

Self-management of long-term oral anticoagulation was as effective as specialist anticoagulation clinic management

Cromheecke ME, Levi M, Colly LP, et al. Oral anticoagulation self-management and management by a specialist anticoagulation clinic: a randomised cross-over comparison. *Lancet*. 2000 Jul 8;356:97-102.

QUESTION

In patients needing long-term oral anticoagulation therapy, is self-management as effective as specialist anticoagulation clinic management?

DESIGN

6-month, randomized {allocation concealed*}†, controlled crossover trial with blinded outcome assessments (patients and clinicians)*.

SETTING

Anticoagulation clinic in the Netherlands.

PATIENTS

50 self-supporting patients (mean age 42 y, 59% men) who were receiving long-term anticoagulation therapy with oral agents. 49 patients (98%) completed the study.

INTERVENTION

Self-managed care involved education about the principles and monitoring of therapy. Live and video instructions were given on

how to use a capillary fingerstick and automated device for self-measurement. Patients were then instructed about dose adjustments of oral anticoagulants by using a standard nomogram. Anticoagulation clinic management included measurements and dosing done at the clinic. After 3 months, patients crossed over to the other management group for 3 more months.

MAIN OUTCOME MEASURES

The primary outcome was number of measurements within 0.5 international normalized ratio (INR) units of the therapeutic target. Secondary outcomes were percentage of time in the target range, number of patients in the target range, and number of patients who achieved better control of anticoagulation during either period.

MAIN RESULTS

The number of self-managed measurements within 0.5 units of the target INR did not differ from clinic management (55% vs 49%, {95% CI for the 6% difference 0.06%

to 12%}‡, $P = 0.06$). 29 patients during self-management (60%) spent > 50% of the time in the target range compared with 25 patients (52%) during clinic management ($P < 0.05$). Of the 49 patients completing the study, 34 (70%) had better control of anticoagulation during self-management, 10 (20%) had better control during clinic management, and 5 (10%) showed no difference.

CONCLUSION

In patients needing long-term oral anticoagulation therapy, self-management was as effective as specialist anticoagulation clinic management.

Source of funding: In part, Roche Diagnostics (monitors and test strips).

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*See Glossary.

†Information provided by author.

‡CI calculated from data in article.

COMMENTARY

Patients who need long-term anticoagulation with vitamin K antagonists must submit to regular prothrombin time (INR) testing, a routine that is at least a nuisance and often at odds with home and work schedules. More patient-centered approaches are needed. Patients readily learn how to self-test and how to self-adjust the warfarin dosage. The therapeutic accuracy of self-management was similar to that of physicians in general practice (1). In this randomized crossover study by Cromheecke and colleagues, Dutch patients seem to be as good as the specialists and the computer algorithms that constitute "standard care." Consistent but indirect evidence suggests that anticoagulation clinics are the gold standard of anticoagulant care (2), and it appears that patients can become experts in managing their own warfarin therapy.

The results of this relatively small study rest on sound methods. Even if the accuracy of either approach to dosing was overstated or understated, the clinical message would be the same. On their own, selected patients do quite well. But how were they selected? Consecutive patients were enrolled, mitigating the possibility of selection bias. These patients, who were described as "self-supporting," may be unusually well educated or self-reliant. Self-managed patients and anticoagulation clinics were tested often, every 1 to 2 weeks. In

addition to patient ability and testing frequency, the costs of home testing limit the generalizability of this study. Insurance companies in the United States, including Medicare, are as yet unwilling to subsidize this technology.

If self-management is sufficiently accurate, does it also limit bleeding and thromboembolic events? At present, we do not know the answer, and only large studies could find a real difference in rates of relatively rare complications. Nevertheless, the convenience factor is important. Patients and physicians can opt for home testing and patient self-dosing. Unfortunately, the choice is difficult because of cost, not because of clinical validity or applicability.

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