Adaptation and initial results of the Polish version of the GA\textsuperscript{2}LEN Chronic Urticaria Quality Of Life Questionnaire (CU-Q\textsubscript{2oL})

Z. Brzoza\textsuperscript{a,*,}, K. Badura-Brzoza\textsuperscript{b}, A. M\l{}yn\k{e}k\textsuperscript{c,d}, M. Magerl\textsuperscript{d}, I. Baiardini\textsuperscript{e}, G.W. Canonica\textsuperscript{e}, K. Weller\textsuperscript{d}, E. Kocatürk\textsuperscript{f}, D. Kalogeromitros\textsuperscript{d,g}, A. Zalewska-Janowska\textsuperscript{c}, T. Zuberbier\textsuperscript{d}, M. Maurer\textsuperscript{d}

\textsuperscript{a}Chair and Clinical Department of Internal Diseases, Allergology and Clinical Immunology, Medical University of Silesia, ul. Ceglana 35, 40-952 Katowice, Poland
\textsuperscript{b}Chair and Clinical Department of Psychiatry, Medical University of Silesia, Katowice, Poland
\textsuperscript{c}Psychodermatology Department, Medical University, Lodz, Poland
\textsuperscript{d}Department of Dermatology and Allergy, Allergie-Centrum-Charité, Charité-Universitätsmedizin, Berlin, Germany
\textsuperscript{e}Allergy and Respiratory Diseases, Department of Internal Medicine, University of Genoa, Genoa, Italy
\textsuperscript{f}Department of Dermatology, Gâytepe Training and Research Hospital, Istanbul, Turkey
\textsuperscript{g}Allergy Unit, University General Hospital "ATTIKON", National University of Athens, Greece

\textbf{A R T I C L E I N F O}

Article history:
Received 9 September 2010
Received in revised form 19 January 2011
Accepted 23 January 2011

Keywords:
Chronic urticaria
Quality of life
Questionnaire

\textbf{A B S T R A C T}

\textbf{Background:} Strong negative influence upon the quality of life in chronic urticaria is well proved. Before the GA\textsuperscript{2}LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q\textsubscript{2oL}) was introduced, the quality of life in chronic urticaria had been measured with general or dermatology specific questionnaires. CU-Q\textsubscript{2oL} was initially developed in Italy and consisted of 23 items divided into 6 quality of life dimensions.

\textbf{Objective:} The aim of our study was to adapt the Polish version of CU-Q\textsubscript{2oL} and to provide initial results from the Polish sample.

\textbf{Methods:} To prepare the Polish version forward and back translation was prepared. After cognitive debriefing, we collected a group of 126 chronic urticaria patients who completed Polish CU-Q\textsubscript{2oL}, Dermatology Life Quality Index (DLQI) and Skindex-29 questionnaire. Disease severity was assessed with Urticaria Activity Score (UAS). We performed the factorial analysis to identify CU-Q\textsubscript{2oL} subscales in our study, internal consistency and convergent validity assessment as well as factors driving the results. Moreover, we analysed tool’s reproducibility and responsiveness.

\textbf{Results:} The factor analysis resulted in six subscales of Polish CU-Q\textsubscript{2oL} version with satisfying face validity: Itching, Swelling/Mental status, Functioning, Sleep, Eating/Limits, Embarrassment. All subscales presented recommended internal consistency and convergent validity. Disease severity was the only factor predicting results of all the subscales. Polish CU-Q\textsubscript{2oL} version was reproducible and sensitive to change. We noticed the highest quality of life impairment in itching and Embarrassment subscales whereas Eating/Limits was the least affected.

\textbf{Conclusions:} Our study supports reliability, responsiveness and validity of the Polish version of CU-Q\textsubscript{2oL} – easy in use, non time-consuming instrument to be used in research, clinical management and treatment outcome assessment and is one more step to confirm quality of life impairment in chronic urticaria.

\textcopyright{} 2011 Japanese Society for Investigative Dermatology. Published by Elsevier Ireland Ltd. All rights reserved.
Patient-reported outcomes for symptoms in CU can be specifically assessed with Urticaria Activity Score (UAS). This instrument is validated for measuring and monitoring disease activity in CU patients and according to current guidelines, it is recommended in clinical practice, trials and therapy effectiveness analyses [8,9]. Quality of life tools measure subjective perception of disease influence. As quality of life assessment is expected to be included in all clinical trials on effectiveness of treatment, it is very important to prepare disease-specific questionnaires [10]. Before the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-QoL) was developed it was only possible to determine quality of life impairment in chronic urticaria by using general or dermatology addressed questionnaires [2,5–7,11]. Keeping in mind the prevalence of CU, it was necessary to create a new instrument designed for urticaria, as well as its adequate translations. The only questionnaire prepared specifically for urticaria is CU-QoL developed in Italy [12]. Afterwards, Spanish and German versions of this questionnaire were introduced [13,14].

