

To Assess the Efficacy of Mometasone and Hydroxypropyl methylcellulose Nasal Spray to Control Symptoms of Allergic Rhinitis: A Comparative Study

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Abstract

Introduction: Allergic Rhinitis is a debilitating disease that affects the quality of life. Treatment of allergic rhinitis includes prevention of exposure to allergens and pharmacological therapy. Pharmacological therapy in the form of nasal sprays play a major role. This study aims at comparing the efficacy of mometasone nasal spray and hydroxypropyl methylcellulose nasal spray in controlling the symptoms of allergic rhinitis.

Methodology: 120 patients who presented with symptoms of allergic rhinitis and fulfilled the inclusion and exclusion criteria were selected as study subjects. They were randomly allocated into two groups. Group A patients received Mometasone nasal spray while Group B patients received Hydroxypropyl methylcellulose nasal spray. Follow up was carried out on 14th and 28th day from the starting of treatment. Efficacy was measured based on a 5 point scale.

Result: Hydroxypropyl methylcellulose nasal spray was superior in controlling symptoms than Mometasone nasal spray on 28th day of treatment.

Conclusion: Both Mometasone and Hydroxypropyl methylcellulose nasal spray are effective in controlling the symptoms of allergic rhinitis. Hydroxypropyl methylcellulose nasal spray is found to be more effective in comparison to Mometasone, on day 28th of treatment in this study.

Keywords: Allergic Rhinitis, Mometasone Nasal Spray, Hydroxypropyl Methylcellulose Nasal Spray.

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Introduction

Allergic rhinitis is defined clinically by combination of two or more nasal symptoms like running nose, blocked nose, sneezing and itching [1]. The prevalence of seasonal

allergic or perennial rhinitis is increasing and it is estimated that 10%-30% of population suffer from the disease. The prevalence of allergic rhinitis has become two to three

times within the past 15 years [2,3]. Allergic rhinitis has been classified by ARIA (Allergic Rhinitis and its Impact on Asthma) as Mild- normal sleep, normal daily activities, normal work and school, no troublesome symptoms. Moderate to Severe - abnormal sleep, impairment of daily activities, problems caused at school or work, troublesome symptoms [4].

The treatment of allergic rhinitis includes first the lack of exposure to allergen and second pharmacological treatment [5]. Hydroxypropyl Methylcellulose nasal spray has appeared in the European market since 1994. It includes a covering device and hydroxypropyl methylcellulose powder. And when the latter meets water vapor on the mucosa, it forms gel and prevents allergen particles in the air from entering mucous membrane [6,7]. There are bulk of studies on effect of corticosteroid nasal spray on pituitary-adrenal axis and most of them have shown little or no impact on pituitary-adrenal axis [5,8]. Although corticosteroid nasal sprays except beclomethasone have good safety profile [9].

Review of Literature

- Nafieseh Sadat Mahmodi [10] *et al* during May 2016 in Iran conducted one study to know the comparison of Nasaleze and mometasone nasal spray to control the symptoms of allergic rhinitis and they found that nasalize is atleast as eeffective as mometasone nasal spray on treatment and decrease of the allergic rhinitis symptoms.
- Haiyun Shi [11] *et al* during February 2017 conducted one study in China on clinical evaluation of nasalize nasal spray on the effect of allergic rhinitis and they found that nasaleze nasal spray is applied to the patients with allergic rhinitis, it can effectively reduce the application amount of nasal spray hormone and there are no obviously adverse reactions.

- Borah Tinku Moni [12] in August 2018 conducted one study in India and the topic was a comparative study to assess the efficacy of hydroxypropyl methylcellulose powder over steroid spray in treatment of allergic rhinitis in the department of Ent and Head & Neck Surgery, Silchar Medical College & Hospital and found that significantly higher efficacies of hydroxypropyl methylcellulose powder over its steroidal counterpart.
- Emberlin JC and Lewis RA[13] conducted one study in 2007 and found that the inert cellulose powder can have significant effects in reducing some symptoms of persistent rhinitis due to house dust mite allergy. There were no adverse reactions.
- Dibildox J [14] conducted one study in mexico in the year 2001 and found that intranasal mometasone furoate has been found to be safe and effective therapy fr the treatment of allergic rhinitis and there were no signs of nasal atrophy.

