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Liraglutide (Saxenda) Combined with Lifestyle Coaching for Weight Loss in a Bariatric Center

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Abstract

Introduction: Overweight and obesity should be viewed as chronic diseases, for which liraglutide (Saxenda) might be a treatment option. The aim of the current study is to describe a real-world experience with the use of liraglutide combined with lifestyle coaching in a bariatric center.

Methods: A retrospective study including all patients (n=124) who enrolled in our lifestyle coaching program combined with the use of liraglutide.

Discussion: Liraglutide was well tolerated. After 1 year of treatment, median Total Weight Loss (TWL) was 11.5% and decrease in total body weight at 4-, and 6-months post initiation were 8.7% and 9.9%, respectively. At 6 months after start of the treatment, 89% had lost at least 5% of their body weight and 52% of participants lost at least 10%. Disappointment in weight loss or effect on satiety are reasons to stop using liraglutide.

Conclusion: The use of liraglutide is well-tolerated and associated with clinically meaningful weight loss in a cohort with a mean BMI of 36 kg/m^2. Gastrointestinal symptoms are not the main reason to stop using liraglutide. Reasons for patients to stop treatment with liraglutide are disappointment in weight loss or effect on satiety and appetite, predominantly after 6 months of use.

Keywords: Weight loss; Weight loss medication; Liraglutide; Saxenda; Lifestyle.

Introduction

Overweight and obesity are globally increasingly prevalent and should be viewed as chronic relapsing diseases that require continuous efforts toward prevention and treatment [1]. Weight loss of over 5% is associated with a lower risk of morbidity and mortality and is known to meaningfully improve health-related quality of life [2-6]. Lifestyle intervention alone - without any weight loss surgery, other treatment, or weight loss medication - results on average in weight loss of 2-5 percent [7] and a gradual regain of the weight often is common [8]. For those patients who want or need over 5% sustained weight loss - but are not willing or eligible to undergo bariatric surgery - weight loss medication might be an option. One of the popular options is the use of li-

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raglutide (Saxenda). Liraglutide is an acylated Glucagon-Like Peptide-1 (GLP-1) analog that has 97% similarity to human GLP-1 and is known to lower body weight by reducing appetite and calorie intake [9]. Randomized controlled trials have proven that liraglutide prescribed up to 3.0 mg a day successfully induced clinically meaningful weight loss compared to a placebo [10]. The use of Liraglutide can come with, mostly mild, side effects such as gastrointestinal complaints and headache. These complaints mostly occur at the start of the treatment but diminish over within weeks [11]. Aim of the current study is to describe real-world experience with the use of liraglutide combined with lifestyle coaching in a bariatric center. In addition, to gain insight in reasons for patients to when and why they stop using liraglutide.

Materials and methods

Study design

This is a retrospective study including all patients (n=124) who enrolled in our lifestyle coaching program combined with the use of liraglutide between July 2019 and July 2021 in our bariatric center. All data were consecutively collected. Informed consent was given by the patients for anonymous use of their data for research purposes before the start of the treatment. The study design and protocol were reviewed and approved by the local Medical Ethics Committee.

Participants

Participants were patients form a large bariatric center with locations spread throughout The Netherlands. They were included in the study if they fulfilled all of the following criteria: had a prescription for liraglutide at the discretion of the physician and were enrolled in the treatment program between July 2019 and July 2021, were ≥18 years of age, and, prior to index date, had BMI≥30 kg/m^2 or BMI≥27 kg/m^2 with at least one weight-related comorbidity (e.g., hypertension, T2D, dyslipidemia, sleep apnea). The complete treatment, medication as well as lifestyle program, was non-reimbursed for all participants (self-paid). There were no starting criteria considering previous weight loss attempts or reasons for weight gain (e.g. endocrinological, genetic).

Treatment program

The lifestyle program started with an intake visit with the physician and lifestyle coach. All factors contributing to overweight (e.g., diet, exercise, mental, social) were explored by using a mind map and participants were encouraged to identify the factors they believed they needed to work on. The program consisted of alternating consultations with the lifestyle coach and the physician. During the first weeks of enrolling in the program and dosage escalation, more frequent consultations were scheduled (i.e. four sessions during the first 5 weeks) as compared to the maintenance phase (monthly sessions during the rest of the first year; Figure 1). Liraglutide treatment initiated at the start of the coaching program at a daily dose of 0.6 mg, followed by a weekly dosage escalation of 0.6 mg up to 3.0 mg max or the maximum tolerable dosage.

Variables

Baseline demographics were collected during the intake visit. In addition to weight data, the prevalence of symptoms, appetite, satiety, and dosage of liraglutide were structurally noted during all visits.

