

ALLERGIC RHINITIS

EFFECT OF TOPICAL STEROIDS ON MUCOCILIARY CLEARANCE AND NASAL SYMPTOM SCORE

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ABSTRACT... Introduction: Allergic rhinitis is one of the most common ENT diseases in Faisalabad. The affects of topical steroids on nasal mucosal environment has not been studied reliably. **Objectives:** To see the affects of topical steroids on symptom score and mucociliary clearance in Allergic Rhinitis. **Rationale:** To see whether symptom score change with change in mucociliary clearance after topical application of steroids. **Study design:** A quasi-experimental study. **Setting:** ENT Unit, Madina Teaching Hospital, Faisalabad (a tertiary care hospital). **Subjects: (sample, sampling technique):** Non-probability convenience sampling. Fifty patients in total. **Intervention:** Saccharine with dye: india ink (Indigocarmine) application on anterior end of inferior turbinate to check mucociliary clearance. **Methods (Main outcome measures):** To assess change in mucociliary clearance time and symptom score (total as well as individual) before and after application of steroid at one, three and six months in patients having allergic rhinitis. Each nasal symptom was scored as zero to 3 on a severity scale (absent-mild-moderate-severe). **Results:** Patients were tested for nasal mucociliary clearance and symptom score before and after application of steroid. The results showed statistically significant difference in these groups. **Conclusions:** 1. Topical steroids modify the nasal mucosal environment in terms of mucociliary clearance and thus affects the patients quality of life in terms of allergic rhinitis symptom score 2. More long term follow up and wider studies are required to study the definite affects of steroids on nasal mucosa.

Keywords: Mucociliary Clearance, Topical Steroids, Saccharine.

INTRODUCTION

Allergic rhinitis affects between 10-15%¹ of the population in England but its prevalence in Pakistan has never been estimated reliably. Most common nasal symptoms of allergic rhinitis are nasal obstruction, rhinorrhoea, itching and sneezing. Nasal congestion associated with allergic rhinitis has been shown to be the most bothersome symptom. The common nasal symptoms of obstruction, rhinorrhea, itching and sneezing are usually used to document symptom severity scale to see the effects on quality of life and to determine outcome of different treatment regimes. Nasal mucociliary clearance is the first line of defense of the ciliated epithelium of the respiratory tract against inhaled particles². Allergic rhinitis causes an impairment of the mucociliary function in the nose^{3,4,5}. Medical treatment in the form of topical nasal sprays and systemic antihistamines are usually the first line treatment in these conditions. Antihistamines and topical steroids has been used quite extensively in the treatment of allergic rhinitis either alone or in combination to control the nasal symptoms. There is good evidence, in the form of randomized controlled trials, to support the use of topical nasal steroids^{6,7}.

Effects of topical steroids on nasal mucosal environment

and patient symptomatology has never been studied in any institution of Pakistan. Although mucociliary clearance time has been shown to be impaired in patients with allergic rhinitis^{3,4,5,8} but the long time studies on the effects of topical steroids on it and thus on symptom score are lacking. This study aims to evaluate subjectively as well as objectively some of the variables in this context. Aim/Objective/purpose: To see the effects of topical steroids on mucociliary clearance in Allergic Rhinitis. Rationale: To see change in symptom score with change in mucociliary clearance.

MATERIALS AND METHODS

A quasi-experimental study of six months duration with non-probability convenient sampling was conducted at Department of Otolaryngology, Madina Teaching Hospital, Faisalabad from June 2009 to December 2009. Madina Teaching Hospital is an 700 bed teaching, tertiary care welfare Hospital covering both rural and urban population. Fifty patients of lower and middle class between 20-40 years of age both male and females having history of allergic rhinitis were included in the study. Inclusion criteria was patients having history of allergic rhinitis with positive skin prick test, raised IgE levels, eosinophilia on blood smear/nasal smear eosinophilia, basophilia and raised neutrophil count.

