Advances In Therapy® | *Volume 20 No. 4 July/August 2003*

Advances In Natural Therapy™

Use of Cellulose Powder for the Treatment of Seasonal Allergic Rhinitis

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ABSTRACT

Our study was designed to determine whether a unique cellulose powder extract could prevent the classic hay fever attack from occurring among volunteers who have suffered for some years. Nasaleze enhances nasal mucus, which allows the filtration of allergens, to ensure that only clean air reaches the lungs. One hundred and two volunteers were recruited and, using a simple five-point scoring system to grade their general well-being and severity of any hay fever attacks, the overall average score was 3.85, indicating that Nasaleze was able to control hay fever very well. Rapid relief of symptoms was also demonstrated, sometimes within minutes after inhalation. Overall, 77% of volunteers reported a significant reduction in the number of challenges throughout the study period and most graded Nasaleze as more effective and reported fewer side effects than with a wide range of chemical treatments.

Keywords: cellulose; seasonal allergic rhinitis; allergen

INTRODUCTION

Approximately 12 million people in the United Kingdom[1] and more than 60 million in the United States[2] have seasonal allergic rhinitis. Symptoms vary from mild discomfort to activity-limiting.

Seasonal allergic rhinitis is characterized by a relatively dry nasal tract, without adequate mucus to absorb airborne dust, animal dander, pollens, and spores and prevent these irritants from reaching the lungs. Each day, up to 20 billion particles enter the nasal passages[3] and are swept to the back of the throat, swallowed, and ultimately destroyed by stomach acid. This process, accomplished by the on going wave action of the nasal hair cells.

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The rising prevalence of seasonal allergic rhinitis parallels the increase in environmental allergens whose presence in the nose trigger the release of histamine and other compounds into the bloodstream.

CAUSES AND SYMPTOMS

An allergic reaction may result when the immune system mistakenly identifies a normally harmless substance as a threat, the filtration system of the nasal tract becomes overloaded from excessive pollution, or the nasal tract dries out. The precise mechanism is unknown but may be genetic.

An allergic reaction is triggered when mast cells found in or near the nose, lungs, skin, eyes, and blood vessels release high concentrations of histamine in response to stimulation by the body's immune defenses.

Histamine, in turn, induces the classic symptoms of seasonal allergic rhinitis, including nasal congestion and itching; runny nose; itchy, watery eyes; swollen, itchy eyelids; difficulty breathing; loss of taste and hearing; dry cough; and headache.

The severity of symptoms varies among individuals and in response to pollen counts and local weather conditions.

TREATMENTS

In the United Kingdom, the allergy market is currently worth about £67.9 million sterling and is growing by about 5.5% each year according to the OTC Bulletin published in June 2003.

Antihistamines

Antihistamines prevent the release of histamine from mast cells or diminish its effect after release. Oral antihistamines are probably the most convenient chemical treatment for most people, although a number of natural alternatives are available.

Older antihistamines cause substantial drowsiness because they can cross the blood-brain barrier; newer, nonsedating antihistamines are longer-acting and better tolerated but still elicit adverse effects.

Topical Agents

The effectiveness of eyedrops and nasal sprays depends, to a considerable degree, on frequent application. Sodium cromoglycate, the most widely used topical treatment, acts by preventing the release of histamine. Instillation is not recommended in the presence of contact lenses or glaucoma.

Nasal sprays, like beclomethasone, reduce inflammation and mucus production. These products are not used in cases of nasal infection and are not licensed for sale over the counter to patients younger than 18 years of age, in the UK.

A number of herbal or plant-based compounds, including garlic, goldenseal, and feverfew, are also available for oral use.

Cellulose powder is used as a thickener in many liquid nasal sprays and is generally regarded as safe. The special proprietary grade of micronized cellulose in this study* used a patented method that ensures delivery into the nose of a suitable amount of material drawn from the container. Compared with liquid nasal sprays, which require preservatives, powdered cellulose inhibits bacterial growth. While not a medicine, it is classified as a medical device that is safe to use throughout the year. The powdered cellulose product addresses the cause of allergic reactions, rather than the symptoms, because it works as a facial mask in preventing inhaled pollen, dirt, and allergens from reaching the lungs. In a healthy individual, the nose and nasal tract extract these materials from the inhaled air, including air that has been exposed to mucus membranes and therefore been stripped of allergens. Mucus has a low surface tension and can easily absorb allergens from air as it passes down into the lungs.

Uniquely, the cellulose powder described herein turns into a gel on contact with the moisture always present in the nasal cavity. This gel is similar to normal mucus and helps to maintain delivery of a supply of clean air to the lungs.

