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Clinical Evaluation of *Medavriddhi* in Hyperlipidemia and its Management with *Lekhaniya Mahakashaya.*

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ABSTRACT:

Introduction: *Dhatu*s are the structural and functional units of human body. The healthy state of body depends on their equilibrium state whereas disequilibrium in *Dhatu*s leads to pathological conditions and diseases. *Meda* is one of the seven *Dhatu*s of human body which is produced from its precursor *Asthi Dhatu*. *Meda Dhatu* can be correlated with lipids and lipoproteins. The state of hyperlipidaemia can be correlated with the state of *Meda Vriddhi*.

Aims and Objectives: This study was carried out to clinically evaluate the features of *Meda Vriddhi* in individuals having hyperlipidaemia as well as to evaluate the efficacy of stipulated poly herbal formulation '*Lekhaniya Kashayam*' to combat the state of *Meda Vriddhi* and subsequently hyperlipidaemia.

Materials and Methods: 35 subjects having hyperlipidaemia have been selected for the study based on inclusion and exclusion criteria and subsequently the features of *Meda Vriddhi* has been clinically evaluated in those subjects. The stipulated poly herbal preparation '*Lekhaniya Kashaya*' was administered in a dose of 50 ml as warm decoction, thrice daily for 60 consecutive days. The efficacy of the drug was evaluated after 60 days based on subjective and objective parameters.

Result and Discussions: The subjective parameters of *Meda Vriddhi* are clinically present in maximum number of individuals having hyperlipidaemia. The result also reveals the significant efficacy of the '*Lekhaniya Ksahaya*' on relevant subjective and objective parameters with a 'p' value <0.001 in the majority of subjective and objective parameters.

Conclusions: The state of hyper lipidaemia can be compared with the state of *Meda Vriddhi* based on the presence of *Meda Vriddhi Lakshana* in subjects having hyper lipidaemia. The therapeutic management with *Lekhaniya Kashaya* can be equally effective to combat the state of *Meda Vriddhi* as well as hyper lipidaemia.

Keywords: *Meda*, *Meda Vriddhi*, Hyper lipidaemia, Dys lipidaemia

INTRODUCTION

According to *Ayurveda*, our human body is composed of three principal components namely *Dosha* (fundamental physiological regulatory principles), *Dhatu* (body tissues) and *Mala* (waste products) [1]. Among these three

