Acta Derm Venereol 2012; 419–425

CLINICAL REPORT

Turkish Version of the Chronic Urticaria Quality of Life Questionnaire: Cultural Adaptation, Assessment of Reliability and Validity

Emek KOCATÜRK[1]*, Karsten WELLER[2]*, Peter MARTUS[3], Selin AKTAŞ[1], Mukaddes KAVALA[1], Şükran SARIGUL[4], Ilaria BAIARDINI[5], Giorgio W. CANONICA[5], Zenon BRZOZA[6], Dimitrios KALOGEROMITROS[2,7]† and Marcus MAURER[2]

[1]Department of Dermatology, Göztepe Training and Research Hospital, Istanbul, Turkey, [2]Department of Dermatology and Allergy, Allergie-Centrum-Charité, [3]Institute for Biostatistics and Clinical Epidemiology, Charité-Universitätsmedizin Berlin, Berlin, Germany, [4]Department of Dermatology, Fatih Sultan Mehmet Training and Research Hospital, Istanbul, Turkey, [5]Allergy and Respiratory Diseases, Department of Internal Medicine, University of Genoa, Genoa, Italy, [6]Chair and Clinical Department of Internal Diseases, Allergology and Clinical Immunology, Medical University of Silesia, Katowice, Poland, and [7]Allergy Unit, University General Hospital "ATTIKON", National University of Athens, Greece

**Both authors contributed equally and should be considered as first authors.*

Chronic spontaneous urticaria has a substantial impact on patients' quality of life. The first disease-specific tool to assess quality of life impairment in this condition, the Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL), was developed recently. The aim of this study was to adapt the original Italian version to the Turkish language and to evaluate its reliability, validity, and sensitivity to change. The Turkish version was developed by performing forward- and back-translation. It was then applied to 140 consecutive patients with chronic spontaneous urticaria, along with the Dermatology Life Quality Index and the Skindex-29. Disease activity was assessed using the Urticaria Activity Score. Sensitivity to change was measured in 101 patients, who completed the instruments twice at intervals of 4 weeks. Confirmatory factor analysis demonstrated that the six-scale structure of the original Italian version ("pruritus", "swelling", "impact on life activities", "sleep problems", "limits", "looks") can be retained in the Turkish instrument. Analysis regarding convergent validity showed good correlations of the Turkish CU-Q_2oL with the other instruments. In addition, it was found to discriminate well between patients with different levels of urticaria activity, and to be sensitive to change. In conclusion, the Turkish version of CU-Q_2oL is a reliable, valid, and sensitive instrument, which will help to characterize better the clinical impact of chronic spontaneous urticaria and treatment outcomes in Turkish patients. Its identical scale structure to that of other CU-Q_2oL instruments makes it ideal for cross-cultural comparisons and for its application in future national and multinational studies. ***Key words: chronic spontaneous urticaria; quality of life; questionnaire; Turkish; validation.***

(Accepted May 16, 2011.)

Acta Derm Venereol 2012; 92: 419–425.

Emek Kocatürk, Fahrettin Kerim Gökay Cad. 165/7 Göztepe, TR-34730, İstanbul, Turkey. E-mail: dremekozgur@gmail.com

Chronic spontaneous urticaria, formerly known as chronic urticaria, is a common skin disorder characterized by the rapid and spontaneous appearance of wheals and/or angioedema (1). Most healthcare providers recognize that urticaria is frequently difficult to treat. However, many do not realize the impact that chronic spontaneous urticaria has on the patients' quality of life (QoL) (2). The disease may dramatically affect patients' QoL; patients with chronic spontaneous urticaria have been reported to experience loss of energy, sleep disturbance and emotional upset, as well as restrictions in mobility, home and work management (3). Researchers define health-related QoL (HRQoL) as the patients' assessment of their current level of functioning and/or satisfaction with their condition, as well as what they perceive as ideal (4). Several studies are available to define QoL in patients with dermatological and other chronic conditions (2). Disease-specific instruments are usually more responsive to changes in QoL than are generic QoL instruments (5). Although there are many generic and dermatological questionnaires available, there were, until recently, no questionnaires specifically designed for chronic spontaneous urticaria. The need for a specific questionnaire to capture physical, psychosocial and practical aspects of HRQoL impairment in patients with chronic spontaneous urticaria prompted Baiardini et al. (6) to develop the first disease-specific tool; the Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL).

