



Research Article

A COMPARATIVE CLINICAL EFFICACY STUDY OF *TRIPHALA KWATH* AND *TRIKATU* CAPSULES IN THE MANAGEMENT OF *MEDOROGA* W.S.R TO DYSLIPIDEMIA

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KEYWORDS: *Medoroga*, Dyslipidemia, *Triphala Kwatha*, *Madhu & Trikatu* Capsules.

ABSTRACT

Medoroga is a condition in which there is an excessive accumulation of *Meda Dhatu* in the body. Accumulation of *Medo Dhatu* in different parts of the body causes blockage of *Strotsa* which ultimately leads to poor nourishment of other *Dhathus*. Lack of exercises and *Kaphavardhak Ahar Viharar* are the two main causes of *Medoroga*. In modern times, way of life has changed drastically to quick nourishments and inactive tendencies throughout the world. Because of these factors, accumulation of *Meda dhatu* happens immensely. In Ayurveda, dyslipidemia is considered under *Medoroga*. Dyslipidemia is an emerging serious health abnormality associated with co-morbidities including CVD that continues to be the leading cause of death worldwide. It is characterized by an increase in cholesterol, triglycerides, LDL levels, and a decrease in HDL levels. The present study has been designed to compare the efficacy of *Triphala Kwath* and *Trikatu* capsules on various clinical parameters in the management of *Medoroga* w.s.r to dyslipidemia. Twenty patients fulfilling the inclusion criteria were randomly selected for the trial and put into two groups of ten patients each. *Trikatu* capsules were given to patients in group I and *Triphala kwath* with *Madhu* and *Trikatu* capsules in combination were given to patients of group II for 8 weeks. Patients were thoroughly assessed on various scientific parameters during the complete trial period. In group II, a significant ($p < 0.001$) improvement was observed in subjective parameters and serum cholesterol, triglycerides, LDL, VLDL levels while in group I, a significant ($p < 0.001$) improvement was observed in HDL only. It may affirmatively be construed from the study that the best impact of the trial drugs was observed with *Triphala Kwatha* with *Madhu* and *Trikatu* Capsule together (i.e. Group II). This combination therapy was most effective in reducing the overall lipid profile with substantial gains related to subjective as well as objective parameters without any adverse effects.

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INTRODUCTION

India is undergoing a rapid epidemiological transition with increasing population, economic wealth and urbanization,^[1] however increase in adverse lifestyles such as smoking and tobacco use, nutritional habits with intake of unhealthy diet, and increasing sedentary lifestyle ultimately leads to non-communicable diseases, including coronary heart disease, cerebrovascular and peripheral artery diseases^[2,3]. Even in rural areas of India non-communicable diseases have become the leading

cause of death^[2,3]. *Medoroga* (Dyslipidemia) is a single contributory factor for many life style diseases. It is characterized by an unusual measure of lipids (triglycerides, cholesterol and fat phospholipids) in the blood. Lipids are the naturally occurring molecules which constitute the structural component of various cell membranes. Lipids have a normal property of *Snehatwa* (lubricity)^[4]. According to Ayurveda, *Medo Dhatu*, *Vasa* and *Majja Dhatu* are the three components of out of seven

Dhatu that comprises human body. These additionally show same property of *Snehatwa* thus lipids can be corresponded with these three elements. They show regular highlights however each one of those are available at destinations and perform various capacities. *Sneha* offers chubbiness, lubricates every cell of the body and provides strength, energy to the body when in normal state^[5], when it is in an upset state it causes *Rasagata Snehavridhi* and leads to *Medodushti* (Dyslipidaemia)^[5]. The depiction of *Medoroga* has been given in different classical texts. It results from various etiological factors, for example, defective eating regimen, doing no physical exercise, getting a charge out of day rest, and taking *Kapha* inciting diet and sugar rich eating routine. The etiological factors are *Kapha* and *Meda Sadharmi Ansha* in overabundance hence produce *Kapha Bhuista Dosha Virddhi*^[6]. That *Dosha Vridhi* because of its very nature influences the *Agni* and produces *Agni Vikriti*. As an outcome, the *Ama* goes straight forward to *Medodhatu* and blends with *Kapha* at the tissue level and causes an increase in *Meda Dhatu*. This results in *Srotasavrodha*, channels of *Dosha* are blocked and thus *Vata* in the *Kostha* causes *Jatharagni Sandhukashan*, which results in food cravings and leads to over-intake of food consequentially leading to *Medoroga*^[6]. "Infections and intricacies that happen in patients of *Medoroga* are difficult to treat, than those of patients who don't have *Medoroga*"^[7]. There is no straight forward reference in *Ayurveda* that can be associated with dyslipidemia. Still, based on description of *Medoroga*, it can be correlated with *Medoroga*. Dyslipidemia incorporates hyperlipidemia and hyper lipoproteinemia which are caused because of abnormally raised degrees of lipoproteins in the blood^[8]. These lipids incorporate phospholipids, cholesterol, cholesterol esters, and triglycerides. Lipoproteins are partitioned into 5 classes based on thickness as (a) HDL (High-thickness lipoprotein), (b) LDL (Low-thickness lipoprotein), (c) IDL (Intermediate thickness lipoprotein), (d) VLDL (Very low thickness lipoprotein), (e) chylomicrons. Dyslipidemia is one of the significant issues, which is characterized by the increased levels of either cholesterol, LDL cholesterol or triglycerides in the serum or both LDL and triglycerides and decrease in HDL in the serum that adds to atherosclerosis^[8]. Atherosclerosis is the major risk factor for morbidity and mortality associated with Cardio-vascular Disease (CVD)^[2,3]. Keeping in view the prevalence and intricacies of *Medoroga*, the present study has been designed to compare the efficacy of *Triphala Kwath*

and *Trikatu* capsules on various clinical parameters in the management of *Medoroga* w.s.r to dyslipidemia.