METHODS

Following recruitment through local and national press releases, 102 volunteers (66 female, 36 male; mean age, 44 years), who had previously used products for seasonal allergic rhinitis, were enrolled in the early spring of 2003. Each participant completed a pretrial questionnaire designed to assess the severity and range of symptoms experienced and the months when they were most distressing (Table 1). Pharmaceutical treatments used in the past were identified, and their effectiveness was rated on a five-point scale (1 = not effective at all to 5 = very effective). General well-being during the study was recorded daily in a take-home diary and graded on a five-point scale (5 = well, no problems; 4 = quite well with occasional sneeze; 3 = can feel an attack coming on, some minor symptoms; 2 = feeling low and definitely suffering; 1 = full hay fever attack with symptoms listed). Also listed were the number and variety of symptoms, the day or time elapsed when recovery began, and the time until symptoms resolved. A global assessment of the cellular powder was provided at the end of the 6-week study.

Participants were instructed to place one puff of the inert cellulose powder into each nostril according to the manufacturer's recommendations. If a full-scale hay fever attack occurred, drug treatment was allowed but was to be recorded in the diary.

The pollen count, obtained from both local and national sources, was monitored and recorded every day throughout the study. A large number of volunteers rode horses and admitted to symptoms throughout the year mainly as a result of daily exposure to hay and horse hair.

The average time to symptom relief in minutes, hours, or days and the total number of days when symptoms occurred were recorded and compared with the predicted onset of action of previously used pharmaceutical alternatives[4] and with the volunteer's own subjective assessment of the efficacy of these products. Data were analyzed by means of a Student's *t* test to gain a probability coefficient that allowed for the calculated number of degrees of freedom.

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*Nasaleze, a registered trademark of Kisska International Ltd, Keighley, West Yorkshire BD21 3ND UK
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Table 1. Time of Hay Fever Symptoms

	Volunteers, no.	
Month	**Male**	**Female**
January	6	18
February	14	19
March	24	45
April	36	66
May	36	66
June	36	66
July	34	66
August	26	58
September	12	27
October	6	14
November	5	13
December	7	19

RESULTS

A wide range of pharmaceutical treatments had been used in the past to alleviate hay fever symptoms, but most of these products were rated as not very effective (Table 2). When exceptions were noted (as with beclomethasone), side effects were often recorded. In contrast, the natural cellulose powder earned, on average, a higher score than all the pharmaceutical alternatives. The scores of 3.8 for men and 3.9 for women represent a minimum 77% success rate, because a rating of 5 equals no symptoms and complete control. The average daily score with the cellulose powder was in excess of 4.0 in over 35% of volunteers and above 3.0 in over 70%, indicating an occasional sneeze but no hay fever symptoms. In only 12% of volunteers was the average daily score less than 2.9. A total symptom-control score of nearly 88% with the cellulose product is therefore warranted. At the end of 6 weeks, more than 70% of volunteers rated the cellulose powder as good or excellent (Table 3). Either of these ratings was more likely in women than in men.

Volunteers were statistically likely ($P<0.005$) to gain relief from symptoms within 0.1 to 3 hours of using the cellulose powder—a rapid onset of action suggesting value in the relief of the most chronic hay fever symptoms.[5]

A comparison of the weekly average scores for volunteers and the reported pollen count in the United Kingdom indicates a small reduction in quality-of-life scores as pollen increased in weeks 3 and 4 of this study (Figure 1); however, high scores throughout the 6-week trial indicated considerable benefit from the test substance.

The single treatment failure occurred in a woman who could not record a score above 1 at any time throughout the study. She reported a wide range of symptoms and a number of concomitant diseases. Her removal from the calculations would result in a slightly higher average score for women.

Table 2. Use of Pharmaceutical Treatments

	Average Efficacy Score	
	Male	Female
Treatment	**Volunteers**	**Volunteers**
Beconase® (steroid nasal inhaler) Glaxo Smith Kline, UK	3.0	3.1
Sodium cromoglycate (antihistamine nasal inhaler) - Various generic manufacturers	1.3	2.1
Opticrom® (eyedrops) Aventis Pharma, UK	1.5	2.0
Clarityn® (oral tablets) Schering Plough, UK	2.0	2.2
Zirtek® (oral tablets) Glazo Smith Kline, UK	1.1	1.8
Piriton® (oral tablets and liquid) Stafford Miller, UK	1.3	1.8
Telfast® (oral caplet) HMR, UK	2.0	1.8
Natural cellulose powder	**3.8**	**3.9**

Scale from 1 (not effective at all) to 5 (very effective).

