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## Original Research

# Patient knowledge of anticoagulant treatment does not correlate with treatment quality



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## ABSTRACT

**Objectives:** The objectives of this study were to investigate whether patient knowledge is a predictor of treatment stability in anticoagulant clinic patients and to evaluate the correlation between the patients' subjective assessment of own knowledge and their score on a validated knowledge assessment instrument.

**Study design:** This is a prospective study where international normalized ratio (INR) stability was followed up 6 months after knowledge assessment.

**Methods:** We analyzed data of 42 consecutive patients new to vitamin-K antagonist (VKA) treatment and 64 experienced patients from an anticoagulant clinic offering patient education. The patients filled out a VKA knowledge assessment questionnaire with 24 items under standardized conditions, and simultaneously, they were asked about their subjective knowledge. Subsequently, time in range of INR (TIR) was collected for each patient.

**Results:** Out of the 106 patients, 52 had 18 or more correct answers (>75%), defined as a 'satisfactory level' of objective knowledge. The average TIR was 73%, and treatment stability was significantly higher in experienced patients than new patients. We found no correlation between objective knowledge and TIR (Spearman rho = -0.03, P = 0.78). Most patients (77%) reported a high subjective knowledge of VKA, but no correlation was found between objective and subjective knowledge (Spearman rho = 0.129, P = 0.19).

**Conclusion:** We observed that many patients had a low level of knowledge of VKA, despite high treatment stability and patient education. The patient's own assessment of knowledge was not found to predict objective knowledge, which could have implications for selection of patients for self-test or self-management of treatment.

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## Introduction

Vitamin-K antagonists (VKA) have been the oral anticoagulants of choice for decades and are still widely used for prevention of venous or arterial thrombo-embolism in several patient groups.<sup>1</sup> The treatment has high efficacy and safety, if

monitored competently, which is most often accomplished in specialized clinics.<sup>2</sup> Current Danish guidelines recommend that the time in range (TIR) of international normalized ratio (INR), defined as the time spent within the designated therapeutic range of the INR should exceed 70%, both on the clinical level and for the individual patient. Nevertheless, this goal can be difficult to meet for each individual patient, even in high-

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quality settings. Many patient-related variables, such as poor compliance, co-morbidities, polypharmacy, irregular intake of vitamin K, or excessive alcohol intake, can contribute to low stability of INR.<sup>3–6</sup> Studies report that patients with better knowledge about these complex factors are more likely to have INR within therapeutic range.<sup>7–10</sup> However, several studies indicate that despite patient education, patient knowledge is still poor and information provided to the patients may either be forgotten or misunderstood.<sup>10–12</sup> Conversely, studies report significant improved patient outcomes when applying tailored patient education, compared to unstructured patient education.<sup>13–17</sup>

A common indication for anticoagulant treatment is atrial fibrillation, a condition with an estimated global prevalence of 33.5 million,<sup>18</sup> which is expected to further increase because of ageing populations and improved treatment of cardiac diseases. Anticoagulant treatment therefore represents a growing burden on public health, requiring many resources for training anticoagulant staff and monitoring patients and potentially impairing quality of life for the patients. In recent years, there has been a great increase in the number of patients offered self-testing or even self-management of VKA treatment. Such procedures can both reduce costs of monitoring and empower patients. Guidelines from the American College of Chest Physicians recommend self-testing or self-monitoring for selected patients.<sup>19</sup> This development induces new challenges for anticoagulant clinic staff regarding selection of patients, since these should be ‘highly motivated’ and ‘well-trained’.<sup>19</sup> In order to select the right patients and evaluate the results of patient education tailored to self-testing, some form of evaluation of the patients’ knowledge, technical ability to perform measurements and motivation should be considered.

In Denmark, there is no validated instrument available for systematic knowledge assessments, and therefore, patient knowledge is evaluated using a variety of methods, including the patients’ own statement of knowledge.<sup>10,20</sup> However, this subjective assessment could easily overestimate the patients’ level of knowledge, which could also depend on the quality of the written information they have received.<sup>21</sup>

The present study introduced systematic knowledge assessment by using an international, validated instrument (Anticoagulation Knowledge Assessment [AKA]<sup>22</sup>), which was translated into Danish and adjusted to the relevant patient population.<sup>20</sup> The adjusted questionnaire consisted of 24 multiple-choice questions covering topics presented for the patients during their patient education, including mechanism of action of VKA, interactions between VKA and dietary components or other medications and possible side-effects. In addition, one question assessed subjective knowledge of VKA treatment.

The present study included two groups of clinic patients: one consisting of patients newly introduced to VKA and the other group consisted of experienced patients. The study had dual aims. Firstly, to test the hypothesis that patient knowledge is a predictor of treatment stability in anticoagulant clinic patients. Secondly to test the hypothesis that a correlation exists between the patients’ subjective assessment of own knowledge and their AKA score. Additionally, the associations of demographic and clinical variables (age, sex, duration of VKA treatment, indication for treatment and

selection for self-testing) with AKA score and treatment stability are investigated.

## Methods

### Setting

This single-center study was conducted in a Danish specialized Anticoagulant Clinic at the Department of Clinical Biochemistry of the Hospital of South West Denmark, Esbjerg, within an 8-month recruitment period in 2013 and a second recruitment period in 2014–2015. The clinic monitors more than 1000 patients and is staffed by nurses and supervised by consultant physicians. The dosage of VKA is determined using a computer-assisted dosage program (DAWN, anticoagulant therapy program; 4S Information Systems, Cumbria, UK).<sup>23,24</sup> The treatment quality of the clinic is high, with an average TIR above 75%.<sup>5</sup> Newly referred patients are offered patient education, consisting of a 1-h session in a small group, where a specially trained nurse informs the patients about basic aspects of VKA treatment. The nurse verifies patient comprehension verbally, which is combined with subjective assessments of patient knowledge.

### Study sample

To be eligible for inclusion, patients had to be >18 years of age and diagnosed with a condition requiring treatment with VKA. Patients were excluded if they had not participated in patient education in the anticoagulant clinic or did not wish to participate in the study. No patients were excluded because of co-morbidities.

In the first recruitment period, 42 consecutive patients new to VKA were included. The data collection was conducted after the patients had their first INR measurement subsequent to patient education (between 7 and 14 days following patient education). In the second recruitment period, 64 patients treated with VKA for more than 6 months and less than 3 years were included (defined as ‘experienced patients’). Patient characteristics are shown in Table 1.

Power calculations were carried out for the second research question, regarding the correlation between subjective knowledge and AKA score. The sample size should be 42

**Table 1 – Characteristics of study patients.**

	Newly diagnosed patients, n = 42	Experienced patients, n = 64
Females	24 (57%)	29 (45%)
Age in years, mean (SD)	62 (17)	67 (13)
Diagnosis		
Venous thrombosis	16 (38%)	21 (33%)
Atrial fibrillation	20 (48%)	35 (55%)
Other <sup>a</sup>	6 (14%)	8 (13%)

There were no significant differences between the two groups.

<sup>a</sup> The majority (n = 12) of patients in this category had mechanical heart valves.

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