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EVALUATION OF EFFICACY OF KARSHANIYA YAVAGU (AN AYURVEDIC PREPARATION) IN MANAGEMENT OF OBESITY

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ABSTRACT
Obesity is the most common metabolic disorder in affluent societies caused by excessive eating, lack of exercise and is a direct result of the modernization combined with lifestyle changes. It is the main underlying cause of life threatening diseases like Diabetes mellitus, Hypertension, Angina Pectoris, and Myocardial Infarction etc. In this study 60 patients were divided in two groups namely A and B. Group A was given Karshaniya Yavagu and Group B was given Placebo (Starch capsule) for 90 days in the OPD of Govt. Ayurved College, Nanded. Comparison of total effect of therapy on weight between two groups was statistically evaluated by chi square test. The Chi square value was 11.831 p<0.05, which was higher than the table value 7.82 (df=3) which suggested that there was significant difference between two groups.

Keywords: Obesity, Sthaulya, Karshaniya Yavagu, Gavedhuka,

INTRODUCTION
The obesity is almost invariably in the developing countries and is the burning question in the same and also developed ones. The world health organization (WHO) also acknowledges that obesity is a worldwide problem[1]. Nowadays scientific technology is markedly developed hence the human being are highly sensitive. A change in life styles creates several different types of health problems including physical, mental, economical and social. The advancement of industrialization and communication is contributing towards sedentary life style, in turn causing chronic non communicable diseases like Diabetes mellitus, Hypertension, Cancer, Ischemic heart disease, Cerebrovascular accidents, Atherosclerosis, Varicosity etc[2].

Obesity is the final common pathway of a complex array of genetic, physiological, nutritional, psychological and cultural influences. Among these social and cultural factors are perhaps the most ubiquitous, social and psychological consequences of obesity include stigmatization and discrimination, down word social mobility, decreased work capacity and dramatic economic losses.

Obesity is a major health problem. It is extremely difficult to assess the size of the problem and compare the prevalence rates in different countries, as no exact figure is available. However it has been estimated to affect 20-40% of adult and 10-20% of children and adolescents in developed countries. A study conducted in Delhi shown that approximately 25% of populations are obese in urban areas[3].

Ayurvedic classics give sufficient focus on obesity (*sthaulya* or *medoroga*) and serves as a guideline to advise diet, etc. present or to control the disease. Present work was conducted on Karshaniya Yavagu having antiobesity properties as mentioned in Ayurvedic classical text Charak Samhita[4].

Objective
The primary objective of the study was to evaluate the efficacy of Karshaniya Yavagu in diagnosed patients of Obesity having age group between 30 to 50 yrs.

MATERIAL AND METHODS
Plant Material
Dried grains of *Coix lacryma-jobi*. (Gavedhuka) mentioned in ayurvedic texts[5] were collected from local market of Nanded, Maharashtra. This raw material was authenticated in the Pharmacognosy Laboratory and Standardized at Drug Testing laboratory, Government Ayurved College, Nanded. Results obtained are compiled in Table 1.

Table 1: Analysis report of *Coix lacryma jobi*. (Gavedhuka)

Testing parameter	Standards	Results
Moisture	10.1-11.3%	10.80%
Mineral matter	0.07-0.99%	0.80%
Ether extract	3.1-3.8%	3.20%
Protein	10.3-12.1%	11.20%
Carbohydrate	72.7-74.3%	73.40%
Fiber	0.29-0.32%	0.30%
Calcium	0.005-0.006%	0.005%
Phosphorus	0.3-0.5%	0.40%
fat	3-4%	3.20%

Drug Preparation (Karshaniya Yavagu)
One part Gavedhuka was taken and roasted on a dry pan for 5 minutes. Then 6 parts of water was poured in a pot and Gavedhuka was added to it. The mixture was allowed to boil for 30 minutes and cooled up to room temperature. Then 5 ml Madhu was added and used as a drug in experimental group[6].

Sample Size Calculation
Sample size calculation was based on the assumption that a sample size of 60 cases would provide a 90% power to detect mean change in frequency of growth per fortnight at 5% level of significance.

Institutional Ethics Committee Approval and Regulatory Compliance

Before the initiation of the study, the study protocol and related documents were reviewed and approved by Institutional Ethics Committee at Govt. Ayurved College and Govt. Ayurved hospital, Nanded, Maharashtra.

Patients Screening and Recruitment

Patients presenting with the signs and symptoms of obesity were selected from OPD or IPD of Government Ayurved College, Nanded, Maharashtra. Detailed past history and present illness as well as medical history was taken to rule out any existing disease. In order to include the subjects having overweight, examinations like weight, BMI, waist circumference, hip circumference, waist hip ratio were carried out at screening.

Before including each subject was informed regarding disease and its available management as well as the medicine (Karshaniya Yavagu).

Inclusion Criteria

1. Patients of either sex having age between 30 to 50 years
2. Patients having B.M.I. more than 25

Exclusion Criteria

1. Patients below 30 years, and above 50 years.
2. Patients having severe cardiac anomalies.
3. Pregnant and lactating women.
4. Obesity produced due to certain secondary causes,
5. Drug induced obesity,
6. Hereditary indisposition
7. Patient suffering from any other grave disease also excluded.
8. Endocrinal origin obesity excluded.
9. Diabetic patient excluded.
10. Patient doing exercise will be excluded.

