Int J Diabetes & Metabolism (2008) 16: 85-87

Effect of *Nigella Sativa* oil on various clinical and biochemical parameters of metabolic syndrome

A Najmi, SF Haque, M Naseeruddin, RA Khan
Departments of Pharmacology and Medicine, JN Medical College AMU Aligarh, India

Abstract
Background: The seeds of *Nigella sativa* plant have been used to promote health and fight disease for centuries especially in the Middle East and Southeast Asia. This plant has been a great focus of research. This clinical study was undertaken to determine the adjuvant effect of *Nigella sativa* oil on various clinical and biochemical parameters of the metabolic syndrome. **Methodology:** This prospective study was conducted at a tertiary health care centre in North India. After final diagnosis and considering inclusion and exclusion criteria, sixty patients were enrolled in this study. Informed and written consent was taken from all the patients enrolled. Approval from institutional ethical committee was obtained. Patients were divided into two groups of thirty. In group I (standard group) patients were given tablet Atorvastatin 10 mg once a day and tablet Metformin 500 mg twice a day for a period of six weeks. In group II (Nigella sativa) group, patients were given tablet Atorvastatin 10 mg once a day, tablet Metformin 500 mg twice a day and *Nigella sativa* oil 2.5 ml twice daily for a period of six weeks. Blood sugar, both fasting and postprandial, fasting lipid profile, body mass index, body weight and waist circumference were recorded before and after completion of therapy. **Result:** The above mentioned methodology was followed and it was found that the difference in percentage improvement in group II was significant with reference to total cholesterol, low density lipoprotein (LDL) and fasting blood glucose ($p<0.05$). **Conclusion:** *Nigella sativa* oil is effective as an add-on therapy in patients with metabolic syndrome. *Nigella sativa* oil has a significant therapeutic activity in diabetic and dyslipidemic patients.

Key words: *Metabolic syndrome, Nigella sativa*

Introduction

Although the modern era of what we now call the 'metabolic syndrome' or the 'insulin resistance syndrome' seems to have started less than two decades ago with the description of syndrome X by Reaven[1] in the late 1980s, the history of this syndrome is much longer. In particular, a considerable number of scientists, starting as early as almost 90 years ago, have described the very common coexistence of the various components of the syndrome, including hypertension, and gave several names to this clustering. On the other hand, during the past few years several international organizations have tried to form a reference context of what is included under the terms 'metabolic syndrome' and 'insulin resistance syndrome', proposing various 'definitions' for them. As public health epidemics go, metabolic syndrome does not seem to pack the punch of more sharply defined health threats, such as lung cancer or heart disease. However, statistics expose some harsh realities. According to a 2002 report from Centre for Disease Control and Prevention, about 22 % of United State adults have metabolic syndrome. Experts believe that reports based on data collected between 1988 and 1994 underestimate the current number of persons who have metabolic syndrome. It has been estimated that metabolic syndrome will soon overtake cigarette smoking as the primary risk factor for cardiovascular diseases.[2] Metabolic syndrome is a stronger predictor of risk for type 2 diabetes mellitus.

The seeds of *Nigella sativa* plant have been used to promote health and fight disease for centuries especially in the Middle East and Southeast Asia. In South Asia, it is called Kalonji, its Arabic name is Habat-ul-Sauda and its English name is Black cumin. This plant has been a great focus of research and has several traditional uses and consequently has been extensively studied for its chemical constituents and biological activities. A lot of animal studies have already been done to determine the various activities of *Nigella sativa* oil on different components of the metabolic syndrome for example blood sugar[3] and blood pressure[4] but no clinical studies have been done in patients with metabolic syndrome. This clinical study was undertaken to know the adjuvant effect of *Nigella sativa* oil on various clinical and biochemical parameters of the metabolic syndrome.

Material and methods

This prospective study was carried out on patients who were

Received on: 03/08/2007
Accepted on: 27/06/2008

Correspondence to: Dr. Ahmad Najmi, Room # 289, Hadi Hasan Hall, A.M.U. Aligarh, India. e-mail najmi.alig@gmail.com

attending the outpatient department of Medicine and Nephrology, J.N. Medical College from April 2006 to March 2007. After final diagnosis and considering inclusion and exclusion criteria, sixty patients were enrolled in this study. Out of the sixty patients, the number of male and female patients was fifty and ten, respectively. Informed and written consent was taken from all patients. Approval from institutional ethical committee was obtained.

Inclusion criteria
Abdominal obesity: waist circumference (> 102 cm for males, > 88 cm for females), serum triglyceride > 150 mg %, serum high density lipoprotein (HDL) <50 mg %; blood pressure > 140/90 mm Hg; fasting blood sugar > 110 mg % To diagnose a patient as a case of metabolic syndrome at least 3 or more criteria with or without treatment should be present.

