Journal of
Clinical & Medical Surgery

www.jclinmedsurgery.com

ISSN 2833-5465
Open Access
Volume 4

Research Article

Probiotics as an Alternative Option in Treatment of Allergic Rhinitis: Comparing Probiotics vs Fexofenadine in treatment of Allergic Rhinitis

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Article Information

Received: Nov 25, 2024
Accepted: Dec 16, 2024
Published: Dec 23, 2024
Archived: www.jclinmedsurgery.com

Abstract

Aims: Intermittent treatment with oral antihistamines and nasal sprays are costly, may not completely resolve symptoms and can cause varying degrees of sedation.

Probiotics are perceived to exert beneficial effects in the prevention and treatment of allergic diseases with no side ef-fects.

Method: A prospective study with 120 patients visiting the ENT OPD was carried out for 1.5 years. Patients were randomly assigned into 2 groups and were followed up for a period of 4 weeks.

Results: Nasal congestion was significantly reduced by using probiotics while other symptoms like running nose, itching, sneezing were reduced more by using fexofenadine 120 mg. The result was statistically significant only for the symptom of nasal congestion.

There was not much variation in results of endoscopic appearance of the hypertrophy of inferior turbinates and in appearance of allergic mucosa.

Headache was the most common adverse effect in the fexofenadine group and allergic reactions was seen in very few patients in probiotics group.

Conclusion: Evaluation of the benefits of probiotics has been hindered due to inadequate clinical trials resulting in the rejection of health claims by regulatory bodies.

Many studies show significant beneficial effects of supplementation only after minimum of 4 weeks of admin-istration. suggesting that supplementation periods in excess of 4 weeks are necessary to assess measurable clinical out-comes.

Keywords: Allergic Rhinitis (AR); Probiotics; Fexofenadine; Antihistamines.

Citation: Raghu K, Jyothi AC. Probiotics as an Alternative Option in Treatment of Allergic Rhinitis: Comparing Probiotics vs Fexofenadine in Treatment of Allergic Rhinitis. J Clin Med Surgery. 2024; 4(2): 1177.

Introduction

Probiotics have several beneficial effects on immunity, inflammatory pathways, and anti-infective properties. Probiotic supplementation could restore immune response, promote eubiosis, and switch off inflammation and hence have been investigated in AR. Also, there is accumulating evidence that some specific strains of probiotics may improve Allergic rhinitis.

Although AR has no significant risk of mortality, the symptoms have a substantial impact on sleep, productivity and quality of life. It is widely prevalent in the population and makes it a very important condition for us doctors to make the patient satisfied and comfortable.

The 2008 ARIA (Allergic Rhinitis and its Impact on Asthma) review defined allergic rhinitis as "a symptomatic disorder of the nose induced after allergen exposure by an Immunoglobulin E (IgE) inflammation".

The medical management of patients with AR includes allergen avoidance, pharmacotherapy, and immunotherapy. Surgery is rarely needed. Genetic studies of allergic rhinitis suggest the predisposition toward allergic rhinitis is regulated by multiple genes and gene–environment interactions [1].

Literature says that an increase Th1 cytokine level and low Th2 cytokine level are seen in patients with allergies.

There have been many studies in the past which state a theory called hygiene hypothesis to explain the basis of allergic diseases. This theory states that due to industrialisation, and advancement in healthcare and overall socio economic conditions of the people, the rate of infections has lowered in children thus leasing to lower exposure to microbes.

This is important for the development of immune system during early years of growth [2].

Several studies have been designed to examine the efficacy of probiotics in many allergic conditions, such as eczema, allergic rhinitis, asthma and food allergies.

The use of probiotics for the treatment of established allergic diseases is not supported by current data, although newer studies have reported positive results.

Manipulation of the intestinal microbiota during infancy offers an attractive approach for management of allergic disease.

However, it is still unclear how this type of lactic acid bacteria leads to changes in the immune system and thus inhibits the development of allergies or relieves their symptoms.

