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Original Article

The Comparison of Nasaleze and Mometasone Nasal Spray to Control the Symptoms of Allergic Rhinitis

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Abstract

Background: Nasal corticosteroids are the main drug class for the treatment of allergic rhinitis, and their long-term continuous use can be problematic. The current study aimed to compare the use of Nasaleze and mometasone nasal spray in patients with allergic rhinitis. **Materials and Methods:** In this study, 64 patients were studied in two groups of 32 patients. Nasaleze was used for the first group and mometasone for the second group for 4 weeks. The severity of sneezing, runny nose, tearing, nasal congestion, itchy eyes, and scratchy throat were evaluated at the onset of the study, and also 14 and 28 days after treatment in the form of a single-blind study. Statistical analysis was performed using SPSS Software (SPSS Inc., Chicago, IL, USA, Version 20). **Results:** The severity of allergic rhinitis symptoms had a significant difference in both groups of Nasaleze and mometasone at three times. Furthermore, in the Nasaleze group, the intensity of tearing significantly reduced 14 and 28 days after treatment compared to the mometasone group. In addition, the mean pretreatment score of allergic had no significant difference in the two groups neither14 days nor 28 days after the treatment. **Conclusion:** The efficacy of Nasaleze nasal spray is very similar to that of mometasone nasal spray to control the symptoms of allergic rhinitis. Therefore, Nasaleze nasal spray can be a suitable alternative for nasal corticosteroids in children older than 18 months, pregnant and lactating women.

Keywords: *Allergic rhinitis, controlling symptoms, mometasone, Nasaleze*

Introduction

Allergic rhinitis is an inflammation with mucous membranes Ig-E immune-mediated, lining the nasal and may also be developed into paranasal sinuses.[1]

The disease symptoms include sneezing, itchy nose, nasal congestion, and runny nose. In most cases, these symptoms are also associated with ocular symptoms (eye redness, watery eyes, itchy, and irritation eyes).[2-4]

The prevalence of seasonal allergic or perennial rhinitis is increasing and it is estimated that 10%–30% of the population suffer from the disease. The prevalence of allergic rhinitis has become two to three times within the past 15 years.[5,6]

The treatment of allergic rhinitis includes first the lack of exposure to allergens and second pharmacological treatment.[3]

In pharmacological treatment, different drugs make the main lines of the treatment of allergic rhinitis that among them oral antihistamines and nasal corticosteroids are the main drug categories.[7]

The most common side effects of antihistamines are drowsiness and dizziness; on the other hand, nasal corticosteroids do not heal eye symptoms; although corticosteroid nasal spray has a good safety profile but it is long-term and continuous use can be problematic, especially for children.[7]

For this reason, using drug with few side effect profiles and enough immunity in the long-term and consistent use seems necessary, especially in children.

Nasaleze is a micronized powder filling hydroxypropyl methylcellulose which is today sold in most countries including the UK. The powder was registered in the medical devices agency in 1994. Cellulose powder is sprayed into the nose by a small pump.[8]

This matter has a natural origin and locally placed on the mucosa and does not have

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precaution and contraindication in children older than 18 months and also in pregnant and lactating women.[8,9]

For this reason, this study examined the effect of Nasaleze compared to mometasone to control the symptoms of allergic rhinitis.

Materials and Methods

This single-blind randomized interventional study was done on 64 cases in May 2015.

Diagnosis of allergic rhinitis was done based on clinical signs (sudden sneezing attacks, runny nose, nasal congestion, itchy nose, cough, postnasal drip, and fatigue) and physical examination by an otolaryngologist.[1]

Inclusion criteria were individuals with the age of 7 years and older who suffered from allergic rhinitis that was in need of medical treatment and patients' agreement to participate in the study.

Exclusion criteria included the following cases:

1. Patients with a history of hypersensitivity associated with asthma and requiring treatment with steroids
2. Patients who had used corticosteroid or antihistamine pills or mouth or nose spray for allergic rhinitis within 1 month before the study
3. Patients who had taken nasal spray of cromolyn sodium within 15 days before the study
4. Patients who did not understand Persian language well.

Patients were randomly divided into two groups of Nasaleze (Nasaleze International Ltd., England) and mometasone (Sinadaro Pharmaceuticals Company, Tehran, Iran, 0.05% nasal spray) using block randomization. In a group of patients, Nasaleze was used as a puff in each nostril for three times a day within 4 weeks and in the other group, spray 100 mcg mometasone was used as two sprays in each nostril once daily for 4 weeks.

The way to take the medicine was orally taught to patients and written in the patients' prescription.

