



RESEARCH ARTICLE

Glycemic Index of Vidavance®, a High Protein and High Fiber Oral Snack Replacement Therapy for Diabetes Patients

Sabharwal M¹, Srivastava PK², Mishra A³, Pillai P³, Mehndiratta C³

¹ Dharma Dibeto Clinics, Greater Kailash II, New Delhi, India 110 006
² Mediception Science Pvt Ltd, Gurgaon, India 122 018
³ Signutra Inc. Nehru Place, New Delhi, India 110 019



PUBLISHED
31 July 2024

CITATION
M, Sabharwal., P.K, Srivastava., et al., 2024. Glycemic Index of Vidavance®, a High Protein and High Fiber Oral Snack Replacement Therapy for Diabetes Patients. Medical Research Archives, [online] 12(7).
<https://doi.org/10.18103/mra.v12i7.5420>

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DOI
<https://doi.org/10.18103/mra.v12i7.5420>

ISSN
2375-1924

ABSTRACT

Background: Food products with a low Glycemic index (GI) and low Glycemic load (GL) help control blood glucose levels, and reduce the risk of diabetes-related morbidity and mortality. Vidavance®, an oral nutritional supplement (ONS) and Medical Nutrition Therapy (MNT) for pre-diabetes and diabetes has high-quality protein blend (soy protein isolate, calcium caseinate), dietary fiber (polydextrose, soy fiber), modified maltodextrin, chromium, and zinc, which are known to influence blood glucose control.

Aim: To determine the GI and GL of the Vidavance® in 31 people with diabetes (T2DM) aged 18 to 60 years, with fasting blood glucose (FBG) >120 mg / dL.

Methodology: The study participants consumed reference food (27.5 g of glucose monohydrate dissolved in 125 ml of water) followed by a three-day washout period. Then Vidavance® test dose (53 g available carbohydrate/100 gm) was given as 47.1.g of ONS mixed in 100 ml water to make up 390 ml). Continuous Glucose Monitoring reading was taken at 0, 15, 30, 45, 60, 90, and 120 minutes after the start of the test meal. The GI was assessed using a validated protocol by FAO and ISO (2010).

Results: 30 participants completed the study, (Mean age 55.2 ± 13.0 years.). The GI of the test food (Vidavance®) was 30.57 (low GI). No hyperglycemic events were observed during the study. The GI value was not influenced by age (years), sex, previous day's dietary intake energy (kcal), and physical activity level. The GL of the test food was 3.85 (low GL).

Conclusion: Vidavance® is a low GI and low GL ONS and hence suitable for diabetic subjects.

Keywords: Glycemic index, nutritional supplement; weight loss, diabetes, CGM

Introduction

Diabetes is a global pandemic ^{1,2}. Globally, one in seven people with diabetes (PD) is an Indian ¹. The global PD number is predicted to rise by 69% by 2045 ¹.

Type 2 Diabetes (T2D) is a major contributor to this increase and is related to changes in lifestyle ³. Indians are genetically and metabolically at higher risk of developing diabetes ^{4,5}. This is further complicated by the increased use of fast food, refined food, sweetened beverages, high-calorie food, and a mechanized low-activity/sedentary lifestyle ^{4,5}. Together these factors contribute to the higher incidence of diet-related non-communicable diseases (DR-NCDs) like T2D and obesity (diabesity) in India ^{4,5}. Further, the recent ICMR-INDIAB-13 study showed that only 36.3% of the PD in India had achieved good glycemic control ⁶.

Though many pharmacological strategies are available to manage diabetes, diet and exercise are important components of a diabetes care program. Medical Nutrition Therapy (MNT) is an important diabetes management strategy ⁵. MNT encompasses individualized diet plans and regular monitoring by registered dietitians and clinicians ⁵.

PD are advised to consume carbohydrates with low Glycemic index (GI) and Glycemic load (GL) as a low GI diet is associated with a decrease in glycosylated hemoglobin (HbA1c), postprandial glucose (PPG), and fewer hypoglycemic episodes than a high GI diet ^{7,8}. Along with it, the diet should contain good quality proteins, fats, and micronutrients in the right proportion ^{5,9}.

Vidavance® is a proprietary oral nutritional supplement (ONS; Signutra Inc) designed to fulfill the dietary needs of PD and/or people at risk of these (T2DM and pre-diabetes). It comprises of a high-quality protein blend (soy protein isolate, calcium caseinate), dietary Fiber (polydextrose, soy fiber), modified maltodextrin, chromium, and zinc, which are known to influence blood glucose control ¹⁰⁻¹⁷.

The primary objective of the study was to estimate the GI and GL value of Vidavance®, in subjects with diabetes (T2DM). The secondary objective was to capture any hypoglycemic event (blood sugar level <70 mg/dl) within a period of 24 hours after giving Vidavance®.

