



## Is Vitamin-D Supplementation has Effect in the Functional Outcome of Osteoporotic Vertebral Fractures

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#### **Abstract**

 $Osteoporosis\ treatment\ is\ rarely\ applied\ in\ clinics\ because\ osteoporosis\ is\ a\ silent$ disease, which is primarily diagnosed after patients have experienced the first fragility fracture. Even after such a fracture, under-treatment is common, because only 10-20 % of patients receive adequate treatment. Vitamin D affects the rate of bone turnover and the overall mineralization of the bone. Thus, vitamin D deficiency is associated with a higher bone turnover and incidence of fracture. It is likely that deficiencies in calcium and vitamin D negatively influence fracture healing. In osteoporotic vertebral compression fractures (OVCFs), supplementation using vitamin D preparations and maintenance of blood vitamin D level within the normal range are necessary for proper fracture union, enhancement of muscle strength and maintenance of body balance. There is still no consensus on what is the best supplementation strategy, in terms of dosage, frequency of treatment and duration and even in terms of fracture union rate, mineralization process, union time and complication rate in OVCF. Hence, we did a study is to confirm the effects of vitamin D supplementation after the onset of OVCF. It is a prospective study done in 30 patients with OVCF in Sree Mookambika Institute of Medical Sciences, Kulasekharam. We have included, Recent OVCF at  $\ge$  1 vertebra level on a simple radiograph, No other abnormal findings of the spine (e.g., infection, tumor), Low serum (OH) vitamin D level (< 30 ng/ml). Total 30 patients were divided into two groups, group-1 includes 15 patients who received the 6 months course of Vitamin-D supplement (Cholecarciferol) 60,000 IU/ week for first 8 weeks followed by 60,000IU twice a month for 4 months and group-2 includes remaining 15 patients doesn't receive Vitamin-D supplement. Both groups were given same analgesics, braces along with supportive measures along with nutritional advice. Simple radiographs were taken to assess fracture union and the serum Vitamin-D level was also monitored by during the follow up period. The severity of low back pain (LBP) was evaluated using a visual analog scale (VAS) with levels 0 to 10. To evaluate functional outcome, Oswestry Disability Index (ODI, version 2.0) and Roland Morris Disability Questionnaire (RMDQ) were used to follow up the patients during intial, 3 months and 6 months. The mean union time of group-1 and group 2 is 12.06±1.06 weeks and 13.3±0.99 weeks respectively. The mean Serum 25(OH) Vitamin-D levels of group 1 patients who received Vitamin-D supplementation done during initial, after 3 months and 6 months follow up are 15.4± 3.61, 20.93±3.49 and 28.85±3.38 respectively and the mean Serum 25(OH) Vitamin-D levels of group 2 patients done during initial, after 3 months and 6 months follow up are 15.67±2.98, 16.4±2.93 and 16.53±3.09 respectively. Our study had significance which gives marginal improvement in functional outcome of osteoporotic vertebral compression fractures by vitamin-D supplementation and a significant improvement in the levels of serum (OH)-D which is beneficial in vitamin-D deficiency patients in maintaining the serum (OH)-D levels and improving calcium bone homeostasis. Vitamin-D supplementation is necessary that it can relatively reduce the risk of future osteoporotic fractures.

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#### **Key Words**

Osteoporosis treatment, fracture healing, body balance, Vitamin D

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#### INTRODUCTION

Fractures caused by osteoporosis occur in one third of females and one fifth of males over 50 years. Globally, approximately 9 million people with osteoporosis suffer a fracture annually <sup>[1]</sup> Thus, because of ongoing demographic changes with an aging population, the incidence of fractures will further increase.

Osteoporosis is characterized by low BMD and microarchitectural deterioration of the bone tissues, leading to an increased risk of fracture<sup>[2]</sup>. Vertebral fractures are the most common osteoporotic fractures in the elderly people. Pathological fractures can occur even with minor trauma as a result of a decrease in bone mineral density (BMD) and low bone quality and they have various clinical courses.

Some vertebral fractures show no symptoms and hence they require no treatment whereas some vertebral fractures improve with conservative treatment, while some others require surgical management<sup>[3]</sup>. Treatment of osteoporotic vertebral compression fractures (OVCF) is important, but prioritizing the existing osteoporosis treatment to prevent further OVCF is considered to be the most important aspect of treatment. Osteoporosis remains an under-recognized and undertreated disease entity in orthopaedic settings, accounting for significant long-term morbidity and mortality<sup>[3]</sup> Osteoporosis treatment is rarely applied in clinics because osteoporosis is a silent disease, which is primarily diagnosed after patients have experienced the first fragility fracture. Even after such a fracture, under-treatment is common, because only 10-20 % of patients receive adequate treatment<sup>[4,5]</sup>. Vitamin D affects the rate of bone turnover and the overall mineralization of the bone. Thus, vitamin D deficiency is associated with a higher bone turnover and incidence of fracture<sup>[6]</sup>. It is likely that deficiencies in calcium and vitamin D negatively influence fracture healing.

