Does self-management of oral anticoagulation therapy improve quality of life and anxiety?

Deborah McCahona, Ellen T Murraya, Kathryn Murrayb, Roger L Holdera and David A Fitzmauricea,*

aPrimary Care Clinical Sciences, School of Health and Population Sciences, Primary Care Clinical Sciences Building, University of Birmingham, Edgbaston, Birmingham B15 2TT, UK and bSacred Heart Rehabilitation Service, St Vincent’s Hospital, 170 Darlinghurst Road, Darlinghurst, Sydney, New South Wales 2010, Australia.

*Correspondence to David Fitzmaurice, Primary Care Clinical Sciences, School of Health and Population Sciences, Primary Care Clinical Sciences Building, University of Birmingham, Edgbaston, Birmingham B15 2TT, UK; E-mail: d.a.fitzmaurice@bham.ac.uk

Received 12 March 2010; Revised 1 October 2010; Accepted 4 October 2010.

Background. Research related to service requirements for anticoagulation management has focussed on clinical and health economic outcomes and paid little attention to the impact of treatment and service delivery on patients’ quality of life. This was the first large UK study to evaluate the effect of patient self-management (PSM) of oral anticoagulation on treatment-related quality of life (TRQoL) and anxiety in comparison with routine care (RC) and to explore the effect of level of therapeutic control on TRQoL and anxiety across and within each model of care.

Methods. A quantitative survey, set in primary care in the West Midlands. The subjects were 517 randomized controlled trial participants, 242 receiving PSM and 275 RC. Postal questionnaires at baseline and 12 months comprised the State Trait Anxiety Inventory and a treatment-specific measure of positive (satisfaction and self-efficacy) and negative aspects (daily hassles, strained social network and psychological distress) of TRQoL. Change in anxiety and TRQoL scores were compared between PSM and RC. Subgroup analysis was based upon level of therapeutic control (high, medium and low).

Results. Overall, 83% (n = 202) PSM and 55% (n = 161) RC patients contributed data. Anxiety scores were similar in both groups. PSM demonstrated greater improvement in self-efficacy than RC across the study period. A statistically significant between-group difference (PSM versus RC) in the self-efficacy also existed in subgroups with medium and high levels of therapeutic control.

Conclusions. PSM is not associated with increased anxiety and has a positive effect upon some aspects of TRQoL compared to RC.

Keywords. Anticoagulation, anxiety, primary health care, quality of life, self-care, warfarin.

Introduction

Patient self-management (PSM) of warfarin therapy is a similar concept to home glucose monitoring.1 In this model of care, the patient is responsible for testing their international normalized ratio (INR) at home using a capillary blood sample on a Point of Care System (PoC), interpreting the result and adjusting their warfarin dose in accordance with the result. Potential advantages of PSM include improved convenience for patients with less interference on lifestyle, better compliance and improved control with less thromboembolic and haemorrhagic complications.2–4

Most research around service requirements for anticoagulation management has focussed on clinical and health economic outcomes,5,6 with little attention paid to the impact of treatment and service delivery on patients’ quality of life. Treatment-related quality of life (TRQoL) encompasses the effects of the illness and its treatment on the patient, as perceived by the patient. Oral anticoagulation therapy may have a number of positive effects with physical, psychological, social and financial consequences. For example, the frequency of INR monitoring may be an important aspect of treatment to provide reassurance through contact with the medical service. However, there are a number of characteristics of anticoagulation that potentially reduce quality of life; the need for regular blood tests and other contacts with the health services, lifestyle limitations, including restrictions on diet and possibly worry about bleeding and or thrombosis.

The earliest data relating to oral anticoagulation therapy and quality of life arose from a study evaluating warfarin’s efficacy at stroke prevention in patients with atrial fibrillation.7 In this study, no difference in quality of life was found between patients taking...
warfarin and those not, with the conclusion that warfarin therapy is not associated with a decrease in perceived health unless major bleeding has occurred, with negative aspects of treatment balanced by confidence in its protective effect. Subsequent data have been conflicting with some studies suggesting a positive impact on quality of life from warfarin therapy, while others reported high levels of dissatisfaction with oral anticoagulation therapy perhaps associated with poor therapeutic control.

European data suggest that patients with better INR control score higher on measures of quality of life. Data from Germany using a TRQoL questionnaire has suggested that self-management of oral anticoagulation, associated with improved therapeutic control, can have a substantial benefit in terms of patients’ perceived health status and satisfaction. The study described an improvement in several TRQoL, including increased general treatment satisfaction and decreased perceived daily hassles and psychological distress in PSM.

