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Randomized control trials

Effects of vitamin D-fortified low fat yogurt on glycemic status, anthropometric indexes, inflammation, and bone turnover in diabetic postmenopausal women: A randomised controlled clinical trial

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SUMMARY

Background & aims: Low levels of serum 25-hydroxy vitamin D (25(OH)D) are common in type 2 diabetic patients and cause several complications particularly, in postmenopausal women due to their senile and physiological conditions. This study aimed to assess the effects of vitamin D-fortified low fat yogurt on glycemic status, anthropometric indexes, inflammation, and bone turnover in diabetic postmenopausal women.

Methods: In a randomized, placebo-controlled, double-blind parallel-group clinical trial, 59 postmenopausal women with type 2 diabetes received fortified yogurt (FY; 2000 IU vitamin D in 100 g/day) or plain yogurt (PY) for 12 weeks. Glycemic markers, anthropometric indexes, inflammatory, and bone turnover markers were assessed at baseline and after 12 weeks.

Results: After intervention, in FY group (vs PY group), were observed: significant increase in serum 25(OH)D and decrease of PTH (stable values in PY); significant improvement in serum fasting insulin, HOMA-IR, HOMA-B, QUICKI, and no changes in serum fasting glucose and HbA_{1c} (significant worsening of all indexes in PY); significant improvement in WC, WHR, FM, and no change in weight and BMI (stable values in PY); significant increase of omentin (stable in PY) and decrease of sNTX (significant increase in PY). Final values of glycemic markers (except HbA_{1c}), omentin, and bone turnover markers significantly improved in FY group compared to PY group. Regarding final values of serum 25(OH)D in FY group, subjects were classified in insufficient and sufficient categories. Glycemic status improved more significantly in the insufficient rather than sufficient category; whereas the other parameters had more amelioration in the sufficient category.

Conclusions: Daily consumption of 2000 IU vitamin D-fortified yogurt for 12 weeks improved glycemic markers (except HbA_{1c}), anthropometric indexes, inflammation, and bone turnover markers in postmenopausal women with type 2 diabetes.

Trial registration: www.irct.ir (IRCT2013110515294N1).

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Abbreviations: 25(OH)D, 25-hydroxy vitamin D; FM, fat mass; FY, fortified yogurt; FSG, fasting plasma glucose; HC, hip circumference; HOMA-IR, homeostasis model assessment of insulin resistance; HOMA-B, HOMA of beta cell function; hs-CRP, highly sensitive C-reactive protein; PY, plain yogurt; QUICKI, quantitative insulin sensitivity check index; sBAP, bone alkaline phosphatase; sNTX, N-terminal type-1 collagen; T2DM, type 2 diabetes mellitus; TC, total cholesterol; TG, triglycerides; METs, metabolic equivalents; WC, waist circumference; WHR, waist to hip ratio.

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1. Introduction

International Diabetes Federation has predicted a rise in the number of diabetic patients throughout the world from 387 in 2014 to 592 million in 2035. In Iran, 8.43% (more than 4 million) of adults suffered from type 2 diabetes mellitus (T2DM) [1]. A great deal of therapeutic expenses is dedicated to diabetes and its complications throughout the world [2]. Postmenopausal diabetic women are more vulnerable due to several factors such as aging, probable co-morbidities such as osteoporosis, and socio-economic conditions.

It has been demonstrated that there is an inverse association between serum 25(OH)D levels and the risk of T2DM [3]. Vitamin D plays an important role in insulin resistance. It also has modulatory effects on growth and differentiation of cells involved in immune-response as well as in production of inflammatory and anti-inflammatory cytokines [4]. Therefore, vitamin D deficiency is associated with autoimmune and inflammatory diseases like diabetes and metabolic syndrome. Vitamin D status is defined on the basis of serum concentrations of 25-hydroxy vitamin D (25(OH)D) as deficient i.e.<50 nmol/l (20 ng/ml), insufficient i.e. 50–74 nmol/l (21–29 ng/ml), and sufficient i.e.>75 nmol/l (30 ng/ml) [5].

