



## Research Article

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### EFFECT OF AN AYURVEDIC COMBINATION IN ABNORMAL SERUM CHOLESTEROL LEVEL AND LIVER ENZYMES: A PILOT STUDY

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#### ABSTRACT

The production of intrinsic cholesterol is mainly regulated by Liver. Nowadays abnormal liver function and resulting metabolic syndrome are very common mainly due to drastic changes in life styles. Hence a drug which is having liver protective effect along with effect in reducing cholesterol levels is more suitable for these conditions. 10 patients having abnormal serum cholesterol levels and liver enzymes were selected for the study from the out-patient department of VPSV Ayurveda College Kottakkal and a pilot clinical trial was conducted using the Phanta kashaya (hot infusion) of 6 common drugs, namely Kiratathiktha [*Andrographis paniculata* (Burm.f.) Wall ex. Nees], Gokshura [*Tribulus terrestris* Linn.], Punarnava [*Boerhavia diffusa* Linn.], Bhringaraja [*Eclipta alba* (L.) Hassk.], Guduchi [*Tinospora cordifolia* Willd. Miers Ex Hook] and Bhoomyamalaki [*Phyllanthus amarus* Schum & Thonb] for 15 days. Serum cholesterol level and liver enzyme values were assessed before and after the study and paired t test was done for evaluation. Total cholesterol, very low-density lipoproteins and triglycerides level decreased significantly whereas level of high density lipoproteins significantly increased. In the case of transaminase values, even though there was reduction in the values, no statistical significance was observed.

**Key words:** Cholesterol, Liver enzymes

#### INTRODUCTION

Liver, the largest internal organ and the largest gland of the human body is the epicentre of intermediary metabolism. It performs versatile and massive biochemical pathways. It destroys bacteria, inactivates antigens and detoxifies harmful chemicals. Thus, multiple and diverse functions of liver have an impact on every tissue in the body. It is the only human internal organ capable of regeneration of lost tissue and as little as 25% of liver tissue can regenerate into a whole liver. Yet this great warrior is afflicted by certain ailments.

The resolution in the 63<sup>rd</sup> World Assembly of the World Health Organization in 2010 on prevention and control of liver diseases represents the first formal declaration by WHO that the burden of liver disease stands for a major global health problem<sup>1</sup>. Liver disease rates are steadily increasing over the years and have been ranked as the fifth most common cause of death in United Kingdom<sup>2</sup>. Also, it is recognized as the second leading cause of mortality amongst all digestive diseases in the US<sup>3</sup>. In the 2010 Global Burden of Disease (GDB) study, more than one million deaths were due to liver cirrhosis<sup>4</sup>. New Global Burden of Disease estimates for liver cirrhosis, published in BMC Medicine, suggest that cirrhosis caused over a million deaths in 2010, with a further million due to liver cancer and acute hepatitis<sup>5</sup>. Drug-induced liver injury is a major clinical problem which has become the leading cause of acute liver failure and transplantation in Western countries. Other important thing is that over the past couple of decades, the prevalence of Non-alcoholic fatty liver disease (NAFLD) and Non-alcoholic steatohepatitis (NASH) are increasing tremendously and even Non-alcoholic fatty liver disease has doubled during the last 20 years<sup>1</sup>. Recent studies show that the prevalence of NAFLD is one-third of the general population<sup>6</sup>. Most of these conditions are not recognisable at the

early stage or even in the progressing stage as there is no specific symptoms and the only parameter recognisable is altered liver function test report. At the end stage of liver diseases, liver transplantation is the only option available nowadays<sup>7</sup>.

The modern pharmacological measures are not addressing the disease, most of them simply suppressing symptoms and ignore the underlying disease processes. More over many current drug therapies for liver disorders are expensive and with side effects. In contrast, many natural products appear to address the cause of many diseases and yield better results. In the era of increasing popularity of herbal medicines, in place of mainstream medicines, discovery of new herbal medicines in this field has its importance. The rich knowledge from different traditional systems of medicine can lead to new avenues in herbal drug discovery process. Studies have already reported that natural sources of medicinal plant are unable to meet the demand for popular herbal products<sup>8</sup> and many combinations of medicinal plants are using effectively in these conditions. But many of them are lacking proper documentation.

