

A Cross-Sectional Study on Assessing Association Between Chronic Low Back Ache and Vitamin-D Deficiency Among Female Population in India.

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Abstract:

Introduction: Vitamin D is commonly referred to as the "sunshine vitamin" or "anti-ricket factor." Inadequate levels of vitamin D have been associated with various musculoskeletal issues such as fibromyalgia, arthralgia, and low back pain. Although a connection between low blood vitamin D levels and chronic low back pain has been suggested, conclusive evidence is still lacking. This study aimed to explore the potential link between chronic low back pain and vitamin D deficiency in the female population of India. Additionally, the research aimed to determine if there was a correlation between the severity of chronic low back pain, as assessed by the Visual Analogue Scale (VAS) score, and blood levels of vitamin D.

Methodology: A cross-sectional study was conducted at R. L. Jalappa Hospital in Kolar from December 2019 to June 2021, utilizing a convenient sampling technique. Female patients aged 18 and above, experiencing chronic low back pain lasting more than 12 weeks without radiculopathy, and seeking treatment at the outpatient department were included. Data collected included age, location, marital status, occupation, body mass index (BMI), VAS score, and vitamin D levels. The data were entered into Microsoft Excel and analyzed using SPSS version 21. Pearson's correlation test was employed to evaluate the relationship between quantitative risk factors and vitamin D levels. Similarly, the Chi-square test was used to examine the association between categorical risk factors and chronic low back pain.

Results: The study encompassed 40 participants with a mean age of 39.43 years. Statistically significant associations were observed between experiencing severe low back pain and residing in urban areas ($P < 0.0001$), having a professional or semi-professional occupation ($P < 0.0001$), possessing a diploma or graduate degree ($P < 0.0001$), and being classified as vitamin D deficient ($P = 0.007$). The study revealed that age ($p = 0.032$) and vitamin D levels ($p < 0.0001$) exhibited a negative correlation with the VAS score.

Conclusion: The study highlighted a notable prevalence of vitamin D deficiency among the participants, particularly among those residing in urban areas. Educated individuals and professionals who spend significant time indoors were identified as having a high-risk for developing low backache.

Keywords: Vitamin-D deficiency, Chronic Low back ache, Visual analogue scale, Female gender AND Risk factors.

INTRODUCTION:

In the early 1900s, Vitamin D was initially classified as a vitamin and later as a prohormone. Commonly referred to as the "sunshine vitamin" or the "anti-ricket factor", it plays a vital role in preventing various musculoskeletal issues, including fibromyalgia, arthralgia, and low back pain. [1] Insufficient Vitamin D levels can lead to reduced calcium absorption and bone mineralization, potentially resulting in osteomalacia or osteoporosis, both of which are associated with low back pain. [2] Despite its role as an anabolic hormone for the musculoskeletal system, the widespread and preventable occurrence of hypovitaminosis-D contributes to

low back pain. [3,4] Chronic low back pain is a global concern, with researchers establishing a clear connection, particularly among females, between Vitamin D, low back pain, and its etiology. [5]

Low back pain is categorized into three durations: acute (up to 6 weeks), sub-acute (6 to 12 weeks), and chronic (over 12 weeks). [6] Notably, around 30 percent of acute low back pain cases progress to chronic low back pain due to symptoms of Vitamin D deficiency. This progression adversely affects quality of life, resulting in functional insufficiency that significantly impacts both social interactions and work engagements. [7] Moreover, when comparing males and females of the same age group, the association between persistent lower back pain and inadequate Vitamin D levels is more pronounced among females. [8]

Despite indications linking low blood Vitamin D levels to chronic low back pain, conclusive evidence remains limited. The existing research landscape lacks comprehensive studies investigating the relationship between Vitamin D deficiency and chronic low back pain. Addressing this research gap, the current study was undertaken to explore the association between chronic low back pain and Vitamin D deficiency in the female population of India. Additionally, this study identified a correlation between chronic low back pain severity, as measured by the Visual Analogue Scale (VAS) score, and blood Vitamin D levels.

MATERIALS AND METHODS

Study Design and Duration:

Between December 2019 and June 2021, a cross-sectional study was conducted at R.L. Jalappa Hospital in Kolar.

Sampling Method:

A non-probability convenient sampling approach was employed for participant selection.

Participants:

The study enrolled female patients aged 18 and above who had been experiencing chronic low back pain for over 12 weeks without radiculopathy. These individuals sought treatment at the hospital's outpatient department.

