Relative risk of self-monitoring warfarin therapy

Results of a meta-analysis show that self-monitoring of warfarin reduces the risk of thromboembolic events compared with usual care, and has no major effect on bleeding complications or mortality. Cost-effectiveness was not assessed in this study.

Overview: Approximately 1 million people in the UK are eligible for oral anticoagulation therapy for a variety of cardiovascular conditions. The drugs reduce the risk of blood clots but increase the risk of serious bleeding and their effects on individual patients need to be monitored regularly, which includes frequent testing and appropriate dose adjustments. There are a number of ways that this can be done, including GP visits, a specialist anticoagulation service, or a hospital-based anticoagulation service. All these require a blood sample to be taken. Self-monitoring devices used by patients in their own home, provide an alternative and can both improve the quality of anticoagulation and be more convenient for patients. Yet, the use of self-testing (patients perform the test, but dosage adjustment is done by physicians) and self-management (patients perform the test and adjust their own dosage) is inconsistent.

Current advice: People with a venous thromboembolism, will usually need anticoagulation treatment for about 6 months, whereas people with atrial fibrillation need long-term anticoagulation therapy.

NICE guidance on atrial fibrillation recommends that an assessment of bleeding risk should be part of the clinical assessment of patients before starting anticoagulation therapy, and that both the antithrombotic benefits and the potential bleeding risks of long-term anticoagulation should be explained and discussed. In patients who require long-term anticoagulation, NICE recommends that self-monitoring is considered if it is preferred by the patient and certain conditions are met. This guidance is in the process of being updated.

However, a more recent guideline on venous thromboembolic diseases, published in June 2012, recommends that self-management or self-monitoring of international normalised ratio should not be offered to patients who have had deep vein thrombosis or pulmonary embolism and are having treatment with a vitamin K antagonist. The guideline development group highlighted that in addition to self-monitoring not being cost effective, there is currently no widely agreed way for providing an education programme for patients wishing to self-monitor or self-manage, also self-monitoring or self-management is not suitable for everyone.

NICE has 4 Technology Appraisal guidance documents on anticoagulation therapies. These are:

- Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation.
- Rivaroxaban for the prevention of venous thromboembolism after total hip or total knee replacement in adults.
- Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism.

New evidence: A meta-analysis of individual patient data, including 11 trials with data for 6417 participants and 12,800 person-years of follow-up, aimed to clarify the value of self-monitoring of oral anticoagulation (Heneghan et al. 2012). The analysis addressed self-monitoring on time to death, first major bleeding event, first thromboembolic event, and in important subgroups of patients (elderly people, people with atrial fibrillation, and people with a mechanical heart valve).
The results showed that self-monitoring reduced the risk of thromboembolic events by 49% compared with monitoring in an anticoagulation-clinic or primary care. The rate of bleeding complications was similar in both groups and self-monitoring did not have a significant effect on mortality.

The benefits of self-monitoring were particularly notable in people younger than 55 years, in whom the likelihood of developing thromboembolic events was reduced by two-thirds, and patients with a mechanical heart valve, whose risk was halved.

Self-monitoring lowered mortality and did not increase complications in people aged 85 and older, who are at high risk of major bleeding, leading the researchers to suggest that age should not be a factor in determining eligibility for self-management.

The researchers added that self-monitoring and self-management of oral coagulation is a safe option for patients of all ages, and suggested that patients should also be offered the option to self-manage their disease with suitable healthcare support as back-up. However, adoption of self-monitoring will depend on findings from economic analyses, which have produced conflicting results. In the UK, a review concluded “in general, patient self-management is unlikely to be more cost-effective than the current specialised anticoagulation clinics,” (Connock et al. 2007), whereas a Canadian study suggested: “self-management is a cost-effective strategy for patients receiving long-term oral anticoagulation therapy for atrial fibrillation or for a mechanical heart valve” (Regier et al. 2006).

**Commentary:** After 60 years of supremacy in the management of patients needing anticoagulation, warfarin now has some competition in novel oral anticoagulants, such as dabigatran, which have been shown to be effective in stroke prevention in atrial fibrillation and in the treatment and prophylaxis of thrombosis.

The novel oral anticoagulants give a level of convenience to the patient as they have stable dosing, removing the need for regular clinical attendance and also far fewer lifestyle and medicine interactions. This has to be balanced with increased cost and far less experience of the agents in clinical practice.

This review, looking at self-management in the chronic use of warfarin, shows that this approach to care gives excellent outcomes and could be a way to assist the health community optimise the use of novel oral anticoagulants. The electronic Medicines Compendium states that there is no specific antidote to rivaroxaban or dabigatran, and excessive anticoagulation may require interruption of treatment.

Within anticoagulation services approximately half the patients on long-term warfarin have atrial fibrillation. Although this study included a cohort of older patients, further information is needed to show that the clear benefit for self-management, shown in this meta-analysis, can be translated to this group of patients, who often have multiple comorbidities and therefore complex care issues.

This should also be seen as a challenge to commissioners of anticoagulation services, the providers of those services and those companies that develop the software and point-of-care testing kits to support the convenience of self-management and monitoring in a high-quality and well-governed framework. – Dr Matthew Fay, General Practitioner Principal Westcliffe Medical Practice, and National Clinical Lead for NHS Improvement Heart and Stroke.