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Research Article

A COMPARATIVE CLINICAL EVALUATION OF *AMRITADYA GUGGULU* WITH AND WITHOUT *YAVAMALAKI CHOORNA* IN THE MANAGEMENT OF DYSLIPIDEMIA

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ABSTRACT

As a result of confronting challenges of modernization, man has adapted himself to the fast paced life by modifying his dietary and lifestyle preferences to suit the modern era. This has resulted in a state of discrepancy between the external environment and his internal mechanism causing multitudes of diseases which referred as "lifestyle diseases". Dyslipidemia is a condition in which the level of lipoproteins (cholesterol, triglycerides or both) is raised in the plasma. For this "Amritadya Guggulu" mentioned in *Chakradatta* and "Yava Amalaki Choorna" mentioned in *Charaka sutra sthana* is selected. The ingredients of *Amritadya Guggulu* like Guduchi, Truti, Vella, Vatsaka, Triphala are *Medohara* and *Tiktarasa pradhana* which is *Kapha vata hara*, *Laghu*, *Kapha shoshaka* effective in case of Dyslipidemia on the other hand *Yava Amalaki choorna* is also having *Medohara* property. In the present study, 40 patients of Dyslipidemia were registered and were randomly placed and observed in two groups, treated with *Amritadya Guggulu* and *Amritadya Guggulu with Yavamalaki Choorna* for 30 days. Each disease feature was scored according to the assessment criteria and each patient was assessed and scored with respect to his/her presenting complaints. Respective scores were subjected for statistical analysis using paired student 't' test for the individuals groups and unpaired student 't' test to compare both the groups.

INTRODUCTION

In today's era lifestyle disorders such as dyslipidemia, obesity, diabetes mellitus, atherosclerosis, coronary artery disease, cerebrovascular accident are more common due to the change in the food habits and the standard of living. These are the major burning problems now days the population are facing.^[1]

Dyslipidemia is defined as abnormal amount of lipids (eg: cholesterol and /or fat) in the blood. In developed countries most dyslipidemias are Hyperlipidaemia; that is, an elevation of lipids in the blood. Cardiovascular disease remains the number one cause of mortality and morbidity that is due to the common risk factors such as Dyslipidemia and Hypertension.^[2]

Total cholesterol increase on the average more than 2mg/Dl per year during early adulthood and continuously increasing. Men 45 years or older and women aged 55 years or older are considered to be have age as a risk factor. In the world wide review, according to W.H.O over all raised cholesterol is estimated to cause 2.6 million deaths of 45% total population and 29.7 million disability.^[3]

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Abnormal cholesterol levels are estimated to cause 18% of the global CVDs and 56% of the global Ischemic Heart Disease (IHD). For every 1% reduction in lipid level, the risk of heart disease reduces by 2.5%. Dyslipidemia is an established risk factor for atherosclerotic disease^[4]. The causes of cardiovascular disorders are multi factorial. Some of these factors related to lifestyles, such as tobacco, smoking, lack of physical activity and dietary habits are thus modifiable. Other modifiable risk factors are elevated blood pressure, Type 2 diabetes, dyslipidemias and non-modifiable factors are age and male gender^[5].

According to Ayurveda Dyslipidemia can be correlated to raise 'Meda' in the body. In Ayurvedic classics, various scholars have tried to use distinct nomenclature for the same like *Rasagata Sneha Vriddi*, *Rasa Rakta gata Sneha Vriddi*, *Medovriddhi*, *Medoroga* or *Medo dosha*, *Sthoulya*, *Ama Medo Dhatu* etc. Attempts were made by various Acharyas stated under broad umbrella of *Santarpanajanya vyadhis*. If we look into Ayurvedic perspective, it becomes clear that *Kapha (Kledaka)*, *Vata (Samana & Vyana) Meda* (fat/lipids) & *Medodhatwagni* are involved in the pathogenesis of *Medoroga* (Dyslipidemia).

