ORIGINAL ARTICLE

Adaptation and Validation of the Spanish Version of the Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL)

A Valero,[1] M Herdman,[2,3] J Bartra,[1] M Ferrer,[4] I Jáuregui,[5] I Dávila,[6] A del Cuvillo,[7] J Montoro,[8] J Mullol,[9] J Sastre,[10] GW Canonica,[11] I Baiardini[11]

[1] Allergy Unit, Pneumology and Respiratory Allergy, Hospital Clínic, Barcelona, Spain
[2] CIBER in Epidemiology and Public Health (CIBERESP), Spain
[3] Health Services Research Unit, IMIM-Hospital del Mar, Barcelona, Spain
[4] Allergy Department, Clínica Universitaria de Navarra, Pamplona, Spain
[5] Allergology Department, Hospital de Basurto, Bilbao, Spain
[6] Immunoallergology Service, Hospital Clínico, Salamanca, Spain
[7] Clínica Dr Lobatón, Cádiz, Spain
[8] Allergy Unit, Hospital La Plana, Villarreal, Spain
[9] Rhinology Unit, Ear, Nose and Throat Department (ICEMEQ), Hospital Clínic, Barcelona, Spain
[10] Allergy Department, Fundación Jiménez Díaz, Madrid, Spain
[11] Allergy and Respiratory Diseases, Department of Internal Medicine, University of Genoa, Genoa, Italy

Abstract

Objectives: The aim of this study was to develop a Spanish version of the Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL) and to test its acceptability, reliability, validity, and sensitivity to change.
Methods: Forward and back translation by bilingual translators followed by pilot testing in patients with urticaria was used to adapt the questionnaire. The Spanish version of the CU-Q_2oL was self-administered alongside the Skindex-29 in an observational, longitudinal, multicenter study. Feasibility was assessed by analyzing missing responses and ceiling and floor effects. Reliability was tested by examining internal consistency (Cronbach α). Construct validity was analyzed by examining convergent and discriminant validity with the Skindex-29 and by evaluating the ability of the CU-Q_2oL to discriminate between patients according to a clinical classification of severity. Sensitivity to change was analyzed in a subgroup of patients who completed a second visit 4 weeks after baseline.
Results: A total of 695 patients were included in the analysis. Mean (SD) age was 42.4 (15.0) years and 62.1% of the sample was female. All of the items on the CU-Q_2oL were answered by 91.9% of the sample. Over 15% of patients scored at the floor (best possible health) on 5 of the 6 dimensions. Cronbach α coefficients were > 0.80 for all dimensions of the CU-Q_2oL, and 0.86 for the overall score. Construct validity was supported by correlations between the CU-Q_2oL and the Skindex-29, which generally fulfilled hypotheses, and by the questionnaire's ability to discriminate between groups with different severities of urticaria. The questionnaire was sensitive to change, with an effect size of 1.0 for the overall score in patients reporting an improvement on the health transition scale.
Conclusions: The Spanish version of the CU-Q_2oL has shown satisfactory reliability, validity, and sensitivity to change. It is suitable for use as an outcome measure for chronic urticaria patients in clinical and research settings.

Key words: Chronic urticaria. Quality of life. Questionnaire. Adaptation. Validation. Spanish.

Resumen

Objetivos: El propósito de este estudio fue desarrollar una versión en español del cuestionario CU-Q_2oL (cuestionario de calidad de vida en urticaria crónica) así como comprobar su aceptación, fiabilidad, validez y sensibilidad a los cambios.
Métodos: Se utilizó el método de traducción-retrotraducción con traductores bilingües y una prueba piloto en pacientes con urticaria para adaptar el cuestionario. La versión española del CU-Q_2oL se administró junto con el Skindex-29 en un estudio multicéntrico, observacional

