Research Article

www.ijrap.net (ISSN:2229–3566)

EFFECT OF TRIPHALA GUGGULU AND PUNARNAVA MANDOOR IN THE MANAGEMENT OF OBESITY: AN OBSERVATIONAL STUDY

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Received on: 17/07/20 Accepted on: 25/08/20

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DOI: 10.7897/2277-4343.1105144

ABSTRACT

Obesity has become an increasing global health problem among all socio-economic groups and leading to various complications like diabetes, cardiovascular diseases and osteoarthritis knee which are responsible for morbidity and mortality. Ayurvedic approach is to provide solution in managing rising cases of obesity among population. Aim of this study was to assess the clinical efficacy and safety of an Ayurvedic preparations Triphala guggulu and Punarnava mandoor in the management of obesity through clinical sign and symptoms, body mass index (BMI), measurement of abdomen, chest, thigh, arm circumference and laboratory investigation. The trial was conducted on 58 subjects aged between 12-60 years of both sexes of obesity. Triphala guggulu 1 g (2 tablets of 500 mg) and Punarnava Mandoor 500 mg (1 tablet of 500 mg) thrice daily with lukewarm water for 12 weeks were used in all study participants. Clinical sign and symptoms, BMI and circumference of body parts reduced from baseline to the end of the treatment in completed 47 subjects out of 58.

Keywords: Ayurvedic medicine, Triphala guggulu, Punarnava Mandoor, Obesity, Medoroga.

INTRODUCTION

Obesity is spreading globally, not limited to developed countries. It has emerged worldwide health problem in all socio-economic society. It is also an epidemic condition in United States and some European countries. Obesity is a harmful condition in which excess body fat has accumulated to an extent resulting a negative effect on health.[1] World Health Organization (WHO) had reported about 13% of the world's adult population (11% of men and 15% of women) were obese in 2016. It is estimated 40 million children under the age of 5 years were overweight or obese up to 2018. Numerous studies clearly showed an increase in mortality rate associated with Body Mass Index (BMI) of at least 30 kg/m^2. Individual with a BMI of at least 30 kg/m^2 have a 50-100% increased risk compared with individuals with BMI 20-25 kg/m^2, due to Cardiovascular disease. Raised BMI is a major risk factor for non-communicable diseases such as cardiovascular diseases, which were the leading cause of death in 2012, diabetes mellitus, osteoarthritis, some cancers. Childhood obesity is associated with a higher chance of obesity, premature death and disability in adulthood but in addition to increased future risks, breathing difficulties, increased risk of fractures, hypertension and early markers of cardiovascular disease (CVD), insulin resistance and psychological effects in obese children.[2] In 1997, The WHO expert consultation on obesity warned of an escalating epidemic of obesity that would put the populations of most countries at risk of developing non-communicable diseases (NCDs).[3] Basically, obesity and the risk of associated diseases to be associated with life style, changes in dietary pattern, physical activity levels, elated to increasing frequencies, malfunctioning of the thyroid, suprarenal, pituitary and testis. Excess intake of high calorific diet is the major auxiliary causes. In Ayurveda, Acharya Charaka has classified the drugs capable of removing fat under the group Lekhaniya mahakashaya (group of ten scarifying dravya) and other Ayurvedic texts also describe Sthaulya roga which is similar to obesity. Ayurvedic drugs have been attributed the properties of correcting the malfunctioning of the glands as well as playing a substantial role in the cure of obesity due to auxiliary causes.[4] Present work was conducted on a combination of Triphala guggulu and Punarnava Mandoor having anti-obesity properties as mentioned in Ayurvedic classical texts.[5-6] Although some studies resulted in initial weight loss but most of the obese patients eventually regained their weight and therefore an effective means to sustain weight loss is still a major challenge, therefore, a study was conducted by selected formulation Triphala guggulu and Punarnava Mandoor which reported having anti-obesity activity by using Kaphavata shamaka (pacifying Kapha and Vatadosha), Dipana (enhancing metabolic fire), Pachana (enhancing digestion) and Lekhana (therapeutic scrapping) properties. The contents of Triphala guggulu are mainly Rechana (a form of osmotic laxative), Deepaniya (promotes digestive and metabolism capacity) and Vata shamaka (pacifying vatadosha) properties and Punarnava Mandoor is Anulomana (mild purgative action), Mutrala (diuretic) and hepatoprotective.

