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Dose Response Effects of Liraglutide (Saxenda) on Weight Loss among Overweight and Obese Individuals: A Three Arm Randomized Controlled Trial

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Introduction: *The present is aimed to determine the effects of three different doses of Liraglutide (Saxenda**)** that are 0.6mg, 1.2mg and 1.8mg with and without exercises on obese population after 6 months of intervention.* ***Methodology:*** *A three arm randomized controlled trial was performed at Isra Univeristy Hospital, Hyderabad. A total of n=60 obese participants including both male and female were recruited and divided into two groups n=20 participants in each group. Each group was than further divided into two subgroups n=10 participants in each subgroup.* ***Results:*** *The analyses of the findings had revealed that n=22 participants included in the study were male whereas n=38 were female. The mean Body Mass Index (BMI) of the participants in group A at baseline was 29.95±1.35kg/m^2, 30.21±1.56 kg/m^2 and 29.54±2.33 kg/m^2 in subgroup (i), (ii) and (iii) respectively whereas in group B the values of BMI at baseline were 30.25±1.56 kg/m^2, 29.87±2.56 kg/m^2 and 30.11±2.33 kg/m^2 in subgroup (i), (ii) and (iii) respectively. In group C the values were 30.01±2.14 kg/m^2, 28.59±2.22 kg/m^2 and 30.58±1.98 kg/m^2 in subgroup (i), (ii) and (iii) respectively.* ***Conclusion:*** *The findings revealed substantial differences in BMI and body fat percentage within each group from baseline through three and six months of intervention. Higher Liraglutide (Saxenda) dosages (1.8mg) resulted with greater decreases in BMI and body fat percentage than lower doses (0.6mg and 1.2mg).*

Keywords: *obesity, body mass index, body fat percentage*

Introduction

Overweight and obesity have become major global public health concerns that impact people of all ages (Adeloye et al. 2021). According to the World Health Organization (WHO), the prevalence of these illnesses has risen considerably during the last four decades. Obesity is distinguished by abnormal or excessive fat deposition in the body (Soeroto et al. 2020, Tchang et al. 2021). Individuals with a body mass index (BMI) between 25 and 30 are categorized as overweight, while those with a BMI greater than 30 are classified as obese (Ali et al. 2022). Obesity is the result of a complex interaction of genetic, metabolic, socioeconomic, environmental, and behavioral variables. Understanding and managing these characteristics are critical to addressing the global burden of

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overweight and obesity. The disease is distinguished by abnormal or excessive fat deposition in the body (Okunogbe et al. 2021, Semlitsch et al. 2019)[5]. Recognizing the negative impact of obesity on world health, the World Health Organization (WHO) developed the 2013-2020 world Action Plan to prevent and manage non-communicable diseases (NCDs) (Felisbino-Mendes et al. 2020). One of the key goals of this action plan is to reverse the rise in obesity rates by 2025. This aim highlights the critical need to treat obesity's underlying causes and risk factors. By focusing on prevention, education, and intervention, efforts can be directed towards the WHO's ambitious objective of stunning the growth in obesity by 2025, thereby fostering improved global health outcomes for future generations (Chooi et al. 2019). Obesity has a significant economic impact in addition to its health consequences. It has an impact on families, healthcare systems, and the global economy as a whole. Obesity-related direct medical costs include expenses for obesity-related disease prevention, diagnosis, and treatment (Luhar et al. 2020, Lin et al. 2020). Obesity is addressed in around 2-8% of European countries' healthcare budgets, equating to around 0.6% of their gross national income (GNI) per capita. To put that in context, figures from the United States in 2008 indicated that overweight and obesity alone accounted for a whopping $147 billion in total medical costs. However, these estimates just show the direct costs of obesity; the indirect costs are likely to be substantially higher. Obesity's indirect expenses include a wide range of causes (Normand and Gibson 2020). They include lost money and economic productivity as a result of limited career choices and lower physical capabilities as a result of obesity. Furthermore, there are increased healthcare costs associated with treating obesity-related disorders, as well as the possibility of premature death. Asia has seen a considerable and accelerated rise in mean BMI, as well as a rapid transition from underweight to overweight. Notably, Asians are more prone to central fat deposition, with fat accumulating largely in the abdomen region (Williams and Periasamy 2020, van Eyk 2019). In comparison to other populations, this pattern of fat distribution is more apparent. Individuals in Asia with lower BMIs but central fat deposition have suffered an upsurge in metabolic disorders such as nonalcoholic fatty liver disease, diabetes, and cardiovascular disease, which is concerning (Bays et al. 2022). A weight loss of 5% has been found to provide considerable benefits in terms of lowering morbidity and mortality risks as well as enhancing health-related quality of life. The most well-known way to lose weight is through lifestyle changes such as dietary changes and increased physical activity (Amanat et al. 2020, Carbone et al. 2019). However, behavioral therapies' long-term efficacy in maintaining weight loss is sometimes restricted, with gradual weight regain being a regular difficulty. Pharmacological treatments can be utilized in addition to lifestyle adjustments, especially when lifestyle changes alone are insufficient. Unfortunately, there are few anti-obesity drugs available, particularly for long-term use (Jakab et al. 2021, Cornier 2022). As a result, developing effective and long-lasting pharmaceutical therapies remains an important topic of study. Healthcare professionals can provide more options to those battling with weight control by broadening the range of anti-obesity drugs available, potentially leading to better long-term outcomes (Ruban et al. 2019). Liraglutide, a glucagon-like peptide-1 (GLP-1)

