European Journal of Medical Research

RESEARCH

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Comprehensive analysis of real-world data on liraglutide treatment in patients with obesity: a multicenter national study

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Abstract

Background The study aimed to evaluate real-world data on liraglutide by assessing its efficacy, associated side effects, adverse events, and impact on metabolic parameters within the context of a multicenter national study.

Methods This retrospective observational study analyzed data from 1009 patients across 38 endocrinology units from Türkiye. Patients with a history of bariatric surgery, those who started orlistat concurrently with liraglutide, and one patient who developed pancreatitis on the 15th day of treatment were excluded from the analyses of weight and laboratory changes.

Results At least one side effect was observed in 48% of the patients, with nausea and vomiting being the most common. The most frequent reason for discontinuing treatment was the cost of the medication (42.6%). The median duration of liraglutide use was 4 months (IQR; 3–6), and the median dose was 2.4 mg (IQR; 1.8–3). Among the entire cohort, 76.4% and 40.9% of patients achieved a 5% and 10% weight loss target, respectively. Significant reductions were observed in metabolic parameters during the treatment. The treatment duration was identified as an independent predictor for achieving 5% and 10% weight loss targets ($B = 0.315$, $p < 0.001$) and 10% weight loss ($B = 0.216$, $p < 0.001$).

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Conclusions Liraglutide effectively results in clinically significant weight loss, achieves expected weight loss targets, and improves metabolic parameters in real-world clinical practice. Therefore, liraglutide is still a reasonable GLP-1 analogue in the obesity treatment. However, it may be associated with various side effects, necessitating close monitoring by clinicians.

Keywords GLP-1 analogue, Liraglutide, Obesity, Overweight

Introduction

The global burden of obesity, along with its related comorbidities and mortality, highlights its priority as a major public health issue worldwide. The World Health Organization (WHO) reports a global adult obesity prevalence of 16% and projects a significant increase in the coming years [1]. Adult obesity prevalence is also rising rapidly across Europe, with Türkiye having the highest rate in the region at nearly 30%, according to WHO data [2, 3].

The current guidelines recommend pharmacotherapy, along with lifestyle changes, for managing obesity in patients with a body mass index (BMI) of ≥ 30 kg/m^2 or a BMI of ≥ 27 kg/m^2 with at least one obesity-related comorbidity [4]. Glucagon-like peptide-1 (GLP-1) analogues are incretin-based treatment options that reduce appetite and increase satiety [4]. These agents also act by stimulating insulin secretion, decreasing glucagon release, and slowing gastric motility [5]. Liraglutide is still a commonly used GLP-1 analogue in obesity treatment, with 97% homology to human GLP-1 [6]. Liraglutide, at a daily dose of 3.0 mg, was approved for obesity treatment, starting at 0.6 mg per day and increasing by 0.6 mg weekly until reaching the maximum dose of 3.0 mg [7].

Randomized clinical trials have found that 3.0 mg of liraglutide treatment, when used as an adjunct to lifestyle modifications, is safe and effective in achieving 5% and 10% weight loss, which is considered a treatment success for an obesity drug [7, 8]. In addition, it has been associated with metabolic improvements, reduced cardiovascular risk factors, improved quality of life, and enhanced physical function [7, 9]. Real-world studies across several populations also confirmed the effectiveness of liraglutide when combined with diet and exercise [10–12].

Despite several real-life interventions across different populations and a few small-sample studies from Türkiye to the best of our knowledge, no large-scale multicenter real-world study has been conducted in the country. This multicenter study from Türkiye aims to evaluate the clinical effectiveness of liraglutide in patients with overweight and obesity by examining weight management, metabolic changes, adverse effects, and reasons for drug discontinuation, in order to highlight the clinical and potential policy-level relevance of real-world evidence in obesity pharmacotherapy.

Materials and methods

Study design

This retrospective observational study involved patients obtained from 38 endocrinology units in 18 different cities throughout Türkiye. The study was approved by the Ethics Committee of Ankara Etlik City Hospital in accordance with the principles of the Helsinki Declaration. Institutional consent was obtained from all participating hospitals and clinics for the use of patient data.

Study population

Patients aged ≥ 18 years with a BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 with at least one weight-related comorbidity (such as hypertension, prediabetes, type 2 diabetes mellitus (DM), or dyslipidemia), who initiated liraglutide treatment between January 2020 and October 2023, were evaluated for inclusion in the study. Consecutive patients who continued liraglutide treatment for at least one month and had at least one follow-up visit during the treatment period were enrolled in the study. Patients who previously used liraglutide, initiated orlistat concurrently with liraglutide, or undergone bariatric surgery or endoscopic bariatric procedures in the last 2 years were excluded.

A total of 1009 eligible patients were enrolled in the entire cohort. Baseline characteristics, adverse effects, and reasons for liraglutide discontinuation were evaluated within this group. The data of one patient who was diagnosed with acute pancreatitis on the 15th day of liraglutide treatment were excluded from further longitudinal analysis. Patients who had initiated orlistat prior to liraglutide treatment and continued its use during the treatment period, as well as those who had undergone bariatric surgery more than two years earlier, were separated from the entire cohort. After removing these patients, the remaining 860 patients were referred to as the liraglutide alone group. The primary outcomes, including changes in body weight and laboratory parameters, were assessed in these 860 patients. Two subgroups—the orlistat plus liraglutide group and the bariatric surgery group—were included in the comparative analyses with the liraglutide alone group. A flowchart illustrating the liraglutide alone group and subgroups is presented in Fig. 1.

