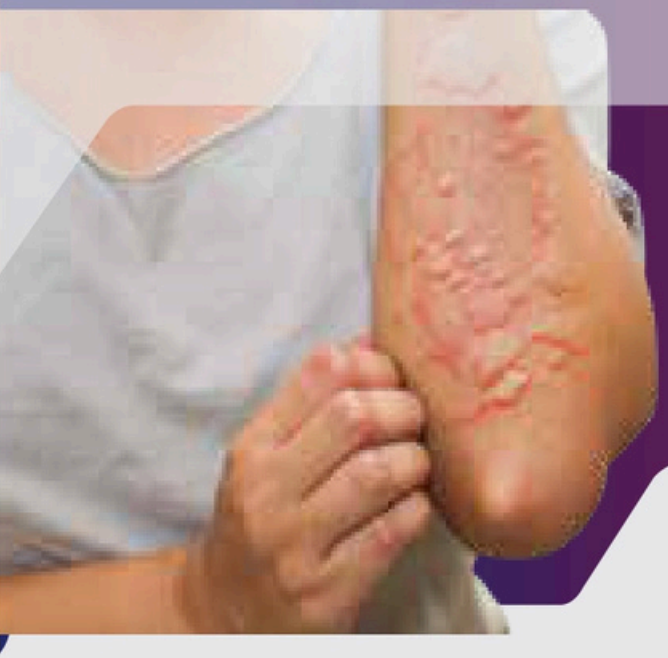


ajanta pharma

My memorable Urticaria Case

Case study 3:

Bilastine for the Management of Chronic Spontaneous Urticaria (CSU): A Case Report

Dr. Sushil Tahiliani
M. D, D. V. & D Consultant Dermatology
P.D. Hinduja Hospital and Medical Research Centre, Mumbai

Expert view - Dr. Sushil Tahiliani

Urticaria affects a significant portion, around 30 - 40%, of the global population at some point in their lives. Acute urticaria is often linked to allergic reactions triggered by medications like nonsteroidal anti-inflammatory drugs (NSAIDs), certain foods, chemicals, or infections. Chronic urticaria (CU) is characterized by the presence of wheals with or without angioedema occurring on a daily or nearly daily basis for at least six weeks. Depending on the triggering factors, CU is categorized into two subtypes: chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU).1 It's noteworthy that up to 40% of urticaria cases persist for more than six weeks, and it's not uncommon for patients to experience the condition for several years, significantly impacting their quality of life. The longer duration and severity of the condition can be compounded by comorbidities such as anxiety and depression, observed in over 30% of CSU patients. Presently, there is no cure for CU; however, symptoms can be effectively managed with the assistance of non-sedating second-generation antihistamines (SGAH), often considered as the first-line treatment, along with various other treatment modalities in the majority of cases.

Bilastine is among the primary therapeutic options for adults dealing with chronic urticaria. It is deemed safe for long-term use. In a multicenter study, bilastine administered at a dose of 20 mg once daily for up to 52 weeks in patients with CSU or pruritus associated with dermatological conditions showed early improvement in disease symptoms, with sustained efficacy throughout the study period. It's worth noting that a single oral dose of bilastine results in peak plasma concentrations being achieved approximately 1.0 to 1.5 hours after administration.[2]

History:

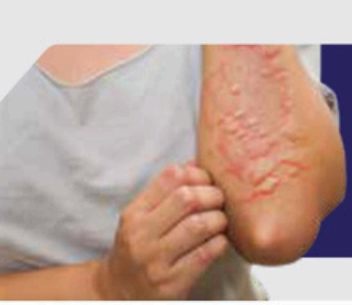
- A 56-year-old male patient has been suffering from severe chronic spontaneous urticaria (CSU) for the past six months.
- Previously treated with loratadine once daily, which did not provide satisfactory control.
- Also prescribed hydroxyzine 25 mg once daily, which induced drowsiness, making it challenging for him to carry out work and drive.
- Despite undergoing multiple courses of prednisolone, the condition remained uncontrolled.
- Additionally, the patient has Type 2 diabetes mellitus, elevated creatinine levels, is obese, and consumes alcohol twice a week.

Clinical Examination

- Extensive hives & itching present throughout the body
- Initial UAS7 score - 28
- Significant angioedema present

Investigations

- Hemoglobin - 13.1 g/dL
- Neutrophil - 72%
- Lymphocytes - 27%
- Creatinine clearance value - 55%
- Blood sugar - Fasting: 130 mg/dL



- HbA1c - 6.7%
- Liver function tests
  - Serum bilirubin - 1.0 mg/dL
  - SGPT - 65 units/liter
- Autologous serum skin test (ASST) – Not done

Diagnosis:

Chronic spontaneous urticaria

Management:

- Given the patient's concurrent health conditions, bilastine 20 mg was commenced due to its hepatic metabolism-free nature and its safety profile, even in cases of compromised renal function.
- Initiated treatment with bilastine 20 mg once daily and instructed to adhere to general measures.

