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Determining the Glycemic Index of Nutritional Product for Diabetes Mellitus- Np through Measuring Glycemic Responses to Reference Food (Glucose) and Test Food (Nutritional product -Np)

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

The objective was to determine the glycemic index (GI) of Nutritional product for Diabetes Mellitus through measuring glycemic responses to reference food (Glucose) and test among nutritional product 13 participants. The study was a self-controlled clinical trial with 13 qualified participants (8 men and 5 women). They were required to go through the study protocol with reference food and test food. For each individual, seven blood samples were taken in the fasting state and at 15, 30, 45, 60, 90 and 120 minutes after ingestion. Our results show that at all measurement points, the blood glucose levels after consumption of test food were lower than after consumption of reference

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food. The incremental area under the curve (iAUC) and a GI value of Nutritional product (NP) were calculated for each meal. Mean ± SD of GI value was calculated for test food for the combined group of subjects. Mean iAUC and GI value of Nutritional product were 62,1 ± 12,5 mmol·min/L and 44,9 ± 7,2, significantly lower to those of reference food, which were 132,6 ± 14,8 mmol·min/L and 100, respectively. Finding from the study demonstrated that Nutritional product (GI = 44,9) would be classified as a low – GI food.

Keywords: Clinical trial; glycemic index; nutritional product; national institute of nutrition.

1. INTRODUCTION

Diabetes has been increasing rapidly and has become a global societal threat that does not respect borders or social class. The global prevalence of diabetes had grown from 4.7% in 1980 to 8.5% in 2014, during which time prevalence had increased or at best remained unchanged in every country. World Health Organization (WHO) estimated that the number of adults living with diabetes had nearly quadrupled since 1980, moving from 108 million in 1980 to 422 million in 2014 [1]. With 463 million adults aged 20 – 79 living with diabetes worldwide, diabetes is now one of the largest global health emergencies of the 21st century. A further 578 million adults were estimated to have impaired glucose tolerance, putting them at high risk of developing diabetes in the future. If this trend continues, there will be 700 million people inflicted by 2045 [2]. Pham Thi Bich Ngoc, Hoang Thi Minh Thai, Dinh Tran Ngoc Huy (2021) also stated nurses helped much in hospitals for help and treatment support.

In recent years, the burden of non-communicable diseases (NCDs), including type 2 diabetes mellitus, in Vietnam has drastically increased. type 2 diabetes mellitus was more prevalent in big cities [3], with rates of both prediabetes and type 2 diabetes mellitus accelerating at alarming rates [4] Surveys from the early 1990s showed that the prevalence of type 2 diabetes mellitus was 1.01% in Hanoi, 0.96% in Hue, and 2.5% in Ho Chi Minh City – the three representative cities of the north, center, and south of Vietnam, respectively [5]. After a decade, the prevalence rate of diabetes of the country increased by 2 times, from 2.7% in 2002 to 5.4% in 2012 [3]. According to International Diabetes Federation (IDF), in Vietnam, the national prevalence of diabetes was 5.5%. By year 2045, it is predicted that the prevalence will be 7.7% [2]. In 2008, National Hospital of Endocrinology showed that the prevalence of type 2 diabetes mellitus was 5.7% at the age from 30-69 years old in big cities but after 10 years (2002-2012) that has increased 211% [3].

The study was conducted to determine the GI of Nutritional product - Np through measuring glycemic responses to reference food (Glucose) and test food (Nutritional product -Np) among eleven selected participants. The importance of Nutritional product variety as well as its value will be greater if it is of low GI value, gaining its place in become a promising solution for diabetic and obese patients' health.

2. METHODS

2.1 Study Subjects

11 Healthy students of Hanoi Medical University, Vietnam were selected using the following criteria:

- Between 20 – 25 years of age,
- Body mass index (BMI): 18.5 ≤ BMI < 23 kg/m²,
- Fasting blood glucose level under 5.6 mmol/L

Voluntarily agree to participate in the study. Subjects were excluded if they met one or more of the following criteria:

+) Individuals who had recently been diagnosed with impaired glucose tolerance or any acute/chronic conditions,
+) Individuals who were consuming medication or drugs known to have influences on carbohydrate metabolism,
+) Women who were pregnant or currently breastfeeding.

