Research Article

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A STUDY OF EFFECT OF LEKHANIYA MAHAKASHAYA ON LIPID PROFILE

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ABSTRACT

Many of the heart diseases are closely associated with rise in the level of serum lipids, the condition known as 'hyperlipidaemia' which further leads to atherosclerosis. In Ayurvedic view, hyperlipidaemia could be considered analogous with increased dusht medo dhatu in the body which is caused by hypo functioning of medo-dhaatwaghi. According to Sharangdhara, any drug possessing laghu and tikshana properties, katu vipaka and ushana virya performs lekhan karma i.e. curretive and absorptive action on Dosha, Dhatu and Mala. Along with lekhan karma, owing to above said attributes, these drugs improve strength of agni particularly Jathragni and dhaatwagni which further reduces and ultimately stops production of Dhust Medo Dhatu in the body. The Lekhaniya Mahakashaya, mentioned in Charaka Samhita possesses above mentioned characteristics. The only need was to prove its hypolipidaemic effect in human body by conducting clinical trials. The present study proved this fact.

KEY WORDS: Hyperlipidaemia, lekhanika mahakashaya, lekhan karma.

INTRODUCTION

In recent decades, because of the changed lifestyle, daily routine, food habits and environmental changes, the population of unhealthy people is increasing even in developed countries. Increasing work load and mental stress, time shortage and fast life is adding more to health problems. Owing to these factors, many ailments are becoming very common now a-day like hyperlipidaemia, and the related diseases. Major outcome of hyperlipidaemia is atherosclerosis which in the heart causes coronary artery disease (CAD) and ischaemic heart disease (IHD)¹.

In the past, clinical trials have been done to assess the obesity reducing effect of lekhanika mahakashaya which is also a result of hypofunctioning of medo dhaatwagni. This research was undertaken to evaluate the changes in the level of serum lipids brought by usage of lekhanika mahakashaya in clinical dosage.

MATERIAL AND METHODS

Drug profile

Lekhaniya Mahakashaya is the third of the 50 mahakashaya described in fourth chapter of Sutra sthan of Charak Samhita² and includes following ten ingredients taken in equal quantity by weight:

Sr. No.	Hindi Name	English Name	Botanical Name	Part Used
1	Mustak	Nut grass	<i>Cyperus rotundus</i>	Bulbous root
2	Kushtha	Costus	<i>Saussurea lappa</i>	Root
3	Haridra	Turmeric	<i>Curcuma longa</i>	Dry rhizome
4	Daruharidra	Indian Berberri	<i>Berberis aristata</i>	Stem wood
5	Vacha	Sweet Flag	<i>Acorus calamus</i>	Dry rhizome
6	Ativisha	Indian Atees	<i>Aconitum heterophyllum</i>	Root
7	Katuka	Picrorhiza	<i>Picrorhiza kurrao</i>	Root
8	Chitrak	Cydon lead wort	<i>Plumbago zelanica</i>	Bark of Root
9	Chirbilwa	Indian Elm	<i>Holoptelia integrifolia</i>	Bark of stem
10	Haimvati	Oris root	<i>Iris ensata</i>	Root

Quality control and standardization of drug

All the contents of the drug were procured by pharmacy department of the college and evaluated for quality and standardization on the basis of following parameters-

- Organoleptic or morphological evaluation – Shape, colour, odour, taste, size and other special features.
- Microscopic evaluation – Quantitative microscopy, stomata, trichomes.
- Physical evaluation – Foreign matter, moisture content, viscosity, solubility, refractive index.
- Toxicity details – Pesticide residues, heavy metals.
- Physicochemical evaluation – Ash value, volatile oil content, extractive values.

