2

4

# Clinical Study of effectiveness of the Amritadya guggulu in Hyperlipidemia (Medho

5 *roga*)

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

#### Abstract

Hyperlipidemia is a medical condition characterized by an increase in one or more of the plasma lipids. According to classical writings, Ayurveda referred to hyperlipidemia as *Medo* Roga. The purpose of the study was to study the effect of Amritadya guggulu on hyperlipidemia. Methodology: Study was Randomized, Comparative clinical study. with duration of the eight weeks and two months follow up period. 44 Patients were selected randomly from outdoor patient department of Swastavritta clinic, National Ayurveda Teaching Hospital, Borella. Treatment effectiveness is based on subjective and objective parameters. . The University of Colombo's Institute of Indigenous Medicine was provided ethical clearance Total cholesterol, Triglyceride, HDL, LDL, VLDL and Risk Ratio in Lipid profile were assessed before and after the treatment. Results: The majority of them were between age of 50 and 59 i.e. 36.4%. All were married, with females accounting for 79.5%. Most of the participants were Buddhist (90.9%) and Sinhala (93.2%). The large amounts, 75%, lived in urban areas. There was a family history of hyperlipidemia in 33.3%. Amrithadya guggulu significantly reduced total cholesterol (p<0.01), LDL (p<0.05), and risk ratio (p<0.05). Significant reduction in BMI and weight (p<0.01). Results showed substantial changes in systolic and diastolic blood pressure levels before and after treatment (p<0.01). Symptoms of hyperlipidemia included thirst (*Thrusha*), hunger (*Kshuth*), daytime sleepiness (Swapna), hyperhidrosis (Ati Sweda), and offensive body odor (Daugandya), lack of body strength(Daurbalya) and difficulty in breathing(Kshudra Shwasa) were greatly reduced (p<0.001), except for Impaired or decreased Sexual Performance(AlpaMaithuna) (p>0.05). The present study concluded as Amritadya guggulu had significant result on elevated lipid profile and symptoms of in hyperlipidemic patients.

## Key words: Amritadya guggulu, Hyperlipidemia, Lipid profile, Medho roga

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

## Introduction

A medical disorder known as hyperlipidemia is defined by a decrease in high-density lipoprotein levels and an increase in one or more plasma lipids, such as triglycerides, cholesterol, and plasma lipoproteins, such as very low-density lipoprotein and low-density lipoprotein<sup>1</sup>. Hyperlipidemias can be categorized as acquired (also known as secondary) when they arise from another underlying condition that alters the metabolism of lipoproteins and plasma lipids, or familial (also known as primary) when they are brought on by particular genetic defects. An genetic disorder known as familial hypercholesterolemia results in elevated LDL (low-density lipoprotein) cholesterol levels from birth, a 1 in 2 (50%) probability of passing on the mutated gene to each of the offspring, and early heart attacks.<sup>2</sup>.Elevated cholesterol raises the risk of stroke and heart disease. High cholesterol is the cause of one-third of ischemic heart disease worldwide. An estimated 2.6 million fatalities (4.5 percent of all deaths) are attributed to elevated cholesterol. As a risk factor for ischemic heart disease and stroke, elevated total cholesterol is a significant contributor to the disease burden in both the developed and developing worlds.<sup>3</sup>. Furthermore, throughout the Asia-Pacific area, cardiovascular disease (CVD) is becoming one of the major health concerns. In 2008, the WHO estimated that the prevalence of dyslipidemia, which is defined as blood levels of TC > 5 mmol/L [190 mg/dL], was significantly lower in Southeast Asia (30.3%) and the Western Pacific (36.7%) than in Europe (53.7%) and the Americas (47.7%)<sup>4</sup>. An independent risk factor for ischemic heart disease is hyperlipidemia. In 2019, ischemic heart disease was the top cause of hospital deaths. For the majority of the primary leading causes of mortality, male fatalities are comparatively higher than equivalent female deaths<sup>5</sup>.

According to basic concepts in Ayurveda text *Amritadya Guggulu* with bee honey was suitable drug for Hyperlipidemia and which is indicated in many Ayurveda texts such as *Govinda Dasji Bhisagratna*, (1956) *Bhaisajya Rathnavali* Volume 2, *MedoRoga*,Chapter 39<sup>6</sup>,*Sri Jagadishvara Prasad Tripathy*,(1983)*Chakradatta*,*Athisthulya* Chikithsa,Chapter,33<sup>7</sup>, *Bulusu Sitaram*(2010) *Bhavaprakasa* of *Bhavamisra* (Original text along with commentary and translation), *Madhyamakhanda*,Chapter 39<sup>8</sup>.

Table 1. Ingredients of Amrtadya Guggulu

| Sanscrit name | Scientific name                | Part used      | Proportion |
|---------------|--------------------------------|----------------|------------|
| Amrita        | Tinosphora cordifolia          | Stem           | 1 Part     |
| Ela           | Elittaria cardamomum           | Seed           | 2 Part     |
| Vidanga       | Embelia Ribes                  | Seed           | 3 Part     |
| Vatsaka       | Holarrhena antidysentrica wall | Stem           | 4 Part     |
| Kalinga       | Holarrhena antidysentrica seed | Seed           | 5 Part     |
| Pathya        | Terminalia chebula             | Fruit          | 6 Part     |
| Amalaki       | Phyllanthus emblica            | Fruit          | 7 Part     |
| Guggulu       | Commiphora mukul               | Oleogum resine | 8 Part     |
|               |                                | (from stem)    |            |

According to the Table 1. drugs were mixed in an increasing order, thus the highest ingredient being *Guggulu*.

