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Original Research Article

A comparative study to assess the efficacy of fluticasone and mometasone in allergic rhinitis

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ABSTRACT

Background: Allergic rhinitis is the most prevalent of allergic diseases in the world. Pharmacotherapy remains the mainstay of treatment. Nasal corticosteroids being the most applicable drugs for its treatment. The objective of this study was to compare the efficacy of fluticasone propionate (FP) and mometasone furoate (MF) nasal sprays in the treatment of allergic rhinitis based on total nasal symptom score (TNSS) questionnaire.
Methods: A prospective, randomized, open-label, parallel-group, comparative study was conducted among 80 allergic rhinitis patients fulfilling the inclusion and exclusion criteria. They were randomly assigned to two groups: FP and MF groups. FP group received 200 µg dose of FP nasal spray (1 spray/nostril) daily and the MF group received 100 µg dose of MF nasal spray (1 spray/nostril) daily for 8 weeks. The effects of the two agents were compared based on TNSS questionnaire in 0, 4 and 8 weeks after the beginning of the treatment.
Results: At the end of eight weeks of treatment, both groups showed statistically significant ($p<0.005$) improvements from their baseline TNSS. Mean TNSS was reduced from to 9.46 to 2.716 in FP group and from 10.18 to 2.504 in MF group.
Conclusions: Both the groups showed a significant therapeutic benefit in patients with allergic rhinitis. Even though, the difference between the two is not significant for 8 weeks therapy.

Keywords: Fluticasone propionate, Mometasone furoate, Allergic rhinitis, Total nasal symptom score questionnaire

INTRODUCTION

Allergic rhinitis is a widespread yet underrated inflammatory disorder of the nasal mucosa induced by allergen exposure triggering IgE-mediated inflammation. Clinically, it is characterized by rhinorrhea, sneezing, nasal itching, and nasal congestion.[1,2] Allergic rhinitis symptoms can give rise to sleep disturbance, fatigue, depressed mood and cognitive function compromise that leads to impairment of quality of life and productivity.[3] Triggers of allergic rhinitis are domestic allergens as mites, domestic animals, insects or of plant origin; common outdoor allergens include pollens and moulds; occupational triggers as latex; tobacco smoke; automobile exhaust include ozone, oxides of nitrogen and sulphur dioxide; aspirin and other nonsteroidal anti-inflammatory drugs. It can also be associated with co-morbid conditions as asthma, atopic dermatitis and nasal polyps. AR has been found to affect about 400 million people worldwide, with higher prevalence's seen in Westernized countries.[4] AR is a global health problem also with considerable economic and societal burdens.

A survey by All India Coordinated Project on Aeroallergens and Human Health, New Delhi, showed

that 20-30% of the population suffers from allergic rhinitis and that 15% develop asthma.

Allergic rhinitis was previously subdivided, based on time of exposure, into seasonal, perennial, and occupational. This subdivision is not entirely satisfactory. The recent classification of allergic rhinitis as suggested by allergic rhinitis and its impact on asthma (ARIA) guidelines is on the basis of duration as 'intermittent' or 'persistent' disease, severity of symptoms and quality of life as 'mild' or 'moderate-severe' (Figure 1).[4]

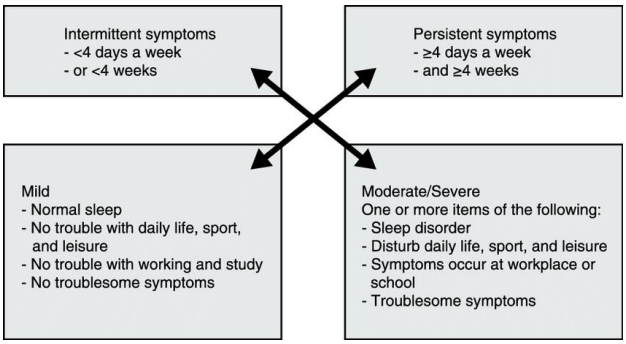

Figure 1: ARIA classification of allergic rhinitis.

Patients with intermittent AR have sneezing, eye symptoms and watery secretions; while patients with persistent AR have seromucous secretions, postnasal drip, smell disturbances, nasal obstruction and may be associated with asthma and chronic sinusitis.

