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Quality of life measurement in urticaria. Position statement of the European Academy of Dermatology and Venereology Task Forces on Quality of Life and Patient Oriented Outcomes and Urticaria and Angioedema

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Urticaria, quality of life, measurement, treatment

Conflict of interest

AYF is joint copyright owner of the DLQI and CDLQI and other quality of life measures. Cardiff University receives royalties from their use. AYF receives a share of these under standard university policy. TZ had grants or contracts from Novartis and Henkel, consulting fees from Bayer Health Care, FAES, Novartis and Henkel, payment or honoraria for lectures or presentations from AstraZeneca, AbbVie, ALK, Almirall, Astellas, Bayer Health Care, Baiersdorf, Bencard, Berlin Chemie, FAES, HAL, Leti, Meda, Menarini, Merck, MSD, Novartis, Pfizer, Sanofi, Stallergenes, Takeda, Teva, UCB, Henkel, Kryolan, L'Oréal. TZ is a member of the board of the German Society for Allergy and Clinical Immunology (DGAKI), Head of the European Centre for Allergy Research Foundation (ECARF) and President of the Global Allergy and Asthma European Network (GA2LEN). AB had ad hoc consultancy, lecturing and travel bursaries from Almirall, Abbvie, Galderma, Lilly, Leo, Janssen, Novartis, UCB, Sanofi and Pfizer. MA received grants, payment or honoraria and consulting fees from companies that manufacture drugs used for the treatment of urticaria including Novartis. JCS received consulting fees from AbbVie, Leo Pharma, Novartis, Pfizer, Sanofi-Genzyme, Trevi, Vifor; honoraria from AbbVie, Almirall, Janssen-Cilag, Eli-Lilly, Leo Pharma, Novartis, Pfizer, Sanofi-Genzyme; support in congress participation (registration fee, accommodation, transportation) from Novartis, Sanofi-Genzyme, Leo Pharma; investigator for AbbVie, Almirall, Amgen,

AnaptysBio, BMS, Boehringer Ingelheim, Celtrion, Galderma, Galapagos, Helm AG, Kliniksa, Incyte, InfraRX, Janssen-Cilag, Leo Pharma, Medimmune, Menlo Therapeutics, Merck, Novartis, Pfizer, Regeneron, UCB, Teva, Trevi. JCS is the President of the Polish Dermatological Society. GBJ had an institutional contract with Abbvie, Novartis, CSLI, Union therapeutics and LEO Pharma; received consulting fees from Novartis, UCB, Boehringer-Ingelheim, Henlez, Union Therapeutics and Sanofi; is a Vice President of the EHSF and Board member of the C3/CHORD. Other authors reported no conflicts of interests.

Data availability statement:

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Abstract

The European Academy of Dermatology and Venereology (EADV) Task Forces on Quality of Life (QoL) and Patient Oriented Outcomes and on Urticaria and Angioedema recommendations for the assessment of Health-related (HR) QoL in all patients with urticaria in research and practice are: to use the DLQI for adults and the CDLQI for children as dermatology-specific and the CU-Q2oL as a disease-specific HRQoL instruments in urticaria; to use generic instruments to provide comparison of data on urticaria with non-dermatologic diseases; to select validated HRQoL instruments with appropriate age limits; to present exact numeric data for HRQoL results, to present the correct title of the HRQoL instrument/s used, its correct abbreviation and a reference to its original publication where possible. The EADV TFs discourage the use of non-validated HRQoL instruments and modified HRQoL instruments that have not undergone standard validation.

Introduction

Chronic urticaria (CU) affects almost 90 million people worldwide.¹ About half of CU patients are refractory to antihistamines and require other treatment options. The distressing itch and sudden

appearance of wheals and/or angioedema make CU a highly burdensome disease. Patients live with a feeling of losing control of their lives and with negative emotions such as self-consciousness, embarrassment and anxiety.² Diminished emotional and physical well-being manifest with sleep difficulties, impairment of sexual functioning, restrictions in social life, sport and leisure activities as well as impaired performance in school and work and a prominent absenteeism.³ Patients with urticaria may experience bullying and its negative consequences because of their disease.⁴ The common association with psychiatric comorbidities such as depression and anxiety in CU patients underlines the importance of assessing patients holistically to address both their physical and mental health needs.⁵

