

EFFICACY OF ORAL BILASTINE MONOTHERAPY VERSUS ORAL PROBIOTICS IN PATIENTS WITH ALLERGIC RHINITIS: AN OBSERVATIONAL COMPARATIVE STUDY

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ABSTRACT

Introduction: Allergic rhinitis (AR) is among the most common chronic disorders encountered in otorhinolaryngology practice, and pharmacotherapy with second-generation oral antihistamines remains the mainstay of symptomatic treatment. Study aimed to compare the efficacy of oral bilastine monotherapy versus oral probiotics in patients with allergic rhinitis over 4 weeks of treatment, with change in Total Nasal Symptom Score (TNSS) from baseline as the primary endpoint and change in Absolute Eosinophil Count (AEC) from baseline as the secondary endpoint. **Methods:** This prospective, observational, comparative study was conducted at a tertiary care center in South India in 2025. 100 patients aged 18–60 years diagnosed with allergic rhinitis with a TNSS >6 were included and allocated into two groups of 50 each. Group Bilastine received oral bilastine 20 mg, and Group Probiotics received oral probiotics once daily for four weeks. Patients were followed up at 4 weeks with TNSS and AEC. Data were analyzed using independent t-test and paired t-test, and chi-square test as appropriate, with $p < 0.05$ considered significant. **Results:** Both groups showed statistically significant within-group reductions in TNSS and AEC from baseline to 4 weeks. However, the bilastine group achieved significantly greater reductions than the probiotic group after 4 weeks, both in TNSS (50.8% vs 35%) and AEC (52.2% vs 40.7%). **Conclusion:** Oral bilastine monotherapy produced significantly greater short-term improvement in nasal symptom scores and peripheral eosinophil counts than oral probiotic monotherapy in patients with allergic rhinitis. Probiotics produced a modest but statistically significant improvement and may hold value as adjunctive rather than stand-alone therapy.

Keywords: Absolute eosinophil count, allergic rhinitis, antihistamine, bilastine, Lactobacillus, probiotics, Total Nasal Symptom Score

INTRODUCTION

Allergic rhinitis (AR) is an IgE-mediated inflammatory disorder of the nasal mucosa triggered by exposure to aeroallergens. It is one of the most common chronic diseases worldwide, affecting an estimated 10–40% of the global population, depending on geography and diagnostic criteria (Bousquet, Anto, et al., 2020; Bousquet, Khaltayev, et al., 2008). The disease is characterized by paroxysmal sneezing, rhinorrhoea, nasal obstruction, and nasal and ocular pruritus, and it frequently coexists with asthma, conjunctivitis, and sleep disturbance, producing a substantial burden on quality of life, work productivity, and healthcare utilization (Bousquet, Anto, et al., 2020). The Allergic Rhinitis and its Impact on Asthma (ARIA) initiative has, over the past two decades, provided an evolving evidence-based framework classifying AR as intermittent or persistent, and mild or moderate-severe, and has guided a stepwise approach to pharmacotherapy that has been progressively updated using GRADE methodology and real-world evidence (Bousquet, Schünemann, et al., 2020; Bousquet, Sousa-Pinto, et al., 2025; Dykewicz et al., 2020).

Second-generation (non-sedating) oral H1-antihistamines remain a first-line option in ARIA-based treatment algorithms because they offer of favorable balance of efficacy, rapid onset of action, and safety relative to first-generation agents (Dykewicz et al., 2020). Bilastine, a highly selective H1-receptor antagonist with negligible central nervous system penetration and no relevant hepatic metabolism, has demonstrated superiority over placebo and comparable efficacy to established antihistamines such as cetirizine, desloratadine, and fexofenadine across multiple randomized trials and meta-analyses, with consistent improvement in total nasal symptom score (TNSS), total symptom score, and quality-of-life measures (Church et al., 2019; Devadason et al., 2021; Kawauchi et al., 2019; Wang et al., 2016). Its once-daily 20 mg dosing, rapid onset within one hour, and sustained 24-hour duration of action have made it an increasingly preferred agent for the symptomatic treatment of AR in adults and adolescents (Church et al., 2019; Devadason et al., 2021).

