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# AN OPEN LABELLED RANDOMISED CONTROLLED CLINICAL TRIAL ON THE EFFECT OF SHUDDHA SHILAJATU IN DYSLIPIDEMIA

**Venupriya Mishra[1]* and Shrilatha Kamath T.[2]**

[1]PG Scholar, Department of PG Studies in Kayachikitsa, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hospital and Research Centre, Udupi - 574118, Karnataka, India.

[2]Professor and Head Department of PG Studies in Kayachikitsa, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hospital and Research Centre, Udupi - 574118, Karnataka, India.

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***Corresponding Author**
**Venupriya Mishra**
PG Scholar, Department of PG Studies in Kayachikitsa, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hospital and Research Centre, Udupi - 574118, Karnataka, India.

## ABSTRACT

Dyslipidemia has attracted global attention due to its role in the pathology of atherosclerotic diseases, particularly coronary heart disease, which is the leading cause of death and illness worldwide. Disorders in lipoprotein metabolism are collectively known as dyslipidemia, characterized by elevated plasma levels of cholesterol and triglycerides, often accompanied by decreased levels of HDL cholesterol. **Objective**: To evaluate the effect of *Shuddha Shilajatu* on serum lipid profile in patients of Dyslipidemia. **Methodology:** An open-label controlled clinical study with a pre- and post-test design involved 30 patients with elevated lipid profiles from Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi. Patients were randomly divided into two groups: Group A (control) received 6 capsules of *Shuddha Guggulu* twice daily before meals, while Group B (study) received 2 capsules of *Shuddha Shilajatu* twice daily before meals for 30 days. Assessments were based on primary and secondary outcome measures, focusing on changes in lipid profile parameters and SF-36 Health Survey Scores before and after treatment. **Results:** Among the patients in Group-A, 7% of patients reported excellent improvement, 40% experienced good improvement and 33% noted moderate improvement. In Group-B 46.66% showed moderate improvement and

33.33% demonstrated mild improvement. **Conclusion:** Group-A showed considerably more relief and improvement than Group-B across multiple metrics, with no significant statistical differences observed.

**KEYWORDS:** Dyslipidemia, *Shonita abhishyanda, Shilajatu, Guggulu.*

## INTRODUCTION

In today's fast-paced modern world, the rise in consumption of high-calorie fast foods has become a significant concern. Factors such as industrialization, workplace stress, poor dietary habits, lack of physical activity, and the prevalence of processed foods including frozen meals and sugary beverages have disrupted metabolic processes, leading to conditions such as Dyslipidemia.[1]

Dyslipidemia has gained worldwide interest in its ability to participate in the pathology of atherosclerotic diseases like coronary heart disease which remains the most common cause of mortality and morbidity. Disorders of lipoprotein metabolism is collectively referred to as 'Dyslipidemias'. It is clinically characterized by increased plasma levels of cholesterol, triglycerides or both, variably accompanied by reduced level of HDL cholesterol.[2]

The global burden of dyslipidemia has increased over the past 30 years due to faulty diet habits, lifestyle and recent altered occupational patterns. The Indian Council of Medical Research (ICMR) surveillance project reported a prevalence of Hyperlipidemia of 37.5% in adults between age group of 20-60 years.[3]

National Commission on Macro-economic & Health (NCMH) in India has estimated that elevated plasma LDL-cholesterol levels being the 15th leading risk factor for death in 1990, rising to 11th in 2007 and 8th in 2019.[4] These statistics increase the responsibility of physicians to a great extent in identifying the cause and treating dyslipidemia.

The concept of dyslipidemia can be elaborated according to ayurvedic classics through relevant references. Dyslipidemia is a *Santarpanjanya vyadhi* and can be correlated with *shonita abhishyanda.*

*Snigdha, madhura, guru, pichhila ahara sevana, chestadwesha and diwaswapna* will lead to *santarpana janya vikara* which includes conditions like *prameha, kustha, sthoulya* and

*srotolepa* which explains the consequences of elevated lipids.[5] This *srotolepa* refers to *dhamani pratichyaya* which is mentioned as one among the *kaphaja nanatmaja vyadhi*.[6]

*Shonita Abhisyanda* occurring due to various dietary habits lead to obstruction in the *srotas* leading to disease entities like *Pandu* (anemia), *Andhya* (blindness), *Shandhya* (infertility) and even *Mrityu* (death). The diseases occur as *shonita abhisyanda* ends up with the *marga uparodha*.[7]