Follow up:

- During the first week, the patient experienced partial alleviation of symptoms, with the UAS7 score improving to 12.

Table 1: Improvement in UAS7 and UCT scores during follow-up visits

	Baseline	Follow-up 1 (after 1 week)	Follow-up 2
Bilastine dose		20 mg once daily	40 mg once daily
UAS7	28	12	6

UAS7 scores at first & second follow up

- At the subsequent follow-up, after increasing the dose to 40 mg, there was better management of urticarial symptoms, resulting in a decrease in the UAS7 score to 6.
- It was recommended to maintain the 40 mg dosage once daily for six weeks until the subsequent follow-up.

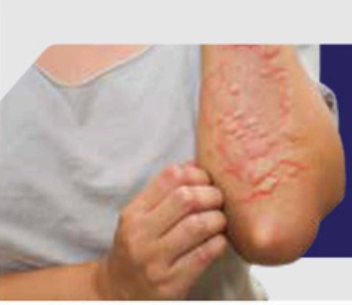
Discussion:

The rational utilization of bilastine in Chronic Spontaneous Urticaria (CSU) in this case resulted in symptom control and enhanced the patient's quality of life. Bilastine emerged as an advantageous option not only for symptom management but also for its non-sedative nature, which ensured minimal interference with the patient's work and driving abilities. Additionally, considering the patient's comorbidities, bilastine proved to be a safe choice, with no adverse effects on hepatic and renal parameters.

Bilastine: Superior e¬fficacy & safety in the management of urticaria

The prevalence of Chronic Urticaria (CU) is notably higher in Asians compared to Europeans and Northern Americans, with a higher occurrence among females during the third to fifth decades of life. Although numerous treatment options are available, managing CU can pose challenges for clinicians, necessitating a thorough understanding and elimination of underlying triggers in all possible cases.[1]

Bilastine's classification as a non-brain penetrating antihistamine, attributed to its high affinity for the p-glycoprotein efflux pump, restricts its penetration through the blood-brain barrier. Furthermore, factors such as molecular weight and electric charge contribute to its non-sedative properties and limited blood-brain-barrier penetration. Besides its non-sedative nature, bilastine



offers several advantages, including potent H1 receptor binding affinity and long-lasting action, without affecting psychomotor or driving performance even at doses as high as 20mg. Its limited potential for drug-drug interactions makes it particularly valuable for use in actively working patient populations.[2]

Recent research indicated a more favorable outcome when increasing the dosage of non-sedating H1 antihistamines (nsAH) compared to using a combination of second-generation and first-generation antihistamines. Updosing nsAH to four times the standard dose is recommended as a second-line treatment in Chronic Urticaria (CU) for patients who do not respond satisfactorily to first-line therapy. Bilastine has demonstrated utility in cases of Chronic Spontaneous Urticaria (CSU) resistant to levocetirizine.[1]

In a retrospective analysis involving 49 adult patients diagnosed with Chronic Spontaneous Urticaria (CSU) who exhibited an inadequate response to prior antihistamine treatments, they were transitioned to bilastine 40 mg once daily and continued on this regimen for a duration of 6 months, with doses adjusted based on individual responses. Following the 24-week period, complete resolution of symptoms was observed in 25 patients (51%), while the remaining 24 patients (49%) experienced well-controlled urticaria. Notably, there was a significant enhancement in both the mean UAS7 score and the mean Dermatology Life Quality Index (DLQI) score compared to baseline at the 24-week mark. This study also encompassed patients who had previously demonstrated unsatisfactory responses to other antihistamines, even at double doses or through combined use.[3]

Figure 1 illustrates the overall progress of patients across different visits. Overall improvement, as gauged by UAS7 scores, revealed complete resolution or well-controlled responses in 42.8% (21 out of 49) of patients by week 4, 71.4% (35 out of 49) by week 8, 91.8% (45 out of 49) by week 16, and 100% (49 out of 49) by week 24.[3]

- At the end of the 24-week period, complete treatment response was observed in 51% of patients (n = 25), while 49% of patients (n = 24) achieved well-controlled urticaria, as depicted in Figure 1.