In Ayurvedic classics there are a number of herbal and herbo-mineral compounds for the management of Dyslipidemia. Although a number of research works have been done on management of Dyslipidemia, still more formulations should be tried for the effective management of this dreadful disease. For this "*Amritadya Guggulu*" mentioned in Chakradatta^[6] and "*Yava Amalaki choorna*" mentioned in *Charaka sutra sthana*^[7] are selected. The ingredients of *Amritadya Guggulu* like *Guduchi*, *Truti*, *Vella*, *Vatsaka*, *Triphala* are *Medohara* and *Tiktarasa pradhana* which is *Kapha vata hara*, *Laghu*, *Shleshma upashoshaka* effective in case of dyslipidemia on the other hand *Yava Amalaki choorna* is also having *medohara* property.

OBJECTIVES

1. To evaluate the efficacy of *Amritadya Guggulu* in management of Dyslipidemia.
2. To evaluate the comprehensive effect of *Amritadya Guggulu* and *Yava Amalaki Choorna* in

Demographic data

Age

Table 1: Age wise distribution of patients

Age in years	No. of patients		Total	Percentage
	Group 1	Group 2		
30-40	4	3	7	17.5%
40-50	8	6	14	35%
50-60	5	9	14	35%
60-70	3	2	5	12.5%

the management of Dyslipidemia.

3. To compare the effect of *Amritadya Guggulu* with and without *Yava Amalaki Choorna* in the management of Dyslipidemia.

Methodology

For the present study 55 patients of either sex of age group 30-70 yrs and diagnosed as Dyslipidemia is selected. The patient will be selected strictly abiding to the inclusion and exclusion criteria. The patients thus selected will be randomly grouped into two group of size each 20. The first group will be administered "*Amritadya Guggulu*" 500mg 2 tablets twice daily before food (morning and night) and the duration of the treatment will be 30 days. The second group will be administered "*Amritadya Guggulu*" same as in first group with "*Yavamalaki Choorna*" for 30days.

Inclusion Criteria

1. The age groups of 30-70 years were selected because *Madhyama vaya* is said to be the most active phase of the life with lots of physical and mental stress, incompatibility in dietary habits which can trigger the disease.
2. Patients presenting with elevated lipid profile values and decreased HDL values are included.
3. There is no hard and fast rule that all the Dyslipidemia patients are obese. So the patients with or without obesity were included, to analyze the effect of therapy on weight and BMI

Exclusion Criteria

1. Patients who have received anti cholesterol medication within last 8 weeks were excluded from the study in order to avoid the counter action of drug
2. Uncontrolled and metabolic disorders other than Dyslipidemia were excluded because the patient having cardiovascular disease and hypertension may need emergency treatment.

Observations

The analyses of observation of clinical study were done by using the appropriate statistical data. The observations documented during the present study with respect to demographic data, clinical data were present in the tables.

In the study maximum patients were seen in the age group 40-60 years

Table 2: Sex wise distributions of patients

Sex	No of patients		Total	Percentage
	Group 1	Group 2		
Male	14	13	27	67.5%
Female	6	7	13	32.5%

In this study maximum patients were male (67.5%), rest (32.5%) were females.

Table 3: Religion wise Distribution of Patients

Religion	No of patients		Total	Percentage
	Group1	Group 2		
Hindu	2	4	6	15%
Muslim	10	6	16	40%
Christian	8	18	18	45%

In this study shows that among 40 patients, maximum number of patients belongs to Christian religion (45%) and Muslim religion (40%), minimum number of patients belongs to Hindu religion (15%).

Marital Status

Table 4: Marital status wise distribution of patients

Marital status	No of patients		Total	Percentage
	Group 1	Group 2		
Married	19	18	37	92.5%
Unmarried	1	2	3	12.5%

In the study among 40 patients, 37 patients (92.5%) were married and 3 patients (12.5%) were unmarried.

Educational Status

Table 5: Education wise Distribution of Patients

Educated	No of patients		Total	Percentage
	Group1	Group2		
Uneducated	0	1	1	2.5%
Primary school	1	1	2	5%
Middle School	2	0	2	5%
High school	2	3	5	12.5%
Graduate	8	10	18	45%
Post graduate	7	5	12	30%

In this study maximum number of patients was graduates (45%)

Socio Economic Status

Table 6: Socio economic Distribution of Patients

Socio economic status	No of patients		Total	Percentage
	Group1	Group2		
Poor-lower middle class	3	1	4	10%
Middle class	8	7	15	37.5%
Upper middle class	9	12	21	52.5%

In this study, maximum patients (52.5%) were upper middle class.