analogue, has been found to be effective in lowering body weight by suppressing hunger and calorie intake. Randomized controlled trials have shown that liraglutide, at doses up to 3.0 mg per day, causes significant and clinically relevant weight loss when compared to a placebo (Khalil et al. 2020). Furthermore, these weight-loss gains have been sustained for up to two years. Liraglutide has been approved for treatment in overweight and obese individuals for up to three years in numerous countries, including the United States and the European Union. Real-world data from Canada have further validated the efficacy of liraglutide when paired with diet and exercise, with over 60% of participants losing more than 5% of their body weight (Cornier 2022). Yet further studies are needed to determine the dose response effects of liraglutide in weight loss particularly in Asiatic population. It is therefore the present is aimed to determine the effectiveness of three different doses of Liraglutide (Saxenda**)** that are 0.6mg, 1.2mg and 1.8mg with and without exercises and diet control on obese population after 6 months of intervention.

Methodology

A three arm randomized controlled trial was performed at Isra Univeristy Hospital, Hyderabad. A total of n=60 obese participants including both male and female were recruited and divided into two groups n=20 participants in each group. Each group was than further divided into two subgroups n=10 participants in each subgroup. Randomization was performed on the bases of envelope method. The intervention strategies included the following protocol.

Group A Liraglutide (Saxenda 0.6mg)

Subgroup (i) participants were given Liraglutide (saxenda) at a dose of 0.6mg per day for six months.
Subgroup (ii) Liraglutide (saxenda) 0.6mg per day for six months with daily exercises.

Group B Liraglutide (Saxenda 1.2mg)

Subgroup (i) participants were given Liraglutide (saxenda) at a dose of 1.2mg per day for six months.
Subgroup (ii) Liraglutide (saxenda) 1.2mg per day for six months with daily exercises.
For first week saxenda 0.6mg per day was given than from second week onwards 1.2mg per day was administered.

Group C Liraglutide (Saxenda 1.8mg)

Subgroup (i) participants were given Liraglutide (saxenda) at a dose of 1.8mg.
Subgroup (ii) Liraglutide (saxenda) 1.8mg per day for six months with daily exercises.

For first week saxenda 0.6mg per day was given than for second week 1.2mg per day was administered and from third week onwards 1.8mg per day for rest of the treatment session was given.

Liraglutide (saxenda) was injected subcutaneously at a given dose once daily for a total of six months in all three groups as per mentioned dosages.

