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RESEARCH ARTICLE

INSULINEMIC EFFECTS OF A FUNCTIONAL INGREDIENT MIX FOR T2DM PATIENTS

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ABSTRACT

Introduction: The purpose of this study is to assess the Insulin Index of a specially developed Functional Ingredient Mix (FIM) for Type 2 diabetic patients. Certain foods cause an Insulin response despite there being no carbohydrates present, and some foods cause a disproportionate insulin response relative to their carbohydrate load. Hence Glycemic Index and Glycemic Load are not reliable markers.

Methods: Five selected healthy individuals were given measured quantity of the Functional Ingredient Mix and their insulin levels were measured for 9 times at 15 minutes intervals for 2 hours. White bread as reference food was given to the same subjects and their insulin levels were recorded for 9 times at 15 minutes interval for two hours.

Results: The average insulin index value for FIM at 15 minutes interval was less than the white bread. At 30 minutes the insulin value was almost half for the FIM in comparison to white bread. The mean insulin values was found to be decreasing with time for FIM.

Conclusion: This study on insulin index with normal, healthy individuals, highlights the fact that the formulated FIM produces less glycemic load which is indicative of the nil insulin burst. FIM supplementation taken regularly may also decrease the medicine requirement of patients with type 2 diabetes when combined with dietary and lifestyle modification as suggested in numerous epidemiological studies.

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INTRODUCTION

With obesity and diabetes reaching epidemic proportions in the developed world, the role of insulin resistance and its sequelae is gaining prominence. Understanding the role of insulin across a wide range of physiological processes and the influences on its synthesis and secretion, alongside its actions from the molecular to the whole body level, has significant implications for much chronic disease seen in westernized population today (Wilcox, 2005). The ability to achieve optimal glycemic control in diabetes management is highly influenced by food intake. The initial focus for nutrition education messages is to aim for consistency in both type and quantity of carbohydrates consumed. However, research in the past decade has acknowledged that not all carbohydrates effect blood glucose levels in the same way. One of the methods for evaluating this effect is known as the glycemic index (GI) (Kirpitch *et al*., 2011).

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It has been suggested that foods with a high glycemic index are detrimental to health and that healthy people should be told to avoid these foods (Sunyer, 2002). Glycemic Index (GI) initially is potentially a useful tool in the treatment of blood lipids-an important risk factor for cardiovascular disease. The glycemic index highlights how foods can widely differ in biochemical properties upon consumption (Fleming and Godwin, 2013). However, the biggest shortcoming of the GI is that it does not account for typical serving sizes. To address this shortcoming, glycemic load concept was suggested, which is just a function of the GI of a particular food with respect to size of serving.

In contrast, the Insulin Index is a measure used to quantify the typical insulin response to various foods. The index is similar to the glycemic index and glycemic load, but rather than relying on blood glucose levels, the insulin index is based upon blood insulin levels. This measure can be more useful than either the glycemic index or the glycemic load because certain foods (e.g., lean meats and proteins) cause an insulin response despite there being no carbohydrates present, and some foods cause a disproportionate insulin response relative to their carbohydrate load (Wikipedia.org). The research on the insulin index of foods is intriguing but limited (Mendosa, 2014). Holt *et al*. (1997) have noted that the glucose and insulin scores of most foods are highly correlated, but high-protein foods and bakery products that are rich in fat and refined carbohydrates "elicit insulin responses that were disproportionately higher than their glycemic responses".

Further, commercially available mixes for T2DM don't have insulin index mentioned on the labels. It is in this context the experiment was carried out to find the Insulin Index of the Functional Ingredient Mix.

Research Method and Designs

The Insulin Index is a relatively expensive, time consuming, and can only be found out by human testing. The selected participants were given orientation about the procedure of testing. A well informed consent form was signed from the participants and the Institutional Research Ethics Committee approved the protocol. The test actually measures the post prandial increase in insulin production after the consumption of the specially formulated Functional Ingredient Mix. To make standardized calculations, the selected subjects took 51.9 gms of the FIM (test food) - measured using digital weighing scale - after a 10-h overnight fast. This dosage to find the insulin secretion was based on the available literature from previous research done by Holt *et al*. (1997) which indicates that test food equal to 1000 calories or 239 kilo joules should be given. Accordingly 51.9 gms of the FIM was arrived at. Functional Ingredient Mix was specially formulated with Quinoa, Green gram, Cinnamon, Fenugreek, Oats, Soy Flour, Broken wheat as main ingredients, packaged as a free flowing powder.

Subjects were asked to refrain from unusual activity and food intake patterns, to abstain from alcohol and legumes the day before the test, and to eat a similar meal the night before test. Similarly, 94 gms of white bread - measured using the same digital weighing scale - considered as reference food of standard size equal to 4.5 slices which was procured from the same bakery for all the selected samples were administered after a wash out period of three days from the test food. The precautions undertook for the test food was also followed before the start of the reference food testing procedure.

