

## Research Article

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## CLINICAL EVALUATION OF LEKHANIYA MAHAKASHAYA IN DYSLIPIDEMIA (MEDODUSHTI)

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#### ABSTRACT

Dyslipidemia is a metabolic imbalance that can result in a variety of diseases, including diabetes, hypertension, hypothyroidism, nephrotic syndrome, and others. The ailment of the era, Dyslipidemia, is primarily brought on by inadequate lifestyle choices. It has been wrongly overlooked for too long as a serious cardiovascular risk factor. According to ancient Ayurvedic texts, every single drug in the composition Lekhaniya Mahakashaya Ghanavati has been shown to have significant lipid-lowering properties. It is more closely related to Medodushti in Ayurveda, a functional illness that is only a precursor stage of Medoroga and is easily curable with the right regimen. Study design: The study was conducted on OPD and IPD patients at the Kayachikitsa department in the Gurukul Campus, Haridwar, Uttarakhand, India, for 50 days. A total of 40 patients in a single group were registered for the trial. It was a prospective, open, single-armed, randomised controlled trial. All of the patients received Lekhaniya Mahakashaya Ghanavati as an oral drug. Result and Discussion: An overall assessment of the drug was done based on the significance of the statistical tests. In the trial, 12.5% of patients had complete relief in signs and symptoms, marked improvement was found in 42.5%, and moderate improvement also accounted for 42.5% of the study population. The drug might be the treatment of choice for individuals with Dyslipidemia who are both diabetic and non-diabetic.

Keywords: Dyslipidemia, Medodushti, Lipids, Lekhaniya Mahakashaya Ghanavati

# INTRODUCTION

Dyslipidemia is among the chronic illnesses diagnosed and treated most frequently. Typically, they are identified by elevated blood levels of triglycerides, cholesterol, or both, together with elevated levels of associated lipoprotein species. The most frequently reported clinical effect of Dyslipidemia is an increased risk of atherosclerotic cardiovascular disease (ASCVD), which is linked to decreased levels of high-density lipoprotein (HDL)-C and elevated levels of triglycerides (TGs), lipoprotein(a) (Lp(a)), and total and low-density lipoprotein (LDL) cholesterol (C).1 According to WHO (data updated in June 2021), an estimated 17.9 million individuals died from CVDs in 2019, representing 32% of all worldwide deaths. Of those deaths, 85% have been because of heart attack and stroke. Over 3 quarters of CVD deaths occur in low- and middle-income countries. By 2030, nearly 25 million people are predicted to die from CVD, primarily heart disease and stroke.2

We cannot locate one-to-one co-relation with a single disease from the Ayurveda treatise, though the concept of abaddha meda given by Acharya Chakrapani is similar to Dyslipidemia.<sup>3</sup> Ama and many of the symptoms of Ras dushti, Rakta dushti, and Medo dushti are similar to the symptoms of Dyslipidemia described in modern texts. Several Ayurvedic academics have made numerous attempts to clinically correlate Rasagata sneha vriddhi (raised lipids in plasma), Raktagata sneha vriddhi (raised lipids in blood), and Rasaraktagata sneha vriddhi (raised lipids in plasma and blood).<sup>4</sup>

There are antihyperlipidemic medications like statins, fibric acid derivatives niacin, etc. in the allopathic medical system; they come with several adverse effects, such as headache, flushing, itching, impotence, blurred vision, myalgia, sleep disturbances, nausea and increased level of Serum Transaminase which can further lead to liver damage etc.<sup>5</sup> Though few studies have been carried out for this emerging problem, there is still a need for effective and safe treatment. Therefore, it is necessary to search for good Ayurvedic remedies as the primary principle of Ayurveda is to maintain a healthy person's health and cure the disease.

Dyslipidemia is a problem of agnimandya and sama rasa production that results in channel obstruction; hence, the chosen medication should have dipana, pachana, kaphanashaka, medoghna, and srotoshodhaka qualities to manage this illness. According to studies on Dyslipidemia, the predominant formulations of laghu, ruksha, and kashaya rasa are more effective at lowering cholesterol and LDL, while laghu, ushna, and katu rasa are more effective at controlling hypertriglyceridemia. <sup>6,7</sup> The contents of Lekhaniya Mahakashaya are laghu, ushna, tikshna, ruksha, and katu-kashaya rasa dominant, hence chosen for treatment.

#### MATERIALS AND METHODS

The study is carried out as per the guidelines of the IEC (Institutional Ethical Committee). IEC number is UAU/GC/IEC/2022/6. CTRI Registration number is CTRI/2022/10/046145.

## **Study Design**

The present study entitled "Clinical Evaluation of Lekhaniya Mahakashaya in Dyslipidemia (Medodushti)" had been designed with the following Aims:

- Conceptual and clinical studies on Dyslipidemia and Medodushti.
- To evaluate the effect of Lekhaniya Mahakashaya on Dyslipidemia (Medodushti).
- 3. To provide a reliable, efficient, cost-effective and safe Ayurvedic treatment for Dyslipidemia (Medodushti).

**Selection of patients:** A total of 40 patients were selected

**Duration of study: 50 days** 

Type of Study: Open-label single-arm Randomized control trial, prospective.

Selected drug: Lekhaniya Mahakashaya in the form of Ghanavati.

