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The role of budesonide and mometasone furoate on the nasal and sinus symptoms in allergic rhinosinuitis: a randomized study

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ABSTRACT

Background: Allergic rhinosinuitis is one of the common clinical problems that otorhinolaryngologist faces daily. Sinusitis symptoms like headache, facial pain and eyelid oedema are frequent in patients with allergic rhinitis, which in turn will affect the cognitive function, productivity and quality of life which impair the efficiency of the individual work performance. It may result in a prescription for antibiotics but the role of antibiotics is debated. Anti-inflammatory drugs such as intranasal steroids play a major role in reducing the symptoms of allergic rhinitis. We plan to compare the efficacy of budesonide nasal spray with mometasone furoate nasal spray in reducing the nasal and sinus symptoms of allergic rhinosinusitis.
Methods: 146 patients of allergic rhinitis with sinusitis symptoms were randomly divided into 2 groups as Group A (n=70) received 256 µg budesonide nasal spray of once daily and Group B (n=76) received 200 µg of mometasone furoate nasal spray daily. The patients were assessed by sino-nasal outcome test (SNOT) score and total nasal symptom score (TNSS) at 2, 6 and 12 weeks interval.
Results: There is significant reduction in both the groups, in respect to the SNOT and TNSS scores. We also observed significant improvement in the SNOT score in the budesonide group when compared with the mometasone furoate group by 6weeks which continued till the 12 weeks (p=0.001).
Conclusions: Budesonide nasal spray is more effective than mometasone furoate spray in managing both sinus and nasal symptoms in allergic rhinitis.

Keywords: Allergic rhinitis, Allergic rhino-sinusitis, Symptoms, Budesonide, Mometasone furoate, SNOT, TNSS, Intranasal steroids

INTRODUCTION

Allergic rhinosinusitis is characterized by extensive infiltration of the nasal and sinus mucosa by inflammatory cells such as eosinophils and basophils, and release of inflammatory mediators such as histamine, prostaglandins and leukotrienes from mast cells.[1]

It is one of the most prevalent conditions among adults in the India, affecting general population in range of 50%. This condition has a considerable economic impact on patients' lives and also it can significantly affect quality of life, academic achievement and work productivity. The incidence of allergic rhinosinusitis is increasing worldwide with increasing environmental pollution.[2]

The pathophysiology of these symptoms is not only due to the direct contact of the allergen to the sinus mucosa but also via reflex activity through the nasal mucosa. Most common symptoms like headache, facial pain,

disturbed sleep, fatigue and irritability along with allergic rhinitis symptoms like nasal congestion, running nose, postnasal drip, itchy eye, nose and throat which in turn will affect the quality of life and impair the efficiency of the individual work performance.[3]

Various modalities exist for the treatment of allergic rhinosinusitis, out of which intranasal corticosteroids (INC) have shown to be the most effective, since they control most of the symptoms of allergic rhinosinusitis with minimal systemic effect. Few trials have studied the effect of INC on the sinus symptoms and no randomized studies; have compared the long term efficacy of budesonide and mometasone furoate in relieving sinus symptoms of allergic rhinitis.[4-6]

METHODS

The study was carried out on 160 patients with allergic rhinosinuitis symptoms in the department of ENT in VMMC, from September 2017 to March 2019. The patients with informed consent, aged above 18 years with persistent allergic rhinitis according to ARIA criteria with sino-nasal symptoms and a positive skin prick test were taken up for the study. More than 3 mm wheal for common aeroallergens was taken as positive for positive skin prick test. The patients were symptomatic for more than a year and had a baseline total sino-nasal outcome test score (SNOT) of ≥5. Patients on oral or topical corticosteroids for any other condition, having contraindication for steroid use, those suffering from other sino-nasal pathology like nasal polyps, deviated nasal septum, alcoholics and smoker were excluded from the study.

Informed consent was obtained from all the patients who were included in the study. The selected patients underwent detailed history taking and thorough ENT examination including anterior rhinoscopy, direct nasal endoscopy, X-ray para nasal sinuses. These patients were then randomized by using random numbers into two study groups. Group A received treatment with budesonide nasal spray at a dose of 256 µg per day once daily and Group B received treatment with mometasone furoate nasal spray at a dose of 200 µg once daily for 12weeks. The patient and researchers were blinded during the study period. Individual case record books were provided to the patients to monitor compliance, during follow up at 2, 6 and 12 weeks.

Assessments

The patients were assessed by using the SNOT and the total nasal symptom score (TNSS) at 2, 6, 12 weeks interval. Thorough history was taken along with nasal and sinus examination was meticulously done during every visit of the patient (2, 6 and 12 weeks). Evaluation of sino-nasal symptoms by using the TNSS scale includes headache, facial pain, eye lid oedema, nasal congestion, sneezing, rhinorrhoea, difficulty in sleeping and pruritus. These symptoms are individually ranked from 0 (no symptoms) to 3 (severe symptoms) and the total score ranges, therefore, from 0 to 15.

