ASIAN JOURNAL OF BIOMEDICAL & PHARMACEUTICAL SCIENCES

e-ISSN: 2249-622X

RESEARCH ARTICLE

An instrument to measure anticoagulation knowledge among Malaysian community: A translation and validation study of the Oral Anticoagulation Knowledge (OAK) Test

Laila Mahmoud Matalqah[*1,2], Khaldoon Radaideh[3], Syed Azhar Syed Sulaiman[1], Mohamed Azmi Hassali[4], Muhamad Ali Sk Abdul Kader[5]

[1]Discipline of Clinical Pharmacy, School of Pharmaceutical sciences, Universiti Sains Malaysia (USM)

[2] School of Pharmacy, Allianze University College of Medical Sciences (AUCMS), Kepala Batas, Malaysia

[3]Allianze University College of Medical Sciences (AUCMS), Kepala Batas, Malaysia

[4]School of Pharmaceutical Sciences, Universiti Sains Malaysi a (USM), Penang, Malaysia

[5]Cardiologist, Department Of Cardiology, Penang Hospital

Received:
18th May 2013
Received in revised form:
30th May 2013
Accepted:
31st May 2013
Available online:
10th June 2013

OPEN ACCESS

Online ISSN 2249–622X
http://www.jbiopharm.com

Cite this article as:
Laila Mahmoud Matalaqah, Khaldoon Radaideh, Syed Azhar Syed Sulaiman, Mohamed Azmi Hassali, Muhamad Ali Sk Abdul Kader. An instrument to measure anticoagulation knowledge among Malaysian community: A translation and validation study of the Oral Anticoagulation Knowledge (OAK) Test. Asian Journal of Biomedical and Pharmaceutical Sciences, 2013, 3: (20), 30-37.

ABSTRACT

Background: There is no a validated knowledge assessment tool to examine the relationship between patient knowledge regarding warfarin therapy and its safe and effective in Malaysia.

Objective: To translate the Oral Anticoagulation Knowledge (OAK) Test into the Malay language (Bahasa Malaysia), and to examine the psychometric properties of the Malaysian version.

Methods: In a prospective, parallel group study, 382 consecutive outpatients with atrial fibrillation prescribed warfarin treatment were identified between September 2011 and January 2013 at Hospital Pulau Pinang and Seberang Jaya Hospitals, Penang, Malaysia. To be included in the study, patients had to (1) have been diagnosed with Atrial Fibrillation at least one year before, (2) use Warfarin for more than 6 months medications, (3) be over 20 years of age, and (4) be able to communicate in the Malaysian language. Patients who had severe health problems or cognitive impairment and could not complete interviews were excluded. A standard translation procedure was used to develop the Malaysian version of the OAK from the original English version. Face-to-face interviews included administration of the translated 20-question test and a collection of socio-demographic data. Medical records were reviewed for INR levels and other clinical data. Reliability was tested for internal consistency using Cronbach's alpha coefficient.

Results: Only 215 were eligible and accepted to complete the questionnaires. The mean±SD of OAK scores was 47.6±17.6. Good internal consistency was found (Cronbach's alpha = 0.767); the test-retest reliability value was 0.871 ($p<0.001$). For known group validity, a significant relationship between OAK categories and TTR (INR) categories (chi-square = 12.24; $p<0.05$) was found.

Conclusion: The findings proved that the Malaysian version of the OAK is a reliable and valid measure of Warfarin knowledge that may be a useful tool for research and clinical practice. There is a need for improvement in patient education, including reinforcement of dietary guidelines for warfarin therapy as well as when it is appropriate to contact the clinic for questions.

Keywords: anticoagulation, warfarin, patient knowledge, Malaysian version.

*Corresponding author: Laila Mahmoud Ali Matalqah | Discipline of Clinical Pharmacy, School of Pharmaceutical sciences, Minden, 11800, Universiti Sains Malaysia (USM), | Email: lmatalqah@yahoo.com|

1. INTRODUCTION

Warfarin sodium has been widely used as anticoagulant since 1954 [1]. The indications for anticoagulant use are expanding; as it becomes a crucial intervention for prevention and treatment of thromboembolic events [2, 3]. For example, anticoagulant therapy is recommended to prevent stroke in patients with atrial fibrillation [4, 5] and it has been found to significantly improve outcome in patients after myocardial infarction [6].

Warfarin is challenging to use in clinical practice for many reasons [2]; it has a narrow therapeutic index, the dose response varies among patients and is subject to adjustment due to genetics and its interactions with other drugs and food [7,8], patient's concurrent disease states, compliance and overall knowledge of therapy [9,10]. Furthermore, the maintenance of the therapeutic level of anticoagulation requires a good understanding of the pharmacokinetics and pharmacodynamics of warfarin and good patient communication [2]. It is therefore important for the patient to be educated fully regarding warfarin therapy as outside the narrow therapeutic range either failure to prevent thromboembolism or serious bleeding with potential fatal complications may occur.

There is a general consensus in the literature that improved patient knowledge about warfarin therapy improves therapeutic outcomes [10-16] and the rate of adverse outcomes events inversely related to the level of their knowledge [1, 14, 16-18].

