Meta-analysis: effect of patient self-testing and self-management of long-term anticoagulation on major clinical outcomes


CRD summary
The review concluded that patient self-testing/self-management was associated with significantly fewer deaths and thromboembolic events, without increasing bleeding complications, for patients requiring long-term anticoagulation with vitamin K antagonists compared with usual clinic care; however, the evidence was of moderate or low strength. The review had several limitations, suggesting its conclusions should be interpreted with caution.

Authors' objectives
To determine whether patient self-testing, alone or in combination with self-adjustment of doses (patient self-management), is associated with a reduction in thromboembolic complications and all-cause mortality without an increase in major bleeding events, when compared with usual care.

Searching
MEDLINE was searched for studies published in English, in peer-reviewed journals, from 2005 to November 2010; search terms were reported. The Cochrane Central Register of Controlled Trials (CENTRAL) was also searched. References before 2005 were identified from a previous systematic review (see Other Publications of Related Interest). Reference lists of relevant articles were also examined to identify further studies.

Study selection
Randomised controlled trials (RCTs) that compared patient self-testing or patient self-management with normal physician care in adult outpatients receiving long-term (over three months) oral anticoagulant therapy were eligible for inclusion. Thromboembolic complications, all-cause mortality, and major bleeding events were the main outcomes of interest.

Most trials recruited mixed populations, but some recruited only patients with mechanical heart valves or with atrial fibrillation. The mean age of participants was 65 years (range 42 to 75); 75% were male. In half of the trials, all patients used warfarin; in most other trials another oral anticoagulant (phenprocoumon, acenocoumarol or fluindione) was used. Self-testing and self-management intervention training included two to four small group sessions (of one to three hours duration) over several weeks, followed by home practice. Most control treatments were given in anticoagulation clinics, or in a primary care or other physician setting.

Two reviewers selected studies for inclusion.

Assessment of study quality
Trial quality was evaluated by assessing the following criteria: allocation concealment, blinding of outcome assessors, analysis using intention-to-treat data, reporting of number of patients who withdrew or dropped out, and funding source.

The authors did not state how many reviewers performed the quality assessment.

Data extraction
Three reviewers extracted data in order to calculate Peto-odds ratios (ORs) or mean differences, with 95% confidence intervals (CI).

Methods of synthesis
Meta-analyses were performed to calculate pooled Peto-odds ratios (using a fixed-effect model), or weighted mean differences (WMD, using a random-effects model). Heterogeneity was assessed using the I² statistic. Sensitivity
analyses were also performed. Publication bias was assessed using Egger's test.

Results of the review
Twenty-two RCTs (n=8,413 participants, range 50 to 2,922) were included in the review. Allocation concealment was adequate in nine trials. Blinding of outcome assessors was described in six trials. Intention-to-treat analyses were used in eight trials. The number of withdrawals and drop-outs was reported in 18 trials. Five trials met all four quality criteria. Follow-up periods ranged from 4.6 months to 9.3 years.

Patients receiving patient self-testing or patient self-management had significantly lower total mortality (OR 0.74, 95% CI 0.63 to 0.87; I²=51%; 13 RCTs) and a lower risk of major thromboembolism (OR 0.58 CI 0.45 to 0.75; I²=27%; 14 RCTs) than usual care. There was no significant difference in risk of a major bleeding event (OR 0.89, CI 0.75 to 1.05; I²=2%; 16 RCTs) or in percentage time spent in the therapeutic range (WMD 1.50%, 95% CI -0.63% to 3.63%; I²=45%; 11 RCTs).

Sensitivity analyses indicated that one particular high quality trial (the largest) was responsible for much of the heterogeneity. Eight of 11 trials found that patient satisfaction, quality of life, or both were better with patient self-testing or patient self-management than with usual care.

There was little evidence of publication bias affecting the results. Further results were reported.

Authors' conclusions
Compared with usual clinic care, patient self-testing with or without patient self-management is associated with significantly fewer deaths and thromboembolic events, without any increase in bleeding complications, for a selected group of motivated patients requiring long-term anticoagulation with vitamin K antagonists. However, the evidence was of moderate strength for thromboembolism and bleeding events, and was low for mortality.

CRD commentary
The review addressed a clear question and was supported by appropriate inclusion criteria. Attempts to identify relevant studies were undertaken by using a previous systematic review, by searching two electronic databases, and by checking references; the limitations of this somewhat basic search were exacerbated by restricting the review to studies published in English, which meant that some relevant studies may have been missed. The authors did not clearly state whether independent duplicate procedures were used to reduce the risk of reviewer error and bias when selecting studies, extracting data, and assessing study quality.

Comprehensive study details were provided, which included the quality assessment results. In light of the clinical and statistical heterogeneity between the trials, the authors may have considered use of a random-effects model to pool the dichotomous data. The number of trials contributing to pooled results appeared contradictory when the forest plots were compared with the table of results, which made interpretation difficult. Limited result details of sensitivity analyses were presented, which made it difficult to assess the validity of the decision to remove the largest high-quality trial from these analyses.

Overall, the review had enough limitations to suggest that its conclusions should be interpreted with caution.

Implications of the review for practice and research
Practice: The authors stated that it was unclear whether the review results could be applied to health care systems in the USA.

Research: The authors stated a need for cost-effectiveness studies.

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