MATERIAL AND METHODS

This is an observational study based on daily OPD practice on 58 patients of age 12-60 years with complaints of Kshudha vriddhi (frequent feeling of hunger), Trishna vriddhi (intense thirst), Ati-

nidra (excessive sleep), Swedadhikya (excessive sweating), Daurgandhya (bad odour), Alas (lazy), Angamarda (generalized body ache), Kshudra shwasa (mild dyspnoea on exertion), Gauravam (heaviness in the body), Daurbalya (weakness), Sandhiruja (pain in the joints), Sarvanga Shoola; raised abdomen, arm, thigh, chest circumference etc. The study was conducted at outpatient department of Central Ayurveda Research Institute, Mumbai for treatment. Present study was carried out in accordance with ethical principles by following international conference of Harmonization - Good clinical practices guidelines (ICP-GCP).

Primary and Secondary outcome measures

Primary outcome measure of study was to evaluate efficacy of Ayurvedic formulation Triphala guggulu and Punarnava Mandoor in the subjects suffering from Obesity (Medoroga or sthaulya) by assessing changes in BMI. The secondary outcome measures were to evaluate the changes in obesity clinical symptoms score, raised abdominal, arm, thigh, chest circumference and pathological investigations like serum cholesterol and serum triglycerides.

Trial interventions

Therapeutic combination of Triphala guggulu 1 gm (2 tablets of 500 mg) and Punarnava Mandoor 500 mg (1 tablet of 500 mg) thrice daily with lukewarm water were given to the participants for a period of twelve weeks. All the trial drugs were manufactured by a Good manufacturing practice certified company as per Ayurvedic Pharmacopoeia of India guidelines.

Inclusion criteria

Subjects of either sex, age between 12-60 years, having symptoms of Obesity (Medoroga or sthaulya) and those who are not taking any oral conventional drug were willing able to participate in the study for twelve weeks were included in the study.

Exclusion criteria

The subjects suffering from the complications of obesity like diabetes, hypopituitarism, muscular hypertrophy, Cushing syndrome and other endocrinology disorders, past history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke or severe arrhythmia in the last six months. Further, uncontrolled hypertension ($\geq$160/100 mm of Hg), prolonged ($\geq$ 6 weeks) medication with corticosteroids, antidepressants, anticholinergics, severe renal or hepatic disorders, pregnant and lactating woman were also excluded from the study.

Withdrawal Criteria

The subjects were free to withdrawn from the trial at any time without the permission of investigator or any reason. Further, the investigator could discontinue the subject if he / she develop any adverse effect or there is non-compliance of the treatment regimen (minimum eighty percentage compliances was essential to continue in the study). In these cases, the actions were taken to know the reason for the withdrawal and recorded in the case report form (CRF).

Study Procedures

On screening visit, voluntary written informed consent was taken. General and systemic examinations as well as bio-chemical investigation, clinical assessment as per obesity symptoms using the subject's answers were graded on a quantitative scale (0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = extreme) were assessed. Total 58 subjects who fulfilled the inclusion and exclusion criteria were enrolled in the study. All enrolled subjects were given a combination of Triphala guggulu 1 gm (two tablets of 500 mg) and Punarnava mandoor 500 mg (one tablet of 500 mg) thrice daily with lukewarm water for 12 weeks. Recruited subjects were advised to carry on their daily activities and exercises that they had been doing before the enrollment and also advised to continue the same till the end of study period. Obesity clinical symptoms were assessed using the subject's answers were graded on a quantitative scale (0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = extreme) and measurement of arm, chest, abdomen and thigh circumference at baseline and end of the 84th day. Safety laboratory investigations were also done at baseline and end of the 84th day. Patient's compliance was monitored by keeping a regular follow up of the patients by personal contact and telephonic communication. Subjects were advised to return empty containers of trial medicines on every follow-up visit in order to check the drug compliance. Any adverse event or Adverse Drug Reaction observed during treatment period if any, were documented and its appropriate and timely management were done and recorded in the CRF.

