

A CLINICAL STUDY OF DYSLIPIDAEMIA AND THE EFFECT OF LEKHANIYE GHAN MAHAKASHAYA IN ITS MANAGEMENT

Sakshi Sharma¹, Roshi Mahajan², Rozy Soan³

¹Assistant professor, Department of Kriya Sharir, ²Assistant professor, Department of Rog Nidana, GAMC Jammu, India

³Medical Officer, Department of ISM, Jammu, India

Email: roshimahajanmd@gmail.com

ABSTRACT

Dyslipidaemia has gained worldwide interest in its ability to participate in the pathology of atherosclerotic diseases like coronary heart disease (CHD) and stroke which dominate the scenario of diseases causing morbidity and mortality in the world. There is evidence that hypertension and dyslipidemia act synergistically to increase CVD risk. Raised total cholesterol is also a major cause of disease burden in both the developed and developing world. From an Ayurvedic perspective, Dyslipidaemia can be included in *Santarpanjanya Vyadhis*. The present clinical study attempts to evaluate the role of *lekhaniye gana kashaya* in the management of dyslipidemia. The lipids, which are elevated in Dyslipidaemia could be correlated to *Sneha*, *Medodhatu* and *Samaras* due to the similarity in their properties. For the purpose of clinical study, 30 patients were registered based on selective parameters and were given 3g of dried *lekhaniye Ghana kashaya* in 3 divided doses for 45 days. After the completion of treatment effects of the therapy were analyzed. The trial drug *lekhaniye gana kashaya* showed highly significant results in almost all the subjective and objective parameters. The study concluded that the trial drug *Lekhniye Gana Kashaya* is an effective drug in the management of dyslipidaemia.

Keywords: Dyslipidemia, Coronary artery disease, *Santarpan janya vyadhi*, *sneha*, *meda dhatu*, and *samarasa*.

INTRODUCTION

As quoted by Acharya Charaka, "A physician should not be embarrassed if he is unable to name a disease as each and every disease cannot be named"¹. This quotation is best fit for today's era where arrays of newer diseases have come into foreground. Popularly referred to as 'Lifestyle Diseases', which are caused mainly due to the interplay of various lifestyles, genetic and environmental factors which have altered over the years due to modernization. The causative factors

generally act by impairing the metabolism of an individual making him prone to series of disorders. Dyslipidaemia is one such disorder which has been identified as a potential risk factor for multitudes of diseases like cardiovascular diseases, metabolic syndrome and even hypertension². Dyslipidaemia is defined as a lipoprotein disorder promoting the development of atherosclerosis. The lipid abnormalities included in this definition are increased low-density

lipoprotein cholesterol, decreased high-density lipoprotein cholesterol, and increased serum triglycerides³. According to WHO, almost 1/5 (18%) of global stroke events and 56 % of global heart diseases are attributable to Dyslipidaemia. In India, persons suffering from the CHD are doubled in the last 20 years⁴. The prevention of cardiovascular disease in adulthood begins with the exact diagnosis and treatment of dyslipidaemia. Though, there is no precise terminology for dyslipidaemia mentioned in the Ayurvedic classics, *Acharya Charaka* has thrown light on the eight varieties of impediments which are designated as *Nindita Purusha*; *Ati Sthaulya* comprises one of them⁵. Dyslipidaemia is *Dhatupradoshaj Vikara*. Being *Medodhatu* dominant, we have correlated it with '*Medodosh*' on the basis of pathophysiology. Also, this excessively increased *Asthayi Medo Dhatu* is *Ama* in nature due to which it is retained in the body for a longer time resulting in further complications. *Ayurveda* with its wide range of herbal wealth can offer effective and valuable remedies in controlling levels of *Abaddha Medas* (free blood lipids) and thus preventing plaque formation. Drugs having properties like *Deepan*, *Amapachan*, *Anulomana*, *Chedana*, *Lekhana* and which may forcefully clear the accumulated and vitiated/ unripe *Dhatu*s and *Malas* from *Srotas* can be successful in managing these conditions. The drug selected for the present study is taken from *Lekhaniya Mahakashaya* described by *Acharya Charaka* in *Charaka Samhita Sutrasthana*⁶. *Lekhaniya Dravyas* can remove improperly processed *Dhatu*s and *Malas* present in microcirculatory channels or *Srotas* of the

body leading to *Srotorodha* (obstruction at the level of microcirculatory channels). Keeping in view, the present study "A Clinical Study of Dyslipidaemia and the effect of Lekhaniye Ghan Mahakashaya in its management" was planned.