A fasting blood sample was collected to test serum insulin levels at 0 minutes (just before consuming the FIM and white bread) and at 15,30,45,60,75,90,105 and 120 minute intervals after consumption of reference and test foods. Subjects were asked to remain seated at tables in a quiet environment and not permitted to eat or drink until the end of the session. The insulin results obtained were analyzed for insulin index.

RESULTS AND DISCUSSION

Insulin is one of the most important hormones in the human body. Diet is the key in regulating the insulin levels and what we eat affects the levels of insulin the body produces. It is particularly important for our bodies to maintain glucose levels every time we eat. Our bodies release insulin right before and during eating, and that insulin starts taking glucose out of the blood, thus lowering blood glucose levels. It does this by both promoting uptake of glucose by cells and the storage of glucose within our cells. Without insulin, hyperglycemic shock and death are likely to happen (Wilcox, 2010).

Table 1 explains the mean insulin levels from 0 minutes to 120 minutes for both the test food and reference food.

Table 1. Mean insulin values across time intervals for white bread and FIM

Duration	Food type			
	White Bread		FIM	
	Mean	Std. Deviation	Mean	Std. Deviation
0 minutes	6.04	0.45	6.06	0.56
15 Minutes	83.02	1.62	50.90	0.82
30 Minutes	80.56	1.58	46.28	1.66
45 Minutes	68.12	1.01	39.94	1.59
60 Minutes	45.60	1.00	34.42	1.45
75 Minutes	32.18	3.65	27.06	3.14
90 Minutes	22.08	1.01	19.18	1.87
105 Minutes	12.72	4.00	14.26	2.74
120 Minutes	8.12	1.17	7.92	0.16
Food Type: F= 1718.088; p-value = 0.000*				

The average insulin index value for FIM scored maximum at 50.9±0.82 µIU/ml at 15 minutes interval, whereas it was much higher at 83.02±1.62 µIU/ml for white bread. Similarly, at 30 minutes it was found to be 80.56±1.58 µIU/ml and 46.28±1.66 µIU/ml for white bread and FIM respectively.

In comparison, the mean value at 45 minutes interval was found to be 68.12 ± 1.01 µIU/ml and 39.94±1.59 µIU/ml for white bread and FIM respectively. The above table also reveals that for white bread it was 45.6 ± 1.00 µIU/ml and 32.18 ± 1.45 µIU/ml at 60 and 75 minutes respectively, whereas FIM mean at 60 minutes was 34.42 ± 1.45 µIU/ml and 27.06 ± 3.14 µIU/ml at 75 minutes duration.

The mean insulin values was found to be decreasing as time interval was increasing with values of 12.72± 4.00 µIU/ml and 14.26± 2.74 µIU/ml for white bread and FIM respectively at 105 minute duration upon consumption. At 120 minute duration the mean value was found to be 8.12 ± 1.17 µIU/ml and 7.92 ± 0.16 µIU/ml for the foods selected for comparison. On performing statistical analysis, results showed that there was a significant difference between the food types across the time intervals (F = 1718.08; P value = 0.000*).

It is observed from the above table that white bread has higher mean insulin response when compared to FIM. This observation also showed significant difference between the two foods studied. (t = 41.45; p value = 0.000*) and is explained in Table 2. From the above findings it is clear that the food type - FIM has its impact in reducing the insulin need when compared to white bread. The insulin data of the Test Food (TF) and Reference Food (RF) with the other variables was compared with the selected subjects which is tabulated below:

Table 2. Mean insulin values for white bread and FIM

Food type	Mean	Standard Error	t-test (p-value)
White Bread	39.82667	10.61249	41.45 (0.000*)
FIM	27.33556	7.812875	

Basic attributes Versus Insulin response to food

Age is not only associated with insulin resistance but is also associated with changes in body composition, which likely contribute to the development of age-related insulin resistance. Aging is associated with detrimental changes in body composition, which persists even when elderly adults are matched to younger adults for BMI. Adiposity, in particular abdominal adiposity, is well accepted as a determinant of insulin resistance and therefore may be a key mediator for the development of age-related insulin resistance (Karakelides *et al*., 2010). Hence the researcher sought to find out the insulin response to test food and reference food with normal, non-diabetic individuals whose BMI were within normal range and also included samples for both gender. The insulin values at 0 minutes, 15 minutes and 120 minutes were analyzed against age, gender, BMI and Hba1c levels which is discussed below.
With reference to Table 3 it can be inferred that all the 5 selected subjects were within the age range of 25 to 40 years out of which 3 were male subjects and 2 were females. The body mass index were within the normal category as recommended by WHO standards with 22.4 observed as the lowest and 24.2 recorded as the highest value for BMI. Similarly, the glycosylated hemoglobin fell under the normal category which ranged from 4.8 to 5.4 per cent.

