

TO STUDY ON LOW BACK PAIN AND ITS ASSOCIATION WITH LEVELS OF VITAMIN D₃.

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ABSTRACT:

Background: Low back pain (LBP) is the highest contributor to disability worldwide, with current intervention strategies only providing small to moderate analgesic effects. The use of vitamin D supplementation for LBP has gained interest due to its proposed anti-inflammatory and neuro modulatory properties. However, it is still unclear whether vitamin D levels differ between those with and without LBP or if vitamin D levels are associated with pain intensity. **Objectives:** We aim to investigate the association between vitamin D levels and LBP and to determine if vitamin D levels correlate with pain intensity in individuals with LBP. **Study Design:** This study was conducted in accordance with the guidelines for performing a Meta analysis and Systematic Review of Observational Studies in Epidemiology (MOOSE). **Materials and Methodology:** A prospective observational study done at department of orthopaedics at simmer hospital(tertiary care hospital), surat conducted to study on low back pain and its association with levels of vitamin D₃. 197 patients were collected using the purposive sampling technique between August 2021 to October 2022. **Results:** The patients' ages ranged from 31 to 40 years on average, with a mean age of 35.31 years and a standard deviation of 11.92 years (range: 18 to 60 years). A greater proportion of men (58.4%) were included in the study than women (41.6%), according to the population breakdown. 62.9% of the 197 patients who suffered from chronic low back pain had inadequate levels of vitamin D₃, 16.8% had insufficient levels, and 20.3% had acceptable levels of vitamin D₃. The mean of vitamin D₃ in the study population was 20.9 ng/mL, with a standard deviation of 19.9 (range: 3.9 to 48.5 ng/mL). The average amount of vitamin D₃ found in females was 19.96 with a standard deviation of 13.11, And the results were as follows: 21.57 12.69. There was a statistically significant inverse connection between the levels of vitamin D₃ and the MODQ score (p 0.05). **Conclusion:** This study's findings provide information regarding the significant frequency of vitamin D₃ deficiency in the Indian population 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.

Key words: Lower back pain, vitamin d3, VAS score, MODQ score.

INTRODUCTION:

Low back pain is the most prevalent orthopaedic condition, impacting most people at some point in their lives. According to the World Health Organization, back Pain is regarded as the major cause of impairment and is the most common reason for contact with an outpatient department. According to some estimates, between 60 and 80 percent of the general population may experience low back pain at some point in their lifetime, and 20 to 30 percent will experience low back pain at any given moment. Low back pain diminishes an individual's quality of life and work performance, increasing days absent from work. Due to activity

restrictions and work absence, low back pain imposes a significant economic cost on individuals, their families, industry, and the government. Therefore, low back discomfort has a considerable socioeconomic impact. In addition to physical impairment, lower back pain has a tremendous psychological influence. Anxiety and despair are prevalent among Indian patients with low back pain. Low back pain affects all demographics, but because it is not a life-threatening illness, it is frequently dismissed as insignificant and disregarded. The sunlight vitamin, vitamin D₃, is one of the most intensively researched nutrients of the 21st century. It is essential for the development and lifelong

maintenance of a healthy skeleton. Most experts concur that this fat-soluble pro-hormone is essential for bone health. Because of its essential involvement in calcium homeostasis and bone mineralization. Several studies have evaluated the Vitamin D₃ status of individuals with nonspecific low back pain and no discernible pathological aetiology. Studies suggest a causal connection between Vitamin D₃ levels and Pain. Multiple researchers have revealed that despite sufficient solar exposure, Indians have an extremely fragile Vitamin D₃ balance due to food abnormalities and aesthetic concerns. Examining Vitamin D₃ levels in Indians with chronic low back pain may show intriguing tendencies. Consequently, the purpose of this study is to determine the precise levels of Vitamin D₃ in patients with idiopathic chronic low back pain, as well as its effects on pain and functional capacity.

MATERIAL AND METHODS:

STUDY DESIGN: Prospective observational study

STUDY PLACE: Department of Orthopedics at tertiary care hospital, Surat

STUDY DURATION: August 2021-October 2022

STUDY POPULATION: Patients with low back pain who have undergone checking of Vitamin D₃ levels in the tertiary center.