Ethical Approval:

Ethical clearance from the institutional ethics committee was obtained before commencing the study (IEC no: DMC/KLR/IEC/231/2021-22).

Inclusion Criteria:

Female patients aged 18 and above with chronic low back pain lasting more than 12 weeks, without radiculopathy, and seeking treatment at the outpatient department were included in the study.

Exclusion Criteria:

The study excluded patients with conditions such as spinal stenosis, disc prolapse, spondylolisthesis, post-spinal surgery, spinal fractures, metabolic disorders, pregnancy and lactation, ongoing treatment for osteoporosis, chronic kidney failure, recent vitamin D therapy within the last 3 months, and psychiatric disorders.

Data collection:

The study involved obtaining data from the patient's medical records regarding their vitamin D levels and pain scores (measured using the Visual Analog Scale or VAS) in cases of chronic low back pain. The analysis utilized the information extracted from the patient's records. Vitamin D levels were evaluated through venous blood samples, with serum 25-OH-vitamin D concentrations measured using the enzyme-linked immunosorbent assay (ELISA) method. In cases of chronic low back pain, serum 25 (OH) Vitamin D concentrations above 30 ng/mL were considered within the normal range, while concentrations below 30 ng/mL indicated a deficiency or inadequacy of Vitamin D. [9]

Upon obtaining informed consent, sociodemographic data were collected as part of the clinical history, including details such as age, gender, marital status, educational background, duration of sun exposure, and dietary choices. Additionally, the Body Mass Index (BMI) was measured and categorized into distinct groups:

underweight (BMI below 18.5), normal weight (BMI 18.5–24.99), overweight (BMI 25–29.99), and obese (BMI 30 or higher kg/m²). [10]

Pain intensity was evaluated utilizing the Visual Analogue Scale (VAS) score, a subjective Likert scale spanning from 0 to 10. Within this scale, 0 denoted the absence of pain, while 10 represented the highest conceivable level of pain. [11] Based on their VAS scores, the research participants were categorized operationally into two groups: those experiencing high pain (VAS score greater than or equal to 6) and those with moderate pain (VAS score less than 6). The investigation focused on exploring the connection between chronic lower back pain and serum vitamin D levels.

Sample size:

The association coefficient (r) between Vitamin D levels and Pain Scores (VAS) was 0.554, according to Vinay Kanaujia et al. [12] Considering a 1 percent alpha error (implying a 99 percent confidence level) and a Power of 90% (with Beta set at 0.10), the formula $n \geq ((Z(1-\alpha/2) + Z(1-\beta)) / (1/2 \log (1+r/1-r)))^2 + 3$ was employed to compute the necessary sample size, resulting in a requirement of 33 individuals. For this study, a total of 40 participants were enlisted, surpassing the calculated sample size.

Data analysis:

The data was input into Microsoft Excel and subjected to analysis through the utilization of the Statistical Package for Social Science (SPSS), employing the standard version 21. To evaluate the relationship between quantitative risk factors and Vitamin D levels, the Pearson's correlation test was employed. This test allowed the assessment of potential correlations between numerical risk factors and the levels of Vitamin D. Likewise, the Chi-square test was employed to examine the potential associations between categorical risk factors and the occurrence of chronic low back pain. This statistical approach facilitated the exploration of connections between various factors and the prevalence of chronic lower back pain.

RESULTS:

Our research involved a total of 40 participants. Table 1 provided information on the age and initial clinical traits of these individuals. The average age of the participants was 39.4 years. Furthermore, the average Body Mass Index (BMI) and Vitamin D levels among the participants were calculated as 27.6 and 25.9 ng/mL, respectively.

Table 1: Distribution of baseline characteristics of the study participants (n=40)

	Age (in years)	Duration of illness (in years)	BMI	VAS score	Vitamin D (in ng/mL)
Mean	39.43	5.30	27.608	5.70	25.90
Median	37.00	5.00	27.300	6.00	25.00
Mode	28 ^a	5	23.6 ^a	4	35
Std. Deviation	7.903	2.312	3.5069	1.324	7.2
Minimum	28	3	21.0	4	15
Maximum	56	14	33.0	8	35
Interquartile range	35.0 - 46.0	4.0 - 6.0	24.1 - 31.0	4.0 - 7.0	20.0 - 35.0

Figure 1 depicted the arrangement of study participants based on their Vitamin D categorization. The occurrence of Vitamin D insufficiency within the study group was observed at a rate of 72 percent.