The conventional drug therapy of Dyslipidemia has many adverse effects such as diabetes, severe myopathy, dyspepsia, headaches, fatigue, joint pain and potential elevation in liver transaminases leading to liver damage.[8]

As *shonita abhishyanda* is a *santarpana janya vyadhi* associated with *shonita dusti* or *pradushana*, the line of treatment such as *apatarpana* and *shonita dusti chikitsa* can be applied to tackle Dyslipidemia. Reviewing the previous works conducted on Dyslipidemia, multiple studies have been carried out using *shodhana*, *bahya chikitsa* and *shamana ausadhis* either in single group pattern or comparative study design but very few are done in RCT study design. This study was intended in a Randomised Control Trial (RCT) pattern with the proved drug for control group and the study drug (*Shuddha Shilajatu*) to avoid bias in the study.

## AIM AND OBJECTIVE

To evaluate the effect of *Shuddha Shilajatu* on serum lipid profile in patients of Dyslipidemia**.**

## METHODOLGY

Ethical Committee clearance has been done with Reference number: SDMCAU/ACA-49/ECH 33/2022-23.

### Study design

◉ Study Type : Interventional
◉ Estimated enrolment: 30 participants
◉ Allocation: Permuted Block Randomisation.
◉ Endpoint Classification: Efficacy study
◉ Intervention Model: Double group

◉ Masking: Open label

◉ Primary Purpose: Treatment.

**Setting**

30 patients suffering from Dyslipidemia/ *Shonita Abhishyanda* were selected for the study from OPD & IPD of Sri Dharmasthala Manjunatheswara Ayurveda Hospital, Udupi. *Shuddha Guggulu* and *Shuddha Shilajatu* capsules were obtained from Sri Dharmasthala Manjunatheswara Ayurveda Pharmacy, Kuthpady, Udupi.

**Intervention**

Patients were assigned into 2 groups, 15 members in each using Permuted block randomisation.

Group A – Control group[9]

Drug- *Shuddha Guggulu*

Mode of administration- Oral Dose- 6 BD (500mg each)

Time of administration- Twice daily 30 mins before food

*Anupana*- Luke warm water

Group B – Study group[10]

Drug- *Shuddha Shilajatu* Mode of administration- Oral Dose- 2 BD (500mg each)

Time of administration- Twice daily 30 mins before food

*Anupana*- Luke warm water.

**Duration of Clinical Study**

Intervention: 30 Days

Follow up: 30 days after the study.

Total duration: 60 days.

**Diagnostic criteria**: NCEP ATP3 Guidelines.[11]

- Total Cholesterol > 200 mg/dl
- LDL Cholesterol > 100 mg /dl
- Triglycerides > 150 mg/dl
- VLDL-cholesterol: >40mg/dl
- HDL Cholesterol Men < 40 mg /dl

Women < 50 mg/dl

**Inclusion Criteria**

1) Patients fulfilling all or any one of the diagnostic criteria.
2) Patients were selected of age group between 18-70 years.
3) Patients willing to sign informed consent.

**Exclusion Criteria**

1) Patients suffering from other systemic illness and metabolic disorders interfering with the treatment protocol.
2) Dyslipidemia due to Consumption of drugs such as glucocorticoids, endocrine pathologies, renal pathologies.
3) Alcoholics and drug abusers.
4) Pregnant females and lactating mothers.

**Assessment Criteria**

Assessment was done on the basis of primary and secondary outcome measures before and after the treatment.

**Primary Outcome Measures**

1) Change from Baseline in Fasting Triglycerides at day 30.
2) Change from Baseline in fasting serum total cholesterol at day 30.
3) Change from Baseline in HDL-C levels at day 30.
4) Change from Baseline in fasting LDL-C at day 30
5) Change from Baseline in fasting VLDL-C at day 30.

**Secondary Outcome Measures**

1) SF-36 Health Survey Score

- Physical functioning
- Limitation of activities
- Physical health problems
- Emotional health problems
- Social activities (emotional factors)
- Pain
- Energy and emotions

- Social activities (physical)
- General health.

2) *Lakshana* of *Sthoulya* were assessed after scoring. Score was given according to the severity of symptoms.

## RESULTS

Parameters were statistically analysed on 0th, 30th day using paired 't' test for numerical data and Wilcoxon Signed Rank test for ordinal data within the groups. Numerical data between the groups were assessed through unpaired 't' test and ordinal data through Mann-Whitney 'U' test.

