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Original article

Patient-related factors in rhinitis and asthma: the satisfaction with allergy treatment survey

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Tel.: +39 02 334541; Fax: +39 02 70058779; frati.f@stallergenes.it**Key words:**

Allergic rhinitis – Asthma – Drug therapy – Patient satisfaction

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Citation: Curr Med Res Opin 2011; 27:1005–11**Abstract****Background:**

Patient satisfaction with the prescribed treatments represents a crucial issue that may have clinical relevance as it may significantly affect treatment compliance. We designed an observational study to evaluate the satisfaction level concerning different pharmacological treatments for allergic rhinitis (AR) and asthma in a real-life setting.

Methods:

The study was conducted in 21 allergy centres homogeneously distributed in Italy. Three hundred and one patients (46.8% males; 53.2% females; mean [SD] age, 33.1 [13.8] years) with AR and/or asthma were consecutively evaluated. Diagnosis, classification, symptom severity, and satisfaction degree (assessed by a questionnaire) were the parameters considered.

Results:

Only 33.5% of the AR patients were satisfied with the rhinitis treatments. Only 40.7% of the asthmatic patients were satisfied with the asthma treatments. Some factors associated with treatment dissatisfaction are as follows: female gender (odds ratio [OR] 2.36; $p < 0.01$), co-morbidity (OR 2.39; $p < 0.05$), rhinitis severity (OR 1.39; $p < 0.05$), asthma severity (OR 2.04; $p < 0.05$), and antihistamine use (OR 2.53); however, the use of bronchodilators had a favourable impact (OR 0.28; $p < 0.05$). The relatively low number of subjects prevented performing stratification of patients by treatment classes.

Conclusion:

The findings of this real-life study strengthen the concept that AR is particularly troublesome and that most allergic patients suffering from both rhinitis and asthma are dissatisfied with prescribed drugs.

Introduction

Allergic rhinitis (AR) and asthma are very common diseases, and their prevalence is still rising as shown by the International Study on Asthma and Allergy in children (ISAAC) in its different phases^{1,2} and by the European Community Respiratory Health Survey (ECRHS)³. The reported prevalence values for AR and asthma ranged from 10% to 20% in children² and from 5% to 18% in adults^{3–5}. The burden of respiratory allergy includes substantial social and economic costs related to the high prevalence and to the impairment of patient's daily activities, productivity, and quality of sleep^{6–8}. Such impairment is particularly significant in patients suffering from both AR and asthma^{9–11}.

A large variety of drug interventions (including oral/intranasal antihistamines, intranasal/inhaled/systemic corticosteroids, antileukotrienes, β_2 -adrenoreceptor agonists) is currently recommended as the primary component for treating the respiratory allergic disorders. Their efficacy and safety have

been widely documented at the evidence based medicine (EBM) level and are implemented in the guidelines at the primary care level^{12–14}. Nevertheless, it seems that there is a discrepancy between the guidelines and patient perception of the efficacy, safety, and tolerability of drug treatments¹⁵. Therefore, patient satisfaction with prescribed treatments represents a crucial issue that may significantly affect treatment compliance. Nevertheless, there is a paucity of data concerning satisfaction of drug treatment for respiratory allergy. In particular, patient satisfaction was evaluated in two studies on AR, reporting good satisfaction to treatment with the antihistamine levocetirizine^{16,17}, and in two studies on asthma, showing instead that there is the need to improve this aspect^{18,19}.

This observational study conducted in allergy centres in Italy was aimed at evaluating the satisfaction level concerning different treatments for AR and asthma in a real-life setting.

Material and methods

Study design

The study was named SAT from the words ‘Satisfaction with Allergy Treatment’. The survey was conducted in 21 allergy centres homogeneously distributed in Italy. It was designed to include samples representative of the general population and to have the ability to identify newly diagnosed cases. Patients were evaluated by using a questionnaire addressed to evaluate the satisfaction level concerning the treatments prescribed for AR and asthma. The questionnaire was developed in the Italian language by a panel of experts, using as an initial model the Patient Satisfaction Questionnaire Short-form, PSQ-18²⁰, and was validated by submitting it to a group of Italian patients suffering from allergic rhinitis and asthma at two different times to state its reproducibility.

The study was approved by the review board of each participating centre, and informed consent was obtained from each patient.

