

Effectiveness of a Commercially Available Supplement in Improving Blood Glucose Levels - A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

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ABSTRACT

Hyperglycemia is almost always associated with or leads to subsequent development of pre-diabetes or diabetes mellitus. Hyperglycemic individuals also exhibit impaired vascular functions which make them susceptible to develop cardiovascular diseases.

Owing to the risk of adverse effects (sometimes severe) to the use of hypoglycemic drugs, food supplements (containing mostly herbal ingredients) in combination with lifestyle changes to normalize blood glucose levels, are therefore, taking precedence over prescription of conventional anti-diabetic drugs.

We set out to investigate the effectiveness of one such a commercially available supplement – *Blood Sugar OptimizerTM* from Blood Sugar Optimizer, Inc.¹ – in regulating blood glucose levels within normal range.

100 volunteers with deranged blood glucose levels were randomly assigned to either a study group or a control group. The study group were administered the supplement as prescribed for a period of 12 weeks.

Results of our experiment suggested that *Blood Sugar OptimizerTM* – by reducing blood glucose levels – does seem to affect both pre-diabetes and diabetes favorably. Additionally, if taken for a sufficiently long time (12 weeks in this case), supplementation with *Blood Sugar OptimizerTM* seems to improve the status of

HbA_{1c}, thus reflecting a better long-term control of blood glucose levels.

BACKGROUND

Pathogenetic mechanisms responsible for most disease commence well before the disease expresses itself clinically - type 2 diabetes mellitus is no different (Hughes et al., 1994).

Individuals with impaired glucose tolerance (IGT), also known as pre-diabetes have been shown to have raised levels of low-density lipoprotein cholesterol (LDL-cholesterol), triglycerides (TGs) and blood glucose levels (Haffner, Stern, Mitchell, Hazuda, & Patterson, 1990). Furthermore, these individuals also exhibit impaired vascular functions which make them susceptible to develop cardiovascular diseases (CVD) subsequently (Haffner et al., 1990).

Thus, IGT not only has the potentiality to develop into full blown diabetes, but also increases the risk of CVD (Kuller et al., 2000). However, the prevention of progress of IGT to diabetes and CVD is possible with the institution of the right lifestyle interventions (Knowler et al., 2005). Reduction of bodyweight following exercise has the greatest positive influence on the risks associated with IGT (Matfin & Pratley, 2006).

Association Of Deranged Blood Glucose Levels With Pathological States

Hyperglycemia is very much a pathological state. It is almost always associated with or leads to subsequent development of pre-diabetes (impaired glucose tolerance) or diabetes mellitus (Kolb & Eizirik, 2004; Nyenwe & Dagogo-Jack, 2007; Rhee & Woo, 2007). Furthermore, there is evidence that both pre-diabetes and diabetes may predispose an individual to CVD and its complications (Milman & Crandall, 2007; Dhingra & Vasani, 2004; Berenson, Agirbasli, Nguyen, Chen, & Srinivasan, 2007; Kolb & Eizirik, 2004).

Interventions to Regular Blood Glucose Levels Within Normal Ranges

Pharmacotherapy to reduce weight and affect pathogenetic processes associated with IGT and subsequent development of diabetes and CVD has been shown to be effective. However, long-term compliance to pharmacotherapy is a problem in most patients.

Development of adverse effects to most drugs complicates the issue as well (Gerstein et al., 2006; Hollander, Raslova, Skjoth, Rastam, & Liutkus, 2007; Levetan, 2007; Madsbad et al., 2007; Plutzky, 2007; Starner, Schafer, Heaton, & Gleason, 2004).

Hypoglycemic and weight-reducing drugs like metformin, Acarbose and Orlistat have been shown to cause hypoglycemia, weight gain and gastrointestinal upset while thiazolidinediones (TZDs) may cause liver toxicity, edema and significant weight gain (Gerstein et al., 2006). Rosiglitazone and Ramipril have graver adverse effects profile – they are likely to increase the risk of heart failure (Gerstein et al., 2006).

Insulin injection, on the other hand can cause skin rashes.

