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Adaptation and initial results of the Polish version of the GA²LEN Chronic Urticaria Quality Of Life Questionnaire (CU-Q₂oL)

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ABSTRACT

Background: Strong negative influence upon the quality of life in chronic urticaria is well proved. Before the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q₂oL) was introduced, the quality of life in chronic urticaria had been measured with general or dermatology specific questionnaires. CU-Q₂oL was initially developed in Italy and consisted of 23 items divided into 6 quality of life dimensions.

Objective: The aim of our study was to adapt the Polish version of CU-Q₂oL and to provide initial results from the Polish sample.

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-Q₂oL, 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-Q₂oL 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.

Results: The factor analysis resulted in six subscales of Polish CU-Q₂oL 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-Q₂oL 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.

Conclusions: Our study supports reliability, responsiveness and validity of the Polish version of CU-Q₂oL – 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.

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1. Introduction

Chronic urticaria (CU) is characterized by the spontaneous occurrence of itchy wheals and/or angioedema for at least 6 weeks. Lifetime prevalence for CU is about 1.8% [1]. The intensity of urticaria symptoms is subject to monthly, weekly and daily fluctuations. Clinical experience strongly emphasises the role of the psychological component in urticaria. CU is a disorder affecting

patient's appearance and severely debilitating daily activities. Patients with urticaria suffer from recurrent wheals or oedema often appearing on their faces. This condition disturbs their self perception in particular, and causes multiple emotional and social problems. CU patients suffer from pruritus which disturbs their sleep cycles. Earlier studies presented urticaria patients as frequently exhibiting psychiatric comorbidity and psychological distress [2–4]. Moreover, strong negative influence upon the quality of life of such patients was proved [2,5]. Quality of life impairment in chronic urticaria is comparable to the one found in coronary artery disease and is higher than in some other dermatologic conditions such as psoriasis, acne and vitiligo [6,7].

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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-Q₂oL) 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-Q₂oL 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-Q₂oL 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-Q₂oL) with an English working translation.

Polish version of CU-Q ₂ oL	English translation
W jakim stopniu, przez ostatnich 15 dni, dokuczały Pani/Panu następujące objawy?	How much have you been troubled by the following symptoms during the past 15 days?
1. Swędzenie	1. Itching
Wcale, Trochę, Umiarkowanie, Mocno, Bardzo mocno	None, a little, moderate, a lot, very much
2. Bąble	2. Wheals
Wcale, Trochę, Umiarkowanie, Mocno, Bardzo mocno	None, a little, moderate, a lot, very much
3. Opuchnięcie oczu	3. Eyes swelling
Wcale, Trochę, Umiarkowanie, Mocno, Bardzo mocno	None, a little, moderate, a lot, very much
4. Opuchnięcie ust	4. Mouth swelling
Wcale, Trochę, Umiarkowanie, Mocno, Bardzo mocno	None, a little, moderate, a lot, very much
Proszę wskazać czy pokrzywka, w ciągu ostatnich 15 dni, ograniczała Panią/Pana w następujących czynnościach życia codziennego?	Please indicate if during the past 15 days you have been limited by urticaria in the following areas of everyday life.
5. Praca	5. Work
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
6. Aktywność fizyczna	6. Physical activity
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
7. Sen	7. Sleep
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
8. Czas wolny	8. Free time
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
9. Stosunki społeczne	9. Social relationships
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
10. Odżywianie	10. Eating
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
Za pomocą poniższych pytań chcemy zbadać dokładnie trudności i problemy, które mogą być związane z pokrzywką (dotyczy to ostatnich 15 dni)	Using the following questions, we would like to investigate precisely difficulties and problems that can be urticaria-related (regarding the past 15 days)
11. Czy ma Pani/Pan problemy z zasypianiem?	11. Have you had difficulty falling asleep?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
12. Czy budzi się Pani/Pan w ciągu nocy?	12. Have you woken up at night?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
13. Czy w ciągu dnia jest Pani/Pan zmęczona/y, ponieważ w ciągu nocy Pani/Pan nie wypoczywa?	13. Have you been tired in the day time because you have not got a good night's sleep?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
14. Czy ma Pani/Pan problemy z koncentracją?	14. Have you had difficulty concentrating?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
15. Czy jest Pani/Pan podenerwowana/y?	15. Have you felt nervous?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
16. Czy czuje Pani/Pan pogorszenie nastroju?	16. Have you felt miserable?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
17. Czy musiała Pani/Pan ograniczyć rodzaj spożywanych pokarmów?	17. Have you had to limit your food choice?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
18. Czy wprawiają Panią/Pana w zakłopotanie zmiany, które z powodu pokrzywki pojawiają się na ciele?	18. Have you been bothered by the symptoms of urticaria that appear on your body?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
19. Czy czuje się Pani/Pan zakłopotana/y w miejscach publicznych?	19. Have you been embarrassed in public places?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
20. Czy ma Pani/Pan problemy z używaniem kosmetyków (np. perfum, kremów, płynów do kąpieli, kosmetyków do makijażu)?	20. Has it been a problem for you to use cosmetics (e.g., perfume, creams, bubble bath, make up)?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
21. Czy musiała Pani/Pan ograniczyć rodzaj używanych ubrań?	21. Have you had to limit your clothing choice?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
22. Czy zmniejszyła się Pani/Pana aktywność sportowa z powodu pokrzywki?	22. Has your sport activity been limited because of urticaria?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often
23. Czy przeskadzają Pani/Panu skutki uboczne leków zażywanych przeciw objawom pokrzywki?	23. Have you suffered from side-effects from the medications you take for urticaria?
Nigdy, Rzadko, Czasami, Często, Bardzo często	Never, rarely, sometimes, often, very often

