Translation, validation and psychometric properties of Bahasa Malaysia version of the Perception of Anticoagulant Therapy Questionnaire (PACTQ)

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ABSTRACT :

Background: Patients' perceptions towards anticoagulation therapy (ACT) are related to the anticoagulation control (ACC). In Malaysia, there is no a validated assessment tool to determine patient perception towards ACT.

Objectives: The aim of this study is to validate the Bahasa Malaysia version of the Perception of Anticoagulant Therapy Questionnaire (BM-PACTQ), which is conceptually equivalent to the original English version and can be used to measure Bahasa Malaysia-speaking patients within the context of Malaysia.

Methods: The translation processes were done according to standard guidelines. A cross-sectional survey was conducted in three tertiary hospitals in Malaysia. A total of 270 patients who fulfilled the inclusion criteria voluntarily answered the 27-item questionnaire which used 5-point Likert rating. The reliability and validity analyses of the BM-PACTQ were performed through internal consistency, test re-test reliability, face validity, content validity, and construct validity.

Results: Good internal consistency was found for convenience and ACT satisfaction (Cronbach's alpha =0.90 and 0.88, respectively), but satisfactory for treatment expectation (TE) (Cronbach's alpha =0.62). The test-retest reliability value was good (>0.90) for all scales. Within BM-PACTQ scales, the individual items produced moderate correlations with their own scales than with other scales ($r \geq 0.45$). Patients had a moderate expectation towards ACT, but had higher convenience and satisfaction towards ACT. Patients who had higher perceptions had significantly good ACC ($p<0.05$).

Conclusions: The BM-PACTQ was found to have good psychometric properties to measure patients' perceptions towards ACT. Therefore, this version can be used in future research to achieve good ACC in anticoagulation patients.

Keywords: Bahasa Malaysia, oral anticoagulant, perceptions, satisfaction, validation

INTRODUCTION:

Patients' beliefs about their medications are important factors that influence their decisions to accept, decline, or adhere to their medications (1). Higher ACT satisfaction has been reported to have good anticoagulation control (ACC) (2). Poor ACC will lead to serious complications among patients such as major hemorrhage and thromboembolic event as highlighted in a many studies (3,4). In these studies, researchers concluded that anticoagulation services should aim for good ACC to optimize benefits and reduce harm to patients. Current practice in anticoagulant management takes patients' perceptions into consideration as they have become an increasingly important subject of investigation. Patients' perceptions appear to vary greatly. The uncertainty and the variability in perceptions among patients would affect their ACC; thus, any decision should be made with caution (5). Taking into account that patients' beliefs are related to ACC, many studies have investigated patients' beliefs or perceptions towards ACT. Some studies uses the Beliefs about Medicines Questionnaire (BMQ) (6–9). Although BMQ has been validated, the questionnaire is still too general and may not be suitable to be used in measuring patients' beliefs about ACT. Due to this reason, many researchers have developed their own questionnaires to measure patients' perceptions about ACT in their studies (10–15). In spite of this, only the Perception of Anticoagulant Treatment Questionnaire (PACTQ) has been validated(13). The PACTQ was developed to determine the burden of disease in patients on long term use of ACT which mainly focused on patients' expectations, convenience, and satisfaction on the ACT. The existing PACTQ has been rigorously translated into 14 languages and validated but to date, studies concerning the psychometric properties of this instrument in ACT in Malaysia has not been widely reported (14).

OBJECTIVES

This study is specifically aimed to determine the validity and reliability of the translated Bahasa Malaysia version of PACTQ (BM-PACTQ), and to identify the suitability of

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the BM-PACTQ in assessing patients' perception towards ACT.