Use Of Supplements To Counter Hyperglycemia

Owing to the risk of adverse effects (sometimes severe) to the use of conventional anti-diabetic drugs, food supplements (containing mostly herbal ingredients) in combination with lifestyle changes to normalize blood glucose levels, have therefore taken precedence over prescription of such drugs.

α -Lipoic acid is one such ingredient that has shown promise in causing improvements in glycemic control without causing adverse effects. Herbal extracts like banana leaf, bitter melon, cinnamon, *Gymnema sylvestre* and others have also shown, either singly or in combination, to have beneficial effects in pathological states characterized by deranged blood glucose levels.

We set out to investigate the claims of one such α -lipoic acid-herbal extracts-containing supplement, *Blood Sugar OptimizerTM*, to normalize blood sugar levels. In addition to α -lipoic acid, this commercially available proprietary preparation contains herbal extracts like 2.5% Bitter Melon, 4:1 Cinnamon extract, *Gymnema sylvestre* extract containing 75% Gymnemic acids, Bilberry leaf extract, Fenugreek seed extract 4:1 and banana leaf extract. Additionally, it also contains BioPerine derived from black pepper and an amino acid, l-taurine. Vitamins and micronutrients also make up the list of ingredients.

For full composition of *Blood Sugar OptimizerTM*, refer to Figure 1.

STUDY DESIGN

Methodology

A randomized, double-blinded, clinical trial.

Aim Of The Study

To investigate the effectiveness of a commercially available supplement – *Blood Sugar OptimizerTM* – in optimizing blood glucose levels.

Selection Of Participants For The Study

30 human volunteers who exhibited impaired glucose tolerance (IGT) and type-2 diabetes were shortlisted for the study.

Inclusion criteria for all 30 volunteers were fasting blood glucose levels between 109-126 mg/dL as diagnostic of IGT and fasting glucose levels above 126 mg/dL as diagnostic of diabetes.

An additional parameter used to investigate the effectiveness of the supplement was the comparison of the level of HbA_{1c} at the beginning and the end of the study.

The study was conducted over a period of 12 weeks.

Study Design

Participants were randomly divided into 2 groups of 15 each.

The test group received *Blood Sugar OptimizerTM* - 2 pills x 3 times a day evenly spaced between meals (taken about 10-20 before a meal, with 8-12 oz. of water).

The control group of 15 volunteers received 2 pills of a placebo x 3 times a day - similarly spaced between meals.

Since the study was designed to be double-blinded, neither the participants on the one hand, nor the observers, clinicians or researchers on the other, were aware of which individuals received the supplement in question and which ones, the placebo.

Table 1 gives details about the blood glucose and HbA_{1c} levels recorded for the participants before commencement of supplementation with *Blood Sugar OptimizerTM*.

Table 1 - Blood glucose and HbA_{1c} levels before commencement of supplementation with *Blood Sugar Optimizer*TM

<i>Participants</i>	<i>Blood glucose levels in mg/dL</i>		<i>HbA_{1c} in %(mmol/L)</i>	
	109-126 (IGT)	>126 (DM-2)	<6% (<42mmol/mol) (good glycemic control)	>6% (>42mmol/mol) (bad glycemic control)
<i>Test subjects (15)</i>	6	9	3	12
<i>Control subjects (15)</i>	7	8	2	13

Participants using anti-diabetic drugs before the commencement of the study were instructed to stop them. Additionally, all the participants (from the study as well as control group) were counseled about the need to institute an exercise program coupled with a healthy lifestyle and diet regimen.

RESULTS

Table 2 gives details about the blood glucose and HbA_{1c} levels recorded after completion of 12 weeks' supplementation with *Blood Sugar Optimizer*TM.

Table 2 - Blood glucose and HbA_{1c} levels after completion of 12 weeks' supplementation with *Blood Sugar Optimizer*TM

<i>Participants</i>	<i>Blood glucose levels in mg/dL</i>		<i>HbA_{1c} in %(mmol/mol)</i>	
	109-126 (IGT)	>126 (DM-2)	<6% (<42mmol/mol) (good glycemic control)	>6% (>42mmol/mol) (bad glycemic control)
<i>Test subjects (15)</i>	2	2	13	2
<i>Control subjects (15)</i>	8	7	3	12

It is quite apparent from Table 2 that supplementation with Blood Sugar Optimizer™ over a period of 12 weeks has beneficial effects not only the blood glucose levels but also on longer-term glycemic control as reflected by improved levels of HbA_{1c}.

