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Prevalence and management of vitamin D deficiency in pregnant women in India: A physician survey

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Abstract

Background: Vitamin D deficiency in pregnancy has important maternal and foetal implications.

Aim: This survey was conducted to understand gynaecologists' perspectives on the prevalence of and management practices for vitamin D deficiency in pregnant women in India.

Methods: This was a questionnaire-based survey conducted across India between October 2021 and December 2021. The questionnaire consisted of 30 questions related to the prevalence and management practices related to vitamin D deficiency among pregnant women.

Results: In total, 39 gynaecologists participated in the study. Vitamin D was recommended to women during pre-conceptual counselling by 82.1% of the gynaecologists. One-third (33.4%) gynaecologists observed that >75% of pregnant women in their clinical practice had vitamin D deficiency, with the women aged >30 years being most likely to have this deficiency. Low back pain and vague body pain were the most common symptoms of vitamin D deficiency observed among pregnant women. Daily 2000 IU as continuous therapy was the most common regimen of vitamin D supplementation preferred by the participating gynaecologists (64.1%), followed by weekly 60,000 IU with monthly maintenance by 10 (25.6%) gynaecologists. Two-third gynaecologists 25 (64.1%) shared that <25% of pregnant women are aware about vitamin D deficiency and its impact. Most gynaecologists (97.4%) opined that various international guideline recommendations for vitamin D supplementation were relevant to Indian clinical practice. Only about 2/3rd (66.7%) were aware about the impact of maternal Vitamin D status on the health and development of the baby. Nanoformulations of vitamin D were thought to have better efficacy and compliance to treatment compared with conventional formulations by most gynaecologists. Finally, majority of the participating gynaecologists expressed a desire to have cross-specialty meetings involving endocrinologists, orthopaedic specialists, and gynaecologists to obtain a comprehensive perspective on the management of vitamin D deficiency in Indian clinical practice.

Conclusion: This survey provided valuable insights from gynaecologists in terms of their understanding of the prevalence and management of vitamin D deficiency among pregnant women in India.

Keywords: Vitamin D nano daily 2 K, gynaecologists, pregnant women, maternal health, foetal health

Introduction

The fortification of foods, improved nutrition, and encouragement of sensible sun exposure resulted in the near eradication of rickets, a complication of vitamin D deficiency, in the second half of the twentieth century; however, there has been a growing resurgence of this highly morbid condition [1]. Despite being a country with ample sunlight, Vitamin D deficiency is very common in India. Community-based Indian studies conducted over the past decade on apparently healthy controls reported a prevalence ranging from 34.5% to 94%. These studies, which included various age groups, reflect the magnitude of the problem [2-6]. Hence, the renewed interest in the study of vitamin D, its deficiency and insufficiency, and their consequences.

Vitamin D decreases the risk of chronic illnesses, including breast, ovarian, prostate, pancreatic, and colon cancers; Hodgkin's lymphoma; autoimmune disease; diabetes; and cardiovascular disease [7]. Vitamin D deficiency has important maternal and foetal implications in the antenatal population. Recent studies have linked maternal vitamin D deficiency to an increased risk of developing gestational diabetes, pre-eclampsia, and early onset severe pre-eclampsia [8, 9]. The foetal complications extend beyond the classical concern of rickets.

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Vitamin D deficiency leads to an increased risk of preterm birth and is associated with small for gestational age babies [9-10]. In this regard, longitudinal studies have identified an association between maternal vitamin D insufficiency during late pregnancy and reduced whole body and lumbar spine bone-mineral content in children of nine years [11]. Moreover, the association between childhood bone health and maternal vitamin D status is well established [12, 13]. Additionally, there is an increased prevalence of eczema and asthma in children born to mothers with vitamin D insufficiency at term [14].

In Indian clinical practice, wide range of disparity has been observed in managing vitamin D deficiency among pregnant women. Gynaecologists generally recommend supplementation doses of 400 or 800 IU per day for pregnant women, without checking the initial serum level [15, 16]. However, the American College of Obstetricians and Gynecologists (ACOG) and Royal College of Obstetricians and Gynaecologists (RCOG) guidelines recommend up to 2000 IU of vitamin D per day during pregnancy and lactation to meet daily requirements [17]. Considering the current management gaps in Indian clinical practice, a questionnaire-based survey was conducted among gynaecologists across India to understand the prevalence of vitamin D deficiency in pregnant women and practices towards management of vitamin D deficiency with respect to dosing regimen and preference of formulations.

