

## EFFICACY OF LIPID BASED OINTMENT AS ADJUVANT THERAPY FOR ALLERGIC RHINITIS

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### ABSTRACT

**Objective:** To find out the efficacy of a commonly used lipid based ointment (petroleum jelly) as adjuvant therapy for allergic rhinitis by comparing the patients using standard treatment versus patients using additional lipid based ointment.

**Study Design:** Randomized controlled trial.

**Place and Duration of Study:** The study was carried out at Combined Military Hospital (CMH) Bahawalpur from July 2014 to August 2015.

**Material and Methods:** Total 300 patients of allergic rhinitis were included in the study through non-probability convenience sampling and randomly divided in two groups of 150 each. In group A patients were treated with traditional treatment of allergic rhinitis including oral antihistamines and intranasal corticosteroids and in group B patients were given oral antihistamine, intranasal corticosteroids and a commonly used ointment (petroleum jelly) for intranasal application. Each symptom of allergic rhinitis (sneezing, itching, rhinorrhoea, nasal congestion) was rated using a 4 point scale ranging from 0 (none) to 3 (severe). All these assessments were then added to calculate the total symptom score (TSS), the maximum of which could be 12. All the patients in both groups were assessed before the start of treatment and after 2 weeks and the mean difference in each symptom and total symptom score (TSS) was compared between the two groups.

**Results:** Treatment including petroleum jelly plus standard treatment caused a significantly better total symptom control than the standard treatment (oral antihistamine and nasal corticosteroids),  $5.38 \pm 3.75$  vs  $6.34 \pm 3.83$  ( $p=0.029$ ). However as far as the individual symptom scores are concerned, best effect of petroleum jelly was seen on rhinorrhoea  $1.38 \pm .93$  vs  $1.79 \pm .92$  ( $p=0.000$ ) and nasal itching  $1.27 \pm .93$  vs  $1.80 \pm .96$  ( $p=0.000$ ).

**Conclusion:** A commonly available lipid based ointment, petroleum jelly, is a safe and effective adjuvant therapy for allergic rhinitis.

**Keywords:** Allergic rhinitis, Petroleum jelly.

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### INTRODUCTION

Allergic rhinitis is a frequent disease of patients in ENT (ear, nose, throat) outpatient department. Majority of patients do not report their symptoms or even get any treatment<sup>1</sup>. The prevalence of allergic rhinitis varies from country to country. This is thought to be due to geographic differences in the types, potency and overall burden of different allergens. Patients also have other associated atopic conditions like asthma, atopic dermatitis, conjunctivitis<sup>2</sup>. About 20-30% of allergic rhinitis cases have asthma and

30-90% of asthmatics have allergic rhinitis<sup>3</sup>. In Pakistan the prevalence has been reported to be 24.62%<sup>4</sup>. Allergic rhinitis is clinically defined as a disease of the nose induced by an IgE-mediated inflammatory response after exposure to an allergen. Various allergens include pollens, dander, house dust mite and molds. In the immediate response to an antigen (the early-phase allergic reaction) inflammatory mediators are released from mast cells in the nasal mucosa. This causes the characteristic nasal symptoms of sneezing, itching, rhinorrhoea and nasal congestion. These symptoms are associated with disturbed sleep, lack of physical activity and absenteeism from schools etc<sup>5</sup>. Excessive rubbing of nose and cleaning the nose repeatedly also

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causes erythema and excoriation of vestibular skin. A late-phase allergic reaction occurs approximately 4 to 12 hours after antigen exposure, with nasal congestion as the predominant symptom. Therapeutic options for allergic rhinitis include avoidance measures, oral antihistamines, intranasal corticosteroids, leukotriene receptor antagonists and immunotherapy. Allergen avoidance is a key factor and first line measure in the therapeutic options. Barrier protection measures for avoiding contact with allergens, such as nose filters, nasally applied cellulose powders and micro-emulsions/ointments are being increasingly developed and evaluated in patients with allergic rhinitis<sup>6,7</sup>. These emulsions and ointments exert their protective effect by creating a lipid barrier which prevents allergens being deposited onto the nasal mucosa and reaching the specific IgE of the mucosal immune system cells<sup>7</sup>.

