

RESEARCH LETTERS

Chronic Spontaneous Urticaria: How to Assess Quality of Life in Patients Receiving Treatment

Because of the long duration and fluctuating severity of symptoms of chronic spontaneous urticaria (CSU), strict criteria are necessary to assess disease activity, disease-specific impairment of quality of life (QoL), and the influence of treatment on these.¹ Two types of assessment have been developed: clinical scoring systems and QoL questionnaires. Perhaps the most effective clinical scoring system is the Urticaria Activity Score (UAS7), which is based on the daily assessment of the key urticaria symptoms, wheals, and pruritus over 7 days.² The documentation of symptoms for several days in a row is critical to ensure UAS results that are truly representative for the patients' disease activity because urticaria symptoms can vary considerably from day to day. This study extended the validation of the German version of the Chronic Urticaria Quality of Life Questionnaire (CU-Q₂oL)^{3,4} by comparing it with the UAS7 and the Dermatology Life Quality Index (DLQI)⁵ in assessing the clinical response to change in therapy in CSU.

Methods. The study took place at the specialist urticaria clinic at the Department of Dermatology and Allergy, Charité–Universitätsmedizin, Berlin, Germany, where 51 patients (12 male and 39 female; age range, 20–80 years) diagnosed as having CSU and having a minimum UAS7 score of 7 out of a possible 42 during the previous week were admitted to the study. The day before the clinic visit, patients completed DLQI and CU-Q₂oL questionnaires to assess the effect of their CSU on their QoL. Following a thorough clinical examination, their therapy was adjusted in an attempt to improve symptom control and QoL. All patients were given a second self-assessment package (UAS7, DLQI, CU-Q₂oL) for completion before their reassessment visit 4 weeks to 3 months later. While the German version of the CU-Q₂oL has been validated previously,⁴ we are not aware of a validation study for the German version of the DLQI. However, this instrument has been shown its high value in multiple German and international health-related QoL studies, and it has been validated as an outcome measure for urticaria-related QoL. Results are presented as mean (SEM) scores, and groups are compared using the Wilcoxon test. Correlations were calculated using Pearson correlation.

Results. The mean (SEM) scores for the UAS7, DLQI, total CU-Q₂oL, and CU-Q₂oL domains before and after adjustment of therapy are shown in the **Table**. The number of patients showing symptomatic improvement, de-

Table. Mean (SEM) Scores for the UAS7, DLQI, Total CU-Q₂oL, and CU-Q₂oL Domains Before and After Adjustment of Therapy^a

Assessment	Mean (SEM)	
	Before Therapy Adjustment	After Therapy Adjustment
UAS7	18.7 (2.1)	14.7 (1.5)
DLQI	7.6 (0.7)	6.5 (0.7)
CU-Q ₂ oL		
Total	42.8 (2.1)	36.2 (2.6)
Functioning	30.7 (2.9)	27.5 (3.0)
Sleep	50.4 (3.1)	41.7 (3.2)
Itching/embarrassment	59.9 (2.9)	50.2 (3.7)
Mental status	48.4 (2.8)	38.9 (3.5)
Swelling/eating	36.6 (3.4)	28.4 (3.5)
Limits and looks	36.3 (3.9)	35.0 (3.4)

Abbreviations: CU-Q₂oL, Chronic Urticaria Quality of Life Questionnaire; DLQI, Dermatology Life Quality Index; UAS7, Urticaria Activity Score.

^aThe maximum scores are 42 for the UAS7, 30 for the DLQI, and 100 for the CU-Q₂oL total score and CU-Q₂oL domains. The minimum for each of the scores is 0. While the DLQI and UAS7 results were calculated as cumulative scores, the CU-Q₂oL scores were computed by using linear transformations of raw scores. The domains of the CU-Q₂oL contained questions relating to functioning (work, physical activities, free time, social relations, sports, and medication adverse effects), sleep (ease of falling asleep, quality of sleep, waking up during the night, and daytime tiredness), itching/embarrassment (pruritus, wheals, whether these are bothersome and embarrassing in public), mental status (ability to concentrate, nervousness, and bad mood), swelling/eating (swelling of the eyes and lips, eating, and limits in choosing food), and limits and looks (the use of cosmetics and the choice of clothes).

finied as a reduction in their score for individual tests, is shown in the **Figure**.

The primary comparisons in this study were between the UAS7 and the 2 QoL assessments. The initial mean (SEM) UAS7 score was only 18.7 (2.1) out of a maximum of 42, indicating that the patients' initial treatment was already reasonably effective. Adjustment of therapy was associated with an improvement of 21% in the UAS7 score ($P=.02$) with 67% of patients showing symptomatic improvement. In contrast, the 14% reduction in the DLQI was not statistically significant ($P=.23$). Furthermore, following treatment adjustment, only 47% reported improvement with even fewer, 29%, showing an improvement in DLQI score of 2.24 or more points, the suggested minimal important difference required to indicate a clinically significant improvement. Although the improvement in the CU-Q₂oL total score of 15% with treatment adjustment was similar to that of the DLQI, the response was less variable and was significant ($P=.001$). Furthermore, 69% of patients reported improvement in their score. Of the CU-Q₂oL domains, "itching/embarrassment," "sleep," and "mental status" achieved the highest initial scores and the most significant improvement following therapy adjustment ($P\leq .001$). There was no significant improvement in the "functioning" or "limits and looks" domains.

