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RESEARCH ARTICLE

DEVELOPMENT OF ADHERENCE TO ANTICOAGULANT THERAPY SCALE: A VALIDITY AND RELIABILITY STUDY

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ABSTRACT

Purpose: Anticoagulants are an important group of drugs used by many patients with different diseases. There are general adherence scales that measure adherence to treatment in the literature. However, the correct use of the drug alone is not sufficient for adherence with warfarin therapy. We aimed to develop Anticoagulant Therapy Adherence Scale for use in patients on warfarin and to examine psycholinguistic and psychometric properties.
Material and Methods: The research was of a methodological and consisted of 170 patients. The validity of the scale was tested by using content validity, explanatory and confirmatory factor analysis. The reliability of the scale was examined by utilizing item-total scale correlations and Cronbach's alpha.
Results: After the scale items were created, opinions were received from twenty experts and content validity indexes were found to be above 0.80. In the explanatory factor analysis, a 3-factor structure with factor loads between 0.30 and 0.81 was obtained. Fit indices obtained in the confirmatory factor analysis were as follows: $\chi 2$ = 181.116, df = 116 $\chi 2$/df value 1.561, Root Mean Square Error of Approximation (RMSEA) = 0.058, Comparative Fit Index (CFI): 0.88 and Goodness Fit Index (GFI): 0.88. Item-total scale correlation coefficients were found to range between 0.57 and 0.25. The Cronbach's alpha reliability coefficient was 0.74 for the overall scale and 0.63, 0.77 and 0.65 for its subscales.
Conclusion: ATAS was found to be a valid and reliable measurement tool in Turkish population. The scale can be used by healthcare professionals to evaluate patients' use of warfarin in a standard way.

Keywords: warfarin, adherence, scale, validity, reliability

INTRODUCTION

Anticoagulants are an important group of drugs used by many patients with different diseases. One of them is warfarin, which is utilized by patients with thromboembolism, cerebrovascular diseases, rhythm disorders and prosthetic cardiac valves. Although the use of warfarin is necessary, its side effects are quite high. If the INR (INR= International Normalized Ratio) value is above the therapeutic range, bleeding is seen; if the INR value is below the therapeutic range, thromboembolism appears (1,2). It is very important that patients adhere to the treatment to prevent side effects. The factors that increase the patient's adherence with warfarin treatment are as follows: knowing the reason and importance of using the drug, taking the drug at the same time every day, using the drug at the recommended dose, continuing the controls at least once every four weeks, continuing the controls in the same hospital, feeding considering the food-drug interactions, having his/her INR level checked 3-7 days after using a new drug, knowing the symptoms of complications, and knowing the methods to prevent complications (3-6).

There are general scales used to evaluate patients' compliance with warfarin in the literature (7-12). Morisky Medication Adherence Scale, one of the most used scales in treatment adherence researches, consists of four items about never forgetting to take medication, having trouble remembering to take the medication, stopping taking medication, and stopping using medication. Six and eight-item versions of this scale are used to assess warfarin compliance (7-13). Warfarin therapy adherence was another scale developed in 2020 to assess warfarin adherence. This scale was an eight-question tool consisting of yes and no answers, like the Morisky Medication Adherence Scale (14). These general scales do not completely include the parameters of adherence with warfarin treatment; they are only items related to the use of the drug, and they evaluate compliance. However, the correct use of the drug alone is not sufficient for adherence with warfarin therapy. The patient's adherence to the treatment should include feeding, going to check-ups and protecting and maintaining their own health, as well as using the drug (4,6,15). Therefore, the development of a scale showing adherence to anticoagulant treatment will provide an accurate assessment of adherence to treatment.

Studies conducted on warfarin in our country are generally studies evaluating the level of knowledge about warfarin and INR levels (16-18). There are limited studies evaluating adherence with warfarin treatment (19-20). General scales were also used in these studies but they were not sufficient to evaluate warfarin adherence in our patients. Our study will contribute to the literature in terms of showing the level of adherence with warfarin in Turkish patients undergoing cardiovascular surgery and providing a tool to measure the compliance of these patients with anticoagulant therapy. There were no reports describing the development of a scale for adherence to warfarin at the time of this study in literature. Therefore, the Anticoagulant Therapy Adherence Scale (ATAS) was decided to developing. Later, an article titled was published (21). This scale was a 20-item scale with four sub-dimensions: attitude towards safe environment and food interaction, attitude toward safe sedation, prevention of trauma and attitudes appropriate approach and attitudes toward the prevention of potential risk. Even if a scale measuring the phenomenon concerned has been developed, researchers may feel the need to develop a new, different scale (22). The study was performed with patients in neurology and cardiology clinics and focused on behavior and attitudes about using anticoagulants (19). With this scale, although it has similarities with the scale we developed, the items do not match exactly, and our scale contains items that the other scale does not include. In this respect, it can be emphasized that the scale is more comprehensive than other scales.

