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Clinical Evaluation of Obenyl Tablet in the management of Obesity

Dnyaneshwar Mote¹, Lata Kide²

¹Principal Investigator, ²Co-Investigator, Vidnyanam Clinic, Katraj-Kondhwa Road, Katraj, Pune, Maharashtra, India.

ABSTRACT

Obesity, defined as abnormal or excessive fat accumulation, which may impair health, is measured by body mass index (BMI) $\geq 30 \text{ kg/m}^2$. In the Asian population, the BMI cut-off of obesity is lower ($\geq 27.5 \text{ kg/m}^2$).^[1] Prevalence rate of Obesity across the globe is alarmingly increasing, irrespective of geographical areas, race, sex and age. Obesity is associated with increased risk of morbidities such as systematic inflammation, insulin resistance, and lipid abnormalities, leading to various non-communicable diseases, including cerebrovascular and cardiovascular diseases and cancer.^[2] To overcome such major concern and address this issue with safer and herbal solution Charak Pharma Pvt. Ltd's, Obenyl Tablet was taken for this Clinical Evaluation study. The study was done on 113 patients with BMI in between 28 to 40. The study is open labelled controlled single arm study. Participants were given Obenyl tablet and allowed to consume regular diet. The study shows Excellent - 20.51% (15 patients), Good - 38.93% (30 patients), Fair - 28.31% (22 patients), Failure - 12.82% (10 patients). Study shows Mean Weight Loss of 3.33Kg at the end of the study. The present study showed the therapeutic results on Completion of 120th Day in comparison to 0 Day, as Obenyl Tablet has showed 87.18% good results.

Key words: Obesity, Sthaulya, Over weight, accumulation of fat, Obenyl Tablet, Ayurveda.

INTRODUCTION

The importance of obesity requires constant emphasis, not only because of excess mortality it carries, but also because of numerous complications & the predisposition it creates to the common & potentially serious conditions such as diabetes mellitus, cardiac disorders etc.^[3] It reduces the efficiency of those affected, it detracts from their ability to participate in many normal activities & it is frequently associated with emotional & other psychological disturbances, all of which may interfere in major way with the wellbeing

of an individual, a family or a community.^[4]

Definition of obesity

Obesity can be defined as an abnormal accumulation of fat in the stores of adipose tissue throughout the body. Obesity represents an accumulation of energy in excess of requirements & that weigh reduction can be achieved only by reducing every intake, by increasing output or by a combination of the two.^[5]

Causes of obesity

1. Genetic & environmental factors (dietetic habits & economic factors)
2. Appetite & feeding pattern (consumption of more calories than required)
3. Less physical activities.
4. Endocrinal factors - Cushing's syndrome, Adrenocortical hyperfunction, Hypothyroidism.
5. Genetical factors - No above-mentioned factors could be held to be responsible for obesity.^[6]

Address for correspondence:

Dr. Dnyaneshwar Mote

Principal Investigator, Vidnyanam Clinic, Katraj-Kondhwa Road, Katraj, Pune, Maharashtra, India.

E-mail: regulatory@charak.com

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Complications of obesity

- Flat feet & Osteoarthritis of knee joint, hip joint & lumber spine.
- Abdominal & diaphragmatic hernias.
- Varicose vein.
- Skin infection around folds of skin & axilla.
- Hyperlipidaemia.
- Cholelithiasis.
- Diabetes mellitus.
- Cardio vascular disorders: Hypertension, coronary atherosclerosis & angina pectoris. Obesity which is not a disease entity in itself but which is cause of hundreds of diseases has become fairly common nowadays. It is also accompanied by risks of early death, hypertension, heart diseases, diabetes etc.^[7]

Ayurveda has prescribed three ways of managing obesity they are diets, deeds & drugs. bearing this in mind it was decided to see effect of herbal Obenyl tablet, in cases of obesity, free from other major illness like Diabetes, Heart diseases etc.

MATERIALS AND METHODS

Total number of 113 patients were selected for the study, out of which 78 patients could complete the study & 35 cases were dropped out. The patients between age group 18-60 yrs. were included in the present study. The patients of both sexes were included in the study. The duration of the study was for 16 weeks.

Dosages of the Medicines

Test Drug was given as 2 tablet 3 times a day with luke warm water. Each tablet contains 500 mg of herbal ingredients.

Diet advice: Patients were kept on low calorie & fat free regular diet.

Criteria for selection of patients

Obese people have high risk of mortality or suffering serious illness. Most data, which relate the level of

fatness to total mortality shows that the risk of mortality starts to increase, appreciably when BMI is above 40.^[8] The definition of obesity in Asian population is BMI in between 28 to 40.^[9]

Category: BMI (Body Mass Index)

- Acceptable range : 20-24
- Overweight : 25-29
- Obesity : 30-40
- Extreme obesity : More than 40

Body mass index (BMI) : $\text{kg}(\text{weight})/\text{m}^2(\text{height})^{[10]}$

Patients with BMI in between 28 to 40 were selected for the present clinical study.