MATERIALS AND METHODS

To fulfill all the aims and objectives of the study, the following materials and methods were used.

Selection of the patients

Patients were randomly selected from OPD/IPD of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Dist. Kangra (H.P.). A detailed history was obtained, physical examination was conducted and relevant investigations were carried out before enrolment of the study subjects.

Total 20 patients were selected for the clinical trial of this research work.

Grouping of Patients

Twenty patients fulfilling the inclusion criteria were randomly selected for the trial and put into two groups of ten patients each.

Group I patients were administered *Trikatu* capsules.

Group II patients were administered *Triphala kwath* with *Madhu* and *Trikatu* capsules.

Dose of Drugs and Route of Administration

Triphala Kwatha 20ml b.i.d with one tsf *Madhu*

Trikatu capsules 500mg b.i.d with water.

Route of Administration- Oral

Duration of Trial- 8 weeks

Inclusion Criteria

1. Diagnosed and confirmed cases of dyslipidemia based on investigations i.e.
 - (a) Serum Cholesterol >200mg/dl and <300mg/dl
 - (b) Serum Triglycerides >150mg/dl and <450mg/dl
 - (c) Serum LDL >100mg/dl and <200mg/dl
 - (d) Serum VLDL >30mg/dl and <100mg/dl
 - (e) Serum HDL <40mg/dl and <20mg/dl
2. Patients between the age group of 40-60 years of either sex who have fulfilled the criteria of objective and subjective parameters.

Exclusion Criteria

1. Patients not willing for the trial.
2. All *Medo Rogi* presenting with complications like *Prameha Pidika*.
3. Drug induced dyslipidemia.
4. Patients having illness like TB, carcinoma, renal and liver disorders.
5. Patients having history of MI and unstable angina.
6. Patients below 40 and above 60 years of age.

7. Patients with Serum Cholesterol>300mg/dl, Serum Triglycerides>450mg/dl, Serum HDL<20mg/dl, Serum LDL>200mg/dl, Serum VLDL>100mg/dl.

Criteria for evaluation

Assessment criteria

Clinical results were assessed based on subjective and objective parameters. Scoring system was adopted to assess subjective signs and symptoms. A special proforma was designed for assessment based on Ayurvedic principles and modern scientific knowledge. Patients were also inquired about any growing feeling of physical and mental well-being after the therapy.

Subjective criteria

It includes signs and symptoms described in Ayurvedic texts. These are the following:

- *Chala- Sphika- Udara -Stana*
- *Kshudra Shwasa*
- *Sandhi Shoola*
- *Kshudha Atimatra*
- *Pipasa Atiyoga*
- *Nidradhikya*
- *Javop rodha*
- *Swedabadha*
- *Daurgandhya*

Table1: Grading of symptoms

| Symptoms | Grading |
|---|---------|
| <i>Chal -sphik- udar- stanam (Movement of Body Parts)</i> | |
| Absence of movement | 0 |
| Little movement after fast activity | 1 |
| Movement after mild activity | 2 |
| Movement even on changing posture | 3 |
| <i>Kshudra Shwasa (Shortness of Breath)</i> | |
| No shortness of breath | 0 |
| Shortness of breath after hard physical exertion | 1 |
| Shortness of breath after mild physical exertion | 2 |
| Shortness of breath even at rest | 3 |
| <i>Sandhi Shool (Pain in Joints)</i> | |
| No pain | 0 |
| Mild pain of low intensity causing no disturbance in routine work | 1 |
| Moderate pain occasionally hampering daily routine work | 2 |
| Severe pain causing a definite interruption in routine work | 3 |
| <i>Kshudha Atimatra (Excessive Hunger)</i> | |
| <2 Chapatis/meal | 0 |
| 2-4 Chapatis/meal | 1 |
| 4-6 Chapatis/meal | 2 |
| >6 Chapatis/meal | 3 |
| <i>Pipasatiyoga (Excessive Thirst)</i> | |
| 1.5 lit/day of fluid | 0 |
| 1.5-2 lit/day of fluid | 1 |
| 2-3 lit/day | 2 |
| 3 lit/day | 3 |
| <i>Nidradhikya (Excessive Sleep)</i> | |
| 6-8 Hrs/day | 0 |
| 8-10 Hrs/day | 1 |
| 10-12 Hrs/day | 2 |
| >12 Hrs/day | 3 |
| <i>Javoparodha (Lassitude)</i> | |

| | |
|--|---|
| Fully active | 0 |
| Hesitate to start work but once start, complete it | 1 |
| Starts but not complete it | 2 |
| Doesn't have the drive, works under compulsion | 3 |
| Swedabadha (Excessive Sweating) | |
| Normal perspiration | 0 |
| Mild perspiration after doing exertion | 1 |
| Heavy perspiration after doing little exertion | 2 |
| Perspiration without exertion | 3 |
| Daurgandhya (Bad Body Odour) | |
| Absence of odour | 0 |
| Occasional bad odour | 1 |
| Persistent bad odour | 2 |
| Persistent bad odour, intolerable to the patient | 3 |

