

Research Article

Comparing hypertonic saline and xylometazoline in allergic rhinitis

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ABSTRACT

Background: Allergic rhinitis (AR) affects productivity, quality of life and performance at work. Pharmacological agents are widely used and nasal irrigation using hypertonic saline is underused.

Methods: All consecutive patients presenting at the outpatient clinic with complaints of AR at Santosh Medical College Hospital from August 1, 2014 to August 31, 2015 were included in the study. Patients were randomly assigned to either xylometazoline nasal drops (0.1%, three times a day, brand Otrivin) or hypertonic seawater saline (2.2%, three times a day, brand Physiomer). They were followed for a period of 2 months. Symptom change was assessed at the start of the treatment and at the end using the Nasal Index Score (NIS), which comprised of grading blocked nose, runny nose, sneezing and eye itching on a 4-point severity scale.

Results: 85 patients were included in the final analysis. On the NIS, patients receiving hypertonic nasal drops showed a decrease in mean score by 0.7, 0.5, 0.7 and 0.7 for blocked nose, runny nose, sneezing and eye irritation respectively, all of which were statistically significant. Additionally, more side effects like bloody nasal discharge, respiratory infections and headache were seen with xylometazoline nasal drops.

Conclusion: Our findings suggest that using hypertonic nasal drops can reduce the dependence on pharmacological agents like xylometazoline, improve symptoms and quality of life with fewer adverse reactions.

Keywords: Allergic rhinitis, Hypertonic nasal drops

INTRODUCTION

Allergic rhinitis (AR) is prevalent worldwide and includes two main clinical entities: seasonal and perennial. AR is a multi-dimensional disease and affects the quality of life, productivity and performance at work, thus making treatment imperative. According to some estimates billions of dollars are spent around the globe on treating AR. In a developing country like India, the disease poses serious threats to the general wellbeing of the people, where an increased level of pollution and other allergens is being witnessed. Airway epithelium actively participates in the airway homeostasis through a series of protective mechanisms, including ciliary beating, secretion of mucus and release of inflammatory

mediators in response to deleterious environmental stimuli. Injury of the nasal mucosa by various pathologies or after a procedure results in the reduction of the protective secretion film and damage to the highly sensitive cilia. Moreover, nasal mucociliary clearance, the time taken by a particle to traverse the length of the nasal cavity, is a general measure of sinonasal health and can be measured in various ways in vivo. It has been reported that airway epithelial cells are markedly implicated in the process of inflammatory cell recruitment.²

Management of AR involves patient education, pharmacological medications and non-pharmacological methods. The administration of intranasal glucocorticosteroids is the most effective pharmacologic

treatment in AR. However many patients are reluctant to continue steroids over a long period of time. As a result, majority of patients with AR are left not treated adequately. Nasal irrigation is a simple, inexpensive procedure that has been used to treat not only AR but many other related conditions. Nasal irrigation involves flushing the nasal cavity with saline solution, which promotes mucociliary clearance by moisturizing the nasal cavity and removing encrusted material. This procedure has been reported to be beneficial but the scientific evidence is lacking and through this study we aim to find if this procedure is any better than the standard care provided to such patients.

METHODS

Study design

After obtaining the approval of the Institutional Ethics Committee, all patients who presented in the outpatient clinic, satisfying our eligibility criteria were enrolled for the study. A set of observations was collected at the time of enrolment and then the patients were randomly assigned to either hypertonic nasal saline or xylometazoline nasal drops. Randomization was done by computer software and was not blinded to the treating clinicians. Then these patients were prospectively followed for a period of 2 months after which any change in patient symptoms was quantified.

Setting

Ghaziabad district, located in the state of Uttar Pradesh, has a population of 2,381,452 according to the most recent census. Santosh Hospital is a 700 bedded teaching hospital with undergraduate and post graduate courses. The hospital covers a large catchment area and caters to patients from nearby villages and cities.

Subjects

All consecutive patients aged 18 years or above, who presented with complaints of allergic rhinitis at our outpatient clinic from August 1, 2014 till August 31, 2015 were asked to be enrolled for the study. Only those patients who had complaints of AR for more than 6

months and could be followed for 2 month after being enrolled for the study were included in the study. We excluded any patient who had received intranasal steroids for the condition in the past two months or who required high doses of inhaled steroids for concomitant asthma.

Data collection and analysis

Patients were provided with a written consent form after which baseline demographic and illness related information was collected. Then patients were randomly put on standard medication for AR xylometazoline nasal drops (0.1%, three times a day, brand Otrivin) or hypertonic seawater saline (2.2%, three times a day, brand Physiomer). At the time of presentation we evaluated patients for blocked nose, runny nose, sneezing and eye itching on a 4-point scale (0=no symptoms; 1=mild symptoms that were not troublesome; 2=moderate symptoms that were frequently troublesome but not sufficiently so to interfere with normal daily activities or sleep; or 3=severe symptoms that interfered with daily activities or sleep). These scores were summed up to produce Nasal Index Score. Then these patients were put on treatment and prospectively followed for a period of 2 month in our outpatient clinic for improvement or worsening of the symptoms. The scores were compared using appropriate statistical tests.

