

Lysulin™, a new supplement for Nutritional Support for People with Diabetes and Pre-diabetes (those at risk of developing diabetes)



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ABSTRACT

Lysulin™ is a new supplement for people with Type 2 diabetes and prediabetes and those at risk of developing diabetes and metabolic syndrome. The patent pending Lysulin formulation contains the essential amino acid, lysine, a mineral, zinc, and vitamin C. All of these ingredients have been shown in over 20 years of R&D and clinical studies to lower blood glucose, lower glycated proteins and improve the lipid profile by lowering cholesterol and LDL and raising HDL. Daily use of Lysulin™ may slow or halt the progression of prediabetes to diabetes and slow or halt the progression of diabetes complications by lowering protein glycation. This paper provides historical background on the effectiveness of the ingredients in Lysulin and provides preliminary data showing that after just one month of Lysulin use, a significantly lower HbA1c was observed.

Introduction

Diabetes mellitus is a leading cause of morbidity and mortality worldwide [1]. The causes of type-2 diabetes are multi-factorial, and the supplement plays an important role on its' incidence, severity and management [2]. Hence studies have frequently focused on dietary components beneficial in the prevention and treatment of diabetes. Recent studies have demonstrated that numerous herbal and nutraceutical products have beneficial effects in patients by improving glucose and lipid metabolism, antioxidant status, disease progression and capillary function [3]. Lysulin™ is a nutraceutical tablet manufactured in the USA which contains the essential amino acid Lysine, a micronutrient Zinc and Vitamin C as the active ingredients, together with other standard excipients (Lysulin Inc, San Diego, CA) (www.lysuln.com). It is considered as a dietary supplement under the Under the Dietary Supplement Health and Education Act of 1994 of the US National Institute of Health (NIH) Food and Drug Regulatory Authority (FDA), as it

contains only amino acids, vitamins and minerals [4]. Lysine is an essential amino acid that plays a major role in calcium absorption, building muscle protein, and the body's production of hormones, enzymes, and antibodies. It has also shown numerous beneficial effects in the treatment/prevention of diabetes and/or its complications in *in-vivo* animal and human studies. In diabetes induced animal models, Lysine has shown beneficial effect in lowering blood glucose as well as acting as an inhibitor of protein glycation [5]. Furthermore, the ability of Lysine to reduce the formation of glycated proteins in diabetes induced rats, have also shown to delay the appearance of the late pathologies associated with protein glycation [6]. Lysine is known to react with glucose with the glycated amino acid being excreted in urine and it has been shown to markedly attenuate the glucose response to ingested glucose without a change in insulin response in humans [7]. Furthermore, studies have shown that it reduces the formation of glycated proteins in diabetes induced animal models [5]. Glycated proteins are known to be

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involved in the pathogenesis of several chronic diabetes complications, including nephropathy leading to chronic kidney disease, neuropathy, and retinopathy, as well as in other macrovascular complications [8-10]. Hence, it is evident that Lysine may have potentially beneficial effect on reduction of blood glucose as well as on the progression of diabetes and its complications. Zinc is involved in numerous metabolic pathways as a cofactor for more than 300 enzymes [11]. Insulin, which contains a variable number of Zinc atoms, are stored in β -cells of the pancreas and released into the portal venous system at the time of β -cells de-granulation. Zalewski, showed that high concentrations of glucose and other secretagogues decrease the islet cell labile Zinc and video fluorescence analysis showed Zinc concentrated in the islet cells was related to the synthesis, storage and secretion of insulin [12]. *In-vitro* data suggest that insulin binds to isolated liver membranes to a greater extent and that there is less degradation when Zinc is co-administered with insulin [13]. It is evident that Zinc plays an important role for insulin action, carbohydrate and protein metabolism [14]. In addition, there is particular interest in the idea that oxidative stress is relevant in the pathogenesis of diabetes and its complications. Impaired synthesis of enzymes, such as superoxide dismutase and glutathione peroxidase, Zinc is a part of these enzymes' structures and its deficiency may impair their synthesis and associated with increased oxidative stress [15]. It has been long known that diabetes is accompanied by hypozincemia [16] and hyperzincuria [17]. Animal studies showed that Zinc supplementation has improved fasting insulin level and fasting glucose in mice models [6,7]. In Korea 44 diabetic patients and 34 normal subjects were supplemented with 50 mg Zinc daily as Zinc gluconate for 4 weeks. The results showed that significant improvement of fasting glucose as well as HbA1c were observed in zinc supplemented diabetic patients with shorter diabetic duration, poorer glycemic control, and marginal Zinc status [8]. A similar study in Iraq noted that receiving 30 mg of Zinc per day for three months for type-2 diabetics has beneficial effects in elevating their serum Zinc level, and in improving their glycemic control that is shown by decreasing their HbA1c concentration [14]. In addition, improved fasting blood glucose levels of up to 30% in patients with cirrhosis through supplementation of Zinc for 2 months has been reported [15]. A recent single blinded trial conducted in Sri Lanka by Gunsekara et al.

on multi-vitamin mineral supplementation with or without Zinc in diabetes demonstrated that only patients receiving Zinc supplementation showed an improved metabolic profile.

