

Comparative clinical effectiveness of oral probiotics and oral fexofenadine in patients with allergic rhinitis: a prospective study

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Abstract.

Background

Allergic rhinitis (AR) is caused by immunoglobulin E (IgE)-mediated reactions to inhaled allergens and is one of the most common chronic conditions globally. Treated by multi modal therapy it involves methods to reducing allergen oral or topical anti-histamines, intranasal or systemic corticosteroids and oral probiotics.

Objective

1. Comparing the efficacy of oral probiotics and fexofenadine 120 mg in alleviating the symptoms of allergic rhinitis.
2. To compare the effect of the two drugs on nasal congestion, rhinorrhea, sneezing, and nasal itching.
3. Evaluating changes in Total Nasal Symptom Score after taking oral probiotics and fexofenadine.
4. Determining the more effective medication for each symptom in patients suffering from allergic rhinitis.

Method

A total of 120 patients visiting ENT OPD, Navodaya medical college, Raichur undergoing treatment for allergic rhinitis were included in the present study for period of 18 months from June 2023 to December 2024. 60 patients were given oral fexofenadine and 60 patients were given oral probiotics. Selection of the patients was done randomly.

Results

The participants were assessed through the Total Nasal Symptom Score (TNSS), where they were evaluated based on nasal congestion, runny nose, sneezing, itching, and other symptoms that impacted their sleep, lifestyle, and productivity. Probiotics yielded a better effect in treating nasal congestion, while fexofenadine 120 mg was more effective in treating the symptoms of runny nose, sneezing, and itching. Out of all the evaluated symptoms, only one of them (runny nose) was found to be statistically significantly reduced with fexofenadine.

Conclusion

Oral probiotics may help in relieving nasal congestion, whereas fexofenadine 120 mg helps in treating rhinorrhea, sneezing, and itching, particularly rhinorrhea.

Recommendation

Larger prospective studies are needed to ascertain efficacy, treatment length, and use as adjunctive therapy in individuals with allergic rhinitis and nasal obstruction.

Keywords: Allergic Rhinitis, Probiotics, Fexofenadine

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Introduction

Allergic rhinitis (AR) is caused by immunoglobulin E (IgE)-mediated reactions to inhaled allergens and is one of the most common chronic conditions globally. AR often co-occurs with asthma and conjunctivitis and is a global health problem causing a major burden and disability worldwide.¹

Symptoms associated with allergic rhinitis are nasal congestion, itching, running nose, sleep disturbance and other symptoms like conjunctivitis, cough and wheeze. Signs are watery nasal discharge with edematous nasal mucosa. Facial appearance characterised by mouth breathing, dark rings under eyes and performance of an allergic salute. Allergic Rhinitis is diagnosed by a clear history and corresponding nasal examination, Skin Prick Test, Serum IgE levels, Nasal allergen challenge.²

Allergic rhinitis is treated by various methods like methods reducing allergen exposure, pharmacological treatment involves oral or topical anti-histamines, intranasal or systematic corticosteroids, Leukotriene receptor antagonists (LTRAS), Decongestants, Immunotherapy.³ Treatment is based on severity of allergic rhinitis (fig 1).

Probiotics are live micro-organisms that confer a beneficial physiological effect on host when administered in adequate amounts.⁴ There is evidence suggesting that alteration of composition and/or size of the gut flora may modulate the IgE response to allergen. Fexofenadine is second generation anti-histamine which acts by blocking histamine effects in your body and is used in seasonal allergic rhinitis and chronic urticaria.⁵ In this study both the drugs are compared with each other in terms of relieving symptoms.

The objectives of this research were to conduct a comparison between the clinical efficacy of oral probiotics and fexofenadine 120 mg for patients having allergic rhinitis, effect on nasal congestion, rhinorrhea, sneezing, and itching, as well as change in the Total Nasal Symptom Score, to identify which treatment is more beneficial symptomatically.