Because of the important roles of calcium and vitamin D in bone health, basic osteoporosis therapy includes their supplementation for individuals at high risk of osteoporosis, including aged postmenopausal females, when dietary calcium and vitamin D intake are insufficient<sup>[7]</sup>.

In osteoporotic vertebral compression fractures (OVCFs), supplementation using vitamin D preparations and maintenance of blood vitamin D level within the normal range are necessary for proper fracture union, enhancement of muscle strength and maintenance of body balance.

There is still no consensus on what is the best supplementation strategy, in terms of dosage, frequency of treatment and duration and even in terms of fracture union rate, mineralization process, union time and complication rate in OVCF. Hence we did a study is to confirm the effects of vitamin D supplementation after the onset of OVCF.

**Aims and Objectives:** To determine the functional outcome and the effect of vitamin D supplementation in osteoporotic vertebral compression fractures.

#### **MATERIALS AND METHODS**

It is a prospective study done in 30 patients with OVCF in Sree Mookambika Institute of Medical Sciences, Kulasekharam. We have included, Recent OVCF at ≥1 vertebra level on a simple radiograph, No other abnormal findings of the spine (e.g., infection, tumor), Low serum (OH) vitamin D level (< 30 ng/ml). We have excluded serum level (OH)vitamin D levels > 30ng/ml, Serum calcium > 10.6mg/dl, Malabsorption disease, lymphoma, sarcoidosis, tuberculosis, hyperparathyroidism, celiac disease, Kidney stone, Renal dysfunction, Previous spine surgery, Contraindication to vitamin D supplementation.

Total 30 patients were divided into two groups, group-1 includes 15 patients who received the 6 months course of Vitamin-D supplement (Cholecalciferol) 60,000 IU/ week for first 8 weeks followed by 60,000IU twice a month for 4 months and group-2 includes remaining 15 patients doesn't receive Vitamin-D supplement. Both groups were given same analgesics, braces along with supportive measures along with nutritional advice.

Simple radiographs were taken to assess fracture union and the serum Vitamin-D level was also monitored by during the follow up period. The severity of low back pain (LBP) was evaluated using a visual analog scale (VAS)<sup>[8]</sup> with levels 0 to 10. To evaluate functional outcome, Oswestry Disability Index (ODI, version 2.0)<sup>[9]</sup> and Roland Morris Disability Questionnaire (RMDQ)<sup>[10]</sup> were used to follow up the patients during intial, 3 months and 6 months.

#### **RESULTS AND DISCUSSIONS**

The mean age of our study is 71.7±3.83 years. Majority of the patients sustained OVCF are between the age of 71-75 years.

In our study majority of the patients were female in total as well as in each group. There were a total of 21 (70%) female patients and 9 (30%) male patients.

In our study most commonly involved OVCF is L1 vertebra which accounts for 10 (33.33%) patients. the second most common is T12 vertebra which was 8 (26.67%) T11 and L2 involvement in 3 (10%) patients each and L3,L4,L5 involvement in 2 (6%) patients each. The mean union time of group-1 and group 2 is 12.06±1.06 weeks and 13.3±0.99 weeks respectively. The mean Serum 25(OH) Vitamin-D levels of group 1 patients who received Vitamin-D supplementation

done during initial, after 3 months and 6 months follow up are 15.4±3.61, 20.93±3.49 and 28.85±3.38 respectively and the mean Serum 25(OH) Vitamin-D levels of group 2 patients done during initial, after 3 months and 6 months follow up are 15.67±2.98, 16.4±2.93 and 16.53±3.09 respectively.

The mean VAS Score of group 1 patients during initial, after 3 months and 6 months are  $8.06\pm0.77$ ,  $4\pm0.63$  and  $1.87\pm0.8$  respectively and the Mean VAS Score of group 2 patients during initial, after 3 months and 6 months are  $7.93\pm0.68$ ,  $4.46\pm0.49$  and  $2.53\pm0.49$  respectively. We had a total Mean VAS score of  $8\pm0.73$  initially and  $2.2\pm0.75$  after 6 months.

The mean ODI scores of group-1 patients during initial, 3 months and 6 months follow-up are 26.86±2.44, 20.87±2.15 and 15.67±2.06. The mean ODI scores of group-2 patients during initial, 3 months and 6 months follow-up are 25.86±2.45,22.93±2.37 and 17.86±2.12.

