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## ORIGINAL ARTICLE

# Factors Associated with Warfarin Therapy Knowledge and Anticoagulation Control among Patients Attending a Warfarin Clinic in Malaysia

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### ABSTRACT

**Objective:** To determine the factors that correlated with the patient's knowledge of warfarin therapy, the level of medication adherence and INR control.

**Methods:** A cross-sectional survey was conducted at the Warfarin Clinic of Hospital Teluk Intan, Malaysia. The systematic random sampling method was used in sample selection and face-to-face interviews using standard questionnaires were administered to determine the demographic characteristics, the patient's knowledge of warfarin therapy and medication adherence. Medical records were reviewed to determine anticoagulation control during the study period.

**Results:** A total of 52 patients were enrolled in the survey (mean  $\pm$  SD age of 58.73  $\pm$  9.55 years), with a response rate of 95%. A large proportion (63.5%) of the respondents had only primary school education and 71.2% were low-income earners (below RM500 per month). About 69% of the respondents were able to read and 53.8% were able to understand Malay (the national language of the country). A majority of the patients (98%) had verbal medication education through medical or nursing officers. Only 44.2% of patients knew about their medications, but the medication adherence was fairly good at 76.1%. The study showed that age, income level, level of education, and literacy in various languages were significantly associated with the patient's knowledge on warfarin therapy ( $p < 0.05$ ). The study also showed a significant difference between those patients who knew/did not know about their medications in terms of warfarin therapy knowledge ( $p < 0.05$ ).

**Conclusion:** Age, income, educational level, literacy and race were significantly correlated with the patient's knowledge of anticoagulation. The study did not find any association between anticoagulation control and the knowledge of anticoagulation.

**Practice Implications:** The disadvantaged groups receiving anticoagulation therapy, including the low-income earners, the elderly, the less-educated and the illiterate, should be given utmost care and attention.

**Key Words:** warfarin, knowledge, patients, education, anticoagulation control.

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## Introduction

Warfarin has been the mainstay oral anticoagulant agent for the last several decades despite its narrow therapeutic index and difficulties to use [1],[2]. It has become a successful agent for the medical management of thromboembolic diseases such as chronic atrial fibrillation, mechanical heart valve replacement, deep vein thrombosis, pulmonary embolism, and valvular heart disease, among others [3]. This has led to a dramatic increase in the number of patients receiving warfarin therapy and those who are referred to anticoagulation clinics. However, warfarin therapy is plagued by the need to frequently fine-tune dosage, based on the International Normalized Ratio (INR), the relatively large variability in dosage requirements based in part on CYP2C9 activity, its slow action dependent onset and offset on the depletion and restoration of vitamin K-dependent clotting factors and many drug interactions [4].

Interactions with other drugs, dietary intake, poor adherence with medication and deficiency in patient knowledge are factors associated with non-therapeutic treatment outcomes [3]. Therefore, it is pertinent to assess the patient's knowledge of and adherence to warfarin therapy. Adhering to prescribed recommendations during treatment is essential, but managing and educating patients with low literacy skills is a challenge for health care providers [3]. The patient's knowledge on warfarin has been shown to be a determinant of anticoagulation control [5] and patient education and counseling is an integral component of a successful warfarin therapy.

Several factors could play a role on the patient's knowledge on warfarin therapy, adherence to its treatment and overall management of the therapy. A multidisciplinary education program may improve the patient's knowledge on warfarin therapy, drug adherence, as well as adherence to medical advice [6]. Malaysia, a multiracial Southeast Asian nation with Malay, Chinese, and Indians as the majority, is an entity with cultural

diversities and distinct genetic variability among the several races. These diversities have important clinical implications on how therapeutic agents with genetic polymorphism such as warfarin, should be used in practice, as well as the impact of cultural practices and knowledge on warfarin therapy. This study therefore, aims to determine the sociodemographic factors associated with the patient's knowledge on warfarin therapy, the level of therapy adherence, and INR control.

## Methods

### Setting

The study was conducted at the Warfarin Clinic of Hospital Teluk Intan, which operates on a once weekly-basis (every Wednesday). The clinic was established in August 1999 to accommodate the expansion in the number of patients undergoing outpatient anticoagulation therapy (i.e. warfarin). A Warfarin dosing protocol was designed to ensure a more efficient and standardized system of evaluating anticoagulation therapy. It consists of dosage initiation, maintenance and adjustment of warfarin based on diagnosis, intervention required if the INR is outside normal therapeutic range and a recommended schedule for the patient's follow-up. All patients on warfarin therapy are referred to this clinic for review and management by a physician. The patient has his/her INR checked before seeing the physician for further management.

