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Glycemic Index of a High Protein, High Dietary Fiber and Low carbohydrate Nutrition Formulation (NUC-RDM)

[1] Nidhi Singh, [2] Debasis Basu, [3] Soutri Ghosh

[1]Co-Founder, Oncoheal, Pune, India. Email ID: nidhisingh295@gmail.com , ORCID ID: 0000000183912889
[2]Healious Global Pvt. Ltd., Kolkata, India, Email ID: drbasu@yahoo.com ORCID ID: 0009000070027792
[3]Chief Clinical Coordinator, Metta Clinic (Metta Care Services), Kolkata, India. Email ID: soutri.metta@gmail.com , ORCID ID:0009000175679965

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Abstract

Low Glycemic Index (GI) diets have been associated with enhancing glycemic control in type 2 diabetes patients. As a result, GI-based carbohydrate consumption is critical for both the management and prevention of type 2 diabetes. Thus, the goal of our study was to study the glycemic response of an oral nutritional supplement high in protein and dietary fiber. The Glycemic index (GI) of test food- Nuc-RDM with water was determined in 15 normal healthy participants. The test food containing 25g of available carbohydrates was given to all study participants. Furthermore, participants were tested three times with 27.5g of glucose (glucose monohydrate) drink as reference food. After consumption of reference and test foods, patients' capillary blood glucose level was measured at fasting (0 minutes), 15, 30, 45, 60, 90, and 120 minutes. Incremental area under the blood glucose curve (IAUC) over these time points was calculated. After consuming the test food, each participant's IAUC was calculated as a percentage of the mean IAUC after ingesting a standard glucose solution by the same participant. This calculation was used to determine the individual glycemic index (GI). The GI of the test food was determined by averaging these individual values. Specifically, the glycemic index of 'Nuc-RDM with water' was found to be 44±7%, classifying it as a low GI food.
Keywords: Glycemic Index (GI), Carbohydrates, Blood glucose level, Oral nutritional supplement

Introduction

Globally, the prevalence of type 2 diabetes (T2DM) is currently rising. More than 537 million individuals worldwide have diabetes, according to data from the WHO and International Diabetes Federation, 10th edition [1]. Globally, 643 million individuals will have diabetes by 2030; this number will increase to 783 million by 2045 and due to the high prevalence of prediabetes, the number of individuals with diabetes is probable to rise further in the decades to come [2]. The main causes of an upsurge in type 2 diabetes are aging populations, urbanization, declining levels of physical activity, and an increase in the incidence of overweight and obesity [1]. According to previous reports, obesity and excessive body weight are two major risk factors for T2DM [2]. Diabetes is a major contributor to renal diseases, cardiovascular disease, blindness, and lower limb amputation in high-income nations. Controlling blood pressure, cholesterol, and blood sugar levels might delay or even prevent complications. Thus, for individuals who have diabetes, it is crucial to regularly monitor these indicators [1].

To prevent and manage type 2 diabetes, treating obesity is essential [3]. Glycemic control in type 1 and type 2 diabetes has always depended heavily on carbohydrate control before the introduction of medicines. Reducing carbohydrate consumption can enhance glycemic management, as dietary carbs raise insulin requirements. Using a very low-carb approach has consistently helped with glycemic control, weight loss, and sustained medication reduction in recent prospective and randomized controlled trials [4]. The quantity and quality of carbohydrates are important factors in the management and prevention of diabetes [5].

GI is a system for classifying carbohydrates based on their impact on blood sugar levels. Specifically, it determines the rate and extent to which carbohydrate-rich foods increase blood sugar levels in comparison to glucose-rich foods [6]. GI is calculated as the IAUC after consuming a 25g portion of the food, expressed as a percentage of the response to 25g of glucose (27.5g of glucose monohydrate) in the same individual. Foods characterized by a GI below 55 are classified as having a low GI, comprising fruits, leafy vegetables, legumes, whole grains, and dairy products [7]. Numerous processed and refined carbohydrates, including instant oatmeal, white bread, and cornflakes, have a glycemic index (GI) ranging from 76 to 100 [8].

Several factors influence a food's glycemic index (GI), including fat, protein, dietary fiber, cooking method, chewing time, and carbohydrate chemical structure. Furthermore, the GI of a food varies depending on whether it is consumed alone or with a combination of other food items. However, dietary fiber, protein, and fat can all contribute to lowering the GI of a food. According to the clinical trials involving a human intervention that demonstrated, a reduction in blood glucose levels following test food consumption for a suitable duration (e.g., two hours or more) in comparison to reference food can validate health claims regarding the decrease in postprandial blood glucose response [9]. Food portion size is vital for controlling blood glucose levels and losing or maintaining weight. However, the utility of GI must be tempered with basic nutrition guidelines for a variety of healthful foods and moderation of low-nutrient foods. According to an international consensus panel, dietary GI labeling should be done in the setting of a healthy diet with other healthy dietary features [10].

