INR Goal Attainment and Oral Anticoagulation Knowledge of Patients Enrolled in an Anticoagulation Clinic in a Veterans Affairs Medical Center

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ABSTRACT

BACKGROUND: In January 2009, the Joint Commission implemented a National Patient Safety Goal (NPSG) for ambulatory care, NPSG 3E, intended to reduce harm associated with the use of anticoagulation therapy. The 2011 NPSG 3E encompasses 8 elements of performance, including requirements that each organization (a) provide education regarding anticoagulation therapy to staff, patients, and families and (b) evaluate its safety practices and take appropriate action to improve its practices. The Alvin C. York (ACY) outpatient anticoagulation clinic provides education to new patients and their families at the initial clinic visit, with follow-up reinforcement of education as needed throughout their care.

OBJECTIVES: To (a) assess the knowledge level of patients receiving warfarin therapy in an anticoagulation clinic using the validated Anticoagulation Knowledge Assessment (AKA) questionnaire and (b) examine the relationship between patient anticoagulation knowledge and anticoagulation control as measured by the international normalized ratio (INR).

METHODS: All ACY Veterans Affairs (VA) anticoagulation clinic patients seen during their routine visit within an 8-week recruitment period from February 2010 to April 2010 were asked to complete the AKA questionnaire. Upon voluntary consent, the questionnaire was completed by the patient either during the clinic visit or returned later by mail. Demographic and clinical data were manually extracted from the computerized patient record system and included age, gender, indication for and duration of anticoagulation therapy, goal INR range, and the 10 INR values preceding the date of consent. A passing score was defined as at least 21 correct responses on the 29-item AKA questionnaire (72.4% correct). Statistical analyses included comparisons of demographic and clinical characteristics for patients with passing versus failing scores, assessed with Pearson chi-square and Fisher's exact test, and bivariate analyses of INR control with anticoagulation knowledge, assessed with Spearman's rho correlation. INR control was defined by 3 outcome measures: number of INRs within therapeutic range, time in therapeutic range (TTR) calculated using the Rosendaal method, and standard deviation (SD) of INR values. Anticoagulation knowledge was assessed with 2 measures: total AKA score and count of correct answers to a subset of 15 AKA items deemed by the investigators to be relevant to INR control.

RESULTS: Of 447 patients enrolled in the anticoagulation clinic, 260 consented to participate in the survey, of whom 185 patients completed the AKA instrument ($n=171$ [92.4%] by mail) and were successfully matched to patient record system data. 178 (96.2%) respondents were male with a mean (SD) age of 68 (10.1) years. The majority of patients were undergoing anticoagulation treatment for atrial fibrillation ($n=113$, 61.1%) or deep venous/pulmonary thromboembolism ($n=48$, 25.9%). The majority of patients had been treated with warfarin for at least 1 year ($n=162$, 87.6%). Most patients had goal INR ranges of 2.0 to 3.0 ($n=166$, 89.7%). Of the 185 patients who completed the questionnaire, 137 (74.1%) achieved a passing score. The mean (SD) AKA questionnaire score was 78.1% (12.1%).

There were 8 questions that were answered correctly by less than 70% of patients and identified as potential deficiencies in patient education. For the 167 patients who had been on warfarin therapy for at least 6 months and had 10 previous INR values, there was no significant Spearman's rho correlation between total number of correct questionnaire responses and INR control, defined as the count of the 10 previous INR values within goal range ($\rho=-0.022$, $P=0.776$), TTR ($\rho=0.015$, $P=0.848$), and SD ($\rho=0.047$, $P=0.550$). There was also no significant relationship between number of correct INR-relevant responses and INR control by any of the 3 outcome measures (count in range $\rho=0.033$, $P=0.676$; TTR $\rho=0.067$, $P=0.388$; and SD $\rho=-0.029$, $P=0.708$).

CONCLUSIONS: Although 74.1% of patients on long-term warfarin therapy achieved a passing score of at least 21 correct answers on the 29-question AKA instrument, there was no significant relationship between patient warfarin knowledge and INR control. Areas for improvement in patient education have been identified and procedures for educational modification are currently in development.

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What is already known about this subject

- Numerous factors complicate the clinical outcomes of warfarin therapy, such as concurrent disease states, drug regimens, diet and alcohol intake, physical illnesses, compliance, and patient knowledge of their responsibilities in therapy.
- In a study of patients aged 80 years or older treated with warfarin, Kagansky et al. (2004) found that insufficient education as perceived by the patient or caregiver was associated with a higher rate of major bleeding events (5.2 per 1,000 patient-months) compared with no education (1.1 per 1,000 patient-months) and education that was patient-rated as sufficient (0.5 per 1,000 patient-months; $P<0.001$).
- Tang et al. (2003) found a slightly positive Pearson correlation (r) between knowledge about warfarin and the number of international normalized ratio (INR) values within target range ($r=0.2$; $P=0.024$), indicating that 4% of variance in INR could be explained by the patient's warfarin knowledge.
- To date, 2 questionnaires measuring patient knowledge of anticoagulation therapy have been validated: the Oral Anticoagulation Knowledge (OAK) test, created and validated by Zeolla et al. (2006), and the Anticoagulation Knowledge Assessment (AKA) questionnaire, designed and validated by Briggs et al. (2005). No analysis of the relationship between patient knowledge of warfarin therapy and therapeutic goal achievement has used a validated instrument.

