

A CLINICAL TRIAL ON THE GLYCEMIC INDEX (GI) OF IR50404 BROWN RICE

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The objective was to determine the glycemic index (GI) of cooked IR50404 Brown Rice (BR) through measuring glycemic responses to reference food (Glucose) and test food (cooked IR50404 BR) among twelve participants. The study was a self-controlled clinical trial with 12 qualified participants (6 men and 6 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 food. The incremental area under the curve (iAUC) and a GI value of IR50404 BR were calculated for each meal. Mean \pm SD of GI value was calculated for test food for the combined group of subjects. Mean iAUC and GI value of IR50404 BR were 100.3 ± 56.7 mmol·min/L and 51.6 ± 14.7 , significantly lower to those of reference food, which were 190.6 ± 73.3 mmol·min/L and 100, respectively. Finding from the study demonstrated that IR50404 BR (GI = 51.6) would be classified as a low – GI food.

Keywords: Clinical trial, glycemic index, IR50404 brown rice

I. 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 425 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 352.1 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 628.6 million people inflicted by 2045.²

In recent years, the burden of non-communicable diseases (NCDs), including diabetes, in Vietnam has drastically increased. Diabetes was more prevalent in big cities,³ with rates of both prediabetes and diabetes accelerating at alarming rates.⁴ Surveys from the early 1990s showed that the prevalence of diabetes 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

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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

Rice is ranked third among world's leading cereal crops,⁶ and also serves as the primary staple food in the Asia – Pacific Region; the region contributes to over 90% of the world's rice production and consumption. In Vietnam, rice plays an indispensable role in national food security and agriculture. Rice is the country's main crop, accounting for more than 90% of total cereal production. Rice also has a direct effect on social security because it is consumed by more than 90 million people and an important source of income for more than 60 million people living in agricultural and rural areas. In Southeast Asia, the Vietnamese consumed the second most of their rice production,⁶ while Thai people consumed only approximately 55% of their rice production.⁷ According to the General Nutrition Survey in 2010, the total daily consumption of rice was more than 370 grams/person.⁸ Therefore, rice has significant nutrition and health implications.

Although IR50404 BR is considered to have low economic value, it has been favoured by farmers and developed widely in Vietnam for years because of its outstanding characteristics, such as short growth duration, high and stable yield, acid sulphate soil – tolerance, and resistance to pests. The study was conducted to determine the GI of cooked IR50404 BR through measuring glycemic responses to reference food (Glucose) and test food (cooked IR50404 BR) among twelve selected participants. The importance of IR50404 rice 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.

II. METHODS

1. Study subjects

12 healthy students of Hanoi Medical University were selected using the following criteria: 1) between 20 – 25 years of age, 2) body mass index (BMI): $18.5 \leq \text{BMI} < 23 \text{ kg/m}^2$, 3) fasting blood glucose level under 5.6 mmol/L, 4) voluntarily agree to participate in the study. Subjects were excluded if they met one or more of the following criteria: 1) individuals who had recently been diagnosed with impaired glucose tolerance or any acute/chronic conditions, 2) individuals who were consuming medication or drugs known to have influences on carbohydrate metabolism, 3) women who were pregnant or currently breastfeeding.

2. Study design

Time and location: Our study was conducted from December, 2018 to April, 2019 at Vietnam National Institute of Nutrition.

Study design: This was a self-controlled clinical trial with crossover experiments to determine the glycemic index of IR50404 Brown Rice 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)⁹ and was in line with the procedure recommended by the Food and Agriculture Organization of the United Nations (FAO).¹⁰

Sample size: According to international standard [TCVN 10036:2013 (ISO 26642:2010),⁹ 5.31], 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, 12 participants were recruited from 35 screened volunteers.

Reference meal: Glucose solution with 50g sugar diluted in 200ml water.

Test meal: The type of rice tested was IR50404 BR (Vietnam). The rice-to-water ratio followed the cooking instruction from the manufacturer. The rice was gently washed, then cooked using a common rice-cooker. Before the real test, the cooked rice was tested twice to check its stability.

All the meals were prepared early in the morning of the test days at Department of Clinical Nutrition and Dietetics – National Institute of Nutrition.

