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Review Article

Role of patient-reported outcome measures in the management of chronic urticaria and angioedema

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ABSTRACT

Due to the lack of reliable biomarkers, patient-reported outcome measures (PROMs) have a crucial role in assessing and monitoring the progression of chronic urticaria (CU) and angioedema (AE). PROMs are described as "any report coming directly from subjects without interpretation of the physician or others about how they function overall or feel in relation to a condition and its therapy." There are four urticaria-specific PROMs, namely, urticaria activity score (UAS), urticaria control test (UCT), CU quality of life (QoL) questionnaire, and urticaria severity score. UAS7 is the most widely used, simple, and validated scoring system to estimate disease activity in chronic spontaneous urticaria cases. UCT on the other hand is a retrospective assessment of the current control of the disease after initiation of the treatment. The current EAACI/GA²LEN/EuroGuiDerm/APAAACI international urticaria guidelines suggest the use of UCT for stepping up or stepping down in the treatment of urticaria. Similarly, the severity and control of AE can be assessed by two PROMs, namely, AE activity score and AE QoL questionnaire.

Keywords: Patient-reported outcome measures, Chronic urticaria, Urticaria activity score, UAS7 score, Urticaria control test

INTRODUCTION

Urticaria is a cutaneous condition that causes pruritus and wheals and may also have associated angioedema (AE). Daily or near-daily wheals and pruritus for 6 weeks or longer constitute chronic urticaria (CU). AE episodes are reported by 40% of chronic spontaneous urticaria (CSU) patients, while only 10% of people with CSU have AE as their first symptom.[1] Up to 1% of people have CU, and usually, lesions develop spontaneously without a clear external reason.[2] CSU is the most common type of CU affecting 66–93% of the cases. Urticaria is a common disorder, with a lifetime prevalence of 7.8–22.3% and a point prevalence of 0.5–1.0%. Physical urticaria is said to occur in 4–33% of patients and cholinergic urticaria in 1–7% of cases. The precise prevalence in India is unknown.[3]

Patient-reported outcome measures (PROMs) have played a crucial role in diagnosing and tracking the various aspects of CU such as the severity and progression of illness, the management of symptoms, and the quality of life (QoL) due to the absence of dependable biomarkers to monitor the condition. They are defined as "any report coming directly from subjects without interpretation of the physician or others about how they function overall or feel in relation to a condition and its therapy."[4] Unsurprisingly, PROMs have also been employed in the management of CU. This review aims to highlight the current unmet clinical needs and offer an overview of the PROMs utilized in CU.

PROMs IN CLINICAL PRACTICE

As of now, six different PROMs are routinely employed in clinical practice and research methodology to measure the different aspects of CU and AE. Four of these PROMs specifically target urticaria:

1. Urticaria activity score (UAS)
2. Urticaria control test (UCT)
3. CU QoL questionnaire (CU-Q2oL)
4. Urticaria severity score (USS).

The other two PROMs are specific to AE:

1. AE activity score (AAS)
2. AE QoL questionnaire (AE-QoL).

UAS7

The UAS7, which happens to be the current, standardized prospective patient-reported measure, is a simple and validated scoring system to estimate disease activity in CSU cases. It has two parts: The number of wheals (0: none–3: >50)

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and the severity of the itch (0: none–3: severe). Patients are needed to record every 24 h, and the total data yields a daily UAS score of 0–6 [Table 1]. The aggregate score over a weeklong period (range 0–42) is seen as an acceptable indicator of CSU activity. Although UAS7 cutoff values have not yet been established, a score of 0 denotes a complete lack of wheals and itch, while a score of 6 denotes the minimal degree of disease activity. According to the suggested cutoff values, minor illness activity is indicated by a UAS7 score of 7–15; moderate disease activity is indicated by a UAS7 score of 16–27; and severe disease activity is indicated by a UAS7 score of 28–42.[5]