The total score of the CU-Q₂oL correlated more strongly ($r=0.39$; $P=.005$) with the UAS7 than did the

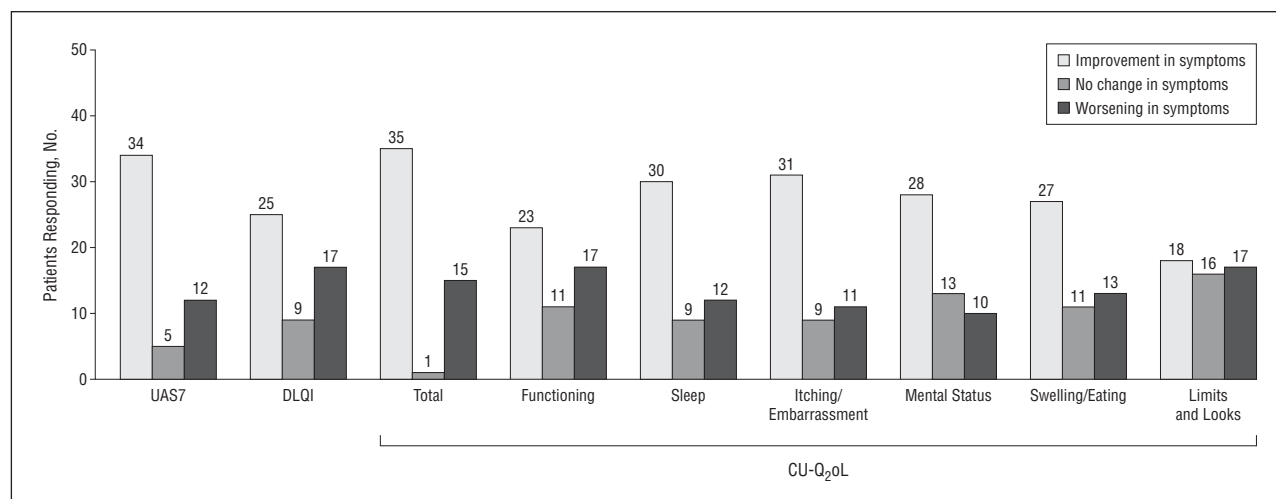


Figure. The number of patients improving or otherwise their Urticaria Activity Score (UAS7), Dermatology Life Quality Index (DLQI), total Chronic Urticaria Quality of Life Questionnaire (CU-QoL), and CU-QoL domain scores following adjustment of therapy. The total number of patients in each column is 51.

DLQI ($r=0.33$; $P=.02$). Of the individual CU-QoL domains, significant correlations with UAS7 were found for functioning ($r=0.31$; $P=.03$), itching/embarrassment ($r=0.54$; $P<.001$), and mental status ($r=0.28$; $P=.048$) domains while those of sleep, swelling/eating, and limits and looks were not.

Comment. The CU-QoL is the first and currently only instrument to assess disease-specific QoL in patients with CSU. The CU-QoL scores detected in this examination are comparable with those of a previous German study⁴ and further support its usefulness. The relatively small improvement of QoL following treatment adjustment mirrors the fact that the disease in the observed patients was already under reasonable control by their previous therapy. It might be considered as a limitation that a spontaneous rather than a treatment-dependent improvement of the disease cannot be fully excluded in this study. However, this does not affect the results on the instruments sensitivity to change.

In conclusion, this study demonstrates that the German version of the CU-QoL is a valid instrument to detect changes in QoL associated with changes in disease activity following changes in therapy and that it is more sensitive in comparison with other, non-disease-specific QoL measures such as the DLQI. Because patient QoL is of paramount importance, we recommend that both the UAS7 and CU-QoL should be used routinely for assessing patient responses to therapy.

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Accepted for Publication: June 20, 2011.

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Financial Disclosure: None reported.

Funding/Support: This study was funded in part by the European Allergy Research Foundation (ECARF; www.ecarf.org) and supported by GA2LEN, the Global Allergy and Asthma European Network (www.ga2len.net).

Additional Contributions: Nikki Rooks, Hesna Goetzluka, and the nurses of the Allergie-Centrum-Charité provided excellent administrative support.

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An Internet-Based Survey and Improvement of Acne Treatment Outcomes

A number of topical agents are effective for the treatment of mild to moderate acne, but patients often do not use their medications as prescribed.¹⁻³ Medication use increases around the time of office visits,⁴ but frequent office visits may not be a practical way to increase compliance. Because adolescents use the Internet regularly, we tested whether a weekly Internet-based communication could improve teenagers' adherence to topical acne therapy.