A number of pharmacologic interventions are prescribed to treat allergic rhinitis. Intranasal corticosteroids (INSs) are recommended in current guidelines as first-line therapy for patients with moderate to severe allergic rhinitis.[5] INSs inhibit the onset of the inflammatory response and reduce nasal mucosa permeability, the number of inflammatory cells and the release of mediators. The most commonly used INSs are fluticasone and mometasone.

This study was undertaken to compare the efficacy of fluticasone propionate and mometasone furoate in alleviating symptoms of allergic rhinitis using TNSS questionnaire.

METHODS

A prospective, randomized, open label, parallel group, comparative clinical study was conducted in the department of ENT, Government medical college Srinagar from August 2019 to March 2020.

The patients clinically diagnosed with moderate to severe allergic rhinitis of either sex were included. The exclusion criteria were medication consumption that may affect allergy symptoms (such as oral antihistamines, decongestants, steroids, or leukotriene antagonists) within 2 weeks prior to the study or during the study period; intranasal corticosteroid use within 2 weeks prior to the study; nasal polyp disease; and pregnant and lactating mothers.

Based on a study conducted by Gholami et al, an absolute precision of 0.3% and confidence interval of 95%, the sample size was calculated to be 74.[6] Sample size was calculated using openepi.

Thus, a total of 80 patients with age varying from 17 to 59 years having allergic rhinitis were included in the study as per the set criteria. The participants were randomly divided into two groups. Of the 80 participants, 3 cases were excluded during the study (1 case from FP group and 2 cases from MF group), 40 cases received FP nasal spray (FP group), and 37 cases received MF nasal spray (MF group). FP group received a 200 µg dose of FP nasal spray (1 spray/nostril) daily for 8 weeks, and the remaining participants (MF group) received a 100 µg dose of MF nasal spray (1 spray/nostril) daily for 8 weeks.

In the initial screening visit, demographic data, history of presenting illness, associated allergic disorders, concomitant medications, physical and clinical examination and details of the drug prescription were recorded for all participants. Instructions about maintenance of daily-activity diaries to record all symptoms once the treatment began was given to the participants.

The patients received study medications for the period of eight weeks and were followed up at fourth week (visit 2) and eighth week (visit 3). Study subjects were evaluated for rhinitis symptoms using a Total nasal symptom score (a 4 points scale). Baseline TNSS and each symptom score were calculated as the mean of the scores after 0, 4 and 8 weeks of initiation of treatment. Efficacy was assessed by mean change in total nasal symptom score (TNSS) at the end of the study. No adverse effect of treatment was reported by any of the patients.

Total nasal symptom scores

The total nasal symptom score (TNSS) is the sum of scores for each of nasal congestion, sneezing, nasal itching, and rhinorrhea at each time point. Each symptom is graded from 0-3, where 0 indicates no symptoms, a score of 1 for mild symptoms that are easily tolerated, 2 for awareness of symptoms which are bothersome but tolerable and 3 is reserved for severe symptoms that are hard to tolerate and interfere with daily activity. TNSS is calculated by adding the score for each of the symptoms to a total out of 12.[7,8]

Data was analysed using SPSS statistics software. All data are expressed as mean. An independent sample t-test was used to compare the improvement rates of the mean TNSS for the two groups. A p value <0.05 was considered statistically significant. A paired t-test was

used to compare the improvement rates of the mean TNSS for each group from w0 to w4 and w8.

Table 1: TNSS as per symptoms.

Score	Symptoms
0=none	No symptoms evident
1=mild	Symptom present but easily tolerated
2=moderate	Definite awareness of symptom; bothersome but tolerable
3=severe	Symptom hard to tolerate; interferes with daily activity

Ethical standards statement

All treatment protocols performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

RESULTS

A total of 80 patients were enrolled in this study, with 41 patients assigned to an FP group and 39 patients assigned to an MF group. However, 3 patients were lost to follow up and were subsequently excluded from this study. The mean age of the patients was 26.35 years (for FP group) and 24.64 years (for MF group). No significant differences were observed between the two groups for baseline demographics or health characteristics (Table 2).

Table 2: Demographic characteristics and baseline data of the both fluticasone propionate (FP) and mometasone furoate (MF) groups.

Variables	FP group	MF group
Number	40	37
Gender N (%)		
Male	17 (42.5)	16 (43.2)
Female	23 (57.5)	21 (56.8)
Age (years)	26.35	24.64

Data are presented as n (%) or mean.