y longitudinal. La viabilidad se evaluó mediante análisis de las respuestas ausentes y los efectos techo y suelo. La fiabilidad se evaluó mediante investigación de la consistencia interna (alfa de Cronbach). La validez de constructo se analizó mediante la evaluación de la validez convergente y divergente con el Skindex-29 y análisis de la capacidad del CU-Q_2oL para discriminar entre diferentes grupos de pacientes clasificados según la gravedad clínica. La sensibilidad a los cambios se analizó en un sub-grupo de pacientes que realizaron una segunda visita 4 semanas después de la primera.
Resultados: Se incluyó un total de 695 pacientes en el análisis. La edad media (DE) fue 42,4 (15,0) años y un 62,1% de la muestra fueron mujeres. Un 91,9% de la muestra contestó todos los ítems del CU-Q_2oL. Más que un 15% de pacientes tenía la puntuación mínima (mejor salud posible) en 5 de las 6 dimensiones. Los coeficientes del alfa de Cronbach fueron > 0,80 para todas las dimensiones del CU-Q_2oL y 0,86 para la puntuación global. La dirección y magnitud de las correlaciones entre el CU-Q_2oL y el Skindex-29 en general cumplieron con las hipótesis realizadas a priori y el instrumento fue capaz de discriminar entre grupos con diferentes niveles de gravedad clínica. El cuestionario se demostró sensible a los cambios con un tamaño del efecto de 1.0 para la puntuación global en pacientes que afirmaron haber experimentado una mejoría en la escala de cambios en el estado de salud.
Conclusiones: La versión española del CU-Q_2oL ha mostrado niveles satisfactorios de fiabilidad, validez y sensibilidad a los cambios. Los resultados indican que puede ser un instrumento apropiado para la medición de resultados en salud en la investigación y la práctica clínica.

Palabras clave: Urticaria crónica. Calidad de vida. Cuestionario. Adaptación. Validación. Español.

Introduction

Chronic urticaria can be defined as the occurrence of widespread daily or almost daily wheals that can be accompanied by angioedema and last for at least 6 weeks [1]. While the wheals are transient, the resolution of angioedema is slower than that of the wheals and could take up to 72 hours. The natural course of chronic urticaria is self-limited, with spontaneous remissions and occasional relapses [2].

A recent study on the general population of Spain estimated the prevalence of chronic urticaria to be 0.6% (95% confidence interval [CI], 0.4-0.8) [3]. This estimate closely agrees with previous results based on a retrospective review of case studies [4]. Chronic urticaria has been shown to have a substantial negative impact on patients' quality of life [5], and affects both their work and social life [6]. Other studies have shown substantial psychological morbidity in patients affected with chronic urticaria [7,8].

There have been relatively few studies on the impact of chronic urticaria on quality of life and these have generally been carried out using either generic health-related quality-of-life (HRQOL) measures, such as the Nottingham Health Profile [5] and the SF-36 [9], or dermatology-specific questionnaires, such as the Dermatology Quality of Life Index [6,10] and the Skindex [8,11]. To date, the only questionnaire specifically developed to measure HRQOL in chronic urticaria patients is the Chronic Urticaria and Quality of Life Questionnaire (CU-Q_2oL) [12]. The questionnaire was developed in Italy and based on content obtained from clinical experts and patients. The final version measures HRQOL in 6 dimensions comprising 23 items and has proven to be reliable, valid, and sensitive to change.

Cross-cultural adaptations of HRQOL questionnaires facilitate comparisons of patients in different countries and are necessary for international studies. However, appropriate procedures are required to ensure that questionnaires are adapted to local conditions and to ensure that equivalent versions are produced [13,14]. The reliability, validity, and sensitivity to change of adapted versions should also be tested, as the process of adaptation can affect the instrument's psychometric properties [15].

The objectives of the present study were to produce a version of the CU-Q_2oL that would be suitable for use in Spain and to validate the new version by testing its reliability, construct validity, and sensitivity to change.