Statistics

All quantitative variables were estimated using measurements of central location (i.e., mean and median) and measurements of dispersion (standard deviation [SD]). The SNOT and TNSS scores were analyzed using paired and independent t-test and one way ANOVA test. The chi square test was used for comparisons of the gender distribution of the groups. A p value of less than 0.05 was considered as statistically significant.

RESULTS

A total of 160 patients were screened after obtaining consent. A total of 80 patients were taken in each group however 10 patients in group A and 4 patient in group B were lost to follow up, therefore the sample size in group A became 70 and in group B became 76.

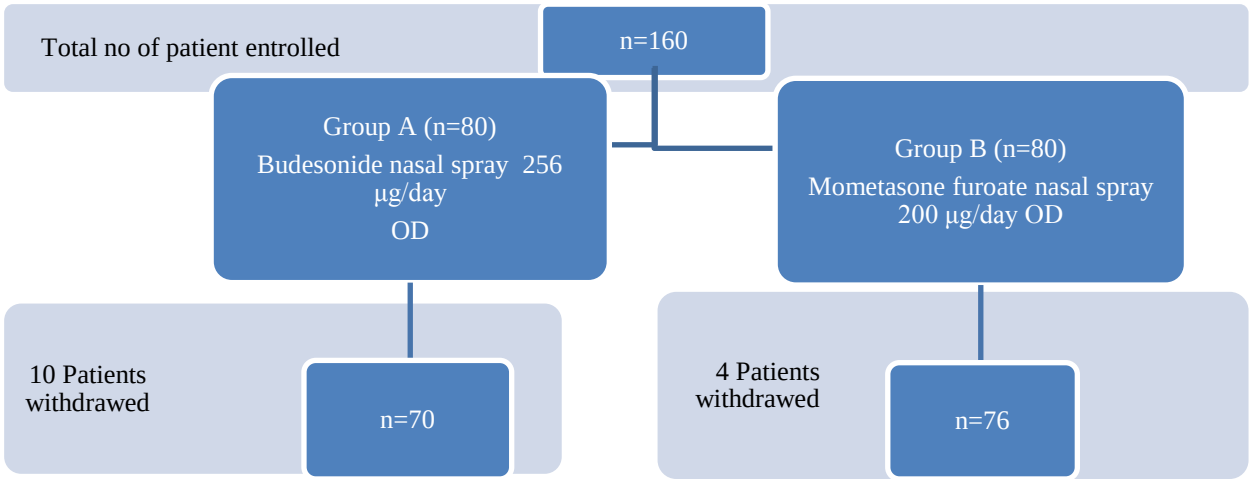

Figure 1: Patient allocation.

Patient population

No statistically significant differences were found between group A and group B in terms of age (28.6±3.4 and 29.5±2.5, respectively), gender (34 females and 36 males, 43 females and 33 males, respectively) (p=0.341 and p=0.544, respectively). A summary of the patient demographics is given in Table 1.

Table 1: Distribution of age and gender in both the groups.

	Group A (n=70)	Group B (n=76)
Average age (SD)	28.6±3.4	29.5±2.5
Female (%)	34	43
Male (%)	36	33
P value	0.341	0.544

SNOT and TNSS scores

The mean baseline SNOT and TNSS score in group A was 6.068±1.15 and 5.12±2.13 and in group B was 6.43±2.41 and 7.11±2.13. There was no statistical difference between the baseline scores of both the groups (p=0.714) and (p=0.812) respectively (Table 2).

Table 2: Baseline SNOT and TNSS score in both groups.

Baseline	Group A (n=70)	Group B (n=76)
SNOT	6.068±1.15	6.43±2.41
TNSS	5.12±2.13	7.11±2.13
P value	0.714	0.812

There was a statistically significant reduction in the SNOT scores in both the groups. In group A the SNOT score reduced from 6.068±1.15 to 3.11 ±1.35 (p=0.000). In group B the SNOT score reduced from 6.43±2.41 to 5.12 ±1.11 (p=0.000). There was no difference in the SNOT scores of both the groups till 2 weeks, however by the 12th week there was a statistically significant difference in the SNOT scores.

Table 3: Distribution of the SNOT and TNSS scores in group A and group B over the study period.

	2 weeks	6 weeks	12 weeks
SNOT			
Group A	6.01±1.03	5.03±1.11	3.11±1.35
Group B	6.12±2.11	5.65±1.87	5.12±1.11
P value	0.65	0.04	0.01
TNSS			
Group A	5.01±2.11	4.43±1.25	2.11±1.34
Group B	6.87±2.01	6.11±1.87	5.43±1.40
P value	0.76	0.32	0.41

The reduction in the TNSS score was also found to be statistically significant in both the groups, the group A score reduced from 5.12±2.13to 2.11±1.34 and in group B reduced from 7.11±2.13to 5.43±1.40. There was no difference in the TNSS scores of both the groups till the end of 12 weeks.

