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Research Article

A COMPARATIVE STUDY TO DETERMINE THE EFFECTIVENESS AND SAFETY OF PROBIOTICS AS AN ADJUNCT TO ANTIHISTAMINES COMPARED TO ANTIHISTAMINES ALONE IN PATIENTS WITH ALLERGIC RHINITIS

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ABSTRACT

Objectives: The objectives of the study are to evaluate the effectiveness and safety of probiotics as an adjunct therapy to antihistamines in comparison to antihistamines alone in individuals suffering from allergic rhinitis (AR).

Methods: A non-blinded, comparative study included 100 patients with AR selected from Government E.N.T Hospital's allergy clinic, Koti, Hyderabad. The participants were categorized into two groups of 50 patients each and received tablet levocetirizine 5 mg in the first group and tablet levocetirizine 5 mg plus capsule Sporlac plus (2.5 billion cells) in second group, for 28 days. Total nasal symptom score (TNSS), complete blood count (CBC), and absolute eosinophil count (AEC) were done at start and at the end of 28 days. Participants were followed up at the end of 28 days.

Results: There were no remarkable variations observed statistically in TNSS scoring and CBC among both groups; however, clinical significance was noted within each group. Mean AEC at baseline and at the end of 28 days in group 1 was 515.8 ± 47.02 cells/µL and 325.5 ± 52.9 cells/µL and in group 2 was 504.5 ± 41.19 cells/µL and 188.3 ± 51.7 cells/µL, respectively. There was a significant variation in average AEC at the end of 28 days of treatment ($p<0.05$). Only mild adverse effects were observed across all groups.

Conclusion: Although both treatments were found to have equal efficacy in alleviating symptoms of AR with good safety profile, probiotics as an adjunct to antihistamine significantly reduced AEC count when compared to anti-histamine alone proven to have more clinical benefit.

Keywords: Probiotics, Probiotics as an add-on, Anti-histamines, Allergic rhinitis, Absolute eosinophil count.

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INTRODUCTION

An allergy refers to an immune system response that triggers inflammation when exposed to typically harmless environmental agents [1]. Allergic rhinitis (AR) is a complex condition commonly marked by the infiltration of the mucosal lining by eosinophils, plasma cells, and mast cells. Despite its high prevalence, the disorder remains challenging to diagnose and prevent effectively [2]. AR manifests in the younger age groups typically and more prevalent in boys. However, in adulthood, the prevalence is more or less equivalent among women and men [3]. The prevalence of AR is substantial, representing 55% of all allergies and affecting 20–30% of adults [4]. Approximately 67.5% of individuals with AR experience moderate-to-severe symptoms [5]. It influences the overall health and well-being in light of its high prevalence and the existence of co-morbidities such as atopy and asthma [6]. The effects impose an impedance to work, raise medicinal service costs spent for the disease, and also affect sleep [5,7].

It is habitually triggered through outdoor and indoor allergic agents, including pollen's, pet dander, dust mites, or particles from clothing and pets [8,9]. The symptoms include nasal obstruction, sneezing, watery secretions or seromucous secretions, eye symptoms, postnasal drip, and odor disturbances [3,9].

Management strategies for AR involve patient education, elimination of allergens and irritants, medication-based therapies, and allergen-specific immunotherapy. Second-generation oral histamine blockers are considered primary treatment in seasonal as well as perennial AR [9,10].

At concentrations reached *in vivo*, oral anti-histamines inhibit interaction of histamine with H1 receptors. They may decrease histamine-induced cytokine production and the ability to block or suppress other mediators involved in early- and late-phase allergic reactions to varying extents [11].

Levocetirizine, the R-enantiomer of cetirizine hydrochloride, is a second-generation H1 histamine receptor inhibitor that can be taken orally. It prompted for relieve symptoms of seasonal AR in adults and children aged 2 years and older, as well as perennial AR in both adults and children as young as 6 months.

Although microbes are primarily known for their association with diseases in humans, their capabilities have also been leveraged for the benefit of society. The word "probiotic" came from the Greek, meaning "for life" described as "Live microorganisms that, when consumed in sufficient quantities, provide health benefits to the host" [12]. It can be incorporated into various products, including foods, medications, and dietary supplements. Species of *Lactobacillus*, *Saccharomyces cerevisiae*, *Escherichia coli*, and *Bacillus*, *Bifidobacterium* are most commonly used as probiotics [13,14]. Probiotic strains exhibit the ability to survive in challenging physiochemical conditions, including the acidic environment of the stomach and the bile salt concentrations in the small intestine [14,15]. It has numerous immunological as well as non-immunological benefits [14-16]. In AR, it is believed that an imbalance in the expression of T helper (Th1 and Th2) cytokines occurs, which may be modulated by specific *Lactobacillus* species, known to be part of the natural intestinal microbiota [17].