The obese patients with diabetes mellitus were included in present study. Patients with known history of and suffering from Cardiac Disorders, Hypertension and Endocrinal disorders like Cushing’s syndrome, adreno-cortical hyper function & hypothyroidism were excluded from the study.

All patients were called for monthly follow up for 4 months. Each patient’s Anthropometric Data like body weight, BMI, Waist Circumference, Hip Circumference, Mid-Thigh Circumference and Mid Arm Circumference were recorded Day 0, 30, 60, 90 and 120.

Table 1: Sex wise distribution of patients

Sex	No. of patients	Percentage
Male	33	42.30%
Female	45	57.69 %

Note: - It can be noted that Obesity sex-wise is more common among females.

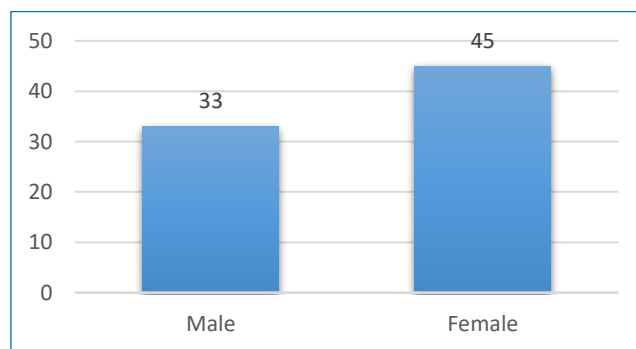


Table 2: Age wise distribution of patients

Age Group	No. of patients	Percentage
18-20	3	3.85%
21-30	7	8.97%
31-40	16	20.51%
41-50	27	34.62%
51-60	25	32.05%

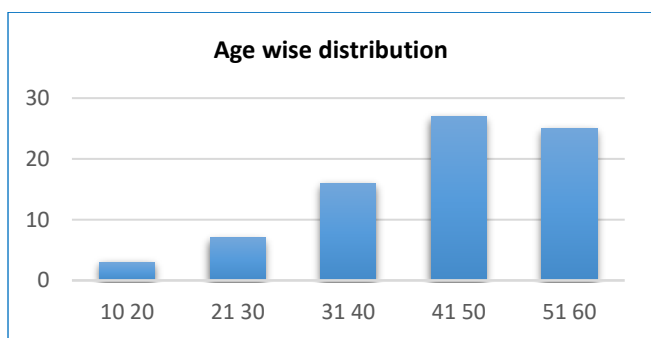
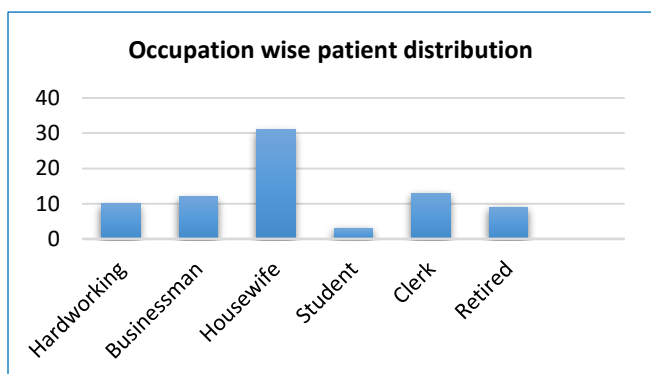


Table 3: Occupation wise distribution of patients

Occupation	No. of patients	Percentage
Hard working	10	12.82%
Businessman	12	15.38%
House-wife	31	39.74%
Student	3	3.85%
Clerk	13	16.66%
Retired	9	11.53%



Statistical Analysis

Data is presented and expressed as Mean ± Standard Deviation, Percentile range. The Baseline Values Were Compared with Follow up Values using ANOVA. <0.05 P value was considered criteria for Level significance.

OBSERVATION

Table 4: Patients with Test medicine showed following overall response.

SN	Response to Treatment	No. of Patients	% of Patients
1.	Excellent	15	20.51
2.	Good	30	38.21
3.	Fair	22	28.21
4.	Failure	10	12.82
5.	Adverse Effect	0	0

As per data collected at the end of study as 87.18% of patients with Obenyl Tablet showed good results.

While 12.82 % of patients showed 15.38% minimum or no results.

No patient had any untoward effects.

