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3-year efficacy and safety for liraglutide 3.0 mg in adults with obesity/overweight, prediabetes and baseline BMI <35 vs ≥35 kg/m² in the SCALE Obesity and Prediabetes, double-blind, placebo-controlled trial

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Background: The 3-year SCALE Obesity and Prediabetes trial (NCT01272219) randomised 2254 adults with prediabetes (female 76%; 48 years; BMI 39 kg/m²) 2:1 to liraglutide 3.0 mg or placebo as adjunct to diet+exercise for 160 weeks.

Methods: This *post-hoc* analysis compared efficacy and safety of liraglutide in subjects with BMI < vs ≥35 kg/m² at baseline. Treatment effect of liraglutide across BMI subgroups was evaluated by statistical testing of interaction between treatment and BMI subgroup.

Results: Baseline characteristics were broadly similar between liraglutide and placebo BMI subgroups except weight-related characteristics (weight, BMI, waist circumference). At 160 weeks, significantly greater mean and categorical weight-losses (WLs) were seen with liraglutide vs placebo for BMI < and ≥35 (mean WL [%]: −6.4, −6.0 vs −1.7, −2.0; % achieved ≥5% WL: 51.1, 48.9 vs 19.7, 25.0; >10% WL: 25.7, 23.7 vs 8.9, 9.8; >15% WL: 8.1, 8.0 vs 2.5, 2.2) as well as greater improvements in glycaemic and quality-of-life endpoints; these treatment effects appeared independent of baseline BMI (interaction p>0.05). While on treatment at 160 weeks, more people with liraglutide vs placebo regressed to normoglycaemia, irrespective of baseline BMI: 66.1, 65.8% vs 34.9, 36.9%.

Rates of AEs, and serious/severe AEs were generally comparable across BMI subgroups. Rates of gallbladder-related AEs, pancreatitis and breast cancer were low and similar for BMI < and ≥35 but higher with liraglutide vs placebo.

Conclusions: 3 years' treatment with liraglutide 3.0 mg had similar effects on body-weight, glycaemic control and safety in subjects with baseline BMI < and ≥35 kg/m².

Key Words: Obesity management, Liraglutide 3.0mg
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