
Effectiveness of immunotherapy for recurring sinusitis associated with allergic rhinitis as assessed by the Sinusitis Outcomes Questionnaire

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Background: Outcomes measurement is a proficient method for determining the effectiveness of medical therapy. Currently, there are no easy-to-use and inexpensive questionnaires available to evaluate the impact of immunotherapy in the treatment of sinusitis by allergists, given the research constraints of a private practice setting.

Objective: To measure the effectiveness of immunotherapy in the overall treatment of atopic patients with associated sinusitis in a private practice setting.

Methods: A total of 114 patients with a history of rhinitis and sinusitis and positive radiographic evidence of sinus disease were consecutively chosen from 3 private practices nationwide and surveyed for global symptoms and specific symptoms related to the nose, sinuses, eyes, and chest with the Sinusitis Outcomes Questionnaire (SOQ). Their medical history, including prior treatment, was evaluated. This questionnaire was administered twice in one sitting, with the first a recall of symptoms before starting immunotherapy and the second an evaluation of current symptoms.

Results: The data revealed that 99% believed immunotherapy worked, with 1% unsure. Patients experienced a 72% decrease in days lost from work or school and a 26% reduction in the use of medications per year. There was a mean reduction of 51% in the overall symptom score of the patients after receiving immunotherapy.

Conclusions: This study demonstrates that the user-friendly SOQ can be effectively and inexpensively used in a private practice setting and suggests that immunotherapy is an effective treatment for patients with sinus disease and allergic rhinitis.

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INTRODUCTION

Sinusitis frequently is a complex condition that affects more than 16% of the adult population in the United States.¹ Sinusitis is the third most frequent diagnosis for which antibiotics are prescribed.² The direct annual costs of treating sinusitis with antibiotics and surgical procedures are estimated at \$5.8 billion.³ The impact on the quality of life for patients with recurrent sinusitis is even higher. Although outcomes measurement is a proficient method for determining the effectiveness of medical therapy, currently there are no easy-to-use and inexpensive questionnaires available to evaluate the impact of immunotherapy in the treatment of sinusitis by allergists, given the research constraints of a private practice setting.

In our private practices, we have observed that there is a subset of patients diagnosed as having perennial allergic rhinitis and associated sinusitis. When these patients underwent immunotherapy for their allergic rhinitis, the instances of sinusitis decreased. This meant fewer sinus surgical procedures, fewer antibiotics, and an increase in the overall health and quality of life for these patients.

To confirm this observation, the authors modified the validated Rhinitis Outcomes Questionnaire (ROQ) to encompass sinusitis and administered it to patients diagnosed as having allergic rhinitis and a documented history of sinusitis. The ROQ and the Sinusitis Outcomes Questionnaire (SOQ) are specifically designed to allow the private practice clinician to gather valid data to evaluate outcomes for the patients they treat, without dedicated research resources.

This study represents the first use of the SOQ. It was used to survey patients undergoing treatment for allergic rhinitis with radiographic evidence of sinus disease. The results from administering the SOQ in 3 different private practices are presented herein as a means to evaluate the effectiveness of immunotherapy in the overall treatment of atopic patients based on such outcomes as quality of life, economic costs, and disease-specific symptoms of allergic rhinitis and associated sinusitis.

METHODS

Patients

Patients were consecutively screened for eligibility during October 2001 from 3 private practices located in Colorado, Connecticut, and California. The survey was distributed to 114 patients diagnosed as having recurring sinusitis and allergic rhinitis who met the inclusion criteria. The sinusitis was treated with multiple courses of antibiotics. All patients selected had to have radiographic evidence (ie, sinus x-ray

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Table 1. The Sinusitis Outcomes Questionnaire*

Name _____ Patient Survey

Age _____ Date _____ SINUSITIS

Part 1**Before** you started your current allergy treatment, how bad were these symptoms when your allergies were most active?

