



Original Research Article

Evaluation of serum Vitamin D₃ level in Vitamin D₃ supplemented 9 to 12 months old children in a tertiary care hospital

Tanmay Mondal¹, Pradip Saha², Sudip Saha^{1,*}

¹Dept. of Paediatrics, Chittaranjan Seva Sadan Hospital, Kolkata, West Bengal, India

²Dept. of Cardiology, Institute of Post Graduate Medical Education and Research, Kolkata, West Bengal, India



ARTICLE INFO

Article history:

Received 04-04-2021

Accepted 16-08-2021

Available online 30-04-2022

Keywords:

Vitamin D3

Electrochemiluminescence immunoassay

Vitamin D deficiency

ABSTRACT

Introduction: Vitamin D deficiency has emerged as a significant public health problem throughout the world. Even in the Indian context, it has been reported to be present in majority of children in spite of wide availability of sunlight. Our objective was to evaluate Serum Vitamin D₃ Level in Vitamin D₃ Supplemented 9 to 12 Months Old Children in a Tertiary Care Hospital.

Materials and Methods: A cross sectional study was conducted in the patients aged 9 months to 12 months attending Out Patient Department and Ward of Tertiary care mother and child hospital, Department of Paediatrics between April, 2019 to March, 2020. Blood sample was collected and analysed by the Electrochemiluminescence Immunoassay (ECLIA) with the help of HITACHI Elecsys Cobas E411 to estimate 25-OH-D level after getting proper consent.

Result: The study done among 100 Vitamin D₃ Supplemented 9 to 12 Months Old Children in a Tertiary Care Hospital resulted standard error 0.0952 and standard deviation 0.9522. The children who had regularly taken vitamin D3 at 400IU/day since birth showed minimum vitamin D3 level at 22.34ng/ml and maximum vitamin D3 level found is 98.18ng/ml with a mean value of 40.67ng/ml that is sufficient.

Conclusion: In our study we have found that if children are given vitamin D3 regularly since birth at 400IU/day the attain desired serum vitamin D3 level irrespective of the brand/preparation.

This is an Open Access (OA) journal, and articles are distributed under the terms of the [Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License](https://creativecommons.org/licenses/by-nc-sa/4.0/), which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprint@ipinnovative.com

1. Introduction

Vitamin D deficiency is a very common nutritional deficiency¹ and also the most common undiagnosed medical conditions in the world. Vitamin-D is a hormone that is active throughout the whole body to regulate calcium and bone metabolism. It also decreases the risk of chronic diseases including auto immune diseases, some malignancies, cardiovascular and infectious diseases. It has been estimated that nearly 1 billion people worldwide have vitamin D deficiency or insufficiency.² In India majority of population lives in areas receiving ample sunlight throughout the year, but still vitamin D deficiency is very

common in all the age groups and both sexes across the country.³⁻⁵ The prevalence of vitamin D deficiency now is 50-90 % in the Indian subcontinent and is attributed to low dietary calcium along with the skin colour and changing lifestyle.³ Vitamin D is deficient in breastfed infants at one end and in older children dietary calcium deficiency at the other end. Between these two extremes, it is likely that vitamin D insufficiency and decreased calcium intake or relatively high phytate intake combine to induce vitamin D deficiency and rickets, which sometimes may be the most frequent cause of rickets globally.⁶ Vitamin D deficiency is defined as serum level of 25(OH)D less than 20ng/dl. It has been estimated the serum 25(OH)D level of 20ng/dl meet the needs of at least 97.5% of entire population across

* Corresponding author.

E-mail address: sudipsaha1973@gmail.com (S. Saha).

all age groups in developed countries.⁷ Hence it has been concluded by INSTITUTE OF MEDICINE (IOM) that 25(OH)D levels >20ng/dL indicates vitamin D sufficiency.⁸ Serum 25(OH)D levels between 12-20ng/ml(30-50nmol/L) as insufficient and <12ng/ml (<30nmol/L) as deficient.⁹ The best available indicators of vitamin D status is 25(OH)D which is the major circulating form of vitamin D with half-life of 2-3 weeks. The recommended vitamin D intake is 400IU/day in infants less than 1 year and 600 IU/day in children more than 1 year of age. (10-12) Post supplementation the level of vitamin D₃ has not been evaluated so far. So, there is immediate need to assess the bio-availability and requirement of vitamin D₃ in children aged at 9 to 12 months.

2. Materials and Methods

It was a cross-sectional study done in the OPD and Ward of a tertiary care hospital between April, 2019 to March, 2020. The study was conducted among 100 children aged between 9 months to 12 months, who have received vitamin D₃ 400 IU/day.

2.1. Exclusion criteria

The patients who are critically sick & hemodynamically unstable or with Known metabolic bone disease or chronic disease known to be associated with bone abnormalities, gut (inflammatory bowel disease, celiac disease), chronic liver disease and metabolic and endocrine diseases or on Concurrent medication which is likely to interfere with vitamin D metabolism (Phenytoin, Phenobarbitone, Carbamazepine, Isoniazid, Rifampicin) and parents not giving consent. After obtaining detailed informed consent, the children were undertaken for study. A pre-designed proforma was filled which included a detailed history, systemic examination, investigations. 4 ml of clotted blood was collected and analysed by the Electrochemiluminescence Immunoassay (ECLIA) with the help of HITACHI Elecsys Cobas E411 to estimate 25-OH-D level. The data were entered into the Microsoft excel enterprise 2007 spreadsheet. The analysis of the available data was done by using IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. 2013.

