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A CASE CONTROL STUDY OF CORRELATION OF VITAMIN D LEVEL WITH SEVERITY OF OSTEOPOROSIS AND EVALUATION OF EffECT OF VITAMIN D SUPPLEMENTATION IN TREATMENT OF OSTEOPOROSIS IN ELDERLY

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Abstract:

Background: Osteoporosis poses a significant public health concern globally, particularly among aging populations. Vitamin D deficiency has been implicated as a contributing factor to bone mineral density (BMD) loss and osteoporotic fractures, although the efficacy of vitamin D supplementation remains debated. This study aimed to investigate the association between vitamin D status and BMD in elderly individuals with osteoporosis, as well as the impact of vitamin D supplementation on treatment outcomes.

Methods: A case-control study was conducted among elderly patients diagnosed with primary osteoporosis, assessing vitamin D levels, dietary intake, sun exposure, and BMD using Dual Energy X-ray Absorptiometry (DEXA). Patients were randomly assigned to receive either standard osteoporosis treatment alone or with additional vitamin D supplementation. Changes in BMD and vitamin D levels were monitored over 12 months.

Results: The study found no significant differences in baseline T-scores or vitamin D levels between the supplemented and control groups. However, after 12 months, the supplemented group showed significantly higher vitamin D levels compared to the control group ($p < 0.001$). While there was no significant difference in T-scores between the groups at 12 months ($p = 0.199$), qualitative analysis revealed a notable reduction in osteoporotic BMD status in the supplemented group compared to controls (5% vs. 35%).

Conclusion: Vitamin D supplementation demonstrated a positive impact on vitamin D levels and qualitative improvement in BMD status among elderly individuals with osteoporosis. Although no significant difference in T-scores was observed between groups at 12 months, the study highlights the potential benefits of vitamin D supplementation in accelerating the therapeutic process and improving bone health in this population. Further research with larger

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sample sizes and longer follow-up periods is warranted to confirm these findings and assess long-term treatment outcomes.

Keywords: Osteoporosis, Vitamin D deficiency, Bone mineral density (BMD), Elderly individuals, Vitamin D supplementation

INTRODUCTION

Osteoporosis is a systemic illness that is defined by the degeneration of bone tissue's microarchitecture and the presence of low bone mass [1]. Osteoporosis is a significant public health issue that affects countries around the world, particularly those that are still developing. The global prevalence of osteoporosis has been reported to be 18.3% [2]. Estimates in Iran indicate that approximately 17% of the general population aged 30 and above have osteoporosis, whereas around 35% experience osteopenia [3]. Early identification of bone fragility fractures is crucial, as it is a significant contributing factor. By identifying these fractures early, many of them can be averted [4]. Various factors, including deficiencies in calcium and/or vitamin D, lack of exercise (sedentary lifestyle), particularly weight-bearing exercise, alcohol abuse, smoking, genetic factors, and environmental and hormonal factors, can impact bone mineral density (BMD) [5, 6].

The impact of biomarkers on the likelihood of fractures has been recorded in certain prior investigations, although the connection between serum 25(OH)D levels, dietary consumption, and sun exposure with bone mineral density (BMD) is still a subject of debate [7, 8]. While some research have demonstrated a favorable correlation between low levels of vitamin D in the blood and low bone mineral density (BMD), other studies have not established a meaningful link between these two factors.

In certain countries, including the UK, vitamin D and/or calcium supplements were once the primary therapy option for preventing and managing fractures in older individuals [14]. Nevertheless, the Randomised Evaluation of Calcium Or vitamin D (RECORD) experiment raised doubts about the significance of vitamin D. It seems that relying alone on this technique may not be enough to prevent more fractures in the elderly who are considered to be in good health [15]. Several other randomized controlled trials also failed to demonstrate a benefit in reducing fractures with the use of vitamin D supplementation [16, 17]. Nevertheless, a comprehensive analysis of randomized controlled studies suggested that a daily intake of 20 µg (800 IU) of vitamin D is required to show any benefit [18].

