ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 9, Issue – 1, January - 2026, Page No.: 95 – 105

Comparison of Efficacy and Safety of Levocetirizine versus Bilastine in Patient of Chronic Spontaneous Urticaria- A Prospective, Randomized, Double Blind 6-Week Study

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How to citation this article: Dr. Shashanka Sekhar Patel, Dr. Sachin K. Hiware, Dr. Sushil Rathi, Dr. Dharmendra Mishra, Dr. Mohini S. Mahatme, Dr. Arjun Jagdish Bathia, Dr. Sriramagiri Sai Vinay, Dr. Rahulkumar Kalidas Kodape, "Comparison of Efficacy and Safety of Levocetirizine versus Bilastine in Patient of Chronic Spontaneous Urticaria- A Prospective, Randomized, Double Blind 6-Week Study", IJMACR- January - 2026, Volume – 9, Issue - 1, P. No. 95 – 105.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Bilastine is a newer second-generation antihistamine. The present study was undertaken to evaluate the efficacy and safety as compared to earlier existing second generation antihistaminics.

Materials and Method: This was a prospective, randomized, double blind, parallel-group comparative

study conducted on 76 patients diagnosed with chronic spontaneous urticaria (CsU). Participants were assigned to receive either levocetirizine 5 mg or bilastine 20 mg once daily for a duration of 6-weeks.

Objectives: The primary objective was to assess the difference in the Mean Total Symptom Score (MTSS) between baseline and the end of the 6-week treatment period. Secondary objectives included evaluating changes in the number of wheals, pruritus severity, wheal size, and interference of wheals with sleep, sedation using a Visual Analogue Scale (VAS), intensity of erythema, and the Scale for Extent of Skin Area Involvement (SESI).

Results: Both bilastine and levocetirizine led to a significant reduction in the Mean Total Symptom Score (MTSS), average number of wheals, and mean pruritus scores from baseline to weeks 1, 3, and 6. However, the reduction in MTSS was significantly greater in the bilastine group. Levocetirizine was associated with a notably higher increase in the Visual Analogue Scale (VAS) score for sedation compared to bilastine. Both medications were generally well tolerated and considered safe.

Conclusion: Bilastine demonstrated greater efficacy than levocetirizine in patients with CsU, with rapid noticeable improvement observed as early as one week—an effect that was not evident in the levocetirizine group.

Keywords: Levocetirizine, Bilastine, Chronic spontaneous urticatia, Total Symptom Score, wheals, Quality of Life

Introduction

Urticaria is defined as a skin disorder characterized by local transient skin or mucosal edema (wheal) and an area of redness (erythema) that typically accompany itchy sensations and diminishes within a day. It's categorized into several types: spontaneous (acute, lasting less than 6 weeks, or chronic, lasting 6 weeks or more), physical (triggered by factors like cold, pressure, heat, sun, or vibration), and other forms (including those caused by water, heat, contact with allergens, or exercise).

Globally, urticaria affects 15-23% of the population, with chronic spontaneous urticaria (CsU) representing the majority (around 80%) of chronic cases. The lifetime prevalence of urticaria in India is commonly cited as 7.8–22%, and the point prevalence is 0.5–1%.

Treatment of CsU is essential as symptoms impair quality of life, the disease is often prolonged and unpredictable, and most patients don't improve without treatment.

First-generation sedating antihistamines are no longer recommended in treatment of urticaria as they carry-over effects of sedation and paradoxical excitation and epilepsy in children[1,2]. The second-generation nonsedating antihistamines are the mainstay of treatment for mast cell–mediated urticaria.

Second-generation H1 antihistamines are helpful in CSU as they block histamine action (reduce wheals and itching). They are safe, long-acting and non-sedating compared to older drugs. In resistant cases dose can be escalated to 4 times. There is improvement in quality of life and daily functioning. Hence, they are first-line therapy recommended by all guidelines.

