ORIGINAL RESEARCH PAPER

Otorhinolaryngology

COMPARATIVE STUDY OF ALLERGIC RHINITIS OUTCOMES WITH AND WITHOUT PROBIOTIC SUPPLEMENTATION

KEY WORDS: Allergic rhinitis; Probiotics; Total Nasal Symptom Score; Lactobacillus.

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ABSTRACT

Background and aims: Allergic rhinitis is a common chronic inflammatory disorder that affects quality of life and daily functioning. Many individuals nevertheless have ongoing symptoms in spite of traditional treatment. Probiotics have emerged as a potential adjunctive treatment due to their immunomodulatory effects.The goal of the current study was to compare the results of individuals with AR who received extra probiotic supplementation vs those who received conventional therapy alone. **Methods:** A total of 44 patients with allergic rhinitis were included in this prospective comparative study, which was carried out over a six-month period at a tertiary care center. The patients were divided chronologically into two groups of 22 each, and Group A received a combination of Lactobacillus paracasei and Lactobacillus fermentum along with antihistamines for six weeks, while Group B received conventional therapy with Antihistamine once daily for the same duration. The Total Nasal Symptom Score (TNSS) was used for statistical analysis using SPSS version 20, and a p-value <0.05 was deemed statistically significant. **Results:** The mean age of participants was 27.64 ± 10.04 years in Group A and 31.5 ± 13.45 years in Group B, with comparable baseline demographic characteristics.The mean pre-treatment TNSS was 11.26± 2.8 in Group A and 10.9± 1.1 in Group B (p=0.57). Both groups showed significant improvement following treatment (p=0.0001). However, Group A demonstrated a greater reduction in TNSS from 11.26± 2.8 to 5 compared to 10.9± 1.1to 6.5±0.5 in Group B, with a statistically significant post-treatment difference between groups (p=0.0001). **Conclusion:** When probiotic supplementation was used in addition to conventional therapy, the symptoms of AR improved more than when conventional therapy was used alone. Probiotics could be a safe and useful supplemental medication for managing AR.

INTRODUCTION:

Allergic rhinitis (AR) is a chronic inflammatory disorder of the nasal mucosa mediated by immunoglobulin E (IgE) following exposure to environmental allergens. According to current data, AR affects approximately 10–30% of the world's population, with a higher prevalence among children and young adults. According to available data, between 10–30% of people worldwide suffer with AR, with children and young adults having a greater prevalence[1].

Allergen avoidance, antihistamines, intranasal corticosteroids, leukotriene receptor antagonists, and immunotherapy are common management strategies for AR; however, long-term use of these medications may be associated to side effects, insufficient symptom relief, recurrence following discontinuation, and poor compliance[2,3]. As a result, interest in complementary and adjunctive therapeutic approaches that may more naturally and safely modulate the immune response has grown.

Probiotics are live microorganisms that, when provided in sufficient amounts, offer health benefits to the host. Common probiotic organisms include species of Lactobacillus, Bifidobacterium, and Saccharomyces. The beneficial effects of probiotics are thought to occur through modulation of the intestinal microbiota, enhancement of epithelial barrier function, and regulation of immune responses[4,5]. According to the "hygiene hypothesis," reduced microbial exposure in early life may increase allergic inflammation[6]. Therefore, probiotics that restore a healthy gut microbiota may aid in lowering allergic inflammation.

Probiotics may enhance immune tolerance by boosting regulatory T-cell activity, balancing Th1/Th2 immune responses, lowering serum IgE levels, and suppressing eosinophilic inflammation; experimental and clinical studies have demonstrated that probiotics can affect cytokine production, including interleukin-10 and interferon-gamma, thereby reducing allergic responses; these immunomodulatory effects have prompted researchers to assess probiotics as adjuncts in the treatment of allergic rhinitis. These immunomodulatory effects have prompted researchers to assess probiotics as supplements in the treatment of AR[7].The effectiveness of probiotics in managing AR has been the subject of numerous randomized controlled trials and systematic reviews reviews, although heterogeneity exists among studies regarding probiotic strains, dosage, and duration of therapy. Further comparative studies are needed to evaluate the effectiveness of probiotic supplementation as an adjunct to standard therapy in AR

METHODS:

The present study was conducted among walk-in patients attending the Department of Otorhinolaryngology at Sapthagiri Institute of Medical Sciences and Research Centre. The study was designed as a prospective comparative study and was carried out over a period of six months, from 1st October 2025 to 1st March 2026.Prior to commencement of the study, approval and clearance were obtained from the Institutional Ethics Committee (SIMS & RC/ EC-22/ PG-01/ 2025-26). Patients diagnosed clinically with AR and fulfilling the inclusion criteria were enrolled in the study after obtaining written informed consent. The inclusion criteria comprised patients aged between 15 and 60 years presenting with symptoms suggestive of AR. Pregnant women and

patients with known congenital or acquired immunodeficiency disorders were excluded from the study.

