

ORIGINAL ARTICLE

Effectiveness of Nurse-led Warfarin Educational Programme on Knowledge and Compliance for Patients Newly Commenced on Warfarin Therapy

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ABSTRACT

Introduction: An effective warfarin educational programme is needed in view of the recent increase in warfarin prescriptions and adverse drug events. Due to the obvious risks of anticoagulants administration, evaluating patients' awareness seems to be crucial. This study aimed to evaluate the effectiveness of a nurse-led warfarin education program on knowledge and compliance among patients newly commenced on warfarin therapy. **Methods:** This study utilised the one-group pre/post-test quasi-experimental approach. A total of 64 stable patients who recently started their prescriptions on warfarin for less than six months were recruited via purposive sampling at a tertiary hospital in Kuala Lumpur, Malaysia. The nurse-led intervention consisted of structured warfarin education. Data collection using Anticoagulation Knowledge Assessment and Morisky Medication Adherence Scale to measure knowledge and compliance with warfarin therapy. **Results:** The mean (SD) knowledge score was 42.58 (13.18) before intervention and increased to 68.91 (17.10) after warfarin educational intervention, while the mean (SD) compliance score was 3.78 (1.76) and decreased to 3.39 (1.51) after intervention. It shows that patients' knowledge and compliance with warfarin therapy have also improved. There was a significant association between knowledge and compliance variables ($P < .001$) after intervention. **Conclusion:** Our findings revealed that a nurse-led warfarin educational program could effectively increase patients' anticoagulation knowledge and also improve their adherence to warfarin therapy. Hence, the study suggests implementing this intervention among a larger sample and poorly literate patients as a way to help them and increase the tendency to prevent warfarin complications.

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INTRODUCTION

Warfarin, the global most widely used anticoagulant drug, can easily be administered at an affordable cost with proven benefits for various medical conditions, such as atrial fibrillation (AF), mechanical heart valve replacement, and venous thromboembolism (1-2). In 2018, a report from New York showed warfarin causes a significant risk of major adverse effect and every year, it result in severe bleeding in 1-2% of patients and brain

haemorrhage in 0.1-5% of patients (3,4). Warfarin usage in Malaysia is 0.3787 defined daily dose (DDD)/1,000 inhabitants/day in 2017 (5). The retrospective cohort study was conducted George et al. (2022) among warfarin patients in Hospital Raja Permaisuri Bainun, Ipoh, Malaysia shows major bleeding occurred among 50.9% of the patients with gastrointestinal bleed, 34 (29.8%), as the common site of bleed (6).

The therapy aims to maintain anticoagulation levels, preventing thromboembolic events without an increased risk of bleeding complications. Its mechanism in increasing individuals' blood clotting period would be assessed by the International Normalised Ratio (INR; 4). Adverse events, which are deemed serious, most likely

will occur during the period when the INR deviates from the normalised therapeutic range (4-5). Patients prescribed with anticoagulation drugs or on warfarin treatment have a higher risk of stroke or recurrent venous thromboembolism. Meanwhile, patients who pass the period of anticoagulation will endure a higher risk of adverse effects, including excessive bleeding and haemorrhage risks that can potentially become fatal. According to this study, 54.9% of participants followed their regimens, but 34.3% of participants had failed to take their warfarin in the previous four weeks. (7). Similar study also found that over 40% of patients had poor warfarin adherence, and the total adherence rate among AF patients living in rural areas was less than 50%. The likelihood of poor warfarin adherence was 56% lower for those who lived with family. (AOR: 0.44; 95% CI: 0.21–0.93) than those living alone (8). The study found that adherence to warfarin among patient with AF was not satisfactory. Prior research has demonstrated that individuals adhere to warfarin therapy at a suboptimal rate, falling between 27.5% to 54.9% (9,10). Warfarin nonadherence is largely caused by a number of circumstances, such as low income, marital status, housing arrangements, complicated dosing regimens, clinical characteristics, inadequate health literacy, and medication regimens (7,9,10).

