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A Clinical Trial on the Glycemic Index of Nutritional Product for Diabetes Mellitus

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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

In the world as well as in Vietnam, diabetes have shown bad effects and there is increasing number of deaths over years because of diabetes as one of three leading causes of deaths. Penalver et al (2016) stated to achieve good metabolic control in diabetes and keep long term, a combination of changes in lifestyle and pharmacological treatment is necessary.
The type of food tested was Nutritional product (Vietnam). Nutritional product solution with 83.3g diluted in 390 ml water. The food-to-water ratio followed the processing instruction from the manufacturer.
In this study we discover a low GI of nutritional product, as of (48.2 ± 5.3). And also, we found out there is decrease (slow) of responses of mean blood glucose (Nutritional product) after 90 minutes

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(4.7 mmol/L) till 120 minutes (4.3 mmol/L). As we conduct this paper with younger subjects, comparing to older people, they can regulate blood sugar better.
Finally, we also compare to other previous studies for literature review.

Keywords: Clinical; glycemic index; nutritional product; diabetes mellitus.

1. INTRODUCTION

In recent years, there is increasing speed of a global threat, diabetes, which does not respect social class/border. During the year 2014, there is a growth to 8.5% from 4.7% in 1980, in term of global prevalence of diabetes. According to WHO, the no. of adults with diabetes increased from 108 million in 1980 to 422 million in 2014 [1]. Among endocrine diseases and metabolic disorders, diabetes is becoming a common and rapidly increasing disease in developed and developing countries all over the world. If 30 years ago, Vietnam faced malnutrition, now we are threatened by obesity and diabetes. Diabetes is one of the three leading causes of death in the world, second only to cardiovascular disease and cancer. Pham Thi Bich Ngoc, Hoang Thi Minh Thai, Dinh Tran Ngoc Huy (2021) also stated important roles of nurses in hospitals for help and treatment support. If we take a number in term of global people or population - adults with diabetes aging from 20 – 79, in the 21st century, diabetes becomes one of the largest global health emergencies. Also there is high risk of diabetes development in future if we see the figure of further 578 million adults , in estimation, having impaired glucose tolerance, according to FAO/WHO, 1998 [2]. The current state of diabetes in the world is estimated by the World Diabetes Association (IDF) with more than 425 million people, meaning that 1 in 11 people has diabetes. In which, 1 in 2 people with diabetes do not know they have the disease (did not go for a diagnostic test for diabetes). Late treatment will lead to many dangerous complications and directly affect the patient's quality of life and health.

How is the situation in Vietnam? The number has increased quickly recently, in term of non-communicable diseases (NCDs), consisting of type 2 diabetes mellitus, esp. in big cities, according to International Diabetes Federation, 2020 [3]. According to statistics, the rate of 1.01% in Hanoi, in term of prevalence of type 2 while 0.96% in Hue, and 2.5% in Ho Chi Minh City. We perform this study in order to estimating, among selected members/participants, the GI of Nutritional product - Np through measuring glycemic responses to reference food (Glucose) and test food (Nutritional product or Np). A low GI value will have a meaning of The importance of Nutritional product variety with greater value and the becoming potential solution for diabetic and obese health of patients.

1.1 Research Question

How we perform the experiments and What are results in term of levels of blood glucose during post-consuming test food compared to post-consuming reference food, at all points? And what are GI value for nutritional product?

We organize our study with introduction, methodology, main results, discussion and conclusion.

2. METHODS

2.1 Study Subjects

Eleven 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) [4] and was in line with the procedure recommended by the Food and Agriculture Organization of the United Nations (FAO) [5].
- ***Sample size:*** According to international standard [TCVN 10036:2013 (ISO 26642:2010) [4], 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, 11 participants were recruited from 37 screened volunteeers.
- ***Reference meal*:** Glucose solution with 50g sugar diluted in 200ml water.
- ***Test food:*** The type of food tested was Nutritional product *(Vietnam*). Nutritional product solution with 83.3g diluted in 390ml water. The food-to-water ratio followed the processing instruction from the manufacturer.

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

The below table also shows us that there is 282.5 kcal (energy), 50 g carbohydrate and 17.5 g protein and 12.5 g fat in test food.