Objective Criteria

- Lipid Profile
- Body Mass Index (BMI),
- Body weight
- Skin Fold Thickness

Investigation Based Criteria

It mainly consists of lipid profile, and patient having deranged lipid value were included in the study i.e.

- Serum Cholesterol >200 mg/dl
- Serum Triglycerides >150 mg/dl
- Serum LDL >100 mg/dl
- Serum VLDL >30 mg/dl
- Serum HDL <40 mg/dl.

Other Investigations

1. Hb gm%
2. TLC (Total leucocyte count)
3. DLC (Differential leucocyte count)
4. ESR (Erythrocyte sedimentation rate)
5. FBS (Fasting blood sugar)

6. Blood urea

7. Serum creatinine

8. SGOT

9. SGPT

10. Urine- routine and microscopy

Selection of Drug

Triphala Kwatha and *Trikatu* Capsules are the important prestigious formulations, which are successfully used from the ancient period. These formulations have been mentioned in various Ayurvedic classics like *Chakradatta*, *Yoga Ratanakara*, *Sharangadhara Samhita* and *Vrinda Madhava*. The reference of *Triphala Kwatha* with *Madhu* used in this trial was selected from *Yoga Ratanakara* for the management of *Medoroga* and *Trikatu churna* from *Sushrut Sutrasthan*. These drugs were prepared by Pharmacy experts of *Charaka Rajkiya Ayurveda Pharmacy*, Paprola, Dist Kangra H.P. as per G.M.P. norms.

Table 2: Pharmacological Characters of Ingredients of *Triphala Kwath* [9]

| S.No | Ingredients | Botanical Name | Family | Rasa | Guna | Veerya | Vipaka | Dosha Karma |
|------|------------------|---|---------------|--|----------------------|---------------|----------------|-------------------|
| 1. | <i>Haritaki</i> | <i>Terminalia chebula Retz.</i> | Combretaceae | <i>Pancharasa (Alavana Kashaya pradhana)</i> | <i>Laghu, Ruksha</i> | <i>Ushna</i> | <i>Madhura</i> | <i>Tridosahar</i> |
| 2. | <i>Bibhitaka</i> | <i>Terminalia bellirica (Gaertn.) Roxb.</i> | Combretaceae | <i>Kashaya</i> | <i>Ruksha, Laghu</i> | <i>Ushna</i> | <i>Madhura</i> | <i>Tridosahar</i> |
| 3. | <i>Amalaki</i> | <i>Emblica officinalis Gaertn.</i> | Euphorbiaceae | <i>Pancharasa (Alavana-Amla pradhana)</i> | <i>Laghu, Ruksha</i> | <i>Sheeta</i> | <i>Madhura</i> | <i>Tridosahar</i> |

Table 3: Pharmacological Characters of Ingredients of Trikatu Capsules [9]

| S.No | Ingredients | Botanical Name | Family | Rasa | Guna | Veerya | Vipaka | Dosha Karma |
|------|-------------|-----------------------------------|---------------|------|-----------------------|-----------------|--------|------------------|
| 1. | Sonth | <i>Zingiber officinale Roscoe</i> | Zingiebraceae | Katu | Laghu Sanigdha | Ushna | Madhur | Kaphvata Shamak |
| 2. | Marich | <i>Piper nigrum L.</i> | Piperaceae | Katu | Laghu Sheeta | Ushna | Katu | Vatkapha Shamak |
| 3. | Pippali | <i>Piper longum L.</i> | Piperaceae | Katu | Laghu Sanigha Tikshna | Anushanas heeta | Madhur | Vatakapha Shamak |

OBSERVATION AND RESULTS

Among 20 registered patients' maximum patients i.e., 55% were in the age group of 40-50 years followed by 45% patients were in the age group of 50-60 yrs. On gender wise distribution majority of patients were females i.e. 75% and 25% of the patients were male. Housewives were predominant group of study than others i.e. 65%. 20% patients were in Govt job; 5% were in private job and 15% patients were engaged in business.

Majority of the patients (70%) were used to consume mixed diet while rest i.e. 30% patients were taking vegetarian diet. Among 20 registered patients, maximum i.e. 65 % had excessive appetite, 35% had normal appetite. Out of 20 patients, 40% have *Mridu Koshtha*, 50% have *Madhyam Koshtha*, 10% have *Krura Koshtha*. Majority of the patients in both groups i.e. 80% had excessive sleep followed by 20% had sound and adequate sleep. Data showed that patients of *Vatakaphaj Prakriti* were maximum (75%), followed by *Pittakaphaj Prakriti* (25%). The effects of therapy on various subjective and objective parameters are given below from Table 4 to 8 and figure1 & 2.

