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ORIGINAL ARTICLE

CLINICO-EPIDEMIOLOGICAL PROFILE AND ASSESSMENT OF QUALITY OF LIFE OF PATIENTS WITH CHRONIC SPONTANEOUS URTICARIA FROM TERTIARY CARE HOSPITAL: A CROSS-SECTIONAL STUDY

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Abstract. *Urticaria is a severely pruritic and debilitating skin disorder having a profound impact on the quality of life. It can be classified as acute and chronic, which can be further classified as chronic spontaneous (CSU) and chronic inducible urticaria (CIndU). There is a notable scarcity of studies investigating the clinico-epidemiological profile of CSU and its impact on the quality of life.* ***Objectives:*** *This study was designed to investigate the clinico-epidemiological profile of patients with CSU, evaluate the severity of CSU using the urticaria activity score (UAS) and determine the impact of the illness on the quality of life using the dermatological quality of life index (DLQI).* ***Materials and Methods:*** *This observational cross-sectional study was conducted at the Department of Dermatology of a tertiary care hospital over a period of 1 year and included 120 patients with CSU. All data was collected using a pre-structured proforma.* ***Results:*** *The average age of the patients was 39.43 ± 12.26 years. 42 (35%) patients were males and 78 (65%) – females. The disease duration at presentation ranged from 2-120 months (mean of 17.76 ± 18.25). Hypertension and diabetes mellitus were the most prevalent comorbidities followed by hypothyroidism, depression, hyperthyroidism and bronchial asthma. Angio-edema was seen in 22 (18.33%) whereas atopy was associated in 18 patients (15.00%). The average UAS7 was 28.87 ± 7.26. Out of 120 patients, 46 (38.33%) were of moderate urticaria (UAS7 16-27) and 74 (61.67%) – severe urticaria (UAS7 28-42). Higher mean age at presentation (41.95 vs 35.39 years), higher proportion of females (66.21 vs 63.04%), longer disease duration at presentation (18.09 vs 17.22 months), higher UAS7 (33.31 vs 21.72) and higher prevalence of atopy and angioedema were seen among the severe compared to the moderate patient group. The average DLQI of patients with severe urticaria was significantly higher (18.61 ± 3.64) compared to the moderate group (12.57 ± 2.90), indicating a more severe impairment of routine activities and poorer quality of life in the severe urticaria group.*

Key words: *urticaria, epidemiology, quality of life*

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INTRODUCTION

Urticaria is a common disabling skin disorder characterized by wheals, angioedema or both, as defined by Cochrane and the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group [1, 2]. It is a severely pruritic and debilitating disease, affecting almost 86 million people worldwide, i.e., 1.1% of the global population, and having a profound impact on the quality of life of the patients [3]. Urticaria continues to present a substantial global health challenge, demonstrating significant variation across regions, countries and territories, as indicated by various studies. The increased occurrence in women and younger demographics, along with varying regional impacts, highlights the necessity for specific interventions and policies aimed at tackling this escalating public health issue [4, 5]. Although urticarial lesions typically resolve within 24 hours, the accompanying angioedema in some cases may take as long as 72 hours to settle down.

Based on its duration, urticaria is classified as acute (AU) – lasting ≤ 6 weeks, and chronic urticaria – lasting > 6 weeks [6]. Chronic urticaria is further subdivided into 2 types: Chronic Spontaneous Urticaria (CSU), which is more common type, in which symptoms arise without any identifiable trigger, and Chronic Inducible Urticaria (CIndU), which is brought upon by specific trigger factors.

Risk factors as elucidated by various clinico-epidemiological studies include infections (such as Helicobacter pylori, Yersinia, Mycoplasma, Mycobacterium tuberculosis, Herpes simplex virus, Hepatitis B virus and Streptococcus), medications like aspirin, codeine, morphine, oral contraceptives and angiotensin-converting enzyme inhibitors, neurological factors such as fibromyalgia and stress. There is also a genetic predisposition, with a notable association observed between CSU and the HLADR B1*04 allele in affected patients [7]. Chronic urticaria often occurs concomitantly with autoimmune diseases such as autoimmune thyroiditis and cryoglobulinemia, suggesting a possible autoimmune basis for the disease [8].