	No problem	Minimal problem	Mild problem	Moderate problem	Severe problem	Very severe problem
Fatigue	0	1	2	3	4	5
Trouble sleeping	0	1	2	3	4	5
Irritability	0	1	2	3	4	5
Dizziness	0	1	2	3	4	5
Postnasal drip	0	1	2	3	4	5
Sore throat	0	1	2	3	4	5
Sinus headache/pressure	0	1	2	3	4	5
Sneezing	0	1	2	3	4	5
Nasal itching	0	1	2	3	4	5
Nasal blockage	0	1	2	3	4	5
Nasal green/yellow mucus	0	1	2	3	4	5
Clear watery mucus	0	1	2	3	4	5
Loss of sense of smell	0	1	2	3	4	5
Snoring	0	1	2	3	4	5
Ear ache	0	1	2	3	4	5
Eye itching	0	1	2	3	4	5
Eye redness	0	1	2	3	4	5
Eye watering	0	1	2	3	4	5
Eye burning	0	1	2	3	4	5
Shortness of breath	0	1	2	3	4	5
Coughing	0	1	2	3	4	5
Wheezing	0	1	2	3	4	5
Chest tightness	0	1	2	3	4	5
Chest pain	0	1	2	3	4	5
Phlegm	0	1	2	3	4	5

In the year before you started your current allergy treatment in this office, how many times did the following happen?

You missed work or school due to allergies, asthma, sinusitis, etc. _____

You went to the emergency room for an allergy-related problem _____

You were hospitalized for an allergy-related problem _____

You had nose, ear or sinus surgery, including tube placement _____

You used antibiotics for sinus, chest or ear infections _____

You had an abnormal sinus CAT scan _____

You had an abnormal sinus x-ray _____

In the year **before** you started your current treatment, how many different **daily** medications, including nasal sprays, inhalers, eye drops and pills, were you taking? _____**Part 2****Currently**, how much of a problem are these symptoms when your allergies are most active?

	No problem	Minimal problem	Mild problem	Moderate problem	Severe problem	Very severe problem
Fatigue	0	1	2	3	4	5
Trouble sleeping	0	1	2	3	4	5
Irritability	0	1	2	3	4	5
Dizziness	0	1	2	3	4	5
Post-nasal drip	0	1	2	3	4	5
Sore throat	0	1	2	3	4	5
Sinus headache/pressure	0	1	2	3	4	5

(Table continues)

Table 1. *Continued*

Sneezing	0	1	2	3	4	5
Nasal itching	0	1	2	3	4	5
Nasal green/yellow mucus	0	1	2	3	4	5
Clear watery mucus	0	1	2	3	4	5
Loss of sense of smell	0	1	2	3	4	5
Snoring	0	1	2	3	4	5
Ear ache	0	1	2	3	4	5
Eye itching	0	1	2	3	4	5
Eye redness	0	1	2	3	4	5
Eye watering	0	1	2	3	4	5
Eye burning	0	1	2	3	4	5
Shortness of breath	0	1	2	3	4	5
Coughing	0	1	2	3	4	5
Wheezing	0	1	2	3	4	5
Chest tightness	0	1	2	3	4	5
Chest pain	0	1	2	3	4	5
Phlegm	0	1	2	3	4	5

How long have you been under the care of Dr. _____

Years _____ Months _____

Are you currently on immunotherapy (allergy shots)?

Do you think that immunotherapy (allergy shots) works for you? **Yes** **No** **(If Yes, proceed)**

In the past year, how many times did the following happen?

You missed work or school due to allergies, asthma, sinusitis, etc. _____

You went to the emergency room for an allergy related problem: _____

You were hospitalized for an allergy related problem: _____

You had nose, ear or sinus surgery, including tube placement: _____

You used antibiotics for sinus, chest or ear infections: _____

Since starting immunotherapy, how many different **daily** medications, including nasal sprays, inhalers, eye drops and pills, are you taking? _____

Thank you for participating in this survey.

