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An Interventional study to observe the Impact of Soluble Fiber blend MYFY on Blood Glucose and Satiety Soluble dietary Fiber and Blood Glucose response

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Abstract: **To determine the blood glucose response of the dietary fiber in healthy volunteers and To determine satiety response of the dietary fiber in healthy volunteers**

Settings and Design: It was an interventional study design conducted in hospital setting for three days.

Methods and Material: This study was done on 32 healthy subjects aged between 18 and 65 years having random blood sugar less than 200 mg/dl and BMI between 18.5 to 27 kg/m2. Soluble non-viscous dietary fiber blend obtained from Wheat Dextrin and Guar Gum named as MYFY was given to subjects. The subjects were randomized in two groups one who consumed standard breakfast (Aloo Paratha and Idli Sambhar) and the other consuming standard breakfast along with MYFY. The subjects were given 5 gms of sachet along with breakfast for 3 days. Blood glucose levels were monitored at the intervals of 15, 30, 60, 90, 120, 150 and 180 minutes to observe the mean plasma glucose response post breakfast. Satiety was analyzed using questionnaire.

Statistical analysis used: Statistical analysis was performed using the Microsoft office excel 2007.

Results: The results revealed that the Glycemic response of MYFY is low. Consumption of MYFY along with food has caused a delay in the peak glycemia by almost 50%. The subjects stayed satiated after eating for almost 45 minutes more after consuming fiber along with food. Thus, the findings concluded that MYFY has effect in lowering the glycemic index of the food by prolonging the peak blood glucose levels. Also, MYFY keeps satiated for longer period of time and reduce the hunger feeling.

Conclusions: There is positive impact of soluble fiber especially Guar Gum and Wheat Dextrin blend MYFY on Glycemic and Satiety response.

Keywords: **Glycemic index, Gaur gum, MYFY, Soluble dietary fiber, Satiety, Wheat Dextrin.**

I. INTRODUCTION

The current prevalence of Type II diabetes in India is nearly about 72.9 million (IDF, 2017). There are many diabetics who prefer to treat or manage the blood glucose levels by natural way and reduce the dosage of medication and insulin. Dietary Fibers (DF) have been identified for their beneficial contribution to overall health. Hypoglycemic effects of fiber in the management of diabetes have been well recognized (Singh and Singh, 2015). Soluble DF (SDF) has specific properties of water holding, cation binding capacity and viscosity because of which it shows hypoglycemic and hypolipidemic effects. Thus, SDF is effective in reducing CHD incidence, Type II Diabetes and Obesity (Longwah. J, 2017 and Gopalan.C, 2007). Study evidences show that soluble fiber have a lowering effect on the Glycemic Index of the food. The beneficial effect of soluble fiber is presumed to be due to its reduction of the glycemic response by forming sponge and delaying gastric emptying (Sierra et al, 2002). Regulatory bodies like National Institute of Nutrition (NIN) and American Diabetic Association (ADA) reported that consuming DF according to the recommended allowance (25 gms for females and 38 gms for males) is beneficial for achieving the hypoglycemic effect. Specifically, Soluble fiber