MATERIALS AND METHODS

The screening instrument (The original PACTQ)

For this study, the use of "warfarin" and "anticoagulant therapy (ACT)" is interchangeable. The original 27 item-PACTQ (see appendix A) consisted of two parts (PACT-Q1 and PACT-Q2) (13). The PACT-Q1, comprised of a multidimensional scale (7 items; A1 to A7), covered the treatment expectations (TE) regarding ACT. The PACT-Q2 consists of two scales which measure conveniences (13 items; B1 to B11, and C1 to C2), and ACT satisfactions (7 items; D1 to D7). Five-point Likert rating (1=not at all; 2=a little; 3=moderate; 4=a lot; and 5=extremely) were used for all PACTQ items. All negative items were reversed accordingly (A3, A5, A7, B1 to B11, and C1 to C2) and the total means for each scale was calculated. Higher scores indicated higher TE, higher convenience and higher satisfaction perceived by the patients towards ACT.

The Translation Process

The translation of this PACTQ was done according to standard recognized methodology of translation as recommended by Sousa and Beaton (16,17). The translation process was done independently by 2 forward-translators and 2 backward-translators who were pharmacists fluent in both English and Malay languages. Each of forward-translators produced an independent forward translation of the original items, instructions, and response choices. The two translated versions were reviewed and compared with the original by researchers before an agreement was reached on the first BM version of PACTQ. Reverse translation process was carried out by two backward-translators. After the reconcilement of the two forward and backward translations, the groups of researchers discuss with the "backward" translators in order to resolve any inconsistencies. Finally, a language expert was consulted to check through the pre-final BM version to ensure coherence and cohesion as well as to correct any mistakes or errors. The BM-PACTQ was pilot tested with 10 patients to clarify whether the patients had any difficulty in understanding the questionnaire and to observe the time patients took to complete the questionnaire. Discrepancies were resolved in a meeting which was attended by three clinical pharmacists who were experts in the field. The psychometric properties of the BM-PACTQ were then subjected to further evaluation. Survey was administered using this BM version (BM-PACTQ). The interview takes about 10–15 min to complete.

Anticoagulation control

The benefit of ACT can only be attained if the patient achieved at least 70% of the International Normalized Ratio (INR) value spent within the therapeutic range(4). Patients' case notes and INR booklets were reviewed to assess each of the individual INR and patient's demographic data. The ACC was assessed by calculating the time in therapeutic range (TTR) using Rosendaal method (18). A patient would be considered to have good ACC if the TTR was above 70% (4).

Data collection

A cross sectional study was conducted at three major tertiary hospitals in Malaysia from April through August 2014. Patients recruited in this study were from Warfarin Medication Therapy Adherence Clinic (W-MTAC). Ethical approval was granted by the Medical Research Ethics Committee (MREC) of the Ministry of Health, Malaysia. The convenient sampling method was employed based on availability of the patients. Patients 18 years old and above, on the long-term ACT and able to communicate in Malay language were included in the study and they were excluded if they had cognitive impairment, had language barriers and did not give written consent. There were two sets of data collection forms. The first set contained individual patient's demographic data, and the second was the instrument, i.e., BM-PACTQ. Consented patients were interviewed face-to-face to complete the 27-item BM-PACTQ.

Statistical analysis

All data were analyzed using SPSS version 20.0. The significant level was set at p value <0.05. Descriptive statistics including mean and standard deviations (SD) for continuous variables, while frequencies and percentages for categorical variables were used to describe the study population. Reliability and validity tests were used to ensure the BM-PACTQ was reliable and valid. For this study, the reliability was determined by assessing the stability of the BM-PACTQ through internal consistency (Cronbach's alpha) and test–retest reliability. A Cronbach's alpha coefficient above 0.7 indicates high internal consistency (19,20). For test re-test reliability, intraclass correlation coefficients (ICCs) were calculated, and positive reliability was assumed when the ICCs was at least 0.70 for all tested subscales in a sample size of at least 50 patients (21). The validity was established through face validity, content validity, and construct validity. The construct validity was assessed through corrected item-total correlations (CITC) and known group validity test. An acceptable level for CITC was set at 0.30 (22). The association between patients' perception and the ACC status was assessed using the t-test. A correlation coefficient between each item and scale (Inter-correlations) was calculated using Pearson coefficient test.