**Dose of drug:** 2 tabs. BD after meals (500 mg each tab.)

Composition of medicine: Musta, Kushtha, Haridra, Daruharidra, Vacha, Ativisha, Katurohini, Chitraka, Chirbilva (Karanja), Katuparni (substitute of Hemwati Vacha taken).

#### **Criteria For Selection of Patients**

#### **Inclusion Criteria**

- 1. Patients having features of Dyslipidaemia (Medodushti).
- 2. Patients from the age group of 20-65 years.
- 3. Patients of either sex.
- 4. Diagnosed and confirmed cases of Dyslipidaemia based on criteria given by NCEP ATP III (Serum Cholesterol ≥ 200 mg/dl, Serum Triglycerides ≥ 150 mg/dl, LDL ≥ 130 mg/dl, HDL ≤ 40 mg/dl, serum CRP level ≥ 5 mg/dl (whether obese or lean patients).

## **Exclusion Criteria**

- 1. Patients of age below 20 and above 65 years.
- Patient having a medical history of unstable angina, myocardial infarction, heart failure, stroke within three months of study, Uncontrolled and insulin-dependent DM, impaired renal functions, jaundice, hepatitis, chronic infection and any other serious disease.
- 3. Pregnant and lactating women.
- 4. Patients having Dyslipidaemia due to drugs, e.g., glucocorticoids and diuretics.
- Patients with depression and severe psychiatric disorders were excluded.

## **Assessment Criteria**

The assessment criteria are based on describing signs and symptoms of Dyslipidemia (Medodushti) in Ayurvedic texts and lipid profiles. The assessment of the trial was done according to the following parameters of Dyslipidemia (Medodushti):

- 1. Subjective
- 2. Objective

### **Subjective Parameters**

- Gatra Guruta (Heaviness in body)
- Kshudra Shwasa (Dyspnea)
- Ati sweda (Excessive sweating)
- Daurbalya (Generalised weakness)
- Kara pada daha (Burning hands and feet)
- Nidra atiyoga (Excessive desire to sleep)

- Trishna (Excessive thirst)
- Aalasya (Laziness)

#### **Objective Parameters**

- Lipid Profile
- BMI
- Body weight

#### OBSERVATIONS AND RESULTS

A total of 45 patients were registered randomly to complete the study goal of 40 patients. The LAMA and dropped out patients were not considered in this study which were in a total of 5. The observations are presented in pie-charts, bar (in %) and tabular form. The result obtained based on observation is stated in the result.

#### **Age Wise Distribution**

A maximum of 47.5 % of patients belonged to the age group of 35-50 years, followed by 42.5 % of patients belonging to 50-65 years of age, and 10% of patients fell under the age group of 20-35 years. (Chart 1)

#### **Sex Wise Distribution**

A maximum number of patients, i.e., 65 %, were of male sex, whereas 35 % were females. None of the patients was transgender. (Chart 2)

#### **Religion Wise Distribution**

A maximum number of patients, i.e., 90%, were from the Hindu Community, whereas 10% were from the Muslim community, and there was no patient from any other community. (Chart 3)

## Socioeconomic Status-Wise Distribution

A maximum of 65% of patients were from the middle and upper middle class, 15% were from the poor and lower middle class, and 5% were rich. (Chart 4)

# **Occupation Wise Distribution of 40 Patients**

Out of 40 patients, a maximum of 45% were doing desk work, followed by 37.5% of housewives, 10% were retired from their jobs, 7.5% were working in the field, and not a single patient was doing any other kind of employment. (Chart 5)

# Area Wise Distribution

70% of patients belonged to urban areas, and 30% to rural areas. (Chart 6)

### Aharashakti Wise Distribution

The highest number of patients in the presenting study had Madhyama Abhyavarana Shakti (55%), Avara Abhyavarana Shakti (45%) and no patient with Pravara Abhyavarana Shakti. (Chart 7)

The highest number of patients in the presenting study had Avara Jarana Shakti (52.5%), followed by Madhyama Jarana Shakti (32.5%) and Pravara Jarana Shakti at the least (15%). (Chart 8)

# **Dietary Habits Wise Distribution**

72.5% of patients were vegetarian, whilst 27.5% of patients had mixed dietary habits. (Chart 9)

### **Bowel Habits Wise Distribution**

52.5% of patients had regular bowel habits, followed by 37.5% of patients who were suffering from constipation and 10% of patients with irregular bowel habits. (Chart 10)

#### **Sleep Pattern Wise Distribution**

52.5% of patients slept soundly, followed by 47.5% with disturbed sleep. (Chart 11)

#### Dominance of Rasa taken in diet by 40 Patients

50% of patients were taking the madhura rasa dominant diet, followed by 25% of patients taking the lavana rasa dominant diet, and no patient was taking tikta and kashaya rasa dominant diet in their regular meals. (Chart 12)

### Dominance of Guna taken in diet by 40 Patients

37.5% of patients were taking the guru guna dominant diet, followed by 30% of patients who were taking the snigdha guna dominant diet, 22.5% with the sheeta guna dominant diet, 5% patients with ushna and laghu guna dominant diet each and no patient was taking rooksha guna dominant diet in their regular meals. (Chart 13)

### Deep fried items intake by 40 Patients

82.5% of patients frequently took extremely unhealthy deep-fried items into their diet. The remaining 17.5% of patients did not report such use of deep-fried items. (Chart 14)