What this study adds

- Of 185 patients who attended an outpatient anticoagulation clinic and received education at the initial clinic visit and as needed thereafter, 137 (74.1 %) achieved a passing score of at least 21 correct answers on the 29-item AKA questionnaire, which compares with an average pass rate of 31.3% reported in previous literature for different anticoagulation knowledge instruments.
- This is the first study to use a validated knowledge assessment questionnaire tool to assess the relationship between warfarin knowledge and therapeutic goal range achievement. Surprisingly, there was no significant correlation between anticoagulation knowledge, defined by the number of correctly answered questions, and INR control, defined as the number of INR values within therapeutic range, time in therapeutic range calculated using the Rosendaal method, or standard deviation of INR values.
- Assessment of patient warfarin knowledge might be used in quality improvement initiatives in anticoagulation monitoring and patient safety including identification of areas of knowledge deficiency.

Anticoagulation with warfarin is a well-established and crucial intervention for the prevention and treatment of thromboembolic events.^{1,2,3} Numerous factors can affect the clinical response to anticoagulants, particularly warfarin, such as a patient's concurrent disease states, drug regimens, diet and alcohol consumption, physical illnesses, compliance, and overall knowledge of therapy.¹⁻⁴ For this reason, patients require a skillful health care provider in addition to a systematic approach to ensure proper patient follow-up during the initiation and continuation of warfarin therapy.

Reflecting these needs, in 2009 the Joint Commission created a National Patient Safety Goal (NPSG) 03.05.01 (or 3E) for ambulatory care to "reduce the likelihood of patient harm associated with the use of anticoagulation therapy."^{5,6} The 2011 NPSG 3E guidelines describe patient education as "a vital component" of a warfarin therapy program, stating that providers should make sure patients understand risks involved with therapy, precautions to take, and the need for close follow-up (Figure 1). Element number 7 of NPSG 3E requires that the organization provide education regarding anticoagulation therapy to staff, patients, and families. Element number 8 requires that "the organization evaluate anticoagulation safety practices, take appropriate action to improve practices, and measure the effectiveness of those actions."^{6,7}

To date, a few studies have shown an association between the outcomes of anticoagulation therapy and health literacy, patient education, or knowledge of warfarin therapy; however, results are mixed.⁸⁻¹² In a sample of 122 patients attending a warfarin clinic, Tang et al. (2003) discovered a positive Pearson correlation (r) between patient knowledge about

warfarin therapy and the percentage of international normalized ratio (INR) values within therapeutic goal range ($r=0.20$, $P=0.024$).¹⁰ Additionally, in a study of patients aged 80 years or older, Kagansky et al. (2004) found that insufficient education on oral anticoagulation therapy (as perceived by the patient or caregiver) was a significant predictive factor for major bleeding events (5.2 per 1,000 patient-months) compared with no education (1.1 per 1,000 patient-months) and education that was patient-rated as sufficient (0.5 per 1,000 patient-months, $P<0.001$). The percentage of INRs within the therapeutic range was highest among patients with perceived satisfactory education (45.1%) compared with those who perceived their education as insufficient (34.9%) or received no education (20.0%, $P<0.001$).¹¹

However, not all studies have found a positive correlation between patient knowledge and outcomes of warfarin therapy. Davis et al. (2005) found that adherence to therapy with warfarin was significantly associated with anticoagulation control, defined as the number of blood tests in appropriate therapeutic range divided by the number of blood tests performed during the 60-day period; however, knowledge of warfarin therapy, assessed with an 18-question multiple-choice test, was not associated with anticoagulation control.¹² Only 14% of patients in the study by Davis et al. achieved good anticoagulation control, defined as more than 70% of INR values within therapeutic range.¹²

The major limitation of all of the aforementioned studies, regardless of their results, was the use of a nonvalidated questionnaire or survey to evaluate patient knowledge. Validation indicates that the questionnaire has been thoroughly tested for content validity, measures of question difficulty, readability, and item/person reliability. To date, 2 questionnaires measuring patient knowledge of warfarin therapy have been validated: the Oral Anticoagulation Knowledge (OAK) test, created and validated by Zeolla et al. (2006),¹³ and the Anticoagulation Knowledge Assessment (AKA) questionnaire, designed and validated by Briggs et al. (2005).¹⁴

Evaluation of current patient knowledge is the first step to improving the quality of anticoagulation therapy and patient care. Deficiencies in patient knowledge can be identified and addressed, creating an ongoing system of quality improvement for anticoagulation monitoring and patient safety. The present study assessed the current knowledge level of patients receiving warfarin therapy in the outpatient anticoagulation clinic at the Alvin C. York (ACY) campus of the Veterans Affairs (VA) Tennessee Valley Healthcare System (TVHS). Study investigators conducted this research to determine if corrective actions were needed to improve patient knowledge in accordance with the standards of NPSG 3E element number 8. Additionally, to date no published studies have used a validated instrument to assess the association of patient anticoagulation knowledge with INR control. Therefore, the present study assessed

FIGURE 1 The Joint Commission's Elements of Performance for NPSG.03.05.01 Effective January 1, 2011. To Reduce the Likelihood of Patient Harm Associated with the Use of Anticoagulant Therapy^a