Methodology

STUDY SUBJECTS

Thirty-one participants from the participant roster of Glycemic Index Testing Centre - Dharma Diabeto Center, New Delhi, aged 18-60 years, with a fasting blood glucose (FBG) >120 mg / dL, no known food allergy or intolerance, and who were not taking any medications known to affect glucose tolerance were included in the analysis. The study excluded participants who had dietary restrictions required to manage diabetes, pregnant and lactating women, individuals recently diagnosed with impaired glucose tolerance, those with any acute or chronic conditions, individuals on medications that could affect nutrient absorption or carbohydrate metabolism, and those who had experienced a major

medical or surgical event within the past three months. Study subjects may or may not have been receiving diabetes treatment.

STUDY DESIGN

This was an observational, single-center, single-arm, study to determine the GI and GL value of Vidavance®, in patients with diabetes. Vidavance® is a scientifically designed Medical Nutrition Therapy (MNT) that helps decrease postprandial glycemia and supports diabetes control in T2DM and prediabetic patients.

The primary investigator followed the Internationally recognized GI protocol issued by the Food and Agriculture Organization (FAO) / World Health Organization (WHO), 1998, and guidelines endorsed by the International Dietary Carbohydrate Task Force for GI methodology. Additionally, also followed the International Organization for Standardization (ISO) method (ISO 26642-2010), which is validated and published elsewhere ¹⁸⁻²¹.

TEST AND REFERENCE FOOD

Vidavance®, the test food for the study is an ONS (diabetic snack replacement medical nutrition therapy) from Signutra Inc. Proximate composition, available carbohydrates (estimated by a direct method, Megazyme Kit, Ireland), and total dietary fiber (Megazyme Kit, Ireland) were estimated at the Food Quality Analysis Lab of the Institution. Snack composition was maintained meeting caloric requirements with less amount of carbohydrate. The test dose was 53 g carbohydrate/100 gm given as 47.1 g of ONS mixed in 100 ml water to make up 390 ml). The reference food for the GI study was Glucose Monohydrate (27.5 g of glucose monohydrate dissolved in 125 ml of water).

STUDY PROCEDURES

A recall questionnaire was circulated among the subjects before the start of the study. The questionnaire asked the subjects about their previous day's meals (24-hour recall), physical activity, smoking, alcohol, and caffeine-containing drinks to ensure that they followed the same diet daily and performed the same level of physical activity on pre-test dates.

The subjects were asked to avoid alcohol and tobacco during the study period. The subjects visited the GI testing centre (study site) each test day in the morning after 10-12 hours of overnight fasting

Before administration of the test product, the subjects were first administered the reference food for three days.

Blood samples were collected at 15, 30, 45, 60, 90, and 120 minutes after consuming glucose solution. After collecting blood glucose samples analysis was done within 30 minutes. This was followed by a washout period of 2-3 days to cancel out any possible carryover effects.

The same 24-hour recall questionnaire was administered again. After this, the subjects were administered the test food for one day in random order. 31 subjects received 53 g of carbohydrates from 100 gm of nutritional product. A CGM device was attached (all participants

received the same CGM device BeatO). FBG was measured at -5 minutes and 0 minutes by the CGM device before consumption of the food. The baseline values were taken as the mean of these two values. Within 12-15 minutes, the participants consumed Vidavance®. The first sip in the mouth was timed as 0 minutes and the first CGM reading was taken conventionally exactly 15 minutes after. CGM data was obtained at 15, 30, 45, 60, 90, and 120 minutes after the start of the test meal.

DATA ANALYSIS

The sample size was determined randomly based on the primary investigator's considerations. The participants'

data were recorded in Microsoft Excel and the R version 4.2.2 was used to analyse the data.

Data were represented as percentages, mean \pm standard deviation, or median. To measure the Glycemic index of Vidavance®, an incremental area under the blood glucose response curve (IAUC) was plotted. The geometrical method using the trapezoidal rule was used to calculate the IAUC while the area below the fasting baseline level was ignored. GI value was calculated by expressing each participant's AUC for the test food as a percentage of the same participant's mean reference IAUC. The mean of the resultant was the GI of the test food.

$$GI \text{ value of test food (\%)} = \frac{\text{Blood glucose (IAUC value for the test food)}}{\text{IAUC value of the reference food}} \times 100$$

The GI values were further tested to see the influence of age (years), sex, and previous days' (of the reference and test food feeding) dietary intake [energy (kcal), protein (g), fat (g), carbohydrates (g), dietary fiber (g)] and physical activity level (PAL -sedentary, moderate, and vigorous levels) using a generalized linear model (GLM).

The Glycemic load (GL) of the test food was calculated too.

