EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 4
Issue: 6
324-329
Year: 2017

EFFECT OF THREE VARIANTS OF BRAND 1(LOCAL) MUESLI IN COMPARISON WITH THE THREE VARIANTS OF BRAND 2 (INTERNATIONAL) MUESLI & CORNFLAKES ON POSTPRANDIALBLOOD GLUCOSE, IN HEALTHY ADULT SUBJECTS: A RANDOMIZED CROSSOVER TRIAL

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Article Received on 21/03/2017 **Article Revised on 12/04/2017** **Article Accepted on 03/05/2017**

ABSTRACT
Compare the efficacy of three variants of brand 1 (Local) muesli in comparison with the three variants of brand 2 (International) muesli &cornflakes on the rate of postprandial blood glucose &GI in adult healthy subjects. Subjects came to the site post 10-12 hours of overnight fast and stayed there at least for a period of 2 hours. The subjects were given the test/reference food once and the standard food thrice on separate days. The gap between any two visits was at least 72 hours to minimize carry-over effects. Capillary blood samples were collected and blood glucose readings were noted down, at eight different time points i.e. -5mins, 0mins (Averaged to obtain Fasting Blood glucose reading), 15mins, 30mins, 45mins, 60mins, 90mins and 120mins to measure GI (glycemic index).From the blood glucose levels, incremental area under the glucose response curve and the glycemic index have been obtained for the each foods. GI value of the three local brands of muesli was found to be 54.74 (SEM 2.17), 52.79 (SEM 2.39), 49.89 (SEM 2.38) respectively, thus, placing it in low GI category.GI value of Cornflakes was found to be 78.21 (SEM 3.78) thus, placing it in high GI category.GI value of the three international brand of Muesli was found to be 60.48 (SEM 2.75), 58.84 (SEM 2.82) ,60.26 (SEM 3.24) respectively thus, placing it in intermediate GI category. On the basis of the results this study indicates that Local brand muesli has lower GI than international brand muesli & cornflakes.

KEYWORD: Glycemic index, Muesli, Cornflakes, postprandial blood glucose, Low- GI food, High- GI food.

INTRODUCTION
Carbohydrates are the main source of energy in the properly balanced diet. If we required to in taking 50% to 70% of energy from carbohydrates containing food, it consists of 10 to 20% of calories from natural sugars and more than 10% of added sugars. The GI of carbohydrate is determined and classified based on a standardized procedure recognized by International Standards Organization.[1] It is defined as the incremental AUC of 2-h blood glucose response after the consumption of fixed amount, usually 50 g, of available carbohydrates of a test food expressed as percentages of the response to the same amount of carbohydrates from either white bread or glucose.[2-5] The GI of food is arbitrarily classified as low if it is <55, intermediate if the value is between 56 and 69 and high if >70, when compared with glucose as the reference.[1]

A Recent study suggest that the general curve shape of low and high-GI foods are nearly too similar, although the highest glucose peak and iAUC values are different between them.[6] High GI foods are rapidly digested and absorbed, resulting in high glycemic response, which stimulates higher insulin secretion. High glycemic and insulinemic leads to postprandial hyperinsulinemia along with an increase in both hunger and voluntary food intake, favoring body weight and body fat gain.[7, 8] A better response on postprandial glucose by low GI food is that a slight increase in circulation level of insulin and gastrointestinal hormones. Therefore, satiety is increased and voluntary food intake is reduced.[7,8] This suggests that a low-GI diet may provide some level of prevention against developing diabetes[9] and obesity[10] and for managing existing CVD[11], some forms of cancer[12] and appetite control.[13,14]

The intake of dietary fiber delays the gastric emptying in healthy subjects.[15] Generally, fiber-rich foods have a low GI, but not necessary that food having low GI has high fiber content. The previous study has shown that

Muesli containing 4 g of beta-glucan has reduced postprandial glucose and insulin levels to breakfast based on high GI products.[16] The glycemic index can be used to find out information about food composition, for practical prospective; and is useful to rank foods by developing a list of categories of low glycemic index foods, such as pearled barley, light refined grains (e.g. whole grain pumpernickel bread, or bread made from coarse flour). Pasta, brown rice puffed rice comes under high GI index food. Low GI foods may not be a good choice of food because they are high in fat. Same as high GI foods may be a good choice because of convenience or have low energy as well as high nutrient content. It is not necessary to avoid all high GI foods.