Formulations of the drug

Following two pharmaceutical preparations of lekhanika mahakashaya were prepared for the clinical trials:-

- Decoction form - The mixture of all the ten contents of drug formulation was turned into Yavkoot choorna (crude powder) for the preparation of decoction.
- Extract form – Extract of each constituent of drug formulation was extracted out separately using suitable method at Amsar Pharmacy Pvt. Ltd, Indore, M.P., India

Dosage**Dosage of decoction of formulation**

According to Sharangdhara Samhita, dosage of decoction formulation of any drug is as follows³-

- (i) 4 taula i.e. 40 ml (Heen matra or low dosage)
- (ii) 6 taula i.e. 60 ml (Madhyama matra or medium dosage)
- (iii) 8 taula i.e. 80 ml (Uttam matra or high dosage)

Now a days, the physical and mental strengths of the people are not strong enough to tolerate the high dosage i.e. uttam matra of any ushana and tikshana drug like Lekhaniya Mahakashaya. So, it was planned to use only low and medium dosage of the drug for clinical trials.

Dosage of extract formulation

According to Sharangdhara, dosage of choorna (powder) form of any drug is 3 to 6 gm or in other words, the dosage range is 4.5 + 1.5 gm under this research work, average of this range i.e. 4.5 gm was chosen to calculate the dosage of extract formulation.

If 4.5 gm of powder of drug formulation is planned to be given to each patient, twice a day for a month, then 270 gm of Lekhaniya Mahakashaya would be required for each patient. For 15 patients, 4050 gm of medicine would be required. In other words, each of the content of formulation is required in quantity of 405 gm. So, 405 gm of each of the contents of formulation were extracted out separately to prepare its extract formulation. The quantity of extract obtained from 405 gm of each of content of formulation was as follows –

Mustak	67.5 gm	Kushtha	67.5 gm
Haridra	57.85 gm	Daruharidra	40.50 gm
Vacha	101.25 gm	Ativisha	40.50 gm
Katuka	101.25 gm	Chitraka	81.00 gm
Chirbilva	81.00 gm	Haimvati	101.25 gm

Thus out of 4050 gm of total quantity of L.M., 739.6 gm of extract was obtained. All these extracts were mixed together very well and this mixture was filled in the empty capsules of double zero size and single zero size. 410 mg of extract mixture was filled in each capsule of double zero size while 136 mg was filled in the each capsule of single zero size.

Considering extract formulation analogous to choorna kalpana, the dosage fixation of extract formulation was done as follows-

The dosage or quantity of extract obtained from 4.5 gm of lekhanika mahakashaya would be-

$$\frac{739.6 \times 4.5}{4050} = 0.820 \text{ gm} = 820 \text{ mg}$$

The dosage range of choorna formulation is 4.5 + 1.5 gm. So, the equivalent dosage of extract formulation came out to be 820 + 274 mg or in other words –

High dosage = 820 + 274 = 1094 mg

Medium dosage = 820 mg

Low dosage = 820 – 274 = 546 mg

In the present study, low and medium dosage of extract formulation of the drug was used for clinical trials for the same reason as mentioned in the case of decoction formulation.

Selection of patients

Hyperlipidaemic patients, registered under outpatient door of Rajvaidya Prem Shankar Govt. Ayurvedic Hospital, Madan Mohan malvia Govt. Ayurvedic College, Udaipur, were selected for clinical trials.

Inclusion criteria

Hyperlipidaemic patients, diagnosed on the basis of serum lipid profile assay; of the age group of 16 to 60 yrs and irrespective of their sex; religion and economical status were selected for trials.

Exclusion criteria

Patients having history of complications or consequential diseases of hyperlipidaemia like myocardial infarction, angina were omitted.

Clinical trial design

30 patients of hyperlipidaemia diagnosed on the basis of biochemical estimation of their lipid profile were selected for clinical trials. Depending upon the type of formulation planned to be given, these patients were divided randomly into two groups entitled F₁ and F₂ each containing 15 patients. Each group was further divided into two sub-groups on the basis of dosage of the formulation planned to be given to the patients as follows-

- a) Sub-group F₁LD - To be treated with heen matra i.e. 40 ml of decoction of Lekhaniya Mahakashaya.
- b) Sub-group F₁MD - To be treated with madhyam matra i.e. 60 ml of decoction.
- c) Sub-group F₂LD - To be treated with heen matra i.e. 546 mg of extract of Lekhaniya Mahakashaya.
- d) Sub-group F₂MD - To be treated with madhyam matra i.e. 820 mg of extract.