Levocetirizine, a selective second-generation H1 antihistamine, is widely used in CsU and allergic rhinitis at a dose of 5 mg. It has minimal sedation, good safety profile and is efficacious for 24 hrs. Bilastine is a potent, non-sedating, second-generation H1 antihistamine potent in treating CsU and allergic rhinitis at a dose of 20 mg.

Bilastine offers better daytime functioning, minimal side effects, no hepatic metabolism and excellent cardiac safety with minimal CNS entry. Its lack of sedation and suitability for dose escalation make it a strong option in resistant CsU cases.

Effective control of symptoms not only improves quality of life and compliance of patients but also reduces associated healthcare costs, potentially leading to decreased healthcare utilization.

With best of our knowledge, there is no head to head direct comparison of the efficacy and safety of bilastine and levocetirizine in treatment of CsU in Indian scenario. Hence, this study was planned with the aim to compare the efficacy and safety of levocetirizine versus bilastine in CsU. Thus, our goal was to assess and compare the efficacy and safety of these two drugs to determine the optimal treatment option for CsU.

Materials and Methodology

A prospective, randomized, comparative, parallel group 6 weeks double blind study was conducted in seventy six patients of chronic spontaneous urticaria (CsU). The study was approved by the Institutional Ethics Committee. Written informed consent was obtained from all patients prior to their inclusion in the study.

Patients diagnosed as CsU by dermatologist were selected on the basis of their chief complaints and past history. All the eligible patients were informed about the study and provided a patient information sheet. A total of 110 patients were screened and 76 eligible patients found to satisfy the inclusion and exclusion criteria were enrolled in the study. Patients were randomly divided into two groups (group A and B) with 38 patients in each group.

Double blinding was ensured by encapsulating levocetirizine or bilastine in identical opaque capsules, labelled as per the randomization code, which was kept sealed until the analysis. Both patients and investigators were blinded.

The study inclusion criteria required patients to be attending the outpatient clinic in the department of dermatology within the age group of 18–65 years, of either gender, with a history of urticarial wheal and/or angioedema for ≥3 days per week for six consecutive weeks for which no obvious cause had been established. Patients with a mean total symptom score (MTSS) (24-hour reflective) of ≥3, Mean number of wheals (MNW)of ≥1,Mean pruritus score (MPS) of ≥2 at screening and patients with normal electrocardiogram (ECG) to be included in the study.

Patients using any other antihistaminics were included in the study after a washout period of seven days. The patients were excluded from the study if patients with acute spontaneous urticaria and all physical and other subtypes of urticaria, such as aquagenic, cholinergic, contact, and exercise induced urticaria, a history of asthma or other disease requiring the chronic use of inhaled or oral corticosteroids in previous eight weeks or systemic corticosteroids in previous three months, history of allergies to the study medication or intolerance to antihistamines, use of a study drug or topical corticosteroids in the previous seven days, a history of failure to respond to previous antihistaminic drug treatment, use of any other immune-modulating therapy. Pregnant women and nursing mothers were excluded from the trial. In addition, subjects with significant hematopoietic, cardiovascular, hepatic, renal, neurologic, psychiatric, respiratory or autoimmune disease were excluded from the study.

Patients who met inclusion criteria were randomly allocated to either Group A or Group B. Sample size was

calculated by using level of Power=80%, Prevalence P1=81, P2=52, Confidence interval=95%, level of significance α=0.05. A difference of 0.7 unit MTSS, assuming a standard deviation of 0.9 was taken from a previous study.[1,2] The total study sample size was rounded to seventy six (38 patients in each group) considering future rate of drop outs.

Block randomization method with a block size of 4 and a 1:1 allocation ratio was used to assign patients to Groups A or B. A statistician generated the randomised treatment allocation sequence using a random number table, which was provided to a third party not involved in the study. This person labelled the containers according to the random allocation sequencing of the patients. The codes used in this random allocation sequence were retained in a sealed envelope, which was opened only after the completion of the study. Study drugs were procured from market and provided free of cost to participants. Study participants received identical plastic containers, each containing 21 capsules of either levocetirizine 5 mg or bilastine 20 mg, was taken once daily in the morning before food. Patients were assessed at baseline (day 0), day 7 (for diary review), day 21 (3 weeks), and day 42 (6 weeks). Medication were initially given for 21 days, with a refill provided on day 21. Compliance was checked by counting unused capsules.

