



Clinical Study

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A clinical study on efficacy of Yavamalaka choorna in dyslipidemia

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ABSTRACT

Dyslipidemia is a disorder characterized by abnormally high concentrations total Cholesterol, VLDL, LDL, triglycerides and decreased concentration of HDL in the blood caused by abnormal lipid and lipoprotein metabolism and has risk of producing various complications like cardiovascular diseases, diabetes, obesity, hypertension, atherosclerosis etc. Dyslipidemia is a condition which shares a lot of similarity in pathogenesis and clinical presentation of Medoroga. It is a single blind comparative clinical study with pre test and post test design where in minimum of 40 patients of Dyslipidemia are randomly grouped into two groups with 20 patients in each. Group A were administered with Yavamalaka Choorna 6 grams BID before food with warm water for 60 days and group B were administered with shuddha guggulu 3 grams BID before food with warm water for 60 days. In this present study there is a significant improvement after treatment in lipid profile, weight loss in both groups, but there are no significant changes between the groups. Percentage of weight loss is more in Group A compared to group B. As there is both groups show significant results, Yavamalaka choorna can be substituted with shuddha guggulu vati. Also yavamalaka Choorna is easily available and cost effective compared with shuddha guggulu.

Keywords: Dyslipidemia, Medoroga, Yavamalaka Choorna, Shuddha Guggulu.

INTRODUCTION

Quality foods are one of the important key factors in lifestyle modification. The food articles for daily consumption are listed in most of the classical texts of Ayurveda. Some of them are Shali (rice), Mudga (green gram), Saindhava Lavana (a type of salt under moderation), Amalaki (*Embelica officinalis* – Indian gooseberry), Yava (*Hordium vulgare*), Antariksha Jala (Pure water), Paya (Milk), Sarpi (ghee), Jangala Mamsa (meat from arid places), Madhu (honey) [1].

Lipids are part of our food. Hence, lipid metabolism is a continuous process. Dyslipidemia, elevation of plasma cholesterol, triglycerides (TGs), or both, or a low high density lipoprotein level, may occur at any stage of life [2]. Observational studies like Framingham Study have documented dyslipidemia as one of the factors that increase the risk of cardiovascular diseases [3]. Cardiovascular diseases are major causes of mortality in the Indian subcontinent, causing more than 25% of deaths. It has been predicted that these diseases will increase rapidly in India and this country will be host to more than half the cases of heart disease in the world within the next 15 years in India [4].

Because dyslipidemia is a chronic condition, it has to be managed by means of long term consumption, with no adverse effect, since they need regular management. The selected option must be economical, easily available, easy to administer and can be practiced for a longer duration. Hence, those among the Nityasevanadravya are preferable. Yava and Amalaki, which are among the food articles for daily consumption, are mentioned to have Medohara action. Yava is having the properties like Ruksha, Guru and Mrudu Gunas which act as Medahara [5]. The Sheetaveerya of the drug causes satiation by balancing the aggravated Agni. Amalaki as Pitta pradhana, Tridoshashamaka, Medoroga Nashaka. Pitta and Agni are interrelated; hence this action of the drug controls derangement of both Agni and Tridosha [6]. It is also having ascorbic acid, carotene and bioflavonoids that act on abnormal lipid levels in blood [7]. Thereby either preventing atherosclerosis or scraping out atherosclerotic plaques.

A clinical study done to evaluate the effect of Yavamalaka churna in prevention of Stoulya, revealed significant reduction in total and LDL cholesterol and enhancement of HDL [8]. Based on these points, Yavamalaka churna is selected for research.

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Research Question

Does the oral administration of 6 g of Yavamalaka Choorna with warm water consumed before food has hypolipidemic effect?

Objectives

Keeping in view, the magnitude of the complications caused by dyslipidemia, this present study, entitled, "A Clinical Study on Efficacy of Yavamalaka Choorna in Dyslipidemia" has been carried out to fulfill the following aims and objectives-

1. To evaluate the efficacy of Yavamalaka Choorna in Dyslipidemia.
2. To evaluate the efficacy of Shuddha Guggulu in Dyslipidemia.
3. To compare the efficacy of Yavamalaka Choorna and Shuddha Guggulu in Dyslipidemia

MATERIALS AND METHODS

Source of data

Subjects visiting S.D.M College of Ayurveda and hospital Hassan.

Method of collection of data

Persons fulfilling the diagnostic and inclusive criteria were selected for the study.