Aim

To compare the efficacy of mometasone nasal spray and hydroxypropyl methylcellulose nasal spray to control symptoms of allergic rhinitis

Objectives

1. To assess the efficacy of mometasone nasal spray to control symptoms of allergic rhinitis.
2. To assess the efficacy of hydroxypropyl methylcellulose nasal spray to control symptoms of allergic rhinitis.
3. To compare the efficacy of hydroxypropyl methylcellulose and mometasone nasal spray to control symptoms of allergic rhinitis.

Methodology

Study Type: Prospective study.

Study Duration: 06 Months (From June 2019 to November 2020)

Study Area: Department of ENT, TMC & Dr. BRAM Teaching Hospital, Hapania, Agartala, West Tripura, PIN-799014.

Study Population: Patients attending to OPD of ENT department, TMC & Dr. BRAM Teaching Hospital with symptoms of Allergic Rhinitis.

Inclusion Criteria

All Patients of age group 12-60 years with symptoms of allergic rhinitis and confirmed by physical examination by otorhinolaryngologist attending ENT department of TMC & DR.BRAM Teaching Hospital and was in need of medical treatment and patient's consent to participate in the study.

Exclusion criteria

- Age less than 12 years and more than 60 years
- Patients with bronchial asthma.
- Patients who had used corticosteroid or antihistaminic in any mode one month before the study.
- Patients who had taken nasal spray of cromolyn sodium within 15 days before study.
- Patient who is not willing to give consent.

Sample size

All patient attending OPD of ENT department, TMC & Dr. BRAM Teaching Hospital and fulfilling the inclusion criteria were included in this study. By this we got 120 patients.

Table 1: Sex-wise Distribution of Patients Receiving Treatments

Treatments	Group A	Group B	Grand Total
Female	26	27	53
Male	34	33	67
Grand Total	60	60	120

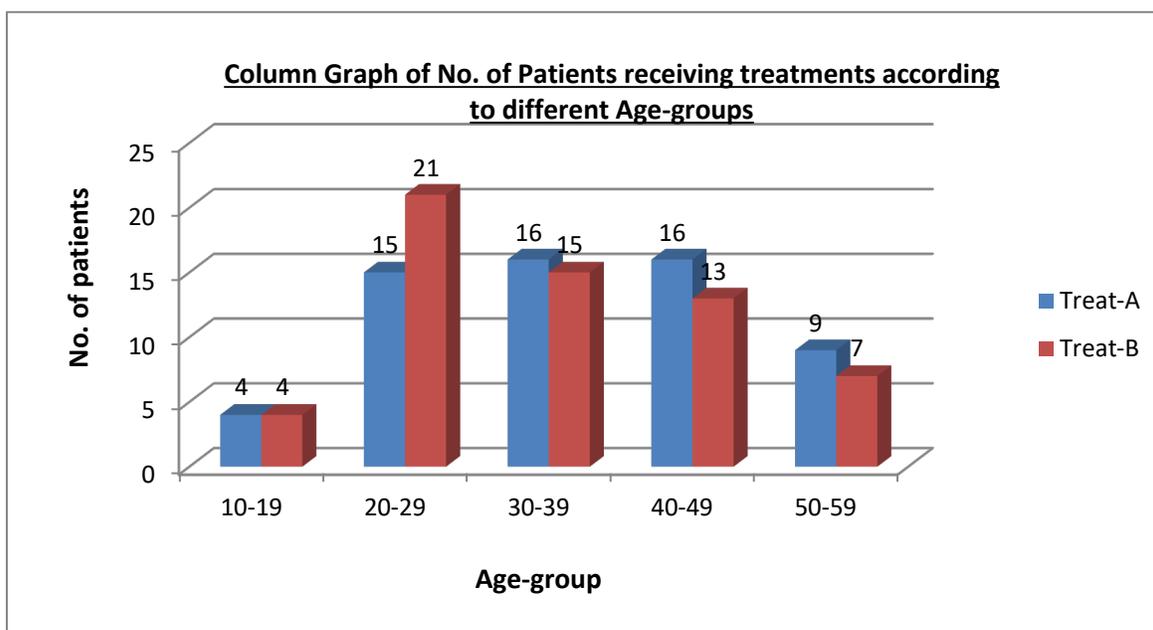


Figure 1

Study Tools and Technique: Diagnosis of allergic rhinitis was done based on clinical signs (sudden attacks of sneezing, runny nose, nasal congestion, itchy nose, cough and post-nasal drip) and physical examination. The study subjects were randomly divided into two groups. One group (Group A) was given MOMETASONE (MOMETASONE FUROATE) NASAL SPRAY 100mcg, 1 puff in each nostril once daily for 28 days. Other group (Group B) was given Hydroxypropyl methylcellulose (HPMC) NASAL SPRAY, 1 puff in each nostril thrice

daily for 28 days. Follow-up was done at 14th day and 28th day of the starting of treatment. The results were assessed by relief of symptoms on a 5 point scale.