Materials and methodology

Design of the Study

An observational comparative study was carried out to compare the effectiveness of oral probiotics of *Lactobacillus paracasei* and *Lactobacillus fermentum* with oral fexofenadine 120 mg in patients having allergic rhinitis.

Setting of the Study & Study Duration

The study was done in ENT Outpatient Department of Navodaya Medical College, Raichur, India. A total of 120 patients with a clinical diagnosis of allergic rhinitis were recruited within an 18 month period between June 2023 and December 2024. The patients who fulfilled the selection criteria

and visited the ENT OPD during the study period were assessed and recruited into the study.

Participants and Inclusion/Exclusion Criteria

Patients who had a clinical diagnosis of allergic rhinitis were included in the study. Patients having other forms of rhinitis along with pregnant and lactating mothers were excluded.

Sampling and Group Assignment

The participants who met the inclusion criteria were assigned to two groups. Group 1 received sachets of Allerbio that contained *Lactobacillus paracasei* and *Lactobacillus fermentum*, and group 2 got oral fexofenadine 120 mg.

Study Sample Size

There were 120 subjects involved in the study. Half of them got one preparation, while the other half got another. There is no sample-size calculation performed by researchers.

Study Variables and Outcome Measures

Effectiveness of the treatment was measured with the help of Total Nasal Symptom Score (TNSS). Symptoms measured with TNSS include nasal congestion, rhinorrhea, sneezing, itching, and symptoms that affect a person's sleep, lifestyle and work.

Potential Biases

To avoid selection bias, random assignment and inclusion/exclusion criteria were used in this research. The same outcome measure was used in both groups.

Ethics

Ethical approval was obtained from Institutional Ethics Committee of Navodaya Medical College, Raichur. The approval date and clearance number were not provided. Confidentiality of participants was assured during the study.

Results

The results were based on analysis of 120 patients with clinical diagnosis of allergic rhinitis, who were treated in its institution on OPD basis. 60 patients were treated with fexofenadine 120mg and 60 were treated with probiotics. Patients were evaluated and compared for improvements in symptoms.

Of the 60 patients of fexofenadine and 60 patients of probiotics, majority of patients 31(52%) and 30 (50%) respectively, had score 2 in TNSS questionnaire for running nose prior to treatment whereas after treatment majority of them, 38 (63%) patients reported score 1 in the fexofenadine group and 26 (43%) patients reported score 1 and 13 (22%) remained in score 2 in the probiotics group. Therefore, a reduction in score was higher in the fexofenadine group compared to the probiotics

group . This result was statistically significant, p value= 0.004511

Of the 60 patients of fexofenadine and 60 patients of probiotics evaluated for itching of nose and eyes, there was significant reduction in the number of patients in score 2, both fexofenadine and probiotics group. But, a reduction in score was higher in the fexofenadine group compared to the probiotics group as 29 patients had reported of score 0 compared to 27 of probiotics. However, this result was statistically insignificant p value=0.73310

Of the 60 patients of fexofenadine and 60 patients of probiotics, evaluation for sneezing showed significant reduction in the number of patients in score 3, 20 patients to 3 patients in fexofenadine and from 19 patients to 4 patients after using probiotics.

There is increase in number of patients reporting score 1 after treatment with both fexofenadine and probiotics group showing that patients had reduced sneezing after treatment with both fexofenadine and probiotics. But there wasn't much comparison in the efficacy of the both fexofenadine and probiotics in the treatment of this symptom. However, this result was statistically insignificant p value= 0.6775

In the treatment of other symptoms like sleep, lifestyle and work patients reported and improvement in scores, from score 2 to score 1 and 0. The number of patients reporting score 0 was

higher in the fexofenadine group ; 31 patients(52%) compared to 27 patients (45%) in probiotics group. However this result was not statistically significant p value=0.4691

In its study nasal congestion was significantly reduced by using probiotics while other symptoms like running nose, itching, sneezing were reduced more by using fexofenadine 120mg. However, the result was statistically significant only for the symptom of running nose.

