

COMPARISON OF ALLERGEN IMMUNOTHERAPY AND DRUG TREATMENT IN SEASONAL RHINOCONJUNCTIVITIS: A 3-YEARS STUDY

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SUMMARY: Drug treatment and specific immunotherapy (SIT) are both effective in seasonal rhinoconjunctivitis, but the former acts only on allergic symptoms while the latter modifies the natural history of the disease. Only a few studies compared the clinical efficacy of the two treatments with contrasting results.

We planned a study to compare the efficacy of SIT (15 patients) and drug treatment (15 patients) in moderate to severe seasonal rhinoconjunctivitis caused by sensitization to grass pollen. SIT was performed by a 5-grass extract standardized in IR and absorbed onto calcium phosphate (Phossta™ Stallergènes, Antony, France) using the conventional build-up phase in 12 weeks and a maintenance treatment with monthly injection for three years. Drug treatment was done with cetirizine as anti-histamine, mometasone furoate as nasal topical steroid, and levocabastine eyedrops. All patients registered during the pollen season their symptoms and drug consumption. After one year 12 of 15 patients treated with SIT had less symptoms and drug consumption in respect to baseline compared to none in drug treated group ($p = 0.021$) and after three years 15 of 15 were improved in group A compared to one of 15 in group B ($p = 0.008$). These findings indicate an higher efficacy of SIT in patients with seasonal rhinitis not only in the long term but also in the first year of treatment.

INTRODUCTION

The management of allergic diseases is based on allergen avoidance, drug treatment, and allergen specific immunotherapy (SIT)(1). In patients suffering from pollinosis only the two last options are feasible with well distinct roles. In fact, anti-allergic drugs act while they are administered, whereas SIT is able to interfere with the natural history of allergy (2), thus acting on allergic symptoms also after discontinuation of the treatment (3-5). On the other hand, the early antiinflammatory effect of SIT may achieve a good symptomatic effect in patients with pollinosis already from the first pollen season following the start of treatment (6-8).

However SIT, mainly for the inconvenience linked to a build-up phase with weekly injections and to a maintenance duration of at least three years, is performed in a minority of the patients who would benefit from its therapeutic action, whereas drug treatment is much more used. Surprisingly, only a few studies compared SIT to drug treatment (9-11).

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We planned a study to compare the efficacy of SIT and drug treatment with commonly used agents in patients with moderate to severe seasonal rhinoconjunctivitis caused by sensitization to grass pollen.

MATERIAL AND METHODS

Patients

The patients of the study were selected from those with moderate to severe seasonal rhinoconjunctivitis but not cough or asthma referring to Pulmonary and Allergic Diseases Department of Lugo Hospital, (Ravenna, Italy) during spring 1999. They were asked, after explaining the characteristics of the different treatments, to choose to undergo SIT plus drug treatment as needed or only drug treatment. The severity of rhinoconjunctivitis was assessed by grading allergic symptoms (sneezing, rhinorrhea, nasal itching, obstruction, and tearing) with the scale 0 = no symptoms, 1 = mild, 2 = moderate, and 3 = severe symptoms, and drug consumption as follows: 0 = no drug, 1 = treatment for less than 10 days, 2 = treatment for 10 to 30 days, and 3 = treatment for more than 30 days.

SIT

SIT was performed by a 5-grass extract standardized in IR (12) and absorbed onto calcium phosphate (Phostal™, Stallergenes, Antony, France) using the conventional build-up phase in 12 weeks, with a top dose of 8 IR, and a maintenance treatment administering this dose with monthly interval, with a 60% reduction during the pollen season, i.e. from April to September. The maintenance treatment was continued for three years, until spring of 2002. All patients registered during the pollen season their symptoms and the drug consumption.

DRUG TREATMENT

The allowed drugs were cetirizine as antihistamine and mometasone furoate as nasal topical steroid for nasal symptoms, and levocabastine eyedrops for ocular symptoms.

