Patient self management of anticoagulants resulted in fewer major complications than clinic-based management


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

METHODS

**Design:** Randomised controlled trial (RCT).

**Allocation:** Concealed.

**Blinding:** Blinded (outcome assessors of complications).

**Follow up period:** Median 11.8 months.

**Setting:** A university affiliated hospital in Barcelona, Spain.

**Patients:** 737 ambulatory patients ≥18 years of age who had received anticoagulant treatment for ≥3 months.

**Intervention:** Self management (n = 368) or clinic-based management (n = 369) of oral anticoagulant treatment with acenocoumarol. Self management training included a small group, education programme delivered by a specialist nurse in two 2-hour sessions. Content included use of a coagulometer, interpretation of international normalised ratios (INRs), and adjustment of doses. Patients tested their INRs once a week using the portable CoaguChek S coagulometer (Roche Diagnostics, 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 (K C10 coagulometer, Aetelung, Germany). A haematologist 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 complications (thromboembolic and haemorrhagic); minor haemorrhagic complications, and death.

**Patient follow up:** 100% (intention to treat analysis).

MAIN RESULTS

The self management group had a higher mean percentage of INR values within the target range than 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 lower rates of major, thromboembolic, and minor haemorrhagic complications, and death, but the groups did not differ for severe haemorrhagic complications (table).

CONCLUSION

Self management of oral anticoagulants resulted in fewer major complications than clinic-based management but similar levels of control.

A modified version of this abstract appears in ACP Journal Club.

Commentary

Patient self management is more than just patient education to improve compliance; patients become decision makers, are empowered in their disease management, and work in partnership with healthcare providers. Menéndez-Jándula et al found that patient self management resulted in similar physiological outcomes and fewer complications than usual care. These findings may be explained by the 3-fold increase in INR test frequency in the self management group, but Beyth et al also found improved outcomes when INR test frequencies were similar for self testing and control groups. Menéndez-Jándula et al therefore suggest that improved clinical outcomes were likely related to increased patient empowerment, adherence, and self awareness of health status.

Self management improves outcomes across a range of disease entities, but is it suitable for everyone? Menéndez-Jándula et al estimated that 50% of patients were able to safely use this strategy; the intervention group included many patients who were older or had lower levels of education. One-fifth of patients randomised to self management dropped out, a small proportion of whom were unable to attain sufficient skill levels. Although this does not affect the interpretation of the findings, it suggests that self management is not appropriate for all patients. RCTs of self management programmes have shown some positive results including reductions in hospital readmissions. A cost effectiveness analysis would have been useful, although existing evidence suggests that self management could lead to substantial savings for the healthcare system. The coagulometers cost approximately US$1000 per patient, and each reagent strip was approximately US$5. This cost is prohibitive for many patients but may be justifiable public spending given the potential savings to the healthcare system. Further research on cost is required to provide the evidence required for policy change.

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Self management v clinic-based management of oral anticoagulant treatment*

<table>
<thead>
<tr>
<th>Outcomes at median 11.8 months</th>
<th>Self management</th>
<th>Clinic-based management</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major complication</td>
<td>2.2%</td>
<td>7.3%</td>
<td>70% (37 to 86)</td>
<td>20 (12 to 46)</td>
</tr>
<tr>
<td>Severe haemorrhagic complication</td>
<td>1.1%</td>
<td>1.9%</td>
<td>43% (1 to 82)</td>
<td>43 (21 to 102)</td>
</tr>
<tr>
<td>Thromboembolic complication</td>
<td>1.1%</td>
<td>5.4%</td>
<td>80% (45 to 93)</td>
<td>23 (14 to 52)</td>
</tr>
<tr>
<td>Minor haemorrhagic complication</td>
<td>1.5%</td>
<td>3.6%</td>
<td>59% (46 to 69)</td>
<td>5 (4 to 7)</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>

*Abbreviations defined in glossary; RRR, NNT, and CI calculated from data in article.