

Multi-Pronged Strategy to combat Vitamin D deficiency in India

C Ramachandran Memorial Lecture

by

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Introduction

- Vitamin D is an important hormone necessary not only for maintaining calcium balance and safeguarding skeletal integrity but also essential for overall health and well being.
- Primarily acquired by exposure to sunlight.
- Food articles commonly consumed by Indians do not provide adequate vitamin D.
- No food articles are adequately fortified in India.
- The most sensitive index in assessing vitamin D status is 25(OH)D
- Nutritional rickets and vitamin D deficiency continues to exist as a major health problem in India.

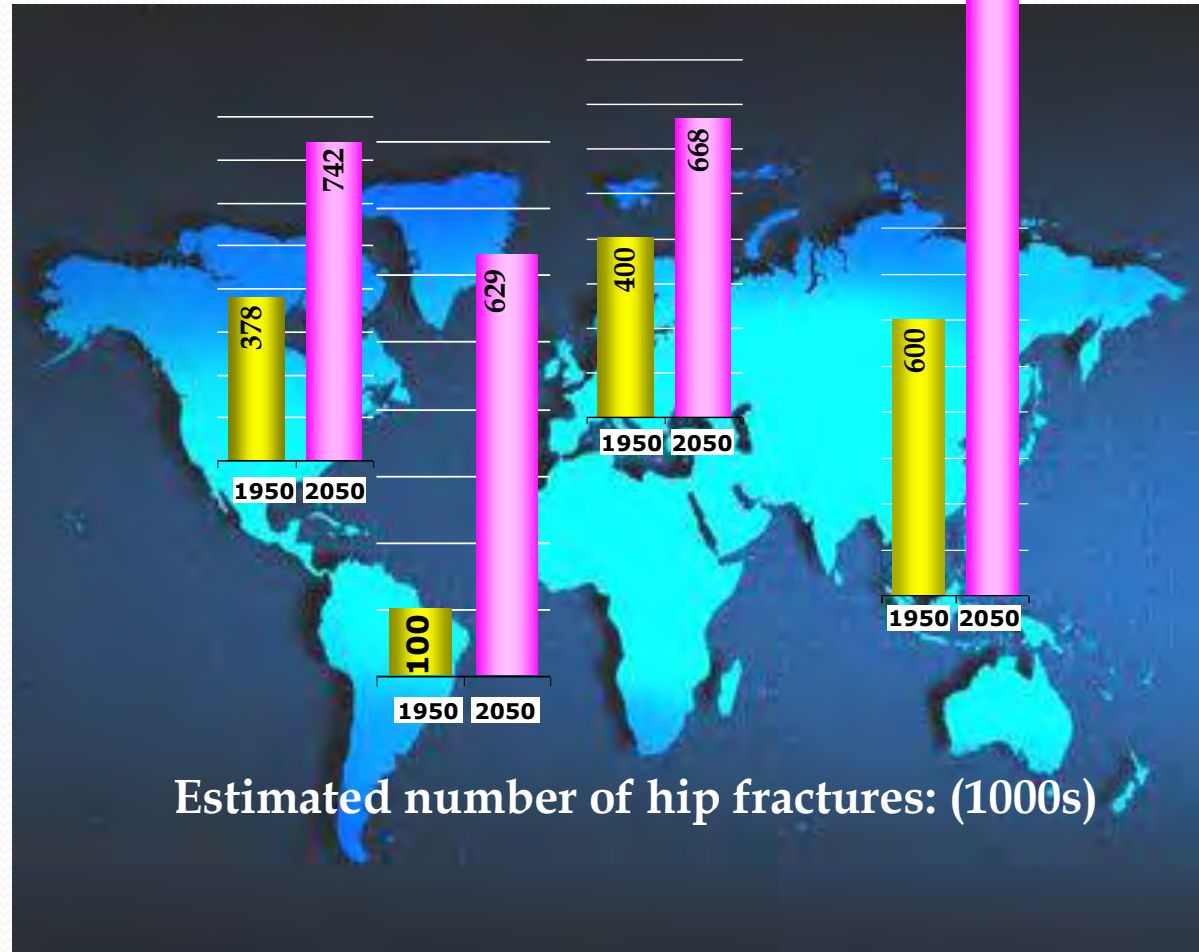
Why Sound Bone Health?

- Poor bone health is responsible for causation of 8.9 million Fractures annually worldwide.
- Life time risk for hip, vertebral and wrist fracture is 30-40%.
- High morbidity and mortality associated with osteoporotic fractures.

Projected Number of Osteoporotic Hip Fractures Worldwide

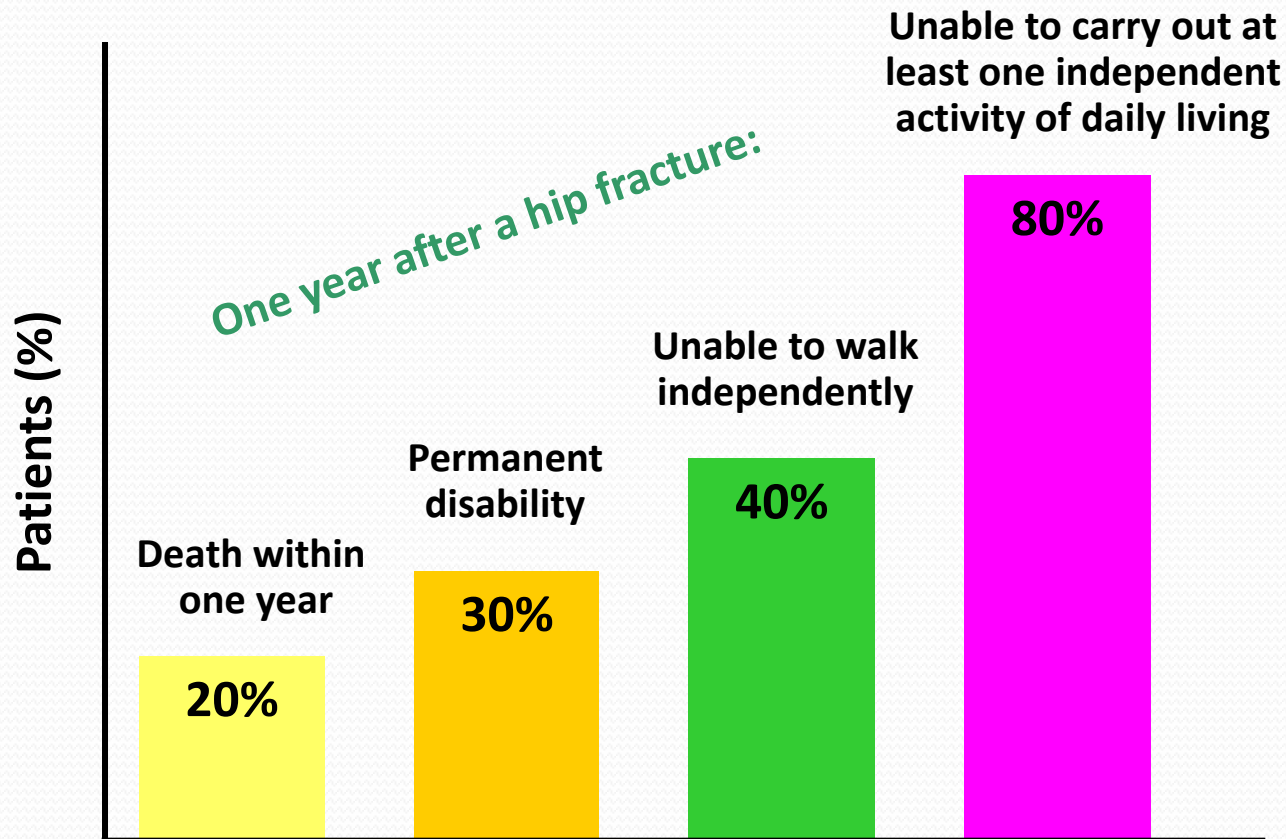
Projected to reach 3.250 million in Asia by 2050

Total number of hip fractures:
1950 = 1.66 million
2050 = 6.26 million



Estimated number of hip fractures: (1000s)

All Fractures are Associated with Morbidity



Should we bother about serum
vitamin D levels?

Adverse effects of Vitamin-D Deficiency

Vitamin D deficiency/insufficiency in Pregnancy & Lactation:

- Adverse maternal outcomes like Osteomalacia and Preeclampsia
- Lower birth weight
- Lower crown heel length, head circumference and mild arm circumference
- Low bone mass
- Poor/ delayed Growth
- Rickets in utero/ at birth
- Tetany
- Neonatal hypocalcemic seizures
- Abnormal enamel formation and dental caries

ADVERSE EFFECTS OF VITAMIN D DEFICIENCY

Children and adolescents:

- Poor growth velocity
 - Rickets
 - Short stature
 - Low bone mass
 - Genu Varum (*Bow legs*)
 - Genu Valgum (*Knock knees*)
- ?Respiratory viral infections (including swine flu)

