
Reliability and validity of the Turkish translation of the beliefs about medicines questionnaire (BMQ-T) in patients with Behçet's disease

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Key words: beliefs about medicines questionnaire (BMQ), Turkish translation reliability and validity, necessity concerns framework, medication beliefs, Behçet's disease

ABSTRACT

Objectives. The aim of this study was to evaluate the reliability and validity of the Turkish translation of the Beliefs about Medicines Questionnaire (BMQ-T, ©Prof. Rob Horne) for patients with Behçet's disease.

Methods. This methodological study enrolled a sample of 125 patients. The scale was adapted to Turkish through a process including translation, comparison with versions in other languages, back translation, and pretesting. Construct validity was evaluated by factor analysis. Medication adherence evaluated as poor, moderate and good according to the Morisky Medication Adherence Scale (MMAS). BMQ-T scores compared along medication adherence status groups.

Results. In our study, as in the original scale, the factor analysis confirmed that the BMQ-T had a four-factor structure explaining 54.73% of the total variance. The BMQ-T had acceptable internal consistency (Cronbach's alpha coefficient: Specific Necessity=.812; Specific Concerns=.672; General Harm=.677; General Overuse=.656), adequate test-retest reliability (intraclass correlation coefficients: Specific Necessity=.715; Specific Concerns=.680; General Harm=.678; General Overuse=.327). Specific Necessity and Specific Concerns scores were significantly different between medication adherence status groups.

Conclusion. The psychometric properties of the BMQ-T were consistent with those reported in the original study. The BMQ-T was found to be a valid and reliable tool for evaluating beliefs about medicines in patients with Behçet's disease.

Introduction

Behçet's disease (BD) is a multisystem vasculitis with unknown etiology char-

acterized by the heterogeneous nature of organ involvement and a fluctuating disease course (1-3). In the clinical practice, it is not possible to define a uniform or standard therapy for BD, since the symptoms widely variable. The management should be tailored to each patient by taking into account the existing symptoms, clinical manifestations and prognostic factors (3). Vascular relapse risk is decreased when BD patients are treated with immunosuppressives with or without anti-coagulation rather than anti-coagulation alone (1). There are various effective treatment alternatives, while, the first and essential step for a successful treatment is patients' adherence to therapy. On the other hand, it is estimated that in developed countries, 40% of patients who suffer from chronic diseases do not adhere to treatment recommendations (4). Moreover, negative attitudes to medicines appear to be prevalent within the community, with many patients being suspicious of medicine, which further disturbs the adherence to treatments. Efforts to improve treatment outcomes require a better understanding of the particular barriers to and facilitators of adherence to therapy, and of patient experiences of taking treatment (5). Treatment adherence is influenced by many factors, among them: i) route of administration, ii) psychosocial factors, iii) fear of side effects, iv) lack of an immediate feeling of benefit, and v) patient attitudes to health and disease and beliefs about medicines (6-9). The causes of nonadherence can be summarized as unintentional and intentional. Intentional nonadherence occurs when the patient decides not to take medication as advised, and appears to be related to patients' beliefs, and their motivation to take the prescribed medication, whereas unintentional nonadherence

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is related with patients' skills or ability to take that medication (*e.g.* forgetfulness or manual dexterity) (10-15). Lack of adherence is a critical issue in not only BD but also in all chronic diseases, and it contributes to a considerable worsening of the disease and an increase in healthcare expenditures. In this context, increasing the level of the patient's adherence will improve the management of a certain disease. For this reason, determining the patient attitudes and beliefs about medication is important, and plays a key role in treatment adherence.

A recent meta-analysis of 94 peer-reviewed papers has identified the importance of patients' beliefs about medicines as potential determinants of adherence (9). Studies spanning 24 long-term conditions, involving over 25,000 patients from 18 countries demonstrate that nonadherence is often linked to doubts about their personal need for the treatment (Necessity beliefs) and to concerns about potential adverse consequences of taking it. In these studies Necessity beliefs and Concerns were assessed using the Beliefs about Medicines Questionnaire (BMQ)[®].

