CLINICAL STUDY ON THE EFFICACY AND SAFETY OF
TRYUSHNADI GUGGULU IN MEDOROGA WITH SPECIAL
REFERENCE TO DYSLIPIDEMIA

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ABSTRACT

Dyslipidaemia is a disorder of lipoprotein metabolism, which can include overproduction or deficiency of lipoproteins or both. The disorder can manifest as an elevation of plasma cholesterol, triglycerides, or both, or a low high density lipoprotein level or all three together that contributes to the development of atherosclerosis. The lipids in contemporary science can be correlated with Medas and hence Medohara treatment can be employed in the treatment of hyperlipidaemia (Medo Roga). The study was conducted in P.G. Department of Kaychikitsa, NIA, Jaipur. 45 clinically diagnosed and confirmed patients of Medoroga (Dyslipidaemia) from OPD/IPD of Arogyashala NIA, Jaipur, SSBH, Kishanpole Jaipur. Patients had been administered Trial Drug 'Tryushnadi Guggulu' in dose of 2 Tab. Twice a day (2gm/day) with lukewarm water for 60 days. Assessments were done fortnightly. Duration of study was months. Patients treated with Tryushnadi Guggulu, showed statistically highly significant results (p value <0.0001, <0.001) regarding subjective parameters – Trishna Atinidra, Atikshudha, Alpaprana, whereas in case of Krathana, Kshudrashwasa, Swedadhikya, Daurgandya, shown significant result (p value <0.05) In case of objective parameters, in Body weight, Waist-Hip Ratio, Total cholesterol, triglycerides, LDL it has shown highly significant results (p value <0.01). In safety parameters, RFT and LFT it has shown non significant results stastically (p value >0.05).

KEYWORDS: Medoroga, Dyslipideamia, Tryushanadi Guggulu.
INTRODUCTION

Abnormal accumulation of *Meda Dhatu* in body is known as *Medodushti*. *Medodushti* includes several numbers of other *Medovikara*, which are collectively known as *Medoroga*. Acharya Charaka has given more emphasis on exogenous type of causes in *Medoroga* i.e. *Meda* potentiating diet whereas Acharya Sushruta & Acharya Vagbhatta stressed mainly on endogenous causes including deranged functions of *Dosha*, *Dhatu*, *Mala*, *Strotasa* etc. Amadosha is the cause behind *Medoroga* specially mentioned by Acharya Vagbhatta. Beejadosha is another important *Nidana* mentioned by Acharya Charaka, in modern science fact is supported with the introduction of hereditary causes of Dyslipidaemia.[1] Acharya Dalhana has quoted three main etiological factors (Vishistaharavashat, Adrishtavashat, Medosavrita Margatvat) of Sthaulya which encompass all the causes leading to an increase in the *Asthayi Medo Dhatu* thereby leading to a state of Dyslipidaemia. *Medoroga* has been narrated as Dushya dominant disorder. Acharya Charaka has accepted “*Ahara*” as most common pathogenic factor for *Medovriddhi / Medodushti* in *Medoroga* whereas Acharya Sushruta has accepted Amadosha. Overeating of Shleshma - Bhuyishtha Ahara, sedentary life-style, day-time sleeping, lack of exercise etc. are various etiological factors for *Medoroga*. Over indulgence with such type of factors leads to increase in Guru, Snigdha, Manda & Sthira Guna in the body, which all are similar to *Guna* of Kapha thereby causing Kapha Bhuyishtha Dosha Vriddhi in the body. As an individual taking high calorie diet but proportionately low energy expenditure due to lack of physical activity i.e. positive energy imbalance leading to accumulation of extra energy in the form of fats (lipids) i.e. excessive accumulation of *Meda Dhatu*. Again on the other hand, in modern science, psychological disorders are also associated with overeating habits, in such patients leading to excessive calorie intake & thereby Dyslipidaemia (*Medoroga*). Hence, Kapha and *Meda Dhatu* two are main *Dosha-Dushya Ghataka* in pathogenesis. Accumulation of Kapha & Meda leads to Srotavarodha causing trapping of Samana Vayu in Koshtha leading to Avarana to Samana Vayu. It leads to Jatharagni Sandhukshana. Increased Jatharagni leads to rapid digestion of ingested food & leaves the person craving for food. This vicious cycle continues resulting in *Meda Atiupachaya*. According to modern science, the digestion of fat starts in duodenum & pancreatic lipase is the main enzyme involved thereafter resulting in the formation of free fatty acids & monoglycerides. So the pathology of Dyslipidaemia can be well correlated with *Ati Snehayukta Anna Rasa* as told by Acharya Sushruta. Two types of *Medodhatu* are found in *Medoroga* as follows:
Baddha Meda Vridhdi: representing the depot fat stored at various places in the body e.g. buttocks, abdomen, shoulders, breast etc.