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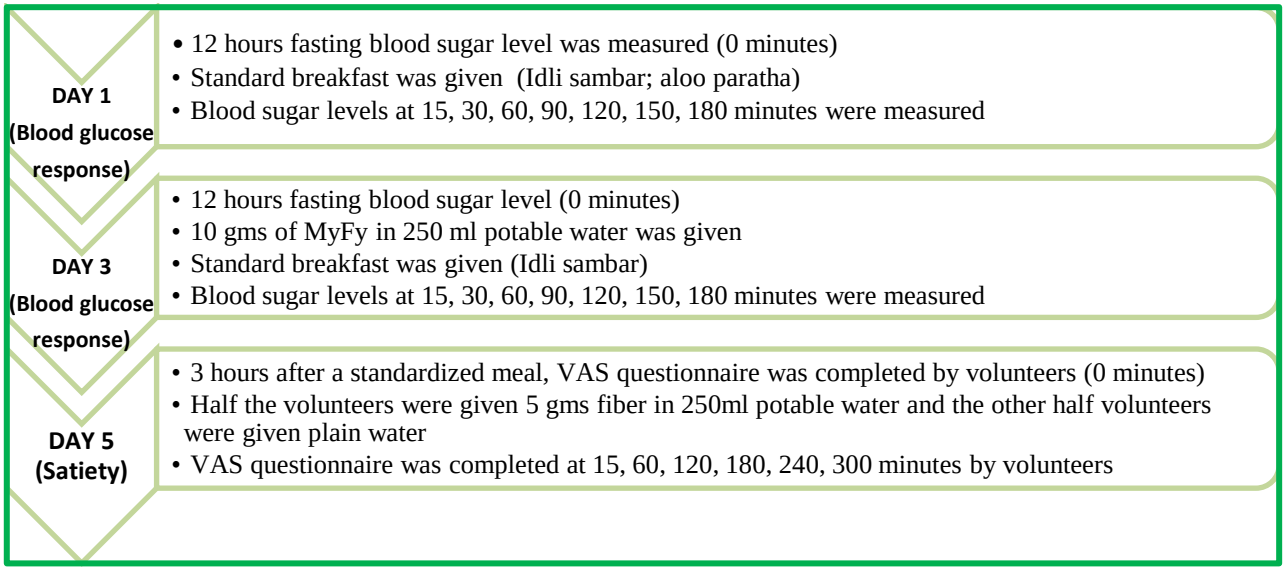
because of the physical properties it has such as water holding capacity, cation binding capacity and viscosity is beneficial for hypoglycemic and hypolipidemic effects (Gopalan. C, 2007). ADA guidelines recommended minimum 14 gms of dietary fiber per 1000 kcals a day to improve the glycemic control (American Diabetic Association). Consumption of soluble dietary fiber reduces postprandial glucose responses after carbohydrate-rich meals, as well as lowering total and LDL cholesterol levels (Chen et al, 2016). Consumption of higher amounts of soluble fiber, especially those with high viscosity, slows gastric emptying time. This delay results in a gradual release of glucose which corresponds to a lower insulin response (Jenkins et al, 2000). Some of the studies have reported that hypoglycemic effect of Guar Gum and Wheat Dextrin is significant. (Weikert et al, 2006 and Qi et al, 2006). Basically, Guar gum is extracted from Guar beans. It is a polysaccharide consisting of galactose and mannose, which is obtained from vegetable seeds such as Cymepsis tetra-ganaloba, a source of pure natural fiber (Behall et al, 2006). Wheat Dextrin is made from either wheat or maize starch, using a highly controlled process of dextrinization followed by a chromatographic fractionation step. During the dextrinization step, the starch undergoes a degree of hydrolysis followed by repolymerisation that converts it into fibre: in addition to the typical starch α-1,4 and α-1,6 digestible linkages, non-digestible glycosidic bonds such as β-1,2 or β-1,3, are formed, which cannot be cleaved by enzymes in the digestive tract. Furthermore, this causes some hindrance to the cleavage of the digestible bonds (Deremaux et al, 2011).

Wheat Dextrin and Guar Gum blend known as MYFY is completely soluble natural dietary fiber. In addition, the present study also indicated the usefulness of soluble fiber in the management of Type II diabetes. MYFY is completely natural and proven to reduce the peak blood glucose levels. Thus, the demonstration of beneficial effects of soluble fiber would have considerable practical significance. Understanding the benefits of addition of Glycemic Index and how one can implement it into the diet, not only allows health care practitioners to educate patients about its use as well as prevents healthcare disorders in healthy individuals. Hence, this study aims to determine the blood glucose response of a dietary fiber with high glycemic index foods.

II. BODY OF ARTICLE

A total of 32 healthy subjects aged between 18 and 65 years of normal health, having random blood sugar less than 200 mg/dl and BMI between 18.5 to 27 kg/m^2 were included. Subjects having any major illnesses or gastrointestinal diseases which might interfere with nutrient absorption or conditions like coronary heart disease, renal disease or vascular disorders were excluded from the study. This study was performed in compliance with ICH E6R1 "Guidance on Good Clinical Practice", Indian Good Clinical Practices Guideline, ICMR Ethical Guidelines for Biomedical Research on Human Subjects, Declaration of Helsinki and relevant SOPs of Jehangir Clinical Development Centre, Pune, Maharashtra, India.

This study was performed to assess the blood glucose response and satiety response of dietary fiber blend, approved by the institutional ethics committee. The study design is as depicted in Figure 1.



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At Visit 1, Subjects were given a detailed description of the nature and purpose of the study. Only those subjects who were willing to participate in the study and have signed the Informed consent were considered for the study. Thereafter, the subjects were evaluated for demographics, medical history, prior medication, physical examination, vital signs, height and body weight. Eligible subjects were requested to come fasting the next day.

At Visit 2, First 16 volunteers were given Aloo paratha. Blood sugar level was measured over the next three hours at 15, 30, 60, 90, 120, 150 and 180 minutes after the end time of breakfast. Next 16 volunteers were given two sachets (10 grams) of fiber dissolved in 250 ml of water. The volunteer was requested to consume it within a 10-minute period. Upon completion of the drink, 15 minutes later breakfast i.e. Idli & Sambhar given. Blood sugar level was measured over the next three hours at 15, 30, 60, 90, 120, 150 and 180 minutes after the end time of breakfast. At Visit 3 Same procedure was repeated and readings were taken.