SAMPLE SIZE: 197 patients were collected using the purposive sampling technique.

STUDY TOOLS: Proforma.

INCLUSION CRITERIA:

- All patients between the age group of 18-60 years
- Patients with both the genders
- Patients with symptomatic low back pain of >15 days

EXCLUSION CRITERIA:

- Clinico-radiological correlation of any spinal pathology
- Vitamin D supplmentation before the study
- History of corticosteroid, bisphosphonate, teriparatide usage
- Pregnant and lactating female
- History of psychiatric illness

DETAILED RESEARCH PLAN:

Only those patients meeting the inclusion criteria were selected for the study. The study was conducted among

the outdoor patients/ the indoor patients admitted to our tertiary care hospital. The study was conducted on patients with low back pain who have undergone checking of Vitamin D₃ levels in the Department of Orthopedics at our tertiary care hospital.

Prior Informed Consent was taken to assess the vitamin D₃ levels; blood samples were collected from the median cubital vein with proper phlebotomy technique.

Proforma was including VAS score and MODQ.

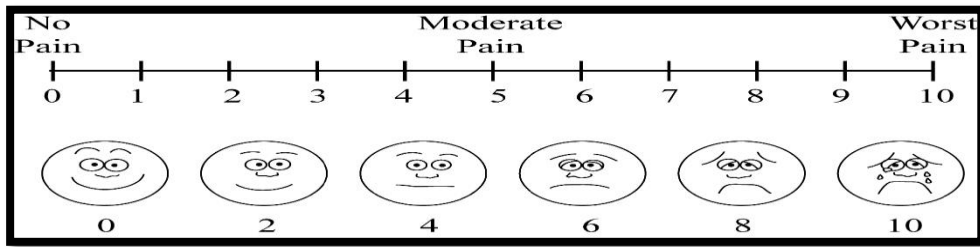
SCORING SYSTEMS USED:

1. VAS (Visual Analog Scale) score:

Visual Analog Scales are psychometric measuring tools designed to demonstrate disease-related symptoms severity in individual patients. It can be used to obtain a quick (statistically measurable and reproducible) classification of the severity of symptoms and the controlling of the disease. VAS can also be beneficial in day-to-day history taking and to monetarize the course of the chronic disease. Patients were classified to be having No Pain, Mild Pain, Moderate Pain, and Worst (Severe) Pain if the VAS scores were 0, 1-3, 4-6, and 7-10 respectively.

2. MODQ (Modified Oswestry Disability Questionnaire) score:

The Modified Oswestry Disability Questionnaire (MODQ) was established to assess the degree to which a patient's functional level is limited by pain in patients with low back pain. The MODQ consists of ten questions that assess pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, travel, and work/homemaking. Each section is scored on a 0-5 scale, with 5 representing the greatest disability. The index is calculated by dividing the summed score by the total possible score, which is then multiplied by 100 and expressed as a percentage. Thus, for every question not answered, the denominator is reduced by 5. If a patient marks more than one statement in a question, the highest-scoring statement is recorded as a true indication of disability. The instrument is self-administered, and the recall phase takes between 3.5 and 5 minutes to complete. The maximum score on the MODQ using the Likert scale is 50 when the values for all parts are combined together. A lower number suggests a higher standard of living. Score: _____ / 50 x 100 = _____ % points



0%-20% (Minimal disability)	The patient can cope with most living activities. Usually, no treatment is indicated apart from advice on lifting, sitting, and exercise.
21%-40% (Moderate disability)	The patient experiences more pain and difficulty with sitting, lifting, and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity, and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60% (Severe disability)	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80% (Crippled)	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%	These patients are either bed-bound or exaggerating their symptoms.

ASSESSMENT OF VITAMIN D₃:

After getting proper informed consent from the patients, the median cubital vein was used to obtain a 5-cc sample of fasting venous blood using sterile phlebotomy methods. The samples were centrifuged at 3000-3500 rpm for 5-10 minutes to separate the serum, which was then frozen at -20°C until analysis. All patients' plasma Vitamin D₃ levels were evaluated using the VITROS® 3600 Immunodiagnostic System, an automated chemiluminescence immunoassay (CLIA) analyser. To prevent circadian fluctuation, all blood samples were drawn between 9:00 and 10:00 am.

