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ORIGINAL RESEARCH ARTICLE

SAFETY PROFILE OF INTRANASAL CORTICOSTEROIDS USED AS TREATMENT IN ALLERGIC RHINITIS PATIENTS ATTENDING ENT OPD AT A TERTIARY CARE CENTRE: A COMPARATIVE STUDY

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ABSTRACT:

Background: Treatment guidelines for allergic rhinitis (AR) recommend use of intranasal corticosteroids (INSs) as mono or adjunctive therapy. However, the adverse event (AE) profiles of oral glucocorticoids, which result largely from systemic absorption of these agents, have raised concerns about their safety. These concerns persist for INSs despite marked clinical differences between them and systemic corticosteroids in absorption and among the INSs in bioavailability, mechanism of action, and lipophilicity, which may contribute to differences in AEs.

Objective: To study the safety profile of different topical intranasal steroids used for treatment of allergic rhinitis and comparison oftheir efficacy and adverse events.

Study design: Prospective study

Setting: This study was conducted in ENT department at Era's Lucknow Medical College and Hospital, Lucknow

Patients: 135 patients of allergic rhinitis.

Results: The statistical tests applied were **repeated measures ANOVA** and the **chi squared** tests.

Conclusions: From this study it can be concluded that the three INS showed beneficial effect on allergic rhinitis. However, with respect to side effects and diminution of symptom scores, nasal endoscopy score and AEC count no significant difference among the groups was found. All three groups were almost similar in their treatment efficacy and side effect profile.

Keywords: Intranasal steroids (INS), allergic rhinitis (AR), adverse events (AE), Fluticasone propionate (FP), Mometasonefuroate (MF), Fluticasone Furoate (FF).

INTRODUCTION:

Allergic rhinitis (AR) is a highly prevalent, chronic disease, with variable reported rates. It was previously regarded as a trivial disease and was often ignored, however, in recent literature its prevalence has been reported to range from 10% - 30% of all adults and as many as 40% of children (Wallace et al., 2008)[1]. In some populations its prevalence rate is reported to be as high as 50% (Bauchau et al., 2005; Katelaris et al., 2012)[2,3]. According to some studies in India (Chhabra et al., 1998; MOEF, 2000; Gaur et al., 2006)[4,5,6] the prevalence of allergic rhinitis in India is around 11-30%.

The approach for treament of AR is based on the patient's age and symptoms severity. Patients are advised to avoid known allergens and they should be educated about their condition. Intranasal corticosteroids have been reported to be the most effective treatment and should be first-line therapy for mild to moderate disease. Moderate to severe disease not responsive to intranasal corticosteroids is treated with second-line therapies, including antihistamines, decongestants, leukotriene receptor antagonists, intranasal mast cell stabilizers and other therapies like nasal irrigation. Immunotherapy is considered in patients with a less than adequate response to usual treatments (Sur et al., 2010)[7].

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The use of intranasal corticosteroids has been found to be highly effective in treating both intermittent and persistent allergic rhinitis. The control of nasal symptoms is achieved in at least 75% of patients, with comparable results in children and adults. Intranasal corticosteroid administration reduces all symptoms of allergic rhinitis including rhinorrhea, itching, sneezing, and blockage, and in some cases relieves eye symptoms. (Welch, 1993)[8].

Currently, the following intranasal corticosteroids are commercially available and approved by FDA for treatment of AR, *viz.*beclomethasonedipropionate (BDP), budesonide (BUD), flunisolide, fluticasone propionate (FP), mometasonefuroate (MF), and triamcinolone acetonide (TAA) (Herman, 2007)[9].

Although topical intranasal steroids are the suggested first line of therapy for AR, however, response to different topical intranasal steroids for treatment of AR is varying (Mandl et al., 1997,Kariyawasam&Scadding, 2010,Aneeza et al., 2013) [10, 11, 12]. However, systematic reviews and some clinical studies indicate that almost all the commercially available topical intranasal steroids have a similar efficacy in treatment of AR and only differences in sensory attributes, documented safety during pregnancy, and cost may contribute to better patient's acceptance of one versus another and promote better adherence to therapy (Herman, 2007;Varshney et al., 2015)[9, 13].

Keeping in view, the lack of a definitive conclusion regarding the comparative safety profile of different topical intranasal steroids in AR, the present study was carried out with an attempt to focus on the efficacy, adverse events and compliance related with different topical intranasal steroids in our settings.

