Association Between Patient Knowledge of Anticoagulation, INR Control, and Warfarin-Related Adverse Events

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Abstract

Background: Whether the level of patient's knowledge about warfarin plays any role in maintenance of therapeutic international normalized ratio (INR) is controversial. Several studies have looked at patients' warfarin knowledge and the level of patients' anticoagulation control (AC). Most studies had small numbers and did not use validated questionnaires. **Objectives:** To use the Oral Anticoagulation Knowledge (OAK) test to assess patients' knowledge of AC and to examine associations between knowledge, INR, and adverse events. **Methods:** In this cross-sectional study, patients were asked to complete the OAK test. Data on clinical and demographic characteristics, INR values, and thrombosis or bleeding events during the preceding 1 year period were collected. Associations between OAK scores, patient characteristics, proportion of therapeutic INRs, and bleeding/thrombosis events were assessed. **Results:** A total of 225 patients completed the OAK test. Mean (SD) age was 70 (13.4) years, 53% were male, and 75% were on warfarin for >3 years. Over the preceding year, 57.3% of INRs were therapeutic, and there were 22 bleeding and 6 thrombotic events. The mean OAK score was 12/20 (passing score = 15/20); 64% of patients failed the OAK test. Predictors of passing the OAK test were younger age ($P = .01$) and higher level of education ($P = .03$). There was no association between OAK score and proportion of therapeutic INRs, or OAK score and bleeding or thrombosis events. **Conclusion:** We used the OAK test to assess patients' AC knowledge. Results suggests that while younger and more educated patients were more likely to pass the OAK test, the OAK test results may not predict INR control or occurrence of bleeding or thrombotic events.

Keywords

INR, patient education, warfarin

Introduction

Oral anticoagulation with warfarin plays a major role in the prevention and treatment of thromboembolic disease. Multiple factors affect the clinical outcome of warfarin therapy. These include a patient's comorbid illness, alcohol, medications, and intake of dietary vitamin K and monitoring adherence. Warfarin therapy also demands significant patient-provider discussion since patients need to understand the indication for warfarin therapy, the importance of compliance, and the need for frequent monitoring. Patients' knowledge of anticoagulation may, therefore, play a fundamental role in the management of warfarin therapy.

Several studies have examined the correlation between patients' warfarin knowledge and level of anticoagulation control.^{1–7} Tang et al reported a positive correlation between patients' knowledge of warfarin therapy and the number of international normalized ratio (INR) values that were within target range.⁶ Kagansky et al found that the risk of major bleeding in patients >80 years was correlated with insufficient

education, polypharmacy, and INR values above the therapeutic range; however, socioeconomic level and cognitive and functional impairments were not associated with risk of bleeding.⁵ Conversely, others have reported that warfarin knowledge is not significantly associated with better anticoagulation control.^{3,7,8}

Currently, 2 validated questionnaires, the Anticoagulation Knowledge Assessment (AKA) test and the Oral Anticoagulation Knowledge (OAK) test, are available to assess patients' knowledge of oral anticoagulation and

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warfarin.^{9,10} The AKA was recently used by Baker et al in a study of 167 patients who had been on warfarin for at least 6 months.⁷ There was no significant relationship between warfarin knowledge and INR control, based on the 10 most recent INRs for each patient in the study by Baker et al.⁷

In comparison with the AKA test, the OAK questionnaire is shorter and adjusted for a seventh-grade level of education. To our knowledge, the utility of the OAK questionnaire to predict clinically relevant outcomes in patients on anticoagulation has not previously been assessed. Hence, we performed an anticoagulation clinic-based study to assess the association between patients' performance on the OAK test and the clinically important outcomes of proportion of therapeutic INRs, thrombotic events, and bleeding events. We hypothesized that patients who scored higher on the OAK questionnaire would have more stable INR levels and fewer clinically relevant adverse events than those with lower scores.

Methods

Study Design and Population

This was a cross-sectional study with a component of retrospective data collection conducted at the outpatient Anticoagulation Clinic (AC) at the Jewish General Hospital, Montreal, Canada. The study was approved by the institutional research ethics committee, and patients provided informed consent to participate.

