

Short communication

The role of patient training in the management of seasonal rhinitis and asthma: clinical implications

Background: Allergic rhinitis is an inflammatory disease often associated with bronchial asthma. Intranasal corticosteroids and oral antihistamines are the first-choice drugs. Patient training is relevant to asthma management, but little is known about its impact on rhinitis. We evaluated the role of patient training in the treatment of allergic rhinitis and its effects on nasal and bronchial symptoms.

Methods: One hundred and one patients (M/F = 62/39, age range 12–62 years) with pollen-induced rhinitis (32 with concomitant mild asthma) were enrolled. They were randomized into three groups: A ($n = 30$) with drug therapy alone, B ($n = 35$) with drug therapy plus training on the use of nasal spray, and C ($n = 36$) the same as B plus a lesson on rhinitis and asthma. All patients received mometasone furoate nasal spray for 8 weeks as regular therapy, plus rescue medications on demand. Symptoms and drug consumption were evaluated during the pollen season.

Results: The rate of noncompliance/dropout was highest in the untrained patients ($P = 0.001$). No difference in nasal symptoms was seen among the three groups. On the other hand, group C had significantly fewer asthma symptoms ($P = 0.02$) and less albuterol use ($P = 0.005$) than group A. Moreover, the trained group globally used less rescue medication than the other groups ($P = 0.02$).

Conclusions: Detailed training of patients seems to improve compliance with treatment, reduce concomitant asthma symptoms, and reduce the use of symptomatic drugs.

F. Gani¹, E. Pozzi¹, M. A. Crivellaro²,
G. Senna², M. Landi³, C. Lombardi⁴,
G. W. Canonica⁵, G. Passalacqua⁵

¹Respiratory Diseases, Allergy Service, University of Turin, Turin; ²Allergy Service, General Hospital, Verona; ³Ospedale Koelliker, Turin; ⁴Pneumoallergology Unit, Sant'Orsola Hospital, Brescia; ⁵Allergy and Respiratory Diseases, Department of Internal Medicine, Genoa, Italy

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Giovanni Passalacqua
Allergy and Respiratory Diseases
DIMI, Pad. Maragliano L.go R. Benzi 10
I-16132 Genoa
Italy

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Allergic rhinitis (AR) is an inflammatory disorder triggered by an IgE-mediated mechanism and subsequently sustained by an immune inflammation, in which cells, mediators, and adhesion molecules are involved (1). The incidence of AR is as high as 40% in the USA, and it seems to increase constantly in Western countries (2–4). The seasonal form of AR (SAR) is probably the most common one. SAR is characterized by watery rhinorrhea, sneezing, and itching, whereas the nasal blockage is usually less severe than in perennial AR; it is frequently associated with conjunctivitis (5). The disease can significantly affect the quality of life of the patients; it has more effect than does moderately severe asthma (6). Oral antihistamines and intranasal corticosteroids are the first-choice drugs (7) for controlling symptoms. When exposure to allergen and symptoms are persistent, there is evidence that continuous treatment

is preferable to on-demand treatment, in order to control the underlying allergic inflammation (8–10). Furthermore, optimal treatment of rhinitis may result in an improvement of associated asthma symptoms and bronchial responsiveness, as demonstrated with intranasal corticosteroids (11–13). Nevertheless, continuous treatment frequently leads to poor patient compliance and, therefore, to the use of additional rescue medications.

In the case of asthma, the role of information and training (nature of the disease, objectives of the treatment, and correct use of the devices) has been found to be essential for a satisfactory clinical outcome (14). Such an approach is still lacking in the management of AR. The present study aimed to determine whether the training intervention can clinically improve rhinitis symptoms and modify asthma symptoms if present.

Material and methods

Study design

The study was designed to use three randomized, open-controlled parallel groups. One hundred and one patients suffering from SAR were randomly allocated into three groups receiving a written prescription of drug therapy alone, or training on how to use the nasal spray, or a detailed lesson on the nature of their disease. The presence and severity of symptoms were assessed during the whole pollen season, as was the intake of drugs.

Patients

One hundred and one patients (62 male, 39 female, age range 12–60 years) were enrolled at the allergy centers of Orbassano, Turin, and Verona (Italy). All patients had suffered for at least 2 years from SAR solely due to pollens (grasses, birch, *Parietaria*, and *Compositae*), as assessed by clinical history, skin testing (class ++ or higher), and RAST (class II or higher). Patients with sensitization to multiple pollens were included, whereas sensitization to cat dander, mites, or mold was a reason for exclusion.