Materials & methods

- Probiotics were used for half the study population. It contained lactobacillus paracasei and lactobacillus fermentum.
- This particular drug is also available in capsule variety but was not used in my study due to the non availability of the same in our hospital.
- Tablet Fexofenadine 120 mg was used for the remaining half of the patients.

Source of data

A total of 120 patients visiting ENT OPD, Navodaya medical college, Raichur undergoing treatment for allergic rhinitis were included in the present study which was done for a period of one and half years from November 2017 to June 2019.

Duration of study

20 months (November 2017 to June 2019).

Study place: Navodaya medical college, Raichur, India.

Study design: Prospective study.

Study period for each patient: 1 month.

Inclusion criteria

1. Patients clinically diagnosed with AR aged between 10 years and 60 years.

2. Patients having good general physical condition.

Exclusion criteria

1) Patients having co-morbidities like hypertension, diabetes mellitus, asthma.

2) Patients who were pregnant and lactating.

3) Patients diagnosed with other types of rhinitis, example infective rhinitis, and vasomotor rhinitis.

4) Post operated cases pertaining to this disease.

Process

From the patients meeting the inclusion criteria detailed history was recorded. A proforma was filled for each patient documenting the name, age, gender, occupation, address, chief complaints with the duration of symptoms, history of the presenting illness, past history including history of any previous surgery, personal history and family history.

Patient were then subjected to a general physical examination and a thorough local examination of the nose, ear and throat.

Diagnostic nasal endoscopy was done for all patients to identify hypertrophic inferior turbinate, allergic mucosa.

Selection of patients was done randomly. 60 patients were given oral fexofenadine 120 mg and remaining half patients were given oral probiotics.

The patients were instructed on how to use the probiotics. They were told to empty the contents into a glass and stir it with 20 ml water or milk and have it once a day according to their convenience.

A face-face follow up appointment was done in 2 weeks after the onset of the medication and were prescribed for another 2 weeks of consumption. Also in the clinic visit, side effects were recorded and any patient problems and also benefits.

The patients were graded according to total nasal symptom score (TNSS) which had 5 categories: nasal congestion, running nose, sneezing, itching, others (which includes sleep, lifestyle and work).

Statistical analysis

Statistical analysis was be done using chi-square test to evaluate the significance of the comparative study between oral probiotics and oral fexofenadine. Paired T test and correlation coefficient were also measured. P value < 0.5 was considered significant.

Results

Nasal congestion

A reduction in score was higher in the probiotics group compared to the fexofenadine group. Result was statistically significant, p value = 0.00023. Most patients had score 2 in TNSS questionnaire for nasal congestion prior to treatment whereas after treatment majority of them, (63%) patients reported score 1 in the fexofenadine group and 28 (47%) patients reported score 0 and 23 (39%) reported score 1 in the probiotics group, which shows that many patients using probiotics had lowering of their TNSS score (Graph 1).

Running nose

Graph 2: A reduction in score was higher in the fexofenadine group compared to the probiotics group. The result was statistically significant, p value = 0.004511. 31(52%) patients in Fexofenadine group and 30 (50%) patients in probiotics group 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.

Itching

Graph 3: 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, the result was statistically insignificant p value = 0.73310.

Sneezing

Graph 4: 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 was incearse in number 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 comparision in the efficacy of both Fexofenadine and probiotics in treatment of this symptom.

The result was statistically insignificant p value =0.6775

Others - sleep, work & lifestyle

In the treatment of other symptoms like sleep, lifestyle and work patients reported an 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

Total scores

Graphs 5,6: Finally upon totaling of the scores, it was seen that there were more patients who achieved the lower score group who had used fexofenadine compared to those who had used probiotics. However this result was statistically insignificant p value = 1.

