Medical Research Archives

ESMED
European Society of Medicine

OPEN ACCESS

Published: March 31, 2023

Citation: Gayathri R, Parkav K, et al., 2023. Glycemic Index of a High Protein and High Fiber Oral Nutritional Supplement Vidaslim®, Medical Research Archives, [online] 11(3). https://doi.org/10.18103/mra.v11i3.3576

DOI
https://doi.org/10.18103/mra.v11i3.3576

ISSN: 2375-1924

RESEARCH ARTICLE

Glycemic Index of a High Protein and High Fiber Oral Nutritional Supplement Vidaslim®

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ABSTRACT

Background: Food products with a low Glycemic index (GI) help control blood glucose levels and may also help reduce body weight. The risk of obesity-related chronic diseases increases with the consumption of refined carbohydrate-rich or a diet with high GI food choices. Vidaslim®, an Oral Nutrition Supplement was formulated by Signutra Inc, with a high protein blend (whey, soy, and casein), dietary Fiber (polydextrose), and several phytonutrients with an attempt to reduce body weight.

Aim: To determine the GI of the Vidaslim® in fifteen overweight / obese people aged between 20 and 45 years.

Methodology: The study participants consumed the test food, Vidaslim® containing 25 g of available carbohydrate. Participants underwent 3 days of reference food (glucose) testing and 1 day of test food with 2 days of wash-out period. In between capillary blood glucose was measured after overnight fasting at 0, 15, 30, 45, 60, 90, and 120 min after consuming the reference and test food in a random order. The GI was assessed using a validated protocol by FAO and ISO (2010). Following this, the glycemic load (GL) of Vidaslim® was also calculated.

Results: Out of 15 participants who completed the study, 3 were removed as statistical outliers (GI > mean ± 2SD), and hence the data was presented for the remaining 12 participants. The mean age of the participants was 28.1±5.4 years, and body mass index (BMI) was 27.2±2.7 kg/m^2. Vidaslim® had a low GI value of 22±3.4 (Mean±SD). The GI value was not influenced by age, sex, dietary total calories, protein, fat, carbohydrates, dietary Fiber, and physical activity levels. The Glycemic Load (GL) of Vidaslim® was 3.43 (low GL).

Conclusion: The oral nutritional supplement, Vidaslim®, has a low GI and GL value, and hence, could be a suitable healthy supplement for those with obesity and diabetes.

Keywords: glycemic index, nutritional supplement, weight loss, obesity, diabetes.

INTRODUCTION

The prevalence of diabetes has been rising rapidly and globally affecting approximately 537 million people (International Diabetes Federation Diabetes Atlas, 10th edition 2021). In 2021, 74.2 million diabetes cases were reported in India, accounting for a 21% increase over a decade. Nearly 6.7 million deaths in 2021 were attributed to diabetes and its complication. [1]Postprandial hyperglycemia is the manifestation of abnormal glucose homeostasis.[2] A low-quality diet increases the risk of poor glycemic control by nearly threefold than those who consume a higher-quality diet.[3] A nutritionally balanced food that curbs post-meal blood sugar spikes is pivotal in diabetes management. Being overweight or obese is a strong predisposing factor for diabetes. Globally, ≈2 billion adults are overweight, and 650 million are obese.[4] The World Obesity Federation estimated that by 2030, there will be one billion people living with obesity.[5] According to the National Family Health Survey (NFHS)-5 (2019-2021), 24% and 23% of women and men, respectively are obese in India.[6] A healthy diet that enables the maintenance of normal body weight can help prevent or delay the onset of diabetes.[7]

Excess dietary carbohydrates are known to predispose to both diabetes and obesity.[8]However, both quantity and type of carbohydrates are important. The glycemic index (GI) and glycemic load (GL) of the carbohydrate determine its quality. The International Scientific Consensus Summit from the International Carbohydrate Quality Consortium recognized GI as a valid and reproducible method of classifying carbohydrate foods. Diets low in GI and GL are considered to be healthier.[9] A low GI diet is associated with a decrease in HbA1c and hypoglycemic episodes than a high GI diet. [10] Recently high GI has been linked to mortality.[9]

Glycemic control can be optimized with low glycemic index diets, specifically in people with prediabetes or diabetes. In addition, a low-GI diet could help in reducing body weight.[11] Postprandial glucose level is lower following a diet low in GI than a high GI diet.[12] The National Dietary Guidelines Consensus Group emphasize the preferential intake of complex carbohydrates and low GI foods and reduce the intake of refined carbohydrates.[13] High-carbohydrate diets with greater unrefined carbohydrates and fiber, predominantly of low GI, are beneficial in impaired glucose tolerance, diabetes, or obesity.

