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Review Article

Bilastine for the treatment of chronic spontaneous urticaria: Consensus statement for Indian patients

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ABSTRACT

Urticaria or hives is a common skin condition that affects population with a lifetime prevalence of up to 22% and point prevalence of 1%. Antihistamines play a very important role in the treatment of chronic urticaria. International guidelines recommend second-generation, non-sedating H1-antihistamines as the first line therapy for management of chronic urticaria. Uncontrolled symptoms in many patients demand a new antihistamine which offers significant efficacy without or with minimal adverse events especially sedation. Bilastine, a second generation H1-antihistamine, offers significant benefits over most antihistamines including once daily dosage, significant efficacy in relieving symptom, minimal risk of drug to drug interactions and adverse events. This consensus statement is prepared to discuss the role of bilastine in the management of chronic urticaria among Indian patients. Comprehensive review of published literature was done to prepare a draft of consensus statement. The draft was circulated to the experts for their review and comments. Final document was prepared with incorporation of their comments.

1. Introduction

Urticaria/ hives is a common dermatological condition having lifetime prevalence of up to 22% and point prevalence of 1%,[1] suggesting a fairly common occurance.[2] In chronic urticaria, symptoms last for more than 6 weeks[3] and this condition affects large number of people across the world, probably up to 3%. Rates of chronic urticaria are more common in females as compared to males. Exact epidemiological evidence on chronic urticaria in Indian population is not known. In a study from India involving patients with urticaria (n=500), physical urticaria was present in 37% cases.[4] whereas in another study, cholinergic urticaria was reported in 4.16% cases.[5]

Urticaria is associated with intense pruritus and wheals are the usual symptoms of urticaria.[6] Symptoms of chronic idiopathic urticaria especially itching and wheals negatively affect patients' quality of life.[7,8] The condition is uncomfortable for the patient[5] and pose significant burden on them.[6] Considering its importance, the Global Allergy and Asthma European Network (GA(2)LEN) consensus recommends health-related quality of life evaluation in clinical trials as well as routine practice.[9]

Unmet needs in the management of chronic urticaria include need for additional tools for diagnosis and an ideal antihistamine which provides excellent efficacy and tolerability. Poor awareness related to disease and treatment and compliance among patients and physicians, cost

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related challenges, and treatments of patients with different comorbidities are some of the important challenges in the management of chronic urticaria.[10]

1.1. Treatment of chronic urticaria

Offering symptomatic relief to the patient by antagonising the effects (wheal and itching) of histamine mediated through H1 receptors is the main goal of urticaria management.[1] Several treatment options including over the counter and prescription medicines are available for management of urticaria. There are differences in the preference and satisfaction of patients with the treatment used for chronic urticaria. An online survey covering patients from France and Germany (n=405) compared treatment satisfaction in chronic urticaria. Patients using prescription treatments were more satisfied and reported greater benefits than those receiving over the counter treatments.[6]

H1 antihistamines present the most useful and widely prescribed medicines because of their long presence in the market. H1 antihistamines are available for clinical use since more than seven decades.[11] Based on their pharmacological properties, antihistamines are classified into two classes; first or second generation drugs.

The older agents i.e. first generation antihistamines are short acting and associated with several adverse events because of their antimuscarinic and sedative actions.[1] Better safety profile, an advantage of second-generation H1 antihistamines makes them first line therapy for chronic urticaria.[10,12] Choice of agent is selected based on the supporting literature related to efficacy and safety.[12]

Effects on central nervous system especially cognitive and psychomotor functions, risk of sedation and drug interactions are considered important safety parameters while selecting an antihistamine.[12] There are several second generation antihistamines with higher therapeutic index than first generation antihistamines.[13] There is extensive literature suggesting effectiveness and safety of newer second generation H1-antihistamines. These agents are generally devoid of serious adverse effects.[11] Usual doses of second generation H1 antihistamines do not provide effective relief of symptoms in several patients.[14] In such patients, although nor approved by the regulatory authorities clinicians increase the dose for better efficacy. This dosage is considered as off-label dosage of antihistamines.[13]

Second-generation agents differ in their adverse event profile such as sedation or impairment of cognitive and psychomotor activities.[12] Considering this, there is an unmet need for a newer antihistamine which provides good efficacy with accepted tolerability profile. Bilastine is a relatively newer H1-antihistamine for treatment of urticaria.[13]

A draft o f consensus statement discussing role of bilastine in the management of chronic urticaria was prepared after a comprehensive literature review and sent for review and comments from the experts. The draft was revised by incorporating suggestions/comments from the experts.

