

# CLINICAL CASE REPORT

Published on 03/25/2023

## High Dose Vitamin D Therapy & Anti-inflammatory Diet (Rheumatoid Arthritis)

DOI:10.5281/zenodo.7799873

By: Eduardo Patrick Beltran M. MD

Internal Medicine - Dermatology

Director of Clinical Research SPIMS

Research Scientist – Vitamin D Expert

[dr.beltran@spinstitute-ms.com](mailto:dr.beltran@spinstitute-ms.com)



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## ABSTRACT

Rheumatoid arthritis (RA) is a chronic autoimmune disease that affects joints, causing inflammation, stiffness, and pain. Current treatments focus on managing symptoms and preventing joint damage, but recent studies have shown that vitamin D deficiency is common in RA patients, and low levels of vitamin D may contribute to the development and progression of RA. The LGS protocol cited in this article, includes high-dose vitamin D + cofactors, along side an anti-inflammatory diet, with the use of probiotics, which has shown promising results in managing RA symptoms. This clinical case described in this article highlights the multifaceted approach required to manage RA, including medication, lifestyle changes, patient education, and regular follow-up and monitoring. The LGS (Leaky Gut Syndrome) Protocol, offers a promising new approach to managing RA patients. HDVD + AID is a very safe and viable therapeutic option that healthcare providers show look into.

## INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune disease that affects approximately 1% of the population worldwide [1]. It is characterized by chronic inflammation of the synovial joints, leading to joint destruction and disability. The exact cause of RA is unknown, but it is believed to be a multifactorial disease involving genetic, dietary, vitamin D deficiency, environmental, and immunological factors.

The pathogenesis of RA is complex and involves various inflammatory markers, including cytokines, chemokines, and autoantibodies. In the early stages of the disease, pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF- $\alpha$ ), interleukin-1 (IL-1), and interleukin-6 (IL-6) are produced by immune cells, leading to the recruitment of immune cells to the site of inflammation and activation of synovial fibroblasts, which then produce matrix-degrading enzymes [2]. These enzymes lead to cartilage and bone destruction, causing joint deformity and loss of function.

As the disease progresses, B cells and T cells become activated and produce autoantibodies such as rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPA) [2]. These autoantibodies contribute to the development of chronic inflammation by forming immune complexes that deposit in the joints and activate complement, leading to the release of pro-inflammatory cytokines.

Current treatment options for RA include non-steroidal anti-inflammatory drugs (NSAIDs), disease-modifying antirheumatic drugs (DMARDs), and biologic agents such as TNF inhibitors

However, these treatments have limitations such as side effects and lack of effectiveness in some patients.

Therefore, alternative treatments such as high-dose vitamin D therapy and an anti-inflammatory diet may offer potential benefits to patients with RA. The LGS protocol, which includes high-dose vitamin D therapy, an anti-inflammatory diet, probiotics, and herbal anti-microbials (if needed) has been reported to show promising results in the treatment of autoimmune disorders, including RA. In this case report we will discuss the clinical outcomes of HDVD+AID of a Brazilian patient with rheumatoid arthritis that achieved remission.

## THE LGS PROTOCOL

The LGS Protocol is a treatment plan that has been adapted from various protocols by Dr. Eduardo Beltran [3], all of which follow somewhat similar recommendations as outlined in the Coimbra Protocol [4,11]. This initial approach was developed by Dr. Cicero Galli Coimbra in Brazil and is based on a high-dose vitamin D therapy. 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 own practice. 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.

While the LGS Protocol is designed in part to address genetic polymorphism, its primary focus is on correcting underlying gut issues that impact microbiome diversity. 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, Mg+, K2 (MK7), B1,B2,B3,B5,B6, B9 & B12, which must be in their methyl form (B9 & B12) [3]. The protocol also uses compounded formulas containing L-Glutamine, Licorice, and Aloe vera extract to improve enterocyte tight junction integrity.

Mitochondrial support is provided through a compounded mix of Co10, L-Carnitine, D-Ribose, & Magnesium complex. The use of Royal Jelly [3] has also been adapted into the protocol due to its ability to improve stem cell function, which has been reported by patients to make them feel better. **More than 25 supplements are compounded and taken on a daily basis as part of the LGS Protocol.**

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.

