Development and Validation of an Instrument to Determine Patient Knowledge: The Oral Anticoagulation Knowledge Test

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BACKGROUND: Studies examining the relationship between patient knowledge regarding warfarin therapy and its safe and effective use are limited by the lack of validated knowledge assessment tools.

OBJECTIVE: To develop and validate an instrument to assess patient knowledge regarding oral anticoagulation therapy.

METHODS: Four nationally recognized anticoagulation experts participated in the instrument development process to ensure content validity. The Oral Anticoagulation Knowledge (OAK) test was administered to subjects on warfarin and a group of age-matched subjects not on warfarin to assess construct validity. A subgroup of warfarin subjects were retested approximately 2–3 months after initial testing to assess test–retest reliability. Internal consistency reliability was assessed by calculating a Kuder–Richardson 20 value. Item analysis was used to assess performance of individual questions.

RESULTS: An initial 23 item instrument was pilot tested for readability and comprehension. The OAK test was administered to 74 subjects taking warfarin and 27 age-matched subjects not on warfarin. Thirty-two subjects on warfarin repeated the OAK test an average of 75 days following initial administration. Subjects taking warfarin scored significantly higher than those not on warfarin (72% vs 52%, respectively; $p < 0.001$), supporting the construct validity of the instrument. Test–retest reliability was acceptable, with a Pearson's correlation coefficient of 0.81. Internal consistency reliability was confirmed by a calculated Kuder–Richardson 20 value of 0.76.

CONCLUSIONS: The OAK test is a brief, valid, and reliable knowledge assessment instrument that may be a useful tool for research and clinical practice to augment patient education programs.

KEY WORDS: anticoagulation, patient knowledge, warfarin.

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Warfarin is widely used for the treatment and prevention of thromboembolic disorders. Patient knowledge is believed to be key to the safe and effective use of warfarin. Patients should be aware of the indications, monitoring requirements, drug–drug and drug–food interactions, and the importance of strict adherence.[1-3] Previous studies have shown that patient knowledge of warfarin is often poor.[4-6] The relationship between their knowledge and outcomes of therapy has been examined in a limited number of studies. A small study identified a lack of patient knowledge regarding the important aspects of warfarin therapy as a determinant of nonadherence to therapy.[7]

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Another investigation showed a weak but significant positive relationship between warfarin knowledge and anticoagulation control. In this study, knowledge was assessed using 9 open-ended questions covering topics including indication, tablet identification, effects of nonadherence, and supra- or subtherapeutic anticoagulation.[6] Kagansky et al.[8] evaluated risk factors for bleeding among older patients on warfarin and found insufficient education to be a major factor predicting bleeding episodes. In contrast to these findings, a recent study found no association between patient knowledge of warfarin therapy and anticoagulation control.[9]

A major limitation of these studies is the fact that patient knowledge was assessed using a variety of methods, none of which was psychometrically validated. Only after a knowledge assessment instrument has been validated can sound scientific conclusions be drawn from its results.[10] Appropriate psychometric methodology must be followed to ensure that an assessment measure is valid and reliable for testing the specific objectives or constructs. In theory, this process demonstrates that an instrument's results are accurate, consistent, reproducible, and stable over time.[10-12] The objective of this study was to develop and validate a brief self-administered instrument for the purpose of assessing patient knowledge of warfarin therapy.

Methods

INSTRUMENT DEVELOPMENT

To ensure content validity, a panel of 4 nationally recognized experts in the area of anticoagulation therapy was identified and asked to participate in the instrument development phase.[10-12] The expert reviewers included 2 pharmacists, a nurse, and a physician and were identified based on their publication record and patient care experience related to warfarin therapy management. The investigators created an initial list of 5 patient knowledge domains including basic drug information, adverse effects, drug–drug interactions, dietary issues/food interactions, and monitoring. Under each domain, important points regarding each topic were identified. The content experts rated each of the topic domains to indicate the percent of questions related to the topic to include on the instrument.[1,3] The experts also ranked each information point in descending order based on its relative importance to patient education. Monitoring was the highest rated topic by the expert reviewers, followed by drug–drug interactions, basic drug information, adverse effects, and dietary issues, respectively. An item bank was developed based on this information.

Up to 10 multiple-choice questions were created for each topic, with a focus on information points ranked as most important by the experts. The multiple-choice question format was chosen due to its ease of administration and ability to psychometrically validate.[11] Each multiple-choice question had 4 possible responses, with one correct answer and 3 distracters. Questions were written at an 8th grade reading level or less, as determined by the Flesch–Kincaid formula calculated by MS Word software. After the initial item bank was compiled, the reviewers were asked to rank the overall quality of each item on a scale of 1 to 5 (1 = poor, 5 = excellent) in terms of how well it tested each information point. These rankings were used to eliminate questions and create a 23 item pilot instrument.