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

	Reference food *(Glucose)*	**Test food (*Nutritional product*)**
Weight (g)	50	83.3
Energy (kcal)	200	282.5
Available carbohydrate (g)	50	50
Protein (g)	0	17.5
Fat (g)	0	12.5

- ***Study variables and data collection:***

Table 2. 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	

Variables	Indicators	Data collection method
	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:***

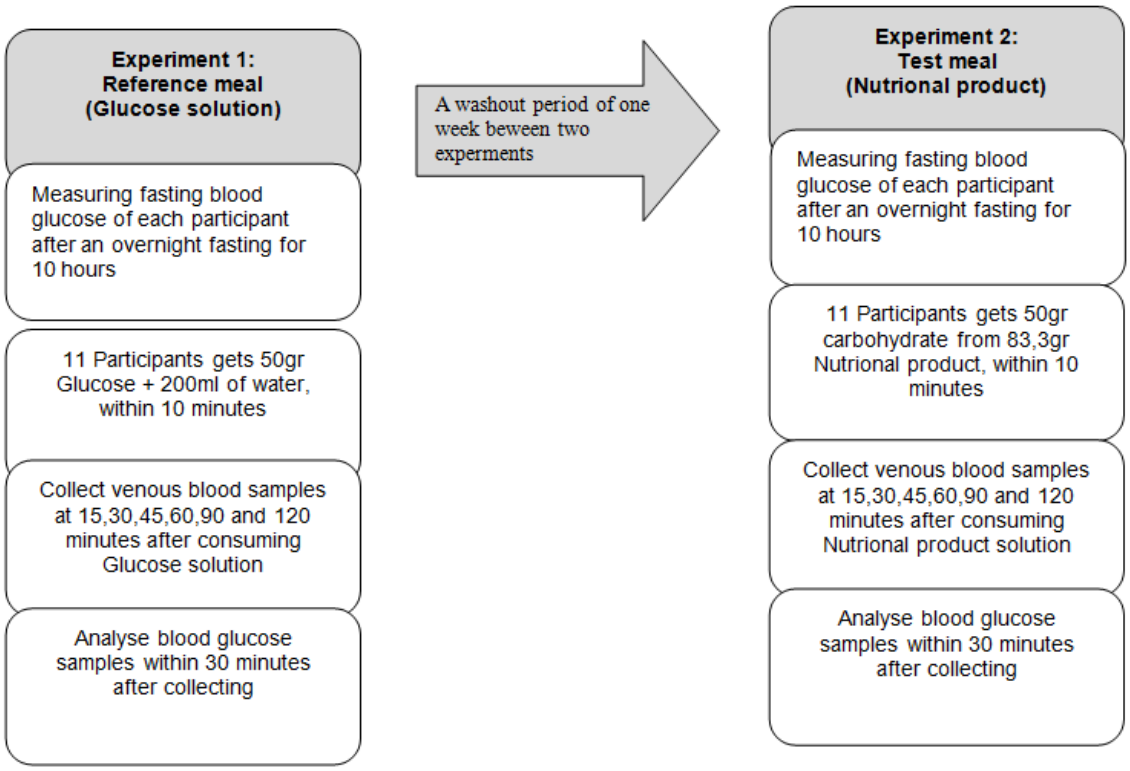

Fig. 1. Study procedures

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 = 11), 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 Features of Subjects

Our experiments conducted with involvement of Eleven healthy volunteers in which there are eight men and three women. Age mean, BMI as of 23.7 ± 0.4 years and 20.7 ± 0.3 kg/ m2, accordingly. Among them, 23.0 ± 1.2 years for women and 24.0 ± 0.3 for men. Weight: 49.1 ± 1.6 kg for women, and 60.2 ± 2.4 kg for men. Also We see in them: Normal heart rates, blood pressures & fasting blood glucose levels (see Table 3).

3.2 Glycemic Response to Nutritional Product

We recognize that:

First, in Table 4: we showed for 11 members, postprandial blood glucose levels results of the reference meal compared to test meal. We found out that levels of blood glucose levels in post-consuming test food : lower than post-consuming reference food, at all points.

Second, there is no big differnce ($p > 0.05$) because we see: 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) at min) or baseline. Then response of blood glucose - Nutritional product as of 5.9 mmol/L at min 15. So theer is significant difference ($p<0.05$): Compared to the reference food (6.5 mmol/L).

Third, at min 30, there is no significant difference ($p>0.05$): peak mean value of Nutritional product (7.0 mmol/L) as lower than the reference meal glucose (7.6 mmol/L).

Last but not least, at min 60, our study revealed that response of glucose (mean) decreased to 6.5 mmol/L and higher than that of Nutritional product, as of 5.5 mmol/L. Then at min 120: there is significant difference ($p >0.05$) :responses of blood glucose (mean)- Nutritional product, with that of the reference food.

We analyzed that:

- Almost there is 2-fold range (responses of blood glucose), between 2 foods with test food, despite of same amount containing in each portion. So, compared to the reference food (Glucose), it creates smaller increase.