Pre-medication estimation of serum lipid profile of the patients

Before starting medication, blood sample of each patient was taken for the biochemical assay of their serum lipid profiles. Purpose of this pre-medication blood sampling and lipid profile assay was two folds-

- i) To confirm the hyperlipidaemic status of the patients before clinical trials.
- ii) To compare this lipid profile with post medication lipid profile of the patients to ascertain the effects of lekhanika mahakashaya on their lipid profile.

Medication of the patients

The medication plan for the patients of different sub-groups was designed as mentioned below-

- a) Patients of sub-group F₁LD were given 40 ml of decoction of lekhanika mahakashaya, 12 hourly i.e. twice a day for one month.
- b) Patients of sub-group F₁MD were given 60 ml of decoction of lekhanika mahakashaya, 12 hourly for one month.
- c) Patients of sub-group F₂LD were given 546 mg of extract of lekhanika mahakashaya, 12 hourly for one month.
- d) Patient of sub-group F₂MD were given 820 mg of the extract of lekhanika mahakashaya, 12 hourly for one month.

Post-medication estimation of serum lipid profile of the patients

After completion of medication for one month, blood sample of each patient was taken and serum lipid profile

assay was done for the comparative study of it with pre-medication lipid profile.

Criteria for overall assessment

Comparative analysis of the pre-medication and post-medication serum lipid profile of each patient was the sole criteria to assess the effect of different formulations of lekhaniya mahakashaya on their lipid profiles.

RESULTS

Sub-group F₁LD - The results showed an average decrease of 21.1% in the level of serum triglycerides, an average decrease of 10.78% in the level of serum cholesterol, an average decrease of 21.27% in the level of serum very low density lipids (VLDL), an average

decrease of 30.24% in the level of serum low density lipids (LDL) and an average decrease of 21.37% in the level of serum total lipids in the patients of this sub-group. Almost no change was found in level of serum high density lipids (HDL).

Sub-group F₁MD - In these patients, an average decrease of 22.57% in the level of serum triglycerides, an average decrease of 20.87% in the level of serum cholesterol, an average decrease of 22.83% in the level of serum very low density lipids, an average decrease of 26.11% in the level of serum low density lipids and an average decrease of 18.02% in the level of serum total lipids was found. But, an average increase of 5.65% was found in level of serum high density lipids.

Table 1: Pre and Post-medication Serum lipid profiles of patients of Sub-group – F₁LD

Sr. No.	OPD. Reg. No.	Serum Triglycerides (mg %)		Serum Cholesterol (mg %)		Serum high density lipids (mg %)		Serum very low density lipids (mg %)		Serum low density lipids (mg %)		Total Lipids (mg %)	
		Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.
1.	8973	296.1	231.8	288.8	206.1	49.8	53.5	59.2	46.36	179.80	106.24	925.4	698.5
2.	8974	267.3	209.0	283.0	216.6	41.6	44.5	53.46	41.80	187.94	126.30	876.2	684.1
3.	059	191	143.7	261.0	205.5	36.4	40.2	38.2	28.74	186.40	136.06	750.5	596.3
4.	060	204.8	153.0	269.4	199.1	48.2	52.9	40.96	30.60	186.26	116.42	771.0	603.0
5.	065	204.6	152.8	290.5	205.5	35.1	39.9	40.92	30.56	214.48	135.05	855.0	605.0
6.	066	151.5	109.5	259.8	200.1	36.9	35.0	30.3	21.09	192.60	144.01	713.0	547.0
7.	067	274.1	254.3	258.1	221.2	42.2	31.3	54.8	50.90	161.10	139.00	833.0	730.0
8.	068	391.6	308.9	258.1	223.1	34.5	25.7	78.3	61.80	181.50	135.60	981.0	782.0
	$\bar{X}$	247.62	195.37	234.99	209.65	40.59	40.37	49.51	38.98	186.26	129.92	834.01	655.73
Average change		50.25		25.34		0.23		10.53		56.34		178.28	
Average change in percentage		21.10%		10.78%		0%		21.27%		30.24%		21.37%	