The participants were divided chronologically into two groups. Group A received a combination probiotic preparation containing Lactobacillus paracasei and Lactobacillus fermentum, administered orally as one capsule daily with water for a duration of six weeks, along with antihistamine therapy. Group B received antihistamine tablet once daily for six weeks.

All participants were assessed using the Total Nasal Symptom Score (TNSS), a standardized scoring system used for evaluating the severity of AR symptoms. The TNSS assessment was performed prior to initiation of treatment and again after completion of six weeks of therapy.

Sample size calculation was performed based on the findings of Monica et al., which reported mean clinical outcome scores of 0.0887 ± 0.776 in the pre-treatment group and 1.89 ± 0.776 in the post-treatment group. Using these parameters, with an absolute precision of 1% and a study power of 90%, the minimum required sample size was calculated to be 18 participants in each group using OpenEpi software. Considering a possible dropout rate of 20%, the final sample size was increased to 22 participants per group. The collected data were entered into Microsoft Excel spreadsheets and statistical analysis was performed using SPSS version 20. Both descriptive and inferential statistical methods were applied for data analysis. A p-value of less than 0.05 was considered statistically significant.

RESULTS:

The study included 22 patients per group with the mean age of participants in Group A was 27.64 ± 10.04 years, while the mean age in Group B was 31.5 ± 13.45 years (p=0.291). The demographics of the patients is mentioned in figure1.

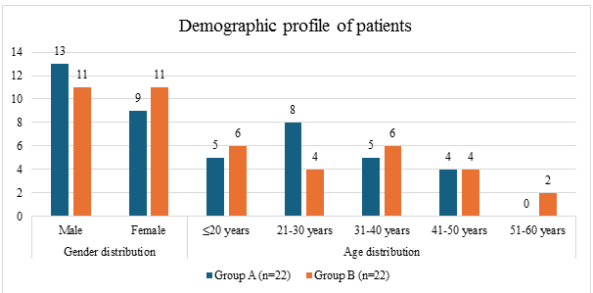

FIGURE 1: Demographic profile of patients with AR.

The mean pre-treatment Total Nasal Symptom Score (TNSS) was comparable between the two groups, with a mean score of 11.26± 2.8 in Group A and 10.9± 1.1in Group B, showing no statistically significant difference at baseline (p=0.57). Following treatment, both groups demonstrated a significant reduction in TNSS scores, indicating marked symptomatic improvement. In Group A, the mean TNSS decreased from 11.26± 2.8to 5, while in Group B it decreased from 10.9 to 6.5. The reduction in TNSS within both groups was statistically highly significant (p=0.0001). Post-treatment comparison between the groups revealed a statistically significant difference (p=0.0001), with Group A demonstrating a greater reduction in symptom scores compared to Group B, suggesting superior efficacy of probiotic supplementation in improving allergic rhinitis symptom (Table 1).

Table 1: Comparison of TNSS between the groups. [^ represent p<0.05 on Unpaired T-test; # represent p<0.05 on Paired T-test].

Groups	Pre-treatment TNSS	Post-treatment TNSS	P-value (Within group)
Group A	11.26± 2.8	5	**0.0001#**
Group B	10.9± 1.1	6.5± 0.5	**0.0001#**
P-value (Between the group)	0.57	**0.0001^**	

The two groups' pre-treatment evaluations revealed a comparable degree of AR symptoms, with no statistically significant changes in rhinorrhea (p=0.19), itching (p=0.711), sneezing (p=0.77), anosmia (p=0.98), or nasal congestion (p=0.09). Most patients in both groups had severe sneezing and anosmia, whereas 63.6% of Group A and 68.2% of Group B patients had significant nasal congestion. Significant clinical improvement in all symptom components was observed in both groups after treatment. Following treatment, the majority of patients showed only mild rhinorrhea, itching, and sneezing, while 45.5% of Group A and 54.5% of Group B participants experienced a complete resolution of anosmia. However, a statistically significant difference was observed in post-treatment nasal congestion scores (p=0.012), with Group A showing better improvement compared to Group B. Complete resolution of nasal congestion was observed in 36.4% of Group A patients compared to only 4.5% in Group B, suggesting superior efficacy of probiotic supplementation in improving nasal congestion symptoms in allergic rhinitis(Table 2).

Table 2: Comparison of components of TNSS during pre-treatment versus post-treatment periods. [*represent p<0.05 on Fischer exact test]

Period of assessment	Components	Groups	Nil (Score 0)	Mild (Score 1)	Moderate (Score 2)	Severe (Score 3)	P-value
Pre-treatment	Rhinorrhoea	Group A	0	7	7	8	0.19
		Group B	0	10	10	2	
	Itching	Group A	1	6	9	6	0.711
		Group B	0	8	9	5	
	Sneezing	Group A	0	1	6	15	0.77
		Group B	1	1	5	15	
	Anosmia	Group A	1	1	5	15	0.98
		Group B	1	1	6	14	
	Nasal congestion	Group A	0	0	8	14	0.09
		Group B	2	2	3	15	
Post-treatment	Rhinorrhoea	Group A	1	16	5	0	0.77
		Group B	1	16	4	1	
	Itching	Group A	1	14	7	0	0.93
		Group B	2	14	6	0	
	Sneezing	Group A	2	14	6	0	0.97
		Group B	3	13	6	0	
	Anosmia	Group A	10	10	2	0	0.53
		Group B	12	10	0	0	
	Nasal congestion	Group A	8	12	2	0	**0.012***
		Group B	1	10	10	1	