This pilot study was aimed to document the efficacy of an Ayurvedic compound, commonly used by traditional Ayurvedic physicians, in altered liver condition. This combination is having 6 common drugs, namely Kiratathiktha [*Andrographis paniculata* (Burm.f.) Wall ex. Nees], Gokshura [*Tribulus terrestris* Linn.], Punarnava [*Boerhavia diffusa* Linn.], Bhringaraja [*Eclipta alba* (L.) Hassk.], Guduchi [*Tinospora cordifolia* Willd. Miers Ex Hook], Bhoomyamalaki [*Phyllanthus amarus* Schum & Thonb]. In many times, altered liver enzyme values were associated with the presence of high cholesterol level. Hence in this study, along with the effect on liver enzymes, cholesterol values were also included.

**MATERIALS AND METHODS**

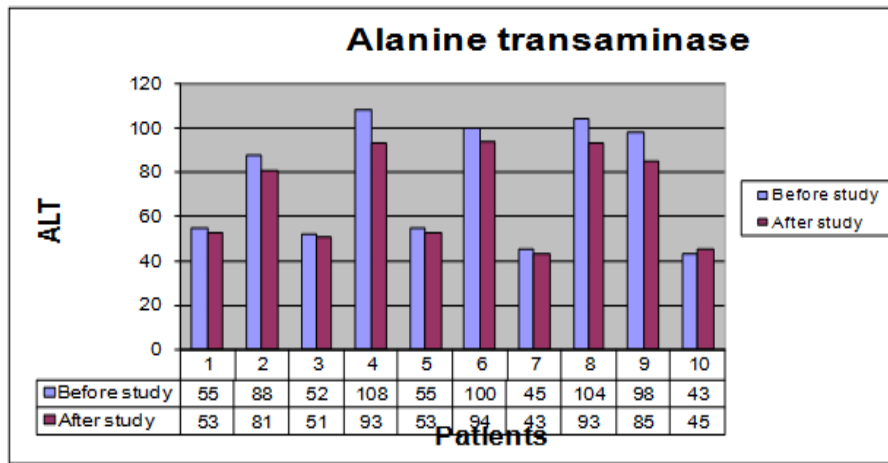
**Preparation of the drug:** All the 6 drugs namely Kiratatiktha [*Andrographis paniculata* (Burm.f.) Wall ex. Nees], Gokshura [*Tribulus terrestris* Linn.], Punarnava [*Boerhavia diffusa* Linn.], Bhringaraja [*Eclipta alba* (L.) Hassk.], Guduchi [*Tinospora cordifolia* Willd. Miers Ex Hook], Bhoomyamalaki [*Phyllanthus amarus* Schum & Thonb] were collected from their natural sources and were authenticated from the taxonomy department of Centre for Medicinal Plant Research, Changuvetty, Kottakkal. Then all of them were properly cleaned and dried in shade. Equal quantities of these drugs were taken and coarsely powdered using a pulverizer with a mesh (pore size of 40 nanometer). Then these were made into separate packets of 20 g. each. Patients with raised alanine transaminase (ALT), aspartate transaminase (AST) and lipid profile of age group 30 – 60 years irrespective of sex were selected for the study. Patients who were taking medications for other conditions, bed ridden patients and pregnant and lactating women were excluded. 10 participants were selected conveniently

from the Kayachikitsa outpatient department of VPSV Ayurveda college Kottakkal as per the inclusion and exclusion criteria. Assessment criteria were ALT, AST and Lipid profile values before and after the study.

Patients were given with the previously packed pouches and advise them to make phanta kashaya kalpana as per the classical reference. Then they were instructed to take 90 ml of this twice daily in empty stomach for 15 days. No special diet modification or lifestyle change was advised during this period. The data were assessed using paired t test and the result was interpreted properly.

