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GLYCEMIC INDEX OF A HIGH PROTEIN, HIGH CALORIE, PEPTIDE BASED NUTRITION FORMULATION

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ABSTRACT

In critically ill patients with diabetes, managing hyperglycemia becomes essential because uncontrolled hyperglycemia is linked to increased mortality, longer stay in hospitals and intensive care units (ICUs), and potentially higher rates of nosocomial infections. Also, research studies have stated that poor outcomes are associated with hyperglycemia in critically ill individuals, whether or not they have diabetes. Nutrition formulations with low glycemic index value could confer benefits like glycemic control decreased inflammation, improved insulin sensitivity, and improve fibrinolytic activity among patients. Thus, studying glycemic index of such formulations may help in improving clinical outcomes for such patients. The Glycemic index (GI) of test food: Nuc Cel 2.0 with water was determined in 15 normal healthy participants. The test food containing 25g of available carbohydrate was fed to all the participants. In addition, on three different occasions, each participant was tested with 27.5g of glucose (glucose monohydrate) drink as reference food. Capillary blood glucose was measured at fasting (0 minute), 15, 30, 45, 60, 90 and 120 minutes for capillary blood glucose after consuming reference and test food for this GI study. Incremental area under the blood glucose curve (IAUC) over these time points was calculated. Each participant's IAUC after consumption of the test food was expressed as a percentage of the mean IAUC after standard glucose taken by the same participant to calculate individual GI. The mean value of the test food is declared as GI of the test food. The Glycemic index of the test food, 'Nuc Cel 2.0 with water'= 36±5%. Nuc Cel 2.0 with water was found to be in the low GI category.

KEYWORDS - Glycemic Index, High Protein, High Calorie, Peptide Based Nutrition

INTRODUCTION

It is difficult to overstate the significance of nutrition in critical care settings. Catabolic stress and a systemic inflammatory response are common in patients suffering from critical illness. Prolonged

hospital stays, higher infectious morbidity, and multi-organ failure are among the complications. Appropriate nutrition therapies, such as parenteral nutrition (PN) or enteral nutrition (EN), have been shown to improve immune responses and lower the metabolic response to stress. In critically ill patients, nutritional care stops additional metabolic decline and lean body mass loss. The use of feeding support in critical patients has been drawn to and acknowledged because it has reduced hospital stays, morbidity rates, and improved patient outcomes.[1]

Given the large variety of nutritional formulas available on the market, determining which one is best for the patient may be difficult. Polymeric or standard formulas are created with the patient's basic macronutrient and micronutrient requirements in mind. Standard formulae are often well tolerated by patients and less expensive. However, in some cases with compromised GI function, a standard formula may not be appropriate, in which case other options such as semi-elemental, elemental, or modular formulas must be considered. [2] The components used in EN products differ greatly. Semi-elemental formulas, include peptides with various chain lengths and fat largely in the form of MCT. Semi-elemental diets are slightly more expensive than polymeric diets (formulas containing intact protein, complex carbohydrates, and long chain triglycerides), but they are widely used because it is suggested that they are better absorbed and tolerated in patients with malabsorptive conditions and are more palatable than polymeric diets.[3] According to studies, patients with chronic diarrhea may benefit from the administration of semi-elemental formula feeds comprising soluble fibre and small peptide-based feeds.[2,4]

In critically ill patients, the rate of hyperglycemia is 40–60%; in individual with diabetes who have had cardiac surgery, it can reach 60–80%. An epidemiological study conducted in the United States indicated that on the day of ICU admission, the mean daily glucose level was raised in 28.6% of patients with diabetes and 9.3% of individuals without the disease. Stress is the main cause of high blood glucose in critically sick patients, and stress-induced hyperglycemia is a risk factor that is independently related to prognosis, even in the absence of a prior diabetes diagnosis. [5]

Glycemic index (GI) of foods / products measures the carbohydrate quality. GI of a product is a standardized relative glycemic response compared to the reference food glucose. Carbohydrate in foods that are digested and absorbed in the blood quickly are high GI foods (≥ 70%) while those that are slowly absorbed are low GI foods (≤ 55%). Many factors in addition, can influence the GI. Fat, protein and dietary fiber can tend to lower the GI of a food. [6] There is considerable evidence that poor outcomes are associated with hyperglycemia in critically ill individuals, whether or not they have

