# **Original Research Article**

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# Isotonic nasal spray versus fluticasone nasal spray in treatment of allergic rhinitis

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#### **ABSTRACT**

**Background:** Allergic rhinitis (AR) is a prevalent disease with great morbidity and causing significant societal and economic burden. Aims and objectives: To compare efficacy of fluticasone nasal spray and isotonic saline nasal spray in allergic rhinitis.

**Methods:** This was a prospective randomized study conducted on patients of allergic rhinitis coming to ENT OPD a tertiary care teaching hospital. Sixty patients diagnosed with concomitant diagnosis of allergic rhinitis was randomly allocated to either Fluticasone propionate nasal spray (n= 30) and isotonic saline spray (n= 30).

**Results:** The most common age group in fluticasone group was 21 to 30 years while in isotonic saline group 31 to 40 years was the most common age group. There was 52.8% of female and 47.2% in fluticasone group while in isotonic saline group, 52.5% of study population were female and 47.5% were male. There was significant improvement in VAS on day 15 and day 30 as compared to day 1 in fluticasone treated subjects as compared to isotonic saline group. After one month, Nasal blockage, nasal discharge, sneezing, nasal itching was improved to 71%, 69%, 81% and 78% in fluticasone treated subjects as compared to isotonic saline group in which improvement was up to 11%, 17%, 09% and 12% respectively and this difference was statistically significant.

**Conclusions:** Fluticasone nasal spray has the potential to enhance patient satisfaction and compliance and reduce the need for polypharmacy in the management of seasonal allergic rhinitis.

**Keywords:** Allergic rhinitis, Fluticasone, Isotonic saline

#### INTRODUCTION

Allergic rhinitis is a symptomatic disorder of the nose induced after allergen exposure due to an IgE-mediated inflammation of the membranes lining the nose. It was defined in 1929. The three cardinal symptoms in nasal reactions occurring in allergy are sneezing, nasal obstruction and mucous discharge.

Allergic rhinitis is a global health problem that causes major illness and disability worldwide. Patients from all countries, all ethnic groups and all ages suffer from allergic rhinitis. Allergic rhinitis affects social life, sleep, school and work. The economic impact of allergic rhinitis is often underestimated because the disease does not induce elevated direct costs. However, the indirect costs are substantial.<sup>1</sup>

Physical and chemical factors can induce nasal symptoms which may mimic rhinitis in subjects with sensitive mucous membranes and even in normal subjects if the concentration of chemical triggers is high enough.<sup>3,4</sup> Sudden changes in temperature can induce nasal symptoms in patients with allergic rhinitis.<sup>5</sup> Chronic effects of cold dry air are important. Skier's nose (cold, dry air) has been described as a distinct entity.<sup>6</sup>

Intranasal corticosteroids are the most effective mode for the management of allergic rhinitis and are able to deliver high concentrations of drugs to the target organ. Low oral bioavailability and high plasma protein binding of fluticasone helps in minimizing systemic adverse effects.<sup>6</sup>

Nasal saline represents a safe and inexpensive therapy for allergic rhinitis. It mechanically cleanses nasal mucosa, improves mucociliary clearance, decreases mucosal oedema and inflammatory mediators. A number of reports have described improved allergic rhinitis-specific outcomes after the use of nasal saline, suggesting that there may be benefit in this population as well.

# Aim and objectives

To compare efficacy of fluticasone nasal spray and isotonic saline nasal spray in allergic rhinitis.

#### **METHODS**

This was a prospective randomized study conducted on 60 patients of allergic rhinitis coming to ENT OPD a tertiary care teaching hospital. Ethical clearance was taken from institutional ethics committee. The study was conducted from March 2015- March 2016 at MGM medical college, Mumbai.

- Group A (i.e. Fluticasone spray 1 puff twice daily in bilateral nostril) followed up after every 15 days for one month.
- Group B (i.e. isotonic saline spray 1 puff twice daily in bilateral nostril) followed up after every 15 days for one month.

#### Inclusion criteria

Patients attending ENT OPD complaining of watery nasal discharge, itching, sneezing, nasal obstruction (3 out of 4) occurring for more than 1 hour on most days either seasonally or throughout the year.

# Exclusion criteria

Exclusion criteria were patients with age less than 12 years, patients who need surgical management for any nasal pathology.

A detailed ENT history was taken from all patients attending the ENT OPD. An informed consent was taken from all the patients included in the study following which clinical examination was done which include general examination, thorough ENT examination and nasal endoscopy.

General examination was done for any features of skin atopy in the form of urticaria or eczema and features of allergic conjunctivitis. Based on clinical symptoms individuals were diagnosed clinically as allergic rhinitis. The symptom severity was scored on visual analog scale of 0-10 for the four cardinal symptoms of allergic rhinitis, namely sneezing, itching, nasal obstruction and rhinorrhoea.

#### Visual analog scale

It will be by rating 0 to 10 on day 1 and then after every 15 days for one month.