Methods

Study Design

This study to adapt and validate the Spanish version of the CU-Q_2oL took place within the context of a larger observational, longitudinal, multicenter study (in press) to examine the management of patients with chronic urticaria in daily clinical practice. The study was performed in the dermatology or allergology departments of hospitals throughout Spain. The study was approved by the Ethics Committee of the Hospital Clínic i Provincial in Barcelona, and all patients provided written informed consent to participate. Although most of the patients who participated in the validation study were only scheduled to make 1 study visit, a subsample of patients were invited to participate in a second visit 4 weeks after the first to assess the responsiveness of the CU-Q_2oL.

Adaptation of the CU-Q_2oL Into Spanish

The CU-Q_2oL was originally developed in Italian [12]. In order to produce a Spanish version for validation, the standard procedure of forward and back translation was used [13]. This consisted of the production of independent versions of the questionnaire in Spanish by 2 professional translators whose mother tongue was Spanish but who were fluent in Italian. These 2 versions were then merged into a first consensus version at a meeting between the translators and the study team. The first consensus version in Spanish was then back-translated into Italian by a translator whose mother tongue was

Italian but who was also fluent in Spanish. The back-translation was reviewed by the study team and the back-translator and checked against the original version to ensure that semantic equivalence between the items had been achieved [14]. Where semantic equivalence had not been achieved, changes were made to the Spanish version. This led to the production of the second consensus version. The second consensus version was tested on 4 patients with urticaria. Patients were asked about their comprehension of the questionnaire, whether it was easy to complete, and whether they would change any of the wording. Further modifications were introduced based on patients' comments to produce the final Spanish version of the questionnaire for validation.

Validation Study

Study population and sample size. Patients who participated in the validation study were Spanish-speaking adults over the age of 18 with a clinical diagnosis of chronic urticaria at the time of the first study visit. A total of 1000 urticaria patients were initially scheduled to participate in the study of patient management and 200 of these were scheduled for a second study visit 4 weeks after the first. Patients received their usual treatment between visits.

Measurement of outcomes. HRQOL was measured using 2 instruments: the CU-Q_2oL and the Skindex-29. The CU-Q_2oL is a disease-specific instrument designed to measure HRQOL in patients with urticaria [12]. It was initially developed in Italy and consists of 23 items measuring 6 dimensions of HRQOL: pruritus (2 items), impact on life activities (6 items), sleep problems (5 items), limits (3 items), looks (5 items), and swelling (2 items). Items are answered on a 5-point Likert-type scale. Scores were transformed to a 0 to 100 scale, with higher scores representing worse HRQOL.

The Skindex-29 was developed to measure HRQOL across a range of dermatological conditions [11]. It consists of 29 items that measure HRQOL in 3 dimensions: emotions (10 items), functioning (12 items), and symptoms (7 items). All items are measured on a 5-point response scale from "never" to "always." For the purposes of the present study, scores were transformed to a 0-to-100 scale, where 0 represented no problems and 100 represented severe problems. The instrument has been adapted for use in Spanish and has proven to be reliable and valid [16].

Other variables. Other data collected included family history of urticaria, age at diagnosis, time with the disease, urticaria subtype and triggers, site and extension of the urticaria, symptoms, presence of angioedema, and severity of urticaria (presence and intensity of symptoms measured by the investigator on a scale of 0 to 3 for both wheals and pruritus). A health status transition item was administered at the second visit to assess changes in patients' self-perceived health and to be able to classify patients as stable, improved, or deteriorated. Patients answered on a Likert-type ordinal scale with 13 response options (greatly improved = +6, no change = 0, and greatly worsened = -6).

Statistical Analysis

Missing responses, floor and ceiling effects, reliability. Missing responses were assessed according to the percentage of patients who had complete responses for all items of the CU-Q_2oL. Ceiling and floor effects (the proportion of patients with the worst and best possible scores, respectively) were calculated for the overall score and by dimension. Questionnaire reliability was studied by determining internal consistency (Cronbach α) for the overall score and by dimension. Cronbach α values of 0.70 or over were defined as satisfactory [17].