Table 4: Effect of Therapy on Subjective Symptoms

| S.No | Symptoms | Group | Mean Score | | % Change | SD± | SE± | 't' | 'p' | Inter-group Comparison |
|------|---------------------------------|----------|------------|-------|----------|-------|-------|-------|--------|--------------------------|
| | | | BT | AT | | | | | | |
| 1 | <i>Chala Sphika Udara Stana</i> | Group-I | 1.375 | 1 | 27% | 0.518 | 0.183 | 2.049 | 0.080 | $t= 2.170$ $p= 0.045$ |
| | | Group-II | 1.4 | 0.5 | 64% | 0.568 | 0.18 | 5.014 | <0.001 | |
| 2 | <i>Kshudra Shwasa</i> | Group-I | 1.375 | 1 | 27% | 0.518 | 0.183 | 2.049 | 0.080 | $t=2.573$ $p=0.020$ |
| | | Group-II | 1.3 | 0.3 | 76% | 0.667 | 0.211 | 4.743 | 0.001 | |
| 3 | <i>Sandhi Shoola</i> | Group-I | 0.25 | 0.125 | 50% | 0.354 | 0.125 | 1.000 | 0.351 | $t=-2.342$ $p=0.032$ |
| | | Group-II | 1.5 | 0.6 | 60% | 0.568 | 0.18 | 5.014 | <0.001 | |
| 4 | <i>Kshudra Atimatra</i> | Group-I | 1.5 | 1.25 | 16.66% | 0.463 | 0.164 | 1.528 | 0.170 | $t=2.399$ $p=0.029$ |
| | | Group-II | 1.3 | 0.6 | 53.84% | 0.675 | 0.213 | 3.280 | 0.010 | |
| 5 | <i>Pipasa Atiyoga</i> | Group I | 1.375 | 1.125 | 18.18% | 0.463 | 0.164 | 1.528 | 0.170 | $t=2.412$ $p=0.028$ |
| | | Group II | 1.3 | 0.4 | 69.23% | 0.568 | 0.18 | 5.014 | <0.001 | |

| | | | | | | | | | | |
|---|--------------------|----------|-------|-------|--------|-------|-------|-------|--------|--------------------------|
| 6 | <i>Nidradhikya</i> | Group I | 1.625 | 1.375 | 15.38% | 0.463 | 0.164 | 1.528 | 0.170 | $t=2.762$ $p=0.014$ |
| | | Group II | 1.2 | 0.6 | 50% | 0.699 | 0.221 | 2.714 | 0.024 | |
| 7 | <i>Javoproda</i> | Group-I | 0.5 | 0.125 | 60% | 0.744 | 0.263 | 1.426 | 0.197 | $t= -2.347$ $p=0.032$ |
| | | Group-II | 1.7 | 0.6 | 64% | 0.568 | 0.18 | 6.128 | <0.001 | |
| 8 | <i>Swedabadha</i> | Group-I | 0.875 | 0.625 | 28% | 0.463 | 0.164 | 1.528 | 0.170 | $t= 2.160$ $p=0.046$ |
| | | Group-II | 0.8 | 0.1 | 87.50% | 0.675 | 0.213 | 3.280 | 0.010 | |
| 9 | <i>Daurgandhya</i> | Group-I | 1.375 | 1.125 | 18.18% | 0.463 | 0.164 | 1.528 | 0.170 | $t=2.437$ $p=0.027$ |
| | | Group-II | 1.3 | 0.5 | 61.50% | 0.789 | 0.249 | 3.207 | 0.011 | |

Table 5: Effect Of Therapy on BMI

| S.No | Category | Group | Mean Score | | % Change | SD± | SE± | 't' | 'p' | Inter-Group Comparison |
|------|----------|----------|------------|-------|----------|-------|-------|-------|--------|------------------------|
| | | | BT | AT | | | | | | |
| 1. | BMI | Group-I | 31.125 | 29.75 | 4.41% | 2.106 | 0.744 | 2.434 | 0.045 | $t=2.138$ $p=0.048$ |
| | | Group-II | 29.8 | 27.7 | 7.04% | 1.951 | 0.617 | 6.034 | <0.001 | |

Table 6: Effect of Therapy on Body Weight

| S.No. | Category | Group | Mean Score | | % Change | SD± | SE± | 't' | 'p' | Inter-Group Comparison |
|-------|-------------|----------|------------|------|----------|-------|-------|-------|--------|----------------------------|
| | | | BT | AT | | | | | | |
| 1. | Body Weight | Group I | 72.7 | 70.5 | 2.90% | 2.37 | 0.838 | 4.968 | 0.002 | $t = 2.128$ $p = 0.049$ |
| | | Group II | 72.42 | 68.3 | 5.68% | 2.063 | 0.652 | 6.88 | <0.001 | |