### Distribution of 40 Patients by Addiction

55% of patients had no addiction, and addiction to smoking contributed to 15%. Alcohol drinking was noticed in 12.5% of patients. Tobacco chewing was seen in 7.5% of patients. (Chart 15)

### Past History and Associated Illness

A maximum of 42.5% of patients were found to have a history of Hypertension, followed by 32.5% of patients having no associated illness, 17.5% of patients having a history of Hypothyroidism, 12.5% of patients reported having a history of Diabetes Mellitus and no patient was found having a history of angina, cerebrovascular accidents and peripheral vascular disease. (Chart 16)

# Family History

A maximum of 45% of the 40 patients had a family history of Hypertension, followed by 35% of patients who had a family history of obesity,15% of patients had no relative family history, 12.5% of patients had Diabetes Mellitus, 10% of patients who had Dyslipidemia and 7.5% of patients had a family history of cerebrovascular accidents. (Chart 17)

# **Distribution of Signs and Symptoms**

Daurbalya (generalised weakness) was present in 70% of the population under inquiry, followed by aalasya (laziness) as a symptom in 60% of patients. In 57.5% of patients, guru gatrata (heaviness in the body) and kara pada daha (burning hands and feet) were present. Nidra atiyoga (excessive desire to sleep) accounted for 37.5% of patients, whereas kshudra shwasa (dyspnea) for 27.5%. Atisweda (excessive sweating) and trishna (excessive thirst) accounted for 25% of the study population. (Chart 18)

# **Incidence of Type of Dyslipidemia in 40 Patients**

Hypercholesterolemia was present in 82.5%, followed by Hypertriglyceridemia in 75% of patients. In 72.5% of patients, high serum LDL was present. 52.5% of patients were subjected to high serum VLDL, and 27.5% had low serum HDL. (Chart 19)

Since observations are on the ordinal scale (gradations), we have used the Wilcoxon Signed Rank test to test efficacy.

The effect of Lekhaniya Mahakashaya Ghanvati on the 6 symptoms was statistically highly significant (P <0.001). The

result was statistically significant for Atisweda (P <0.05) and not statistically significant for Trishna (P >0.05). (Table 1 and Chart 20)

Since it was a single group and observations were quantitative, we used the paired-t Test. The result was highly significant in lowering S. Cholesterol, S. Triglycerides, S. LDL and S. VLDL (P < 0.001) when treated with Lekhaniya Mahakashaya Ghanvati. However, the result was not significant in raising S. HDL (P > 0.05). (Table 2 and Chart 21)

Lekhaniya Mahakashaya Ghanavati had a statistically highly significant (P < 0.001) response to lowering Body weight and BMI. (Table 3 and Chart 22)

The drug showed very significant results in reducing random blood sugar levels (P<0.01). However, the drug was not significant in increasing haemoglobin levels. (Table 4 and Chart 23)

#### DISCUSSION

The contents of Lekhaniya Mahakashaya Ghanavati are Musta, Kushtha, Haridra, Daruharidra, Vacha, Ativisha, Katurohini (Kutaki), Chitrak, Chirbilva (Karanja), Katuparni. They contain laghu, ushna, tikshna guna, tikta-katu rasa and lekhana, deepana, pachana, and srotoshodhana properties and thus increase agnibala (digestive fire and enzymes) and reduce Kapha, ama and kleda. Lekhana property pacifies excessive Meda and Sthaulya. The srotoshodhana property removes the avarana of Vata caused by Kapha and Meda. Hence, Lekhaniya Mahakashaya Ghanavati can be used in Ama, Kapha, Meda and kleda bahula aavarana yukta samprapti janya vyadhi. Due to its lekhana property of the contents, it scrapes and expels the vitiated Kaphadi doshas from the srotasa. Agni and ama play a significant part in the pathogenesis of Dyslipidemia, and any medication with dipana, pachana, ama-nashaka, Kapha-Medohara, rasayana, and srotoshodhaka properties is extremely effective in Dyslipidemia as per one of the recent studies.

Starting from the amashaya, where the deepana-pachana guna of these drugs helped in the pachana of ama in the body. Also, Medoghna, Kapha-Vatahara guna and srotosodhaka guna helped remove blocked channels of the body. The obstructive Kapha and other material had been cleared out from the srotasa with the above diathesis. So, the normalised function of the stomach also helped the digestion of ama. These drugs are katu and tikta rasa pradhana. Ushna veerya and laghu ruksha guna helped eliminate the vitiated Kapha. It also corrected the vitiation of both Meda and Kapha, the primary entity of the samprapti, thus breaking the samprapti (correcting the vitiation of Meda and Kapha) treated the disease.

As the drug is ushna and teekshna, it also helped improve the dhatvagni (as Ayurveda believes the disease is amajanya). In this way, the properties of all the ten contents of the drug help in the samprapti vighatana of the disease. (Figure 1)

# **Demographic Profile**

**Age-** Maximum number of patients, i.e., 47.5%, were under 35-50 years old. Males who are 45 years of age or older are more likely to have Dyslipidemia. The lipid research clinics study also shows that total cholesterol rises with age in both sexes and is most noticeable between the ages of 20 and 50. The fifth and sixth decades have a higher risk of CAD and stroke.

