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## Research Article

# VITAMIN D DEFICIENCY (VDD) IN CHILD-MOTHER PAIR AND PERIODIC LARGE DOSE SUPPLEMENTATION: EXPLORING A 'SUITABLE' INTERVENTION STRATEGY

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### ABSTRACT

Vitamin D is an essential vitamin known as the sunlight vitamin; it is synthesized in the skin when exposed to the sun's radiation. Vitamin D deficiency causes rickets, osteoporosis, cardiovascular diseases, and diabetes among others. We aimed to evaluate a large bulk dose of vitamin D (600000 IU) to a child and its mother (720000 IU) compared with a lower bulk dose (180000 IU) to both for improving serum 25(OH)D level. This study was a randomized controlled trial. Healthy volunteers i.e. 31 mothers and 30 children were given the above doses at 0-day, and at every 2 months upto 6 months i.e. 4 doses. Face to face interviews of parents of all the children were based on a questionnaire that included variables such as socio demographic information, vitamin D intake and laboratory investigations. Analysis was performed using Stata (Version 11.2). A value of  $p < 0.05$  was considered significant. At the baseline and at 6 months 25-Hydroxyvitamin D, Calcium and Alkaline Phosphatase were measured. The baseline results showed 59% children deficient, 34% insufficient and 7% sufficient. For mothers, 72% were deficient and others insufficient. Mean maternal 25(OH)D concentration was low in both the vitamin D low dose and high dose groups at baseline (15.37 vs 10.32 ng/ml). This is highly significant. We found that both lower bulk dose and higher bulk-dose vitamin D of maternal supplementation provides increased 25(OH)D i.e. more than 20ng/ml over a 187-day period; for children both lower and higher doses were more effective than the mothers.

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## INTRODUCTION

Vitamin D is a fat soluble vitamin and its synthesis in the body is dependent on multiple factors like latitude, atmospheric pollution, skin pigmentation, duration and time of exposure to sunlight. Vitamin D is obtained from sun exposure, vitamin D fortified food and vitamin D supplements<sup>1</sup>. In West Bengal Vitamin D deficiency as determined by low blood level of 25-Hydroxy vitamin D is common both in under five children and their mothers and prevails in epidemic proportions all over the Indian subcontinent with a prevalence rate of 70% -100% in the general population<sup>2</sup>. Vitamin D plays an important role on bone metabolism through regulation of calcium and phosphate homeostasis and may also play an important role in immune system regulation<sup>3</sup>. It is produced by the body during exposure to sunlight, but is also found in oily fish, eggs and fortified food products<sup>4</sup>. In India, consumed food items such as dairy products are rarely fortified with vitamin D. Indian socio

religious and cultural practices do not facilitate sun exposure. Vitamin D deficiency has a bearing not only on Skeletal but also on extraskeletal diseases<sup>2</sup>. It is a significant public health problem globally. It is widespread in all age groups in India inspite of availability of sun shine<sup>5</sup>. Periodic large dose vitamin D supplementation is widely used and is an attractive option. This is similar to the situation in many regions of India. Tests were conducted on families from low socio-economic group (urban poor) from the Metropolitan city of Kolkata. Diet in this population provides little vitamin D or its precursors. Exposure to sunlight is minimal and is avoided by most people in India. Only option to address this health problem is supplementation. In India, fortified food is not possible so vitamin D is obtained only by vitamin D supplements. In this study, we evaluated the dose of vitamin D supplementation to preschool children and their mother and attempted to evaluate the bulk of higher dose and a bulk of lower dose vitamin D supplementation of Indian children and their mothers.

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**METHOD**

**MATERIALS AND METHODS**

Healthy non pregnant women aged 18 yrs or older and their children aged 1 to less than 5 yrs were included in the study. We recruited these children and mothers from the family welfare clinic of Infectious Diseases Hospital outdoor clinic after written informed consent of the mother. They came from the municipal urban communities in the metropolitan city of Kolkata, India. The socio-economic and demographic features of these families are shown in Table 1.