3. Results and Analysis

100 total children taken for the study of which 47 were male and 53 were Female.

The Table 1 shows that the study done among 100 Vitamin D₃ Supplemented 9 to 12 Months Old Children in a Tertiary Care Hospital resulted standard error 0.0952 and standard deviation 0.9522 The children who were regularly given vitamin D₃ at 400IU/day since birth showed minimum vitamin D₃ level at 22.34ng/ml and maximum vitamin D₃ level at 98.18ng/ml with a mean value of

40.67ng/ml.

The Table 2 shows that among 47 male children mean vitamin D₃ level is 41.29ng/ml where standard deviation is 9.61 and mean standard error is 1.40. Among 53 girl children mean vitamin D₃ level is 40.13ng/ml where standard deviation is 14.08 and standard error is 1.93. Test statistics showed $P > 0.05$, therefore there is no gender preponderance.

The Table 3 shows that the study done among 100 Vitamin D₃ Supplemented 9 to 12 Months Old Children showed mean values does not differ a lot among different age groups.

Vitamin D deficiency is commonly being detected in India as well as worldwide. Studies from various parts of India and among all age groups from neonates to adolescents as well as pregnant and lactating mothers have reported vitamin D deficiency. A study done by V. Jain at the All India Institute of Medical Sciences, New Delhi, revealed 98 infants born at term with appropriate weight aged 2.5 to 3.5 months, revealed that vitamin D deficiency and insufficiency was found to be high in breastfed infants.¹⁰ Another study conducted by Harinarayanan CV & Joshi SR. showed that Vitamin D deficiency is epidemic in India despite of plenty of sunshine.³ Wagner CL et al. showed that Circulating 25-hydroxyvitamin D levels in fully breastfed infants on oral vitamin D supplementation showed mean value of 43.6ng/ml and 42.5ng/ml at the age of 4 months and 7 months respectively.¹¹ In their study as defined by circulating 25(OH) D levels <20 ng/mL, 24 infants out of the 33 infants (72.7%) had evidence of deficiency at one month of age. The change in values between 1 and 4 months and 1 and 7 months was statistically significant ($P \leq .0001$). As predicted, no statistically significant differences were observed between months 4 and 7 ($P = .66$). Repeated measures ANOVA indicated overall significance ($P < .0001$). No toxicity was detected in the infants based on serum calcium, phosphorus, and creatinine levels, neither any adverse health effects were seen with vitamin D supplementation. They concluded that 400IU per day of an oil emulsion vitamin D₃ preparation is effective in raising the infants' levels to the desired target of >30 ng/ml. Infant's 25(OH)D levels consistently and significantly increased to a plateau by three months of therapy on the daily oil emulsion preparation dispensed as 400IU per day. Overall, the infant's circulating 25(OH)D levels increased 37% above baseline. It is not surprising that the infants who are almost solely dependent on the mother for their vitamin D have corresponding deficiency. Their findings in that study support the recent recommendation of starting vitamin D supplementation in all breastfed infants within the first few days after delivery. The 400IU/day dose was adequate in helping the infant maintain adequate vitamin D status during the six-month study period. This result correlates with our study which has shown mean

Table 1: Descriptive Statistics of age and vitamin D3. N= 100

	N Statistic	Minimum Statistic	Maximum Statistic	Mean Statistic	Std. Error Std. Error	Std. Deviation Statistic
Age in months	100	9.0	12.0	10.320	.0952	.9522
Vitamin d3 level	100	22.34	98.18	40.6797	1.21489	12.14892
Valid N (listwise)	100					

Table 2: Sex wise distribution of vitamin d3. N=100

Gender	Number	Vitamin d3 level (mean value)	Std. Deviation	Std. Error mean	Test statistics
Male	47	41.2917	9.61888	1.40306	T=0.473 Df=98
Female	53	40.1370	14.08953	1.93535	P>0.05(0.638)

Table 3: Distribution of vitamin d3 in the study according to age

Age grade Vit D level	Mean	N	Std. Deviation	Std. Error of Mean	Range
9 months age	41.8786	22	10.16069	2.16627	42.44
10 months age	42.6797	36	11.31673	1.88612	59.48
11 months age	37.6037	30	14.14733	2.58294	75.84
12 months age	40.1717	12	12.41245	3.58317	38.13
Total	40.6797	100	12.14892	1.21489	75.84

value of 40.67. In our study 100 children were included; among them 47 are boys and 53 girls who uninterruptedly had taken D3 supplementation. In our study the children who regularly took vitamin D3 at 400IU/day since birth showed minimum vitamin D3 level at 22.34ng/ml and maximum vitamin D3 level at 98.18ng/ml with a mean value of 40.67ng/ml that is sufficient. In the recent past the recommendation for vitamin D supplementation regarding infants was 200 IU/daily, the dosage was calculated based on the evidence that 200 IU/d allows to keep the level of 25(OH) D on the level of 11ng/ml.¹² However, in connection with recent knowledge of normal vitamin D status, the recommendation was revised. The recommended vitamin D intake is 400IU/day in infants less than 1 year and 600 IU/day in children more than 1 year of age.^{7,13,14}