1.2. Guideline/consensus recommendations for the treatment of chronic urticaria

The EAACI/GA2LEN/EDF/WAO guideline[15] published in 2009 recommend use of second generation antihistamines as first line agent for the treatment of chronic urticaria. An updated consensus statement (2017)of expert dermatologists from India[1] also strongly recommends preference for newer second generation H1-antihistamines as first line treatment and up-dosing of these agents up to four times the usual dose, if first line therapy is ineffective.[1] According to the Asia-Pacific consensus statement, bilastine has the highest number of properties for an ideal antihistamine.[16] Moreover, recent survey also suggests use of bilastine as a preferred choice due to its high efficacy, safety, suitability for use in special populations, and no sedation.[10]

1.3. Bilastine in the treatment of chronic urticaria

Bilastine is an oral non-sedating second generation H1 antihistamine.[17–25] Pharmacokinetic properties of oral bilastine show rapid absorption[12,17,26] with bioavailability and Tmax of 60.67 %[17] and 1-1.5 h ours respectively.[17,27] Absorption of bilastine is linear and dose dependent.[26] Taken with fasting, bilastine is absorbed rapidly. As food or fruit juice, delay the absorption,[25] bilastine should not be taken with food.[28] Bilastine is recommended to be taken at least one hour prior to meal or at least two hours later.[25]

Bilastine undergoes negligible metabolism,[29] but no hepatic metabolism[26] and is almost exclusively removed through renal excretion.[29] It is largely excreted unchanged.[8] Bilastine does not affect activity of several isoenzymes of CYP 450 system[29] hence has minimal risk of drug-drug interaction.[8,12] The oral dose of bilastine adults and adolescents is 20 mg once-daily.[18] In patients with renal impairment, bilastine can be used in the dose of 20-mg per day.[8,18] It is not distributed to the central nervous system, is scarcely metabolized, and elimination is through the kidneys and faeces, with a 14-hour elimination half-life. It has no effect on cytochrome P450. Uptake of bilastine is increased with its concurrent intake with ketoconazole, erythromycin, or diltiazem.[30] No cardiotoxic effects have been observed, and the therapeutic dose does not alter the state of alertness.[28]

1.4. Efficacy of bilastine in urticaria

Pharmacokinetic properties of bilastine give rapid onset and long duration of action.[8,31] Bilastine 20 and 50 mg showed significant reduction of wheal and flare from 1.5 hour post dose than placebo, and significant effect lasted for 24 h our after dosing.[27] A study in healthy male volunteers

evaluating inhibition of skin wheal and flare responses over 24 hours showed no significant differences between bilastine 20 mg and cetirizine 10 mg. Onset of action of bilastine was faster than cetirizine and bilastine 50 mg had a longer duration of action than 20 mg.[32]

Several clinical trials have evaluated effects of bilastine in chronic urticaria.[21,22] A placebo controlled trial showed significantly better effect on urticaria symptom score with bilastine. No significant differences in primary endpoint and tolerability profile was observed as compared to other second-generation antihistamines i.e. cetirizine, levocetirizine and desloratadine.[20]

In another multicentre, randomized clinical trial,[21] efficacy and safety of bilastine 20 mg was compared with levocetirizine 5 mg once daily in patients with chronic urticaria having moderate-to-severe symptoms (n=535; age 18-70 years). In this 28 days study, bilastine was significantly better than placebo in reducing symptom score from day 2. Bilastine showed significant improvement in quality of life, discomfort, and sleep disruption ($P < 0.001$) as compared to placebo. Efficacy was similar to levocetirizine and tolerability profile with placebo.[21] A Japanese trial among adult patients with chronic spontaneous urticaria compared effects of once daily bilastine 20 mg and 10 mg given for 2 weeks. Bilastine was significantly better than placebo in reducing total symptom score. Improvement in total symptom score started from day 1 was maintained during the treatment period. The DLQI scores also improved as compared to placebo.[23] Another long-term study showed that bilastine 20 mg once daily is safe and well tolerated for 52 weeks in patients with chronic spontaneous urticaria. Symptoms were controlled early and maintained throughout the treatment.[22]

Bilastine improves quality of life in concurrence with symptomatic improvement.[33] In children (2-12 years of age) with chronic urticaria, bilastine 10 mg is similar in safety and tolerability as that of placebo.[34] In several countries, it is approved for the symptomatic treatment of allergic rhinitis and chronic urticaria in adults and children >12 years of age.[35,36]

1.5. Up-dosing with bilastine

Balancing efficacy and safety is important especially when using higher doses for controlling the symptoms.[37] Many patients with urticaria need higher doses and in them second generation antihistamines can be administered up to four times normal dose.[37]

Many studies[38–40] evaluated effects of bilastine in the higher than 20 mg per day. In a study (n=115) among adults patients with chronic spontaneous urticaria and some other pruritic conditions initial dose 20 mg once daily was doubled in those showing less than 30% improvement in pruritus score at week 2. It was significantly effective in decreasing weekly pruritus severity score from baseline to week 8. Up-dosing in non-responders (n = 31) was effective in improving efficacy with good tolerability profile. The Dermatology Life Quality Index (DLQI) was significantly improved at weeks 4 and 8 ($p < 0.001$) in all groups.[39]

A randomized crossover study[40] evaluated effects of up-dosing of bilastine in cold contact urticaria (n=20). Bilastine 20 mg was significantly effective in reducing critical temperature thresholds (CTT), the primary efficacy endpoint. Increasing dose to 80 mg significantly improved the effectiveness of bilastine. Bilastine 80 mg, resulted in response rate of 95% and symptom freedom rate of 60%. Up-dosing to 80 mg also resulted in significant reduction in microdialysis levels of histamine, IL-6 and IL-8 after 1-3 hours of cold challenge. Treatment was well tolerated without higher sedation after increase in the dose.