SUBJECTS

Adults (aged >18 y) currently receiving warfarin therapy and who were able to read and complete the questionnaire independently were eligible to participate in the study. Subjects were recruited from 2 suburban chain community pharmacies, 2 suburban supermarket pharmacies, 1 urban anticoagulation clinic, and an urban family medicine practice located in the Northeastern US. Signs and brochures were placed in the pharmacy sites to recruit patients. Clinic staff identified patients receiving warfarin therapy in the non-pharmacy sites. A cover letter describing the goals of the study was provided to people who agreed to participate. No additional assistance was provided to those completing the instrument, and each one completed a brief demographic questionnaire. The study protocol was reviewed and approved by the local institutional review boards for each site.

PSYCHOMETRIC AND STATISTICAL ANALYSIS

Instrument validity is ideally established by comparing the new instrument being developed with a gold standard, if one exists. When no gold standard exists, ensuring content and construct validity are appropriate methods to develop a knowledge instrument. Reliability is also a vital attribute of a sound knowledge instrument. An instrument is said to be reliable when scores are consistent over time and the variability of the instrument's results are due to true differences among the individuals being measured.[12]

Content validity refers to the extent to which a set of items reflects the intended content domain.[10] A systematic approach to identifying important topic domains and developing specific items based on feedback from national experts in the field ensured the content validity of the Oral Anticoagulation Knowledge (OAK) test. Construct validity determines the instrument's ability to function for its intended purpose.[11] The contrasted groups method was employed in this study to determine construct validity. It was hypothesizing that, if the OAK test is a valid measure of warfarin knowledge, patients taking warfarin, because they are more knowledgeable, should achieve significantly higher scores than those not on warfarin. To confirm this hypothesis, the final instrument was administered to a group of age-matched subjects not on warfarin who were recruited from the 4 pharmacy study sites. Content validity would be confirmed if the mean OAK test score for subjects on warfarin was significantly higher than those not on warfarin.

The test–retest method was used to demonstrate the stability of the instrument over time. A subset of patients on warfarin completed the instrument approximately 2–3 months after the initial administration, a time period considered sufficient to reduce the impact of recall.[12] A correlation coefficient was calculated between the test scores from each administration. A coefficient of 0.80 or higher is considered acceptable for demonstrating test–retest reliability.[12] Further, a Kuder–Richardson 20 (KR-20) coefficient value, a measure of internal consistency, was calculated for the instrument. This measure takes into account the variance of results on each item in relation to the overall instrument variance and provides an indicator of uni-dimensionality of the characteristic being tested. A KR-20 value of 0.70 or greater is considered acceptable.[11,12]

In addition to the psychometric analyses, an analysis of the relative difficulty of each item was performed. This identified questions that best differentiate people taking warfarin from those not on warfarin, as well as questions that were too easy or difficult.

Statistical analyses were performed using Minitab 14 statistical software. Item analysis and KR-20 values were obtained using examSYSTEM II software. Descriptive statistics were used to report patient demographics. OAK test scores were calculated for each subject as the percentage of correct responses on the final instrument. χ^2 Analysis was performed to compare demographic characteristics between patients on warfarin and those not on warfarin. Pearson's correlation coefficient was used for the test–retest reliability analysis. Student's *t*-test was used to compare the differences in mean scores of subjects taking warfarin with those not on warfarin therapy.

Results

INSTRUMENT DEVELOPMENT AND ADMINISTRATION

A total of 78 multiple-choice questions were developed. After reviewing and ranking of individual questions by the content experts, 55 questions were eliminated, resulting in a 23 item pilot instrument. The initial pilot instrument was administered to 11 subjects on warfarin therapy, and questions were revised or reworded based on their feedback.

A total of 75 subjects on warfarin and 27 not on warfarin were recruited. One patient taking warfarin was excluded because of omissions on the OAK test. Thirty-two subjects were retested approximately 75 days after initial administration. The demographic characteristics of the subjects in each group were similar (Table 1, $p > 0.05$). The majority were white, over the age of 60, and had graduated from high school. Mean duration of warfarin use was 5.5 years.

Based on the item analysis, 3 questions were removed from the final OAK test. Two questions were deemed too easy because greater than 90% of the people taking warfarin answered them correctly. One other question was removed because it was redundant and sufficiently tested by other items. The final 20 item OAK test was analyzed for validity and reliability. The final instrument and answer key is available at http://acpcommunity.acp.edu/OAK.pdf.

