



Research Article

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ANTI HYPERTRIGLYCERIDEMIC ACTIVITY OF MESHASHRINGYADI GUGGULU (FORMULATED): A CLINICAL TRIAL

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ABSTRACT

Hypertriglyceridemia is a commonly encountered lipid abnormality frequently associated with other lipid and metabolic disorder. It is defined as an abnormal concentration of triglyceride in the blood and has been associated with atherosclerosis even in the absence of hypercholesterolemia and is identified as a potential risk factor for multitudes of diseases like Cardiac Vascular Disease (CVD), metabolic syndrome & even Hypertension. The state of Apakva Kapha and Margavarana in Rasa-Raktavaha Srotasa can be compared with the state of Hypertriglyceridemia. Hence a compound was formulated named Meshashringyadi Guggulu containing equal parts of Meshashringi, Lasuna, Katuki and Guggulu along with life style modification. An open labelled clinical study with pre-test & post-test design was carried on 20 patients of either sex of Hypertriglyceridemia. These patients were given Capsule Meshashringyadi Guggulu two capsules of 500mg each thrice daily before breakfast, lunch and dinner with lukewarm water for the duration of eight weeks. These patients were also advised strict life style modifications. Analysis of data showed that combined effect of the trial drug and life style intervention provided statistically significant changes in S. Triglyceride levels in these patients of Hypertriglyceridemia. As Hypertriglyceridemia is a condition arising from faulty life style, its management needs equal attention for treatment and prevention which can be achieved by administering Medohara drugs having Agnideepana properties and following appropriate life style modification.

Keywords: Hypertriglyceridemia, Meshashringyadi Guggulu, Lifestyle intervention, Medohara

INTRODUCTION

21st century is the era of science and technology. Newer inventions of the science have made human life very fast and easy. With the help of Science, man is climbing the steps of success but moving away from Nature. This condition has given birth to Life style diseases. Large numbers of young people are dying of cardiovascular diseases, cancers and other lifestyle diseases in modern times, especially in India the situation is quite alarming. The World Health Organization (WHO) has identified India as one of the nation that is going to have most of the lifestyle disorders in the near future. By 2020, world's 60% of heart disease is expected to occur in India¹.

Unhealthy fast food, lack of exercise, irregular sleep, stress, various addictions etc. are some factors which contribute greatly to such diseases. These factors generally act by impairing the metabolism of an individual making him prone to series of disorder. Hypertriglyceridemia is one such a common disorder in today's era. Hypertriglyceridemia is defined as an abnormal concentration of triglyceride in the blood resulted from a disorder of lipoprotein metabolism² and has been associated with atherosclerosis even in the absence of hypercholesterolemia³. As per National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III) guidelines, a normal triglyceride level is 150 mg/dl⁴. In India prevalence of triglyceride level >150mg/dl is 3.4%⁵ and the incidences are increasing every year. Hypertriglyceridemia may be primary or secondary in nature. This may result from primary inborn defects of lipoprotein production or metabolism, but in most cases, it is secondary to an unhealthy lifestyle (e.g. excessive smoking or alcohol consumption), other health disorders (e.g. obesity, diabetes,

hypothyroidism, infection, obstructive liver disease etc.), or certain medications (e.g. B blockers, steroids etc.).

Extreme high levels of triglycerides causes, inflammation of pancreas, risk for fatty liver, lipemia retinalis and chylomicron syndrome. Even though, Hypertriglyceridemia is essentially asymptomatic, it is identified as a potential risk factor for various diseases like Coronary Heart Diseases (CHD), Cerebrovascular accidents (CVA), metabolic syndrome and atherosclerosis. The National Cholesterol Education Program (NCEP) opines, triglyceride to be an independent risk factor for coronary heart disease (CHD), even after adjustment for High density lipoprotein (HDL) & Low density Lipoprotein (LDL)⁶. In western system of medicine, management of elevated serum triglycerides include both dietary management and drug therapy which includes lipid lowering drugs like statins, resins, niacin and fibrates which give rapid relief but long term side effects such as hepatic or renal impairment, malaise, Liver enzyme elevation etc.