Exclusion criteria
Pregnancy, Type I diabetes mellitus, impaired liver function test, Patients with chronic renal disease, primary dyslipidemia, myopathy

All the patients were thoroughly examined and detailed histories were taken. The baseline parameters of our study include weight, body mass index, waist circumference, fasting and postprandial blood sugar, lipid profile: total cholesterol (TC), low density lipoprotein (LDL), high density lipoprotein (HDL) and triglyceride (TG). The baseline parameters were recorded before therapy and after completion of therapy.

***Nigella sativa* Oil**
Nigella sativa oil (Kalonji oil, Mohammedia Products, Red Hills, Nampally, Hyderabad) was procured from local market at Aligarh. As per manufacturer's information, it was prepared by steam distillation at Hyderabad, A.P., India

Study Groups
Sixty patients were divided on the basis of clinical profile and therapeutic intervention.

Group 1 (Standard group): Patients having obesity, diabetes and dyslipidemia and treated by standard regimen (n =30).
Group 2 (*Nigella sativa* group): Patients having obesity, diabetes and dyslipidemia and treated by standard regimen plus *Nigella sativa* oil (2.5 ml) given twice daily per orally for a period of six weeks (n= 30).

Statistical analysis
Percentage improvement in each parameter was calculated. The difference in percentage improvement for each parameter between the two groups was calculated. To determine whether difference of percentage improvement in two comparable groups was significant, unpaired t test was applied between Groups 1 and 2. All the statistical analyses were done by using SPSS software.

Results
Body weight reduction in both groups is shown in Table 1.

Table 1: Body weight reduction in both groups

Parameter	Group	No. of patients (N)	Mean percentage improvement	Std. Deviation
Body mass index	1	30	0.019	1.275
	2	30	0.048	2.341
Abdominal circumference	1	30	0.167	0.641
	2	30	0.523	0.982
FBS	1	30	18.463	6.772
a	2	30	29.239	6.094
PPBG	1	30	19.875	6.216
	2	30	23.388	8.543
Body weight	1	30	0.133	0.528
	2	30	0.641	1.151
TC	1	30	16.925	6.252
	2	30	26.871	6.753
TG	1	30	14.183	0.009
	2	30	12.027	0.547
HDL	1	30	13.968	3.194
	2	30	15.894	2.153
LDL	1	30	15.947	5.750
	2	30	23.890	7.298

Standard regimen: Metformin (500 mg twice a day) and Atorvastatin (10 mg once a day).

Mean and standard deviation of percentage reduction in group 1 is 0.1331 ± 0.5280, which is lower compared to group 2 (0.6411 ± 1.1505). Reduction in abdominal circumference in group 2 was (0.5228±0.9816) which is more than in group 1(0.1668±0.6406). Reduction in body mass index (BMI) of group 2 is (0.0483±2.3408) which is higher than in group 1. Reduction in fasting blood sugar in group 2 was (29.2392±6.0937) which is significantly higher (p value=0.001) than in group 1(18.4637±6.7724). Reduction in postprandial blood sugar in group 2 was higher (23.3879±8.5426) than in group 1 (19.8745±6.2160). Reduction in total cholesterol in group 2 was (26.8714±6.7530), which was significantly more (p = 0.001) than in group 1 (16.9249 ± 6.2515). Reduction (12.0269 ± 0.55) in triglyceride in group 2 was less than in group 1 (14.1829±0.0090). Increase in HDL in group 2 was (15.8937±2.1528), more than in group 1 (13.9678±3.1939). Reduction in LDL in group 2 was (23.8898±7.2984) was more than in group 1 (15.9471±5.7503). This reduction was significant (p = 0.012)

Discussion
Until now, various animal studies have been done to investigate various parameters of the metabolic syndrome. Most of the studies have reported favorable effect of *Nigella sativa* on various components of the metabolic syndrome. The root cause of all the abnormalities in the metabolic syndrome is obesity[5]. In our study we have chosen three clinical criteria to measure obesity. These include body weight, abdominal circumference and body mass index. Waist circumference[6] has very crucial role in the detection and diagnosis of the metabolic syndrome. Overweight and obesity are associated with insulin resistance and the metabolic syndrome. However, the presence of abdominal

obesity correlated, highly, with the metabolic risk factors than an elevated BMI. Therefore, the simple measure of waist circumference is recommended to identify the body weight component of the metabolic syndrome. Some male patients develop multiple metabolic risk factors when the waist circumference is only marginally increased, e.g., 94 to 102 cm (37 to 39 in). Such patients may have a strong genetic disposition to insulin resistance. They should benefit from changes in life style similar to men with categorical increases in waist circumference.

In our study the reduction in abdominal circumference in the *Nigella sativa* group was more than in the standard group but this difference was not statistically significant.