Exclusion criteria was concomitant asthma and other co morbidities, history of any other nasal disease or previous history of nasal surgery. All the patients were thoroughly interviewed and complete ENT examination including nasal endoscopy with 0, 30, and 70 degree telescopes was done. Subjective assessment of the patient by the clinician was done. The nasal symptoms of obstruction, rhinorrhoea, sneezing and itching were graded from zero to three (absent, mild, moderate and severe) depending upon the severity of the symptoms. The sum of individual nasal symptoms gave total symptom score(TSS). The objective measure included was mucociliary clearance time which was assessed by application of saccharine mixed with indigo carmine 1cm behind the anterior end of inferior turbinate. The time taken until the patient tastes sweet/ change of color in oropharynx just below the soft palate since its application was noticed by the examiner. The test was carried out at 30 degree room temperature and on sunny days only.

The nasal symptom score, total symptom score(TSS) and mucociliary clearance time(MCCT) was assessed before(zero) and at one, three and six months after the application of beclomethasone dipropionate nasal spray (440microgram/day).

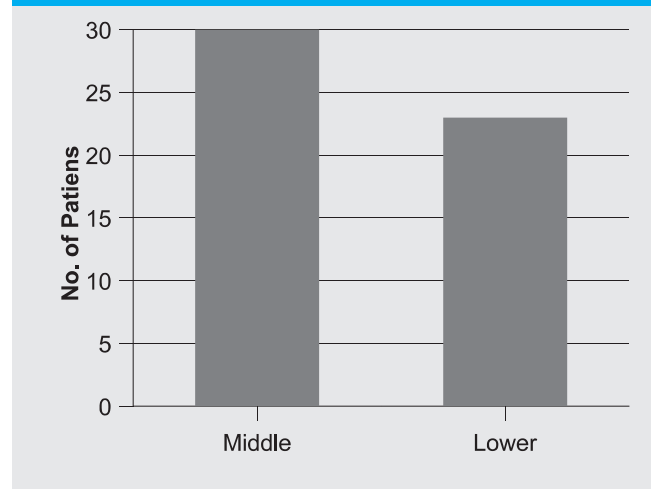
STATISTICAL ANALYSIS

Data analysis was performed using a commercial statistics program (statistical package for social sciences) computer program (SPSS, version 17, Chicago, IL). z-test was used for continuous variable and chi-square test was used for nominal and ordinal variables.

RESULTS

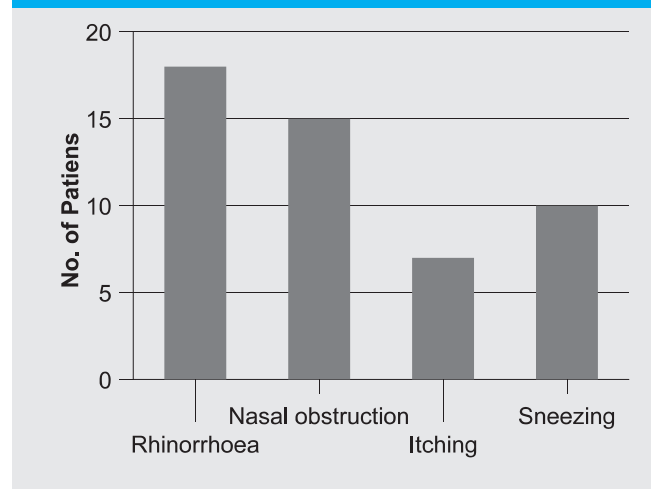
Fifty patients presented through outdoor. Twenty two out of fifty (44%) were females and the rest (56%) were males. All of them were 20 years and above. Mean age of presentation was 25.46 years. All of them belong to lower/middle class of socioeconomic strata. 40% belonged to middle class and 60% to lower class (Fig-I).

Fig-1. Socioeconomic status



All the patients were interviewed thoroughly. 20% presented with sneezing as their major complaint, 12% with itching, 38% with rhinorrhoea and 30% with nasal obstruction (Fig-II).