Totally 120 patients attending ENT OPD at Navodaya Medical College, Raichur, were included in the study. The participants were screened using the inclusion and exclusion criteria that were pre-defined. The inclusion criterion was patients with a clinical diagnosis of allergic rhinitis and excluding patients having other forms of rhinitis, pregnant women, and lactating mothers. Out of the 120 patients, 60 patients were administered with the Allerbio sachets with Lactobacillus paracasei and Lactobacillus fermentum and 60 patients were administered with fexofenadine 120 mg. However, the records used in the current study do not indicate the total number that was screened for eligibility, exclusions in the screening, and any dropouts and reasons.

TABLES

Table 1 : Nasal congestion

SCORE	PRE-TREATMENT		POST-TREATMENT		
	FEXOFENADINE	PROBIOTICS	FEXOFENADINE	%	PROBIOTICS
0	4	4	6	10	28
1	13	18	38	63	23
2	31	31	14	24	8
3	12	7	2	3	1

Table 2: Running Nose

SCORE	PRE-TREATMENT		POST-TREATMENT	
	FEXOFENADINE	PROBIOTICS	FEXOFENADINE	PROBIOTICS
0	0	0	3	20
1	2	2	38	26
2	31	30	18	13
3	27	28	1	1

Table 3: Itching

SCORE	PRE-TREATMENT		POST-TREATMENT	
	FEXOFENADINE	PROBIOTICS	FEXOFENADINE	PROBIOTICS
0	13	14	29	27
1	28	26	30	31
2	19	20	1	1
3	0	0	0	0

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Table 4: Sneezing

SCORE	PRE-TREATMENT		POST-TREATMENT	
	FEXOFENADINE	PROBIOTICS	FEXOFENADINE	PROBIOTICS
0	0	0	3	2
1	5	7	38	38
2	35	34	16	16
3	20	19	3	4

