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Araştırma Makalesi / Research Article

ORAL ANTİKOAGÜLAN KULLANAN HASTALARIN RİSKLİ DAVRANIŞLARININ BELİRLENMESİ VE YENİLİKÇİ ÇÖZÜMLER

DETERMINATION OF DRUG-RELATED RISK BEHAVIOURS OF PATIENTS USING ORAL ANTICOAGULANTS AND INNOVATIVE SOLUTIONS

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ÖZET

Çalışmanın amacı, oral antikoagülan kullanan hastaların ilaç kullanımıyla ilgili riskli davranışlarını belirlemek ve böylelikle hastaların ihtiyaçlarına yönelik gerekli çözüm önerilerinde bulunabilmektir. Bu çalışma prospektif, tanımlayıcı ve kesitsel olarak kardiyoloji ile kalp damar cerrahi polikliniklerinde gerçekleştirildi. Çalışmanın verilerinin toplandığı 2 aylık sürede polikliniğe başvuran oral antikoagülan kullanan hastalardan çalışmaya katılmayı kabul edenlerden veriler toplandı. Çalışmaya katılan hastaların varfarin tedavisi dışında antikoagülan tedai kullanımı görülmemiştir ve katılımcıların %57,8'i (n:59) 65 yaşın üzerindedir. Çalışmaya katılan hastaların çoğunun tedaviye bağlı kanama, ilaç-gıda etkileşimleri ve INR değerlerini bilmedikleri, oral antikoagülan hakkında bilgi eksikliği nedeniyle ilaçları eksik veya aşırı doz kullandıkları belirlenmiştir. Doktorlar ve hemşireler, yüksek riskli ilaç grubundan olan oral antikoagülanları kullanan hastaların eğitiminde önemli rol oynamaktadırlar. Cep telefonu uygulamaları hastaların ilaç alım saatlerini hatırlatmak için kullanılabilir.

Anahtar kelimeler: Hasta eğitimi, Hasta güvenliği, Mobil sağlık, Varfarin

ABSTRACT

The aim of this study is to gather valuable information about the drug-related risk behaviours of patients to be exposed to use the oral anticoagulants so that we provide necessary solutions founded on the needs of patients. This study was conducted as a prospective, descriptive and cross-sectional study in the cardiology and cardiovascular services of outpatient clinics. The study data related to the patients subjected to use the oral anticoagulants during the 2-month period were collected. There seemed no anticoagulant treatment except for warfarin treatment among the patients participated in the study, where %57.8 (n:59) of participates were over 65 years old. It was determined that most of the patients in the study reported that they have no knowledge about the findings of bleeding, do not know the drug/food interactions and INR values, used missing or overdose the drugs due to the lack of knowledge about oral anticoagulant use. The physicians and nurses play a great role on the education of patients using the oral anticoagulants that take in the medicines with high-risk. Information systems such as mobile phone applications and computer applications can also be used to remind the patients.

Keywords: Mobile health, Patient education, Patient safety, Warfarin

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INTRODUCTION

Along with the lifespan prolongation of human beings, the frequency of chronic diseases increases seriously so does the incidence of coronary heart diseases. The trend to usage of anticoagulants has also increased due to their therapeutic and prophylactic effects in cardiac diseases such as myocardial infarction, coronary heart diseases and rhythm disorders. The purpose of anticoagulant therapy is to prevent the fibrin accumulation and thrombus formation by restricting the blood clotting (Taze Koksal & Avsar, 2015). Additionally, the long-term use of anticoagulants is also required for deep vein thrombosis, rheumatic heart valve diseases, bypass graft survival after valve replacement (Alay et al., 2011; Yucel et al., 2001), pulmonary emboli, atrial fibrillation (AF) (Gupta et al., 2018) and cerebral ischemic attacks (Dogu & Acaroglu, 2016; Tezer et al., 2008). However, the anticoagulant drugs have a special place in the treatment of diseases as the frequencies of use and side effects are serious and fatal (Shaha et al., 2015).

The role of physicians and nurses is great in the education of patients using OAC, which is a medicine with high-risk. Physicians and nurses should be trained in the subjects such as the use of anticoagulants, control times, INR value, bleeding findings, medication usage times, nutrition and daily life activities, and the patients should be followed up at regular intervals.

