

NAGILLA SATIVA: A NON-CONVENTIONAL HERBAL OPTION FOR THE MANAGEMENT OF SEASONAL ALLERGIC RHINITIS

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ABSTRACT

Seasonal allergic rhinitis (SAR) is one of the top reasons for patient visits to primary care physicians because of its bothersome symptoms. This highly prevalent disease also impairs quality of life, sleep, and work. Oral antihistamines are one of the most frequently prescribed medications for the management of SAR but they have their own side effects. Hence the effects of traditional *Nigella sativa* seeds, on seasonal allergic rhinitis were studied in 20 patients. Daily dosages of 250 mg of seeds for a 15 days period significantly reduced the symptom severity scores of allergic rhinitis in patients. It was concluded that *Nigella sativa* seeds could be successfully used for seasonal allergic rhinitis.

Keywords: Seasonal Allergic Rhinitis, *Nigella sativa* and Anti-allergic.

INTRODUCTION

Allergic rhinitis is one of the most common reasons for patients to visit to primary care physicians, because of its bothersome symptoms (Bousquet *et al.*, 2004). It is an extremely common condition, affecting approximately 20% of the population (Chervinsky *et al.*, 2005). Seasonal allergic rhinitis, a highly prevalent disease also results in loss of productivity and constitutes a significant burden on quality of life of patients. Allergic rhinitis involves inflammation of the mucous membrane of nose, eyes, Eustachian tubes, middle ear, sinuses, and pharynx (Krouse *et al.*, 2005, Pecova *et al.*, 2005).

The mediators that are immediately released include histamine, tryptase, kinins and heparin. The mast cells quickly synthesize other mediators including leukotrienes and prostaglandins. These mediators via various interactions, ultimately leads to the symptoms of rhinorrhea (Meltzer, 2005).

Oral antihistamines are one of the most frequently prescribed medications for

management of allergic rhinitis, but they have their own undesired effects like insomnia, headache, dry mouth and day time sedation. Because of the concerns about the side effects of conventional medicine, the use of natural products as an alternative to conventional treatment in healing and treatment of various diseases has been on the rise in the last few decades (Chakravarty *et al.*, 1993, Meltzer-2005, Meltzer *et al.*, 2006).

Among the promising medicinal plants, *N. sativa* a dicotyledon of the Ranunculaceae family is an amazing herb with a rich historical and religious background (Huffman, 2003). Historically it has been recorded that ancient Egyptian and Greek physicians to treat headache, nasal congestion, toothache, as well as a diuretic to promote menstruation and increase milk production prescribed *NSativa* seeds, commonly known as black cumin or Kalongi (Ali *et al.*, 2003). The seeds contain both fixed and essential oils, proteins alkaloids and saponin. Much of the biological activity of the seeds has been shown to be due to thymoquinone (Omar *et al.*, 1999), the major

component of essential and fixed oil (Salem, 2005).

Hence the study was conducted to evaluate the effectiveness of *N. sativa* on seasonal allergic rhinitis symptom scores.

MATERIALS AND METHODS

The twenty untreated patients, suffering from seasonal allergic rhinitis, seeking outpatient treatment were selected from different primary care clinics and enrolled. All patients were excluded who had a previous history of major psychiatric illness, current dependence on alcohol or other drugs of abuse like sedatives or hypnotics as well as cardiac and liver diseases.

A signed informed consent was obtained from the participants of both sexes before they were enrolled in the study. The study period consisted of fifteen days for each patient, with daily patient's follow up visits.

The required information such as name, age, sex, occupation, duration of disease, previous medication, laboratory investigations, and dates of follow up visits, medical history and physical examination were recorded on a Performa, especially designed for this study. Adults with symptomatic SAR were randomized in a single-blind manner to receive 250 mg of *Nagilla sativa* seeds orally per day.

All the patients were also assessed on the basis of physiological parameters, which include the systolic blood pressure, diastolic blood pressure, pulse rate and body temperature. All patients have completed the treatment program.

They were observed and rated for the presence or absence of SAR symptoms expressed during the previous 24 hours by an observer. During study period an observer completed the symptoms severity questionnaire, which contains 20 typical symptoms. Subjects indicated the degree to which they had experienced each symptom and same observer than rated the presence and

intensity of symptoms on 5-point scale (Table-1). The composite score for subjects reported symptoms was obtained by adding the scores from the individual items together.

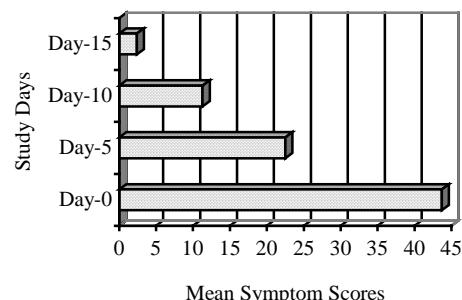


Fig. 1: Effects of *N. sativa* Treatment on subjective Symptoms of Seasonal Allergic Rhinitis.