Validity. Validity was tested in 2 ways. Convergent validity was tested by estimating the Spearman rank correlation between individual dimension scores and global scores on the CU-Q_2oL and the Skindex-29. Correlations of < 0.40, 0.40-0.60, and > 0.60 were defined as weak, moderate, and strong, respectively [18]. The pattern of correlations between the CU-Q_2oL and the Skindex-29 were expected to reflect the similarities and differences in content between the different measures; in other words, we expected the pruritus and swelling dimensions of the CU-Q_2oL to correlate most strongly with the symptoms dimension on the Skindex-29, we expected the impact on daily activities and limits dimensions to correlate most strongly with the Skindex functioning dimension, and we expected the CU-Q_2oL sleep problems and looks dimension to show a less clear pattern of correlations, as there are no similar dimensions on the Skindex.

Known-group validity was tested by determining whether the CU-Q_2oL was able to discriminate between patients with different degrees of severity of urticaria as measured by the investigator's assessment of the severity of wheals and pruritus. Between-group comparisons were performed using an analysis of variance (ANOVA) and between-group effect sizes for the overall score on both indices were calculated as the difference between group means divided by the pooled standard deviation.

Sensitivity to change. Sensitivity to change was assessed by using a paired *t* test to determine whether the instrument could detect a difference between mean scores at the 2 visits in patients reporting at least a minor improvement (ie, patients scoring +2 or -2 or greater) on the health status transition item at the second visit. Effect sizes were also calculated for the overall score and dimension scores of both instruments. Effect sizes were calculated as the difference between group means at the 2 visits divided by the pooled standard deviation and could range from 0 to positive infinity. Values of approximately 0.2 are considered to represent a small change, approximately 0.5 a moderate change, and approximately 0.8 or higher a large change in the attribute of interest [19].

Results

Sample Characteristics

A total of 695 patients included at baseline provided sufficient data for analysis. Mean (SD) age was 42 (15) years, and 62.1% were women. The main diagnosis was spontaneous urticaria in 68% of the sample (Table 1). The most frequent comorbid condition was allergic rhinitis, which was present in 27% of patients. A total of 95.7% of patients were receiving treatment for chronic urticaria, and most (93.4%) were receiving H_1 antihistamines.

Table 1. Sample Demographic and Clinical Characteristics (N = 695)

Sex, N (%)	
Male	429 (62.%)
Age, y, mean (SD)	42.4 (15.0)
Body mass index, kg/m^2, mean (SD)	24.9 (3.8)
Type of residence, n (%)	
Rural	77 (11%)
Suburban	125 (18%)
Urban	490 (71%)
Type of urticaria, n (%)[a]	
Spontaneous urticaria	475 (68%)
Physical urticaria	423 (60%)
Cold contact	24 (3%)
Pressure	154 (22%)
Heat contact	38 (6%)
Solar	58 (8%)
Dermographic	143 (21%)
Vibratory	5 (1%)
Other types of urticaria	235 (34%)
Cholinergic	114 (16%)
Exercise-induced	46 (7%)
Aquagenic	40 (6%)
Contact	35 (5%)
Comorbidity, n (%)	
Allergic rhinitis	190 (27%)
Atopic dermatitis	93 (13%)
Drug allergies	90 (13%)
Asthma	81 (12%)
Contact dermatitis	58 (8%)
Food allergies	52 (8%)
Others	58 (8%)

Scoring Distributions and Reliability

Of the 695 patients included at the baseline visit, 56 (8.1%) had at least 1 missing response on the CU-Q_2oL. The item with the highest proportion of missing responses (3.9%) was item 4 (lip swelling). As shown in Table 2, pruritus had the highest score of the CU-Q_2oL dimensions. Neither the overall score nor any of the dimensions showed any relevant ceiling effects, although a number of the dimensions showed relevant floor effects (ie, with no reported problems in that dimension), particularly the swelling dimension (64.2% scoring at the floor). The dimensions of limits and looks also had notable floor effects (21.1% and 20.2%, respectively). Internal consistency evaluated using the Cronbach α was above 0.80 in all dimensions and for the overall score.

