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Original article

Development, Reliability Testing and Validation of the Questionnaire for Assessing Patient Knowledge about the Impact of Food on the Efficacy of Oral Anticoagulants

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SUMMARY

Oral anticoagulants, vitamin K antagonists (varfarin and acenocoumarol), are widely used for primary and secondary prevention of thromboembolic events. Previous studies have shown that patients had a low level of knowledge on warfarin, especially its interactions with food.

The study was aimed at the development, reliability testing and validation of the questionnaire on patients' knowledge about the impact of food on the efficacy of oral anticoagulants.

We performed a prospective study based on the development, validation and testing the reliability of the questionnaire on patient knowledge about the impact of food on the efficacy of oral anticoagulants. The study involved patients from the General Hospital "Studenica" in Kraljevo.

The study included 226 subjects. The questionnaire consisted of 10 questions. Cronbach α coefficient, after the elimination of inappropriate questions, was 0.882. The questionnaire consisted of two factors which represented 50.07% and 10.03% of the variance of the questionnaire.

This is a unique, reliable and valid questionnaire that measures the level of patient knowledge on the impact of food on the efficacy of oral anticoagulants. Using this questionnaire, as an instrument, makes it possible to identify patients who use oral anticoagulants with insufficient knowledge about possible drug-food interactions.

Key words: **anticoagulants, knowledge, food**

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INTRODUCTION

Oral anticoagulant therapy (OAKT) is used for primary and secondary prevention of thromboembolic events in conditions such as atrial fibrillation, artificial heart valves, and recurrent thrombosis (1). Oral anticoagulant drugs that are commonly used are vitamin K antagonists (warfarin and acenocoumarol). Dosing is individual, and the parameter for monitoring the patient anticoagulation state is INR (International normalized ratio of prothrombin time). Optimal therapeutic range of INR depends on an indication and is usually between 2 and 3 (2, 3). Side effects of this therapy are bleeding and thromboembolic events that are directly connected with the coagulant status of a patient (4). Fluctuations of INR occur frequently due to a dosage regimen, changes in intake of foods rich in vitamin K, changes in absorption of drugs and vitamin K, changes in metabolism of OAKT, changes in synthesis of coagulation factors dependent on vitamin K, comorbidities, concomitant therapy and patient's compliance to the prescribed dosage regimen (2, 3). As the effect of the therapy is reflected in the INR, its value is in reverse correlation with the intake of foods rich in vitamin K, and it is very important for patients to understand this issue for the success of therapy (5). At the time of the commencement of anticoagulation therapy, the attending physician should inform the patient not only about the drug benefits, dosing regimen, regular monitoring of anticoagulant status and adverse effects, but also about the impact of food on efficacy (6).

Patients who are on OAKT are told to keep constant intake of food rich in vitamin K on a weekly basis (3). They should be informed about possible changes of INR if they take certain foods, for example, avocado and soy milk (high content of vitamin K) will decrease INR and fish oil, mango and grapefruit juice will increase the effect OAKT and INR (7).

Previous studies that dealt with assessing the knowledge of patients on oral anticoagulant therapy indicated that patients avoid to answer the questions concerning the food or give wrong answers. So far, there are only two validated questionnaires which measure the knowledge of patients on anticoagulant therapy, OAK (Oral Anticoagulation Knowledge) from 2006, and AKA (Anticoagulation Knowledge Assessment) from 2005 (8, 9). Baker et al. in their study of the relation between patient knowledge of OAKT and their INR values used the AKA questionnaire. Among the eight most common questions that were answered incorrectly, four were related to eating habits (10). In other studies which evaluated the patient knowledge by the same questionnaire, 60-80% of patients were not aware of the interactions of food with warfarin (11, 12).

A researcher from Germany, in a cluster study with 22 centers, evaluating patient knowledge about OAKT found that 2/3 of the patients were not familiar with the fact that their therapy required constant intake of foods rich in vitamin K, while 17% thought that vegetables should be absolutely out of use (13).

Even 21.8% of patients examined in one Brazilian study did not know that food was one of the predictive factors for their anticoagulation status (14). Only a third of the patients knew that during oral anticoagulant therapy they should respect the rules of regularity concerning the intake of salads and vegetables. About 11% were probably misinformed and assumed that the vegetables should be avoided (10). Avoidance of vegetables in order to reduce variation in intake of vitamin K is not compatible with a healthy diet, as recommended by the current guide (15).