The BMQ is composed of two sections: the General section (BMQ-General), which assesses more general beliefs about medicine and includes the General Harm and the General Overuse scales; and the Specific section (BMQ-Specific), which explores beliefs about particular medication and comprises the Specific Necessity and Specific Concerns scales (10, 16).

The BMQ has been adapted and used in many countries (6, 9, 12, 17), but it has not yet been adapted to the Turkish language. In addition, as far as we know, there is no study assessing the belief about the medicine of patients with BD. In the present study, we aimed to investigate the validity and reliability of a Turkish translation of the BMQ in patients with BD.

Methods

Study design, sample and setting

The study was planned and applied as a methodological study. This study was conducted in a single rheumatology center. The study was approved by the

Ethical Review Board of the hospital and written informed consent was obtained from each participant.

Patients with BD who were being followed-up at the tertiary rheumatology outpatient clinic were invited to participate to the study. The inclusion criteria for the study as follows: i) fulfilling the International Study Group Criteria for BD (18); ii) being at age 18 years or older; iii) ability to read and write Turkish; iv) willingness to participate; and v) physically and cognitively able to communicate. The exclusion criteria consist of: i) having a major psychiatric disease diagnosis; ii) having cognitive impairment; iii) concurrent terminal illness or being clinically unstable. Ultimately, a total of 140 patients with BD were enrolled in the study. Of these, 15 patients did not complete the all questionnaires, who were omitted from the analysis. Consequently, data analyses were subjected to remaining 125 patients.

Demographic and disease-related variables

Demographic and disease-related variables including age, gender, duration of disease, age of diagnosis, educational background, marital and work status, and disease properties were recorded. Disease activity scores [Behçet's Disease Current Activity Form (BDCAF) (19) and Behçet's Syndrome Activity Score (BSAS) (20)] were recorded.

Beliefs about medicines questionnaire (BMQ)

BMQ was an established instrument for assessing people's perceptions and expectations about medications. It contains a general and a specific section, with 2 scales each. The scales of the BMQ-General are General Harm with 4 items and General Overuse with 4 items. The BMQ-Specific consists of two five-item scales assessing patients' beliefs about the necessity of prescribed medication for controlling their disease and their concerns about potential adverse consequences of taking it. Respondents indicate their degree of agreement with each statement on a five-point Likert scale, ranging from 1=strongly disagree to 5=strongly

agree. Scores obtained for individual items within both scales are summed. A mean score for each scale are computed by dividing total scores for that scale by the number of items in the scale, resulting in a mean score range of 1-5 for each scale. Higher scores indicate stronger beliefs in the concepts represented by the scale. A necessity-concerns differential is calculated as the difference between the necessity and the concerns scales, with a possible range of -4 to +4. This differential can be thought of as an indicator of how the individual judges their personal need for the treatment (necessity beliefs) relative to their concerns about taking it (10, 16).

Morisky Medication Adherence Scale (MMAS)

Medication adherence was assessed using the Morisky Medication Adherence Scale, which is a validated and reliable measure, developed by Morisky, Green, and Levine (1986). In this scale, patients were asked to respond "yes" or "no" to the following questions: Do you ever forget to take your medicine? Are you careless at times about taking your medicine? Do you sometimes stop taking your medicine when you are feeling well? When you feel worse due to the medicine, do you stop taking it? Adherence was assessed on a scale of 0 to 4, in which higher scores correspond to lower medication adherence and vice versa. Participants were then stratified into three groups according to their scores: 0 = high medication adherence; 1, 2 = medium medication adherence; 3, 4 = low medication adherence (21, 22).

Procedure

Written authorization to translate the original English version of the BMQ into Turkish was obtained from the Originator (Prof. Rob Horne UCL School of Pharmacy, University College London). The English version was independently translated into Turkish by two bilingual (Turkish and English) experts. One of them was a registered nurse and the other was a rheumatologist. A third bilingual expert reviewed the two Turkish-translated versions

and created another version. This version was back translated to English by two bilingual experts who had not read the original version. Thereafter, all three versions (original, translated, and back-translated) were assessed by a panel of three bilingual experts in the field (23, 24). Following the translation/back-translation procedure, the final version was checked using a pre-test technique to verify that they were able to understand the instructions, the questions, and the different answering options (24, 25) and to ensure that the language used fits the target population of the scale. Two weeks later, the Turkish version of the BMQ was administered again to 41 patients. These results were used to evaluate test-retest reliability.

