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Determination of Glycemic Index and Glycemic Load of Pronocte Protein Powder in Healthy Human Adult Subjects, Under Fasting Conditions

Research Article

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Abstract

Study background: Malnutrition, particularly micronutrient deficits, is common among cirrhotic patients, necessitating interventions to preserve muscle mass. Late-evening snacks with specific nutritional content are crucial for this population. The pronocte protein powder was developed with nutritional value.

Objective: To investigate the glycemic index and glycemic load of pronocte protein powder in healthy human adult participants during fasting conditions.

Methods: This was a single-center study, 13 healthy human adult subjects participated, and the data is available for 10 subjects. The study was conducted as per the recommendations of WHO.

Results: The peak capillary blood glucose was 108.2±12.9 mg/dL at 45 min in the test group (Pronocte protein powder) and 151.7±23.6 mg/dL at 45 min in the reference group (Glucon-D). The mean blood glucose incremental area under the curve for the test group was 1056.1 mg.min/dL and for the reference group 3932.3 mg.min/dL.

Conclusion: The glycemic index of pronocte protein powder was 26.9% which is low as per GI classification. The glycemic load is 2.22 per typical serving of 30gm which is low as per the classification of glycemic load. Pronocte protein powder can serve as a late-night snack. This will prevent the catabolic phase in cirrhosis patients..

Keywords: Malnutrition; Pronocte Protein Powder; Glucon-D; Glycemic Index; Glycemic Load; Cirrhosis

Introduction

Malnutrition or alterations in certain aspects of nutritional status, such as micronutrient deficits driven by various mechanisms, including poor nutritional intake and absorption or increased losses are commonly seen in patients with various conditions. Muscle atrophy and sarcopenia are among the most serious concerns in cirrhosis patients. Patients with cirrhosis frequently enter a catabolic phase overnight due to a lack of glycogen stores in the liver. Cirrhotic patients must preserve muscular mass [1].

One strategy to accomplish this is to eat a late-night snack that can aid in avoiding the formation of a catabolic phase with muscle loss.[1] Overnight fasting of cirrhotic patients has a similar effect to 3 days of fasting in a normal individual [2].

Nocturnal supplementation is recommended by both the American Society for Parenteral and Enteral Nutrition and the European Society for Clinical Nutrition and Metabolism guidelines to avoid increased utilization of lean body stores to meet energy needs in fasted patients suffering from liver cirrhosis. Late-evening / night snacks having various nutritional content (rich in branched-chain amino acids (BCAA) and/or carbohydrates) have been demonstrated to ameliorate the extent to which fat and nitrogen are

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utilized in the fasted state in patients with liver cirrhosis and improve overall nitrogen balance and living standard [3].

The administration of a carbohydrate-based nutritional course that is gradually digested and absorbed could potentially compensate for deterioration in liver function, thereby supporting higher utilization of this substrate for energy needs in the fasting state. Foods with low glycemic index are typically absorbed more slowly overnight, which may result in increased carbohydrate utilization and reduced fat and protein mobilization from the adipocyte and lean tissue [3].

The glycemic index is a scale that helps rank carbohydrate-containing foods, depending on how they affect the blood glucose levels in 2-3 hours after having food/food product as compared to pure glucose, which is assigned a glycemic index value of 100 [4]. Glycemic load is a more effective predictor of whether the meal consumed in a typical (recommended) serving is healthy or not.[5]

Pronocte protein powder was developed by Azista Industries Pvt Ltd. an associate of Hetero Healthcare Ltd as a late evening/night snack to prevent the development of catabolic phase with muscle loss mostly in people with hepatic cirrhosis.

Nutritional science revolves around the concept of food as medicine. Natural products are becoming more vital for treating medical issues. The idea of food as medicine inspired the innovation of pronocte protein powder. The current study was conducted to determine the glycemic index and glycaemic load of pronocte protein powder in healthy human adult volunteers under fasting conditions, which would be utilized as a late evening/night snack by cirrhosis patients.

Materials and Methods

Subjects fulfilling the inclusion and exclusion criteria and willing to participate in the clinical study were included in the study after obtaining their written informed consent. This study was approved by the Institutional Ethics Committee, Ramdev Rao Hospital, Hyderabad. This trial was registered at Clinical Trail Registry-India (CTRI Number- CTRI/2022/02/040477) before initiating the study. At baseline, the demographic data (age, gender, height, weight, BMI), and vitals were recorded along with clinical examination.

After an overnight fast of 8-10 hours, on the day of the study [6], during period 1, subjects received either pronocte protein powder or glucon D as per randomization. After the washout phase of 2-3 days, during period 2, those subjects who consumed pronocte protein powder during period 1 received and consumed glucon D and vice versa. (i.e., the subjects were crossed over during the period 2). At the end of period 2, all the subjects received both study products.

Each subject received and consumed 182 grams of pronocte protein powder (equivalent to 50 grams of glucose) or 50 grams of glucon D with 240 ml of water during each study period (Period 1 and Period 2) as per randomization. The study products were consumed within the time frame of 10-12 min. The subjects were restricted from performing any physical activity during the 2 hours of the study period.