Unhealthy lifestyle and food habits have largely contributed to the rising prevalence of obesity and other diet-related non-communicable diseases (DR-NCDs) including type 2 diabetes mellitus, hypertension, and cardiovascular diseases, in India.[13] Low GI diets reduce glycated hemoglobin (HbA1c), fasting glucose, body mass index (BMI), total cholesterol, and low-density-lipoprotein (LDL)-cholesterol,[11] In addition, low GI diets also decrease insulin resistance, free fatty acids levels, inflammation and endothelial dysfunction.[14] All these help reduce the risk of obesity and DR-NCDs.[15] Hence an optimum diet comprising carbohydrates constituting 50–60% of total caloric intake from low GI foods, soluble and insoluble fibers, and fruits and vegetables.; protein accounting for 10–15% of daily caloric intake and fat providing less than 30% of total energy per day is ideally recommended for a healthy life.[13]

Vidaslim® is a proprietary oral nutritional supplement (ONS) which was designed keeping in view the dietary needs and recommendations for preventing obesity and DR-NCDs. Vidaslim® comprises a high protein blend (whey, soy, and casein), dietary Fiber (polydextrose), green tea extract (catechins), *Phaseolus vulgaris* extract L-carnitine, and myo-inositol, which are known to influence blood glucose control and/or facilitate body weight reduction.[16–24] .

The present study was carried out to measure the GI of the oral nutritional supplement Vidaslim® in Asian Indian obese or overweight individuals as this product was specifically developed for overweight and obese.

METHODOLOGY

Participants (Fifteen overweight/obese participants aged 18–45 years with body mass index (BMI) ≥23.0 kg/m^2 with no known food allergy or intolerance and who were not taking any medications known to affect glucose tolerance were recruited from the participant roster of Glycemic Index Testing Center, Madras Diabetes Research Foundation (MDRF). Participants on special diet restriction, pregnant and lactating mothers, with a known history of diabetes mellitus, presence of disease or on a drug(s) that may influence digestion and absorption of nutrients and have had a major medical or surgical event in the last 3 months were excluded from the study.

Test and Reference Food

The test food, Vidaslim®, is a food supplement 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. The amount of test food for the GI study (containing 25 g of available carbohydrates) was 117.4 g of ONS mixed in 390 ml of water. The reference food was

25 g of glucose monohydrate dissolved in 125 ml of water.

Glycemic Index Testing

All participants underwent three days of reference food testing and one day for the test food in random order with a minimum of 2–3 days wash-out between measurements to minimize carry-over effects. The participants visited the GI testing Center each test day in the morning after 10–12 hours overnight fast. A brief questionnaire on the previous day's meals (24-hour recall), physical activity, smoking, alcohol, and caffeine-containing drinks was obtained to ensure that the participants followed the same diet daily and performed the same level of physical activity on pre-test dates. Participants had to refrain from smoking and alcohol during the study period. Female participants were not tested during menstrual period days and their tests were rescheduled. The duration of the study was two months.

Participants unfamiliar with blood sampling via finger-pricking (capillary blood sampling) performed a practice test to acquaint themselves with the procedure. Fasting blood samples were taken at -5 mins and 0 min by finger-prick, using an automatic lancet device before consumption of the food, and the baseline value was taken as a mean of these two values. The participants then consumed 25g of the available carbohydrate portion of the test food, i.e., Vidaslim®, within 12–15 minutes per the ISO protocol. The first sip in the mouth was set as time 0, and the first blood sample was taken conventionally exactly 15 min afterwards, and further capillary blood samples were obtained at 30, 45, 60, 90, and 120 minutes after the start of the test meal. Participants were given 125 ml of water during the next two hours for both test and reference food testing.

The Incremental Area Under the blood glucose response Curve [IAUC] was calculated. The coefficient of variation (CV) >30% was identified as an outlier as suggested by the ISO protocol and removed from further analysis. The individual GI calculation was based on each participant's IAUC post-ingestion of the test meal, which was calculated as a percentage of the mean IAUC after the same subject consumed standard glucose. The mean group value of the test food was considered as the GI of the test food.

