Blood Glucose Lowering Effects of *Nigella Sativa* L. Seeds Oil in Healthy Volunteers: a Randomized, Double-Blind, Placebo-Controlled Clinical Trial

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Abstract

Background: Several formulations of the *Nigella sativa* L. seeds (Black seed) have been used in traditional medicine for treatment and prevention of a wide range of diseases including diabetes. But blood glucose lowering effects of its oil in a clinical study is of an interest.

Objective: The present study was undertaken to explore the possible blood glucose lowering effects of the Black seed oil on healthy subjects.

Methods: A randomized clinical trial was conducted in 70 healthy subjects referring to Bagiatallah hospital. The subjects were randomly selected and enrolled in to two groups of 35 each. One group received 2.5 ml Black seed oil and the other group received similarly 2.5 ml mineral oil two times a day. The fasting blood glucose, HbA1c, liver and renal function test was determined at the baseline and after two months.

Results: Results showed that significant decrease in fasting blood glucose and HbA1c levels in Black seed oil treated patients as compared to control group at the end of the study. No notable liver, kidney and gastrointestinal side effects were observed in these two groups.

Conclusion: Administration of 5 ml Black seed oil daily to healthy subjects for two months had beneficial effects on improving glycemic profile without any adverse effects.

Keywords: *Nigella sativa*, Black seed oil, Blood glucose, Traditional medicine

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Introduction

Diabetes mellitus is the most common metabolic disorder and is a major public health problem [1]. Apart from conventional diabetes therapy, several studies have shown that some plants used in traditional medicine have beneficial effects in diabetic patients [2, 3]. Recently, researchers have taken interest into the *Nigella sativa* seeds in different forms: the seed itself, the seed extract, its oil and its volatile substances. *N. sativa* commonly known as black seed or black cumin belongs to Ranunculaceae family. The plant seeds are often used as a spice and food preservative by the people in Asia, Middle East and Africa [4]. Black seed have been used in Iranian traditional medicine as a remedy for a variety of ailments including diabetes [5, 6]. Recent experimental studies have shown the therapeutic effects Black seed oil on diabetic animals [7, 8]. However its effects on blood glucose in human subjects is of an interest. Although a clinical study [9] had shown therapeutic effects Black seed oil on different components of the metabolic syndrome including blood glucose but in that study the placebo was not used in control group, blood HbA1c level was not determined and duration of the study was short. Therefore, the present study was undertaken to determine the effects of 5ml daily Black seed oil on blood glucose and HbA1c level and its possible adverse effects during two months study on healthy voluntary subjects.

Materials and Methods

The Black seed oil were purchased from local market and identified by a botanist (Y. Ajani). The seeds oil was extracted by cold press machine. The mineral oil was purchased from drug store. Both the oils were filled in 150 ml bottles and marked as A and B.

Study protocol

Participants

A total 70 Iranian healthy male and female volunteers (35 male and 35 female) were selected and enrolled in the study. The volunteers were visited by investigators and informed about the rationale and main aims of the study. A written informed consent was obtained from the volunteers. The medical ethics committee of the Bagiatallah University of Medical Sciences approved the protocol. Block randomization was used for treatment allocation.

Inclusion criteria

The healthy male and female volunteers with fasting blood glucose 80 – 126 mg/dl, body weight between 55 to 85 kg and age of 25 to 60 years were participated in the trial.

Exclusion criteria

Alcohol consuming, cigarette smoking, pregnant and breast-feeding s volunteers were excluded in the trial.

Study groups

All 70 volunteers were randomly assigned to groups of 35 each. One group received 2.5ml daily Black seed oil and the other group received 2.5ml mineral oil (placebo) two times a day after the meals. The study was double-blind.

Blood biochemical parameters

The fasting blood glucose, HbA1c, SGOT, SGPT, BUN and serum creatinine levels were determined at the baseline and after 2 months in both groups.

Blood samples were drawn after an overnight (12h) fasting. Fasting glucose levels were determined by the glucose-oxidase method using a Beckman Glucose-2 Analyzer immediately.