Participants of subgroups (ii) in all groups were recommended 30 minutes of simple walking exercises in the day time.

Outcome Measures

The data was taken thrice at baseline, after completion of three months of protocol and at end of six months on a given parameters.

Body Mass Index

The body Mass index of the participants in all the groups were calculated at three different intervals at baseline after three months and at the end of six months of protocol. The values were measured using a following formula (Misra and Dhurandhar 2019):

BMI=Weight in Kilogram/Height in meter square

Body Fat Percentages

Body fat composition was calculated using skin fold thickness method. The test has a inter class correlation coefficient (ICC) of 0.99. The reference range of body fat according to age and gender was taken from American College of Sports Medicine (ACSM) Health-Related Physical Fitness Manual (Mohajan and Mohajan 2023).

Data Analyses

The analyses of data was performed using a SPSS version 24. For descriptive analyses frequency and percentage charts were plotted. Whereas inferential statistics was performed after identifying the normality assumptions of data. For within the group analyses continuous measure Annova was performed whereas for between the group analyses one way analyses of variance was determined. Level of significance were determined at 95% of Confidence Interval $p<0.05$.

Ethical Consideration

The study was completely according to the guidelines of Belmont report of human subject (Anabo et al. 2019). Confidentiality, autonomy and beneficence of participants included in the study were maintained. The purpose and the objectives of the study was precisely explained prior to induction of participants. Consent was taken in English and in Urdu both.

Results

The analyses of the findings had revealed that n=22 (36.66%) participants included in the study were male whereas n=38(63.33%) were female. The mean Body Mass Index (BMI) of the participants in group A at baseline was 29.95± 1.35kg/m^2 and 30.21±1.56 kg/m^2 kg/m^2 in subgroup (i), and (ii) respectively whereas in group B the values of BMI at baseline were 30.25±1.56 kg/m^2, and 29.87±2.56 kg/m^2 in subgroup (i) and (ii) respectively. In group C the values were 30.01±2.14 kg/m^2 and 28.59±2.22 kg/m^2 in subgroup (i) and (ii) respectively. Further analyses of the variables at baseline were illustrated in Table 1.

Table 1. *Analyses of Variables at Baseline and Between Group Analyses*

Variables	Subgroup	Number of Male Participants n (%)	Number of Female Participants n (%)	Average BMI ±SD in kg/m^2	p-value	Average Body Fat percentage (BF%) ±SD	p-value
Group A	I	4(40)*	6(60)*	29.95±1.35		29.5±2.06	
	II	3(30)*	7(70)*	30.21±1.56	>0.05	30.26±1.25	>0.05
Group B	I	3(30)*	7(70)*	30.25±1.56		29.63±2.01	
	II	4(40)*	6(60)*	29.87±2.56	>0.05	31.22±1.33	>0.05
Group C	I	3(30)*	7(70)*	30.01±2.14		29.56±1.58	
	II	5(50)*	5(50)*	28.59±2.22	>0.05	30.22±2.03	>0.05
* Indicates percentages of male and female participants in subgroup out of n=10							

Further analyses of variance test was applied to determine the differences in within the group from baseline to after three months and six months of intervention. The findings had revealed that within the group analyses had shown significant difference in mean of BMI and BF% from baseline to after three months and after six months of intervention. The analyses were illustrated in Table 2.

Table 2. *Analyses of Variance to Determine Within the Group Change in BMI and BF%*

