Effects of liraglutide on weight control and blood pressure in type 2 diabetes mellitus Iraqi patients

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Abstract

Background: Diabetes mellitus is the most common endocrine illness, affecting an increasing number of people all over the world. It is caused by a lack, or inadequate synthesis of insulin by the pancreas leading to an increase in blood glucose concentrations. Type 2 diabetes mellitus is the most strongly linked disease to obesity of all disorders. The number of obesity-related diabetes is predicted to reach 300 million by 2025. The term 'diabesity' was coined as a result of this strong link, therefore, weight loss is seen as a key therapeutic goal in the prevention and management of type 2 diabetes mellitus. Liraglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist that stimulates insulin secretion in a glucose-dependent manner. Also, it has weight-losing benefits which is assumed to be due to appetite suppression and delayed gastric emptying.

Objectives: To evaluate the effectiveness of Liraglutide on weight management, body mass index, renal function and blood pressure in type 2 diabetic mellitus obese patients in Iraq.

Methods: An open-label therapeutic trial was conducted from November 2021 to June 2022 at Baquba Teaching Hospital/ Diyala. Fifty patients (23 males and 27 females) with Type 2 Diabetes mellitus for 2 - 4 years were included in the study. They were obese, hypertensive and dyslipidemic. They received metformin and liraglutide for 12 weeks as 0.6 mg/day during the first week, which was gradually increased to 1.2 mg and up to 1.8 mg/day according to patient tolerance and requirement for control at the beginning the study. The patients had their height as well as body weight measured, body mass index calculated, blood pressure measured and renal functions tested. The statistical analysis was performed using SAS (Statistical Analysis System - version 9.1). Two-way ANOVA and Least significant differences (LSD) post hoc test were performed as well as paired *t*-test. $P< 0.05$ was considered statistically significant.

Results: Treatment with liraglutide for 12 weeks has resulted in a significant decrease in body weight, BMI, and blood pressure ($P<0.05$). The changes in the results of renal function test of liraglutide-treated patients were not significant.

Conclusion: In obese type 2 diabetic patients, liraglutide has the potential of reducing body weight, body mass index and blood pressure. It seemed safe in terms of its systemic effects.

Keywords: Blood pressure, Body weight, Diabetes mellitus, Iraqi patients, Obesity.

Introduction:

Diabetes mellitus (DM) is the most common endocrine illness, affecting an increasing number of people all over the world (1). It is caused by a lack, or inadequate synthesis of insulin by the pancreas, which causes an increase in blood glucose concentrations. DM can damage a variety of biological systems, including blood vessels, eyes, kidneys, heart, and nerves (1). Within 34 years, the number of diabetic patients has quadrupled (from 108 million in 1980 to 422 million in 2014), while the global prevalence of DM among individuals over the age of 18 has increased to 8.5% in 2014 from 4.7% in 1980 (2). DM is expected to be the 7th leading cause of death by 2030, according to the WHO (3). Obesity, unhealthy diet, physical inactivity, advancing age, insulin resistance, a family history of diabetes, genetic variables, race and ethnicity are all risk factors for type II diabetes (4). Insulin sensitivity in the body tissues, reduced insulin production, and an increased risk of obesity have all been linked to these genes (4). The complications of DM may be short-term (Hypoglycemia, hyperglycemia, diabetic ketoacidosis, and hyperosmolar hyperglycemia) or long-term (neuropathy, nephropathy, retinopathy, and cardiovascular disease) (5). Regarding the treatment of type 2 diabetes mellitus (T2DM), lifestyle changes alone can help people having reduced glucose tolerance to avoid developing diabetes. Also, it might sometimes be the only treatment option in the early stages of the

