Review Article

High Dose-Short Duration Therapy of Cholecalciferol as a New Therapeutic Approach in the Treatment of Chronic Low Back Pain Associated with Vitamin D Deficiency

Abstract:

Chronic low back pain (CLBP) is a significant health issue, often linked to widespread vitamin D deficiency, particularly in Indian populations where prevalence exceeds 70%. This review evaluates the efficacy and safety of conventional weekly vitamin D supplementation (60,000 IU) versus high-dose, short-duration oral cholecalciferol nano-syrup therapy (60,000 IU/day for 10 days). While weekly regimens achieve vitamin D sufficiency rates of 44–68%, the high-dose nano-syrup therapy consistently attains 100% sufficiency within 10 days, alongside marked improvements in Visual Analog Scale (VAS) and Modified Oswestry Disability Questionnaire (MODQ) scores, with reductions of up to 75% and 40%, respectively. The nano-syrup approach also demonstrated a favorable safety profile, with no serious adverse events reported. These findings suggest that high-dose, short-duration vitamin D therapy offers a more effective and efficient alternative for managing vitamin D deficiency and associated CLBP, highlighting its potential for broader clinical application.

Keywords: Chronic low back pain, Vitamin D deficiency, Nano-syrup, High-dose therapy, Cholecalciferol

Introduction:

Chronic low back pain (CLBP), is defined as the pain or, localized below the costal margins and above the inferior gluteal folds, which may be accompanied by sciatica and persist for ≥ 12 weeks[1]. Low back pain is one of the most prevalent orthopaedic complaints that may result in significant loss of functionality of individuals across all age groups[2]. In addition to physical impairment, lower back pain bears a tremendous psychological influence such that anxiety and despair are prevalent among patients with low back pain overall affecting their quality of life[2,3].

The estimated worldwide lifetime prevalence of low back pain varies from 50% to 84% [4,5]. The occurrence of low back pain in India is also alarming with nearly 60% of the people in India have suffered from low back pain at some time during their lifespan [6]. Few studies have also found that individuals of lower economic status had a higher prevalence of CLBP than those of higher economic status [7].

A vitamin that is known to play a very important part in maintaining good health is Vitamin D, which is a fat-soluble vitamin [8]. Various names like sunshine vitamin and antirachitic factor have been given to this vitamin [9]. Vitamin D's distinctiveness lies in the fact that it is synthesized in our skin when we are exposed to sunlight. Ample sunlight exposure and food items like oily fish (Salmon) are the main sources of vitamin D [9].

Vitamin D measured as a 25(OH) D level of >30 ng/ml is generally considered "Sufficient", whereas a 25(OH) D level of 20-29.9 ng/ml is "Insufficient", and a 25(OH) D level of <20 ng/ml as "Deficient" [10]. Serum 25(OH) D level of >150 ng/ml is generally considered a "Toxic level" [10].

The results from various meta-analyses indicate that vitamin D deficiency was more prevalent among people with LBP than in those who did not experience any back pain [9].

Similarly, an extensive meta-analysis conducted by Zadro et al. concentrating on the relationship between Vitamin D and LBP, likewise uncovered a positive connection between LBP and lack of Vitamin D [9].

In a review observational examination done by Gokcek and Kaydu, it was found that decreased degrees of Vitamin D were related to increased severity of LBP [9].

Also, in Indian patients with Chronic Low back pain, the Prevalence of Vitamin D deficiency was found to be 70-90% [9,11,12].

Vitamin D is a proven anabolic hormone that promotes skeletal muscle and bone health as well as maintains immune function, with its inherent anti-inflammatory effects [13].

Thus, Vitamin D deficiency is an overtly underestimated, preventable and correctable etiological factor for CLBP [13].

Other than problems with the skeletal system, other health issues like increased risk of diabetes mellitus type 2, cancer, and cardiovascular diseases are associated with Vitamin D deficiency [13].

Vitamin D treatment regime:

Vitamin D treatment regime is given in Table 1 as per Indian Clinicians [14]:

Individuals	Dosage	Duration
Asymptomatic	800-2000 IU/Day	-

Symptomatic Vitamin D insufficient	60,000 IU/Week	Initiation dose of 8 weeks If unsatisfactory, once a week for 8 weeks Maintenance dose of once a month
Symptomatic Vitamin D deficient	60,000IU/Week	Initiation dose of 12 weeks If unsatisfactory, once a week for 8 weeks Maintenance dose of once a month

Table 1: Treatment regime for Vitamin D deficiency/insufficiency

Problems with Current Weekly supplementation of Vitamin D for the treatment of Vitamin D deficiency:
Even after weekly supplementation at the end of the study period, the group of participants have not been able to reach the sufficiency level (>30 ng/ml).

Few Indian studies indicate the problem:

1. A study done in Srinagar in 2015 by Mohammad Shafi Kuchay et.al., showed that Vitamin D supplementation of 60,000 IU for 4 weeks followed by 60,000 IU/ Month till 12 months, resulted in **68% of patients** reaching sufficiency level with **42% patients** remaining either in insufficiency/deficiency states [15].

2. Another study done by Goswami R et.al. in AIIMS Delhi, showed that weekly supplementation of 60,000 IU vitamin D for 8 weeks resulted in **56% of patients** reaching sufficiency level while again **44% of patients** remained either in insufficiency/deficiency states [16].