Endoscopic changes

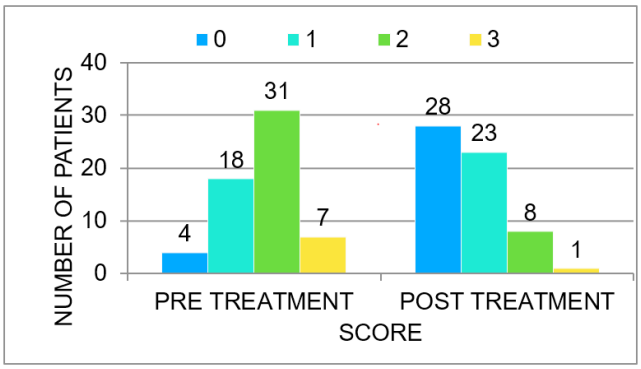
In Fexofenadine group, initially 22 patients (37 %) had grade III appearance of hypertrophy of inferior turbinate which reduced to 5 patients having grade III appearance after treatment. In probiotics group, initially 18 patients (30%) had grade III appearance of hypertrophy of inferior turbinate which reduced to 4 patients having grade III appearance after treatment.

However this was not statistically significant as both groups were at par and had slightly any variation Table 2.

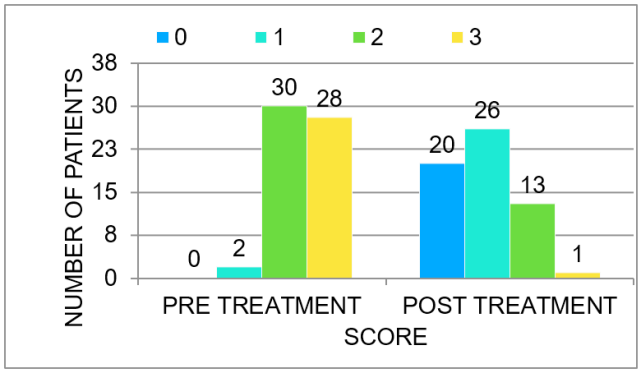
In Fexofenadine group, 41 patients (68%) and 38 (63%) patients of probiotics group had appearance of allergic mucosa like the pale mucosa and mulberry appearance of the nasal mucosa. Hence this was not statistically significant as there is no variations in the result.

Side effects

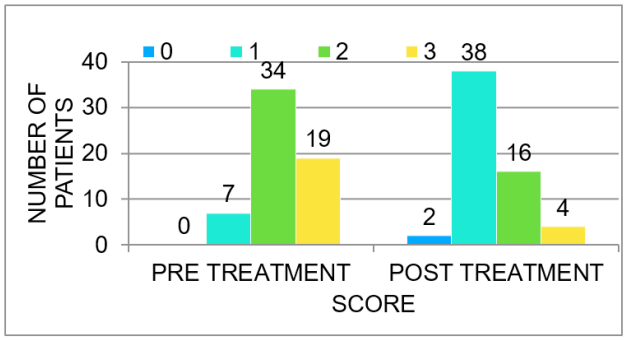
It was noted that patients who were taking Fexofenadine, headache was reported by the maximum number people 19 patients (32%), followed by drowsiness seen in 15 patients (25 %) and then followed by dryness of nose which was seen in 14 patients (23%) (Table 3). Those who were given probiotics, allergic reactions was the adverse effect seen in majority - 9 patients (15%) and then followed by constipation and nausea seen in 7 patients (12%) each.



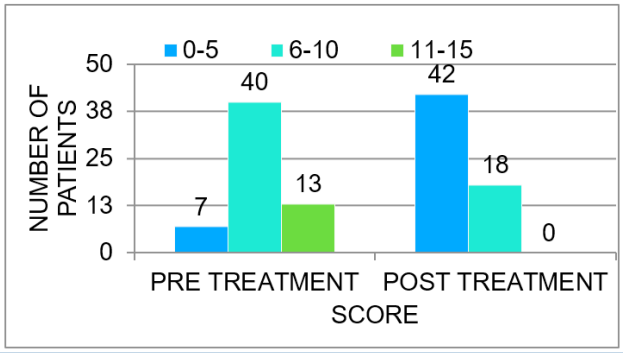
Graph 1: Nasal congestion probiotics.



