

A Novel Solution for Treatment of Allergic Rhinitis: Observational Clinical Trial

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Background: Allergic rhinitis has been recognized as an increasing world health disease that is of vital importance to patients' lives. In this study, we aim to reduce the duration of allergic rhinitis treatment and remove its symptoms effectively.

Materials and Methods: Newly diagnosed 50 patients with allergic rhinitis were included in the study. 25 patients with allergic rhinitis used our mixed herbal solution (group I) and 25 patients used medical drugs like intranasal corticosteroids, anti-histamines, and anti-leukotrienes (group II). Allergic rhinitis symptoms were compared between the patients according to total nasal symptom scale.

Results: In group I, the rhinorrhea score was significantly lower after the treatment ($p<0.05$). The post-treatment itching score was significantly lower in group I than in group II ($p<0.05$). In group I, the nasal congestion score was meaningfully lower than in group II after treatment ($p<0.05$). The sneezing score was knowingly lower after the treatment in group I ($p<0.05$). The results showed that the severity of all nasal symptoms decreased statistically and clinically after the treatment.

Conclusion: The study suggested that the new treatment with the mixed herbal solution has been superior to treatments including corticosteroid, anti-histamine, and anti-leukotriene.

Keywords: Allergic rhinitis, rhinorrhea, novel treatment, herbal drug

Introduction

Allergic rhinitis is certified as a growing world health disease with considerable importance for patients' lives (1). This disease occurs as a result of seasonal clouds of dust of pollen and other allergic substances. Furthermore, symptoms of allergic rhinitis may be persistent or intermittent (2). Some various symptoms may occur in allergic rhinitis. These symptoms are a

nasal obstruction, rhinorrhea, sneezing and itching. Allergic conjunctivitis may accompany to these symptoms. Allergic rhinitis affects people's daily life in many ways. School success, social life and work may be significantly affected by this disease. The disease can wake people up from sleep, so cause daily inattentiveness, and even traffic accidents (3). The symptoms of this disease are tried to be controlled by many

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drugs which are oral, intranasal and topical nasal antihistamines, intranasal corticosteroids and anti-leukotrienes (4-6). These treatments can be used in single or combination form. Since these treatments need to be used for a long period of time, many patients do not use these medications regularly. So, the treatment is unlikely to be successful. This problem leads us to search for a new method that can treat symptoms of allergic rhinitis in a short time (7).

In this study, we aimed to eliminate symptoms of allergic rhinitis in a short time. We searched some herbal blend solution on allergic nasal mucosa of rats. We prepared a mixture with a combination of four different herbal oils. These oils are used in the treatment of various diseases among the population, but not in the treatment of allergic rhinitis. We used this herbal blend solution on nasal mucosa of rats externally for three days. Then, we showed that allergic activity of nasal mucosal diminished. There is no mucosal complication on rats. So, we decided to use on voluntary patients.

Materials and Methods

The ethical approval was obtained from the ethics committee of The Adana City Hospital in Adana in Turkey. The patent of our treatment has also been approved. The approval number is 2018/13253.

Preparing the Herbal Solution

Different herbal oils were used in different rates and their mixture patents are under the legal protection. These oils were sterile oils that are mined by the various distillation methods. We do not share the names and the rates due to confidentiality. This mixture is called as ALMEV-RI®.

This study was conducted as a controlled double-blinded observational clinical study. We

included newly diagnosed 50 patients with allergic rhinitis in our study. We excluded other diseases such as nasal polyps, sinusitis or non-allergenic conditions.

Before treatment, we asked all patients for their allergic symptom score. For this purpose, we used the Total Nasal Symptom Scale. The scale includes four nasal symptom scores like rhinorrhea, nasal obstruction, nasal itching, and sneezing, and is scored as 0, I, II, III. (0: no symptom, I: low symptom, II: average symptom, III: high symptom).

The patients were treated with our mixed herbal solution or medical drugs such as intranasal corticosteroids, antihistamines, and antileukotrienes. We also asked the patients' symptoms after the treatments. 25 patients who did not want to use medication for a long time (no drug patients, NDP) and 25 patients who wanted to use medical drugs (drug patient, DP) were included in the study.

We applied the solution on anterior nasal mucosa (conchal and septal) of NDP by rubbing once a day. We applied the solution for three consecutive days. We advised the patients not to use water on nasal mucosa for 3 hours after rubbing the solution. One week later, we applied the solution to nasal mucosa of NDP once again. The 25 patients used medical drug treatments (DP) such as intranasal corticosteroids, anti-histamines, and anti-leukotrienes. The patients used an intranasal corticosteroid twice a day, oral antihistamines and antileukotrienes once a day for a month. At the end of one-month follow-up, symptom scores and examination findings of the patients were noted. We compared these two groups for allergic rhinitis symptoms.

Statistical Analysis

Standard deviation, mean, median lowest, highest, frequency and ratio values were utilized in the descriptive statistics of the data. The distribution of the variables was assessed with the Kolmogorov-Smirnov test. ANOVA independent sample t-test was used for the analysis of quantitative independent data. Chi-square test was used for analysis of qualitative independent data, and Fischer test was used when chi-square test situations were not met. Mc-Nemar test was used in the analysis of the dependent qualitative data. The analyses of data is made use of SPSS 22 program.