Moreover, they have mentioned that Powder form of *Amritadya Guggulu* administrating with bee honey that is a *Anupana* (vehicle). *Anupana* is a vehicle taken with medicine and which assists the action of main ingredient and plays an integral part of absorption of the medication (*Charaka Samhitha, Chikithsa Adyanaya*)<sup>9</sup> As well as bee honey has hypolipidaemic action<sup>10</sup>.In this case bee honey will facilitated absorption of *Amritadya Guggulu* to the body.

According to Ayurveda theories Hyperlipidemia also caused by imbalance of agni and increase of *Kapha* and *Medodhathu*. So *Kaphamedhagna* (Reduced *Kapha* and *Medodhathu*) treatment is essential in this condition. According to the above text books in Ayurveda, which

- were Bhaisajya Rathnavali and Chakradatta have mentioned that Amritadya Guggulu has
- 76 the effect of hypolipideamic actions<sup>6,7,8</sup>.

75

78

79

# Table 2. Properties of ingredients of Amritadya Guggulu according to Ayurveda<sup>11</sup>

| Name of the ingredient               | Rasa                                          | Guna                                                                          | Virya   | Vipaka  | Dosha<br>Ghana                                              | Karma                                                              |
|--------------------------------------|-----------------------------------------------|-------------------------------------------------------------------------------|---------|---------|-------------------------------------------------------------|--------------------------------------------------------------------|
| Tinosphora<br>Cordifolia             | Tiktha,<br>Kasaya<br>Madhura                  | Guru,<br>Snigda                                                               | Ushna   | Mdhura  | Pitta,vata,k<br>apha<br>shamaka                             | Rakthashodaka<br>,<br>Deeepana,<br>Pachana                         |
| Elittaria<br>cardamomum              | Katu.<br>Tikta                                | Ruksha,<br>Laghu                                                              | Seeta   | Katu    | Pitta,vata,k<br>apha<br>shamaka                             | Hardya,<br>Muthrajanaka,<br>Deepana,<br>Pachana                    |
| Embelia Ribes                        | Katu,<br>Tikta,                               | Lagu,<br>Thishna                                                              | Ushna   | Katu    | Vata,Kaph<br>a shamaka                                      | Deepana<br>Pachana                                                 |
| Holarrhena<br>antidysentrica<br>wall | Tiktha,<br>Kasaya<br>Katu                     | Ruksha,<br>Laghu                                                              | Sheetha | Katu    | Kapha,<br>Piththa-<br>shamaka                               | Lekhana,Deep<br>ana,<br>Rakthshodaka,<br>Dhathushosha<br>na        |
| Holarrhena<br>antidysentrica<br>seed | Tiktha,<br>Kasaya<br>katu                     | Ruksha,<br>Laghu                                                              | Sheetha | Katu    | Kapha,<br>Piththa-<br>shamaka                               | Deepana,<br>Sangrahi,<br>Vathanulomaa                              |
| Terminalia<br>chebula                | Madura,<br>Amla,<br>Katu,<br>Tikta,Kas<br>aya | Ruksha,<br>Laghu                                                              | Ushna   | Madhura | Vatha-<br>shamaka                                           | Deepana,<br>Pachanama,<br>Mruduvirecha<br>na                       |
| Phyllanthus<br>emblica               | Madura,<br>Amla,<br>Katu,<br>Tikta<br>Kasaya  | Ruksha,<br>Guru                                                               | Sheetha | Madhura | Vata,<br>Kapha<br>shamaka<br>Specially<br>pitta-<br>shamana | Dahaprasham<br>ana,<br>Medya,<br>Hardya,<br>Yakruythuththe<br>jaka |
| Commiphora<br>Mukul                  | Tiktha,<br>Kasaya,<br>Madura,<br>katu         | Purana-<br>Laghu,<br>Theeksh<br>na,Ushn<br>a,,Sara,<br>Sukshm<br>a,<br>Navina | Ushna   | Katu    | Pitta,,vata,<br>kapha<br>shamaka                            | Lekhana,<br>Vedanasthapa<br>na,<br>Deepana,<br>Anulomana           |

| Pichchil     |  |  |
|--------------|--|--|
| a.<br>Snigda |  |  |
|              |  |  |

Acharya Charaka describes in detail the etiology, pathogenesis, pathophysiology, signs and symptoms, complications, prognosis, and management of *sthaulya* in the chapter "Ashtaunindeetiya Adhyaya." Atisthaulya is also described in relation to Nanatmaja Vikara of kapha. Acharya Charaka also introduces the concepts of Bandha and Abaddhameda in relation to *sthaulya*: Baddhameda refers to solid or obvious fat of the body, while Abaddhameda refers to free or mobile fat. He explains that Atisantarpana (over-nourishment) results in obstructive pathology in the Rakta Marga (blood channels) and causes morbid Medodhatu (fat tissue) and Kaphadosha. The text also explains in detail about Kapha and Vata, their causes for Vriddhi (growth) and Prakopa (aggravation), and provides a complete picture of the pathophysiology of Avarana (blockage)<sup>13</sup>.