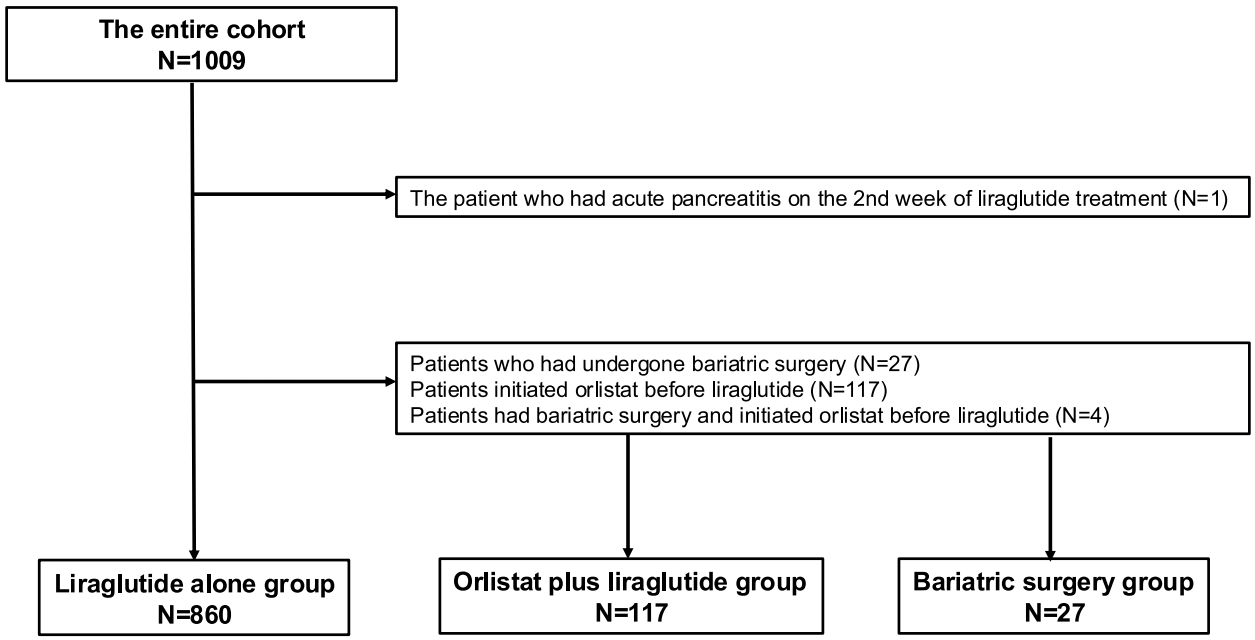


Fig. 1 The flow chart of patients in the liraglutide group and subgroups

Baseline data source

Baseline characteristics, including age, gender, comorbidities, chronic drug use, education, income status, alcohol consumption, smoking, dietitian support and exercise adherence, and baseline blood pressure measurements were recorded from patient records. The maximum dose and total duration of liraglutide treatment, the number of doctor visits during treatment, adverse effects, and reasons for drug discontinuation were documented. Missing data on these topics were completed by contacting available patients via phone call.

Patients were questioned about their diet and exercise status during the liraglutide treatment. Dietitian support was defined as having consulted a dietitian and adhering to personalized recommendations during the treatment period, while exercise adherence was defined as engaging in at least 30 min of physical activity on a minimum of two days per week.

Body weight and laboratory parameters

The initial body weight and BMI were recorded from hospital records. Follow-up body weight data at the 1st, 3rd, 6th, and 12th months of treatment were also obtained from the patient records, provided that the patient adhered to treatment up to these time points.

Laboratory parameters, including fasting plasma glucose (FPG), HbA1c, serum lipids, creatinine, and alanine aminotransferase (ALT) levels, were attained from hospital records at baseline and at the 3rd, 6th, and 12th months of the treatment when available. Metabolic dysfunction-associated steatotic liver disease (MASLD) was evaluated using the Fibrosis-4 (FIB-4) index, calculated with the following formula: Age (years) * AST (U/L)/ [Platelet count (10^9/L) * $\sqrt{}$ALT (U/L)] [13].

Outcomes

The primary outcome of the study was the change in body weight from baseline to the endpoints at the 1st, 3rd, 6th, and 12th months, as well as the proportion of patients who achieved 5% and 10% weight loss overall and at these specific time points. The predictive parameters for achieving overall 5% and 10% weight loss were also examined. Secondary outcomes included changes in laboratory parameters from baseline to the 3rd, 6th, and 12th months.

Subgroups

Comparative analyses were conducted between the liraglutide alone group and two other subgroups—patients using orlistat plus liraglutide, and those with a history of bariatric surgery. Within the liraglutide alone group, comparisons were performed between patients with and without type 2 DM. Patients in the liraglutide alone group were also analyzed according to age groups: under 40 years, 40 to 64 years, and 65 years and older. Another comparison was performed according to obesity class, defined as follows: BMI of 25.0 to 29.9 as overweight, BMI of 30.0 to 34.9 as class 1 obesity, BMI of 35.0 to 39.9

as class 2 obesity, and BMI equal to or greater than 40.0 as class 3 obesity [14].

