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**Original Research Article** 

## Self-Prepared Hypertonic Saline Nasal Irrigation as an Effective Adjuctive Treatment in Allergic Rhinitis along with Intranasal Steroids and Oral Antihistaminics: A Randomized Controlled Trial

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#### Abstract

**Background:** Allergic rhinitis is a global health problem, and the symptoms deeply affect a patient's quality of life (QoL). The current treatment protocols consist of antihistamines and nasal steroids as mainstay. In any setting, AR usually requires chronic treatment, which raises safety concerns about long term drug usage and also its economic burden. Nasal irrigation with saline appears to be useful adjunctive tool improving nasal symptoms and QoL, and also decreasing drug consumption in a cost-efficient manner.

**Methods:** A hospital based, open label, randomized controlled trial was conducted with 100 patients to assess the adjuvant effect of nasal irrigation in cases of allergic rhinitis undergoing regular treatment with oral anti-histaminic and intranasal steroids. 100 patients of AR were randomized into two groups – one receiving oral antihistaminic and intranasal steroid and the other group additionally also received nasal irrigation with self-prepared hypertonic saline for a period of 3 weeks with follow up at 6 weeks. Both the groups were compared on the basis of total symptom score and Rhino-conjunctivitis Quality of Life Questionnaire (RQLQ).

**Results:** The study group was superior to the control group in terms of total symptom score and QoL (both P<0.001).

**Conclusion:** Hypertonic Saline nasal irrigation when combined with Intranasal corticosteroids and oral antihistaminic demonstrates superior efficacy in managing symptoms and improving QoL. It also decreases drug dependence and is safe, easy to prepare and cost effective. Hence it is a worthy adjunctive tool to be considered in AR.

**Keywords:** Nasal Irrigation, Hypertonic Saline, Allergic Rhinitis, Intranasal Corticosteroids, Oral Antihistaminic.

#### Introduction

Allergic rhinitis is a very common medical condition in today's world, affecting

individuals of both genders and all ages, affecting between 10 and 40% of the world's

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population [5] With increasing urbanization and the steady deterioration of air quality and increase in air pollution, the prevalence rate of AR has been on the rise in recent years. AR is characterized by classical symptoms such as nasal congestion; sneezing; rhinorrhoea; itching of nose, palate along with ocular symptoms like redness, watering and itching of eyes. The symptoms of persistent allergic rhinitis and the negligence to get prompt medical attention can deeply affect a patient's physical, social and emotional functioning including their quality of life (QoL) and also compromise their productivity and sleep quality (SQ) [1-6].

Therapeutic options available to achieve symptomatic relief includes allergen avoidance and several pharmacological interventions with Intranasal corticosteroids (INSs) and oral antihistamines as recommended first-line therapy.

Very often there is incomplete remission of symptoms and need for chronic drug use in patients with AR raising concerns of longterm drug usage. In a constantly recurring condition like AR, maintenance therapy has an important role and there has been an ongoing search for non-pharmacological alternatives. Amongst them, saline nasal irrigation (SNI) has shown to be of benefit in AR. Nasal irrigation with normal saline has a direct mechanical cleansing action of the nasal mucosa from allergens or other exogenous particles [7] and prevents drying and deposition of secretions and hence improve local environment of nasal cavity. It also increases the mucociliary action [8] thus improving the physiological function of nasal cavity.

Although Normal saline was commonly used, several studies have demonstrated increased effectiveness with hypertonic solutions and increased alkalinity or pH [9,10]. The possible mechanism of action would be that hypertonic solutions induce an

osmosis gradient related movement of water across the nasal mucosa, hence decreasing mucosal oedema. Moreover, studies have shown that alkaline pH has a promotional effect on mucociliary clearance. [11] SNI offers an inexpensive option for maintenance therapy in allergic rhinitis patients all over the world, is relatively safer for long-term use and does not require medical prescription and can also be made at home, making it more easily accessible. Hence, this study was done with the aim of assessing the effects of hypertonic saline nasal irrigation, both positive and negative and the feasibility of considering it as an adjuvant measure in treating allergic rhinitis patients by comparing AR patients receiving oral anti histaminic and intranasal steroids with and without hypertonic saline nasal irrigation.

#### **Materials and Methods**

This was a hospital based, parallel, open label, 1:1 randomized controlled trial which was conducted with 100 patients to assess the adjuvant effect of hypertonic saline nasal irrigation in cases of allergic rhinitis undergoing medical treatment with oral antihistaminic and intranasal steroids.

### Subjects:

All Patients with symptoms of AR (as per ARIA guidelines) who fulfilled the inclusion criteria were considered as part of the study population after Informed Consent from the patients and due permission from the Institutional Ethics Committee and Review Board.

