Coimbra Protocol

Information Packet

"For a healthy person, I can say without a doubt that 10,000 IU of vitamin D a day will not pose any risk, quite the contrary. For those who suffer from any autoimmune disease, this dose will bring partial relief, but will not eliminate the problem. Higher doses can be used, provided this supplementation is done under medical supervision."

Dr. Cícero Coimbra

Cicero Coimbra MD, Ph.D. is a neurologist and professor at the Federal University of São Paulo, Brazil. Over the past two decades, he has created a clinical protocol to treat autoimmune diseases with the reestablishment of adequate systemic levels of vitamin D. This therapeutic approach relies on doses of vitamin D that range from 40,000 IU to 300,000 IU per day; therefore, this is a medical treatment that must always be carried out under the supervision of a qualified doctor.

In 1991, Dr. Coimbra started his post-doctorate program at the University of Lund, Sweden, testing potential treatments for ischemic brain damage in rats. As a general rule in research work, he needed to be as up to date as possible on the latest findings related to his field of interest, which was clinical neuroscience. It was then that he realized that much of the therapeutic progress achieved in clinical and experimental research was never applied to clinical practice. In spite of their immediate applicability, these practices were not being taught in medical schools, even after several corroborative reports.

Through his research, based on the current medical literature, Dr. Coimbra came to believe that vitamin D could be a fundamental therapeutic resource since it stimulates the production of regenerative substances in the brain. So, in 2001 he began administering vitamin D in physiological doses - 10,000 IU/day - to Parkinson's Disease patients. Such a dose is the amount our own body produces when exposed to the sun for a few minutes. One day, a patient came back for a return appointment after 3 months of taking 10,000 IU/day. This patient also suffered from vitiligo, an autoimmune disease, and Dr. Coimbra noticed that a big lesion the man had on his face on the previous visit was barely visible. The lesion had almost disappeared in just a few months of administering 10,000 IU daily.

Dr. Coimbra decided to search the medical literature for the effects of vitamin D on the immune system and found a significant number of published papers supporting an important immunoregulatory role of this hormone. Because multiple sclerosis is the most common neurological autoimmune disease, he started prescribing vitamin D to MS patients. That was the beginning of what is presently known as the Coimbra Protocol.

With such doses, around 10,000 IU/day, Dr. Coimbra saw a remarkable clinical improvement in the vast majority of his patients. From that point on, the doses were further increased, always supported by laboratory tests to ensure patients would not experience side effects. The results were that many of these patients found themselves completely free of the symptoms and manifestations of the disease. During the next ten years, Dr. Coimbra and his staff gradually modified and perfected the treatment, mostly in terms of the prescribed daily doses, which grew steadily higher. From 2012 on, the desired level of efficacy was achieved and the Coimbra Protocol became very similar to what it is today.

What is Vitamin D?

Vitamin D is actually a steroid hormone - not a vitamin. It is necessary to regulate at least 229 of our genes and thousands of functions in our cells, including the cells of our immune system. Vitamin D is primarily produced by the skin when exposed to sunlight. This is one possible reason why populations that live further from the equator and have less exposure to sunlight have increased incidences of autoimmune conditions, specifically multiple sclerosis.

What is a physiological dose of vitamin D?

A physiological, safe dose of vitamin D is about 10,000 IU/day. This is the amount our own body produces when exposed to 20-30 minutes of the midday sun. With this daily dose, no precautions or medical supervision is necessary. The Institute of Medicine indicates that 10,000 IU/day is considered the "NOAEL"- No Observed Adverse Effect Level.

Why do patients on the Coimbra Protocol need such high doses of vitamin D?

With adequate levels of vitamin D, essential cellular processes will unfold properly. However, the majority of patients with autoimmune diseases have an increased resistance to the effects of vitamin D. This resistance is mostly due to genetic polymorphisms, and may also be influenced by other factors. Consequently, these patients require higher levels of vitamin D to overcome this resistance.

Why is vitamin D effective for autoimmune diseases?