The aim of this study is to determine the drug-related risk behaviours of patients who use OAC and thus to be able to provide necessary solutions regarding the needs of the patients.

METHODS

The design, Universal and Sample

The present work is a prospective, descriptive and cross-sectional study conducted 2016 in the outpatient clinics of cardiology and cardiovascular services of a training-research and a state hospital. The universe of study is composed of the patients (using OAC) who applied and/or were followed for a period of 2 months. The sample of study was consisted of 102 participants. The data were collected by the researchers through the face-to-face interview technique using the data collection form generated in accordance with the literature.

Data Collection Tool

The data collection form consisted of three parts: (I) "descriptive information on patients", (II) "perception of health status" and (III) "drug-related risk behaviours of patient". In many surveys conducted in our country and abroad, the perceived health status was assessed with the question that is "How do you assess your health when encountering to people who are in the same socio-economic situation as you are"(Tugut & Bekar, 2008). The responses to the health status questionnaire were rated as 1 for the "very good" response, 2 for the "good" response, 3 for the "bad" response, and 4 for the "very bad" response.

Statistical analysis

The data were coded in a statistical program, and the related statistical evaluation was performed by using the mean, percent and Chi-square values. The significance of difference between the percentages was determined by t-test approach. The value of $p<0.05$ was considered as statistically significant.

Ethical Considerations

The study has been conducted in accordance with the principles of the Helsinki Declarations and approved by the local Institutional Reviev Board (2016-102-28/09). Written informed consent was obtained from all subject.

Limitations of research

The main limitation of our study was relatively small size of our series. Secondly, some details of history and factors that may influence the outcome may not be completely documented. Thirdly, our study findings may potentially have been influenced by confounding factors. Finally, this was a single-institution study. Further prospective, controlled trials on larger series are necessary for making more precise interpretations.

RESULTS

The mean age of the participants was 65.01 years of age (SD=10.3) and 59.8 % have an additional chronic disease. Most participants were female, married, primary school and had social security.

In the study, 62.7% (n: 64) were reported as "good", 27.5% (n:28) as "bad" and only 9.8% (n:10) as "very good" when the patients' perceptions of health status were examined. According to the results obtained, it was found that there was no statistically significant difference (p>0.05) between the perception of health status and the knowledge of life-threatening conditions of OAC drugs. Similarly, the same result was observed for the relation between the state of perception of health status and being informed.

The patients use of OAC, it was determined that they used the OAC for averagely 7.70±6.2 years, 9.8% (n: 10) knew the reason for using the OAC, 45.1% (n: 46) knew the OAC's creating life-threatening situation, 81.4% (n:83) knew their OAC dose, 90.2% (n: 92) had at least one drug group that they use other than OAC (Table 1). When the drugs used by the patients were asked, it was found that 65.7% (n:67) used antihypertensive, 35.3% (n:36) used antiarrhythmic drug, 26.5% (n:27) used antidiabetic, 13.7% (n: 14) used diuretic, 12.7% (n:14) used proton pump inhibitor, 7.8% (n:8) used anti-hyperlipidaemia, 8.8% (n:9) used hypothyroid and 2.9% (n:3) used antipsychotic drugs.

Table 1. Distribution of Characteristics Related to OAC Use of Patients (n:102)

There was no statistically significant difference between the patients' receiving training regarding the use of OAC and the descriptive information about the patients together with the knowing the reasons of use, carrying documents and knowing the dosage given by the medication (p> 0.05) throughout the usage of the drugs whereas a statistically significant difference was noted between patients' receiving training on the use of OAC and their knowledge of the INR value (p <0.05, X^2 = 9.908).

Patients (83.3%) who did not receive any training on OAC use were found to have no knowledge about the presence of life-threatening conditions (45.1%) and this was statistically significant (p<0.05, X^2=9,231). Additionally, among 70.6% (n:72) of patients did not anticipate whether there are any effects of foods on the drugs of OAC or not. On this basis, the food they consume could lead to increase or decrease the effect of the medicine, this was noticed to be statistically significant (X2 = 12.509, p <0.05) (Table 2).

It was seen from the participating that the trained patients related to the use of OAC drugs reported the use of OAC during treatments/interventions in a statistically significant amount (X^2 = 6.623, p <0.05) (Table 2).

