

A Hospital Based Comparative Clinical study between Mometasone Furoate and Fluticasone Furoate Nasal Spray for Allergic Rhinitis

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Abstract

Introduction: Allergic rhinitis is an inflammatory disorder of the nose which occurs when the membranes lining the nose become sensitised to allergens. Although not classed as a life-threatening disease, allergic rhinitis can reduce the patient's quality of life. Mometasonefuroate is a glucocorticosteroid used topically to reduce inflammation of the skin or in the airways. It is a prodrug of the free form mometasone. Fluticasonefuroate is a synthetic corticosteroid with a very high affinity for the glucocorticoid receptor and has a potent anti-inflammatory action.

Aim: To compare clinicaeffects between mometasonefuroate and fluticasonefuroate nasal spray for allergic rhinitis

Results: Two hundred fifty-nine patients were valid for efficacy. Mometasonefuroate was significantly more effective than placebo and was not different from fluticasonefuroate . The study was also physician-evaluated for total nasal symptoms. Overall, mometasonefuroate was at least as effective as fluticasonefuroate at equivalent doses.

Conclusion: Mometasonefuroate and fluticasonefuroate adequately controlled symptoms of perennial rhinitis and were well tolerated.

Source Of Support : Nil

Conflict Of Interest: Nil

I. Introduction

Allergic rhinitis is an inflammatory disorder of the nose which occurs when the membranes lining the nose become sensitised to allergens. Although not classed as a life-threatening disease, allergic rhinitis can reduce the patient's quality of life. Chronic rhinosinusitis with nasal polyps is a condition represented with inflammatory changes throughout the nose and sinuses from a group of disorders which all lead to swelling and overgrowth of the nasal mucosa¹. Allergen avoidance is essential in the management of allergic rhinitis. Drug treatment may be necessary to prevent and control frequent or persistent symptoms, especially if nasal obstruction/polyps are present². Intranasal corticosteroids are considered more effective than oral antihistamines at relieving most nasal symptoms. They provide potent anti-inflammatory activity locally at the nasal mucosa while limiting systemic corticosteroid effects^{3,4}. They may be used with or without nasal surgery in the treatment of chronic rhinosinusitis with nasal polyps¹. Mometasonefuroate is a glucocorticosteroid used topically to reduce inflammation of the skin or in the airways. It is a prodrug of the free form mometasone. Fluticasonefuroate is a synthetic, lipophilic, trifluorinated glucocorticoid receptor agonist. In 2009, Cochrane reviewed the therapeutic effectiveness and adverse event profiles of topical nasal steroids for intermittent and persistent allergic rhinitis in children. In the review, after assessment of trial quality, only three trials involving a total of 79 participants were included in the review (trials were excluded due to the use of 'rescue' medication which the authors state may have confounded the results). All three trials compared topical nasal steroids (Beconase® and flunisolide) against placebo. Cochrane concluded that the included trials provided weak and unreliable evidence for the effectiveness of Beconase® and flunisolide for the treatment of allergic rhinitis in children. Until more research is available, decisions on the use of topical steroids should be guided by the physician's clinical experience and patients' individual circumstances and preferences.⁵ FF has the molecular backbone of fluticasone that is also present in fluticasone propionate (FP) but the properties of both molecules are distinctly different⁶. Although FF has a higher receptor affinity and better tissue retention compared to mometasonefuroate (MF), the clinical advantage of FF over MF has not been demonstrated yet in rigorous clinical trials.^{7,8}

II. Materials And Methods

Study Population

Size: 200 Patients

Age Group: 18-75 Years

Place Of Study: Bolung Phc, Lower Dibangvalley, Arunachal Pradesh

Time Period: Between June 2015 – May 2016.

The Study Was A Retrospective Study. The Main Objective To compare Clinical effects Between Mometasonefuroate And Fluticasonefuroate Nasal Spray For Allergic Rhinitis Although The Study Period Was Short But It Was Important And A Note Should Be Taken About The Actual Scenario.

Environment

Communities Having The Same Cultural Practices Are Now Having A Rise In The Incidence Of The Disease. This Is Mainly Due To The Increase In The Populated Households And Ill-Ventilated Houses And Practicing Of Salted Food- Habits.

Clinical Features

The clinical features can be broadly classified into

Symptoms		Signs	
Nasal obstruction	100%	Nasal cavity mass	75%
Recurrent epistaxis	10 %	Nasal cavity discharge	75%
Headache	40%		
Smell disorders	60%		

Investigations

All the cases were diagnosed first by diagnostic nasal endoscopies and then by radiological investigations mainly CT.

