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Effect of Anti Reflux Medication in Patients with Laryngopharyngeal Reflux and Non-Allergic Rhinitis

Bhushan Chauhan[1*], Komal Chauhan[2]

[1]ENT, Maharishi Markandeshwar (Deemed to be University), located in Mullana, Ambala, India

[2]Department of Food Science and Technology, National Institutre of Food Technology Entrepreneurship and Management, Kundli, Sonepat, 131028, India

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[*]**Corresponding author:** Bhushan Chauhan, ENT, Maharishi Markandeshwar (Deemed to be University), located in Mullana, Ambala, India

ABSTRACT

The study has been conducted to assess the effect of anti-reflux medication in patients with clinical manifestations of laryngopharyngeal reflux and non-allergic rhinitis. Patients were screened for NAR and LPR using nasal endoscopy, Total Nasal Symptom Score (TNSS), Reflux Symptom Index (RSI) and Reflux Finding Score (RFS). The selected patients were randomly divided into control (n=34) and treated (n=38) groups and the therapeutic protocol involved a three-month course of anti-reflux medication with periodic assessments at 0, 4, 8, and 12 weeks. The control and treated groups received starch (20mg) and omeprazole (20mg) capsules, twice a day respectively. The patients were evaluated for TNSS, RSI and RFS periodically. The results indicated a decreasing trend in TNSS (10±0.14 - 3±0.11) and marked ($p \leq 0.05$) improvement in LPR symptoms in the treated group for nasal parameters, while the control group showed no significant change ($p \geq 0.05$) in TNSS (9.81±0.12 - 9.68±0.14) and LPR symptoms. Likewise, the RSI and RFS scores demonstrated a decreasing trend in the treated group, with a significant ($p \leq 0.05$) decrease at 12th week. The post supplementation, RSI and RFS scores in the treated group showed a substantial percent decrease (-58.4% and -50% respectively) indicating positive effects of omeprazole in counteracting LPR manifestations. The study provides evidence supporting the efficacy of anti-reflux medication in alleviating LPR symptoms in patients with non-allergic rhinitis. The positive impact on TNSS, RSI, and RFS scores highlights the potential of anti-reflux therapy as a viable treatment option for individuals with interconnected upper airway conditions.

Keywords: Total Nasal Symptom Score; Rhinorrhea, Reflux Symptom Index; Reflux Finding Score; Non-Allergic Rhinitis; Laryngopharyngeal Reflux

1. INTRODUCTION

Laryngopharyngeal reflux (LPR) and non-allergic rhinitis (NAR) are two distinct yet interconnected conditions that significantly impact the upper respiratory tract. LPR, an extra esophageal manifestation of gastroesophageal reflux disease (GERD), involves the regurgitation of gastric contents into the larynx and pharynx, leading to various upper airway symptoms [1]. Non-allergic rhinitis, on the other hand, encompasses a spectrum of nasal disorders characterized by rhinorrhea, nasal congestion, sneezing and itchy nose without an identifiable allergic trigger [2]. While these conditions have traditionally been studied independently, emerging research suggests a potential link between them, prompting investigations into shared pathophysiological mechanisms and treatment modalities [3].

The connection between LPR and NAR has gained attention due to overlapping symptoms and the recognition of reflux as a contributing factor to upper airway diseases. LPR, initially described by Cherry and Margulies, (1968) as ulcers and granulomas of the larynx [4]. However, recent studies have shown the role of reflux in aggravating upper airway diseases [5]. Non-allergic rhinitis, characterized by nasal symptoms unrelated to allergies, represents a diagnostic challenge and often requires a comprehensive approach for effective management. In recent years, the focus has shifted towards exploring the efficacy of anti-reflux medications in patients presenting with both LPR and NAR [6]. The rationale behind this investigation lies in the potential of refluxed gastric contents to reach the upper airways, triggering inflammation, mucosal congestion, and nasal symptoms [7]. Additionally, the esophageal-nasal reflex mechanism, stimulated by vagal nerve response, has been proposed as a contributor to nasal mucosal congestion and increased mucus secretion [8]. Thus, the study aims to investigate the intricate relationship between LPR and NAR shedding light on the potential benefits of anti-reflux medications in managing these coexisting conditions.

2. MATERIALS AND METHODS

2.1 Study Population

A placebo controlled prospective clinical study was undertaken in the department of Ear Nose and Throat (ENT) and Head and Neck surgery in tertiary care hospital. The ethical approval was obtained from Institutional ethical committee for clinical trials prior to commencement of study. The study consisted of two weeks of screening involving nasal endoscopy and skin prick test followed by 12 weeks of treatment period **(Figure 1)**. The periodical visits were monthly scheduled for three months followed by two weeks of follow up. The participants who showed interest and were ready for voluntary participation were briefed about the study protocol and were asked to submit the informed consent.

