Comparative study of 3% hypertonic saline, Normal saline and 0.5% diluted betadine saline in the treatment of allergic rhinitis

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Abstract

Introduction: Allergic rhinitis is a diagnosis associated with a group of symptoms affecting the nose. Treatments for allergic rhinitis include: Nasal corticosteroid sprays, antihistamines, decongestants, Leukotriene inhibitors, allergy shots (immunotherapy). Nasal irrigation is common to both modern and traditional therapy regimes. 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 irrigation over that of normal saline over that of diluted betadine saline nasal irrigation in the treatment of allergic rhinitis.

Materials and Methods: Prospective randomized comparative study was done on 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.

Introduction

Allergic rhinitis is a diagnosis associated with a group of symptoms affecting the nose. These symptoms occur when you breathe in something you are allergic to, such as dust, animal dander, or pollen. Treatments for allergic rhinitis include: Nasal corticosteroid sprays, antihistamines, decongestants, Leukotriene inhibitors, allergy shots (immunotherapy).

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 antisepsis 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 irrigation over that of normal saline over that of diluted betadine saline nasal irrigation in the treatment of allergic rhinitis.

Aims and Objectives

1. This study is directed towards finding efficacy of 3% hypertonic saline, normal saline and diluted betadine saline (0.5%) in the treatment of allergic rhinitis using pre and post treatment AEC, Diagnostic nasal endoscopy, radiological scores of X-ray of paranasal sinuses (Water's view).
2. To assess the tolerance to normal saline, 3% hypertonic saline and 0.5% diluted betadine saline nasal irrigation with respect to scores given after querying the patients.
3. To know the impact of normal saline, hypertonic saline and diluted betadine saline nasal irrigation on the "quality of life" using sinonasal outcome test (SNOT-20).

Materials and Methods

The present study was conducted in the Department of Otorhinolaryngology, A.J. Institute of Medical sciences, Mangalore. The study was approved by A. J. Institute of Medical science, Institutional Ethics Committee for Human Subjects Research.

Study Design

Prospective randomized comparative study.

Selection of participants: This is a study of all cases of allergic rhinitis attending the Department of E.N.T (In Patients and Out Patients) to all the units from 1st January 2016 to 31st march 2017 in A.J.Institute of Medical Science and Research Centre, Mangalore. 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.

Inclusion Criteria

1. All cases of allergic rhinitis in the age group of 15 - 50 years were included.
2. Both sexes were included.
3. Patients who had been treated with antibiotics, β2 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.

Allergic rhinitis was diagnosed by:

A. CHARECTERISTIC SYMPTOMS

1. Rhinorrhea
2. Itching
3. Sneezing
4. Redness of eyes, swelling
5. Nasal obstruction and congestion

B. Absolute Eosinophil Count

Exclusion Criteria

1. Patients who were immunocompromised i.e. suffering from diseases like Diabetes and HIV.
2. Patients with polyps and mucocele that obstructs the sinuses.
3. All children less than 15yrs and adults greater than 50yrs.

Methods used to assess the outcome

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.

SNOT-20 questionnaire

included 20 items that affected the patient‟s health including need to blow nose, sneezing, runny nose, cough, postnasal discharge, thick nasal discharge, ear fullness, dizziness, ear pain, facial pain/pressure, difficulty falling asleep, wake up at night, lack of a good night‟s sleep, wake up tired, fatigue, reduced productivity, reduced concentration, frustrated/restless/irritable, sad & embarrassed.

Patient rates the severity of their condition on each of the 20 items using a 0-5

Category rating system:

1. Not present/no problem
2. Very mild problem
3. Mild or slight problem
4. Moderate problem
5. Severe problem
6. Problem as “bad as it can be”

X-ray paranasal sinuses water’s View

Post treatment x-ray of the paranasal sinuses (Water ‟s view) was taken at the end of 4 to 6 weeks and compared with the pretreatment xray. The pre and post treatment x-rays were graded according to Berg *et al.* (1981) (Table 1), by a consultant who was blinded about the mode of treatment for each side of the sinus, and change in grading was recorded. Radiological scores were given accordingly as mentioned below.

Table 1: Radiological grading of X-ray paranasal sinuses according to Berg et al.

Grade	Radiological Finding	Radiological Score
I	No mucosal hypertrophy	1
II	Mucosal thickening of <0.5 cm but no fluid level	2
III	Mucosal thickness >0.5 cm but no fluid Level	3
IV	Attenuating tissue or fluid Occupying sinuses or fluid level	4

AEC (Absolute Eosinophil Count)

Done in all patients with allergic rhinitis pretreatment and post-treatment. 50 to 450 cells/microliter of blood are considered normal.

Lund-Kennedy scoring system

based on Nasal Endoscopic evaluation. Endoscopic staging was performed bilaterally during the pretreatment, and post treatment at 1 month. Polyps are graded as absent (0), present in the middle meatus (1), or present beyond the middle meatus (2). Discharge is graded as not resent (0), thin (1), or thick and purulent (2). Edema, scarring, and crusting are each graded as absent (0), mild (1), or severe (2).

