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Research Article
Allergic

Comparative analysis of efficacy and safety of Bilastine 20 mg and Levocetirizine 5 mg in the treatment of Allergic Rhinoconjunctivitis

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Objective: The present study was conducted to assess the efficacy and safety of bilastine 20 mg and compare the results with that of levocetirizine 5 mg in the treatment of allergic rhinoconjunctivitis. **Material and Methods:** It was a prospective study conducted in the Department of Ophthalmology and Department of Otorhinolaryngology at a tertiary institute of southern Rajasthan, India during the period of 6 months from September 2019 to February 2020. 100 patients of chronic allergic rhinoconjunctivitis were included in the study, of which 50 were treated with Bilastine 20 mg, and the rest 50 patients were treated with levocetirizine 5 mg. The primary assessment was done by calculating the total symptom score (TSS) before and after the 7th and 14th post-treatment day. **Results:** The age of the patients ranges from 10 years to 65 years with a mean age of 32±5.2 years. The primary efficacy parameter for assessment was a reduction in total symptom score (TSS). Both bilastine 20 mg and levocetirizine 5 mg significantly reduced the TSS on the 7th and 14th post-treatment days (p-value< 0.001). There was no significant difference between TSS of bilastine and levocetirizine after 7 days (p-value= 0.41) and after 14 days treatment (p-value= 0.68). Adverse events were reported by 10% of patients in the bilastine group and by 38% of patients in the levocetirizine group. **Conclusion:** Bilastine is a selective H1 antihistamine with good efficacy and excellent safety profile and it is highly recommended to use it as a first-line treatment for allergic rhinoconjunctivitis.

Keywords: Allergic rhinoconjunctivitis, Anticholinergic, Antihistamines, Total symptom score, Urticaria

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Introduction

Allergic rhinoconjunctivitis is a common problem worldwide and its incidences are increasing day by day [1]. Data suggest that approximately 10-40% of the global population is affected by allergic rhinoconjunctivitis [2-5]. Allergic diseases impose a negative impact on a patient's physical, social, and psychological functioning with an adverse effect on a person's work capacity and quality of life.

H1 antihistamines are used as first-line treatment to treat allergic rhinoconjunctivitis for a long time [6-8]. First-generation H1 antihistamines have many side effects including anticholinergic effects, sedation, and interaction with alcohol and other drugs. Second-generation H1 antihistamines are free of anticholinergic effects, cause no sedation, and do not interact with alcohol or other drugs and thus, are used as first-line treatment for allergic diseases.

Bilastine is a newer generation, selective H1 antihistamine of the piperidine family. It was first approved by the European society of physicians in 2010 for symptomatic treatment in allergic rhinoconjunctivitis (seasonal or perennial) and now it is available worldwide [9].

Bilastine displays only limited penetration across the blood-brain barrier so does not cause sedation or somnolence and does not alter the cognitive performance of the patient, also does not potentiate the effects of alcohol. It does not exhibit any anticholinergic or cardiotoxic effect. So bilastine is comparatively safe and well-tolerated H1-antihistamine for the treatment of allergic rhinoconjunctivitis.

The present study has been performed to compare the efficacy and safety of bilastine 20 mg with levocetirizine 5 mg for the treatment of allergic rhinoconjunctivitis.

Material and Methods

It was a prospective study conducted in the Department of Ophthalmology and Department of Otorhinolaryngology at Ananta Institute of Medical Sciences, Rajsamand during the period of 6 months from September 2019 to February 2020.

Study design: Prospective, randomized, double-blind study.

Study population: 100 patients Who attended ENT or Ophthalmology outdoor with the clinical diagnosis of allergic rhinitis or allergic conjunctivitis during the study period, were included in the study. Out of 100 patients, 50 were treated with Bilastine 20 mg, and the rest 50 patients were treated with levocetirizine 5 mg. Both the medicines were advised to take once a day orally for 2 weeks.

Inclusion criteria:

All the patients who attended ENT or ophthalmology outdoor with the clinical diagnosis of allergic rhinitis or allergic conjunctivitis during the study period were included in the study.

Exclusion criteria:

01. Non-allergic rhinitis
02. History of intake of any type of anti-allergic medication for the past 2 weeks
03. Patients are unable to complete the questionnaire or not willing to take part in the study.

Assessment:

Primary outcome: All the study participants were advised to record their total symptom score (TSS) daily for 2 weeks (14 days). TSS was calculated daily as the sum of four nasal symptoms (sneezing, itching, rhinorrhea, and congestion) and three non-nasal symptoms (ocular symptoms- tearing, itching, and redness) symptom score (NSS and NNSS respectively).

Secondary outcome: All the patients in both groups were asked to report any adverse events suffered during and after the treatment.

Statistical analysis

Data analysis was performed using Statistical Package for Social Sciences (SPSS) software, version 19.0. Data of both the groups were compared and analyzed by Chi-square test or Student's t-test.

Results

100 patients with a clinical diagnosis of allergic rhinoconjunctivitis were included in the study and were randomized to double-blind treatment with bilastine 20mg and levocetirizine 5mg once daily for 2 weeks.

The age of the patients ranges from 10 years to 65 years with the mean age of 32±5.2 years.

The primary efficacy parameter for assessment was a reduction in total symptom score (TSS). Both bilastine 20 mg and levocetirizine 5 mg significantly reduced the TSS on the 7th and 14th post-treatment days (p-value< 0.001). There was no significant difference between TSS of bilastine and levocetirizine after 7 days (p-value= 0.41) and after 14 days treatment (p-value= 0.68). this shows that the symptom-relieving effect of both bilastine and levocetirizine are comparable (Table 1).

Table-1. Effect of treatment on total symptom score (TSS) in bilastine and levocetirizine groups.