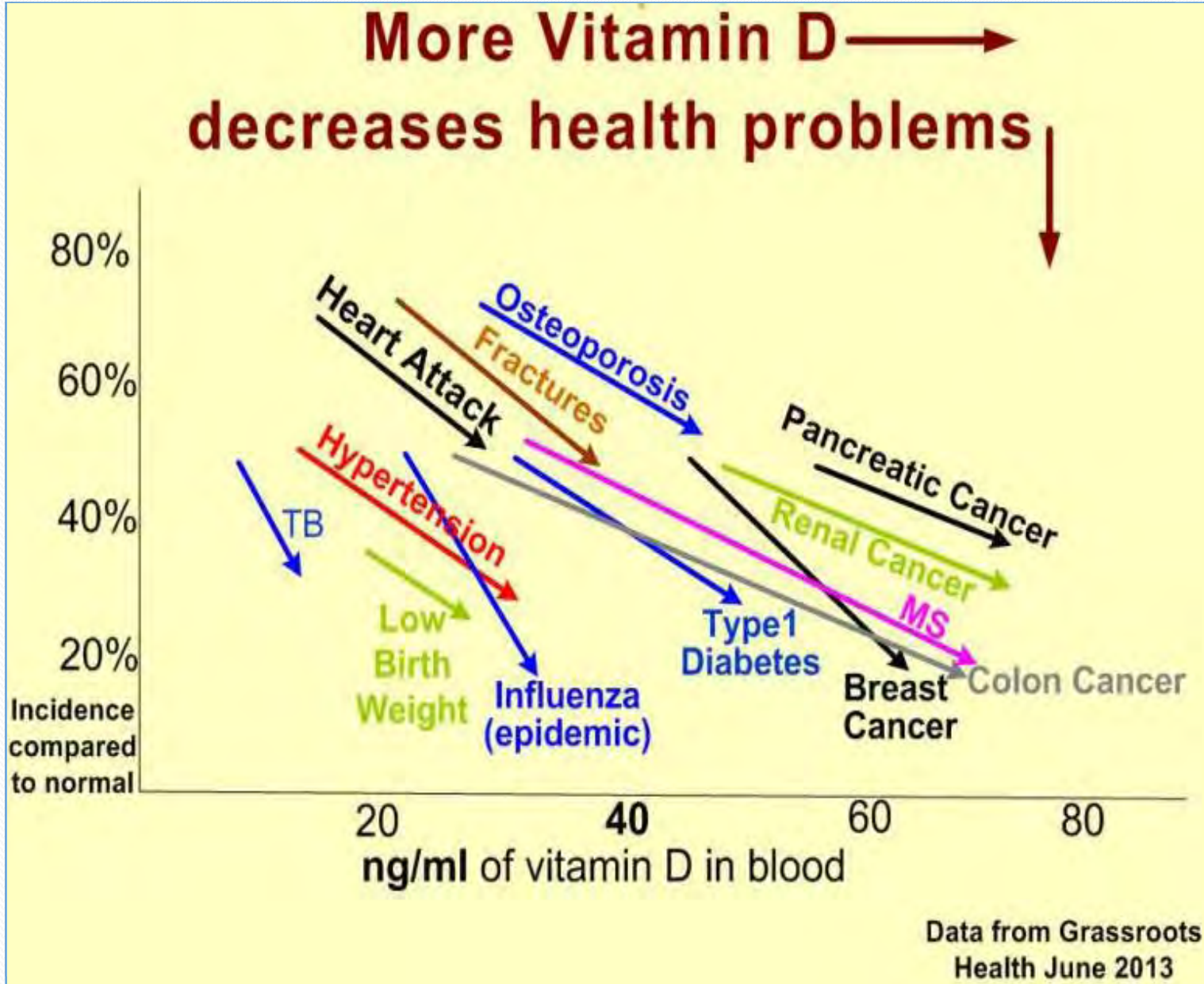
Adult & old age:

- Muscle pain & fatigue
 - Osteomalacia
 - Osteoporosis
 - Hip, Spine, Forearm and other fractures.
- ?Increase prevalence of autoimmune disorders, cardiovascular diseases, skin disorders, cancers and infections.

Extra-skeletal Benefits

- It is a potent immune system modulator and prevents development of **autoimmune disorders and** respiratory infections **like influenza virus**
- It inhibits uncontrolled proliferation and stimulates differentiation of cells thereby **preventing common cancers and skin disorders.**
- Plays a role in **insulin secretion** under conditions of increased insulin demand and **increases insulin sensitivity.**
- Decreases cardiovascular mortality

Vitamin D- Published Strength of Evidence



WHY DO I CALL IT A
WONDER VITAMIN?

Vitamin D: A New Promising Therapy for Congenital Ichthyosis.

Sethuraman G¹, Marwaha RK², Challa A³, Yenamandra VK³, Ramakrishnan L⁴, Thulkar S⁵, Sharma VK³.

Author information

Abstract

Severe vitamin D deficiency and rickets are highly prevalent among children with congenital ichthyosis. We report an incidental observation of a dramatic and excellent clinical response with regard to skin scaling and stiffness in children with congenital ichthyosis after short-term high-dose vitamin D supplementation that has not been previously described. Seven children with congenital ichthyosis (5 with autosomal recessive congenital ichthyosis; 2 with epidermolytic ichthyosis) and severe vitamin D deficiency (and/or rickets) were given 60,000 IU of oral cholecalciferol daily for 10 days under supervision. All children were subsequently put on recommended daily allowance of 400 to 600 IU of cholecalciferol. The main outcome measures observed and studied were reduction in skin scaling and stiffness of the extremities. All cases had severe vitamin D deficiency (serum 25-hydroxyvitamin D < 4 ng/mL) and secondary hyperparathyroidism. Six patients had clinical and radiologic evidence of rickets. Significant improvement in scaling was noticeable by day 5, showing further improvement by day 10, in 6 of the 7 cases. At 1 month, the skin had become near normal in all the cases of autosomal recessive congenital ichthyosis. Remarkable reduction in stiffness was also observed in all children. Supplementation with high-dose vitamin D followed by recommended daily allowance appears to be an effective form of therapy in the management of congenital ichthyosis with vitamin D deficiency.

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Hypovitaminosis D and hypocalcemic seizures in infancy

Mehrotra P, Marwaha RK, Aneja S, Seth A, Singla BM, Ashraf G, Sharma B, Sastry A, Tandon N.

BACKGROUND:

Hypocalcaemia accounts for a majority of seizures in infants reporting to the emergency ward of our hospital.

OBJECTIVE:

To evaluate the role of Vitamin D deficiency in the etiology of hypocalcemic seizures in infancy.

DESIGN AND SETTING:

Cross sectional hospital based study, from April 2006-March 2007.

SUBJECTS:

60 infants with hypocalcemic seizures and their mothers (study group) and 60 healthy breastfed infants with their lactating mothers (control group).

MEASUREMENTS:

Vitamin D [25(OH) D] and intact para-thormone levels.

Conclusion

- Infants born to vitamin deficient mothers are at a significantly higher risk of developing hypocalcemic seizures.

Effect of vitamin D supplementation on muscle energy phospho-metabolites: a ^{31}P magnetic resonance spectroscopy-based pilot study

2014, Vol. 39, No. 4, Pages 152-156 (doi:10.3109/07435800.2013.865210)

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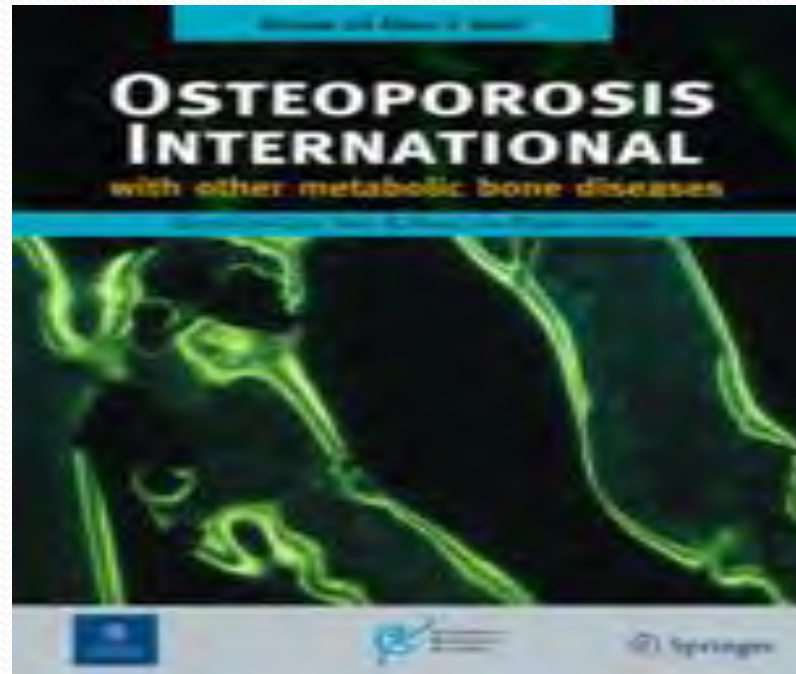
³BR Sur Homeopathy Medical College, Delhi, India

- There is scarcity of data on the effect of vitamin D deficiency (VDD) on muscle energy metabolism
- The study recruited 19 healthy subjects with low serum 25(OH)D levels (<5 ng/mL)
- Subjects supplemented with cholecalciferol at a dose of 60,000 IU/week for 12 weeks
- Prevalence of low phosphocreatine/inorganic phosphate (PCr/Pi) ratio and high phosphodiester (PDE) values in normal Indian population may be attributed to vitamin D deficiency
- Serum 25(OH)D level plays an important role in improving the skeletal muscle energy metabolism

Results & Conclusion

- Significant improvement in PCr/Pi ratio ($p=0.01$) and marked reduction of PDE/ATP ($p=0.04$) and Pi/ATP (0.04) based on ^{31}P MRS after 12 wks of vitamin D supplementation was observed.
- These results indicate serum 25 (OH)D level plays an important role in improving the skeletal muscle energy metabolism.

BONE HEALTH IN HEALTHY INDIAN POPULATION AGED 50 YEARS AND ABOVE



Marwaha R K et al. Osteoporosis International 2011; 22, 2829-36

Original Article

**Establishment of Age-Specified Bone Mineral Density Reference
Range for Indian Females Using Dual-Energy X-Ray
Absorptiometry**

*Raman K. Marwaha,*¹ Nikhil Tandon,² Parjeet Kaur,² Aparna Sastry,¹ Kuntal Bhadra,¹
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Comparison of reference NHANES III and Hologic reference standards with Indian Standards

Reference	Sex	Total Hip	Forearm	Lumbar Spine
NAHANES III	Male	1.041±0.144	----	----
	Female	0.942±0.122	----	----
HOLOGIC	Male	----	0.679±0.054	1.121±0.110
	Female	----	0.564±0.051	1.084±0.111
INDIANS	Male (404)	0.988±0.131	0.611±0.052	0.976±0.105
	Female (404)	0.901±0.111 P < 0.01	0.538±0.044 P < 0.001	0.954±0.095 P < 0.001

Comparison of mean BMD values in Healthy & apparently healthy Indian Males

(20- 30 yrs)

	Jawans study (Lunar)	Lucknow study (Lunar)	ICMR Study (Hologic)
Height	173 cm	172.5 cms	172 cms
Weight	68.8 kgs	65.1 kgs	67 kgs
BMI	22.8	21.3	22.6
Total Hip BMD			
20 – 30 years	1.142 (0.128)	1.018 (0.133)	0.988 (0.131) p<0.001
Femur Neck BMD			
20-30 years	1.130 (0.127)	1.019 (0.131)	0.894 (0.131) p<0.001
Femur Trochanter BMD			
20-30 years	0.936 (0.132)	0.859 (0.114)	0.723 (0.113)
Radius 33% BMD			
20-30 years	0.748 (0.72)	0.891 (0.085)	0.725 (0.062)
Radius UD BMD			
20-30 years	0.451 (0.080)	0.525 (0.064)	0.465 (0.054)
L1-L4 BMD			
20-30 years	1.175 (0.134)	0.531 (0.065)	0.976 (0.105) p<0.001

RESULTS

- Prevalence of Osteoporosis:
562 subjects (35.1%) [M-24.8%; F-42.5%]
- Prevalence of Osteopenia:
792 subjects (49.5%) [M-54.3%; F-44.9%]

Prevalence of osteoporosis increased significantly with age.