The aim of our research network was to develop Polish version of CU-QoL in consistency with actual guidelines, and to provide initial results from the Polish sample [15–18].

Table 1
Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-QoL) with an English working translation.

<table>
<thead>
<tr>
<th>Polish version of CU-QoL</th>
<th>English translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>W jakim stopniu, przez ostatnich 15 dni, dokuczały Pani/Panu następujące objawy?</td>
<td>How much have you been troubled by the following symptoms during the past 15 days?</td>
</tr>
<tr>
<td>1. Śwędzenie</td>
<td>1. Itching</td>
</tr>
<tr>
<td>2. Bąble</td>
<td>2. Wheals</td>
</tr>
<tr>
<td>3. Opuchnięcie oczu</td>
<td>3. Eyes swelling</td>
</tr>
<tr>
<td>4. Opuchnięcie ust</td>
<td>4. Mouth swelling</td>
</tr>
<tr>
<td>Wcale, Troche, Umiarkowanie, Mocno, Bardzo mocno</td>
<td>None, a little, moderate, a lot, very much</td>
</tr>
<tr>
<td>W jakim stopniu, przez ostatnich 15 dni, dokuczały Pani/Panu następujące czynności codziennego życia?</td>
<td>Please indicate if during the past 15 days you have been limited by urticaria in the following areas of everyday life.</td>
</tr>
<tr>
<td>5. Praca</td>
<td>5. Work</td>
</tr>
<tr>
<td>6. Aktywność fizyczna</td>
<td>6. Physical activity</td>
</tr>
<tr>
<td>7. Sen</td>
<td>7. Sleep</td>
</tr>
<tr>
<td>8. Czas wolny</td>
<td>8. Free time</td>
</tr>
<tr>
<td>9. Social relationships</td>
<td></td>
</tr>
<tr>
<td>10. Odżywianie</td>
<td>10. Eating</td>
</tr>
</tbody>
</table>

Table 1

Poręcznik.

2. Methods

2.1. Translation of the questionnaire

To prepare the Polish version forward and back translation was performed. First, the original Italian version was translated into Polish by two professional Polish translators trained in medical translation. These versions were merged during the consensus meeting. We introduced some changes for clarity and afterwards back-translation into Italian by native translators was performed. This version was analysed with a back-translator. The Polish version was accepted and used after small revision of sentences in terms of style. Afterwards, for cognitive debriefing analysis, 10 chronic urticaria patients were asked to express their opinions regarding questions’ clarity, understandability and interpretation. In their opinion all the items were clear and understandable [17–20].

Answers to items were presented on a five-point Likert scale. Scores were calculated in 0–100 scale. The higher the score, the higher the quality of life impairment. The Polish version of the CU-QoL with an English working translation is presented in Table 1.

2.2. Patient sample and data collection

Data were collected from April 2007 until May 2010 at the Department of Internal Diseases, Allergology and Clinical Immunology, Medical University of Silesia. The questionnaire package included written informed consent, sociodemographic items, the Polish version of CU-QoL questionnaire, UAS, Dermatology Life Quality Index (DLQI) and Skindex-29. It was distributed in 163 consecutive CU patients and, when completed, provided personally or mailed back to us. Diagnosis of CU was established on the precise medical history and physical examination.

2.3. Measurement of outcomes

CU-QoL was initially developed in Italy and consisted of 23 items divided into 6 quality of life dimensions: “pruritus” (2 items), “impact on life activities” (6 items), “sleep problems” (5 items), “limits” (3 items), “looks” (5 items), and “swelling” (2 items). Likert scale is used in answers. This instrument has proven to be reliable, valid and sensitive to change [12].

To assess disease intensity UAS was used. This tool is based on the assessment of wheals and pruritus, which are basic urticaria symptoms. As it is advised to document patient’s self-perception score for several days, patients in our study performed a daily assessment during one-week yielding a total score of 0–42 (UAS-7). Total score was a sum of scores of 7 consecutive days [8,9].