In Malaysia, two previous studies have been conducted to assess the patients' knowledge and relate to INR control [19, 20]. A major limitation of these studies is the fact that patient knowledge was assessed using questionnaire which was not psychometrically validated. Only after a knowledge assessment instrument has been validated can sound scientific conclusions be drawn from its results [21]. Appropriate psychometric methodology must be followed to ensure that an assessment measure is valid and reliable for testing the specific objectives or constructs. In theory, this process demonstrates that an instrument's results are accurate, consistent, reproducible, and stable over time [21-23].

Currently, only two valid and reliable anticoagulation knowledge questionnaires are available; the Oral Anticoagulation Knowledge (OAK) test, created and validated by Zeolla et al. [13], and the Anticoagulation Knowledge Assessment (AKA) questionnaire, designed and validated by Briggs et al. [24]. Both have been validated for content validity, construct validity, and reliability. The Oral Anticoagulation Knowledge (OAK) test is a 20 item multiple choice test that has been used in a previous study to assess patients' knowledge warfarin [25] and translated into other languages e.g., Arabic [26]. The validity of the instrument was assessed of data collected from 74 subjects taking warfarin and 27 age-matched subjects not on warfarin.

Our aims in the current study were to translate the OAK into Malay language and document some of its psychometric properties among Malaysian people with atrial fibrillation treated with warfarin. Furthermore, we aimed to measure the level of warfarin knowledge among Malaysian community.

2. METHODS

A cross-sectional study design and methodology were used to elaborate the study data. This study was conducted in the Cardiology Clinic (109) which operates on Monday and Tuesday and Warfarin Clinic which operates on a once weekly- basis (every Wednesday) of HPP, Penang, Malaysia. Simultaneously, the research was conducted at Cardiology clinic at SJH. General Penang Hospital is the largest public and tertiary hospital in Penang Island followed by SJ Hospital at the mainland of Penang state.

This study was approved by Medical Research Ethics Committee (MREC) of the Ministry of Health, Malaysia with a NMRR registration ID (NMRR-11-455-9067) by the Clinical Research Centre (CRC) at Hospital Pulau Pinang (HPP) and Seberang Jaya Hospital (SJH). Written consent was signed by each patient for interview.

Instrument translation

The instrument consisted of three parts; part A is a collected socio-demographic data, part B is the medical and laboratory data to be collected from the patients' records and part C is the 20-question OAK test. Parts A and C of the data collection sheets were translated together to Malay language according to the international guidelines [27, 28] as follows:

- The original questionnaire was forward translated from English to the Malay language to produce a version that was semantically and conceptually as close as possible to the original questionnaire. Translation was done by two qualified, independent linguistic translators; one from the language and translating center (Pusat Bahasah dan Terjemahan) at Universiti Sains Malaysia (USM) and the other translator was a senior linguistic lecturer at University. Both are native speakers of Malaysian and professional in English. Each translator produced a forward translation of the original questionnaire into the target language without any mutual consultation. Three researchers, who are Malaysian, reviewed the two primary versions and compared them with the original.
- Backward translation from Malay to English was carried out by another translator, after

repeated discussion between the translators and Malaysian researchers. Inconsistencies were resolved in a consensus meeting and a final version, ready for testing, was generated.

- A pilot test for the translated questionnaire was conducted by distributing it to 20 Malaysian patients to check the readability of the translated version and then seek individual feedback. If the time allowed, we asked the participant to fill both versions of the questionnaires. These individuals were not included in the study. The patients' comments were discussed by the researchers. Minor necessary changes to the survey have been done before implementing it on the large scale.
- Three Malaysian pharmacy lecturers who are experts in the field judged the face and content validity of the questionnaire. The final Malay version of the questionnaire was completed and made available for the reliability and validity study. It takes about 10 minutes to complete the questionnaire.

Sample and settings

A convenience sample of 382 patients on warfain therapy was identified between September 2011 and January 2013 at both hospitals. To be included in the study, patients had to (1) have been diagnosed with Atrial Fibrillation at least one year before, (2) use Warfarin for more than 6 months medications, (3) be over 18 years of age, and (4) be able to communicate in the Malaysian language. Patients who had severe health problems or cognitive impairment and could not complete interviews were excluded. Face-to-face interviews included administration of the translated 20-question test and a collection of socio-demographic data. Only 215 were eligible and accepted to complete the questionnaires. Patients who did not complete the questionnaire (n=11) and those who did not have completed INR records were excluded from the analysis (n=8). A total of 196 were included in the analysis.

After the interview, medical records were reviewed for INR levels, concurrent medications, other medical history, and the history of minor or major bleeding. In addition, 60 patients from the sample were randomly selected and agreed for a one-month reliability test-retest analysis. 52 patients completed the test-retest after one month and 8 after 2 months as their appointment date. All patients were interviewed face-to-face by two native Malaysian pharmacists along with the investigator who is also pharmacist.