However, there is a notable scarcity of studies, especially from North India, investigating the clinico-epidemiological profile of CSU and its impact on the quality of life of patients. Therefore, this study was designed and conducted with the primary objective of studying the clinico-epidemiological profile of CSU and determining the impact of the disease on the quality of life of patients with CSU.

Aims and Objectives

This study was designed to study the clinico-epidemiological profile of patients with CSU, evaluate the severity of CSU using the urticaria activity score (UAS) and determine the impact of the illness on the quality of life of patients using the dermatological quality of life index (DLQI).

MATERIALS AND METHODS

This observational cross-sectional study was conducted at the Department of Dermatology of a tertiary care hospital of North India over a period of 1 year. 120 patients clinically diagnosed with CSU were enrolled in the study. All CSU patients enrolled in the study were above 18 years of age and had an Urticaria Activity Score-7 (UAS7) of > 15 at presentation (mild cases were excluded from the study). Patients with a positive Autologous Serum Skin Test (ASST) were also excluded from the study.

A thorough clinical assessment and physical examination of the study subjects was performed and all the required data was collected using a pre-structured proforma. Assessment of disease severity according to UAS was done according to the number of wheals per day and the intensity of pruritis experienced by the patient. UAS7 is the sum of the combined score of the number of wheals and severity of itch to determine disease activity over 7 days. The maximum score for a 7-day period is up to 42 [9]. A UAS7 score of zero indicates complete control, and a score of < 7 (1-6) indicates good control of disease. A score exceeding 28 indicates severe disease.

The data was compiled and analyzed using MS Excel (R) Office 365, GraphPad prism 8.4.2 and SPSS version 25. Fisher's exact test or Chi-square test was utilized to compare proportions (categorical variables). Continuous variables were analyzed using the Mann–Whitney test/Student's T-test (Independent group/Unpaired data) and Wilcoxon sign rank test/Paired T-test (for paired data) based on the normality of the data. A univariate regression analysis was conducted to assess the severity of urticaria using the Spearman correlation coefficient. A p-value below 0.05 was deemed statistically significant.

RESULTS

This study included 120 patients clinically diagnosed with CSU who presented to our Dermatology outpatient department during the one-year study period. The average age of the patients with urticaria enrolled in this study was 39.43 ± 12.26 years, with a median age of 37 years and an interquartile range of 30-48.25

years. 42 (35%) patients were males and the remaining 78 (65%) – females (Figure 1). Our study showed a higher proportion of female participants.

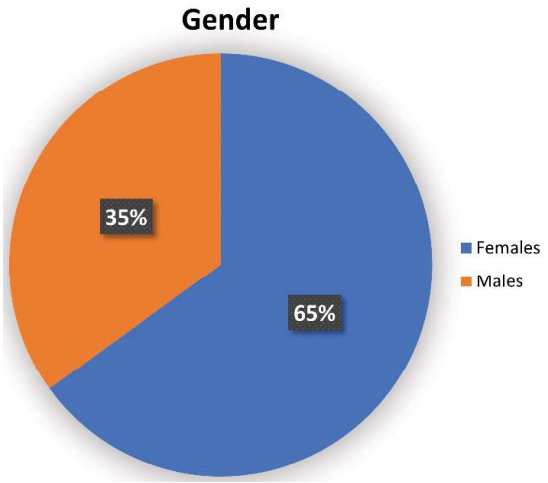

Fig. 1. Gender-wise distribution of cases

Among the patients enrolled in the study, 60 (50%) were from rural backgrounds and 60 (50%) were from urban backgrounds. The subjects were equally distributed based on their residence. Among the participants, 101(84.17%) were married and 19 (15.83%) – unmarried. Housewives constituted a significant share (45%) of the patients enrolled in the study.