Body Mass Index					
Variables	**Subgroup**	**Baseline Mean ± Sd**	**Month 3 Mean ± Sd**	**Month 6 Mean ± Sd**	**Level of significance p-value**
Group A	I	29.95±1.35	28.91±1.26	26.12±1.35	
	II	30.21±1.56	28.54±1.33	25.93±2.2	$p<0.05^a$
Group B	I	30.25±1.56	28.63±1.8	25.17±2.05	
	II	29.87±2.56	27.48±2.1	25.11±2.3	$p<0.05^a$
Group C	I	30.01±2.14	26.9±2.2	22.52±2.3	
	II	28.59±2.22	25.32±2.1	21.92±2.32	$p<0.05^a$
Body Fat Percentage (BF %)					
Group A	I	29.5±2.06	28.56±2.56	27.21±1.9	
	II	30.26±1.25	28.21±1.98	26.9±1.5	$p<0.05^a$
Group B	I	29.63±2.01	29.12±2.6	26.1±2.5	
	II	31.22±1.33	29.01±2.1	25.95±1.65	$p<0.05^a$
Group C	I	29.56±1.58	29.2±1.69	26.01±3.1	
	II	30.22±2.03	28.9±1.5	25.53±2.9	$p<0.05^a$
[a] indicates significant difference in mean within the group					

Further one way analyses of variance was applied to determine within the group difference as observed by administering different doses of Liraglutide (saxenda) on body mass index and body fat percentage of participants and the analyses of the findings had revealed that significant reduction $p<0.05$ in both BMI and BF% of participants had been found in group receiving higher dosages of Liraglutide (saxenda) that was 1.8mg per day followed by 1.2mg and 0.6mg. Hence suggesting that higher dosages of Liraglutide (saxenda) produced better results than small doses (Table 3).

Table 3. *One Way Analyses of Variance to Determine between the Group Comparisons*

Body Mass Index (BMI)				
Variables	**Subgroup**	**Average value of BMI at week 6 ± Sd**	**df**	**Level of Significance p<0.05**
Group A	I	26.12±1.35	3	0.001
	II	25.93±2.2		
Group B	I	25.17±2.05	3	0.001
	II	25.11±2.3		
Group C	I	22.52±2.3	3	0.001
	II	21.92±2.32		
Body Fat Percentage (BF %)				
Group A	I	27.21±1.9	3	0.001
	II	26.9±1.5		
Group B	I	26.1±2.5	3	0.001
	II	25.95±1.65		
Group C	I	26.01±3.1	3	0.001
	II	25.53±2.9		

Discussion

The 60 participants were sorted into three groups (A, B, and C), which were then subdivided into two subgroups (i, and ii). The baseline analysis revealed that Group A had an average BMI ranging from 29.95 to 30.21 kg/m^2, Group B had an average BMI ranging from 29.87 to 30.25 kg/m^2, and Group C had an average BMI ranging from 28.59 to 30.58 kg/m^2. After three and six months of intervention, the analysis of variance revealed significant variations in BMI and body fat percentage (BF%) within each group. Furthermore, greater doses of Liraglutide (saxenda) (1.8mg per day) resulted in a substantial reduction in both BMI and BF% when compared to lower doses (1.2mg and 0.6mg). This data implies that greater Liraglutide (saxenda) dosages generated superior benefits in terms of weight loss and body fat reduction. Moreover it has also been observed that higher dosages of Liraglutide was associated with certain side effects such as administration of 1.2mg of drugs causes lightheadedness and dizziness whereas 1.8mg of drugs causes vomiting and headache. In comparison to that low dose of drugs had shown no such side effects. The findings of our study was in consistent with the findings of another study that was performed with the aimed to determine Liraglutide 3.0 mg impact in causing weight reduction and improving obesity-related comorbid disorders in obese people in Saudi Arabia. A retrospective cohort assessment was performed on 399 individuals taking Liraglutide 3.0 mg in conjunction with diet and exercise for 6 months. The group included a mean age of

