

## Effect of Vitamin-D supplementation in adults presenting with chronic lower back pain

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<sup>1,2,4,5</sup> Conception of study

<sup>1,2,4,6</sup> Experimentation/Study conduction

<sup>3</sup> Analysis/Interpretation/Discussion

<sup>1,3</sup> Manuscript Writing

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### Abstract

**Introduction:** Chronic pain in the lower back of adults is a common problem and mostly associated with Vitamin D deficiency. Along with standard treatment, vitamin D supplementation can help in early and better relief from back pain.

**Objective:** To assess the effectiveness of vitamin D supplementation in patients with chronic lower back pain.

**Study Design & Methods:** This Quasi-experimental trial was conducted at the Department of Orthopaedics, Benazir Bhutto Hospital for 6 months. The patients aged between 15 to 55 years with chronic low back pain were included and pain score was noted by using a visual analogue scale (VAS). Patients were prescribed with oral vitamin D3 with a dose of 50,000 IU weekly for eight weeks (induction phase) and oral vitamin D3 with a dose of 50,000 IU once monthly for 6 months (maintenance phase). Outcome parameters included pain measured by VAS, functional disability by modified Oswestry disability questionnaire scores, and Vitamin-D3 levels at baseline, 2, 3, and 6 months post-supplementation.

**Results:** The mean age of patients was 44.2 1± 11.92 years. There were 337 (56.2%) male patients while 263 (43.8%) female patients. Baseline mean vitamin-D levels were 13.32 ± 6.10 ng/mL and increased to 37.18 ± 11.72 post supplementation (P < 0.0001). There was a significant decrease in the pain score after 2<sup>nd</sup>, 3<sup>rd</sup> & 6<sup>th</sup> months (61.7 ± 4.8, 45.2 ± 4.6 & 36.9 ± 7.9, respectively) than 81.2 ± 2.4 before supplementation (P < 0.001). The modified Oswestry disability score also showed significant improvement after 2<sup>nd</sup>, 3<sup>rd</sup> & 6<sup>th</sup> months (35.5 ± 11.4, 30.2 ± 9.4 & 25.8 ± 10.6, respectively) as compared to baseline 46.4 ± 13.2 (P < 0.001). About 418 (69.7%) patients attained normal levels after 6 months.

**Conclusion:** Prescription of Vitamin D in addition to standard therapy for chronic lower back pain can be beneficial in getting relief from pain and improving the functional ability of the patient.

**Keywords:** Vitamin D supplementation, pain, functional disability, chronic lower back pain.

## Introduction

Chronic lower back pain is the most common disorder of the spine in adults and the most common complaint among the pain of musculoskeletal structures.<sup>1, 2</sup> It is a serious disorder, which may cause the loss of functional ability and also reduce the movements of the body as well. It can be characterized in three types, depending on the duration of pain: acute type (lasting < 6 weeks), sub-acute type (lasting from 6 to 12 weeks), and the chronic type (lasting >12 weeks). About 30% of acute low back pain becomes chronic.<sup>3</sup> Literature highlights that the deficiency of serum vitamin D causes prolonged chronic pain in the musculoskeletal system as well as neuromuscular disorder.<sup>4,5</sup> People usually complain more predominantly about pain in the lower extremity of the spine. The weakness of the proximal muscles causes the trouble during a walk and a disturbed gait or abnormal walking array. Therefore, chronic lower back pain is considered as the symptom which indicates the deficiency or insufficiency of vitamin D in the blood. Chronic lower back pain may also disturb and reduce the quality of life and leads to functional disability, thus harm social life activities.<sup>6</sup>

The prevalence of vitamin D deficiency is high in the Indo-Pak subcontinent and observed from 50 to 90% in this region. It is known that less intake of dietary vitamin D as well as the skin color and altering lifestyle of people in this region regardless of the availability of sufficient sunlight.<sup>7</sup> Alfaraj et al., found that about 83% individuals of chronic lower back pain had vitamin D deficiency in the blood,<sup>8</sup> while this rate was 81.7% as reported by Lotfi et al.,<sup>9</sup> Hwan-Kim et al., reported the frequency in 74.3% cases<sup>10</sup> while lowest in a study by e Silva et al., i.e. 22.5%.<sup>11</sup>

The association of chronic lower back pain with vitamin D deficiency is more prominent in females of old age as compared to males of the same age group. But, Kim et al., conducted a study on 350 individuals diagnosed to have chronic lower back pain, and found no relationship of vitamin D insufficiency with the sex of the individuals.<sup>10</sup> Numerous hypotheses clarify the fact that the insufficiency of vitamin D is associated with lower back-ache. It has been discovered through previous literature that in cases of vitamin D deficiency, the neuromuscular disorders can happen as a consequence of hypersensitivity and sensorial hyper-innervations in the muscles.<sup>12</sup>

The rationale of the study was to find the beneficial role of vitamin D supplementation in addition to the

standard treatment of chronic lower back pain. The findings of this study would help us to obtain the beneficial role of vitamin D supplements to prescribe to individuals who have chronic lower back pain in a local clinical set-up.