* This questionnaire was developed by the American College of Allergy, Asthma, and Immunology (ACAAI) Rhinitis/Sinusitis Committee and is available on the ACAAI Web site at <http://www.acaa.org/sinusitis.html>.

films or computed tomograms [CTs] validated by an independent radiologist) of at least 1 episode of sinusitis before starting immunotherapy. They also had to be receiving immunotherapy for perennial allergic rhinitis and associated sinusitis for a minimum of 1 year. Immunotherapy was for either 1 perennial allergen or any combination of dust mites, animal danders, mold spores, and pollens. Patients agreed to participate without compensation for their time. There was no outside funding for this study.

Questionnaire Design

The SOQ was designed to be quickly self-administered to evaluate the effectiveness of immunotherapy. It was adapted from a previous questionnaire⁴ developed with the input from members of the Rhinitis/Sinusitis Committee of the American College of Allergy, Asthma, and Immunology.

The SOQ differs from the ROQ by the addition of 2 sinusitis-specific questions regarding an abnormal sinus CT and an abnormal sinus x-ray film. The SOQ was validated

using the same statistical methods used to validate the ROQ.^{5,6} The survey consists of 5 sections (Table 1). The first section assesses global symptoms and the next 3 evaluate specific symptoms of the nose and sinuses, eyes, and chest. Each of the 26 symptom questions is scored on a Likert scale from 0 to 5, indicating the severity of symptoms for a possible symptom score between 0 and 130. The higher the score, the more symptomatic the patient. The fifth section explores the economic burden of their disease by assessing lost days of work or school, emergency department visits, hospitalization, nose, ear, or sinus surgery, antibiotics for sinusitis, bronchitis and otitis, and daily medications, including nasal sprays, inhalers, eye drops, and pills.

The questionnaire was designed to be completed in its entirety in 5 minutes or less. It was administered to each patient in 2 iterations during the same sitting. The first was a recall of symptoms before starting immunotherapy and the second was an evaluation of current symptoms. Patients were

also asked if they thought immunotherapy worked or was effective for them.

RESULTS

The 114 patients, 71 females and 43 males, were all white and aged 8 to 65 years. They received immunotherapy for a minimum of 1 year, with a mean duration of 3.3 years. Ninety-nine percent of the patients believed that immunotherapy worked, whereas 1% was unsure. None of the patients reported that immunotherapy did not work. There was a mean reduction of 51% in the overall symptom score of the patients after receiving immunotherapy. The mean $\pm$ SD symptom score from the first questionnaire before starting immunotherapy was 56.4 ± 23 . The mean $\pm$ SD symptom score from the second questionnaire after undergoing immunotherapy for at least 1 year was 28.6 ± 21 . Thus, the improvement demonstrated was $51\% \pm 26\%$ ($P < .001$; Table 2). Sinusitis symptoms showed improvement along with rhinitis symptoms. Patients reported 61% improvement in sinus pain, 50% improvement in nasal green or yellow mucus, and 49% improvement in nasal blockage. Additionally, there was a 26% reduction in the use of medications per year, a 54% reduction in nasal or sinus surgical procedures, and 72% fewer days lost from work or school per year after starting immunotherapy.

DISCUSSION

The data collected in this study with the SOQ support immunotherapy as an effective method for treating allergic rhinitis patients with sinusitis documented by history and radiographic imaging. Immunotherapy was associated not only with a reduction in symptoms, but also with a decrease in the use of more expensive health care resources, including antibiotics and sinus surgical procedures. Immunotherapy also improves quality of life and overall health as evidenced by a decrease in absenteeism from work or school.

This study used a retrospective survey in private allergy practices, and the results obtained were evaluated using appropriate statistical methods and found to be valid, reliable, and responsive. Symptoms reflective of the sinuses improved along with rhinitis symptoms. The reliability of the questionnaire for symptoms of the nose, including the sinuses, and chest was found to be 0.84 and 0.88, respectively. Reliability of 0.80 is considered research quality.⁷ Eye symptoms were found to have a reliability of 0.94, proving to be superior in terms of reliability. The responsiveness of the items on the questionnaire was sizable and statistically significant in demonstrating a decrease in symptoms. All the differences were significant at $P < .001$.