Subjects

A total of 301 patients (46.8% males and 53.2% females; mean [SD] age, 33.1 [13.8] years) with AR and/or asthma were consecutively evaluated. A detailed clinical history was taken, and a complete physical examination was performed. The patients were included in the study on the basis of a diagnosis of AR and/or asthma.

Skin-prick tests (SPT) were performed as stated by the European Academy of Allergy and Clinical Immunology²¹. The panel consisted of house dust mites (*Dermatophagoides farinae* and *Dermatophagoides*

pteronyssinus), cat, dog, grass mix, mugwort, ragweed, *Parietaria officinalis*, birch, hazel, olive tree, cypress, *Alternaria tenuis*, *Cladosporium*, and *Aspergillus* mix (Stallergenes, Milan, Italy).

The diagnosis and severity classification of intermittent AR (IAR) or persistent rhinitis (PER) was made on the basis of a history of nasal symptoms and positive SPT result according to the validated criteria proposed by the ARIA document⁹.

The diagnosis and severity classification of asthma were made according to GINA criteria, including the reversibility-to-bronchodilation test¹².

Satisfaction level

The satisfaction with treatment was assessed by the specific questionnaire. Patients had to declare if they were satisfied concerning the prescribed drugs for AR and asthma. Different drugs were considered for rhinitis, including intranasal, oral and depot corticosteroids, intranasal and oral antihistamines, and antileukotrienes. Inhaled, oral and depot corticosteroids, short-acting and long-acting β_2 -agonists, antileukotrienes, and others were considered for the asthma treatment. The satisfaction score consisted of a four-point scale as follows: 1 was for completely satisfied, 2 was for satisfied, 3 for dissatisfied, and 4 for completely dissatisfied. The questionnaire also included possible co-morbidities such as sinusitis, nasal polyps, peptic ulcer, diabetes, and hypertension.

Statistical analysis

Continuous and/or discrete parameters were reported as mean, SD, third quartile, and frequency. Categorical parameters were reported in contingency tables. Homogeneity of data was evaluated by χ^2 Fisher exact test. Confidence interval (CI) at 95% was also considered.

The relationships between the satisfaction-to-treatment grade and rhinitis and/or asthma severity were calculated by the linear relationship coefficient. The relative risk (RR) and CI were calculated to evaluate the influence of the single treatments on the satisfaction grade. In this regard, the satisfaction grade was transformed into a dichotomous variable: grades 1 and 2 = satisfied; grades 3 and 4 = unsatisfied. The relative risk was calculated by also considering it a reference risk (value = 1) for a treatment not assumed. The dependence of satisfaction grade on the treatment was further analysed using a logistic model. Satisfaction, as a dichotomous variable, was considered the dependent variable; the independent variables were gender, age, severity of rhinitis and asthma, treatment, co-morbidity, and polysensitisation.

The treatments were subdivided as follows:

Treatments for rhinitis were corticosteroids (including intranasal, oral, and injective), antihistamines (intranasal and oral), and others (antileukotrienes and others).

Treatments for asthma were corticosteroids (including inhaled, oral, and injective), bronchodilators (short-acting β_2 -agonists and long-acting β_2 -agonists), and others (antileukotrienes, anticholinergic, theophyllin, and others).

The α value concerning statistical significance was set at 0.05. Statistical analysis was performed using the statistical package BMDP Dynamic produced by BMDP Statistical Software, Inc. (Los Angeles, CA, USA).

Results

On the basis of the clinical diagnosis, 127/301 (42.2%) patients had AR alone; 162/301 (53.8%), AR associated with asthma; and 12 (4%), asthma alone. The severity of AR was evaluated on 285 patients; of them, 155 (54.4%) patients had IAR, 52 with mild and 103 with moderate-to-severe symptoms; and 130 (45.6%) patients had PER, 57 with mild and 73 with moderate-to-severe symptoms (Figure 1A). The asthma severity was evaluated on 171 asthmatic patients, 94 (55%) had the intermittent form, and 77 (45%), the persistent form (52 mild, 23 moderate, and 2 severe; Figure 1B).

The most relevant sensitising allergens are reported in Figure 2. Grasses were the most important cause of sensitisation, giving positive SPT results in 38.6% of patients, followed by *Dermatophagoides*, positive in 34.4% of patients and *Parietaria*, positive in 22.5% of patients. A total of 168/301 (56%) of patients were monosensitised, and the others were polysensitised.

