

Original Article

Evaluation of Vitamin-D3 levels in patients with Chronic Low Back Pain and their outcome after Vitamin-D3 supplementation

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ABSTRACT

Introduction: Vitamin D3 has a significant role to play in bone metabolism and neuromuscular function and its deficiency leads to rickets in children and Osteomalacia in adults. Vitamin D3 deficiency is also associated with non-specific symptoms such as fatigue and chronic pain. Several researchers have indicated that Vitamin D3 deficiency may be possibly related to musculoskeletal pain. Hence, Chronic low back pain, one of the symptoms resulting from Vitamin D3 deficiency may decrease quality of life by leading to functional insufficiency and thereby affecting social and work life. Therefore, in our study we aim to evaluate the levels of serum vitamin D3 in chronic low back pain patients and the effect of Vitamin D3 supplementation in improving the pain associated with chronic low back pain.

Materials and methods: Male and female patients between the age groups of 18 to 70 years attending the Outpatient Department of Orthopaedics, KMCH with symptoms of chronic low back pain after ruling out any pathological diseases of the spine were recruited in our study. The baseline levels of serum Vitamin D3 was checked in all the patients. Accordingly, those patients found to be having Vitamin D3 insufficiency or deficiency were started on Oral dose of Vitamin D3 (60000 IU) once weekly for 12 weeks. Follow up of patients were done at 3 months and 6 months and Vitamin D3 supplementation continued until normal range of Vitamin D3 is obtained.

Results: A total of 100 potentially eligible patients were screened for study participation. 19 patients were ineligible due to normal Vitamin D levels. Hence, 81 patients were included in the study. 30 patients (37 %) were male and 51 patients (63%) were female. The mean age (SD) of the male patients was 45.7 yrs (SD =13.8) and among the females was 41.5 yrs (SD = 17.4). Prior to inclusion into this study, the participants Mean (SD) VAS and MODQ was found to be 8 (3.56) [VAS range from 0-10] and 45(11.42) [MODQ range from 0 to 50] respectively showing that the majority of the patients had severe pain and disability at the onset of the study. Baseline Mean (SD) Vitamin D level was found to be 18.05 ng/ml (SD= 5.73). 48 patients (59.3%) were found to have deficient Vitamin D levels at baseline and 33 patients (40.7%) were Vitamin D insufficient. Serum Vitamin D levels increased significantly to 31.07 ng/ml (SD=11.55) post supplementation (P <0.01) at 3 months and 40.67ng/ml (SD=9.45) at 6 months respectively (P value<0.01). Significant reduction in pain score was observed post supplementation. The Mean VAS score at

3months and 6 months decreased to 3 (2.35) and 2 (2.12) respectively (P value<0.001 ,which was statistically significant). The mean MODQ at 3 months and 6 months decreased to 31(9.67) and 23 (8.55) respectively (P value <0.001, statistically significant).

Conclusion: The findings of our study establishes that Vitamin D3 deficiency is associated with chronic low back pain which in turn is associated with diminished functional capacity. The management of chronic low back pain should include an evaluation of the patient's Vitamin D3 status along with recommendations for appropriate Vitamin D3 supplementation for those individuals found to be deficient in Vitamin D3.

Keywords: Chronic low back pain, Serum Vitamin D3, VAS (Visual Analogue Score) MODQ (Modified Oswestry Disability Questionnaire).

INTRODUCTION

Chronic low back pain is often progressive and the cause may be difficult to ascertain. Vitamin D deficiency has been correlated with chronic musculoskeletal pain including low back pain.¹⁻⁵ A high prevalence of Vitamin D deficiency has been reported in patients with chronic low back pain in comparison to the general population.⁶⁻⁹ Two probable theories have been postulated- Firstly, the diffuse musculoskeletal pain, weakness and paraesthesia may be caused by hypovitaminosis D and secondly, hypovitaminosis D could play a role in the development of modic changes by increasing the susceptibility to inflammation in the vertebral end plates.

