

Allergic rhinitis: The patient's perspective

William Storms, MD,^a Eli O. Meltzer, MD,^b Robert A. Nathan, MD,^a and
John C. Selner, MD^c *Colorado Springs and Denver, Colo., and San Diego, Calif.*

A self-administered screening questionnaire was sent to 15,000 households randomly selected from a nationwide panel of approximately 200,000 households. This questionnaire was used to select a balanced sample of 1450 persons with ≥ 7 days of nasal/ocular symptoms in the previous 12 months. These persons received a second questionnaire that contained detailed questions regarding symptoms, triggers, patient attitudes, and medical treatment. Of the 1065 people who responded to the second questionnaire, 481 were identified as having self-reported seasonal or perennial allergic rhinitis. Our major findings regarding the attitudes toward their disease expressed by these 481 respondents are as follows. Although 53% of our study population regarded their symptoms as mild, 47% reported onset before age 17, suggesting that many have become accustomed to their symptoms. The level of allergen avoidance was generally low; only 38% took any allergen avoidance measures in the home. The level of self-medication was high; 92% reported self-medication with prescription and nonprescription drugs. Finally, 26% believed that their symptoms were "well controlled" or "completely controlled," and 52% believed that effective treatments were available. Our findings suggest the need for a greater effort on the part of health care providers to identify patients with allergic rhinitis and to educate them about their disease. (*J Allergy Clin Immunol* 1997;99:S825-8.)

Key words: Allergic rhinitis, nasal symptoms, environmental triggers, self-medication, nationwide survey

The most common allergic condition, allergic rhinitis, presents several diagnostic challenges. Standardized diagnostic criteria are not available. The symptoms (itching, sneezing, nasal discharge, or blockage) may prompt physicians and patients alike to think first of a viral cause (i.e., the common cold) and not an allergic reaction. Many patients have coexisting allergic and nonallergic factors that trigger their rhinitis. A careful history is critical, but who has not had nasal symptoms at some time? Patients with mild symptoms may not attribute them to allergies. Indeed, it has been suggested that there is no clear boundary marking onset of the allergic response; rather, there may be a continuum, with patients experiencing occasional symptoms of rhinitis at one end and, on the other, patients with severe, chronic disease.¹ Therefore, what a patient says may not fully reflect the clinical reality.

Management of this disorder is also less straightfor-

ward than it may appear at the outset. First, there is the issue of defining clinically relevant outcomes. Functional status and well-being are increasingly recognized as important outcomes.² A related issue concerns the point at which the primary care physician should refer the patient for evaluation by a specialist. It is important for doctor and patient to arrive at an understanding of treatment expectations.

This article is intended to help clinicians address these diagnostic and management issues. It reports on a community-based, nationwide sample of people with self-reported allergic rhinitis with 7 days or more of symptoms in the previous 12 months. These patients were surveyed with regard to their perceptions of their symptoms, their perceptions of the safety and effectiveness of treatment, and how these perceptions affect their decision to seek medical advice.

MATERIAL AND METHODS

Sample

Target households were selected from a nationwide panel of approximately 200,000 households maintained by a market research firm, National Family Opinion Inc. of Toledo, Ohio. Details regarding recruitment and updating of this database have been published elsewhere.³

Survey

In 1993, a self-administered screening questionnaire was sent to 15,000 randomly selected households from the nationwide panel, with the request that it be answered by the household member who knew the most about the family's health status and history in the previous 12 months. A total of 9946 households (66.3%) responded; 5273 of these households contained a total of 8394 persons with nasal/ocular symptoms (sneezing, runny nose, stuffy nose or head, itchy eyes, or watery eyes). A balanced sample of 1450 persons with 7 or more days (singly or consecutively) of these symptoms within the previous year were selected to receive a questionnaire containing detailed questions regarding symptoms, triggers, patient attitudes, and medical treatment. A total of 1065 people (73.4%) responded to this second questionnaire. Among the questions asked was, "Which of the following best describes the group of symptoms you indicated?" Options provided were (1) a common cold; (2) a seasonal allergy (i.e., hay fever); (3) an allergy I have all the time; (4) an allergy only when exposed to triggers (i.e., dust, pollution); (5) sinus problems; and (6) other (please specify). Subjects who answered items (2) or (3) were assumed to have seasonal or perennial allergic rhinitis, respectively, and were included in our analysis.