RESULTS

Respondents' characteristics

A total of 270 patients was recruited in this study. The demographic data are shown in Table 1. The mean (SD) age was 57.63 (12.59) years, and most of the patients (82.2%) were Malays. Almost half (45.2%) of them had completed secondary education. The most common indications for ACT used were Atrial Fibrillation (AF) (70.4%) and majority (81.5%) underwent ACT more than one year.

Reliability and validity testing

Internal consistency

The internal consistency and the corrected item-total correlation (CITC) are presented in Tables 2. The internal consistency values of the convenience scale and ACT satisfaction scale were 0.90 and 0.88 respectively, which indicate good reliability of the instrument. The internal consistency for TE was 0.62, which was relatively low. However, there was no improvement of the Cronbach's alpha if any item was deleted from the scales. All items reached the expected level of CITC, ranging from 0.50 (A6) to 0.80 (B8), indicating that the items were measuring the same concept which proved the BM-PACTQ had good construct validity.

Table 1: Patients demographic (n=270)

Characteristic	Hospital A (n=88)	Hospital B (n=88)	Hospital C (n=94)	Total (n=270)
Age (mean ± SD)	55.47±14.25	62.31±7.02	55.27±13.84	57.63±12.59
Age Group (years) n, (%)				
< 50	25 (28.4)	3 (3.4)	26 (27.7)	54 (20.0)
50 – 60	26 (29.5)	32 (36.4)	31 (33.0)	89 (33.0)
> 61	37 (42.0)	53 (60.2)	37 (39.3)	127 (47.0)
Gender				
Male	44 (50.0)	29 (33.0)	41 (43.6)	114 (42.2)
Female	44 (50.0)	59 (67.0)	53 (56.4)	156 (57.8)
Race				
Malay	76 (86.4)	68 (77.3)	78 (83.0)	222 (82.2)
Others	12 (13.6)	20 (22.7)	16 (17.0)	48 (17.8)
ACT Indication(s)				
[a]* Atrial Fibrillation	46 (52.3)	88 (100.0)	56 (59.6)	190 (70.4)
Heart valve replacement	31 (35.2)	-	26 (27.7)	57 (21.1)
Other	11 (12.5)	-	12 (12.7)	23 (8.5)
Duration of ACT[a]**				
< 1 year	17 (19.3)	25 (28.4)	8 (8.5)	50 (18.5)
1 – 5 year	39 (44.3)	24 (27.3)	44 (46.8)	107 (39.6)
> 5 year	32 (36.4)	39 (44.3)	42 (44.7)	113 (41.9)
Education level [a]*				
Tertiary	9 (10.2)	41 (46.6)	22 (23.4)	72 (26.7)
Secondary	50 (56.8)	31 (35.2)	41 (43.6)	122 (45.2)
Primary	21 (23.9)	9 (10.2)	22 (23.4)	52 (19.3)
No education	8 (9.1)	7 (8.0)	9 (9.6)	24 (8.9)

[a]chi-squared tests; *p value < 0.001, **p value < 0.005

Test re-test reliability

The test re-test was calculated with an interval of 30 days for 50 patients. The result showed that all subscales of the BM-PACTQ have good ICCs (TE=0.91, convenience=0.95, and ACT satisfaction=0.95).

Floor and ceiling effects

Floor and ceiling effects were considered to be present if more than 15% of respondents achieved the lowest possible score in the former or the highest possible score in the latter (21). The ceiling effects ranged from 0.4% to 8.9%, whereas floor effects ranged from 0.4% to 0.7%, which indicate no floor or ceiling effects were present in the BM-PACTQ.