Methods. This investigator-blinded, randomized, prospective study was approved by the Wake Forest University Health Sciences institutional review board, Winston-Salem, North Carolina. Twenty male and female participants, aged 13 to 18 years, with mild to moderate acne, were prescribed topical benzoyl peroxide, 5% gel, daily for 12 weeks. They were randomized 1:1 to a control group or to an Internet-based survey group; participants in the Internet survey group were sent a weekly e-mail containing a link to a survey assessing their acne severity and treatment. In the survey, the following questions were asked (with potential answer choices):

1. How many days did you apply the drug this week (1-7 times)?
2. How easy was it to use the study drug as prescribed (Very easy; OK; Inconvenient; Very difficult)?
3. Did using the medication interfere with your daily routine (Yes; No)? If Yes, how much (Just another thing to do; Completely interrupted my day)?
4. How useful was the medication in treating your acne (Acne is clear; No change; Acne much worse)?
5. How severe is your acne now (Clear; Mild; Moderate; Severe)?
6. Have you had any side effects (Yes; No)? If yes, what side effect did you experience?

If participants in the Internet survey group completed at least 5 surveys during a 6-week period, they received a \$5 gift card to Amazon.com. In addition, each completed survey provided the participant an additional chance to win an iPod Nano at the study conclusion. Adherence was monitored objectively with electronic monitors that recorded the date and time when the medication containers were opened (medication event monitoring system caps).⁵ Adherence was rated as a percentage of days the medication container was opened; adherence could be greater than 100% if the container was opened more than once per day. Participants were not informed of the monitoring until the last study visit. Their acne severity was also evaluated via Acne Global Assessment as well as by inflammatory and noninflammatory lesion counts at baseline, week 6, and week 12 (end of study).

Results. Of the 20 enrolled participants, 8 from the control group and 7 from the Internet survey group completed the 12-week study (**Figure 1**). Overall adherence ranged from 58% to 132% for the Internet survey group, and from 4% to 80% for the control group. Median adherence was 74% in the Internet group and 32% in the control group ($P < .01$). In the control group, mean adherence dropped rapidly ($P = .02$), but there was no statistically significant change in adherence over time for the Internet survey group ($P = .10$) (**Figure 2**). Within the Internet survey group, there was no significant difference between patient-reported adherence via the Internet survey and adherence measured via medication event monitoring system caps ($P = .11$).

Baseline severity was similar between the 2 groups. While the Internet survey group demonstrated a greater mean percentage reduction of noninflammatory and total lesion counts (44% vs 11% and 36% vs 13%, respectively), this difference was not statistically significant

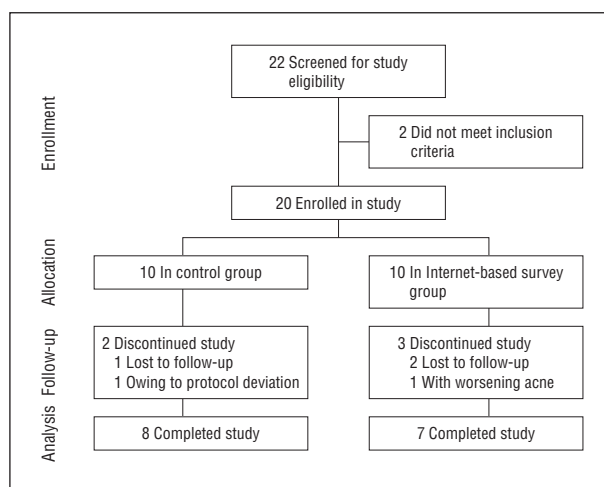


Figure 1. CONSORT flowchart.

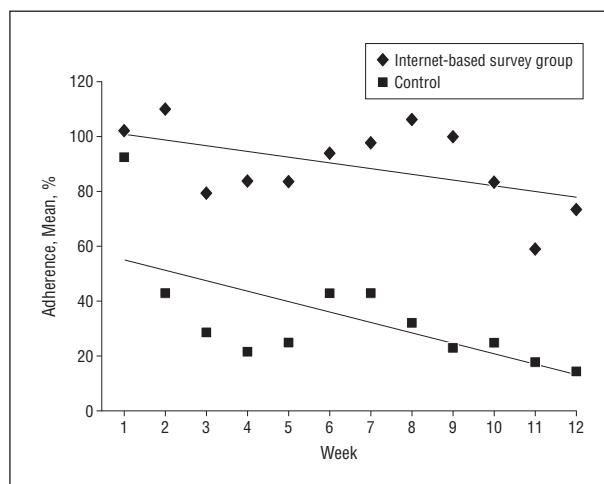


Figure 2. Mean adherence over time. Mean adherence was measured using electronic monitors (medication event monitoring system caps). Adherence was rated as a percentage of days the medication container was opened; adherence could be greater than 100% if the container was opened more than once per day. The group randomized to the Internet-based survey had better adherence to treatment over time. With the exception of week 1, the difference in adherence was statistically significant at all time points (Kruskal-Wallis; $P < .05$).