Research has demonstrated that *Lactobacillus* can inhibit systemic immune markers, such as interleukin (IL), from peripheral blood mononuclear cells [18]. It impacts T regulatory cells by generating semi-mature dendritic cells and raising the expression of CD40, which can inhibit IL-4 and IL-5 while activating regulatory cytokines such as transforming growth factor-β and IL-10 [19]. *Bifidobacterium* has been shown to reduce eosinophil levels and lower interferon-gamma in peripheral blood [18]. Probiotics may also boost local IgA production, directly impacting mucosal defenses [19].

There are no known absolute contraindications [20]. While adverse effects are infrequent, gas and bloating are common side effects associated with the consumption of probiotic supplements. Till now, no harmful or disease-causing traits have been identified in *Lactobacilli* or *Bifidobacterium* species [21].

As there were numerous studies supporting the benefits of gut bacteria in AR and lack of studies comparing risk benefits of using probiotics as an adjunct for anti-histamines in AR, it is critical need for the present study, to evaluate the clinical benefit and safety profile of probiotics as an adjunct to anti-histamine (Levocetirizine) when compared with anti-histamine (Levocetirizine) alone in the management of AR.

METHODS

A comparative clinical study was performed in a non-blinded, parallel-group format at Allergy Clinic at the Government E.N.T. Hospital in Koti, Hyderabad, for a duration of 12 months from August 2020 to July 2021. Ethical approval was granted at the Ethics Scientific Committee of Osmania Medical College, Hyderabad Ref. no.: ECR/300/Inst/AP/2013/RR-19. The participants for this study were selected based on the inclusion and exclusion criteria mentioned below. They were explained about the study in their own understandable language, and written informed consent was obtained.

Inclusion criteria

1. Age group: The study included patients aged 18–60 years
2. Sex: The study included both male and female patients
3. Participants were required to demonstrate good overall health, confirmed through medical history, physical examinations, and laboratory evaluations
4. Clinical symptoms included patients with classical features of AR such as nasal congestion, episodes of sneezing, watery nose secretions, nasal irritation, and postnasal drip The symptoms and signs of upper respiratory tract over a duration of a month or more, to exclude the possibility of common cold and minor infections
5. Patients who had a positive reaction to one or more allergens in the past 1 year
6. In the preliminary evaluation, women with childbearing potential are expected to be negative for the pregnancy tests
7. Individuals with a total nasal symptom score (TNSS) are expected to have AR symptoms.

Exclusion criteria

1. Structural abnormalities affecting nasal airflow, upper respiratory or sinus infections requiring antibiotic treatment within 14 days before screening, or viral upper respiratory infections within 7 days before screening
2. A history of recurrent or chronic sinusitis, chronic purulent postnasal drip, rhinitis medicamentosa, or asthma that required consistent use of inhaled corticosteroids or systemic corticosteroids
3. Individuals with co-morbid diseases (e.g., gastrointestinal, cardiovascular, infections)
4. Women who were pregnant or breastfeeding were not included in the study.
5. Participants under treatment with cromolyn, nedocromil, oral corticosteroids, antihistamines, leukotriene modifiers, intranasal ipratropium bromide, intranasal saline, systemic antibiotics, or allergen immunotherapy.

A total of 100 patients were randomly categorized into two groups, consisting of 50 patients per group,

- Group I received tablet levocetirizine 5 mg over a period of 4 weeks
- Group II received tablet levocetirizine 5 mg and capsule Sporlac plus (2.5 billion cells) for 4 weeks.

Capsule Sporlac plus – *Lactobacillus acidophilus* (r 0052), *Lactobacillus rhamnosus* (r 0011), *Bacillus* (snz 1969), *Bifidobacterium bifidum*, *Bifidobacterium longum* (r 00175), *Saccharomyces boulardii* – probiotic more than 2.5 billion cells.

A detailed history was taken from all participants. A thorough general and an ENT examination of the participants were done before beginning the study. All relevant findings were noted.

Participants were advised to refrain from taking any medications other than those provided during the study. They were also instructed to discontinue the study medication if they experienced any significant adverse effects and to report these to the doctors at the allergy clinic. Compliance was confirmed by inspecting empty blister packs during follow-up visits. Patients were also re-assured that they are free to withdraw from the study anytime.

TNSS, complete blood picture, and absolute eosinophil count (AEC) were assessed of all participants during the beginning and after 28 days of treatment.

