Effect of Nigella Sativa Tablets on Various Parameters of Insulin Resistance Syndrome in Fatty Liver Disease at Peshawar Cantonment

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Abstract: Background and aim the seeds and oil of the plant Nigella Sativa have been used for centuries to promote health and fight disease all over the world especially in the Southeast Asia and in Middle East countries. This plant have been focused much by various researchers. This clinical study was carried out to know the ad on effects of tablets Nigella Sativa on different clinical and bio chemical parameters of the insulin resistance syndrome in the fatty liver disease. Patients and methods this clinical study was conducted in the medicine department. From Jun 2013 to May 2014 at Combined Military Hospital Peshawar cantonment a tertiary care hospital. 60 Patients who full filled the inclusion and exclusion criteria after confirmation of diagnosis were enrolled in this study. All the patients were properly consented in writing. The hospital ethical committee approval was also got. Two equal groups of patients were made having 30 each. In group I (The control group), patients were prescribed tablets Pioglitazone 30 mg PO BD, Tablets Rosuvastatin 10 mg PO at night and Tablets Metformin 500 mg PO BD for a period of 08 weeks. In group II (The Nigella Sativa group) the patients were advised Tab Nigella Sativa 600 mg PO BD along with standard treatment for a duration of 08 weeks. Fasting and postprandial blood sugar, waist circumference and fasting lipid profile were recorded before and after completion of treatment. Result the tablet Nigella Sativa group presented significant improvements (P < 0.05) with respect to total cholesterol (TC), Low density lipoprotein cholesterol (LDL-C) and Fasting blood glucose (FBS). Conclusion in insulin resistance cases in fatty liver disease Nigella sativa tablets was found to be effective as an ad-on therapy. In diabetic and dyslipidemic patients Nigella sativa tablets has a significant activity.

Key words: Prevalence · Fatty Liver Disease · Non-Alcoholic Fatty Liver Disease · Non-Alcoholic Steatohepatitis · Ultrasound · Nigella Sativa

INTRODUCTION

Nonalcoholic fatty liver disease (NAFLD) is the top most cause of abnormalities in LFT's among adult population of western countries. The NAFLD spectrum ranges from simple steatosis to nonalcoholic steatohepatitis (NASH), which can further progress to end stage liver disease. NAFLD is generally associated with obesity, dyslipidemia, type 2 diabetes and insulin resistance, these all are components of metabolic syndrome. In short NAFLD is hepatic manifestation of the metabolic syndrome [1-4]. Obesity is a major health problem associated with diabetes and hypertension Too much weight may increase the risk of NAFLD [5, 6]. Plants have a vital role as therapeutic agents as well as biologically active substances including hyppolipidaemic and hypoglycemic agents [7].

The seeds and oil of the Plant *Nigella Sativa* have been used for centuries around the globe especially in the Middle East and in South Asia to promote health and

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fight disease. It is called habat-ul-Sauda in Arabic, in south Asia it is called Kalonji and in English it is known as black cumin. A lot of animal studies have been done already regarding its activities on various components of fatty liver disease, for example blood sugar and blood pressure [8, 9]. However no clinical study have been done in Fatty Liver disease patients. This clinical study was carried out to know the ad on effect of tablets Nigella Sativa on different clinical and biochemical parameters of the insulin resistance syndrome in Fatty Liver disease.

MATERIALS AND METHODS

This prospective study was carried out in medicine department Combined Military Hospital (CMH) Peshawar cantonment for a period of 12 months (From June 2013 to May 2014). A total of 60 patients (50 male, 10 females) on confirmation of diagnosis and who meets the inclusion and exclusion criteria were nominated for this clinical study. All the participants were consented in writing the institutional ethical committee approval was also obtained.

Inclusion Criteria:

- Fasting blood sugar (FBS) > 110mg%
- Blood pressure (BP) > 140/90mmHg
- Abdominal obesity: Waist circumference
  > 102cm for male patients
  > 88 cm for female patients
- Serum high density Lipoprotein (HDL-C) < 50mg%
- Serum triglyceride > 150mg%
- Ultrasonography manifestation of fatty liver.

Exclusion Criteria: Patients with impaired liver function test, Pregnancy, chronic renal failure, Diabetes mellitus type I, myopathy and primary dyslipemia were excluded from the study.

A thorough examination of all the patients was done also a detailed history was taken.

In our study following base line parameters were measured.

- Lipid profile fasting: Total cholesterol (TC) high density lipoprotein cholesterol (HDL-C), Low density lipoprotein cholesterol (LDL-C) and triglyceride (TG).
- Blood sugar fasting and postprandial
- Waist circumference; abdominal obesity the baseline parameters values before and after completion of therapy were recorded.

Tablets Nigella Sativa: Tablets Kalonji 300mg (Nigella Sativa) manufactured by top treatment products Lahore, Pakistan was procured from local market at Peshawar. It is purely a natural product as per manufacturer information.

Study Groups: Based on clinical profile and the therapeutic intervention the 60 patients were divided in to two equal group of 30 each.

- The control group (n = 30): Patients with dyslipidemia, obesity and diabetes; standard regimen were given to all of them.
- The *Nigella Sativa* group; (n = 30); Patients with dyslipidemia, obesity and diabetes; in additional to standard regimen Tablets *Nigella Sativa* 600mg per orally (PO) twice daily for a duration of 08 weeks.