UCT

The UCT is a 4-item retrospective (last 4 weeks) tool that measures the intensity of the medical manifestations of CSU and their impact on patient's QoL, the frequency of therapy inadequacy to manage the symptoms, and the degree to which the medical complaints were controlled. The ultimate goal of developing the UCT was to ascertain the symptom management status in every kind of CSU. Answers are given a score between 0 and 4, with a total score between 0 and 16 denoting complete control. A UCT score of 11 or less denotes insufficient illness control, while a score of 12 or more denotes effectively managed CSU.[6]

CU-Q2oL

The CU-Q2oL is a 23-question survey designed specifically for CSU patients that cover a variety of characteristics of how the condition affects their daily lives. It includes questions on itching, swelling, activities of normal day-to-day living, the period of rest, visible external attributes, and limits.[7] A greater decrease in QoL associated with the health aspect is reflected by a higher CU-Q2oL score. Scores range from 23 to 115. This questionnaire which provides more details on aspects pertinent to CSU is a useful tool for documenting and analyzing changes in CSU QoL over time and/or in response to therapies.

Table 1: Urticaria activity score once-daily version: daily scoring for itch and hives.

Itch severity score	Itch severity	Hive severity score	Number of hives per 24 hours
0	None	0	None
1	Mild (present but not annoying or troublesome)	1	<20
2	Moderate (troublesome but does not interfere with normal daily activity or sleep)	2	20-50
3	Intense (interferes with normal daily activity or sleep)	3	>50

Condition-specific QoL takes into account the perception of the affected individual on the physiological repercussions of the disease and the treatment modalities. This subjective tool is now fundamental in the assessment of, particularly, chronic diseases such as CSU and serves to compare treatments. QoL questionnaires can be used to gauge and monitor changes in several parameters including emotional changes; this is unlike symptom scoring. Given the extremely low fatality rate and unpredictable nature of CSU episodes, the management of disease control must place a high priority on the QoL. The impact of various illnesses can be examined using the general QoL questionnaires, allowing for some cross-population comparison.

USS

The USS is a PROM that uses 12 specific questions to assess the patient's QoL, the severity of the urticaria, and the treatment's overall effectiveness.[8] The Likert intensity scale, varying from 0 to 7, is used in the grading of 10 questions: 0 corresponding to the absence of symptoms, impairment of QoL, medication, and 7 corresponding to the very strong manifestation of symptoms, QoL impairment, and high medication use. The remaining two questions are used to determine the amount of surface area of the body that is affected, using a scoring range from 0 to 8 to correspond to the increased surface area of the body affected by CU. The scoring for the question about oral corticosteroid use is multiplied by two as it is considered to have a significant correlation to increased disease activity. The final score comes out to be in the range of 0–93; the higher the score, the higher the impact on the patient's QoL and disease severity.

AAS

The AAS was developed for all types of AE cases, including those with recurrent AE associated with CU and those with bradykinin-mediated recurrent AE, like hereditary AE. It is the first standardized, symptom-specific PROM for assessing disease activity in AE. It is a five-item tool where the main question is if AE had occurred within the past 24 h. If the response to that question is affirmative, further, inquiries should be made on the degree of physical discomfort, functional capacity, esthetic effect, and the general evaluation of the seriousness of the disease.[9] The point value assigned to each element ranges from 0 (none) to 3 (severe). As a consequence, the scores obtained on the AAS may vary anywhere from 0 to 15 (for the AAS score on a daily basis), 0–105 (daily AAS score), 0–105 (over a period of 7 days), and 0–420 (AAS28) [Table 2].

AE-QoL

The AE-QoL is the first validated 17-item questionnaire aimed at measuring the consequences of AE on health-related QoL (HRQoL) from the patient's perspective. The 17

Table 2 : Angioedema activity score.

Score	Dimension	Answer options
-	Have you had a swelling episode in the past 24 h?	No, yes
0–3	At what time (s) of the day was this swelling episode (s) present? (please select all applicable times)	Midnight–8 am, 8 am–4 pm, 4 pm–midnight
0–3	How severe is/was the physical discomfort caused by this swelling episode (s) (e.g.: Pain, burning, itching?)	No discomfort, slight discomfort, moderate discomfort, severe discomfort
0–3	Are you able to perform your daily activities during this swelling episode (s)?	No restriction, slight restriction, severe restriction, no activities possible
0–3	Do/did you feel your appearance is/was adversely affected by this swelling episode (s)?	No, slightly moderate, severely
0–3	How would you rate the severity of this swelling episode?	Negligible, mild, moderate, and severe

items cover 4 spheres related to the impact of AE which is functioning, fatigue/mood, fears/shame, and food.[10] There is a wide range of possible values, from 0 to 85. A higher score indicates a stronger disturbance in QoL. It seeks to present a thorough understanding of how recurrent AE affects several aspects of one's HRQoL.