Convergent Validity

Our initial hypotheses regarding likely correlations between the CU-Q_2oL and Skindex-29 were generally fulfilled (Table 3). The pruritus and swelling dimensions of the CU-Q_2oL correlated most strongly with the Skindex symptoms dimension, while the impact on life activities and limits dimensions correlated most strongly with the Skindex functioning dimension. The CU-Q_2oL sleep dimension showed almost identical correlations with all 3 dimensions of the Skindex-29, whilst the looks dimension correlated most strongly with the emotions and functioning dimensions, which might also be expected. The correlation between the overall scores on the 2 instruments was 0.81.

Known-Group Validity

As shown in Table 4, the CU-Q_2oL generally differentiated well between different levels of severity of wheals and pruritus as rated by the study investigators. In most of the dimensions and in the overall score, a fairly clear gradient could be seen between the 3 different levels of severity, with patients evaluated as having the most severe problems by investigators scoring highest (poorest health) on the CU-Q_2oL. Using ANOVA, statistically significant differences ($P < .001$) were observed between the different categories of severity in all dimensions on the wheals and pruritus indices. Between-group effect sizes for the overall scores were 0.4 between mild and moderate wheals, 0.2 between moderate and severe wheals, 0.6 between mild and moderate pruritus, and 0.3 between moderate and severe pruritus.

Sensitivity to Change

In order to test the instrument's sensitivity to change, the CU-Q_2oL was administered on a second occasion 4 weeks after the first to a total of 111 patients. Of these, 16 (14.4%) reported no change in health status on the health transition

Table 2. Score Distributions and Reliability of Cu-Q_2 oL, Overall and by Dimension (baseline visit)

Cu-Q_2 oL	Number of items	Mean Score (0-100)	SD	Patients Scoring Floor Values, %	Patients Scoring Ceiling Values, %	Cronbach αa
Overall score	23	22.2	15.6	2.5	0	0.86
Pruritus	2	46.1	23.6	5.6	4.1	0.86
Swelling	2	10.8	19.5	64.2	1.4	0.87
Impact on life activities	6	21.0	18.2	16.4	0.1	0.81
Sleep problem	5	24.4	21.0	16.5	0.1	0.82
Limits	3	20.8	18.7	21.1	0.1	0.83
Looks	5	17.8	17.2	20.2	0	0.83

Table 3. Pearson Correlation Coefficients Between CU-Q_2oL and Skindex-29 Dimensions at Baseline[a]

CU-Q_2oL	Emotions	SKINDEX-29 Functioning	Symptoms
Pruritus	0.40	0.39	0.50
Swelling	0.32	0.33	0.39
Impact on daily activities	0.66	0.73	0.60
Sleep problems	0.59	0.59	0.61
Limits	0.65	0.69	0.55
Looks	0.67	0.68	0.56

[a]All correlations were statistically significant at $P < .0001$

Discussion

This study has shown that the Spanish version of the CU-Q_2oL is a reliable, valid, and sensitive instrument for use in Spanish patients with chronic urticaria. Disease-specific questionnaires such as the CU-Q_2oL are particularly useful for measuring HRQOL, as they are usually more sensitive to changes in patient health status than generic measures [20] and tend to discriminate better between patient subgroups. Currently, the CU-Q_2oL is the only disease-specific instrument for chronic urticaria available in Spain. The present Spanish adaptation will also provide a useful starting point for further adaptations that would make the instrument available to the approximately 450 million Spanish speakers worldwide.

