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Original Article

Anthropometric outcomes in type 2 diabetic patients with new dapagliflozin treatment; actual clinical experience data of six months retrospective glycemic control from single center

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ABSTRACT

Introduction: Dapagliflozin is an antidiabetic drug that has been used as a member of the new antidiabetic drug group that acts by inhibiting SGLT-2 and increasing urinary glucose excretion. With numerous controlled experimental studies of dapagliflozin, evaluation of real-life data after entry into clinical practice is an important condition. In our study, the effects of dapagliflozin on glycemic control and anthropometric measurements were investigated retrospectively.
Methods: A-total of thirty-one type 2 diabetics were enrolled in the study. Data of before dapagliflozin and three and six months of treatment were recorded.
Results: Dapagliflozin reduced HbA1c levels by 0,9% at 3 months and 0,79% at 6 months. Fasting plasma glucose decreased 41,1 mg/dl in the 3rd and 42 mg/dl in the 6th, postprandiyal glucose decreased 86,3 mg/dl in the 3rd and 74,2 mg/dl in the 6th. In the 3rd and 6th, body weights decreased by 3,3 kg and 4,2 kg, BMI decreased by 1,3 kg/m^2 and 1,6 kg/m^2 respectively. Similarly, it was observed that the waist circumference decreased by 1,3 cm at the end of 6th.
Conclusion: Our data show that SGLT-2 inhibitors provide glycemic control with reduce HbA1c levels by 0.8–0.9%, and reduce fasting and postprandial plasma glucose levels without increasing the risk of hypoglycemia and causing weight lose around 5% at the six mounths. SGLT-2 inhibitors were found to be more effective in reduce postprandiyal plasma glucose in patients who did not use insulin and fasting plasma glucose in patients with diabetes mellitus less than 10 years.

1. Introduction

Diabetes Mellitus (DM) is a chronic metabolic disease in which the organism can not adequately use carbohydrates, fat and proteins due to insulin deficiency, defects in tissues affected by insulin, or both [1]. In Europe, the prevalence of diabetes between the 20–79 years is estimated to be 8.8% in 2017, which is expected to be 10.2% in 2045 [2]. While there are 58 million diabetics in Europe in 2017, it is estimated that this figure will increase to 66.7 million by 2045 [2]. In 2014, 9.3% of the entire population in the United States of America was diagnosed with diabetes and the diabetic population reached 29.81 million [3]. TURDEP-I (Türkiye Diyabet, Hipertansiyon, Obezite ve Endokrinolojik Hastalıklar Prevalans Çalışması) study showed, type 2 DM prevalence of 7.2% according to the results in Turkey between September 1997 and March 1998, while TURDEP-II study conducted between January 2010 and June 2010, this ratio was observed to have reached 13.7% [4,5]. According to the International Diabetes Federation (IDF), there are approximately 425 million people with diabetes in the world, and 12% of their health spending is due to diabetes and related conditions [2]. Four quarters of diabetic patients live in low- and middle-income countries, while two-thirds of the patients live in urban areas [2]. Despite all the precautions in the last 12 years, the prevalence of DM in our country is about 2 times higher.

Type 2 diabetes accounts for about 90–95% of all diabetic patients [3]. Chronic hyperglycemia developed in these patients is associated with the development of microvascular complications such as retinopathy, neuropathy, and nephropathy, which are caused by diabetes [6]. Lifestyle changes such as weight loss,

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exercise, and dietary restrictions are included in the initial treatment of Type 2 DM patients. Lifestyle changes are not sufficient in the majority of patients and pharmacotherapy is required [7].

The kidneys increase body glucose by producing glucose through gluconeogenesis and reabsorbing glucose from plasma [8]. SGLT-2 is responsible for 90% of glucose reabsorption in proximal tubules [9]. Inhibition of SGLT-2 reduces glucose reuptake from the kidneys and decreases plasma glucose levels by increasing urinary glucose excretion [10]. Dapagliflozin is the first SGLT-2 inhibitor drug approved in the European Union in 2012 and in the United States in 2014 for use in diabetes [11]. SGLT-2 inhibitors offer a new treatment option independent of insulin action. SGLT-2 inhibitors are especially beneficial in the treatment of overweight or obese diabetic patients because of the weight loss feature. In some studies, increased urinary infections and genital infections have been reported, but the long-term effect of these increases has not been determined.

In this study, changes in anthropometric values and glycemic control parameters were evaluated retrospectively in patients using dapagliflozin. The data were collected by scanning electronic files as single centered real-life study data and the results of patients in the third and sixth months were evaluated. When the literature is reviewed, it is seen that there are few studies on the use of dapagliflozin with real life data. This study aimed to give an idea about the positive and negative effects of the use of dapagliflozin in the treatment of diabetes and to contribute to the literature.