**Sex-** Maximum patients were males, i.e., (65%). Women over 50 (post-menopausal women) are more likely than males in that age range to acquire Dyslipidemia, whereas men under 50 are more likely than women to do so.<sup>10</sup>

Socioeconomic Status- Maximum (65%) patients were from the middle and upper middle class. The high prevalence in middle-class society demonstrated their lack of knowledge regarding food consumption and choice. This could also result from local eating customs, where fried and fatty meals are prevalent among all socioeconomic strata.

**Habitat-** 70% of patients belonged to urban areas. This information is compatible with Haridwar City's population characteristics. Additionally, the urban environment is polluted, and people live stressed, sedentary lifestyles with poor dietary habits. The reason might be a result of a fast-paced existence.

**Appetite-** A maximum of 42.5% of patients were observed to have good appetite. The number of patients still had a healthy appetite and digestive ability was high. It is now known that obese people eat more than normal to maintain the needed energy level of their fat deposits. In comparison to lean people, total daily energy expenditure is higher in obese people.<sup>11</sup>

**Dietary Habits-** 72.5% of patients were vegetarians. A vegetarian diet won't help with hyperlipidemia because the food is so heavy in carbohydrates, and meals are cooked in oils that include saturated fats.<sup>12</sup>

**Dominant Rasa in Diet-** 50% of patients were taking madhura rasa dominant diet. Madhura rasa atisevana also brings on santarpanajanya vyadhis like Sthaulya, Prameha, and others. Madhura, amla, and lavana rasa dominating dravyas should not be used excessively since they enhance Kapha and Pitta in the body and vitiate Meda and Rasa dhatu, which are the fundamental causes of Dyslipidemia.

**Dominant Guna in Diet-** A maximum of 37.5% of patients were taking the guru guna dominant diet, followed by 30% of patients taking the snigdha guna dominant diet. A diet emphasising the guru and snigdha gunas makes the body more Kapha and Pitta. Due to its opposite character from Agni, it also vitiates Agni. A diet that is snigdha guna dominant vitiates the body's Rasa, Rakta, Mansa, and Meda dhatu. These all are the basic factors for the manifestation of Dyslipidemia.

**Deep Fried Items**- Deep-fried items were frequently taken by 82.5% of the patients. It is well known that frequent frying in the same oils can release toxic chemicals. Being heavy, deep-fried items might hinder the Jatharagni and lead to the production of ama at the level of both digestion and metabolism.

**Sleep Pattern-** 47.5% of patients were observed having disturbed sleep at night. This finding demonstrates that a life full of stress and disrupted sleep is a more significant contributing factor (partantra nidana) to the development of Dyslipidemia.

#### Clinical Profile

**Effect on Gatra Guruta-** Guru guna, primarily accountable for Gatra guruta, is also a causal element for increasing ama, resulting in pralepa in rasavaha and raktavaha srotasa, by clearing srotorodha, tikshna, ushna, and ruksha guna of the drug-assisted to subside Guruta.

Effect on Kshudra shwasa- Dyspnea happens when the actual breathing that is taking place is insufficient to meet the body's

demand for ventilation. Patients with Dyslipidemia frequently experience dyspnea when they exert themselves, especially if the disease is linked to obesity or cardiovascular abnormalities. Because Hridaya is the moola of Rasavaha srotasa and Pranavaha srotasa. Pranavaha srotodushti was seen in the patients as partantra srotodushti, according to Ayurveda. All of the patients in the current research were found to have Rasavaha srotasa dusti, which results in the partantra dusti of Pranavaha srotasa. Increased Meda or Sthaulya contributes to Pranavaha srotasa's partantra srotodushti. The drug decreased ama and Meda while boosting Agni's strength. Breathlessness was, therefore, relieved by a reduction in Meda and Kapha.

Effect on Atisweda- A metabolic waste product (mala) of Meda is sweda. In typical circumstances, Sweda keeps the body's natural kleda bhava in place since it is essential for maintaining sneha/snigdhata in the skin and maintaining body and scalp hairs. When kitta Meda is formed unusually, swedavriddhi naturally takes place. Sweda is also created more to keep the amount of kleda bhaga in the body at a regular level. Waste products are inevitably generated in excess when Medo dhatu's metabolism is compromised. This causes excessive perspiration. The sweat glands have to work harder to eliminate these waste materials when there is an abnormal accumulation of undesired waste minerals in the body. Kleda is an apya substance, a bodily fluid that exists within and outside cells. 13 Ati pravritti of swedavaha srotasa will thus occur when kleda is created in excess, leading to swedadhikya. Kleda and Meda were all diminished by the drug's katu, ushna, Agni deepana, ama-pachana, and lekhana properties, in addition to swedadhikya.

Effect on Daurbalya- Strororodha causes dourbalya to appear, eventually interfering with the next dhatu's nutrition because of increased kleda. Dourbalya is an ailment associated with morbid Vata and refers to generalised fatigue. Vata movement becomes clogged when Kapha Medo margavarana lasts for an extended period, and the obstructed Vata eventually attains prakopa. Beyond the area of hindrance due to lack of proper nutrition, Dhatu undergoes kshaya, which also aggravates Vata dosha. Last but not least, Dhatukshaya, Ojo kshaya, and Vata vriddhi cause the body to become weak, resulting in either shrama or klama (i.e., severe exhaustion after doing any kind of work or fatigue without any activity). Lekhaniya Mahakashaya Ghanavati decreased kleda as well as srotorodha.