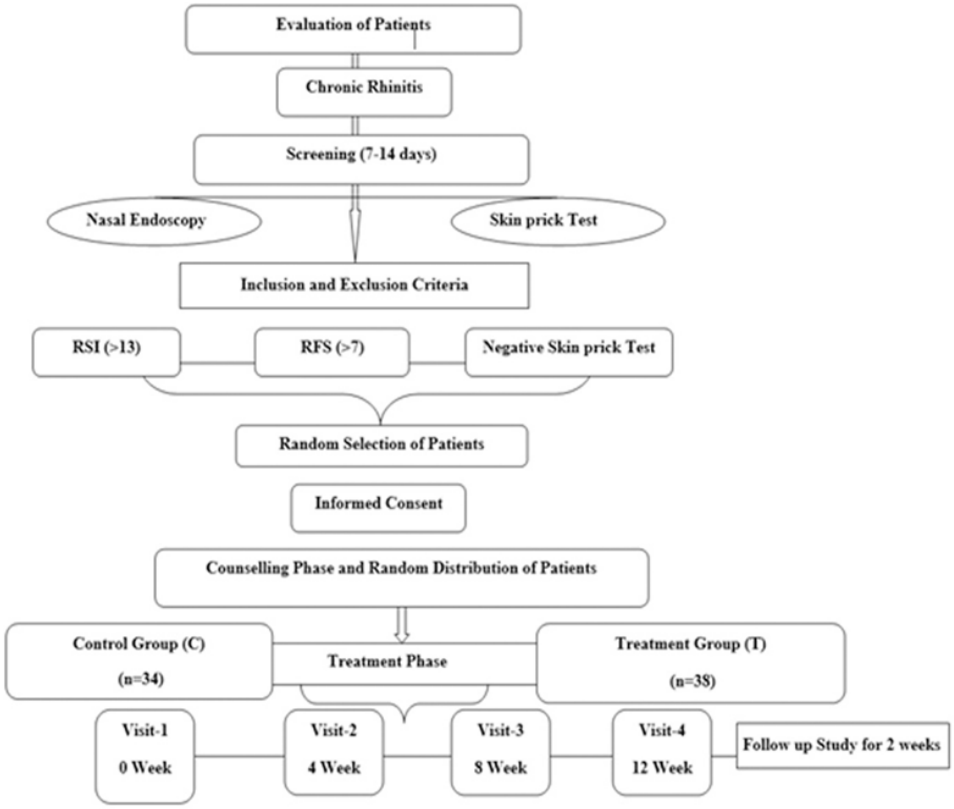

Figure 1. Schematic representation of the study

2.2 Sample Size

The sample size was calculated using G power software with 95% confidence level and margin of error 5%. The sample size comprised of 72 subjects.

2.2.1 Inclusion Criteria

Patients with symptoms of chronic rhinitis for more than three months having skin prick test (SPT) negative, reflux symptom index (RSI >13) and reflux finding score (RFS >7) were included in the study.

2.2.2 Exclusion Criteria

The study excluded pregnant and lactating mothers, as well as individuals with metabolic disorders. Additionally, patients with acute or chronic nasal infection, allergic rhinitis, deviated nasal septum, turbinate hypertrophy, nasal polyps, mass lesions of the nasal cavity were excluded. Further, patients using antihistamines, decongestants, intranasal and/or systemic corticosteroids, proton pump inhibitors, or histamine H2 receptor antagonists were not included in the study. The exclusion criteria also encompassed smokers and individuals with a history of previous sinonasal surgery.

2.3 Skin prick test

A skin prick test was performed on patients to assess sensitization for various aeroallergens namely dust mites, cockroach, mixed mould, mixed grass and cat [9]. Subjects were asked to refrain themselves from using oral

antihistamines for a minimum of 72 hours prior to the test. The patients were subjected to both positive histamine control and a negative glycerin control with wheal size measured 15 minutes post- application. A positive test was defined as a wheal diameter of 3 mm or more, coupled with a non-reactive negative control. Patients who showed negative reaction to all the tested aeroallergens in the skin prick test were included in the study.

2.4 Patient Selection

A total of 83 adult patients (≥18 years and ≤75 years) with chronic rhinitis, laryngopharyngeal reflux, and negative skin prick test were selected for the study. The selected patients were suffering for more than three months from either of the nasal symptoms such as sneezing, nasal blockage, runny nose, nasal itching.

