

RESULTS AND DISCUSSION

The MMRM approach yielded a weight loss difference of 4.6% (95% CI: 2.6%; 6.5%; $p < 0.0001$), and the covariate approach yielded a weight loss difference of 4.6% (95% CI: 2.8%; 6.5%; $p < 0.0001$), with both estimates favoring liraglutide 3.0 mg.

CONCLUSION

The estimated placebo-subtracted weight loss for liraglutide at week 56 of approximately 4.6% in medication-adherent individuals therefore indicates that underlying assumptions are robust. We believe this finding is an important supplement to the study's primary outcome and can inform practitioners' expectations when prescribing liraglutide 3.0 mg in combination with IBT for 56 weeks.

KEY WORDS

liraglutide, obesity, weight loss, scale-IBT

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EARLY RESPONDERS TO LIRAGLUTIDE 3.0 mg AS ADJUNCT TO DIET+EXERCISE FROM THE SCALE MAINTENANCE TRIAL

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INTRODUCTION

The SCALE Maintenance trial randomized adults with obesity (BMI ≥ 30 kg/m²) or overweight (BMI ≥ 27 kg/m²) + comorbidities who lost $\geq 5\%$ of initial body weight (BW) during a 4–12-week low calorie diet (1200–1400 kcal/day) run-in period (mean weight loss [WL]: 6.0%) prior to randomization to liraglutide 3.0 mg or placebo as an adjunct to diet and exercise.

METHODOLOGY

This *post-hoc* analysis of SCALE Maintenance compared outcomes in liraglutide 3.0 mg early responders vs. early non-responders (definition: ERs vs. ENRs; $\geq 4\%$ vs. $< 4\%$ WL at week 16 post-randomization). Efficacy outcomes are observed means or proportions for those completing 56 weeks' treatment. The safety analysis set is used for adverse events (AEs).

RESULTS AND DISCUSSION

Mean characteristics at randomization (n=212) for liraglutide 3.0 mg were: 46 years old, 84% female, BMI 36 kg/m². Of those completing 56 weeks' treatment, (n=159); 118 (74.2%) were ERs to liraglutide 3.0 mg and 41 (25.8%) ENRs. At week 56, mean WL was -9.2% in ERs vs. +0.3% in ENRs in addition to run-in WL. 89.8% of ERs maintained run-in weight loss (or lost further weight) during 56 weeks vs. 41.5% of ENRs. The percentage of those who regained all run-in WL by week 56 was 0.0% for ERs vs. 4.9% for ENRs. Percent achieving $\geq 5\%$, $> 10\%$ or $> 15\%$ WL at week 56 was 66.9%, 43.2% and 18.6% for ERs vs. 14.6%, 0.0%, and 0.0% for ENRs. ERs had greater change in mean waist circumference: -7.3 cm vs. +0.3 cm in ENRs. Changes in systolic/diastolic blood pressure were -0.2/+1.9 mmHg in ERs vs. -0.3/+1.6 mmHg in ENRs. Changes in HbA_{1c} in ERs and ENRs were: -0.2% and -0.1% and fasting plasma glucose: -0.5 and -0.6 mmol/L. ERs with AEs was 91.2% vs. 94.3% for ENRs. Serious AEs were 4.4% vs. 0.0% and gastrointestinal AEs 78.1% vs. 60.4% for ERs vs. ENRs, respectively.

CONCLUSION

Among those who completed 56 weeks' treatment on liraglutide 3.0 mg, a greater additional WL of -9.2% was observed for ERs vs. +0.3% for ENRs, with a similar proportion experiencing AEs.

KEY WORDS

scale-maintenance, liraglutide, early responders, obesity