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 criterias are not met. Therapeutic high dose recommendations on the LGS Protocol start of with **500 IU/kg/day** [3]. This starting dose was established after noticing improvement in gut health, toxin clearance and when dysbiosis improved, indicating that high-dose vitamin D requirements were in fact less than initially thought.

**CLINICAL CASE**

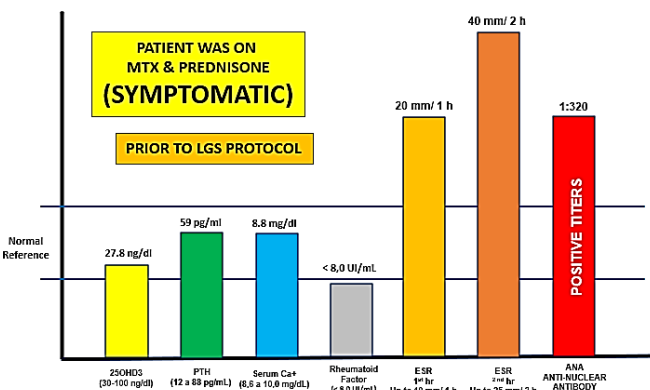
The article describes a case of a 37-year-old female patient who presented with bilateral pain in multiple joints, specifically in her hands, elbows and knees, in 2014. Despite seeking medical attention and being prescribed ibuprofen, the patient did not show any improvement. The patient was later diagnosed with rheumatoid arthritis in 2015 after consultation with a rheumatologist and was started on treatment with methotrexate (MTX) associated with prednisone and a PPI. However, over time, MTX and prednisone were no longer able to control her symptoms as previously and her symptoms soon returned. In *image A* we can observe the affected finger that appears edematous and erythematous, with tenderness to palpation and decreased range of motion. The joint was warm to the touch, suggestive of visible synovial thickening or effusion.

These symptoms are typical of inflammatory arthritis, and specifically, RA, characterized by joint inflammation and destruction where the body's immune system attacks the synovial membrane, which lines the joints and produces synovial fluid [5]. The inflammation leads to cartilage and bone damage, causing pain, swelling, and stiffness in affected joints. RA commonly affects the small joints of the hands and feet, and is often symmetrical, affecting the same joint on both sides of the body as found in this case.

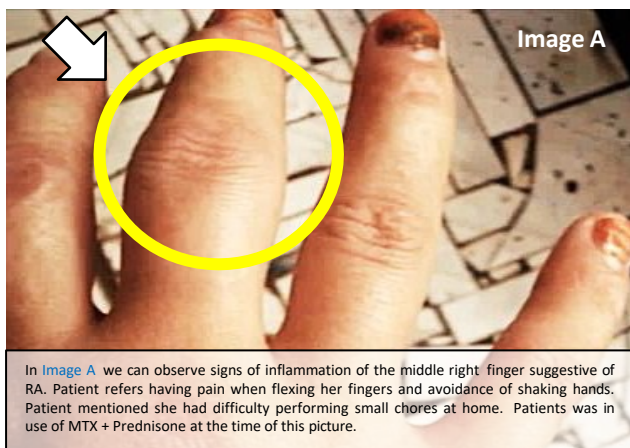
The swollen and painful middle right finger is likely due to synovitis, or inflammation of the synovial membrane, in the joint of the middle finger. Treatment usually involves nonsteroidal anti-inflammatory drugs (NSAIDs) or disease-modifying antirheumatic drugs (DMARDs) to reduce inflammation and slow disease progression.

In **Fig 1.0** we can appreciate her laboratory results prior to starting the LGS Protocol. Patient was on MTX & prednisone. Initial laboratory data was provided by the patient where we can observe a low vitamin D status of 27.8 ng/dl and a PTH level of 59 pg/ml. Patient had a negative rheumatoid factor and a positive ANA titer 1:320 which is a sign of active disease. Erythrocyte sedimentation rate (ESR) was elevated. In RA, the chronic inflammation of the synovial membrane that lines the joints can lead to the release of inflammatory cytokines and acute-phase reactants, such as C-reactive protein (CRP) and ESR. These markers can be useful in monitoring disease activity and response to treatment in RA, as they tend to correlate with the degree of inflammation and joint damage. It is possible for some patients with Rheumatoid Arthritis (RA) to have a negative rheumatoid factor (RF) but a positive ANA (antinuclear antibody) test [6]. Rheumatoid factor is an antibody that is found in the blood of many people with RA, but it is not present in all cases. In fact, up to 30% of patients with RA have negative RF tests.