2.5 Efficacy Trials

The subjects fulfilling the inclusion and exclusion criteria were selected and randomly divided into two groups viz., Control (C) and Treated (T). The selected patients were given treatment for 12 weeks. The control group served as placebo and was supplemented with starch capsules (20mg) twice a day. The treated group was supplemented with omeprazole 20mg twice daily. The patients were directed to take medication in morning and evening half an hour before the meals. Furthermore, they were asked to make periodical visits to the hospital every month for three months (0, 4, 8 and 12 weeks) to submit the duly filled self- administered questionnaires (TNSS and RSI) and for laryngoscopy examination (RFS). Nevertheless, in case of any discomfort, they were asked to report immediately to the hospital. Follow ups were also taken telephonically to check the compliance of the study. Thereafter, on completion of treatment phase, patients were asked for follow up for another two weeks.

2.6 Clinical Outcome Measurements

2.6.1 Total Nasal Symptom Score (TNSS)

The patients were asked to fill and submit self-administered questionnaire comprising of assessment of TNSS [10]. The severity of nasal symptoms such as sneezing, nasal blockage, runny nose, nasal itching were assessed using TNSS. Patients were asked to score each symptom on a scale from 0 to 3 wherein 0 (none) signified no symptoms; 1 (mild) for tolerable symptoms with least awareness; 2 (moderate) for definite awareness of symptoms that were bothersome but tolerable; and 3 (severe) if the symptoms were hard to tolerate and interfered with activities and/or sleeping. The total scores were calculated using nasal symptom score ranging from 0 to 12.

2.6.2 Reflux symptom index (RSI)

The reflux symptom index evaluated nine symptoms associated with laryngopharyngeal reflux, including hoarseness, throat clearing, excess throat mucus, difficulty in swallowing, coughing out mucus, breathing difficulties, troublesome cough, sensation of something sticking in the throat, and heartburn **(Table 1)**. Participants rated the severity of these symptoms on a scale ranging from 0 (no problem) to 5 (severe problem). The RSI is a reliable tool for accurately documenting LPR-related symptoms and has been demonstrated to be both valid and highly reproducible [11]. A score exceeding 13 was indicative of LPR.

Table 1: Reflux Symptom Index

Symptoms	Scores					
Hoarseness or other voice problem	0	1	2	3	4	5
Clearing throat	0	1	2	3	4	5
Excess throat mucus or postnasal drip	0	1	2	3	4	5
Difficulty swallowing food, liquid or pills	0	1	2	3	4	5
Coughing after eating or after lying down	0	1	2	3	4	5
Breathing difficulties or choking episodes	0	1	2	3	4	5
Troublesome or annoying cough	0	1	2	3	4	5
Sensation of something sticking in throat or lump in throat	0	1	2	3	4	5
Heart burn, chest pain, indigestion or stomach acid coming up	0	1	2	3	4	5

How each symptom affected you in last one month
0: No problem
5: Severe problem

2.6.3 Reflux finding score (RFS)

RFS is an eight-item clinical severity rating scale derived from laryngopharyngeal examinations **(Table 2)**. The scale serves as an accurate and efficient tool for assessing treatment efficacy in individuals with LPR [12]. A score higher than seven indicates a likelihood of more than 95% of having LPR. Notably, the RFS is user-friendly, requiring less than one minute for completion, and demonstrates excellent reproducibility both between different observers and within the same observer over time. While each item on the RFS is inherently subjective, the overall finding score reliably captures improvements associated with anti-reflux medication.

Table 2: Reflux Finding Score

Symptoms	Scores
Subglottic Oedema	0 Absent 2 Present
Ventricular Obliteration	0 None 2 Partial 4 Complete
Erythema/ Hyperemia	0 None 2 Arytenoid only 4 diffuse
Vocal cord edema	0 None 1 Mild 2 Moderate 3 Severe 4 Obstructing
Diffuse laryngeal edema	0 None 1 Mild 2 Moderate 3 Severe 4 Obstructing
Posterior Commissure hypertrophy	0 None 1 Mild 2 Moderate 3 Severe 4 Obstructing
Granuloma/ Granulation Tissue	0 Absent 2 Present
Thick endo laryngeal mucus	0 Absent 2 Present

Ranges from 0 (lowest possible) to 26 (highest possible)

2.7 Statistical Analysis

The results are depicted as mean and standard deviation. The analysis was done using SPSS 18 (IBM software). The paired sample t-test and chi square was used for statistical analysis. $p \leq 0.05$ was considered as significant.

3. RESULTS

3.1 Study Population

Patients were screened for nasal symptoms and LPR, out of which 83 participants meeting the inclusion and exclusion criteria were selected. The selected candidates were randomly divided into two groups namely control (C) and treated (T). Of the total, 72 patients completed the study with 34 and 38 subjects in control and treated groups respectively. The patients were further categorized into three age groups (18-40; 41-60 and 61-75 years). The maximal percent of patients were in the age group of 18-40 years in both control (38.2%) and treated groups (39.5%) while the least was exhibited in the 61-75 years of age group (26.5% and 26.3%) **(Figure. 2A)**.

