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A COMPARATIVE STUDY ON LEKHANIYA MAHAKASHAYA GHAN VATI AND MUSTADI GHAN VATI IN THE MANAGEMENT OF DYSLIPIDEMIA

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ABSTRACT

Introduction: Dyslipidemia is an abnormal amount of lipids (e.g., triglycerides, cholesterol, and/or fat phospholipids) in the blood. This is often due to diet and lifestyle. It is also known as hyper-lipoproteinemia. *Jatharagnimandya* (weakness of digestive fire) and *Medodhatvagnimandya* help in the vitiation of *Kapha dosha* (humor) and *Medo Dhatu* (Fatty tissue) is further involved in the pathogenesis of dyslipidemia. **Aim:** To evaluate the comparative effect of *Lekhaniya mahakasaya Ghan vati* and *Mustadi Ghan vati* in management of Dyslipidemia. **Material and Methods:** Patients with a high lipid profile were selected and randomly divided into two groups of 15 patients each. *Lekhaniya mahakasaya Ghan vati* and *Mustadi Ghan vati* were given in equal dose and for equal duration (6 weeks). Body Mass Index (BMI), weight, and lipid profile parameters were taken for assessment and statistically interpreted with paired and unpaired 't' tests before and after treatment. **Result:** Group-A and Group-B have provided statistically highly significant relief in weight and BMI ($p<0.001$). But Group A provided significant improvement in S. Cholesterol, S.Triglycerides, S.LDL, S.VLDL ($p<0.05$) and insignificant relief in S.HDL ($p>0.05$) whereas in *Mustadi Ghan vati* (Group-B) insignificant relief found in all lipid parameters ($p>0.05$).
Conclusion: Both drugs have the same role in the decrease in weight and BMI but there is a difference in effect on lipid parameters.

Keywords: Dyslipidemia, *Jatharagnimandya, Medodhatvagnimandya*, *LMG*, *MG.*

INTRODUCTION

Dyslipidemia may be manifested by elevation of the total cholesterol, the "bad" low-density lipoprotein (LDL) cholesterol, very-low-density lipoprotein (VLDL) cholesterol, and the triglyceride concentrations, and a decrease in the "good" high-density lipoprotein (HDL) cholesterol concentration in the blood. It is also known as hyper-lipoproteinemia because these fatty substances circulate in the blood attached to protein. Many heart diseases are associated with a rise in the level of serum lipids, the condition known as Dyslipidemia which further leads to atherosclerosis. Hereditary factors may be involved in its cause too.[1] Many scholars have performed some clinical research on Hyperlipidaemia/ Dyslipidaemia and suggested correlations with it, like *Rasagata Sneha Vriddhi*, *Raktagata Sneha Vriddhi*, *Rasa-Raktagata Sneha Vriddhi*, and *Medoroga.* But there was no comprehensive comparative clinical work performed on *Lekhaniya Mahakashaya gana.* The drugs of *Lekhaniya mahakashaya gana*[2] have *Ushna, Tikshna, Katu,* and *Sroto-Shodhaka* properties so this *Dasemani Gana* (Group of ten drugs) was selected for a clinical trial in form of *Ghan vati. Lekhaniya mahakashaya Ghana vati* (Group A) was taken for a clinical trial in parallel to *Mustadi*[3] *Ghan vati* have also *Tikta, Katu, Kashaya rasa, Katu Vipaka,* and *Kapha-Vata Shamaka* properties which have been already dictated for the treatment of *Santarpanjanya vyadhi*[4](hyper-nourishing diseases). Because dyslipidemia can be co-related with *Vriddha Asthayi Medo Dhatu* and taken in the category of *Santarpanjanya vyadhi,* this study was planned to assess the efficacy of *Lekhaniya Mahakashaya Ghan Vati (LMG)* and *Mustadi Ghan vati (MG)* comparatively in management of dyslipidemia.

Hypothesis:

H_0: There is no difference in the effect of *Lekhaniya mahakashaya Ghan vati* and *Mustadi Ghan vati* in the management of Dyslipidemia.

H_1: There is a difference in the effect of *Lekhaniya mahakashaya Ghan vati* and *Mustadi Ghan vati* in the management of Dyslipidemia.

Aim and Objectives:

To evaluate the comparative effect of *Lekhaniya mahakasaya Ghan vati* and *Mustadi Ghan vati* in management of Dyslipidemia.