Table 2. Distribution of Information About Patients' Knowledge on The Use of OAC According To Their Status of Being Trained (n:102)

When the knowing of INR value according to the age group was examined, it was seen that patients older than 65 years did not know INR value in a rate which is higher than other age groups and this situation was statistically significant (X^2 = 20.494; p<0.05). When the difference between the percentages was examined, there was a statistically significant difference between the percentage of those who know the INR value (11.9%) and the percentage of the individuals that do not know (88.1%) among the patients over 65 years of age (t = -3.401; p <0.00).

Patients stated that they should report to the physician and nurses about conditions such as unstoppable bleeding (35.3%), small bruises (38.2%), blood in sputum (37.3%) and nose/gum bleeding (37.3%), and 28.4% (n: 29) of the patients stated that they did not know the situations that should be reported to doctors and nurses, when the facts that the patients should pay attention during the use of OAC. It was seen that 49.0% (n: 50) of the patients did not know what they needed to know and pay attention to some activities such as that could cause injuries in daily activities, using machine for shaving, applying pressure to the small incisions, and urgently resorting to a health centre is the incision is bigger. Patients using OAC of 75.5% (n:77) reported using OAC during treatment/interventions (endoscopy, colonoscopy, tooth extraction or preoperative processes, etc.) and 70.6% of patients reported (n:72) additional medication use to physicians and nurses.

Table 3 provides information about when patients took the drug, drug-nutrient interactions, cases of forgetting to take the drug, and behaviors when they forgot to take the drug.

It was determined that 76.5% (n:78) of patients did not know the INR value, 75.5% (n:75) had regular laboratory tests once a month and 97.1% (n:99) did not have any documents about the tests (Table 3). The study has shown that 83.3% (n: 85) of the patients did not receive any training related to the use of OAC. 5.9% (n: 6) were trained by nurses when 10.8% (n:11) were trained by physicians and 90.2% of patients reported that they needed training on OAC use (Table 3).

DISCUSSION

Age is a major factor in increasing the risk of bleeding in patients using OAC. Every decade over the age of 40 years is important for raising the risk of bleeding (Fitzmaurice, 2002). In their study, Walvik J et al. (Wallvik et al., 2007) found that the risk of haemorrhage increases with increasing age in patients using OAC. In addition, the age factor is an important risk factor for the use of OAC drugs(Ozer & Ozdemir, 2009) , due to the increase in the number of drugs used and the risks of drug interactions that may occur due to the increase in age and the increase in chronic diseases. More than half of the patients (57.84.0%) were over 65 years of age. When we investigated the relationship between age and knowing the cause of OAC use, it was found that the patients over 65 years did not know the reason of using the drug compared to other age groups and this was statistically significant ($p<0.05$).

Drugs such as corticosteroids, barbiturates, oestrogens, antihistamines, diuretics, influenza vaccine, multivitamin supplements containing vitamin K, ribavirin, rifampin, azathioprine and anti-acids have been shown to reduce the effect of OAC (Johnson, 2013; Taze Koksal & Avsar, 2015; Uygungul et al., 2014), while drugs such as omeprazole, quinidine, propafenone, tetracycline, cephalosporin, erythromycin, amoxicillin/clavulanate, azithromycin, diltiazem, metronidazole, propranolol, thyroid hormones, tramadol, quinidine, antiarrhythmic (especially amiodarone), cholesterol drugs, and NSAIDs may increase the prothrombin duration and INR value when used with OAC, increase the effect of OAC and create a risk for bleeding (Dogu & Acaroglu, 2016; Fitzmaurice, 2002; Hirsh J, Dalen J, Anderson DR, Poller L, Bussey H, Ansell J, 2001; Johnson, 2013; W. et al., 2007). Among these drug groups, patients in the study were using antiarrhythmic, diuretic, proton pump inhibitor, cholesterol and antipsychotic drugs.

Quirke et al. (W. et al., 2007) reported that drug interactions were the most important cause of over-coagulation in their study they carried out on patients, who used warfarin among the oral anticoagulants. It was determined that more than half of the patients in our study (59.8%) had chronic diseases other than those requiring OAC use, and nearly all of the patients (90.2%) were using additional medicines other than OAC. It has been reported that drugs used due to chronic diseases increase or decrease the effect of the drug by interacting with OAC, resulting in serious complications such as haemorrhage (Fitzmaurice, 2002).

