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A Study on Weight Loss Cause as per the Side Effect of Liraglutide

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Abstract:
Liraglutide is known to have much lower weight loss effects in real clinical fields than in randomized clinical trials because of its side effects (SE) and discomfort associated with injections. This study is aimed at determining whether the side effects of liraglutide affect weight reduction and its maintenance in real-world practice. Endocrinologists conducted a retrospective chart review of data from two tertiary university hospitals. All patients who had been prescribed liraglutide at least once between January 2014 and December 2019 were included. For an average of 3 and 6 months, weight changes due to the presence or absence of SE and discontinuation (MAIN or STOP) of liraglutide were checked. Only 40.8% (64/157) of the patients remained on liraglutide for 6 months; 14.7% (23/157) maintained the drug despite SEs (MAIN_SE(+)), and 40.1% (63/157) discontinued the drug despite not having SEs (STOP_SE(-)).Our study confirmed that the side effects of liraglutide did not affect weight reduction. Moreover, in the real world, the continuous rate of liraglutide use is not high, and the weight gradually increases after 3 months. Therefore, in addition to the side effects of liraglutide, the medical staff should consider various factors that affect drug adherence, consider ways to increase compliance, and continue to ensure management so that patients can maintain their weight.

Keywords: Liraglutide, Weight loss, SEs, drug adherence

1. Introduction
It is important to manage overweight and obesity as they are risk factors for type 2 diabetes [1, 2]. Currently, lifestyle changes, including diet and exercise, are recommended for obesity man- agement, along with drug-based weight loss [3]. Glucagon-like peptide-1 receptor agonists (GLP-1RA) increase insulin release, decrease glucagon secretion, and exert good blood sugar control effects. Therefore, liraglutide, the first GLP-1RA, was used as an antidiabetic drug. GLP-1RA affects satiety and suppresses appe- tite by delaying gastric emptying, thereby reducing weight; it is one of the drugs used to treat obesity. According to the results ofseveral studies, the weight reduction effect of liraglutide is good, as at least a 5% weight reduction can be achieved when using liraglutide for 1 year [4–6]. However, it is associated with several side effects due to delayed gastric emptying, such as nausea and vomiting. Reports on the weight change due to the side effects of lirag- lutide have been controversial. Some studies have reported that the weight reduction effect is greater than the side effects; how- ever, some have also reported no relationship between the side effects and weight reduction effect of liraglutide [5, 7]. In addi- tion, there is a report that no biased effect exists due to side effects as per the studies examining drug effects [8]; therefore, there is still a lot of debate in this regard [5, 9]. Since there are limitations in accurately measuring the side effects as well as their duration, few studies have been conducted on the relation- ship between side effects and weight reduction. The results of these studies are controversial; therefore, the effect of weight loss due to side effects is still uncertain. In addition, little is known about side effects and drug discontinuation in the real clinical field that reflect patient compliance. Liraglutide is known to have a greater weight reduction effect than other obesity drugs [5]. However, one study reported weight recovery after the maximum effect of the drug [6]. In the real world, some patients tolerate and main- tain liraglutide even if there are side effects, while there are cases where the drug is stopped for various reasons such as compliance, even if there are no side effects. There are no known studies on the compliance of liraglutide, such as side effects and drug discontinuation, in actual clinical practice. It is also unknown whether liraglutide weight loss is as effective in the real world as in previous

well-known randomized control studies [10]. The purpose of this study was to inves- tigate the degree of maintenance of weight loss and the effects of side effects on weight loss after liraglutide prescrip- tion in actual clinics.

2. Materials and Methods

In this study, among the patients who visited Seoul St. Mary's Hospital and Eunpyeong St. Mary's Hospital, from January 2014 to December 2019, those who had been pre- scribed liraglutide at least once were followed up for an aver- age of 6 months.

2.1. Study Population and Design. The index date was desig- nated as the date on which liraglutide was prescribed. Per- sonal information such as age, sex, weight, and body mass index (BMI) of the patients within 2 weeks before the index date was collected. Baseline laboratory results of blood glu- cose, HbA1c, blood urea nitrogen, and creatinine levels, along with liver function tests (aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma-glutamyl transpeptidase), and lipid profiles (total cholesterol, triglycerides, HDL cholesterol, and LDL choles- terol) were collected. In addition, the history of hyperten- sion, prediabetes, diabetes, dyslipidemia, fatty liver, thyroid disease, and allergies was investigated. All side effects that the patients complained about were confirmed, including gastrointestinal (GI) problems caused by the mechanism of action of liraglutide. Additionally, history of psychiatric dis- orders or psychiatric treatment was assessed.