**OBSERVATIONS AND RESULTS**

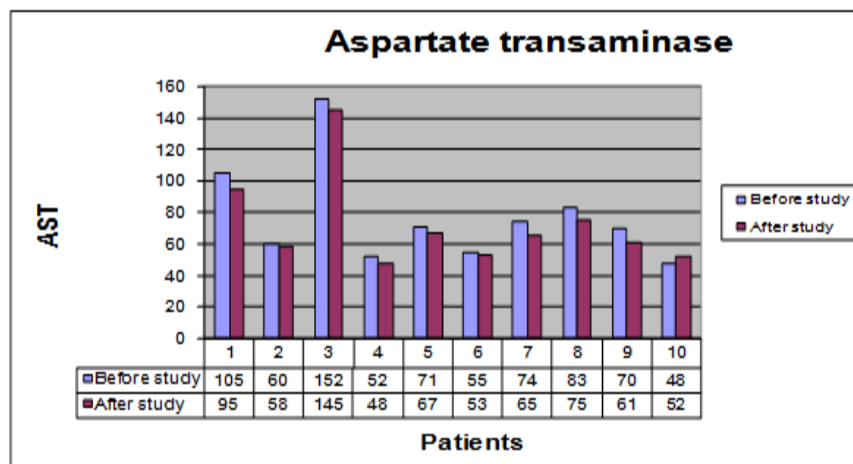
All 10 patients were having raised ASL, AST and lipid profile values. Before and after values were recorded and analyzed statistically using paired t test. The results of AST were shown in the table no. 1 and the graph no. 1. It shows a significant decrease in the ALT value after the treatment with p value of 0.05.



Graph 1: ALT values of 10 patients before and after the study

Table 1: Paired t test values of ALT

	Mean	SD	Paired t	P
Before treatment	82.5	24.3	1.66	0.05
After treatment	74	20.74		

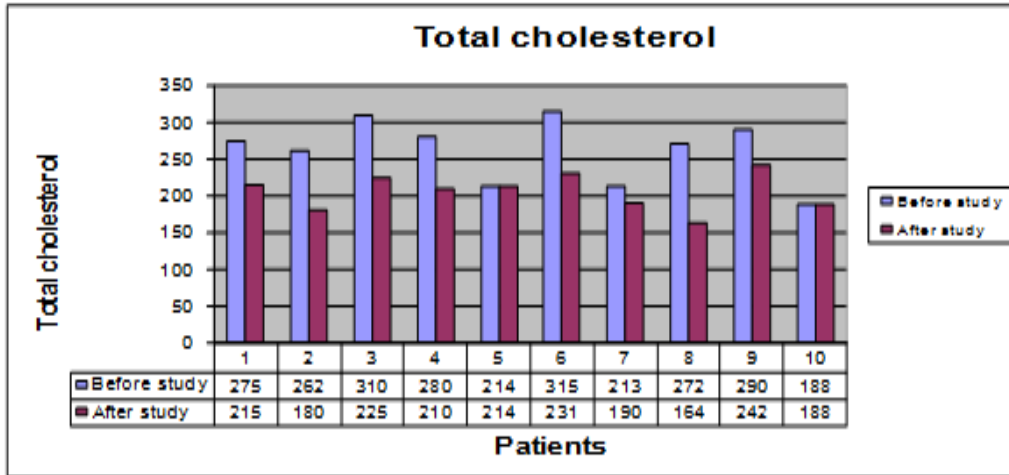


Graph 2: AST values of 10 patients before and after the study

**Table 2: Paired t test values of AST**

	Mean	SD	Paired t	p
Before treatment	85.75	30.5	1.29	0.10
After treatment	79.71	31.84		

There is a significant reduction in the total cholesterol level with a p value of 0.001 (Graph 3 and Table 3).

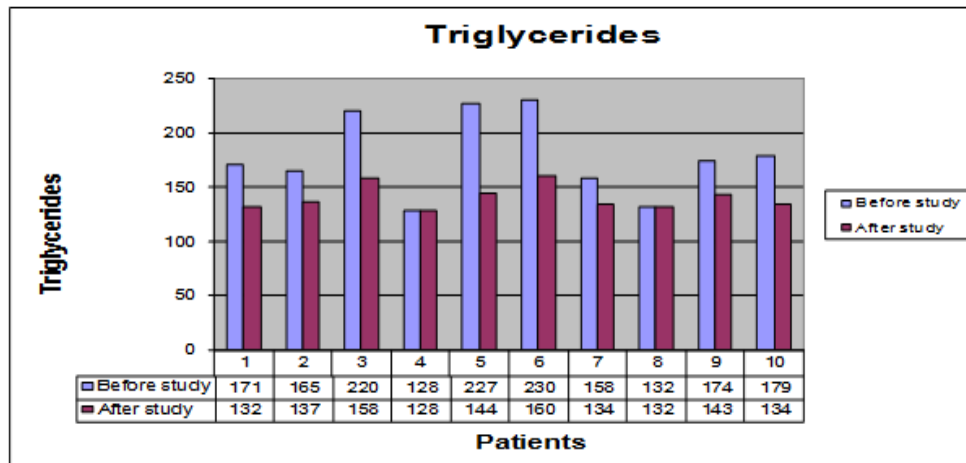


**Graph 3: Total cholesterol values of 10 patients before and after the study**

**Table 3: Paired t test values of Total cholesterol**

	Mean	SD	Paired t	p
Before treatment	261.9	43.04	4.724	0.001
After treatment	205.9	24.64		

