Oral Anticoagulation: Clinic Management or Self-Management?

Cromheecke ME, Levi M, Cooly LP, del Mol BJ, Prins MH, Hutten BA, et al. Oral anticoagulation self-management and management by a specialist anticoagulation clinic: a randomized crossover comparison. Lancet 2000;356:97–102.

Study Overview

Objective. To compare outcomes of self-management versus specialty management of chronic oral anticoagulation.

Design. Randomized crossover trial with a nonrandom control group for patient satisfaction measures.

Setting and participants. Fifty consecutive subjects attending outpatient cardiology or internal medicine clinics at the Academic Medical Centre in Amsterdam, Netherlands. All patients included in the study had been on an oral anticoagulation agent for at least 6 months (mean ± SD, 4.0 ± 2.2 years). Patients (60% men) took anticoagulants for various indications, with a variety of target INRs. Most patients received a high school (48%) or higher (44%) level of education. The article did not provide other information about demographics and comorbidities. In order to compare patient satisfaction scores, the authors formed a separate control group made up of 44 patients attending an anticoagulation clinic. The control patients were matched to the 50 crossover patients by age, gender, and indication for anticoagulation. No demographic or clinical information was presented on the control group.

Intervention. All crossover patients took part in a small-group structured educational program consisting of two 2-hour sessions. The first session taught patients basic physiology and principles of anticoagulation therapy; the second provided interactive training on the use of self-monitoring equipment (CoaguChek coagulometer, Roche Diagnostics, Almere, Netherlands) and working with a dosing scheme. Other support, including a 24-hour-a-day help desk, was available to patients throughout the study.

Patients were randomized into 2 groups: 1 group self-managed their anticoagulation for 3 months then were managed by an anticoagulation clinic for 3 months; the other group was treated in the reverse order.

Main outcome measures. The primary outcome was the proportion of measurements within 0.5 INR units of the therapeutic target in each 3-month study period. Prothrombin times were measured in a central laboratory every 1 to 2 weeks; clinicians and study patients did not receive these results. Investigators assessed patient satisfaction using a previously developed instrument [1]. Clinical outcomes (ie, bleeding and thrombotic events) also were measured, though the study was not powered to detect small but meaningful differences in these outcomes.

Main results. 49 patients completed the study and contributed usable data, with 45 crossover patients providing usable satisfaction data. During self-management periods, 55% of measurements were in the target range versus 49% of measurements from the anticoagulation clinic period ($P = 0.6$). Other measures showed a trend slightly favoring self-management. Patients were more satisfied in all 5 measured scales after their self-management periods compared with the control group ($P = 0.022$ to < 0.001). Scores of crossover patients at the beginning of the self-management period were not significantly different from control group scores. No patients experienced major bleeding episodes. During specialty management periods, there were 3 minor bleeding complications, all involving patients with INRs greater than 4.0, and 1 clinically suspected but unconfirmed thrombotic event (INR = 1.4). One minor bleeding episode (INR = 2.4) and no diagnosed thrombotic events occurred during self-management. The differences in the numbers of adverse events were not statistically significant. Controlling for the order of management did not alter the overall results.

Conclusion

Self-management is as good or better than specialty clinic management for monitoring oral anticoagulation. Patients are more satisfied with self-management.

Commentary

Several studies have documented the feasibility of self-managing oral anticoagulation [1]. This is first to compare

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self-management with an anticoagulation clinic, generally considered to be the gold standard [2]. The study was well designed; however, the nonrandomized patient satisfaction analysis raises concerns about selection bias, which may have inflated outcome differences. The smaller numbers did not allow for a meaningful assessment of clinical outcomes. A much larger randomized, controlled clinical trial would be needed to address the question of whether either system leads to better clinical outcomes. While there is published evidence to suggest that self-management is cost-effective compared with primary care management of anticoagulation therapy [3], it is not clear what the marginal cost-benefit ratio is compared with specialty care.

Applications for Clinical Practice

Cromheecke et al's study builds on evidence that patient self-management of oral anticoagulation therapy is safe and effective. Moreover, along with other research [2] this study suggests that self-management may be superior for some patients. While the evidence is sufficient for the widespread implementation of self-management programs, some caveats must be heeded. The positive trials provided substantial training and support to patients. When a patient can be started on self-management is not clear. Optimal test frequencies have not been determined. In addition, the largest study on self-management recruited any patient expecting lifelong anticoagulation therapy; it did not report how long patients had been on therapy and excluded new patients [1]. Finally, the long-term clinical and cost-effectiveness is yet to be addressed. Despite these issues, anticoagulation self-management programs should be developed in most adult outpatient settings.

References

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3. Taborski U, Wittstamm FJ, Bernardo A. Cost-effectiveness of self-managed anticoagulant therapy in Germany. Semin Thromb Hemost 1999;25:103–7.