Statistical analysis

Normal distribution of the variables was assessed using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Categorical variables were compared using the Chi-square test or Fisher's exact test when Chi-square assumptions were violated due to low expected cell counts. Changes in the body weight and laboratory parameters from baseline to the 1st, 3rd, 6th, and 12th months were analyzed using the Friedman test. Post-hoc pairwise comparisons were conducted with the Wilcoxon test, applying Bonferroni correction to adjust for multiple comparisons among these endpoints. Subgroup comparisons by age and obesity class were made using the Kruskal–Wallis test, while the Mann–Whitney U test was used for other two-group comparisons of nonparametric variables within the subgroup analysis. The Chi-square test was employed to compare the achievement of 5% and 10% weight loss across all subgroups. Categorical variables were presented as numbers and percentages, normally distributed variables as means ± standard deviations, and non-normally distributed variables as medians and interquartile ranges (IQR) (25–75). Univariate analysis was conducted to identify potential factors for inclusion in the multivariable logistic regression analyses to determine the final predictive factors for 5% and 10% weight loss. For all tests, p-values less than 0.05 were considered statistically significant.

Results

Study population and baseline characteristics

The mean age of the entire cohort was 43 ± 12 years, with a median BMI of 37 (IQR 33.3–41.8) kg/m^2. Out of the 1009 patients, 788 (78.1%) were female. Among the 860 patients in the liraglutide alone group, the mean age was 43 ± 12 years, the median BMI was 36.7 kg/m^2 (IQR 33.2–41.3), and 673 (78.3%) were female. The general characteristics, obesity category, dietitian support, and exercise adherence, comorbidities, and baseline blood pressure measurements of all patients and those in the liraglutide alone group are detailed in Table 1.

Adverse effects and the reasons for discontinuation

At least one side effect was observed in 484 (48%) of the 1,009 patients. The most common side effect of liraglutide was nausea and vomiting, observed in 391 (38.8%) of the patients. The most common reason for discontinuing was the cost of drug, with 430 (42.6%) patients citing this reason, followed by intolerance due to gastrointestinal side effects in 231 (22.9%) patients, and loss of motivation in 191 (18.9%) patients. The side effects experienced by the patients and the reasons for discontinuing treatment are shown in Table 2.

The details related to liraglutide treatment

The median duration of liraglutide use in the liraglutide alone group was 4 months (IQR 3–6), with a median liraglutide dose of 2.4 mg (IQR 1.8–3). In this group, 338 (33.5%) used the maximum dose of 3.0 mg/day. In addition, 219 (21.7%) patients used a maximum dose of 2.4 mg/day, 218 (21.6%) patients used 1.8 mg/day, 66 (6.5%) patients used 1.2 mg/day, and 19 (1.9%) patients used a dose of 0.6 mg/day. The median duration maintained at the maximum dose of 3 mg/day was 60 days (IQR 30–120). During liraglutide treatment, the median number of doctor follow-up visits was 2 (IQR 1–4).

Change in body weight

Liraglutide resulted in significant weight loss in the liraglutide alone group from baseline to the 1st, 3rd, 6th, and 12th months ($p < 0.001$). The median body weight change was −4 kg (IQR −6, −3) at the first month, −7.5 kg (IQR −11, −5) at the 3rd month, −11 kg (IQR −15.8, −7) at the 6th month, and −13.5 kg (IQR −19, −9) at the 12th month from baseline ($p < 0.001$). Among the 860 patients, body weight data were available for 633 at the 1st month, 651 at the 3rd month, 310 at the 6th month, and 103 at the 12th month. In the entire cohort, 76.4% of patients achieved a ≥ 5% weight loss, while 40.9% achieved a ≥ 10% weight loss during liraglutide treatment. Of these, 40.1%, 75.1%, 88.7%, and 95.1% achieved a weight loss of ≥ 5% at the 1st, 3rd, 6th, and 12th months of treatment, respectively. Similarly, 4.1%, 31.6%, 61.6%, and 73% of the patients attained ≥ 10% weight loss at the 1st, 3rd, 6th, and 12th months. Figure 2 illustrates the absolute weight changes and the proportions of weight loss among the patients.

Change in laboratory parameters and FIB-4 index

A significant difference was observed during liraglutide treatment in FPG, HbA1C, total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglyceride, and ALT levels in the liraglutide alone group (Table 3). In the post-hoc analysis, FPG and HbA1C levels were significantly reduced when comparing changes from baseline to the 3rd, 6th, and 12th months ($p < 0.001$ for each). Significant decrease in LDL-C and triglyceride levels were observed between baseline and the 3rd, 6th, and 12th months ($p < 0.001$, $p < 0.001$, and $p = 0.01$, respectively). In addition, the total cholesterol levels showed a significant reduction when comparing baseline to the 3rd and 6th months of treatment ($p < 0.001$ for each), but this difference was not significant between baseline and the 12th month ($p = 0.024$).