The most important co-morbidities were rhinosinusitis (19% of patients), sleep disturbance (7.7% of patients), hypertension (6.8% of patients), and peptic ulcer (4.5% of patients).

Data on treatments were available for 293 patients. Figure 3A shows the results for allergic rhinitis. Oral antihistamines were the most prescribed drugs as 240 patients assumed them, and intranasal corticosteroids were used by 144, oral corticosteroids were assumed by 33, intranasal antihistamines by 25, intramuscular corticosteroids by 13, and antileukotrienes by 10 patients. The distribution was similar between monosensitised and polysensitised patients.

Figure 3B shows the different treatments for allergic asthma (data available for 170 patients). Short-acting β_2 -agonists were the most prescribed drugs as 85 patients assumed them, inhaled corticosteroids were used by 77 patients (45.3%), long-acting β_2 -agonists were prescribed to 63 (37%) and antileukotrienes to 46 patients (27%), and oral corticosteroids were assumed by 28

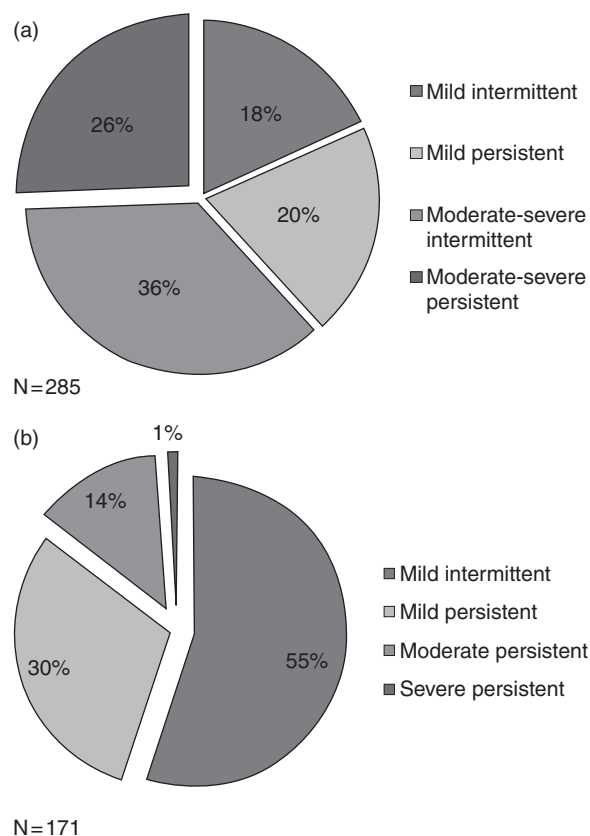


Figure 1. (A) Percentage distribution of rhinitis classification according to the ARIA guidelines. (B) Percentage distribution of asthma classification according to the GINA guidelines.

patients (16.5%). The distribution was similar between monosensitised and polysensitised patients. Figure 4 reports that only 33.5% of the patients were satisfied with rhinitis treatments, and only 40.7% of patients were satisfied with asthma treatments.

Interferential analysis

Satisfaction grade was significantly related with both rhinitis severity ($r = 0.26$; $p < 0.01$) and asthma classification ($r = 0.21$; $p < 0.01$). Particularly, the satisfaction degree was higher in patients with mild rhinitis than in patients with moderate-to-severe rhinitis, as reported in Figure 5.

About AR treatments, significant findings were obtained for intranasal antihistamines and oral corticosteroids. Only one patient out of 22 treated with topical antihistamines was satisfied: the RR (CI 95%) was 0.13 (0.02–0.87; $p < 0.05$); only 5/33 patients treated with oral corticosteroids were satisfied, with RR = 0.42 (0.19–0.97; $p < 0.05$).