Baseline fasting capillary blood glucose levels were recorded using a glucometer (Freestyle optium). Capillary blood samples were for determining blood glucose using a glucometer at 7-time points i.e. at fasting state 30 mins before consumption of study product (considered as 0 min), 15 min, 30 min, 45 min, 60 min, 90 min, and 120 minutes after completion of study product consumption [7].

The compliance was recorded by the study nurse after the complete consumption of the study product (Pronocte protein powder / Glucon-D). Vital parameters were recorded along with any undesirable effects developed, during the entire study period. Standard summary statistics (arithmetic mean and standard deviation) were calculated for demographics and vital parameters.

Blood glucose curves were constructed from capillary blood glucose values for each subject at time 0, 15, 30, 45, 60, 90, and 120-minute intervals after consumption of the test product (Pronocte protein powder) or reference product (Glucon D). The incremental area under the curve (IAUC) was calculated by the trapezoidal rule in every subject separately [8], as the sum of the surface of trapezoids between the blood glucose curve and horizontal baseline going parallel to X axis from the beginning of blood glucose curve at time 0 to the point at 120 min to reflect the total rise in blood glucose concentration after consuming the reference food (Glucon D) and test food (Pronocte protein powder). The mean IAUC for all 10 subjects for reference product (Glucon D) and test product (Pronocte protein powder) were calculated.

The Individual glycemic index (GI) was calculated as

$$= \frac{\text{IAUC for the test food}}{\text{x̄ IAUC for the reference food}} X\,100$$

The calculation of glycemic load (GL) i.e., the impact that the carbohydrate-containing food has on blood sugar. GL = GI (%) x grams of carbohydrate in the typical serving of food eaten. GL would be the sum of the GL of each food that is part of the food.

$$\text{Glycemic Load(GL)} = \frac{\text{Net carbohydrates in a typical serving x GI}}{100}$$

Safety variables were recorded during the entire study period.

Results

Out of 13 subjects enrolled, 3 were outliers and were eliminated from the analysis. Demographic data is available for 10 subjects. Out of 10 subjects, 4 were males and 6 were females, the mean age was 34.4 ± 8.3yrs, and the mean height, weight, and BMI was 162.2 ± 7.1cms, 64.3 ± 7.3 Kgs and 24.3 ± 1.1 respectively.

Table 1: Demographic data (n=10)

Parameters	Value	
Number of Subjects (n)	10	
Sex (M: F)	Male	4
	Female	6
Age (Yrs)	Min	22
	Max	45
	Mean ± SD	34.4 ± 8.3
Height (cms)	Min	150
	Max	171
	Mean ± SD	162.2 ± 7.1
Weight (Kg)	Min	53.6
	Max	78.6
	Mean ± SD	64.3 ± 7.3
BMI	Min	22.8
	Max	26.9
	Mean ± SD	24.3 ± 1.1

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Table 2: Capillary blood glucose levels (mg/dL) (n=10)

S No	Test food (Pronocte) arm							Reference food (Glucon D) arm						
	Time Points (min)							Time Points (min)						
	0	15	30	45	60	90	120	0	15	30	45	60	90	120
1	87	100	106	112	100	97	97	88	127	151	132	144	124	102
2	100	119	98	104	113	113	105	106	144	161	161	129	109	90
3	98	102	110	123	117	113	108	96	156	186	197	163	150	100
4	80	83	90	90	101	98	90	85	119	150	166	157	138	97
5	96	99	96	102	88	101	92	91	113	124	145	134	117	96
6	102	109	104	95	100	117	110	98	131	171	166	175	104	84
7	101	121	114	111	104	109	104	106	135	143	142	130	120	96
8	95	108	102	96	101	100	93	108	117	116	129	135	108	101
9	101	113	119	121	117	106	108	89	139	154	163	150	127	79
10	98	101	115	128	106	99	90	93	108	111	116	107	111	115
Mean	95.8	105.5	105.4	108.2	104.7	105.3	99.7	96.0	128.9	146.7	151.7	142.4	120.8	96.0
±SD	±7.1	±11.1	±9.2	±12.9	±9.0	±7.3	±8.1	±8.3	±15.1	±24.0	±23.6	±19.6	±14.5	±10.0

The capillary blood glucose response from 0 min to 120 min with the test product (Pronocte protein powder) and reference product (Glucon-D). The mean fasting capillary blood glucose was 95.8 ± 7.1 mg/dL in the test group and 96.0 ±8.3mg/dL in the reference group at baseline (0 min). The peak capillary blood glucose of 108.2±12.9 mg/dL was at 45 min in the test group and 151.7±23.6 mg/dL at 45 min in the reference group.

The mean capillary blood glucose response with test and reference products (mg/dL) is shown in (Figure 1).