Table 3. Features of the subjects

Characteristics	Men *(n=8)*	Women *(n=3)*	Both sexes *(n=11)*
	X ± SD	X ± SD	X ± SD
Age *(years)*	24.0 ± 0.3	23.0 ± 1.2	23.7 ± 0.4
Weight *(kg)*	60.2 ± 2.4	49.1 ± 1.6	
Height *(cm)*	169.9 ± 3.2	154.2 ± 1.5	
BMI *(kg/m²)*	20.8 ± 0.5	20.6 ± 0.4	20.7 ± 0.3
Fasting Blood Glucose Level *(mmol/L)*	5.1 ± 0.1	5.3 ± 0.1	5.1± 0.1

Table 4. Levels of Postprandial blood glucose in post-consuming Glucose solution & Nutritional product

Time	Postprandial blood glucose *(mmol/L)*		
	Glucose	Nutritional product	*p-value**
0 min	5,4 ± 0,1	5,2 ± 0,1	*0,2*
15 min	6,5 ± 0,2	5,9 ± 0,2*	*0,026*
30 min	7,6 ± 0,2	7,0 ± 0,2	*0,108*
45 min	7,3 ± 0,3	6,4 ± 0,3	*0,082*
60 min	6,5 ± 0,3	5,5 ± 0,3	*0.061*
90 min	5,8 ± 0,3	4,7 ± 0,2*	*0,01*
120 min	5,4 ± 0,3	4,3 ± 0,3*	*0,03*

**Mann-Whitney U test*

3.3 A Index of Glycemic GI)- Nutritional Product

We see: changes in members' blood glucose for 2 hours were reflected by iAUCs, during post-consumption of different test meals. There is variation among all members in iAUCs post-drinking Nutritional product and post- drinking glucose (see Fig. 2). But then a common trend shown in their results. We see the iAUC for glucose solution for each member: significantly bigger than their iAUC for Nutritional product.

We recognized that:

- iAUC of Nutritional product mean value as of 66.7 ± 11.7 mmol·min/L, lower (considerably) compared to the reference food (132.0 ± 18.8 mmol·min/L). Also compared to reference food (GI=100), GINP (Mean ± SD) mean value as of 48.2 ± 5.3, so lower significantly (see Table 5).

We analyzed that:

- Responses of blood glucose to the same food, fluctuated among various members. This is because of natural differences, I.e weight and metabolism.

- Using reference food (for calculating GI) cause reduction in variation among subjects' blood glucose, as a result, the same food arising from those differences.

- Moreover, We recognized that iAUCNp iAUCGluco - mean value, GINp among male members as of 134.8 ± 21.5 (mmol-min/L), 66.5 ± 11.1 (mmol-min/L), 49.9 ± 5.6, accordingly and iAUCNp iAUCGluco mean value, GINp among female members as of 124.8 ± 46.6 (mmol-min/L), 67.3 ± 36.8 (mmol-min/L), 43.5 ± 14.1. Then we see: iAUCNp, iAUCGluco, and GINp mean values between men and women: there is no statistical difference (see Table 5).

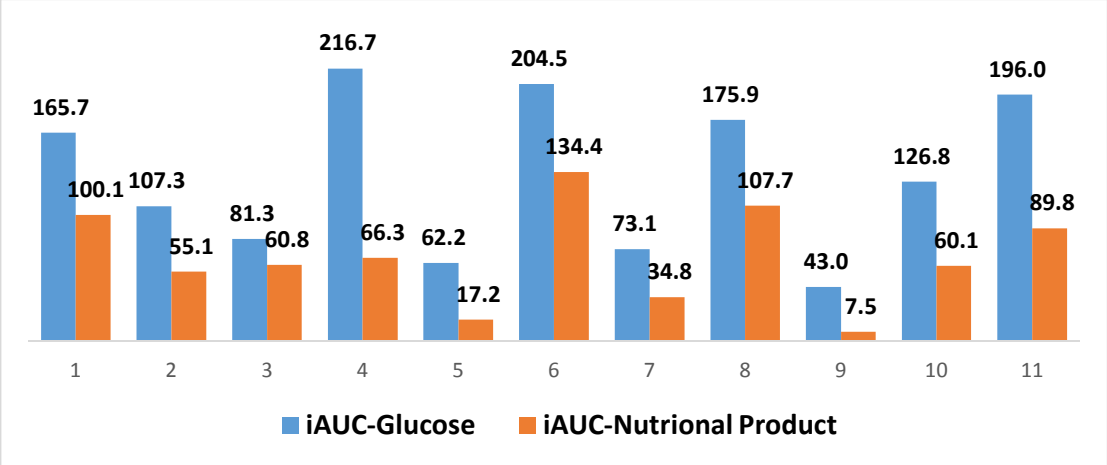

Fig. 2. Area of incremental under curve (iAUC) post-consumption Glucose solution & Nutritional product of all members

