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KEY WORDS: Allergic rhinitis, Efficacy, Hydroxypropylmethylcellulose, Antihistaminic, Steroids nasal spray

A COMPARATIVE STUDY TO ASSESS THE EFFICACY OF HYDROXYPROPYLMETHYLCELLULOSE POWDER OVER STEROID SPRAY IN TREATMENT OF ALLERGIC RHINITIS IN THE DEPTT. OF ENT AND HEAD & NECK SURGERY, SILCHAR MEDICAL COLLEGE & HOSPITAL

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ABSTRACT

Objective: To assess the efficacy of Hydroxypropylmethylcellulose powder over steroid nasal spray in treatment of allergic rhinitis.

Methods: A prospective study of 60 patients suffering from allergic rhinitis was conducted in the ENT and Head & Neck surgery Department, Silchar medical College and Hospital from April 2018 to August 2018.The study subjects were divided into two groups A and B. Group A was treated with oral antihistaminic and steroid nasal spray, while group B was treated with oral antihistaminics and HYDROXYPROPYLMETHYLCELLULOSE powder nasal spray for 4 weeks. The treatment outcomes were evaluated after 14 days and 28 days from the beginning of treatment, by assessing relief of symptom on a five point scale.

Results: There was almost similar score in both the groups ranging between score 3 and 4(i.e., relief of nasal obstruction and sneezing) after 14 days of treatment (62% vs 64%). But after 28 days there was significantly better improvement score of group B study subjects over group A in score 5 (i.e., complete relief from symptoms (83.3% vs. 66.6%).In both the groups, mild sedation at the beginning of the treatment was reported in some patients, which is a well known side effect of antihistaminics.

Conclusion: The result obtained comparing both the groups indicated high efficacy of hydroxypropylmethylcellulose powder over steroid nasal spray in the treatment of allergic rhinitis.

INTRODUCTION

- Allergic rhinitis is defined clinically by combination of two or more nasal symptoms like running nose, blocked nose, sneezing and itching.[1] Allergic rhinitis occurs when these symptoms are the result of IgE mediated inflammation following exposure to allergen. Allergic rhinitis is a global health problem and its prevalence is increasing.
- Global prevalence of Allergic rhinitis is estimated to be ranging from 0.8% to 39.7% .[1]
- Allergic rhinitis has been classified by ARIA(Allergic Rhinitis and its Impact on Asthma) as:[2]

Intermittent symptoms <4 Days per week or < 4 weeks

persistent symptoms > 4 days per week or >4 weeks

MILD	MODERATE TO SEVERE
Normal sleep	Abnormal Sleep
Normal daily activities	Impairment of daily activities
Normal work and school	Problems caused at school or work
No troublesome symptoms	Troublesome symptoms

- There is undoubtedly a genetic component in Allergic rhinitis. The best established risk factor is family history of allergy. The increase in prevalence of Allergic rhinitis observed over last 40 years is unlikely to be due to changes in the genetic pool, but instead can be due to environmental pollution that may induce a Th2-like inflammation. Several studies support the Hygiene-hypothesis. Most Allergic rhinitis patients can be diagnosed by history, clinical examination and SPT (skin prick test) or radio-allergo-sorbent-test (RAST) for specific IgE. In this study diagnosis was made on the basis of history and clinical examination.

- **In history we asked for symptoms like**

→ Nasal obstruction
→ Running nose
→ Sneezing
→ Headache
→ Itching of nose
→ Ocular symptoms

The management of Allergic rhinitis consists of:[1]

- **Environmental control measures** include avoidance of allergen (primary prevention) which result in delay in atopic sensitization, graded exposure (desensitisation) to allergen as secondary prevention
- **Pharmacotherapy** includes antihistaminics, topical glucocorticoids as nasal spray, nasal decongestants, sodium cromoglycate, ipratropium bromide, systemic steroids, antileukotrienes
- **Immune therapy**

HPMC (Hydroxy-Propyl-Methyl-Cellulose)

HPMC powder is a nasal spray.

HPMC[11]

- An odourless, tasteless micronized powder and is a synthetic modification of natural polymer cellulose (vegetable origin)
- In this study it was used in combination with anti-histaminics in treatment of Allergic rhinitis.
- Preparation based on HPMC powder is registered as a class 1 medical device under EU directive 93/42/EEC and is currently on sale on many countries including India.[5]

MECHANISM OF ACTION

1. ABSORBS MOISTURE within the airway
2. Swells to form a PROTECTIVE GEL LAYER over the nasal mucosa
3. This BARRIER PREVENTS AIRBORNE ALLERGEN from diffusing and binding to receptor sites
4. Avoid mast cell degranulation

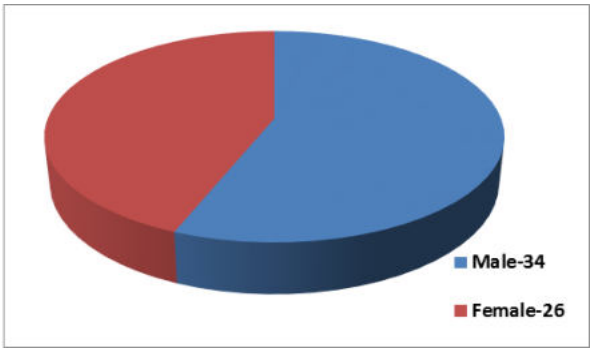
- Rapid swelling occurs in first 5 minutes (1.17 micrometre per second), & then continues at slower rates for over 100 minutes .[8]
- In several studies, it has been shown that diffusion of allergen had a significant reduction through the HPMC layer, at all points of time. The mesh size in the HPMC gel is also notably smaller.