Factors that influence the blood coagulation mechanism may increase the risk of bleeding or thrombi, such as genetic influence and comorbidities, food (excessive intake of food rich in vitamin K), drug interaction (such as those with anti-inflammatories), poor medication compliance, and inadequate patient knowledge (11-12). Majority of the 99 randomly chosen patients who were recruited in the Warfarin Anticoagulation Clinic at the Mayo Clinic in Florida understood that they were taking warfarin to treat atrial fibrillation. Both the informed and the ignorant patient groups, however, were ignorant of their risk of stroke both on and off warfarin, as well as their risk of significant bleeding or unfavorable side effects from their medication. 76.6% of the 350 patients had inadequate knowledge, and 23.4% had adequate understanding (13). "Patients' lack of knowledge, misconception of the symptoms, inaccurate and poor documentation, insufficient communication and cooperation, and the lack of patient integration into the therapy are the causes of unsatisfactory oral anticoagulation management" (7,10,12). Better adherence is consistently associated with improved physical and mental health outcomes. It is, therefore, crucial to increase patient's knowledge about warfarin therapy. Therefore, this study aimed to evaluate the effectiveness of a nurse-led warfarin education program on knowledge and compliance among patients newly commenced on warfarin therapy.

MATERIALS AND METHODS

Study Design

Patients who began warfarin therapy were recruited in a pre- and post-test one-group quasi-experimental procedure conducted at an anticoagulant clinic in a tertiary hospital in Kuala Lumpur, Malaysia. The clinic operates on a weekly basis (every Wednesday). The INR levels were screened before consultation with the physician for further management, followed by a warfarin educational session. We designed a quasi-experimental study because this design is frequently used when it is not logistically feasible to conduct a randomized controlled trial due to effect of missed clinic visits on among patients on warfarin therapy during pilot study. It is challenging for researchers to follow up with patients who live far away, especially those outside of Selangor.

This study followed the Transparent Reporting of Evaluations with Nonrandomised Designs (TREND) checklist for nonrandomized controlled trials.

Study Setting and Participants

A purposive sampling was used to recruit 64 patients according to the inclusion criteria: a) adults aged 18 years old who started warfarin therapy less than six months (who had been attending the anticoagulation clinic for more than five visits); b) patients who were clinically stable before the recruitment date and were currently on active prescriptions for warfarin according to the clinic records; and c) filling out the questionnaire independently, physical and psychological well-being to accurately answer the questions. The inclusion criterion of patients with more than five clinic visits was selected based on the researcher's clinical experience and literature review (14-16). Although they received different therapeutic dosages of warfarin therapy, most of the patients showed stable INR levels after the fifth visit (15-16). The medical records of the selected participants were examined to evaluate the overall management of warfarin therapy, including the five most recent INRs recorded and the prescribed warfarin doses. Patients with psychiatric illness and bleeding disorders were excluded from this study.

Research Instrument

Data were collected using a set of questionnaires consisted of three sections: sociodemographic characteristics, Anticoagulation Knowledge Assessment (AKA)(15-16), and Morisky Medication Adherence Scale (MMAS-8;18).

The demographic characteristics were used to gather patient's characteristics, while the Anticoagulation

Knowledge Assessment and MMAS-8 were distributed to determine the level of knowledge and compliance before and after the nurse-led warfarin educational programme.

The AKA questionnaire was developed based on validated questionnaires from previous studies to assess patients' knowledge of warfarin (15-16). The questionnaire is a 29 item, multiple-choice instrument and consistent with best practices for assessing validity and reliability of patient knowledge instruments. There are twenty-nine items relating to knowledge of warfarin therapy, INR results, food, signs and symptoms, side effects, and complications when patients were on other medications. The warfarin knowledge questionnaire involves choices of the "Right Answer" and the "Wrong Answer." Patients were given a score of 1 for every correct answer and 0 for a wrong answer. The mean cut-off points were categorised as adequate knowledge ($\geq 42.6\%$) and inadequate knowledge ($< 42.6\%$) based on normality test. The self-answer part for warfarin compliance comprises eight items, with a score of 1 given to the response of "yes" and 0 to the response of "no," with a maximum total score of 8. The mean score cut-off points are classified as compliance (≤ 3.78) and non-compliance (> 3.78). The content validity for Anticoagulation Knowledge Assessment and Morisky Medication Adherence Scale (MMAS-8) was assessed by three expert panels consisting of cardiologists, head of pharmacist and clinical nurse specialists to considering three criteria: relevant to the construct, clarity and similarity to other items. Revisions were made as suggested by the experts; items were reworded and changes made to the sentence structure. No items were deleted from the questionnaires. Regarding each item's evaluation criteria, we always maintained the statement when relevance and clarity were greater than 80%. In case of similarity with other items, we removed them. The inventory was translated from English to Malay language using a back-to-back translation that was compliance standard protocol described in translation guidelines. The medical professional reviewed the questionnaire and confirmed the translation. Moreover, the questionnaire was reviewed and approved by an Malay educator to guarantee the correctness of both questionnaires and understanding by non-medical people. The adapted data collection instruments was pretested among 30 atrial fibrillation stable patients admitted to the ward. All surveyed patients indicated that all sections were clear and easy to understand. During the pilot study analysis, we found that the participants filled in all questionnaire items, and no missing data were found. In this study, the internal consistency reliability of Kuder-Richardson 20 (KR-20) for the knowledge and compliance sections was 0.738 and 0.812, respectively, which indicates good reliability. Therefore, the research team used the same questionnaire for the main study. Furthermore, we excluded the pilot study participants from the main study.

