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Is Vitamin D therapy being overstressed in patients of Low back pain with associated Vitamin D Hypovitaminosis? - A prospective comparative study.

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BACKGROUND: Back pain is the common complaints found in orthopedic clinics . More than 90% of patients complaining of LBP have nonspecific LBP. Growing evidence suggests an association of–Vitamin-D deficiency with chronic musculoskeletal pain including low back pain (LBP). Evidence on the efficacy of vitamin-D supplementation in symptom improvement in chronic pain including CLBP is conflicting. The present study is performed with an aim to assess the efficacy and safety of vitamin-D3 supplementation in improving pain in CLBP Patients having below normal vitamin-D levels.
MATERIAL & METHODS: This prospective randomized study was conducted in two Tertiary level hospitals in South Bengal from April 2018 to March 2019. Patients of either gender, aged 18 – 75 years with CLBP for ≥ 3 months, without leg pain with any specific cause, having low plasma 25-Hydroxyvitamin D3 levels (< 30 ng/mL) were eligible for study recruitment. Voluntary patients were randomly assigned to receive a vitamin D dosage of 60 000 IU or placebo (vitamin), which was administered orally every day for 10 days. The subjects were blinded for intervention. Patient characteristics and outcome measures were collected at baseline, 2 and 6 months post supplementation.
RESULT: 55 CLBP patients were included in the final analysis (27 in Vitamin supplementation group and 28 in placebo group). . Improvement of Vitamin D level was observed in both groups, 53.48 ng/dL in Vitamin supplementation group and 32.1 in placebo group (p value >0.1, not significant). Reduction in pain score was observed post supplementation. Mean VAS scores were 3 and 2.1 at 2, 6 months, respectively for Vitamin supplementation group, as compared to 2.91 and 2.14 for placebo group (P > 0.975, insignificant).
DISCUSSION: Our study could not justify the role of therapeutic medication (Vitamin D supplementation) to achieve normal Vitamin-D levels in patients with musculoskeletal pain. Though it is important to screen vitamin-D status of at risk populations, it is more advisable to get adequate sunlight exposure as well as dietary supplementation along with physical exercise and postural care and lifestyle modification to mitigate the morbidity associated with abnormal vitamin-D homeostasis.

Keywords: *Vitamin D, Chronic Low Back Pain (CLBP)*

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Back pain is the common complaints found in orthopedic clinics[1] .There are three diagnostic categories for LBP which include radiculopathy, specific LBP and nonspecific LBP. Nonspecific LBP is defined as symptoms without clear specific cause, for example, infection, malignancy, spondyloarthritis, spinal stenosis and fracture. More than 90% of patients complaining of LBP have nonspecific LBP.[5] Known associated factors with LBP are increased age, female sex, high body mass index, smoking, psychological factors and strenuous physical activity.[6] Growing evidence suggests an association of–Vitamin-D deficiency with chronic musculoskeletal pain including low back pain (LBP) . A high prevalence of vitamin-D deficiency has been reported in patients with CLBP in comparison to the general population [1, 4]. The mechanisms underlying these associations remain unclear . Vitamin D plays an important role in the immune system.[11–13] Regulation of inflammatory cytokines by vitamin D may be correlated with chronic pain conditions. However, there are

conflicting data about the association of low levels of vitamin D and CLBP.. The prevalence of vitamin-D deficiency is found to be 50% – 90% on the Indian subcontinent and is attributed to low dietary intake, skin color and changing lifestyle despite the availability of ample sunlight[8]. Evidence on the efficacy of vitamin-D supplementation in symptom improvement in chronic pain including CLBP is conflicting. The present study is performed with an aim to assess the efficacy and safety of vitamin-D3 supplementation in improving pain in CLBP Patients having below normal vitamin-D levels.

I. Methods

This prospective randomized study was conducted in two Tertiary level hospitals in South Bengal-1) 0rthopaedic clinic of Calcutta National Medical College & hospital, Kolkata and 2) Gynecology department of COM & JNM Hospital (after approval from the Institute ethics committee). Patients were recruited from April 2018 to March 2019. The study was conducted in eastern India (south Bengal) which has a humid subtropical climate that is mild with dry winters, hot humid summers, and moderate seasonality.

Inclusion Criteria

Patients of either gender, aged 18 – 75 years with CLBP for ≥ 3 months, without leg pain with no specific cause, having low plasma 25-Hydroxyvitamin D3 levels (< 30 ng/mL) were eligible for study recruitment. The diagnosis of CLBP was established based on signs and symptoms and investigations like magnetic resonance imaging.