Standard Regimen: Tablets Pioglitazone 30 mg PO twice daily, Tab Metformin 500 mg PO twice daily and Tablets Rosuvastatin 10 mg PO at night.

Statistical Analysis: The difference in percentage improvements among the two groups in each parameter were calculated and compared. The SPSS software was used while applying un-paired t test.

Table 1: Clinical and biochemical parameters of controls (Group-1) and treated subjects (Group 2)

Parameter	Mean %age improvement	
	Group I Control (n=30)	Group II Treated (n=30)
Abdominal circumference	0.167±0.6408	0.533±0.9821
Total cholesterol	16.9254±6.2521	26.8719±6.7535
Triglyceride	14.1834±0.0095	12.0274±0.5479
High density lipoprotein	13.9683±3.1944	15.8942±2.1532
Low density lipoproteins	15.9475±5.7508	23.8901±7.2989
Fasting blood sugar	18.4642±6.777	29.2397±6.0942
Postprandial blood sugar	19.8747±6.2165	23.3884±8.5431

The results are tabulated in table-II which are very clear and are self explanatory.

Table 2: Comparison of Tablets Nigella Sativa treated subjects with standard subjects

Parameter	Group 1 (control subjects)	Group 2 (treated subjects)	P Value
Reduction in FBG(mg/dl)	18.4642±6.777	29.2397±6.0942	0.000
Reduction in PPBG(mg/dl)	19.8747±6.2165	23.3884±8.5431	*NS
Reduction in abdominal circumference(cm)	05.233±0.9821	0.5233±0.9821	NS
Reduction in total cholesterol(mg/dl)	16.9254±6.2521	26.8719±6.7535	0.000
Reduction in TG(mg/dl)	14.1834±0.0095	12.0274±0.5479	NS
Increase in HDL-C(mg/dl)	13.9683±3.1944	15.8942±2.1532	NS
Reduction in LDL-C (mg/dl)	15.9475±5.7508	23.8901±7.2989	0.013

*Not significant

DISCUSSION

Obesity and overweight are clearly linked with insulin resistance, fatty liver and the metabolic syndrome. It has been found that presence of abdominal obesity is even more highly associated with metabolic risk factors, than elevated body mass index. Therefore, to identify the body weight component of the metabolic syndrome/fatty liver the simple measurement of waist circumference is recommended. When the waist circumference is only marginally increased e, g 94-102 cm (37 to 39 inches) some male patients can develop multiple risk factors.. In our research work Nigella sativa group showed more reduction in abdominal circumference in contrast to patients in control group but statistically this reduction was not significant.

Blood glucose fasting and postprandial are other parameters for the diagnosis of fatty liver disease. The risk of microvascular complications in patients with type 2 diabetes have been seen to be significantly minimized by improved glycemic control [10]. The cut-off point for blood sugar fasting in our study was 110 mg %, which is in accordance to recommendation of ATP III criteria for the fatty liver disease diagnosis. In the tab Nigella sativa group reduction in the fasting blood glucose was higher significantly (p=0.000) as compared to control group. The percentage improvement in postprandial blood sugar in the Nigella Sativa group was also more as compared to control group, but was not significant statistically [11].

Tablets *Nigella sativa* has shown wonderful effects in regulating lipid profile. In the Nigella sativa group the reduction in total cholesterol was more and statistically significant (p = 0.000) in contrast to the control group. Previous studies have also revealed *Nigella sativa* oil and seeds to have cholesterol lowering effects. They suggested different modalities of Nigella Sativa effectiveness in controlling the lipid profile. For example inhibition of de novo cholesterol synthesis or stimulation of bile acid excretion [12- 14]. It is also a known fact that these both effects lead to decrease in serum cholesterol level. To identify the mechanism of action of *Nigella*

sativa seed/tablets further research is required. Another mode regarding *Nigella Sativa* that was postulated is that it enhances the LDL-C receptors production [15]. As Nigella sativa seeds contains various unsaturated fatty acids *i.e.* linoleic acid, linolenic acid, archidonic, eicosadienoic, almitoleic and oleic acid which may be causative factor for the improvement in lipid profile [16]. The normal HDL level varies slightly according to sex. In our study, the cut off point for HDL was 50mg % for both the sexes. A single cut off point was selected for the purpose of simplicity. In the Tablets *Nigella Sativa* group HDL level was increased more as compared to control group, but the difference noted in both the groups was found not significant statistically previous researchers with regard to the effect of *Nigella Sativa* seed / oil have reported varying results on HDL levels. An increase in HDL level was reported in some studies while others stated about no effect of *Nigella Sativa* on HDL level [17, 18].

In our study, in the Tablets *Nigella Sativa* group reduction in LDL level was more as compared to control group also this reduction was statistically significant (P = 0.013). Previous researchers have also reported similar results in various animal and human studies.

In our study in accordance to ATP ill guidelines the cut-off point for triglyceride (TG) was 150 mg%. In the *Nigella Sativa* group reduction in triglyceride level was less as compared to the control group which is in accordance with previous studies [17, 18].

CONCLUSION

Tablets *Nigella Sativa* has shown beneficial results in total cholesterol (TC), LDL cholesterol and fasting blood sugar (FBS). Tablets *Nigella Sativa* is a natural remedy which utilization in insulin resistant cases in fatty liver disease can provide tremendous results. Therefore more research is needed to find out varied mode of actions by which *Nigella Sativa* act on different clinical and biochemical parameters of insulin resistance syndrome in fatty liver disease.

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