Thirty-two patients also suffered from mild intermittent asthma (14); they were stratified into the three groups. The presence and severity of SAR and asthma symptoms had been evaluated by a visual analog scale (VAS) (0 cm: no symptoms, 10 cm: severe symptoms) in the previous pollen season; all patients had moderate/severe rhinitis with continuous symptoms (VAS: mean 6.55 ± 2.6). Exclusion criteria were as follows: anatomical abnormalities of the upper respiratory airways (septal deviation, polyposis), previous or ongoing immunotherapy, pregnancy/lactation, chronic treatment with systemic corticosteroids, malignancies, and major psychiatric disorders. The cultural level of the patients differed, but patients differing in this respect were equally distributed within the three groups. The demographic data of the population are summarized in Table 1.

Drug therapy and patient training

All patients received regular therapy with mometasone furoate nasal spray (two puffs per nostril q.i.d. = 200 µg/day). Rescue medications on demand were allowed as follows: cetirizine, loratadine, or fexofenadine (one tablet q.i.d. on demand), inhaled albuterol (one to two puffs of 100 µg on demand), and azelastine eye-drops (one to two drops on demand). The use of an intranasal corticosteroid was decided on the basis of a recent meta-analysis of efficacy (15). This is in agreement with the recent consensus statement (7), which recommends this treatment for moderate rhinitis. Mometasone was chosen because of its favorable profile of safety and efficacy (16) and its once-daily use. The patients were instructed to start their therapy at the onset of nasal symptoms and to continue it for 8 weeks.

The first group of patients (group A = 30 patients) was given only the drug with the instructions provided by the manufacturer. The second group (group B = 35 patients) received a brief written instructions on the use of the device. The third group (group C = 36 patients) also attended a 1-h informal lesson on the clinical and pathogenic aspects of SAR, the treatment strategy, the correct use of medications, and the possible side-effects of drugs. A trained allergist (one per clinic) gave the lesson to patients, and the set of slides used was the same in the three clinics.

Evaluated parameters

All patients completed a symptom diary, recording the presence and severity of their symptoms. Symptoms were subdivided as follows: nasal (itching, sneezing, rhinorrhea, and blockage), ocular (itching, redness, lacrimation, and swelling), and respiratory

(cough, wheezing, and chest tightness). The severity of symptoms was graded on a 10-cm visual analog scale (0: no symptoms, 10: severe symptoms). Patients were also required to record carefully each dose of each drug taken, in addition to the nasal corticosteroid. The compliance with therapy was evaluated on the basis of the returned diaries and canisters.

Statistical analysis

Specific software (SAS for Windows, Version 6.12, SAS Institute) was used. The chi-square and Fisher's exact tests were applied to dichotomical variables. Symptom and drug scores were nonnormally distributed; therefore, they were analyzed by Wilcoxon and Kruskal-Wallis tests. ANOVA was used to analyze the age of patients. Group A vs B plus C, group A vs B, and A vs C were compared. *P* values of 0.05 or less were considered significant.

Results

The three groups were homogeneous for age (ANOVA, $P=0.27$), sex (chi square, $P=0.275$), presence of asthma, cigarette smoke, and degree of instruction, as shown in Table 1. Six patients dropped out because they did not attend the final visit, and 16 patients did not comply with the treatment prescribed (Table 1). Interestingly, there was a significant difference in dropout and noncompliance rate within the three groups, in favor of the trained/instructed patients (chi square; $P=0.001$).

The six dropouts were excluded from the symptom/drug intake analysis. There was no significant difference in the total ocular and nasal symptom scores (mean of the 8 weeks) among the three groups. On the other hand, a significant difference ($P=0.02$) was found between group A and group C in respiratory symptoms (Table 2). Interestingly, if wheezing alone was considered, a significant difference between group A and group C could be found ($P=0.05$, not shown).

