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PREVALENCE OF VITAMIN D DEFICIENCY AND TO EVALUATE THE EFFICACY OF VITAMIN D GRANULES 60,000 IU SUPPLEMENTATION IN VITAMIN D DEFICIENT APPARENTLY HEALTHY ADULTS IN URBAN AREAS

Orthopedics

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ABSTRACT

Healthy adults were screened for 25(OH)D by Enzyme linked immunoassay method. Those found to be deficient or insufficient in vitamin D (defined as 25(OH)D <30 ng/ml) were supplemented with oral vitamin D_3 granules 60,000 IU/week for eight weeks. Serum 25(OH)D level was estimated at the end of 8 weeks.

Results: A total of 100 subjects (age 20-50 years) were enrolled for the study. Baseline data and follow up data was available for 90 subjects who consumed a total of eight sachets as per the study protocol. Of these 90 subjects, 91% subjects were found to be vitamin D deficient (<20 ng/ml) , 8.89% were vitamin D insufficient and 0.11% were vitamin D sufficient. The mean plasma vitamin D 25(OH)D level was 12.43 ng/ml (±4.29) at baseline. At the end of the study, the mean 25(OH)D plasma level was noted to be 46.34 ng/ml (±13.57). The mean change from baseline was 23.91 ng/ml (±13.25).

Conclusion: This study showed that vitamin D deficiency is highly prevalent in the urban healthy adult population. Eight weeks of vitamin D3 60,000 IU/week oral granules supplementation increased serum 25(OH) D to optimal levels.

KEYWORDS

Vitamin D, 25(OH) D, cholecalciferol

Introduction:

Vitamin D, the antiricketic factor is a lipid soluble vitamin synthesized inside our body and it functions as a hormone. It is also known as the sunshine vitamin because of its unique property as it synthesized under the skin during exposure of sunlight ultraviolet under irradiation waveband 290 - 315 nm in human [1]. It has major role in "Calcium-Vitamin D-Parathyroid hormone" endocrine axis, calcium homeostasis and bone mineral metabolism [2]. It is now well known for its wide range of functions in the body like cell differentiation, inhibition of cell growth as well as immunomodulator [3-5].

The amount of vitamin D in the blood depends on the production of vitamin D in the skin and intake of vitamin D through the food or vitamin D supplements. But nearly 90% of vit D synthesis occurs in the body through sun exposure depending on factors like latitude, atmospheric pollution, skin colour, coverage of body parts, application of sunscreen lotions, duration and time of exposure to sunlight. Majority of Indian population receive sufficient sunlight throughout the year and hence there was a misconception that Vitamin D deficiency is generally not seen in Indian population [6]. But literature seen in many studies showed that Vit D deficiency is commonly seen in Indian population in different age groups and both the gender. [2,7,8] Approximately one billion people have seen with Vit D deficiency or insufficiency worldwide [9]. In India also, more than 90% of apparently healthy Indians have subnormal D levels [2]. Several studies have shown a high prevalence (50-97%) of vitamin D deficiency in tropical and subtropical regions of India [10-11].

Eventhough majority of the Indian population resides in areas where sunlight is available throughout the year, still vitamin D deficiency is major growing concern [7]. Chronic vitamin D deficiency in adults causes osteoporosis, osteomalacia, muscle weakness,increased risk of falls and bone fractures. Sufficient vitamin D level is important for immune system and deficiency is related to various autoimmune diseases involving the T helper type 1 lymphocyte like type 1 diabetes, systemic lupus erythematosus, psoriasis rheumatoid arthritis etc. Insufficient vitamin D blood levels are also responsible for increased chances of hypertension, myocardial infarction and even can cause death due to cardiovascular problems[12].

The standard commonly used parameter for assessing vitamin D level is serum 25- hydroxyvitamin D, {25(OH) D }concentration. It gives best assessment of vitamin D status as 25(OH)D has a half-life of nearly 21days and is the major circulating metabolite of vitamin D representing vitamin D inputs from cutaneous synthesis and dietary intake[13].