### MATERIAL AND METHODS

This randomized controlled trial was performed at the ENT department, Combined Military Hospital (CMH) Bahawalpur from July 2014 to August 2015. Total 300 patients of allergic rhinitis fulfilling the inclusion criteria were

below six years of age were not included in the study. Consent was taken from patients before start of the study. The cases were randomly divided into two groups of 150 each through convenience sampling. Group A cases were given oral antihistamine (Cetirizine HCl), intranasal corticosteroids (flunisolide) and commonly used lipid based ointment (petroleum jelly) for intranasal application. All the cases included were instructed with practical demonstration how to apply petroleum jelly intranasally with the help of cotton bud and little finger. Group B patients were given oral antihistamine (Cetirizine HCl) and intranasal corticosteroid (flunisolide). Patients individual symptom score and total symptom score (TSS) was recorded at the start of treatment and after 2 weeks of treatment. Each of the symptoms of allergic rhinitis (sneezing, itching/burning, rhinorrhoea, nasal congestion) were rated using a 4 point scale ranging from 0 (none) to 3 (severe). All these assessments were then added to calculate the total symptom score (TSS), the maximum of which could be 12. All the patients in both groups were assessed before the start of treatment and after 2 weeks and individual symptom scores along with total



**Figure: Comparison of TSS (total symptom score) before and after treatment between two groups.**

selected from outpatient department of CMH Bahawalpur. Inclusion criteria for allergic rhinitis included symptoms of sneezing, itching, rhinorrhoea, nasal congestion. Patients included were not having any treatment for allergic rhinitis for the last one month. Patients having sensitivity to petroleum jelly, infection, nasal polyposis, deviated nasal septum, and recent nasal surgery were excluded from study. Patients

symptom scores (TSS) were compared between both groups.

Data were analyzed using statistical package for social sciences (SPSS) version 19. Frequency and percentage were calculated for qualitative variables while mean and standard deviation (SD) were calculated for quantitative variable. Independent samples t-test was used to compare the quantitative variable while chi square test

was used to compare qualitative variable between the two groups. A  $p$ -value  $<0.05$  was considered significant.

## RESULTS

In the study total 300 patients were included, 150 in each group. There were 51 females (34%) in group A and 99 (66%) males. In group B, there were 57 (38%) females and 93 (62%) males. Mean age of cases in group A was

$2.51 \pm .57$  and in group B was  $2.44 \pm .61$ . After the treatment, mean symptom score in group A came to be  $1.27 \pm .93$  and in group B was  $1.80 \pm .96$ . Mean TSS i.e. total symptom score in group A was  $9.70 \pm 2.26$  and in group B was  $9.70 \pm 2.29$  before start of treatment. TSS came to be  $5.38 \pm 3.75$  and  $6.34 \pm 3.83$  in group A and B respectively showing a significant difference between the two groups ( $p=0.029$ ) (fig). From the results it is evident that the treatment including petroleum

**Table-I: Comparison of individual symptom scores & total symptoms score (TSS).**

Symptoms	Before start of treatment			After 2 weeks of treatment		
	Group A (n=150) Mean $\pm$ SD	Group B (n=150) Mean $\pm$ SD	$p$ value	Group A (n=150) Mean $\pm$ SD	Group B (n=150) Mean $\pm$ SD	$p$ value
Sneezing	$2.58 \pm .49$	$2.56 \pm .49$	.642	$1.26 \pm .94$	$1.30 \pm .98$	.676
Rhinorrhoea	$2.44 \pm .61$	$2.51 \pm .55$	.326	$1.38 \pm .93$	$1.79 \pm .92$	.000
Nasal congestion	$2.15 \pm .74$	$2.18 \pm .76$	.761	$1.46 \pm 1.05$	$1.44 \pm 1.10$	.873
Itching and Burning	$2.51 \pm .57$	$2.44 \pm .61$	.335	$1.27 \pm .93$	$1.80 \pm .96$	.000
Total symptom score(TSS)	$9.70 \pm 2.26$	$9.70 \pm 2.29$	1.00	$5.38 \pm 3.75$	$6.34 \pm 3.83$	.029

$36.04 \pm 14.10$  years and in group B was  $35.14 \pm 14.12$  years. During the study there were two cases who reported sensitivity to petroleum jelly i.e intense itching over area of application and they were excluded from study.

