A nurse-led clinic and computer decision-support software for anticoagulation decisions were as effective as a hospital clinic

Fitzmaurice DA, Hobbs FD, Murray ET, et al. **Oral anticoagulation management in primary care with the use of computerized decision support and near-patient testing. A randomized, controlled trial.** Arch Intern Med. 2000 Aug 14/28;160:2343-8.

QUESTION

For patients who require oral anticoagulation, is a primary care, nurse-led clinic that uses on-site testing and computerized decision-support software more effective than routine hospital care for maintaining appropriate international normalized ratios (INRs)?

DESIGN

Randomized (unclear allocation concealment*), unblinded,* controlled trial, stratified by practice size, with 1-year follow-up.

SETTING

12 of 21 potential general practices and 3 hospital clinics in Birmingham, England, United Kingdom.

PATIENTS

224 adult patients (55% men) who were receiving warfarin. Follow-up was 82%.

INTERVENTION

122 patients were allocated to nurse-led management in a primary care setting. The nurse met with the patient, measured the INR with on-site equipment, and used the computer program (Anticoagulation Management Support System [Softop Information Systems, Warwick, England, United Kingdom]) to direct dosing decisions. The program was based on the British Society of Haematology guidelines and had 2 main ranges of INR (2.0 to 3.0 and 3.0 to 4.5). If a dosing change was suggested, the nurse verified the change with medical staff at the clinic. 102 patients were allocated to hospital-based care (2 of the 3 sites were staffed by a physician during the study, and 1 site started with physician supervision before switching to a technician and another computer decision-support program.)

MAIN OUTCOME MEASURES

Proportion of patients who achieved appropriate INR control and mean percentage of time each patient spent within a therapeutic range of INR.

MAIN RESULTS

8 patients in the nurse-led group returned to hospital clinic care. Patients in the nurse-led group had a higher percentage of time spent in the therapeutic INR range than did patients in the hospital group (69% vs 57%, $P < 0.001$). The groups did not differ for the proportion of tests in therapeutic range (although both groups improved from baseline levels), all-cause mortality (3 deaths in each group), serious adverse events (3 in each group), or overall adverse events. The mean intervention cost per patient was U.S. $270 in the nurse-led group and $110 in the hospital group.

CONCLUSION

A nurse-led clinic in the primary-care setting that included on-site blood tests and a computer decision-support program for patients who were receiving warfarin was at least as effective as a hospital-based clinic.

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*See Glossary.

COMMENTARY

The growing number of patients receiving long-term oral anticoagulation has created a substantial primary-care management burden. To achieve benefit–risk ratios similar to those reported in randomized controlled trials, patients' INRs must be maintained in a narrow therapeutic range. However, primary-care providers have difficulty in replicating the success observed in the trial setting. Approximately 50% of the time, patients who are receiving anticoagulants are not within the therapeutic range (1). For patients with atrial fibrillation, the combined rate of major bleeding complications and stroke is 2 to 3 times higher in the "usual"-care setting than in special anticoagulation clinics (2). Anticoagulation management clinics are more likely than usual-care settings to achieve optimal anticoagulation because of dedicated providers, appropriate follow-up, access to INR monitoring, decision-support systems, and patient education (2, 3). Specialized ambulatory anticoagulation management services may be provided in a hospital environment and are often delivered by nonphysician providers or pharmacists who are directed by a physician who has no responsibility for the primary care of the patients. With appropriate restructuring, optimal long-term anticoagulation may be achieved within a primary-care setting with improved overall continuity of care.

The stratified randomized controlled trial by Fitzmaurice and colleagues shows the effectiveness of primary-care anticoagulation management that is delegated to a nurse with access to on-site INR testing and computerized decision support. Consequently, this study supports the notion that the special features of anticoagulation management services can be incorporated into primary care (2). Promising strategies include patient self-monitoring and self-management (3).

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References

1. **Samsa GP, Matchar DB, Goldstein LB, et al.** Quality of anticoagulation management among patients with atrial fibrillation: results of a review of medical records from 2 communities. Arch Intern Med. 2000;160:967-73.
2. **Ansell JE.** The quality of anticoagulation management. Arch Intern Med. 2000;160:895-6.
3. **Ansell JE, Hughes R.** Evolving models of warfarin management: anticoagulation clinics, patient self-monitoring, and patient self-management. Am Heart J. 1996;132:1095-100.