Vitamin D has a significant role to play in bone metabolism and neuro muscular function. The supplementation with calcium and Vitamin D has demonstrated Vitamin D's effectiveness in lowering the risk of fracture in osteoporotic patients. Recent research has shown a much broader role of Vitamin D and increasing number of investigations are being performed to show the effects of hypovitaminosis D and Vitamin D supplementation on different health aspects. Physiologically, Vitamin D plays a crucial role in the maintenance of extracellular calcium levels, which is a pre requisite for adequate musculoskeletal function¹⁰⁻¹³

The rationale of our study is to find the beneficial role of vitamin D supplementation in addition to the standard treatment of chronic low back pain

MATERIALS AND METHODS:

Study design: Hospital based prospective Cohort study

Sample Size: 100

Study Sample Collection: Male and female patients between the age groups 18-70 years attending the Out Patient Department of Orthopaedics, KMCH presenting with chronic low back ache. The patients were asked to complete the baseline pain related questionnaire. The questionnaires included VAS (Visual Analogue Score) to measure chronic low back pain intensity, functional disability using MODQ (Modified Oswestry Disability Questionnaire)¹⁴, work status.

Duration of study; 1 year (May 2024- May 2025)

Inclusion Criteria: Patients of both genders aged 18-70 years with chronic low back pain $\geq$ 12 weeks with or without leg pain.

Exclusion criteria: Patients were excluded if they had evidence of other causes of neuropathy or painful inflammatory conditions like Diabetes Mellitus, Rheumatoid arthritis and symptomatic osteoarthritis of the hip and knee. Patients diagnosed with epilepsy, psychiatric diseases, substance abuse, metabolic bone diseases like hypo or hyperparathyroidism, chronic renal disease, medical or surgical disorders affecting Vitamin D metabolism(gastric surgery, chronic liver disease, renal failure, intestinal malabsorption, systemic infection, cancers etc) were also excluded. Patients on corticosteroids or bisphosphonates or teriparatide , pregnant and lactating mothers were also excluded. Patients taking Vitamin D supplements during the past 3 months were also excluded from our present study.

Definition of Vitamin D levels :

Vitamin D₃ deficiency was graded based on Holick's classification as follows- Vitamin D₃ deficiency was defined as a 25(OH) D₃ level of ≤ 20 ng/ml. Vitamin D insufficiency as $>20 - 29$ ng/ml and normal level as ≥ 30 ng/ml.

Data Collection Method:

Only those patients meeting the inclusion criteria were enrolled from the OPD. Informed Consent was taken from each patient to assess the Vitamin D levels. Blood samples taken from Median Cubital Vein and those patients found to be having Vitamin D deficiency or insufficiency were started with Oral dose of Vitamin D₃ (60000IU) once weekly for 12 weeks. Repeat Serum Vitamin D₃ was checked after 12 weeks. Those patients with inadequate Vitamin D₃ levels even after 12 weeks were continued with Oral dose of Vitamin D₃ (60000IU) until Vitamin D₃ levels became normal. General follow up of patients was done at 3 months and 6 months respectively. The patients were assessed at baseline and at each follow up for pain intensity by using VAS (Visual Analogue Score) and functional disability by using Modified Oswestry Disability score.

Statistical Analysis: All the statistical tests were performed using SPSS software and analysis done using chi square test. P- Value of <0.05 was considered statistically significant.

RESULTS:**Table 1 : Baseline demography characteristics**

	Male (% of N)	Female (% of N)
Patients	30 (37%)	51 (63%)
Total (N)	81	

Table 2 : Age(in years) characteristics

	Mean (SD)
Male	45.7 (13.8)
Female	41.5(17.4)

Table 3 : Vitamin D status at baseline among men and women

	Sufficient	Insufficient	Deficient
Men	-	13 patients	17 patients
Women	-	20 patients	31 patients
Total	-	33 patients (40.7%)	48 patients (59.3%)

***Deficient** Vit D levels < 20 ng/ml

***Insufficient** Vit D levels (21- 29 ng/ml)

***Sufficient** Vit d levels ≥ 30 ng/ml

Table 4 : Table showing mean Vitamin D levels at baseline and after supplementation

