Real-world persistence with liraglutide 3.0 mg for weight management and the SaxendaCare® patient support program

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Summary
Objective: Weight management medications can significantly increase patients’ chances of achieving a clinically meaningful weight loss if patients persist with treatment. This retrospective observational study of de-identified medical records of 311 patients is the first real-world study examining persistence with liraglutide 3.0 mg in Canada, and also investigates associations between the SaxendaCare® patient support program and persistence and weight loss.

Methods: Overall persistence was assessed, as well as associations of enrollment in SaxendaCare®, persistence and weight loss.

Results: Overall mean (standard deviation) persistence with liraglutide 3.0 mg was 6.3 (4.1) months, and 67.5% (n = 210) and 53.7% (n = 167) of patients persisted for ≥4 and ≥6 months, respectively. Enrollment in SaxendaCare® was associated with significantly longer persistence with liraglutide 3.0 mg and greater weight loss. Patients enrolled in SaxendaCare® (n = 119) persisted for 7.9 (4.0) versus 5.2 (3.8) months for those not enrolled (n = 184) (p < 0.001), and had significantly greater percent weight loss after 6 months regardless of the duration of their persistence (−7.9% vs −5.5% from baseline, p < 0.01).

Conclusions: These findings suggest that, in clinical settings, persistence with liraglutide 3.0 mg can exceed 6 months, and that enrolling in SaxendaCare® may be associated with comparatively longer persistence and, regardless of persistence, greater weight loss.

KEYWORDS
Liraglutide 3.0 mg, obesity, persistence, SaxendaCare®

1 | INTRODUCTION

Compliance with obesity medications is notoriously poor; two real-world USA database studies revealed that only 1–4% and 6–27% of patients persisted with obesity medication for longer than 1 year.1,2 To date, only persistence with orlistat has been investigated in Canada, and findings showed that 18% of patients were persistent at 6 months, with discontinuation rates much higher than those reported in clinical trials.3

Significant weight loss was observed with liraglutide 3.0 mg as adjunct to healthy eating and exercise in the Satiety and Clinical Adiposity – Liraglutide Evidence (SCALE) clinical trials, which...
assessed a total of 5539 patients with type 2 diabetes, prediabetes, sleep apnea or without diabetes.5–7 Twice the number of patients with overweight or obesity who were randomized to liraglutide 3.0 mg in the SCALE trials achieved a mean weight loss of ≥5% of initial weight versus placebo (46–63% versus 21–27%, respectively) and improvements in weight-related outcomes compared with placebo (including cardiovascular outcomes, improved glycemic control, cholesterol levels, blood pressure and obstructive sleep apnea) were observed over a maximum trial period of 56 weeks.4–9 Reduced risk of cardiovascular disease following treatment with liraglutide 1.2–1.8 mg has also been shown in other studies.10,11

Real-world evidence (RWE) is a measure of effectiveness in routine clinical practice that can complement and expand on insights from randomized clinical trials (RCTs). This evidence can be sourced from databases, patient medical chart reviews and registries.12 A RWE study of data from six weight management clinics in Canada, showing that patients on liraglutide 3.0 mg lost a mean of 7.1% (standard deviation [SD] 5.4%) body weight after 6 months of treatment, has been previously reported by this research team.13 The current study reports a secondary analysis that expands on medication persistence findings and investigates the associations between enrollment in the patient support program SaxendaCare® and both persistence with liraglutide 3.0 mg and weight loss.

2 | METHODS

In this post-hoc analysis of the retrospective observational RWE study, persistence with liraglutide 3.0 mg prescribed for weight management, in addition to diet and exercise, was investigated. Persistence (defined in this study as the period of time from treatment initiation to patient-reported discontinuation, loss of patient to follow-up including if >90 days lapsed between follow-up visits, or study end) with liraglutide 3.0 mg overall and persistence for at least 4 and 6 months were assessed, in line with the time points specified in the primary study.13 Associations among SaxendaCare® enrollment, persistence and weight loss in all patients with available data were also investigated.