ASSESSMENT OF LEAN MUSCLE MASS AND IT'S DISTRIBUTION BY DXA IN HEALTHY INDIAN FEMALES

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and Thyroid Research Centre, INMAS, DRDO, MOD
Presently Scientific Advisor and Senior consultant
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Comparison of lean mass in the present study with data from NHANES (1999-2004)

Age (y)	Female		
	NHANES (1999-2004)	Present Study	Difference
Total Lean Mass (Kg)	Mean	Mean	%
16-19	39.6	32.6*	-21.5
20-39	42.3	34.8	-21.6
40-59	43.0	34.6	-24.3
60-79	40.3	32.8	-22.9
Leg Lean Mass (Kg)			
16-19	13.1	11.0*	-19.1
20-39	13.8	11.6	-19.0
40-59	13.7	10.7	-28.0
60-79	12.5	9.8	-27.6
Arm Lean Mass (Kg)			
16-19	3.9	3.3*	-18.2
20-39	4.3	3.7	-16.2
40-59	4.4	3.5	-25.7
60-79	3.9	3.3	-18.2
Trunk Lean Mass (Kg)			
16-19	19.5	15.4*	-26.6
20-39	21.1	16.7	-26.3
40-59	21.9	17.7	-23.7
60-79	20.8	17.1	-21.6

* In the present study this age group was from 18-20 years

Conclusion

- Indian women had lower muscle mass when compared with Caucasian by 15-28% (*Borrud LG 2010*) and Chinese (9%) counter parts (*Cheng Q 2013*).
- These differences can probably be explained by racial, anthropometric and life style factors (diet & physical activity).
- Early menopause in Indian women when compared to their Caucasian counterparts (*Singh M et al 2012, Kto I et al 1998*) may also contribute to lower lean mass in older women (*Mithal et al 2013*)

The prevalence of and risk factors for radiographic vertebral fractures in older Indian women and men: Delhi Vertebral Osteoporosis Study (DeVOS)

**Raman K. Marwaha • Nikhil Tandon • Yashdeep Gupta •
Kuntal Bhadra • Archana Narang • Kalaivani Mani •
Ambrish Mithal • Subhash Kukreja**

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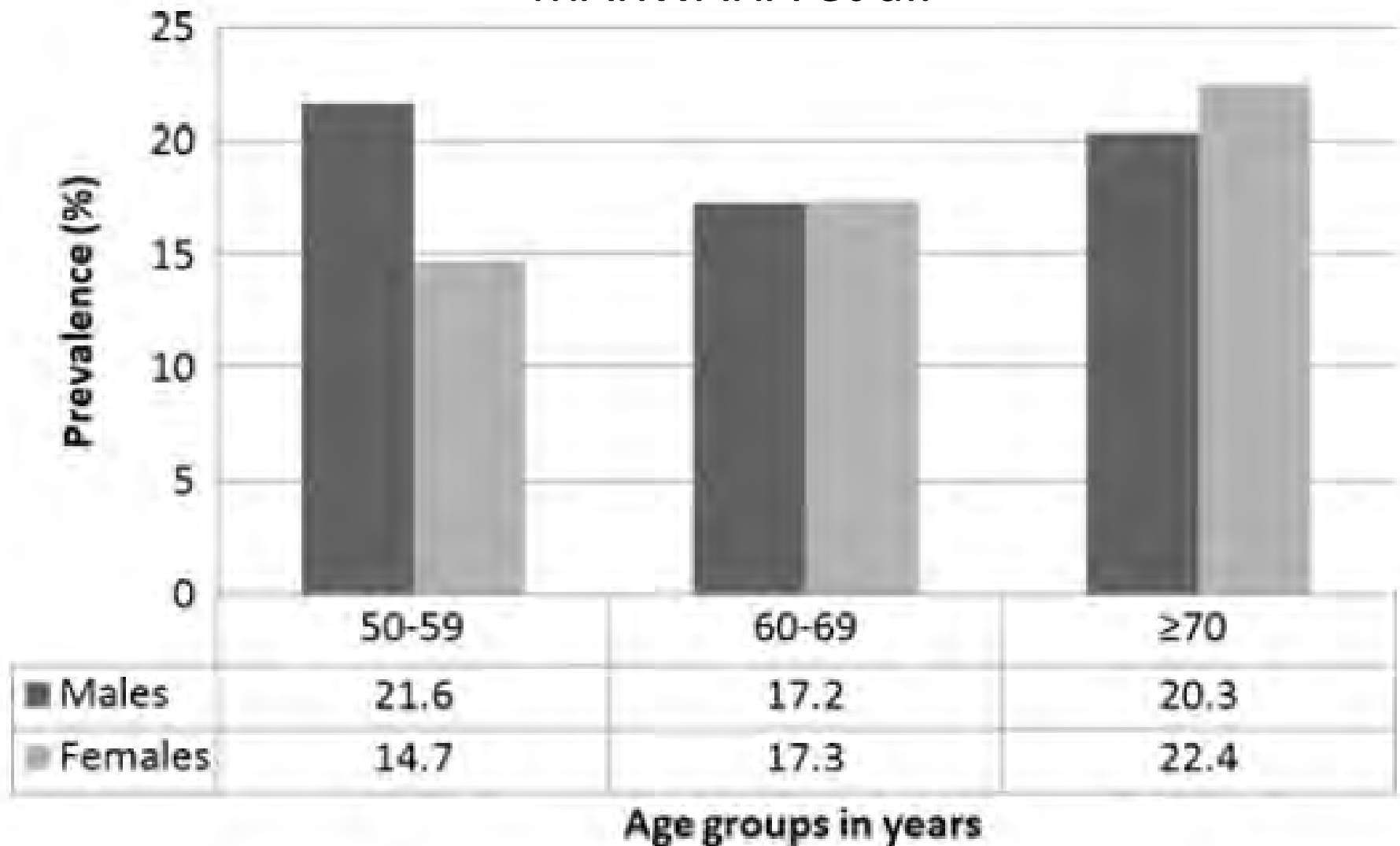


Fig. 1 Prevalence of vertebral fractures in males and females according to age strata

Effects of sports training & nutrition on bone mineral density in young Indian healthy females

Raman K. Marwaha, Seema Puri*, Nikhil Tandon**, Sakshi Dhir*, Neha Agarwal*, Kuntal Bhadra & Namita Saini[†]

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Table III. Bone mineral density (BMD) parameters of the sports girls and controls

Parameter	Control girls (n=96)	Sports girls (n=90)
Total body (g/cm ²)	1.07 ± 0.087	1.13 ± 0.1*
Total femur (g/cm ²)	0.96 ± 0.12	1.08 ± 0.14*
Femur neck (g/cm ²)	1.07 ± 0.87	1.04 ± 0.13
33% radius (g/cm ²)	0.60 ± 0.09	0.65 ± 0.55*
Lumbar spine (L1-L4) (g/cm ²)	1.07 ± 0.13	1.18 ± 0.14*

Values are given as mean ± SD; **P*<0.001 compared to controls

Comparison of lean mass and its distribution between sportswomen and age matched healthy controls

	Normal controls N=116	Sports women N=104	P-Value
Total lean mass (Kg)	31.355±3.506	33.667±3.488	<0.0001
Trunk lean mass (Kg)	14.788±1.663	16.041±1.808	<0.0001
Leg lean mass (Kg)	10.580±1.391	11.408±1.443	<0.0001
Arm lean mass (Kg)	3.127±0.570	3.326±0.526	0.008
ASMI (Kg/m ²)	5.49±0.62	5.84±0.57	<0.0001

Normal levels of circulating 25(OH)D ?

- Exact cut-offs for “deficiency” and “insufficiency” remain controversial
- **Several classifications exist e.g. Lips P:**
 - <5 ng/mL - severe hypovitaminosis D
 - 5-10ng/mL - moderate hypovitaminosis D
 - 10-20 ng/mL - mild hypovitaminosis D

IOM Recommendations (AI)

Age	Children	Men	Women	Pregnancy	lactation
Birth-12 months	400IU				
1-18yrs	600 IU	600IU	600 IU		
19-50 Yrs		600 IU	600 IU	600 IU	600 IU
51-70 Yrs		600 IU	600 IU		
71+		600 IU	600 IU		

Is vitamin D deficiency a major public health issue?



**The American Journal of
CLINICAL NUTRITION**

**Vitamin D and bone mineral density status
of healthy schoolchildren in northern
India^{1,2,3}**

Raman K Marwaha, Nikhil Tandon, Devi Reddy HK Reddy,
Rashmi Aggarwal, Rajvir Singh, Ramesh C Sawhney, Bobbin
Saluja, M Ashraf Ganie and Satveer Singh

ORIGINAL RESEARCH COMMUNICATION

Vitamin D and bone mineral density status of healthy schoolchildren in northern India

Raman K Marwaha, Nikhil Tandon, Devi Reddy HK Reddy, Rashmi Aggarwal, Rajvir Singh, Ramesh C Sawhney, Bobbin Saluja, M Ashraf Ganie and Satveer Singh

Background: Current data on the prevalence of vitamin D deficiency in India are scarce.

Objective: We assessed the calcium-vitamin D-parathyroid hormone axis in apparently healthy children from 2 different socioeconomic backgrounds in New Delhi, India.

Design: Clinical evaluation for evidence of vitamin D deficiency was carried out in 5137 apparently healthy schoolchildren, aged 10–18 y, attending lower (LSES) and upper (USES) socioeconomic status schools. Serum calcium, inorganic phosphorus, alkaline phosphatase, 25-hydroxyvitamin D [25(OH)D], and immunoreactive parathyroid hormone were measured in 760 children randomly selected from the larger cohort. Bone mineral density of the forearm and the calcaneum was measured in 555 children by using peripheral dual-energy X-ray absorptiometry.



Vitamin-D Status in Indian Children

- Clinical vitamin D deficiency in 556/5137 (10.82%)
 - Genu Varum in 7.5% [B=8%, G=7.2%]
 - Genu Valgum in 3.3% [B-2.4%, G-3.9%]
- Low 25(OH)D levels in 84-92%
- 25(OH)D higher in boys than girls
- Mean 25(OH)D values ranged from 11.8±7.2 ng/ml to 12.74±6.17ng/ml

Vitamin D status in pregnant Indian women across trimesters and different seasons and its correlation with neonatal serum 25-hydroxyvitamin D levels

Marwaha RK, Tandon N, Chopra S, Agarwal N, Garg MK, Sharma B, Kanwar RS, Bhadra K, Singh S, Mani K, Puri S.

The present cross-sectional study was conducted to determine the vitamin D status of pregnant Indian women and their breast-fed infants. Subjects were recruited from the Department of Obstetrics, Armed Forces Clinic and Army Hospital (Research and Referral), Delhi. A total of 541 apparently healthy women with uncomplicated, single, intra-uterine gestation reporting in any trimester were consecutively recruited.

