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Clinical Study to Evaluate the Efficacy of *Lekhaniya Mahakashaya* in the Management of *Medoroga* w.s.r. to Dyslipidemia

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ABSTRACT:

Dyslipidemia is a life style disorder related to lipo-protein metabolism. It is a silent disorder with a high rate of complications, morbidity like cardio-vascular diseases diabetes, hyper-tension, atherosclerosis, etc. and mortality. It is manifested as i) rise in plasma levels of total cholesterol, triglycerides or both ii) decrease in HDL level and iii) increase in LDL and VLDL levels. It can be correlated to *Medoroga*. In present clinical study, 30 patients suffering from *Medoroga* were selected from O.P.D and I.P.D. of Jammu Institute of Ayurveda and Research, Jammu. Written and informed consent of patients was taken before inclusion in the trial. It was a Prospective Open Clinical Trial. So, only one group with 30 patients was administered *Lekhaniya Mahakashaya* in *Ghana* form filled in capsule of 500 mg. in the dose of 3 gm/day in three divided doses (2 capsules TDS) with *Ushanodaka* before meals for 45 days. All the patients were statistically analyzed before and after the treatment.

Keys words: *Medoroga, Lekhaniya, Mahakashaya, Ushanodaka.*

INTRODUCTION

The human life is rapidly changing in its food, standard of living and environment. Because of changes in food pattern and sedentary lifestyle, a majority of population is suffering from metabolic disorders. Change in the normal metabolic processes due to abnormal chemical reactions in the body leads to metabolic disorders. Dyslipidemia is considered as metabolic disorder related to lipoprotein metabolism, manifested as rise in plasma levels of total cholesterol, triglycerides (TGs), or both, or a decrease in HDL (high density lipoprotein) level or all three together that contributes to the formation of atherosclerosis in any stage of life. There is no any description of dyslipidemia found in *Ayurvedic* texts. So it cannot be compared with particular disease in *Ayurveda*. It can be included under *Santarpanjanya Vyadhi*. *Medodhatu* (abnormal form of adipose tissue) can be correlated with dyslipidemia due to resemblance of their etiopathogenesis and clinical features. Bad food habits, sedentary lifestyle, presence of dyslipidemia in family, intake of alcohol, cigarette smoking and stress are the main etiological factors of

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dyslipidemia. According to *Ayurveda Guru*, *Madhur*, Sheet, *Snigdha*, *Kaphamedavardhaka Ahar*, *Avyayam*, *Diwaswapa*, *Achinta* and *Bijadosha* are the main causative factors for *Medoroga*[1]. All these *hetus* lead to aggravation of *Kapha* and *Meda* which causes S*rotorodha*. Due to *Srotorodha*, there is obstruction to the normal movement of *Vayu*. This obstructed *Vayu* comes into the *Koshtha* and causes *Jatharagni Sandhukshana* (increase capacity of digestion) which causes early digestion of ingested food leading to voracious hunger and craving for large quantity of food[2]. According to *Acharya Dalhan*, *Agnimandya and Ama* production are responsible for this condition. All metabolic activities in the body mainly depends on proper functioning of *Agni*[3]. *Agnimandya* causes improper digestion of food and produces *Ama*. In *Ayurveda Ama* is believed to be the key factor in the pathogenesis of metabolic disorders. This *Ama* causes obstruction in *Srotas* (channels of metabolic processes) which leads to disease formation[4]. Due to impairment in the fat metabolism excess fat get accumulated in blood and adipose tissue. Due to *Medodhatwagnimandya*, formation of abnormal *Poshaka Medodathu* in large quantity takes place. This abnormally formed *Poshaka Medodathu* in large quantity get accumulated in *Rasa Dhatu*[5]. Accumulation of *Poshakamedodhatu* results into the formation of disorder called as *Dhamanipratichaya*. *Dhamanipratichaya* is one of the 20 *Nanatmaja Vyadhis* of *Kapha Dosha*[6]. *Samprapti* of *Medoroga* starts with accumulation of aggravated *Kapha* and *Medas* in the various *Srotasa* causing *Srotorodha*. This excess of *Kapha and Medas* in the blood is referred as *Shonitabhishyandana* in which there is excessive accumulation of *Kapha and Meda* within the *Rasadhatu* (plasma) and *Raktadhatu* (blood vessels) which forms the *Upalepa* within the walls of the *Dhamani* and adheres to it[7]. In *Ayurveda* to remove this *Upalepa* of *Kapha Meda Apatarpana*, *Karshana* and *Kaphamedanashana Chikitsa* is given by *Acharya Charak*[8]. *Yava* is mentioned in *Bhavprakash* for the management of *Medoroga* which helps in *Sampraptivighatana*[9].