Occupation**Table 7: Occupation wise Distribution of Patients**

Occupation	No of patients		Total	Percentage
	Group1	Group2		
House wife	4	5	9	22.5%
Business	10	8	18	45%
Carpenter	1	0	1	2.5%
Teacher	2	3	5	12.5%
Banker	1	1	2	5%
Engineer	2	3	5	12.5%

In this study maximum number of patients (45%) were in business.

Nature of Work**Table 8: Nature of Work wise Distribution of Patients**

Nature of work	No of patients		Total	Percentage
	Group1	Group 2		
Sedentary	14	12	26	65%
Physical stress	4	4	8	20%
Mental stress	2	4	6	15%

In this study, maximum number (65%) of patients had sedentary nature of work.

Addictions**Table 9: Addiction wise Distribution of Patients**

Addiction	No of patients		Total	Percentage
	Group1	Group2		
Tea and Coffee	7	10	17	42.5%
Alcohol	11	8	19	47.5%
No addictions	2	1	3	7.5%

Diet**Table 10: Diet wise Distribution of Patients**

Diet	No of patients		Total	Percentage
	Group1	Group2		
Mixed	16	13	29	72.5%
Vegetarian	4	7	11	27.5%

In this study, maximum number of patients (72.5%), had mixed diet

Observation Based on Lipid Profile Values**Total Cholesterol****Table 11: Distribution as per Total Cholesterol**

Range	No of patients		Total	Percentage
	Group 1	Group 2		
120-180	0	2	2	5%
181-240	13	7	20	50%
>240	7	11	18	45%

In this study maximum number (50%), patients had total cholesterol between 181-240mg/dl

LDL

Table 12: Distribution as per LDL level

Range	No of patients		Total	Percentage
	Group1	Group2		
100-160	14	8	22	55%
>160	6	12	18	45%

In this study maximum number of patients (55%), had LDL Cholesterol level between 100-160mg/dl.

HDL

Table 13: Distribution as per HDL

Range	No of patients		Total	Percentage
	Group1	Group2		
<40	2	3	5	12.5%
40-60	16	16	32	80%
>60	2	1	3	7.5%

In this study 12.5% patients had HDL below 40mg/dl, 80% patients had HDL between 40-60 mg/dl and rest 7.5% had HDL above 60mg/dl.

VLDL

Table 14: Distribution as per VLDL

Range	No of patients		Total	Percentage
	Group1	Group2		
5-30	2	1	3	7.5%
>30	18	19	37	92.5%

In this study maximum number of patients (92.5%) had VLDL range above 30mg/dl

Triglycerides

Table 15: Distribution as per Triglycerides

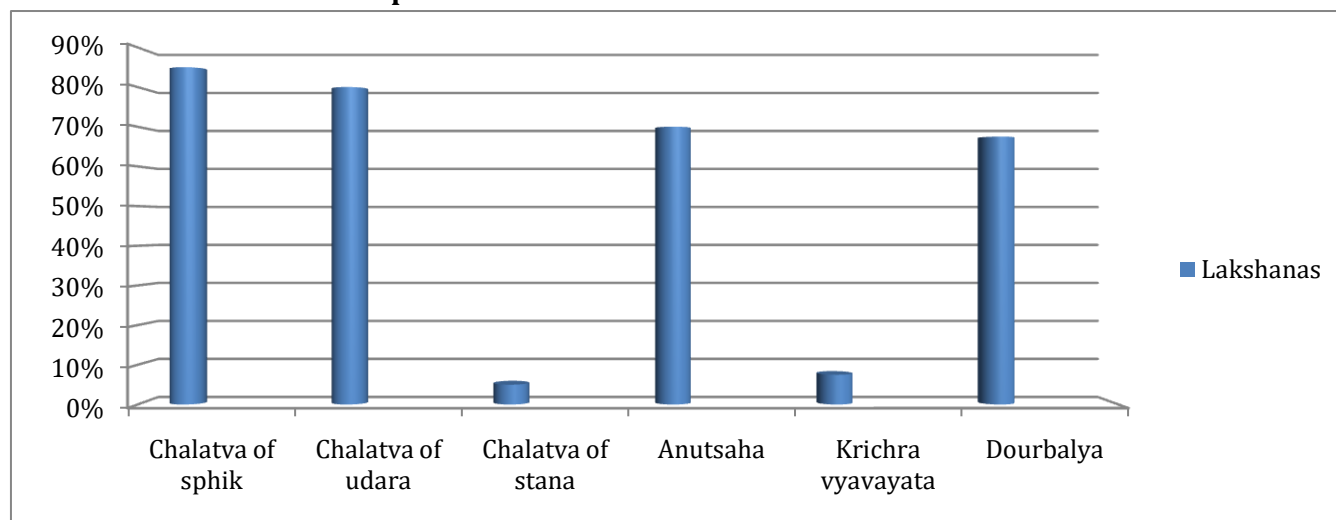
Range	No of patients		Total	Percentage
	Group1	Group2		
<150	4	3	7	17.5%
151-240	12	15	27	67.5%
>240	4	2	6	15%

