

Full Length Research Paper

***Nigella sativa* provides protection against metabolic syndrome**

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The seeds of *Nigella sativa* have been used in folk medicine all over the world. The plant has been of interest due to its low degree of toxicity and beneficial pharmacological properties like antihypertensive, hypoglycemic, antifungal, anti-inflammatory, antihistaminic, antioxidant, along with significant anti-neoplastic activities. The present clinical study was undertaken to ascertain the adjuvant effect of *Nigella* seeds on various clinical and biochemical parameters of metabolic syndrome. After final diagnosis and considering inclusion and exclusion criteria, one hundred and fifty nine patients were enrolled in this study. Patients were divided into two groups. In Group I (standard group), patients were advised to take simvastatin 10 mg once a day, metformin 500 mg twice a day, Enalapril 10 mg once a day, Atenolol 50 mg once a day and clopidagrel 75 mg once a day for a period of six weeks. In Group II (*Nigella* seeds group), patients were advised the above standard medication plus *Nigella* seeds 250 mg twice daily for a period of six weeks. Blood sugar both fasting and postprandial, fasting lipid profile and different parameters of obesity were recorded before therapy and after completion of therapy. It was found that the addition of *Nigella* seeds provide beneficial effects in all the clinical and biochemical parameters for the adult's treatment panel-III of metabolic disorders especially in fasting blood sugar, low density lipoproteins and high density lipoproteins. No sign of toxicity of the plant appeared in the Group II. Improvement in all other parameters like blood pressure, circumference of waist and serum triglyceride was also observed. Thus, *Nigella* seeds were found to be effective as an adjuvant therapy in patients of dyslipidemia and hyperglycemia.

Key words: *Nigella sativa*, toxicity, hyperglycemia, adjuvant, antihistaminic, antioxidant, patients.

INTRODUCTION

The United States program on cholesterol education panel on adult treatment reported metabolic disorders as a very high risk factor for cardiovascular complications that need more attention of health care professionals. The etiology treatment, prophylaxis and prevention of metabolic disorders are now the focal point of medical research projects (Ford et al., 2002). Metabolic syndrome has very old historical back ground. Experts believe that

this term was first used in 1956, but their common usage started in 1977 to address various risk factors with diabetes that have been noted one hundred years ago. Actually, risk factors associated with diabetes were noted in 1920-1923 for the first time (Joslin, 1921; Kylin, 1923). Avogaro, Crepaldi and their team identified ten cases having moderate obesity with diabetes mellitus type II, elevated cholesterol level and elevated triglyceride. But these effects are controlled on changing their life style and diet (using low calories and low carbohydrate diet).

The issues about obesity and insulin resistance being causes of metabolic syndrome are the roaring issue of physician's debates. Some believe that obesity and

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insulin resistance are causes/consequences of metabolic disorders. Systemic inflammation markers including increased level of C-reactive protein, fibrinogen, interleukin-6 and tumor necrosis factors TNF α , etc, have been established. Many other investigators found various other causes, including elevated levels of uric acid, which may occur due to intake of fructose in diet (Nakagawa et al., 2006; Hallfrisch, 1990; Reiser et al., 1989). The various factors which may be considered responsible for the occurrence of metabolic syndrome include old age, overweight and abnormal obesity with central adiposity. It reflects that there are strong relations between increased adiposity and waist circumference. However, it is also worth mentioning that people with normal body weight have been found with insulin resistance syndrome (Fauci, 2008). Metabolic syndrome has a very strong relationship with disorders of lipodystrophy. Both forms of lipodystrophy may cause enhancement of insulin resistance and many other factors responsible for metabolic syndrome (Fauci, 2008).

