Validation of A Knowledge Test For Turkish Patients on Warfarin Therapy at An Ambulatory Anticoagulant Clinic

Antikoagülan Polikliniğinde Varfarin Tedavisi Alan Türk Hastalarda Bilgi Testinin Validasyonu

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ABSTRACT
INTRODUCTION: The aim of the present study was to evaluate the validity and reliability of an oral anticoagulation knowledge test for Turkish patients on warfarin therapy at an anticoagulant outpatient clinic.
METHODS: This study was conducted at an ambulatory anticoagulation clinic with patients over 18 years old who had been using warfarin for at least six months. Demographic and clinical data were collected from all patients. Internal consistency was calculated using the Kuder Richardson coefficient, and test-retest reliability of the Turkish version of the Oral Anticoagulation Knowledge test was assessed.
RESULTS: Patients' (n=240, 133 female) mean age was 59.83±11.93 (26-90) years. The mean score Oral Anticoagulation Knowledge test score was 14.19±3.01. The test-retest reliability of the scale (n=30) was moderate for the total score (p<0.001). The Kuder-Richardson 20 value, a measure of internal consistency, was calculated as 0.671. Patients with a younger age and higher education level were more likely to have higher levels of anticoagulation knowledge than patients with a higher age and lower education level (p<0.05 for both comparisons).
DISCUSSION AND CONCLUSION: The Turkish version of the Oral Anticoagulation Knowledge test can be used to determine patients' knowledge regarding oral anticoagulation.
Keywords: Warfarin, anticoagulant, knowledge, pharmacist
ÖZ
GİRİŞ ve AMAÇ: Bu çalışmanın amacı, antikoagülan polikliniğinde varfarin tedavisi alan Türk hastalar arasında oral antikoagülan bilgi testinin geçerliği ve güvenilirliğini değerlendirmektir.
YÖNTEM ve GEREÇLER: Çalışma, en az 6 aydır varfarin kullanan 18 yaşından büyük hastalar ile antikoagülasyon polikliniğinde gerçekleştirildi. Hastaların demografik ve klinik

verileri toplandı. Kuder Richardson katsayısı ve test-tekrar test güvenirliği kullanılarak Oral Antikoagülasyon Bilgi Testi'nin Türkçe versiyonunun iç tutarlılığı değerlendirildi.

BULGULAR: 240 hastanın (133 kadın) yaş ortalaması 59,83 ± 11,93 (26-90) idi. Oral Antikoagülasyon Bilgi Testi'nin ortalama skoru 14,19 ± 3,01 olarak hesaplandı. Ölçeğin test-tekrar test güvenirliği (n = 30) toplam skor için orta düzeyde bulundu (p<0,001). İç tutarlılık güvenirliği, hesaplanan Kuder-Richardson 20 değeri (0,671) ile doğrulandı. Daha genç ve yüksek eğitim düzeyindeki hastalar, daha ileri yaşta ve düşük eğitim düzeyindeki hastalarla karşılaştırıldığında daha yüksek antikoagülasyon bilgisine sahipti (Her iki karşılaştırma için p <0,05).

TARTIŞMA ve SONUÇ: Sonuç olarak, Oral Antikoagülasyon Bilgi Testi'nin Türkçe versiyonunun hastaların oral antikoagülasyon hakkındaki bilgilerini belirlemek amacıyla kullanılabilecek uygun bir test olduğu görülmüştür.

Anahtar Kelimeler: Varfarin, antikoagülan, bilgi, eczacı

INTRODUCTION

Warfarin is mostly used as an oral anticoagulant for the prophylaxis and management of primary and secondary thromboembolism.[1-3] Although the new oral anticoagulants have been developed recently; warfarin is the most commonly prescribed vitamin K antagonist in clinical settings.[2-4] However; patients are subject to risks while being treated with warfarin.[1,2] Bleeding is a common adverse event that occurs at an annual rate of 7-8% among patients treated with warfarin. Additionally, It was reported that the most common cause of drug-induced emergency department admissions was related to warfarin use.[5] Warfarin's narrow therapeutic range and wide dose-response variability should be considered when managing its use in treatment.[1] Patients treated with warfarin should be closely monitored to ensure their adherence to warfarin therapy and to detect and prevent.[6] Serious problems may occur if the patients adhere poorly to medication, especially those with a narrow therapeutic range such as warfarin. Missed doses decrease the efficacy of the medication, and overdoses cause various adverse effects.[7]