Table 1 Basal characteristics, comorbidities, and blood pressure measurements of the patients

	All patients	***Liraglutide alone group***
Number	1009	860
Age (years)	43 ± 12	43 ± 12
Sex (female), *n* (%)	788 (78.1)	673 (78.3)
Baseline body weight (kg)	101 (90–116)	100 (89–115)
BMI (kg/m^2)	37 (33.3–41.8)	36.7 (33.2–41.3)
Dietitian support, *n* (%)	541 (53.7)	459 (53.4)
Adherence to exercise, *n* (%)	422 (42)	361 (42)
Obesity category, n (%)		
Overweight	66 (6.5)	60 (7)
Class 1 obesity	306 (30.4)	269 (31.3)
Class 2 obesity	305 (30.3)	266 (30.9)
Class 3 obesity	331 (32.8)	265 (30.8)
Education status, n (%)		
Illiterate	6 (0.6)	5 (0.6)
Primary School	133 (13.2)	105 (12.2)
High School	319 (31.6)	271 (31.5)
Bachelor's Degree	436 (43.2)	380 (44.2)
Master's Degree	115 (11.4)	99 (11.5)
Smoking status, n (%)		
Non-smoker	673 (66.7)	570 (66.3)
Ex-smoker	98 (9.7)	82 (9.5)
Current smoker	238 (23.6)	208 (24.2)
Alcohol consumption, n (%)		
Abstainer	791 (78.4)	678 (78.8)
Occasional drinker	196 (19.4)	161 (18.7)
Frequent drinker	22 (2.2)	21 (2.4)
Income status, n (%)		
Has enough money to meet basic needs but cannot save	282 (27.9)	247 (28.7)
Has enough money to meet basic needs and can save a very small amount	435 (43.1)	364 (42.3)
Has enough money to meet basic needs and can save a good amount	232 (23)	191 (22.2)
Unknown	60 (5.9)	58 (6.7)
Comorbidities, n (%)		
Diabetes mellitus	148 (14.7)	131 (15.2)
Prediabetes	327 (32.4)	280 (32.6)
Hypertension	260 (25.8)	222 (25.8)
Dyslipidemia	664 (65.8)	596 (66.2)
Atherosclerotic cardiovascular disease	48 (4.8)	40 (4.7)
Heart failure	20 (2)	14 (1.6)
Hepatosteatosis	258 (25.6)	217 (25.2)
Obstructive sleep apnea	57 (5.6)	45 (5.2)
Blood pressure measurements		
Systolic (mmHg)	120 (110–130)	120 (110–130)
Diastolic (mmHg)	80 (70–82)	80 (70–82)

BMI Body mass index

Parametric data were presented as mean ± SD, while nonparametric data were presented as median and IQR (25–75).

No difference was observed in the post-hoc analysis in HDL-C level. ALT levels were also found to be reduced at the 3rd, 6th, and 12th months as compared to baseline ($p < 0.001$, $p < 0.001$, and $p = 0.005$, respectively). There was no change in the FIB-4 index at the specific endpoint during liraglutide treatment ($p > 0.05$ for each).

Table 2 Adverse events associated with liraglutide treatment and reasons for discontinuation (N = 1009)

	N (%)
Adverse effects	
Gastrointestinal	
Nausea/vomiting	391 (38.8)
Dyspepsia/abdominal pain	48 (4.8)
Constipation	32 (3.2)
Diarrhoea	26 (2.6)
Elevated liver enzymes	7 (0.7)
Change taste sensitivity	6 (0.6)
Dermatological	
Local allergic reaction	34 (3.4)
Urticaria	6 (0.6)
Neuropsychiatric	
Headache	87 (8.6)
Fatigue	18 (1.8)
Unhappiness/depressive symptoms	13 (1.3)
Cardiac and metabolic	
Tachycardia	41 (4.1)
Hypoglycaemia	2 (0.2)
Menstrual irregularities	2 (0.2)
Reasons for discontinuation	
Cost	430 (42.6)
Intolerance due to gastrointestinal side effects	231 (22.9)
Loss of motivation	191 (18.9)
Inability to achieve sufficient weight loss	144 (14.3)
Difficulty with injections	84 (8.3)
Fear of drug side effects	10 (1)
Pregnancy planning	5 (0.5)
Mood changes	5 (0.5)
Urticaria	3 (0.3)
Hallucinations	1 (0.1)
Increased blood pressure	1 (0.1)
Seriously adverse events leading to discontinuation	
Elevated liver enzymes (more than fivefold increase)	3 (0.3)
Increased lipase	3 (0.3)
Cholecystitis	2 (0.2)
Ileus	1 (0.1)
Pancreatitis	1 (0.1)
Diagnosis of malignancy (Rectal gastrointestinal stromal tumour)	1 (0.1)

Comparison between the orlistat plus liraglutide group versus liraglutide alone group

The median dose of liraglutide was 2.4 mg (IQR 1.8–3) in the liraglutide alone group and 3.0 mg (IQR 1.8–3) in the orlistat plus liraglutide group (p = 0.02). The duration of treatment was similar between the groups ($p = 0.221$). The proportions of patients achieving 5% and 10% weight loss during treatment were 88% and 53% in the orlistat plus liraglutide group, respectively, which were higher than those in the liraglutide alone group ($p = 0.001$ and $p = 0.007$, respectively). When the differences among each endpoints analyzed, the proportions of patients achieving 5% and 10% weight loss were significantly higher in the orlistat plus liraglutide group at the end of the first month of treatment ($p < 0.001$ and $p = 0.028$, respectively). However, this significant difference did not persist at the 3rd, 6th, and 12th months (p > 0.05 for each).