HRQoL and other patient-reported outcome instruments should be available in the local language. Cross-cultural adaptations of HRQoL questionnaires provide the opportunity to compare data from studies originating from different countries. Until now, CU-Q_2oL has been validated for use only in Germany (7), Spain (8) and Poland (9). The aim of this study was to adapt the CU-Q_2oL to the Turkish language and to evaluate its reliability, validity and sensitivity to change.

 doi: 10.2340/00015555-1199
 ISSN 0001-5555

MATERIALS AND METHODS

CU-Q_2oL Questionnaire

The CU-Q_2oL Questionnaire is a 23-item HRQoL questionnaire, which was originally developed in Italy (6). It measures six dimensions (scales) of HRQoL using a five-point Likert-type scale: "pruritus" (2 items), "swelling" (2 items), "impact on life activities" (6 items), "sleep problems" (5 items), "limits" (3 items) and "looks" (5 items). The scores of the scales are calculated by using linear transformations of raw scores; the minimum possible score is 0 and the maximum possible score is 100 for each scale.

Translation of the questionnaire

To generate the Turkish version of CU-Q_2oL, the standard procedure for translation and cultural adaption was used (10). The original Italian version of CU-Q_2oL was translated into Turkish by two native Turkish speakers with expert knowledge in Italian. A consensus version of both translations was translated back to Italian by an Italian fluent in Turkish. The back-translated version was reviewed by the Italian and Turkish authors (Baiardini and Kocatürk) and the final consensus version (Table SI; available from: http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1199) was approved by both.

Patients and data acquisition

The study included 140 consecutive chronic spontaneous urticaria patients over 18 years of age, who were seen in our specialized urticaria outpatient clinic. The questionnaires used in this study were given to the patients to be completed at home and patients were scheduled for a second visit 4 weeks later, when they were asked to complete and return the same questionnaires a second time. The data acquisition phase started in February 2009 and ended in February 2010. All patients received symptomatic treatment according to the current EAACI/GA2LEN/WAO/EDF guideline recommendations (11) and all patients gave informed consent. This study was approved by the local ethics committee.

Measurements of quality of life impairment and disease activity

Quality of life was assessed with the Turkish version of CU-Q_2oL, the Dermatology Life Quality Index (DLQI) and the Skindex-29. The DLQI (12, 13) and Skindex-29 (14, 15) are HRQoL instruments for any kind of skin disease. Both have been validated for the use in Turkey (13, 15). Disease activity was measured with the Urticaria Activity Score (UAS7), a validated scoring system combining the intensity of itch and the number of wheals every day for one week that leads to a score between 0 and 42 (16).

Patients documented their symptoms for calculation of the urticaria activity score (UAS7) twice; i.e. during the week before the QoL questionnaires were completed for the first time and during the week before the QoL questionnaires were completed the second time.

In addition, an autologous serum skin test (ASST) (17) was performed in all patients. Furthermore, data sheets recorded gender, age, duration of the disease, presence of angioedema and type of treatment.

Determination of CU-Q_2oL scales

The factor structure in our analysis was compared with the results of Baiardini et al. (6) using confirmatory factor analysis (CFA). The model of Baiardini et al. was constructed using varimax factor rotation leading to orthogonal factors. In exploratory factor analysis this is the standard approach. However, in CFA correlated factors are assumed to obtain a satisfactorily fit. Furthermore, the unstandardized regression coefficients of items 1 and 2 and of items 3 and 4 are set as identical to make the model identified. In Model 1 orthogonal factors were assumed, in Model 2 correlated factors. The correlation of factors was modelled by including one additional second-level factor, which might be interpreted as "burden of disease". Furthermore, additional correlations between error terms of selected pairs of items using the criterion $r \geq 0.35$ were included. The factor loadings (standardized path coefficients), the χ^2 discrepancy measure and the comparative fit index (CFI) are reported. This index, introduced by Bentler (18), compares the model under investigation with the model assuming independent items. It ranges between zero and one, and values > 0.90 or 0.95 indicate a satisfactory fit. A further detailed justification of this index has been given by Byrne (19).

Internal consistency

Cronbach's α coefficient was used to test the internal consistency of the Turkish CU-Q_2oL scales. We used the suggested guidelines for interpretation of Cronbach's α coefficient: < 0.60 unacceptable, 0.60–0.65 undesirable, 0.65–0.70 minimally acceptable, 0.70–0.80 respectable, 0.80–0.90 excellent and > 0.90 excessive consistency (20).

Convergent validity

The convergent validity of the scales was determined by calculating the correlation of the Turkish CU-Q_2oL scales to scales or items of the DLQI and Skindex-29 questionnaire (Pearson's correlation). Even though single items are not validated as a criterion for validity, we used this criterion as an "alternative criterion".

