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Liraglutide 3.0 mg as an adjunct to intensive behaviour therapy in individuals with obesity: SCALE IBT 56-week randomised, double-blind, placebo-controlled trial

T WADDEN,[1] J SHAW TRONIERI,[1] D SUGIMOTO,[2] MT LUND,[3] P AUERBACH,[3] C JENSEN,[3] D RUBINO[4]

[1]Department of Psychiatry, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA; [2]Cedar Crosse Research Center, Chicago, IL, USA; [3]Novo Nordisk A/S, Søborg, Denmark; [4]Washington Center for Weight Management and Research, Arlington, VA, USA

Objectives: In this 56-week, randomised, double-blind, US-based multicentre trial (NCT02963935) we investigated the effects of liraglutide 3.0 mg vs. placebo, as adjunct to intensive behaviour therapy (IBT) (i.e. reduced calorie intake, increased physical activity [max target: 250 minutes/week], and 23 counselling sessions). Here we report the effects of treatment on weight change (co-primary endpoints: mean change in body weight [%] and proportion of individuals losing ≥5% body weight), glycaemic variables, cardiometabolic risk factors, safety and tolerability.

Methods: Individuals aged ≥18 years with a body mass index (BMI) ≥30 kg/m^2 and without diabetes were randomised 1:1 to liraglutide 3.0 mg or placebo along with IBT. Continuous and categorical variables were calculated using analysis of covariance (ANCOVA) and logistic regression respectively, with treatment, gender and BMI as factors and baseline endpoint as a covariate. Missing values were handled using a jump-to-reference multiple imputation model.

Results: There were 282 individuals in the full analysis set; 142 were randomised to liraglutide 3.0 mg (45 years, 16% male, 109 kg, 39 kg/m^2) and 140 to placebo (49 years, 17% male, 107 kg, 39 kg/m^2); 99% and 93% completed the trial, respectively. The intention to treat analysis demonstrated weight loss at 56 weeks of 7.5% with liraglutide 3.0 mg and 4.0% with placebo (estimated treatment difference (ETD) [95% CI], 3.5% [5.3, 1.6]; *p*=0.0003). Weight loss in individuals on trial product at 56 weeks was 9.1% (n=114) and 4.8% (n=103), respectively. The proportion of individuals achieving ≥5% weight loss was 61.5% with liraglutide 3.0 mg and 38.8% with placebo (estimated odds ratio (OR) 2.5 [1.5, 4.1], *p*=0.0003). Significant improvements in secondary efficacy outcomes at 56 weeks were seen for liraglutide 3.0 mg vs placebo (Table). Lipids were improved vs baseline but no significant differences between treatment arms were observed at 56 weeks (all *p*>0.05). Liraglutide 3.0 mg was generally well tolerated and no new safety signals were observed in this study. The most frequent adverse events were gastrointestinal (liraglutide 3.0 mg: 71%; placebo: 49%).

Conclusions: Treatment with liraglutide 3.0 mg as an adjunct to IBT resulted in significantly greater weight loss, as compared with IBT and placebo.

Table. Summary of secondary efficacy results at 56 weeks

	Liraglutide 3.0 mg N=142	**Placebo N=140**	**Estimated treatment difference (ETD) or odds ratio (OR) [95% CI]**	***P*-value**
Proportion achieving >10% weight loss	30.5	19.8	OR 1.8 [1.0, 3.1]	0.0469
Proportion achieving >15% weight loss	18.1	8.9	OR 2.3 [1.1, 4.7]	0.0311
Change in waist circumference, cm	–9.4	–6.7	ETD -2.7 cm [–4.7, –0.8]	0.006
Change in HbA_{1c}, %	–0.16	–0.06	ETD -0.10% [–0.16, –0.04]	0.0008
Change in fasting plasma glucose, mmol/L	5.16	5.39	ETD –0.23 mmol/L [–0.36, –0.11]	0.0002
Blood pressure (BP) at 56 weeks, mmHg				
Change in systolic BP	–2.79	–0.60	ETD -2.2 mmHg [–4.9, 0.5]	0.11
Change in diastolic BP	–1.01	–0.84	ETD -0.2 mmHg [–2.2, 1.8]	0.87
Change in heart rate, bpm	1.87	0.57	ETD 1.3 bpm [–0.8, 3.4]	0.23

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