GRADING SYSTEM USED:

Vitamin D₃ deficiency was graded based on HOLICK's classification of vitamin D₃ deficiency, which is as under.

- Sufficient: ≥ 30 ng/mL
- Insufficient: 20.1- 29.9 ng/mL
- Deficient: ≤ 20 ng/mL

DATA ANALYSIS:

The association of low back pain with serum vitamin D₃ levels will be evaluated. Data will be recorded on a predesigned proforma and entered into Statistical Analysis: Data entry will be done in Microsoft Excel.

Data analysis would be done by appropriate statistical tests - Descriptive analysis & Chi-square test. Mean, and frequencies will be recorded for the age, gender, marital status, work profile, duration of symptoms, visual analog scale (VAS) for Pain, and levels of vitamin D₃. Stratification of data will be performed for gender and vitamin D₃ levels. Pearson's correlation will be used to assess the correlation of vitamin D₃ levels with low back pain.

EXPECTED RESULT:

We expect a positive relationship between low vitamin D₃ levels and low back pain. An increase in the vitamin D₃ level will lead to a decrease in MODQ score and vice versa. No significant correlation between levels of vitamin D₃ and VAS score is expected.

RESULTS:

In this observational study, based on our inclusion criteria, a total of 197 patients were included. In our study, the age of the patients ranged from 18 to 60 years with mean age of 35.31 years, the majority of the patients were in 31-40 age group years (38%). There were 58% male patients and 42% female patients.

Table 1: Age wise distribution of cases:

		Frequency(n)	Percentage (%)
Age Category	≤30	54	27.4
	31-40	76	38.6
	41-50	43	21.8
	51-60	24	12.2

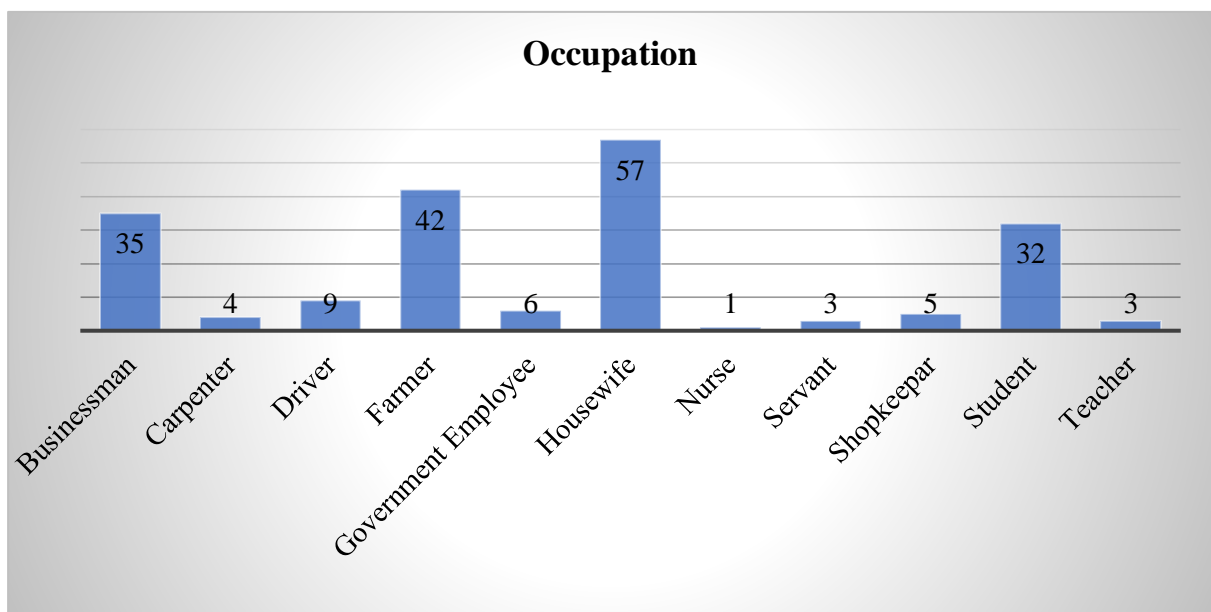
		Frequency(n)	Percentage (%)
Gender	Female	82	41.6
	Male	115	58.4

Table 2: Gender wise distribution of cases:

Table 3: Religion wise distribution among cases:

		Frequency(n)	Percentage (%)
Religion	Others	7	3.6
	Hindu	172	87.3
	Muslim	18	9.1

Chart 4: Occupation wise distribution among cases:



Most common occupation seen was farmer (21.3%) followed by businessman 17.8%. housewife was 28.9%.