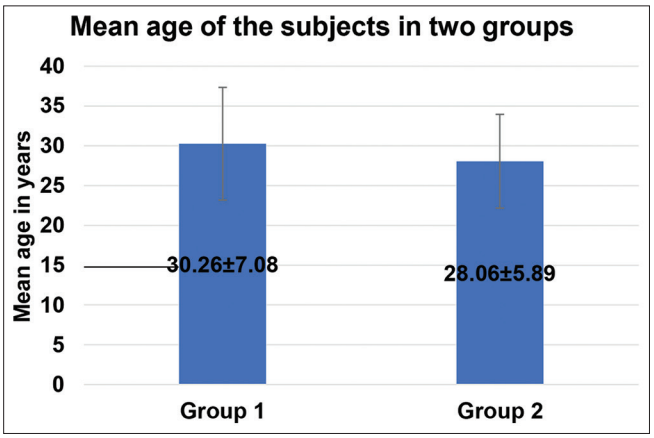

Fig. 1: Bar diagram showing age-wise distribution of subjects in two groups. Number of participants in each group (n)=50, Distribution of data based on age given in Mean±Standard deviation

Table 1: Demographic distribution of the participants

Demographic parameters	Group 1 (n=50)	Group 2 (n=50)
Age (in completed years)		
Mean age	30.26	28.06
Standard deviation	7.08	5.89
Range	18 to 44	19 to 43
t-value	1.689	
p-value	0.094	
GENDER		
Male	28 (56%)	24 (48%)
Female	22 (44%)	26 (52%)
Total	50 (100%)	50 (100%)
Chi-square-value	0.641	
p-value	0.423	

Number of participants in each group (n)=50, Distribution of data based on age given in Mean±Standard deviation, Distribution of data based on gender given in Chi-square value

Table 2: Severity of nasal congestion at baseline and after 28 days of treatment

Severity of nasal congestion at baseline	Baseline		At end of 28 days	
	Group 1 (n=50) (%)	Group 2 (n=50) (%)	Group 1 (n=50) (%)	Group 2 (n=50) (%)
Normal (0)	1 (2)	1 (2)	34 (68)	38 (76)
Mild (<6)	10 (20)	12 (24)	13 (26)	10 (20)
Moderate (6–9)	17 (34)	22 (44)	3 (6)	2 (4)
Severe (10–12)	22 (44)	15 (30)	0 (0)	0 (0)
Chi-square value with Yate's correction (df)	1.929 (3)		0.299 (2)	
p-value	0.587		0.861	

Number of participants in each group (n)=50; data regarding the severity of nasal congestion at baseline and after 28 days of treatment are given in Chi-square value with Yate's correction

Table 3: Severity of running nose at baseline and after 28 days of treatment

Severity of running nose	Baseline		At end of 28 days	
	Group 1 (n=50) (%)	Group 2 (n=50) (%)	Group 1 (n=50) (%)	Group 2 (n=50) (%)
Normal	0 (0)	0 (0)	24 (48)	32 (64)
Mild (<6)	1 (2)	3 (6)	20 (40)	12 (24)
Moderate (6–9)	19 (38)	18 (36)	6 (12)	6 (12)
Severe (10–12)	30 (60)	29 (58)	0 (0)	0 (0)
Chi-square value with Yate's correction (df)	0.25 (2)		3.143 (2)	
p-value	0.882		0.208	

Number of participants in each group (n)=50; data regarding severity of running nose at baseline and after 28 days of treatment is given in Chi-square value with Yate's correction

Table 4: Severity of itching at baseline and after 28 days of treatment

Severity of itching	Baseline		At end of 28 days	
	Group 1 (n=50) (%)	Group 2 (n=50) (%)	Group 1 (n=50) (%)	Group 2 (n=50) (%)
Normal	2 (4)	2 (4)	33 (66)	38 (76)
Mild (<6)	12 (24)	14 (28)	15 (30)	10 (20)
Moderate (6–9)	18 (36)	23 (46)	2 (4)	2 (4)
Severe (10–12)	18 (36)	11 (22)	0 (0)	0 (0)
Chi-square value with Yate's correction (df)	1.92 (3)		1.115 (2)	
p-value	0.589		0.573	

Number of participants in each group (n)=50; data regarding the severity of itching at baseline and after 28 days of treatment is given in Chi-square value with Yate's correction

