

A randomized comparative evaluation of combined effect of statin and nut mixture with statin alone on triglyceride level in patients with known hypertriglyceridemia

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Abstract: Hyperlipidemia condition indicates higher triglyceride and cholesterol level that may lead to atherosclerosis, a healthy diet is the primary step to reduce the lipid levels. The dietary dosage of nuts and other selective natural substitutes minimize the lipids in blood and help in improving the antioxidant level. The present study to find the effect of combining various ingredients such as nuts (Almond, Hazelnut, pine nut, pistachio, peanut), seeds (flax, pumpkin), cocoa, green tea along with Alpha Lipoic Acid (ALA), L - Carnitine, ProQ₁₀ for reducing the ill effects of hyperlipidemia patients. The study revealed significant decrease in triglyceride levels on consuming the above ingredients with ($p < 0.05$) along with proper diet.

Keywords: Hyperlipidemia, Atherosclerosis, nuts, seeds, cocoa, green tea, ProQ₁₀.

Introduction

Fat is good source of energy [1,2], due to present day dietary habits and work culture the society is facing alarming cases of hyperlipidemia, diabetics etc., Mass communication and technology has made a great effort in educating, people are aware of health issues and their consequences. Now the trend is towards eating the natural healthy food and patients prefer a natural substitute instead of synthetic chemicals.

Nuts are rich in nutrients [3] and is abundant in protein, fibers, tocopherols and is the best source of unsaturated fatty acids etc., The studies have proved a correlation between nut consumption and reduction in cardio vascular disease [4], gallstones, hypertension and has reduced the cholesterol level in blood. Flax seeds and pumpkin seeds are a source of magnesium, potassium serves as antioxidant [5] recommended for diabetic patients. Cocoa and green tea are rich in flavanols [6], regulates glucose level for obese, reduces depression and promotes good sleep. L-carnitine [7,8] has helped in reducing the triglyceride level for hypertriglyceridemia and ALA can help in improving the arterial tone. ProQ₁₀ [9] has reduced the cardio vascular mortality and highly recommended for Type 2 diabetic patients as antioxidant [10] to decrease the oxidative stress.

Almond, Cashew, Peanut, Hazelnut, Pinenut, Pistachio, Sunflower seed in the above takes care of daily requirement of dietary fiber that contains anti-oxidants, Vitamin A, C, E, Zinc & selenium. The nuts composition helps by increasing super oxide dismutase and Glutathione peroxidase also reduces heart attack, lipid peroxidation, platelet aggregation and stroke. Flax and Pumpkin seed are good source of potassium, magnesium and B vitamins that helps to control high blood pressure and in the relaxation of blood vessels.

Cocoa, Green tea and grape seed extracts are rich in flavonoids, reduces excess weight, keeps skin healthy, and fights signs of aging and mood depression, promotes good sleep. Alpha Lipoic Acid (ALA) and

Acetyl-L-Carnitine added in the product maintains healthy arterial tone and recommended for normal functioning of heart and liver as it breaks down the fatty acids. Pro Q₁₀ ensures healthy heart as the co enzyme is required for deriving energy and relieves from fatigue, signs of anxiety/depression and promotes a calm sleep.

Experimental Methods

Aim of this study is to find a natural substitute for obese, hyperlipidemic affected diabetic patients. Tree nuts such as almond, cashew, hazelnut, pine nut, peanut and pistachio were powdered, mixed with flax, pumpkin seeds along with cocoa, green tea in appropriate proportion. ALA, L-Carnitine with Pro Q₁₀ were combined with the above mixture as per recommended quantity.

60 volunteering patients aged from 35 to 50 years suffering from hyperlipidemic, diabetic and had BMI more than 25 were considered for the study. Statin drugs are prescribed to lower the cholesterol level that leads to free radicals generation and oxidation. The study was conducted at Chennai, Tamilnadu, India during October 2014-December 2014. The above composition was given to the patients in a powdered form named SUBTRECH and were advised to take 10 grams twice daily along with their regular diet and statin. The powder can be dissolved in water or milk should be taken after food. The composition is given below in table.1

Table 1: The major ingredients in 10 grams of SUBTRECH (Binding Constituents Not Listed)

Name of the ingredient	Quantity (Grams)	Name of the ingredient	Quantity (Grams)
Pistachio	0.0015	Alpha lipoic acid	0.00005
Pumpkin seed	0.002	Pro Q ₁₀	0.000005
Flax seed	0.0025	Green Tea Extract	0.00015
Sunflower seed	0.0025	Acetyl L Carnitine	0.00005
Hazelnut	0.001	Grape seed extract	0.000005
Almonds	0.002	Cocoa Powder	0.005
peanut	0.00075		
Pine nut	0.0005		

The above table shows the major ingredients that were considered for analysis and it includes other binding constituents that are not listed.

Results

The triglyceride for an adult is recommended to be less than 200 mg/dl. The 60 patients were classified into three groups based on their triglyceride levels. Each group (250-300, 300-350, 350-400) had 20 patients of which 10 patients were given only statin drugs and to the remaining 10 patients were given statin along with SUBTRESH. All 60 patients completed the study, mean of triglyceride levels of the patients after every 30 days for three months are given in table 2.

