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Randomized Controlled Trial

Effect of high and low glycemic index breakfast on postprandial metabolic parameters and satiety in subjects with type 2 diabetes mellitus under intensive insulin therapy: Controlled clinical trial

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SUMMARY

Background and aim: The results of studies evaluating the metabolic effects of glycemic index (GI) in subjects with type 2 diabetes mellitus (DM2) have been contradictory. Consequently, the benefits of its application are controversial and polarized opinions of international organizations have been disclosed. The above situation leads this study to evaluate the acute effect of low and high GI breakfast on the glycemic response and satiety in subjects with DM2 under intensive insulin therapy (IIT).

Methods: A controlled, crossover and single-blind clinical trial was developed involving 10 obese subjects with DM2 under IIT, with a period of at least six months under IIT and with fast insulin prescription before breakfast. Subjects ingested on two different occasions a high or low GI breakfast. In both stages, glycemia was evaluated at 0 (basal), 30, 60 and 120 min, and satiety and satiation were evaluated through a visual analogue scale.

Results: In contrast to high GI breakfast, the low GI meal generated a significant decrease of 46% for the area under the curve of glucose (Δ 1940 mg/dL × 120 min, $p = 0.022$) and in mean glycemia evaluated at 30, 60 and 120 min. Moreover, in the low GI stage 8 of 10 patients achieved a 2 h postprandial glycemia lower than 180 mg/dL, without statistical significance. A nonsignificant increase of 12.7% (Δ 1.06 cm, $p = 0.271$) in satiety at 120 min in the low GI stage was observed.

Conclusion: In contrast to high GI breakfast, the low GI breakfast generated a significantly lower glycemic response. This assay allowed for the contribution of more in depth nutritional recommendations for this group of patients.

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1. Introduction

Currently, diabetes mellitus (DM) is considered to be an epidemic of the 21st century due to the high worldwide incidence observed in 2015 (415 million adults). It is noteworthy that the International Diabetes Federation (IDF) projects that 642 million people will have the disease by the year 2040 [1]. Of all of the people affected by diabetes worldwide, approximately 90% corresponds to cases of type 2 diabetes mellitus (DM2) [2], which is characterized by the presence of chronic hyperglycemia produced by metabolic disorders [3].

Nutritional therapy is an essential intervention in patients with DM2 because of its importance in metabolic control and prevention of micro and macrovascular complications. In this context, to promote the intake of foods of low glycemic index (GI) is favorable for the dietary management of these subjects [4] by associating them to a better glycemic control, which results in reducing levels of HbA1c, glycemic response and postprandial insulin [5], in contrast to high GI or conventional diets [4,6].

However, the results of different investigations that evaluate the metabolic effects of food, preparations or low GI diets in healthy subjects with type 1 diabetes mellitus (DM1) and DM2 have been contradictory [7–9]. As a consequence, the benefits of using the GI are resulted in the controversial and polarized opinions of international organizations.

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The absence of sufficient solid evidence to consider the role of GI as a factor of clinical relevance in glucose metabolism, along with the absence of studies revealing its metabolic effects in subjects with DM2 under intensive insulin therapy (IIT), drives this study to determine the acute effects of GI of a preparation on the glycemic response and satiety in subjects with DM2 under IIT.

2. Material and methods

The study involved 10 subjects with DM2 diagnosis, under IIT (age 55 ± 6 years, BMI 34.7 ± 2.4 kg/m^2, nine women and one man), with a period of at least of six months under IIT and with fast insulin prescription before breakfast. Subjects were between 35 and 65 years of age, BMI between 25 at 39.9 kg/m^2 and HbA1c less than or equal to 10% (86 mmol/mol). The following were excluded: pregnant/breastfeeding women, those with neurological disease, untreated endocrine disorder, kidney disease in stage IV or V, cancer, liver disease, chronic obstructive pulmonary disease, human immunodeficiency virus, a history of stroke, acute myocardial infarction or gastrointestinal resection. Subjects were interviewed using a form to collect information on morbidity and surgical history, insulin scheme, food allergies and intolerances, and laboratory tests, among others. Height (m), weight (kg) and BMI (kg/m^2) were also determined according to standard techniques at the beginning of the intervention [10,11]. Subjects who agreed to participate in this study signed a written informed consent. The study was approved by the Bioethics Committee for Research of the Pharmacy Faculty of the Universidad de Valparaíso, Chile.

