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Applied nutritional investigation

Safety and efficacy of coffee enriched with inulin and dextrin on satiety and hunger in normal volunteers

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ABSTRACT

Objectives: This study assessed the safety and efficacy of a new beverage on suppressing hunger and improving feelings of satiety in healthy volunteers.
Methods: In the safety study, participants (n = 269) received either 1) a control beverage-coffee alone (group C); 2) the study beverage-coffee, whey protein, inulin, and dextrin (group S); or 3) an inulin-enriched beverage (I group). The study was held over a 7-d period during which participants were required to consume 2 cups of coffee a day.
Results: There were no significant differences between the groups in any reported adverse effects, apart from more abdominal pain after the first cup in group I versus S ($P < 0.05$).
Conclusions: This study showed that a coffee beverage enriched with inulin, dextrin, and whey is safe and has possible benefits with regard to feelings of hunger and satiety 2 h after ingestion.

Introduction

Coffee is a widely consumed beverage and its consumption has been associated with health benefits in epidemiologic studies [1,2]. While it has been suggested that usual amounts of caffeinated coffee consumed may not have short-term effects on appetite and energy intake [3], other studies have shown a positive effect of coffee on satiety and energy balance [4,5]. Proposed putative mechanisms for this effect include a stimulatory effect of coffee on the incretin hormones glucagon-like peptide-1 (GLP-1) and glucose dependent insulinotropic peptide (GIP) [6,7].

Satiety may be related to the ingestion of both solid and liquid food [8]. In this regard, substances which may attenuate a feeling of hunger appearing shortly after consuming a meal and which could be added to coffee have been evaluated. While the sensory and cognitive effect of liquids on endocrine variables may account for the low satiety value of beverages [6], nutrients such as dietary fiber are well known for their high satiety impact [9]. Thus, fiber-enriched meals decrease glucose, insulin, and ghrelin as well as GLP-1 [10]. In addition, slowly digested carbohydrates such as dextrin, as a precursor of short chain fatty acids and GLP1 precursors in L cells, may also decrease the feeling of hunger [11]. Finally, whey protein has been shown to decrease appetite and increase satiety when administered with or without sweetened beverages [12,13]. In comparison with other macronutrients, protein had a greater satiating potential and led to weight loss [14,15]. Therefore, whey protein was added to the beverage mixture.

A new beverage containing coffee, inulin, and dextrin as well as whey protein has recently been developed with the aim of suppressing hunger and improving feelings of satiety. All the components: inulin, dextrin, and whey protein were described as affecting hunger feeling and satiety [7,9,11,12] and were included in a coffee beverage at a ratio of 22.2%, 22.2%, and 33.3% respectively to create a balanced beverage together with coffee (22.2%). The present study was conducted to assess both the safety and efficacy of the beverage as well as possible effects on modulating levels of GLP1, ghrelin, and leptin.

Materials and methods

The study was performed at the Institute for Nutrition Research at the Rabin Medical Center, Petah Tikva, Israel over a 6-mo period from June 2012 to November 2012.

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Participants

Participants for the safety and efficacy studies were recruited from the nursing school of the Rabin Medical Center, Petah Tikva, Israel as well as local health and educational institutions using flyers detailing the aims of the study and requirements of the participants. Requirements for inclusion included an age range between 18 and 70 y; body mass index (BMI) between 19 and 29 kg/m^2; and a history of coffee ingestion of at least 2 cups/d. This BMI was chosen to include volunteers from the general population since, in the country of the study, the adult BMI is estimated to be 26.9 ± 4.8 kg/m^2 [16]. The volunteers filled a questionnaire and were excluded if they reported one or more of the following conditions or diagnosis: intolerance to lactose; history of cardiac arrhythmia; hypersensitivity to milk, gluten, inulin, or other known allergies; significant body weight fluctuations during the past year; smoking; inflammatory bowel disease; pregnancy or lactation; presence of an eating disorder including binge eating and bulimia nervosa, with an eating disorder inventory SCOFF score of <23 and/or a cognitive restraint subscale score of <10 [17]; and ongoing intensive physical training. Participants were recruited for either the safety or efficacy studies. The study was approved by the local Ethics Committee of the Rabin Medical Center, Petah Tikva, Israel and all participants were required to provide both verbal and written consent.

Target beverages

The following three beverages were compared in the study: 1) a control beverage (C), comprising a Brazilian coffee (manufactured by Strauss Coffee Plant, Safed, Israel) containing 2 g of coffee; 2) the study beverage (S), comprising 2 g of coffee (manufactured by Strauss Coffee Plant, Safed, Israel), 2 g of whey protein (K-pro 1070, Ba'Emek, Israel), 2 g of inulin (FibrulinDS2, Cosucra, Belgium), and 3 g of dextrin (Nutriose FM06, Roquette, France); and 3) an inulin-enriched beverage (I), comprising 2 g of coffee, 2 g of whey protein, and 5 g of inulin from the same manufacturers (see appendix).

