

# THE EFFECTIVENESS OF TOPICAL INTRANASAL STEROIDS VERSUS SYSTEMIC ANTI-ALLERGIC DRUGS IN ALLERGIC RHINITIS: A RANDOMIZED CONTROLLED TRIAL

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## ABSTRACT

**Objectives:** To compare efficacy of mometasone furoate topical intranasal therapy alone and combination of oral anti-histamine and anti-leukotriene therapy in seasonal allergic rhinitis.

**Methods:** A randomized control trial at Department of Otorhinolaryngology, Head and Neck surgery, Pakistan Institute of Medical Sciences, Islamabad, and Khyber Teaching Hospital, Peshawar-Pakistan, was done in 1 year, from 25th Oct 2016 to 24th Oct 2017. A total of 146 patients were selected and divided into group A & group B (each group have 73 patients). The treatment given was topical Steroid (Mometasone) to Group A and oral antihistamine (loratadine 10mg), antileukotriene (Montelukast 10mg) to Group B. All patients who were included in our study were examined on three consecutive occasions, i.e. at zero presentation day, at 2 weeks and 4 weeks. Patient nasal symptom score was recorded and improvement noticed.

**Results:** All 146 patients were selected and were divided into two groups with each group consists of 73 (50%) patients. Male to female ratio was 1:1.8 and mean age was  $27.93 \pm 7.8$ . Out of all patients 124 (84.9%) were responders and 22 (15%) were non-responders. 69 (94.5%) patients of group A were responders while 4 (5.5%) were non-responders. On the other hand, in group B, 55 (75.3%) were responders and 18 (24.7%) were non-responders

**Conclusion:** Intranasal Mometasone furoate spray as a first line therapy was more effective than combined oral anti-histamines and leukotriene receptor antagonists in allergic rhinitis.

**Keywords:** Allergic Rhinitis, intranasal glucocorticoids, intranasal steroids, Mometasone furoate spray, antihistamine, anti-leukotrienes.

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## INTRODUCTION

Allergic Rhinitis is an inflammation of the nasal mucosa, which is characterized by nasal obstruction, rhinorrhea, sneezing, itching in the nose, eyes and throat. The most appropriate allergic rhinitis management is a combination of educating patient and symptomatic pharmacotherapy. The main goals of this treatment are to relieve symptoms of the patient and quality of life improvement. Rhinitis is defined as inflammation of the membranes lin-

ing the nose & paranasal sinuses and is characterized by one or more of the following nasal symptoms: sneezing, itching, rhinorrhea and nasal congestion. Rhinitis is frequently accompanied by symptoms that involve the eyes, ears and throat.<sup>27</sup> Allergic rhinitis (AR) is a chronic disorder with high prevalence leading towards quality of life impairment. The most appropriate AR management is a combination of educating patient to avoid specific allergen and symptomatic pharmacotherapy.<sup>4</sup> The main goals of this treatment are to relieve symptoms of the patient, improve individual's quality of life and to modify the immune response of the allergic disease.<sup>6</sup>

Although AR is a mild disorder, but it is seemed more as irritation rather than a disease. Mostly, AR is under diagnosed, sometimes misdiagnosed leading towards mistreatment.<sup>7</sup> Children are found to be more effected with AR in terms of sleep quality, social activities, daily school

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performance and health status (physical & emotional).<sup>9</sup>

The symptoms of Allergic rhinitis results from an interaction between IgE antibodies on mast cells located in the upper airway<sup>10</sup> and inhaled allergens, it is possible to achieve quick relief of symptoms by direct application of topical medication to the nasal mucosa. Topical Intra-nasal steroids are the most effective drugs associated with improvement in Allergic rhinitis, more effectively covering allergic symptoms, with the benefits, such as better patient compliance, cost-effectiveness, and with less side effects. Specific topical medications include mometasone furoate, triamcinolone, beclomethasone, fluticasone propionate, fluticasone furoate. Topical steroids improve mucociliary clearance,<sup>11</sup> which results in modification of nasal mucosal environment. The use of antihistamines such as loratadine (10mg) and montelukast (10mg) in combination has generally resulted in greater efficacy than when these agents were used alone. Montelukast has a favorable safety profile it decreases nasal mucosal congestion and mucus production. According to recent study loratadine-montelukast combination therapy causes decrease in nasal obstruction.<sup>12,13</sup> But add on topical mometasone furoate to Montelukast and loratadine is the most effective treatments of all to AR.

Nasal congestion is most common and bothersome symptom among patients of AR. Evidence exist that sleep related issues are also reported among AR patients including sleep breathing disturbance, snoring, sleep apnea, sleepiness and day time fatigue.<sup>14</sup> Topical nasal corticosteroids had high efficacy as anti-inflammatory agents in AR patients. It is a routine practice of ENT practitioners to prescribe steroids and antihistamines as AR treatment modality.