Methods

Survey Design

This questionnaire-based survey was conducted from October-2021 to December-2021 and involved 39 gynaecologists across all zones of India. All participants were informed that participation in the survey was voluntary and that the data collected were anonymous, confidential, and restricted. Written informed consent was obtained from all participants before the initiation of the survey.

Survey questionnaire

The questionnaire (Supplementary information) consisted of questions on profiles of pregnant women with vitamin D deficiency, symptoms of vitamin D deficiency, current clinical practice in the management of vitamin D deficiency including dose, frequency of administration, and preference of formulations, clinical experience with the use of a vitamin D 2000 IU formulation daily in terms of taste and patient compliance, product handling, efficacy, and ease of use, and on the convenience of a delivery system with a unique measuring cap to ensure accurate daily dosing of 2000 IU vitamin D. Participants were asked to respond to questions based on their experience with treating 10 patients each.

Data Analysis

In all, 39 gynaecologists from across India participated in the survey. The answers to the questionnaire were analysed and interpreted. Data were analysed using the Statistical Package for the Social Sciences (SPSS) IBM statistics v20.

Results

Patient profiling and diagnosis of vitamin D deficiency in pregnant women

In routine clinical practice, 82.1% of the gynaecologists opined that they recommended vitamin D to women during

preconceptual counselling. Table 1 shows gynaecologists' perspectives on prevalence, symptoms and diagnosis of vitamin D deficiency in pregnant women. One-third gynaecologists (33.4%) observed that >75% of pregnant women in their clinical practice had vitamin D deficiency. Twenty gynaecologists (51.3%) reported that the most common age group among pregnant women with vitamin D deficiency was >30 years. Low back pain and vague body pain were the most common symptoms amongst pregnant women as observed by 23 (59.0%) gynaecologists. More than half the gynaecologists (51.5%) said that they do not diagnose vitamin D deficiency but empirically treat all women, whereas approximately 1/4th of the gynaecologists (25.6%) reported that they diagnosed vitamin D deficiency using serum vitamin D estimations (Table 1). Gynaecologists mentioned that they commonly recommended vitamin D testing for women with infertility or polycystic ovarian disorder and for postmenopausal women.

Table 1: Physicians' perspectives on prevalence, symptoms, and diagnosis of vitamin D deficiency in pregnant women

Parameter, n (%)	Overall (N = 39)
Proportion of pregnant women with vitamin D deficiency	
<25%	6 (15.4)
25%-50%	15 (38.5)
50%-75%	5 (12.8)
>75%	13 (33.4)
Age groups for presentation of vitamin D deficiency	
20-25 years	1 (2.6)
26-30 years	7 (17.9)
>30 years	20 (51.3)
All age groups	11 (28.2)
Common symptoms at presentation of vitamin D deficiency	
Asymptomatic	2 (5.1)
Asymptomatic, weakness and difficulty in walking, low back pain and vague body pain	5 (12.8)
Weakness and difficulty in walking, low back pain and vague body pain	8 (20.5)
Low back pain and vague body pain	23 (59.0)
Preponderance of GDM, pre-eclampsia, preterm labour	1 (2.6)
Diagnosis of vitamin D deficiency	
Do not diagnose but empirically treat all women	20 (51.5)
Clinical features	6 (15.4)
Clinical features + serum vitamin D estimations	3 (7.7)
Serum vitamin D estimations	10 (25.6)

GDM, gestational diabetes mellitus

Management of vitamin D deficiency in pregnant women in Indian clinical practice

Daily 2000 IU continuous therapy was the most common regimen preferred for treating vitamin D deficiency in pregnant women (64.1%), followed by weekly 60,000 IU with monthly maintenance (25.6%). The less common regimens were weekly 8000-12,000 IU as continuous therapy or daily 400 IU as continuous therapy, which were recommended by only 5.1% of gynaecologists each. The recommended dose of vitamin D was 60000 IU weekly for infertility, polycystic ovarian disorder. Nearly half the gynaecologists (48.7%) prescribed vitamin D supplementation throughout pregnancy and lactation. Thirty-six gynaecologists (92.3%) opined that 2000 IU was the optimal dose of vitamin D for daily therapy. Almost 2/3rd of the gynaecologists (64.1%) stated that <25% of

pregnant women were aware of vitamin D deficiency and its impact on maternal and foetal health (Table 2).

