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Original Research Article

A randomized study comparing the efficacy of mometasone furoate and fluticasone furoate on the ocular and nasal symptoms of allergic rhinitis

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ABSTRACT

Background: Ocular symptoms like itching, redness and congestion are common in patients with allergic rhinitis. These symptoms affect the quality of life and increase the burden on the healthcare cost. Intranasal steroids are effective in reducing the nasal and ocular symptoms of allergic rhinitis. We aim to compare the efficacy of mometasone furoate nasal spray and fluticasone furoate nasal spray in reducing the nasal and ocular symptoms of allergic rhinitis.
Methods: 90 patients with perennial allergic rhinitis and ocular symptoms were randomly divided into 2 groups. Group A (n=46) received 200 µg of mometasone furoate nasal spray once daily and Group B (n=44) received 110 µg of fluticasone furoate nasal spray daily. The patients were assessed by total ocular symptom score [TOSS] and total nasal symptom score [TNSS] at 2, 6 and 12 weeks interval.
Results: There was a statistically significant reduction in both the groups in respect to the TOSS and TNSS scores. However the improvement in the TOSS score in the fluticasone furoate group was more than the mometasone furoate group by 6 weeks (p=0.0009), which continued till the 12 weeks (p=0.045).
Conclusions: Fluticasone furoate is more effective than mometasone furoate in managing the ocular and nasal symptoms of allergic rhinitis.

Keywords: Allergic rhinitis, Allergic rhinoconjunctivitis, Ocular symptoms, Mometasone furoate, Fluticasone furoate, Intranasal steroids

INTRODUCTION

Allergic rhinitis is one of the commonest condition for which ENT consultation is sought. With increasing pollution and environmental exposure the incidence of allergic rhinitis is increasing worldwide.[1] Nearly 30% of these patients will experience ocular symptoms like itching, tearing and congestion which can be quite bothersome to the patient and affects their quality of life.[2] The pathophysiology of these symptoms is not only due to the contact of the allergen directly to the conjunctiva but also via reflexes through the nasal mucosa.[2] Allergic eye disease represents a spectrum of disorders, comprising seasonal allergic conjunctivitis (SAC), perennial allergic conjunctivitis (PAC), atopic giant papillary conjunctivitis (GPC), atopic kerato-conjunctivitis (APC) and vernal kerato-conjunctivitis (VKC). Of these types SAC and PAC are self-limited and do not cause ocular surface damage whilst AKC and VKC can compromise the cornea, causing ulcers and scarring.[3] Various modalities exist for the treatment of allergic rhinitis out of which intranasal corticosteroids

(INC) have shown to be the most efficacious.[4] They control all the symptoms of allergic rhinitis and have minimal systemic absorption. There are a few trials which have studied the effect of INC on the ocular symptoms like itchiness, redness; tearing and swelling of eyes and no randomized studies which have compared the long term efficacy of mometasone furoate and fluticasone furoate in relieving ocular symptoms of allergic rhinitis.[5-7]

METHODS

Subjects

The study was approved by the Institute Review Board and the Institute Ethics committee and was carried out on 100 patients with allergic rhinitis having ocular symptoms in the department of ENT of our institute from June 2015 to August 2016. The patients who were willing for the study, aged above 18 years with persistent allergic rhinitis according to ARIA criteria[8] with ocular symtomsand a positive skin prick test were taken up for the study. A wheal >3 mm for common aeroallergens was taken as a positive skin prick test. The patients were symptomatic for more than a year and had a baseline total ocular symptom score ≥4. Patients on oral or topical corticosteroids for any other condition, having contraindication for steroid use, those suffering from concomitant eye disorder/disease like glaucoma, corneal ulcer, atopic or vernal kerato conjunctivitis, etc. Patients with concomitant nasal pathology like nasal polyps, deviated nasal septum, etc. and those who smoke were also excluded from the study.

After obtaining ethical committee clearance and informed consent, the selected patients underwent thorough history taking, clinical examination and ocular tests by an ophthalmologist, which were recorded in the proforma. These patients were then randomized by the investigator using computer generated random numbers into two study groups. Group A received treatment with mometasone furoate nasal spray at a dose of 200 µg per day once daily and Group B received treatment with fluticasone furoate nasal spray at a dose of 110 µg once daily for 3 months. The patient, investigator and the pharmacist were blinded during the study period. The patients were asked to maintain a treatment diary and to bring it during follow up at 2, 6 and 12 weeks in order to monitor compliance.