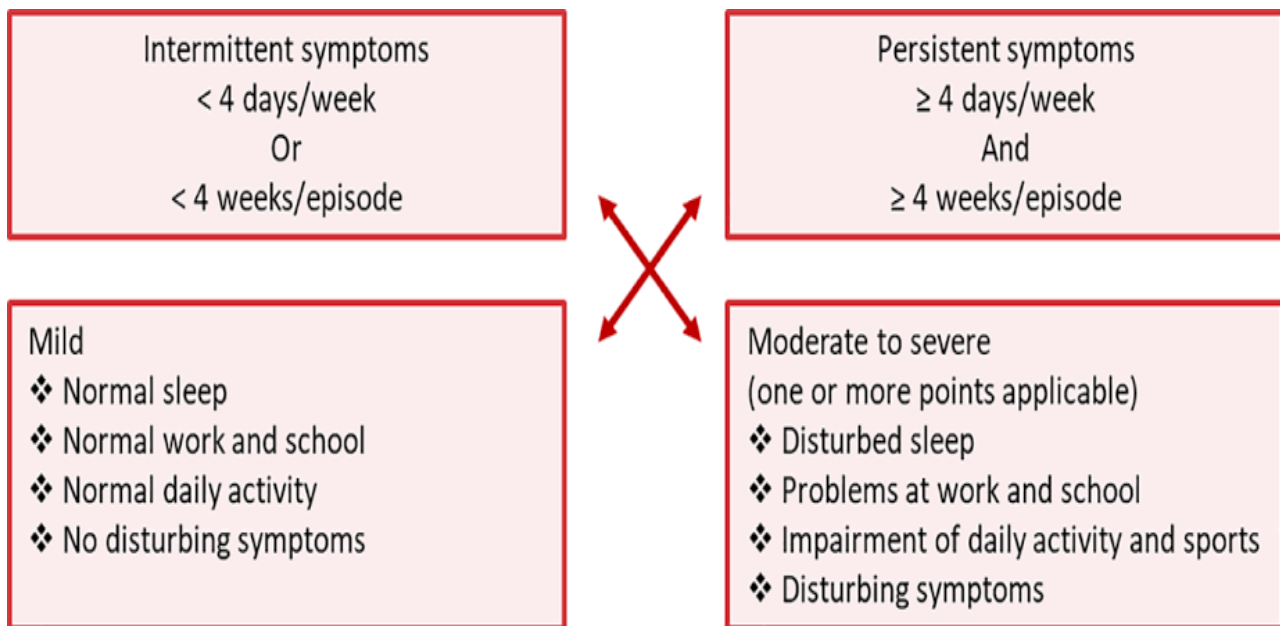


Fig 1 : ARIA classification of Allergic Rhinitis

Total nasal symptom score (TNSS)		
Symptom	Domain	Scale
Rhinorrhoea	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3
Nasal itching	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3
Nasal obstruction	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3
Sneezing	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3

Fig 2 : Total Nasal Symptom Score Questionnaire

Discussion

In its study probiotics group showed statistically significant result for nasal congestion scores, p value = 0.00023 as there is reduction in score of nasal congestion that was seen in more patients of probiotics group compared to that of fexofenadine group. One of the limitations of antihistamines is the lack of good control of the system of nasal congestion. Thus ,decongestants are often combined with antihistamines, which have shown greater benefit in improving nasal congestion than having antihistamines alone .6

Of the 120 patients evaluated for running nose,. Therefore, a reduction in score was higher in the fexofenadine group compared to the probiotics group. This result was statistically significant.

Of the 120 patients evaluated for itching ,the result was statistically insignificant .In evaluation, sneezing , showed an increase in number patients reporting score 1 after treatment with both fexofenadine and probiotics group showing patients had reduced sneezing after treatment with fexofenadine and probiotics. But there wasn't much comparison in the efficacy of both fexofenadine and probiotics in this treatment of this

symptom.

In the treatment of other symptoms like sleep, lifestyle and work patients, the number of patients reporting score 0 was higher in the fexofenadine group ; 31 patients (52%) compared to 27 patients (45%) in probiotics group . Finally upon totalling of the scores, it was seen that there were more patients who achieved a lower score group in fexofenadine group compared to probiotics group.

The results of sneezing, itching and other symptoms like sleep , lifestyle and work was statistically insignificant. Hence the total of TNSS scores also showed statistically insignificant results.

In its study nasal congestion was significantly reduced by using probiotics while other symptoms like running nose, itching , sneezing were reduced more by using fexofenadine 120mg. However, the result was statistically significant only for the symptom of running nose

In a pilot trail using probiotics *L. paracasei* (LP-33) to manipulate the gut microfloral ecosystem and showed that this strain had positive impact on the quality of life of perennial rhinitis sufferers. Results reveal that both scores of frequency and level of bother to overall quality of significantly decreased

in the LP-33 group compared with the placebo. In a randomised, prospective, double blind, controlled trial study of 187 preschool children of 2-5 years of age suffering from allergic asthma and/ or rhinitis was conducted done by Giovanni et al 7 to examine whether long term consumption of fermented milk containing a specific *Lactobacillus casei* may improve their health status it was found that, in the children with rhinitis, the annual number of rhinitis episodes was lower.

In a study done by Xiao et al 8 in adults with Japanese cedar pollen seasonal allergic rhinitis treated with *B.longum* BB536, *L.casei* strain Shirota, *L.acidophilus* L-92 or fermented milk containing LGG and *L.gasseri* TMC 1551 did not show any clinical benefit.

There are studies that also demonstrated that *L.casei* reduced the number of rhinitis episodes in 64 preschool with allergic rhinitis .9

Miyabe et al 10 studied the effect of fexofenadine upon cedar pollinosis. They found that fexofenadine administered before or after the onset of cedar pollinosis prevented or controlled nasal obstruction, sneeze and rhinorrhea.