One of the strengths of our study is that this scale was developed as a result of our qualitative research. Performing scale development studies in both qualitative and quantitative steps enables the development of measurement tools with stronger psychometric properties (23). It is recommended to create an item pool as a result of scanning all the data obtained from the content analysis of the qualitative research and the relevant literature (23,24). Before this scale was developed, a qualitative study was conducted with patients who underwent cardiovascular surgery and used warfarin. The results of the research shed light on the creation of the scale (25). In this respect, scale items were created considering both patient experiences and the literature. The aim of our study was to develop an anticoagulant adherence scale and to examine its validity and reliability level.

MATERIAL AND METHODS

This was a methodological study.

Settings and Participants

Data were collected at a university hospital in İzmir. The study population consisted of patients in the cardiovascular surgery and cardiology clinics. Patients who were administered anticoagulant therapy in the abovementioned two clinics and who fulfilled the inclusion criteria were included in the sample. The inclusion criteria were using warfarin for at least one month, being 18 years old and literate, having no auditory or vision problems, not being diagnosed with any psychiatric conditions (dementia alzaimer, schizophrenia, delirium etc) and volunteering to participate in the study. It has been reported in the literature that the number of patients in scale development studies should be 5-10 times the number of items in the scale developed (26). The draft scale was composed of 31 items. Therefore, 170 patients were included in the sample, which was more than five times the number of items in the scale.

Data were collected by the researchers at face-to-face interviews between October 2017 and May

2019. Before data collection, informed consent was obtained from the participants. It took approximately 15 min for each participant to complete the forms.

Creation of the Item Pool

To evaluate adherence to anticoagulant therapy, the relevant literature was examined, and points concerning adherence to anticoagulants were determined (1,15,27). The features to be measured were determined by evidence from the literature. A minimum of four items were created for each feature. After a detailed literature review, a draft scale of 31 questions was prepared.

Pilot Test

The draft scale, revised in accordance with the expert opinions, was piloted on a sample of 15 patients meeting the inclusion criteria for the study to evaluate to what extent the items reflected the features to be measured and whether responses to the items produced valid measurements. The patients were asked whether the items were understandable, and their suggestions about the items were obtained. It has been reported that piloting is an important step in developing a scale, and the sample on which a scale is piloted must be representative of the target population.29, 30 Some of the patients reported that they did not experience constipation and therefore did not find the item about constipation understandable. Therefore, item 16, “I avoid straining when I have constipation”, was changed to “I avoid having constipation”. Item 31 “I receive information about my anticoagulant therapy from the nurse/doctor working in the health center where my treatment is followed” was changed to “I try increasing my information about my anticoagulant drug at every opportunity”. In accordance with the suggestions from the patients, the latest version of the scale was obtained. The patients administered the pilot test were not included in the study sample.

Psychometric Examination

Factor analysis was performed to determine the construct validity. With factor analysis, it was tried to determine whether the scale measures the structure it wants to measure. There are two types of factor analysis approaches: exploratory and confirmatory. If the main purpose of research is to discover, Exploratory factor analysis (EFA) should be used. In exploratory factor analysis, there is a process to find factors based on the relationships between the variables (31). In this study, Confirmatory Factor Analysis (CFA) was performed together with exploratory factor analysis. Kaiser-Meyer Olkin (KMO) coefficient was calculated as a result of exploratory factor analysis and Barlett Spehericity test was performed. In order for the data to be suitable for factor analysis, the KMO should be higher than 0.60 and the Barlett test should be significant at the $p<0.001$ significance level (32).

Exploratory factor analysis was performed with principal component analysis and the varimax rotation technique. Concerning overlapping, each item should load on at least two subscales, and the difference should be less than 0.1 between their factor loads. Following EFA, CFA was made with AMOS 24.