Table 5: Severity of sneezing at baseline and after 28 days of treatment

Severity of sneezing	Baseline		At end of 28 days	
	Group 1 (n = 50) (%)	Group 2 (n = 50) (%)	Group 1 (n = 50) (%)	Group 2 (n = 50) (%)
Normal	0 (0)	0 (0)	25 (50)	31 (62)
Mild (<6)	0 (0)	0 (0)	19 (38)	12 (24)
Moderate (6–9)	12 (24)	21 (42)	6 (12)	7 (14)
Severe (10–12)	38 (76)	29 (58)	0 (0)	0 (0)
Chi-square value with Yate's correction (df)	3.664 (1)		2.3 (2)	
p-value	0.056		0.317	

Number of participants in each group (n)=50; Data regarding the severity of sneezing at baseline and after 28 days of treatment are given in Chi-square value with Yate's correction

Table 6: Distribution of severity of allergic rhinitis by TNSS scoring at baseline and after 28 days of treatment

Severity of allergic rhinitis by TNSS	Baseline		At end of 28 days	
	Group 1 (n=50) (%)	Group 2 (n=50) (%)	Group 1 (n=50) (%)	Group 2 (n=50) (%)
Normal	0 (0)	0 (0)	11 (22)	12 (24)
Mild (<6)	0 (0)	0 (0)	35 (70)	34 (68)
Moderate (6 to 9)	21 (42)	29 (58)	4 (8)	4 (8)
Severe (10 to 12)	29 (58)	21 (42)	0 (0)	0 (0)
Chi-square value with Yate's correction (df)	2.56 (1)		0.125 (2)	
p-value	0.109		0.939	

Number of participants in each group (n)=50; Data regarding severity of TNSS at baseline and after 28 days of treatment is given in Chi-square value with Yate's correction, TNSS: Total nasal symptom score

Table 7: Mean AEC at baseline and after 28 days of treatment

AEC (in cells/µL)	Baseline		At end of 28 days	
	Group 1 (n=50)	Group 2 (n=50)	Group 1 (n=50)	Group 2 (n=50)
Mean	515.8	504.5	325.5	188.3
Standard deviation	47.02	41.19	52.9	51.7
Range	450–670	400–590	220–490	112–329
t-value	1.278		137.2	
p-value	0.204		**<0.001	

**Significant, *P*<0.05 – Significant, Number of participants in each group (n)=50; AEC: Absolute eosinophil count, Data regarding absolute eosinophil count are given as Mean±Standard Deviation

Table 8: Distribution by findings of complete blood picture at baseline and after 28 days of treatment

Complete blood picture	Baseline		At end of 28 days	
	Group 1 (n=50) (%)	Group 2 (n=50) (%)	Group 1 (n=50) (%)	Group 2 (n=50) (%)
Both eosinophilia and lymphocytosis	39 (78)	40 (80)	0 (0)	0 (0)
Eosinophilia only	11 (22)	10 (20)	0 (0)	0 (0)
Lymphocytosis only	-	-	32 (64)	30 (60)
Normal	-	-	18 (36)	20 (40)
Total	50 (100)	50 (100)	50 (100)	50 (100)
Chi-square value	0.06		0.17 (1)	
p-value	0.806 (Not Significant)		0.680 (Not Significant)	

Number of participants in each group (n)=50; Data regarding complete blood picture are given as Chi-square value

Table 9: Distribution by clinical efficacy of the treatments in two groups

Clinical efficacy parameters	Group 1 (n=50) (%)	Group 2 (n=50) (%)	Risk difference % (95% CI)	Odds ratio (95% CI)	p-value
TNSS score of 0 at the end of 28 days of treatment-Successful treatment	11 (22)	12 (24)	−2 (−18.5−−14.5)	1.12 (0.44–2.84)	0.812
Mean change in AEC from baseline to 28 days of treatment	190.3 (170.4–210.2)	316.2 (297.6–334.7)	-	-	<0.001
Normal cytology in CBP at the end of 28 days of treatment- Successful treatment	18 (36)	20 (40)	−4 (−23.0–15.0)	1.185 (0.53–2.66)	0.68

Number of participants in each group (n)=50, TNSS: Total nasal symptom score, AEC: Absolute eosinophil count, CBP: Complete blood picture, p<0.05 – Significant