Exclusion Criteria

Patients were excluded if they had evidence of other causes of neuropathy or painful conditions like diabetes mellitus, rheumatoid arthritis, and symptomatic osteoarthritis of the hip, knee, and ankle. Patients diagnosed with epilepsy, psychiatric diseases, and substance abuse, metabolic bone disease (hypo- or hyperparathyroidism), chronic renal disease, and 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 consuming drugs altering bone metabolism like corticosteroids or bisphosphonates, pregnant and lactating mothers, and women intending to be pregnant were also excluded. Patients taking

Vitamin-D supplements during the past 3 months were also excluded from the present study.

Measurement of fasting Plasma Vitamin-D Levels [25-Hydroxyvitamin D (25(OH) D3)] for each patient done twice in the study- one baseline after enrollment in study and second one two months after therapy.

Definition of Vitamin-D Levels

According to the level of 25(OH) D3, vitamin-D 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 > 29 ng/mL.We took the cut off level of <29 ng/Ml as Hypovitaminosis D in our study.

Study Procedure: After recording the medical history and systemic physical examination, laboratory and radiological investigations including fasting plasma 25(OH) D3 levels were performed to categorize diagnoses. Age, gender, education, substance abuse status, BMI were assessed for each patient. . Voluntary patients were randomly assigned to receive a vitamin D dosage of 60 000 IU or placebo (vitamin), which was administered orally every day for 10 days. The subjects were blinded for intervention. The patients were advised to home-exercise and were given prescriptions of NSAID (Ibuprofen 400 mg tds for 7 days and then sos) . They were instructed to record the usage of ibuprofen after 7 days from the first visit to upto 1 month.

Study endpoints included plasma 25(OH) D3 levels after completion of 8 weeks of therapy, change in pain score from baseline as measured by VAS at 2 months and 6 months post therapy. Patient characteristics and outcome measures were collected at baseline, 2 and 6 months post supplementation.

Statistical analysis of differences among the two groups was compared by chi-square tests. A level of $P < 0.05$ was considered as statisticall1y significant.

II. Results

A total of 70 eligible patients were screened for study participation and randomized in two groups. 15 patients lost to follow up. Hence, 55 CLBP patients were included in the final analysis (27 in Vitamin supplementation group and 28 in placebo group). Substance abuse was observed in 12 (21.8%) patients. The mean age of patients was 53.6 (range 36 – 71 years) with 20 (40%) being men. The mean BMI of study patients was 20.9. Prior to inclusion into this study the participants' mean duration of CLBP was 10.6 (6-15) months and mean VAS was found to be 8.5 (8.51 in Vitamin D supplementation group and 8.46 in placebo group) indicating majority had severe pain at study inclusion. Baseline mean vitamin-D levels were found to be 19.55 and 20.37 ng/mL in two groups respectively. Improvement of Vitamin D level was observed in both groups, 53.48 ng/dL in Vitamin supplementation group and 32.1 in placebo group (p value >0.1, not significant).

Reduction in pain score was observed post supplementation. Mean VAS scores were 3 and 2.1 at 2, 6 months, respectively for Vitamin supplementation group, as compared to 2.91 and 2.14 for placebo group ($P > 0.975$, insignificant).

According to patients' records during the study, 29.6% (8/27) and 35.7% (10/28) of patients used ibuprofen (200 mg) daily or for more than 5 days per week, in the drug and placebo groups, respectively. There was no statistically significant difference between the two groups in analgesic usage also.

III. Discussion

There is a controversy regarding the correlation of hypovitaminosis D with LBP and the role of vitamin D in improvement of LBP. Both hypovitaminosis D and LBP are growing health problems. In addition, there is some evidence indicating that the supplementation of vitamin D is safe and valuable.[31, 36]

Vitamin-D plays a key role in the etiology and progression of various chronic pain conditions by exerting anatomic, hormonal, neurological, and immunological influences on pain expression.Vitamin-D deficiency causes muscle weakness and pain in adults as well as children. Vitamin D has also exhibited immunomodulatory actions [11, 12, 13] . Improvement in bone density and musculoskeletal symptoms are associated with vitamin-D supplementation. Its supplementation could reduce the synthesis of inflammatory cytokines and increase the anti-inflammatory cytokines. Vitamin-D deficiency can affect patients of all ages and might be an underlying factor in undiagnosed musculoskeletal pain. It is a potentially treatable problem and supplementation can be an adjuvant therapy for musculoskeletal pain. Results showed that all of patients achieved normalization of vitamin-D levels after supplementation.

Dietary history was not recorded since dietary intake of vitamin D without supplementation is a minor source of the body's requirement of vitamin D.[34,35] The major source of vitamin D is cutaneous synthesis upon exposure to ultraviolet light,36 and the duration of sun exposure is more important than the size of sun contact area (Holick et al [13]). The present study was conducted all round the year to mitigate the effect of sun exposure.

Obesity has also been linked with vitamin-D deficiency in both adults and children in many studies [27-30]. This is due to vitamin- D stores entrapped in adipose tissue. Contrary to that most of our patients are within normal range of BMI.