**Effect on Kara-pada daha-** Kara-pada daha was significantly reduced after the treatment. The probable reason could be the tikta rasa and sheeta veerya of a few contents of the drug, which are responsible for Pitta shamaka and daha shamaka results.

Effect on Nidra atiyoga and Aalasya- A person becomes inert in all respects due to the morbid Kapha and an inactive lifestyle. An increase in daytime sleep duration, anxiety, and depression can all cause an increase in the tamo bhava, which can then cause ati nidra. Srotorodha or manasa Tamo adhikya (Manovaha srotasa) is responsible for Nidra atiyoga (Tamo Sleshma samudbhava).

Aalasya is a similar characteristic of Kapha dushti. When hetu, such as guru, snigdha, and madhura ahara, are consumed, kleda, abhishyanda, and srotorodha are increased, followed by aalasya. Properties like laghu, ruksha, and ushna could be found in Lekhaniya Mahakashaya Ghanavati. It reduces abhishyanda, srotorodha, and alasya while aiding with kleda upashoshana.

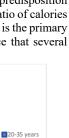
**Effect on Trishna-** Increased Vata and Pitta in koshtha sthana cause ati-Pipasa. To pacify trishna, no medication contains

madhura vipaka or madhura rasa. Most likely, this is what contributed to trishna's insignificant result.

**Effect on Lipid profile-** Some of the constituent drugs of LMG contain saponins and tannins that are known to reduce cholesterol by preventing its absorption, interfering with its entero-hepatic circulation, and increasing its faecal excretion and faecal bile acid excretion. <sup>14</sup> The contents of Lekhaniya Mahakashaya possess these chemical constituents.

Effect on Body Weight and BMI- Due to genetic predisposition and sedentary lifestyle changes, an increase in the ratio of calories or energy consumed to calories or energy expended is the primary cause of weight gain or obesity. There is evidence that several

> 0-65 years 42.50%



■36-50 years

■51-65 years

Chart 1: Age

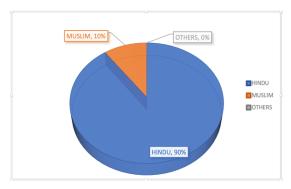
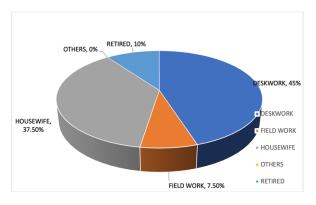


Chart 3: Religion



**Chart 5: Occupational Status** 

naturally occurring secondary metabolites, including polyphenols, flavonoids, terpenoids, alkaloids, saponins, carboxylic acids, glycosides, tannins, and curcumin, have antiobesity activity through a variety of modes of action. <sup>15</sup> The drug contains the chemical mentioned above components, which boost metabolism and burn extra fat for energy, causing a reduction in body fat, weight, and BMI.

**Effect on RBS and Hemoglobin-** Alkaloids, flavonoids, tannins, saponins, terpenoids, phenolics, and curcumin are phytoconstituents that significantly manage diabetes by interfering with glucose metabolism. <sup>16</sup> The drug contains the above chemical components, which correct metabolic rate and have an antihyperglycemic action.

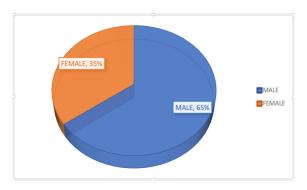
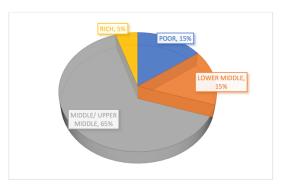


Chart 2: Sex



**Chart 4: Socioeconomic Status** 

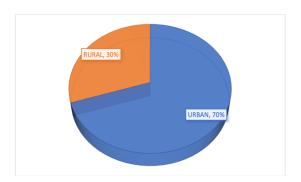


Chart 6: Area-wise distribution

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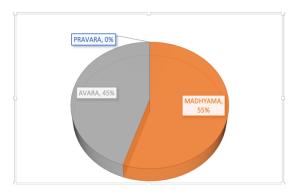


