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Topical 10% Nigella Sativa (Black Seed) Ointment A Remedy for Atopic Dermatitis.

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Abstract: *Atopic dermatitis a common dermatological disease worldwide occurs commonly during early infancy and childhood. Multiple modalities used in the treatment ; each has advantages and side effects.*
Patients and Methods:
A single-blind, placebo-controlled therapeutic trial from January 2017 to August 2018To evaluate the efficacy and safety of topical 10% Nigella sativa (black seed) ointment in the treatment of atopic dermatitis. Sixty patients with atopic dermatitis were included in this study, they were divided into two groups; each one consisted of thirty patients. Group one treated with topical 10% Nigella sativa ointment; group two treated with topical vaseline alone. Patients were evaluated clinically byusing severity scoring of atopic dermatitis Index before and after therapy. All patients were without treatment at least 2 weeks before the study, and were instructed to apply the study medications topically twice daily (morning and evening) for 2 weeks. The patients followed regularly every 2 weeks for 2 months to assess the improvement, to record any side effects and relapse. Both medications were statistically significant for the treatment of atopic dermatitis, but topical 10% Nigella sativa ointment, was superior to topical vaseline alone in response to therapy (p- value < 0.0005). Also the relapse rate in patients treated with Nigella sativa ointment was lower than the patients treated with vaseline alone, but not reach the significant level (p-value 0.26).
Conclusions:
Topical 10% Nigella sativa ointment is an effective, safe and non-costly a mode of therapy for localized atopic dermatitis lacking side effects.
Key words:*Nigella sativa, atopic dermatitis(AD),Vaseline.*

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I. Introduction

Atopic dermatitis (AD) :itchy, chronic or chronically relapsing, inflammatory skin condition. The rash characterized by itchy papules (occasionally vesicles in infants), which become excoriated and lichenified, and typically have a flexural distribution. The eruption frequently associated with other atopic conditions in the individual or other family members [1].

Epidemiology:

The prevalence of AD increased two folds to ten folds in the last four decades,affect approximately 10-20% of the population [2].

AD is most prevalent in the most developed countries and least prevalent in the most underdeveloped countries [1].

It's frequency among Iraqi infants (1–12 months) in Baghdad was 23.4 with the mean age of onset 4.2± 2.8 months, which indicates a late onset in Iraqi infants in comparison with Western countries with M:F ratio 1.6:1. While among developed countries sex distribution was equal [3].

Other study in sulaymaniyah, the frequency among infants and children less than 16 years old was 20.5 with an equal sex distribution [4].

AD can occur in any age but it's more common in children: 60% of of AD present in the first year of life, usually after 2 months of age and 80%-90% before the age of 5 years, but the onset may be delayed until childhood or adult life [1].

Some 60-70% of children with AD will clear by their early teens, although subsequent relapses are possible [5].

Diagnosis of AD:

The diagnostic criteria of Hanifin and Rajka are useful in classifying cases. These criteria have been simplified as the UK working party's diagnostic criteria for AD:

1.Major criteria:Most have 3 of the following:

Pruritus , Typical morphology and distribution , Flexural lichenification in adults , Facial and extensor involvement in infancy , Chronic or chronically relapsing dermatitis , Personal or family history of atopic disease (asthma, allergic rhinitis).

2. Minor criteria: Most have 3 of the following:

Xerosis, Ichthyosis , Hyperlinear palms , Keratosis pilaris , IgE reactivity (Immediate skin test reactivity, RAST test positive) .Elevated serum IgE , Early age of onset , Tendency for cutaneous infections. (especially s.aureus and herpes simplex virus) , Tendency to non specific hand / foot dermatitis , Nipple eczema , Cheilitis , Recurrent conjunctivitis , Dennie – Morgan infra orbital fold , Keratoconus , Anterior sub capsular cataracts , Orbital darkening , Facial pallor / facial erythema , Pityriasis alba , Itch when sweating , Intolerance to wool and lipid solvents , Perifollicular accentuation , Food hypersensitivity , White dermographism or delayed blanch to cholinergic factors , Course influenced by environmental and / or emotional factors[1,2].

Nigella Sativa :

It is an annual herbaceous plant that belongs to the Ranuculacea family with many beneficial properties as antitumor, antidiabetic, antihypertensive, antioxidative and antibacterial.

