

Study of Effect of Low-Calorie Diet, Exercise and Orlistat on Weight and BMI of the Obese Patients: A Prospective Study

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Citation: Mohanani L, Chittawar S (2020) Study of Effect of Low-Calorie Diet, Exercise and Orlistat on Weight and BMI of the Obese Patients: A Prospective Study. Med Clin Rev Vol.6 No.1:12

Abstract

Background: Overweight and obesity among children and adolescents is an epidemic on the rise, as management strategy behavioral therapy is not sufficient for sustained weight reduction and therefore pharmacological treatment is the need of the hour.

Aims and objectives: This study aimed to determine the effect of diet, an exercise in combination with Orlistat on weight and BMI of the obese patients.

Materials and methods: In this prospective observational study, we studied the effects of orlistat, exercise and diet on BMI and body weight in a cohort of 100 obese subjects aged between 11-40 came at Harmony Super speciality clinic 62 old MLA Qts, Jawahar Chowk Bhopal.

Results: Majority of the patients were young and working-age group (21-40 years). We found that orlistat has a significant role in weight reduction, post-treatment average reduced by 20 kg, post-treatment BMI reduced by 8 kg/m² and HbA1c reduced by 2% after treatment. Patients who were on low-calorie diet i.e. consumed only 1000-1100 kcal recorded a weight loss of 28.92 ± 6.41% and BMI reduction of 23.75 percentage. Subjects who did exercise for >75 min per day recorded a weight loss of 28.71 ± 7.01% and BMI loss of 21.57 ± 7.24 percentage.

Conclusion: Orlistat in combination with low calorie diet and exercise has shown statistically significant weight and BMI reduction among the obese subjects.

Keywords: Orlistat; Caloric diet; Exercise

Received: December 23, 2019; **Accepted:** January 23, 2020; **Published:** January 30, 2020

Introduction

Overweight and obesity are defined as abnormal or excessive fat accumulation or additional adipose tissue mass that presents a risk to health. A measure of obesity is the Body Mass Index (BMI) which is calculated by dividing weight (in kilograms) by the squared height (in meters). A person with a BMI of 30 or more is considered obese and BMI equal to or more than 25 is considered overweight. Obesity is known risk factor of major health problems especially the heart disease, stroke, type 2 diabetes, hypertension, dyslipidemia and advanced mortality due to cancers like breast, rectum, colon, and esophagus [1].

The incidence of obesity is on the rise and impacting more people all over the world, it is estimated that globally ~1.2 billion people are overweight and ~300 million are obese [2].

Main causes of obesity are intake of high calorie (junk, sugary, etc.) food which gives persistent positive energy, lack of physical exercise or consumption calorie intake and leisure lifestyle. In most of setting these factors are interlinked and become a major factor of obesity. The minimum requirement for weight management is to achieve the negative energy balance i.e. restriction of high-calorie intake and burning of intake calories via physical exercises [3].

Diet and exercise are useful strategies for losing weight and controlling obesity, for the moderately obese adults, but it has been noticed that the individuals could not maintain the lower weight for long periods after losing it [4].

Most of the anti-obesity medicines act on the central nervous system to suppress the hunger and reduces the intake amount

of food, but these drugs known to cause heart disease, increase in blood pressure, etc. A new drug orlistat, which is a lipase inhibitor, has emerged as an effective treatment for weight loss [5].

Orlistat (C29H53NO5) is a gastrointestinal lipase (digest fats) inhibitor, which in turn reduces the fat absorption in the intestine by up to 25%. In 18 years and older patients, it has shown good safety profile, well tolerance level, minimum systemic absorption and resulted in sustained reduction of weight and BMI when used with a low calorie diet and moderate exercise. Orlistat is approved in more than 120 countries used by more than 22 million [6].

Based on the clinical efficacy and safety characteristics, orlistat in combination with low caloric diet and moderate exercise is the treatment of choice for obesity.

Materials and Methods

This was a prospective, randomized (using simple randomization method using SPSS ver. 20); study was carried out at Harmony Super speciality clinic 62 old MLA Qts, Jawahar Chowk Bhopal for 12 months between June 2018 to June 2019. Before commencing this study approval from Institutional Ethics Committee and an informed and formal consent was secured from the subjects.