Abaddha Meda Vridhdi: representing the fat which circulates freely in the form of plasma lipids.

The term Dyslipidaemia is used to describe disordered lipid metabolism in the body. The Dyslipidaemia in obesity and diabetes is generally associated with an insulin resistant state. Life style management including dietary modification, active exercises & quitting smoking are a good measure to lower the risk associated with Dyslipidaemia. Effective weight loss lowers the raised serum cholesterol level. Abaddha or Baddha Meda Dushti mentioned in Prameha & Sthaulya in Ayurveda can be considered as Dyslipidaemia. So, Medoroga should be treated on the lines of management of Sthaulya and Prameha.

AIMS AND OBJECTIVES
2. To evaluate clinical efficacy of Tryushnadi Guggulu in the management of a series of patients suffering from Medoroga (Dyslipidaemia).
3. To evaluate clinical safety of Tryushnadi Guggulu in the management of a series of patients suffering from Medoroga (Dyslipidaemia).

MATERIALS AND METHODS
a) Selection of cases
The study had been conducted on 45 clinically diagnosed and confirmed patients of Medoroga (Dyslipidaemia) from OPD/IPD of Arogyashala NIA, Jaipur, SSBH, Kishanpole Jaipur.

b) Inclusion criteria
1. Patients between the age group of (25-55) year of either sex.
2. Diagnosed cases of Dyslipidaemia & Medoroga on the basis of criteria given by NCEP-ATPIII (Serum Cholesterol ≥ 200 mg/dl, Serum Triglycerides ≥ 150mg/dl, LDL Cholesterol ≥ 130mg/dl, HDL Cholesterol < 40mg/dl)
3. Patients with positive Serum CRP Test.
4. Patients willing to sign the consent form.
c) Exclusion criteria
1. Patients with age below 25 year & above 55 year.
2. Patients having medical history of -
   Unstable angina, Myocardial Infarction, Heart failure or stroke within 3 months of Study,
   Uncontrolled Hypertension (Diastolic Blood Pressure > 100 mmHg),
   Uncontrolled Diabetes Mellitus, Impaired Renal function (Creatinine ≥ 2 mg/dl), ALT and
   AST >2 times of upper limit of normal (40mg/dl). Pregnancy, Lactation and patients having
   Dyslipidaemia due to drugs e.g. Glucocorticoids, Diuretics.

d) Drug administration
‘Tryushnadi Guggulu’ in dose of 2 Tablets twice a day (2gm/day) with lukewarm water after
meal for 60 days.

ASSESSMENT
- Assessment of the patient was done fortnightly for a period of 60 days.
- Improvement in the symptoms, if any & other effects were noted down.
- Laboratory investigations were repeated after completion of the treatment i.e. after 60
days.

Criteria for assessment
1. Assessment of Efficacy
The effect of trial drug had been assessed in following subjective, objective, hematological
and bio-chemical parameter –

a) Subjective parameter
For subjective parameter following symptoms (Ma. Ni. Medoroganidana/3) had been
assessed fortnightly:-
1. Kshudrashwa (dyspnoea)
2. Trisha (excessive thirst)
3. Moha (syncope)
4. Atinidra (excessive sleep)
5. Krathana (snoring)
6. Angasada (Lethargy)
7. Atikshudha (excessive hunger)
8. Swedadhikya (excessive sweating)
9. **Daurgandya** (foul odour)
10. **Alpapranā** (generalized weakness)
11. **Alpamaithuna** (sexual weakness).

Assessment of all the above symptoms had been done by using “Symptom Rating Scale” as following:

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>0</td>
</tr>
<tr>
<td>Mild</td>
<td>1</td>
</tr>
<tr>
<td>Moderate</td>
<td>2</td>
</tr>
<tr>
<td>Severe</td>
<td>3</td>
</tr>
</tbody>
</table>

B) Objective Parameter

1) **Anthropometric Assessment**

The following Anthropometric assessments were done before & after the treatment using weighing machine & measurement tape:
- Weight of the Patient (in Kg)
- B.M.I.
- Waist - Height Ratio
- Waist - Hip Ratio

2) **Biochemical Parameter Assessment**: Following Biochemical parameters were done before & after the treatment –

- **Haematological**
  - Haemoglobin (gm %)
  - Total Leucocytes count (TLC) in /mm$^3$
  - Erythrocyte sedimentation rate (ESR) in mm/hour.