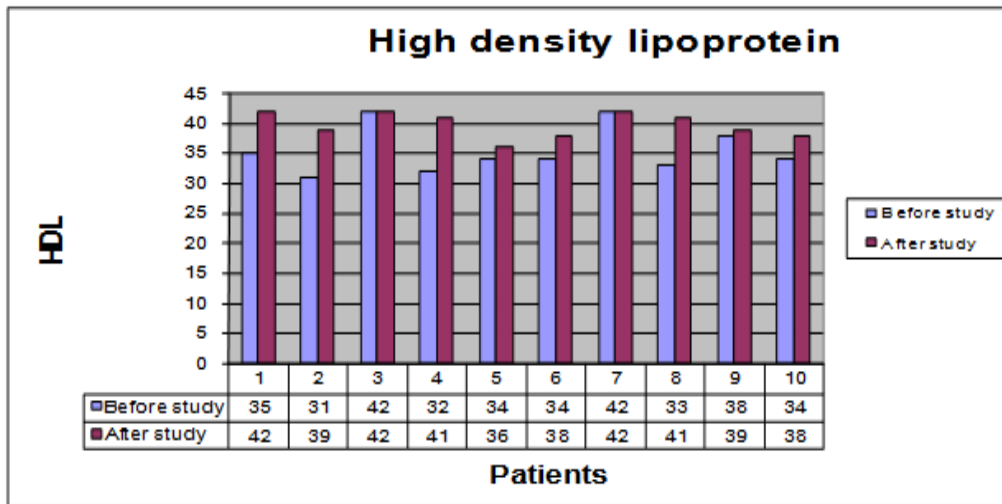
In the case of triglycerides also there is a significant reduction (Graph 4 and table 4).



**Graph 4: Triglycerides values of 10 patients before and after the study**

**Table 4: Paired t test values of Triglycerides**

	Mean	SD	Paired t	p
Before treatment	178.4	36.69	4.360	0.001
After treatment	140.2	11.06		

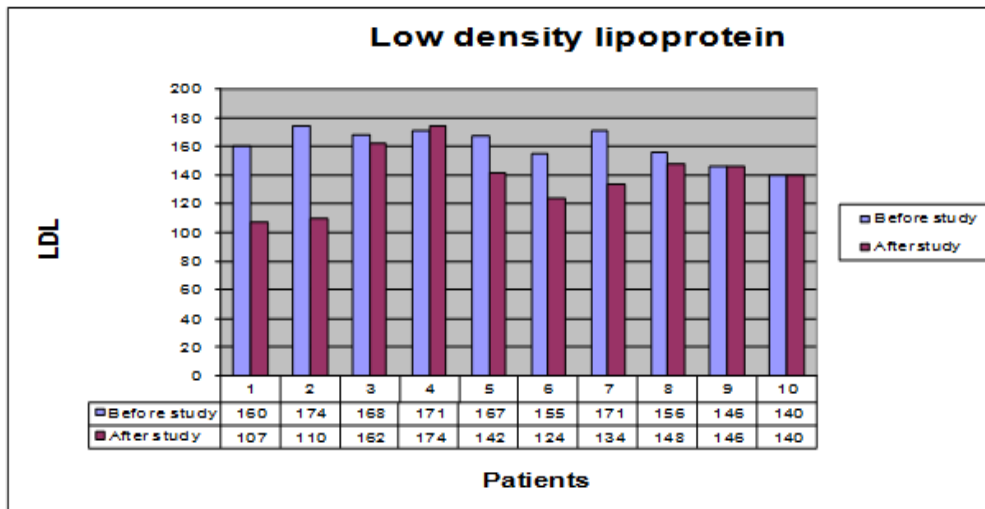


Graph 5: HDL values of 10 patients before and after the study

Table 5: Paired t test values of HDL

	Mean	SD	Paired t	P
Before treatment	35.5	3.89	-3.89	0.003
After treatment	39.8	2.1		

The High density lipoprotein significantly increased with a p value of < 0.01 (Graph 5 and table 5).