components, *Dhatu*s are the structural and functional units of our body. The main function of '*Dhatu'* as mentioned by *Acharya Sharangadhar* is - "*Dhatava Deha Dharanat*" [2]. The literary meaning of the word '*Dharana'* is 'holding, bearing, keeping, retention, preserving, protecting, maintaining, possessing etc.' [3]. So, we can say that, which holds up our body or which maintains our body's normalcy should be referred as *Dhatu*. In *Charaka Samhita*, *Dhatus* have been classified into two categories - one is *Prasada Dhatu* (should be taken for the essential structural components of body like *Rasa, Rakta, Mamsa* etc.) and other is *Mala Dhatu* (should be taken for the waste materials like *Sweda, Mutra, Purisha* etc.) [4]. In general, the term *Dhatu* should be regarded for the *Prasada Dhatu* as mentioned by *Acharya Charaka*. According to all the principal scholars, *Dhatu*s are the metabolic substrates produced by the action of *Dhatwagni* from *Ahara Rasa*. Three principal hypothesis has been proposed altogether by different scholars to explain the process of formation of *Dhatu*s in human body (which is known as *Dhatupaka*) - *Kshiradadhi Nyaya* (theory of transformation), *Kedarikulya Nyaya* (theory of transmission) and *Khalekapote Nyaya* (theory of selectivity) [5]. *Dhatu*s are said to be of seven different types, each of them has their own distinct functions within our body and accordingly there are distinct clinical conditions caused by their altered state - both in terms of deficiency as well as increment. *Meda* (lipids and adipose tissues) is one of such Dhatu, which is derived from its precursor *Mamsa Dhatu* (muscle tissues) and gives formation to its successor *Asthi Dhatu* (bony tissues) as per the theory of transformation [6]. The major physiological function of *Meda Dhatu* is said to be *Snehana* (provides moistening to all other *Dhatus, Ashayas* and *Srotas*), *Swedana* (expelling out *Kleda* through *Lomakupa*), *Drirhatvam* (framing the structure of body) and *Asthi Pustima* (nourishment of bones) [7]. The pathological alteration of *Meda Dhatu* are presented in two states: one is in form of *Meda Vriddhi (aggregation of Meda)* and another is in form of *Meda Kshaya (depletion of Meda)* [8]. Conceptually according to *Ayurveda*, all the diseases arise due to mainly depletion of *Dhatu*s (*Dhatu Kshaya*) except few exceptions. On the other hand, aggregation of *Dhatu*s (*Dhatu Vriddhi*) manifests their own clinical features and should be interpreted as a specific pathological condition rather than a definite disease. The *Meda Dhatu* comprises two parts, one is the *Sthula Sthayi Dhatu* which remains in the pocket of fat in *Vapabaha* i.e abdominal fat [9]. The other part of *Meda* is *Drava Meda* which circulates through body and different *Srotas* to provide nutrition to all the *Dhatus* [10]. The crude *Meda* may be co related with adipose tissue and the *Drava Meda* may be compared with circulatory lipids and lipoproteins. Hyperlipidaemia is an increase in one or more of the plasma lipids, including triglycerides, cholesterol, cholesterol esters and phospholipids and or plasma lipoproteins including very low-density lipoprotein and low-density lipoprotein, and reduced high-density lipoprotein levels [11]. Lipoproteins are large macromolecular complexes composed of lipids and proteins that transport poorly soluble lipids (primarily TGs, cholesterol, and fat-soluble vitamins) through body fluids (plasma, interstitial fluid, and lymph) to and from tissues. Lipoproteins play an essential role in the absorption of dietary cholesterol, long-chain fatty acids, and fat-soluble vitamins; the transport of TGs, cholesterol, and fat-soluble vitamins from the liver to peripheral tissues; and the transport of cholesterol from peripheral tissues to the liver and intestine [12]. Disorders of lipoprotein metabolism are collectively referred to as "dyslipidaemias.". Hyperlipidaemia falls within the category of dyslipidaemia. Hypercholesterolemia and hypertriglyceridemia are the main cause of atherosclerosis which is strongly related to ischemic heart disease (IHD). Hyperlipidaemia in general can be classified into two categories - (1) Primary hyperlipidaemia: it is also called familial due to a genetic defect, it may be monogenic (a single gene defect) or polygenic (multiple gene defect) (2) Secondary hyperlipidaemia: it is also called acquired because it is caused by another disease like diabetes, nephritic syndrome, chronic alcoholism, hypothyroidism and with use of drugs like corticosteroids, beta blockers and oral contraceptives [13]. The main cause of hyperlipidaemia includes changes in lifestyle habits in which risk factor is mainly poor diet in which fat intake form saturated fat and cholesterol exceeds 40 percent of the total calories uptake [14]. Generally hyperlipidaemia does not have any obvious symptoms but they are usually discovered during routine examination or until it reaches the danger stage of a stroke or heart attack. Patients with high blood cholesterol level or patients with the familial forms of the disorder can develop xanthomas which are deposits of cholesterol may form under the skin, especially under the eyes. At the same time, patients with elevated levels of triglycerides may develop numerous pimple-like lesions at different sites in their body.

With the above background this study was conducted with

the following aims and objectives:

Aims and Objectives of the Study:

1.To evaluate the concept of *Meda Dhatu* in relation with various forms of lipids and lipoproteins.

2.To evaluate the clinical symptoms of *Meda Vriddhi* in individuals having hyperlipidaemia.

3.To evaluate the efficacy of the stipulated poly herbal formulation (*Lekhaniya Kashaya*) to combat the state of *Meda Vriddhi* and subsequently the state of hyperlipidaemia.

