Research Article

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EFFICACY AND SAFETY STUDY OF TRIPHALA IN PATIENTS OF DYSLIPIDEMIA: A PILOT PROJECT

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ABSTRACT

Dyslipidemia has been found to be one of the most important contributing factors of coronary artery disease. The prevalence of dyslipidemia is very high in India, which requires urgent intervention strategies to prevent and manage this important cardiovascular risk factor. This study was aimed to explore the efficacy of Triphala churna on Dyslipidemia. It was Randomized, clinical study. Total 15 patients were selected from Kayachikitsa & Geriatric OPD as well as from peripheral diagnostic camps. Triphala churna 5 gm twice a day was given for continuous 30 days. Body weight and lipid profile were assessed before and after treatment. Safety was assessed by the incidence of adverse events. Significant changes were found in lipid levels and body weight. There was improvement in bowel habits. No any adverse effect was found. It can be concluded that Triphala churna might be a preferable medicine to control lipids.

Key words: Dyslipidemia, coronary artery disease, Triphala churna, lipid profile

INTRODUCTION

Cardiovascular diseases (CVD) are the most widespread cause of death and disability in both developed as well as developing countries.[1] South Asians have the highest rates of Coronary Artery Disease (CAD).[2] It is usually due to atherosclerosis of large and medium sized arteries and dyslipidemia is one of the most important contributing factors.[3] The prevalence of dyslipidemia is very high in India, which requires urgent intervention strategies to prevent and manage this important cardiovascular risk factor.[4]

Triphala is a combination of three medicinal plants Amalaki (*Emblica officinalis* L.), Haritaki (*Terminalia chebula* Retz.) and Bibhitaki (*Terminalia bellerica* Roxb.) in equal proportions.

In Ayurvedic practice, Triphala is used for weak digestion & assimilation of food and constipation.[5, 6] It is also reported as an anti-inflammatory, hypoglycemic & an anti-aging properties.[7]

In a search of herbal medicines for Dyslipidemia, some animal studies were found on Triphala. They observed significant reduction in lipid levels in Triphala treated hypercholesteremic rats as compared to control. The hypolipidemic action of Triphala was assumed to be due to the presence of flavonoids and polyphenolics.[8]

Need of study - No any human study was conducted on Triphala as a hypolipidemic drug. So this pilot study was designed to evaluate the effect of Triphala on Dyslipidemia.

Aim - The aim was to explore the efficacy of Triphala churna on Dyslipidemia.

Objectives

- To evaluate effect of Triphala churna on the serum level of Total cholesterol, HDL, LDL, VLDL & Triglycerides
- To evaluate the effect of Triphala churna on weight & bowel habit.

MATERIAL AND METHOD

Study design - It was Randomized, clinical study.

Ethical clearance – It was obtained from Institutional Ethics committee of Datta Meghe Institute of Medical sciences, Sawangi (IEC No. DMIMS (DU)/IEC/2015-16/1770).

Source of data collection - The patients were selected from Kayachikitsa & Geriatric OPD of Mahatma Gandhi Ayurved College, Hospital & Research center, Salod.

Inclusion Criteria

- Male or female patient, of any race of age group 40 years to 70 years.
- Patients having Total cholesterol 200-270 mg/dL and/or LDL 130-200mg/dL and/or Sr. Triglycerides 150-280 mg/dL
- Being mentally able to understand all study requirements and sign the informed consent form.
- Patients of controlled hypertension and/or Diabetes were enrolled and related medications were continued throughout the study.

Exclusion Criteria

- Patients with myocardial infarction, stroke, transient ischemic attack, cardiovascular surgery or major operations within 6 months prior to screening visit.
- Patients who are already on lipid-lowering medications
- Patients with renal dysfunction.
- Patients with uncontrolled diabetes mellitus
- Patients with uncontrolled metabolic or endocrine disease knowing to influence lipid values.

- Patients who are known to be HIV positive.
- Patient who is on antipsychotic medication.
- Pregnant or lactating women

Method of data collection

Total 20 patients were selected for the study. Out of that 15 were completed the study. All the patients were thoroughly examined and investigated for lipid profile. Patients fulfilling the inclusion criteria were given Triphala churna 5 gm twice a day (at 9-10 a.m. ---- 9-10 p.m.) for continuous 30 days. After 30 days of treatment, Body weight and lipid profile were repeated to assess its Effect. A bowel habit was also noted before & after treatment. Safety was assessed by noting down any incidence of adverse events.

Assessment criteria

Efficacy of Triphala was assessed on following parameters
Body weight in Kg
Lipid profile – Total cholesterol, HDL, LDL, VLDL, Triglycerides

Statistical analysis

Statistical analysis was done by using descriptive and inferential statistics using Student's paired t test. The software used in the analysis was SPSS 17.0 version and $p<0.05$ is considered as level of significance.