Each patient received one capsule daily (levocetirizine 5 mg or bilastine 20 mg) at 10 a.m. Demographic and clinical details (age, sex, height, weight, history, and examinations) were recorded in a case report form. Lab investigations (CBC, eosinophil count, blood urea, serum creatinine, SGOT, SGPT, bilirubin, and alkaline phosphatase) were conducted at baseline and end of study. 10 ml blood was drawn from the antecubital vein following all aseptic precautions.

Patients received a 21-day symptom diary at enrolment and were called on day 7 to review diary entries. On day 21, the diary was assessed, and a new 24-day diary were provided. A final assessment was done at 6 weeks. Patients recorded wheal counts, pruritus scores, sleep interference (SIWS), and Visual Analogue Scale (VAS) for sedation. Wheals and pruritus were recorded twice daily, SIWS in the morning, and VAS in the evening.

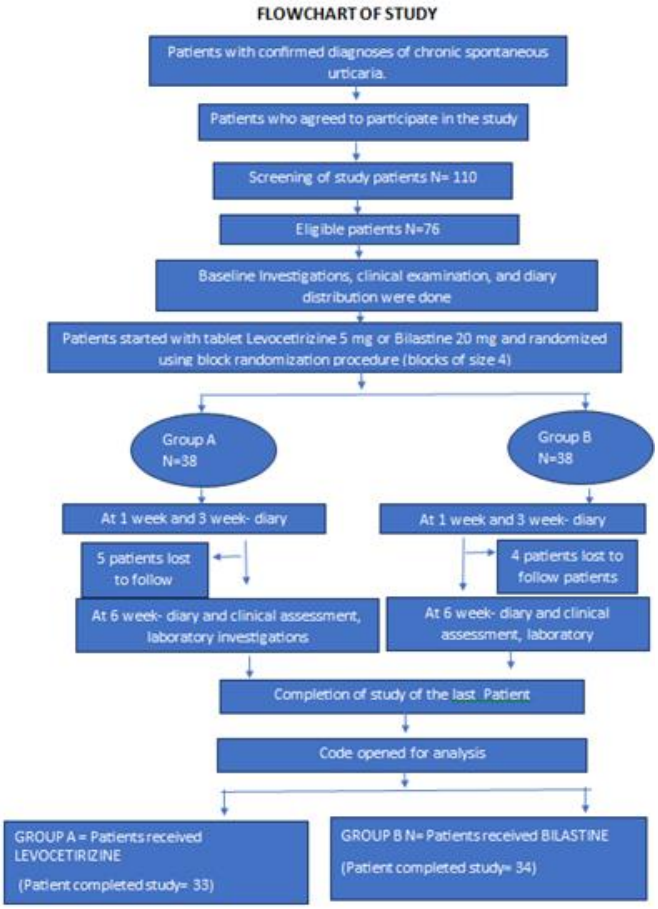
Patients attended Skin OPD at weeks 1, 3, and 6 for diary checks, assessments, and drug dispensation. They were instructed to visit before taking the 10 a.m. dose. Clinical assessments were performed by the principal investigator and consultant dermatologist. Patients counted wheals were confirmed by the investigators. Wheal size was measured using a ruler, and erythema was scored by colour intensity. Skin involvement was graded using the "rule of 9" and recorded as SESI.