THE ADVANTAGES OF PROM

CSU happens to be a debilitating skin condition characterized by the absence of reliable biomarkers to appropriately gauge the progression of the disease. PROMs are excellent and validated prognostic markers for the proper assessment of treatment progression and disease severity. In fact, the EAACI/GA²LEN/EuroGuiDerm/APAAACI international urticaria guidelines recommend the usage of UCT to ascertain the requirements of patients, modifying the treatment algorithm in accordance with the result of complete symptom control through pharmacological agents [Figure 1]. Therefore, PROMs assist clinicians in the accurate assessment of symptom severity of CSU as the patients evaluate and score themselves.[1]

Furthermore, the PROMs happen to be convenient, effective, and robust tools for measuring QoL, and as they are self-administered, the disease progression and impact on patients' QoL can be documented outside clinic visits, and hence lead to a reduction of overall clinic costs.

Application of PROM in clinical trials and studies

The inherently fluctuating nature of the symptoms accompanying CU provides a major roadblock for doctors to ascertain the degree of severity to which the illness presented itself in the clinical setting. Certain factors like autoimmunity play a key, predictive role in the therapeutic management of CSU in patients. In fact, a 6-month prospective trial for omalizumab conducted among 117 patients with CSU in Denmark found a mean baseline improvement of UA7 scores from 29.3 to 11.9 after a 3-month interval indicating the efficacy of treatment.[11]

Ever since the establishment of a validated scorer of the likes of the UAS, it has been used, since then, in several studies based on the efficacy of the medicines used for CSU.[12]

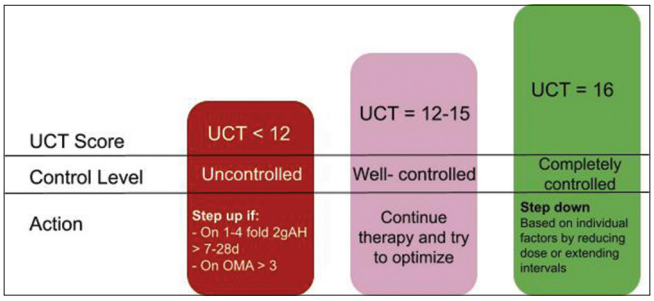

Figure 1: EAACI/GA²LEN/EuroGuiDerm/APAAACI international urticaria guidelines recommend the usage of urticaria control test for stepping up or stepping down in the management of urticaria. 2gAH: 2nd generation H1-antihistamine, OMA: Omalizumab.

Patients who had a UAS7 score of <16 at baseline were frequently included in omalizumab randomized controlled trials.[13-16] At week 12, 52% of the patients had a UAS7 score below 6, and 36% of the patients had a complete response (UAS7 = 0), according to Saini *et al*.[13] Likewise, 336 CSU patients with a UAS7 score of <16 were included in a study by Kaplan *et al*.[14] The study had also involved the same number of patients with a UAS7 score above or equal to 16. After starting treatment, 34% of the individuals in the omalizumab group had achieved a UAS7 score of 0 as opposed to only 5% in the placebo group.[14] Following the failure of first-line treatment with antihistamines, a second randomized controlled trial involved 49 CSU patients who had immunoglobulin E (IgE) autoantibodies toward Thyroid peroxidase (TPO) and a UAS7 score of more than 10.