Table 4. Mean Overall and Dimension CU-Q_2oL Scores by Severity of Wheals and Pruritus at Baseline

	Severity of Wheals			Severity of Pruritus		
Dimension	Absent/Mild	Moderate	Severe	Absent/Mild	Moderate	Severe
Pruritus	39.6 (21.1)	51.3 (21.7	58.5 (30.3)	32.6 (19.0)	45.7 (19.1)	54.7 (27.9)
Swelling	6.9 (14.1)	12.4 (20.0)	21.7 (29.8)	7.1 (13.5)	9.0 (16.1)	15.5 (25.3)
Impact on daily activities	17.0 (15.6)	24.3 (18.6)	29.0 (22.7)	12.8 (13.0)	21.2 (15.3)	25.8 (22.5)
Sleep problems	20.0 (18.6)	26.9 (20.4)	35.4 (26.3)	14.3 (15.3)	24.6 (18.9)	30.1 (24.2)
Limits	18.7 (17.4)	22.0 (19.2)	26.4 (20.4)	15.8 (14.8)	21.0 (16.7)	23.5 (22.6)
Looks	15.4 (15.3)	18.7 (17.2)	23.9 (23.1)	12.9 (13.4)	18.2 (16.1)	19.4 (20.0)
Overall	18.6 (13.5)	24.6 (15.4)	30.4 (19.9)	14.8 (11.1)	22.2 (13.1)	26.6 (19.1)

Table 5. Change Score and Effect Sizes in Patients Reporting Improvement in the Health State Transition Item (n = 95)

Dimension	Visit 1	Visit 2	*P* Value	Effect Size
Pruritus	50.1 (24.6)	24.2 (17.0)	< .0001	1.3
Swelling	9.9 (19.1)	3.9 (12.3)	< .0008	0.4
Impact on daily activities	23.1 (18.5)	10.6 (11.2)	< .0001	0.9
Sleep problems	28.8 (22.1)	13.9 (15.5)	< .0001	0.8
Limits	23.4 (19.8)	12.1 (14.7)	< .0001	0.7
Looks	19.0 (18.6)	10.7 (13.5)	< .0001	0.5
Overall	24.4 (16.1)	12.5 (11.0)	< 0001	1.0

item and 95 (85.6%) reported an improvement in health status. None of the patients reported worse health status. Table 5 shows the mean scores at visits 1 and 2 for patients reporting an improvement in their health status, as well as the effect sizes for the change in score. All changes in score on the CU-Q_2oL dimensions and the overall score were statistically significant at $P < .0008$ or more. All effect sizes were 0.4 or over and the largest were seen on the pruritus dimension (effect size = 1.3) and the overall score (effect size = 1.0).

During the present adaptation of the questionnaire, few translation problems arose and the process may have been facilitated to some extent by the linguistic similarities between Spanish and Italian, which share similar roots.

The fact that there were few missing responses on the questionnaire suggests that it is easy to use, although it would have been interesting to include a direct question for patients on this aspect in the present study. Although no ceiling effects were observed, floor effects on 3 dimensions exceeded the threshold of 15% recommended in the literature [21]. This can affect a dimension's capacity to reflect change (in this case improvement), as patients scoring the maximum cannot show further improvement. Interestingly, the dimensions with the highest floor effects (swelling, limits, and looks) were also those with the lowest effect sizes in the analysis of sensitivity to change.

In terms of reliability, the Spanish version of the CU-Q_2oL performed very well in the present study with Cronbach α values over the recommended 0.70 threshold [22] in all of the dimensions and for the overall score. In fact, the symptoms dimensions and the overall score approach an α value of 0.90, which is the recommended threshold for questionnaires to be used at the individual patient level [21]. Internal consistency results were generally comparable with, or better than, those seen for the original instrument [11].