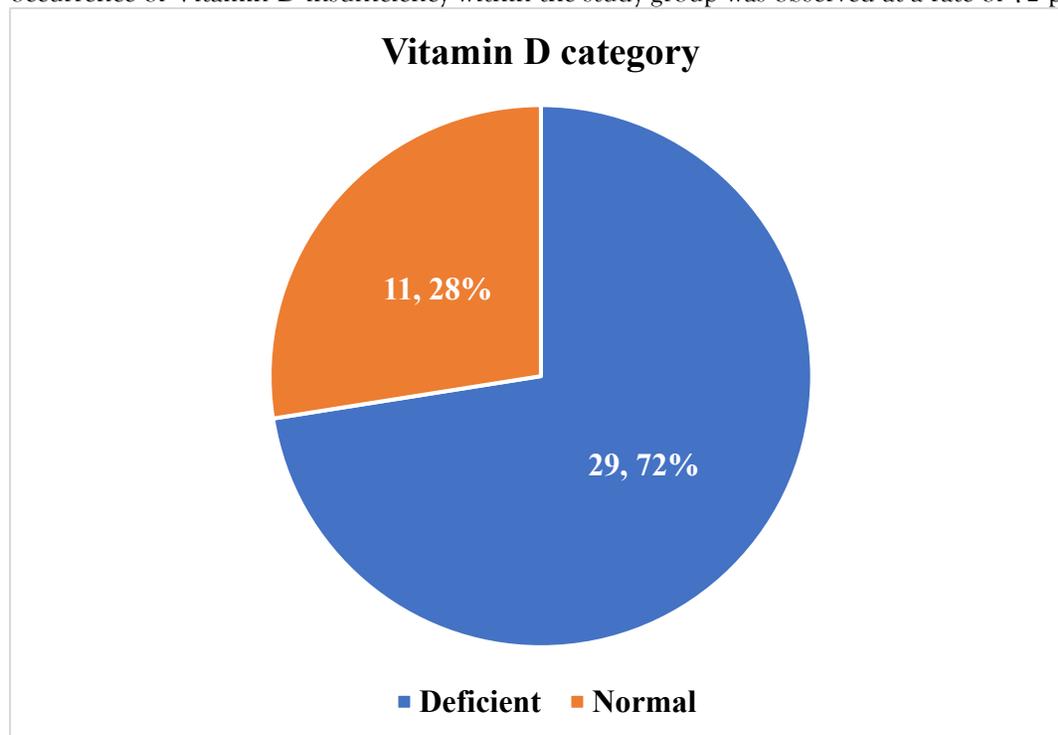


Figure 1: Distribution of the study participants according to the vitamin D category (n=40)

Figure 2 illustrated the dispersion of study participants in relation to their Body Mass Index (BMI). It was observed that approximately one-third of the participants fell into the overweight category, while an additional one-third were categorized as obese.

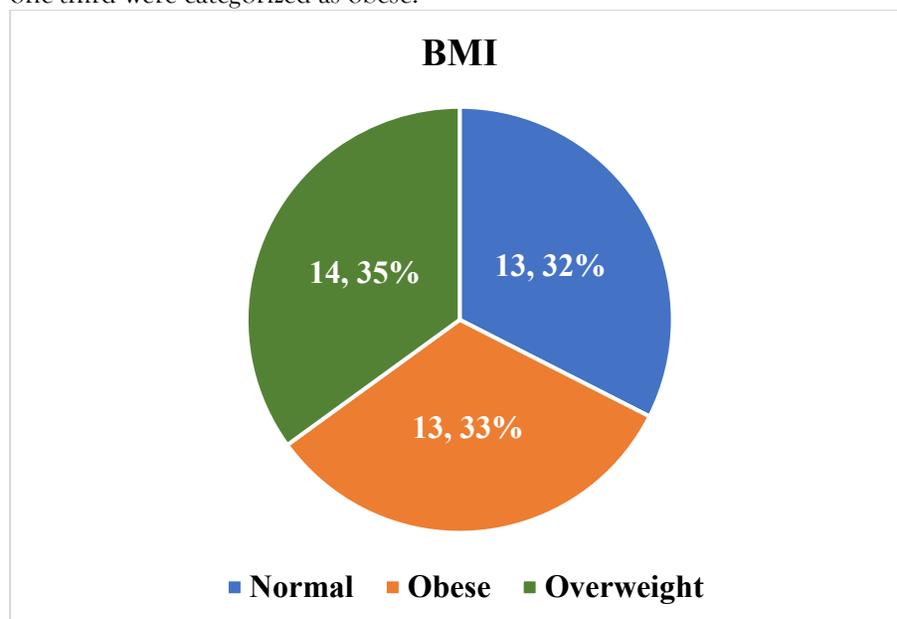


Figure 2: Distribution of the study participants according to their BMI category (n=40)

