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# Evaluation of Different Steroid Nasal Spray in Chronic Rhinosinusitis: A Comparative Study

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**ABSTRACT:**
**Aim:** In this study, we compared the efficacy of fluticasone propionate (FP) and mometasonefuroate (MF) nasal sprays in the treatment of allergic rhinitis based on total nasal symptom score (TNSS) questionnaire.
**Methodology:** For this study, 60 chronic rhinitis patients based on inclusion criteria were randomly assigned to two groups: FP and MF groups. FP group received 200 µg dose of FP nasal spray (2 sprays/nostril) daily and the MF group received 100 mg dose of MF nasal spray (2 sprays/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:** Patients in both groups exhibited significant improvement in their TNSS (P Value<0.001). A detailed TNSS analysis showed MF to be more effective for relieving all symptoms than FP. The most difference is in decreasing postnasal discharge (PND) symptom. However, the difference for relieving all symptoms is not significant (P value>0.05).
**Conclusion:** In conclusion, FP and MF are significantly effective in relieving of chronic rhinitis symptoms. Even though, the difference between the two is not significant for 8 weeks therapy.
**Keywords** Fluticasone Propionate, MometaseoneFuroate, Chronic Rhinitis, Total Nasal Symptom Score (TNSS) questionnaire

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## INTRODUCTION

Chronic rhinosinusitis (CRS) is a common disorder with a marked impact on the quality of life and health burden.[1]It effects 5 to 15% of population.[2] Medical treatment should be considered the cornerstone of disease treatment of CRS, with sinus surgery reserved for medical failures or patients' complications. Short and long-term antibiotic therapy, topical and systemic steroids, topical and oral decongestants, oral antihistamines, mast cell stabilisers, antileukotriene agents, mucolytics, topical antibiotics, topical and systemic antimycotics, proton pump inhibitors, bacterial lysates, immunotherapy, phytotherapy and avoidance of environmental factors have all been used in the management of chronic rhinosinusitis. All these topical therapies aim at reducing mucosal inflammation, reducing bacterial burden and improving mucociliary clearance. Advantages of topical medical therapy include direct delivery onto diseased tissue, potential for delivering higher local drug concentrations, and minimizing systemic absorption however the disadvantages include epistaxis, patient discomfort, variable absorption and factors like deviated nasal septum and hypertrophied turbinates which impair efficient topical drug delivery to the target mucosa.[3] Unlike oral corticosteroids, which have a significant side effect profile, topical intranasal corticosteroids (INCS) remain well tolerated with an excellent long-term safety profile. It is for this reason that they are considered first-line therapy for CRS.[4,5] The mode of action of INCS is complex. Although it remains unknown whether INCS penetrate the nasal mucosa, their lack of systemic absorption supports a local action on the nasal mucosa. Intranasal corticosteroids are known to influence epithelial cells through their direct binding to glucocorticoid receptors within the cells [6] and are believed to directly affect mast cells, Langerhans Cells, macrophages, and fibroblasts and also reduce the influx of inflammatory cells. In this way, they are thought to have direct effects on both the early phase response as well as the secretion of inflammatory mediators (interleukin-1, -2, -4, -6, -8, tumor necrosis factor-a, Granulocyte-macrophage colony-stimulating factor), released during the delayed inflammatory response.[7,8]Numerous well-performed high-level randomized controlled trials (RCTs) have been published supporting the effectiveness of INCS in the management of CRS with and without nasal polyposis. A recently published Cochrane review, including 18 randomized placebo-controlled trials, demonstrated improvements in symptom scores and endoscopic disease severity scores in both chronic rhinosinusitis without nasal polyps (CRSsNP) and chronic rhinosinusitis with nasal polyps (CRSwNP) patients. In the CRSwNP cohort, reductions in polyp size and improvements in quality of life scores and olfaction scores were also observed.[9]This high level of evidence has resulted in position papers recommending the routine use of INCS in the management of CRS with and without nasal polyposis with a level A-1 recommendation.[4,5] To eradicate biofilms and increase mucociliary clearance, local medication is very effective; therefore, treatment with local therapeutic agents has been increasingly considered as an important type of CRS treatment. Numerous new compounds and drugs have been developed for CRS. Saline and corticosteroids remain the most important in the local treatment of CRS; however, charged or hydrophilic drugs are unable to adequately cross the biofilm.[10] Moreover, owing to the rapid mucociliary clearance, the residence time of drugs in the cavity is markedly short, which may seriously limit the passive diffusion of drugs through the epithelium.[11] Nasal administration is a promising way of drug delivery but necessitates a good device for improved drug delivery.[12] A nasal spray is the most commonly used nasal drug delivery equipment, presenting advantages of portability and convenience. However, it also has some disadvantages; e.g., the drug may fail to reach

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the entirety of the sinuses and superior nasal parts, is discharged into the throat by nasal cilia, swallowed into the stomach, or cannot play a role in the treatment of nasal diseases. Moreover, patients may experience an unpleasant taste, odor, or feel on using nasal sprays. The problems associated with most nasal drug delivery devices include the particle size of drops or powders, the location and form of drug deposition, and the loss of drugs from the nasal cavity after administration. To resolve these problems, various nasal drug delivery devices with new functions have been developed.[13]

## AIM OF THE STUDY

Purpose of our research was to compare the efficacy of fluticasone propionate (FP) and mometasonefuroate (MF) nasal sprays in the treatment of chronic rhinitis based on total nasal symptom score (TNSS) questionnaire.

