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Original Article

A Comparative Study to Assess the Efficacy and Safety of Bilastine Versus Fexofenadine for the Treatment of Chronic Urticaria

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ABSTRACT

Background: Chronic Urticaria (CU) is a debilitating dermatological condition significantly impacting patient quality of life. Second-generation H1-antihistamines, such as bilastine and fexofenadine, are universally recommended as the first-line pharmacologic treatments. A direct comparative analysis is required to determine their relative efficacy and safety in achieving sustained symptom control and improving patient-reported outcomes. **Materials and Methods:** A prospective observational study was conducted, involving 73 adult patients diagnosed with CU. Each patient was observed for periodic reduction in symptoms over the duration of 4 weeks along with overall quality of life assessment before and after treatment. Efficacy was evaluated using the Urticaria Activity Score (UAS) as the primary endpoint and the Dermatology Life Quality Index (DLQI) as the secondary endpoint. Statistical analysis was performed using Microsoft Excel and SPSS (version 27). **Results:** The study cohort comprised 73 patients with a mean age of 35.75 ± 13.22 years. Both treatment groups (Bilastine and Fexofenadine) were comparable at baseline with no significant difference in initial symptom distribution. Clinical improvements in effectiveness were observed through both DLQI and UAS score evaluations. Bilastine consistently outperformed fexofenadine with statistically significant difference of $p<0.001$, showing a marked reduction in disease activity over the treatment period. **Conclusion:** Bilastine demonstrated superior efficacy compared to fexofenadine in alleviating CU symptoms and improving patient quality of life. Both medications were well tolerated, with adverse effects occurring infrequently and no major safety concerns emerging from the comparative analysis. This study recommends bilastine as a highly effective and safe first-line treatment option for chronic urticaria.

Keywords: Bilastine, Chronic Urticaria, DLQI, Fexofenadine, Urticaria activity score.

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INTRODUCTION

Chronic Urticaria (CU) is a common and frequently debilitating dermatological condition defined as the spontaneous or inducible appearance of wheals (hives), angioedema, or both, lasting for a duration that exceeds six weeks.[1] It affects an estimated 0.5% to 1% of the global general population and exhibits a higher incidence among females.[2] CU is broadly categorized into Chronic Spontaneous Urticaria (CSU), with no identifiable trigger, and Chronic Inducible Urticaria (CIndU), in which symptoms are triggered by specific physical or external stimuli.[2] The disease exerts a profound negative impact on patients, manifesting as severe pruritus, sleep disturbances, significant emotional distress (including anxiety and depression), and consequential limitations in daily activities, social interactions, and professional productivity.[3]

The pathophysiology of CU is complex and focuses on inappropriate activation and degranulation of mast cells and basophils within the skin.[1] This process is driven by the release of pro-inflammatory mediators, particularly histamine.[4] In CSU, autoimmune mechanisms autoantibodies against IgE or the high-affinity FcεRI on mast cells, which are thought to be responsible for maintaining mast cell activation over time. The existence of a systemic pro inflammatory state, characterized by elevated levels of cytokines like IL-6 and TNF-alpha, further emphasizes the complex and multi-faceted nature of the disease.[5]

Second-generation H1-antihistamines are suggested as the first-line treatment for CU due to the key role of histamine (particularly H1) in the disease's pathophysiology, according to major worldwide guidelines such as EAACI, GA²LEN, EDF, and WAO.[6] These agents are preferred over older compounds due to their high selectivity for peripheral H1-receptors, improved

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pharmacokinetic profiles, and reduced Central Nervous System (CNS) side effects like sedation and anticholinergic effects, resulting in better patient adherence and safety.[7]