We included patients aged ≥ 18 years who were able to read English or French at a seventh-grade level and had been followed at the AC for at least 1 year. Patients were recruited over an 8-week period in 2012. The study sample size was limited to the number of patients who attended and consented to be part of the study during the 8-week period. Patients who refused to participate or subsequently withdrew consent after inclusion were excluded from the study. Participants were asked to complete the OAK questionnaire at a usual AC visit.

Study Setting and Data Collection

The Jewish General Hospital (JGH) is 637-bed tertiary care center affiliated with McGill University in Montreal, Canada. The AC is located within the outpatient department of the hospital and is staffed by hematologists, phlebotomists, a licensed nurse, and a clinic administrator. The majority of JGH inpatients and outpatients who require anticoagulation management are referred to the AC, which currently services ~2400 patients. At the first visit, patients are assessed by the clinic nurse who provides group teaching sessions on the topics of warfarin, INR measurement, and dietary and medication interactions with warfarin, and schedules the patient for regular follow-up visits at the clinic.

For this study, patients were asked to complete the OAK questionnaire (English or a professionally translated French version) while waiting for the phlebotomist. Patients were required to complete the questionnaire independently and without help from family members or caregivers. After completion of the questionnaire, the patient's AC chart and electronic medical record were abstracted by trained abstractors using standardized case report forms to record information on age, gender, indication for anticoagulation (deep vein thrombosis [DVT], pulmonary embolism [PE], atrial fibrillation, mechanical valve, lupus anticoagulant, etc), target INR range, planned duration of warfarin therapy, as well as the primary and secondary outcomes of the study (see below). Outcomes data were retrospectively collected for one calendar year before the date the patient entered the study. Abstractors were kept blinded to OAK scores.

OAK Questionnaire

The OAK questionnaire (see the appendix) was developed by 4 anticoagulation experts.¹⁰ Five patient-knowledge domains are captured by the questionnaire in a multiple-choice format, including basic drug information, adverse effects, drug-drug interactions, dietary and food interactions, and anticoagulation monitoring. The OAK questionnaire consists of 20 questions (each with 1 correct answer and 3 distractors), worded at seventh-grade level, which have been evaluated for internal consistency and test-retest reliability. Answering 15 or more questions correctly (ie, $\geq 75\%$ correct) is considered adequate knowledge of AC therapy, that is, a "passing grade."¹⁰

Primary and Secondary Study Outcomes

The primary outcome of the study was proportion of therapeutic INRs, defined as the number of INR values within the target INR range—target range decided by the patient's physician—divided by the total number of INRs performed during a period of one calendar year prior to the date of entry into the study.

The secondary outcomes of the study were major bleeding events and thromboembolic events. Major bleeding was defined using the International Society on Thrombosis and Haemostasis criteria as clinically overt bleeding accompanied by one or more of the following: a decrease in hemoglobin level by 2 or more grams per deciliter over a 24-hour period, transfusion of 2 or more units of packed red blood cells, or bleeding at a critical site including intracranial, intraspinal, intraocular, pericardial, intra-articular, retroperitoneal, and intramuscular with compartment syndrome.¹¹ Thromboembolic events were defined as stroke, systemic embolism or venous thromboembolism (VTE). Stroke diagnosis was confirmed either clinically, based on typical symptoms lasting at least 24 hours, or radiologically, based

on brain imaging results. Systemic embolism was defined as any acute onset arterial thromboembolic event such as acute limb ischemia, splenic infarct, or renal infarct. VTE was defined as DVT of the proximal or distal venous system diagnosed with duplex ultrasound or venography; or PE diagnosed with spiral computed tomography or ventilation-perfusion lung scintigraphy.

Statistical Analysis

Our analysis plan was developed a priori. Patient characteristics were described using means (standard deviations [SD]) or proportions, as appropriate. The mean number of INRs per patient was calculated by dividing the total number of INRs by the total number of patients. The proportion of therapeutic, supratherapeutic, and subtherapeutic INRs were calculated as number of INRs in each category (using the patient's target range as a reference) divided by total number of INRs. Associations between patient characteristics and OAK test failure were assessed using unadjusted and adjusted logistic regression. Association between OAK test failure and proportion of therapeutic INRs, mean OAK test score, and adverse events (bleeding, embolism) and proportion of therapeutic INRs and adverse events were assessed using 2-tailed *t* tests. A *P* value of $<.05$ was considered to represent statistical significance. When assessing for relationship between baseline variables, OAK score, and OAK test failure and adverse outcome, the models were adjusted for age, gender, education level, indication for anticoagulation, years known to AC clinic, and OAK scores.

