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RESEARCH ARTICLE

Treatment Evaluation with Mometasone Furoate, Alone or in Combination with Desloratadine/ Montelukast in Moderate Severe Allergic Rhinitis

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Introduction: Allergic rhinitis is one of the most common allergic diseases, characterized by the inflammation of the nasal mucosa. Eosinophils play a predominant pro-inflammatory role in allergic inflammation. This study assesses the effect of mometasone furoate alone or in combination with desloratadine/montelukast in patients with moderate-severe allergic rhinitis.
Material and method: This is a prospective study that took place over 8 weeks on 70 patients diagnosed with moderate-severe allergic rhinitis with sensitization to the pollen of Ambrosia elatior. The patients were evaluated on the basis of their symptoms using the total score of nasal symptoms, the score of individual nasal symptoms and the number of eosinophils in the nasal secretion.
Results: All 3 groups of patients had an improvement on the total nasal symptoms score. However, the combination of mometasone furoate with desloratadine provided statistically significant benefits on the total score of symptoms and on nasal itching as compared with mometasone furoate alone.
Conclusions: The association of mometasone furoate with desloratadine should be considered first-line treatment of moderate-severe allergic rhinitis due to the benefit both on the total symptom score and on of nasal itching.

Keywords: allergic rhinitis, mometasone furoate, montelukast, pollen, desloratadine

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Introduction

Allergic rhinitis is one of the most common allergic diseases, affecting 25% of the world population [1]. Despite the high prevalence is still under-diagnosed and often treated unsuccessfully. The disease is morphologically characterized by inflammation of the nasal mucosa and eosinophils play a predominantly pro-inflammatory role.

Treatment options are multiple, intending to improve symptoms and reduce nasal mucosa inflammation, nasal corticosteroids being the most effective medication [2].

Originally Ambrosia elatior pollen was considered the main factor of allergies in America, but at present is one of the main sources of allergies in Europe.

This study evaluates the effect of mometasone furoate (MF) alone or in combination with desloratadine (DS)/ montelukast (MTL) on symptoms and on the number of eosinophils from nasal secretion in patients with moderate-severe rhinitis.

Material and method

We performed a prospective study on a total of 70 patients (male/female ratio = 23/47), aged 15–53 years with a history of allergic rhinitis with sensitization to Ambrosia elatior pollen.

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Study protocol was approved by the Ethics Committee of the University of Medicine and Pharmacy from Craiova and all subjects gave their consent before the study. All patients were assessed at the beginning of pollen season and after 8 weeks of treatment.

The criteria for study inclusion: patients with symptoms of moderate-severe allergic rhinitis for at least 2 years during the season of Ambrosia elatior, age >15 years, positive prick skin tests to pollen of Ambrosia elatior, presence of eosinophilia in nasal secretion.

Exclusion criteria: non-allergic rhinitis, patients with cataract, glaucoma, patients who have previously received specific medication (intranasal corticosteroids in the last 4 weeks, oral antihistamine a week before, nasal decongestants 24 hours before, systemic/oral corticosteroids sin the previous week), noncompliance to treatment, epistaxis in the last year, infections of the upper and lower airways, asthma, bronchiectases, pregnancy, lactation, other systemic diseases that interfere with test results and validity.

Anamnesis searched for information regarding the presence of symptoms (sneezing, nasal itching, rhinorrhea, nasal congestion). Their intensity was calculated by total and individual nasal symptoms score using visual analogue scale (0 – no symptoms, 4 – symptoms extremely bothersome).

Allergy skin prick tests could reveal the allergen trigger: Ambrosia elatior pollen.

Table I. Results recorded at the beginning of the study

Mean ± SD (Min–Max)	MF	MF+DS	MF+MTL	p test K-W
	Initial	Initial	Initial	
Itching	3.18 ± 0.25 (2.7–3.8)	3.27 ± 0.27 (2.5–3.7)	3.2 ± 0.32 (2.6–3.6)	0.437
Sneezing	2.84 ± 0.51 (1.9–3.6)	2.92 ± 0.62 (1.8–3.8)	2.8 ± 0.43 (2.1–3.5)	0.746
Rhinorrhea	3.07 ± 0.30 (2.6–3.5)	2.99 ± 0.27 (2.5–3.4)	3.12 ± 0.29 (2.6–3.7)	0.240
Congestion	2.43 ± 0.54 (1.6–3.5)	2.61 ± 0.61 (1.5–3.6)	2.47 ± 0.66 (1.6–3.7)	0.581
Total symptoms	2.98 ± 0.41 (2.2–3.6)	3.02 ± 0.35 (2.4–3.6)	3.03 ± 0.42 (2.3–3.5)	0.867
Eosinophils	42.13 ± 10.62 (22–60)	39.4 ± 8.95 (21–56)	41.57 ± 12.06 (17–58)	0.996