MATERIALS & METHODS

1. **Source of Data:** Patients suffering from *Medoroga* were selected from OPD and IPD of Jammu Institute of Ayurveda and Research and Hospital, Jammu after fulfilling Inclusion and Exclusion criteria.
2. **Selection of Drug:** The drug selected for the present study is taken from *Lekhaniya Mahakashaya* described by *Aacharya Charaka* in *Charaka Samhita Sutrasthana* Chapter 4. *Lekhaniya Dravyas*[10] are capable of removing improperly processed *Dhatus* and *Mala* present in micro-circulatory channels or *Srotas* of the body leading to *Srotorodha* (obstruction at the level of microcirculatory channels).

In *Sharangdhara Samhita Purvardha*, while describing the *Gunas* of *Lekhana Dravyas* clearly indicates *Medohara* effect of *Lekhana Dravyas*[11]**.**

Ingredients of *Lekhaniya Mahakashaya*[12] *(Table 1)*

The form mentioned in the classics is *Kwatha* form or decoction which, was modified and made into *Ghana* form and filled in capsules for better efficacy and patient's compliance. Then it was dried and powder was filled in capsules of 500mg each.

Inclusion Criteria

1. Age Group between 20-60 years of both the sex.
2. The Patients with elevated minimum of one lipid profile with or without overweight.
3. Fresh cases were included.

Exclusion Criteria

1. Pregnant and Lactating women.
2. Patients diagnosed with systemic disorders such as uncontrolled diabetes, hypertension.
3. Patients having past history of myocardial infarction, stroke, severe pulmonary dysfunction interfering with the treatment.

Diagnostic Criteria

Diagnosis was based on the following parameters of Dyslipidemia;

1. **Subjective Parameters**[13]**:**

- *Angachaltva*
- *Alasya*
- *KshudraShwasa*
- *Nidratiyoga*
- *Daurbalyata*
- *Swedadhikya*
- *Atikshudha*
- *Gaurava*

2. Objective Parameters:

I. A. Body Weight

B. BMI

II Lipid Profile- (12 hours fasting):

A. Serum Cholesterol
B. Serum Triglycerides
C. Serum HDL
D. Serum LDL
E. Serum VLDL

RESULTS

Effect of therapy on subjective criteria

Maximum 80.6% relief was observed in *Alasya*, followed by in *Angagaurva* (72%), *Daurbalya* was reduced by 46.9%, *Kshudra Shwasa* relieved by 53%, *Swedadhikya* by 37.8%, *AtiKshudha* by 20% and 26.6% reduction was observed in *Angachalatava.* Relief observed in *Nidradhikya* was 29.2%. All these results were statistically highly significant (P<0.001) except *Nidradhikya* and *Atikshudha* both of which are significant. (Table No.2)

Effect of therapy on weight and B.M.I.

B.M.I: In B.M.I, 1.7% reduction was observed at statistically highly significant level (p <0.001). (**TableNo.**3)

Body Weight: Reduction in body weight was 1.9% at statistically highly significant level (p <0.001). (**TableNo.**3)

Effect of therapy on lipid profile

S.Cholesterol: 4.5% reduction was observed in S.Cholesterol; the results were statistically highly significant (p<0.001). S.Triglyceride: S.Triglyceridewas decreased by 2.0%. The results were statistically significant (p<0.01). S.HDL: S.HDL level was increased up to 2.7% (p<0.001). It is also statistically highly significant. S. LDL: Reduction observed in S.LDL was 2.0% the results were statistically significant (p<0.01). S.VLDL: There was 4.4% decrease in S.VLDL the results were statistically significant (p<0.01). Table No.4

Overall effect of therapy:- It is seen that 50% of the patients got Marked improvement (50-75% relief), 40% patients were moderately improved (25-50% relief) & 10% patients were Improved (10-25% relief). None of the patients got Complete remission (75- 100% relief), nor Unchanged (0-10% relief).