About asthma treatments, significant findings were found for short-acting β_2 -agonists and oral corticosteroids. In fact, 47 of 79 (59.5%) patients who were treated with

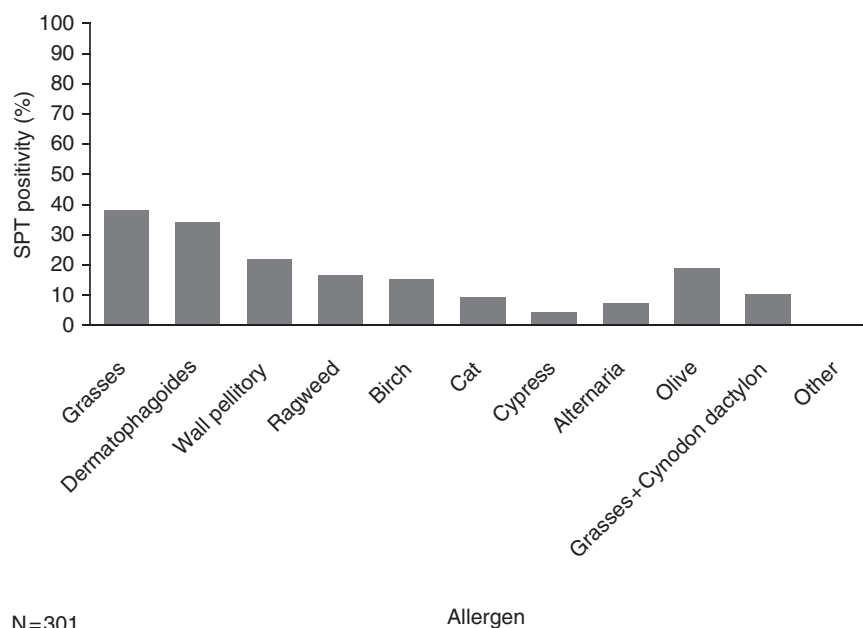


Figure 2. Percentage distribution of sensitisation for single allergen.

short-acting β_2 -agonists were satisfied: the RR (CI 95%) was 2.79 (1.74–4.47; $p < 0.05$); only 4/25 patients treated with oral corticosteroids were satisfied, with RR = 0.35 (0.14–0.88; $p < 0.05$).

The presence of co-morbidities was significantly associated with dissatisfaction: only 41/161 patients with AR were satisfied, with RR = 0.55 (0.39–0.77; $p < 0.05$), whereas 38/102 patients with allergic asthma were satisfied, with RR = 0.8 (0.55–1.16; $p = \text{n.s.}$).

Logistic regression analysis showed that there were some factors associated with treatment dissatisfaction in both AR and asthma. About rhinitis, female gender had 2.36 odds ratio (OR; $p < 0.01$); co-morbidity, 2.39 OR ($p < 0.05$); and rhinitis severity, 1.39 OR ($p < 0.05$). About asthma, asthma severity had 2.04 OR ($p < 0.05$), and antihistamine use 2.53 OR, whereas the use of bronchodilators had 0.28 OR ($p < 0.05$).

Discussion

The patient's 'common-sense' beliefs about illnesses and their treatments are in general known to influence the adherence to drug therapy^{22,23}. In particular, in asthmatic patients, it was reported that adherence to medications is influenced by the way they evaluate their personal need for medication relative to their concerns about the potential negative effects^{24,25} and that patients with persistent asthma perceive their symptomatic experience of asthma as an episodic condition and, thus, doubt their need for daily medications²⁵. Concerning the few data available on patient perception in AR, two studies conducted on

adults¹⁶ and children²⁶ showed that the second-generation antihistamines were perceived to produce a significantly higher satisfaction, because of better efficacy and tolerability, than the first-generation antihistamines.

The present study was aimed at evaluating treatment satisfaction in a cohort of Italian patients suffering from AR and asthma. The analysis of the basal characteristics of the patients showed that the majority of them (about 54%) had AR and asthma, whereas only 4% had asthma alone; this finding confirms the asthma prevalence found in a recent survey in Italy, that was approximately 3%²⁷. On the other hand, this study shows that IAR was slightly more frequent than PER, and moderate-to-severe symptoms were more frequent in both classes, this finding also confirming previous observations²⁸. Asthma severity was essentially mild in the considered group. Therefore, the present cohort was characterised by patients with intense rhinitis and mild asthma. These characteristics may be considered a good mirror of the common type of patients who visited allergy centres in Italy as previously reported^{29,30}.

Grass pollen and mites were the most representative cause of allergy in this cohort, thus confirming a European trend³¹. Another interesting issue is represented by the high co-morbidity with rhinosinusitis: it was reported that AR may favour the inflammation/infection of paranasal sinuses³².

