

Effect of Diet Therapy and Guggulu (*Commiphora Mukul*) on Obesity- A Comparative Clinical Study

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ABSTRACT

Background and Objectives: The prevalence of excess weight gain is a global health problem. Obesity is a risk factor for many cardiovascular and other ailments. Diet therapy is a principal therapy which focuses on reduction in food intake. Guggulu is the principal ingredient of several Ayurvedic formulations used for obesity. In this background the present study was intended to evaluate the efficacy of guggulu and dietary counseling in obesity.

Methodology: It was a randomized, parallel group, single centre, comparative clinical study. All norms of Good Clinical Practice and ethics were abided. The patients were randomly assigned in two groups. To subjects of one group, dietary counseling was advised, whereas other group subjects received guggulu, 3grams per day for 30 days. Weight, BMI, Waist Circumference and Waist Hip Ratio were considered as parameters. Descriptive statistics and t test were employed.

Results and conclusion: Since the compliance with the dietary guidelines was strictly followed only 24 subjects completed the study in dietary counseling group. In other group B 31 subjects completed the trial. The dietary counseling reduced the weight, BMI, Waist Circumference and Waist Hip Ratio significantly where as Guggulu did not show efficacy on these parameters.

Keywords: Obesity, Dietary Counseling, Guggulu.

INTRODUCTION

Excess accumulation of fat leading to adverse effect is known as obesity. Body mass index (BMI) is an index of weight-for-height that is commonly used to classify overweight and obesity in adults. The World Health Organization (WHO) definition is: 1) A BMI greater than or equal to 25 is overweight and, 2) A BMI greater than or equal to 30 is obesity. BMI provides useful population-level measure of overweight and obesity as it is the same for both sexes and for all ages of adults. However, it should be considered as rough guidance because it may not correspond to the same degree of fatness in different individuals. ^[1] Obesity and overweight occurs due to imbalance

between calories consumed and calories utilized. Globally, there have been two reasons for overweight and obesity: 1) an increased intake of energy-dense foods that are high in fat, salt and sugars but low in vitamins, minerals and other micronutrients; and, 2) decrease in physical activity due to the increasingly sedentary nature of many forms of work, changing modes of transportation, and increasing urbanization. ^[2]

Changes in dietary and physical activity patterns are often result of sedentary lifestyle, not sleeping enough, endocrine disruptors, such as some foods that interfere with lipid metabolism, medications that make patients put on weight, medical and

psychiatric illness and infectious agents. Overweight and obesity are the fifth leading risk for global deaths. At least, 2.8 million adults die each year as a result of being overweight or obese. In addition, 44% of the diabetes burden, 23% of the ischemic heart disease burden and between 7% and 41% of certain cancer burdens are attributable to overweight and obesity. WHO global estimates for the year 2008, reported 1.5 billion people were overweight, of these, over 200 million men and nearly 300 million women were obese. Overall, more than one in ten of the world's adult population was obese. [3]

Existing treatments for obesity include diet, exercise, behavior therapy, pharmacotherapy and surgical intervention. Several pharmacotherapies for treating overweight and obesity exert their primary action by either suppressing appetite, limiting food absorption, reducing food intake, altering metabolism or increasing energy expenditure. [4]

The preferred treatment modality for weight loss is dieting and physical exercise. But due to busy schedules and sedentary lifestyle both methods never seems to be practiced in a regular manner. On the other hand weight loss surgery runs out of the option considering the cost involved. There is a gradual shift towards an increase use of drugs. Drugs are pharmacological agents that reduce or control weight. These drugs alter one of the fundamental processes of the human body, weight regulation, by altering appetite, metabolism, or absorption of calories. [5]

Diet Therapy: Diets based on healthy eating with modest reductions of energy should always be used as first line of obesity treatment in combination with a change in eating behavior and lifestyle. The individualized diets are calculated based on the nutritional requirements of a person taking account of age, weight, sex and activity level. The diet prescribed provides 600kilocalories less than calculated nutritional requirements which will induce effective and desirable levels of weight loss.

These diets should be appropriately restricted in energy but still provide the correct balance of all nutrients. [6]

In Āyurveda, Obesity is regarded 'Sthaulya', a disorder of Adipose tissue and fat metabolism and one of the undesirable Physical Constitutions. *Sthaulya* is considered as a disorder of over nutrition. [7] Eight morbidities of obesity as described in *Carakasamhitā* are, reduced life span, Laziness, Difficulty in sex, Weakness, Foul Smelling body, Excess Perspiration, Increased Appetite and Thirst. [8]