Outcomes

The patients were assessed using the Total ocular symptom score [TOSS] and the Total nasal symptom score [TNSS] at 2, 6 and 12 weeks interval. The average score for preceding 1 week and the day of visit were calculated. At each visit the patient underwent thorough history taking, clinical, nasal and ocular examination. The eye symptoms are evaluated with TOSS which includes redness, swelling, itching and watering of eyes, each scored from 0 (none of the time) to 4 (all of the time), the maximum score being 16. Evaluation of nasal symptoms using the TNSS scale includes nasal congestion, sneezing, rhinorrhea, 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 TOSS 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 136 patients were screened and after obtaining consent 100 patients agreed for the study. A total of 50 patients were taken in each group however 4 patients in group A and 6 patient in group B were lost to follow up, therefore the sample size in group A became 46 and in group B became 44.

Patient population

No statistically significant differences were found between group A and group B in terms of age (30.6 ± 2.2 and 31.1 ± 1.6, respectively), gender (25 females and 21 males, 23 females and 21 males, respectively) (p=0.226 and p=0.843, 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=46)	Group B (n=44)	P value
Average age (SD)	30.6±2.2	31.1±1.6	0.226
Female (%)	25 (54.34)	23 (52.27)	0.843
Male (%)	21 (45.66)	21 (47.73)	

TOSS and TNSS scores

The mean baseline TOSS and TNSS score in group A was 4.85±2.15 and 5.56±2.24 and in group B was 4.80±2.41 and 5.40±2.31. There was no statistical difference between the baseline scores of both the groups (p=0.914) and (p=0.739) respectively (Table 2).

There was a statistically significant reduction in the TOSS scores in both the groups. In group A the TOSS score reduced from 4.85±2.15 to 2.55±1.08 (p=0.000). In group B the TOSS score reduced from 4.80±2.41 to

2.10±1.02 (p=0.000). There was no difference in the TOSS scores of both the groups till 2 weeks, however by the 6th week there was a statistically significant difference in the TOSS scores (p=0.0009) , which continued till the 12th week (p=0.045).

Table 2: Distribution of the TOSS and TNSS scores in group A (mometasone furoate) and group B (fluticasone furoate) over the study period.

	Baseline	2 weeks	6 weeks	12 weeks	P value
TOSS group A (mean±SD) (n=46)	4.85±2.15	3.80±1.42	3.12±1.20	2.55±1.08	0.0000
TOSS group B (mean±SD) (n=44)	4.80±2.41	3.86±1.35	2.30±1.06	2.10±1.02	0.000
P value	0.914	0.837	0.0009	0.045	
TNSS group A (mean±SD) (n=46)	5.56±2.24	4.87±2.12	3.48±1.76	2.37±1.23	0.000
TNSS group B (mean±SD) (n=44)	5.40±2.31	4.60±1.90	3.14±1.88	2.15±1.41	0.000
P value	0.739	0.526	0.378	0.431	

The reduction in the TNSS score was also found to be statistically significant in both the groups, the score reduced from 5.56±2.24 to 2.37±1.23 (p=0.000) and in group B reduced from 5.40±2.31 to 2.15±1.41 (p=0.000). There was no difference in the TNSS scores of both the groups till the end of 12 weeks.

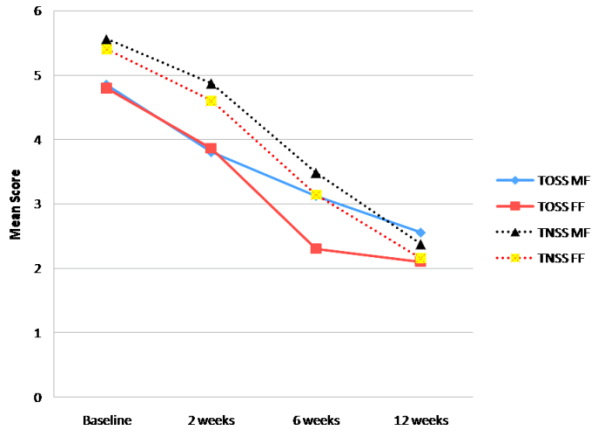

Figure 1: Distribution of the TOSS and TNSS scores in the mometasone furoate [MF] (group A) and fluticasone furoate [FF] (group B) over the study period.

The distribution of the TOSS and TNSS (Figure 1) scores and the statistical analysis in both the groups over the study period is given in Table 2.