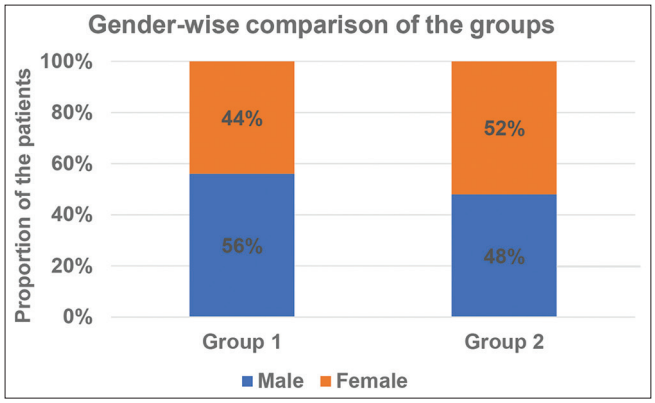

Fig. 2: Bar diagram showing the comparison of groups by gender. Number of participants in each group (n)=50; Proportion of male and female participants in each group (expressed in %)

The principal efficacy criterion was the reduction in the severity of symptoms that are assessed by the TNSS [17], which include nasal blockage, watery discharge from the nose, nasal itching, and sneezing and were assessed through patient interviews and categorized based on their intensity.

- Grade 0: None – lack of symptoms
- Grade 1: Mild – presence of tolerable symptoms
- Grade 2: Moderate – symptoms cause discomfort but remain manageable
- Grade 3: Severe – symptoms are challenging to endure and disrupt daily activities.

The total TNSS score is calculated by summing the individual scores for each nasal symptom [22].

The AR is graded depending upon the severity and total score as (1) mild <6; (2) moderate – 6–9; and (3) severe 10–12. Along with the patients' opinion, the E.N.T. doctor's assessment of symptoms and signs were also recorded during the beginning and at the end of the study.

Follow-up

Patients were instructed to return to the hospital after 4 weeks for follow-up. During this visit, clinical improvement in symptoms and signs, as well as any adverse effects reported by the patients, was noted. All investigations conducted before the start of treatment were also repeated.

Statistical analysis

The data were compiled into tables, and analysis was performed using the Statistical Package for the Social Sciences (SPSS). The Student's *t*-test was used to evaluate the statistical significance between the two drugs. Probability value: A value of <0.05 was considered significant, and more than 0.05 was considered not remarkable.

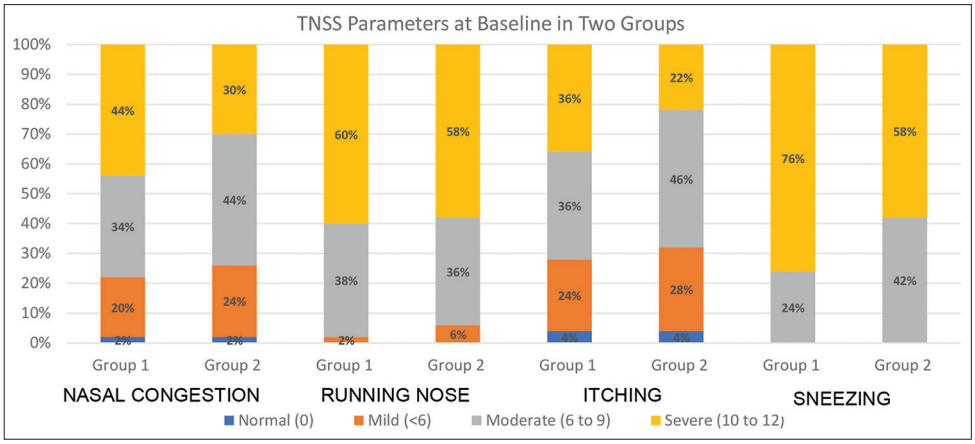

Fig. 3: Severity of TNSS scoring parameters at baseline in two groups. Number of participants in each group (n)=50; Proportion of participants showing normal, mild, moderate, and severe forms of nasal congestion, running nose, itching, and sneezing at baseline (expressed in %). TNSS: Total nasal symptom score