Results

The ages of patients and gender distribution did not differ meaningfully in group I and group II (Table 2). In group I and group II, rhinorrhea score did not differ significantly before the treatment. In group I, the rhinorrhea score was significantly lower than in group II after the treatment ($p<0.05$). In group I, the rhinorrhea score reduced significantly after treatment ($p<0.05$). In group II, rhinorrhea score did not differ after treatment (Table 3). In group I and group II, the itching score did not differ significantly before the treatment. In group I, the post-treatment itching was significantly lower than in group II ($p<0.05$). In group I, the post-treatment itching score decreased significantly ($p<0.05$). In group II, post-treatment itching score did not meaningfully become different (Table 3).

Table 1. Demographic variables and the symptom scores

Variables	Mean	N (%)
Age	43.8±17.1	
Gender	Male/Female	32/18
Rhinorrhea Before Treatments	0	3 (6%)
	I	2 (4%)
	II	10 (20%)
	III	35 (70%)
After Treatments	0	11 (22%)
	I	22 (44%)
	II	15 (30%)
	III	2 (4%)
Itching Before Treatments	0	0
	I	0
	II	1 (2%)
	III	49 (98%)
After Treatments	0	18 (36%)
	I	8 (26%)
	II	22 (44%)
	III	2 (4%)
Nasal Congestion Before Treatments	0	3 (6%)
	I	21 (42%)
	II	19 (38%)
	III	7 (14%)
After Treatments	0	21 (42%)
	I	13 (26%)
	II	15 (30%)
	III	1 (2%)
Sneezing Before Treatments	0	0
	I	1 (2%)
	II	1 (2%)
	III	48 (96%)
After Treatments	0	22 (44%)
	I	9 (18%)
	II	16 (32%)
	III	3 (6%)

Table 2. Demographic variables between the groups

Variables		Group I		Group II		P
		Mean±SD/N%	Median	Mean±SD/N%	Median	
Age	Years	44.2±14.4	40	43.4±19.6	47	0.992
Gender	Male	18	72%	14	56%	0.239
	Female	7	28%	11	44%	

Table 3. The comparison of the symptoms between the groups

Variables	Degree	Group I		Group II		X ² (p)
		N	%	N	%	
Rhinnorrhea Before Treatments	0	0	0	3	12%	0.157
	I	1	4%	1	4%	
	II	2	8%	8	32%	
	III	22	88%	13	52%	
After Treatments	0	8	32%	3	12%	<0.001
	I	17	68%	5	20%	
	II	0	0	15	60%	
	III	0	0	2	8%	
<i>Before/After Difference (p)</i>		<0.001		0.125		Mc-Nemar
Itching Before Treatments	0	0	0	0	0	NS
	I	0	0	0	0	
	II	0	0	1	4%	
	III	25	100%	24	96%	
After Treatments	0	18	72%	0	0	<0.0001
	I	5	20%	3	12%	
	II	2	8%	20	80%	
	III	0	0	2	8%	
<i>Before/After Difference (p)</i>		<0.001		0.250		Mc-Nemar
Nasal Congestion Before Treatments	0	2	8%	1	4%	0.157
	I	15	60%	6	24%	
	II	4	16%	15	60%	
	III	4	16%	3	12%	
After Treatments	0	18	72%	3	12%	<0.001
	I	7	28%	6	24%	
	II	0	0	15	60%	
	III	0	0	1	4%	
<i>Before/After Difference (p)</i>		<0.001		0.500		Mc-Nemar
Sneezing Before Treatments	0	0	0	0	0	NS
	I	1	4%	0	0	
	II	0	0	1	4%	
	III	24	96%	24	96%	
After Treatments	0	21	84%	1	4%	<0.001
	I	4	16%	5	20%	
	II	0	0	16	64%	
	III	0	0	3	12%	
<i>Before/After Difference (p)</i>		<0.0001		0.031		Mc-Nemar

In group I and group II, the nasal congestion score did not differ significantly ($p>0.05$) before the treatment. In group I, the nasal congestion score was meaningfully lower ($p<0.05$) than in group II after treatment. In group I, the nasal congestion score was suggestively lower after the treatment ($p<0.05$). In group II, the nasal congestion score did not show any significant changes after the treatment (Table 3).

