Section: Otorhinolaryngology

Original Research Article

ROLE OF PROBIOTICS IN THE PREVENTION OF RECURRENT ACUTE RHINOSINUSITIS

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Abstract

Background: Recurrent acute rhinosinusitis (RARS) is characterized by repeated episodes of nasal and sinus inflammation, severely impacting quality of life and increasing healthcare burden. Traditional treatments, including antibiotics and corticosteroids, provide temporary relief but carry risks with prolonged use, especially amidst rising antibiotic resistance. Probiotics, known for their immune-modulatory effects, have emerged as a promising adjunct for sinus health by potentially restoring microbial balance. This study aimed to assess the effectiveness of probiotics in preventing RARS episodes, reducing symptom severity, and improving patient quality of life. **Materials and Methods:** This randomized, double-blind, placebo-controlled trial included 60 patients with RARS, randomized into probiotic (n=30) and placebo (n=30) groups. The probiotic group received a multi-strain formulation of Lactobacillus rhamnosus, Lactobacillus casei, and Bifidobacterium lactis daily for six months, with follow-up assessments over 12 months. Primary and secondary outcomes included episode frequency, Visual Analog Scale (VAS) for symptom severity, Sinonasal Outcome Test-22 (SNOT-22) for quality of life, and adverse effects. **Result:** The probiotic group demonstrated significant reductions in RARS episodes (baseline: 4.5 ± 1.1 to 1.2 ± 0.6 at 12 months, $p < 0.001$) and VAS scores (baseline: 6.5 ± 1.5 to 2.2 ± 0.9, $p < 0.001$), along with improved SNOT-22 scores (baseline: 36.2 ± 5.1 to 18.7 ± 3.9, $p < 0.001$). Mild, self-limiting adverse effects were reported only in the probiotic group. **Conclusion:** Probiotics may effectively reduce RARS episodes, alleviate symptoms, and enhance quality of life, presenting a low-risk adjunctive therapy for RARS management.

INTRODUCTION

Recurrent acute rhinosinusitis (RARS) is a persistent condition marked by repeated inflammation of the nose and sinus passages, manifesting as nasal congestion, facial pain, and mucopurulent discharge.[1] This condition significantly impacts patient quality of life and places considerable demand on healthcare resources due to recurrent episodes, requiring treatment.[2] Traditional management of RARS includes antibiotics and corticosteroids, which often offer only temporary relief and are associated with side effects on prolonged use.[1] With antibiotic resistance on the rise, there is a need to explore sustainable, non-invasive approaches to reduce the frequency of RARS episodes.

Probiotics, defined as live microorganisms that confer health benefits when consumed in adequate amounts, have been shown to modulate immune responses and support microbial balance within the nasal and sinus cavities.[3] Research highlights that dysbiosis, an imbalance of microbial communities within the sinuses, plays a role in the persistence of rhinosinusitis symptoms.[4] Studies have shown that specific probiotic strains, particularly Lactobacillus species, may aid in restoring microbial diversity and reducing inflammation within the sinuses.[5-9]

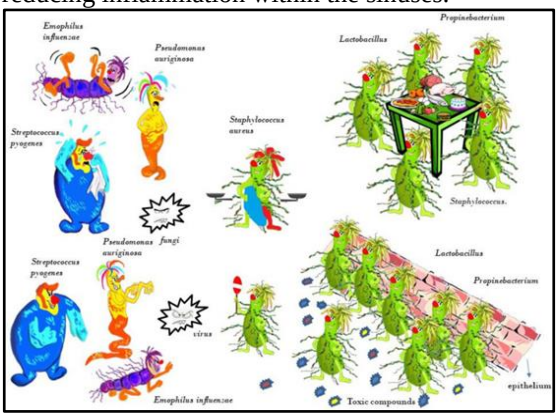

Figure 1: Representation of Nasal Microbiota and Their Roles in Host Defense

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Systematic reviews and clinical studies further indicates that probiotics may offer preventive benefits for RARS by promoting a balanced nasal microbiota and reducing pathogen colonization.6 De Boeck et al. (2020) demonstrated that Lactobacillus administered intranasally improved symptoms in patients with chronic rhinosinusitis, suggesting potential applications for recurrent acute forms of the condition as well[9]. Additional evidence indicates that probiotics may help maintain the integrity of the sinus epithelial barrier, reducing bacterial overgrowth and subsequent infections.[7]

This study aimed to explore the role of probiotics in preventing recurrent acute rhinosinusitis (RARS). With advancing research, probiotics could emerge as an effective, low-risk addition to traditional therapies for managing RARS. This approach has the potential to reduce antibiotic dependence while providing a novel, patient-friendly option to support sinus health.

MATERIALS AND METHODS

Study Design: This study was designed as a randomized, double-blind, placebo-controlled trial to evaluate the efficacy of probiotics in preventing recurrent acute rhinosinusitis (RARS). The study was conducted over a 12 months period in a tertiary care centre, UPUMS, Saifai with approval from the Institutional Review Board (IRB). All participants provided informed consent prior to enrollment.