Table 7: Effect of Therapy on Skin Fold Thickness

| S.No | Categories | Group | Mean Score | | % Change | SD± | SE± | 't' | 'p' | Inter group Comparison |
|------|-------------|----------|------------|-------|----------|-------|-------|--------|--------|--------------------------|
| | | | BT | AT | | | | | | |
| 1 | Bicep | Group-I | 2.95 | 2.68 | 9.1% | 0.368 | 0.130 | 6.251 | <0.001 | $t = 2.1$ $p = 0.047$ |
| | | Group-II | 2.89 | 2.34 | 19% | 0.344 | 0.108 | 8.199 | <0.001 | |
| 2 | Tricep | Group-I | 3.2 | 2.987 | 9.3% | 0.470 | 0.166 | 4.389 | 0.002 | $t=2.516$ $p= 0.023$ |
| | | Group-II | 3.04 | 2.48 | 18.42% | 0.401 | 0.127 | 11.225 | <0.001 | |
| 3 | Suprailliac | Group-I | 5.66 | 4.9 | 13.4% | 1.013 | 0.358 | 5.127 | 0.001 | $t=2.101$ $p=0.052$ |
| | | Group-II | 5.63 | 3.96 | 29.66% | 0.885 | 0.279 | 13.19 | <0.001 | |

Table 8: Effect of Therapy on Serum Lipid Profile

| S.No | Lipid Profile | Group | Mean Score | | % Change | SD± | SE± | 't' | 'p' | Inter group Comparison |
|------|--------------------|------------|------------|---------|----------|--------|--------|-------|--------|------------------------|
| | | | BT | AT | | | | | | |
| 1 | Serum Cholesterol | Group-I | 240.75 | 211.75 | 12.04% | 36.269 | 12.823 | 2.262 | 0.058 | t=10.9 p<0.001 |
| | | Group-II | 230.7 | 134.2 | 41.82% | 31.43 | 9.94 | 9.708 | <0.001 | |
| 2 | Serum Triglyceride | Group-I | 270.375 | 268.125 | 0.83% | 28.085 | 9.93 | 0.227 | 0.827 | t=18.2 p<0.001 |
| | | Group-II | 296.875 | 143 | 51.60% | 79 | 25.2 | 6.04 | <0.001 | |
| 3 | Serum LDL | Group-I | 95.5 | 87.87 | 7.9% | 30.56 | 10.807 | 0.706 | 0.503 | t=5.36 p<0.001 |
| | | Group-II | 128.4 | 48.5 | 62.22% | 28.7 | 9.1 | 8.70 | <0.001 | |
| 4 | Serum HDL | Group-I | 34.25 | 61.37 | 44.19% | 7.7 | 2.7 | -9.84 | <0.001 | t=10.7 p<0.001 |
| | | Group-II | 33.2 | 37.2 | 10.75% | 7 | 2.2 | 1.7 | 0.107 | |
| 5 | Serum VLDL | Group-I | 38.25 | 36.25 | 5.2% | 3.5 | 1.2 | 1.5 | 0.155 | t=9.02 p<0.001 |
| | | Group - II | 35.2 | 17.7 | 49.71% | 6.819 | 2.156 | 8.1 | <0.001 | |