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disease (6). Physical activity lowers the risk of T2DM by 30-50% and risk reductions can be seen with as little as 30 minutes of moderate daily exercise (7). Insulin resistance is the leading cause of hyperglycemia in people with T2DM, and the best approach to treat it is via physical activity (8). Reduced body weight, reduced insulin resistance, and therefore metabolic syndrome-related effects of hypertension, dyslipidemia, and inflammation as well as improved endothelial function are all possible protective mechanisms (7). Different classes of drugs are used for the treatment of DM (9).Despite the fact that fatty acids are necessary for optimal insulin secretion, persistent exposure of β cells to excessive fatty acids is linked to a significant reduction in glucose-stimulated insulin secretion and insulin production. Also, the increased production of uncoupling protein 2 (UCP-2) in β cells is another way by which high fatty acids may affect insulin release in response to glucose (10). Nonetheless, diet modification, physical exercise, and behavioral therapy are all examples of lifestyle therapies used in obesity treatment. A variety of drugs are used for the treatment of obesity (11), (12). Of interest is the drug Liraglutide which is a glucagon-like peptide-1 (GLP-1) receptor agonist that can be administered subcutaneously as an additional treatment to diet and exercise for obese T2 diabetics (13). Liraglutide stimulates insulin secretion in a glucose-dependent manner, lowers plasma glucagon levels, delays stomach emptying, suppresses appetite via neural mechanisms, and lowers hepatic glucose synthesis (14),(15),(16). In clinical studies, gastrointestinal symptoms such as nausea and vomiting, risk of pancreatitis, and an increase in heart rate were all reported as side effects. As a consequence, weight reduction in obese diabetic patients may pave the way for successful and long-term control of their diabetes. The current study aims to evaluate the effectiveness of Liraglutide on weight management, body mass index, blood pressure as well as renal function in obese T2 diabetic Iraqi patients.

Methods

A therapeutic trial open-label study was conducted from November 2021 to June 2022 at Baquba Teaching Hospital/ Diyala. Fifty patients (23 males and 27 females) with T2 diabetic for 2 to 4 years were included in the study. They were obese, hypertensive and dyslipidemic. The recruited patients were on treatment with statins, angiotensin receptor blockers and metformin before starting the study. Liraglutide was added for 12 weeks (by subcutaneous route) as 0.6 mg/day during the first week, which was gradually increased to 1.2 mg and up to 1.8 mg/day according to patient tolerance and requirement for control at the beginning the study. Patients who have met the above criteria undergone measurements for their body weight and height to calculate their body mass index, blood pressure as well as testing their renal function. Statistical analysis was performed using SAS (Statistical Analysis System - version 9.1). Two-way ANOVA and Least significant differences (LSD) post hoc test were performed to assess significant differences among means. The Chi-square test and the paired *t*-test were performed as needed. P< 0.05 was considered statistically significant.

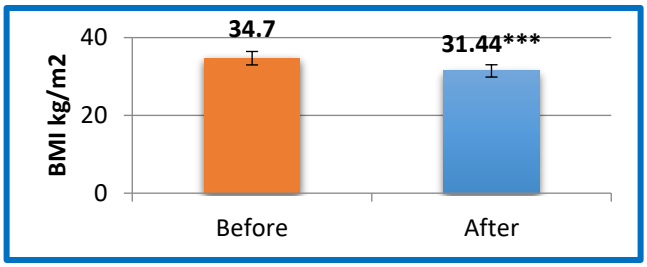
Results:

Liraglutide, body weight and BMI: A significant decrease of the body weight was achieved among male and female participants after using liraglutide for 12 weeks. A significant decrease in BMI was seen for male and female participants after using liraglutide for 12 weeks (Table 3.1 and Figure 3.1).

Table 3.1: Mean±SD of body weight before and after treatment with liraglutide

Parameters	Gender	Use of Liraglutide		*P* value
		Before	After	
Weight (Kg)	Male	101.9±3.90	91.4±3.02	P<0.05
	Female	94.9±2.51	86.4±1.87	P<0.05
	LSD	7.97		
BMI (Kg/M²)	Male	32.6±0.87	29.4±0.70	P<0.05
	Female	36.4±0.93	33.2±0.66	P<0.05
	LSD	2.27		

Each value represents mean ±SD. LSD: Least Significant Difference.