Procedure

Exposure phase of the safety study

Participants were randomized to one of the three study groups using a computer-generated randomization system. The study was held over a 7-d period during which participants were required to consume 2 cups of coffee a day and to detail the way they prepared the coffee i.e. whether milk, sugar, or sugar substitute, such as Sucrazit (Biskal Ltd, Israel), were added. Participants were then required to complete a questionnaire 3 to 4 h after consuming each cup of coffee regarding the presence of any adverse effects, including abdominal pain, gas, fatigue, nausea, abdominal swelling, and diarrhea. In addition, participants were required to complete a summary questionnaire regarding the taste and any after-taste of the coffee and their satisfaction or dissatisfaction with the texture of the coffee. Finally, participants were requested to describe any other negative aspects of the coffee and suggestions for improvement.

Exposure phase of the efficacy study

A controlled, comparative, randomized, double-blind study was conducted to assess the efficacy of the inulin-protein and inulin-dextrin-protein-enriched coffee on satiety. The efficacy study was conducted over 2 d separated by 1 wk. Following an overnight fast, participants who had not participated in the safety study, were invited to attend a first meeting where they received an explanation regarding study procedures. Thereafter, subjects were provided with a cup containing a coffee bag mixed with 150 cc of hot water and 50 mL 3% milk and sweetener (Sucrazit, Biskal Ltd, Israel), if required, in the regular way of the participants. Participants were then requested to complete a questionnaire assessing satiety and hunger measured by a visual analog scale (VAS) assessed immediately before as well as every 15 min after drinking the beverage, for a period of 3 h. The analog scale consisted of 100 mm horizontal lines ranging from the most negative to the most positive sensation of appetite, hunger level, and satiety [18]. Participants drew a vertical axis on the horizontal line to indicate their hunger and satiety levels. Distances on the VAS were measured from the left border of the line in mm resulting in a score between 0 and 100, This VAS has been validated by Roben et al. [19]. The second phase of the study was conducted 1 wk later. Participants were randomized to three groups, as described above, with 12 participants in each group. Participants were provided with a cup of coffee according to their group (C, S, or I) and satiety and hunger were again measured by the VAS score immediately before as well as every 15 min after drinking the beverage, over a period of 200 min.

Table 1
Demographic characteristics of the safety study participants

	Group I	Group S	Group C
Number	87	93	89
Sex (M:F)	57:30	68:28	63:26
BMI (SD)	23.9 (2.8)	23.4 (2.6)	23.4 (2.6)
Age (y) (SD)	30 (13.0)	27.8 (12.1)	29.0 (12.0)

BMI, body mass index; SD, standard deviation
Group I was receiving coffee enriched with inulin, group S was the study group, and group C the control group. BMI is expressed in kg/m^2. Results are expressed in mean and standard deviation

Table 2
Number of side effects reported by participants during the safety study.

Side effect	Group I n = 87	Group S n = 93	Group C n = 89
Cutaneous eruption	1	1	0
Redness	0	0	1
Breathing difficulties	0	3	3
Serious cough	0	1	5
Nasal discharge	3	4	5
Excessive lacrimation	1	0	1
Hypersalivation	1	7	2
Abdominal discomfort	26	14	17
Abdominal distention	17	12	13
Vomiting	5	1	0
Meteorism	30	29	25
Constipation	6	7	5
Diarrhea	16	17	9

Each volunteer could report one or more side effects from the list. Group I was receiving coffee enriched with inulin, grossup S was the study group, and group C was the control group

Measurements

Ghrelin, leptin, and GLP-1 were determined in blood samples at baseline 08:00 and 2 h after coffee ingestion using ELISA commercial kits (Millipore, Billerica, MA, USA). Blood was drawn at 08:00 and 10:00 into EDTA tubes and immediately centrifuged at 2000 rpm for 15 min. The generated plasma was then used for the assessment of GLP-1 and leptin. For ghrelin quantification, 4-(2-aminoethyl) benzenesulfonyl fluoride hydrochloride (AEBSF) was added to a final concentration of 1 mg/mL to each blood sample drawn into EDTA-tubes. After centrifugation plasma fractions were acidified with HCl to a final concentration of 0.05 N. Intact and des-octanoyl-ghrelin was determined in our conditions, therefore, ghrelin values correspond to total ghrelin plasma level. All plasma samples were stored at –80°C until use. In addition, plasma glucose, urea, and creatinine were taken at baseline.

Statistical analysis

A power analysis was performed and a number of 36 volunteers were proposed to achieve a decrease of 5% for a P value of <0.05. Paired tests and Wilcoxon matched-pairs signed rank tests were used. Significance level of $P < 0.05$ test was accepted. Kruskal-Wallis test and Dunn's multiple comparisons test were used in the efficacy trial comparing the two cup ingestions as well as the side effects. For the 15 min repeated questionnaires, a one-way repeated measures analysis of variance and Tukey's multiple comparison test, (significance level $P < 0.05$) was used.

Results

Safety study

Of the 300 potential participants screened, 15 were excluded by the SCOFF questionnaire so that 285 healthy, non-obese

Table 3
Demographic characteristics of efficacy study participants

	Group I	Group S	Group C
Number	12	11	12
Sex (M:F)	9:3	5:6	3:9
BMI (SD)	24.6 (2.2)	23.2 (2.4)	23.3 (2.6)
Age (y) (SD)	38.2 (14.5)	38.8 (12.1)	37.2 (13.5)

BMI, body mass index; SD, standard deviation
BMI and age are expressed in mean and standard deviation