To analyze the reliability of the scale, item-to-total scale correlation and Cronbach’s alpha reliability coefficient were utilized (24,28).

Data Collection Tools

Data were gathered at face-to -face interviews using a sociodemographic and clinical features form and the ATAS developed by the researchers.

Sociodemographic and Clinical Features Form

The sociodemographic and clinical features form, created by the researchers, was composed of questions about sociodemographic features, including age, gender and educational status, and clinical features, such as availability of the INR device, duration of warfarin use and cause of warfarin use.

Adherence to Anticoagulant Therapy Scale

The draft scale was composed of 31 items based on expert opinions and the results of the piloting study. Responses to the items were scored on a five-point Likert scale: one corresponding to completely disagree, two disagree, three partly agree, four agree and five completely agree. Items 7, 8, 12 and 25 were scored in the reverse order.

Ethical Considerations

Ethical approval was obtained from Dokuz Eylül University Ethical Committee for Noninterventional Research (with 2892 Protocol number, decision number of 2016/24-03 on 08.09.2016), and written permission was obtained from the clinics where the study was conducted. Informed consent was obtained from all the participants.

Data Analysis

Before performing analyses, the obtained data were checked to determine whether any responses were missing. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to determine whether the data were normally distributed, and their results at p>0.05 were considered to show a normal distribution of the data. Skewness and kurtosis values between -1 and +1 were also considered to show a normal distribution of the data (24,32).

The obtained data were analyzed with IBM SPSS for Windows version 24.0 and IBM SPSS AMOS version 24. Data on sociodemographic and clinical features were analyzed with numbers, percentages, means and standard deviations. The validity of the draft scale was tested with the content validity index and the construct validity index. The construct validity was tested with exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). The reliability of the draft scale was tested with item-to-total correlation analyses, Cronbach's alpha reliability coefficient and the Spearman-Brown correlation coefficient (28,31).

RESULTS

Descriptive Statistics

Out of 170 patients with a mean age of 58.88±13.98 years, 51.88% (n=88) were female. Of all the participants, 49.41% (n=84) were primary school graduates, only 2.4% (n=4) had an INR test device, and 77.64% (n=132) were taking warfarin after cardiac valve surgery. The causes of warfarin use were rhythm disorders in 7.4% of the patients (n=13) and peripheral embolism in 14.96% of the patients (n=25). The mean duration of warfarin use was 64.47±76.80 months and ranged from one month to 26 years. A total of 84.2% (n = 135) of the patients reported that the INR values were generally in the therapeutic range.

Validity and Reliability Analysis

In the present study, the understandability of the items created was checked by a Turkish language and literature teacher. Then, expert opinions about the items were requested from 20 academicians specializing in surgical disease nursing. These experts were asked to use the Davis technique and to score the items on a four-point scale: one corresponding to unacceptable, two partly acceptable, three quite acceptable and four acceptable. They were also requested to write their suggestions when the score they assigned to an item was three or lower. The content validity index of the scale was found to be 0.96 and was found to be higher than 0.80 for all items. In accordance with the suggestions of the experts, some items were excluded, but other items were added; as a result, a draft scale composed of 31 items was formed (24,33). The results revealed a normal distribution of the data. Following normality analyses, item-to-total correlations were examined. Since the data were normally distributed, the Pearson correlation coefficient was calculated. The items with item-to-total correlation coefficients lower than 0.20 were not included in the analysis. Items 4 (r=0.048, p=0.533), 7 (r=0.144, p=0.061), 9 (r= .079, p=0.304), 12 (r= 0.072, p=0.353) and 26 (r=0.028; p=0.713) were deleted. The Kaiser-Meier Olkin value, used to determine whether a given sample is sufficient to perform a factor analysis, was found to be 0.723. This showed that a factor analysis could be performed. Bartlett's test of sphericity was $\chi 2$=996,459 at p=0.00, indicating the multivariate nature of the data obtained. The significant results of Bartlett's test (p: 0.000) indicated that the correlation matrix of the items in the scale was appropriate to make an EFA.

To reveal the underlying factor structure of the scale, EFA was performed. Principal component analysis was used to determine subscales. The items with factor loads lower than 0.30 based on principal component analysis and the varimax rotation technique were deleted (22). Table 1 shows the factor loads of the items. Items loaded on more than a factor were examined to determine whether there was overlap. The absence of a difference in factor loads of an item higher than 0.1 showed that the item overlapped. Overlapping items 1 (r=0.412, r=0.334) and 16 (r=0.319 r=0.390) were excluded from the scale.