Study procedure

60 clinically diagnosed patients were randomly divided into 2 groups namely Group A and B.

Group-A (Experimental group, n=30) – These patients were given Karshaniya Yavagu, along with low calorie diet.

Dose – 2 pala = 80 ml.

Time of administration – early morning - empty stomach

Group–B (Control group, n=30) – These patients were given starch capsule (500mg) along with the low calorie diet.

Dose – 1 capsule once a day.

Time of administration – early morning - empty stomach

At the screening visit, following written informed consent, obese patients were considered for study. Patients were assessed and evaluated on the basis of objective and subjective parameters at interval of 30 days for 3 months. All the patients were given simple and light food. Patients were followed up after 4th, 8th and 12th week. Laboratory investigations were repeated after treatment.

Parameters of Assessment

Assessments of the patients were done on basis of following parameters.

1. Weight
2. BMI (BMI = weight (kg)/Height (m)^2
3. Waist circumference.
4. Hip circumference

5. Waist Hip ratio

Statistical Analysis

The data collected from the CRF were then subjected to demographic and statistical analysis. Paired and Unpaired 't' test was applied to the data generated. The 't' test, probability, co-relations, demography, sampling, graphical presentations and other statistical methods were applied to find out the significance of the improvement.

RESULTS

Of the 78 screened patients, 18 did not meet the inclusion criteria and hence were not included in the trial. All patients completed the study. No patient was dropped out or withdrawn due to the adverse event or an adverse reaction. Study treatment did not cause any significant change in vital signs like pulse rate, body temperature, respiratory rate, and the blood pressure. Of 60 patients included in the trial, 20 (33.33%) were men while 40 (66.67%) were women and the mean age was 41.59 + 12.43 years. Patients included in the trial range from 30 years to 50 years of age. Patients from Age group 40-44 yrs (30%) and 45-50 yrs (26.67%) shows more prevalence. Out of 60 patients of obesity 14 (23.33%) patients were vegetarian and 46 (76.67%) patients consuming mixed diet. Consumption of heavy, oily food is causative factor of obesity. Most of the patients were non vegetarian (i.e. Mixed diet) so this data can support the responsible diet factor of obesity. Of 60 patients of obesity 15 patients (25%) were of Vata-Kapha Prakruti, 31 (51.67%) patients were of Kapha-Pitta Prakruti, and 14 (23.33%) patients were of Vata-Pitta Prakruti. It can be suggested that Kapha Pradhan Prakruti is more prone for obesity. Out of 60 patients of obesity, 14 (23.33%) Patients were found with Manda Agni, Vishama Agni was found in 16 (26.67%) patient. And there were 30 (50%) of Tikshna Agni. This can be concluded that due to Tikshna Agni patient eats more ultimately causing obesity.

Mean weight in the patients of experimental group at baseline visit (Day 1) was 71.55 ± 09.71 and it decreased moderately to 69.92 ± 09.46 after 12th week. Also mean weight of control group patients was 70.83 ± 07.74 at baseline visit and it remains almost unchanged at the end of 12th week decreased i.e. 70.45 ± 07.79. Mean BMI in patients of experimental group at baseline was 29.68 ± 2.34 which was decreased moderately to 28.99 ± 2.10 whereas mean BMI in patients of control group at baseline was 28.15 ± 2.28 which was decreased moderately to 28.99 ± 2.10.

Mean waist circumference in experimental group at baseline was 97.83 ± 10.69 which was decreased moderately to 96.13 ± 10.33 whereas Mean BMI in patients of control group at baseline was 97.2 ± 9.96 which was decreased moderately to 97± 10.03. Mean hip circumference in experimental group at baseline was 104.7 ± 9.21 which was decreased moderately to 103.66 ± 8.86 whereas Mean BMI in patients of control group at baseline was 100.63 ± 6.37 which was almost unchanged at the end of 12th week i.e. 100.37 ± 6.33. Mean waist hip ratio in experimental group at baseline was 0.93 ± 0.07 which was decreased slightly 0.92 ± 0.07 whereas mean waist hip ratio of control group at baseline was 0.96 ±

0.06 which was almost unchanged at the end of 12th week i.e. 0.96 ± 0.06.

All parameters at baseline and end of study were evaluated for both the groups and results found are summarized in Table 2 and 3.

After comparing results of both study groups it was found that Experimental drug revealed mild effective results over placebo group which are concluded in Table 4 and 5.