About treatments, oral antihistamines were the most used drugs for AR as well as short-acting β_2 -agonists for asthma. In other words, the reliever drugs are the preferred therapeutic options. However, the satisfaction level was very low: only one-third of the AR patients and 40% of

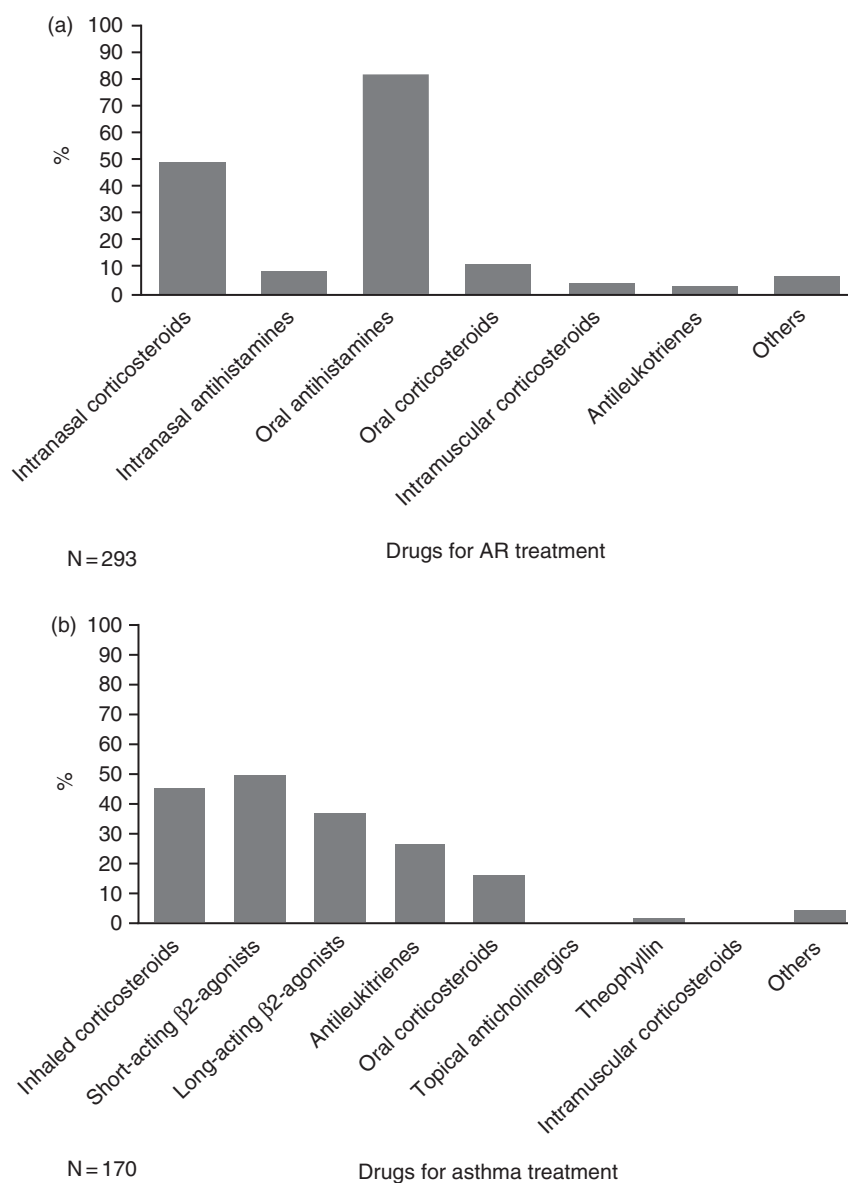


Figure 3. (A) Percentage distribution of treatments for allergic rhinitis. (B) Percentage distribution for asthma treatments.