Wank et al.[8] showed a relationship between the level of medication adherence and the level of knowledge about the medication among patients using warfarin. In the study conducted in Turkey, poor medication adherence in the patients receiving anticoagulant therapy was associated with poor time in therapeutic range (TTR), poor warfarin knowledge, and a higher bleeding score.[9] Based on the findings of multicentre study conducted in Turkey, poor knowledge about potential warfarin-food interactions was more common in older patients.[10] To our best knowledge, there is no valid and reliable anticoagulation knowledge test in Turkish. Few validated anticoagulation knowledge tests exist for this purpose.[11-13] The Oral Anticoagulation Knowledge (OAK) test used in our study was short when compared with other questionnaires[11-12] and is commonly used as a reliable and valid tool in the United States,[14] Malaysia[15] and Brazil[1] to identify and evaluate patients' knowledge about anticoagulation. The aim of the present study was to evaluate the validity and reliability of a knowledge test for Turkish patients on warfarin therapy at an ambulatory anticoagulant clinic.

MATERIALS AND METHODS

Participant and setting

Previous research has suggested that the number of test items should be multiplied by 10 to give the number of participants, so a total of 200 patients was required for an adequat sample size for this methodological study.[16] Allowing for a 20% loss due to missing data or participants discontinuing during the study, the necessary sample size was calculated as a total of 240 patients.

This methodologic study was conducted at the Outpatient Anticoagulation Clinic of a university hospital located in Istanbul between 15 April 2017 and 15 October 2017. The clinic

mostly provided a service that adjusted patients' warfarin dose according to their international normalised ratio (INR). Patients over 18 years old who had been using warfarin for at least the past 6 months and had at least four INR measures in their medical records, were eligible for this study. Patients who could not read were excluded from the study.

The study was approved by the Ethical Committee of Marmara University, Institute of Health Sciences. Informed consent was obtained from all participants.

Data collection

Patients' demographic and clinical data including their age, gender, education level, the total number of medications used, indication for oral anticoagulant therapy, and previous INR measurements were collected using individual interviews and patients' medical charts. Individual interviews were conducted by a single researcher (MT). At least four consecutive INR measurements taken at least a month and no more than 2 months apart were retrospectively recorded from patients' medical charts. Patients' TTR was calculated using the method developed by Rosendaal et al.[17]

Translation and Cross-cultural Adaption of The OAK test

Permission to use the OAK test for the present study was obtained from Zeolla et al.[14] This knowledge test includes a total of 20 questions about follow-up, drug-drug interactions, fundamental medication information, adverse effects and nutritional problems. Higher test scores indicated a better level of oral anticoagulant knowledge.[14] Patients were classified into three groups according to their total score of the OAK test score based on previous studies.[1,13,18] Patients with total OAK test scores of less than 10 (< 50%) had low anticoagulation knowledge, and patients with total OAK test scores between 10 and 15 (50–75%) had moderate anticoagulation knowledge. Finally, patients with total OAK test scores of more than 15 (> 75%) had good anticoagulation knowledge.

The original English test was translated to Turkish independently by two native speakers of Turkish who also were fluent in English. Then, two of the researchers (MS and RD) researchers reviewed the translations and reconciled them into one Turkish version. This Turkish version was back-translated backward to English independently by two native speakers of English who were also fluent in Turkish. Differences between this draft English version and the original English version were evaluated by two researchers (MT and BO). After the translation process, the draft Turkish version was evaluated for grammar, conceptual equivalence and cultural compatibility by experts (two clinical pharmacists, an internal medicine specialist, a cardiologist, and a nurse) and also a Turkish literature lecturer. A pilot study was conducted in a group of patients (n = 20) to perform cultural adaptation. It took approximately 10–12 minutes to complete the test. To assess test-retest reliability, the knowledge test was completed by 30 patients from the study population within a duration of 2 weeks. To analyse construct validity, demographic and clinical data in each anticoagulant knowledge group were evaluated.

Data Analysis

Categorical data were presented as numbers and percentages. Continuous data were presented as mean ± standard deviation (SD) or median and interquartile range (IQR). Normality of distribution was using the Kolmogorov-Smirnov test. Test-retest reliability was assessed using the Spearman's correlation test. To measure internal consistency, a Kuder-Richardson 20 (KR-20) coefficient value was calculated for the OAK test. Continuous data between two and three or more groups were analysed using the Mann-Whitney U test or Kruskal Wallis tests, respectively. Categorical data were analysed by using the chi-square test. In this study, *p* values < 0.05 were statistically significant.

RESULTS

This study was conducted among 240 patients (133 female) who were being treated with warfarin. Demographic and clinical characteristics of patients have been presented in Table 1.

