

## SUBLINGUAL VITAMIN D<sub>3</sub> DRUG THERAPY IN VITAMIN D DEFICIENCY PATIENTS AT PRAVARA RURAL HOSPITAL

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### ABSTRACT

The present study was aimed to study the effect of Sublingual Vitamin D<sub>3</sub> on Serum Vitamin D level in Vitamin D deficiency patients. This was a cross-sectional and interventional study. All the Vitamin D deficiency patients of age 18-60years and either gender, willing to participate in the study were included. Patients who had greater than 20 ng/ml were excluded from the study. The total number of participants in our study was 200, out of these 111 males and 89 females, the mean age in our study was 51.07 ± 7.39Yrs. All volunteers were given sublingual vitamin D<sub>3</sub> (60,000IU) in six doses every fifteen days of follow up for 3 months. The subject's serum 25(OH)D levels were estimated before and after treatment of sublingual vitamin D<sub>3</sub>. There was statistically significant difference in serum vitamin D<sub>3</sub> level before 16.61±6.71 ng/ml and after 35.80±7.80 ng/ml after treatment with Sublingual Vitamin D<sub>3</sub>. Six doses of 60,000IU of Vitamin D<sub>3</sub> sublingual route having improved role of serum 25(OH)D levels in treatment of Vitamin D<sub>3</sub> deficiency patients.

**Keywords:** Vitamin D<sub>3</sub>; Sublingual route; Serum Vitamin D.

### INTRODUCTION

Vitamin D is involved in regulating the calcium homeostasis and exerts beneficial effects on skeletal health of the bones. Serum concentrations of 25-hydroxyvitamin D (25[OH]D) are measured to assess vitamin D status, which is mainly determined by sunlight (ultraviolet-B [UV-B]) induced vitamin D production in the skin and, to a lesser extent, by dietary or supplemental vitamin D intake [1]. The Institution of Endocrinology Clinical Practice Guidelines pointed out that vitamin D deficiency was defined as a serum 25-hydroxyvitamin D (25-OHD) content less than 20ng/mL (or 50nmol/L) [2].

The epidemic of vitamin D deficiency in India, irrespective of their age, gender, race is likely to significantly contribute to the increasing burden on the healthcare system. Traditional and social taboos often dictate lifestyle patterns such as clothing that may limit sun exposure and vegetarianism which certainly limits vitamin D abundant dietary options. Most Indians are vegetarians, and they are socioeconomically backward people constitute a large percentage of the population in India. The underprivileged generally suffer from overall poor nutrition.

Vitamin D rich dietary sources are limited and unaffordable to most of the Indians. Vitamin D supplements are available, but most Indians are not aware that they need additional vitamin D. Additionally, the cost of these supplements is essentially prohibitive

to the majority. Fortification of staple foods with vitamin D may prove to be a more viable solution towards attaining vitamin D sufficiency in India [3].

Vitamin D is endogenously synthesized in human beings from photoconversion of 7-dehydrocholesterol in the skin to cholecalciferol on exposure to ultraviolet radiation of sun. In a tropical country like India, where sunlight exposure is abundant, vitamin D deficiency seems unlikely. However, as opposed to this, various studies have highlighted that 70-100% Indians in different age groups vitamin D insufficient or deficient [4].

Comparing to commonly used capsules, tablets of oral dosage forms, the sublingual absorption is generally faster and more efficient. The percentage of each dose absorbed is generally higher than that achieved by oral ingestion. To reach a systemic circulation of administered sublingually is reached within 10-15 minutes, which is much faster than when ingested orally [5].

The aim of this paper is to impress upon the practicing physicians in India about the gravity of the vitamin D deficiency problem throughout India, so that they may take necessary caution and care in the diagnosis and treatment of vitamin D deficiency [4].

**Objective:** To study the age-wise distribution of the participants, estimation of serum vitamin D level before and after therapy of sublingual vitamin D<sub>3</sub> drug.

### MATERIAL AND METHODOLOGY

**Study design:** This was an Interventional study

**Ethics approval:** The study was registered in the Clinical Trial Registry of India and the International



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clinical trial registry platform (CTRI/2017/03/008033). Informed consent was taken from the participants.

**Study location:** The study was conducted in collaboration with the Department of Family and General Medicine in Pravara Rural hospital.

**Sample size:** 200 Participants

**Inclusion criteria:** Patients who had less than 20ng/ml of serum 25(OH)D level, patients between 18-60years, and of either sex.

**Exclusion criteria:** Patients taking Vitamin D or Calcium supplements.

**Methodology:** All volunteers fulfilling the Inclusion were given sublingual vitamin D<sub>3</sub> tabulates in 6 doses for 3 months, one tablet (60,000 International Units) every 15 days of follow up. The subject's serum 25(OH) D levels were estimated at the baseline (Before taking into study) and after treatment (End the end of the study). There is no financial burden on patients because this is a sponsored project given by Director of Research (Pravara Institute of Health Sciences and Duram Pharmachem Private Limited (Mumbai).

