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# THE ROLE OF LIRAGLUTIDE TREATMENT ON WEIGHT LOSS FOR PATIENTS WITH SUBOPTIMAL INITIAL RESPONSE OR WEIGHT REGAIN AFTER BARIATRIC SURGERY

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**Abstract:**

**Background:**

Glucagon-like peptide-1 receptor agonists (GLP1-RAs) are a form of incretin-based therapy that treats hyperglycemia and, in some situations, cardiovascular risk in persons with type 2 diabetes. **Aim**: Is to determine the efficacy and safety of prescribing GLP1-RAs for patients who had suboptimal initial response or regained weight after bariatric surgery.

**Patients and Methods :** A retrospective cross-sectional study was done from the 1st of February /2023 to the 1st of August/2024 in Al-Sadr Teaching Hospital, Iraq. Clinical data including (age, sex, height, weight, BMI, any chronic disease, time of bariatric surgery) were collected. Eighty-six patients were divided into two groups for the study. Seventy-two patients in the first group who gained weight after the weight nadir at least a year after bariatric surgery, 14 patients in the second group who had suboptimal initial response 12 months following bariatric surgery. Liraglutide was administered for 4 -8 months for both groups.

**Results:**

The study revealed that 70.9% of patients from both groups responded to the GLP1 therapy, with slightly higher responsiveness in the weight regain group (73.61%) than in the Suboptimal initial response group (57.14%), the difference was not statistically significant (p = 0.358). Both groups significantly reduced their BMI, with a mean pre-treatment to post-treatment BMI difference of 6.02 ±1.97 in the Suboptimal initial response group and 6.06 ± 1.21 in the weight regain group. However, there was no statistically significant difference between the two groups (p=0.18). Both groups lost weight, with the Suboptimal initial response group losing 10.9% of their weight from pretreatment to post-treatment and the weight regain group gaining 11.3%. There was no statistically significant difference between the two groups (p = 0.112).

**Conclusion:**

We discovered that liraglutide 3.0 mg helped post-bariatric surgery patients who had either too much weight gain or insufficient weight loss.

**Keywords :**bariatric surgery, wight loss,GLP1

## Introduction

Although the prevalence rates for weight regain vary depending on the weight parameters used to define as "regain" ,[1] it is now well-established that a large proportion of patients experience significant weight regain during long-term follow-up (.[2-5] Compared to lifestyle interventions, bariatric surgery is superior for long-term weight loss maintenance and improvement in overall health and quality of life . [6] However, weight loss after bariatric surgery differs substantially between individuals .[7] Most patients regain some weight after their lowest weight (nadir weight) has been reached.[8]

## Causes of Weight Regain:

While procedural failures such as gastro-gastric fistulas, dilated gastric fundus, and expansion of the gastric pouch or gastro-jejunal stoma might result in weight gain ,[9,10] the most common causes are thought to be dysregulated (e.g., loss-of-control eating) or maladaptive (e.g., grazing) eating, noncompliance with dietary recommendations, return to previous eating habits, sedentary lifestyle, and physiological compensatory mechanisms such as changes in hormones that regulate energy intake, leading to increased appetite, food cravings, and increased caloric intake .[9,11] Comorbid psychiatric disorders, especially a history of depression, have also been implicated as potential causes of treatment failure.[12]

Three maladaptive eating behaviors—grazing, loss-of-control eating, and binge eating—are frequently reported among bariatric surgery patients. Grazing is defined as the uncontrolled, unplanned, and repetitive consumption of small quantities of food between meals . [13]

## Glucagon like peptide-1 receptor agonists:

Glucagon-like peptide-1 (GLP-1) receptor agonists are a form of incretin-based therapy that is used to treats hyperglycemia and, in some situations, cardiovascular risk in persons with type 2 diabetes. These medicines work on numerous physiological mechanisms implicated in type 2 diabetes, including boosting insulin production and reducing glucagon [secretion] to manage glucose levels .[14] They also transiently slow gastric emptying, reduces appetite, and facilitates weight loss and other metabolic improvements .[15]

## Expression and regulation

Glucagon-like peptide-1 (GLP-1) is a pleotropic hormone secreted by the intestinal enteroendocrine L cells in response to nutrients .[16,17] Glucagon-like peptide-1 is secreted by the distal ileum and colon in response to nutrient and neural inputs .[18] GLP-1 levels are lowest during fasting and rapidly increase after feeding .[19] Neurotransmitters released by vagal and enteric neurons also increase GLP-1 secretion. [20]The neurons in the brain are the primary source of endogenous GLP-1, which is

secreted in response to leptin and stomach distention. Figure 1 shows the pleiotropic actions of GLP-1RA. [21]

