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Nigella sativa-A Herbal Remedial Solution for Hyperlipidemia: An Interventional Study

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ABSTRACT

Background: Hyperlipidemia, often hereditary, increases the risk of vascular diseases, leading to stroke and heart disease. It is a major cause of cardiovascular issues, with a prevalence of 38.7%. This study aimed to assess the impact of *Nigella sativa* Seed Powder Capsules on the lipid profiles of hyperlipidemic patients.

Methods: Conducted at various clinics in Faridabad, 100 adults were divided into Experimental and Non-experimental groups. Both received diet counseling, physical activity guidance and a 30-day run-in period. The Experimental group took 2 g of *Nigella sativa* daily, while the control group received a placebo (2 g wheat germ). After 3 months, lipid profiles were analyzed using SPSS.

Result: Results showed a significant reduction in cholesterol for the experimental group (193.20±15.77 mg/dl) compared to the control (211.42±11.23 mg/dl). The study concluded that Nigella Sativa positively lowered cholesterol, LDL and triglycerides while increasing HDL in hyperlipidemic adults.

Key words: Black Cumin, Cholesterol, Herbal remedy, Hyperlipidemia, Kalonji, *Nigella sativa*, Onion seeds.

INTRODUCTION

The prevalence of coronary heart disease and hyperlipidemia is rising, largely due to high cholesterol levels, which contribute to atherosclerosis and increase the risk of heart disease. Poor lifestyle and eating habits are major contributors. In India, hyperlipidemia affects 25-30% of the urban population and 15-20% of the rural population, with high LDL and triglycerides and low HDL being common trends. Hyperlipidemia, defined by elevated blood lipid levels, increases the risk of stroke and heart disease.

Nigella sativa, also known as Kalonji, is a widely used spice with various health benefits, including lowering cholesterol, managing diabetes, improving skin and treating asthma. Rich in thymoquinone, an enzyme that dissolves fats and inhibits lipid oxidation, it has potential as a natural remedy for hyperlipidemia, offering fewer side effects than long-term statin use. Thymoquinone is a molecule which is monoterpene. Its chemical name is 2-methyl-5-isoprophyl-1, 4-benzoquinone. It has a lot of pharmacological properties. It is also found that thymoquinone has strong lipophilicity property which makes it able to dissolve fats, oils and lipids faster. In liposomes, thymoquinine inhibits the non enzymatic lipid perroxidation. It has been found that it works as a free radical scavenger. It is also strong inhibitor of the production of eicosanoid, which is called thromboxane B2 and leucotrienes B4, it inhibits both cyclooxygenase and lipoxygenase. These are the reasons why it is assumed that the intake of kalonji powder shall reduce the lipid levels positively.

A systematic review and meta-analysis of randomized placebo-controlled trials was conducted by Sahebkar *et al.,* (2016), on effect of Nigella Sativa on Plasma Lipid Concentrations in Humans. Around 17 registered clinical trial were studied up till 2015. The data was taken from Pubmed, Google Scholar, Scopus, web of Science *etc.* The studies concluded that the consumption of *Nigella sativa* had lowered the serum lipid levels. There was a positive impact of the consumption of Nigella Sativa on serum Lipid levels thus lowering LDL and increasing HDL Levels.

Another systematic review and meta-analysis was conducted by Khotbehsara *et al.* (2017) to study the effect of *Nigella sativa* on Glucose Homeostasis and Serum Lipids among Type 2 Diabetes population. Various publications on clinical trials of Nigella Sativa were studied published till Feb 2017. The papers were searched on Medline, Scopus, Pubmed and other registered clinical trials. The data revealed that use of Nigella Sativa improved fasting blood sugar and reduction in hyperlipidemia significantly. Both serum lipids and Glucose homeostatis had a positive effect by consumption of Nigella Sativa, hence it can be used as a alternative medicine.

Study objective

This study aimed to evaluate the effects of *Nigella sativa* seed powder capsules on the lipid profiles of hyperlipidemic patients in Faridabad. Approved by the University's Ethics

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Committee and registered under the Clinical Trials Registry of India (CTRI/2020/10/028186), the study was conducted across different pathology centers in the city, targeting adults aged 25-45 with borderline hyperlipidemia not on medication.

