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Biochemical Effect of *Nigella sativa* (Black Cumin) on Glucose and Lipid Profile among Sudanese Diabetic Patients

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Abstract

Background: Diabetes mellitus (DM) is a common chronic disease; it is associated with alterations of blood glucose and lipid profile. Current evidence indicated beneficial effects of some medicinal herbs on metabolic parameters. **Aim:** The aim of this study was to investigate the effect of Nigella Sativa (NS) supplementation on blood glucose and lipid profile levels among type 2 DM Sudanese patients. **Materials and Methods:** the experimental study was conducted at Gezira state-Khartoum during the period from November 2019 to February 2020. Forty-five diabetic patients were randomly selected. Study population was classified into three groups; each contained 15 patients; glucose and lipid profile were estimated in all participants three times, the first one in day 0, the second after 15 days of daily intake of NS and the last sample after 30 days. Group 1 was given NS at concentration of 1 gram, and group 2 was given NS at concentration of 2 grams, while group 3 was given at concentration of 3 grams. **Results:** The included patients in the groups used NS with different dose, showed significant ($P < 0.05$) improvement with reference to blood glucose, while there was no significant improvement of lipid profile in all groups. **Conclusion:** Using regular NS can improve blood glucose level but has no effect on serum lipids. Concentration of two grams of NS has a better effect on blood glucose control.

Subject Areas

Diabetes & Endocrinology

Keywords

Diabetes, Glucose, Herbal Medicine, Lipid Profile

1. Introduction

Diabetes mellitus (DM) is a common chronic disease that affects people of all ages and imposes a large economic burden on the health care system. DM is characterized by chronic elevation of blood glucose which is a central factor in the production of reactive oxygen species (ROS) that in turn promote cellular damage and contribute to the development and progression of diabetic complications [1]. Pancreatic β-cells are particularly susceptible to damage by oxidative stress when exposed to chronic hyperglycemia because they are low in free-radical quenching enzymes. Furthermore, ROS can suppress the insulin response and contribute to the development of insulin resistance—a key pathological feature of type 2 DM [1]. Therefore, adequate glycemic control is essential for preventing complications associated with type 2 diabetes. Intensive glucose-lowering strategy has been found to reduce the risk of microvascular endpoints in patients with type 2 diabetes by up to 25% [2]. Moreover, clinical trials showed that a 1% decrease in HbA1c reduces cardiovascular complications by 14% [2] [3]. On the other hand, patients with type 2 DM have a complex alteration in plasma lipids characterized by elevated level of triglycerides (TG), decreased level of high-density lipoprotein cholesterol (HDL-c), and a preponderance of the low-density lipoprotein cholesterol (LDL-c). The abnormalities in circulating lipids and lipoproteins are considered to be important risk factors for cardiovascular diseases in diabetic individuals [4]. *Nigella sativa* (NS) seeds, an annual Ranunculaceae herbaceous plant, have been used in folk medicine to treat mild hypertention [5]. Regarding glucose lowering effects; NS has been reported in different diabetic animal models to be of desired outcome [6] [7]. Benhaddou-Andaloussi and colleagues [8] have demonstrated that NS ethanol extract exhibits a remarkable ability *in vitro* to concomitantly increase insulin secretion, induce proliferation of pancreatic β-cells, and stimulate glucose uptake in skeletal muscle and fat cells. In another study, the same investigators reported that treatment with NS ethanol extract, in diabetic "Merionesshawi" rats, caused a progressive normalization of glycaemia, albeit slower than that of metformin controls and exerted an insulin sensitizing action, compared to diabetic controls [9].