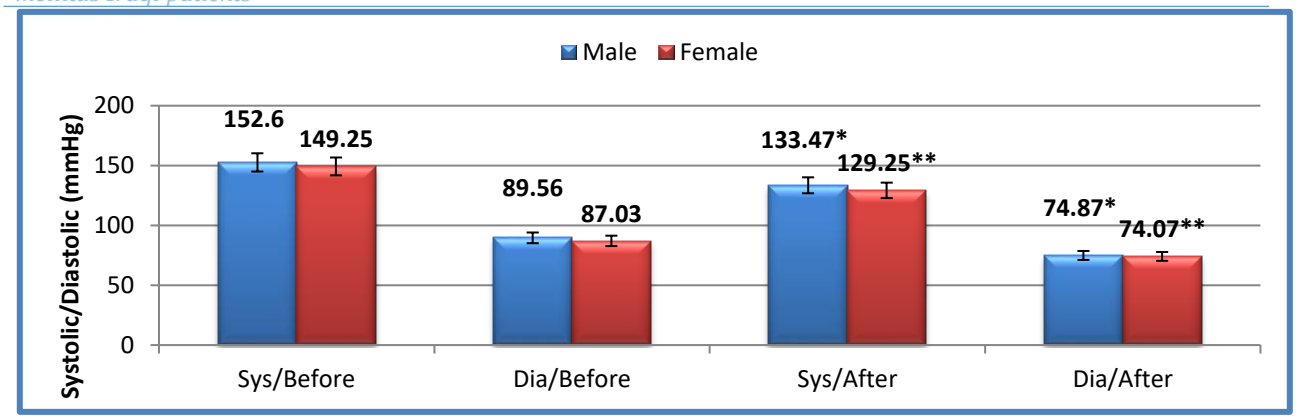
**** significant difference in the BMI of all patients.*

Figure 3.1. The effect of liraglutide on BMI (kg/m^2) of all the patients before and after 12 weeks of treatment with liraglutide.

Liraglutide and Blood pressure: A significant decrease of the blood pressure (P<0.05) was achieved for male and female patients after 12 weeks of using liraglutide (Table 3.4 and Figure 3.5).

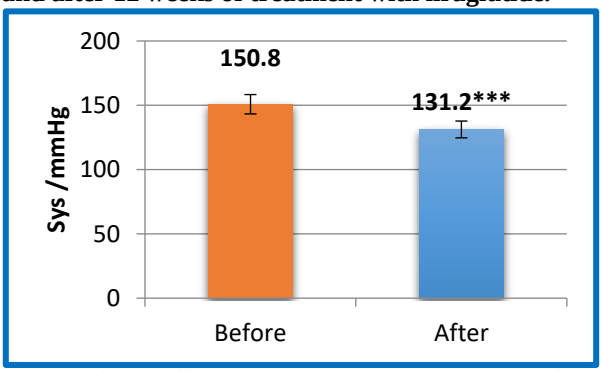
Table3.2. Mean±SD of blood pressure before and after treatment with liraglutide

Gender	Systolic blood pressure/mmHg		P value	Diastolic blood pressure/mmHg		P value
	Before	After		Before	After	
Male	152.6±3.27	133.5±2.23	P<0.05	89.6±2.84	74.8±1.76	P<0.05
Female	149.3±2.71	129.3±2.32	P<0.05	87.0±2.12	74.1±2.28	P<0.05
LSD	7.48			6.42		



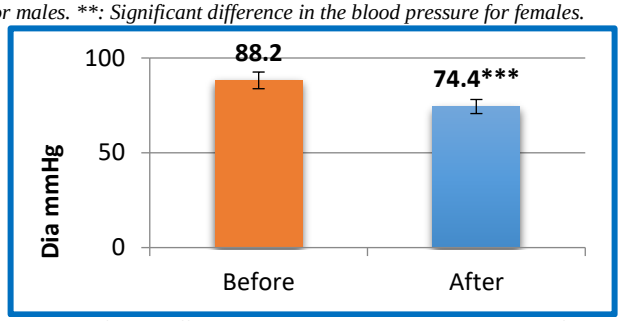
Sys: Systolic. Dia: Diastolic.: Significant difference in the blood pressure for males. **: Significant difference in the blood pressure for females.*

Figure 3.2. The effect of liraglutide on blood pressure (mmHg) of male and female patients before and after 12 weeks of treatment with liraglutide.