Meals containing low GI foods reduce both postprandial blood and insulin responses. Some animal studies suggest that integrating slowly digested starch in the diet it delays the onset of insulin resistance. One of epidemiology studies suggest that low GI diet is accompanying to reduce a risk of developing non-insulin diabetes in human. A clinical trial in normal, diabetic and hyperlipidemic subject shows that low-GI diets reduce mean blood glucose concentration, reduce insulin secretion and reduce serum triglycerides in individuals with hypertriglyceridemia. Digestibility of the carbohydrate in low GI food is generally less then high GI foods.[17]

Definition of glycemic index (GI)

The glycemic index is defined as the incremental area under the blood glucose response curve of a 50g carbohydrate portion of a test food expressed as a percent of the response to the same amount of carbohydrate from a standard food taken by the same subject. The current study was performed to compare the GI values of three variants of a local brand of Muesli with that of three variants of an international brand of Muesli and on the international brand of cornflakes.

SUBJECTS AND METHODS

Subjects

In these studies approximately 40-50 subjects were screened to get at least 30 evaluable subjects. The potential subjects were screened as per the inclusion and exclusion criteria only after obtaining written informed consent from each subject. Normal healthy adult subjects of both sex without any medical conditions with body mass index between 18.5 and 22.9kg/m^2 and fasting blood glucose below 100 mg/dl were enrolled in the study. Subjects, suffering from Diabetes Mellitus, liver or thyroid disorders, hyperlipidemic individuals, with a family history of type 2 diabetes any medication consumption in the past one week or suffering from any illness, any form of dieting or consumption of a special diet were excluded from the study. Subjects were abstained from alcohol and caffeine containing drinks for at least 12 hours prior to the blood glucose monitoring and instructed to avoid intense physical activity for at least 24 hours prior to blood glucose monitoring. No concomitant medications were allowed during the study.

METHODS

This study was conducted in accordance with ICH-GCP, DOH and applicable regulatory requirement and written approval were taken from ethics committee. At each visit, subjects arrived at the study centre after fasting (except for water) for 10-12 hours overnight. The subjects were provided with the test /reference food once and the standard food thrice on separate days. Glucose (as a standard food this translates) was prepared by dissolving 25 g of glucose powder in 200mL of water to prepare a solution with 25g of available carbohydrate content. Glucose solution was given to the subjects to consume on three different days after a gap of 72 hours. The test/reference breakfast meals have been served to participants after a gap of 72 hours, for each product respectively. Subjects were given skimmed milk along with the test/reference product. Along with this subjects were asked to consume 200mL of water in 10-12mins.Each subject acted as his or her own control. The gaps between any two-test days have been at least 72 hours to minimize carry-over effect.

The study was conducted total 28+ 2 days. On day of Screening Visit 1, to taken informed Consent form to each individual subject, to check inclusion exclusion criterial of subject, medical/surgical history, demography, anthropometry (Including Height, weight, BMI, and waist circumference, physical examination, vital signs (BP, pulse, temperature), urine Pregnancy test, Concomitant medications (if any) laboratory assessments, fasting Blood Glucose were perform. During Visit 2, 3 and 4 base line glucose were measured. And visit5 to visit11 consider as treatment visit to given study meal to each eligible subjects and to obtain glycemic index of each subject respectively. If subjects were undergoing any adverse events, it was recorded and reported to the ethics committee.

Randomization procedure

The randomization for a study was generated using the PROC PLAN on statistical software SAS® 9.2 or higher version. A randomization allocation of 1:1:1:1 were used to assign subjects to any of the four groups. All subjects enrolled in the study were given a randomization number, which was remained same throughout the study.