MATERIALS AND METHODS

The conceptual understanding regarding *Meda Vriddhi* in state of hyperlipidaemia was verified through a clinical study. Assessment of *Meda Vriddhi was* done on the basis of some subjective criteria and objective criteria. The study has been also carried out to evaluate the clinical efficacy of the stipulated poly herbal preparation of decoction of *Lekhaniya Mahakashaya* to combat *Meda Vriddhi* and subsequently hyperlipidaemia. This poly herbal preparation was administered to the patients included in the study to observe the improvement of subjective and objective criteria. The subjective and objective criteria were evaluated before and after treatment.

Selection of the Patients:

35 patients were selected from OPD and IPD of IPGAE&R, at SVSP hospital, Kolkata irrespective of their sex, occupation and religion. The patients having elevated level of serum lipids and lipoproteins were selected for the study and subsequently the features of *Meda Vriddhi* were evaluated on the basis of subjective and objective parameters. Prior to carry out the study the respective ethical clearance was taken.

Inclusion Criteria:

1. Patients above 20 years of age and below 70 years of age, irrespective of their occupation, sex, and religion.
2. Patients who are willing to include themselves in the study.
3. Patient having elevated serum total cholesterol level (>150 mg/dl).
4. Patient having elevated serum triglycerides level (>200 mg/dl).
5. Patients satisfying the maximum subjective criteria of *Meda Vriddhi.*

Exclusion Criteria:

1. Patients below 20 years and above 70 years of age.
2. Patients those who are not willing to include themselves in the study.
3. Patients having serum total cholesterol level <150 m/dl.
4. Patients having serum triglyceride level <200 mg/dl.
5. Patients suffering from IHD, other types of cardiovascular diseases, hypertension, gall bladder diseases, hypothyroidism, malignancy, or any other endocrinal disorder.

Subjective Parameters: [15]

1. *Snigdha Angataa* (visible glaze of body)
2. Kshudra *Swasa* (mild difficulty in respiration)
3. *Sharira Durgandhata* (bad odour of body)

Objective Parameters:

1. Estimation of serum total cholesterol level.
2. Estimation of serum triglyceride level.

Adoption of Drug:

Drugs which expel the *Dhatu*s and *Mala*s of the body after drying up their moisture are known as *Lekhana*. In *Charaka Samhita, Sutrasthana*, 4th chapter *Acharya Charaka* has given examples of ten standard drugs having *Lekhana* property categorised under the therapeutic section "*Lekhaniya Mahakashaya'* [16]. Among these ten drugs the following drugs have been taken in equal amount each to make a decoction with 16 part of water following the standard procedure as described in *Sharangadhar Samhita* [17], of which 50 ml has been used as warm decoction in single dose and was given thrice daily - once at early morning in empty stomach, once before lunch and once before dinner. The ingredient of the stipulated poly herbal formulation '*Lekhaniya Kashaya'* are as following: 1. Tuber of *Mustaka* (Cyperus rotundus Linn.) 2. Rhizome of *Haridra* (Curcurma longa Linn.) 3. Stem of *Daruharidra* (Berberis aristata D.C.) 4. Rhizome of *Vacha* (Acorus calamus Linn.) 5. Tuber of *Ativisha* (Aconitum heterophyllum Wall.) 6. Root of *Chitraka* (Plumbago zeylanica Linn.).

Study Protocol:

1. Duration of Study: Duration of study was 60 days.

2. Assessment Criteria: Assessment has been done on the basis of subjective and objective criteria before and after treatment. For the statistical evaluation, each of the

subjective parameters have been arranged as per gradation as mentioned below and evaluated thereafter (Table 1)

3. Follow up of the Subjects: All the subjects have been reviewed after two month from the date of administration of first dose. Any special information regarding the general health of the subject has been recorded accordingly.

4. Study Sample: Total 35 subjects having hyperlipidaemia was selected for the study and subsequently the features of *Meda Vriddhi* were evaluated in those individuals.

5. Statistical Analysis: The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation (SD) and Standard Error (SE). Paired 't' test was carried out at $P<0.05$ and $P<0.001$. The obtained results were interpreted as - $P<0.05$ is significant & $P<0.001$ is highly significant.