2.2 Study Design

- *Time and location*: Our study was conducted from December, 2020 to April, 2021 at National Institute of Nutrition, Vietnam.

- *Study design*: This was a self-controlled clinical trial with crossover experiments to determine the glycemic index of Nutritional product on healthy adults. The protocol was adapted from TCVN 10036:2013 (Vietnam Standards and Quality Institute [VSQI], 2013), equivalent to ISO 26642:2010 (International Organization of Standardization [ISO], 2010) [6] and was in line with the procedure recommended by the Food and Agriculture Organization of the United Nations (FAO) [7].
- *Sample size:* According to international standard [TCVN 10036:2013 (ISO 26642:2010) [6], the method for the determination of the GI of carbohydrates in foods required a selection of a minimum of 10 healthy subjects. In this study, 13 participants were recruited from 37 screened volunteers.
- *Reference meal*: Glucose solution with 50g sugar diluted in 400ml water.
- *Test food:* The type of food tested was Nutritional product *(Vietnam*). Nutritional product solution with 99.0g diluted in 417ml water. The food-to-water ratio followed the processing instruction from the manufacturer.

All the meals were preapared early in the morning of the test days at National Institue of Nutrition, Vietnam.

The below table 2 tells us that some elements some may have a hypoglycemic effect. In type 2 diabetes, if the patient does not improve the increase in blood sugar with daily nutrition and exercise, the patient can use oral drugs or injections to stabilize sugar levels in blood. In order for the disease not to progress seriously, diabetics need to have a plan to monitor their carbohydrate intake, as well as limit the use of processed foods, low in fiber; Eat lots of green vegetables and foods with a low glycemic index.

Table 1. Weight, energy and nutrients content of reference food and test food

	Reference food *(Glucose)*	**Test food (*Nutritional product*)**
Weight (g)	50	99
Energy (kcal)	200	436.1
Available carbohydrate (g)	50	50
Protein (g)	0	19.6
Fat (g)	0	17.5

Table 2. Nutrition facts of Test food (Nutritional product, Vietnam)

No	**Ingredients**	**Unit**	**Power per 100g**
1	Energy	Kcal	440.5
2	Protein	g	19.8
3	Lipid	g	17.7
4	MUFA	g	3.4
5	PUFA	g	0.92
6	Carbohydrate	g	50.5
7	Polyols	g	19.5
8	FOS	g	5.8
9	Betaglucan	mg	105
10	Choline	mg	176
11	Taurine	mg	34.5
12	Chitosan	mg	140
13	Lutein	mg	16.7
14	Inositol	mg	520
15	Vitamin C	mg	41.3
16	Vitamin B1	mg	0.51
17	Vitamin B2	mg	0.48
18	Vitamin B6	mg	0.51

No	Ingredients	Unit	Power per 100g
19	Acid Folic	mcg	390.8
20	Vitamin A	IU	1441
21	Vitamin K1	mcg	34.1
22	Biotin	mcg	5.2
23	Vitamin E	IU	8.4
24	Vitamin D3	IU	256.1
25	Vitamin B12	mcg	0.5
26	Calcium (Ca)	mg	387.7
27	Phosphorus (P)	mg	325.6
28	Magnesium (Mg)	mg	69.3
29	Iron (Fe)	mg	8.9
30	ZinC (Zn)	mg	7.5
31	Copper (Cu)	mcg	845.5
32	Manganese (Mn)	mcg	289.9
33	Iodine (I)	mcg	54.1
34	Molybdenium (Mo)	mcg	27.3
35	Selenium (Se)	mcg	22.9
36	Chromium (Cr)	mcg	15.1