Correlations between the Skindex-29 and the CU-Q_2oL at the level of individual dimensions were generally moderate to high, and the pattern of correlations suggested that hypotheses were met and that convergent validity was observed. The high overall correlation (0.80) between the 2 measures suggests that they are measuring quite similar content and that there may be some redundancy between the 2 measures. In future studies involving patients with chronic urticaria, this might indicate that including the 2 measures together would not be an efficient measurement strategy and that it would be preferable to include, say, the CU-Q_2oL together with a more generic measure [23], unless the aim was to compare HRQOL across different types of dermatology patients, in which case the Skindex-29 might be appropriate.

Substantial differences in score were also seen between patients classified according to the severity of their wheals and pruritus. Between-group effect sizes for the overall score ranged from 0.2 to 0.6, indicating that differences between groups were small to moderate according to Cohen's classification [19]. Although severity was investigator-rated and may therefore be liable to some subjectivity, there was a substantial gradient in CU-Q_2oL scores between severity ratings. This suggests reasonable agreement between patient and investigator assessments. The results of analyzing known-group validity also shows that although scores for pruritus and wheals were fairly similar across all 3 categories of severity, they were slightly higher for wheals, suggesting that they might have a slightly more marked impact on HRQOL (Table 4).

The questionnaire also proved sensitive to change with generally moderate-to-high effect sizes between visits [19]. As mentioned above, lower effect sizes in some dimensions may be associated with floor effects, particularly in the swelling dimension. In the present study, although we applied a commonly used methodology [18,24] to assess the questionnaire's sensitivity to change, it would also have been interesting to incorporate clinicians' views on change in health status in the analysis.

Our study had some limitations. It was not possible to analyze test-retest reliability, as there were too few patients who reported their health status as unchanged when the second version was administered. Likewise, we did not examine the new version's factor structure, although the high internal consistency seen in all the dimensions provides support for a scoring strategy based on the existing dimension structure. Finally, further testing of the instrument's sensitivity to change by applying the questionnaire before and after an intervention of recognized efficacy is advisable, as this would provide additional information as to how the questionnaire is likely to perform in conditions of, for example, a randomized clinical trial.

In conclusion, the Spanish version of the CU-Q_2oL has proven to be a reliable, valid, and sensitive instrument to assess HRQOL in patients with chronic urticaria. These results indicate that the instrument is suitable for use with Spanish urticaria patients in research and clinical settings. Future studies should investigate its test-retest reliability and provide additional data such as population reference values, which will help to interpret scores.

Acknowledgments

The authors would like to thank Isabel del Campo of UCB Group, Spain and Eva Mateu of Infociencia SL for their help with the study. Funding for this study was provided by UCB Pharma, Spain.

Anyone wishing to use the Spanish version of the CU-Q_2oL should contact Dr Canonica at the Department of Internal Medicine, University of Genoa, Genoa, Italy.