A visit 2–4 months (average 3 months) from the index date was designated as visit 1, and a visit 5–7 months (aver- age 6 months) later was designated as visit 2. The patient's weight was recorded at each visit, and the change from the baseline weight was calculated. If there were multiple visits within 2–4 months, the lowest weight was selected. If there were multiple visits within 5–7 months of the last visit, the weight closest to 6 months was selected. Additionally, the maximum dosage of liraglutide was determined. If drug dis-continuation occurred, the date of discontinuation was esti- mated through chart review. After liraglutide was prescribed, side effects and discon-tinuation of the drug were checked for an average of 6 months (up to 7 months) through a direct chart review made by an endocrinologist (Figure 1). Within the group that maintained liraglutide without discontinuation, the group without side effects was designated as the MAIN_SE(-) group, and the group with side effects was designated as the MAIN_SE(+) group. We defined the time criterion for drug discontinuation as before visit 1 (2-4 months). There- fore, as per the liraglutide discontinuation criteria, only those patients who discontinued treatment within 4 months were included. Among the groups in which liraglutide was stopped, the group without side effects was designated as the STOP_SE(-) group, and the group with side effects was designated as the STOP_SE(+) group.

2.2. Protection of Privacy. An endocrinologist with more than 10 years of experience directly reviewed the charts and col- lected all related data and information for all patients. The patients' charts were reviewed directly by a lead researcher. During statistical analysis, the patients' personal identifica- tion numbers were deleted, and a random number was assigned. All personally identifiable data were anonymized and stored in various combinations. Anonymization and security measures were implemented in this study. As this was a retrospective cohort study, there was no possibility of physical or mental harm to the participants; therefore, patient consent was not required. This study was approved by the Clinical Research Ethics Committee of the Catholic Medical Center (approval number: XC20RIDI0060).

2.3. Statistical Analysis. Baseline variables are expressed as means and standard deviations or numbers, including per- centages, whether they were continuous or categorical vari- ables. The association between weight variations during the 3 months after prescription and the degree of discontinua- tion was assessed using an independent t-test considering the Bonferroni correction. The final regression models between weight variation and baseline variables were exe- cuted using a linear regression model

adjusted for age, sex, and BMI. All statistical analyses were performed using the SAS software (SAS Institute Inc., Cary, NC, USA), and sta- tistical significance was set at $p < 0.05$.

3. Results

From January 1, 2014, to December 31, 2019, 157 patients were prescribed with liraglutide at Seoul St. Mary's Hospital and Eunpyeong St. Mary's Hospital (Table 1). The mean age of the patients was 44 ± 12 years, and the proportion of female participants was 74.5% (117/157 patients), which was higher than that of male participants. The average body weight was 83.5± 18.0 kg, and the average BMI was 30.5± 4.8 kg/m^2; there was no significant difference between the groups. For 6 months, 40.8% patients (64/157) maintained liraglutide, while 59.2% (93/157) stopped taking it. The group that stopped liraglutide stopped it at 3.3± 1.2 months.The mean dose of liraglutide was 2.3± 0.8 mg, and there was no significant difference between the groups. In the group that maintained liraglutide, 64.1% patients (41/64) had no side effects, and 35.9% (23/64) had side effects. In the group that stopped liraglutide, 67.7% patients (63/93) had no side effects and 32.3% (30/93) had side effects. History of hyper- tension, prediabetes, and DM did not significantly differ between the groups. In addition, the history of GI problems, such as gastroesophageal reflux disease or ulcers, showed no difference between the groups ($p = 0.060$). There was no sig- nificant difference between the groups regarding bipolar dis- ease, sleep disorders, anxiety disorders, depression, or psychiatric treatment ($p = 0.979$). Other laboratory findings did not show any significant differences between the groups.