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Blood HbA1c was determined by commercially available kits using NycoCard, Axis-Shield PoC AS, Oslo, Norway. All other blood sample parameters were determined by auto analyzer Hitachi 902 using commercially available kits (Pars Azmon).

Assessment of adverse effects

All the volunteers were asked to note any adverse effects.

Statistical analysis

The t-tests were used for data analyses. Values of P below 0.05 were considered as statistically significant.

Results

All the volunteers in both the groups were completed the study.

The demographic and baseline data of both groups are summarized in table 1.

Blood biochemical parameters

The average finding of blood parameters in two groups at the baseline and after 2 months of the study are summarized in table 2.

Glucose

The average of fasting blood glucose level in Black seed oil group at the beginning of the study was 102.4 ± 20.8 mg/dl that decreased to 91.5 ± 12.5 mg/dl at the end of the study. The average fasting blood glucose level in placebo group at the beginning of the study was 98.6 ± 12.0 mg/dl that increase to 101.0± 14.8 mg/dl at the end of the study. Statistical analysis revealed that fasting blood glucose level in Black seed oil group was significantly decreased (p=0.006) as compared to control group at the end of the study.

Table 1- The demographical data of the subjects who participated in the trial. The data are given as mean ± SD

	Groups	
	Black seed oil	**Placebo**
Age (year)	42.3 ± 13.8	36.3 ± 13.6
Weight (kg)	72.7 ± 13.3	71.2 ± 11.8
Sex (male/female)	48.5% male 51.5% female	51.5% male 48.5% female

Table 2- The average blood parameters at baseline and after 2 months of the study in placebo and Black seed oil treated groups. The data are given as mean ± SD

	Groups			
	Placebo		**Black seed oil**	
	Baseline	**After 2 months**	**Baseline**	**After 2 months**
FBS (mg/dl)	98.6 ± 12.0	101.0 ± 14.8	102.4 ± 20.8	91.5 ± 12.5*
HbA1c (%)	5.6 ± 0.5	5.8 ± 0.5	5.7 ± 0.7	5.3 ± 0.4**
Creatinine (mg/dl)	0.89 ± 0.1	0.90 ± 0.1	0.92 ± 0.2	0.89 ± 0.21
BUN (mg/dl)	13.7 ± 2.9	19.6 ± 2.5	13.7 ± 5.6	14.2 ± 38
Total bilirubin (mg/dl)	0.69 ± 0.12	0.69 ± 0.12	0.71 ± 0.14	0.80 ± 0.29
SGOT (U/L)	19.9 ± 5.4	18.6 ± 4.6	22.8 ± 9.8	21.4 ± 13.7
SGPT (U/L)	15.3 ± 7.0	14.5 ± 7.1	19.8 ± 13.6	14.1 ± 7.5
ALK (IU/L)	188.6 ± 62.5	196.0 ± 58.4	202.6 ± 68.4	191.0 ± 50.5

p< 0.05* Fasting blood glucose and HbA1C levels significantly decreased (*p=0.006 and **p=0.000 respectively) in Black seed oil treated group comparing to the control group

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Glycosylated hemoglobin

The average HbA1c level in Black seed oil group at the beginning of the study was 5.7 ± 0.7 % that decreased to 5.3 ± 0.4 % at the end of the study. The average blood HbA1c level in placebo group at the beginning of the study was 5.6 ± 0.5 % that increase to 5.8 ± 0.5 % at the end of study. Statistical analysis revealed that HbA1c level in Black seed oil group was significantly decreased (p=0.000) as compared to control group.

Other biochemical parameters

Laboratory evaluations revealed no significant difference in fasting blood SGOT, SGPT, ALK, BUN, and creatinine levels in Black seed oil group compared to control group upon completion of study.

Safety and tolerability

During 2 months of the study no adverse reaction were noted by any volunteers in any groups except transient nausea in Black seed oil treated group. No notable liver enzyme and kidney functional adverse effects were observed at the end of the study in both the groups.

Discussion

In present study we observed the beneficial effect of black seed oil 5 ml daily on blood HbA1c glucose levels in healthy volunteers. The blood glucose lowering effects of black seed oil in present study agree with the previous trials [9].

