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Original Article

Examining the Effect of Needs-Based Education on the Knowledge of Patients Undergoing Oral Anticoagulant Therapy

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Abstract

Background and aims: Anticoagulant medications are widely utilized for both preventive and therapeutic purposes in medical practice, particularly in the management of coronary artery disorders. However, their use is associated with an increased risk of bleeding complications. Conversely, education tailored to patients' levels of understanding has been shown to influence rates of hospital readmission and the occurrence of complications related to medication use. Therefore, this study aimed to evaluate the impact of needs-based education on the knowledge of patients receiving oral anticoagulant (OAC) therapy.

Methods: This study employed a quasi-experimental design with a pre-test and post-test approach, including a control group. Conducted in 2024, it involved 70 patients receiving OAC medications. Sampling was executed using a convenience method followed by block randomization. The intervention group received needs-based education through educational pamphlets and face-to-face instruction. Data collection instruments included a demographic information form and a drug knowledge questionnaire, administered before and six weeks after the intervention. Data analysis was performed using SPSS software version 19, applying appropriate statistical tests.

Results: Prior to the intervention, no statistically significant differences were observed between the two groups regarding demographic characteristics or mean drug knowledge scores ($P>0.05$). The pre-intervention drug knowledge scores for the intervention and control groups were 20.58 ± 8.97 and 24.94 ± 9.46, respectively, with no significant difference noted ($P=0.054$). Post-intervention, the mean drug knowledge scores increased to 30.85 ± 7.45 in the intervention group and 25.37 ± 8.58 in the control group, demonstrating a significant difference between the two groups ($P=0.006$).

Conclusion: Needs-based education is effective in enhancing knowledge about OACs and promoting medication adherence. It is recommended that educational programs be designed based on patient needs to ensure they are engaging and informative, thereby fostering motivation and enthusiasm for learning among patients.

Keywords: Oral anticoagulants, Needs-based education, Knowledge

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Introduction

Anticoagulant medications have extensive preventive and therapeutic applications in medical practice, particularly in the treatment of patients with coronary artery disorders, atrial fibrillation (1), valvular heart diseases, as well as in the prevention of ischemic strokes, transient ischemic attacks (TIA) (2, 3), knee replacements (3), deep vein thrombosis (DVT) (4), and pulmonary embolism. However, their use is also associated with an increased risk of bleeding (1).

Statistics indicate that the number of patients receiving warfarin in the United States in 2020 was 11,467,999 (5). A study by Munir et al including 1,204,507 patients with atrial fibrillation (AF) over a follow-up period of 2.4 years revealed that oral anticoagulants (OACs) were prescribed to 586,896 patients, representing 48.7% of the cohort studied (6). In Italy, the use of these medications has been reported to encompass approximately one million individuals (7).

OACs are categorized into two subclasses: vitamin K antagonists (VKAs) (such as warfarin) and direct OACs (including apixaban, dabigatran, and rivaroxaban) (8). These medications possess a narrow therapeutic index, meaning that the therapeutic and toxic doses are

closely aligned, which underscores the importance of maintaining therapeutic levels in the bloodstream (9, 10). Factors such as dietary interactions, genetic variability, concurrent medication use, and non-adherence to treatment necessitate careful and frequent adjustments of medication dosages (11, 12). Failure to adequately monitor these medications can result in various complications, including insufficient dosing that may lead to blood clot formation and potential mobilization to vital organs such as the heart, brain, and lungs, thereby increasing the risk of myocardial infarction and ischemic stroke (13). Consequently, it is imperative for patients undergoing anticoagulant therapy to receive comprehensive and high-quality education.

Among the adverse clinical outcomes associated with the use of OACs are primary outcomes, such as an international normalized ratio (INR) that falls outside the normal therapeutic range, as well as secondary outcomes, including DVT, pulmonary embolism, multiple hemorrhages, decreased hemoglobin levels, organ dysfunction, recurrent hospital admissions, and increased mortality (14, 15).