• No significant symptoms: 0-3

Mild: 4-7Moderate: 8-9Severe: 10

After treatment the patients were given a questionnaire. Analysis showed that total symptoms including nasal blockage, nasal discharge, sneezing, nasal itching were the main outcome parameters evaluated.

Baseline investigations are done for all the patients:

- Complete blood count (CBC)
- Absolute Eosinophil Count (AEC)

These investigations were done prior to beginning of the study. After the complete assessment, all the patients were included in treatment protocol.

# Statistical analysis

All observations were collected as per the proforma and results were being analysed statistically using t test for quantitative data and chi square test for qualitative data. P value < 0.05 considered as significant.

# RESULTS

The most common age group in fluticasone group was 21 to 30 years while in isotonic saline group 31 to 40 years was the most common age group amongst study population. There was 52.8% of female and 47.2% of male in fluticasone group while in isotonic saline group, 52.5% of study population was female and 47.5% were male.

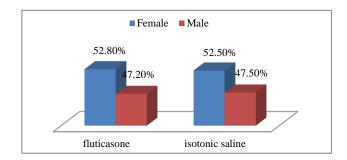


Figure 1: Gender distribution.

Table 1: VAS score at various interval of time amongst different study group.

VAS	Fluticasone	Isotonic saline	P value
Day 1	$8.07 \pm 1.60$	$8.18 \pm 1.47$	0.93(NS)
Day15	$4.2 \pm 1.2$	$8.10 \pm 1.2$	0.0001(S)
Day 30	$1.74 \pm 2.09$	$7.7 \pm 1.3$	0.0001(S)

There was significant improvement in VAS on day 15 and day 30 as compared to day 1 in fluticasone treated subjects as compared to isotonic saline group.

After one month, nasal blockage, nasal discharge, sneezing, nasal itching was improved to 71%, 69%, 81% and 78% in fluticasone treated subjects as compared to isotonic saline group in which improvement was up to 11%, 17%, 09% and 12% respectively and this difference was statistically significant.

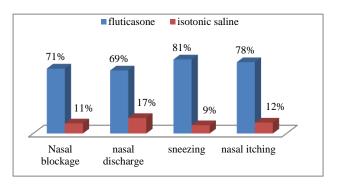


Figure 2: Percent improvement in nasal symptom score.

There was no significant difference in mean values of AEC, Hb, TLC, lymphocyte, monocyte and platelet levels in both the groups.

# **DISCUSSION**

Allergic rhinitis is present when these symptoms are triggered by an allergen. Perennial allergic rhinitis is most often attributed to dust mites, mold spores, and animal dander, whereas seasonal allergic rhinitis is attributed to a large variety of pollens that varies based on geographical region.<sup>7</sup>

Medical therapy focuses on treatment of conditions causing mucosal hypertrophy, primarily allergic and vasomotor rhinitis. When topical glucocorticoids were used in allergic rhinitis it decrease capillary permeability, produces vasoconstriction, and reduces edema and inflammation in the nasal mucosa.

Topical steroids are being used quite extensively in the treatment of allergic rhinitis to control the nasal symptoms. Popularity of this class of medication is based on a well-established combination of efficacy, tolerability and safety and is considered to be the most effective

treatment of rhinitis. Although current literature suggests that the use of intranasal steroids is quite safe. 8-10

In our study, VAS score was improved significantly in fluticasone group as compared to isotonic saline group on day 15 and day 30. Fluticasone treatment group showed a greater numerical decrease in nasal symptoms in most of the individuals as compared to isotonic saline group.

A increasing indication of prolonged administration fuel the debate regarding long term effect on local nasal structure fluticasone was also superior to placebo for reductions in ocular symptoms of adults and adolescents suffering from seasonal and perennial AR. 11-16 The mechanism by which it alleviates allergic conjunctivitis has yet to be fully elucidated. Possible mechanisms include: reduced nasal inflammation resulting in reduced release of inflammatory mediators and, hence, less activation of inflammatory cells in the neighboring tissues; improved drainage away from the eye down the nasolacrimal duct; and modulation of a nasoocular neurogenic reflex. It is unlikely that the observed effect results from systemic action of FF, since it has a low absolute bioavailability.

Similarly in the various studies fluticasone furoate nasal spray has been demonstrated to be significantly more effective than placebo at relieving symptoms of both seasonal allergic rhinitis and perennial allergic rhinitis in children, adolescents, and adults in double-blind, controlled clinical studies. <sup>17–25</sup>

#### **CONCLUSION**

The role of intranasal steroids in the treatment of AR is well established. They are proven to be efficacious and are recommended as first-line therapy for individuals with persistent moderate/severe rhinitis. Fluticasone with high topical potency and low potential for systemic effects is a good candidate for rhinitis treatment. As expected for all new drugs, long-term safety and efficacy studies are required, which can establish the potential modification of AR course.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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