Multiple studies done i.e. Teet Pullerits, Marcy Detineo, Fuad M Baroody, Sandra M, Gawichik, Price D, they assessed and compared the effects of nasal steroids, anti-leukotriene, and a combination of anti-leukotriene and antihistamine for seasonal AR treatment. Result of their study showed that mean symptoms score with topical steroid nasal spray and combined anti-leukotriene and antihistamine, 1.1+0.5 and 1.5+0.4 respectively. So, they have concluded that intranasal steroids are much better than combined anti-leukotriene and antihistamine in controlling allergic rhinitis.<sup>15</sup>

In his two studies Gill MZ, concluded that intra-nasal steroids improve mucociliary clearance and improves the patient quality of life. In our study we will compare the efficacy of topical intranasal steroid with oral antihistamine

and antileukotrienes. This study results may recommend better management of patients in future and decrease morbidity accordingly. Allergic Rhinitis is one of very common allergic diseases round the world and also in Pakistan.

## MATERIAL AND METHODS

A Randomized Control Trial at Department of Otorhinolaryngology, Head and Neck surgery, Pakistan Institute of Medical Sciences Islamabad, was completed in 1 year from 25/10/2016 to 24/10/2017. All patients presenting to PIMS OPD in ENT department with symptoms of allergic rhinitis, both male and female, age between 15 to 50 years were included while patients with perennial allergy, patients taking immunotherapy, patients not willing for the study, lactating and pregnant females, patients allergic to cats and dogs' fur and patients with chronic medical conditions were excluded. Patients OPD numbers were recorded. Randomly patients were divided into two groups i.e. group A and B by lottery method. All patients were assessed clinically for allergic rhinitis (sneezing, nasal obstruction, rhinorrhea, nasal itching). After clinical diagnosis of seasonal allergic rhinitis informed written consent for study was taken.

The patients were examined at first presentation to OPD and were assessed by symptoms of allergic rhinitis by nasal symptoms score. Each patient was given a diary in which he/ she had to rate the severity of symptoms i.e. nasal obstruction, rhinorrhea, nasal itching, sneezing. The sum of all four nasal symptoms rating constitute the total nasal score. To group A treatment given was Mometasone Furoate nasal spray 110 mcg once daily i.e. 2 sprays in each nostril were prescribed for 2 weeks and to group B tablet loratadine 10mg plus tablet Montelukast 10mg once daily were prescribed. Then patients of both groups were assessed for improvement in symptoms at first follow up visit according to nasal symptoms score at 2 weeks.

Again, treatment was given to both Group A and Group B for next 4 weeks duration. At last visit (6 weeks of treatment) improvements of symptoms were compared for both groups according to nasal symptoms score. On every follow-up visit total nasal symptoms scores were entered on questioner. Improvement was considered significant when nasal symptoms score improved by at least 1 unit. Data was written/recorded in questioner. Sum of the nasal symptoms score were calculated on every visit. Final outcome was measured on last visit. The patient's response of both groups was compared by using the chi square test and the P value was turned out to be 0.001.

**RESULTS**

All 146 patients were selected and were divided into two groups i.e. 73 in each group. Out of all patients 53(36.3%) were male and 93 (63.7%) were female, male to female ratio was 1:1.8. In this study the minimum age of patient was 15 years and maximum age was 48 years and the mean age was 27.93±7.8.

Out of all patients 124 (84.9%) were responders and 22 (15%) were non-responders. 69 (94.5%) patients of group A were responders while 4 (5.5%) were non-responders. On the other hand, in group B, 55 (75.3%) were responders and 18 (24.7%) were non-responders. The patient’s response of both groups was compared by using the chi square test and the P value was turned out to be

**Table 1: Age of patient**

Patient's age	N	Minimum	Maximum	Mean	Std. Deviation
	146	15.00	48.00	27.93	7.893

**Table 2: Sex of patient.**

Sex of Pt	Frequency & %ages
Male	53 (36.3%)
Female	93(63.7%)
Total	146

**Table 3: Comparison of patient’s response of both groups using chi square test.**

GROUPS	RESPONSE		P-value*
	Responder	Non- Responder	
A	69 (94.5%)	4 (5.5%)	0.001
B	55 (75.3%)	18(24.7%)	
Total	124 (84.9%)	22 (15%)	

0.001.