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-Q₂oL 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-Q₂oL 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-Q₂oL 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-Q₂oL, 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-Q₂oL 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-

Q₂oL to be filled 4 weeks after the first completion (following previous one-week UAS assessment).

2.4. Statistical analysis

As CU-Q₂oL 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-Q₂oL vs. DLQI and Skindex-29 was used to assess convergent validity. Multiple linear regression analysis was applied to test predictors of CU-Q₂oL 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 age 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 2

Results of Dermatology Life Quality Index (DLQI) items and Skindex-29 domains (SD-standard deviation).

	Mean	SD
DLQI item 1	1.67	0.72
DLQI item 2	1.48	0.92
DLQI item 3	1.19	1.17
DLQI item 4	0.83	1.06
DLQI item 5	1.02	1.05
DLQI item 6	0.35	0.79
DLQI item 7	0.92	1.27
DLQI item 8	0.69	0.90
DLQI item 9	0.53	0.92
DLQI item 10	0.52	0.92
Skindex-29 symptoms	34.7	8.42
Skindex-29 functioning	23.9	7.49
Skindex-29 emotions	26.3	11.2

Table 3

Composition and internal consistency of the Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q₂oL) subscales.

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

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).

CU-Q ₂ oL subscale	DLQI item	R Spearman	p
Itching	1	0.67	<0.001
Functioning	3, 5, 6, 7 – mean	0.64	<0.001
Eating/Limits	4	0.56	<0.001
Embarrassment	2	0.45	0.003

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.

3.2. 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).

Table 5

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

CU-Q ₂ oL subscale	Skindex-29	R Spearman	p
Itching	Item 10	0.68	<0.001
Swelling/Mental status	Emotions	0.64	<0.001
Functioning	Functioning	0.61	<0.001
Sleep	Item 2, 29 – mean	0.57	<0.001
Embarrassment	Item 20	0.60	<0.001

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).

CU-Q ₂ oL subscale	UAS-7		Age		Sex		Disease duration	
	p	Beta	p	Beta	p	Beta	p	Beta
Itching	<0.001	0.55	0.29	–0.25	0.93	0.02	0.68	0.12
Swelling/Mental status	0.03	0.36	0.11	0.37	0.29	–0.18	0.31	0.28
Functioning	0.02	0.37	0.83	–0.05	0.37	–0.15	0.94	0.02
Sleep	0.03	0.36	0.24	0.28	0.37	–0.15	0.38	–0.24
Eating/Limits	0.02	0.37	0.58	0.13	0.26	–0.19	0.95	0.02
Embarrassment	0.04	0.33	0.60	0.12	0.19	–0.22	0.65	0.13

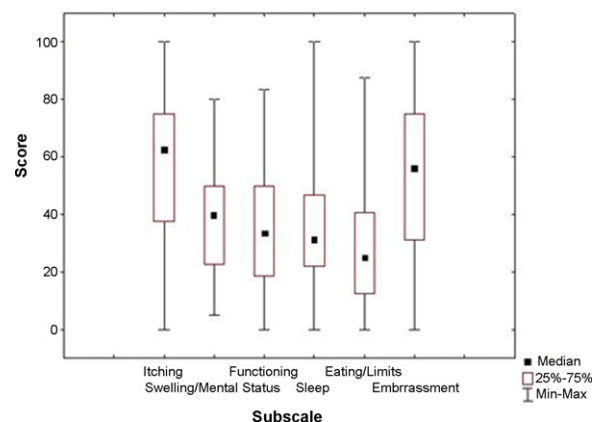


Fig. 1. Initial results of the Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q₂oL).

