Patient self-management of anticoagulants reduced arterial thromboembolism and adverse effects

Ménendez-Jándula B, Souto JC, Oliver A, et al. **Comparing self-management of oral anticoagulant therapy with clinic management: a randomized trial.** Ann Intern Med. 2005;142:1-10. **Clinical impact ratings:** GIM/FP/GP ★★★★★☆☆ Hematol/Thrombo ★★★★★★☆

QUESTION

Is patient self-management of oral anticoagulants as efficacious and safe as management in an anticoagulation clinic?

METHODS

Design: Randomized controlled trial.
Allocation: Concealed.*
Blinding: Blinded (assessors of complications).*
Follow-up period: Median 11.8 months.
Setting: A hospital in Barcelona, Spain.
Patients: 737 ambulatory patients ≥ 18 years of age who had been receiving long-term anticoagulant therapy for ≥ 3 months. Exclusion criteria were severe physical or mental illness without a responsible caregiver, and inability to understand Spanish.
Intervention: Self-management (n = 368) or clinic-based management (n = 369) of oral anticoagulant therapy with acenocoumarol. Self-management comprised a small-group educational program, delivered in two 2-hour sessions by a specially trained nurse. Patients were in-stricted on use of a coagulometer, interpretation of international normalized ratios (INRs), and adjustment of doses. They tested their INRs at home once a week using the portable CoaguChek S coagulometer (Roche Diagnostics, Mannheim, Germany) and determined the appropriate anticoagulant dose and time of the next INR test. Clinic-based management comprised patient visits to the hospital every 4 weeks to check INRs (KC 10 coagulometer, Amelung, Lemgo, Germany). A hematologist adjusted the dose and made the next appointment for INR testing.
Outcomes: Percentage of INR values within target range and percentage of time within target range; major bleeding (life-threatening bleeding or bleeding requiring transfusion or hospital admission); minor bleeding; arterial thromboembolism (stroke, arterial embolism, valve thrombosis, or transient ischemic attack); venous thromboembolism (deep venous thrombosis, pulmonary embolism, or superficial thrombophlebitis); and death.
Patient follow-up: 100% (intention-to-treat analysis).

MAIN RESULTS

The self-management group had a higher mean percentage of INR determinations within the target range than did the clinic-based group (58.6% vs 55.6%, mean difference 3.0%, 95% CI 0.4 to 5.4). The groups did not differ for percentage of time within the target range (64.3% vs 64.9%, P = 0.2). The self-management group had a lower rate of minor bleeding, arterial thromboembolism, combined major bleeding or any thromboembolism, and death than did the clinic-based group; the groups did not differ for major bleeding or venous thromboembolism (Table).

CONCLUSION

Patient self-management of oral anticoagulants resulted in similar levels of control and major bleeding and lower rates of arterial thromboembolism and death than clinic-based management.

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*See Glossary.

Self-management vs clinic-based management of oral anticoagulant therapy†

Outcomes at median 11.8 mo	Self	Clinic-based	RRR (95% CI)	NNT (CI)
Major bleeding	1.1%	1.9%	43% (–82 to 82)	Not significant
Minor bleeding	15%	36%	59% (46 to 69)	5 (4 to 7)
Arterial thromboembolism	0.8%‡	4.6%‡	82% (44 to 94)	27 (16 to 63)
Venous thromboembolism	0.3%‡	1.4%‡	80% (–29 to 97)	Not significant
Major bleeding or any thromboembolism	2.2%	7.3%	70% (37 to 86)	20 (12 to 46)
Death	1.6%	4.1%	60% (1 to 84)	41 (20 to 2994)

†Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.
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COMMENTARY

The study by Ménendez-Jándula and colleagues and a study by Körtke and Körfer (1) are the largest randomized trials on self-management of treatment with vitamin K antagonists. Both studies showed a larger fraction of INR results within the therapeutic range in the treatment group. Ménendez-Jándula and colleagues also assessed "time within therapeutic range" and found it to be similar in the self-management and clinic-based groups. This is easily explained as patients usually self-tested weekly, regardless of whether the INR result was within the therapeutic range. In the clinic-based group, the interval between tests was gradually increased to 4 weeks after acceptable INR results were obtained.

Surprisingly, there were fewer arterial thromboembolic events and minor bleeding episodes with self-management, despite similar time spent within the therapeutic range in the 2 groups. One explanation is the greater compliance, awareness of risk factors for complications, and responsibility of patients in the self-management group. A selection bias may also exist given that 22% of patients randomized to self-management withdrew early.

The incidence of thromboembolic complications in the clinic-based group was high (5.4%), albeit similar to what the authors found in their review of other studies. Most patients in the study of Ménendez-Jándula had atrial fibrillation, and these patients may have been at high risk for stroke because of concomitant risk factors. However, Körtke and Körfer (1) reported only 2.1% of patients with thromboembolic complications, which raises the possibility of suboptimal conventional management. This is problematic given the open design of the study.

Overall, anticoagulation self-monitoring provides INR control that is as good as, or better than, that by a conventional laboratory, is convenient for patients, and may decrease adverse outcomes. Whether self-monitoring is widely used in clinical practice depends on its cost-effectiveness and whether health insurers will cover the costs of self-monitoring devices, which are prohibitive for most patients.

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Reference

1. **Körtke H, Körfer R.** Ann Thorac Surg. 2001;72:44-8.