Disease severity scoring

The disease symptoms included sneezing, runny nose, tearing eyes, nasal congestion, itchy eyes, and scratchy throat were evaluated in a single-blind method by an otolaryngologist at the onset of the study, 14 and 28 days after the treatment and were recorded on the data sheet of each patient. (Grade 0 = no symptoms; 1 = very mild symptoms so that we rarely notice; Grade 2 = mild symptoms so that frequently repeat but they do not interfere with everyday tasks; Grade 3 = moderate symptoms that there are always permanent, but they do not interfere with everyday tasks; Grade 4 = severe symptoms that they sometimes interfere with everyday tasks; Grade 5 = very severe symptoms that they interfere with everyday tasks).

Statistical analysis

In this study, Chi-square test was used to compare the frequency distribution of drugs between the two groups at different times.

Mann–Whitney test was used to compare the severity of sneezing, runny nose, watery eyes, nasal congestion, itchy eyes, and scratchy throat.

Independent *t*-test was used to compare the mean score of allergic (the sum of severity score of various symptom at a particular time) between the two groups before and after treatment.

Statistical analysis was performed using SPSS Software Version 20 (SPSS Inc., Chicago, IL, USA). In all tests, $P < 0.05$ was considered the level of statistical significance.

Results

Out of 64 patients included in the study, 27 and 37 cases were male and female, respectively.

Table 1 shows the frequency distribution of patients' sex in the two groups of Nasaleze and mometasone.

Chi-square test showed that the frequency distribution of sex had not a significant difference in the two groups ($P = 0.45$).

As shown in Table 2, the mean age of the patients was 27.4 ± 14.5 years with maximum and minimum of 5 and 65 years and it was 29.1 ± 12 years with maximum and minimum of 11 and 52 years for Nasaleze and mometasone groups, respectively.

The results of *t*-test showed that the mean age of the patients was not significantly different in the two groups ($P = 0.65$).

Table 3 shows the frequency distribution of sneezing severity in the two groups at the different times.

Friedman test revealed that the severity of sneezing had a significant difference in both Nasaleze ($P < 0.001$) and mometasone ($P < 0.001$) groups among three times (baseline, 14 and 28 after treatment).

As shown in Table 3, the severity of sneezing has decreased over time.

Table 1: Patients' Distribution frequency of sex in both group

Sex	Nasaleze *n*=32(%)	Mometasone *n*=32(%)	*P*
Male	12 (37.5%)	15 (46.9%)	0.45
Female	20 (62.5%)	17 (53.1%)	

Table 2: The mean age of the patients in both groups

Variables	Nasaleze		Mometasone		*P*
Values	Mean±SD	Min,Max	Mean±SD	Min,Max	
Age	27.4±14.5	5-65	29.1±12	11-52	0.62

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Mann–Whitney test also showed that the severity of sneezing has no significant difference before treatment ($P = 0.31$), 14 days after treatment ($P = 0.61$), and 28 days after treatment ($P = 0.29$).

Friedman test also indicated a significant difference for symptoms such as the severity of a runny nose, nasal congestion, itchy eyes and itchy throat in both Nasaleze ($P < 0.001$) and mometasone ($P < 0.001$) groups among three times.

Mann–Whitney test also indicated no significant difference for symptoms such as the severity of runny nose, nasal congestion, itchy eyes and itchy throat in both groups before the treatment and in 14 and 28 days after treatment.

The severe tearing eyes significantly reduced only in Nasaleze group 14 days ($P = 0.03$) and 28 days after treatment ($P = 0.045$) compared to mometasone group.

On the mean score of the allergic, repeated measures ANOVA showed that there was a significant difference in both Nasaleze ($P < 0.001$) and mometasone ($P < 0.001$) groups among three times.

Independent *t*-test also indicated [Table 4 and Figure 1] that the mean of allergic score was not significantly different in the two groups before treatment ($P = 0.52$), 14 days ($P = 0.96$) and 28 days after treatment ($P = 0.72$). It is also worth to note that the fifth score was not observed in any of the allergic rhinitis symptoms (sneezing, runny nose, watery eyes, nasal congestion, itchy eyes, and scratchy throat).

Discussion

This study aimed to clinically evaluate the effect of Nasaleze nasal spray to control the symptoms of allergic rhinitis compared to mometasone nasal spray in patients with allergic rhinitis from May to September 2015.

According to the various studies on nasal corticosteroids, nowadays different medications form the main lines to treat allergic rhinitis which are the most effective treatment for this disease.[7]

Therefore, in this study, the effect of receiving Nasaleze has been compared with mometasone to control the symptoms of allergic rhinitis.

According to this study, the severity of sneezing, runny nose, nasal congestion, itchy eyes, and scratchy throat were significantly decreased in both treatment groups after taking the drug. The reduction of symptoms has been almost similar in both groups, and even decrease of symptoms such as tearing eyes was higher in patients receiving Nasaleze than that in patients receiving mometasone.

