OP-18

EFFICACY AND SAFETY OF LIRAGLUTIDE 3.0 mg IN INDIVIDUALS WITH OVERWEIGHT OR OBESITY AND TYPE 2 DIABETES (T2D) TREATED WITH BASAL INSULIN: THE SCALE INSULIN TRIAL

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INTRODUCTION

Liraglutide 3.0 mg is approved for weight management in adults with and without T2D. Liraglutide up to 1.8 mg has been used in combination with insulin for treatment of T2D, but combination of a 3.0 mg dose with insulin has previously not been investigated.

METHODOLOGY

The 56-week double-blind SCALE Insulin trial randomised individuals with T2D with overweight or obesity (BMI ≥27 kg/m²) to liraglutide 3.0 mg or placebo, both as adjunct to intensive behaviour therapy (IBT). All study participants were on stable treatment with basal insulin and up to 2 oral antidiabetic drugs. Primary endpoints were mean change in body weight (%), and proportion with weight loss (WL) ≥5% at week 56, using all observed values regardless of week 56 treatment status, and a jump-to-reference multiple imputation approach to missing data, based on values from placebo group.

RESULTS

Mean baseline characteristics at randomisation (n=198) for liraglutide 3.0 mg included: 55.9 years of age, 54.5% females, 101 kg, BMI 35.9 kg/m², diabetes duration 11.4 years and HbA1c 7.9%. Corresponding placebo values (n=198) were: 57.6 years, 50.0% females, 99 kg, BMI 35.3 kg/m², 12.8 years, and HbA1c 8.0%. Of those randomised, 195 were exposed to liraglutide 3.0 mg and 197 to placebo, with 166 (83.8%) and 168 (84.8%) still on drug at 56 weeks. Respective mean weight change at week 56 was –5.85% and –1.53%, respectively, estimated treatment difference (ETD) –4.32 (p<0.0001). WL ≥5% was observed in 51.80% participants on liraglutide and 23.98% on placebo, odds ratio (OR) 3.41 p<0.0001. Respective values for >10% WL were 22.77% and 6.55%, OR 4.21, p<0.0001 (other efficacy outcomes in table). HbA1c reduction was greater with liraglutide than placebo (–1.09 vs –0.55%, p<0.0001), and there were respective changes in insulin dose of +2.8 U and +17.8 U from a baseline mean (both groups) of 38 U (ETD -15 U, p<0.0001). Documented hypoglycaemia (on-drug) occurred at respective rates of 7.42 and 9.38 events/subject-year with liraglutide 3.0 mg and placebo, with 3 and 2 severe events in each group respectively. Adverse event incidence was similar for liraglutide 3.0 mg and placebo, except gastrointestinal events (liraglutide 3.0 mg, 62.1%; placebo, 46.7%).

CONCLUSION

In insulin-treated T2D, liraglutide 3.0 mg was superior to placebo with respect to mean and categorical weight loss, as well as improvements in glycaemic control without increasing the risk of hypoglycaemia. No new safety or tolerability issues were observed.

KEY WORDS

liraglutide, basal insulin, obesity, scale-insulin, type 2 diabetes, overweight