Chart 7: Incidence of Abhyavarana Shakti

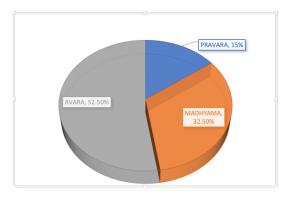


Chart 8: Incidence of Jarana Shakti

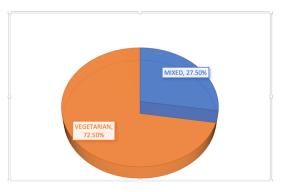


Chart 9: Dietary Habit

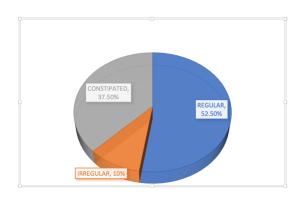


Chart 10: Bowel Habit

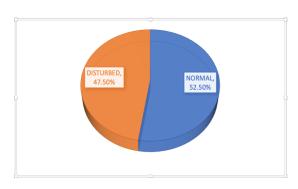


Chart 11: Sleep Habit

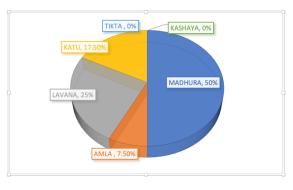


Chart 12: Dominant Rasa in Diet

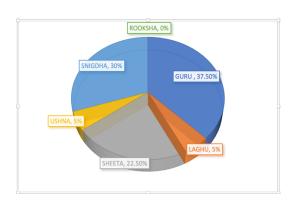


Chart 13: Dominant Guna in Diet

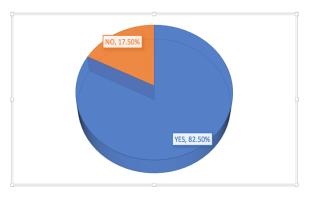
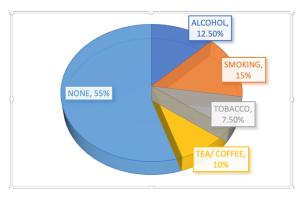
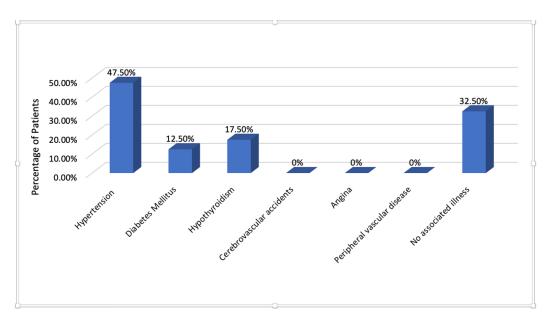


Chart 14: Deep fried items Intake

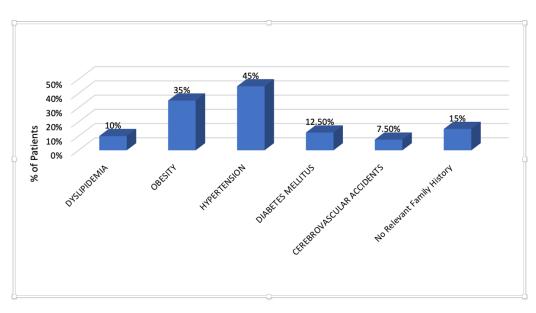
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**Chart 15: Addiction** 



**Chart 16: History and Associated Illness** 



**Chart 17: Family history** 

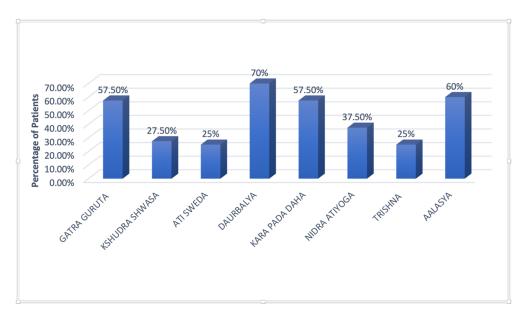


Chart 18: Distribution of Signs and Symptoms

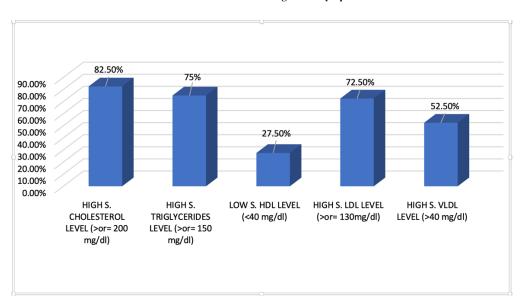


Chart 19: Incidence of Type of Dyslipidemia

Table 1: Efficacy of Lekhaniya Mahakashaya Ghanavati on Subjective Parameters

| Subjective    | Number   | Mee  | dian | Standard | Deviation | %       | Wilcoxon     | P-       | Result        |
|---------------|----------|------|------|----------|-----------|---------|--------------|----------|---------------|
| Parameters    | of       | BT   | AT   | BT       | AT        | relief  | $\mathbf{W}$ | Value    |               |
|               | Patients |      |      |          |           |         |              |          |               |
| Gatra Guruta  | 23       | 1.00 | 0.00 | 1.21     | 0.38      | 86 %    | -276.000     | < 0.05   | Highly        |
|               |          |      |      |          |           |         |              | (<0.001) | Significant   |
| Kshudra       | 11       | 0.00 | 0.00 | 0.71     | 0.27      | 81.25 % | -66.000      | < 0.05   | Highly        |
| Shwasa        |          |      |      |          |           |         |              | (<0.001) | Significant   |
| Ati Sweda     | 10       | 0.00 | 0.00 | 0.99     | 0.42      | 55 %    | 28.000       | < 0.05   | Significant   |
|               |          |      |      |          |           |         |              | (=       |               |
|               |          |      |      |          |           |         |              | 0.016)   |               |
| Daurbalya     | 28       | 3.00 | 0.00 | 1.35     | 0.47      | 84.81 % | -406.000     | < 0.05   | Highly        |
|               |          |      |      |          |           |         |              | (<0.001) | Significant   |
| Kara pada     | 23       | 1.50 | 0.00 | 1.17     | 0.47      | 73.47 % | -276.000     | < 0.05   | Highly        |
| daha          |          |      |      |          |           |         |              | (<0.001) | Significant   |
| Nidra atiyoga | 15       | 0.00 | 0.00 | 1.14     | 0.49      | 67.74 % | -105.000     | < 0.05   | Highly        |
|               |          |      |      |          |           |         |              | (<0.001) | Significant   |
| Trishna       | 10       | 0.00 | 0.00 | 0.88     | 0.77      | 21.05 % | -10.000      | >0.05    | Insignificant |
|               |          |      |      |          |           |         |              | (=0.125) | _             |
| Aalasya       | 24       | 2.00 | 0.50 | 1.25     | 0.59      | 60 %    | -253.000     | < 0.05   | Highly        |
|               |          |      |      |          |           |         |              | (<0.001) | Significant   |