RESULTS

Table 1: Characteristics of patients in the two treatment groups.

Variable	Group receiving Hypertonic nasal drops	Group receiving Xylometazoline
Number of patients	40	45
Men/ Women	23/17	24/21
Mean age in years (SD)	31.8 (8.4)	32 (9.2)
Mean duration of illness in years	4.4	4.3
Smoker (Y/N)	16/24	18/27

Table 2: Comparing mean symptom score before and after treatment.

Symptom	Before treatment		After treatment		Change in mean symptom score	
	Group A	Group B	Group A	Group B	Group A	Group B
Blocked nose	2.8	2.9	2.1	2.5	0.7**	0.4
Runny nose	2.4	2.3	1.9	1.9	0.5*	0.4*
Sneezing	1.8	1.6	1.1	1.2	0.7***	0.4
Eye irritation	1.4	1.6	0.7	1.3	0.7*	0.3

Group A= Group receiving Hypertonic nasal drops; Group B= Group receiving Xylometazoline; p-value is <0.05, ** p-value is <0.001; ***p-value is <0.0001

Of 91 patients who fulfilled our eligibility criteria, 85 patients completed the follow up and were included in the final analysis. 40 patients were put on hypertonic saline treatment and 45 patients were randomized to xylometazoline nasal drops. Mean duration of illness was 4.4 years in the group receiving hypertonic saline and 4.3 years in the group receiving xylometazoline nasal drops. Demographic profile of patients in the two treatment groups was similar as shown in Table 1. On individual parameters, patients receiving hypertonic nasal drops showed a decrease in mean score by 0.7, 0.5, 0.7 and 0.7 for blocked nose, runny nose, sneezing and eye irritation respectively, all of which were statistically significant. Although, patients receiving xylometazoline also demonstrated a decline in mean scores for all four parameters, the difference of means was not statistically significant, with overlapping confidence intervals and therefore not conclusive of its beneficial action. Refer to Table 2 for details. Moreover we studied the patients for any adverse effects during the course of the treatment. It was seen that only 10% of the patients receiving hypertonic saline had a bloody nasal discharge as compared to 24% of the patients who received xylometazoline. Similar fewer episodes of headaches and respiratory infections were seen in the group of patients who were on hypertonic saline.

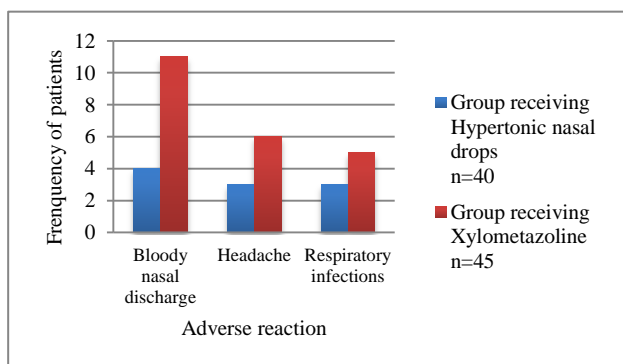


Figure 1: Adverse drug reactions seen in patients.

DISCUSSION

The therapeutic approach to AR requires a comprehensive treatment of the allergic inflammation of the airways (ARIA). The recommendations for treatment depend on disease severity along with its effects on patients' quality of life. Nasal irrigation is a simple and inexpensive treatment that improves symptoms of a variety of sinonasal diseases, reduces the use of resources and helps minimize resistance to antibiotics.³ AR is an inflammatory condition of the nasal mucous membrane and its incidence seems to be increasing. It involves the release of histamine, leukotriene, prostaglandins, and other inflammatory mediators, which result in the characteristic symptoms of rhinitis: rhinorrhoea, nasal blockage, itching, and sneezing. Intranasal budesonide delivered via inhalers or as an aqueous nasal spray has been shown to relieve symptoms in both adults and

children with either seasonal or perennial allergic rhinitis. Despite the presence of effective pharmacological treatments, patients tend to prefer non-pharmacological treatments. A rather simple and inexpensive non-pharmacologic treatment is hypertonic saline, which can do down on costs for the patients. A recently conducted meta-analysis demonstrated that saline nasal performed regularly over a limited period of up to 7 weeks was observed to have a positive effect on all investigated outcome parameters in adults and children with AR.¹ Some researchers have debated on the use of isotonic vs hypertonic saline to be used for irrigation. However no prospective clinical trial has demonstrated the superior efficacy of one over other, although the available evidence leans towards the use of hypertonic saline. Our study has showed significant improvement in symptoms of AR with the use of 2.2% hypertonic seawater saline nasal drops. The International Consensus article in Allergy (International Rhinitis Management Working Group, 1994) published by the Allergy Foundation recommended the routine use of isotonic and hypertonic lavages for rhinitis. Previously some trials have shown compliance issues with the use of higher concentrated saline nasal drops (30-35 gm/l). Better clinical outcomes along with higher treatment compliance with 2.2% hypertonic nasal drops were seen in the findings of this study. Also to be understood is the fact that "nasal irrigation" can have different meanings for different clinicians. It may range from nasal drops to irrigating with almost 200 ml of saline. Clinical outcomes will vary accordingly.