The detailed survey included a series of questions designed to evaluate how allergic rhinitis sufferers perceive their symptoms and their expectations regarding medical care. Respondents were questioned about their level of satisfaction with symptom control and current reasons for seeking or not seeking medical

From ^aAsthma and Allergy Associates, Colorado Springs; ^bthe Allergy and Asthma Medical Group and Research Center, San Diego; and ^cthe Allergy Respiratory Institute of Colorado, Denver.

Reprint requests: William Storms, MD, 2709 North Tejon Street, Colorado Springs, CO 80907.

Copyright © 1997 by Mosby-Year Book, Inc.

0091-6749/97 \$5.00 + 0 1/0/81434

S825

PLAINTIFFS'
TRIAL EXHIBIT

PTX0042

MEDA_APTX03502663

CIP2170
Argentum Pharmaceuticals v. Cipla Ltd.

IPR2017-00807

PTX0042-00001

TABLE I. Demographic characteristics of study population

Characteristic	Number (%)
Total	481 (100.0)
Gender	
Male	206 (42.8)
Female	271 (56.3)
Age (yr)	
<18	57 (11.9)
18–34	99 (20.6)
35–49	161 (33.5)
50–64	92 (19.1)
≥65	52 (10.8)
Region	
Northeast	
New England	25 (5.2)
Middle Atlantic	77 (16.0)
Midwest	
East North Central	69 (14.3)
West North Central	36 (7.5)
South	
South Atlantic	81 (16.8)
East South Central	23 (4.8)
West South Central	56 (11.6)
West	
Mountain	39 (8.1)
Pacific	75 (15.6)
Population density	
Rural	
<100,000	108 (22.5)
Urban	
100,000–499,999	73 (15.2)
500,000–1,999,999	102 (21.2)
≥2,000,000	198 (41.2)
Household income (\$)	
<12,500	43 (8.9)
12,500–24,999	89 (18.5)
25,000–39,999	109 (22.7)
40,000–59,999	126 (26.2)
≥60,000	114 (23.7)

help. They were also asked to indicate whether during the past 12 months their symptoms were “completely controlled,” “well controlled,” “somewhat controlled,” “poorly controlled,” or “not controlled.” They also reported factors that affected their symptoms, including potential allergens, time of day, and season. In addition, they were asked to indicate their level of agreement with a number of statements concerning symptoms, such as “My symptoms are mild.”

Perceptions of physician interactions were indicated by respondents' behavior in seeking treatment from a physician, including estimation of the length of time that elapsed after symptom onset before they consulted a physician. Use of self-medication (nonprescription, prescription, or both) before consultation with a physician was also probed.

RESULTS

Population demographics

A total of 481 subjects were included in the final analysis. Most of the respondents were white (93%), and there were slightly more females than males (56% versus

TABLE II. Response to survey question, “Which of the following best describes your behavior in seeking treatment from a doctor for your rhinitic symptoms?”

Responses of 481 persons with self-reported allergic rhinitis	Number (%)
I see a doctor about my symptoms as soon as they begin	240 (49.9)
I discuss my symptoms with my doctor only when I am seeing him for another reason	87 (18.1)
My symptoms have to be severe enough to limit normal daily activities before I seek treatment from a doctor	77 (16.0)
I do not see a doctor for my symptoms	77 (16.0)

43%). The study population represented all geographic regions of the mainland United States, with an equal distribution among rural and urban areas. Full details of the population demographics are given in Table I.

Perception of symptoms

Onset. The age at which patients first started experiencing nasal/ocular symptoms was ≤3 years in 9% of patients, between 4 and 10 years in 20%, between 11 and 17 years in 18%, and between 18 and 34 years in 31%. After age 34, the likelihood of symptom onset diminished; only 13% reported symptom onset after age 34. The age at symptom onset was similar in males and in females.

Patients were more likely to experience symptoms in the spring and fall; 64% and 54%, respectively, reported that their symptoms were most severe at these times. In contrast, only 10% and 25% reported that their symptoms were worst in winter or summer. A circadian pattern was also evident, with 42% reporting that their symptoms were worst immediately after awakening and 10% reporting that their symptoms were worst during the night. Thirty-two percent of our study group reported that their symptoms were worsened only by exposure to environmental triggers such as pollen or air pollution.

Description of symptoms. Subjects were asked to indicate their level of agreement with statements about their symptoms. To the statement “My symptoms are an inconvenience,” 87% agreed. To the statement “My symptoms are mild,” 53% agreed. To the statement “I have learned to live with my symptoms,” 80% agreed.

