Main Article

Study to Assess the Efficacy of Different Concentration of Nasal Douching on Symptoms and Mucociliary Clearance in Persistent Allergic Rhinitis

https://doi.org/10.47210/bjohns.2022.v30i2.680

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ABSTRACT

Introduction

Allergic rhinitis (AR) is acknowledged as a significant health challenge on a global scale affecting 08 – 39.7% of total population. The management of Allergic rhinitis encompasses patient education on avoidance of allergens as well as the use of pharmacotherapy and allergen- specific immunotherapy. Avoidance of allergen may not be practically applicable always and the pharmacological treatment has side effects on long term use. Hence an alternate treatment modality is required to alleviate the symptom for long duration with less side effects.

Materials and Methods

We conducted a randomized double blinded prospective study on 75 patients with allergic rhinitis. They were randomized into 3 groups, 1st group using isotonic saline irrigation, 2nd group using hypertonic nasal irrigation and 3rd group as control. The evaluation was done using SNOT22 score and nasal mucociliary clearance time.

Results

Isotonic Saline Nasal Irrigation was found to reduce overall symptoms better than Hypertonic Saline Nasal Irrigation group. Nasal douching also improved Nasal Mucociliary Clearance. Isotonic Saline Nasal Irrigation restored Mucociliary Clearance better than Hypertonic Saline Nasal Irrigation. Compliance to treatment was found to be good for short term.

Conclusion

Nasal irrigation along with other medications definitely had better outcome in symptom control in patients with AR. However studies to know the effect of nasal douching in AR for longer duration are needed.

Keywords

Rhinitis, Allergic; Nasal Douching; Normal Saline; Hypertropic Saline; Mucociliary Clearance; Nasal

Allergic rhinitis (AR) is acknowledged as a significant health challenge on a global scale affecting 08 – 39.7% of total population, which can significantly impair quality of life and lead to a number of indirect costs.[1] It is a most prevalent chronic non-communicable health problem. The incidence is increasing due to industrialization and urbanization.[2] The prevalence of seasonal AR (SAR) is 10% of normal population and of perennial AR is 10-20%.[3] AR impairs Quality of life, sleep and causes daytime fatigue.[4]

The management of AR encompasses patient education on avoidance of allergens as well as the use of pharmacotherapy and allergen-specific immunotherapy. Avoidance of allergen may not be practically applicable always. The main stay of pharmacotherapy is administration of intranasal corticosteroids spray, oral/

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nasal antihistamines, decongestants and leukotriene receptor modifiers. A pronounced fear of cortisone affecting the growth in children on long term use and its effect on intraocular pressure exists among patients and prescribing physicians. The other medications used have their adverse effects on chronic usage and causes financial burden.[5]

In light of this, non-pharmacologic therapy approaches are of great importance. One such approach is nasal irrigation using saline solutions, which is recommended as complimentary treatment of AR by several international guidelines.[6]

Flushing the nasal cavity using saline solution is called nasal irrigation or nasal douching. The practice of nasal irrigation likely originated in the Ayurvedic medical tradition in which it is known as "jalaneti". It can be done with a special type of douching bottle, nasipot or even with a 20cc syringe. It was also used at the University of California, San Diego[7]. Nasal irrigation using physiological ("normal", 0.9%) saline or slightly concentrated saline (2-3%) can be used as a rinse of the nasal cavity.[8]

The mechanism of saline irrigation is not fully known, but commonly proposed are mechanical clearance of stickymucous, removal of airborne allergens and the inflammatory mediators, thus reducing the subsequent inflammatory cascade of AR.[9] And it mproves the mucociliary clearance physiologically by propelling the superficial gel layer and hydrating the sollayer.[10]

Theoretically and in-vitro, isotonic saline should maintain the normal physiology of nasal mucosa and the mucociliary clearance. The hypertonic solution due to its higher osmotic pressure should reduce the nasal mucosal edema and remove airborne allergens effectively.[11]

However in-vivo, the optimal concentration of saline solution for irrigation remains unclear. Hence we conducted this randomized controlled trial in our department to assess the effect of different concentration of saline douching on alleviating the symptoms of AR and its effect on nasal mucociliary clearance in same patients.

Materials and Methods

A Prospective Randomized Double Blinded Control study of 75 patients with symptoms of persistent allergic rhinitis attending our ENT OPD was conducted.

Seventy five subjects with symptoms of allergic rhinitis were considered for the study. The study population was between 15 to 55 years of age, of either gender.