Materials and Methods:

Selection of the Patients: Patients were selected irrespective of caste, sex, profession, etc. from O.P.D. and I.P.D. of Govt. Akhandanand Ayurveda College & Hospital, Ahmedabad and Govt. Maniben Ayurved Hospital, Ahmedabad.

Ethical Clearance

As this was clinical research, Institutional Ethics Committee (IEC) approval was taken before initiation of research vides its letter No.34/INSTITUTIONAL ETHICAL COMMITTEE, Dt.25/06/2016. Adverse drug reaction (ADR) if any was duly noted and reported. Written consent for the presence of each patient was taken before starting the treatment. Basic information about the disease and treatment was given to the patient. The study has also been registered in CTRI (Clinical Trials Registry- India) on 06/01/2017, under CTRI/2017/01/007642 [Registered on: 06/01/2017].

Inclusion Criteria:

- Patients between the age of 18-and 60 yrs. were taken for study.
- If anyone or many parameters among the lipid profile of an individual are found to be within the limit

given below, then the subject will be included in the study.

Serum-cholesterol: 200mg/dl or more,
Serum triglycerides -150mg/dl or more,
Serum LDL - 100mg/dl or more,
Serum VLDL-10-30mg/dl or more,
Serum HDL - <40mg/dl.

Exclusion Criteria:

- Patient having age <18 or >60 yrs.
- Patient having serious cardiac problems- M.I., Cardiac Failure.
- Patients with endocrinal disorders like diabetes mellitus, and hypothyroid were excluded.

- Patients having a history of obesity and Hyper-lipidemia due to drugs e.g. corticosteroids, Anti-depressant drugs were not taken for study.
- When Lipid profile parameters were come in a "very high range, patients were excluded which is given below-

  Serum cholesterol->300mg/dl.

Serum triglycerides->500mg/dl.

Serum LDL- >190mg/dl.

Plan of Study:-

Study Type: - Single-blind, parallel, clinical trial with the random sampling method.

No. of Groups: Two

Sample Size: 30 (15 patients in each group).

Drugs and Posology:

Group A: Patients were treated with *Lekhaniya mahakashaya Ghan vati*, 6 *Vati* (500 mg each vati) two times a day (total 6gm per day), before a meal with Lukewarm water for 6 weeks.

Group B: Patients were treated with *Mustadi Ghan vati*, 6 *Vati* (500 mg each vati) two times a day (total 6gm per day), before a meal with Lukewarm water for 6 weeks.

Follow-up: Follow-up was done for 4 weeks after the completion of treatment to see the continuous effect of the trial drug.

Criteria for Assessment: -

Assessment of therapy was done on lipid profile, Weight, and BMI of patients before and after treatment.

Statistical Analysis: The information gathered based on the above observations was subjected to statistical analysis. The Paired t-test was carried out for all parametric data to analyze the effect of individual therapy in both groups after and before the treatment. Whereas Unpaired 't' was applied for the comparison of both groups.

The obtained results were interpreted as i.e. given below.

- Insignificant $p>0.05$
- Significant $p<0.05$
- Highly significant $p<0.001$

Result:

Overall % relief in Objective parameters:

In Group A overall % relief is 5.36% in S. Chol, 16.03%% in S.Trigly., 12.95 % in S.LDL, 24.88% in S.VLDL, 0.18% in S.HDL, 4.97% in weight and 5.11% in BMI. In Group B overall % relief was 1.84% in S. Chol, 9.60%% in S.Trigly., 9.40 % in S.LDL, 9.70% in S.VLDL, 0.18% in S.HDL, 4.15% in weight and 4.11% in BMI. (Table No. 1, 2, 3, 4, 5, 6, 7). In S. Chol., S. Trigly., S.LDL and S. VLDL lipid parameters there were significant results found but insignificant results were seen in S.HDL whereas highly significant results were seen in weight and BMI. In all lipid parameters, there was insignificant result observed whereas highly significant result was seen in weight and BMI. (Table No.8)**.** In comparison, in most lipid parameters there was no significant differences seen in between Group A and Group B. (Table No.9)