Known group validity

To support the construct validity, known group validity was performed by assessing the correlation between the mean score of each BM-PACTQ scale and ACC status using t-test analysis. It was hypothesed that patients who had higher perception scores had good ACC. The mean (SD) TTR was 69.34 (21.36), and 53% of the patients had good ACC. The total mean scores (SD) of TE, convenience and ACT satisfaction scales were 3.7 (0.60), 4.25 (0.57), and 4.18 (0.56) respectively. This indicated that patients had moderate TE, but had higher convenience and satisfaction towards ACT. Result showed that patients who had good ACC significantly had higher TE, convenience and ACT satisfaction ($p<0.001$, $p=0.01$, and $p<=0.001$ respectively). The results confirmed the above hypothesis. There was a significant difference between the age group in TE [$F(2,266)=5.792$, $p=0.003$]. However, post-hoc test showed that younger patients had significantly lower TE compared to others aged group ($p<0.05$). Result also showed patients aged 50 to 60 years old had higher convenience than younger and elderly patients ($p=0.029$ and $p=0.024$ respectively). Similarly, they also had higher ACT satisfaction compared to younger patients (($p=0.023$). In all categories of educational level, the mean scores in all perception scales significantly increased as the educational level increased ($p<0.05$). Among the ACT users, AF patients had higher TE than Heart valve replacement (HVR) patients ($p=0.001$) and higher satisfaction than other ACT users ($p=0.011$). However, no significance was found between them in their convenience towards ACT. Married patients had higher TE than single patients ($p=0.018$), but their perceptions of convenience and ACT satisfaction were similar towards ACT. It was also found that there was no significant difference in patients' perceptions in terms of gender.

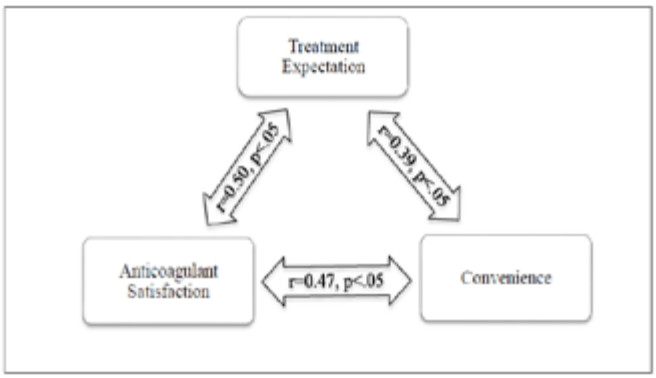
Table 2: Reliability test for each scale of BM-PACTQ

Scale	Question No.	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Treatment expectation	A1	.37	.58
	A2	.42	.55
	A3	.37	.57
	A4	.31	.59
	A5	.35	.58
	A6	.30	.60
	A7	.40	.59
Convenience	B1	.74	.89
	B2	.81	.88
	B3	.74	.88
	B4	.66	.89
	B5	.68	.89
	B6	.72	.87
	B7	.70	.89
	B8	.80	.88
	B9	.76	.89
	B10	.67	.89
	B11	.36	.93
	C1	.56	.89
	C2	.56	.89
Satisfaction	D1	.67	.86
	D2	.56	.88
	D3	.50	.88
	D4	.71	.86
	D5	.76	.85
	D6	.76	.85
	D7	.76	.85

Convergent and discriminant validity

For convergent validity, higher inter-correlations between items and scales would be expected. The value of a correlation coefficient above 0.45 between an item and its own scale was considered as an adequate evidence of convergent validity (20). Whereas, discriminant validity

refers to items that are not conceptually related having no significant correlation with the other construct. A correlation value of less than 0.90 is an indication of substantial non-collinearity between the constructs, demonstrating that the constructs are distinct from each other (23). Results showed that the correlations between the item-scale measurements were above 0.45. Additionally, as presented in Figure 1, all scales are not highly correlated with each other as their coefficient values (r) were less than 0.90 Thus, this indicated BM-PACTQ had good convergent and discriminant validity.