With modernization, excess of the indoor activities and sedentary life style in indian population prevalence of vitamin D is increasing particularly true in the urban population. This study tries to find the prevalence of vitamin D level in the and efficacy of Vit. D granules 60,000 IU supplementation in vitamin D deficiency apparently healthy volunteers.

Aim: To assess the prevalence of vitamin D deficiency in apparently healthy adults in urban population and evaluate the efficacy of Vit. D granules (60,000 IU) supplementation in apparently healthy volunteers with vitamin D deficiency.

Material and Methods

This prospective, open labelled drug study was undertaken on volunteers in outpatient department of orthopaedics, in north Indian government medical institute. The recent Endocrine Society Clinical Practice Guidelines published in July 2011 were considered for classification of vitamin D deficiency. These guidelines define vitamin D deficiency as 25(OH)D level below 20 ng/ml, vitamin D insufficiency as 25(OH)D level at 21-29 ng/ml and sufficiency, if the 25(OH)D level is above 30 ng/ml [14]. The study protocol was approved by the Indian council of medical research and institutional ethical review board. The written informed consent was taken in the local language from all volunteers.

Study Population

100 adult healthy volunteers (age 20-50 years) residing in urban area that may be attendants of the patients, staff, students and other employees were screened for vitamin D deficiency in orthopaedics dept and sent to the Biochemistry laboratory. The subjects were enrolled in the study according to the specified inclusion and exclusion criteria. The study included apparently healthy volunteers having 25(OH) D levels <30 ng/ml and the willing to give written consent. The study excluded children, pregnant and lactating mothers, any acute illness or terminal illness, uncontrolled hypertension or uncontrolled

diabetes, any form of endocrine disorder which could alter the plasma levels of vitamin D or subjects receiving any medicine in the preceding one week.

Study Procedures: Subjects who had 25(OH) D levels less than 30 ng/ml measured by using Enzyme linked Immunoessay (ELISA) method were supplemented with vitamin D 60,000 IU every week for eight weeks to rapid restore vit. D level. Subjects were instructed to consume whole sachet with water on every sunday as per the recommended schedule. Serum vitamin 25(OH)D estimation was repeated after eight weeks. The primary endpoint of this study was to assess the prevalence of vitamin D deficiency in urban healthy adult population and the secondary endpoint was to evaluate the efficacy of oral cholecalciferol 60,000 IU granules in increasing 25(OH)D levels after 8 weeks. Adverse events (AEs) were monitored during the study for safety assessment.

Statistical Analysis:
The data were expressed as means with one standard deviation (SD). Discrete data were expressed as numbers (counts) with percentages (proportions). Vitamin D status (ranking data) was compared between baseline and the follow-up period was analyzed for differences using Wilcoxon sign rank test. Vitamin D levels and change from baseline in vitamin D levels were analyzed for differences in different subgroups gender, age groups using one way ANOVA.

Results:
Even after strict follow-up, out of 100, only 90 subjects consumed all eight sachets of cholecalciferol and completed the study. The compliance was low even after full motivation, probably due to their busy schedule, forgetfulness, other priorities and thereby inability to come for follow up i.e after completion of 8 weeks for second blood sample or it may be because of not knowing the consequences of vit. D deficiency.

The demographic data showed that the number of female subjects were more 56 (62.2%) as compare to number of male subjects i.e 34 (37.7%) . The mean age was 28.65 years (±6.4). Of these, 48 (53.33%) subjects were ≤30 years, 32 (35.55%) were in the age group of 31-40 years and only 10 (11.11%) were in the age group of 40-50 years.

Vitamin D status at baseline is shown in Table 1. The mean plasma 25(OH)D was 12.43 ng/ml (±4.29) and the range was 7.6-27.34 ng/ml. It was observed that most of the subjects 90% were vitamin D deficient and 8.89% were vitamin D insufficient and 0.11% were vitamin D sufficient Table 2. The change in vitamin D plasma levels at follow up was evaluated for 90 subjects (Table 1). The follow-up 25(OH)D mean plasma levels were noted to be 46.34 ng/ml (±13.57) in the range of 25.45 - 78.72 ng/ml. Comparison between baseline and at the end of study shown in figure I &II. The mean change was 33.91 ng/ml (±18.34) (Table 1). There was a nearly 3-fold increase in the 25(OH)D levels with this vitamin D granule formulation without any AEs reported during the study period.