- **Bio-chemical**
  - Lipid profile
  - Serum Total cholesterol (TC)
  - Serum Triglycerides (TG)
  - Serum Low Density Lipoprotein (LDL)
  - Serum Very Low Density Lipoprotein (VLDL)
  - Serum High Density Lipoprotein (HDL)
  - Fasting Blood sugar
- C-Reactive Protein Test

**Assessment of Safety of Trial drug:**

The safety of trial drug had been assessed on following parameters –

1. Any adverse effect/side effect if developed had been recorded and reported in final report of study.
2. Following laboratory investigations had been carried out before and after trial
   a. Liver Function Test -
   b. Renal Function Test -

**OBSERVATION**

In this study majority of patients were married (76%) hindu (71%) males (64%) aged between 25-35 years (42%). Most of them were Businessmen (44%) of middle class (44%). *Vata Kaphaja sharirika Prakriti* (49%) along with *Rajsika Manas Prakriti* (51%) was present in the majority of the patients. Although *Pitta Kaphaja Prakriti* (33%) along with *Tamsika Manas Prakriti* (38%) was also present in fair number of patients. Majority of patients had *Madhyama* type of sara (58%), *Samhanana* (56%), *abhyaavaharana Shakti* (62%) and Jarana Shakti (67%), with *Madhyama Koshtha* (56%).

Most of the cases have history of *Vishamagni* (40%) along with habit of taking *Madhura rasa* dominant diet (89%). Day time sleeping (49%) and *Samashana* (44%) followed by *Vishmashana* (36%). Hypertension was the most common associated disease (36%) along with BMI of 25-29.99(54%).

High levels of cholesterol, LDL and TGs were present in 16%, 20% and 27% of cases respectively followed by borderline high levels of the same in 22%, 7% and 24% of cases respectively. Optimum level of HDL (40-60 mg/dl) was present in maximum number patients (98%).

**RESULTS**

- All the Results have been calculated by using Software: In Stat Graph Pad 3.
- For Nonparametric Data **Wilcoxon matched-pairs signed ranks test** was used While for Parametric Data **Paired ‘t’ Test** was used for results Calculation.
- Among 45 patients registered for present clinical trial, 42 patients completed total trial duration while 03 patients dropped out during study.
Table no. 1 showing effect of Therapy on Subjective Parameters. (Wilcoxon matched-pairs signed ranks test).

<table>
<thead>
<tr>
<th>Variable (n=42)</th>
<th>Mean</th>
<th>Mean Diff.</th>
<th>% Relief</th>
<th>SD±</th>
<th>SE±</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kshudrashwasa</td>
<td>0.381</td>
<td>0.190</td>
<td>0.190</td>
<td>49.86%</td>
<td>0.454</td>
<td>0.070</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Trisha</td>
<td>0.428</td>
<td>0.234</td>
<td>0.190</td>
<td>44.39%</td>
<td>0.397</td>
<td>0.061</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Moha</td>
<td>0.142</td>
<td>0.0238</td>
<td>0.119</td>
<td>83.80%</td>
<td>0.327</td>
<td>0.050</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Atinindra</td>
<td>0.642</td>
<td>0.238</td>
<td>0.404</td>
<td>62.92%</td>
<td>0.798</td>
<td>0.123</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Krathana</td>
<td>0.309</td>
<td>0.142</td>
<td>0.166</td>
<td>53.72%</td>
<td>0.377</td>
<td>0.058</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Angasada</td>
<td>0.166</td>
<td>0.047</td>
<td>0.119</td>
<td>71.68%</td>
<td>0.327</td>
<td>0.050</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Atikshudha</td>
<td>0.404</td>
<td>0.047</td>
<td>0.357</td>
<td>88.36%</td>
<td>0.576</td>
<td>0.089</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Swedadhikya</td>
<td>0.452</td>
<td>0.214</td>
<td>0.238</td>
<td>52.65%</td>
<td>0.655</td>
<td>0.1012</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Daurgandhaya</td>
<td>0.166</td>
<td>0.028</td>
<td>0.142</td>
<td>85.52%</td>
<td>0.354</td>
<td>0.0546</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Alpaprana</td>
<td>0.452</td>
<td>0.0714</td>
<td>0.381</td>
<td>84.29%</td>
<td>0.582</td>
<td>0.089</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Alpamaithuna</td>
<td>0.142</td>
<td>0.023</td>
<td>0.119</td>
<td>83.80%</td>
<td>0.37</td>
<td>0.0502</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Table No. 2 Showing effect of Therapy on Anthropometric Parameters (Paired ‘t’ Test & Wilcoxon matched-pairs signed ranks test).