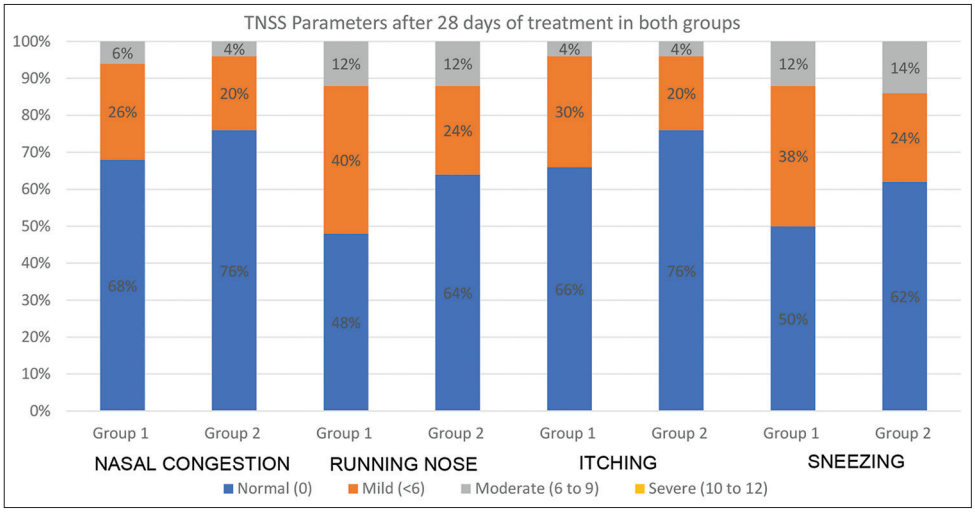

Fig. 4: Severity of TNSS scoring parameters after 28 days of treatment in two groups. Number of participants in each group (n)=50; Proportion of participants showing normal, mild, moderate, and severe forms of nasal congestion, running nose, itching, and sneezing after 28 days in each group (expressed in %). TNSS: Total nasal symptom score

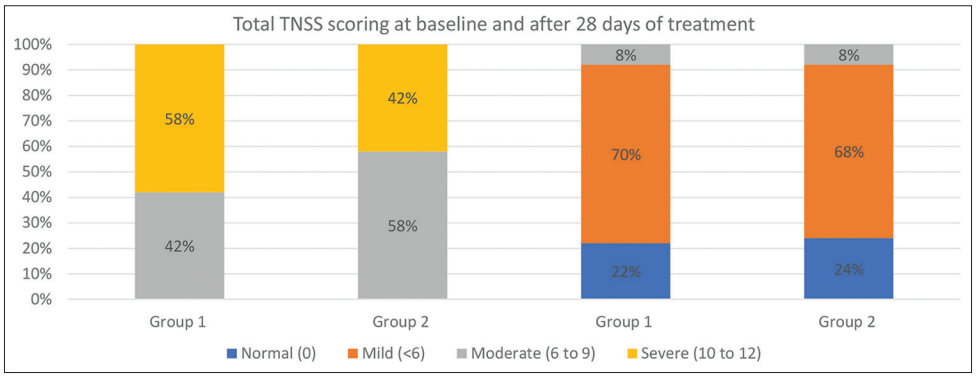

Fig. 5: Severity of allergic rhinitis by TNSS scoring at baseline and after 28 days of treatment in two groups. Number of participants in each group (n)=50; Proportion of participants showing normal, mild, moderate, and severe forms of nasal congestion, running nose, itching, and sneezing at baseline compared with after 28 days of treatment (expressed in %). TNSS: Total nasal symptom score

RESULTS

Demographic distribution of participants

Distribution of subjects by age

Average age of the subjects in the first group is 30.26 ± 7.08 years. Average age of the subjects in group 2 is 28.06 ± 5.89 years (Table 1 and Fig. 1). The variations in average age among both groups are not significant (p>0.05).

Gender distribution of subjects

Out of 50 subjects in group 1, 28 (56%) subjects are males and 22 (44%) subjects are females.

Out of 50 subjects in group 2, 24 (48%) subjects are males and 26 (52%) subjects are females. Both groups do not show any remarkable variations with respect to gender (p>0.05) (Table 1 and Fig. 2).

Distribution of the groups by presenting symptoms

Nasal congestion

There were no major changes among the groups regarding the severity of nasal congestion at baseline and even after 28 days of treatment (p>0.05) (Figs. 3 and 4) (Table 2).

Running nose

There were no major changes among the groups regarding to the severity of runny nose at baseline and even after 28 days of treatment (p>0.05) (Figs. 3 and 4) (Table 3).

Itching

There were no major changes among the groups regarding the severity of itching at baseline and even after 28 days of treatment (p>0.05) (Figs. 3 and 4) (Table 4).

Sneezing

There were no major changes among the groups regarding the severity of sneezing at baseline and even after 28 days of treatment (p>0.05) (Figs. 3 and 4) (Table 5).