Discussion:
Following increased awareness of vitamin D deficiency among the general population in India, a lot of concern to correct vitamin D deficiency state is going on. High prevalence of varying degrees (50-90%) of Vit D deficiency with low dietary calcium intake in Indian population reported in various studies already published[7,15-18]. Marwaha et al showed that 91.2% subjects of >50 years of age had vitamin D deficiency and 6.8% subjects were vitamin D insufficient [7]. Shah P showed that vitamin D deficiency is highly prevalent in the urban healthy adult population. Eight weeks of vitamin D3 60,000 IU/week oral granules supplementation increased serum 25(OH)D to optimal levels [15]. Malhotra N reported that there is a huge prevalence of hypovitaminosis D in the Indian population, studied the efficacy and safety of oral vitamin D supplementation in apparently healthy adult women. Monthly cholecalciferol given orally, 60,000 IU/month during summers and 120,000 IU/month during winters, safely increases 25-hydroxyvitamin D (25 (OH) D levels to near normal levels [16]. Recent clinical practice guidelines also recommend vitamin D oral supplementation 50,000-70,000 IU/week for eight weeks in vitamin D deficiency to normalize 25(OH)D levels to above 30 ng/ml.. In India, the 60,000 IU granule formulation has been available since many years and is commonly prescribed by physicians across the country in vitamin D deficiency patients. In our study, regular supplementation of vitamin D granules over eight weeks has resulted in increase in plasma vitamin D levels in the subjects. While analyzing the results, it was observed that the subjects had consumed the study drug either with water or with milk. Follow-up and evaluation of regular supplementation for sustained improvement in 25(OH)D levels is needed . Subjects were not on specific diet, lifestyle, sun exposure are some of the limitations in our study.

Conclusion:
It is said that "Prevention is better than cure". This is true for Vit D insufficiency and deficiency which are easily preventable. Monthly oral administration of 60,000 IU cholecalciferol is effective in raising serum 25(OH)D to desired levels (>30 ng/ml).

Table 1 - Change in Vitamin D 25(OH)D Plasma Levels

25 (OH)D	No. of subjects	Mean	SD	95% cl	
Baseline (ng/ml)	90	12.43 ng/ml	± 4.29	10.28	11.95
Follow-up (ng/ml)	90	46.34 ng/ml	±13.57	25.35	29.13
Change (ng/ml)	90	23.91 ng/ml	±18.34	17.96	21.88

Table 2: Vitamin D 25(OH)D Status at Baseline

Plasma vitamin D status No	Number	%
Deficiency (<20 ng/ml)	81	90
Insufficiency (20-30 ng/ml)	8	8.89
Sufficiency (>30-40 ng/ml)	1	0.11

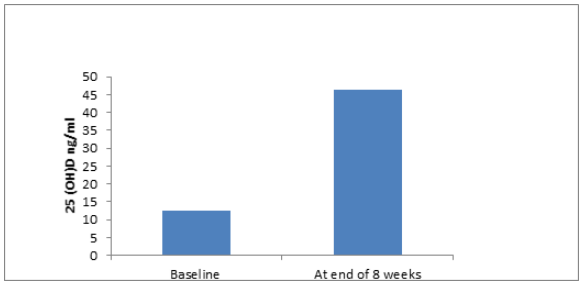

Figure I - Change in 25(OH) D levels during the study

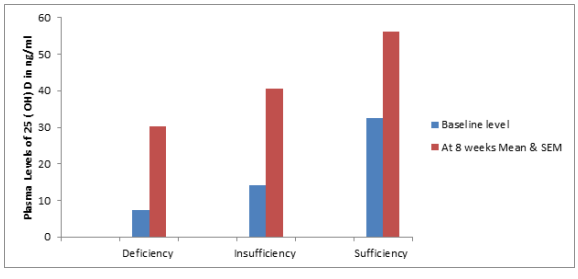

Figure II- Change at different 25(OH) D serum concentration levels during the study

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