Patients receiving omalizumab at week 24 reported a drop in UAS7 score from baseline of 17.8 points as opposed to a reduction of 7.9 points in the placebo group.[15,16]

AWARE was a multi-centric and non-interventional study conducted across several continents that aimed to observe the efficacy of different diagnostic approaches to CSU, and PROMs served to be an important prognostic marker as the appropriate therapy leads to a sustained improvement in the QoL.[17]

In an Indian study, 48 individuals with CU who experienced symptoms every day had their QoL evaluated using the CU-Q2oL.[18] The study discovered that sleep disruption,

influence on daily activities, restrictions, and appearance were all affected, although to a lesser degree, than the category of physical symptoms. All in all, the study demonstrated the utility of regular application of CU-Q2oL to evaluate baseline QoL impairment and treatment outcomes, both during first and follow-up visits.

Availability of PROMs in apps

Applications developed for chronicling the daily symptoms, disease control, and regular assessments of QoL of CSU patients are highly desirable. They can help in determining the important triggers (such as stress, temperature changes, and infections), as well as the effects on everyday life (such as poor sleep, missed work or school, and other comorbidities). Moreover, apps tracking individual issues and day-to-day conditions can greatly assist the physician in formulating the optimal treatment plan. Many patients, especially those with a higher educational degree, have expressed their eagerness to avail of communication technologies and apps to keep track of their disease as well as interact daily with their physicians, as demonstrated by this UCARE CURCIT analysis study.[19] Yet, a recent study done by Antó *et al*. demonstrated a global lack of such apps for patients with CSU.[20] This study conducted both automatic and manual searches to discover five apps for CU self-evaluation which are as follows: TARGET My Hives, UrCare, UrticariApp, and SymTrac™ HIVES. However, only two allowed for the documentation of triggers, and three allowed for the input of medications used. None of the five covered comorbidities or provided individualized advice.

This reveals a dearth of availability of CU-driven apps on iOS and Android platforms for patients.

Impact of the pandemic on CSU

The COVID-19 pandemic has been a major cause of disturbance in the health-care system and patient welfare. Patients and their physicians have fallen victim to the disruptions due to travel restrictions, lockdowns, and changing management patterns in addition to the psychological aspect of dealing with the pandemic. A study conducted in 110 health-care centers reported a more than 50% decrease in CU patients visiting for treatment, with more consultations being done online than face-to-face. They also reported a CU exacerbation in one in three patients suffering from COVID-19.[21] A study in Turkey reported markedly higher disease activity in male CSU patients as compared to female ones.[19]

Another Turkish study successfully used PROMs for the evaluation of changes in disease activity during the pandemic period. The mean UAS7 was 7.5 ± 10.2 before the pandemic and 8.5 ± 11.2 during the pandemic indicating a slightly higher disease activity. The mean UCT score during the pandemic was found to be 11.0 ± 3.7.[20]

Limitations of PROMS

The major limitation of all PROMs is the absence of properly validated questionnaires designed specifically for children and adolescents.[22] Till now, generic tools like the CDLQI are utilized for measuring disease activity in this age group.[23] Information regarding prevalence could perhaps be gathered with the help of school-based programs because childhood CSU cases seldom appear before specialists and tend to be handled by general physicians at home. CSU questionnaires, specifically those targeting the pediatric population and adolescents, need to be designed in the quest to begin clinical investigations.

Although UAS7 has emerged as the gold standard to evaluate disease progression routinely, it presents its own set of issues. As it is a prospective tool, it poses the inherent problem of assessing CSU activity when the physician encounters a CSU patient for the 1st time. The UAS7 scoring also depends on patients themselves as they need to complete it every day, without fail until their next appointment. Furthermore, even though AE and chronic inducible urticaria (CIndU) subtypes of urticaria are associated with CSU in many patients, they are not included in the scoring.[7] To address these apparent limitations of the UAS, the UCT came to be developed. The major benefit of the UCT happens to be its retrospective nature which renders it totally distinct from any past interactions with patients, and the relative ease of completion for patients and physicians alike. The ideal practice in the clinical setting will be to combine these two questionnaires in CU patients, as they focus on entirely different aspects, and hence, it will offer the physician a more complete picture of the disease's activity as well as the measures to manage it.