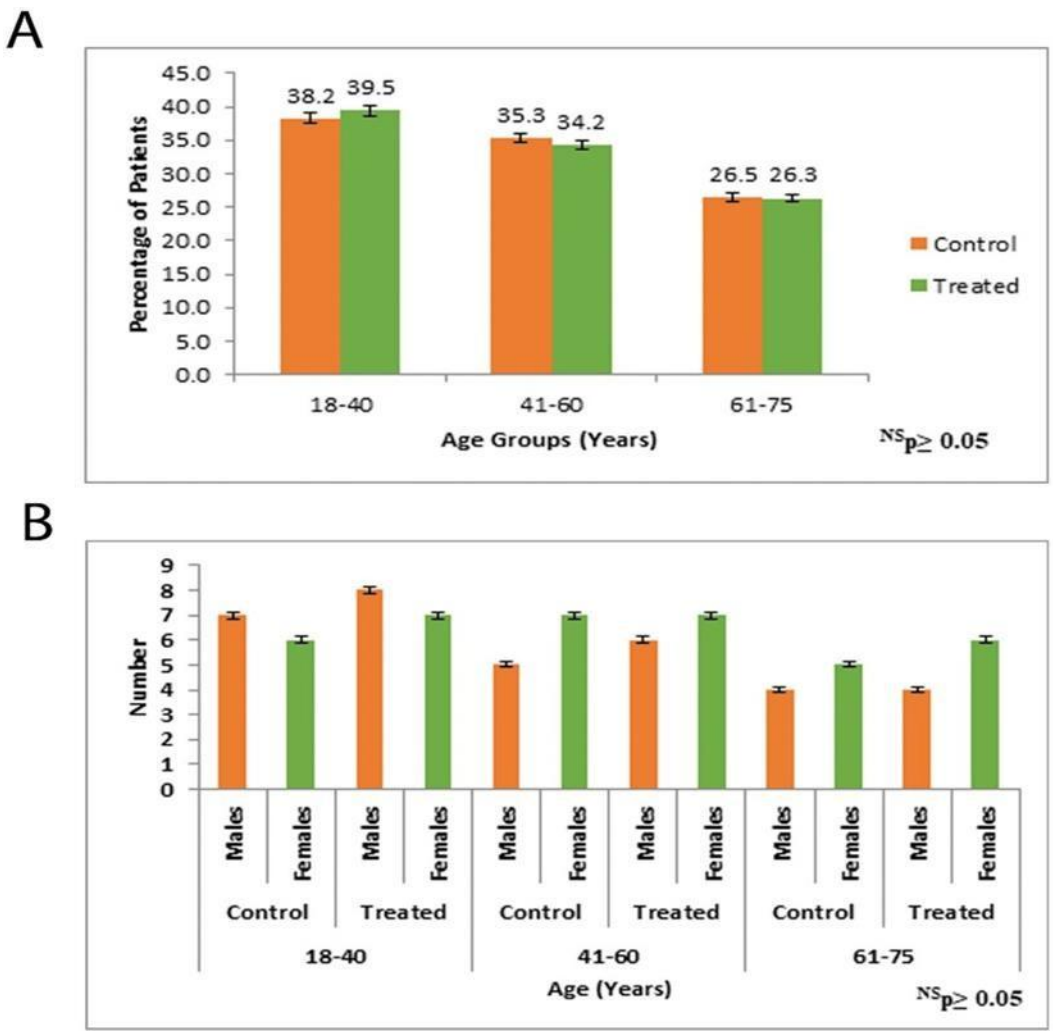

Figure 2(A). Percent distribution of patients in varied age groups (B) Gender-wise distribution of patients in varied age groups

The gender wise mean age in all the three categories of age groups is depicted in Table 3. The mean age in both the groups for males and females varied between 31.6-32.4 and 33.8-34.3 years; 52.4-52.6 and 49.8-54.3 years; and 65.3-63.2 and 62.8-64.6 years in all the three categories of different age groups (18-40; 41-60 and 61-75 years) respectively.