VALIDITY AND RELIABILITY

The OAK test has a 7th grade reading level based on the Flesch–Kincaid analysis. The mean score for subjects taking warfarin was significantly higher than the score for those not taking warfarin ($p < 0.001$; Table 2), supporting construct validity. Test–retest reliability was confirmed (Pearson's correlation coefficient = 0.81; $p < 0.001$), and the internal consistency reliability was acceptable (KR-20 = 0.76, Table 2).

Table 1. Demographic Characteristics

Characteristic	Warfarin Subjects (n = 74)	Non-Warfarin Subjects (n = 27)
Male, n (%)	32 (43)	10 (37)
Age (y), n (%)		
31–45	6 (8)	2 (7)
46–60	17 (23)	5 (19)
61–75	25 (34)	11 (41)
≥76	26 (35)	9 (33)
Race/ethnicity, n (%)		
white	53 (72)	22 (81)
African American	19 (26)	3 (11)
other	2 (3)	2 (7)
Annual income ($), n (%)		
<15 000	17 (23)	3 (11)
15 000–40 000	23 (31)	9 (33)
41 000–70 000	17 (23)	8 (30)
>70 000	9 (12)	2 (7)
NR	8 (11)	5 (19)
Education completed, n (%)		
below 12th grade	11 (15)	3 (11)
high school	39 (53)	13 (48)
college	15 (20)	9 (33)
graduate school	9 (12)	2 (7)
Duration of warfarin use,[a] y	5.5 ± 5.7	NA

NA = not applicable; NR = not reported.
[a]Mean ± SD.

ITEM ANALYSIS

The instrument was also analyzed to determine item difficulty and its ability to discriminate between groups. The 7 questions with the largest differences between groups are listed in Table 3.

Although this study was not designed to evaluate differences in test scores based on demographic characteristics, a post hoc one-way ANOVA indicated that age was significantly corrected with performance on the OAK test. Patients taking warfarin aged 31–45 (n = 6) scored significantly higher than those older than 75 years (n = 26). No differences in scores were seen based on other demographic characteristics or study site.

Discussion

Subjects were able to complete the test with only written instructions. Only one survey was excluded because of omissions, suggesting that the OAK test can be administered with little oversight in a clinical practice setting. While the instrument has a 7th grade reading level, the words "Coumadin" and "warfarin," which appear throughout the instrument, may artificially increase the reading level.

The methods used in this study are consistent with best practices for assessing validity and reliability of health-related patient knowledge instruments.[13-17] Content validity of the OAK test was ensured by the use of nationally recognized experts in the field of anticoagulation therapy. Construct validity was supported by significant differences in scores between patients receiving warfarin versus those not on warfarin. Presumably, the warfarin group received some education when therapy was initiated; however, we did not assess this. It is possible that our subjects were a self-selected group and included those who were most knowledgeable.

The OAK test was shown to have good internal consistency reliability, with a KR-20 score above the accepted standard of 0.70. Test length and homogeneity of the population can affect internal consistency results. Internal consis-

Table 2. OAK Test Scores and Internal Consistency Coefficient

Variable	Warfarin Subjects (n = 74)	Non-Warfarin Subjects (n = 27)
Scores (mean ± SD)		
initial test[a]	72 ± 17.2[b]	52 ± 10.9
retest[c]	75 (14.1)	NA
Kuder–Richardson 20	0.76	0.56

NA = not applicable; OAK = Oral Anticoagulation Knowledge.
[a]Percent of items answered correctly.
[b]$p < 0.001$ for comparison with non–warfarin subject score.
[c]n = 32 for retest scores; mean duration between tests was 75 days.

tency increases as test length increases and is optimized by a homogeneous study population. The OAK test is relatively brief and was studied in a diverse population, further supporting its internal consistency reliability. Stability over time was confirmed by test–retest correlation. Mean scores were increased only slightly on the retest, possibly due to subjects seeking information after the initial test administration.

Numerous factors influence the effectiveness and safety of warfarin therapy.[18] The effectiveness of management services to improve control, reduce thromboembolic events, and minimize major bleeding may be related, at least in part, to ongoing patient education.[19] However, it is not known to what extent enhancing patient knowledge about warfarin contributes to improved outcomes compared with other functions performed by anticoagulation care providers. Therefore, the importance of these instructional activities can only be speculated.