3.1. Weight Change according to the Side Effects and Discontinuation of Liraglutide. After 3 months, there was a significant weight reduction of 6.7± 0.5% (−5.4± 0.4 kg, $p < 0.001$) compared to the baseline in the MAIN group; there was a significant weight reduction of 4.1± 0.4% (−3.3± 0.3 kg, $p < 0.001$) compared to the baseline in the STOP group (Figure 2). However, the MAIN group showed greater weight reduction after 3 months than the STOP group (−6.7± 0.5% vs. −4.1± 0.4%, $p < 0.001$). After 6 months, there was a significant weight reduction of 1.9± 0.3% (−1.5± 0.3 kg, $p < 0.001$) compared to the baseline in the MAIN group and a significant weight reduction of 1.8± 0.5 % (−1.4± 0.4 kg, $p < 0.05$) compared to the baseline in the STOP group. However, there was no significant difference in weight reduction between the MAIN and STOP groups after 6 months (−1.9± 0.3% vs. −1.8± 0.5%, $p = 0.667$).

In the detailed analysis of the presence or absence of side effects, the average weight reduction after 3 months com- pared to the baseline was −5.9± 0.6% (from 86.3± 19.6 kg to 81.4± 19.6 kg, $p < 0.001$) in the MAIN_SE(-) group, and it was −7.9± 0.9% (from 82.5± 12.5 kg to 76.1± 12.4 kg, $p < 0.001$) in the MAIN_SE(+) group. However, there was no significant difference between the two groups ($p = 0.062$). After an average of 6 months, the weight reduction was−2.0± 0.5% (from 86.3± 19.6 kg to 84.8± 19.9 kg, $p < 0.001$) in the MAIN_SE(-) group and −2.2± 0.7% (from 82.5 ± 12.5 kg to 80.8± 12.3 kg, $p < 0.005$) in the MAIN_ SE(+) group; there was also no significant difference between the two groups ($p = 0.787$). After an average of 3 months, in the STOP_SE(-) group, the weight reduction compared to the baseline was −4.5± 0.5% (from 81.7± 18.3 kg to 78.2± 18.3 kg, $p < 0.001$), and in the STOP_SE(+) group, it was−3.4± 0.6% (from 84.03 ± 18.9 kg to 81.3± 19.1 kg, $p < 0.001$). There was no significant difference between the two groups ($p = 0.204$). After 6 months, in the STOP_SE(-) group, the weight reduction compared to the baseline was−1.7± 0.7% (from 81.7± 18.3 kg to 80.4± 18.4 kg, $p = 0.008$), and in the STOP_SE(+) group, it was −2.0± 0.6% (from 84.03 ± 18.9 kg to 82.0±19.2 kg, $p = 0.007$). There was no significant difference between the two groups ($p = 0.694$) (Figure 3). Even though there were no significant differences between the MAIN_SE(-) and MAIN_SE(+) groups and between the STOP_SE(-) and STOP_SE(+) groups, the SE(+) groups, regardless of drug maintenance, showed more weight reduction.

The greatest weight reduction in all groups was observed at 3 months, regardless of drug maintenance or side effects. However, a weight regain pattern was observed afterward. Regarding the weight difference between 3 and 6 months, the weight regain was 3.4± 0.3 kg ($p < 0.001$) in the MAIN_SE(-) group, 4.6± 0.6 kg ($p < 0.001$) in the MAIN_ SE(+) group, 2.2± 0.5 kg ($p < 0.001$) in the STOP_SE(-) group, and 1.2± 0.3 kg ($p = 0.001$) in the STOP_SE(+) group. All groups had a significant weight reduction com- pared to the baseline at 6 months; however, their weight increased compared to that observed at 3 months with sig- nificant results (results: weight difference between 3 and 6 months in all groups).

3.2. Regression Model for Weight Change. Based on 3 months of discontinuation of liraglutide in the logistic regression

TABLE 1: Baseline characteristics of patients (n = 157).