The treatment interventions for Group A (*Shuddha Guggulu*) and Group B (*Shuddha Shilajatu*) demonstrated significant improvements in lipid profiles and overall quality of life. In Group A, serum cholesterol decreased by 17.6%, triglycerides reduced by 36.25%, LDL levels dropped by 14.7%, and HDL showed an increase of 4.72%. Group B also experienced favorable lipid profile changes, with cholesterol levels decreasing by 13.7% and LDL reducing by 8.84%. Both groups exhibited notable improvements in quality of life as measured by the SF-36 scale. Group A showed a 9.71% improvement in physical functioning, a 25.2% reduction in pain levels, and a 27.3% enhancement in general health. Group B demonstrated a 20.65% improvement in physical functioning, a 30% reduction in activity limitations, a 31.7% decrease in pain levels, and a 32.4% increase in overall health. Additionally, emotional health improved by 13.5%, and there was a 21.6% rise in energy and well-being in Group B.

**Statistical analysis within the group on the effect of treatment on Lipid Profile Parameters**

| Effect of treatment on Total Cholesterol | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Group** | **Mean** | | **BT - AT** | **% of Relief** | | | | | | |
| | **BT** | **AT** | | | | **SD** | **SEM** | **Median** | **t** | **P** |
| **Group A N=15** | 226.867 | 186.933 | 39.934 | 17.6% | **BT** | 32.852 | 8.482 | 236.000 | 5.520 | (P=<0.001) |
| | | | | | **AT** | 39.933 | 10.067 | 200.000 | | |
| **Group B N=15** | 272.867 | 235.333 | 37.534 | 13.7% | **BT** | 53.416 | 0.679 | 262.000 | 2.473 | (P=0.027) |
| | | | | | **AT** | 56.521 | 0.804 | 235.000 | | |

| Effect of treatment on Triglycerides | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Group | Mean | | BT - AT | % of Relief | | | | | | |
| | BT | AT | | | | SD | SEM | Median | t | P |
| Group A N=15 | 295.667 | 188.467 | 107.200 | 36.25 % | BT | 113.403 | 29.281 | 265.000 | 4.048 | (P = 0.001) |
| | | | | | AT | 39.849 | 10.289 | 188.000 | | |
| Group B N=15 | 281.800 | 238.733 | 43.067 | 15.2% | BT | 53.416 | 0.679 | 233.000 | 1.356 | (P = 0.197) |
| | | | | | AT | 56.521 | 0.804 | 182.000 | | |

| Effect of treatment on LDL | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Group | Mean | | BT - AT | % of Relief | | | | | | |
| | BT | AT | | | | SD | SEM | Median | t | P |
| Group A N=15 | 136.600 | 116.433 | 20.167 | 14.7% | BT | 26.403 | 6.817 | 138.000 | 5.492 | P=<0.001 |
| | | | | | AT | 24.958 | 6.444 | 117.500 | | |
| Group B N=15 | 177.133 | 161.467 | 15.667 | 8.84% | BT | 41.057 | 10.601 | 179.000 | 2.096 | P=0.055 |
| | | | | | AT | 36.130 | 9.329 | 158.000 | | |

| Effect of treatment on VLDL | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Group | Mean | | BT - AT | % of Relief | | | | | | |
| | BT | AT | | | | SD | SEM | Median | t | P |
| Group A N=15 | 59.000 | 44.493 | 14.507 | 24.58% | BT | 22.716 | 5.865 | 53.000 | 3.217 | P=0.006 |
| | | | | | AT | 16.819 | 4.343 | 40.400 | | |
| Group B N=15 | 54.733 | 50.733 | 4.00 | 7.30% | BT | 24.604 | 6.353 | 46.000 | 0.887 | P=0.390 |
| | | | | | AT | 25.836 | 6.671 | 39.000 | | |

| Effect of treatment on HDL | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Group | Mean | | BT - AT | % of Relief | | | | | | |
| | BT | AT | | | | SD | SEM | Median | t | P |
| Group A N=15 | 40.200 | 42.100 | 1.900 | 4.72% | BT | 10.897 | 2.814 | 38.000 | 0.796 | P= 0.439 |
| | | | | | AT | 7.450 | 1.924 | 42.000 | | |
| Group B N=15 | 46.067 | 45.200 | 0.867 | 1.88 % | BT | 7.488 | 1.933 | 47.000 | 0.542 | P= 0.597 |
| | | | | | AT | 9.049 | 2.336 | 48.000 | | |

