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The effect of enriched chicory inulin on liver enzymes, calcium homeostasis and hematological parameters in patients with type 2 diabetes mellitus: A randomized placebo-controlled trial

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ABSTRACT

Backgrounds and aims: Type 2 diabetic mellitus (T_2DM) as one of the main causes of morbidity and mortality is associated with immune system disturbances and metabolic abnormalities. In the current study we aimed to evaluate the effects of enriched chicory inulin supplementation on liver enzymes, serum calcium and phosphorous concentrations and hematological parameters in patients with T_2DM.

Methods: Forty-six diabetic females patients were randomly allocated into intervention ($n = 27$) and control ($n = 22$) groups. Subjects in the intervention group received a daily dose of 10 g of chicory and subjects in control group received a placebo for two months. Anthropometric variables, glucose homeostasis, hematological parameters and metabolic indices including serum alanine aminotransfersae (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), calcium and phosphorous as well as creatinine concentrations, glomerular filtration rate (GFR) and blood pressure were assessed at the beginning and end of the trial.

Results: Significant reductions in fasting serum glucose (FSG), Hb A_1C, AST and ALP concentrations were observed in chicory-treated group. Systolic and diastolic blood pressures were also reduced in chicory-treated group. Serum calcium significantly increased after chicory supplementation but no change in placebo treated group has been occurred ($P = 0.014$). Supplementation with enriched chicory for two months significantly reduced hematocrit and mean corpuscular volume (MCV) values ($P < 0.05$). Changes in serum insulin, creatinine and GFR were not significant.

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Conclusion: The present study showed beneficial effects of oligofructose-enriched chicory on the improvement of the glucose and calcium homeostasis, liver function tests, blood pressure and reduction in hematologic risk factors of diabetes in female patients with T_2DM. Further studies in both genders are needed to generalize these findings to total population.
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1. Introduction

Type 2 diabetes mellitus (T_2DM) is one of the serious costly diseases that affects approximately 347 million people worldwide; it has been estimated that the global prevalence of T_2DM would reach to 366 million people in 2030 [1]. T_2DM is associated with numerous co-morbidities including cardiovascular events, hypertension, renal and ocular disturbances and impaired mental status which finally leads to poor life expectancy among these patients [2].

T_2DM is also associated with altered vitamin and mineral metabolism leading to various metabolic complications in these patients; change in mineral homeostasis including ionized calcium, magnesium and bone mineral content is a metabolic consequence of insulin dependent diabetes mellitus in both adult and children [3,4] and finally leads to low bone mineral density, secondary hyperparathyroidism, hypovitaminosis D and osteoporosis [5]. Moreover, calcium insufficiency negatively influences glycemia and contributes in developing T_2DM [6]. Additionally, recent evidence suggests that change in hematologic indices might contribute to abnormal glucose metabolism and diabetes by increasing insulin resistance and hepatic dysfunction [7,8]. Liver dysfunction as a secondary outcome of diabetes [9] or as a consequence of altered mineral metabolism [10] leads to endothelial dysfunction and cardiovascular events in patients with T_2DM [11]. Increased hematocrit values and blood viscosity are proposed as major risk factors in developing T_2DM by limiting delivery of glucose, insulin and oxygen to metabolically active tissues [12].

Chicory inulin is a natural linear fructan that is not digested in the upper part of the gastrointestinal tract but is fermented in the cecocolon [13] and exerts more health and nutritional benefits when enriched with oligofructose than its lone form [14]. It has been suggested that oligofructose enriched-inulin enhances intestinal calcium absorption and improves bone markers in healthy postmenopausal women [15]. Also, chicory supplement decreases iron over load and improves liver function; in a study by Hashemi et al. [16], supplementation with oral chicory inulin for three months reduced serum alanine aminotransferase (ALT), aspartate amino transferase (AST) and improved iron homeostasis in patients with Beta thalassemia. However data regarding the potential health benefits of chicory inulin enriched with oligofructose in liver function, calcium homeostasis and hematological parameters as well as blood pressure and creatinine in T_2DM are not available. Considering its potential health benefits, the current trial aimed to investigate the role of chicory inulin enriched with oligofructose on glucose homeostasis, hematological parameters, calcium and phosphorous concentrations, liver function tests, blood pressure and glomerular filtration rate (GFR) in patients with T_2DM.

2. Materials and methods

2.1. Patients

In the current double-blinded placebo-controlled trial, seventy females with T_2DM were enrolled (Fig. 1). Subjects were recruited from outpatient endocrinology and metabolism clinics of Tabriz University of Medical Science. Inclusion criteria were as follows: age between 30–65 years, having T_2DM for more than 6 months and having BMI between 25 and 34.99 kg/m^2. Exclusion criteria were as follows: taking insulin therapy, lipid lowering medications, antibiotics, antacids, antidiarrheal, anti-inflammatory or laxatives drugs for at least 3 months prior participation or during the trial, any history of gastrointestinal and cardiovascular disease, renal dysfunction, thyroid or liver abnormalities, being pregnant or lactating and prebiotics or probiotics consumption during and three months before recruitment in the trial.

2.2. Study design

From seventy recruited subjects, sixteen participants were excluded because of not meeting the inclusion criteria. Among fifty four T_2DM patients random permuted block procedure was performed and participants were randomly allocated into prebiotic-treated ($n = 27$) or placebo ($n = 27$) groups.

Patients in the intervention group received a daily dose of 10 g chicory inulin enriched with oligofructose (Frutafit IQ, Sensus, Borchwef 3, 4704 RG Roosendaal, The Netherlands) and placebo group received 10 g Maltodextrin (Jiujiang Hurirong Trade Co., LTD, China) as placebo for two months. Both supplements and placeboes were similar in appearance and taste and were identically packaged. Subjects were advised to receive the supplement or placebo packages in two divided dosages with breakfast and dinner. Randomization procedure was performed by a third investigator with no clinical involvement in the trial to ensure the integrity of the blinding. A follow-up procedure was done with telephone contacts every two weeks to ensure that subjects consumed the supplements regularly. Written informed consent was obtained from all of the participants before participation in the trial and the study protocol was approved by the ethics committee of Tabriz University of Medical Sciences. The current trial was also registered in the Iranian Registry of Clinical Trials (Identifier: IRCT201203103565N4).

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