However, there is a clear association between low levels of vitamin D and an increased likelihood of experiencing bone loss, bone turnover, and other illnesses related to the bones [19]. However, the diet appears to lessen the impact of seasonal changes in vitamin D levels in regions with a northern latitude, where the sunshine quality for vitamin D synthesis declines [19]. Hence, it would be prudent and beneficial to take into account all the variables associated with vitamin D status, such as sunlight exposure, dietary intake (with or without supplementation), and serum vitamin D levels, in order to evaluate its impact on bone health and potentially other vitamin-related ailments. This study aims to assess the association and correlation between vitamin D status, including serum levels, dietary intakes, and sun exposure, with bone mineral density (BMD).

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

MATERIAL AND METHODS-

This case-control study was conducted at the Department of Orthopaedics in a tertiary care center in central India. The objective was to determine the correlation between the severity of osteoporosis and vitamin D levels in elderly patients presenting with generalized body pain. Additionally, the study aimed to assess the impact of vitamin D supplementation on the treatment of osteoporosis. The study included individuals as case who met the following criteria: (1) diagnosed with primary osteoporosis, (2) aged over 60 years, of both sexes, and (3) had vitamin D levels below 20ng/mL and controlled were also matched but they were not taking vitamin D supplementation. The study eliminated patients with secondary osteoporosis, malignancies, secondary infection, and those who were hesitant to follow-up and participate. A comprehensive medical history, including detailed information about past and current fractures, was obtained, and a complete examination was conducted. The patients' food patterns, duration of sun exposure, and milk intake were assessed using the dietary recall approach. The examinations conducted included standard hemogram, serum blood sugar, liver and renal function tests, serum vitamin D levels, and measurement of Bone Mineral Density (BMD) using Dual Energy X-ray Absorptiometry (DEXA). An assessment of bone mineral density (BMD) was conducted for the hip region, specifically including the trochanter, femoral neck, and intertrochanteric areas, as well as for the lumbar spine (Lumbar vertebrae L1-L5). T-scores were acquired. The DEXA machine was programmed with software that incorporated the Asian reference values for T and Z scores. Every patient was treated in accordance with the established treatment procedure for osteoporosis. The patients were all instructed to both get sufficient sun exposure and consume meals that are high in calcium and vitamin D. Patients with vitamin D levels below 20 ng/ml were assigned randomly to one of two groups. The first group, consisting of 40 individuals, received the standard treatment for osteoporosis, which included a monthly dose of 150mg of ibandronic acid for 6 months, along with a tablet containing 500mg of calcium supplementation. Additionally, these patients were given a weekly oral nanosolution containing 60,000 IU of vitamin D for 6 months. The second group consisted of 40 patients and served as the control group. No additional Vitamin D supplementation was provided to this group, while the rest of the anti-osteoporotic treatment remained the same as in group I.Both groups of patients were monitored at 3 months, 6 months, and 1 year, during which their bone mineral density (BMD) and serum vitamin D levels were assessed at each visit.Patients with blood vitamin D levels below 10ng/ml were classified as having vitamin D deficiency, patients with serum vitamin D levels between 10-20 ng/ml were classified as having vitamin D insufficiency, and patients with serum vitamin D levels over 20ng/ml were classified as having normal vitamin D levels. The BMD was assessed based on the T scores and utilized for the assessment of osteoporosis. Patients with T scores below -1 were considered to have normal bone density, patients with T scores between -1 and -2.5 were diagnosed with osteopenia, and patients with T scores over -2.5 were classified as having osteoporosis.The data was evaluated using web-based freeware. The chi-square test was used to compare the proportional data, whereas the Student "t"-test was used to examine mean differences. Paired 't'-tests were used to analyze changes within the group. The study maintained a confidence level of 95%, hence a "p" value below 0.05 was deemed statistically significant..