The protective effect of NS has been attributed to its strong antioxidant properties, which are related to its ability to scavenge various reactive oxygen species [10], block lipid peroxidation as well as enhance antioxidant enzymes [11] [12]. In spite of the extensive discussion on the hypoglycemic and antioxidant effects of NS on diabetic animal models; there is still scant evidence about these effects on humans. Najmi and colleagues [13] reported that NS oil (2.5 mL twice daily for 6 weeks) has a beneficial effect on fasting blood glucose, total cholesterol, and LDL-cholesterol in obese diabetics, suggesting that NS oil is effective as an "add-on" therapy in patients of insulin resistance syndrome. The results of a more recent study were carried out, which indicated that NS in a dose of 2 g/day for 12 weeks might be a beneficial adjuvant to oral hypoglycemic agents in type 2 diabetic patients [13]. However, there is still a concern about persistence of these

effects upon long-term use of NS. Therefore, the objective of this study was to investigate the effect of NS supplementation on glucose level as well as lipid profile in type 2 Sudanese diabetic patients.

2. Materials and Methods

The study took place in Gezira State, Central Sudan. Forty-five diabetic patients were randomly selected during the period from November 2019 to February 2020. Study population was classified into three groups containing 15 patients each; glucose as well as lipid paramenters were investigated thrice in all participants in the three groups, one in day 0, other one after 15 days of daily intake of NS and one more 15 days later. Group 1 was given NS at concentration of 1 g, group 2 was given NS at concentration of 2 g while group 3 was given NS at concentration of 3 g. Groups were classified according to glucose level primarily (group one glucose level's mean was below 180 mg/dL, group two glucose level's mean was below 220 and more than 180 mg/dL while group three glucose level's mean was higher than 220 mg/dL). All participants provided written informed consent and they agreed to participate in the study. All participants with cardiovascular problems were excluded.

2.1. Sample Collection and Testing

Under aseptic condition; 5.0 mL of venous blood was taken (after 10 hours fasting) prior and after the intake of NS from each patient by vein puncture technique and were divided into two tubes; one with fluoride oxalate anticoagulant while the other plain (has no anticoagulant), samples were centrifuged at 3000 rpm for five minutes to obtain plasma and serum, respectively. Samples were then pipetted into small eppendorf tubes for measurement of glucose as well as lipid profile. Kits were supplied by Dade Behring, Germany. Assays were performed according to the manufacturer's instructions, using the automated assay analyzer (Dimension Clinical Chemistry System, Germany). LDL-C was calculated using the Friedewald formula [14].

2.2. Statistical Analysis

All data were extracted to Microsoft office excel (Microsoft office excel for windows 2007) and SPSS (SPSS for windows version 19). Normal distribution of studied variable was examined using T-test. Unpaired T-test and Mann-whiteney U test were also used to assess any significant differences in the means of the studied variables.

2.3. Ethical Consideration

The study approval from the Al-Neelain University Faculty of Medical Laboratory Sciences, all participants were informed of the importance of the study.

3. Results

The blood glucose was gradually significantly decreased in patients used NS,

while cholesterol, triglyceride, LDL and HDL were insignificantly affected in all groups with different dose of NS, as presented in Table 1, Table 2 and Table 3. The level of blood glucose was reduced among patients who received one gram of NS to about 32 mg after 30 days of regular use. It is reduced by about 49 mg in the group that used 2 grams. Also, it is reduced by about 39 mg in the group that used 3 grams. This indicated 2 grams of NS has a better effect on the control of blood glucose.

Regarding lipids, there is an effect among the groups, but there is no clinically significant reduction.

Table 1. Glucose, cholesterol, HDL, LDL and triglyceride levels among patients treated with one gram of NS.

Variables	Before treatment N = 15	15 DAYS N = 15	30 DAYS N = 15	*P. value*
Glucose	178 ± 58	166.2 ± 51.1	146 ± 44.8	0.00
Cholesterol	217 ± 46	193 ± 39	219 ± 78	0.00
HDL	63 ± 28	55.8 ± 25.6	58 ± 26	0.01
LDL	127 ± 42	110.4 ± 75.8	140 ± 76	0.10
Triglycrides	140 ± 29	133.7 ± 40.3	138 ± 62	0.20

Table 2. Glucose, cholesterol, HDL, LDL and triglyceride levels among patients treated with two grams of NS.