****: Significant difference in the systolic blood pressure of all patients.*

Figure 3.3. The effect of liraglutide on systolic blood pressure (mmHg) of all patients before and after 12 weeks of treatment with liraglutide.



****: Significant difference in the diastolic blood pressure of all patients*

Figure 3.4. The effect of liraglutide on diastolic blood pressure (mmHg) of all patients before and after 12 weeks of treatment with liraglutide.

Liraglutide and renal function:

The decrease in the renal function parameters for male and female participants after 12 weeks of using liraglutide was not statistically significant (P>0.05; Table 3.5).

Table 3.5: Mean±SD of renal function parameters before and after treatment with liraglutide

Gender	Creatinine		BUN		P value
	Before	After	Before	After	
Male	0.8±0.03	0.8±0.03	26.4±1.48	25.9±1.40	
Female	0.8±0.03	0.8±0.03	26.0±1.50	25.6±1.39	P>0.05
LSD	0.09	4.09			

Discussion:

Demographic data of participants: The mean age of the patients enrolled in current study was lower than the 59.8 years of patients enrolled in a Japanese study (17), in which the gender distribution of patients was comparable to that in current study (51.2% males and 48.8% females). Liraglutide, body weight and BMI: The weight reduction observed in the current study following the use of liraglutide is comparable to another study which detected a mean weight reduction of 4.2Kg in 15 patients (96.8 Kg to 92.6 Kg after three months of treatment with liraglutide) (18). The latter study reported a weight reduction between 7 to 9 kg within 20 weeks of treatment with 3 mg of liraglutide/ day. The weight-losing benefits of GLP-1 (liraglutide) were assumed to be due to appetite suppression and delayed gastric emptying (18). Another study conducted in Spain had shown a reduction of the mean BMI from 40.66 Kg/m^2 before treatment with liraglutide to 38.94 Kg/m^2 after 6 months of treatment with the dose of 1.8 mg/day, which was not significant (19). BMI is strongly correlated with weight (20), which explains the decrease in BMI of participants in the current study.

Liraglutide and blood pressure: The reduction of blood pressure that was found in the current study was also reported by another study where a significant decrease in the mean SBP from 126.6±10.4 mmHg at baseline to 122.5±7.29 mmHg after the use of liraglutide and a decrease in the mean DBP of 76.5±8.37 mmHg at baseline to 74.3±6.22 mmHg (21). Another study had

shown a significant decrease in mean SBP from 140.0±16.6 mmHg at baseline to 134.1±15.2 mmHg after the use of liraglutide for 3 - 6 months and a decrease in the mean DBP of 82.5±10.8 mmHg at baseline to 79.3±9.5 mmHg (22). Being one of the Glucagon-like peptide (GLP)-1 receptor agonists, liraglutide has effects on the cardiovascular system, including blood pressure lowering which may also be due to the associated weight loss (23), natriuresis (24), and/or vasodilation (25)**.**

Liraglutide and renal function: The non-significant change of renal functions that was found in the current study after 12 weeks of treatment with liraglutide was also reported by a previous study on 152 obese T2 diabetics who were followed up every two months. They were started on an initial dose of liraglutide of 0.6mg daily, increased weekly by 0.6mg to the maintenance dose of 1.8mg daily. These was a non-significant change in renal function test (26). This may indicate the safety of liraglutide as it does not affect renal functions.

Conclusion:

In obese type 2 diabetics, liraglutide has the potential of reducing body weight, body mass index and blood pressure. It seems safe in terms of its systemic effects.

Ethical Clearance: Ethical Approval was obtained from the Scientific Research Ethics Committee and Department of Pharmacology/ College of Medicine, University of Baghdad and that at Baqubah Teaching Hospital/ Diyala.

Conflict of interest: None.