These results indicate a lack of knowledge and inadequate patient education about the interactions among OAKT and food. Since this interaction is essential to the effectiveness of therapy, INR stability and reduction of side effects, adequate patient education has to be provided. The study was aimed at the development, reliability testing and validation of the questionnaire which will assess patient knowledge about the impact of food on the efficacy of vitamin K antagonist.

MATERIAL AND METHODS

POPULATION AND THE SAMPLE

The study included patients who were on oral anticoagulant therapy with antagonists of vitamin K (regardless of duration of use), and it was approved by the Ethics Committee of the General Hospital "Studenica" Kraljevo. There were 226 patients older than 18 years who agreed to participate in the study and complete the questionnaire. All 226 patients were asked to complete a questionnaire in April and May 2016. The study excluded subjects who refused to participate in the study, did not understand the information about the study even after the oral explanation, illiterate and cognitively impaired patients.

CONSTRUCTION OF THE NEW QUESTIONNAIRE

Development of the questionnaire on patients' knowledge about the impact of food on the efficacy of

oral anticoagulant therapy (FOAK) had three steps: theoretical, empirical and analytical. The first step was theoretical and referred to review of literature in order to establish theoretical rationale for the questionnaire. The second step was empirical and related to the administration of questionnaires and data collection, while the last step was analytical, implying statistical data processing for the purpose of the validation of the questionnaire.

The items in the questionnaire were divided into two parts, one with general issues related to the patient and therapy, and others with specific statements about the impact of food on the effect of anticoagulant drugs. Questions about food corresponded to the categories of food: vegetables, fruits, milk and milk products, meat and eggs, oil and beverages (16). Each item was constructed in the form of positive statement which should reflect certain element of knowledge. Five possible answers were offered for each statement, in the form of the Likert scale: "completely disagree", "partially disagree", "neither agree nor disagree", "partially agree" and "completely agree".

Each answer was rated from 1 to 5, so the lower score corresponded to better knowledge. The statements were formulated either affirmatively or negatively, in order to minimize the tendency of respondents to answer in a consistent manner, using the answers of only one part of the Likert scale. For this purpose, the questionnaire included a question that stands out from the rest and reflects social desirability (17).

Validation of content (*Content validity*) and clarity of the questions was done by a team of one subspecialists in cardiology and one in hematology from the general hospital „ Studenica“ in Kraljevo, who were familiar with prescribing OAKT. For each question, they were given an option to adapt it, and they were also asked to propose new questions, if considered absolutely essential. After reviewing the initial pool of questions, 15 remained in the final version of the questionnaire that were rated as the clearest and the most relevant.

RELIABILITY TESTING

Reliability of the questionnaire was tested by three methods. First, internal consistency was determined through the calculation of Cronbach's alpha for the questionnaire as a whole. Second, the questionnaire was divided by split-half method into two parts with the same number of questions, and Cronbach's alpha for each of the parts was calculated. Using the alphas for both parts, number of questions in each part and average correlation between questions in both parts of the questionnaire, the Spearman-Brown coefficient for the questionnaire as a whole was calculated by the Spearman-Brown "prediction" formula (18, 19). Third, the mean score and its variances were calculated for each question in order to check their suitability for measurement of the full extent of knowledge.

FACTORIAL ANALYSIS

Exploratory factorial analysis of the questionnaire was made in order to discover the principal factors (20). First, suitability of the questionnaire and sample for factorial analysis was tested by Kaiser-Meyer-Olkin measure of sampling adequacy and by the Bartlett's test of "sphericity". Then, the factors were extracted at first without rotation, with conditions that "eigen values" had to be greater than 1.0, and using Scree-plot (the extracted factors were above the "elbow" of the graph). Second, referent "axes" were rotated orthogonally, by the varimax method, and another extraction of the factors was made, using the same criteria as for the unrotated solution. Extracted factors were than named accordingly.

VALIDITY

Criterion *validity* was estimated based on the correlation with a similar questionnaire, which was considered the "gold" standard for measuring patients' knowledge. However, since questionnaires designed to assess the knowledge of patients on anticoagulant therapy were not available to us we could not carry out convergent criterion validation. However, we conducted divergent validation of the questionnaire using the Short Subjective Well-being Scale (SSWS). The permission to use the Short Subjective Well-being Scale in Serbian language (which measures feeling of well-being, and was previously validated in Serbian population) was granted by Doc Dr. Veljko Jovanović, psychologist, University of Novi Sad, Serbia (21, 22). The correlations between scores on the questionnaires were calculated. All calculations were performed by SPSS statistical software, version 18.0 (23).