- According to the Table 2.2 Ayurveda each ingredient of *Amritadya guggulu* has properties of
  *Kapha Vata shamaka* which caused to reduce signs and symptoms of *Medo roga*.
- 92 Objectives

- 93 To study the effect of the *Amritadya guggulu* on Hyperlipidemic patients.
- 94 Methodology
  - Present study was Randomized, Comparative clinical study. Duration of the clinical research was eight weeks and two months follow up period. 44 Patients were selected randomly from outdoor patient department of *Swastavritta* clinic from, National Ayurveda Teaching Hospital(NATH), Borella. Ethical Clearence was granted by Ethics Review Committee of Institute of Indigenous Medicine, University of Colombo. Patients were registered for the study, after collecting their consent his/her willingness to the volunteer participation for the research. Patients were d examine their general health condition with relevant blood tests.

- 103 Inclusion criteria:-Patients who exhibit high levels of total cholesterol, LDL, VLDL,
- triglycerides, and lower HDL (serum total cholesterol >240 mg/dl, HDL < 40 mg/dl, serum
- triglycerides >150 mg/dl, LDL >160 mg/dl, and VLDL >30 mg/dl) and in between the ages
- of 30 and 75 years were included in the study.
- 107 Exclusion criteria: Patients with known heart diseases (eg :- Angina, Congenital heart
- diseases), with severe hypertension (>160/100Hgmm), age below 29 and over 76 years, and
- pregnant and lactating mothers, patients with chronic disease conditions -excluded.
- Each selected patients were screened with lipid profile test, liver function tests, fasting blood
- sugar, serum creatinine, and GFR tests before starting the treatment and after completing the
- 8-week period. Data on socio-demographic characteristics such as age, gender, religion,
- ethnicity, and others were gathered through a questionnaire. Patients visited the clinic once
- more after the follow-up period for a final. check-up.
- Patients were prescribed with Amritadya Guggulu powder 7.5g mixed with one and half
- teaspoon of bee honey, Morning (Around 8.00 a.m.) and evening(Around 8.00 p.m.) after
- meal according to the prescription in *Bhaisajya Rathnavali* <sup>6</sup>.
- After the treatment period, each patient was assessed through lipid profile, liver function tests
- 119 (SGPT, SGOT), serum creatinine, eGFR and fasting blood sugar tests. The signs and
- 120 symptoms of *Medoroga*(Hyperlipidemia)as*Thrusha* (Thirst),*Kshuth* (Hunger),*Swapna*
- 121 (Daytime Sleepiness) ,Ati Sweda (Hyperhidrosis) Daurgandya (Offensive Body Odor).
- 122 Daurbalya (lack of Body Strength) and Kshudra Shwasa (Difficulty in breathing) and
- 123 Maithuna (Impaired or decreased Sexual Performance)and complications of Medoroga
- 124 (Hyperlipidemia) were assessed before and after treatment. Additionally physical
- examinations (wight, waist circumference, MUAC -mid-upper arm circumference and vital

- signs blood pressure, pulse, and respiratory rate) were measured at each weekly clinic visit.
- 127 Efficacy of the treatment is determined on subjective and objective parameters.

129

130

131

132

133

# Results

# Table 3. Distribution of the Sociodemographic characteristics of the respondents.

| Characteristics | Frequency (N)    | Percentage %    |
|-----------------|------------------|-----------------|
|                 | rrequestion (rv) | z ezeezinige /o |
| Age             |                  |                 |
| 30-39           | 5                | 11              |
| 40-49           | 9                | 21              |
| 50-59           | 16               | 36              |
| 60-69           | 9                | 21              |
| 70-79           | 5                | 11              |
| Gender          |                  |                 |
| Male            | 9                | 20.5            |
| Female          | 35               | 79.5            |
| Civil status    |                  |                 |
| Unmarried       | 0                | 0               |
| Married         | 44               | 100             |
| Monthly income  |                  |                 |
| Below 10000     | 21               | 47.7            |
| 10000-20000     | 1                | 2.3             |
| 20000-30000     | 6                | 13.6            |
| 30000-40000     | 1                | 2.3             |
| 40000-50000     | 5                | 11.4            |
| Above 50000     | 10               | 22.7            |
| Occupation      |                  |                 |
| Government      | 5                | 11.4            |
| Private         | 12               | 27.3            |
| Self occupation | 3                | 6.8             |
| Not engaged in  | 24               | 54.5            |
| occupation      |                  |                 |
| Religion        |                  |                 |
| Buddhist        | 40               | 91              |
| Catholic        | 2                | 4.5             |
| Hindu           | 2                | 4.5             |
| Race            |                  |                 |
| Sinhala         | 41               | 93.2            |
| Tamil           | 3                | 6.8             |
| Education       |                  |                 |
| Primary         | 5                | 11.4            |

| Up to O/L      | 18 | 40.9 |
|----------------|----|------|
| Up to A/L      | 15 | 34.1 |
| Degree         | 6  | 13.6 |
| Living area    |    |      |
| Urban          | 33 | 75.0 |
| Suburban       | 7  | 15.9 |
| Rural          | 4  | 9.1  |
| Family history |    |      |
| Yes            | 15 | 34.1 |
| No             | 29 | 65.9 |

In the present study as shown in Table 3. Most of them were 50-59 age group i.e.36.4%. All were married and female 79.5% .Most individuals in private employment (27.3%) and a larger number not engaged in any occupation (54.5%), Higher percentage (47.7%) of them earned below 10,000 Sri Lankan Rupees. The majority of participants were Buddhist 90.9%. Sinhala ethnicity was predominant 93.2%. Most of the respondents were education level up to O/L(40.9%). A majority lived in urban areas 75%. Family history of hyperlipidaemia 33.3%.