A plant widely used as folk medicine to treat many diseases like asthma[7], and as asthma and AD share many genetic and atiopathogenic factors so Nigella Sativa was tried in the treatment of AD as topically. The seeds of Nigella sativa Linn. (Ranunculaceae), commonly known as black seed or black cumin, are used in folk (herbal) medicine all over the world for the treatment and prevention of a number of diseases and conditions that include asthma, diarrhoea and dyslipidaemia. This article reviews the main reports of the pharmacological and toxicological properties of N. sativa and its constituents.

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, the major component of the essential oil, but which is also present in the fixed oil.

The pharmacological actions of the crude extracts of the seeds (and some of its active constituents, e.g. volatile oil and thymoquinone) that have been reported include protection against nephrotoxicity and hepatotoxicity induced by either disease or chemicals. The seeds/oil have antiinflammatory, analgesic, antipyretic, antimicrobial and antineoplastic activity. The oil decreases blood pressure and increases respiration. Treatment of rats with the seed extract for up to 12 weeks has been reported to induce changes in the haemogram that include an increase in both the packed cell volume (PCV) and haemoglobin (Hb), and a decrease in plasma concentrations of cholesterol, triglycerides and glucose[15].

II. Patients And Methods

A single blind, placebo controlled therapeutic trial conducted at the Department of Dermatologyin baghdad teaching hospital from January 2017 to August 2018.

60 patients with clinical diagnosis of AD according to Hanifin and Rajka UK Working party's criteria were included in this study.

Group (1):

30 patients with clinical diagnosis of AD treated by topical 10% Nigella sativa oil in ointment; ranging from 4 months to 25 yeas with a median of 4 years and mean + SD of 6.35+6.54 years.16 patients (53.3%) were females and 14 patients (46.7%) were males.

Group (2):

30 patients with clinical diagnosis of AD treated by topical vaseline ranging from 5 months to 37 years with a median of 5.25 years and mean + SD of 6.63+7.09. 17 patients (56.7%) females and 13 patients (43.3%) were males.

Oral consent from each patient or / and his parents was taken after explaining the nature of the trial, and instructed to not take any Topical or systemic therapy for AD least 2 weeks before starting our present treatment.

Onset and duration , Nature of symptoms and severity (pruritus, sleep loss) , Personal or family history of atopic diseases , Precipitating and aggravating factors, was taken.

A careful examination of the atopic dermatitis patients carried out:

Pattern and distribution ,Sites involved , Morphology of lesion (erythema, oozing, papules, vesicles, excoriation, and lichenification) and its tendency towards acute or subacute or chronic course.

We applied the severity scoring of atopic dermatitis: the SCORAD Index: Consensus Report of the European Task Force on Atopic Dermatitis, which was used before and after the treatment for each patient [6].

The ointment was prepared by 10g Nigella sativa oil and mixed with 90g of vaseline to get concentration of 10%.

The Topical Nigella sativa oil 10% to group 1 and topical vaseline to group 2applied on the affected areas twice daily (morning and evening)for 2 weeks, seeing regularly every 2 weeks for 2 months to assess the response , to record any side effects, and clinical relapse.

GROUP ONE

30 patients included in this study, 7 of them defaulted from the study, so 23 patients completed the course of the study; ranging from 4 months to 25 years with a median of 4 years and mean + SD of 7.013+7.56 years.

12 patients (52.17%) females and 11patients (47.83%) were males.

Duration of AD ranged from 2 weeks to 10 years with a mean + SD of 1.59+2.57.

Sites of involvement: as table (1).

Stages of AD:

Subacute in 20 patients (86.96%), acute in 2 patients (8.69%) and chronic in 1 patient (4.35%).

Personal history of atopic diseases was as table (2).

The average SCORAD before the treatment was 55.80+10.37 (SEM=2.16), while after the treatment SCORAD changed into a mean + SD of 9.86+13.99 (SEM=2.9). These changes was statistically significant (p-value = 0.00000000017). Table (3).

One patient defaulted from the study after completion of 2 weeks duration of treatment because he was not satisfied. Only 22 patients completed the course of the study. From those 11 patients (50%) had sustained improvement without any obvious relapse during the follow up period of 2 months and 11 patients (50%) got relapse within 1st 2 weeks after completion of therapy, no side effects had been recorded for all treated patients.

GROUP TWO:

30 patients included in this study, six of them defaulted from the study; So 24 patients completed the course of the study. Ranging from 5 months to 37 years with a median of 5.25 years and mean + SD of 6.89+7.56 years, there is no statistically significant difference between group one and two regarding their age and gender.

Thirteen patients (54.17%) were females and eleven patients (45.83%) were males.