To confirm the accuracy of our CU-QoL, we used the Polish version of DLQI and Skindex-29 questionnaire [21,22]. Those instruments were developed to evaluate the quality of life in different dermatological conditions. DLQI consists of ten items covering 6 domains, i.e., symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Each of 10 items is scored from 0 to 3. All items are added to form the total score. The higher the score is, the higher quality of life impairment. DLQI was proved to be an appropriate, valid, reliable, sensitive and clinically useful outcome measure in patients with CU [23,24]. Skindex-29 is an instrument consisting of 29 items grouped in three domains, i.e., emotions (10 items), functioning (12 items) and symptoms (7 items). It is widely used in scientific research. Answers are graded on a 5-point response scale.

To assess reproducibility CU-QoL was administered after one week to 36 patients who declared the same symptoms intensity. In order to test the instrument’s sensitivity to change 74 patients who reported diminished symptoms were mailed a second copy of CU-QoL to be filled 4 weeks after the first completion (following previous one-week UAS assessment).

2.4. Statistical analysis

As CU-QoL questionnaire is newly developed and so far it has been analysed on three patient populations, the factorial analysis was used to determine potential subscales with proper item division of the Polish questionnaire version – the principal component method with Varimax rotation was performed. To retain factors an eigenvalue ≥1.0 was chosen. Single items were assigned to the factor when loading with a factor loading ≥0.5 [14,25]. Afterwards face validity and clinical research utility for subscales were analysed [16].

The internal consistency for each subscale was evaluated using the alpha Cronbach’s coefficient. We accepted the following ranges for coefficient value interpretation: <0.60 – unacceptable, 0.60–0.65 – undesirable, 0.65–0.70 – minimally acceptable, 0.70–0.80 – respectable, 0.80–0.90 – excellent, >0.90 – excessive consistency [14].

Spearman rank correlation between subscales of CU-QoL vs. DLQI and Skindex-29 was used to assess convergent validity. Multiple linear regression analysis was applied to test predictors of CU-QoL results. Disease activity, sex, age and disease duration period were used as independent factors.

In reproducibility analysis we used intraclass coefficient (ICC). ICC values range between 0.40 and 0.75 indicates good reproducibility, meanwhile values ≥0.75 point at excellent reproducibility [12,26]. Wilcoxon and Pearson tests were used in responsiveness analysis. In UAS score comparisons we used paired Student’s t-test.

Statistical analysis was performed using Statistica 8.0 PL (Statsoft INC., USA).

3. Results

3.1. Subject characteristics

We included 126 patients (who provided sufficient data for analysis) – 89 women (70.6%) and 37 men (29.4%) into the study. This group was adequate for factor analysis as a minimum sample size of 5 subjects per variable is recommended [14]. All participants signed an informed consent form. The questionnaire packages were provided personally in 43 cases or mailed back in 83 cases. The mean disease duration of the study sample was 45.4 ± 14.1 years. In this group 24 (19.0%) subjects were single and 102 (81.0%) were married, employed 84 (66.7%), unemployed 13 (10.3%), housewives 9 (7.1%), students 12 (9.5%), retired 8 (6.4%). The mean disease duration was 35.9 ± 40.4 months. Disease activity as assessed using the UAS-7 score was 24.3 ± 11.1 (UAS-7 score of 10 cognitive debriefing patients...
Table 3
Composition and internal consistency of the Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) subscales.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Item no.</th>
<th>Cronbach’s α coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itching (I)</td>
<td>1, 2</td>
<td>0.72</td>
</tr>
<tr>
<td>Swelling/Mental status (II)</td>
<td>3, 4, 14, 15, 16</td>
<td>0.74</td>
</tr>
<tr>
<td>Functioning (III)</td>
<td>5, 6, 8, 9, 22, 23</td>
<td>0.89</td>
</tr>
<tr>
<td>Sleep (IV)</td>
<td>7, 11, 12, 13</td>
<td>0.85</td>
</tr>
<tr>
<td>Eating/Limits (V)</td>
<td>10, 17, 20, 21</td>
<td>0.82</td>
</tr>
<tr>
<td>Embarrassment (VI)</td>
<td>18, 19</td>
<td>0.83</td>
</tr>
</tbody>
</table>

Table 4
Relationship between the Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) subscales and respective Dermatology Life Quality Index (DLQI) items (R – correlation coefficient, p – statistical significance).

<table>
<thead>
<tr>
<th>CU-Q2oL subscale</th>
<th>DLQI item</th>
<th>R Spearman</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itching (I)</td>
<td>Item 10</td>
<td>0.67</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Functioning (III)</td>
<td>Item 3, 5, 6, 7 – mean</td>
<td>0.64</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Eating/Limits (V)</td>
<td>Item 4</td>
<td>0.56</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Embarrassment (VI)</td>
<td>Item 2</td>
<td>0.45</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Table 5
Relationship between the Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) subscales and Skindex-29 items and domains (R – correlation coefficient, p – statistical significance).