One of the principal risk factors related to OAC use is bleeding. It is estimated that over 6 million patients in the United States are treated with anticoagulants. A significant proportion of these patients present to emergency departments due to acute bleeding, resulting in higher morbidity and mortality rates compared to individuals not receiving anticoagulant therapy (16). Lin et al reported that 1.3-7% of patients receiving anticoagulants experience significant bleeding annually, with 0.6-0.8% experiencing fatal bleeding (17).

Factors such as the dosage of medication, duration of treatment, and adherence to the therapeutic regimen significantly influence readmission rates among patients undergoing anticoagulant therapy. A critical element affecting adherence among users of OACs is the level of knowledge patients possess regarding their condition and treatment regimen. In essence, education tailored to patients' levels of understanding can impact readmission rates and the incidence of complications related to medication use (2).

Currently, the American Society of Hematology guidelines for the optimal management of anticoagulation therapy advocate for supplemental patient education—defined as any educational content exceeding that typically provided by prescribing clinicians or dispensing pharmacists—during the initiation of anticoagulation therapy. However, the guidelines do not specify the content or format of this supplemental education (18).

The results of several studies indicate that the level of awareness regarding the correct use of medications among patients receiving anticoagulant therapy is often low (19, 20). Consequently, it is essential to create an appropriate educational environment tailored to individuals' levels of knowledge (21).

Various educational methods are available, including face-to-face instruction, the use of educational aids, videos, pamphlets, and the dissemination of educational materials through social networks, as well as cognitive-behavioral interventions (22). A systematic review conducted by Sim et al revealed no significant difference in patient awareness between traditional and modern educational methods. However, modern educational approaches tend to reduce both the duration and cost of training (23).

While most studies affirm the positive effects of education on improving clinical outcomes and enhancing patient adherence to treatment, research indicates that individuals' educational needs vary based on factors such as age, prior experiences and expectations, gender, education level, receptiveness to learning, race, and socio-economic status. Therefore, effective education necessitates the active involvement of patients in identifying their educational priorities, focusing on areas they perceive as requiring further instruction (24, 25).

Selecting a suitable and comprehensive educational method that aligns with patients' conditions and needs is crucial for enhancing learning outcomes related to health behavior change. Needs-based education, which is rooted in shared decision-making principles and aligns with adult learning theory, emphasizes that learning should correspond to diverse personal backgrounds and specific needs. This approach entails assessing patient requirements and the necessary information prior to the educational intervention, thus allowing the educational program to be tailored accordingly (26).

Given that one of the primary responsibilities of nurses is to provide continuous, accurate education that is appropriate to each patient's level of awareness and individual needs, and considering the scarcity of similar studies in this area, this study aims to evaluate the effect of needs-based education on improving the knowledge of patients undergoing treatment with OACs at educational hospitals affiliated with Shiraz University of Medical Sciences in 2024.

Materials and Methods

Study Design and Setting

This study employed a quasi-experimental research design featuring a pre-test/post-test format with a control group. Following approval from the Ethics Committee of Shahid Beheshti University of Medical Sciences and the acquisition of necessary permissions from Namazi, Al-Zahra, and Shahid Faghihi hospitals, the research was conducted in 2024 involving patients receiving OACs during their hospitalization.

Study Participants and Sampling

The sample size was determined using the following formula:

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 (s_1^2 + s_2^{\ 2})}{(\bar{x}_1 - \bar{x}_2)^2}$$

, which was determined based on the findings from the study by Sudas Na Ayutthaya et al (14), taking into account a Type I error rate of 0.05 (corresponding to a z-value of 1.96) and a Type II error rate of 0.15, which provides a statistical power of 90%.

Thus, 32 individuals were allocated to each group, and accounting for a 10% dropout rate, a total of 35 participants were selected. The inclusion criteria for the study included: being recipients of OAC medications, aged 18 to 80 years, having no learning disabilities, demonstrating the ability to perform self-care processes, and the absence of active bleeding (23). Participants who did not attend all educational sessions or who withdrew their consent were excluded from the study.

