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Original Research Article

Effect of a Combined Nutraceutical Supplement on the Lipid Profile of Hypercholesterolemic Men

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ABSTRACT

BACKGROUND: The prevalence of hypercholesterolemia is on the rise in India. Hypercholesterolemia is implicated in the development of coronary heart disease. Current projections suggest that one fifth of the deaths in India are due to coronary heart disease. Evidence point to nutraceutical supplements with a hypocholesterolemic effect as capable of reducing the risk of coronary heart diseases.
AIM & OBJECTIVE: To examine the hypocholesterolemic effect of nutraceuticals an investigation was undertaken to determine the effectiveness of a combined nutraceutical supplement on hypercholesterolemic men.
MATERIALS AND METHODS: A pre-test, post-test experimental research design was used in this study. First screening for hypercholesterolemia was done on 90 males between 25-60 years. After screening, a purposive sample of 40 males having borderline hypercholesterolemia above 200mg/dl and below 240mg/dl, with a cardiovascular risk ratio above 4.5 were chosen for the study, The participants were included in the study after obtaining their consent to participate in the study. Out of the subjects chosen 20 were randomly assigned to the experimental group and administered the combined nutraceutical supplement which contained curcumin, lycopene, lutein and proanthocyanidin twice a day for a period of 60 days. The remaining 20 subjects who were in the control group did not receive any supplement. Fasting blood samples were collected from all the subjects both on the1st and 60th day for estimation of lipid profile. Paired t-test was used to compare the changes in the lipid profile between and within groups, p-value<0.05 was considered as significant.
RESULT: At baseline, both the experimental and control groups were similar with respect to anthropometric and lipid parameters. The experimental group showed significant reductions in levels of VLDL (mg/dl), triglyceride (mg/dl) and CHO/HDL with a concomitant increase in HDL (mg/dl) as compared to the control group. Total cholesterol (mg/dl), LDL (mg/dl), CHO/HDL levels decreased significantly in the experimental group after 60 days of supplementation with the combined nutraceutical supplement as compared to the initial levels.
CONCLUSION: The results of the study endorse the lipid lowering properties of the combined nutraceutical supplement.

Keywords: Nutraceutical, hypercholesterolemia, Lipid profile.

INTRODUCTION

Hypercholesterolemia is defined as excessively high plasma cholesterol levels. Hypercholesterolemia has emerged as a strong risk factor for Cardio vascular diseases (Stapleton, Goodwill, James, Brock

& Frisbee, 2010). The prevalence of hypercholesterolemia is very high in India. One fifth of the deaths in India are from coronary heart disease linked to hypercholesterolemia. It is therefore imperative that cholesterol levels are kept within normal limits and hypercholesterolemia is treated. Two major therapies have evolved to deal with elevated cholesterol levels namely drugs and diet (Luz, Nishiyama & Chagas, 2011). Lipid-lowering drugs help to reduce cholesterol level but are often associated with several undesirable side effects such as myositis, rhabdomyolysis, hepatic dysfunction and kidney failure (Catapano, 2012). Alternatively, food supplements with hypocholesterolemic effect are found to have no such side effects. Supplements are administered as whole foods such as red yeast rice (Bogsrud et.al., 2010), fish oil (Nestel, 2007; Eslick, Howe, Smith, Priest & Benosussan, 2009) oats (Kelly, Summerbell, Brynes, Whittaker & Frost, 2007), garlic(Ackermann et al., 2001; Piscitelli, Burstein, Welden, Gallicano & Falloon, 2001) or as an extract of bioactive components such as curcumin, lycopene, lutein, proanthocyanidin and omega 3 fatty acids. Epidemiological studies have shown that nutraceutical supplements such as proanthocyanidin (Park, Park, Kim & Kang, 2003), curcumin (Yuan et al., 2008), lycopene (Palozza, Catalano, Simone Mele & Cittadini, 2012) and lutein (Kim & Kim 2010) demonstrate consistent protective effects against the risk of hypercholes-terolemia and several other chronic diseases (Nasri, Baradaran, Shizard & Kopoei, 2014). On the basis of these claims a study was undertaken to evaluate the effect of combined nutraceutical supplement composed of proanthocyanidin, curcumin, lycopene and lutein on the lipid profile of hypercholesterolemic men.

MATERIALS & METHODS

Study Design: A pre-test post-test experimental design was adopted for the study.