Perception of physician interaction

Extent of physician consultation. Sixty-three percent of subjects had consulted a physician about their symptoms during the previous 12 months. Unless symptoms became severe enough to limit daily activities, study subjects tended to discuss their rhinitis during a visit that was scheduled for some other reason (Table II). Those

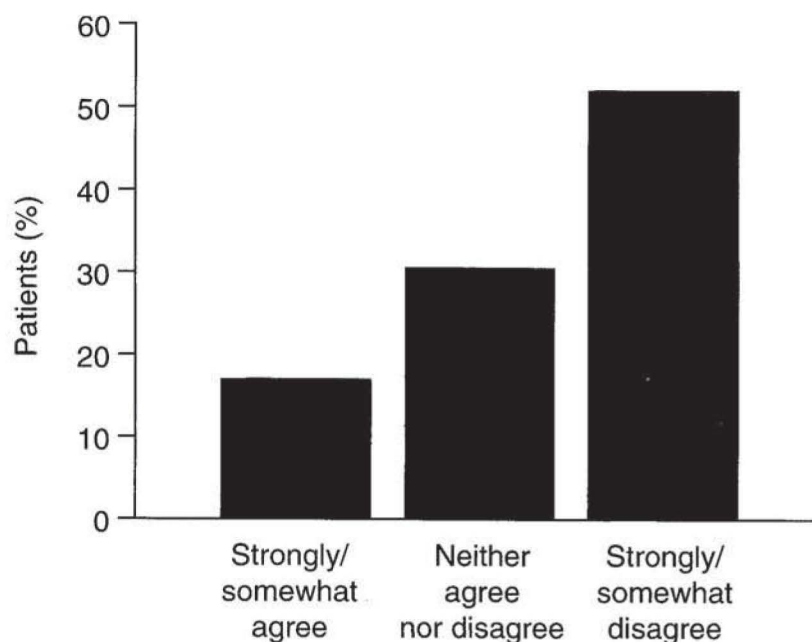


FIG. 1. Survey of 481 people with self-reported allergic rhinitis. Responses to the statement "I don't believe treatment is available that will help my rhinitic symptoms."

who did consult a physician during the previous 12 months waited a mean of 7.85 days after onset of their symptoms before doing so.

Type of physician consulted. Fifty-six percent of subjects reported that a general or family practitioner first diagnosed their symptoms. Fifty-nine percent reported that a general or family practitioner was the type of physician seen most often for their symptoms. Although the initial diagnosis was made by an allergist in only 17% of subjects, 52% reported that they had at some time seen an allergist for their symptoms. When asked to specify reasons for seeing a specialist, 55% reported referral by another physician, 28% reported seeking specialist treatment on their own initiative, and 11% were referred by a friend or family member.

Perception of treatment

Degree of satisfaction. Of those subjects who had consulted a physician, 92% reported self-medicating before their visit; 46% had tried only nonprescription medications, 17% had tried only prescription medications, and 29% had tried both. Of the total study population, 26% believed that their symptoms were completely or well controlled during the past 12 months, 52% reported that their symptoms were somewhat controlled, and 22% reported that their symptoms were poorly controlled or not controlled (Table III). When asked to indicate level of agreement with the statement "I don't believe treatment is available that will help my symptoms," 18% agreed (Fig. 1). Of subjects who had stopped seeing a doctor

TABLE III. Perceptions of symptom control and side effects in 481 persons with self-reported allergic rhinitis

	Number (%)
Degree of symptom control	
Complete or well controlled	125 (26.0)
Somewhat controlled	250 (52.0)
Poorly or not controlled	106 (22.0)
Side effects from drugs taken for symptoms	
Experiences symptoms	149 (31.0)
Avoids some drugs because of side effects	313 (65.1)
Worries about side effects	231 (48.0)

for their symptoms, 19% did so because they believed effective treatments were not available and 44% because they had found effective treatment.

Side effects. When asked to indicate level of agreement with the statement "I experience side effects from the medications I take for my symptoms," 31% agreed. Sixty-five percent agreed with the statement "Because of the side effects, there are some drugs I would not take for my symptoms." Forty-eight percent agreed with the statement "I worry about side effects from the drugs I take for my symptoms."

