International Dairy Journal 73 (2017) 50–56

Contents lists available at ScienceDirect

International Dairy Journal

journal homepage: www.elsevier.com/locate/idairyj

Dietary calcium from dairy, body composition and glycaemic control in patients with type 2 diabetes pursuing an energy restricted diet: A parallel group randomised clinical trial

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ARTICLE INFO

Article history:
Received 27 October 2016
Received in revised form
1 May 2017
Accepted 1 May 2017
Available online 13 May 2017

ABSTRACT

In a 12-week duration parallel group randomised clinical trial, we evaluated the effect of increasing calcium (Ca) intake on body composition and insulin resistance in patients with type 2 diabetes (T2DM). Thirty-six subjects with low habitual Ca intake (<600 mg d^{-1}), consumed low-Ca diet (CD group, 800 mg d^{-1}) or high-Ca fat-free milk diet (MD group, 1500 mg d^{-1}). MD group final anthropometric measures (body weight, BMI, waist circumference, waist-hip ratio, and fat mass) decreased compared with baseline. MD group showed greater decrease in waist circumference compared with CD group. Final fasting glucose decreased in CD group compared with baseline. Both groups reduced glycated haemoglobin. Consumption of high-Ca diet from dairy for 12 weeks was effective in reducing abdominal adiposity, but provided no additional effect on glycaemic control in overweight patients with T2DM.

1. Introduction

Type 2 diabetes mellitus (T2DM) is a worldwide public health problem, causing high social and economic costs due to its chronic nature and to the severity of its complications (ADA, 2016). Insulin resistance (IR) characterizes this metabolic disorder and there is usually a relative (rather than absolute) insulin deficiency (ADA, 2016). Therefore, the assessment of insulin sensitivity and β-cell function are useful to identify metabolic abnormalities related to T2DM (Ghasemi et al., 2015).

In overweight patients with T2DM, there are evidences supporting the importance of dietary intervention to prevent the occurrence of metabolic abnormalities (ADA, 2016). Although the traditional dietary intervention does not emphasise the role of micronutrients, dietary calcium (Ca) seems to improve weight loss and glycaemic control in T2DM subjects (Abargouei, Janghorbani, Salehi-Marzijarani, & Esmaillzadeh, 2012; Soares, Murhadi, Kurpad, Ping-Delfos, & Piers, 2012). However, daily Ca intake is low (~500 mg d^{-1}) in industrialized countries, due to the increased consumption of processed foods and reduced consumption of dairy (Imamura et al., 2015).

On the other hand, there is no consensus among authors concerning the effects of Ca supplementation with or without vitamin D, on adiposity, glucose homoeostasis and insulin sensitivity (Ferreira, Torres, & Sanjuliani, 2013; Jones et al., 2013; Nikooyeh et al., 2011; Stancliffe, Thorpe, & Zemel, 2011; Torres, Francischetti, Genelhu, & Sanjuliani, 2010). The beneficial effects of increased Ca intake appear to be most significant in low habitual Ca consumers (less than 600 mg d^{-1}) (Zemel et al., 2009), receiving energy-restricted diet (Abargouei et al., 2012; Stonehouse et al., 2016) and Ca bioavailable supplements such as citrate or fat-free dairy products (Freitas, Martino, Ribeiro, & Alfenas, 2012; Soares, Ping-Delfos, & Ghanbari, 2011). Besides, few studies assessed the influence of dietary Ca on glycaemic control in T2DM subjects, and most (Pittas, Lau, Hu, & Dawson-Hughes, 2007; van Dam, Hu, Rosenberg, Krishnan, & Palmer, 2006; Pittas et al., 2006; Villegas et al., 2009), but not all (Nikooyeh et al., 2011; Tabesh, Azadbakht, Faghihimani, Tabesh, & Esmaillzadeh, 2014), were observational. Therefore, considering the potential beneficial effects of adequate Ca intake on glycaemic control and the few data regarding the usefulness of dietary Ca on T2DM treatment, this study evaluated the effect of increased Ca intake from dairy on body composition and IR in overweight T2DM subjects.

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http://dx.doi.org/10.1016/j.idairyj.2017.05.001
0958-6946/

2. Participants and methods

2.1. Ethics aspects

This study was conducted according to the Declaration of Helsinki guidelines and all procedures involving human participants were approved by the Committee of Ethics in Human Research of the Federal University of Viçosa, Brazil. Written informed consent was obtained from all subjects. The present trial was registered at www.clinicaltrials.gov, as "Dietary Calcium Supplementation, Gut Permeability and Microbiota in Type 2 Diabetics" (ID no. NCT02377076).

2.2. Participants

This study enrolled 36 subjects with T2DM (48.7 ± 8.9 years old and body mass index (BMI) of 30.7 ± 4.5 kg m^{-2}), of both genders, presenting low habitual Ca intake (<600 mg d^{-1}). Power calculations (Mera, Thompson, & Prasad, 1998) indicated that seventeen individuals were necessary to detect 1% change in glycated haemoglobin (HbA1c) ($\alpha = 0.05$; power = 80%) presented by our subjects at baseline.