Table 3: Mean Age of Patients in Control and Treated Groups

Age (Years)	Control		Treated		Significance
	Males	Females	Males	Females	p≥0.05

18-40	31.6±5.3 (n=7)	33.8±4.5 (n=6)	32.4±5.6 (n=8)	34.3±2.9 (n=7)
41-60	52.4±6.1 (n=5)	49.8±4.6 (n=7)	52.6±2.6 (n=6)	54.3±2.8 (n=7)
61-75	65.3±2.7 (n=4)	62.8±3.1 (n=5)	63.2±2.6 (n=4)	64.6±3.2 (n=6)

In control and treated groups, the maximal percentage of males were in the age group of 18-40 years (n=7; 53.8% and n=8; 53.3% respectively) while the highest percentage of females were observed in 41-60 years in control (n=7; 58.3%) and in treated groups in 18-40 years (n=7; 53.8%) and 61-75 years (n=6; 60%) of age groups **(Figure 2B)**. Results showed no significant difference ($p \geq 0.05$) in gender and age wise distribution in both the groups.

3.2 TNSS

TNSS depicts the severity of nasal symptoms over a period. The TNSS questionnaire was filled by each patient at 0, 4, 8 and 12 weeks. Each symptom was rated on a scale of 0-3 with 0 as normal and 3 with intolerable symptoms. The results showed that mean TNSS of both the groups viz. control and treated, were 9.81±0.12 and 10±0.14 respectively at 0th week. Four symptoms namely rhinorrhea, nasal congestion, sneezing, and itchy nose were evaluated for TNSS score. The TNSS score for each symptom in treated group showed a decreasing trend resulting in marked ($p \leq 0.05$) improvement at 12th week (3.0±0.11) (Fig.3). On the contrary no significant change ($p \geq 0.05$) was observed in control group (9.68±0.14) in either of the symptoms evaluated.

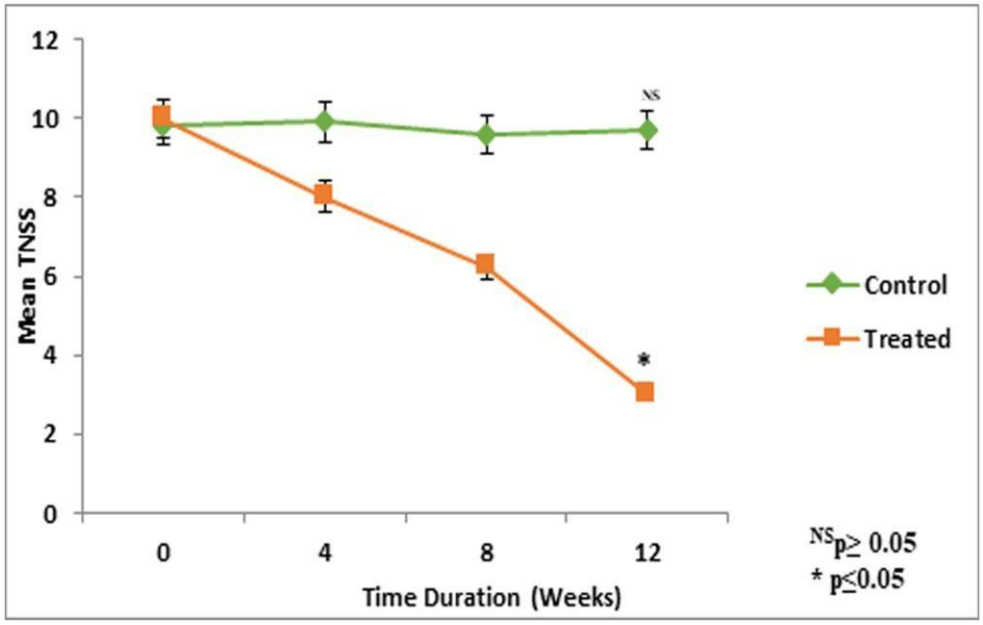

Figure 3. TNSS score in control and treated groups

3.3 RSI

RSI scores improved in the treated group with anti-reflux medication. The scores showed a decreasing trend in the treated group from 27.9±1.17 to 11.6±1.05 with a highest percent difference in RSI at 4th week (- 58.4%). The RSI scores of treated groups decreased significantly ($p \leq 0.05$) and the mean scores at 12th week was less than 13 indicating marked improvement in LPR symptoms. On the other hand, no change ($p \geq 0.05$) was observed in control group (27.8 ±1.02 to 27.6±1.12) **(Figure 4A)**.

3.4 RFS

The patients were subjected to laryngopharyngeal examination at each visit. As per the observations made by physician, the RFS scores for each symptom were assessed and the rating was done. Similar trend was observed in RFS scores of treated groups showing marked decrease from 12.6±0.17 to 6.3±0.04. RFS scores for the treated group decreased below seven at 12th week indicating marked improvement ($p \leq 0.05$) in LPR symptoms thereby conferring RSI and TNSS scores. On the contrary no significant change was observed in control group (12.5±0.14-12.3±0.21) **(Figure 4B)**.