According to Tibb Islami system of medicine, herbs are the main source of drugs from ancient ages. *Nigella* is a genus of about 14 species of annual flowering plants in the family Ranunculaceae, native to southern Europe, North Africa and Southwest Asia. The seeds and oil of *Nigella sativa*, commonly known as karayal (English: small fennel, black cumin; Sanskrit: kalonji, kalajira, kalajaji, mugrela, upakuncika), have great food and medicinal value. *N. sativa* is used in different spices in Indopak and Middle East. It is also used as a flavoring agent in pulses, vegetables and curries. In vegetables, salads, pad fruits and poultry recipes, they are used as pepper (Diwivedi, 2003). The seeds contain numerous esters of unsaturated fatty acids with terpene alcohols (7%), linoleic acid (50 to 60%), oleic acid (20%), eicodadienoic acid (3%) and dihomolinoleic acid (10%). Saturated fatty acids (palmitic and stearic acid) to about 30% or less are also present. In addition, it contains an essential oil, mostly thymoquinone, by which it acquires an aromatic flavor. Alkaloids like nigellimin, nigellimin-N-oxide, nigellidin and nigellicin are found in trace amounts. The seeds, on steam-distillation, produce a yellowish brown volatile oil with an unpleasant odor. The oil contains carvone, d -limonene, and a carbonyl compound, nigellone. In the essential oil, thymoquinone was identified as the main component (up to 50%) besides p-cymene (40%), pinene (up to 15%), dithymoquinone and thymohydroquinone (Sharma et al., 2009).

Moreover, it has been shown that *N. sativa* has bronchodilatory (El-Dakhkhny, 1965; Mahfouz and El-Dakhkhny, 1962), antibacterial (Topozada et al., 1965), hypotensive (Mahfouz et al., 1962), antioxidant (Burits and Bucar, 2000) and antidiabetic properties (Meral et al., 2001). The oil of *N. sativa* is a potent analgesic and anti-inflammatory drug in rats (Hajhashemi et al., 2004) and had *in vitro* and *in vivo* cytotoxic and immunosuppressive

properties (Islam et al., 2004). The petroleum ether extracts exerted lipid lowering and insulin-sensitizing actions in rats (Mai et al., 2004). Currently, it is already identified that the different ingredient of *Nigella* seeds that are causing wonderful effects in insulin sensitization are thymoquinone, unsaturated fatty acids, thymol and lipase.

MATERIALS AND METHODS

Seeds of *N. sativa* (Sheikh Pansar Store, Qissa Khwani Bazar, Peshawar, KPK), standard drugs used were the tablets enalapril 10 mg, atenolol 50 mg, simvastatin 10 mg, clopidagrel 75 mg and metformin 500 mg (obtained from MSD Karachi; ICI Karachi; Willsons Islamabad; Bosch Karachi and Aventis Karachi). Laboratory reagents used were total cholesterol reagent, triglyceride reagent, high density lipoprotein (HDL) cholesterol reagent, low density lipoprotein (LDL) cholesterol reagent and blood glucose reagent (obtained from Pioneer, Italy; Globe, Italy; Human, Germany; Human, Germany; and Globe, Italy).

Preparation of *Nigella* capsules

The seeds of *N. sativa* were encapsulated in hard gelatin capsule of size "0" at the hospital Pharmacy department of CMH, Peshawar. Each capsule contained 250 mg *N. sativa* seeds.

Criteria for inclusion and exclusion

The current study was carried out on recently diagnosed cases of metabolic disorder in the Department of Medicine, Combined Military Hospital, Peshawar, in the period of March 2006 to August 2006. A total of 159 patients were included in this study; the number of male participants was 113 and the female were 46. The ages of male participants ranged from 25 to 65 years and most of them were in the range of 40 to 60 years. All these patients were screened as per adult treatment panel –III specification and confirmed as having metabolic disorders. The patients were advised to visit the hospital for check up after their discharge from hospital, at regular interval of one week. The parameters considered for inclusion were:

1. Obesity of abdominal origin: Circumference of waist >102 cm in case of male participants and >88 cm in case of female participants.
2. Level of serum triglycerides > 150 mg%
3. Serum level of HDL <50 mg % (Female) and <40 mg% (male)
4. Limits of blood pressure: systolic > 130 mm Hg, Diastolic > 85 mm Hg
5. Fasting blood glucose level > 110 mg%.

To label a case as a confirmed patient of metabolic disorder a minimum 4 or > 4 criteria must be present. Meanwhile, the criteria for exclusion were:

1. Pregnancy
2. Diabetes mellitus type-I
3. Acute and chronic coronary disorders and accidents of cerebrovascular system.
4. Abnormal values of liver enzymes (liver function test)
5. Chronic renal disease patients
6. Strong family history of dyslipidemia.

A total of 159 patients were enrolled in the study and all of them

were instructed to bring changes in their diet habits and life style as desired.