In some vegetables (broccoli, Brussel sprouts, parsley, spinach, etc.) the content of vitamin K is high. In patients using OAC, sudden changes in the amount of food or vegetables consumed in large quantities of these vegetables may cause low anticoagulant effect, reducing the effectiveness and safety of the drug (Baysal & Midilli, 2018; Bushra et al., 2011; Othilia et al., 2003). Dietary and drug interactions are among the least known among OAC patients (Nasser et al., 2012). In our study, over half (70.6%) of the patients do not know that food can change the effect of the medicine.

The majority of patients in the study of Mercan and Enc stated that OAC was used for 11 years or more. Almost all of the patients knew the reason for the use of the drug, while the vast majority did not know their drug doses (Sevda Mercan, 2011). It was determined that the patients who participated in the study knew that OAC used medication for an average of 5.69 ± 6.12 years and that the majority of patients knew about the cause of using the drug, but that about half of the patients did not know that OAC was a life-threatening drug.

In the study, it was determined that almost all of the patients (97.1%) did not carry any documentation that shows they use OAC. This rate was 78% in the study of Mercan and Enc and 87.6% in the study of Koksal and Avsar. Carrying a card is recommended (Sevda Mercan, 2011; Taze Koksal & Avsar, 2015) in terms of directing the intervening person in cases of loss of consciousness, injury or accident caused by any reason.

Hylek et al. (Hylek et al., 2007) reported that 54% of patients had bleeding after discharged from the hospital, 31.7% of these bleedings were older than 75 years of age, in the study on patients over 65 years of age using OAC for atrial fibrillation. Jenner (Jenner & Simmons, 2015) has worked with patients who are taking warfarin for atrial fibrillation and has developed an algorithm that shows the doses of drugs that patients should use according to changes in INR results, and has provided access to patients on a website they can access. For the patients, this site was very comfortable. self-management has been provided in terms of diseases of patients with this method. Otherhals et al. (Oterhals et al., 2014) reported that European cardiac nurses need to improve their knowledge and practice patterns on oral anticoagulation therapy. This area of knowledge is important in order to deliver optimal care to cardiac patients and to minimise adverse effects of the treatment.

Korkmaz et al. reported (Korkmaz et al., 2015) that 64.0% of patients had received education related to warfarin usage, and 63% of these (n=46) said this education came from physicians while 37% said it came from nurses. In our study, the majority of patients (83.3%) were not trained in the use of OAC and the proportion of trainees (16.7%) was very low. The rate of receiving the relevant education from the nurses (5.9%) is lower than the physicians (10.8%). Patient training is important in the use of OAC and compliance with care. Training the patient and his/her relatives is the main task of the physician and the nurse. Since nurses are the health professionals who spend the most time with patients and have a lot of communication, they can determine the knowledge level of the patients, and in this context, patients can be trained about the OAC treatment.

Kim et al. (Kim et al., 2011) reported that 85.6% of the patients stated that if they forgot to take the warfarin dose they would receive twice as much warfarin the next day. In our study, 38.2% of patients reported that they would not take warfarin until the next day's dose if they forgot to take warfarin. Taking a low dose or high dose of warfarin can cause serious complications that will endanger your life. So it should be taken into account by the nurses and their doctors what they will do when the patient forgets to take the drug dose.

Patients using OAC should be careful in their daily activities. Koksal and Avsar (Taze Koksal & Avsar, 2015) stated that more than half of the patients did not know that they should avoid the activities that may cause bleeding in their daily activities. In the study of Mercan and Enc (Sevda Mercan, 2011) it was determined that 25.4% of the patients did not take any measures during their daily activities and 9.6% did not know that they should take these measures. In our study, it was seen that the patients did not have enough information about daily life. Nearly half of the patients stated that they did not know what to look out for in daily life.

Although warfarin is effective in preventing thrombolytic events, its use is a complex and high-risk drug. New oral anticoagulants (dabigatran, rivaroxiban and apixaban) used in recent times are easier to use than warfarin. Simple forms of use and routine coagulation monitoring are not required. Drug-drug and drug-food interactions are important advantages of being less or not at all. They are used clinically in AF and hip / knee implant surgery(Johnson, 2013).

