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Original Article

Pharmacology Section

Efficacy and Safety of H2 Blockers as an Add-on Therapy to H1 Antihistamines in Allergic Rhinitis: An Open Label Randomised Controlled Trial

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ABSTRACT

Introduction: Allergic Rhinitis (AR), affecting 10-25% of the global population, is commonly treated with antihistamines and corticosteroids. H2-blockers, when combined with H1 antihistamines, enhance treatment efficacy and reduce symptoms. There is a need to conduct studies to establish more evidence around this combination and aid in the informed clinical decision-making process.

Aim: To compare the efficacy of Bilastine versus Bilastine combined with Famotidine in the management of AR at days 7 and 14 and also to compare serum IgE levels at days 0 and 14 among both groups.

Materials and Mehods: This open-label Randomised Controlled Trial (RCT) was conducted in the Pharmacology and Otorhinolaryngology department of Agartala Government Medical College (AGMC) and Govind Ballabh Pant Hospital (GBPH) between 1st February 2023 and 30th June 2024. The study included 340 newly diagnosed acute AR patients aged 18 years and above from the ENT OPD. Participants were diagnosed by clinicians based on signs and symptoms such as nasal itching, sneezing, a runny nose, and nasal obstruction, with symptoms persisting for more than four consecutive weeks. Randomised participants received either Bilastine 20 mg daily or Bilastine combined with Famotidine 40 mg daily for 14 days. The primary outcomes were nasal and non nasal symptom scores, while secondary outcomes included serum IgE levels. Data were collected in an approved Case Report Form (CRF) and statistically analysed using the Independent t-test, Mann-Whitney U test, Wilcoxon signed-rank test, and Chi-square test.

Results: The study included 340 participants aged between 18 and 80 years, comprising 178 (52.4%) males and 253 (74.4%) from urban areas. Rhinorrhea (83 cases, 24.4%) and nasal congestion (79 cases, 23.2%) were the most common symptoms. The combination therapy led to a significantly faster reduction in nasal symptoms (p-value=0.001). Serum IgE levels decreased in both groups (p-value=0.001 in Group A, p-value<0.001 in Group B), with a cut-off for serum IgE being <150 mg/dL. Adverse reactions were minimal, with two cases of nausea and bloating in Group A and two cases of nausea in Group B.

Conclusion: AR predominantly affected younger adults (ages 21-25 years). Combination therapy showed no adverse effects and provided faster symptom relief while reducing serum IgE levels.

Keywords: Bilastine, Famotidine, Immunoglobulin subunits, Randomised allocation, Serum IgE response

INTRODUCTION

AR, affecting 10-25% of the global population, is a significant public health concern, with notable regional and demographic variations [1]. It is primarily caused by an IgE-mediated [2] Type I hypersensitivity reaction, leading to inflammation of the nasal mucosa and systemic symptoms [3]. Current treatments focus on alleviating nasal symptoms but often neglect the broader systemic effects, which impact patients' overall quality of life [4]. The hygiene hypothesis suggests that reduced microbial exposure in modern environments contributes to increased allergic sensitisation, highlighting the complex nature of AR [5]. Despite its prevalence, the relationship between environmental factors and the rise of AR remains poorly understood [6]. Additionally, limited research exists on the long-term efficacy and safety of combining H1 and H2 antihistamines. Previous studies [7,8] mainly utilised cimetidine, while ranitidine combined with levocabastine [9] and cimetidine combined with chlorpheniramine [10] were also tried on trial participants in the treatment of AR.

Current management strategies primarily target nasal symptoms [11] while often underestimating systemic implications [4]. This study investigates the potential synergistic effects of combining the non sedating second-generation H1 antihistamine Bilastine with H2-blockers. Famotidine, a long-acting H2-blocker, requires once-daily dosing and is relatively cheaper than other H2 antihistamines previously tried in treating AR. The lack of awareness about this combination has further burdened patients [12].

Given this background, the present study was conducted to compare the efficacy of Bilastine alone versus Bilastine combined with Famotidine. Total Nasal Symptom Score (TNSS) were employed and Total Non-Nasal Symptom Score (TNNSS) to assess efficacy at days 7 and 14. The study also aimed to evaluate the proportion of participants achieving a symptom-free status by day 14. Secondary objectives included measuring serum IgE levels at days 0 and 14. By evaluating both efficacy and safety, the study aims to provide insights into the potential benefits of this combination therapy, offering an improved approach to managing AR.