The parameters used to evaluate efficacy included the following: (i) the number of wheals, scored as 0 (none), 1 (1–5), 2 (6–15), 3 (16–25), and 4 (>25); (ii) pruritus, rated as 0 (none), 1 (mild), 2 (moderate), 3 (severe), and 4 (very severe); (iii) mean total symptom score (MTSS), determined by summing the mean number of wheals (MNW) and the mean pruritus score (MPS); (iv) wheal size, scored as 0 (no wheal), 1 (<0.5 cm), 2 (0.6–2.0 cm), 3 (2.1–4.0 cm), and 4 (>4.0 cm); (v) scale for interference of wheals with sleep (SIWS), graded as 0 (none), 1 (mild), 2 (moderate), and 3 (severe); and (vi) a visual analogue scale (VAS) for sedation, ranging from 0 to 100, where 0 indicates alertness and 100 indicates extreme sleepiness.

The ideal diary times were 7 a.m. and 7 p.m., with the morning entry before medication and a 12-hour interval between entries. Investigator and patient used the same wheal-counting scale. Investigators assessed wheal

numbers at baseline and 6 weeks. The Mean Number of Wheals (MNW), Mean Pruritus Score (MPS), and Mean Total Symptom Score (MTSS) were calculated by averaging diary scores from same-day and previous-night entries during follow-ups.

Statistical tests used were non parametric Friedman test with Dunn's multiple comparison post hoc test, Wilcoxon test, Mann-Whitney Rank Sum test and parametric paired 't' test and unpaired 't' test. GRAPH PAD PRISM version 10.00 software was used for statistical analysis. Analysis of data was done by intention to treat.



Results

Among the seventy-six patients who were randomized and allocated to the treatment, 67 patients completed the study according to the protocol. Total 9 patients lost to follow up at the end of first week or week 1 of the study, five in levocetirizine group and four in bilastine group. P value less than 0.05 ($p< 0.05$) was considered as statistically significant. Values are expressed as mean (SD).

Mean difference in MTSS at baseline and week 1, baseline and week 3, baseline and week 6 was reduced significantly in bilastine group compared to levocetirizine group at all the three intervals. Change in MTSS In bilastine group week 1 vs week 6 and week 3 vs week 6 shows significant statistical significance. However in levocetirizine group only week 1 vs week 6 shows significant statistical significance.

Mean difference in MNW was reduced significantly in bilastine group as compared to levocetirizine group at baseline and 6 week intervals. Comparison of MNW In levocetirizine group week 1 vs week 6 shows statistical significance. In bilastine group week 1 vs week 6 & week 3 vs week 6 shows significant statistical significance.

Mean difference in MPS was reduced significantly in bilastine group as compared to levocetirizine group at baseline & weeks 6. Comparison of MPS in levocetirizine group week 1 vs week 6 shows significant statistical significance. In bilastine group week 1 vs week 6 & week 3 vs week 6 shows significant statistical significance.

Change in SIWS, number of wheals, size of wheals, scale for intensity of erythema, SESI and VAS for sedation at baseline and week 6. It revealed statistically significant reduction in SIWS, number of wheals, size of wheals, scale for intensity of erythema and SESI at baseline and week 6 within both group. VAS for sedation showing significant increase at week 6 compared to baseline was observed only in levocetirizine group.

Table 1: Baseline demographic data and clinical characteristics of CSU patients

Characteristic	Levocetirizine group (n=33)	Bilastine group (n=34)	p value
Number of patients recruited	38	38	NA
Number of patients at follow-up	33	34	NA
Age (years)	39.5±14.29	39.2±13.61	0.935[a]
Male : Female ratio	M:16, F:15 16:15	M:17, F:17 17:17	NA
Height (centimeters)	165.60±8.08	165.15±8.45	0.821[a]
Weight (kilogram)	62.42±10.11	63.56±10.61	0.656[a]
Duration of lesion (months)	6.63±2.82	6.97±2.77	0.627[a]
TLC	7742.42±1677.06	7305.80±1833.7	0.313[b]
Neutrophils (%)	54.63±7.70	51.18±8.89	0.094[b]
Lymphocytes (%)	28.06±3.28	29.18±3.98	0.216[b]
Eosinophils (%)	5.30±2.22	6.91±1.44	0.001[b]
Monocytes (%)	2.48±1.12	1.94±1.22	0.063[b]
Basophils (%)	1.42±1.06	1.08±0.93	0.17[b]
SGOT (IU)	27.51±13.00	29.79±14.63	0.50[b]
SGPT (IU)	24.15±9.83	26.5±12.55	0.39[b]
Sr. Bilirubin (mg %)	0.71±0.25	0.59±0.31	0.09[b]
Alk. pho (IU)	77.45±15.04	75.67±23.72	0.71[b]
Sr. creatinine (mg %)	0.92±0.18	0.80±0.18	0.013[b]
Blood urea (mg %)	16.90±4.66	16.20±5.19	0.56[b]