Assessment of INR control

Patients' INR readings were collected from 2010 till their most recent reading. The INR control was assessed in 2 different ways; the mean percentage days in range and the percentage of visits where the INR readings were in range. For patients' INR control assessment, the target range of the INR at the time of the study was defined as follows: 2.0–3.0 for lone atrial fibrillation, 2.5 –4.0 for atrial fibrillation with prosthetic valve replacement or pulmonary embolism [29].

We assessed INR control by calculating the time in therapeutic range (TTR method or Rosendaal method) for each patient using an adapted linear interpolation method, defined as the proportion of person-time within the target therapeutic range over the total person-time of follow-up [30]. In Rosendaal method the difference between 2 consecutive INR readings, which was within the target range, was divided with the total difference between them. The formula below describes this calculation:

$$Percentage\ days\ in\ range = \frac{\text{INR difference within target range}}{\text{Total INR difference}} \text{ X } 100\%$$

Several studies have provided strong evidence of a link between TTR and definitive outcomes [12, 31, 32]. The most direct evidence for TTR as a predictor of adverse events comes from a study that divided patients into three groups by TTR:< 60%, 60%–75%, and > 75% [33]

The second method involved the number of visits where the INR reading was within the range divided by total number of visits [34]. The result was then converted into percentage. The formula below describes this calculation:

$$Percentage\ visits\ in\ range = \frac{\text{No. of visits where INR reading was within the range}}{\text{Total number of visits to clinic}} \text{ X } 100\%$$

STATISTICAL ANALYSIS

All data entry and analyses were performed using SPSS version 19.0 Microsoft program (SPSS Inc, Chicago, IL). The significance level was set at $p < 0.05$. Descriptive statistics including mean and standard deviations (SD) for continuous variables, frequencies and percentages for categorical variables were used to describe the study population. Chi-square test and ANOVA tests were used to detect the differences between categorical and continuous variables among the groups, respectively.

To test reliability, the internal consistency was assessed using Cronbach's alpha, and the test-retest reliability was assessed using Spearman's rank correlation. The criterion for accepting Cronbach's alpha is a score above 0.7 [35].

The scores of knowledge were categorized as low (< 50%), medium (50-75%) and high (>75%). Known group validity was assessed through the association of level of knowledge and OAK categories using chi-square tests. The data were also stratified by education level, stroke risk as measured by CHADS2 score (age ≥ 75 years, hypertension, diabetes mellitus, heart failure, and prior stroke) [36] and duration of warfarin use.

3. RESULTS:

Characteristics	Total sample (n=196)	Level of knowledge			*P* Value
		Poor knowledge OAK < 50% (n=100)	Moderate Knowledge OAK: 50-75 % (N=74)	High Knowledge OAK ≥75% (N=22)	
Age (mean ± SD)	61.1 ± 12.2	63.1 ± 10.3	58.4 ± 11.3	60.3 ± 11.7	0.145*
Age group	**n(%)**	**n(%)**	**n(%)**	**n(%)**	
<45	30(15.3)	9(9.0)	16(21.6)	5(22.7)	0.087$
45-64	90(45.9)	45(45.0)	35(47.3)	10(45.5)	
>65	76(38.8)	46(46.00	23(31.1)	7(31.8)	
Sex					
Male	120(61.2)	62(62.0)	47(63.5)	11(50.0)	0.507$
Female	76(38.8)	38(38.0)	27(36.5)	11(50.0)	
Race					0.296$
Malay	84(42.9)	43(43)	34(45.9)	7(31.8)	
Chinese	26(13.3)	13(13)	7(9.5)	6(27.3)	
Indian	86(43.9)	44(44)	33(44.6)	9(40.9)	
Education					< 0.001$
No formal education	34(17.4)	24(24.0)	10(13.5)	0(0)	
Primary	58(29.6)	39(39.0)	15(20.3)	4(18.2)	
Secondary	73(37.2)	35(35.0)	33(44.6)	5(22.7)	
College/ University	31(15.8)	2(2.0)	16(21.6)	13(59.1)	
Occupation					0.478$
Unemployed	73(37.2)	40(40.0	27(36.5)	6(27.3)	
Employed	46(23.5)	22(22.0)	19(25.7)	5(22.7)	
Retired	77(39.3)	28(28.0)	28(37.8)	11(50.0)	
Monthly income					0.001$
< RM 2000	149(76.0)	83(83.0)	56(75.7)	10(45.4)	
RM 2000- RM4000	31(15.8)	12(12.0)	13(15.6)	6(27.3)	
>RM 4000	16(8.2)	5(5.0)	5(6.7)	6(27.3)	
Marital Status					0.038$
Unmarried	22(11.2)	7(7.0)	11(14.9)	4(18.2)	
Married	144(73.5)	80(80.0)	53(74.6)	11(50.0)	
Widow/ divorced	30(15.3)	13(13.0)	10(13.5)	7(31.8)	
Duration of warfarin use					0.030$
≤ 2 years	68(34.7)	45(45.0)	19(25.7)	4(18.2)	
2 years – 5 years	59(30.1)	25(25.0)	27(36.5)	7(31.8)	
≥ 5 years	69(35.2)	30(30.0)	28(37.8)	11(50.0)	
CHADS2 score					
0-2	158(80.6)	81(81.0)	60(81.1)	17(77.3)	0.666$
3	28(14.3)	12(12.0)	12(13.2)	4(18.2)	
≥4	10(5.1)	7(7.0)	2(2.7)	1(4.5)	
Medical History					
Hypertension	116	70(70.0)	35(47.3)	11(50.0)	0.472$
Diabetes Mellitus	66	34(34.0)	25(33.8)	7(31.8)	0.962$
MI	29	14(14.0)	12(16.2)	3(13.6)	0.884$
CHF	47	26(26.0)	16(21.6)	5(22.7)	0.300$
CAD	24	11(11.0)	11(14.9)	2(9.1)	0.437$
Previous stroke	18	13(13.0)	3(4.1)	2(9.1)	0.114$
Hyperlipidemia	78	43(43.0)	24(32.4)	11(50.0)	0.177$
Valve replacement	20	10(10.0)	8(10.8)	2(9.1)	0.949$
TTR% (INR control) mean ± SD	53.6 ± 24.8	49.5 ± 26.0	56.3 ± 23.6	67.7 ± 15.1	0.039*
INR (% of readings in normal range)	51.6 ± 21.91	48.3 ± 22.6	55.2 ± 21.4	56.5 ± 17.0	0.087*
20 question- OAK percentage mean± SD	47.6 ± 17.6	33.4 ± 11.0	57.2 ± 5.8	80.4 ± 7.2	<0.001*
Warfarin dose (mg) mean ± SD	3.5 ± 1.5	3.2 ± 1.5	3.7 ± 1.6	3.5 ± 1.5	0.196*
Number of medication Mean ± SD	3.8 ± 1.6	4.0 ± 1.6	3.7 ± 1.5	3.5 ± 1.4	0.227*