TEMPORAL STABILITY

Temporal stability of the FOAK questionnaire results was tested by the second completion of the questionnaire by the investigators who repeatedly interviewed the patients one month after the first encounter. The

patients were invited to the second encounter by phone.

RESULTS

CHARACTERISTICS OF THE SAMPLE

The first version of the food-oral anticoagulants interactions knowledge (FOAK) questionnaire contained 15 questions, and was completed by 226 patients treated with oral anticoagulants in Kraljevo municipality. Of all respondents, 53.5% (121) were male and 46.5% (105) female. The average age was 71.56 ± 6,49 years, a range of 45 to 90 years. An average number of years of school education was 9.25 ± 3.64 with a minimum of 0 and a maximum of 17 years spent in school. About 68.1% of patients were on OAK treatment for more than one year, 20.8% from 6 months to a year, 8.0% from 3 to 6 months and 3.1% for less than 3 months. Two point seven percent of patients of received information about the impact of food on the effect of anticoagulant therapy from their selected general practitioners, 46.5% from specialists and 50.9% of respondents did not receive any information from doctors, but educated themselves from other patients or read articles on the Internet. Among respondents there were 50% (113) of those with atrial fibrillation, 18.6% (42) with recurrent thrombosis, 5.3% (12) with artificial heart valves, and 26.1% (59) who used anticoagulant therapy for other reasons.

RELIABILITY TESTING

After testing original 15 items of the questionnaire, and examining the resulting of correlation matrix, mean values, variance, "skewness" and kurtosis of distributions of responses for each of the items, 5 items were removed, leaving final version of the FOAK questionnaire with 10 items. (Appendix 1) Cronbach's alpha of the final version with 10 items was 0.882. Mean values of responses, standard deviations "skewness" and kurtosis and the value of the corrected total score, for each item are shown in Table 1. After division of the questionnaire by the split-half method, the Spearman-Brown coefficient for the questionnaire as a whole was calculated by the Spearman-Brown "prediction" formula, and its value was 0.820.

Appendix 1

"Knowledge of patients about the effects of nutrition on its impact on oral anticoagulant therapy" (FOAK)

I Please carefully read each sentence and answer by rounding the exact statement that refers to your information.

1. Gender:
   - Male
   - Female
2. Age _____
3. The length of therapy with anticoagulant drugs:
   - Up to 3 months;
   - 3 to 6 months;
   - From 6 months to one year;
   - More than a year.
4. Years spent in education (enter the number) _____
5. Information on the impact of food on therapy to you by:
   - Elected by a general practitioner;
   - Medical specialists;
   - Other.
6. Clinical diagnosis for using oral anticoagulant therapy:
   - Atrial fibrillation;
   - Recurrent thrombosis;
   - Artificial heart valve;
   - Other.

II Please carefully read each statement and respond by rounding the exact statement to which you agree

1. It is allowed to consume vegetables as you want.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
2. From the daily diet we should exclude vegetables.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
3. From week to week the vegetables from the group of green leafy vegetables like spinach, cabbage, spinach should be consumed in the same quantities.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
4. Green leafy vegetables has no impact on the value of INR.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
5. Vegetables from the group of legumes such as beans, peas, green beans do not lead to changes in the values of INR.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
6. It is allowed to eat all kinds of fruit as you like because it does not affect the value of the INR.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
7. Berry fruits affects the INR.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
8. If you increase your intake of fruits such as melon, pear, apricot your INR will be reduced.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"

9. Meat has no impact on the INR.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"
10. Alcohol has impact on the INR.
    1. "completely agree"
    2. "partially agree"
    3. "neither agree nor disagree"
    4. "partially disagree"
    5. "completely disagree"

Table 1. **Mean, standard deviation, variance skewness, kurtosis, and the value of the corrected total score**

Item	Mean response	Standard deviation	Variance	Skewness	Kurtosis	„Corrected" total score
1.	2.61	1.127	1.271	.390	-1.091	.615
2.	3.17	1.323	1.749	-.139	-1.308	.761
3	2.96	1.064	1.132	-.121	-.063	.669
4	3.48	1.799	3.237	-.498	-1.623	.775
5	2.72	1.103	1.217	.019	-1.496	.672
6	2.64	.899	.809	-.191	-.705	.542
7	2.87	.809	.655	-.117	1.533	.488
8	2.96	.729	.532	.332	3.202	.479
9	2.22	1.000	1.000	.459	-.817	.621
10	2.46	.718	.516	-.947	-.462	.614