DISCUSSION

The results have provided evidence to prove reliability and validity of the BM-PACTQ as all the tests met all the necessary standards suggested by various researchers, thus confirming the findings of the original PACTQ (13,14). The reliability was confirmed when the results exhibited excellent Cronbach's alpha value. The respective Cronbach's alpha values of the BM version were 0.62, 0.90, and 0.88 for the TE, convenience and ACT satisfaction scales. This was considered to be more reliable compared to the original version (Cronbach's alpha; Convenience=0.84, ACT satisfaction=0.76) (13). The reliability was also supported by satisfactory test-retest when the ICC for TE, convenience, and ACT satisfaction were above 0.7 (21). The validity was confirmed through content validity, construct validity, convergent validity, and discriminant validity. Construct validity was supported by the sufficient CITC and known group validity. Results showed that the CITC was good (> 0.30) (22). Furthermore, results drawn from the known group validity proved the hypothesis that when patients had higher perception scores towards ACT they would have good ACC. All these indicate that the questionnaire had good construct validity. A positive relationship between perceptions and ACC was supported by Choudhury and Lip (24) which revealed that an understanding on how patients felt about warfarin therapy was important, as this may be a potential reason for non-compliance and in turn would cause poor ACC (24). More recent studies confirmed that higher satisfaction, fewer concerns, and better warfarin adherence were associated with good INR control (2). Convergent and discriminant validity are important aspects of the validity process. A weaker correlation between the BM-PACTQ scales but higher correlations within the item in each scale was expected. Convergent and discriminant validity were proven when the Inter-correlations between items and scale of BM-PACTQ were above 0.4 (20) and Pearson coefficient between the scale was less than 0.9 (23).

In this study, the TE scale or BM-PACT-Q1 was unidimensional. Thus, all items in this scale can be analyzed together. The above findings contradicted with the original study (13). The author (13) summarized that this scale was multidimensional and therefore the items needed to be analyzed separately. A possible explanation for this might be due to the difference in patients' selection criteria. The original study administered the TE questionnaire only for new patients at day 1 of the ACT initiation and for patients with deep venous thrombosis (DVT), pulmonary embolism (PE) or AF only, whereas in this study, it was administered to all patients regardless of the indication or the duration of ACT used. Although the results were different, this study showed that the TE scales had good construct and convergent validity. The present findings for BM-PACTQ2 (convenience and ACT scales) were consistent with original research (13). According to Terwee et. al. there was a possibility of missing an extreme item in the lower or upper end of the scale if floor or ceiling effects occurred and this indicated limited content validity (21). Thus, this can reduce the reliability of the measurements tool because the instruments was unable to distinguish patients with the lowest or the highest possible score. It can be concluded that the BM-PACTQ had good reliability because no floor or ceiling effects observed in all the scales. Generally, patients had moderate expectations towards ACT, but had higher convenience and satisfaction towards ACT. The results were similar with those of the previous studies (25,26). In contrast, satisfaction was moderate in other studies (2). The present study found that educated patients had better perceptions towards ACT than lower educated patients. Study conducted by Doris et al. showed similar results (27). Furthermore, these results showed concordance with those of other studies which revealed that younger patients had higher satisfaction (13,28) and higher convenience towards ACT (13) than elderly patients. Married patients had significantly good ACC and higher TE than single patients. As observed in previous studies, there was no significant difference between the perceptions of female patients and those of the male patients towards ACT (26). Interestingly, this study found that longer duration of ACT was not significantly related with patients' perceptions. Since patients had different perceptions towards ACT, all healthcare professionals must identify their patients' perceptions because this information can help them to develop suitable education programs to improve the quality of W-MTAC service as well as specific target to achieve good ACC.

LIMITATION

Our findings in this paper nonetheless had at least four limitations. First, these data applied only to anticoagulant clinic patients. Second, the survey administered using face-to-face interview. Third, these findings of the present study were limited by the use of a cross sectional design. And fourth, nonprobability convenience sampling technique was employed. The findings might not be transferable to warded patients or generalizable to studies in which the questionnaires are answered by patients themselves as well as other research designs and sampling techniques.

CONCLUSION

In the present study, the BM PACTQ was found to have good psychometric properties in measuring patients' perceptions towards ACT. A measure of patients' perceptions towards ACT using a validated questionnaire may help to optimize the W-MTAC management to achieve the good ACC in

anticoagulated patients.

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