Data regarding the relationship between patients' knowledge and anticoagulation control are conflicting. In one study, a weak correlation was found between anticoagulation control and knowledge regarding warfarin therapy.[6] However, the population (n = 122) studied in this investigation was non-English speaking patients managed in a clinic in Hong Kong. The majority of subjects were elderly and many were illiterate. Patient knowledge was determined using a series of 9 orally administered questions, with the majority requiring only dichotomous (eg, yes or no) answers. The authors provided no information regarding the validity or reliability of these questions. In another study, elderly patients who were "well informed" about anticoagulation therapy were less likely to have bleeding complications, and their international normalized ratios (INRs) were significantly more likely to be in the therapeutic range compared with the INRs of those who received "insufficient" or no instruction. However, the authors failed to describe the questionnaire used to assess the quality of patient education.[8] In contrast to these findings, no association was observed between anticoagulation control and knowledge in 52 patients managed in 2 anticoagulation clinics in New York City.[9] Knowledge regarding warfarin therapy was determined using a self-administered, 18 item, multiple-choice instrument. Again, the authors provided no information regarding the validity or reliability of the knowledge instrument they developed.

In the absence of a valid and reliable instrument, it is not possible to accurately measure patient knowledge, the impact of instructional activities on patient knowledge, or the relationship between patient knowledge, anticoagulation control, and outcomes. A recent study reported the development and validation of a warfarin knowledge questionnaire similar to the OAK test.[20] The Anticoagulation Knowledge Assessment (AKA) test is a 29 item, multiple-choice instrument that measures patient knowledge in 9 content areas. The validity of the instrument was assessed using a Rasch model analysis of data collected from 60 patients managed in 2 anticoagulation clinics who had received warfarin therapy for a mean of 28 months. One of the anticoagulation clinics served primarily African Americans, Hispanics, and Latinos in the inner city. The other clinic served primarily white patients in a suburban community. The majority (80%) of patients who participated in the study had 12 or more years of education. The instrument was designed to be self-administered at a 6th grade reading level. Content validity of the instrument was determined using an analysis of Marzano's taxonomy, which verified that the AKA instrument contains a variety of questions of varying levels of cognitive difficulty. Construct validity of the instrument was determined using a 31 item appropriateness checklist.[21]

Overall, the AKA instrument appears to adequately measure patient knowledge in a variety of content areas using questions of modest cognitive difficulty. However, the authors did not report whether they performed key reliability assessments (eg, internal reliability or test–retest reliability). With the availability of valid and reliable measures of warfarin knowledge, future research can be carried out to examine the relationship between patient's knowledge and anticoagulation control.

Table 3. Percentage of Respondents Answering Key Questions Correctly

Instrument Question Stem	Warfarin Group (n = 74)	Non–Warfarin Group (n = 27)
A patient on Coumadin (warfarin) therapy should contact the physician or healthcare provider who monitors it when…	85	58
The PT/INR (Protime) test is…	89	54
A patient with a PT/INR (Protime) value below their "goal range"…	77	50
Skipping even one dose of your Coumadin (warfarin) can…	68	33
Once you have been stabilized on the correct dose of Coumadin (warfarin), about how often should your PT/INR (Protime) value be tested…	81	21
When it comes to diet, people taking Coumadin (warfarin) should…	43	25
Each time you get your PT/INR (Protime) checked, you should…	78	50

INR = international normalized ratio; PT = prothrombin time.

Limitations

The goal of this study was to develop and validate a knowledge instrument that can be used in diverse patient populations for future research and in clinical practice. A large percentage of subjects enrolled was white, which may limit the instrument's applicability in other patient populations. While the sample size was adequate to demonstrate the instrument's performance, the relatively small number of subjects may also limit the ability to generalize the results to all patients on warfarin. The instrument was found to have a 7th grade reading level, and patients with limited education may find it difficult completing the OAK test without assistance. In addition, the type or amount of previous education regarding warfarin therapy received by the subjects was not assessed. It is possible that subjects on warfarin were already well educated on the topic, which could explain the relatively high mean scores in this group.

Patients not receiving warfarin had a mean score of 52%, which is perhaps higher than expected. Most of these subjects were elderly and were recruited from one of the pharmacy sites. It is likely that these subjects took medications regularly and possessed general knowledge regarding appropriate medication use. Some of the items on the OAK test probably assess these more general topics. The multiple-choice format also permitted guessing, which may have increased scores in both groups. Finally, subjects who were cognitively impaired were not specifically excluded. However, all patients must have been able to complete the OAK test without assistance, making it unlikely that anyone with substantial cognitive impairment was included.

Conclusions

The OAK test is a valid and reliable instrument that may be useful in research efforts to determine the relationship between patient knowledge and outcomes. In clinical practice, this instrument could be incorporated into structured patient education activities to determine a patient's knowledge deficits and measure changes in patient knowledge over time.