In parallel, scientific interest has grown in the role of the gut microbiome in allergic disease pathogenesis, based on the hypothesis that specific probiotic strains can favorably modulate the Th1/Th2 cytokine balance underlying IgE-mediated hypersensitivity (Vliagoftis et al., 2008). Several randomized, placebo-controlled trials have evaluated *Lactobacillus paracasei* strains, alone or as adjuncts to standard antihistamine therapy, in patients with seasonal and perennial AR, with mixed but generally encouraging results on symptom scores and quality of life (Costa et al., 2014; Ivory et al., 2008; Luo et al., 2022; Ouwehand et al., 2009; Peng & Hsu, 2005; Wang et al., 2004; Zajac et al., 2015). Peng and Hsu (2005) demonstrated symptomatic benefit with heat-killed *Lactobacillus paracasei* in house-dust-mite-induced perennial AR, while the GA2LEN study found that *Lactobacillus paracasei* LP-33 improved rhinitis-related quality of life. However, it did not significantly change the total nasal symptom score when used as an adjunct to loratadine

(Costa et al., 2014). A recent systematic review and meta-analysis concluded that the evidence for probiotics in AR remains promising but heterogeneous, reflecting differences in bacterial strain, dose, duration, and outcome measures across studies (Zajac et al., 2015).

The pathophysiology of AR follows the classical early- and late-phase allergic response: allergen cross-linking of IgE on mast cells triggers immediate release of histamine, leukotrienes, and prostaglandins, producing the early symptoms of sneezing, itching, and rhinorrhoea, followed several hours later by a late-phase response dominated by recruitment of eosinophils, basophils, and T-helper-2 (Th2) lymphocytes into the nasal mucosa, which sustains nasal congestion and mucosal hyperreactivity (Bousquet, Anto, et al., 2020). Eosinophils are central effector cells in this late-phase response, releasing major basic protein, eosinophil cationic protein, and a range of cytokines that perpetuate mucosal inflammation and tissue remodeling (Bousquet, Anto, et al., 2020; Klimek et al., 2019). Because of this mechanistic centrality, eosinophil enumeration, whether as a peripheral blood absolute eosinophil count (AEC) or as a nasal smear/nasal cytology eosinophil percentage, has long been used as a practical, low-cost, objective correlate of allergic inflammatory activity that can be trended alongside subjective symptom scores in both clinical practice and comparative therapeutic research (Klimek et al., 2019).

Despite this growing body of literature, there remains a paucity of head-to-head comparative data evaluating a standard second-generation antihistamine against oral probiotic monotherapy, rather than probiotics used adjunctively in a single cohort of AR patients. Hence, the present study was designed to compare the efficacy of oral bilastine monotherapy versus oral probiotics in patients with allergic rhinitis over 4 weeks of treatment, with change in TNSS from baseline as the primary endpoint and change in AEC from baseline as the secondary endpoint.

METHODS

Study design and setting

This was a prospective observational comparative study conducted in the Department of Otorhinolaryngology, Navodaya Medical College Hospital and Research Center, Raichur, Karnataka, India, from March 2025 to November 2025. The study was conducted after getting clearance from the Institutional Human Ethics Committee (NMC/RCR/IHEC/111/2024-25).

Study Population

Patients presenting to the ENT outpatient department who were diagnosed with allergic rhinitis. Patients aged 18 to 60 years, with a TNSS > 6, were included in the study. Pregnant patients, patients with immunocompromised states or already receiving anti-allergic medication, and non-allergic rhinitis cases were excluded from the study. Those who satisfied the eligibility criteria above were enrolled after obtaining written informed consent.

