

Daily Application Of The Homeopathic Remedy Zicam Allergy Relief Significantly Improves The Quality Of Life And Impairment In Patients With Seasonal Allergic Rhinitis

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Citation

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Abstract

Background: Zicam Allergy Relief is an over the counter homeopathic nasal gel intended to be used for the treatment of seasonal allergic rhinitis (hay fever) and related upper respiratory type allergies.

Objective: The objective was to investigate the efficacy of treatment for seasonal allergic rhinitis (hay fever) and related upper respiratory type allergies. Efficacy was determined by analysis of the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ).

Method: 32 outpatients with seasonal allergic rhinitis were enrolled into the clinical study, (a placebo-controlled, double blind randomized study) (time of treatment 14 days). Efficacy was determined by assessing the improvement in the quality of life as measured by means of the RQLQ. Results: After the two weeks trial period, the overall RQLQ scores of the treated patients improved by 52% + 7 from baseline whereas patients receiving placebos had an overall improvement of 19% + 14 ($p < .05$).

Conclusions: Four-times daily application of Zicam Allergy Relief, improved patient-reported quality of life and reduced impairment in day to day activities.

INTRODUCTION

Allergic rhinitis commonly referred to, as hay fever may be a response to allergens such as pollens and molds. (1)

Outdoor allergens are an important part of the exposures that lead to allergic disease. Primary sources for outdoor allergens include vascular plants (pollen, fern spores, soy dust), and fungi (spores, hyphae) with nonvascular plants, algae, and arthropods contributing smaller numbers of allergen-bearing particles (2)

Respiratory allergic diseases include seasonal allergic rhinitis or hay fever, perennial allergic rhinitis and allergic asthma. While the prevalence of allergies and associated conditions is difficult to assess through epidemiological questionnaires (3), recent estimates show 20% to 25% of the U.S population is afflicted with allergic rhinitis (4). The prevalence of rhinoconjunctivitis in adults has been reported to be from 14% to 25% (5,6). Allergic rhinitis is currently the most common of all chronic diseases in children.

Unfortunately, untreated allergic rhinitis not only detrimentally affects children's physical and psychosocial well-being, quality of life, and capacity to function and learn, but it is also associated with and may contribute to

potentially serious sequelae, including asthma, sinusitis, and otitis media (7)

Although not life threatening, both allergic rhinitis and seasonal allergic rhinoconjunctivitis have detrimental effects on the physical and psychological well being of those afflicted. Also, epidemiological studies have demonstrated that allergic rhinitis and asthma frequently coexist and there maybe a causal link between the two. (1) The impact on a patient's quality of life due to this affliction has been well studied and documented.

The assessment of quality of life is the subjective value that an individual places upon satisfaction or dissatisfaction with his or her life and maybe influenced by many circumstantial factors. The primary goal of an allergy treatment is to improve the patient's quality of life; thus, instruments such as the RQLQ to have been developed to assess and measure improvements in the quality of life after treatment. (8)

There is a growing body of evidence supporting the use of homeopathic remedies for the treatment of allergies. A recent study compared a homeopathic preparation with placebo in perennial allergic rhinitis. This study

demonstrated that subjects in the homeopathic group had a significant objective improvement in nasal airflow compared with the placebo group (mean difference 19.8 l/min, 95% confidence interval 10.4 to 29.1, P=0.0001) (9) Another study investigated the efficacy and tolerance of a homeopathic nasal spray in cases of hay fever (seasonal allergic rhinitis) in comparison with the conventional intranasal cromolyn sodium therapy. (10) The homeopathic remedy consisted of a fixed combination made up of *Luffa operculata*, *Galphimia glauca*, histamine, and sulfur and the main outcome measure of the efficacy was the quality of life as measured by means of the Rhinoconjunctivitis Quality of Life-Questionnaire (RQLQ). The results showed that, for the treatment of hay fever, the homeopathic nasal spray is as efficient and well tolerable as the conventional therapy with cromolyn sodium.