All statistical analyses were performed using SAS version 9.3. For descriptive statistics, we used PROC MEANS for continuous variables to compute means and standard deviations and PROC FREQ for categorical variables to obtain proportions. For binary variables OAK test failure and occurrence of adverse events, we fitted a logistic model. We first modeled the odds of failing the OAK test and then the odds of experiencing an adverse event. For both models, we adjusted for different covariates (confounders), defined a priori.

Results

Of the 252 patients who provided consent to participate during the 8-week study recruitment period, 225 (89%) returned a completed OAK questionnaire. Baseline characteristics of the enrolled patients are summarized in Table 1. The mean (SD) age was 70 (13.4) years, and 120 (53.4%) were male. Most patients were anticoagulated for atrial fibrillation ($n = 147$, 65.4%). Other indications for anticoagulation included mechanical heart valves ($n = 24$, 10.7%), DVT and PE ($n = 19$, 8.5%), cerebrovascular accident (CVA) or transient ischemic attack (TIA; $n = 25$, 11.2%), and thrombophilia ($n = 18$, 8%). The majority of patients had been followed at the clinic for more than 2 years ($n = 204$, 90%).

About two thirds of patients had some university or college education ($n = 82$, 36.4%) or a university degree ($n = 65$, 28.9%).

The mean (SD) OAK score in the study population was 12.3 (4.4) out of 20. Based on a pass score of ≥ 15 correct answers, 64.4% ($n = 145$) of patients failed the OAK questionnaire (Table 2). Table 2 shows the average OAK scores and failure rates for each of the listed patient characteristics. In multivariable analyses, we found that age greater than 75 years and having less education were independent predictors of failing the OAK test. Interestingly, number of years known to the AC, which reflects duration of anticoagulation, did not have an impact on passing or failing the OAK test (Table 2).

To assess whether our primary outcome, proportion of therapeutic INRs, was associated with OAK test results, we collected all INRs performed during the 1-year study period (Table 3). Among 2773 INR tests performed, representing an average of 12.3 INR tests per patient, 57.3% were in the therapeutic range, 17.4% were supratherapeutic, and 25.1% were subtherapeutic. There were no statistically significant differences between patients who failed versus those who passed the OAK test in the mean number of INRs performed and the percentage of INRs that were in therapeutic, subtherapeutic, or supratherapeutic ranges (Table 3).

We used multivariable analysis to identify patient characteristics that might identify patients with better proportion of therapeutic INR. None of the characteristics examined, including age, sex, education level, indication or duration of anticoagulation, were associated with better proportion of therapeutic INR (data not shown).

There were a total of 28 (12.4%) major outcome events during the 1-year study period (Table 4). Bleeding was the most common presentation. Table 4 shows the types of events and INRs at the time of event occurrence.

The mean (SD) OAK score among patients who experienced an adverse outcome event was 13.2 (4.5) versus 12.2 (4.3) in those who did not experience an adverse outcome event ($P = .24$; Table 5). There were no statistically significant differences in mean OAK score between patients who experienced bleeding outcome events, or thromboembolic outcome events, compared to patients who experienced no outcome events.

Finally, we performed a multivariable analysis to identify patient characteristics that might be associated with occurrence of adverse outcome events (Table 2). None of the examined characteristics, including age ($P = .28$), gender ($P = .48$), education level ($P = .69$), years known to AC, indication for anticoagulation or duration of anticoagulation ($P = .06$) were associated with the occurrence of adverse clinical events.

Discussion

We used the validated OAK test to examine the relationship between knowledge of anticoagulation, proportion of therapeutic INR, and anticoagulant-related adverse outcome events

Table 1. Baseline Characteristics of Study Patients (N = 255).