We excluded patients suffering with chronic diseases like epilepsy, psychiatric illness, and chronic inflammatory conditions as these patients must be taking anticonvulsants or corticosteroids as these drugs increase the catabolism of vitamin-D [26,31] and are likely to be at higher risk of developing hypovitaminosis .

In this prospective trial we assessed the efficacy of vitamin-D supplementation in deficient patients having CLBP. The results of the present study show an improvement in CLBP, both in the placebo and vitamin D3 groups, and no statistically significant difference between the two groups was observed. There was no significant difference in the use of ibuprofen among the two groups.

Our finding is in concordance with the results of two studies that were performed on post-menopausal women with back pain; no significant difference was seen between placebo and vitamin D in improving back pain.[20, 21]

Warner [22] and coworkers showed, in comparison to placebo, ergocalciferol 200000mIU/month for 3 months did not significantly decrease VAS score of musculoskeletal pain in a study involving 50 women with mean age of 56 years. The mean age of patients in our study was 53.6. However, two recent meta-analyses by Straube [29, 30] revealed contrasting outcomes between results of randomized clinical trials (RCTs) and other study designs. The effectiveness of vitamin D for chronic pain treatment was observed in 10% and 95% of RCTs and non-RCT or observational studies, respectively, although the meta-analyses were conducted on small and non-homogenous studies. However, a good number of studies [23, 26] showed a good effect of vitamin D3 in alleviating chronic pain including CLBP.

Altogether, there is a need for more investigation to establish the effect of vitamin D on chronic pain. Studies with randomized controlled trial designs, longer duration, bigger sample size, different outcome assessment and different age groups are recommended.

IV. Conclusion

Our study could not justify the role of therapeutic medication (Vitamin D supplementation) to achieve normal Vitamin-D levels in patients with musculoskeletal pain. Though it is important to screen vitamin-D status of at risk populations, it is more advisable to get adequate sunlight exposure as well as dietary supplementation along with physical exercise and postural care and lifestyle modification to mitigate the morbidity associated with abnormal vitamin-D homeostasis.

CONFLICT OF INTEREST: The authors revealed no conflict of interest.

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	Pre intervention VAS score (mean)	Post intervention VAS score at 2 month (mean)	Post intervention VAS score at 2 month (mean)	P value
Vitamin D group	8.5	3	2.11	Not significant In between 0.975 – 0.99
Placebo group	8.46	2.92	2.14	Inference: Vitamin D Therapy has got no benefit over placebo therapy in LBP treatment

TABLE 1: changes of VAS score from baseline to post intervention in both groups.

	Baseline Vitamin D3 level in blood (mean)	Post intervention Vitamin D3 level in blood (mean)	P- Value
Vitamin D Group	19.5	53.48	P- value not significant In between 0.1- 0.25
Placebo Group	20.37	32.1	Inference: though Vitamin D therapy increased blood levels more than placebo group, this is also statistically insignificant.

TABLE 2: changes of Vitamin D3 level in blood from baseline to post intervention in both groups.

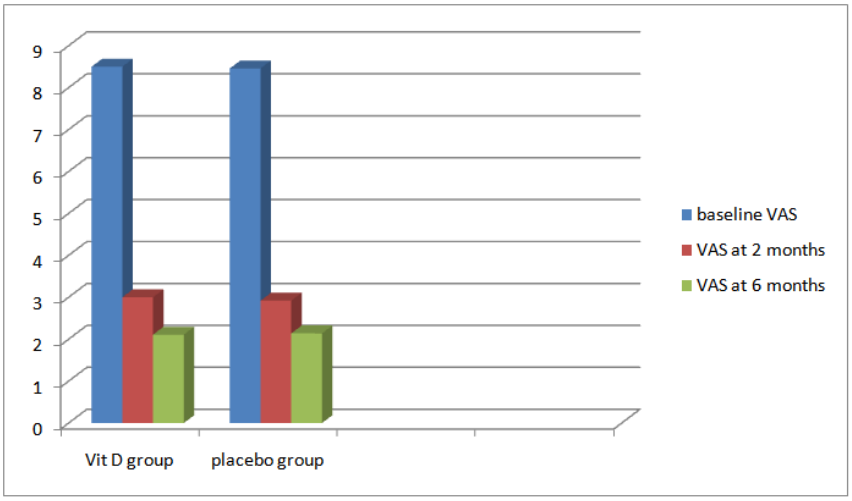

DIAGRAM 1: bar diagram showing changes of VAS score from baseline to post intervention at 2 and 6 months in both groups.