Sample size and sampling

Considering an estimated minimum mean difference ($\mu_1 - \mu_2$) between TNSS reduction in bilastine and placebo as 1, and an average standard deviation (σ) of 1.8, at 95% confidence interval ($Z_{1-\alpha/2} = 1.96$), with 80% power ($Z_{1-\beta} = 0.84$), the sample size is calculated as $N = (Z_{1-\alpha/2} + Z_{1-\beta})^2 * 2 * \sigma^2 / (\mu_1 - \mu_2)^2 = 50$ for each group (Devadason et al., 2021; Zajac et al., 2015).

Consecutive sampling of patients attending the ENT outpatient department during the study period who were diagnosed with allergic rhinitis and satisfied the inclusion and exclusion criteria was considered for enrollment. A total of 100 patients who completed the study were enrolled, allocating 50 patients alternately to each treatment arm during consecutive enrolment.

Study Procedure

Eligible, consenting patients underwent a detailed history, general physical examination, systemic examination, and otorhinolaryngological examination, including diagnostic nasal endoscopy, to confirm the diagnosis of allergic rhinitis and to score baseline symptom severity.

Before baseline assessment and evaluation, patients taking topical nasal decongestants, intranasal corticosteroids, oral antihistamines, or leukotriene antagonists were required to complete a 7-day washout period to reduce the chance that these drugs would affect baseline symptom scores and treatment outcomes. During the pre-baseline drug history, adherence to the washout period was verified.

Patients were then alternatively allocated to one of two treatment groups: Group A (Bilastine): oral bilastine 20 mg once daily for 4 weeks. Group B (Probiotics): oral probiotics once daily for 4 weeks, containing *Lactobacillus paracasei* GMNL-133 and *Lactobacillus fermentum* GMNL-090 at a combined dose of 4 billion colony-forming units. The probiotic used in the study was AllerBio® Anti-Allergic Probiotic Sachet (1 g), manufactured by Fourrts. The formulation contains the probiotic components specified by the manufacturer. The product was stored according to the manufacturer-recommended storage conditions to maintain probiotic viability. Patient compliance was assessed through sachet count at follow-up visits and patient-reported adherence.

Patients were evaluated at baseline and reassessed at the end of 4 weeks of therapy for Symptom Severity by Total Nasal Symptom Score (TNSS) and Absolute Eosinophil Count (AEC). The current investigation was open-label, and neither the subjects nor the treating investigators were blinded to treatment allocation.

Rescue medication was allowed in the event of a severe aggravation of symptoms during the 4-week research period. We recorded any use of rescue medication, along with the treatment's dosage, frequency, and duration, in the patient's case file. Only two cases, one in each group, required rescue medication.

Patients who needed rescue medication were not automatically disqualified unless withdrawal or another predefined exclusion criterion was met.

The participants were also informed about the slower onset of action anticipated with probiotic monotherapy. It was emphasized that the treatment was meant to be continued for the duration of the study rather than being stopped early due to a lack of immediate symptom relief. Throughout the four-week follow-up period, adherence and continuation were tracked by frequent telephonic calls, and follow-up evaluations were conducted in accordance with the predetermined study schedule. There were no dropouts or losses to follow-up recorded in the final dataset.

Diagnosis and severity assessment

The diagnosis of allergic rhinitis was established clinically by a history of at least two of the cardinal symptoms (sneezing, rhinorrhoea, nasal obstruction, nasal or ocular itching) occurring on exposure to identifiable or presumed aeroallergens, supported by diagnostic nasal endoscopy findings (pale, oedematous nasal mucosa, watery secretions, and/or turbinate hypertrophy) consistent with allergic rather than infective or structural pathology, in keeping with standard ARIA-based diagnostic practice (Bousquet, Anto, et al., 2020; Bousquet, Schünemann, et al., 2020).