Characteristic	n (%) ^a
Age	
Mean (SD)	70 (13.4)
Age category	
20-50 years	19 (8.4%)
51-65 years	52 (23.1%)
66-75 years	63 (28%)
76-85 years	74 (32.8%)
>85 years	17 (7.5%)
Gender	
Male	120 (53.4%)
Female	105 (46.6%)
Indications for anticoagulation ^b	
Atrial fibrillation	147 (65.4%)
Artificial heart valves	24 (10.7%)
DVT/PE	19 (8.5%)
CVA	25 (11.2%)
Other	18 (8%)
Target INR ^c	
2.0-3.0	189 (84%)
2.5-3.5	33 (14.6%)
Other	3 (1.3%)
Duration of anticoagulation	
1-2 years	21 (9%)
>2 years	204 (90%)
Education level	
Grade school only	15 (6.7%)
High school only	63 (28%)
Some university/college	82 (36.4%)
University graduate	65 (28.9%)

Abbreviations: DVT, deep vein thrombosis; PE, pulmonary embolism; CVA, cerebrovascular accident; INR, international normalized ratio.

^aUnless otherwise indicated.

^bPatients with more than one indication for anticoagulation were included in all applicable categories.

^cINR target was determined by the treating physician.

among patients attending a high-volume AC in a tertiary care, university-affiliated center in Montreal, Canada. The OAK test addresses 5 patient knowledge domains including basic drug information, drug-drug interaction, adverse effects, dietary and food interactions, and monitoring.

We found that majority of patients (64.4%) failed the OAK test. Age older than 75 years and less education were independent predictors of OAK test failure. We found no difference in the mean number of INR tests performed and proportion of therapeutic INRs among patients who passed versus those who failed the OAK test. Similarly, there was no statistical difference between percent-therapeutic INR achieved by patients who passed versus failed the OAK test and, therefore, no association between OAK test results and proportion of therapeutic INR.

We noted that 57.3% of INRs in our clinic were within therapeutic range (Table 3), which is comparable to published Canadian clinic time in therapeutic ranges of 53%

and 65% for community and hospital-based AC clinics, respectively.¹²

Among our study population, 12.4% of patients experienced a major adverse thrombotic or bleeding event during the 1-year study period, with bleeding as the most common adverse event. We found no difference in the mean OAK score achieved by patients who had an adverse event versus those who did not. Overall, the OAK test failed to identify patients who by virtue of their anticoagulation knowledge might be more likely to have nontherapeutic INRs or experience more adverse events.

The strengths of our study include that we used a validated questionnaire to assess knowledge of anticoagulation among English- and French-speaking patients, we recruited a large group of heterogeneous patients at a high-volume AC clinic that allows more robust generalizability of our study results to clinical practice, we captured data using standardized case report forms, and we were able to

Table 2. Relationship Between Baseline Variables, OAK Score, OAK Test Failure, and Adverse Events.