Values are expressed in mean (SD) a Unpaired t-test. B Mann–Whitney rank sum test.

Table 2: Comparison of mean difference in CSU patients in Levocetirizine and Bilastine group

	MTSS			MNW			MPS		
Interval	Mean difference in Levocetrizine group (n=33)	Mean difference in Bilastine group (n=34)	p-value	Mean difference Levocetrizine group (n=33)	Mean difference Bilas group (n=34)	p-value	Mean difference Levocetrizine group (n=33)	Mean difference Bilastine group(n=34)	p-value
Baseline & week 1	-1.24± 0.79	-1.78± 0.81**	0.0082	-0.75 ± 0.67	-1.08 ± 0.63	0.051	-0.4 ± 80.38	-0.70± 0.47	0.0559

Baseline & week 3	-1.78± 0.97	-2.15± 0.99	0.1494	-1.04 ± 0.73	-1.20 ± 0.61	0.3526	-0.74 ± 0.51	-0.94± 0.77	0.2320
Baseline & week 6	-2.45± 1.23	-3.91± 1.19***	<0.0001	-1.24 ± 0.91	-1.96 ± 0.83**	0.0016	-1.21 ± 0.73	-1.95± 0.86***	0.0006

P < 0.01**, P < 0.001*** are indicated in the table. Mann-Whitney Rank Sum test used.

Table 3: Comparison of MTSS, MNW, MPS in CSU patients according to diary assessment in Levocetirizine and Bilastine group

	MTSS				MNW				MPS			
Interval	Levocetrizine group (n=33)	p-value	Bilastine group (n=34)	p-value	Levocetrizine group (n=33)	p-value	Bilastine group (n=34)	p-value	Levocetrizine group (n=33)	p-value	Bilastine group (n=34)	p-value
Baseline	6.24 ± 1.09		5.7 ±1.17		3.09 ± 0.76		2.91 ± 0.79		3.15 ± 0.71		2.8 ±0.77	
1 week	5 ± 0.84**	0.0051	3.92 ± 1.07***	0.0007	2.33 ±0.68**	0.0051	1.82 ± 0.78***	<0.0001	2.67 ± 0.55*	0.016	2.1 ± 0.61*	0.0185
3 week	4.45 ± 0.64***	<0.0001	3.56 ± 0.82***	<0.0001	2.04 ±0.47***	<0.0001	1.71 ± 0.65***	<0.0001	2.4 ± 0.50***	<0.0001	1.85 ± 0.56***	0.0002
6 week	3.78 ± 1.16***	<0.0001	1.78 ± 0.80***	<0.0001	1.85 ± 0.86***	<0.0001	0.96 ± 0.63 ***	<0.0001	1.93 ± 0.71 ***	<0.0001	0.83 ± 0.57***	<0.0001

