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EVALUATION OF ANTIOBESITY PROPERTIES OF AYURVEDIC INTERVENTION VACHA KUTAKI YOGA- "AN OBSERVATIONAL STUDY"

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ABSTRACT

Obesity has become an increasing global health problem among all socio-economic groups and leading to various complications like diabetes, cardio vascular diseases and osteoarthritis knee which are responsible for morbidity & mortality. Ayurvedic approach to pathogenesis of *medoroga* or *sthaulya* can provide solution in managing rising cases of obesity among population by using various preparations. *Vacha kutaki yoga* is one of such Ayurvedic preparations. An observational study was design with the aim to assess the clinical efficacy and safety of *Vacha kutaki yoga* in the management of obesity through clinical symptoms, Body Mass Index (BMI), measurement of abdomen, chest, thigh, arm circumference and laboratory investigation on 100 patients of obesity (*medoroga* or *sthaulya*). *Vacha kutaki yoga* 1 gm (two capsules of 500 mg) thrice daily with lukewarm water for 12 weeks were used in all study participants. Clinical symptoms, BMI and circumference of body parts reduced significantly from baseline to the end of the treatment in completed 84 subjects aged between 12-60 years of both sexes. This study demonstrated the effectiveness of *Vacha kutaki yoga* in the management of obesity (*medoroga* or *sthaulya*).

KEYWORDS: Ayurvedic medicine, *Acorus calamus, Medoroga*, Obesity, *Picrorriza kurroo*.

INTRODUCTION

Obesity is spreading globally; it is not limited to developed countries. It has emerged worldwide health problem in all socio-economic society. It 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 alarmed and reported that 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. It is an epidemic condition in United States and some European countries. Numerous studies clearly showed an increase in mortality rate associated with Body Mass Index (BMI) of at least 30 kg/m². Individual with a BMI of at least 30 kg/m² have a 50-100% increased risk compared with individuals with BMI 20-25 kg/m², due to Cardio vascular 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, malfunctioning of the thyroid, suprarenal, pituitary and testis. Excess intake of high calorific diets are the major auxiliary causes. In Ayurveda, Acharya charak has classified the drugs capable of removing fat under the group Lekhaniya mahakashaya. These drugs have been attributed the properties of correcting the malfunctioning of the glands in the modern sense as well as playing a substantial role in the cure of obesity due to auxiliary causes.^[4] Present work was conducted on Vacha kutaki yoga, a combination of two medicinal plants, Vacha (Acorus calamus Linn.) and Kutaki (Picrorrhiza kuroo Royle ex

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Benth.) having antiobesity properties as mentioned in Ayurvedic classical texts. 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 Vacha kutaki which reported having antiobesity activity by using dipana (enhancing metabolic fire), pachan (enhancing digestion) and lekhan (therapeutic scrapping) properties.

MATERIALS AND METHODS

This is an observational study based on day to day clinical practice on 100 patients of age 12-60 years with complaints of Kshudha vriddhi, Trishna vriddhi, Atinidra. Swedadhikya, Daurgandhya, Aalasaya, Angamarda, Kshudraswasa, Gaurav, Daurbalya, Sandhisula, Sarvangshoola; raised abdomen, arm, thigh, chest circumference etc. the study was conducted at outpatient department of Central Ayurveda Research Institute, Mumbai in accordance with Schedule Y of Drugs and Cosmetics Act, India and Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human participants, adopted from World Medical Association (WMA)-Declaration of Helsinki.

Trial interventions

Vacha kutaki yoga {Combination of equal quantity of Vacha (Acorus calamus Linn.) and Kutaki (Picrorrhiza kuroo Royle ex Benth.)} 1 gm (two capsules of 500 mg) thrice daily with lukewarm water were given to the participants for a period of twelve weeks. The trial drug was manufactured by a Good manufacturing practice certified company.

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 12 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 compliance 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.

Outcomes

Primary outcome measure of study was to evaluate efficacy of Ayurvedic formulation Vacha kutaki yoga 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 symptoms score, raised abdominal, arm, thigh, chest circumference and pathological investigations like serum cholesterol and serum triglycerides.

Study procedures

On screening visit, subject's 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 and then he/she was registered for the trial. Total 100 subjects who fulfilled the inclusion and exclusion criteria were enrolled in the study. All enrolled subjects Vacha kutaki powder 1 gm (two capsules of 500 mg) thrice daily with lukewarm water for 12 weeks were used in the study. 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) at baseline and end of the 84th day. Safety laboratory assessments were also done at end of the intervention period. Patients compliance was monitored by keeping a regular follow up of the patients by personal contact, telephonic communication. Subjects were advised to return empty containers of trial medicines on every follow-up visit in order to check the drug compliance. Subjects visited for 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 systemic physical examination was done. Assessment of the clinical symptoms of obesity by using VAS score. Pathological investigations such as serum cholesterol and serum triglycerides were performed at baseline and at the end of 84th day. 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 CRFs.