Table 5: Lifestyle wise distribution among cases:

		Frequency(n)	Percentage (%)
Lifestyle	Heavy	48	24.4
	Moderate	95	48.2
	Sedentary	54	27.4

Moderate lifestyle was observed in 48.2% followed by sedentary with 27.4%

Table 6: Smoking distribution among cases:

		Frequency(n)	Percentage (%)
Smoking	No	95	48.2
	Yes	102	51.8

Smoking was seen in 51.8%

Table 7: Socio economic distribution among cases:

		Frequency(n)	Percentage (%)
Socio Economic Status	APL	168	85.3
	BPL	29	14.7

Table 8: Vitamin D₃ distribution among cases:

		Frequency(n)	Percentage (%)
Vitamin D ₃	Deficient	124	62.9
	Insufficient	33	16.8
	Sufficient	40	20.3

Table 9: Association of Vitamin D₃ with Age:

		Vitamin D ₃			Total	Chi-square value	p-value
		Deficient	Insufficient	Sufficient			
Age Category	≤30	33	7	14	54	9.59	0.14
	31-40	51	10	15	76		
	41-50	25	8	10	43		
	51-60	15	8	1	24		

In this study Table 9 showed that vitamin D₃ deficiency was more among 31-40 year , but no statistical difference was observed.

Table 10: Association of Vitamin D₃ with Gender:

		Vitamin D ₃			Total	Chi-square value	p-value
		Deficient	Insufficient	Sufficient			
Gender	Female	53	14	15	82	0.35	0.84
	Male	71	19	25	115		

Table 10 showed that vitamin D₃ deficiency was more among males than females, but no statistical difference was observed. While insufficient Vitamin D₃ was more among males than females, no statistical difference was observed. Sufficient Vitamin D₃ was high in Male.

Table 11: Association of Vitamin D₃ with Religion:

		Vitamin D ₃			Total	Chi-square value	p-value
		Deficient	Insufficient	Sufficient			
Religion	Others	4	1	2	7	0.78	0.94
	Hindu	109	28	35	172		
	Muslim	11	4	3	18		

In this study Table 11 showed that vitamin D₃ deficiency was more among Hindus than other religions, but no statistical difference was observed. While insufficient Vitamin D₃ was more among Hindus, no statistical difference was observed. Sufficient Vitamin D₃ was more in Hindu.

Table 12: Association of Vitamin D₃ with lifestyle:

		Vitamin D			Total	Chi-square value	p-value
		Deficient	Insufficient	Sufficient			
Lifestyle	Heavy	29	13	6	48	7.99	0.09
	Moderate	58	12	25	95		
	Sedentary	37	8	9	54		

In this study Table 12 showed that vitamin D₃ deficiency was more among moderate than other lifestyles, but no statistical difference was observed. While insufficient Vitamin D₃ was more among heavy lifestyle, no statistical difference was observed. Sufficient Vitamin D₃ was high in moderate lifestyle.

Table 13: Association of Vitamin D₃ with Smoking:

		Vitamin D ₃			Total	Chi-square value	p-value
		Deficient	Insufficient	Sufficient			
Smoking	No	57	18	20	95	0.83	0.66
	Yes	67	15	20	102		

In this study Table 13 showed that vitamin D₃ deficiency was more among smokers than non-smokers, but no statistical difference was observed. While insufficient Vitamin D₃ was more among non-smokers than smokers, no statistical difference was observed. Sufficient Vitamin D₃ was same in both the group.

