


A randomised controlled trial and cost-effectiveness study of systematic screening (targeted and total population screening) versus routine practice for the detection of atrial fibrillation in people aged 65 and over. The SAFE study

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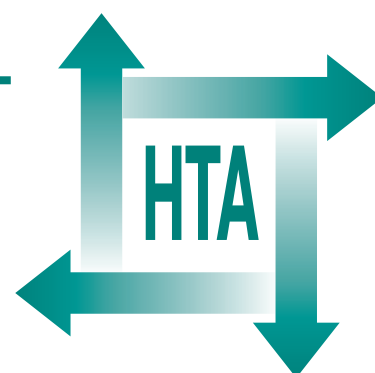
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Executive summary

Health Technology Assessment 2005; Vol. 9: No. 40

Health Technology Assessment
NHS R&D HTA Programme





Executive summary

Background

Atrial fibrillation (AF) is a major risk factor for stroke. This risk can be reduced through treatment with antithrombotic therapy, with a risk reduction of up to 68% observed with warfarin therapy. Guidelines for treatment of AF recommend ages 65 years and over as an indication for treatment with antithrombotic therapy in the presence of AF. This raises the question of whether screening for AF would be a useful policy, and if so what would be the best method for screening. There are no good data on the prevalence of AF in the UK. One small UK study (four practices, $n = 3001$) demonstrated that systematic nurse-led screening detected more cases than opportunistic case finding; however, most of those cases detected were already diagnosed. Two further single practice-based studies investigated the role of practice nurses in the screening process and whole population screening, but were too small to be meaningful.

Objectives

- To evaluate the incremental cost-effectiveness of targeted, population and opportunistic screening with prompts compared with routine clinical practice.
- To evaluate the relative cost-effectiveness of different methods of recording and interpreting the ECG within a screening programme.
- To identify the prevalence and incidence of AF in patients aged 65 years and over.

Methods

This multicentred randomised controlled trial involved patients aged 65 years and over from 50 primary care centres across the West Midlands. These purposefully selected general practices were randomly allocated to 25 intervention practices and 25 control practices. GPs and practice nurses in the intervention practices received education on the importance of AF detection and ECG interpretation. Patients in the intervention practices were randomly allocated to systematic ($n = 5000$) or opportunistic screening ($n = 5000$).

Prospective identification of pre-existing risk factors for AF within the screened population enabled comparison between targeted screening of people at higher risk of AF and total population screening. AF detection rates in systematically screened and opportunistically screened populations in the intervention practices were compared with AF detection rate in 5000 patients in the control practices. The screening period was 12 months.

Results

The total number of patients included in each arm was: control 4936, opportunistic screening 4933 and systematic screening 4933. Baseline prevalence of AF was 7.2%, with a higher prevalence in males (7.8%) and patients aged 75 years and over (10.3%). The control population demonstrated higher baseline prevalence (7.9%) than either the systematic (6.9%) or opportunistic (6.9%) intervention population. In the control population 47 new cases were detected (incidence 1.04% per year). In the opportunistic arm 243 patients without a baseline diagnosis of AF were found to have an irregular pulse, with 177 having an ECG, yielding 31 new cases (incidence 0.69% per year). A further 44 cases were detected outside the screening programme (overall incidence 1.64% per year). In the systematic arm 2357 patients had an ECG yielding 52 new cases (incidence 1.1% per year). Of these, 31 were detected by targeted screening and a further 21 by total population screening. A further 22 cases were detected outside the screening programme (overall incidence 1.62% per year).

In terms of ECG interpretation, computerised decision support software (CDSS) gave a sensitivity of 87.3%, a specificity of 99.1% and a positive predictive value (PPV) of 89.5% compared with the gold standard (cardiologist reporting). GPs and practice nurses performed less well. The only difference in performance between intervention populations and controls was that practice nurses from the control arm performed less well than intervention practice nurses on interpretation of limb-lead (PPV 38.8% versus 20.8%) and single-lead (PPV 37.7% versus 24.0%) ECGs.

The within-trial economic evaluation results showed the lowest incremental cost to be for the opportunistic arm, with an incremental cost-effectiveness ratio of £337 for each additional case detected compared to the control arm.

Opportunistic screening dominated both more intensive screening strategies. Model-based analyses showed small differences in cost and quality-adjusted life-years for different methods and intensities of screening, but annual opportunistic screening resulted in the lowest number of ischaemic strokes and greatest proportion of cases of AF diagnosed. Probabilistic sensitivity results indicated that there was a probability of approximately 60% that screening from the age of 65 was cost-effective in both men and women.

Conclusions

The prevalence of AF in this population was found to be 7.2%. The incidence ranged from 1.04 to 1.64% per annum. Within the trial, in terms of a screening programme, the only strategy that improved on routine practice was opportunistic screening, at a cost of £337 per additional case detected. Model-based analyses indicated that there was a probability of approximately 60% of annual opportunistic screening being cost effective. Use of CDSS may be considered for analysis of ECGs for detection of AF.

Recommendations for research

It is suggested that the following topics are worthy of further investigation.

- How does the implementation of a screening programme for AF influence the uptake and maintenance of anticoagulation in patients aged 65 years and over?
- An evaluation of the role of CDSS in the diagnosis of cardiac arrhythmias.
- What is the best method for routinely detecting paroxysmal AF?
- How can healthcare professionals' performance in ECG interpretation be best improved?
- The development of a robust economic model to incorporate data on new therapeutic agents for use as thromboprophylactic agents for patients with AF.
- An evaluation of the relative risk of stroke for patients with incident as opposed to prevalent AF.

Publication

Hobbs FDR, Fitzmaurice DA, Jowett S, Mant J, Murray E, Bryan S, *et al.* A randomised controlled trial and cost-effectiveness study of systematic screening (targeted and total population screening) versus routine practice for the detection of atrial fibrillation in people aged 65 and over. The SAFE study. *Health Technol Assess* 2005;**9**(40).

NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts. Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 96/22/11. The contractual start date was in June 2000. The draft report began editorial review in August 2004 and was accepted for publication in May 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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ISSN 1366-5278

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.