



## Research Article

### THERAPEUTIC POTENTIAL OF *THRIPHALA RASAYANA* IN PRIMARY HYPERLIPIDEMIA- AN EXPERIMENTAL COMPARATIVE STUDY

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#### ABSTRACT

**Background:** Elevated concentration of lipids in the blood is considered as the well-established and strong risk factor for cardiovascular disease. Primary hyperlipidaemia occurs solely due to interaction of mutated gene with unprecedented epidemiologic transitions associated with lifestyle changes and dietary patterns. Early detection and management of asymptomatic hyperlipidaemia is imperative to reduce the incidence of cerebrovascular, peripheral vascular and coronary artery diseases. Preferred screening test i.e. lipid panel test will be substantial on many levels including mortality, morbidity and staggering financial burden related with vascular endothelial dysfunction and atherosclerotic changes. Simple, low-cost and potential pharmacological interventions with Ayurveda drugs are highly beneficial in these preventable epidemics. The main ingredient, "*Triphala*" in the trial drug is considered as the best known rejuvenative (*Rasayana*) combination, which stimulate and correct the impaired inherent digestive capacity (*Dhatwagni*) by removing the inflammatory and obstructive causes (*Srothorodha*) associated with the dysfunctions in lipid metabolism. **Objective:** This study aims to evaluate the effect of an Ayurveda formulation on lipid level in patients with primary Hyperlipidaemia. It also ascertains the safety of the therapeutic formulation by evaluating the variations in the blood biochemical parameters. **Methods:** The study design was an experimental comparative study intended to compare the effect of potentiated *Triphala rasayana* with standard anti-lipidemic drug in primary hyperlipidaemia. 29 cases in study group and 15 samples in control group participated in the trial. The data was analysed by using appropriate statistical techniques. **Results:** In the study group the values of total cholesterol, LDL and Atherogenic index shows more significant result than the control group receiving conventional anti-lipidemic drug. **Conclusion:** strategies for early detection and comprehensive management with Ayurveda formulations can be highly effective in reducing the global burden of vascular dysfunction related with hyperlipidaemia.

**KEYWORDS:** *Triphala, Rasayana*, Anti-oxidants, Endothelial dysfunction, Cardiovascular disease.

#### INTRODUCTION

The prevalence of cardiovascular disease (CVD) continues to increase globally. CVDs generally refers to complex pathophysiological conditions that alter the total cross sectional area of blood vessels and opposes the blood flow particularly in systemic circulation<sup>[1]</sup>. Abnormal blood concentrations of lipids are closely interconnected in the pathogenesis of CVD. Hyperlipidaemia is a major metabolic disorder, contributing substantially to the development and clinical expressions of vascular abnormalities. <sup>[2]</sup> Disorders of lipid metabolism are increasingly prevalent in this era due to the interaction of mutated inherited factors with changes in lifestyle, unbalanced food habits and stressful mental conditions. Vascular endothelium is considered as an interface between blood stream and

vessel wall, actively involved in homeostasis <sup>[3]</sup>. Any variation in the functional ability of this interface is believed to be primary importance in the pathogenesis of disease related with circulatory system. Endothelial dysfunction is an early indicator of chronic inflammatory process i.e. atherosclerosis and other life threatening complications <sup>[4]</sup>. Free radical scavenging and neutralising effects of Antioxidants help to maintain the physiological redox balance, gets depleted in chronic conditions like hyperlipidaemia. Abnormalities in lipid metabolism disrupt the normal biochemical balance required for cardiovascular performance and create accelerated atherogenic events. Direct effect of impaired lipid metabolism in turn leads to myocardial dysfunction, reperfusion injury and decrease stress adaption. In

these circumstances interventions with natural antioxidant supplements may play a key role in normalizing altered lipid metabolism and preventing unwanted oxidative reactions. Therefore an early detection of cases with positive family history and management with Ayurveda formulations definitely have a reiterated role in preventing deleterious consequences of vascular injury and subsequent myocardial oxidative stress associated with Hyperlipidaemia.