METHODS

- Type of study : Prospective
- Place : Silchar Medical College & Hospital in the Department of E.N.T and Head & Neck Surgery
- Period : April 2018 to August '2018
- Similar studies carried out by *Minov JB1, KArazinska-bislimovska J1, petrova T2, Vasilebsk K3, stoleski S1* and *mijakoski D1,2017* was used as a model.

- **Inclusion Criteria**
  →Allergic rhinitis caused by Sensitization to allergens.
  →Both SAR (Seasonal Allergic Rhinitis) and PAR (Persistent Allergic rhinitis) cases (severity based on AR guidelines)

- **EXCLUSION CRITERIA**
  →Non Allergic rhinitis and other forms of rhinitis
  →Patients with nasal polyp and structural deformities
  →Sample Size : **60** patients → **34** males : **26** Females



The study subjects were divided into two groups

Group A		Group B	
Anti-Histaminics	Steroid Nasal Spray	Anti-Histaminics	HPMC Nasal Spray
Once daily at bedtime	One puff in each nostril twice daily	Once daily at bedtime	One puff in each nostril thrice daily

Follow up : for One month with intermediate visits at 14 days and 28 days

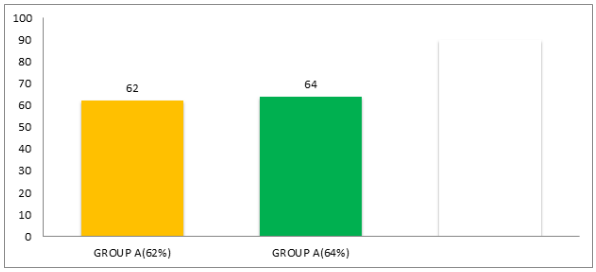
The results outcomes were evaluated by assessment of symptoms on a 5 point scale.

POINT SCALE SYMPTOMS 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 blockage, sneezing, running nose) **5** Complete relief of symptoms

- The data obtained were statistically processed by descriptive and inferential methods using the Statistical Package for Social Sciences version (SPSS). Analysis of the data included average points scored out of total score (total score is taken as 150) in both the groups by z value.
- *P value* <0.05 were considered statistically significant.

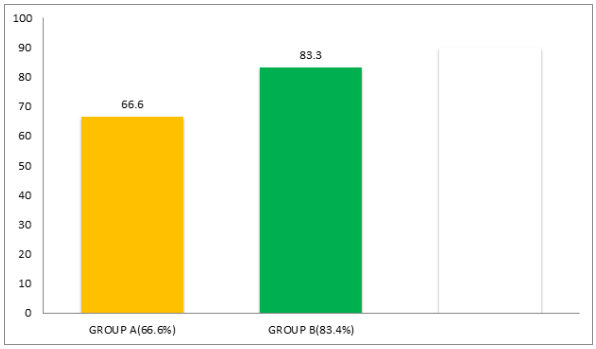
RESULTS AND DISCUSSION

- At the beginning of the study, all the subjects were symptomatic.
- After 14 days
- the average percentage of score for symptom relief was measured and found to be almost similar in both the groups and most of the points were 3 or 4 (62% Vs 64%,z value is –o.239 and p value is 0.964)



Assessment of the study subjects for relief of symptoms were done by 5 point scale as documented above.

- Treatment outcome after 28 days
- We found significantly higher percentage of average score with improved symptom as point 4 and 5 in group B, than Group A (83.3% in Group B vs 66.6% in Group A,z value is -3.333 and p value is 0.00086,which is significant).



- Side effects of mild sedation were reported at 14 days by
- 8 subjects in Group A
- 6 subjects in Group B
- 15 subjects from Group A reported that symptoms got relieved after usage of steroid nasal spray for 2 – 3 hours but there was recurrence and it also caused sore throat and nasal irritaton. *(It is a proven fact that prolonged use of steroid spary causes epistaxis and nasal irritation along with its contraindication for use in pregnancy , breast feeding mother and children below 2 years of age)*
- Whereas HPMC powder showed a significant reduction of symptom in all points of time and no such adverse reactions and contraindications were seen in subjects of Group B.
- The sedation is due to a well known central effect of anti-histaminics, as it was used in both the groups.
- Similar findings were reported in several trials done abroad investigating efficacy and safety of HPMC powder in treatment of Allergic rhinitis. [8-12]
- Regarding safety profile[7,12], HPMC powder is quite safe in children, pregnancy, breast feeding mothers as it is an inert barrier. Also HPMC powder fits with ARIA (Allergic Rhinitis and its Impact on Asthma) guidelines.

CONCLUSION

- In conclusion, this prospective & comparative study to assess the efficacy of HPMC powder over steroid nasal spray for treating Allergic rhinitis, led to results which showed significantly higher efficacies of HPMC powder over its steroidal counterpart, suggesting that its use is definitively beneficial in the treatment of Allergic rhinitis.

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