RESEARCH QUESTION

What is the safety profile of various intranasal steroids used for treatment of allergic rhinitis?

AIMS AND OBJECTIVES

The present study was carried out with the following aim and objectives:

AIM

- To study the safety profile of different topical intranasal steroids used for treatment of allergic rhinitis.

OBJECTIVES

- To compare the efficacy of different topical intranasal steroids in patients with allergic rhinitis
- To assess the adverse events of different topical intranasal steroids in patients with allergic rhinitis
- To evaluate the compliance of patients with allergic rhinitis using different topical intranasal steroids

METHODS:

The present study was conducted in the ENT department at Era's Lucknow Medical College and Hospital, Lucknow to compare MometasoneFuroate (MF), Fluticasone Furoate (FF) and Fluticasone Propionate (FP) intranasal sprays given in management of allergic rhinitis patients.

Study Design: A Prospective study.

Study Period: 24 Months (January2015 to January2017)

Sample size: The sample size for the study was calculated from the Department of Community Medicine, Era's Lucknow Medical Collegebased on the study of Gross *et al*. (2002).

The Sample size came out to be, n = 45 in each group.

Inclusion Criteria

- Patients presenting with symptoms and signs suggestive of both intermittent and persistent allergic rhinitis between 10 years to 60 years of age.

Exclusion criteria

- Patients with severe DNS causing nasal obstruction, nasal polyp.
- Patient who had taken oral or topical steroid in the last 3 months.
- Any systemic disease (Hypertension, Diabetes Mellitus)
- Any chronic illness (Tuberculosis, Asthma).
- Pregnant and lactating women.

Subjects

The patients having allergic rhinitis attending ENT OPD were invited to participate in this study. The diagnosis was made on the basis of history and clinical examination. Out of these, 135 patients of allergic rhinitis fulfilling the inclusion criteria and not falling into the domain of exclusion criteria were included in the study. Before inclusion into study, patients were properly informed regarding the nature of disease process and the proposed interventions. Written and informed consent was taken. Patients were randomly divided in three groups of 45 patients each, and were administered three proposed medications as under:

Medications:

1. Group I: 45patients were administered Fluticasone furoate 110 microgram once daily, administered as two actuation in each nostril once daily (each spray delivers 27.5 microgram of drug).
2. Group II:45 patients were administered Fluticasone Propionate 200 microgram once daily, administered as two actuation in each nostril once daily (each spray

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delivers 50 microgram of drug).

3) Group III:45 patients were administered Mometasonefuroate

4) 200 microgram once daily, as two actuation in each nostril once daily (each spray delivers 50 microgram of drug).

METHODOLOGY

Patients were selected consecutively as and when they presented during the study period considering the inclusion and exclusion criteria and randomly allotted to the groups by computer generated software.

Procedure

A detailed history and clinical examination of patients of allergic rhinitis was done. Subjective scoring for rhinitis symptoms, diagnostic nasal endoscopy and absolute eosinophil count was done in all the patients and was repeated at every visit. On subsequent visits the patients were also enquired about the onset of action and any adverse events. All the demographic data, investigative findings were compared among the above groups.

Evaluation of nasal symptoms

The subjective scoring of rhinitis symptoms was done using the Visual Analog Scale of 1 to 10, with 1 representing 'least' and 10 'worst'. Symptom score was assessed for following four symptoms nasal obstruction, watery nasal discharge, sneezing, and nasal itching. Mean of the symptom scores for the four individual symptoms were calculated on each visit.

Nasal endoscopy score

Diagnostic nasal endoscopy was performed on each patient with a 4 mm 0° endoscope. Before endoscopy both nostril were packed with gauze soaked in 4% xylocaine for 20 minutes. The nasal endoscopic findings were graded for following signs: Discharge (Scores of 0, none; 1, mucoid discharge present), Nasal mucosa color (0, pink; 1, pale or bluish), Swollen edematous turbinates (0, absent; 1, present). The scores of right and left nasal cavities were calculated separately and were averaged to obtain combined DNE score.

Absolute eosinophil count- The absolute eosinophil count was performed on venous blood drawn from patients' cubital vein using standard technique. The eosinophil count of more than 440 cells/cumm was considered as positive for blood eosinophilia.

Adverse events- Patients were asked to record any adverse event of the drug and to seek immediate consultation if they were serious. Patients were enquired for any adverse events on each visit.