Nurse-led Warfarin Educational Programme

The nurse-led warfarin educational programme was communicated through a slideshow presentation, which includes six components of structured warfarin educational therapy. The six components are: 1) warfarin indication, 2) dosage, 3) dietary restrictions, 4) drug interactions, 5) restricted activities, and 6) recognising signs and symptoms of complications. The aim of the educational session is to increase and support participants to better understand warfarin therapy, besides ensuring compliance with the treatment. The contents were reviewed by a cardiovascular expert, the head pharmacist, and a clinical nurse specialist to ensure accuracy.

Although similar studies have been undertaken in other settings, it is worthwhile to replicate them in the present setting due to its uniqueness of multi-cultural background and the major concern of non-compliance in the current setting (14-15). The slideshow serves as an additional visual aid to enhance the effect of the verbal information of health teaching provided by nurses. Warfarin information has empowered patients and their families to participate in the warfarin therapy treatment process and created a patient-sided driver motivator for successful recovery. Cengiz et al. (2015) and Wajid et al. (2019) stated that audio-visual education for CAD patients before any procedure engenders a more positive outcome on knowledge and anxiety, blood pressure, and heart rate levels when compared to verbal information (12,13). The sessions were conducted by a researcher who was trained in anticoagulation therapy management.

Data Collection

Data collection begins upon approval from the hospital director and clinical research centre. The list of potential subjects eligible for possible inclusion was obtained from the nurses in-charge in the clinic. Sixty-four participants were actively involved pre- and post-intervention. The sessions were conducted individually within 20 to 30 minutes, which included checking vital signs and INR level and giving the structured warfarin education programme. In the pre-intervention phase, knowledge and compliance of patients on warfarin therapy were measured using a set of questionnaires, and the INR measurements were obtained for the baseline. The participants were given clear instructions on how to answer the questions. All participants answered the questionnaires independently. The patients attended the warfarin educational programme session immediately after the pretest. Participants were given a one-month appointment prior to the INR levels screening. They were contacted weekly by phone for the first month to discuss their status. The rationale for the decision to collect post-intervention data after one month was based on a report that the risk for major bleeding during the first month of warfarin therapy is about 10 times higher than the risk after the first year (19). Post-tests were scheduled

a month post-warfarin educational session with similar tests as in the pre-intervention, and the INR levels were measured by the same researcher for consistency and reliability.

Ethical Consideration

Permission to carry out the proposed study was granted by the Director of Cardiology, Department of Nursing Administration, and the Medical Research Ethics Committee (MREC), Ministry of Health (MOH; NMRR-11-715-10253). Patients received written and oral information about the flow and aims of the study, as well as potential benefits to their consent and participation in the study. Patients were also informed that they may withdraw from the study at any time without disclosing the reason and negative consequences for their medical care. The researcher emphasised that participation in the study is voluntary, and the confidentiality and anonymity of the subjects were assured throughout the coding of all data.

Statistical Analysis

All statistical analyses were conducted via SPSS Software Version 23.0 (IBM Corp., Armonk, NY, USA). Frequencies and percentages were used to represent categorical variables, while mean and standard deviations were used to impart continuous variables. The analysis was performed with a 95% confidence interval. Descriptive statistics represented the overview of participants' demographic profile concerning age, gender, marital status, race, educational level, occupational status, indication of warfarin, and frequent visits to check INR level. The paired t-test determined the differences between pre- and post-intervention knowledge and compliance scores with INR results. Pearson correlation was used to examine the relationship between two dependent variables (knowledge and compliance scores). A p-value of < 0.05 is considered as statistical significance.