Subjects were recruited through public advertisements in the town of Viçosa, Minas Gerais, Brazil. Recruitment initiated on 2nd February 2014 and ended on 3rd June 2015 when the required number of subjects for the study was obtained. Eligible subjects were adults of both genders with T2DM treated with only diet or with diet plus oral hypoglycaemic agents, that had BMI between 25.1 and 39.9 kg m^{-2}, had low habitual Ca intake (<600 mg d^{-1}), were between 20 and 59 years of age, had a dietary restraint <14 (Strunkard & Messic, 1985), had light to moderate physical activity levels (PAL) (Pardini et al., 2001), and had T2DM for at least one year and no more than 10 years.

Exclusion criteria were: (1) smoking; (2) use of Ca, vitamin D, zinc (Zn) or magnesium (Mg) supplements or medication that affects the metabolism of these micronutrients; (3) use of drugs (except hypoglycaemic drugs), herbs, or diets for weight loss; (4) on hormone replacement therapy; (5) menopause or post menopause; (6) recent weight gain or loss (±5 kg) over the previous three months; (7) recent change in PAL over the previous 3 months; (8) aversion or intolerance to the shakes provided during the study; (9) alcohol consumption of more than 12 g d^{-1} for women and 24 g d^{-1} for men; (10) eating disorders; (11) endocrine (except T2DM and obesity), kidney, or liver pathology; (12) Ca malabsorption; (13) history of recurrent nephrolithiasis; (14) history of gastric surgery or current gastric disease including gastroparesis; (15) consumption of more than 350 mg d^{-1} of caffeine; (16) pregnancy or lactation; (17) anaemia; and (18) changes in medication type or dosage during the study.

2.3. Study design

This was a 12-week duration, parallel group randomized clinical trial. Participants were initially randomly assigned by simple randomization procedures (computerised random numbers) to high-Ca fat-free milk group (MD) (equivalent to ~3 fat-free milk portions) or low-Ca control group (CD) groups in 1:1 ratio. Participants and data analysts were blinded. An energy restricted diet (restriction of 500 kcal d^{-1}) containing 800 mg of dietary Ca d^{-1} was prescribed. Subjects daily consumed in the laboratory a breakfast shake containing 700 mg d^{-1} (MD) (equivalent to approximately 3 servings of fat-free milk) or 6.4 mg d^{-1} (CD) of Ca. All other meals were consumed in free-living condition in both groups. Participants were instructed to maintain constant PAL and medication use during the study.

Food intake, body composition [fat mass (FM) and fat-free mass (FFM)], anthropometric [body weight, waist circumference (WC), waist-hip ratio (WHR)], and biochemical variables [serum glucose, triglycerides (TG), HbA1c, fructosamine, insulin, HOMA-IR, HOMA2-IR, TyG] were evaluated at baseline and after 12 weeks of intervention (Fig. 1).

2.4. Dietary intervention

Each participant's daily energy requirement was based on the Estimated Energy Requirement (EER; Trumbo, Schlicker, Yates, & Poos, 2002). Then, 500 kcal d^{-1} were subtracted for dietary restriction. Diets were prescribed according to the American Diabetes Association nutrition recommendations (ADA, 2016) and considering the nutritional composition of the breakfast shakes provided during the study. MD and CD prescribed diets presented similar contents of macronutrients, vitamin D, P, Mg, Zn, and dietary fibre. MD prescribed diet contained 1500 mg d^{-1} and CD had 800 mg of Ca d^{-1}. Participants were given meal patterns and one list discriminating the types of foods to help them in their food choices. The foods were grouped in that list considering their energy and Ca content. Participants received individualized nutritional counselling every 2 weeks to increase prescribed diet adherence. An experienced dietitian assessed eating patterns and habitual food intake, exercise and medication patterns. Nutrition counselling was provided to stimulate healthy eating habits, including adequate consumption of dietary fibre, water; besides avoiding alcohol consumption, etc., according to ADA recommendations (ADA, 2016). Energy and nutrient requirements were adjusted according to the nutritional requirement of each subject right before the beginning of the second experimental group. In the washout period, participants were told to maintain their normal diet, which was assessed through three non-consecutive days (two weekdays and a weekend day) food records.

2.5. Breakfast shakes

Twelve shake types (six for MD and six for CD experimental group) were developed for consumption at breakfast to add variety to diet. Shake flavours (frozen fruit pulps or chocolate powder) were the same for both groups. They presented similar macronutrient, vitamin D, sodium, and dietary fibre contents, differing mainly in their Ca content (Table 1). Shakes were also visually very similar, ensuring participants remained unaware of group differences and the purpose of the intervention. High-Ca shakes contained fat-free milk powder (Itambé® enriched with iron, vitamins A, C, and D, and Ca) reconstituted in water (250 mL). To ensure similarity to high-Ca shakes, low-Ca shakes contained whey protein (BemVital®, Diacom), sucrose, sodium chloride (Cisne®), and a powder supplement containing iron (iron chelate) and vitamins A (retinol acetate), C (ascorbic acid), and D3 (cholecalciferol). The supplement was prepared by a certified compounding pharmacy. Shakes were prepared mixing all the ingredients in a blender right before ingestion. Breakfast shake flavours were offered in random order, according with study group.

Subjects daily consumed a shake in the laboratory for 12 consecutive weeks. In case any subject eventually could not come to the laboratory, the shake was consumed in their homes/jobs.

2.6. Food intake assessment

Habitual Ca consumption was assessed at baseline using a quantitative food frequency questionnaire (QFFQ) (Ribeiro & Cardoso, 2002). Food intake at baseline and after 12 weeks of each