The randomized subject was received any of the products mentioned below

Arm 1 - Consuming Muesli 1
Arm 2 - Consuming Muesli 2 } Local Brand
Arm 3 - Consuming Muesli 3
Arm 4 - Consuming Muesli 4
Arm 5 - Consuming Muesli 5 } International Brand
Arm 6 - Consuming Muesli 6
Arm 7 - Consuming Cornflakes

Experimental Meal

The experimental cereals were a two different brand Muesli and Cornflakes. These cereals are used because it is very popular breakfast cereals. Each experimental meal provided 25 g of available carbohydrate. This amount of meal and milk were shown in table no. 1.

Table 1: Product dispensed calculations

Local Brand

Variant	Net wt. (g)	Skimmed Milk (ml)	Available CHO (muesli)	Available CHO (skimmed milk)	Total available CHO
Muesli 1	31	120	19.5	5.5	25
Muesli 2	30	120	19.7	5.5	25.2
Muesli 3	30	120	19.5	5.5	25

International Brand

Variant	Net wt. (g)	Skimmed Milk (ml)	Available CHO (muesli)	Available CHO (skimmed milk)	Total available CHO
Muesli 4	30.0	90.0	23.0	4.2	25.4
Muesli 5	28.0	84.0	22.5	3.9	25.3
Muesli 6	30.0	90.0	23.0	4.2	25.6

Cornflakes

For 25 g Available CHO	Quantity	CHO/100g	Total CHO	Available CHO
Cornflakes(g)	23	26.1	21.4	20.8
Skimmed milk (ml)	92	5.5	4.2	4.2
Total	-	-	25.7	25.0

Blood Sampling: During study capillary blood samples were collected and blood glucose readings were noted down as per the glucometer at eight different time points i.e. -5mins, 0mins (Averaged to obtain Fasting Blood glucose reading), 15mins, 30mins, 45mins, 60mins, 90mins and 120mins.. Capillary blood samples have been used in order to improve sensitivity and to remove the potential for variations in measured GI due to fluctuations in factors such as ambient temperature. Prior to a finger-prick, subjects were encouraged to rub their hands to increase the blood flow. Fingers were not squeezed to extract blood from the fingertip in order to minimize plasma.

Statistical analysis: Statistical analyses was conducted using Microsoft Excel Spread Sheets and on statistical software SAS® 9.2 or higher version. Glycemic index data, the area under the curve was calculated as the incremental area under the blood glucose response curve (iAUC), ignoring the area beneath the fasting concentration. This was calculated geometrically by applying the trapezoid rule. For the standard food (glucose solution) that was administered on 3 occasions, the mean iAUC was calculated. Levels of inter and intra-individual variation of the three reference glucose was assessed by determining Co-efficient of Variation (CV %) and ones above 30% were excluded.

GI of the food for each subject was obtained from the following:

$$\text{GI value of test/reference food (\%)} = \frac{\text{iAUC of test/reference food}}{\text{Mean iAUC of glucose}} \times 100$$

Individual GI values for any subject that were greater than two standard deviations for the mean of the group (Mean + 2 S.D.) were considered as outliers.

Results were expressed as mean± SEM.

RESULTS

A total of 39 subjects completed the study and the data of 39 subjects was considered for statistical analysis. Those subjects had CV above 30% and had GI beyond the range of Mean + 2 SD hence were excluded from analysis.

Demographics and Physical characteristics

The physical characteristics of the study subjects are mentioned in the Table 3.

Table 2: Demographic data analysis

Parameters	
No. of Subjects enrolled	**40 (21 Females, 19Males)**
Age(yrs.)	
Mean	24.43
SD	6.86
Range	19-43
Median	21
Weight(Kg)	
Mean	52.31
SD	6.62
Range	39-74
Median	51
BMI (kg/m^2)	
Mean	20.35
SD	1.41
Range	18.5-22.9
Median	20.15

Glycemic response of food: The mean incremental areas under the glycemic response curves for the standard and test foods are shown in Figure 1.