The incremental area under the curve and individual glycemic index (GI) was calculated.

$$\text{Individual Glycemic Index} = \frac{\text{IAUC for the test food(Pronocte protein powder)}}{\bar{x}\ \text{IAUC for the reference food(Glucon D)}} X\,100$$

$$\text{Mean Glycemic Index (GI)} = \frac{\text{Sum of the individual glycemic index (GI)}}{\text{Total number of subjects}}$$

$$\text{Mean Glycemic Index (GI)} = \frac{40.6 + 27.4 + 41.8 + 38.3 + 4.6 + 17.0 + 25.4 + 14.7 + 34.7 + 24.1}{10} = \frac{268.6}{10}$$

Glycemic index (GI %) = 26.86 % = 26.9%

Classification of glycemic index:

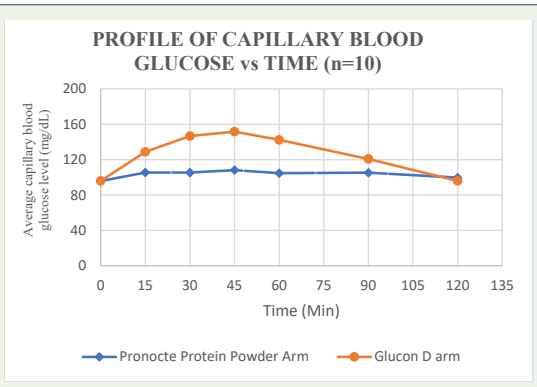

Figure 1: Profile of capillary blood glucose versus time

Low GI ≤55%

Medium GI 56 – 69%

High GI ≥70%

Thus, the glycemic index of the test product (Pronocte protein powder) 26.9 % is low GI.

Glycemic load

The Glycemic load was calculated as the GI (%) multiplied by the grams of carbohydrate in the typical serving scoop of 30 gm of pronocte protein powder. The GL for a food would be the sum of the GL of each food that is part of the food, and GL was calculated by the formula:

$$\text{Glycemic Load GI\%} = \frac{Net carbohydrates in a typical serving}{100} X \text{GI\%}$$

- Each 30-gram pronocte protein powder contains 8.25 grams of carbohydrates.
- Typical serving = 30gm of pronocte protein powder.

$$\text{Glycemic Load (GL)} = \frac{8.25}{100} X 26.9\%$$

Glycemic Load (GL) = 2.22

Classification of glycemic load

Low GL ≤10

Medium GL 11-19

High GL ≥20

Thus, the glycemic load of the test product (pronocte protein powder) in a typical serving of 30 gm is 2.22 low.

The glycemic load is a better predictor of whether the food eaten in moderate (recommended) servings is healthy or not.

The test and reference products were tolerated without any adverse events.

Discussion

Liver cirrhosis is a major health issue with a high morbidity and

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mortality rate around the world. Cirrhotic individuals have aberrant metabolism, including enhanced fat oxidation, reduced glucose oxidation and protein energy deficiency which are the primary causes of poor prognosis.

Cirrhotic people who are malnourished have visceral protein sources depleted by up to 80%. Protein is recognized as a significant component of the diet in cirrhosis and is particularly important to avoid malnutrition and tissue wasting. Tissue loss and muscle wastage will persist unless these nutrients are reintroduced into the body [9].

New recommendations have been proposed by researchers studying the protein requirements of cirrhotic patients that have changed practice guidelines. Patients with cirrhosis should consume 1.0-1.5 g/kg protein per day to prevent muscle catabolism [10].

Researchers have also suggested that eating a carbohydrate and protein-rich nighttime snack may aid with nitrogen balance, muscular cramping, and muscle breakdown by providing the body with carbohydrate energy overnight and avoiding gluconeogenesis. Patients with liver cirrhosis were advised to have a late-night snack to alleviate their morning hunger.

It is recommended by researchers that a simple addition of protein and carbohydrate-rich late evening snacks help preserve nitrogen balance and improve and prevent muscle cramps and breakdown by providing the body with carbohydrate energy and preventing gluconeogenesis [10].

Recent progressive studies showed that late evening snacks had various physiological effects such as antihypertension, obesity, and anti-amnesia properties and that helps in maintaining a greater health-related quality of life (QOL) for patients with cirrhosis.

Late evening snack holds the promise as an intervention to reverse anabolic resistance and sarcopenia of cirrhosis with improved quality of life in patients with cirrhosis. Late evening snacks should be considered as an appropriate nutrition support for people with cirrhosis [11].

The present study provides valuable insights into the potential role of pronocte protein powder as a late-night snack for patients with cirrhosis and other health conditions prone for muscle loss. Its low glycemic index and load make it a promising option for preventing the catabolic phase and preserving muscle mass.

Conclusion

In the present study, the glycemic index of pronocte protein powder is low (26.9%) and the glycemic load of 2.22 per typical serving of 30gm is also low. Consuming the recommended serving scoop of 30 gm will help in preventing sarcopenia in patients with cirrhosis and various other health conditions. A low glycemic index will help reduce fat and protein mobilization from adipocyte and lean tissue and increase carbohydrate utilization. The study findings provide valuable data for developing nutritional interventions to manage unique nutritional challenges faced by patients with medical conditions.

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