<table>
<thead>
<tr>
<th>CU-Q2oL subscale</th>
<th>Skindex-29</th>
<th>R Spearman</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itching (I)</td>
<td>Item 2, 29 – mean</td>
<td>0.57</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Functioning (III)</td>
<td>Item 20</td>
<td>0.60</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 6
Factors influencing the Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) results (UAS-7 – Urticaria Activity Score one-week assessment, p – statistical significance).

<table>
<thead>
<tr>
<th>CU-Q2oL subscale</th>
<th>UAS-7</th>
<th>Age</th>
<th>Sex</th>
<th>Disease duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>p</td>
<td>p</td>
<td>p</td>
<td>p</td>
</tr>
<tr>
<td>Itching (I)</td>
<td>&lt;0.001</td>
<td>0.55</td>
<td>0.29</td>
<td>0.25</td>
</tr>
<tr>
<td>Functioning (III)</td>
<td>0.03</td>
<td>0.36</td>
<td>0.11</td>
<td>0.37</td>
</tr>
<tr>
<td>Eating/Limits (V)</td>
<td>0.02</td>
<td>0.37</td>
<td>0.83</td>
<td>0.05</td>
</tr>
<tr>
<td>Embarrassment (VI)</td>
<td>0.04</td>
<td>0.33</td>
<td>0.58</td>
<td>0.13</td>
</tr>
</tbody>
</table>

3.2. Identification and validation of Polish scales

As shown in Table 3 the factor analysis resulted in a six-factor solution for the Polish CU-Q2oL version. Our solution explains 73.6% of the variance. It proves strong validity. All items were assigned to factors and each item was assigned only to one factor.

Internal consistency of six subscales of CU-Q2oL was calculated by Cronbach’s alpha coefficient. Functioning (III), Sleep (IV), Eating/Limits (V) and Embarrassment (VI) subscales presented excellent consistency. Internal consistency of Itching (I) and Swelling/Mental status (II) subscales was respectable (Table 3).

was 22.8 ± 9.4). All patients were treated according to the current recommendations [27]. Mean DLQI result was 9.02 ± 6.96. Our subjects presented mild and moderate burden on Skindex-29 domains. The results of DLQI items and Skindex-29 domains are presented in Table 2.

In our analysis 20 of 2898 (0.69%) items were left without any answer. Half of those missing items were questions 22 and 23.

3.3. Convergent validity

We noticed statistically significant moderate and strong correlations between CU-Q2oL subscales and respective DLQI and Skindex-29 items and domains: Itching (I) vs. DLQI item 1 and Skindex-29 item 10, Swelling/Mental status (II) vs. Skindex-29 – emotion domain, Functioning (III) vs. DLQI item 3, 5, 6, 7 (mean value) and Skindex-29 – functioning domain, Sleep (IV) vs. Skindex-29 – item 2 and 29 (mean value), Eating/Limits (V) vs. DLQI item 4, Embarrassment (VI) vs. DLQI item 2 and Skindex-29 item 20 (Tables 4 and 5).

3.4. CU-Q2oL initial scores

Initial results of our analysis in the Polish sample are presented in Fig. 1. Itching and Embarrassment subscales seem to be the most impaired. Other subscales were less affected. The subscale presenting the lowest grade of impairment was Eating/Limits. The range of our results points at a wide distribution of the analysed parameters.

3.5. Factors influencing CU-Q2oL results

Disease symptom intensity as assessed with UAS-7 significantly predicted CU-Q2oL score in all the subscales. In our sample sex, disease duration and age were the factors which did not predict any of the subscales (Table 6).

3.6. Reproducibility and responsiveness analyses

Of 36 patients who reported the same symptom severity after one week, 31 mailed us back the CU-Q2oL completed for the second time. Reported symptom stability was confirmed with the lack of statistically significant UAS-7 score change (20.3 ± 6.1 vs. 18.9 ± 5.7; p > 0.05). For each item we analysed ICC. For item 7, 8...
and 16 we observed good reproducibility. ICCs were \( \geq 0.75 \) for the other items (excellent reproducibility).

From the group of patients who reported diminished symptoms, 52 mailed us a second copy of CU-Qol filled 4 weeks after the first one. Significant UAS-7 reduction (23.9 \( \pm \) 9.1 vs. 14.6 \( \pm \) 7.2; \( p = 0.01 \)) confirmed improved health status in those patients. When comparing CU-Qol domains we detected statistically significant reduction in all analysed subscales (Table 7). Analysis of UAS-7 and CU-Qol scores changes correlation revealed statistical significance \( (r = 0.49, p < 0.001) \). It suggests that Polish version of CU-Qol is responsive to expected changes in intensity of urticaria symptoms.