On the other hand, ANA tests look for antibodies that attack the body's own cells, including the nucleus of cells. A positive ANA test indicates that a person's immune system is producing antibodies against its own tissues, which is a common feature of autoimmune diseases such as RA.



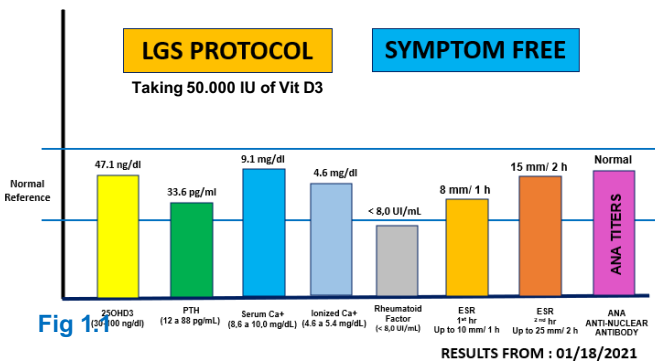
**Fig 1.0** RESULTS FROM : 26/12/2019



In *Image A* we can observe signs of inflammation of the middle right finger suggestive of RA. Patient refers having pain when flexing her fingers and avoidance of shaking hands. Patient mentioned she had difficulty performing small chores at home. Patients was in use of MTX + Prednisone at the time of this picture.

In 2019, the patient started a treatment with high doses of vitamin D (50,000 IU of vitamin D3) along with cofactors and an anti-inflammatory diet that excluded lectins, gluten, dairy, and sugar, along with probiotics. Use of Curcumin combined with piperine (1000/10 mg) twice a day was prescribed. Curcumin + Piperine has shown to reduce swelling faster in RA patients [7]. 600 mg of R-ALA was given once a day for enhancing endotoxemia clearance [8,9,10]. Her Lipid profile was altered prior to initiating the LGS protocol. After three months of discontinuing methotrexate and prednisone and adhering to the LGS protocol, the patient noticed a significant improvement in her condition, with no more bouts of pain. Patient was honest enough in saying that she still felt sceptical regarding the LGS protocol since she knew that methotrexate takes a few weeks to leave the body and

perhaps that she still was benefiting from residual MTX. After a few months later, she realized that her **symptom-free state** regarding joint pain was still present, reaching to a personal conclusion that it was attributed to the high doses of vitamin D, anti-inflammatory diet, and use of probiotics. Laboratory testing was done every 4 months. Results obtained on 01/18/2021 showed vitamin D levels (25OHD3) to 47.1 ng/dl, PTH levels were 33.6 pg/ml showing partial inhibition. Serum and Ionized calcium was within normal range with no signs of induced vitamin D toxicity. ESR and ANA titers were both within normal range. Lipid profile normalized after 5 months treatment indicating improvement of LPS/ Endotoxin clearance [12,13,14]. In **Figure 1.1** we can observe noticeable laboratory improvement that correlated with her clinical improvement. Patient was symptom free and declared officially in remission. Mechanism of LPS/endotoxin/exotoxin clearance can be appreciated on **Figure 1.2**.



It's important to note that these signs of improvement may take time to develop and may not be evident in all patients. Additionally, even when a patient achieves clinical remission, they still require ongoing treatment with HDVD + AID and monitoring to prevent disease flare-ups and joint damage in the future.

**Patients continues to take 50,000 IU of vitamin D3 and has been symptom-free for four consecutive years.**

**DISCUSSION**

Current treatments for RA aim to manage symptoms and prevent joint damage, but they are not curative, and patients may still experience flares and complications. Therefore, there is growing interest in exploring new therapies for RA.