Considering its favourable properties, bilastine can be useful in the management of urticaria in the normal as well as higher dose (up to fourfold), if useful dose is not effective.[41]

Overall, bilastine is a suitable H_1 -antihistamine for up-dosing up to fourfold in difficult-to-treat patients with urticaria.

1.6. Tolerability and adverse events with bilastine

Bilastine does not produce significant adverse effect on body parameters or electrocardiogram.[35] Central nervous system related adverse events of antihistamines are based on the potential of the agent to bind with H1 receptors in the brain.[42] P-glycoprotein limits entry of bilastine into the brain.[12,31] Bilastine has very low cerebral histamine H1-receptor occupancy.[12] It is non-sedative antihistamine[12,17,18,24,25 26,29,32,40,43,44] A positron emission tomography (PET) study showed minimal H1 receptor occupancy with bilastine 20 mg and satisfied the criteria of non-sedation on PET scan.[45]

It has been shown that normal dose of bilastine with alcohol does not result in higher CNS depressant effects as compared to alcohol alone.[46] Bilastine also does not interact with benzodiazepines.[42] In a placebo-controlled study (n=22) bilastine 20 mg and 40 mg (once daily for 8 days) did not impair driving.[47] Different tests including imaging, psychomotor functions and subjective assessment suggest that bilastine does not have effect on CNS.[42] In another study among patients with allergic rhinitis and/or chronic urticaria, 7 days treatment with bilastine 20 mg in did not impair psycho motor performance.[44] A study in healthy volunteers also showed no sleepiness with bilastine 20 mg. The authors of this study concluded that bilastine may be a safe alternative for pilots with urticaria.[24] Considering non-impairment of driving ability,[35] it may be used in drivers with chronic urticaria.[12] Bilastine is highly selective.[26,35] and potent inhibitor of H1 receptor.[35] It is devoid of anticholinergic effects[34,47]

Table 1: Consensus statements for the use of bilastine in chronic urticaria

1. Bilastine is strongly recommended as a first line therapy in chronic urticaria in adult patient in standard dose of 20 mg once daily
2. No laboratory tests are routinely required before initiation of bilastine in normal dose
3. Bilastine should be taken one hour before or two hours after food or fruit juice to avoid its reduced effect[24,25]
4. Duration of treatment of bilastine is decided based on clinical features and course of condition
5. Dosage adjustment is not required in elderly patients[36] or those with renal impairment.[8,18] Administration with P-glycoprotein inhibitors should be avoided in moderate or severe renal impairment.[36]
6. Hepatic impairment is not expected to result in increased systemic exposure of bilastine beyond safety limits.[36]
7. In otherwise healthy patients with difficult to control urticaria, bilastine can safely be increased up to four fold.
8. Bilastine should not be used in patients with a history of QTc prolongation and/or torsade de pointes or history of hypersensitivity
9. As there is no sufficient evidence, bilastine should be avoided during pregnancy.[36]
10. In the absence of information about excretion in human breast milk,[36] decision of using bilastine should be made based on risk and benefit ratio
11. Safety and efficacy of bilastine in children under 12 years of age is not determined[36]

and cardiovascular effects.[18,26,48] In a prospective study, bilastine 20 mg was well tolerated by patients with 65 years or more age.[49] No environmental concerns exist from bilastine use in patients with urticaria.[19]

1.7. Consensus group Statements

The Consensus Group encourages initiatives to increase awareness of chronic urticaria among patients in India. The group also encourages different activities including physician education and guideline adherence to optimize treatment outcomes in these patients. The Consensus Group feels that more activities should be taken at the national level to raise awareness of guidelines. The Consensus Group also urges treating physicians to consider factors which achieve better patient adherence when prescribing antihistamines. These factors include convenience of treatment regimen, onset of symptom relief, duration of action, and tolerability profile. Bilastine due to its simple regimen, fast onset and long duration of action and good safety profile closely meets the criteria for the ideal antihistamine. The consensus statements for the use of bilastine in chronic urticaria are summarised in Table 1 .

The Consensus Group recommends that further research on chronic urticaria is required in India, including patient attitudes towards treatment and adherence and clinical trials with H1 antihistamines.

2. Conclusion

More research is required on the epidemiology and burden of urticaria in India. Considering under treatment of urticaria, efforts are needed to raise awareness about its burden, and optimization of treatment by adherence to treatment guidelines. Non- sedating antihistamines are recommended as first-line in the treatment for chronic urticaria. Availability of several such agents offers opportunity to the physicians to follow guideline recommendations for urticaria. Bilastine because of its well demonstrated efficacy in international trials, excellent tolerability profile, fast onset and long duration of action and non-sedative nature because of minimal CNS penetration can be considered as a well suited first line antihistamine in the treatment of chronic urticaria.

3. Conflict of Interest

None.

4. Support

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