From the above data it can be said that *Lekhaniya Ghana* Capsules showed a good result on all the subjective and objective parameters. In this study it was also observed that the patients who shed their excess weight during the course of study showed a better improvement in the lipid profile as compared to the patients whose weight remained constant. Thus a relationship can be established between obesity and dyslipidemia which is in accordance with the *Poshya PoshakaMedaDhatu* relation as stated by *Ayurveda*.

DISCUSSION

The hypo-functioning of the *Jatharagni* leads to improper digestion of the food yielding improperly formed *Rasa* in *Amashaya* which is known as *Ama.* This *Ama,* circulating along with the *Rasa Rakta* complex is capable of vitiating the *Doshas* and causes a variety of diseases. This state of circulating *Ama* is called as *Samavastha.* Improper digestion by *Dhatvagni* can also result into *Ama* formation which can be also known as *Sama Dhatu.* This *Ama* is *Guru, Snigdha, Picchila and Durgandhi* in nature and is the root cause of all the diseases. *The Atipicchila Guna* of *Ama* leads to accumulation of lipoproteins in the arterial extra-cellular matrix which results in the retention of lipoproteins particles by binding them & slowing their egress from the intima. *Ama Asthayi MedoDhatu* (lipoproteins) when in excess undergoes chemical modifications by oxidation leading to release of free radicals causing subsequent tissue injury.

Ama while circulating in the body causes disturbance to the movement of *Vayu,* vitiation of all three *Doshas, Srotorodha, Balabhransha, Alasya, Apakti, Daurbalya* and *Gaurava* of *Hridaya.*

Also symptoms like obstruction of vessels, metabolic defects, generalized fatigue and pathological conditions progressing to heart disease are seen in dyslipidemia. Thus from the above the nature of *Medo Dhatu* getting involved in dyslipidemia is *Ama* in nature[14].

The total effect of the *Lekhaniya Ghana* is *Tridosha Shamaka* especially *Kapha Pitta Shamaka*[15]. It pacifies the vitiated *Kapha Dosha* which is dominant in the pathogenesis of dyslipidemia as well as depletes the excessively produced *Rasa, Mamsa, Meda, Vasa*, *Sweda*, and *Kleda* which are all similar in attributes to *Kapha Dosha*. Thus it is known to act against the *Kaphapradhana*

pathogenesis of dyslipidemia. *Kutaki* and *Chitrak* have mild purgative action which causes *Anulomana* of *Vayu* which further corrects the body *Vayu* bringing an end to the *Vatapradhana Samprapti*[16]. The drugs like *Mustak* and *Kusth* are *Mutravirechana* which bring about diuresis relieving the body of the excess of *Kleda*. *Mustak*, *Kusth*, *Kutaki*, *Ativisha*, *Chitrak, Chirbilav, Haridra* and *Daruharidra* known to act on *Medo Dhatu* and allied *Dhatus* and are indicated in diseases like *Kushtha, MedoRoga, Prameha, Udara raga* and *Amadosha*. Hence due to similarity of *Dosha* and *Dushyas* can be successfully used in dyslipidemia. These drugs relieve the body of excess of *Kapha, Meda, Kleda, Vasa,* and *Svveda* by diminishing their *Drava Guna*. Drugs like *Chitrak, Mustak* and *Ativisha* bring about augmentation of the digestive fire leading to proper formulation of the *Rasadi Dhatus*. *Kusth, Musta, Kutaki, Haridra, Daruharidra* digests the *Ama Dosha* present at the *Jatharagni* level as well as the *Medodhatvagni* level. Also drugs like *Vacha, Chitrak,* and *Hemvati Vacha* are *Rasayana* in nature which lead to formation of optimal *Dhatus* and protect the body from injury due to vitiated *Doshas*[17].