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

Table 1 Distribution of age gender and history of fractures	
Characteristics	**Description**
Age Distribution	
	Age Range: 60 to 78 years
	Most Common Age Group: 66-70 years (41.3%)
Gender Distribution	
	Female Patients: 63.7%
	Male Patients: 36.3%
	Female to Male Ratio: 1.75:1
History of Fractures	
	Group I Patients with History of Fractures: 10%
	Group II Patients with History of Fractures: 12.5%

World Health Organization (WHO) criteria for the clinical diagnosis of osteoporosis based on bone mineral density (BMD) T-scores. A T-score of -1 or higher indicates normal bone density, while a T-score between -1 and -2.5 signifies osteopenia, a condition characterized by lower than normal bone density but not low enough to be classified as osteoporosis. A T-score of -2.5 or lower indicates osteoporosis, a condition of significantly reduced bone density, and individuals with a T-score of -2.5 or lower along with an existing fracture are classified as having severe osteoporosis. This classification system provides a standardized method for diagnosing and categorizing osteoporosis severity based on BMD measurements and fracture history.

Table 2. WHO criteria for clinical diagnosis of osteoporosis	
BMD T-score	**Diagnosis**
T-score ≥ -1	**Normal**
-1 > T-score > -2.5	**osteopenia**
T-score ≤ -2.5	**Osteoporosis**
T-score ≤ -2.5 with existing fracture	**Severe osteoporosis**

RESULTS

Table 3 presents a comparison of two groups for T-Score and Vitamin D levels at baseline. Group I, consisting of 20 individuals, shows a mean T-Score of -2.93 with a standard deviation (SD) of 0.24, while Group II, also comprising 20 individuals, has a mean T-Score of -2.89 with an SD of 0.19. The statistical analysis using the 't' test reveals a t-value of -0.772 and a p-value of 0.442, indicating no statistically significant difference in T-Score between the two groups at baseline. Regarding Vitamin D levels, Group I has a mean of 12.55 ng/mL with an SD of 2.35, whereas Group II has a mean of 11.88 ng/mL with an SD of 2.39. The 't' test results in a t-value of 1.273 and a p-value of 0.207, suggesting no statistically significant difference in Vitamin D levels between the two groups at baseline. These findings

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

suggest that, based on the parameters measured, there is no significant distinction between Group I and Group II in terms of T-Score and Vitamin D levels at the baseline assessment.

Table 3: Comparison of two groups for T-Score and Vitamin D levels at baseline

Parameter	Group I (n=20)		Group II (n=20)		Statistical significance	
	Mean	SD	Mean	SD	't'	'p'
T-Score Baseline	-2.93	0.24	-2.89	0.19	-0.772	0.442
Vit D Baseline	12.55	2.35	11.88	2.39	1.273	0.207

Table 4 displays the between-group comparison of Vitamin D deficiency status at baseline. In Group I, out of 20 individuals, none were classified as having normal levels of Vitamin D. However, 15 individuals (87.5%) were categorized as having insufficiency, and 5 individuals (12.5%) were classified as having deficiency. Similarly, in Group II, none of the 20 individuals had normal Vitamin D levels, with 15 individuals (87.5%) falling under the category of insufficiency and 5 individuals (12.5%) categorized as deficient. The Chi-square test ($\chi 2$) yielded a value of 0 with a p-value of 1, indicating no statistically significant difference in Vitamin D deficiency status between Group I and Group II at baseline. These results suggest that both groups exhibited similar patterns of Vitamin D deficiency at the initial assessment.

Table 4: Between Group Comparison of Vitamin D Deficiency status at baseline

SN	Status	Group I (n=20)		Group II (n=20)	
		No.	%	No.	%
1	Normal	0	0	0	0
2	Insufficiency	15	87.5	15	87.5
3	Deficiency	5	12.5	5	12.5
x 2=0; p=1					

Table 5 presents a comparison of two groups for T-Score and Vitamin D levels at 12 months. In Group I, consisting of 20 individuals, the mean T-Score is 0.25 with a standard deviation (SD) of 1.76, while in Group II, also comprising 20 individuals, the mean T-Score is -0.29 with an SD of 1.95. The statistical analysis using the 't' test results in a t-value of 1.296 and a p-value of 0.199, indicating no statistically significant difference in T-Score between the two groups at 12 months.