## METHODOLOGY

Sixty adult patients with two or more symptoms of CRS for a period of 12 weeks or more were included in this study. Symptoms included mucopurulent nasal discharge, nasal congestion, facial pressure or pain, sneezing, decreased sense of smell or ear fullness. Patients with nasal polyposis, Impacted DNS touching lateral wall of nose, severely hypertrophied nasal turbinates were excluded. However, patients with mild DNS which could not impede topical delivery of drugs were included in the study. Patients were randomly distributed into two groups of twenty patients receiving treatment for 8 weeks were as follows as:

1. Group A: Patients were advised to use two puffs of intra nasal Fluticasone Propionate (FP), every morning.
2. Group B: Patients were advised to use two puffs of intra nasal MometaseoneFuroate (MF), every morning.

Rhinitis symptoms were measured using a 4-point scale. Scores as follows:
0 denoted “none” (no noticeable symptoms);
1 denoted “mild” (symptoms are noticeable but not bothersome);
2 denoted “moderate” (symptoms are noticeable and occasionally bothersome but do not disturb daily activities and sleep);
3 denoted “severe” (symptoms are generally bothersome and disturb daily activities and sleep). The examiner recorded the patient scores for six nasal symptoms (nasal congestion, rhinorrhea, postnasal drip (PND), nasal itching, smelling disorder and sneezing). Baseline TNSS and each symptom score were calculated as the mean of the scores after 0, 4 and 8 weeks of initiation of treatment. Statistical analysis was performed using SPSS 25.0. All data are expressed as mean±standard deviation. 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 week 0 to week 4 and week 8. A p value<0.001 was considered statistically significant.

## RESULTS

The mean age of the patients was 21.46 (9.624) years (for FP group) and 20.136 (9.198) years (for MF group). No significant differences were observed between the two groups for baseline demographics or health characteristics. (Table 1) The FP and MF groups experienced improvement in allergic rhinitis nasal symptoms, with symptom improvements

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of nasal congestion, rhinorrhea, PND, nasal itching, smelling disorder and sneezing achieving statistical significance (p value<0.001) from week 0 to week 4 and from week 0 to week 8. Improvement in nasal symptoms for MF group was better than FP group, but this difference was not significant. (p value<0.05) (Table 2)

**Table 1- Demography of characteristics and baseline data of the both fluticasone propionate (FP) and mometasonefuroate (MF) groups**

| Variables | FP group (n%) | MF group (n%) |
|---|---|---|
| Number | 30 | 30 |
| Gender | | |
| Male | 13 (47.2%) | 16 (48.5%) |
| Female | 17 (52.8%) | 14 (51.5%) |
| Age (y) | 21.46 (9.624) | 20.136 (9.198) |

**Table 2- Changes in total nasal symptom score of individual symptoms (mean ±Standard deviation) at the end of week 8th.**

| Symptoms | FP group | MF group |
|---|---|---|
| Nasal congestion | -0.436 (0.502) | -0.5 (0.509) |
| Rhinorrhea | -0.282 (0.456) | -0.286 (0.46) |
| Sneezing | -0.128 (0.339) | -0.071 (0.262) |

## DISCUSSION

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). Some studies found that FP and MF are effective and safe in allergic rhinitis. Some of their results are consistent with our results, and some of them are not. Mandl*et al.* indicated that Mometasonefuroate and fluticasone propionate adequately controlled symptoms of perennial rhinitis and were well tolerated.[14]Their results are in harmony with our results. In a recent study, Yonezaki*et al.* found that fluticasone furoate was significantly preferred over mometasonefuroate in allergic rhinitis.[15]Their results are not consistent with our results. In another study, researchers found that following the 4-w therapy, mometasonefuroate (MF) nasal spray provided greater improvement compared to fluticasone propionate (FP) nasal spray for symptoms of childhood perennial allergic rhinitis. Based on their Total Symptom Scores (TSSs) questionnaire, the MF group experienced more effective relief of nasal symptoms, whereas the FP group experienced more effective relief of non-nasal symptoms.[16] A meta-analysis comparing hypertonic saline irrigation with isotonic saline irrigation reported that patients with sinusitis benefited more with improved symptoms from hypertonic saline irrigation than from isotonic saline irrigation, especially in the younger population. Corticosteroids, the most potent anti-inflammatory agents, are often used to controlCRS.[17]There is considerable evidence that topical corticosteroids are often used in thetreatment of patients with CRS. A study[18] reported that large-volume corticosteroidirrigation improves the symptoms of patients with CRS after sinus surgery. In many studies it has been highlighted that corticosteroid irrigation should be considered as a part of important therapy in postsurgical CRS. Some studies have evaluated the adverse events of nasal corticosteroids. These studies have observed that nasal corticosteroids are safe. No major adverse events happened. Intranasal corticosteroids used for chronic rhinosinusitis.[19-22] The first-generation corticosteroids include beclomethasone dipropionate, flunisolide, budesonide, and triamcinolone. The second-generation consisted of fluticasone furoate, fluticasone propionate, ciclesonide, mometasonefuroate (MF), and betamethasone

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sodium phosphate. The most widely used corticosteroids administered via intranasal spray are fluticasone propionate, MF, and beclomethasone. From a recent Cochrane review of intranasal corticosteroid use for CRS, studies comparing intranasal use of fluticasone propionate and beclomomethasonedipropionate in CRS patients reported no difference in overall symptom improvement between both groups.[23] In addition, no difference in the improvement of sinonasal symptoms was observed between intranasal fluticasone propionate and MF.

## CONCLUSION

The results of our 8-w 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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