The European Academy of Allergology and Clinical Immunology (EAACI)/ the Global Allergy and Asthma European Network (GA²LEN)/ the European Dermatology Forum (EDF)/ the World Allergy Organization (WAO) guideline for the definition, classification, diagnosis and management of urticaria stated that patients should be assessed for disease activity, impact and control at the first and every follow up visit. Baseline assessment of urticaria activity and Health-Related Quality of Life (HRQoL) are indispensable for guiding treatment decisions, providing better insights into the patients' disease burden, as well as facilitating, improving and standardizing the increasingly important documentation work.⁶

The purpose of this paper organized jointly by the European Academy of Dermatology and Venereology (EADV) Task Force (TF) on Quality of Life (QoL) and Patient Oriented Outcomes and the EADV TF on Urticaria and Angioedema is to present current knowledge about QoL assessment in urticaria, including data on urticaria-specific HRQoL instruments and influence of different treatment methods on HRQoL, and to make practical recommendations concerning the assessment of QoL in people with urticaria.

Methods

Members of the EADV TFs on QoL and Patient Oriented Outcomes and Urticaria and Angioedema were invited to participate. A literature search was performed using the PubMed

database, which was searched from the beginning to January 2024 using the key word combinations: “urticaria, quality of life” (all fields). All publications written in English or those having English abstracts were considered. All those EADV TFs members who volunteered were allocated a section of the identified articles to review.

Exclusion criteria:

- Review articles, guidelines, protocols
- Studies without HRQoL assessment
- Measurement of HRQoL in conditions other than urticaria
- Studies where HRQoL was studied in urticaria and other diseases but results on urticaria were not presented and/or discussed separately

All publications were independently assessed by two co-authors based on selected exclusion criteria. The assessments were compared and discrepancies discussed and resolved. The remaining publications were analyzed in detail and the results are presented below. Position statements were formed and accepted by voting of all authors.

Results

From the 1309 articles identified in the literature search, 1025 were excluded based on the exclusion criteria, leaving 284 publications for the further analysis.^{2,3,7-288}

Instruments used to assess HRQoL impairment in urticaria

HRQoL of patients with urticaria was measured by generic, dermatology-specific and disease-specific instruments. Instruments that were used in more than one study are presented in Figure

1. The following instruments were used in one study each: Nottingham Health Profile,² Satisfaction Profile,¹² a quality of life index designed by Lamy (7th revision),¹⁵ Children's Life Quality Index,²⁴ Short Form-6D,¹³³ Quality of Life Instrument for Turkish People with Skin Diseases,¹⁷ ItchyQoL,²⁶⁴ Family Dermatology Life Quality Index²⁴¹ and Chronic Urticaria

Patient Perspective.¹²² The Dermatology Life Quality Index (DLQI) was the most frequently used HRQoL instrument. It was used in studies on urticaria performed in at least 33 different countries. The DLQI scores from the studies included are presented in Supplementary Table 1. The Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) was the second most frequently used instrument. This urticaria-specific instrument has also been translated into different languages and used in studies performed in different countries. The CU-Q2oL scores from the studies included are presented in Supplementary Table 2. Detailed characteristics of identified urticaria-specific instruments are presented in Table 1. Modified versions of the DLQI were used in seven studies.^{16,25,35,36,47,66,110} In one study a single DLQI item was used to collect information on sexual impact of skin diseases, including urticaria.¹⁴⁰ A modified version of the CU-Q2oL was used in one study.⁵⁸ A single subscale of the SF-36 Health Survey was used in one clinical trial.¹¹ Study-specific questionnaires, with limited or no validation, with item(s) related to the QoL of patients with urticaria were used in four studies.^{2,74,76,129} A single question on QoL was used in two studies.^{30,265} A visual analogue scale rated from 0 to 10 was also used to measure QoL in one clinical trial on urticaria.¹¹

Correlation between HRQoL impairment and urticaria severity

Urticaria Activity Score (UAS) values significantly correlated with DLQI and CU-Q2oL scores with moderate to high levels of correlation.^{42,71,78,84,86,102,109,127,177,188,273} In one study where HRQoL of patients with urticaria was measured by the CU-Q2oL and EQ-5D and disease severity by the UAS almost all of the correlations with the CU-Q2oL were statistically significant both between summary scores and at the level of individual dimensions, and correlation coefficients were higher than those with the generic EQ-5D.¹⁸⁰ UAS7 scores also correlated with HRQoL impairment in children with urticaria measured by the CDLQI.¹⁰⁶ The Urticaria Severity Score showed significant correlation with the DLQI.⁵²

Assessment of HRQoL changes in urticaria clinical trials

Placebo-controlled clinical trials

Antihistamines,^{8,16,25,28,31,33,39,51,95,113} omalizumab,^{120,123,124} rilonacept²⁷² and hydroxychloroquine¹⁴⁵ showed significantly better effect on patients' HRQoL than placebo.