OBSERVATIONS

Following observations were noted after completion of 30 days of treatment.

Table 1: Comparison of weight before and after treatment

	Mean	N	Std. Deviation	Std. Error Mean	t-value	p-value
B.T.	60.13	15	3.97	1.02	3.05	0.009,S
A.T.	59.73	15	3.88	1.00		

Table 2: Comparison of Total Cholesterol before and after treatment

	Mean	N	Std. Deviation	Std. Error Mean	t-value	p-value
B.T	230.40	15	29.79	7.69	3.24	0.006,S
A. T.	189.33	15	32.65	8.43		

Table 3: Comparison of HDL (High density lipoprotein) before and after treatment

	Mean	N	Std. Deviation	Std. Error Mean	t-value	p-value
Pre Test	34.73	15	8.68	2.24	1.14	0.27,NS
Post Test	38.66	15	9.27	2.39		

Table 4: Comparison of LDL (Low density lipoprotein) before and after treatment

	Mean	N	Std. Deviation	Std. Error Mean	t-value	p-value
Pre Test	147.40	15	41.92	10.82	0.80	0.43,NS
Post Test	135.40	15	29.50	7.61		

Table 5: Comparison of Triglycerides before and after treatment

	Mean	N	Std. Deviation	Std. Error Mean	t-value	p-value
Pre Test	201.46	15	45.24	11.68	4.95	0.0001,S
Post Test	149.66	15	43.58	11.25		

Table 6: Comparison of VLDL (Very low density Lipoprotein) before and after treatment

	Mean	N	Std. Deviation	Std. Error Mean	t-value	p-value
Pre Test	41.80	15	9.15	2.36	5.03	0.0001,S
Post Test	31.93	15	9.33	2.41		

RESULT AND DISCUSSION

The present study was conducted to assess the efficacy of Triphala churna on lipid levels in dyslipidemic patients. significant change in weight was found in one month of treatment. In one study, they also found Triphala effective in reducing the weight of obese individuals.[9]

In another animal study, Triphala administration was found to be effective in decreasing weight as well as inhibiting elevation of LDL, VLDL and blood glucose levels. It also increased the HDL levels [8] and protecting liver function.[10] It also decreased lipid peroxidation[11] which is a major factor in the progression of atherosclerosis.

In one more study, they observed significant reduction in Triphala treated hypercholesteremic rats as compared to control. It was said that the hypolipidemic action of Triphala may be due to the presence of flavonoids and polyphenolics.[8]

In this study, Total cholesterol level was also decreased significantly. Amalaki (*Emblica officinalis* L.) is one of the content of the Triphala. It might be due to its property of decreasing the absorption of fats and cholesterol.[12]

Haritaki has very similar properties to Amalaki in regards to healthiness of heart. Multiple studies on Haritaki (*Terminalia chebula*) demonstrated that it can lower triglycerides and LDL level.[13, 14]

HDL levels were not increased significantly. But in the contrary, above animal study on Haritaki found increased HDL levels.
Out of 15 patients, LDL was decreased in 11 patients but 4 patients had increased LDL. Hence the difference was not statistically significant.

There was significant decrease in the levels of VLDL and Triglycerides. One data suggested that hypertriglyceridemia is a dominant additional coronary risk factor, when it coincides with a high level of LDL.[15]

It was also found to be effective in normalizing bowel. No adverse features were found in any patient.

Overall efficacy of Triphala on lipid levels were found to be satisfactory

Probable mechanism of action of Triphala - The liver is a multipurpose organ in the body regulating various metabolic pathways. It is the main site for formation and clearance of lipoproteins. It gets fatty acids and cholesterol from peripheral tissues and diet, convert them into lipoprotein complexes and releases it back into the circulation. Hence liver diseases can affect plasma lipid levels in a variety of ways. Cholesterol biosynthesis in the body is mainly maintained in the liver by the enzyme HMG-Co A and HMGR.

In one study, dyslipidemia was found in patients with liver cirrhosis. So, the proper screening of patient is important for appropriate intervention to prevent cardiovascular events.[16]

It is claimed that Amalaki, one of the components of Triphala has various biological activities such as improves digestion, [17] improves liver function and hepatoprotective[18] Triphala is having balancing and Rejuvenating effect on Vata, Pitta and Kapha.

It is known that Colon health is important. Proper regulation of the colon is a key to good health and longevity. Triphala works well as a colon cleanser and is a rasayana (rejuvenation) for the colon. It is rich in fibres which help in digestion and regulation of bowel. In the present study significant decrease in Total cholesterol, Triglyceride and VLDL may be due to reduction in absorption of cholesterol.[19]Oral administration of Haritaki reported to increase gastric emptying might be the reason of decreased absorption.[20]

CONCLUSION

On the basis of these findings, Triphala could be potentially effective and safe in Dyslipidemia. This study can be replicated in large number of patients for further evaluation of results and to investigate the mechanism of action.

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