The state of Apakva Kapha and Margavarana in Rasa-Raktavaha Srotasa can be compared with the state of Hypertriglyceridemia. Aparipakva Kapha Meda present in *Rasa Rakta Vaha Srotasa* results in obstruction to the movement of *Vata & Rakta* through affected channel finally ends up in disease manifestation according to the site of affliction.

The pursuit of finding the new safe and effective drug for dyslipidaemia is a continuous process. *Ayurveda* emphasizes wide range of herbal and mineral drugs in this regard which are *Kaphamedohara*, *Shaulyahara* and *Hridya* which either individually or in combination will have a positive role in

reducing elevated lipid profile. So, an attempt has been made to evaluate the effect of *Meshashringyadi Guggulu* capsule which contains equal part of whole plant of *Meshashringi*, bulb of *Lasuna*, root of *Katuki* and gum resin of *Guggulu* and lifestyle intervention in the management of Hypertriglyceridemia.

MATERIALS AND METHODS

Source of Data: Patients were selected from the O.P.D. of Kayachikitsa dept. I.P.G.T & R.A Hospital, Jamnagar, Gujarat. The patients were registered and treated on outpatient basis during the period April 2016 to December 2016.

Sample size and sampling method: Irrespective of gender, socio - economic status and religion, 22 patients fulfilling the inclusion criteria were registered for the study. There were 2 drop outs and study was completed with 20 patients who were assigned under a single group.

Before conducting the clinical study approval from the Institutional Ethics Committee was taken. (No. PGT/7/-A/Ethics/2015-16/1490 Dt.25-08-2015). The study has also been registered in CTRI [CTRI/2016/03/006709 (Registered on: 04/03/2016)]

Diagnostic Criteria: The diagnosis was based on serological investigation i.e. serum Triglyceride level > 150 mg/dl

Inclusion Criteria: Patients of either sex, within the age group of 25-60 years with serum triglyceride levels > 150 mg/dl and < 500mg/dl were included.

Exclusion Criteria: Age below 25 and above 60 years, patients suffering from type 1 Diabetes mellitus and uncontrolled type 2 diabetes mellitus or stage III- hypertension, drug induced & uncontrolled dyslipidemia (esp. Primary), systemic illness like tuberculosis, carcinoma and endocrine disorders, patient having the past history of myocardial infarction & unstable angina or patients having major renal or liver disorders were excluded.

Investigations: Specific investigation – Serum triglyceride along with other lipid profile- S. cholesterol, VLDL, S. LDL, S. HDL- (12 hr. fasting blood sample) along with other Blood investigations like Haemoglobin%, Total leucocyte count, Differential count, Erythrocyte sedimentation rate, Random blood sugar were done in all the registered patients. Urine investigations - Urine Sugar, microscopic, albumin was also done. All these investigations were done before initiating the treatment and after 8 weeks of treatment.

Study Design: It was an interventional clinical study with pre-test and post-test design.

Intervention: Patients were given Capsule *Meshashringyadi Guggulu* 2 capsules of 500mg each thrice daily before breakfast, lunch and dinner with lukewarm water for the duration of eight weeks. These patients were also advised strict life style modifications like increase in the daily physical activity and changes in diet i.e. Nidana Parivarjana & Pathya Palana as mentioned for Santarpanotha Vyadhi in Ayurvedic Classics.

Assessment criteria

Assessment of combined effect of *Meshashringyadi Guggulu* capsule and lifestyle modification on Serum Triglycerides was done on the basis of pre-test on (0 day) & post-test on (56th day) values of Serum Triglycerides.

Statistical methods

The data was collected before & after intervention and assessed statistically by using descriptive statistics, paired sample 't' test.

OBSERVATION

Total 22 patients were registered for the present study to evaluate the role of *Meshashringyadi Guggulu* capsule and lifestyle intervention in the management of hypertriglyceridemia. 20 patients completed the treatment while 2 patients left the treatment.

