Hemoglobin a1c (hba1c) shows improvement in glycemic control in as little as two weeks following the addition of lysulin™, to the treatment of diabetes

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ABSTRACT

Some recent reports have questioned the utility of HbA1c in measuring the effectiveness of therapy in the treatment of diabetes. Still, HbA1c remains the gold standard for following diabetes management and is traditionally tested every 3 or 6 months using a blood sample analyzed in a clinical laboratory. HbA1c measures the glycation of hemoglobin and is used to quantify the average blood glucose levels over the past 2 to 3 months. Innovative continuous glucose monitoring (CGM) systems are vying to become the new gold standard because they measure and record the blood glucose every 5 minutes and compute the daily average glucose levels and provide a calculated HbA1c equivalent. We report herein that HbA1c measurements can detect improvements in glycemic control in as little as two weeks after initiating the use of Lysulin. Innovative, self-administered home testing products for CGM and HbA1c (A1cNow®) may improve the management of diabetes by more frequently monitoring the effectiveness to changes in therapy and the A1cNow test is available at www.lysulin.com. We report herein that some patients with Type 2 diabetes have seen an improvement in HbA1c in as little as 2 weeks after including Lysulin into their therapeutic management. This observation has been confirmed by using CGM to monitor daily blood glucose values. The most dramatic improvement has been observed when Lysulin and Metformin are used together to manage patients with Type 2 diabetes. Lysulin™ is a new diet supplement for people suffering with Type 2 diabetes, prediabetes and those at risk of developing diabetes and metabolic syndrome. The patent pending Lysulin formulation contains an essential amino (lysine), a mineral (zinc) and vitamin C. Each 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 improving cholesterol (lowering LDL and raising HDL). This paper provides evidence that confirms the effectiveness of Lysulin and illustrates how HbA1c can be used to more frequently measure rapid improvements in glycemic control. Additionally, CGM has been used to show that improvements in glycemic control can be achieved in only 1 week following inclusion of Lysulin.

Introduction

Diabetes mellitus is a leading cause of morbidity and mortality worldwide [1-5]. The causes of Type-2 diabetes are multi-factorial, and the diet plays an important role on its' incidence, severity and management [6]. 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

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and lipid metabolism, antioxidant status, disease progression and capillary function [7]. LysulinTM is a nutritional supplement 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). It is classified as a dietary supplement under the Dietary Supplement Health and Education Act of 1994 of the US National Institute of Health (NIH) Food and Drug Regulatory Authority [8]. In clinical studies with Type 2 patients, we have monitored the effectiveness of including Lysulin into diabetes management using HbA1c tests (both laboratory and home tests) and also with the Abbott LibrePro CGM. We were pleased to find that in some patients CGM showed an improvement in just 7 days following inclusion of Lysulin. Interestingly, improvements in HbA1c could be observed in as little as 2 weeks following the inclusion of Lysulin.

Test results

Volunteer patients were advised to take one LysulinTM tablet 3 times a day and asked to measure HbA1c at time zero and at 1, 2 and 3 months. A subset of these patients also received an Abbott LibrePro CGM and had HbA1c measured at 2 weeks and 4 weeks following inclusion of Lysulin. By way of example, the following patient had been using 850 mg of Metformin with 36 units of intermediate insulin daily for two months but still exhibited poor glycemic control prior to inclusion of Lysulin. The LibrePro daily glucose testing on this patient is shown in **FIGURE 1**.

The laboratory HbA1c observed with this test subject dropped from 12.6% on day zero down to 11.3% in just 2 weeks. At 4 weeks the HbA1c had dropped to 9.8%, and at 6 weeks it was 8.7%. In double blind, placebo controlled studies, the placebo group showed no significant change in daily glucose profiles or HbA1c (manuscript in preparation, studies ongoing).

TABLE 1 as shown, a dramatic drop in HbA1c was observed in 1 month after starting Lysulin, with continued drops in the subsequent 2 months. We believe that this may the largest recorded drop in HbA1c observed in a newly diagnosed patient with Type 2 diabetes **(TABLE 2)**.