Study variables and data collection:

Table 3. Study variables

Variables	Indicators		Data collection method
Characteristics	General information	Name	Questionaire
		Age	
		Gender	
	Medical history		
	Anthropometric	Body weight	TANITA digital scale
		Height	SECA Stadiometer
		BMI	BMI (kg/m²) = Weight (kg)/Height (m²)
	Blood Pressure		Electronic blood pressure monitor
	Heart rate		Count the number of pulse beats in 60 seconas
	Screening fasting blood glucose level		Capillary blood samples were determined by the Accu –Chek Glucosmeter
Glycemic Response	Blood glucose respones	Fasting	Venous blood samples were analysed by the automatic biochemical machine AU480 (Germany)
		After 15min	
		After 30 min	
		After 45 min	
		After 60 min	
		After 90 min	
		After 120 min	
Glycemic Index	Incremental area under the blood curve value for Nutritional product (iAUCNP)		The incremental area under the blood glucose curve (iAUC) was computed by the trapezaoidal method
	Incremental area under the blood curve value for Glucose (iAUCGlucose)		
	Glycemic Index of Nutritional product (GINP)		GI= iAUCNP/ iAUCGlucose *100

Study procedures

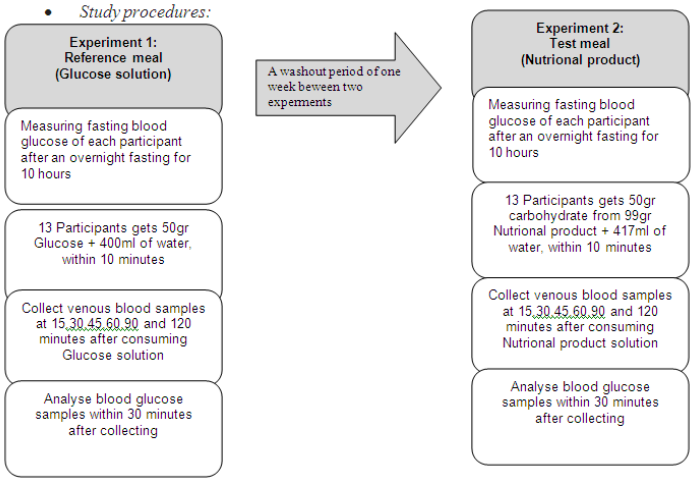

Fig. 1. Study procedures

2.3 Data Analysis

Statistical analysis was performed using SPSS software version 22.0. We used descriptive statistics to characterize the study sample, continuous data were presented as mean ± standard deviation (SD). Due to the small sample size (n = 13), the Mann-Whitney U test was used to compare the significance of differences of the glycemic response as well as the value of iAUC between test meal and reference meal. The Wilcoxon signed - rank test was used for comparisons at baseline and after intervention. There were no missing values for variables used in this analysis. All statistical significance was set at $p < 0.05$.

3. RESULTS

3.1 Characteristics of Subjects

Thirteen healthy volunteers participated in this study. The subjects were comprised of eight men and five women. Their mean age and BMI were 23.5 ± 0.3 years and 20.7 ± 0.3 kg/ m2, respectively. Table 4 also showed that all participants had normal fasting blood glucose levels. Also we could see Women's weight difference influences the results due to metabolic and hormonal aspects, esp. Overweight and less physical activity will be among reasons causing diabetes type 2.

3.2 Glycemic Response to Nutritional Product

Results of postprandial blood glucose levels of the reference meal compared to test meal among eleven volunteers were presented in Table 5. On all occasions, the blood glucose levels after consumption of test food were lower than after consumption of reference food.