Mean symptom score of sneezing in group A patients before start of treatment was  $2.58 \pm .49$  and in group B was  $2.56 \pm 0.49$ . After two weeks of treatment this score came to be  $1.26 \pm .94$  and  $1.30 \pm .98$  in both groups respectively. Mean symptom score of rhinorrhoea in group A patients before start of treatment was  $2.44 \pm .61$  and in group B was  $2.51 \pm .55$ . However after two weeks of treatment this score came to be  $1.38 \pm .93$  and  $1.79 \pm .92$  in groups A and B respectively. Mean symptom score of nasal congestion in group A patients before start of treatment was  $2.15 \pm .74$  and in group B was  $2.18 \pm .76$ . After two weeks of treatment the mean score was  $1.46 \pm 1.05$  and  $1.44 \pm 1.10$  in both groups respectively. Mean symptom score nasal itching and burning in group A patients before start of treatment was

jelly caused a significantly better total symptoms control,  $1.24$  vs  $2.33$  ( $p=0.000$ ). However as far as the individual symptom scores are concerned, best effect of petroleum jelly was seen on nasal itching/burning and rhinorrhoea ( $p=0.000$ ). Otherwise both the treatments had almost similar effect on sneezing, rhinorrhoea and nasal congestion as shown in table.

## DISCUSSION

Petroleum jelly also known as petrolatum or white petrolatum is a semi solid lipid based ointment which is a mixture of long chain hydrocarbons. It is commonly used for dry skin, nasal dryness and to prevent nasal crusting. It is very safe with rare sensitivity. During our study five cases reported sensitivity to jelly i.e intense itching over area of application. There is only one published case report of lipid pneumonia caused by its intranasal application<sup>8</sup>. Otherwise many studies have been carried out and show no significant side effects<sup>9</sup>. Petroleum jelly exerts its effect by forming a barrier layer and preventing

access of allergens to the mucosa. Various studies have been performed which indicated beneficial effects of applying barrier ointments in allergic rhinitis. In the study performed by Ojeda et al, a similar emulsion was used for intranasal application and it showed significant reduction in the total nasal symptom score and no side effects were observed<sup>7</sup>. Similar results were shown in the study performed by Andersson et al<sup>10</sup>. Andersson et al performed another single blinded, placebo controlled study and they showed a significant drop in a 2-macroglobulin levels in nasal lavage fluid indicating decrease in inflammation<sup>11</sup>. Schwetz found in their study that the blocker was significantly more effective than placebo and reduced the typical symptoms of allergic rhinitis in response to nasal challenge with allergen by nearly 60% as compared to placebo which reduced symptoms by 25%<sup>12</sup>. Geithoff et al also reported significant reduction in overall symptoms after application of lipid based ointment in allergic rhinitis<sup>13</sup>. In our study there was significant reduction in TSS (total symptom score) in the group of patients using additional petroleum jelly along with standard treatment of allergic rhinitis than the other group which was using only the standard treatment (oral antihistamines and nasal corticosteroids). It is obvious that one can not apply this barrier ointment over whole of the nasal mucosal surface but it can reduce the overall load of daily allergens and can be helpful in decreasing symptoms of nasal allergy. Anterior accessible area which can easily be covered with petroleum jelly to decrease the overall burden of allergens is sufficient for the purpose.

According to the results of present study and all the other similar studies it is evident that lipid based ointment such as petroleum jelly has much efficacy and very low side effect profile. These ointments can be considered a promising adjuvant therapy for allergic rhinitis. They have

additional benefit of reducing nasal erythema and excoriation which is caused by excessive rubbing and cleaning of nose due to itching.

## CONCLUSION

A commonly available lipid based ointment petroleum jelly is a safe and effective adjuvant therapy for allergic rhinitis.

## CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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