RESULT

Demographic Characteristics

Participant characteristics are shown in Table I, with 64 (100%) participants involved in this study. The average age of the participants is 42 (SD = 6.57) years, and the majority of them (39, 60.9%) are between 41 to 50. Of 64 patients, 36 (56.2%) are females and the rest (43.8%) are males. Most of the patients are married 45 (70.3%), of Malay ethnicity (40.6%), have a secondary level of education (n = 31, 48.4%), working (n = 39, 60.9%), and the most common indication on warfarin is atrial fibrillation (n = 25, 39%). Furthermore, 31 patients had frequent visits for INR check-ups, i.e., 6–10 times (48.4%).

Knowledge and Compliance Scores on Warfarin Therapy
The mean (SD) knowledge score for warfarin therapy is 42.58 (13.18) pre-intervention, which increased to

Table I: Baseline demographic profile of Patients Newly on Warfarin Therapy(N=64)

Variables	No. of respondents (n= 64) %(n)
Age, Mean(SD)	42.16 (6.57)
20 - 30	5 (7.8)
31 - 40	12(18.8)
41 - 50	39(60.9)
51- 60	8(12.5)
Gender, n (%)	
Male	28 (43.8)
Female	36 (56.2)
Marital status, n(%)	
Single	2 (3.1)
Married	45 (70.3)
Divorced/Alone	17 (26.5)
Race, n (%)	
Malay	26 (40.6)
Chinese	24 (37.5)
Indian	14 (21.9)
Educational Level, n (%)	
None	8 (12.5)
Primary	7 (10.9)
Secondary	31 (48.4)
Tertiary	18 (28.1)
Occupational status, n (%)	
Employee	39 (60.9)
Unemployed	25 (39.1)
Indication on warfarin therapy, n(%)	
Atrial Fibrillation	25(39)
Deep Vein Thrombosis	16(25)
Prosthetic Heart valves	14(21.9)
Others	9(14)
Frequency visit INR Check-up, n (%)*	
<5 times	22 (34.4)
6-10 times	31 (48.4)
>10 times	11 (17.2)

*INR= International Normalized Ratio



Fig. 1: Total Knowledge Score on Warfarin Therapy Pre-and Post-Intervention (N=64)

68.91 (17.10) after warfarin educational intervention (Fig.1). Of the 64 patients, 33 (51.6%) had inadequate knowledge of warfarin therapy. However, the results showed that after one month of warfarin educational sessions, the percentage had declined, with only 9.4% of patients having inadequate knowledge. Prior to the warfarin educational session, the mean (SD) compliance

score was 3.78 (1.76) and decreased to 3.39 (1.51) post-intervention (Fig.2). Similarly, patients' compliance with warfarin therapy had also improved from 46.88% (n = 30) to 50% (n = 32). The results showed a significant difference in mean knowledge scores between pre- and post-intervention. The warfarin education by nurses has improved the knowledge of warfarin therapy in most of the patients. The most poorly answered question is related to the food that contains vitamin K. There is no significant difference in compliance scores between pre- and post-intervention (P = .088), although the results show a slight improvement (Table II).

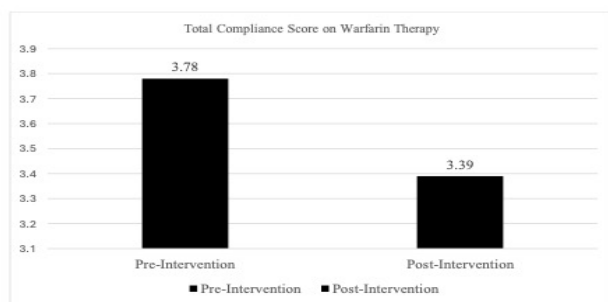


Fig. 2: Total of Compliance Score on Warfarin Therapy Pre- and Post-Intervention (N=64)

Table II: Differences between mean knowledge and compliance score pre- and post-intervention (N=64)

Variables	Mean (SD)	t	df	p-value
Knowledge Scores	Pre-Intervention 42.58 (13.18)	-10.722	63	<0.001*
	Post-Intervention 68.91 (17.10)			
Compliance Scores	Pre-Intervention 3.78 (1.76)	1.731	63	0.088
	Post-Intervention 3.39 (1.51)			

*Statistically significance at p<0.001

Correlation between knowledge and compliance scores pre- and post-intervention

The relationship between knowledge and compliance scores pre- and post-intervention was evaluated using the Pearson correlation coefficient. No correlation between knowledge and compliance scores pre-intervention (r = -0.198, P = .117) is observed. In contrast, knowledge is positively and moderately correlated with compliance scores post-intervention (r = -0.417, p < 0.001; Table III).