The GI shows, the rate at which food enters the bloodstream. As a result, foods with a lower GI absorb more slowly, lowering the glycemic response and the subsequent release of insulin. Consuming foods high in glycemic index (GI) is positively correlated with a higher risk of T2DM [11]. For people who have already been diagnosed with diabetes, eating a lower-GI diet may also reduce their risk of complications. Low-GI diets significantly reduced A1C by 0.5% when compared to participants who followed a high-GI diet, according to a Cochrane analysis conducted on a total of 11 studies enrolled approximately, 402 cases who were with DM [12]. According to a systemic review, it was found that in patients with any of the four primary metabolic diseases; obesity, metabolic syndrome, diabetes, and cardiovascular disease: a low-glycemic index diet is superior for controlling body mass, BMI, FBG, and HbA1c% [13]. Glycemic index-based carbohydrate consumption plays a vital role in both the management and prevention of T2DM [7]. Thus, the purpose of our study was to assess the glycemic response of oral nutritional supplements (NUC-RDM) which are low in carbohydrates, high in protein, and high in dietary fiber.
As per the previous report, the internationally recognized GI protocol established by the "Food and Agriculture Organization" and the World Health Organization (FAO/WHO) in the 19^{th} century [14], incorporating the recommended guidelines from the International Dietary Carbohydrate Task Force for GI methodology [15], and following to the standards which were established by the International Organization for Standardization (ISO) [16]. These guidelines have been previously validated and published for GI research [17,7].

Methodology

Participants were chosen from the Glycemic Index Testing Centre- MDRF participant list. This study enrolled participants who met the inclusion and exclusion criteria given below.

In this study, we included both male and female participants aged 18 to 45 years with a Body Mass Index (BMI) ≤ 22.9 kg/m². They were willing to consume test and reference foods and had no known food allergies or intolerances, nor were they taking drugs that could affect glucose tolerance. Also, participants with dietary restrictions, pregnant women, a history of diabetes mellitus, conditions or medications affecting digestion and nutrient absorption, and major medical or surgical events within the past three months were excluded.

In this current investigation, we used a standardized protocol which involved 3 days of reference food testing and 1 day of testing one food item, randomly ordered, followed by a 3-day washout period. Before each test, participants fasted for 10-12 hours and reported to the GI testing center in the morning. To maintain consistency, participants were instructed to maintain their regular diet and regular day-to-day physical activity levels on the days preceding each test and to abstain from smoking, alcohol, and caffeine-containing beverages. A brief questionnaire, including a 24-hour dietary recall, was administered to ensure compliance. Female participants were not tested during menstruation. However, fasting blood samples were obtained by simple and traditional process i.e., finger-prick, then by using automatic lancet device at -5 and 0 minutes before food ingestion, with the baseline value calculated as the mean of these two readings. In a random order and on different occasions, the participants consumed a 25g accessible carbohydrate amount of the test food: Nuc-RDM (NUCGNEX Lifesciences Pvt. Ltd.) with water. Furthermore, we performed the traditional process of collecting capillary blood samples 15 minutes after the first bite or sip in the mouth, followed by capillary blood samples 30 minutes later, 45 minutes, 60 minutes, 90 minutes, and 120 minutes after the initial bite or sip. During the remaining 2 hours of GI testing, participants were given 125ml of water.

Test and reference food

The Food Quality Analysis Lab at the Madras Diabetes Research Foundation calculated available carbs, and proximate and total dietary fiber using the direct approach. All study participants were given feed for GI tests comprising 25g accessible carbohydrate: 69g Nuc-RDM mixed with water (235ml) (Table 1).

Food for GI testing	**Food weight containing 25g available carbohydrate**
Nuc-RDM with water	69g of Nuc-RDM and 235ml of water

Table 1: Food for GI testing quantity providing 25g available carbohydrate

Ethical Consideration

The reference feed for GI investigations was 27.5g of glucose dissolved in 125 ml of water. The test feed was standardized based on the available carbs content and created at the Madras Diabetes Research Foundation's test kitchen using the NUCGNEX (NUCGNEX Lifesciences Pvt. Ltd.) powder sample.

The methodology employed in this study followed international standards for ethical research involving human subjects. This study obtained written informed consent from all participants, approved by the institutional ethics committee of Madras Diabetes Research Foundation, Chennai, India. Also, this study was registered with the Indian clinical trial registry under registration number CTRI/2023/04/051530.

Statistical analysis

The GI used in this study, involved fifteen healthy adults with normal BMI. According to the ISO GI procedure, two persons with more than 30% CV were excluded as outliers. In addition, two volunteers withdrew from this study for personal reasons. Thus, the GI for Nuc-RDM with water was determined based on 11 people. In the present study, capillary blood glucose was evaluated geometrically with the help of the trapezoid technique, omitting the area below the fasting baseline [7,10,14-18].

To calculate the means and standard errors of the means (SEM) - IAUCs, we conducted the tests on reference and test foods. By dividing each participant's IAUC following the test food by their mean reference IAUC, the GI value was calculated. The test food's GI was the average of the results.