### Study Design

This was a cross-sectional study conducted over 4 months. A face-to-face interview using a structured questionnaire was performed by trained data collectors at the anticoagulation clinic. During the study, the patient's current and previous INRs were also assessed to evaluate the level of anticoagulation control.

### Sampling

A randomized systematic sampling was used in the patient's selection. A minimum sample size of 47 patients was needed to detect an estimation of 20% patients who had poor knowledge on warfarin therapy, with 10% accuracy (EpiInfo version 6).

Patients eligible for inclusion in the study were those who had been to the anticoagulation clinic for more than 5 visits. This criterion was set up because most previous studies showed the patient INR to be stable after the fifth visit. Fifty-two patients responded to the questionnaires. The medical records of the selected patients were then reviewed to assess the overall management of warfarin therapy, including the 5 most recent INRs recorded and warfarin doses prescribed.

### Data Collection Procedure and Instruments

Data were collected using a standardized form and two questionnaires (one for adherence assessment and the other for knowledge evaluation). The collected data included: demographic information such as the highest level of education, household income and literacy level; indication for and duration of warfarin therapy; and concurrent drug therapies. The patient's source(s) of information on their warfarin therapy, access to the warfarin booklet and understanding of its contents were also recorded. The patient's adherence to warfarin therapy was assessed through counting of tablets and a 4-item Moriskey questionnaire during the session.

The questionnaire to assess warfarin therapy knowledge was designed in 3 major Malaysian languages; Malay, Chinese and Tamil. It was validated by an expert panel consisting of 2 physicians and 2 senior pharmacists employed at the study hospital. The forward-backward translation method was used in translating the questionnaire into each language, to ensure conceptual equivalence. Face-to-face interviews were conducted by three researchers trained in questionnaire administration, who did not work in the clinic, as an effort to decrease potential bias.

The patient's knowledge of warfarin therapy was also evaluated during the interview sessions. The standardized assessment of knowledge consisted of questions that were intended to determine

the patient's knowledge of: indication, dose, mechanism of action, administration time, importance of blood monitoring, food-warfarin interactions, drug-warfarin interactions, actions to be taken in case of missed doses, adverse effects and the actions to be taken if an adverse effect occurs. The precautionary steps on certain occasions such as warfarin in pregnancy and before tooth extraction, were also asked. For the purposes of analysis, each question was assigned a point and the total point obtained, indicated the patient's overall knowledge on warfarin therapy.

The patient's medical profiles were further reviewed to determine the indication of warfarin therapy. The 5 most current INR values were reviewed and compared with target INRs specified in the local anticoagulant protocol. An audit concerning the management of anticoagulation was also conducted. The anticoagulation protocol provided guides for healthcare providers in patient management and ensured uniformity and continuity of service. The audit of patient management helped the investigators to ensure that other factors were considered in the analysis.

### Statistical Analysis

Descriptive statistics were used to present the data on demographic characteristics, literacy level, adherence to warfarin therapy, and knowledge of warfarin therapy. Continuous variables were expressed as mean  $\pm$  standard deviation (SD), whereas categorical variables were expressed as percentages and frequencies. Factors thought to contribute to the patient's knowledge on warfarin therapy and adherence, were analyzed using correlation analysis. The a priori level of significance for all analyses was two-tailed at 0.05. All statistical analyses were performed using SPSS software, version 11.0.

### Results

A total of 55 patients were selected for the study, with 52 responding to all the study questionnaires (95% response rate). The male to female ratio of the participants

was 1.1:0.9. The mean age  $\pm$  SD of the respondents was  $58.73 \pm 9.55$  years, with nearly half of them in the 60-79 year-old category. Two-thirds of the study patients were Malay and an overwhelming proportion of the patients (86.5%) had been to the anticoagulation clinic for more than 10 times. Moreover, the vast majority of the patients (63.5%-71.2%) belonged to the low household income category and had only primary school education. Most of the patients lived within more than 10 kilometers radius away from the clinic. The majority (61.5%) of the patients had received warfarin therapy due to chronic atrial fibrillation. The detailed patient's characteristics are presented in [Table/Fig 1].