Aim & Objectives

1. To study etiopathogenesis of Dyslipidaemia in Modern and Ayurvedic contexts.
2. To evaluate the clinical efficacy of Lekhaniya Mahakashaya in the management of Dyslipidaemia.

Material and Methods

Study Protocol:

1. Conceptual

The available literature was scrutinized for the study of *medoroga* w.s.r. to Dyslipidemia in various *Ayurvedic* and Modern texts.

2. Clinical Study

• Trial type

Prospective Open Clinical trial

• Sample size:

Total 30 patients were registered fulfilling all the inclusion criteria.

• Selection Criteria

For clinical part of study, 30 patients of Dyslipidaemia were randomly selected from the OPD and IPD of Jammu Institute of Ayurveda and Research hospital, Jammu.

Method of preparation of Drug: The drug selected for the present study taken from *Lekhaniya Mahakashaya* is a combination of ten drugs with mainly *Lekhana* (depleting agents) property.

Si.No	Sanskrit Name	Botanical Name	Proportion
1.	<i>Mustak</i>	<i>Cyperus rotundus</i>	1 part
2.	<i>Kusth</i>	<i>Saussurea lappa</i>	1 part
3.	<i>Haridra</i>	<i>Curcuma longa</i>	1 part
4.	<i>Daruharidra</i>	<i>Berberis aristata</i>	1 part
5.	<i>Vacha</i>	<i>Acorus calamus</i>	1 part
6.	<i>Ativisha</i>	<i>Aconitum heterophyllum</i>	1 part
7.	<i>Katurohini</i>	<i>Picrorrhiza Kurroa</i>	1 part
8.	<i>Chitrak</i>	<i>Plumbago zelanica</i>	1 part
9.	<i>Chirbilav</i>	<i>Holoptella integrifolia</i>	1 part
10.	<i>Hemvati Vacha</i>	<i>Iris integrifolia</i>	1 part

Preparation of Drug:

Under expert guidance of Dravya Guna Department, the raw material was collected. The drug was prepared in the college pharmacy. *Kwath* of *Lekhaniya Dravyas Yavakuta* (coarse powder) was taken and heated slowly until *Ghana* is formed. Then it was dried and powdered which was filled in capsules of 500mg each. Modified method for preparation of the *Ghana* was used as per the suggestions of the *Rasa shastra* experts. To prevent the loss of active principles, present in the volatile oils of *Musta*, *kutha* and *Vacha*, these drugs were added later on to the prepared *Ghana*, the raw ingredients were taken in equal proportion. All the drugs except *Musta*, *Kushtha* and *Vacha* were taken as coarse powder and made into a decoction by adding 16 parts water. The rest three drugs were added to the decoction when 1/8" of it is left. The decoction when reduced to 1/4 was filtered and again heated to form *Ghana*. Fine powder of *Ghana* was made when dry and filled in capsules of 500 mg each.

Posology

Drug – *Lekhaniya Mahakashaya* in *Ghana* form filled in capsule of 500mg.

Dose – 3g /day in three divided doses.

Duration – 45 days

Anupana – *Ushanodaka*

Kala - *Pragbhukata* (Before Meals)

Follow up - 14 days.

Criteria for selection of patients

Inclusion Criteria:

- Patients who are willing for the trial.
- Clinically diagnosed and confirmed patients of Dyslipidaemia, with raised blood lipid level. (including borderline high) were selected.
- Patients between age group of 18 to 60 years with or without obesity.

Exclusion Criteria:

- Patients suffering from D/M, Nephrotic syndrome, Hypothyroidism, Pregnant women.
- Liver disorders such as Obstructive jaundice, Hepatitis, Chronic infections and
- Patients having Dyslipidaemia due to drugs e.g. glucocorticoids, diuretics. other serious diseases.

- Patients being obese due to other conditions like endocrinal disorders, hormonal therapy

Concomitant medication: Known hypolipidaemic drugs like statins, fibrates were stopped during therapy.

Investigations:

- Routine Hematological examination before treatment to rule out any pathological conditions.
- Lipid profile before and after treatment.
- Blood sugar, Serum proteins, Blood urea, Serum Creatinine, LFT (liver function test) if needed. ' ECG in selected patients if indicated

Criteria of Assessment

Improvement in associated symptoms was assessed by scoring and gradation method based on subjective and objective parameters of Dyslipidaemia.

