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The Persian Version of the Chronic Urticaria Quality of Life Questionnaire: Factor Analysis, Validation, and Initial Clinical Findings

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ABSTRACT

Chronic urticaria (CU) also known as chronic idiopathic urticaria results in a lowered quality of life (QoL). Disease specific questionnaires are necessary to assess QoL in CU patients. Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) is the only available and validated disease specific questionnaire in the assessment of QoL in CU patients originally developed in Italian language. The aim of the current study was to develop the Persian version of the CU-Q2oL with an acceptable reliability and validity.

Using the standard methods provided by guidelines, CU-Q2oL was translated into Persian. A total number of 110 patients with confirmed diagnosis of CU were asked to fill the questionnaire. Determination of scales was performed in addition to checking the data for internal consistency and known group validity. Urticaria activity score 7 (UAS-7) was used to assess the severity of the CU in the population study. The 6 dimensional scale of Persian CU-Q2oL was determined using the Exploratory Factor Analysis. About 68% of the variance was explained by these 6 factor structure higher than 59.9% of the original Italian version.

All 6 factors showed acceptable internal consistency as measured by Cronbach α coefficient. There was a significant correlation between UAS-7 and total CU-Q2oL score. UAS7 and the presence of angioedema were predictors of CU-Q2oL score.

The Persian version of CU-Q2oL was shown to be a valid and reliable tool to be used in the future clinical studies. Cultural considerations must be kept in mind in adoption of CU-Q2oL to other languages.

Keywords: Adaptation; Chronic urticaria; Persian; Quality of life; Questionnaire; Validation

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INTRODUCTION

Chronic urticaria (CU) also known as chronic idiopathic urticaria is a common skin disorder affecting about 1 in 100 individuals.[1,2] It is defined by the appearance of itchy wheals with or without angioedema in all or most days of the week lasting for at least 6 weeks[1] and characterized by periods of remission and relapses. Clinical management of CU is a difficult goal and the true etiology of CU remains unknown in up to 90% of cases.[1] CU patients suffer from physical, social, and psychological morbidities resulting in a low quality of life.[3-5]

Assessment of quality of life (QoL) in CU patients is a mandatory step in the clinical researches as well as the routine management of disease. Researchers shall accurately evaluate QoL to achieve an unbiased judgment regarding the efficacy of the desired treatment.[6] Physicians also benefit from the assessment of QoL in their routine management of CU to provide better therapeutic options in order to increase the well being of their patients.[6]

Health-related QoL (HRQoL) is defined as the patients' evaluation of their own well being comparing to what they consider as ideal.[7] Although several studies evaluated the impact of CU on the QoL of patient, most of them used generic questionnaires designed for the assessment of QoL in general such as Nottingham Health Profile or in dermatological disease like Dermatology Quality of Life Index.[8] To answer the need for a disease specific questionnaire to investigate the different aspects of CU on the physical and psychological well being of patients, Baiardini et al. developed the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) originally available in Italian language.[9] CU-Q2oL showed good reliability and validity both in its original language and when translated and adopted in several other languages including Brazilian-Portuguese, German, Polish, Spanish and Turkish.[3,6,9-12]

Adaption of CU-Q2oL questionnaire provides a suitable tool to compare the result of studies performed in various countries on the clinical aspects of CU.[10] The aim of the current study was to develop the Persian version of the CU-Q2oL with an acceptable reliability and validity. This questionnaire can be used for further clinical researches on CU on Persian population as well as providing a unified measurement for evaluation of QoL in Persian speaking CU patients at the routine clinical setting.

MATERIALS AND METHODS

Study Design and Data Collection

The current study was designed to validate the Persian version of the CU-Q2oL questionnaire to be used as a measurement tool for QoL in Persian CU patients for future studies. CU-Q2oL was originally designed in Italy and included 23 items in 6 dimensions of quality of life: 2 items about pruritus, 6 items about impact on life activities, 5 items about sleep problems, 3 items about limits, 5 items about looks, and 2 items about swelling. Every item could be answered in Likert scale by never, rarely, sometimes, often, very often or in some occasions by none, a little, moderate, a lot, very much. Scores were converted into a 0 to 100 scale. A higher score demonstrated a worse HRQoL.