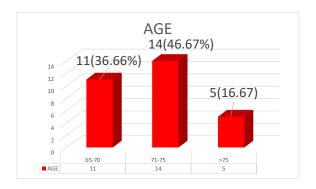


Fig. 1: Age distribution of patients in our study

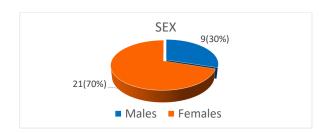


Fig. 2:Sex distribution among patients in our study

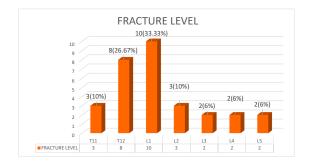


Fig. 3: Fracture at different vertebra levels among patients in out study

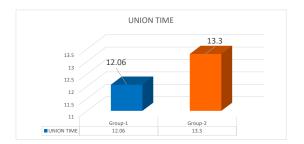


Fig. 4: Mean fracture union time in both groups.

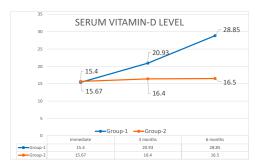


Fig. 5: Mean serum 25(OH) Vitamin-D levels of both groups during the follow up



Fig. 6: Mean VAS score of both groups during the follow up

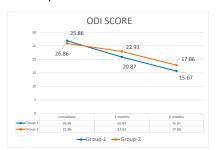


Fig. 7: Mean ODI score of both groups during the follow up

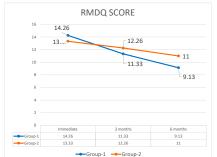


Fig. 8:Mean RMDQ score of both groups during the follow up

Table 1: Comparison of age with other studies

Studies	Mean age
Iwata A et al. [11]	76.7 years
Present study	71.7 years

Table 2: Comparison of sex distribution with other studies

Studies	Males (%)	Females (%)
Kuo YR et al.[12]	24.2	75.8
Present study	30	70

Table 3: Comparison of osteoporotic vertebral fracture levels with other studies

studies							
Studies	T11	T12	L1	L2	L3	L4	L5
	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Ko S et al. <sup>[13]</sup>	7.6	33	27.6	13.8	7.6	7.6	2.3
Present Study	10	26.67	33.33	10	6	6	6

Table 4: Comparison of Union time between two groups

Groups	Union time in weeks
Group-1	12.06±1.06
Group-2	13.3±0.99

Table 5: Comparison of Mean Serum 25(OH) Vitamin-D levels during follow up with other studies

Studies	Serum 25(OH) Levels (ng/ml)			
	Immediate	After 6 months		
Goswami R et al.[15]	9.2±3.40	29.9±8.35		
Present study	15.4± 3.61	28.85±3.38		

Table 6: Comparison of Mean VAS Score between two groups during follow up in our study.

Groups	Mean VAS score			
	Immediate	3 months	6 months	
Group-1	8.06±0.77	4±0.63	1.87±0.8	
Group-2	7.93±0.68	4.46±0.49	2.53±0.49	

Table 7: Comparison of Me	an ODI and RMDQ	with other studies
Studies	Mean ODI	Mean RMDQ

	Immediate	3 Months	6 Months	Immediate	3 Months	6Months
Ko S <i>et al.</i> <sup>[12]</sup>	24.88±10.46	21.07±7.28	16.92±7.95	14.40±5.38	11.96±4.22	9.11±4.58
Present study	26.86±2.44	20.87±2.15	15.67±2.06	14.26±2.51	11.33±1.73	9.13±1.58

The mean RMDQ scores of group-1 patients during initial, 3 months and 6 months follow-up are 14.26±2.51, 11.33±1.73 and 9.13±1.58. The mean RMDQ scores of group-2 patients during initial, 3 months and 6 months follow-up 13.33±2.41, 12.26±2.29 and 11±1.86.

The mean age of our study is 71.7 years. Iwata  $A^{[11]}$  in their study on OVF they had a mean age of 76.7 years. In our study majority of the patients were female in total as well as in each group. There was a total of 21 (70%) female patients and 9 (30%) male patients. Kuo YR<sup>[12]</sup> 38 (24.2%) males and 119 (75.8%) females.