Table 2 outlines the association between distinct risk factors and the categorization of VAS score among the enrolled study participants. A profound and statistically significant correlation was established between certain factors and the likelihood of encountering elevated pain levels, as indicated by the VAS score category. Specifically, individuals who resided in urban settings exhibited a notably strong association with heightened pain experiences ($p < 0.0001$). Moreover, those engaged in professional and semi-professional occupations demonstrated a similar substantial association to increased pain ($p < 0.0001$). Likewise, participants possessing diploma and graduate qualifications displayed a marked association for experiencing high pain levels ($p < 0.0001$). Additionally, a noteworthy association emerged between participants identified as vitamin D deficient and the incidence of elevated pain ($p = 0.007$). This discernible pattern was derived from the rigorous application of the Chi-square test, highlighting the significant impact of these factors on the likelihood of encountering intensified pain sensations within the context of the VAS score assessment.

Table 2: Association between risk factors and VAS score category among the study participants (n=40)

S. No	Variables		VAS score category		Total	Table value*	P-Value	
			High pain	Moderate pain				
1	Place	Rural	n	2	25	20.455	< 0.0001	
			%	7.4%	92.6%			100.0%
		Urban	n	11	2			13
			%	84.6%	15.4%			100.0%
2	Marital status	No	n	2	4	0.002	1.00	
			%	33.3%	66.7%			100.0%
		Yes	n	11	23			34
			%	32.4%	67.6%			100.0%
3	Occupation	Agricultural	n	2	12	21.567	< 0.0001	
			%	14.3%	85.7%			100.0%
		Clerical	n	0	2			2
			%	0.0%	100.0%			100.0%
		Housewife	n	2	13			15
			%	13.3%	86.7%			100.0%
		Professional	n	6	0			6
			%	100.0%	0.0%			100.0%
Semi-Professional	n	3	0	3				
	%	100.0%	0.0%	100.0%				
4	Education	Diploma	n	2	0	22.607	< 0.0001	
			%	100.0%	0.0%			100.0%
		Graduate	n	9	2			11
			%	81.8%	18.2%			100.0%
		Primary	n	2	18			20
			%	10.0%	90.0%			100.0%
		Secondary	n	0	7			7
			%	0.0%	100.0%			100.0%
5	Diet	Mixed diet	n	9	25	2.147	0.075	
			%	26.5%	73.5%			100.0%
		Vegetarian	n	4	2			6
			%	66.7%	33.3%			100.0%
6	BMI category	Normal	n	7	6	4.274	0.118	
			%	53.8%	46.2%			100.0%

		Obese	n	2	11	13		
			%	15.4%	84.6%	100.0%		
		Overweight	n	4	10	14		
			%	28.6%	71.4%	100.0%		
7	Vitamin D category	Deficient	n	13	16	29	5.405	0.007
			%	44.8%	55.2%	100.0%		
		Normal	n	0	11	11		
			%	0.0%	100.0%	100.0%		

* Fischer exact test value

Table 3 elucidates the connection between various risk factors and the Pain score derived from the VAS pain scale. Our investigation revealed noteworthy findings: age demonstrated a negative correlation with the VAS score ($p = 0.032$), and similarly, Vitamin D levels exhibited a negative correlation with the VAS score ($p < 0.0001$). Both of these associations were statistically significant, characterized by p-values lower than 0.05.