3. A very interesting study by Dr C.V Harinarayan in Bangalore revealed that 60,000 IU/Week for 8 Weeks followed by a bimonthly dose of 60,000 IU for 12 weeks leads to **47% of patients** reaching sufficiency level while again **53% of patients** remained either in insufficiency/deficiency states [17].

Problems with Weekly supplementation of Vitamin D in Vitamin D deficiency associated with Low Back Pain:

1. Problem with the percentage of Patients reaching sufficiency:

A study by Ghai et.al. study in 2017 in Chandigarh, showed that weekly supplementation of 60,000 IU of Cholecalciferol for 8 weeks followed by a monthly dose of 60,000 IU of cholecalciferol was able to achieve sufficiency (25(OH)D level >29 ng/ml) in only **66%** of patients with **34%** patients remaining again in the deficiency/insufficiency state [18].

Another trial by Kaunteya Krishna Das et.al. in Madhya Pradesh showed that weekly supplementation of 60,000 IU of Cholecalciferol for 12 weeks achieved sufficiency in only around **44%** and **50%** of men and women respectively [19].

One of the main reasons for this may be that Conventional Vitamin D formulations such as Granules and Capsules have been used in these trials.

Introduction to Oral Cholecalciferol Nano Syrup:

Oral Cholecalciferol Nano Syrup can be used to overcome the disadvantages of Granules and Capsules. Nano-syrup formulation has been proven to have better bioavailability than conventional Vitamin D3 formulations [20.21].

Introduction to High Dose-Short Duration therapy for Chronic Low back pain:

Two Indian clinical trials highlight the efficacy and safety of Oral Cholecalciferol Nano-Vitamin D3 Oral Syrup as High-Dose-Short Duration Vitamin D therapy for Chronic Lower Back Pain.

1. Lakkireddy M et.al. did a trial in 2019, in Hyderabad, which showed that Oral Nano Cholecalciferol Supplementation of 60,000 IU/day for 10 days resulted in 100% of patients achieving levels of 25(OH)D >30 ng/ml [22].

2. Similar study done by K Santha Bai et.al in Andhra Pradesh in 2024, patients showed that Oral Nano-Vitamin D3 Cholecalciferol Supplementation of 60,000 IU/day for 10 days resulted in 100% of patients achieving levels of 25(OH)D >30 ng/ml [13].

Efficacy of Oral Cholecalciferol Nano-syrup as High Dose-Short Duration Therapy in Chronic Low Back Pain:

Lakkireddy et.al. Showed that 10 days of continuous therapy of 60,000 IU Oral Nano Syrup leads to an increase of 25(OH) D level to a mean of 96.75 ng/ml and a reduction of 75% in VAS Pain score and 40% in MODQ from baseline [22].

In addition, K Santha Bai et.al showed that 10 days of continuous therapy of 60,000 IU Oral Nano Syrup led to an increase of 25(OH) D level to a mean of

80.8 ng/ml and a reduction of 18% in VAS Pain Score and 27% in MODQ from baseline [21].

Author	Regime	Baseline Vitamin D	Final Vitamin D	%Reduction in MODQ	%Reduction in VAS
Lakkireddy M et.al. [22]	Oral Nano Syrup 60,000 IU/day for 10 days	16.69 ng/ml	96.75 ng/ml	39.65%	75%
K Santha Bai et.al. [13]	Oral Nano Syrup 60,000 IU/day for 10 days	14.5 ng/ml	80.8 ng/ml	26.6%	17.5%

Table 2: Efficacy of Oral Cholecalciferol Nano-syrup as High Dose-Short Duration Therapy in Chronic Low Back Pain

Safety of Oral Cholecalciferol Nano-syrup as High Dose-Short Duration Therapy in Chronic Low Back Pain:

In both of the trials, no serious adverse event was reported [13,22].

Comparison of Efficacy in Weekly vs Daily Therapy of Vitamin D:

Author	Regime	Effects seen	Baseline Vitamin D	Final Vitamin D	%Reduction in MODQ	%Reduction in VAS
Ghai B et.al. [18]	**60,000 IU Weekly for 8 weeks followed**	**8 weeks**	**12.80 ng/ml**	**36.07 ng/ml**	**19%**	**55.55%**

	by 60,000 IU monthly for next 6 months					
Kaunteya Krishna Das et.al. [19]	**60,000 IU Weekly for 12 weeks**	**12 weeks**	**11.62 ng/ml**	**29.72 ng/ml**	**4.11%**	**22.29%**
K Santha Bai et.al. [13]	**60,000 IU/day for 10 days**	**12 weeks**	**14.5 ng/ml**	**80.8 ng/ml**	**26.6%**	**17.5%**
Lakkireddy M et.al. [22]	**60,000 IU/day for 10 days**	**21st Day**	**16.69 ng/ml**	**96.75 ng/ml**	**39.65%**	**75%**

Table 3: Comparison of Weekly vs Daily Oral Cholecalciferol Supplementation in Low Back Pain

Conclusion:

Vitamin D deficiency is quite prevalent in chronic low back pain. Traditionally, Vitamin D supplementation is administered either as capsules or granules, typically on a weekly basis. However, research has shown that weekly supplementation may not achieve sufficiency in 100% of the population. The use of conventional Vitamin D formulations could be a contributing factor to this issue. In this context, oral cholecalciferol nano-syrup may offer a significant advantage. High-dose, short-duration therapy for chronic low back pain might be a more effective alternative to weekly supplementation, potentially improving efficacy without compromising safety.

Competing Interests Disclaimer:

Authors have declared that they have no known competing financial interests, non-financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Disclaimer (Artificial intelligence)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

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