No statistical significance was observed for the intake of oral antihistamines, although the comparison between group A and group C showed a near-significant difference (Table 3). Furthermore, a

Table 1. Demographic data and dropouts

	A (n=30)	B (n=35)	C (n=36)	Analysis
Mean age $\pm$ SD	31.1 $\pm$ 10	29 $\pm$ 11.2	30.9 $\pm$ 11.4	ANOVA $P=NS$
Female	8	16	15	χ^2 $P=NS$
Male	22	19	21	χ^2 $P=NS$
Asthma	9	9	14	χ^2 $P=NS$
Multiple sensitization	14	20	17	χ^2 $P=NS$
Smokers	7	11	10	χ^2 $P=NS$
University	3	2	3	χ^2 $P=NS$
Secondary school	10	10	12	χ^2 $P=NS$
Primary school	17	24	22	χ^2 $P=NS$
Dropout	4	0	2	
Noncompliant	9	3	4	
Total (dropout plus noncompliant)	13	3	6	χ^2 $P=0.001$

Table 2. Symptoms

	Group A	Group B	Group C	P
Nasal symptoms (itching, sneezing, rhinorrhea, blockage)	62.6 ± 51.0	64.7 ± 50	54.1 ± 62	NS
Ocular symptoms (redness, itching, swelling, lacrimation)	51.3 ± 52.8	46.0 ± 52	42.6 ± 55	NS
Respiratory symptoms (cough, wheezing, tightness)	16.2 ± 24.0	11.7 ± 20	6.00 ± 15	Kruskal-Wallis: $P=0.025$; A vs C, $P=0.02$

Table 3. Drug intake over 8 weeks

	Group A	Group B	Group C	P
Oral antihistamines (tablets taken)	8.3 ± 15	4 ± 11.3	1.3 ± 6.1	Kruskal-Wallis: NS Wilcoxon: A vs C, $P=0.08$
Oral antihistamines (subjects taking < 1 tablet/week)	20 (77%)	30 (86%)	33 (97%)	Fisher's test: A vs B plus C, $P=0.08$ A vs C, $P=0.036$
Inhaled albuterol (subjects taking at least one dose)	6 (23.8%)	2 (5.7%)	0	Fisher's test: A vs B plus C, $P=0.05$ A vs C, $P=0.005$
All concomitant drugs: oral/inhaled steroids, eye-drops, albuterol (subjects taking at least one dose)	13 (50%)	12 (34%)	5 (14.7%)	Chi-square: A vs B plus C, $P=0.02$ A vs C, $P=0.003$

significant difference among the groups was observed when we considered the use of one tablet/week or more than one tablet/week of oral antihistamines.

On the other hand, a significant difference in the use of inhaled albuterol (Fisher test) among the groups was observed (A vs B plus C: $P=0.005$; A vs C: $P=0.005$). When the use of on-demand medications (i.e., other than nasal steroid) was considered, a significant difference could be found between the group A (control group) and groups B plus C and C. The medication intake analysis is shown in Table 3.

Discussion

AR can be considered a chronic inflammatory disorder, at least until exposure to the causal allergen (17). Therefore, continuous treatment would allow an optimal control of symptoms (10) and a reduction in the intake of rescue drugs; a favorable effect on concomitant asthma (if any) is also expected. In the present trial, we aimed to assess the possible effects of a correct training of rhinitic patients. All patients received the same drug therapy, and the three groups differed only in the training provided.

The first remarkable finding was the high occurrence of dropouts/noncompliant patients in the control group as compared to the two trained groups. This would suggest that detailed information/training is relevant to the subsequent compliance with the prescribed treatment. The severity of symptoms during the pollen season did not differ

among the groups, but this factor was counterbalanced by the significantly higher use of rescue medications in the untrained groups: this fact suggests that the control group (no training) had an unsatisfactory control of their symptoms.

Probably, the most interesting finding is the asthma control. The group receiving detailed information/training had a significantly lower occurrence of symptoms, as confirmed by a lower intake of bronchodilator. This latter result is in agreement with other previous clinical observations (12, 13, 18) and indirectly confirms the model of united airways disease (19). The exact pathogenic mechanism linking the upper and lower respiratory airways is still unclear and a matter of debate; nevertheless, it is becoming clear that the therapeutic approach to rhinitis has important effects also on asthma. Therefore, the training of rhinitic patients seems to be as important as the training of asthmatics. An optimal control of rhinitis would improve symptoms and reduce the inappropriate use of rescue medications, thus reducing costs and side-effects.

The clinical effects of a training program are difficult to assess in clinical practice. In our study, we attempted to keep stable the most important variables (i.e., demographics, drug treatment, and evaluated parameters), in order best to detect the effects of the investigational variable. On the basis of the present results and experimental design, we believe that the training of patients can play a relevant role in the clinical outcomes expected from the treatment of AR.

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