a catastrophic event occurs.

The ‘gold-standard’ for the diagnosis of AF is its detection on an electrocardiogram (ECG) by a trained clinician. Systematic population screening for AF using this technique would be too expensive and time consuming to be practical, and so opportunistic, rather than systematic, screening is encouraged.4

This study reports experience with a novel portable device (AFS instrument), which uses plethysmographic analysis of finger-tip pulsation to detect AF.

METHOD

A total of 594 patients, aged >60 years, were included in the study. Ethical approval was obtained and individual patients provided consent for testing. There were no specific exclusion factors. The patients were either attending hospital outpatient departments or were inpatients in two hospitals in South Wales and New York, and were not specifically patients with cardiac symptoms or diagnoses.

The screening technique involves a finger-probe instrument (as used in pulse oximetry) that utilises the principle of photoplethysmography. In the study, each patient’s pulse rhythm was assessed by fitting the probe around the tip of their index finger and recording, and storing on a laptop computer, the pulse waveform pattern for 30 seconds. This pattern was then analysed by the specifically developed software, Fast Fourier Transform Analysis,5 to determine pulse rate variability, and expressed as an index of deviation from normal sinus wave form. As the pulse in AF is classically ‘irregularly irregular’, this formed the basis for detecting AF.

During the study, the interpretation of records was undertaken later, although ‘blinded’ to the results of pulse palpation and electrocardiography. A 12-lead ECG was recorded immediately after the finger probe had been disconnected. Later, the ECG was interpreted by a consultant cardiologist who reported on the presence or absence of AF...
without knowledge of the patients’ histories, their pulse rates or rhythms, or the findings of the finger-probe device.

This methodology allowed a comparison of a cardiologist’s interpretation of the ECG with the AFS instrument results, and thus an analysis of the utility of the AFS as compared to the current gold standard for detecting AF.

RESULTS
A total of 594 patients were tested. The results are expressed as false positives, where the instrument suggested AF but this was not detected on the 12-lead ECG, and as false negatives, where the 12-lead ECG showed AF, but the instrument did not — the 12-lead ECG/cardiologist being the ‘gold-standard’. Modifying the index for diagnosis of AF on the AFS screening instrument resulted in changes in the test characteristics (Table 1). To correctly detect all cases of AF (100% sensitivity), a false-positive rate of 8.9% (specificity 91.1%) was obtained. The false positives were accounted for by the presence of ventricular and supraventricular ectopic beats.

DISCUSSION
Summary of main findings
The AFS instrument uses Fourier analysis to derive the spectrum for a perfect sinusoidal waveform. This is used electronically as the baseline template. In sinus rhythm, the variance from that template is zero. The clinical trial results show there is a threshold above which AF is highly likely to be present. As with other clinical tests, varying the diagnostic ‘cut-point’ alters the test characteristics. These results are based on a single test (or exposure). It would be expected that two or more exposures would further reduce the false-negative rate.

Strengths and limitations of the study
The electronic nature of the instrument allows the testing process to be carried out under minimum supervision in any setting; for example, a GP surgery or pharmacy. It is unlikely that it would perform differently outside a hospital environment. The settings for this study were chosen for pragmatic reasons: these patients were due to have ECG recordings as part of their routine hospital management. The prevalence of AF outside hospital is likely to be lower, even in patients of the same age range, and while this would not affect the sensitivity and specificity, the post-test probability would be affected.

Implications for clinical practice
Until now the cost-effectiveness and efficacy of a routine screening programme has not been shown to have adequate merit over and above opportunistic screening. The application of Wilson and Jungner’s long-established criteria for screening programmes to the use of this instrument allows the authors to propose that its use be considered in the early detection of AF in the community setting. It provides a reliable and accurate table-top instrument that allows a low-cost routine screening process leading to a confirmatory ECG.

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Ethical approval
Approval was obtained for the study from lechyd Morgannwg Local Research Ethics Committee, Swansea.

Competing interests
The authors have a share interest in the instrument described.

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REFERENCES

Table 1. Results as false negatives and false positives (n = 594) at different settings of the screening instrument.

<table>
<thead>
<tr>
<th>Index</th>
<th>False negative, n (%)</th>
<th>False positive, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.30</td>
<td>11 (1.85)</td>
<td>23 (3.80)</td>
</tr>
<tr>
<td>0.25</td>
<td>4 (0.67)</td>
<td>35 (5.80)</td>
</tr>
<tr>
<td>0.20</td>
<td>0 (0)</td>
<td>53 (8.90)</td>
</tr>
</tbody>
</table>

How this fits in
This article describes an electronic instrument with a high sensitivity and high specificity for detecting atrial fibrillation. It has the potential to deliver a community-based screening programme for atrial fibrillation. Despite high sensitivity and specificity, the instrument is intended for screening and not diagnosing, as it is not intended to replace the gold standard of interpretation of the 12-lead electrocardiogram.