**Effect of comparison of interventions between the groups**

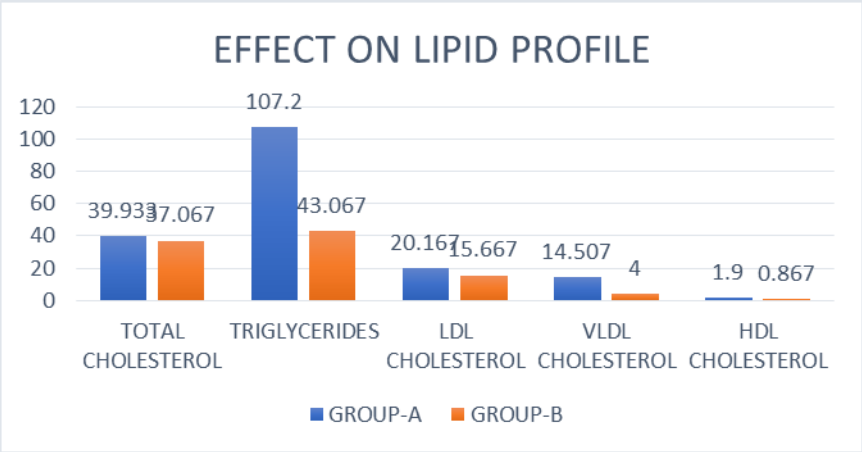
| Effect on Total Cholesterol | | | | | | |
|---|---|---|---|---|---|---|
| Group | Mean | SD | SEM | Median | Unpaired T Test | |
| | | | | | t value | P value |
| Group A N=15 | 39.933 | 28.016 | 7.234 | 49.000 | | |
| Group B N=15 | 37.067 | 58.721 | 15.162 | 18.000 | 0.171 | P = 0.866 |

| Effect on Triglycerides | | | | | | |
|---|---|---|---|---|---|---|
| Group | Mean | SD | SEM | Median | Unpaired T Test | |
| | | | | | T value | P value |
| Group A N=15 | 107.200 | 102.555 | 26.479 | 49.000 | | |
| Group B N=15 | 43.067 | 123.037 | 31.768 | 18.000 | 1.551 | P = 0.132 |

| Effect on HDL | | | | | | |
|---|---|---|---|---|---|---|
| **Group** | **Mean** | **SD** | **SEM** | **Median** | **Unpaired T Test** | |
| **Group A N=15** | -1.900 | 9.247 | 2.388 | -3.000 | **t value** | **P value** |
| **Group B N=15** | 0.867 | 6.198 | 1.600 | 0.000 | -0.963 | P=0.344 |

| Effect on LDL | | | | | | |
|---|---|---|---|---|---|---|
| **Group** | **Mean** | **SD** | **SEM** | **Median** | **Unpaired T Test** | |
| **Group A N=15** | 20.167 | 14.222 | 3.672 | 22.000 | **t value** | **P value** |
| **Group B N=15** | 15.667 | 28.955 | 7.476 | | 0.540 | P= 0.593 |

| Effect on VLDL | | | | | | |
|---|---|---|---|---|---|---|
| **Group** | **Mean** | **SD** | **SEM** | **Median** | **Unpaired t Test** | |
| **Group A N=15** | 14.507 | 17.462 | 4.509 | 9.000 | **t value** | **P value** |
| **Group B N=15** | 4.000 | 17.460 | 4.508 | 10.000 | 1.648 | P= 0.111 |




**Effect on BMI**

Group-A demonstrated a more significant reduction in BMI, decreasing by 3.42%, while Group-B experienced a reduction of 1.32%.

**Effect on Random Blood Sugar Levels**

Overall, group A showed a greater improvement in random blood sugar levels, with an increase of 11.96%, compared to group B, which experienced a 3.56% improvement.

**Effect on *Sthoulya lakshanas***

Marked reduction in the symptoms of *sthoulya* was observed, it was seen that *angachalatwa* was reduced by 34.45% in group-A and by 30.39 %in group-B, *alasya* by 23.99% in group-A

and 53.84% in group-B, *kshudra swasa* by 29.39 % in group-A and 55.96 % in group-B, *dourbalya* by 44.44 % in group-A and 26.80 % in group-B, *nidradhikyata* by 54.53 % in group-A and 48.26 % in group-B , *swedadhikyata* by 78.57 % in group-A and 5.54 % in group-B , *anga gauravata* by 15.40 % in group-A and 57.13% in group-B, *atipipasa* by 56.55 % in group-A and 10.82 % in group-B & *atikshudha* by 83.71 % in group-A and 8.30 % in group-B, *daurgandhya* by 73.90 % in group-A and 17.83 % in group-B, *snigdhangata* by 67.73% in group-A and 17.64 % in group-B, and *gatra sada* by 14.63 % in group-A and 46.49 % in group-B, *alpavyavayata* by 63.59 % in group-A and 21.81% in group-B.

