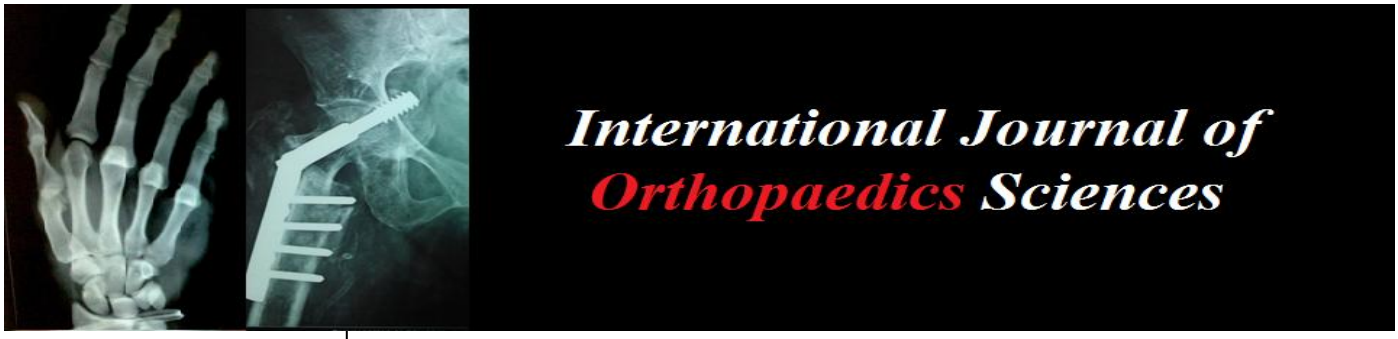

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Dr. Ravikant Jain
Professor and Head of department, Department of Orthopedics, Sri Aurobindo Medical College & PG Institute, Indore, Madhya Pradesh, India

Dr. Rajeev Shukla
Associate Professor, Department of Orthopedics, Sri Aurobindo Medical College & PG Institute, Indore, Madhya Pradesh, India

Dr. Mohammad Danish
Junior Resident, department of Orthopedics, Sri Aurobindo Medical College & PG Institute, Indore, Madhya Pradesh, India

Dr. Ajay Varun
Junior Resident, department of Orthopedics, Sri Aurobindo Medical College & PG Institute, Indore, Madhya Pradesh, India

Dr. Tanveer Sheikh
Junior Resident, department of Orthopedics, Sri Aurobindo Medical College & PG Institute, Indore, Madhya Pradesh, India

Correspondence
Dr. Rajeev Shukla
Associate Professor, Department of Orthopedics, Sri Aurobindo Medical College & PG Institute, Indore, Madhya Pradesh, India

Outcome analysis of vitamin-D supplementation in patients with fibromyalgia

Dr. Ravikant Jain, Dr. Rajeev Shukla, Dr. Mohammad Danish, Dr. Ajay Varun and Dr. Tanveer Sheikh

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Abstract
Objective: To investigate the vitamin D level and score the pain of fibromyalgia (FM) using VAS scoring at pre- planned intervals.
Materials and Methods: 50 patients presenting with FM, treated with vitamin D supplementations were prospectively followed for average duration of 6 months and correlation was also calculated between vitamin D and VAS score.
Result: There were 60% female and 40% male and the average age of the patients with FM was 45.066±17.7 female and 43.30.±18.1 male. The mean pain VAS score decreased at intervals (day 1, 3 months and 6 month) in both age and gender group. A significant reduction in pain intensity was observed after each months of vitamin D therapy with $p < 0.001$. Low Vitamin D level was significantly correlated with VAS on Day 1 and 03 months intervals (r=0.23 p=0.876, r=0.18 p=0.903, r=0.268 p=0.59 and r=0.172 p=0.234, r=0.267 p=0.61, r=0.413, p=0.003) but negative correlated was found on high Vitamin D level after 06 month with VAS score (r=-0.058 p=0.691 and r=-0.070 p=0.630 in respectively)
Conclusion: In conclusion, our study confirmed low vitamin D level was significantly correlated with VAS score on Day 1 and 03 months intervals and then negative correlation was found on high vitamin D level after 06 month with VAS. Furthermore, vitamin D was closely related with pain and disease severity.