1. Use only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available. Note: For pediatric patients, prefilled syringe products should be used only if specifically designed for children.
2. Use approved protocols for the initiation and maintenance of anticoagulant therapy.^b
3. Before starting a patient on warfarin, assess the patient's baseline coagulation status; for all patients receiving warfarin therapy, use a current International Normalized Ratio (INR) to adjust this therapy. The baseline status and current INR are documented in the medical record.^b
4. Use authoritative resources to manage potential food and drug interactions for patients receiving warfarin.
5. When heparin is administered intravenously and continuously, use programmable pumps in order to provide consistent and accurate dosing.
6. A written policy addresses baseline and ongoing laboratory tests that are required for anticoagulants.
7. Provide education regarding anticoagulant therapy to prescribers, staff, patients, and families. Patient/family education includes the following:^b
 - The importance of follow-up monitoring
 - Compliance
 - Drug-food interactions
 - The potential for adverse drug reactions and interactions
8. Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions in a time frame determined by the organization.^b

^aThe Joint Commission. Accreditation program: ambulatory care. National Patient Safety Goals;⁶ and the Joint Commission. Accreditation program: hospital. National Patient Safety Goals.⁷

^bOnly performance elements 2, 3, 7, and 8 apply to the ambulatory care setting.

the association of performance on the AKA questionnaire (Appendix)¹⁴ with anticoagulation control defined using 3 methods: (a) number of INRs within therapeutic range, (b) time in therapeutic range (TTR), and (c) anticoagulation stability measured as the standard deviation (SD) of INR values (lower SD values indicate greater stability).

Methods

Study Design and Setting

This was a single-center cross-sectional analysis of all current patients in the VA TVHS ACY anticoagulation clinic. This study was approved by the Institutional Review Board and Research and Development committees within TVHS. The outpatient anticoagulation clinic at the ACY campus of the VA TVHS was established in 2007 and is currently staffed with a doctor of pharmacy and a licensed practical nurse. Since initiation of the ACY anticoagulation clinic, patients and/or their primary caregivers are educated by the clinical pharmacy specialist at their first visit regardless of length of warfarin therapy prior to their initial clinic visit. At the time of this study, there were 447 patients enrolled in the anticoagulation clinic.

Study Sample

All 447 ACY clinic patients seen during their routine visits within an 8-week recruitment period from February 2010 to April 2010 were asked by the clinical pharmacy specialist to

complete the AKA questionnaire. Patients were excluded if they refused participation, could not voice understanding after reading the informed consent, or if the study investigators felt in their best clinical judgment that the patient did not understand consent. Patients without at least 10 INR readings from the ACY clinic prior to the consent date and patients who had been enrolled in the clinic less than 6 months were eligible to complete the AKA questionnaire but were not included in the data analysis of the relationship between INR control and warfarin knowledge.

Study Procedures

Once consent was received, the AKA instrument was given to the patient. Patients were instructed to complete the questionnaire independently and without assistance. The patient could either fill out the questionnaire while in the office or take it home and mail it back to the clinic. If the patient requested to complete the survey at home, a postage-paid self-addressed envelope was provided for the return of the completed survey. Surveys were coded sequentially upon order of consent and paired with patient identifiers. This step was performed so that demographic data and the patient's 10 INR measurements could be extracted manually from the computerized patient record system (CPRS) at a later date. Missing answers in survey responses were scored as incorrect answers. Results of the AKA instrument as completed by the enrolled patients were

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FIGURE 2 Patient Selection Flowchart

^aPrimary outcome: total score on the validated AKA.

^bSecondary outcome: correlation of warfarin knowledge with anticoagulation control.

AKA = Anticoagulation Knowledge Assessment questionnaire (Appendix), INR = international normalized ratio.

compiled with demographic and clinical information, including indications for anticoagulation and duration of warfarin treatment, from the patients' medical records.

Definitions of Study Variables

The primary outcome was the level of knowledge as determined by the score on the AKA questionnaire. The AKA questionnaire is made up of 29 multiple choice questions. Each question was worth 3.45 points. Correctly answering 21 questions (72.4%) or more was needed for determination of adequate knowledge of anticoagulation therapy (passing score). The secondary outcome was INR control, defined using 3 different methods: (a) the count of the 10 most recent INR values within therapeutic goal range (0, 1, 2, 3, etc.), (b) TTR calculated using the Rosendaal Method,¹⁵ and (c) anticoagulation stability measured as the SD of INR values. These measures have been used in previous studies of INR control.^{8,10,16,17} The 10 INR values obtained prior to the date of patient consent were assessed for evaluation of a patient's recent INR control at the time of assessment of warfarin knowledge using the AKA instrument.

Two different scoring methods for the AKA instrument were used to assess correlation of warfarin knowledge with

INR control. The first was the total count of correct answers for the instrument, with a maximum of 29. The second scoring method eliminated questions that were deemed by the investigators to be of limited relevance to INR control, for a total maximum score of 15 (Appendix).

Statistical Analysis

Associations between the independent variables and passing versus failing score, measured as a binomial, were assessed using Fisher's exact test or Pearson chi-square test for categorical variables. Because the data were not normally distributed, Spearman's rho correlation analysis was used instead of a Pearson correlation to assess the relationships between each of the 3 measures of INR control and both measures of anticoagulation knowledge. Analyses were performed with an a priori alpha value of 0.05 using SPSS version 17.0 (SPSS Inc., Chicago, IL) and the GraphPad InStat statistical package (GraphPad Software Inc., La Jolla, CA).

