

Treatment of Acne Vulgaris With Nigella Sativa Oil Lotion

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ABSTRACT:

BACKGROUND:

Acne vulgaris is the most common chronic inflammatory disease of the skin. Despite the vast array of treatment modalities available for acne, there is considerable dissatisfaction in acne treatment among patients and doctors. Cost limitation, adverse effect or lack of efficacy limit the use of current therapy. Herbs and their extracts have been used for treatment of skin disease for centuries. One of the most popular herbs in our society is Nigella sativa; this plant had diverse clinically useful activity.

OBJECTIVE:

To use nigella sativa oil as natural plant remedy in the treatment of acne vulgaris.

METHODS:

This study was conducted in the Department of Dermatology and Venereology in Baghdad Teaching Hospital, Iraq during the period between October 2005 and April 2006. In this single-blind randomly controlled therapeutic study, ninety three patients were enrolled, their ages ranged from 13-23 years. There were 51 females and 42 males. The patients were divided into 2 groups; group A (47 patient) instructed to use nigella sativa oil lotion twice daily for 2 months, while group B (46 patient) used a control solution. Acne vulgaris was graded as mild and moderate acne by counting the number of papules and pustules. Statistical analysis was carried out by computer using t-test, f-test, and chi-square when needed.

RESULTS:

Eighty-one patients completed the study. In group A (43 patients), we noted a significantly reduced mean lesion count of papules and pustules after 2 months of therapy. The response of patients to treatment was good in 58%, moderate in 35% and no response in 7%. The satisfaction of patients with treatment was full in 67%, partial in 28%, and no satisfaction in 5%. In group B (38 patients), the lesions showed no significant reduction after 2 months and the response of patients to treatment was good in 8%, moderate in 34%, and no response in 58%. The satisfaction of patients with treatment in this group was full in 8%, partial in 24%, and no satisfaction in 68%. The mean difference in outcome after 8 weeks between the 2 study groups was statistically significant.

CONCLUSION:

The nigella sativa oil lotion has proved its efficacy as a topical therapy for acne vulgaris. This is a new natural plant extract, which lacks any side effects.

KEYWORDS: nigella sativa, lotion, acne vulgaris

INTRODUCTION:

Nigella sativa is annular herbaceous plant, widely cultivated throughout South Europe, Egypt, Syria, Saudi Arabia, Turkey, Iran, and Iraq. Nigella sativa 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 the major component of its oil (Ali and Blunden, 2003). It has been shown that Nigella sativa seed and oil are effective anti-microbial (Toama et al., 1974), immunomodulatory (Haq et al., 1999), antioxidant (Kruk et al., 2000), anti-inflammatory (Al-Ghamdi, 2001) and with antitumor activity (Ait Mbareket et al., 2007). The diversity of therapeutic activity of Nigella sativa seeds are due to the diversity of the active compounds that it contains. Remedy extracted from nigella sativa showed promising results in many dermatological conditions. A successful remedy extracted from nigella sativa in treatment of impetigo, scabies, pediculosis and dermatophytosis (Hadi, 2001).

Moreover nigella sativa oil has been used in treatment of recurrent aphthous ulceration and atopic dermatitis (Ali, 2004). This leads us to consider the

possibility of using nigella sativa oil lotion in the treatment of acne vulgaris.

Acne is a major skin problem among the youth, and usually initiated by androgen and propagated by bacterial flora of hair follicles like Propionibacterium acnes (P-acne). Natural treatments for acne vulgaris have much to offer although clinical studies are lacking (Yarnell and Abascal, 2006). The aim of the present work is to evaluate nigella sativa oil lotion in treatment of acne vulgaris

METHOD:

This study was conducted in the Department of Dermatology and Venereology in Baghdad Teaching Hospital, Iraq during the period between October 2005 and April 2006. Ninety three patients were enrolled, their ages ranged from 13-23 years with a mean age 18.3 ± 3.5 SD. There were 51 females and 42 males. Acne vulgaris was graded as mild and moderate acne by counting the number of papules and pustules. Full history was taken from each patient regarding age, gender, and duration of the disease, previous treatment and ensured that every patient had stopped any systemic and topical treatment at least 2 months before starting the present therapy. Physical examination was carried out to