- *Kruskal Walis was conducted
- $Chi-square test was conducted

Table 1: Demographic characteristics of Atrial fibrillation patients.

OAK's Questions	Malay group		Indian group		Chinese group	
	Corrected item : total Correlation	Cronbach's alpha if item deleted	Corrected item : total Correlation	Cronbach's alpha if item deleted	Corrected item : total Correlation	Cronbach's alpha if item deleted
Question 1	0.125	0.842	0.090	0.712	0.091	0.749
Question 2	0.089	0.846	0.151	0.720	0.031	0.767
Question 3	0.306	0.806	0.081	0.786	0.052	0.769
Question 4	0.067	0.854	0.080	0.786	0.177	0.731
Question 5	0.035	0.867	0.368	0.695	0.261	0.706
Question 6	0.213	0.828	0.165	0.761	0.278	0.703
Question 7	0.040	0.861	0.021	0.699	0.050	0.783
Question 8	0.113	0.843	0.126	0.792	0.135	0.786
Question 9	0.176	0.835	0.099	0.780	0.165	0.736
Question 10	0.093	0.846	0.446	0.661	0.113	0.745
Question 11	0.330	0.805	0.167	0.641	0.131	0.742
Question 12	0.402	0.790	0.230	0.641	0.006	0.772
Question 13	0.080	0.846	0.269	0.752	0.020	0.761
Question 14	0.070	0.853	0.281	0.793	0.035	0.763
Question 15	0.345	0.810	0.463	0.699	0.109	0.746
Question 16	0.033	0.849	0.347	0.647	0.163	0.740
Question 17	0.242	0.823	0.179	0.663	0.221	0.723
Question 18	0.235	0.827	0.430	0.598	0.419	0.679
Question 19	0.223	0.829	0.153	0.669	0.286	0.712
Question 20	0.280	0.716	0.296	0.636	0.379	0.685
Cronbach's alpha for total items among the group		0.842		0.703		0.749
Cronbach's alpha was 0.767 for the total scale with significant intra-class correlation coefficient (p<0.001).						

Table 2: The reliability test among different races

Clinical and demographic data

The final analysis included 196 patients with AF. The characteristics of the total and knowledge groups are shown in Table 1. Out of 196 AF patients, 100 (51.02%), 74 (37.75%) and 22 (11.23%) were in the low, acceptable and good knowledge groups, respectively. Significant differences were found in educational levels, monthly income, marital status, duration of warfarin therapy, INR level, and OAK scores among the three groups (p<0.05). No significant differences (p > 0.05) were found among the three groups in terms of age, sex, race, employment, history of having diseases and medication number.

TTR% (INR control)	**High Knowledge OAK ≥75% n (%)**	**Moderate Knowledge OAK:50-75 % n (%)**	**Poor knowledge OAK<50% n (%)**	**OAK score mean±SD**
TTR >75 % good control	10 (54.4)	19 (25.7)	19 (19)	68.7 ± 16.0
TTR:60-75% moderate control	8 (36.4)	19 (25.7)	23 (23)	43.8±17.3
TTR <60 % poor control	4 (18.2)	36 (48.6)	58 (58)	38.2 ± 12.79
Total	22 (100)	74 (100)	100 (100)	
Chi-square with four degrees of freedom = 12.24, p =0.0156				

Table 3 Relationship between knowledge categories and INR control groups

Reliability

Cronbach's alpha test of internal consistency for the 20-items OAK were 0.842, 0.703, 0.749 among Malay, Indian and Chinese races, respectively, which are within the recommended value [35]. Its item total correlation coefficient ranged from 0.006–0.446 (Table 2). Test–retest reliability of OAK was confirmed with Pearson's correlation coefficient of 0.871 (p < 0.001).