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

	Reference meal (Glucose)	Test meal (IR50404 BR, boiled)
Weight (g)	50	146
Energy (kcal)	200	242
Available carbohydrate (g)	50	50
Protein (g)	0	5.5
Fat (g)	0	2.2

Study variables and data collection:

Table 2. Study variables

Variables	Indicators	Data collection method
Characteristics	General information	Name
		Age
		Gender
	Medical history	Questionnaire
	Anthropometric	Body weight
		TANITA digital scale
		Height
	BMI	SECA Stadiometer 217
		$BMI \left(\frac{kg}{m^2} \right) = \frac{Weight (kg)}{Height^2 (m^2)}$
Glycemic Response	Blood pressure	
	Electronic blood pressure monitor (Omron HEM 700)	
	Heart rate	
	Count the number of pulse beats in 60 seconds.	
	Screening fasting blood glucose level	
	Capillary blood samples were determined by the Accu-Chek Glucometer	
	Blood glucose response	Fasting
		After 15 min
		After 30 min
		After 45 min
		After 60 min
		After 90 min
		After 120 min
	Venous blood samples were analysed by the automatic biochemical machine AU480 (Beckman Coulter company, Germany)	

Variables	Indicators	Data collection method
Glycemic Index	Incremental area under the blood glucose curve value for IR50404 Brown Rice ($iAUC_{Rice}$)	The incremental area under the blood glucose curve ($iAUC$) was computed by the trapezoidal method.
	Incremental area under the blood glucose curve value for Glucose ($iAUC_{Glucose}$)	
	Glycemic index of IR50404 Brown Rice (GI_{Rice})	$GI_{Rice} = \frac{iAUC_{Rice}}{iAUC_{Glucose}} \times 100$

Study procedures:

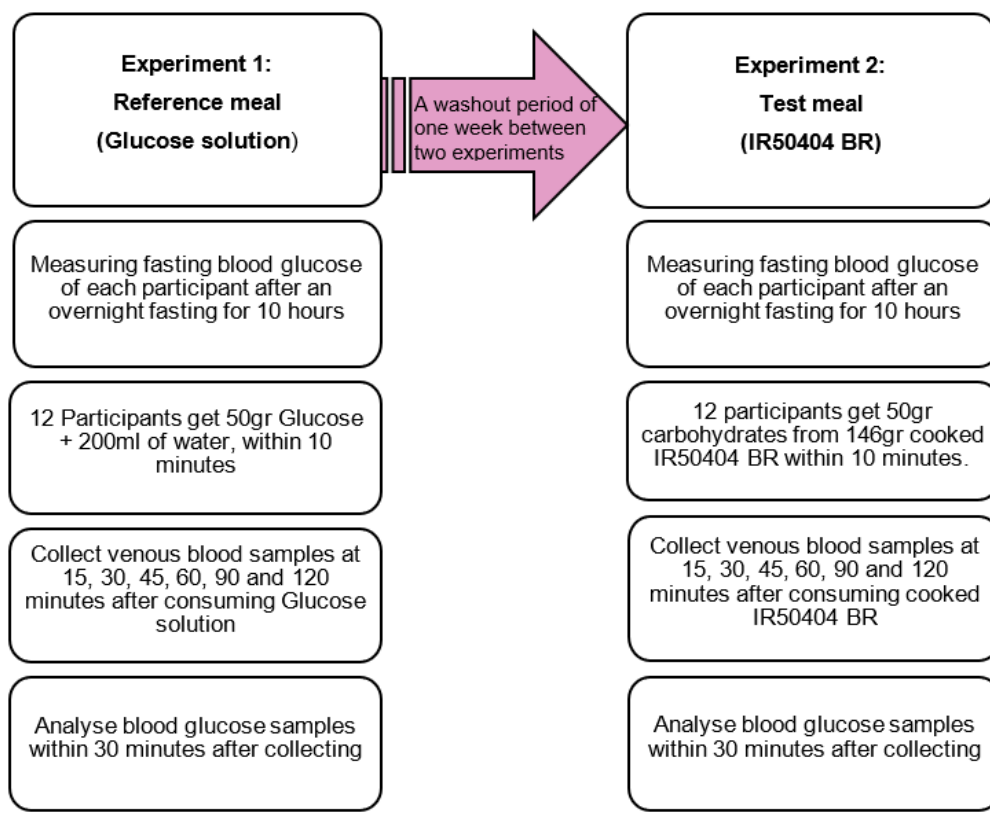


Figure 1. Study procedures

3. Data analysis

Statistical analysis was performed using Stata software version 14.0. We used descriptive statistics to characterize the study sample, continuous data were presented as mean \pm standard deviation (SD). Due to the small sample size ($n = 12$), 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 $p < 0.05$.

4. Ethics

Ethical approval of this study was obtained from National Institute of Nutrition Ethics Committee (Approval number: 137/VDD -

QLKH). 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.