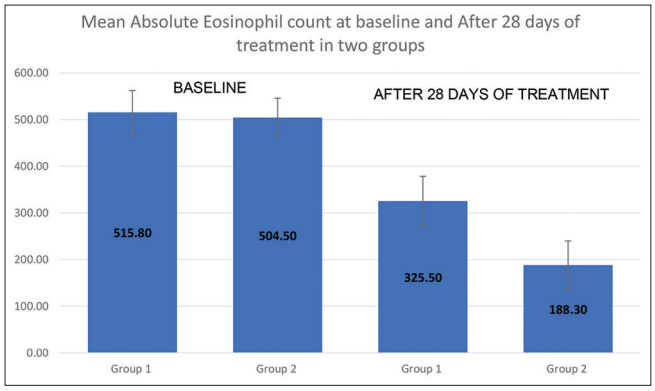

Fig. 6: Mean AEC at baseline and after 28 days of treatment in two groups. Number of participants in each group (n)=50; AEC: Absolute eosinophil count, Data regarding absolute eosinophil count are given as Mean±Standard Deviation

Out of 50 subjects in group 1, 21 (42%) subjects were having moderate grade of AR and 29 (58%) subjects were having severe grade of AR by TNSS system at baseline. Out of 50 subjects in group 2, 29 (58%) subjects were having moderate grade of AR and 21 (42%) subjects were having severe grade of AR by TNSS system at baseline (Fig. 5) (Table 6). None of the patients in both group 1 and group 2 had mild grade of AR by TNSS system at baseline. Two groups were not showing any remarkable variations with respect to severity of AR at baseline (p>0.05).

Out of 50 subjects in group 1, 35 (70%) subjects were having mild grade of AR and 4 (8%) subjects were having moderate grade of AR by TNSS system after 28 days of treatment (Fig. 5) (Table 6). Out of 50 subjects in group 2, 34 (68%) subjects were having mild grade of AR and 4 (8%) subjects were having moderate grade of AR by TNSS system after 28 days of treatment. None of the patients in both group 1 and group 2 have severe grade of AR by TNSS system after 28 days of treatment. 11 (22%) subjects in group 1 and 12 (24%) subjects in group 2 had achieved normal grade by 28 days of treatment (Fig. 5) (Table 6). Two groups were not showing any marked variations with respect to the severity of AR after 28 days of treatment (p>0.05).

Therapeutic benefit of two treatments was assessed by achieving a TNSS score of 0 at the end of 28 days. The number of patients who achieved a TNSS score of 0 at the end of 28 days is marginally higher in the second group (24%) than the first group (22%) (Fig. 5), so the variations are not significant statistically (OR=1.120; 95% CI=0.44–2.84; p=0.812, Not significant) (Table 9). The risk of having AR symptoms at the end of 28 days is less in group 2 compared to group 1 by 2% (risk difference is −2.0 with 95% CI of −18.5–−14.5).

Mean AEC of the subjects in group 1 at baseline is 515.8 ± 47.02 cells/µL and ranges from 450 to 670 cells/µL. Mean AEC of the subjects in group 2 at baseline is 504.5 ± 41.19 cells/µL and ranges from 400 to 590 cells/µL (Fig. 6). The difference in mean AEC at baseline is not significant between both groups (p>0.05) (Table 7).

Average AEC of the subjects in the first group after 28 days of treatment is 325.5 ± 52.9 cells/µL and ranges from 220 to 490 cells/µL. Mean AEC of the subjects in group 2 after 28 days of treatment is 188.3 ± 51.7 cells/µL and ranges from 112 to 329 cells/µL. The difference in mean AEC after 28 days of treatment is significant between two groups and the values were significantly higher for participants in Group 1 compared to Group 2 (p<0.05).

Average change in the AEC with treatment in group 1 is 190.3 (170.4–210.2) cells/µL and in group 2 is 316.2 (297.6–334.7) cells/µL. Second

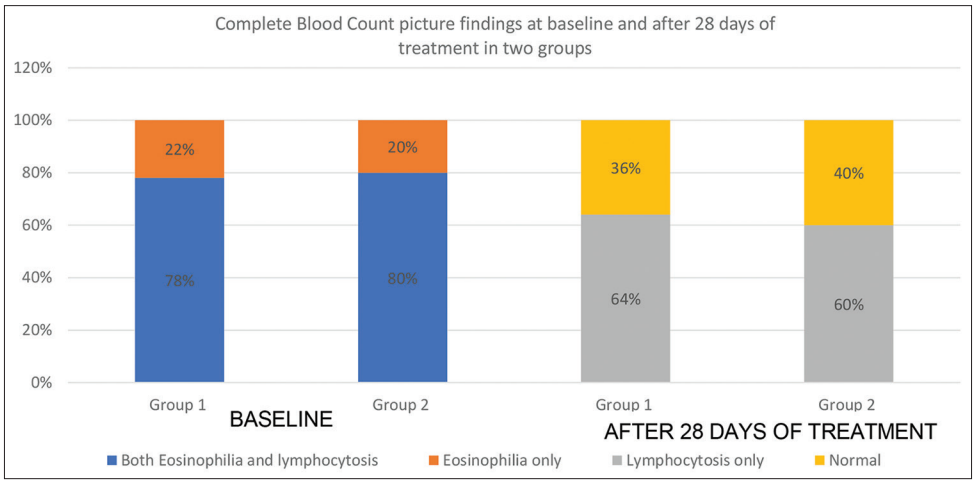

Fig. 7: Comparison of the groups by baseline complete blood picture after 28 days of treatment. Number of participants in each group (n)=50; Proportion of participants in each group showing normal, both eosinophilia and lymphocytosis, eosinophilia only, and lymphocytosis only in complete blood count (expressed in %)

group showed a significantly greater reduction in AEC compared to first group (p<0.001) (Table 9).

