

Determination of the Glycemic Index for UltraGlycemX™ Medical Food

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ABSTRACT

The rate of carbohydrate digestion and absorption is an important factor in postprandial glycemic response. The Glycemic Index (GI) allows the classification of carbohydrate foods according to their glycemic response; the higher the glycemic index of a food, the higher its potential for raising blood sugar. The GI of a food is therefore an important tool to provide dietary guidance to individuals with blood sugar dysregulation. The glycemic index is determined experimentally by measuring the glycemic response of an individual food as compared to the response elicited by an equivalent amount of a carbohydrate standard (reference food). The objective of this study was to determine the glycemic index of UltraGlycemX™, a newly developed medical food designed for the nutritional support of patients with insulin resistance and dysglycemia. UltraGlycemX contains specific carbohydrates, fibers and proteins that are likely to result in a lower GI. The method developed by Wolever and Jenkins, using white bread as a reference food, was selected to determine the glycemic index of UltraGlycemX. A GI of 52, averaged from 4 volunteers, classifies this medical food in the desirable low GI range, and supports the use of this product for nutritional support in individuals with insulin resistance and dysglycemia.

INTRODUCTION

Glycemic control is the central focus in glucose and insulin management. Because carbohydrates have the greatest effect on the glycemic response to a meal, the carbohydrate content of food has long been the core of glycemic control. "Diabetic exchange lists," which classify foods based on their total carbohydrate content, are generated and published in the U.S. in order to help diabetic patients calculate the carbohydrate content of their diets.¹ In these exchange lists, starchy foods are grouped together, and equivalent gram amounts are considered to be interchangeable. Truswell describes the criteria for diabetic exchange lists as "available carbohydrates

[that] are assumed to be all digested and absorbed at the same rate, and to have the same effect on postprandial blood glucose, except for sugar, or sucrose, which is absorbed more rapidly."²

The concept of glycemic index (GI) developed as the result of intensive carbohydrate research which showed that similar amounts of carbohydrate in foods did not elicit similar postprandial glycemic responses.^{3,4} The GI is a value assigned to single foods based on their postprandial glycemic response, where glycemic response is defined as the rise in blood glucose after the ingestion of a standardized carbohydrate test food. GI is thus an important concept in differentiating carbohydrate sources and their effects on blood glucose levels, and a well-validated, well-accepted tool worldwide. GI tables have been developed which rank carbohydrate foods according to their GI values: the higher the GI, the higher the food's potential for raising blood sugar.

In 1996, Bidlack reported that out of the 11 million individuals in the U.S. with diabetes mellitus, 90 percent are NIDDM or Type II diabetics.⁵ Additionally, it is estimated that nearly 25 percent of the non-diabetic adult population may be insulin resistant with normal blood sugar control.⁶ This condition appears to be an underlying risk factor for the development of hypertension, cardiovascular disease and Type II diabetes. Insulin resistance is the result, in part, of a higher carbohydrate, higher GI food consumption pattern. Clearly, low GI foods are desirable as part of a meal plan for individuals who have insulin and blood glucose dysregulation.

The method developed by Wolever and Jenkins to determine GI is the most widely accepted method today.⁷ Initially, GIs were calculated using glucose as the standard, but subsequent studies indicated that the use of white bread as the reference food provided more reliable results.^{8,9,10} This is due in part to the observation that white bread stimulates more insulin secretion than glucose. It has also been suggested

that glucose's sweetness and its high osmolarity causes delayed gastric emptying, making it a poorer choice as a reference food.

The "International Tables of Glycemic Index" have been compiled using the GIs obtained from results of separate studies reported by many research groups.¹¹ The values are based on the consumption of 50 grams of the food, with either white bread or glucose used as

the reference foods. In some cases, more than one value is reported for the same food. Factors that may explain the differing results for glycemic responses in some foods include starch accessibility (i.e., the use of resistant starch or high amylose starch), food form, fiber content, type of fiber, and the amount of protein in the meal. Table 1 lists some of the entries found in the above mentioned tables, along with their respective references.