Follow-Up Assessment

Follow-up visits on day 14, day 28, day 42, day 56, day 70, and day 84. On each follow-up visit, patient's general and systemic physical examination was done. Assessment of the clinical symptoms of obesity by using of quantitative scale (0 = none, 1 = mild, 2 = moderate, 3 = severe and 4 = extreme) and measurement of arm, chest, abdomen, and thigh circumference were assessed. Pathological investigations such as serum cholesterol and serum triglycerides were performed at baseline and at the end of 84th day.

Statistical Analysis

The data on qualitative parameters has been represented as *n* (%) and on continues variable has been represented as mean and percentage. The data related to chief complaints was analyzed using Excel version 2019.

RESULTS

This study was conducted on 58 subjects. Out of these, 47 were completed the study and eleven were dropped out due to loss to follow up. The demographic data of 47 subjects are in (Table 1). Mean body weight is 78.08 kg, height 1.61 meter. No significant changes were observed at the end of treatment from baseline in any of the vital signs i.e. pulse rate, body temperature, respiratory rate, systolic and diastolic blood pressure.

Effect of treatment on outcomes measures

At baseline visit mean BMI was 29.91 kg/m^2; which was significantly reduced to 27.18 kg/m^2 after 84 days of treatment with these medicines (Figure 1). At baseline visit, mean circumference of abdomen was 105.61 centimeters (cm), which was significantly, reduced to 96.08 cm after 84 days of treatment with these medicines (Figure 2). At baseline visit mean circumference of chest was 100.07 cm, which was also significantly reduced to 96.51 cm after 84 days of treatment with these medicines (Figure 2). At baseline visit mean circumference of thigh was 57.05 cm, which was also significantly reduced to 55.30 cm after 84 days of treatment with these medicines (Figure 2).

Table 1: Demographic profile and baseline characteristics of study subjects (n = 47)

Variables	n (%)
Age (in years)	
12-20	03 (06.39)
21-30	07 (14.89)
31-40	10(21.28)
41-50	16 (34.04)
51-60	11 (23.40)
Gender	
Male	04 (08.51)
Female	43 (91.49)
Marital status	
Married	42 (89.36)
Educational status	
Illiterate	12 (25.53)
Read & write	35 (74.47)
Habitat	
Urban	45 (95.74)
Rural	02 (04.26)
Economic Status	
Above poverty Line	36 (76.60)
Below poverty line	11 (23.40)
Occupation	
Desk Work	06 (12.76)
Field work	09 (19.15)
House Wife	32 (68.09)
Dietary Habits	
Veg	17 (36.17)
Non-Veg	30 (63.83)
Built wise	
Heavy	33 (70.21)
Medium	14 (29.79)
Shareerika prakriti	
Pitta-Kaphaja	36 (76.60)
Vata-Pittaja	01 (02.12)
Vata-Kaphaja	10 (21.28)

Table 2: Effect of treatment on circumference of body parts in the subjects of Obesity (n = 47)

Region of the body (in Centimeter)	Start of the treatment (Mean)	End of the treatment (Mean)	Percentage of relief
Abdomen	105.61	96.08	9.02
Chest	100.07	96.51	3.55
Thigh	57.05	55.30	3.06
Triceps	33.02	31.78	3.75

Table 3: Effect of treatment on chief complaints in the subjects of Obesity (n = 47)

