Effect of a Nutritional Supplement Combination on Blood Glucose Measurements in Adults with Type 2 diabetes

DOI 10.14200/jrm.2023.0005

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ABSTRACT

We studied the effect of a dietary supplement on blood glucose. This prospective, single-arm, unblinded clinical interventional study investigated the impact of a nutritional supplement combination on fasting glucose and glycated hemoglobin (A1c) levels, which were measured before and after the intervention. The supplement, which consisted of organic mulberry leaf extract, LactoSpore probiotics, and Fenumannan prebiotic, was given to adult (age ≥21 years) prediabetics and adults with type 2 diabetes (A1c >5.60 mg/dL). The study protocol comprised six phases including initial and final tests for fasting glucose and A1c, and a 12-week period of supplement administration. The statistical analyses were carried out using SPSS and Intellectus Statistics. A total of 24 participants completed the study. A reduction of 0.94% in the A1c level and 40.52% in the fasting glucose level were found. These preliminary findings suggest that the nutritional supplement combination might be clinically effective in reducing fasting glucose and A1c in prediabetic adults and those with type 2 diabetes.

Keywords: Type 2 diabetes; Prediabetes; Fasting glucose; Glycated hemoglobin A1c; Natural glucose modulator; Organic mulberry leaf extract; LactoSpore probiotics; Fenumannan prebiotic

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INTRODUCTION

In the current context of the global increase in the prevalence of prediabetes and type 2 diabetes,[1] the need for innovative approaches to improve glucose management is becoming urgent.[2] To that end, this study addresses the potential impact of a nutritional supplement combination on fasting glucose and glycated hemoglobin (A1c) in prediabetic and type 2 diabetic adults. This nutritional supplement is formulated with three key components: organic mulberry leaf extract, LactoSpore probiotics and Fenumannan prebiotic. Organic mulberry leaf extract is derived from the leaves of the mulberry tree (*Morus* species). It contains the compound 1-deoxynojirimycin (DNJ), which has been found to inhibit certain enzymes involved in carbohydrate metabolism. Specifically, DNJ inhibits the activity of alpha-glucosidase, an enzyme that breaks down complex sugars into simple sugars, resulting in a slower release of glucose into the bloodstream. By reducing the rate at which carbohydrates are broken down and absorbed, organic mulberry leaf extract can help lower blood sugar levels and prevent spikes in glucose levels after meals.[3]

LactoSpore is a trademarked probiotic ingredient that contains the spore-forming bacterium *Bacillus coagulans*. Probiotics are live microorganisms that confer health benefits when consumed in adequate amounts. Research suggests that certain strains of probiotics, including *B. coagulans*, may help improve glycemic control.[4] They can enhance insulin sensitivity, increase the production of short-chain fatty acids (SCFAs) in the gut, and modulate the gut microbiota composition. SCFAs produced by *B. coagulans* can influence glucose metabolism and improve the body's ability to regulate blood sugar levels. Subjects who ingested yogurt with *Bifidobacterium* BB-12 probiotics showed lower expression of Toll-like receptor 2 (TLR-2) such that the immune response caused by inflammation was decreased. These results demonstrated a potential anti-inflammatory effect of BB-12 in healthy adults and also indicated that the matrix to which the probiotics is added may influence the immunomodulatory properties.[5]

Fenumannan is a trademarked prebiotic ingredient derived from fenugreek seeds (*Trigonella foenum-graecum*). Prebiotics are nondigestible fibers that promote the growth and activity of beneficial bacteria in the gut. Fenumannan contains a high concentration of galactomannan, a type of soluble dietary fiber. Research suggests that galactomannan can help lower blood sugar levels by slowing down the absorption of glucose in the small intestine, thus reducing postprandial blood sugar spikes. Additionally, galactomannan acts as a prebiotic; it provides nourishment for beneficial gut bacteria, which can positively impact overall gut health and glucose metabolism.[6]

METHODS

This study employed a prospective interventional pre-post experimental design (Table 1) to investigate the impact of a nutritional supplement combination on fasting glucose and hemoglobin A1c levels in adults with prediabetes and type 2 diabetes. Each participant served as their own control. Participants taking hypoglycemic drugs were not excluded from the study because we aimed to provide a broad representation of potential users. However, any changes in dosing would exclude a participant from the study. In addition, participants did not use other over-the-counter (OTC) products for the duration of the study and no physical exercise interventions were implemented, ensuring that any observed changes can be primarily attributed to nutritional supplementation.