Known-group validity

Known-group validity was tested by determining whether the CU-Q_2oL was able to discriminate between patients with different urticaria activity as measured by the UAS7 score. UAS7 scores were categorized by quartiles and the differences between group comparisons were performed using analysis of variance (ANOVA).

Sensitivity to change

A total of 101 out of 140 patients returned for a second visit. The changes in the CU-Q_2oL total scores and UAS7 scores between the two visits were calculated and the correlation between the changes in the two variables was analysed (computing of rank correlation coefficient Spearman's rho).

Multiple linear regression

Multiple linear regression analysis (stepwise) was used to assess significant predictors of the different CU-Q_2oL scores. Gender, age, disease activity, disease duration, presence of angioedema and ASST results were used as independent variables, the CU-Q_2oL total score and CU-Q_2oL scale scores were used as dependent variables.

Statistical analyses

Statistical analyses (including multiple linear regression) were performed, and graphics generated, using SPSS (SPSS; Chicago, IL, USA). $p < 0.05$ was considered as statistically significant.

Table I. *Characteristics of the study sample (*n = *140)*

Characteristics	
Gender, *n* (%)	
Female	98 (70.0)
Male	42 (30.0)
Age, years, mean (SD)	38.7 (12.6)
Duration of disease, months, mean (SD)	45.5 (88.2)
Angioedema, *n* (%)	83 (59.3)
Autologous serum skin test, *n* (%)	
Positive	102 (72.9)
Negative	38 (27.1)
Treatment, *n* (%)	
None	37 (26.4)
Antihistamines	93 (66.4)
Autochemotherapy	7 (5.0)
Systemic corticosteroids	1 (0.7)
Occupation, *n* (%)	
Housewife	75 (53.5)
Employee	24 (17)
Retiree	12 (8.5)
Student	11 (8)
Workman	5 (3.5)
Other	18 (12.9)

SD: standard deviation.

RESULTS

Characteristics of the study sample

A total of 140 patients (70% female; age range 18–68 years; mean age ± standard deviation (SD): 38.7 ± 12.6 years) participated in this study. The mean duration of disease was 45.5 ± 88.1 months (median: 12.0, range: 2–480 months). Eighty-three patients (59%) had additional angioedema and 102 (73%) showed a positive ASST. The distribution of patients regarding occupation was as follows: housewives 75 (53.5%), employees 24 (17%), retirees 12 (8.5%), students 11 (8%), workmen 5 (3.5%), small retailers 4 (3%), managers 4 (3%), teachers 1 (1%), nurses 1 (1%), policemen 1 (1%), and unemployed 2 (1%). The characteristics of the participants are shown in Table I.

The mean UAS7 at visit 1 was 19.3 ± 10.5 (range 0–42). The mean DLQI and Skindex-29 scores of the study sample were 8.6 ± 6.9 (range 0–30) and 40.6 ± 19.4 (range 5.2–88.8).

Factor analysis and internal consistency

The results of the confirmatory factor analysis are shown in Table II. For each scale Cronbach's α and for each item the factor loadings for uncorrelated (Mo-

Table II. *Results of confirmatory factor analysis (CFA). A satisfactory internal consistency of the Turkish version of the Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL) was found. The comparative fit index (CFI) is explained in the methods section. A satisfactorily model has a CFI > 0.9. Although this criterion is not met, the discrepancy between the Turkish version of CU-Q_2oL and the original Italian instrument (6) is not high. Model 1 ignores correlations among the six factors, whereas Model 2 takes these correlations into account*

Overall measures of fit			Model 1	Model 2
χ^2			737	401
Degrees of freedom			232	221
CFI			0.605	0.884
			Factor loadings	
Scale	Cronbach's α	Item explanation (short formulation)	Model 1	Model 2
Pruritus	0.727	Itching	0.761	0.738
		Wheals	0.750	0.780
Swelling	0.880	Swelling of the eyes	0.879	0.885
		Swelling of the lips	0.894	0.888
Impact on life activities	0.835	Work	0.738	0.733
		Physical activities	0.729	0.724
		Sleep	0.611	0.656
		Free time	0.755	0.754
		Social relationships	0.794	0.799
		Eating	0.454	0.434
Sleep problems	0.865	Difficulty falling asleep	0.758	0.652
		Wake up at night	0.837	0.710
		Tired during the day	0.792	0.751
		Difficulty concentrating	0.751	0.795
		Feel nervous	0.618	0.625
Limits	0.504	Feel blue	0.651	0.655
		Limits in choosing food	0.572	0.452
		Limits in sport activities	0.304	0.412
Looks	0.677	Bothered by the symptoms	0.761	0.741
		Embarrassed in public	0.739	0.741
		Limits in using cosmetics	0.299	0.241
		Limits in choosing clothes	0.461	0.451
		Medication side-effects	0.338	0.385