Chart 14: Association of Vitamin D₃ with Occupation:

In this study Fig 14 showed that vitamin D₃ deficiency was more among housewife than other occupation, but no statistical difference was observed. While insufficient Vitamin D₃ was more among farmers compared to other occupation, no statistical difference was observed. Sufficient Vitamin D₃ was seen in housewife.

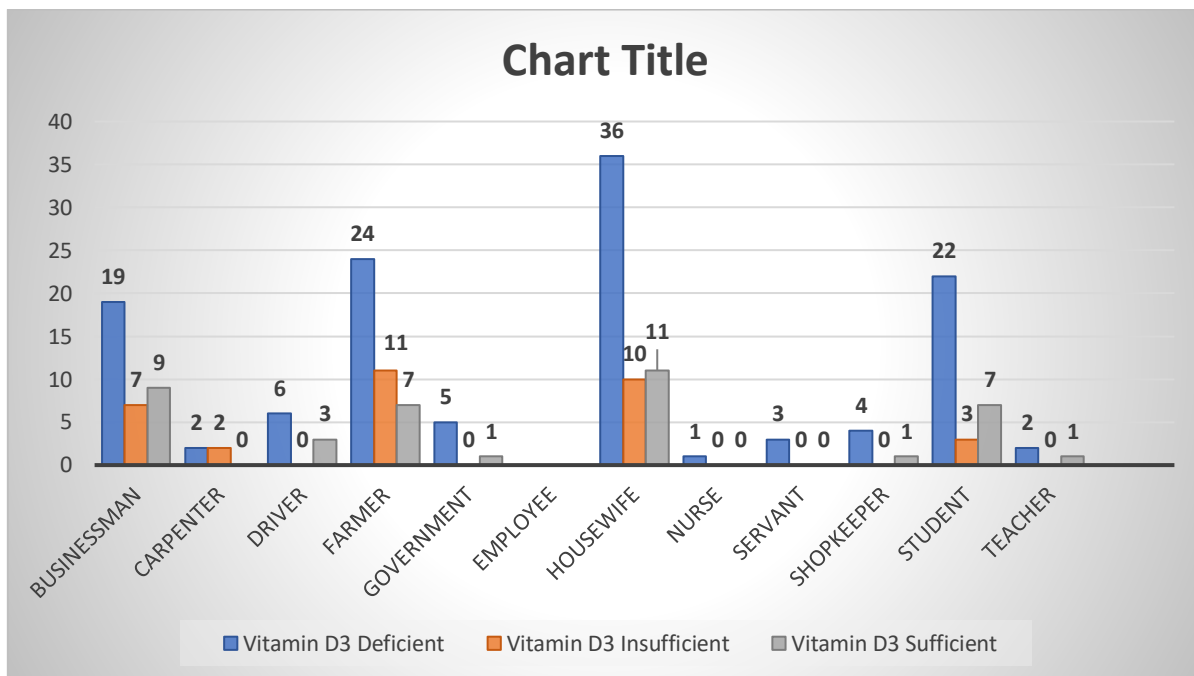


Table 15: Association of Vitamin D₃ with Socioeconomic status:

		Vitamin D ₃			Total	Chi-square value	p-value
		Deficient	Insufficient	Sufficient			
Social Economic Status	APL	104	30	34	168	1.03	0.6
	BPL	20	3	6	29		

In this study Table 15 and Fig 15 showed that vitamin D₃ deficiency was more among APL than BPL, but no statistical difference was observed. While insufficient Vitamin D₃ was more among APL than BPL, no statistical difference was observed. Sufficient Vitamin D₃ was more among APL.

Table 16: Association of Vitamin D₃ with BMI and MODQ:

Pearson Correlations			
		BMI	MODQ
Vitamin D ₃	Pearson Correlation	0.071	-0.155
	p-value	0.323	0.030
	N	197	197

In this study Table 16 showed that vitamin D₃ deficiency with MODQ showed negative correlation i.e. with increase in MODQ score vitamin D₃ level decreases. While no statistical significance was seen in vitamin D₃ and BMI.

