Does the Birmingham model of oral anticoagulation management in primary care work outside trial conditions?

DA Fitzmaurice, ET Murray, KM Gee and TF Allan

SUMMARY

The effectiveness of the Birmingham model of primary care oral anticoagulation management has previously been demonstrated within a randomised controlled trial. The aim of this study was to assess the effectiveness of the Birmingham model in routine care. All patients from 12 primary care centres attending either practice-based or hospital-based anticoagulation clinics were retrospectively followed up from October 1996 to March 1998. Outcome measures were therapeutic International Normalised Ratio (INR) control, haemorrhagic and thrombotic episodes, and recall frequency; 452 patients who had two or more INR results during the follow-up period were investigated. There were no significant differences between practice-based and hospital-based populations in terms of the percentage time in range, (69% and 64% respectively). The proportion of tests in range was significantly higher in the practice-based group (61% practice-based, 57% hospital-based; P = *0.015). There was no difference between the two populations in terms of mean follow-up time (36 days in each group). There were no significant differences between groups for the number of clinical outcomes per patient. This study confirmed that, within these practices, oral anticoagulation management is safe and effective using the Birmingham model.*

Keywords: *oral anticoagulation therapy; INR; International Normalised Ratio; primary care.*

DA Fitzmaurice, MD, MRCGP, senior lecturer; ET Murray, MSc, research fellow; KM Gee, MSc, research fellow; and TF Allan, MSc, lecturer, Department of General Practice, University of Birmingham.

Address for correspondence

Dr DA Fitzmaurice, Department of General Practice, Medical School, University of Birmingham, Edgbaston B15 2TT.
E-mail: d.a.fitzmaurice@bham.ac.uk

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Introduction

THE Birmingham model of oral anticoagulation management comprises near-patient testing for International Normalised Ratio (INR) measurement and computerised decision support software (CDSS) for interpretation of the INR within a practice nurse-run primary care clinic. Equivalent INR control between practice-based and hospital-based patients has been previously demonstrated in a Medical Research Council (MRC)-funded study in 12 practices.[1] This study reports the level of oral anticoagulation control for patients from the same practices for an 18-month period after the completion of the original study. Of nine intervention practices, six continued to run oral anticoagulation clinics. Of these, four used Coaguchek (Roche Diagnostics) and two used Thrombotrak (Nycomed UK) for INR estimation. They all continued to use AMSS software (Softop Ltd) as the CDSS for warfarin dosing.

Method

Retrospective data were collected for patients receiving warfarin. Data were collected from October 1996 to March 1998. Patients were classified into two main groups: practice-based and hospital-based. Outcome measures were: INR control based on: (a) number of tests performed within target INR range; and (b) individual proportion of time spent within therapeutic target range, haemorrhagic and thrombotic episodes, and recall times.

Hospital clinic INR data and recall dates were collected from computer and paper records at two hospitals in Birmingham (University Hospitals and City Hospital NHS trusts) and practice clinic data were collected from CDSS used within the practice clinics. General practice notes of all patients were searched for haemorrhagic or thrombotic events related to warfarin therapy. Haemorrhagic incidents were described in terms of serious (requiring admission to hospital, blood transfusion or surgery) or non-serious (any other bleed). All thrombotic events were classified as serious.[2-4] Patients who died during the study period had cause of death identified. Data were entered onto an SPSS database for statistical analysis. Analyses were undertaken to compare practice-based and hospital-based patients in the total population.

Results

Four hundred and fifty-two patients were identified (122 practice-based, 330 hospital-based) who had two or more INR results during the study period. These comprised 235 out of 287 who completed the original study, (69 practice-based, 166 hospital-based) and 217 newly identified

Table 1. INR control and clinical outcomes.

	Percentage of time in range (95% CI)	Proportion of tests in range (95% CI)	Thrombotic (events per 100 patient years)	Haemorrhagic (events per 100 patient years)
Practice-based clinic $n = 122$	69% (65–73)	61% (58–64)	2.5	3.3
Hospital-based clinic $n = 330$	64% (61–67)	57% (56–59)	2.9	4.1

HOW THIS FITS IN

What do we know?

The Birmingham model of oral anticoagulation in primary care, utilising near-patient testing and computerised decision support software is effective under trial conditions.

What does this paper add?

The Birmingham model remains effective in routine care.

patients (53 practice-based, 164 hospital-based). Fifty-two patients who completed the original MRC study were not included (11 died, 32 moved away, and nine discontinued warfarin in the period between studies). Thirty-seven patients discontinued warfarin (eight practice-based, 29 hospital-based), four moved away (two practice-based, two hospital-based), and four from the hospital group were lost to follow-up during the study period. There were no significant differences between the two populations in terms of the percentage time in range (69% practice-based, 64% hospital-based). The proportion of tests in range was significantly higher in the practice-based group (61% practice-based, 57% hospital-based, test of proportions: $z = 2.43$, $P = 0.015$). (Table 1.) Mean recall time was virtually identical in both groups at 36 days. There were no significant differences between groups for the number of clinical outcomes per patient. There were four deaths (3.2/100 patient years) in the practice group and 13 in the hospital group (3.8/100 patient years). No deaths were related to warfarin therapy in either group.

Discussion

These data demonstrate equivalent control between practice-based and hospital-based populations on any of the parameters applied, with both groups spending over 60% of time within therapeutic range (comparable to the original study). These data compare well with other published studies[5-7] and suggest that findings from the original study can be translated into routine practice. These findings need to be replicated in more diverse practices before generalisability can be ultimately confirmed.

Reference

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