Among 22 patients, maximum patients (42%) were from the age group of 40-50 years followed by 26% patients of 30-40 years age group and 24% patient from age group of 50-60 years. Among 22 patients, 52% patients were female followed by 48% patients who were male; 62.85% patients had sedentary type of work, 80 % patients belonged to urban area; majority patients i.e. 62.85% belonged to upper middle class; 62.85% patients were having the habit of day time sleep; 31.42% patients were having the habits of tobacco chewing & smoking, 42.85% patients were suffering from diabetes & hypertension. 65.71% patients were taking vegetarian diet. A maximum 54.2% patients were having abnormal BMI.

Among 22 patients, maximum 54.54% patients were observed having serum triglyceride between 200-499 mg/dl followed by 45.45% patients who were having serum triglyceride between 150-199 mg/dl (Table 1). Maximum 50% patients were observed having serum cholesterol <200mg/dl followed by 31.81% having serum cholesterol between 200-239 mg/dl and 18.18% patients who were having ≥ 240 mg/dl. (Table 2). Among 22 patients, maximum 45.45% patients were found to have serum LDL <100 mg/dl followed by 27.27% each patient who were having serum LDL between 100-129 mg/dl and 130-159mg/dl. (Table 3)

Among 22 patients, maximum 40.90% patients were observed having serum VLDL between 30-60 mg/dl followed by 31% having serum VLDL ≥ 60 mg/dl and 27.27% having serum VLDL <30 mg/dl (Table 4). Maximum 50% patients were observed to have serum HDL <40 mg/dl followed by 40.90% patients were having serum HDL between 40-60 mg/dl and 9.09% patients were having serum HDL ≥ 60 mg/dl. (Table 5).

Associated symptoms like Bharavridhi (Weight gain) was observed in 15 patients (68.18%), Anga Gaurava (heaviness in the body) was observed in 16 patients (72.72%), Daurbalya (fatigue) was observed in 07 patients (31.81%), Alasya (lethargy) was observed in 08(36.36%) patients and Sandhishula (discomfort in joints) was observed in 09 patients (40.90%). (Table 6).

RESULTS

Trial drug provided 26.95% and 4.13% decrease in S. Triglyceride and S. Cholesterol respectively. Reduction in S. Triglyceride was statistically significant while reduction in S. Cholesterol was statistically insignificant. Similarly trial drug provided 27.07%, 3.54% and 0.75% reduction in S.VLDL, S.LDL and S.HDL respectively. The reduction in S.VLDL was statistically significant but it was statistically insignificant in S.LDL and S.HDL. (Table 7)

Table 1: Range of Serum triglyceride observed in 22 patients of hypertriglyceridemia

| S. Triglycerides (mg/dl) | No. of patients | % |
|--------------------------|-----------------|-------|
| 150-199 | 10 | 45.45 |
| 200-499 | 12 | 54.54 |

Table 2: Range of Serum cholesterol observed in 22 patients of hypertriglyceridemia

| S.Cholesterol (mg/dl) | No. of patients | % |
|-----------------------|-----------------|-------|
| <200 | 11 | 50 |
| 200-239 | 07 | 31.81 |
| ≥240 | 04 | 18.18 |

Table 3: Range of Serum LDL observed in 22 patients of hypertriglyceridemia

| S.LDL (mg/dl) | No. of patients | % |
|---------------|-----------------|-------|
| <100 | 10 | 45.45 |
| 100-129 | 06 | 27.27 |
| 130-159 | 06 | 27.27 |

Table 4: Range of Serum VLDL observed in 22 patients of hypertriglyceridemia

| S.VLDL (mg/dl) | Trial group | % |
|----------------|-------------|-------|
| <30 | 06 | 27.27 |
| 30-60 | 09 | 40.90 |
| ≥60 | 07 | 31.81 |

Table 5: Range of Serum HDL observed in 45 patients of hypertriglyceridemia

| S.HDL(mg/dl) | Trial group | % |
|--------------|-------------|-------|
| <40 | 11 | 50 |
| 40-60 | 09 | 40.90 |
| ≥60 | 02 | 9.09 |