evaluate the severity of acne. Scoring the severity of acne was according to the following rule (Feldman et al., 2004). Mild acne, in which the count of pustules is less than 20, and the count of papules is less than 10. 2. Moderate acne, in which the count of pustules ranges between 20-40, and the count of papules ranges between 10-30. 3. Severe acne, in which the count of pustules is more than 40, and the count of papules is more than 30. Comedonal type, severe acne, and nodulo-cystic lesions were excluded from the present study. In this method, the Nigella sativa oil was bought from local market (Camel brand, Saudi Arabia). Nigella sativa oil lotion (10%) was prepared through the following methods: Firstly we prepare the solvent by adding 200 ml of ethylene glycol to 200 ml of ethyl alcohol and 600 ml distilled water in a ratio of 2:2:6 (Hadi, 2001).Nigella sativa oil lotion 20% was prepared by taking 80 ml from the above solution and adding to them 20 ml of Nigella sativa oil; the oil lotion was placed in dark container. Oral consent was taken from each patient before therapy. Patients were divided randomly into 2 groups.: Group A: In this group, 47 patients (mean age 18.2 ± 3.5 years) were treated with 10% Nigella sativa oil lotion. Each patient was instructed on how to use the lotion topically, twice daily for 2 months and clinical evaluation was carried out monthly. The assessment was carried out by counting the inflammatory lesions (papules and pustules) and watching for any side effects. Group B: In this group, 46 patients (mean age 17.5 ± 3.5 years) were treated in the same manner as Nigella sativa oil lotion, but using the control solution (consist of ethylene glycol ,ethyl alcohol and distilled water in a ratio of 2:2:6). These cases were followed up for 2 months by counting the number of papules and pustules and observing any side effects. The response of patients to treatment was classified as: Good response, in which the reduction in the count of inflammatory lesions (papules and pustules) is more than 50%. Moderate response, in which the reduction in the

count of inflammatory lesions (papules and pustules) ranged from 10-50%. No response, in which the reduction of papules and pustules is less than 10%. The satisfactions of the patients to the treatment are classified into: 1. Full satisfaction. 2. Partial satisfaction. 3. No satisfaction (Sharquie et al., 2006). Statistical analysis was carried using SPSS version 16. Both descriptive and analytic data were used. Calculation of mean and SD was carried out for ages, papules and pustules. The analytic test used was t-test to compare the mean difference in outcome between the 2 study groups after 8 weeks, and chi-square for qualitative data.

RESULTS:

Ninety three patients were included in the study, and 81 patients completed the course of treatment. In group A there were 43 patients, 23 females (60%) and 20 males (40%), while in group B, there were 38 patients, 18 females (54%) and 20 males (46%). Twelve patients (16.7%) did not complete the treatment and were considered defaulters for unknown reasons. Table 1 shows the mean SD of the papules and pustules count before and after therapy. In group A there was a significant reduction in the mean SD of papules at the end of the study. For pustules, there was also a significant reduction in mean SD of pustules at the end of the study. In group B there was a non significant reduction of papules noted at the end of the study. The reduction in pustules at the end of study was also statistically non significant. Table 2 shows the mean difference in outcome after 8 weeks between the 2 study groups. Table 3 shows the response to treatment in both groups. Assessment of patient satisfaction in group A showed 29 patients (67%) fully satisfied, 12 patients (28%) partially satisfied, and 2 patients (4.6%) not satisfied. In group B this showed, 26 patients (68.4%) not satisfied, 9 patients (23.6%) partially satisfied, and 3 patients (8%) fully satisfied. For sex, age of patients and duration of the disease, the present work showed no difference in response to therapy.

Table 1 : Mean ± SD of papules and pustules counts before and after therapy.

Group		Mean ± SD		
		0 week	4 week	8 weeks
Group A	papules	12.60 ± 4.27	11.65 ± 4.20	6.98 ± 4.50
	pustules	20.86 ± 5.30	18.49 ± 6.17	10.70 ± 6.03
Significance	papules	p=0.0001		
	pustules	p=0.0001		
Group B	papules	12.26± 4.15	12.66 ± 4.57	11.95 ±4.82
	pustules	21.03 ± 5.34	20.58 ± 6.00	19.21 ± 7.58
Significance	papules	p=0.352		
	pustules	p=0.248		

Table 2: The mean difference in outcome after 8 weeks between the 2 study groups.

Type of lesion	Group A	Group B	t-test	p-value
Papule	5.1 ± 1.4	1.1 ± 0.8	8.55	0.001
Pustule	12.7 ± 3.5	1.5 ± 1.2	11.45	0.0001

Table 3 : The response to treatment after 8 weeks between the 2 study groups.