Table 2: Effect of Karshaniya Yavagu in Experimental group (Group A)

Parameter	Mean	SD	SE	t	t_{table}	P
Weight	1.63333	1.59129	0.29052	5.62191	2.05	P<0.05
BMI	0.68933	0.71656	0.13082	5.26907	2.05	P<0.05
Waist Circumference	1.66666	1.57762	0.28803	5.78637	2.05	P<0.05
Hip Circumference	1.03333	1.3034	0.2379	4.3422	2.05	P<0.05
W/H Ratio	0.00666	0.00758	0.00138	4.81663	2.05	P<0.05

Table 3: Effect of Placebo drug in Control group (Group B)

Parameter	Mean	SD	SE	t	t_{table}	P
Weight	0.38333	1.13474	0.20717	1.85028	2.05	P>0.05
BMI	0.14733	0.46252	0.08444	1.74471	2.05	P>0.05
Waist Circumference	0.2	0.88668	0.161885	1.23544	2.05	P>0.05
Hip Circumference	0.2666	0.52083	0.09509	2.8043	2.05	P>0.05
W/H Ratio	0.00076	0.00656	0.00119	0.63925	2.05	P>0.05

Table 4: comparison between experimental and placebo group results

Parameter	Mean of Diff.	Comb. SD.	SE	t	t_{table}	P
Weight	1.25	1.90993	0.49314	2.53476	2.00	P<0.05
BMI	0.5420	0.36369	0.09390	5.77169	2.00	P<0.05
Waist Circumference	1.46666	1.63754	0.42281	3.46883	2.00	P<0.05
Hip Circumference	0.76666	0.985076	0.25434	3.01427	2.00	P<0.05
W/H Ratio	0.0059	0.00647	0.00167	3.7515	2.00	P<0.05

Table 5: Total Effect of Therapy on weight in 60 patients of Obesity

Sr. No.	Total Effect of Therapy on Weight	Total effect of therapy on weight					
		Experimental		Control		Total	
		No. of patients	%	No. of patients	%	No. of patients	%
1	Marked effective (Wt. Loss above 10%)	01	03.33	0	00.00	1	01.66
2	Moderate Effective (Wt. Loss above 5%)	01	03.33	0	00.00	1	01.66
3	Mild effective (Wt. Loss effective 5%)	24	80.00	14	46.67	38	63.33
4	No effect	04	13.33	16	53.33	20	33.33

DISCUSSION

Obesity is a chronic disease, prevalent globally among the affluent and sedentary subjects and affects the young and old equally. The prevalence of obesity is increasing worldwide, and becoming a major health problem in developed as well as developing countries. The incidence of childhood obesity is also a rising problem in front of us. Now a day people have no time to give attention for their health. Life style is changing rapidly and life become very fast and busy. Excessive use of fast food, faulty dietary habits, lack of exercise, mental stress and strain, all these have become major part of life style which are responsible for many types of Grave diseases, obesity is one of them. Obesity is not like other disease which shows symptoms in primary stage. That is why it is generally ignored until it becomes the cause of other diseases[7].

After observing the Table no. 4, it can be clearly reveal that significant improvements was observed in all the experimental group; Placebo group show no improvement. When both groups were compared the results found are noted below.

Weight - it was found that the total difference of mean was 1.25 with unpaired 't' value was 2.53 which was higher than the value given in the table at p<0.05 significance level, hence the drug of Experiment was more effective than the drug of control group(df=58).

BMI - it was found that the mean difference was 0.54, with unpaired t' value was 5.77, which was higher than the value given in the table at p<0.05 significance level (df=58), hence, drug of experimental group was more effective than the drug of control group.

Hip Circumference - it was found that, the mean difference was 0 .77, with Unpaired "t' value was 3.01, which was higher than the table value at p<0.05 significance level (df=58) .hence the drug of experiment group was more effective than the drug of control group.

Waist-Hip Ratio - it was found that the mean of difference was 0.0059, and unpaired 't' value was 3.7515, which was higher than the value given in the table at p<0.05 level of significance(df=58), Hence the drug of Experimental group was effective than the drug of control group.

Although the sample size is small, the present study is directs towards the effective treatment of obesity and controlling its complications through Ayurveda. Thus Karshaniya yavagu can be suggested as adjuvant to main line treatment of obesity.

CONCLUSION

Based upon the results of the study displayed in the form of tables and graphs and critically discussed in the previous chapter, the following conclusions are drawn –

- Obesity is more common in female gender (66.67%).
- Patients of age group 40-44 years (30%) are more prone to weight gain.
- The present study shows higher incidence of obesity in individuals taking mixed kind of diet (91.67%).
- It is observed that Weight, Body Mass Index, Waist Circumference, Hip Circumference, and Waist to Hip ratio of experimental group shown significant results, but in control group Hip Circumference was significant. Weight, BMI, Waist Circumference and Waist–Hip Ratio shown insignificant results.

After comparing the results of both groups it is concluded that experimental group has shown the significant result over control group. Hence the drug in the experimental group has shown significant effect than drug in the control group. The study is a step in the series of developments in the field of Ayurveda to find satisfactory solutions in the treatment of obesity. It is on the horizon of hopes that researchers of future era may undertake the management of obesity by "Kashaniya Yavagu", on the basis of more sophisticated ultra modern parameters. So that physicians of coming era definitely will render helping hand to the crippled mankind suffering from obesity. However I do not claim the outcome credited through my work is a milestone in the field of research. But my sincere efforts have a beam of ray in the field of research particularly in Ayurveda.

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