Controlled (two/three arms) clinical trials

Different antihistamines showed improvement of HRQoL without significant differences between agents.^{41,57,62,87,89,196,226} Combined treatment with antihistamines and montelukast led to additional HRQoL improvement.¹³⁸ Omalizumab showed better effects than ciclosporin.⁹⁶

Open label studies

Antihistamines,^{21,23,36,68,93,107,114,144,183,211} omalizumab,^{40,104,121,135,160,166,167,179,195,214,248,273} barzolvolimab,²³⁷ ligelizumab,²⁵⁶ intravenous immunoglobulins,⁸⁸ and narrow-band ultraviolet B phototherapy⁷⁶ resulted in significant improvement of patients' HRQoL.

There were multiple trials of “alternative” treatment methods of different quality.

Gender differences of HRQoL impairment in urticaria

There was no statistically significant difference between the mean total DLQI score of male and female patients in several studies.^{32,205,214} There were no significant differences between men and women in Skindex-29 total score, symptoms and emotions domains, whereas there was a significant difference found in the function domain.¹¹⁹ In a study of CU, sleep was more affected in females than in males, especially with difficulty in falling asleep, but there were no differences between males and females in other parameters.⁵⁸ Female gender was associated with higher quimp compared to male gender in several studies.^{53,194,260,264} In one study of CU from Nepal, the mean DLQI scores of men were higher than of women.¹⁸⁶ The family QoL scores of co-habitants measured by the FDLQI were found to be not associated with the cohabitants' gender.²⁴¹

HRQoL impairment in children with urticaria

HRQoL in children with urticaria was most frequently measured by using the CDLQI.^{24,95,106,152,239,268} In one study the dermatology-specific measure, the CDLQI, was used in parallel with the generic CLQI.²⁴ In one clinical trial authors reported that they had studied HRQoL in children with urticaria using the DLQI (also called “DLQ” and “DQLI”): however the adult DLQI is not validated for use in children.²²² In another study adolescents answered some study-specific HRQoL-related questions (“How does your CIU affect your life, in general?” and “Does it bother you to have this condition? How?”).⁷⁴ CU-Q2oL was used in 7-17 years old children despite it not being validated for use in this age group.¹⁶⁹

COVID-19 and HRQoL impairment in urticaria

The CU-Q2oL median score in patients with new-onset chronic spontaneous urticaria after COVID-19 vaccination was 62 (range: 43-72).²⁸⁸

Discussion

Urticaria significantly decreases patients’ HRQoL. The EAACI/GA²LEN/EDF/WAO guideline⁴ and British Association of Dermatologists guidelines²⁸⁹ recommend regular assessment of the impact of urticaria. The DLQI and the CU-Q2oL are the most widely used HRQoL instruments to measure impact of urticaria on patients’ lives. There are many validated different language versions of the DLQI (>140 translations) and the CU-Q2oL questionnaires. The DLQI was used in 20 randomised clinical trials of urticaria.²⁹⁰ There is an established score descriptors banding system for the interpretation of DLQI scores.²⁹¹ The ability to use a measure that has a validated system to interpret scores and has a known Minimal Clinical Important Difference (MCID) are important aspects when choosing which HRQoL instrument to use.²⁹² The EAACI/GA²LEN/EDF/WAO guideline considers that determination of MCIDs for instruments that assess disease activity or impact in urticaria is of high importance.⁶ There are MCIDs for the