DISCUSSION

Term fat is often meant "lipids", under which there are several classes of lipids present e.g. Triglycerides, conjugated lipids (phospholipids), cholesterol, etc.[5] Lipoproteins are macromolecular complexes that carry hydrophobic plasma lipids, particularly cholesterol and triglycerides, in the plasma. Elevated lipoprotein levels in most patients with Dyslipidemia reflect the adverse impact of a sedentary lifestyle, excess body weight, and diets high in total and saturated fat superimposed on a genetic background that confers susceptibility to increased circulating lipids.[6] In our bodies, many issues are rich in lipids. They are *Medodhatu*, *Vasa* and *Majjadhatu*. *''Medhyati snihyati anen iti medah'',* literally word meda is derived from the root *'stimida snehane'* which stands for *Sneha*, fats, oil, etc. All these structures have *Snehatva* (oiliness) as a common feature and smoothen (*Snehyati*) the body. All three differ in their site and function. But all those who have *snehan lakshan*, only convert to other forms as *meda*, *vasa*, *majja*, etc, by digestive process (*avasthapaka*) and metabolic processes (*dhatvagnipaka*). The formation of *Medo Dhatu* is from *Mamsa Dhatu* when acted upon by

Meda Dhatvagni on *Meda poshaka Ansha*. If any disturbances are found in these above pathways during the formation of *Medo Dhatu*, it may lead to *Medo Vriddhi*. It can be assumed that in the pathogenesis of dyslipidaemia, due to *agnimandya* (especially *Medodhatwagnimandya*) which is caused by *Vishista-Aharavashat*, i.e. *Ati-snigdha, guru, pichhila ahara* & *Ati-sampuranat*, *Avyayamata*, *Divaswapnata* (faulty dietary and lifestyle factors), *Adrishtavashata* or *Beeja doshavastha* (Hereditary or genetic factors) or *Medasavritta Margatvata* (obstruction to path of *vayu* by *Meda*). Due to all these factors, excessive accumulation of *aparipakva* or *ama kapha Dosha* and *meda dhatu* in various *Srotas* leads to *Rasa-Raktagata Sneha vridhhi.* Further, if these *Aparipakva Kapha* and *meda* increase in *Rasa-Raktavaha Srotas* results in obstruction to the movement of *Vata* and *Rakta*, which finally manifest as a diseased condition. Also, *Aprakruta Kapha* and *Meda* can increase ether due to *Jatharagnimandhya* or *Dhatwagnimandhya*. *Jatharagnimandhya* may lead to *Amarasa* and further decrease *Medodhatwagni*. Due to all these causative factors, *Ama Sthayi Medo Dhatu* or *Ama asthayi Medo Dhatu* occurs. *Ama asthayi Medo Dhatu* leads to *Dyslipidemia*.[7]

***Lekhaniya mahakashaya Ghan vati* (Group A):**

As per Shushrut, the drugs which perform *lekhana karma* are mainly constituted of *vayu* and *agni mahabhoot*. Hence, the properties of wholesome formation of *Lekhaniya Mahakashaya Gana* are *Rasa-Katu, Tikta; Vipaka- Katu; Virya- Ushna* and *Guna-Laghu, Tikshna* and *Ruksha.* It pacifies the vitiated *kapha dosha* and *medo dhatu,* which are dominant in the pathogenesis of dyslipidemia. It also depletes the excessively produced *rasa, meda, vasa, sweda, and kleda*, which are all similar in attributes to *kapha dosha*. Thus, it has the potential to act against the *santarpanottha* pathogenesis of dyslipidemia and also bring about a reduction in *vruddha sthayi medo dhatu* which is reflected by the results in anthropometric measurements, weight, and BMI. So it can be concluded from the above properties that *Lekhaniya Mahakashaya Gana* has ideal properties to diminish Dyslipidemia (*Medo-dosha*).[8],[9] Saponins and tannins present in some of the constituent drugs of LMG, are known to prevent cholesterol absorption, interfere with its entero-hepatic circulation, and increase its fecal excretion and fecal bile acid excretion, thereby leading to a reduction in cholesterol.[10]

***Mustadi Ghana vati* (Group B):**

Mustadi Kwath is indicated in all the *Santarpanjanya* diseases or diseases taking place due to overnutrition. *Mustadi Ghana vati*, a modified form of *Mustadi Kwath* is one such ideal formulation. In the contents, *Aragvadha* and *Triphala* have mild purgative action which causes *Anulomana* of *Vayu* which further corrects the body *Vayu* bringing an end to the *Vatapradhana* Samprapti. The drugs like *Patha* and *Gokshur* are *Mutravirechana* which bring about diuresis relieving the body of the excess of *Kleda*. *Aragvadha*, *Kutaj*, *Patha*, *Nimba*, *Khadir*, *Haridra*, and *Daruharidra* are known to act on *Medo Dhatu* and allied *Dhatus* and are indicated in diseases like *Kushtha*, *Medo Roga*, and *Prameha*. These drugs relieve the body's excess of *Kapha*, *Meda*, *Kleda*, *Vasa*, and *Sweda* by diminishing their *Drava Guna*. Drugs like *Neem, Patha, and Triphala* bring about augmentation of the digestive fire leading to the proper formation of the *Rasadi Dhatus*. *Patha*, *Musta*, *Triphala*, *Haridra*, and *Daruharidra* digest the *Ama Dosha* present at the *Jatharagni* level as well as the *Medodhatvagni* level. Also, drugs like *Triphala*, *Khadira* are *Rasayana* in nature which lead to the formation of optimal *dhatus* and protect the body from injury due to vitiated Doshas.