(Table/Fig 1) Patient's Characteristics

Patients' Characteristics	N = 52
Age (years)	
Mean ( $\pm$ SD)	$58.73 \pm 9.55$
Median	59.50
Range	36-77
Mode	52.00
Gender	
Male	25
Female	27
Race	
Malay	36
Indian	10
Chinese	5
Others	1
No of visits	
Less than 5	0
5 to 10	7
More than 10 times	45
Indication for starting warfarin therapy	
Chronic atrial fibrillation with factors for stroke	32
Deep vein thrombosis	13
Severely dilated cardiac chambers, LV aneurysm	3
Deep vein thrombosis (below knee)	1
Deep vein thrombosis (above knee)	1
Not stated	2
Household income (per month)	
Less than RM 500	39
RM 500 to RM 1000	8
RM 1001 to RM 2000	2
More than RM 2000	3
Education level	
No formal education	9
Primary school	33
Secondary school	8
Higher education level	2
Distance From Hospital	
Less than 1 kilometer	7
1 to 5 kilometers	17
5 to 10 kilometers	6
More than 10 kilometers	22
Transportation to Anticoagulation Clinic	
Car Transportation	37
Bus	11
Taxi	3
Walking	1

Opportunities to receive education on warfarin therapy were determined during the interview sessions. On normal clinic days, patients should receive counseling from the prescriber or nurses regarding warfarin therapy as soon as possible, after initiation of therapy. In this study, no documentation was found in the patient's medical records, on whether the patients had been educated on warfarin therapy. However, the majority of the patients (94.2%) admitted that they received education on warfarin from medical officers (93.9%). Nearly all the patients were given a warfarin booklet, but only 78.4% indicated that they read it. Of this,

85% reported that they understood the contents of the booklet.

The international normalized ratios (INRs) for all patients were reviewed. The complete medical records of two patients could not be found and they were therefore excluded from further evaluations. Only 10% of study participants had 80% or more of their 5 consecutive INR readings within the targeted range. About 16% had 4 to 5 (80-100%) INR readings outside the target range and 6% had 3 (60%) INR readings within the supratherapeutic range [Table/Fig 2].

(Table/Fig 2) Patients literacy level, access to education on warfarin therapy, and INR readings

N = 52		
Spoken language ability		
Speak & understand 1 language	52	100%
Speak & understand 2 languages	19	36.5%
Speak & understand 3 languages	8	15.4%
Speak & understand 4 languages	4	7.7%
Spoken language		
Malay	48	92.3%
Hokkien	11	21.1%
English	3	5.8%
Tamil	6	11.5%
Mandarin	6	11.5%
Cantonese	4	7.7%
Literacy level		
Literate	36	69.2%
Illiterate	16	30.8%
Factors associated with literacy		
Gender (literate)	21 (88.3%)	
Female	13 (41.7%)	p = 0.037
Education level (literate)		
No formal education	1 (3.8%)	
Primary school	25 (69.4%)	
Secondary school	8 (22.2%)	p < 0.001
Tertiary school	3 (8.6%)	
Income per month (literate)		
No income	0 (0%)	
Less than RM 500	24 (66.7%)	
RM 500 to RM 1000	7 (19.4%)	
RM 1001 to RM 2000	2 (5.6%)	p = 0.001
More than RM 2000	3 (8.3%)	
International normalized ratio (INR)		
Patient who had 80% INR reading within target range	5	10%
Patient whose INR did not achieve target range		
1 reading	14	28%
2 readings	17	34%
3 readings	8	16%
4 readings	4	8%
5 readings	4	8%
Patient who had INR above the target range		
1 reading	17	34%
2 readings	4	8%
3 readings	3	6%
Education on warfarin therapy		
Claimed to have been educated	50	94.2%
Claimed not provided any education	2	5.8%
Warfarin booklet (N = 51)		
Patient who read the book	40	78.4%
Patient who didn't read the book	11	21.6%
Understanding of warfarin book content (N = 40)		
Patient who claimed understanding of the contents	34	85%
Patient who didn't understand the contents	6	15%

A review of the patient's medical records and appointment schedules found that all patients adhered to the appointment schedules of the clinic. The patient's warfarin therapy adherence was assessed using the 4-item Moriskey instrument and was further verified by pill counting. A total of 12 patients (23.1%) had poor adherence when assessed using Moriskey instrument; 10 patients (19.2%) claimed that they had sometimes forgotten to take medications, while the other 2 claimed that they had inadequate medications refill (an insufficient supply of medication). About 58% of the non-adhered patients

missed a warfarin dose once a month, whereas 25% and 17% missed 2 to 4 doses and at least 5 doses per month, respectively. Patients were asked further questions about the awareness of their current warfarin dose and this was correlated with what was prescribed in the medical profile. This study found that the proportion of agreement of self-reported awareness of the warfarin dose by the patient, as compared to the assessments in medical records, was 92%, ( $N=52$ ) kappa = 0.923,  $p<0.001$ . Only 44.2% were aware of the warfarin doses prescribed to them [Table/Fig 3]