Table 2: Prescription patterns for the management of vitamin D deficiency

Parameter, n (%)	Overall (N = 39)
Preferred dosing regimen of vitamin D supplements	
Weekly 60,000 IU followed by monthly maintenance	10 (25.6)
Weekly 8000-12,000 IU, continuous therapy	2 (5.1)
Daily 2000 IU, continuous therapy	25 (64.1)
Daily 400 IU, continuous therapy	2 (5.1)
Preferred duration of vitamin D supplementation	
Less than 3 months	1 (2.6)
3-6 months	12 (30.8)
3-6 months, full term, up to 9 months	1 (2.6)
Full term, up to 9 months	5 (12.8)
Full term, up to 9 months and throughout pregnancy and lactation	1 (2.6)
Throughout pregnancy and lactation	19 (48.7)
Optimal dose of vitamin D for daily therapy	
400 IU	1 (2.6)
800 IU	1 (2.6)
1200 IU or 2000 IU	1 (2.6)
2000 IU	36 (92.3)
Patient awareness on vitamin D deficiency and its implications on maternal and foetal health	
<25%	25 (64.1)
25%-50%	10 (25.6)
50%-75%	3 (7.7)
>75%	1 (2.6)

Most gynaecologists (97.4%) opined that they were aware of the ACOG, Canadian Pediatric Society, and Endocrine Society recommendations for vitamin D supplementation (daily 1500-2000 IU) and that these recommendations were relevant to the Indian population. Moreover, 87.2% of gynaecologists opined that vitamin D deficiency during pregnancy increases the risk of pregnancy-related complications, such as gestational diabetes, pre-eclampsia, or preterm labour. According to 66.7% gynaecologists, maternal vitamin D status has an impact on foetal health and impairs the development of bones and teeth, and 30.7% felt that vitamin D deficiency only impairs the development of bones and teeth, while only 2.6% felt that maternal vitamin D status has no impact on foetal health. More than half the gynaecologists (53.8%) felt that the current Indian recommendations for vitamin D supplementation during pregnancy should be revised while majority (79.5%) did not express concern about the development of hypervitaminosis due to use of 2000 IU/day of vitamin D.

Most gynaecologists (89.7%) were of the opinion that the awareness level about the importance of vitamin D during pregnancy has increased after the pandemic, while 10.3% thought that awareness levels have remained the same. With regard to compliance among patients, 46.2% gynaecologists stated that most patients adhered to the prescribed regimen, 43.6% felt that patients tended to become irregular after 2-3 months of therapy, and only 10.3% thought that patients did not take vitamin D supplements regularly. All survey participants acknowledged that they used vitamin D nano-formulations in their practice, with most of them (92.3%) agreeing that nano-formulations have better efficacy than conventional formulations, 2.6% feeling that conventional formulations are better, and 5.1% opining that there was no difference between the two types of formulations. In this

regard, 82.1% felt that compliance among patients to nano-formulations was better, 5.1% felt that compliance to conventional formulations was better, and 12.8% did not see any difference with respect to compliance between the two formulations.

All gynaecologists mentioned that they recommended the 2000 IU daily nano-formulation of vitamin D for pregnant and lactating patients, and they largely had no concerns about using a dose of 2000 IU daily in pregnant patients. Table 3 summarizes the reasons provided by participating gynaecologists for prescribing nano formulation 2000 IU daily with the novel delivery system. ACOG/RCOG recommendations regarding the use of 2000 IU vitamin D during pregnancy was the leading reason (41.1% participants).

Majority of the gynaecologists (53.8%) gave a score of 5 for the novel delivery system, 33.3% gave a score of 4, 10.3% gave a score of 3, and 2.6% gave a score of 2. All the gynaecologists agreed that the unique delivery system provides dosing convenience to pregnant women during the daily administration of vitamin D.

