OA-GE-12

EFFECT OF WEIGHT LOSS ON PHYSICAL FUNCTION MEASURED BY THE 6-MINUTE WALKING DISTANCE TEST IN INDIVIDUALS WITH OBESITY: RESULTS FROM THE SCALE IBT TRIAL OF LIRAGLUTIDE 3.0 mg

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INTRODUCTION
The SCALE IBT trial (NCT02963935) was a 56-week, randomized, double-blind, US-based multicenter trial of liraglutide 3.0 mg vs placebo, with intensive behavior therapy (IBT) (i.e., reduced calorie intake, increased physical activity [max target: 250 min/week], and 23 counseling) in both arms. The secondary endpoint was the change in 6-minute walking distance (6MWD), a test for walking capacity measured by total distance walked along a 20-m marked walkway over 6 minutes.

METHODOLOGY
For the trial, individuals aged ≥18 y with a BMI ≥30 kg/m^2 and without diabetes were randomized 1:1 to IBT plus liraglutide 3.0 mg or placebo.The change in body weight and 6MWD from baseline to week 56 was calculated using ANCOVA. Linear regression was used for the correlation analysis of the association between 6MWD and BMI. There were 282 randomized individuals in the full analysis set (47 y, 17% male, BMI 39 kg/m^2).

RESULTS
At 56 weeks, mean weight loss was 7.5% with liraglutide 3.0 mg and 4.0% with placebo, estimated treatment difference (ETD[95% CI] 3.5% [1.6, 5.3]; p=0.0003). Improvement in 6MWD was 49.5 m vs. 46.4 m, from a mean baseline of 439 m (ETD [95% CI] 3.1 [-12.7, 18.9]; p=0.70). Linear regression of baseline 6MWD vs. baseline BMI showed that on average an individual with a BMI that was 1 kg/m^2 lower compared to another individual was able to walk 4.9 m longer in 6 minutes (slope [95% CI] -4.9 m/(kg/m^2) [-6.2, -3.6]; p<0.0001).

CONCLUSION
This *post-hoc* analysis showed that greater weight loss was associated with greater improvements in 6MWD in a linear manner, indicating gains in walking capacity.

KEY WORDS
liraglutide, scale, IBT

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WEIGHT LOSS WITH LIRAGLUTIDE 3.0 mg VERSUS PLACEBO FOR INDIVIDUALS WHO ADHERE TO THE TRIAL DRUG: A SECONDARY ANALYSIS FROM SCALE IBT

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INTRODUCTION
The objective of the SCALE IBT trial was to compare the weight loss of liraglutide 3.0 mg to placebo, both in combination with 56 weeks of intensive behavior therapy (IBT). The primary outcomes of the study were assessed in the intention-to-treat sample, regardless of individuals' medication adherence. The weight loss estimated in the primary analysis, regardless of drug adherence, was 7.5% versus 4.0% for liraglutide 3.0 mg and placebo, respectively, reflecting a treatment difference favoring liraglutide 3.0 mg of 3.5% (95% CI: 1.6%; 5.3%; p=0.0003). In this pre-specified secondary analysis, we sought to determine the expected effect of liraglutide 3.0 mg on weight loss, as compared to placebo, if all randomized individuals had adhered to study drug for 56 weeks.

METHODOLOGY
A total of 282 individuals with obesity (BMI ≥30 kg/m^2) were randomized in a 1:1 ratio to 56 weeks of IBT combined with daily injections of either liraglutide 3.0 mg or placebo. The weight loss, based on the assumption that all individuals adhered to the medication, was estimated using two different approaches. The first approach (mixed model repeated measures; MMRM) estimated the weight loss that would have been achieved if all individuals adhered to the trial drug by utilizing information from individuals still on drug after the point of a given individual's discontinuation to provide a (counter-factual) weight change as if the individual in question had not discontinued the drug. The second (covariate) approach used a regression model to calculate the weight change of individuals with full adherence to trial drug by including adherence as a moderator of the effect of treatment condition on weight change.