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
urticaria. A Japanese study has reported long term safety of bilastine 20mg per day given for one year in patients with CSU. Bilastine is well tolerated even in supratherapeutic doses. 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 thyroid-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>
<thead>
<tr>
<th>Parameter</th>
<th>Result</th>
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<tbody>
<tr>
<td>Mean age</td>
<td>30.5 years</td>
</tr>
<tr>
<td>Male n (%) Female n (%)</td>
<td>13 (43.33%) 17 (56.67%)</td>
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<tr>
<td>Duration of chronic spontaneous urticaria</td>
<td>3 months to 3 years (mean 18.9 months)</td>
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</table>
chronic spontaneous urticaria.

7. Source of Funding

None.

8. Conflict of Interest

None.

References


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