Results and discussion

In this study, individuals had an average age of 24 ± 1 year and an average BMI of 21 ± 0.4 kg/m2, according to the results. The average of IAUC for the reference food stood at 3329 ± 226 mg/dL min, while for the test food, it measured 1382 ± 176 mg/dL*min. The estimated GI test indicated that the test food (NUC-RDM with water) had a GI of 44 ± 7, categorizing it as a low-GI food (GI ≤ 55 on the glucose reference scale) In addition, we calculated the Standard Error of the Mean for several parameters, including age, BMI, mean IAUC with water, and GI at 1 year, which were 0.4 Kg/m2, 226 mg/dl, and 176, respectively, as represented in the following Figure 1.

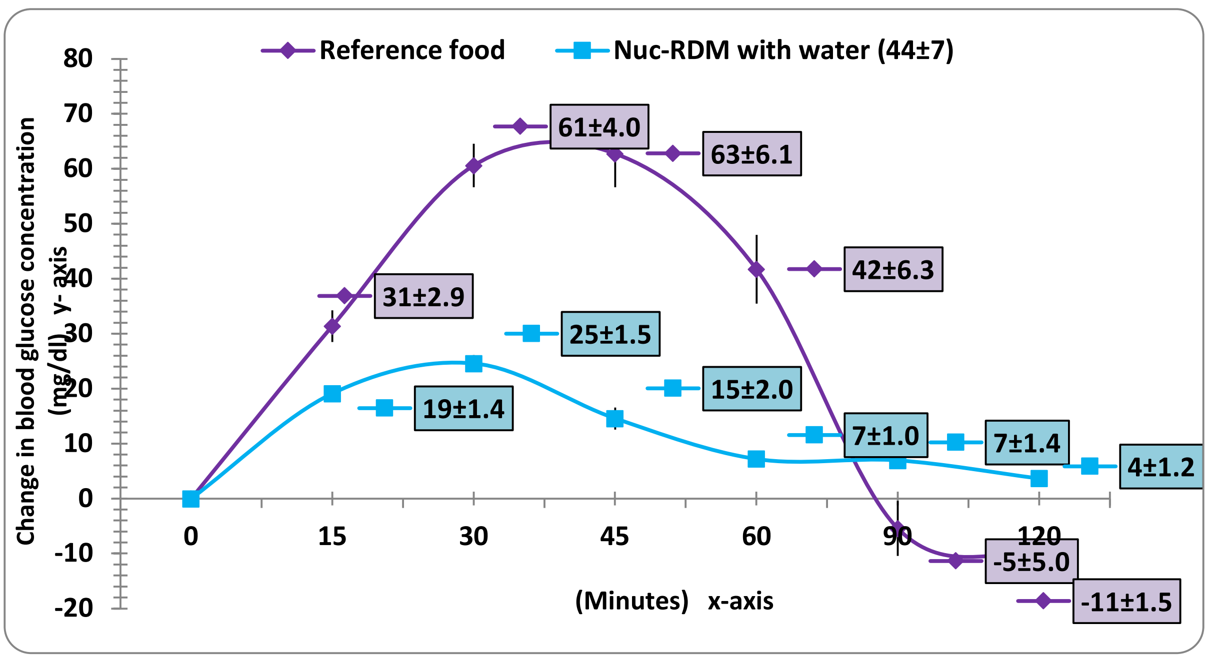

Figure 1: Comparison of Blood Glucose Changes between Reference Food (Glucose) and Test Foods Over 2 hours

Simple sugars and processed meals are more frequently consumed than complex carbs. To stop the pandemic, and spread of this metabolic disorder, it is crucial to consume carbs with a low GI.[18] According to a previously published systematic review and meta-analysis, individuals with T2DM who practice low-GI diets have better control over their HbA1c and fasting blood glucose levels than those who practice higher-GI diets or control diets [19].

Therefore, in particular diabetics, especially those in the early stages, changing from higher to lower glycemic load foods may partially improve glycemic control [20]. In the present study, we used NUC-RDM power sample (NUCGNEX Lifesciences Pvt. Ltd.) which is enriched with a combination of complex carbohydrate sources like resistant maltodextrin, hydrolyzed guar gum, inulin, and fructo oligosaccharides contributing to the low GI profile of the formulation. The unique blend of protein, carbohydrate fiber, and other micronutrients in the formulations may play a significant role in regulating blood glucose levels and promoting significant weight loss. Clinical improvements (better blood pressure, cholesterol, or glycemia) could arise from even a small amount of weight loss.

Conclusion

According to the results of the present study, we concluded that the test food, "Nuc-RDM (NUCGNEX Lifesciences Pvt. Ltd.) with water," had a Glycemic Index of 44±7%, categorizing it as a low GI food. The low GI of the product is attributed to its protein and fiber content. The GI value remained unaffected by variables such as age (years), sex and dietary factors including energy intake (kcal), protein, fat, carbohydrates, and dietary fiber. As a low GI diet leads to better control of blood sugar levels, thus the formula of Nuc-RDM can be provided as an adjuvant with regular meals for the management and prevention of T2DM and associated disease conditions. In a nutshell, remission from diabetes is no longer a myth but rather a reality. However, long-term interventions with larger participant cohorts are necessary for long-term efficacy, with an emphasis on improving approaches to effectively address metabolic complexity

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