## Material & Methods

### Objective

To assess the effectiveness of vitamin D supplementation in patients with chronic lower back pain.

**Study Design:** Quasi-experimental trial.

**Venue:** Department of Orthopaedics, Benazir Bhutto Hospital, Rawalpindi.

**Duration:** Two year period i.e. from March 2015 to March 2017.

**Sample size:** A sample size of n = 600 was estimated by keeping confidence level = 95%, a margin of error = 4%, and percentage of efficacy from previous literature i.e. 66%<sup>13</sup> after supplementation of vitamin D for treatment of chronic lower back pain.

**Sampling technique:** Non-probability, consecutive sampling.

**Selection criteria:** Patients age 15 to 55 years of both genders who had chronic lower back pain were recruited for the study. Patients of spinal stenosis, disc prolapse, degenerative spinal pathologies, neurological disease, metabolic bone disorder (hypo- or hyperparathyroidism), pregnant women, chronic kidney failure, and chronic liver disease were not included.

**Data collection Method:** Patients fulfilling selection criteria were enrolled from OPD. Informed consent was taken and demographics were noted. A blood sample was taken and sent to the laboratory for assessment of vitamin D level at presentation. Patients were also assessed for pain intensity by using VAS and functional disability assessed by the modified Oswestry disability score. Then individuals were prescribed oral vitamin D3 supplements of dose 50000 IU weekly for eight weeks (induction phase) and then oral vitamin D3 with a dose of 50000 IU once monthly for 6 months (maintenance phase). Then all the patients were followed-up in OPD after 2, 3, and 6 months. On each visit, a blood sample was taken and sent to the laboratory for assessment of vitamin D level and patients were assessed for pain intensity by using VAS and functional disability assessed by using a modified Oswestry disability score scale. Vitamin D3 levels were measured and labeled as normal if vitamin

D level > 29 ng/mL post supplementation. All the data was gathered on preformed proforma.

**Data analysis:** Gathered information was entered into SPSS and was also analyzed. Change in pain score modified Oswestry disability score, vitamin D level were assessed by applying paired sample t-test. P-value ≤ 0.05 was considered significant.

## Results

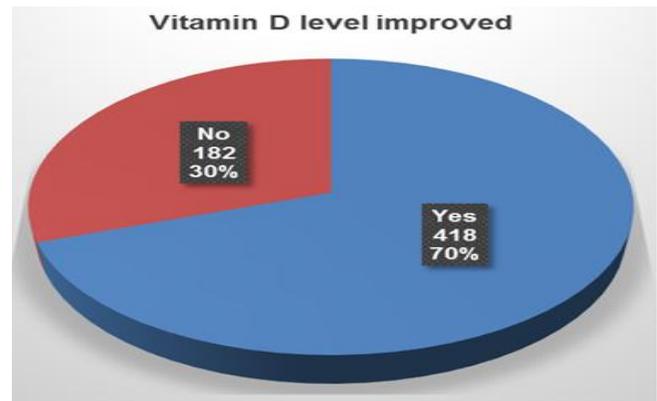
The mean age of patients was 44.21 ± 11.92 years. There were 337 (56.2%) male patients while 263 (43.8%) female patients. The mean duration of chronic back pain was 3.1 ± 1.1 years. About 454 (75.66%) patients have deficient vitamin-D3 levels. (Table 1) Baseline mean vitamin-D levels were 13.32 ± 6.10 ng/mL and increased to 37.18 ± 11.72 post supplementation (P<0.0001). There was a significant decrease in the pain score after 2<sup>nd</sup>, 3<sup>rd</sup>& 6<sup>th</sup> months (61.7 ± 4.8, 45.2 ± 4.6 & 36.9 ± 7.9, respectively) than 81.2 ± 2.4 before supplementation (P < 0.001). The Modified Oswestry disability score also showed significant improvement after 2<sup>nd</sup>, 3<sup>rd</sup>& 6<sup>th</sup> months (35.5 ± 11.4, 30.2 ± 9.4 & 25.8 ± 10.6, respectively) as compared to baseline 46.4 ± 13.2 (P < 0.001). (Table 2) In the study, 418 (69.7%) individuals achieved normal levels (>29 ng/mL) after 6 months of supplementation. (Figure-1)

**Table 1: Demographics of patients**

<b>n</b>	600
<b>Age</b>	44.21 ± 11.92 years
<b>Gender</b>	
Male	337 (56.17 %)
Female	263 (43.83%)
<b>Duration of symptoms</b>	3.1 ± 1.1 years
<b>Vitamin D deficiency at baseline</b>	454 (75.66%)

**Table 2: Change in outcome after vitamin D supplementation**

	Base line	After 2 months	After 3 months	After 6 months	P-value
<b>Vitamin D level</b>	13.3 ± 6.1	21.22 ± 4.9	29.6 ± 6.3	37.18 ± 11.7	<0.0001
<b>Pain score</b>	81.2 ± 2.4	61.7 ± 4.8	45.2 ± 4.6	36.9 ± 7.9	<0.0001
<b>Modified Oswestry Disability score</b>	46.4 ± 13.2	35.5 ± 11.4	30.2 ± 9.4	25.8 ± 10.6	<0.0001