In our study most commonly involved OVF is L1 vertebra which accounts for 10 (33.33%) patients. the second most common is T12 vertebra which was 8 (%) T11 and L2 involvement in 3 (10%) patients each and L3, L4, L5 involvement in 2 (6%) patients each. Ko S<sup>[13]</sup> in his study on Osteoporotic vertebral fractures there were 10(7.6%) vertebral fractures at T11, 43 (33%) vertebral fractures at L1, 18(13.8%) vertebral fractures at L2, 10 (7.6%) vertebral fractures at L3, 10 (7.6%) vertebral fractures at L5. The mean union time of group-1 and group-2 is

12.06 $\pm$ 1.06 weeks and 13.3 $\pm$ 0.99 weeks respectively. Normally the osteoporotic bone will have union at around 3 months. Osteoporotic vertebral fracture and delayed union mainly occurred at thoracolumbar levels (T11-L1) in 73 patients (58.9%) and 12 patients (75%), respectively in Abe T<sup>[13]</sup> study.

The mean Serum 25(OH) Vitamin-D levels of group 1 patients who received Vitamin-D supplementation done immediately during fracture presentation, after 3 months and 6 months are 15.4±3.61, 20.93±3.49 and 27±3.38 respectively and the mean Serum 25(OH) Vitamin-D levels of group 2 patients done immediately, after 3 months and 6 months are 15.67±2.98, 16.4±2.93 and 16.53±3.09 respectively. We had an improvement in the supplementation group compared to non-supplementation group. Goswami<sup>[15]</sup> a study on 43 patients he had an initial value of 9.2±3.40 after 60,000 IU weekly supplementation of cholecalciferol, they had an improvement in 6 months follow up to 29.9±8.35.

The mean VAS Score of group 1 patients during immediate fracture presentation, after 3 months and 6 months are 8.06±0.77, 4±0.63 and 1.87±0.8 respectively and the Mean VAS Score of group 2 patients before, after 3 months and 6 months are 7.93±0.68, 4.46±0.49 and 2.53±0.49 respectively.

The mean Oswestry Disability Index (ODI) scores of group-1 patients received vitamin-D supplementation during initial, 3 months and 6 months follow-up are 26.86±2.44, 20.87±2.15 and 15.67±2.06. The mean ODI scores of group-2 patients during initial, 3 months and 6 months follow-up are 25.86±2.45, 22.93±2.37 and 17.86±2.12. The mean RMDQ scores of group-1 patients during initial, 3 months and 6 months follow-up are 14.26±2.51, 11.33±1.73 and 9.13±1.58. The mean Roland Morris Disability Questionnaire (RMDQ) scores of group-2 patients during initial, 3 months and 6 months follow-up 13.33±2.41, 12.26±2.29 and 11±1.86. There was a marginal significant improvement in the functional outcome assessed by ODI and RMDQ scores in group-1 who had supplementation than group-2 who doesn't received any supplementation of vitamin-D.

Which was comparable with Ko S<sup>[13]</sup> study, where they had Mean ODI score of ODI scores of patients received vitamin-D supplementation during initial, 3 months and 6 months follow-up are 24.88±10.46, 21.07±7.28 and 16.92±7.95, The mean RMDQ scores of the same during initial, 3 months and 6 months follow-up are 14.40±5.38, 11.96±4.22 and 9.11±4.58 respectively.

Conservative treatment is the traditional line of management of osteoporotic vertebral fractures. Short period of bed rest, analgesic medications, antiosteoporosis pharmacotherapy, bracing support for the fracture along with guided physical therapy and

postural correction aid in lasting alleviation of the pain. Vitamin D repletion was necessary and vitamin D supplementation were given as an adjuvant treatment. In addition, it has been confirmed that to maximize the efficacy of anti-restorative osteoporotic treatment and anti-fracture effect, supplementation of vitamin D for vitamin D-deficient patients is mandatory<sup>[16]</sup>.

Chevalley<sup>[17]</sup> recently reported that vitamin D may have a positive influence on fracture healing and adequate vitamin D status plays an important role in the functional recovery after fracture, but the mechanism and the magnitude of the effect remain to be determined.

Esposti<sup>[18]</sup> reported that the group of patients receiving calcium/ vitamin D supply in addition to osteoporosis drugs had a lower risk of both subsequent fracture and all-cause mortality during the 3-year follow-up in cohort of osteoporosis patients with a recent fracture.

### **CONCLUSIONS**

There are not many studies that have investigated the effects of vitamin D supplementation after the onset of OVF on fracture union, functional outcome, incidence of nonunion and so on. Our study had significance which gives marginal improvement in functional outcome of osteoporotic vertebral compression fractures by vitamin-D supplementation and a significant improvement in the levels of serum (OH)-D which is beneficial in vitamin-D deficiency patients in maintaining the serum (OH)-D levels and improving calcium bone homeostasis. Vitamin-D supplementation is necessary that it can relatively reduce the risk of future osteoporotic fractures.

**Limitation:** The limitations of this study are presented below. First, the biggest drawback is that the sample. size is little statistically significant. The follow-up period of 6 months is short and there was limited information on long-term results when the baseline sufficiency status of vitamin D was maintained.

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