Whether items loaded on each subscale were related to each other or belonged to the same factor was examined, and each subscale was named; that is, subscale 1 was called drug use and consulting a doctor, subscale 2 was called changing eating habits, and subscale 3 was called avoiding complications and management of bleeding. Items and subscales of the scale are shown in Table 1. Following the EFA, a CFA was made (Figure 1). The CFA revealed $\chi 2$=181.116, df=116, $\chi 2$/df=1.561, Root Mean Squre Error of Approximation (RMSEA)=0.05, Comparative Fit Index (CFI)=0.88 and Adjustment Goodness of Fit Index (AGFI)=0.85.

Table 1. Factor loads of scale items and subscales

Scale Items		Subscales		
		Subscale 1 ***"Drug use and consulting a doctor"***	**Subscale 2** ***"Changing eating habits"***	**Subscale 3** ***"Avoiding complications and management of bleeding"***
1.	Item 2: I always have my bleeding time (INR level) measured at the same health center.	.60		
2.	Item 5: I take care to take my anticoagulant at the same time.	.40		
3.	Item 6: If I forget to take anticoagulant, I will take it at the recommended dosage when I remember it on the same day.	.38		
4.	Item 8: I increase / decrease my anticoagulant dose depending on my INR test result.	.30		
5.	Item 11: I pay attention to my diet as recommended by healthcare professionals.		.76	
6.	Item 13: As my tendency for bleeding increases, I consume such foods as red pepper, garlic and green tea in a limited amount daily.		.77	
7.	Item 14: I consume green leafy foods such as broccoli, lettuce, cabbage, spinach, parsley and purslane in a limited amount daily.		.80	
8.	Item 17: When I get a cut, I apply pressure on it for at least 5 minutes.			.37
9.	Item 18: If I have a bleeding that continues for ten minutes, I will immediately contact the nearest health institution.	.55		
10.	Item 19: I will definitely consult my doctor / nurse if I start using a new medication during my anticoagulant therapy.	.78		
11.	Item 21: Before I go to the dentist, I ask my doctor (who follows my anticoagulant therapy) to adjust my anticoagulant dose.	.58		
12.	Item 22: When I go to another health institution, I definitely tell the healthcare professionals (physician, nurse, dietician) that I take an anticoagulant.	.74		
13.	Item 25: When I have pain, I take my pain medication without consulting a doctor.	.50		
14.	Item 28: I am careful not to cut / injure my hand when dealing with home and garden work in daily life (such as cooking or using cutting tools) or at work.			.81
15.	Item 29: I take care not to get injured while cutting my nails.			.72
16.	Item 30: I watch the bruises that occur on my body without any bumps and black stools.			.60
17.	Item 31: I always try increasing my knowledge of my anticoagulant.			.43

The latest version of the scale was found to account for 43.16% of the total variance. Items 2, 5, 6, 8, 18, 19, 20, 21 and 22 were loaded on factor 1, items 11, 13 and 14 were loaded on factor 2, and items 17, 28, 29 and 30 were loaded on factor 3. Concerning reliability analyses, item-to-total correlations were examined, and items 4, 7, 9, 12 and 26, having correlation coefficient lower than 0.20, were deleted. The correlation coefficients for the remaining items varied between 0.57 and 0.25. Cronbach's alpha was evaluated: it was 0.74 for the overall scale, 0.65 for the drug use and consulting a doctor subscale, 0.77 for the changing eating habits subscale and 0.63 for the avoiding complications and management of bleeding subscale.