Baseline Variable	OAK Score (Out of 20)	OAK Test Failure		Occurrence of Adverse Outcome Events	
	Mean (SD)	n (%)	OR Adjusted ^a (95% CI)	n (%)	OR Adjusted (95% CI)
Whole population (N = 225)	12.3 (4.4)	145 (64.4)	—	36 (16)	—
Gender					
Male (n = 120)	12.5 (4.3)	73 (60.8)		20 (16.7)	
Female (n = 105)	12.2 (4.4)	72 (68.6)	1.21 (0.64, 2.28)	16 (15.2)	0.94 (0.41, 2.15)
Age (years) category					
<50 (n = 19)	14.9 (3.5)	8 (42.1)		3 (15.8)	
50-65 (n = 52)	13.9 (3.8)	30 (57.7)	1.61 (0.50, 5.21)	11 (21.2)	1.59 (0.32, 7.92)
66-75 (n = 63)	13.3 (3.7)	34 (54.0)	1.46 (0.46, 4.60)	9 (14.3)	0.94 (0.18, 4.99)
>75 (n = 91)	10.2 (4.4)	73 (80.2)	3.78 (1.15, 12.36)	13 (14.3)	1.21 (0.23, 6.47)
Education level ^b					
College/university graduate (n = 66)	14.0 (3.9)	31 (47.0)		11 (16.7)	
Some college or university (n = 81)	12.7 (3.9)	54 (66.7)	2.44 (1.17, 5.09)	15 (18.5)	1.01 (0.38, 2.71)
High school or grade school only (n = 75)	10.7 (4.4)	58 (77.3)	3.15 (1.44, 6.90)	9 (12.0)	0.52 (0.17, 1.64)
Years known to the AC clinic					
>3 years (n = 171)	12.3 (4.2)	108 (63.2)		29 (17.0)	
<3 years (n = 54)	12.4 (4.4)	37 (68.5)	1.53 (0.74, 3.17)	7 (13.0)	0.57 (0.21, 1.52)
VTE indication					
No (n = 186)	11.9 (4.3)	126 (67.7)		31 (16.7)	
Yes (n = 39)	14.3 (4.2)	19 (48.7)	2.07 (0.30, 14.32)	5 (12.8)	0.45 (0.06, 3.44)
Cardiac indication ^c					
No (n = 49)	14.4 (4.0)	23 (47.0)		7 (14.3)	
Yes (n = 176)	11.8 (4.3)	122 (69.3)	3.54 (0.55, 22.66)	29 (16.5)	1.09 (0.17, 6.98)
Thrombophilia indication					
No (n = 221)	12.3 (4.4)	143 (64.7)		36 (16.3)	—
Yes (n = 4)	15.8 (3.3)	2 (50.0)	1.63 (0.11, 24.00)	0 (0.0)	—

Abbreviations: AC, anticoagulation; CI, confidence interval; OAK, oral anticoagulation knowledge; OR, odds ratio; VTE, venous thromboembolism.

^aAdjusted for gender, age, education level, VTE indication, cardiac indication, thrombophilia indication, years known to the AC clinic, and OAK score.

^bRemoved 3 patients with missing information.

^cCardiac indication = atrial fibrillation, mechanical heart valves, or cerebrovascular accident/transient ischemic attack.

retrospectively collect INR and clinical data for all of the patients. As part of the study inclusion criteria, patients had to be able to independently complete the OAK test, allowing us to determine patient knowledge without influence or input from caregivers. In contrast, in some studies patients or caregivers were allowed to complete the study questionnaires, which can introduce bias when trying to determine the effect of age and level of education on patients' knowledge of anticoagulation.⁵ Due to time and resource constraints, most AC clinics provide a single educational session on anticoagulation when patients are first started on warfarin. Further education is provided on an individual basis as patients attend the clinic and interact with the clinic staff on a regular basis, similar to the model at our center. We therefore believe that a strength of our study design is

that it reflects "real-life" patient knowledge. We chose patients who had already received anticoagulation education, had been on warfarin for more than a year, and were in regular contact with the health care team at the AC clinic. Therefore, the results of our study reflect the level of knowledge that chronically anticoagulated patients retain.

Our study has certain limitations. It was conducted in a single, university-affiliated AC, which may limit its generalizability to nonacademic centers with different educational approaches. The study period was limited to 8 weeks; therefore, our sample size was limited to the number of patients who attended and consented to participate in the study during the study period. For this study, we did not have the resources to perform prospective data collection for the outcome events. We administered the OAK test at one point in time,

Table 3. Association Between OAK Test Results and Proportion of INR in Therapeutic, Supratherapeutic, and Subtherapeutic Ranges.

	Total Population (N = 225)	OAK Score ^a		P Value ^b
		Pass (n = 80)	Fail (n = 145)	
Number of INR tests performed in last year	2773	1039	1734	—
Mean number of INR tests per patient, in last year	12.3	13.0	12.0	.307
% of INR tests in therapeutic range	57.3% (n = 1591)	56.8% (n = 590)	57.7% (n = 1001)	.255
% of INR tests in supratherapeutic range	17.4% (n = 484)	17.0% (n = 177)	17.7% (n = 307)	.756
% of INR tests in subtherapeutic range	25.1% (n = 698)	26.2% (n = 272)	24.6% (n = 426)	.423

Abbreviations: OAK, Oral Anticoagulation Knowledge test; INR, international normalized ratio.

^aPass score = 15/20 or higher.

^bTwo-tailed, equal variance.