At minute 0 or baseline, the same of mean fasting blood glucose responses between glucose (5.2 mmol/L) and Nutritional product (5.4 mmol/L), indicating that there was no significant difference between them ($p > 0.05$). Next, at minute 15, the blood glucose response of Nutritional product was 5.6 mmol/L. Compared to the reference food (6.5 mmol/L), the difference was significant ($p < 0.05$). Following that, mean blood glucose response of Nutritional product measured at minute 30 was 6.5 mmol/L while the value of glucose was 7.5 mmol/L. The mean peak value of Nutritional product (6.5 mmol/L) were lower than the reference meal glucose (7.5 mmol/L) at minute 30, but the difference between them were significant ($p < 0.01$).

Findings from this study demonstrated that at minute 30, mean blood glucose response of reference food was reduced to 6.5 mmol/L and higher than mean blood glucose response of Nutritional product, was 7.5 mmol/L. Subsquently, at minute 90, mean blood glucose response of Nutritional product was significantly reduced to 5.5 mmol/L and significantly lower than the reference food (5.9 mmol/L). Finally, at minute 120, mean blood glucose responses of Nutritional product showed significantly difference with that of the reference food ($p > 0.05$).

Table 4. Characteristics of the subjects

Characteristics	Men *(n=8)*	Women *(n=5)*	Both sexes *(n=13)*
	X ± SD	X ± SD	X ± SD
Age *(years)*	24,0 ± 0,3	22,8 ± 0,6	23,5 ± 0,3
Weight *(kg)*	60,0 ± 2,3	50,3 ± 1,5	
Height *(cm)*	169,6 ± 3,0	157,1 ± 2,0	
BMI *(kg/m²)*	20,8 ± 0,5	20,4 ± 0,3	20,7 ± 0,3
Fasting Blood Glucose Level *(mmol/L)*	5,1 ± 0,2	5,0 ± 0,2	5,0 ± 0,2

Table 5. Postprandial blood glucose levels after consumption of Glucose solution and Nutritional product

Time	Postprandial blood glucose *(mmol/L)*		
	Glucose	Nutritional product	*p-value**
0 min	5,3 ± 0,1	5,4 ±0,1	*0,724*
15 min	6,5 ± 0,2	5,6 ± 0,1*	*0,002*
30 min	7,5 ± 0,2	6,5 ±0,1*	*0,001*
45 min	7,1 ± 0,3	6,0 ± 0,3*	*0,01*
60 min	6,5 ±0,3	5,8 ±0,3	*0,125*
90 min	5,9 ± 0,2	5,5 ± 0,3	*0,614*
120 min	5,6 ± 0,3	5,3 ± 0,3	*0,418*

**Mann-Whitney U test*

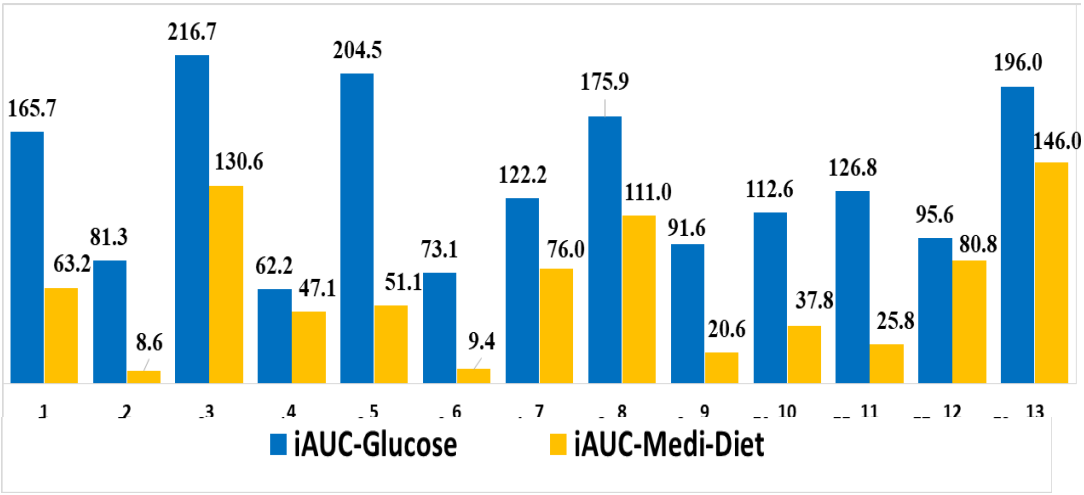

Fig. 2. The incremental area under curve (iAUC) after consuming Glucose solution and Nutritional product of all partcipants