A. Subjective parameters:

- *Chal sphik udhara sthana*
- *Kshudra shwasa*
- *Alasya*
- *Swedadhikya*
- *Atikshuda*
- *Gaurava*.

B. Objective Parameters:

For the assessment of objective improvement,

- Hb %
- Lipid profile
- BMI.

Study Duration

45 days and follow up of 14 days.

- 1st assessment – Before the treatment
- 2nd assessment – 14th day after initiation of medicine
- 3rd assessment – 28th day after treatment
- 4th assessment – 45th day (end of follow up)
- To assess the overall 1st and 4th assessment were considered.

Statistical Analysis:

Statistical analysis was done for subjective and objective parameters before treatment, after treatment, and Follow up. Analysis was done by calculating Mean, Standard Deviation (S.D), Standard Error (S.E), t-Value and P- Value at 0.001 levels.

Result: In the present study, 30 patients of dyslipidaemia were registered and given the *lekhanīye mahakashaya Ghana*. The effect of the therapy on the sub-

jective and objective parameters is presented in tabular form.

Table 1: Effect of Therapy on Subjective criteria:

Symptoms	N	Mean score		Mean (X)	%age Relief	S.D. +	S.E. +	't'	'p'	Result
		B.T.	A.T.							
<i>Chalsphik udar sthan</i>	21	2.86	2.1	.76	26.6	.44	.1	8.0	>.001	H.S.
<i>Kshudra shwasa</i>	16	3.2	1.5	1.7	53	.5	.12	14.1	>.001	H.S.
<i>Alasya</i>	11	3.1	.5	2.5	80.6	.52	.16	16.2	>.001	H.S.
<i>Swedadhikya</i>	16	2.5	1.6	.94	37.8	.44	.11	8.5	>.001	H.S.
<i>Atishudha</i>	8	3.75	3.0	.75	20	.46	.16	4.6	>.01	S.
<i>Gaurava</i>	18	2.5	.7	1.8	72	.43	.1	17.63	>.001	H.S.

The above table indicates that maximum 80.6% relief was observed in *Alasya*, followed by in *Angagaurva* (72%), *Kshudra Shwasa* relieved by 53%, *Swedadhikya* by 37.8%, and 26.6% reduction was observed in *Chalsphik udar sthan*.

All these results were statistically highly significant (P<0.001); whereas relief observed in *Nidradhikya* was 29.2% and in *Ati Kshudha* 20%.

Table 2: Effect of Therapy on Weight And BMI:

Investigation	Mean score		Mean (X)	%age Relief	S.D. +	S.E	't'	P	Result
	B.T	A.T							
B.M.I	28.7	28.2	0.5	1.7%	.19	.03	12.9	<.001	H.S
Body weight	73.2	71.8	1.4	1.9%	.81	.15	9.3	<.001	H.S

The above table shows that reduction in weight was 1.9% whereas B.M.I was reduced by 1.7% and both the results were statistically highly significant. (p<0.001).

Table 3: Effect of therapy on Lipid Profile

Investigation	Mean score		Mean (X)	%age Relief	S.D. +	S.E	't'	P	Result
	B.T	A.T							
B.M.I	241.5	230.5	11	4.5%	2.5	.46	23.9	<.001	H.S
Body weight	190.8	189.6	1.2	.68%	1.97	.36	3.33	<.01	S
LDL	168.47	166.1	2.4	1.4	2.2	.4	5.9	<.001	H.S
HDL	48.53	49.80	-1.3	2.7	1.7	.31	-4.2	<.001	H.S
VLDL	38.53	37.2	1.33	3.45	2.2	.40	3.32	<.01	SIG

The above table portrays that S. cholesterol was reduced by 4.5% and S.LDL reduced by 1.4%; Also S.HDL level was increased by 2.7%. All results were statistically highly significant (P<0.001), whereas S. Triglyceride was decreased by 0.68% and S. VLDL by 3.45%; both are statistically significant (P<0.001).