Table 4. Major Adverse Events During Study Follow-Up.

Total Major Adverse Events (n = 28)	INR at Presentation
Decrease in Hgb and pRBC transfusion	
GI bleed (n = 4)	5.0, 5.9, 4.2, 4.7
Hematuria (n = 2)	2.3, 4.1
Hemoptysis (n = 1)	2.0
Subcutaneous hematoma (n = 5)	3.5, 2.2, 5.0, 11.4, 5.3
Unknown source of bleed (n = 2)	5.3, 5.0
Bleeding at critical site	
Intracranial (n = 3)	3.7, 2.6, 2.7
Intra-articular (n = 2)	3.8, 1.2
Intramuscular (n = 3)	2.9, 4.6, 4.3
Stroke and systemic embolism	
Transient ischemic attack (n=3)	3.0, others unknown
Omental infarct (n = 1)	2.3
Amaurosis fugax (n = 1)	4.5
Hemorrhagic stroke (n = 1)	3.7
Venous thromboembolism (n = 0)	N/A

Abbreviations: INR, international normalized ratio; Hgb, hemoglobin; pRBC, packed red blood cells; GI, gastrointestinal.

Table 5. Association Between Mean OAK Score and Occurrence of an Adverse Outcome Event.

	Mean (SD) OAK Score (Out of 20)		P
	Patients With Adverse Outcome Event	Patients Without Adverse Outcome Event (n = 189)	
Any adverse event (n ^a = 24)	13.4 (4.5)	12.2 (4.3)	.24
Thromboembolic event (n = 5)	15.4 (2.9)		.10
Bleeding event (n = 19)	12.6 (5.0)		.71

Abbreviation: OAK, Oral Anticoagulation Knowledge test.

^aN represents the number of patients who experienced an adverse outcome event, not the number of events.

then retrospectively reviewed relevant outcome data during the year preceding the date of completion of the OAK test. Hence, we cannot rule out the possibility that OAK scores may have changed over time. However, we note that patients generally did quite poorly on the OAK test, and think it is unlikely that scores would have worsened over time; if

anything, attending an AC clinic might have increased their knowledge, not diminished it.

While we used a professional translator to translate the OAK questionnaire into French, this translated version has not been tested for internal or external validity. An element of selection bias might have been introduced into the study

during patient recruitment. Patients were expected to complete the OAK questionnaire on their own. They might have refused participation if they sensed that they were unable to read or understand the questionnaire, which may have selected for younger, more educated study participants. Since clinical data were collected exclusively from our hospital charts, primary and secondary adverse outcomes that occurred and were managed outside of our hospital would not have been captured and could have led to underestimation of adverse outcome event rates. However, this is expected to have been rare as patients are captive to our hospital. Also, there were unlikely to be any missing INR values as all patients were regularly monitored by our AC clinic.

Previous studies examining patient education and knowledge of anticoagulation have had conflicting results.^{2,5,6} Furthermore, these studies were limited in that they did not use standardized, validated questionnaires to assess patient knowledge of anticoagulation.

Tang et al, using a Chinese-language knowledge test, found that anticoagulant knowledge test scores decreased with increasing age, while longer duration of anticoagulant therapy was associated with improved test scores.⁶ We similarly found that patients older than 75 were more likely to fail the OAK test; however, longer duration of anticoagulation was not associated with better test results in our study. Level of education has been shown to be associated with higher anticoagulant knowledge level.¹³ Similarly, in our study, we found that higher education level was associated with better OAK scores.

Baker et al used the AKA questionnaire to assess anticoagulation knowledge in relation to INR control.⁷ Although 74.1% of patients achieved a passing AKA score, there was no relationship between warfarin knowledge and INR control. Conversely, in our study, the majority of patients (64.4%) failed the OAK test; however, we were similarly unable to establish an association between patients' knowledge of anticoagulation and proportion of therapeutic INR. A recent meta-analysis by Wong et al studied the effect of supplemental patient education versus usual care on time in therapeutic range, hemorrhagic and thrombotic events, as well as knowledge test scores in patients anticoagulated with oral vitamin K antagonists.¹⁴ Overall, they found no evidence that supplemental patient education improved anticoagulation control or clinical outcomes.¹⁴ Given the constraints of a cross-sectional study with limited sample size and power, we were also unable to demonstrate that better knowledge of anticoagulation leads to better proportion of therapeutic INR and reduced occurrence of adverse outcome events when patients are provided with one structured AC education session followed by regular follow-ups in an AC clinic.