Glycemic Index Testing Center, Madras Diabetes Research Foundation (MDRF) followed the Internationally recognized GI protocol issued by FAO/WHO, 1998 and guidelines endorsed by the International Dietary Carbohydrate Task Force for GI methodology. Glycemic Index Testing Center, Madras Diabetes Research Foundation (MDRF) also followed the ISO method (ISO 26642-2010), which is validated and published elsewhere,.[2,25–27]

Statistical analysis

The GI study included 15 overweight/obese participants, out of which 2 participants showed a coefficient of variation (CV) >30% as within individual variability with reference glucose fed on three occasions and hence were removed from the analysis. Outliers who had values beyond mean ± SD in this study were excluded. Participants with IAUC 0 were also removed. The GI of the test food was finally based on 12 participants' data. The GL of the test food was also calculated.

The IAUC of changes in blood glucose concentration was calculated for the reference and test food based on the geometrical method using the trapezoid rule, simultaneously ignoring the area below the fasting baseline level. [25–27]The mean and standard errors (SD) of the AUC were calculated for the reference and test food. 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.

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

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 based (sedentary, moderate, and vigorous) levels] using a generalized linear model (GLM).

The following formula was used to calculate the GL of the test food

GL value 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 our center and all participants gave informed consent. The study was registered with the clinical trial registry of India as CTRI/2021/01/030413. The study method is summarized in **Figure 1**.

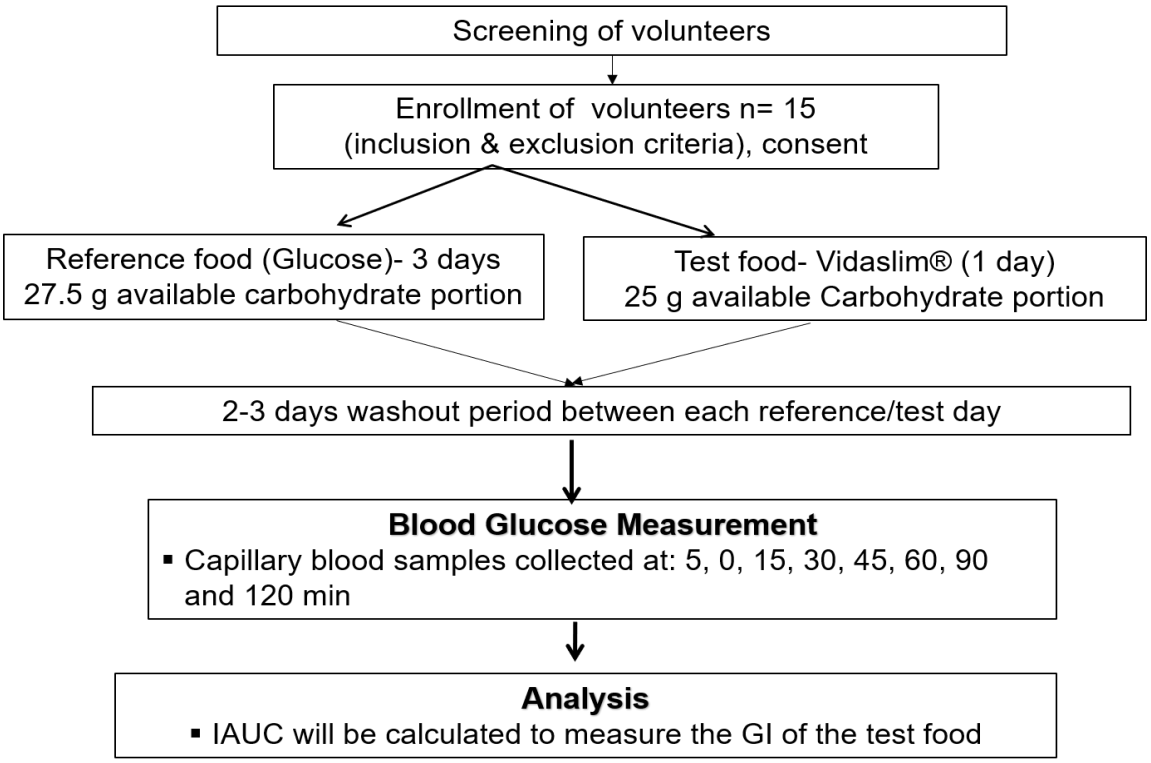

Figure 1: Study protocol including screening of partcipants, study method, and analyses

RESULTS

The mean age of the participants was 28.1±5.4 years and the mean BMI 27.2±2.7 kg/m^2. Using linear regression models including terms for major potential confound factors and energy intake, GI was inversely related to BMI: the coefficient (for the highest compared to the lowest percentile) was −0.479 (**Table 1**). No consistent association was found with age.