Known group validity

Table 3 shows the distribution of the three knowledge groups according to their RTT level. As hypothesized, patients who reported poor control of their INR (RTT<60%) also reported lower levels of knowledge about Warfarin. Chi-square test shows a significant relationship between OAK categories and INR control categories (Chi-square= 12.24, p = 0.0156). Around 58% of patients with low knowledge have a poor INR control group as compared to 18.2% of the high knowledge group (Table 3). ANOVA test was conducted to compare the mean of OAK scores for those with poor, moderate and good INR control. There was a significant difference between the mean of OAK scores for the good INR control group (68.7 ± 16.0), the moderate control group (mean±SD 43.8±17.3) and for the poor control group (mean±SD 38.2 ± 12.79); with p < 0.05

Patients' Knowledge about warfarin

Table 4 shows the percentage of subjects who correctly answered each corresponding question. The participants were asked to answer one question out of 4 choices and they were advised not to answer if they do not know the answer. This is mainly to reduce the chances of guessing the answer as possible. Only four questions were answered correctly by more than 70% of the respondents. Patients generally knew the colors of their warfarin tablets and knew how to differentiate between different strength (1 mg, 3 mg and 5 mg) (question 2), the reason for taking warfarin (question 8), what is INR (question 7), what they will do if they miss a dose (question 16).

Oak's questions	Answered Correctly	Missing
Q1: Missing one dose	21.5%	3
Q2: How to distinguish between different strength of warfarin	89.0%	4
Q3: When to contact physician	45.9%	3
Q4: Eating a large amount of leafy greens vegetables While taking warfarin	28.5%	6
Q5 Types of vitamins interacts with warfarin	42.4%	6
Q6 When is it safe to take a medication that interacts with warfarin	14.0%	5
Q7 what is PT/INR test	72.1%	5
Q8 warfarin may is used to	86.0%	4
Q9 Consequences of a PT/INR value below their "goal range	47.7%	5
Q10 Taking a medication containing aspirin or other Non-steroidal anti-inflammatory medications with warfarin	26.7%	9
Q11 person on warfarin should seek immediate medical attention	33.1%	5
Q12 Skipping even one dose of your warfarin	23.3%	8
Q13 Drinking alcohol while taking warfarin	59.3%	8
Q14 how often should your PT/INR value be tested	42.5%	3
Q15 When is it important for a patient on warfarin to monitor for signs of bleeding	48.8%	8
Q16 The best thing to do if you miss a dose of Warfarin is to	80.0%	6
Q17 Regarding diet while taking warfarin	35.5%	8
Q18 Before checking PT/INR	29.1%	5
Q19 over-the-counter products interact with warfarin	47.7%	7
Q20 Consequences of PT/INR value above the goal range	40.7%	7

Table 4: Proportion of participant answered correctly

However, only 40– 50% of patients knew about which vitamin interact with warfarin (question 5), what is INR test and interpretation (questions 9, 14 & 20) over the counter medication interaction with warfarin (question 19), and when they should monitor sign of bleeding (question 15). Their deficiency in knowledge was even more obvious with respect to the dietary modifications (questions 4 & 17); medication interaction with warfarin (questions 6 & 10), the consequence of missing or skipping a dose and its management (question 1 & 12), and when they should seek an immediate medical attention (question 11).

	Time in therapeutic range (TTR%)[a]	Number of INR in range
	Spearman's Rho (*P*)	**Spearman's Rho (*P*)**
Total OAK score	0.192 (0.012)	0.160 (.038)
Total		

[a]Time in therapeutic range was calculated using the Rosendaal method (1993)
[b]Number in range is the count of INR values in therapeutic range, with a maximum of 10, measured prior to the consent date for participation in the study.

Table 5: Spearman's Rho Correlation Analysis of Anticoagulation Knowledge with INR Control

Relationship between warfarin knowledge and anticoagulation control

There was a significant positive association between patients' warfarin knowledge and the time spent with the therapeutic range (TTR %) (r = 0.192; P = 0.012) and the number of INR values within the target range (INR%) (r = 0.160, P = 0.038) (Table 5).