Data were sourced from patients attending the Wharton Medical Clinic (WMC), a network of six Ontario Health Insurance Plan (OHIP) secondary care weight and diabetes management clinics in Ontario, Canada, where patients had been prescribed liraglutide 3.0 mg for weight management.

All patients, regardless of enrollment into SaxendaCare®, attended the WMC every 3 to 4 weeks and participated in lifestyle interventions (such as educational videos, individual or group sessions with a bariatric educator, and meetings with a dietitian or counsellor for patients who required it) to assist with weight loss alongside medication, according to the WMC Weight Management Protocol described elsewhere13 and in line with liraglutide 3.0 mg monograph recommendations,14 with the number of visits varying between patients.

Patients were offered enrollment into SaxendaCare® to receive additional support, which they could access for a period of 16 weeks. SaxendaCare® is a free, guided support program that uses evidence-based behavior change techniques to help patients achieve weight management goals. The aim of the program is to motivate patients to maintain their weight loss efforts and to encourage physical activity and healthy eating strategies. At the time this study was conducted, patients enrolled in SaxendaCare® v1.0 (henceforth referred to as SaxendaCare®) were provided weekly emails, one-on-one personalized meetings with a nurse or dietician and access to the SaxendaCare® website. In addition to providing a practical curriculum to aid with weight loss and weight management, SaxendaCare® helped patients familiarize themselves with treatment by providing injectable pen training, a dosing schedule and reminders about dosing and re-fills.

Patients were informed of the SaxendaCare® program at initiation of treatment with liraglutide 3.0 mg and given the opportunity to enrol, and were further encouraged to do so at subsequent appointments. Evidence of patients being informed about SaxendaCare® by their physician, and of patient- or SaxendaCare®-reported enrollment status, was required for patient data to be included in associations regarding SaxendaCare® enrollment status. Funding for SaxendaCare® prior to launch was provided by Novo Nordisk A/S. Novo Nordisk Canada Inc. funded all operational aspects of SaxendaCare® post-launch. Visits and consultative services for patients attending the WMC were billed to OHIP. Medication was covered by a patients’ insurance plan if eligible, provided as free samples by their physician and/or paid for by the patient. All decisions to prescribe medication were made by the healthcare professional in consultation with the patient and independently of the study.

2.1 | Data source

Analyses were performed on a database of de-identified WMC patient electronic medical records (EMR). The database contains demographic and clinical parameters and diagnostic and prescription information. WMC patients indicated whether they were willing to consent to the use of their electronic medical data for research purposes and were informed that their participation or lack of participation would not alter treatment. Patients who opted out or had not expressly given consent for their data to be used for research by WMC were not included in this study.13

The selection period for treatment initiation was 15th September 2015 to 30th September 2016, with baseline demographic data based on the 12-month period prior to initiation. Baseline weight was the most recent weight measurement in the 3 months prior to initiation, and patient follow-up was a minimum of 6 months and up to 18 months. Last date of follow-up was 30th April 2017. Index date was the date liraglutide 3.0 mg treatment was initiated during the selection period. As patients do not always initiate treatment immediately upon prescription, the date of initiation of liraglutide 3.0 mg was estimated using a back-calculation from the dose reported at the
follow-up visit after date of first prescription. This back-calculation was in line with the dosing outlined in the product monograph and is described in the Supporting Information (Table S1).

2.2 Study participants

Patients met the following inclusion criteria: at least one prescription for liraglutide 3.0 mg for weight management, issued at the discretion of a physician according to the label for this medication, in line with monograph recommendations and Canadian treatment guidelines; treatment had to be initiated during the selection period; patients were ≥18 years of age at index with at least one reported baseline weight measurement in the 3 months prior and at least one visit to WMC within 6 months after index; included patients had a baseline body mass index (BMI) ≥30 kg/m² or BMI ≥27 kg/m² with at least one weight-related comorbidity (e.g. hypertension, type 2 diabetes, dyslipidemia) and a self-reported failed previous weight management intervention (target weight loss unspecified).