Table 4. Effect of the treatment on lipid profile before and after by using Paired sample T test.

|                      | Mean   | ı      | Mean  | Std.   | SEM  | 95% C. | I.D    | T     | P     |
|----------------------|--------|--------|-------|--------|------|--------|--------|-------|-------|
|                      | BT     | AT     | Def.  | D.     |      | Lower  | Upper  | value | value |
| Total<br>Cholesterol | 265.15 | 244.87 | 20.28 | 44.828 | 6.75 | 6.65   | 33.91  | 3.00  | .004  |
| Triglycerides        | 171.69 | 175.07 | -3.38 | 56.800 | 8.56 | -20.64 | 13.88  | 39    | .695  |
| HDL                  | 52.95  | 52.69  | .26   | 9.1588 | 1.38 | -2.53  | 3.039  | .18   | .855  |
| LDL                  | 178.32 | 157.14 | 21.18 | 46.352 | 6.98 | 7.09   | 35.278 | 3.03  | .004  |
| VLDL                 | 34.77  | 34.57  | .20   | 11.917 | 1.79 | -3.42  | 3.820  | .11   | .913  |
| Risk Ratio           | 5.20   | 4.85   | .35   | 1.094  | .16  | .02078 | .6860  | 2.14  | .038  |

BT-Before Treatment, AT-After treatment, Mean Def.-Mean Difference, Std.D.-Slandered Deviation, SEM-

143 Slandered error of mean, C.L.D-Confidence Interval Difference.

There was a statistically significant reduction in total cholesterol (mean difference = 20.28, p = 0.004), indicating a positive effect of the treatment. There was higher mean difference. As well as a significant reduction in LDL levels was observed (mean difference = 21.18, p = 0.004), suggesting that the treatment had a positive impact on LDL cholesterol. However significant change was not found in VLDL levels (mean difference = 0.20, p = 0.913

Also significant change was observed in the risk ratio (mean difference = 0.35, p = 0.038), which indicates an improvement in cardiovascular risk. Significant change was not observed in triglyceride levels (mean difference = -3.38, p = 0.695), suggested that the treatment did not have a notable effect on triglycerides. Result was found as significant change was not observed in HDL levels (mean difference = -0.26, p = 0.855), indicating that the treatment did not affect the good cholesterol.

Table 5. Effect of treatment on BMI within group before and after by using Paired sample T test.

|     | Mean   |        | Mean SD |       | SEM 95% ( |       | 95% C I. D. |       | P     |
|-----|--------|--------|---------|-------|-----------|-------|-------------|-------|-------|
|     | BT     | AT     | deff.   |       |           | Lower | Upper       | value | value |
| BMI | 26.900 | 26.039 | .861    | 1.730 | .260      | .335  | 1.388       | 3.303 | .002  |
|     |        |        |         |       |           |       |             |       |       |

The Paired Samples T-Test results indicated a statistically significant reduction in Body Mass Index (BMI) before and after the treatment. The mean difference in BMI is 0.861, with a standard deviation of 1.730. With a p-value of 0.002 and a t-value of 3.303, the results show that the reduction in BMI after treatment is statistically significant at a 95% confidence level.

Table 6. Effect of treatment on Liver function and Kidney function test parameters within group before and after by using Paired sample T test

| Mean |    | Mean | Std. d. | SEM | 95% C.I.D. |       | T     | p     |
|------|----|------|---------|-----|------------|-------|-------|-------|
| BT   | AT | def. |         |     | Lower      | Upper | value | value |

| SGPT     | 31.334  | 31.227 | .106   | 18.544  | 2.795  | -5.531 | 5.744  | .038  | .970 |
|----------|---------|--------|--------|---------|--------|--------|--------|-------|------|
| SGOT     | 32.911  | 28.584 | 4.327  | 21.279  | 3.208  | -2.142 | 10.796 | 1.349 | .184 |
| Se. Cre. | .799    | .842   | 042    | .108    | .016   | 075    | 009    | -2.58 | .013 |
|          |         |        |        |         |        |        |        |       |      |
| GFR      | 102.641 | 82.370 | 20.271 | 124.792 | 18.813 | -17.66 | 58.212 | 1.078 | .287 |
|          |         |        |        |         |        |        |        |       |      |

.

Within Group the Paired Samples T-Test results for liver and kidney function parameters showed the following: SGPT with mean difference = 0.106, and p-value of 0.970, indicating no significant change. SGOT with mean difference = 4.327, and p-value of 0.184, indicating no significant change. For kidney function, Serum Creatinine: Mean difference = -0.042, with a p-value of 0.013, indicating a statistically significant change. eGFR with mean difference = 20.271, and p-value of 0.287, indicating no significant change. The results suggested that there were no significant changes in liver function (SGPT and SGOT) or eGFR, but there was a significant change in serum creatinine levels within Group before and after the treatment, with a p-value of 0.013.

Table 7. Effect of treatment on weight before and after by using Paired sample T test.

|        |        |        | Mean Std. d. |        | SEM   | <b>SEM 95% C.I.D</b> |       |       | P     |
|--------|--------|--------|--------------|--------|-------|----------------------|-------|-------|-------|
|        | AT     | BT     | def.         |        |       | Lower                | Upper | value | value |
| weight | 64.415 | 62.523 | 1.892        | 3.7769 | .5694 | .743                 | 3.040 | 3.323 | .002  |

In the group the Paired Samples T-Test results showed a statistically significant reduction in weight before and after the treatment. The mean weight difference is 1.892, with a standard deviation of 3.7769. With a t-value of 3.323 and a p-value of 0.002, this change is significant at a 95% confidence level. Reduction in weight is treatment effectively reduced weight within Group .