Study Procedure

After getting clearance from the Institutional Ethics Committee, the patients were selected as per the inclusion and exclusion criteria. They all were given the written informed consent, which were signed. Detailed evaluation were done including general examination, systemic examination and ENT examination. Pre nasal irrigation AEC, x-ray PNS Water’s view, DNE were done. All of them were asked to fill a SNOT-20 questionnaire and grade their symptoms. Patients in all three groups were given a detailed class on method of doing saline nasal irrigation.

Step 1: Gather the Supplies

1. 10cc plastic syringe was given to all
2. Plastic cannula
3. A container
4. Commercially available 0.9% normal saline (for Group A)
5. Commercially available 3% hypertonic saline (for Group B)
6. Preparation of 0.5% diluted betadine saline: add 25ml of 10% betadine solution in 500ml normal saline (for Group C),
7. Using the formula (Initial conc.)(Initial volume) = (Final conc.)(Final volume)

Step 2: Procedure of Nasal Irrigtion

1. Lean over the sink; tilt the head to one side.
2. Insert the cannula into uppermost nostril
3. Breathe through your mouth
4. Push the handle of the syringe so that the solution flows into the upper nostril.
5. In few moments, the solution will begin to drain from the lower nostril.
6. Continue until the syringe is empty, then exhale gently through both Nostril
7. Gently blow the nose
8. Refill the syringe, turn the head to the opposite side and repeat with the other nostril.
9. To do daily 3 times for 4weeks.

Step 3: Clean the Equipment

1. Wash the syringe and the cannula daily with warm water and detergent; rince thoroughly.
2. Store unused saline solution in the sealed container; it can be kept at room temperature and reused for 5 days.

Same SNOT-20 questionnaire was asked to fill at the end of 4weeks to assess quality of life. The collected data underwent statistical analysis.

Statistical Analysis

The following parameters were assessed:

1. Age and Sex distribution of patients with AR.
2. 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.
3. 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.
4. Assessment of Tolerance to all three treatments by scoring post irrigation nasal irritation.

Results

Table 2: Age distribution of patients with allergic rhinitis

Diagnosis		Group			Total
		0.5%	0.9%	3%	
Allergic rhinits	Age				
	15-20	3	4	2	9 (15.0)%
		15.0%	20.0%	10.0%	
	21-30	6	6	5	17(28.3%)
		30.0%	30.0%	25.0%	
	31-40	7	5	7	19 (31.7%)
		35.0%	25.0%	35.0%	
	41-50	4	5	6	15(25.0%)
		20.0%	25.0%	30.0%	
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 3: Sex distribution in AR cases.

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

Among 60 AR patients 33(55%) were females and 27(45%) were males.

Table 4: 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 5: AEC: Mean values with sd and 'p' values

		N	Mean	Std. Deviation	Mean Difference	SD of diff	t value	p	
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 6: AEC: Kruskal wallis test.

Group	N	Mean difference	S.D 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 7: DNE Lund kennedy score: Mean values with sd and p values

Group		N	Mean	Std Deviation	Wilcoxoxn 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 8: DNE-Lund kennedy score: Kruskal wallis test

Group		N	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		

Kruskal Wallis Test is done to compare the outcome with 3 treatments in case of AR showed value of 0.0514 which is statistically not significant.

Table 9: Ray PNS water' view berg et al scoring: Mean values with SD and 'p' values

Group		N	Mean	Std. Deviation	Wilcoxon signed rank test pvalue	
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 10: Ray PNS: Kruskal wallis test

Group		N	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 11: Snot 20 Analysis: Mean values with SD and 'p" values

Group		N	Mean	Std. Deviation	Mean Difference	S.D 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					

Table12: Snot 20: Kruskal wallis test with post hoc analysis

Group	N	Mean Difference	S.D of Difference	Kruskal Wallis test value	p	
o.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	Mannwhitne y 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 19.064with '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 13: 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

Allergic rhinitis is a diagnosis associated with a group of symptoms affecting the nose. These symptoms occur when you breathe in something you are allergic to, such as dust, animal dander, or pollen. Treatments for allergic rhinitis include: Nasal corticosteroid sprays, antihistamines, decongestants, Leukotriene inhibitors, allergy shots (immunotherapy).[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 antisepsis 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. The present study was conducted at A. J. Institute of Medical Science, Mangalore and was taken up to assess the efficacy of 3% hypertonic saline, 0.9% normal saline and 0.5% diluted betadine saline irrigation in the treatment of allergic rhinitis. 60 individuals who were diagnosed with allergic rhinitis divided into three groups and treated accordinglyand assessed using subjective and objective parameters i.e. AEC, SNOT-20questionnaire, Lund-Kennedy endoscopic scores and X-ray PNS Water's view.These parameters were assessed preirrigation and post irrigation at the 1 month follow up.

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 ystematically 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 signicant 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 μM 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 ± 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 motily 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 antisepsis 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

The study was aimed to find out the efficacy of 3% hypertonic saline, 0.9% normal saline and 0.5% diluted betadine saline irrigation in the treatment of allergic rhinitis.: 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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Conflicts of Interest: None.

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