<table>
<thead>
<tr>
<th>Parameters(n=42)</th>
<th>Mean</th>
<th>Diff</th>
<th>% Relief</th>
<th>SD±</th>
<th>SE±</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Weight (kg)</td>
<td>71.71</td>
<td>69.73</td>
<td>1.97</td>
<td>2.75%</td>
<td>1.137</td>
<td>0.175</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>B.M.I. (Kg/m²)</td>
<td>27.19</td>
<td>26.52</td>
<td>0.67</td>
<td>2.47%</td>
<td>2.67</td>
<td>0.413</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Waist-Height Ratio</td>
<td>0.57</td>
<td>0.55</td>
<td>0.028</td>
<td>4.93%</td>
<td>0.091</td>
<td>0.0141</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Waist-Hip Ratio</td>
<td>0.95</td>
<td>0.93</td>
<td>0.018</td>
<td>1.97%</td>
<td>0.022</td>
<td>0.0034</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Table No. 3 Showing effect of Therapy on Lipid Profile (Paired ‘t’ Test & Wilcoxon matched-pairs signed ranks test).

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Variable (42)</th>
<th>Mean</th>
<th>Mean Diff.</th>
<th>%Relief</th>
<th>SD</th>
<th>SE</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sr.TC</td>
<td>240.21</td>
<td>184.43</td>
<td>55.78</td>
<td>23.44%</td>
<td>46.83</td>
<td>7.22</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>2</td>
<td>Sr.TG</td>
<td>216.55</td>
<td>151.55</td>
<td>65</td>
<td>30.01%</td>
<td>48.41</td>
<td>7.47</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>3</td>
<td>Sr.LDL</td>
<td>123.98</td>
<td>105.29</td>
<td>18.69</td>
<td>15.07%</td>
<td>24.52</td>
<td>3.78</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>4</td>
<td>Sr.VLDL</td>
<td>30.071</td>
<td>30.048</td>
<td>0.0238</td>
<td>0.79%</td>
<td>11.62</td>
<td>1.79</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>5</td>
<td>Sr.HDL</td>
<td>45.881</td>
<td>46.357</td>
<td>-0.476</td>
<td>1.03%</td>
<td>2.233</td>
<td>0.34</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Table No. 4 Showing effect of Therapy on Safety Parameters( Paired ‘t’ Test).

<table>
<thead>
<tr>
<th>Variable(n=42)</th>
<th>Mean</th>
<th>Mean Diff.</th>
<th>% Relief</th>
<th>SD±</th>
<th>SE±</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Urea</td>
<td>33.57</td>
<td>31.52</td>
<td>2.048</td>
<td>6.10%</td>
<td>8.439</td>
<td>1.302</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Sr. Creatinine</td>
<td>0.840</td>
<td>0.754</td>
<td>0.0857</td>
<td>10.19%</td>
<td>0.3136</td>
<td>0.0483</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>AST</td>
<td>41.92</td>
<td>40.88</td>
<td>1.146</td>
<td>2.73%</td>
<td>17.517</td>
<td>2.736</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>ALT</td>
<td>34.11</td>
<td>30.11</td>
<td>4.000</td>
<td>11.72%</td>
<td>15.153</td>
<td>2.330</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>ALP</td>
<td>181.5</td>
<td>171.4</td>
<td>10.09</td>
<td>5.56%</td>
<td>45.50</td>
<td>7.022</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Total Bil.</td>
<td>0.664</td>
<td>0.634</td>
<td>0.030</td>
<td>1.5%</td>
<td>0.2612</td>
<td>0.0403</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>
DISCUSSION

