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# **Probiotics in Allergic Rhinitis**

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# Abstract

**Introduction:** Allergic rhinitis is characterized by inflammatory changes in nasal mucosa caused by exposure to inhaled allergens. Over the years, potential role of various anti histamine - steroid nasal sprays in allergic rhinitis has been evaluated with varied outcomes.

Conclusive evidence is still lacking concerning the effectiveness of combining probiotics with anti-

histamine - steroids in reducing the symptoms of allergic rhinitis.

**Aim:** To know the efficacy of the usage of probiotics on Serum Ige levels and symptoms in patients diagnosed as a case of allergic rhinitis.

**Methods:** This prospective randomized controlled trial was done on 30 patients aged 20-50 years, with symptoms of allergic rhinitis and raised serum Ige levels.

Study participants were allocated to anti histaminesteroid nasal spray-probiotics combined therapy (study group) and anti-histamine - steroid nasal spray mono therapy (control group). The symptoms of allergic rhinitis and serum Ige levels were recorded. Participants were followed for 06 months. Descriptive and inferential statistics were carried out using SPSS. P value <0.05 was considered statistically significant.

**Result:** The mean age of participants was  $36.30\pm11.54$  years. Both groups were homogenous for age, gender, allergic symptoms, and IgE levels at baseline. At 06-month follow-up, a significant reduction in symptoms was found in each group with no significant difference observed in Ige levels between the groups. However, the mean percent change in serum Ige levels from baseline to 06 months was significantly more in the study group than in the control group (43.74% vs 26.95%).

**Conclusion:** All the study parameters improved in both groups. The addition of probiotics to antihistamine-steroids improves its effectiveness in reducing serum IgE levels and symptoms of allergic rhinitis. However further studies are needed to confirm the benefits of probiotics in improving symptoms of allergic rhinitis.

Keywords: Probiotics, Allergic rhinitis, Serum Iger levels

### Introduction

- Allergic rhinitis (AR) is the most common atopic disease all over the world affecting 10-30% of the population.<sup>[1]</sup>
- Allergic rhinitis is characterized by inflammatory changes in nasal mucosa caused by exposure to inhaled allergens.<sup>[2]</sup>

• Rhinitis is defined clinically as having two or more symptoms of anterior or posterior rhinorrhoea, sneezing, nasal blockage and/or itching of the nose during two or

more consecutive days for more than one hour on most days.<sup>[2]</sup>

• AR is diagnosed when these symptoms are seen on exposure to allergen resulting in Ige mediated reaction.

#### • AR is subdivided into

 $\geq$ 

- Intermittent allergic rhinitis (IAR)
- Persistent allergic rhinitis (PAR)

Over the years, potential role of



histamine-steroid nasal sprays in allergic rhinitis has been evaluated with varied outcomes.

➢ Probiotics are live micro-organisms that when administered in adequate amounts, confer a health benefit on the host. Probiotics may stimulate the immune system at all mucosal surfaces and exert primary prevention of atopic diseases and cause a reduction in allergic rhinitis symptoms and decline inflammatory parameters.<sup>[3]</sup>

Conclusive evidence is still lacking concerning the effectiveness of combining probiotics with antihistamine - steroids in reducing the symptoms of allergic rhinitis.

## Materials and methods

This prospective randomized controlled trial was done on 30 patients diagnosed with allergic rhinitis who were aged 20-50 years, with active symptoms of allergic rhinitis and raised serum Ige levels.

## Study design

Prospective Cohort Study

### Study period

1 year Place of study Patients attending ENT outpatient department fulfilling the inclusion criteria were included. **Study subjects** 

30 newly diagnosed cases of allergic rhinitis

#### **Data collection**

The patient's data like – age, gender, symptoms of allergic rhinitis and Serum Ige levels were collected at baseline and after 6 months.