**Table 1** Socio Economic status of the families

Variables	Number (%)
<b>House Type</b>	
House with cement floor, wall & roof	10 (32%)
Lives & cooks in one room	10 (32%)
Currently breast fed	20 (71%)
<b>Mothers Education</b>	
Illiterate	1 (3%)
Can sign only	2 (6%)
1-5 years of school	5 (16%)
6-10 years of school	17 (55%)
>10 years of school	8 (26%)
<b>Fathers Education</b>	
Illiterate	0
Can sign only	1 (3%)
1-5 years of school	5 (16%)
6-10 years of school	15 (49%)
>10 years of school	10 (32%)
<b>Mothers Occupation</b>	
House wife	27 (87%)
Maid servant	3 (10%)
Leather factory	1 (3%)
<b>Fathers Occupation</b>	
Not working	1 (3%)
Driver	4 (13%)
Daily Labor	11 (36%)
Private Company	6 (19%)
Business	9 (29%)
<b>Family income per month</b>	
Rs. Upto 3000/-	3 (10%)
Rs. 3100/- to 5000/-	5 (16%)
Rs. above 5000/-	23 (74%)

The study protocol was approved by the Ethics Review Committee of the Society for Applied Studies. In this study we administered a lower bulk dose and a higher bulk dose of vitamin D (Calcirol Sachet 60,000 IU) supplements orally and randomly assign to vitamin D deficient and insufficient preschool children and their mothers. Only those children and mothers were included in the study whose 25(OH)D blood level was <20 ng/ml. Any one of the mother or child pairs with (baseline) serum 25(OH)D levels <12 ng/ml in Group 1 and the other i.e. one with 25(OH)D levels ≥12 & <20 ng/ml was Group 2. Group 1 child received vitamin D supplements of higher bulk dose of 10 sachets i.e. 600,000 IU and mother received 12 sachets i.e. 720,000 IU. In Group 2 both mother and child received a lower bulk dose of vitamin D (3 sachets) i.e. a total 1,80,000 IU Calcirol sachet at 0 day, 3 months and 6 months respectively.

**Sample Size**

We planned to recruit a total of 30 children and 30 mothers. Assuming 50% positivity for vitamin D deficiency we expected 15 of them in each group to be positive with a confidence interval of 13 to 17 for this sample size.

**Statistical Analysis**

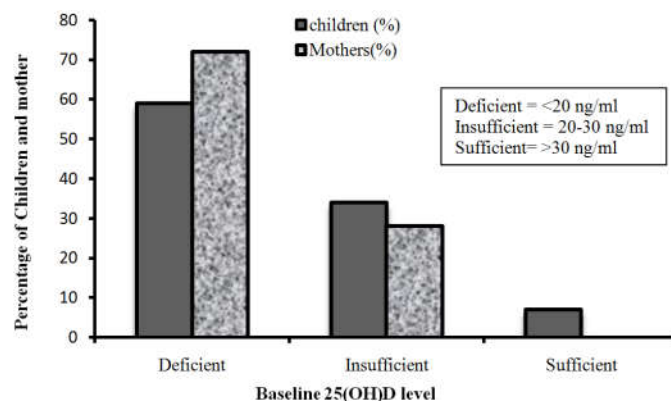
The primary outcome of the children’s vitamin D status was measured by the serum 25(OH)D concentration. Although there is no universal agreement regarding the definition of sufficiency, we considered deficiency as less than 20 ng/ml, insufficiency as 20 to 30 ng/ml and sufficiency as more than 30 ng/ml. The mothers and their children who took high dose vitamin D supplementation were in group1 and those who took a lower dose were in group 2. Group 1 and group 2 were compared at entry into the study to detect potential differences with regard to socio-demographic and baseline characteristics. Data were handled with Excel 2003 (Micro soft Corp) and analyzed with Stata 11.2 software<sup>6</sup>. A paired t test was used to compare normally distributed continuous variables with baseline values within subjects.