Table III: Correlation between knowledge and compliance scores pre-and post-intervention (N=64)

Knowledge and Compliance Scores	Pearson Correlation (r)(n=64)	
	Correlation Coefficient	p-value
Pre-Intervention	-0.198	0.117
Post-Intervention	-0.417	<0.001*

*Statistically significance at p<0.001

Difference of Compliance Scores on INR Result

No difference is noted in the mean of INR results (within the therapeutic range and out of the therapeutic range) between the compliance scores. The results indicate that compliance did not influence the INR results pre-intervention (P = .428). However, the results show a significant difference in mean compliance scores post-intervention (p < 0.001; Table IV).

Table IV: Difference between compliance scores and INR results pre-and post-warfarin education intervention (N=64)

Compliance Scores and INR results	Mean (SD)	t	df	p-value
Pre-intervention	Within TR 3.50 (1.886)	-0.798	62	0.428
	Outside TR 3.89 (1.716)			
Post-intervention	Within TR 2.17 (1.071)	-8.695	62	<0.001*
	Outside TR 4.40 (0.976)			

*Statistically significance at p<0.001

Within TR = Within Therapeutic Range; Outside TR = Outside Therapeutic Range)

DISCUSSION

The complexities of warfarin therapy require the patients to have adequate knowledge to ensure the treatment benefit is achieved and to minimise complications. This study intends to evaluate the effectiveness of a designed warfarin educational programme on patients' knowledge and compliance with warfarin therapy.

The current study showed that most of the patients have adequate knowledge concerning warfarin therapy after the intervention. The results showed a significant difference between pre- and post-intervention knowledge scores. In the post-intervention phase, majority of participants correctly answered the questions on the actions to be taken when a dose of the medication is missed, besides types of food and other drug interactions with warfarin. More than half (50%) of the patients could answer the questions about dietary intake and the interaction of warfarin with other drugs, such as paracetamol. For a medication that could be dangerous like warfarin, it is important to ensure that people understand the information and can take part in making health decisions (David & Sara, 2024). The present study also indicates that warfarin educational programme had improved patients' knowledge, which is consistent with the suggestion from a previous study that warfarin education helped develop patients' warfarin knowledge and understanding of warfarin therapy (10,12,13). The effectiveness of the health education intervention may be affected by the mode of health education delivery and the content. Prior to their planned admission, the slideshow presentation will provoke patients' curiosity and information-searching activity. The slideshow also served as a reminder of their questions and worries during the health education

session, which was further enhanced by applying the patient-centred approach. Health literacy is an important factor that individuals can achieve and understand the information and services necessary to make appropriate decisions involving their health.

During the education session, a trustful nurse-patient relationship was established in which patients were encouraged to express their feelings or anything they deemed to be significant. The results showed that patients who went for the warfarin educational programme had higher knowledge scores in contrast to patients who did not. Moreover, a statistically significant difference in mean knowledge scores between pre- and post-intervention was noted. Consistently, these findings correlate with Cengiz et al. (12,13), who revealed that the warfarin educational programme provided improved patient knowledge in diminishing the occurrence of side effects, such as better anticoagulation control. Although most healthcare centres distribute written patient education materials, such as warfarin booklets, to provide information about warfarin therapy, healthcare professionals cannot assume that the patients read and understand their content. Moreover, questioning the patients based on the assumption that they are illiterate might humiliate them. Therefore, it is important to implement other effective methods of education, such as a slideshow presentation. Older patients with low levels of literacy are the ones at risk of not adhering to the regime because they are not sure of questions to ask their healthcare providers. This situation is further hampered by the humiliation of the perception of others associating them with illiteracy. Consequently, it is the responsibility of healthcare providers especially nurses to disseminate educational materials in a way that will satisfy the unique learning requirements of patients with low literacy levels (15).