Regarding Vitamin D levels, Group I has a mean of 37.23 ng/mL with an SD of 7.61, while Group II has a mean of 27.45 ng/mL with an SD of 8.58. The 't' test yields a t-value of 5.391 and a p-value of less than 0.001, indicating a statistically significant difference in Vitamin D levels between the two groups at 12 months. Specifically, Group I exhibits higher Vitamin D levels compared to Group II at the 12-month assessment. These findings suggest that while there is no significant difference in T-Score between the two groups, there is a significant

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

difference in Vitamin D levels, with Group I showing higher levels compared to Group II at 12 months.

Table 5: Comparison of two groups for T-Score and Vitamin D levels at 12 months

SN	Parameter	Group I (n=20)		Group II (n=20)		Statistical significante	
		Mean	SD	Mean	SD	't'	'p'
1	T-Score	0.25	1.76	-0.29	1.95	1.296	0.199
2	Vitamin D (ng/ml)	37.23	7.61	27.45	8.58	5.391	<0.001

Table 6 provides a comparison of the difference in the change of bone mineral density (BMD) in different contemporary studies between placebo and vitamin D supplemented groups.

1. Dawson-Hughes et al. (1997) measured the percentage change overall at 12 months. The case group exhibited a 168% change, whereas the placebo group showed a 146% change, resulting in a 22% difference in change between the case and placebo groups.

2. Gardos et al. (2003) measured the percentage change in BMD (mg/cm2) at the L2-L4 vertebrae over 12 months. They found a 2.98% change in the case group compared to a -0.21% change in the placebo group, resulting in a 3.17% difference in change between the case and placebo groups.

3. Larsen et al. (2017) assessed the change in BMD over 1 year and 2 years. At 1 year, the case group showed a change of 0.03, while the placebo group had a change of 0.04, resulting in a -33.30% difference in change between the case and placebo groups. At 2 years, the case group exhibited a change of 0.14, whereas the placebo group had a change of -0.02, resulting in an 800% difference in change between the case and placebo groups.

4. The present study, for which the details are provided in the table, measured the change in T-score over 12 months. The case group showed a change of 3.18, while the placebo group had a change of 2.6, resulting in a 30.00% difference in change between the case and placebo groups.

These findings illustrate the varying degrees of change in BMD between case and placebo groups across different studies, highlighting the potential impact of vitamin D supplementation on bone health.

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

Table 6 : Difference in Change of BMD in different contemporary studies in placebo and vitamin D supplemented groups

SN	Author (Year)	Method of measurement / Study Period	Change in Case Group	Change in Placebo group	% Difference of change between case and placebo group
1	Dawson-Hughes *et al.* (1997)18	% Change Overall 12 months	168%	146%	**22%**
2	Gardos*et al.* (2003)19	% Change in BMD (mg/cm^2) L2- L4 12 months	2.98%	-0.21%	**3.17%**
3	Larsen *et al.* (2017)12	Change in BMD 1 year	0.03	0.04	**-33.30%**
		2 years	0.14	-0.02	**800%**
4	**Present study**	**Change in T-score 12 months**	**3.18**	**2.6**	**30.00%**