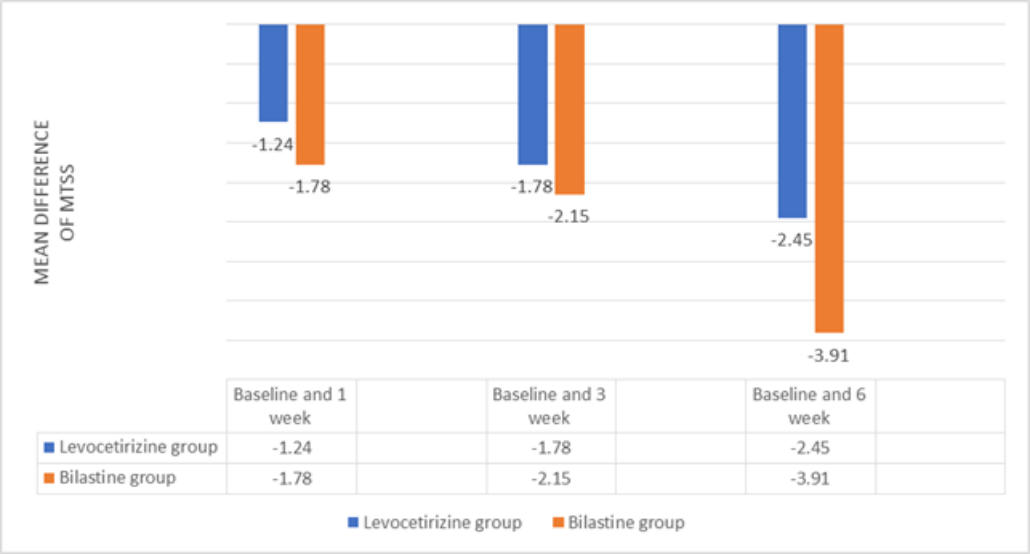
P < 0.05*, P < 0.01**, P < 0.001*** are indicated in the table. Non parametric Friedman test with Dunn's multiple comparison post hoc test used.

Table 4: Comparison of mean difference in SIWS, number of wheals, size of wheals, scale for intensity of erythema, SESI and VAS for sedation at baseline and 6 weeks in Levocetirizine and Bilastine group

Parameter	Levocetirizine group (n=33)	Bilastine group (n=34)
SIWS	-0.67	-0.97
Number of wheals	-1.24	-1.94**
Size of wheals	-0.85	-1.55***
Scale for intensity of erythema	-0.75	-1.29***
SESI	-0.94	-1.26
VAS for sedation	3.09	1.55***

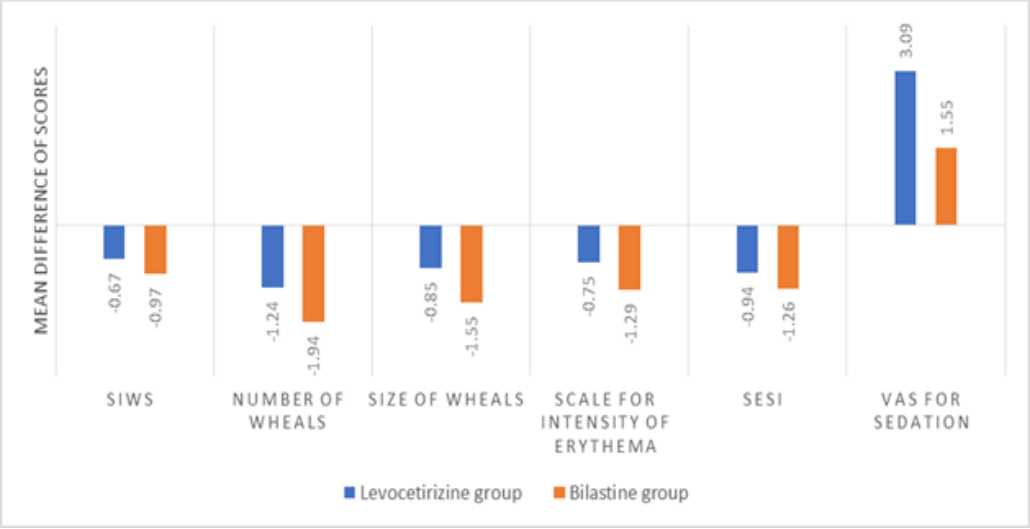
P < 0.05*, P < 0.01**, P < 0.001*** are indicated in the table. Mann-Whitney Rank Sum test

Graph 1: Comparison of mean difference in MTSS from baseline to one



Three and six week in Levocetirizine and Bilastine group

Graph 2: Comparison of mean difference in scores at baseline and six week



Between Levocetirizine and Bilastine group

Discussions

Chronic spontaneous urticaria (CSU) is a condition characterized by recurrent wheals and pruritus lasting longer than six weeks without an identifiable external trigger. It is thought to be mediated by the aberrant release of histamine and other inflammatory mediators from mast cells and basophils[1]. Effective management requires adequate symptomatic control, often using second generation antihistamines like levocetirizine and bilastine which aim at reducing itch and wheal frequency.