del 1) and correlated factors (Model 2) are reported. Cronbach's α ranged between 0.68 and 0.88 (between minimally acceptable and excellent) except for the scales "limits" with Cronbach's alpha equal to 0.50. The CFI was considerably higher in Model 2. Both Models 1 and 2 showed high factor loadings for all items related to the scales "pruritus", "swelling", "impact on life activities" and "sleep problems". Moreover, factor loadings did not depend on whether correlated or uncorrelated factors were assumed. In contrast, for the scales "limits" and "looks" smaller factor loadings were observed.

According to the criterion "CFI > 0.9" none of the models gave a highly satisfactory fit. However, it is obvious that Model 2 with CFI = 0.884 at least gives a moderately satisfying fit and that the discrepancy between the analysis of Baiardini et al. (6) and our analysis was not high. Including 5 more correlations or paths into Model 2 would improve the model to obtain a CFI of 0.906, but these are difficult to interpret and might be spurious (results not given).

Five additional item correlations in Model 2, not explained by the factor structure, were found between "eating behaviour" and "limits in choosing food" ($r = 0.458$), "sleep" and "difficulties falling asleep" ($r = 0.388$), "sleep" and "wake up at night" ($r = 0.548$), "feel nervous" and "feel blue" ($r = 0.483$) as well as between "limits in using cosmetics" and "limits in choosing food" ($r = 0.416$).

Convergent validity

The CU-Q_2oL scale I (pruritus) was found to correlate with Skindex-29 item 10 (pruritus) ($r = 0.55$, $p < 0.001$) and DLQI item 1 (itching/soreness/pain/burning) ($r = 0.64$, $p < 0.001$). The CU-Q_2oL scale II (swelling) has no analogous item in the Skindex 29 or DLQI questionnaire. since it is a specific symptom of urticaria. Therefore no correlation was computed for this scale. The CU-Q_2oL scale III (impact on life activities) was found to correlate with the Skindex-29 functioning scale ($r = 0.74$, $p < 0.001$) and with DLQI items 3 (shopping, home, garden), 5 (social leisure), 6 (sports), 7 (work, studying) and 8 (problems with partner/friends/relatives) ($r = 0.72$, $p < 0.001$). The CU-Q_2oL scale IV (sleep problems) was found to correlate with Skindex-29 items 2 (sleep) and 30 (fatigue) ($r = 0.59$, $p < 0.001$). Because the DLQI has no analogous item relating to sleep, concentration or nervousness, no correlations with this instrument were analysed. The CU-Q_2oL scale V (limits) was found to correlate with Skindex-29 items 6 (depression), 23 (frustration) and 26 (humiliation) ($r = 0.49$, $p < 0.001$) as well as with DLQI item 6 (sports) ($r = 0.41$, $p < 0.001$). The CU-Q_2oL scale VI (looks) was found to correlate with Skindex-29 items 8 (problems with partner/friends/relatives), 12 (shame), 14 (doing things alone), 21 (embarrassment), 28 (bothered by skin symptoms) ($r = 0.62$, $p < 0.001$) and DLQI items 2 (embarrassment) and 4 (chose of clothing) ($r = 0.59$, $p < 0.001$).

In addition to the scale scores, the correlation between the total scores of CU-Q_2oL and DLQI as well as between total scores of CU-Q_2oL and Skindex-29 was found to be statistically highly significant ($r = 0.77$, $p < 0.001$ and $r = 0.74$, $p < 0.001$).

Known-group validity

Using ANOVA, statistically significant differences between CU-Q_2oL scores were observed between the different categories of urticaria activity in the UAS7 score quartile groups (Table III). There was a significant difference in CU-Q_2oL scores between the 1st and 2nd, the 1st and 3rd, the 1st and 4th as well as 2nd and 4th UAS7 quartile ($p < 0.05$, $p < 0.001$, $p < 0.001$ and $p < 0.001$); but differences between the 2nd and 3rd as well as between the 3rd and 4th quartile were not found to be significant ($p = 0.09$, $p = 0.19$). The CU-Q_2oL total score rose with increasing UAS7 scores.