2. Methods

Type 2 DM patients who applied to the Endocrinology outpatient clinic of Uludağ University Medical Faculty between September 2016 and November 2017, or who were hospitalized between the same dates and who used dapagliflozin for the first time, were included in the study. In our study, 78 files were scanned retrospectively. Before the drug was started, the patients who were followed up for the third month and the sixth month after the drug was started, and the assessed data were available, were included in the study.

A total of 31 patients, 22 female and 9 male, were included in the study. The data files of the patients were obtained through detailed examination. The presence of hypertension, the duration of the illness and the medications used were recorded and detailed. Anthropometric evaluation used height, body weight and waist circumference values measured during physical examination of patients. The fasting plasma glucose, postprandial plasma glucose and HbA1c values measured at our center were recorded and used as glycemic control parameters. HbA1c level was measured in Adams A1c HA 8160 device with ion exchanger high performance liquid chromatography (HPLC) principle. BMI was calculated by dividing the meters of the height in kilograms by body weight. The measured values of the patients before using dapagliflozine and the values measured in the third and sixth months were recorded and 0–3 month and 0–6 month changes were calculated.

3. Statistical analysis

All data were transferred to the computer and analyzed for statistical analysis using the application-statistical analysis program of SPSS for Windows, version 23 (IBM Corporation, New York, United States), which accessible from our network. Independent sample T test or Mann Whitney U variance analysis test was used for according to the provision of the normal distribution assumption. To compare numerical data in dependent groups, dependent sample T-test or Wilcoxon test was used according to the provision of the normal distribution assumption. As the descriptive values, the mean (+/− standard deviation) or median (min-max) according to the distribution of the data for the continuous variables (such as fasting plasma glucose, postprandial plasma glucose, weight), and the number (n) and percentage (%) values for the categorical variables (sex, duration of illness, etc.) were given. The significance level of p value less than 0.05 was regarded as statistically significant.

4. Results

The study included 31 patients, including twenty-two (%71) females and nine males (%29). The average age of the patients was 57,4 in total, 60,2 in males and 56,2 in females. The number of patients under 55 years old was 15 (48%) and the number of patients over 55 years old was 16 (52%). Seventeen of the patients had a history of hypertension while fourteen of the patients had no history of hypertension. The number of patients with a disease duration less than 10 years was 14 (45%), while the number of patients with disease duration of 10 years and over was 17 (%55). A total of eight patients were on treatment of insulin and oral antidiabetic (OAD), while 23 patients were on OAD combination without insulin. Table 1 shows the baseline characteristics and averages of the parameters investigated in the patients who started dapagliflozin, and the distributions of these values in terms of both men and women are also shown in the same table. In Table 2 and Table 3, three and six-month mean differences were given together with the measured third and sixth month values after the using dapagliflozin. There was a mean reduction 3.3 kg (±2.5) in weight, 1.3 m (±1.3) in waist circumference and 1.3 kg/m^2 (±1) in BMI at the 3rd month. These changes were statistically significant ($p < 0.001$). The mean fasting plasma glucose level was reduced by 42.1 mg/dl (±72.1), the mean postprandial plasma glucose level was reduced by 74.2 mg/dL (±94.4), and the HbA1c average was reduced by % 0,79 (±1,7) at the 6th month. These reductions were statistically significant.

In Table 4, it is shown whether the mean changes in weight, waist circumference and BMI calculated at the third and sixth months after the use of dapagliflozin are influenced by age, gender, disease duration, hypertension history and using insulin.

In Table 5, it is shown whether the mean changes in HbA1c, fasting plasma glucose and postprandial plasma glucose calculated at the third and sixth months after the use of dapagliflozin are influenced by age, gender, disease duration, hypertension history and using insulin.

5. Discussion

SGLT-2 is responsible for 90% of the glucose uptake in proximal tubules [9]. Dapagliflozin inhibits the SGLT-2 molecule, reducing plasma sugar independently of insulin release [10]. Studies with dapagliflozin were in the age range of 60–63 in several studies,

Table 1
Baseline characteristics of the full analysis.

	All patients	Men	Women
Age (years)	57,39 (±9,2)	60,2 (±10)	56,2 (±8,9)
Weight (kg)	87,4 (±17,8)	93,1 (±15,6)	85 (±18,4)
BMİ (kg/m^2)	33,2 (±6,8)	32 (±5,4)	33,7 (±7,3)
Waist circumference (cm)	106,4 (±15,3)	108,1 (±10,6)	105,7 (±17)
HbA1c (%)	8,5 (±1,9)	8,2 (±2)	8,6 (±1,9)
FPG (mg/dl)	192,7 (±62,6)	180 (±43,6)	198 (±69,1)
PPG (mg/dl)	269 (±79,2)	238,1 (±50,9)	281,7 (±86)

BMİ:Body mass indeks, FPG:Fasting plasma glucose, PPG:postprandial plasma glucose.