After obtaining the necessary permissions and visiting the selected hospitals affiliated with Shiraz University of Medical Sciences, participants were recruited through convenience sampling based on the inclusion criteria. Both verbal and written consent were obtained from each participant. Patients were then randomly assigned to either group A (intervention) or group B (control) using a block randomization method with blocks of four. For example, if a block was designated as BABA, patients were assigned in the following order: control, intervention, control, intervention. Subsequently, patients in a block designated AABB were assigned as intervention, intervention, control, and control. The number of individuals allocated to each group was approximately equal.

In this study, in addition to random allocation, sequence concealment was implemented to ensure the integrity of the randomization process. Initially, a random sequence was generated, and based on the sample size of the study, several envelopes were prepared. Each random sequence was recorded on a card and placed inside the envelopes in sequential order. To maintain the integrity of the random sequence, the exterior of the envelopes was numbered accordingly. The envelopes were then sealed and placed in a box in the designated order. At the onset of participant enrollment, one of the envelopes was opened in sequence based on the eligibility of the participants, revealing the assigned group for that individual. Participants were assigned to their designated groups in the order they entered the study, utilizing the randomized blocks.

Data Collection Tools and Technique

Demographic Information Questionnaire

The questionnaire consisted of various questions, including gender, age, education level, place of residence, employment status, reason for hospitalization, reason for visit, disease diagnosis, history of illness, history of hospitalization due to complications related to anticoagulant use, type of anticoagulant medication, duration of medication use, other medications taken, use of herbal supplements, and dietary habits. The content validity of the questionnaire was assessed by seven faculty members at the university, and modifications were made based on their feedback and subsequently approved.

Anticoagulation Knowledge Tool (AKT) Questionnaire

The AKT was developed for the first time in 2016 by Obmiro et al It comprises 28 items, featuring both open-ended and multiple-choice questions, divided into two sections: the first section (n = 20 items) assesses general anticoagulation knowledge related to all available OACs, while the second section (n = 8 items) is specific to VKAs therapy. Each response is scored with a zero (incorrect answer) or one (correct answer) by clinicians to evaluate patient knowledge. A maximum score of 25 is achievable for the first section, and a maximum score of 35 for patients taking VKAs who complete both sections.

The validity of the tool was evaluated using the Content Validity Index (CVI), which was calculated to be 0.92. Additionally, the reliability of the tool was assessed through internal consistency, yielding a Cronbach's alpha coefficient of 0.7, as confirmed by previous research (19). The validity and reliability of the AKT in Iran were further assessed in a study conducted by Houshyar et al (27). To evaluate face validity, the questionnaire was reviewed by cardiologists, general practitioners, and nurses, and their suggestions for modifications were implemented.

For reliability assessment, the test-retest method was employed, resulting in a correlation coefficient of 99.4%. The total score for the AKT ranges from 0 to 34, with scores of 0 to 12 indicating poor knowledge, 13 to 24 indicating moderate knowledge, and 25 to 34 indicating good knowledge. Following translation and psychometric testing of the tool by Houshyar et al the format of the questions was revised to include 10 short-answer questions and 10 three-option questions in the general information section about anticoagulants, as well as 4 short-answer questions and 4 three-option questions specific to warfarin (27). In this study, the reliability of the questionnaire was re-evaluated using internal consistency, yielding a Cronbach's alpha coefficient of 0.78.

Intervention

The researcher introduced themselves and outlined the objectives of the study, subsequently obtaining informed verbal and written consent from eligible participants. Participants were initially selected through convenience sampling and then randomly allocated into control and intervention groups using block randomization.

Initially, both the Demographic Information Questionnaire and the AKT questionnaire were administered. In the subsequent phase, participants in the intervention group received basic and advanced needs-based education tailored to the results obtained from the AKT regarding several key areas: timing of doctor visits, monitoring INR levels, activity restrictions, duration for returning to daily activities, medication side effects, self-care methods, patient awareness of medications, and factors affecting treatment adherence. This education was supplemented with educational pamphlets and face-to-face training conducted on the day of the interview.