Table 1: Beta coefficients of confounders with GI of Vidaslim®.

Variables	**Beta coefficient**	**P value**
Age (years)	0.178	0.82
BMI (kg/m^2)	-0.479	0.729
*Total energy (Kcal/d)	0.002	0.741
Sex (male/female)	11.91	0.81
* Based on 24 h dietary recalls collected on the days of reference and test food feeding BMI, body mass index, GI, glycemic index		

Postprandial blood glucose concentration (mg/dL) at 15, 30, 45, 60, 90, and 120 min after ingestion of test food was lower than the reference food. The blood glucose excursions (mg/dl) for 2 hours following the intake of test food were minimal (**Figure 2**).

The GI of the test food (Vidaslim®) was 22±3.4 (low GI category). The GI value was not influenced by age (years), sex, previous day's dietary intake [energy (kcal), protein (g), fat (g), carbohydrates (g), dietary fiber (g)], and physical activity level (Table 2). The GL of the test food (Vidaslim®) was 3.43 (low GL category).

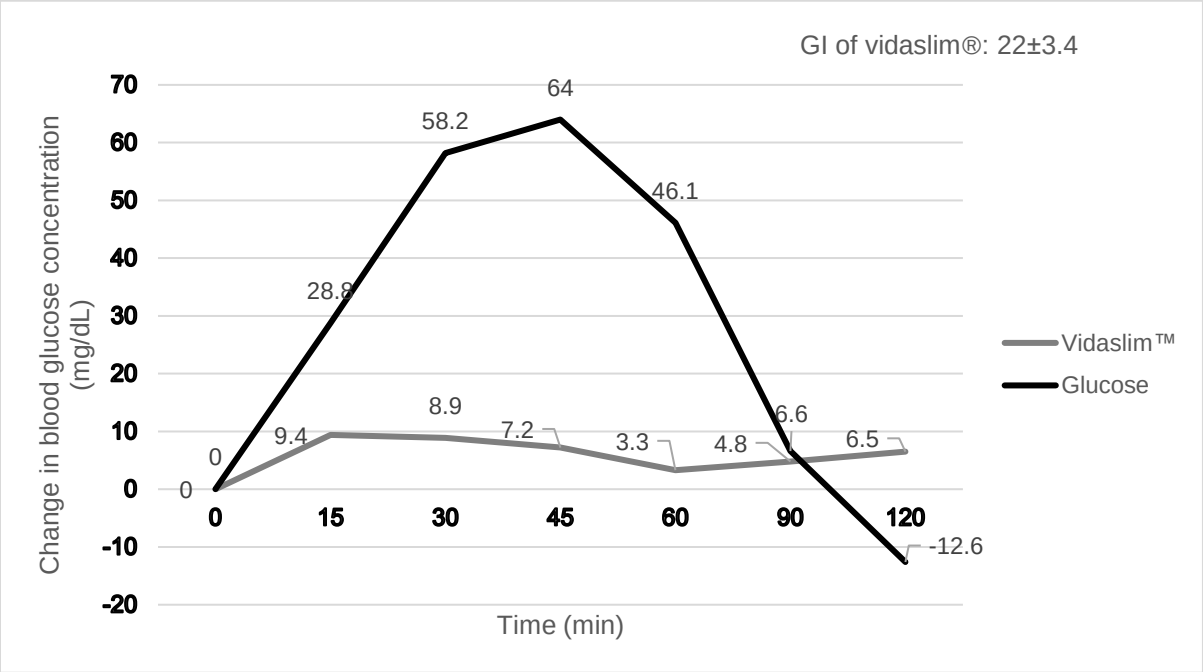

Figure 2: Glycemic Index (GI) of the nutritional supplement compared to reference food

Discussion

The concept of GI is valuable in understanding the effects of the glycemic property of carbohydrate-containing foods on the risk of obesity and diabetes. The study reports a low GI of 22 for Vidaslim®, which was much lower than the standard cutoff of 55 for foods as having low GI. The study reported a low GL of 4.86 which fell into the low GL category of 0-10.

