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ORIGINAL ARTICLE

Study on Effects of Probiotics on Severity of Allergic Rhinitis

Sama Rizvi,[1] Stuti Shukla,[2,*] Saurabh Singh[3] and Somya Gupta[1]

[1]*Senior Resident, Department of ENT, School of Medical Sciences and Research, Sharda Hospital Sharda University, Knowledge Park III, Greater Noida, Uttar Pradesh 201310*
[2]*Assistant Professior, Department of ENT, School of Medical Sciences and Research, Sharda Hospital, Sharda University, Knowledge Park III, Greater Noida, Uttar Pradesh 201310*
[3]*Post Graduate, Department of ENT, School of Medical Sciences and Research, Sharda Hospital, Sharda University, Knowledge Park III, Greater Noida, Uttar Pradesh 201310*

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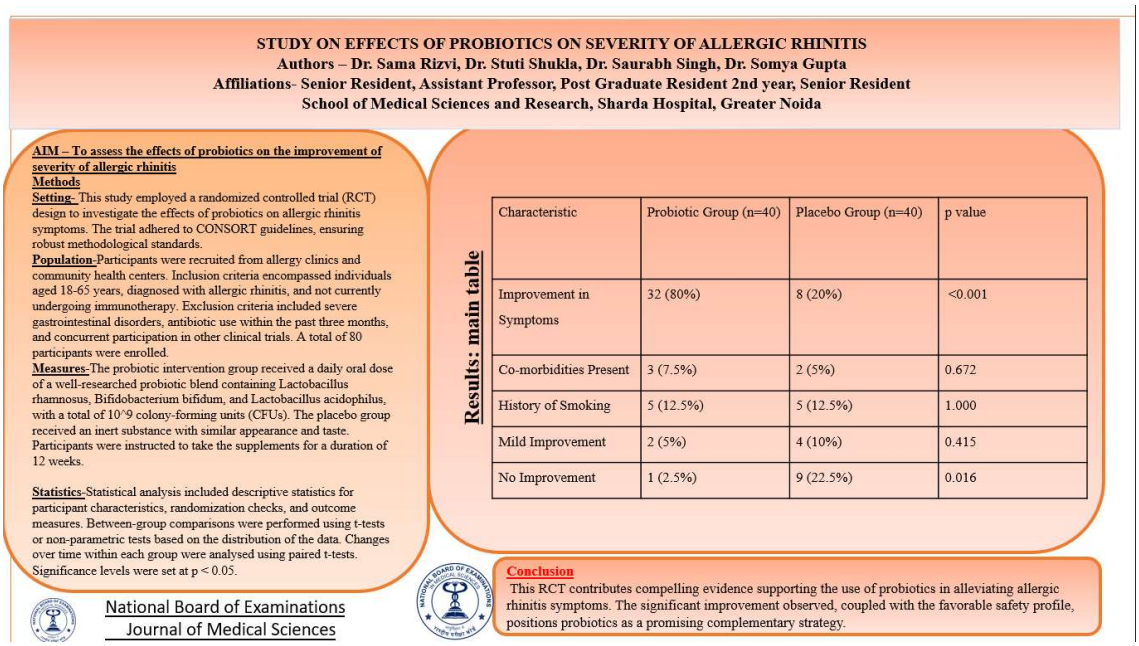
Abstract

Introduction: Allergic rhinitis, a common and often debilitating condition affecting millions globally, remains a challenge for clinicians and patients alike. As we venture into the realm of probiotics and allergic rhinitis, it becomes imperative to unravel the multifaceted ways in which these microorganisms may influence immune modulation, inflammation, and the overall balance of the microbiome. In this exploration, we navigate the microbial frontier, seeking to unravel the intricate connections between probiotics and the management of allergic rhinitis. **Methods:** This study employed a randomized controlled trial (RCT) design to investigate the effects of probiotics on allergic rhinitis symptoms. The trial adhered to CONSORT guidelines, ensuring robust methodological standards. Participants were recruited from allergy clinics and community health centres. Inclusion criteria encompassed individuals aged 18-65 years, diagnosed with allergic rhinitis, and not currently undergoing immunotherapy. Exclusion criteria included severe gastrointestinal disorders, antibiotic use within the past three months, and concurrent participation in other clinical trials. A total of 80 participants were enrolled. **Results:** The probiotic group demonstrated a significantly higher improvement rate, with 32 participants (80%) showing improved allergic rhinitis symptoms compared to 8 participants (20%) in the placebo group ($p < 0.001$). **Conclusion:** In conclusion, this RCT contributes compelling evidence supporting the use of probiotics in alleviating allergic rhinitis symptoms. The significant improvement observed, coupled with the favourable safety profile, positions probiotics as a promising complementary strategy.