Dietary schedule

National program on cholesterol education adult therapies panel –III recommends the following dietary schedule: Taking of cholesterol free and non fatty food, utilization of non fat cooking techniques example utilization of non sticky pans avoid barbeque, roast, dry fruits and seeds.

Exercise

Participants of all the groups included in this prospective study were advised to strictly adhere with the following exercise schedule: take 60 min walk early morning or late evening on empty stomach or at least 90 min walk after meal at least 6 days a week on regular basis.

Investigations required

The routine investigations carried out were blood glucose level fasting and random, test for renal function determination, lipid profile test, urine routing examination and test for liver function determination.

Study groups

These include: Group I (standard): Participating patient who were advised to strictly follow standard prescription as advised and Group II (*Nigella* seeds group): Participating patients in this group were advised to take *Nigella* seeds 250 mg capsule eligible for oral (PO) intake twice daily (BD) in addition to standard treatment already advised for a duration of six weeks.

Standard treatment

The following medicines were advised in routine for treatment of various complications: simvastatin 10 mg PO OD, metformin 500 mg PO BD, enalapril 10mg PO OD, atenolol 50mg PO OD and clopidagrel 75 mg PO OD.

RESULTS

Classification of cases as per adult treatment panel-III criteria

Approximately, the percentage of selected patients having the symptoms of metabolic syndrome are: obesity (94%), lower serum HDL level (88%), elevated serum triglyceride levels (85%), blood sugar fasting > 120 mg%, (64%) and elevated level of blood pressure (63%). This is shown in Table 1.

Different clinical and biochemical parameters

Body mass index (BMI)

According to the World Health Organization, the cut-off

point of body mass Index is > 31 kg/m² in case of metabolic disorder cases. There was an improvement in the overall body mass index in all cases of concerned groups. Comparatively, there was more improvement found in *Nigella* seeds group patients after completion of therapy. It was found that the difference in improvement was not in significant range. The mean ± standard deviation of body mass index values before and after treatment is given in Table 2.

Circumference of abdomen

According to adult treatment panel-III specifications, obesity of the abdomen is accurately determined by measurement of waist circumference. The cut-off point of waist circumference for male >120 cm and for female is >88 cm.

Metabolic risk factors are highly linked with abdominal obesity as compared to increased body mass index. In both groups, abdominal size was comparatively reduced. Relatively more reduction in abdominal girth was seen in *Nigella* seeds group. Mean ± standard deviation of abdominal circumference values before and after treatment is shown in Table 2.

Circumference of hip

In both groups, the circumference of hip was reduced. However, in *Nigella* seeds group there was more reduction as compared to standard group, although the reduction was not in a significant range. Mean ± standard deviation of hip circumference values before and after treatment are given in Table 2.

Body weight

There was a reduction in the body weights of both groups concerned. *Nigella* seeds group showed more improvements as compared to the standard, but the difference in the group was not significant. The mean ± standard deviation values of body weight reduction before and after treatment are mentioned in Table 2.

Waist hip ratio

According to the World Health Organization specifications of metabolic disorders for males, the cut-off point waist hip ratio is > 0.9 and for female it is > 0.85. There was improvement in waist hip ratio in both groups involved. *N. sativa* group, however, showed more improvement followed by the standard group patients, although the difference among the group was not significant. Mean ± standard deviation of waist hip ration values before and after treatment are given in Table 2.

Table 1. Classification of cases according to adult treatment panel-III criteria.

Parameter	Total number of patients (n = 159)	
	Number of patients	Percentage (%)
Abdominal obesity	152	93.7
Fasting blood glucose \geq 110 mg	102	63.7
Blood pressure \geq 130/85 mm Hg	100	62.5
Serum triglyceride \geq 150 mg %	135	84.3
Serum HDL < 40 mg/dl (male), < 50 mg/dl (female)	140	87.5

Table 2. Effect of standard and *Nigella sativa* group treatment on clinical and Biochemical parameters.