Variables	Before treatment N = 15	15 DAYS N = 15	30 DAYS N = 15	*P. value*
Glucose	188 ± 58	169 ± 71	139 ± 45	0.00
Cholesterol	225 ± 25	196 ± 41	219 ± 78	0.00
HDL	55 ± 02	57 ± 20	59 ± 11	0.01
LDL	127 ± 44	115 ± 45	121 ± 17	0.14
Triglycrides	122 ± 35	123 ± 17	131 ± 22	0.24

Table 3. Glucose, cholesterol, HDL, LDL and triglyceride levels among patients treated with three grams of NS.

Variables	Before treatment N = 15	15 DAYS N = 15	30 DAYS N = 15	*P. value*
Glucose	226 ± 44	202 ± 42	187 ± 46	0.00
Cholesterol	258 ± 64	232 ± 58	255 ± 82	0.00
HDL	76 ± 36	64 ± 38	86 ± 51	0.01
LDL	133 ± 65	141 ± 59	146 ± 53	0.15
Triglycerides	146 ± 58	138 ± 34	112 ± 54	0.32

4. Discussion

The aim of this study was to assess effects of NS on the glucose as well as the lipid parameter's level. The results of the present study revealed that NS enhanced glycemic control, manifested by the significant reduction in glucose level in all participants compared to the corresponding baseline. This indicates the persistence of NS short term improvement in glycemic control (one month) in type 2 diabetic patients. This was also reported in another study conducted earlier [15]. The reduction in blood glucose level encountered here in agreement with the findings of previous studies conducted on streptozotocin induced diabetic rats treated with crude NS [16], or with NS oil [17]. Moreover, significant decline in blood sugar was recorded when NS volatile oil, 2.5 mL twice daily was added to metformin in the treatment of type 2 diabetic patients or those with insulin resistance syndrome [18]. Regarding lipid profile; findings presented in the current study revealed insignificant reduction in cholesterol, triglycerides and LDL levels. Some findings presented in the current study were in accordance with results present in other studies in the literature while some were not. In a study by Najmi and colleagues, NS in spite of change in LDL and HDL, could not reduce blood cholesterol and triglyceride in metabolic syndrome patients [13]. Ibrahim *et al.* [19] also did not find any significant change in blood HDL in metabolic syndrome patients with NS supplementation but found reduction of serum cholesterol, LDL, and triglycerides. A study of Husseini and colleagues on type II diabetic patients did not show any significant change in Triglyceride, LDL-, and HDL, with consumption of NS and just showed only reduction of Cholesterol in serum [20]. Dehkordi *et al.* [21] did not report any change in serum level of Triglyceride and HDL in patients with mild hypertension by NS supplementation. Also, in a study of Qidwai *et al.*, NS supplementation did not have significant effect on lipid profiles [22]. Badar and colleagues recently, in 2017, conducted a study in King Fahd Hospital of the University of Dammam, Saudi Arabia; they indicated a significant decline in choleterol, LDL, cholesterol/HDL and LDL/HDL ratios, moreover, HDL was reported to be significantly elevated as well [23]. However, earlier (in 2016) Mohtashami and colleagues in Chaloos, Northern Iran investigated the effects of bread with NS on Lipid Profile and concluded that no significant association exists regarding triglyceride, cholesterol, LDL and HDL [24]. Earlier (in 2015), Kaatabi and colleagues conducted a study in University of Dammam, Dammam, Saudi Arabia as well titled "Nigella sativa Improves Glycemic Control and Ameliorates Oxidative Stress in Patients with Type 2 Diabetes Mellitus: Placebo Controlled Participant Blinded Clinical Trial", they concluded a significant relationship between NS intake and the level of glucose [25]. The variations between the previous studies and the current study may be related to the duration time of the study and the dose form of NS. In addition life style and activity factors not included in this study

From general previous studies conducted addressing this issue, has considerably moderate study populations, further large-scale studies are needed to be con-

ducted for better judge the efficiency of NS in controlling glucose, total cholesterol and LDL levels both in the short as well as the long term.

5. Conclusion

The results of this study indicated that use of NS was found to be effective in reduction of blood glucose in type 2 DM, regular use of 2 grams has better control effect. But no improvement occurs on serum lipids.

Conflicts of Interest

The authors declare no conflicts of interest.

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