Of these 541 women, 299 (first trimester, ninety-seven; second trimester, 125; third trimester, seventy-seven) were recruited in summer (April-October) and 242 (first trimester, fifty-nine, second trimester, ninety-three; third trimester, ninety) were recruited in winter (November-March) to study seasonal variations in vitamin D status.

Clinical, dietary, biochemical and hormonal evaluations for the Ca-vitamin D-parathormone axis were performed. A subset of 342 mother-infant pairs was re-evaluated 6 weeks postpartum.

Vitamin D Status in three trimesters of pregnancy

- Mean serum [25(OH)D]: **9.32±4.89ng/ml**
- Hypovitaminosis D : **96.3%** subjects (**36.8%** mild, **41.8%** moderate **17.7%** severe).
- Trimester Prevalence:
summers : **96.9%** vs. **92%** vs. **98.7%**
winters : **100%** vs. **97.9%** vs. **95.6%**
- A strong positive correlation was noted in 25(OH)D levels in mother infant pairs (**r=0.324,p=0.001**)

VITAMIN D STATUS IN INDIAN ADULTS

Delhi:

Variables	Soldiers Winter	Physicians & Nurses Winter	Physicians & Nurses Summer	Pregnant Women Summer	New Borns Summer
25(OH)D (ng/ml)	18.85 ± 4.62	3.19 ± 1.39	7.18 ± 3.19	8.76 ± 4.29	6.68 ± 1.99
iPTH (pg/ml)	17.6 ± 4.8	38.8 ± 18.2	ND	ND	ND

Goswami R et al & Marwaha et al AJCN 2000; 72:472-5

Lucknow:

67% of the subjects had serum 25(OH)D levels < 15 ng/ml

Arya V, Osteoporosis Int 2004

Kashmir Valley:

Vitamin D deficiency (25 (OH)D < 20 ng/ml) reported in **83%**.

Mild hypovitaminosis D – **25%**

Moderate hypovitaminosis D – **33%**

Severe hypovitaminosis D – **25%**

Zargar et al Postgraduate Medical Journal 2007

Tirupati:

- Mean 25(OH)D values in Males:

Urban-18.54±0.8 ng/ml, Rural-23.73±0.8 ng/ml.

- Mean 25(OH)D values in Females:

Urban- 15.5±0.3 ng/ml, Rural- 19±0.89 ng/ml.

Harinarayan CV et al: AmJClinNutr 2007

Delhi Rural:

Mean vitamin D levels in Females – 10.7 ± 6.3 ng/ml

Mean Vitamin D levels in Males – 17.68±9.6 ng/ml

Goswami R et al JAPI 2008

VITAMIN D STATUS IN HEALTHY INDIANS AGED 50 YEARS AND ABOVE

Marwaha RK et al JAPI 2013

- Methods:
- Total no. of subjects evaluated: 1346 (Male: 643, Females: 703)
- Mean age: 58 ± 9.5 years (range 50 – 84 years)
- Mean 25(OH)D levels: Males- 9.7 ± 6.8 ng/ml, Females- 9.6 ± 7.51 ng/ml
- **Prevalence of Vit D deficiency was noted in 92% subjects.**

Vitamin D nutritional status of exclusively breast fed infants and their mothers

Seth A, Marwaha RK, Singla B, Aneja S, Mehrotra P, Sastry A, Khurana ML, Mani K, Sharma B, Tandon N.

BACKGROUND:

Vitamin D nutrition has a profound effect on the development of an infant. Vitamin D status of mothers and their infants are closely correlated. While hypovitaminosis D has emerged as a significant public health problem across all age groups, there is limited information of this condition in lactating mothers and their breast fed infants.

AIM:

To evaluate the vitamin D status of lactating mothers and their breast fed infants.

SUBJECTS AND METHODS:

180 healthy lactating mothers and exclusively breast fed infants, 2-24 weeks old, were recruited for the study. The mother-infant pairs underwent concurrent clinical, biochemical and hormonal evaluation for calcium-vitamin D-PTH axis.



Vitamin-D status in lactating mothers and their exclusively breast fed infants

Vitamin D status of Lactating mothers:

- **180 mother-infant pairs** from Kalavati hospital were undertaken for the study
- Prevalence of hypovitaminosis D was seen in S: **93.8%** [25(OH)D < 20 ng/ml]
- Mean serum 25(OH)D: **10.9±5.8 ng/ml**

Seth A and Marwaha RK et al;JPEM 2009

Vitamin D status of Neonates and Infants :

- Clinical features of vitamin D deficiency : **3.9%** (7/180)
- High prevalence of low serum 25(OH)D levels in **80-91%** infants 2 -24 weeks old.
- Mean 25 (OH)D=11.55±8.3 ng/ml.
- **Infants born to mothers with 25(OH)D< 10ng/ml had four times higher risk of developing moderate to severe hypovitaminosis D when compared to those with 25(OH)D levels > 10 ng/ml**

(Seth A & Marwaha RK et al;JPEM 2009,Bhalala et al;Indian Pediatrics)

Conclusion

- Recent studies from across the country clearly reveal a very high prevalence (60%-97%) of vitamin D deficiency in Indians of all age groups and both genders.
- It is a major public health problem which needs urgent attention.

Marwaha R K & Goswami R (2010) Vitamin D deficiency and its health consequences in India. In Holick MF (ed) Vitamin D: physiology, molecular biology and clinical applications, 2nd edn. Humana Press, New York, pp 529-542.

Presentation of Vitamin D deficiency:

Symtomatic: Rickets in children

Osteomalacia in adults

Osteoporosis and Fractures in Elderly

non-specific symptoms like pain, myalgias
weakness etc

Rx: high dose of vitamin D₃ followed by maintenance dose.

Asymtomatic/ Non-specific presentation:

Form the bulk of vitamin D deficient subjects in general population

Overcoming Vitamin D deficiency

- Consumption of foods rich in vitamin D
- Sunlight
- Supplementation
- Fortification

Vitamin D status of apparently healthy schoolgirls from two different socioeconomic strata in Delhi: relation to nutrition and lifestyle

- Prevalence of low serum 25(OH)D D was seen in **90.8 % of girls**
- Daily intake of Vitamin D through meals was 2-2.5 ug/day (**80-100 IU/day**) using vitamin D values in foods provided by US food Agricultural Dept.
- Significant correlation between serum 25-hydroxyvitamin D and estimated sun exposure ($r\ 0.185, P = 0.001$) and percentage body surface area exposed ($r\ 0.146, P = 0.004$)



Conclusion

- **In the absence of vitamin D fortification of foods, diet alone appears to have an insignificant role.**
- **Physical activity and adequate sun exposure are vital for attaining peak bone mass in Indian context.**

Food Sources of Vitamin D

- Cod liver oil – 1 TBS • 1,360 IU
- Salmon 3.5 oz. • 360
- Mackerel 3.5 oz. • 345
- Tuna, canned, in oil, 3 oz. • 200
- Sardines 3.5 oz. • 250
- Milk (fortified) 8 oz. • 98
- Ready to eat cereal (fortified) $\frac{3}{4}$ - • 40
1 cup
- Egg 1 whole • 20
- Liver, 3.5 oz. • 15
- Cheese, swiss 1 oz. • 12

- Dietary advice will not be effective in India:

A) Foods rich in vitamin D are very few

B) Indians being vegetarian by nature, do not consume these foods

- It is therefore important that either adequate sun exposure, supplementation or food fortification strategy be adopted to improve vitamin D status of general public.

How much sun exposure?

- What is the best time for sun exposure?
 - What % body surface area should be exposed
 - Duration of Exposure in winter and summer?
- ❖ Vitamin D synthesis depends on:
- Age
 - Amount of vitamin D obtained from diet
 - Skin pigmentation
 - Sunshine intensity