Table 6. The iAUC and GI of Nutritional product and Glucose

Index	Mean (95% CI)	Men *(n=8)*	Women *(n=5)*	p-value*
		X ± SD	X ± SD	
iAUC Np (mmol-min/L)	62,1 ± 12,5	74,0 ± 18,4	43,2 ± 10,8	0.435
iAUC Glucose (mmol-min/L)	132,6 ± 14,8	136,6 ± 21,2	126,2 ± 20,6	1,000
GI Np	44,9 ± 7,2	49,7 ± 9,2	37,2 ± 12,1	0,622
Margin of Error *(%)*	16,0			

**Mann-Whitney U test*

Although each portion contained the same amounts of carbohydrate, there was an almost two – fold range in blood glucose responses between two foods with the test food (Nutritional product) creating a smaller increase in blood glucose response compared to the reference food (Glucose).

3.3 The Glycemic Index (GI) of Nutritional Product

The iAUCs of each participant reflected changes in their blood glucose over 2 hours after consuming different test meals. As shown in Figure 2, both the iAUCs after drinking Nutritional product and after drinking glucose varied considerably among all participants. However, their results shared a common trend. Each individual's iAUC for glucose solution was significantly greater than their iAUC for Nutritional product, despite the fact that the portions had the same amount of 50 grams of carbohydrates.

As shown in Table 6, the mean iAUC value of Nutritional product was 62.1 ± 12.5 mmol·min/L, significantly lower compared to the reference food (132.6 ± 14.8 mmol·min/L). The mean value of GI_{NP} (Mean ± SD) was 44.9 ± 7.2, which was significantly lower than the reference food (GI = 100).

Due to natural differences, such as body weight and metabolism, blood glucose responses to the same food varied among different individuals. The use of the reference food to calculate GI values reduced the variation between the subjects' blood glucose results to the same food arising from those differences. Therefore, the GI values for the same food varied less among the subjects than their glucose iAUC values.

Table 5 also showed that the mean value of iAUCNp, iAUCGluco, GINp among male participants were 74.0 ± 18.4 (mmol-min/L), 136.6 ± 21.2 (mmol-min/L), 49.7 ± 9.2, respectively and the mean value of iAUCNp, iAUCGluco, GINp among female participants were 43.2 ± 10.8 (mmol-min/L), 126.2 ± 20.6 (mmol-min/L), 37.2 ± 12.1. There were no statistical differences in the mean iAUCNp, iAUCGluco, and GINp values between men and women.

4. DISCUSSION

Findings from this study indicated that there was a significantly greater inter-subject variation of blood glucose response to glucose solution than to Nutritional product at all measurement intervals up to 2 hours. The blood glucose levels rose consistently from the baseline, reached the peak at minute 30, decreased, and lowered than the baseline value at minute 120. We also observed a slow reduction of mean blood glucose responses of Nutritional product after 30 minutes (6.5 mmol/L) until 120 minutes (5.3 mmol/L). This situation was vital in prolonging satiety duration of participants after ingestion of Nutritional product. Since our study included younger subjects, they likely were able to regulate blood sugar better than older individuals.

The GI is an important parameter of food quality which compares the hyperglycemic effect of a tested meal with a standard food, such as pure glucose. Results obtained from our study revealed that Nutritional product had low GI value (44.9 ± 7.2). The reason low GI of Nutritional Product that was the manufacturer uses polyols and FOS to replace maltodextrin, lactose and add more insulin *(see table 2: Nutrition facts of Test food*). And then we can make assessment on its hypoglycemic effect.