Data analysis

All statistical analyses were conducted using the SPSS for Windows version 21.0 statistical software (IBM Inc, USA). Descriptive statistics (means, standard deviations [SDs], frequency distributions, percentages) were computed.

Internal consistency of BMQ-Turkish Translation (BMQ-T) was evaluated by Cronbach's alpha coefficient from baseline results of the patients. The BMQ-T questionnaire was applied two times at a two-week interval by the same researcher. Intraclass correlation coefficient (ICC) was calculated to assess test-retest reliability, and the paired samples t test was performed to represent there is no differences between first and second BMQ-T points. The measure validity of the BMQ was assessed by computing the correlation coefficient between the BMQ-T scores and the MMAS. Patients were grouped in three categories according to MMAS scores. Mean BMQ scores of these groups were compared using ANOVA, with Tukey HSD as the post hoc test. Construct validity was evaluated by exploratory factor analysis. Principle component analysis (PCA) was conducted with varimax rotation. The Kaiser-Meyer-Olkin test was performed to evaluate sample adequacy. The number of components was determined according to eigenvalue. In this

Table I. Clinical features of patients (n = 125).

Characteristics	n (%)
Oral aphthae	125 (100.0)
Papulopustular skin lesion (acneiform, ostiofolliculitis, etc.)	120 (96.0)
Genital ulcer	106 (84.8)
Erythema nodosum	65 (52.0)
Ocular involvement	52 (41.6)
Joint (arthritis) involvement	37 (29.6)
Vascular involvement	22 (17.6)
Central nervous system involvement	7 (5.6)
Gastrointestinal system involvement	1 (0.8)
Pathergy positivity	58 (46.4)
HLA-B51, positive, (n=43)	30 (69.8)
BDCAF (mean ± SD), (range 0-12)	4.79 ± 2.05
BSAS (mean ± SD), (range 0-100)	45.22 ± 23.56
Used drugs*	
Colchicine	96 (76.8)
Azathioprine	56 (44.8)
Corticosteroids	20 (16.0)
Anticoagulant	9 (7.2)
Cyclosporine A	6 (4.8)
Infliximab	5 (4.0)
Cyclophosphamide	5 (4.0)
NSAIDs	4 (3.2)
Methotrexate	3 (2.4)
Sulfasalazine	2 (1.6)
Experiencing drug related adverse events	40 (32.0)
Gastrointestinal (abdominal pain, distension, nausea, vomiting, diarrhea, loss of appetite)	20 (16.0)
Elevation in liver enzymes	10 (8.0)
Skin (pruritis, rash, ecchymosis, acne, alopecia)	6 (4.8)
Constitutional (weakness, fatigue, headache, dizziness)	2 (1.6)
Allergic reactions	1 (0.8)
Diminished libido	1 (0.8)

Data represented either as the mean ± SD or as the frequency; *More than 1 agent might have been used in the same patient; NSAIDs: nonsteroidal anti-inflammatory drugs; BDCAF: Behçet's disease current activity form; BSAS: Behçet's syndrome activity score; SD: standard deviation.

study, *p* values less than .05 were considered to be statistically significant.

Results

Participant characteristics

A total of 125 patients had completed the study protocol. The mean age of these patients was 31.42±8.11 years. Mean disease duration was 9.34±5.76 years. The study population was male predominant (91.2%) and about half of the patients were single (53.6%). Twenty-nine (23.2%) of the patients were primary school graduate, 41 (32.8%) were high school graduate, and 55 (44.0%) were university and higher graduate. All of the patients had current or a history of oral aphthae. Other skin lesions, such as papulopustular lesions, genital ulcers, and erythema nodosum were present in 96.0%, 84.8%, and 52.0% of the patients, respectively. The most frequent organ involvement was ocular disease with a frequency

of 41.6%. Other involvements such as joint, vascular, central nervous system, and gastrointestinal diseases were seen in 29.6%, 17.6%, 5.6%, and 0.8% of patients, respectively. The pathergy test was positive in 46.4% of the patients. The HLA-B51 test was positive in 30 of 43 patients who were tested. The clinical features of the study group are presented in Table I.