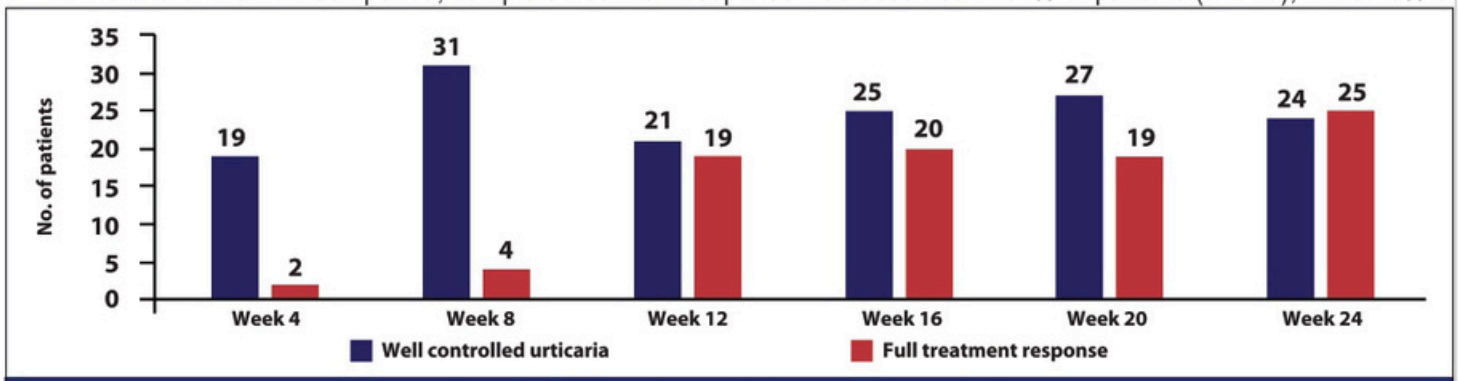


Figure 1: Week wise categorization of patients

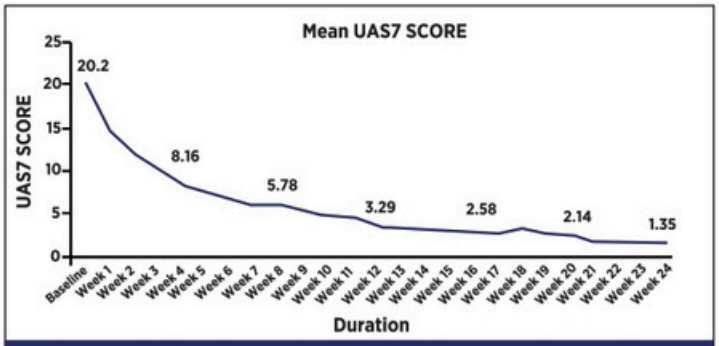


Figure 2: Week wise change in mean UAS7 score

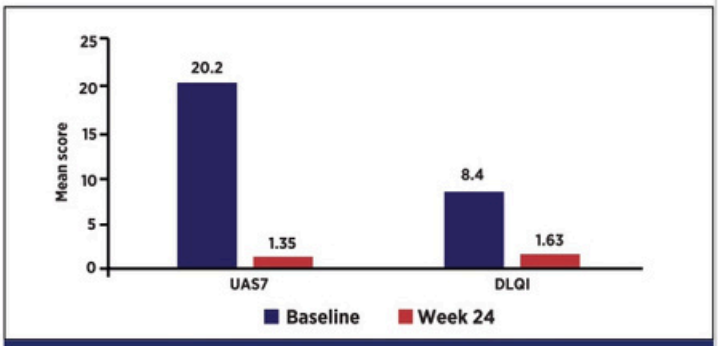
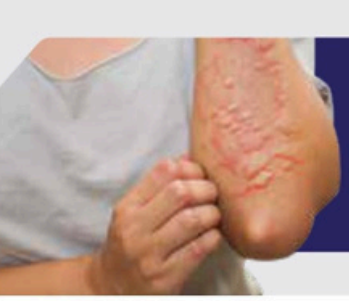


Figure 3: Change in mean score

- Over the course of 24 weeks, there was a consistent downward trend in the Mean UAS7 score, as illustrated in Figure 2.
- At the end of the 24-week duration, the Mean UAS7 score stood at 1.35 ± 1.61, a statistically significant reduction compared to the baseline, as shown in Figure 3.

In summary, bilastine emerges as an optimal first-line antihistamine for chronic urticaria, offering long-term safety and significant



improvements in UAS7 and quality-of-life scores. For patients with inadequate responses to commonly used antihistamines, switching to bilastine at 40 mg/day has shown promise in relieving symptoms of CSU.[3]

ASST: Autologous serum skin test; **BID**: Twice a day; CU: Chronic urticaria; **CSU**: Chronic spontaneous urticaria; **CIndU**: Chronic inducible urticaria; **DLQI**: Dermatology life Quality Index; **HbA1c**: Glycated haemoglobin; **OADs**: Oral antidiabetic drugs; **OD**: Once daily; **nsAH**: nonsedating H1 antihistamine; **NSAIDs**: Nonsteroidal anti-in_ammatory drugs; **SGAH**: Second generation antihistamines; **SGOT**: Serum glutamic-oxaloacetic transaminase; **SGPT:** Serum glutamic pyruvic transaminase; **T2DM**: Type 2 diabetes mellitus; **UAS7**: Urticaria activity score summed over 7 days

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