Table 3: Correlation between risk factors and VAS score among the study participants (n=40)

		Age	Duration of illness	BMI	Vitamin D
VAS score	Pearson correlation test	- 0.340	0.080	0.057	- 0.846
	P - Value	0.032	0.622	0.725	< 0.0001
	N	40	40	40	40

DISCUSSION:

In our study, the mean age of the study participants was 39.43 years. Similar results were shown by a study done by Ghai et al., in 2015, in Chandigarh, among 328 patients, concluding that the mean age of the study participants was 43.8 years. [13] A similar result was shown by another study done by Mukesh Kumar et al., in 2020, in Karachi, Pakistan, among 1152 cases which states that the mean age was 41.76 years. [14] Thus individuals with age more than 40 years can be considered high risk for developing low back pain. In our study majority of the participants (67.5%) were residing in rural. About 37.5 percent of the study participants were housewives and about 35 percent were agricultural workers. About 35 percent were overweight and about 32.5 percent were obese. The prevalence of vitamin D deficiency among the study participants is 72.5 percent. A study done by Ghai et al., in 2015, in Chandigarh, among 328 patients, conclude that about 58 percent of women and 66 percent of men were diagnosed with hypovitaminosis D. [13] A study done by Lakkireddy et al., in Telangana, in 2019, among mechanical low backache patients of age 18 to 45 years found that the prevalence of hypovitaminosis is 96 percent which is much higher than our study. [15] This difference may be due to differences in the sampling technique and study design. Our study concludes that an individual's age and Vit-D level have a negative correlation with VAS score. Our study also states that individuals who were classified as vitamin D deficient have a statistically significant association with experiencing high pain with respect to the VAS score category. A clinical trial done by Ghai et al., in 2017, in Chandigarh, among 68 patients, with the aim of assessing the effect of Vit-D supplementation in improvement in the VAS score by the patients, had given evidence about the above discussion, that is apart from normalizing the levels, vitamin-D therapy in deficient CLBP patients may enhance pain severity and functional capacity. [16] Another study done by Brady et al., in 2019, to see if supplementing with vitamin D improves back pain symptoms in vitamin D deficient and overweight people, conclude that there were no significant changes in back pain severity or disability scores between the vitamin D and placebo groups (all $p > 0.05$). There was a substantially higher reduction in back pain disability scores in the vitamin D group compared to the placebo group in those with 25(OH)D concentrations 30 nmol/L at baseline ($n = 20$). [17] But in contrast to the above findings, a double-blinded randomized clinical trial, done by Sandoughi et al.,

in 2015, with the aim of describing the effect of Vit-D supplementation for chronic low backache against placebo therapy states that both vitamin D and placebo treatments improved CLBP, according to our findings, and there was no significant difference between the above two groups. [18] Thus, this discussion needs further research. The above discussion is also supported by a systematic review done by Zadro et al., in 2017, in England, with 29 cross-sectional study articles with the aim of assessing the association between Vit-D levels and low backache concludes that LBP is associated with vitamin D deficiency, with strong association seen in younger women and those with severe Vit-D deficiency. But their finding of association between Vit-D levels and pain intensity isn't clear. [19] Another study done by Wei Xu et al., in 2021, in China, with the aim of whether inflammatory indicators play a role in the link between vitamin D levels and pain outcomes concludes that non-specific LBP patients reported decreased vitamin D levels and increased levels of inflammatory markers. IL-6 may have a role in the link between hypovitaminosis D and Non-specific Chronic-LBP. [20] This discussion opens a new path for advanced research with various settings.

Strength and limitations:

All the records were verified by a single investigator and the same investigator had entered the data in excel which eliminated the interviewer bias. Also, this study had been completed with a fair sample size as per the calculated minimum sample requirement which substantiates the generalizability of the results. Yet this study is a cross-sectional study which has certain limitations. The associations found in the study needed not to be a causative factor due to lacking temporality. To confirm this evidence further research which better study designs were needed. In our study, convenient, non-probability sampling techniques were used. This may have a bias in the prevalence obtained from the results.

CONCLUSION AND RECOMMENDATIONS:

A robust association exists between Vitamin D deficiency and the occurrence of chronic low back pain within the female population of India. The average Vitamin D levels among females experiencing lower back pain appear notably diminished when contrasted with the general population. Correspondingly, the prevalence of Vitamin D deficiency among Indian females afflicted with chronic back pain is remarkably elevated. Among these females, those who possess a deficiency in Vitamin D, reside in urban areas, pursue professional occupations, and hold graduate degrees, while also spending substantial time indoors for work and daily activities, are identified as being at a high-risk for developing chronic low back pain. Consequently, the diligent surveillance and maintenance of optimal vitamin D blood levels have the potential to mitigate the likelihood of chronic low back pain occurrence among females.

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