4. Conclusion

Vitamin-D as a hormone is active throughout the whole body to regulate calcium and bone metabolism. Various studies at different times revealed poor Vitamin D status irrespective of age, sex, and geography. Vitamin D concentration in breast milk is low and inadequate for the needs of the growing infant. 400 IU of vitamin D has been shown to maintain serum 25(OH)D concentrations at approximately around 50 nmol/L in breastfed infants. Thus, for all new-borns, 400 IU of vitamin D supplementation is recommended up to one year of age; it is also recommended, that supplementation should be started in the first few days of life.

In our study we have found that if children are given vitamin D3 regularly since birth at 400IU/day they attain

desired serum vitamin D3 level irrespective of the brand or preparation. It would have been better study if we could have done a double blinded randomised control trial between two groups of children, one group without vitamin D₃ Supplementation and another group with vitamin D₃ Supplementation subject to ethical clearance.

5. Sources of Funding

No financial support was received for the work within this manuscript.

6. Conflicts of Interest

No conflicts of interest.

References

- Holick MF. Vitamin D: extraskeletal health. *Rheum Dis Clin North Am.* 2012;38(1):141–60. doi:10.1016/j.rdc.2012.03.013.
- Holick MF. Vitamin D deficiency. *N Engl J Med.* 2007;357(3):266–81. doi:10.1056/NEJMra070553.
- Harinarayanan CV, Joshi SR. Vitamin D status in India -Its implications and remedial measures. *J Assoc Physicians.* 2009;57:40–8.
- Marwaha RK, Sripathy G. Vitamin D and Bone mineral density of healthy school children in northern India. *Indian J Med Res.* 2008;127(3):239–44.
- Harinarayan CV. Prevalence of vitamin D insufficiency in postmenopausal south Indian women. *Osteoporos Int.* 2005;16(4):397–402. doi:10.1007/s00198-004-1703-5.
- Pettifor JM. Nutritional rickets: deficiency of vitamin D, calcium or both? *Am J Clin Nutr.* 2004;80(6):1725–9. doi:10.1093/ajcn/80.6.1725S.
- Ross AC, Manson JE, Abrams SA, Aloia JF, Brannon PM, Clinton SK, et al. The 2011 report on dietary reference intakes for calcium and vitamin D from the Institute Of Medicine: What

- clinicians need to know? *J Clin Endocrinol Metab.* 2011;96(1):53–8. doi:10.1210/jc.2010-2704.
8. Gordon CM, De Peter K, Feldman HA, Grace E, Emans SJ. Prevalence of vitamin D deficiency among healthy adolescents. *Arch Pediatr Adolesc Med.* 2004;158(6):531–7. doi:10.1001/archpedi.158.6.531.
 9. Munns CF, Shaw N, Kiely M, Specker BL, Thacher TD, Ozono K, et al. Global consensus recommendations on prevention and management of nutritional rickets. *J Clin Endocrinol Metab.* 2016;101(2):394–415. doi:10.1210/jc.2015-2175.
 10. Jain V, Gupta N, Kalaivani M, Jain A, Sinha A, Agarwal R, et al. Vitamin D deficiency in healthy breastfed term infants at 3 months & their mothers in India: Seasonal variation & determinants Indian. *J Med Res.* 2011;133(3):267–73.
 11. Wagner CL, Howard C, Hulsey TC, Lawrence RA, Taylor SN, Will H, et al. Circulating 25-hydroxyvitamin d levels in fully breastfed infants on oral vitamin d supplementation. *Int J Endocrinol.* 2010;p. 235035. doi:10.1155/2010/235035.
 12. Misra M, Pacaud D, Petryk A. Vitamin D deficiency in children and its management: review of current knowledge and recommendations. *Pediatrics.* 2008;122(2):398–417. doi:10.1542/peds.2007-1894.
 13. Aloia JF. The 2011 report on dietary reference intake for vitamin D. Where do we go from here? *J Clin Endocrinol Metab.* 2011;96(10):2987–96. doi:10.1210/jc.2011-0090.
 14. Heaney RP, Holick MF. Why the IOM recommendations for vitamin D are deficient. *J Bone Miner Res.* 2011;26(3):455–67. doi:10.1002/jbmr.328.

Author biography

Tanmay Mondal, Senior Resident

Pradip Saha, Assistant Professor

Sudip Saha, Associate Professor

Cite this article: Mondal T, Saha P, Saha S. Evaluation of serum Vitamin D₃ level in Vitamin D₃ supplemented 9 to 12 months old children in a tertiary care hospital. *Panacea J Med Sci* 2022;12(1):73-76.