Table 6: Associated complaints presented by study subjects of hypertriglyceridemia

| Associated Complaints | No. of patients | % of patients |
|-------------------------------|-----------------|---------------|
| Bharvridhi | 15 | 68.18 |
| Angagaurava | 16 | 72.72 |
| Sphika Stana Udara Avalambala | 00 | 00 |
| Daurbalya | 07 | 31.81 |
| Alasya | 08 | 36.36 |
| Sandhishula | 09 | 40.90 |

Table 7: Effect of therapy on S. lipid profile

| Investigation | No of patients | Mean | | Mean diff | % change | S.D (±) | SE (±) | 't' | P |
|-----------------|----------------|--------|--------|-----------|----------|---------|--------|------|-------|
| | | B.T | A.T | | | | | | |
| S. Triglyceride | n=20 | 314.13 | 229.48 | 84.65 | 26.95 | 186.46 | 38.88 | 2.18 | <0.05 |
| S. Cholesterol | n=20 | 192.54 | 184.58 | 7.96 | 4.13 | 31.30 | 6.39 | 1.25 | >0.05 |
| S.VLDL | n=20 | 62.08 | 45.08 | 17.0 | 27.07 | 15.64 | 3.19 | 1.78 | <0.05 |
| S.LDL | n=20 | 103.98 | 100.30 | 3.68 | 3.54 | 30.08 | 6.14 | 0.60 | >0.05 |
| S.HDL | n=20 | 44.63 | 44.29 | 0.33 | 0.75 | 6.18 | 1.26 | 0.26 | >0.05 |

BT: Before Treatment, AT: After Treatment

Table 8: Effect of therapy on associated symptoms of the patients of hypertriglyceridemia

| Parameters | No. of patients | Mean | | Mean diff. | % | 'W' | P |
|---------------|-----------------|------|------|------------|-------|-----|--------|
| | | B.T | A.T | | | | |
| Bhara Vriddhi | 15 | 3.22 | 2.94 | 0.28 | 8.69 | 15 | <0.05 |
| Anga Gaurav | 16 | 1.84 | 1.21 | 0.63 | 34.23 | 69 | <0.05 |
| Sandhishula | 09 | 2.20 | 1.40 | 0.80 | 36.36 | 36 | <0.05 |
| Daurbalya | 07 | 1.91 | 0.58 | 1.33 | 69.63 | 66 | <0.001 |
| Alasya | 08 | 1.61 | 1.07 | 0.54 | 33.54 | 28 | <0.05 |

BT: Before Treatment, AT: After Treatment

Effect of therapy on associated symptoms

Trial drug provided 8.69% and 34.23% reduction in Bhara Vriddhi and Anga Gaurava respectively which both were statistically significant, while trial drug provided 36.36% and 69.63% relief in Sandhishula and Daurbalya respectively. The reduction of Sandhishula was statistically significant but relief in Daurbalya was statistically highly significant and Alasya was relieved by 33.54% which was statistically significant (Table 8).

DISCUSSION

Patients of hypertriglyceridemia are asymptomatic. Diagnosis is mainly done on the basis of 12 hour fasting serum triglyceride

levels. Fasting samples were taken as triglycerides are found to be high in blood 4-5 hours after meals. And also the reference values are based on fasting triglyceride levels. Among the total number of patients, maximum patients (42%) were found in the age group of 40-50 yrs. From the demographic data, it can be assessed that, incidence of hypertriglyceridemia is more in 40-50 years age group. This shows a positive relation between hypertriglyceridemia and age. 62.85% patients were from upper middle class. It may be just due to dietary habits, lifestyle and also might be due to awareness among the people about the disease which made them to undergo routine examinations. 96.3% of the patients were literates, which show the increased awareness among people towards screening and detecting the risk factors of coronary artery disease. 62.85% patients had