❖ Regional and seasonal variation of UVB irradiation in different parts of India

Marwaha R K et al, Osteoporosis International, 2015

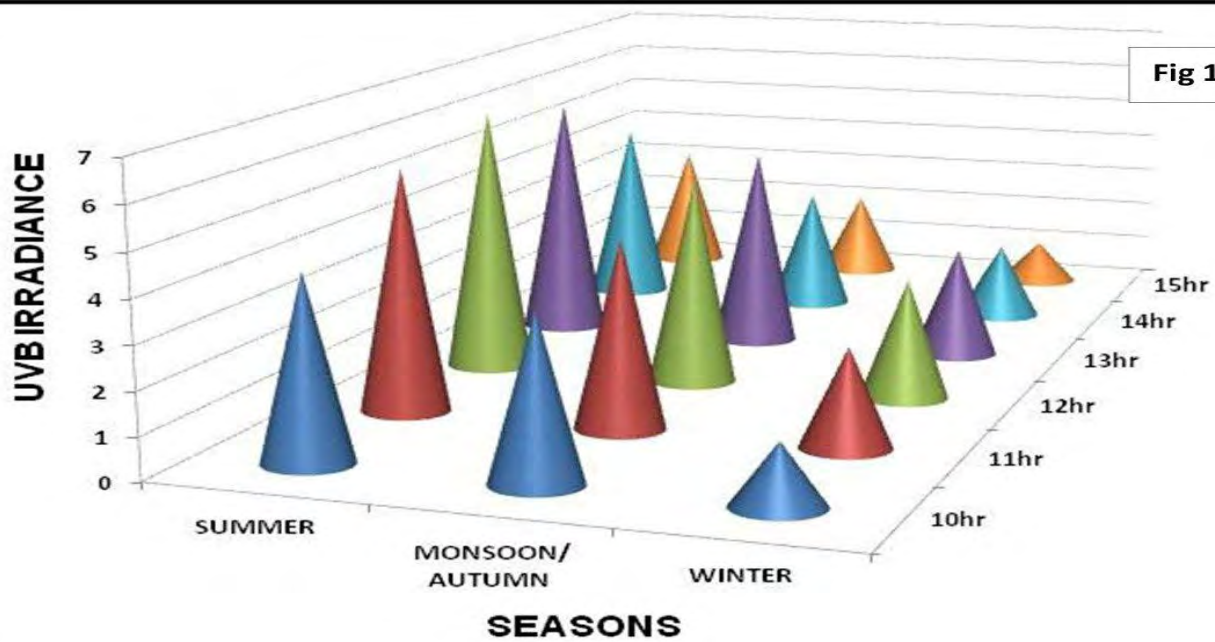
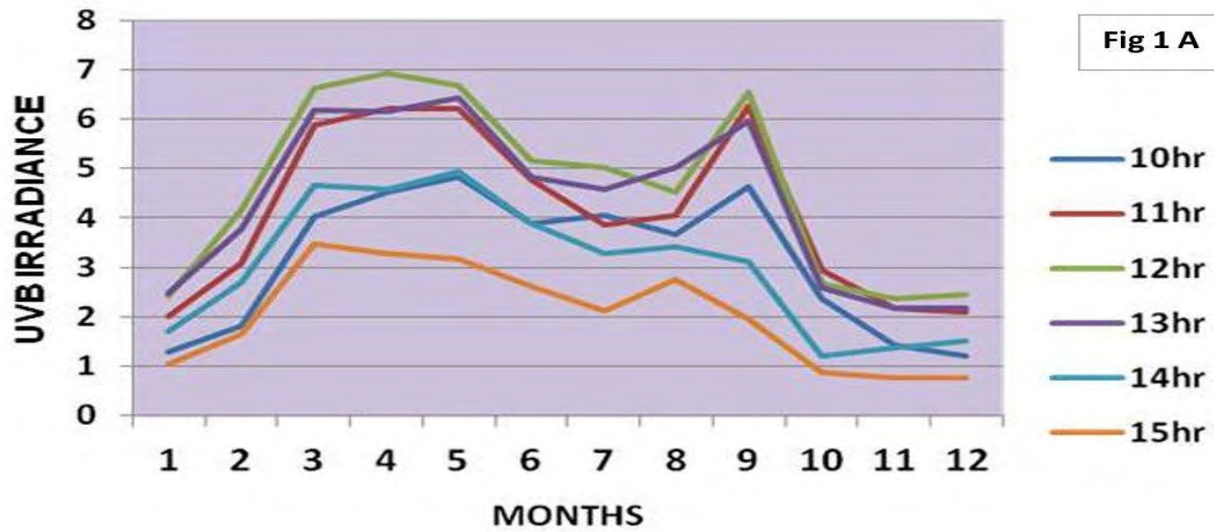
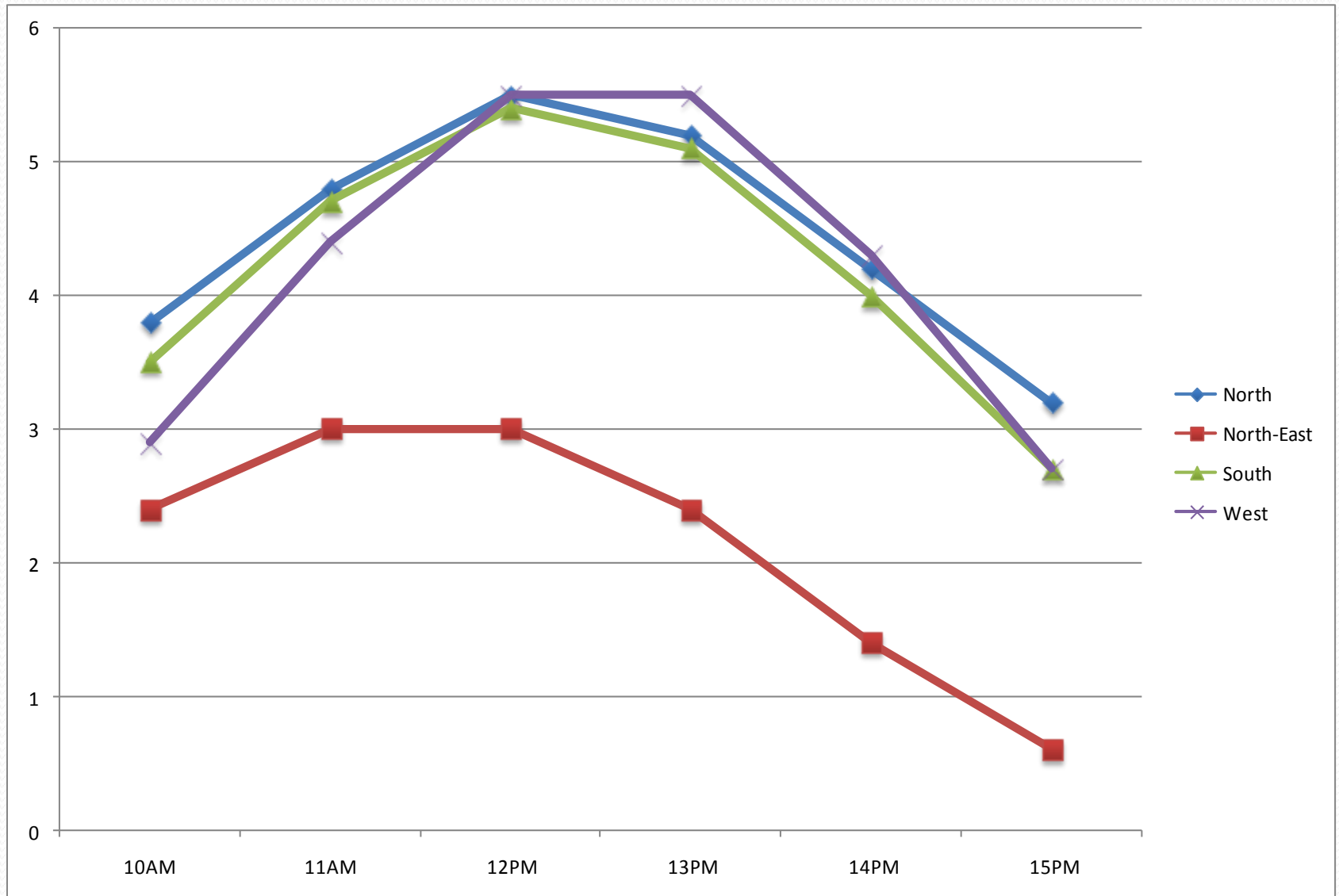


Figure 1: Hourly Pattern of Mean UVB Index at different geographic locations



Impact of Solar UVB radiation (290 – 320 nm) on vitamin D synthesis in children with Type IV and V skin

R.K. Marwaha¹, V. Sreenivas², D. Talwar^{3,†}, V.K. Yenamandra^{2,‡}, A. Challac^{2,†}, R. Lakshmy⁴, V.K. Sharma³ and G. Sethuraman^{3,*}

DOI: [10.1111/bjd.13887](https://doi.org/10.1111/bjd.13887)

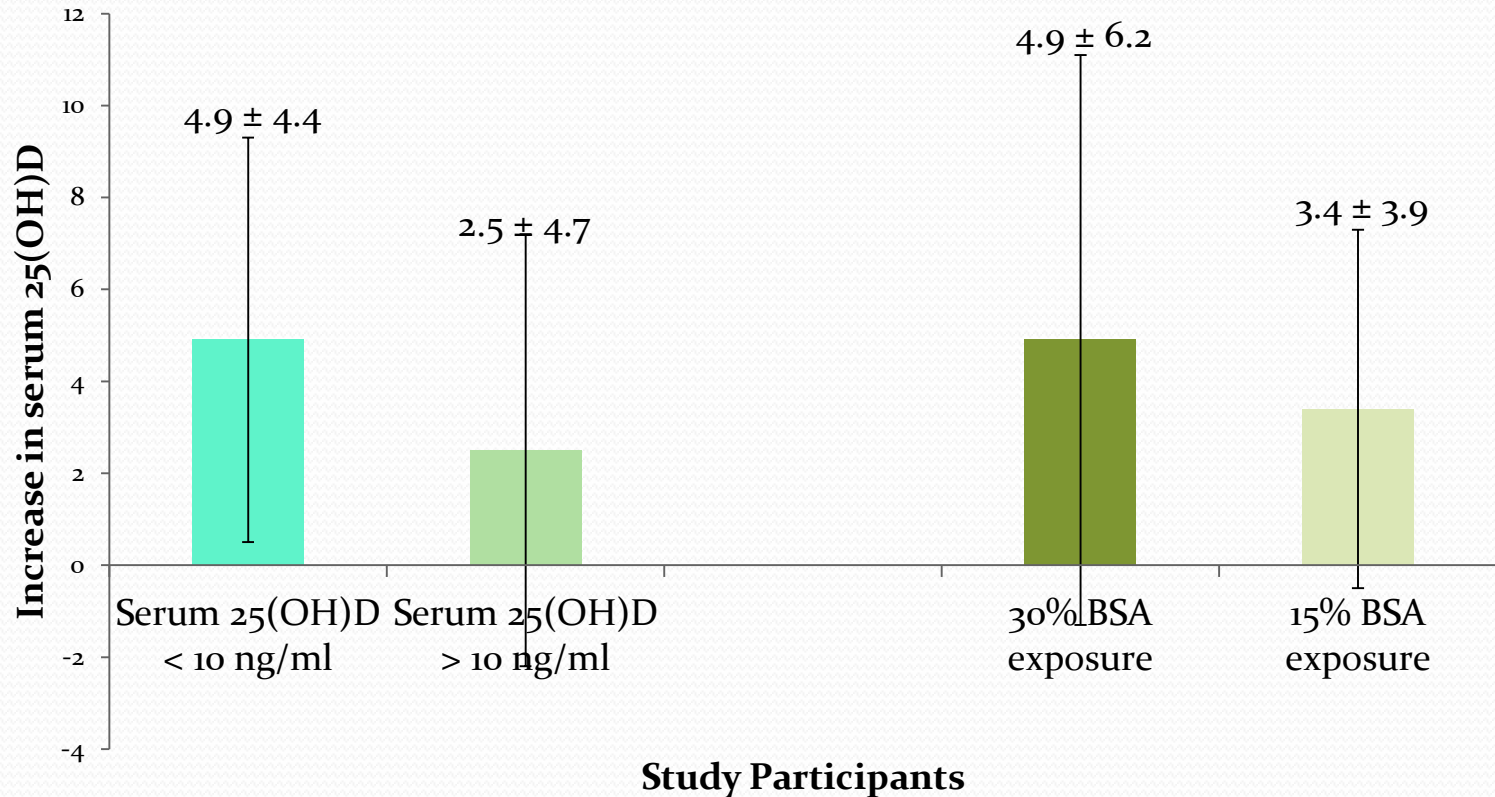
- Inadequate exposure to sunlight is an important contributing factor for VDD
- Significant increase in serum 25(OH)D concentrations is observed with exposure to artificial source ultraviolet B irradiation

Table 2: Changes in biochemical parameters following 4 weeks of sun-exposure in Summer

	Serum 25 (OH) D (ng/mL)			Calcium (mg%)			ALP (IU)		
	Pre	Post	<i>P</i> value	Pre	Post	<i>P</i> value	A	Post	<i>P</i> value
Overall n=71	9.3 ± 5.5	13.3 ± 6.9	< 0.001	9.8 ± 0.5	10.2 ± 0.5	< 0.001	270.2 ± 136.2	207.6 ± 107.5	< 0.001
Boys n=36	11.3 ± 4.9	14.6 ± 6.7	< 0.001	10.0 ± 0.2	10.3 ± 0.4	< 0.001	336.2 ± 89.1	263.3 ± 58.8	< 0.001
Girls n=35	7.2 ± 5.3	11.9 ± 6.9	< 0.001	9.6 ± 0.6	10.1 ± 0.6	< 0.001	200.3 ± 143.3	148.8 ± 116.4	< 0.001

Impact of Solar UVB radiation (290 – 320 nm) on vitamin D synthesis in children with Type IV and V skin in summer

Marwaha RK *et al.* *British Journal of Dermatology* April 2015.