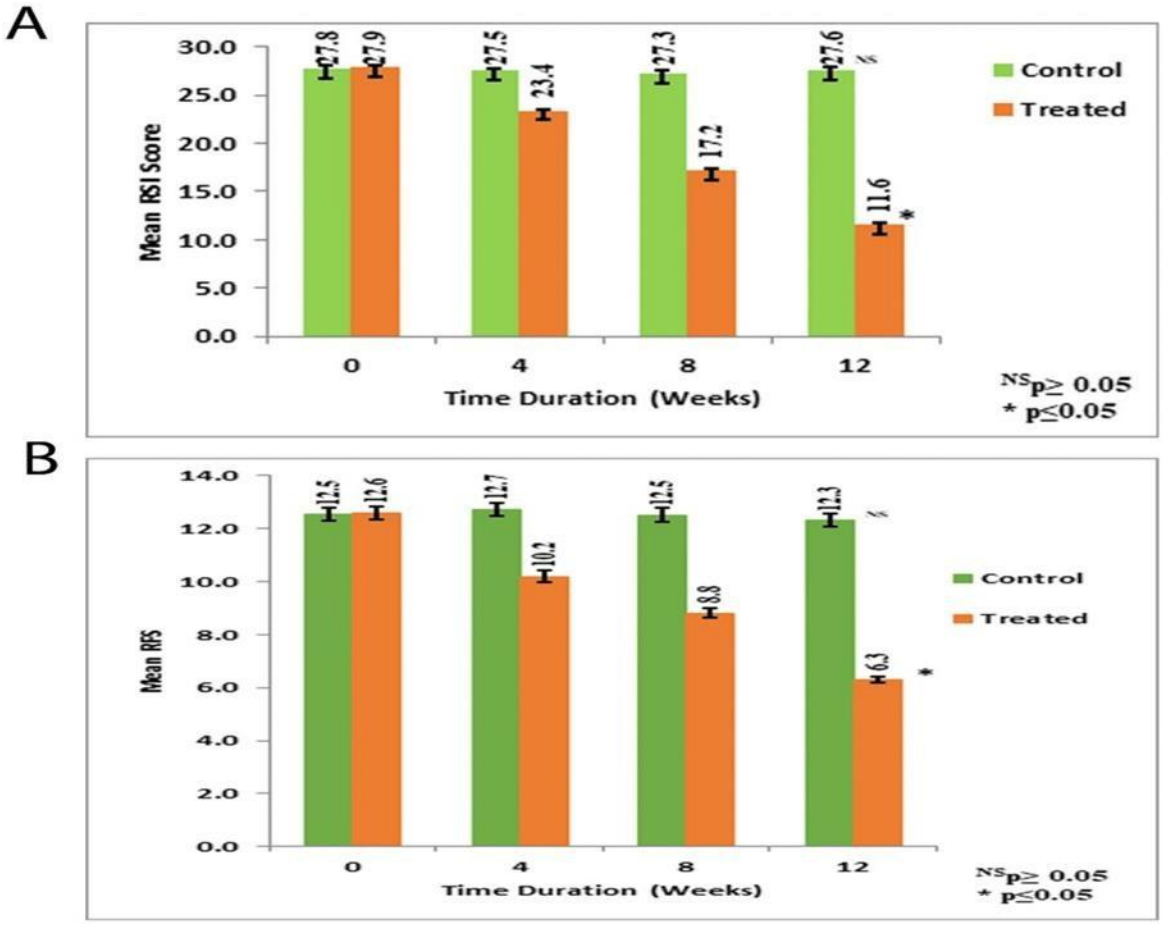

Figure 4(A). Mean RSI score in control and treated groups (B) Mean RFS score in control and treated group

3.5 Comparison of Pre and Post treatment

The percent difference between pre and post treatment in TNSS, RSI and RFS in treated group showed a decreasing trend with marked improvement ($p \leq 0.05$) in respective scores. On the contrary no improvement was observed in control group. It is evident that anti reflux treatment to patients with LPR symptoms for a period of 12 weeks brought significant improvement in non-allergic rhinitis with percent difference of -70% in TNSS; -58.4% in RSI and -50% in RFS scores (Fig. 5A). Furthermore, the percent difference observed from 0th day to 12 weeks in treated patients for rhinorrhea (-70%), nasal congestion (-77.8%), sneezing (-70%) and itchy nose (-63.6%) was significant in comparison to their counterparts (-4%, 5%, - 4.2%, -1.03%) **(Figure 5B).**