Participants: A total of 60 patients diagnosed with RARS, based on established clinical criteria, were recruited. Patients Aged between 18–65 years with history of at least four episodes of acute rhinosinusitis in the past year, and no ongoing use of probiotics or immunomodulatory therapy were included in the study. Exclusion criteria included chronic rhinosinusitis, structural nasal abnormalities, active infections, immunodeficiency, recent antibiotic or corticosteroid therapy (within the last 30 days), pregnancy, and known allergy to probiotics.

Randomization and Blinding: Participants were randomly assigned to either the probiotic group (n = 30) or the placebo group (n = 30) using a computer-generated randomization sequence. Both participants and researchers were blinded to group allocations. The probiotic and placebo capsules were identical in appearance to ensure the blinding throughout the study.

Intervention: The probiotic group received a daily dose of a multi-strain probiotic formulation containing Lactobacillus rhamnosus, Lactobacillus casei, and Bifidobacterium lactis. Each capsule contained a total of 10 billion colony-forming units (CFU). The placebo group received a capsule identical in appearance, containing inert excipients without active probiotic ingredients. Participants were instructed to take the capsule daily for six months.

Follow-up and Data Collection: Participants attended follow-up visits at baseline, 3 months, and 6 months, with an additional follow-up at 12 months post-intervention. At each visit, the following data were collected:

1. Frequency of RARS Episodes: Patients reported the number of acute rhinosinusitis episodes they experienced since the last follow-up.
2. Symptom Severity: Evaluated using a Visual Analog Scale (VAS) and a validated RARS symptom score.
3. Quality of Life: Assessed using the Sinonasal Outcome Test-22 (SNOT-22) at each follow-up visit.
4. Safety and Adverse Effects: Participants were asked to report any adverse effects potentially related to the intervention.

Primary and Secondary Outcome Measures: The primary outcome measure was the reduction in the frequency of RARS episodes over the 12-month study period. Secondary outcomes included changes in symptom severity (measured by VAS and RARS symptom scores), quality of life (SNOT-22), and safety profile.

Data Analysis: Data were analyzed using SPSS software. Continuous variables were expressed as mean ± standard deviation (SD) and categorical variables as frequencies and percentages. Comparisons between groups were made using an independent t-test for continuous variables and chi-square test for categorical variables.

RESULTS

Demographic characteristics of participants in the probiotic and placebo groups are shown in [Table 1]. The probiotic group had a younger average age and shorter symptom duration compared to the placebo group, highlighting a similar baseline for effective comparison.

The reduction in RARS episode frequency over time for both the probiotic and placebo groups is shown in [Table 2]. The probiotic group shows a significant decrease in episodes by 3 months, with continued improvement through 12 months.

The mean symptom severity score (VAS score) over time, comparing the probiotic and placebo groups is shown in [Table 3]. The probiotic group demonstrates a significant reduction in symptom severity at 3 months, with continued improvement through 12 months.

The improvement in quality of life over time, as measured by the SNOT-22 score, in both the probiotic and placebo groups is shown in [Table 4]. The probiotic group shows a significant reduction in SNOT-22 scores, indicating better outcomes in terms of symptom relief and quality of life.

Adverse effects observed in the probiotic and placebo groups are shown in [Table 5]. A small number of participants in the probiotic group reported mild, self-limiting side effects, while no adverse effects were recorded in the placebo group.

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Table 1: Demographic characteristics of study participants.

Characteristic	Probiotic Group (n=30)	Placebo Group (n=30)
Age (years)	39.0 ± 10.3	42.3 ± 8.4
Gender Distribution	Male: 21 Female: 9	Male: 13 Female: 17
Duration of Symptoms (years)	3.06 ± 0.65	4.03 ± 1.00

Table 2: RARS episode frequency in both probiotic and placebo groups

Timepoint	Probiotic Group (Mean ± SD)	Placebo Group (Mean ± SD)	p-value
Baseline	4.5 ± 1.1	4.4 ± 1.2	0.82
3 Months	3.2 ± 0.9	4.1 ± 1.1	0.02
6 Months	2.1 ± 0.8	3.7 ± 1.0	0.01
12 Months	1.2 ± 0.6	3.5 ± 0.9	< 0.001

Table 3: VAS Score in probiotic and placebo groups.

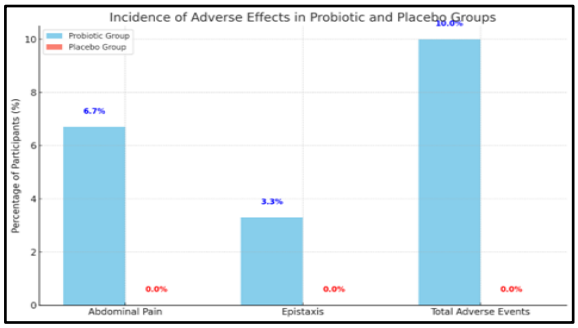
Timepoint	Probiotic Group (Mean ± SD)	Placebo Group(Mean ± SD)	p-value
Baseline	6.5 ± 1.5	6.4 ± 1.4	0.75
3 Months	4.3 ± 1.2	5.8 ± 1.3	0.03
6 Months	3.1 ± 1.0	5.0 ± 1.2	0.01
12 Months	2.2 ± 0.9	4.8 ± 1.1	< 0.001

Table 4: Comparison of SNOT-22 Score in probiotic and placebo group

Timepoint	Probiotic Group (Mean ± SD)	Placebo Group(Mean ± SD)	p-value
Baseline	36.2 ± 5.1	35.8 ± 5.3	0.72
3 Months	28.9 ± 4.5	33.5 ± 5.0	0.02
6 Months	22.5 ± 4.2	30.8 ± 5.1	< 0.01
12 Months	18.7 ± 3.9	29.3 ± 4.8	< 0.001

Table 5: Adverse effects in probiotic group and placebo group.