Among 50 subjects in group 1 at baseline, 39 (78%) subjects are having both eosinophilia and lymphocytosis and 11 (22%) subjects are having only eosinophilia. Out of 50 subjects in group 2 at baseline, 40 (80%) subjects are having both eosinophilia and lymphocytosis and 10 (20%) subjects are having only eosinophilia (Fig. 7). Two groups are not showing any significant difference with respect to the proportion of blood cells in complete blood picture at baseline (p>0.05) (Table 8).

Out of 50 subjects in group 1 after 28 days of treatment, 32 (64%) subjects are having lymphocytosis only and 18 (36%) subjects are having normal blood picture. Out of 50 subjects in group 2 after 28 days of treatment, 30 (60%) subjects are having lymphocytosis only and 20 (40%) subjects are having normal blood picture. Two groups do not show any significant difference with respect to the proportion of blood cells in complete blood picture even after 28 days of treatment (p>0.05).

Participants who achieved normal cytology at the end of 28 days are marginally higher in second group (40%) relative to the first group (36%), so variation is not significant statistically (Fig. 7) (OR=1.185; 95% CI=0.53–2.66; p=0.680, Not significant). The risk of having abnormal blood picture with treatment of 28 days is less in group 2 compared to group 1 by 4% (risk difference is −4.0 with 95% CI of −23.0−−15.0) (Table 9).

DISCUSSION

Probiotics show remarkable benefits by combating immune activation to trigger and maintain the balance of immune response. Research shows gut microbiota contribute to immunomodulation and improves body's defense to fight infectious diseases as they can reinforce intercellular junctions of the gastrointestinal tract minimize the inflammatory- cytokines that trigger T-helper 1 line lymphocytes and thereby alleviate allergic responses [23]. Additional interactions within the human body are mediated by network between the digestive system and the brain [24].

Only a single probiotic strain was used in research although modern research focused on asses the efficiency of medication by utilizing multiple strains of probiotics. A literature review spotted that lactobacillus and *Bifidobacterium* are more commonly used in research [18]. As compared to single-strain preparations, multispecies preparations have been shown to produce augmented positive health benefits which could be a due to synergistic effects between strains [25].

Fassio F *et al.* in their narrative review on house dust mite related respiratory allergies and probiotics, mentioned observations of Kalliomaki *et al.* and Jerzynska *et al.* Kalliomaki *et al.* observed a significant decrease in the incidence of atopic dermatitis by age 2 through supplementation with *Lactobacillus rhamnosus* for 24 weeks during pregnancy and for 6 months after birth and Jerzynska *et al.* in his study involving children with AR, the addition of gut microbiota to sublingual immunotherapy resulted in improved symptom scores and was associated with the activation of T-regulatory cells after 5 months of treatment. In addition, the administration of *Lactobacillus acidophilus* and *Bifidobacterium lactis* in children with allergic asthma led to improved asthma control test scores [19].

Nevertheless, the current strategies do not support using probiotics as a primary prevention strategy. Supplementation is reinforced by the World Allergy Organization, which draws its support on provisional evidence that probiotics would not harm while there is no concrete evidence for efficacy [26].

CONCLUSION

Tablet levocetirizine 5 mg exhibits comparable efficacy in the management of AR when compared to capsule Sporlac plus (2.5 billion cells) as an adjunct to tablet levocetirizine 5 mg. There were no remarkable variations observed statistically in TNSS and CBC among both groups; however, clinical significance was noted within each group. The reduction in AEC was significantly greater in Group 2 compared to Group 1 (p<0.001).

Nonetheless, additional studies considering larger sample size, dosage of probiotics, and extended study period are necessary for favorable outcomes.

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AUTHORS' CONTRIBUTIONS

Dr. Monica N and Dr. Nagur Sharone Grace were part in data collection and wrote the manuscript, and Dr. Veena B and Dr. Sarath Chandra were part in data compiling and analysis.

CONFLICT OF INTEREST

Declared None.

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