FACTORIAL ANALYSIS

Factorial analysis was made by the principal components method. The Kaiser-Meyer-Olkin measure of sampling adequacy was 0.891 and the Bartlett's test of sphericity was significant (p = 0.000). Two factors were extracted before and after orthogonal rotation, explaining in total 60.114% of variance. The first factor bears 5.08 „eigenvalues" (50.08% of variance) and the second 1.04 „eigenvalues" (10.04% of variance).The rotated component matrix is shown in the Table 2. The first factor includes 7 questions (1, 2, 3, 4, 5, 9, 10) and second 3 (6, 7, 8). The first factor according to the issues that belong to him can be called "the knowledge about the most common consumed food" and a second "knowledge about less consumed food" (Table 3).

Table 2. **Percentage of variance, cumulative percentage of variance and "eigenvalues" of the two factors after rotation**

Factors	„Eigenvalue"	Percentage of variance	Cumulative percentage of variance
1	5.008	50.077 %	50.077 %
2	1.004	10.037%	60.114%

Table 3. **The rotated component matrix of the FOAK scale. Items within the shaded cells belong to the corresponding factor**

Item	Factor 1 - most commonly consumed food	Factor 2 - less consumed food
It is allowed to consume vegetables as you want.	**.641**	.287
From the daily diet vegetables.should be excluded	**.811**	.272
From week to week the vegetables from the group of green leafy vegetables like spinach, cabbage, spinach should be consumed in the same quantities.	**.664**	.343
Green leafy vegetables have no impact on the value of INR.	**.863**	.220
Vegetables from the group of legumes such as beans, peas, green beans do not lead to changes in the values of INR.	**.762**	.178
It is allowed to eat all kinds of fruit as you like because it does not affect the value of the INR.	.317	**.696**
Berry fruits affects the INR.	.206	**.749**
If you increase your intake of fruits such as melon, pear, apricot your INR will be reduced.	.201	**.772**
Meat has no impact on the INR.	**.610**	.321
Alcohol has impact on the INR	**.705**	.162

VALIDITY

Divergent criterion validity was tested through non-parametric correlation between scores of the FOAK scale and scores of the SSWS scale. Non-parametric correlation was chosen due to not-normal distribution of some of the scores. Based on the correlation coefficient of and the two scales (ϱ = -0 .027), it can be concluded that there was no correlation, which supports the divergent validity.

TEMPORAL STABILITY

The FOAK scale showed satisfactory temporal stability: when rating was repeated on the same patients one month later, the correlation between the scores (Pearson's coefficient) was 0.931 (p = 0.001). Cronbach's alpha after the repeated rating was 0.837.

DISCUSSION

The final version of the questionnaire "Food-oral anticoagulants interactions knowledge" (FOAK) showed high reliability with Cronbach' s coefficient 0.882, good construction and homogeneity of issues when splitting a questionnaire in two parts with the alpha values, 0.868 and 0.750. It also showed the temporal stability and divergent validity. Exploratory factor analysis indicated the presence of two factors that explained 60,114% variation.

The first factor relates questions (7 total) dedicated to the most common foods in the diet, vegetables, against which the patients have the most prejudices (especially green leafy vegetables), including meat and alcohol. Therefore, this factor can be called "Knowledge of patients about the most common foods in the diet." The internal consistency of this factor was high, Cronbach coefficient is 0.877, and it explained 50.077% of the variability.

In a study which evaluated the knowledge of patients about oral anticoagulant warfarin conducted by Baker et al. using AKA questionnaire, 55% of respondents answered correctly to the question about the effect of spinach on warfarin. This result is similar to 53.5% of correct answers to the question about the impact of green leafy vegetables on the INR in our questionnaire (10). In the same study, 31.9% of patients considered that green leafy vegetables should be absolutely eliminated from diet, while in our study, 76% of respondents either did not know (52.2%) or in varying degrees disagreed (23.8%) that green leafy vegetables should be consumed in constant amounts. Our results are similar to data from a study conducted by Shrestha et al. using AKA questionnaire (12). For groups of leguminous vegetables, opinions were divided, compared to 26.4% and 39.5% of respondents from these two studies, in which the respondents believed that the peas and celery have more influence on warfarin compared to cabbage and broccoli. That alcohol has an impact on the effect of anticoagulant therapy had absolutely or partially confirmed 40.7% of respondents, while the rest were not sure which was better, compared with 62% and 73.5% of the respondents in the mentioned studies, who thought that alcohol has no effect on warfarin (10, 11).

