A randomised controlled trial of patient self management of oral anticoagulation treatment compared with primary care management

Fitzmaurice D A, Murray E T, Gee K M, Allan T F, Hobbs F D

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Patient self-management of oral anticoagulation treatment (i.e. warfarin) was studied. The self-management approach involved two training sessions of between one and two hours where patients were taught how to test the international normalised ratio (INR) using a Coaguchek near patient testing device. The patients were also given a protocol for adjusting their warfarin dose and access to a research nurse in the event of uncertainty.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had been on long-term warfarin anticoagulation treatment for at least 6 months, had satisfactory INR control, and were older than 18 years. The patients also had to have sufficient vision, manual dexterity and cognitive ability to operate a Coaguchek near patient testing system.

Setting
The setting was the community and primary care. The study was undertaken in the West Midlands, UK.

Dates to which data relate
Neither the dates of the effectiveness and resource use data, nor the price year were reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The resource use data were collected prospectively from the same patient sample that provided the clinical effectiveness data.

Study sample
A practice nurse screened all patients registered at the six general practices who met the clinical inclusion criteria to assess whether they were suitable for self-management. All patients who met the two series of criteria were invited to discuss and to join the study. A total of 206 patients met the clinical criteria. Seventy-eight of these patients met the second set of criteria, but 22 refused to participate in the study. Of the 56 patients included in the study, 30 were
randomised to self-management and 26 were allocated to usual care. No sample size or power calculations were reported.

**Study design**
This was a multi-centred randomised controlled trial that involved six general practices. The patients were randomised to the two treatment groups using computer generated coding. The patients were followed up for 6 months. Seven patients allocated to self-management withdrew from the study prior to its completion, leaving 23 patients for inclusion in the analysis. There did not appear to be any loss to follow-up in the usual care group. There was no blinding to the treatment allocation.

**Analysis of effectiveness**
The analysis of clinical effectiveness was conducted on the basis of treatment completers only. The primary health outcomes were INR results and the number of adverse events. The patients were advised to test the INR every 2 weeks, or weekly if a dose adjustment was made. The quality of life (QOL) was also assessed from a random sample of patients (8 patient self-managed and 8 controls). QOL estimations were derived from a validated questionnaire on warfarin treatment in addition to the SEIQoL tool. The two groups were shown to be comparable at baseline in terms of age, clinical indications for warfarin treatment and pre-study management.

**Effectiveness results**
There were no significant differences between the two groups in the INR percentage time in range (74% patient self-management versus 77% controls) or the proportion of tests in range (66% versus 72%) for the study period. Also, there was no significant change between pre-study and study data for either group.

There were seven minor adverse effect and no major adverse events among the self-management groups, compared with no minor and one serious adverse event in the usual care group. QOL was similar in the two patient groups.

**Clinical conclusions**
The authors concluded that the self-management of anticoagulation therapy is as safe as management in a nurse-led general practice clinic.

**Measure of benefits used in the economic analysis**
No measure of benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

**Direct costs**
The perspective of the study was not explicitly stated, but it was consistent with that of the health care provider. The direct costs were for follow-up attendance, test strip, advice, internal and external quality controls, training sessions and equipment. The resource use data were collected as part of the clinical study. The self-management patients recorded the number of test strips used on a clinical report form, and the practice nurse monitored contact with these patients. All resource use data for the usual care group were taken from medical records. All unit costs and quantities were reported separately. The unit costs for the usual care group and room hire, staff time to attend self-management training, and consultations with the practice nurse were taken from published studies. The cost of test strips and the testing machine were obtained from the manufacturer. External quality assessment costs were taken from the National External Quality Assessment Scheme. The price year was not reported. Discounting was not undertaken.

**Statistical analysis of costs**
The cost data were treated deterministically.
Indirect Costs
No indirect costs were included in the study.

Currency
UK pounds sterling ( ).

Sensitivity analysis
No sensitivity analysis was undertaken.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean cost each year was 425.23 for self-management patients and 89.71 for patients receiving usual care, (p<0.001).

Synthesis of costs and benefits
The clinical benefits and costs were not combined because this was, in effect, a cost-consequences analysis.

Authors' conclusions
The self-management of anticoagulation therapy is a clinically safe but more expensive option than management in a nurse-led general practice clinic.

CRD COMMENTARY - Selection of comparators
The comparator used in this study was chosen because it represented usual care in the authors' setting. You should consider how this relates to usual practice in your own setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The clinical effectiveness data were taken from a randomised controlled trial. This was appropriate for the study question. Although the authors showed that the two patient groups were comparable at baseline, they did not consider how their sample related to the wider patient population. No power calculations were reported. Hence, the sample size might have had insufficient statistical power to detect differences in the outcomes. The analysis of the clinical effectiveness data was conducted on the basis of treatment completers only. This provided a biased estimate of the effectiveness of the intervention, which is likely to overstate its effectiveness in the real world.

Validity of estimate of measure of benefit
No measure of health benefit was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
While the economic perspective of the study was not stated in the paper, a health care provider view appears to have been adopted. With this in mind, all appropriate costs appear to have been included in the study. Resource use and the unit costs were reported separately, which will enable the results of this study to be applied to other settings. However, the price year was not reported, which will prevent any future reflation exercises. No statistical or sensitivity analyses of the resources used and their unit costs were conducted. This limits the generalisability of the study findings and means
that the extent of uncertainty around the results has not been assessed. No discounting was undertaken. Most of the costs were spread over 5 years and a 6% rate on interest was reported.

**Other issues**
The results of this study were presented in a comprehensive manner, with the results of the analysis reported in full. The authors' conclusions reflected the scope of the analysis. The authors acknowledged that the results of self-management might be influenced by the element of self-selection in the study design (only motivated and compliant patients were recruited). However, they referred to studies that have shown patients with diabetes and hypertension respond positively to self-management, and suggested that the same might be true of patients on anticoagulation therapy. The authors noted that their choice of comparator might impact on the generalisability of their findings, as it might not represent usual current practice across the UK.

**Implications of the study**
The authors suggested that further studies are needed to elucidate whether this model of care is suitable for a larger population. They also suggested that further studies are needed to elucidate definitions for the selection of patients and the frequency of testing for optimum management.

**Source of funding**
Funded in part by an unrestricted research grant from Roche Diagnostics UK.

**Bibliographic details**

**PubMedID**
12401823

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Administration, Oral; Adult; Aged; Anticoagulants /administration & dosage; Delivery of Health Care /economics /methods; Drug Administration Schedule; England; Female; Health Care Costs; Humans; International Normalized Ratio; Male; Middle Aged; Patient Satisfaction; Primary Health Care; Quality Assurance, Health Care; Self Administration /economics; Warfarin /administration & dosage

**AccessionNumber**
22002001953

**Date bibliographic record published**
30/04/2005

**Date abstract record published**
30/04/2005