Statistical analysis

The analysis of the data using statistical software SPSS 15.0 data describing quantitative measures are expressed as median or mean \pm SD or SE or the mean with range. Qualitative variables are presented as counts and percentage.

RESULTS

This study was conducted on 100 subjects. Out of these, 84 were completed the study and 16 were dropped out due to loss to follow up. The demographic data of 84 subjects are in [Table-1]. Mean body weight is 79.15 kg, height 1.63 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.

Treatment outcomes

At baseline visit mean BMI was 29.65 kg/m², which was significantly reduced to 28.63 kg/m² after 84 days of treatment with these medicines [Graph 1]. At baseline visit, mean circumference of abdomen was 91.43 centimeters (cms), which was significantly, reduced to 86.40 cms after 84 days of treatment with these medicines [Graph 2]. At baseline visit mean circumference of chest was 87.14 cms, which was also significantly reduced to 85.13 cms after 84 days of treatment with these medicines [Graph 2]. At baseline visit mean circumference of thigh was 45.95 cms, which was also significantly reduced to 44.24 cms after 84 days of treatment with these medicines [Graph 2]. At baseline

visit mean circumference of triceps was 28.75 cms, which was also significantly reduced to 27.79 cms after 84 days of treatment with these medicines [Graph 2]. At baseline visit, the mean obesity clinical symptoms score was 58.36, which was significantly reduced 32.00 after 84 days of treatment with these medicines [Graph 3]. The percentage of relief on chief complaints like Kshudha vridhi (polyphagia) was 40.92%, Trishna vriddhi (polydypsia) 43.96%, Swetadhikya (excessive sweating) 43.80%, *Daurgandhya* (foul smell in body) 50.19%, Ati nidra (excessive sleep) 43.92%, Hriddrava (palpitation) 47.20%, Kshudra swasa (Dysponea on exertion) 50.00%, Angamarda (Fatigue) 35.51%, Gaurava (feeling of heaviness) 47.64%, Alasva (laziness) 46.30%, Daurbalya (weakness) 48.85%, Sandhisula (joints pain) 40.51%, Sarvangashool (body ache) 42.32%, Pipilaka sancharvat vedana (tingling sensation) 50.47%, Mutra krichhata (difficulty in urination) 48.35%, Constipation 41.57% and Shaitya (feeling of coldness) 45.31% was observed in the trial participants. Pathological investigation such as serum cholesterol and serum triglycerides were changed significantly [Table-3].

Table-1: Demographic profile and baseline characteristics of study subjects (n = 84).

Variables	N (%)			
Age (in years)				
12-20	04 (04.77)			
21-30	15 (17.86)			
31-40	28 (33.34)			
41-50	27 (32.15)			
51-60	10 (11.91)			
Gender				
Male	08 (09.53)			
Female	76 (90.48)			
Marital status				
Married	68 (80.96)			
Educational status				
Illiterate	12 (14.19)			
Read & write	72 (85.72)			
Habitat				
Urban	64 (76.19)			
Rural	20 (23.81)			
Economic Status				
Above poverty Line	49 (58.34)			
Below poverty line	35 (41.67)			
Occupation				
Desk Work	18 (21.43)			
Field work	22 (26.19)			
House Wife	44 (52.38)			
Dietary Habits				
Veg	26 (30.96)			
Non-Veg	58 (69.05)			
Built wise				
Heavy	60(71.60)			
Medium	24(28.40)			
Sharirika prakriti				

Pitta-Kaphaja	56 (66.66)
Vata-Pittaja	06 (7.14)
Vata-Kaphaja	22(26.19)

Table 2: Effect of treatment on circumference of body parts in the subjects of obesity (n=84).

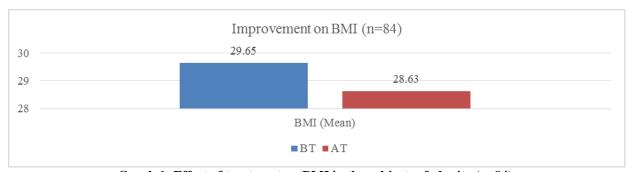
Region of the body (in Centimeter)	Start of the treatment (Mean)	End of the treatment (Mean)	Percentage of relief
Abdomen	91.43	86.40	5.50
Chest	87.14	85.13	2.30
Thigh	45.95	44.24	3.72
Triceps	28.75	27.79	3.33

Table 3: Effect of treatment on chief complaints in the subjects of obesity (n=84).