For both the FP and MF groups, we analyzed the change in TNSS from baseline (week 0) to week 4 and week 8 of the treatment. The TNSS was the sum of the four nasal symptom scores. No statistically significant differences were observed between the two groups for baseline (W0) TNSS scores (baseline TNSS scores for FP group is 9.46 and for MF group is 10.18).

The FP and MF groups experienced improvement in allergic rhinitis nasal symptoms, with symptom improvements of nasal congestion, rhinorrhea, nasal itching, and sneezing achieving statistical significance (p value <0.001) from w0 to w4 and from w0 to w8. Improvement in nasal symptoms for MF group was better than FP group, but this difference was not significant (p value <0.05) (Figure 2 and Table 3).

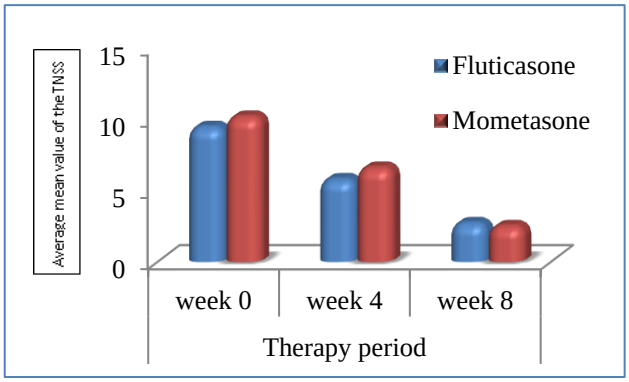

Figure 2: Mean value of TNSS in W0, W4 and W8.

Table 3: Changes in TNSS from baseline (W0) of individual symptoms.

Group	FP group	MF group
Nasal congestion		
W0-W4	-1.310	-1.781
W4-W8	-0.410	-0.475
Rhinorrhea		
W0-W4	-1.578	-1.709
W4-W8	-0.291	-0.297
Nasal itching		
W0-W4	-1.492	-1.719
W4-W8	-0.103	-0.185
Sneezing		
W0-W4	-1.415	-1.398
W4-W8	-0.137	-0.079

Data are presented as means.

DISCUSSION

Presently prevalence of allergic rhinitis is increasing and various epidemiologic studies suggest that 20 to 30% of adults and up to 40% of children are affected.[9] Global climate changes leading to elevated levels of carbon dioxide, increased plant productivity and increase in airborne pollen may explain the increasing prevalence.[10] Symptoms can have significant negative impact on the patients' quality of life, often interfere with sleep and contribute to poor performance at work.

In the present study the baseline data show no significant difference between the study groups with respect to demographic parameters. This proves the homogeneity of the study patients in the two groups. The efficacy of the study drugs was assessed by the total nasal symptom score.

We found MF sprays to be more effective than FP sprays for relieving nasal symptoms, as evidenced by the

differences in TNSS between the two groups. But this difference was not significant (p value ≤0.05). Mandl et al indicated that Mometasone furoate and fluticasone propionate adequately controlled symptoms of perennial rhinitis and were well tolerated.[11] Their results are in harmony with our results. Some studies found that FP and MF are effective and safe in allergic rhinitis.[11-18] Some of their results are consistent with our results.

However, this study was subject to few limitations. First, recall bias contributed to the inconsistent TNSS results. It can be to a greater extent reduced by employing various examinations, such as nasal peak expiratory flow rate (nPEFR) and the eosinophil percentage in nasal smears, to reduce questionnaire bias. Second, we did not stratify the severity of patients' allergic rhinitis in this study; otherwise, the possible response differences to treatment for moderate, severe intermittent, or severe persistent types of allergic rhinitis could have been analyzed. At last, we did not have patient data on family member smoking habits and household pets, which are the factors that may affect severity of allergic rhinitis symptoms.[19]

CONCLUSION

In our study, both the treatment groups demonstrated significant therapeutic benefit in patients with AR. FP and MF treatment were associated with a significant improvement in mean TNSS (p value <0.001). A further detailed analysis of TNSS indicated that MF was more effective than FP for relieving nasal symptoms except sneezing, but this difference was not statistically significant.

In conclusion, the results of our 8 weeks treatment program showed that FP and MF nasal sprays were effective for improving the symptoms of allergic rhinitis significantly. Although the TNSS for the FP and MF group did not show a significant difference between them.

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

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