OAK test sensitivity and specificity

In order to identify patients with poor anticoagulation control, sensitivity and specificity of OAK were evaluated. Only two groups of OAK scores were used; low knowledge patients as one group, and medium and high knowledge patients together as the second group. INR control group was also dichotomized; good INR control TTR% ≥60% and poor INR control (TTR% <60). The OAK sensitivity and specificity were 58.3% and 58.0%, respectively (Table 6). The positive and negative predictive values were 57.1% and 59.2%, respectively

TTR% (INR control)	**High knowledge OAK≥ 50 % n (%)**	**Low knowledge OAK<50% n (%)**	
TTR≥ 60 % good control	56 (25.7)	42 (23)	**Positive predictive value= 56/98= 57.1%**
TTR <60 % poor control	40 (48.6)	58 (58)	**Negative predictive value=58/98=59.2%**
Total	96 (100)	100 (100)	
	Sensitivity=56/96 58.3%	**Specificity=58/100 58.0%**	

Table 6 Sensitivity and specificity of OAK test

4. DISCUSSION

The original 20-item OAK test is a valid and reliable instrument that was tested by Zeolla et al. [13] on two population samples of patients who were using warfarin, and it was found that the scale was reliable with good predictive validity. It is a useful tool to determine the relationship between patient knowledge and outcomes [13]. This study was the first to systematically translate and validate the OAK into the Malaysian language and to assess the level of warfarin knowledge among Malaysian community. An extensive approach was followed for translating a questionnaire into another language that was in compliance with the standard procedure detailed in translation guidelines [27, 28] where cultural and language equivalence, as well as psychometric properties were checked. After translation of OAK test, the reliability and validity of the newly translated version were proved to have been maintained. The reliability of the OAK was confirmed using measures of internal consistency and test-retest, and validity was examined through known group validity.

Our study among Malaysian patients showed that the OAK had good internal consistency (a=0.767) and good test-retest reliability (0.871). The sample of patients in this study was larger than the sample used in the previous validation study [13]. The known group comparison

analysis indicated that the Malaysian version of the OAK is a valid instrument for measuring warfarin knowledge because the instrument was able to differentiate between patients who were clinically different. Only four questions were answered correctly by more than 70% of the respondents (Table 4). The most frequently missed questions (answered by less than 70%) covered dietary modifications; medication interaction with warfarin; missing or skipping a dose and interpretation of INR values. These frequently missed questions indicate potential areas for improvement in patient education, including reinforcement of dietary guidelines for warfarin therapy as well as when it is appropriate to contact the clinic for questions. Both areas represent potential starting points for re-education of current patients and primary education for new patients seen in the clinic.

Evaluation of anticoagulation knowledge has yielded undesirable pass rates in previous literature with between 50-80% of patients having little knowledge about important basic aspects [1, 11, 17, 37-42]. Tang et al. [16] found that only 18% of patients achieved a passing score of at least 70%. Davis et al. [43] found that 37% of patients achieved a passing score of at least 70% on a novel 18-question multiple-choice test. Using a previously created 20-question true-or-false questionnaire, Hu et al. [44] found a 39% pass rate, defined as a score of at least 80%. Recently, Baker et al. [45] found that 74.1% of respondents achieved the passing score of 72.4% of AKA test. In using OAK test with defining a passing score of 75%, of questions answered correctly, we found that only 11.2% of our patients achieved a passing score, with a mean OAK score of 48% for the whole sample.

Correlations were interpreted using the following criteria: 0–0.25 = little or no correlation, 0.25–0.5 = fair correlation, 0.5–0.75 =moderate to good correlation and greater than 0.75 = very good to excellent correlation [46]. Data from the Spearman's rho analyses revealed a statistically significant small positive correlation between patients' knowledge and the number of INR values that were within the therapeutic range. These results add to the existing literature that has found mixed results when assessing the relationship between patient warfarin knowledge and INR control [14-16]. Tang et al. [16] did find a small positive correlation between anticoagulation knowledge and the number of INR values within target range, showing that 4% of variance in INR could be explained by anticoagulation knowledge. However, Davis et al. [43] and Baker [45] showed no significant association between knowledge or education and the proportion of INRs within the therapeutic range. In this study, higher level of education [37] and longer duration of therapy [16] were found to be associated with better knowledge of warfarin therapy among patients.

5. CONCLUSION

The present study assessed anticoagulation knowledge of patients receiving warfarin therapy in anticoagulation clinic using a validated instrument and found a pass rate of 11.2%, much lower than reported previously in the literature. We found a statistically significant small positive relationship between 2 measures of INR control and anticoagulation knowledge. However, this is the first report of the relationship between INR control and anticoagulation knowledge as assessed by the Malaysian version of OAK questionnaire, and it is possible that this assessment instrument, although previously validated, was not sufficiently sensitive in detecting clinically important warfarin knowledge.

In summary, the Malaysian version of the OAK proved to be reliable and valid measure of warfarin knowledge; with an acceptable test retest reliability and validity. It is a simple questionnaire that can be used in clinical practice by face-to-face interviews to overcome non-response by those who cannot read, as well as by self administration.

6. ACKNOWLEDGEMENT

The authors would like to thank all the staff of Department of cardiology Pulau Pinang Hospital and Seberang Jaya Hospital and all subjects who voluntarily participated in this study. We are grateful to Zeolla et al. (*Annals of Pharmacotherapy;* 2006; 40(4):633-8) for permission to use the questionnaire for our study.