CONCLUSION

The concept of dyslipidemia can be correlated according to *Ayurvedic* classics through indirect relevant references. It can be inferred as *Vriddha Asthayi 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*. *Lekhaniya Mahakashaya* was found to exert a cyto-protected effect against dyslipidemia induced degenerative organ changes in vitro-study. *Lekhaniya Mahakashaya* drugs have significant effect on *Medodushti Lakshnas* and in reduction of objective parameters like weight and B.M.I.

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Table No.1:Ingredients of *Lekhaniya Mahakashaya*[12]

S.NO	SANSKRIT NAME	BOTANICAL NAME	PROPORTION
1	*Mustak*	*Cyperus rotundus*	*1 part*
2	*Kushtha*	*Saussurea lappa*	*1 part*
3	*Haridra*	*Curcuma longa*	*1 part*
4	*Daruharidra*	*Berberis aristata*	*1 part*
5	*Vacha*	*Acorus calamus*	*1 part*
6	*Ativisha*	*Aconitum heterophyllum*	*1 part*
7	*Katurohini*	*Picrorrhiza kurroa*	*1 part*
8	*Chitrak*	*Plumbago zelanica*	*1 part*
9	*Chirbilav*	*Holoptella integrifolia*	*1 part*
10	*Hemvativacha*	*Iris integrifolia*	*1 part*

Table No.2: EFFECT OF THERAPY ON SUBJECTIVE CRITERIA

S.No	Symptoms	N	Mean Score		Mean	%age Relief	S.D. S.E.	S.E	't'	'p'	Result
			B.T.	A.T.	(X)		±	±			
1.	***Angachaltva***	21	2.9	2.1	0.76	26.6	0.44	0.l	8	**<0.001**	HS.
2.	***Alasya***	11	3.1	0.5	2.5	80.6	0.52	0.2	16.2	**<0.001**	H.S.
3.	***KshudraShwasa***	16	3.2	1.5	1.7	53	0.5	0.1	14.1	**<0.001**	H.S.
4.	***Nidratiyoga***	9	2.7	1.9	0.78	29.2	0.44	0.2	5.3	**<0.01**	Sig.
5.	***Daurbalyata***	17	3.2	1.7	l. 5	46.9	0.5	0.1	12.3	**<0.001**	HS.
6.	***Swedadhikya***	16	2.5	1.6	0.94	37 .8	0.44	0.1	8.5	**<0.001**	HS .
7.	***Atikshudha***	8	3.8	3	0.75	20	0.46	0.2	4.6	**<0.01**	Sig.
8.	***Gaurava***	18	2.5	0.7	1.8	72	0.43	0.1	17.6	**<0.001**	H.S.

TableNo.3: EFFECT OF THERAPY ON WEIGHT AND B.M.I.

Investigation (n=30)	Mean Score		Mean (X)	%age Relief	S.D.	S.E.	't'	'p'	Results
	B.T.	A.T.			±	±			
BMI	**28.7**	**28.2**	**0.5**	**1.7%↓**	**0.19**	**0.03**	**12.9**	**<0.001**	**H.S.**
Body weight	**73.2**	**71.8**	**1.4**	**1.9%↓**	**0.81**	**0.15**	**9.3**	**<0.001**	**H.S.**

Table No.4:EFFECT OF THERAPY ON LIPID PROFILE

Investigation (n=30)	Mean Score		Mean	%age	S.D.	S.E.	't'	'p'	Result
	B.T.	A.T.	(X)	Relief	±	±			
Cholesterol	241.5	231	11	4.5 ↓	2.5	0.5	24	<0.001	H.S.
Triglycerides	190.8	190	1.2	.68 ↓	2	0.4	3.3	<0.01	Sig.
LDL	168.5	166	2.4	1.4 ↓	2.2	0.4	5.9	<0.001	H.S.
HDL	48.53	49.8	-1.3	2.7 ↑	1.7	0.3	-4.2	<0.001	H.S.
VLDL	38.53	37.2	1.33	3.45 ↓	2.2	0.4	3.3	<0.01	Sig.