Among the current treatment agents, colchicine was the most commonly used one (76.8%). Sixty-seven patients were using at least one immune suppressive drug (azathioprine, cyclosporine A and cyclophosphamide). Other medications such as corticosteroids and anticoagulant agents were being used in 20 and 9 patients, respectively. Other medicines including infliximab, sulfasalazine, methotrexate, and nonsteroidal anti-inflammatory drugs (NSAIDs) were being used by a minority of the patients (each, <5%).

Drug-related adverse events were experienced by 32.0% of the patients. Among those, gastrointestinal and hepatic side effects were the leading ones (16.0% and 8.0%, respectively) (Table I).

According to the MMAS scores, 32 (25.6%) patients had high, 69 (55.2%) patients had moderate, and 24 (19.2%) patients had low medication adherence. Total MMAS score were 1.43 ± 1.16 (min-max, 0-4).

Reliability

The BMQ-Specific Necessity Cronbach's alpha coefficient was .812, BMQ-T-Specific Concern Cronbach's alpha coefficient was .672, BMQ-T-General Harm Cronbach's alpha coefficient was .677, BMQ-T-General Overuse Cronbach's alpha coefficient was .656. The total BMQ-T-Specific Cronbach's alpha coefficient was .774, the total BMQ-T-General Cronbach's alpha coefficient was .730. The paired samples t test demonstrated that there was no difference between test and retest scores of the whole scales of BMQ-T ($p > .05$). In the correlation analysis performed for the test-retest reliability, an adequate statistically significant and positive correlation was observed between the first test and the retest scores ($p < .05$) (Table II).

Validity

The Morisky scale classifies patient adherence as high, medium, and low. In our comparative analysis, a statistically significant difference was found between these groups with respect to the total BMQ-T scores (except for BMQ-T-General Harm). We performed a post hoc analysis to identify the cause of this difference; we found that the BMQ-T-Specific Necessity mean score of patients with high Morisky drug adherence was higher from those in the medium and low drug adherence groups ($p = .022$), BMQ-T-Specific Concerns mean score of patients with high Morisky drug adherence was lower from those in the medium and low drug adherence groups ($p = .006$) and BMQ-T-General Overuse mean score of patients with medium Morisky drug ad-

Table II. Comparison and correlations of the BMQ-T test-retest scores.

Application	Test (n=125)	Retest (n=41)	t	p*	r	p**
BMQ-T-Specific Necessity	3.69 ± 0.80	3.61 ± 0.91	1.301	.201	.715	< .001
BMQ-T-Specific Concerns	3.22 ± 0.78	3.23 ± 0.73	1.636	.110	.680	< .001
BMQ-T-General Harm	2.37 ± 0.71	2.38 ± 0.82	.755	.455	.678	< .001
BMQ-T-General Overuse	2.68 ± 0.75	2.67 ± 0.75	-.391	.698	.327	.017

Note: BMQ-T: Turkish version of the Beliefs About Medicines Questionnaire; *Paired samples t test; **Intraclass correlation coefficient (ICC).

Table III. Comparison of the BMQ-T with the Morisky scale sub-groups.

	Morisky drug adherence			F*	p
	High	Medium	Low		
BMQ-T-Specific Necessity	4.00 ± 0.63	3.63 ± 0.86	3.43 ± 0.75	3.95	.022 [†]
BMQ-T-Specific Concerns	2.91 ± 0.81	3.25 ± 0.76	3.58 ± 0.67	5.335	.006 [‡]
BMQ-T-General Overuse	2.59 ± 0.70	2.59 ± 0.73	3.05 ± 0.77	3.86	.024 [‡]
BMQ-T-General Harm	2.31 ± 0.81	2.36 ± 0.67	2.50 ± 0.71	.545	.581

Note: *Oneway ANOVA; [†]Statistically significant between high and low scores; [‡]Statistically significant between high and low scores; [‡]Statistically significant between medium and low scores.

herence was lower from those in the low drug adherence groups ($p = .024$) (Table III). There was no correlation between BMQ-T-General Harm score and both the total MMAS and classified MMAS scores.