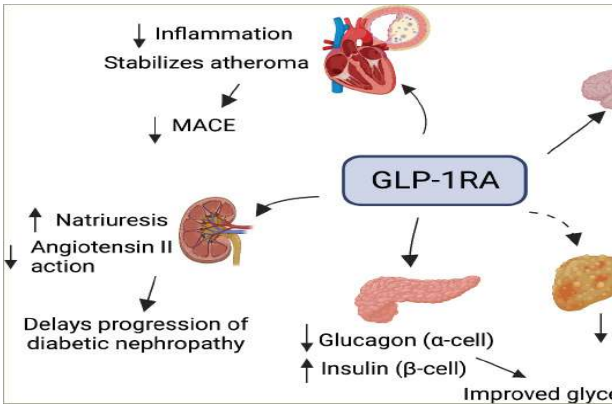


**Figure 1:** Therapeutic benefits of glucagon-like peptide-1 receptor agonists in obesity, diabetes and diabetes-related complications[(21)]. *GLP-1RA = glucagon-like peptide-1 receptor agonist; MACE = major adverse cardiac events. Dashed arrow indicates indirect effect.*

**GLP-1 receptor agonist for the treatment of weight regain after bariatric surgery:**

Bariatric surgery is now the most effective treatment for severe obesity, resulting in long-term weight loss, alleviation of cardiovascular risk factors and obesity-related comorbidities, and reduced all-cause mortality.[22] However, depending on the definition used, about (16–37%) experience significant weight regain thus reducing the long-term benefits of the procedure.[8] A viable standard therapy for weight regain following bariatric surgery has yet to be identified. Lifestyle changes are typically reinforced with further behavioral interventions and, on occasion, weight-loss medicines. Revisional surgery may be deemed appropriate when the underlying cause of weight regain is suspected to be anatomical. Other treatments, such as distal Roux-en-Y gastric bypass and biliopancreatic diversion, are generally reserved for refractory cases.[23,24] Glucagon-like peptide-1 receptor agonists (GLP1-RAs) are currently the most effective pharmacotherapy for weight loss with an average reduction in body weight of up to 15%]. Their safety profile is well-established primarily featuring mild to moderate gastrointestinal side effects that are usually transient. Additionally, they offer demonstrated cardiorenal benefits.[25,26] However, their efficacy in addressing weight regain following bariatric surgery remains unclear]. —In observational studies or case reports, the efficacy of GLP1-RAs in patients with weight regain following bariatric surgery is primarily restricted to liraglutide.[27,28] A study by Miras AD et al. [29] randomly assigned patients with chronic or recurrent type 2 diabetes (T2D) after bariatric surgery to receive liraglutide (1.8 mg, daily subcutaneously or a placebo. Although the primary endpoint was change in HbA1c, the data revealed a significant difference in mean weight reduction of 4.2 kg favoring liraglutide versus placebo after 26 weeks.[29]

Following bariatric surgery, the L-cells in the colon and distal small intestine are rapidly exposed to nutrients which increases the release of gut hormones, particularly postprandial GLP-1 and peptide YY. Due to their ability to increase satiety and decrease hunger, both

hormones collectively decrease food intake- a major contributor to postoperative weight loss .[30] Some studies suggest that these hormonal adaptations may attenuate over time .[31]

**Aim Of The Study**

This study aims to evaluate the efficacy and safety of GLP1-RA treatment in patients who experienced either suboptimal initial weight loss or subsequent weight regain following bariatric surgery.

**Patients And Methods**

A retrospective longitudinal study was conducted on patients who underwent bariatric surgeries between January 2020 to June 2023 at Al-Sadr Teaching Hospital and other private hospitals in Iraq . The data were collected from February 1, 2023, to August 1, 2024 Clinical data [-including age, sex, height, weight, and BMI-), were collected by reviewing the medical records and laboratory data of all obese patients with obesity having undergone bariatric surgery during study period.

The study included 86 patients diveded into two groups. The first group consisted of 72 patients who regained weight after initially achieving a normal BMI (18.5 to 24.9 kg/m²) and then experienced an increase of >50% of their lowest weight . The second group include[included] 14 patinets who had a suboptimal initial response[included] 12 months after the bariatric surgery. For both groups, liraglutide 3.0 mg was prescribed for 4-8 months. These patients were advised to undergo revision surgery, but they refused.

**Exclusion criteria:** Patients were excluded if they had a history of diabetes type 1, severe liver, kidney, or cardiovascular disease.