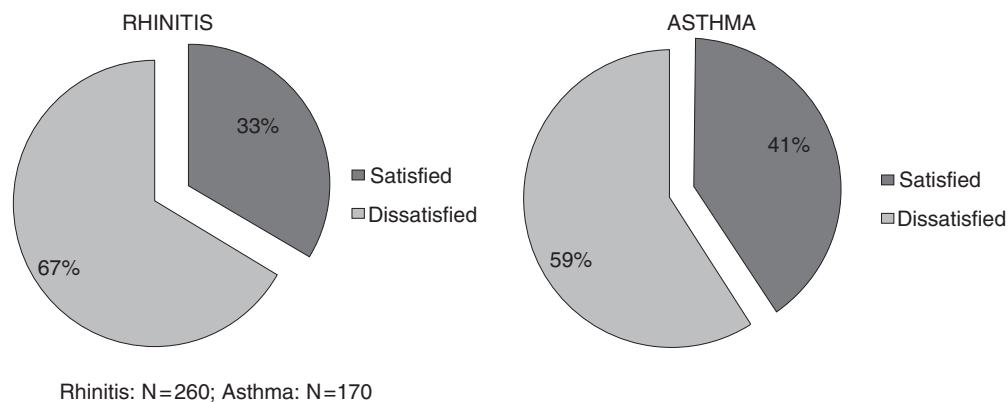


Figure 4. Percentage of satisfied and dissatisfied patients with rhinitis and asthma.

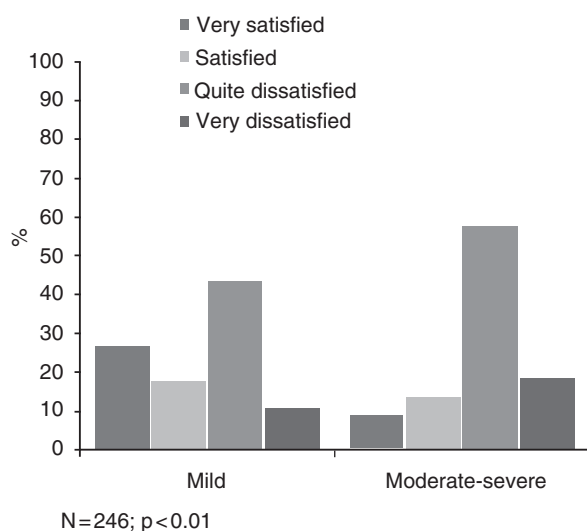


Figure 5. Percentage of satisfied and dissatisfied patients with mild or moderate-to-severe rhinitis.

the asthmatic patients were satisfied with the prescribed drugs. Interestingly, some factors were associated with the low satisfaction degree: female gender, AR, symptom severity, the type of treatment (such as intranasal antihistamines or oral corticosteroids; the first for lower efficacy and last for a possible steroidophobia), and the presence of co-morbidities. Only bronchodilators provided the best satisfaction profile. The main limitation of this study is that the relatively low number of patients prevented performing a stratification of subjects by treatment classes. Also, the limited number of patients biased some statistical observation; for example, the relationship between satisfaction grade and both rhinitis severity ($r=0.26$) and asthma classification ($r=0.21$) was significant, but the obtained 4% of proportion of variability in satisfaction grade correlated with disease severity may be not clinically important.

These results must be discussed with those in the recent literature. In a study conducted in Finland, about 80% of AR patients were satisfied with the current medications³³, while in a study conducted in France for assessing the grade of satisfaction, only 34% and 23% of patients were very satisfied with antihistamines and local corticosteroids, respectively³⁴.

Concerning asthma, in 'The Living & Breathing Study' conducted in Scotland, about 90% of the surveyed patients felt that their asthma was under control, but two-thirds experienced the symptoms at least 2–3 times a week; 58% were very satisfied with their asthma care, but this rate dropped to 33% when the respondents were shown the asthma guidelines regarding what to expect from the treatment. Eighty percent of the patients were never given a written personal asthma plan³⁵. Thus, patient

satisfaction seems poorly related to the actual control of asthma because of insufficient knowledge on the disease.

In conclusion, this study strengthens the concept that the satisfaction with drug treatments is a relevant aspect in allergic patients, and this must be carefully evaluated in further studies on large populations of patients providing stratification of patients by treatment classes. Such research should meet the need indicated by the current recommendations to evaluate the patient-reported outcomes to understand better the patient-related factors influencing both clinical trials and real-life management results³⁶. This issue confirms the importance of optimising drug treatment, especially by increasing patient education. In patients who remain dissatisfied by drugs allergen immunotherapy, as suggested by Demoly *et al.*³⁴, might be considered as a further treatment option.

Transparency

Declaration of funding

Stallergenes Italia partially sponsored the present study.

Declaration of financial/other relationships

S.Sc., S.So., P.P., and F.F. have disclosed that they are employees of Stallergenes Italia. G.C. and C.I. have disclosed that they act as scientific and editorial consultants for Stallergenes. CMRO peer reviewers may have received honoraria for their review work. The peer reviewers on this manuscript have disclosed that they have no relevant financial relationships.

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