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Research Article

Determination of the Glycemic Index of a Diabetes Truffle

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Abstract

The purpose of this study was to determine the Glycemic Index (GI) of a chocolate truffle created specifically for people with diabetes. The study design was an open-label, randomized crossover study. Study participants were required to ingest 25 grams of truffle carbohydrate (test meal) or 25 grams of carbohydrate solution (reference meal); the sequence was determined by randomization. Blood samples were obtained from the non-dominate ring finger just prior to ingestion of the test or reference meal, after an overnight fast, and were repeated at 15, 30, 45, 60, 90 and 120 minutes after beginning ingestion of the meal. Glycemic index was calculated using the method of incremental areas under the blood glucose response curve (incremental AUC). Twelve healthy volunteers were recruited and completed the study; average age was 29 (range 21-63), 50% were women, and 83% of the study population were Caucasian. The mean blood glucose incremental area under the curve for the reference meal was 3092.7 mins. mg/dL compared to 178.6 mins. mg/dL for the test meal. The GI of the diabetes truffle is 6, indicating that it is a low GI (<55) food.

Keywords: Glycemic index, Diabetes mellitus, Truffle

Introduction

The concept of Glycemic Index (GI) was developed in an attempt to quantify the variation in rates of absorption of Carbohydrates (CHO) into the blood stream and their subsequent effect on postprandial blood glucose responses. Thus, GI is the classification of carbohydrates based on their ability to raise blood glucose levels [1]. The GI concept was originally introduced as a means of classifying different sources of CHO and CHO-rich foods in the diet, according to their rates of absorption and their subsequent effects on postprandial blood glucose levels. Foods with a high GI produce a higher overall increase in postprandial blood glucose levels, including a greater blood glucose rise during the first 2 hours after consumption than do foods with a low GI.

Low-GI CHOs are classified as CHOs that are digested and absorbed slowly and lead to a low glycemic response. Such foods have a glycemic index of 55 or below. High-GI CHOs are rapidly digested and absorbed and show a high glycemic response; such foods have a glycemic index of 70 and higher. Foods with an intermediate glycemic index score of 56-69 (medium glycemic index) have a modest effect on change in blood sugar levels.

Raw Amour organic chocolate truffles are 100% organic, 97% raw, vegan, low calorie (44-51 calories per truffle), and are free of refined sugar, dairy, gluten, soy lecithin, genetically modified organisms, artificial sweeteners, flavor extracts, food coloring, and preservatives [2]. Three years ago a new chocolate truffle created specifically for the diabetes community became available. Compared to the original chocolate truffle, this "diabetes" truffle replaces agave nectar in the truffle shell with an organic erythrotol, and organic cashew butter has been substituted for most of the agave in the truffle center. While these ingredients have glycemic indexes of close to zero, the glycemic index of this truffle (and its effect on blood sugar levels) has not been determined. The purpose of this study was to determine the GI of a chocolate truffle created specifically for people with diabetes.

Subjects and Methods

This study was approved by the Albany College of Pharmacy and Health Sciences Institutional Review Board (IRB) and written informed consent was obtained prior to each person's participation in the study. All procedures followed were in accordance with the Helsinki Declaration of 1975 as revised in 1983. Study participants from the College

*Corresponding author: : Dr. Michael P. Kane, Department of Pharmacy Practice, School of Pharmacy and Pharmaceutical Sciences, Albany College of Pharmacy and Health Sciences, Clinical Pharmacy Specialist, Albany Medical Center Division of Community Endocrinology, 106 New Scotland Avenue, Albany, NY 12208, USA, Tel: 518-694-7239, Fax: 518-694-7382, Email: michael.kane@acphs.edu community were recruited via an IRB-approved study flyer placed on bulletin boards at the college Student Center. Study inclusion criteria included: age 18 years or greater, healthy (non-diabetic) adult, willingness to fast for 10 hours prior to each of three study visits, and willingness to undergo seven finger sticks over a two-hour period, on three separate occasions over 15 days. Exclusion criteria were age under 18 years, diagnosis of diabetes or pre-diabetes and known allergy to chocolate or to organic cashew butter.

Subjects were asked not to smoke or consume alcohol, or to undertake any vigorous activity for 24 hours prior to each study visit. Each patient fasted beginning at 22:00 hours the night before the scheduled visit (although water was allowed in moderation), and each study day started at 08:00 hours (\pm 20 minutes). A baseline finger-stick blood glucose measurement was performed immediately prior to study item administration.

The study design was an open-label, randomized crossover study. Study participants were required to ingest 25 grams of truffle carbohydrate (test meal) once or 25 grams of carbohydrate solution (reference meal) twice over the course of the study. The sequence of administration was determined by randomization. Since 25 grams of truffle carbohydrate equated to 71 grams of truffle (approximately 7.1 truffles), 73 grams of truffle mix were placed into unit-dose serving cups to allow an accurate test meal measurement. The only difference from this truffle mix and the commercial product is that the commercial product is poured into molds and refrigerated. The reference meal consisted of 45 ml of a 180 ml 100 gram oral glucose tolerance test (Glutol, Perrigo, Minneapolis, MN; lot #5110811) diluted with 105 ml of bottled water. Test and reference meals were ingested within 5 minutes. Blood samples were obtained from the non-dominate ring finger just prior to ingestion of the test or reference meal and were repeated at 15, 30, 45, 60, 90 and 120 minutes after beginning ingestion of the meal. The meter was calibrated prior to each day of use using a single control solution (One-Touch Verio Level 3 control solution, lot #5Z3P66). Each finger-stick blood sample was obtained using a single-use capillary blood sampling device (Unistik 2, Owen-Mumford, Oxford, England). The same investigator (MPK) performed all blood glucose measurements,