Figure 1: Effect of Therapy on BMI, Body Weight and Skin Fold Thickness

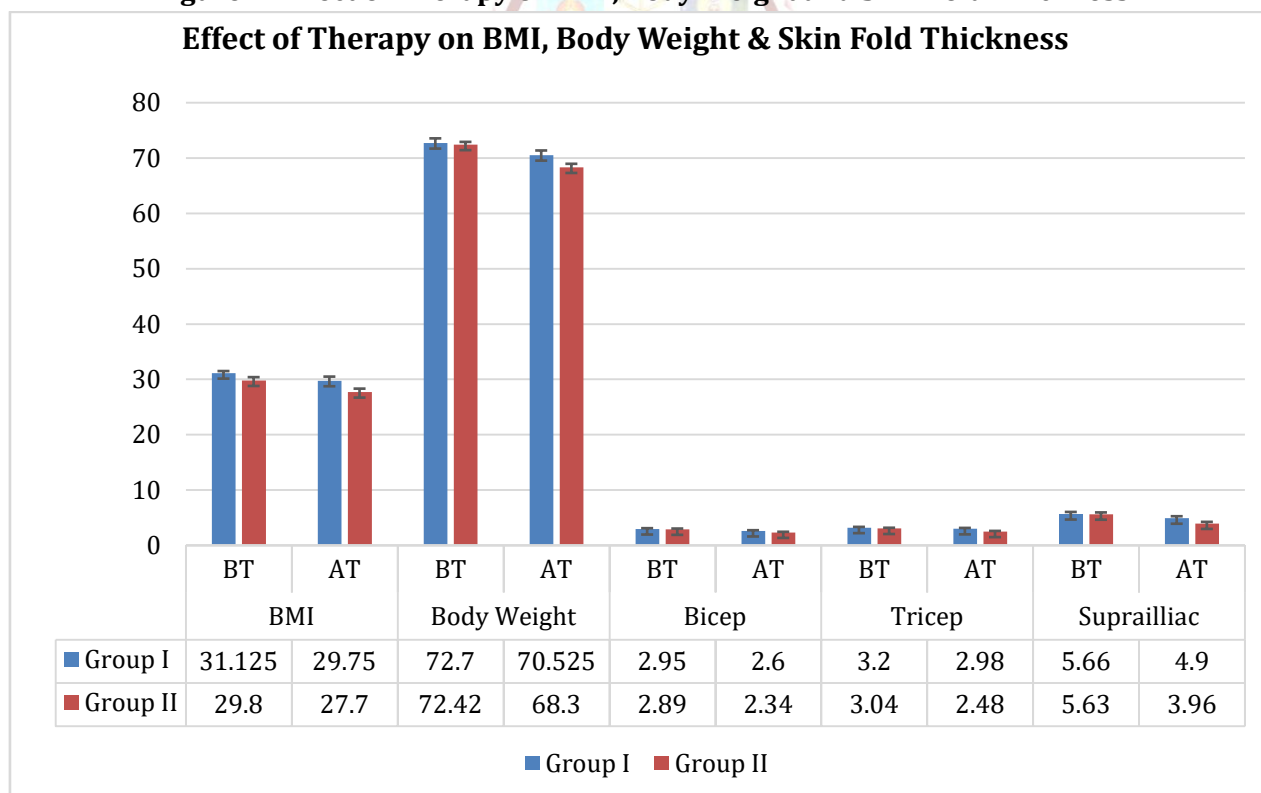


Figure1.*BT (Before Treatment), AT (After Treatment)

Figure 2: Effect of Therapy on Serum Lipid Profile

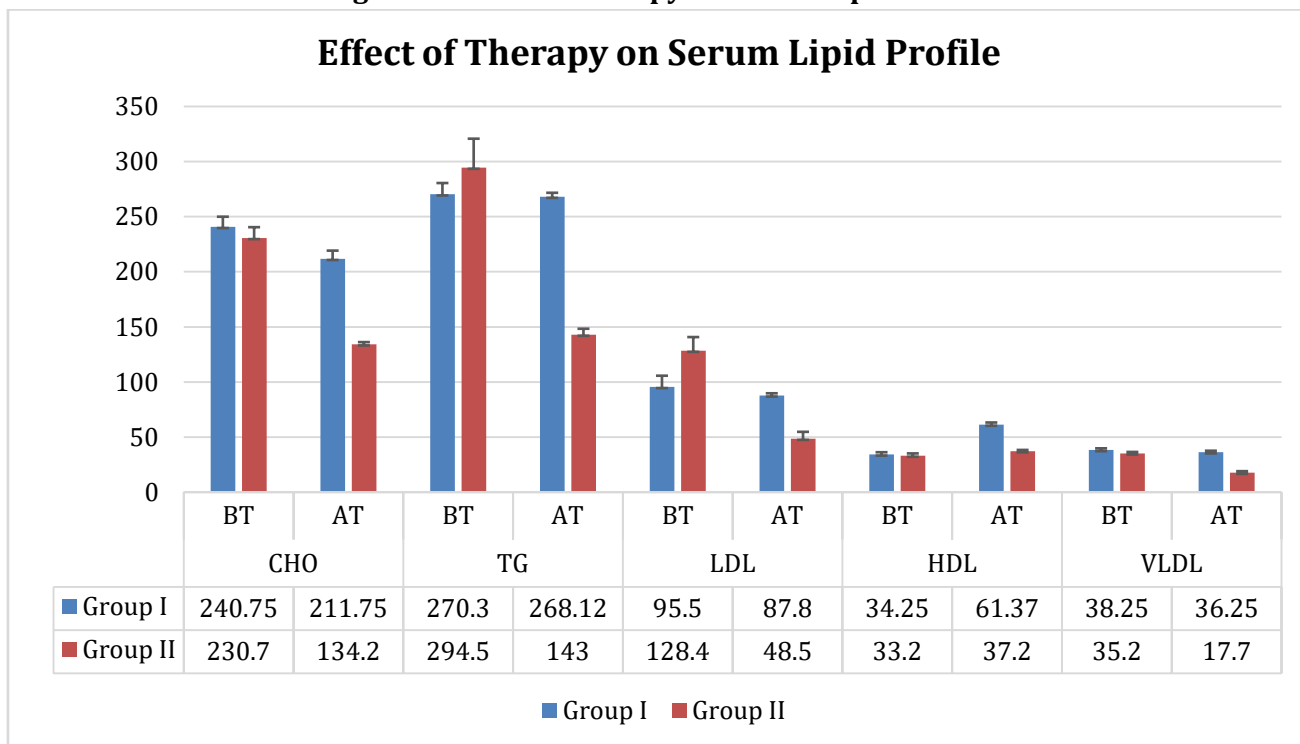


Figure 2.*BT (Before Treatment), AT (After Treatment), CHO (Cholesterol), TG (Triglycerides), LDL (Low Density Lipoproteins), HDL (High Density Lipoproteins), VLDL (Very Low-Density Lipoproteins)

DISCUSSION

In subjective parameters a highly significant ($P<0.001$) improvement was found in *Chala Sphika Udara Stana, Sandhi Shoola, Pipasa Ati Yoga, Pipasa Ati Yoga, Javoprodha* and significant improvement was found in *Kshudra Shwasa, Kshudha Atimatra, Nidradhikya, Swedabadha* and *Daurgandhya* in patients of Group II. While in Group I, insignificant improvement was found in the above mentioned subjective parameters as shown in Table 4.