Total Nasal Symptom Score (TNSS) is a composite clinician- or patient-rated symptom severity score of the cardinal nasal symptoms of allergic rhinitis (sneezing, rhinorrhoea, nasal obstruction, and nasal itching) using the iTNSS questionnaire. Each symptom was graded as 0 (no symptoms), 1 (mild), 2 (moderate), or 3 (severe), and the symptom scores were summed to obtain the TNSS score. Higher TNSS score denotes greater severity; only patients with a baseline score greater than 6 were eligible for enrolment, restricting the study population to those with at least moderate symptomatic disease at presentation (Downie et al., 2004).

We estimated absolute eosinophil count (AEC) from venous blood collected in EDTA vacutainers, processing samples within 4-6 hours of collection using an automated 5-part differential hematology analyzer based on flow cytometry and light-scatter principles to identify and quantify eosinophils. AEC was calculated as eosinophil percentage of the total leukocyte count and expressed in cells/mm³. It is considered a marker of systemic eosinophilic/allergic inflammatory activity.

Statistical analysis

Data were entered into Microsoft Excel (Office 365) and analyzed using IBM SPSS version 21. Continuous variables (age, TNSS, AEC) are expressed as mean $\pm$ standard deviation and were compared between groups using the independent-samples Student's t-test; Within-group change from baseline to 4 weeks was assessed using the paired-samples t-test for each group separately. Categorical variables (gender distribution) were compared using the chi-square test of independence. A two-tailed p-value <0.05 was considered statistically significant.

RESULTS

Of the 100 enrolled patients diagnosed with allergic rhinitis who completed the study, 50 were in the bilastine group and 50 in the probiotic group. There were no losses to follow-up. Baseline and outcome data for TNSS and AEC were complete for all 100 patients.

Baseline characteristics

Table 1 summarises baseline demographic and clinical characteristics of the two groups. The overall cohort comprised 63 male (63%) and 37 female (37%) patients, with an age range of 23–33 years. The mean age in both groups was around 26 years and statistically comparable. The gender distribution was also similar in both groups, with no statistically significant difference.

Similarly, there were no significant differences in baseline disease severity between the treatment groups. The mean baseline TNSS was 8.14 ± 1.05 in the bilastine group and 8.44 ± 1.05 in the probiotic group ($p = 0.156$). The baseline AEC was 663.16 ± 66.65 cells/mm³ and 644.52 ± 72.45 cells/mm³, respectively, with no statistically significant difference ($p = 0.184$).

Table 1: Baseline demographic and clinical characteristics

Characteristic	Bilastine group (n=50)	Probiotic group (n=50)	Test statistic	p-value
Age, years (mean $\pm$ SD)	26.14 ± 1.65	25.84 ± 1.88	$t = 0.848$	0.399
Gender			$\chi^2 = 0.17$	0.680
Male, n (%)	30 (60.0%)	33 (66.0%)		
Female, n (%)	20 (40.0%)	17 (34.0%)		
Baseline TNSS (mean $\pm$ SD)	8.14 ± 1.05	8.44 ± 1.05	$t = -1.42$	0.156
Baseline AEC, cells/mm ³ (mean $\pm$ SD)	663.16 ± 66.65	644.52 ± 72.45	$t = 1.34$	0.184

SD = standard deviation; TNSS = Total Nasal Symptom Score; AEC = Absolute Eosinophil Count.

* $p < 0.05$ considered statistically significant.

Symptom Severity Outcome (TNSS)

Both treatment groups showed a highly significant reduction in TNSS from baseline to 4 weeks (paired t-test, $p < 0.001$ for each group). Mean TNSS fell from 8.14 ± 1.05 to 4.06 ± 1.33 in the bilastine group, a mean reduction of 4.08 ± 0.88 points (50.8% reduction from baseline). In the probiotic group, mean TNSS fell from 8.44 ± 1.05 to 5.54 ± 1.37 , a mean reduction of 2.90 ± 0.84 points (35.0% reduction from baseline). The between-group difference in TNSS reduction was statistically significant, favoring bilastine (independent t-test, $t = 6.85$, $p < 0.001$). Post-treatment TNSS at 4 weeks was also significantly lower in the bilastine group than the probiotic group (4.06 ± 1.33 versus 5.54 ± 1.37 ; $p < 0.001$).