Parameter	Standard group		<i>Nigella sativa</i> group	
	Pre -treatment mean \pm SD	Post- treatment mean \pm SD	Pre- treatment mean \pm SD	Post -treatment mean \pm SD
Body mass index (Kg/meter ²)	30.5885 \pm 3.8928	30.2914 \pm 3.5813	30.7469 \pm 0.0926	30.1013 \pm 3.0666
Abdominal circumference(CMS)	101.4000 \pm 6.0754	100.8135 \pm 6.2014	101.3446 \pm 6.2017	100.1317 \pm 6.3337
Hip circumference (SMS)	108.8428 \pm 4.3742	107.2574 \pm 4.3324	109.1248 \pm 4.5879	107.0491 \pm 4.4918
Body weight (Kg)	73.5491 \pm 6.8997	72.9768 \pm 6.5589	73.8833 \pm 7.2811	72.6433 \pm 6.8611
Waist hip ratio	0.8996 \pm 0.8806	0.8818 \pm 0.5289	0.8987 \pm 0.2394	0.8795 \pm 0.3362
Systolic blood pressure (mm of Hg)	153.9667 \pm 20.7025	133.5987 \pm 8.8952	157.8959 \pm 22.9762	131.9648 \pm 9.6993
Diastolic blood pressure (mm of Hg)	89.7452 \pm 11.5329	85.8428 \pm 9.4259	89.0364 \pm 12.5166	84.959 \pm 10.8278
Fasting blood glucose (mg/dl)	125.3794 \pm 21.7153	106.7962 \pm 11.7525	136.6934 \pm 32.6883	97.4522 \pm 12.9222
Postprandial blood glucose (mg/dl)	161.6000 \pm 33.9664	144.0997 \pm 17.6862	175.9352 \pm 53.9382	139.4813 \pm 27.4716
Total cholesterol (mg/dl)	224.8838 \pm 38.4255	198.9394 \pm 39.2288	246.7810 \pm 80.4742	187.1617 \pm 56.7351
Triglyceride (mg/dl)	201.6355 \pm 32.8171	157.1233 \pm 16.9635	235.8696 \pm 65.9980	152.4935 \pm 38.9283
High density lipoprotein (mg/dl)	44.2574 \pm 5.5308	55.7938 \pm 7.9489	45.1238 \pm 4.3993	60.7314 \pm 6.5567
Low density lipoprotein (mg/dl)	140.3916 \pm 16.7548	129.3516 \pm 12.6931	164.7946 \pm 32.3265	118.9891 \pm 20.5218

Blood pressure

According to adult treatment panel-III specifications for metabolic disorders, the cut-off point in case of male and female both for blood pressure in > 130/85 mm Hg, but for convenience and keeping in mind the regional trends, our inclusion criteria was > 140/90 mm Hg. In both groups, both systolic and diastolic blood pressure was reduced, but more reduction in blood pressure was found in *Nigella* group as compared to the standard. The difference in systolic and diastolic blood pressure among these groups was, however, not significant. Mean \pm standard deviation of systolic and diastolic blood pressure value difference are mentioned in Table 2.

Blood sugar

According to adult treatment panel-III specifications, the cut-off limit for fasting blood sugar is > 110 mg%, but we had taken > 120 mg% because of convenience and regional trends. It has been observed that cut-off limits for many of these are flexible than normally desired for

identification of various risk factors that enhance chances for occurrence and aggravation of cardiovascular complication. Based on the results obtained, there was reduction in fasting blood sugar of both groups involved, but there was more significant reduction in fasting blood sugar (P value < .05) in *Nigella* seeds group. Random blood sugar was also reduced in all the two groups. Also, the reduction was more in *Nigella* seeds group as compared to standard group, but the results were not statistically significant. Mean \pm standard deviation of fasting and random blood sugar value difference before and after treatment are mentioned in Table 2. The mean \pm S.D. of pre and post treatment values of postprandial blood glucose are also listed in Table 2.

Total cholesterol (TC)

There was reduction in total cholesterol level in both groups involved. *Nigella* seed group showed more improvement as compared to standard group, but the results were not statistically significant. The mean \pm standard deviation of total cholesterol values before and

Table 3. Group statistics for independent sample t test.