7. REFERENCES

1. Roche-Nagle, G., Chambers, F., Nanra, J., et al. (2003). Evaluation of patient knowledge regarding oral anticoagulants. Ireland Medicine Journal, 96(7): 211-3.
2. Ansell, J., Hirsh, J., Hylek, E., et al. (2008) Pharmacology and management of the vitamin K antagonists. Chest, 133:160S-198S.
3. Schulman, S., Beyth, R.J., Kearon, C., & Levine, M.N. (2008). Hemorrhagic complication of anticoagulant and thrombolytic treatment: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th edition). Chest. 133:257S-298S.
4. Connolly, S.J., Laupacis, A., Gent, M., Roberts, R.S., Cairns, J.A., & Joyner, C. (1991). Canadian Atrial Fibrillation Anticoagulation Study. Journal of American College of Cardiology,18:349-55.
5. Ezekowitz, M.D., Bridgers, S.L., James, K.E. et al. (1992). Warfarin in the prevention of stroke associated with nonrheumatic atrial fibrillation. New England Journal of Medicine. 327:1406-12.
6. Smith, P., Arnesen, H., & Holme, I. (1990). The effect of warfarin on mortality and reinfarction after myocardial infarction. New England Journal of Medicine, 323:147-52.
7. Holbrook, A.M, Pereira. J.A., Labiris, R., et al. (2005). Systematic overview of warfarin and its drug and food interactions. Archives of Internal Medicine, 165:1095-1106
8. Greenblatt, D.J., & von Moltke, L.L. (2005). Interaction of warfarin with drugs, natural substances and foods. Journal of Clinical Pharmacology, 45:127-32
9. Taylor, F.C, Ramsay, M.E, Tan, G., Gabbay, J., Cohen, H. (1994). Evaluation of patients knowledge about anticoagulation treatment. Quaity Health Care. 3(2):7985.
10. Barcellona,D., Contu, P., & Marongiu, F. (2002). Patient education and oral anticoagulation therapy. Haematologica, 87(10):1081-86.
11. Jank, S., Bertsche, T., Herzog, W., & Haefeli, W.E. (2008). Patient knowledge on oral anticoagulants: results of a questionnaire survey in Germany and comparison with the literature. International Journal of Pharmacology & Therapeutic. 46(6):280-8.