Until now, The Diabetes Associations in worldwide have been recommended to use low or moderate GI foods in clinical nutrition and GI has been recognized as an indicator for classification of rich carbohydrate food. Thus, low and moderate Nutritional product varieties, such as Nutritional product in this study, are ideal to prevent NCDs, and it would be a promising product in controlling posprandial blood glucose for Vietnamese. In our study, due to limited resources, we didn't perform a multivariate statistical analysis. According to Bronus et al, for routine use of the GI method, glucose measurement was enough, and until now, most GI studies have not measured the postprandial insulinemic responses accompanying the glycemic responses of the test food examined. However, measurement of insulin response to foods, and the introduction of an insulinemic index concept could be value in investigating health issues. Therefore, measurement of both glucose and insulin was recommended for more metabolic studies.

Scientists also mentioned research works are important [8-12] and roles of banks in financing this industry [13-18]. The management is also mentioned and roles of nurses need to be enhanced [19-25].

5. CONCLUSION

Based on the clinical trial of 13 participants through 2 experiments, we concluded:

The glycemic response after consumption of 50 grams carbohydrate from Nutritional Product was lower than after consumption of 50 grams carbohydrate from glucose at all time points of the experiments. Finding from the study demonstrated that Nutritional Product is a low – GI food with a GI value of 44.9.

6. RECOMMENDATION

Causes of gestational diabetes During pregnancy, the placenta produces stimulation to maintain the pregnancy. These stimuli make the cells more resistant to insulin. Normally, the pancreas will produce enough insulin to overcome this resistance, but in some cases, the pancreas does not produce enough insulin, causing the amount of sugar to be transported into the cells to decrease, and the amount of sugar to accumulate in the blood. high blood pressure, leading to gestational diabetes.

Pregnant women who are overweight, have a family history of diabetes, or have been diagnosed with impaired glucose tolerance are all at increased risk for gestational diabetes.

6.1 The Physiological Variations of Women

Men and women are equally at risk for diabetes. When a person has diabetes, their body cannot use insulin properly and this leads to high blood sugar. Over time, high blood sugar can damage the nervous system, increasing the risk of cardiovascular complications. Not to mention, the psychological guilt because of illness, depression and anxiety during treatment also makes mental health decline.

6.2 The Capacity of a Hypoglycemic Effect of the Supplement

6.2.1 Vitamin D

Vitamin D deficiency is considered a potential risk for type 2 diabetes.

In one study, 72% of participants with type 2 diabetes were vitamin D deficient. After two months of taking 4,500 IU of vitamin D supplements daily, both fasting blood sugar and A1C improved.

How it works: Vitamin D may improve the function of pancreatic cells that make insulin.

Dosage: Users should consult their doctor to determine the best dose.

Note: Vitamin D can cause mild to moderate conflicting reactions with some medications.
(source: vinmec.com. Access date 21/10/2021)

In summary, in the context of diabetes, this research helps to determine the glycemic index (GI) of Nutritional product for Diabetes Mellitus through measuring glycemic responses to reference food (Glucose) and test among nutritional product.

And Is the dietary supplement affordable for everyone? Yes, affordable. We would suggest patients pay attention to food with vitamin D because Vitamin D may improve the function of pancreatic cells that make insulin.

Next, Did the weight differences influence the results to any extent? Yes, overweight indicated as one reason for diabetes. And we could see Women's weight difference influences the results due to metabolic and hormonal aspects, esp. Overweight and less physical activity will be among reasons causing diabetes type 2.

Another visualized variable is that the rate of caloric consumption could influence the results by having less weight. How is this aspect controlled in the study? Well in this study, we would recommend people should balance body and not overweight. Patients need do more physical exercises and brain activity to reduce caloric.

CONSENT AND ETHICAL APPROVAL

Ethical approval of this study was obtained from National Institute of Nutrition Ethics Committee. All participants were given information on the purpose, the associated risks and benefits of the study. All participants were required to provide written informed consent before inclusion in the study.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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