We purposefully excluded smoking as a variable while performing statistical analysis because conflicting evidence exists about the role of smoking in developing allergic rhinitis. Bousquet et al demonstrated in a large study of over 1000 patients of allergic rhinitis that smoking was found not to alter nasal symptoms or nasal-specific quality of life. A review found a significant association between AR and second hand smoking. However, the percent difference between age groups was not statistically significant. A recently published systematic review and meta-analysis observed very modest associations between smoking and some allergic diseases among adults.

Although the exact mechanism of action of hypertonic saline is not known, in vitro studies have demonstrated that saline has an anti-inflammatory activity because it reduces the production and release of interleukin 8 by the respiratory epithelium. It is yet to be understood whether saline plays only a mechanical role of clearing up the mucous or does different trace elements in seawater bring a change in the chemical environment. The sinus irrigation by itself prevented the need for surgery in 58% of patients with chronic sinusitis over a year. Earlier clinicians would advise nasal irrigation as an adjunct to nasal steroids. Recent evidence challenges these assumptions and nasal saline drops are considered underused today.

Limitations

This study was performed at a tertiary level hospital with a specific socio-demographic profile. So the results of this study might not be generalizable to other geographical areas. Furthermore, we did not blind the clinicians or the patients, which would introduce bias in our observations. Our sample size is fairly small and randomized double-blinded control trials are warranted in future to confirm our findings. The nasal index score quantifies subjective information and may cause a bias in the observations.

CONCLUSION

Our study has demonstrated that hypertonic nasal seawater saline 2.2%, three times a day is more effective in controlling the symptoms of patients of allergic rhinitis as compared to xylometazoline nasal drops 0.1%, three times a day, along with an improved quality of life. Although clinical benefits take longer time to appear with the use of hypertonic saline nasal drops, these patients experience fewer adverse reactions. Further study is required to confirm our findings by conducting a multi-centric double-blinded randomized controlled trial.

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Ethical approval: Approved by Institutional Ethics Committee

REFERENCES

- Hermelingmeier KE, Weber RK, Hellmich M, Heubach CP, Mösges R. Nasal irrigation as an adjunctive treatment in allergic rhinitis: a systematic review and meta-analysis. *Am J Rhinol Allergy*. 2012;26(5):e119-25.
- Tabary O, Muselet C, Yvin JC, Halley-Vanhove B, Puchelle E, Jacquot J. Physiomer reduces the chemokine interleukin-8 production by activated human respiratory epithelial cells. *Eur Respir J*. 2001;18(4):661-6.
- Papsin B, McTavish A. Saline nasal irrigation: Its role as an adjunct treatment. *Can Fam Physician*. 2003;49:168-73.
- Aberg N, Hesselmar B, Aberg B. Increase of asthma, allergic rhinitis, and eczema in Swedish school children between 1979 and 1991. *Clin Exp Allergy*. 1995;25:815-9.
- Howarth PH. The cellular basis for allergic rhinitis. *Allergy*. 1995;50(Suppl):6-10.
- Brogden RN, McTavish D. Budesonide. An updated review of its pharmacological properties, and therapeutic efficacy in asthma and rhinitis. *Drugs*. 1992;44:375-407.
- Fokkens WJ. Nasal corticosteroids, first choice in moderate to severe allergic rhinitis. What prevents general practitioners from using them? *Allergy* 2003;8:724-6.
- Garavello W, Romagnoli M, Sordo L, Gaini RM, Di Bernardino C, Angrisano A. Hypersaline nasal irrigation in children with symptomatic seasonal allergic rhinitis: a randomized study. *Pediatr Allergy Immunol*. 2003;14(2):140-3.
- Bousquet PJ, Cropet C, Klossek JM, Allaf B, Neukirch F, Bousquet J. Effect of smoking on symptoms of allergic rhinitis. *Ann Allergy Asthma Immunol*. 2009;103(3):195-200.
- Hur K, Liang J, Lin SY. The role of secondhand smoke in allergic rhinitis: a systematic review. *Int Forum Allergy Rhinol*. 2014;4(2):110-6.
- Saulyte J, Regueira C, Montes-Martínez A, Khudyakov P, Takkouche B. Active or passive exposure to tobacco smoking and allergic rhinitis, allergic dermatitis, and food allergy in adults and children: a systematic review and meta-analysis. *PLoS Med*. 2014;11(3):e1001611.
- Tabary O, Muselet C, Yvin JC, Halley-Vanhove B, Puchelle E, Jacquot J. Physiomer reduces the chemokine interleukin-8 production by activated human respiratory epithelial cells. *Eur Respir J*. 2001;18(4):661-6.
- Hartog B, van Benthem PP, Prins LC, Hordijk GJ. Efficacy of sinus irrigation versus sinus irrigation followed by functional endoscopic sinus surgery. *Ann Otol Rhinol Laryngol*. 1997;106(9):759-66.
- Brown CL, Graham SM. Nasal irrigations: good or bad? *Curr Opin Otolaryngol Head Neck Surg*. 2004;12(1):9-13.

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