Results

Of the 260 anticoagulation clinic patients who consented during the 8-week enrollment period, 186 (71.5%) returned a completed questionnaire (Figure 2). One patient was lost due

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TABLE 1 Baseline Characteristics of Patients Who Completed the AKA Questionnaire (N= 185)

Parameter	n	(%)
Age (mean = 68; SD = 10.1 years)		
Younger than 50 years	6	(3.2)
50 to 59 years	22	(11.9)
60 to 69 years	73	(39.5)
70 to 79 years	61	(33.0)
80 years or older	23	(12.4)
Gender		
Male	178	(96.2)
Female	7	(3.8)
INR goal		
2.0-3.0	166	(89.7)
2.5-3.5	15	(8.1)
Other	4	(2.2)
Indication^a		
Atrial fibrillation	113	(61.1)
Valve replacement	18	(9.7)
DVT/PE	48	(25.9)
CVA/TIA	12	(6.5)
Other	9	(4.9)
Duration of warfarin therapy		
Less than 6 months	11	(5.9)
6 months to 1 year	12	(6.5)
1 to 3 years	53	(28.6)
3 to 5 years	38	(20.5)
More than 5 years	71	(38.4)

^aPatients with multiple indications for anticoagulation were included in all applicable categories. Therefore, indications sum to more than 100%. AKA = Anticoagulation Knowledge Assessment questionnaire (Appendix); CVA = cerebral vascular accident; DVT = deep venous thrombosis; INR = international normalized ratio; PE = pulmonary embolism; SD = standard deviation; TIA = transient ischemic attack.

TABLE 2 Frequently Missed Questions^a

Question	Answered Correctly
#25 – foods that affect warfarin	33%
#16 – liquids that affect warfarin	42%
#26 – generic and brand warfarin	45%
#5 – effect of spinach in diet	55%
#6 – effect of alcohol on INR	62%
#21 – symptoms of side effects of warfarin	65%
#28 – expected duration of warfarin therapy	66%
#15 – side effects of elevated INR	67%

^aIndicates questions that were answered correctly by less than 70% of respondents. See Appendix for Anticoagulation Knowledge Assessment questionnaire for full question text. Of 186 respondents, 171 (91.9%) returned the survey by mail. INR = international normalized ratio.

to the inability to match his or her questionnaire with patient identifiers for data extraction purposes, leaving 185 patients for data analysis. Demographic and clinical data are in Table 1. The mean (SD) age of patients in the sample was 68 (10.1) years with 178 male patients (96.2%). The majority of patients were being treated for atrial fibrillation (n = 113, 61.1%). Other indications included deep venous thrombosis/pulmonary embolism (DVT/PE; n = 48, 25.9%), valve replacement (n = 18, 9.7%), cerebral vascular accident/transient ischemic attack (CVA/TIA; n = 12, 6.5%), and other indications (n = 9, 4.9%). Indication categories are not mutually exclusive—that is, patients with multiple indications were included in all applicable categories. Most patients (n = 162, 87.6%) had been treated for at least 1 year, with 11 patients (5.9%) treated for less than 6 months and 12 patients (6.5%) treated for 6 months to 1 year. In the assessment of individual goal INRs predetermined by the provider referring the patient to the clinic, 166 patients (89.7%) had a goal range of 2-3, 15 patients (8.1%) had a goal range of 2.5-3.5,

and 4 patients (2.2%) had a unique goal range.

Of the 185 patients who completed the 29-item AKA questionnaire, 137 (74.1%) achieved a score of at least 21 correct items (72.4%). The mean (SD) AKA questionnaire score was 78.1% (12.1%), representing approximately 22.6 correct responses. Eight questions were answered correctly by less than 70% of patients (Table 2). No patient achieved a score of 100%. For the correlation analyses, 11 patients who had been treated for 6 months or less and 7 patients with an insufficient number of INRs were excluded, leaving a total of 167 patients for data analysis. Demographic and clinical characteristics of patients included in the correlation analyses are shown in Table 3. Comparing subgroups categorized by passing versus failing AKA score, no statistically significant between-group differences were found.

Spearman's rho correlation (rho) analyses (Table 4) showed no significant correlations between total number of correct AKA answers and any of the 3 measures of INR control, whether defined as the count of the 10 previous INR values within goal range (rho = -0.022, P = 0.776), TTR (rho = 0.015, P = 0.848), or SD (rho = 0.047, P = 0.550). In sensitivity analyses limited to 15 AKA items deemed by the study investigators to be relevant to INR control (Appendix), there were no significant relationships between number of correct INR-relevant responses and INR control (rho = 0.033, P = 0.676; rho = 0.067, P = 0.388; rho = -0.029, P = 0.708).

Discussion

Currently 2 anticoagulation knowledge questionnaires have been validated for content validity, construct validity, and reliability. The AKA questionnaire used a review of published literature and anticoagulation clinic protocols, as well as interviews with anticoagulation pharmacists for content validity. AKA investigators created a 29-item instrument covering 9 content areas, including medication, medication administration, medication interactions, activity, diet, side effects, informing health

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TABLE 3 Demographics and Clinical Characteristics of Patients (n=167) in Spearman's Rho Correlation Analysis

Parameter	Patients with Passing Score ^a (n=124)	Patients with Failing Score ^a (n=43)	P Value ^b
Age – mean [SD] in years	68.0 [9.9]	70.6 [10.9]	
Gender			
Male	119 (96.0)	42 (97.7)	1.000
Female	5 (4.0)	1 (2.3)	1.000
INR Goal Range			
2.0-3.0	112 (90.3)	37 (86.0)	0.408
2.5-3.5	9 (7.3)	5 (11.6)	0.356
Other	3 (2.4)	1 (2.3)	1.000
Indication ^c			
Atrial fibrillation	79 (63.7)	27 (62.8)	1.000
DVT/PE	31 (25.0)	11 (25.6)	0.843
Valve replacement	12 (9.7)	5 (11.6)	0.770
CVA/TIA	8 (6.5)	2 (4.7)	1.000
Other	6 (4.8)	1 (2.3)	0.681
Duration of warfarin therapy			
6 months to 1 year	9 (7.3)	1 (2.3)	0.456
1 to 3 years	36 (29.0)	17 (39.5)	0.254
3 to 5 years	30 (24.2)	6 (14.0)	0.199
Greater than 5 years	49 (39.5)	19 (44.2)	0.595

^aPassing score was defined as at least 21 questions answered correctly or an AKA questionnaire score of 72.4%.