6. Dietary Restrictions: All the subjects included in the study have been advised to avoid fatty substance, milk, egg, butter, ghee and excessive oily and fried foods. Similarly, they have also been advised for morning walk and free hand exercise for 30 minutes, brisk walking for minimum 30 minutes after having principal meal and to avoid day-sleep, continuous sitting and other sedentary habits.

OBSERVATIONS & RESULTS

Among the 35 subjects total 3 subjects were dropped out during study course. Hence complete clinical survey has been done in 32 subjects. Distribution of subjective parameters of *Meda Vriddhi* among the 32 subjects having hyperlipidaemia shows that, *Snigdha Angata* present in 28 subjects (87.5 %), *Kshudra Swas* present in 29 subjects (90.62 %) and *Sharir Durgandhata* present in 31 subjects (96.87%) [Table no. 2]. Statistical analysis of subjective and objective parameters of *Meda Vriddhi* in 32 subjects having hyperlipidaemia before and after treatment shows that *Lekhaniya Kashaya* has significant efficacy on both the subjective and objective parameters with 'p' value <0.001. [Table no. 3].

DISCUSSION

According to *Charaka Samhita* it has been said that, '*Vikara Dhatu Vaishyamam, Samyam Prakriti Uchyate*' that is any disturbance in the equilibrium state of *Dhatu* is known as *Vikara* and maintenance in the equilibrium state of *Dhatu* is known as *Prakriti* [18]. Although the word '*Dhatu'* altogether refers to the three basic components i.e. *Dosha, Dhatu* and *Mala* which are responsible for maintenance of the body but here we should make emphasis on its meaning of body tissues. The process of genesis of any disease starts from intake of *Nidan* (causative factors) which leads to several alterations in state of *Dosha, Dhatu* and *Mala* which ultimately leads to manifestation of diseases. While discussing the theory of *Swabhavoparama Vada*, *Acharya Charaka* has clearly mentioned that, disturbance in the equilibrium of the causative factors causes imbalance of *Dhatus* of the body. Conversely, the maintenance of the former's equilibrium maintains the latter's balance [19]. Thus it can be stated that, in our body *Dhatu Samya* (state of equilibrium between *Dosha* and *Dhatu*s) is dependent on several internal and external factors, alterations of which leads to the state of *Dhatu Vaishamya* (state of disequilibrium between *Dosha* and *Dhatu*s) which is responsible for manifestation of diseases. If we consider in accordance with our central topic that, *Vikara* is caused by *Vaishamya* in *Dhatu*s only and not in *Dosha*s then this kind of inference may lead us to a wrong conclusion. One of the basic difference between *Dosha* and *Dhatu* lies in the fact that the former possesses the independent capability to vitiate itself along with other elements like *Dhatu* and *Mala* - '*Swatantryena Dustikatritwam Doshatwam*' but the latter i.e. *Dhatu* lacks this quality [20]. So the state of *Dhatu Vaishamya* should be always considered as a secondary phenomenon in relation with the effect of *Nidan Sevan* (intake of causative factors), primary one should be *Dosha Vaishamya*. The state of *Vaishamya* of any Dhatu can be interpreted in two ways - one in the sense of *Dhatu Kshaya* (depletion of *Dhatu*s) and other in the sense of *Dhatu Vriddhi* (aggregation of *Dhatu*s). Conceptually, it can be said that *Dhatu Kshaya* is the essential phenomenon for occurring any type of disease whereas *Dhatu Vriddhi* is not observed in the pathogenesis of any disease except the few like *Meda Roga, Raktapitta* etc. [21]. The state of *Dhatu Vriddhi* should be understood as a pathological condition of body which may act as predisposing factor for many other diseases rather than a separate disease.