The GL of the test food = GI of the test food x carbohydrate/100

ETHICAL CONSIDERATIONS

The evaluation process employed in the study was as per

the international standards put forth for regulating ethical research with humans and was approved by the institutional ethics committee of The Good Society of Ethical Research, India on 13th July 2022 and all participants gave informed consent. The study has been registered with the clinical trial registry of India as CTRI/2022/07/056471.

Results

Thirty-one subjects were included in the analysis; 21 females and 10 males; the mean age of the participants was 55.2 ± 13.0 years. The participants had multiple symptoms of diabetes, its complications, and comorbid conditions as shown in **Table 1**.

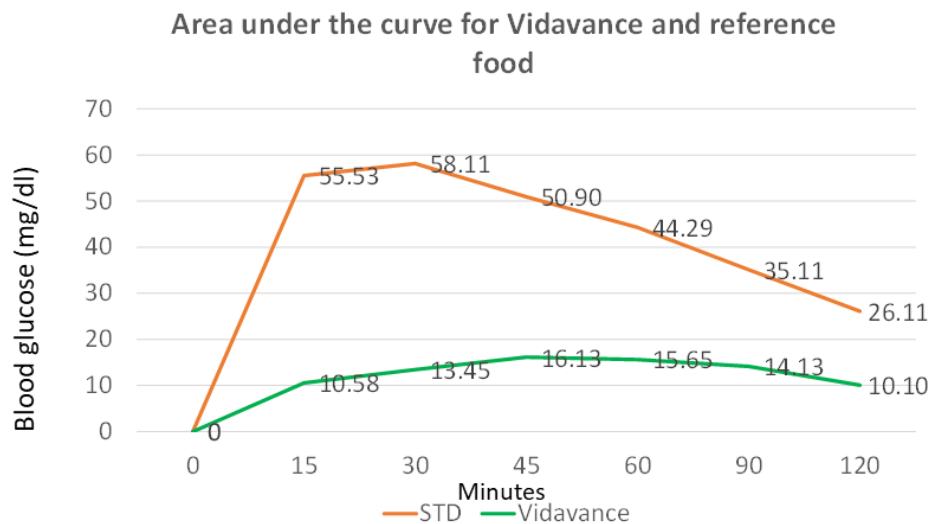
Table 1: Symptom profile and comorbid conditions of the participants

Symptoms of diabetes, its complications, and comorbid conditions	No of participants
Weakness	27
Lethargy	28
Nocturia	22
Polyuria	19
Constipation	11
Gastritis	20
Blurring vision	11
Tingling/burning sensation in legs	16
Hypoglycemia	26
Breathlessness	9
Cardiovascular disease	5
Chronic kidney disease	1
Hypertension	1
Dyslipidemia	3
Neuropathy	1

CGM showed that postprandial blood glucose concentration (mg/dL) at 15, 30, 45, 60, 90, and 120 min after ingestion of test food (Vidavance®) was lower than the reference food (Glucose monohydrate). The blood glucose excursions (mg/dl) for 2 hours following the intake of test food were minimal, uniform, and sustained while following reference food consumption; the blood glucose

levels exhibited a spike at around 15 minutes and then decreased gradually at 2 hours (**Figure 1**). The GI of the test food was 30.57 (low GI). No hyperglycemic events were observed during the study. The GI value was not influenced by age (years), sex, and the previous day's dietary intake [energy (kcal)] (**Table 2**). The GL of the test food (Vidavance®) was 3.85 (low GL).

Figure 1: Area Under the curve for Vidavance® and reference standard (STD) food



iAUC for Vidavance® = **1500.7**
 iAUC for Reference food = **4908.8**

Table 2: Beta coefficients of confounders with Glycemic Index of Vidavance®.

Variables	Beta coefficient	P value
Age (years)	-0.108	0.563
Sex (male/female)	0.012	0.0484
*Total energy (Kcal/100 gm)	426 Kcal	

* Based on 24 h dietary recalls collected on the days of reference and test food feeding

P<0.05 was significant

Discussion

Diet and exercise are important lifestyle management strategies for people with diabetes (PD). However, often this is the most neglected part of the diabetes management program, often due to a lack of time to prepare low GI and low GL meals. Thus, according to the ICMR-INDIAB-13 study, almost three-fourths of the PD need something apart from medications to control their blood sugar levels ⁶.

Low GI (GI<55) and low GL (<75) foods are considered ideal for patients with diabetes (PD) ^{22,23}. GI is a strong predictor of Glycemic variations and therefore it is important to determine the GI of food to understand the food’s impact on glycemia ⁸. GL is related to the carbohydrate content of the food. Low-carbohydrate and low-GI meals have a significantly lower PPG than low-GI high-carbohydrate meals ⁸.

High postprandial glucose is associated with DR-NCD ²⁴⁻²⁶. In this study, participants also had DR-NCDs like CVDs, CKD, and neuropathy. The study also showed that the participants had several symptoms of diabetes such as polyuria, nocturia, lethargy, weakness, tingling/burning sensation in legs, and blurring vision. These are indicative of poor PPG control.