Selection Of The Subjects: All male employees of a Multinational Wellness Company in Aminjikarai, Chennai, who volunteered to participate in the study, were first screened for hypercholesterolemia. 90 males aged 25-60 years attended the camp on a fixed date at 8.00 am in the fasting state. Blood was drawn from each individual by a trained lab technician for the purpose of estimating lipid profile which included estimations of triglyceride (TG-mg/dl), high density lipoprotein(HDL-mg/dl), low density lipoprotein(LDL-mg/dl), very low density lipoprotein (VLDL-mg/dl), total cholesterol (TC-mg/dl) and cardiovascular (CV) risk ratio. The blood analysis report of the screening phase indicated 55 males to be hypercholesterolemics. Out of this 40 hypercholesterolemic men were chosen for the study based on the following inclusion criteria.

Inclusion criteria:

1. Borderline hypercholesterolemics with a total cholesterol level above 200mg/dl and below 240mg/dl.
2. Borderline hypercholesterolemics with a cardiovascular risk ratio above 4.5.
3. Willingness to participate in the study.

The remaining subjects were rejected either for not satisfying the inclusion criteria or for meeting the condition in the exclusion criteria such as:

1. Using medication for hypercholesterolemia.
2. Under a specific diet regimen for hypercholesterolemia.
3. Having complications like thyroid disorders, neurological disease, cancer etc.

Sampling Technique

Purposive sampling technique was used for the selection of subjects in the study. Borderline hypercholesterolemic subjects who satisfied the inclusion criteria were selected. Based on the inclusion criteria 40 subjects were selected, 20 subjects were assigned to the experimental group and 20 to the control group

respectively. Subjects in the experimental group received the combined nutraceutical supplement for a period of 60 days whereas those in the control group did not receive any supplement.

Particulars Of Supplement

The supplement referred as Combined Nutraceutical Supplement is manufactured by Oriens Global Marketing Pvt. Ltd., The supplement was given in the form of capsules which contained a combination of curcumin, lycopene, lutein and proanthocyanidin.

The composition of the Combined Nutraceutical Supplement is given in table 1

Table 1: Composition of Combined Nutraceutical Supplement

Ingredients	A Amount (one capsule)
Curcumin	100 mg
Lutein	5 mg
Lycopene	10 mg
Proanthocyanidin	100 mg

Certification Of The Supplement

The combined nutraceutical supplement is an approved product under FSSAI certification.

Data Analysis

Descriptive analysis was used to analyze the data from demographic profile and student's t-test was used for comparing the mean anthropometric measurement and lipid profile values.

Ethical Consideration

The study was approved by the Ethical Committee instituted by the Department of Home Science, Queen Mary's College, Chennai. Written consent was obtained from the subjects prior to their participation in the study.

RESULTS

Details regarding health profile of subjects are presented in table 2.

Table 2: Descriptive Analysis Of Health Profile Of Hypercholesterolemic Men

Particulars	No =40	Percent (%)
Age		
25-35 years	11	27.5
35-45 years	12	30
45-55 years	15	37.5
55-60 years	2	5
Family history of hypercholesterolemia		
Yes	17	42.5
No	23	57.5
Duration of hypercholesterolemia		
<2 years	31	77.5
2-5 years	5	12.5
5-10 years	4	10
Life style		
Sedentary	17	42.5
Moderate	18	45
Heavy	5	12.5
Type of diet		
Vegetarian	3	7.5
Non-vegetarian	37	92.5
Lacto vegetarian	0	0
Ova vegetarian	0	0
Lacto ova vegetarian	0	0
Smoking habit		
Yes	9	22.5
No	31	77.5
Drinking habit		
Yes	15	37.5
No	25	62.5

The data from demographic profile showed that most of the subjects (37.5%) were within the age range of 45-55 years, more than one third (42.5%) of the subjects had a family history of hypercholesterolemia. Three fourths of the subjects (77.5) were recently detected hypercholesterolemics i.e., within a period 2 years. Nearly half (45%) the subjects led a moderate life style in accordance to the FAO classification of lifestyle (1985). With regard to food habits followed, it was clear that almost all the subjects (92.5%) were non vegetarian. In addition, a sizeable number were found to be in the habit of smoking (22.5%) and drinking (37.5%) respectively.

Comparison of anthropometric measurements:

The measurements of the experimental and control group for anthropometric parameters such as weight(kg), BMI(kg/m^2), waist circumference (inches), hip circumference (inches) and waist to hip ratio as assessed in the post intervention period is presented in table 3.