III. RESULTS

1. Characteristics of Subjects

Table 3. Characteristics of the subjects

Characteristics	Men (n = 6)		Women (n = 6)		Both sexes (n = 12)	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	22.5	1.8	20.7	1.0	21.6	1.7
Weight (kg)	62.2	6.3	48.8	2.4	-	-
Height (cm)	169.6	3.3	155.7	3.4	-	-
BMI (kg/m ²)	21.6	2.0	20.1	0.8	20.9	4.7
Heart Rate (BPM)	72.2	7.9	74	10.4	73.1	8.8
Systolic (mmHg)	119.7	9.6	106.2	5.5	112.9	10.3
Diastolic (mmHg)	72.3	4.8	67.2	2.5	69.8	4.6
Fasting Blood Glucose Level (mmol/L)	4.75	0.3	4.6	0.7	4.7	0.5

Twelve healthy volunteers participated in this study. The subjects were comprised of six men and six women. Their mean age and BMI were 21.6 ± 1.7 years and 20.9 ± 4.7 kg/m², respectively. Table 3 also showed that all participants had normal heart rates, blood pressures and fasting blood glucose levels.

2. Glycemic response to cooked IR50404 Brown Rice

Results of postprandial blood glucose levels of the reference meal compared to test meal among twelve volunteers were presented in Table 4.

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, there was an overlapping of mean fasting blood glucose responses between

glucose and IR50404 BR (5.2 mmol/L), indicating that there was no significant difference between them ($p > 0.05$). Next, at minute 15, the blood glucose response of IR50404 Brown Rice was 5.6 mmol/L. Compared to the reference food (6.3 mmol/L), the difference was significant ($p < 0.05$). Following that, mean blood glucose response of IR50404 BR measured at minute 30 showed a significant difference with that of reference food as well ($p < 0.05$). The mean blood glucose of IR50404 BR was 7.2 mmol/L while the value of glucose was 7.8 mmol/L. A steady rise in blood glucose was evident after ingestion of reference and test meals with the peak reaching at minute 45. The mean peak value of IR50404 (7.3 mmol/L) was lower than the reference meal glucose (8.1 mmol/L), but the difference between them was

not significant ($p > 0.05$). Findings from this study demonstrated that at minute 60, mean blood glucose response of reference food was reduced to 7.4 mmol/L and significantly higher than mean blood glucose response of IR50404, which was maintained temporarily at 6.3 mmol/L. Subsequently, at minute 90, mean blood

glucose response of IR50404 was significantly reduced to 5.4 mmol/L and significantly lower than the reference food (6.4 mmol/L). Finally, at minute 120, mean blood glucose responses of IR50404 showed no statistically significant difference with that of the reference food ($p > 0.05$).

Table 4. Postprandial blood glucose levels after consumption of Glucose solution and cooked IR50404 Brown Rice

Time	Postprandial blood glucose (mmol/L)		
	Reference meal (Glucose)	Test meal (Cooked IR50404 BR)	p-value*
0 min	5.2 ± 0.4	5.2 ± 0.4	0.9769
15 min	6.3 ± 0.5	5.6 ± 0.4	0.0015
30 min	7.8 ± 0.7	7.2 ± 0.6	0.0496
45 min	8.1 ± 0.8	7.3 ± 1.2	0.0831
60 min	7.4 ± 1.1	6.3 ± 1.1	0.0209
90 min	6.4 ± 0.8	5.4 ± 0.7	0.0072
120 min	5.1 ± 1.2	4.9 ± 0.4	0.5636

*: 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 (IR50404 BR) creating a smaller increase in blood glucose response compared to the reference food (Glucose).

3. The glycemic index (GI) of cooked IR50404 Brown Rice

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 eating the cooked IR50404 BR 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 cooked IR50404 BR, despite the fact that the portions had the same amount of 50 grams of carbohydrates.