Table 2. Average Symptom Scores of the 114 Patients for Both Iterations of the Questionnaire

Questionnaire item	Mean score before treatment	Mean score after treatment	Average score decrease	SD	Improvement, %
Fatigue	2.31	1.44	0.87	1.61	62
Trouble sleeping	2.07	1.11	0.96	1.62	54
Irritability	1.98	1.23	0.75	1.27	62
Dizziness	0.86	0.49	0.37	1.53	57
Postnasal drip	3.25	1.86	1.39	1.28	57
Sore throat	2.32	1.07	1.25	1.37	46
Sinus pain	3.42	2.10	1.32	1.51	61
Sneezing	2.80	1.32	1.48	1.45	47
Nasal itching	2.54	1.14	1.40	1.53	45
Nasal blockage	3.30	1.62	1.68	1.68	49
Nasal green or yellow mucus	2.70	1.34	1.36	1.51	50
Clear watery mucus	2.57	1.28	1.29	1.66	50
Loss of sense of smell	2.11	0.87	1.24	1.38	41
Snoring	1.78	1.16	0.62	1.67	65
Earache	1.33	0.58	0.75	1.80	44
Eye itching	2.46	1.29	1.17	1.56	52
Eye redness	2.12	1.08	1.04	1.61	51
Eye watering	2.19	1.06	1.13	1.64	48
Eye burning	1.89	0.93	0.96	1.60	49
Shortness of breath	2.13	0.94	1.19	1.64	44
Coughing	2.13	1.01	1.12	1.73	47
Wheezing	1.92	0.83	1.09	1.61	43
Chest tightness	1.90	0.76	1.14	1.73	40
Chest pain	1.11	0.49	0.62	1.69	44
Phlegm	2.10	0.93	1.17	1.34	44
Muscle strength	1.07	0.68	0.39	1.61	64
Total	56.4	28.6	27.8		51

The effectiveness of this instrument is its reliance on the patient history. In the private practice setting, patient histories are routinely used not only to make an initial diagnosis but also to establish a treatment plan. For the purposes of this study, no distinction was made between chronic sinusitis and recurrent sinusitis. First, there is little consensus on the definitions of recurrent and chronic sinusitis. Second, we decided that it did not affect our objective of measuring the outcome of immunotherapy to treat sinusitis in patients with allergic rhinitis. Finally, if treating these patients for allergic rhinitis would improve their sinusitis, there was no need to differentiate between those with recurrent and chronic conditions. Use of the SOQ can evaluate the benefit of immunotherapy in patients with sinusitis in association with allergic rhinitis.

An important aspect of this study is that it can be duplicated in a cost-effective manner by other clinicians in a private practice setting. Allergists in private practice have access to a large number of patients and often use a variety of treatment strategies, including immunotherapy. Questionnaires such as the SOQ enable clinicians to collect high-quality data to determine the effectiveness of treatments used and, if useful, to report the results to managed care organizations.

The SOQ can also be used for a prospective study, at the start of immunotherapy with follow-up 12 to 24 months later, but this can pose challenges in a busy private practice setting. Without dedicated resources, it can be difficult to collect follow-up questionnaires. Similarly, in a managed care setting, it is not always feasible to perform expensive tests, including rhinoscopy and follow-up imaging studies.

One limitation in the study design was the inclusion of only patients still undergoing immunotherapy for a minimum of 12 months. Patients who had stopped immunotherapy before 1 year for any reason were excluded from the study. These selection criteria increased the likelihood that patients continuing immunotherapy report an improvement in symptoms. Typical reasons for discontinuing immunotherapy include

cost, changing health care plan, inconvenience, and failure to notice a rapid improvement in symptoms.

Despite research limitations (eg, time, staff, funding), effective results can be obtained in the private practice setting. Furthermore, the SOQ is a high-quality, user-friendly outcomes instrument that can be inexpensively used. The SOQ results from this study suggest that immunotherapy is beneficial in treating sinusitis in patients receiving immunotherapy for allergic rhinitis. A prospective, randomized, controlled study will be required to confirm the findings of this retrospective study.

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