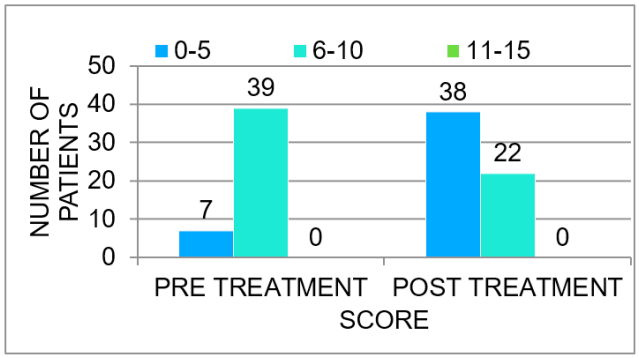
Graph 2: Running nose probiotics.



Graph 4: Sneezing probiotics.



Graph 5: Total Fexofenadine.



Graph 6: Total probiotics.

Table 1: Total probiotics.

Score	Pre treatment		Post treatment	
	Fexofenadine	Probiotics	Fexofenadine	Probiotics
0-5	7	7	42	40
10-Jun	40	39	18	20
15-Nov	13	0	0	0

Table 2: Endoscopic appearance of hit.

Grade	Pre treatment		Post treatment	
	Fexofenadine	Probiotics	Fexofenadine	Probiotics
I	20	25	27	28
II	18	17	28	28
III	22	18	5	4

Table 3: Side effects.

	Headache	Nausea	Allergic Reaction	Drowsiness	Constipation	Dryness
FEXOFENADINE	19	7	0	15	0	14
PROBIOTICS	3	7	9	0	7	0

Table 4: Showing the age distribution of patients involved in the study.

Age in years	Frequency		Percentage	
	Fexofenadine	Probiotics	Fexofenadine	Probiotics
20-Nov	6	6	10	10
21-30	22	27	37	45
31-40	26	23	43	39
41-50	6	4	10	6
51-59	0	0	0	0
TOTAL	60	60	100	100

Discussion

Probiotics are perceived to exert beneficial effects in the prevention and treatment of allergic diseases via modifying the gut ecosystem and it can improve the quality of life of patients with perennial allergic rhinitis.

As mentioned in Table 4, of the 120 cases of AR analysed the maximum incidence was found in the age group of 31-40 years (43%) followed by 21-30 years (37%) in fexofenadine group and 21-30 (45%) followed by 31-40 (39%) in the probiotics group. It was observed that of the 120 cases diagnosed to be AR, 69 (58%) patients were females and 51 (42%) male patients.

It is widely known that possible beneficial effects of any consumed probiotics such as Lactobacillus bacteria depend on their capability to survive different conditions during gastroduodenal transit like bile acids, pH, or enzymes. The ultimate goal of AR treatment is to reduce impairments that are of concern to patients through adequate disease control, and then to improve the quality of life of chronic sufferers.

Antihistamines are considered to be the first-line treatment for mild disease. Some of the newer agents in this category, such as Fexofenadine, have shown efficacy in reducing nasal congestion in clinical trials of allergic rhinitis.

The prevalence of AR peaks in the second to fourth decades of life and then gradually diminishes [3]. One of the limitations of antihistamines is the lack of good control of the symptom of nasal congestion and its side effects profile. Thus, decongestants are often combined with antihistamines, which have shown greater benefit in improving nasal congestion than having antihistamines alone.

Antihistamines effectively treat allergic rhinitis by improving the symptoms of sneezing, itching, rhinorrhea, and to a lesser extent, nasal congestion. Antihistamines are considered to be the first-line treatment for mild disease [4].

In our study, both the probiotics and Fexofenadine group showed statistically significant results to nasal congestion but insignificant result for other nasal symptoms and also for reduction in hypertrophy of inferior turbinate and appearance of allergic mucosa of the nose on endoscopic visualization.