MATERIALS AND METHODS

An open-label RCT was conducted at a tertiary care hospital of North East India over a period of 1.5 years, from 1st February 2023 to 30th June 2024, bearing the identification number {IEC No. Ref.No.F.4 (6-13)/AGMC/Medical Education/IEC Approval/2022/21,854, dated 9.1.2023}. This academic trial was registered with the Clinical Trials Registry of India (CTRI) under the registration number CTRI/2023/03/050870.

Inclusion criteria: Newly diagnosed acute AR patients aged 18 years and above from the ENT OPD were included in the study. Patients were diagnosed by clinicians based on signs and symptoms such

as nasal itching, sneezing, a running nose, and nasal obstruction, with symptoms persisting for more than four consecutive weeks.

Exclusion criteria: Patients with perennial rhinitis, recent treatment for conditions requiring specific medications (e.g., hypertension, diabetes), those on anti-inflammatory drugs, individuals whose jobs involved driving or operating heavy machinery, and pregnant or lactating women were excluded from the study [13].

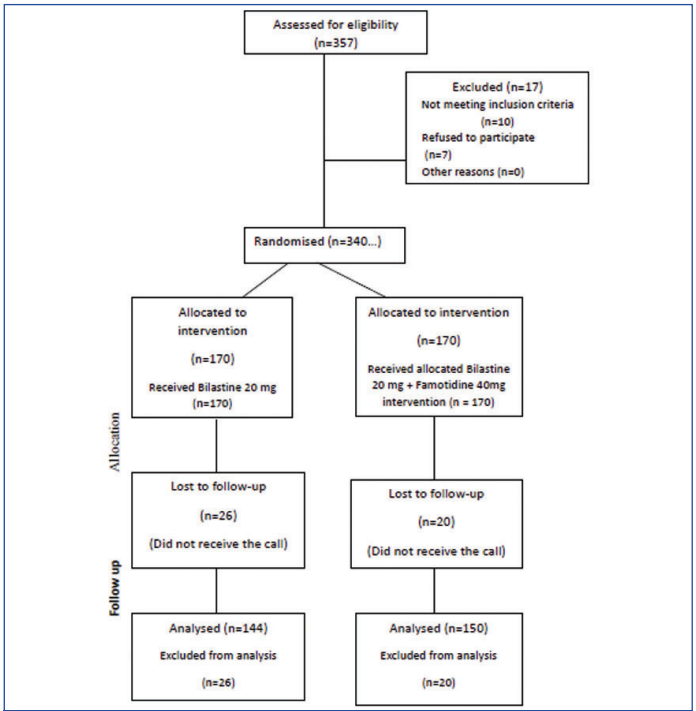
Sample size: Based on a previous study [14] with a standard deviation of 0.7, a power of 80%, and a true difference of 0.7, 152 participants per group were required. After accounting for a 10% dropout rate, 170 participants per group (340 total) were determined. The sample size was calculated using the following formula...

$$n=\frac{2\delta^2 (^{z} 1-\alpha+^{z} 1-\beta)^2}{(\mu_t-\mu_S-\delta)^2}$$

- δ=Superiority limit of the difference in means.
- μt=Mean of test treatment.
- μs=Mean of standard treatment.
- μt - μs=Expected mean difference.
- σ=Standard deviation.
- α=Significance level.
- 1 - β=Power.

The sample size was calculated using N-Master Software [15]. Permuted variable block randomisation with block sizes of 4, 6, and 8 was implemented using Sealed Envelope Ltd. software (2022). Allocation concealment was ensured through the Sequentially Numbered Opaque Sealed Envelope (SNOSE) method [16], with independent oversight by a pharmacology faculty member to maintain objectivity and integrity.

It was an open-label trial with two groups: one group received Bilastine (H1 antihistamine), and the other received Bilastine plus Famotidine (H1 + H2 blocker). After randomisation, one group of participants received Tab. Bilastine 20 mg once daily for 14 days, while the other group received both Tab. Famotidine 40 mg once daily and Tab. Bilastine 20 mg for the same duration. Total nasal and non nasal symptom scores were assessed on days 0, 7, and 14 Out of the total 340 participants, Groups A and B each had 170 participants. In Group A, 144 participants completed follow-up on both Day 7 and Day 14, with 26 lost to follow-up. Similarly, in Group B, 150 participants followed-up on both days, with 20 lost to follow-up [Table/Fig-1].



[Table/Fig-1]: Participant flow diagram.