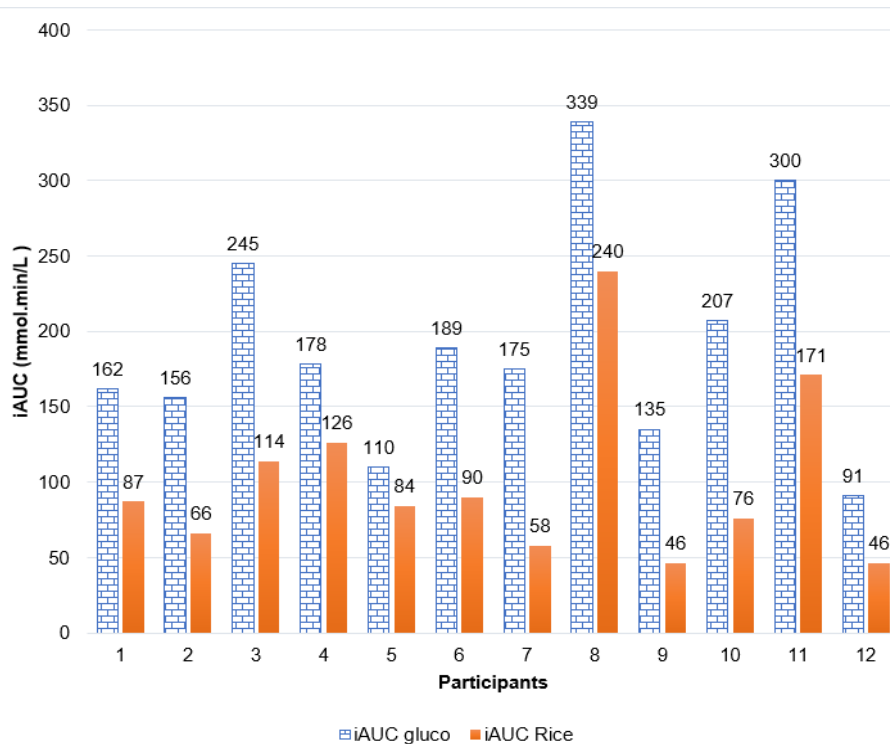


Figure 2. The incremental area under curve (iAUC) after consuming Glucose solution and IR50404 Brown Rice of all participants

As shown in Table 5, the mean iAUC value of IR50404 BR was 100.3 ± 56.7 mmol·min/L, significantly lower compared to the reference food (190.6 ± 73.3 mmol·min/L). The mean value of GI_{Rice} (Mean \pm SD) was 51.6 ± 14.7 , which was significantly lower than the reference food ($GI = 100$).

Table 5. The iAUC and GI of IR50404 Brown Rice and Glucose

	Mean (95% CI)	Men	Women	p*
$iAUC_{Rice}$ (mmol×min/L)	100.3 ± 56.7 (67.5 – 133.1)	95.3 ± 73.2	105.3 ± 40.6	0.3358
$iAUC_{Glucose}$ (mmol×min/L)	190.6 ± 73.3 (142.8 – 225.5)	170.0 ± 89.6	211.2 ± 52.7	0.1495
GI_{Rice}	51.6 ± 14.7 (43.2 – 60.2)	53.6 ± 16.5	49.6 ± 13.9	0.6310

*: Mann – Whitney U test between men and women

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 $iAUC_{Rice}$, $iAUC_{Glucose}$, GI_{Rice} among male participants were 95.3 ± 73.2 (mmol·min/L), 170.0 ± 89.6 (mmol·min/L), 53.6 ± 16.5 , respectively. The mean $iAUC_{Rice}$ and $iAUC_{Glucose}$ values were higher among female participants

(105.3 ± 40.6 mmol·min/L and 211.2 ± 52.7 mmol·min/L, respectively). However, the mean GI_{Rice} among female participants was lower (49.6 ± 13.9). There were no statistical differences in the mean $iAUC_{Rice}$, $iAUC_{Glucose}$, and GI_{Rice} values between men and women ($p > 0.05$).

IV. DISCUSSION

Findings from this study indicated that there was a significantly greater inter-subject variation of blood glucose response to glucose solution than to IR50404 BR at all measurement intervals up to 2 hours. The blood glucose levels rose consistently from the baseline, reached the peak at minute 45, decreased, and lowered than the baseline value at minute 120. We also observed a slow reduction of mean blood glucose responses of IR50404 BR after 90 minutes (5.4 mmol/L) until 120 minutes (4.9 mmol/L). This situation was vital in prolonging satiety duration of participants after ingestion of brown rice. These results were in line with results from Bui Thi Nhung et al. That study was designed to evaluate the effect of a 4 - month pre-germinated brown rice (PGBR) administration on various parameters in Vietnamese women aged 45 – 65 years with impaired glucose tolerance (IGT). Sixty subjects were divided into white rice (WR) or PGBR group. In the PGBR group, blood glucose was ($p < 0.0001$) significantly reduced after intervention (5.31 mmol/L) compared to the baseline (6.05 mmol/L). In the WR group, the results found no reduction but an increase from 5.73 mmol/L to 5.89 mmol/L ($p = 0.246$).¹¹ In the study mentioned above, the results of the fasting blood sugar concentration were higher than ours (6.05 mmol /L compared to 4.7mmol/L). It was possibly due to differences in age of subjects between 2 studies (45 - 65

years of age compared to 20-25).¹¹ Since our study included younger subjects, they likely were able to regulate blood sugar better than older individuals. On the other hand, this difference could be explained by the different criteria for selecting subjects between 2 studies.