A significant increase in the mean baseline melanin Index was also observed in the study group following sun exposure (forearm: 47.4 ± 5.7 vs. 49.0 ± 5.2 , $p < 0.001$; inner arm: 40.0 ± 5.3 vs. 42.6 ± 5.1 , $p < 0.001$), which was similar in both boys and girls.

Table 4: Change in biochemical parameters among school children with sun exposure in Winter

Characteristic	N	Pre Exposure Winter	Post exposure Winter	P
25(OH)D (ng/ml)		6.3 ± 4.6	5.1 ± 2.7	0.001
PTH (pg/ml)		82.1 ± 73.2	77.6 ± 68.6	0.20
Calcium (mg/dl)		10.2 ± 0.6	10.0 ± 0.7	0.004
Phosphate (mg/dl)		4.1 ± 0.7	4.1 ± 0.6	0.74
ALP (IU/ml)		197.5 ± 93.7	214.7 ± 111.0	0.02

Discussion Cont.

- Estimated average requirement of vitamin D by IOM is 600 IU/day meaning thereby that 600 IU/day are required to maintain baseline levels of serum 25(OH)D (*Black LJ etal 2012; J Nutr; 142: 1102-8*).
- Supplementing 100 IU vitamin D will raise serum 25(OH)D levels by 1 ng/ml. (*Black LJ etal 2012; J Nutr; 142: 1102-8*).
- Since the increase in serum 25(OH)D following 4 wks of exposure is 3.4-4.9 ng/ml depending on %BSA exposed, it is presumed to be equivalent of supplementing approx. 340 to 490 IU of vitamin D daily.

Discussion Cont.

- This additional increase in serum 25(OH)D levels by 3.4 to 4.9 ng/ml in the present study would therefore indicate that approximately 940-1090 IU of vitamin D is being synthesized daily in the skin with 15-30% BSA exposed following 4 wks of sun exposure.
- We therefore propose that children with vitamin D deficiency can be supplemented with 4 wkly doses of 60,000 IU cholecalciferol to bring the baseline levels in the range of 20-30 ng/ml and then expose themselves to sunlight everyday for 15-30 minutes with 15-30% BSA during noon time to maintain serum (25OH)D within normal ref range.

Discussion Cont.

- This additional increase in serum 25(OH)D levels by 3.4 to 4.9 ng/ml in the present study would therefore indicate that approximately **940-1090 IU** of vitamin D is being synthesized daily in the skin with 15-30% BSA exposed following 4 wks of sun exposure.
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Types of fortification

- **Mass fortification:**

To fortify foods that are widely consumed by the general population

Usually mandatory

Best option when majority of the population has an unacceptable risk, in terms of public health, of becoming deficient in specific micronutrients.

Types of fortification Cont...

- **Target fortification**

Foods aimed at specific population subgroups are fortified
eg young children/ elderly, pregnant women

May be mandatory or voluntary

- **Market-driven fortification**

To allow food manufacturers to voluntarily fortify foods
available in the market place.

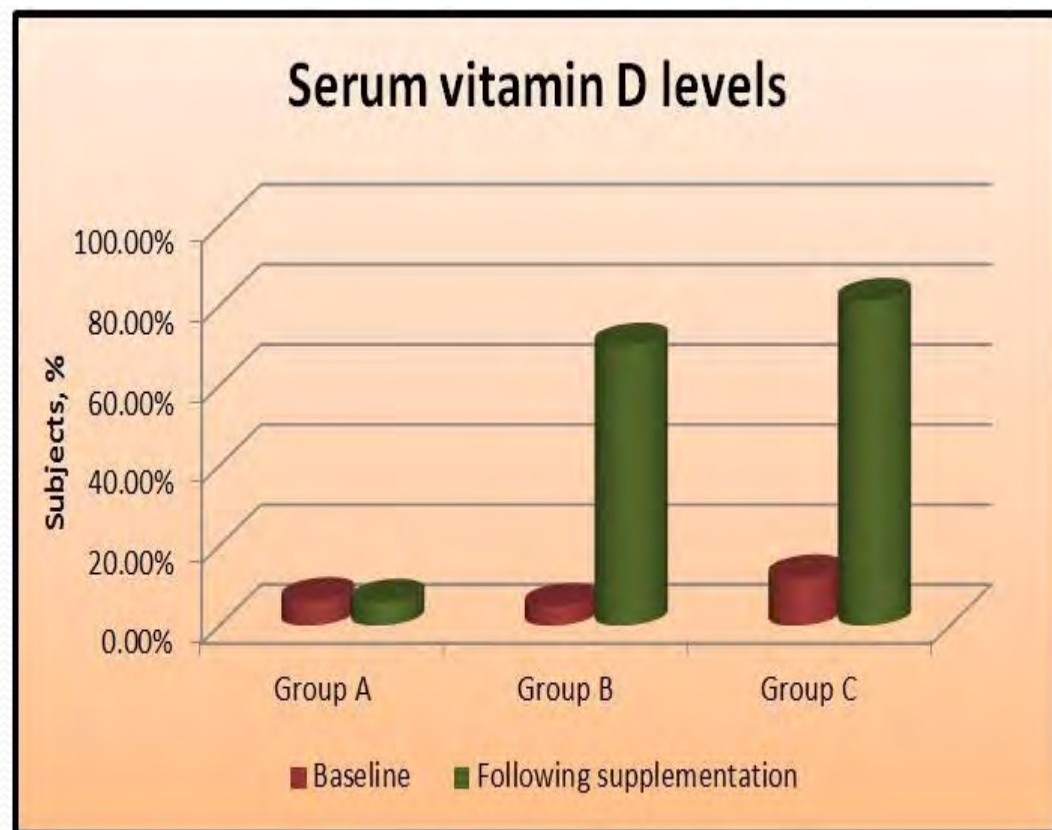
Always voluntary, but governed by regulatory limits

**A Randomized Double Blind Controlled
Trial to Investigate the Effects of Vitamin
D fortified milk on Serum Vitamin D
levels in school children, aged 8-12 years**

Impact of vitamin D fortified milk supplementation on vitamin D status of healthy school children aged 10–14 years

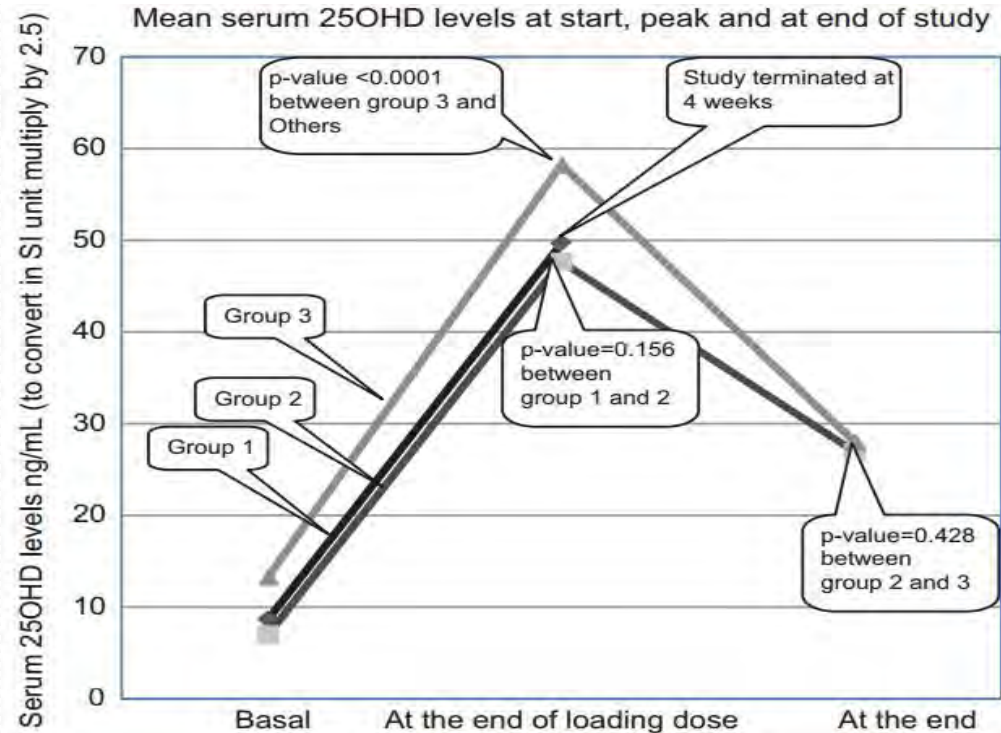
R. Khadgawat • R. K. Marwaha • M. K. Garg •
R. Ramot • A. K. Oberoi • V. Sreenivas • M. Gahlot •
N. Mehan • P. Mathur • N. Gupta

- Effects of vitamin D fortification of milk in school children studied
- 713 children randomized into three groups:
 - ✓ **Group A** - 200 mL of unfortified milk per day
 - ✓ **Group B** - 200 mL of milk fortified with 600 IU of vitamin D per day
 - ✓ **Group C** - 200 mL of milk fortified with 1000 IU of vitamin D per day
- Fortification of milk is a safe and effective strategy to deal with widespread vitamin D deficiency



Efficacy of vitamin D loading doses on serum 25-hydroxy vitamin D levels in school going adolescents: an open label non-randomized prospective trial

- Study subjects (n=482) were divided into three groups receiving 60,000 IU of vitamin D3 weekly for 4, 6 and 8 weeks, respectively, followed by 600 IU daily for 12 weeks
- All three vitamin D loading doses were equally efficacious
- This is an effective strategy for achieving vitamin D sufficiency in Indian adolescents



Planned Intervention

- **Group A** – no fortification, control group, received 200 ml of unfortified milk daily for 12 weeks
- **Group B** – 200 ml of milk fortified with 600 IU of vitamin D daily for 12 weeks
- **Group C** - 200 ml of milk fortified with 1000 IU of vitamin D daily for 12 weeks

Randomized by computer generated block randomization plan



Total no of subjects **796**

Number of subjects excluded

- 10 – Receiving vitamin D supplements
- 5 – Serum TSH >10 mIU/mL
- 2 – Type 1 diabetes mellitus
- 2 – Celiac disease
- 1 – Receiving antitubercular therapy

Randomization

Group A
Unfortified milk
(N = 255)

Could not complete
(N = 18)

Subjects analyzed
(N = 237)

Group B
Fortified with 600 IU of
vitamin D (N = 263)