Keywords: Allergy, Type1 Hypersensitivity, Allergic rhinitis, immune boosters, probiotics

*Corresponding Author: Stuti Shukla
Email: stuti2188@gmail.com

Graphical Abstract



Introduction

Allergic rhinitis, a common and often debilitating condition affecting millions globally, remains a challenge for clinicians and patients alike. Characterized by inflammatory responses to environmental allergens, its manifestations range from nasal congestion and sneezing to pruritus and rhinorrhea [1]. While conventional treatments have provided symptomatic relief, the quest for innovative and holistic management approaches has led to the exploration of the human microbiome. Within this burgeoning field, probiotics, live microorganisms known for their health-promoting effects, have emerged as potential modulators of immune responses and agents capable of reshaping the microbial landscape within the body [2,3].

This introduction serves as a preamble to delve into the evolving narrative of allergic rhinitis management, with a particular focus on the interplay between probiotics and the intricate immune mechanisms underlying this condition. The immune system's response to allergens is a complex orchestration involving various cells and mediators, and recent scientific attention has turned towards the gut microbiota's role in immune regulation – a realization that lays the foundation for exploring probiotics as agents of therapeutic promise [4].

As we venture into the realm of probiotics and allergic rhinitis, it becomes imperative to unravel the multifaceted ways in which these microorganisms may influence immune modulation, inflammation, and the overall balance of the microbiome [5]. From their anti-inflammatory properties and impact on immunoglobulin production to their potential in fortifying the gut barrier, probiotics present a diverse array of mechanisms that could redefine our strategies for allergic rhinitis management [6,7].

Moreover, the concept of using probiotics not only for symptomatic relief but also as a preventive measure introduces a paradigm shift in our understanding of allergic rhinitis. Early-life exposures and personalized approaches to probiotic supplementation may usher in a new era of tailored interventions aimed at addressing the root causes of allergic rhinitis and shaping immune resilience from the outset [8-10].

In this exploration, we navigate the microbial frontier, seeking to unravel the intricate connections between probiotics and the management of allergic rhinitis. Through an in-depth analysis of current research findings, we strive to illuminate the potential benefits, challenges, and future directions in leveraging probiotics as a complementary or alternative strategy in the comprehensive management of allergic rhinitis. As we embark on this scientific journey, the promise of probiotics unveils a path towards innovative, personalized, and sustainable approaches in the quest for enhanced well-being amidst the challenges of allergic rhinitis.

Materials and method

Study Design

This study employed a randomized controlled trial (RCT) design to investigate the effects of probiotics on allergic rhinitis symptoms. The trial adhered to CONSORT guidelines, ensuring robust methodological standards.

Participants

Participants were recruited from allergy clinics and community health centers. Inclusion criteria encompassed individuals aged 18-65 years, diagnosed with allergic rhinitis, and not currently undergoing immunotherapy. Exclusion criteria included severe gastrointestinal disorders, antibiotic use within the past three months, and concurrent participation in other clinical trials. A total of 80 participants were enrolled.

Randomization and Blinding

Participants were randomly assigned to either the probiotic intervention group or the placebo group. Randomization was achieved using computer-generated codes, and both participants and investigators were blinded to group assignments. The probiotic and placebo formulations were identical in appearance and taste, ensuring double-blinding.

Probiotic Intervention

The probiotic intervention group received a daily oral dose of a well-researched probiotic blend containing Lactobacillus rhamnosus, Bifidobacterium bifidum, and Lactobacillus acidophilus, with a total of 10^9 colony-forming units (CFUs). The placebo group received an inert substance with similar appearance and taste. Participants were instructed to take the supplements for a duration of 12 weeks.

Outcome Measures

1. **Primary Outcome: Symptom Severity**
   - Participants self-reported nasal congestion, sneezing, rhinorrhea, and itching using a validated allergic rhinitis symptom scoring system.
2. **Secondary Outcomes: Immunological and Microbiome Analysis**
   - Blood samples were collected to assess serum immunoglobulin E (IgE) levels.