III. RESULTS

Blood Glucose Response: The results indicate that Dietary Fiber Blend MYFY showed significantly less blood glucose response on high GI food such as Idli Sambhar at 30 min, 90 min, 120 min and 150 min respectively. Peak blood glucose level is seen within 15 minutes, in volunteers consuming standard breakfast, whereas peak blood glucose level is seen at 30 minutes in volunteers consuming fiber along with standard breakfast. This suggests that, glycaemic response to fibre-breakfast is lower than those of the control breakfast.

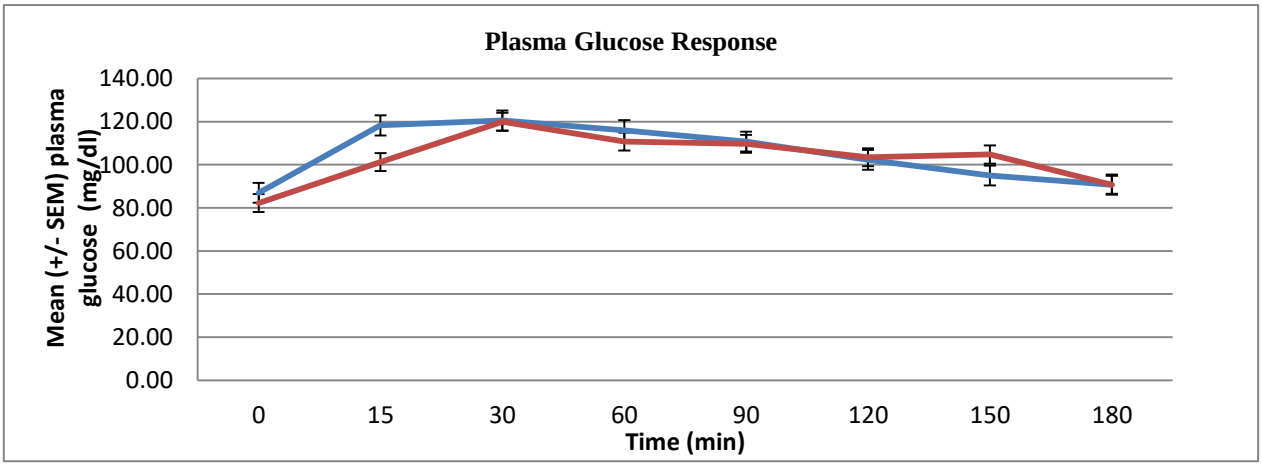

Figure 2: Mean Plasma Glucose response post consumption of MYFY

Satiety

The VAS scores depicted that volunteers consuming fiber with a standardized meal stayed satiated for almost 45 minutes more as compared to volunteers consuming standardized meal without fiber.

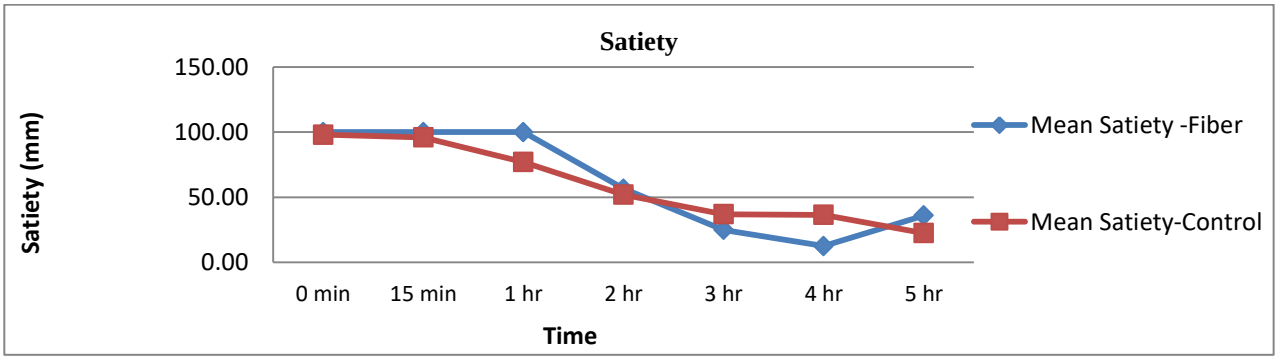

Figure 3: Satiety Response post consumption of MYFY

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IV. DISCUSSION

A survey conducted in Indians reported an average Dietary fiber intake of 20 to 22 gms per day in normal individuals. The recommended intake of dietary fiber reported by NIN and WHO is 25 g/day for females and 38 g/day for males. Flourished food industries have made the natural foods more processed, refined to add taste, texture, increase shelf life, etc. they are made devoid of dietary fiber high in sugar and fat content. Due to flawed lifestyles, indulgence in processed food, lack of awareness, physical inactivity etc. our meals are devoid of dietary fiber and there is deficit of 5-10 gms in our diets.