Chart 16: Association of Vitamin D₃ with MODQ:

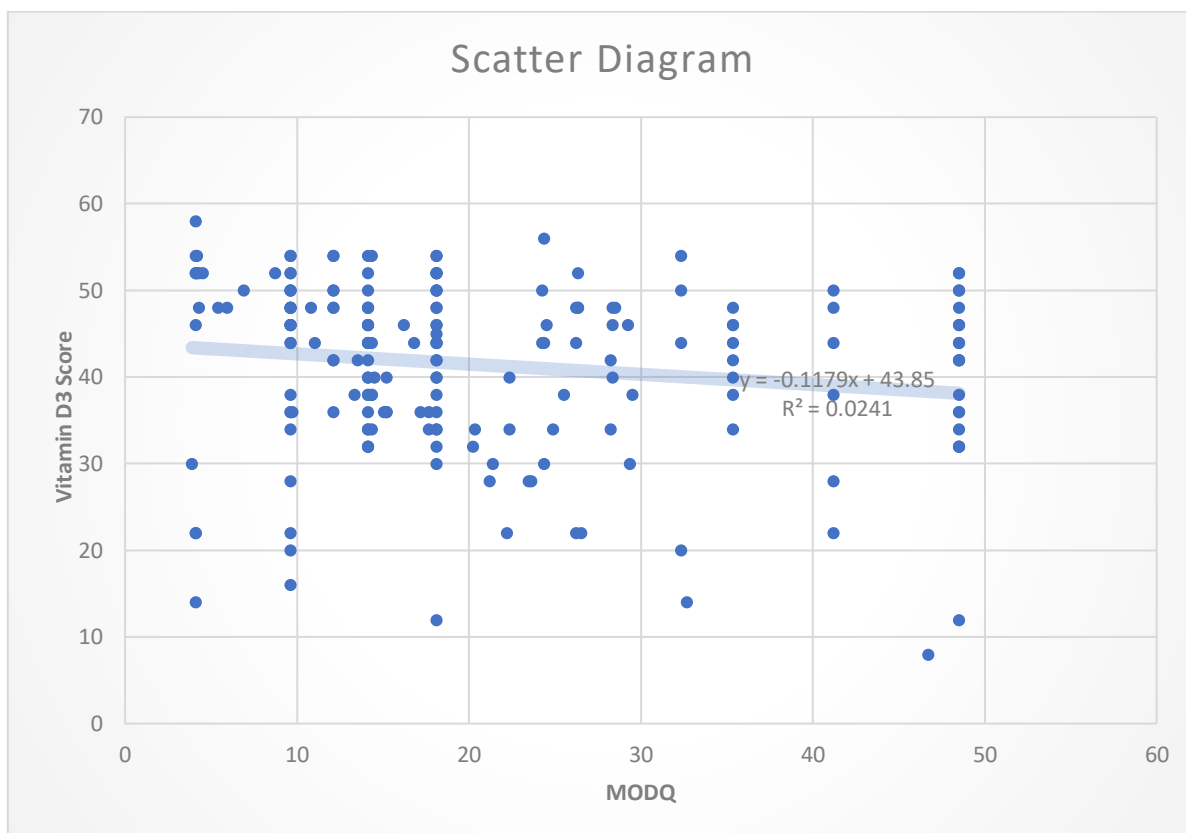


Table 17: Association of Vitamin D₃ with VAS score:

Spearman's rho Correlations			
			Vas
Spearman's rho	Vitamin D ₃	Correlation Coefficient	-
		p-value	0.980
		N	197

IN THIS STUDY TABLE 17 SHOWED THAT VITAMIN D DEFICIENCY AND VAS SHOWS NO CORRELATION

Table 18: Association of Vitamin D₃ with SLRT:

		Vitamin D ₃
SLRT Right	Pearson Correlation	0.057
	Sig. (2-tailed)	0.28
	N	197
SLRT Left	Pearson Correlation	0.058
	Sig. (2-tailed)	0.419

IN THIS STUDY TABLE 18 SHOWED THAT VITAMIN D DEFICIENCY AND SLRT HAD NO CORRELATION.