Vitamin D is the largest regulator of activity in the immune system. Vitamin D suppresses autoimmunity by suppressing the Th17 reaction, which is caused by overproduction of an "immune messenger" (cytokine) called "interleukin 17". Production of interleukin 17 is a natural phenomenon and is beneficial in adequate, regulated amounts. Since autoimmune disease is the result of a dysregulated immune system that produces an aberrant immunological Th17 reaction, Vitamin D is the substance needed to modulate this process. Vitamin D also induces the proliferation of regulatory immune cells called "T lymphocytes".
Vitamin D does not suppress the immune system, but rather empowers the immune system against viruses, bacteria, and other microorganisms.

What is the ideal dose of vitamin D?

The ideal level of vitamin D varies based on the individual. The test that measures the serum level of vitamin D is called 25(OH)D3. However, serum vitamin D levels are not used for dose adjustments on the Coimbra Protocol. The test that can evaluate each patient's magnitude of resistance to vitamin D is the PTH – parathyroid hormone. Parathyroid hormone, or parathormone, is a hormone released by the parathyroid glands. Vitamin D suppresses the PTH; consequently, as vitamin D levels go up, PTH levels go down. If PTH were completely suppressed, this would mean that vitamin D would be working at its maximum biological potential. Since PTH cannot be completely suppressed, for it also has its purposes in the body, PTH levels are kept at its lowest normal limit. When PTH levels are at a minimum, the best biological effect of vitamin D is reached for that individual, regardless of the reason why they have a resistance.

How is the Coimbra Protocol applied?

Although the protocol includes other supplements besides vitamin D, achieving the correct level of vitamin D for each patient accounts for 95% of the treatment. Therefore, PTH levels are measured regularly during the treatment. If PTH is not at its minimum normal limit, vitamin D daily doses are increased until the desired PTH level is achieved. During the treatment, PTH levels are expected to go down to their lowest normal limit and stay there. When this happens, the resistance to vitamin D is overcome and the patient starts benefiting from its powerful immunodulatory effects. It usually takes two years to adjust the dosage of vitamin D. After this period, the treatment consists of maintenance of the proper levels of PTH and calcium.

What are the required lab tests?

Some of the tests required by the protocol include, but are not limited to:

- PTH
- 24H Calciuria
- B12 vitamin
- 25(OH)D3
- Total and Ionized Calcium
- Urea and Creatinine
- Albumin
- Ferritin
- Serum Phosphate
- 24H Phosphaturia
- TSH and FT4
- Bone Densitometry

Are there side effects to the Coimbra Protocol?

The possible side effects of taking high doses of vitamin D for extended periods of time are an excess of calcium - in the blood (hypercalcemia) or in the urine (hypercalciuria), and loss of bone mass.
Excess calcium can be easily avoided with a diet free of dairy and calcium-enriched foods, and regular lab tests to ensure calcium levels are kept under control.
To avoid loss of bone mass, patients on the protocol are instructed to practice a daily routine of aerobic exercise, like a 30 minute fast walk, for example. Those who cannot practice aerobic exercise might need medication, such as bisphosphonates, to prevent osteoporosis.

What is the recommended diet for the Coimbra Protocol?

The diet restrictions are related exclusively to the amount of calcium the foods contain. Dairy and calcium enriched foods must be avoided, nuts should be consumed in moderation. Again, every patient is different, so the test results will ultimately determine if the diet is being correctly followed or if more restrictions are needed. Also, patients need to drink 2.5 L of liquid a day, to ensure that the kidneys will be able to eliminate excess calcium without difficulty.

What other supplements are part of the Coimbra Protocol?

Recommended supplements can vary from physician to physician. Some of the supplements prescribed include, but are not limited to:

- Magnesium (Glycinate, Malate, Citrate, etc.)
- Magnesium Chloride
- Vitamin B2 - Riboflavin
- Omega 3
- Vitamin B12
- Chromium Picolinate
- Selenium
- Choline
- CoQ10

Additional Resources:

- https://www.coimbraprotocol.com/
- https://www.amazon.com/dp/B01BVRZX02/ Multiple Sclerosis and (lots of) Vitamin D: My Eight-Year Treatment with The Coimbra Protocol for Autoimmune Diseases

Is there any scientific evidence for vitamin D and autoimmunity?

The correction of vitamin D deficiency in autoimmune diseases is a therapeutic approach based on scientific evidence. Studies have shown that vitamin D, in addition to the known role in calcium homeostasis, has numerous actions in the body, with major interventions in the immune system.

There are thousands of scientific, peer-reviewed studies that show the relationship between multiple sclerosis and vitamin D3 deficiency, as well as the benefits of vitamin D supplementation for patients with such conditions.