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diabetes. Therefore, it becomes significant to identify and treat hyperglycemia in inpatients in order to lower the risk of worse outcomes. This can be accomplished by achieving optimal dietary support and adequate glycemic control. In order to support outstanding clinical outcomes for critically ill individuals, peptide-based nutrition formulations with low GI values offer benefits like improved nitrogen balance, improved absorption, gut integrity restoration, and effective glycemic management.[7,8]

METHODOLOGY

STUDY PARTICIPANTS:

The study included 15 participants chosen from the Glycemic Index Testing Centre- MDRF participant list. The stdy enrolled participants who met the inclusion and exclusion criteria given below:

INCLUSION:

a. Age -18 to 45 years,
b. Both men and women
c. BMI ≤22.9 kg/ m^2
d. Willingness to consume the test & reference foods
e. No known food allergy or intolerance
f. No medications known to affect glucose tolerance

EXCLUSION:

a. Specific diet restriction
b. Pregnant and lactating mother
c. Known history of diabetes mellitus
d. Presence of disease or drug(s) which influence digestion and absorption of nutrients
e. Major medical or surgical event in last 3 months

ETHICAL CONSIDERATIONS: Participants were provided complete information about the study methodology as well as the opportunity to ask questions. The procedure employed in this study was in compliance with international norms for conducting ethical human research and was approved by the Madras Diabetes Research Foundation's institutional ethics council in Chennai, India, and all participants provided informed consent. The study was recorded into clinical trial registry, of India CTRI/2023/04/051513.

TEST AND REFERENCE FOOD

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All individuals completed 3 days of reference food testing and 1 day of testing for 1 test food in random order, with 3 days washout between measurements to minimize carryover effects. After a 10- to 12-hour overnight fast, participants visited the GI testing center in the morning on each test day. To ensure that the participants maintained the same diet and physical activity on pretest dates and refrained from smoking and alcohol during the study period, a brief questionnaire on the previous day's diet (24hr recall) including last previous meal - dinner, physical activity, smoking, alcohol, and caffeine containing drinks was obtained. Female subjects were not tested during their menstrual periods and were thus postponed.

The Food Quality Analysis Lab at the Madras Diabetes Research Foundation evaluated available carbs, proximate and total dietary fibre (Annexure 1). All study participants were given foods for GI tests (Table 2) comprising 25g accessible carbohydrate from Nuc Cel 2.0 mixed with water (109ml). The reference diet for GI investigations was 27.5g of glucose dissolved in 125ml of water. The test dishes were standardized based on the available carbs content and created at the Madras Diabetes Research Foundation's test kitchen using NUCGNEX powder samples**.**

GI methodology:

Fasting blood samples were obtained by finger-prick using an automatic lancet device at -5 and 0 minutes before food ingestion, with the baseline value calculated as the mean of these two readings. The participant then consumed 25g available carbohydrate portion of the test foods: Nuc Cel 2.0 or glucose with water in random order and on separate occasions. The initial bite/sip in the mouth is set as time 0, and the first blood sample is taken conventionally 15 minutes later, with further capillary blood samples taken at 30, 45, 60, 90, and 120 minutes from the commencement of the test meal. During the remaining 2 hours of GI testing, participants were given 125ml of water.

This study used an internationally recognized GI protocol developed by FAO/WHO in 1998[9], as well as guidelines developed by the International Dietary Carbohydrate Task Force for GI methodology [10] and ISO[11,] which have been validated and published elsewhere for GI[. 12,13].

Statistical analysis

The GI study involved fifteen healthy- adults. According to the ISO GI procedure, two persons with more than 30% CV were excluded as outliers. In addition, one individual had a mean plus 2SD for the test food - Nuc Cel 2.0 with water. Another two volunteers withdrew out of the study due to personal reasons. As a result, the GI for Nuc Cel 2.0 with water was determined based on 10 healthy adults.

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The IAUC of blood glucose for the reference and test foods was computed geometrically using the trapezoid rule, omitting the area below the fasting baseline.[6, 9-14] For the reference and test foods, the mean and standard error of the mean (SEM) - IAUC were determined.

The GI value was obtained by dividing each participant's IAUC after the test food by the same participant's mean reference IAUC. The GI of the particular test food was the mean of the resulting values.