DISCUSSION:

Chronic low back pain is a prevalent complaint that is noticed in the Indian population. It is also a typical symptom that patients report with when they visit the orthopaedic outpatient department. Patients in the 18-60 age range who had been complaining of low back pain for more than three months and who visited in tertiary care hospital during August 2021-October 2022 were included in this observational study with the purpose of determining the association between the levels of vitamin D₃ and patients who suffer from chronic low back pain, as well as investigating the effects of vitamin D₃ on pain and functional capacity. In our study, the percentage of participants who fell into each category, based on the various levels of serum vitamin D₃, were as follows: In 20.3% of the cases, vitamin D₃ levels were measured to be 30 ng/mL, which is considered to be normal or sufficient. In 16.8% of the cases, vitamin D₃ levels were measured to be between 20.1 and 29.9 ng/mL, which is considered to be insufficient. In 62.9% of the patients, vitamin D₃ levels that were less than 20 ng/mL, which is considered to be inadequate. The standard deviation of the mean vitamin D₃ level in the serum was 12.8 (range:3.9-48.5). This percentage was 81.7% in the study carried out by Lotfi et al. 24, 74.3% in the study carried out by Hwan-Kim et al. 25, and 22.5% in the study carried out by eSilva et al. 26. The study carried out by Alfaraj et al. 23 found that 83 percent of patients with chronic low back pain had vitamin D₃ deficiency. There is a high prevalence of vitamin D₃ deficiency (55.55% cases) and insufficiency (38.46% cases) (combined: 94.01%) in the general population of North India, according to research carried out by Kalra Sanjay et al.145 in an orthopaedic outpatient department in 234 female patients who presented with musculoskeletal symptoms. This research was carried out in 234 female patients. According to the findings of Elamin IE Abdelgadir et al.134, 63.9% of patients had vitamin D₃ deficiency, 17.9% of patients had vitamin D₃ insufficiency, and 18.1% of the sample tested exhibited vitamin D₃ sufficiency. Both univariate and multivariate analysis were utilised by Maier Steffen Maier et al. 24 in order to determine the risk factors that contribute to insufficient levels of vitamin D₃. In total, 84% of patients had levels of

vitamin D₃ that were insufficient, and among those with insufficient levels, 60% of cases were vitamin D₃ deficient. Only 16% of the samples had concentrations within the desired range of 30 to 60 ng/mL. According to the findings of Zeliner BS et al.148, 86.2% of participants had insufficient levels of 25-hydroxyvitamin D (less than 30 ng/mL), and among those cases, 53.2% had vitamin D₃ levels that were too low (less than 20 ng/mL). In our study, there were significantly more male patients (58.4%) than female patients (41.6%). The mean levels of vitamin D₃ in men were 21.5 12.6, and in women they were 19.9 13.11, respectively. In the present investigation, we found that there was no statistically significant correlation between the sexes and vitamin D₃ levels (p = 0.501). In agreement with our findings is a study that was carried out by Hwan-Kim et al. 25 on 350 patients diagnosed with CLBP. In this investigation, the researchers discovered that there was no significant link between the levels of vitamin D₃ and gender. According to the findings of Bogunovic L. et al.142, the incidence of low vitamin D₃ levels was substantially more common in men. Elamin IE Abdelgadir et al. 134 observed that the vitamin D₃ deficiency appeared to be more severe in males; the mean level of 25(OH) D was 18.6 12.4 ng/mL, while the mean level of vitamin D₃ in females was 20.6 16.5 ng/mL. The researchers concluded that the vitamin D₃ deficiency appeared to be more severe in males. Still, the change did not nearly reach statistical significance. According to the findings of Mithal A. et al,143,144, the main factors that are significantly associated with lower 25(OH) D levels are older age, female sex, higher latitude, winter season, darker skin pigmentation, less sunlight exposure, dietary habits, and the absence of vitamin D₃ fortification. According to the findings of our research, the average age of the patients was 35.31 years, with a standard deviation of 11.92 years (range 18 to 60 years). The majority of the participants, or 38.6%, were in the age bracket of 31 to 40 years old. In the course of our research, we came across no evidence of an age-related correlation that was statistically significant (p = 0.499). According to the findings of Maier S., Gerrit et al.146, levels of vitamin D₃ were not affected by factors such as age, sex, or sickness. In our study, there were significantly