Comparison between the patients with and without bariatric surgery

The median dose and duration of liraglutide treatment were similar between the groups ($p = 0.460$, $p = 0.988$, respectively). Additionally, the proportions of patients achieving 5% and 10% weight loss overall, as well as at the 1 st, 3rd, 6th, and 12th months of treatment, were similar between the two groups ($p > 0.05$ for each).

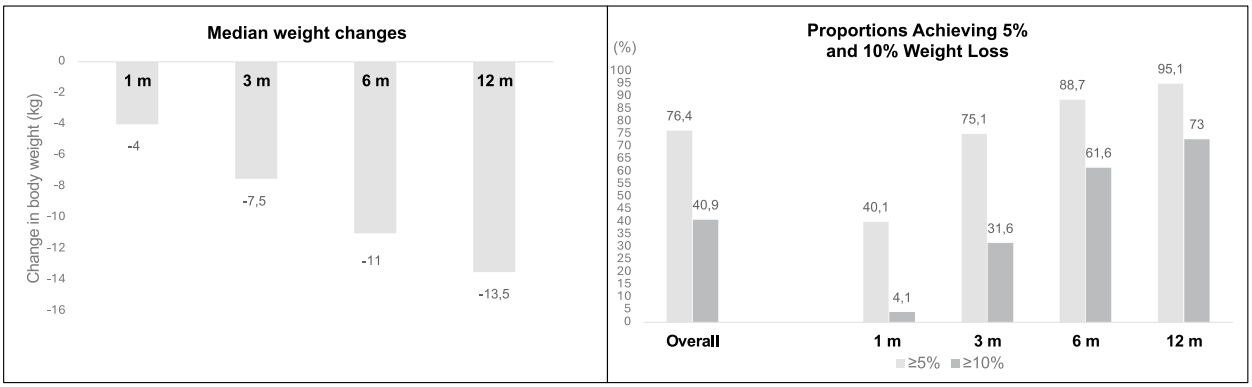
Comparison between the patients with and without type 2 DM

The data belonging to 131 patients with DM and 729 patients without DM were compared. There was no significant difference in the duration of total liraglutide treatment or the median dose of liraglutide between the two groups ($p = 0.052$, $p = 0.649$). No significant difference was observed in the proportions of achieving 5% and 10% weight loss, either overall or at the 1 st, 3rd, 6th, and 12th months of treatment ($p > 0.05$ for each). The median reduction in HbA1c levels among patients with DM was as follows: −0.4 (IQR −1.2, −0.1) at the 3rd month, −0.7 (IQR −1.5, −0.2) at the 6th month, and −0.85 (IQR −1.7, −0.3) at the 12th month from baseline, respectively.

The impact of dietitian support and exercise adherence, age, and obesity class

There was no significant difference in the proportion of patients achieving 5% or 10% weight loss, either overall or at the 1 st, 3rd, 6th, and 12th months of treatment, between those who received dietitian support and adhered to exercise recommendations ($p > 0.05$ for each).

When patients were categorized according to their age as < 40 years, 40–64 years, and ≥ 65 years, the number of patients in these groups were 340 (39.5%), 490 (57%), and 30 (3.5%), respectively. The median duration of liraglutide treatment was 3 months (IQR 2–6), 4 months (IQR 3–7), and 4 months (IQR 3–9) among these groups, respectively ($p < 0.001$). The median dose of liraglutide was 2.4 mg (IQR 1.8–3) in the < 40 and 40–64 years age groups, and 1.8 mg (IQR 1.2–2.4)



Overall (n= 860), 1 m (n= 633), 3 m (n= 651), 6 m (n= 310), 12 m (n= 103).

Fig. 2 Absolute weight changes and proportions achieving 5% and 10% weight loss during liraglutide treatment

Table 3 Changes in laboratory parameters and FIB-4 index of patients during liraglutide treatment

	Baseline value	Change from baseline to 3 months	Change from baseline to 6 months	Change from baseline to 12 months	*P*
FPG, mg/dl	95 (87–105)	−5 (−13, 1)	−6 (−13, 2)	−8 (−14, 0)	**< 0.001***
HbA1C, %	5.6 (5.4–6)	−0.2 (−0.2, 0)	−0.3 (−0.6, 0)	−0.4 (−0.8, −0.2)	**< 0.001***
Total cholesterol mg/dl	202 (174–229)	−11 (−24, 1)	−9 (−25, 6)	−7 (−20, 7)	**0.003***
LDL-C, mg/dl	123 (100–145)	−7 (−20, 2)	−7 (−22, 5)	−7 (−18, 7.5)	**< 0.001***
HDL-C, mg/dl	48 (41–56)	0 (−3, 3)	0 (−3, 4)	1 (−3.5, 6)	0.027
Triglyceride, mg/dl	135 (97–195)	−11 (−39, 9)	−12 (−35, 8)	−12 (−12, 8)	**< 0.001***
Creatinine, mg/dl	0.72 (0.63–0.83)	0 (0, 0.1)	0.02 (−0.1, 0)	0.01 (−0.1, 0.08)	0.108
ALT, mg/dl	21 (16–32)	−1 (−6, 3)	−2 (−7, 1)	−2.5 (−8, 3)	**0.027***
FIB-4 index	0.61 (0.42–0.83)	0 (−0.09, −0.08)	0.01 (−0.6, 0.13)	0.013 (−.16, 0.12)	0.562