Certain areas of CSU exist, which are improperly covered by current scoring systems, such as stress and other emotional factors. Stress happens to play a significant role in disease activity and progression of CSU as demonstrated by a pilot study that tried an innovative approach of implementing a complete treatment program, including the psychological aspect. About 75% of the patients who had reported being unaffected by standard therapy demonstrated significant improvement with next to no disease activity as opposed to pre-treatment scores. This provided support for the idea that there is a relationship between psychological variables and the manifestation of sickness.[24]

The AEQoL, although being utilized regularly in clinical studies, has a slightly elevated respondent burden along with a complicated method and interpretation of score computation.[22]

The CUQoL, despite serving as an excellent tool, is flawed in the sense that it takes longer and more effort to calculate its scores. Furthermore, it excludes the commonly seen influence of AE on the QoL.[25] Due to this, people diagnosed with AE are often barred from participating in clinical

Table 3 : Advantages and disadvantages of the PROMs.

PROMs	Advantages	Disadvantages
UAS	• Validated and reliable • Easy to understand.	• Not suitable for CIndU.
UCT	• Standardized and quantitative assessment of disease control • Simple and easy-to-administer tool, hence very useful in clinical research • Evaluate the effectiveness of treatment interventions and monitor changes in disease control over time.	• Cultural and language differences may influence the results • May not capture fluctuations in disease control between assessments • May not capture other aspects of urticaria, such as QoL or specific symptoms.
Cu-Q2oL	• Accurately assesses the impact of CU on patients' QoL • Tracks changes in QoL over time. • Accurately evaluates the effectiveness of interventions and treatments • Covers a broad range of physical, emotional, and social aspects, providing a comprehensive evaluation.	• Only applicable for CSU and not suitable for CIndU • Validated for adults • Lack of categorization of severity • Lack of specific questions about the impact of AE.
AE-QoL	• Provides specific and targeted assessment of the impact of AE on the QoL of patients. • Identifies and quantifies the burden of AE beyond the clinical symptoms, leading to a more holistic approach to patient care. • Evaluates the effectiveness of interventions and treatments in improving patients' QoL.	• Relies on self-reporting which may introduce subjective biases and variations • May not be sensitive to subtle changes in QoL over time • Limited to the specific domains covered by the questionnaire • It may not be representative of all areas of one's QoL that are impacted by AE.
AAS	• Provides a standardized approach to treatment • Enables longitudinal monitoring of disease progression and treatment effectiveness by tracking the frequency and duration of AE attacks • The structured framework contributes to the systematic collection of data useful for research purposes.	• Does not account for variations in the etiology or specific triggers of AE • Solely measures the frequency and length of AE episodes and may not completely reflect the complete range of symptoms or the effect on the patient's QoL. • Results may be affected by individual interpretation and recall bias.

RROMs: Patient-reported outcome measures, UAS: Urticaria activity score, UCT: Urticaria control test, Cu-Q2oL: Chronic urticaria quality of life questionnaire, AE-QoL: Angioedema quality of life questionnaire, AAS: Angioedema activity score, AE: Angioedema, QoL: Quality of life

studies. To account for the more accurate assessment of AE in CSU patients, there is a regular use of the AE-QoL in clinical practice and other studies.

Even though several validation studies exist for other languages, studies are yet to be published in Indian languages and this becomes a major challenge for physicians residing in the Indian subcontinent to interact with patients, especially those who are not conversant in English [Table 3].

CONCLUSION

PROMs have emerged as significantly valuable tools in the assessment of patient-condition for various diseases and conditions, including in the management of CU. These various instruments can serve as a major boost to monitor progress or deterioration, in the conditions of patients with CU and can hence be used for comprehensive treatment or management. The application of PROMs could also be extended beyond the traditional setting of a health-care facility. In fact, they can also make access to doctors easier for CU patients; PROMs can function through smartphone apps and computer programs to facilitate the consultation process between a patient and a physician electronically without the need for a face-to-face meeting.

While, presently, international guidelines do exist, the treatment and scoring of urticaria are still somewhat heterogeneous. It is therefore imperative to bring diagnostic and therapeutic approaches in sync with each other for the exhaustive management of CU.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

Dr. Aarti Sarda, Dr. Abhishek De, Sandipan Dhar are on the editorial board of the Journal.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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