The compliance levels in this study were similar before and after the intervention. In the pre-intervention, 78% of the patients confessed that they sometimes missed their medication. Previous studies found that one of the factors that may contribute to non-compliance among patients with warfarin therapy is an individual's acceptance of illness (11,13,16,20). This malady not only causes the treatment effectiveness to decline but also increases the costs of managing chronic conditions. Among the significant predictors of compliance, particularly among chronically affected patients who need long-term treatments, are treatment-related costs (6). Compliance is mainly related to behavioural factors, thus requiring a longer period and constant reminders to practice. Some of the patients may find it difficult to remember to take their medicine due to the complex treatment regimen (8,11-12).

Knowledge among patients is certainly associated with better-quality compliance among them. Before the intervention, the need to consider food consumption rich

in vitamin K and the effect of vitamin K on the action of warfarin were not clearly understood by the participants. However, the findings revealed that participants can justify and report the effect when they consume vitamin K-rich food during post-intervention. The results show that participants' knowledge and compliance scores are significantly associated after the intervention. There is a consensus in the literature that enhanced patient knowledge and compliance with warfarin therapy will improve therapeutic outcomes (15,17,21).

Socio-demographic characteristics in this study, such as age, educational level, race, and the number of visits to the INR clinic, did not affect the compliance scores on warfarin therapy. A study by Shrestha et al. (11) reported no difference in the level of compliance to drugs between age groups. However, despite this study exhibiting no difference between compliance scores and socio-demographic characteristics following educational intervention, other studies reported the opposite. Several demographic and medical factors could potentially complicate successful warfarin management and alter the effect of the treatment, such as age, marital status, medical indication for warfarin, dietary regimen, drug interaction, and genetic factors (10-12).

Non-compliance has become a major cause of failure in controlling the INR levels, as suggested by the present study. Results of the compliance scores and INR differed before and after warfarin education intervention. However, a significant correlation between compliance scores and INR results could be seen after educational intervention. Primary causes of warfarin complications, like haematuria, nausea, or stomachache, are the results of non-compliance and low levels of patient knowledge about oral anticoagulant therapy, as confirmed by a study (7,12,15). Many factors, including experienced dosage regulation, adequate patient education, and patient adherence to the treatment regimen, influence the achievement of optimal therapeutic ranges. The occurrence of a bleeding episode may affect general health status and overall quality of life among patients on warfarin therapy. The findings of this study could help physicians, pharmacists, allied healthcare professionals, and the family members of the patients to better understand the physical, mental, social and environmental difficulties which patients usually face during warfarin therapy. The nurse-led plan probably helped build trust, making it a safe space where patients could ask questions and talk about problems. This connection could have led to long-lasting changes in behaviour. A safer and more effective treatment can be assured to support patients' optimal self-care behaviours and promote medication compliance with the provision of continuous education to the patients on warfarin. In meeting the ever-changing needs of the patient, implementing warfarin education by cardiology nurses is a dynamic strategy.

Nevertheless, the present study is not without limitations. A quasi-experimental design only allows the measurement of one experiment group. The research design renders it impractical for any conclusions about the association between an intervention and a particular result. Furthermore, due to time constraints, this study could only proffer short-term follow-up among patients. Alternately, long-term follow-up with more patients may be advantageous in investigating the predictive effect of study characteristics and the predictors of knowledge and compliance associated with warfarin therapy.

CONCLUSION

In line with the current increase in patients on warfarin therapy, the need for an efficient warfarin education programme has become more apparent. In conclusion, an educational programme using slideshows as an audio-visual aid supplement was deemed effective in improving the quality of life among patients and encouraging compliance with warfarin therapy. Warfarin educational programme was shown to significantly increase knowledge and improve compliance. The effect of the intervention was the result of combined educational intervention approaches used in this study, which used a slideshow presentation and patient-centred information sessions. Patient education on oral anticoagulation will continue to serve as a positive change for patients and the nursing staff.

Relevance to clinical practice: This important finding will allow healthcare providers especially nurses to assess of patients' adherence to warfarin therapy in case of poor INR control and when the prescribed treatment seems to have failed. Nurses must recognize the signs of warfarin toxicity so they can inform the doctor in charge. By providing a special counselling room to identify specific barriers for each patient and address their learning needs can be solved by adopting appropriate techniques to improve medication adherence. Hence, workshops or any training programs should be created to help healthcare providers especially nurses' understand the potential psychological and physical side effects of anticoagulant therapy and to help them establish preventative measures. Future research could developed education via mobile technologies on enhancing warfarin therapy adherence and explore the involvement of patients' relatives in medication adherence.

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