1. Allergic rhinitis with no relief of symptoms.
2. Allergic rhinitis with apparent relief of symptoms with periodic flare ups.
3. Mild relief of symptoms.
4. Relief of major symptoms (nasal obstruction, sneezing, running nose).
5. Complete relief of symptoms.

Result

Data collected was entered in Microsoft excel and analyzed by SPSS version 23.0 software with suitable statistical tests. P value less than 0.05 was considered significant.

Table 2: Patients Outcome on 14th day

Treatments	1	2	3	4	Grand Total
Group A	2	19	16	23	60
Group B	3	17	22	18	60
Grand Total	5	36	38	41	120

Null hypothesis: There is no difference in response between patients of Group A and Group B in terms of patient symptoms on 14th day

Alternate Hypothesis: There is difference in response between patients of Group A and Group B in terms of patient symptoms on 14th day

Table 3

Symptoms	1	2	3	4	Row Totals
A	2 (2.50) [0.10]	19 (18.00) [0.06]	16 (19.00) [0.47]	23 (20.50) [0.30]	60
B	3 (2.50) [0.10]	17 (18.00) [0.06]	22 (19.00) [0.47]	18 (20.50) [0.30]	60
Coloumn Total	5	36	38	41	120

The Chi-square statistic was 1.862. The p-value was 0.6002. The result was not significant as $p > 0.05$

Conclusion: There was same response in patients of Group A and Group B in terms of patient symptoms on 14th day

Table 4: Patients Outcome on 28th day

Treatments	1	2	3	4	5	Grand Total
Group A	5	5	15	13	22	60
Group B	1	1	5	25	28	60
Grand Total	6	6	20	38	50	120

Null hypothesis: There is no difference in response between patients of Group A and Group B in terms of patient symptoms on 28th day

Alternate Hypothesis: There is difference in response between patients of Group A and Group B in terms of patient symptoms on 28th day

Table 5

Symptoms	1	2	3	4	5	Row Totals
A	5 (3.00) [1.33]	5 (3.00) [1.33]	15 (10.00) [2.50]	13 (19.00) [1.89]	22 (25.00) [0.36]	60
B	1 (3.00) [1.33]	1 (3.00) [1.33]	5 (10.00) [2.50]	25 (19.00) [1.89]	28 (25.00) [0.36]	60
Coloumn Total	6	6	20	38	50	120

The Chi-square statistic was 14.8428. The p-value was 0.05039. The result was significant as $p < 0.05$

Conclusion: There was difference between response in patients of Group A and Group B in terms of patient symptoms on 28th day.

Test for relief of Major symptoms & complete relief of symptoms:

Null Hypothesis: There was same relief of major symptoms & complete relief of symptoms in patients of Group A and Group B on 28th day

Alternate Hypothesis: There was more relief of major symptoms & complete relief of symptoms in patients of Group A and Group B on 28th day

Value of z (two sample proportion test) is - 3.7158.

p-value was 0.001. The result was significant as $p < 0.05$

Conclusion: There was more relief of major symptoms & complete relief of symptoms in patients of Group B as compared to patients of Group A on 28th day.

Discussion

In this study we found that Hydroxypropyl methylcellulose powder nasal spray is better in comparison to mometasone nasal spray after 28 days of treatment. No serious side effects were found in any of these drugs in

our study. Dosage of Mometasone is convenient for the patient as it is once daily use. On the other hand we use Hydroxypropyl methylcellulose nasal spray three times daily. 7 patients felt that three times daily dose is difficult to maintain. 7 patients of group A and 13 patients of group B complained of nasal irritation and sometimes throat irritation also but it usually subsides after 15-20 mins.

In many other studies all over the world, we found similar efficacy and side effects with Hydroxypropyl methylcellulose nasal spray. Due its natural origin and lack of systemic absorption, it is very good options for children, pregnant woman and lactating mother.

Conclusion

Both Mometasone and Hydroxypropyl-methylcellulose nasal spray are effective in controlling the symptoms of allergic rhinitis. Hydroxypropyl-methylcellulose nasal spray is found to be more effective in comparison to Mometasone, on day 28th of treatment in this study. Considering all these we can

consider HPMC powder for the treatment of allergic rhinitis. Due to its safety profile it can be used in pregnancy, lactation, children and steroid phobia patient.

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