In the present study the peak rise in the blood glucose levels was delayed significantly and the subject also felt less hungry and satiated for much more time than normal. This suggested that medical nutrition therapy inclusive of diet rich in soluble fiber has significant impact on Blood glucose and Glycemic control profile. These results were found to be consistent with three randomised trials, including The Diabetes Prevention Program trial, The Finish Diabetes Prevention study and The China Da Qing Diabetes Prevention study which also demonstrated that the progression from impaired glucose tolerance to type II diabetes may be delayed or even prevented by diet and exercise. (Tuomilehto et al, 2001 and Knowler et al, 2002). Furthermore, dietary interventions including the diet rich in fiber aimed at improving diet quality have been shown to be effective for controlling Type II diabetes.

In the present study, subjects received soluble dietary fiber in the form of sachets of 5 gms per day. Soluble Dietary Fiber has been associated with lower postprandial glucose levels and increased insulin sensitivity in diabetic and healthy subjects; these effects were generally attributed to the viscous and/or gelling properties of soluble fiber. Soluble Dietary Fiber exerts physiological effects on the stomach and small intestine that modulate postprandial glycemic responses, including delaying gastric emptying, which accounts for ~35% of the variance in peak glucose concentrations following the ingestion of oral glucose.

The present study reported about the delayed rise in peak blood glucose by approximately 50% post meal along with this blend of guar gum and wheat dextrin soluble fiber. This fiber modulated the glycemic responses predominantly because of the Viscosity and Gel forming properties by delaying the gastric emptying time and thus slow release of macronutrients for absorption.

In addition to this, it also exerted the impact on the Satiety hormones, including CCK, GlP-1, PYY and Ghrelin. Greater Satiety was reported in the present study after the intake of fiber. There are several ways in which dietary fiber may affect obesity development. The ingestion of fiber has been hypothesized to suppress energy intake by inducing satiation and satiety (Freeman, 2002). Fiber acts as a physiological obstacle to energy intake by: (1) fibre displaces available calories and nutrients from the diet and (2) fibre reduces the absorption efficiency of the small intestine. Soluble fiber containing wheat fiber and guar gum provides satiety, fills you up and satisfies your appetite for a longer period. This makes it easier to deny unhealthy food cravings and avoid junk food binges. Thus, regular consumption of this soluble fiber will help in losing weight.

The possible mechanisms are, it decreases gastric mobility, decreases gastric emptying and thus prolongs the colonic transit time. It also changes the degree of fermentation of colon content. This in all decreases Ghrelin, increases Cholecystokinin (CCK), increases Peptide YY (PYY), increases Glucagon Like Peptide -1 (GLP-1). These results were found to be consistent with another study where wheat dextrin intake of about 5gms per day reported to show positive impact on satiety (Gutkoski et al, 2007 and Howarth et al, 2001). Also, the intake of diet rich in guar gum of about 10gms per day reported to show weight loss (Yoon et al, 2008).

In addition to this Increasing Soluble Dietary Fiber intake, which is one of the goals of nutritional counselling, deserves greater attention due to its ability to reduce Triglycerides, total cholesterol levels and hyperglycaemia in patients with impaired glucose tolerance and Type II diabetes. Previous studies have demonstrated that high-fiber diets (30 g/day) altered biochemical parameters, reduced the severity of type II diabetes and decreased the occurrence of risk factors associated with cardiovascular disease. No significant adverse reactions were found, with the exception of increased flatulence in some patients.

V. CONCLUSION

The present study demonstrated that high doses of soluble Dietary fibre were able to improve numerous metabolic indicators in patients with Type II diabetes; however, further research is required to determine the specific mechanisms underlying the effects of Dietary fibre. Such findings may have a large impact on the prevention and clinical treatment of Type II diabetes. In conclusion, the present study demonstrated that Medical nutrition therapy inclusive of diet rich in Soluble dietary fibre was able to delay the peak rise in blood glucose, maintain the glycaemic control and improve the satiety levels. To the best of our knowledge, the present study is the first to demonstrate that increased intake of soluble Dietary Fibre over a short-duration in Indian patients with Type II diabetes was able to significantly improve blood glucose levels. Therefore, the authors of the present study recommend that dietary guidelines for patients with Type II diabetes should stress the importance of increased soluble Dietary Fibre intake.

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