Real-world persistence and weight loss by obesity class with liraglutide 3.0 mg: a *post hoc* analysis of the real-world effectiveness study in Canada

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Background

- The effectiveness of liraglutide 3.0 mg for chronic weight management in routine clinical practice was demonstrated in a study conducted at Wharton Medical Clinics in Canada.[1]
- The objective of this *post hoc* analysis was to evaluate the treatment effect of liraglutide 3.0 mg in individuals by obesity class.

Methods

- Using a database of de-identified electronic medical records (EMR), a cohort of liraglutide 3.0 mg initiators between September 2015 and September 2016 was identified.
- The full cohort was split by BMI (kg/m^2): obesity class I (30–34.9), class II (35–39.9), and class III (≥40). Individuals with a BMI <30 were excluded.
- Persistence on liraglutide 3.0 mg, time to maintenance dose, and weight loss (WL) for each BMI cohort were analysed.
  - » Paired t-tests were used to analyse differences in body weight within obesity classes.
  - » One-way analysis of variance (ANOVA) was used to compare continuous variables and an extended Fisher's exact test was used to compare categorical endpoints between obesity classes.
  - » A log-rank test was used to evaluate statistical significance between obesity classes for both persistence on liraglutide 3.0 mg and time to maintenance dose.

Results

- Baseline characteristics and adherence to the diet and exercise programme across BMI cohorts are reported in Table 1.
- Mean time to maintenance dose was just over 9 weeks (days, mean±SD: class I, 64.2±56.4; class II, 76.4±56.3; class III, 71.4±54.5; Table 2), compared with the 4 weeks (28 days) recommended by the label,[2] and did not significantly differ between obesity classes (p=0.5085).
- Persistence, reported as mean time on liraglutide 3.0 mg, was around 6 months (months, mean±SD: class I, 6.7±4.0; class II, 6.0±3.5; class III, 6.3±4.5) and did not significantly differ between obesity classes (p=0.3580).

Table 2: Time to maintenance dose and maximum dose for each BMI cohort

	BMI cohort (kg/m^2)		
	30–34.9	35–39.9	≥40
Mean time to maintenance dose, days (SD)	64.2 (56.4)	76.4 (56.3)	71.4 (54.5)
Mean maximum dose, mg (SD)	2.7 (0.6)	2.8 (0.5)	2.7 (0.7)

Maximum dose was defined as the highest dose ever noted between index date and discontinuation of liraglutide 3.0 mg. For individuals who reached the maintenance dose of 3.0 mg, time to maintenance dose was defined as the time between index date and date of reported maintenance dose; individuals who did not achieve the maintenance dose of 3.0 mg were considered censored at their discontinuation date. SD, standard deviation.

- At 4 months, 71.4%, 68.7%, and 65.8% of individuals in obesity class I, II, and III remained on treatment with liraglutide 3.0 mg respectively. At 6 months, 57.1%, 51.8%, and 53.4% remained on treatment (Figure 1).
- At 6 months after liraglutide initiation, WL of 6.2 kg (95% CI: –7.8,–4.7; %WL, 7.0), 6.7 kg (95% CI: –8.5,–5.0; %WL, 6.6), and 8.0 kg (95% CI: –9.3,–6.8; %WL, 6.1) was achieved in obesity class I, II, and III respectively (Figure 2).
  - » Compared with baseline, all obesity classes achieved significant WL at 6 months (all p<0.001); however, there were no significant differences between the three classes (p=0.192).

Figure 1: Kaplan–Meier plot illustrating the persistence on liraglutide 3.0 mg by BMI cohort