Recently, a homeopathic remedy for the treatment of seasonal allergic rhinitis trademarked Zicam Allergy Relief was developed as a therapeutic option. The product consist of a novel gel delivery system which contains an emulsification of benzalkonium chloride, glycerine, hydroxyethylcellulose, sodium chloride, and sodium hydroxide, pH 7.2 in which active ingredients are dissolved. The active ingredients are comprised of *Luffa operculata*, *Galphimia gluaca*, histamine and sulfur. The goal of this study was to test the effectiveness of Zicam Allergy as a treatment for allergic rhinitis.

METHODS

Study Design: This study was conducted at one site in California in the spring of 2000. IRB protocol approval was granted by the Copernicus Group Institutional Review Board, protocol number NOB1-00-040. All patients gave written, informed consent prior to participation.

Patients of either gender, aged 18 to 65 years, currently experiencing mild to moderate seasonal allergic rhinitis symptoms and who had had a history or allergic rhinitis were enrolled in the study. Patients were excluded from the trial if any individual symptom was considered too mild or if symptoms were too severe (average RQLQ scores of less than 1 indicated symptoms were too mild or greater than 3 indicated symptoms were too severe /scale range 0 to 4). Other exclusion criteria included an upper respiratory tract infection within 30 days of the study. Eligible patients were randomized to self-administer the homeopathic remedy Zicam Allergy Relief trademark Nasal Spray, dosage 0.15ml per application, 4 times per day/per nostril over 14

consecutive days. The study site administrator distributed the nasal gels to the subjects, demonstrated the correct way to self-administer the medication and instructed them to spray one dose per nostril every four hours during waking hours (9:00 am, 1:00 PM, 5:00 PM, and 9:00 PM) for a period of 14 days. The Zicam allergy relief nasal gel applicators as well as the placebo gel applicators were supplied by Botanical Laboratories. All applicators supplied similar metered doses of the nasal gel. The nasal gel consists of an emulsification of benzalkonium chloride, glycerine, hydroxyethylcellulose, sodium chloride, and sodium hydroxide, pH 7.2. The composition of the Zicam Allergy relief was identical to that of the placebo nasal gel except that the placebo gel did not contain the active ingredients: *Luffa operculata*, *galphimia gluaca*, histamine and sulfur.

The Relative Quality of Life Questionnaire (described below) was self-administered just prior to initial treatment for baseline analysis, after 1 week of continuous treatment and after 2 weeks of continuous treatment.

Study Instruments: The self-administered study questionnaire RQLQ is a validated instrument used to assess the improvement in the quality of life of test subjects. (8). Disease-specific quality of life was assessed using the Rhinoconjunctitis Quality of life Questionnaire (RQLQ), which measures the effect of allergic rhinitis symptoms on 7 domains: 1) activities (social, work, recreational), 2) sleep, 3) emotions, 4) nasal symptoms, 5) ocular symptoms, 6) non ocular / non nasal symptoms (thirst, concentration, headache etc...) and 7) practical problems. (11,12) the questionnaire asks patients to rank the various domains according to a 0 to 4 number scale. In addition to the RQLQ questionnaire, each patient throughout the entire pilot study also kept a daily symptom record card.

The scoring methodologies for the RQLQ have been previously described by Juniper et al. (11,13) Briefly, patients scored individual domain of the RQLQ on a 5 point symptom scale (0=not affected, 1=mildly affected, 2=modestly bothered, 3=moderately bothered, 4=severely bothered). The overall RQLQ score was an average of the scores of the 7 separate domains. A higher score indicates greater impairment and a negative change from baseline (i.e. a decrease in score) indicates improvement.

Outcome Measures:The primary outcome measure was the change from baseline in the overall RQLQ score over the 2-week period double-blind treatment period. Secondary

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outcomes were the changes from baseline in scores in each of the 7 RQLQ domains over the two-week period.

Statistical methods

Patients were included in the intent-to treat if they were at the very least modestly troubled by symptoms; the overall average baseline score for all participants was 1.89 ± .28. Comparisons were made between placebo and the Zicam allergy relief treated group. A dose response assessment was not attempted. The statistical method used to analyze and compare the data was by the non-parametric one-way analysis of variance or ANOVA by GraphPad Prism version 2.0 software (GraphPad Software, Inc., San Diego, Ca.). A P value of < .05 was considered significant.