Participants mean age was 59.8±11.9 (26-90) years old. Mean OAK test score was 14.2 ± 3.0. The most frequent wrong responses were related to drug-drug and drug-food interactions. Less than half of the patients did not know was the correct way to distinguish between different strengths of warfarin. The correct answer for this question varied from that in the original scale developed by Zeolla et al.[14] due to differences between the national health systems in each country. This was emphasised in the validation study of the Brazilian version of the OAK test.[1] The right answer in Turkish version was 'size' rather than 'color', and this was taken into consideration during scoring. The percentage of correct answers, corrected item-total correlation and Kuder-Richardson coefficients if each item was deleted have been shown in Table 2.

The Kuder-Richardson 20 coefficient was 0.671. There was a strong correlation between test-retest results of patients' total score on the OAK test at baseline and 2 weeks later ($r=0.739$; $p<0.001$; data not shown).

Patients with a younger age and higher education level were more likely to have higher OAK test scores than patients with a higher age and lower education level ($p<0.05$; Table 3). There was no significant difference in TTR scores or the number of medications used between patients with low, moderate and high anticoagulant knowledge ($p>0.05$; Table 3). Evaluation of related factors (demographic and clinical characteristics of the patients) in groups according to patients' anticoagulant knowledge have been shown in Table 3.

DISCUSSION

In this study, the validity and reliability of the Turkish version of the OAK test were evaluated. The Turkish version of the OAK test was valid and reliable. The Kuder-Richardson 20 value in the study conducted in Brazil was calculated as 0.818.[1] In the United States, the Kuder-Richardson value was found to be 0.76.[14] Although the value obtained in our study was acceptable, it was lower than the value obtained in the previously mentioned studies. The rate of the right responses in the present study was similar to that obtained by Praxades et al.[1] The total number of correct responses in studies carried out in the United States[14], Brazil[1], India[18] and Saudi Arabia[13] were also similar to our study.

According to a study conducted in India, 50% of patients using oral anticoagulants had OAK test of less than 10, 37% had scores between 10 and 15 and 13% had scores over 15.[18] According to a study conducted in Denmark, patients had low knowledge of vitamin K antagonist.[19] In a study conducted in Toronto, more than half of the participants had insufficient knowledge about the vitamin K antagonists.[20] Patients had higher knowledge levels in our study compared to theses previous studies. In a study conducted in Brazil, which is similar to Turkey, 71% had insufficient knowledge.[1] In a study conducted in Malaysia, it was 11.2%.[15] When the OAK test score in a study conducted in Singapore was evaluated, patients had a moderate knowledge level.[8] However, another study was reported that more than half of the sample had a poor knowledge level.[13] Consistent with this study, similar results, ranging from 61.2% to 70%, were found in other studies.[21,22] These results highlight the need for intensive training and awareness programs to increase patient knowledge on such serious issues.

Female participants had better knowledge of oral anticoagulants than male participants in the present study. Similar results were obtained in a study conducted in Saudi Arabia.[13,21] In the other studies, contrasting results were obtained.[20,22,23] Studies conducted in Toronto[20] and in North India[2] indicated that the total OAK test score was higher when participants had a higher the education level. These results were similar to our findings and those from other studies, which showed that OAK test scores were lower in older patients.[2,14, 24,25]

In this study, no significant correlation was found between TTR and the OAK test scores, which suggested that there was no correlation between good anticoagulant knowledge and good INR control. A similar result was obtained in studies conducted in Saudi Arabia.[13,23]

Like our study, some international studies evaluating the relationship between patients' knowledge about oral anticoagulants and anticoagulation control using the Rosendaal method concluded that there was no significant relationship between them.[15,26,27] In another study conducted in the United States, there was no significant correlation between patients' warfarin knowledge and their INR control.[28] In a study conducted in China, a different result was obtained.[29] Shilbayeh et al.[13] stated that incompatible results could be attributed to differences in test items, languages, settings, INR control measures, and different sample sizes.

When examining the oral anticoagulation knowledge tests developed so far, the scale we used in terms of both content and validity was like the scale developed by Briggs et al.[11] However, while the scale we used was valid only for vitamin K antagonists, a scale developed by Obamiro et al.[12] can be used for vitamin K antagonists and direct-acting oral anticoagulants. While this scale includes multiple choice and open-ended questions, the scale we used included only multiple-choice questions. Based on our best knowledge, there is no existing validated test that assess patients' knowledge of oral anticoagulants in our country.

