

# **CLINICAL CASE REPORT**

# High Dose Vitamin D Therapy & Anti-inflammatory Diet

(Insulin Dependent - Diabetes Mellitus)

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# High Dose Vitamin D Therapy & Anti-inflammatory Diet

(Diabetes Mellitus - Insulin dependent)

#### ABSTRACT

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Diabetes is a chronic metabolic disease that affects millions of people worldwide. The prevalence of diabetes has been increasing rapidly, with estimates projecting that 783 million people worldwide will have diabetes by 2045. The United States has also seen a significant rise in diabetes cases, with over 34 million people living with the disease.

This article presents a clinical case of a 48-year-old male patient with a 10-year history of diabetes and hyperlipidemia, who was insulin dependent and taking metformin and atorvastatin. Despite these medications, the patient's A1C was 9.5, and his doctor was considering increasing his insulin dose. Additionally, the patient reported experiencing peripheral neuropathy and chronic pain in his lower extremities and behind his knees.

The patient reached out to Dr. Eduardo Beltran and was introduced to the protocol and underwent a 12-month period treatment with the LGS Protocol, which involved taking 50,000 IU of vitamin D3 daily, along with cofactors and 600 mg of alpha-lipoic acid BID. The patient was able to lose over 45 pounds during this period and continues to do so. Medications were gradually discontinued. By month 4, the patient no longer required any medications, and continued taking only the supplements of the protocol. After 12 months into the protocol his A1C was significantly reduced to 5.6. The patient is now in complete remission.

This case study highlights the potential benefits of a holistic approach to managing diabetes, which focuses on lifestyle modifications, diet and natural interventions. The LGS Protocol, which emphasizes the importance of adequate vitamin D levels, alpha-lipoic acid, and healthy eating habits, has shown promising results in helping patients achieve better outcomes. These findings suggest that a comprehensive approach to diabetes management may be a viable alternative to traditional medications and help patients achieve long-term remission.

#### INTRODUCTION

Diabetes is a major global health concern that affects millions of people worldwide. The prevalence of diabetes has been increasing at an alarming rate over the past few decades, largely due to changing dietary and lifestyle habits. According to the International Diabetes Federation, approximately 537 million adults were living with diabetes in 2021, and this number is expected to rise to 783 million by 2045 [1].

Diabetes is a metabolic-immune disorder characterized by impaired glucose metabolism, resulting in elevated blood glucose levels. The pathophysiology of diabetes involves either insufficient insulin production or the body's inability to effectively use insulin. Insulin is a hormone that regulates glucose metabolism and allows glucose to enter cells where it can be used for energy. When insulin function is impaired, glucose accumulates in the bloodstream, leading to hyperglycemia.

There are several types of diabetes, including type 1 diabetes, type 2 diabetes, and gestational diabetes. Type 1 diabetes is an

autoimmune disease that occurs when the immune system mistakenly attacks and destroys insulin-producing cells in the pancreas. Type 2 diabetes is a metabolic-immune disorder that develops when the body becomes resistant to the effects of insulin [2].

Inflammation and oxidative stress play a crucial role in the development and progression of diabetes. Chronic inflammation can impair insulin sensitivity and lead to insulin resistance, which can cause blood glucose levels to rise, leading to the development of type 2 diabetes. Inflammatory biomarkers such as C-reactive protein (CRP) and tumor necrosis factor-alpha (TNF- $\alpha$ ) are elevated in people with diabetes and are associated with an increased risk of complications [3].

Diabetes is also considered a nutritional disease, as poor dietary choices and obesity are major risk factors for its development. Vitamin D deficiency is prevalent among individuals with diabetes, and this deficiency may contribute to the development and progression of the disease [4]. Vitamin D has been shown to improve beta cell function, which is important for insulin secretion [4]. Additionally, alpha-lipoic acid is a potent antioxidant that has been shown to reduce hyperglycemia and improve insulin sensitivity, making it beneficial for individuals with diabetes [5].