Could not complete
(N = 20)

Subjects analyzed
(N = 243)

Group C
Fortified with 1000 IU
of vitamin D (N = 258)

Could not complete
(N = 25)

Subjects analyzed
(N = 233)

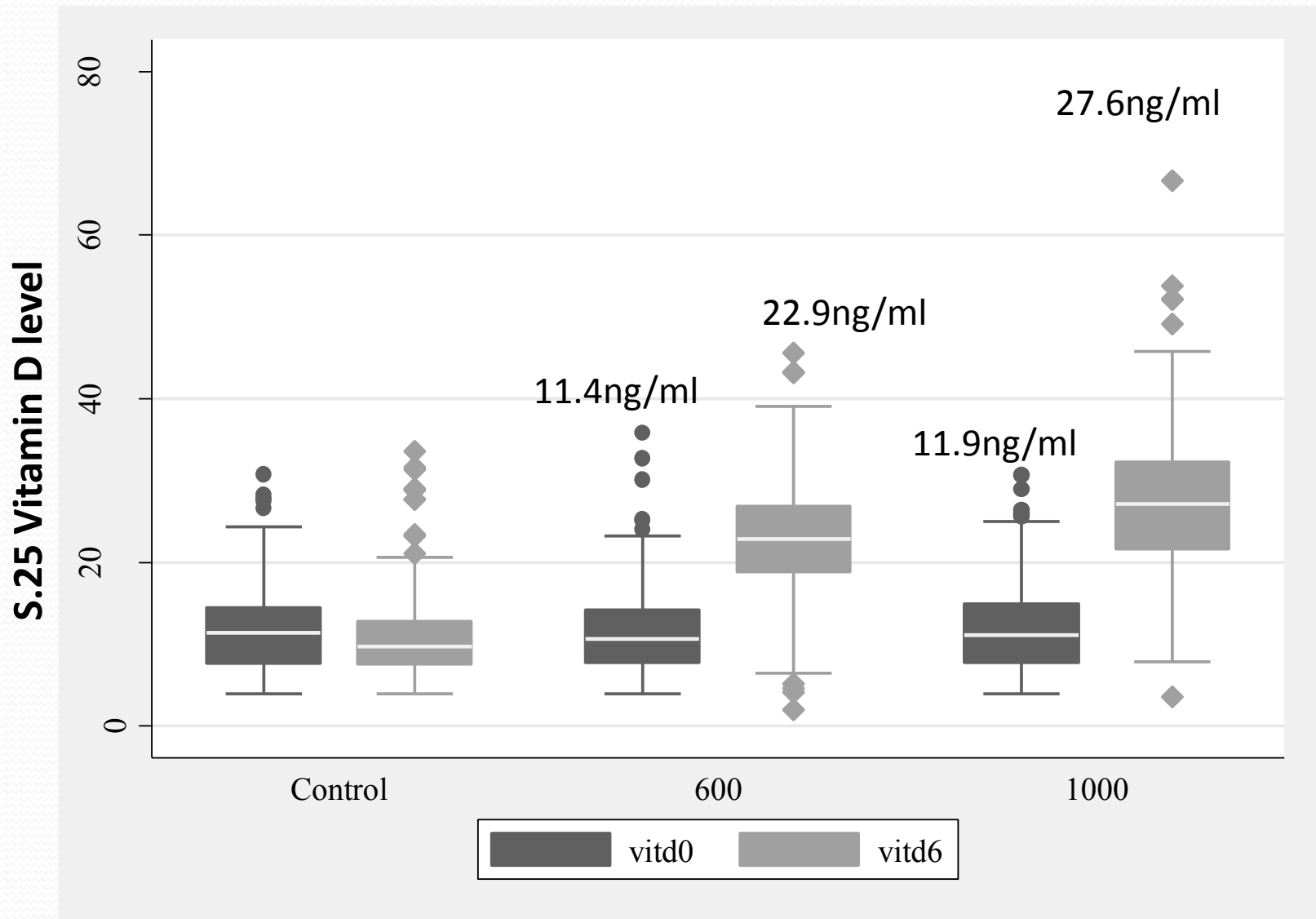
Results: Characteristics of Subjects at Baseline

Parameter	Group A (No fortification)	Group B (600 IU)	Group C (1200 IU)	Group D (1800 IU)
Age (in years)	11.74 ± 1.05	11.75 ± 1.08	11.75 ± 1.08	11.75 ± 1.08
BMI (Kg/meter ²)	18.94 ± 3.33	18.84 ± 3.66	18.84 ± 3.66	18.84 ± 3.66
Serum calcium (mg/dl)	9.8 ± 0.6	9.7 ± 0.7	9.7 ± 0.7	9.7 ± 0.7
Serum phosphate (mg/dl)	5.06 ± 0.5	5.1 ± 0.5	5.1 ± 0.5	5.1 ± 0.5
Serum alk phosphatase (IU/L)	270 ± 90	267 ± 82	263 ± 87	267 ± 87
Urine calcium creatinine ratio	0.04 ± 0.05	0.05 ± 0.07	0.05 ± 0.06	0.05 ± 0.05
S.25(OH)D (ng/ml)	11.74 ± 5.2	11.4 ± 5.22	11.94 ± 5.63	11.69 ± 5.36
S.25(OH)D <5 ng/ml (n/%)	19 (8.01%)	23 (9.46%)	17 (7.29%)	59 (8.27%)
S.25(OH)D 5-<10 ng/ml (n/%)	76 (32.06%)	82 (33.74%)	79 (33.90%)	237 (33.24%)
S.25(OH)D 10-<20 ng/ml (n/%)	127 (53.58%)	126 (51.85%)	109 (46.78%)	362 (50.77%)
S.25(OH)D 20-30 ng/ml (n/%)	14 (5.90%)	9 (3.7%)	27 (11.58%)	50 (7.01%)
S.25(OH)D >30 ng/ml (n/%)	1 (0.42%)	3 (1.23%)	1 (0.42%)	5 (0.7%)

Vit D deficiency - 92.3%
 - Severe 8.27%
 - Moderate 33.24%
 - Mild 50.77%

Vitamin D sufficiency (>30ng/ml) 0.7%

The mean improvement in serum vitamin D level after fortification



Percentage increase in Serum 25 (OH)D in supplementation groups (B+C)

<u>S. 25(OH)D</u>	<u>Mean</u>	<u>SD</u>
< 5	429.11 %	198.2
5-10	209.38 %	106.9
10-20	95.75 %	58.2
20-30	43.76 %	36.4
<u>>= 30</u>	<u>-29.07 %</u>	<u>40.4</u>
Total	157.22 %	138.3

The % increase in serum 25(OH)D levels following fortification is significantly higher in subjects with very low serum 25(OH)D levels.

Improvement in Serum vitamin D level after fortification

	Group A (Control)		Group B (600 IU/D)		Group C (1000 IU/D)	
	Before	After	Before	After	Before	After
< 5	8.01%	6.75%	9.46%	1.23%	7.29%	0.42%
5-10	32.06%	46.83%	33.74%	2.05%	33.90%	0.84%
10-20	53.58%	40.5%	51.85%	26.74%	54.50%	17.59%
20-30	5.90%	4.64%	3.70%	57.61%	11.58%	45.06%
≥30	0.42%	1.26%	1.23%	12.34%	0.42%	36.05% 82.1%

Safety of intervention

-
- Not a single case of hypercalcemia or hypercalciuria as evaluated by serum calcium and Uca/cr ratio was observed in the study.
- No other adverse outcome was observed

Conclusion

We conclude that supplementing milk fortified with vitamin D to children is an effective and safe method of addressing the major public health issue of vitamin D deficiency in children.

Overcoming Vitamin D deficiency

- Sunlight / consumption of foods rich in vitamin D
- Fortification
- Supplementation

Impact of Two Regimens of Vitamin D Supplementation on Calcium - Vitamin D - PTH Axis of Schoolgirls of Delhi

RAMAN K MARWAHA, NIKHIL TANDON*, NEHA AGARWAL†, SEEMA PURI†, RASHMI AGARWAL, SATVEER SINGH AND KALAIVANI MANI#

- 124 schoolgirls from lower socioeconomic strata (LSES) and 166 from upper socioeconomic strata (USES) received cholecalciferol granules (60,000 IU) either two-monthly or monthly for one year
- PTH response was inconsistent
- Oral 60,000 IU vitamin D3 supplement, having different regimen, showed significant increase in serum 25(OH)D levels in vitamin D deficient schoolgirls

Effect of vitamin D supplementation on serum 25(OH)D and PTH levels

	LSES		USES	
	One-monthly (n=64)	Two-monthly (n=60)	One-monthly (n=85)	Two-monthly (n=81)
Serum 25(OH)D(nmol/L)				
Baseline	32.93(1.37)	31.20(1.68)	30.80(1.39)	29.13(1.54)
6 month	43.90(1.50)	39.53(2.01)	46.81(1.45)	39.55(1.24)
12 month	59.33(2.64)	53.0(3.05)	49.94(2.01)	38.25(2.13)
Serum PTH (pg/mL)				
Baseline	37.64(2.19)	36.41(2.63)	34.98(2.51)	34.40(2.00)
6 month	30.87(1.82)	29.10(2.35)	28.35(1.74)	26.90(1.77)
12 month	55.96(3.08)	60.81(4.07)	35.01(2.58)	34.66(2.54)

Marwaha RK, Tandon N, Agarwal N, Puri S, Agarwal R, Singh S, *et al.* Impact of two regimens of vitamin D supplementation on calcium - vitamin D - PTH axis of schoolgirls of Delhi. *Indian Pediatr.* 2010;47(9):761-9.

(Cont.)

Baseline: 93.7 % school girls were vitamin D deficient

Despite 1 year of supplementation, overall Vitamin D sufficiency was achieved in only 50% of subjects (LSES : 67.8%, USES : 31.9%)

Inability to achieve vitamin D sufficiency in majority of children was probably because of poor absorption due to the fact that fat soluble vitamin D3 was supplemented with water

Research brief

Mohammad Shafi Kuchay*, Ganesh Sudhakar Jevalikar, Ambrish Mithal, Sunil Kumar Mishra and Navin Dang

Efficacy and safety of a single monthly dose of cholecalciferol in healthy school children

Objective:

The study aimed to evaluate the efficacy and safety of a single monthly dose of cholecalciferol in healthy school children.

Methods:

- 118 children selected to receive vitamin D supplementation in the form of oral cholecalciferol (60,000 IU) with milk under supervision.
- Serum calcium and 25OHD levels were analyzed from 0 to 12 months.

Results:

- Mean 25OHD levels increased significantly from 12.04 ± 5.27 ng/mL (baseline) to 32.6 ± 7.05 ng/mL (after 12 months) ($p < 0.001$).
- 96% achieved > 20 ng/dl & 62% achieved > 30 ng/dl
- None developed hypocalcaemia.