Fig-2. Major presenting complaints



79% had history of seasonal allergic rhinitis in one of their parents also. All the patients underwent full ENT examination. 67% had mild and 33% had moderate inferior turbinate hypertrophy at the time of presentation.

All of them also had mild to moderate hypertrophy of their middle turbinates. All the patients were positive for blood and nasal smear eosinophilia. Nasal smear cytology was also positive for basophilia and neutrophilia. 59% had

Table-1. Mean Total symptoms score and mucociliary clear time

	TSS (Total Symptom Score)	MCCT (Mucociliary Clearance time)
0 / M	7.8	13.5 Minutes
01 / M	2.72	9.2 Minutes
03 / M	2.28	9.1 Minutes
06 / M	1.62	9.2 Minutes

0/M - Before steroid application
03/M - Three month after steroid application

01/M - One month after steroid application
06/M - Six month after steroid application

Table-2. Mean Individual nasal symptom score

	Nasal Obstruction	Rhinorrhea	Sneezing	Itching
0 / M	2	2.48	2.08	1.28
01 / M	0.54	1.04	0.82	0.36
03 / M	0.44	0.78	0.72	0.34
06 / M	0.36	0.48	0.58	0.2

0/M - Before steroid application
03/M - Three month after steroid application

01/M - One month after steroid application
06/M - Six month after steroid application

positive skin prick test for various allergens which are more prevalent in Faisalabad. All had total IgE count above 500mg/dl. Mucociliary clearance test with saccharine and dye (india ink) was performed in all those who gave consent to participate in the study. Rinoclenil (beclomethasone) nasal spray at a dose of 110 micrograms to each nostril twice a day was administered for the next six months. Mucociliary clearance time was measured again at one, three and six months interval. Symptom scores were measured before steroid application and at one, three and six month after steroid application. There were no drop outs in the follow up period. Only two patients out of 50 presented one and three days later than their scheduled follow up. A significant difference was observed in nasal mucociliary clearance before and after steroid application ($P < 0.05$).

Steroid application significantly decreased the total symptom score ($P < 0.05$) as well as individual nasal symptom scores of nasal obstruction, rhinorrhoea, sneezing and itching ($P < 0.05$) (table-I and II).

DISCUSSION

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 are considered to be the most effective treatment of rhinitis. Although current literature suggests that the use of intranasal steroids is quite safe^{7,9,10} increasing indication of prolonged administration fuel the debate regarding long term effect on local nasal structure

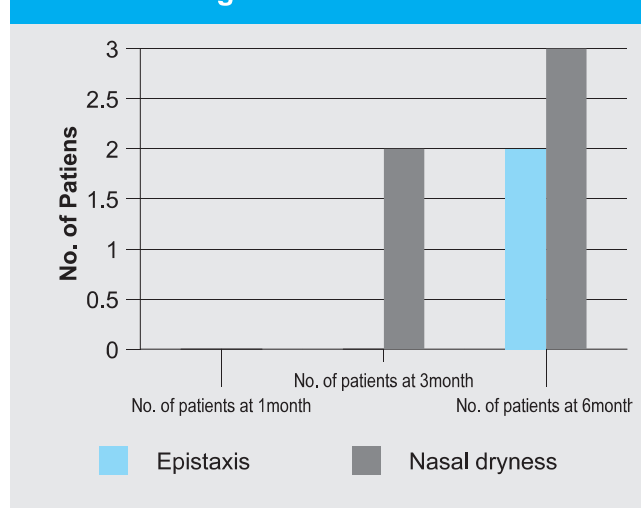
and functions. Rationale behind using beclomethasone for our study was that it was cost effective and funded by the hospital so its compliance in our low and middle class set of patients was excellent. Moreover there is no significant difference in efficacy between the various preparations^{7,9,11}. Although the steroids are shown to be effective as early as 12 hours¹² and attain their maximum effect in few days⁷, we measured the initial response after one month to have a safe cushion to see the initial response and then at third month and after six months period to see if the initial improvement of symptoms and mucociliary clearance persists with continuous usage of drug. We also monitored any change in nasal mucosa macroscopically or in MCCT, any adverse effect of the drug on either and whether the symptom control is related to mucociliary clearance. The nasal obstruction is one of the most bothersome symptom in a vast majority of patients^{13,14} and effects night time sleep and thus has a direct effect on quality of life¹⁵.