Bilastine and fexofenadine are widely used, non-sedating second-generation H1-antihistamines. Bilastine is a novel, highly selective compound with a unique pharmacokinetic profile: it undergoes negligible metabolism by hepatic Cytochrome P450 enzymes (CYP3A4) and is excreted largely unchanged[8]. This characteristic minimizes the potential for drug-drug interactions, offering a reliable therapeutic response with once-daily dosing.[8] **Fexofenadine**, an active metabolite of terfenadine, is also a highly selective H1-receptor antagonist that is rapidly absorbed, minimally metabolized in the liver, and predominantly excreted via the biliary route.[9] Both agents competitively antagonize histamine at H1 receptors, thereby effectively blocking the histamine-mediated responses that cause the clinical symptoms of urticaria.[9]

image1

Despite the documented individual efficacy of bilastine and fexofenadine, there have been few direct, comparative clinical trials evaluating their long-term effectiveness and safety in individuals with chronic urticaria.[3] The need for careful comparison persists, as any variation in efficacy would be essential in determining initial therapy choices. This study was therefore conducted to investigate the clinical effectiveness and safety profile of bilastine versus fexofenadine in adult patients with chronic urticaria.

METHODOLOGY

- **Study Design:** The study was a Randomized Prospective Observational study carried out among chronic urticaria out-patients in MVJ Medical College and Research Hospital.
- **Ethical Clearance:** Ethical Clearance was obtained from the Institutional Ethics Committee of MVJ College and Research Hospital with IEC number, MVJMC and RH/IEC-03/2025.
- **Setting:** Department of Dermatology at MVJ Medical College and Research Hospital, Bangalore Hoskote, Karnataka.
- **Duration:** The total duration of study was 6 months starting from March 2025 to August 2025.

Sample size Calculation

The numbers to be included in the study was calculated using the following formula for the sample size estimation with quantitative outcome variables

Where, Z = standard normal variate (at 5% type1 error $p<0.05$) it is 1.96

p = the expected prevalence based on previous studies, found to be 0.05

d = absolute error on precision, which is 0.05

Sample Size = **73**

Study Population

73 adult patients presented to the Out Patient Department (OPD) who were diagnosed with Chronic Urticaria.

Inclusion Criteria

- All patients presented with Chronic Urticaria.
- Those who have not received systemic corticosteroids, immunosuppressants, or biologics (e.g., omalizumab) in the past 4 weeks.
- Willingness to comply with study procedures and follow-up visits.
- Ability to provide written informed consent.

Exclusion Criteria

- History of hypersensitivity to bilastine, fexofenadine, or other antihistamines.
- Patients with other skin diseases (e.g., atopic dermatitis, psoriasis) that could interfere with symptom evaluation.
- Pregnant or breastfeeding women.
- Severe renal or hepatic impairment.
- Concurrent use of strong CYP3A4 inhibitors or medications that significantly affect antihistamine metabolism.
- Patients with uncontrolled systemic diseases (e.g., severe cardiovascular disorders, uncontrolled diabetes, active infections).
- History of psychiatric disorders that could interfere with compliance.

Data Collection and Instruments

Patient data was collected using a standardized Case Report Form (CRF) after obtaining informed consent. Baseline data included demographics (age, gender), clinical characteristics, and past medical/medication history. The treatment allocation was randomized. Efficacy and quality of life outcomes were assessed periodically before and after drug administration over the four-week observation period.

Effectiveness Measures

- **Urticaria Activity Score (UAS):** Used as the **primary effectiveness outcome** to quantify disease activity based on the daily severity of wheals and pruritus.[10]
- **Dermatology Life Quality Index (DLQI):** Used as the **secondary effectiveness outcome** to evaluate the overall impact of CU on patient-reported quality of life.[11]
- **Safety Assessment:** The nature, severity, and frequency of all adverse events associated with each treatment regimen were meticulously documented throughout the study.

Statistical Analysis

Data analysis was performed using Microsoft Excel and the Statistical Package for the Social Sciences (SPSS version 27). Continuous variables were summarized using mean Standard Deviation (SD), and categorical variables using frequencies and percentages. Appropriate inferential statistics, including correlation analysis, were used to compare mean UAS and DLQI scores between the bilastine and fexofenadine groups over time. A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

Patient Demographics and Baseline Characteristics

Total of 73 patients with chronic urticaria were analysed, the majority of patients belonged to the age group of 18-30 (42.5%), 31-40 (28.8%), 41-50 (15.1%), 51-60 (8.2%), 61-70 (2.7%) followed by 71-80 (2.7%) as shown in Table 1 and Figure 1.