The major source of vitamin D in human is cutaneous synthesis. Factors such as exposure duration, season, latitude, aging, skin pigmentation, and continuous usage of sunscreens may affect vitamin D synthesis. People also receive vitamin D from foodstuffs such as oily fish, fish liver oil, wild mushrooms, and egg yolk, which are the richest sources of vitamin D but some of these foods are not part of the usual intake in many countries. The average intake of vitamin D varies from one country to another, due to the differences in dietary patterns and food fortification rights. This intake seems to be higher in the countries fortifying foodstuffs [6]. In Iran, fortification of foods with vitamin D is not customary. According to the latest advice from Institute of Medicine, a recommended dietary allowance (RDA) of 600 IU/day of vitamin D is needed for ages 1–70 y to provide at least serum 25(OH)D of 50 nmol/l [7]. The Endocrine Society recommended 600 IU/day based on bone health and muscle function protection; however, it is unknown whether the mentioned dose is enough to supply all the potential non skeletal functions of vitamin D [5]. The Society has also stated that consistent daily intake of at least 1500–2000 IU/day is needed to raise serum 25(OH)D above 75 nmol/l; hence it is necessary to improve vitamin D intakes via supplementation or food fortification.

High prevalence of vitamin D deficiency or insufficiency among Iranian population [8] and lack of accessible vitamin D-fortified foodstuffs warrants conducting scientific-based studies to introduce suitable staple foods for vitamin D fortification. Recently, some clinical trials have been carried out in Iran on the effect of vitamin D fortified foods, like Persian yogurt drink (Doogh; consists in plain yogurt, water, and salt), milk, and orange juice [9,10]. This study aimed to assess the effects of vitamin D-fortified low fat yogurt on glycemic control, anthropometric indexes, inflammation, and bone turnover in diabetic postmenopausal women. Yogurt could be a good choice for vitamin D fortification due to extensive consumption among Iranian people and also an appropriate replacement for milk in subjects who are not able to consume it. Moreover, unlike Doogh (1.6 g/100 g fat and 380 mg/100 g Na) or sugary juices, low-fat yogurt (1.4 g/100 g fat and 65 mg/100 g Na) is safe for those who suffer from diseases like hypertension or diabetes.

2. Methods

2.1. Study design and participants

This single center study was a randomized, placebo-controlled, double-blind parallel-group clinical trial on diabetic postmenopausal women registered at Isfahan Endocrine and Metabolism Research Center. To calculate the sample size, suggested formula for parallel-design randomized controlled trial was used based on $\alpha = 0.05$, 90% power, and a standardized effect size of $\Delta = 1$ in NTX [11] as a key variable. We reached to 22 participants per group.

We studied 148 medical records of diabetic women who did not use insulin. The diagnosis of T2DM was based on WHO criteria [12]. Among the records, postmenopausal women who had not menses for at least 12 months were selected. The cases were enrolled in the study if they met these inclusion criteria: (*i*) not taking vitamin D, calcium, or omega-3 supplements within the past 3 months before the intervention, (*ii*) not taking drugs which have obvious interaction with vitamin D or influence its metabolism i.e. corticosteroids or estrogens, (*iii*) baseline serum 25(OH)D < 125 nmol/l, and (*iv*) not having history of malignancy, renal failure, liver, endocrinologic, or inflammatory disorders. All subjects had to spend a 3 weeks run-in period during which they were instructed by a dietitian to follow a weight-maintenance diet according to American Diabetes Association guidelines [13]. After that period, subjects who had weight changes were excluded and the others were randomly divided to 2 groups. The equivalent amounts of dairy products were replaced by 1 serving (100 g) per day of low-fat yogurt in their diet. During the intervention, the exclusion criteria were: (*i*) any change in type or dosage of oral anti-diabetic drugs or usage of insulin, (*ii*) intake of vitamin D, calcium or omega-3 supplements, and (*iii*) disobedience to the study protocol.

2.2. Study protocol

The study protocol was approved by the Ethical Committee of Research, Isfahan University of Medical Sciences on 19 July 2013 (registration number: 192015). The study protocol and its progress were recorded at www.irct.ir (registration ID: IRCT2013110515294N1). At first, the study protocol and objectives were fully explained to each subject and then written informed consent was obtained from all participants.

2.3. Randomization and blinding

Study's enrolled patients underwent permuted block randomization. Each block had permuted, even-numbered, randomly varying block sizes with 1:1 allocation ratio. The block sizes were concealed till the end of the study. Subjects were randomly allocated to the 'FY' (received vitamin D-fortified low fat yogurt, containing 2000 IU vitamin D in 100 g) or 'PY' (received plain low fat yogurt without additive) treatment groups. The random sequence was generated by an investigator uninvolved in recruiting subjects. Both participants and investigators were blinded to the content of interventions.

2.4. Outcome measurements

The project was launched at late fall (December 2013), going on during the winter, and finished after 12 weeks of intervention in the middle of March, 2014 in order to minimize the cutaneous synthesis of vitamin D. Participants consumed one serving of low

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