Diagnostic criteria ^[9]

Total cholesterol:	>200 mg/dL [>5.18 mmol/L]
LDL-cholesterol:	>100 mg/dL [>2.59 mmol/L]
VLDL-cholesterol:	>40mg/dl [>1.04 mmol/L]
Triglycerides:	>150 mg/dL [>3.88 mmol/L]
HDL-cholesterol:	Men - <40 mg/dL [<1.04 mmol/L] Women - <50 mg/dL [<1.29 mmol/L]

Inclusive criteria

- Age group: 18-60 yrs
- Sex: Either gender
- Subjects having all or at least any one of the diagnostic criteria were selected for the study.

Exclusion criteria

1. Subjects having history of serious cardiac disorders like myocardial infarction, cardiac failure, etc.
2. Subjects having any major illness, diabetes mellitus, was poorly controlled or newly diagnosed or if the patient was taking some new therapy or recently adjusted therapy
3. Subjects having a history of thyroid disorder, renal disorder, cholelithiasis and PCOS.
4. Dyslipidemia due to Consumption of drugs such as glucocorticoids.
5. Pregnant females and lactating mothers.

Concomitant medication

1. Known lipid-lowering drugs like statins or fibrates were stopped during the study.

Study design

Groups

The Subjects with dyslipidemia willing to undergo study and fulfilling the inclusive criteria were randomly divided into two groups.

Group A: A group of 20 Subjects were given with Yavamalaka Choorna in a dosage of 6g twice daily with warm water before half an hour of food for 2 months.

Group B: A group of 20 Subjects were administered with Shuddha Guggulu Vati in the dosage of 3g twice daily with warm water as Anupana before food.

Assessment Criteria

Biochemical tests: Total cholesterol, LDL, VLDL, Triglycerides, HDL

Data Analysis

The findings before and after treatment were recorded and evaluated statistically by using Paired and Unpaired t test.

Preparation of Yavamalaka Choorna

Source and authentication of Drugs: The drugs were procured and authenticated from SDM College of Ayurveda Hassan.

Genuine dry deseeded Amalaki(*emblica officinalis*) and Grains of good quality Yava (*Hordium vulgare*) were bought from the market. They were mixed in equal quantity, powdered and preserved in tight lidded bottle.

Preparation of Shuddha Guggulu Vati

Source and authentication of Drugs: The drugs were procured and authenticated from SDM College of Ayurveda Hassan.

Ashodhita Guggulu is broken into small pieces and bundled in a piece of the cloth and boiled in Dola Yantra containing Gomutra. The boiling is continued till the Guggulu becomes a soft mass. It is then taken out of the cloth and spread over a smooth wooden board smeared with ghee or oil. By pressing with fingers. The sand and other remaining foreign impurities are removed. It is taken out and again fried with ghee and ground in stone mortar (khalva). This is Shodhita Guggulu. Then it is rolled into pills of 500mg each and dried.

IEC clearance number- SDMCAH/IEC/54/12-13 was gained from the institution for the study

RESULTS

Effect of Treatment

In the present study, 40 patients of dyslipidemia were registered and were randomly placed under 2 Groups. 20 patients were treated in Group A with yavamalaka choorna and 20 patients were treated in Group B with shuddha guggulu. The Effects of these treatments on the objective parameters are presented.

Table 1: Effect on lipid profile of Group A

Lipid values	Mean score		Difference In Means	Paired "t" Test				
	BT	AT		% Relief	S.D.	S.E.M	't'	P
Cholesterol	213.7	185.7	28.00	13.10	12.31	4.2	4.57	<0.001
Triglyceride	225.9	181.7	44.20	18.68	32.67	11.82	2.28	<0.001
HDL	41.6	48.3	6.7	16.10	2.76	2.24	4.06	<0.001
LDL	132.8	114..7	18.10	13.62	5.42	2.37	4.38	<0.001
VLDL	38.7	31.4	7.30	18.86	4.56	3.12	4.78	<0.001

The above table illustrates that in Group A. S.Cholesterol was reduced by 13.10 %, S.Triglyceride was reduced by 18.68 %, HDL was raised by 6.7 % LDL was reduced by 13.62 %, VLDL was reduced by 18.86 % which were all statistically significant at $p < 0.001$.

Table 2: Effect on Weight of Group A

Mean score		Difference in Means	Paired "t" Test				
BT	AT		% Relief	S.D.	S.E.M	't'	P
71.00	68.6	2.4	4.78	0.977	0.218	12.244	<0.001

The table indicates 4.78 % reduction in weight which is statistically significant at $p < 0.001$.