Discussion

Osteoporosis is a prevalent condition affecting the skeletal system, which is marked by weakened bone strength, making individuals more susceptible to fractures. Both bone quantity and bone quality contribute to bone strength [20]. After reaching the age of 50, the occurrence of osteoporosis and the occurrence of fractures caused by osteoporosis increase significantly with age [21,22]. Given the rising life expectancy and growing emphasis on the health and well-being of older individuals, there has been a shift in attention towards comprehending the development and treatment of conditions affecting the elderly, including osteoporosis. Research has demonstrated that vitamin D improves the process of absorbing calcium and phosphate in the intestines [21]. Insufficient levels of vitamin D are linked to reduced absorption of calcium, an unfavorable calcium balance, and an increase in parathyroid hormone (PTH) as a compensatory response. This leads to excessive breakdown of bone tissue [21,22]. Studies conducted on a broad population have shown a correlation between the levels of serum 25(OH)D3 and bone mineral density in both males and females [23]. Research has demonstrated that taking a vitamin D3 supplement of 400 IU has a beneficial effect on the bone mineral density (BMD) of the hip. The study found a positive impact on musculoskeletal system health [24]. Nevertheless, there is a lack of clinical evidence supporting the efficacy of vitamin D treatment in the elderly. Therefore, this study was conducted to evaluate the vitamin D levels in older individuals with osteoporosis and to examine their correlation with the severity of osteoporosis. Additionally, the study aimed to investigate the effectiveness of vitamin D supplementation in the treatment of osteoporosis in the elderly. A randomized clinical trial is the optimal design for prospectively evaluating the effectiveness of an intervention. They are often regarded as the epitome of evidence-based

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medicine [25]. One significant benefit of randomized controlled trials (RCTs) is its ability to directly examine cause-effect correlations while minimizing bias and confounding factors. In our study, the patients were randomly assigned to one of two groups. Specifically, 40 patients (50%) received vitamin D supplementation in addition to the standard treatment for osteoporosis, making up Group I or the case group. The remaining 40 patients (50%) did not receive any additional treatment alongside the standard treatment, forming the placebo group or Group II. The two groups were carefully selected to have similar age, gender, and clinical characteristics. The study included individuals with ages ranging from 60 to 78 years. The average age of patients was 67.29±3.76 years. The majority of cases (41.3%) fell within the age range of 65 to 70 years. In contrast to the current study, Dawson-Hughes et al [26] included individuals above the age of 65 in their study and reported that the average age of their patients was over 70 years. Grados et al [27] reported that the average age of their patients was 75 years in a separate research. Mukaiyama et al [28] said that the average age of their patients was 69.4 years. However, in their study, Larsen et al [29] reported a lower mean age of patients compared to ours (61.1±7.6 years). Typically, the age of 65 or older is when the ability of the skin to synthesize vitamin D decreases to its lowest point. Nevertheless, this decrease does not occur at the same time and occurs gradually. In this study, we classified individuals aged 60 and above as elderly. We employed purposive sampling to specifically identify patients whose vitamin D levels were below the usual range. The disparity in the average age of patients in various datasets could perhaps reflect the mean lifespan in different settings. In India, the average life expectancy is comparatively lower, and the average age of the elderly in the present study is slightly lower.

The current investigation revealed an imbalanced male-female ratio, with 63.7% of patients being female. Women have a significantly higher frequency of osteoporosis compared to men [30]. In affluent countries such as the United States, where there are organized health records, the occurrence of osteoporosis is nearly four times greater in women compared to males [31]. In various intervention trials, a skewed gender ratio has been seen, with a higher proportion of women relative to men. In their investigation, Dawson-Hughes et al [26] reported a male-female ratio of 0.83. However, Gardoset al [27] and Mukaiyamaet al [28] specifically conducted their investigation using only female participants. In their study, Larsen et al [29] had a larger proportion of males (M:F 1.62) compared to females.

All the cases in the current investigation exhibited T-scores below -2.5, which is symptomatic of osteoporosis. The average vitamin D levels were 12.55±2.35 ng/ml and 11.88±2.39 ng/ml, respectively. 87.5% of patients in both the case and control groups had insufficient levels of Vitamin D, while 12.5% had deficient levels. This indicates a complete match between the two groups.