All subjects having persistent Allergic rhinitis with all four cardinal signs of AR, ie nasal obstruction, nasal discharge, sneezing and itching were considered in the study.

Subjects with other nasal pathology like nasal polyposis, gross impacted DNS, septal perforation, repeated episodes of epistaxis, recent sinonasal surgery and cystic fibrosis were excluded from the study. Hypertensive, pregnant and lactating women and subjects taking other treatment for AR like immunotherapy were also excluded from the study.

All subjects were explained about the study in detail and included in the study after written informed consent was obtained by all, as per Helsinki declaration. Patients were Randomized into 3 groups by simple random table method. All patients were prescribed intranasal corticosteroids and oral antihistamines. Along with it,Group A patients used Isotonic saline nasal irrigation (ISNI)/ Normal saline nasal irrigation and Group B patients used Hypertonic saline nasal irrigation (HSNI) as adjuvant. Group C patients were control group, who were not advised any irrigation.

A preformed questionnaire based on SNOT- 22 were given to all subjects at beginning of the study and Total Symptom Score (TSS) was recorded. The Nasal Mucociliary clearance (NMC) time was assessed by using Saccharine test time (STT) and documented.

Nasal irrigation with 250 ml of Isotonic saline solution was advised twice daily for group A patients using nasal douching bottle. Similarly group B patients were advised irrigation with commercially available 3% hypertonic saline solution.

All subjects were assessed weekly for 8 weeks. The

Total symptom score, nasal mucociliary clearance time and four main symptoms of AR, Nasal discharge , nasal obstruction , sneezing and Itching scores were recorded at 4th and 8th week.

Descriptive and inferential statistical analysis was carried out. One- way ANOVA test is used to compare the means between the groups. Chi-square / Fisher Exact test has been used to find the significance of study parameters on categorical scale between the groups. Statistical software SPSS22.0 and R environment ver.3.2.2 were used.

Results

Of the 75 patients involved in our study the 10 patients were lost for followup, bring the total count to 65. The age distribution of patients in the study was as mentioned in the Table I.

Table I: Age in years- Frequency distribution in three groups of patients studied

AGE IN YEARS	GROUP A	GROUP B	GROUP C	TOTAL
< 30	12 (54.5%)	7 (36.8%)	13 (54.2%)	32 (49.2%)
30-40	8 (36.4%)	11(57.9%)	7 (29.2%)	26 (40%)
> 40	2 (9.1%)	1 (5.3%)	4 (16.7%)	7 (10.8%)
Total	22 (100%)	19 (100%)	24 (100%)	65 (100%)
Mean ± SD	29.36 ± 7.96	31.31 ± 7.12	29.91 ± 9.01	30.13 ± 8.05

There were 31 female and 34 male patients enrolled into 3 groups in the study. The TSS was compared among the 3 groups using ANNOVA test. There was no significant difference between the groups at the beginning of the study. At 4th and 8th week there was statistically significant difference between the groups as shown in table II.

Table II: Comparison of TSS in three groups of patients studied

TOTAL SYMPTOMS SCORE	GROUP A	GROUP B	GROUP C	TOTAL	P VALUE
Before treatment	66.64 ± 7.29	67.05 ± 5.99	66.96 ± 4.34	66.88 ± 5.86	0.972
4th week of treatment	19.32 ± 2.57	20.05 ± 2.22	23.83 ± 3.02	21.2 ± 3.32	<0.001**
8th week of treatment	17.05 ± 3.76	20.11 ± 3.21	21.96 ± 2.58	19.75 ± 3.78	<0.001**

Table III: comparison of STT in three groups of patients studied

SACCHARINE TEST TIME	GROUP A	GROUP B	GROUP C	TOTAL	P VALUE
Before treatment	18.57±3.49	18.05±3.65	17.54±3.46	18.04±3.5	0.613
4th week of treatment	12.32±1.86	13.89±2.48	15.93±2.61	14.11±2.77	<0.001**
8th week of treatment	12.37±1.98	14.96±2.38	15.22±2.48	14.18±2.61	<0.001**

The NMC was measured by Saccharine test among the groups. The mean NMC time at the beginning of the study in all groups was 18.04 + 3.5 minutes. At 4th and 8th week the STT decreased significantly in group A and group B as in Table III.

Comparision of the individual scores of the 4 cardinal symptoms of AR, nasal obstruction score, nasal discharge score, sneezing score and itching scores in the groups at beginning, 4th and 8th week of treatment was done using Chi-square / Fisher Exact tests.