GI[9,10] value of test food (%) = $\frac{\text{Blood glucose IAUC value for the test food}}{\text{IAUC value of the reference food}} \times 100$

The GI values were subsequently evaluated using regression to see the influence (interaction) of age (yrs), sex, and previous day's food intake [energy (kcal), protein (g), fat (g), carbs (g), and dietary fibre (g)] and found no significant correlation.

RESULTS AND DISCUSSION

The study included almost equal proportion of men and women with mean age 24 ± 1 years and average body mass index 21 ± 0.4 kg/m^2**.** The average of IAUC for the reference food stood at 3329 ± 226 mg/dL min, while for the test food, it measured 1322 ± 185 mg/dL*min. The graph showing change in blood glucose between reference food (Glucose) and test food are given in **Fig.1. The glycemic index of test food Nuc Cel 2.0 was 36±5 and was found to be in the low GI category (**GI ≤ 55 on the glucose reference scale)

In critically ill patients, enteric and parenteral nutrition are routinely utilized to add a quick or persistent glucose load, resulting in hyperglycemia. Management of hyperglycemia in critically ill patients is crucial as uncontrolled hyperglycemia is associated with higher mortality, hospital and intensive care unit (ICU) length of stay, and perhaps incidence of nosocomial infection in critically ill patients. It is suggested that severely ill diabetic individuals keep their blood glucose levels between 140 and 180 mg/dL. Continuous blood glucose monitoring and adequate medical nutrition therapy, on the other hand, improve patient outcomes. [8,15,16] Medical nutrition therapy (MNT) is an important component of complete diabetes and hyperglycemia care in the hospital critical care setting.[17,18] In this present study the based product developed showed a low GI category choice. The GI value was not influenced by age (yrs), sex, diet [energy (kcal), protein (g), fat (g), carbohydrates (g), and dietary fibre (g)]. Several benefits are reported with the use of low-GI supplements, which are found to have a beneficial effect on the lipid profile. Low-GI feeds also relate with decreased chronic inflammation, improved insulin sensitivity, and improved fibrinolytic activity. Moreover, low-GI value in the

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nutritional feeds proves to be beneficial over a diet based on mere carbohydrate quantity intake computation.[19]

Additionally, patients with a wide range of acute, chronic, and genetic conditions may have feeding complications. These complications can result from challenges with tolerating, digesting, or absorbing polymeric foods, which can make it difficult to achieve or maintain adequate or appropriate energy, macronutrient, and micronutrient requirements with a standard oral diet. [3] Moreover, gastrointestinal dysfunction is common in critically ill patients and is associated with worse clinical outcomes.[20] Growing clinical evidence suggests that people with eating difficulties may benefit from 100% whey protein based semi-elemental meals in terms of health and nutrition. These diets have been developed to be easily absorbed and tolerated. They contain peptides, essential fatty acids, medium chain triglycerides, vitamins, and minerals. [3]

A meta-analysis of studies comparing relatively newer enteral low-carbohydrate high-monounsaturated fatty acid (LCHM) formulae with older formulations found that the postprandial rise in blood glucose was lower in the newer formulations by 18- 29 mg/dl.[20] Recent studies highlights the importance of GI in the Indian population for management of hyperglycemia. Additionally, research shows that while deciding which carbohydartes to include in a diet, one should take their GI value into account. The amount of carbohydrates consumed affects insulin responses and blood glucose levels. The usage of low-GI supplements has been linked to a number of advantages, including positive effects on the lipid profile. Reduced chronic inflammation, enhanced insulin sensitivity, and increased fibrinolytic activity are also associated with low-GI diets. Furthermore, low-GI diets work better than diets based only on calculating the amount of carbohydrates consumed.[19]