The baseline demographic data and clinical characteristics of patients in both treatment groups for chronic spontaneous urticaria were comparable. This homogeneity strengthens the validity of the efficacy and safety outcomes assessed in the study. The mean age of patients in both groups was approximately 39 years, with no significant difference (Levocetirizine: 39.5 ± 14.29;

Bilastine: 39.2 ± 13.61, p = 0.935). This indicates that the study enrolled patients from a similar age demographic, enhancing the reliability of comparisons in treatment outcomes.

The gender ratio was relatively same (M:16, F:15 for Levocetirizine and M:17, F:17 for Bilastine) in our study. This finding is different from few studies where female predominance is more.[1,2,3] This finding in our study is consistent with epidemiological studies indicating that CSU can affect both genders but may have a higher prevalence in females, potentially due to hormonal factors.[5]

By end of first week bilastine showed significant and prompt reduction in MTSS which hints towards rapid onset of action and rapid relief of symptoms in comparison to levocetirizine. Trends in reduction of MTSS is similar with other study[1] but reverse result was seen in a study[2] in which more decrease in MTSS was seen with levocetirizine. By the end of 6 weeks bilastine showed much more reduction in MTSS in comparison to levocetirizine which can be clinically elicited by reduction in symptoms.[3]

A significant decrease in Mean Number of Wheals (MNW) and Mean Pruritus Score (MPS) was observed after four weeks of treatment with levocetirizine and bilastine was equal in both group. The enhanced efficacy of bilastine, especially at the 6-week mark, reinforces its consideration as a first-line option in the treatment of CSU. A previous study[2] indicated that bilastine significantly reduced MPS from baseline to two weeks.

Both levocetirizine and bilastine effectively lowered SIWS, the number, size of wheals, and measures of erythema (intensity and severity), SESI indicating that both medications are successful in managing the primary symptoms of CSU. These findings align with previous studies that have shown both agents to be effective antihistamines for treating CSU.[2]

The findings of our study show that sedation was more in the levocetirizine group as compared to bilastine at week 6 and the difference was statistically significant. It showed a significant increase in sedation at 6 weeks when compared to baseline only in levocetirizine group. Systemic administration of antihistamines may more frequently associate with their well-known side-effect, sedation, which is more common with first-generation antihistamines. This finding was in line with a study[2,3] which was a comparative study of the effect of bilastine and levocetirizine on cognitive functions. Concerning somnolence, in our study, we observed only 4 subjects had an adverse event of excessive sedation in bilastine group whereas in levocetirizine group 10 subjects reported excessive sedation.

The greater decrease in MTSS with bilastine may be attributed to its pharmacodynamic profile. Data have shown that bilastine exerts dual anti-inflammatory activity by inhibiting the release of histamine, IL-4 and tumour necrosis factor (TNF)-α from human mast cells and granulocytes. Its improved efficacy over levocetirizine can be clinically significant especially since patients often present with a range of symptoms that require comprehensive management.[2] Notably, bilastine demonstrated superior efficacy in nearly all parameters, with a significantly greater reduction in the size of wheals and severity of erythema compared to levocetirizine.

Conclusion

Bilastine showed faster & greater improvements in symptoms and reduced sedation. It's dual action and tolerability make it an effective H1-antihistaminic for chronic spontaneous urticaria. Bilastine has shown rapid

onset and long-lasting effects on symptomatic relief, concerning urticaria.

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