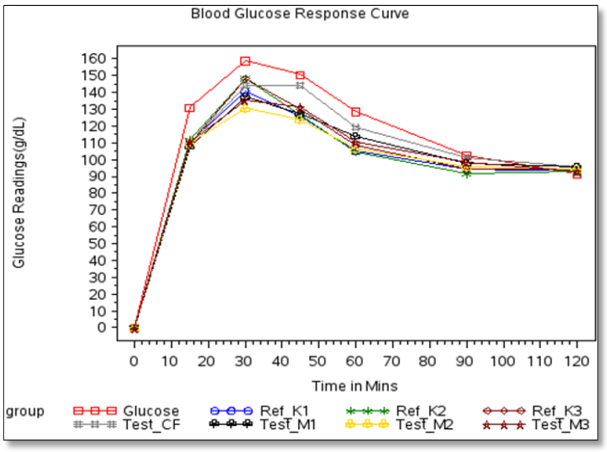

Figure 1. Blood Glucose response Curve

The differences in glucose response between the test & reference foods were analyzed.

Table 3 shows the iAUC for the test foods, reference food & glucose. Significant differences were found in the iAUC between the test & reference products.

Table 3: Incremental area under the blood glucose response curve (iAUC) for test/reference foods

Test foods	iAUC ± SEM
Mean Standard food (glucose)	3345.78 ± 153.69
Test food Muesli 1 (M1)	1986.80 ± 132.41
Test food Muesli 2 (M2)	1759.49 ± 119.10
Test food Muesli 3 (M3)	1993.48 ± 157.12
Reference food Muesli 4 (M4)	1946.57 ± 110.21
Reference food Muesli 5 (M5)	1905.37 ± 103.50
Reference food Muesli 6 (M6)	2009.93 ± 108.67
Reference food Cornflakes(CF)	2668.34 ± 136.88

Table 4: Mean Glucose value (with Mean, CV% and SD)

SUBJECT NO.	iAUC			Mean	SD	%CV
	S1	S2	S3			
1	5260.89	4971.05	2719.77	4317.24	1391.01	32.22
2	3700.50	2083.55	2990.46	2924.84	810.47	27.71
3	1541.25	2868.75	1551.82	1987.27	763.40	38.41
4	6817.50	4912.50	5455.38	5728.46	981.42	17.13
5	2171.44	2374.00	2304.38	2283.27	102.92	4.51
6	3476.88	3514.29	2572.50	3187.89	533.27	16.73
7	3658.83	2655.00	2781.17	3031.67	546.79	18.04
8	3517.44	2226.35	2410.00	2717.93	698.46	25.70
9	2250.47	2611.18	2959.60	2607.09	354.58	13.60
10	2424.00	3885.00	3069.88	3126.29	732.13	23.42
11	5636.25	6127.50	5450.52	5738.09	349.79	6.10
12	4568.50	3171.77	3780.00	3840.09	700.30	18.24
13	6648.75	2928.75	4152.91	4576.80	1895.88	41.42
14	4545.00	4935.00	4933.64	4804.55	224.77	4.68
15	2974.00	2226.51	2436.09	2545.53	385.58	15.15
16	2874.00	3158.10	2526.45	2852.85	316.35	11.09
17	4610.89	3563.50	3727.50	3967.30	563.37	14.20
18	4425.90	5692.50	4940.87	5019.76	636.97	12.69
19	2743.42	3036.67	3412.50	3064.20	335.39	10.95
20	2433.78	1953.06	2452.73	2279.86	283.18	12.42
21	3521.25	3697.50	3615.00	3611.25	88.18	2.44
22	4863.75	5096.25	3618.75	4526.25	794.47	17.55
23	4038.75	3532.50	3941.25	3837.50	268.60	7.00
24	2933.86	3206.01	3752.14	3297.34	416.71	12.64
25	2985.16	2827.50	2876.25	2896.30	80.72	2.79
26	3202.97	3165.47	4298.18	3555.54	643.42	18.10
27	1427.14	2820.00	2714.91	2320.68	775.61	33.42
28	3291.00	4102.50	4927.50	4107.00	818.26	19.92
29	2120.00	537.32	1708.66	1455.33	821.19	56.43
30	1964.25	2238.83	3022.50	2408.53	549.16	22.80
31	2061.05	2261.79	1290.43	1871.09	512.78	27.41
32	3394.04	3030.37	3412.50	3278.97	215.49	6.57