**Figure 1: Improvement in vitamin-D level after supplementation**

## Discussion

Chronic lower back-ache or back pain is the common disorder of spine in adults all over the world.<sup>14</sup>It causes hindrance in daily life activities, decreased social functioning, and weakened the quality of lifestyle.<sup>15</sup>It has been observed and identified that insufficiency and deficiency of serum vitamin D are significantly involved in several chronic spinal diseases and also chronic painful disorders.<sup>16, 17</sup>A significant relationship between lower back pain and deficiency of serum vitamin D has been reported in the literature. But, there is a lack of adequate convicting proof concerning the ideal concentration of vitamin D in blood in such conditions.<sup>18</sup>

In our study, the mean vitamin-D levels at baseline were 13.32 ± 6.10 ng/mL and increased to 37.18 ± 11.72 post supplementation (P < 0.0001). Pain was

significantly reduced after 2, 3, & 6 months ( $61.7 \pm 4.8$ ,  $45.2 \pm 4.6$  &  $36.9 \pm 7.9$ , respectively) than  $81.2 \pm 2.4$  before of vitamin D supplementation ( $P < 0.001$ ). There was a significant improvement in modified Oswestry disability score after 2<sup>nd</sup>, 3<sup>rd</sup> & 6<sup>th</sup> month of treatment ( $35.5 \pm 11.4$ ,  $30.2 \pm 9.4$  &  $25.8 \pm 10.6$ , respectively) as compared to baseline  $46.4 \pm 13.2$  ( $P < 0.001$ ). In the study, 418 (69.7%) individuals improved the vitamin D level to normal concentration ( $>29$  ng/mL) after 6 months of treatment.

Ghai et al. also found similar findings and reported that mean vitamin D concentration was  $12.8 \pm 5.73$  ng/mL at the time of inclusion in the study, which was improved to  $36.07 \pm 12.51$  ng/mL after vitamin D supplementation ( $P < 0.01$ ), while 66% individuals showed normal vitamin D level in the blood ( $> 29$  ng/mL) after 6 months use of vitamin D supplements. The researcher's also observed that there was a significant decrease in the pain score (VAS) after at 2, 3& 6 months [ $61 \pm 19$ ,  $45 \pm 19$ &  $36 \pm 18$ ,  $P < 0.001$  on each follow-up visit] than to pain score at baseline i.e.  $81 \pm 19$ . The functional ability score was also reduced after 2, 3& 6 months [ $36 \pm 12$ ,  $31 \pm 13$ & $26 \pm 10$ ,  $P < 0.001$  on each follow-up visit] as compared to functional ability score at baseline i.e.  $45 \pm 16$ .<sup>13</sup>

Another trial also found that in a cohort of 49 adults the mean serum vitamin D level was 23.7 nmol/L, while the mean pain score was 5.07 and mean the quality of life was 3.55 before supplementation of vitamin D. After the use of vitamin D supplements (as prescribed), the mean serum vitamin D concentration was improved to 118.8 nmol/l ( $P < 0.001$ ), mean the quality of life to 2.8 nmol/l ( $P < 0.001$ ) while mean pain score reduced to 2.8 ( $P < 0.001$ ).<sup>19</sup>

Yilmaz et al. observed that with supplementation of vitamin D, the mean pain score was reduced from  $7.4 \pm 1.4$  to  $3.9 \pm 2.3$  while disability score was improved to  $21.6 \pm 34$  to  $53.5 \pm 39.7$  while vitamin D level was improved from  $10.6 \pm 5.1$  to  $46.5 \pm 24$  ng/ml ( $p < 0.05$ ).<sup>20</sup> Gendelman et al.,<sup>20</sup> assessed the effect of supplementing vitamin D with a dose of 4000IU for the amount of pain and serological components in individuals having musculoskeletal pain in a randomized controlled trial. They reported that supplementation of vitamin D can help to decrease the pain significantly i.e. 48.6 than placebo i.e. 54.6  $\pm 28.3$ .<sup>21</sup>

Low vitamin D concentration in blood is a significantly associated factor for the development of lower back pain in adults along with other risk factors. Appropriate examination and addition of vitamin D supplements to the standard therapy can efficiently

interrupt the malicious cycle of the lower back pain along with significant improvement in the vitamin D concentration in the body, effective pain relief and significant functional improvement of back-bone without compromising the health of an individual or any side effects. Improvement in the concentration of the vitamin D in the blood is insignificantly associate to its concentration at the initial level and obese persons show significantly less improvement.<sup>22</sup>

## Conclusion

Prescription of Vitamin D in addition to standard therapy for chronic lower back pain can be beneficial in getting relief from pain and improving the functional ability of the patient. Thus in the future, we can be able to get a better outcome of treatment of chronic back pain and more satisfaction of the patient.

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