

## Study Of 3% Hypertonic Saline, Normal Saline and 0.5% Diluted Betadine Saline in the Treatment of Allergic Rhinitis: A Prospective Randomized Comparative Analysis

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### Abstract

**Background:** A collection of symptoms affecting the nose is linked to the diagnosis of allergic rhinitis. The following are some ways to treat allergic rhinitis: antihistamines, decongestants, nasal corticosteroid sprays, leukotriene inhibitors, and allergy injections (immunotherapy). In both contemporary and conventional treatment regimens, nasal irrigation is used. It is commonly known that using regular saline, diluted betadine saline, and hypertonic saline improves mucociliary clearance. Aim of this study was to compare the efficacy of hypertonic saline nasal irrigation over that of normal saline over that of diluted betadine saline nasal irrigation in the treatment of allergic rhinitis.

**Methods:** This prospective randomized comparative study was conducted in Department of Otorhinolaryngology, ANMMCH, Gaya, and Bihar from February 2025 to July 2025. 60 diagnosed cases of allergic rhinitis patients by dividing into three groups and treated with 3% hypertonic saline, normal saline and 0.5% diluted betadine saline. The outcome between pre and post treatment was compared.

**Results:** Among the three groups no statistically significant difference is seen in outcome.

**Conclusion:** There was significant outcome following nasal irrigation, in all the three treatments but no significant differences between the treatments. All three modalities of treatment improve the quality of life.

**Keywords:** Allergic rhinitis, Povidone-iodine, Diagnostic nasal endoscopy.

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### Introduction

The diagnosis of allergic rhinitis is linked to a collection of symptoms that impact the nose. When you breathe in something to which you are allergic, like dust, pollen, or animal dander, you get these symptoms. Nasal corticosteroid sprays, antihistamines, decongestants, leukotriene inhibitors, and allergy injections (immunotherapy) are among the treatments for allergic rhinitis.

Both modern and traditional treatment plans frequently use nasal irrigation. The possible positive physiological benefits of topical saline are the subject of numerous theories. There have been suggestions for improved mucus clearance, increased ciliary beat activity, antigen, biofilm, or inflammatory mediator elimination, and a protective function on the sinonasal mucosa. Povidone-iodine's (PVP-I) microbicidal activity spectrum is wide. No resistance forms, in contrast to local antibiotics and other antiseptic chemicals.

Therefore, in addition to the traditional areas of usage, such hand and skin disinfection, mucosal antiseptics, and wound care, the chemical has beneficial indications, such as cleaning bodily cavities. The use of normal saline, diluted betadine saline, and hypertonic saline has been shown to improve mucociliary clearance. The purpose of this study was to evaluate the effectiveness of diluted betadine saline nasal irrigation, normal saline, and hypertonic saline nasal irrigation in treating allergic rhinitis.

### Material and Methods

The present Prospective randomized comparative study was conducted in the Department of Otorhinolaryngology, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar from February 2025 to July 2025.

All cases of allergic rhinitis in the age group of 15 - 50 years, both sexes, and who had been treated with antibiotics,  $\beta_2$  agonists, antihistaminics, topical steroids and systemic steroids were included in the study, but the treatment was stopped one month prior to the beginning of the study. Patients who were immunocompromised i.e. suffering from diseases like Diabetes and HIV, Patients with polyps and mucocele that obstructs the sinuses and children less than 15 yrs and adults greater than 50yrs were excluded in this study

All those patients who met the inclusion and exclusion criteria and who responded for follow-up are our sample size. During this period, patients who were diagnosed with allergic rhinitis in the age group of 15 - 50 years were selected. They were randomized into three groups. Those who got admitted and those who attending OPD on Mondays and Tuesdays as Group A, on Wednesdays and Thursdays as Group B and on Fridays and Saturdays as Group C. Group A included cases treated with 0.9% normal saline (solution A) irrigation three times a day in both nostrils for a period of 4 weeks and the cases in Group B were treated with 3% hypertonic saline (solution B) irrigation, three times a day in both nostrils for the same period. Group C included

cases treated with 0.5% diluted betadine saline (solution C) irrigation three times a day in both nostrils for a period of 4 weeks.

