Original Article

Impact of Vitamin D repletion on treatment of chronic lower back pain

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Abstract

Background: Chronic lower back pain is precisely a distressing condition not only because of associated physical debilitation but the psychological hassle as well. Along with various etiological factors, low vitamin D levels in the body is also a significant cause of this ailment. This study focuses on monitoring the effect of Vitamin D repletion on intensity of chronic (non-traumatic) lower back pain.

Methodology: This longitudinal-prospective analysis was conducted upon a sample of 374 lower back pain patients presenting with vitamin D deficiency from February to October 2018. Inquiries were made regarding basic socio-demographics, history of chronic lower back pain, dietary and medicinal supplement usage, hours of sun exposure and pain levels, assessed using a Visual Analogue Scale (VAS). The vitamin D levels and the VAS pain score were assessed upon baseline visit to the orthopedic outpatient department and followed up after 2 months (1st follow up visit) and 6 months (2nd follow up visit). Data obtained was analyzed using SPSS version 21.0 and Microsoft Excel 2013.

Results: Among the 374 respondents, 52.67% were males while 47.33% were females with the mean age of 47.5 years. The mean baseline (pre-intervention) vitamin D levels were found to be 10.3 ng/ml, which raised significantly to 34.3 ng/ml. The mean (pre-intervention) VAS score dropped significantly, from 81.9 at baseline visit to 31.4 at 2nd follow up visit.

Conclusion: It is concluded that vitamin D repletion has a marked impact on reducing the intensity of chronic lower back pain. Future studies may confirm further to validate the findings of this research.

Keywords

Chronic Pain, Lower Back Pain, Vitamin D Deficiency, Vitamin D Repletion & Biochemical Marker.
Introduction

Back pain is the one of the most reported pain followed by headache, burdening healthcare industry globally. Back pain is a clinical scenario with increasing severity of pain reported by patients as the ailment progresses\(^1\&2\).

Lower back pain casts its effects on almost every part of the sufferer’s life including routine activities, internal thinking and emotions, day to day public interactions and general well-being\(^3\&4\). In the developed countries, lower back pain falls within a group of conditions mainly musculoskeletal disorders, which brings about greater functional debilitation among adults than disorders of any other nature\(^3\&4\).

Numerous factors have been deemed responsible in the vast etiology of lower back pain, one among which is low vitamin D levels in the body\(^5\). The belief that chronic lower back may indeed be a result of vitamin D deficiency is strengthened by many instances of co-occurrence of the two conditions, however, further research is required yet to establish a clear causality\(^5\&6\). Deficiency of vitamin D has long been associated with chronic musculoskeletal pain and particularly, pain in the lower back. A heightened incidence (up to eighty-three percent) of vitamin D deficiency is reported among chronic lower back pain sufferers and comparison of vitamin D levels fall short in the general populace\(^5\&6\).

The underlying mechanisms of this correlation remain elusive. In theory, two probable associations have been proposed. The first theory suggests that diffuse pain in bones may be caused by vitamin D deficiency\(^7\). The second theory proposes that vitamin D deficiency may play a part in developing modic alterations by making the vertebral endplates more prone to inflammation\(^8\). Regardless of which theory is more accurate, deficiency of vitamin D eventually contributes to greater chronic lower back pain\(^7\&8\). The condition is particularly worrisome in the Indian subcontinent, where hypovitaminosis is reported from 50% to 90% owing to low dietary intake, dark skin tones and scarce exposure to sunlight\(^7\&8\).

In the face of the easy and large scale availability of numerous pharmacologic agents and just as many corrective interventions (invasive), most patients continue to battle much morbidity due to this condition, ranging from physical debilitation to reduction in health-related quality of life\(^3\). This research is a step forward in the direction, exploring the association of two aforementioned conditions; hypovitaminosis and chronic lower back pain, as the goal through this research is to determine whether correcting vitamin D deficiency by repletion leads to any improvement.

Methodology

This prospective cohort study was conducted upon a sample 374 lower back pain patients presenting with vitamin D deficiency at Indus Medical College, Tando Muhammad Khan (TMK) from February to October 2018. The study was conducted after seeking approval from the Institutional Review Boards & Ethical Review Committee of Indus Medical College. Proper consents were received from each patient before the study they were given the right to withdraw at any time without their care or legal rights being affected by the disagreement.

A pilot study showed that that low vitamin D levels were reported among 57.9% of the subjects. Thus the current sample size (374) was calculated using OpenEpi sample size calculator keeping 95% confidence interval and 5% margin of error.

Patients aged between 18-75 years with chronic (≥ 3 months) lower back pain that is
unresponsive to pharmacologic and physical therapies were included in the sample without observing any gender bias if the pain score was reported to be at least 50 on the VAS. A low plasma 25 Hydroxy-vitamin D3 level (< 30 ng/mL) was a pre-requisite of inclusion.

While patients with a history of diabetic neuropathy or painful conditions resulting from rheumatoid arthritis or patients suffering from symptomatic osteoarthritis of the knee, hip and ankle joint were excluded from the sample. Moreover, patients taking medication like corticosteroids or bisphosphonates, capable of disturbing bone metabolism were also excluded.

Data regarding basic socio-demographic characteristics of the study subjects, history of chronic lower back pain, dietary and medicinal supplement usage, hours of sun exposure and pain levels, was recorded by means of a structured questionnaire. Lower back pain was assessed using a VAS scale. Both vitamin D and VAS score were noted first on the baseline visit to the orthopedic out-patient department and next follow-up visits were planned after 2 (1st follow up visit) months and 6 months (2nd follow up visit).