**RESULT AND DISCUSSION**

This study was conducted on mother and child pairs from the urban and periurban community of Kolkata, India. A total of 32 mothers and 29 children completed the initial study. Nine mothers and twelve children were excluded because their serum 25(OH)D levels were >20 ng/ml. The remaining 23 mothers and 17 children took vitamin D. Among them 10 mothers and 10 children took high bulk dose vitamin D supplementation (group-1) and 10 mothers and 6 children took low bulk dose vitamin D supplementation (group-2). Among them four mothers and one child lost to follow up and one child’s laboratory test was a failure.

The mean age of all mother was 25.66 yrs (SD 5.4, 95% CI: (23.70 to 27.61)) and children were 29.28 months (SD 12.68, 95% CI: (24.45 to 34.10)). The study children came from a relatively poor community in a metropolitan city in India. The average family income was \$133 per month. Among the study children, 42% families lived only in one room. 29% family members lived cement with floor, wall and the roof pacca house. Seventy four percent mothers and seventy six percent fathers had school education of six years and more.

Only 13% mother had job as a maid servant and all others were house wife. Those not in jobs were indoors most of the time. Twenty three percent mothers told that they did not keep their child in the sunlight because they had no sufficient space for sunlight. Percentage of vitamin D deficiency and insufficiency in mothers were 72% and 28% respectively and higher than children (Fig 1).



**Fig 1** Baseline distribution of 25(OH)D levels in percentage of mothers and children.

Maternal baseline alkaline phosphatase of group-1 was comparatively higher than in group 2. After supplementation alkaline phosphatase was decreased both in group 1 and in group 2 but this is not significant. For children, baseline alkaline phosphatase was higher in group-1 than in group-2. Alkaline phosphatase (13.1) % decreased after supplementation in group-1 and 3.0% decreased in group-2. Sixty nine percent children drank milk within 24 hours and 81% children drank milk within 7days. But 17% mothers drank milk within 24 hours and 34% mothers drank milk within 7 days.

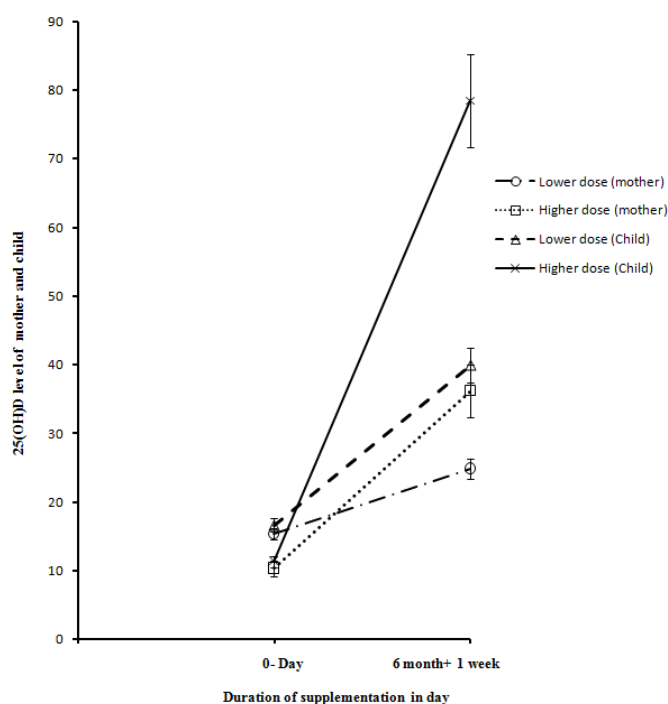
In this pilot study we examined blood vitamin D (25(OH)D) levels of mother child pairs and those with <20 ng/ml were administered two levels of lower bulk dose and higher bulk doses of vitamin D under supervision at start, at three months and at six months. While periodic supplementation was found effective, some children with higher of the two dose regimens showed high blood levels of 25(OH)D, nearly touching the upper comfort level i.e., >150 ng/ml<sup>7</sup>. Acceptance of periodic large dose supplementation was good and no side effect other than the biochemical high level of blood vitamin D concentration in a few children was seen. We compared the effect of a lower bulk dose vs a higher bulk dose vitamin D supplementation in below 5 year children and their mothers with low vitamin D status (Table 2).