MATERIALS AND METHODS

A sample of 100 participants was randomly divided into experimental and control groups. Both groups received dietary counseling and followed a restricted diet. The experimental group took 2 g of *Nigella sativa* daily, while the control group received wheat germ placebo capsules. After 60 days, lipid profiles were reassessed using the Friedewald Equation Test.

Capsule formulation

The experimental group received 500mg capsules of Nigella Sativa powder, while the control group received 500 mg wheat germ placebo capsules. Both groups took 4 capsules daily, 2 before lunch and 2 before dinner, for 60 days. The capsules for both experimental and controlled group were manufactured by Atrey Pharmaceuticals Private Limited.

Run-in period

Participants followed a 30-day diet plan tailored to hyperlipidemia and received counseling on dietary modifications. Caregivers were also involved to ensure adherence to the diet and capsules.

Inclusion and exclusion criteria

Participants were 25-45 years old, newly diagnosed with hyperlipidemia (total cholesterol 201-220 mg/dl) and not on statins. Smokers, heavy drinkers, diabetics and those with cardiovascular diseases were excluded.

Statistical analysis

Data was analyzed using SPSS, with t-tests, paired t-tests and chi-square tests applied to assess the results. Lipid profiles, including cholesterol, LDL, HDL and triglycerides, were compared before and after intervention.

RESULTS AND DISCUSSION

The study was conducted with the objective to assess the effect of Nigella Sativa Seed Powder Capsules on the lipid profile of hyperlipidemic patients. None of the participants complained of any discomfort while taking the capsules. The lipid profiles were checked after a period of 90 days. The data was analyzed on SPSS version 21.

Baseilne analysis

Table 1 showed the comparison of subjects based on demographic profile between the Experimental and the Non Experimental Group at baseline level. In context with occupation, religion, education, marital status and family income there was no statistical difference in experimental and non experimental group (P= 0.77, P=0.60, P=0.91, P=0.71 and P=0.90 respectively). This reveals that the demographic profile of both the groups was similar.

Table 2 and Fig 1 depicted the comparison of subjects based on the age groups between the experimental and the non experimental groups at baseline level. The data revealed that there is no significant difference in the age group of both the experimental and non experimental group (P=0.79). This reveals that the age group in both the groups was similar.

Table 1: Comparison of subjects based on demographic profile between experimental and non experimental group (baseline).

Demographic profile		Experimental group N (%)	Non experimental group N (%)	Chi-square	P value
Occupation	Home maker	7(14%)	4(8%)	1.09	0.77
	Self employed	15(30%)	18(36%)		
	Service	24(48%)	24(48%)		
	Student	4(8%)	4(8%)		
Religion	Hindu	43(86%)	40(80%)	1.87	0.60
	Christian	2(4%)	1(2%)		
	Muslim	3(6%)	4(8%)		
	Sikh	2(4%)	5(10%)		
Education	Undergraduate	4(8%)	6(12%)	0.52	0.91
	Graduate	27(54%)	27(54%)		
	Postgraduate	17(34%)	15(30%)		
	Other	2(4%)	2(4%)		
Marital Status	Married	28(56%)	29(58%)	1.37	0.71
	Unmarried	20(40%)	19(38%)		
	Other	2(4%)	2(4%)		
Family Income per annum	< 5 lacs	19(38%)	16(32%)	0.57	0.90
	5 lacs to 10 lacs	18(36%)	19(38%)		
	10 lacs to 15 lacs	7(14%)	7(14%)		
	>15 lacs	6(12%)	8(16%)		

Table 3 showed the comparison of subjects based on the lipid profile between experimental and non experimental groups at baseline level. It was found that there was no significant difference in the mean value of total cholesterol levels, HDL, LDL and Triglycerides of both the groups at baseline level (P=0.06, P=0.83, P=0.39 and P=0.45 respectively). This depicts that the lipid profile was similar in both the groups at baseline level.

As the baseline data was statistically non significant, Dietary pattern and physical activity were modified for a period of one month and later Intervention was done and the following results were found.

