

Self-Testing and Self-Management of Oral Anticoagulation

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Summary and Conclusions

TECHNOLOGY AND TARGET GROUP Nearly 140 000 patients in Sweden are treated with oral anticoagulants (antithrombotic drugs), specifically vitamin K antagonists (AVK). These drugs attenuate the ability of the blood to coagulate and are used to prevent blood clots. Warfarin is the most commonly used AVK drug in Sweden.

Sensitivity to AVK drugs varies by individual. Even in a single individual, sensitivity varies over time and is influenced, eg, by diet and other drugs. Hence, thorough and regular control of individual treatment intensity is required. Inappropriate dosage increases the risk for complications. If dosage is too low, the risk increases for blood clot formation, while an excessively high dose may cause bleeding. In Sweden, specialized clinics or primary care services manage anticoagulant therapy by analyzing blood samples.

Portable, easy-to-use analytical instruments are now available to check blood coagulation. These systems can be used for both self-testing and self-management. In self-testing, patients perform the test by taking a blood sample via a finger prick and report the results to a clinic. Healthcare staff then set the drug dosage based on values reported by the patient. In self-management, patients not only perform the test, but also set the drug dosage on their own. Before self-testing or self-management can begin, the patient must complete a training program. Healthcare staff also need to be educated to arrange and carry out patient education. Furthermore, healthcare staff must have the skills to manage quality control in the long term through followup and assessment.

In Sweden, the use of self-testing/self-management is limited, with an estimated 800 users. Based on a literature review and a questionnaire to staff of specialized services for anticoagulant treatment and primary health care, an estimated 10% to 20% of all patients treated with AVK drugs may be candidates for self-management in Sweden. This corresponds to between 15 000 and 25 000 patients.

PRIMARY QUESTIONS What are the benefits of self-testing and self-management compared to using conventional management (testing and dosing at healthcare facilities) for patients needing long-term treatment with AVK drugs? What risks are associated with the different

methods? The aim is also to compare the methods in terms of quality of life and cost-effectiveness.

PATIENT BENEFIT The assessment included 12 randomized controlled trials (RCTs) that compared self-management to conventional management. In these RCTs, quality and internal validity were rated as high in 2 trials, medium in 3 trials, and low in 7 trials. Three studies on self-testing alone were included, whereof quality and internal validity were rated as medium in 1 study and low in 2 studies.

Results from the literature review suggest that self-management is at least as safe as conventional management in a selected sample of patients. The studies lasted between 3 and 38 months, with an average length of 12 months. Mortality and the prevalence of blood clots and serious bleeding were the main effect measures used in this assessment. Meta-analyses of the studies included show a lower prevalence of thromboembolism during self-management compared to conventional management. The prevalence of serious bleeding, however, did not differ between the groups.

Mortality, including all causes of death, was lower in the self-management group. However, the design of the studies differed, creating some uncertainty in interpreting the results of the meta-analyses.

Since conventional management in Sweden is generally of higher quality than conventional management in most of the studies reviewed, some uncertainty exists as to whether the findings are fully applicable to Swedish conditions.

The main benefit of self-management is an improved quality of life for some patients, eg, they are more independent from health services. Conditions for successful treatment outcomes are that patients have the ability to manage the necessary devices and that they comply with the self-management training program. Hence, individual assessments regarding motivation and appropriateness must be performed.

Long-term followups are lacking, so self-management cannot be evaluated in relation to conventional management in the longer term.

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ETHICAL ASPECTS Although self-management requires patients to take greater responsibility for their own treatment, the health services and the attending physician continue to carry responsibility. An important ethical aspect concerns the need for a system to follow up on each patient. If the followup system is inadequate there is a risk that, in the longer term, self-management patients may not continue to regularly check their anticoagulation by blood analysis as needed. It is also important for health services to regularly check on the technical performance of the devices and on how the patients maintain these instruments.

Self-testing devices are not currently subsidized by society, and patients must bear this cost themselves. Hence, not every patient has an equal opportunity to use self-testing/self-management.

ECONOMIC ASPECTS Cost estimates based on Swedish conditions indicate that the direct costs for self-management are comparable with, or somewhat higher than, the direct costs for conventional management. Considering the indirect costs of lost productivity, however, self-management could be cost-saving. From a cost-effectiveness standpoint, self-management is more favorable if treatment takes place during an extended period and if the patient's time represents a high opportunity cost.

SBU's appraisal of the evidence

Self-management is at least as safe as conventional management for patients who are motivated and can manage the routines on their own (Evidence Grade 1)*. The benefits of self-management for these patients mainly involve improvements in quality of life, eg, greater independence from health services. There is insufficient* scientific evidence to assess self-management in relation to conventional management over the longer term.

There is insufficient* scientific evidence to compare self-testing alone with conventional management.

There is insufficient* scientific evidence to assess the respective cost-effectiveness of self-testing and self-management.

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*Criteria for Evidence Grading SBU's Conclusions;

Evidence Grade 1 – Strong Scientific Evidence. The conclusion is corroborated by at least two independent studies with high quality and internal validity, or a good systematic overview.

Evidence Grade 2 – Moderately Strong Scientific Evidence. The conclusion is corroborated by one study with high quality and internal validity, and at least two studies with medium quality and internal validity.

Evidence Grade 3 – Limited Scientific Evidence. The conclusion is corroborated by at least two studies with medium quality and internal validity.

Insufficient Scientific Evidence – No conclusions can be drawn when there are not any studies that meet the criteria for quality and internal validity.

Contradictory Scientific Evidence – No conclusions can be drawn when there are studies with the same quality and internal validity whose findings contradict each other.

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PO Box 5650, SE-114 86 Stockholm, Sweden • alert@sbu.se

This summary is based on a report prepared at SBU in collaboration with Prof. **Tomas Lindahl**, Linköping University Hospital, Linköping and Assoc. Prof. **Peter Svensson**, Malmö University Hospital, Malmö. It has been reviewed by Prof. **Sam Schulman**, McMaster University, Hamilton ON, Canada. Project director: **Johan Wallin**, SBU, wallin@sbu.se.

The complete report is available only in Swedish.