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Original Article

The Effect of Rasasinex, A Combination of Black Seed and Olive Oil, in the Treatment of Allergic Rhinitis in Children

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Abstract

Background: Allergic rhinitis (AR) is a high-prevalent disease. The prevalence of this disease in Iran is reported between 10% and 15%. Rasasinex, a nasal spray solution is an herbal solution that contains black seed extract (Nigella Sativa) and olive oil (Olea Oil). Due to the high prevalence of AR and excessive use of anti-histamine compounds, we aimed to assess the effect of Rasasinex, which is a combination of black seed and olive oil, in the treatment of childhood AR.

Methods: This is a retrospective study conducted on records of children with mild and persistent AR who were divided into two groups of 50. In group 1, records of patients who received oral antihistamine treatment with Rasasinex were assessed. On the other hand, group 2 was treated routinely with only oral antihistamine treatment. The symptoms and signs were recorded in a checklist.

Results: In this study, 37 (74%) patients in group 1 and 33 (66%) patients in group 2 were boys. The mean age in group 1 was 6.1 ±0.28 years and in group 2 was 6.8±0.34 years. Our results showed a significant difference in the improvement of AR symptoms in children treated with Rasasinex compared to children treated with antihistamine ($p<0.0001$). The mean duration of symptoms in the first group was 4.27 days and in the second group was 14.05 days. Therefore, in the first group, more children had symptom improvement on the same day of starting the drug, and the lack of improvement in group 1 was less than in the second group. Besides, most of the children taking Rasasinex had improvement in symptoms within less than three days of taking the drug.

Conclusions: The use of Rasasinex for four weeks has been significantly effective in reducing and improving the AR symptoms in children so most of the patients reported improvement of symptoms up to three days. Therefore, it seems that it can be used in these patients.

Keywords: Rasasinex, Allergic rhinitis, Children, Nigella sativa, Olive oil.

Introduction

Allergic rhinitis (AR) is a symptomatic disease in the nose, which is induced after contact with an allergen and is caused by IgE-dependent inflammation of the membranes covering the nose [1]. This health problem affects all ethnicities and age groups, and hurts the economy and family life of the affected person, the health care system, and the economy of the society in general [2,3]. The prevalence of this disease in the world is between 9% and 92% [4], and in Iran, it is reported between 10% and 15% [5-8] with an increasing trend [9]. The administration of antihistamines and corticosteroids are the first-line treatments of AR, which have limited therapeutic effects and mostly reduce the symptoms of the disease temporarily, and on the other hand, their long-term use is associated with side effects [10].

Rasasinex, a nasal spray solution (Salamat Gostar Artiman Company, Iran), is an herbal solution that contains black seed extract (Nigella Sativa) and olive oil (Olea oil). This drug relieves the symptoms of nasal congestion caused by allergies, chronic and acute sinusitis, seasonal allergies, chronic headaches, and cold migraines, relieves fatigue and colds, and strengthens memory. The dosage of this medicine for children aged 1 to 6 years old is one puff in each nasal cavity in the morning and at night. For adults and people over 6 years old, 2 puffs are needed in each nasal cavity in the morning and at night. So far, only sensitivity to the products used in this drug has been reported and no other side effects have been observed.

Due to the high prevalence of AR and excessive use of anti-Histamine compounds, to reduce the symptoms and on the other hand, with the increasing tendency to use the medical herbs, it seems necessary to find effective herbs in the treatment of this condition. As there are previous studies that show the effectiveness of black seeds in the treatment of allergic diseases and AR [11-13], and due to the shortage of evidence on the use of Rasasinex, we aimed to investigate the Rasasinex effect, a combination of black seed and olive oil, in the AR treatment. We hypothesized that in case of a considerable effect of using this drug on AR in children, clinicians could manage their patients more accurately.

Methods

Settings and Design

This is a retrospective study conducted on 100 records of children with mild and persistent AR who were divided into two groups of 50. In group 1, records of patients who received oral antihistamine treatment with Rasasinex were assessed. On the other hand, group 2 was treated routinely with oral antihistamine treatment and did not receive Rasasinex. Rasasinex consists of 40% black seed powder, and 60% olive oil, and is standardized based on 0.23 mg/ml of transanthol.

Records of patients aged > 1 year with AR who received treatment for 4 weeks were included in this study. Records of patients with the following criteria were excluded:

Presence of nasal polyps, deviation of the nasal septum, asthma and lung diseases, infectious sinusitis, and any infection in the respiratory tract, etc. Mild AR was indicated by normal sleep, normal daily activity, normal work or school activity, and no bothersome symptoms. Likewise, persistent AR was noted by the occurrence of symptoms for more than 4 days per week, and/or more than four weeks of involvement per episode.