Parameter	Group 1	Group II	T value	Sig. (2-tailed)
	Post treatment mean \pm SD	Post treatment mean \pm SD		
Body mass index	30.2914 \pm 3.5813	30.1013 \pm 3.0666	1.013	0.297
Abdominal circumference	100.8135 \pm 6.2014	100.1317 \pm 6.3337	0.562	0.563
Hip circumference	107.2574 \pm 4.3324	107.0491 \pm 4.4918	0.165	0.934
Body weight	72.9768 \pm 6.5589	72.6433 \pm 6.8611	0.088	0.829
Waist hip ratio	0.8818 \pm 0.5289	0.8795 \pm 0.3362	0.109	0.923
Systolic blood pressure	133.7189 \pm 8.8952	131.9648 \pm 9.6993	-1.319	0.320
Diastolic blood pressure	85.8428 \pm 9.4259	84.959 \pm 10.8278	0.571	0.586
Fasting blood glucose	106.7962 \pm 11.7525	97.4522 \pm 12.9222	-0.113	0.010
Postprandial blood glucose	144.0997 \pm 17.6862	139.4813 \pm 27.4716	-1.293	0.197
Total cholesterol	198.9394 \pm 39.2288	187.1617 \pm 56.7351	1.913	0.148
Triglyceride	157.1233 \pm 16.9635	152.4935 \pm 38.9283	1.815	0.146
High density lipoprotein	55.7938 \pm 7.9489	60.7314 \pm 6.5567	-4.240	0.003
Low density lipoprotein	129.3516 \pm 12.6931	118.9891 \pm 20.5218	-3.971	0.003

No. of patient in group-I =78; no. of patient in group-II =81. P value<.05 is taken as significant.

after treatment is shown in Table 2.

Triglyceride (TG)

According to adult treatment panel-III specification of triglyceride, TG >150 mg% is called dyslipidemia. There was reduction in triglyceride in both groups after taking the concerned therapies. Meanwhile, triglyceride level was comparatively more reduced in *Nigella* seed group as compared to standard group, although the results were not statistically significant. Mean \pm standard deviation of triglyceride level values before and after treatment are mentioned in Table 2.

High density lipoprotein (HDL)

According to adult treatment panel-III specification, the cut-off limit in case of male for high density lipoproteins is < 40 mg% and for female it is < 50 mg%. A single cut-off limit of < 50 mg% in case of both genders was taken by us due to feasibility and convenience. There was an increase in high density lipoproteins in all the three groups. *Nigella* seeds group showed better results and were also found statistically significant (P value < .05). The mean \pm standard deviations of high density lipoproteins values before and after treatment are hereby mentioned in Table 2.

Low density lipoprotein (LDL)

According to adult treatment panel-III criteria, low density lipoproteins >130 mg% is called dyslipidemia. There was

reduction in low density lipoproteins in all the three groups concerned. *Nigella* seeds group showed more significant results (P value < .05) as compared to the standard therapy group. Mean \pm standard deviation of low density lipoproteins values before and after treatment are shown in Table 2.

Statistical analysis

Mean \pm standard deviation of every concerned parameter before and after treatment were calculated with tabulation of values from both groups included in this prospective study. All the data received during different trials were statistically analysed while making utilization of t test unpaired among standard group-I and *Nigella* seeds group also called group-II. The 14th version of SPSS software utilized for statistical work was involved in this perspective study. Results are shown in Tables 3 and 4.

DISCUSSION

The present study elaborates the medicinal, pharmacological and traditional value of folk remedies, which may help the researchers to set their minds on approaching the utility, efficacy and potency of *N. sativa*. In our study obesity was measured through a total of five parameters. All the parameters were considered equally important, including body mass index, circumference of waist, circumference of hip, weight of body and hip waist ratio. National program on cholesterol education guidelines about diet and desired changes in life style were strictly followed as recommended for both the two groups; *Nigella* seeds and standard group. In addition to

Table 4. Group statistics for Independent sample t test.