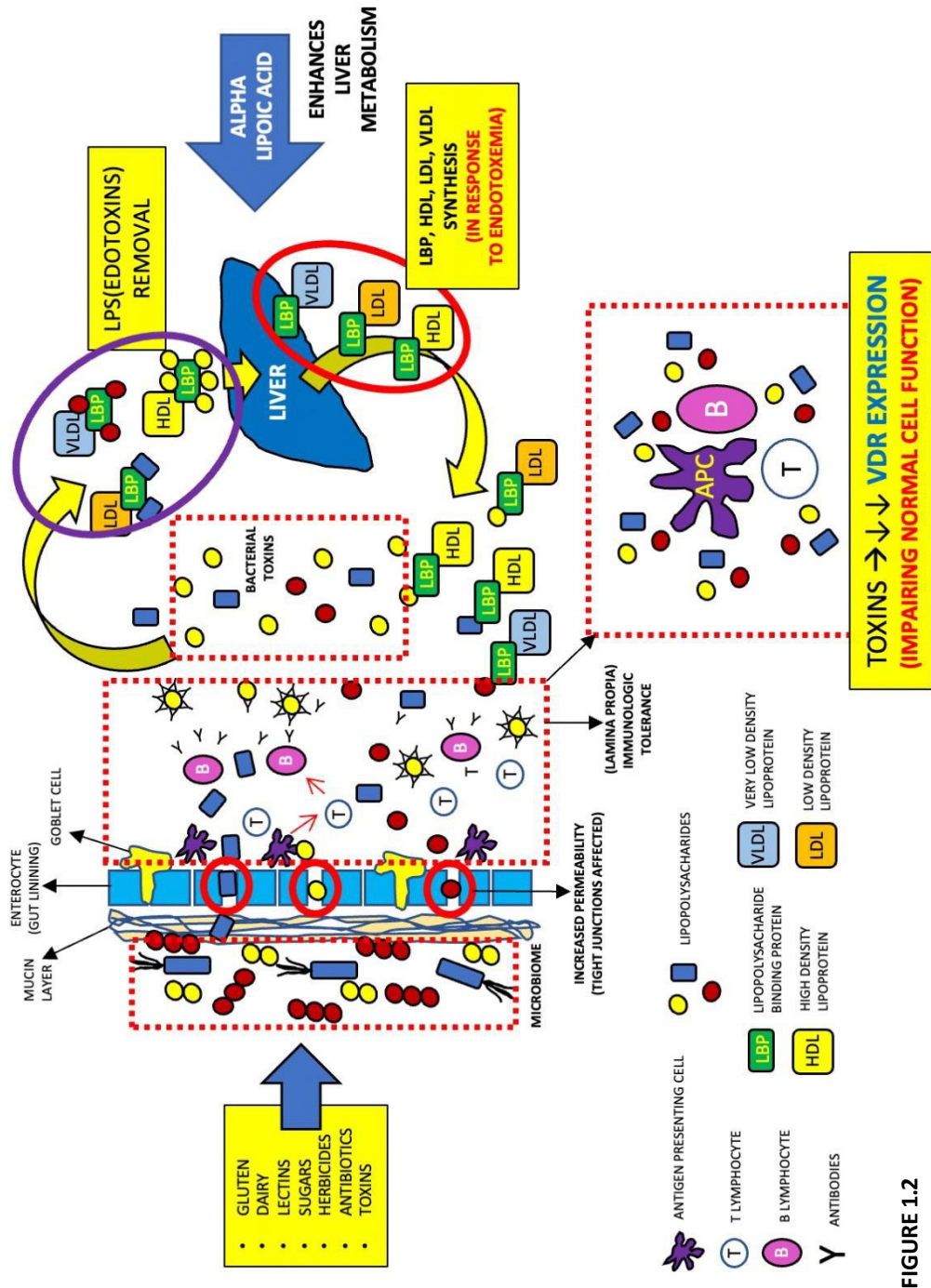
One promising approach is the use of high-dose vitamin D therapy in combination with an anti-inflammatory diet and probiotics, as seen in the LGS protocol. Vitamin D deficiency is common in patients with RA, and low levels of vitamin D may contribute to the development and progression of RA. The LGS protocol excludes foods that can cause inflammation, such as lectins, gluten, dairy, and sugar, and includes probiotics to support gut health, which is crucial in regulating immune function and inflammation.