In this study maximum number of patients (67.5%) had Triglycerides between 151-240mg/dl, 15% patients had Triglycerides below 150mg/dl and 15% patients had triglycerides above 240 mg/dl.

Table 16: Lakshanas wise Distribution of Patients

Lakshanas	No. of Patients		Total	Percentage
	Group 1	Group 2		
<i>Chalatva of sphik</i>	18	16	34	85%
<i>Chalatva of udara</i>	17	15	32	80%
<i>Chalatva of sthana</i>	2	0	2	5%
<i>Anutsaha</i>	15	13	28	70%
<i>Krichra vyavaya</i>	2	1	3	7.5%
<i>Dourbalya</i>	10	17	27	67.5%
<i>Dourgandhya</i>	7	9	16	40%
<i>Swedaavabhaada</i>	9	10	19	47.5%
<i>Kshudaatimaatra</i>	0	7	7	17.5%
<i>Pipaasaatiyoga</i>	0	0	0	0

Graph 15: Lakshanas wise Distribution of Patients



In this study, maximum numbers of patients (85%) have *Chalatra of Sphik*.

RESULTS

Effect of treatment

In the present study, 40 patients of Dyslipidemia were registered and treated with *Amritadya Guggulu* and *Amritadya Guggulu* with *Yavamalaki Choorna* for 30 days. Each disease feature was scored according to the assessment criteria and each patient was assessed and scored with respect to his/her presenting complaints. Respective scores were subjected for statistical analysis using paired student 't' test for the individuals groups and unpaired student 't' test to compare both the groups. Following are the obtained result data of both the groups.

Table 17: Effect on lipid profile of Group 1

Lipid value	Mean score		Difference in mean	% improvement	S.D± S.E	T value	p	Remarks
	BT	AT						
S. Chol	235.65	185.75	49.90	21.17	17.19±3.84	12.98	<0.001	H.S
LDL	147.15	115.30	31.85	21.64	23.07±5.16	6.172	<0.001	H.S
HDL	48.8	49.95	1.15	2.35	2.36±0.53	2.17	0.043	S
VLDL	36.7	33.2	3.5	9.53	2.89± 0.64	5.41	<0.001	H.S
TGL	186.7	150.75	35.95	19.2	25.19±5.63	6.380	<0.001	HS

The above table illustrates that, In Group 1 S. Cholesterol was reduced 21.17% after 30 days of treatment, LDL was reduced by 21.64%, VLDL was reduced by 9.53%, S. Triglycerides were reduced by 19.2% which were all statistically significant at $p < 0.001$ and HDL was increased by 2.35%. There is a statistically significant change in HDL ($P = 0.043$).