Let's take a look at a few examples:

In 2009, a study presented at the annual meeting of the American Academy of Neurology found that high doses of vitamin D dramatically cut the relapse rate in people with multiple sclerosis. Patients in the high-dose group were given escalating doses of vitamin D for six months, to a maximum of 40,000 IU daily. Then doses were gradually lowered over the next six months, averaging out to 14,000 IU daily for the year. The patients given high-dose vitamin D in the study had lower relapse rates, and their T cell activity dropped significantly, when compared to the group who took lower doses

Burton, Jodie. "Is Vitamin D a Ray of Hope for Patients With MS?" Neurology Reviews 7;17.7 (2009) 1-16.

In 2011, a study conducted with 209 patients of systemic lupus erythematosus at the Ohio State University Medical Center found that the majority of patients included in the study had vitamin D deficiency. The authors concluded that vitamin D levels were negatively correlated with lupus disease activity. In other words, the more vitamin D in the blood, the lower the lupus disease activity, and vice versa.

Rovin, Brad H.; Vitamin D Deficiency As Marker for Disease Activity and Organ Damage in Systemic Lupus Erythematosus: [abstract]. Arthritis Rheum 2011;63 Suppl 10 :2276.

In 2013, a study supervised by Dr, Coimbra assessed the effect of prolonged administration of high-dose vitamin D on the clinical course of vitiligo and psoriasis. In this study, nine patients with psoriasis and 16 patients with vitiligo received 35,000 IU daily for six months in association with a low-calcium diet and hydration (minimum 2.5 L daily). The clinical condition of patients significantly improved during the treatment, with no signs of toxicity observed.The results of the trial suggest that, at least for patients with autoimmune disorders like vitiligo and psoriasis, a daily dose of 35,000 IU of vitamin D is a safe and effective therapeutic approach for reducing disease activity.

Finamor, Danilo C; Coimbra."A pilot study assessing the effect of prolonged administration of high daily doses of vitamin D on the clinical course of vitiligo and psoriasis." Dermato-Endocrinology 5.1 (2013): 222–234.

In 2015, a study published in PLOS Medicine demonstrated a genetic correlation suggesting that lack of vitamin D may be a cause of multiple sclerosis. Using a technique called Mendelian randomization, the authors examined 14,498 people with multiple sclerosis and 24,091 healthy controls. The study concluded that a genetically lowered vitamin D level is strongly associated with increased susceptibility to multiple sclerosis. According to Dr. Benjamin Jacobs, "This study reveals important new evidence of a link between vitamin D deficiency and multiple sclerosis. The results show that if a baby is born with genes associated with vitamin D deficiency they are twice as likely as other babies to develop MS as an adult. This could be because vitamin D deficiency causes multiple sclerosis."

Mokry, Lauren E.; Ross, Stephanie; Ahmad, Omar S.; Forgetta, Vincenzo; Smith, George D.; Leong, Aaron; Greenwood, Celia M. T.; Thanassoulis, George; Richards, J. Brent. "Vitamin D and Risk of Multiple Sclerosis: A Mendelian Randomization Study." PLOS Journal, 25 Aug. 2015. DOI: 10.1371/journal.pmed.1001866.

In 2015, a study published by the MS Society Cambridge Centre for Myelin Repair demonstrated the important role of vitamin D in myelin repair. Researchers identified that the vitamin D receptor protein pairs with an existing protein, called the RXR gamma receptor, already known to be involved in the repair of myelin. By adding vitamin D to brain stem cells where the proteins were present, they found the production rate of oligodendrocytes (myelin making cells) increased by 80 percent.

Kohlhaas, Susan. "Vitamin D could repair nerve damage in multiple sclerosis, " University of Cambridge. 07 Dec. 2015.

The benefit of vitamin D modulating therapy is not limited to patients with Multiple Sclerosis. It can also help with most common autoimmune diseases, such as Rheumatoid Arthritis, Lupus, Psoriasis, Crohn'sDisease, and others.

Cícero Coimbra, MD, Ph.D.

"Seeing MS patients getting back to a normal life, young people no longer at risk of going blind or paraplegic - such experience gives great satisfaction to the doctor who has them under his/her care. It has been very gratifying."
Dr. Cícero Coimbra