ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 9, Issue, 10, pp.59879-59881, October, 2017

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

EFFECTS OF ANNUAL ONE SINGLE MEGA-DOSE VITAMIN-D BY PARENTERAL ROUTE AS VITAMIN-D SUPPLEMENTATION A PROSPECTIVE INTERVENTIONAL STUDY

***,[1]Gokhale, S. G. and [2]Gokhale, S.**

[1]Department of Pediatrics and Neonatology, Rajhans Hospital and Research Center, Saphale, India, 401102
[2]Director- Neuro ICU, BANNER -UNIVERSITY MEDICAL CENTER, UA College of Medicine, 1501, N Campbell Avenue, TUCSON AZ 85724

ARTICLE INFO

Article History:
Received 16th July, 2017
Received in revised form
22nd August, 2017
Accepted 04th September, 2017
Published online 31st October, 2017

Key words:

Vitamin-D deficiency,
Annual Mega Dose
Therapy Variable Responses
Genetic Factors.

ABSTRACT

Objective: Vitamin- D deficiency is very common and various modalities are suggested to treat the same. Annual Single dose of Vitamin-D is one of the few options tested by some authors. Here we present reports of our Annual Single Mega-dose of Vitamin-D injection as Supplementation Therapy. Type of study-This was a prospective interventional study.
Design: This was open, uncontrolled dose finding design. Participants- 18 Women participated in study. Vitamin-D Doses- All these participants received one single mega-dose of 600,000 IU by intramuscular route. Final blood sampling was done one year after the mega-dose.
Results: All those with Vitamin-D levels more than or equal to 50 nanograms/ml in Last/ final sampling were grouped as 'YES' response candidates. Out of 18 participants; 11/18 or 62% showed Vitamin-D levels more than 50nanograms/ml. Both groups were at par in terms of all parameters like Base line Hemoglobin and Vitamin-D levels, BMI, Age and Parity.
Conclusion: In our series all participants of Indian Ethnicity had good vitamin-d levels to start with but one single megs-dose failed to maintain it for one year in all subjects again pointing to prominent role of genetic factors in Calcium and Vitamin-D metabolism.

Citation: Gokhale, S. G. and Gokhale, S. 2017. "Effects of annual one single mega-dose vitamin-D by parenteral route as vitamin-d supplementation a prospective interventional study", *International Journal of Current Research*, 9, (10), 59879-59881.

INTRODUCTION

Vitamin- D deficiency is very common and various modalities are suggested to treat the same. Food fortification, modifying life style etc have their own pros and cons and then overall benefits are of limited value. Pharmacological interventions like Vitamin-D supplementations are advocated and tried. Different patterns of treatment have been tried, patient compliance being a major factor. Annual Single dose of Vitamin-D is one of the few options tested by some authors. Here we present reports of our Annual Single Mega-dose of Vitamin-D injection as Supplementation Therapy.

Study and Results

18 participants whose vitamin-D levels were more than 50nanograms/ml were enrolled for this project. This was an active interventional project from November 2014 to December 2016. Age ranged from 19-49 years. Blood samples for VitaminD/ Hemoglobin estimations were collected by peripheral venepuncture. Hemoglobin was estimated by standard Drabkin's Reagent Method. Vitamin D (25OH D) - estimations were performed with LCMSMS-Liquid Chromatography Tandem Mass Spectrometry. All these participants received one single mega-dose of 600,000 IU by intramuscular route. Final blood sampling was done one year after the mega-dose. All those with Vitamin-D levels more than or equal to 50 nanograms/ml in Last/ final sampling were grouped as 'Good' response candidates. Out of 18 participants; 11/18 or 61% showed Vitamin-D levels more than 50nanograms/ml (Good Response) and 7/18 or 39% had vitamin-D levels lower than 50nanograms/ml (Poor Response) Both groups were at par in terms of all parameters like Base line Hemoglobin and Vitamin-D levels, BMI, Age and Parity.