**Table 2** Comparison of Metabolic Responses to Lower bulk dose and higher bulk dose vitamin D supplementation

	Lower Bulk Dose Supplementation	Higher Bulk Dose Supplementation
<b>Mother</b>		
<u>Alkaline Phosphatase (U/L)</u>		
Day 0	96.5 ± 36.45 (64-174)	112 ± 27.03 (66-155)
Day 187	82.8 ± 28.38 (45-143)	95.63 ± 26.26 (58-134)
<u>Calcium (mg/dl)</u>		
Day 0	9.36 ± 0.34 (9.1-10.1)	9.21 ± 0.4 (8.6-10)
Day 187	9.16 ± 0.29 (8.8-9.7)	9.13 ± 0.18 (8.9-9.5)
<u>25-Hydroxy Vitamin D (ng/ml)</u>		
Day 0	15.37 ± 2.83 (8.56-18.59)	10.32 ± 3.44 (5.81-15.18)
Day 187	24.89 ± 4.18 (17.91-29.33)	36.16 ± 10.07 (16.26-44.67)
<b>Child</b>		
<u>Alkaline Phosphatase (U/L)</u>		
Day 0	250 ± 91.27 (182-429)	291 ± 98.19 (193-528)
Day 187	242.5 ± 61.6 (177-351)	252.86 ± 48.58 (192-338)
<u>Calcium (mg/dl)</u>		
Day 0	9.73 ± 0.77 (9-11.1)	9.96 ± 0.35 (9.4-10.4)
Day 187	9.32 ± 0.68 (8.4-10.1)	9.74 ± 0.28 (9.3-10.1)
<u>25-Hydroxy Vitamin D (ng/ml)</u>		
Day 0	16.66 ± 2.43 (13.48-19.85)	11.30 ± 2.36 (7.64-16.31)
Day 187	39.95 ± 6.35 (31.63-49.3)	78.49 ± 19.14 (43.24-98.89)

We found that both lower bulk dose and a higher bulk-dose vitamin D of maternal supplementation of 25(OH)D has increased more than 20 ng/ml over a 187-day period. We also observed that in mothers of lower bulk-dose supplementation of 25(OH)D increased but was not sufficient (25(OH)D <30 ng/ml). Again for children, 25(OH)D increased and was sufficient (25(OH)D > 30 ng/ml) in both groups (Fig-2).

Association of Vitamin D deficiency was significant with weight of mother (P=0.012) but this was not so with the children's weight (p=0.644). Vitamin D deficiency has been widely reported in all ages in India<sup>5</sup>.



**Figure 2** Mean 25(OH)D serum level of mothers before and after supplementation of high bulk dose vitamin D (720000 IU) mothers and for children (600000 IU) compared with low bulk dose supplementation of (180000 IU) vitamin D, both in children and mothers.

Periodic supplementation of vitamin D in large doses has been shown to be an effective option. Varied doses have been evaluated and both correction and over correction of deficiency have been reported. High dose periodic therapy regimens with large dose vitamin D3 was shown to cause increased and sustained higher levels of 25(OH)D especially the regimen with a total of 600,000 IU. The therapy is safe and can lead to hypercalcemia only with very high doses. Doses of 1,50,000 to 3,00,000 IU can be effective with less side effects<sup>8</sup>. Our bodies can obtain vitamin D from diet and also make it from sun exposure. Even with these two routes for receiving vitamin D however, inadequate vitamin D is common and deficiencies can be found in all ethnic groups and across all ages, a major concern given the many ways that vitamin D helps to protect our health. There are a number of factors that increase the risk of having inadequate vitamin D; among them are lifestyle, sunscreen use, geographic location, skin tone, age and body weight. There is an urgent need to determine the optimal dose of vitamin D to ensure vitamin D sufficiency in pregnant and lactating women when sun exposure is adequate.

In Conclusion, the preliminary findings suggest that low dose and bulk dose supplementation of child with vitamin D is more effective in children than mothers. Further low dose supplementation of mother had poor response. So we should use a large population in the study to find out how many days vitamin D supplementation will be effective.

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