In this study most participants were female, comprising 57.5% (*n*=42) of the total, while males were 42.5% (*n*=31) of the total, as shown in Figure 2.

Treatment Group versus Symptoms

The participants were assessed for the symptoms of chronic urticaria, wherein symptoms such as pruritus, wheals, angioedema, swelling of lips, swelling of eyes, dermographism were closely examined and reported at the start of treatment.

At baseline, pruritus was present in all patients across both groups (100%). Wheals were reported in 91.9% of patients receiving Fexofenadine and 97.2% of those receiving Bilastine ($p = 0.317$). Angioedema was slightly more frequent in the Bilastine group (13.9%) compared to the Fexofenadine group (5.4%), with no significant difference ($p = 0.216$). Swelling of lips (13.5% vs 5.6%, $p = 0.430$) and swelling of eyes (2.7% vs 5.6%, $p = 0.615$) were uncommon in both groups. Dermographism was observed in 37.8% of Fexofenadine patients and 38.9% of Bilastine patients ($p = 0.926$).

Overall, there was no statistically significant difference in baseline symptom distribution between the two treatment groups, confirming that both cohorts were comparable prior to initiation of therapy. As summarised in Table 2.

Primary Efficacy Outcome (UAS)

Evaluation of the Urticaria Activity Score (UAS) demonstrated a progressive reduction in disease activity in both groups over the four-week treatment period, confirming the efficacy of both second-generation antihistamines. The descriptive statistics of the study population are summarized in Table 3 and Figure 3.

The mean age of participants was 35.75 ± 13.22 years. A progressive reduction in Urticaria Activity Score (UAS) was observed over the treatment period. The mean UAS decreased from 27.86 ± 4.13 at baseline (week 0) to 19.21 ± 5.31 at week 1, 11.07 ± 4.39 at week 2, 5.58 ± 2.93 at week 3, and further to 2.67 ± 2.46 at week 4, indicating a substantial improvement in disease activity.

The study demonstrated that both Fexofenadine and Bilastine were effective in reducing urticaria symptoms over 4 weeks. However, Bilastine consistently produced a greater reduction in UAS scores at each follow-up interval, with statistically significant differences ($p < 0.001$), indicating superior clinical effectiveness compared to Fexofenadine, as shown in Table 4.

Secondary Efficacy Outcome (DLQI)

The secondary effectiveness of treatment was assessed using DLQI scores. At baseline, the mean DLQI scores were 6.70 ± 4.32 in the Fexofenadine group and 5.42 ± 3.37 in the Bilastine group, with no statistically significant difference between the two groups ($p=0.244$). Following treatment, a marked reduction in DLQI scored was observed in both groups, with mean post-treatment values of 1.81 ± 1.99 for Fexofenadine and 1.06 ± 1.15 for Bilastine. Although the improvement was more pronounced in the Bilastine group, the difference in post-treatment DLQI scores between the two treatment arms did not reach statistical significance ($p = 0.172$).

The findings indicate that both Fexofenadine and Bilastine were effective in significantly reducing DLQI scores, with comparable outcomes between the two groups, a shown in Table 5 and Figure 4.

Safety and Tolerability Profile

Both bilastine and fexofenadine were found to be exceptionally well tolerated by the study population. The overall incidence of adverse effects was low, consistent with the favourable safety profile of non-sedating second-generation H1-antihistamines. The adverse events reported across both groups included minor and transient symptoms such as headache, drowsiness, fatigue, nausea, abdominal pain, diarrhoea, and cough.

The severity of the adverse events was assessed with CTCAE (Common Terminology Criteria for Adverse Events) grading scale as shown in the Table 6.