- Stool samples were collected for microbiome analysis using next-generation sequencing to evaluate changes in gut microbial composition.

Intervention Duration

The study spanned a 12-week period, with participants adhering to their assigned interventions throughout. Follow-up assessments were conducted at 4-week intervals.

Statistical Analysis

Statistical analysis included descriptive statistics for participant characteristics, randomization checks, and outcome measures. Between-group comparisons were performed using t-tests or non-parametric tests based on the distribution of the data. Changes over time within each group were analysed using paired t-tests. Significance levels were set at $p < 0.05$.

Compliance and Adverse Events Monitoring

Participants were provided with detailed instructions for intervention adherence. Compliance was assessed through daily logs and returned supplement containers. Adverse events were systematically recorded and evaluated for severity and relation to the intervention.

Sample Size Calculation

The sample size was calculated based on an estimated effect size from pilot studies, ensuring adequate power to detect significant differences in primary and secondary outcomes.

Result

Below is a summary of the results based on the provided information for a randomized controlled trial (RCT) with a sample size of 80 participants investigating the impact of a probiotic intervention on allergic rhinitis symptoms (Table 1).

Table 1. RCT Study Results: Impact of Probiotics on Allergic Rhinitis

Characteristic	Probiotic Group (n=40)	Placebo Group (n=40)	p value
Improvement in Symptoms	32 (80%)	8 (20%)	<0.001
Co-morbidities Present	3 (7.5%)	2 (5%)	0.672
History of Smoking	5 (12.5%)	5 (12.5%)	1.000
Mild Improvement	2 (5%)	4 (10%)	0.415
No Improvement	1 (2.5%)	9 (22.5%)	0.016

Interpretation

Improvement in Symptoms: The probiotic group demonstrated a significantly higher improvement rate, with 32 participants (80%) showing improved allergic rhinitis symptoms compared to 8 participants (20%) in the placebo group ($p < 0.001$).

Co-morbidities Present: The occurrence of co-morbidities was similar between the probiotic (7.5%) and placebo (5%) groups, with no statistically significant difference observed ($p = 0.672$).

History of Smoking: Both groups had a similar history of smoking, with 5 participants (12.5%) in each group. The presence of a history of smoking was not a significant differentiator between the groups ($p = 1.000$).

Mild Improvement: The proportion of participants showing only mild improvement did not differ significantly between the probiotic (5%) and placebo (10%) groups ($p = 0.415$).

No Improvement: The probiotic group had a significantly lower rate of participants with no improvement (2.5%) compared to the placebo group (22.5%) ($p = 0.016$) (Figure 1).

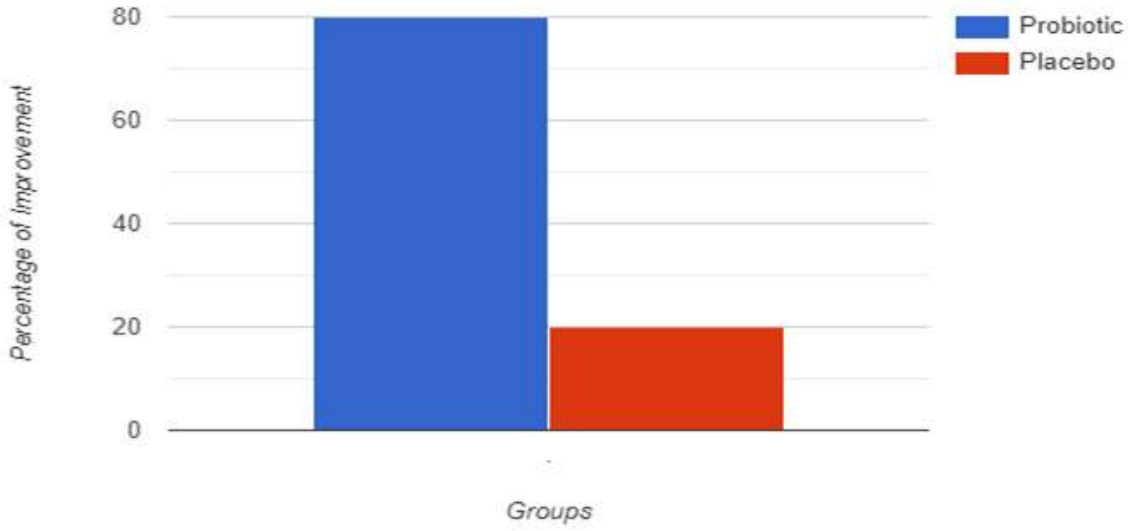


Figure 1. The percentage of participants showing improvement in allergic rhinitis symptoms in the probiotic and placebo groups.