CONCLUSION

Lekhaniya Mahakashaya Ghan vati (Group-A) has provided significant improvement in S. Cholesterol, S. Triglycerides, S.LDL, S. VLDL ($p<0.05$) and insignificant relief in S.HDL ($p>0.05$) whereas *Mustadi Ghan vati* (Group-B) has insignificant relief in all lipid parameters ($p>0.05$). Both the drugs had provided statistically highly significant relief in weight and BMI ($p<0.001$). It is concluded that statistically, there is no difference in the effect of *Lekhaniya mahakashaya Ghan vati* and *Mustadi Ghan vati* in Dyslipidemia.

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Tables:

Table 1: Effect of trial drug on total serum cholesterol.

Gr.	Mean Value S. Chol. (mg/dL)		Diff.	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
A	227.69	215.47	12.21	5.36↓	14.97	3.87	3.159	0.007	S
B	224.79	220.63	4.15	1.84↓	35.49	9.16	0.453	0.657	IS

Table 2: Effect of therapies on S. Triglycerides.

Gr.	Mean Value S.TG. (mg/dL)		Diff.	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
A	205.68	172.70	32.98	16.03↓	32.81	8.47	3.893	0.002	S
B	157.96	142.79	15.17	9.60↓	33.46	8.64	1.756	0.101	IS

Table 3: Effect of therapies on LDL.

Gr.	Mean Value S.LDL (mg/dL)		Mean Diff.	%	Paired 't				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
A	143.85	125.22	18.63	12.95↓	21.29	5.49	3.387	0.004	S
B	142.04	128.69	13.35	9.40↓	13.35	9.73	1.372	0.192	IS

Table 4: Effect of the trial drugs on S. VLDL.

Gr.	Mean Value S. VLDL. (mg/dL)		Diff.	%	Paired 't				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
A	38.60	29.00	9.60	24.88↓	9.97	2.58	3.729	0.002	S
B	29.94	27.03	2.91	9.70↓	8.15	2.10	1.380	0.189	IS

Table 5: Effect of trial drug on S.HDL.

Gr.	Mean Value S.HDL (mg/dL)		Diff.	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
A	41.93	42.00	-0.08	-0.18	7.587	1.96	-0.039	0.969	IS
B	49.47	49.56	-0.09	-0.18	3.95	1.02	-0.087	0.931	IS

Table 6: Effect of therapy on body weight.

Gr.	Mean Value (kg)		Diff.	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
A	83.97	79.80	4.17	4.97 ↓	0.957	0.247	16.898	<0.001	HS
B	75.06	71.99	3.07	4.15 ↓	1.249	0.323	9.528	<0.001	HS

Table 7: Effect of therapy on Body mass index.

Gr	Mean Value (kg/m^2)		Diff.	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
A	30.17	28.64	1.53	5.11↓	0.474	0.122	12.467	<0.001	HS
B	31.86	30.54	1.32	4.11↓	0.684	0.177	7.478	<0.001	HS

Table 8: Percentage-wise improvement in objective parameters and comparative effect of therapy statistically between group A and group B.

Lipid parameters & Others	Gr. A Mean % Relief	Significance	Gr. B Mean % Relief	Significance	Comparative Significance Difference
S. Chol.	5.36%	S	1.84%	IS	IS
S. Trigly.	16.03%	S	9.60%	IS	IS
S.LDL	12.95%	S	9.40%	IS	IS
S. VLDL	24.88%	S	9.70%	IS	IS
S.HDL	0.18%	IS	0.18%	IS	IS
Weight	4.97%	HS	4.15%	HS	S
BMI	5.11%	HS	4.11%	HS	IS

Table 9: Statistically, the overall comparative difference in the effect of therapy (based on Lipid profile).

Gr.	N	Total Mean Diff	Unpaired 't' test				
			S.D. (±)	S.E. (±)	't'	'p'	Significance
A	15	73.34	45.930	11.859	1.676	0.105	IS
B	15	35.49	74.427	19.217			

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