Follow up

Patients were followed for 3 weeks, with visits to hospital as follows.

- 1st visit- at the start of treatment
- 2nd visit-after 7 days
- 3rd visit-after 14 days
- 4th visit-after 21 days

STATISTICAL TOOL EMPLOYED

The statistical analysis was done using **SPSS (Statistical Package for Social Sciences) Version 23.0 statistical Analysis Software**. The statistical tests applied were **repeated measures ANOVA** and the **chi squared tests**. The values were represented in Number (%) and Mean ± SD.

RESULTS:

This study was carried out in the ENT Department, Era's Lucknow Medical College & Hospital, Lucknow comparing Fluticasone furoate (FF), Fluticasone Propionate (FP), MometasoneFuroate (MF) nasal spray for management of allergic rhinitis. A total of 154 patients were enrolled in the study and 19 patients were lost in follow up. A total of 135 patients fulfilling the inclusion criteria and not falling into the domain of exclusion criteria were enrolled in the study. These patients were randomly divided into three groups as under:

Table 1: Distribution of Study Population.

S. No.	Group	Nasal Spray Used	No. of patients	Percentage
1-	Group I	Fluticasone furoate	45	33.33
2-	Group II	Fluticasone propionate	45	33.33
3-	Group III	Mometasone furoate	45	33.33
		Total	**135**	**100.00**

Out of 135 patients included in the study, 45 (33.33%) were administered Fluticasone furoate (Group I), another 45 (33.33%) were administered Fluticasone propionate and rest 45 (33.33%) were administered Mometasonefuroate.

On Visit 1, average symptom score was found to be maximum for Group II (7.51±1.16) followed by that for Group III (7.47±1.27) and minimum for Group I (7.36±1.21). Difference in average symptom score among the above three groups was not found to be statistically significant (p=0.811).

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Table 2: Intergroup Comparison of Average Symptom Score at different visits.

Visit	Group I n=45		Group II n=45		Group III n=45		ANOVA F	ANOVA p
	mean	sd	mean	sd	mean	sd		
Visit1	7.36	1.21	7.51	1.16	7.47	1.27	0.196	0.822
Visit2	4.91	1.12	4.95	1.07	4.96	1.13	0.024	0.976
Visit3	3.98	1.08	3.89	1.05	3.91	1.06	0.085	0.918
Visit4	2.78	0.93	2.73	1.07	2.73	0.89	0.032	0.969
F	389.36		489.13		417.25			
p-value	<.0001		<.0001		<.0001			

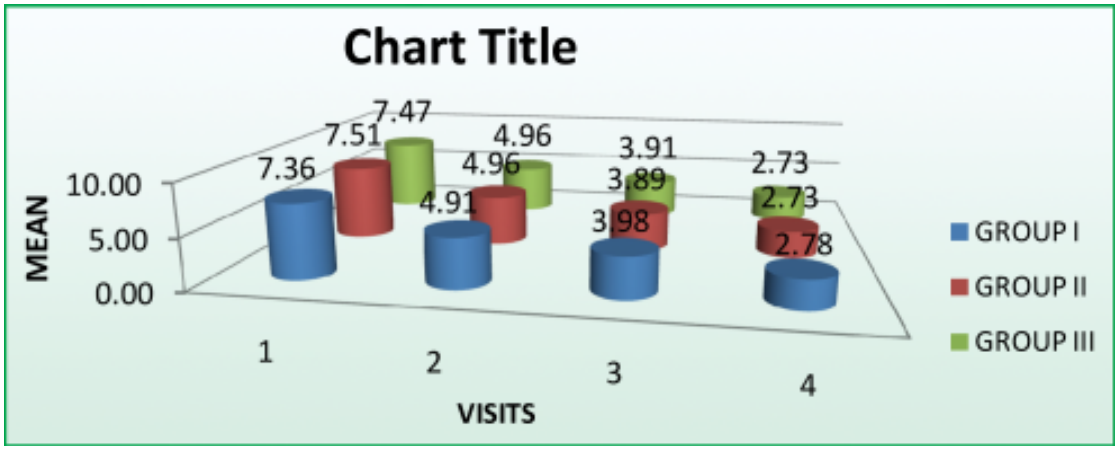

FIG-1 scores in relation to visits.