ALT Alanine aminotransferase, *FIB-4* Fibrosis −4 index, *FPG* Fasting plasma glucose, *HDL-C* High-density lipoprotein cholesterol, *LDL-C* Low-density lipoprotein cholesterol

Data were presented as median and IQR (25–75).

* Pairwise comparisons were statistically significant in the post hoc analysis.

in the ≥ 65 years group ($p < 0.001$). No significant difference was observed among the age groups in the overall proportions achieving 5% and 10% weight loss ($p = 0.430$ and $p = 0.556$, respectively). The proportions achieving 5% and 10% weight loss at the 1 st, 3rd, 6th, and 12th months were also similar across the groups ($p > 0.05$ for each).

The median dose and duration of liraglutide were similar among the different obesity categories ($p = 0.476$ and $p = 0.906$, respectively). The median total weight loss was −5.5 kg (IQR −9, −3), −7 kg (IQR −12, −4.5), −8.5 kg (IQR −12, −5), and −10 kg (IQR −16, −5) in the overweight, class 1, class 2, and class 3 obesity groups, respectively ($p < 0.001$). However, there was no significant difference in the overall proportions achieving 5% and 10% weight loss from baseline to 1 st, 3rd, 6th, and 12th months among the groups ($p = 0.557$ and $p = 0.129$, respectively).

The predictive parameters for achieving overall 5% and 10% weight loss in liraglutide alone group

Univariate analysis demonstrated a significant association between both liraglutide dose and treatment duration and achieving ≥ 5% ($p < 0.001$, $R^2 = 0.184$; $p < 0.001$, $R^2 = 0.170$, respectively) and 10% total weight loss ($p < 0.001$, $R^2 = 0.232$; $p < 0.001$, $R^2 = 0.196$, respectively). However, age, gender, education status, baseline body weight, BMI, FPG, HbA1c, LDL, and triglyceride levels were not significantly associated with weight loss.

A multiple logistic regression analysis was performed to determine the independent predictive parameters for achieving overall 5% and 10% weight loss. In a model including age, gender, baseline body weight, the dose and duration of liraglutide treatment, only the duration of the treatment was found as an independent predictor for 5% weight loss (B = 0.315, OR: 1.370, 95% CI

0.222–0.406, p < 0.001) and 10% weight loss (B = 0.216, OR: 1.241, 95% CI 0.144–0.309, p < 0.001).

Discussion

The present study revealed that liraglutide is an effective treatment for adult obesity, achieving 5% weight loss in 76.4% of patients and 10% weight loss in 40.9% of patients from their initial body weight, regardless of age, obesity class, liraglutide dose, or implementation of diet and exercise. The duration of liraglutide treatment is found to be the only predictive factor for achieving 5% and 10% weight loss. In addition, liraglutide resulted in improvements in FPG and HbA1c levels in both patients with and without type 2 DM. Nearly half of the patients experienced at least one side effect, with nausea and vomiting being the most common. The most frequent reason for discontinuation was the cost of the drug, followed by intolerance due to gastrointestinal side effects. Serious adverse effects, such as pancreatitis, ileus, cholecystitis, and markedly increased liver enzymes, were observed in fewer than 1% of patients.

GLP-1 analogues are playing an increasingly important role in the pharmacological treatment of obesity. Despite newer agents like semaglutide and tirzepatide gaining prominence with the current evidence from many studies, liraglutide remains a significant option due to its longer clinical experience, greater availability, and cost-effectiveness as compared to semaglutide and tirzepatide in many countries around the world [15–17].

To date, outcomes from real-world studies of liraglutide across various populations have been reported. The first published real-world data on liraglutide came from Canada, where the researchers reported a median weight loss of 8 kg over 6 months with daily 3.0 mg liraglutide treatment combined with diet and exercise [10]. Other real-world studies demonstrated a weight loss of 5 to 8 kg during 6 to 12 months of liraglutide treatment [7, 11, 18]. The present study revealed a median weight loss of 7.5 kg by the third month, with a continued linear trend throughout the treatment, reaching a median weight loss of 13.5 kg by the end of the first year. The percentage of patients achieving a 5% weight loss was reported as 64.1% in 6 months in Canada, 40% in 7 months in Switzerland, 52.6% in 6 months in Saudi Arabia, and 68.3% in 6 month in Italy [10, 11, 18, 19]. The rates of achieving 10% weight loss during the specified periods were reported as 34.5%, 14%, 27.8%, and 20% in these respective studies. The present study determined slightly higher rates when compared with these previous reports, with 76.4% achieving 5% weight loss and 40.9% achieving 10% weight loss from baseline. Furthermore, this clinically meaningful weight loss was observed by the first month of the treatment. These slightly higher rates may be explained by the close follow-up of patients, which could improve compliance with the medication. In the present cohort, patients had a median of 2 doctor visits during the median of 4-month follow-up period.