In Ayurveda perspective, lipid components in the body can be treated as derivative of fat tissue (*Medho dhatu*). While analysing the *Kapha bhava* in Hyperlipidaemia cases, it is observed that its qualities are similar to *Bahu drava* stage. Chakrapani comments that the *Bahu drava* condition of *Kapha* itself causes *Bahuabadhata* of *Medo dhatu*<sup>[5]</sup>. According to the basic concepts, lipid tissue and *Kapha dosha* are mutually inter related having similar basic properties. The etiological factors responsible for all metabolic syndromes such as Diabetes mellitus, obesity, and other disorders related with over nourishment are similar to that of *Kapha dosha* and lipid tissue vitiation<sup>[6]</sup>. In Hyperlipidaemia, the inherent low level digestive capacity leads to the formation of toxic substances called *Ama* in the body<sup>[7]</sup>. Impaired tissue formation and toxic products from metabolic error can hamper tissue formation along with the vitiation of blood. These pathological processes in turn leads to obstruction and vitiation of channels. Similar process can be observed in Hyperlipidaemia, also closely inter connected to life limiting conditions. Drugs and combinations having *Rasayana* properties particularly *Thriphala rasayana* definitely has potential benefits over this impaired lipid metabolism.

## MATERIALS AND METHODS

**Study design:** An experimental comparative study – The trial drug “*Thriphala choorna*” potentiated with decoction made of *Khadira* and *Asana* administered to the study group, its effect was compared and statistically analysed with the control group receiving standard anti-lipidemic drug (statin).

**Study setting:** Adequate sample size diagnosed with primary hyperlipidaemia was consecutively allocated from the outpatient department of Kayachikitsa, Govt. Ayurveda College Hospital, Thiruvananthapuram.

**Inclusion criteria:** Both male and female cases in the age group of 20-60 years identified with primary Hyperlipidaemia.

**Exclusion criteria:** Acquired causes of secondary Hyperlipidaemia such as Diabetes mellitus, thyroid dysfunction, and nephrotic syndrome, chronic liver and renal failure are excluded from the study.

Possibilities of oral medications including contraceptive pills and hormone therapies potentially affect lipid metabolism are also excluded from the trial.

**Procedure:** Hyperlipidaemia in most of the cases are asymptomatic and assigned as the leading risk factor associated with cardiovascular disease. Preliminary data was collected by using fasting lipid profile test. A well-structured clinical research proforma was set up for the data collected from the history taking, initial screening tests and cardiovascular system examination.

As per the inclusion and exclusion criteria samples were consecutively allocated in to the study and control group till attaining the sample size of total 44 patients. Base line data collection and laboratory investigations were done before and after intervention with the trial drug. Both male and female cases in the age limit of 20-60 from the study setting were selected for the study. They were subjected to detailed general and systemic examination and investigations including complete blood count, fasting lipid profile, liver function tests, renal function tests and other relevant biochemical assessment to exclude secondary hyperlipidaemia were done at the clinical lab settings in the Govt. Ayurveda College Hospital, Thiruvananthapuram. The trial drug was administered to the samples confined to the study group in capsule form. Two capsules of the trial drug, with *Anupana* of lukewarm water were given thrice a day after food for one month, whereas standard lipid lowering therapy with statin was strictly followed in the control group. All cases in both the groups were advised to follow dietary regimen suitable for hyperlipidaemia. After the trial of one month duration the response to the treatment was assessed. The collected data obtained before and after the study was subjected to statistical analysis using appropriate statistical techniques. In order to find out the effectiveness of both modern and Ayurveda management before and after the trial, paired t test was computed. For comparing the effectiveness between the trial and control groups, student t test was performed.

**Drug review:** The trial drug in the present study is a therapeutic formulation mentioned in chapter on *Sthoulya* (obesity) treatment of *Chikitsamanjari*<sup>[8]</sup>, an Ayurveda text which explicitly details the traditional keralite management for general diseases. The formula consists of *Thriphala* a well-recognized and highly efficacious poly herbal *Rasayana* combination consisting of fruit rind of the plant species *Emblica officianalis*, (*Amalaki*), *Terminalia bellerica* (*Vibhitaki*) and *Terminalia chebula* (*Haritaki*) potentiated in the concentrated decoction of *Khadira*

(*Acacia catechu*) and *Asana* (*Pterocarpus marsupium*) by a process called *Bhavana* (potentiation) which helps to impart the properties of *Khadira* and *Asana* in to the *Thriphala*. While analysing the aetiopathogenesis of primary hyperlipidemia, it is evident that there is an inherent inactivity of digestive fire and accumulation of toxic products in the form of vitiated *Kapha*, *Medas* having qualitative changes. *Thriphala* is considered as the best drug with enormous rejuvenating capacity can reverse the metabolic errors by its specific action on *Kleda*, *Medas* and *Kapha* (*Soshana* properties).