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EXTRACTO

TRASFONDO: Los estudios que evalúan la relación entre el conocimiento del paciente sobre su terapia con warfarina y su uso efectivo y seguro son limitados por la falta de instrumentos validados de evaluación de conocimiento.

OBJETIVO: El propósito de este estudio fue desarrollar y validar un instrumento para evaluar el conocimiento del paciente sobre su terapia de anticoagulación.

MÉTODOS: Cuatro expertos en anticoagulación reconocidos nacionalmente participaron en el proceso de desarrollo del instrumento para asegurar validez del contenido. Se administró la Prueba de Conocimiento de Anticoagulación Oral a sujetos en terapia con warfarina y a un grupo de sujetos pareados por la edad que no usaban warfarina para evaluar la validez de construcción. A un sub-grupo de pacientes en warfarina se les repitió la prueba aproximadamente 2–3 meses luego de la primera prueba para evaluar la confiabilidad prueba–reprueba. La confiabilidad de consistencia interna se evaluó calculando el valor de coeficiencia Kuder–Richardson 20. Se usó un análisis de ítems para evaluar las preguntas individuales.

RESULTADOS: Se realizó una prueba piloto de un instrumento de 23 ítems para evaluar legibilidad y comprensión. La Prueba de Conocimiento de Anticoagulación Oral se le administró a 74 sujetos que usaban warfarina y 27 sujetos pareados por la edad que no usaban warfarina. Treinta y dos sujetos en warfarina repitieron la prueba en un promedio de 75 días luego de la primera administración. Los sujetos en warfarina obtuvieron una puntuación significativamente mayor que los que no usaban warfarina (72% vs 52%, respectivamente; $p < 0.001$), apoyando así la validez de construcción del instrumento. La confiabilidad prueba–reprueba fue aceptable, con un coeficiente de correlación de Pearson de 0.81. La confiabilidad de consistencia interna fue confirmada por un valor de Kuder–Richardson 20 calculado de 0.76.

CONCLUSIONES: La Prueba de Conocimiento de Anticoagulación Oral es un instrumento breve, válido, y confiable de evaluación de conocimiento que puede ser útil para la investigación y en la práctica clínica para mejorar los programas de educación al paciente.

Giselle Rivera-Miranda

RÉSUMÉ

CONTEXTE: Les études évaluant la relation existant entre les connaissances du patient concernant le traitement à la warfarine et son utilisation sécuritaire et efficace sont limitées par le manque d'outils validés d'évaluation des connaissances.

OBJECTIF: Développer et valider un instrument permettant d'évaluer les connaissances du patient envers l'anticoagulothérapie orale.

MÉTHODOLOGIE: Quatre experts de l'anticoagulothérapie reconnus nationalement ont participé au processus de développement de l'instrument d'évaluation afin d'en assurer la validité du contenu. Le test de connaissances de l'anticoagulothérapie orale (OAK) a été administré à des patients prenant de la warfarine ainsi qu'à un groupe de sujets appariés pour l'âge et ne prenant pas de warfarine pour évaluer la validité de l'instrument. Un sous-groupe de patients recevant la warfarine a fait l'objet d'une analyse répétée environ 2–3 mois après l'évaluation initiale afin de déterminer la reproductibilité test–retest. La reproductibilité interne a été déterminée à partir du calcul de la valeur Kuder–Richardson 20. Une analyse a été effectuée afin d'évaluer la performance des questions de l'instrument.

RÉSULTATS: Un instrument comportant 23 questions a été testé pour en évaluer la lisibilité et la compréhension. Le test OAK a été administré à 74 patients traités à la warfarine ainsi qu'à 27 sujets appariés pour l'âge et ne prenant pas de warfarine. Vingt-deux patients du groupe traités à la warfarine ont répété le test OAK en moyenne 75 jours après le premier test. Le pointage des patients sous warfarine était significativement plus élevé que celui obtenu par les sujets ne prenant pas de warfarine (72% vs 52%, respectivement; $p < 0.001$), confirmant la validité de l'instrument. La reproductibilité test–retest était acceptable, avec un coefficient de corrélation de Pearson de 0.81. La valeur Kuder–Richardson 20 a été de 0.76, confirmant ainsi la reproductibilité interne.

CONCLUSIONS: Le test OAK est un instrument court, valide, et reproductible permettant l'évaluation des connaissances en regard de l'anticoagulothérapie orale et pouvant s'avérer utile en recherche et en clinique pour améliorer les programmes d'éducation des patients.

Alain Marcotte