Table 5. The GLucose and iAUC and GI - Nutritional product

Index	Mean (95% CI)	Men *(n=8)*	Women *(n=3)*	p-value*
		X ± SD	X ± SD	
iAUC Np (mmol-min/L)	66,7 ± 11,7	66,5 ±11,1	67,3± 36,8	0,84
iAUC Glucose (mmol-min/L)	132,0 ± 18,8	134,8 ± 21,5	124,8 ± 46,6	0,84
GI Np	48,2 ± 5,3	49,9 ± 5,6	43,5 ± 14,1	0,68
Margin of Error *(%)*	11%			

**Mann-Whitney U test*

4. DISCUSSION

Our study has revealed that:

- Firstly, at all points of measurement in 2 hrs, a bigger variation of inter-subject of responsding blood glucose, than to nutritional product.
- Secondly, At min 30 it - baseline value has reached the peak (I.e, levels of blood glucose) and we see it lower than baseline value at min of 120,
- Thirdly, we found out there is decrease (slow) of responses of mean blood glucose (Nutritional product) after 90 minutes (4.7 mmol/L) till 120 minutes (4.3 mmol/L).

As we conduct this paper with younger subjects, comparing to older people, they can regulate blood sugar better.

In this study we discover a low GI of nutritional product, as of (48.2 ± 5.3). When we compare impact of hyperglycemic of a tested meal with a standard food, the vital parameter can be The GI. And manufacturer using isomalt sugar to replace maltodextrim, lactose with more inulin : might be the cause (*Appendix: Nutrition facts of Test food*).

Until now, The Diabetes Associations in worldwide pointed that: firstly, GI as indicator to classify rich carbohydrate food; and secondly, for clinical nutrition, a low or moderate GI foods suggested to use, which prove meaning of using low and moderate Nutritional products (like in the study) as ideal to prevent NCDs, and as potential product to control posprandial blood glucose (in case of Vietnamese). In this paper, multivariate statistical analysis were not be used. While GI method, accoording to Bronus et al, measurement of glucose as enough, and until now, most GI studies not measuring responses of postprandial insulinemic going with responses of the glycemic for examined test food. In order to investigate issues of health, it is valuable with introduction of a concept of insulinemic index.

5. CONCLUSION

With 2 testing experiments, together with support of 11 participants via clinical trial, this is foundation to draw our conclusion as below:

> *First, levels of blood glucose during post-consuming test food lower than post-consuming reference food, at all points.*
>
> *Second, Study recognized that Nutritional product (GI = 48.2) was as a low – GI food. This is low GI value for nutritional product.*

Other supporting solutions including: Last but not least, Pham Thi Bich Ngoc, Hoang Thi Minh Thai, Dinh Tran Ngoc Huy (2021) also mentioned roles of nurses and nursing is important in taking patients' healthcare [6]. And Huy, D.T.N (2015) also mentioned management principles in order to manage better companies such as hospitals for serving better patients or clients [7].

DISCLAIMER

The company name used for this research is commonly and predominantly selected in our area of research and country. There is absolutely no conflict of interest between the authors and company because we do not intend to use this company as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the company rather it was funded by personal efforts of the authors.

ETHICAL APPROVAL AND CONSENT

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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APPENDIX

Nutrition facts of Test food (Nutritional product, Vietnam):

No	Ingredients	Unit	Power per 100 g
1	Energy	Kcal	339
2	Protein	g	21
3	Lipid	g	15
4	MCT	g	1.3
5	Inulin	g	1.6
6	Isomalt	g	60
7	Prenulin	g	0.5
8	Acid alpha lipoic	g	0.05
9	Nanocurcumin	mg	50
10	Extractum Gymnematis sylvestris	g	1
11	Colostrum	mg	300
12	Lysine	mg	311.5
13	Taurine	mcg	43.3
14	MUFA	mg	105
15	PUFA	mg	115
16	Phosphorus (P)	mg	317
17	Calcium (Ca)	mg	600
18	Potassium (K)	mg	206.8
19	Sodium (Na)	mg	59.3
20	Magnesium (Mg)	mg	23.1
21	ZinC (Zn)	mg	1.48
22	Iron (Fe)	mg	3.02
23	Iode	mcg	15.6
24	Mangan (Mn)	mcg	1.93
25	Copper (Cu)	mcg	18.5
26	Vitamin A	IU	460.1
27	Vitamin D3	IU	49.3
28	Vitamin E	IY	1.18
29	Vitamin B1	mg	0.5
30	Vitamin B2	mg	0.75
31	Vitamin B3	mcg	1.133
32	Vitamin B5	mg	0.83
33	Vitamin B6	mcg	0.25
34	Acid Folic	mcg	50
35	Vitamin B12	mcg	0.8
36	Vitamin K1	mcg	18
37	Vitamin C	mg	50

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