There was a statistically highly significant decrease ($p<0.001$) in BMI by 7.04% in group II. In group I, only statistically significant ($p=0.045$) improvement i.e., 4.41% was observed as shown in Table 5.

On intergroup comparison, statistically significant difference was found between the results of both the groups ($p=0.048$). There was a highly significant decrease ($p<0.001$) in weight by 5.68% in group II. In group I, statistically significant ($p=0.002$) improvement i.e., 2.90% was observed as shown in Table 6.

On intergroup comparison, a significant difference was found between the results of both the groups ($p=0.049$).

There was a highly significant decrease ($p<0.001$) in Skinfold Thickness of biceps by 19% in group II. In group I, only 9.1% decrease in Skinfold thickness of biceps was observed after the therapy

which was statistically significant ($p<0.001$). On intergroup comparison, a significant difference between the results of both the groups ($p=0.047$). There was highly significant decrease ($p<0.001$) in Skinfold thickness of Triceps by 18.42% in group II. In group I, only 9.3% decrease in Skinfold thickness of Triceps was observed after the therapy which was significant ($p=0.002$). On intergroup comparison, a significant difference was found between the results of both the groups ($p=0.023$). There was a highly significant decrease ($p<0.001$) in skinfold thickness of suprailiac by 29.66% in group II. In group I, only 13.4% decrease in skinfold thickness of suprailiac was observed after the therapy which was significant ($p=0.001$). On intergroup comparison, there was no significant difference between the results of both the groups ($p=0.052$) as shown in Table 7 and fig. no. 1.

Serum Lipid Profile

There was a highly significant decrease ($p<0.001$) in serum cholesterol by 41.82% in group II. In group I, only 12.04% decrease in serum cholesterol was observed after the therapy which was not significant ($p=0.058$). On intergroup comparison, a highly significant difference was found between the results of both the groups ($p<0.001$). There was a highly significant decrease ($p<0.001$) in serum triglycerides by 51.60% in group II. In group I only 0.83% decrease in serum

triglycerides was observed after the therapy which was not significant ($p=0.827$). On intergroup comparison, a highly significant difference was found between the results of both the groups ($P<0.001$). There was a highly significant decrease ($p<0.001$) in serum LDL by 62.22% in group II. In group I, only 7.9% decrease in serum LDL was observed after the therapy which was not statistically significant ($p=0.503$). On intergroup comparison, a highly significant difference was found between the results of both the groups ($p<0.001$). There was a significant increase ($p=0.005$) in serum HDL by 44.19% in group I. In group II, only 10.75% increase in serum HDL was observed after the therapy which was not significant ($p=0.107$). On intergroup comparison, a highly significant difference was found between the results of both the groups ($p<0.001$). There was a highly significant decrease ($p<0.001$) in serum VLDL by 49.71% in group II. Decrease by 5.2% in serum VLDL was observed in group 1 after the therapy which was not significant ($p=0.155$). On intergroup comparison, a significant difference was found between the results of both the groups ($p<0.001$). So, in group II, a highly significant ($p<0.001$) improvement was found in serum cholesterol, triglycerides, LDL, VLDL while in group I, a statistically highly significant ($p<0.001$) improvement was observed in HDL only as shown in Table 8 and figure 2.

Insignificant results were found in the other parameters including TLC, DLC, ESR, FBS, Blood urea, Serum creatinine etc.

The Inter-group comparison showed that *Triphala Kwath* with *Madhu* and *Trikatu* capsules in combination are more effective in dyslipidemia as compare to only single drug i.e., *Trikatu* capsules. The difference was statistically significant. Hence the study proved the efficacy of *Triphala Kwath* with *Madhu* and *Trikatu* capsules in combination with the symptomatology of *Medoroga* (Dyslipidemia). No side effects of *Triphala Kwath* with *Madhu* and *Trikatu* Capsules were reported as evident by the fact that no patient complained of any untoward symptom after the administration of drug.

An ideal drug is the one that breaks the pathogenesis of the disease without producing any side effects. It is the total effect of all the ingredients that plays a vital role in the treatment of disease. In *Medoroga*, *Vata* and *Kapha Doshas* are involved along with *Medodhatvagni mandya* and *Srotorodha*. So, drugs used in the present study have *Vatakapha Shamak*, *Deepana*, *Pachna*, *Srotoshodhna*, and *Medohar* properties. Ingredients of present trial

drugs i.e., *Triphala Kwath* and *Trikatu* capsules possess most of the above said properties which are desirable in an ideal *Medohara* drug. *Triphala Kwatha* contains drugs which are mainly *Laghu*, *Ruksha Guna*, *Ushna Virya* and *Tridoshhara*. Because of all these properties *Triphala* work as *Medohara*. *Trikatu* being *Katu Rasa* and *Katu Vipaka*, *Ushna Virya* and *Laghu Ruksha Guna* in nature just inverse to *Medodhatu* diminish the amount of *Medodhatu* in body. *Madhu* was used as *Anupaan* in the present study which potentiates the action of the drug. Because of *Kashaya Rasa*, *Guru*, *Ruksha Guna* it acts as *Tridoshshamak* and *Medoghana*.