In the combination of Tryushnadi Guggulu, highest is the concentration of Guggulu which has Pravabha of Medo-Vatahara. Acharya Sushruta also quoted its property of Lekhana directly. In this formulation, all 8 Dravyas have dominant Katu Rasa, 3 Dravyas having dominancy of Kashaya & Tikta Rasa. Katu, Tikta & Kashaya Rasa have potential to pacify the Kapha Dosha. Among these three, Katu Rasa has potential of Agnisandipana & Mamsavilekhanam, which helps to normalize the Jatharagni to form nutritional Anna Rasa as substrate which further give qualitative nutrition to next Dhatus & help in modification or normalization of Dhatwagni. It also helps to scrap out the Abaddha Mamsa-Medo Dhatus from the body. Tikta Rasa has properties of Deepana, Pachana, Kleda-Meda Shoshaka, Srotovishodhaka & potent in Lekhana property, thus helps to break the pathogenesis of Medoroga. Kashaya Rasa also has property of Sharira-Kleda Shoshana. All these dominant Rasa in this formulation thus helps in breakage of pathogenesis of Disease. Besides this, there is dominancy of Laghu, Ruksha & Tikshna Gunas in the Tryushnadi Guggulu which also helps in Kapha-medashamana property & Kleda-medashoshana. 4 Dravyas out of 8 in the formulation possesses Tiksha & Ruksha Guna and all 8 Dravyas possesses Laghu Guna. This formulation has 6 Dravyas with dominant Ushnavirya which also helps to pacify the Vata -Kapha Dosha. With all these properties, Sukshma property of Guggulu helps in Bhedana of Avarana of Samana Vayu. Vatanulomana-Vataharanam properties of some Dravyas help to normalize the Apana Vayu. Thus by controlling the Apana Vata, other types of Vata can also be normalized in their functions by virtue of all the properties of various Dravyas present in the Formulation.

Shunthi possess hypolipidaemic/antiatheroclerotic antidiabetic and cardiotonic properties. Maricha useful in controlling not only the glucose and lipid levels but this may also be helpful in strengthening the antioxidants potential. Pippali possess anti diabetic and anti hypolipidaemic activity. Aqueous extract of Piper longum root significantly reduced the TC, TG, LDL-C and VLDL-C levels with an increase of HDL-C. Chitraka has been proved for Hypolipidaemic activity, Antiatheroclerotic, cardiotonic activity. Itiogawa M et. al. (1991) Cardiotonic action of plum bagin on guinea pig papillary muscle, Planta medica Vol. 57(4) PP: 317-319. Mustaka has showed reduction in weight along with a decrease in serum cholesterol and triglycerides. Vidanga possess the lipid-lowering and antioxidant potential. Vacha extract demonstrated significant hypolipidaemic activity. Guggulu’s The antioxidant property helps to stop the oxidation of cholesterol and subsequent hardening
of arteries reduces the stickiness of platelet and also lowers the risk of coronary artery
disease. It increases the faecal excretion of bile acids (cholic and deoxycholic acids),
cholesterol and lowers the intestinal absorption of fats and cholesterol. Guggulu has
hypolipidemic and hypoglycemic properties.[13]

All these recent researches help in proving the Hypolipidemic activity of the Ayurvedic
formulation of this clinical trial.

So it can be concluded that the classical Ayurvedic preparation Tryushnadi Guggulu can be
used as a effective and safe drug for the management of Dyslipidaemia vis-a-vis Medoroga.

CONCLUSION

• In Dyslipidaemia there is disequilibrium of Agni (especially Jatharagni and
  Medodhatwagni) resulting in the formation of Dushtameda.
• Restoration of Agni to normal physiological states, removal of Amadosha and
  accumulated Sama Meda from the body are main principles of management of
  Dyslipidaemia.
• Tryushnadi Guggulu, showed statistically highly significant results in Trishna Atinidra,
  Atikshudha, Alpaprana, whereas in case of Krathana, Kshudras awasa, Swedadhikya,
  Daurgandya, shown significant result.
• Highly significant results in reducing serum cholesterol, serum triglycerides, serum LDL
  along with highly significant results in Anthropometric parameters i.e. reduction in body
  weight and waist-hip ratio was observed in this trial.
• There was no significant change in safety parameters i.e. Renal Fuction Test & Liver
  Function Test.
• So, from the result of present study it can be concluded that Tryushnadi Guggulu
  responded very well to Dyslipidaemia of the patients and is safe for the patients.
• All the patients registered for the current clinical trial tolerated Ayurvedic formulation
  very well except only one patient who developed burning sensation in abdomen due to
  Pittaja Prakriti.

Thus, it concluded that Tryushnadi Guggulu can be used as effective and safe treatment
for Dyslipidaemia (Medoroga).[14]
REFERENCES


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