	No improvement	Moderate improvement	Good improvement
	n (0-10%)	n (10-50%)	n (>50%)
Group A n=43	3 (6.9)	15 (34.8)	25 (58.1)
Group B n=38	22 (57.9)	13 (34.2)	3 (7.9)
	Chi-square = 9.88	p=0.0001	

DISCUSSION:

Current treatments of acne include topical and oral antibiotics, topical antimicrobial, topical and oral retinoids. All acne treatment has potential side effects, some of which may be severe (Charakida et al., 2007). Many patients fail to improve with these agents due to the cost, adverse effects leading to noncompliance (irritation) or lack of therapeutic benefit (antibiotic resistance). The use of oral antibiotics and systemic retinoids increase both the cost and risk of adverse effects (Heffernan et al., 2007).

To overcome the problems of conventional therapies many studies have been done to find new effective and safe treatment of acne vulgaris. One of these methods to overcome the problems of conventional therapy is the use of medicinal plants in the treatment of acne vulgaris. One of the well-known medicinal plants used is *Nigella sativa*, this plant have been used traditionally in Middle Eastern folk medicine as natural remedy for various diseases for over 2000 years (Zaoi et al., 2002). More than 150 studies conducted since 1959 confirmed the pharmacological effectiveness of *Nigella sativa* seed constituents (Salem, 2005).

The present study shows that after 8 weeks treatment of patients with mild to moderate inflammatory acne vulgaris with *Nigella sativa* oil lotion, there was statistically significant decrease in total lesion counts and significant improvement in patient's disease state. The effects of *Nigella sativa* oil on acne lesions could be attributed to the:-

I: Anti-inflammatory Effect

It is well known that Acne vulgaris is a genuine

inflammatory disease, and evidence exists indicating that appropriate anti-inflammatory therapy has the potential to effectively treat this condition (Zouboulis, 2004). *Nigella sativa* is well known to have anti-inflammatory effect. The anti-inflammatory effect of *Nigella sativa* was found to be comparable to that produced by aspirin, crude fixed oil of *Nigella sativa* and pure thymoquinone inhibit COX and 5-LO pathways of arachidonate metabolism in rat peritoneal leukocytes (Al-Ghamdi, 2001). Another study done by El-Dakhakhny et al., (2002) found that *Nigella sativa* oil produce a concentration dependent inhibition of 5-LO production and 5-hydroxy-eicosatetra-enoic acid (5-HETE) production. Recently, a study done by El-Gazzar et al., (2006) showed that thymoquinone downregulates leukotriene biosynthesis. *Nigella sativa* may lead to improvement of patients with acne through its anti-inflammatory effect.

II: Immunomodulatory Effect

Patients with inflammatory acne develop an immune response to *P. acnes*; circulating immune complexes have been reported to be elevated in some acne patients, the degree of elevation have been correlated with the severity of acne inflammation (Dreno et al., 2004).

Nigella sativa is well-known immunomodulatory and several studies were done to show its efficacy (Salem, 2005). So immunomodulatory effect of *Nigella sativa* may play a role in its anti-acne action.

III: Antimicrobial Effect

It is believed that *P. acnes* playing a significant role in acne pathogenesis (Farrar and Ingham,

2004). Studies in vitro revealed that exposure of the gram-positive bacterium *Staphylococcus aureus*, the gram-negative *Pseudomonas aeruginosa* and *E. coli* and the yeast *Candida albicans* to ethereal extract of *Nigella sativa* lead to eradication of the above organisms (El-Tahir and Bakeet, 2006). Thymoquinone was found to be effective against several bacterial species include *Salmonella*, *Shigella shigae*, *Bacillus cereus*, *Vibrio cholera*. In addition, *Nigella sativa* oil found to be effective against multi-drug resistant strains of *Staphylococcus Aureus*, *Mycobacterium tuberculosis*. One of the components of *Nigella sativa* (α -pinene) had in vitro effect against *P. acnes* (El-Tahir and Bakeet, 2006). *Nigella sativa* oil lotion may act on *P. acnes* which is one of the major factors involved in the development of acne, so this will lead to improvement of patients condition. The 10% *Nigella sativa* oil lotion showed no side effects, and can be considered very safe when compared with other topical therapies like tretinoin and benzoyl peroxide that are commonly associated with local and systemic side effect such as local irritation, burning sensation, dryness of skin, peeling and teratogenic effects (Charakida et al., 2007; Heffernan et al., 2007).

The present study recommends the use of 10% *Nigella sativa* oil lotion as a topical therapy for acne vulgaris, as it is a natural plant extract.

CONCLUSION:

10% *Nigella sativa* oil lotion is an effective, safe, non-costly, and well-tolerated topical treatment of mild and moderate acne vulgaris.

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