Statistical analysis

Baseline demographics and clinical data were reported for all participants as n (percentage) and mean (SD) or median (interquartile range), as appropriate. A multiple linear regression analysis was performed to determine the predictive value of age, sex and 12 weeks %TWL on 12 month %TWL. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 26. The STROBE cohort reporting guidelines were used [12].

Results

Cohort

Out of the 124 evaluated participants, 82(66%) completed the 12-month lifestyle program while using liraglutide. A total of 31 (25%) participants discontinued the use of liraglutide before the end of the 12-month program. 11(8.9%) participants were lost to follow-up, they did not respond to calls and e-mails. On average, participants were 50 years old at inclusion, the majority was female (82%), and the average starting weight was 105 kg with a mean starting BMI of 36 kg/m^2. Among all subjects, 15% were currently being treated for hypertension, 2% for diabetes, 2% had obstructive sleep apnea syndrome, and 8% reported current smoking (Table 1).

Weight loss

Treatment with liraglutide, in addition to lifestyle coaching, was associated with a median 11.5% TWL after 1 year of treatment. Median decrease in body weight at 4-, 6- and 12-months post initiation were 8.7%, 9.9% and 11.2%, respectively (Figure 2) At 6 months after the start of the treatment, 89% had lost at least 5% of their body weight and 52% of participants lost at least 10%. At 12 months after the start of the treatment this was still 87.8% with 5% weight loss and 64.6% of participants lost 10%. (Table 2A). Furthermore, a multiple linear regression was run to predict %TWL at 12 months from age, sex and 12 week %TWL. These variables statistically significantly predicted %TWL at 12 months (R^2= 0.62, F(3,77)=40.99, p<0.000). All three variables added statistically significantly to the prediction, p<0.05. Patients predicted %TWL at 12 months is equal to -4.169+0.110 (age) – 1.753(Sex) + 1.069 (%TWL at 12 weeks), where Sex is coded as male=0 female=1.

Weight recurrence

After 12 months 51 patients (63%) had gained some weight compared to the 12 week measurement. No change in weight between these timepoints was seen in 3 patients (3.7%).

Patient experience

Tolerability: The use of liraglutide was well tolerated, with only mild symptoms, predominantly prevalent during the dosage escalation phase and consisting mainly of gastro-intestinal symptoms and fatigue (Table 2B).

Effect: Participants reported to feel less hungry (61.3%) or to have no appetite at all (35.6%). In addition, satiety was reported to be better in 95.2% of the participants (Table 2B). Unfortunately, monitoring comorbidities was not part of the follow-up.

Dosage: Within the first 4 months of their treatment, a total of 9(7.3%) participants discontinued the use of liraglutide. Of the remaining 115 participants who were using liraglutide at 4 months post-initiation, 92(80%) reached the dose of 3.0 mg daily, whereas 7(6%) were still using 0.6 mg, 8(7%) were using 1.8 mg and another 8 (7%) were using 2.4 mg. Reasons for not uptitrating to the maximum dosage were mainly: already experiencing enough satiety and weight loss at a lower dose, costs, or because of symptoms (Table 2B).

Discontinuation of liraglutide: A total of 31(25%) participants stopped using liraglutide during the 12-month program. The majority of those who stopped, discontinued between 6-12 months post-initiation (51.6%) (Table 2B). Reasons to stop using liraglutide were mainly being disappointed with the weight loss result (32.2%) or with the effect on appetite/satiety (16.1%). Furthermore, a total of 6 patients chose to discontinue their liraglutide use for reasons unrelated to the treatment, such as divorce, malignity, death of spouse, and COVID (Table 2B). Reasons for discontinuing liraglutide are not clearly associated with the amount of time that it had been used before discontinuation (Figure 3).

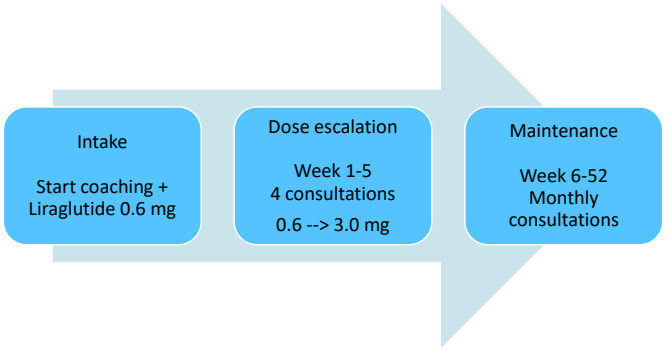

Figure 1: Treatment program.