Critically, comparative safety analysis revealed no major safety concerns or statistically significant difference in the frequency or severity of these mild adverse effects between the bilastine and fexofenadine treatment groups.

The evaluation of safety profile between Fexofenadine and Bilastine using chi - square test revealed that adverse events were infrequent and comparable across both treatment groups. Overall, no statistically significant differences were found between the two groups, as shown in Table 6.

DISCUSSION

International guidelines, particularly those from the EAACI/GA²LEN/EDF/WAO consortium, unanimously recommend second-generation H1-antihistamines as the cornerstone of CU management. These agents offer high receptor selectivity, longer duration of action, and reduced sedative effects compared to first-generation antihistamines. Among them, bilastine and fexofenadine have emerged as leading options. Bilastine is distinguished by its minimal hepatic metabolism, and very low potential for drug-drug interactions. Fexofenadine is similarly selective and non-sedating, with proven safety in long-term administration. However, very few direct head-to-head studies exist comparing these two drugs specifically in CU populations, and this gap provided the rationale for the present investigation.

Our study enrolled 73 patients with chronic urticaria in a prospective observational design. Baseline demographic and clinical characteristics were well balanced between treatment groups, with most patients falling in the 18-40 age bracket and females representing the majority (57.5%). The primary presenting symptom across both arms was pruritus, which was present in all patients, followed by wheals, angioedema, and dermographism. Importantly, no significant baseline differences were observed between the bilastine and fexofenadine groups, ensuring comparability of outcomes.

The primary endpoint, reduction in UAS7 scores, demonstrated a substantial decline in disease activity over the four-week follow-up. Mean UAS decreased from 27.86 ± 4.13 at baseline to 2.67 ± 2.46 at week 4, indicating nearly complete resolution of activity in the majority of patients. When analysed by treatment group, bilastine consistently outperformed fexofenadine. For instance, at week 4, mean UAS was 1.53 ± 1.39 in the bilastine group compared to 3.78 ± 3.19 in the fexofenadine group, a statistically significant difference ($p < 0.001$). This suggests that bilastine not only reduces symptom severity but also achieves remission more rapidly. The progressive weekly decline in UAS with bilastine highlights its faster onset and sustained efficacy, corroborating earlier pharmacokinetic data reporting rapid absorption and prolonged receptor occupancy.

Table 1: Age distribution of enrolled 73 patients with Chronic Urticaria.

AGE IN YEARS	FREQUENCY (*N*=73)	PERCENTAGE %
18-30	31	42.5
31-40	21	28.8
41-50	11	15.1
51-60	6	8.2
61-70	2	2.7
71-80	2	2.7

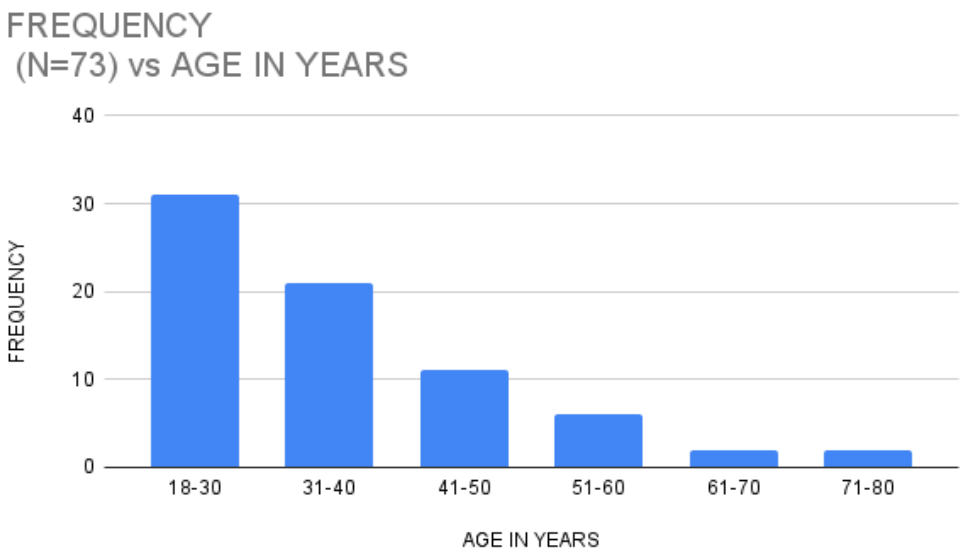

Figure 1: Graphical representation of age distribution.