**Liraglutide administeration:**

Liraglutide administered as daily subcutaneous injection at a starting dose of 0.6 mg, then increase by 0.6 mg every two weeks until reaching maximum dose of 3.0 mg. In general, patients were seen by the treating physician 4-8 months after Liraglutide therapy initiation and the new weight and BMI were recorded.

Weight regain was defined as any weight gain following the weight nadir (the least post operative weight mostly reached by 12-18 months) at least 12 months after bariatric surgery. Insufficient weight loss was defined as 20% or less total body weight loss from the day of surgery[(33)] .

The indication to initiate Lariglutide therapy and the agent prescribed was at the decision of the treating physician, taking the overall weight status, cardiovascular risk profile, and patient preferences into consideration.

The main aim was percentage change in body weight from baseline to week 24. Percentage body weight loss was calculated as **100 × [(body weight at baseline − bodyweight at week 24) / bodyweight at baseline]** [(33)] .

Responders were identified as individuals who achieved a weight loss of at least 3%-5% following four to six months of administration

of liraglutid, according to Swiss reimbursement rules based on statistical analyses from the SCALE trials [34, 35]

Side effects of Lariglutide were also recorded including nausea, vomiting, flatulence, diarrhoea, headache, dizziness, and injection site reaction.

**Ethical consideration**

Prior to study initiation, agreements of the Ethical Committee of College of Medicine, University of Basrah, Basrah Health Directorate and the Scientific Ethical Committee at the Scientific Council of the Iraqi board for Health Specialization to approve carrying out this study before the data collection.

**Statistical analysis**

Data were entered and analyzed using the Statistical Package for the Social Sciences (SPSS) version 21 and the level of significance (P-value) was set at less than 0.05

**Results**

The demographic analysis in Table I shows no significant gender disparity between the two groups (p = 0.958), suggesting comparable gender distribution. Similarly, age differences between the two groups were not statistically significant (p = 0.82).

**Table I: Patients Characteristics**

| Characteristics | Suboptimal initial response (n = 14)(%) | Weight regain (n = 72) (%) | P- value |
|---|---|---|---|
| **Gender Female (62)** | 10 (71.4%) | 52 (72.2%) | 0.958** |
| **Male (24)** | 4 (28.6%) | 20 (27.7%) | |
| **Characteristics** | | | |
| **Age (years) Range (Mean)** | 37 – 54 (44.1) | 39 - 54 (42.5) | 0.82* |

*Chi-square ($\chi^2$) **Independent samples t-test

Table II showed treatment efficacy, highlighting that 70.9% of patients from both groups responded to the GLP1 therapy, with slightly higher responsiveness in the weight regain group (73.61%) than in the suboptimal initial response group (57.14%). However, the difference was not statistically significant (p = 0.358).

**Table II: Response to Treatment**

| Response to treatment (N) (%) | Suboptimal initial response (n = 14) (%) | Weight regain (n = 72) (%) | P- value |
|---|---|---|---|
| **Responded (61) (70.9%)** | 8 (57.14%) | 53 (73.61%) | 0.358* |
| **No Response (25) (29.1%)** | 6 (42.85%) | 19 (26.38%) | |

*Chi-square ($\chi^2$)

Analysis of weight differences (Table III) reveals that both groups achieved reductions in weight, with the percentage of pretreatment to post-treatment weight difference being 10.9 % in the suboptimal initial response group and 11.3 % in the weight regain group. However, the difference between the two groups was not statistically significant (p = 0.112).

**Table III: Weight differences between the two groups**

| weight | Suboptimal initial response (n = 14) (Mean ± SD) | Weight regain (n = 72) (Mean ± SD) | P-value |
|---|---|---|---|
| **Pretreatment** | 92.7 ± 6.60 | 93.5 ± 7.30 | 0.34 |
| **Post-treatment** | 82.6 ± 6.23 | 82.9 ± 6.40 | 0.78 |
| **Percent of weight loss** | 10.9 % | 11.3 % | 0.112 |

*Independent samples t-test

Analysis of BMI differences (Table IV) reveals that both groups achieved substantial reductions in BMI, with the mean pretreatment to post-treatment BMI difference being 6.02 ± 1.97 in the Suboptimal initial response group and 6.06 ± 1.21 in the weight regain group. However, the difference between the two groups was not statistically significant (p = 0.18).

