Patient-Managed Anticoagulation: Effective but More Costly?

Fitzmaurice DA, Murray ET, Gee KM, et al. A randomised controlled trial of patient self management of oral anticoagulation treatment compared with primary care management. J Clin Pathol 2002;55:845–9.

Study Overview

Objective. To test whether patient self-management of warfarin oral anticoagulation is as safe (in terms of clinical effectiveness) as primary care management, as assessed by therapeutic international normalized ratio (INR) control.

Design. Randomized controlled trial.

Setting and participants. 6 primary care practices in England. Participants were patients older than 18 years who were receiving long-term anticoagulation for at least 6 months and who had demonstrated INR control within 0.5 of target range for at least 60% of the time during the previous year. Among these patients, clinic nurses selected patients who were otherwise healthy and who they deemed physically and cognitively capable of self-management.

Methods. After informal discussion, eligible patients were invited to participate. Patients agreeing to enter the study were randomized to the self-management group (intervention) or to the routine management group (control). The intervention group attended a training course (2 workshops over 2 weeks) covering aspects of anticoagulation management, including use of the "near patient testing device" (Thrombotrak), quality control procedures, and algorithm-based INR adjustment. For 6 months, patients performed an INR test every 2 weeks or 1 week after a dose adjustment. Telephone support with the research team and clinic staff was provided. Patients recorded INR values, warfarin dose, adverse events, advice received, and number of test strips used. Quality control was provided by the device manufacturer and the research team. Internal quality control was not defined, but external quality control consisted of periodic plasma samples. Patients in the control group were managed as before in routine clinics using the same near patient testing device. A random sample of patients from both groups was selected at the conclusion of the study for interview. Issues relevant to their experience (eg, training, attitudes to self-management) were discussed and a quality of life questionnaire completed.

Main outcome measures. INR control in terms of percentage of time within the therapeutic window and proportion of tests within the therapeutic window, adverse events, and costs. McNemar's test for dependent proportions, χ^2, and log linear modeling were used for analyses. Secondary measures (criteria for selecting patients for self-management, attitudes towards self-management, and quality of life) were primarily descriptive. Cost data were collected over the 6-month follow-up period on a per patient basis, focusing on the use of key resource items.

Main results. Of 206 patients who were preliminarily eligible, 56 ultimately entered the study (26 control versus 30 self-management). Most patients who did not participate were considered inappropriate for self-management by practice nurses (62%), while the remainder declined to enroll. 7 patients in the self-management arm were excluded from analysis because of poor compliance, poor interim assessment by staff, or withdrawal from study. Age (mean, 60–70 years) and indications for anticoagulation were similar between groups, with most (55%) patients receiving anticoagulation for atrial fibrillation. There were no significant differences in the pre-study (6 months) INR percentage in range (66% self-management versus 76% control). There were no significant differences in INR control between the groups in terms of percentage of time in range (74% self-management versus 77% control) or proportion of tests in ranges (66% self-management versus 72% control). There were no serious adverse events in the self-management group and 1 in the control group (a fatal retroperitoneal hemorrhage). Use of telephone support was minimal. The self-management group performed more tests per patient than in the control group (14.6 versus 5.3; $P < 0.001$). The mean cost for each patient-year in the self-management arm was $662 (converted U.K. £) compared with $141 in the control arm ($P < 0.001$). Finally, a common theme from the post-study interviews was

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increased anxiety and obsession with health; no difference in quality of life was seen between the 2 groups.

Conclusion. These are the first U.K. data to demonstrate that patient self-management is as safe as primary care management for a selected population. However, these results were associated with a greater cost per patient per year.

Commentary

Oral anticoagulation can be challenging for patients and health care providers. Drug-drug interactions, diet, stress, health, compliance, and genetics are among multiple factors that contribute to variability in INR values for a patient over time, even for patients who have been on chronic therapy. Such variability places patients at risk for adverse events from either subtherapeutic levels or bleeding from hypoprothrombinemia [1]. In many medical centers, patients are managed in dedicated anticoagulation clinics where close management can lead to better control and reduced adverse events [2].

Self-management may be an even better means of achieving tighter control while reducing medical visits and use of resources. Over a decade ago, Ansell et al demonstrated the feasibility and safety of self-management using prothrombin time measurements [3]. More recently, a randomized multicenter trial in Germany found structured self-management to be superior to conventional care in terms of tighter control at 3 and 6 months and in measures of quality of life [4]. Fitzmaurice and colleagues seek to add to this evidence in this well-designed randomized study in the U.K.

In this trial, self-management appeared to be as effective and safe in controlling INR values as routine clinic-based care, albeit at a higher cost. The control arm's INR "time in range" better reflected conventional practice than in previously published randomized studies. Importantly, these patients were highly selected, and overall represented a small percentage (16%) of patients attending anticoagulation clinics, leaving one to wonder how applicable self-management is to the average patient. Additionally, the authors failed to use an intention-to-treat analysis, excluding 7 (23%) patients from the intervention arm for various reasons. If we are to apply these results to our patients, the outcomes of the excluded patients are as important to the study as those of the patients included in the analysis. Finally, the cost results are provocative (a four- to fivefold increase for the self-management arm) and are contrary to the savings proposed in earlier studies [4] and to what one might intuitively have expected from reduced clinical visits. Whether this cost disparity would become more equitable over time remains to be seen.

Applications for Clinical Practice

With sufficient training, education, and tools, selected patients can successfully and safely manage their INR values. As with diabetic patients, anticoagulation self-management represents an important shift in care into the hands of patients.

–Review by David R. Spigel, MD

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