The correlation between UAS7 scores and CU-Q_2oL total scores at baseline ($r = 0.48$, $p < 0.001$, $n = 140$) as well as between UAS7 scores and CU-Q_2oL total scores at the second visit ($r = 0.58$, $p < 0.001$, $n = 101$) were found to be statistically significant.

Table III. *Known group validity. The Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL) total scores with respect to different categories of urticaria activity (UAS7 quartile groups) are shown. The CU-Q_2oL total score was found to be able to discriminate between patients with different disease activity. The CU-Q_2oL total scores raises with increasing urticaria activity,* $p < 0.001$ *(analysis of variance (ANOVA), test for linear trend). Post-hoc comparisons: pairwise comparisons, hierarchically ordered. First step: 1st vs. 4th* ($p < 0.001$), *second step (Bonferroni correction factor 2): 1st vs. 3rd ($p < 0.001$), 2nd vs. 4th ($p < 0.001$), third step (Bonferroni correction factor 3): 1st vs. 2nd ($p = 0.015$), 2nd vs. 3rd ($p = 0.093$), 3rd vs. 4th quartile ($p = 0.19$)*

	Total CU-Q_2oL Score						
UAS7 score	*n*	Mean	SD	Minimum	Maximum	First quartile	Last quartile
1st quartile (0–10)	34	20.8	11.5	2.2	41.3	11.2	30.3
2nd quartile (11–18)	40	29.5	13.9	5.4	66.3	20.8	35.1
3rd quartile (19–28)	33	37.7	17.6	2.2	78.4	24.5	51.1
4th quartile (29–42)	33	46.8	21.3	14.1	94.6	29.3	58.9
Total	140	33.4	18.7	2.2	94.6	19.6	44.3

SD: standard deviation.

Sensitivity to change

Of 101 patients, the UAS7, as well as the CU-Q_2oL, were collected twice at intervals of 4 weeks. The UAS7 was 18.5 ± 10.7 at baseline and 13.0 ± 9.7 at the second visit, while the CU-Q_2oL total score was 33.9 ± 19.6 and 22.6 ± 16.2. Fig. 1 shows the correlation between UAS7 changes and CU-Q_2oL total score changes between the two visits, which was found to be statistically significant ($r = 0.44$, $p < 0.001$).

Quality of life scores

The CU-Q_2oL scores of the observed patient population are shown in Fig. 2. The most affected scales were "pruritus" and "sleep problems", while "swelling" was the least affected. The median and mean scores, respectively, of the scales were as follows: "pruritus" 50.0 and 57.3, "swelling" 12.5 and 21.6, "impact on life activities" 25.0 and 28.5, "sleep problems" 45.0 and 44.1, "limits" 33.3 and 32.1, "looks" 20.0 and 24.3.

Multiple linear regression analyses

Multiple linear regression analyses revealed that the only predictor of the CU-Q_2oL total score was disease activity ($p < 0.001$) as measured by UAS7. The presence of angioedema only slightly missed the significance level ($p = 0.07$).

The results of multiple linear regression analysis to determine the factors influencing CU-Q_2oL scale scores were as follows. Disease activity affected all CU-Q_2oL scales ("pruritus" $p < 0.001$, "swelling" $p < 0.001$, "impact on life activities" $p < 0.001$, "sleep problems" $p < 0.001$, "limits" $p < 0.05$, "looks" $p < 0.01$). Gender significantly affected "sleep problems" ($p < 0.05$); women were more affected than men. Age significantly predicted "pruritus" ($p < 0.05$), and presence of angioedema predicted the results of the "swelling" scale $p < 0.001$) and of the "limits" scale ($p < 0.05$). Duration of disease and ASST results did not affect any of the CU-Q_2oL scales.

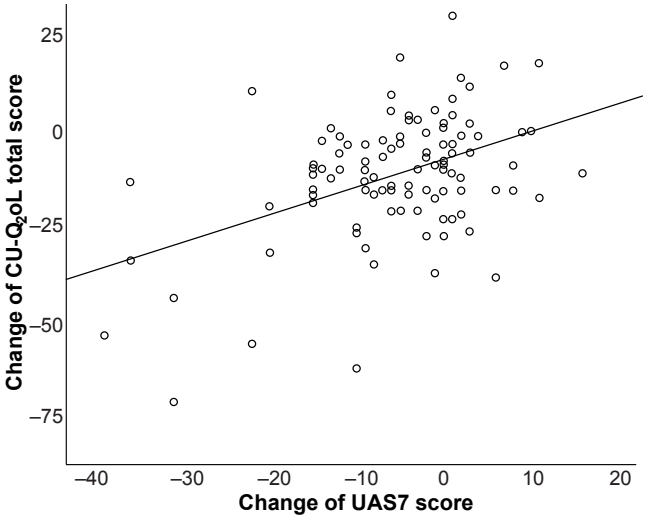

Fig. 1. Sensitivity to change of the Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL). The correlation between Urticaria Activity Score (UAS7) score changes and CU-Q_2oL total score changes between the first and second visit are shown. Each dot represents one patient. The correlation between the UAS7 changes and CU-Q_2oL total score changes were statistically significant ($p < 0.01$, r (Spearman's rho) = 0.29).