Table 1: Participant demographics.

Characteristics	
Total participants (initial)	30
Total participants (completed)	24
Male (*n*)	9
Female (*n*)	15
Age (years)	≥21
Condition	Type 2 diabetes with A1c >5.60 mg/dL

The supplement is composed of organic mulberry leaf extract with DNJ at 0.14% and quercetin 3-(6-malonylglucoside Q3 mg) at 1500 mg, LactoSpore probiotics (containing 1 billion *B. coagulans* MTCC 5856 spores at 10 mg), and Fenumannan (consisting of 60% galactomannan) at the 400-mg per serving size (three capsules). Participants were advised to consume three capsules of the supplement before each meal, for a total of nine capsules daily.

This study used an experimental quantitative methodology, with a pre-post design, to discern changes in blood glucose levels before and after supplement administration.

PARTICIPANT SELECTION

Potential participants were identified in the clinics of Dr. Edgardo Ramírez, NL, in San Juan and Mayagüez, Puerto Rico. The initial recruitment effort yielded 30 adult participants, 24 of whom (9 males and 15 females) completed the study.

INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria were: 1. Adults over 21 years of age, and 2. Diagnosed with prediabetes or type 2 diabetes, with an A1c level higher than 5.60 mg/dL.

Exclusion criteria included a diagnosis of terminal illnesses and/or disabilities that could hinder the implementation of the selfcare protocols stipulated in the study design, and deviation from the prescribed use of the supplement during the study period. Participants were also told not to add any new medications with hypoglycemic effects, change the dose of current hypoglycemic medications, or modify dietary or exercise habits during the study period.

STUDY PROCEDURE

The laboratories participating in this research performed baseline and end-of-study measurements of glucose and A1c levels. This allowed precise determination of any metabolic changes in the study participants, both before and after the intervention.

The study required an initial baseline fasting glucose and A1c test previous to supplementation, and a follow-up laboratory test after the 12-week period of supplementation. After the end of the supplementation period and subsequent laboratory testing, the results were analyzed using advanced statistical software to determine if there were significant differences in the study endpoints before and after the intervention.

STATISTICAL ANALYSIS

For the statistical analysis, the Social Sciences Statistical Program (SPSS) and Intellectus Statistics software were used. A Wilcoxon signed-rank test was conducted to compare the initial A1c and fasting glucose levels with the final levels after 12 weeks of supplement administration.

RESULTS

Although the initial recruitment effort yielded 30 adult participants, only 9 males and 15 females completed the study. The initial average A1c value was found to be approximately 7.95 mg/dL (Table 2). After the interventions, the final average A1c value significantly decreased to approximately 7.51 mg/dL. The results of the two-tailed Wilcoxon signed rank test were not significant based on an alpha value of 0.05 (V=171.00, z=−1.00, P=0.158). This indicates that the difference between the initial median A1c level (7.47) and final median A1c level 7.40 mg/dL is explainable by random variation. Figure 1 presents a boxplot of the ranked scores for the initial and final A1c levels.

In this study, the average starting fasting glucose level was approximately 171.6 mg/dL. Following

Table 2: Study results.

Characteristics	
Initial average A1c (mg/dL)	~7.95
Final average A1c (mg/dL)	~7.51
Initial average fasting glucose (mg/dL)	~171.6
Final average fasting glucose (mg/dL)	~113.2
A1c result (*P*-value)	0.158
Fasting glucose result (*P*-value)	0.002

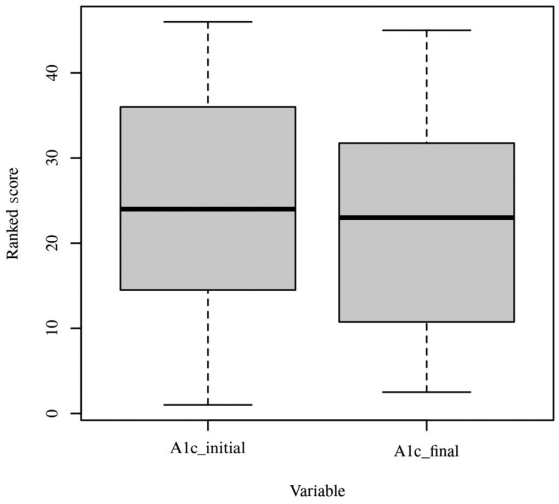

Figure 1: Ranked scores for the initial and final glycated hemoglobin (A1c) levels.