Table 3: Comparison Of Anthropometric Measurements Between experimental And Control Group During Post Intervention Period

Anthropometric measurements	Experimental group n=20			Control group n=20			P value
	Mean	S.D	S.E	Mean	S.D	S.E	
Weight (kg)	68.2	7.4	1.7	70.3	10.1	2.248	0.468
BMI (kg/m^2)	25.1	2.9	0.7	24.5	6.3	1.408	0.725
Waist circumference (inches)	36	2.1	0.5	37	2.6	0.591	0.212
Hip circumference (inches)	39.4	3.2	0.7	40.5	3	0.667	0.268
Waist to hip ratio	1.7	9.6	2.1	2.3	3.7	0.00	0.000*

***Significant at five percent level**

From table 3 it is evident that the waist to hip ratio of the experimental group is significantly lower ($p<0.05$) than the control group. A closer look at table 3 reveals a lower mean body weight (kg), waist circumference (inches), hip circumference (inches) in the experimental group as compared to the control group although the differences are not found to be significant.

Comparison of Lipid Profile Values

Comparison of lipid profile values between experimental and control group:

HDL (mg/dl) levels of the experimental group after supplementation with the combined nutraceutical supplement was significantly higher ($p \leq 0.05$) than the control group which did not receive any such supplement (Table 4). Further significantly lower values ($p \leq 0.05$) for CHO/HDL ratio, VLDL and TG(mg/dl) levels were recorded in the experimental group after 60 days of supplementation with combined nutraceutical supplement as compared to the control group which did not receive any supplement. However, no significant difference was found between the experimental and control group during the post intervention period for LDL and TC (mg/dl) levels.

Table 4: Comparison Of Lipid Profile Values Between Experimental And Control Group & Between Pre And Post Intervention Period Of The Experimental Group

Lipid profile parameters	Between experimental and control group in the post intervention period			Between Pre and Post Intervention Period of the experimental group		
	Experimental group n=20	Control group n=20		Experimental Group		
				Pre intervention period n=20	Post intervention period n=20	
	Mean±S.D	Mean±S.D	P value	Mean±S.D	Mean±S.D	P value
LDL (mg/dl)	136±16.6	137.2±36.4	0.894	150.7 ± 16.2	136.0±16.6	0.007*
HDL (mg/dl)	47.4±4.6	43±5.4	0.008*	47.2±2.7	47.4±4.6	0.867
VLDL (mg/dl)	30±9.5	38.3±10.1	0.011*	30.9±12.6	30.0±9.5	0.800
Triglyceride (mg/dl)	147.7±46.6	185.4±49.8	0.018*	155.2±62.8	147.7±46.6	0.673
Total cholesterol (mg/dl)	210.2±16.1	221.8±35	0.189	228.8±13.3	210.2±16.1	0.000*
CHO/HDL ratio	4.6±0.7	5.2±0.7	0.008*	4.8±0.1	4.5±0.6	0.020*

***Significant at five percent level**

Comparison of pre and post intervention lipid profile values of the experimental group

A significant decrease in LDL, TC(mg/dl) and CHO/HDL levels in the experimental group after 60 days of supplementation with combined nutraceutical supplement was observed as compared to the initial values (Table 4). But no significant decrease in the levels of TG, VLDL and HDL(mg/dl) were recorded after 60 days of supplementation with combined nutraceutical supplement as compared to the initial values in the experimental group.

DISCUSSION

In the present study, the reduction in the waist to hip ratio in the experimental group indicates a healthier redistribution of subcutaneous fat. In other words a lower waist to hip ratio is indicative of lesser fat deposition in the abdominal region. Mobilization of fat from fat depots is

reflected by a decrease in waist and hip circumference and thereby a reduced waist to hip ratio in the experimental group. The decrease in the waist to hip ratio could be attributed to the effect of supplementation with combined nutraceutical supplement that contains curcumin, lycopene, lutein and proanthocyanidin all of which are known to impact lipid metabolism. However the lack of a significant difference in all other anthropometric measurements between the experimental and control group are similar to the observations reported by Alwi et al., (2008) who found no significant difference in BMI, hip circumference and waist to hip ratio after 4 months of supplementation with curcumin in patients with acute coronary syndrome. Zahedani et al.,(2015) and Lorenz et al., (2012) also found no significant changes in anthropometric measurements such as weight, BMI, waist circumference and hip circumference after supplementation with proanthocyanidin and lycopene respectively.