Meltzer et al 11 studied the efficiency of fexofenadine in children with seasonal allergic rhinitis, found that it significantly reduced the total symptom score, sneezing ,rhinorrhea, itching nose/mouth/throat/ears/ itchy watery red eyes.

In study, Day et al 12 examined fexofenadine 120 mg, and placebo in an environmental exposure unit. Five symptoms of nasal congestion; sneezing ; rhinorrhea; itchy nose, palate , and/or throat and itchy, watery red eyes were evaluated, as well as total symptom score. The primary endpoint of the study was the measure of time to onset for clinically important relief, in which clinically important relief was defined by relaxed criteria of three consecutive time points where the subject experienced “slight” to “complete” relief. Median time to onset for clinically important relief was 60 minutes for fexofenadine and 100 minutes for placebo.

Fexofenadine showed an overall beneficial effect on the symptoms of SAR as measured by TSS and individual nasal symptom scores. The consistency of these findings reinforces the strength of the global evidence of clinical efficacy.

Generalizability

The study results could be generalized to the case of allergic rhinitis patients clinically diagnosed and treated in comparable ENT clinics. This is because the findings indicate that oral probiotics would be more effective in the alleviation of nasal congestion whereas fexofenadine 120 mg would work better for alleviation of rhinorrhea, sneezing and itching. However,

generalization is hampered by single centre design, sample size of 120 and lack of enough comparison groups.

Limitations

The study had several limitations, including the one-center design, a small number of subjects used, the use of self-reported TNSS results, and short follow-up period. It could have also been affected by lack of information regarding dropouts and possible confounders.

Conclusion

Although allergic rhinitis has no significant risk of mortality, the symptoms have a substantial impact on sleep, productivity and quality of life. The present study suggests that oral probiotics may be beneficial in alleviating nasal congestion in patients with allergic rhinitis, while fexofenadine 120 mg provides superior relief of rhinorrhea, sneezing, and itching. Among these symptoms, only the improvement in rhinorrhea was statistically significant in favor of fexofenadine. Probiotics may therefore represent a promising adjunctive therapeutic option, especially for patients with predominant nasal congestion.

Recommendations

Use of Oral Probiotics

Oral probiotics can be used as adjunctive treatment in patients with allergic rhinitis, especially where nasal obstruction is the dominant symptom. This will serve to supplement, but not substitute, conventional treatment.

Choice of Fexofenadine

In cases where rhinorrhea, sneezing and nasal itching are the main symptoms, then the preferred dose of fexofenadine is 120 mg. This is according to the study that revealed its superiority in the treatment of such symptoms.

Further Clinical Studies

It would be advisable for further research to be carried out using larger numbers of people in multicentre prospective trials for a longer period of time.

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List of Abbreviation

ABBREVIATION	MEANING
ENT	Ear, Nose and Throat
OPD	Outpatient Department
TNSS	Total Nasal Symptom Score
AR	Allergic Rhinitis
SD	Standard Deviation
<i>L. PARACASEI</i>	<i>Lactobacillus paracasei</i>
<i>L. FERMENTUM</i>	<i>Lactobacillus fermentum</i>

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Conflict of interest

NO CONFLICT OF INTEREST

Author Contributions

All authors contributed to the conception and design of this study. All authors contributed to subject recruitment, evaluation, data collection, data analysis and interpretation, and manuscript writing. All authors have read and critically revised this manuscript, have approved the final version, and are responsible for the integrity and validity of the work.

Author Biography

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to appropriate ethical and institutional requirements.

Personalization

Throughout the manuscript, personalized expressions such as “our study,” “our findings,” “we observed,” and “we found”

should be replaced with neutral academic expressions such as “this study,” “the findings,” “the analysis showed,” and “the results indicated.” This maintains an objective and formal academic tone.

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