In the study conducted by Emberlin *et al*., Nasaleze significantly reduced the severity of sneezing, runny nose, nasal congestion, itchy eyes, and scratchy throat compared with placebo.[10]

Table 3: Distribution frequency of sneezing severity in both groups at different times

Baseline	Sneezing	Nasaleze *n*=32(%)	Mometasone *n*=32(%)	P_1
	0	10 (31.2)	7 (21.9)	0.31
	1	9 (28.1)	5 (15.6)	
	2	6 (18.8)	11 (34.4)	
	3	1 (3.1)	7 (21.9)	
	4	6 (18.8)	2 (6.2)	
14 days	0	21 (65.6)	22 (68.8)	0.61
	1	5 (15.6)	6 (18.8)	
	2	2 (6.2)	4 (12.5)	
	3	2 (6.2)	0 (0.0)	
	4	2 (6.2)	0 (0.0)	
28 days	0	23 (71.9)	26 (81.2)	0.29
	1	5 (15.6)	5 (15.6)	
	2	0 (0.0)	1 (3.1)	
	3	3 (9.4)	0 (0.0)	
	4	1 (3.1)	0 (0.0)	
P_2		<0.001	<0.001	

P_1: Friedman test, P_2: Mann-Whitney U-test

Table 4: The mean of allergic score in both groups at different times

Time	Nasaleze Mean±SD	Mometasone Mean±SD	P_1
0	8.7±3.1	9.1±2.7	0.52
14	3.97±2.9	3.94±2	0.96
28	2.7±2.5	2.5±1.6	0.72
P_2	<0.001	<0.001	

P_1: Independent t-test

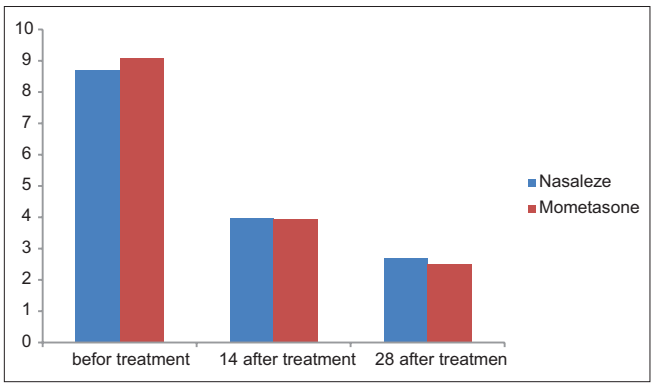

Figure 1: The mean of allergic score in both groups at different times

The study conducted by Mohammad Reza Fathololoomi *et al*., showed that nasal corticosteroids do not heal eye symptoms.[11] In this study, Nasaleze caused a further reduction in the severity of tearing compared to mometasone.

Nasaleze is more effective on the symptoms such as tearing eyes probably because of the barrier effect of the active substance in Nasaleze (hydroxypropyl methylcellulose) and prevention of immunological reactions.

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The effectiveness of nasal corticosteroids on tearing is caused by lower blood absorption and this drug type providing more local effects such as preventing nasal congestion.

Nasaleze is a hydroxypropyl methylcellulose filler micronized powder which has been embedded in a releasing system.[8]

The mechanism of hydroxypropyl methylcellulose is not clear; however, it seems that cellulose reacts with moisturizing the inside of the nose, creates an impermeable barrier on the nasal mucosa, prevents the binding of allergens to the nasal mucosa and stimulates the release of vasoactive substances from the nasal mucosa cells.[8]

However, the barrier effect of this substance may play an important role in relieving the symptoms of nasal allergic rhinitis and confirm the observed effects.

There are bulks of studies on the effect of corticosteroid nasal sprays on pituitary-adrenal axis, and most of them have shown little or no impact on pituitary-adrenal axis.[3,12] Although corticosteroid nasal sprays except for beclometasone have good safety profile,[13] long-term and continuous use of them can be problematic, especially in children who simultaneously use inhaled or topical corticosteroids.[3]

Furthermore, given that there are little information about the use of corticosteroid nasal sprays in pregnant women[14] and in this study, it has been revealed that Nasaleze spray is at least as effective as mometasone spray in controlling the symptoms of allergic rhinitis due to the natural origin and lack of systemic absorption and its local impact on mucous membranes in children older than 18 months, pregnant and lactating women, it can be a good alternative for nasal corticosteroids.

In 2%–10% of patients taking corticosteroid nasal sprays, there are side effects such as dryness, irritation, and discomfort due to nasal spray penetration into the throat.[15]

In the study questionnaire, the rate of the side effects was not examined. Although patients taking Nasaleze did not complain about certain side effects, it seems there are no side effects for Nasaleze spray.

Future clinical studies can be conducted on determining the side effects of Nasaleze and comparing them with the side effects of corticosteroid nasal sprays.

Conclusion

Given the results of this study, Nasaleze is at least as effective as mometasone nasal spray on the treatment and decrease of the allergic rhinitis symptoms and because of locally placing on mucous membranes and the lack of blood absorption, using this drug can be considered for the treatment of allergic rhinitis in children over 18 months, pregnant and lactating women.

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Conflicts of interest

There are no conflicts of interest.

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