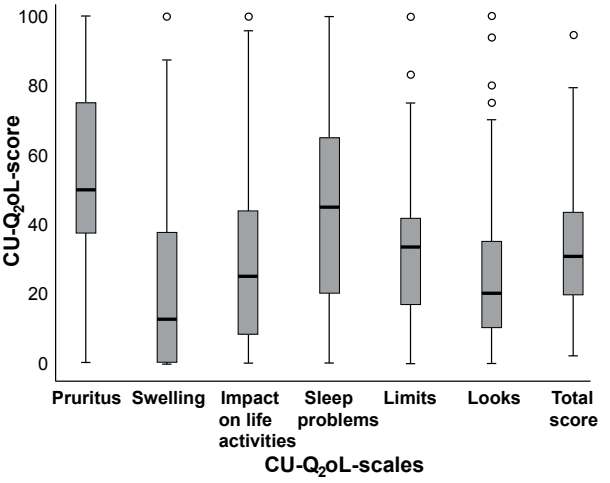

Fig. 2. Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL) scale scores and CU-Q_2oL total score in the examined population. The box-and-whisker plots represent the distribution of the CU-Q_2oL scale scores and of the CU-Q_2oL total score in the examined patient population. The middle lines of each box represent the median score of that scale, the lower and upper end of the boxes represent the 25th percentile and the 75th percentile, the whiskers represent the inner fences. The whiskers extend to 1.5 times the height of the box or, if all values are in that range, to the minimum or maximum values. Circles within the figures represent outliers.

DISCUSSION

The detection of HRQoL impairment has become increasingly important during recent years and is also strongly recommended by leading health authorities (21). The major reason to apply the concept of QoL in urticaria is that solely counting the hives and rating of pruritus is not suitable for gaining full comprehension of the full impact of chronic spontaneous urticaria on the patients (22). Although there are many generic and dermatology-specific QoL questionnaires available, there were, until recently, no instruments specifically designed for patients with urticaria. Therefore, in 2005, Baiardini et al. (6) presented the first and, as of yet, only, disease-specific tool for chronic spontaneous urticaria, i.e. the CU-Q_2oL. Disease-specific instruments have the advantage that they are usually more sensitive as well as more responsive to QoL changes than generic instruments. The objective of this study was to adapt the original Italian version of CU-Q_2oL to the Turkish language and to evaluate its reliability, validity, and sensitivity to change. During this process, we regarded it as most desirable to retain the scale structure of

the original Italian instrument, to generate a tool that not only allows a better characterization of the degree and pattern of QoL impairment in the Turkish patient population, but that also allows a comparison of its results with those obtained by CU-Q_2oL questionnaires in other languages.

The results of this study show that the Turkish version of the CU-Q_2oL is characterized by a satisfactory internal consistency when the original Italian six-scale structure is retained. This means that the questions of the Turkish CU-Q_2oL can be grouped together to the same scales as in the original Italian version. In particular, CFA revealed satisfactory results for the scales "pruritus", "swelling", "impact on life activities" and "sleep problems", but to a lesser degree for the scales "limits" and "looks". The fact that the fit was bad for a model assuming uncorrelated factors must be expected from the different approaches in exploratory vs. CFA. After adjustment for these correlations the fit was 0.884, which though not extremely good is acceptable. This means that the discrepancy between the analysis of Baiardini et al. (6) and our analysis was not high. Omission of the scales "limits" and "looks" revealed an excellent CFI of 0.938 (results not given in detail). Interestingly the 2nd-level factor structure with one factor provided a satisfactory fit for the correlations between the factors, which indicates that the CU-Q_2oL total score might be a valid and useful index for the overall disease burden in chronic spontaneous urticaria. This is particularly interesting, because, as of yet, the CU-Q_2oL has been primarily regarded as a profile rather than an index instrument.