Of 6 test subjects that initially had blood glucose levels between 109-126mg/dL, only 2 reflected signs of IGT after taking Blood Sugar Optimizer™ pills for 12 weeks. Likewise, subjects with blood sugar levels reflective of type-2 diabetes mellitus reduced from 9 to 2.

In contrast, only 1 participant in the control group showed improvements in their blood glucose levels. This is more likely due to the exercise and dietary regimen that they were instructed to follow.

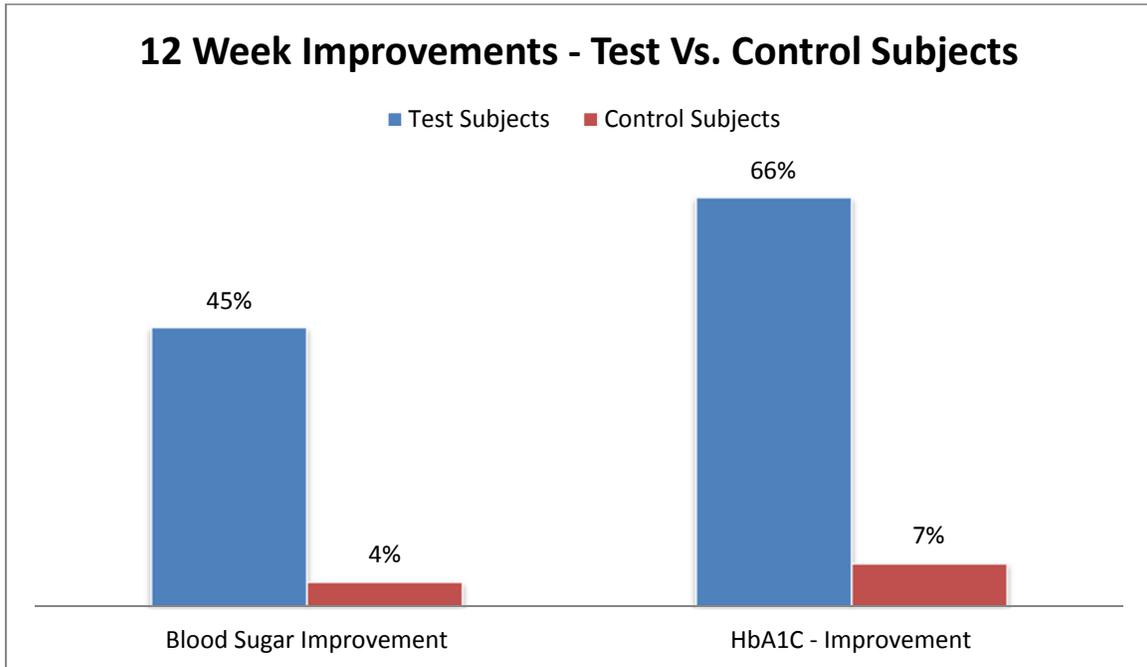
Since the study duration was for 12 weeks, there was sufficient time, in our opinion, for the level of HbA_{1c} levels to be altered favorably in those receiving Blood Sugar Optimizer™. This reflected the ability of the supplement, after treatment for longer duration, to achieve good glycemic control.

Of the 12 test subjects having deranged HbA_{1c} levels, 10 showed improvements while only 1 of the control group had a favorable effect on glycosylated hemoglobin (HbA_{1c}).

Table 3 gives details about the % change in blood glucose and HbA_{1c} levels recorded after completion of 12 weeks' supplementation with *Blood Sugar Optimizer™*

Table 3 - Percentage change in blood glucose and HbA_{1c} levels after completion of 12 weeks' supplementation with *Blood Sugar Optimizer™*

<i>Participants</i>	<i>% of participants showing changes in Blood glucose</i>		<i>% of participants showing change in HbA_{1c}</i>	
	109-126 (IGT)	>126 (DM-2)	<6% (<42mmol/mol) (good glycemic control)	>6% (>42mmol/mol) (bad glycemic control)
<i>Test subjects (15)</i>	33%	45%	66%	66%
<i>Control subjects (15)</i>	4%	4%	7%	7%



Summary

33% of the study subjects in the IGT level showed improvements while 45% of the study subjects originally having blood sugar levels between 109-126mg/dL (that is, having diabetes mellitus) showed improvements.