In the present study, a significant decrease in the total cholesterol, triglycerides, LDL and VLDL in *Triphala Kwath* with *Madhu* treated patients may be due to reduction in the absorption of cholesterol^[10]. Oral administration of *T. Chebula* is reported to increase gastric emptying, which might be the reason for the decrease in the cholesterol absorption.^[11] Drugs like Statins reduce LDL cholesterol by inhibiting HMG-CoA reductase in the liver. In our study, we have observed a reduction in the LDL cholesterol after *Triphala Kwath* with *Madhu* administration. This may be due to, at least in a part, the HMG-CoA reductase inhibitory action of *Triphala*^[10].

It is claimed that *Amalaki*, one of the components of *Triphala* has various biological activities such as improves digestion^[12], improves liver function and hepatoprotective^[13]. *Triphala* has a balancing and rejuvenating effect on *Vata*, *Pitta* and *Kapha*. It is known that colon health is important. Proper regulation of the colon is a key to good health and longevity. *Triphala* works well as a colon cleanser and as a *Rasayana* (rejuvenation) for the colon. It is rich in fibers, which helps in digestion and regulation of bowel. Oral administration of *Haritaki* reported to increase gastric emptying, might be the reason of decreased absorption^[11]. Most probably in the present study significant decrease in total cholesterol, Triglyceride and VLDL on the administration of *Triphala Kwath* may be due to reduction in absorption of cholesterol^[14], results in improved liver functions^[13], and decrease lipid peroxidation^[15].

Madhu has been used both as food and medicine since ancient times. *Madhu* is a natural product that has been widely used for its therapeutic effects. *Madhu* as *Anupana* was used in the present study in combination with *Triphala Kwath+Trikatu* Capsules. As mentioned in Ayurveda *Anupana* (vehicle) is defined as the *Pana* which is taken immediately after *Oushadhaanga* (part of

medicine) and *Oushadhi yoga* (medicine formulation).^[16] *Anupana* is defined as that, which enhances the properties of medicines along with it is taken. The mechanism by which *Madhu* exerts its effect as a natural product, may be due to its inhibitory effect on HMG-CoA reductase, which is very important in the production of cholesterol in the body, thereby effectively preventing hypercholesterolemia, lowering LDL, triglycerides and increasing HDL levels. These actions effectively reduce the risk of major coronary events, including first and second heart attacks and stroke, in adults with unhealthy cholesterol levels^[17].

Trikatu being of *Katu*, *Tikta Rasa* and *Katuvipaka* in nature^[1], i.e., just opposite of *Medodhatu*, reduce the quantity of *Medodhatu* and also make the channels patent for easy conduction of nutrients for nourishment to following *Dhatu*s. Several popular preparations of *Trikatu* have been mentioned by the Ayurvedic physicians for the treatment of many *Kaphavataja* diseases, including *Agnimandya* (poor digestion) and *Ama* (undigested food and its toxic byproducts). By therapeutic actions such as *Deepana* (appetizer), *Pachana* (digestive), *Rukshana* (producing dryness), *Lekhana* (producing sliminess), *Karshana* (extraction), and *Shoshana* (absorption), *Tikshna* (sharp), *Laghu* (light) and *Sukshma* (micro in size)^[1], as a whole *Trikatu* reduces the quantity of *Meda* (which has the nature of *Ama*) and also makes the channels patent to carry on the nutrients to subsequent *Dhatu*s as per the chronological order mentioned in Ayurveda. These pharmacological actions may be due to its chemical substance piperine which enhances the secretion of digestive juices and might catalyze the functions of enzymes in small intestine too, i.e. it helps in improving the function of *Jatharagni* (digestive fire). Improvement of *Jatharagni* function, in total, also helps in a finer disintegration of nutrients, in turn helping maximum absorption for nourishing rest of the *Dhatu*s, and thus also facilitates the function of *Bhutagnis* (metabolism). In short, *Trikatu* acts against the deposition of lipids and thus helps clean the eventually blocked channels^[18]. So, *Trikatu* Capsules probably acts by blocking the formation of different lipids or cholesterol at various stages in the biosynthetic pathway. Because it is a *Rasayana*, it may also cause an increase in the HDL cholesterol^[18].

CONCLUSION

It can be inferred from the present study that the best effects of the Trial drugs were seen with *Triphala Kwatha* with *Madhu* along with *Trikatu* Capsule together (Group II), which is most effective in reducing the overall lipid profile i.e.,

serum cholesterol, serum triglyceride, LDL, VLDL and increasing the HDL, with substantial gains related to subjective as well as objective parameters and that too, without any adverse effects. It can be concluded that *Triphala Kwath* with *Madhu* and *Trikatu* Capsules are effective in treating *Medoroga* (dyslipidemia) when given in combination.

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