Leaky gut syndrome, or increased intestinal permeability, is another factor that may contribute to the development of diabetes [6]. This condition can lead to chronic inflammation and oxidative stress, impairing insulin sensitivity and contributing to the development of diabetes.

Vitamin D is known to play a crucial role in regulating insulin production in the body. It does so by acting on the beta cells of the pancreas, which are responsible for producing insulin [5].

When vitamin D is synthesized in the skin or ingested through the diet, it gets converted into its active form, which is known as calcitriol. This active form of vitamin D binds to a specific receptor called the vitamin D receptor (VDR) that is present on the surface of beta cells  $\boxed{7}$ .

When the VDR is activated by calcitriol, it promotes the expression of genes that are involved in the production and secretion of insulin [7]. It also enhances the sensitivity of beta cells to glucose, which means that they are better able to detect changes in blood sugar levels and respond by secreting the appropriate amount of insulin.

In addition to its effects on beta cells, vitamin D also helps to reduce insulin resistance by promoting the uptake of glucose by muscle and fat cells [8]. This means that vitamin D helps to improve the overall efficiency of insulin in the body, which can have important implications for the management of diabetes.

Overall, vitamin D plays a crucial role in regulating insulin production and glucose metabolism in the body. A deficiency in vitamin D can lead to impaired insulin production and increased insulin resistance, which can contribute to the development of type 2 diabetes.

Understanding the pathophysiology and underlying risk factors of diabetes is crucial for effective prevention and management. Lifestyle modifications, including dietary changes and regular physical activity, may help prevent and manage diabetes. Additionally, addressing inflammation, nutrient deficiencies such as vitamin D, and leaky gut syndrome may offer new strategies for preventing and managing this chronic disease.



Alpha-lipoic acid (ALA) is a natural antioxidant that has been shown to have a number of beneficial effects on the body, including its ability to regulate insulin production and improve glucose metabolism. ALA acts as a cofactor for several enzymes involved in energy metabolism and has been found to have a positive effect on insulin sensitivity [9].

One of the keyways in which ALA helps to regulate insulin production is by activating an enzyme called AMP-activated protein kinase (AMPK). AMPK is an important regulator of energy metabolism in the body and plays a key role in glucose uptake and utilization in muscle and fat cells [10].

When AMPK is activated by ALA, it promotes the uptake of glucose by muscle and fat cells, which helps to lower blood sugar levels. It also stimulates the production and secretion of insulin by beta cells in the pancreas, which helps to further lower blood sugar levels [10].

In addition to its effects on AMPK, ALA has been shown to have a number of other beneficial effects on insulin production and glucose metabolism. For example, it has been found to reduce oxidative stress in the beta cells of the pancreas, which can help to protect them from damage and improve their function.

ALA has also been shown to increase the activity of the enzyme pyruvate dehydrogenase (PDH), which is involved in the metabolism of glucose in the body [11]. By increasing the activity of PDH, ALA helps to improve the efficiency of glucose metabolism and reduce insulin resistance.

Overall, ALA is a natural compound that has been shown to have a number of beneficial effects on insulin production and glucose metabolism. By activating AMPK, reducing oxidative stress, and improving glucose metabolism, ALA can help to regulate insulin production and improve blood sugar control in individuals with diabetes.

Understanding the pathophysiology and underlying risk factors of diabetes is crucial for effective prevention and management. Lifestyle modifications, including dietary changes and regular physical activity, may help prevent and manage diabetes. Additionally, addressing inflammation, nutrient deficiencies such as vitamin D, and leaky gut syndrome may offer new strategies for preventing and managing this chronic disease.

## THE LGS PROTOCOL

The LGS Protocol is a comprehensive treatment plan that has been adapted from various protocols by Dr. Eduardo Beltran, all of which follow somewhat similar recommendations as outlined in the Coimbra Protocol. Dr. Coimbra's research has been instrumental in identifying the presence of single nucleotide polymorphisms (SNPs), which have been found to be prevalent in more than 80% of patients that have undergone genetic testing in our practice [12].