Guggulu: Guggulu is an exudate obtained in the form of oleo gum resin from plant stem of *Commiphora mukul* (Hook.ex Stocks) belonging to family Burseraceae. It is known to have analgesic, anti inflammatory and anti hyperlipidemic action. Guggulu is the principal ingredient of several Ayurvedic formulations used for obesity. [9] The extract of this gum, called gugalipid or guglipid, has been used in Ayurvedic medicine abundantly. Guggulucontains essential oil, resin, gum, and bitter compounds. The major chemical constituents of gugguluare Z-guggulsterone, E-guggulsterone, guggullignans I & II, gugglutetrols; mukulol; allylcembrol; c-27 guggulusterols I, II, III; Z-guggulusterol; E-guggulusterol etc. These constituents are responsible for several pharmacological activities like anti-inflammatory, analgesic, cleaning of wound and healing due to its antibacterial action. Guggulu is a natural health product used primarily to reduce elevated blood cholesterol levels. It has been used for many years as a hypocholesterolaemic agent in India. [10] Guggulu has been extensively studied for its chemistry (Khanna et al., 1969; Patil et al., 1972, pharmacology (Malhotra and Ahuja, 1972) and clinical efficacy (Malhotra and Ahuja, 1971). A number of steroidal compounds have been isolated which have anti inflammatory capacity (Arora et al., 1971.1972). Fraction A isolated from guggulu was also shown to have antihyperlipidemic activity (Mehta et al., 1968; Das et al., 1973; Nityanand et al.,

1973).^[11] Satyavati et al reported that Crude Guggulu was found to reduce the body weight of hydrogenated groundnut oil treated rabbits.^[12] Vriddha Vagbhata quotes *Guggulumedoanilāpaharam*, which implies that guggulu is best drug to treat obesity.^[13] Guggulu is processed with either of Gudūci Kwātha, Triphalā Kwātha, Godugdha or Pancha Tikta Kwātha before using.

MATERIALS AND METHODS

It was a randomized, parallel group, single centre, comparative clinical study. Written informed consent was taken before conducting the study related procedures. Subjects were included in the study if indicated YES to all inclusion and NO to exclusion criteria. A total of 70 Patients approaching the OPD and IPD of Government Ayurveda Medical College (GAMC), Mysore were selected with respect to age, irrespective of sex, caste, religion and socio economic status fulfilling the diagnostic criteria. Subjects were randomly assigned in two groups A and B, in 1:1 ratio comprising 35 in each group. Ethical clearance was taken from Institutional ethics committee of GAMC, Mysore.(Ref No IEC/PG/AS(2)-1/2013-14)

Inclusion criteria:

- Male and/or female patients
- Age between 20-45 years
- BMI between >30 to 40kg/m²
- Willing to come for regular follow-up visits
- Able to give written consent

Exclusive criteria:

- Intake of over the counter weight loss agents, centrally acting appetite suppressants in the previous six months
- Pathophysiological/ genetic syndromes associated with obesity (Cushing's syndrome, Turner's syndrome, Prader-Willi syndrome)
- Patients with evidence of malignancy
- Patients with poorly controlled Diabetes Mellitus (HbA1c > 10%)
- Patients with poorly controlled Hypertension (>160/100 mm Hg)

- Patients on prolonged (> 6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc. or any other drugs that may have an influence on the outcome of the study
- Patients suffering from major systemic illness necessitating long term drug treatment (Rheumatoid arthritis, Tuberculosis, Psycho-Neuro-Endocrinal disorders etc.)
- Patients who have a past history of Atrial Fibrillation, Acute Coronary Syndrome, Myocardial Infarction, Stroke or Severe Arrhythmia in the last 6 months
- Symptomatic patient with clinical evidence of Heart failure.
- Patients with concurrent serious hepatic disorder (defined as Aspartate Amino Transferase (AST) and / or Alanine Amino Transferase (ALT), Total Bilirubin, Alkaline Phosphatase (ALP) > 2.5 times upper normal limit) or Renal Disorders (defined as S.Creatinine > 1.2mg/dL), Severe Pulmonary Dysfunction (uncontrolled Bronchial Asthma and / or Chronic Obstructive Pulmonary Disease (COPD), or any other condition that may jeopardize the study.
- History of HIV and other viral infections
- Alcoholics and/or drug abusers
- Prior surgical therapy for obesity
- History of hypersensitivity to any of the herbal extracts or dietary supplements.
- Pregnant/ lactating women.
- Patients who have completed participation in any other clinical trial during the past six months.
- Any other condition which the principal investigator thinks may jeopardize the study

Assessment criteria: Body weight, B.M.I, Waist circumference and Waist Hip Ratios were the parameters assessed before (BT) and after (AT) the intervention. Descriptive statistics and t test were employed as statistical methods.

Intervention:

Group A: Dietary Counseling was advised

Group B: Guggulu 3grams per day, orally in divided dose after food.

Duration: 30 days

Guggulu was used from the drug store of Govt. Ayurveda Medical College (GAMC), Mysore. Teaching hospital of GAMC, Mysore receives the medicines from Government Central Pharmacy, Bangalore. It was identified vide ref DI/PG-AS(2)-1/2013-14 by teaching staff of Department of Dravyaguna and Rasashastra evam Bhaishajya Kalpanā. Sample specimen is retained in Post Graduate Department of Samhitā Siddhanta.

Dietary Counseling Protocol:

- ✓ Ideal Body Weight (IBW) of the subject was calculated by formula $IBW = \text{Normal BMI} \times \text{Height in (mt)}^2$
- ✓ For the obtained IBW energy requirement was estimated as per ICMR guidelines^[14] considering Age, Sex and level of activity.
- ✓ Subject's food preferences and dietary pattern were noted.
- ✓ As per dietary guidelines of obesity approximately 600kcal of energy was reduced and Dietary advice was given in the form of diet chart.
- ✓ The chart was customised for individual use, which included his/her food pattern, energy requirement and food preferences.
- ✓ The counseling was aimed at motivating subjects to abide by the protocol to achieve weight loss and other health benefits.