Table 8. Effect of treatment on FBS before and after by using Paired sample T test.

| Mean | Mean |      | S.D. | SEM | 95% C.I.D |       | T     | P     |
|------|------|------|------|-----|-----------|-------|-------|-------|
| BT   | AT   | def. |      |     | Lower     | Upper | value | value |

| FBS | 109.25 | 113.16 | -3.918 | 15.198 | 2.291 | -8.539 | .702 | -1.710 | .094 |
|-----|--------|--------|--------|--------|-------|--------|------|--------|------|
|     |        |        |        |        |       |        |      |        |      |

Paired Samples T-Test results indicated that there was no statistically significant change in fasting blood sugar (FBS) within Group before and after the treatment. The mean difference in FBS is -3.918, with a standard deviation of 15.198. The t-value is -1.710, and the p-value is 0.094, which is greater than 0.05, showing that the change is not statistically significant.

# Table 9. Effect of treatment on Systolic and Diastolic blood pressure within group before and after by using Paired sample T test.

|                  |        |        |        |        | Mean  | SD    | SEM    | 95% CI | D     | T | P |
|------------------|--------|--------|--------|--------|-------|-------|--------|--------|-------|---|---|
|                  | AT     | BT     |        |        |       | Lower | Upper  | value  | value |   |   |
| Systolic<br>.BP  | 121.14 | 109.55 | 11.591 | 11.603 | 1.749 | 8.063 | 15.118 | 6.627  | .001  |   |   |
| Diastolic<br>.BP | 76.59  | 71.14  | 5.455  | 8.478  | 1.278 | 2.877 | 8.032  | 4.268  | .001  |   |   |

The Paired Samples T-Test results indicate significant changes in both systolic and diastolic blood pressure within the group on before and after the treatment. The mean difference was 11.591, and p-value of 0.001, indicating a statistically significant reduction in systolic blood pressure. The mean difference is 5.455, with a p-value of 0.001, indicating a statistically significant reduction in diastolic blood pressure. Both p-values were well below the 0.05, suggesting that the treatment had a significant effect on reducing both systolic and diastolic blood pressure within group.

Table 10. Effect of the symptoms before and after on the treatment by using Wilcoxon signed rank test.

| Symptoms | Z value | Mean     | P value  |      |
|----------|---------|----------|----------|------|
|          |         | Negative | Positive |      |
| Thirst   | -5.23   | 17.58    | 15.00    | .001 |
| Hunger   | -4.80   | 15.00    | 00.00    | .001 |

| Sleepiness             | -4.94 | 18.24 | 27.50 | .001 |
|------------------------|-------|-------|-------|------|
| Hyperhidrosis          | -4.09 | 12.20 | 7.50  | .001 |
| Body Odor              | -4.96 | 14.50 | 00.00 | .001 |
| Sexual performance     | 677   | 8.88  | 7.00  | .499 |
| Body strength          | -4.75 | 18.38 | 20.50 | .001 |
| Difficult in breathing | -5.23 | 18.00 | 00.00 | .001 |

In study group Thirst, Hunger, Sleepiness, Hyperhidrosis, Body Odor, Body Strength, and Difficulty in Breathing all showed statistically significant improvements after treatment, with p-values <0.001. The Z-values for these symptoms are relatively high (ranging from -4.09 to -5.23), indicating substantial changes in symptom severity from pre-treatment to post-treatment. However there were not Significant Improvement in Sexual Performance(p>0.05). Sexual performance has a p-value of 0.499, indicating no statistically significant change. The Z-value for sexual performance is -0.677, much lower than for the other symptoms. This result suggests that the treatment did not have a measurable effect on sexual performance in this group.

Table 11. Effect of the symptoms of Santhoma, Xanthelasma and Arcus cornea before and after treatment by using Wilcoxon signed rank test.

| Symptoms     | Z value | Mean Rank | P value  |       |
|--------------|---------|-----------|----------|-------|
| .<           |         | Negative  | Positive |       |
| Arcuscorneae | 0.00    | 00.00     | 00.00    | 1.000 |
| Santhoma     | 0.00    | 00.00     | 00.00    | 1.000 |
| Xanthalesma  | -1.00   | 00.00     | 00.00    | 1.000 |

In group B all three symptoms Arcus cornae, Santhoma, and Xanthalesma have p-values of 1.000. This indicates that there was no measurable improvement in these symptoms after

treatment. Arcus cornae and Santhoma has a Z-value of 0.000, which suggested that there was no observed change in severity for any of these symptoms.

# 218 Table 12. Effect of the complication before and after on the treatment.

| Symptoms             | Z value | P value  |          |      |
|----------------------|---------|----------|----------|------|
|                      |         | Negative | Positive | 7/1/ |
| Pendulous abdomen    | -1.73   | 00.00    | 2.00     | .083 |
| Pendulous<br>Buttoks | -1.73   | 00.00    | 2.00     | .083 |
| Pendulous<br>Breast  | -1.73   | 00.00    | 2.00     | .083 |

In group B the p-values for all three parameters Pendulous Abdomen, Pendulous Buttocks, and Pendulous Breast was 0.083. These values were still above the standard threshold of 0.05, meaning they are not statistically significant. The Z-values for all three symptoms were - 1.732, indicating some change was observed, but it was not substantial enough to reach statistical significantly.