These SNPs include vitamin D genes such as CYP2R1, CYP27B1, VDBP, and VDR, as well as genes responsible for the methylation cycle, such as MTHFR and MTR.

The LGS Protocol is designed to address genetic polymorphism, but its primary focus is on correcting underlying gut issues that impact microbiome diversity [12]. Nearly all patients in our practice exhibit some degree of dysbiosis, SIBO, SIFO, or the presence of biofilms. To address these issues, the protocol introduces an anti-inflammatory diet (AID) that is free from gluten, dairy, lectins, and

sugar, as well as highly processed carbohydrates. In addition to this diet, the LGS Protocol also incorporates supplements that enhance liver metabolism with R-Alpha Lipoic Acid, Omega 3, Mg+, K2 (MK7), B1,B2,B3,B5,B6, B9 & B12, which must be in their methyl form (B9 & B12). The protocol also uses compounded formulas containing L-Glutamine, Licorice, and Aloe vera extract to improve enterocyte tight junction integrity [12].

Mitochondrial support is provided through a compounded mix of Co10, L-Carnitine, D-Ribose, & Magnesium complex. The use of Royal Jelly has also been adapted into the protocol due to its ability to improve stem cell function, which has been reported in several studies and by our patients that mention they feel better on it. More than 25 supplements are compounded and taken on a daily basis as part of the LGS Protocol [12].

In cases of severe dysbiosis, SIBO, SIFO, or the presence of biofilms, antimicrobial herbs or biofilm disruptors such as oregano oil, berberine, garlic, licorice, juniper, and others are used. Patients may sometimes require the use of digestive enzymes when SIBO/SIFO is present [12].

Two vitamin D dosage modalities are incorporated into the LGS protocol. A **physiologic dose** of **200IU/kg/day** is prescribed when high dose vitamin D criteria are not met. **Therapeutic high dose** recommendations start with **500 IU/kg/day**. The starting dose was established after observing that patients when they improved their gut health, and dysbiosis was corrected, high-dose vitamin D requirements tended to decrease [13,14].

In general, the LGS Protocol is a comprehensive and integrative approach to treating autoimmune and nutritional disorders, particularly those related to gut health and vitamin D deficiencies. The protocol addresses genetic polymorphism, microbiome diversity, and inflammation, among other factors, through a combination of diet, supplements, and medication, as needed. By taking a holistic and personalized approach, the LGS Protocol has shown promising results in improving the health and well-being of patients with various conditions, including diabetes, chronic pain, and neuropathy.

## **CLINICAL CASE**

This clinical case of a 48-year-old male patient from Peru who had been suffering from diabetes and hyperlipidemia for 10 years, underscores the importance of individualized and comprehensive treatment approaches that target the root cause of chronic conditions, instead of solely treating their symptoms. Despite being on insulin and metformin, the patient's A1C remained high at 9.5 and he suffered from peripheral neuropathy and pain in his lower extremities. However, his endocrinologist did not offer any other therapeutic measures apart from increasing his insulin dosage.

The patient, in a bid to find a more effective treatment approach, sought out Dr. Eduardo Beltran via tele-consult and was introduced to the LGS Protocol. This protocol involves a combination of high-dose vitamin D3 (HDVD) and cofactors, as well as alpha-lipoic acid (ALA) supplementation. Dr. Beltran prescribed 50,000 IU of vitamin D3 and 600 mg of ALA twice a day. Remarkably, after just four months on the LGS Protocol, the patient's 25OHD3 levels increased significantly from 22 ng/dl to 149 ng/ml, and his 1,25OHD levels improved from 42 pg/ml to 64 pg/ml. Furthermore, his PTH was partially inhibited at 26 pg/ml, and his serum and ionized calcium levels were normal, with no signs of vitamin D toxicity at four months into the protocol.