We did not analyze pass/fail scores for individual questions in the OAK test. In future studies, the failure rate for each of the 5 domains examined by the OAK test could be determined to identify content areas of weakness. An

educational intervention involving those areas could be conducted followed by prospective follow-up of INR control and adverse events to determine whether such targeted patient education is associated with improved INR control and reduced adverse clinical events.

In summary, the results of our study suggest that degree of self-knowledge of anticoagulation, as assessed by the OAK questionnaire, may not translate to therapeutic INR or reduced occurrence of adverse clinical outcomes. This suggests that other factors may be more important in determining anticoagulation-related outcomes, or that the OAK questionnaire may not capture the specific knowledge that is key to influencing anticoagulation-related outcomes.

Given the result of our study and the recent systematic review and meta-analysis published by Wong et al, which showed that supplemental patient education is not associated with improved clinical outcomes and anticoagulation control, there is currently no evidence that a change in our clinical practice would result in better outcomes.¹⁴ Randomized controlled trials involving educational interventions with very well-defined educational objectives and adequate follow-up periods are needed to determine whether supplemental patient education has an impact on anticoagulation control and relevant clinical outcomes.

Appendix

The Oral Anticoagulation Knowledge (OAK) Test

Instructions: For each question, place an X in the box next to the answer you think is correct or best completes the sentence correctly. Please answer all questions.

1. Missing one dose of Coumadin (warfarin):
  - ☐ a. has no effect
  - ☐ b. can alter the drug's effectiveness
  - ☐ c. is permissible as long as you take a double dose the next time
  - ☐ d. is permissible as long as you watch which foods you eat
2. You can distinguish between different strengths of Coumadin (warfarin) tablets by what?
  - ☐ a. color
  - ☐ b. shape
  - ☐ c. size
  - ☐ d. weight
3. A patient on Coumadin (warfarin) therapy should contact the physician or health care provider who monitors it when:
  - ☐ a. another physician adds a new medication
  - ☐ b. another physician stops a current medication