Follow-up educational sessions were conducted in

the second and fourth weeks via telephone, in-person meetings, and text messages. Two contact numbers were collected from each participant, with one designated for addressing questions related to the intervention group. In contrast, the control group received only routine care, which included periodic visits. Throughout the intervention period, the researcher was available to answer questions from participants in the intervention group via phone calls every two weeks.

To prevent information sharing between the intervention and control groups, participants were selected from different hospitals. At the end of the sixth week, both the intervention and control groups re-completed the questionnaires. To uphold ethical principles in research participation, the educational content provided to the intervention group was shared with the control group at the conclusion of the study. In total, 70 participants were enrolled in the study; however, one participant from the intervention group withdrew (Figure 1).

Data Analysis

Data analysis for the study was conducted using SPSS version 16 (Chicago, IL, USA). Descriptive statistics, including mean, standard deviation, frequency, and percentage, were utilized to summarize the data. The normality of the data was assessed using the Kolmogorov-Smirnov test. Fisher's exact test was employed to compare demographic variables between the two groups, while the independent t-test was used for between-group comparisons, and the paired t-test was applied for within-group comparisons. A significance level of 0.05 was established for all statistical tests.

Results

The mean age of participants in the intervention group was 58.94 ± 13.98 years, while in the control group, it was 58.34 ± 12.72 years ($P = 0.853$). In terms of gender distribution, half of the participants in the intervention group (50%) were male, compared to 60% in the control group. Most participants in both the intervention group (76.5%) and the control group (74.3%) reported having no education or only primary education. Additionally, a majority of participants in the intervention group (73.5%) and the control group (62.9%) had underlying health conditions. The intervention and control groups were found to be homogeneous across all demographic characteristics ($P > 0.05$) (Table 1).

The independent t-test indicated that prior to the intervention, the mean AKT scores in the intervention and control groups did not differ significantly ($P > 0.05$). However, after the intervention, the mean AKT score in the intervention group was significantly higher than that in the control group ($P < 0.01$). The paired t-test results showed that in the intervention group, the mean AKT score after the intervention was significantly higher than the mean score before the intervention ($P < 0.001$).