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 ; $p \geq 0.05$). For each item we analysed ICC. For item 7, 8

Table 7

Change score of the Polish version of the GA²LEN Chronic Urticaria Quality of Life Questionnaire (CU-Q₂oL) in patients reporting symptoms improvement after 4 weeks (*p* – statistical significance).

Subscale	CU-Q ₂ oL baseline			CU-Q ₂ oL after 4 weeks			<i>p</i>
	Median	75%	25%	Median	75%	25%	
Itching (I)	60.7	76.4	37.8	47.3	61.3	23.5	<0.001
Swelling/Mental status (II)	32.3	41.2	19.6	28.9	37.7	14.5	0.02
Functioning (III)	36.2	45.1	23.7	28.6	38.1	16.9	0.01
Sleep (IV)	37.4	50.2	24.1	29.7	41.2	14.7	0.01
Eating/Limits (V)	19.8	36.4	12.6	15.4	30.1	8.7	0.02
Embarrassment (VI)	55.1	72.3	39.4	44.5	59.2	27.3	<0.001

and 16 we observed good reproducibility. ICCs were ≥ 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-Q₂oL filled 4 weeks after the first one. Significant UAS-7 reduction (23.9 ± 9.1 vs. 14.6 ± 7.2 ; $p = 0.01$) confirmed improved health status in those patients. When comparing CU-Q₂oL domains we detected statistically significant reduction in all analysed subscales (Table 7). Analysis of UAS-7 and CU-Q₂oL scores changes correlation revealed statistical significance ($r = 0.49$, $p = <0.001$). It suggests that Polish version of CU-Q₂oL 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-Q₂oL 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-Q₂oL 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-Q₂oL questions in our study is relatively small. Half of them concerned two items, i.e., 22 and 23. Item no. 22 concerns sport – as we suppose it is not properly applicable to some patients who do not present any sport activity, whereas other patients, in spite of doctor's indications, do not use drugs, which partly explains some missing answers in item no. 23 [28].

The consequences of our factorial analysis were quite satisfying as the analysis allowed us to retain all the items. It resulted in a six-factor solution explaining over 73% of variance, proving its strong validity. Factor solution in German CU-Q₂oL version explained over 70% of variance whereas in Italian it was nearly 60% [12,14]. We identified six subscales with satisfying face validity. Factor I – *Itching* subscale – groups together two items concerning pruritus and wheals as related to each other. Factor II – *Swelling/Mental status* subscale – to our surprise combines physical and mental items. We speculate that swelling (a symptom frequently assessed by patients as more severe than pruritus) can cause anxiety and mood disturbances. Factor III – *Functioning* subscale – contains items related to daily activities. Factor IV – *Sleep* subscale – consists of items explicitly related to sleep problem. Factor V – *Eating/Limits* subscale – combines factors concerning limitations in choice of food and wear/cosmetics usage. It suggests a common course of these aspects as related to restrictions. Factor VI – *Embarrassment* subscale – groups items indicating that patient's embarrassment is

not only the result of urticaria symptoms such as wheals, pruritus or swelling but maybe even of risk of their occurrence.

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 subscale *Itching*. “Impact on live 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 those 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 uniform that tool. In the Spanish CU-Q₂oL 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-Q₂oL. Correlations between DLQI, Skindex-29 and CU-Q₂oL were moderate and strong, which indicates the compatibility within these measures. All CU-Q₂oL items were found to be internally consistent. The Polish version of CU-Q₂oL 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 Mlynek 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-Q₂oL 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-Q₂oL 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