Discussion and conclusion

The American Diabetes Association recommends that HbA1c testing should be performed routinely in all patients with diabetes, first to document glycemic control and thereafter as part of continuing care [9]. They further recommend that this testing be performed at least two times a year [9]. Some physicians feel that testing should be performed more often, especially during changes in therapy [10]. Our findings substantiate this recommendation for testing HbA1c more often. A detailed mathematical model for the HbA1c test also concluded that the HbA1c change toward treatment goal

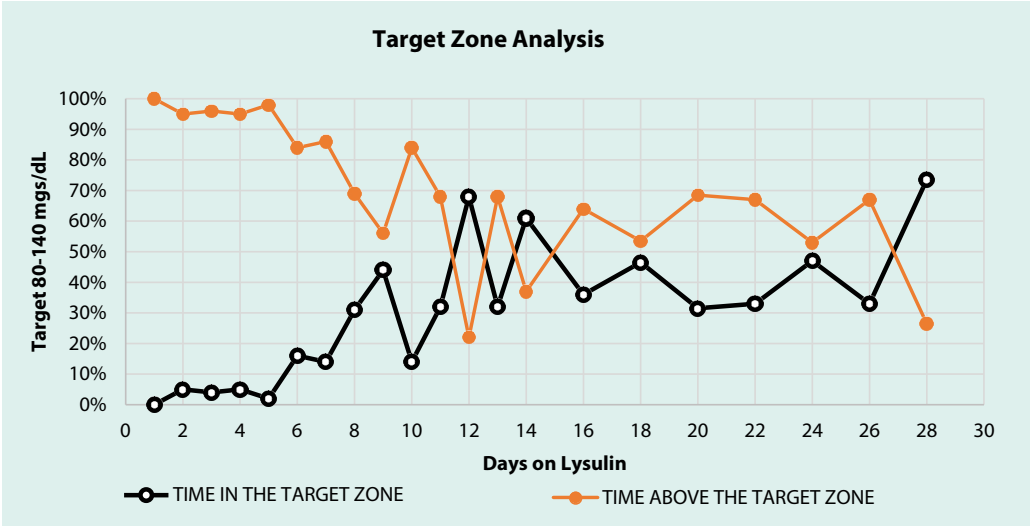

Figure 1. Percent of time observed above and in the target glucose zone after inclusion of Lysulin in a subject with Type 2 diabetes.

Table 1. A second test subject (MR) was diagnosed with Type 2 diabetes with a laboratory HbA1c of 12.8%. This subject immediately started 2000 mg per day of Metformin, 2 mg Lisinopril and 2 servings a day of Lysulin. The following drop in HbA1c was observed:

Time	HbA1c	Test Method
Day 0	12.80%	Laboratory
4 week	7.90%	A1cNow
8 week	5.80%	A1cNow
12 week	5.40%	Laboratory

Table 2. A third test subject (CB) was diagnosed with Type 2 diabetes with a laboratory HbA1c of 7.4%. This subject immediately started taking 2 servings of Lysulin a day with no other medication and the following drop in HbA1c was observed:

Time	HbA1c	Test Method
Day 0	7.40%	Laboratory
4 week	6.10%	A1cNow
8 week	5.80%	A1cNow
12 week	5.70%	Laboratory and A1cNow
16 week	5.20%	A1cNow

value was 50% reached in about 30 days [11]. The need clearly exists a need for drugs and supplements that can lower blood glucose and glycated proteins and improve the lipid profiles for people with Type 2 diabetes and prediabetes. LysulinTM is a new supplement with ingredients that have been independently shown to have these properties [3]. All of the ingredients are generally recognized as safe and have been used by many as individual supplements. LysulinTM has the unique advantage of putting all three ingredients into a single dosage allowing for a simpler scheduling, ease of use and compliance. We have presented data which confirms that Lysulin does lower blood glucose and HbA1c after just one month of use. Several new double blind, placebo-controlled studies are underway to further prove the effectiveness of LysulinTM in helping to better manage diabetes and slow the progression of disease complications. In addition, home testing for HbA1c and CGM can be used to measure the effectiveness of therapy modifications in a much shorter time frame than was previously practical. Accordingly, we assert that more frequent home testing of HbA1c and CGM may lead to better disease management, particularly if changes are made to therapy. The results presented in this manuscript illustrate the benefit of including Lysulin with other oral diabetes medications for better diabetes management.

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