Table 2: Triglyceride levels of patients after every 30 days of consuming SUBTRECH. Statistical Results

S.no	Triglyceride Level	After 30 days		After 60 days		After 90 days	
		Statin only	Statin + SUBTRECH	Statin only	Statin + SUBTRECH	Statin only	Statin + SUBTRECH
1	250-300	210±2 mg/dl	207 ± 2 mg/dl	205± 2 mg/dl	202 ± 2 mg/dl	190± 1 mg/dl	180 ± 2 mg/dl
2	300-350	250± 3 mg/dl	246±2 mg/dl	220± 1 mg/dl	215 ± 2 mg/dl	201 ± 2 mg/dl	192± 2 mg/dl
3	350-400	300± 2 mg/dl	296 ± 2 mg/dl	260 ± 2 mg/dl	258±2 mg/dl	205 ± 4 mg/dl	194± 2 mg/dl

Statistical t test was employed for triglyceride values between the groups and Anova for data within the same groups for patients triglyceride levels after 30, 60, 90 days and the results are given below in table 3.

Table 3: Statistical Results For Patient Data

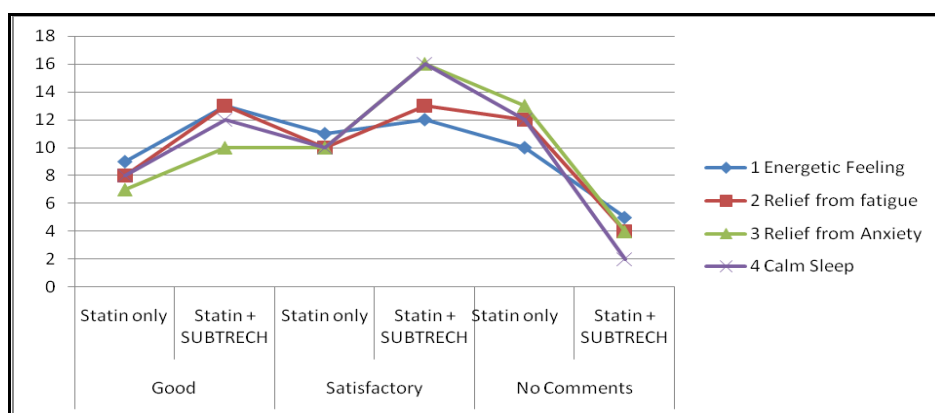
S.No	Triglyceride Levels	Between Groups T test $\hat{Q} = p \text{ value} < 0.05$	With in groups (Anova)	
			statin users	Statin + SUBTRECH
1	250-300	P=0.019	P=0.086	P=0.013
2	300-350	P=0.16		
3	350-400	P=0.003		

At the end of 90 days a survey was conducted from the patients on energy, fatigue, anxiety and sleeping pattern as a feedback. The patient reports regarding the drug along with statin and patients consuming only statin drug was obtained and the summarized details are given below in table.4

Table 4: Patient Feedback summary for statin drug and statin with SUBTRECH after 90 days

S.No	Factors	Good		Satisfactory		No Comments	
		Statin only	Statin + SUBTRECH	Statin only	Statin + SUBTRECH	Statin only	Statin + SUBTRECH
1	Energetic Feeling	9	13	11	12	10	5
2	Relief from fatigue	8	13	10	13	12	4
3	Relief from Anxiety	7	10	10	16	13	4
4	Calm Sleep	8	12	10	16	12	2

The results shows a marked decrease in triglyceride level of patients. The patients above 350 mg/dl had a very good response with their level decreased to 194 mg/dl after 90 days, most of them in this group found energetic, relieved from fatigue, anxiety and had a satisfactory sleep. The levels for patient with statin and statin with SUBTRECH had similar levels but after 3 months their levels were better, less by 10 mg/dl. The triglyceride levels for the middle group ranging from 300 to 350 had a steady decrease in the levels and reported they had a satisfactory relief from fatigue, anxiety and had a good sleep. The final group of patients with levels less than 300 had their levels controlled after 90 days. In all the three groups the patients with statin and SUBTRECH had a better decrease than with statin drug users. The chart for the above patient survey reports is shown in the figure.1 below.

**Figure 1: Chart Showing Patient reports on SUBTRECH after 90 days of consumption**

Conclusion

Patient reports suggest that on using a natural constituent SUBTRECH consistently shows a significant decrease in their triglyceride levels. The first two months triglycerides levels of patients only on statin and for patient with statin and SUBTRECH were nearly the same but after 90 days there was a difference

of nearly 10 mg/dl lesser than patients administered with statin alone. The feedback response for SUBTRECH users feeling energetic, relief from fatigue, anxiety and sleep response were better ranging from 10% to 55% more in good and satisfactory. The results indicate, the natural constituents yield promising results with reduced triglyceride levels ($p=0.013$) which is less than ($p<0.05$) after 90 days of usage and takes care of comorbid conditions for patients with diabetics and hyperlipidemia.

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