sedentary type of work. Due to modern technologies physical stress is reduced, as a result energy intake is more than energy expenditure. This might be the added risk factor for the Hypertriglyceridemia. 31.42 % patients having habit of smoking, tobacco chewing and occasional alcohol consuming. Small amount of alcohol raise the HDL-C cholesterol which is a coronary protective factor; but large amount, increases LDL, VLDL and Triglyceride which are strongly atherogenic. Smoking does not lead to increase in cholesterol level, rather it deteriorates oxygen delivery and causes mild coronary vasoconstriction of myocardium, increases platelet activity and damages the endothelium. Thus leading to atherogenic changes, a risk factor for coronary artery diseases. Vegetarian diet pattern was dominant, milk and milk products, oily and fried foods were consumed by majority of the patients. Cotton seed oil, groundnut oil for cooking was used by most of the patient. Non vegetarian diet included eggs, chicken, mutton, beef which have more of unsaturated fats, which when consumed in excess, increases the lipids. Hence the incidence of hypertriglyceridemia was high with those who were having mixed diet pattern. Day time sleep is one of the important cause which vitiate Kapha Dosh, a key factor in the genesis of Kapha Meda Margavarana. Even day time sleep signifies the sedentary lifestyle which has a direct effect on the disease.

After the completion of eight weeks intervention it was found that there was a marked decrease in serum Triglyceride level with pre-test to post-test mean difference was 84.65 mg/dl, which was statistically significant. The trial drug also provided statistically significant reduction in B.M.I & body weight. This is attributed to effect of combination of Cap. Meshashringyadi Guggulu along with lifestyle changes. As Meshashringyadi Guggulu is mainly having Tikta, Kashaya and Katu Rasa, Ushna Virya, and Kaphameda Shamaka Dravyas. Lasuna & Guggulu have established lipid lowering property. Extract of Meshashringi leaves also possess anti hyperlipidemic & anti diabetic effect, Katuki has Pitta Virechaka property, increases the secretion of bile & thus excessive triglyceride can be removed with bile from liver. Further Meshashringi and Katuki have Pachana property which removes Ama. Guggulu due to its Lekhana and Sukshma Srotogami property opens the obstructed channel. Lasuna & Guggulu are also Rasayana & thus more beneficial for re-establishment of physiology of Vata & Rasa Dhātu. In total the combination of all the above properties and their relative effects may increase Agnibala and reduce Ama, Kapha and Meda. Hence Meshashringyadi Guggulu along with lifestyle intervention reduces Kapha and Medas and there by acts on hypertriglyceridemia (Kapha Medo Margavarana) which was observed in this study with the significant results.

CONCLUSION

Hypertriglyceridemia is one of the major modifiable risk factor for diabetes mellitus, atherosclerotic diseases like coronary artery diseases, stroke etc. A precise reference of Hypertriglyceridemia is not available in Ayurveda but it can be understood in terms of *Kapha Medo Margavarana Janya Vyadhi* and is a Medo Dushti predominant disorder. As patients are asymptomatic diagnosis can be made on biochemical investigations i.e. on serum triglyceride. Meshashringyadi Guggulu along with appropriate life style modification has significantly reduced raised serum triglyceride level and thus Meshashringyadi Guggulu is safe and cost effective and promising drug for hypertriglyceridemia.

REFERENCES

1. http://www.searo.who.int/india/topics/cardiovascular_diseases/NCD_Resources_clinical_management_guidelines_for_cad.pdf accessed on 09-12-2016.
2. Kasper, Braunwald, Fauci, Hauser, Longo, Jameson, Harrison's Principles of Internal Medicine- Volume I, 7th edition, McGraw-Hill Book Co-Singapore for manufacture and exports Textbook of Internal Medicine, Chapter 356; Disorders of Lipoprotein Metabolism, pg no.31453156.
3. Isis commences ISIS-APOCIIIrx phase I trial in hypertriglyceridemia <http://www.newsmedical.net/tg/feed/hypertriglyceridemia.aspx> accessed on 09-12-2016.
4. J. I. Cleeman, Executive summary of the third report of the national cholesterol education program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (adult treatment panel III) JAMA.2001;285(19):2486-2497. [PubMed]
5. Rajmohan L et al., Association between isolated hypercholesterolemia, isolated hypertriglyceridemia and coronary artery disease in south Indian type 2 diabetic patients. Indian Heart Journal 2000; 52 (4) 400-406.
6. J. I. Cleeman, "Executive summary of the third report of the National Cholesterol Education Program (NCEP) 2001 expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (adult treatment panel III)," The Journal of the American Medical Association, vol. 285, no. 19, pp. 2486-2497.

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