Our subgroup and univariate analyses indicated that achieving 5% and 10% weight loss was independent of age, gender, BMI, educational status, and adherence to diet and exercise. Most studies in the literature combined liraglutide treatment with diet and exercise. In the current study, almost half of the patients received dietitian support and performed at least 30 min of exercise on at least 2 days per week. However, no significant effect of diet and exercise on weight loss was observed in both the comparative and regression analyses. It's important to note that the implementation of diet and exercise was based on patients'self-reports and was not standardized, which may affect the reliability of this data. A recent real-world cohort study from Korea similarly reported that liraglutide is effective for weight loss even in the absence of intensive lifestyle modifications [20].

Supporting some of the data in the literature, the reduction in body weight was greater in patients with higher BMI classes. However, similar percentages of patients across different obesity classes in this study achieved 5% and 10% weight loss. The researchers from Canada suggested that liraglutide 3.0 mg treatment led to similar significant weight loss in patients, regardless of obesity class [21]. In contrast, a 56-week randomized controlled study of liraglutide reported contrasting results, indicating that liraglutide was less effective in patients with a BMI higher than 40 kg/m^2 compared to those with a lower BMI [7]. Another issue that needs to be discussed is the dose of liraglutide. A daily dose of 3.0 mg is considered the maximum effective dose of liraglutide, and randomized studies, as well as many other observational studies, have been conducted with patients receiving this maximum dose. In this study, the median dose of liraglutide was 2.4 mg per day, and only 33.5% of all patients were maintained on the maximum dose. Few studies have investigated the effect of lower doses of liraglutide. In this context, a study from Belgium analyzed weight loss with different doses of liraglutide and found that clinically meaningful weight loss can be achieved even when using submaximal doses [22]. Additionally, the Swiss cohort of 277 patients, who used a median dose of 1.5 mg per day, also demonstrated clinically significant weight loss, irrespective of the maximum dose [11]. The researchers of this study emphasized that persistence with the treatment for over 7 months helped patients achieve greater weight loss. Similar findings were observed in the present study. Although univariate analysis showed that both the dose and duration of liraglutide treatment were significantly associated with 5% and 10% weight loss, the effect

of liraglutide dose did not persist in the multiple logistic regression analysis. Instead, the duration of the treatment was found to be the only predictive factor for achieving the treatment targets. However, it is noteworthy that the reduced number of patients beyond six months—likely due to the reasons for drug discontinuation previously described—limits the interpretation of long-term outcomes.

Besides effective weight management, liraglutide also found to be associated with improvements on metabolic parameters. Despite discrepancies among various randomized controlled and observational studies, most have demonstrated significant reductions in glucose parameters and blood pressure measurements, as well as improvements in serum lipid levels [11, 18, 23]. The Canadian cohort revealed a 0.4% decrease in HbA1c levels, while the Swiss cohort reported a 0.3% reduction [10, 11]. Another study, including 448 patients with type 2 DM using liraglutide from France, Italy, and Germany, demonstrated a 1.08% reduction in HbA1c from baseline to 24 months [24]. Another retrospective study reported a decrease similar to our study, with a 0.8% reduction in HbA1c in patients with type 2 DM and obesity over 24 months of liraglutide treatment [23]. Data from Japan also revealed that liraglutide significantly improved glucose metabolism, decreasing HbA1c levels by 1.5% after 12 months of treatment [25]. Our comparative analysis of patients with and without DM showed that, while both groups achieved similar weight loss, patients with DM experienced a 0.85% reduction in HbA1c by the end of 12 months of treatment. Changes in ALT levels during liraglutide treatment have been evaluated in a limited number of studies. Although previous studies have reported conflicting results regarding changes in ALT levels during treatment, our results indicated a significant decrease at each endpoint [11, 18]. The Swiss cohort demonstrated a decrease in both ALT levels and the nonalcoholic steatohepatitis fibrosis score during 10 months of liraglutide treatment [11]. Several studies also reported decreased liver fibrosis scores in type 2 DM patients using liraglutide [26, 27]. However, we did not observe any difference in FIB-4 indexes during the treatment. The results of the present study also suggested a decrease in total cholesterol, LDL-C, and triglyceride levels, but no change in HDL levels.

In line with the previous data, patients with a history of bariatric surgery experienced similar weight loss to those without such a history [11, 28, 29]. According to the current knowledge, there is a lack of data in the literature evaluating the combination of liraglutide and orlistat. Our study adds a new finding to the literature, suggesting that orlistat may enhance weight loss during the first month of treatment when combined with liraglutide. However, its benefits were not observed in the subsequent months.