Thus the state of *Meda Vriddhi* can be correlated with the state of hyperlipidaemia. Interestingly, modern science also supports the concept of *Meda Dhatu Vaishamya* in terms of *Meda Dhatu Vriddhi* in principal meaning rather than *Meda Dhatu Kshaya* as described here- "disorders of

lipoprotein metabolism are collectively referred to as 'dyslipidaemias'. Dyslipidaemias are generally characterized clinically by increased plasma levels of cholesterol, TGs, or both, variably accompanied by reduced levels of HDL cholesterol" [22]. If we compare between the causes of *Medavaha Srotadusti* which leads to *Meda Vriddhi* as described in different *Ayurvedic* compendiums and the predisposing factor of secondary hyperlipidaemia, we will observe there are striking similarities in between of these two as shown in Table no. 4 [23].

The clinical features of *Meda Vriddhi* are categorically described in *Ayurvedic* compendiums like *Snigdha Angata, Swasa, Sharira Durgandhata* etc. whereas modern science describes hyperlipidaemia as mostly a serological alteration with no obvious symptoms at first stage. In this study the authors have found that, all the major clinical symptoms of *Meda Vriddhi* are clinically present in majority cases of hyperlipidaemia as shown in the Table no. 1. This observation can open a new dimension in clinical presentations of hyperlipidaemia. Excess deposition of lipids within different channels including lymphatic channels can lead to feasible visible glaze over the skin. Similarly, excess deposition of lipids within coronary arteries can reduce the oxygen supply to the cardiac muscles and can lead to ischemia in cardiac muscles which may represent as breathing distress during mild to moderate physical exertion. Hyperlipidaemia can lead to atherosclerosis within coronary artery which may give rise to coronary artery diseases with primary manifestations like angina and excess sweating. Likewise, it can be hypothetically said that, lipids act as store house of heat within our body, so whenever there is excess lipid deposition within our body also may lead to excess deposition of heat, which can alter the thermoregulation within our body, to compensate which excess sweating may occur which may be responsible of bad odour of body complying the clinical presentation of *Sharira Durgandhata* in case of *Meda Dhatu Vriddhi*. Table 3 shows us the therapeutic management with stipulated poly herbal formulation '*Lekhaniya Kashaya'* is equally efficacious in combatting both the cases of *Meda Vriddhi* and hyperlipidaemia with 'p' value <0.001 in all the subjective and objective parameters.

If we analyse the property of all the *Lekhaniya Dravyas* in the stipulated poly herbal therapeutic preparation, then we will find that, majority of the *Lekhaniya Dravyas* have *Katu, Tikta* and *Kashaya Rasa, Laghu, Ruksha, Ushna Guna, Ushna Virya , Katu Vipaka*. By virtue of all these properties, these *Dravya*s are capable of *Sneha* and *Drava Soshana, Kapha - Meda Vilayana* and *Kapha - Meda Soshana* as shown in the table no. 5. Thus, it can be said that, by virtue of *Rasa, Guna, Virya* and *Vipaka* - all the drugs are capable of scavenging and absorbing *Meda Dhatu* and ultimately lead to the reduction of excess fat - both in stored and soluble form. There is more scope for further phytochemical and biochemical research on how these drugs are capable of reducing the excess level of lipids and lipoproteins by virtue of their alkaloids and other chemical compounds.

CONCLUSIONS

Meda is considered as one of the *Dhatu*s of human body. Conceptually any disease occurs due to disequilibrium state of *Dhatu*s - known as *Dhatu Vaishamya* or *Dhatudusti*. This disequilibrium may occurs in two ways - in form of *Dhatu Kshaya* (depletion of *Dhatu*s) and *Dhatu Vriddhi* (aggregation of *Dhatu*s). Where pathogenesis of majority of the diseases shows the evidence of *Dhatu Kshaya*, the event of *Dhtau Vridhhi* mostly manifested as an altered pathological state within our body (known as *Vikriti*) rather than a full-fledged disease. Similarly, the state of hyperlipidaemia also generally detected during routine blood investigations rather than manifesting as a definite disease. Hyperlipidaemia is an altered state of human body where there is an increase in one or more of the plasma lipids, including triglycerides, cholesterol, cholesterol esters and phospholipids and or plasma lipoproteins including very low-density lipoprotein and low-density lipoprotein, and reduced high-density lipoprotein levels. The state of hyperlipidaemia can be conceptually compared with the state of *Meda Vriddhi* due to structural similarities between lipids and *Meda Dhatu*. This study has found that, although the state of hyperlipidaemia can be taken mostly as a non-clinical event but the clinical features of *Meda Vriddhi* can be found in the individuals having hyperlipidaemia. The study has also found that, the therapeutic management of *Meda Vriddhi* with stipulated poly herbal formulation '*Lekhaniya Kashaya'* is equally efficacious in combatting hyperlipidaemia also. Thus, this clinical study paves ways for further research in management of hyperlipidaemia with various other poly herbal formulations following the line of *Meda Vriddhi Chikitsa*.

