Multicomponent comprehensive care improved control and may have decreased major bleeding in older patients on warfarin

Beyth RJ, Quinn L, Landefeld CS. **A multicomponent intervention to prevent major bleeding complications in older patients receiving warfarin. A randomized, controlled trial.** Ann Intern Med. 2000 Nov 7;133:687-95.

QUESTION

In older patients requiring warfarin, is multicomponent comprehensive care (MCC) more effective than usual care for reducing major bleeding events?

DESIGN

Randomized {allocation concealed*}†, blinded (data collectors and outcome assessors),* controlled trial with 6-month follow-up.

SETTING

Cuyahoga County, Ohio, United States.

PATIENTS

325 patients (mean age 75 y, 57% women) who were ≥ 65 years of age, received ≥ 10 000 units of intravenous unfractionated heparin, resided in the area, and had planned warfarin treatment for ≥ 10 days. Exclusion criteria included treatment with warfarin in the previous 6 months, admission from a nursing home, or enrollment in another clinical trial. Follow-up was complete.

INTERVENTION

163 patients were allocated to MCC, which consisted of a guideline-based consultation and patient education, coaching, and self-monitoring of prothrombin time with a portable monitor. Home visits were made 3 days after discharge to assess the patients' ability to use the monitor. Patients monitored their prothrombin time 3 times during the first week after hospital discharge, once per week for the rest of the first month, and monthly thereafter. 162 patients allocated to usual care were managed by their personal physicians.

MAIN OUTCOME MEASURE

Occurrence of a first major bleeding event (loss of ≥ 2.0 units of blood in ≤ 7 d or life-threatening blood loss).

MAIN RESULTS

Of the MCC group, 28% were self-managed, 31% were managed by another person, 22% were monitored conventionally, and 19% refused allocation and were managed by their physician. Patients in the MCC group spent a greater proportion of time with their international normalized ratio (INR) in the therapeutic range (56% vs 32%, $P < 0.001$). Cumulative incidences of major bleeding at 6 months for the MCC and usual-care groups were 5.6% vs 12% ($P = 0.05$). The point estimates are in the Table.

CONCLUSION

In older patients requiring warfarin, multicomponent comprehensive care improved control and may have decreased major bleeding events more than did usual care at 6 months.

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For correspondence: Dr. R.J. Beyth, Baylor College of Medicine and Houston Center for Quality of Care and Utilization Studies, Houston VAMC (39A), 2002 Holcombe Boulevard, Houston, TX 77030, USA. FAX 713-558-4593. ■

*See Glossary.

†Information provided by author.

Multicomponent comprehensive care (MCC) vs usual care for patients requiring warfarin‡

Outcome at 6 mo	MCC	Usual care	RRR (95% CI)	NNT
Major bleeding	4.9%	10.5%	53.2% (–2.7 to 78.9)	Not significant

‡Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data provided by author.

COMMENTARY

The study by Beyth and colleagues has attempted to compare a thromboembolism service and anticoagulation clinic with usual care for managing patients requiring anticoagulation therapy. The study intervention involves both inpatient and outpatient management components but contains elements not yet commonly incorporated into specialty consultation services (e.g., a lay educator and point-of-care INR testing). Not all patients in the MCC group received all components (28% were self-tested), so it is difficult to say which of the components are most important.

Although 6 of the 8 major bleeding events in the MCC group occurred in patients who declined the intervention, 3 of these bleeding events occurred during hospitalization when patient behavior and attitudes toward care would have less effect on outcome. Furthermore, almost 50% of all major bleeding events occurred during the index hospitalization, not during subsequent outpatient warfarin therapy. Thus, assigning and understanding any effect of the patient's decision to decline the intervention on their bleeding episode would be difficult.

About 20% of those patients who were offered the intervention declined it. Although this finding may be in keeping with patient participation in other clinical trials, clinicians should remember that not all components of this intervention are applicable to every patient.

The authors did not do a formal cost analysis. The INR monitors are expensive (> U.S. $500; > Cdn $800) and generally not covered by third-party payers. Most of the nondiagnostic components of the intervention program, however, can and are done by other health professionals, such as pharmacists or nurses, in established thromboembolism services and anticoagulation clinics. The clinical benefits and thus the potential cost benefits of coordinated approaches to anticoagulation management as described in this study await a larger randomized trial (1).

Intuitively, the components of this intervention are sensible, and certain elements (e.g., heparin nomograms, anticoagulation monitoring sheets, and patient education) can be easily adapted to care maps and other standardized approaches to patient management. However, more evidence is needed to determine the best approach for managing patients requiring anticoagulation therapy.

Bill Bartle, PharmD
Sunnybrook and Women's College Health Sciences Centre
Toronto, Ontario, Canada

Reference

1. **Ansell J, Hirsh J, Dalen J, et al.** Managing oral anticoagulant therapy. Chest. 2001;119 (Suppl 1):S22-38.