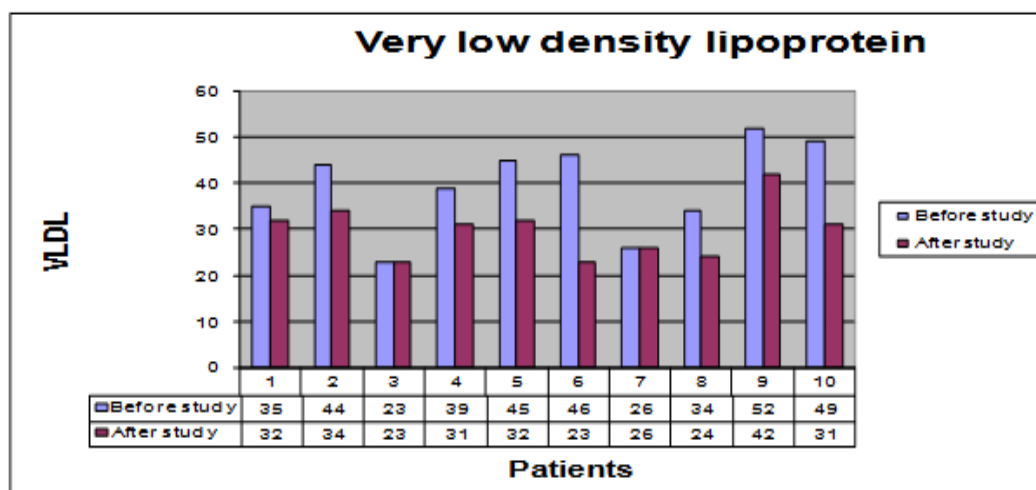


Graph 6: LDL values of 10 patients before and after the study

Table 6: Paired t test values of LDL

	Mean	SD	Paired t	P
Before treatment	160.8	3.89	2.94	0.016
After treatment	138.7	2.1		

There is only a slight reduction in the Low-density lipoproteins with a p value of < 0.05 (Table 6 and Graph 6). Very low-density lipoproteins were significantly reduced with a p value of < 0.01 (Graph 7 and Table 7).



Graph 7: VLDL values of 10 patients before and after the study

Table 7: Paired t test values of VLDL

	Mean	SD	Paired t	p
Before treatment	39.3	9.68	3.98	0.002
After treatment	29.8	5.96		

## DISCUSSION

After the intervention, total cholesterol, very low-density lipoproteins and triglycerides decreased significantly whereas high-density lipoproteins significantly increased which is a positive finding. In the case of low density lipoproteins, only a mild reduction was noticed. In the case of transaminase values, even though there is reduction in the values, no statistical significance was observed.

Most of these plants have significant effect on pathological liver conditions and on cholesterol values as per reported animal and culture studies<sup>9-18</sup>. But the clinical effect of them in single form or in combination was not documented yet. From this study it was evident that the combination is very much effective in lowering the cholesterol level even with 15 days of medication. This effect may be due to the presence of Beta sitosterol and tannin present in most of these plants. Tinosporin and tinosporidin present in *Tinospora cordifolia* has got significant antioxidant and liver cell degenerative properties. Moreover, this is a famous Rasayana drug as per Ayurveda<sup>19</sup>. Andrographin, Andrographaloid and other related bitter alkaloids present in the *Andrographis paniculata* have got excellent liver protective, antioxidant and wound healing properties. It is already proved its positive effect in liver damage and also in hypercholesterolaemic conditions in rat<sup>20</sup>. Presence of these secondary metabolites may be the contributing factor for the result.

Even though there is a visible change in the transaminase level, there is no statistical significance. Usually the changes in the liver enzymes level will take place only by at least 30 – 45 days<sup>22</sup>. Here the interventional period was only 15 days. This may be the reason for not getting a significant change in the ALT and AST level.

## CONCLUSION

This combination is effective in reducing lipid parameters. Further studies have to be conducted with enhancement in the period of intervention so as to reach a conclusion on the efficacy. Other such combinations also must be studied in an evidence based manner

so as to augment the Ayurvedic management in such clinical conditions.

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