Table 2: TNSS at baseline, 4 weeks, and change from baseline

Parameter	Bilastine group (n=50)	Probiotic group (n=50)	Test statistic	p-value (between groups by 't' test)
TNSS, baseline (mean $\pm$ SD)	8.14 ± 1.05	8.44 ± 1.05	$t = -1.42$	0.156
TNSS, 4 weeks (mean $\pm$ SD)	4.06 ± 1.33	5.54 ± 1.37	$t = -5.48$	$<0.001^*$
Mean reduction from baseline	4.08 ± 0.88	2.90 ± 0.84	$t = 6.85$	$<0.001^*$
% reduction from baseline	50.8%	35.0%	—	—
Test statistic	$t = 17.02$	$t = 11.88$	—	—
Within-group p-value (baseline vs 4 weeks, paired t-test)	$<0.001^*$	$<0.001^*$	—	—

SD = standard deviation; TNSS = Total Nasal Symptom Score. $*p < 0.05$

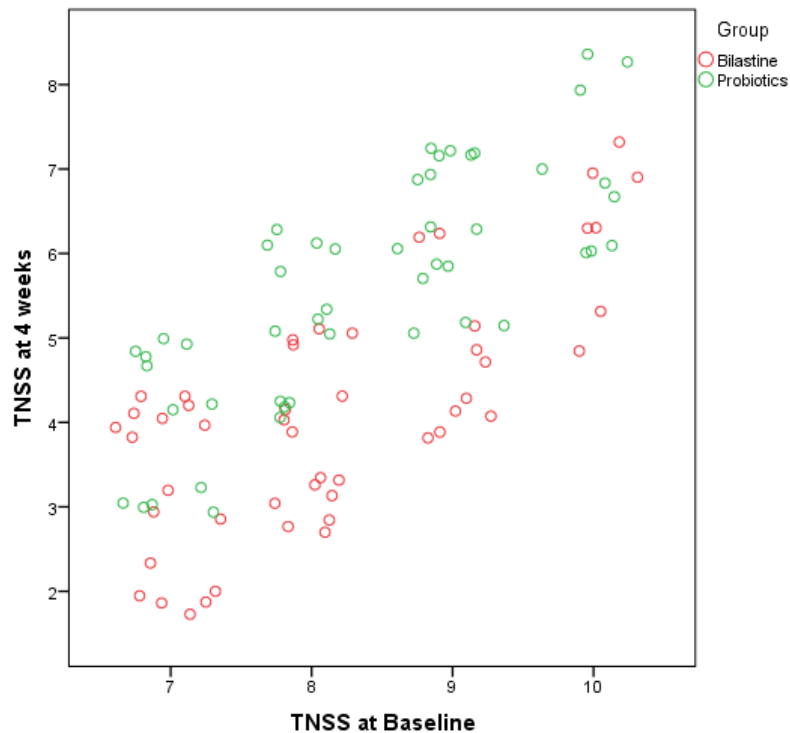


Figure 1: TNSS at baseline and at 4 weeks in Bilastine and Probiotics group – Jitter Plot