Keywords: fibromyalgia, vitamin D, pain

Introduction
Fibromyalgia syndrome (FMS) is non-inflammatory diseases with widespread musculoskeletal (MSK) distributions, the cause of which is not fully understood [1]. It is a complex syndrome accompanied by many systemic disorders and is observed in all ages, genders, and races. It is ten times more frequent in women [2]. Its prevalence increases with age but is most usually seen between the ages of 20 and 55 years [3]. Though symptoms regarding many systems may be observed, the most disturbing symptom is widespread pain. This is an important issue not only for the patient but also for the treating doctor. Unfortunately, there is no known effective therapy of FMS. It is not a life-threatening disease; but, it could lead to serious health expenses owing to the difficulties encountered in its therapy [4]. The symptoms of FMS are similar to symptoms observed in vitamin D deficiency. Recently, researchers have been curious about this issue and have conducted a number of studies [5- 9]. While there were factors that can cause confusion such as methodological differences and heterogeneous patient populations in these studies, vitamin D deficiency was reported in a considerable proportion of patients with FMS in almost every study. Despite this fact, the relationship between FMS and serum vitamin D levels is controversial. Patient's pain can be reduced, thus the quality of life can be improved with an inexpensive therapeutic method such as vitamin D replacement. In a placebo-controlled study carried out on this topic, vitamin D replacement was found to be ineffective [9]. However, the number of patients was insufficient in this study. Additionally, all of the participants did not continue with the above mentioned study. In this prospective study, the aim was to assess the effect of vitamin D levels on clinical symptoms and disease associated pain scores in patients with FMS who were observed to have vitamin D deficiency.

Material and Method

Patient Selection

This study was conducted in the department of Orthopedics, Sri Aurobindo Medical College And Post Graduate Institute, Indore, Madhya Pradesh. Ethical approval for the study was obtained from the Ethics Committee of our Institute. Written informed consent was obtained from all study participants prior to the study. Inclusion criteria, according to revised American College of Rheumatology (ACR) preliminary diagnostic criteria [10], patients were diagnosed as primary FMS and asked to to participate in this study. Age above 18 years and both gender (male and female) were enrolled for this study. Exclusion criteria were chronic inflammatory disorders, hypertension, hypercholesterolemia, or diabetes, to be undergoing anti-coagulant therapy, or being predisposed to thrombotic or bleeding disorders and calcium metabolic disorders.

Procedure Planed

The study is a consecutive prospective study. Consent was obtained from all subjects who participated in the study. Total fifty consecutive male and pre-menopausal female patients above 18 years with FMS were recruited. The demographic characteristics of all subjects were divided in groups according to the gender and age. Examination of vitamin D level and scoring of pain was done using visual analog scale (VAS) scoring system at pre planed interval on day 1, 3 months and 6 month and correlation was calculated between vitamin D and VAS score.

Statistical Analyses

The Statistical Package for Social Sciences (SPSS 20, SPSS Inc, Chicago, IL) was used for all statistical analyses. The differences among cases and controls were determined by independent samples t test. Values <0.05 were considered to be statistically significant. Person's correlation test was used to illustrate the relationship between variables.

Results

In the study, all the patients were divided in groups according to the gender and age. Out of 50 patients there were 60% female and 40% male and the average age of the patients with FM was 45.066±17.7 and 43.30.±18.1 years in females and males respectively. According to the gender, vitamin D level in male and female, on the first day was 24.97±5.22 and 22.34±8.60 respectively and vas score was 6.30±0.80 and 6.63±1.12 respectively. After 03 months vitamin D level was 36.16±3.60 in males and 22.34±8.60 in females and vas score was 3.50±0.94 and 3.76±1.35 in males and females respectively. At 06 month vitamin D level was 47.34±5.85 in males and 50.63±10.72 in females and vas score was 0.95±0.68 and 1.03±1.27 in males and females respectively (Table 1) ($p < 0.05$).

According to the ages, 03 groups were divided (18-50, 50-70 and >70). On first day, vitamin D level was (21.72±7.37, 25.79±7.18 and 28.15±6.72 respectively) and vas score was (6.40±1.40, 6.85±0.94 and 6.0±0.81 respectively). After 03 month vitamin D level was (34.45±35.43±6.30and 38.2±4.6) and vas score was (3.5±1.19, 4.07±1.32 and 3.5±0.577) and after 06 months vitamin D level was (48.29±8.33, 35.43.43±6.30 and 49.37±4.5) and vas score was (0.09±0.85, 1.21±1.32 and 1.0±0.81) respectively (Table 2) ($p < 0.05$). Following vitamin D supplementation, the mean pain VAS score decreased at intervals (day 1, 3 months and 6 month) in both age and gender group. A significant reduction in pain intensity was observed after each months of vitamin D therapy $p < 0.001$.

Low Vitamin D level was significantly correlated with VAS in 1 Day and 03 months intervals (r=0.23 p=0.876, r=0.18 p=0.903, r=0.268 p=0.59 and r=0.172 p=0.234, r=0.267 p=0.61, r=0.413, p=0.003) but negative correlated was found on high Vitamin D level after 06 month with VAS score (r=-0.058 p=0.691 and r=-0.070 p=0.630 in respectively) (Table 3).

