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


**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 instructed 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.

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

**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**