# Sampling method

Systemic random sampling

## **Inclusion criteria**

- Age group: 20 50 years
- Newly diagnosed cases based on symptoms of allergic rhinitis and Serum Ige levels.

## **Exclusion criteria**

- Other forms of rhinitis
- Old cases of allergic rhinitis who were on treatment.



Fig. 1:

# Results

The mean age of participants was 36.30±11.54 years.

# Table 1: Age Distribution

| Age   | Control Group |      | Study Group |      |
|-------|---------------|------|-------------|------|
|       | Ν             | %    | Ν           | %    |
| 21-30 | 05            | 33.3 | 07          | 46.7 |
| 31-40 | 02            | 13.3 | 04          | 26.7 |











## Fig. 3:

## Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. Results on continuous measurement is presented as Mean & SD and categorical as Frequency & percentage. Inferential statistics like Mann-Whitney U test was used to compare IgE values between the groups. Mc Nemar test was used to compare the pre and post categorical variables. Chi-square test/ Fisher Exact test was assessed to check homogeneity between the groups. P value less than 0.05 was considered statistically significant.

| 41-50 | 06 | 40.0  | 03 | 20.0  |
|-------|----|-------|----|-------|
| 51-60 | 02 | 13.3  | 01 | 6.7   |
| Total | 15 | 100.0 | 15 | 100.0 |

P=0.506, Chi-square test/ Fisher Exact test

Inference: Both the groups are homogeneous for age distribution

Table 2: Sex Distribution

| Sex    | Control Group |      | Study Group |       |
|--------|---------------|------|-------------|-------|
|        | Ν             | %    | Ν           | %     |
| Female | 08            | 53.3 | 10          | 66.7  |
| Male   | 07            | 46.7 | 05          | 33.3  |
| Total  | 15            | 100  | 15          | 100.0 |

P=0.455, Chi-square test/ Fisher Exact test

Inference: Both the groups are homogeneous for sex distribution

Table 3: Comparison of symptoms within a group at baseline and 6 months

| Symptoms      |     | Control Gro | Control Group |        | Study Group |           | P value |
|---------------|-----|-------------|---------------|--------|-------------|-----------|---------|
|               |     | Baseline    | 6 months      |        | Baseline    | 6 months  |         |
| Anterior      | Yes | 12(80.0)    | 03(20.0)      | 0.012* | 07(46.7)    | 0         | 0.001*  |
| rhinorrhea    | No  | 03(20.0)    | 12(80.0)      |        | 08(53.3)    | 15(100.0) |         |
| Posterior     | Yes | 10(66.7)    | 03(20.0)      | 0.039* | 12(80.0)    | 02(13.3)  | 0.002*  |
| rhinorrhea    | No  | 05(33.3)    | 12(80.0)      | _      | 03(20.0)    | 13(86.7)  | _       |
| Sneezing      | Yes | 13(86.7)    | 02(13.3)      | 0.001* | 13(86.7)    | 0         | 0.001*  |
|               | No  | 02(13.3)    | 13(86.7)      |        | 02(13.3)    | 15(100.0) | -       |
| Nasal Block   | Yes | 13(86.7)    | 0             | 0.001* | 14(93.3)    | 0         | 0.001*  |
|               | No  | 02(13.3)    | 15(100.0)     |        | 01(6.7)     | 15(100.0) |         |
| Itching nose  | Yes | 15(100.0)   | 02(13.3)      | 0.001* | 13(86.7)    | 03(20.0)  | 0.006*  |
|               | No  | 0           | 13(86.7)      | _      | 02(13.3)    | 12(80.0)  | -       |
| L 1           | Yes | 13(86.7)    | 0             | 0.001* | 14(93.3)    | 04(26.7)  | 0.006*  |
| Itchy eyes    | No  | 02(13.3)    | 15(100.0)     | _      | 01(6.7)     | 11(73.3)  | _       |
| Loss of smell | Yes | 13(86.7)    | 0             | 0.001* | 02(13.3)    | 0         | 0.001*  |
|               | No  | 02(13.3)    | 15(100.0)     | _      | 03(20.0)    | 15(100.0) | _       |
| Snoring       | Yes | 12(80.0)    | 05(33.3)      | 0.065  | 14(93.3)    | 02(13.3)  | 0.001*  |
|               | No  | 03(20.0)    | 10(66.7)      | 1      | 01(6.7)     | 13(86.7)  | 1       |
| Halitosis     | Yes | 10(66.7)    | 0             | 0.001* | 12(80.0)    | 0         | 0.001*  |
|               | No  | 05          | 15(100.0)     | 1      | 03(20.0)    | 15(100.0) | 1       |