Adverse effects

The incidence of adverse effects was 22.6% in the mometasone group and 14.8% in the fluticasone group; the overall incidence of adverse effects was 18.7%. The common adverse effects which were recorded were dryness and crusting of the nose, pharyngitis and mild burning sensation in the nose. All of these were mild and none of the patients had to discontinue the use of nasal sprays. None of the patients developed epistaxis.

DISCUSSION

There have been a few previous studies analyzing the efficacy of various intra nasal steroids in controlling the ocular symptoms of allergic rhinitis. One of the earliest studies in this regard was conducted in 2004 by Bernstein et al, who established the efficacy of Fluticasone propionate in controlling the ocular symptoms of seasonal allergic rhinitis.[9]

Kaiser et al in 2007 furthered the research on this topic and analyzed the efficacy of fluticasone furoate in controlling the ocular symptoms of allergic rhinitis.[10] This was also confirmed by Rodriego et al in 2011, who conducted a systematic review on the efficacy of fluticasone furoate versus placebo for the treatment of ocular and nasal symptoms of allergic rhinitis and concluded that fluticasone furoate nasal spray at a dose of 110 mcg once daily is effective in improving ocular and nasal symptoms.[6] They demonstrated significant benefits in the quality of life.

One of the pioneer studies which set the benchmark for further research and established the role of fluticasone furoate was conducted by Jacobs et al in 2009; he also analyzed various doses and duration of treatment.[11]

The efficacy of mometasone furoate in controlling the ocular symptoms in allergic rhinitis was analyzed by Bielory et al in 2008 and he found it to be effective.[7]

There has been one study comparing fluticasone furoate and mometasone furoate conducted in 2013 by Hamizan et al.[12] He found fluticasone furoate to be more effective however he followed the patients for only a month and the sample size was small.

In our study both the drugs were found to be effective in reducing the ocular symptoms of allergic rhinitis. There was a statistical significant reduction in the TOSS scores in both the fluticasone furoate group (p=0.000) and in the mometasone furoate group (p=0.000). There was no difference in the TOSS values in both the groups till 2 weeks, however by the end of 6 weeks the reduction in the ocular symptoms in the fluticasone furoate group became statistically significant (p=0.0009) as compared to the mometasone furoate group. This difference was seen till the end of 12 weeks (p=0.045). This is consistent with the study by Keith et al who reviewed and compared various studies analyzing the efficacy of intra nasal corticosteroids in relieving the ocular symptoms of allergic rhinitis in which he concluded that various intra nasal steroids differed in their efficacy in controlling the ocular symptoms of allergic rhinitis and concluded that fluticasone furoate seemed to be the most effective in this regard.[13]

There was a statistically significant reduction in the TNSS by 2 weeks in both the groups, which was maintained till the 3rd month (p=0.000 in group A and p=0.000 in group B). There was no difference in the score between both the groups till 3rd month (p=0.431), proving that both the drugs are equally efficacious in reducing the nasal symptoms of allergic rhinitis.

Many mechanisms have been proposed for the action of intra nasal steroids in reducing the ocular symptoms of allergic rhinitis like systemic activity of absorbed drug; improved drainage of allergen laden ocular secretions because of decreased inflammation and swelling of the lower end of the nasolacrimal duct; ocular deposition of drug *via* the nasolacrimal duct; and attenuation of the nasal-ocular reflex. Out of these only the reduction of the naso ocular reflex due to the anti-inflammatory activity of intra nasal steroids has been proven.[14-16]

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. Besides this the patients were a heterogeneous group since although all had symptoms more than a year, they differed in the actual duration of their symptoms.

The ocular safety of intra nasal steroids has been established and only a few ocular adverse reactions have been reported during many years of extensive use, suggesting good safety profile of these drugs.[17,18] The relative ocular safety of intra nasal steroids is supported in a longer term study by Bernstein in which patients treated with mometasone furoate nasal spray showed no clinically significant increase in intraocular pressure (IOP) or risk of subcapsular cataracts.[19]

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.[20,21]

CONCLUSION

Ocular symptoms are common in patients with allergic rhinitis and can affect the quality of life. Both fluticasone furoate and mometasone furoate are effective in reducing the ocular and nasal symptoms of allergic rhinitis; however fluticasone furoate is more effective in reducing the ocular symptoms. Hence intranasal fluticasone furoate can be recommended as an effective and safe modality for control of both nasal and ocular symptoms of allergic rhinitis.

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