Table 1. Glycemic Index (GI) of Commonly Eaten Foods

Food (50 grams)	GI against white bread standard	GI against glucose standard
rye bread	90 ¹¹	60 ¹¹
white bread	100 ¹²	69 ¹³
whole wheat bread	99 ¹³	72 ¹⁴
white rice	81 ¹⁴	72 ¹⁴
brown rice	81 ¹⁵	76 ¹⁵
high amylose	66 ¹⁶	66 ¹⁴
potato (new), boiled	80 ^{17, 15}	70 ¹⁴
(russet), baked	128 ¹⁷ 80 ¹⁴	56 ¹⁴
sweet potato	70 ^{15, 17}	48 ¹⁴
milk (skim)	46 ¹⁷	32 ¹⁴
corn flakes	109 ¹³	80 ¹⁴
sweet corn	80 ^{15, 17}	59 ¹⁴
soybeans	25 ¹¹	18 ¹⁷
soymilk	N/A	31 ¹⁸
green peas, frozen	65 ¹⁷	51 ¹⁴
kidney beans	43 ^{15, 18, 13}	29 ¹⁴
lentils	38 ¹⁵	29 ¹⁴
pearl barley	36 ¹⁵	25 ¹¹
spaghetti, boiled 5 min	45 ¹⁷	50 ¹⁴
boiled 15 min	61 ¹⁷	-
apple	53 ¹⁷	39 ¹⁴
banana	84 ^{19, 17}	62 ¹⁴
underripe	59 ¹⁵ 43 ¹¹	30 ¹¹
orange	59 ^{17, 20, 15}	40 ¹⁴
orange juice	67 ¹⁷	46 ¹⁴
fructose	31 ¹⁷	20 ¹⁴
glucose	138 ¹⁷	100 ¹⁴
sucrose	89 ¹⁷	59 ¹⁴

The aim of the present study was to determine the GI of the newly developed medical food UltraGlycemX™, a product designed for the nutritional support of patients with insulin resistance and hyperinsulinemia.

METHODS

Subjects

Volunteers for this study were five apparently healthy subjects – 2 females and 3 males between the ages of 42 and 59 – with no known history of dysglycemia. Subjects were advised to make no changes in their current supplements, medications, diet or physical activity. Informed consents were signed prior to the start of the study.

Test foods

Medical Food: UltraGlycemX™ is a soy protein based product with the following composition: vanadium, magnesium, biotin and vitamin E to support improved insulin responsiveness; chromium and alpha-lipoic acid to support improved insulin-stimulated glucose disposal and tolerance; vitamins A, E, beta-carotene, and the minerals zinc, selenium, copper and manganese to nutritionally modulate the oxidative stress associated with insulin resistance; soluble fiber, including guar gum and locust bean gums, for delayed gastric emptying; a proprietary carbohydrate blend of high amylose corn maltodextrins (AmyloSTAR™) to improve insulin and glucose response; fructose as sweetener because of its low glycemic potential. This information is referenced in the UltraGlycemX Monograph, HealthComm International, Inc., 1999. The complete nutrient profile of this product is shown in Table 2.