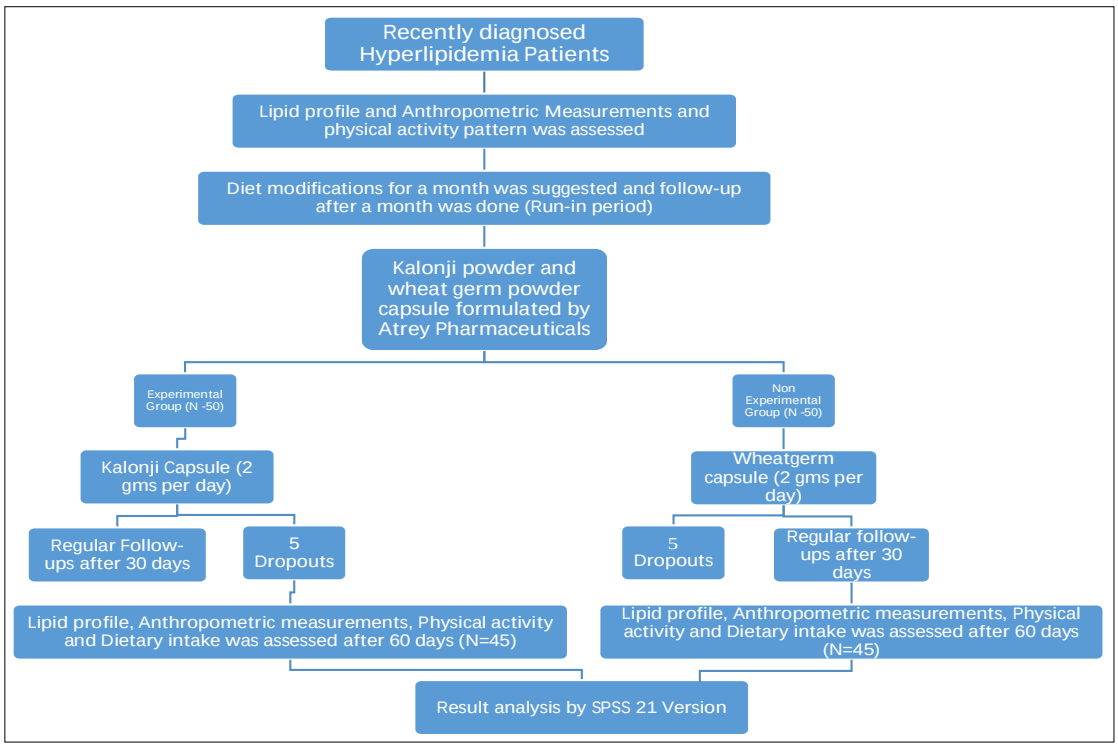

Fig 1: Flow chart of the process.

Table 2: Comparison of subject based on age groups between experimental and non experimental groups (baseline).

Age group	Experimental group (N)	Non experimental group (N)	Chi-square	P value
25-30 years	15 (30%)	18 (36%)	1.67	0.79
30-35 years	16 (32%)	13 (26%)		
35-40 years	13 (26%)	13 (26%)		
40-45 years	6 (12%)	6 (12%)		

Table 3: Comparison of subjects based on lipid profile between experimental and non experimental groups (baseline).

Lipid profilemg/dl	Experimental group mean±SD	Non experimental group mean±SD	T-test	P value
Total cholesterol (mg/dl)	217.70±12.33	221.92±10.51	1.842	0.06
HDL (mg/dl)	33.72±4.66	33.92±4.91	0.205	0.83
LDL (mg/dl)	108.86±10.50	111.22±16.57	0.852	0.39
Triglycerides (mg/dl)	144.6±13.10	146.40±9.71	0.755	0.45

Table 4: Comparison of subjects based on dietary intake between experimental and non experimental groups (run in).

Dietary intake	Experimental group mean±SD	Non experimental group mean±SD	T test	P value
Total calorie (kcal)	1276.67±290.71	1383.43±433.48	1.446	0.151
Carbohydrates (g)	175.54±39.97	190.22±59.60	1.456	0.158
Protein (g)	53.35±6.70	54.09±8.64	1.416	0.128
Fat (g)	21.28±4.85	23.06±7.22	1.446	0.151

Table 4 depicted the comparison of subjects based on the dietary intake between experimental and non experimental groups in the run in period.

A run in period was given to the subjects for a month where according to the Ideal Body Weight, appropriate diet was given to the subjects for a month. It was found that there was no significant difference in the mean intake of Total calorie, carbohydrate, protein and fat advised to the experimental and non experimental group (P= 0.151, P= 0 .151, P = 0.018 and P= 0.151 respectively). This reveals that the dietary intake of both the groups was same before intervention.