Nasal obstruction score was comparable between the groups before the start of treatment. At 4 weeks the score was considerabley reduced in group B compared to other 2 groups. At 8th week NO score was significantly better in group B compared to group A and C. the scores in group A ranged from 0-3, group B 0-2, group C 2-3 indicating HSNI reduced nasal obstruction better than NSNI and no irrigation.

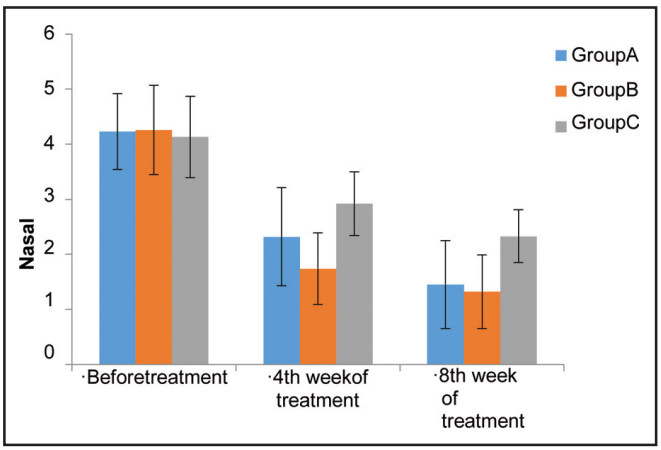

Fig. 1. Comparison of nasal obstruction score between the three groups.

Nasal discharge score was better reduced in group A than the other two groups. At 8th week, score in Group A ranged between 0-2, group B 1-3 and in group C 2-4. NSNI had reduced Nasal discharge better than HSNI and no irrigation group.

When sneezing was compared at 4th and 8th week, it was reduced in group A using NSNI than group B and C. Though the score range in all group was from 0-3, 72.7% had scores of 0-1 in group A, 52.6% had it in the

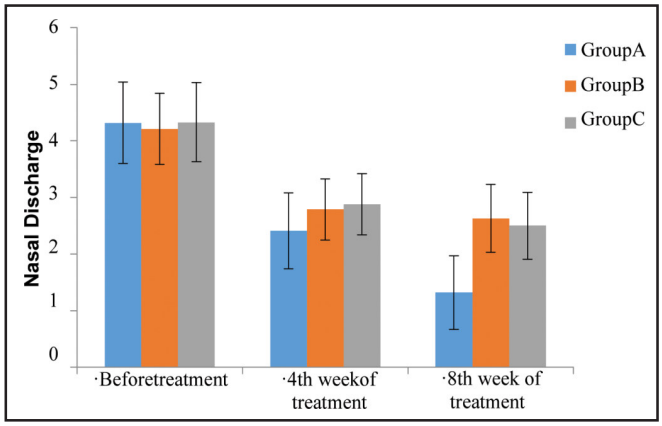

Fig. 2. Comparison of nasal dischargescore between the three groups.

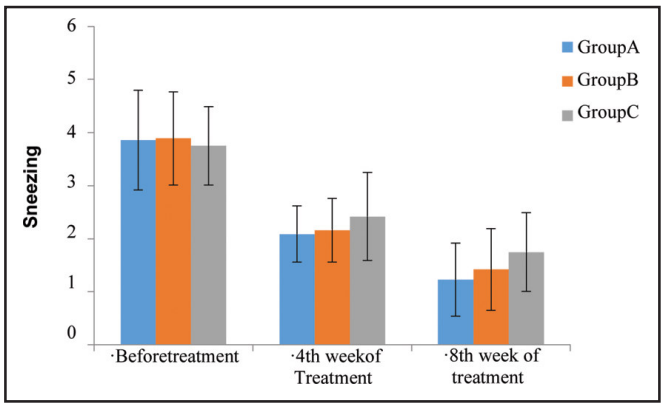

Fig. 3. Comparison of sneezing score between the three groups.