Clinical Symptoms	Start of the treatment (Mean)	End of the treatment (Mean)	Percentage of relief
Kshudha vridhi (frequent feeling of hunger)	04.00	02.07	48.25
Trishna vriddhi (intense thirst)	4.03	2.15	46.65
Swedadhikya (excessive sweating)	2.28	3.12	27.10
Daurgandhya (bad odour)	2.20	1.17	46.81
Ati-nidra (excessive sleep)	4.13	2.80	32.20
Hriddrava (palpitation)	4.13	1.81	56.17
Kshudra Shwasa (mild dyspnoea on exertion)	5.29	2.70	48.96
Angamarda (generalized body ache)	1.17	0.85	50.00
Gaurava (heaviness in the body)	03.00	1.31	56.33
Alas (laziness)	3.88	2.30	40.72
Daurbalya (Weakness)	2.5	1.28	48.80
Sandhiruja (pain in the joints)	4.8	2.69	43.95
Sarvanga Shoola (body ache)	4.61	2.34	49.24
Pipilakasancharvat vedana (tingling sensation)	4.2	2.03	51.66
Mutra krichhata (difficulty in urination)	0.85	0.46	45.88
Koshta baddhta (constipation)	1.50	0.66	56.00
Shaitya (feeling of coldness)	1.18	0.63	46.61

Table 4: Assessment of pathological and bio-chemical investigation (n = 47)

Laboratory Parameters	Start of the treatment (Mean)	End of the treatment (Mean)	Percentage of Relief
Serum cholesterol (mg/dl)	237.58	209.73	11.72
Serum Triglycerides (mg/dl)	151.13	131.15	13.22

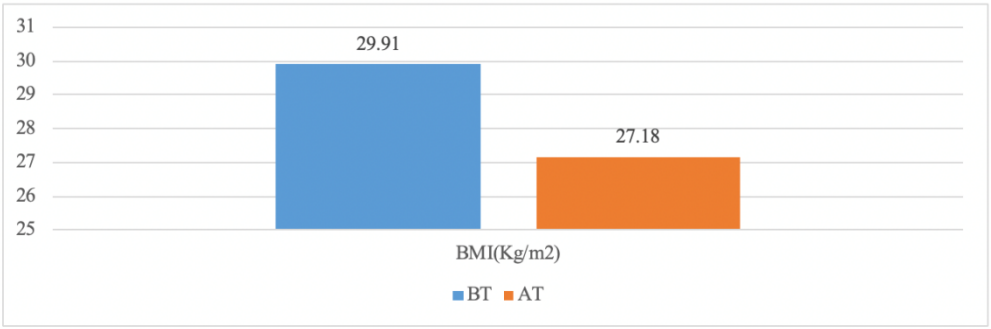

Figure 1: Effect of treatment on BMI in the subjects of Obesity (n = 47)

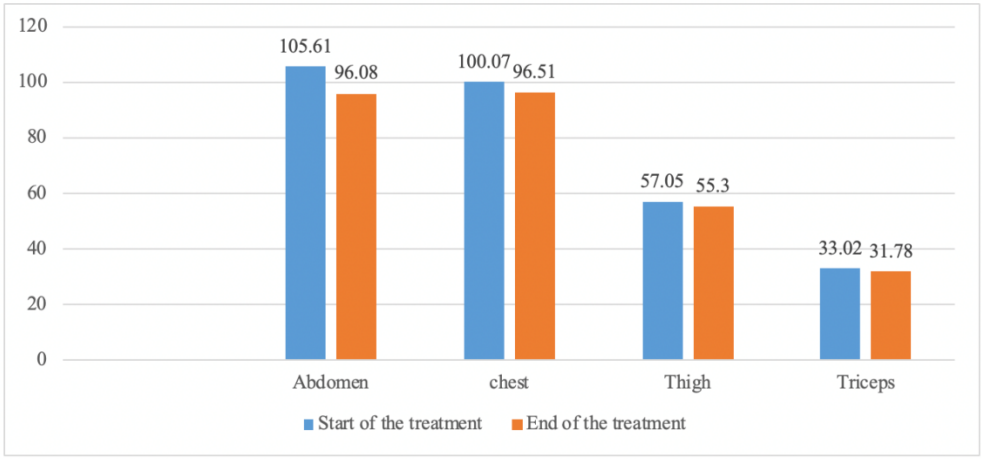

Figure 2: Effect of treatment on circumference of body parts in the subjects of Obesity (n = 47)