Second factor derived from analyzing FOAK questionnaire, which we called "Knowledge of patients about foods that are rarely consumed", contains only three questions. This factor has a slightly lower internal consistency, compared to the first, with Cronbah coefficient of 0.750 and explains 10.04% of the variance. Issues that are included in the second factor relate to the patients' knowledge about the impact of fruit on the effect of oral anticoagulant therapy. Medical professionals generally do not warn patients about these foods, because our eating habits are such that the fruit is rarely consumed and require the use of larger amounts in order to have an impact on the effect of therapy. As inadequate anticoagulation leads to serious side effects that can be fatal or extremely reduce the quality of life of the patient. It is important that patients know that fruit may influence their anticoagulation status.

Comparing the scores of the first and second factor, it was noted that the first factor had a higher average score than the second (19.10 > 9.19). This result indicated that patients had higher knowledge of the first domain, probably because of food categories and warnings from doctors. The factors divide items on those about foods with which patients are more or less familiar with. Scores of the first and second factor individually correlated significantly with the years spent on education (as distribution was normal Pearson's coefficient was used: r =.237, p = 0.01; 0.146 p = 0.05). The correlation between the total questionnaire score and the duration of therapy was not significant (0.31 p = 0.647) as shown by Hasan et al. and Rocha HT et al. in their studies (14, 24). On the other hand, Shrestha et al. showed a significant correlation between the total score of patients' knowledge and the length of therapy (11).

Previous studies of knowledge of patients about anticoagulant therapy showed that it was not satisfactory and that patients generally do not know the official dietary recommendations during oral anticoagulant therapy; this became apparent in our study, too (10-12, 24, 25).

Patient knowledge about the impact of food on the effect of vitamin K antagonist is important because greater awareness leads to a reduction in variations of anticoagulation status and adverse effects (26-28). Lack of knowledge of patients can be identified and repaired by creating a system to improve the quality of anticoagulant monitoring and patient safety. Although the best strategy for education of the patients have not been determined yet, they must be informed orally, at first, then acquainted with information from the existing brochures and later their knowledge should be evaluated by various questionnaires including FOAK that will indicate the need for additional education.

CONCLUSION

Based on the results of this study, we believe that FOAK is a useful tool for testing patient knowledge

about the effects of nutrition on anticoagulant therapy and could be of great importance for improving quality of life of these patients and reduction of side effects.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Izrada, ispitivanje pouzdanosti i validacija upitnika za procenu znanja bolesnika o uticaju hrane na efikasnost oralne antikoagulansne terapije

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SAŽETAK

Oralni antikoagulansi, antagonisti vitamina K (varfarin i acenokumarol) u širokoj su upotrebi za primarnu i sekundarnu prevenciju tromboembolijskih događaja. Dosadašnje studije su pokazle da bolesnici imaju nizak nivo znanja o varfarinu, posebno njegovoj interakciji sa hranom.

Cilj studije bio je izrada, ispitivanje pouzdanosti i validacija upitnika o znanju bolesnika o uticaju hrane na efikasnost oralnih antikoagulanasa.

Sprovedena je prospektivna studija bazirana na izradi, proveri pouzdanosti i validaciji upitnika o znanju bolesnika o uticaju hrane na efikasnost oralnih antikoagulanasa. Studija je sprovedena na bolesnicima u Opštoj bolnici "Studenica" u Kraljevu.

U istraživanju je učestvovalo 226 ispitanika. Upitnik se sastojao od 10 pitanja. Kronbahov koeficijent α, nakon eliminacije neadekvatnih pitanja, iznosio je 0,882. Upitnik čine dva faktora, koji predstavljaju 50,07% i 10,03% varijanse upitnika.

Ovo je jedinstven, pouzdan i validan upitnik koji meri nivo zananja bolesnika o uticaju hrane na efikasnost oralnih antikoagulanasa. Upotrebom ovog upitnika, kao instrumenta, moguće je identifikovati bolesnike koji koriste oralne antikoagulanse sa nedovoljnim znanjem o mogućoj interakciji leka sa hranom.

Ključne reči: **antikoagulansna terapija, znanje, namirnice**