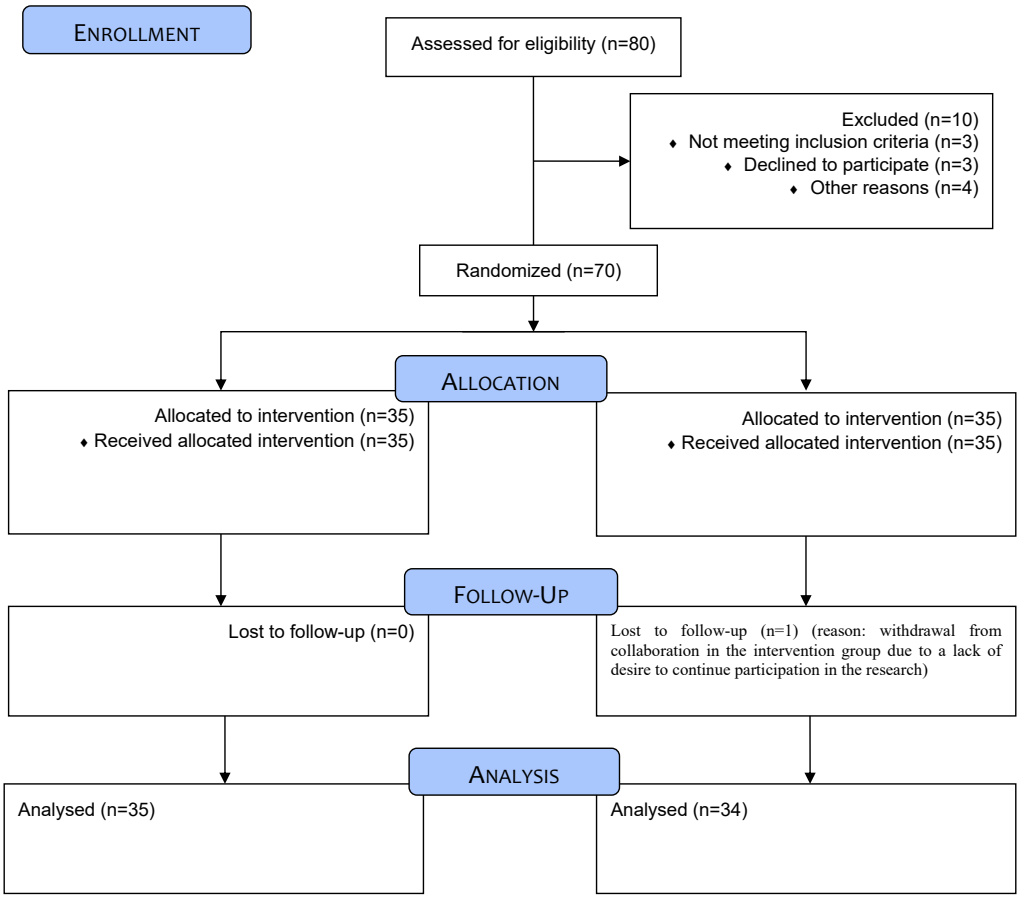

Figure 1. Consort flow diagram

Table 1. Comparison of demographic characteristics of participants between the intervention and control groups

Variables		Intervention (n=34) Frequency(%)	Control (n=35) Frequency(%)	*P* value*
Age	25-40	3(8.8)	3(8.6)	0.853
	41-55	10(29.4)	13(37.1)	
	56-70	13(38.2)	11(31.4)	
	70<	8(23.5)	8(22.9)	
Gender	Male	17(50)	21(60)	0.472
	Female	1(50)	14(40)	
Educational status	No education or early childhood education	12(35.3)	15(42.9)	0.691
	Primary education	14(41.2)	11(31.4)	
	High school education	5(14.7)	4(11.4)	
	Bachelor's degree	3(8.8)	5(14.3)	
Suffering from an underlying disease	Yes	25(73.5)	22(62.9)	0.440
	No	9(26.5)	13(37.1)	

Fisher's exact test *

Conversely, in the control group, there was no significant difference in the mean AKT score before and after the intervention ($P>0.05$) (Table 2).

Table 2. Comparison of AKT scores between the intervention and control groups

AKT	Intervention (n=34) Mean±SD	Control (n=35) Mean±SD	*P* value*
Before	20.58±8.97	24.94±9.46	0.054
After	30.85±7.45	25.37±.58	0.006
P value**	0.001>	0.187	

Independent t-test, **Paired t-test*

Discussion

This study aimed to determine the impact of needs-based education on the knowledge of patients treated with OACs in educational hospitals affiliated with Shiraz University of Medical Sciences in 2024.

In the initial analysis, statistical tests demonstrated that there were no statistically significant differences in demographic characteristics between the two patient groups, indicating that the groups were homogeneous regarding these factors. The findings revealed that the mean knowledge score concerning anticoagulant medications among patients before the intervention did not differ significantly between the groups. This finding aligns with the results of a prospective study conducted by Cao et al in China, which showed that prior to the intervention, the average knowledge about the medication in both groups was not significantly different ($P>0.001$) (28).

Following the intervention, the mean knowledge regarding anticoagulant medications in the intervention group significantly improved. In contrast, the control group did not exhibit a statistically significant difference in knowledge from the pre-test to the post-test. This indicates that needs-based education effectively enhanced the medication knowledge of patients undergoing treatment with OACs. Most studies in this area support the findings of the present study.

For instance, a randomized controlled trial by Liang et al in China reported that educational interventions improved the level of knowledge and awareness among patients ($P=0.03$) (29). Similarly, a study by Ibrahim et al in Nigeria found that education delivered through group discussions significantly enhanced patients' knowledge and awareness ($P=0.001$) (30). In Turkey, a clinical trial conducted by Baysal and Midilli demonstrated that one-on-one education, supported by written and visual materials, effectively increased patients' knowledge of warfarin ($P<0.05$) (31). Additionally, a study by Hamtaei Gashti et al in Tehran indicated a significant improvement in patients' medication knowledge following educational interventions ($P<0.05$) (32).