Authors' cntributions:

Ahmed J. Abdulrahman: student
Mohammed A.H. Jabarah: supervisor
Samer A. Najjar: supervisor

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تقييم فاعلية الليراجلوتايد في ادارة الوزن والتحكم في ضغط الدم لدى مرضى السكري من النوع الثاني في العراق

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الخلاصة
الخلفية: أكثر من 100 مليون شخص في جميع أنحاء العالم (6٪ من السكان) يعانون من مرض السكري ، وهو أكثر أمراض الغدد الصماء انتشارًا. ينتج عن عدم قدرة البنكرياس أو ضعف قدرتها على انتاج ما يكفي من الأنسولين ، مما يرفع مستويات الجلوكوز في الدم. بالإضافة إلى ذلك ، فإن مرض السكري من النوع 2 هو الحالة الأكثر ارتباطًا بالسمنة من جميع الاضطرابات ، وبحلول عام 2025 ، من المتوقع أن يتضاعف عدد الأشخاص المصابين بمرض السكري المرتبط بالسمنة إلى 300 مليون. بسبب هذا الارتباط الوثيق ، تم إنشاء كلمة "مرض السكري" ، وأصبح فقدان الوزن معروفًا الآن كهدف علاجي مهم في الوقاية من مرض السكري من النوع 2 والسيطره عليه. يعزز ليراجلوتيد ناهض مستقبلات GLP-1 إفراز الأنسولين بطريقة تعتمد على الجلوكوز. بالإضافة إلى ذلك ، فإنه يوفر مزايا لفقدان الوزن ، والتي يعتقد أنها ناجمة عن تأخر إفراغ المعدة وكبح الشهية. نتيجة لذلك ، كان **الهدف:** من الدراسة الحالية هو تقييم فعالية الليراجلوتايد في إدارة الوزن ومؤشر كتلة الجسم ووظيفة الكلى وضغط الدم لدى مرضى السكري من النوع 2 العراقيين الذين يعانون من السمنة المفرطة.
طريقة البحث: أجريت دراسة مستقبلية ذات تسمية مفتوحة من تشرين الثاني 2021 إلى حزيران 2022 في مستشفى بعقوبة التعليمي / ديالى. في الدراسة الحالية ، كان 50 مريضًا (23 ذكرًا و 27 أنثى) مصابين بمرض السكري من النوع 2 من 2 إلى 4 سنوات وكانوا يعانون من السمنة المفرطة وارتفاع ضغط الدم وخلل الدهون. لقد تلقوا الميتفورمين وليراجلوتيد لمدة 12 أسبوعًا بمقدار 0.6 ملغم يوميًا للأسبوع الأول ، ثم تم رفعه بعد ذلك إلى 1.2 ملغم وفي النهاية 1.8 ملغم يوميًا بناءً على التحمل والحاجة في بداية الدراسة. تم إجراء قياسات لضغط الدم ووزن الجسم ومؤشر كتلة الجسم ووظائف الكلى. تم استخدام SAS لإجراء التحليل الإحصائي (نظام التحليل الإحصائي - الإصدار 9.1). بالإضافة إلى اختبار t المقترن ، تم إجراء اختبار ANOVA ثنائي الاتجاه واختبار الفروق الأقل أهمية (LSD). يتم تعريف ذات دلالة إحصائية على أنها $P < 0.05$.
النتائج: وفقًا لنتائج الدراسة ، أدى استخدام الليرلوتيد لمدة 12 أسبوعًا إلى انخفاض كبير في ضغط الدم ووزن الجسم ومؤشر كتلة الجسم ($P < 0.05$). ومع ذلك ، لوحظت تغيرات غير مهمة في وظائف الكلى لدى الأفراد الذين يستخدمون الليرلوتيد ($P > 0.05$). ا
الاستنتاج: الليراجلوتايد لديه القدرة على خفض ضغط الدم ، ومؤشر كتلة الجسم ، ووزن الجسم في مرضى السكري من النوع 2 الذين يعانون من السمنة المفرطة. ومع ذلك ، بدا أنها آمنة من حيث آثارها على اجهزة الجسم.
الكلمات المفتاحية: ضغط الدم ، وزن الجسم ، السكري ، مرضى العراق ، السمنة.