In this study, 100 obese subjects with BMI ≥ 30 kg/m², both male and female were included. Patients on other medication that can alter body weight; patients with cardiovascular disease; having a respiratory disorder; chronic diarrhea; pregnant and lactating mothers are excluded from this study. After enrollment height, weight, BMI were measured and blood test to record the HbA1c was done for all the subjects.

All the patients were prescribed the orlistat 120 mg three times a day, 1 hour before breakfast, lunch, and dinner. Subjects were educated about the importance of healthy and low-calorie diet with daily exercise in weight reduction. All the subjects were monitored for a year to record diet and exercise habits.

Data Analysis

All the data analysis was performed using IBM SPSS ver. 20 software. Data was recorded in mean, SD and percentage of the data. One-way ANOVA and Independent sample t-test was performed to compare the means. A P value <0.05 was considered significant while P-value >0.05 was considered as insignificant.

Results

Majority of the patients were in the age group of 21-30 years (46%) followed by 31-40 years (24%) and 11-20 years (20%). Mean age of the study population was 27.80 ± 8.51 years. Out of 100 patients, 87% were taking orlistat (Tables 1-5).

Discussion

In a UK based study on 151 young children patients While Bet al found that orlistat was prescribed to 59% patients by the general practitioners, orlistat was majorly prescribed to the patients of age more than 16 years and no comorbidities were recorded

Table 1. Comparing the change in weight, BMI and hbA1c among the patients taking orlistat.

Variable		Mean	SD	P value
Weight (kg)	Pretreatment (n=87)	88.70	14.060	<0.001
	Post treatment (n=87)	68.02	10.292	
BMI(kg/m ²)	Pretreatment (n=87)	35.1075	4.83142	<0.001
	Post treatment (n=87)	27.0000	3.48482	
HbA1c (%)	Pretreatment (n=28)	8.2857	2.11778	<0.001
	Post treatment (n=28)	6.3357	1.15861	

P value was calculated using Paired Samples Statistics. P value of <0.05 is considered as significant.

Table 2. Weight loss (kg) among the patients using orlistat.

Weight loss (kg)	Frequency	Percent
<5	1	1.1
5-10	6	6.9
10-15	19	21.8
15-20	18	20.7
>20	43	49.4
Total	87	100.0

Data are expressed as no of patients and percentage

Table 3. Effect of orlistat on various parameters at 8th, 16th and 24th weeks.

Parameter	Day 0 [Mean \pm SD]	8 WEEKS [Mean \pm SD]	16 WEEKS [Mean \pm SD]	24 WEEKS [Mean \pm SD]
Weight[kg]	88.70 \pm 14.06	82.43 \pm 12.34	74.25 \pm 11.23	68.02 \pm 10.29
BMI[kg/m ²]	35.10 \pm 4.83	31.23 \pm 4.23	29.34 \pm 3.83	27.00 \pm 3.48
HbA1c	8.28 \pm 2.11	7.23 \pm 2.01	6.11 \pm 1.45	6.33 \pm 1.15

Table 4. Comparing Weight and BMI loss among the patient's conclusion different set of calories.

Calorie intake from Diet	Weight loss (%)	BMI loss (%)
1000-1100	28.92 \pm 6.41 (34)	23.75 \pm 6.25(35)
1100-1200	22.32 \pm 6.79 (28)	18.03 \pm 7.05 (28)
1200-1300	19.50 \pm 8.83 (10)	17.01 \pm 8.93 (10)
1300-1400	16.57 \pm 7.13 (7)	15.08 \pm 7.46 (8)
1400-1500	16.83 \pm 6.67 (6)	16.25 \pm 6.08 (6)
>1500	15.50 \pm 8.41 (8)	14.92 \pm 7.52 (8)
P value	0.006	0.002

Data are expressed as mean \pm SD (no of patients)

Table 5: Effect of exercise of the weight and BMI loss among the study cohort.