The table also clearly depicts the difference in test food and reference food for each subjects selected for the study. The insulin secretion at 0 minutes scored high for subject 1 at 6.5 µIU/ml for reference food whereas for test food it was 6.8 µIU/ml for subject 1.

Generally the insulin is said to peak at 15 minutes after consumption of any food or meal. In this present study the peak values of insulin was noted at 84.1 µIU/ml at 15 minutes for subjects 2 and 5 for reference food indicating more amount of insulin is required for the metabolism of reference food whereas only a maximum of 51.6 µIU/ml of insulin is secreted for test food denoting that FIM requires only less insulin need for its metabolism than the white bread making it as a good meal supplement for patients with type 2 diabetes and a snack option for the general population. The descriptive measures such as individual mean and standard deviation for various time duration which is reported in Table 1 is also graphically visualized in Figure 1. Further, multiple comparisons are performed using Benferroni method of calculation to see the difference between 9 time points which showed that there is a significant difference at all time points studied and the results reflects that FIM can be used which is noticed to reduce the insulin need and therefore safely consumed by patients with type 2 diabetes without affecting the glycemic load.

Table 3. Comparison of insulin values between Test food * and Reference food* with other attributes

Subjects/ Variables	Age (years)	Gender	BMI	A1C % (mmol/mol)	Insulin Values					
					0 minute		15 minutes		120 minutes	
					RF	TF	RF	TF	RF	TF
1	35	M	22.4	4.8 (29.0)	6.5	6.8	83.2	49.6	6.2	7.8
2	25	M	22.5	5.1 (32.2)	5.8	5.7	84.1	51.6	9.2	7.8
3	28	M	23.1	5.4 (35.5)	5.4	5.5	80.2	51.2	8.6	7.9
4	40	F	23.8	5.0 (31.1)	6.1	5.8	83.5	50.6	8.7	7.9
5	32	F	24.2	5.0 (31.1)	6.4	6.5	84.1	51.5	7.9	8.2

* TF - FIM, RF - White bread

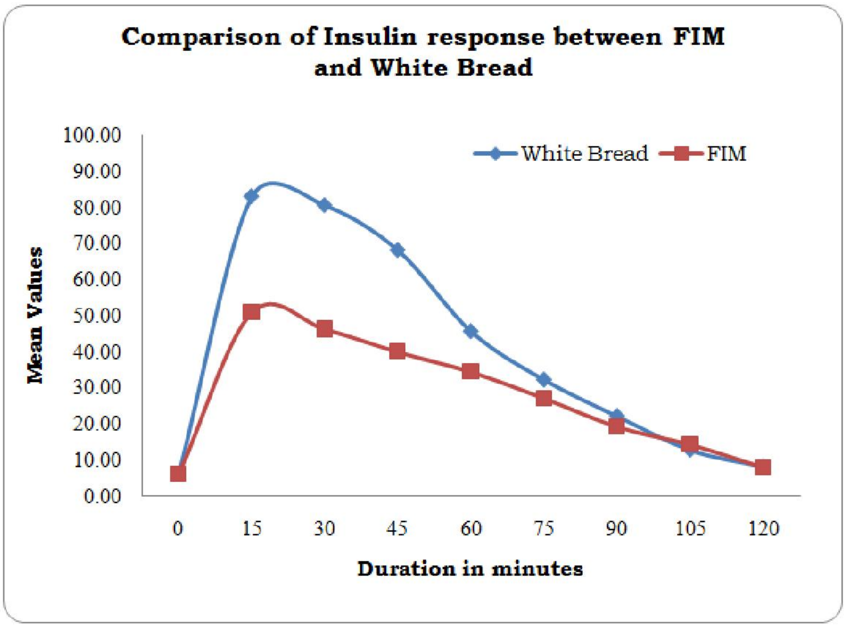

Figure 1. Comparison of insulin response between FIM and white bread

This present study attempt on insulin index with normal, healthy individuals, highlights the fact that the formulated FIM produces less glycemic load which is indicative of the nil insulin burst. Therefore hypoglycemic shock will not happen with respect to individuals with diabetes.
Also it can be said that longer duration of FIM supplementation may also decrease the medicine requirement when combined with dietary and lifestyle modification as suggested in numerous epidemiological studies.

Though none of the currently marketed proprietary foods that are prescribed or sold as over-the-counter formula for individuals with type 2 diabetes contain the details of glycemic load, glycemic index or insulin index, this researcher thought fit and proper to provide the details of the same with an idea to rule out the deleterious effect on consumption while addressing the functionality of Functional Ingredient Mix.

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