Table 18: Effect on lipid profile Group 2

Lipid value	Mean score		Difference in mean	% improvement	S.D±S.E	T value	p	Remarks
	BT	AT						
S. Chol	237.7	181.1	56.6	23.8	23.71±5.30	10.67	<0.001	H.S
LDL	160.4	124.8	35.55	22.1	20.22±4.52	7.86	<0.001	H.S
HDL	47.45	50.15	2.7	3.49	3.09±0.69	-3.89	<0.001	HS
VLDL	38.75	32.35	6.4	16.51	4.60± 1.03	6.21	<0.001	H.S
TGL	191.15	142.9	48.25	25.2	21.969±4.91	9.82	<0.001	HS

The above table illustrates that, S. Cholesterol was reduced 23.71%, LDL was reduced by 22.1%, VLDL was reduced by 16.5%, S. Triglycerides were reduced by 25.2 % and HDL was increased by 3.49% which were all statistically significant at $p < 0.001$.

Effect on weight and BMI

Table 19: Effect on weight & BMI in Group 1

	Mean score		X	% IMP	S.D± S.E	t-value	p	Remarks
	BT	AT						
Weight	70.32	70.1	0.225	0.31	0.69± 0.15	1.44	0.165	NS
BMI	25.29	25.22	0.071	0.28	0.22±0.050	1.39	0.17	NS

In Group1, this table indicates 0.31% reduction in weight and 0.28% reduction in BMI, both are not statistically significant at p =0.165 and p=0.17.

Table 20: Effect on weight & BMI in Group 2

	Mean score		X	% IMP	S.D±S.E	t-value	p	Remarks
	BT	AT						
Weight	75.65	75.15	0.5	0.66	0.79± 0.17	3.247	0.011	S
BMI	26.98	26.80	0.18	0.66	0.28±0.063	2.85	0.010	S

In Group 2, this table indicates 0.66% reduction in weight and 0.66% reduction in BMI, both are statistically significant at p =0.011 and p=0.010.

Effect of treatment between Group 1 and Group 2

Table 21: Effect on Lipid profile in both Groups (Unpaired t Test)

Parameter	Group 1			Group 2			t	P	Remarks
	Mean	SD	SE	Mean	SD	SE			
Total Cholesterol	49.9	17.19	3.84	56.6	23.71	5.3	0.034	0.97	NS
LDL	31.85	23.07	5.16	35.55	20.22	4.52	-0.14	0.88	NS
VLDL	3.5	2.89	0.64	6.4	4.6	1.03	-2.67	0.01	S
TG	35.95	25.19	5.63	48.25	21.96	4.91	-1.64	0.1	NS

This table indicates there is no significant difference between two groups except VLDL (P=0.01)

Table 22: Effect on HDL in both the Groups

Parameter	Group 1			Group 2			t	p	Remarks
	Mean	SD	SE	Mean	SD	SE			
HDL	-1.15	2.36	0.530	-2.7	3.09	0.69	1.58	0.12	NS

The difference in the mean values of the two groups is not great enough to reject the possibility that the difference is due to random sampling variability. There is not a statistically significant difference between the input groups (P = 0.122).

Table 23: Effect on BMI and Weight in both the Groups

Parameter	Group 1			Group 2			t	p	Remarks
	Mean	SD	SE	Mean	SD	SE			
BMI	0.12	0.20	0.04	0.18	0.29	0.06	-0.78	0.43	NS
Weight	0.37	0.74	0.14	0.54	.84	0.188	-0.74	0.48	NS