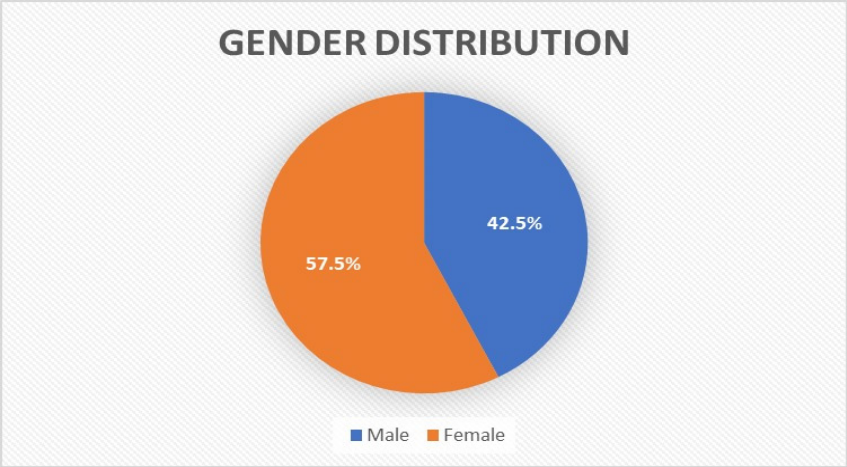

Figure 2: Gender distribution of enrolled 73 patients with Chronic Urticaria.

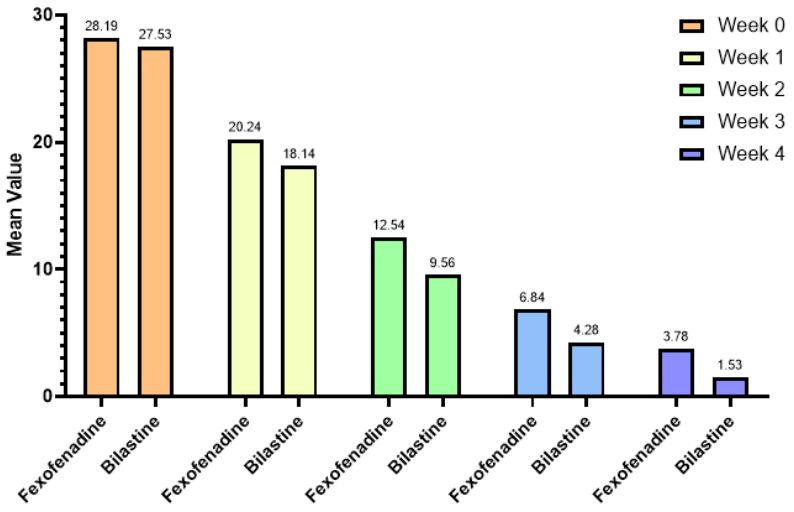

Figure 3: Progressive reduction in UAS score over the weeks.

Quality-of-life outcomes, measured using DLQI, further validated the clinical relevance of symptom reduction. Baseline DLQI scores were 6.70 ± 4.32 in the fexofenadine group and 5.42 ± 3.37 in the bilastine group, with no significant difference at the outset. Post-treatment, DLQI improved markedly in both groups, reaching 1.81 ± 1.99 with fexofenadine and 1.06 ± 1.15 with bilastine. Although bilastine produced numerically greater improvements, the between-group difference was not statistically significant (p = 0.172). This implies that while bilastine is superior in reducing urticarial activity per se, both drugs are equally capable of restoring patient's functional well-being and psychosocial quality of life.