A long-term study (median 9.5 years follow-up) by Jenkins et al involving a large population of people (N=137,851) living across five continents found that a diet with a high glycemic index increased the risk of CVD by 51% and 21%, respectively in patients with and without pre-existing CVD. Further, a high glycemic index had the tendency to increase the risk of CVD-related mortality.[9] The Chennai Urban Rural Epidemiology Study examined the association between dietary carbohydrates, GL or GI and the risk of diabetes in a randomly selected population (N=1843). The study found that the odds of diabetes were significantly higher with higher dietary carbohydrate GL and GI are inversely associated with higher dietary fiber (OR 0.31 [95 % CI 0.15, 0.62]; $p < 0.001$).[28]

The International Diabetes Federation (IDF) recognizes postprandial hyperglycemia as an important target in the management of diabetes because it is associated with DR-NCD.[29] The IDF recommends diets with a low GL as they are beneficial in improving glycemic control and hence the emphasis on dietary interventions which can lower postprandial glucose.[30]

The GI is also a strong predictor of glycemic variations. Hence, determining of GI of foods is essential to understand their impact on glycemia. Postprandial glucose was significantly lower following a low-GI diet with low-carbohydrate meals than a low-GI diet with high-carbohydrate meals.[32] Replacing a high GI meal with a low GI meal reduced postprandial hyperglycemia and energy intake due to change in the macronutrient composition of the meal and higher dietary content.[33,34] Hence the development of low-GI food options is the need of the hour. Vidaslim® being a low GI option with a higher protein, and soluble Fiber content with other health-beneficial ingredients can be a healthier choice both for prevention and control of obesity or diabetes.

Asian Indians are more susceptible to metabolic diseases owing to their protein deficit staple diet and relatively greater body fat than Caucasians.[35–38] The higher protein intake of Vidaslim® (from milk and soy) can help to improve the protein content of the diet.

Even modest weight loss can have profound clinical benefits. A moderate carbohydrate and low GI diet was associated with greater reductions in BMI than a moderate carbohydrate and high GI diet.[39] A decrease in fasting insulin, insulin resistance, and β cell function was noted with greater in a moderate carbohydrate and low GI diet than in a low-fat and high-GI diet.[39] Due to the lower GI and GL of Vidaslim®, it can be incorporated in low GI diet plans and in dietary interventions for obesity, diabetes targeting weight loss, and glycemic

control. Such studies can throw more light on the health benefits of long-term consumption of Vidaslim®.

The unique combination of the ingredients in the Vidaslim® formulation, which includes, proteins (calcium caseinate and soy protein isolate), dietary fiber (Polydextrose), phytonutrients, in combination with vitamins and minerals, fiber. After spray drying, might have resulted in the formation of a complex matrix which results in slow digestion and absorption of the digestible carbohydrate component present in the formulation. These individual ingredients are known for their beneficial effects on diabetes and obesity.[16–24] This dietary combination could possibly influence physiological and physical functions such as delayed gastric emptying, slower amylolysis and absorption, from the gut, increase satiety and thermogenesis, and regulated glucose homeostasis, and thus can aid weight loss in the longer term..[17,19,21,24,40–44] The three proteins, whey, soy, and casein, are high-quality proteins.[45] Whey and casein are complete milk proteins.[45,46] The release of amino acids from whey protein is faster and high, while casein releases the amino acids slowly and steadily.[45] Soy protein is a plant-based complete protein rich in arginine, phenylalanine, and tryptophan. These proteins are part of low GI diet for obesity as they promote weight loss through satiety-induced negative energy balance.[41,45,46] Compared to isoenergetic carbohydrate consumption, protein is more satiating. A protein-based diet promotes weight loss by reducing energy consumption.[44] Excessive energy intake and inadequate energy expenditure are obesity traits.

Melson et al. found that energy intake at lunch was higher in participants who consumed a carbohydrate liquid breakfast (769 ± 259 kcals) than those who consumed soy (664 ± 296 kcals) or whey protein (654 ± 252 kcals) at breakfast.[47] There was no significant difference in energy consumption at lunch between soy and whey protein. Soy and whey protein liquid breakfast were significantly associated with a higher thermic response than carbohydrate breakfast.[47] Diet-induced thermogenesis is highest with protein (nearly 15%–30%) while about 5-10% for carbohydrates and 3% for fat.[41] Baer et al. further showed that a whey protein-based diet significantly reduced body weight and fat mass by 1.8 kg ($p<0.006$) and 2.3 kg ($p<0.005$), respectively, compared to isoenergetic carbohydrate, after 23 weeks in overweight and obese adults.[48]