### 4. Discussion

The importance of the disorder’s severity assessment from a patient’s subjective point of view is widely accepted. Quality of life assessment is necessary in disease course and treatment effectiveness analysis. As CU is a disease with a profound effect on the quality of life and daily activities, its precise assessment is of great value [1]. In research across different skin disorders more general questionnaires are needed, although the usage of general instrument when the specific one is available may result in inadequate results. CU-Qol is the only questionnaire designed specifically for CU patients. It is simple in use, non-time consuming and can be completed in no more than 5–7 min.

As CU-Qol is a relatively new questionnaire in our adaptation we performed the procedures needed during the process of preparing the language version of a newly developed instrument [15–18]. In our opinion the number of missing answers to CU-Qol questions in our study is relatively small. Half of them concerned doctor’s indications, do not use drugs, which partly explains some inadequate results. CU-Qol is the only questionnaire designed for CU patients. It is simple in use, non-time consuming and can be completed in no more than 5–7 min.

In our opinion, the composition of our subscales is quite coherent. In general, it looks different in comparison to the Italian item division although some similarities can be observed. Italian domain “pruritus” is identical to our sub-scale Itching. “Impact on daily activities” domain is partly similar to our Functioning. In Baiardini et al. version “swelling” is a single domain whereas in our version those items are associated with the items concerning mental status. Italian “sleep problems” also contains items related to mental status meanwhile in our version it is limited only to sleep problems. Italian “limits” and “looks” domains are different from our Eating/Limits and Embarrassment [12].

On the other hand, our results are quite similar to the study on German population. We achieved two identical scales: Sleep and Functioning. Items forming two separate scales in our study – Itching and Embarrassment, in the German version are combined together. Questions related to mental status in the German version form “mental status” domain, whereas in the Polish version these questions are attached to those concerning swelling, forming together Swelling/Mental status subscale. Items concerning eating in the German version together with items related to swelling form common domain; whereas in the Polish version together with the questions related to limitations form Eating/Limits subscale [14]. Close similarity to the German division into domains gives a chance for comparative studies in the future. However, at this stage only item-by-item comparisons between Italian, German and Polish instruments are possible. It is not surprising as factorial analysis in those studies was performed on different populations and a limited number of patients. Further studies with larger samples will probably allow to confirm that tool. In the German CU-Qol adaptation, domain construction was taken directly from the Italian pattern without previous factorial analysis [13].

After the correlation with other dermatological quality of life questionnaires estimation, we proved convergent validity of all subscales of Polish CU-Qol. Correlations between DLQI, Skindex-29 and CU-Qol were moderate and strong, which indicates the compatibility within these measures. All CU-Qol items were found to be internally consistent. The Polish version of CU-Qol met the standards for reliability and responsiveness.

When analysing initial results of our study, we noticed that Itching and Embarrassment subscales of our instrument were the most impaired. The same results were obtained from the study on German population [14]. This fact is not surprising as pruritus is the main and particularly debilitating symptom in urticaria. It is consistent with clinical knowledge and observations from other studies [6,13,14,29]. Moreover, the level of impairment in Functioning subscale was parallel in both studies. Similarly, to German experience, Swelling/Mental status subscale in our study was markedly impaired. Contrary to the German results, in the Polish sample Sleep problem was not so affected. In Eating/Limits subscale we noticed the smallest quality of life impairment, which is to some extent consistent with the results from the Mlynęk et al.
study [14]. We can speculate that it is because of the fact that urticaria patients do not always experience food or wear limitations. Besides, the usage of cosmetics in male and older patients is not so frequent, which partly explains this observation. As in our previous study [14] we must underline that CU-Q2L does not provide a “total score” and only subscale scores can be compared. Quality of life impairment as assessed with DLQI and Skindex-29 was similar in both studies.

There are still a lot of unexplored areas in urticaria pathogenesis and effective treatment. Taking into consideration the role of psychological disturbances in this disorder, quality of life impairment assessment must always be performed. Our study is one more step in this process. We proved that the Polish version of CU-Q2L is a valid, reliable and responsive instrument to apply in Polish patients with chronic urticaria, useful in quality of life assessment and according to the authors’ intention it can be a complement of clinical measure and can aid treatment-decision making [12]. Therefore this instrument is suitable in clinical settings and research.

References