Table 3: Reasons for prescription and of novel nano-formulation of vitamin D 2000 IU with the unique delivery system

Options, n (%)	Overall (N = 39)
1	16 (41.1)
2	8 (20.5)
3	4 (10.3)
1, 2, and 3	5 (12.8)
1 and 3	3 (7.7)
1 and 2	2 (5.1)
4	1 (2.6)

Option 1: ACOG/RCOG recommendations regarding the usage of 2000 IU vitamin D during pregnancy

Option 2: First-ever formulation with 2000 IU vitamin D in liquid nanotechnology

Option 3: Accurate dose delivery using the novel delivery system

Option 4: Any other - Covid pandemic triggering the use of vitamin D supplementation in treatment

With regard to the taste of the new nano-formulation, 79.6% gynaecologists gave a score of 5 (best), 17.9% gave a score of 4, and only 2.6% gave a score of 3. Finally, majority of the gynaecologists (77.0%) mentioned that they would be interested in attending cross-specialty meetings on vitamin D involving endocrinologists, orthopaedics, and gynaecologists to gain complete perspective on the management of Vitamin D deficiency. Antenatal counselling sessions and information brochures were generally thought to increase awareness on the importance of vitamin D during pregnancy and lactation by the participating gynaecologists.

Discussion

The present nationwide, physician-based survey evaluated trends in current clinical practice with regard to the management of vitamin D deficiency among pregnant women in India. In the present survey, 82.1% of gynaecologists recommended vitamin D to women during

pre-conceptual counselling. Several studies showed an association between preconception maternal vitamin D status and adverse pregnancy outcomes^[18]. It is recommended that all women should be screened at a preconception visit for vitamin D deficiency to ensure improved perinatal outcomes.

Deficiency of vitamin D during pregnancy is reflected in lower maternal weight gain, disturbed skeletal homeostasis in the infant, and in extreme situations, reduced bone mineralization, rickets, and fractures. For women with vitamin D deficiency, education on vitamin D in the diet and supplementation should be a part of preconception care. Women at risk for vitamin D deficiency include women who are not exposed to enough sunlight and whose dietary vitamin D intake is low (no dairy and egg or lactose intolerance)^[19-22].

According to 51.3% of gynaecologists, the common age group for vitamin D deficiency was above 30 years. Vitamin D deficiency is a common problem in reproductive-aged women and has become a major public health problem worldwide. Several studies on vitamin D status in pregnant women and women of childbearing age have been conducted and have shown that an average of more than 95% of individuals have low vitamin D status^[20-22].

Low back pain and vague body pain were the most common symptoms among pregnant women with vitamin D deficiency in the present survey, followed by weakness and difficulty in walking. These were in line with the published data that showed that vitamin D deficiency has been associated with increased musculoskeletal pain, particularly back pain, and decreased muscle strength in pregnancy^[23-26].

Nearly two-thirds of the participating gynaecologists noted that <25% of pregnant women were aware of vitamin D deficiency. Morales-Suarez *et al.* suggest that supplementary vitamin D for pregnant women is important for reducing the risk of gestational diabetes, hypertension, pre-eclampsia, early labour, and other complications^[27]. In the absence of Indian guidelines for routine vitamin D supplementation during pregnancy and lactation, 97.4% of the gynaecologists stated that they were aware of the ACOG Canadian Pediatric Society, and Endocrine Society guidelines and opined that these guideline recommendations for vitamin D supplementation are relevant in the Indian scenario. Majority of the gynaecologists (87.2%) opined that vitamin D deficiency during pregnancy increases the risk of pregnancy-related complications, such as gestational diabetes, pre-eclampsia, or preterm labour.

In our survey, most gynaecologists were aware about the impact of maternal vitamin D status on foetal development and health. Harvey *et al* reported that modest evidence exists for a positive relationship between maternal vitamin D status and birth weight^[28]. Some earlier studies have shown that severe maternal vitamin D deficiency was associated with a smaller head circumference at birth^[29, 30], yet some have not^[31, 32]. However, the clinical relevance, if any, of the inverse relationship between maternal vitamin D status and head circumference at birth remains unexplained. It is unknown whether this reflects differences in brain size or in skull bones' structure, and it needs to be explored in future studies.