The rhinorrhoea, sneezing and itching effects day time work more significantly. The symptoms are associated with an impairment of mucociliary clearance^{4,5} which may be used to divide the patients into different categories according to the severity for treatment purposes or research work. Our study showed a significant improvement in TSS ($P < 0.05$), INSS of nasal obstruction, rhinorrhoea, sneezing and itching ($P < 0.05$) and MCCT ($P < 0.05$) after one month of topical steroid therapy showing that beclomethasone topical spray used alone is quite effective in controlling symptoms of seasonal allergic rhinitis and improves MCC (table-I and II). A number of studies^{16,17,18,19,20} has shown similar results. We also studied whether this improvement in TSS, INSS can be documented objectively by measuring improvement in MCCT. A study by Lee and Gendeh²¹ showed some improvement in MCCT after eight weeks of treatment though that improvement was not statistically significant. Our study showed a significant improvement in MCCT after four weeks of treatment indicating objectively the efficacy of drug in controlling the disease. Similar studies conducted with other topical steroids has shown same type of results^{22,23}. Previous studies on allergic rhinitis has shown correlation between symptomatology and mucociliary clearance but those studies were done before the initiation of therapy^{4,5}. We

studied the relationship between the improvement of symptoms (total as well as individual) and mucociliary clearance both subjectively and objectively with topical steroid therapy at one, three and six months (table-I and II) and has shown same type of relation suggesting that improvement of patients symptoms can be documented objectively by measuring the mucociliary clearance time. The saccharine mixed with indigo carmine is a standard method of measuring the mucociliary clearance time. In literature, rhinomanometry is used to objectively document the nasal obstruction by nasal airflow studies²² and rhinoscintigraphy² for mucociliary clearance time which we have not used due to shortage of resources.

The improvement in TSS, INSS and MCCT were studied at third and six months to see if the initial improvement in symptoms and MCC persisted with continuous usage of the drug or to document any bad effect of drug on nasal mucosal functions. The study revealed that improvement in TSS, INSS and MCCT persisted with continuous usage though further improvement at third and six months compared to improvement in the first month is not statistically significant suggesting that persistent usage of topical steroid (beclomethasone) does not impair MCC and thus have no significant bad effect on nasal mucosal function. The INSS at one, three and six months was analyzed to see if an improvement in TSS is a true representative of improvement in INSS which proved to be true. We studied the safety of drug by measuring the effect of drug on nasal mucosa

Fig-3. Adverse effects



macroscopically, MCCT or any other adverse effects. Macroscopically the color of nasal mucosa remain unaffected after six months of therapy. The improvement in MCCT with the continuous usage of drug remained continuous although that was not statistically significant. We reviewed the adverse effects of therapy on nasal mucosa but only two patients got mild epistaxis (4%) and three (6%) developed grade I nasal dryness after six months of therapy (Fig-III). So, we can conclude that beclomethasone nasal spray is quite effective for control of symptoms of allergic rhinitis and agree that long term usage of topical intranasal steroids is quite safe^{7,9,10,24,25} with no significant adverse effects on local nasal structure and functions. No one study is definite. Further refined studies under similar environment with larger group of patients is needed.

CONCLUSIONS

1. Topical steroids modify the nasal mucosal environment in terms of mucociliary clearance and thus affects the patients quality of life in terms of allergic rhinitis symptom score.
2. More long term follow up is required to study the definite affects of steroids on nasal mucosa.

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**“A hero is no braver than an ordinary man,
but he is braver five minutes longer.”**

(Ralph Waldo Emerson)