DISCUSSION

The clinical study entitled “A Clinical Study of Dyslipidaemia and the effect of Lekhaniye Ghan Mahakashaya in its management.” was conducted in PG department of Jammu Institute of Ayurveda and Research and Hospital, Jammu. The study has made an attempt to analyze Dyslipidemia from every aspect. Although there are no direct references of this disease

in *brihtrayi*. The patients were classified into 3 groups Hypercholesterolaemia, Hypertriglyceridemia, Hypercholesterolaemia and Hypertriglyceridemia. It was observed in the study that 40% patients had hypercholesterolemia, 46.67% patients had hypertriglyceridemia and remaining had both. Dyslipidaemia is more commonly found in age group between 40-50 years and of that 60% patients were male supporting the general fact that up to menopause the incidence of dyslipidaemia is less in females. It was also reported that most of the patients were obese, only 10% patients were having BMI in normal range. The study also indicated that 70% patients were not accustomed to any kind of exercise and 90% patients had a sedentary lifestyle. The trial drug chosen in this study showed highly significant results on all the subjective criteria except *Atikshudha* which was significant. The results were highly significant in S. cholesterol and S. HDL.

Probable Mode of action of drug

For an *Ayurvedic* drug to act on Dyslipidaemia it should have *Amapachana* and *Shodhana* qualities at the *Rasa Dhatu* level, *Rasa* being the nutritive pool from which *Rakta*, *Mamsa*, *Meda* etc. *Dhatu*s derive their nutrition, It should reach till the level of *Meda Dhatu* after traversing the *Rasadi Dhatu*s. It should impede the pathology resulting in an excess of *Meda Dhatu* by rectifying pacified *Medodhatvagni*. It should cause *Lekhana* and *Upshoshana* of the *Kapha*, *Mamsa*, *Meda*, *Vasa*, *Kleda* and *Sweda*. *Lekhaniya Mahakashya* can be indicated in all the *Santarpanjanya* diseases. *Lekhaniya Ghana* Capsules, a modified form of *Lekhaniya Mahakashya* is one such ideal formulation. It possesses almost all the qualities required for a drug to treat Dyslipidaemia. *Lekhaniye gana* capsule is having *tikta*, *katu rasa* and *kashaya anurasa*⁷. *Tikta rasa* is *deepana*, *pachana*, *lekhana*, *upshoshana*, *srotoshodhana* and *sthirikarana* in nature⁸. *Tikta rasa* is *laghu* in nature thereby relieving the symptom *gaurava*. By its *pachana* property it leads to digestion of *ama* at *jatharagni* level. *Katu Rasa* due to its *agni* and *vayu* dominancy augments the digestive fire leading to augmentation of *medodhatvagni* causing depletion of *sneha*, *sweda*, *kleda*

and *mala*, also decreasing the *mamsa* and *medo dhatu*⁹. It also relieves the obstructions of the channels thereby curing the *sanga* pathology. *Kashaya* rasa is the most *ruksha rasa* among the six *rasas*. By the virtue of *shoshana* property, it absorbs the *medo dhatu*, *kleda*, *sweda* and *kapha dosha* thus relieving the *atipravatti* pathology¹⁰.

CONCLUSION

Dyslipidemia is arguably the biggest contributing factor to the development of atherosclerosis and subsequent CVD in obesity. The link between obesity and dyslipidemia is directly affected by body fat distribution and insulin resistance. The increasing prevalence of obesity in the world makes the ideal monitoring of lipids even more important. On the basis of this study it can be concluded that the concept of Dyslipidaemia can be elaborated according to *Ayurvedic* classics through indirect relevant references. It can be inferred as *Vridhdha Asthaya Medo Dhatu* which is *Ama* in nature. It can be treated on the principles of *Apatarpana* and by following the line of treatment of *Sthaulya* or *Prameha* since all the three arise due to *Medo Dushti*. *Lekhaniya Mahakashya* drugs have highly significant effect on *Medodushti Lakshanas* and in reduction of objective parameters like weight, BMI and other investigations. Dietary and lifestyle changes are also supportive to therapy in dyslipidaemia and obesity. However, this is a time bound small study on a few numbers of patients of dyslipidaemia and with limited resources. Therefore, to reach concrete conclusions it is proposed that the same project must be conducted on a larger series.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL: Roshi Mahajan et al: A Clinical Study Of Dyslipidaemia And The Effect Of Lekhaniye Ghan Mahakashaya In Its Management. International Ayurvedic Medical Journal {online} 2020 {cited April, 2020} Available from:

http://www.iamj.in/posts/images/upload/3182_3187.pdf