In the current study, the mean T-scores in the study group exhibited a shift from -2.93±0.24 to 0.25±1.76, resulting in a total change of 3.18. In contrast, the mean T-scores in the control group showed a change from -2.89±0.19 to -0.29±1.95, resulting in a total change of 2.60. Therefore, it may be concluded that the percentage change in T-scores was 30% more in the case group compared to the control group. The pattern of change in bone mineral density

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

(BMD) status in the placebo group and case group in various contemporary studies is as follows: The pattern of change in bone mineral density has been assessed in various groups using different methodologies. In this current investigation, we examined the subject in relation to the alteration in T-scores, while earlier studies [29,26, 27] have examined it in terms of the alteration in absolute BMD values. To ensure comparability of results across various trials, we standardized the change seen in each study by expressing it as a proportional change in bone mineral density (BMD) or T-scores. We next examined the percentage difference in change between the placebo and supplemented groups. The various studies have shown a wide range of differences in the change of bone mineral density (BMD) between the groups who received supplements and those that received a placebo over a one-year period. The differences ranged from a decrease of 33.3% to an increase of 22%. Two research have demonstrated the advantageous effects of adding vitamin D supplementation. These investigations, referenced as [26] and [27], have reported a percentage difference of 22% and 3.17% respectively between the groups that received the supplementation and the groups that received a placebo. The results of the current investigation align with the findings of Dawson-Hughes et al [26], who demonstrated a 22% difference in change between the case and placebo groups after one year. This is similar to the 30% difference observed in the present study. The study conducted by Larsen et al [29] revealed that the percentage change in bone mineral density (BMD) was 33.3% lower in the group that received supplements compared to the group that received a placebo after one year. However, in the second year of the intervention, they observed that the percentage change in BMD was 800% higher in the supplemented group compared to the placebo group. It is important to recognize that the differences in treatment response observed in various research may be attributed to variations in the characteristics of individuals included in those studies. The current study was conducted in a tropical region where there is an abundant natural supply of vitamin D, while most previous studies have been conducted in western countries where sun exposure is relatively lower. Variances in diet may potentially have a role in the disparity observed in the study's results. A challenge in comparing the findings of the current investigation with earlier studies was the variation in measurement methods. In this study, we primarily examined the qualitative changes from osteoporosis to osteopenic and normal bone mineral density (BMD) status. We assessed the outcomes using T-scores. The decision to use T-scores instead of direct BMD measurements was based on the need to conduct a combined assessment for both males and females. Using BMD values as the sole measurement could have complicated the analysis due to the variation in absolute BMD values between males and females. Additionally, normative values are influenced by age. Therefore, using T-scores allowed for standardization of results. The remarkable treatment response observed in the study conducted by Larsen et al [29] may be attributed to the fact that the study focused on a specific group of pre-diabetic patients. However, the results showed that vitamin D supplementation had a promising effect in the second year of intervention, suggesting that systemic disorders could influence the impact of vitamin D supplementation on the improvement or deterioration of bone mineral density in osteoporosis patients. The variations in outcomes of various research must also be taken into account in light of disparities in starting vitamin D levels. In the current study, neither of the groups had vitamin D levels within the normal range. The mean vitamin D levels were 12.55±2.35 ng/ml and 11.88±2.39

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

ng/ml in the supplemented and placebo groups, respectively. In their study, Dawson-Hughes et al. [26] observed that the initial levels of 1,25-OH Vitamin D were 33.3±13.6 ng/ml and 33.0±16.3 ng/ml in the placebo and supplemented groups, respectively. In a separate investigation, Grados et al. [27] specifically selected subjects with vitamin D levels below 12 ng/ml. In contrast, Larsen et al. [29] found that the supplemented group had vitamin D levels of 58.5±23.0 nmol (equivalent to 23.4 ng/ml), whereas the placebo group had levels of 59.0±18.4 nmol (equivalent to 23.6 ng/ml). The variations in the initial vitamin D levels could potentially influence the result.