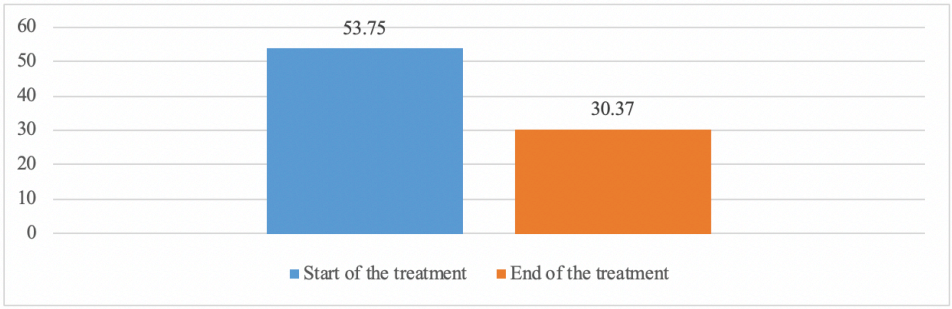

Figure 3: Effect of treatment on chief complaints in the subjects of Obesity (n = 47)

At baseline visit mean circumference of triceps was 33.02 cm, which was also significantly reduced to 31.78 cm after 84 days of treatment with these medicines (Figure 2). At baseline visit, the mean obesity clinical symptoms score was 53.75, which was significantly reduced 30.37 after 84 days of treatment with these medicines (Figure 3). The percentage of relief on chief complaints like Kshudha vridhi (frequent feeling of hunger) was 48.25%, Trishna vriddhi (intense thirst) 46.65%, Swedadhikya (excessive sweating) 27.10%, Daurgandhya (foul smell in body) 46.81%, Ati-nidra (excessive sleep) 32.20%, Hriddrava (palpitation) 56.17%, Kshudra shwasa (mild dyspnoea on exertion) 48.96%, Angamarda (generalized bodyache) 50.00%, Gauravam (heaviness in the body) 56.33%, Alas (laziness) 40.72%, Daurbalya (weakness) 48.80%, Sandhiruja (pain in the joints) 43.95%, Sarvanga Shoola (body ache) 49.24%, Pipilakasancharvat vedana (tingling sensation) 51.66%, Mutra krichhata (difficulty in urination) 45.88%, Koshta baddhta (constipation) 56.00% and Shaitya (feeling of coldness) 46.61% was observed in the trial participants. Pathological investigation such as serum cholesterol and serum triglycerides were changed significantly (Table 3).

DISCUSSION

Obesity is mentioned in Ayurvedic classics as Medoroga or sthaulya and it is as old as the history of mankind. Acharya Charaka described that continuous intake of causative factors aggravate Kaphadosha and Mala dhatus due to similar properties resultant its Meda obstruct the Srotas (functional channels) and produce the obesity. He had also described Sthaulya is the most hazardous amongst all the diseases.[7] Description of Medo roga remains a tremendous scope of research in the field of obesity. According to allopathic medicine, obesity increases the probability of various diseases and conditions, mostly CVD, diabetes mellitus, osteoarthritis knee, obstructive sleep apnea, certain types of cancer and depression.[8] The metabolism and endocrine glands is the functioning to create the obesity. It is a collection of disorders characterized by defective regulation of carbohydrate, lipids and protein metabolism. The most common cause of obesity is excess calorie intake coupled with physical inactivity. On the basis of studies, dysfunction of the leptin systems plays a role in human obesity. Basically, it is generated by a combination of excessive food intake, lack of physical activity, and genetic susceptibility. A limited caseis caused by genes, endocrine disorders, medications, or mental disorder.[9] The view that obese people eat little yet gain weight due to a slow metabolism is not medically supported.[10] Usually, the obese people have a greater energy expenditure than their normal counterparts due to the energy required to maintain an increased body mass.[11]

