International Journal of Otorhinolaryngology and Head and Neck Surgery
Singh R et al. Int J Otorhinolaryngol Head Neck Surg. 2017 Jan;3(1):104-107
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

Original Research Article

DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20164810

Comparative study of intranasal hypertonic seawater saline versus intranasal normal saline in allergic rhinitis

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Received: 16 October 2016
Accepted: 15 November 2016

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ABSTRACT

Background: Allergic rhinitis (AR) is a chronic disease with variable response to therapy. Nasal irrigation with saline, including hypertonic saline, has been recommended for sinonasal conditions.
Methods: All consecutive patients reporting with AR symptoms established by ARIA at a zonal and tertiary care referral hospital from July 1 to September 30, 2015 were enrolled in the study. Patients were randomly divided into two groups. Patients in Group A were treated with hypertonic seawater saline (HSS) 2.2% Group B with normal saline (NS) 0.9% respectively. Symptoms were assessed at the start of the treatment and after 2 months using 4 point scale. 60 patients were included in final analysis.
Results: The mean total nasal symptoms post treatment when compared to pre-treatment were low in both the groups [2.19 (pre- treatment) vs. 1.03 (post treatment) in Group A and 2.18 (pre-treatment) vs. 1.46 (post treatment) in Group B] and the difference was statistically significant for both groups (P =0.0001). On comparing post-treatment symptom scores between both groups, Group a benefitted more than Group B and it was statistically significant (P =0.002). The difference in individual symptom improvement (except sneezing) post treatment exhibited a statistical significance in Group A. No side-effects were seen with either of the sprays.
Conclusions: In our study, both treatments provided clinically meaningful responses, but the overall result favored HSS. Hence, HSS can be an effective and safe therapy for AR.

Keywords: Allergic rhinitis, Hypertonic seawater saline, Intranasal, Isotonic saline

INTRODUCTION

Allergic rhinitis (AR) is a global health problem that affects quality of life (QOL) and work performance. The direct cost of the treatment and indirect cost due to loss of productivity related to missed days at work is significantly high.[1-4]

Management of AR includes patient education, allergen avoidance, pharmacotherapy and immunotherapy. In patients with moderate to severe AR and nasal congestion as major symptom, intranasal corticosteroids are recommended as first line therapy.[5]

A pronounced fear of adverse effect of long term intranasal steroids exists among patients and prescribing physicians as well.[6] In view of this, saline nasal irrigation has been recommended as complementary treatment of AR.[7] Hypertonic seawater saline (HSS) has recently been identified as important in management of sinonasal

conditions.[8- 11] Aim of our study was to compare efficacy of HSS and NS in alleviating symptoms of AR.

METHODS

The study was performed at a zonal and tertiary care referral hospital. It was a prospective randomized single blinded trial. Between July 1st to September 30, 2015, all consecutive patients aged 18 years and above with established criteria for AR as per allergic rhinitis and its impact on asthma (ARIA) 2010 were enrolled in the study.

Exclusion criteria were pregnancy, lactation, significant psychological problem, smoking, and recent sinonasal surgical intervention. Patients on systemic steroids in previous 30 days for any skin condition, asthma and auto-immune disease were excluded. Use of topical steroids, antihistaminics, decongestants or mast cell stabiliser in previous 2 weeks for allergy or allergic conjunctivitis and Immunotherapy in last 2 years were also excluded from the study.

70 patients met the above criteria .The study population was randomly assigned into two groups of 35 each. Group A was treated with HSS (2.2%, 2 sprays in each nostril 3 times a day) and Group B with NS (0.9%, 2 sprays in each nostril 3 times a day). The procedure of instilling sprays was demonstrated to each patient and the same was repeated by patients in front of clinician to confirm uniformity in technique of drug administration.

5 patients of Group A and 3 patients of Group B were lost to follow up during 2 months post treatment. Hence, 30 patients were taken in each group for further statistical evaluation.

At time of presentation, patients were evaluated for four symptoms i.e. sneezing, rhinorrhea, nasal congestion and itching on a 4 point scale as given in Table 1. A mean symptom score was calculated before treatment and compared to the score after 2 months of treatment for statistical significance. Data was entered in MS office excel sheet and analysed using Epi Info 7.0 version for windows. Data was subjected to test of normality using "Shapiro's- Wilk test". Variables were found to be distributed non-normally, hence for further analysis non-parametric tests viz Mann-Whitney U test and Wilcoxon signed rank test were used. P <0.05 was considered statistically significant.

Table 1: 4 point scale for symptom evaluation.

0	**Never**	**No problem**
1	Rarely	Problem present but not disturbing
2	Quite often	Disturbing problem but not hampering any activity or sleep
3	Very often	Problem hampering some activities or sleep

RESULTS

Baseline characteristics of patients in the two groups are described in Table 2. Sneezing and rhinorrhoea were the most disturbing symptoms in both groups.

Table 2: Baseline characteristics of patients in the two groups.

Variables	Group A	Group B
Number of patients	30	30
Male/Female	16/14	15/15
Mean age (in years)	35.5	32.5

On evaluation of symptom score before treatment, Group A had a mean score of 2.19 (SD 0.419, SE 0.075) and Group B had a mean score of 2.18 (SD 0.398, SE 0.073). On applying Mann-Whitney U Test, it was observed that there was no statistically significant difference (P =0.974) between the two groups and hence both groups were comparable with near equal symptom profile.