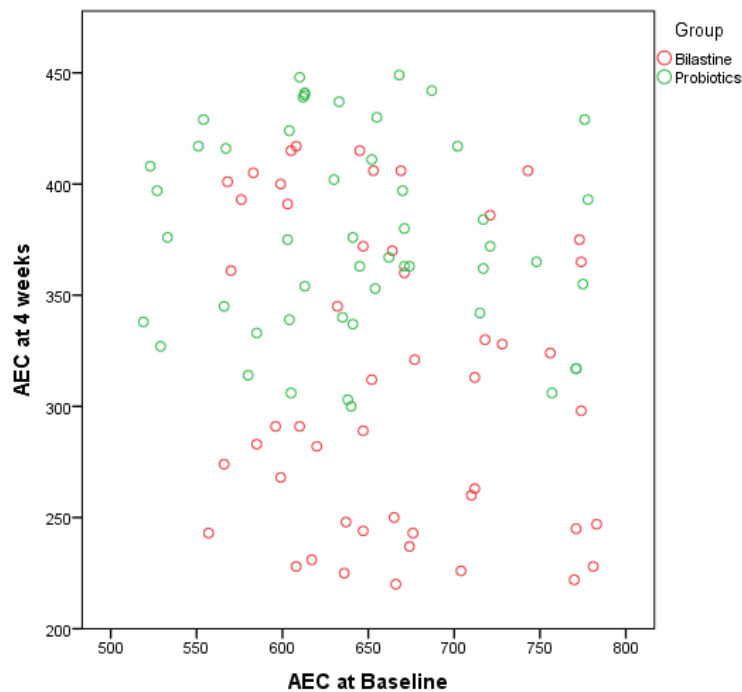
Absolute Eosinophil Outcome

Both groups also showed highly significant within-group reductions in AEC over the 4-week treatment period (paired t-test, $p < 0.001$ for each group). Mean AEC fell from 663.2 ± 66.7 cells/mm³ to 313.1 ± 67.3 cells/mm³ in the bilastine group, a mean reduction of 350.1 ± 102.7 cells/mm³ (52.2% reduction from baseline). In the probiotic group, mean AEC fell from 644.5 ± 72.45 cells/mm³ to 376.8 ± 44.5 cells/mm³, a mean reduction of 267.8 ± 89.1 cells/mm³ (40.7% reduction from baseline). The absolute reduction in AEC was significantly greater in the bilastine group. Post-treatment AEC at 4 weeks remained significantly lower in the bilastine group than the probiotic group (313.1 ± 67.3 versus 376.8 ± 44.5 cells/mm³; $p < 0.001$).

Table 3: Absolute Eosinophil Count (AEC) at baseline, 4 weeks, and change from baseline

Parameter	Bilastine group (n=50)	Probiotic group (n=50)	Test statistic	p-value (between groups by 't' test)
AEC, baseline, cells/mm ³ (mean $\pm$ SD)	663.16 $\pm$ 66.65	644.52 $\pm$ 72.45	t = 1.34	0.184
AEC, 4 weeks, cells/mm ³ (mean $\pm$ SD)	313.06 $\pm$ 67.32	376.76 $\pm$ 44.47	t = -5.58	<0.001*
Mean reduction from baseline, cells/mm ³	350.10 $\pm$ 102.67	267.76 $\pm$ 89.07	t = 4.28	<0.001*
% reduction from baseline	52.2%	40.7%	—	—
Test statistic	t = 26.13	t = 22.27	—	—
Within-group p-value (baseline vs 4 weeks, paired t-test)	<0.001*	<0.001*	—	—

SD = standard deviation; AEC = Absolute Eosinophil Count. * $p < 0.05$

**Figure 2: AEC at baseline and at 4 weeks in Bilastine and Probiotics group – Jitter Plot**

DISCUSSION

In this observational comparative study of 100 patients with allergic rhinitis, oral bilastine monotherapy produced significantly greater improvement than oral probiotic monotherapy in both the TNSS and the AEC over a 4-week treatment period. Both treatments produced statistically significant within-group improvement from baseline, indicating a therapeutic effect of probiotics. However, the magnitude of benefit was consistently and substantially smaller than that achieved with bilastine, with large effect sizes favoring the antihistamine on both outcome measures.

Bilastine is a second-generation, non-sedating H1-antihistamine that acts as a highly selective inverse agonist at the peripheral histamine H1 receptor. It has minimal affinity for other receptor systems and negligible penetration of the blood-brain barrier because it is of P-glycoprotein substrate. It is not appreciably metabolized by the hepatic cytochrome P450 system, giving it a low potential for sedation and drug-drug interaction relative to older antihistamines (Church et al., 2019; Kawauchi et al., 2019). Following oral dosing of 20 mg once daily, bilastine has a rapid onset of action (within about one hour) and a duration of effect covering a full 24-hour dosing interval, properties that plausibly underlie the fast, substantial reduction in TNSS observed in the bilastine arm of the present study (Church et al., 2019; Devadason et al., 2021).

