

## TO ASSESS AND COMPARE THE EFFICACY OF TREATMENT OF ALLERGIC RHINITIS USING THREE DIFFERENT SALINE PREPARATIONS.

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### Abstract

**Aim:** to assess and compare the efficacy of 3% hypertonic saline irrigation with 0.9% normal saline and 0.5% diluted betadine saline irrigation.

**Materials and Methods:** present prospective comparative study was conducted on 60 randomly selected patients confirmed of allergic rhinitis visited the department of ENT, Nalanda Medical College and Hospital, Patna, Bihar, India. Patients were divided into three groups. The outcome between pre and post treatment was compared.

**Results:** Females outnumber males. Within each group pre and post treatment showed statistical significant difference but between three groups no statistically significant difference is seen in outcome.

**Conclusion:** reports outcome following nasal irrigation in all the three treatments was found statistically significant but between the treatments no statistically significant difference observed.

**Keywords:** nasal irrigation, rhinitis, 3% hypertonic saline, 0.9% normal saline, 0.5% diluted betadine saline

### Introduction

Allergic rhinitis is the 6th leading causes of chronic disease. Rhinitis affects quality of life, performance and attendance at school, and work. It has significant impact on healthcare costs. Regardless of age, gender of race, almost anyone may develop allergies. Allergic or Atopic disease are extremely important in general health picture since 10% of the people at some time during their life suffer from major allergy and another 40% suffer from a minor allergy, yet there is little concern for this major public health problem<sup>1</sup>.

The prevalence of Allergic rhinitis is also high in developing nations: rhino-conjunctivitis was 15.3% amongst 11 to 15 year old school-going children in northern Africa<sup>2</sup>. Allergic sensitization can involve practically any tissue or body to produce a multitude of manifestations but due to its location, the nasal mucous membrane is frequently overwhelmed by excessive allergen contact giving rise to a typical triad of symptoms-rhinorrhoea, nasal obstruction and paroxysmal attack of sneezing collectively called Allergic rhinitis. Many forms of treatment are in use from (antihistamines) autohaemotherapy, intraturbinate injection of steroids to the intranasal dexamethasone aerosol<sup>3</sup>.

Nasal irrigation is common to both modern and traditional therapy regimes. Many theories exist for the potential beneficial physiological effects of topical saline.

Improvement in mucus clearance, enhanced ciliary beat activity, removal of antigen, biofilm or inflammatory mediators and a protective role on sinonasal mucosa have all been proposed. Hence the present investigation was planned to assess and compare the efficacy of 3% hypertonic saline irrigation with 0.9% normal saline and 0.5% diluted betadine saline irrigation.

### Materials and Methods

The present prospective comparative study was conducted on 60 randomly selected patients confirmed of allergic rhinitis visited the department of ENT, Nalanda Medical College and Hospital, Patna, Bihar, India.

**Inclusion Criteria:**

1. Patients above 18 years of age of either sex
2. Diagnosed cases of allergic rhinitis
3. Those who give informed consent

**Exclusion Criteria**

1. Patients with diabetes mellitus, HIV etc.
2. Patients with polyps and mucocele that obstructs the sinuses

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

### Sample selection

The sample size was calculated using a prior type of power analysis by G\* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum

sample size was calculated, following these input conditions: power of 0.80 and  $P \leq 0.05$  and sample size arrived were 14 participants in each group. The final sample achieved was 60 (20 per group).

### Grouping

Group I: 0.5% diluted betadine saline irrigation

Group II: 0.9% normal saline irrigation

Group III: 3% hypertonic saline irrigation

### Methodology

After taking detailed history and recording demographic data, a comprehensive clinical examination of each patient was done. Patients in all three groups were given a detailed class on method of doing saline nasal irrigation. Pre and post mean Absolute Eosinophil Count (AEC) and Lund-Kennedy Endoscopic Score were calculated at the end of 1 month following nasal irrigation in all three Groups.

### Statistical Analysis

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using SPSS version 20 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. The variables were assessed for normality using the Kolmogorov Smirnov test. Descriptive statistics included computation of percentages, means and standard deviations. Test applied for the analysis were Independent sample t-test and One-way ANOVA. Level of significance was set at  $p \leq 0.05$ .

### Results

**Table 1:** Distribution of Mean age of the study groups

Group	Mean	Std. Dev	p-value
I	30.17	2.05	0.441 (NS)
II	31.23	1.18	
III	30.69	2.11	

Test applied: One-way ANOVA

**Table 2:** Gender wise distribution of the study groups

Group	Gender		Total
	Female	Male	
I	11	9	20
II	13	7	20
III	10	10	20
Total	34	26	60 (100.0%)
p-value	0.181 (NS)		

Test applied: chi-square test

**Table 3:** Mean comparison of Pre and Post Absolute Eosinophil Count (AEC)

Group	Mean Absolute Eosinophil Count		p-value
	Pre	Post	
I	688.21	576.32	0.001
II	684.43	581.45	0.001
III	678.81	542.61	0.001
p-value	0.441 (NS)		0.078 (NS)

Test applied: Paired t-test and One-way ANOVA

**Table 4:** Mean comparison of Pre and Post Lund-Kennedy Endoscopic Score

Group	Mean Lund-Kennedy Endoscopic Score		p-value
	Pre	Post	
I	6.68	1.94	0.001
II	6.74	1.61	0.001
III	6.98	2.42	0.001
p-value	0.891 (NS)		0.278 (NS)

Test applied: Paired t-test and One-way ANOVA

### Discussion

Saline irrigation is regarded as an adjunctive therapy of AR without severe adverse effects. The entire mechanism of the effect of saline irrigations has not been fully understood, but the clearance of mucus and the removal of airborne allergens and inflammation mediators are believed to contribute to its therapeutic effects.<sup>4</sup> The restoration of the muco-ciliary transport function is also evident in patients using saline irrigation. Saline is an easily available over-the counter medication, with very few adverse effects reported in patients who use it for nasal irrigation (e.g., nasal bleeding). Therefore, saline irrigation is convenient and effective, and may be used as an alternative treatment for AR.<sup>5</sup>

Our study reported improvement in allergic rhinitis in patients administered with 3% hypertonic saline. This is in similarity with the majority of studies<sup>6</sup> on the effects of saline solution of different osmolarities on mucociliary clearance have reported hypertonic saline to be more effective than normal saline in improving mucociliary clearance [27], few studies have found no difference between hypertonic and normal saline.<sup>7</sup> Interestingly, a study<sup>8</sup> reported that irrigation with hypertonic saline restored impaired mucociliary clearance in chronic sinusitis patients, while isotonic saline improved mucociliary clearance in allergic rhinitis and acute sinusitis patients, suggesting that nasal irrigation with isotonic or hypertonic saline may improve mucociliary clearance time in various nasal pathologies.<sup>9</sup>

### Conclusion

The present study concluded that the outcome following nasal irrigation in all the three treatments was found

statistically significant but between the treatments no statistically significant difference observed. Comparatively 3% hypertonic normal saline followed by diluted 0.5% betadine saline showed better improvement.

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