^bAssociations between variables were assessed using Fisher's exact test or Pearson's chi-square test.

^cPatients with multiple indications for anticoagulation were included in all applicable categories. Therefore, indications sum to more than 100%.

AKA=Anticoagulation Knowledge Assessment questionnaire (Appendix); CVA=cerebral vascular accident; DVT=deep venous thrombosis; INR=international normalized ratio; PE=pulmonary embolism; SD=standard deviation; TIA=transient ischemic attack.

care providers, procedures, and lab monitoring. For content validity they used the Marzano's Taxonomy. For reliability and overall analysis of their instrument, they used the Rasch dichotomous model.¹⁴ The AKA questionnaire was employed in our study because of its range of topics important in warfarin education. Patient responses provide objective data about different aspects of practice that are taught in patient education. Thus, the instrument served as a good quality control measure of patient counseling effectiveness.

Evaluation of anticoagulation knowledge has yielded undesirable pass rates in previous literature. Using a novel survey containing 7 open-ended questions, Tang et al. found that only 18% of patients achieved a passing score of at least 70%.¹⁰ Davis et al. found that 37% of patients achieved a passing score of at least 70% on a novel 18-question multiple-choice test.¹² Using a previously created 20-question true-or-false questionnaire, Hu et al. (2006) found a 39% pass rate, defined as a score of at least 80%.¹⁸ In using the AKA questionnaire in the ACY VA TVHS anticoagulation clinic and defining a passing score as at least

TABLE 4 Spearman's Rho Correlation Analysis of Anticoagulation Knowledge with INR Control

	Number in Range ^a	Time in Therapeutic Range ^a	Standard Deviation ^a
	Spearman's Rho (P)	Spearman's Rho (P)	Spearman's Rho (P)
Total AKA score	-0.022 (0.776)	0.015 (0.848)	0.047 (0.550)
INR-relevant AKA items ^b	0.033 (0.676)	0.067 (0.388)	-0.029 (0.708)

^aNumber in range is the count of INR values in therapeutic range, with a maximum of 10, measured prior to the consent date for participation in the study. Standard deviation was calculated for the same 10 INR values. Time in therapeutic range was calculated using the Rosendaal method.¹⁵

^bCount of correct answers in a subset of AKA items deemed by the investigators to be relevant to INR control (Appendix).

AKA=Anticoagulation Knowledge Assessment questionnaire; INR=international normalized ratio.

72.4% (21 of 29) of questions answered correctly, we found that 74.1% of our patients achieved a passing score. However, patient education methods and study methodology for the previous studies varied among anticoagulation clinics and patient samples, making direct comparison of study results difficult.

Eight questions were answered correctly by less than 70% of patients. Four frequently missed questions covered dietary modifications; 2 addressed medication information; 1 addressed side effects; and 1 addressed informing health care providers. The 4 most frequently missed questions were evaluated for possible causes of patients' incorrect answers. Question 5 addressed dietary modifications, and 59 (31.9%) patients picked the answer indicating that green leafy vegetables should be avoided completely instead of the choice for dietary consistency from week to week. Question 16 also addressed dietary concerns with 63 (34.1%) patients choosing orange juice instead of nutritional supplement as the agent that can decrease effectiveness of warfarin. This problem could have been due to confusion over discussion in the clinic regarding other juices, such as cranberry and grapefruit, which can increase the anti-coagulant effect of warfarin. On question 25, another dietary evaluation, 44 (23.8%) and 73 (39.5%) patients, respectively, answered celery and green beans instead of cole slaw for having the most effect on their warfarin therapy. Finally, the outcomes for question 26 reflected a conflict in the teaching styles of the ACY clinic staff and the investigators who created the AKA questionnaire. The question asked patients what they should do if they had both brand and generic warfarin at home. The correct answer was to take one or the other but not both. However, another answer stated not to take either until speaking with their health care professional. Patients in the ACY clinic are taught to call the clinic with any questions they may

have or changes in medications/diet. Therefore, both answers could be considered correct.

These frequently missed questions indicate potential areas for improvement in patient education, including reinforcement of dietary guidelines for warfarin therapy as well as when it is appropriate to contact the clinic for questions. Both areas represent potential starting points for re-education of current patients and primary education for new patients seen in the clinic. At this point, re-evaluation of the current educational techniques is indicated for identification of areas where improvements may be made.

There were no statistically significant differences in demographic or clinical characteristics between pass and fail groups, including duration of treatment or indication of therapy, age, or gender. Data from the Spearman's rho analyses revealed no statistically significant correlations between warfarin knowledge and INR control. These results add to the existing literature that has found mixed results when assessing the relationship between patient warfarin knowledge and INR control. Tang et al. did find a small positive correlation between anticoagulation knowledge and the number of INR values within target range, showing that 4% of variance in INR could be explained by anticoagulation knowledge.¹⁰ However, Davis et al. showed no significant association between knowledge or education and the proportion of INRs within the therapeutic range.¹² Our study revealed a higher pass rate of 74.1% as compared with pass rates reported previously in the literature, but it is possible that the AKA questionnaire was not sufficiently sensitive in detecting warfarin knowledge that is clinically important in the 3 measures of INR control.