Safety analysis confirmed that both agents were well tolerated. Adverse events were mild and infrequent. Fexofenadine was associated with drowsiness (5.4%) and fatigue (10.8%), while bilastine produced isolated cases of headache (5.6%) and diarrhoea (5.6%). Importantly, no serious adverse events occurred, and the differences between groups were statistically insignificant. This reflects the established favourable safety profiles of both drugs, consistent with prior reports. Hindmarch and Bhatti (2004) specifically demonstrated that fexofenadine does not impair psychomotor performance, while Sastre and Mullol (2017) emphasized bilastine's negligible hepatic metabolism and low risk of interactions, a valuable property in polypharmacy settings.

Our findings align with several previously published reports (Shah *et al.*, 2022; Agrawal *et al.*, 2022) which show a strong agreement with a randomized three-arm clinical trial that compared bilastine, fexofenadine, and levocetirizine in patients with chronic spontaneous urticaria. That study demonstrated that all three agents significantly reduced UAS7 and improved quality-of-life measures, but bilastine consistently achieved the greatest reduction in UAS scores over four weeks, followed by fexofenadine, while levocetirizine was comparatively less effective. Both studies observed that bilastine and fexofenadine provided effective symptom control, with bilastine showing marginally superior response rates (De *et al.*, 2021) described bilastine's effectiveness in refractory CSU populations, highlighting its value in difficult-to-treat cases.[12] Similarly, (Marzano *et al.*,

Table 2: **Summary of baseline symptoms assessment versus Treatment plan.**

SYMPTOM ASSESSMENT	FEXOFENADINE	BILASTINE	*P*- VALUE
PRURITUS present PRURITUS absent	Count- 37 Frequency- 100% Count- 0 Frequency- 0%	Count- 36 Frequency- 100% Count- 0 Frequency- 0%	0.000
WHEALS present WHEALS absent	Count- 34 Frequency- 91.9% Count- 3 Frequency- 8.1%	Count-35 Frequency- 97.2% Count- 1 Frequency-2.8%	0.317
ANGIOEDEMA present ANGIOEDEMA absent	Count- 2 Frequency- 5.4% Count- 35 Frequency- 94.6%	Count- 5 Frequency- 13.9% Count- 31 Frequency- 86.1%	0.216
SWELLING OF LIPS present SWELLING OF LIPS absent	Count- 5 Frequency- 13.5% Count- 32 Frequency- 86.5%	Count-2 Frequency- 5.6% Count- 34 Frequency- 94.4%	0.430
SWELLING OF EYES present SWELLING OF EYES absent	Count- 1 Frequency- 2.7% Count- 36 Frequency- 97.3%	Count- 2 Frequency- 5.6% Count- 34 Frequency- 94.4%	0.615
DERMOGRAPHISM present DERMOGRAPHISM absent	Count- 14 Frequency- 37.8% Count- 23 Frequency- 62.2%	Count- 14 Frequency- 38.9% Count- 22 Frequency- 61.1%	0.926

Table 3: **Descriptive statistics of UAS score.**

	AGE	UAS (WEEK 0)	UAS (WEEK 1)	UAS (WEEK 2)	UAS (WEEK 3)	UAS (WEEK 4)
MEAN	35.75	27.86	19.21	11.07	5.58	2.67
STANDARD DEVIATION	13.224	4.131	5.310	4.385	2.934	2.459