Table 5 and showed the comparison of subjects based on GPAQ Activity level in both experimental and non experimental group during run in period. It was found that there was no significant difference in the activity levels of both the groups at the baseline level (P=0.64).

Post intervention analysis

Table 6 showed the comparison of subjects based on lipid profile between experimental and non experimental groups (post intervention). It was found that the difference in Total Cholesterol, HDL, LDL and Triglycerides between experimental group and non experimental group post intervention was statistically significant (P<0.05, P<0.05, P<0.05, P<0.05 respectively). There was more reduction in the total cholesterol, LDL and Triglycerides of experimental group as compared to the non experimental group while there was more increase in the HDL level of experimental group as compared to the HDL levels of non experimental group.

A similar result was revealed in a systematic review conducted by Sahebkar *et al.* (2016) where there was a negative correlation of Nigella Sativa on serum Lipid levels thus lowering LDL and increasing HDL Levels.

Table 5: Comparison of subjects based on gpaq between experimental and non experimental groups (run in period).

Activity level	Experimental group N	Non experimental group N	Chi-square	P value
Sedentary	3 (6%)	2 (4%)	0.211	0.64
Moderate	47 (94%)	48 (96%)		

Table 6: Comparison of subjects based on lipid profile between experimental and non experimental groups (post intervention).

Lipid profile (mg/dl)	Experimental group mean±SD	Non experimental group mean±SD	T-test	P value
Total cholesterol (mg/dl)	193.20±15.77	211.42±11.23	6.31	0.00*
HDL (mg/dl)	43.13±4.62	37.42±4.73	-5.79	0.00*
LDL (mg/dl)	93.80±9.17	103.49±15.08	3.68	0.00*
Triglycerides (mg/dl)	122.89±11.37	134.98±10.58	5.22	0.00*

* P value < 0.05.

Table 7: Comparison of subjects based on lipid profile between pre and post intervention (experimental groups).

Lipid profile (mg/dl)	Pre intervention mean±SD	Post intervention mean±SD	Difference mean±SD	Paired t-test	P value
Total cholesterol (mg/dl)	218.96±11.01	193.20±15.77	25.76±14.65	11.79	0.00*
HDL (mg/dl)	33.60±4.24	43.13±4.62	-9.53±2.63	-24.28	0.00*
LDL (mg/dl)	109.27±10.71	93.80±9.17	15.47±4.42	23.47	0.00*
Triglycerides (mg/dl)	145.91±11.62	122.89±11.37	23.02±7.29	21.18	0.00*

* P value < 0.05.

Table 8: Comparison of subjects based on gender and lipid profile between experimental and non experimental groups (post intervention).

Gender	Lipid profile (mg/dl)	Experimental group mean±SD	Non experimental group mean±SD	T-test	P value
Male	Total cholesterol (mg/dl)	195.93±9.99	210.27±10.36	4.32	0.00*
	HDL (mg/dl)	43.29±5.30	36.70±5.05	-3.96	0.00*
	LDL (mg/dl)	93.43±8.31	103.03±12.74	2.56	0.01*
	Triglycerides(mg/dl)	124.29±8.31	136.03±11.10	3.36	0.00*
Female	Total cholesterol(mg/dl)	191.97±17.79	213.73±12.85	4.22	0.00*
	HDL (mg/dl)	43.06±4.37	38.87±3.76	-3.18	0.00*
	LDL (mg/dl)	93.97±9.66	104.40±19.41	2.44	0.01*
	Triglycerides (mg/dl)	122.26±12.02	132.87±9.47	2.99	0.00*

*P value < 0.05.

Table 7 depicted the comparison of subjects based on lipid profile between pre and post intervention in experimental group. The data stated there was a significant difference in total cholesterol, HDL, LDL and Triglycerides pre and post intervention in experimental group ($P<0.05$). The total cholesterol, LDL and Triglycerides reduced after the intervention, while HDL levels increased after intervention of *Nigella sativa.*

Table 8 depicted the comparison of subjects based on gender and lipid profile between experimental and non experimental group post intervention.

It was revealed that there was a significant difference in the total cholesterol, HDL, LDL and triglycerides of male subjects in between the experimental and non experimental groups ($P<0.05$). The reduction of Total cholesterol, LDL and triglycerides amongst the male subjects was more in the experimental group as compared to the non experimental group while the increase in HDL levels of male subjects was more in the experimental group as compared to the non experimental group.