A total number of 110 patients with a confirmed diagnosis of CU were investigated at the department of Allergy and Clinical Immunology, Children's Medical Center. Diagnosis was confirmed after taking detailed medical history and physical examinations. The ethics committee of Tehran University of Medical Sciences approved the process of this study and informed consents were obtained from all patients. Patients were asked to fill and return the questionnaire when they visited the hospital during their routine follow-up. Subjects were also asked to fill and return the same questionnaire 1 week after the first visit to check the reliability of the evaluation process. Due to social and cultural issues, we were unable to use electronic mails for the follow-up process and all patients filled and returned the questionnaire in our hospital. Patients' demographic data and medical records were also reviewed.

Translation of CU-Q2oL into Persian

The original Italian version of CU-Q2oL was adopted into Persian using the standard methodology for translation and cross-cultural adoption.[13] First, 2 native Persian speakers who were fluent in Italian translated the original Italian version of the questionnaire into Persian. Both translations were reviewed by several medical experts in our department and a consensus version was back-translated into Italian by a native Italian speaker who was expert in Persian. This version was reviewed by Italian and

Persian authors and changes were made to the translated Persian version if there was any significant differences between the original and back-translated Italian versions. Finally, 11 patients were asked to fill the questionnaire and express their opinion regarding the difficulty in understanding and interpretation of the questions in a face to face interview. Since there was no significant problem at this point, the Persian version was used for remaining patients without further changes.

Measurements

Patients' Urticaria Activity Score 7 (UAS-7) was used to evaluate the clinical severity in CU patients. [14] UAS-7 is recommended by diagnosis guidelines of European Academy of Allergology and Clinical Immunology (EAACI), the Global Allergy and Asthma European Network (GA2LEN), the European Dermatology Forum (EDF), World Allergy Organization (WAO) [14] to assess the disease activity of CU. This system allocates a score of 0 to 3 to each of pruritus and wheals, according to their severity, as the most important symptoms of CU with a score between 0 and 6 for each day. This score is calculated for 7 consecutive days and the final score is between 0 and 42.

Statistical Analysis

The first step in the validation process of Persian version of CU-Q2oL was to determine the appropriate structure of scales. Exploratory Factor Analysis (EFA) was used to determine the scale of CU-Q2oL mainly due to the cultural aspects and since this questionnaire is new.[6] Using Varimax factor rotation with Kaiser normalization, data were reduced into summary scores. The criterion applied to retain scales was an Eigen value > or = 1.0 for that scale. This analysis was performed to examine which scale is the most appropriate suitor for each of the items. The critical threshold for each item to meet this condition has been pre-set at 0.5.

After determining scales, internal consistency was tested by calculating Cronbach α coefficient for each scale. Paired t-test was performed to evaluate the reliability of the questionnaire by comparing the results of CU-Q2oL scores at the baseline and one week later. Known-group validity was tested by determining whether the CU-Q2oL was able to distinguish between patients with different urticaria activity as measured by the UAS-7. The differences between group comparisons were determined using analysis of variance (ANOVA).

Multiple linear regression analysis was performed to evaluate the probable significant predictors of different CU-Q2oL scores. Sex, age, duration and severity of disease, and the presence of angioedema were considered as independent variables while total and scale scores of CU-Q2oL were considered as dependent variables.

All statistical analyses were performed using the SPSS version 21 (IBM New York, USA). A *P*-value lower than 0.05 was considered as statistically significant.

RESULTS

Patients' Characteristics

A total number of 110 patients (20 males and 90 females) were enrolled in this study. The mean (SD) age of the patients was 33.6 (10.8) years ranging from 18 to 67 years. Majority of the patients (69.1%) aged between 20 and 40 years. The mean (SD) duration of disease was 62.5 (96.3) months ranging from one month to 40 years. A considerable subgroup of patients (30.9%) had CU for more than 5 years. Out of 110 patients, 94 (85%) were receiving the standard treatment of CU at the time of the study. Angioedema was present in 75 (68.2%) patients. None of the patients reported any difficulty in understanding or answering the Persian version of CU-Q2oL questionnaire. Most patients completed and returned the questionnaire in about 2-3 minutes and no patient needed more than 5 minutes in this process.

Determination and Validation of Persian CU-Q2oL Scales

Of the 110 CU patients enrolled in this study, no missing response in the CU-Q2oL questionnaire was observed. The factor analysis was performed using a 6 factor structure for Persian CU-Q2oL data. The results of 6 dimensional factor analyses are summarized in Table 1. About 68% of the variance was explained by this 6 factor structure higher than 59.9% of the original Italian version, [9] indicating a good validity. The determined sets of scales for Persian CU-Q2oL are shown in Table 2. The mean (SD) total CU-Q2oL was 58.43 (16.83). The mean (SD) score for factor I, II, III, IV, V and VI were 56.33 (23.63), 59.45 (20.62), 67.94 (19.93), 51.76 (20.49), 49.64 (21.92), and 49.92 (21.4), respectively.