Other products used regularly in the past by volunteers included Benadryl, Otrivine, Flixonase, Triludan, Sudafed, New Era, Rhinocourt, Atarax, Phenergan, Vallergan, Semprex, and Zaditen.

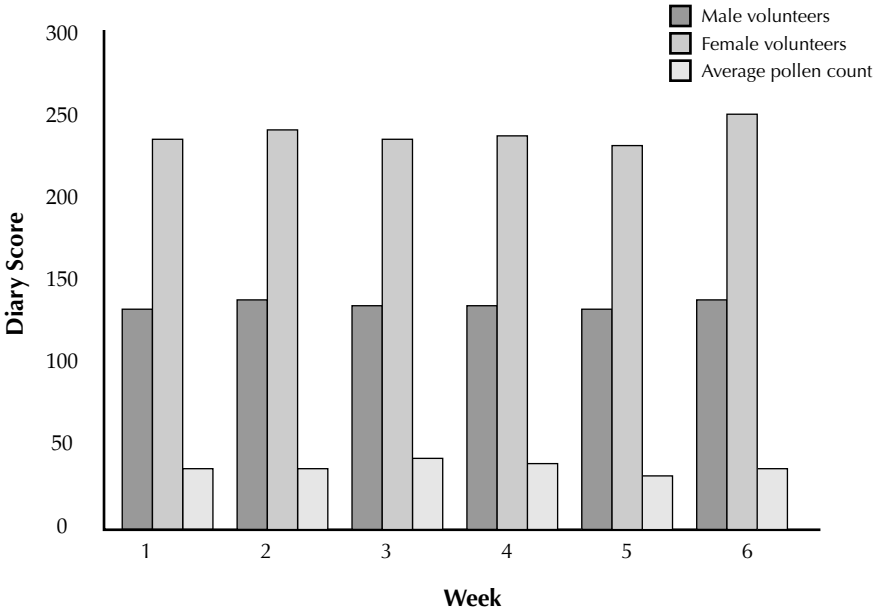
Table 3. Global Assessment of Efficacy of Cellulose Powder

	Overall Impression, %	
Volunteers	**Good**	**Excellent**
Male	76	69
Female	80	75
Total	78	72

Side effects were infrequently reported, but in week 1, 10% of volunteers noted that it was easy to inhale a large amount of powder, which caused an uncomfortable sensation at the back of the throat. One person reported itchy eyes, and another mentioned a sore throat; both symptoms may have been related to hay fever. Difficulty gauging how much powder remained in the bottle (opaque white plastic) was a common complaint, and in one case when the powder ran out, serious hay fever symptoms occurred immediately. Nine volunteers reported being able to smell the powder on inhalation, but this was not regarded as a problem.

Six women and two men required additional treatment with pharmaceutical products; however, volunteers who took more than the recommended one puff in each nostril per day could derive increased and accelerated relief of symptoms.

Figure 1 Average Weekly diary scores*



* Maximum score: 180 for men, 330 for women

DISCUSSION

In this pilot investigation, an inert cellulose powder placed into a novel, patented delivery system relieved classic hay fever symptoms, sometimes within minutes but usually within 3 hours of inhalation. The volunteers selected had a long history of multiple symptoms requiring chemical treatments that were, at best, only moderately effective. Of the 102 volunteers, 78 volunteers reported no hay fever episode during the study and experienced their first season free of sore throat, runny nose, sneezing, and watery eyes. The cellulose powder was easy to take and effective; the overall success rate exceeded 77%.

Although a short period of experimentation appears to be necessary before effective use of the product, adequate instructions are provided in patient leaflets supplied by the manufacturer (not used in this study). A metered-dose delivery system is under consideration that would allow more frequent use of the product (when the pollen count is especially high) and easier identification of the need for a new supply. The ability to filter air in the nasal passages appears to be superior to air purifiers and room air-conditioning filters.

Most volunteers observed that previous drug treatment had never alleviated all symptoms, whereas resolution of symptoms was complete with the cellulose powder.

This pilot investigation demonstrated that inert cellulose powder, delivered into the nasal cavity, prevents allergic reaction to pollen and other irritants and represents a safe and natural alternative to pharmaceutical preparations. Treatment with cellulose powder should be started as early as possible and continued throughout the pollen season, with the number of applications per day increased as appropriate. This product is suitable for use by individuals with diabetes and asthma, pregnant women, and children.

Further work should be done to ascertain the exact degree of efficacy, perhaps by adopting a double-blind placebo-controlled design for future evaluations, but in the meantime, Nasaleze treatment represents a real opportunity to significantly improve the quality of life for hay fever sufferers everywhere.

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