Number indicates mean scores of 20 symptoms reported in 20 patients.

*P<0.001 versus pretreatment day 0.

Table-1
Subjective Symptoms of Seasonal Allergic Rhinitis

No.	Symptoms
1	Nasal congestion.
2	Sneezing.
3	Itching.
4	Restlessness.
5	Watery eyes.
6	Red eyes.
7	Eye swelling
8	Rhinorrhea.
9	Ear pressure.
10	Postnasal drip.
11	Irritability and tense
12	Anosmia.
13	Earache.
14	Headache.
15	Trouble getting to sleep
16	Nighttime awakening.
17	Daytime drowsiness.
18	Malaise.
19	Bothered with noise
20	Skin clammy and damp

5-Point Scale Symptoms.

0 = not at all.	1 = a little.
2 = moderately.	3 = quite a bit.
4 = extremely	

Table-2
Physiological parameters in patients treated with *N. sativa*

Physiological Parameters	Day-0	Day-15	P-Value
Mean Systolic Blood Pressure (mm of Hg)	115.7 ± 0.6	115.4 ± 0.1	N.S.
Mean Diastolic Blood Pressure (mm of Hg)	71.3 ± 0.9	71.0 ± 0.7	N.S.
Mean Pulse Rate (Beats/Minute)	102 ± 0.6	82 ± 0.2	P<0.001
Mean Temperature (°F)	99.8 ± 0.2	98.0 ± 0.1	P<0.001

n= 20, P<0.001 = Highly Significant. N.S = Non Significant.

STATISTICAL ANALYSIS

All data were expressed as means. Differences between means of treatment days were tested for significance by using the paired Student's t-test. For all analyses, P values less than 0.05 was considered significant.

RESULTS

Twenty patients of seasonal allergic rhinitis, who began the study, completed the therapy, for fifteen days. During study it was observed that all subjects of both sexes were ranging in age from 20-40 years ($x=22.1 \pm 1.3$). All had subjective symptoms of seasonal allergic rhinitis. A mean score of symptoms 43.7 ± 0.5 was obtained during the pretreatment baseline period that is on day 0 of study. But after administration of *N. sativa* seeds the seasonal allergic rhinitis symptoms score decreased from 43.7 ± 0.5 to 22.5 ± 0.6 on day 5, 11.3 ± 0.5 on day 10, and 2.4 ± 0.09 on day 15 of study. Thus the effects of *N. sativa* seeds to decrease the symptoms were highly significant ($P<0.001$) on day 5, 10, and 15 of study as compared with pretreatment baseline period that is on day 0 of study.

While no significant decrease in systolic and diastolic blood pressure was observed. On the other hand, there was a small but statistically significant decrease in pulse rate and body temperature observed from day 5 to day 15 of study (Table-2).

DISCUSSION

Seasonal allergic rhinitis is a significant problem for patients because its symptoms can impact on daily life functioning, particularly when they disrupt sleep leading fatigue and irritability during the day.

The body tissues, creating allergic reactions like seasonal allergic rhinitis, release histamine. There is an indication from the traditional use of *N. sativa* seeds that its active ingredients have a substantial impact on inflammatory and allergic diseases mediated by histamine (Kalus et al., 2003).

Following this study, *N. sativa* seeds was administered to adults in the treatment of seasonal allergic rhinitis with effective results and with no signs of toxicity.

Indeed, the anti-allergic effects of *N. sativa* seeds components could be attributed to its anti-histaminic effects (Majed et al., 2001). *In vitro* studies support this notion. Aqueous extract of *N. sativa* has shown relaxant and anti-histaminic effects on pre-contracted guinea pig tracheal chains (Boskababy et al., 2004).

In addition, the potent inhibitory effects of *N. sativa* seeds on histamine release from rat peritoneal mast cells, stimulated by different secretagogues; antigen sensitized cells, was found to be mediated by decreasing intracellular calcium by inhibition of protein kinase C, a substance known to trigger the

release of histamine (Chakravarty, 1993; Gillani *et al.*, 2001).

Moreover, thymoquinone, the major component of *N. sativa* seeds totally abolish the effects of histamine and were suggested to be mediated, at least in part, by inhibition of histamine release, lipoxygenase products of arachidonic acid metabolites like leukotrienes and possibly by non-selective blocking of the histamine receptors, which might explain the beneficial traditional therapeutic use of *N. sativa* towards seasonal allergic rhinitis (Majed *et al.*, 2001, Meltzer *et al.*, 2006).

CONCLUSION

N. sativa treatment improved the symptom scores in patients with symptomatic seasonal allergic rhinitis. *N. sativa* seed is a complex substance of more than 100 compounds, and most of which have not yet been identified and studied. So further studies are required to explore different components of *N. sativa* seeds and their specific cellular and molecular targets.

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