Experimentally all these drugs have proven anti-lipidemic and anti-oxidant properties<sup>[9]</sup>. The therapeutic properties of *Haritaki* is specifically indicated in inflammatory process i.e. atherosclerosis due to lipid accumulation and the resulting vascular abnormalities (*Dhamani pratichayam*)<sup>[10]</sup>.

**RESULTS**

**Interpretation of data related to demographic and socio- economic background**

**Age:** majority of the patients belonged to the age group 40-49 (55.2%)

**Sex:** females constituted 58.6% in the study group and 66.7% in the control group

**Religion:** maximum number of patients in the study group (69%) and in the control group (86.7%) belonged to Hindu community. 17.2% in the study group and 6.7% in the control group belonged to Muslim community and the remaining in both groups from Christian community.

**Educational status:** majority of patients in both groups were having higher level of education. 20.7% in the study group and 26.7% in the control group were educated below matriculation, whereas 6.9% in the study group and 6.7% in the control group were uneducated.

**Domicile:** 93.1% of samples in the study group belonged to rural population and the remaining belonged to urban population. 80% of control group belonged to rural population. The immense burden of

most of the non-communicable disease including metabolic disease in rural area may be due to lack of awareness in healthy life style and diet patterns.

**Socio economic status:** 75.9% in study group and 46.75 in the control group were from middle class family. 6.9% in the study group and 20% in the control group were in the poor class and remaining belonged to affluent economic status.

**Occupation:** House makers constitute 44.8% in the study group and 66.7% in the control group. 34.5% in the study group and 26.7% in the control group were employees leading with sedentary work life and heading serious work place health issues. Manual workers constitute 20.7% in the study group and 6.7% in the control group.

**Interpretation of data related to life style behaviours**

**Diet:** Majority of patients 82.8% in the study group and 93.3% in the control group were following non vegetarian diet.

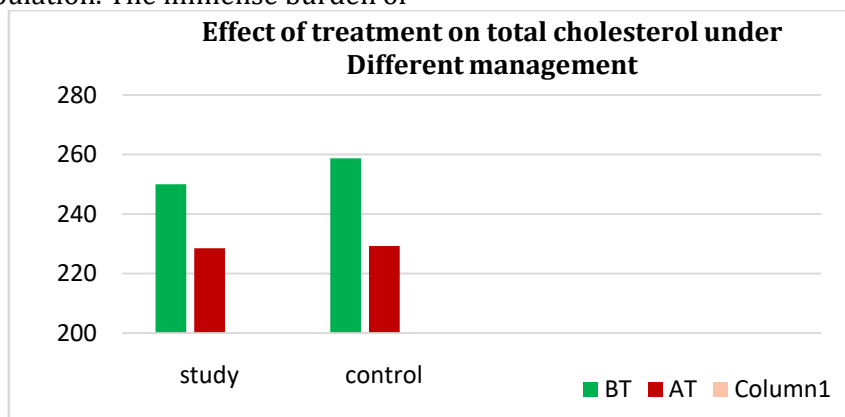
**Sleep:** Sleep pattern shows that most of the cases in both groups had sound sleep and day sleeping was not practiced by all in this study

**Exercise:** All the patients were doing mild to moderate activity occasionally; nobody was practicing regular exercise.

**Family history:** In the study group 51.7% and in the control group 53.3% had a positive family history of hyperlipidaemia.

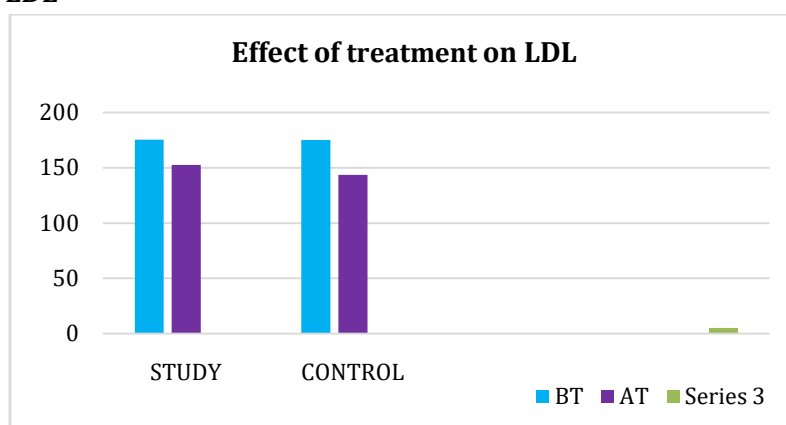
**Interpretation of data related to hyperlipidaemia**