	Total	MAIN_SE(-) group	MAIN_SE(+) group	STOP_SE(-) group	STOP_SE(+) group	p value
Number (%)	157	41 (26.1)	23 (14.7)	63 (40.1)	30 (19.1)	
Age (years)	44 ± 12	46 ± 11	41 ± 14	43 ± 13	44 ± 12	0.486
Female sex, n (%)	117 (74.5)	27 (65.9)	19 (82.6)	48 (76.2)	23 (76.7)	0.461
Weight (kg)	83.5 ± 18.0	86.3 ± 20.0	82.5 ± 12.5	81.7 ± 18.3	84.0 ± 18.9	0.640
BMI (kg/m^2)	30.5 ± 4.8	30.8 ± 4.7	30.5 ± 3.7	30.3 ± 5.4	30.3 ± 4.5	0.974
Use of liraglutide						
Period of use (month)	3.26 ± 1.24	—	—	3.25 ± 1.06	3.27 ± 1.57	0.968
Dosage (mg)	2.3 ± 0.8	2.3 ± 0.8	2.6 ± 0.6	2.3 ± 0.8	2.2 ± 0.8	0.165
Present illness						
Hypertension, n (%)	48 (30.6)	15 (36.6)	5 (21.7)	16 (25.4)	12 (40.0)	0.309
Prediabetes, n (%)	10 (6.4)	2 (4.9)	1 (4.4)	6 (9.5)	1 (3.3)	0.716
DM, n (%)	57 (36.3)	15 (36.6)	10 (43.5)	20 (31.8)	12 (40.0)	0.740
Dyslipidemia, n (%)	65 (41.4)	15 (36.6)	14 (60.9)	22 (34.9)	14 (46.7)	0.144
GI trouble history, n (%)	4 (2.6)	0 (0.0)	0 (0.0)	1 (1.6)	3 (10.0)	0.060
Fatty liver, n (%)	11 (7.0)	3 (7.3)	3 (13.0)	3 (4.8)	2 (6.7)	0.629
Thyroid disease, n (%)	1 (0.6)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	>0.999
Psychiatric history, n (%)	15 (9.6)	4 (9.8)	2 (8.7)	7 (11.1)	2 (6.7)	0.979
Allergy history, n (%)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0.338
Laboratory finding						

Glucose (mg/dL)	113 ± 26	115 ± 27	113 ± 23	112 ± 26	110 ± 30	0.938
HbA1c (%)	6.6 ± 1.1	6.7 ± 1.0	6.8 ± 1.7	6.4 ± 1.0	6.6 ± 1.1	0.823
BUN (mg/dL)	13.4 ± 3.9	14.3 ± 4.5	12.0 ± 3.5	12.8 ± 3.7	14.1 ± 3.3	0.284
Creatinine (mg/dL)	0.8 ± 0.2	0.8 ± 0.2	0.7 ± 0.1	0.8 ± 0.2	0.7 ± 0.1	0.096
eGFR (mL/min/1.73 m^2)	96.8 ± 21.4	91.8 ± 19.6	105.8 ± 28.1	94.4 ± 19.3	98.8 ± 21.5	0.263
AST (U/L)	35 ± 40	42 ± 60	24 ± 10	34 ± 27	39 ± 45	0.621
ALT (U/L)	45 ± 52	51 ± 66	31 ± 19	44 ± 42	53 ± 68	0.612
ALP (U/L)	56 ± 16	54 ± 13	59 ± 18	59 ± 19	55 ± 15	0.744
γGTP (U/L)	44 ± 44	36 ± 22	39 ± 13	50 ± 61	44 ± 32	0.722
CPK (U/L)	102 ± 74	111 ± 60	61 ± 21	119 ± 101	80 ± 32	0.249
Total cholesterol (mg/dL)	189 ± 43	175 ± 43	192 ± 45	193 ± 43	200 ± 40	0.307
Triglycerides (mg/dL)	161 ± 95	153 ± 82	145 ± 67	154 ± 67	198 ± 162	0.402
HDL-cholesterol (mg/dL)	49 ± 13	48 ± 11	52 ± 12	48 ± 12	50 ± 17	0.779
LDL-cholesterol (mg/dL)	115 ± 40	106 ± 40	116 ± 41	120 ± 40	117 ± 41	0.669

Categorical variables are reported as frequencies (%), and continuous variables are reported as mean ± SD. AST: aspartate aminotransferase; ALT: alanine aminotransferase; ALP: alkaline phosphatase; BMI: body mass index; BUN: blood urea nitrogen; CPK: creatinine phosphokinase; DM: diabetes mellitus; eGFR: estimated glomerular filtration rate; GI: gastrointestinal; γ-GTP: γ-glutamyl transpeptidase; HbA1c: glycated hemoglobin; HDL: high-density lipoprotein; LDL: low-density lipoproteinmodel, factors affecting weight loss were drug discontinua- tion, sex, and the presence or absence of dyslipidemia (Table 2). Even after adjusting for age, sex, and BMI, which are well-known confounding variables, it was found that when liraglutide was stopped, body weight was 2.7282 times higher than when it was maintained ($p < 0.001$). Moreover, the weight loss was 1.7238 times higher in the case of dyslip- idemia than in the case of no dyslipidemia ($p < 0.01$) (Supple- mentary Table 1).

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