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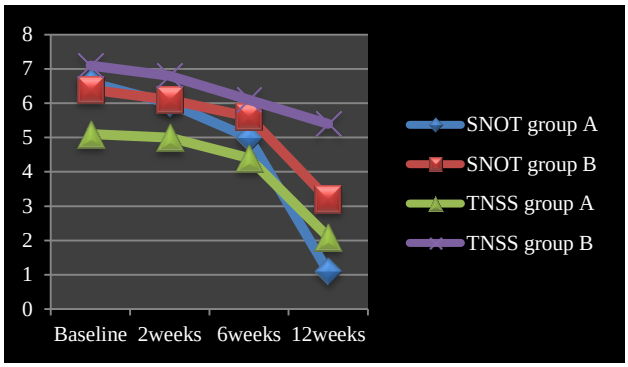

Figure 2: Distribution of the TOSS and TNSS scores in Group A and Group B over the study period.

Adverse effect

Local adverse events in patients from all age groups are mild in intensity and self-limiting, and resolve without discontinue the use of nasal sprays (Table 4).

Table 4: Adverse effect of Group A and Group B.

Symptoms	Group A (%)	Group B (%)
Dryness and crusting of the nose	5	6
Pharyngitis	3	4
Headache	4	1
Viral infection	3	5
Epistaxis	Nil	1
Respiratory infection	2	3

DISCUSSION

There have been a few previous studies analyzing the efficacy of various intra nasal steroids in controlling symptoms of allergic rhinosinusitis especially budesonide and mometasone furoate. Lavigne et al investigated the effects of intra sinus instillation of budesonide in patients with chronic rhinosinusitis who were also allergic and documented a regression of more than 50% of total nasal symptom scores over a 3-week period with a concomitant

reduction in $CD3^+$ T cells, eosinophils, and cells expressing IL-4 and IL-5.[7]

These findings were confirmed in a later study by Lund et al in a double-blind, placebo-controlled, randomized trial of 134 patients with chronic rhinosinusitis with allergy without nasal polyps treated with topical intranasal budesonide for 20 weeks. In this study, both symptom score and peak inspiratory nasal flow were improved.[8]

The efficacy of mometasone furoate in controlling the symptoms in allergic rhinitis was analysed by Bielory et al in 2008 and he found it to be effective.[9]

Rodríguez et al as reported in a recent cost-effectiveness analysis when compared to beclomethasone diproprionate, the therapy with mometasone furoate for treating children suffering from allergic rhinitis showed a greater improvement, better efficacy, safety and lower total treatment cost.[10]

In our study both the drugs were found to be effective in reducing the sinus symptoms of allergic rhinosinusitis. There was a statistical significant reduction in the SNOT scores in both the budesonide group and in the mometasone furoate group. There was no much difference in the SNOT values in both the groups till 2 weeks, however by the end of 6 weeks the reduction of symptoms in the budesonide group became statistically significant (p=0.04) as compared to the mometasone furoate group. This difference was seen till the end of 12 weeks (p=0.01). There was a statistically significant reduction in the TNSS by 2 weeks in both the groups, which was maintained till the 3rd month. There was no difference in the score between both the groups till 12 weeks proving that both the drugs are equally efficacious in reducing the nasal symptoms of allergic rhinitis with sinusitis. This is consistent with the study by Keith et al who reviewed and compared various studies analysing the efficacy of intra nasal corticosteroids in relieving the symptoms of allergic rhinitis in which he concluded that various intra nasal steroids differed in their efficacy in controlling the sinus symptoms of allergic rhinitis and concluded that budesonide seemed to be the most effective in this regard.[11]

Many mechanisms have been proposed for the action of intra nasal steroids in reducing the sinus symptoms of allergic rhinitis like systemic activity of absorbed drug; improved drainage of allergen laden sinus secretions due to decreased inflammation and oedema of the maxillary ostium.[12,13]

Last but not least, it is a fact that all steroids suppress gene expression of factors responsible for generating and supporting inflammatory processes but furoate earn special attention as their lateral furoate ester chain makes the molecules highly lipophilic. Thus, the molecules are easily absorbed by mucous membranes, epithelium and cell membrane phospholipids. This minimizes their general action and maximizes local action, sometimes associate with local adverse effect.[14]

There is also some concern regarding the safety and systemic absorption of intra nasal steroids and the possibility of suppression of the hypothalamus-pituitary-adrenal axis. However many studies have established the safety of intra nasal steroids and have proven that the systemic bioavailability of these drugs is low.[15,16] Neil et al also found that budesonide nasal spray may be clinically effective in decreasing the symptoms of chronic rhinosinusitis and does so without suppression of the hypothalamic-pituitary adrenal axis in patients with chronic rhinosinusitis.[17]

Limitation

The limitation of the study is the short duration of follow up and lack of an objective way to monitor compliance of the patients to the intra nasal steroids and also small sample size.

CONCLUSION

Both budesonide and mometasone furoate are effective in reducing the sinus and nasal symptoms of allergic rhinosinusitis; but budesonide has been demonstrated to be safe, effective and, if compared to its competitors, it shows symptom control greater than the other products in the market. Therefore, budesonide is more effective in reducing the sinus symptoms like facial pain, eye oedema along with allergic rhinitis symptoms with less local adverse effect. Hence intranasal budesonide can be recommended as an effective and safe modality for control of both nasal and sinus symptoms of allergic rhinitis.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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