Table 3: Comparison of symptoms before and after treatment in Group A and in Group B using Wilcoxon Signed rank test.

	Symptoms (Post treatment –Pre treatment)	Ranks			P value
		Negative	Positive	Ties	
Group A	Sneezing	23	0	7	0.0001
	Rhinorrhea	25	0	5	0.0001
	Congestion	21	0	9	0.0001
	Itching	16	0	14	0.0001
	Mean	30	0	0	0.0001
Group B	Sneezing	26	0	4	0.0001
	Rhinorrhea	13	0	17	0.001
	Congestion	9	0	21	0.003
	Itching	15	0	15	0.0001
	Mean	30	0	0	0.0001

Negative rank= post treatment symptom < pre-treatment symptom; Positive rank= post treatment symptom > pre-treatment symptom; Ties =post treatment symptom = pre-treatment symptom.

Table 4: Difference in symptom scores between Group A and Group B (pre and post treatment) using Mann Whitney U Test.

	Symptoms	Mean Ranks		Mann Whitney U	P value
		Group A	Group B		
Pre treatment	Sneezing	29.50	31.50	420.000	0.545
	Rhinorrhea	33.27	27.73	367.000	0.150
	Congestion	33.10	27.90	372.000	0.220
	Itching	27.33	33.67	355.000	0.138
	Mean	30.57	30.43	448.000	0.974
Post treatment	Sneezing	27.75	33.25	367.500	0.184
	Rhinorrhea	26.40	34.60	327.000	0.049
	Congestion	25.60	35.40	303.000	0.017
	Itching	25.92	35.08	312.500	0.029
	Mean	29.50	31.50	420.000	0.545

P value <0.05 is significant.

On comparing symptom scores of Group A and B before and after treatment, it was seen that mean scores after treatment for Group A was 1.03 (SD 0.4795, SE 0.0875) and for Group B was 1.46 (SD 0.5581, SE 0.1019). On applying Wilcoxon – Signed rank test, it was observed that the difference in pre and post treatment symptom scores were statistically significant (P value for Group A = 0.0001 and P value for Group B = 0.0001) for both groups as given in Table 3. Hence, both Group A and Group B were benefitted.

We also compared the symptom scores post-treatment between both the groups by applying Mann-Whitney U test and found it to be statistically significant (P =0.002). Patients in Group A showed more improvement than patients in Group B as shown in Table 4.

On evaluation of individual symptoms (sneezing, rhinorrhea, nasal congestion and itching) within the groups, before and after treatment, both groups showed improvement of symptoms after treatment. Post treatment comparison between groups showed symptom improvement among patients received HSS compared to patients who received NS which was statistically significant except for sneezing, P =0.184 as in Table 3 and Table 4.

No adverse events were reported and patient satisfaction and compliance with both HSS and NS was good.

DISCUSSION

AR is IgE mediated inflammatory reaction due to allergen exposure. It contributes to major disease burden because of its prevalence, impact on QOL, impact on work/school performance and productivity, economic burden and associated co-morbidities like asthma and allergic conjunctivitis. Depending on severity of symptoms and QOL outcomes, AR can be classified as ‘mild’ or ‘moderate/ severe’ and depending on this subdivision, a stepwise therapeutic approach is proposed. The treatment of AR combines pharmacotherapy, immunotherapy and education.[12]

AR involves cells, mediators, cytokines, chemokines, neuropeptides and adhesion molecules which cooperate in a complex network to produce the specific symptom of AR and the non-specific hyper reactivity.[13] This results in characteristic symptoms of AR i.e. sneezing, rhinorrhea, nasal congestion and itching.

AR being a chronic problem requires long term medication. Most patients resort to complementary and alternative medicine (CAM) due to fear of side-effects of long term medication. Literature suggests CAM is high in rhinology patients.[14]

Routine use of saline irrigation has been recommended for prevention of symptoms of rhinitis.[7,10,15,16] However, it is to be understood that ‘nasal irrigation’ can have different meanings ranging from nose drop to irrigation with almost 200 millilitres saline. Better clinical outcomes have been seen with 2.2% hypertonic saline.[8-11,17]

Saline has anti-inflammatory action by reducing production and release of Interleukin-8 by respiratory epithelium. It is assumed that mucociliary function improves because of direct clearing up of mucin, crust, debris, allergens and inflammatory mediators.[18] The hypertonicity of seawater saline solution affects pH and may have positive effect on physiology of nasal mucosa. Magnesium being the dominant cation in HSS, extends anti-inflammatory effect on mucosa and immunological response.[19]

Strengths and limitations

Despite the fact that our sample size was fairly small, our findings add to the existing literature and hopefully shows a way to larger randomized double-blinded control trials to confirm our findings.

CONCLUSION

Our study has demonstrated that HSS offers advantage over treatment with NS in regards to symptomatic improvement in AR. Hence, HSS is safe, effective, well-tolerated and simple measure to reduce symptoms of AR. Further multicentric double-blinded randomized controlled trial is required to confirm our findings. However, optimal dose and mode of application of salt solutions need to be clarified.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Singh R, Galagali JR, Kumar S, Bahurupi Y, Chandrachood M. Comparative study of intranasal hypertonic seawater saline versus intranasal normal saline in allergic rhinitis. Int J Otorhinolaryngol Head Neck Surg 2017;3:104-7.