On Visit 2, average symptom score of Group III (4.96±1.13) was found to be higher than that of Group II (4.95±1.07) and Group I (4.91±1.12) but difference in average symptom score among the groups was not found to be statistically significant (p=0.976).

On Visit 3, average symptom score of Group I (3.98±1.08) was found to be higher than that of Group III (3.91±1.06) and Group II (3.89±1.05) but difference in average symptom score among the groups was not found to be statistically significant (p=0.918).

On Visit 4, average symptom score of Group I (2.78±0.93) was found to be higher than that of Group II (2.73±1.07) and Group III (2.73±0.89) but difference in average symptom score among the groups was not found to be statistically significant (p=0.969).

On comparing the average symptom scores of the three Groups from the first visit to the fourth visit, the decrease in average symptom scores was found to be highly significant (p<0.0001) in all the three Groups.

On Visit 1, nasal endoscopy score for Group I (2.87±0.34) was higher than that of Group II (2.76±0.43) and Group III (2.78±0.42). Difference in nasal endoscopy score among the above three groups was not found to be statistically significant (p=0.384).

On Visit 2, nasal endoscopy score of Group II (1.82±0.68) was found to be higher than that of Group III (1.73±0.65) and Group I (1.80±0.63) but difference in nasal endoscopy score among the groups was not found to be statistically significant (p=0.799). On Visit 3, nasal endoscopy score of Group I (1.36±0.61) was found to be higher than that of Group III (1.33±0.64) and Group II (1.31±0.60) but difference in nasal endoscopy score among the groups was not found to be statistically significant (p=0.943).

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Table 3 : Intergroup Comparison of Nasal Endoscopy Scores at different time interval.

Visit	Group I n=45		Group II n=45		Group III n=45		ANOVA F	ANOVA p
	mean	sd	mean	sd	mean	sd		
Visit 1	2.87	0.34	2.76	0.43	2.78	0.42	0.965	0.384
Visit 2	1.80	0.63	1.82	0.68	1.73	0.65	0.225	0.799
Visit 3	1.36	0.61	1.31	0.60	1.33	0.64	0.059	0.943
Visit 4	0.78	0.60	0.69	0.56	0.67	0.52	0.496	0.610
F	180.377		165.31		176.7			
p-value	<.0001		<.0001		<.0001			

On Visit 4, nasal endoscopy score of Group I (0.78+0.60) was found to be higher than that of Group II (0.69+0.56) and Group III (0.67+0.52) but difference in nasal endoscopy score among the groups was not found to be statistically significant (p=0.61).

On comparing the nasal endoscopy scores of the three Groups from the first visit to the fourth visit, the decrease in nasal endoscopy scores was found to be highly significant (p<0.0001) in all the three Groups.

On Visit 1, absolute eosinophil count for Group I (522.22±191.77) was higher than that of Group II (517.22±163.32) and Group III (512.33±144.04). Difference in absolute eosinophil count among the above three groups was not found to be statistically significant (p=0.962).

On Visit 2, absolute eosinophil count of Group II (469.33±94.83) was found to be higher than that of Group I (465.56±104.65) and Group III (461.56±92.86) but difference in absolute eosinophil count among the groups was not found to be statistically significant (p=0.931).

On Visit 3, absolute eosinophil count of Group I (451.44±94.26) was found to be higher than that of Group II (447.51±66.53) and Group III (431.33±62.37) but difference in absolute eosinophil count among the groups was not found to be statistically significant (p=0.452).

On Visit 4, absolute eosinophil count of Group II (437.00±51.22) was found to be higher than that of Group I (425.11±56.56) and Group III (423.22±54.62) but difference in absolute eosinophil count among the groups was not found to be statistically significant (p=0.427s).

On comparing the absolute eosinophil countof the three Groups from the first visit to the fourth visit, the decrease in absolute eosinophil countwas found to be significant (p<0.001) in all the three Groups.

No side effect was observed in majority of patients included in the study (85.9%). Headache (5.9%) was the most common side effect in the study population followed by throat irritation (n=7; 5.2%), nasal burning (n=4; 2.96%) and least common side effect was epistaxis which was found in none of

Table 4: Intergroup Comparison of Absolute Eosinophil Count at different time.