The Inclusion criteria included- (1) age 18– 65 years, (2) clinically diagnosed as AR for more than 1 year (3) TNSS >5 at the screening visit (4) willing to participate in the study and give consent (5) treatment naïve for the current episode of AR (minimum flush out period of 7 days necessary with no treatment) (6) baseline investigations within normal limits. Patients who have non – allergic rhinitis, subjects with clinically significant nasal structural abnormalities e.g., nasal polyps, who require or have taken systemic steroids in the last one month or those who have chronic rhinosinusitis or ciliary motility disorders or any other chronic disease and were unwilling to perform nasal irrigation for a long time were excluded out of the study.

#### Study design:

All patients with AR symptoms underwent a screening visit where baseline investigations were carried out and case record proforma along with baseline TSS and RQLQ were filled.

On the second visit, the patients fulfilling the inclusion criteria were allocated into two groups with the help of simple randomization with a 1:1 allocation ratio  $-1^{st}$  group received oral anti-histaminic and intranasal steroids for 3 weeks whereas the  $2^{nd}$  group along with the above also received hypertonic saline nasal irrigation.

The saline solution used for irrigation was 1.25% Buffered Hypertonic saline which was made at home and had the following composition as instructed: sodium chloride 3 g and baking soda 1 g in 240 ml prior boiled, lukewarm water) – given twice daily via a red syringe bulb with nozzle for 3 weeks.

The patients were asked to follow up after 3 weeks where they were asked to fill the proforma along with TSS and RQLQ. The participants were also asked to record any burning sensation or any other negative effects of the intervention during the study.

The efficacy of the product was assessed between the two groups by a change in the Total Symptom Score (TSS) based on the patient's evaluation of symptom severity. Secondary outcome measures include assessment of change in quality of life using the Rhino-conjunctivitis Quality of Life Questionnaire (RQLQ).

## Total nasal symptom score:

Total Symptom Score (TSS) is a cumulation of Nasal symptom scores (NSS) and Non-Nasal symptom scores (NNSS) based on the patient's evaluation of symptom severity. The NSS takes into account 4 nasal symptoms - nasal congestion, nasal itching, nasal discharge, and sneezing. The NNSS encompasses eye symptoms like redness of eyes, itching of eyes, watering of eyes, foreign body sensation and burning in eyes along with itching of palate and throat. All symptoms were graded on a 4-point scale from 0 (no symptoms) to 3 (severe symptoms that are bothersome and interfere with daily activities or sleep) [12]. Therefore, a higher TSS indicates higher severity of symptoms of AR.

# Rhino-conjunctivitis Quality of Life Questionnaire (RQLQ) [13]:

The effect on quality of life was assessed using the self-administered Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) [13]. It is based on 7 domains – 1) Sleep 2) Activity limitations 3) Eye symptoms 4)Non hay fever symptoms 5)Nasal symptoms 6)Practical problems 7)Emotional function. The patients score each problem on a seven-point scale ranging from 0 (not troubled at all) to 6 (extremely troubled/all the time).

### Statistical Analysis:

Quantitative data are represented with the help of Mean and Standard deviation. Qualitative data are presented with the help of frequency and percentage. Comparison among the study groups for quality of life and total symptom score was done with the help of repeated measures ANOVA test. A 'pvalue' of less than 0.05 is considered statistically significant.

### Results

110 subjects were initially screened for the study, but 10 subjects refused to participate or had problems in follow up after which 100 subjects were randomized into two groups with the help of simple randomization with a 1:1 allocation ratio  $-1^{st}$  group received oral anti-histaminic and intranasal steroids for 3 weeks whereas the  $2^{nd}$  group along with the above also received hypertonic saline nasal irrigation.

#### Demographic data

The mean age in the study population was found to be around 34.5 years. Most of the study population were female (51%) with males constituting 49 % of the participants. There were no significant differences between the two groups in sex, age, duration of disease, prior treatment history, and severity of disease (all P>0.05), presenting comparability. The most common nasal symptom in the patients of allergic rhinitis in the study was found to be recurrent sneezing (83%). it was followed by rhinorrhea or nasal discharge at 70 %, The most common ocular symptom in the patients of allergic rhinitis in the study was found to be watering of eyes (75%).

## Effectiveness of hypertonic saline nasal irrigation

It was noted that there was improvement seen

in both the groups. However mean TSS and mean RQLQ showed greater reduction in group B – that is group that received nasal irrigation along with oral antihistamines and intranasal steroids as compared to the group only receiving oral antihistamines and intranasal steroids. The difference in the mean TSS and mean RQLQ between the two groups was found to be statistically significant with a p value of less than 0.001.At the follow up visit-3-week post stoppage of treatment, the mean TSS and mean ROLO was seen to rise in both groups, but it increased less in group B compared to group A. The results are summarized in Table 1.