A proforma was filled which contained the basic details of the patient (name, age, sex, occupation, address) along with a detailed history and clinical examination. Informed consent was taken. A preoperative SNOT-20 questionnaire, X-ray Water's view, AEC and DNE- Lund-Kennedy method was done. These four parameters were reassessed at the end of 1 month following nasal irrigation in all three Groups.

The improvement before and after nasal irrigation in 3 groups through Paired „t“ test and Wilcoxon signed rank test using the parameters – a subjective Snot-20 questionnaire, AEC, Lund-Kennedy Endoscopic scores and the X-ray PNS Water's view. The significance of the difference before and after treatment when compared to 0.9% normal saline, 3% hypertonic saline and 0.5% diluted betadine saline calculated using the Kruskal–Wallis test. Assessment of Tolerance to all three treatments by scoring post irrigation nasal irritation.

**Results**

**Table 1: Age distribution of patients with allergic rhinitis**

Diagnosis		Group			Total
		0.5%	0.9%	3%	
Allergic rhinitis	Age in years				
	15-20	3 15.0%	4 20.0%	2 10.0%	9(15.0%)
	21-30	6 30.0%	6 30.0%	5 25.0%	17(28.3%)
	31-40	7 35.0%	5 25.0%	7 35.0%	19(31.7%)
	41-50	4 20.0%	5 25.0%	6 30.0%	15(25.0%)
	Total	20(100.0%)	20(100.0%)	20(100.0%)	60(100.0%)

In case of AR 9 (15%) were in the age group between 15-20years, 17(28.3%) were between 21-30yrs, 19(31.7%) were in between 31-40yrs and 15(25%) were in the age group of 41-50 yrs.

**Table 2: Sex distribution in AR cases**

Gender	Group			Total
	0.5%	0.9%	3%	
Female	9 45.0%	10 50.0%	14 70.0%	33 55.0%
	11 55.0%	10 50.0%	6 30.0%	27 45.0%
Total	20(100.0%)	20(100.0%)	20(100.0%)	60(100.0%)

**Table 3: Complaints of sample population**

	Group			Total
	0.5%	0.9%	3%	
Recurrent sneezing	9	6	8	23
Nasal obstruction	6	4	4	14
Nasal discharge	5	7	2	14
Headache	4	3	3	10

Of the 60 individuals, Recurrent sneezing (23 patients) in case of AR.

**Table 4: AEC: Mean values with SD and 'p' values**

Group	No.	Mean	Std. Deviation	Mean Difference	SD of diff	t-value	p-value		
0.5%	PRE	20	704.30	159.477	177.400	108.516	7.311	.00	HS
	POS	20	526.90	165.113					
0.9%	PRE	20	696.80	160.737	140.400	65.040	9.654	.00	HS
	POS	20	556.40	153.914					
3%	PRE	20	672.35	107.827	184.750	82.770	9.982	.00	HS
	POS	20	487.60	122.474					

**Table 5: AEC: Kruskal wallis test**

Group	No.	Mean difference	SD of difference	Kruskal wallis test value	p	
0.5%	20	177.400	108.516	3.269	0.195	NS
0.9%	20	140.400	65.040	2.692	0.260	NS
3%	20	184.750	82.770	0.569	0.752	NS

The parameter AEC is considered to assess the outcome of treatment in patients with AR cases. Group A (treated with 0.9% normal saline), pretreatment mean is 696.8 and post treatment mean is 556.4 with SD 153.914 post treatment. Paired 't' test done to analyse pre and post treatment AEC showed t value of 9.654 with 'p' value of 0.000 which is statistically highly significant. Group B (treated with 3% hypertonic saline), pretreatment mean is 672.35 and post treatment mean is 487.6 with SD 122.47 post treatment. Paired 't' test done to analyse pre and

post treatment AEC showed t value of 9.982 with 'p' value of 0.000 which is statistically highly significant. Group C (treated with 0.5% diluted Betadine saline), pretreatment mean is 704.3 and post treatment mean is 526.9 with SD 165.113 post treatment. Paired 't' test done to analyse pre and post treatment AEC showed t value of 7.311 with 'p' value of 0.000 which is statistically highly significant. Kruskal Wallis Test is done to compare the outcome with 3 treatments in case of AR showed value of 2.692 with 'p' value 0.260 which is statistically not significant.