Table II. Results recorded after 8 weeks

Mean ± SD (Min–Max)	MF	MF+DS	MF+MTL	p test K-W
	Final	Final	Final	
Itching	0.82 ± 0.29 (0.3–1.3)	0.64 ± 0.23 (0.2–1.1)	0.84 ± 0.29 (0.3–1.2)	0.034
Sneezing	0.94 ± 0.30 (0.4–1.6)	0.87 ± 0.35 (0.2–1.6)	0.89 ± 0.39 (0.4–1.5)	0.771
Rhinorrhea	0.91 ± 0.43 (0.1–1.5)	0.77 ± 0.38 (0.1–1.4)	0.75 ± 0.32 (0.2–1.4)	0.230
Congestion	0.36 ± 0.20 (0–0.8)	0.33 ± 0.26 (0–0.8)	0.31 ± 0.17 (0–0.6)	0.728
Total symptoms	0.57 ± 0.29 (0.2–1.1)	0.41 ± 0.27 (0–0.9)	0.47 ± 0.27 (0.1–0.9)	0.113
Eosinophils	4.29 ± 2.21 (2–11)	3.79 ± 1.89 (3–8)	4.13 ± 1.65 (2–8)	0.791

The number of eosinophils in the nasal secretion obtained by nasal lavage was compared with 100 white elements, the presence of more than 10% eosinophils on smear of nasal secretion being considered hypereosinophilic.

After evaluating and setting the final diagnosis, the patients have received oral and/or topical nasal.

The study group was divided into 3 groups of patients:

- Group A = 24 patients treated with intranasal mometasone furoate 200 μg/day;
- Group B = 25 patients treated with intranasal mometasone furoate 200 μg/day + oral desloratadine 5 mg/day;
- Group C = 21 patients treated with intranasal mometasone furoate 200 μg/day + oral montelukast 10 mg/day.

Final reassessment was performed after 8 weeks, and treatment effectiveness was assessed by total and individual nasal symptom score and by the number of eosinophils in nasal secretion.

Fisher and Kruskal-Wallis tests were used for assessment of the compatibility for gender and ages between the 3 groups. As the data recorded for most of the studied parameters did not have a gaussian distribution (Anderson-Darling test p-value <0.05) and due to the relatively small number of subjects in each group, we used nonparametric tests: the Kruskal-Wallis test in order to compare values between all 3 groups, and the Mann-Whitney test in order to compare values between pairs of groups.

Results

The three groups were compatible in terms of gender distribution (Fisher test p = 0.457) and age (Kruskal-Wallis test p = 0.316). There were no significant differences between score values recorded at the beginning of the study between the patients of the three groups, which is extremely important in order to assure the relevance of possible differences at the end of the study (Table I).

At 8 weeks after initiation of the treatment, a statistically significant improvement in terms of final total score of symptoms and the number of eosinophils in nasal secretion was recorded in all the 3 groups. Final score values for nasal itching were also significantly different between the three groups (Kruskal-Wallis test p = <0.05, Table II).

Comparing the therapeutic effects of the mometasone fuoate with the combination between mometasone furoate and desloratadine we found a statistically significant higher improvement on total symptoms (p = 0.027) and nasal itching (p = 0.025, Table III) when using the combined treatment.

The other individual parameters compared did not reveal statistically significant differences, although in terms of percentages there was a better improvement in the case of sneezing when combining mometasone furoate with desloratadine, compared to mometasone furoate administered alone (70.14% vs. 66.86%). Moreover, rhinorrhea and congestion have also improved when combining mometasone furoate with desloratadine, percentage values being close to those found in the association of mometasone furoate with montelukast, but without having a statistically significant difference.

Table III. p values of the comparison for the recorded differences

p test Mann-Whitney	MF vs MF+DS	MF vs MF+MTL	MF+DS vs MF+MTL
Itching	0.025	0.936	0.032
Sneezing	0.245	0.918	0.413
Rhinorrhea	0.555	0.116	0.305
Congestion	0.258	0.936	0.501
Total	0.027	0.206	0.658
Eosinophils	1.000	0.855	0.886

The combination between mometasone and montelukast did not lead to any significant difference as compared to mometasone alone for all measured parameters.

Discussions

This study shows that although intranasal corticosteroids are the most effective in the treatment of allergic rhinitis [2]. When used in combination with oral antihistamine, they add an extra benefit on the total score of nasal symptoms and nasal itching.

Anolik R et al. [3] showed that mometasone furoate mono-therapy seems to be an effective treatment in allergic rhinitis and that the combination between mometasone furoate and loratadine has similar benefits. Also, David J. Amrol [4] showed that adding oral antihistamines to intranasal corticosteroids does not bring any additional benefits.

Pullerits T et al. [5] have studied the effect of intranasal corticosteroids, antileucotrienes and the combination between antileucotrienes and antihistamines in patients with seasonal allergic rhinitis and have shown that intranasal corticosteroids are more effective than antileucotrienes alone or in combination. Another study made by Pinar E [6] showed that mometasone furoate used in combination with desloratadine has improved the total nasal symptom score after 2 weeks of treatment and in combination with montelukast has improved the quality of patients' life that had allergic rhinitis.

A meta-analysis conducted by Penagos M et al. [7] has shown that the addition of antihistamines to intranasal corticosteroids increases the effectiveness on nasal symptoms in patients with persistent rhinitis. A recent study [8] has demonstrated in vitro anti-inflammatory effect greater on eosinophilic inflammation using the combination of mometasone furoate and desloratadine. Another study made by Navarro [9] shows that most physicians prefer the combination between oral antihistamine and intranasal corticosteroids regardless of the rhinitis frequency and intensity.

Conclusions

Although the monotherapy with mometasone furoate can improve nasal symptoms, the combination with desloratadine should be considered first-line treatment when trating moderate to severe allergic rhinitis with sensitization to Ambrosia elatior pollen due to the benefit on the total nasal score and that of the nasal itching one.

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