Primary Hyperlipidaemia is mainly due to the interaction of genetic causes with unhealthy lifestyle habits and dietary patterns. Among the various etiological; factors described in Ayurveda classics, *Beeja dushti* is an inevitable factor. su.soo.15/34. Patients having *VataKapha* constitution tend to predominate in hyperlipidaemia affecting 63% in the study group and 72% in the control group, indicates that *Vathakapha prakrithi* persons are more prone to dysfunction in lipid metabolism.



Interpretation of data related to response of treatment effect of treatment on total cholesterol level in the study group mean value of total cholesterol was reduced from 250 to 228.5 after treatment. The P value shows statistically significant change at 0.1% level, whereas in the control group the mean value of total cholesterol was reduced from 258.7 to 229.3 after the study, showing significance at 5% level.

**Effect of treatment on LDL**



In the control group the mean value of LDL was 175.1 which came down to 143.7 after treatment showing a significance at 1% level. In the study group the mean value of LDL was reduced from 175.3 to 152.4 after treatment show a significant 0.1% level.

**Table 1: Effect of treatment on HDL**

Group	Stage	Mean	SD	Paired t	P
Study	BT	43.3	13.3	0.9	P<0.05
	AT	45.2	12.2		
Control	BT	44.3	9.8	1.41	P<0.05
	AT	48.7	9.0		

Regarding HDL the mean value of 44.3 in the control group and 43.3 in the study group was increased to 48.7 and 45.2 respectively after the treatment. But these marginal changes were found to be not statistically significant.

**Table 2: Effect of treatment on TGL**

Group	Stage	Mean	SD	Paired t	P
Study	BT	156.9	43.1	0.4	P<0.05
	AT	154.4	49.8		
Control	BT	196.1	63.4	1.1	P<0.05
	AT	184.6	55.8		

In the control group the mean value of Triglyceride after treatment showed a decrease in the average value from 196.1 to 184.6, whereas in the study group the mean value was reduced from 156.9 to 154.4. The changes obtained in both groups were not found statistically significant (P>0.05).

**Effect of treatment on atherogenic index and HDL ratio**

**Table 3: Effect of treatment on atherogenic index**

Group	Stage	Mean	SD	Paired t	P
Study	BT	5.2	1.7	2.63	P<0.05
	AT	4.4	1.6		
Control	BT	5	1.1	3.47	P<0.01
	AT	3.8	1.1		

**Table 4: Effect of treatment on HDL ratio**

Group	Stage	Mean	SD	Paired T	P
Study	BT	0.2	0.1	1.87	P<0.05
	AT	0.3	0.1		
Control	BT	0.2	0.0	3.21	P<0.01
	AT	0.3	0.1		

Regarding atherogenic index and HDL ratio, it was found in the control group that a pre therapy mean value of 5 and 0.2 respectively was reduced to 3.8 and raised to 0.3 respectively. On statistical analysis these changes were found to be statistically significant ( $P < 0.01$ ). In the study group, regarding Atherogenic index and HDL ratio after treatment the mean value of 5.2 and 0.2 become 4.4 and 0.3 respectively. The changes in the Atherogenic index were found to be statistically significant ( $P < 0.05$ ) but changes in the HDL ratio was found to be statistically not significant.

## DISCUSSION

Abnormalities related with the synthesis of endogenous substances from vascular endothelium and alterations in vascular biology are identified as an important biomarker for cardiovascular diseases. The development and progression of atherosclerosis and resulting perfusion injuries are mainly due to metabolic dysfunctions.