The mechanism involved in the glucose lowering effect of black seed oil is not clear. Few studies have been conducted on the characterization of the bioactives and mechanisms mediating its anti-hyperglycemic action. In an experimental studie Alsaif [7] reported that blood glucose lowering effect of black seed oil was due to improved insulin insensitivity in diabetic rats. Another study proposed its hypoglycemic effect is due to improved extrapancreatic actions of insulin rather than by stimulated insulin release [8]. Furthermore Abdelmeguid et al [10] reported that the anti-hyperglycemic effect of black seed oil and its active component thymoquinone could be due to reduction of oxidative stress, thus preserving pancreatic β-cell integrity leading to increased insulin levels. Furthermore the black seed oil contains many bioactive constituents such as thymoquinone, p-cymene, pinene, dithymoquinone and thymohydroquinone [11]. Presence of these chemicals with diverse pharmacological effects such as anti-inflammatory, hypoglycemic activity, antioxidation, may interact with several metabolic pathways of human body which can directly or indirectly influence glucose or insulin metabolism [10, 12].

Thus, considering the results of the present and previous trials, further clinical trials concerning the safety and efficacy of black seed oil in the treatment of type 2 diabetes mellitus as well as more studies addressing the bioactives and mechanisms involved in the anti-hyperglycemic action of black seed oil seem necessary.

Conclusions

The results suggest that Black seed oil may be effective and safe in the treatment of type 2 diabetes mellitus.

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References

1. American Diabetes Association. Screening for type 2 Diabetes. *Diabetes* Care 26: 2003; (Suppl.1), S21 - S24.

2. Huseini HF, Larijani B, Fakhrzadeh H, Radjabipour B, Toliat T, Reza M. The efficacy of Silybum marianum (L.) Gaertn. (silymarin) in the treatment of type II diabetes: a randomized, double-blind, placebo-controlled, clinical trial. *Phototherapy Res*. 2006; 20: 12; 1036 - 9.

3. Afifi-Yazar FU, Kasabri V, Abu-Dahab R. Medicinal Plants from Jordan in the Treatment of Diabetes: Traditional Uses vs. In Vitro and In Vivo Evaluations - Part 2. *Planta Med*. 2011; 77 (11): 1210 - 20.

4. Salehi surmaghi MH. *Nigella sativa*. In *Herbal Medicine and Herbal Therapy,* volum 2, Donyay Taghziah press. Tehran Iran, 2008, 216 - 9.

5. Jazayeri GhA. Black Cumin. In *Zaban-e-khorakiha,* volum 3, Amir kabir press: Tehran Iran, 2004, 53 - 4.

6. Haji Sharifi A. Black Cumin. In *Secretes in Medicinal Pla*nts (3rd ed) Hafez-e-Novin press: Tehran Iran, 2003, 658 - 61.

7. Alsaif MA. Effect of *Nigella sativa* oil on impaired glucose tolerance and insulin insensitivity induced by high-fat-diet and turpentine-induced trauma. *Pak. J. Biol. Sci.* 2008; 11 (8): 1093 - 9.

8. El-Dakhakhny M, Mady N, Lembert N, Ammon HP. The hypoglycemic effect of *Nigella sativa* oil is mediated by extrapancreatic actions. *Planta Med.* 2002; 68 (5): 465 - 6.

9. Najmi A, Haque SF, Naseeruddin M, Khan RA Effect of *Nigella sativa* oil on various clinical and biochemical parameters of metabolic syndrome. *Int. J. Diabetes & Metabolism* 2008; 16: 85 - 7.

10. Abdelmeguid NE, Fakhoury R, Kamal SM, Al Wafai RJ. Effects of *Nigella sativa* and thymoquinone on biochemical and subcellular changes in pancreatic β-cells of streptozotocin-induced diabetic rats. *Diabetes* 2010; 2 (4): 256 - 66.

11. Geng D, Zhang S, Lan J. Analysis on chemical components of volatile oil and determination of thymoquinone from seed of Nigella glandulifera. Zhongguo Zhong Yao Za Zhi 2009; 34 (22): 2887 - 90.

12. Ali BH, Blunden G. Pharmacological and toxicological properties of *Nigella sativa*. *Phytother. Res*. 2003; 17: 299 – 305.

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