(Table/Fig 3) Warfarin therapy Adherence

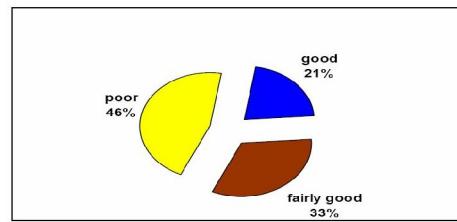
Claim of warfarin therapy adherence ( $N=52$ )	
Claimed to adhere	43 (80.8%)
Claimed not adhere	9 (19.2%)
Score of 4-item Morisky questionnaire	
0 (fully adhere)	35 (67.3%)
1 (satisfactory adherence)	3 (5.8%)
2 (average adherence)	2 (3.8%)
3 (poor adherence)	12 (23.1%)
4 (non-adherence)	0 (0%)
Reasons for non-adherence ( $N=12$ )	
Forgot to take	10 (83.3%)
Not enough medication	2 (16.7%)
Frequency of non-adherence per month ( $N=12$ )	
Once	7 (58.3%)
2-4 times	3 (25.0%)
5 or more times	2 (16.7%)
Factors associated with warfarin therapy adherence	
Education level	$r_s = -0.417, p = 0.02$
Income per month	$r_s = -0.306, p = 0.028$

Assessment of the knowledge on warfarin therapy was conducted using the knowledge questionnaire. The results showed that a majority (67.3%) of the patients had poor knowledge of different tablet dosage forms and their strength. The knowledge concerning the indication for warfarinization was also assessed. The proportion of patients who knew the indication and those who did not, was almost equal. Nearly 71.2% of the patients understood the mechanism of action of warfarin. The patient's knowledge was assessed, regarding the following: missed doses and actions to be taken, importance of INR monitoring, warfarin-food interactions, warfarin-drugs interactions, adverse events of warfarin and actions to be taken when they are perceived to occur and precautions to be taken while on warfarin therapy. [Table/Fig 4] summarizes these key findings.

(Table/Fig 4) Patient's knowledge on warfarin therapy

Knowledge domain	Correct Answer N (%)
Dosage	(32.7)
Indication	(53.8)
Mechanism of Action	(73.1)
Administration time	(94.2)
Action to take after missing a dose	(75.0)
Blood test for INR	(57.7)
Food-warfarin interaction	(5.8)
Drug-warfarin interaction	(38.5)
Alcohol-warfarin interaction	(65.4)
Side effects	(32.7)
Precautions	(55.8)

The overall score for each patient's knowledge on warfarin therapy was calculated (i.e. a point was given for each correct answer). An overall total score above 80% was considered as good knowledge, 50% to 80% as fairly good and less than 50% as poor knowledge. [Table/Fig 5] shows the overall scores.



(Table/Fig 5) Overall patients' knowledge on warfarin therapy

[Table/Fig 6] presents the factors that might be associated with the patient's knowledge on warfarin therapy. Correlation analysis showed that the patient's knowledge on warfarin therapy was significantly associated with their age ( $r_s = -0.367, p = 0.007$ ), household income ( $r_s = 0.291, p = 0.036$ ), educational level ( $r_s = 0.328, p = 0.018$ ) and the number of readable languages ( $r_s = 0.387, p = 0.005$ ).

The average percentage of INR that achieved targeted range (over 5 readings) was  $41.92 \pm 25.44$ , with a median of 40%. None of the factors was associated with the anticoagulation control.

(Table Fig 6) Patients' knowledge of warfarin therapy and the associated contributing factors

Factors	r value	p value
Age	-0.367	0.007*
Household income	0.343	0.013*
Educational level	0.341	0.013*
Hone distance from hospital	-0.036	0.799
Number of understandable language	-0.102	0.473
No of readable language	0.387	0.005*
Percentage of INR within targeted range	0.183	0.195
Moriskey scale	-0.111	0.435
	t value	p value
Gender	-0.298	0.767
Claimed had been explained on warfarin therapy before	-0.518	0.607
Given anticoagulation book before	-0.962	0.341
	F value	p value
Races	1.403	0.253

\*significant at a value < 0.05

## Discussion and Conclusion

### Discussion

Unlike most previous studies on the patient's knowledge on warfarin therapy [5], this study also assessed the incidence of the international normalized ratio (INR) at or outside the targeted range via the assessment of the patient's medical records. Ninety percent of the 50 patients reviewed, had an INR that might indicate an inadequate therapy or over-warfarinization. However, no relationship was found between the patient's knowledge and anticoagulation control. This was contrary to a previous study where the patient's education and knowledge were identified as important factors which could affect the anticoagulation control [5]. Prior knowledge of warfarin has been associated with a decreased risk of bleeding. Written and verbal information has been shown to improve anticoagulation control. While past studies suggest that patient education may be associated with better clinical outcomes, doubts remain about the effectiveness of patient education strategies [7].