Duration of AD ranged from 2 weeks to 11 years with a mean + SD of 2.66 + 2.60 years.

Sites of involvement were as table (1).

Stages of AD were as follows:

Subacute in 19 patients (79.17%), acute in 3 patients (12.5%), subacute and chronic in the same patient in 2 patients (8.33%).

Family history of atopic diseases was as table (2).

Clinical results:

The average SCORAD before the treatment was 51.96+13.97 (SEM=2.85), while after the treatment SCORAD Index changed into a mean + SD of 29.27 + 20.40 (SEM=4.16). These changes were statistically significant (p-value = 0.000003), Table (4).

Two patients defaulted from the study because they were not satisfied and only 22 patients completed the course of the study. From those 3 patients (13.64%) had sustained improvement during follow up period of 2 months and 19 patients (86.36%) got relapse within 1st 2 weeks after completion of therapy, no side effects had been recorded for all treated patients.

Comparison between the two groups had been shown that patients treated with 10% Nigella sativa ointment were statistically more significant in response to therapy than group treated with vaseline alone ($p<0.0005$), Table (5).

Table (1): Distribution of atopic dermatitis patients according to the sites of involvement

Site	Group			
	One		Two	
	No.	%	No.	%
Face	9	39.13	10	41.66
Flexure	8	34.78	7	29.17
Extensor	6	26.08	7	29.17
Neck	5	21.73	6	25
Hand& Feet	5	21.73	6	25
Trunk	1	4.34	2	8.33

There is more than one site in the same patient Table (2): Distribution of atopic dermatitis patients according to personal or family history of atopic diseases.

	Group							
	One				Tow			
	Family history		Personal history		Family history		Personal history	
	No.	%	No.	%	No.	%	No.	%
Asthma	6	26.09	4	17.39	8	33.33	4	16.66
Allergic rhinitis(AR)	2	8.69	1	4.35	7	29.16	0	0
AD	2	8.69	1	4.35	2	8.33	0	0
Asthma& AD	2	8.69	0	0	1	4.16	0	0
AR& AD	2	8.69	0	0	2	8.33	0	0
Negative	9	39.13	17	73.91	4	16.65	20	83.33

Table (3): SCORAD Index before and after treatment with topical 10% Nigella sativa ointment.

SCORAD Index	Before	After
Mean	55.80	9.86
SD	10.37	13.99
P-value	0.00000000017	

Table (4): SCORAD Index before and after treatment with topical vaseline (petrolatum)

SCORAD Index	Before	After
Mean	51.96	29.27
SD	13.97	20.40
P-value	0.000003	

Table (5): Comparison in response to therapy between group treated with topical 10% Nigella sativa ointment and group treated with topical vaseline alone.

Group	No.	SCORAD before therapy			SCORAD after therapy		
		Mean	+/- SD	SEM	Mean	+/-SD	SEM
One	23	55.8	10.37	2.16	9.86	13.99	2.9
Tow	24	51.96	13.97	2.85	29.27	20.4	4.16

t-test = -3.788, $p<0.0005$.

III. Conclusions

Nigella Sativa is a plant widely used as folk medicine to treat many diseases like asthma[7],and as asthma and AD share many genetic and atiopathogenic factors so Nigella Sativa was tried in the treatment of AD as topical ointment in 10% concentration.

The results of present study had been shown that both topical 10% Nigella Sativa ointment and vaseline were effective in treatment of AD, but Nigella Sativa ointment was much more superior to topical vaseline alone (p-value <0.0005). Also the relapse rate on follow up was much less in group treated with Nigella Sativa ointment when compared with group treated with vaseline alone, but not reach the significant level (P-value<0.26).

The encouraging results obtained in this trial compared favorably with other established treatments, all of which had side effects for example topical corticosteroids although is gold standard in treatment of AD but associated with alot of side effects and high relapse rate [1].Or the possible enhancement of ultraviolet carcinogenicity that blamed to cause by topical calcinurin inhibitors (pimercrolimus and tacrolimus) [8,5],while topical Nigella Sativa had no such carcinogenic effect because it had been used for many years as food and medicine.

The mechanisms of action of Nigella Sativa in treatment of AD are probably related to its antihistaminic, anti-inflammatory, antioxidant, immunomodulator and antimicrobial effects [9,10,11,12,13,14].So in conclusion topical 10%. Nigella Sativa ointment found to be a good option for localized atopic dermatitis, as it was safe, effective, non costly and lacking side effects.

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