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Table no. 1 Grading of Symptoms

A. *Snigdha Angata*:

Characteristics	**Score**
No feasible visible glaze	0
Feasible visible glaze at some part of body	1
Feasible visible glaze in buttock, thigh and abdomen	2
Feasible visible glaze all over the body	3

B. *Kshudra Swas*:

Characteristics	**Score**
No difficulty in respiration after exertion	0
Mild difficulty in respiration after exertion	1
Moderate difficulty in respiration after exertion	2
Severe difficulty in respiration after exertion	3

C. *Durgandhata of Sharir*:

Characteristics	**Score**
No body odour	0
Body odour after 12 hours of bath	1
Body odour after 6 hours of bath	2
Body odour after 3 hours of bath	3

Table no. 2: Distribution of Subjective Parameters:

No.	**Subjective Parameters**	**No. of Subjects**	**Percentage**
01.	*Snigdha Angata*	28	87.5%
02.	*Kshudra Swas*	29	90.62%
03.	*Sharir Durgandhata*	31	96.87%

Table no. 3: Showing the statistical analysis of subjective and objective parameters in 32 subjects having hyperlipidaemia before and after treatment:

Parameters	**Mean At**	**Mean BT**	**SD +/-**	**SE +/-**	**'t' value**	**'p' value**
Snigdha Angata	2.28	0.812	0.696	0.12	12.2	<0.001
Kshudra Swasa	2.13	0.437	0.77	0.136	12.5	<0.001
Sharira Durgandhata	2.56	0.91	0.663	0.12	13.75	<0.001
Serum Total Cholesterol	210.25	200.5	3.53	0.63	15.6	<0.001
Serum Triglycerides	166.7	158.6	3.18	0.56	14.4	<0.001

Table no. 4: Comparison between the causative factors of *Medavaha Srotadusti* (leading to *Meda Vriddhi*) and predisposing factors of secondary hyperlipidaemia:

Sl. No.	Factors	*Meda Vriddhi Hetu*	Predisposing factors of secondary hyperlipidaemia
01.	*Avyayama* (lack of physical exercise / extreme sedentary habit)	++	++
02.	*Divaswapna* (habit of day sleeping / sedentary habit)	++	++
03.	*Medyanam Atibhakshanam* (excessive intake of fatty substance)	++	++
04.	*Varuni Madya Atisevanam* (excessive intake of alcohol rich in trans-fat)	++	++

Table 5: Pharmacological Properties of ingredients of poly herbal formulation '*Lekhaniya Kashaya*':

Name	Parts Used	*Rasa*	*Guna*	*Virya*	*Vipaka*
Mustaka [24]	Tuber	*Tikta, Katu, Kashaya*	*Laghu, Ruksha*	*Sita*	*Katu*
Haridra [25]	Rhizome	*Tikta, Katu*	*Laghu, Ruksha*	*Ushna*	*Katu*
Daruharidra [26]	Stem	*Tikta, Kashaya*	*Laghu, Ruksha*	*Ushna*	*Katu*
Vacha [27]	Rhizome	*Katu, Tikta*	*Laghu, Tikshna*	*Ushna*	*Katu*
Ativisha [28]	Tuber	*Katu, Tikta*	*Laghu, Ruksha*	*Ushna*	*Katu*
Chitraka [29]	Root	*Katu*	*Laghu, Ruksha, Tikshna*	*Ushna*	*Katu*