CONCLUSION

In this respect, there is the risk of thrombosis or bleeding, since approximately half of the patients in the study did not know and reported bleeding findings and did not know the drug/food interactions and INR value, and that half of them did not know that OAC was a potentially life-threatening.

It is suggested that physicians and nurses provide training on the use of OAC drugs and that these trainings should be repeated at regular intervals in terms of safe drug use. In the educational context, audio and visual materials can be used and brochures

can be given at the end of the training. The study found that the proportion of patients reporting that they had training needs was greater than the number of patients indicating that they had no training in OAC use. According to the results of the study, the fact that the educated patients also had training needs related to the use of OAC can be interpreted as the training should be repeated at intervals. The education of the discharged patient and family from hospital should be provided. As in the case of diabetes, the outpatient clinics of a nurse who is trained in the use of OAC can be made available. Information systems such as mobile phone applications and computer applications can also be used to remind this patients whose age is older and who cannot remember the time of drug use in hospital and at social care. SMS services can be given within the scope of mobile health services in the use of oral anticoagulants, in reminding the use of drugs, monitoring and disease management (Hall et al., 2015; Hamine et al., 2015).

In addition, the drug reminder program on android mobile phones can be useful to remind not the patients to forget their medication hours. Mobile support can be given to the patients with the drug dose embedded into the reminder programs, frequency of use or specific drug usage hours. The use of oral anticoagulants from commercially available drug reminder boxes can be encouraged. Doctors and nurses may be given cards showing the patients using oral anticoagulants. The importance of carrying these cards is explained to the patients.

CONFLICTS OF INTEREST

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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TABLES

Table 1. Distribution of Characteristics Related to OAC Use of Patients (n:102)

	Frequency (n)	Percentage (%)
Duration of use ($\overline{X}$:7.70±6.2)		
1- 4 years	39	38.2
5- 9 years	36	35.3
> 10 years	27	26.5
The reason of OAC use		
Valve problems	38	37.3
Rhythm impairment	4	3.9
After CABG and valve surgery	21	20.6
Blood coagulation disorder	24	23.5
Stent operation	5	4.9
I do not know	10	9.8
The status of knowing the reason of using OAC		
Yes	92	90.2
No	10	9.8
Knowing the status of OAC's creating life-threatening situations		
Yes	56	54.9
No	46	45.1
Knowing the drug dose		
Yes	83	81.4
No	19	18.6
Presence of drugs used other than OAC		
Yes	92	90.2
No	10	9.8

Table 2. Distribution of Information About Patients' Knowledge on The Use of OAC According To Their Status of Being Trained (n:102)

	Status of having training regarding the use of OAC				Statistical analysis
The status of nutrients' changing the effects of OAC	Yes		No		
	n	%	n	%	$X^2=12.509$
Yes	11	64.7	19	22.4	$p:0.002$
No	6	35.3	66	77.6	
Reporting the OAC usage during treatments/operations	Yes		No		Statistical analysis
	n	%	n	%	
Yes	17	100.0	60	70.6	
No	0	0	5	5.9	$X^2= 6.623$
I did not encounter such a situation	0	0.0	20	23.5	$p: 0.036$

Table 3. Risk Behaviors of Patients Using Oral Anticoagulants

	Frequency (n)	Percentage (%)
OAC using times		
After breakfast	18	17.6
After lunch	2	2.0
After dinner	34	33.3
Before going to bed	45	44.1
When I remember	3	2.9
Knowing the nutrients that increase or decrease the effects of OAC		
Yes	30	29.4
No	72	70.6
The status of forgetting to use OAC		
Yes	62	60.8
No	40	39.2
The patient's behaviour when he/she forgets to use OAC		
I do not forget	39	38.2
I do not use that day until the next days dose	39	38.2
I get it when I remember	20	19.6
I take double doses the next day	4	4.0
Knowing the INR value		
Yes	Yes	Yes
No	No	No
Frequency of having OAC related blood tests		
Once a week	7	6.9
Every 15 days	8	7.8
Once in a month	77	75.5
Once in two months	4	3.9
As the doctors suggest	5	4.9
Once in 3 months	1	1.0
Carrying document / identity for OAC usage		
Yes	3	2.9
No	99	97.1