Patients were excluded if they reported previously taking or were currently taking any glucagon-like peptide-1 (GLP-1) receptor agonist (i.e. liraglutide for weight management or type 2 diabetes, exenatide or exenatide extended-release, or dulaglutide) or if they had ever undergone bariatric surgery.

Patients who met the inclusion criteria and none of the exclusion criteria were included in the analyses. Additionally, two persistence cohorts of patients were identified: those who persisted on liraglutide 3.0 mg for at least 4 months after the index date (≥4 months) and those who persisted on liraglutide 3.0 mg for at least 6 months after the index date (≥6 months). Patients with available data regarding SaxendaCare® enrollment status were included in analyses of the associations between SaxendaCare® enrollment and persistence and weight loss.

2.3 Variables and outcomes

Baseline body weight was the most recent weight measurement within 3 months prior to initiation of liraglutide 3.0 mg. Other baseline characteristics were taken from the most recent information within 12 months prior to treatment initiation.

The primary outcome was persistence overall with liraglutide 3.0 mg, as well as persistence at 4 and 6 months after initiation of treatment. Other outcomes, for which comparisons were performed between patients enrolled in SaxendaCare® versus patients not enrolled, were as follows: persistence overall, persistence at 4 and 6 months after initiation of liraglutide 3.0 mg, absolute and percent difference in body weight at 6 months after initiation, and proportion of patients losing ≥5% and >10% of their body weight.

Persistence was defined as the time between index date and discontinuation of liraglutide 3.0 mg, with discontinuation defined as patient self-reported discontinuation at a WMC visit, a gap of >90 days between visits or the end of the follow-up period (30th April 2017), depending on which occurred earliest. Patients were flagged if they persisted to 4 months and 6 months after index date.

2.4 Statistical methods

Baseline demographics and clinical data were reported for all patients as n (%) or mean (SD) as appropriate. The period of follow-up (minimum 6 months, maximum 18 months) allowed for the collection of data on persistence from patients who had follow-up data for both shorter and longer periods of time. Individuals lost to follow-up were included but censored at date of loss.

Persistence was presented for all patients and by enrollment in SaxendaCare® using a Kaplan–Meier plot, and a log-rank test was used to compare those enrolled and not enrolled in SaxendaCare®. Mean (SD) and median (interquartile range, IQR) time persistent on liraglutide 3.0 mg were reported for each group. The difference in mean persistence between SaxendaCare® groups was compared using an independent t-test. Fisher’s exact test was used to compare the percentage of patients persistent with liraglutide 3.0 mg for 4 and 6 months, by SaxendaCare® enrollment.

Difference in mean percent body weight change after 6 months was compared between those enrolled in SaxendaCare® and those not enrolled using an independent t-test, and 95% confidence intervals were calculated. Fisher’s exact test was used to analyse the difference between proportions of patients with ≥5% and >10% decrease in body weight, respectively, at 6 months’ follow-up, between the two SaxendaCare® groups.

2.5 Data access and cleaning methods

Missing data were not imputed, but were reported as a proportion for all analyses. All analyses were conducted by IQVIA (Montreal, QC, Canada) using SAS version 9.3 (SAS Institute, Inc., Cary, NC, USA). No study size calculations were performed in this analysis.

The study design and protocol were reviewed and approved by the Center for Independent Research Ethics Board Intelligence (CIRBI), and full methodological details, together with de-identification methods, have been reported elsewhere. Further information is also available in the Supporting Information.

3 RESULTS

In total, 311 patients fulfilled the inclusion criteria (see patient flow diagram, Figure 1). Eight patients had unknown or missing data regarding SaxendaCare® status, thus 303 patients were included in the SaxendaCare® analysis: 119 enrolled and 184 not enrolled (Figure 1).