## Safety and tolerability of saline nasal irrigation

To assess the safety and tolerability, patients were asked about the adverse effects, if any faced by the participants during use of the intervention. No major side effects were recorded by the study participants.

	Mean TSS		Mean RQLQ	
	Group A	Group B	Group A	Group B
	(control)	(test)	(control)	(test)
Week 0 (D1)	22 (2.3)	21.0 (3.1)	121.5 (10.2)	120.5 (8.2)
Week 1 (D7)	16.9 (2.1)	14.7 (2.9)	92.8 (9.2)	97.3 (5.7)
Week 2 (D14)	15.6 (1.8)	11.3 (1.9)	68.8 (12.6)	84.1 (9.3)
Week 3 (D21)	14.8 (1.2)	9.9 (1.5)	59.8 (12.1)	77.6 (8.9)
Week 6 (D42)	18.8 (14)	12.8 (1.8)	83.7 (12.6)	95.5 (8.4)
Week 0 (D1)	22 (2.3)	21.0 (3.1)	121.5 (10.2)	120.5 (8.2)
	p value <0.001		p value <0.001	

Table 1: Comparison of TSS and RQLQ between the two groups during the course of the study



Chart 1: Comparison of the two groups according to mean TSS from week 0 to week 6



#### Discussion

Allergic rhinitis is a very common condition with high economic burden. Moreover, even though not life threatening, it is known to deeply effect the patient's quality of life. The first line of management for AR currently includes oral anti histaminic and intra nasal steroids. Despite long term usage, a huge fraction of these patients remains symptomatic.

Nasal irrigation is currently recommended as an adjunctive treatment modality in many Sino nasal disease such as rhinosinusitis and AR [14,15]. Many hypotheses have been given regarding the mechanism of action of saline irrigation. Different tonicities of saline solution have been used in different studies. Hypertonicity has the potential to cause osmotic pressure-induced water transport across the nasal mucosa hence decreasing mucosal oedema and improving mucociliary clearance [10]. Satdhabudha, A, and O Poachanukoon. et al [12] conducted a study that supports that regular use of 1.25% buffered hypertonic saline was found to be advantageous over isotonic normal saline in allergic rhinitis for improvement in Mucociliary clearance time assessed via the saccharin clearance test (SCT), symptom score and OoL.

Our study was done to assess the effect of hypertonic saline nasal irrigation as an adjuvant treatment measure in AR along with oral anti histaminic and intra nasal steroids in AR. Our results indicate that both clinical symptoms and the QoL of patients with AR are significantly improved when nasal irrigation is additionally performed along with oral anti histaminic and intra nasal steroids. These findings were comparable to study conducted by Rogkakou, A *et al.* [16], a randomized open study on adult patients of AR which demonstrated that the addition of hypertonic nasal saline spray appeared to have significant additional benefit on improving symptom reduction and QoL. Cordray, Scott *et al* [17] in his study assessing the effectiveness of hypertonic sea water spray used by 15 AR patients for 1 week. The assessment was based on the "Rhino conjunctivitis Quality of Life Score" and showed clinically and statistically significant improvements (p < 0.0001) of symptoms. Li *et al.* [18] showed greater symptom reduction in AR patients who received combination of SNI and steroids.

The primary strength of our work is in the intervention- hypertonic saline nasal irrigation – which can be easily prepared at home and is cost effective, easy to administer and relatively safe with no major side effects. This study included AR patients of varying severity hence our results can be generalized to a larger population. The process of randomization decreases the chances of bias and makes the study more reliable.

Our study also has some limitations. No blinding was done but the process of blinding was technically difficult in the setting of nasal irrigation and the use of a placebo irrigation solution would have certain impracticalities. One of the drawbacks was also the lack of an objective scoring system. The possible mechanism underlying the positive effects of nasal irrigation was not studied in this setting.

Our findings are consistent with previous studies [12,16,17] showing that nasal saline irrigation with hypertonic saline can be considered as an adjunctive treatment for AR and can be a both safe and effective option that can help achieve an at home and inexpensive method to control the persistent and hard to alleviate symptoms seen in allergic rhinitis.

#### Conclusion

Our study shows that hypertonic saline nasal irrigation appears to have an additional

advantage in the treatment of allergic rhinitis when given along with intranasal steroids and oral anti histamines. It has shown to not only reduce the symptoms but also improve the quality of life of patients with allergic rhinitis in a safe, easily accessible and cost-effective manner. It plants a fertile seed for future studies about the scope of saline irrigation in AR.

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