Table 2: Pre and Post-medication Serum lipid profiles of patients of Sub-group – F₁MD

Sr. No	O.P.D. Reg. NO.	Serum Triglycerides (mg%)		Serum Cholesterol (mg%)		Serum high density lipids (mg%)		Serum very low density lipids (mg%)		Serum low density lipids (mg%)		Total Lipids (mg%)	
		Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.
1.	70	177.7	131.5	229.0	170.1	34.1	34.8	35.50	26.30	169.70	120.00	690.0	618.6
2.	421	238.0	184.0	282.1	231.6	34.4	32.9	47.60	36.80	200.10	161.84	847.2	673.63
3.	567	189.5	149.3	242.0	193.3	31.1	33.4	37.90	29.86	173.00	130.04	708.9	574.6
4.	078	191.4	136.9	220.4	171.4	44.6	46.4	38.28	27.38	137.52	097.62	691.3	529.1
5.	1185	208.4	164.0	246.0	201.4	32.3	37.5	41.68	32.80	173.02	131.10	737.5	605.4
6.	1186	181.3	146.5	263.6	213.9	46.5	51.0	36.26	29.30	180.24	133.60	757.5	636.91
7.	1187	221.6	178.0	256.4	194.7	42.4	44.3	44.32	35.60	169.70	114.80	789.2	642.3
	$\bar{X}$	201.13	155.74	248.5	196.63	37.9	40.04	40.30	31.10	171.90	127.00	745.94	611.5
Average change		45.39		51.87		2.14		9.20		44.90		134.44	
Average change in percentage		22.56%		20.87%		5.64%		22.82%		26.11%		18.02%	

Table 3: Pre and Post-medication Serum lipid profiles of patients of Sub group – F₂LD

Sr. No.	O.P.D. Reg. No.	Serum Triglycerides (mg%)		Serum Cholesterol (mg%)		Serum high density lipids (mg%)		Serum very low density lipids (mg%)		Serum low density lipids (mg%)		Total Lipids (mg%)	
		Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.
1.	496	162.6	120.2	252.0	207.0	33.6	34.4	32.52	24.04	185.88	133.58	702.1	554.8
2.	499	199.1	143.2	205.5	168.4	32.8	36.1	39.82	28.64	142.88	103.66	654.9	528.4
3.	567	188.9	143.7	238.0	188.1	30.0	31.9	37.78	28.74	170.22	129.46	694.8	654.8
4.	568	391.6	264.0	269.6	198.7	34.5	28.6	78.32	52.80	157.0	117.3	966.6	691.0
5.	1250	219.2	162.4	220.8	181.0	36.6	38.8	43.84	32.48	139.36	108.72	697.0	564.1
6.	1252	181.0	133.0	288.0	222.0	37.8	43.4	36.20	26.60	214.0	152.0	796.6	622.0
7.	1253	206.0	153.0	248.0	179.5	39.1	42.2	41.20	30.64	157.7	106.66	735.1	553.0
8.	1254	161.0	128.0	242.2	190.1	38.1	42.4	32.32	25.60	171.88	132.5	687.3	561.7
	$\bar{X}$	213.75	155.96	245.51	191.85	35.31	37.22	41.87	30.69	167.36	122.98	741.88	591.22
Average change		57.79		53.66		1.91		11.18		44.38		150.66	
Average change in percentage		27.03%		21.85%		5.40%		26.70%		26.51%		20.30%	