The key components of whey protein stimulate the pancreatic secretion of insulin and incretin peptides and intestinal secretion of cholecystokinin and peptide tyrosine; Increased secretion of glucagon-like peptide-1 modulates gastric emptying and food transit time. The whey protein-induced insulin secretion suppresses appetite, reduces gastric emptying, and decreases hepatic glucose production through central mechanisms.[42] Several studies have shown the utility of whey protein in controlling postprandial glucose in people with diabetes.[18,22,23,49]

Polydextrose is a low-calorie, low-glycemic carbohydrate with favorable physiological effects on glucose homeostasis and lipid metabolism. The energy value of polydextrose is merely 1 kcal/g. The low glycemic index (4–7) of polydextrose is ideally suited for a diabetic diet.[21] When consumed with glucose, polydextrose reduces the glycemic index of glucose by 11% by reducing the absorption of glucose.[50] The effect of polydextrose is evident in the postprandial setting rather than the fasting setting. Polydextrose is associated with reduced insulin response.[17,21] A polydextrose diet (substituting 30% of available carbohydrates with polydextrose) at breakfast and lunch reduced the peak glucose response after breakfast and insulin response after breakfast and lunch in overweight adults.[51]

Green tea extracts are known for their antioxidant properties. Evidence on the effect of green tea extract on diabetes and obesity is evolving. A meta-analysis of 27 trials showed that green tea could significantly lower the fasting blood glucose levels.[24] Preclinical studies have shown some anti-obesity effects.[19]

Phaseolus vulgaris extract (kidney beans extract) is known to induce weight loss and reduce body fat mass, body fat percentage, overweight percentage, and BMI in a short period. Those treated with *Phaseolus vulgaris* extract (along with protein, up to 75.4 ± 1.2 g/100 g of the extract, carbohydrates, 14.5 ± 0.6 g/100g and fat 2.8 ± 0.2 g/100g) for 35 days (2,400 mg per day) showed a 2.24 kg weight loss compared to 0.29 kg with placebo.[43] One study showed that *Phaseolus vulgaris* extract containing α-amylase inhibitor and phytohemagglutinin could reduce postprandial glucose, insulin, and C-peptide excursions and suppress ghrelin secretion. *Phaseolus vulgaris* extract also affected satiety sensations by inducing a lower desire to eat.[53] Preclinical studies have shown that alpha-amylase inhibitors could reduce blood glucose levels. The anorexigenic action of the alpha-amylase inhibitor in *Phaseolus vulgaris* extract leads to reduced intake of food and hence weight reduction.[54]

Carnitine has a crucial role in fatty acid metabolism and is suggested to have a potential adjuvant role in treating or preventing insulin resistance and type

2 diabetes.[16] Inositol has been suggested as a strategy for improving glycemic control in people with diabetes because of its effect on both fasting blood glucose and HbA1c levels.[20]

Thus, the test food, Vidaslim®, is a scientific and judicious blend of proteins, fibers, carbohydrates, and other nutrients with several functional benefits and is poised to fulfil the body's metabolic needs, attenuate postprandial hyperglycemia, and support healthy weight loss.

Our study shows that the GI of Vidaslim® is low in the real-world setting. We allowed participants to have their normal diet other than at the time of testing the product. The study had some limitations. There was no means of knowing the influence of regular diet on the GI of Vidaslim®. The blood for tests was withdrawn by the participants themselves so there could have been some bias regarding the timing of withdrawal. This study was conducted on obese/overweight people and people with diabetes were excluded.

CONCLUSION

In summary, the Glycemic index of the Vidaslim® is 22 (SD 3.4) and is hence classified as a low GI food product). The GI value of Vidaslim® was not influenced by age, sex, dietary calories, protein, fat, carbohydrates, dietary fiber, and physical activity levels. The glycemic load of Vidaslim® is 3.43 (low GL category). Based on our study results, Vidaslim® could be a suitable healthy supplement for obesity and diabetes. Future large-scale clinical trials involving diabetic participants would further explain the usefulness of low GI supplements in those with diabetes.

Ethics Compliance: Ethical Compliance was obtained from Madras Diabetes Research Foundation, Chennai.

Conflict of interest: None

Funding: None

Acknowledgements

All named 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 thank Dr. Atul Mishra from Signutra Inc and Dr. Punit Srivastava of Mediception Science Pvt. Ltd (www.mediception.com) for providing medical writing support in the preparation of this manuscript.

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