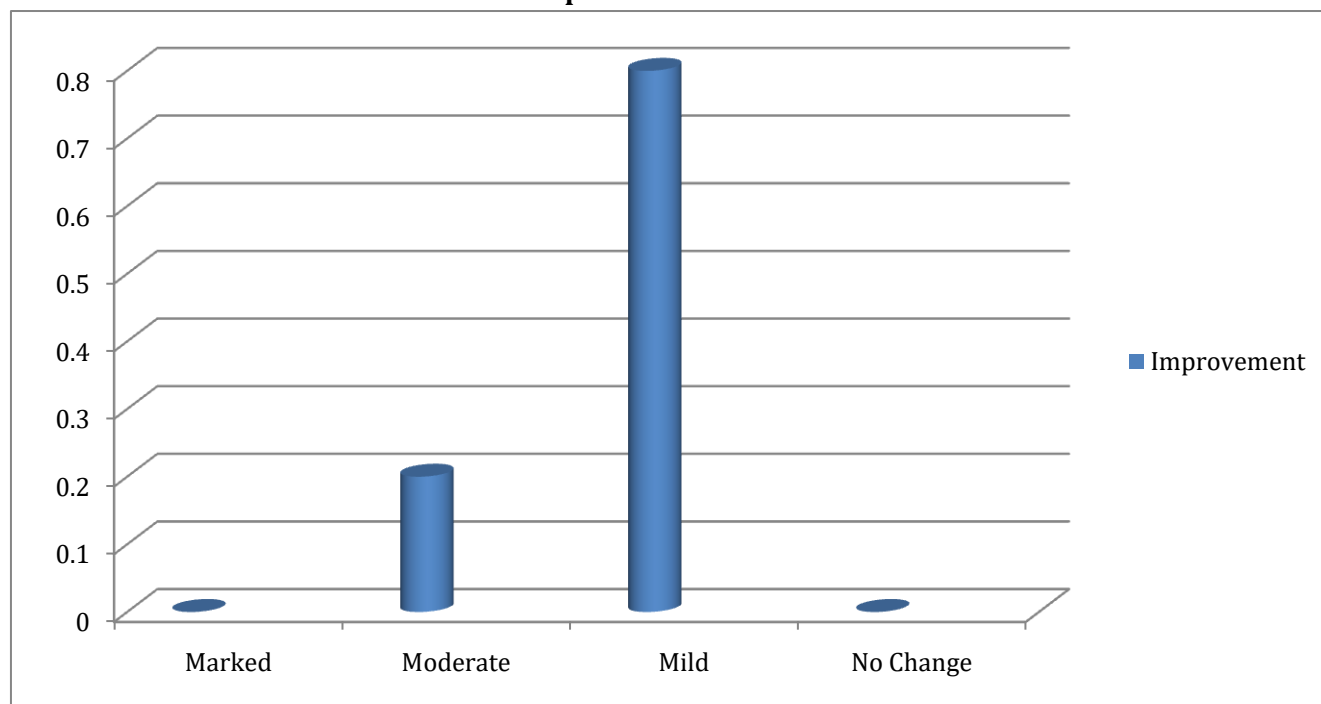
There is a no statistically significant difference between BMI of the input groups (P = 0.43) and Weight of two groups (P = 0.48).

Overall Result

Table 24: Overall result

Improvement	No. of patients			%
	Group 1	Group 2	Total	
Marked (>50%)	0	0	0	0
Moderate (>25%)	3	5	8	20%
Mild (<25%)	17	15	32	80%
No change (0%)	0	0	0	0

Graph 1: Overall Result



DISCUSSION

The following Table no-25 depicts the efficacy of medications on lipid profile parameters and other factors of among two groups.

Lipid profile Parameters	Efficacy
Total cholesterol	In Group 1, 21.17% reduction was observed in Total Cholesterol while 23.8% reduction was observed in Group 2. Both the results were statistically significant ($P < 0.001$). The percentage of relief was more in Group 2.
S. LDL	Reduction observed in S.LDL was 21.6% in Group 1 while 22.1% reduction was observed in Group 2. Both the results were statistically significant ($P < 0.001$). Thus, Group 2 provided little better result in reduction of S.LDL
S. HDL	S.HDL level was increased up to 2.35% in Group 1 while in Group 2 by 3.49%. Both the results were statistically significant in Group 1 ($P = 0.043$) and Group 2 ($P < 0.001$). But percentage relief was more in Group 2.
S. VLDL	In Group 1, there was 9.35% reduction in S.VLDL while 16.51% reduction was found in Group and both the results were statistically significant ($P < 0.001$). But the percentage of relief was more in Group 1.
S. Triglyceride	S. Triglyceride reduced by 19.2% in Group 1, whereas 25.2% reduction was observed in Group 2. Both the results were statistically significant ($P < 0.001$). However the percentage of relief was more in Group 2.
Weight	In Group 1 there was only 0.31% reduction which is statistically insignificant ($p = 0.165$) while in Group 2 there was 2.20% reduction which is statistically significant ($p = 0.004$). But percentage relief was more in Group 2.
BMI	In Group 1, 0.53% reduction which is statistically significant ($p = 0.027$) while in Group 2 there was 2.14% reduction which is statistically significant ($p = 0.002$). But percentage of relief was more in Group 2.
<i>Sthoulya lakshanas</i>	After the 30 days of treatment, <i>Amritadya Guggulu</i> in Group 1 and <i>Amritadya Guggulu</i> with <i>Yavamalaki Choorna</i> in Group 2 have not produced appreciable changes in the <i>Lakshanas</i> of <i>Medoroga</i>