DLQI²⁹³ and for the Thai national version of the CU-Q2oL.¹⁰³ In order for QoL measurement to be carried out routinely in a busy clinic, it is essential that the measure used be short, easy to understand, able to be completed unaided and have a simple method of scoring.²⁹⁴ Both patients and dermatologists prefer brief instruments, and a short time needed for completion is crucial.²⁹⁵ Therefore the Chronic Urticaria Patient Perspective (“CUPP”),¹²² a shortened 10-items version of the urticaria-specific CU-Q2oL may be of practical importance. However, there is no information concerning its use. There is only one published study on the use of the CholU-QoL,²⁵⁰ a measure that is specific for cholinergic urticaria in addition to the study on its development.¹⁴⁹ The CU-QoL was developed especially for Korean patients with urticaria²⁹⁶ and has been used in clinical studies from Korea. In general, instruments developed for specific countries may have some benefits reflecting specific regional interests and traditions but their use limits the possibility of comparing the results with studies from other countries.²⁹⁷ The DLQI and CU-Q2oL scores presented in Supplementary Tables 1 and 2 show score differences between countries and between different studies in the same country. It was previously shown that the impact of separate HRQoL items or domains may not be identical even in neighboring countries.²⁹⁸ However, in most studies on urticaria patients from different countries experienced a moderate or very large effect on their life quality, according to the DLQI score descriptors. Not surprisingly, selected groups of patients, for example those refractory to antihistamines and hence candidates for omalizumab treatment, experienced an extremely large effect on their lives. In a reflection of the impact of effective therapy, in one clinical trial from India comparing loratadine with rupatadine, patients had baseline mean DLQI scores of 2 and almost zero after the treatment.²²⁶

Overall, HRQoL instruments have been frequently used as outcome measures in clinical trials on urticaria. Antihistamines and omalizumab resulted in a better effect than placebo on the HRQoL of patients with urticaria. However, there was no clear preference of one antihistamine over another. Unfortunately, many studies had open and uncontrolled designs and often too few

patients were included. The number of patients included in trials with QoL assessment is often low, which could lead to not obtaining scientifically relevant data in some clinical trials, even though they manage to demonstrate statistically significant differences in favor of a selected product or technology.²⁹⁹

Several studies used the DLQI MCID and a DLQI total score of 0-1, corresponding to ‘no effect on patient’s life’, to evaluate the efficacy of different treatments. Modern drugs make it possible to achieve ‘no effect on patient’s life’ according to the DLQI banding descriptions for many patients, at least for some of the time. In several reports of clinical trials no exact numeric data for the scores of the HRQoL instruments used were presented. This is especially inopportune for HRQoL instruments with established values for severity bandings and MCID (e.g. the DLQI), as the scores cannot be interpreted using these unless the exact numeric scores are given. Therefore the EADV TFs encourage authors to always present the exact numeric data for HRQoL data.

A comparative study with non-dermatologic diseases showed that HRQoL in patients with urticaria was more impaired compared to patients with post-myocardial infarction or with diabetes.¹⁹¹ Urticaria in children had a similar QoL impact to that of asthma and psoriasis.²⁴ However, for the most reliable comparison patients with different diseases should be matched at least by disease severity, and patient age and sex.³⁰⁰

As in many other skin diseases,³⁰¹⁻³⁰⁵ studies in urticaria showed either no gender differences or more severe impact in females. The higher DLQI scores of male Nepalese patients in one study may reflect distinct regional cultural attitudes.¹⁸⁶ Similarly, a greater impact of acne on male patients than on female patients was reported in only a single study, and other studies showed no differences or a higher impact on female patients.³⁰¹ The family QoL scores of cohabitants of patients with urticaria were not associated with the cohabitants’ gender.²⁴¹ In the same way no significant differences were previously found between mothers’ and fathers’ assessment of family impact measured by another family QoL instrument – the atopic dermatitis-specific Dermatitis Family Impact questionnaire.³⁰⁶

In most studies the HRQoL of children with urticaria was measured using the CDLQI, that was designed to measure the impact of any skin disease on the lives of children.³⁰⁷ The CDLQI is also in general the most frequently used dermatology-specific HRQoL instrument for children. Many translations of this questionnaire are available.²⁹⁷ CDLQI score meaning bands have been proposed.³⁰⁸ The mean CDLQI scores in children with urticaria correspond to a “small effect” on patient’s HRQoL,^{24,239} excepting those patient groups who are eligible for distinct types of therapy (e.g. omalizumab). Despite the similar structures of the CDLQI and the DLQI questionnaire it is inappropriate to combine the results of these instruments because they have different questions specific to the different age groups for which the questionnaires are designed, and the score band descriptors are not identical.³⁰⁹