Total symptom score	Bilastine group (mean±SD)	Levocetirizine group (mean±SD)	p-value
Pre-treatment score	7.47±2.10	7.41±2.06	0.88
Post-treatment score (on 7th day)	3.66±1.80 (0.0001*)	3.97±1.99 (0.0001*)	0.41
Post-treatment score (on 14th day)	2.79±1.05 (0.0001**)	2.88±1.14 (0.0001**)	0.68

*P-value between pre-treatment and 7th post-treatment day score.

**P-value between pre-treatment and 14th post-treatment day score.

Adverse events were reported by 10% of patients in the bilastine group and by 38% of patients in the levocetirizine group. The most common adverse event was somnolence followed by fatigue and dry mouth. All the adverse events were mild in severity (Table 2).

Table-2. Adverse events reported during 2 weeks of treatment with bilastine and levocetirizine.

Adverse events	Bilastine group (n=50)	Levocetirizine group (n=50)
Headache	1	2
Somnolence	1	11
Fatigue	3	3
Dry mouth	0	3
Total	5 (10%)	19 (38%)

Discussion

Allergic rhinoconjunctivitis affects people of all ages and harms a person's work efficiency and quality of life [10-17]. Second generation oral H1 antihistamines such as Bilastine, are prescribed as a first-line medication to treat allergic rhinoconjunctivitis [7,8,18,19].

Bilastine is a potent and highly selective oral H1-antihistamine that meets all the criteria of ARIA guidelines for medications to treat allergic rhinitis. The present study was specifically designed to assess the efficacy and safety profile of bilastine for the treatment of chronic allergic rhinosinusitis and to compare these with that of levocetirizine.

In the present study, both bilastine 20 mg and levocetirizine 5 mg significantly reduced the TSS on the 7th and 14th post-treatment days (p-value< 0.001). Pre-treatment TSS in the bilastine group was 7.47±2.10 which was reduced to 3.66±1.80 on the 7th post-treatment day and further reduced to 2.79±1.05 on the 14th post-treatment day. Similarly, pre-treatment TSS in the levocetirizine group was 7.41±2.06 which was reduced to 3.97±1.99 on the 7th post-treatment day and further reduced to 2.88±1.14 on the 14th post-treatment day. There was no significant difference between TSS of bilastine and levocetirizine after 7 days (p-value= 0.41) and after 14 days treatment (p-value= 0.68). Adverse events were reported by 10% of patients in the bilastine group and by 38% of patients in the levocetirizine group. The most common adverse event was somnolence followed by fatigue and dry mouth. All the adverse events were mild in severity (Table 2).

Our findings of the efficacy of bilastine are following the preliminary findings of Kuna P et al who performed a similar study with 683 patients in 2009. They compared the effect of bilastine with cetirizine and placebo. The mean TSS on the 14th day was reduced in the bilastine and cetirizine group to a similar and significantly greater extent, compared with the placebo group (p-value<0.001). Also when the comparison is done for adverse events, significantly fewer patients in the bilastine group experience somnolence (p value<0.001) and fatigue (p-value = 0.02) than patients in the cetirizine group [20].

Another study was performed in the past by Bachert C et al with a comparison of bilastine 20 mg, Desloratadine 5 mg, and placebo. A total of 721 patients of rhinoconjunctivitis were included in the study. TSS was significantly reduced in the bilastine group with the placebo group (p value< 0.001). The safety profile of bilastine and desloratadine was comparable to placebo [21].

Similar studies were carried out by Davila et al. and Bartra et al in 2011 and the results were following the present study.

They analyzed the data about the effect of bilastine upon nasal obstruction and ocular symptoms in 2-4 weeks duration clinical trial. Davila found a significant reduction in nasal obstruction symptom score after two weeks of treatment of bilastine 20 mg or cetirizine 10 mg or desloratadine 5 mg when compared to placebo. (p-value < 0.001). similarly, Bartra et al. found bilastine more effective in relieving ocular symptoms than placebo and as effective as other active comparators [22,23].

Zuberbier T et al. performed a placebo-controlled comparative study of the safety and efficacy of bilastine 20 mg and levocetirizine 5 mg for the treatment of chronic urticaria. They found the efficacy of bilastine 20 mg was comparable to levocetirizine 5 mg in the treatment of chronic urticaria. The differences in overall adverse events were not significant among the treatment groups [24].

In summary, the present study confirms and support the literature that bilastine 20 mg is a novel, safe, and effective treatment option for patients with chronic allergic rhinosinusitis

Limitations

01. Small sample size

02. The study was conducted over a short period

Conclusion

Bilastine is a new generation, non-sedating H1 antihistamine of the piperidine family. The present study was a comparative analysis of efficacy and safety between bilastine 20 mg and levocetirizine 5 mg for the treatment of chronic allergic rhinoconjunctivitis. The study suggests that a therapeutic dose of 20 mg bilastine meets current EAACI/ARIA criteria for medications used in the treatment of allergic rhinoconjunctivitis. Bilastine has similar efficacy to another second-generation H1 antihistamine with a more favorable safety profile so it can be used as a first-line treatment of allergic rhinoconjunctivitis.

What does the existing study add to the existing knowledge?

Many antihistamines are used as first-line treatment for allergic rhinoconjunctivitis but older generation antihistamines have some safety issues so newer medications are used nowadays.

Bilastine is a newer generation non-sedative H1 antihistamine with comparable efficacy and a better safety profile.

The present study adds various benefits of bliastine over other antihistamines and supports the fact that bilastine can be used as a first-line treatment for allergic rhinoconjunctivitis.

Author Contribution

Dr. Devendra Sharma: Study concept and design, revision and proof.

Dr. Hemendra Bamaniya: Data Analysis, statistics, and final drafting

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