Mode of action of Amritadya Guggulu

Amritadya Guggulu is an *Oushada yoga* explained under *Chakradatta Sthoulya adhikara*. It contains *Amrutha (Guduchi)*, *Truti (Ela)*, *Vella (Vidanga)*, *Vatsaka (Kutaja Twak)*, *Kali (Vibhitaki)*, *Pathya (Haritaki)*, *Amalaki* and *Guggulu* in increasing quantity. As the drugs are mixed in an increasing order, thus the highest ingredient being *Guggulu* which is best *Vata* and *Medohara*^[8]. Dyslipidemia if seen through the lens of Ayurveda may be taken as *Medo roga* or *Medo dosha*, as *Bahu abaddha medas* which circulates all over the body. *Tikta katu*, *Kashaya rasas* will cause *Medo vilayana*. The drugs such as *Guggulu*, *Haritaki*, *Vibhitaki*, *Vidanga*, and *Guduchi* are *Rooksha*, *Sookshma* and *Ushna* in nature thus penetrating into the deeper channels and removing Sanga/obstruction.

In case of Hyperlipidaemia, obstruction may be seen as atherosclerosis seen due to deposition of fat in arteries. Hence by the virtue of above properties, it helps in liquefaction of these fatty blockages. Drugs such as *Amalaki*, *Ela*, and *Kutaja* by virtue of their *Sheeta veerya*, pacifies the *Theekshnagni*.

Haritaki is 3rd highest dose amongst the ingredients, which is *Kashaya rasa pradhana* and best *Vatanulomana*^[9].

Discussion on Mode of Action of Yavamalaki Churna

The combination of *Yava* and *Amalaki* acts on basis of principle "*Guru Cha Apatarpana*"^[10].

The drug *Yava* is having the properties like *Madhura*, *Ruksha*, *Sheeta* and *Guru* gunas which helps in correcting the pathogenesis of *Medodushti*. The *Sheeta veerya* of the drug causes satiation by balancing the aggravated *Agni*. *Yava* is best drug in "*Purisha janana*"^[11] (more production and increasing the bulkiness of fecal matter). 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* 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. 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 located in hypothalamus 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.

Classics have dealt *Amalaki* 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 *Lavana varjita* 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.

Thus the combination of drug will have property of *guru* i.e., takes long duration for complete metabolism and *Apatarpana* i.e., will not nourish by means of calories.

CONCLUSION

The causes of elevated lipid profile are mainly uncontrolled erratic diet, supplemented with lack of exercises. i.e., increased input of energy with decreased energy output. Hyperlipidaemia in Ayurvedic literature is explained in bits and fragments under the broad umbrella of *Sthoulya-Medoroga-Prameha*.

As it is a *Santarpanottha vikara*, hence the ideal management protocol is *Rookshana*. *Amritadya Guggulu* has given significant result on elevated lipid profile. "*Guru Cha Apatarpana*" principle plays an important role in *Medoroga* management in reducing its symptoms by *Vighatana* of its *Samprapti*. So in Group 2 *Yavamalaki Choorna* is taken along with *Amritadya Guggulu*.

Both the groups (1 and 2) 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 and BMI, but compare to group 1, in group 2 good weight loss was observed. *Amritadya Guggulu* and *Yavamalaki Choorna* however did not produce any significant change in *Lakshanas*, which were ascertained before

and after the study. The reason could well be, short study duration of 30 days which was taken and gross physical changes in body in reality is difficult. Hence by this study, it can be claimed that *Amritadya Guggulu* has significant effect on elevated lipid profile and if along with *Yava Amalaki choorna* it shows more effect.

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