The primary outcome variables were the Total Nasal Symptom Score (TNSS) and Total Non Nasal Symptom Score (TNNSS). The TNSS assessed symptoms such as sneezing, congestion, itching, and rhinorrhoea [17]. Non nasal symptoms included ocular itching, tearing, redness, and itching of the palate [18]. Each symptom was graded from 0 (no symptom) to 3 (severe) [17,18]. Rescue medication, if needed, was planned to be provided as per Global Initiative for Asthma (GINA) guidelines [19].

Data were collected in an approved case record form and kept confidential. The parameters assessed included age, gender, demographic distribution, common symptomatology, associated comorbidities, TNSS and TNNSS, serum IgE values, and adverse drug reactions.

STATISTICAL ANALYSIS

Data were analysed using Statistical Package for the Social Sciences (SPSS) version 25.0, employing descriptive statistics, unpaired t-tests, Chi-square tests, Wilcoxon signed rank tests, and Mann-Whitney U tests. A p-value < 0.05 was considered statistically significant.

RESULTS

Participants, were aged in between 18-80 years, with mean age being 39.41 years. Males with 178 participants were predominant (52.3%), while majority (247) of the participants hailed from urban demography (74.4%). The most reported symptom among participants was a running nose, experienced by 83 individuals (24.4%). This was followed by nasal congestion and sneezing, reported by 79 participants (23.2)% respectively. Other frequently observed symptoms included nasal itching (69 participants, 20.3%), throat pain (12 participants, 3.5%), and redness of the eyes (18 participants, 5.3%). Notable co-morbidities included pharyngitis in 22 participants (6.5%), Eustachian Tube Dysfunction in 21 participants (6.2%), Acute otitis media in 19 participants (5.6%), and Chronic Suppurative Otitis Media in 18 participants (5.3%). A less commonly reported condition was epistaxis, observed in 36 participants (10.6%), while other conditions such as lower respiratory tract infections (LRTI), congested nasal mucosa, and chronic rhinosinusitis were reported with lower frequency [Table/Fig-2].

Category	Sub-category/ condition	Total frequency (%)	Group A (n)	Group B (n)	p-value
Gender	Male	178 (52.3%)	92	86	0.59
	Female	162 (47.7%)	78	84	0.59
Residence	Rural	87 (25.6%)	40	47	0.46
	Urban	253 (74.4%)	130	123	0.46
Most common symptoms	Running nose	83 (24.4%)	45	38	0.45
	Nasal congestion	79 (23.2%)	42	37	0.61
	Sneezing	79 (23.2%)	38	41	0.80
	Nasal itching	69 (20.3%)	34	35	1.00
	Throat pain	11 (3.2%)	6	5	1.00
	Redness, watering, burning eyes	19 (5.6%)	10	9	1.00
Co-morbid conditions	Pharyngitis	22 (6.5%)	13	9	0.51
	Eustachian Tube Dysfunction (ETD)	21 (6.2%)	11	10	1.00
	Acute Otitis Media	19 (5.6%)	9	10	1.00
	Chronic Suppurative Otitis Media (CSOM)	18 (5.3%)	10	8	0.81
	No co-morbid conditions	260 (76.5%)	132	128	0.70

[Table/Fig-2]: Baseline demographic and clinical characteristics.

The data in [Table/Fig-3,4] summarises the changes in TNSS over time in the two study groups (A and B), each initially comprising 170 participants. The table shows a significant reduction in median TNSS from Day 0 to Day 14 in both groups. Similarly, Group B showed a reduction from 5 to 1 on Day 7 and 0 on Day 14. The p-value was statistically significant at Day 7 between Group A and Group B (p-value=0.001). The table also provides median and interquartile range (IQR) data, highlighting the decreasing trend in TNSS over time. Group A had a narrower IQR throughout, indicating more consistent responses, while Group B had a wider baseline IQR, suggesting greater initial symptom variability. By Day 14, both groups reached a median TNSS of 0, reflecting substantial symptom resolution.

Day	Group A (n)	Median (IQR)	Group B (n)	Median (IQR)	p-value
Day 0	170	5 (4-6)	170	5 (4-6)	1.00
Day 7	144	2 (1-3)	150	1 (0-2)	< 0.001
Day 14	144	0 (0-1)	150	0 (0-1)	1.00

[Table/Fig-3]: Median and Interquartile Range (IQR) of Total Nasal Symptom Score (TNSS).