Benefits of self-management on quality of life have also been shown in asthma and diabetes however previous work in the UK has failed to elicit any meaningful information with regard to oral anticoagulation service delivery and patients’ quality of life. Another review of self-management suggested that efficacious self-management encompasses ability to monitor one’s own condition and to affect the cognitive behavioural and emotional responses necessary to maintain a satisfactory quality of life. This description is particularly pertinent to self-management of a treatment like oral anticoagulation involving careful titration of a drug to ensure appropriate dosing and prevention of possible adverse sequelae.

We have previously reported the clinical and health economic findings of the SMART study, which investigated patients’ self-management of oral anticoagulation versus routine care (RC) in the UK. A secondary aim of the SMART study was to determine the impact of patient self-management upon patient reported outcomes, such as anxiety and TRQoL. The aim of this paper was (i) to evaluate the effect of patient self-management on TRQoL and anxiety in comparison with traditional management, (ii) to explore the effect of level of therapeutic INR control on TRQoL and anxiety and (iii) to determine if level of therapeutic INR control has a similar effect on TRQoL and anxiety in both PSM and RC.

**Methods**

**Trial design**

Full details of the SMART trial have been reported elsewhere. Intervention (PSM) patients attended a training programme before commencing self-management. This comprised education about their treatment and training to use the PoC system (Coaguchek S, Roche Diagnostics). Full details of the programme have been previously described. During the study period, intervention patients managed their own anticoagulation for a period of 12 months, with INR testing every 2 weeks (1 week after a dosage change). PSM were able to contact a health professional as and when required and attended a practice-based clinic for a progress review every 3 months. RC patients continued with their prestudy care, either attending a hospital or practice-based anticoagulation clinic. Frequency of INR testing and contact with health professionals for the RC patients was dictated by level of therapeutic control and local protocols for oral anticoagulation management and ranged from weekly to three monthly.

Postal questionnaires were sent to trial participants at baseline and 12 months and comprised two instruments measuring state anxiety and TRQoL. State anxiety was measured by the Spielberger State-Trait Anxiety Inventory and refers to emotional reactions characterized by subjective conscious feelings of tension, apprehension, nervousness and worry. This inventory utilized six items each with a four-point scale to measure anxiety. Total scores were calculated and inflated to produce results equivalent to the standard 20-item questionnaire, with higher scores indicating greater reported anxiety. TRQoL was measured using an oral anticoagulation (warfarin therapy)-specific instrument, developed by Sawicki through a clinical impact method in which items were selected from a large pool of statements based upon the importance given to them by patients. The questionnaire consisted of 32 statements covering five aspects of TRQoL (general treatment satisfaction, self-efficacy, daily hassles, strained social network and psychological distress). The general treatment satisfaction domain comprised five statements, self-efficacy four items, strained social network and daily hassles comprised eight items each and seven statements contributed to the psychological distress domain. The structure of the original questionnaire was preserved; however, some statements were adapted to suit the UK population. Patients were asked to indicate the degree to which statements were applicable to their individual situation with a minimum score of one indicating total disagreement and a maximum score of six indicating total agreement. For each domain, the total score was divided by the number of items resulting in a maximum score of six for every topic. Higher scores for the self-efficacy and general treatment satisfaction and lower scores for the daily hassles, psychological distress and strains social network domains were indicative of better TRQoL.