Visit	Group I n=45		Group II n=45		Group III n=45		ANOVA F	ANOVA p
	mean	sd	mean	sd	mean	sd		
Visit 1	522.22	191.77	517.22	163.32	512.33	144.04	0.039	0.962
Visit 2	465.56	104.65	469.33	94.83	461.56	92.86	0.071	0.931
Visit 3	451.44	94.26	447.51	66.53	432.33	62.37	0.799	0.452
Visit 4	425.11	56.56	437.00	51.22	423.22	54.62	0.855	0.427
F	17.84		14.47		24.11			
p-value	<.001		<.001		<.001			

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Table 5: Intergroup Comparison of Side Effects in Study Population.

Side Effects	Total	%	Group I (n=45)		Group II(n=45)		Group III(n=45)	
	135	100	No.	%	No.	%	No.	%
No side effect	116	85.93	40	88.89	36	80	40	88.89
Any Side effect	19	14.07	5	11.11	9	20	5	11.11
Epistaxis	0	0	0	0	0	0	0	0
Headache	8	5.92	3	6.67	3	6.67	2	4.44
Nasal burning	4	2.96	0	0	3	6.67	1	2.22
Throat irritation	7	5.19	2	4.44	3	6.67	2	4.44
χ^2=3.9128 (df=8); p= 0.678								

the (0%) patients. Side effects were found in higher proportion of patients of Group II (20%) as compared to Group I (11.11%) and Group III (11.11%). Incidence of headache was found similar in patients of Group I (6.67%) and Group II (6.67%) as compared to Group III (4.44%). Incidence of throat irritation was higher in Group II (6.67%) as compared to Group I and Group III (4.44%). Incidence of nasal burning was higher in Group II (6.67%) as compared to Group III (2.22%) and Group I (0.00%). Difference in incidence of side effects in above three groups was not found to be statistically significant (p=0.678).

DISCUSSION:

Allergic rhinitis (AR) is an inflammatory condition of the upper airways that occurs in response to exposure to airborne allergens (typically tree, grass, and weed pollens and some molds) in sensitized individuals. It has an adverse effect on quality of life, sleep, cognition, emotional life and work performance[14].

In present study, at admission average symptom scores were 7.36±1.21, 7.51±1.16 and 7.47±1.27 respectively in FF, FP and MF groups (Table 2). Considering the fact score 1 represented least concern and 10 most concern, these scores were above the midpoint and hence were skewed towards higher concern. However, on first follow up itself (visit 2), the scores were at or close to midpoint values *viz.* 4.91±1.12, 4.95±1.07 and 4.96±1.13 respectively in FF, FP and MF groups. On every week the extent of decline in average symptom score showed an incremental pattern. On final follow up at week 3 (visit 4), the mean scores in FF, FP and MF groups were 2.78±0.93, 2.73±1.07 and 2.73±0.89 respectively, thus indicating that the scores were skewed towards least concern.

On comparing the average symptom scores of the three Groups from the first visit to the fourth visit, the decrease in average symptom scores was found to be highly significant (p<0.0001) in all the three Groups. All the groups encountered a significant reduction from trends towards most concern to trends towards least concern. A similar efficacy of MF and FP with respect to reduction in symptom score was also observed by Mandl*et al.* (1997)[10] among patients with perennial rhinitis. In their study the extent of reduction was 37% and 39% for MF and FP. In present study extent of reduction in symptom score was much higher 63.45% for MF and 63.6% for FP. Gupta and Gupta (2004)[15] in their study on adult patients with moderate to severe perennial allergic rhinitis compared MF and FP nasal sprays also observed significant reduction in symptom scores but did not find a significant difference between two drugs, a finding similar to present study. Thus the findings of present study also endorsed the findings of these studies which failed to find out a significant difference in symptom score reduction among the different drugs being evaluated in present study.

In present study, at baseline nasal endoscopy scores in FF, FP and MF groups were 2.87±0.34, 2.76±0.43 and 2.78±0.42 respectively (Table 3). At baseline the groups were matched. These scores were obtained for presence of three features, *viz.*, nasal discharge, nasal mucosa color and swollen/edematous turbinates, *i.e.* the maximum possible total score was 3. The mean scores, thus indicated the presence of all the 3 symptoms in majority of cases (mean values >2.5 for all the three groups) and as such a high order of severity. For these signs too, a significant reduction was observed from first follow up (visit 2) itself when mean scores in three groups

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became 1.80±0.63, 1.82±0.68 and 1.73±0.65 respectively. By the last follow up (visit 4), mean scores in three groups became 0.78±0.60, 0.69±0.56 and 0.67±0.52 respectively.