Baseline demographics for all patients and the SaxendaCare® enrollment cohorts are shown in Table 1. The majority of patients were white middle-aged females (49–50 years) with mean (SD) BMI
3.1 | Persistence

For all patients (n = 311), mean (SD) persistence was 6.3 (4.1) months on liraglutide 3.0 mg, with a median (IQR) of 6.4 months (2.9, 9.0) (Figure S1). Of these, 67.5% of patients (n = 210) persisted with liraglutide 3.0 mg for at least 4 months (≥4-month cohort) and remained persistent for a mean (SD) of 8.5 (3.1) months. Furthermore, 53.7% (n = 167) of patients persisted for at least 6 months (≥6-month cohort) and remained persistent for a mean of 9.4 (2.9) months. Of the patients who persisted for ≥4 months, but not 6 months (n = 43), 12 failed to achieve a ≥5% weight loss at 4 months +/- 30 days (weight data were not available for 6 patients at +/- 30 days). Among all patients, 28.3% (n = 88) were followed-up for over a year after treatment initiation, and of these, 27.3% (n = 24) were still persistent with liraglutide 3.0 mg. Conversely, among all patients, 25.1% (n = 78) had discontinued treatment after less than 3 months.

For patients enrolled in SaxendaCare®, mean (SD) overall persistence on liraglutide 3.0 mg was 7.9 (4.0) months, compared with 5.2 (3.8) months for those not enrolled (p < 0.001) (Figure 2). Of the enrolled patients, 83.2% (n = 99) persisted with liraglutide 3.0 mg for at least 4 months and remained persistent for a mean (SD) of 9.1 (3.3) months. This compares with 57.1% (n = 105) of patients not enrolled who persisted for at least 4 months (p < 0.001) and remained persistent for a mean (SD) of 7.9 (2.7) months. Of patients enrolled in SaxendaCare®, 72.3% (n = 86) were persistent for at least 6 months, whereas only 40.8% (n = 75) of those not enrolled persisted (p < 0.001) (Figure 3). Both enrolled and not-enrolled patients who persisted for at least 6 months remained persistent for a similar mean (SD) duration [9.6 (3.2) and 9.1 (2.3) months, respectively].

3.2 | Weight loss

Weight loss observed for patients enrolled in SaxendaCare® was consistently greater than for those not enrolled (Table 2). Enrolled patients experienced greater percent weight loss, regardless of persistence, after 6 months (7.9% vs 5.5%, p < 0.01). For enrolled patients who persisted for ≥4 months, the mean (SD) percent weight loss from baseline was 7.0% (4.3) compared with 5.7% (3.9) for those not enrolled (1.4% difference, p < 0.05). For those persisting for ≥6 months, percent weight loss was 8.2% (5.2) versus 6.2% (5.5) for those not enrolled (2.0% difference, p < 0.05) (Table 2).

Among all patients with SaxendaCare® enrollment status, the proportion with weight losses of both ≥5% and >10% after 6 months was significantly greater for enrolled patients (p < 0.01 and p < 0.05, respectively), compared with those not enrolled, regardless of persistence. The proportion with ≥5% weight loss was significantly greater for enrolled patients persisting at ≥6 months (p < 0.05) (Figure 4).

4 | DISCUSSION

Persistence with medication has been associated with positive health outcomes in a range of diseases.16 This study found that average patient persistence with liraglutide 3.0 mg can exceed 6 months in a real-world clinical setting, with around 68% of all patients persisting with treatment for at least 4 months and around 54% persisting for at least 6 months.

In the SCALE program, the percentage of patients who persisted with liraglutide 3.0 mg treatment was slightly higher than in this study, with 72–77% of patients remaining on treatment (provided free of charge to all patients) during the 32- or 56-week clinical trials.4–7 However, patients in the present study persisted for longer than has been reported in previous RWE studies; results can be compared with the only other similar study of weight loss medication performed to
date in Canada, where 18% of patients persisted with orlistat at 6 months. Comparisons can also be made with recent real-world studies in different patient populations; in a real-world USA study of common weight loss medications, 41.8% of patients persisted on liraglutide 3.0 mg at 6 months, while lower rates of persistence were seen with other medications: 27.3% of patients persisted on phentermine/topiramate, 18.1% on naltrexone/bupropion and 15.9% on naltrexone/bupropion and 15.9% on naltrexone/bupropion and 15.9%