In Ayurveda, Nidana Parivarjana (avoidance of etiological factors), Kaphavata shamaka (pacifying Kapha and Vatadosha) and Lekhana (therapeutic scrapping), Guru (heavy food) and Apatarpana (depleting procedure) drugs mentioned for the management of obesity.[12] Studies was also suggested for the treatment of Sthaulya roga by drugs having Apatarpana and Lekhana karma properties.[13] The trial drug, Triphala guggulu contains Triphala (an equal quantity combination of Haritaki (*Terminalia chebula*), Vibhitaki (*Terminalia bellirica*), Amalaki (*Emblica officinalis*), Pippali (*Piper longum*) and Guggulu (*Commiphora wightii*). Triphala is promote proper digestion and absorption of food, decreased total cholesterol, triglycerides and low-density lipoprotein cholesterol, improve circulation, relax bile ducts, prevent immunosenescence, maintain homeostasis of the endocrine system and increase production of red blood cells and hemoglobin.[14-15] It is a potential therapeutic agent for weight loss and reduction of body fat.[16] Pippali (*Piper longum*) is Katu (pungent taste), Tikta rasa (bitter taste); Laghu (light to digest), Sara (instability), Tikshna guna (high property), Ushna veerya (hot potency), Madhura vipaka (sweet bio transformed), Kaphavata Shamaka (pacifying Kapha and Vatadosha) in their property and works against Kaphadosha and reduce the fat.[17] A study on Pippali suggests that Piperine gets absorbed very quickly across the intestinal barrier through the intracellular pathway. It may modulate membrane dynamics due to its easy partitioning, so helping in efficient permeability across the barriers andkeeps a lipid lowering effect and anti-obesity activity without any change in appetite.[18-19] Guggulu (*Commiphora wightii*) is Tikta (bitter taste), Katu rasa (pungent taste); Laghu (light to digest), Ruksha (dryness inducing), Vishada (clears channels), Sukshma (minute), Sara (instability); Katu vipaka (pungent bio transformed) and Ushna veerya (hot potency) in their properties.[20] It is best drug for obesity.[21] The second trial drug, Punarnava Mandoor works in above context by its effect on Srotas (functional channels) and Agni (digestive factors) by enhancing digestive capacity as a result of their Dipana (enhancing metabolic fire), Pachana (enhancing digestion) properties.[22] It is known to be effective in reducing belly and hip fat through reducing the basal metabolic rate and increases lipid metabolism in the body. Therefore, Triphala guggulu and Punarnava Mandoor mobilized Medo dhatu (fat tissue) from the body after Dhatu paka (transformation of Dhatu) and Medo dhatu was converted in to Purisha (faeces) and Mutra (urine) by Pachana of Meda (fat). Increase in Purisha and Mutra volume resulted in Srotoshuddhi (purification of channels) and Laghutva (feeling of lightness) in the body. Efficacy of the trial drug was due to the combined effect on Medo dhatu (fat tissue), Ama dosha (indigested substance), Dhatwagni (metabolic factors located in dhatu) and Jatharagni (metabolic factors located in digestive tract)[23] through Dipana, Pachana, Kaphavata Shamaka properties.

CONCLUSION

The present study data shows that Triphala guggulu and Punarnava mandoor provided significant relief in obesity (Medo roga or Sthaulya) in both the sexes. The study reveals that the selected management is potential to reduce symptoms of obesity (Medo roga or Sthaulya) with added advantage of being free from adverse reaction. There were some limitations in this study as no comparator group was taken to compare the efficacy of trial drug. In future study, these points will be taken into account.

ACKNOWLEDGEMENT

The Authors are thankful all the patients for the participation in the study. The Author (s) is also thankful to Director General, Nodal Officer, senior technical officers of CCRAS for support. All authors have no competing interest in the trial of drug.

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Cite this article as:

Anil Mangal *et al*. Effect of Triphala guggulu and Punarnava Mandoor in the management of obesity: An Observational Study. Int. J. Res. Ayurveda Pharm. 2020;11(5):71-76 http://dx.doi.org/10.7897/2277-4343.1105144

Source of support: Nil, Conflict of interest: None Declared