Internal Consistency

Internal consistency results using the Cronbach's α coefficient test for 6 scales showed an excessive

Table 1. Different levels of Scale determination for the Persian version of CU-Q2oL Questionnaire

Component	Initial Eigen values			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
(A) Results of Varimax rotation with Kaiser normalization						
1	8.434	36.671	36.671	4.069	17.693	17.693
2	1.965	8.543	45.214	3.258	14.166	31.859
3	1.643	7.143	52.357	2.709	11.779	43.638
4	1.403	6.099	58.456	2.104	9.149	52.787
5	1.176	5.113	63.570	1.796	7.807	60.594
6	1.034	4.497	68.067	1.719	7.473	68.067

The criterion applied to retain scales was an eigen value > or = 1.0 for that scale.

Item no.	Item name	Scales					
		I	II	III	IV	V	VI
(B) Matrix of components resulting in 6 diverse scale solutions							
1	Pruritus	0.279	**0.790**	0.084	0.203	-0.015	0.002
2	Wheals	0.089	**0.800**	0.125	0.283	0.031	0.138
3	Eyes swell	0.180	0.200	-0.021	**0.761**	0.177	0.073
4	Lips swell	0.128	0.110	-0.020	**0.838**	0.020	0.158
5	Work	0.246	0.417	-0.034	-0.012	**0.558**	0.286
6	Physical activities	0.106	0.005	0.180	0.086	**0.726**	-0.069
7	Sleep	**0.597**	**0.552**	0.238	0.080	0.151	-0.118
8	Spare time	0.392	**0.634**	0.274	-0.021	0.159	0.106
9	Social relations	0.253	**0.623**	0.112	0.006	0.391	0.251
10	Eating	0.198	0.180	**0.616**	**0.518**	0.109	0.020
11	Difficulty falling asleep	**0.754**	0.335	0.130	0.076	0.144	-0.091
12	Waking up at night	**0.623**	0.287	0.328	0.191	0.271	-0.133
13	Diurnal tiredness	**0.834**	0.138	0.095	0.136	0.101	0.154
14	Concentration	**0.744**	0.161	0.020	0.042	0.108	0.343
15	Nervousness	**0.733**	0.071	0.146	0.219	0.030	0.333
16	Feeling blue	**0.531**	0.265	0.319	0.033	-0.054	**0.571**
17	Limit food	0.038	0.203	**0.797**	0.100	-0.075	0.093
18	Embarrassed by signs	0.188	0.335	0.035	0.267	0.409	0.373
19	Embarrassed in public	0.131	0.067	0.167	0.184	0.108	0.804
20	Limits cosmetics	0.066	-0.169	**0.601**	0.042	0.386	0.114
21	Limits clothes	0.315	0.240	**0.632**	-0.199	0.128	0.040
22	Limits sport	0.255	0.129	**0.577**	-0.299	0.250	0.221
23	Medication side-effects	0.044	0.255	0.338	0.249	0.423	0.180

This indicates which scale is the most appropriate suitor for each of the items. The critical threshold for each item to meet this condition has been pre-set at 0.5 (see bold values)

consistancy for scales I and II (0.934 and 0.943, respectively), excellent for scale IV (0.837), respectable for scale III (0.796), minimally acceptable for scale VI (0.686), and undesirable for scale V (0.637). Although Cronbach's α coefficient was below our desired value for scale V, since Baiardini et al. considered a Cronbach's α higher than 0.5 as acceptable, we decided not to omit this scale.

Reliability

The mean (SD) total CU-Q2oL score was 52.49 (17.83) at the baseline and 53.2 (16.56) one week later. No

Table 2. Scales of the Persian CU-Q2oL

Scale no.	Scale name	Questionnaire item no.	Questionnaire item names
I	Functioning/ Mental status	5,6,9,14,15,22	Work, Physical activities, Social relations, Concentration, Nervousness, Limits sport
II	Sleep/ Eating/ Embarrassment	7,10,11,12,13,18	Sleep, Eating, Difficulty falling asleep, Waking up at night, Diurnal tiredness, Embarrassed by signs
III	Itching/ Mental status	1,2,16	Pruritus, Wheals, Feeling blue
IV	Limits/ Functioning	8,17,20	Spare time, Limit food, Limit cosmetics
V	Looks/ Embarrassment	4,19	Lips swell, Embarrassed in public
VI	Looks/ Medication	3,23	Eyes swell, Medication side-effects

significant change in total CU-Q2oL score was observed during this period (*P*-value = 0.545). Similar to total score, no significant difference was observed in the scores of any of the 6 dimensions of CU-Q2oL at the baseline and re-test.