It was revealed that there was a significant difference in the Total Cholesterol, HDL, LDL and Triglycerides of female subjects in between the experimental and non experimental groups ($P<0.05$). The reduction of Total cholesterol, LDL and Triglycerides amongst the female subjects was more in the experimental group as compared to the non experimental group while the increase in HDL levels of female subjects was more in the experimental group as compared to the non experimental group.

Similar results were observed in a study conducted by Sabzghabaee *et al*. (2012) where it showed the similar results and depicted that Nigella Sativa had beneficial effect on lowering hyperlipidemia. In this study the total Cholesterol and LDL levels lowered by the consumption of *Nigella sativa* however the Triglyceride levels increased. The reason for the positive effect of Nigella Sativa on lowering the Lipid profile is assumed to be the high antioxidant level of the spice which also inhibits the absorption of cholesterol in the small intestine. This study revealed that Nigella Sativa can be used as a remedy for hyperlipidemia however more study on a larger sample size was needed.

This study was conducted with an objective to assess the effects of Nigella Sativa Seed Powder Capsules on the lipid profile of hyperlipidemic patients. The present study revealed that there was higher reduction in the lipid parameters–Total Cholesterol, LDL, Triglycerides and also increase in HDL parameters of the subjects of experimental group as compared to non experimental group (post intervention) and the differences were statistically significant. In another study conducted by Kirn-e-Muneera *et al.* (2015) revealed similar results, by stating that Nigella sativa showed 48.4% decrease in cholesterol levels in hyperlipidemic subjects. Their LDL reduced by 70% and triglycerides by 25.3%. The HDL showed 53.5% increase. Another study reporting the similar results by Tasawar *et al.* (2011), found that Kalonji seeds have a positive effect in lowering the serum lipid levels of cardiac adults.

The current study revealed that there was reduction in the lipid profiles of the subjects of the experimental group post intervention. The differences were highly significant. In a study conducted by Sabzghabaee *et al.* (2012) showed the similar results and depicted that *Nigella sativa* had beneficial effect on lowering hyperlipidemia. In this study the total cholesterol and LDL levels lowered by the consumption of *Nigella sativa* however the Triglyceride levels increased. The reason for the positive effect of *Nigella sativa* on lowering the Lipid profile is assumed to be the high antioxidant level of the spice which also inhibits the absorption of cholesterol in the small intestine. This study revealed that Nigella Sativa can be used as a remedy for hyperlipidemia however more study on a larger sample size was needed.

It was also observed during the intervention that none of the subjects complained of any discomfort while consuming the capsules in both the groups. This depicted that consumption of 2 gms of *Nigella sativa* for a period of two months did not have any toxic effect. In a study conducted by Ali *et al*. (2003) showed similar results, stated that *Nigella sativa* seed and its oil have positive effects as an antioxidant, analgesic, anti-inflammatory, anti mutagenic, anticarcenogenic, antihepato, anti nephro toxic, respiratory and immunological, antidiabetic, antiulcer, antimicrobial and has positive effects on cardiovascular and blood health. Doses even up to 50 mg /kg or10 ml oil/ kg also had no negative effect on rats. Although acute administration of a high dose like 2 gm/kg resulted in respiratory problem and hypo activity. Another study conducted by Zaoui *et al.* (2002), supporting the present results by providing conclusion that after 12 weeks of doses up to 2 ml/kg of Kalonji oil, there was no toxic effect on the rats however their weight reduced, lipid levels and serum glucose levels reduced while there was no increase in the serum hepatic enzyme. There was also an increase in the Hemoglobin level while a decrease in the platelet count.

CONCLUSION

The present study was conducted with the objective to assess the effect of Nigella Sativa on Lipid Profile of Indian population and it was concluded that there was a positive effect of 2 g/day consumption of Nigella Sativa for 60 days on lowering the cholesterol, LDL and triglyceride of hyperlipidemic adult Indian population and also increases the HDL of the participants.

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Disclaimers

The views and conclusions expressed in this article are solely those of the authors and do not necessarily represent the views of their affiliated institutions. The authors are responsible for the accuracy and completeness of the

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Informed consent

All the participants were informd about the study and approval from CTRI was taken: CTRI/2020/10/028186

Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this article. No funding or sponsorship influenced the design of the study, data collection, analysis, decision to publish, or preparation of the manuscript.

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