



Short Communication

Bilastine in higher doses in chronic spontaneous urticaria

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ABSTRACT

Objective: To evaluate efficacy and safety of bilastine in higher than usual doses in patients with chronic spontaneous urticaria (CSU).

Material and Methods: Adult patients with CSU with pruritus and wheal score of more than two were investigated for complete blood count, urine examination, blood sugar level and thyroid-stimulating hormone level and treated with bilastine 20 mg (one tablet) before breakfast. In patients who did not show satisfactory response, dose was increased to 40 mg (two tablets) before breakfast at the end of one week and 80 mg (two divided doses) at the end of two weeks, if no response seen after the end of one week. Symptoms were evaluated using urticaria activity score (UAS) and sedation score.

Results: A total of 30 patients (mean age 30.5 years; 56.67% females; baseline mean UAS 5.2) with mean duration of CSU of 18.9 months were enrolled. Fourteen (51.85%), 10(37.04%) and 2(7.41%) patients became symptom-free with 20,40, and 80 mg dose of bilastine respectively whereas 1(3.70%) patient not responding to 80 mg bilastine required cyclosporine. After 1 week of treatment, 3 patients were lost to follow up. Bilastine was well tolerated without any serious adverse events.

Conclusion: Bilastine is effective and well tolerated in higher (up to 4 times) than normal doses in the management of chronic spontaneous urticaria.

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1. Introduction

Chronic spontaneous urticaria is a common dermatological condition. Although it is not a life threatening condition, patients suffering from this condition report significant impairment in the quality of life.¹ Several mediators are involved in the pathogenesis of allergic conditions. Out of these, histamine is an important mediator in pathophysiological course of allergic reactions including allergic rhinitis and urticaria. Because of the central role of histamine, antihistamines are considered as the mainstay of treatment in patients with chronic urticaria. Among the available antihistamines, first generation agents because of their potential to cross blood brain barrier are associated with adverse events related to central nervous system especially sedation. Second-generation H-1 antihistamines score over their first generation counterparts in this regards. Considering the advantages, current clinical guidelines

recommend second-generation H1- antihistamines as initial treatment of chronic urticaria.² Although many second generation antihistamines are available in the market, each has its own advantages and limitations. Bilastine is a new addition to the list of available agents with promising profile.

Bilastine is a potent and specific H1-antihistamine with quick onset and long duration of action with good response in the treatment of chronic spontaneous urticaria (CSU).³ Moreover, it has several clinical advantages because of its pharmacological profile which make it suitable for use in CSU. Bilastine is not associated with risk of cardiotoxicity. Similarly, it does not interact with cytochrome P450 resulting in very less risk of drug to drug interactions. Dosage modification is not required in patients with renal impairment. In a double blind clinical trial, bilastine 20 mg administered for 28 days has been shown to provide significant reduction in clinical features and improved patient quality of life in patients with chronic idiopathic

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urticaria.⁴ A Japanese study has reported long term safety of bilastine 20mg per day given for one year in patients with CSU.⁵ Bilastine is well tolerated even in supratherapeutic doses.^{3,6} Overall, evidence for its usage in dose above than routine dose is limited. There is a need for evaluating efficacy and safety of bilastine in Indian patients with CSU.

2. Objective

The objective of this study was to evaluate effects of bilastine when administered in higher than usual doses in patients with CSU.

3. Materials and Methods

A total of 30 adult patients with CSU with pruritus and wheal score of more than two were attending dermatology clinic were enrolled after taking their written informed consent. Those with physical urticaria or urticarial vasculitis were not included. Other excluded patients included presence of gastric ulcer and/or duodenal ulcer or gastritis, a history of allergic reaction to any non-steroidal anti-inflammatory drug or history of symptom exacerbation by pressure. Pregnant women or lactating mothers were also not included in the study.

Complete blood count, urine examination, blood sugar level and thy roid-stimulating hormone level were checked after enrollment. Those satisfying enrollment criteria were given bilastine 20 mg (1 tablet) before breakfast. Follow up was done every week until four weeks. If the patient did not respond, dose was increased at the end of 1 week to 40 mg (2 tablets) before breakfast, and 80 mg (2 divided doses) at the end of 2 weeks. Symptoms were evaluated using urticaria activity score (UAS) i.e. number of wheals and intensity of itching. Wheal score: 0- no wheals; 1-< 20 wheals; 2-20-50 wheals; 3- >50 wheals. Severity of itch:0- none; 1-mild; 2-moderate; and 3- severe. Scores for every day were recorded for 7 days to calculate weekly UAS (minimum score 0 and maximum score 42). UAS score was calculated at baseline and then after 2 and 4 weeks of treatment. Sedation was also graded on 4 point scale; 0- no sedation; 1- mild sedation; 2-moderate sedation; and 3- severe sedation.

4. Results

A total of 30 patients with CSU were included in the study. Table 1 shows baseline characteristics of the patients.

Table 1: Baseline characteristics of the patients

Parameter	Result
Mean age	30.5 years
Male n (%) Female n (%)	13 (43.33%) 17 (56.67%)
Duration of chronic spontaneous urticaria	3 months to 3 years (mean 18.9 months)

The mean age of patients was 30.5 years. Out of 30 patients, 17(56.67%) were females and 13(43.33%) were males. Microcytic anemia was observed in four patients. In three patients, levels of thyroid stimulating hormone (TSH) levels were high.

The mean duration of chronic spontaneous urticaria was 18.9 months. At baseline mean UAS was 5.2. After one week of treatment the UAS reduced to 3.2. At the end of one week, 3 (10%) patients were lost to follow up, possibly due to poor response to treatment. Out of remaining 27 patients, 13 (48.15%) were symptomatic. In these patients, dose of bilastine was doubled and after two weeks of treatment, UAS reduced to 2.1 and three (23.08%) patients of 13 patients were symptomatic. In these patients dose was again increased as mentioned before. At the end of four weeks, UAS was < 1.

Safety of bilastine was satisfactory in our study. It was very well tolerated without any serious adverse events. Headache was reported by two patients at dose double than normal. One patient who received 4 times higher dose reported somnolence.

Fourteen (51.85%), 10(37.04%) and 2(7.41%) patients became symptom-free with 20,40, and 80 mg dose of bilastine respectively whereas 1(3.70%) patient not responding to 80 mg bilastine required cyclosporine.

5. Discussion

Bilastine is a comparatively newer H1 receptor antagonist without sedative side effects or cardiotoxic effects. It has been shown to be effective in reducing symptoms of allergic rhinoconjunctivitis and urticaria.⁷ In this study, we evaluated the effects of bilastine in normal doses and higher than normal doses in those not showing improvement of symptoms. Our results showed that bilastine can be effective in higher doses (up to 4 fold) in those patients who do not show improvement with routine doses. A well-designed clinical trial among patients with acquired cold urticaria, bilastine (20 mg to 80 mg OD) reported response rate of 60% with similar rate of adverse events as placebo. This suggests safety of bilastine at higher (2-4 times) than recommended daily dose.⁶ There is no clinically relevant increase in QTc interval.⁸ In our study, there were no serious adverse events. Patients reported minor and transient adverse events in the form of headache and somnolence with higher than normal doses. Sedation was not reported by patients at normal doses.

Small sample size, no comparative arm and single centre study are the limitations of our study. Larger, multicentric studies are needed to confirm these observations.

6. Conclusion

Overall, our results suggest that bilastine is safe and effective in higher doses (up to 4 fold) in patients with

chronic spontaneous urticaria.

7. Source of Funding

None.

8. Conflict of Interest

None.

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