Vitamin D3 sachet with a dosage of 60,000 IU was administered orally every week for eight weeks to all study participants. Participants with a serum vitamin D level of less than five ng/ml were administered a daily dose of 60,000 IU initially for five days, after which the aforementioned routine induction dosage regimen was followed for the coming eight weeks. Vitamin D levels were assessed prior to administering the induction therapy and again after it completed. Failure to achieve vitamin D level of greater than 29 ng/mL after completion of induction therapy merited that the induction be repeated again.

Those achieving vitamin D levels at par with standards for normal populace after completion of induction therapy were administered a maintenance dose (60,000 IU) once monthly for the coming 4 months. Treatment was brought to a halt after the vitamin D level of the participants rose to a value greater than 60 ng/ml. Data obtained was analysed using SPSS version 21.0 and MS. Excel 2013. Student t-test was used to compare the pre and post intervention VAS pain scores. A p value of less than 0.05 was considered statistically significant. The primary endpoint was a self-perceived drop in back pain below the set stand point of 20 on the VAS score and the secondary endpoint was an increase in vitamin D level above 50 ng/dl.

### Results

Among 374 respondents, 197(52.67%) were males while the remaining 177(47.33%) were females with a mean age of 47.5 years with a majority of the respondents falling within the age group of 46 to 55 years.

| Variable | Sub-category | Males (n=374) | Females (n=374) |
|----------|--------------|--------------|-----------------|
| Gender   |              |              |                 |
|          | Males        | Females      |
|          | Up to 25 years | 3 (0.8) | 0 (0) |
|          | 26 to 35 years | 39 (10.42) | 14 (3.74) |
|          | 36 to 45 years | 30 (8.02) | 64 (17.11) |
|          | 46 to 55 years | 66 (17.64) | 87 (23.2) |
|          | 56 years & above | 59 (15.77) | 12 (3.20) |

*values are given as n(%)
The cumulative mean baseline (pre-intervention) vitamin D levels were found to be 10.84 ng/ml among males and 9.70 ng/ml in females, which was raised significantly after intervention i.e. 30.82 ng/ml in males and 29.3 ng/ml in females observed at 1st follow-up visit while further increase was observed in both genders at the 2nd follow up visit as shown in table 2. The cumulative mean (pre-intervention) VAS score dropped significantly from 74.7 (males) and 89.9 (females) at baseline visit to 30.23 (males) and 32.7 (females) at 2nd follow up visit.

| Parameter          | Pre Intervention | Post Intervention | P-Value |
|--------------------|------------------|--------------------|---------|
| Vitamin D Levels (ng/mL) |                  |                    |         |
| Male               | 10.84            | 30.82              | (p < .05) |
| Female             | 9.70             | 29.3               | (p < .05) |
| VAS Pain Score     |                  |                    |         |
| Male               | 74.7             | 49.52              | (p > .05) |
| Female             | 89.9             | 57.3               | (p < .05) |

*Values indicate mean of the reported variable pre & post intervention in both genders.

Discussion

Our study yielded results that were in line with the underlying hypothesis. Back pain did quantifiably decrease as apparent through the decrease in VAS Pain Score upon repletion of Vitamin D levels among the study subjects. This is synonymous with findings noted in literature9&10, it is reported that the functional abilities and VAS pain score showed significant improvements after Vitamin D supplementation. It can be observed in the results that the incidence of lower back pain peaked during the age when osteoporosis sets in and takes effect (Table 1). The incidence of lower back pain was witnessed more among females as compared to males irrespective of the age group (Table 1) these findings are also supported by previous research which states that the complaints of lower back pain are reported more from female gender11&12.

Another notable observation that can be derived from the results is that women, in general, reported lower mean vitamin D levels across all events of scrutiny (Table 2). The reasons may be that women, mostly women undertake the domestic role, have fewer chances of exposure to direct sunlight and lead less healthy lifestyles with poor dietary intake. Males on the other hand mostly work outdoors and are more exposed to sun and consume more nutritious meals than their counterparts13&14. Additionally, females reported higher VAS Pain Score across all levels in comparison to males. This may be in part due to the lower vitamin D levels (Table 2). The literature, however, contradicts this finding and when our results suggest a lesser pain threshold and a greater tendency among females to feel more pain than their male counterparts, the literature reports that females actually possess a greater pain threshold15&16.

It was also noted that a greater increase in the vitamin D levels was observed (both among males and females) in the 1st follow up visit. It was observed that the Vitamin D level raised up to 184% in males and 202% in females (Table 2). While an additional increase of 17.72% in males and 38.95% in females was observed in the 2nd follow up visit. This finding matches the one that is previously reported in literature i.e. among the patients with inadequate production of Vitamin D in the body, supplemental vitamins aid in enhancing the level of vitamin D in serum17.

As for the pain alleviation, a mean decrease in VAS pain score was observed in both males
and females in the 1st follow up visit (Table 2). After that, an additional decrease in the VAS pain score was (38.95% and 42.9% for males and females respectively) observed at the 2nd follow up visit. An interestingly inferred that pain alleviation per % increase for vitamin D level is more sensitive at higher vitamin D levels than at lower vitamin D levels. This interventional study holds certain limitations. The associated precipitating factors were not monitored. Moreover, there was no control group for comparative analysis that might yield more significant results. Further, these results do not provide a generalized view although the sample size was sufficient but confined to a single region of Pakistan.

**Conclusion**

The current research showed that Vitamin D supplementation is beneficial for patients with chronic lower back pain. Despite of the fact that the study yielded significant results but these findings must be interpreted carefully as it covers only a certain district of Pakistan that does not certify the population effect of Vitamin D supplementation on pain. Expanded descriptive research based on large sample size, differential assessment and diverse study sites must be taken into account for better display of results.

**Conflicts of Interest**

None.

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