BT: Before Treatment, AT: After Treatment

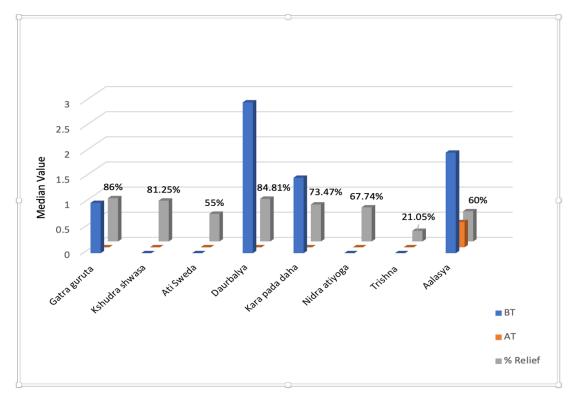


Chart 20: Efficacy of Lekhaniya Mahakashaya Ghanavati on Subjective Parameters

Table 2: Efficacy of Lekhaniya Mahakashaya Ghanavati on Objective Parameters (Lipid Profile)

| Biochemical Values (mg/dl) | M       | ean     |        | dard<br>ation | Standar | d Error | N  | %<br>relief | t-<br>Value | P- Value | Result        |
|----------------------------|---------|---------|--------|---------------|---------|---------|----|-------------|-------------|----------|---------------|
|                            | BT      | AT      | BT     | AT            | BT      | AT      |    |             |             |          |               |
| S. Cholesterol             | 233.05  | 185.38  | 49.86  | 26.45         | 7.89    | 4.18    | 40 | 20.45       | 6.008       | < 0.05   | Highly        |
|                            |         |         |        |               |         |         |    | %           |             | (<0.001) | Significant   |
| S. Triglycerides           | 207.193 | 126.059 | 93.806 | 47.574        | 14.832  | 7.522   | 40 | 39.16       | 6.272       | < 0.05   | Highly        |
|                            |         |         |        |               |         |         |    | %           |             | (<0.001) | Significant   |
| S. HDL                     | 48.149  | 49.835  | 9.678  | 16.62         | 1.53    | 2.63    | 40 | 3.50        | -0.654      | >0.05    | Insignificant |
|                            |         |         |        |               |         |         |    | %           |             | (0.517)  |               |
| S. LDL                     | 143.32  | 114.08  | 42.98  | 24.73         | 6.797   | 3.911   | 40 | 20.39       | 4.257       | < 0.05   | Highly        |
|                            |         |         |        |               |         |         |    | %           |             | (<0.001) | Significant   |
| S. VLDL                    | 38.699  | 24.966  | 25.64  | 9.566         | 4.05    | 1.51    | 40 | 35.49       | 3.712       | < 0.05   | Highly        |
|                            |         |         |        |               |         |         |    | %           |             | (<0.001) | Significant   |

BT: Before Treatment, AT: After Treatment

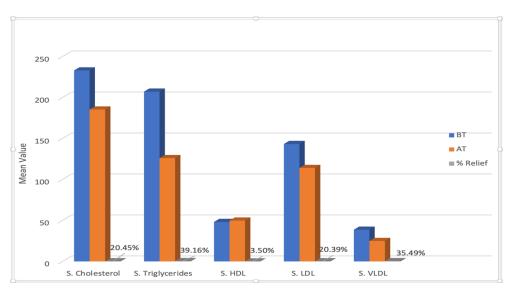


Chart 21: Efficacy of Lekhaniya Mahakashaya Ghanavati on Lipid Profile

Table 3: Efficacy of Lekhaniya Mahakashaya Ghanavati on Objective Parameters (Body Weight & BMI)

| Objective<br>Parameters | Me    | ean   |       | dard<br>ation | Standar | d Error | N  | % relief | t- Value | P- Value | Result      |
|-------------------------|-------|-------|-------|---------------|---------|---------|----|----------|----------|----------|-------------|
|                         | BT    | AT    | BT    | AT            | BT      | AT      |    |          |          |          |             |
| Body weight             | 71.95 | 68.75 | 11.20 | 10.60         | 1.77    | 1.67    | 40 | 4.45 %   | 9.682    | < 0.05   | Highly      |
|                         |       |       |       |               |         |         |    |          |          | (<0.001) | Significant |
| BMI                     | 25.89 | 24.73 | 3.51  | 3.26          | 0.55    | 0.52    | 40 | 4.49 %   | 9.916    | < 0.05   | Highly      |
|                         |       |       |       |               |         |         |    |          |          | (<0.001) | Significant |