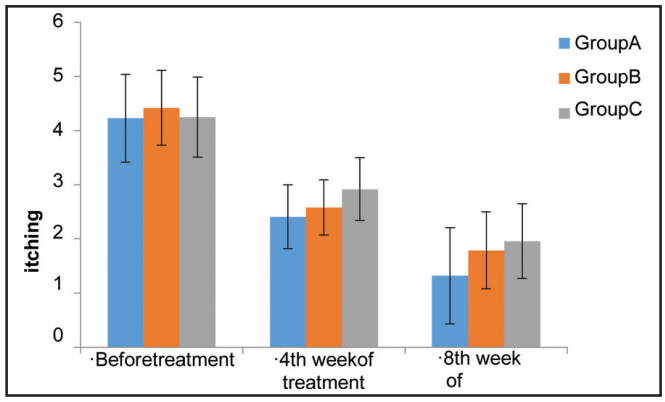

Fig. 4. Comparison of nasal itching score between the three groups.

range of 0-1, and only 41.7% in group C ranged between 0-1.

The last symptom which was compared was itching. The score varied from 0-3 in all groups, but 11 patients had scores 0-1 in group A, only 5 patients had scores of 0-1 in group B and 6 patients had scores of 1 as least score in group C.

Some patients were lost to followup in all groups, more in group B with 6 patients. Adverse effects, like local discomfort and ear block sensation was seen in some patients in group A and group B. Few patients in group B complained of burning sensation in nose after HSNI, 2 patients discontinued the HSNI after experiencing severe burning sensation in nose. Epistaxis was noted in 1 patient in group B, but was controlled by nasal pinching and botroclot nasal drops. There was no need for nasal packing in the patient.

Discussion

AR is an important disease with large burden worldwide and needs multistage and multimodal treatment approach. In our study, patients from Group A and Group B showed more improvement in their symptoms than group C patients. The TSS in group A reduced from 66.64+7.29 to 17.05+3.76, in group B from 67.05+5.99 to 20.11+ 3.21 and in group C from 66.96+ 4.34 to 21.96+ 2.58. There was statistically significant *p value* when the TSS scores were compared between the groups. This proves that nasal irrigation definitely aids in reducing the symptoms when used along with other medications. Our study was in accordance with study conducted by Dr Rajiv kumar and et al, which showed statistically significant improvement with nasal irrigation as an adjuvant to pharmacotherapyin AR patients.

A systemic review and meta analysis done by Kristina E and group concluded that nasal irrigation reduced the symptoms by 27.66% and medicine consumption was decreased by 2.99%.[5]

A review study done by Head K and et al comprising of 14 studies also mentioned saline irrigation improved patient reported disease severity compared to no saline irrigation at up to four weeks but with low quality evidence.[6]

Garavello et al compared nasal irrigation group and no irrigation in children with AR which showed 3% reduction in rhinitis score and 100% reduction in medicine consumption. Our study showed similar results with considerable reduction of symptoms in group A and group B respectively when compared with group C with no nasal irrigation.[12]

When the TSS in group A and group B was compared in our study there was a difference of 3.06 in the TSS, suggesting NSNI had better effect in reducing the symptoms than HSNI. When individual symptoms were compared NSNI was more effective than HSNI in reducing nasal discharge and sneezing. Nasal obstruction was reduced more effectively in group B patients using HSNI than NSNI and no irrigation groups. When itching score was compared among the groups, there was no significant difference between the groups.

However Chia-Ling and team found HSNI reduced symptoms of AR better than NSNI in their review study.[13]

Nasal mucocilaiary clearance is affected in AR, which predisposes to rhinosinusitis as studied by Vlastos and team.[14] In our study we found statistically significant difference between the 3 groups. The mean STT before treatment was 18.04+3.5, this was reduced to 12.37+ 1.98 in group A, 14.96+ 2.38 in group B and to 15.22+ 2.48 in group C. Nasal irrigation restores the impaired mucociliary clearance, this was also observed by Ural and team in their study of impact of isotonic and hypertonic saline solutions on MCC activity in various nasal pathologies.

NSNI was found to be more effective than HSNI in our study. Ural and team also found NSNI to be more effective in restoring MCC in AR patients.[15] However review article by Lei Liu concluded that HSNI significantly improved MCC than NSNI.

Compliance for nasal irrigation was found to be good in our study for 8 weeks. Keeri et al reported 95% of their patients found nasal irrigation easy and simple method and 84.7%were comfortable with irrigation.[16]

Conclusion

Nasal irrigation along with other medications definitely had better outcome in symptom control in patients with AR. NSNI was found to reduce overall symptoms better than HSNI group. Nasal douching also improved NMC, NSNI restored MCC better than HSNI. Compliance to treatment was found to be good for short term. However studies to know the effect of nasal douching in AR for longer duration are needed.

Acknowledgements

Dr K P Suresh, PhD Biostatistics for the Statistical Analysis Reporting and for reviewing methodology and results.

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