33	3422.78	3355.00	3140.45	3306.08	147.38	4.46
34	3309.38	3392.78	3139.25	3280.47	129.21	3.94
35	3400.00	3120.68	2975.74	3165.47	215.65	6.81
36	3176.86	2509.38	2558.57	2748.27	371.99	13.54
37	3397.50	2630.00	2615.00	2880.83	447.51	15.53
38	3945.00	2971.07	3067.50	3327.86	536.63	16.13
39	4042.50	3645.94	3619.17	3769.20	237.06	6.29
40	4507.50	3049.29	3202.50	3586.43	801.34	22.34
GS Intra CV% (within subject CV) observed more than 30% have been excluded in analysis						

Table 5: GI of test/ references food

Test foods	GI
Test food Muesli 1 (M1)	54.74
Test food Muesli 2 (M2)	49.89
Test food Muesli 3 (M3)	52.79
Reference food Muesli 4 (M4)	60.48
Reference food Muesli 5 (M5)	58.84
Reference food Muesli 6 (M6)	60.26
Reference food Cornflakes(CF)	78.21

DISCUSSION

Carbohydrates consumed with the daily diet are the cause of fluctuations in the concentrations of glucose in the blood, known as the glycemic effect. Glucose content in blood after eating any meal, and usually reaches its maximum after 20-30 min after ingestion of food and then gradually decreases to 1-2 hours to return to fasting levels. Knowing the GI along with information on their composition and nutrient content is important in terms of knowing the effect of carbohydrates on health.

The study was designed to compare the glycemic index of three variants of Local brand muesli in comparison with the three variants of International brand muesli & cornflakes in healthy volunteers. 39 subjects completed the study. Our hypothesis was that the GI of Local brand muesli & cornflakes was lower than the GI of the three variants of International band muesli.

GI value of Muesli 1 was found to be 54.74 (SEM 2.17) thus, placing it in low GI category.GI value of Muesli 2 was found to be 52.79 (SEM 2.39) thus, placing it in low GI category.GI value of Muesli 3 was found to be 49.89 (SEM 2.38) thus, placing it in low GI category.GI value of Cornflakes was found to be 78.21 (SEM 3.78) thus, placing it in high GI category.GI value of Muesli 4 was found to be 60.48 (SEM 2.75) thus, placing it in intermediate GI category.GI value of Muesli 5 was found to be 58.84 (SEM 2.82) thus, placing it in intermediate GI category.GI value of Muesli 6 was found to be 60.26 (SEM 3.24) thus, placing it in intermediate GI category.

The postprandial glucose response was reduced at the initial postprandial phase after the test meal compared to the reference meal. Similar results have previously been presented showing a lower early postprandial blood glucose response after the intake of cereal bran flakes when compared to corn flakes.[18]

We observed a variation of glycemic index to test & reference muesli. This might be probably a result of differences in processing. The range of GI values for international brand muesli was different than that of local brand Muesli, probably because of the variability in formulation. There are several factors that may alter the GI of a food, including the presence of other macronutrients such as fat and protein. The ingredients and form of a food product affect its GI value.

One of the possibility of this difference in the GI values between the local & international brand might be the ingredients used in muesli, Uncooked rolled oats alone have a GI of 59 (SE 4).[19] Raisins and other dried fruits, the commonly added ingredients, show low to medium GI values (30–65).[19, 20] The available carbohydrate in oat foods is derived predominantly from starch, with the remainder coming from added and endogenous sugars.[21] Sugar is often added to commercial products (GI of sucrose- 68 (SE 5)) but does not appear to have had a large effect on the GI of these products. The lack of cooking to gelatinize the starch and open up the flake structure appears to maintain the glycemic response in the low to medium range.

CONCLUSIONS

The results of this study indicate that local brand muesli tested in this trial has lower GI than international brand muesli & cornflakes.

ABBREVIATIONS

GI- Glycemic index
DOH- Declaration of Helsinki
SEM-Standard error mean
CVD-Cardio vascular diseases
ICH-GCP- International conferences of harmonization-Good clinical practices
iAUC- Incremental area under curve
SD- Standard deviation
WC- Wrist circumferences
BMI-Body mass index
CV%- Coefficient of variation

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