Body mass index[7] is also an important marker of obesity. Most people with categorical obesity BMI $\geq$30 kg/m^2 have postprandial hyperinsulinemia and relatively low insulin sensitivity, but variation in insulin sensitivities exists even within the obese population. Overweight persons BMI of 25 to 29.9 kg/m^2 also exhibit a spectrum of insulin sensitivities, suggesting an inherited component to insulin resistance.
In our study *Nigella sativa* oil has given positive results with reference to BMI. Reduction in BMI in the *Nigella sativa* group was higher than in the standard group but this difference was not significant. In the same way, body weight was also reduced more in *Nigella sativa* group as compared to the standard group but this difference was not significant. Fasting and postprandial blood sugar[8] is a very important parameter for the diagnosis of metabolic syndrome. Near-normal or improved glycemic control[8] has been shown to significantly diminish the risk of microvascular complications in patients with type 2 diabetes mellitus. That is why this criterion is included in most of the definitions of metabolic syndrome. In our study our cut-off point for fasting blood glucose was 110 mg% which is taken from ATP III criteria[6] for the diagnosis of metabolic syndrome. Reduction in fasting blood sugar in *Nigella sativa* group was significantly higher (p=0.0001) than in the standard group. Postprandial blood sugar is also an important measurement of glycemic control. Percentage reduction in postprandial blood sugar was also greater in the *Nigella sativa* group compared to the standard group but this difference was not significant. In our study, reduction in total cholesterol in the *Nigella sativa* group was significantly higher (p= 0.0001) than in the standard group. Previous studies[10] also reported a cholesterol lowering effect of *Nigella sativa* oil. In our study, the triglyceride cut-off range was 150 mg%, which was taken from ATP III guidelines. Reduction in triglyceride in the *Nigella sativa* group was less than in the standard group. Previous studies[10] have reported that *Nigella sativa* oil has no significant effect on triglyceride levels. In our study the cut-off point for HDL was 50 mg%. Although normal HDL levels vary slightly according to gender, in our study we have taken a single cut-off point as 50 mg% for both sexes for the purpose of simplicity. The increase in HDL in the *Nigella sativa* group was more than in the standard group but this increment was not significant. Previous studies reported variable results on the effect of *Nigella sativa* oil on HDL levels. Some studies[10] reported that HDL increased while some[3] reported that *Nigella sativa* had no effect on HDL. Reduction in LDL in the *Nigella sativa* group was more than in the standard group and this reduction was significant (p=0.012). Previous research workers[10] also reported the same results in various animal studies. *Nigella sativa* has beneficial effects on fasting blood sugar, total cholesterol and LDL. More research is required to determine the various mechanisms by which *Nigella sativa* acts in such a diverse way on various components of the metabolic syndrome. *Nigella sativa* is one such remedy that may prove beneficial in the future for the prevention and treatment of the metabolic syndrome.

Acknowledgments
Thanks are due to Dr. M.T. Salman for help in statistical analysis. Thanks are also due to Mr. Aijaz, in charge of the Central Medicine lab for his technical assistance.

References

1. Reaven GM. Banting lecture 1988: role of insulin resistance in human disease. Diabetes 1988; 37: 1595-1607
2. Eckel RH, Krauss RM. American Heart Association call to action: obesity as a major risk factor for coronary heart disease. AHA Nutrition Committee. Circulation 1998; 97:2099-2100.
3. Bamosa A, O et al. Effect of oral ingestion of Nigella sativa seeds in some blood parameters. Saudi Pharm J 1997; 5: 126-129.
4. Aqel, M. The relaxing effect of the volatile oil of *Nigella sativa* seeds on vascular smooth muscle. Dirasat Series B, Pure Applied Sci 1992; 19: 91-100.
5. Vega GL. Obesity, the metabolic syndrome, and cardiovascular disease. Am Heart J 2001; 142:1108-16.
6. National Institutes of Health: Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Executive Summary. Bethesda, Md.: National Institutes of Health, National Heart Lung and Blood Institute, 2001 (NIH publication no. 01-3670). Accessed online March 18, 2004
7. Szapary PO, Hark LA, Burke FM. The metabolic syndrome: a new focus for lifestyle modification. Patient Care 2002; 36:75-88.
8. Tests of glycemia in diabetes. Diabetes Care 1998; 21(suppl 1):S69-71.
9. Second report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (adult treatment panel II). Bethesda, MD: National Cholesterol Education Program, National Institutes of Health, National Heart, Lung, and Blood Institute, 1993; DHSS publication no. (NIH) 93-3095:5.
10. Bamosa AO, Ali BA, al-Hawsawi ZA. The effect of thymoquinone on blood lipids in rats. Indian J Physiol Pharmacol 2002; 46:195-201.