Exercise time of patients (min)	Weight loss (%)	BMI loss(%)
>15min	14.20 \pm 7.12 (29)	23.17 \pm 6.91 (29)
15-30	14.78 \pm 6.97 (17)	20.77 \pm 7.10 (17)
30-45	15.17 \pm 7.48 (17)	23.37 \pm 7.37 (18)
45-60	19.80 \pm 5.45 (10)	20.55 \pm 6.16 (11)
60-75min	21.75 \pm 9.10 (4)	15.82 \pm 8.81 (4)
>75	28.71 \pm 7.01 (14)	21.57 \pm 7.24 (14)
P value	0.001	0.010

Data are expressed as mean \pm SD (no of patients)

in this group. Similarly, in the current study the majority of the patients were young and working-age group (21-40 years) and

none of them reported any comorbidities after prescribing the orlistat [5,6].

Current study records that the subjects prescribed with orlistat show average weight loss of 28.92 ± 6.41 kg in 100 subjects in 12 months. Similar results were recorded by Bakris et al. in their 1 year inadequately controlled subjects on orlistat have recorded a weight loss of 5.4 kg which is lower than our results. This difference could be due to different study setting and level of control used on both studies [7].

Similarly, Broom et al in their 54-week study recorded a mean weight loss of 5.8 kg in a cohort of 531 patients prescribed to orlistat, this similar our result but the difference in mean could be due to the large size of the cohort which is difficult to control on diet and exercise factor [8].

Our study recorded a significant reduction in BMI among 87 subjects prescribed to orlistat. In a similar study by Kempf et al., they recorded the mean reduction in BMI by 2.3 kg/m^2 which is similar to our findings and strengthen the efficacy of orlistat [9]. Another study by Bakris et al. have recorded a mean reduction in BMI by 1.9 kg/m^2 which is same as our results where BMI reduced significantly [7].

Jacob et al. in their study on 2550 overweight obese patients with type 2 diabetes. Subject who were treated with orlistat 120 mg three times a day ($n=1279$) provided significantly larger mean decreases in HbA1c compared with placebo (-0.74% vs. -0.31% ; $p<0.0001$). Similar results were recorded in our study where a significant reduction in glycemic level is seen after prescribing orlistat [10].

In the present study, the patients who did exercise for a longer period showed more weight and BMI loss as compared to patients with less exercise time. Those patients who did exercise for >75

min had the weight of $28.71 \pm 7.01\%$ and BMI loss of $21.57 \pm 7.24\%$. Similarly, observations were made by Ross et al. in their study where a bodyweight reduction of 7.5 kg and BMI reduction of $31.3 \pm 2.0 \text{ kg/m}^2$ were recorded for patients who have done the exercise for 60 min [11]. Similarly, Donnelly et al. established the association of weight loss with exercise in 141 overweight or obese (BMI 31 kg/m^2) men and women, where weight losses were 3.9 ± 4.9 and 5.2 ± 5.6 kg respectively which is similar to our findings and strengthen the idea of exercise for weight loss [12].

Davidson et al. in their study found that the orlistat combined with diet and exercise in the greater weight reduction as compared to placebo (8.8% versus 5.8%, $p<0.001$, respectively) at 1 year. After 2 years of treatment, patients lost 7.6% of their total body weight from baseline as compared to placebo with a weight loss of 4.2%. Similarly, in the present study, those patients who had low-calorie intake had maximum weight and BMI loss. Those patients who consumed only 1000-1100 calorie had a weight loss of $28.92 \pm 6.41\%$ and BMI loss of $23.75 \pm 6.25\%$ [5].

Small sample size was the main limitations of the present study; a large randomized clinical trial is needed to strengthen the present study findings.

Conclusion

Various studies have shown that Orlistat provides a significant weight loss more than diet and exercise alone can provide in overweight and obese adults. The current study also concludes similarly were post-treatment with orlistat mean weight reduced by 20 kg, reduced by 8 kg/m^2 and HbA1c reduced by 2%. Subjects on 1000-1100 calorie diet recorded a weight loss of $28.92 \pm 6.41\%$ and BMI reduction of $23.75 \pm 6.25\%$. Subjects spent >75 mins/per day for physical exercise recorded a weight loss of $28.71 \pm 7.01\%$ and BMI loss of $21.57 \pm 7.24\%$.

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