In future studies, the potential impact of duration of warfarin therapy on patients' anticoagulant knowledge test result should be evaluated. Besides patients' anticoagulant knowledge level, the problems related with medication administration (such as the dose adjustment difficult; which was particularly due to limited the strengths of warfarin tablets in Turkey) might be also assessed. It is necessary to provide comprehensive patient education for patients' receiving warfarin therapy. Using the OAK test in a clinical setting could provide an opportunity for health care providers to identify and resolve patients' misunderstandings and/or correct any misinformation they may have encountered. This brief test could easily be conducted in outpatient clinics, as it only requires a short time to complete (10–12 minutes).

STUDY LIMITATIONS

The generalizability of the results to different patient groups in Turkey may be limited in this study; because it was conducted in a single outpatient clinic in Turkey. Another limitation of the study was that the OAK test was designed by Zeolla et al.[14] was to be self-administered by individuals with at least a seventh-grade education level. However, in the most of studies that have used the OAK test, including the present study, it was used with individuals who had an education level lower than this.

CONCLUSION

The Turkish version of OAK test can be used to determine patients' knowledge regarding oral anticoagulation. This scale would be helpful for identifying patients who need education and counselling regarding warfarin therapy. In addition, it can be used to assess changes in patient knowledge after education and/or counselling. The test can be used to identify and resolve patients' misunderstandings about anticoagulant therapy and/or correct misinformation to which they may have been exposed. Test items may remind patients and providers of key points to consider during warfarin therapy.

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CONFLICT OF INTEREST

None

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TABLES

Table 1. Demographic and clinical characteristics of the participant (n=240)

Characteristics	
Age, mean (SD) **median (25-75 percentile)**	59.8 (11.9) 61.0 (52.0-68.8)
Age group, n (%)	
18-40	16 (6.7)

41-60	102 (42.5)
61-80	116 (48.3)
>80	6 (2.5)
Sex, n (%)	
Female	133 (55.4)
Male	107 (44.6)
Marital status, n (%)	
Married	199 (82.9)
Single	41 (17.1)
Education, years, mean (SD)	6.6 (3.7)
median (25-75 percentile)	5.0 (5.0-8.0)
Education group according to the years of education, n (%)	
<8 years	164 (68.3)
≥ 8 years	76 (31.7)
TTR, mean (SD)	52.2 (30.4)
median (25-75 percentile)	52.0 (28.0-77.0)
Group of TTR, n (%)	
TTR<50%	114 (47.5)
TTR 50–75%	64 (26.6)
TTR>75 %	62 (25.8)
The number of medications used, mean (SD)	3.68 (2.37)
median (25-75 percentile)	3.0 (2.0-5.0)
Polypharmacy **(*defined as concurrent use of 5 or more medications*)** **n (%)**	
Yes	174 (72.5)
No	66 (27.5)
Indication, n (%)	
Prosthetic heart valve	126 (46.5)
AF	62 (22.9)
Valvular Heart Disease	35 (12.9)
DVT/PTE	44 (16.3)
Acute MI/Recurrent TIA	5 (1.5)
20 question- Oral Anticoagulation Knowledge percentage mean± SD **median (25-75 percentile)**	14.2±3.0 12.0 (14.0-16.0)
Oral Anticoagulation Knowledge categories n(%)	
<50 % (low level of knowledge)	21 (8.8)
50–75 % (moderate level of knowledge)	134 (55.8)
>75 % (high level of knowledge)	85 (35.4)

SD, standard deviation; TTR, time in therapeutic range; AF, atrial fibrillation; DVT, deep vein thrombosis; PTE, pulmonary thromboembolism; MI, myocardial infarction; TIA, transient ischemic attack.

Table 2. The percentage of correct answers, corrected item-total correlation and Kuder-Richardson coefficients if item deleted (n=240)