\*Statistically significant p<0.05, Mc Nemar test

Inference: Both the groups are homeogenous for

symptoms at baseline

At 6 month follow-up,

• significant reduction in symptoms and Serum Ige levels was found in

each group

- however, no significant difference observed in Ige levels between the groups.
- Mean percent change in serum Ige levels from baseline to 6 months was significantly more in the study group than control group (43.74% vs 26.95%).

| Serum IgE    | Group   | Ν  | Mean    | Std. Deviation | P value |
|--------------|---------|----|---------|----------------|---------|
| Baseline     | Control | 15 | 349.267 | 118.68         | 0.419   |
|              | Study   | 15 | 393.200 | 158.43         |         |
| 6 months     | Control | 15 | 255.133 | 123.35         | 0.310   |
|              | Study   | 15 | 221.200 | 126.27         |         |
| Baseline – 6 | Control | 15 | 94.13   | 47.73          | 0.005*  |
| months       | Study   | 15 | 172.0   | 94.88          |         |

Table 4: Comparison of Ige levels between the group at baseline and 6 months

\*Statistically significant p<0.05, Mann-Whitney U test

## Inference

No statistically significant difference is observed for IgE levels at baseline and after 06 months. However the reduction in IgE levels are significantly higher in Group 2 when compare to Group 1



### Fig 4:

#### Discussion

Data in our study showed that both the study group and the control group were homogenous in distribution concerning age, gender, symptoms of allergic rhinitis and serum IgE levels at the beginning of the study.

Symptoms of allergic rhinitis had reduced similarly in both the groups Serum IgE levels showed no much difference between the groups at the end of the  $6^{th}$  month. However, the mean percent change in serum IgE levels from baseline to 6 months was significantly more in the study group than in the control group (43.74% vs 26.95%).

➤ A four-week clinical trial on the usage of a Probiotic – mixture of Bifidobactrium longom and Lactobacillus plantarum was done by Min-Gyu Kang et al in the year 2020 on patients with perineal allergic rhinitis and found improvement in symptoms of allergic rhinitis and might reduce the secretion of IL-4, IL-5, IL-13, IgE levels.<sup>[4]</sup>

> DJ Costa et al in the year 2014 did a double blind, Randomised, placebo-controlled trial on Efficacy and safety of the Probiotic Lactobacillus paracasei LP-33 in allergic rhinitis patients. He included 425 patients in his study and concluded that Probiotics improves the quality of life of subjects with persistent allergic rhinitis who were currently being treated with oral H<sub>1</sub>antihistamine and consistent improvement of ocular symptoms was seen with no change in nasal symptoms.<sup>[5]</sup>

## Conclusion

• All the study parameters improved in both groups.

• The addition of probiotics to antihistamine-steroids improves its effectiveness in reducing serum IgE levels and symptoms of allergic rhinitis.

• However further studies are needed to confirm the benefits of probiotics in improving symptoms of allergic rhinitis.

## Ethical committee clearance: Taken

#### Abbreviations

IgE: Immunoglobulin E, AR: Allergic rhinitis, IAR: Intermittent allergic rhinitis, PAR: Persistent allergic rhinitis, ENT: Ear nose throat, IL: Interleukin.

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