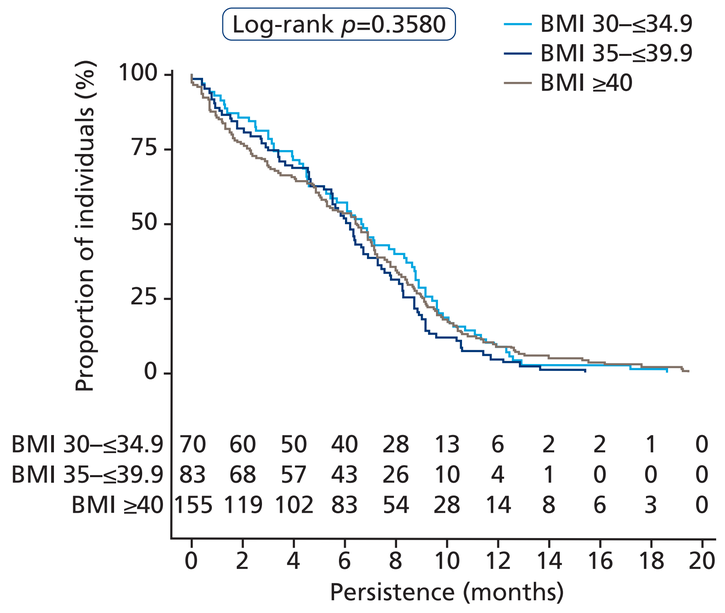
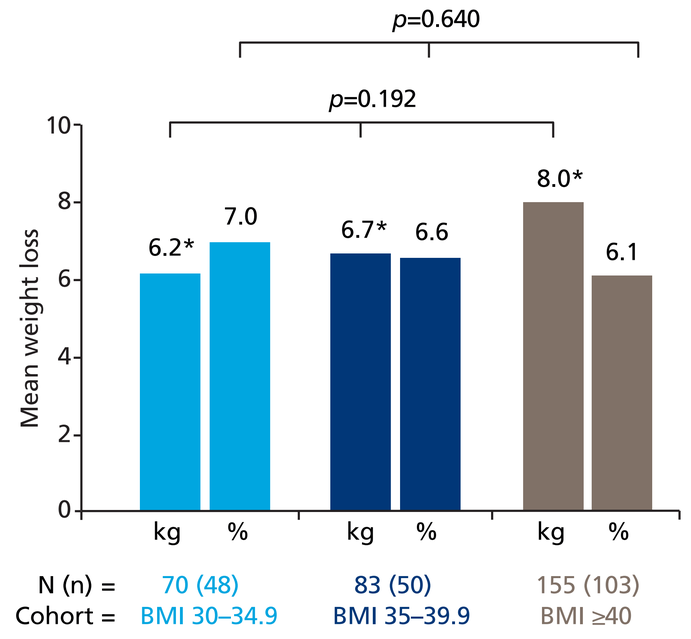


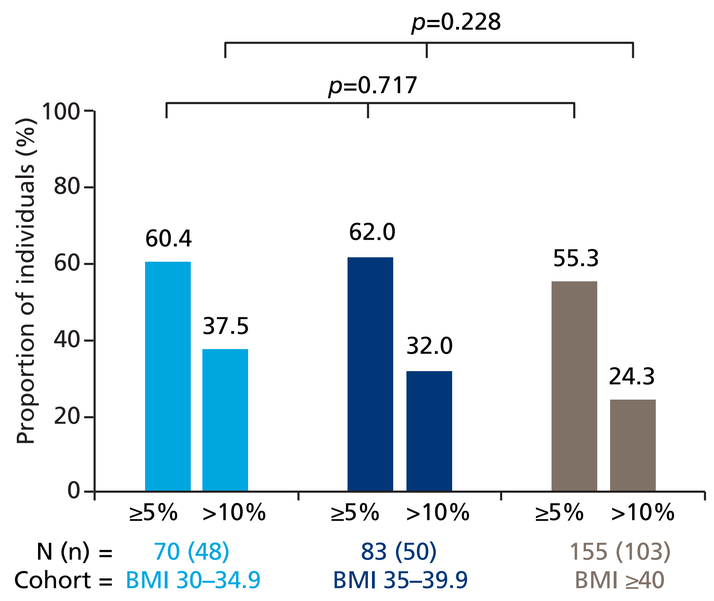
Figure 2: Weight loss at 6 months (kg, %) **Key result**



*p<0.001 vs. baseline. N, number of individuals at baseline; n, number of individuals with a weight measurement at 6 months.