Questions with correct answers	Percentage of correct answers (n)	Corrected Item-Total Correlation	Kuder-Richardson coefficients if item deleted
1. Missing one dose of warfarin: *Correct answer:* b. can alter the drug's effectiveness	66.7 (160)	0.293	0.654
2. You can distinguish between different strengths of warfarin tablets by what? *Correct answer:* c. size	36.2 (87)	0.205	0.665
3. A patient on warfarin therapy should contact the physician or healthcare provider who monitors it when: *Correct answer:* d. all of the above	85.0 (204)	0.189	0.665
4. Occasionally eating a large amount of leafy greens vegetables while taking warfarin can: *Correct answer:* b. reduce the effectiveness of the warfarin	41.7 (100)	0.295	0.654
5. Which of the following vitamins interacts with warfarin? *Correct answer:* d. vitamin K	40.8 (98)	0.438	0.635
6. When is it safe to take a medication that interacts with warfarin? *Correct answer:* b. if your healthcare provide is aware of the interaction and checks your PT/INR ("Protime") regularly	60.8 (146)	0.214	0.664
7. PT / INR ("Prothrombin Time") test: *Correct answer:* a. a blood test used to monitor your warfarin therapy	98.3 (236)	0.063	0.672
8. Warfarin may be used to: *Correct answer:* a. treat people that already have a blood clot	99.2 (238)	0.129	0.670
9. A patient with a PT/INR ("Protime") value below their "goal range": *Correct answer:* b. is at an increase the risk of having a clot	77.9 (187)	0.365	0.646
10. Taking a medication containing aspirin or other non-steroidal anti-inflammatory medications such as ibuprofen while on warfarin will: *Correct answer:*	60.0 (144)	0.339	0.648

b. increase your risk of bleeding from the warfarin			
11. A person on warfarin should seek immediate medical attention: *Correct answer:* b. if they notice blood in their stool when going to the bathroom	48.3 (116)	0.292	0.654
12. Skipping even one dose of your warfarin can: *Correct answer:* c. cause your PT/INR("Protime") to be below the "goal range"	79.2 (190)	0.261	0.658
13. Drinking alcohol while taking warfarin: *Correct answer:* b. may affect your PT/INR ("Protime")	82.1 (197)	0.367	0.647
14. Approximately how often should you have PT / INR ("Prothrombin Time") measured when you are stabilized with the correct warfarin dose (PT / INR is at target values)? *Correct answer:* b. once a month	94.2 (226)	0.251	0.662
15. It is important for a patient taking warfarin to monitor for signs of bleeding: *Correct answer:* b. at all times	80.8 (194)	0.038	0.681
16. The best thing to do if you miss a dose of warfarin is to? *Correct answer:* b. take the next scheduled dose and tell your healthcare provider	81.2 (195)	0.169	0.668
17. When it comes to diet, people taking warfarin should: *Correct answer:* c. be consistent and eat a diet that includes all types of food	84.2 (202)	0.086	0.675
18. Each time you get your PT/INR ("Protime") checked, you should: Correct answer: d. let your doctor know if you missed any doses of warfarin	90.0 (216)	0.108	0.671
19. Which of the following over-the-counter products is most likely to interact with warfarin? *Correct answer:* b. herbal / dietary supplements	32.9 (79)	0.421	0.638
20. A patient with a PT/INR("Protime") value above the "goal range": *Correct answer:* c. is at an increased risk of bleeding	79.6 (191)	0.313	0.652

Table 3. Factors (demographic and clinical characteristics of the patients) in groups according to patients' anticoagulant knowledge (n=240)

	The anticoagulation knowledge test score			
	<50% (n=21)	**50-75% (n=134)**	**>75% (n=85)**	**p**
Age mean±SD median (25-75 percentile)	64.4±13.0 68.0 (53.5-72.5)	61.2±11.3 61.0 (53.8-69.2)	56.4±11.9 58.0 (48.0-64.0)	<0.01
Education, years. *mean±SD* median (25-75 percentile)	6.5±4.0 5.0 (5.0-9.5)	5.4±2.9 5.0 (5.0-5.0)	8.5±3.9 8.0 (5.0-11.0)	<0.001
TTR, mean±SD median (25-75 percentile)	49.5±27.0 45.0 (29.0-74.5)	51.4±30.8 50.5 (28.0-76.0)	54.0±30.8 59.0 (26.0-80.5)	NS
The number of medications used, *mean±SD* median (25-75 percentile)	3.6±2.4 3.0 (2.0-5.0)	3.7±2.4 3.0 (2.0-5.0)	3.7±2.3 3.0 (2.0-5.0)	NS
Gender				
Female n(%)	5 (2.1)	81 (33.8)	47 (19.6)	<0.01
Male n(%)	16 (6.7)	53 (22.1)	38 (15.8)	
Education group according to the years of education				
<8 years n(%)	15 (6.2)	108 (45.0)	41 (17.1)	<0.01
≥ 8 years n(%)	6 (2.5)	26 (10.8)	44 (18.3)	
Marital status				
Married n(%)	19 (7.9)	107 (44.6)	73 (30.4)	NS
Single n(%)	2 (0.8)	27 (11.2)	12 (5.0)	

SD, standard deviation; TTR, time in therapeutic range; NS, nonsignificant.