Five additional item correlations, not explained by the scale structure, were found. It is obvious that the additional correlations between the items "eating behaviour" and "limits in choosing food" and between the items "sleep" and "falling asleep", and "wake up at night" are due to the fact that they cover identical topics, although they have been related to different scales by Baiardiani et al. (6). This might be considered as a weakness of the original Italian version. The same probably holds for the items "feel nervous" and "feel blue". The additional correlation between items "limits in using cosmetics" and "limits in choosing clothes" is less problematic as both items are related to the same scale.

One limitation of the CU-Q_2oL instrument is its lack of questions regarding sexual activity. In our study we saw that nearly 40% of patients indicated impairment in their sexual life due to their urticaria in the Skindex-29 and DLQI questionnaires. In line with these results, O'Donnell et al. (3) also found that 47% of patients experience problems in their sexual life due to chronic urticaria. Therefore, it might be useful to add a question on limitations in sexual life to the CU-Q_2oL instrument.

The scales with the highest mean CU-Q_2oL scores were "pruritus" and "sleep problems". This is consistent with the results found in the Spanish (8) and German (7) population, and underlines the major impact of pruritus on QoL in patients with chronic spontaneous urticaria. One limitation of our study is that the results were obtained from a selected patient population presenting in a specialized urticaria outpatient clinic. Therefore, a selection effect cannot be excluded. However, the fact that the extent, as well the pattern, of QoL impairment measured by CU-Q_2oL in our study was comparable to the results obtained by other authors (7, 8) suggests that a possible selection bias is rather small.

Correlations between the Turkish CU-Q_2oL scales and Skindex-29, as well as DLQI items and dimensions, were generally moderate to high. In addition, the overall correlations (correlation of the total scores) were high between the three instruments. This suggests that the Turkish CU-Q_2oL is a valid tool for the detection of QoL impairment and that there may be some redundancy with the Skindex-29 and the DLQI. This largely confirms the results found by Valero et al. (8) during their validation of the Spanish version of CU-Q_2oL.

Chronic spontaneous urticaria is a fluctuating disease. Disease activity can change dramatically over time without any intervention. On the other hand, symptomatic treatment can also modify disease activity and severity. For this reason, it is important to have patient-reported outcomes available that are able to mirror these changes in clinical studies but also in routine care. Notably, the CU-Q_2oL was able to distinguish patient groups with different degrees of urticaria activity. The higher the disease activity (UAS7 score), the higher the QoL impairment as detected by the CU-Q_2oL total score. In addition, the CU-Q_2oL was found to be sensitive in detecting changes in disease activity. Between the first and the second visit, the mean UAS7 score dropped by one-third, accompanied by a comparable decline in the mean CU-Q_2oL total score. The most likely explanation for the reduction in disease activity is a successful treatment adjustment after the first visit. This demonstrates that the Turkish CU-Q_2oL questionnaire is a suitable tool to detect QoL changes following changes in disease activity.

The CU-Q_2oL detects many different aspects and consequences of chronic spontaneous urticaria. It is important to consider which factors are important drivers of the CU-Q_2oL scores as well as of QoL impairment in general. We found that the only predictor of the CU-Q_2oL total score was disease activity. Since presence of angioedema only slightly missed the significance level, it should also be considered as a possible and relevant driver of QoL impairment in those patients where it occurs. Regarding the Turkish CU-Q_2oL scales, disease activity was again a major driver of all scale scores. Interestingly, gender significantly affected "sleep problems" with women being more affected than men, and age significantly predicted the values of the "pruritus" scale.

Less surprisingly, the presence of angioedema predicted the results of the "swelling" scale and of the "limits" scale. The duration of the disease, as well as the ASST status, did not affect any of the CU-Q_2oL scales.

In conclusion, this study demonstrates that the Turkish version of CU-Q_2oL is a reliable, valid and sensitive tool, which will help to characterize better the impact of chronic spontaneous urticaria on the patients' lives. Its ability to detect changes in QoL impairment over time makes it additionally and particularly useful for the evaluation of the disease course and treatment outcomes. Its identical scale structure, as compared to CU-Q_2oL instruments in other languages, enables its use in cross-cultural comparisons and makes it a valuable tool for future national or multinational studies.

ACKNOWLEDGEMENTS

The authors thank Elizabeth Ann Doyle for proofreading the manuscript and to Şule Sağlam and Alus Baykan for their help in the translation process.