TABLE 1 Baseline characteristics for all patients and patients with SaxendaCare® enrollment status

| Variable                        | All patients (n = 311) | Patients with SaxendaCare® enrollment status (n = 303) |
|---------------------------------|------------------------|-------------------------------------------------------|
|                                 | Enrolled in SaxendaCare® (n = 119) | Not enrolled in SaxendaCare® (n = 184) |
| Age (years), mean [SD]          | 49.7 [11.6]            | 50.45 [12.4]   | 49.27 [11.2]   |
| Sex, n female (%)               | 258 (83)               | 103 (86.6)    | 150 (81.5)     |
| Race*, white, n (%)             | 241 (77.5)             | 92 (77.3)     | 144 (78.3)     |
| Weight (kg), mean [SD]          | 114.8 [26.3]           | 114.3 [27.5]  | 114.0 [24.3]   |
| BMI (kg/m²), mean [SD]          | 40.7 [7.1]             | 40.3 [7.6]    | 40.7 [6.5]     |
| Overweight (27–29.9), n (%)     | 3 (1.0)                | 3 (2.5)       | 0 (0.0)        |
| Obesity class I (30–34.9), n (%)| 70 (22.5)              | 31 (26.1)     | 38 (20.7)      |
| Obesity class II (35–39.9), n (%)| 83 (26.7)             | 25 (21.0)     | 56 (30.4)      |
| Obesity class III (≥40), n (%)  | 115 (49.8)             | 60 (50.4)     | 90 (48.9)      |
| Pre-diabetes, n (%)             | 62 (19.9)              | 28 (23.5)     | 32 (17.4)      |
| Type 2 diabetes, n (%)          | 16 (5.1)               | 3 (2.5)       | 11 (6.0)       |
| Hypertension, n (%)             | 103 (33.1)             | 40 (33.6)     | 57 (31.0)      |
| Dyslipidemia, n (%)             | 190 (61.1)             | 68 (57.1)     | 117 (63.6)     |
| HbA1c, † (%), mean [SD]         | 5.8 [0.9]              | 5.7 [0.6]     | 5.9 [1.0]      |

*Proportion missing: n = 22, n = 13, n = 8, respectively.
†Proportion missing: n = 143, n = 58, n = 82, respectively.
BMI, body mass index; HbA1c, glycated hemoglobin; n, no. of patients; SD, standard deviation.

FIGURE 2 Treatment persistence with liraglutide 3.0 mg by SaxendaCare® enrollment. SaxendaCare® support was provided for 4 months from enrollment. Analysis of treatment persistence based on patients with SaxendaCare® enrollment status (n = 303). Follow-up data were included for all patients for a minimum of 6 months up until 18 months as determined by the study design. This means that a decreasing number of patients were eligible for follow-up with regards to persistence from 6 months and onwards. Because enrollment in the 4-month SaxendaCare® support program was ongoing from treatment initiation, the dates of engagement and discontinuation with the program are unknown.

FIGURE 3 Proportion of patients persistent for ≥4 and ≥6 months by SaxendaCare® enrollment. Analysis of treatment persistence based on patients with SaxendaCare® enrollment status (n = 303). p values are from Fisher’s exact tests between the enrolled and not enrolled patient groups. CI, confidence interval.
on lorcaserin (all \(p < 0.001\)).\(^2\) In a prospective study of 2092 Arabic patients with obesity treated with liraglutide 3.0 mg in the UAE, 38% (\(n = 787\)) persisted for \(\geq 16\) weeks and 16% (\(n = 340\)) persisted for \(\geq 28\) weeks.\(^17\) It would be difficult to determine why the levels of persistence were higher in this Canadian study compared to the USA and UAE studies due to heterogeneity of the studies, as well as differences in the medical programs offered in each country and region. For example, the USA and UAE studies relied, at least in part, on pharmacy records to determine persistence while our study relied on self-reporting. Self-reporting could have overestimated persistence as a result of the time between actual discontinuation and its reporting at follow-up, or due to social desirability bias. Alternatively, the USA and UAE studies could have underestimated persistence by relying on dispensation records, given that the current study suggests that patients may deviate from the recommended dosing titration and/or may use a lower than recommended maintenance dose of liraglutide 3.0 mg. Thus, patients may still be taking medication at a lower dose, but be incorrectly classified as having run out.