The duration of disease at presentation was widely variable and ranged between 2-120 months. The mean duration of the illness among the study participants was 17.76 ± 18.25 months with a median duration of 12 months. Interquartile range was 6-24 months.

Figure 2 illustrates the comorbidity profile of the study subjects. A total of 9 patients had hypertension (7.50%) and 8 patients had diabetes mellitus (6.67%). Hypertension and diabetes mellitus were the most prevalent comorbidities in the study followed by hypothyroidism in 6 patients (5.0%), depression in 2 patients (1.67%), hyperthyroidism in 1 patient (0.83%) and bronchial asthma in 1 patient (0.83%). Angioedema was seen in 22 patients (18.33%) whereas atopy was associated in 18 patients (15.00%) of chronic urticaria.

Table 1 shows the UAS scores of the cases. The average UAS7 was 28.87 ± 7.26, with a median score of 28.

The range of UAS7 scores seen in the study was 16-42 with an interquartile range of 24-35 (Figure 3).

Figure 4 shows the severity assessment among study subjects. Out of 120 patients, 46 (38.33%) were of moderate urticaria with their UAS7 ranging between 16-27, and 74 (61.67%) were of severe urticaria, with their UAS7 ranging between 28-42. Mild cases with UAS ≤ 15 were excluded from the study.

The patients diagnosed with severe urticaria had a higher mean age at presentation (41.95 years) compared to the moderate group (35.39 years) and

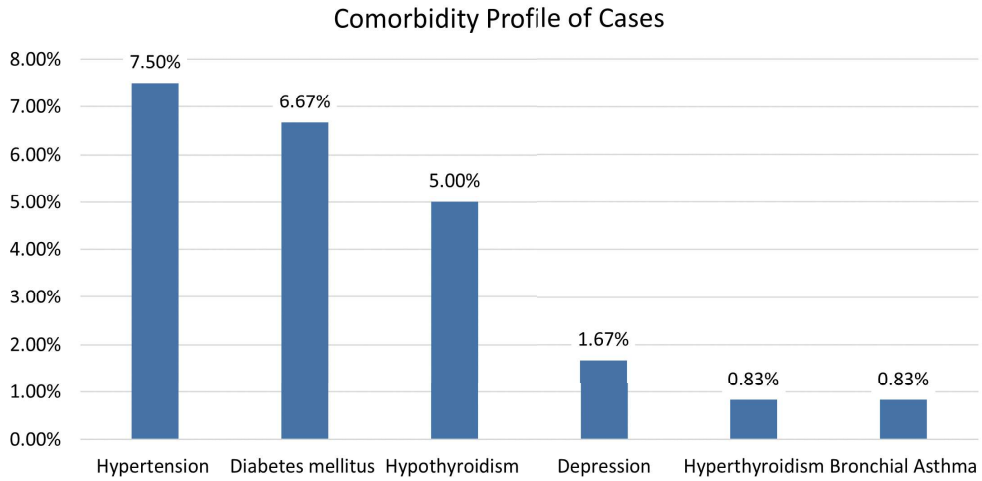

Fig. 2. Comorbidity profile of cases

Table 1. Urticaria Activity Score 7 (UAS7) of the cases

UAS7	Wheals	Itching	Total
Mean ± SD	15.62 ± 3.74	13.25 ± 4.19	28.87 ± 7.26
Range (Min-Max)	8-21	5-21	16-42
Median (Interquartile Range)	14 (14-18.75)	14 (10-14)	28 (24-35)