In this study, we observed that the group receiving vitamin D supplementation had a superior outcome compared to the group receiving a placebo, even when considering qualitative aspects. At the conclusion of the trial, it was found that only 5% of patients in the group receiving supplements had bone mineral density (BMD) in the osteoporotic range, compared to 35% of patients in the placebo group. This is a significant difference of 30%. These data provide further evidence for the observations made regarding the change in T-scores. After conducting a thorough examination of the existing literature, we found no studies that assessed the outcome in qualitative terms. The possible explanation for this could be that other workers primarily focused on the quantitative change in bone mineral density (BMD) rather than the qualitative improvement in BMD status. Nevertheless, previous research has assessed the qualitative effect by measuring the decrease in non-vertebral fracture occurrence over a period of up to 3 years [26]. Nevertheless, this study was constrained to a single year evaluation, making it challenging to analyze the qualitative alterations related to a decrease in fracture occurrence. Additionally, the study's sample size was a hindrance to examining the outcome in relation to fracture risk. Various research have shown design-related variations, but the majority of professionals concur that incorporating vitamin D supplementation significantly accelerates the restoration of BMD status. In this study, we also assessed the effect of adding vitamin D supplementation on the levels of vitamin D in the blood. Initially, all patients in both groups had insufficient or deficient levels of vitamin D. However, after one year of treatment, 95% of patients in the supplemented group and 65% in the placebo group had successfully reached normal vitamin D levels. While the improvement in vitamin D levels in the supplemented group can be attributed to the vitamin D supplementation, the positive change in vitamin D status in the placebo group can be attributed to the general recommendation of sufficient sun exposure and consumption of diets that are high in calcium and vitamin D. This supplementary intervention could potentially contribute to improved and expedited outcomes in both groups. Lifestyle and dietary factors may significantly influence the degree of change in vitamin D levels. During their research, No significant adverse effects or complications were observed in any of the two groups in the present investigation. No harmful effects have been identified in the several research we have analyzed. The present study's findings demonstrate the role of vitamin D.Supplementation could be a beneficial method to accelerate the alteration in bone mineral density (BMD) of elderly individuals receiving treatment for osteoporosis. Dawson-Hughes et al. [26] demonstrated that in males, the case group experienced a rise of 11.8 ng/ml in 25-OH vitamin D3 levels, while the placebo group experienced a decrease of -2.68 ng/ml. In females, the case group showed an increase of 16.1 ng/ml, while the placebo group showed a slight increase of 0.7 ng/ml. These

ISSN:0975 -3583,0976-2833 VOL 14, ISSUE 12, 2023

findings suggest that gender differences may influence the direction of change, even in the placebo group. In this study, we implemented extra supplementation in the form of dietary modifications and increased exposure to sunlight. The present study had two limitations: the length of the study and the sample size. As a result, it was not possible to investigate the long-term influence of vitamin D supplementation in terms of the rate of change in bone mineral density (BMD). Considering the varying rate of change in T-scores at different stages of the study, as observed in the current study and described by Larsen et al [29], who noted different patterns of treatment response in the placebo and supplemented groups during the first and second year of therapy, it is crucial to determine if the advantages of including vitamin D supplementation continue beyond the initial 12-month period. Due to the lack of long-term follow-up and a limited sample size, the current study is unable to determine the potential benefits of increasing vitamin D supplementation in relation to the risk of fractures. Therefore, it is advisable to do more research with a longer period of observation and a larger group of participants.

CONCLUSION

Based on the current study, it can be inferred that vitamin D supplementation accelerates the process of bone mineral density transition, hence aiding in bone production. This supplementation also improved the vitamin D levels in aged individuals. However, the effectiveness of this supplementation appeared to reach its maximum level after 12 months, since there was no significant difference in the average BMD T-scores between the two groups. Considering the widespread vitamin D deficiency in older individuals with osteoporosis, it is advisable to suggest vitamin D supplementation due to its ability to accelerate the therapeutic process.

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