Parameter	Group 1	Group II	T value	Sig. (2-tailed)
	Post treatment mean \pm SD	Post treatment mean \pm SD		
Body mass index	30.2914 \pm 3.5813	30.1217 \pm 3.0677	1.027	0.308
Abdominal circumference	100.8135 \pm 6.2014	100.3418 \pm 6.2448	0.568	0.563
Hip circumference	107.2574 \pm 4.3324	107.0380 \pm 4.3807	0.164	0.941
Body weight	72.9768 \pm 6.5589	72.9322 \pm 6.7500	0.091	0.829
Waist hip ratio	0.8818 \pm 0.5289	0.8794 \pm 0.2251	0.112	0.924
Systolic blood pressure	133.7189 \pm 8.8952	140.2037 \pm 9.5882	-1.039	0.318
Diastolic blood pressure	85.8428 \pm 9.4259	82.848 \pm 10.7167	0.581	0.588
Fasting blood glucose	106.7962 \pm 11.7525	103.3511 \pm 12.9111	1.121	0.311
Postprandial blood glucose	144.0997 \pm 17.6862	141.4813 \pm 29.5751	0.285	0.166
Total cholesterol	198.9394 \pm 39.2288	184.0506 \pm 56.6240	1.893	0.148
Triglyceride	157.1233 \pm 16.9635	151.2924 \pm 38.9172	1.814	0.143
High density lipoprotein	55.7938 \pm 7.9489	60.6203 \pm 6.4456	-4.280	0.002
Low density lipoprotein	129.3516 \pm 12.6931	119.8780 \pm 20.4107	-3.968	0.004

Number of patients in Group I = 78; Number of patients in Group II = 81. P value < .05 is taken as significant.

routine prescription, *Nigella* seeds capsule (250 mg PO BD) was added in the therapy to all participants of *Nigella* seeds group. All five parameter showed improvement as a result of therapy.

Diabetes mellitus type-2 and cardiovascular diseases are strongly linked with obesity (Abdel-Barry et al., 2000; Aqel, 1992). Insulin resistance does not develop in majority of obese population, although it is a very important component of metabolic disorders. Persons classified as lean by body weight or BMI may also develop insulin resistance because they may be considered metabolically obese due to central fat deposition. Visceral adipose tissue has been considered as the main tissues site where fats are deposited, which have direct link with the metabolic consequences of obesity (Zaoui and Cherrah, 2000). It is considered that insulin resistance is the first physical event caused by visceral or central adiposity of fats. These consequences are due to increases in influx of free fatty acids in systemic and portal circulations. No such clinical study on anti-obesity activity of *Nigella* seeds had been done in Pakistan so far. Moreover, the exact mode of action of *Nigella sativa* regarding its anti-obesity action is not fully known.

A slight anorexic effect was shown by petroleum ether extract of *Nigella* seeds during an animal study on rats (Knowler et al., 2002). The different ingredients of *Nigella* seeds, especially lipase, are considered as causative factors for this type of action. Metabolic syndrome is caused by apple shaped or android type of obesity. The central obesity can be measured by waist-hip ratio measurement, ratio in desired range, men < 0.9 and for women < 0.8 and waist measurement; more than 102 cm in case of male and more than 88 cm in case of female participants are considered at high risk for the occurrence

and development of metabolic disorders. According to guidelines of adult treatment penal-III, the circumference of waist has very vital role in diagnosis of metabolic disorders. However, metabolic risk factors are more strongly linked with the presence of abdominal obesity than an increase body mass index. Therefore, this is the reason that simply waist circumference measurement is considered sufficient to identify the body weight component of the metabolic disorders.

In this study, the tablets enalapril 10 mg PO OD plus Atenolol 50 mg PO OD were advised to treat hypertension in the standard group, and in *Nigella* seeds group, capsule of *Nigella* seeds (250 mg PO BD) was added as an adjunct therapy. Marked reduction in hypertension was observed in *Nigella* seeds group with relation to results in standard prescription group for hypertension. The results are quite similar to results produced by other similar studies previously carried out (Bustos and Hernandez, 1998). In this study, metformin (500 mg PO BD) was advised in both groups to control and treat elevated blood glucose levels. In *Nigella* seeds groups, capsules of *Nigella* seeds (250 mg PO BD) were added as additional to standard therapy. Thus, the addition of *Nigella* seeds provided beneficial effects in all the clinical and biochemical parameters for the adult's treatment of panel-III of metabolic disorders.

Conclusion

Addition of *Nigella* seeds provided beneficial effects among all five parameters for the adult's treatment panel-III of metabolic disorders, especially in fasting blood sugar, low density lipoproteins and high density lipoproteins. Improvements were also seen in all other

parameters like blood pressure, circumference of waist and serum triglyceride in all the groups, including *Nigella* seeds and standard regimen group. In *Nigella* seeds group, improvement in fasting blood sugar, low density lipoprotein and high density lipoproteins were found statistically significant (P value < 0.05). Insulin-sensitizing action of *Nigella* seeds is the most important and beneficial action in metabolic disorders patients.

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