The EADV TFs strongly recommend that for use in clinical research studies, HRQoL questionnaires with appropriate age limits be selected. The CDLQI has been validated for children from the age of four years to 16 years. For younger children the dermatology-specific proxy instrument the Infants and Toddlers Dermatology Quality of Life (InToDermQoL) and its epidermolysis bullosa-specific module have been developed and validated.³¹⁰⁻³¹² Score meanings and the MCID for the InToDermQoL have been described.^{313,314} In children older than one year but younger than three years, the mean total InToDermQoL score in urticaria was much lower than in epidermolysis bullosa, allergic dermatitis and diaper dermatitis but higher than in molluscum contagiosum and pigmented nevi. In children with urticaria older than three years, the mean total InToDermQoL score was higher than in alopecia and molluscum contagiosum, similar to that in atopic dermatitis but lower than in epidermolysis bullosa. The HRQoL impairment scores in children with urticaria in that study, in which only ten patients with urticaria were included,³¹² correspond to a mild effect on patients’ HRQoL, according to the proposed score bands of the InToDermQoL questionnaire.³¹³ There is a lack of data on QoL impairment in young children with urticaria. The EADV TF on QoL and Patient Oriented Outcomes therefore has initiated an international study to measure HRQoL in young children

with urticaria and invites interested professional groups and pediatric dermatologists to join this activity. Information on how to get access to the most frequently used HRQoL instruments for adults with urticaria and dermatology-specific HRQoL instruments for children, together with information on their sensitivity to change, availability of score meaning descriptors, MCIDs and different language versions are presented in Table 2.

COVID-19 can trigger the onset of acute urticaria, the exacerbation of chronic urticaria and vaccination against SARS-CoV-2 can also lead to new onset urticaria as well as worsening of chronic urticaria in a minority of subjects.³¹⁵ Significant impairment of HRQoL, with high CU-Q2oL scores, was reported in patients with new-onset of chronic spontaneous urticaria after COVID-19 vaccination.²⁸⁸ It is generally considered that active management of symptomatic urticaria before vaccination and informing patients about the low recurrence rate may facilitate the safe completion of the vaccination program for patients with urticaria.³¹⁶ Clear and concise recommendations, as were developed for patients with atopic dermatitis,³¹⁷⁻³¹⁹ may decrease the negative psychologic impact over these concerns and thereby increase adherence to vaccination.

In several studies incorrect titles and abbreviations for the DLQI and in particular for the CU-Q2oL were used. It is especially confusing when in some publications authors used the abbreviation “CU-QoL” for the CU-Q2oL questionnaire because the abbreviation “CU-QoL” is attributed to another urticaria-specific HRQoL instrument, the Chronic Urticaria-Specific Quality of Life Scale developed for Korean patients with urticaria.²⁹⁶ This may lead to misinterpretation of HRQoL results quoted in publications. The EADV TFs recommend that the correct title of any HRQoL instrument should be used, along with its correct abbreviation and the reference to its original publication, where possible. It is important to select validated HRQoL instruments which have been validated for the age range of the subjects studied.

QoL assessment in dermatology is a rapidly developing field with a gradual shift from theory to research use and finally to routine clinical practice.²⁹⁵ Many ways in which HRQoL data can be

useful to enhance the quality of patient care in dermatologic practice have been identified.³²⁰ It is possible to find more information on HRQoL assessment in skin diseases in other publications of the EADV TF on QoL and Patient Oriented Outcomes.^{301-305,320-332} Research priorities for future studies are presented in Table 3. The list of TFs' statements is presented in Table 4. All authors voted for each of these statements.

The main statements

The EADV Task Forces recommend that HRQoL is assessed in patients with urticaria in clinical research and in routine clinical practice.

The EADV Task Forces recommend the use of the dermatology-specific DLQI for adults and the CDLQI for children and the disease-specific CU-Q2oL as HRQoL instruments in urticaria.

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Table 1. Detailed characteristics of identified urticaria-specific instruments

Table 2. Information on how to get access to the most frequently used HRQoL instruments for adults with urticaria and dermatology-specific HRQoL instruments for children together with

information on their sensitivity to change, availability of score meaning descriptors, MCIDs and different language versions

Table 3. Research priorities for future studies

Table 4. TFs’ statements

Figure 1. The frequency of use of HRQoL instruments in publications describing urticaria research

Supplementary Table 1. DLQI scores identified from included studies

Supplementary Table 2. CU-Q2oL scores identified from included studies