The GI of the test food was found to be low in the present study. The ingredients used to design the nutritional formula, such as medium-chain triglycerides (MCTs) powder, whey protein concentrate, whey protein hydrolysate, inulin, corn powder, fructooligosachharides and resistant maltodextrin, all of these could have played a role to produce this product as a low GI. The formula provides 38% of total calories as complex carbohydrate. Resistant maltodextrin and corn powder constitute for the carbohydrate source. The protein content of the formula is 29% of total calories and the high quality of protein blend made up of whey protein concentrate and whey protein hydrolysate meeting for dietary essential amino acid requirements. Whey is an ideal protein source during metabolic stress and also helps to maintain glutamine levels and enhances gut integrity.[20] Whey protein hydrolysate is a peptide-based source. Peptide-based formulas facilitates an optimal digestive process leading to

efficient nutrient absorption. Randomized controlled trials in critically ill patients receiving 100% whey, peptide-based EN have shown improved nitrogen balance, shorter hospital LOS, decreased weight loss, systemic inflammation, and stool frequency and volume, and reduction in hyperglycemia and insulin usage. [21] Nuc Cel 2.0 provides 33% of total calories from fat and is enriched with medium chain triglycerides (MCT) that could improve thermogenesis and weight management. Research also shows medium chain triglycerides are associated with increased insulin-mediated glucose metabolism. [22] Per 100g of Nuc Cel 2.0 contains 9g of soluble and insoluble blend of dietary fiber in the form of inulin and fructooligosaccharides. Dietary fiber plays an important role in postprandial glycemic response by their effects on intestinal motility and gastrointestinal hormones and enzymes. Recent studies have indicated that EN formulations with fiber are safe for patients with critical illness and may help with reduce incidence and severity of diarrhea.[23] Overall, Nuc Cel 2.0 has a well-balanced energy distribution between macronutrients, has low GI, is a peptide-based formulation. These features make Nuc Cel 2.0 an ideal and effective supplement for nutrition management of critically ill patients. Moreover, this formulation contains 32 essential vitamins, minerals and trace elements that allow the product to be used as sole source of nutrition.

This nutritional supplement can be used as both tube feed for critically ill patients and as oral feed. It is high in protein and high in calories as the supplement provides 36g protein and 490 kcal per 100g and is designed to be titrated from 2 kcal/mL to 2.2 kcal/mL for tube feeding. The purpose of the test food, is to help the early recovery of critically ill patients especially controlling the hyperglycemia and meeting their other demands. The product's ingredients were chosen for their general health advantages when they were formulated. Hereby, Nuc Cel 2.0 is a low GI special nutrition formulation and contains high calorie, high protein thus enhancing nutritional management of critically ill patient with or without diabetes.

Strength and Limitation of the study

The strength of the current study is a preliminary understanding of glycemic index and the low glucose response of a peptide- based formulation (Nuc Cel 2.0) among health volunteers. The limitation of the study is GI is measured as the area under the 2 h post prandial glycemic response. However, long-term interventional studies with such products on the daily 24 h glycemic response among critically ill patients are warranted, which may help in understanding the benefits of such supplements in critically ill patients.

CONCLUSION

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In the Indian setting with high carbohydrate diets, lower protein and dietary fibre intake in general, a glycemia-targeted specialized nutrition, which is low in GI and contains optimal protein, is acknowledged as an important aspect of the nutritional management of critically ill patients.[19]

'Nuc Cel 2.0 was found to be a low GI choice. Thus, Nuc Cel 2.0 is a peptide based Low GI formulation, it is enriched with macronutrients and micronutrients like proteins, essential fatty acids, dietary fiber, prebiotics, probiotics, antioxidants, vitamins and minerals which can help in enhancing nutrition management of critically ill patients; thus, making it ideal for effective use in nutrition management of critically ill patients. However, RCTs are necessary to support the use of low GI high protein and fibre formulations in critical care settings.

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Table 1: The Nutrition Composition of test supplementation (Nuc Cel 2.0**)**

Celnutra 2.0 Powder	Water	Energy (kcal)	Protein (g)	Carb (g)	Fat (g)	Fiber (g)	Sodium (mg)	Potassium (mg)	Phosphorous (mg)
50g/5 scoops	70 ml	245	18	23	8.75	4.61	66.93	104	71.2
100g/10 scoops	140 ml	490	36	46	17.5	9.2	134	208	142.4

Table 2 Food for GI testing quantity providing 25g available carbohydrate

Food for GI testing	Food weight containing 25g available carbohydrate
Nuc Cel 2.0 with water	Nuc Cel 2.0 and 109ml of water

Figure 1 Graph showing change in blood glucose between reference food (glucose) and test foods over a period of 2 hours

Glycemic Index (GI) of Nuc Cel 2.0 with water and reference food (Glucose)