	Median and IQR			p-value		
Group	Day 0	Day 7	Day 14	Day 0 vs Day 7	Day 7 vs Day 14	Day 0 vs Day 14
A	5 (4–6)	2 (1–3)	0 (0–1)	0.001	< 0.001	< 0.001
B	5 (4–6)	1 (0–2)	0 (0–1)	0.001	0.01	< 0.001

[Table/Fig-4]: Comparison for Total Nasal Symptom Score (TNSS).

The data in [Table/Fig-5,6] highlights that the median TNNSS progressively decreased from 2 on Day 0 to 1 on Day 7 and 0 on Day 14. This reduction was statistically significant at all intervals (p-values: 0.01, 0.01, and 0.000). At baseline, both groups had similar symptom severity, with slightly higher IQR in Group B. By Day 7, median scores dropped to 1, with narrower IQRs in Group A. By Day 14, both groups reached a median score of 0, indicating marked and consistent symptom improvement over time.

	Median and IQR			p-value		
Group	Day 0	Day 7	Day 14	Day 0 vs Day 7	Day 7 vs Day 14	Day 0 vs Day 14
A	2 (1–3)	1 (0-2)	0 (0–1)	0.01	0.01	0.00
B	2 (1–3)	1 (0-2)	0 (0–1)	0.01	0.01	0.00

[Table/Fig-5]: Comparison for Total Non Nasal Symptom Score (TNNSS).

Day	Group A (n)	Median (IQR)	Group B (n)	Median (IQR)	p-value
Day 0	170	2 (1–3)	170	2 (1–3)	1.00
Day 7	144	1 (0–2)	150	1 (0–2)	1.00
Day 14	144	0 (0–1)	150	0 (0–1)	1.00

[Table/Fig-6]: Median and Interquartile (IQR) and for Total Non Nasal Symptom Score (TNNSS).

[Table/Fig-7] shows that both Group A and Group B experienced a significant reduction in serum IgE levels from Day 0 to Day 14. Although Group A started with a slightly higher mean IgE level (454.12 vs. 432.84 IU/mL), the differences between groups at baseline (p-value=0.064) and at Day 14 (p-value=0.569) were not statistically significant. This suggests that both interventions were similarly effective in reducing IgE levels over the 14-day period.

[Table/Fig-8] shows that at Day 0, a higher proportion of participants in both groups had high IgE levels (>150 IU/mL), with Group A showing 78.2% and Group B 71.5% having high levels (p-value =0.041). By Day 14, both groups saw a significant reduction in participants with high IgE levels, with Group A having 1.9% and Group B having 5.9% (p-value=0.025), indicating an improvement in IgE levels over time.

Group	±Serum IgE		Mean Difference	p-value
	IgE at Day 0	IgE at Day 14		
Group A	454.12±390.82	58.91±54.69	395.21	0.001
Group B	432.84±381.91	56.60±48.26	376.24	<0.001
p-value	0.064	0.569		

[Table/Fig-7]: Comparison of serum IgE Level within in the study Group-At Day 0 and at Day-14.

Variable	Group A	Group B	p-value
Serum IgE (Day-0)			0.041
Total participants	170	170	
IgE advised	163	158	
Normal (<150)	37 (21.8%)	45 (28.5%)	
High (>150)	126 (78.2%)	113 (71.5%)	
Serum IgE (Day-14)			0.025
Total participants	144	150	
IgE advised	09	103	
Normal	107 (98.1%)	97 (94.1%)	
High	2 (1.9%)	6 (5.9%)	

[Table/Fig-8]: Comparison of serum IgE Level in the study group.
*Serum IgE was advised in 163 subjects in Group A and 158 subjects in Group B as the others had not consented to perform the tests.

Both Group A and Group B showed significant improvement in TNSS and TNNSS scores by Day 14, with Group A having a slightly higher proportion of symptom-free participants. Adverse effects were lower in Group A (1.4% on Day 7 and 1.4% on Day 14) compared to Group B (2.6% on Day 7 and 1.4% on Day 14). Nausea and bloating were common reactions, with Group B reporting more nausea on Day 14. Overall, both groups improved, but Group A had fewer side-effects [Table/Fig-9].