MASTER CHART:

serial no	sex	age	BMI	Substance abuse	duration of LBP in month	Pre study VAS score	Baseline vit D3	therapy given	vitamin D3 at 2m	VAS at 2m	VAS at 6m	Analgesic use in 1st mon
1	m	42	23.2	no	6	9	25	vit D supplement	55	4	2	regular
2	f	45	20	no	8	8	23	Vit D supplement	59	3	2	infrequent
3	F	60	24	Yes	11	9	17	vit D supplement	50	4	3	regular
4	F	55	19.6	no	7	8	22	vit D supplement	61	3	2	infrequent
5	m	62	22.1	yes	12	9	19	vit D supplement	58	4	2	infrequent
6	m	50	20	no	6	9	24	vit D supplement	60	4	3	regular
7	f	42	18.8	no	9	8	16	vit D supplement	51	3	2	infrequent
8	f	44	21	no	7	9	15	vit D supplement	49	3	3	infrequent
9	f	65	25	no	15	9	14	vit D supplement	53	4	2	regular
10	f	56	18.7	no	12	8	19	vit D supplement	52	3	1	infrequent
11	m	66	21.8	no	11	9	16	vit D supplement	59	3	2	infrequent
12	m	54	23.9	Yes	15	8	23	vit D supplement	62	3	1	infrequent
13	m	59	19.7	no	8	9	26	vit D supplement	58	2	2	infrequent
14	f	41	18.4	no	11	9	14	vit D supplement	48	3	2	regular
15	f	39	19.4	no	10	8	19	vit D supplement	49	2	2	infrequent
16	f	43	19.8	no	8	8	17	vit D supplement	54	3	1	infrequent
17	f	58	20.1	no	10	9	22	vit D supplement	59	4	2	regular
18	f	70	23.3	no	5	8	18	vit D supplement	45	3	3	infrequent
19	f	37	17.8	no	11	8	15	vit D supplement	51	2	3	infrequent

20	m	65	20.2	Yes	13	9	21	vit D supplement	52	3	2	infrequent
21	m	55	23.4	no	12	8	22	vit D supplement	55	2	2	infrequent
22	f	43	19.5	no	10	8	24	vit D supplement	53	2	1	infrequent
23	m	53	20	Yes	9	9	20	vit D supplement	55	3	2	regular
24	f	55	19.6	no	14	9	16	vit D supplement	50	3	3	infrequent
25	f	36	20.5	no	12	8	17	vit D supplement	48	3	2	infrequent
26	m	57	18.7	Yes	11	8	25	vit D supplement	53	2	2	regular
27	f	50	24.1	no	6	9	19	vit D supplement	45	3	3	infrequent

1	F	55	19.6	no	13	9	23	placebo	34	4	2	regular
2	f	59	20.6	no	8	8	21	placebo	32	3	3	infrequent
3	f	46	21.5	yes	9	9	17	placebo	29	4	2	regular
4	m	50	20	no	6	8	22	placebo	31	2	3	infrequent
5	m	63	23.1	yes	10	8	19	placebo	30.5	3	2	infrequent
6	f	43	17.9	no	11	9	17	placebo	29	3	3	infrequent
7	f	62	23	no	7	7	23	placebo	33	2	2	infrequent
8	f	66	19.3	no	12	9	16	placebo	31	3	2	regular
9	f	53	22.5	no	10	8	20.5	placebo	34	2	2	infrequent
10	m	62	25.2	yes	8	8	19	placebo	32	3	2	infrequent
11	m	71	20.2	no	14	8	24	placebo	31	2	1	infrequent
12	f	57	21.3	no	9	9	17	placebo	31.5	3	2	regular
13	f	55	21.8	no	10	8	18	placebo	32	2	3	infrequent
14	f	59	22	no	11	8	25	placebo	35	2	1	infrequent
15	f	58	23	no	6	9	21	placebo	33	2	2	infrequent
16	m	49	19	yes	13	8	22	placebo	34	3	2	infrequent
17	m	63	23.7	no	10	9	19	placebo	30	4	2	regular
18	m	61	18.8	no	9	8	17	placebo	31	3	3	regular
19	f	37	17.9	no	13	9	22	placebo	32	4	3	regular
20	f	44	19.7	no	8	8	19	placebo	31	3	2	infrequent
21	f	49	21.6	no	12	9	26	placebo	33	3	2	infrequent
22	f	48	22.1	no	6	9	17	placebo	27	4	2	regular
23	f	61	19.1	no	12	8	24	placebo	36	2	2	regular
24	f	58	24.6	no	11	9	20	placebo	33	3	1	infrequent
25	m	60	21.6	yes	14	9	22	placebo	35	3	2	regular
26	m	58	19.9	yes	10	8	18	placebo	31	3	2	infrequent
27	f	46	18.9	no	15	9	23	placebo	36	3	3	infrequent
28	m	54	20.2	no	13	9	19	placebo	32	4	2	regular

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