REFERENCES

1. Maurer M. Chronic urticaria. In: Zuberbier T, Grattan C, Maurer M, editors. Urticaria and angioedema. Berlin: Springer-Verlag, 2010: p. 44–55.
2. Weldon DR. Quality of life in patients with urticaria. Allergy Asthma Proc 2006; 27: 96–99.
3. O'Donnell BF, Lawlor F, Simpson J, Morgan M, Greaves MW. The impact of chronic urticaria on the quality of life. Br J Dermatol 1997; 136: 197–201.
4. Hyland ME. A brief guide to the selection of quality of life instrument. Health Qual Life Outcomes 2003; 1: 24.
5. Guyatt GH, Jaeschke R, Feeny DH, Patrick DL. Measurement in clinical trials: choosing the right approach. In: Spilker B, editor. Quality of life and pharmacoeconomics in clinical trials, 2nd edition. Philadelphia: Lippincott-Raven Publishers, 1996: p. 41–48.
6. Baiardini I, Pasquali M, Braido F, Fumagalli F, Guerra L, Compalati E, et al. A new tool to evaluate the impact of chronic urticaria on quality of life: chronic urticaria quality of life questionnaire (CU-QoL). Allergy 2005; 60: 1073–1078.
7. Młynek A, Magerl M, Hanna M, Lhachimi S, Baiardini I, Canonica GW, et al. The German version of the Chronic Urticaria Quality-of-Life Questionnaire: factor analysis, validation, and initial clinical findings. Allergy 2009; 64: 927–936.
8. Valero A, Herdman M, Bartra J, Ferrer M, Jáuregui I, Dávila I, et al. Adaptation and validation of the Spanish version of the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL). J Investig Allergol Clin Immunol 2008; 18: 426–432.
9. Brzoza Z, Badura-Brzoza K, Mlynek A, Magerl M, Baiardini I, Canonica GW, et al. Adaptation and initial results of the Polish version of the GA(2)LEN Chronic Urticaria Quality Of Life Questionnaire (CU-Q(2)oL). J Dermatol Sci 2011; 62: 36–41.
10. Baiardini I, Bousquet PJ, Brzoza Z, Canonica GW, Compalati E, Fiocchi A, et al. Recommendations for assessing patient-reported outcomes and health-related quality of life in clinical trials on allergy: a GA(2)LEN taskforce position paper. Allergy 2010; 65: 290–295.
11. Zuberbier T, Asero R, Bindslev-Jensen C, Canonica GW, Church MK, Giménez-Arnau AM, et al. EAACI/GA2LEN/EDF/WAO Guideline: Management of urticaria. Allergy 2009: 64; 1427–1443.
12. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI) – a simple practical measure for routine clinical use. Clin Exp Dermatol 1994; 19: 210–216.
13. Oztürkcan S, Ermertcan AT, Eser E, Sahin MT. Cross validation of the Turkish version of dermatology life quality index. Int J Dermatol 2006; 45: 1300–1307.
14. Chren MM, Lasek RJ, Quinn LM, Mostow EN, Zyzanski SJ. Skindex, a quality-of-life measure for patients with skin disease: reliability, validity, and responsiveness. J Invest Dermatol 1996; 107: 707–713.
15. Aksu AE, Urer MS, Sabuncu I, Saracoglu ZN, Chren MM. Turkish version of Skindex-29. Int J Dermatol 2007; 46: 350–355.
16. Młynek A, Zalewska-Janowska A, Martus P, Staubach P, Zuberbier T, Maurer M. How to assess disease activity in patients with chronic urticaria? Allergy 2008; 63: 777–780.
17. Konstantinou GN, Asero R, Maurer M, Sabroe RA, Schmid-Grendelmeier P, Grattan CE. EAACI/GA(2)LEN task force consensus report: the autologous serum skin test in urticaria. Allergy 2009; 64: 1256–1268.
18. Bentler PM. Comparative fit indexes in structural models. Psychol Bull 1990; 107: 238–246.
19. Byrne BM. Structural equation modeling with AMOS: basic concepts, applications and programming. Mahwah, NJ: Lawrence Erlbaum Associates, 2001.
20. Streiner D, Norman G. Health measurement scales, 2nd edition. Oxford: Oxford University Press, 1995.
21. Baiardini I, Bousquet PJ, Brzoza Z, Canonica GW, Compalati E, Fiocchi A, et al. Recommendations for assessing patient-reported outcomes and health-related quality of life in clinical trials on allergy: a GA(2)LEN taskforce position paper. Allergy 2010; 65: 290–295.
22. Maurer M, Weller K, Bindslev-Jensen C, Giménez-Arnau A, Bousquet PJ, Bousquet J, et al. Unmet clinical needs in chronic spontaneous urticaria. A GA2LEN task force report. Allergy 2011; 66: 317–330.