Presentation in Figure of Observation and Test Results

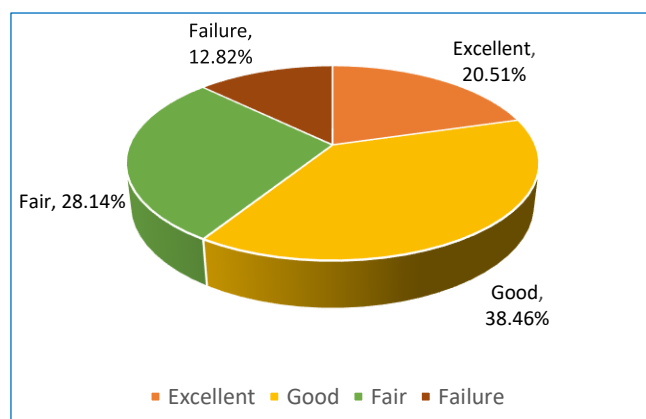


Table 5: Effect of Obenyl Tablet on Anthropometric Variables

Anthropometric variables	Day 0	Day 30	Day 60	Day 90	Day 120
Weight (kg)	75.45	75.57	74.36	73.18	72.12
	± 11.70	± 11.3	± 11.22	± 11.24	± 11.19*

BMI (kg/m ²)	32.67 ± 1.50	32.58 ± 1.51	28.50 ± 1.48	28.43 ± 1.49	28.40 ± 1.44
Waist circumference (cm)	98.97 ± 8.99	98.42 ± 8.58	96.67 ± 8.07	96.10 ± 9.77	95.01 ± 8.83*
Hip circumference (cm)	104.9 9 ± 8.62	104.9 2 ± 9.13	103.3 1 ± 8.14	103.0 2 ± 8.37*	102.37 ± 8.03**
WHR	0.94 ± 0.08	0.93 ± 0.07	0.93 ± 0.07	0.93 ± 0.07	0.92 ± 0.08
Neck circumference (cm)	37.7 ± 5.16	36.91 ± 4.82	36.35 ± 4.70	36.17 ± 4.24*	35.89 ± 4.16**
Mid upper arm circumference (cm)	31.94 ± 2.84	31.67 ± 3.15	31.17 ± 2.79	31.5 ± 3.0	31.25 ± 2.73
Mid-thigh circumference (cm)	54 ± 6.26	53.89 ± 5.69	52.03 ± 8.19	51.78 ± 5.37	51.35 ± 4.92
*p < 0.05, **p < 0.01, ***p < 0.001 as compared to day 0.					

The average age of the recruited participants was 38.7 ± 9.42 years. There was clinically significant difference observed pre and post treatment in case of weight loss. The mean weight loss showed was 3.3 kg.

The circumferential measures (waist, hip and neck) showed gradual reduction throughout the study period, which was statistically significant on day 90 (HC and NC) and day 120 (all three). The significant decrease in waist and hip did not reflect in corresponding decrease in waist-to-hip ratio. The other circumferential measures (MUAC and MTC) although showed reduction, but did not reach to statistical significance.

DISCUSSION

Lipogenesis occurs in the liver and adipose tissue where carbohydrate and protein consumed in the diet can be converted to fat. The carbohydrates can be stored as glycogen in the liver and muscle and can be converted to triglycerides in the liver and transferred

to adipose tissue for storage.^[11] The aim of Current study was to evaluate the efficacy of Obenyl Tablet in Obese Patients and to determine whether the Herbs will act as Fat Burners or Not. We observed significance Change in Waist, Hip and Neck Circumference, It proves that Obenyl has helped in releasing Fats from Peripheral Adipocytes and further oxidation of fat (Fat Burning).

The physiological process of fat burning occurs when fats are liberated from adipocytes into circulation to supply the needed energy.^[12] Fat Burner termed is used for Herbal Supplements that claimed to acutely increase fat metabolism, impair fat absorption, increase weight loss, and increase fat oxidation during exercise.^[13] A good fat burner must burn the stored fats, break down and mobilize the fat cells, increase the metabolic rate, and inhibit the enlargement of fat cells.^[14] Fat-burning supplements include conjugated linoleic acid.^[15] Which is found in Amla, hirada, the ingredients from Obenyl tablet. herbal ingredients has the Fat burners ability.^[16] there are foods & Herbs that have the ability to burn fat as they are ingested.^[17] As the Obenyl showed Significant Mean Weight Loss of 3.33kg, the Herbs in Obenyl Must have been acting like Fat Burners.

Fat burner is not meant to replace a good diet and exercise plan. The best way to help the body stimulate /metabolism and activate the fat burning abilities is to eat thermogenic foods, drink plenty of water, exercise regularly.^[18] Along with Herbal Medications such as Obenyl Tablet.

CONCLUSION

The study was carried out in 78 patient suffering from obesity. The obese patient with endocrine disorders e.g. Cushing's syndrome, Hypothyroidism were excluded from the study. The Obese patients with diabetes mellitus were included in study. The patients with Obenyl Tablet showed 87.18% good results. The Study shows significant reduction in Waist, Hip and Neck Circumference and mean weight loss showed was 3.3 kgs. No adverse effects and weight gain were observed in the course duration. Hence, it can be

concluded that Obenyl Tablet is effective treatment in obesity with no side effects.

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