more patients who identified as Hindu (87.3%), compared to Muslims (9.1%) and others (3.6%). There was no statistically significant correlation found between vitamin D₃ levels and religious affiliation. Diamond TH, Levy S, Smith A, Day Plv et al.¹⁵⁷ discovered that among 600 individuals, 68.1% of Muslim women had vitamin D₃ insufficiency, which was defined as serum 25(OH) D levels of less than 30 nmol/L. In our study, the majority of patients were housewives (28.9%), followed by farmers (21.3%) and businesspeople (17.9%). There was not a significant correlation found between the levels of vitamin D₃ and the occupations of the participants ($p > 0.001$). Among the male patients, Harin Jeong et al.¹⁵⁸ found that there was a substantial link between vitamin D₃ deficiency and working conditions among shift workers, office employees, and permanent workers. This correlation was detected in all three types of workers. There was shown to be no statistically significant link between any working situation and the female subjects. According to the results of our research, 48.2% of patients belonged to a moderate lifestyle, and 27.4% of patients belonged to a sedentary lifestyle. There was not a significant correlation found between the levels of vitamin D₃ in the body and the lifestyle choices people made ($p = 0.002$). Within our sample of 197 patients, we found that 51.8% of them were smokers. Smokers were found to have significantly lower levels of serum vitamin D₃, although there was no statistically significant difference identified between the two groups. This discovery is consistent with the findings that were presented by E. C. Brot, Ugenia Cutillas-Marco et al.,¹³³. Smoking is a strong driver of serum 25(OH) D, and a considerable rise in this risk of having vitamin D₃ deficiency is associated with this behaviour, as shown by Eva N. Kassi et al.¹⁴⁴. The smoking habit has a major impact on calcium and vitamin D₃ metabolism, an effect that is not likely to be explained by other lifestyle factors that can confuse the issue. The depression of the vitamin DPTH system that is observed in smokers may represent another potential mechanism for the harmful effects of smoking on the bone and may add to the reported risk of osteoporosis among smokers. [Citation needed] In our research, there were a greater number of patients classified as APL (85.3%), compared to BPL (14.7%). There was found to be no statistically significant connection between the levels of vitamin D₃ and socioeconomic status ($p = 0.408$). During the course of their research, Davis, Shani Vann et al.,¹⁵⁹ came to the conclusion that the connection between socioeconomic status and vitamin D₃ levels was tenuous but reliable. There was no correlation found between any other measure of socioeconomic status and vitamin D₃ levels. However, not all of these factors were taken into account in the covariate analysis even though they are known to be related with low socioeconomic status and to be

capable of reducing vitamin D₃ consumption as well as production. In the end, no indicator of socioeconomic position was able to provide a satisfactory explanation for vitamin D₃ levels. Socioeconomic position does not predict vitamin D₃ level. The majority of patients in our study had an SLRT of 80 degrees, with 43.34 percent on the right side and 46.38 percent on the left side correspondingly. On the other hand, there was no significant association found between the levels of vitamin D₃ and SLRT on either the right or the left side. According to the results of our study, 52.64% of patients experienced moderate pain (VAS score: 4-7), whereas 45.15% of patients experienced severe pain (VAS score: 7-10). According to the findings of our research, there is no statistically significant connection between vitamin D₃ levels and VAS score ($p = 0.256$). According to the findings of our research, the majority of patients (58.2%) had a severe level of disability, while 36.3% of patients had a moderate level of disability. There was a statistically significant inverse association between the levels of vitamin D₃ and the MODQ score ($p = <0.05$), which means that as the levels of vitamin D₃ increased, the MODQ score decreased and vice versa. According to the findings of Bischoff et al.⁹³, patients who are 60 years old or older and have a deficiency in vitamin D₃ have lower levels of muscle strength and functional capacity than patients who have normal levels of vitamin D₃. In their study, Panagiotis et al.¹⁶¹ found that postmenopausal women with vitamin D₃ insufficiency had weaker muscles, which led to a reduction in their overall functional capacity. According to the findings of a study on patients with chronic low back pain (CLBP) carried out by Hwan Kim et al.²⁵, there is no correlation between vitamin D₃ deficiency and functional ability.

CONCLUSION:

This study's findings provide information regarding the significant frequency of vitamin D₃ deficiency in the Indian population 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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