Known-Group Validity

The mean (SD) UAS-7 score was 25.34 (11.42). Patients were categorized into quartile groups according to their UAS-7 score. ANOVA test was performed to evaluate significance of differences in total CU-Q2oL score among these groups. The mean (SD) Total CU-Q2oL scores for these 4 quartile groups were 50.7 (14.5), 67.6 (13.1), 71.8 (18.7) and 67.2 (19.3), respectively. Total CU-Q2oL score of 1st quartile was significantly different from 2nd, 3rd and 4th quartiles (*P*=0.003, *P*<0.001, and *P*<0.001, respectively). However, no significant difference was observed among 2nd, 3rd and 4th quartiles. There was also a significant correlation between UAS-7 scores and total CU-Q2oL score using the Pearson correlation coefficient test (*P*<0.001, r=0.492).

Multiple Linear Regressions

None of the items including sex, age, and duration of disease was significant predictors of total CU-Q2oL scores or any of its 6 factors. In contrast, UAS-7 score and the presence of angioedema were significantly predictor of high CU-Q2oL scores. Table 3 presents the results of multiple linear regressions analysis.

Table 3. Multiple linear regression analysis for the evaluation of the probable significant predictors of CU-Q2oL scores.

	I	II	III	IV	V	VI	Total CU-Q2oL score
Sex, Beta (*P*-value)	0.001 (0.99)	0.02 (0.79)	0.1 (0.26)	0.24 (0.01*)	0.02 (0.81)	0.04 (0.68)	0.06 (0.44)
Age, Beta (*P*-value)	0.01 (0.88)	-0.03 (0.69)	0.16 (0.08)	-0.002 (0.98)	-0.04 (0.68)	0.12 (0.2)	0.03 (0.72)
Duration of disease, Beta (*P*-value)	-0.14 (0.13)	-0.14 (0.11)	-0.13 (0.14)	0.06 (0.51)	-0.08 (0.38)	-0.09 (0.35)	-0.15 (0.09)
UAS-7, Beta (*P*-value) score	0.36 (<0.001*)	0.46 (<0.001*)	0.46 (<0.001*)	0.27 (0.004*)	0.17 (0.07)	0.26 (0.005*)	0.48(<0.001*)
Angioedema, Beta (*P*-value)	-0.13 (0.17)	-0.2 (0.02*)	-0.08 (0.34)	-0.05 (0.56)	-0.32 (0.001*)	-0.36 (<0.001*)	-0.2 (0.02*)

*: Statistically significant, Beta: standardized coefficients

DISCUSSION

CU patients suffer a significant impairment in their QoL which is even considered to be equal to coronary artery disease by some authors.[8] Evaluation of QoL in CU patients is an essential step to monitor the effectiveness of treatment both at the clinical setting and research projects on CU.[10] Before the introduction of CU-Q2oL by Baiardini et al.[9] in 2005, several generic as well as dermatology specific questionnaires were used to evaluate QoL in CU patients. CU-Q2oL, as the sole disease-specific tool for measurement of QoL of CU, has been converted into several languages including Brazilian-Portuguese, German, Polish, Spanish and Turkish.[3,6,10-12] The results of the current study, with an aim to adopt the CU-Q2oL questionnaire to Persian language with about 60 million native speakers and an estimated 110 million total speakers, showed a reliable and valid structure.