Patients in the SCALE Obesity and Pre-diabetes trial lost 8.0% (8.4 kg) of body weight after 56 weeks of liraglutide 3.0 mg treatment versus 2.6% (2.8 kg) for placebo,\(^4\) and it is noteworthy that this is numerically less than the weight lost by patients enrolled in SaxendaCare\(^\circledR\) after only 6 months. The present study also indicates that patients enrolled in SaxendaCare\(^\circledR\) may remain persistent for longer than those who do not enrol. Furthermore, those enrolled in SaxendaCare\(^\circledR\) may experience greater weight loss compared with those not enrolled, regardless of persistence. The positive associations revealed in this study between enrollment in the SaxendaCare\(^\circledR\) program and both persistence and weight loss suggest that SaxendaCare\(^\circledR\) could be a valuable accompaniment to treatment with liraglutide 3.0 mg.

A number of RCTs have investigated the impact of digital patient support programs on weight loss.\(^18-20\) A systematic review of the impact of several of these programs demonstrated average weight losses ranging from 1.97 kg in 16 weeks to 7.10 kg in 5 weeks.\(^18-20\) These findings add strength to the proposition that digital patient support platforms, as exemplified by SaxendaCare\(^\circledR\), can influence weight loss.

The strengths of our study are that it is the first to examine both persistence with liraglutide 3.0 mg and the SaxendaCare\(^\circledR\) support program in Canada. There are also some limitations: patients were referred to the WMC, and those who did not choose to initiate liraglutide 3.0 mg were not included in this study, therefore, these results may be more applicable to patients who are motivated to lose weight using pharmacotherapy, compared with the general population. The exact date of initiation of liraglutide 3.0 mg was not always known and was estimated by back-calculation using the dose reported at the recorded date of initiation. Enrollment status and persistence
with liraglutide 3.0 mg were both largely self-reported and enrollment with SaxendaCare® generally occurred after patients had started treatment, with each follow-up clinic visit providing an opportunity for physicians to encourage enrollment. Thus, the 4-month period of SaxendaCare® support could have fallen at any time during follow-up. Because enrollment with SaxendaCare® could have been an indicator of a more motivated patient, this could have contributed to the positive associations observed in this study. A further limitation is that the study design allowed for a minimum follow-up period of 6 months. The majority of patients began liraglutide 3.0 mg treatment later in the inclusion period and had close to the minimum required follow-up period; therefore, persistence >6 months may be underestimated in this study. Finally, the current version of SaxendaCare® does not offer weight-loss support via phone calls with a coach, as was available with SaxendaCare® v1.0 used in this study. This feature was removed from the current version of SaxendaCare® due to low utilization, therefore the impact of this limitation is anticipated to be minimal with regards to translatability of these results.

5 CONCLUSIONS

This is the first real-world study examining treatment persistence with liraglutide 3.0 mg, as well as associations between SaxendaCare®, and both persistence and weight loss with liraglutide 3.0 mg, in Canada. Results suggest that persistence with liraglutide 3.0 mg can exceed 6 months in a real-world clinical setting. Enrollment in the SaxendaCare® patient support program was associated with greater treatment persistence and, regardless of persistence, greater weight loss.

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DISCLOSURES

• Sean Wharton: owner and medical director of the Wharton Medical Clinic (WMC), and internal medicine specialist at Hamilton Health Sciences. He has previously received research grants from Canadian Institutes of Health Research (CIHR) and Mitacs; previous funding from Novo Nordisk, Bausch Health, Eli Lilly, Janssen and AstraZeneca for advisory work.
• Christiane Lundegaard Haase: employee of Novo Nordisk A/S.
• Elham Kamran: research coordinator at WMC, and a member of this working group.

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• Christiane Lundegaard Haase: employee of Novo Nordisk A/S.
• Elham Kamran: research coordinator at WMC, and a member of this working group.

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of this article.

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