On comparing the baseline nasal endoscopyscores of the three Groups from the first visit to the fourth visit, the decrease in average symptom scores was found to be highly significant (p<0.0001) in all the three Groups. The efficacy of the three study groups was found to be similar at all the study intervals. Thus findings of nasal endoscopy score also reflected similar pattern of changes as observed for symptom scores. Similar to present study, Tsang *et al.* (2003)[16] in their study also showed that endoscopic scores follow similar trend of change as observed for clinical symptom scores among patients with allergic rhinitis undergoing treatment with topical corticosteroids. In present study, we used multiple criteria for validation. Although symptom scores are often criticized for their subjectivity, however, endoscopic scores are a better and more objective in nature. But, the pattern of response for three drugs did not alter.

Most of the studies in past have focused only on the symptomatic response, however, in present study we intended to correlate the symptomatic response with physiological changes too.

With respect to side effect profile, in present study majority of patients did not have any side effect (n=116; 85.93%) (Table 5). Headache was the most common side effect (n=8; 5.92%) followed by throat irritation (n=7; 5.19%), nasal burning (n=4; 2.96%) and epistaxis (n=0; 0%). Statistically, no significant difference among groups was observed with respect to side effects and their types. The side effects of nasal steroids are mild and may include headache, throat irritation, mildly unpleasant smell or taste or drying of the nasal lining. In some people, nasal steroids cause irritation, crusting, and bleeding of the nasal septum, especially during the winter. Use of a proper spray pattern can help to reduce these side effects. In present study, a careful demonstration of method of use was carried out and each patient was explained about the proper angulation and distance from nasal septum in order to avoid the problem of irritation and stinging. No major side effects were noticed in present study. None of the patient had to discontinue from study owing to presence of side effect. A low occurrence of adverse events while using FF and FP for treatment of perennial/seasonal AR was also reported by Meltzer *et al.* (2008).

On the basis of observations made in present study, all the three topical corticosteroids displayed similar efficacy and side effect profile. In present study, using multiple outcome criteria, it was established that all the three corticosteroids in question have a good efficacy in both symptomatic as well as physiological attenuation of seasonal allergic rhinitis. It is one of the pioneering studies that not only studied the outcome through various subjective as well as objective criteria but was also able to establish an association among different outcome criteria.

CONCLUSION:

The present study was carried out to compare Fluticasone furoate (FF), Fluticasone propionate (FP), Mometasonefuroate (MF) intranasal steroids for management of allergic rhinitis (AR). For this purpose a total of 135 patients of AR were selected. The following were the findings of this study:

1. At baseline (Visit 1) as well as at different follow up intervals (Visits 2 to 4) statistically no significant difference among the groups was observed with respect to average symptom score.
2. In all the groups, a declining trend of average symptom scores was observed with significant decline in average symptom scores from first follow up (visit 2). Mean change from baseline was maximum at 4th visit in all the groups.
3. At baseline (Visit 1) as well as at different follow up intervals (Visits 2 to 4) statistically no significant difference among the groups was observed with respect to average nasal endoscopy score.
4. In all the groups, a declining trend of average nasal endoscopy scores was observed with significant decline in mean endoscopy scores from first follow up (visit 2). Mean change from baseline was maximum at 4th follow up in all the groups.
5. At baseline (Visit 1) as well as at different follow up intervals (Visits 2 to 4) statistically no significant difference among groups was observed with respect to absolute eosinophil count.
6. In all the groups, a declining trend of absolute eosinophil count was observed with significant decline in mean value from first follow up (visit 2). Mean change from baseline was found to be maximum at 4th follow up in all the groups.
7. Majority of the patients did not have any side effect (n=116; 85.93%). Headache was the most common side effect (n=8; 5.92%) followed by throat irritation (n=7; 5.19%), nasal burning (n=4; 2.96%) and epistaxis (n=0; 0%). Statistically, no significant difference among groups was observed with respect to side effects and their types.

On the basis of above findings it can be concluded that all the three topical intranasal steroids showed a beneficial effect on allergic rhinitis. However, with respect to side effects

and diminution of symptom scores, nasal endoscopy score and AEC count no significant difference among the groups could be found. All the three groups were almost similar in their treatment efficacy and side effect profile.

DISCLOSURES:

(a) Competing interests/Interests of Conflict- None
(b) Sponsorships – None
(c) Funding – None
(d) Written consent of patient- Taken

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