Hence, lowering PPG is considered an important diabetes management strategy and is recommended by the International Diabetes Federation (IDF) ^{24,25}. Low GI/GL dietary interventions help in improving Glycemic control including lowering PPG ²⁷. The PRIDE study (Partial meal

Replacement on Glycemic level and Body weight in Indian Patients with T2DM) showed that partial meal replacement with ONS can positively impact FBG, PPG, and HbA1c, and can be an option to manage diabetes ²⁸. Our study showed that the ONS Vidavance® has a low GI of 30.57 and low GL of 3.85, and is thus an ideal snack replacement for PD. We also show minimal Glycemic variation with Vidavance® and a decrease in PPG as compared to reference food.

The scientific and judicious blend of proteins, fibers, carbohydrates, and other nutrients in Vidavance® are likely to be responsible for the low GI/GL benefit and the PPG lowering effect. The key ingredients of interest in Vidavance® include soy protein isolate, calcium caseinate, soy Fiber, Polydextrose, modified maltodextrin, chromium, zinc, antioxidants, and vitamins. The ingredients of Vidavance® also play an important role in decreasing the risk of diabetes. A high fiber, low GI, low GL nutrition blend with proteins and low-calorie carbohydrate significantly decreases the risk of diabetes as compared to a high GI, high GL and low fiber diet ^{29, 12-14,30}.

The maltodextrin component of Vidavance® is a low-palatable, viscous, fiber with ample evidence showing that it reduces the Glycemic response to food ³¹. There is a reduction in PPG as well ³².

Polydextrose is a low-calorie (only 1 kcal/g), sugar-free, low-GI (4-7) carbohydrate, that also improves satiety, and thus is ideally suited for a diabetic diet ^{10,11}.

Polydextrose reduces glucose absorption and thereby reduces its GI by 11%³³. When given in combination with soy protein or maltodextrin, as in Vidavance[®], there is a reduction in energy intake, gastric emptying rate, appetite, and Glycemic response^{12,13}. Decreased food and energy intake helps in losing weight and thereby obesity-related diabetes³⁴.

Asian Indians are more susceptible to metabolic diseases owing to their protein deficit staple diet and relatively greater body fat than Caucasians.^{9,35-37} Vidavance[®] contains a high-quality blend of protein (soy protein isolate, calcium caseinate) with Protein Digestibility Corrected Amino Acid Score (PDCAAS) 1³⁸. A diet rich in high-quality protein can help induce satiety and reduce fat mass¹⁴.

The micronutrient components present in Vidavance[®] are also beneficial for diabetes. E.g. Chromium enhances insulin activity, improves blood sugar metabolism, and decreases diabetes-associated oxidative stress^{15,16}. Zinc has a protective effect on vision and prevents diabetic retinopathy¹⁷. High blood sugar increases the risk of retinopathy. 11 patients in this study complained of blurring vision before the test.

Judicious macronutrient and fiber composition of a diet can help change a high GI meal to a low GI meal with a significant reduction in PPG^{39,40}. Vidavance[®] is a low GI/GL option with high protein and soluble Fiber and other micronutrients conferring health benefits in diabetes. Hence, Vidavance[®] can be a healthy ONS and Medical Nutrition Therapy (MNT) of choice both for the prevention and control of diabetes.

Strengths And Limitations

The study shows that Vidavance[®] demonstrated a low GI/GL and reduction in PPG in a real-world setting, where participants ate their normal diet. We only standardized the same diet that they ate on the test day

as taken on the previous day. The study, however, had some limitations. The study assessed the effect of a single meal replacement with Vidavance[®] for one day only.

Physical activity can also affect the energy and blood glucose level. Hence, further trials are required to study the effect of Vidavance[®] when people go about their normal daily routine. The components of Vidavance[®] can also help in weight loss and this effect too can be studied in a real-world setting.

Conclusion

The Glycemic index of the Vidavance[®] is 30.57, which is below 55 and hence is classified as a low GI food product/ONS. The Glycemic load is 3.85 which is low GL. The GI value of Vidavance[®] was not influenced by age, sex, and dietary calories. Based on our study results, the ONS and MNT Vidavance[®] could be a suitable healthy supplement for diabetes. Future large-scale clinical trials are required to study the long-term effect of Vidavance[®] on diabetes and weight management.

Ethics Compliance: The study was approved by the Good Society Ethical Research-Independent Ethics Committee.

Conflict of interest: None

Funding: None

Acknowledgements

The authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work, and have given final approval for the version to be published. The authors thanks Pramod Pillai, Sanjay Singh of Signutra Inc and Mediception Science Pvt. Ltd. (www.mediception.com) for providing medical writing support in the preparation of this manuscript.

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