Compliance. The level of compliance reported by this population was high. When asked whether they took more medication than their physician recommended,

TABLE IV. Responses to survey question "Which of the following do you do to help control your symptoms? (Check all that apply)"

Responses of 481 persons with self-reported allergic rhinitis	Number (%)
Avoid smoke-filled places (bars, restaurants)	219 (45.5)
Vacuum my house frequently	184 (38.3)
Dust my house frequently	164 (34.1)
Don't have pets inside my house	100 (20.8)
Avoid outdoor activities	90 (18.7)
Avoid wearing perfume	83 (17.3)
Wash bedding in hot water	72 (15.0)
Wrap mattresses in plastic cover	29 (6.0)
Do not have carpeting (or rugs) in my bedroom	20 (4.2)
Medication/see doctor	18 (3.7)
Keep only furniture and necessities in my bedroom	14 (2.9)
Air filter/cleaner	14 (2.9)
Do not have carpeting (or rugs) in my house	10 (2.1)
Treat carpets or furniture with acaricides or tannic acid	7 (1.5)
Humidifier/vaporizer	2 (0.4)
Wear dust/face mask	1 (0.2)
All others	17 (3.5)
None of the above	122 (25.4)

92% answered seldom or never. When asked whether they took less, 68% answered seldom or never.

Nonpharmacologic measures. The most common allergen avoidance measures were dusting and vacuuming in the home and avoiding smoke-filled locations such as bars and restaurants (Table IV).

DISCUSSION

The portrait that emerges from this study is one of a somewhat stoic population of patients who consider consulting a physician only after they have been significantly troubled or inconvenienced by their condition.

Further, patients may not report their symptoms fully to a physician. Often, the subject of their rhinitis is brought up only in passing, in the course of a visit for some other reason—hardly an optimal context for the physician to make an accurate diagnosis or develop a management plan. The physician may also underestimate the severity of disease because patients, when asked about their symptoms, are likely to describe them as mild; 53% of the study population responded in this fashion. Yet the reality may be otherwise. Data suggest that allergic rhinitis can result in a measurable decline in general health status.^{4,5} Patients may not be aware of this decline because they have been living with their condition their entire adult life (47% reported onset of allergic rhinitis before 17 years of age) and have become accustomed to their state of health. Often, it is only when they notice an improvement after receiving treat-

ment that they realize their previous health status was less than optimal. These considerations lead us to suspect that allergic rhinitis may be underdiagnosed.

Allergen avoidance, particularly in the bedroom (where patients may spend 8 hours or more daily), is an important step in management. Yet in our study population there were few measures taken against dust mites, such as mattress encasement, hot water wash of bedding, acaricide treatment of carpets, and removal of carpeting from the bedroom. This finding suggests a need for more patient education regarding effective allergen avoidance measures.

When selecting a management strategy, it is also important to keep in mind that most patients have had prior experience with medication that resulted in either an inadequate therapeutic response or adverse effects. In our study, there was a high level of self-medication (92%) involving prescription and nonprescription drugs, without much hope of success: only 52% believed effective treatments were available; 31% had experienced side effects; 48% were concerned about adverse effects. Dosing regimens should take into account our finding that symptoms are worse in the morning than in the evening.

For patients who remain unresponsive to apparently optimal pharmacologic therapy, referral should be considered. An allergist can help identify allergic triggers. This is particularly important when better environmental control measures are being considered; such measures can be implemented only after important allergens have been identified through a detailed history and skin testing. The allergist can also, if indicated, institute specific immunotherapy.

In conclusion, there is a need to educate patients about allergic rhinitis, its symptoms, and the problems they may cause. The health care provider should listen carefully and be aware of what is left unsaid as well as what is actually said. Such attentiveness may take additional time, but our study suggests that it would be time well spent.

REFERENCES

1. International Rhinitis Management Working Group. International consensus report on the diagnosis and management of rhinitis. *Allergy* 1994;49(suppl):1-34.
2. Stewart AL, Greenfield S, Hays RD, et al. Functional status and well-being of patients with chronic conditions: results from the Medical Outcomes Study. *JAMA* 1989;262:907-13.
3. Stewart WF, Lipton RB, Celentano DD, Reed ML. Prevalence of migraine headache in the United States: relation to age, income, race, and other sociodemographic factors. *JAMA* 1992;267:64-9.
4. Bousquet J, Bullinger M, Fayol C, Marquis P, Valentin B, Burtin B. Assessment of quality of life in patients with perennial allergic rhinitis with the French version of the SF-36 Health Status Questionnaire. *J Allergy Clin Immunol* 1994;94:182-8.
5. Meltzer EO, Nathan R, Selner JC, Storms W. Quality of life and rhinitic symptoms: results of a nationwide survey with the SF-36 and RQLQ questionnaires. *J Allergy Clin Immunol* 1997;99:S815-9.