Table 1: Vitamin D level and pain score of patient using VAS scoring at intervals according to Gender

	Male	Female
Vitamin D Level: Normal level: 20 ng/ml-50ng/ml		
Day1 ng/ml	24.97±5.22	22.34±8.60
3 month ng/ml	36.16±3.60	35.21±7.12
6 month ng/ml	47.34±5.85	50.63±10.72
P vale	$p < 0.05$	$p < 0.05$
Vas Score : For Pain 0-10		
Day1	6.30±0.80	6.63±1.12
3 month	3.50±0.94	3.76±1.35
6 month	0.95±0.68	1.03±1.27
P vale	$p < 0.05$	$p < 0.05$

Δ difference Mean ± SD, A paired Student's t test was used for statistical analysis. $P < 0.05$.

Table 2: Vitamin D level and pain score of patient using VAS scoring at intervals according to Age

	18-50	50-70	>70
Vitamin D Level: Normal level: 20 ng/ml-50ng/ml			
Day1 ng/ml	21.75±7.37	25.79±7.18	28.15±6.72
3 month ng/ml	34.45±5.76	35.43±6.30	38.2±4.6
6 month ng/ml	48.29±8.33	51.64±11.73	49.37±4.5
P vale	$p < 0.05$	$p < 0.05$	$p < 0.05$
Vas Score : For Pain 0-10			
Day1	6.40±10.4	6.85±0.94	6.0±0.81
3 month	3.50±1.19	4.07±1.32	3.5±0.57
6 month	0.09±0.85	1.21±1.5	1.0±0.81
P vale	$p < 0.05$	$p < 0.05$	$p < 0.05$

Δ difference Mean±SD, A paired Student's t test was used for statistical analysis. $p< 0.05$.

Table 3: Correlation between Vitamin D levels and VAS score at intervals in patients with fibromyalgia

	Vit. 1Day	Vit. 03 Month	Vit. 06 Month
VAS 1Day	0.23 p=0.876	0.18 p=0.903	0.268 p =0.59
VAS 03 Month	0.172 p =0.234	0.267 p =0.61	0.413** p=0.003
VAS 06 Month	-0.058 p =0.691	-0.070 p =0.630	0.235 p=0.100

**. Correlation is significant at 0.01 level

Discussion

FM is a common condition characterized by long-term, generalized bodyache and pain in joints, muscles, tendons, and other soft tissues. It is a chronic disorder that is difficult to treat. Recently Vitamin D has shown promising impact in the treatment of this disorder. In this study we assessed whether supplementation of a high dose of vitamin D provide beneficial analgesic effects in patients with FM. We have demonstrated that patients treated with vitamin D supplementation had a significant reduction in VAS score at regular follow-up. It is not clear whether low level of vitamin

D contributes to FMS symptoms as a cause or whether it is a result of this clinical condition [11, 12]. According to the first claim, vitamin D receptors are found in neurons and glial cells, in the brain, and vitamin D acts as other neuropeptides. In the second claim, patients with FMS are less exposed to sunlight due to their reduced functional capacity [13, 14]. Low levels of vitamin D have been shown more often in FMS than in other rheumatological diseases. Plotnikoff *et al*. [15] have reported that 89% of subjects with generalized muscle pain were deficient in vitamin D. Olama *et al*. [16] has suggested that FMS patients with low level of Vitamin D were more likely to had impairment in memory, confusion, mood disturbance, sleep disturbance and restless leg syndrome.

VAS scale measures the severity of pain. The scale is adapted to Turkish norms and is used in numerous studies measuring pain [17]. Wepner *et al*. [18] investigated the effect of vitamin D on patients with FM using a VAS scoring system. A marked reduction in pain intensity was noted during the treatment period. Wehby *et al*. [19] used VAS to measure health-related quality of life in patients with oral clefts. Dhanani *et al*. [20] used VAS to determine the difference in pain associated with changes in quality of life in patients with rheumatic disease. We concluded that the VAS can be accepted as a valid and reliable method of assessing pain.

In a conclusion, vitamin D deficiency should be kept in mind in treating with FMS pain. There is a necessity for both education of health professional and the general public concerning the optimization of vitamin D status in the management of such patients. We want to say that an early prevention should be considered in FMS patients in terms of osteoporosis and hence pain severity. These results have led to a new understanding of the treatment in FMS, Significant reduction in pain intensity was observed after each months of vitamin D therapy. Low Vitamin D level was significantly correlated with VAS on 1 Day and 03 months intervals, then negative correlation was found with high Vitamin D level after 06 month .

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Informed Consent: Written informed consent was obtained from patients who participated in this study.

Ethical Approval: The study was approved by the Institutional Ethics Committee

Conflict of Interest: No conflict of interest was declared by the authors.

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