Table 3: Effect on BMI of Group A

Mean score		Difference in Means	Paired "t" Test				
BT	AT		% Relief	S.D.	S.E.M	't'	P
27.88	26.92	0.953	3.41	0.48	0.15	6.28	<0.001

The table indicates the reduction in BMI by 3.41 % which is statistically significant at $p < 0.001$.

Table 4: Effect on lipid profile of Group B

Lipid values	Mean score		Difference In Means	Paired "t" Test				
	BT	AT		% Relief	S.D.	S.E.M	't'	P
Cholesterol	208.2	182.3	25.9	12.43	17.84	4.98	5.704	<0.001
Triglyceride	220.9	179.5	44.1	19.96	18.9	5.73	4.534	<0.001
HDL	39.0	44.6	5.58	14.30	14.02	3.88	2.721	<0.001
LDL	127.5	109.9	17.58	13.78	14.75	4.09	1.853	<0.001
VLDL	40.9	28.2	8.66	21.17	8.94	2.48	4.301	<0.001

The above table illustrates that in Group B. S.Cholesterol was reduced by 12.43 %, S.Triglyceride was reduced by 19.96 %, HDL was raised by 6.7 % LDL was reduced by 14.30 %, VLDL was reduced by 21.17 % which were all statistically significant at $p < 0.001$.

Table 5: Effect on Weight of Group B

Mean score		Difference in Means	Paired "t" Test				
BT	AT		% Relief	S.D.	S.E.M	't'	P
69.28	67.6	1.68	2.42	1.59	0.714	2.383	<0.001

The table indicates 2.42 % reduction in weight which is statistically significant at $p < 0.001$.

Table 6: Effect on BMI of Group B

Mean score		Difference in Means	Paired "t" Test				
BT	AT		% Relief	S.D.	S.E.M	't'	P
28.37	27.50	0.87	3.06	0.67	0.187	5.704	<0.001

The table indicates the reduction in BMI by 3.06 % which is statistically significant at $p < 0.001$.

Effect of Treatment Between Group A And Group B

Table 7: Comparison between group A and group B on S.Cholesterol

Group	N	AT-BT	Unpaired 't' test			
			S.D.	S.E.M	't'	P
A	20	28.00	12.31	4.20		
B	20	25.9	17.84	4.94	-0.872	0.808

The comparative Effect on cholesterol between the two groups is statistically insignificant at $p = 0.808$.

Table 8: Comparison between group A and group B on S.Triglyceride

Group	N	AT-BT	Unpaired 't' test			
			S.D.	S.E.M	't'	P
A	20	44.20	12.31	11.82		
B	20	44.1	18.9	15.73	-1.279	0.394

There is not a statistically significant difference between the input groups ($P = 0.394$).

Table 9: Comparison between group A and group B on HDL

Group	N	AT-BT	Unpaired 't' test			
			S.D.	S.E.M	't'	P
A	20	-6.7	2.76	2.24		
B	20	-5.58	5.46	3.88	0.246	0.541

There is not a statistically significant difference between the input groups ($P = 0.541$).

Table 10: Comparison between group A and group B on LDL

Group	N	AT-BT	Unpaired 't' test			
			S.D.	S.E.M	't'	P
A	20	18.10	15.42	2.37	-0.622	0.632
B	20	17.58	14.75	4.09		

There is not a statistically significant difference between the input groups ($P = 0.632$).

Table 11: Comparison between group A and group B on VLDL

Group	N	AT-BT	Unpaired 't' test			
			S.D.	S.E.M	't'	P
A	20	7.30	4.56	3.12		
B	20	8.77	8.94	2.48	-0.486	0.227

There is not a statistically significant difference between the input groups ($P = 0.227$).

Table 12: Comparison between group A and group B on Weight

Group	N	AT-BT	Unpaired 't' test			
			S.D.	S.E.M	't'	P
A	20	2.24	0.977	0.218		
B	20	1.68	1.59	0.714	-0.695	0.216

There is not a statistically significant difference between the input groups (P = 0.216).

Table 13: Comparison between group A and group B on BMI

Group	N	AT-BT	Unpaired 't' test			
			S.D.	S.E.M	't'	P
A	20	0.953	0.48	0.153	-1.279	0.394
B	20	0.87	0.67	0.187		

There is not a statistically significant difference between the input groups (P = 0.394).

