

## ROLE OF LIFESTYLE INTERVENTION IN THE MANAGEMENT OF HYPERTRIGLYCERIDEMIA (MEDO VRIDDHI) – A CLINICAL TRIAL

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### ABSTRACT

Hypertriglyceridemia is a common life style disorder disease in today's era and is identified as a potential risk factor for multitudes of diseases like Cardiac Vascular Disease (CVD), metabolic syndrome, hypertension & even acute pancreatitis. As it is a life style related disorder, so modification of life style is initial step and corner stone in the management of hypertriglyceridemia. Hence a trial has been planned to evaluate the role of life style intervention in the management of hypertriglyceridemia. AIMS & OBJECTIVES: To assess the clinical efficacy of lifestyle intervention in the management of Hypertriglyceridemia. MATERIALS & METHODS: 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 *Sooji* powder capsule for placebo effect, two capsules of 500mg thrice daily before breakfast, lunch and dinner with lukewarm water for the duration of eight weeks. These patients were advised strict life style modifications. OBSERVATIONS AND RESULTS: Analysis of data showed that life style intervention provided statistically significant changes in S. Triglyceride levels in these patients of Hypertriglyceridemia.

CONCLUSION: It was concluded that Hypertriglyceridemia can be effectively managed by following appropriate life style modification.

**Keywords:** Hypertriglyceridemia, metabolic syndrome, life style intervention

### INTRODUCTION

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. Too many people are dying

relatively younger from cardiovascular diseases, cancers and other lifestyle diseases in modern era. 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 India<sup>1</sup>.

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 metabolism<sup>2</sup> and has been associated with atherosclerosis even in the absence of hypercholesterolemia<sup>3</sup>. As per National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III) guidelines, a normal triglyceride level is 150 mg/dl<sup>4</sup>. In India prevalence of triglyceride level >150mg/dl is 3.4%<sup>5</sup> 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.). However the most common forms of hypertriglyceridemia are related to overweight and sedentary life style which leads to insulin resistance. This setting of hypertriglyceridemia is typical for metabolic syndrome and diabetes mellitus type II.

The pursuit of finding the new safe and effective way for the management of life style disorder disease is a continuous process.

Intensive lifestyle modification, including dietary counselling to achieve appropriate diet composition, physical activity, and a program to achieve weight reduction in overweight and obese individuals are the main initial treatment of hypertriglyceridemia<sup>6</sup>.

So, an attempt has been made to evaluate the effect of strict 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<sup>7</sup> and has been registered in CTRI<sup>8</sup>.

**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 Di-

abetes 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 were 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 Sooji powder 2 capsules of 500mg each thrice daily before breakfast, lunch and dinner with lukewarm water for the duration of eight weeks. These patients were 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. (Annexure 1)*

**Assessment criteria:**

Assessment of effect of 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 AND RESULTS:**

**Observations:**

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 had habits of tobacco chewing & smoking, 42.85% patients were suffering from diabetes & hypertension. 65.71% patients were taking vegetarian diet. 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 No.1.1). 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- 1.2). Among 22 patients, maximum 45.45% patients were found to have serum LDL <100 mg/dl followed by 27.27% each patient who was having serum LDL between 100-129 mg/dl and 130-159mg/dl. (Table- 1.3)

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- 1.4.). 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-1.5).

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-1.6).

### **Results:**

Life style modification 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 the therapy 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 signifi-

cant but it was statistically insignificant in S.LDL and S.HDL. (Table-2.1)

### **Effect of life style intervention on associated symptoms:**

Life style modification 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 (Table2.2)

### **DISCUSSION**

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. 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. Vegetarian diet pattern was dominant, milk and milk products, oily and fried foods were consumed by majority. Cotton seed oil, groundnut oil for cooking, was used by most of the patient. Non vegetarian diet included eggs, chicken, mutton which has more of unsaturated fats, which when con-

sumed 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 causes which vitiate *Kapha Dosha*, 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 therapy provided statistically significant reduction in B.M.I & body weight. This is attributed to the effect of strict lifestyle changes.