The results of 6 dimensional factor analysis showed an acceptable validity for this structure. Although some studies persuaded to outline a Spanish and Turkish versions of CU-Q2oL decided to retain the original 6 scales,[3,10] others such as studies on the German and Polish versions of CU-Q2oL determined a new 6 scales structure according to the results of their factor analysis.[6,11] Moreover, Brazilian-Portuguese version of CU-Q2oL determined a 3-scale structure.[12] After determination of Persian CU-Q2oL scales, several differences with the original study were observed. Factor I, functioning/ mental status, collected items related to activity and some items from mental status without considering the remaining 17 items. In contrast with the original Italian version,[9] Persian speaking patients considered problem in concentration, nervousness and limited actions in sport in association with their function. This can be easily explained since these conditions highly affect the function and efficacy of patients both in doing their jobs and their day-to-day activities including exercise and performing any sports. Factor II includes items relating to sleep problems in addition to problems in eating and embarrassing by signs. It is noteworthy that there is a connection between sleeping and eating in Persian culture and many individuals may consider these 2 factors as measures for their quality of life. Factor III, itching/ mental status, consisted of pruritus and wheals which were both included in the original version in the category of pruritus[9] in addition to feeling blue or depressed. In the German version of CU-Q2oL, there was also 2 other items, bothered by signs, and embarrassed in public, which were allocated in factor III in addition to pruritus and wheals of the original version.[6] It seems that whereas German patients consider pruritus and wheals to result in being bothered and embarrassed in public, Persian speaking patients are more likely to feel depressed as a result of these 2 physical symptoms of CU. Factor IV, includes impairments in spare time, limitations in food, limitations in cosmetics. Factor V, includes looks/ embarrassment, lips swelling, and feeling embarrassed in public. This finding is in contrast with findings of German authors who suggested that lips swelling interfere with eating and does not result in feeling embarrassed.[6] Factor VI, includes looks/ medication, eyes swelling, and medication side-effects.

The 6-factor structure of Persian CU-Q2oL showed good validity since all scales had an acceptable consistency and all items seems to be placed properly into various scales based on the cultural background of Persian speaking people. In addition, all items were categorized according to the statistical analysis and no revision or editing was undertaken to change this desired structure.

Total CU-Q2oL was significantly correlated with UAS-7 indicating the validity of this questionnaire. UAS-7 is widely used to access the activity and severity of CU.[6] There was also a significant difference between the UAS-7 score of CU patients with a total CU-Q2oL score at the 1st quartile, with this score in individuals with a total CU-Q2oL score in the 2nd, 3rd, and 4th quartiles. Although CU patients in the higher quartiles showed higher disease activity as measured by UAS-7, this difference was not significant probably due to the low number of cases in each group and/or the narrow range of this item. The mean (SD) total CU-Q2oL was 58.43 (16.83) in the current study, much higher than of reported values of Turkish and Spanish studies which reported a total CU-Q2oL around 25%. This higher total CU-Q2oL score was accompanied by a higher UAS-7 score in comparison to the mentioned studies which indicated worse quality of life in Persian speaking patients comparing to Turkish and Spanish speaking patients.[3,10]

The results of multiple linear regression showed that UAS-7 was the predictor of total CU-Q2oL as well as all of its factors excluding factor V. This was expected as previous studies also reported UAS-7 as

the best predictor of CU-Q2oL scores since it presents the activity of CU.[6,11] Although other studies did not show a significant prediction of CU-Q2oL scores by the presence of angioedema,[6,10,11] this item was a significant predictor of total CU-Q2oL as well as factors II, V and VI. A simple explanation for this outcome is that factor V and VI are directly associated with swelling of lips and eyes. Factor II includes items regarding the sleep problems as well as problem in eating and the feeling of embarrassment by signs. It is likely for CU patients to feel embarrassed because of angioedema in addition to suffering from sleep difficulties. Although Młynek et al. reported sex as a predictor of CU-Q2oL scores,[6] the analysis of the current studies as well as another study by Polish authors[11] showed that neither sex, nor age, and duration of disease were significant predictors of total CU-Q2oL scores or any of its 6 factors.

There are still many undiscovered areas in the pathogenesis as well as the treatment of CU. Treatment of CU is not effective in many cases and such patients suffer from psychological turbulences and experience a low QoL.[13,15,16] Assessment of QoL in CU patients using a disease-specific tool such as CU-Q2oL is essential for the better management of disease and provides standard measurement for clinical researches on the therapeutic approaches.[10]

The Persian version of CU-Q2oL is a valid and reliable tool to be used in the future clinical studies. Moreover, it can be used to compare the QoL in Persian speaking population with other patients around the world with available validated CU-Q2oL in their maternal language. Cultural considerations should be kept in mind in the process of validating this questionnaire into other languages especially regarding the determination of scales and patients' view on their symptoms. Evaluation of minimum important difference of the Persian version of CU-Q2oL will be the subject of further studies.

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