# Table 13. Treatment's effect on the lipid profile both before and after treatment follow-

# 226 up using the Paired Sample T test.

|                  | Mean   |        | Mean SD |        | SEM    | 95% CID |        | T     | р     |
|------------------|--------|--------|---------|--------|--------|---------|--------|-------|-------|
|                  | AT     | BT     | def.    |        |        | Lower   | Upper  | value | value |
| Follow up<br>TC  | 263.54 | 223.16 | 40.38   | 42.944 | 8.766  | 22.241  | 58.508 | 4.606 | .001  |
| Follow up<br>Try | 156.39 | 160.66 | -4.27   | 59.337 | 12.112 | -29.326 | 20.785 | 353   | .728  |

| follow up<br>HDL        | 56.912 | 54.791 | 2.12  | 13.971 | 2.851 | -3.778 | 8.020  | .744  | .465 |
|-------------------------|--------|--------|-------|--------|-------|--------|--------|-------|------|
| Follow up<br>LDL        | 176.17 | 136.24 | 39.93 | 45.789 | 9.346 | 20.602 | 59.272 | 4.273 | .001 |
| follow up<br>VLDL       | 31.254 | 32.133 | 879   | 11.888 | 2.426 | -5.899 | 4.140  | 362   | .720 |
| Follow up<br>risk ratio | 4.7804 | 4.220  | .56   | 1.100  | .224  | .095   | 1.024  | 2.493 | .020 |

The Paired Samples T-Test results showed statistically significant changes in Total Cholesterol with the mean difference is 40.38, and the p-value is 0.001, indicating a statistically significant change in total cholesterol levels after the follow-up. LDL with the mean difference was 39.93, and p-value of 0.001, showing a significant increased in LDL levels after the follow-up. Risk Ratio with the mean difference is 0.56, and p-value of 0.020, indicating a significant change in the risk ratio after the follow-up.

There were no statistically significant changes of Triglycerides with the mean difference was -4.27, and p-value of 0.728, indicating no significant change in triglyceride levels. HDL with the mean difference was 2.12, and p-value of 0.465, indicating no significant change in HDL levels. VLDL with the mean difference is -0.879, with a p-value of 0.720, indicating no significant change in VLDL levels.

Table 14: Treatment effects on FBS, kidney function test, and liver function test before and after follow-up using the Paired Sample T test.

| 1/1/1             | Mean   |        | Mean SD |        | SEM    | 95% C.I.D |         | t value | P     |
|-------------------|--------|--------|---------|--------|--------|-----------|---------|---------|-------|
|                   | AT     | BT     |         |        |        | Lower     | Upper   |         | value |
| Follow-up<br>SGOT | 23.916 | 23.625 | .291    | 9.87   | 2.014  | -3.876    | 4.459   | .145    | .886  |
| Follow-up<br>SGPT | 24.500 | 24.083 | .416    | 11.57  | 2.362  | -4.469    | 5.303   | .176    | .862  |
| Follow-up S.cr.   | .775   | .733   | .041    | .10    | .0219  | 003       | .087    | 1.900   | .070  |
| follow-up         | 116.95 | 86.724 | 30.229  | 168.07 | 34.307 | -40.740   | 101.199 | .881    | .387  |
| Follow-up FBS     | 115.12 | 106.04 | 9.083   | 48.84  | 9.971  | -11.543   | 29.710  | .911    | .372  |

243

244

245

246

247

248

249

250

252

253

254

255

256

257

258

259

260

261

262

263

264

265

266

267

268

269

Table 14. represented the results of a paired samples t-test, comparing pre- and follow-up

values for various parameters (SGOT, SGPT, serum creatinine, GFR, and FBS) across group.

According to the Observations SGOT: No significant difference (p = .886).SGPT: no

significant differences (p = .862).

Serum Creatinine.: not significant (p = .070).GFR : no significant differences (p = .387).FBS

: no significant differences (Group B: p = .372). The results of the Paired Samples Test

indicate that there were no statistically significant differences between the pre- and follow-up

measurements across all variables. Overall, the analysis suggests that there were no

substantial changes in SGOT, SGPT, serum creatinine, GFR, or FBS levels from pre- to

251 follow-up measurements in group.

#### **Discussion**

## Hypolipidemic Action of Amritadya Guggulu according to Ayurveda

According to the antient text Amritadya Guggulu contained Amrita (Tinosphora (Holarrhena cordifolia),Ela(Elittaria cardamomum),Vidanga( Embelia Ribes), Vatsaka antidysentrica wall),Kalinga(Holarrhena antidysentrica (Terminalia seed),Pathya chebula), Amalaki (Phyllanthus emblica) and Guggulu (Commiphora mukul) in increasing quantity. Most of the ingredients were kaphahara in mode of action. As the drugs are mixed in an increasing order, thus the highest ingredient being Guggulu which was Kaphahara<sup>9</sup>. Additionally, the largest concentration of Guggulu is seen in Shuddha Guggulu. Furthermore, it possesses the qualities of *Katu rasa*, *laghu ruksha guna*, *Ushnaveerya*, Katuvipaka, and KaphaVata Shamaka. Additionally, it has the following qualities: Kleda-Meda Shoshaka (scrap out excess Meda and Kapha), Srotovishodhaka (open the microchannels), Paachana (improves digestive power), Deepana (enlighten the Agni), and potent in Lekhana property<sup>14</sup>. According to Ayurvedic teachings, hyperlipidemia is also brought on by an increase of Kapha and Medodhathu and an imbalance in Agni. Therefore, treatment with Kaphamedhagna is crucial for this illness. Therefore, all of these constituent qualities assisted in eliminating excess Meda and Kapha and dismantling the pathophysiology of hyperlipidemia.