- [1] Zuberbier T, Balke M, Worm M, Edenharter G, Maurer M. Epidemiology of urticaria: a representative cross-sectional population survey. *Clin Exp Dermatol* 2010;35:869–73.
- [2] Staubach P, Eckhardt-Henn A, Dechene M, Vonend A, Metz M, Magerl M, et al. Quality of life in patients with chronic urticaria is differentially impaired and determined by psychiatric comorbidity. *Br J Dermatol* 2006;154:294–8.
- [3] Brzoza Z, Kasperska-Zajac A, Badura-Brzoza K, Matysiakiewicz J, Hese RT, Rogala B. Decline in dehydroepiandrosterone sulfate observed in chronic urticaria is associated with psychological distress. *Psychosom Med* 2008;70:723–8.
- [4] Yang HY, Sun CC, Wu YC, Wang JD. Stress, insomnia, and chronic idiopathic urticaria – a case-control study. *J Formos Med Assoc* 2005;104:254–63.
- [5] Baiardini I, Giardini A, Pasquali M, Dignetti P, Guerra L, Specchia C, et al. Quality of life and patients’ satisfaction in chronic urticaria and respiratory allergy. *Allergy* 2003;58:621–3.
- [6] 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.
- [7] 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.
- [8] Mlynek A, Zalewska-Janowska A, Martus P, Staubach P, Zuberbier T, Maurer M. How to assess disease activity in patients with chronic urticaria? *Allergy* 2008;63:777–80.
- [9] Zuberbier T, Asero R, Bindslev-Jensen C, Canonica GW, Church MK, Giménez-Arnau A, et al. EAACI/GA(2)LEN/EDF/WAO guideline: definition, classification and diagnosis of urticaria. *Allergy* 2009;64:1417–26.
- [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 GA²LEN taskforce position paper. *Allergy* 2010;65:290–5.
- [11] Ozkan M, Oflaz SB, Kocaman N, Ozseker F, Gelincik A, Büyükköztürk S, et al. Psychiatric morbidity and quality of life in patients with chronic idiopathic urticaria. *Ann Allergy Asthma Immunol* 2007;99:29–33.
- [12] Baiardini IM, Pasquali M, Braidò 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-Q₂oL). *Allergy* 2005;60:1073–8.
- [13] 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;18:426–32.
- [14] Mlynek 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;64:927–36.
- [15] Finlay AY. Quality of life measurement in dermatology: a practical guide. *Br J Dermatol* 1997;136:305–14.
- [16] Floyd FJ, Widaman KF. Factorial analysis in the development and refinement of clinical assessment instruments. *Psychol Assess* 1995;7:286–99.
- [17] U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research; U.S. Department of Health and Human Services FDA Center for Biologics Evaluation and Research; U.S. Department of Health and Human Services FDA Center for Devices and Radiological Health. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. *Health Qual Life Outcomes* 2006;4:79–98.
- [18] Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. *Value Health* 2005;8:94–104.
- [19] 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.
- [20] Herdman M, Fox-Rushby J, Badia X. A model of equivalence in the cultural adaptation of HRQOL instruments: the universalist approach. *Qual Life Res* 1998;7:323–35.
- [21] Szepletowski J, Salomon J, Finlay AY, Klepacki A, Chodyncka B, Marionneau N, et al. Wskaźnik wpływu dolegliwości skórnych na jakość życia – Dermatology Life Quality Index (DLQI): polska wersja językowa. *Dermatol Klin* 2004;6:63–70.
- [22] Steuden S, Janowski K. Zastosowanie kwestionariusza Skindex do pomiaru jakości życia u pacjentów z łuszczycą. *Przegl Dermatol* 2001;88:41–8.
- [23] Lennox RD, Leahy MJ. Validation of the Dermatology Life Quality Index as an outcome measure for urticaria-related quality of life. *Ann Allergy Asthma Immunol* 2004;93:142–6.
- [24] Shikier R, Harding G, Leahy M, Lennox R. Minimal important difference (MID) of the Dermatology Life Quality Index (DLQI): results from patients with chronic idiopathic urticaria. *Health Qual Life Outcomes* 2005;3:36–40.
- [25] Gorsuch RL. Factor analysis. Hillsdale, NJ: Lawrence Erlbaum; 1983.
- [26] Rosner B. Fundamentals of biostatistics. Belmont, CA: Duxbury Press; 1995. p. 519.
- [27] Zuberbier T, Asero R, Bindslev-Jensen C, Canonica GW, Church MK, Giménez-Arnau AM, et al. EAACI/GA(2)LEN/EDF/WAO guideline: management of urticaria. *Allergy* 2009;64:1427–43.
- [28] Maurer M, Ortonne JP, Zuberbier T. Chronic urticaria: a patient survey on quality-of-life, treatment usage and doctor–patient relation. *Allergy* 2009;64:581–8.
- [29] Maurer M, Ortonne JP, Zuberbier T. Chronic urticaria: an internet survey of health behaviours, symptom patterns and treatment needs in European adult patients. *Br J Dermatol* 2009;160:633–41.