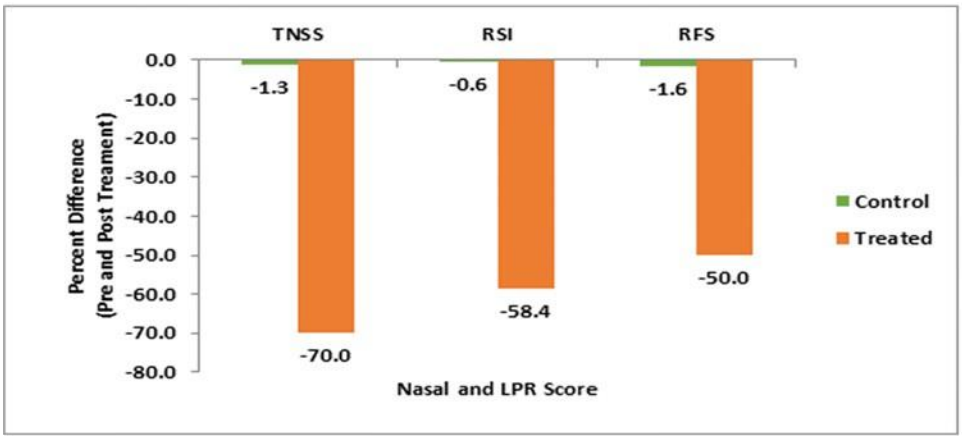

Figure 5A

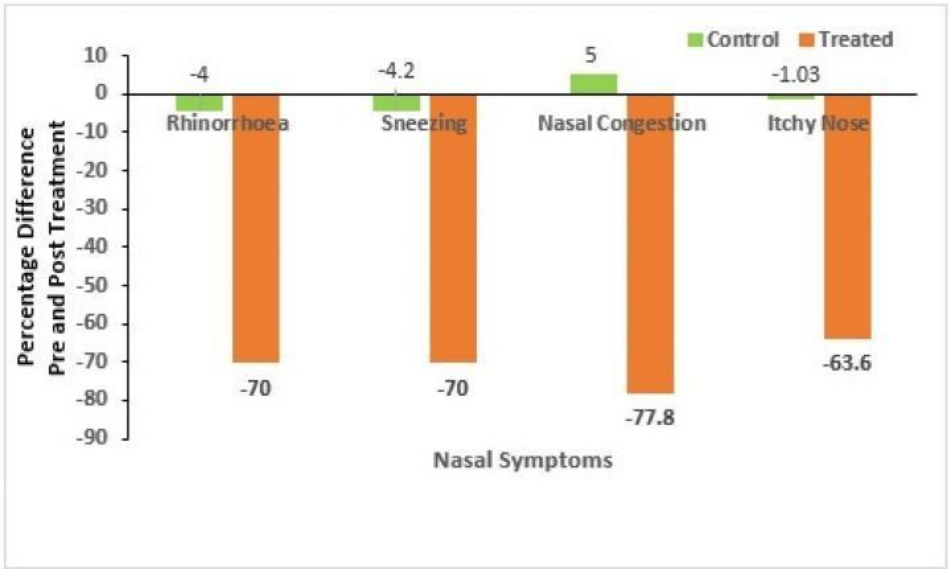

Figure 5B

Figure 5. Percent difference in nasal and LPR score in control and treated groups (5A) and percent difference in nasal symptoms in control and treated groups (5B)

4. DISCUSSION

The study was conducted in the tertiary hospital and the patients were screened for non-allergic rhinitis symptoms and laryngopharyngeal reflux symptoms through nasal endoscopy, TNSS, RSI and RFS. They were subjected to skin prick test for common aeroallergens. Patients fulfilling the inclusion and exclusion criteria were selected.

The selected patients were randomly divided into two groups viz. Control and Treated. The study protocol, its objectives and outcome were clearly defined to the patients and the leaflets about the study were distributed to them

along with the informed consent. The patients were assured that the complete confidentiality of the data would be maintained throughout as well as after completion of the study. They were asked to submit the informed consent wherein they were to agree and submit their consent for voluntary participation in the study. A brief induction to fill the self-administered questionnaires of TNSS and RSI was given. The scoring method was also explained for the respective questionnaires. The therapeutic protocol involved regular intake of medicines for a period of three months. For compliance and assessment, they were asked to visit the hospital periodically at 0, 4, 8 and 12 weeks. They were also asked to report immediately (telephonically or physically) to the concerned physician for any discomfort or any other acute manifestation during the study.

The control and treated groups were supplemented starch (20mg) and omeprazole capsules (20mg) twice a day. They were directed to take medication in morning and evening half an hour before meals for the scheduled period. The patients were also evaluated for RFS through laryngoscopy examination at each visit. After completion of study, the patients were followed up for another two weeks to report for any kind of discomfort or side effects associated with the medication. The results are discussed under the varied clinical outcomes.