The symptoms and signs were recorded in a checklist, including the

presence of sleep disorders, disturbances in daily activities, at work or school, rhinorrhea, nasal congestion, continuous sneezing, itching of the nose, ears, or eyes, nocturnal snoring, intermittent sore throat, coughing, and headache.

To check the signs and symptoms, scores from 1 to 4 were considered for each, score 1 means no sign or symptom, 2 means mild sign or symptom (without causing discomfort), 3 means moderate sign or symptom (causing discomfort), and 4 means a severe sign or symptom (disruption of the daily life process). The records of patients who were followed up four weeks after the treatment were assessed.

Ethical Considerations

This study was approved by the Ethics Committee of the Vice-Chancellor of Research at Qom Islamic Azad University with the following code: IR.IAU.QOM.REC1400.021

Statistical Analysis

After collecting the data, they were analyzed using IBM SPSS version 26. Results were reported by descriptive statistics (frequency, percentage, mean, and standard deviation). The chi-square test was used for comparing qualitative variables and the independent t-test was used for quantitative variables. A p-value < 0.05 indicated statistical significance.

Results

In the study, 37 out of 100 patients in group 1 and 33 out of 50 patients in group 2 were boys, making up 74% and 66% of each group, respectively, with no significant difference between groups (p= 0.51). The mean age in group 1 was 6.1 ±0.28 years and in group 2 was 6.8±0.34 years. The highest frequency of AR occurred in 7-year-old children, with no significant difference between groups regarding age (p=0.14). Regarding sleep disorders, 54% (27 cases) and 62% (31 cases) of groups 1 and 2 had mild sleep disorders, respectively. The remaining had no sleep disorder, and there was no significant difference between the two groups (p=0.54). Mild impairment in daily activity was reported in 30% (15 cases) of group 1 and 26% (13 cases) of group 2. No disruption in daily activity was reported in 70% (35 cases) of group 1 and 74% (37 cases) of group 2, with no significant difference between the two groups (p=0.65).

In group 1, 4% (2 cases) had mild impairment at work/school, while in group 2, 100% (50 cases) had no disruption, with no significant difference between the two groups (p=0.15).

Regarding the severity of symptoms, no significant difference was observed between the groups regarding rhinorrhoea (p=0.09), consecutive sneezing (p=0.42), nose/eyes/ears/throat itching (p=0.15), nocturnal snoring (p=0.10), cough (p=0.15), and headache (p=0.22). However, a significant difference was noted in the case of nasal congestion(p=0.012) and intermittent sore throat(p=0.015) (Table 1).

The duration of disease symptoms in group 1 varied, with 40% (20 cases) less than 10 days, 18% (9 cases) 10-30 days, 14% (7 cases) 1-2 months, 4% (2 cases) 2-3 months, 8% (4 cases) for 3-4 months, 2% for more than 4 months, and 14% (7 cases) continuously. In the second group, symptoms occurred in 22% (11 cases) less than 10 days, 40% (20 cases) 10-30 days, 12% (6 cases) 1-2 months, and 14% (7 cases) 2-3 months, with no significant difference in duration before treatment (p=0.058).

Table 1 The severity of symptoms in children with AR

Symptoms	Group 1 (oral antihistamine treatment with Rasasinex)	Group 2 (only oral antihistamine treatment)	*P*-value
Rhinorrhoea			0.09
Mild	14% (7 cases)	10% (5 cases)	
Moderate	22% (11 cases)	40% (20 cases)	
Severe	20% (10 cases)	26% (13 cases)	
No rhinorrhoea	44% (22 cases)	24% (12 cases)	
Nasal congestion			0.012
Mild	16% (8 cases)	18% (9 cases)	
Moderate	28% (14 cases)	30% (15 cases)	
Severe	38 % (19 cases)	12% (6 cases)	
No rhinorrhoea	18% (9 cases)	40% (20 cases)	
Consecutive sneezing			0.42
Mild	12% (6 cases)	20% (10 cases)	
Moderate	24% (12 cases)	32% (16 cases)	
Severe	16% (8 cases)	14% (7 cases)	
no consecutive sneezing	48% (24 cases)	34% (17 cases)	
nose/eyes/ears/throat itching			0.15
Mild	14% (7 cases)	20% (10 cases)	
Moderate	10% (5 cases)	18% (9 cases)	
Severe	12% (6 cases)	2% (1 case)	
No inching	64% (32 cases)	60% (30 cases)	
Nocturnal snoring			0.10
Mild	10% (5 cases)	14% (7 cases)	
Moderate	10% (5 cases)	16% (8 cases)	
Severe	26 % (13 cases)	8% (4 cases)	
No Nocturnal snoring	54% (27 cases)	62% (31 cases)	
Intermittent sore throat			0.015
Mild	10% (5 cases)	2% (1 case)	
Moderate	4% (2 cases)	2% (1 case)	
Severe	0	0	
No sore throat	86%(43 cases)	96% (48 cases)	
Cough			0.15
Mild	8% (4 cases)	20% (10 cases)	
Moderate	6% (3 cases)	4% (2 cases)	
Severe	6% (3 cases)	0	
No cough	80% (40 cases)	76% (38 cases)	
Headache			0.22
Mild	6% (3 cases)	6% (3 cases)	
Moderate	6% (3 cases)	0	
Severe	0	0	
No headache	88% (44 cases)	94% (47 cases)	