- 270 The resin known as guggul (gum guggul) is made by the Commiphora mukul. Guggulipid,
- 271 which is extracted from *guggul*, contains plant sterols (guggulsterones E and Z), which are its
- bioactive compounds. Research has shown that guggulipid significantly lowers serum total
- 273 cholesterol, LDL, and triglycerides while increasing HDL<sup>15</sup>.
- 274 In connection with sthaulya, Acharya Charaka also presents the ideas of Baddha and
- 275 Abaddhameda: Abaddhameda denotes free or mobile fat, whereas Baddhameda denotes solid
- or visible body fat<sup>13</sup>. Abaddha medas, which travel throughout the body. Medovilayana
- 277 (liquefaction of fat ) will result from *Tikta*, *Katu*, and *Kashaya rasas*. Drugs that are *Rooksha*,
- 278 Sookshma, and Ushna in nature, such Guggulu, Haritaki, Vidanga, and Guduchi, penetrate
- 279 deeper channels and eliminate Sanga or blockage. Because fat deposits in the arteries,
- obstruction in the case of hyperlipidemia may manifest as atherosclerosis. Therefore, it aids
- 281 in the liquefaction of these fatty obstructions due to the aforementioned qualities.
- 282 Theekshnagni are calmed by drugs like Ela, Amalaki, and Kutaja by their Sheeta veerya.
- 283 Haritaki is 3<sup>rd</sup> highest ingredient amongst the ingredients, which is Kashaya rasa
- 284 *pradhana* and best Vatanulomana<sup>16</sup>.
- 285 A statistically significant decrease in total cholesterol was seen in our study (mean difference
- = 20.28, p = 0.004), suggesting that the treatment was effective. The mean difference was
- greater. Additionally, a significant decrease in LDL levels was observed (mean difference =
- 288 21.18, p = 0.004), indicating that the therapy improved LDL cholesterol. The risk ratio also
- showed a significant change in our study (mean difference = 0.35, p = 0.038), indicating a
- 290 reduction in cardiovascular risk.

# Effect on Lipid profile

- 292 A previous study found that one group received 30 days of treatment with Amritadya
- 293 Guggulu, and another group received 30 days of treatment with Amritadya Guggulu
- 294 combined with Yavamalaki Choorna. Both groups' total cholesterol, LDL, VLDL, and
- 295 triglycerides were statistically significant at p<0.001, but the group that only received
- 296 treatment for Amritadya Guggulu exhibited a statistically significant decrease in HDL
- 297  $(P=0.043)^{16}$ .

291

298

## **Antiobesity effect**

- 299 Additional findings showed that the Body Mass Index (BMI) decreased statistically
- 300 significantly both before and after the treatment. The results demonstrated that the decrease in

BMI following therapy is statistically significant at a 95% confidence level, with a mean difference of 0.861 and a p-value of 0.002. According to a previous study, *Amrithadya* guggulu treatment within a group was substantially linked with BMI (p<0.001). <sup>16</sup>.

Weight loss before and after treatment was statistically significant, according to the results of our study; this difference is significant at a 95% confidence level. Weight loss is a treatment that successfully decreased weight in the study group. A previous study found a strong correlation between weight and receiving *Amrithadya guggulu* within a group (p<0.001)<sup>17</sup>.

#### **Effect on Blood pressure**

With a p-value of 0.001, the medication significantly decreased the group's systolic and diastolic blood pressure in the current study. According to previous research, *guggulu's* hypotension activity was caused by *Meda Shoshana* (lowering *Meda*), *Srotovishodhana* (cleaning the channels), and *Lekhana* (scraping) properties, which are dominant in the body's circulatory system<sup>20</sup>

## Effect on Sign and symptoms of Medoroga

Thirst, hunger, sleepiness, hyperhidrosis, body odor, body strength, and difficulty breathing all exhibited considerable improvement in the current investigation, indicating that treatment significantly improved these symptoms. According to a previous study, *Amritadya Guggulu* is useful in managing *medogoga* since it possesses *Rasa- Katu, Tikta, Kashaya, Guna- Laghu, Ruksha* and *Virya- Ushna, Vipaka- Katu*, and *Dosha Karma- Kapha Vatashamaka*. The drug's components were clearly detected in *Kapha*-predominant pathologies by its *Rasapanchaka* (Five taste)<sup>18</sup>. It resulted in the symptoms becoming less severe.

Arcuscornae ,Santhoma and Xanthalesma did not exhibit any statistically significant changes when compared before and after. Additionally, no statistically significant alterations were seen in the pendulous breast, pendulous buttocks, or pendulous abdomen. This implied that the medication had no effect on these physical traits. It can result in a longer treatment period than two months. However, a previous study found that when hyperlipidemic individuals received the Ayurvedic medications *Navaka Guggulu* and *Sthaulyahara Kashaya*, the results showed statistically significant cases of pendulous breast, pendulous buttocks, and pendulous abdomen.<sup>19</sup>.