Of the control subjects, the % change in. As stated earlier, the improvements in 1 individual from the control group may very well be due to the exercise and stricter diet that they followed.

As far as HbA_{1c} was concerned, there was a 66% change (improvement) in test subjects while only 7% change was reflected in control subjects.

DISCUSSION

As stated earlier, *Blood Sugar Optimizer™* contains α -lipoic acid, a mixture of herbal extracts, vitamins, micronutrients and an amino acid, l-aurine.

Role of α -Lipoic acid

α -Lipoic acid found in large quantities in spinach, broccoli and tomatoes, is a natural antioxidant. Scientific evidence suggests that α -lipoic acid supplementation may improve glycemic control in IGT as well as diabetes (Cummings et al., 2006; Ziegler et al., 1999). Furthermore, α -lipoic acid may also prevent neuropathies and other complications associated with ill-controlled type-2 diabetes mellitus (Ziegler et al., 1999; Ziegler et al., 1997).

α -Lipoic acid has also been shown to play a role in the prevention of CVD – may prevent oxidative damage to LDL-C, thereby reducing the development of atherogenesis and risk of CVD (Wollin & Jones, 2003). α -Lipoic acid may also contribute to improved regulation of vascular tone and blood pressure (McMackin et al., 2007).

A recently published study, in addition to reporting the ability of α -lipoic acid to reduce atherogenicity and cardiovascular risks, concluded that α -lipoic acid in combination with moderate exercise may reduce body fat% and waist and hip circumferences as well (McNeilly et al., 2007). Thus, notwithstanding the direct effects of α -lipoic acid in preventing diabetes and CVD, by improving obesity status, α -lipoic acid may have an additional indirect role to play in regulating blood glucose levels.

Role of herbal Extracts in Blood Sugar Optimizer™

Blood Sugar Optimizer™ contains a mixture of herbal extracts like 2.5% Bitter Melon, 4:1 Cinnamon extract, *Gymnema sylvestre* extract (containing 75% Gymnemic acids), Bilberry leaf extract, Fenugreek seed extract 4:1 and banana leaf extract.

These, either singly or in combination, have been shown to cause anti-diabetic and anti-lipidemic actions (Ocvirk, Kistler, Khan, Talukder, & Hauner, 2005; Fernandes, Lagishetty, Panda, & Naik, 2007; Yin, Zhang, & Ye, 2004; Hui, Tang, & Go, 2005; Wang et al., 2007; Nerurkar et al., 2007; Deng, 2004); these are:

1. Reduction in blood glucose levels (fasting as well as postprandial)
2. Reduction in blood cholesterol
3. Regulation of secretion of insulin
4. Increased sensitivity to insulin
5. Regulation of HbA_{1c} levels
6. Improved body composition
7. Reduction in anthropometric measurements and obesity
8. Reduction in oxidative stress

Role Of Other Ingredients In Blood Sugar Optimizer™

Biotin, vitamins belonging to the class B (thiamine mononitrate, niacinamide, pantothenic acid, pyridoxine-HCL and methylcobalamine), vitamin E and vitamin C (ascorbate), micronutrients like zinc, magnesium, manganese, chromium and selenium are the other ingredients present in *Blood Sugar Optimizer™*.

Micronutrients (chromium in particular) and antioxidants like vitamins help restore normal levels of blood glucose (Zemel & Bruckbauer, 2008; Huang, Korivi, Tsai, Yang, & Tsai, 2005). This over a period of time improves HbA_{1c} profile and the risk of developing obesity and CVD.

seems to improve the status of HbA_{1c} thus reflecting a better long-term control of blood glucose levels and a decrease in glycosylation of proteins.

CONCLUSION

Based on our findings, we conclude that *Blood Sugar OptimizerTM* does seem to affect both IGT and diabetes favorably by reducing blood glucose levels. Additionally, if taken for a sufficiently long time (12 weeks in this case), supplementation with *Blood Sugar OptimizerTM*

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