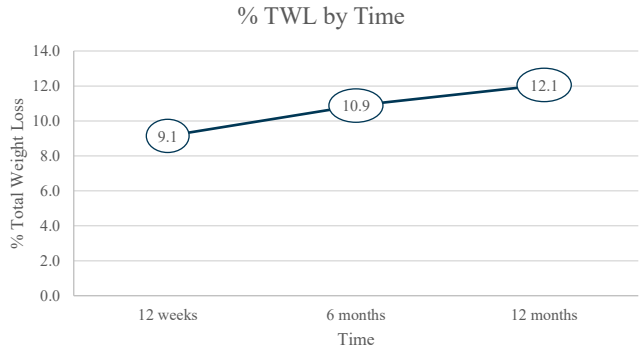

Figure 2: % Total Weight Loss over time.

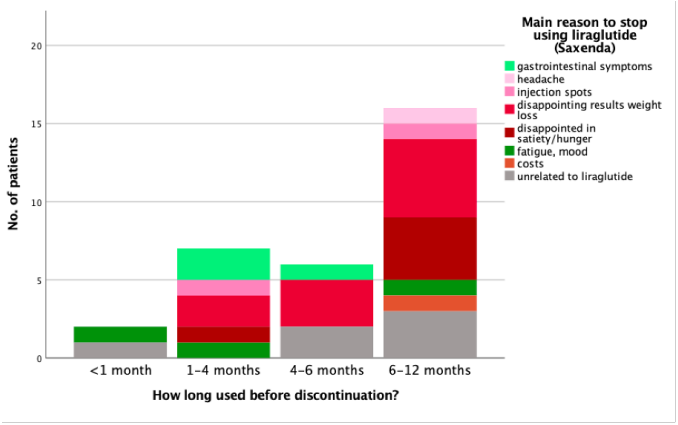

Figure 3: Reasons to stop using liraglutide plotted against the period of use before discontinuation.

Table 1: Baseline characteristics.

Baseline characteristics	n=124
Age, yrs, mean (SD)	50.1(11.1)
Gender, female (%)	101(82)
Weight, kg, mean (SD)	104.9(20.4)
BMI, kg/m^2, mean (SD)	36.1(5.6)
Hypertension (%)	19(15.3)
Diabetes (%)	2(1.6)
Dyslipidemia (%)	11(8.9)
Obstructive sleep apnea syndrome (%)	3(2.4)
Smoking (%)	10(8.1)

SD: Standard Deviation.

Table 2A: Baseline characteristics.

Weight variables	Median [min-max] (IQR)	n
Start weight (kg)	102.5 [73.0-180.0] (88.7-114.1)	124
Start BMI	34.9 [27.3-60.3] (32.4-38.6)	124
Weight loss after 4 months (kg)	9.1 [1.0-27.1] (6.1-12.0)	113(91%)
TWL after 4 months (%)	8.7 [1.0-22.4] (6.3-11.4)	113(91%)
Weight loss after 6 months (kg)	10.7 [2.0-33.1] (7.5-13.8)	102(82%)
TWL after 6 months (%)	9.9 [1.9-27.4] (7.1-14.1)	102(82%)
Weight loss after 12 months (kg)	12.0 [-7.0-37.0] (9.0-15.0)	82(66%)
TWL after 12 months (%)	11.5 [-6.0-30.1] (8.5-15.6)	82(66%)
At least 5% TWL after 4 months, n (%)	100(80.6)	113(91%)
At least 5% TWL after 6 months, n (%)	91(89.2)	102(82%)
At least 5% TWL after 12 months, n (%)	72(87.8)	82(66.1%)
At least 10% TWL after 6 months, n (%)	52(51.0)	102(82%)
At least 10% TWL after 12 months, n (%)	53(64.6%)	82(66.1%)

TWL: Total weight loss (%).

Table 2B: Treatment.

Patient reports	
Tolerability: symptoms during 1st month	n=124
Nausea, n (%)	84(68.3)
Vomiting, n (%)	4(3.3)
Pyrosis, n (%)	18(14.6)
Fatigue, n (%)	20(16.3)
Constipation, n (%)	41(33.3)
Dizziness, n (%)	11(8.9)
Effect: perception of appetite*	n=124
No appetite, n (%)	43(34.7)
Less hungry, n (%)	76(61.3)
Same appetite as before start treatment, n (%)	5(4.1)
Effect: perception of satiety*	n=124
No effect on satiety, n (%)	6(4.8)
More satisfied, n (%)	118(95.2)
Dosage at 4 months, n (%)	n=115
0.6 mg	7(6.1)
1.2 mg	0
1.8 mg	8(7.0)
2.4 mg	8(7.0)
3.0 mg	92(80.0)
Liraglutide discontinued, n (%)	31(25)
Stopped during 1st month, n (%)	2(1.6)
Stopped between 1-4 months of use, n (%)	7(5.6)
Stopped between 4-6 months of use, n (%)	6(4.8)
Stopped between 6-12 months of use, n (%)	16(12.9)
Reasons for discontinuation	
Gastrointestinal symptoms, n (%)	3(9.7)
Headache, n (%)	1(3.2)
Injection spots, n (%)	2(6.5)
Disappointing results weight loss, n (%)	10(32.3)
Disappointed effect appetite/satiety, n (%)	5(16.1)
Fatigue, mood, n (%)	3(9.7)
Costs, n (%)	1(3.2)
Unrelated to Liraglutide, n (%)	6(19.4)