TABLE 2. NUTRIENT PROFILE OF UltraGlycemX™

Nutritional Information	Amount 2 Scoops (1 Serving)	% U.S. RDI		
Servings per container	14		Minerals and Trace Elements	
Serving size	50 g		Sodium	170 mg
Calories	150		Potassium	580 mg
Protein	15 g		Calcium (phosphate)	500 mg 50%
Carbohydrate	23 g		Phosphorous	400 mg 40%
Complex	20 g		Magnesium (citrate)	200 mg 50%
Simple	3 g		Zinc (picolinate)	15 mg 100%
Fat	2 g		Copper (lysinate)	1.5 mg 75%
Cholesterol	0		Manganese (Manganese Chelazome®)	1 mg 50%
Fiber	7 g		Molybdenum (amino acid chelate)	38 mcg 50%
Vitamins			Chromium (polynicotinate)	500 mcg 420%
Vitamin A (retinyl palmitate)	2500 IU	50%	Selenium (selenomethionine)	150 mcg 210%
Beta-carotene (mixed carotenoids)	2500 IU	50%	Vanadium (vanadyl sulfate)	2.5 mg **
Vitamin D	100 IU	25%	Accessory Nutrients	
Vitamin C (UltraPotent C®)	250 mg	420%	Inositol	100 mg **
Vitamin E (mixed tocopherols)	200 IU	670%	Alpha-lipoic Acid	200 mg **
Vitamin B1 (thiamin hydrochloride)	1 mg	70%		
Vitamin B2 (riboflavin)	1 mg	60%		
Vitamin B3 (niacin 10 mg, niacinamide 10 mg, niacinamide ascorbate 19 mg)	39 mg	200%		
Pantothenic acid (calcium pantothenate)	5 mg	50%		
Vitamin B6 (pyridoxine HCl)	1 mg	50%		
Vitamin B12 (cyanocobalamin)	3 mcg	50%		
Biotin	5 mg	1670%		
Folic acid	200 mcg	50%		

Reference Food: Wonder® Bread, a commercial white bread, was used as the reference food (100% GI). The amount of white bread consumed in each determination was calculated from the ingredients listed in the manufacturer's label: 1 slice contains: 12 g carbohydrate, 1 g fat, 2 g protein, 0 g fiber.

Study Design

The Wolever and Jenkins method was used to determine the GI.²⁰ This method consists of feeding subjects 50 grams of available carbohydrate in white bread after a 10-hour overnight fast; finger stick blood glucose is measured by glycometer at 0, 15, 30, 45, 60, 90 and 120 minutes after ingestion. If baseline values are not achieved at 120 minutes, determinations continue to 150 and 180 minutes, as needed. The procedure is done on three separate occasions, at least two days apart, in order to standardize the response. The same procedure is then repeated with 50 grams of available carbohydrate of the test food.

Glycemic-response curves are calculated for the bread and the test food in each instance. The area under the glycemic-response curve (AUC) for each food is expressed as a percent of the mean response to the standard food taken by the same subject, and the resulting values are averaged to obtain the GI value for the food. The area beneath the blood glucose response that is still above the baseline level in a fasting state is used as the AUC; no number below baseline should be taken into consideration. The following formula is used to calculate the GI:

$$\frac{\text{glycemic response of a 50 g portion food}}{\text{glycemic response of a 50 g portion white bread}} \times 100 \quad \text{eq.1}$$

In the present study, using 50 grams of available carbohydrate in the test food would calculate out to be greater than three full servings (16 grams of available carbohydrate per standard serving of UltraGlycemX). This would be a large and unlikely serving size, consisting of 45 grams protein, 21 grams fiber, and 450 total calories. Considering that Wolever has reported data testing several vegetables using 25 g portions,²¹ and that his group has recently completed studies using 30 g carbohydrate portions of foods,²² we chose to use a dose of 32 grams available carbohydrate (2 servings of UltraGlycemX). The same amount of carbohydrate in white bread corresponded to 2.75 slices.

Clinical Assessment

Capillary blood glucose levels were determined using blood obtained from a finger prick at the times stated in the procedures outlined above. Blood glucose values were determined using a commercially available glucometer (Accu-Chek Advantage Blood Glucose Monitor, Boehringer Mannheim Diagnostics) and glucose analyzer strips (Accu-Chek Comfort Curve, Boehringer Mannheim). Subjects participated in 3 separate determinations each of white bread and the test food spaced no closer than two days apart. Subjects were continuously monitored for unusual symptoms during the course of the GI determinations.