using a single One-Touch Verio blood glucose monitoring meter (LifeScan, Inc.; Zug, Switzerland) according to the manufacturer's instructions. Glucose test strips with the identical lot number (LifeScan, Inc.; Zug, Switzerland #3937609) were used for the study. Ingestion of up to 240 cc of bottled water was allowed during each two-hour sampling period. The methodology employed in carrying out this study follows the methodology recommendations by *Brouns et al.* [3].

Glycemic index in this study was calculated using the method of incremental areas under the blood glucose response curve (incremental AUC) as recommended by *Brouns et al.* [3]. This approach uses the mean of the ratios method (f:r) where f is an individual subject's incremental AUC after consuming the test meal (truffle pudding) and r is the incremental AUC for the same subject after consuming the reference meal (glucose solution). The individual values of f:r were averaged over all subjects to calculate the GI for the test food.

Results

Twelve healthy volunteers from the College community were recruited for this study. The average age was 29 (range 21-63), 50% were women, and 83% of the study population were Caucasian. With the exception of one study participant at week 2, all test and reference meals were ingested within 5 minutes. In the one case, participant #11 was withdrawn from further study that day, but was allowed to return 5 days later to complete week 2 testing (truffle test meal) and 7 days later to complete week 3 testing (glucose reference meal).

The mean blood glucose incremental area under the curve for the reference meal was 3092.7 mins.mg/dL compared to 178.6 mins.mg/dL for the test meal (Figure 1). The GI of the diabetes truffle is 6; foods with a glycemic index of less than 55 are considered to be low glycemic.

The mean blood glucose responses to the test and reference meals are shown in Figure 2. The average peak rise in glucose level after truffle administration was $5 \pm 5 \text{ mg/dL}$ (range 0-16 mg/dL) compared to an average glucose increase of $67 \pm 20 \text{ mg/}$





dL (range 35-103 mg/dL) in the glucose group. Whereas almost 80% of the glucose test group achieved peak glucose within 30 (20.8%) or 45 minutes (58.3%) after test administration, there was no typical time to peak glucose concentration in the truffle group. In this group, only 16.7% of the truffle group achieved peak glucose levels between 30-45 minutes with peak glucose levels generally occurring at time 60, 90, or 120 minutes.

Discussion

The GI is widely recognized as a reliable, physiologically based classification of foods according to their effects on postprandial blood sugars [1]. This study reports the GI of a chocolate truffle created specifically for people with diabetes. This information is of importance to people with diabetes as most sweets significantly raised blood sugars. This truffle was found to have a glycemic index of 6, and is therefore classified as a low glycemic index food (0-55).

Methodology for glycemic index studies typically recommends the use of 50 grams of CHO for the test and reference meals. In the case of foods with low to moderate CHO density, however, it is considered reasonable to lower the CHO load to 25 grams to avoid an unrealistically large meal size [3]. In addition to the 25 grams of CHO, each truffle pudding serving contains 5.8 grams of protein and 37.2 grams of fat. Interestingly, while it took the equivalent of just more than seven diabetes truffles to achieve a CHO load of 25 grams for the purpose of this study, the recommended diabetes truffle serving size is two truffles.

There was an average 5 mg/dL peak increase in blood sugar levels in healthy (non-diabetes) volunteers after ingestion of the test meal, which was more than 3.5 times the recommended diabetes truffle serving size. In contrast, there was an average increase in peak blood sugar of 67 mg/dL in patients after ingestion of the reference meal. The low glycemic effect of the diabetes truffle could be due to its relatively high lipid content, as fat slows the absorption of glucose into the blood stream. While this truffle was not tested in a diabetes population, it is expected that its ingestion would have a very modest effect on blood sugars in diabetes patients because of the truffle's very low GI, as well as the much lower expected quantity of ingestion. There are several study limitations associated with this study. First, study participants were not required to ingest the same meal the evening before each study day. Second, patients were on the honor system for fasting, as they were ambulatory study patients and there was no way to verify an overnight fast. Similarly, the honor system was also employed regarding the request of no vigorous exercise and no alcohol or smoking for 24 hours before each study appointment. However, study participants did serve as their own control, treatments were randomized, and perhaps the study participants were vested in this study as all were students, staff or faculty from the institution where the study was performed.

The results of this study demonstrate that the Raw Amour diabetes truffle is a low glycemic index food, and may therefore represent an attractive dessert option for patients with diabetes.

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Authors' Contribution: MPK and RAH designed the research study; MPK conducted the research; RAH performed the statistical analysis; MPK and RAH wrote the manuscript; MPK and RAH had primary responsibility for final content. Both authors read and approved the final manuscript.

Conflict of Interest

Study supplies were funded by a grant from Raw Amour, and truffle mix was provided by Raw Amour, manufacturer of the diabetes truffle.

Raw Amour was not involved with study design, patient recruitment, data analysis, or manuscript preparation.

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