Conclusions:

Vitamin D supplementation (60,000 IU monthly) is reasonable, safe and cost-effective regimen for children to attain and maintain vitamin D sufficiency.

Definition of Miscellization

- Micellization is a new delivery system for fat soluble nutrients that disperse fatty microscopic water-soluble and micellar spheres enabling them to reach the absorptive surface of the intestinal tract, facilitating maximum absorption.
- In the absence of data in humans with regard to efficacy of micellized vitamin D₃, we undertook a small study comparing it's efficacy vis-a- vis fat soluble vitamin D₃

Efficacy of Micellized vs Fat soluble Vitamin D in healthy School Children

Marwaha R K et al, JPEM, 2016

- Total No of Children Recruited : 156 (B-32, G-124)
- Group A received fat soluble vitamin D₃ (Calcirol) 60,000 IU/Month for 6 months with milk.
- Group B received water miscible vitamin D₃ (DePura), 60,000IU/month for 6 months.
- Both groups were given vitamin D₃ under supervision

Results

Baseline Parameters:

- Overall prevalence of vitamin D deficiency : 98.7%
- Severe deficiency (<5 ng/dl) – 80.8%
- Moderate deficiency (5-10 ng/dl) – 7.7%
- Mild deficiency (10-20 ng/dl) – 10.3%
- No difference in mean baseline serum 25(OH)D, PTH between the two groups

Mean hormonal and biochemical parameters pre and post vitamin D supplementation

Total (n=56)			Gr. A (N=54) Fat Soluble			Gr. B (n=102)		
	post	P-value		pre	post		P-value	pre
3.7	34.5±9.6	<0.001	6.1±4.4	29.8±10.2	<0.001	5.3±3.4	37.1±8.3	
131	41.2±25.0	<0.001	118.8±205.2	45.0± 20.8	0.009	77.3±58.0	39.1±26.9	
0.4	9.8±0.5	0.6	9.7± 0.4	9.7± 0.5	0.70	9.9± 0.4	9.9±0.5	
0.5	4.3±0.5	<0.001	4.1± 0.5	4.4± 0.5	<0.001	4.1±0.4	4.2±0.6	
±123.7	170.1±90.9	<0.001	282.7±162.2	251.2± 101.2	0.13	171.9±72.8	126.7±43.2	

Superiority of micellized (water soluble) vitamin D3 over fat soluble vitamin D3

- Mean rise of serum 25(OH)D was (31.1mg/ml) in DePura group as against 23.7ng/dl in Calcirol group suggesting better absorption of water soluble vitamin D₃ in children.
- The rise in serum 25(OH)D was also significantly higher than that observed by Kuchay et al (21.1ng/dl) when they supplemented children with fat soluble Vitamin D₃.

Cont.

- 100% subjects in Gr. B (DePura) achieved serum 25(OH)D levels of >20ng/dl as against 83.3% in group A (Calcirol).
- Furthermore, significantly higher number of subjects from Gr. B (78.4%) achieved >30ng/dl as against 48.2% in Gr. A and 61% in a study by Kuchay et al respectively.

Cont.

- Additional advantages of using micellized form of vitamin D:
 - Can be consumed directly or mixed with food/water/beverages.
 - Allergy: milk/casein, wheat/glutien, eggs, fish, nuts, corn and soya etc

Conclusion

- High prevalence of vitamin D deficiency continues to be present among school children despite creating awareness in public at large for one and half decade.
- Miscible vitamin D₃ is more efficacious than fat soluble vitamin D₃.
- However, more large scale randomized clinical trials in different age groups are required to establish it's efficacy over fat soluble vitamin D₃.

Impact of three different daily doses of vitamin D3 supplementation in healthy pre-pubertal school girls from North India

Raman Kumar Marwaha,¹ A Mithal,² Neetu Bhari,³ G. Sethuraman,³ Sushil Gupta,⁴ Manoj Shukla,⁴ Archana Narang,⁵ Aditi Chadda,⁵ Nandita Gupta,⁶ V Sreenivas,⁷ MA Ganie⁶

International Life Sciences Institute (India),¹ Medanta Hospital Gurgaon,² Department of Dermatology, All India Institute of Medical Sciences, New Delhi,³ SGPGI, Lucknow, Uttar Pradesh,⁴ Dr. B. R. Sur Homeopathic Medical College, New Delhi,⁵ Department of Endocrinology, All India Institute of Medical Sciences, New Delhi,⁶ Department of Biostatistics, All India Institute of Medical Sciences, New Delhi,⁷ India.

Conflict of interest: None

AIM

- Information with regard to daily doses of vitamin D₃ supplementation in pre-pubertal children is lacking.
- In view of the above, we undertook this study to evaluate the adequacy and efficacy of daily supplementation of 600IU, 1000IU and 2000IU vitamin D₃ in pre-pubertal girls.

Results

- Of 240 recruited girls, 216 completed the study.
- Prevalence of vitamin D deficiency (<20 ng/ml): 100%
- Mild, moderate, and severe deficiency in 44.09%, 52.27% and 3.64% children, respectively.
- Overall increase in serum 25(OH)D following 6 months of supplementation was 19.24 ± 8.18 ng/ml ($p < 0.01$)

Results Cont.

- The increase in the serum 25(OH)D levels was maximum with 2000 IU (24.20 ± 8.28 ng/ml), followed by 1000 IU (17.96 ± 6.55 ng/ml) and 600 IU (15.48 ± 7.00 ng/ml).
- Post-supplementation serum 25(OH)D levels of 20 ng/ml or more were seen in 91% in group A, 97% in group B and 100% group C.

Table 1: Changes in hormonal parameters following vitamin D supplementation

	Group A:600IU (n=74)	Group B: 1000IU (n=67)	Group C: 2000IU (n=75)	Total
Serum 25(OH)D (ng/ml)				
Baseline	10.13±3.51	10.21±3.71	9.8±3.73	9.99±3.64
Post-treatment	25.61±6.29	28.17±6.81	34.00±9.92	29.23±8.00
Mean change	15.48±7.00	17.96±6.55	24.20±8.28	19.24±8.18
P value	p=<0.01	p=<0.01	p=<0.01	p=<0.01
Serum procollagen type-I N propeptide (PINP) levels (mcg/L)				
Baseline	557.44±211.89	508.63±166.52	560.43±218.31	538.9±199.8
Post-treatment	628.12±180.26	684.16±214.86	664.61±276.13	655.5±218.24
Mean change	70.68±208.46	175.53±212.36	104.18±253.75	116.6±222.29
Median (IQR)	54.29(59.24-225.15)	158.55(40.99-270.25)	53.10(64.60-216)	
P value	p=<0.01	p=<0.01	p=<0.01	p=<0.01
Serum C-terminal telopeptide of type I collagen (CTX) levels (mcg/L)				
Baseline	0.856±0.24	0.649±0.18	0.683±0.16	0.745±0.23
Post-treatment	0.463±0.24	0.348±0.20	0.263±0.14	0.382±0.23
Mean change	0.393±0.36	0.301±0.21	0.420±0.24	0.363±0.29
Median (IQR)	0.375(0.102-0.606)	0.291(0.177-0.470)	0.412(0.270-0.624)	
P value	p=<0.01	p=<0.01	p=<0.01	p=<0.01

Conclusion

- Supplementation with all three daily doses of vitamin D₃ resulted in more than 90% subjects achieving serum 25(OH)D levels of ≥ 20 ng/ml.
- In view of comparable reduction in CTX and increase in PINP and urinary ca^{+2}/cr ratio following supplementation in all three groups, it may be safe to assume that 600-1000 IU per day would be adequate daily dose to maintain normal serum 25(OH)D levels of 20 ng/ml in pre-pubertal girls.

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131	41.2±25.0	<0.001	118.8±205.2	45.0± 20.8	0.009	77.3±58.0	39.1±26.9	
0.4	9.8±0.5	0.6	9.7± 0.4	9.7± 0.5	0.70	9.9± 0.4	9.9±0.5	
0.5	4.3±0.5	<0.001	4.1± 0.5	4.4± 0.5	<0.001	4.1±0.4	4.2±0.6	
±123.7	170.1±90.9	<0.001	282.7±162.2	251.2± 101.2	0.13	171.9±72.8	126.7±43.2	

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Cont.

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Conclusion

- High prevalence of vitamin D deficiency continues to be present among school children despite creating awareness in public at large for one and half decade.
- Miscible vitamin D₃ is more efficacious than fat soluble vitamin D₃.
- However, more large scale randomized clinical trials in different age groups are required to establish it's efficacy over fat soluble vitamin D₃.

Supplementation in pregnancy



	Group A (no vitamin D) (n = 14)	Group B (one dose of 60 000 U vitamin D) (n = 35)	Group C (two doses of 120 000 U vitamin D each) (n = 35)	P-value
Baseline 25OHD (nmol/l)	25.8 (18.9–30.7)*	33.4 (22.6–47.7)	40.1 (26.9–58.4)	< 0.01
25OHD at delivery (nmol/l)	23.8 (17.2–32.6)	30.9 (24.8–48.1)	53.4 (41.2–88.0) [†]	< 0.001
Serum calcium at delivery (mmol/l)	2.31 ± 0.18	2.28 ± 0.27	2.29 ± 0.21	0.41
Increment of 25OHD (nmol/l)	0.4 (–6.5–16.8)	–2.1 (–10.7–13.1)	13.4 (0.2–42.0) [‡]	< 0.01
25OHD >80 nmol/l at delivery (nmol/l)	1/14 (7%)	2/35 (5.7%)	12/35 [§] (34.2%)	0.003
25OHD at delivery conducted in winter (nmol/l)	14.9 (n = 1)	26.9 (22.9–33.3) (n = 11)	43.7 (35.3–62.0) (n = 14)	< 0.01 [§]
25OHD >80 nmol/l at delivery in winter	0/1	0/11	3/14 (21%)	0.23 [§]

	Group A	Group B	Group C	
circumference	33.6 ± 0.8	34.4 ± 0.6	34.5 ± 0.9	
Length	49.4 ± 2.4	50.1 ± 0.9	50.3 ± 0.9	
Weight (kg)	2.8 ± 0.4	3.0 ± 0.4	3.1 ± 0.4	

Anthropometric indices: Differences persisted at 9 months

Sahu et al, EJCN, 2009

Words of Wisdom

- The richest wealth is Wisdom
- The strongest weapon is Patience.
- The best security is Faith.
- The greatest tonic is Laughter.
- Surprisingly all are free and so is Wonder Vitamin D



Acknowledgement

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Dr Bhavna

Kalawati Saran Hospital:

Dr Anju Seth

Sur Homeopathy College:

Dr Archana Narang
Dr Neena

Thank You!