With regard to lipid profile estimations, the overall effect of the combined nutraceutical supplement on the experimental group was a reduction in TG, LDL, VLDL, TC, CHO/HDL and increase in HDL levels. The findings of the present study are similar to reports from studies conducted on animals and human beings. El-Nashar and Abduljawad (2012) found an increase in HDL levels of male albino rats administered lycopene which is attributed to a reduction in the extent of lipid peroxidation. Similarly Blum*et al*., (2006) in a study on 32 women and 16 men showed that consuming high amounts of tomato (300 g daily) could significantly increase the serum HDL level (15.2%). Likewise Alwi et al, (2008) obtained 11.3% increase in HDL level in coronary syndrome patients after low-dose supplementation of 15mg curcumin as compared to placebo group. On the other hand consumption of 16 fl oz fresh carrot juice for 90 days helped to maintain HDL levels in hyperlipidemic men (Potter, Foroudi, Stamatik, Patil & Deyhim, 2011).Parallel reductions in the concentrations of LDL-C and apo B along with an increase in HDL-C was observed after supplementation with 150ml of red grape juice containing proanthocyanidin in healthy human volunteers for one month(Ansari, Rasmi & Ramezani 2010).In animals, Kim and Kim, (2010) reported a 48% reduction in atherogenic index with dietary curcumin supplementation in Sprague Dawley rats for a period of 8 weeks as compared to the control group. The hypolipidemic effect of curcumin is attributed to the disruption in micelle formation which in turn prevents absorption of cholesterol and promotes fecal excretion of total steroids and bile acids.

Castilla *et al.*,(2006) showed that 150ml of red grape juice supplementation twice per day for one month in healthy human volunteers decreased cardiovascular risk ratio. Similarly grape seed extract supplementation reduced TC/ HDL-c risk ratio by 52% in the male albino rats who were fed 4.63 mg/kg body weight of grape seed extract for 14 days (Adawi, Moshan, Yousef & Sewedy, 2006). Lorenz et al., (2012) has also reported that rats treated with 5mg/kg body weight of lycopene for 1 month showed a significantly improved ratio of LDL/HDL as compared to placebo group. Likewise Lee et al., (2015) has also documented that consumption of tomato juice for six weeks decreased LDL-C/HDL-C in hyperlipidemic subjects.

Pashine, Singh, Vaish, Ojha and Mehdi (2012) demonstrated that supplementation with curcumin for a period of 3 months reduced VLDL levels significantly in overweight hyperlipidemic subjects which is similar to the findings obtained in the present study. A significant reduction in VLDL and TG was found in male wistar rats upon administration of daucus carota seeds at 400mg/kg body weight for a period of 7 days (Singh, Dhongade, Singh & Kashyap, 2010). The hypolipidemic activity of daucus carota seeds is attributed to increased plasma antioxidant status and reduced lipid peroxidation.

Alternately supplementation with lycopene for a period of three weeks in both men and women reduced LDL level by 12.9% without any changes in concentration of HDL and TG respectively. It has been proposed that lycopene reduced cholesterol levels by its suppression of cholesterol synthesis, increase in LDL degradation, and inhibition of the hydroxy-methyl-glutaryl-coenzyme, a HMGCoA -reductase enzyme (Silaste et al., 2007). On the other hand long-term supplementation with grape seed extract (GSE) also reduced plasma LDL in rats. It is suggested that the reduction in LDL is mediated through inhibition of pancreatic lipase, cholesterol esterase, cholesterol micellization and bile acid binding (Pilehvar, Tabrizi and Javadi, (2013)).

The results obtained in the present study for decrease in total cholesterol is similar to the observation by Gandhi, Khan and Chakraverty (2011) who found a decrease in total cholesterol in healthy humans after 15 days of supplementation with 500 mg/twice a day of soluble curcumin when compared with the values recorded on the first day. It is suggested that the hypocholesterolemic effect of curcumin could be due to decreased intestinal absorption of cholesterol brought about by a decreased uptake of cholesterol in the enterocytes. Similarly the effect of lycopene is considered to be due to compounds inhibiting the activity of an essential enzyme involved in cholesterol synthesis (i.e., macrophage 3-hydroxy-3-methyl glutaryl coenzyme A reductase (Witztum,1994). In the same manner, Singh, Dhongade, Singh and Kashyap (2010) reported significant lowering of serum total cholesterol in rats treated with daucus carota seed extract for a period of 1 week. The hypolipidemic activity of daucus carota seeds is attributed to increased plasma antioxidant status and reduced lipid peroxidation.

CONCLUSION

Supplementation with lycopene; curcumin; lutein and proanthocyanidin in the form of the Combined Nutraceutical supplement resulted in increased HDL and decreased TC, LDL, VLDL and TG(mg/dl) levels in hypercholesterolemic men. It can therefore be concluded that the combined nutraceutical supplement which contains curcumin, lycopene, lutein and proanthocyanidin has a lipid lowering effect in hypercholesterolemic subjects. In addition, a decrease in cardio vascular risk ratio was also observed after supplementation with the combined nutraceutical supplement. Thus, the combined nutraceutical supplement could be recommended as a hypolipidemic supplement for hypercholesterolemics.

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