	Mean Vit D3 at baseline	Mean Vit D3 after supplementation(at 3 months)	Mean Vit D3 after supplementation (at 6 months)	P value
Vitamin D	18.05 ng/ml (SD= 5.73)	31.07ng/ml (SD=11.55)	40.67ng/ml (SD=9.45)	<0.01

*comparison between baseline and after treatment done by paired t- test

Table 5 : Clinical efficacy analysis

Efficacy Parameter	Months	Mean (SD)	P value
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VAS (0-10)	0 m	8 (3.56)	-
	3 m	3 (2.35)	<0.001
	6 m	2 (2.12)	<0.001
MODQ(0 -50)	0 m	45(11.42)	-
	3 m	31 (9.67)	<0.001
	6 m	23 (8.55)	<0.001

Results analysis: A total of 100 potentially eligible patients were screened for study participation. 19 patients were ineligible due to normal Vitamin D levels. Hence, 81 patients were included in the study. 30 patients (37 %) were male and 51 patients (63%) were female. The mean age (SD) of the male patients was 45.7 yrs (SD =13.8) and among the females was 41.5 yrs (SD = 17.4). Prior to inclusion into this study, the participants Mean (SD) VAS and MODQ was found to be 8 (3.56) [VAS range from 0-10] and 45(11.42) [MODQ range from 0 to 50] respectively showing that the majority of the patients had severe pain and disability at the onset of the study.

Baseline Mean (SD) Vitamin D level was found to be 18.05 ng/ml (SD= 5.73). 48 patients (59.3%) were found to have deficient Vitamin D levels at baseline and 33 patients (40.7%) were Vitamin D insufficient. Serum Vitamin D levels increased significantly to 31.07 ng/ml (SD=11.55) post supplementation (P <0.01) at 3 months and 40.67ng/ml (SD=9.45) at 6 months respectively(P value<0.01).

Significant reduction in pain score was observed post supplementation. The Mean VAS score at 3months and 6 months decreased to 3 (2.35) and 2 (2.12) respectively (P value<0.001 ,which was statistically significant). The mean MODQ at 3 months and 6 months decreased to 31(9.67) and 23 (8.55) respectively (P value <0.001, statistically significant).

DISCUSSION

Chronic low back pain is one of the most common disorder of spine in adults all over the world¹⁵. It causes hindrance in daily activities, thereby decreasing social functioning and thus decreases the quality of lifestyle. It has also been observed that insufficient and deficient levels of Vitamin D are significantly involved in severe chronic spinal diseases and chronic painful disorders¹⁶⁻¹⁷. Vitamin D is involved in Calcium homeostasis and is needed for the proper functioning of bones, muscles and nerves. It also has anti-inflammatory properties. Multiple factors like geographical location, sunlight exposure, malnutrition and ethnicity affects the serum levels of Vitamin D.

Vitamin D plays a key role in the etiology and progression of various chronic pain conditions and associated co-morbidities by exerting anatomic, neurological, hormonal and immunological influences on pain expression. Vitamin D deficiency is known to induce muscle weakness and pain in adults as well as children¹⁸⁻¹⁹. Vitamin D is also known to have immunomodulatory property. Vitamin D supplementation is often associated with improvement in bone density and musculoskeletal pain by reducing the synthesis of inflammatory cytokines and increasing the anti-inflammatory cytokines²⁰⁻²¹.

Vitamin D suppresses Tumour Necrosis Factor Alpha(TNF- α), Macrophage Colony Stimulating factor (M-CSF) and Nitric Oxide synthase in astrocytes and microglia. TNF- α has been implicated at both the peripheral and central levels of pain sensitization. M-CSF is a cytokine that stimulates proliferation, differentiation and survival of monocytes and macrophages. Macrophages can release many inflammatory mediators including pro-inflammatory cytokines particularly TNF- α and interleukin-1 beta, Nerve growth Factor, Nitric Oxide and prostanooids.

CONCLUSION:

The findings of our study provides information regarding the association of vitamin D3 deficiency and patients with chronic low back pain, which is associated with diminished functional capacity. Clinical guidelines for the management of chronic low back pain should include an evaluation of the patient's vitamin D3 status, along with recommendations for appropriate vitamin D3 supplementation for individuals who are found to be deficient in vitamin D3.

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