P value Wording

>0.05 Not significant

0.01-0.05 significant

0.001-0.01 Very significant

<0.001 Extremely significant

RESULTS

BASELINE CHARACTERISTICS

Thirty-two patients were included in the study. Baseline data for quality of life questionnaire RQLQ scores indicated that patients were modestly troubled by allergic rhinitis symptoms. The average RQLQ score at baseline was 1.89 ± .28 (scale 0 to 4). Individual RQLQ domain scores at baseline indicated that symptoms in the following domains: miscellaneous non-nasal non-ocular symptoms, ocular symptoms and activity impairment were least troubling. Patients reported high levels of impairment in sleep and nasal symptoms.

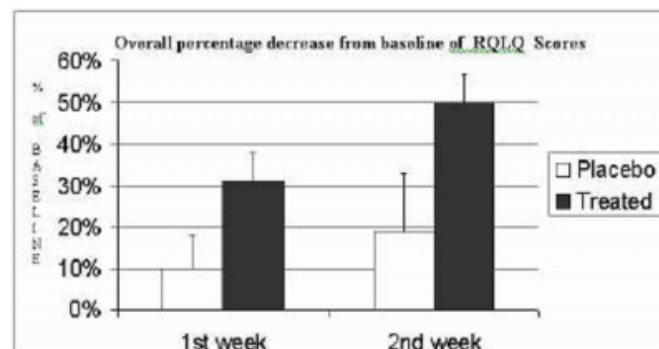
OUTCOMES

Quality of life. Zicam Allergy Relief was very effective at improving health-related quality of life in patients with seasonal allergic rhinitis. The average RQLQ scores of patients receiving treatment improved by 52% ± 7 after a two week treatment period whereas patients receiving placebos had an overall improvement of 19% ± 14 (Fig.1)

Figure 1. The average RQLQ scores of patients receiving treatment improved by 31% ± 7% after one week of treatment whereas untreated patients receiving placebos improved by 10% ± 8%. After two weeks, the RQLQ of

patients receiving treatment improved by 52% ± 7% whereas patients receiving placebos had an overall improvement of 19% ± 14%.

Figure 1



Within 2 weeks, improvements in all domain groups were seen in subjects receiving Zicam allergy medication (significance accepted at p(0.05). In contrast, no improvement was seen in the placebo group during this time period (Fig 2). This included work (p(0.001), social p(0.01), recreation (p(0.001), hay fever (p(0.002), practical problems (p(0.05), nasal symptoms (p(0.001), ocular symptoms (p(0.001), emotions (p(0.001), sleep (p(0.01), and non-nasal/non-ocular symptoms (p(0.001).

Figure 2. Graph indicates a decrease from baseline in Rhinoconjunctivitis Quality of Life Questionnaire scores over the two-week trial period. A decrease from baseline indicates a recorded improvement in the quality of life. Individual RQLQ domain scores are represented (A-G). Within 2 weeks, improvements in all domain groups were seen in subjects receiving Zicam allergy medication (a non-parametric one-way analysis of variance or ANOVA analysis, significance accepted at p(0.05). These included: A) Nasal symptoms (p(0.001), B) Ocular symptoms (p(0.001), C) Activities: work (p(0.001), social p(0.01), recreation (p(0.001), D) Emotions (p(0.001), E) Non-nasal symptoms/non-ocular symptoms (p(0.002), F) practical problems (p(0.05) and G) sleep (p(0.01) In contrast, no significant improvement was seen in the placebo group during this time period (significance accepted at p(0.05).