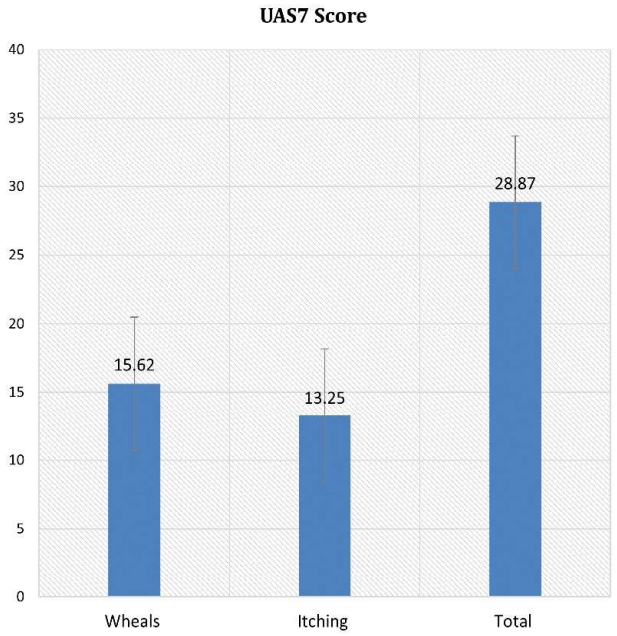

Fig. 3. Urticaria Activity Score 7 (UAS7) of cases

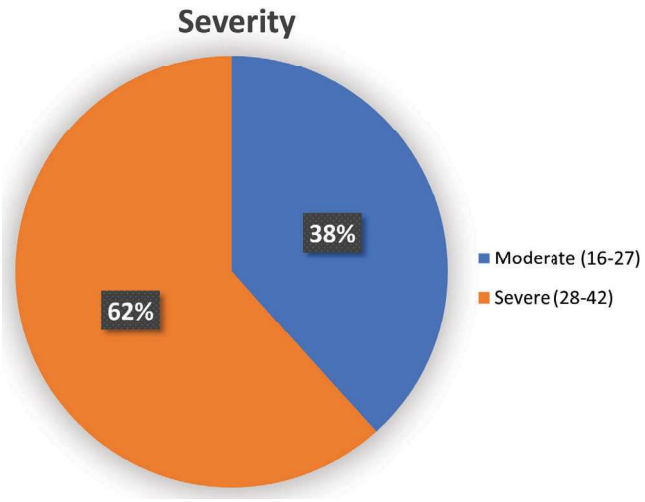

Fig. 4. Severity assessment among cases

this difference was statistically significant (p-value = 0.0040). Among the moderate category, out of 46 patients, 29 (63.04%) were females and 17 (37.96%) were males, whereas in the severe category, out of 74 patients, 49 (66.21%) were females and 25 (33.79%) – males. No significant gender-based differences were seen between the groups based on severity (p-value = 0.7245).

The average duration of disease at presentation was also comparable between the moderate and severe groups (17.22 vs 18.09 months). Atopy was present in 5 out of 46 (10.86%) patients with moderate urticaria and 13 out of 74 (17.56%) patients with severe disease. The difference, however, was not statistically significant (p-value = 0.3195). Associated angioedema was present in 5 out of 46 (10.86%) patients with moderate urticaria and 17 out of 74 (22.90%) patients with severe urticaria. This difference was also not statistically significant (p-value = 0.0985).

Figure 5 shows the UAS7 score comparison among moderate and severe urticaria patients. It was seen that the UAS7 score was significantly higher in patients with severe urticaria in comparison to those with moderate disease (33.31 vs 21.72). This trend was statistically significant with a p-value of < 0.0001.

Assessment of DLQI among urticaria patients revealed that the mean DLQI was 16.29 ± 4.47, with a median level of 16. The interquartile range was 13-19, with a range of 6-26.

DLQI was affected in all 74 patients with severe urticaria and all 46 patients with moderate urticaria. The average DLQI of patients with severe urticaria was higher (18.61 ± 3.64) compared to the moderate group (12.57 ± 2.90), indicating a more severe impairment of routine activities and poorer quality of life in the severe urticaria group. This trend was statistically significant with a p-value of < 0.0001.