References

1. Greaves M. Chronic urticaria. N Engl J Med. 1995;332:1767-72.
2. Kaplan AP. Clinical practice. Chronic urticaria and angioedema. N Engl J Med. 2002;346:175-9.
3. Gaig P, Olona M, Muñoz Lejarazu D, Caballero MT, Domínguez FJ, Echechipia S, García Abujeta JL, Gonzalo MA, Lleonart R, Martínez Cócera C, Rodríguez A, Ferrer M. Epidemiology of urticaria in Spain. J Invest Allergol Clin Immunol. 2004;14:214-20.
4. Champion RH, Roberts SO, Carpenter RG, Roger JH. Urticaria and angio-oedema. A review of 554 patients. Br J Dermatol. 1969;81:588-97.
5. 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.
6. Poon E, Seed PT, Greaves MW, Kobza-Black A. The extent and nature of disability in different urticarial conditions. Br J Dermatol. 1999;140:667-71.
7. Picardi A, Abeni D, Melchi CF, Puddu P, Pasquini P. Psychiatric morbidity in dermatological outpatients: an issue to be recognized. Br J Dermatol. 2000;143:983-91.
8. Staubach P, Eckhardt-Henn A, Dechene M, Vonend A, Metz M, Magerl M, Breuer P, Maurer M. Quality of life in patients with chronic urticaria is differentially impaired and determined by psychiatric comorbidity. Br J Dermatol. 2006;154:294-8.
9. Ozkan M, Oflaz SB, Kocaman N, Ozseker F, Gelincik A, Büyüköztürk S, Ozkan S, Colakoglu B. Psychiatric morbidity and quality of life in patients with chronic idiopathic urticaria. Ann Allergy Asthma Immunol. 2007;99:29-33.
10. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)–a simple practical measure for routine clinical use. Clin Exp Dermatol. 1994;19:210-6.
11. Chren MM, Lasek RJ, Flocke SA, Zyzanski SJ. Improved discriminative and evaluative capability of a refined version of Skindex, a quality-of-life instrument for patients with skin diseases. Arch Dermatol. 1997;133:1433-40.
12. Baiardini I, Pasquali M, Braido F, Fumagalli F, Guerra L, Compalati E, Braga M, Lombardi C, Fassio O, Canonica GW. A new tool to evaluate the impact of chronic urticaria on quality of life: chronic urticaria quality of life questionnaire (CU-Q2oL). Allergy. 2005;60:1073-8.
13. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed measures. J Clin Epidemiol. 1993;46:1417-32.
14. Herdman M, Fox-Rushby J, Badía X. A model of equivalence in the cultural adaptation of HRQOL instruments: the universalist approach. Qual Life Res. 1998:7:323-35.
15. Deyo RA. Pitfalls in measuring the health status of Mexican

Americans: comparative validity of the English and Spanish Sickness Impact Profile. Am J Public Health. 1984;74:569-73.
16. Jones-Caballero M, Peñas PF, Garcia-Diez A, Badia X, Chren MM. The Spanish version of Skindex-29. Int J Dermatol. 2000;39:907-12.
17. Scientific Advisory Comittee of the Medical Outcomes Trust. Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res. 2002;11:193-205.
18. Valero A, Alonso J, Antépara I, Baró E, Colás C, del Cuvillo A, Ferrer M, Herdman M, Marti-Guadaño E, Monclús L, Navarro-Pulido AM, Sastre J, Izquierdo I, Mullol J. Health-related quality of life in allergic rhinitis: comparing the short form ESPRINT-15 and MiniRQLQ questionnaires. Allergy. 2007;62:1372-8.
19. Cohen J. Statistical power analysis for the behavioral sciences, 2nd edn. Hillsdale, NJ: L. Erlbaum Associates, 1998.
20. Klassen AF, Newton JN, Mallon E. Measuring quality of life in people referred for specialist care of acne: comparing generic and disease-specific measures. J Am Acad Dermatol. 2000;43(2 Pt 1):229-33.
21. McHorney CA, Tarlov AR. Individual patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995;4:293-307.
22. Hays RD, Anderson R, Revicki D. Psychometric considerations in evaluating health-related quality of life measures. Qual Life Res. 1993;2:441-9.
23. Leong KP, Yeak SC, Saurajen AS, Mok PK, Earnest A, Siow JK, Chee NW, Yeo SB, Khoo ML, Lee JC, Seshadri R, Chan SP, Tang CY, Chng HH. Why generic and disease-specific quality-of-life instruments should be used together for the evaluation of patients with persistent allergic rhinitis. Clin Exp Allergy. 2005;35:288-98.
24. Juniper EF, Thompson AK, Ferrie PJ, Roberts JN. Development and validation of the mini Rhinoconjunctivitis Quality of Life Questionnaire. Clin Exp Allergy 2000;30:132-40.

Manuscript received February 20, 2008; accepted for publication April 4, 2008.

Antonio Valero

Unitat d'Al·lèrgia
Servei de Pneumologia i Al·lèrgia Respiratòria
Hospital Clínic i Provincial
C. Villarroel, 170
08036 Barcelona, Spain
E-mail: valero@clinic.ub.es