*Patient reported, during uptritation phase.

Discussion

Liraglutide with lifestyle coaching is effective, well-tolerated, and associated with clinically meaningful weight loss in people who are overweight or living with obesity. The majority (81%) of patients reach at least 5% TWL at 4 months post-initiation. After 6 months of treatment, more than half of them reached at least 10% TWL (51%). Reasons for patients to stop treatment with liraglutide are disappointment in weight loss or effect on satiety and appetite, mainly after the first 6 months of use.

The current weight loss result is in line with earlier publications in various clinical and controlled settings [10,13]. At our center, we believe that specifically the combination of weight loss medication with lifestyle coaching is crucial for achieving solid weight loss and maintaining it. This statement is supported by a recent study, in which participants were prescribed liraglutide 3.0 mg for weight loss. Their weight measurements were taken for a period of 6 months after initiation. In this study, no structured lifestyle coaching was done- instead, patients were instructed 'to maintain a healthy lifestyle, such as avoiding high-calorie and high-fat diet, and by undertaking regular exercise' [14]. Although weight loss after 6 months was still significant- average TWL of 6% while 53% achieved at least 5% body weight loss- the results would probably have been better with more coaching. Moreover, a recent paper by Capristo et. al underlined the effect of lifestyle coaching in addition to the use of liraglutide by demonstrating that very comprehensive lifestyle modifications- i.e., prescription of a very low-calorie diet and intensive sports regime combined with liraglutide use - resulted in an average of 24% TWL [15].

Frequent coaching is especially crucial at the start of liraglutide treatment. First, this is the phase of uptitration and therefore this is the moment that patients need more motivation and reassurance regarding potential side effects. Second, it is well known that early weight loss is considered to be predictive of a better long-term weight loss [16,17].

In our cohort, 80% reached the dose of 3.0 mg daily. Reasons for not uptitrating to the maximum dosage were patient driven. This stresses the importance of adequate guidance of patients and an individual approach for optimal, personalized care. Already in the 70s of the previous century, it was demonstrated that when verbal reinforcement and positive feedback were used, intrinsic motivation tended to increase [18].

Over the course of one year, 25% discontinued the use of liraglutide for various reasons and at different time points. This proportion is in line with other publications [14,19]. The majority of participants who chose to stop using liraglutide in the second half of the year were disappointed in the weight loss and/or the amount of satiety that they experienced. In the study from Rubino et al. reasons such as personal issues are mentioned and a patient that wished to undergo surgical treatment instead of continuing with medication. On the other hand, discontinuation because of gastrointestinal symptoms occurred only in the first 6 months. This is in line with the randomized clinical trial of Rubino et al., demonstrating the decrease of gastrointestinal symptoms after the first weeks of use [19].

Limitations of the study

It is important to note that for all participants, the treatment program as well as the use of liraglutide were not reimbursed, therefore, study participants may represent a population more motivated to lose weight than the general eligible population as was confirmed in one study on the effect of funding on weight loss after gastric banding: Self-pay patients initially achieved more weight loss [20]. Moreover, our results may not be generalizable to patients who are living with more severe obesity (BMI>50) or younger patients. In the current study the comorbidities were not monitored over time. Therefore, no conclusions can be made on the effect of liraglutide treatment on comorbidity reduction or remission. How-

ever, literature describes a positive effect of weight loss on the reduction of comorbidities in patients with obesity [21,22].

Conclusion

The use of liraglutide is well-tolerated and associated with clinically meaningful weight loss in a cohort with a mean BMI of 36 kg/m^2. Gastrointestinal symptoms are not the main reason to stop using liraglutide. Reasons for patients to stop treatment with liraglutide are disappointment in weight loss or effect on satiety and appetite, predominantly after 6 months of use.

Declarations

Conflict of interest statements: The authors have no conflicts of interest to declare.

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