His A1C was initially 9.5 (Figure 1.0) and dropped to 6.0 (Figure 1.1). Patient referred feeling much better and felt less need of eating and had lost 20 pounds without doing any exercise and discontinued all medications including his insulin injections. His lipid profile improved significantly and no longer required using statins (Lipitor).

Currently, he is in complete remission and requires no medication. This case highlights the remarkable potential benefits of highdose vitamin D therapy and alpha lipoic acid in improving glycemic control, promoting weight loss, and reducing medication dependence in patients with diabetes and its associated complications.



In Figure 1.0 we can observe a low 250HD3 which indicates vitamin D deficiency and an apparent "normal" 1,250HD3. This is a common phenomenon which indicates active disease process where the body is consuming the 250HD3 (reserve) in order to keep up with the metabolic demand of calcitriol (active hormone). PTH was elevated due to vitamin D deficiency and A1C level was high (9.5) which could cause serious complications if no future interventions took place.



In Figure 1.1 we can see a significant increase in 25OHD3 (calcifediol) that of 149 ng/dl which is way above normal reference range and a 1,25OHD3 of 64 pg/ml which is within optimal range. This significant difference between both metabolites suggest polymorphisms of CYP27B1 and VDR genes. PTH was partially inhibited which suggested that vitamin D resistance was overturned, and calcium levels were stable within normal reference range. No toxicity was caused by 50.000 IU/day of cholecalciferol during 4 consecutive months.

After following the LGS Protocol for 12 months and still taking 50.000 IU of D3/day, he referred feeling much better and was able to lose over 45 pounds. He had no more peripheral neuropathy and his A1C dropped to 5.6 which is considered normal range. His 25OHD3 level was 152 ng/dl and 1,25OHD3 was at 72 pg/ml. No vitamin D toxicity was evident after 1 year on the protocol (Figure 1.2).



Overall, this case underscores the importance of exploring alternative treatment approaches, particularly for individuals who may not be responding well to conventional therapies. This personalized and comprehensive approach to treating chronic conditions can lead to better patient outcomes and quality of life, with the potential to revolutionize how we approach treatment in the future.

# DISCUSSION

The patient continued to take 50,000 IU of D3 per day for 12 months while following the LGS Protocol, which led to significant improvements in his health. He lost over 45 pounds, experienced no further peripheral neuropathy, and his A1C levels dropped to a normal range. Currently, he is in complete remission and no longer requires medication.

This case study highlights the potential benefits of high-dose vitamin D therapy and alpha-lipoic acid for patients with diabetes and associated complications. The Protocol, has been shown to be effective in improving glycemic control, promoting weight loss, and reducing the need for medication.

The importance of individualized treatment plans is emphasized, as not all chronic conditions can be treated with a standard approach. The LGS Protocol offers a personalized and comprehensive approach to treating chronic conditions, with the potential to revolutionize how we approach treatment in the future. Patients with diabetes and hyperlipidemia may find hope and improved outcomes through alternative treatment approaches like the LGS Protocol.





# CONCLUSION

In conclusion, this clinical case emphasizes the importance of personalized and comprehensive approaches to treating chronic conditions like diabetes and hyperlipidemia. The LGS Protocol, which combines HDVD, cofactors, and ALA supplementation, has shown promise in improving glycemic control, promoting weight loss, and reducing medication dependence in patients with these conditions. This case study demonstrates how the protocol helped a patient achieve remarkable improvements in his health, leading to complete remission and no longer requiring medication. By exploring alternative treatment approaches, clinicians can potentially provide better patient outcomes and quality of life. The LGS Protocol offers hope to patients suffering from chronic conditions and may revolutionize how we approach treatment in the future.

## NOTES

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#### **HUMAN ETHICS**

Consent was obtained by all participants in this study

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