Limitations

First, the collection of survey data from patients was not standardized. Patients could complete the knowledge test in the clinic, take it home and return it by mail, or return it at their next scheduled appointment. Fifteen patients (8.1%) completed the questionnaire at the facility; the other 171 patients (92.4%) completed the questionnaire outside of the facility. Although patients were expected to complete the questionnaire independently regardless of the site of completion, there was no way to prevent patients from eliciting assistance from various resources to help them complete the questionnaire. This problem may have contributed to an inflated pass rate in this study. Second, 66 respondents (35.7%) left at least 1 question unanswered. Of the 66 respondents with incomplete questionnaires, 12 left more than 4 unanswered questions, 3 missed entire pages, and 2 failed to complete the questionnaire. Because unanswered questions were considered incorrect answers, the latter 5 patients received a failing score. This decision may have contributed to cases that were judged as knowledge failures who would have achieved pass scores if all of the questions had

been answered. If a similar study is conducted in the future, it would be beneficial for patients to complete the questionnaire in a standardized, monitored environment and have completion of the entire questionnaire verified before submission to prevent these limitations from recurring. Third, of 447 patients treated in the clinic, 260 consented, but not all 187 nonconsenting patients refused participation. Some were excluded by the investigators because of inability to voice understanding of the project or because the investigators determined, using their best clinical judgment, that the patient would be unable to understand consent. These exclusion factors are related to mental capacity, a potential confounding factor in this study's results; however, counts of patients excluded for these reasons were not tracked during sample selection, and we are unable to report them. Fourth, the limited patient population available within the VA anticoagulation clinic setting of this study presents a significant limitation; the study sample consisted of veterans, most of whom are older males.

Conclusions

The present study assessed anticoagulation knowledge of patients receiving warfarin therapy in a VA outpatient anticoagulation clinic using a validated instrument and found a pass rate of 74.1%, much higher than reported previously in the literature. We found no statistically significant relationships between 3 measures of INR control and anticoagulation knowledge. However, this is the first report of the relationship between INR control and anticoagulation knowledge as assessed by the AKA questionnaire, and it is possible that this assessment instrument, although previously validated, was not sufficiently sensitive in detecting clinically important warfarin knowledge. The frequently missed questions indicate potential areas for improvement in patient education. Re-evaluation of the current educational techniques is underway for identification of areas where improvements may be made.

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DISCLOSURES

The authors report no financial or other conflicts of interest related to the subjects or products discussed in this article. A poster abstract of this research was presented at the 2010 Annual Meeting of the American College of Clinical Pharmacy, October 19, 2010, in Austin, Texas.

Study concept and design were shared equally by Baker, Pierce, and Ryals. Data collection and interpretation were performed primarily by Baker with assistance from Pierce and Ryals. The 3 authors shared in writing the manuscript, and the revisions were made primarily by Baker.

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REFERENCES

1. Ansell J, Hirsh J, Hylek E, Jacobson A, Crowther M, Palareti G. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th edition). *Chest*. 2008;133(6 Suppl):160S-198S. Available at: http://chestjournal.chestpubs.org/content/133/6_suppl/160S.full.pdf+html. Accessed January 12, 2011.
2. Schulman S, Beyth RJ, Kearon C, Levine MN. Hemorrhagic complications of anticoagulant and thrombolytic treatment: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th edition). *Chest*. 2008;133(6 Suppl):257S-298S. Available at: http://chestjournal.chestpubs.org/content/133/6_suppl/257S.full.pdf+html. Accessed January 12, 2011.
3. Barcellona D, Contu P, Marongiu F. Patient education and oral anticoagulation therapy. *Haematologica*. 2002;87(10):1081-86. Available at: <http://www.haematologica.org/cgi/reprint/87/10/1081>. Accessed January 12, 2011.
4. Taylor FC, Ramsay ME, Tan G, Gabbay J, Cohen H. Evaluation of patients' knowledge about anticoagulation treatment. *Qual Health Care*. 1994;3(2):79-85. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1055201/pdf/qualhc00011-0015.pdf>. Accessed January 12, 2011.
5. Sipkoff M. Joint Commission sets anticoagulant therapy safety goal. *Drug Topics*. August 20, 2007. Available at: <http://drugtopics.modernmedicine.com/drugtopics/Treatment+Areas/Joint-Commission-sets-anticoagulant-therapy-safety/ArticleStandard/Article/detail/450166>. Accessed January 12, 2011.
6. The Joint Commission. Accreditation program: ambulatory care. National Patient Safety Goals. Effective January 1, 2011. Available at: http://www.jointcommission.org/assets/1/6/2011_NPSGs_AHC.pdf. Accessed January 12, 2011.
7. The Joint Commission. Accreditation program: hospital. National Patient Safety Goals. Effective January 1, 2011. Available at: http://www.jointcommission.org/assets/1/6/2011_NPSGs_HAP.pdf. Accessed January 12, 2011.
8. Estrada CA, Martin-Hryniewicz M, Peek BT, Collins C, Byrd JC. Literacy and numeracy skills and anticoagulation control. *Am J Med Sci*. 2004;328(2):88-93.
9. Fang MC, Machtinger EL, Wang F, Schillinger D. Health literacy and anticoagulation-related outcomes among patients taking warfarin. *J Gen Intern Med*. 2006;21(8):841-46. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1831580/pdf/jgi0021-0841.pdf>. Accessed January 12, 2011.
10. Tang EO, Lai CS, Lee KK, Wong RS, Cheng G, Chan TY. Relationship between patients' warfarin knowledge and anticoagulation control. *Ann Pharmacother*. 2003;37(1):34-39.
11. Kagansky N, Knobler H, Rimon E, Ozer Z, Levy S. Safety of anticoagulation therapy in well-informed older patients. *Arch Intern Med*. 2004;164(18):2044-50. Available at: <http://archinte.ama-assn.org/cgi/reprint/164/18/2044.pdf>. Accessed January 12, 2011.
12. Davis NJ, Billett HH, Cohen HW, Arnsten JH. Impact of adherence, knowledge, and quality of life on anticoagulation control. *Ann Pharmacother*. 2005;39(4):632-36.
13. Zeolla MM, Brodeur MR, Dominelli A, Haines ST, Allie ND. Development and validation of an instrument to determine patient knowledge: the oral anticoagulation knowledge test. *Ann Pharmacother*. 2006;40(4):633-38.
14. Briggs AL, Jackson TR, Bruce S, Shapiro NL. The development and performance validation of a tool to assess patient anticoagulation knowledge. *Res Social Adm Pharm*. 2005;1(1):40-59. Available at: <http://download.journals.elsevierhealth.com/pdfs/journals/1551-7411/PIIS1551741104000038.pdf>. Accessed January 12, 2011.
15. Rosendaal F, Cannegieter S, Van Der Meer F, Briet E. A method to determine the optimal intensity of oral anticoagulant therapy. *Thromb Haemost*. 1993;69(3):236-39.
16. Hirschl M, Pluschnig U, Kundi M, Katzenschlager R. Oral anticoagulation in older patients with vascular or cardiovascular diseases. Aged over 70 years: same risk? Same benefit? *Int Angiol*. 2003;22(4):370-75.
17. Sconce E, Avery P, Wynne H, Kamali F. Vitamin K supplementation can improve stability of anticoagulation for patients with unexplained variability in response to warfarin. *Blood*. 2007;109(6):2419-23.
18. Hu A, Chow C, Dao D, Errett L, Keith M. Factors influencing patient knowledge of warfarin therapy after mechanical heart valve replacement. *J Cardiovasc Nurs*. 2006;21(3):169-75.