In the group treated with Rasasinex, symptoms improved with varying durations: 16% (8 cases) immediately, 50% (25 cases) in less than 3 days, 18% (9 cases) in 4-10 days, and 8% (4 people) in 10-30 days. In the antihistamines alone group, 2% (1 case) improved immediately, 8% (4 cases) in less than 3 days, 66% (33 cases) in 4-10 days, and 6% (3 cases) in 10-30 days. There was a significant difference in improvement between the two groups ($p<0.0001$).

The mean duration of symptoms before taking the drug was 45.11 days in the case group and 50.84 days in the control group, with no significant difference ($p=0.15$). The mean duration of symptoms in the first group was 4.27 days and in the second group was 14.05

days, showing a significant difference in the drug effectiveness (p=0.001).

Discussion

In this study, we compared the condition of patients with Rasasinex drug and the control group and there was a significant difference between the clinical symptoms in children before the start of treatment, except in cases of nasal congestion and intermittent sore throat, which were more in group 1. Likewise, there was a significant difference in the improvement of AR symptoms in children treated with Rasasinex compared to children treated with antihistamines. The mean duration of symptoms in the first group was 4.27 days and in the control group was 14.05 days so that in the Rasasinex group, more children had symptom improvement on the same day of starting the drug, and the lack of improvement in the case group was less than the control group, and most of the children taking Rasasinex had improvement in symptoms within less than 3 days of taking the drug. To the best of our knowledge, there is no previous study that assessed the effect of Rasasinex as a combination of olive oil and black seed. Therefore, we mentioned the relevant studies. Mohamed Alsamarai *et al.* assessed the effect of topical black seed oil in the treatment of AR in 68 patients. They found that the use of black seed oil locally is effective in the treatment of AR [11]. In the same line, we mentioned that the use of Rasasinex nasal spray, which contains black seed and olive oil, significantly reduced the symptoms of AR in children.

In a meta-analysis by Gholamnejad *et al.* who assessed the clinical and experimental effects of black seed and its components in allergic and respiratory diseases, it was determined that the use of black seed or black seed oil for 15 to 30 days in patients with AR causes a decrease in body temperature. In the elderly, the use of black seed extract or seeds for 3 to 12 weeks improved symptoms and pulmonary function [12]. Similarly, the findings of our study also reduced the AR symptoms in the group treated with black seed extract.

In the study by Rezaeian *et al.*, which assessed the effectiveness of black seed extract as a nasal spray on patients with rhinosinusitis without nasal polyps, 65 patients with mild to moderate chronic rhinosinusitis without nasal polyps were examined based on the inclusion criteria. In the intervention group, they received N.sativa nasal spray (1 gram per day) and in the placebo group, they received 2 puffs of 0.65% sodium chloride spray. In this study, 31 patients (19 men and 12 women) were in the intervention group and 34 patients (18 men and 16 women) were in the placebo group. Our results showed that the evaluation scores in both groups decreased significantly. However, these scores in the intervention group were significantly lower than the placebo group (p<0.0001) [13]. Despite the differences in the drug used, the findings of this study were consistent with ours.

Strengths and Limitations

The AR treatment is mainly corticosteroids and antihistamines, which have side effects, especially in children. As the trend of using effective herbal supplements is increasing and based on the properties of black seed and the results of this study, it is suggested to use black seed nasal spray before prescribing antihistamines and corticosteroids. We evaluated the records and regarding the retrospective nature of this study, we could not assess the non-compliance or variations in adherence that can significantly affect the outcomes. This study assessed the effectiveness of Rasasinex over 4 weeks. However, AR is a

chronic condition that may require long-term management. A longer follow-up period would provide more comprehensive insights into the sustained effectiveness and potential recurrence of symptoms after discontinuation of the treatment.

It is suggested that future studies be conducted on the effectiveness of other herbal plants in improving AR. It is suggested that in future studies on the effectiveness of black seed extract, which is suitable for local use, its use in the recovery of other allergic diseases such as eczema be assessed. Also, it is suggested that future studies be conducted on the effectiveness of black seed on allergic asthma due to its anti-inflammatory properties.

Conclusion

The use of nasal spray containing black seed and olive oil (Rasasinex) for four weeks has been significantly effective in reducing and improving the AR symptoms in children, so most patients reported improvement of symptoms up to three days. Therefore, it seems that it can be used in these patients.

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