This clinical case explains how the patient adhered to the LGS protocol and experienced significant improvement in symptoms after three months, remaining symptom-free for four years. However, it is important to note that all of our patients from many different countries have benefited from HDVD+AID to one extent or another. Improving their quality of life significantly.

This clinical case shows that this patient with RA was able to achieve clinical remission, which means that the disease is no longer active and there are no signs of inflammation or joint damage. Signs of improvement that the patient showed were the following:

- 1.Reduction in joint swelling:** The edema and erythema of the affected fingers decreased, and the joint feel less boggy and no longer tender to palpation. Same was observed on all other compromised joints.
- 2.Increased range of motion:** The patient showed increased range of motion in both hands and all fingers. Knees no longer showed signs of pain or stiffness. Range of motion was restored.
- 3.Decreased pain:** The patient showed no more pain during physical activity and no longer relied on pain medication.
- 4.Improved grip strength:** The patient showed having greater ability to grip and hold objects with both affected hands, indicating improved joint function.
- 5.Normalization of acute phase reactants:** As the inflammation in the joint decreased, the patient's blood tests showed a reduction in markers of inflammation (ESR). Her ESR was found to be within normal range (**Fig 1.1**)

# Leaky Gut and Bacterial Toxin Clearance



**FIGURE 1.2**

Overall, managing autoimmune diseases such as RA requires a comprehensive approach that addresses both the underlying immune dysfunction and the symptoms experienced by the patient. Vitamin D, an anti-inflammatory diet, and probiotics may offer a complementary approach to traditional therapies for RA, but further research is still necessary. Regular monitoring and follow-up are crucial to ensuring patient safety and treatment effectiveness.

### **CONCLUSION**

Rheumatoid arthritis (RA) is a debilitating condition that affects a significant proportion of the population worldwide. The current treatments for RA focus on managing symptoms and preventing joint damage, but they are not curative, and patients may still experience flares and complications despite treatment. This highlights the need for alternative treatment options that can address the underlying immune dysfunction that drives the disease.

One such alternative approach is the LGS protocol, which involves high-dose vitamin D + cofactors, an anti-inflammatory diet, probiotics and at times use of biofilm disruptors (herbal antimicrobials) when needed. Vitamin D is crucial for bone health and immune function, and studies have shown that low levels of vitamin D may contribute to the development and progression of RA. The anti-inflammatory diet, which excludes lectin, gluten, dairy, and sugar, can help to reduce inflammation, while probiotics can improve gut health and regulate immune function. The use of ALA has been seen to improve faster toxin clearance and improving overall liver function.

The promising results from this clinical case involving the LGS protocol suggests that this approach may be effective option in managing RA symptoms and treating root cause. Medical professionals should be knowledgeable about the potential benefits of high-dose vitamin D therapy and anti-inflammatory diets, along with other complementary therapies, to provide the best possible care for their patients.

A more holistic approach to medicine, which considers the patient as a whole and not just the disease, is crucial for managing chronic diseases effectively. Doctors should not only focus on managing symptoms but also on addressing the underlying causes of the disease, including immune dysfunction, lifestyle factors, and environmental factors.

Therefore, it is crucial that medical students and residents receive a comprehensive training that includes a multidisciplinary approach to the management of chronic diseases. They should be aware of the potential benefits of complementary therapies such HDVD + AID and how to integrate them into patient care plans.

By incorporating holistic approaches into medical education, we can ensure that future medical professionals are equipped with the knowledge and skills necessary to provide patients with the most comprehensive and effective care possible.

In conclusion, a multifaceted approach that addresses both the underlying immune dysfunction and the symptoms experienced by the patient were necessary for the effective management of her RA. While traditional treatments can provide relief, alternative therapies such as the LGS protocol offer a complementary approach that can improve patient outcomes. However, patients need to adhere to the diet and perform regular follow-ups and monitoring in order to avoid future pitfalls.

### **NOTES**

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### **HUMAN ETHICS**

Consent was obtained by all participants in this study



**Video Link**

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