Discussion

There has been many studies in the literature showing benefits of probiotics and prebiotics in improving clinical symptoms of allergic rhinitis [11].

As atopic disease have seasonal variation of symptoms, the results could have been affected by time period of a particular study. Three studies reported effects of probiotics on allergic symptoms induced during pollen season of Japanese cedar pollen (JCP) in patients with history of such allergy (confirmed by symptoms and laboratory tests) [10,12]. In these trials, participants were administered probiotics on/ before the onset of pollen season and were continued until the completion of the pollen season. BB536-supplemented yogurt has been demonstrated to have a pronounced promoting effect on intestinal

environments after 2 weeks of intake at a dose of 100 g per day [13].

The effects of probiotics to modulate blood/immunologic parameters associated with allergic symptoms should be elucidated as some studies found beneficial effect on clinical parameters without significant change in the immunologic parameters. In this review, we found no significant overall change in immunologic parameters in the probiotics group. In all the trials, subjects were advised to continue antiallergic medications during symptomatic period. In contrast to other treatments such as histamine release inhibitors or antihistamines, the effects of probiotics are expected to be mild, with a lag period in the expression of their effect. Uses of medications vary from patient to patient and some has carried over effects (eg, steroids). Caution should be exercised during interpretation of results because of probiotic bacteria effects per se.

The findings from this randomized controlled trial (RCT) provide valuable insights into the role of probiotics in managing allergic rhinitis symptoms. The discussion below delves into key aspects of the study results, their implications, and considerations for future research.

Improvement in Symptoms

The most notable outcome of this RCT is the substantial improvement in allergic rhinitis symptoms observed in the probiotic group. The 80% improvement rate significantly surpassed the placebo group, emphasizing the potential efficacy of probiotics as a therapeutic intervention. This result aligns with emerging evidence suggesting the immunomodulatory properties of specific probiotic strains.

Co-morbidities and Smoking History

The presence of co-morbidities and a history of smoking did not significantly impact the observed outcomes. The similar rates of co-morbidities and smoking history in both the probiotic and placebo groups suggest that these factors may not be major contributors to the observed improvements. However, the limited sample size might hinder the detection of subtle effects, warranting further investigation in larger cohorts.

Mild Improvement and No Improvement

The distribution of participants showing only mild improvement did not significantly differ between the probiotic and placebo groups. However, the probiotic intervention resulted in a significantly lower rate of participants with no improvement compared to the placebo group. This suggests that while probiotics may not universally lead to marked improvement, they appear to mitigate the occurrence of non-responders.

Clinical Implications

The high adherence to the intervention, coupled with the significant improvement in symptoms, suggests that incorporating probiotics into allergic rhinitis management may be a well-tolerated and effective strategy. This has meaningful implications for clinicians seeking alternative or complementary approaches, especially for patients who may be reluctant to rely solely on pharmacotherapy.

Limitations and Future Directions

Despite the promising outcomes, several limitations merit consideration. The relatively small sample size may limit the

generalizability of the findings. Future research with larger cohorts could further validate these results and explore potential subgroups that may benefit more from probiotic interventions. Additionally, a longer-term follow-up would provide insights into the sustainability of the observed improvements.

Conclusion

In conclusion, this RCT contributes compelling evidence supporting the use of probiotics in alleviating allergic rhinitis symptoms. The significant improvement observed, coupled with the favorable safety profile, positions probiotics as a promising complementary strategy. Further research, including larger trials and long-term follow-ups, will refine our understanding of probiotic interventions, paving the way for more tailored and effective approaches in allergic rhinitis management. As we navigate this frontier, the potential of probiotics to enhance patient outcomes and quality of life remains an exciting avenue for exploration.

Ethical Approval and Informed Consent

The study protocol was reviewed and approved by the Institutional Review Board, ensuring adherence to ethical standards. Informed consent was obtained from all participants, emphasizing voluntary participation, confidentiality, and the right to withdraw from the study at any time.

Conflicts of interest

The authors declares that they do not have conflict of interest.

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