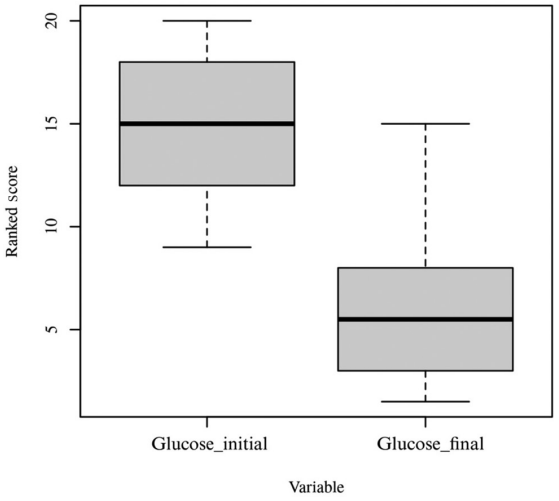

Figure 2: Ranked scores for the initial and final glucose levels.

the supplementation interventions, the mean fasting glucose level dropped remarkably to approximately 113.2 mg/dL. The results of the two-tailed Wilcoxon signed rank test were significant based on an alpha value of 0.05 (V=55.00, z=−2.81, P=0.002). This indicates that the differences between the initial and final glucose levels was not likely due to random variation. The median initial glucose level (163.00 mg/dL) was significantly larger than the median final glucose level (108.00 mg/dL). Figure 2 presents a boxplot of the ranked scores for the initial and final glucose levels.

DISCUSSION

A decrease in the average A1c value was observed in this study, from an initial value of 7.95 mg/dL to a final value of 7.51 mg/dL, indicating a potential improvement in type 2 diabetes. In addition, a significant drop was also recorded in the average fasting glucose level, from 171.6 mg/dL at the beginning of the study to 113.2 mg/dL after administering the supplement over a period of 12 weeks. These results provide support for the effectiveness of the intervention. The Wilcoxon test for comparing initial and final A1c levels showed a reduction of 0.94%. Even though this change was not statistically significant, it reflected a clinically relevant reduction and points toward a reducing trend that may need more time to become statistically significant. It is important to highlight that the red blood cell lifespan is around 90 days. Regarding fasting glucose, the results of the Wilcoxon test revealed a significant reduction of 40.52% between the initial and final levels.

Preliminary evidence suggests that organic mulberry leaf extract, LactoSpore probiotics and Fenumannan prebiotic may contribute to a reduction of fasting glucose and A1c levels in adults with prediabetes or type 2 diabetes. This is an important finding that adds to the growing body of evidence suggesting a beneficial role for natural blood glucose level modulators in managing these difficult conditions.[7]

This preliminary study revealed a trend toward a reduction (0.94%) of A1c, a long-term measure of glucose management effectiveness. In contrast, a more notable reduction was observed in fasting glucose levels (40.52%). This difference in magnitude between the changes in fasting glucose and A1c levels may be due to differences in the degree to which these two parameters reflect blood sugar control. While fasting glucose levels provide a short-term measure, A1c levels provide a long-term measure, as mentioned before.

Limitations of this study included a lack of blinding and randomization, small sample size, and the loss of some participants to follow up. Furthermore, given the 12-week duration of the study, the possibility that seasonal variations might have influenced participants' dietary habits and physical activity cannot be ruled out. While our results

are promising, they underline the necessity for randomized controlled trials. Only through such rigorous study designs can we ascertain whether the observed benefits were directly attributable to the intervention and were not confounded by external factors.

Lastly, this discussion would not be complete without mentioning the impact of the principles of nutritional kinetics when interpreting the results. As we explained in another paper, nutrient studies must consider the specific form and dosing of a nutrient, as well as the potential need for higher amounts in some individuals and longer periods of time to observe metabolic effects. Therefore, higher doses of the nutritional supplement combination and/or a longer study duration may have been optimal.[8] In summary, this study makes a significant step toward determining the role of nutritional supplement combinations in management strategies for prediabetes and type 2 diabetes.

ACKNOWLEGMENTS

This study was part of a master's degree thesis (JNP), and support was provided by Weil Group Inc. (Puerto Rico) and Livestream Group Pte, Ltd. (Singapore).

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