DISCUSSION

Considering symptoms presenting in Dyslipidemia, it is easy to consider the involvement of Kapha and pitta dosha.

In Hypercholesterolaemia, manifestations like Atherosclerosis, increased LDL, xanthomas and xanthelasma can be understood as Dhamani pratichaya, malasya adhikyam^[10] kleda and sneha upadehatvam^[11] respectively. In Hypertriglyceridaemia, xanthomas and eruptive xanthomas and lipaemia retinalis etc can be understood as pidika^[12] and raga yathaswam^[13].

In combined hyper cholesterolaemia, in this type there will be both Cholesterol and Triglyceride increase presenting with combined symptoms. Most of the times the patients comes with secondary causes of Hyperlipidaemia like obesity, diabetes mellitus, alcohol abuse, renal failure, Nephrotic syndrome etc indicates the predominance of Kapha and medodhatu in Medoroga.

As risk of CHD is at high significance in patients with Dyslipidemia is indicated by the symptoms explained as kaphaja nanatmaja vikara like Dhamani pratichaya and Hridayopalepa.

Coming to the treatment aspect guru cha atarpana, vata, sleshma medo hara, vyayama, rukshana and Shodana are the principles of treatment in Medoroga. Guru cha atarpana, vata sleshma medohara in the form anna pana and even aushada becomes major part of treatment. Nidana parivarjana stands as prime step in treatment and vyayama acts as both sleshma and medo hara.

A total of 40 patients fulfilling the inclusion criteria were registered and randomly grouped under 2 different groups i.e Group A and Group B with 20 patients each. Group A was administered with Yavamalaka choorna 6g twice a day before food and Group B was administered with shuddha guggulu 3g twice a day before food.

In this study it was found that the incidence was highest in the age group of 41-50 years constituting 37.5% of total number of patients. 35% patients were in the age group of 20-40 yrs and 27.5% were in the age group of 51 – 60 years. This is in concurrence with the increased incidence of Dyslipidemia in the middle age groups. But a conclusion cannot be drawn as the sample size is small. In the sample taken for the study, 62.5% patients were males in comparison to 37.5% of female patients. This indicates the increased incidence of Dyslipidemia in the male population but a conclus

the incidence of Hindus was 80%, and Muslims was 20%. As the sample size is small it doesn't represent the geographical as a hole.

Majority of the patients were graduates constituting 50%, 7.5% had their high school education, 15% were primary educated, 15% had their middle school education, 17.5% had their PUC education, 10% of the sample were uneducated. Most of the patients were married comprising of 67.5% and the remaining 32.5% were unmarried.

Majority of patients belonged to the upper middle class 42.5%, 50% were in lower middleclass, 7.5% were belonged to upper class This is in concurrence that Dyslipidemia is ubiquitous regardless of economic status. Maximum number of patients were no physical work (50%), 27.5% were belong to mild physical work, 17.5% were belong to moderate physical work, 5% were belong to heavy physical work.

In this study it was found that 17.5% of the patients had tea/coffee addiction. 40% were addicted to smoking. 10% were addicted alcohol and 52.5% had no addictions. It is difficult to draw any conclusions as the sample size is small. 72.5% of the patients were using mixed diet while 27.5% were using vegetarian diet. This indicates importance of samisha ahara in causing Medoroga. As the sample size is small it is difficult to draw a definite conclusion. In the present study, 57.5% of patients had habit of day sleep and 42.5% patients didn't had day sleep. this shows the day sleep as one nidana of Medoroga. 25% of patients had a family history of Medoroga and Dyslipidemia while 75% didn't had any family history of same. 67.5% were belong to urban area, 32.5% patients were belong to rural area. It indicate thr prevalence of dyslipidemia more in the urban area. A majority of patients (40%) belonged to Kaphavata Prakriti, 30% belonged to Kapha-Pitta Prakriti. 12.5% belonged to Kapha prakriti and 17.5% belonged to Vatapitta Prakriti. Thus kapha predominant either associated with Vata or Pitta, is more in predisposing the disease Medoroga and Dyslipidemia.