Construct validity was evaluated by factor analysis. The original scale consisted of four components. As a result of our analysis, that the items separated into four components in Principle Component Analysis. The total explained variance was 54.73%, and the lowest item load was .46. The Kaiser-Meyer-Olkin measure of sample adequacy was found to be .71 (Table IV).

At the result of the PCA, item 5 was classified more closely with General Overuse questions, rather than its components. But the factor load with Specific Concerns questions was calculated as .318. The factor structure we have achieved was considered to be highly consistent with the original structure of the scale, and it had an appropriate and close scoring and classification to the original.

We calculated a Necessity Concerns Differential (NCD) by subtracting mean Concerns Scale scores from Necessity scale scores (scale scores range from -4 to +4). The mean Necessity-Concerns differential was found to be 0.47 ± 0.91 (range -1.8 to 3).

Discussion

This was the first study to assess the reliability and validity of the Turkish translation of the BMQ. The prevalence rate of BD was between 20-421 among 100,000 in adolescent/adult population in Turkey (26-28). BD, for many patients, is a disease that impairs the quality of life by frequently relapsing mucocutaneous manifestations. However, there are also many who carry an increased risk of significant morbidity or even mortality as a consequence of vital organ involvement. Many factors, including patient's sex, age of disease onset, the disease duration and patient attitudes and beliefs about medication need to be considered when planning treatment for a patient with BD. In this context, we decided to conduct the study in these patients. This study results supported the validity and reliability of the BMQ-T.

The BMQ-T showed adequate reliability for clinical application. Internal consistency of the total BMQ-T (Specific and General) was supported by Cronbach's alpha coefficients (.774 and .730 respectively). In the correlation analysis performed for the test-retest reliability, an adequate statistically significant and positive correlation was observed between the first test and the retest scores (Table II). The validity of the BMQ-

Table IV. Results of the principal components analysis with varimax rotation of the BMQ-T (n = 125).

	Original Component	New Component			
		1 (SN)	2 (GO)	3 (SC)	4 (GH)
Without this medicine I would be very ill	SN (item 4)	.814			
My health, at present, depends on this medicine	SN (item 1)	.761			
My life would be impossible without this medicine	SN (item 3)	.752			
My health in the future will depend on this medicine	SN (item 7)	.682			
This medicine protects me from becoming worse	SN (item 10)	.667			
If doctors had more time with patients they would prescribe fewer medicines	GO (item 18)		.672		
People who take medicines should stop their treatment for a while every now and again	GO (item 12)		.633		
Doctors place too much trust on medicines	GO (item 17)		.619		
I sometimes worry about long-term effects of this medicine	SC (item 5)		.549		
Doctors use too many medicines	GO (item 11)		.538		
Having to take this medicine worries me	SC (item 2)			.608	
This medicine is a mystery to me	SC (item 6)			.584	
This medicine disrupts my life	SC (item 8)			.544	
I sometimes worry about becoming too dependent on this medicine	SC (item 9)			.539	
All medicines are poisons	GH (item 16)				.788
Medicines do more harm than good	GH (item 15)				.737
Natural remedies are safer than medicines	GH (item 14)				.533
Most medicines are addictive	GH (item 13)				.461
Eigenvalue		3.75	3.34	1.40	1.37
% of variance		20.83	18.53	7.77	7.59
Cumulative % of variance					54.73

SN: Specific Necessity; SC: Specific Concerns; GH: General Harm; GO: General Overuse.

