Impact of weight loss on patient-reported outcomes in the SCALE Obesity and Prediabetes trial of liraglutide 3.0 mg as adjunct to a diet and exercise (D&E) programme

Objectives
- Obesity is a chronic disease with many complications, including a detrimental effect on health-related quality of life (HRQoL).¹
- Reductions in body weight have been shown to reduce complications associated with obesity and improve quality of life.²
- The SCALE (Safety and Clinical Adiposity – Liraglutide Evidence) Obesity and Prediabetes trial investigated the efficacy and safety of liraglutide 3.0 mg for weight management in adults who did not have type 2 diabetes but who had obesity (body mass index (BMI) ≥30 kg/m²) or overweight (BMI ≥27kg/m²) with ≥1 weight-related comorbidity.³
- The trial also explored the impact of liraglutide 3.0 mg and placebo as adjunct to diet and physical activity on patient-reported outcomes.
- Here we report change in patient-reported HRQoL from baseline to week 56.

Methods
- Patients were randomised 2:1 to once-daily liraglutide 3.0 mg (N=2487) or placebo (N=1244).
- All participants were counselled on a 500 kcal/day deficit diet and increased physical activity to a 150 minutes/week.
- HRQoL was assessed using two separate health questionnaires: – Impact of Weight on Quality of Life (IWQOL-Lite).⁴
- Five domains are assessed: physical function, self-esteem, sexual life, public distress and work.
- An overall total score is calculated by combining the scores from each domain.
- Higher scores indicate better quality of life. Clinically relevant changes are improvements of 7.7–12 points (depending on baseline score).⁵
- Short-Form 36 Health Survey v2 (SF-36), which measures health status.⁶
- Four domains are assessed: physical functioning, role-physical, bodily pain, general health, social functioning, vitality, role-emotional, and mental health.
- Two overall scores are calculated by combining scores from the domains: an overall physical component summary score (PCS) and an overall mental component summary score (MCS).
- Higher scores indicate better health status. Clinically meaningful changes are improvements of at least 2 points for the PCS.⁶
- Questionnaires were administered only in countries with validated translations (approximately 82% of the study population).
- For IWQOL-Lite: n=1890 liraglutide 3.0 mg, n=886 placebo
- For SF-36: n=1689 liraglutide 3.0 mg, n=796 placebo
- In total, 2046 participants (liraglutide 3.0 mg) and 1020 participants (placebo) were randomised to baseline.
- This post hoc analysis was based on the categorical weight change from baseline for liraglutide 3.0 mg and placebo.

Table 1 Baseline characteristics

<table>
<thead>
<tr>
<th>Overall trial population</th>
<th>HRQoL-assessed population</th>
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<tbody>
<tr>
<td><strong>Liraglutide 3.0 mg</strong></td>
<td><strong>Placebo</strong></td>
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<tr>
<td><strong>(N=2487)</strong></td>
<td><strong>(N=1244)</strong></td>
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<td><strong>(N=1244)</strong></td>
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<tr>
<td>Mean age, years</td>
<td>45.2±12.1</td>
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<tr>
<td>Sex, % female</td>
<td>78.7</td>
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<tr>
<td>Weight, kg</td>
<td>106.2±21.7</td>
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<td>BMI, kg/m²</td>
<td>38.3±6.4</td>
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<td>HbA₁c, %</td>
<td>5.6±0.4</td>
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<tr>
<td>Hypertension, % of patients</td>
<td>34.2</td>
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<tr>
<td>Osteoarthritis, % of patients</td>
<td>29.6</td>
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</tbody>
</table>

Data are all randomised patients. Data are observed means ± SD, or percentage. BMI, body mass index; HRQoL, health-related quality of life; SD, standard deviation.

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References

Conclusions
- Higher proportions of subjects achieving greater categorical weight loss were observed with liraglutide 3.0 mg versus placebo as adjunct to diet and physical activity.
- Greater improvements in IWQOL-Lite total scores and SF-36 physical component summary scores were observed with greater categorical weight loss.

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Liraglutide 3.0 mg is not approved for weight management outside Canada, EU, Mexico and US.