12. Barcellona, D., Contu, P., & Marongiu, F. (2006). A ''two-step'' educational approach for patients taking oral anticoagulants does not improve therapy control. Journal of Thrombosis and Thrombolysis,22:185-90.
13. Zeolla, M.M., Brodeur, M.R., Dominelli, A., Haines, S.T., Allie, N.D. (2006). Development and validation of an instrument to determine patient knowledge: the oral anticoagulation knowledge test. Annals of Pharmacotherapy;40(4):633-8.
14. Kagansky, N., Knobler, H., Rimon, E., Ozer, Z., & Levy, S. (2004). Safety of Anticoagulation Therapy in Well-informed Older Patients. Archives of Internal Medicine.164:2044-50.
15. Khan, T.I., Kamali, F., Kesteven, P., Avery, .P, & Wynne, H. (2004). The value of education and self-monitoring in the management of warfarin therapy in older patients with unstable control of anticoagulation. British Journal of Haematology.126:557-64.,
16. Tang, E.O., Lai, C.S., Lee, K.K., Won,g R.S., Cheng, G., & Chan, T.Y. (2003). Relationship between patients' warfarin knowledge and anticoagulation control. Annual of Pharmacotherapy;37:34-9.
17. McCabe, P.J., Schad, S., Hampton, A., & Holland, D.E. (2008). Knowledge and self-management behaviors of patients with recently detected atrial fibrillation. Heart Lung, 37(2):79-90.
18. Pernod, G., Labarère, J., Yver, J., et al. (2008). EDUC'AVK: Reduction of Oral Anticoagulant-related Adverse Events after Patient Education: A Prospective Multicenter Open Randomized Study. Journal of General Internal Medicine, 23(9):1141-6.
19. Hasan, S.S., Shamala, R., Syed, I.A. et al. (2011). Factors Affecting Warfarin-Related Knowledge and INR Control of Patients Attending Physician- and Pharmacist Managed Anticoagulation Clinics. Journal of Pharmacy Practice.DOI: 10.1177/0897190011415684
20. Yahaya, A.H.M, Hassali, M.A, Awaisu, A., Shafie, A.A. (2009). Factors associated with warfarin therapy knowledge and anticoagulation control among patients attending a warfarin clinic in Malaysia. Journal of Clinical Diagnostic Research;3:1663-70
21. Devellis R.F. (1991). Scale development: theory and applications. Newbury Park, CA: Sage Publications.
22. Streiner, D.L., & Norman, G.R. (1989). Health measurement scales: a practical guide to their development and use. New York: Oxford University Press.
23. Kline P. (1986). A handbook of test construction: introduction to psychometric design. New York: Methuen & Co.
24. Briggs, A.L., Jackson, T.R., Bruce, S., & Shapiro, N.L. (2005). The development and performance validation of a tool to assess patient anticoagulation knowledge. Research in Social & Administrative Pharmacy, 1(1):40-59.
25. Winans, A.R., Rudd, K.M., Triller, D. (2010). Assessing anticoagulation knowledge in patients new to warfarin therapy. Annual of Pharmacotherapy;44(7-8):1152-7.
26. Khudair, I.F., & Hanssens, Y.I. (2010). Evaluation of patients' knowledge on warfarin in outpatient anticoagulation clinics in a teaching hospital in Qatar. Saudi Medicine Journal, 31(6)672-7.
27. Guillemin, F., Bombardier, C., & Beaton, D. (1993). Cross-cultural adaptation of health- related quality of life measures: literature review and proposed guidelines. Journal of Clinical Epidemiology, 46:1417-32.
28. Wild, D., Grove, A., Martin, M., et al. (2005). Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health;8: 94-104
29. ACCF/AHA/HRS. (2011) Guideline Management of Patients with Atrial Fibrillation. Circulation,123:104–123 and 1161–1167.
30. Rosendaal, F.R., Cannegieter, S.C, van der Meer, F.J, & Briet, E. (1993). A method to determine the optimal intensity of oral anticoagulant therapy. Thrombosis Homeostasis 69:236-9.
31. Jones, M., McEwan, P., Morgan, C.L., Peters, J.R., Goodfellow, J., & Currie, C.J. (2005). Evaluation of the pattern of treatment, level of anticoagulation control, and outcome of treatment with warfarin in patients with nonvalvar atrial fibrillation: A record linkage study in a large British population. Heart, 91:472–7.
32. Veeger, N.J, Piersma-Wichers, M., Tijssen, J.G.P, Hillege, H.L, Meer, J. (2005). Individual time within target range in patients treated with Vitamin K antagonists: Main determinant of quality of anticoagulation and predictor of clinical outcome. A retrospective study of 2300 consecutive patients with venous thromboembolism. Britain Journal of Haematology;128:513-19.
33. White, H.D., Gruber, M., Feyzi, J., et al. (2007). Comparison of outcomes among patients randomized to warfarin therapy according to anticoagulant control: Results from SPORTIF III and V. Archives of Internal Medicine;167:239-45.
34. Rose, A.J., Berlowitz, D.R., Frayne, S.M., & Hylek, E.M. (2009). Measuring quality of oral anticoagulation care: extending quality measurement to a new field. Joint Commission on Accreditation of Healthcare Organizations, 35(3):146-55
35. Nunnally, J.C., & Bernstien, I.H. (1994). Psychometric Theory, 3rd ed. New York: McGraw-Hill.
36. Gage, B.F., Waterman, A.D., Shannon, W., Boechler, M., Rich, M.W., & Radford, M.J. (2001). Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA, 285: 2864-70.
37. The Newcastle Anticoagulation Study Group. (1998). Effectiveness of anticoagulation among patients discharged from hospital on warfarin. Medical Journal Australian 169:243-6.
38. McCormack, P.M., Stinson, J.C., Hemeryck, L., & Feely, J. (1997). Audit of an anticoagulant clinic: doctor and patient knowledge. Ireland Medicine Journal, 90(5):192-3.
39. Cheah, G.M., & Martens, K.H. (2003). Coumadin Knowledge Deficits: Do Recently Hospitalized Patients Know How to Safely Manage the Medication? Home Healthcare Nurse, 21(2):94-100.
40. St-Louis, L., & Robichaud-Ekstrand, S. (2003). Knowledge level and coping strategies according to coagulation levels in older persons with atrial fibrillation. Nursing and Health Science,5:67-75.
41. Dantas, G.C., Thompson, B.V., Manson, J.A., & Tracy, C.S. (2004). Upshur RE. Patients' perspectives on taking warfarin: qualitative study in family Practice BMC. Family Practice, 5(15).
42. Lane, D.A., Ponsford, J., Shelley, A., Sirpal, A., & Lip, G.Y. (2006). Patient knowledge and perceptions of atrial fibrillation and anticoagulant therapy: Effects of an educational intervention programme. International Journal of Cardiology,110:354-8.
43. Davis, N.J, Billett, H.H., Cohen, H.W., & Arnsten, J.H. (2005). Impact of Adherence, Knowledge, and Quality of Life on Anticoagulation Control. Annual of Pharmacotherapy, 39:632-6.
44. Hu, A., Chow, C., Dao, D., Errett, L., & Keith, M. (2006). Factors Influencing Patient Knowledge of Warfarin Therapy After Mechanical Heart Valve Replacement. Journal of Cardiovascular Nursing, 2; 21(3):169-75.
45. Baker, W.J., Pierce, K.L., & Ryals, C.A. (2011). INR goal attainment and oral anticoagulation knowledge of patients enrolled in an anticoagulationclinic in a Veterans Affairs Medical Center. Journal of Managed Care Pharmacy, 17(2),133-42
46. Cohen, J.W. (1988). Statistical power analysis for the behavioural sciences, 2nd ed., Hillsdale, NJ: Lawrence Erlbaum Associates.

Conflict of Interest: None Declared