**Table IV: BMI differences between the pre- and post-treatment**

| BMI | Suboptimal initial response (n = 14) (Mean ± SD) | Weight regain (n = 72) (Mean ± SD) | P-value |
|---|---|---|---|
| **Pretreatment BMI** | 36.04 ± 3.66 | 35.27 ± 3.79 | 0.40 |
| **Post-treatment BMI** | 30.02 ± 4.45 | 29.21 ± 4.36 | 0.250 |
| **The mean difference between pre and post-treatment BMI** | 6.02 ± 1.97 | 6.06 ± 1.21 | 0.18 |

*Independent samples t-test

The adverse effects summarized in Table V, indicate a 30.2% overall incidence rate, with nausea being the most frequent (16.3%). Other effects like constipation (7%) and vomiting (2.3%) were less common.

**Table V:Adverse effects of liraglutide treatment**

| Adverse Event | Count | New Percentage (%) |
|---|---|---|
| **Nausea** | 14 | 16.3% |
| **Constipation** | 6 | 7.0% |
| **Vomiting** | 2 | 2.3% |
| **Gall stone** | 2 | 2.3% |
| **Pancreatitis** | 1 | 1.2% |
| **Medullary Thyroid Carcinoma** | 1 | 1.2% |
| **Diarrhea** | 1 | 1.2% |
| **Headache** | 1 | 1.2% |
| **Dizziness** | 1 | 1.2% |
| **Injection site reaction** | 1 | 1.2% |
| **All** | 26 | 30.2% |

## Discussion

There are few alternatives for managing weight regain or Suboptimal initial response following bariatric surgery, and as the number of patients undergoing bariatric surgery rises, more therapeutic options are desperately needed.[36]

In our study, there was no statistical significance difference between the gender and weight loss in the two groups. Similarly, age differences between them were not statistically significant, with mean age 44.1 years among the Suboptimal initial response group, and 42.5 years among the weight regain group.

Compared to other studies, Jensen et al.[37] had a higher mean age of 50.0 years (range from 44.3 to 57.8 years), and Females constitute 82.0 % of their study population.

A study by Muratori et al.[38] in Italy on Efficacy of liraglutide 3.0 mg treatment on weight loss in patients with weight regain after bariatric surgery had a comparable mean age of 43.6 ± 9.9 years, with females constituting 96.7% of their study population.

Regarding the treatment efficacy, it was 70.9% of the total patients responded to the GLP1 therapy, with slightly higher responsiveness in the weight regain group (73.61%) than in the Suboptimal initial response group (57.14%). However, the difference was not statistically significant.

This was consistent with other study by Rye et al. [28] demonstrated that the use of 5% as a criterion at 16 weeks to predict clinically significant weight reduction at 28 weeks is supported by their examination of early responders and early non-responders. This cutoff has been demonstrated to predict better weight loss and changes in glycemic markers at 16 weeks, and it has been used in the non-surgical population to distinguish early responders from early non-responders.[39]

A study by Muratori et al.[38] showed a lower percentage of (5%) who had a partial or no response to liraglutide.

In our study, both groups achieved reductions in weight, with the percentage of pretreatment to post-treatment weight difference being 10.9% in the Suboptimal initial response group and 11.3 % in the weight regain group. However, the difference between groups was not statistically significant.

Compared to other studies, an observational study from Canada by Wharton et al.[36] showed that liraglutide (3.0 mg, daily subcutaneous injection) reduced weight loss by 5.5% over 7.6 months in patients who had undergone prior bariatric surgery. They discovered that regardless of the type of bariatric surgery they underwent, patients who used liraglutide 3.0 mg after having bariatric surgery and experienced either excessive weight gain or insufficient weight reduction were able to achieve a statistically meaningful weight loss.[36] Muratori et al.[38] found that all patients had a considerable weight loss after a mean follow-up of 10.5 months, regardless of whether they had lost enough weight or gained it back after surgery. The restoration of food control is most likely the cause of the significant weight loss that all patients experienced following liraglutide treatment. Additionally, they found that weight loss happened independent of how much time had passed since bariatric surgery. they took into account the extent of weight gain rather than the amount of time that passed between bariatric surgery and the initiation of liraglutide therapy because some patients saw weight gain even after a lengthy period of time. [38]

Pjecki et al.[40] reported on 15 patients with prior bariatric surgery, and either excess weight loss less than 50% after 2 years of follow-up or more than 15% weight regain from nadir, who received liraglutide at doses from 1.2 to 3.0 mg daily for eight to 28 weeks follow-up.

Significant weight loss was achieved compared with baseline (100.9 ± 18.3 kg. vs 93.5 ± 17.4 kg, $p < 0.0001$).