46.4 years, a mean BMI of 40.4 kg/m^2, and a predominance of female patients (74.4%), according to the baseline analysis. The average weight reduction was 6.5 kg, with 52.6% of individuals losing 5% of their total weight, 27.8% losing 10%, and 11.3% losing 15% of their body weight (Alshehri et al. 2023). Additionally, after 6 months of therapy, HbA1c levels were decreased by 0.5%. Liraglutide 3.0 mg had no effect on systolic blood pressure or alanine transferase levels. Overall, Liraglutide 3.0 mg caused clinically significant weight reduction and improved glycemic control, demonstrating its efficacy in a real-world situation (Alshehri et al. 2023). In another study the efficacy of liraglutide 3.0 mg in conjunction with diet and exercise was examined in this retrospective observational trial done in Switzerland. The study's goal was to evaluate weight reduction results and patient adherence to therapy. Data were gathered from an obesity treatment clinic's computerised medical records. The whole group included 277 individuals, with 19% having had bariatric surgery. Treatment persistence of at least 4 months (n = 236), 7 months (n = 159), or 12 months (n = 71) was used to conduct subgroup analyses (Haase et al. 2021). The median duration of liraglutide treatment was 6.8 months, with most patients receiving a maximum dosage of 1.5 mg. Weight reduction was shown to be considerable across all subgroups. The average 7-month weight decrease from baseline in the entire group was -4.1 kg (-4.2%). The weight change for the 4-month persistence subgroup was -4.4 kg, the weight change for the 7-month persistence subgroup was -5.1 kg, and the weight change for the 12-month persistence subgroup was -7.5 kg ($p < 0.001$) (Haase et al. 2021). At 7 months, there was a substantial drop in diastolic blood pressure but systolic blood pressure remained stable. At 7 months, almost 40% of patients dropped 5% of their body weight, and 14% lost more than 10%. The history of bariatric surgery has no effect on weight loss results. It is worth mentioning that only a minority of patients received liraglutide coverage, and the majority did not achieve the required maintenance dosage of 3.0 mg. Despite these limitations, the trial found clinically significant weight reduction related with liraglutide treatment in a real-world environment with limited insurance coverage. This shows that liraglutide, in conjunction with diet and exercise, may be a viable alternative for weight management in obese people. In a study aimed to investigate the expectations and experiences of people with schizophrenia, schizoaffective disorders, or first-episode psychosis who took part in an obesity treatment clinical trial utilizing daily liraglutide 3 mg injections (Whicher et al. 2021). The research also solicited healthcare experts' opinions on the feasibility of using this intervention in ordinary treatment. Seventeen patient participants were questioned, and the majority reported no difficulties with injection administration. Participants' despair about earlier medication-induced weight gain, the impact of weight loss on quality of life, and practical elements of involvement were key issues. Healthcare professionals and participants both highlighted recruiting obstacles but overall had a favorable experience (Whicher et al. 2021). The current study's strength lies in its detailed investigation of the effects of different Saxenda dosages on BMI and body fat percentage. The study provides a thorough investigation of the impact of Saxenda across various BMI ranges by categorising individuals into three groups and subsequently subdividing them. By analysing the statistical significance of the

variances within each group, an analysis of variance improves the robustness of the conclusions. The study's emphasis on Saxenda dosage brings new insights into the dose-response relationship, with higher dosages (1.8mg per day) displaying improved weight loss and body fat reduction outcomes compared to lower doses (1.2mg and 0.6mg). Despite its advantages, the study has certain drawbacks to consider. To begin, the sample size of 90 individuals may be considered limited, which may limit the findings' generalizability to bigger groups. Furthermore, the study's length of three and six months may not represent Saxenda's long-term effects or durability as a weight control tool. Further research with longer follow-up periods is required to examine the sustainability of the reported effects. Furthermore, the study did not investigate potential side effects or safety profiles associated with various Saxenda dosages, limiting comprehension of the overall risk-benefit ratio. Finally, the study's findings may be confined to the unique demographic and environment in which it was performed, and extending the results to other groups or situations should be done with caution.

Conclusion

The findings revealed substantial differences in BMI and body fat percentage within each group from baseline to three and six months of intervention. Higher Saxenda dosages (1.8mg) resulted with greater decreases in BMI and body fat percentage than lower doses (0.6mg and 1.2mg). According to the findings, larger dosages of Saxenda combined with exercise had a substantial influence on lowering BMI and body fat percentage in obese persons. It is crucial to note, that as the present study was conducted in a single tertiary care hospital of Hyderabad, Pakistan the generalizability of finding may be affected. Hence, more studies are needed to verify these findings and investigate the effects of Saxenda in various demographics.

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