- At 6 months, the proportion of individuals achieving WL of ≥5% was 60.4% in obesity class I, 62.0% in obesity class II, and 55.3% in obesity class III. Slightly fewer individuals achieved >10% WL (class I, 37.5%; class II, 32.0%; class III, 24.3%; Figure 3). There were no significant differences in proportions achieving ≥5% and >10% WL between BMI groups (p=0.717 and p=0.228, respectively).

Figure 3: Categorical weight loss of ≥5% and >10% at 6 months



N, number of individuals at baseline; n, number of individuals with a weight measurement at 6 months.

Table 1: Baseline demographics

Variable	Full cohort*	Obesity class I BMI 30–34.9 kg/m^2	Obesity class II BMI 35–39.9 kg/m^2	Obesity class III BMI ≥40 kg/m^2
N	311	70	83	155
Age, years	49.7 (11.6)	53.0 (10.6)	47.8 (11.5)	49.4 (12.0)
Sex, female, n [%]	258 [83.0]	61 [87.1]	73 [88.0]	121 [78.1]
Race, white, n [%]	241 [77.5]	50 [71.4]	63 [75.9]	125 [80.6]
BMI, kg/m^2	40.7 (7.1)	32.9 (1.5)	37.2 (1.5)	46.3 (5.6)
Weight, kg	114.8 (26.3)	90.9 (11.1)	103.7 (11.6)	132.1 (24.9)
HbA_{1c}, %	5.8 (0.9)	5.9 (1.3)	5.8 (0.7)	5.9 (0.7)
SBP, mmHg	127.2 (11.2)	121.6 (9.8)	124.5 (9.3)	131.3 (11.3)
Diabetes				
None, n [%]	233 [74.9]	54 [77.1]	67 [80.7]	111 [71.6]
Prediabetes, n [%]	62 [19.9]	10 [14.3]	14 [16.9]	36 [23.2]
Type 2 diabetes, n [%]	16 [5.1]	6 [8.6]	2 [2.4]	8 [5.2]
Adherence to exercise programme				
No physical activity, n [%]	41 [13.2]	4 [5.7]	13 [15.7]	23 [14.8]
Some physical activity, n [%]	78 [25.1]	20 [28.6]	17 [20.5]	41 [26.5]
Meeting or exceeding, n [%]	105 [33.8]	23 [32.9]	32 [38.6]	48 [31.0]
Adherence to diet				
Never, n [%]	16 [15.1]	2 [2.9]	5 [6.0]	8 [5.2]
Sometimes, n [%]	40 [12.9]	11 [15.7]	14 [16.9]	15 [9.7]
Always, n [%]	77 [24.8]	19 [27.1]	18 [21.7]	38 [24.5]

Data are mean (±SD) unless otherwise stated. An individual was determined to have T2D if they were taking any prescription with ATC code of A10 with start date prior to their index date, had FPG >7 mmol/L at least two times in the year prior to their index date or HbA_{1c} >6.5% in the year prior to their index date. FPG, fasting plasma glucose; SBP, systolic blood pressure; SD, standard deviation. *Full cohort includes individuals with a BMI <30, who were excluded from the analysis.

Discussion

- Similar to the findings of the SCALE Obesity and Prediabetes *post hoc* BMI analysis,[3] the treatment effect of liraglutide 3.0 mg in this real-world study did not differ between classes of obesity.
- This study used a longitudinal database of de-identified EMR data that is representative of the specific target population of pharmacotherapeutic weight management interventions in a government-funded weight management clinic.

Conclusion

- The results of this analysis suggest that individuals taking liraglutide 3.0 mg in a real-world setting can achieve clinically significant weight loss, with similar treatment effect, time to maintenance dose, and treatment persistency, regardless of obesity class.

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References: (**1**) Wharton *et al.* European Congress on Obesity (ECO) 2018, 23–26 May 2018, Vienna, Austria, Poster T4LB2; (**2**) European Medicines Agency. 2015. Saxenda® EPAR summary. Available at: https://www.ema.europa.eu/en/documents/overview/saxenda-epar-summary-public_en.pdf; (**3**) le Roux *et al. Obesity Facts* 2017;10:531–44