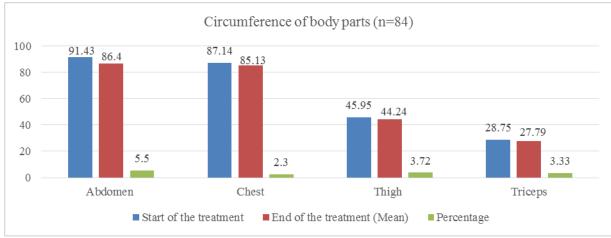
Clinical Symptoms	Start of the treatment (Mean)	End of the treatment (Mean)	Percentage of relief
Kshudha vridhi (Polyphagia)	3.47	2.05	40.92
Trishna vriddhi (Polydypsia)	3.98	2.23	43.96
Swetadhikya (Excessive sweating)	4.84	2.72	43.80
Daurgandhya (Foul smell in body)	2.55	1.27	50.19
Ati nidra (Excessive sleep)	4.03	2.26	43.92
Hriddrava (Palpitation)	3.75	1.98	47.20
Kshudra swasa (Dysponea on exertion)	4.58	2.29	50.00
Angamarda (Fatigue)	2.14	1.38	35.51
Gaurava (Feeling of heaviness)	5.10	2.67	47.64
Alasya (Laziness)	4.19	2.25	46.30
Daurbalya (Weakness)	3.48	1.78	48.85
Sandhisula(Joints pain)	4.69	2.79	40.51
Sarvangashool (Body ache)	4.30	2.48	42.32
Pipilaka sancharvat vedana	3.17	1.57	50.47
(Tingling sensation)	5.17	1.57	50.47
Mutrakrichhata (Difficulty in urination)	0.91	0.47	48.35
Koshtabadhata (Constipation)	1.90	1.11	41.57
Shaitya (Feeling of coldness)	1.28	0.70	45.31

Table 4: Assessment of pathological and bio-chemical investigation (n=84).

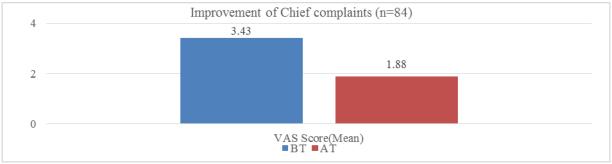
Laboratory Parameters	Start of the treatment (Mean)	End of the treatment (Mean)	Percentage of Relief
Serum cholesterol (mg/dl)	318.33	226.85	28.73
Serum triglycerides (mg/dl)	163.18	140.40	08.06



Graph 1: Effect of treatment on BMI in the subjects of obesity (n=84).



Graph 2: Effect of treatment on circumference of body parts in the subjects of obesity (n=84).



Graph 3: Effect of treatment on chief complaints in the subjects of obesity (n=84).

DISCUSSION

Obesity is mentioned in Ayurvedic classics as Medoroga or sthaulya and it is as old as the history of mankind. Description of *Medoroga* remains a tremendous scope of research in the field of obesity. Acharya charak described that continuous intake of causative factors aggravate kapha dosha and mala dhatus due to similar properties resultant its meda obstruct the srotas and produce the obesity. He has also described Sthaulya is the most hazardous amongst all in Ashtauninditeeya chapter in their text. [6]

According to modern 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.^[7] 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 cases are caused by genes, endocrine disorders, medications, or mental disorder. [8] The view that obese people eat little yet gain weight due to a slow metabolism is not medically supported. [9] Usually, the obese people have a greater energy expenditure than their normal counterparts due to the energy required to maintain an increased body mass.^[10]

In Ayurveda, the first line of management in Sthaulya or Medoroga is Nidana parivarjanam (avoidance of causative factors). Vata-kapha shamak and lekhan drugs mentioned for the management of obesity. [11] Vacha and kutaki mobilized medodhatu from the body after dhatupaka. Medodhatu was converted in to mala (faeces) and mutra (urine) by pachan of meda. Increase in mala and mutra volume resulted in srotosuddhi (purification of channels) and *laghutwa* (lightness) in the body. These drugs have deepen (appetizer), pachan (digestive), lekhan (scraping) properties. Ayurveda has also suggested the treatment of sthaulya roga by drugs having Apatarpana and lekhan karma properties. [12] Efficacy of the trial drug was due to the combined effect of medodhatu, amadosha, dhatagni and koshthagni. The ingredients of Vacha (Acorus calamaus Linn) have katu, tikta rasa; laghu, sara, tikshna guna; ushna veerya; katu kaphavata shamaka, Akash-Vayu-Agni vipaka; mahabhoot pradhan properties. [13] These properties work against kapha, and resultant is reduced fat. Kutaki (Picrorrhiza kurroo) havings katu, tikta rasa, laghu, ruksha guna, sheeta virya, katu vipaka and kapha pitta shamaka properties. [14, 15] It is effective for dissolving the excess fat which was accumulate around the liver and gastro intestinal tract. [16] Both the ingredients of Vacha kutaki yoga are the member of Lekhniya mahakashaya (a

group of scraping drugs), which was specially designed for *lekhan karma* (scraping properties). [17] *Lekhan* property (scraping) is useful in removing any blockage in micro vessels as well as macro vessels. 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 in to account.

CONCLUSION

The present study data shows that *vacha kutaki yoga* provided significant relief in obesity (*medoroga* or *stahulya*) in both the sexes. The study reveals that the selected management is potential to reduce symptoms of obesity (*medoroga* or *sthaulya*) with added advantage of being free from adverse reaction.

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