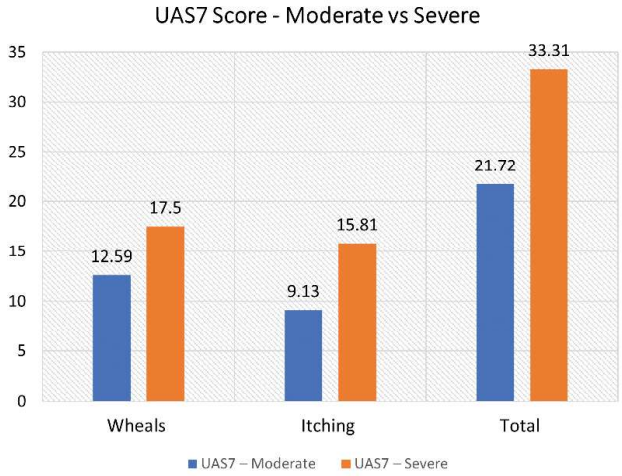

Fig. 5. UAS7 score comparison among the moderate and severe urticaria patients

DISCUSSION

This was an observational cross-sectional study conducted over a period of 1 year and included 120 patients clinically diagnosed with CSU. In our study, the average age of patients with CSU was 39.43 years, with maximum patients 50 out of 120 (41.67%) belonging to the age group of 31-45 years, followed by 37 (30.83%) in age group of 18-30 years, 24 (20%) in age group of 46-60 years and 9 (7.50%) in age group

of > 61 years. In their studies, Mahajan et al. [10], Alwafa et al. [11], Mariyath et al. [12] and Nitin Joseph et al. [13] reported similar presentation age of 32.69 ± 13, 31.22 ± 10.15, 35 and 31.2 ± 20.7 years, respectively.

In our study, 78 (65%) patients were females and the remaining 42 (35%) were males. The study showed a predominance of females (65%), which could be attributed to hormonal factors. The study done by Alwafa et al. demonstrated a similar female preponderance, with 34 out of 40 (85%) patients being females and 6 (15.0%) being male [11]. Other studies such as those by Dabas et al. [14], Nguyen HT et al. [15] and Tirupati et al. [16] have also demonstrated a stark female preponderance of chronic spontaneous urticaria.

The mean duration of the disease in the present study was 17.76 ± 18.25 months, with a median duration of 12 months. In their studies, Alwafa et al. [11] and Khursheed et al. [17] demonstrated that disease duration at presentation ranged between 6-48 months, with a mean duration of 15.35 ± 11.31 and 15 months, respectively. The disease duration was almost similar to that seen in our study. However, the studies done by Mahajan et al. [10], Tirupati et al. [16] and Xin Wang et al. [18] demonstrated a slightly higher disease duration at presentation, which was 37.52 ± 37.57, 24.35 and 23.28 ± 51.72 months, respectively. The reason for this difference could be that patients with ASST-positive CSU exhibited prolonged disease duration and these patients were excluded from our study.

8.33% of patients with urticaria included in our study experienced angioedema and 15% of the study subjects had atopy. Angioedema was more prevalent among the severe urticaria group (22.90%) as compared to the moderate urticaria group (10.86%).

In their studies, Alwafa et al. [11], Mariyath et al. [12] and Khursheed et al. [17] reported that 32.5%, 63% and 24% of patients with urticaria, respectively, had a history of angioedema; this is a higher proportion than that reported in our study. The reason for this disparity might be because we specifically included ASST-negative patients, whereas angioedema might be more prevalent among ASST-positive patients. Nguyen HT et al. [15] found that among 97 patients, 19 (20%) had concurrent angioedema and 20 patients (21%) had a family history of atopy (asthma, allergic rhinitis, atopic dermatitis, or urticaria), which was comparable to our findings.