Study group	TNSS		TNNSS	
	Day-7 (N%)	Day-14 (N%)	Day-7 (N%)	Day-14 (N%)
Group A	37 (21.7)	111 (65.3)	106 (62.4)	138 (81.1)
Group B	59 (34.7)	120 (70.5)	106 (62.4)	133 (78.2)
p-value	0.049	0.086	---	0.18
Drug -efficacy by proportion of symptom free status				
	Day-7		Day-14	
	Group A	Group B	Group A	Group B
Follow-up patients	144	150	144	150
Adverse effects	2 (1.4%)	4 (2.6%)	3 (1.44%)	2 (1.4%)
Adverse reactions among both groups on taking medication at day 7 and 14				
	Group A		Group B	
	Day-7 (N=2)	Day-14 (N=3)	Day-7 (N=4)	Day-14 (N=2)
Nausea	1 (50%)	1 (25%)	2 (50%)	2 (100%)
vomiting	0	0	1 (25%)	0
Bloating sensation	1 (50%)	2 (75%)	1 (25%)	0
Types of adverse reactions on day 7 and 14 in groups A and B				

[Table/Fig-9]: Drug-efficacy by proportion of symptom free status, adverse reactions and its types among the groups.

DISCUSSION

In this study, findings on AR reveal several key insights into its demographic factors, symptoms, and treatment outcomes. Research by Varshney J and Varshney H, highlighted that AR tends to affect younger individuals, which was consistent with present study results; most patients were aged 21 to 25 years, with an average age of 39.41 years [12]. In terms of gender, while a study by Deb A et al., found a higher prevalence among females, our study showed a slight male dominance (52.3%), likely

due to Tripura's higher male workforce [20], leading to increased healthcare access for men [21].

The study also revealed a significant urban-rural disparity, with 74.4% of participants from urban areas. This aligns with findings from Cingi C et al., who noted higher AR prevalence in urban areas due to environmental factors like air pollution [22]. Symptomatically, the most common manifestations in this study—running nose, nasal congestion, sneezing, and nasal itching—echo the findings of Small P et al., reinforcing the consistent symptomatology of AR [23].

Regarding co-morbidities, present study identified pharyngitis, eustachian tube defects, and otitis media as the most frequent, contrasting with Deb A et al.'s report of bronchial asthma and sinusitis. In terms of treatment, the study examined the efficacy of combining anti-H1 and anti-H2 antihistamines, finding that combination therapy with Bilastine and Famotidine led to quicker symptom relief compared to Bilastine alone [21]. While both therapies proved effective by Day 14, the combination therapy had a faster onset of relief (p-value<0.01). This result aligns with findings from Carpenter GB et al., and underscores the benefits of dual antihistamine therapy for the management of AR [10].

The study also observed a reduction in serum IgE levels, in line with findings from Borro M et al., and Baroody F and Naclerio R, with both treatment groups showing significant improvements [24,25]. Radiological findings revealed that most participants had normal studies, with some cases of sinusitis and other ear/nose issues comparable to those reported by Messineo D et al., [26].

Adverse reactions were minimal, with nausea and bloating being the most common side-effects, and no severe reactions were reported, aligning with previous studies on the safety of Bilastine and Famotidine [27]. Overall, this study emphasises the importance of tailored interventions for AR, considering age, gender, environmental factors, and treatment efficacy. The findings contribute to a growing understanding of AR's diverse impact and management strategies, highlighting the potential of combination therapies for faster and safer symptom relief.

The present study, along with research conducted by Carpenter GB et al., evaluated the effectiveness of combining anti-H1 and anti-H2 antihistamines (Bilastine and Famotidine) versus using anti-H1 alone in the treatment of AR [10]. Both studies found that combination therapy provided more rapid relief, particularly within the first week, as evidenced by a greater reduction in the TNSS. By the end of two weeks, however, both treatments achieved similar effectiveness in alleviating nasal and non nasal symptoms. Statistical analysis reinforced the superiority of combination therapy in the short term, with significant differences observed in symptom reduction between Day 0 and Day 7. By Day 14, the outcomes were comparable between the groups, with both treatments effectively normalizing IgE levels in most participants. These findings support the clinical use of combined anti-H1 and anti-H2 antihistamines, particularly for faster symptom relief in AR, and suggest that this approach could improve clinical guidelines for managing the condition.

Limitation(s)

The study had several limitations that should be considered when interpreting the results. Firstly, it was conducted at a single centre, which limits the generalisability of the findings to broader populations. Secondly, although the same physician sample was used throughout the study, variations in the physician sample batch could introduce inconsistencies in treatment. These factors may impact the external validity of the study. Additionally, while the study demonstrates the efficacy of combination therapy with Bilastine and Famotidine in managing AR, its results may not be fully representative of all patient populations, particularly those with different comorbidities or treatment histories.

CONCLUSION(S)

In conclusion, while the study provides valuable insights into the management of AR, its limitations in terms of study design and sample population should be considered when interpreting the results and applying them to wider clinical practice.

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