GLP-1 analogue treatment was significantly associated with gastrointestinal complaints, including nausea, vomiting, dyspepsia, diarrhea, and constipation, and known to be transient [30]. According to our results, gastrointestinal events were among the most common adverse effects during liraglutide treatment and led to drug discontinuation in approximately 20% of patients, making it the second most common reason after drug cost. These findings are consistent with those of several observational studies. A very recent large cohort study emphasized that weight reduction with GLP-1 analogue treatment is associated not only with the dose and active agent of the medication but also with persistence in medication use [31]. The researchers highlighted the need for a detailed analysis of the reasons behind treatment discontinuation. The findings of our study contribute to this field by offering a comprehensive analysis of the reasons behind liraglutide treatment discontinuation. A large randomized controlled liraglutide study determined that gastrointestinal events were the most common reasons for withdrawal of liraglutide [7]. Supporting this data, a recent Portugal cohort study reported the most common withdrawal reasons as gastrointestinal intolerance, drug cost, and inefficacy [32]. Serious adverse events, including markedly increased liver enzymes, ileus, cholecystitis, and pancreatitis, were also observed in a small number of patients in our cohort. Although data from a post-marketing adverse event reporting system recently indicated that liraglutide is the GLP-1 analogue most commonly associated with pancreatitis, real-world interventions with liraglutide have reported much lower rates of this adverse effect [7, 33]. The present study reported only one case of acute pancreatitis, diagnosed during the second week of treatment. Other rare, unexpected adverse events in our cohort were depressive symptoms, menstrual irregularities, and change in taste sensitivity. Among these, depressive symptoms and mood changes resulted in drug discontinuation in some of the patients. Limited data are available in the literature regarding the relationship between GLP-1 analogues and depression; however, to the best of our knowledge, no observational studies have specifically investigated emotional disorders during liraglutide treatment [34]. Similarly, while changing taste sensitivity has been speculated to be associated with GLP-1 analogues, there are no long-term, large-scale studies evaluating this condition [35]. This study also alerts clinicians that liraglutide may be associated with a broader range of drug-related events than previously recognized. More detailed, long-term observational studies are needed to address this gap in the literature.

This study has merits as it represents a multicenter, real-world investigation involving one of the largest cohorts reported in the literature. The analysis of various clinical and laboratory factors, along with a detailed investigation of drug-associated adverse effects and reasons for discontinuation, strengthens our results and may contribute new findings to the literature. However, the study has some limitations. Firstly, the retrospective design restricts access to all weight data and laboratory parameters, resulting in missing data at each endpoint. Additionally, due to the aforementioned reasons for treatment discontinuation, the number of patients who maintained liraglutide use for one year is very low. The reduction in patient numbers beyond six months limits the evaluation of long-term outcomes. In addition, although all authors were requested to include patients consecutively, due to the retrospective nature of this observational study, some unexpected confounding factors and selection bias cannot be completely ruled out. Lastly, since not all patients adhered to a standardized diet and exercise program, and the data on diet and exercise were based on patient self-reports, the possibility of subjective reporting bias cannot be excluded. Therefore, the findings related to the effects of diet and exercise may be somewhat limited and should be interpreted with appropriate consideration of these limitations.

Conclusion

Liraglutide effectively leads to clinically significant weight loss and meets expected weight loss targets in real-world clinical practice. Additionally, it facilitates improvements in metabolic control for patients. Therefore, liraglutide is still a reasonable GLP-1 analogue in the obesity treatment. However, it may be associated with both expected and unexpected adverse effects that clinicians need to monitor closely. Further prospective long-term real-world studies, particularly those incorporating standardized lifestyle interventions in obesity management, may help address the limitations of this study and reinforce our findings, thereby strengthening the evidence base for clinical and policy decisions.

Abbreviations

ALT	Alanine aminotransferase
BMI	Body mass index
DM	Diabetes mellitus
FPG	Fasting plasma glucose
FIB-4	Fibrosis-4
GLP-1	Glucagon-like peptide-1
HDL-C	High-density lipoprotein cholesterol
IQR	Interquartile range
LDL-C	Low-density lipoprotein cholesterol
WHO	World Health Organization

Acknowledgements
None

Author contributions
Conceptualization; S.H., C.H., B.Ç.H. Data curation; S.H., B.Ç.H., H.D., B.T., R.Ç., M.G., L.K., S.K., Z.Y.Ş.A., M.S., G.T., D.B., B.İ.A., A.O.K., M.A., İ.T., P.K., A.O., E.D.Ö., S.B., M.K., B.Ç., Ş.B.P., İ.Y., E.B., G.K., S.F., N.İ.Y., A.Ö., B.Ö., Ş.T., S.N.F., H.B., B.K., O.S.B., A.K.Ç., B.E., K.U., F.K., A.B., S.Ç.D., D.Y., O.D., M.A., Ö.T., K.K., K.K., S.T., T.B., S.E.Y., A.K.Ü, G.Y.K., M.Ş., Y.A., M.K., T.S., M.C.,F.B., A.S. Formal analysis; S.H., C.H, İ.D. Methodology: S.H., C.H, İ.D, E. C, A.S, V.D.Y. Supervision; C.H, V.D.Y., F.B., A.S. Writing—original draft; S.H. Writing—review & editing; S.H., C.H., F.B, T.S., V.D.Y, A.S. All authors read and approved the final manuscript.

Funding
None.

Data availability
The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate
This study protocol was reviewed and approved by "Scientific Research Assessment and Ethics Committee of Ankara Etlik City Hospital" on January 31, 2024, with the approval number AEŞH-BADEK-2024-101.
Informed consent was obtained from participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 12 March 2025 Accepted: 20 June 2025
Published online: 10 October 2025

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