**Overall effect of treatment**

The overall assessment in this study was based upon the effect of treatment on parameters of lipid profile and BMI. The findings indicated that in Group A, 7% of patients achieved excellent improvement, 40% had good improvement, 33% experienced moderate improvement, and 20% showed mild improvement. Conversely, Group B had no patients classified in the excellent or good improvement categories, with 46.66% demonstrating moderate improvement and 33.33% showing mild improvement.

## DISCUSSION

*Shuddha Shilajatu*, is primarily characterized by its *katu* and *tikta rasa*. Additionally, it possesses *sara guna*, *natyushna veerya*, and *katu vipaka*, which together contribute to its *vata-kapha hara* properties.[12] *Shilajatu* is also recognized for its *medachhedakara* property.[13] This means it can help in breaking down and eliminating excess lipids from the body, potentially improving lipid profiles and promoting cardiovascular health.

*Shuddha shilajatu* is effective in managing dyslipidemia due to its rich chemical constituents, including fulvic acid and various minerals like sterols, tri- terpenes, ellagic acid, benzoic acid, m- hydroxyl benzoic acid, 3 benzo coumarins and as many as 18 free amino acids components promote lipid metabolism, aiding in the breakdown of fats and helping to lower LDL and triglycerides while potentially increasing HDL.[14] The powerful antioxidants in *shilajatu* reduce oxidative stress, protecting blood vessels and enhancing heart health. Additionally, its anti-inflammatory properties address chronic inflammation linked to dyslipidemia. *Shilajatu's* ability to support hormonal balance and improve insulin sensitivity further optimizes metabolic functions, contributing to healthier lipid profiles. In summary, the combination of these properties positions this drug as a valuable candidate for managing conditions like dyslipidemia, promoting better metabolic health and balance in the body.

*Guggulu* was chosen as the control drug in the dyslipidemia study due to its established efficacy in lipid metabolism. The primary characteristics of *Shuddha guggulu* comprises of *tikta* and *katu rasa*. Along with this, it also possesses *laghu, teekshna*, *rooksha*, *sukshma*, *sara guna*, *ushna veerya* and *katu vipaka.*[15] Based on the *karma* of *shilajatu*, it is said to possess *lekhana* and *medohara* property and is indicated in *sthoulya.*[16] Its key chemical constituents, such as guggulsterones, stimulate lipid metabolism by lowering LDL (bad cholesterol) and triglycerides while increasing HDL (good cholesterol), crucial for heart health. Research indicates that the oxidation of LDL plays a crucial role in the development of atherosclerosis, and antioxidants that inhibit this oxidation may help to slow or even prevent the progression of the disease. Guggulsterones, which are the lipid-lowering agents found in *guggulu*, have demonstrated the ability to effectively inhibit LDL oxidation in vitro, as previously mentioned in the context of antioxidant activity. Therefore, the dual action of *guggulu* as both an antioxidant and a lipid-lowering agent renders it particularly advantageous in combating atherogenesis. *Guggulu* also enhances thyroid function, promoting metabolic activity and better lipid regulation.[17] Its anti-inflammatory properties help reduce chronic inflammation associated with dyslipidemia, while supporting liver detoxification maintains healthy lipid levels.[18] Additionally, *Guggulu* aids in weight management, further contributing to its hypolipidemic effects. *Shuddha Guggulu* demonstrated a more significant reduction in BMI, which can be attributed to *Guggulu's medoghna* property and is a key to its ability to promote fat metabolism and decrease inflammation. As a result, it significantly improves body composition and helps lower BMI. Guggulu also showed a greater improvement in random blood sugar levels, which can be attributed to *Guggulu's* ability to support metabolic health and regulate blood sugar levels due to its anti-inflammatory and insulin-sensitizing properties. These effects can enhance glucose metabolism, leading to better overall control of blood sugar. Backed by clinical studies and ayurvedic tradition, *Shuddha guggulu* serves as a robust agent for managing lipid profiles.

## CONCLUSION

No adverse effects or reactions were observed in any patients during the treatment period or follow up. In conclusion, the study demonstrates that *Shuddha shilajatu* has a significant lipid-lowering effect and effectively alleviates the signs and symptoms of *shonita abhishyanda*. However, *Shuddha guggulu* showed considerably more relief and improvement

than *Shuddha Shilajatu* across multiple metrics, with no significant statistical differences observed.

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