A Randomized, Double-Blind, Placebo-Controlled Trial Using Liraglutide for Weight Regain after RYGB

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Background

Obesity is a continuing global epidemic. Bariatric surgery, such as Roux-en-Y gastric bypass (RYGB), paired with lifestyle modification, remains the gold standard for treating obesity. However, weight recidivism is common years after RYGB. Conservative modalities alone are rarely successful in reversing weight regain while revisional surgeries can increase risk to the patient. Liraglutide is a glucagon-like peptide-1 receptor agonist (GLP-1RA) approved for weight management at 3.0 mg/day via subcutaneous injection. This study will examine the effects on liraglutide 3.0 mg on weight regain after RYGB.

Methods

A 56 week, double-blind, placebo-controlled study was conducted in 132 patients, who achieved ≥25% total body weight loss (TBWL) status-post-RYGB and regained ≥10% TBWL after reaching nadir weight. Patients were 18-120 months post-RYGB and met criteria for weight management pharmacotherapy. Using a 2:1 block randomization method, patients were stratified by gender and percent post-operative TBWL (≤25 or 25–49.9%) to receive liraglutide 3.0 mg/day (n=89) or placebo (n=43). Both arms attended clinic visits every 3 months from baseline to 56 weeks and received lifestyle counseling from registered dieticians. The primary endpoint was the proportion of patients losing >5% of baseline body weight.

Results

- At baseline, patients were 47.2 years (SD=10.05), 99.3 kg (SD=18.76), had a BMI 35.6 kg/m2 (SD=4.68), and had RYGB 73.1 months (SD=47.8) prior.
- **At week 56, the median percentage body weight lost from baseline (BWL-B) was 9.65% in the liraglutide arm and -1.81% in the placebo arm (p<0.00001).**
- **After 56 weeks, 68.97% of patients on liraglutide lost ≥5% BWL-B versus 4.76% of patients on placebo (p<0.0001).**
- **48.28% of patients on liraglutide lost ≥10% BWL-B versus 0% on placebo (p<0.0001).**
- **24.1% of patients on liraglutide lost ≥15% BWL-B versus 0% of patients on placebo (p<0.013).**
- **20.7% of patients on liraglutide arm achieved or surpassed their prior post-op nadir weight. 0% on placebo arm met this goal (p=0.024).**
- Non-serious adverse events in the liraglutide arm were mostly GI related (41.6%). Serious adverse events occurred in 4.5% of the liraglutide arm and 14% of the placebo arm. No deaths occurred in either group.

Conclusion

In this study, liraglutide 3.0 mg/day, in addition to lifestyle modification, was significantly more effective than placebo in treating weight regain in patients after RYGB without increased risk of serious adverse events.

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