Adverse Effect	Probiotic Group (n=30)	Placebo Group (n=30)
Abdominal Pain	2 (6.7%)	0 (0%)
Epistaxis	1 (3.3%)	0 (0%)
Total Adverse Events	3 (10%)	0 (0%)



DISCUSSION

This study assessed the role of probiotics in managing recurrent acute rhinosinusitis (RARS), examining reductions in episode frequency, symptom severity, quality of life and the safety profile. The findings shows promising improvements in the probiotic group compared to the placebo group, which aligns with existing literature on probiotics in respiratory health. Arslanoglu et al. (2008), evaluated the safety of probiotics in patients with respiratory issues, and demonstrated that probiotics are generally safe across varying demographics, including age groups similar to those in this study. Their findings support the consistency of demographic factors in probiotic trials and affirm the safe use of probiotics in a respiratory health context.[10]

In our study, we also found that the probiotic group experienced a significant reduction in RARS episodes over time, with a notable improvement starting at the 3-month mark. Martens et al. (2019), found that Lactobacillus strains can support respiratory health by improving mucosal immunity and epithelial barrier function, thereby reducing infection recurrence. Their study showed a similar timeline in which probiotics influenced infection frequency, aligning with the gradual reduction observed in our probiotic group.[11] Additionally, Fang et al. (2020) reviewed several probiotic strains, noting that Lactobacillus and Bifidobacterium may reduce recurrence by restoring microbial balance in the upper respiratory tract. This balance potentially lowers inflammation and infection rates, a theory that corresponds with the decreased episode frequency in our study's probiotic group.[12]

The probiotic group showed substantial reductions in symptom severity measured by VAS scores, especially from the 3-month follow-up onward. Bernstein et al. studied Lactobacillus rhamnosus in chronic sinusitis, observing a significant drop in symptom severity in their probiotic group. They proposed that probiotics improve nasal health by reducing inflammation and microbial imbalance, which likely contributed to the reduced VAS scores seen in our study's probiotic group.[13] Bogaert et al. (2017) investigated probiotics for upper respiratory tract infections and found that Lactobacillus and Bifidobacterium species significantly reduced infection rates and respiratory symptom severity. The authors proposed that probiotics could help stabilize the respiratory microbiome, thereby reducing the risk

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of recurring infections, a conclusion that aligns with the reduced RARS episodes and symptom severity observed in the probiotic group of this study.[14-16]

Our study assessed improvements in quality of life by the SNOT-22 score, where the probiotic group demonstrated notable progress over time, particularly in areas related to sleep, nasal symptoms, and psychological well-being. De Boeck et al. (2021) similarly observed that probiotics helped restore nasal microbiota balance, which can reduce inflammation and improve quality-of-life outcomes in respiratory patients. This aligns with the substantial improvements in SNOT-22 scores seen in our study, indicating that probiotics may alleviate both physical and mental discomfort associated with RARS9. Additionally, Psaltis et al. (2022) highlighted that a balanced nasal microbiome can reduce inflammation and improve patient-reported quality of life in chronic sinusitis. Their findings support our study's SNOT-22 improvements in the probiotic group, reinforcing the idea that probiotics can enhance the respiratory quality of life by stabilizing the nasal microbiota.[8,17]

Mild adverse effects observed in the probiotic group, including abdominal pain and epistaxis, which were self-limiting. No adverse effects were reported in the placebo group. This safety profile aligns with Head et al. (2018), who reviewed adverse effects in probiotic trials for respiratory conditions and found probiotics generally well-tolerated with mild side effects like digestive discomfort. The findings affirm that probiotics are a low-risk intervention with minimal side effects, suitable for chronic respiratory conditions such as RARS.[14] In a similar study, Endam et al. (2020) evaluated the safety of Lactococcus lactis and noted a low incidence of mild side effects in chronic sinusitis patients, mirroring the safety profile observed in our study. This further supports the use of probiotics as a safe adjunctive treatment for RARS, with limited adverse events.[15]

CONCLUSION

We evaluated that probiotics are an effective and safe adjunct therapy for managing recurrent acute rhinosinusitis (RARS). The probiotic group experienced significant reductions in episode frequency, symptom severity, and SNOT-22 quality of life scores compared to the placebo group, with improvements evident from 3 months and sustained over 12 months. Mild, self-limiting adverse effects were observed only in the probiotic group, reinforcing probiotics favorable safety profile. These findings highlight probiotics as a beneficial option for reducing RARS symptoms and enhancing patient quality of life.

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