4.1 Demographic profile

The patients were assessed for demographic profile for getting an insight of their age and gender. The results showed no significant variation ($p \geq 0.05$) in age and gender of the patients in both the groups. Similar findings were reported earlier by Dagli et al [5]. Similarly, Katle et al [13] illustrating that there was no marked difference in reflux episodes, bolus exposure and the proximal extent of refluxate in patients aged over and under 45 years old.

4.2 Pathophysiological mechanisms

Numerous proposed mechanisms elucidate the correlation between acid reflux and chronic nasal symptoms or rhinosinusitis. Individuals with chronic rhinosinusitis exhibit a greater prevalence of proximal gastroesophageal reflux compared to their healthy counterparts [13]. The exposure to gastric acid may exacerbate inflammation in the mucosa of upper airways and sinuses impairing mucociliary motility leading to sinus ostia obstruction, thereby fostering recurrent infections [7]. Alternatively, a second mechanism involves vagally-mediated neuroinflammatory changes [8]. Autonomic dysfunction can trigger reflex sinonasal swelling and inflammation resulting in blockage of ostia. Likewise, Wong et al [14] elucidated that the infusing saline with hydrochloric acid in the lower esophagus increased nasal mucus production and nasal symptom scores.

4.3 TNSS

The nasal symptoms namely rhinorrhea, nasal congestion, sneezing, and itchy nose were scored by the patients in both the groups on a scale of 0-3 (none to mild to severe) and TNSS was calculated as an average for each parameter

on a scale of 0-12. The study showed a decreasing trend in the treated group for each nasal parameter. On the contrary no significant change was observed in control group. The results point towards the efficacy of the anti-reflux medication in non-allergic rhinitis patients with LPR symptoms. Halstead, [15] in a study emphasized that gastroesophageal reflux (GER) serves as a significant inflammatory cofactor in chronic sinusitis, otitis media, and rhinitis, although it might manifest because of chronic illness in older children [15]. The results of our study are consistent and in concordance with Bothwell et al. [16] involving a study with 30 children aged 1 to 16 years. The study revealed a marked reduction in the need for sinus surgery in children following reflux treatment. Likewise, Di Baise et al. [17] conducted a study, which involved 19 patients and a mean follow-up of six months reported improvement in sinus symptoms of 12 patients [17].

4.4 RSI

The patients were assessed on a scale of 0 to 5 (none to severe) for reflux symptom index using varied LPR- related symptoms namely hoarseness of voice, clearing of throat, excess throat mucus, difficulty in swallowing, coughing after lying down, breathing difficulties, troublesome cough, sensation of something sticking in the throat, and heartburn. The score of more than 13 was considered as manifestation of laryngopharyngeal reflux. The control group showed slight variation (27.8±1.02 to 27.6±1.12) while a decreasing trend was observed in treated group (27.9±1.17 to 11.6±1.05) over a period of three months with maximal decrease on 12th week. The mean scores of treated groups (11.6±1.05) at 12th week were less than 13 indicating the positive effects of omeprazole in counteracting the manifestations associated with LPR. The results align with earlier research that has documented evidence of amelioration in sinus symptoms following acid suppressive therapy [15-17]. Di Baise et al. [6] elucidated an improvement in sinus symptoms among individuals with gastroesophageal reflux disease following a three-month course of omeprazole, thereby conferring the association between two disorders [6].

4.5 RFS

The patients were examined at each visit for RFS for seven items namely subglottic edema, ventricular obliteration, erythema/ hyperemia. vocal cord edema, diffuse laryngeal edema, posterior commissure hypertrophy, granuloma/ granulation tissue, thick endo laryngeal mucus. The RFS scores of treated groups showed a decreasing trend (12.6±0.17 to 6.3±0.04) than their counter parts (12.5 ±0.12 -12.3±0.14). The maximal reduction in mean scores of treated groups was observed on 12th week (-50%). The results elucidate that the mean scores substantially decreased and were rated less than seven at 12th week. The RFS more than seven has more than 95% probability of having LPR. Thus, the study concludes that marked improvement in LPR symptoms in patients is attributed to anti reflux medication. Earlier studies by various researchers, have consistently reported substantial improvement in symptoms related to RSI and RFS after a four-month course of Proton Pump Inhibitor (PPI) therapy [18-20].

5. CONCLUSION

The study revealed marked improvement in TNSS, RSI and RFS in the treated group in comparison to the control group indicating the efficacy of anti-reflux medication in mitigating non-allergic rhinitis symptoms associated with LPR. Further research with large sample size and extended follow-up duration may be undertaken to validate the findings. Consequently, treatment strategies aimed at enhancing the quality of life for individuals affected by the co-existence of LPR and non-allergic rhinitis may be developed accordingly.

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