Evaluation of computerized decision support for oral anticoagulation management based in primary care

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SUMMARY

Background. *Increasing indications for oral anticoagulation has led to pressure on general practices to undertake therapeutic monitoring. Computerized decision support (DSS) has been shown to be effective in hospitals for improving clinical management. Its usefulness in primary care has previously not been investigated.*

Aim. *To test the effectiveness of using DSS for oral anticoagulation monitoring in primary care by measuring the proportions of patients adequately controlled, defined as within the appropriate therapeutic range of International Normalised Ratio (INR).*

Method. *All patients receiving warfarin from two Birmingham inner city general practices were invited to attend a practice-based anticoagulation clinic. In practice A all patients were managed using DSS. In practice B patients were randomized to receive dosing advice either through DSS or through the local hospital laboratory. Clinical outcomes, adverse events and patient acceptability were recorded.*

Results. *Forty-nine patients were seen in total. There were significant improvements in INR control from 23% to 86% (P>0.001) in the practice where all patients received dosing through DSS. In the practice where patients were randomized to either DSS or hospital dosing, logistic regression showed a significant trend for improvement in intervention patients which was not apparent in the hospital-dosed patients (P<0.001). Mean recall times were significantly extended in patients who were dosed by the practice DSS through the full 12 months (24 days to 36 days) (P=0.033). Adverse events were comparable between hospital and practice-dosed patients, although a number of esoteric events occurred. Patient satisfaction with the practice clinics was high.*

Conclusion. *Computerized DSS enables the safe and effective transfer of anticoagulation management from hospital to primary care and may result in improved patient outcome in terms of the level of control, frequency of review and general acceptability.*

Keywords: oral anticoagulation; warfarin; primary care; computerized decision support (DSS).

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Submitted: 29 November 1995; accepted: 29 April 1996

Introduction

INDICATIONS for warfarin use are expanding, particularly in prophylaxis against stroke in the management of non-rheumatic atrial fibrillation[1,2,3] (although concerns exist over selection bias observed in the stroke prevention trials).[4] Increased use of warfarin prophylaxis creates expanding demands for regular monitoring of anticoagulated patients. The projected scale of demand may be gauged from prevalence data on atrial fibrillation, with United States rates of 0.3% in 65–69 year olds, 1.5% in those between 70–79 and 3% in over 80s.[5]

Measurement of oral anticoagulant control in any population is expressed in terms of the International Normalised Ratio (INR),[6] where levels of control are the percentages of INR results falling within the therapeutic range for each indication.[7] Close anticoagulation monitoring is essential since the incidence of major bleeding events is 3% (relative risk of 6.6) in warfarin-treated patients.[8]

Anticoagulation management is traditionally undertaken in hospital because INR measurement involves a laboratory blood test and expert judgement is needed for dose adjustment. However, control achieved in many hospital clinics is often unsatisfactory[9,10] and no better than some general practice clinics.[11] Hospital clinic control can be improved using computerized decision support systems (DSS) to around 80% of patients within recommended therapeutic ranges, compared with around 50% pre-DSS.[12]

Expanded indications for oral anticoagulation have resulted in overloaded hospital anticoagulant clinics.[13] Some hospitals have attempted the transfer of oral anticoagulant monitoring to primary care, although most primary care doctors do not feel skilled enough to perform the service[14] and report a lack of resources.[15] Primary care use of DSS could overcome one of these problems by advising on optimal anticoagulation. This pilot study was designed to test the efficacy and safety of this intervention, to inform on the feasibility of a major trial, and to provide preliminary data on costs.

Subjects and methods

The study, based at two Birmingham inner city primary care practices, ran for 12 months from late 1993. In both practices previous anticoagulation control was provided from hospital clinics. The DSS was a DOS-based programme (Anticoagulation Management Support System, Warwick), previously validated in hospital settings[14,16] and operated on dedicated 386SL laptop computers for the trial.