- ☐ c. another physician changes a dose of a current medication
  - ☐ d. all of the above
4. Occasionally eating a large amount of leafy greens vegetables while taking Coumadin (warfarin) can:
- ☐ a. increase your risk of bleeding from Coumadin (warfarin)
  - ☐ b. reduce the effectiveness of the Coumadin (warfarin)
  - ☐ c. cause upset stomach and vomiting
  - ☐ d. reduce your risk of having a blood clot
5. Which of the following vitamins interacts with Coumadin (warfarin)?
- ☐ a. vitamin B₁₂
  - ☐ b. vitamin A
  - ☐ c. vitamin B₆
  - ☐ d. vitamin K
6. When is it safe to take a medication that interacts with Coumadin (warfarin)?
- ☐ a. if you take the Coumadin (warfarin) in the morning and the interacting medication at night
  - ☐ b. if your healthcare provider is aware of the interaction and checks your PT/INR ("Protime") regularly
  - ☐ c. if you take your Coumadin (warfarin) every other day
  - ☐ d. it is never safe to take a medication that interacts with Coumadin (warfarin)
7. The PT/INR ("Protime") test is:
- ☐ a. a blood test used to monitor your Coumadin (warfarin) therapy
  - ☐ b. a blood test that is rarely done while on Coumadin (warfarin)
  - ☐ c. a blood test that checks the amount of vitamin K in your diet
  - ☐ d. a blood test that can determine if you need to be on Coumadin (warfarin)
8. Coumadin (warfarin) may be used to:
- ☐ a. treat people that already have a blood clot
  - ☐ b. treat people that have high blood sugar levels
  - ☐ c. treat people with high blood pressure
  - ☐ d. treat people with severe wounds
9. A patient with a PT/INR ("Protime") value below their "goal range":
- ☐ a. is at an increase the risk of bleeding
  - ☐ b. is at an increase the risk of having a clot
- ☐ c. is more likely to have a skin rash from the Coumadin (warfarin)
  - ☐ d. is more likely to experience side effects from Coumadin (warfarin)
10. Taking a medication containing aspirin or other non-steroidal anti-inflammatory medications such as ibuprofen (Motrin®/Advil®) while on Coumadin (warfarin) will:
- ☐ a. reduce the effectiveness of the Coumadin (warfarin)
  - ☐ b. increase your risk of bleeding from the Coumadin (warfarin)
  - ☐ c. cause a blood clot to form
  - ☐ d. require you to increase your dose of Coumadin (warfarin)
11. A person on Coumadin (warfarin) should seek immediate medical attention:
- ☐ a. if they skip more than two doses of Coumadin (warfarin) in a row
  - ☐ b. if they notice blood in their stool when going to the bathroom
  - ☐ c. if they experience a minor nosebleed
  - ☐ d. if they develop bruises on their arms or legs
12. Skipping even one dose of your Coumadin (warfarin) can:
- ☐ a. cause your PT/INR ("Protime") to be above the "goal range"
  - ☐ b. increase your risk of bleeding
  - ☐ c. cause your PT/INR ("Protime") to be below the "goal range"
  - ☐ d. decrease your risk of having a clot
13. Drinking alcohol while taking Coumadin (warfarin):
- ☐ a. is safe as long as you separate your dose of Coumadin (warfarin) and the alcohol consumption
  - ☐ b. may affect your PT/INR ("Protime")
  - ☐ c. does not affect your PT/INR ("Protime")
  - ☐ d. is safe as long as you are on a low dose
14. Once you have been stabilized on the correct dose of Coumadin (warfarin), about how often should your PT/INR ("Protime") value be tested?
- ☐ a. once a week
  - ☐ b. once a month
  - ☐ c. once every other month
  - ☐ d. once every 3 months
15. It is important for a patient on Coumadin (warfarin) to monitor for signs of bleeding:
- ☐ a. only when their PT/INR ("Protime") is above the goal range

- ☐ b. at all times
  - ☐ c. only when their PT/INR ("Protime") is below the goal range
  - ☐ d. only when you miss a dose
16. The best thing to do if you miss a dose of Coumadin (warfarin) is to?
- ☐ a. double up the next day
  - ☐ b. take the next scheduled dose and tell your healthcare provider
  - ☐ c. call your healthcare provider immediately
  - ☐ d. discontinue Coumadin (warfarin) altogether
17. When it comes to diet, people taking Coumadin (warfarin) should:
- ☐ a. never eat foods that contain large amounts of vitamin K
  - ☐ b. keep a diary of all of the foods they eat
  - ☐ c. be consistent and eat a diet that includes all types of food
  - ☐ d. increase the amount of vegetables they eat
18. Each time you get your PT/INR ("Protime") checked, you should:
- ☐ a. skip your dose of Coumadin (warfarin) on the day of the test
  - ☐ b. avoid eating high fat meals on the day of the test
  - ☐ c. avoid foods high in vitamin K on the day of the test
  - ☐ d. let your doctor know if you missed any doses of Coumadin (warfarin)
19. Which of the following over-the-counter products is most likely to interact with Coumadin (warfarin)?
- ☐ a. nicotine replacement therapies
  - ☐ b. herbal/dietary supplements
  - ☐ c. allergy medications
  - ☐ d. calcium supplements
20. A patient with a PT/INR ("Protime") value above the "goal range":
- ☐ a. is at an increased risk of having a clot
  - ☐ b. is more likely to have drowsiness and fatigue from Coumadin (warfarin)
  - ☐ c. is at an increased risk of bleeding
  - ☐ d. is less likely to experience side effects from Coumadin (warfarin)

Answer Key

- 1. **B**
- 2. **A**

- 3. **D**
- 4. **B**
- 5. **D**
- 6. **B**
- 7. **A**
- 8. **A**
- 9. **B**
- 10. **B**
- 11. **B**
- 12. **C**
- 13. **B**
- 14. **B**
- 15. **B**
- 16. **B**
- 17. **C**
- 18. **D**
- 19. **B**
- 20. **C**

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