**INR Goal Attainment and Oral Anticoagulation Knowledge of Patients
Enrolled in an Anticoagulation Clinic in a Veterans Affairs Medical Center**

APPENDIX Anticoagulation Knowledge Assessment (AKA) Questionnaire^a

1. Which one of these medications is recommended if you are taking Coumadin (warfarin) and want relief from a headache?
 - a. Advil
 - b. Motrin
 - c. Aspirin
 - d. Tylenol
2. Which of the following food items would interfere with your Coumadin (warfarin) medication?
 - a. Bacon
 - b. Broccoli
 - c. Bananas
 - d. Peeled cucumbers
3. While on Coumadin (warfarin) medication, in which of the following would you go directly to the emergency room?
 - a. Small bruises
 - b. Your appetite dramatically increases
 - c. Nosebleed which will not stop bleeding
 - d. Gums which bleed for a few seconds after brushing teeth
4. You just remembered that you forgot to take your evening Coumadin (warfarin) medication dose last night. You would—
 - a. skip the dose of Coumadin (warfarin) you missed
 - b. take the missed Coumadin (warfarin) dose right now
 - c. wait and take 2 doses of Coumadin (warfarin) this evening
 - d. take one-half of the missed dose of Coumadin (warfarin) right now
5. While on Coumadin (warfarin) you—
 - a. should not eat spinach
 - b. can eat spinach one time a month
 - c. can eat as much spinach as you would like whenever you would like
 - d. can eat spinach but need to eat the same amount regularly every week
6. While out with friends for dinner, you have just finished your third glass of wine. This amount of alcohol consumed in a single evening will—
 - a. cause a decrease in your INR
 - b. cause an increase in your INR
 - c. not affect you or your Coumadin (warfarin) in any way
 - d. make you sick when taking Coumadin (warfarin) medication
7. While in your pharmacy, you notice multivitamins are on sale. After some thought, you decide that you may need a multivitamin. You would—
 - a. purchase the multivitamin and begin taking it regularly
 - b. not take a multivitamin because it will cause a blood clot while taking Coumadin (warfarin)
 - c. start taking it and bring the multivitamin to your next Coumadin Clinic visit to show the pharmacist
 - d. purchase the multivitamin but not start taking it until you talked with the pharmacist at your Coumadin Clinic
8. If you ran out of your prescription for your Coumadin (warfarin) you would—
 - a. borrow Coumadin (warfarin) from a friend, as long as it is the same dose as yours
 - b. call and ask for refills for that day so you do not miss a dose of Coumadin (warfarin)
 - c. wait until your next appointment that is just a few days away to get a new prescription
 - d. do nothing because you have taken Coumadin (warfarin) long enough, otherwise there would be more refills on your prescription
9. Which of the following is an effect of Coumadin (warfarin) medication that will most likely be experienced?
 - a. Stroke
 - b. Leg Clot
 - c. Bruising
 - d. Blood in the urine
10. You have a cold, which includes a runny nose and cough. You—
 - a. could safely take Nyquil to help get rid of the runny nose and cough
 - b. take your friend's medication that he/she uses for a bad cold because he/she is also on Coumadin (warfarin) medication
 - c. would call the Coumadin Clinic and tell him/her you are on Coumadin (warfarin) medication and ask what you can take for your cold
 - d. decide it is safer to suffer through the cold because most cold medications will interact with your Coumadin (warfarin) medication
11. When making a dental appointment while taking Coumadin (warfarin) medication, you need to remember you—
 - a. cannot have procedures done on your teeth while taking Coumadin (warfarin)
 - b. must tell your dentist you are taking Coumadin (warfarin) well in advance of having any procedure done
 - c. can have procedures done and there is not a need to tell the dentist about the Coumadin (warfarin)
 - d. can have the dental procedure done if when you arrive at your dental appointment you tell the dentist you are taking Coumadin (warfarin)
12. When the need arises to take an antibiotic (to get rid of an infection) while taking Coumadin (warfarin), you need to—
 - a. take half of the prescribed length of therapy, and then call the Coumadin clinic
 - b. refuse to take any new medication because you are taking Coumadin (warfarin)
 - c. wait until your next Coumadin clinic visit and then tell the pharmacist about the antibiotic
 - d. call the Coumadin Clinic right away and let them know you are starting a new medication
13. Coumadin (warfarin) works—
 - a. in my liver to make my blood thicker
 - b. in my liver to make my blood thinner
 - c. in my kidneys to make my blood thicker
 - d. in my kidneys to make my blood thinner
14. The best time of day for me to take my Coumadin (warfarin) is—
 - a. at lunchtime
 - b. in the evening
 - c. in the morning before breakfast
 - d. any time of day when I remember
15. Which of the following is an effect of my Coumadin (warfarin) medication that I will most likely experience if my INR is too high?
 - a. A clot in the leg
 - b. Minor bleeding
 - c. Clot in the lung
 - d. Bleeding in the brain