DISCUSSION

In this project at the time of enrolment, all members had normal serum levels of vitamin-D; and had received one megadose as maintenance dose. It has been noted that a single dose *o*f 600,000 IU of cholecalciferol rapidly enhances 25(OH)-D with vitamin D deficiency (Cristiana Cipriani *et al*., 2010; Malcolm *et al*., 2014). In a series of Australian Participants (Terrence H Diamond *et al*., 2005) one single

Corresponding author:* **Gokhale, S. G.
Department of Pediatrics and Neonatology, Rajhans Hospital and Research Center, Saphale, India, 401102

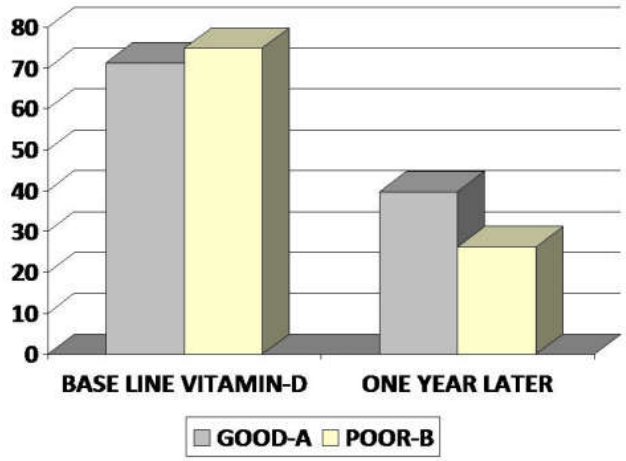

Table. Comparing our series with other two

ATTRIBUTE	OUR SERIES	DIAMOND [3]	GOSWAMI [5]
PARTICIPANTS -ETHNICITY	INDIAN	AUSTRALIANS	ASIAN INDIAN
GEOGRAPHIC LOCATION	INDIA	AUSTRALIA	UK
FIRST VITAMIN-D	6.5 to 19.03 NG/ML OR 16.5-47.5 NM/L	ALL WERE DEFICIENT IN VIT-D	13.5 NM/L- MEAN LEVEL
DEFICIENCY CORRECTED	18,00,000 IU- CORRECTIVE DOSES	NO SUCH DOSES GIVEN	NO SUCH DOSES GIVEN
VIT-D AFTER CORRECTION	136-235 NM/L –AT 180 DAYS		
BASE LINE VITAMIN-D	**136 TO 235 NM/L**	**<12.5 to 49 NM/L**	**13.5 NM/L**
MAINTENNACE DOSE GIVEN	600,000 IU ONE INJECTION	600,000 IU ONE INJECTION	60K /WEEK FOR 8 WEEKS
VIT-D ONE YEAR LATER	55-117 NM/L-	60-86 NM/L- AT ONE YEAR	24.7NM/ML AT ONE YEAR
CORRECTIVE DOSES	GIVEN 1,800,000 IU	----------	----------
MAINTENNANCE	GIVEN 600,000	GIVEN 600,000 IU	DOSING ALL INCLUSIVE
TOTAL DOSE	24,00,000 IU	600,000 IU- ONE INJECTION	480,000 IU ONLY ORAL
STATUS AFTER ONE YEAR	62% =70-117 , 32%=50-77 NM/L VIT-D LEVEL	60-86 NM/L- AT ONE YEAR	24.7 NM/ML
REMARKS	ERRATIC AND UNPREDICTABLE RESPONSES	600K IU/YEAR IS EFFECTIVE	INSUFFICIENT DOSES?

mega-dose of Vitamin-D not only corrected baseline deficiency but helped in maintaining the serum levels for one year. However, in studies recruiting Asian Indians (Dange and Patil, 2015; Goswami *et al*., 2008), the response was not satisfactory. We had results comparable to this from our earlier studies (Sanjay *et al*., 2017). Similar to this, in this series of ours; all participants of Indian Ethnicity had good vitamin-d levels to start with but one single megs-dose (all of them had received corrective doses) failed to maintain it for one year in all subjects (Table) again pointing to prominent role of genetic factors in Calcium and Vitamin-D metabolism.