Table 4: Pre and Post-medication Serum lipid profiles of patients of Sub group – F₂MD

Serial No.	O.P.D. Reg. No.	Serum Triglycerides (mg%)		Serum Cholesterol (mg%)		Serum high density lipids (mg%)		Serum very low density lipids (mg%)		Serum low density lipids (mg%)		Total Lipids (mg%)	
		Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.	Pre. Med.	Post Med.
1.	1080	178.7	129.2	295.0	202.1	43.0	44.70	35.74	25.84	216.26	131.56	815.8	578.7
2.	1081	186.6	132.4	260.0	197.7	41.60	43.90	37.32	26.48	181.08	127.32	708.2	571.9
3.	1256	188.0	122.2	268.6	188.8	30.0	42.6	37.6	24.44	193.0	121.76	748.5	542.5
4.	1257	233.0	176.5	229.8	181.4	37.8	42.9	46.6	35.3	145.4	98.2	731.6	577.3
5.	1259	191.0	134.5	270.0	203.1	50.3	56.8	38.2	26.9	181.5	119.3	781.6	596.8
6.	1260	192.2	129.7	261.0	201.0	32.8	37.3	38.44	25.64	189.76	137.76	747.52	581.7
7.	1261	180.1	148.0	230.0	187.0	40.2	46.5	36.02	29.6	161.78	110.9	688.9	568.5
	$\bar{X}$	192.8	138.93	259.2	194.44	39.39	44.96	38.56	27.79	181.25	120.97	746.02	573.91
Average change		53.87		64.76		5.57		10.77		60.28		172.11	
Average change in percentage		27.94%		24.98%		14.14%		27.93%		33.26%		23.07%

Graph 1: Pre and post-medication levels of serum lipids (average) of sub-group – F₁LD **Graph 3: Pre and post-medication levels of serum lipids (average) of sub-group – F₂LD** **Graph 2: Pre and post-medication levels of serum lipids (average) of sub-group – F₁MD** **Graph 4: Pre and post-medication levels of serum lipids (average) of sub-group – F₂MD**

Sub-group F₂LD - In these patients, an average decrease of 27.04% in the level of serum triglycerides, an average decrease of 21.86% in the level of serum cholesterol, an average decrease of 26.7% in the level of serum very low density lipids, an average decrease of 26.52% in the level of serum low density lipids and an average decrease of 20.31% was found in the level of serum total lipids. But, an average increase of 5.41% was found in level of serum high density lipids.

Sub-group F₂MD - In these patients, an average decrease of 27.94% in the level of serum triglycerides, an average decrease of 24.98 in the level of serum cholesterol, an average decrease of 27.93% in the level of serum very low density lipids, an average decrease of 33.26% in the level of serum low density lipids and an average decrease

of 23.07% was found in the level of serum total lipids. An average increase of 14.14% was also found in level of serum high density lipids.

DISCUSSION

Comparative study of results shows that the patients of sub- group F₂MD which were treated with 820 mg of extract, twice a day for one month, got maximum benefit among four sub-groups. Patients of sub-group F₁LD which were treated with 40 ml of decoction formulation, twice a day for one month, got least benefit among four sub-groups. It was also proved that extract formulation yields better hypolipidaemic effect than decoction formulation. The madhyam matra (medium dose) of decoction as well as extract formulation yields better

hypolipidaemic effect than Heen matra (low dose). It was found that Lekhaniya Mahakashaya has got maximum depleting effect on serum low density lipids.

Probable mode of action

The hypolipidaemic effect of the Lekhaniya Mahakashaya can be attributed to the following factors:

Firstly, one constituents of this formulation viz. Katuka has choleric and cholegogue-purgative actions. Since, bile salts are required for absorption of fat and lipids from gut, their excretion would lead to decreased absorption of fat and lipids in the gut increasing faecal fat and bile salt contents. Subsequently, concentration of lipids in serum is decreased.