The probiotic formulation used in this study combined *Lactobacillus paracasei* GMNL-133 and *Lactobacillus fermentum* GMNL-090. Probiotic strains of this type are proposed to act on the gut-associated immune system, promoting a shift away from the Th2-skewed cytokine profile (interleukin-4, interleukin-5, interleukin-13) that drives IgE-mediated allergic inflammation, and towards a more balanced or Th1/regulatory T-cell profile, partly through increased interferon-gamma production and modulation of dendritic cell signaling (Vliagoftis et al., 2008; Zajac et al., 2015). Because this mechanism acts upstream, on immune priming and regulation, rather than directly blocking histamine at the receptor level, its clinical effect would be expected to be slower in onset and more variable in magnitude than a direct H1-antagonist, which is consistent both with the smaller effect size observed here and with the mixed results reported across the probiotic trial literature (Luo et al., 2022; Ouwehand et al., 2009; Wang et al., 2004; Zajac et al., 2015).

The present study findings are broadly consistent with the existing literature on bilastine. Randomized, placebo-controlled trials and meta-analyses have repeatedly shown bilastine to produce significant, clinically meaningful reductions in TNSS, total symptom score, and rhinitis-related quality of life, with efficacy comparable to other second-generation antihistamines such as cetirizine, desloratadine, and fexofenadine (Church et al., 2019; Devadason et al., 2021; Kawauchi et al., 2019; Wang et al., 2016). In the phase III trial by Okubo et al. (2017) in Japanese patients with perennial AR, bilastine 20 mg once daily

produced a significantly greater reduction in TNSS than placebo within 2 weeks. Most comparative trials, however, position bilastine as non-inferior rather than clearly superior to other antihistamines, with its principal advantages lying in rapid onset of action and a favorable non-sedating profile rather than a larger ceiling effect on symptom scores (Church et al., 2019; Wang et al., 2016). The considerably larger effect size seen here for bilastine relative to probiotics is therefore better explained by the comparatively modest efficacy of probiotic monotherapy in this indication than by any unusual potency of bilastine itself.

The probiotic findings are also consistent with the wider literature, which describes a real but generally modest and inconsistent effect of *Lactobacillus*-based probiotics on AR symptoms. Peng and Hsu (2005) reported symptomatic improvement with heat-killed *Lactobacillus paracasei* in children with house-dust-mite-induced perennial AR, and other trials of *Lactobacillus paracasei* strains have shown improvement in quality-of-life measures and, in some studies, modest reduction in nasal and ocular symptom scores (Ivory et al., 2008; Luo et al., 2022; Ouwehand et al., 2009; Wang et al., 2004). By contrast, the GA2LEN double-blind, placebo-controlled trial of *Lactobacillus paracasei* LP-33 as an adjunct to loratadine found improved rhinitis-related quality of life but no significant change in total nasal symptom score (Costa et al., 2014), and a systematic review and meta-analysis concluded that evidence for probiotics in AR remains promising but heterogeneous across strains, doses, and outcome measures (Zajac et al., 2015). The present study adds to this literature by comparing probiotic monotherapy directly against an active, guideline-endorsed antihistamine rather than placebo. The results suggest probiotics exert a statistically significant symptomatic and eosinophil-lowering effect, consistent with modulation of the Th1/Th2 balance (Vliagoftis et al., 2008), but one that does not match the magnitude achieved with a modern second-generation antihistamine over 4 weeks.