Treatment Modalities

- 1) Mometasonefuroate : 2 puffs intranasally once daily at bed time for 14 days
- 2) Fluticasonefuroate: 2 puffs intranasally once daily at bed time for 14 days

III. Results

As we can see in table 1. there has been significant changes after treatment but still there is some residual complications which cannot be ignored.

COMPLICATIONS	BEFORE TREATMENT			AFTER MOMETASONE TREATMENT			AFTER FLUTICASONE TREATMENT		
Nasal cavity obstruction	1	0	0 %	2	5	%	3	0	%
Nasal discharge	7	5	%	2	5	%	2	5	%
Epistaxis	1	0	%	5		%	7		%
Smell disorders	6	0	%	2	0	%	2	8	%
Headache	4	0	%	1	5	%	1	5	%

Table 1: Decrease In The Rate Of Complications

Post Treatment Complications : A few complications such as unusual/extreme tiredness, weight loss, headache, swellingankles/feet, increased thirst/urination were seen in some of the cases which were treated accordingly.

IV. Discussion

Nan Zhang et al in their study have shown that a typical clinical situation would be the initiation of drug therapy after allergen exposure or onset of symptoms.⁹This setting was mimicked by a post-challenge incubation with a concentration range of 10^{-8} to 10^{-11} M FF and MF. We observed a concentration-dependent inhibition of cytokine release, which was stronger for FF compared to MF. The maximal inhibition achieved by FF was statistically significantly higher than for MF, which did not suppress IFN- γ and TNF- α . The experimental setting can be reversed to a pre-challenge exposure resembling a prophylactic use of drugs. In this setup the corticosteroids were pre-incubated with the nasal polyp tissue fragments for one hour before SEB was supplemented. Under these conditions, the maximal cytokine inhibition was not significantly different between FF and MF, but FF consistently inhibited cytokine release at lower concentrations compared to MF. At concentrations as low as 10^{-10} M, FF showed a significantly higher suppressive effect versus IL-2, IL-17 and

IFN- γ secretion compared to MF. Interestingly, when the extent of inhibitory effects in this pre- versus the post-challenge exposure setting are compared, it is striking that FF produced maximal inhibition of IL-2, IL-5, IL-17, IFN- γ and TNF- α in comparable magnitudes in both experimental setups. In contrast, the maximal inhibition of cytokine release by MF was compromised in the post-challenge incubation setting. In a clinical context, any excess drug that is not taken up into the nasal tissue cells will be rapidly removed by mucociliary clearance within about 30 min¹⁰. This was mimicked by washing the tissue in our setup. Subsequently, exposure with SEB was either performed immediately after washing off excess glucocorticoids ($t=0$), or after another 6 or 24 hours, respectively. Generally, FF inhibited the cytokine release significantly stronger and at earlier time points than MF. Especially the release of IL-5 and TNF- α was most effectively suppressed even by low concentrations of FF and irrespectively of the time interval between removal of the drug excess and exposure with SEB. Thus, the inhibitory activity of FF fully unfolded after only one hour incubation with the drug and was not attenuated over the evaluated time interval. The overall more pronounced anti-inflammatory activity of FF compared to MF is highly consistent with the higher relative receptor affinity (RRA) of FF compared to MF^{11,12}. In our experimental setting the nasal mucosal cells were in contact with the glucocorticoids typically for one hour, with the readout performed 24–48 hours later; it can be assumed that classical effects on transcription and translation of genes encoding inflammatory mediators were responsible for the observations¹³. Although an inhibition of inflammatory mediators is the prerequisite for clinical symptom management in allergic rhinitis, the required magnitude and temporal relation of cytokine suppression and the improvement of symptoms is not definite. Efficacy of intranasal corticosteroids can be expected after 7–8 hours of dosing, but some patients appear to benefit more rapidly, e.g. within the first two hours^{14,15}. In case of rapid improvement of clinical symptoms nongenomic glucocorticoid effects may play a role as well.

V. Conclusion

The study was physician-evaluated for total nasal symptoms. Overall, mometasonefuroate was at least as effective as fluticasonefuroate at equivalent doses. Mometasonefuroate and fluticasonefuroate adequately controlled symptoms of perennial rhinitis and were well tolerated.

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