Since this study was partly designed to test methodologies for a larger trial, two control populations were used. In practice A (fundholding), all patients were dosed by the practice DSS advice with previous hospital dosing providing historical control data. In practice B (non-fundholding), patients were randomized to either practice-dosing by DSS (B intervention patients) or hospital-dosing (B control patients) following the INR result. All patients receiving warfarin were included in the trial. Patients commencing warfarin therapy during the study period were sent to the practice clinic by the hospital.

At the initial visit, back-data and relevant medical histories were collected and a venous blood sample taken for INR estimation. At follow-up visits, haemorrhagic or thrombotic episodes and any changes in other therapy were noted, compliance checked and venous blood taken for INR estimation. Clinics were run by practice nurses, although a doctor was always available. Blood samples were sent to the local hospital laboratory for testing and results were faxed back to the practice the same afternoon. INR results were recorded on patient-held records. Patients whose warfarin dose was determined using DSS in the practice had their cards posted with dose instructions the same evening. Hospital-dosed patients had their cards posted after a decision by a consultant haematologist; copies were sent to the practice.

Data were collected on cumulative INRs, morbidity data, and patient satisfaction, using a validated postal questionnaire.[17] The relative INR control was analysed using the McNemar test for dependent proportions, using logistic regression of INR versus time utilised to identify trends. Paired *t* testing was undertaken on those patients included in the study for the 12 months to demonstrate any differences in patient recall time.

Results

Forty-nine patients were on warfarin during the 12 months; 26 in practice A and 23 in practice B (9 control, 14 intervention), for the clinical indications shown in Table 1. Validation checks in practice A revealed that one patient with a prosthetic heart valve was not taking warfarin (referred for out-patient stabilization) and two patients on unnecessary long-term warfarin for isolated deep-vein thromboses suffered in previous years.

Table 1. Clinical indications for anticoagulation.

Clinical indication	Practice A	Practice B (Control)	Practice B (Intervention)
Treatment of deep vein thrombosis	3	0	1
Treatment of pulmonary embolism	1	1	0
Treatment of systemic embolism	2	1	0
Atrial fibrillation	9	1	2
Prevention of thrombo-embolism in myocardial infarction	1	2	0
Mechanical prosthetic heart valve	6	2	5
Recurrent DVT and pulmonary embolism	4	2	6

Table 2. Adverse events.

Event	Practice A	Practice B (Intervention)	Practice B (Control)
Deaths	1	1	2
Thrombotic episodes	0	1 (unconfirmed)	0
Haemorrhagic episodes	6 (3 epistaxes; 1 GI bleed; 1 haemoptysis; 1 bruising)	3 (2 epistaxes; 1 bruising)	5 (3 epistaxes; 1 gum bleed; 1 haematoma)

Levels of INR control

A and B intervention patients showed an improvement in INR control compared with the pre-study, with A's rise (from 23% to 89%) achieving significance ($P<0.001$) using the McNemar test for dependant proportions. The improvement in B intervention patients from 43% to 75%, failed to achieve significance ($P<0.25$). However, logistic regression of percentages in range versus time showed a significant trend for improvement in both A (24 rising to 36 days) and B intervention patients (32 to 40 days) ($P<0.001$), with no significant difference in trend between these two groups ($P=0.44$). In contrast, the B control patients (40 to 41 days) displayed no significant trend over time ($P=0.88$). Control patients were consistently under-anticoagulated compared with intervention patients.

Improved INR control is reflected in the increased recall time (and decreased number of appointments) in the intervention groups as compared with the control group. Paired *t* testing on patients who were involved for the whole study period (12 months) showed a significant increase in recall intervals for intervention-only patients ($P=0.033$).

Adverse events and patient satisfaction

One thrombo-embolic event occurred; an axillary vein thrombosis not confirmed by venography. Most bleeding episodes were minor epistaxes. The patient with haemoptysis was found to have hereditary telangiectasia (Table 2).

Twenty-five (56%) anonymous patient satisfaction questionnaires were returned with only two (8%) patients expressing any dissatisfaction with the practice clinic. Negative comments related only to the delay between having blood taken and receiving the result, and the need to venepuncture for the trial. Although this was a low response, no patients requested a return to hospital care.