Data Analysis

Blood glucose values were obtained in mg/dL and were converted to mmole/L using 180.16 mg/mole as the molecular weight of glucose. The calculation of GI index was performed by trapezoidal integration, using the incremental AUC method.²³ After calculation of the AUC, equation 1 was used to obtain the GI value.

RESULTS

Four of the five subjects completed the trial. The subject who did not complete the trial was intolerant to the dose of test food (double the recommended amount contained in one serving). She reported symptoms of nausea following ingestion and chose to discontinue participation. No adverse events were reported by any subject.

The GI of UltraGlycemX™ was calculated for the 4 subjects who completed the trial. As shown in table 3, the average GI for UltraGlycemX in the four subjects was 52.

TABLE 3. GLYCEMIC INDEX (GI) FOR 4 SUBJECTS USING 2.75 SLICES WHITE BREAD (32 GRAMS CARBOHYDRATE), AND 4 SCOOPS OF ULTRAGLYCEMTM (32 GRAMS CARBOHYDRATE)

subject	White Bread (mg min/dL)		UltraGlycemX (mg min/dL)		Glycemic Index
	N	mean(sd)	N	mean(sd)	mean(sd)
1	3	3,634.8 (685.6)	3	1,447.8 (664.5)	40 (20)*
2	3	1,924.4 (456.9)	3	1,486.3 (700.6)	77 (41)*
3	3	2,241.9 (835.6)	4	1,291.9 (341.8)	58 (27)*
4	3	1,597.2 (366.3)	3	505.3 (192.8)	32 (14)*
				Average	52 (25)

N= number of determinations

*sd - Since the values for white bread and UltraGlycemX are independent estimates of one component of the GI, the Standard Deviations (sd) needed to be estimated.

Of the several ways to do this bootstrapping, determining GI for every possible combination of measurements or reliance on an equation was chosen. The formula used was: $CV_{xy} = [CV_x^2 + CV_y^2]^{1/2}$.

DISCUSSION

The average GI obtained for the medical food was 52 when referenced against white bread. Because white bread has a GI of 70 when measured against glucose, the bread-referenced GI of UltraGlycemTM is calculated as 36 when referenced to glucose. This value is well within the “desirable low range” of 0 to 55, as defined for glucose-referenced foods by Brand-Miller et al, and thus would be considered a low GI food.²⁴ The inter-individual variability observed in the study is to be expected, emphasizing the fact that individual variation should be taken into account when designing a healthy meal plan for individuals with insulin resistance and hyperlipidemia.

The low GI of this medical food may be related to a variety of factors. Soluble fibers in the product such as guar and locust bean gum have been shown to delay absorption by retarding gastric emptying.²⁵ Studies demonstrated that the use of guar gum in particular resulted in a blunting of the glycemic response to the next meal, also known as the “second meal effect.”²⁶ High amylose content carbohydrates have been shown to have a positive effect on glycemic response as well.²⁷ The proprietary high-amylose resistant starch blend in UltraGlycemX supplies 13 grams of carbohydrate per serving. Behall et al showed that

subjects consuming high amylose crackers had a lower glycemic response after 30 minutes as compared to amylopectin.²⁸ The sweetener used in the product is fructose. Fructose appears to be absorbed more slowly than glucose, producing a smaller rise in blood sugar than either sucrose or glucose. Since it is a non-insulin-mediated uptake, it has little stimulatory effect on insulin.^{29,30} Although there is no data reported to date regarding the GI of pure soy protein, soy products such as soy beans and soy milk are known to have low GIs as well (Table 1).

UltraGlycemX was formulated to provide available carbohydrate and protein calories in a low GI form. Additionally, it is fortified with a micronutrient core to improve cellular sensitivity to insulin. Taken together, the product qualifies as a low GI food and may serve as useful nutritional support for individuals with insulin resistance and dysglycemia.

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