Jensen et al.[37] showed that in patients treated with liraglutide (*n*=29), a total body weight loss of ≥5% of baseline weight was achieved by 69.0% (*n*=20), ≥10% loss by 31.0% (*n*=9), and ≥15% loss by 3.5% of the patients (*n*=1).

A prospective observational study from the United Arab Emirates by Suliman et al.[41] including patients with previous bariatric surgery and obesity without Type 2 DM showed a 6.1% weight loss after 16 weeks of therapy with liraglutide (3.0 mg, daily subcutaneous injection) .

Horber et al.[42] demonstrated that patients with liraglutide treatment lost 15 ± 5% of, their body weight (i.e., 13 ± 4 kg) after 24 months, achieving a similar weight to their weight NADIR after LRYGB. This finding is in line with a recent short-term study of 20 patients with a loss of mean weight of 9.7% in 28 weeks by Rye et al. [28]

In a 2017 retrospective analysis, Stanford et al.[43] shown that patients who have insufficient weight loss or weight gain following bariatric surgery may benefit from pharmacotherapy-induced weight loss. Following surgery, 54% of patients in that research lost 5% of their total weight while taking concurrent medication; 30% lost more than 10%, and 15% lost more than 15%. As a result, liraglutide appears to be the most effective medication available for treating insufficient weight loss or weight gain following bariatric procedures.[43]

In a retrospective metanalysis in Italy by Vinciguerra et al.[44] , carried out on 119 patients who did not respond well to bariatric surgery, demonstrates that high-dose liraglutide is a successful weight-loss medication. Fifty percent of individuals lost five to ten percent of their body weight after three months of treatment. Treatment resulted in a weight loss of more than 9% after 24 weeks. The decrease in satiety and gradual increase in stomach capacity, which are the primary mechanisms of action of restrictive surgery, are among the primary issues for poor response to bariatric surgery. Liraglutide appears to work directly in the hypothalamic regions in this situation, enhancing the satiety stimulation and decreasing the perception of hunger while also peripherally slowing down the emptying of the stomach. [45]

Analysis of BMI differences in this study reveals that both groups achieved substantial reductions in BMI, with the mean pretreatment to post-treatment BMI difference being 6.02 ±1.97 in the Suboptimal initial response group and 6.06 ± 1.21 in the weight regain group.

Compared to other studies, Jensen et al.[37] showed comparable results, with mean BMI before treatments 34.0 (min 31.7, max 38.7) and BMI after treatment 31.5 (min 28.5, max 36.2).

Vinciguerra et al.[44] showed a significant reduction in BMI of 3.09 (*P*-value < 0.0001).

Rye et al.[28] showed that the median BMI change was 3.5 kg/m2 at 16 weeks and 4.7 kg/m2 at 28 weeks after therapy. Muratori et al.[38] showed that the median change in BMI in all patients of 4.5 kg/m2 regardless of the surgery.

In our study, the adverse effects indicate a 30.2% overall incidence rate, with nausea being the most frequent (16.3%). Other effects like constipation (7%) and vomiting (2.3%) were less common.

Comparably, Jensen et al.[37] showed that adverse events were reported in 36.0% of the patients, all of which were transient, considered mild, and primarily related to the gastrointestinal system, with nausea being the most common side effect (22%).

Wharton et al.[36] showed that total of 92 side effects were reported among 59 of 117 patients (50.4%). Gastrointestinal side effects were the most prevalent, with the top three most frequently reported side effects being nausea (n = 34 of 117, 37.0%), constipation (n = 13 of 177, 14.1%) and diarrhea (n = 8 of 117, 8.7%). Overall, the medication appeared to be well tolerated, with only three patients reporting discontinuing due to adverse events (ie, two patients due to an allergic reaction, and one patient due to pancreatitis).[36]

**Conclusion**

in this study, we found that post-bariatric surgery patients with insufficient weight loss or excessive weight regain who use liraglutide 3.0 mg were able to achieve a considerable weight loss, and reduction in BMI. Further, post-bariatric surgery patients taking liraglutide 3.0 mg have a tolerable side effect profile.

**Recommendations**

More and larger studies are required to evaluate the safety and efficacy of Liraglutide therapy, in addition, comparison of liraglutide between different types of bariatric surgery are required.

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**Authors' Contributions:**
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Work concept and design 1,2
Data collection and analysis 1,2
Responsibility for statistical analysis 1,2
Writing the article 1,2
Critical review, 1, 2
Final approval of the article 1,2

Each author believes that the manuscript represents honest work and certifies that the article is original, is not under consideration by any other journal, and has not been previously published.
**Availability of Data and Material:** The corresponding author is prompt to supply datasets generated during and/or analyzed during the current study on wise request.

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