Cost-analysis of the intervention

Table 3 shows that capital costs of the DSS and computer were offset by savings (realizable to fundholding practices) from patients not attending the hospital out-patients clinic. Benefit was enhanced when improved clinical control decreased patient attendance rates. Using average hospital review rates, an estimated 148 additional appointments would have been offered to the 26 practice A patients during the 12 months without DSS. Direct costs to the practice include staff costs, consumables (stamps and telephone calls), and the charge for the hospital blood tests. Costs to the practice, therefore, are dependent upon the number of patients attending the clinic and the comparative cost of a local hospital anticoagulation appointment.

The cost per visit at the review frequency in this trial was £10.05 (staff costs based on seven minutes per visit to the GP at £2.92; practice nurse at £1.13; test cost £5; consumables £1 per test). Forty-five pounds were saved for each avoided out-patient attendance, making the cost saving per visit £34.95 to fundholders. The capital outlay of £2000 for the software would be offset by savings after 92 patient visits. Capital costs are non-recurring, therefore, overall cost savings to the National Health Service would accrue in subsequent years.

Discussion

Despite the small numbers involved, this study has shown that warfarin monitoring can be safely and effectively undertaken in primary care by using computerized decision support. The model evaluated is similar in scale to practice nurse-run asthma or diabetic clinics. Problems expressed by patients with the practice

Table 3. DSS costs versus hospital costs for practice A (26 patients with 140 appointments).

DSS Costs Item	Cost	Total
Capital		
Computer software	£2000	
Laptop computer	£1200	
Running costs		
Blood tests (@ £5 per test)	£1500	
Consumables		
(@ £5 per clinic)	£250	
Computer maintenance		
(after 1st year)	£540/year	
Staff costs		
1. Practice nurse time		
(@ £9.69 per hour, Grade G)		
Start-up time (6 clinics @ 4 hours/clinic)	£233	
Running clinic (44 clinics @ 2 hours/clinic	£853	
2. Doctor time (@ £25 per hour)		
Start-up time (6 clinics @ 1 hour/clinic)	£150	
Running clinic (44 clinics @ 1/2 hour/clinic	£550	
First year		£6736
Subsequent years		£3696
Hospital Costs Item	**Cost**	**Total**
Direct costs		
Clinic appointment (140 appts @ £45/visit)*	£6300	
Indirect costs		
Patient time (1hr/visit)*	108 hours	
Patient transport costs (£5/visit)	£700	
First year		£6300 #
Subsequent years		£6300 #
Possible Savings		
First year		-£436
Subsequent years		£2604

*140 clinic appointments offered. 108 clinic attendances. #Direct costs only identified.

clinics (the need for venepuncture and the delay in receiving results) could be overcome by the utilization of near-patient testing for INR within practice-based clinics.

The improvement in INR control is most likely the result of the utilization of DSS, but with the small numbers involved other factors may have contributed. The continuity of care provided by a practice nurse-run clinic might also be expected to result in improved compliance.

It has been suggested that DSS provides initial support for less experienced personnel and that its usefulness declines with time, although this has been disproved in hospital practice.[12,16] Furthermore, as time trends have shown in this study, improvements in INR control are sustained beyond plateau performance. The consistency of dosing advice provided by DSS would also allow for sustained performance even following a change in clinic operator.

There are potentially significant advantages for patients in this model of care. Ease of access to the clinic and shorter waiting times may improve patient satisfaction. Although practices were minimally disrupted during the trial, additional practice staff costs were incurred. Currently these could only be met in the UK in fundholding practices, where significant savings could be expected. The level of these savings will necessarily depend on the local costs from the provider unit and the throughput of patients. The greater the number of patients seen in a high-cost provider environment, the more economically efficient DSS becomes.

Although the study numbers are small, statistically significant improvements were shown. This trial provides evidence that oral anticoagulant management can be safely and effectively devolved from secondary to primary care by using computerized DSS. An intervention such as this, which produces improved patient outcomes and high patient acceptability with reduced overall cost of care, is likely to prove highly cost-effective in formal health technology assessment.

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