**Statistical analysis:** Wilcoxon matched-paired test was applied

## RESULTS

**Table 1: Age wise distribution of participants**

Age Groups (Years)	Gender		
	Male	Female	Total
≤ 30	00	02	02
≥ 31- ≤ 40	15	11	26
≥ 41 - ≤ 50	41	26	67
≥ 51 - ≤ 60	55	50	105
Total	111	89	200

**Table 2: Distribution of participants according to estimate of serum Vitamin D3 level**

	serum Vitamin D3 level (ng/ml)	
	Baseline visit	At the end the 6 <sup>th</sup> Follow up visit
Mean ±SD	16.61±6.71	35.80±7.80
Median	15.60	36.00
test	Wilcoxon matched paired test P<0.0001 Significant	

Total number of participants in our study was 200 ,111 males and 89 females, the mean age in our study was 51.07 ± 7.39Yrs., patient with Minimum age was 26.0 Yrs., and Maximum was 60 Yrs. (Table 1)

Significant increase in serum vitamin D level was seen after sublingual vitamin D3 tablets treatment. (Table 2)

## DISCUSSION

Currently, 25(OH)D levels below 20 ng/mL or 50 nmol/L, with resultant consistent increased of Parathyroid hormone and reduction in intestinal calcium absorption, are considered indicative of vitamin D deficiency [6,7]. Our results show age-wise distribution of the total number of participants (Table 1) were 200, 111 males and 89 females, and this results accordance with Qureshi D et al. [8] and Ravinandana et al [9] male 45(73.4%), female 15 (26.6%). the mean age in this study was 51.07 ± 7.39Years this is compared to other research Flojaune et al study [10] mean age was 51.8±4.7 in our minimum study age was 26.0 years similar study Jessica Kendrick et al. [11] study was found 27 years, and Maximum age was - 60 Years comparing another study Thomas Larsen et al. age was 60 years [12].

The reason for the possible difference in the pattern for young and old subjects is uncertain. The higher body mass index in the older group could have had an effect or possibly the liver 25-hydroxylase reached its maximum capacity earlier (that is at a lower precursor concentration) in the older subjects, thus blunting the induced rise in calcidiol. Some other explanations must be sought for the slower rate of decline in the older subjects. Metabolic consumption appears to be slower. By itself, this would have been predicted to lead not only to a slower clearance but to a higher initial concentration as well. so, there is seemingly a need to invoke two differences in the handling of vitamin D between the younger and older ages [13].

Estimated of serum 25(OH)D level according to the participants (Table number : 02) at the baseline it was 16.61±6.71 ng/ml, a significant increase in serum vitamin D level was seen after sublingual vitamin D<sub>3</sub> tablets treatment it was increased to 35.80 ±7.80 ng/ml, this result supported to the Vitamin D sufficiency is defined in terms of the serum level of the prohormone 25(OH)D required for bone health, which is 30 to 32 ng/ml, it maintenance of a 30 to 32 ng/mL serum level requires approximately 2,200 to 3,000 IU/d of vitamin D from all sources, including ultraviolet light exposure, food, and supplements [14-16].

Marium et al studied-on effect of oral Vitamin D in the dose of 60000IU every Two monthly for four months. The mean serum vitamin D before treatment was 27.1±7.7ng/mL, which increased to 42.0±9.1ng/mL, there was a statistically significant increase in serum Vitamin D levels after treatment [13]. A sixteen weeks of study Ryan et al., Vitamin D deficient patients were treated with oral Vitamin D 2000IU daily for three months. There was statistically significant and increased mean serum Vitamin D level from 34.3±2.2 to 100.9±6.6ng/mL [17].

Davide et al studied the effect of oral Vitamin D 2800ID daily dose on hypertensive patients after a period of two months. The mean serum vitamin D levels before treatment was 18.3±2.8ng/ml, which increased to 38.4±3.2ng/ml, which was statistically significant [18]. Similarly, W.R. Chen et al. observed a statistically significant increase in mean serum vitamin D levels from 19.4 ±11.6 to 34.1 ±12.2.3ng/ml after treatment with Vitamin D 2000IU daily for six months [19].

A one month of study Anand Vaidya et al studied in

Vitamin D deficient patients were treated with oral Vitamin D<sub>3</sub> 15,000 IU daily. There was statistically significant increase in mean serum Vitamin D from 16.55± 1.93 to 51.9± 3.1 ng/ml [20].

Miles D. Witham et al randomized clinical trial observed in serum 25(OH) D levels increased from at the baseline level of 18 to 28 ng/ml after treatment of 100000 U of oral cholecalciferol every 3 months for one year [21]. Above the all the studies vitamin D was administered orally daily was given for longer duration whereas, in our study sublingual vitamin D<sub>3</sub>, 60,000 International Units was given every 15 days here the results are showing the increased serum vitamin D level might be the sublingual route of administration of vitamin D<sub>3</sub> is the novelty of our study.

## CONCLUSION

The sublingual route of vitamin D<sub>3</sub> therapy showed the increase of serum vitamin D levels significantly in Vitamin D deficiency patients.

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**Conflict of interest :** Nil

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