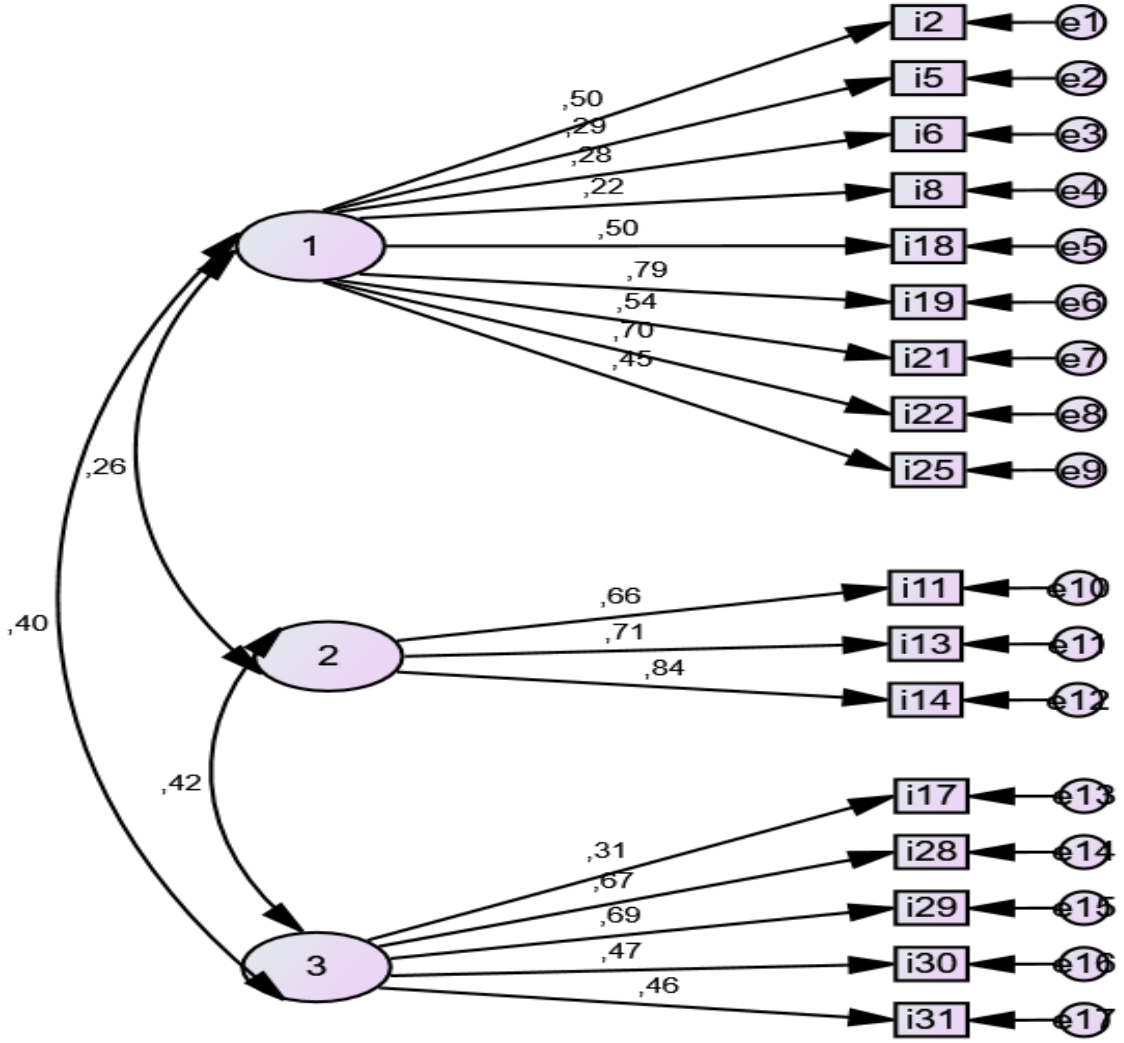

Figure 1. Sub-dimensions and Factor Loads According To The Results Of Confirmatory Factor Analysis of Anticoagulant Therapy Adherence Scale

DISCUSSION

The ATAS was developed to measure adherence to warfarin in patients receiving this drug.

Validity

The draft version of the ATAS was created in light of the results of a qualitative assessment of the study sample and evidence from the relevant literature. The content validity is evaluated by experts using the Davis technique. According to this technique, the items are scored on a four-point scale; one corresponding to unacceptable, two partly acceptable, three quite acceptable and four acceptable. Experts are requested to provide their suggestions about the items to which they assign a score of three or a lower. The scores corresponding to quite acceptable and acceptable are added and the obtained total score is divided by the number of experts. The result yields the content validity index of a given scale. A content validity index of 0.80 shows that a scale has acceptable validity (34).