**Statistical analysis**

Data from the questionnaires were entered into a Microsoft Access database and analysed using the
statistical packages for social sciences (SPSS-14) Windows package. All variables were assessed for normality. Individuals were included in the analysis if they had returned both a baseline and an end of study questionnaire. To maximize the data set, each study participant contributed all available data to the primary analysis. Only incomplete domains of TRQoL and anxiety were excluded because missing data items prevented calculation of final scores. Patients that withdrew from the intervention (PSM) and returned to RC during the 12-month study period were included in the PSM group. Exclusions from the secondary analysis were made where percentage time in range during the study period was missing because subgroup analysis based on level of therapeutic control was not possible. Parametric tests were used for all data with a normal distribution and non-parametric tests were used otherwise. To remove the effect of person-to-person differences, mean change in anxiety and each domain of TRQoL between baseline and end of study were calculated. The Mann–Whitney U-test was used to evaluate differences between PSM and RC groups with respect to mean change in TRQoL and anxiety score across the 12-month study period. One way-between-groups (PSM versus RC) analysis of covariance (ANCOVA) was used to adjust for previously reported significant differences in baseline characteristics between the PSM and RC groups. Since the groups were dissimilar with respect to age only, ANCOVA with age as a covariate was used to compare differences in mean change in anxiety and TRQoL score across the study period between PSM and RC. Percentage time in therapeutic range was calculated based upon INR measurements within target range obtained during the 12-month study period expressed as a percentage of the total number of measurements performed. PSM and RC groups were further divided into three subgroups (high, medium and low) according to percentage of time spent within therapeutic range (TTR) during the study period. In accordance with the British Society for Haematology guidelines, the high TTR group included individuals spending >70% time within their therapeutic range, the medium TTR group; individuals spending 50–69% time within their therapeutic range and the low TTR group comprise individuals spending ≤49% time within therapeutic range. The Mann–Whitney U-test was used to evaluate differences in mean change in TRQoL and anxiety score across the 12-month study period between TTR groups and PSM and RC groups at each level of TTR.

**Results**

Overall, 242 patients received allocated intervention (PSM). Of these, 193/242 (80%) completed 12 months PSM and 49 (20%) participated in <12 months PSM and returned to RC. Fully completed baseline and 12-month anxiety questionnaires were returned by 199 (80%) of patients allocated to PSM; 81% (156/193) completing 12 months PSM and 88% (43/49) not completing 12 months PSM. With respect to TRQoL, 83% (202/242) PSM contributed data to the primary analysis: 80% (155/193) completing PSM and 96% (47/49) not completing 12 months PSM. Overall, 64% (n = 156; 123 completing and 33 not completing PSM) returned data for all five domains of TRQoL at baseline and 12 months and 19% (n = 46; 39 completing and 17 not completing PSM) returned data for five domains of TRQoL at baseline and 12 months and 19% not completing PSM returned data for all five domains of TRQoL at baseline and 12 months and 19% (n = 46; 39 completing and 17 not completing PSM) returned data for all five domains of TRQoL at baseline and 12 months.

A statistically significant between-group difference in self-efficacy also existed in two of the three TTR...
groups. In both the medium and the high TTR groups, PSM patients demonstrated a significantly greater improvement in self-efficacy in comparison with RC (PSM 1.73 versus RC –0.09, \( P = 0.05 \); PSM 2.36 versus RC 0.05, \( P = 0.01 \) respectively) (Table 2). The only other significant between-group difference (PSM versus RC) observed across the study period existed in the low TTR group with PSM patients demonstrating a significantly greater improvement in general treatment satisfaction than RC (PSM 2.25 versus RC –0.77; \( P = 0.05 \)) (Table 2).

**Effect of level of therapeutic control on TRQoL and anxiety within each study arm**

Within each study, arm significant changes across the study period were also observed at different levels of therapeutic control (Table 2). Within the PSM arm, a statistically significant improvement in self-efficacy existed across the study period in the high TTR group (2.36, \( P < 0.001 \)). In addition, at this level of therapeutic control, a significant reduction in daily hassles was observed (–1.12, \( P = 0.022 \)) (Table 2). The only other significant between-group difference (PSM versus RC) observed across the study period existed in the low TTR group with PSM patients demonstrating a significantly greater improvement in general treatment satisfaction than RC (PSM 2.25 versus RC –0.77; \( P = 0.02 \)) (Table 2).

Within the RC study arm, strained social network significantly increased across the study period in the high TTR group (2.14, \( P = 0.002 \)). Similarly, in the medium TTR group, a significant increase in psychological distress (1.84, \( P = 0.03 \)) was observed. Improvements were observed in two domains of TRQoL in the low TTR group with both self-efficacy and daily hassles showing improvement across the study period (2.13, \( P = 0.05 \), –2.64, \( P = 0.01 \), respectively). At this level of therapeutic control, however, a significant increase in psychological distress (2.07, \( P = 0.02 \)) and strained social network also existed (2.20, \( P = 0.02 \)). Similarly, a significant increase in anxiety was also observed at this level of therapeutic control (1.90, \( P = 0.02 \)) (Table 2). Table 3 presents all non-significant results for change in TRQoL and anxiety during the study period within and across the PSM and RC arms of the study.