Zinc absorption is also known to be altered in patients with diabetes [13]. Numerous studies have shown that Zinc supplementation improves glycemic control in patients with type-2 diabetes, with a resultant reduction in HbA1c of around 0.5% in pooled analysis [14]. A study conducted in Bangladesh demonstrated that individuals with pre-diabetes are also known to have lower serum Zinc concentrations compared to those who are healthy [15]. Furthermore, a recently concluded clinical trial on patients with pre-diabetes demonstrated that Zinc supplementation helps to reduce blood glucose and insulin resistance, while improving β -cell function. Furthermore, disease progression to diabetes was also reduced and beneficial effects of supplementation were also noted on total and LDL cholesterol [16]. Ascorbic acid (vitamin C), an antioxidant vitamin, plays an important role in protecting free radical-induced damage. Previous study has shown decrease in basal vitamin C level in type 2 diabetes. Vitamin C is structurally similar to glucose and can replace it in many chemical reactions and thus is effective for prevention of nonenzymatic glycosylation of protein [17]. Furthermore, randomized controlled trials have shown that supplementation of Vitamin C reduces blood glucose, serum lipids and improves HbA1c in type 2 diabetes [18,19]. Hence, we postulate that a product containing Lysine, Zinc and Vitamin C will have beneficial effects on glycemic control in those with diabetes and help to reduce disease progression in patients with pre-diabetes (those at risk of developing diabetes).

Preliminary data

Volunteers were recruited to take one Lysulin™ tablet 2 or 3 times a day and requested to measure HbA1c at time zero and at 1, 2 and 3 months. The following **FIGURE 1** shows that participants had a significant drop in their HbA1c after just 1 month of taking daily Lysulin™.

Discussion and conclusion

There exists a need for drugs or supplements that can lower blood glucose and glycated proteins and improve the lipid profiles for people with Type 2 diabetes and prediabetes

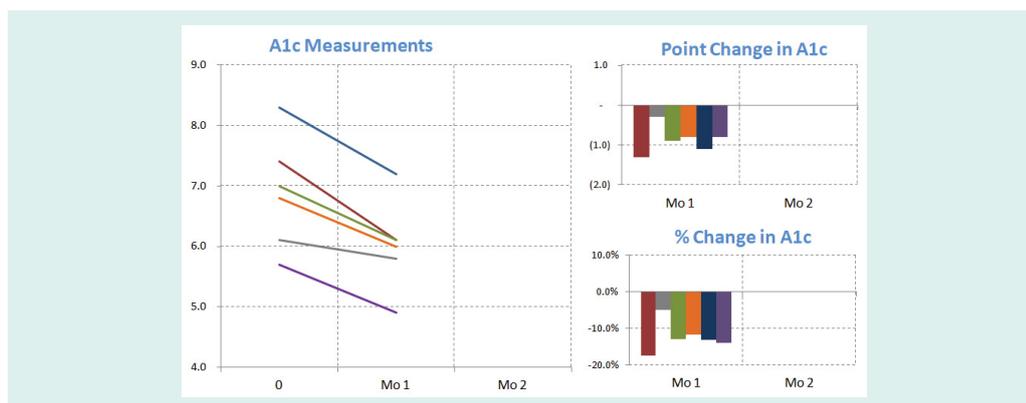


Figure 1. HbA1c measured at initiation and 1 month after taking Lysulin daily.

and those at risk of developing diabetes. Lysulin™ is a new supplement with ingredients that have been shown to have these properties. All of the ingredients are generally recognized as safe and have been used by many as individual supplements. Lysulin™ has the advantage of putting all three ingredients into a single tablet allowing for a simpler

scheduling for ease of use. We have presented data which illustrates that Lysulin does lower blood glucose and HbA1c after just one month of use. Several new double blind, placebo-controlled studies are underway to prove the effectiveness of Lysulin™ helping to better manage diabetes and slow the progression of disease complications.

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