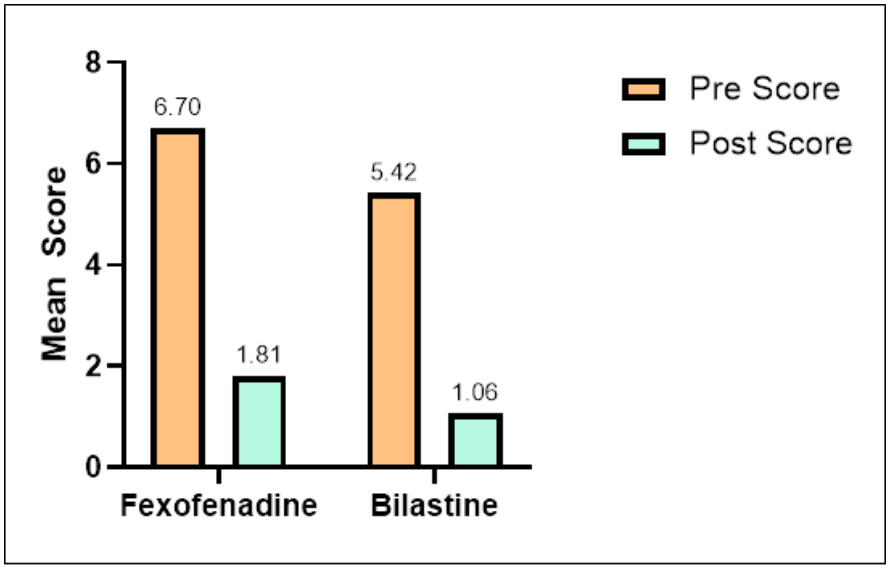

Figure 4: Progressive reduction in DLQI scores Pre-treatment and Post-treatment.

Table 4: Primary effectiveness study in both groups.

TREATMENT PLAN	MEAN	STANDARD DEVIATION	SIGNIFICANCE
UAS (WEEK 0) Fexofenadine Bilastine	28.19 27.53	3.414 4.784	<0.001
UAS (WEEK 1) Fexofenadine Bilastine	20.24 18.14	5.857 4.518	
UAS (WEEK 2) Fexofenadine Bilastine	12.54 9.56	4.592 3.637	
UAS (WEEK 3) Fexofenadine Bilastine	6.84 4.28	2.544 2.763	
UAS (WEEK 4) Fexofenadine Bilastine	3.78 1.53	3.190 1.394	

Table 5: Secondary effectiveness study in both groups.

Treatment plan	Mean	Standard deviation	Significance (2-tailed)
DLQI sum (Pre-treatment) Fexofenadine Bilastine	6.70 5.42	4.320 3.367	0.244
DLQI sum (Post-treatment) Fexofenadine Bilastine	1.81 1.06	1.998 1.145	0.172

2020; Shen *et al.*, 2022). underscored the overall efficacy of second-generation antihistamines, though they pointed out the lack of direct comparative trials.[13] Our study therefore bridges this gap by providing real-world, head-to-head evidence favouring bilastine in terms of UAS7 reduction.

Beyond clinical efficacy, pharmacological distinctions between bilastine and fexofenadine may explain the observed differences. Bilastine's excretion unchanged via urine and faeces bypasses hepatic metabolism, rendering it safer for patients with liver impairment and less prone to interactions with CYP450 substrates.[14] Fexofenadine, while safe, undergoes partial biliary excretion, which may limit its use in patients with hepatic impairment.[15] These differences could have practical relevance in long-term management, particularly in patients with comorbidities such as cardiovascular disease, diabetes, or chronic infections.

The strengths of this study include its prospective design, direct comparison of two widely used antihistamines, and the use of validated outcome measures (UAS7 and DLQI). The consistent superiority of bilastine in reducing disease activity supports its consideration as a preferred agent in routine practice. Nevertheless, several limitations must be acknowledged. The follow-up duration was limited to four weeks, which may not fully capture relapses or long-term tolerability. The sample size was adequate for detecting significant differences, however the single-centre design limits its external validity. Additionally, the study did not explore up-dosing strategies or combinations with other antihistamines, which are common in refractory CU cases.