STATISTICAL ANALYSIS

The frequency of improvement of symptom score and drug consumption in the two groups of patients treated with SIT plus drug treatment as needed or with only drug treatment was compared by the chi squared test, with a p value lower than 0.05 considered as significant.

Results

An overall number of 30 patients was included in the study, 15 (8 males and 7 females, mean age 24.2 years, range 18-33 years) formed the group treated with SIT plus drug treatment (group A) and 15 (6 males and 9 females, mean age 23.9 years, range 18-29 years) formed the group treated only with drugs (group B).

The patients of group A received during the three years a cumulative dosage of 163.12 IR (range 151.2-169.2).

The table 1 shows the mean symptom score and drug consumption at baseline and after one and three years. Both symptoms and drug consumption were considered improved when under the score 2 (moderate symptoms, drug for less than 10 days). By this assessment, after one year 12 of 15 patients were improved in group A compared to none in group B ($p = 0.021$) and after three years 15 of 15 were improved in group A compared to one of 15 in group B ($p = 0.008$).

	Group A			Group B		
Symptoms	Baseline	1 year	3 years	Baseline	1 year	3 years
Sneezing	2.44	1.82	1.41	2.36	2.54	2.66
Rhinorrhea	2.03	1.78	1.32	2.04	2.26	2.53
Itching	2.06	1.76	1.30	2.10	2.18	2.24
Obstruction	2.26	1.98	1.46	2.38	2.38	2.49
Tearing	2.04	1.69	1.27	1.96	2.12	2.19
Drugs						
Antihistamine	2.38	1.85	1.27	2.33	2.45	2.49
Nasal steroid	2.09	1.90	1.44	1.99	2.23	2.71
Cough	0	0	0	0	3	7
Asthma	0	0	0	0	1	5

Table 1: Mean symptom scores and drug consumption in the two groups treated with SIT plus drug treatment as needed (group A) or drug treatment alone (group B).

DISCUSSION

A large number of studies demonstrated the clinical efficacy of SIT in rhinitis and asthma caused by inhalant allergens and particularly in pollen-induced seasonal allergy (1). A recent consensus document on allergic rhinitis suggested to consider SIT as a treatment option in patients with both intermittent or persistent moderate to severe rhinitis (2), but the number of patients treated with SIT compared to conventional drug treatment is quite low. On the other hand, the two treatments are used in combination in most cases, and an important outcome measure in controlled studies on SIT is the sparing effect on drug consumption, but direct comparison of their relative value was rarely done.

A study from Juniper *and al.* (9) compared the efficacy of SIT with that of budesonide nasal spray in patients with seasonal rhinitis and found a significant superiority of drug treatment, but it has to be noted that SIT was performed by a low potency extract administered in a few, preseasonal doses, and this would hardly represent an optimal model for immunotherapy.

By a different approach, Varney *and al.* reported that SIT with a conventional protocol was effective in patients with severe seasonal rhinitis in whom treatment with anti-allergic drugs did not achieve a sufficient control of nasal symptoms (10).

In the present study, the effectiveness of drug treatment with antihistamines and nasal corticosteroids was clearly lower than obtained with SIT, with a significant difference in the number of patients clinically improved already both after one year and a further increase after three years, when all patients treated with SIT showed a clinical benefit compared to only one of 15 treated with drugs alone.

Another positive aspect consisted in the prevention of asthmatic symptoms in rhinitic patients achieved by SIT, compared to their development in one-third of patients treated with drugs alone. This confirms a well-known effect of SIT, recently described also in a large population of children with seasonal rhinitis (13).

In conclusion, this study adds new data to the comparison between SIT and drug treatment, demonstrating higher efficacy of SIT in patients with seasonal rhinitis not only in the long term but also in the first year of treatment and confirming the preventive effect on development of asthma of SIT but not of drug treatment including topical nasal corticosteroids.

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