- VITAMIN-D BINDING PROTEIN--We had not done any such genetic studies but it is known that Vitamin D-binding protein is coded by Genes like TT, TK or KK. It has been shown that increments in serum 25(OH) D in response to treatment depend on the heritability/ genotype of vitamin D-binding protein carried by the individual. KK genotype shows highest increments followed by TK and then last on list is TT variant (Sanjay *et al*., 2017; Fu *et al*., 2009). This may explain the variability or low levels in spite of good dosing.
- 'HIGH 24-25 HYDROXYLASE ENZYME ACTIVITY'--24-25 Hydroxylase enzymes convert active 25-OH-D to inactive 24-25- OH-D. It is postulated that Indians have higher 24-25 Hydroxylase activity, which is also been proved in laboratory using tissue culture techniques (Sanjay Fu *et al*., 2017; Awumey Fu *et al*., 1998). This may again explain poor response in spite of good doses.
- Probably there few other genetic factors as well. Studies in Twins have confirmed role of genetic factors in determining bone resorption and formation, calcium excretion, and the hormones regulating these processes (Fu *et al*., 2009; Hunter *et al*., 2001). Can this be an adaptation, or an evolutionary change to prevent excessive levels of vitamin-D?

REFERENCES

Awumey EM, Mitra DA, Hollis BW, *et al*. 1998. Vitamin D metabolism is altered in Asian Indians in the southern United States: a clinical research center study *J Clin Endocrinol Metab*., 83:169-173

Cristiana Cipriani, Elisabetta Romagnoli, Alfredo Scillitani 2010. Effect of a Single Oral Dose of 600,000 IU of Cholecalciferol on Serum Calciotropic Hormones in Young Subjects with Vitamin D Deficiency: A Prospective Intervention Study *J Clin Endocrinol Metab*., 95: 4771–4777.

Dange, S. V. and S. H. Patil, 2015. Study of Effect of Two Dosage Regimens of Vitamin D in Obese, Vitamin-d Insufficient Adults-The Indian Practitioner Volume 68, Issue 12.

Fu L, Yun F, Oczak M, *et al*. 2009. Common genetic variants of the vitamin D binding protein (DBP) predict differences in response of serum 25-hydroxyvitamin-D (25(OH)) to vitamin D supplementation *Clin Biochem*., 42:1174-1177.

Goswami R, Gupta N, Ray D, Singh N, Tomar N. 2008. Pattern of 25-hydroxy vitamin D response at short (2 month) and long (1 year) interval after 8 weeks of oral supplementation with cholecalciferol in Asian Indians with chronic hypovitaminosis D *Br J Nutr*., Sep; 100(3):526-9. doi: 10.1017/S0007114508921711. Epub 2008 Feb 6. PMID: 18252022

Hunter D, De Lange M, Snieder H, MacGregor AJ, Swaminathan R. 2001. Genetic contribution to bone metabolism, calcium excretion, and vitamin D and parathyroid hormone regulation *J Bone Miner Res*., Feb; 16(2):371-8. PMID: 11204437

Malcolm D. Kearns, Jessica A. Alvarez, Vin Tangpricha Large, Single-Dose, 2014. Oral Vitamin D supplementation in adult populations: A systematic review, *Endocr Pract*., 20(4): 341–351. doi:10.4158/EP13265.RA.

Sanjay G. Gokhale and Sankalp Gokhale, 2017. Effect of Two High Dose vitamin D by parenteral route in treating vitamin D Deficiency -a prospective interventional study, *The Journal of Maternal-Fetal & Neonatal Medicine*, https://doi.org/10.1080/14767058.2017.1338257

Sanjay G. Gokhale and Sankalp Gokhale, 2017. Poor responders- four mega-doses in treating vitamin-d deficiency and variable outcomeprospective interventional study, *Am J Ther*., doi: 10.1097/MJT.0000000000000636 (Epub ahead of print) PMID: 28857761

Terrence H Diamond, Kenneth W Ho, Peter G Rohl and Matthew Meerkin, 2005. Annual intramuscular injection of a mega-dose of cholecalciferol for treatment of vitamin D deficiency: efficacy and safety data MJA -Volume 183 Number 1- 4.

****