**Diet and exercise**, the cornerstones of weight loss, can effectively lower Triglyceride levels. In this study patients were advised to follow *Pathya like* intake of *Kullatha, Yava, Mudga, Horse gram, old honey, old rice, Takra* etc. *Kullatha* is well known for *Medohara* and *Vatahara* property. *Mudga* is astringent and sweet in taste, unctuous and non slimy. It is dry, easily digestible, water absorbent; mitigate *Kapha* and *Pitta* and rich in protein. Study suggest that in high-protein diets, weight loss is initially high due to fluid loss related to reduced carbohydrate intake, overall caloric restriction and ketosis-induced appetite suppression. However, in fact, protein intake also stimulates insulin secretion<sup>9</sup>. *Yava* is having the properties like *Ruksha and Laghu and is rich in fibre* which acts as *Medohara*. Dietary fibre prevents absorption of glucose from intestine and helps increase peristaltic movement and reduce blood cholesterol<sup>10</sup>. *Takra* is having *Amla* and *Kashaya Rasa*. *Kashaya*

*Rasa* reduces vitiation of *Kapha* and thus having *Medohara* property while *Amla Rasa* reduces vitiation of *Vata*.

Excessive caloric intake not utilized by the body is converted to triglycerides which are stored in adipose tissue. Lower triglycerides are typically observed with both acute exercise and sustained aerobic exercise training<sup>11</sup>. Triglycerides are used as energy by skeletal muscles during endurance exercise. The enzyme lipoprotein lipase (LPL) splits triglycerides from VLDLs, making them available for uptake by skeletal muscles. Chronic exercise training also increases hepatic HDL production which protect against heart disease.

Therefore, lower caloric intake and increased exercise help prevent this conversion and result in lower triglyceride levels. In total the combination of all the above properties and their relative effects may increase *Agnibala*, reduces *Ama*, vitiated *Kapha* and *Meda*. Hence lifestyle intervention reduces *Kapha and Medas* and thereby acts on hypertriglyceridemia (*Kapha Medo Margavarana*) which is observed in this study with the significant results.

## CONCLUSION

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 of hypertriglyceridemia are asymptomatic, diagnosis can be made on biochemical investigations i.e. on serum triglyceride. Study concluded that appropriate life style modification has significant role in managing raised serum triglyceride level.

**Annexure: 1**

Patients are advised to do *Nidana Parivarjana* and *Pathya Palana* as mentioned for *Santarpanoth Vyadhis* in Ayurvedic classics.

**Nidana Parivarjana:** Like Heavy, oily foods, milk and dairy products, sweets, butter, Ghee, cheese, Paneer, red meat, cold drinks, refined carbohydrate, hydrogenated oil, smoking, ex-

cess alcohol intake, sedentary life, stress life etc.

**Pathya Palana:** Diet like light and dry food substances, eat old rice, *Chapatti*, *Mudga*, *Kullatha*, *Kodrava*, horse gram, green gram, green leafy vegetable and salads, dried beans, peas, pulses, old honey, *Takra*, drinking warm water before meals, daily active exercise.

**Table 1.1:** 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 1.2:** 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 1.3:** 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 1.4:** 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 1.5:** 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 1.6:** Associated complaints presented by study subjects

Associated Complaints	No. of patients.	% of patients.
<i>Bharvridhi</i> (weight gain)	15	68.18
<i>Angagaurava</i> (feeling of heaviness of body)	16	72.72



<i>Sphika Stana Udara Avalambala</i>	00	00
<i>Daurbalya</i> (weakness)	07	31.81
<i>Alasya</i> (Lazyness)	08	36.36
<i>Sandhisula</i> (joint pain)	09	40.90

**Table 2.1:** 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

**Table 2.2:** Effect of life style intervention on associated symptoms:

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

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