Houshyar et al identified a direct and significant relationship between knowledge of anticoagulants and treatment adherence among elderly patients with atrial fibrillation ($P=0.02$), emphasizing the need for educational interventions aimed at enhancing knowledge of anticoagulants (27). Therefore, improving patients' understanding of OACs is highly beneficial, and implementing effective, practical interventions by nurses should be prioritized in the care of these patients.

The alignment of findings across various studies can be attributed, as posited by the researcher, to the intrinsic nature of education. Providing information on a specific topic, in any format, can significantly enhance patients' knowledge and awareness. Educational interventions have consistently been a focal point of healthcare, and patient education is a primary responsibility of nurses that begins even before patient admission and extends beyond discharge.

The key strength of the present study lies in its needs-based educational design and methodology. In needs-based education, patient requirements and necessary information are assessed prior to the educational session, allowing the educational program to be tailored accordingly, primarily based on the principles of shared decision-making. The first and most fundamental step

in planning a needs-based educational program is to recognize the strengths and weaknesses of the healthcare setting. Identifying these needs provides a foundation for establishing objectives and creates an appropriate context for organizing human, material, and spiritual resources (33).

Despite some commonalities, significant differences exist between the present study and the reviewed studies. The current study focuses specifically on patients using OACs, where correct usage is critical, as improper use can lead to severe complications. In contrast, the target group in the study by Hamtaei Gashti et al (32) comprised patients with multiple sclerosis. Additionally, the research environments differ, as the study conducted by Baysal and Midilli took place in Turkey, while Ibrahim et al's study was carried out in Nigeria, both of which have distinct healthcare systems and access to educational resources compared to Iran.

Given the consistent findings in the literature indicating that educational interventions positively impact patients' medication knowledge; it can be concluded that the hypothesis is confirmed: needs-based education is effective in enhancing the medication knowledge of patients undergoing treatment with OACs.

Conclusion

The results of this research confirm and support most of the research hypotheses, particularly the assertion that "needs-based education is effective in improving the knowledge of patients treated with OACs." By enhancing patients' understanding of anticoagulant medications and consequently increasing adherence to treatment, such educational interventions can reduce the risk of bleeding in these patients. Nurses and physicians play a crucial role in patient education, and advancements in technology have made access to educational resources—and even remote nursing—much easier. However, a critical aspect often overlooked in educational interventions is the design of programs tailored to the specific needs of patients. Effective programs should not only address these needs but also avoid being repetitive or tedious. When patients perceive a genuine need for education, they are typically more motivated and eager to learn. Based on the results of this research, it can be inferred that education positively influences treatment adherence.

However, this study has several limitations, including a small sample size, the duration of participant involvement, and specific study characteristics such as continuous follow-up, the provision of education tailored to participants' needs, and the presentation of educational content in verbal, written, and telephonic formats. Additionally, the use of non-random sampling necessitates caution when generalizing the results. Future studies are recommended to compare needs-based education with remote education concerning clinical outcomes for patients undergoing treatment with OACs. Furthermore, research should examine the impact of needs-based education using applications designed to assess treatment adherence and relevant laboratory indicators.

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Authors' Contribution

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Competing Interests

The authors declare that there were no conflicts of interest associated with this study.

Ethical Approval

The study was conducted in accordance with the Declaration of Helsinki, and Institutional Review Board approval was obtained (IR.SBMU.PHARMACY.REC.1402.153). Prior to the commencement of data collection, the researcher provided participants with a clear explanation of the study's scientific basis and their roles within it, ensuring they fully understood the undertaking. Each participant was informed of their voluntary participation and their right to withdraw from the study at any time. The researcher outlined the primary objective of the study and assured participants that their data would remain strictly confidential. All participants signed an informed consent form.

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