The statistical methods employed in this study ensured rigorous evaluation of treatment outcomes. The Friedman test was used for within-group comparisons of repeated UAS7 measurements across four weeks, thereby accounting for the related nature of longitudinal data. Between-group comparisons of continuous non-parametric outcomes (UAS7 and DLQI) were performed using the Mann-Whitney U test, which is robust to non-normal distributions. Baseline categorical variables such as gender distribution, clinical symptoms, and adverse events were analysed using Chi-square or Fisher's Exact test depending on expected cell frequencies. The choice of non-parametric methods enhances the validity of our results, as its appropriate for the moderate sample size and the ordinal nature of outcome scale.

Table 6: Summary of safety profile of both the treatment groups.

Adverse event	Ctcae grade	Fexofenadine	Bilastine	*p*- value
HEADACHE present HEADACHE absent	Grade-1 MILD	Count- 0 Frequency- 0% Count- 37 Frequency-100%	Count- 2 Frequency- 5.6% Count- 34 Frequency- 94.4%	0.240
DROWSINESS present DROWSINESS absent	Grade-1 MILD	Count- 2 Frequency- 5.4% Count- 35 Frequency- 94.6%	Count-0 Frequency- 0% Count- 36 Frequency-100%	0.493
FATIGUE present FATIGUE absent	Grade-1 MILD	Count- 4 Frequency- 10.8% Count- 33 Frequency- 89.2%	Count- 0 Frequency- 0% Count- 36 Frequency- 100%	0.115
NAUSEA present NAUSEA absent	Grade-1 MILD	Count- 1 Frequency- 2.7% Count- 36 Frequency- 97.3%	Count- 1 Frequency- 2.8% Count- 35 Frequency- 97.2%	1.000
ABDOMINAL PAIN present ABDOMINAL PAIN absent	Grade-1 MILD	Count- 1 Frequency- 2.7% Count- 36 Frequency- 97.3%	Count- 1 Frequency- 2.8% Count- 35 Frequency- 97.2%	1.000
DIARRHEA present DIARRHEA absent	Grade-1 MILD	Count- 0 Frequency- 0% Count- 37 Frequency- 100%	Count- 2 Frequency- 5.6% Count- 34 Frequency- 94.4%	0.240
COUGH present COUGH absent	Grade-1 MILD	Count- 1 Frequency- 2.7% Count- 36 Frequency- 97.3%	Count- 0 Frequency- 0% Count- 36 Frequency- 100%	1.000

CONCLUSION

Both bilastine and fexofenadine proved effective and well tolerated in the treatment of chronic urticaria. Bilastine, however, demonstrated superior efficacy in reducing disease activity, as measured by UAS7, while quality-of-life improvements were comparable between the two drugs. These findings reinforce current guideline recommendations for second-generation antihistamines as first-line therapy and highlight bilastine as a potentially more effective option in symptomatic control. Timely administration, favourable safety profiles, and once-daily dosing of both drugs played pivotal roles in improving adherence and overall patient well-being, underscoring their importance in the comprehensive management of chronic urticaria.

Future prospects on this research should focus on larger, multicentric trials with extended follow-up to evaluate sustained efficacy, long-term safety, and cost-effectiveness. Comparative studies incorporating refractory populations and exploring up-dosing regimens will further clarify the relative positions of bilastine and fexofenadine in treatment algorithms. Moreover, biomarker-driven studies identifying endotypes (e.g., autoimmune vs. non-autoimmune CSU) may allow personalized selection of antihistamines, thereby optimizing outcomes.

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ABBREVIATIONS

CU: Chronic Urticaria; **CSU:** Chronic Spontaneous Urticaria; **CIndU:** Chronic Inducible Urticaria; **CNS:** Central Nervous System; **EAACI:** European Academy of Allergy and Clinical Immunology; **GA²LEN:** Global Allergy and Asthma European Network; **EDF:** European Dermatology Forum; **WAO:** World Allergy Organization; **CRF:** Case Report Form; **UAS:** Urticaria Activity Score; **DLQI:** Dermatology Life Quality Index; **SD:** Standard Deviation; **SPSS:** Statistical Package for the Social Sciences; **CTCAE:** Common Terminology Criteria for Adverse Events.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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