**INR Goal Attainment and Oral Anticoagulation Knowledge of Patients
Enrolled in an Anticoagulation Clinic in a Veterans Affairs Medical Center**

APPENDIX Anticoagulation Knowledge Assessment (AKA) Questionnaire^a (continued)

16. Which of the following drinks can decrease the effectiveness of your Coumadin (warfarin)?
a. Deans 2% low-fat milk
b. Hershey's chocolate shake
c. Tropicana orange juice
d. Ensure nutritional supplement
17. While taking Coumadin (warfarin), which of the following represents a situation when you should go to the emergency room?
a. You cough up blood
b. Your nose bleeds slightly while blowing it
c. Your gums bleed after brushing your teeth then it stops quickly
d. You have cut yourself while shaving and you control the bleeding
18. Your neighbor brings over this great "all natural" herbal supplement she just bought from her chiropractor. She swears that this helps all her aches and pains and recommends that you take it when you ache. Your decision is to—
a. take her advice, realizing that you could use this herbal supplement
b. start taking the herbal supplement and tell your pharmacist at the next office visit
c. ask your pharmacist if the herbal supplement will interact with your medications before you take it
d. avoid taking herbal supplements altogether because all medications interact with Coumadin (warfarin)
19. Once you have reached a stable Coumadin (warfarin) dose, a PT/INR blood test—
a. should be checked once a year
b. should be checked once every 3 months
c. should be checked at least once every 4 weeks
d. does not need to be checked once you are on a stable Coumadin (warfarin) dose
20. The results of your PT/INR test tells the pharmacist—
a. how thick or thin your blood is while taking Coumadin (warfarin)
b. how well your kidneys are working since taking Coumadin (warfarin)
c. what your average blood sugar level was since taking Coumadin (warfarin)
d. how much alcohol you have been drinking since taking Coumadin (warfarin)
21. While taking Coumadin (warfarin), you should call your Coumadin Clinic when you get:
a. a backache
b. an upset stomach
c. a tension headache
d. diarrhea for more than 1 day
22. While on Coumadin (warfarin) you need to be routinely monitored for which of the following:
a. PT/INR tests
b. Potassium levels
c. Blood glucose levels
d. Kidney function tests
23. Which of the following may have a significant effect on how well your Coumadin (warfarin) works?
a. Changes in your mood
b. Changes in sleep habits
c. How much water you drink
d. Using over the counter medications
24. While taking Coumadin (warfarin), which of the following should lead you to the emergency room?
a. Loss of appetite
b. Brown loose stools
c. Urine becomes red in color
d. A quarter size bruise on your arm
25. Which of the following foods could affect how well your Coumadin (warfarin) works?
a. Celery
b. Carrots
c. Cole slaw
d. Green beans
26. You have generic and brand Coumadin (warfarin) tablets at home that are both the same dose. You should—
a. take both because they work differently
b. take only brand or generic, but not both
c. not take either until you call the Coumadin Clinic
d. alternate days by taking brand on one day and generic on the next day
27. Once your Coumadin (warfarin) is stopped, how long does it take to get the medication to get out of your system?
a. 5 hours
b. 5 days
c. 5 weeks
d. 5 months
28. After starting Coumadin (warfarin), how long (in months/years) would you expect to be taking Coumadin (warfarin)?
a. 1 year
b. 1 month
c. It depends on each person's needs
d. If you start Coumadin (warfarin), you will have to be on the medication for the rest of your life
29. Which of the following activities are more risky while taking Coumadin (warfarin)?
a. Playing football, because you can hit your head
b. Taking a bath, because soap interacts with Coumadin (warfarin)
c. Playing cards because using your hands a lot will cause a blood clot
d. Walking a lot, because exercise is not good for you while taking Coumadin (warfarin)

^aCorrect answers are underlined. Items that were deemed relevant by the study investigators for inclusion in sensitivity analyses of knowledge with INR control are shaded in gray.

INR=international normalized ratio; PT=prothrombin.