**DISCUSSION**

There are different authors who have conducted studies on treatment of allergic rhinitis i.e. Juel-Berg N<sup>5</sup> and his colleagues did a meta-analysis included five randomized controlled trials with a total of 990 patients and found that intranasal steroids were superior to oral anti-allergic drugs in improving total nasal symptoms score.<sup>5</sup> Feng S, et al<sup>16</sup> conducted a study to perform a systematic review and meta-analysis of randomized controlled trials to compare the symptomatic management of corticosteroid nasal spray plus antihistamine (local spray or oral) with that of either therapy given alone, or placebo in pa-

tients with allergic rhinitis and found that intranasal corticosteroid plus oral antihistamine have similar efficacy to intranasal corticosteroid alone, greater efficacy than oral antihistamines alone or placebo in reducing nasal symptoms for AR patients.<sup>16</sup> Another study done by Teet Pullerits and his colleges done a study on allergic rhinitis in Sweden. They compare topical nasal steroid (Fluticasone Propionate) and oral antihistamine and antileukotriene in the treatment of seasonal allergic rhinitis. This study shows that topical steroid have much better effect in lowering seasonal allergic rhinitis symptoms i.e. the mean symptoms score at start of treatment with oral antihistamine and antileukotriene 1.9±1.5 and after 6 weeks of treatment 1.5±0.4 and the mean symptoms score at start of treatment with topical steroid 1.5±1.4 and after 6 weeks of treatment 1.1± 0.5, with the P value of p-0.003.

In a study by Jia MH<sup>8</sup> and colleagues evaluated the effect of nasal glucocorticoid combined with second-generation antihistamines or leukotriene receptor antagonists on the treatment of moderate severe allergic rhinitis, and came up with conclusion that, nasal glucocorticoid alone or combined with second generation antihistamines or leukotriene receptor antagonists can effectively control nasal symptoms of moderate to severe allergic rhinitis.<sup>8</sup> Another study by Price D and his colleges on allergic rhinitis in UK. They compare topical nasal steroid (Mometasone) and oral antihistamine in the treatment of seasonal allergic rhinitis. According to this study topical steroid has much more better effects in lowering seasonal allergic rhinitis symptoms i.e. Percent reduction in allergic rhinitis symptoms after 4 weeks of treatment for topical steroid is 75.2 % versus oral antihistamine treatment is 65.3%. The P value of 0.04.

Disease burden is increasing due to its immediate effect on job performance of patients. Clinically, AR which is the most common type than non-allergic (NAR) rhinitis and it is IgE mediated. It is estimated that 40-45% of western population are affected by rhinitis. However, evidence proved that 20-40% of rhinitis occurrence is associated with non-allergic rhinitis. Literature showed that frequency of upper respiratory diseases and associated risk factors may be influenced by climatic and environmental conditions.<sup>2</sup>

Other study by Sandra M, Gawchik and his colleges done on seasonal allergic rhinitis in USA. They compare topical nasal steroid (Triamcinolone Acetonide) and oral antihistamine in the treatment of seasonal allergic rhinitis. This study shows that topical steroid is better in

lowering seasonal allergic rhinitis symptoms i.e. Percent reduction in seasonal allergic rhinitis symptoms after 4 weeks of treatment fortopical steroid is 70% versus oral antihistamine treatment is 55%. The P value is 0.002.

Mercy Detineo, Fuad M Baroody and his colleagues done a study on allergic rhinitis in USA. They compare topical nasal steroid (Fluticasone Propionate) and oral antihistamine and antileukotriene in the treatment of seasonal allergic rhinitis. This study shows that topical steroid has much more good effects in lowering seasonal allergic rhinitis symptoms i.e. the mean symptoms score at start of treatment with oral antihistamine and antileukotriene is  $2.6 \pm 0.2$  and after 2 weeks of treatment is  $1.7 \pm 0.2$  and the mean symptoms score at start of treatment with topical steroid  $2.8 \pm 0.2$  and after 2 weeks of treatment  $1.4 \pm 0.2$ . The P value is  $p < 0.01$ .

In the study of these authors, some consider day or only night symptoms of allergic rhinitis because their treatment would improve sign and symptoms of only day or night time while others consider pollen allergy and took some of their patients to the site of pollen, where the patient to be exposed to specific allergens, some others consider only one symptom of nose and not all, some consider a specific session.

The benefit of our study is that it was carried out in Islamabad and here there are multiple allergens including pollen allergy, so there was no need to take patient to any specific site to have him exposed to that specific allergen especially pollen. In this study all symptoms of nose that occur in AR were considered. In this study we also looked for all symptoms of nose which occur both day and night and seasonal relation was taken into consideration too. As with symptoms, treatment with a nasal steroid also provide significantly better protection against the pollen induced development of nasal eosinophilia compared with that of other treatment groups.

## CONCLUSION

Intranasal Mometasone furoate spray as a first line therapy was more effective than combined oral anti-histamines and leukotriene receptor antagonists in allergic rhinitis.

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**AUTHOR'S CONTRIBUTION**

Following authors have made substantial contributions to the manuscript as under

- Junaid M:** Write-up of manuscript data collection, data compilation.
- Muhammad N:** Conception, data collection.
- Umair M:** Proof Reading, helping in writing manuscript.
- Arif AU:** Bibliography.
- Din I:** Proof Reading.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.