In Group A 13.10% reduction was observed in S.Cholesterol while 12.43% reduction was observed in Group B. Both the results were statistically significant (P < 0.001). But percentage relief was more in Group A. S.Triglyceride reduced by 18.68% in Group A, whereas 19.93% reduction was observed in Group B. Both the results were statistically significant (P < 0.001). However percentage relief was more in Group B. S.HDL level was increased up to 16.10% in Group A while in Group B by 14.30%. Both the results were statistically significant (P < 0.001). But percentage relief was more in Group A. Reduction observed in S.LDL was 13.62% in Group A while 13.78% reduction was observed in Group B. Both the results were statistically significant (P < 0.001). Thus, Group B provided little better result in reduction of S.LDL. In Group A, there was 18.86% reduction in S.VLDL while 21.17% reduction was found in Group and both the results were statistically significant (P < 0.001). But percentage relief was more in Group B. Among all lipid parameters the percentage reduction in Cholesterol, increase HDL was more seen in Group A than Group B. The percentage increase in LDL, VLDL, and Triglycerides was more in Group B than Group A. In Group A there was 4.78% reduction which is statistically significant (p < 0.001) while in Group B there was 2.42% reduction which is statistically significant (p < 0.001). But percentage relief was more in Group A. In Group A, 3.41% reduction which is statistically significant (p < 0.001) while in Group B there was 3.06% reduction which is statistically significant (p < 0.001). But percentage relief was more in Group B.

The combination of Yava (*Hordium vulgare*) and Amalaki (*emblica officinalis*) are effective in Medoroga as it fulfills the criteria of Guru Cha Atarpana. The drug Yava (*Hordium vulgare*) is having the properties like Ruksha, guru and mrudu gunas which act as Medahara. The Sheeta veerya of the drug causes satiation by balancing the aggravated Agni. One of the actions of this drug is pureesha krut. It shows the drug increases the quantity of faeces by eliminating excess of fat and faeces is the only route to eliminate lipid from the body. The action of Yava (*Hordium vulgare*) can be explained in the terms of modern science as follows. The barley is rich in fiber and constitutes around 3.9% of the drug. There are many drugs which are rich in fiber but the type of fiber is responsible for its action. It is the barley which is rich in water soluble fiber and body needs this type of fiber. Even wheat is rich in fiber but that is not rich in water soluble fiber. The functions attributed to water soluble fiber are many in number. Few of them are explained here. The fiber increases the gastric emptying time by taking long duration to get partly digested. There by it initiates the satiety

centre and reduces the food intake. Even its movement through the intestines is sluggish. It hinders the absorption through the villi thereby reducing the energy uptake. It mainly affects the absorption of fat, as the fat is having high molecular weight. It also affects the enteric re-absorption of cholesterol there by reducing the cholesterol level and initiates the movement of stored fat. All these actions bring about increased gastric emptying time, excess utilization of energy, mobilization of stored fat for the purpose of utilization, hampered re-absorption of enteric cholesterol and fat [14].

Classics have dealt Amalaki (*emblica officinalis*) as Pitta pradhana Tridosha shamaka. Pitta and Agni are interrelated; hence this action of the drug controls derangement of both Agni and Tridosha. Till recent days it was believed that the different actions of the drug are due to its rich vitamin C content. But now it is established that the different types of tannins present in it is responsible for its multi-factorial action. These tannins are said to be useful in maintenance of micronutrient level in the body system. Thus it gives strength but does not yield energy i.e. it helps in the utilization of stored energy. The vilavana pancha rasa may be responsible for good actions as sarva rasa sevana results health. The sheeta Virya pacifies agni thereby inducing satiety. Thus the combined action of all the properties of the drug is responsible for its beneficiary effects. There are many works done on the drug Amalaki regarding its different action but there is no only single factor responsible for its action [15].

CONCLUSION

The present study was conducted on dyslipidemia stressing upon literary, diagnostic as well as therapeutic standpoint of dyslipidemia under the light of both modern and Ayurveda. Dyslipidemia can be studied under the broad umbrella of Medoroga. By the literary research it can be concluded that the Medoroga chikitsa by the of principle GURU CHA ATARPANA which plays an important role in Medoroga in reducing its symptoms by vighatana of its Samprapti. Dyslipidemia is one of the major modifiable risk factors for atherosclerosis and its consequences. Both the groups (A and B) showed reduction in serum T. cholesterol, T.G., LDL, VLDL and statistically significant increase in HDL levels. In both groups there was reduction in body weight but compare to group B, in group A good weight loss was noted. There was no statistically significant difference between the results of group A and group B. Yavamalaka choorna can be substitute for Shuddha Guggulu Vati.

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Conflict of Interest: None Declared.

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