The subjects participated in a controlled, crossover, single-blind, clinical trial, which required attendance on two separate occasions, with an average difference of seven days, at the stage of high and low IG respectively. That is, the 10 subjects in the sample were controls of themselves.

In both stages, the following requirements were validated in an interview: to continue with a regular diet and, the day before the stage: no physical exercise, no smoking, eating standardized preparations in the last two meal times and to maintain the dose of oral hypoglycemic agents (OHA) during the study. Subjects, upon fasting for 10 h, attended the laboratory Assessment of Nutritional Status of Faculty of Pharmacy, Universidad de Valparaíso, Chile, where immediately after the administration of insulin, they consumed a high GI breakfast (in the first stage) and a low GI breakfast (in second stage).

Capillary glycemia was measured in each subject at 0 (basal) minutes before and 30, 60 and 120 min after the intake of high and low GI breakfast. Additionally, a Visual Analogue Scale (VAS) was applied immediately after breakfast intake (postprandial immediately) and 2 h after intake (tardy postprandial).

2.1. Nutritional recommendations and breakfast composition

The total energy expenditure of each participant was calculated using the formula for a given local population by Carrasco et al. [12], which is adjusted to the weight of each patient, with an application of negative energy balance according to the nutritional status. High and low GI breakfast amount of carbohydrates (CH) were determined from a range of 35–40 g of CH, corresponding to 20% of the daily caloric expenditure. The GI of each breakfast was calculated by adding the GI of each food, resulting from the multiplication of the proportion of total available CH by GI of food [13]. GI values of each food incorporated in the preparation [14] and the amount of dietary fiber of Chilean food chemical composition table [15] were used. High GI breakfast (GI of 80) was made up of half-fat liquid milk, low-fat white bread, jam and an apple, and low GI breakfast (GI of 45) was made up of a diet yoghurt smoothie, an apple and a pear. The nutritional composition of both breakfasts is shown in Table 1. In each patient, isocaloric and isogluicidic breakfasts were prepared in the Laboratory of Food Science at the Pharmacy Faculty, Universidad de Valparaíso, Chile.

2.2. Metabolic parameters and satiety

Capillary glycemia was determined using a glucometer (One-Touch Ultra 2 Johnson & Johnson®) with an intra-assay coefficient of variation of less than 4.4%. The VAS applied was a tool that allowed the participant to give a subjective valuation on variables such as hunger, satiety, plenitude, desire to eat a salty, sweet, tasty or fatty food and some type of liquid, through a numerical scale from 0 to 10 cm [16].

2.3. Statistic analysis

The sample size was determined using the Fernández equation [17] based on the results of postprandial glycemia obtained by Gonçalves and Dullius in a study with subjects with DM2 under treatment with OHA, insulin and mixed treatment [18]. The area under the curve (AUC) for the measurements of glycemia was calculated using the trapezoidal method [19]. Glucose AUC and VAS between the stage of high and low GI were compared in each subjects using the Student t test for related samples or Wilcoxon, as appropriate. The computer program SPSS 20.0 (SPSS Inc., Chicago Illinois®) was used for statistical analysis and statistical significance was considered at $p < 0.05$. The table data are presented as mean ± SD and figures as mean or boxplot, as appropriate.

3. Results

3.1. Glycemia

The basal characteristics of the subjects are shown in Table 2. In contrast to the high GI breakfast intake, lower glucose AUC was observed when the subjects consumed a low GI breakfast, with a significant difference of 46% (Δ 1940 mg/dL × 120 min, $p = 0.022$)

Table 1
Nutritional composition of breakfasts.

Nutrients (n = 10)	High GI	Low GI
Calories	210.6 ± 14.7	196.2 ± 12.8
Carbohydrates (g)	37.5 ± 2.6	37.5 ± 2.6
Fiber (g)	2.2 ± 0.2	4.9 ± 0.5
Proteins (g)	7.5 ± 0.4	6.6 ± 0.4
Lipids (g)	3.2 ± 0.2	3.3 ± 0.2

Values expressed as mean ± SD.

Table 2
Basal characteristics of the study subjects.

Variables (n = 10)	
Age (years)	55 ± 6
Gender (% female)	90
BMI (kg/m^2)	34.7 ± 2.4
Weight (kg)	86.7 ± 9.1
HbA1c	
%	8.9 ± 0.8
mmol/mol	74
Basal glycemia (mg/dL)	158.5 ± 53.1
Oral hypoglycemic agents (%)	70
IIT duration (years)	5 ± 4.4

Values expressed as mean ± SD, except as indicated. IIT: intensive insulin therapy.

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