Figure 2

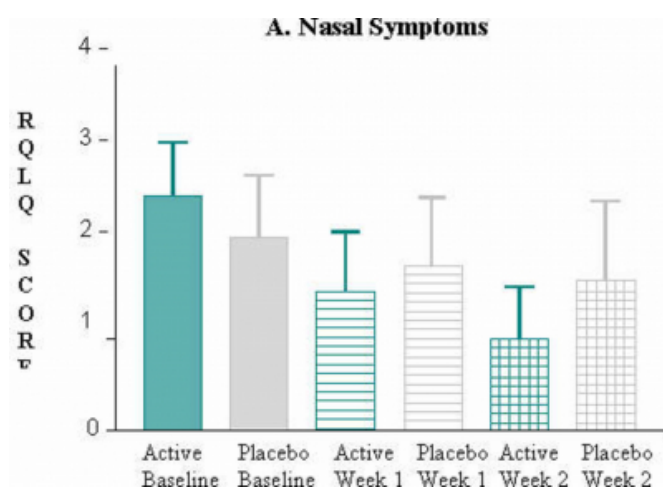


Figure 5

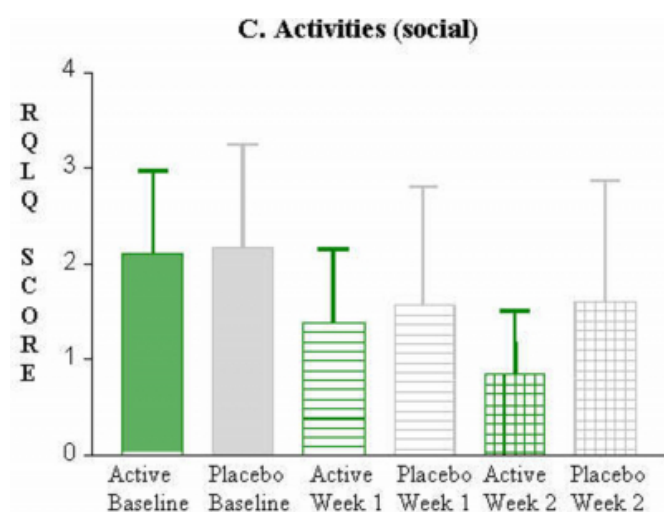


Figure 3

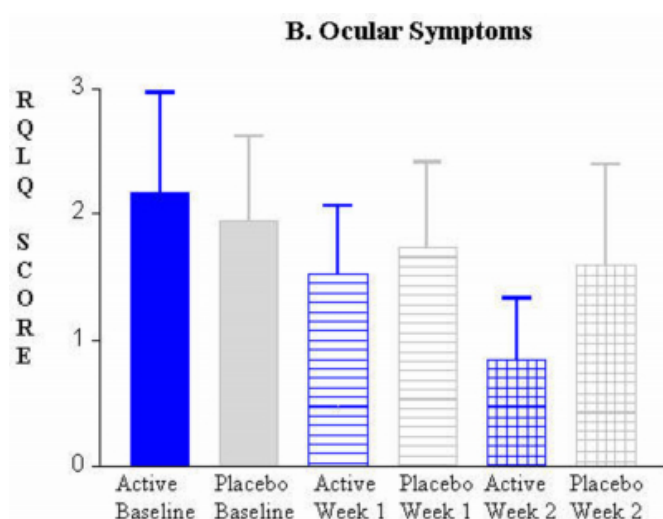


Figure 6

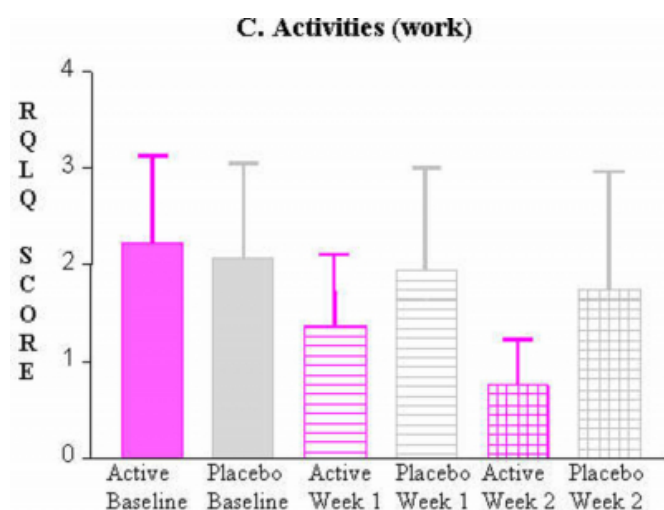


Figure 4

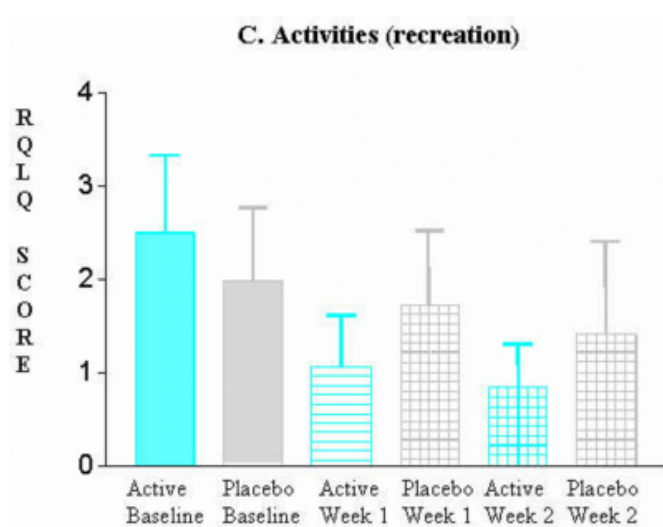


Figure 7

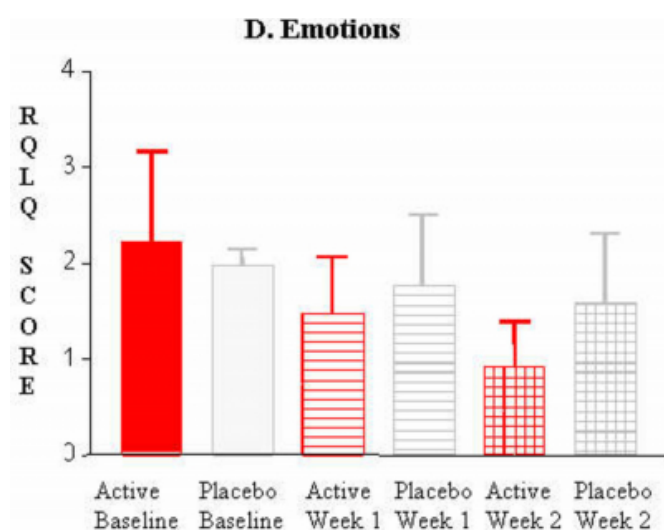


Figure 8

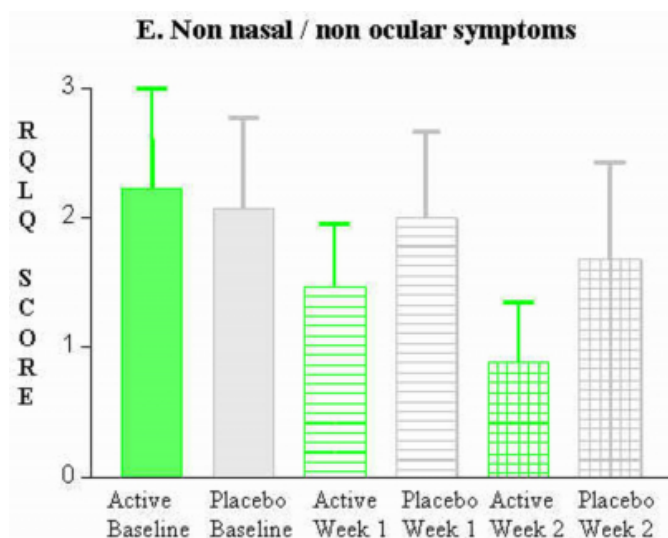


Figure 9

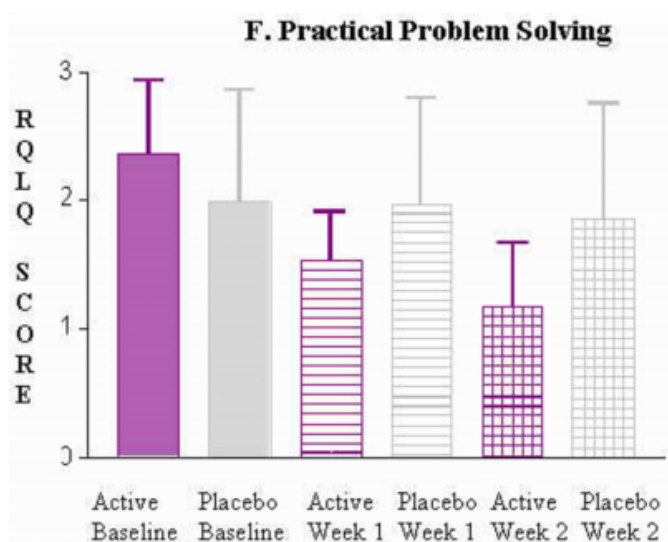
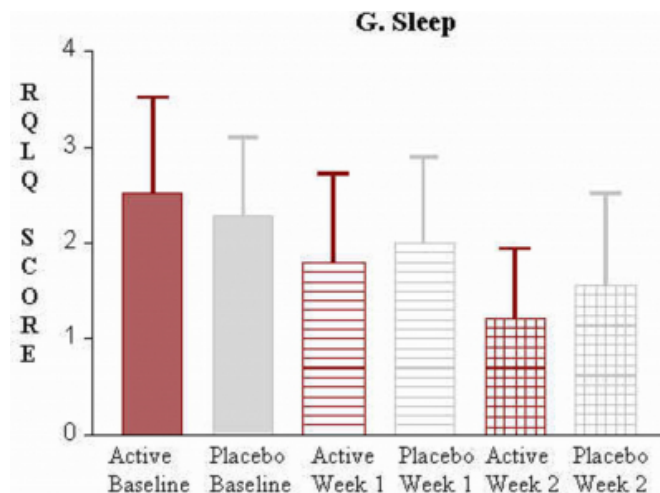


Figure 10



Impairment. The four times per day treatment with the Zicam Allergy Relief was statistically superior to placebo in improving patient-reported impairment various activities (social, work/school and recreational) over the 2-week trial period. Activities impairment was reduced by 49.3% from baseline in treated patients versus 18% in the placebo group by the end of the 2-week treatment period.

DISCUSSION

It is estimated that 20% to 25% of the U.S population is afflicted with allergic rhinitis (4) with the prevalence or rhinoconjunctivitis in adults being 14% to 25% (5,6). In addition, allergic rhinitis is currently the most common of all chronic diseases in children. This translates to 50 million people in the United States alone (14) with the prevalence of allergic rhinitis noted to be rising, and we begin to see the importance of a safe adequate treatment