25TH NATIONAL & 11TH INTERNATIONAL ANNUAL CONGRESS
ON RESEARCH AND TECHNOLOGY OF IRANIAN MEDICAL SCIENCES STUDENTS
URMIA UNIVERSITY OF MEDICAL SCIENCES, URMIA, IRAN

Effect of Empagliflozin on Cardiometabolic Side Effects of Atypical Antipsychotics in Patients With Psychiatric Disorders: A Randomized Clinical Trial

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Citation:
Aminzadeh SS, Beheshtirouy S, Rezaee H, Shaseb E. Effect of Empagliflozin on Cardiometabolic Side Effects of Atypical Antipsychotics in Patients With Psychiatric Disorders: A Randomized Clinical Trial. *Iranian biomedical journal* 2024; 28(7): 461.

ABSTRACT

Introduction: Atypical antipsychotics, or second-generation antipsychotics, are prescribed for psychiatric disorders. These agents aimed to decrease the extrapyramidal side effects of typical (first-generation) antipsychotics. However, metabolic side effects of atypical antipsychotics, such as weight gain, diabetes, and dyslipidemia, are non-negligible. This study aimed to assess the effect of empagliflozin, an antidiabetic agent with cardiovascular benefits, on the cardiometabolic side effects of atypical antipsychotics.

Methods and Materials: This pilot randomized clinical trial was conducted on 36 patients with psychiatric disorders. Patients were included if they were aged between 18 and 65 years, had confirmed mental disorders based on the DSM-V-TR criteria, received atypical antipsychotics within the past 6 months, and had stable weight (less than 5% change within the past 3 months). Pregnant and breastfeeding patients were excluded from the study. The participating patients were randomly assigned to 18 in the empagliflozin group and 18 in the control group. Patients in the empagliflozin group received empagliflozin 10 mg daily along with their routinely prescribed atypical antipsychotics for 12 weeks. Patients in the control group did not receive any extra medication. For all of the patients, cardiometabolic parameters were measured at baseline and the end of the 12-week study. These parameters included systolic and diastolic blood pressure (SBP and DBP), LDL, HDL, TG, FBS, body weight, body mass index (BMI), and waist circumference.

Results: Based on the results, the level of FBS was significantly decreased in the empagliflozin group (p = 0.033). Moreover, weight (p-value = 0.00), BMI (p = 0.00), waist circumference (p = 0.00), and SBP (p = 0.043) were significantly improved in the intervention group (p = 0.05). There was no significant change in the empagliflozin group's DBP or TG, LDL, and HDL levels (p = 0.05). No significant difference was observed in cardiometabolic parameters in the control group, except for DBP.

Conclusion and Discussion: BMI, weight, and waist circumference were significantly decreased in patients who received empagliflozin. Moreover, empagliflozin use resulted in a significant reduction in SBP. The results of this study demonstrated that patients affected by psychiatric disorders might benefit from routine doses of empagliflozin to alleviate cardiometabolic side effects. To the best of our knowledge, this is the first clinical trial evaluating the efficacy of empagliflozin on cardiometabolic effects of atypical antipsychotics. The results support the two preclinical studies previously performed on rats.

Keywords: Empagliflozin, Mental disorders, Patients