For the practising otorhinolaryngologist or primary care physician managing a patient with at least moderately severe allergic rhinitis (TNSS >6, as used in this study's eligibility criteria), these findings support the continued use of a second-generation oral antihistamine such as bilastine as first-line pharmacotherapy when the clinical priority is rapid, substantial reduction in nasal symptoms and objective allergic inflammatory activity within a 2–4 week time frame (Bousquet, Sousa-Pinto, et al., 2025; Devadason et al., 2021; Dykewicz et al., 2020). Where patients specifically request a non-antihistamine or 'natural' therapeutic option, express concern about antihistamine side effects (even though bilastine itself has a favourable non-sedating profile), or are being considered for adjunctive or maintenance therapy once acute symptoms have been controlled, oral probiotics containing *Lactobacillus paracasei* and *Lactobacillus fermentum* strains may be considered as an option that produced a statistically significant, if more modest, benefit in this cohort; however, patients and clinicians should be counselled that, based on this and comparable studies, probiotic monotherapy alone is unlikely to match the speed or magnitude of symptom control achieved with a modern antihistamine in moderately-severe disease (Luo et al., 2022; Ouwehand et al., 2009; Peng & Hsu, 2005; Wang et al., 2004).

This study has several limitations that should be considered when interpreting the results. The study was open-label, with neither participants nor investigators blinded, and included no placebo or double-dummy arm. The absence of blinding may also have introduced observer and reporting bias, particularly for the subjective TNSS. The study was conducted at a single tertiary-care center, which may limit generalisability to other populations and practice settings. Because enrolment spanned different seasons, unequal seasonal exposure between the two treatment groups cannot be completely excluded. The follow-up period was limited to 4 weeks; longer-term efficacy, durability of response after treatment discontinuation, and relapse rates were not assessed. The diagnosis of allergic rhinitis was established clinically and endoscopically in keeping with ARIA-based practice, without confirmatory skin prick testing or serum allergen-specific IgE; despite the exclusion of clinically evident non-allergic rhinitis, patients with non-allergic or mixed rhinitis phenotypes may therefore have been enrolled, which would be expected to dilute the measured treatment effect in both arms. Peripheral absolute eosinophil count is a systemic hematological measure and, at best, an indirect surrogate of allergic inflammatory activity. It does not demonstrate change in local nasal mucosal immune function, for which nasal cytology, nasal eosinophil counts, or mucosal cytokine profiling would have been required.

A notable strength of this study was the completeness of follow-up. All enrolled participants completed the scheduled 4-week assessment despite the comparatively high baseline symptom burden (TNSS >6), giving a 100% completion rate with no dropouts. We used careful participant selection, thorough counseling on the treatment and course of therapy, reinforcement of treatment adherence at each visit, and frequent follow-up/contact with participants to achieve this. Regardless of the level of clinical improvement, participants were made aware at enrolment of the significance of finishing all planned tests. This study addresses an important gap in the literature by directly comparing probiotic monotherapy with the standard second-generation antihistamine bilastine in patients with allergic rhinitis. These findings provide locally relevant comparative evidence regarding the relative short-term effects of these two treatment approaches. Future research should include randomized controlled trials with placebo controls to establish the efficacy of bilastine and probiotics in achieving significant results in allergic rhinitis.

CONCLUSION

In this observational comparative study, oral bilastine monotherapy achieved significantly greater short-term improvement than oral probiotic monotherapy in both symptom severity (TNSS) and absolute eosinophil count in patients with allergic rhinitis, with both absolute and percentage measures of change favoring bilastine. Probiotics produced statistically significant, though comparatively modest, improvement on both measures, suggesting a smaller therapeutic effect that may be better suited to an adjunctive rather than stand-alone therapeutic role. These findings support current guideline-based positioning of second-generation oral antihistamines as first-line pharmacotherapy for allergic rhinitis.

Conflicts of Interest

The authors declare no conflicts of interest.

AI Usage Statement

Artificial intelligence (AI)-based tools were used solely to support the language refinement of the manuscript, including improvements in grammar, clarity, and readability.

Data Availability Statement

Data are available upon request from corresponding author with justification

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