Contents of Lekhaniya Mahakashaya contain essential fatty acids (polyunsaturated fatty acids) e.g. linolenic acid. Studies, have shown that intake of diet containing linolenic acid alter the fatty acid composition of the plasma lipoproteins and lessens their capacity to carry lipids, cholesterol in particular with a consequent lower levels of them in blood.

Probable mode of action from Ayurvedic point of view

Hyperlipidaemia is caused by hypo-functioning of 'Medo-dhaatwagni'. As a result of this condition, 'dushta medo-dhaatu' i.e. unwanted quantity of lipids is increased in the body.

As per Sushruta, the drugs which perform lekhan karma are mainly constituted of Vayu and Agni mahabhoot⁴. Hence, the properties of wholesome formulation of Lakhaniya Mahakashaya are as follows –

Rasa - Katu, Tikta

Vipaka - Katu

Virya - Ushna

Guna - Laghu, Tikshana, Ruksha

All these properties of Lakhaniya Mahakashaya render it a Medo-dhaatu depleting formulation, because, these properties are contrary to the properties of Medo-dhaatu⁵.

Secondly these properties of Lakhaniya Mahakashaya, make it a 'jatharaagni' promoting formulation. Jatharaaghi stimulation corrects hypofunctioning of Medo-dhaatwagni and checks increase in the quantity and subsequent deposition of Medo-dhaatu in the body.

Relevant actions of Lakhaniya Mahakashaya because of each one of these properties are as follows:-

Laghu guna is characteristic of drugs constituted of 'Vaayu and Agni mahabhoota'. Drugs, possessing this property produce lightness in the body and promote the jatharaagni. Both of these actions help in reducing accumulation of medo dhaatu in the body. Tikshna guna is characteristic of drugs, constituted of Agni mahabhoota. These drugs perform action of shodhana, lekhan and kapha-hara karma. Owing to the above mentioned properties, Lekhaniya Mahakashaya is igneous in nature, stimulates jatharaagni and performs lekhan karma in the body.

When we look at characteristics and actions of contents of Lekhaniya Mahakashaya individually, we find each of the contents contribute to lekhan karma. Katuka is 'pitta rechaka and pitta virechana' (choleric and chologogue purgative drug). This drug excretes pitta (bile) which is required for the 'ahaar paaka'. This results into depletion of dhaatu, mainly Medo and Mans dhaatu. By inducing virechana, it performs shodhan karma reducing medo-

dhaatu in the body⁶. Haridra and Daruharidra stimulate agni and performs lekhan karma because of their katu-tikta taste, katu vipaka, ushna virya and laghu, ruksha guna. Tikshana guna of Vacha, Chitraka and Kushtha⁷ along with above mentioned characteristics aids more to lekhan karma. Chirbilva and Haimvati mainly perform lekhan karma on dhaatu and body because of their properties. Contrary to other contents of Lekhaniya Mahakashaya, Mustak and Ativisha performs 'grahi' karma hence, they check the excessive motions caused by Katuka. Grahi karma, also helps re-absorption of water in large intestine reducing the risk of patient getting dehydrated because of loose motions. So, it is concluded that each of the content of the Lekhaniya Mahakashaya contributes to make it an ideal hypolipidaemic formulation.

CONCLUSION

Lekhaniya Mahakashaya has got hypolipidaemic effect and the most probable mode of action is by excreting bile in faeces reducing absorption of all types including fats lipids in the gut. In comparison to the decoction formulation, the extract formulation of Lekhaniya Mahakashaya yields better hypolipidaemic effect and the madhyam matra of extract or decoction formulation yields better hypolipidaemic effect than Heen matra of respective form. Further, it was concluded that Lekhaniya Mahakashaya has got maximum effect on low density lipids and least on high density lipids. At the same time, it was concluded that more precise clinical trials should be taken to ascertain the exact details of pharmacological action of Lekhaniya Mahakashaya on serum lipids and lipoproteins before recommending it as an established hypolipidaemic formulation.

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