**Table 6: DNE Lund kennedy score: Mean values with sd and p values**

Group	No.	Mean	Std. Deviation	Wilcoxon signed rank test p value		
0.5%	PRE	20	6.25	1.118	0.00	HS
	POS	20	1.65	1.387		
0.9%	PRE	20	7.05	0.945	0.00	HS
	POS	20	1.95	1.234		
3%	PRE	20	6.25	1.118	0.00	HS
	POS	20	2.35	1.226		

**Table 7: DNE-Lund kennedy score: Kruskal wallis test**

Group	No.	Mean	Std. Deviation	Kruskal wallis test p value		
PRE	0.5%	20	6.25	1.118	0.00	HS
	0.9%	20	7.05	0.945		
	3%	20	6.25	1.118		
POS	0.5%	20	1.65	1.387	0.514	NS
	0.9%	20	1.95	1.234		
	3%	20	2.35	1.226		

**Table 8: Ray PNS water' view berg et al scoring: Mean values with SD and 'p' values**

Group		No.	Mean	Std. Deviation	Wilcoxon signed rank test p value	
0.5%	PRE	20	1.40	0.821	0.039	Sig
	POS	20	1.00	0.00		
0.9%	PRE	20	2.30	1.261	0.001	HS
	POS	20	1.10	0.447		
3%	PRE	20	1.85	1.089	0.012	Sig
	POS	20	1.20	0.410		

**Table 9: Ray PNS: Kruskal wallis test**

Group		No.	Mean	Std. Deviation	Kruskal wallis test p value	
Pre	0.5%	20	1.40	0.821	0.581	NS
	0.9%	20	2.30	1.261		
	3%	20	1.85	1.089		
Post	0.5%	20	1.00	0.00	0.381	NS
	0.9%	20	1.10	0.447		
	3%	20	1.20	0.410		

Kruskal Wallis Test is done to compare the outcome with 3 treatments in case of AR showed value of 0.381 which is statistically not significant.

**Table 10: Snot 20 Analysis: Mean values with SD and 'p' values**

Group		No.	Mean	Std. Deviation	Mean Difference	SD of Difference	t-value	p	
0.5%	PRE	20	70.40	6.916	46.350	9.086	22.814	0.00	HS
	POS	20	24.05	6.304					
0.9%	PRE	20	70.40	6.916	46.700	8.670	24.089	0.00	HS
	POS	20	23.70	6.027					
3%	PRE	20	82.10	13.038	56.050	13.149	19.064	0.00	HS
	POS	20	26.05	6.493					

**Table 11: Snot 20: Kruskal wallis test with post hoc analysis**

Group	No.	Mean Difference	SD of Difference	Kruskal Wallis test value	p	
0.5%	20	46.350	9.086	10.784	0.005	HS
0.9%	20	46.700	8.670			HS
3%	20	56.050	13.149			HS
Post Hoc Analysis						
Parameter	Diagnosis		Group	Mann whitney test p value		
Snot-20	Allergic Rhinitis		0.5%-0.9%	0.901		NS
			0.5%-3%	0.010		SIG
			0.9%-3%	0.012		SIG

Group A (treated with 0.9% normal saline), pretreatment mean is 70.40 and post treatment mean is 23.70 with SD 6.027 post treatment. Paired 't' test done to analyse pre and post treatment showed value of 24.08 with 'p' value of 0.000 which is statistically highly significant.

Group B (treated with 3% hypertonic saline), pretreatment mean is 82.10 and post treatment mean is 26.05 with SD 6.49 post treatment. Paired 't' test done to analyse pre and post treatment showed value of 19.064 with 'p' value of 0.000 which is statistically highly significant. Group C

(treated with 0.5% diluted Betadine saline), pretreatment mean is 70.40 and post treatment mean is 24.05 with SD 6.304 post treatment. Paired 't' test done to analyse pre and post treatment showed value of 22.81 with 'p' value of 0.000 which is statistically highly significant.

Kruskal Wallis Test is done to compare the outcome with 3 treatments in case of AR showed value of 10.784 with p value 0.005 which is statistically highly significant. Post hoc analysis in case of AR showed 0.5% diluted betadine and 0.9% saline is better than 3% hypertonic saline.