for the disease. Untreated allergic rhinitis may develop into a chronic state of inflammation and nasal obstruction that can lead too much more serious diseases in both the upper and lower airways. Allergic rhinitis is closely associated with, and may be a causative factor in, asthma, sinusitis, otitis media with effusion (OME), and polyps (1) It is now recognized that adequate pharmacotherapy for seasonal allergic rhinitis must not only control symptoms such as runny nose or watery eyes, but should also help patients feel better and function better in their everyday lives. Although many over the counter remedies are available including antihistamines, a substantial percentage of those afflicted will seek medical attention. The apparent need for safe over the counter remedies with a low incidence of side effects has resulted in increased efforts to develop new compounds to treat allergic rhinitis.

The goal of this study was to test the effectiveness of a new treatment for seasonal rhinitis (Zicam Allergy). This treatment contains Luffa operculata, galphimia gluaca, histamine and sulfur. In this study, we found Zicam Allergy to be very effective at improving the quality of life in subjects suffering from seasonal rhinitis. The subjects receiving Zicam Allergy showed improvement in all domains tested whereas the subjects receiving the placebo medication showed no improvement. Since hay fever, nasal and ocular symptoms are the primary complaints of allergic rhinitis sufferers, we were especially interested in Zicam allergy's effectiveness on these domains. We found that Zicam allergy was very effective in relieving these symptoms ($p(0.002)$, $p(0.001)$ and $p(0.001)$ respectively). The fact that Zicam Allergy is a homeopathic preparation without the side effects seen with many other OTC medications makes it an attractive alternative for allergy sufferers.

DISCLOSURE STATEMENT

The author Dr. Sion Nobel was employed by Barron Biotechnologies to conduct this study and serve as independent principal investigator. Barron Biotechnologies was contracted by Gumtech International, the manufacturer of Zicam Allergy Relief to organize a clinical

allergy study with the drug. The author was paid a nominal fee based on patient enrollment in the study. Barron Biotechnologies is an independent company which has no vested interest in Gumtech. Barron Biotechnologies received some money but no stock or stock options from Gumtech as payment for the contract. No payments of any kind from Gumtech to Barron Biotechnologies or from Barron Biotechnologies to the author were ever dependent upon any outcomes.

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