The results of glycemia changes over time of subjects in our study were also lower than those in Nghiem Nguyet Thu's study using Vibigaba 2 Rice.¹² In our study, changes in postprandial blood glucose after ingestion of IR50404 BR in comparison to the baseline were recorded as increases of 0.4 ± 0.0 mmol/L after 15 minutes, 2.0 ± 0.1 mmol/L after 30 minutes, 2.1 ± 0.7 mmol/L after 45 minutes, 1.1 ± 0.6 mmol/L after 60 minutes, 0.2 ± 0.2 mmol/L after 90 minutes, and a final decrease of 0.3 ± 0.1 mmol/L after 120 minutes; while these data in the study using Vibigaba 2 Rice were 1.2 ± 0.7 , 2.4 ± 0.8 , 2.2 ± 1.2 , 1.2 ± 0.8 , 0.2 ± 1.3 , 0.4 ± 0.7 , respectively. This finding indicated that the carbohydrate metabolism of IR50404 Brown Rice was slower than that of Vibigaba 2 Rice at the same time after eating rice cooked from these two types of rice. The reason was probably due to the difference not only in the composition of protein and fat, but also in the quality of carbohydrate content between these two types of rice.

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 IR50404 BR had low GI value (51.6 ± 14.7). Many studies have shown large variations in the GI of rice, and consequently, these findings have led to large disagreements as to whether rice should be considered a high or low GI food. The great difference in GIs of rice is thought to be due to a number of reasons. Some studies have shown

that the classification of rice as low or high GI food appeared to mainly depend on the amylose content of the commercial varieties.¹³ Miller et al determined the GI of white and brown varieties of three rice varieties (Doongara, Calrose, and Pelde) and concluded that rice with a high amylose fraction of about 28% produced a lower blood glucose and insulin response. Doongara, a high amylose rice (28% amylose rice) produced significantly lower GIs for both the white (GI = 64) and brown types (GI = 66). The other two medium amylose (20%) varieties, Calrose and Pelde, had higher GI values (Calrose WR – 83, Calrose BR – 87, Pelde WR – 93, Pelde BR – 76).¹⁴ Findings from a study on three common varieties of Bangladeshi rice by Fatema et al also confirmed these results. The amylose content of the three tested rice samples (BR - 14, BR - 29 and BR - 44) were 27, 29.4 and 27.2% respectively and they could be categorized as having low GI values of 54.5, 50.3, 43.1, respectively.¹⁵ Studies conducted on local rice varieties showed similar trends. White basmati rice, a popular Indian rice with a medium amylose content (20 – 25%) had a GI around 50 – 58.¹⁶

Food processing methods also effect the GI of the final product. In this study, IR50404 BR was eaten in the boiled form as rice is predominantly boiled in daily life. It is evident that the method of cooking directly correlates with digestibility and the glycemic response. In a study among Vietnamese processed rice products, Tran Quoc Cuong et al reported that red rice and sticky rice had high GIs (75.1 ± 8.9 and 79.7 ± 4.3 respectively) while steamed, thin rice pancakes, rice vermicelli and broken rice had low GI values (the GI are 38.7 ± 4.4 ; 51.2 ± 5.1 & 53.0 ± 6.6 respectively) 17. In addition, Ranawana et al stated that a longer cooking time elicited greater glycemic responses as

well as GI values 16. In high temperature for a long period, the carbohydrate structure would changed. White basmati rice cooked for 10 minutes and had a low GI of 50, but basmati and wild rice, brown and white basmati rice, cooked for 25 minutes, were considered high GI foods.¹⁶

To date, previous studies in human has indicated that brown rice was a better selection to prevent glycemia after meal and intolerance of blood glucose, type 2 diabetes.^{18,19,20} Until now, diabetes associations 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 GI rice varieties, such as IR50404 Brown Rice in this study, are ideal to prevent NCDs, and it would be a promising product in controlling postprandial 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 concept²¹ could be value in investigating health issues. Therefore, measurement of both glucose and insulin was recommended for more metabolic studies.²²

V. CONCLUSION

Based on the clinical trial of 12 participants through 2 experiments, we concluded:

The glycemic response after consumption of 50 grams carbohydrate from cooked IR50404 Brown Rice was lower than after consumption

of 50 grams carbohydrate from glucose at all time points of the experiments.

Finding from the study demonstrated that IR50404 Brown Rice is a low – GI food with a GI value of 51.6.

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