Headache was the most common adverse effect seen in the Fexofenadine group and the allergic reactions seen in very few patients was the adverse effect noted most commonly noted in the probiotics group.

Miyabe et al [5] (2003) 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.

In an industry-sponsored study [6], Meltzer et al studied the efficacy of Fexofenadine in children with seasonal allergic rhinitis, found that it significantly reduced the total symptom score, sneezing, rhinorrhea, itchy nose/mouth/throat/ears, itchy watery red eyes.

In a study [7] Day et al, examined Fexofenadine 120 mg, and placebo in an environmental exposure unit. Five symptoms of nasal congestion, sneezing, rhinorrhea, itchy nose, palate, throat; and itchy, watery red eyes were evaluated, as well as a total symptom score (the sum of the individual symptoms excluding nasal congestion).

The primary endpoint of the study, showed median time to onset for clinically important relief was 60 minutes for Fexofenadine and 100 minutes for placebo.

One of the studies done for reporting on side effects of antihistamines [8] Ngamphaiboon et al showed that in paediatric patients with allergic rhinitis, Headache was the most common reported adverse event.

Another study on side effects [9], Howarth et al reported headache in 7% of the participants receiving placebo and in 8% of the patients in the Fexofenadine group. Drowsiness was reported by 3% of patients in both the fexofenadine and placebo groups.

Donohue et al [10] showed that no acute toxicity developed with any strains of probiotics tested in their animal study. Data revealed that it is almost impossible to ingest a lethal dose or a dose enough to induce any serious side effects.

Evaluation of substantiation of the benefits of probiotics has been hindered due to inadequate clinical trial design [11] resulting in the rejection of health claims by regulatory bodies [12]. While randomized controlled trials are considered the gold standard for assessing clinical efficacy, they are often impractical in the nutrition and complementary medicine disciplines due to the heavy investment required and the need for large participant populations.

Intermittent treatment with oral antihistamines and nasal sprays are costly, may not completely resolve symptoms and can cause varying degrees of sedation.

Immunotherapy to induce de-sensitization by modifying the allergic response to allergens may offer long-term resolution of symptoms. However, it requires continuous and expensive medical treatment and is not always effective [13].

Nasal congestion was significantly reduced by using probiotics while other symptoms like running nose, itching, sneezing were reduced more by using Fexofenadine 120 mg. However, the result was Statistically significant only for the symptom of running nose.

From multiple examples above, it shows that probiotics are a strong contender for the treatment of allergic rhinitis and further studies need to conducted to use them for their complete potential.

This overview supports the assumption that administration of Lactobacillus strains could positively affect AR patients by alleviating allergic symptoms. Negative effects were not reported; thus, the treatment with probiotic Lactobacillus strains appears to be suitable for AR patients.

However, the comprised studies differ widely in used Lactobacillus strains, amount of administered Lactobacillus bacteria, form and duration of administration, accompanied therapy, and measured parameters.

Conclusion

However, in a number of studies, significant beneficial effects of supplementation were not seen until after a minimum of 4 weeks of administration [14] suggesting that supplementation periods in excess of 4 weeks are necessary to assess measurable clinical outcomes.

Lactobacillus species showed several effects on immunological parameters in allergic disease, but the exact mechanism is still unclear. Additionally, no specific Lactobacillus strain emerged as the most efficient one, and their modulatory effects seem to be strain-dependent.

Many parameters may influence the effect of probiotics, and therefore, a clear recommendation for a specific strain, and the dosage and timing of application is not yet possible. Further investigations and solid studies addressing mechanisms underlying the observed beneficial effects of probiotic treatments in rhinitis patients are required to make conclusive statements and to develop safe and less invasive or adjunctive therapies, respectively.

Declarations

Conflict of interest: The authors declare that they have no conflict of interest. This article does not contain any studies with animals performed by any of the authors.

Informed consent: Informed consent was obtained by all individuals participating in the study.

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