The Indian traditional system of medicine, Ayurveda has rich source of concepts and potential therapeutic strategies available for the correction of these physiological alterations related with lipid metabolism. According to the concepts and basic principles of Ayurveda, normal digestive capacity of the body i.e., "Agni" play an important role in digestion and metabolism of the body. So any abnormality in the structural and functional mechanism facilitate digestive capacity (Agni) will disrupt the ability of the tissues to perform essential biochemical reactions including metabolism and transport of lipids. In primary hyperlipidaemia, interference of lipid metabolism is attributed to the interaction of mutated gene with unhealthy life style habits and dietary patterns. As per the basic concepts of Ayurveda, there is always an inherent reduced digestive capacity (diminished *Jataragni* and *Dhattwagni*) associated with patients having hampered lipid metabolism. Nutrient and tissue part *Rasa dhatu* formed during improper digestion are unable to perform the normal functions and are unable to transform subsequent tissues, particularly the *Medho dhatu*. As per *Ashtangahrudaya*, chapter on knowledge of *Dosha* (*Doshadivijnaneeyam*) specific function are assigned to different tissues of the body. Functions like nourishment (*Preenana*) for *Rasa dhatu*, lubrication or unctuousness (*Snehana*) for *Medhodhatu* (lipid tissue) etc. Any derangement in normal metabolism these functions and qualities of formed tissues become in a pathological condition. Thus unhealthy life style and unwholesome dietary habits along with inborn metabolic error is actively involved in aetio-pathogenesis of primary hyperlipidaemia.

There is an extensive research data available to prove the free radical scavenging property and inhibitory effects of *Triphala* powder on lipid peroxide formation. Polyphenols in *Triphala* powder possess anti-mutagenic activity. Flavonoids present in the combination particularly in *Emblica* possess diverse anti-oxidant and cardio protective action. It also effectively inhibits hepatic HMG-COA reductase activity and reduces the lipid levels. Tannoids of *Emblica* are potent inhibitors of aldosereductase is effective in the prevention and management of secondary complications. Catechin a bioflavonoid is actively present in *Acacia catechu* possesses antioxidant property and protects heart from oxidative damage. Pterocarpin and liquitrigenin present in *Pterocarpus mausupium* identified as having the property of reducing total cholesterol, LDL and Atherogenic index.

Therapeutic Formulations especially *Rasayana prayogas*, having direct effect on digestive functions (i.e., *Agni deepana* and *Ama pachana*) and *Medho dhatu* (lipid tissues) are beneficial in the prevention and management of secondary complications like cardiovascular disease. *Triphala* powder is considered as the best drug having *Rasayana* (anti-oxidant) property. Due to the *Kleda*, *Meda*, *Kapha soshana* and *Lekhana* properties it reduces the *Bahudrava* nature of *Kapha dosha* takes part in the pathogenesis of metabolic disorder. It is evident that vitiated digestive capacity actively involved in the disease pathology. The trial drug possesses *Deepana* (improving the functioning of digestive capacity) and *Pachana* i.e. detoxifying the impure toxic products produced as a result of excess lipid accumulation in the body (lipotoxicity). According to *Charaka samhita* "Vibhitaki" (*Terminalia bellerica*) specifically indicated in lipid abnormalities (*Medhovikara*). *Sodalanighandu*, describes the *Medhohara* property of *Acacia catechu* (*Khadira*). With all these references and scientifically proven properties, an ingredient present in the trial drug was effective in the management and prevention of complications in hyperlipidaemia.

## CONCLUSION

The main conclusions derived from the study are potentiated *Triphala rasayana* can lower the total cholesterol and LDL level at a more significant level when compared to the control group. Regarding atherogenic index and HDL ratio, the changes in atherogenic index were found to be statistically significant, whereas the changes and results observed in HDL, Triglyceride and HDL ratio were not statistically significant. Reports of renal and liver function tests before and after the trial proved that the trial drug produced no toxic effects on normal

physiology. Since primary hyperlipidaemia is an inherent defect, long term therapy is required to reverse the pathology. With this short period of assessment and limited sample size, we cannot draw a final conclusion about the long term potential benefits of *Thriphala rasayana*. Early diagnosis and judicious use of treatment strategies described in Ayurveda formulations can prevent secondary complications related with cardiovascular system. Treatment with drugs having antioxidant and free radical scavenging properties (*Rasayana prayogas*) explained in Ayurveda classics are highly beneficial in the management of non-communicable diseases. Particular care should be taken to prevent the harmful complications of metabolic error and vascular remodelling by educating the population about the necessity of early detection and proper managements.

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