Treatment compliance: The compliance with the dietary counseling was monitored by 24 hour diet recall method. Each subject of Group A was told to record all that they eat and drink along with quantity and time of intake. These records were reviewed every Sunday to monitor the treatment compliance. Those who followed advice that met 600 ± 100 kcal was considered for the study. The compliance with Guggulu intake was monitored by periodic reviews, observing the left over medicine.

Data reporting: All the data required by the protocol was noted in a Case Report Forms

(CRF), monitored and reviewed periodically.

RESULTS

Of the 35 subjects of group A, 6 were removed from the study on account of poor compliance whereas 5 did not turn up for successive follow ups. Hence only 24 subjects completed the study. In group B there were 4 drop outs, 31 completed the trial.

Of the 55 subjects 41 (74.5%) were female, 45 (81.82%) had sedentary life style and 10 (18.2%) had moderate activity ratio. Only 3 (5.5%) subjects were from rural habitat. All belonged to middle socio economic status. Maximum (35 patients) were in the age group of 30-40yrs (63.64%). 9 patients (16.36%) had the chronicity of less than 3 years, 30 patients (54.55) had 3-6years chronicity and 16 (29.1%) had chronicity ranged between 6-9yrs.

Comparing the mean values of the assessment parameters between the groups, it was observed that mean difference in weight of two groups was 5.06, whereas Mean difference in BMI was 1.7. The mean difference of waist circumference was 3.75, whereas that of wait hip ratio was 0.0086.

Weight: The mean weight of subjects of group A got reduced by approximately 3.42kg. The mean weight of subjects of group B got reduced by approximately 0.55kg. Statistically the change in weight of group A is highly significant (p value 0.000).

BMI: The mean BMI of subjects of group A got reduced by approximately 1.34. Statistically the change in BMI is highly significant (p value 0.000). In group B the change was not significant.

Waist circumference: The mean Waist circumference of subjects of group A got reduced by approximately 2.08 cm. statistically the change is highly significant (p value 0.000).

Waist Hip ratio: The mean Waist Hip ratio of subjects of group A was 0.94 ± 0.09 , which reduced to 0.92 ± 0.09 after the intervention. The mean Waist Hip ratio of

subjects of group B was 0.95 ± 0.06 which was found 0.95 ± 0.06 after the intervention.

Statistically the change in weight of group A is highly significant (p value 0.000).

Table 1: Showing the descriptive statistics

Group	N	Weight		BMI		Waist Circumference		Waist Hip Ratio	
		BT	AT	BT	AT	BT	AT	BT	AT
A	24	82.79 \pm 9.25	79.37 \pm 9.73	33.31 \pm 2.47	31.97 \pm 2.69	104.25 \pm 10.9	102.17 \pm 10.97	0.94 \pm 0.09	0.92 \pm 0.09
B	31	87.85 \pm 10.76	87.30 \pm 10.98	35 \pm 2.75	34.76 \pm 2.77	108 \pm 8.03	107.77 \pm 8.22	0.95 \pm 0.06	0.95 \pm 0.06

DISCUSSION

The study was initiated with the objectives of evaluating the effect of guggulu in reducing the weight and waist circumference of obese patients and comparing it with the effect of dietary counseling. The trial began on 9th August 2013 continued for 8 months. Before treatment parameters of the subjects served as baseline values which were compared with the values obtained at the end of trial. Descriptive statistics and student's T test were employed for statistical evaluation.

The dose of guggulu quoted in Ayurvedic literature is 2-4 grams,^[15] hence 3gm per day was decided as the dose. Many physicians in GAMC, Mysore prescribe it in the same dose and so far no adverse events are recorded. Guggulu did not produce any significant changes in the pulse rate, body temperature and systolic/diastolic blood pressures, indicating that guggulu does not affect the sympathetic nervous system or thyroid function. Although the food intake was not quantitated, drug therapy appeared not to have an anorexient effect. Guggulu was not found efficacious in reducing the body weight and waist circumference in this trail. Since the trend of weight reduction was positive with mean reduction of approximately 0.5kg per month, the intervention may require longer duration or/with a higher dose. Guggulu in compound form viz, Navakaguggulu may produce better result.

Reduction in the intake of food is important component of dietary counseling. Other components of counseling are, advising less amount of carbohydrates, avoiding simples sugars, advising high protein high fibre diet with minimal fat and increasing the physical activity level. This study was carried with minimal invasion

hence only calorific reduction considered. The result was found highly significant. Many patients faced difficulty in following, but with stronger motive 24 subjects noticed significant reduction in their waist circumference and body weight.

CONCLUSION

24 subjects that followed the dietary guidelines showed remarkable improvements in reducing their weight and waist circumference. The subjects who received guggulu 3mg in the form of fine powder for 30 days did not showed weight reduction.

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