DISCUSSION:

Probiotics have been used clinically to treat a range of inflammatory conditions. They have also been shown to improve symptoms in about two thirds of patients with irritable bowel syndrome in a controlled trial and to reduce the incidence of hepatic encephalopathy in patients with liver cirrhosis. Additionally, their use has been shown to reduce the incidence of hepatic encephalopathy in patients with liver cirrhosis and to alleviate symptoms in almost two thirds of individuals with irritable bowel syndrome in a controlled trial[8–10]. The current study assessed the efficacy of probiotic supplementation in patients with AR and showed a significant improvement in symptom severity among patients receiving probiotics.

The current study showed that the two groups' mean pre-treatment TNSS were similar, indicating similar baseline symptom severity prior to the start of treatment. Following therapy, both groups showed statistically significant

reductions in TNSS scores, indicating that probiotics was effective in improving AR symptoms; however, the reduction in TNSS was significantly greater in the probiotic supplementation group. Group A's mean TNSS decreased from 11.26 to 5, with a highly significant post-treatment intergroup difference (p=0.0001). These results suggested that probiotic supplementation offered additional therapeutic benefit when combined with conventional therapy.

Probiotic organisms like Lactobacillus species are known to restore intestinal microbial balance, enhance mucosal immunity, suppress Th2-mediated allergic responses, and promote regulatory T-cell activity. These mechanisms reduce inflammatory cytokine release and serum IgE-mediated responses, thereby reducing nasal mucosal inflammation and improving allergic symptoms. Restoring gut microbial balance, boosting mucosal immunity, reducing Th2-mediated allergy reactions, and stimulating regulatory T-cell activity are all documented benefits of probiotics such Lactobacillus species. By lowering serum IgE-mediated reactions and inflammatory cytokine production, these processes lessen nasal mucosal inflammation and alleviate allergy symptoms[11, 12]. Similar mechanisms have been described in previous studies evaluating probiotics in allergic disorders.

The results of this study are similar to those of Perrin Y et al.'s randomized crossover trial, which assessed oral probiotic formulations containing Lactobacillus paracasei NCC2461 in patients with allergic rhinitis. The study showed that nasal symptom scores improved and emphasized the advantageous immunomodulatory effects of Lactobacillus paracasei in the treatment of AR [13].In a similar vein, Nembrini C et al. used Lactobacillus paracasei NCC2461 in a randomized, placebo-controlled research during the grass pollen season and found that probiotic-treated individuals had improved symptoms of allergic rhinitis and modulated allergic immune responses. Their results corroborate the probiotic group's superior TNSS reduction in the current study[14].Oral probiotic therapy improved nasal mucosal responses after allergen challenge in patients with seasonal allergy rhinitis, according to another randomized clinical trial by Ivory K et al. According to the study, probiotics can lessen allergic inflammation and modify local immune responses in the nasal mucosa[15].Lactobacillus salivarius significantly decreased rhinitis symptoms and medication use in children with allergic rhinitis, according to a randomized double-blind controlled trial conducted by Lin T et al. Their results provide more evidence that probiotics can be used as an adjuvant treatment for AR[16].

The present study had certain limitations that should be considered while interpreting the results. The sample size was relatively small, with only 22 participants in each group, which may limit the generalizability of the findings to the wider population. Long-term evaluation of symptom recurrence, sustained efficacy, and safety of probiotic supplementation was limited by the study's short duration of follow-up at a single tertiary care facility. Furthermore, the TNSS)was the primary tool used in the trial to evaluate clinical improvement; objective laboratory markers such serum IgE levels, eosinophil counts, cytokine profiles, or allergen sensitivity testing were not included. Treatment results may also have been impacted by differences in dietary practices, medication compliance, and exposure to environmental allergens. Furthermore, only a specific combination of probiotic strains (Lactobacillus paracasei and Lactobacillus fermentum) was evaluated, and therefore the results may not be applicable to other probiotic formulations. Larger multicentric randomized controlled trials with longer follow-up periods and objective immunological assessments are required to validate the findings of the present study and establish standardized probiotic protocols for allergic rhinitis management.

CONCLUSION:

Although several studies have demonstrated beneficial effects of probiotics in allergic rhinitis, some variability in treatment outcomes has been reported due to differences in probiotic strains, dosage, duration of treatment, patient characteristics, and outcome assessment methods. Nevertheless, the present study adds to the growing body of evidence supporting probiotic supplementation as a safe and effective adjunctive therapy in allergic rhinitis. The significantly greater reduction in TNSS observed in Group A suggests that probiotics may enhance the efficacy of conventional treatment and improve overall symptom control in allergic rhinitis patients.

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