**Discussion**

**Summary of the main findings**

This study was the largest UK-based randomized control trial to evaluate the effect of PSM on TRQoL and anxiety in comparison with RC. In addition, stratification of the study population in accordance with time spent within therapeutic range during the study period allowed further exploration of TRQoL and anxiety across the two arms of the study and within each of the study arms at different levels of therapeutic control. In agreement with previous studies, this trial demonstrated a greater significant improvement in self-efficacy in patients self-managing their warfarin therapy compared with patients receiving RC.\(^{10–12}\) This could be because patients managing their warfarin therapy are more aware of changes to their INR than those receiving RC and due to their increased knowledge, the ability to measure their INR and take adaptive action, perceive greater self-efficacy. In addition to demonstrating an effect of PSM on self-efficacy, the results also suggest an effect of level of therapeutic control on this aspect of TRQoL. In both the medium and the high TTR groups, a significantly greater
improvement in self-efficacy was observed in PSM patients compared with those receiving RC. While at lower levels of therapeutic control, no significant improvement in self-efficacy existed in comparison with RC or within the PSM arm of the study. The results of the current study further enhance findings of recent research and reinforce evidence demonstrating that self-management of warfarin therapy is a safe and effective alternative to routine management.1,2,15,20

In accordance with other studies, the PSM patients in the current trial reported a significant decrease in perceptions of daily hassles during the study period.10–12 Although this decrease was reported at each level of therapeutic control within the PSM arm of the study, it was only significant in PSM participants with the highest levels of therapeutic control.

In contrast to previous trials, a significant decrease in perceptions of psychological distress existed only within the PSM arm of the study in the medium TTR group. Change in psychological distress across the study period within each of the study arms and between the two arms of the study failed to reach significance.10–12 In terms of anxiety, it is reasonable to anticipate feelings of increased anxiety in PSM patients, which are attributable to the prestudy education programme and a greater knowledge of their warfarin treatment. Indeed, in this study, the largest increase in anxiety was observed in PSM patients with low therapeutic control. The magnitude of change in anxiety observed however did not reach statistical significance and is unlikely to be clinically significant. These data suggest that PSM has no detrimental effect on levels of anxiety.

**Limitations of the study**

1. The study was limited by a lower overall response rate in the RC group (59% RC versus 83% PSM).
While the PSM group regularly (3 monthly) met with the researchers to review progress those continuing with RC had no contact with the research team during the study period and did not actively participate in the study. It is possible therefore that the differential response rate is an artefact of study design and/or RC patients perceived their response to the study questionnaire as less important or less useful than those undertaking self-management.

2. The PSM and RC groups were dissimilar at baseline with respect to age. One-way between-groups (PSM versus RC) ANCOVA (with age as a covariate) however confirmed that the observed differences in mean change in anxiety and TRQoL score across the study period between PSM and RC remained after allowing for a possible association with age.

3. Within the RC arm of the study in those with lower levels of therapeutic control, a significant improvement in self-efficacy was observed. It is possible however that this improvement in self-efficacy in individuals with poorer therapeutic control receiving RC is an artefact of greater contact and reassurance from health care professionals due to more frequent visits to the anticoagulation clinic for INR testing.

4. At lower levels of therapeutic control, a significant difference between PSM and RC existed for change in treatment satisfaction across the study period. Therefore, despite poorer therapeutic control requiring more frequent INR testing and dosage adjustment, PSM patients in the current study were more satisfied with their treatment than those receiving RC. This observation however contradicts previous suggestion that high levels of treatment dissatisfaction are associated with poor therapeutic control. Similarly, the improvement in treatment satisfaction observed in the low TTR group is not supported at higher levels of therapeutic control and therefore is likely to be a spurious finding.

5. Results related to lowest TTR group should be interpreted with caution due to the limited sample size available for analysis at this level of therapeutic control.

Conclusions and implications for further research
This study has demonstrated that self-management of oral anticoagulation does not adversely effect level of anxiety and provides an increase in self-efficacy compared to RC, which is greatest in patients achieving the highest level of therapeutic control. Furthermore, findings suggest that PSM provides a decrease in daily hassles associated with highest levels of therapeutic control. These findings along side the counter-intuitive findings for example significant improvement in treatment satisfaction in PSM patients with poorest therapeutic control are worthy of further investigation.

Acknowledgements
The authors thank the practices and patients who participated in this trial.

Declaration
Funding: UK Medical Research Council (G9900263). National Health Service career scientist award to DF. Medical Research Council health services research fellowship to EM. Trial registration details: ISRCTN 19313375.

Ethical approval: West Midlands Research Ethics Committee and all relevant local research ethics committees.

Conflicts of interests: none.

References