Perhaps, there could be some explanations for the low patient's knowledge of anticoagulation. There might be flaws in the nature and extent of information provided by healthcare personnel on anticoagulation, as well as the method of delivery. This was shown by a low score

of the patient's knowledge in those patients who claimed to be educated by prescribers or nurses. A lack of knowledge and skills among health care professionals providing anticoagulation services might contribute to reluctance in advising patients on the risks and complication of anticoagulation. More widespread dissemination of guidelines to the medical staff is required, with specific instructions for counseling patients receiving anticoagulation. The other possible factor involved, might be the patient's inability to understand and retain the advice given. Poor doctor-patient communication has been well described for other chronic conditions [8]. More effective communication arises from understanding the patient's expectations, involving patients in negotiating their treatment plan and the continuity and accessibility of the staff. Better levels of the knowledge of the patients may also be achieved if the information is reinforced by simple measures such as repetition or use of written materials. The availability of a non-physician counselor such as a clinical pharmacist or a nurse practitioner, has also been shown to increase the patient's knowledge about medical treatments [9].

There was a difference in the patient's knowledge of anticoagulation among the different age groups. The elderly patients had poor knowledge on the subject as compared to the younger ones. This might be due to the inability to remember, and to the fact that the former category is often given many medications. Improvement in enhancing the knowledge of anticoagulation among elderly patients is needed, as they are at a high risk of side effects. There is also a need of specific anticoagulation dosing and introduction of an initiation protocol for the elderly, as a study showed that the protocol performs better than empirical dosing for older patients [10].

Household income and education level are the other factors which are found to be associated with the patient's knowledge of anticoagulation. Patients with low anticoagulation knowledge were found to

have low levels of education and low household income. For patients with low household income, medication and treatment adherence may be major problems. A study on the knowledge of cardiovascular disease among the Canadian population, found that patients from a low socioeconomic background had poor knowledge of disease<sup>11</sup>. Thus, the educational approach in enhancing the patient's knowledge should consider individual differences.

Illiteracy has become an increasingly important problem, especially, as it relates to health care. Literacy is defined as the basic ability to read and speak in the common language (Malay language in the Malaysian context). Health care professionals cannot assume that all patients know how to read, but direct questioning based on the assumption that the inability to read amounts to illiteracy often causes shame and embarrassment. Assessing a patient's reading skills in the clinical setting is important and provides insight into an individual's ability to function adequately in the healthcare environment. In this study, the illiteracy rate was almost 30%. This was probably because a majority of the study patients had low levels of education. The illiteracy levels also had a significant correlation with the knowledge of poor patients towards warfarin therapy. In the United States, researchers have found that illiteracy directly correlated to poorer health and disease.<sup>12</sup> The consequences of health illiteracy are lack of knowledge about medical care, lack of understanding of services, poorer adherence rate, increased rate of hospitalization and increased health care cost [13].

The purpose of written patient education materials (warfarin booklet in this case) is to provide information about health promotion, diagnostic procedures, treatments and medications. Patients need information that they can understand in order to undertake self-care behaviours. The potential for serious adverse effects of anticoagulation therapy requires that written patient informational material is at

a reading level that patients can understand. Older patients with poor reading abilities are at a greater risk of not following instructions because of the difficulty that they have in formulating questions to ask to their healthcare provider and are further hampered by the burden of shame and embarrassment associated with illiteracy. Healthcare providers have a responsibility to use education materials that will meet the unique learning needs of patients with low literacy. Understandable information is important in reducing health care barriers to patient education and improved patient outcomes. There are many steps which can be taken to improve patient communication. Providing visual materials (for instance photos or drawings) while verbally explaining instructions to patients could increase the probability that patients will recall the information when compared to only providing instruction verbally. Another medium that could be used is the audiotape. In one study, researchers found that patients with low literacy chose an audiotape over a paper tool written at an appropriate grade level [14],[15].

## **Conclusion**

Warfarin still remains the drug of choice for patients with thromboembolic diseases, and therefore appropriate educational strategies must be considered. The patient's age, educational status and household income were significantly associated with his/her knowledge of anticoagulation.

## **Practice implications**

The disadvantaged groups receiving anticoagulation therapy, including the low-income earners, the elderly, the illiterates, and those with low levels of education, should always be given utmost care and attention to enhance their knowledge and awareness on warfarin therapy.

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