Specific scales was assessed in different languages including Portugal, English, German and Italian. In the Portuguese, German, and Italian versions of the BMQ-Specific, the results had provided good support for confirming the reliability. In our study, the Cronbach's alphas for the Necessity and Concerns scales (0.812 and 0.672 respectively) were in agreement with the values of Portuguese (0.757 and 0.665, respectively), Italian (0.78 and 0.72, respectively) and English versions (ranged from 0.55 to 0.86 and from 0.63 to 0.80 for the Necessity and Concerns scales, respectively) (12, 16, 29). However, the German version values (0.83 for both scales) were higher than the Cronbach's alphas attained for the Portuguese, Italian, English and our study results (30). In our study, the BMQ-T-General results also provide good support for confirming the reliability. The Cronbach's alphas for the Overuse and Harm scales (.656 and .677, respectively) were in agreement with the values reported for the original English version, in which Cronbach's alpha ranged from .60 to .80 and from .47 to

.83 for the Overuse and Harm scales, respectively (16). These previous studies validating the BMQ-T indicate this scale has adequate reliability, and similar results were found in our study. In our study, the construct validity of the scale was evaluated by factor analysis. The Kaiser-Meyer-Olkin measure of sample adequacy was found to be .71 and considered adequate. The total explained variance was 54.73%, and the lowest item load was .46. The factor structure we have achieved was considered to be highly consistent with the original structure of the scale, and it had an appropriate and close scoring and classification to the original (Table IV). Finally, the construct validity of our translated questionnaire was evaluated as satisfactory. The MMAS is commonly used in medication adherence studies (13). Morisky *et al.* (21) developed a brief, easily understood, and valid scale to be administered to patients in the clinical setting. In the present study, the medication adherence was evaluated with MMAS. According to the MMAS

scores, medium and high levels of medication adherence were observed in the majority of the patients. While reported average medication adherence scores range between 43-78% in clinical trials, it is estimated that in developed countries (31), 40% of patients who suffer from chronic diseases do not adhere to treatment recommendations (4). In the present study, medication adherence in BD patients seems to be better as compared to the historical data in other patient populations, while to our knowledge no data existed in BD patients. While we categorized our data into three groups according to MMAS scores, there was a statistically significant difference among these groups for BMQ-T scores except for BMQ-T-General Harm (Table III). It has been reported that General Harm and General Overuse beliefs were associated with Specific Concerns about medication prescribed for them by their doctors (7, 16). Our findings are consistent with theoretical predictions that non-adherence is likely to be more closely with specific beliefs than with general beliefs (32).

Several validation studies focused on different languages for this scale have been conducted on different diseases. It is reported that the two sections of the BMQ can be used in combination or separately. Salgado *et al.* (12) have done just Portuguese validation of the BMQ-Specific sections. De las Cuevas *et al.* (17) on psychiatric patients, Perpiñá Tordera *et al.* (6) on Asthma patients also have made on the validity of the scale. They found compatible with the original version of the results. In our study, similar to the original version and previous studies, both general and specific parts of the scale was found to be validated.

Patient's with stronger beliefs in the necessity of their medication (high scores on the BMQ-Necessity scale) were significantly more adherent. Those with stronger concerns (high scores on the BMQ-Concerns scale) were significantly less adherent (10). In our study, we also found similar results. We have found that, the patients with higher drug adherence had also higher Specific Necessity scores, those

with lower drug adherence, had higher Specific Concerns scores.

The Turkish translation of the BMQ exhibited good to excellent internal consistency and its structure and content provided a perfect fit to those of the original questionnaire. Our findings underscore the usefulness of the BMQ-T for assessing beliefs that patients with BD hold about the medicines they use. Therefore, further studies are needed to investigate the reliability and validity of this scale in different clinical settings and different populations.

Conclusion

The Turkish version of the BMQ is a simple, and inexpensive to administer, and a convenient measurement of patients' attitudes and beliefs about their medication in patients with BD. In addition, it was demonstrated to have acceptable reliability and validity.

Limitation

This study depends on a patient-reported questionnaire; therefore, this is a potential limitation of the present study. Natural drawbacks of this type of study, such as recall bias and false declarations of patients, might cause potential risk of bias.

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