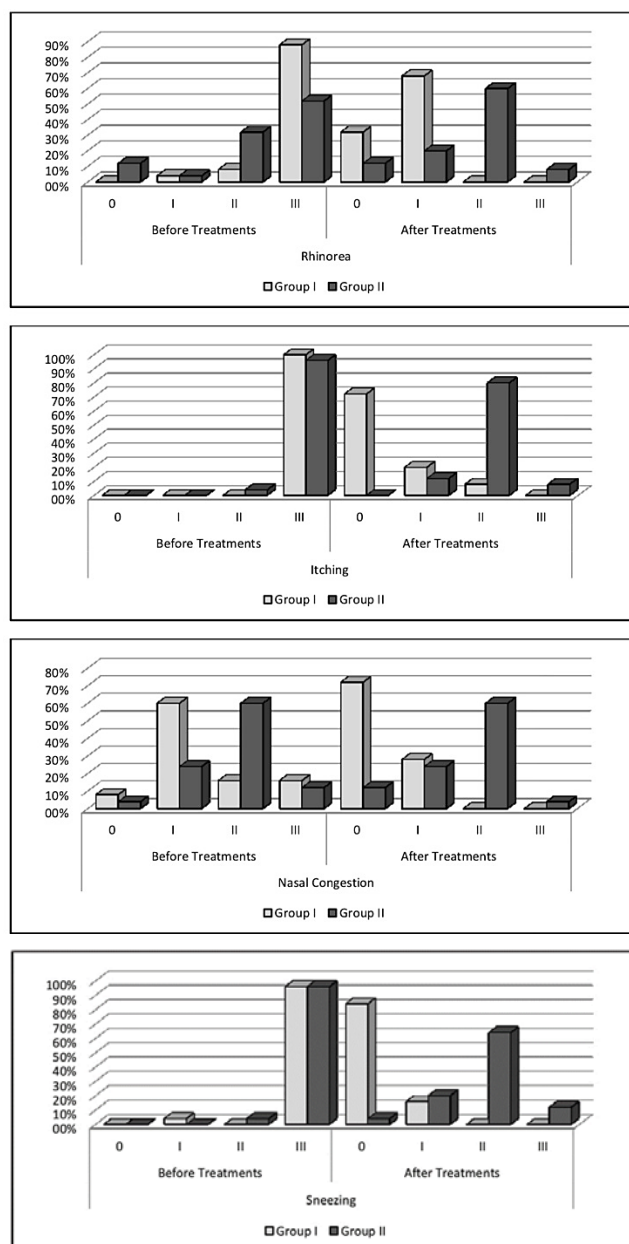


Figure-1. Comparison of the groups according to itching, sneezing, rhinorrhea, and nasal congestion

In group I and group II, the sneezing score did not differ significantly before the treatment. In group I, the sneezing score was significantly lower than in group II after treatment ($p<0.05$). In group I, the sneezing score was knowingly lower after treatment. In group II, posttreatment sneezing decreased significantly ($p<0.05$).

Discussion

Many studies have been reported all over the world about the treatment of allergic rhinitis. The most widely accepted treatment modalities are systemic or topical antihistamines and corticosteroids. However, the current treatment methods cause time and financial losses.

Many drugs are used to treat allergic rhinitis. Successful results were obtained with these drugs, such as systemic or topical intranasal corticosteroids, mast cell stabilizers, nasal anticholinergics, leukotriene-receptor antagonists, and antihistamines (4-6). Especially, guidelines recommend intranasal corticosteroids as a medication for patients with average to high allergic rhinitis symptoms (7).

Wide clinical evidence shows that topical nasal corticosteroids accommodate greater donations of allergic rhinitis symptoms than antihistamines. However, a recent study reports fluticasone propionate and cetirizine in the treatment of allergic rhinitis. The investigators found that fluticasone propionate and cetirizine were equally effective. The long duration and cost of these treatment modalities limit their use in the society. These treatments should be used for at least one month to be effective. The effect of our medication occurs in three days and removes symptoms of allergic rhinitis to a very large extent (% 95 over).

Some guidelines recommend prescribing one therapy, an intranasal topical corticosteroid for

the first treatment of perennial allergic rhinitis over 12 years of age (8). However, we think that the treatment duration is very long in this way.

The use of topical corticosteroids and topical antihistaminic nasal sprays has disadvantages. For example, the use of nasal corticosteroids is only effective after the first week of use, and regular use of this drug is required (9-12). However, the majority of the patients do not use this medication regularly. On the other hand, local side effects, such as mucosal irritation or epistaxis, may be commonly seen. Some health care providers are concerned that intranasal corticosteroids may produce adverse effects like growth changes. In a recent study, Lee et al. were able to determine a small, but statistically significant reduction in growth velocity after the treatment with fluticasone furoate nasal spray (13). In this context, we did not observe any adverse effects in the patients who used our solution.

Topical antihistamines used in the treatment are very poor in taste and can be left by patients after a few uses. Our treatment method may be superior to both antihistamine and corticosteroid treatment. Because it is effective in a short period of time, it can be tolerated and creates pleasure in the patients. The other problem is concha hyperplasia which is often accompanied by nasal obstruction chronically. A concha hyperplasia may be caused by increased blood vessels in the nasal mucosa and common venous sinusoid in the lamina propria of the inferior concha (10). There are many available treatment methods around the world for this problem.

Turbineotomy, which is a surgical treatment method of concha hyperplasia, has produced many problems in spite of positive results in patients. One of them is the emergence of nasal

dryness. Hofer et al. reported that a nasal dryness developed after anterior turbinectomy (11). In our study, in the patients with concha hyperplasia who used the herbal solution, we observed that the concha size decreased by more than 50 and nasal dryness did not develop. There were not any negative reports from patients.

Conflict of Interests

The authors declare that they have no conflict of interest in the current study.

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