Construct validity shows to what degree items of a scale measure features planned to be measured. Factor analysis is a method utilized to test construct validity. It reveals the underlying structure of a measurement tool and is directed towards compiling many interrelated variables and discovering fewer conceptually significant variables (28,32). During the process of developing a scale, an EFA and CFA are used. While the EFA shows the factor structure, the CFA confirms the factor structure determined. To evaluate sample adequacy in the EFA, Kaiser-Meier-Olkin (KMO) is the most frequently used technique (31,35). In the current study, KMO and Bartlett's test

results were evaluated. KMO values 0.90 - 1.00 are regarded as marvelous, 0.80 - 0.89 meritorious, 0.70 - 0.79 middling, 0.60 - 0.69 mediocre, 0.50 - 0.59 miserable and 0.00 - 0.49 unacceptable (26). To determine whether given data are multivariate, the significance of Bartlett's test results is examined (28,32). In the present study, the KMO value was 0.836, and Bartlett's χ2 was 1327.248, which showed that the obtained data were sufficient to perform an EFA (26).

Following the EFA, a CFA was made. In the literature, many fit indices are used to determine the fit adequacy of the model tested in CFA. The most commonly used fit indices are Chi-Square Fit Test (Chi-Square Goodness), Goodness of Fit Index (GFI), Adjusted Goodness of Fit Index (AGFI), Comparative Fit Index (CFI), Normed Fit Index (NFI), Non-Norrmed Fit Index (NNFI), Standardized Root Mean Squre Residual (SRMR), and Root Mean Squared Approximation Errors (RMSEA). Since the fit indices have strengths and weaknesses in evaluating the fit between the theoretical model and the real data, it is recommended to use many fit index values to reveal the fit of the model (31,36). Gerbing and Anderson (1992) state that different fit indices can be reported depending on the purpose of the researcher (37). In confirmatory factor analysis; χ2/df between 0-2 is a perfect fit; Between 2 and 3 shows that it is acceptable. In our study, χ2/df was calculated as 1.561. While the AGFI value between 0.90 and 1.00 is a perfect fit; Between 0.85 and 0.90 is considered an acceptable fit. In our study, the AGFI value was calculated as 0.85 (27,36). In the present study, the results of the CFA were as follows: χ2=181.116, df=116, χ2/df= 1.561, RMSEA= 0.05, CFI: 0.88 and AGFI=0.85. These findings indicated that the construct validity of the scale was achieved.

Reliability

Reliability and item analyses are utilized to evaluate the content and construct of a scale and its power and adequacy to question a phenomenon. Cronbach's alpha coefficient is used to determine the power, adequacy and reliability of continuous, interval and Likert scales to measure a phenomenon questioned. Cronbach's alpha ranging from 0.60 to 0.70 shows that a scale has acceptable reliability, and Cronbach's alpha higher than 0.70 and between 0.70 and 0.90 shows that a scale is highly reliable (22). In the present study, Cronbach's alpha was found to be 0.74 for the ATAS, 0.65 for its drug use and consulting a doctor subscale, 0.77 for its changing eating habits subscale and 0.63 for its avoiding complications and management of bleeding subscale.

Another method used to measure the reliability of a scale is to determine the mean value of item-to-total score correlation coefficients. In this method, correlations between the total score of a scale and each item are considered (24). In the current study, based on the item-total score correlations, items 4, 7, 9, 12 and 26 were deleted since they had correlation coefficients smaller than 0.20.

CONCLUSION

As a result of examining the psycholinguistic and psychometric features of the draft scale, the ATAS, composed of 17 items and three subscales, was obtained. The scale has no cut-off point. Subscale scores can be obtained by adding the items belonging to the sub-dimensions. High scores obtained from the scale indicate increased compliance with anticoagulant treatment. The highest and lowest scores received from the scale were calculated by reversing, 85 and 17, respectively. The ATAS is a valid and reliable tool that can be used to measure adherence to warfarin in the Turkish population.

The scale can be used by healthcare professionals to evaluate patients' adherence to anticoagulant treatment. The scale can be used in studies in which the adaptation process of patients receiving anticoagulant therapy is evaluated (e.g., the effect of adherence on quality of life, complications, and hospitalizations.

By removing the food selection items of the scale we have developed, the scale can be adapted to patients using new-generation anticoagulants. Since no cultural validity and reliability study was conducted in English, only the English translation of the scale was made. It is recommended to validity and reliability analyses of this developed scale in different languages and cultures.

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