In this study, hypertension (7.50%) and diabetes mellitus (6.67%) were the most prevalent comorbidities, followed by hypothyroidism in 6 patients (5.0%), depression in 2 patients (1.67%), hyperthyroidism in 1 patient (0.83%) and bronchial asthma in 1 patient (0.83%). This correlation might be explained by the increased occurrence of urticaria in patients with autoimmune disorders like hypothyroidism due to a possible underlying autoimmune mechanism, which might play a role in the pathogenesis of urticaria. In a study done by Kocaturk et al. to determine the effect of COVID-19 vaccination on urticaria exacerbation, female sex, occurrence of constitutional symptoms after vaccination and disease duration shorter than 24 months were the risk factors for urticaria exacerbation post vaccination [19].

A severity assessment of the study subjects was done based on the UAS7 score. The average UAS7 in our study was 28.87 ± 7.26 with a median of 28. In the study done by Mahajan et al., the mean urticaria activity score was significantly higher in the ASST-positive patients (6.13 ± 1.6) than in the ASST-negative group (5.13 ± 1.6) [10]. This score for the ASST-negative patients is significantly lower compared to our study. This difference arose because in the current study we have specifically concentrated on moderate and severe cases of urticaria. In 2021, Sadowska-Przytocka A et al. found an average UAS of 2.72 in CU patients, which is a significantly lower value compared to our study due to the same reason [20].

46 (38.33%) patients with UAS7 scores of 16-27 were classified as having moderate urticaria while 74 (61.67%) patients with UAS7 scores of 28-42 were classified as belonging to the severe category. Nguyen HT et al. reported that among their 97 patients, 39.2% had moderate disease, which is comparable to our findings. Additionally, 40.2% had severe disease, while a smaller proportion, 15.5%, had mild disease [15]. Similar findings were reported by Alwafa et al. [11] and Metwalli et al. [21], who reported that the majority of patients belonged to the severe urticaria group (47.5% and 46.7%, respectively) followed by the moderate group (32.5% and 33%, respectively). In contrast to the aforementioned studies, our study reported a greater percentage of severe urticaria cases due to the exclusion of mild cases from our study.

The mean DLQI among the study subjects was 16.29 ± 4.47, with a median of 16. The average DLQI of patients with severe urticaria was higher (18.61 ± 3.64) as compared to the moderate group (12.57 ± 2.90) and this difference was statistically significant (p-value < 0.0001). The study done by Paudel et al. found a much less significant impairment of quality of life (QoL) of CSU patients, with a mean total DLQI score of 8.30, indicating a moderate impairment in the QoL [22]. Other studies like that done by Basra et al. have also reported a mean DLQI of 9.80, within the range of 7.16-13.40 [23]. However, in the study done by Staevska et al., although the DLQI was high-

er in urticaria patients, an increasing improvement in QoL was noted with increasing doses of levocetrizine and desloratadine [24]. The higher DLQI score recorded in our study could be due to the exclusion of mild cases from our study.

Study Limitations

1. The study did not include ASST-positive patients.

2. Patients with mild urticaria were excluded from the study

CONCLUSIONS

CSU is a severely debilitating skin disease with a significant impact on the quality of life of the patients as well as significant financial burden incurred for treatment. There is a marked variation in the prevalence and epidemiology of CSU across regions, thus region specific studies are required to devise effective management strategies. It commonly affects adults in the age group of 18-45 years, with a stark female preponderance. Most patients suffer from severe urticaria (based upon the UAS7 score) with a markedly affected quality of life thereby contributing to disease burden. Early detection and patient compliance to treatment are a must to achieve early disease control and limit the impact of the disease on the quality of life.

Conflict of Interest Statement: *The authors declare no conflicts of interest related to this work.*

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Ethical statement: *This study has been performed in accordance with the ethical standards as laid down in the Declaration of Helsinki.*

Informed Consent from Participants: *Informed consent was obtained from all participants included in the study.*

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