BT: Before Treatment, AT: After Treatment

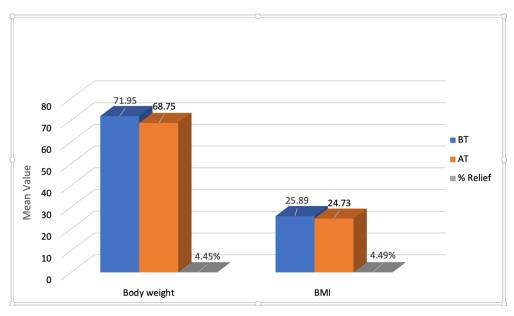


Chart 22: Efficacy of Lekhaniya Mahakashaya Ghanavati on Body Weight and BMI

Table 4: Efficacy of Lekhaniya Mahakashaya Ghanavati on other Parameters (Random Blood Sugar & Haemoglobin)

| Objective<br>Parameters | Mean   |        | Standard<br>Deviation |       | Standard Error |      | N  | % relief | t- Value | P- Value | Result       |
|-------------------------|--------|--------|-----------------------|-------|----------------|------|----|----------|----------|----------|--------------|
|                         | BT     | AT     | BT                    | AT    | BT             | AT   |    |          |          |          |              |
| Hb%                     | 13.13  | 12.92  | 1.29                  | 1.21  | 0.21           | 0.19 | 40 | 1.64 %   | 1.144    | >0.05    | Insignifican |
|                         |        |        |                       |       |                |      |    |          |          | (0.260)  | t            |
| RBS                     | 123.19 | 108.52 | 35.35                 | 11.97 | 5.59           | 1.89 | 40 | 11.9 %   | 2.795    | < 0.01   | Very         |
|                         |        |        |                       |       |                |      |    |          |          | (=0.008) | Significant  |

BT: Before Treatment, AT: After Treatment

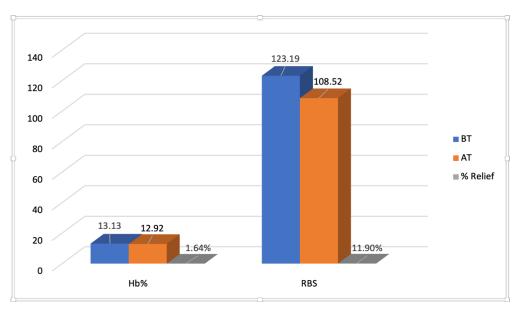


Chart 23: Efficacy of Lekhaniya Mahakashaya Ghanavati on Random Blood Sugar and Haemoglobin

| Status             | Number of Patients | %     |
|--------------------|--------------------|-------|
| Control of disease | 5                  | 12.5% |
|                    |                    |       |

Table 5: Overall Effect of Lekhaniya Mahakashaya Ghanavati on Subjective Parameters

| Status              | Number of Patients | %     |
|---------------------|--------------------|-------|
| Control of disease  | 5                  | 12.5% |
| Markedly improved   | 17                 | 42.5% |
| Moderately improved | 17                 | 42.5% |
| Mildly improved     | 10                 | 25%   |
| No improvement      | 0                  | 0%    |

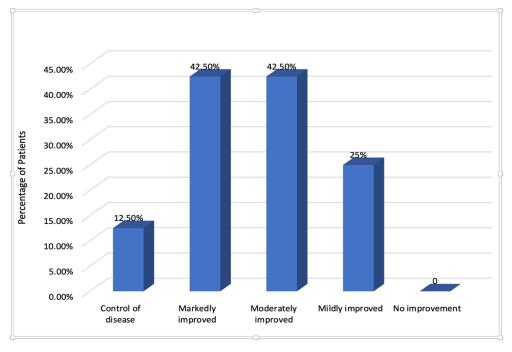


Chart 24: Overall Effect of Lekhaniya Mahakashaya Ghanavati on Subjective Parameters

### **CONCLUSION**

Wilcoxon signed-rank test was applied on graded subjective parameters. A paired-t test was used on the objective parameters. The test was carried out at the  $\leq 0.05$ ,  $\leq 0.01$ ,  $\leq 0.001$  level of 'p'. The results were statistically significant. Hence, it was concluded that Lekhaniya Mahakashaya provided better relief to patients with Dyslipidemia (Medodushti). Studies on statins have shown that people who use them for a longer period of time are more likely to acquire diabetes. Treatment of Dyslipidemia with statins is not the greatest option since the adarasha (best) chikitsa is one that both cures the disease and does not cause any additional diseases. Lekhaniya Mahakashaya Ghanavati might be a preferable option in the management of Dyslipidemia because it not only normalised lipid profiles but also decreases the risk of developing metabolic syndrome by lowering weight and RBS to some amount, hence reducing the risk of developing diabetes.

The overall effect of therapy was assessed by improvement in all subjective parameters of individual patients. Marked improvement was found in 42.5% of patients, and moderate improvement also accounted for 42.5% of the study population, followed by 25% of patients under the mild improvement category and 12.5% of patients successfully controlled their disease. During the trial period, no ADR was observed. Not a single patient fell under the no improvement category. So, it can be concluded that patients with Dyslipidemia (Medodushti) can be effectively managed through Ayurveda without fearing side effects and complications and maintain a quality life.

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