**Table 12: Analysis of post irrigation nasal irritation**

	Group			Total
	0.5%	0.9%	3%	
0	8(40%)	12(60%)	10(50%)	30(50%)
1	2(10%)	6(30%)	7(35%)	15(25%)
2	5(25%)	2(10%)	2(10%)	9(15%)
3	2(10%)	0(0%)	1(5%)	3(5%)
4	3(15%)	0(0%)	0(0%)	3(5%)
Total	20(100%)	20(100%)	20(100%)	60(100%)

In case of AR irritation in Group A 12(60%) told never (0) and none told always, Group B 10(50%) told never, 7(35%) told almost never and 1 told almost always. Group C 8(40%) told never 2(10%) said almost always and 3(15%) said always.

### Discussion

One diagnosis linked to a collection of symptoms affecting the nose is allergic rhinitis. Inhaling allergens like dust, pollen, or animal dander causes these symptoms. Allergy shots (immunotherapy), nasal corticosteroid sprays, antihistamines, decongestants, and leukotriene inhibitors are among the treatments for allergic rhinitis.[1, 2, 3]

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. The microbicidal action spectrum of povidone-iodine (PVP-I) is broad. Unlike local antibiotics and other antiseptic substances, no resistance develops. Hence alongside the classical fields of application, such as the disinfection of the skin and hands, mucosal antiseptics and wound treatment, there are also useful indications for the substance, i.e. rinsing of body cavities. Improvement in mucociliary clearance is well documented, with the use of normal saline, diluted betadine saline as well as hypertonic saline. This study was designed to compare the efficacy of hypertonic saline nasal douching over that of normal saline over that of diluted betadine saline nasal douching in the treatment of allergic rhinitis.

A hypothesis generating study done by Rabago D et al. using in-depth long interviews of 28 participants in a prior qualitative nasal irrigation study. All participants were receiving daily nasal irrigation. Transcripts of interviews were systematically examined. Twelve of 21 subjects with allergic rhinitis spontaneously reported that HSNI improved symptoms. Two of 7 subjects with asthma and 1 of 2 subjects with nasal polyposis reported a positive association between HSNI use and asthma or nasal polyposis symptoms. Transcript content was organized into themes that included: (1) HSNI resulted in improvement of

allergic rhinitis and asthma symptoms, and (2) HSNI should be used for symptoms of allergic rhinitis.[5] In our study also there was a significant difference following post nasal irrigation in all 3 groups including the hypertonic saline in AR cases, but no significant difference among the 3 treatments.

A study done by J H Kim et al.[6] investigated the effect of Betadine on ciliated human respiratory epithelial cells. Epithelial cells from human sinonasal mucosa were cultured at the air-liquid interface. The cultures were tested with Hanks' balanced salt solution containing 10 mM HEPES (control), 100  $\mu$ M ATP (positive control), 5 per cent Betadine or 10 per cent Betadine (clinical dose). Ciliary beat frequency was analyzed using a high-speed camera on a computer imaging system. Undiluted 10 per cent Betadine (n = 6) decreased the proportion of actively beating cilia over 1 minute (p < 0.01). Ciliary beat frequency decreased from  $11.15 \pm 4.64$  Hz to no detectable activity. The result was similar with 5 per cent Betadine (n = 7), with no significant difference compared with the 10 per cent solution findings. In conclusion betadine, at either 5 or 10 per cent, was ciliotoxic.[6] In our study we used 0.5% diluted betadine saline which poses significantly lesser risk to ciliary motility but encompasses its antibiotic property and following the study it is concluded that diluted betadine solution is significantly better than 3% and equivalent to 0.9% saline.

A study done by Reimer K et al.[4] is a study with 10 genotypically different MRSA isolates showed an optimum bactericidal effect. Since recent results are now also available on the toxicological safety of PVP-I preparations for the ciliated epithelium of the nasal mucosa and the good tolerability on skin and other mucous membranes is a known factor, a controlled clinical study is currently being carried out to eliminate colonizations of MRSA. Evidence has also recently been produced of the antiviral activity of PVP-I (povidine iodine) against herpes simplex, adeno and enteroviruses, as well as its high degree of efficiency against Chlamydia. Hence alongside the classical fields of application, such as the disinfection of the skin and hands, mucosa antiseptics and wound treatment, there are also useful indications for the substance, i.e. rinsing

of body cavities and joints and application to the eye.[4]

### Conclusion

Thus there was significant outcome following nasal irrigation, in all the three treatments but no significant differences between the treatments. All three modalities of treatment improve the quality of life.

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