## 331 Conclusion

- 332 Amrithadya guggulu treatment resulted in a statistically significant decrease in the study
- group's total cholesterol (p<0.01), LDL (p<0.05), and risk ratio (P<0.05). Weight and Body
- Mass Index (BMI) decreased statistically significantly (p<0.01). Both the diastolic and
- systolic blood pressures changed significantly before and after the treatment, according to the
- 336 results with p<0.01. Symptoms of hyperlipidemia of Thrusha (Thirst), Kshuth
- 337 (Hunger), Swapna (Daytime Sleepiness), Ati Sweda (Hyperhidrosis), Daurgandya (Offensive
- 338 Body Odor), Daurbalya (lack of Body Strength) and Kshudra Shwasa (Difficulty in
- breathing)(p<0.001) were statistically significant observed (p<0.05), except Alpa Maithuna
- 340 (Impaired or decreased Sexual Performance) (p>0.05). Amritadya Gugguluis considered to be
- a effective Ayurvedic drug for the treatment of hyperlipidemia.

## 342 References

- 343 1.Shattat G. F. A Review Article on Hyperlipidemia: Types, Treatments and New Drug
- 344 Targets. Biomed Pharmacol J 2014;7(2)
- 345 2. National Human Genome Research Institute. About familial hypercholesterolemia
- 346 [Internet]. 2013 [cited 2024 Dec 16]. https://www. Genome.gov/25520184 /learningabout-
- 347 familial-hyperchol
- 3. World Health Organization, The Global Health Observatory, https://www.who.int/data/
- 349 gho/indicator-metadata-registry/imr-details/3236
- 4. Chao-Feng Lin a b 1, Ya-Hui Chang c 1, Shih-Chieh Chien d, Yueh-Hung Lin b, Hung-Yi
- 351 Yeh a Epidemiology of Dyslipidemia in the Asia Pacific Region, International Journal of
- 352 Gerontology, Volume 12, Issue 1, March 2018, Pages 2-6
- 5, Ministry of Health Sri Lanka. Annual health bulletin Sri Lanka 2019 [Internet]. Colombo:
- 354 Ministry of Health Sri Lanka; 2019 [cited 2024 Dec 16], http://www.health. gov.
- 355 lk/moh\_final/english/public/elfinder/files/publications/AHB/2 020/AHB% 202019.pdf
- 6. Govinda Dasji Bhisagratna. Bhaisajya Rathnavali, Volume 2. Medo Roga, Chapter 39.
- 357 Chaukhamba Sanskrit Sansthan; 1956.p551
- 358 7. P.V.Sharma. Chakradatta: Athisthulya Chikithsa, Chapter 33. Chaukhamba Sanskrit
- 359 Series; 1983.p308

- 360 8. K.R.Srikanthamurthi, (Original text along with commentary and translation).
- Madhyamakhanda, Chapter 39[13]. Chaukhamba Sanskrit Series; 2002.p502
- 9. Mehatre DD. Utility and importance of Anupana: A review. International Journal of Herbal
- 363 Medicine. 2014;2(4):31–34
- 364 10.Moon KJ, Rahman KA, Rahman H, Afroz R, Amin MR, Alima F, et al. Lipid-lowering
- effect of natural honey in comparison to atorvastatin on hyperlipidemic rats. Journal of Dhaka
- 366 Medical College. 2017;26(2).
- 367 11. Ayurveda Pharmacopoeia. Volume 1, Part 3. Department of Ayurveda
- 368 12. Agnivesa, Charaka, Dridhabala. Charaka Samhita, Su/12/4. In: Sharma PV, editor. Delhi:
- 369 Chaukhamba Sanskrit Pratishthan; 2014. p. 144.
- 370 13.Agnivesa, Charaka, Dridhabala. Charaka Samhita, Ni./4/7. In: Sharma PV, editor. Delhi:
- 371 Chaukhamba Sanskrit Pratishthan; 2014. p. 270.
- 372 14. Sandeep Singh ,S. G. Chavan , M. A. Hullur, 2016, A clinical study on hyperlipidemia
- 373 with medohar guggulu and lekhaniya mahakashaya , International Ayurvedic Medical
- Journal, Volume 4; Issue 05; april; 2016
- 375 15.Catherine Ulbricht et al,2005,Guggul for hyperlipidemia: A review by the Natural
- 376 Standard Research Collaboration, Complementary Therapies in Medicine Volume 13, Issue 4,
- 377 December 2005, Pages 279-290
- 378 16. Komala A, Santosh V R,2021, A comparative clinical evaluation of Amritadyaguggulu
- with and without Yavamalaki choornain the management of dyslipidemia, International
- Journal of Research in Ayush and Pharmaceutical Sciences, October 2021 Vol 5 Issue 10
- 381 17.Chhabra S, et al. A comparative clinical study of the efficacy of amritadya guggulu with
- triphala kwatha and with madhudak in the management of Medoroga (obesity). Int J
- 383 Ayurvedic Herb Med. 2015;5(6):xx-xx
- 18. Raina T. Mode of action of amritadya guggulu in the management of sthoulya with
- 385 respect to obesity. Ayur Pharma Res. 2018;6(8):49-54.
- 386 19. Prasad SVLN, et al. Efficacy and safety of an Ayurvedic regimen in Medoroga. Indian J
- 387 Tradit Knowledge. 2009;8(3):379-386.
- 388 20. Mamata Bhagwat1, Shrilatha Kamath, 2022, Effect of shuddha guggulu on metabolic
- 389 syndrome a case report, International Journal of Ayurvedaand Pharma Research
- 390 IJAPR | September 2022 | Vol 10 |