More than half the gynaecologists in our survey felt that the current Indian recommendations for vitamin D supplementation during pregnancy should be revised as they

opined that the currently recommended dose is insufficient to meet the needs during pregnancy and lactation. Palacios *et al* reported that supplementing pregnant women with more than the current vitamin D recommendation may reduce the risk of gestational diabetes^[33, 16].

Most gynaecologists (79.5%) in the present survey were not concerned about the development of hypervitaminosis D in their patients with the use of 2000 IU vitamin D daily. Most countries have prudently set the safe upper level at 50 µg daily (2000 IU) for adults^[34]. However, this level was set despite the availability of adequate studies of dose-response relationships or toxicity. There is no convincing evidence that daily intakes of up to 125 µg (5000 IU) elicit severe adverse effects^[35]. It has been reported that an intake of 1250 µg (50,000 IU) once every 2 weeks for several years, equivalent to 89.3 µg (3571 IU) daily, did not cause hypercalcaemia or other evidence of hypervitaminosis D^[36]. Some studies showed that even a daily consumption of up to 250 µg (10,000 IU) of vitamin D over long periods did not cause adverse effects in healthy adults^[37, 38], though some studies revealed a negative impact on bone mineral density by using high-dose vitamin D supplementation of 10,000 IU/day^[39]. Nevertheless, supplementation of >10,000 IU of vitamin D is rarely necessary for clinical practice.

Most survey participants (92.3%) reported that nanoformulations have better efficacy and adherence to treatment than conventional formulations of vitamin D. The utilization of nanoemulsions over conventional coarse emulsions as delivery vehicles for lipophilic nutrients and bioactives has gotten a substantial thrust in the nutrition and food industry in the recent past. *In vitro* and *in vivo* bioavailability studies of vitamin D in simulated gastrointestinal systems, animal and human subjects have shown that the bioavailability of nanoformulations of D3 was significantly greater than conventional fat-soluble oral preparations^[40]. Nanoparticle-based formulations of vitamin D3 have been found to be effective and safe with good tolerability in the correction of vitamin D levels in patients with documented deficiency or insufficiency of vitamin D^[41].

The findings of this study provided insights to understand the different modalities or approaches followed by Indian gynaecologists for their patients and their expectations with respect to product features for future optimization. However, this study has certain limitations such as low sample size of practicing clinicians and empirical method of data collection. Prospective studies with a large sample size across geographical locations will provide more insights on management practices among pregnant and lactating women.

Conclusion

This survey provided valuable insights from gynaecologists' in terms of their understanding of the prevalence and management of vitamin D deficiency among pregnant women in India. The survey findings indicate that there is a need to increase awareness among pregnant and lactating women regarding the various treatment options available and their benefits with regard to efficacy and compliance specifically in regions with high prevalence of vitamin D deficiency.

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Conflict of interest

Both authors received research grant from Abbott for participation in the survey.

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Supplementary

Table 1: Survey questionnaire

No.	Question
Q1	In which patient profiles do you usually recommend testing of vitamin D levels?
Q2	What is the dose for which vitamin D is prescribed for the following profiles?
Q3	Do you recommend Vitamin D to women approaching you for pre-conceptual counseling?
	Yes: Dose _____ and duration _____ No
Q4	In your practice, what percentage of pregnant women are vitamin D deficient?
	a) Up to 25% b) 25%-50% c) 50%-75% d) >75%
Q5	What is the most common age group amongst pregnant women presenting with vitamin D deficiency in your practice?
	a) <20 years b) 20-25 years c) 26-30 years d) >30 years e) Similar incidence across all age groups
Q6	What are the common symptoms that pregnant women with vitamin D deficiency present to you with?
	a) Asymptomatic b) Weakness and difficulty in walking c) Low back pain and vague body pain d) Any other
Q7	How do you diagnose vitamin D deficiency during pregnancy?
	a) Do not diagnose but empirically treat all women b) Clinical features c) Serum vitamin D estimations d) Any other
Q8	Which regimen do you prefer for treating vitamin D deficiency in pregnant women?
	a) Weekly 60,000 IU followed by monthly maintenance b) Weekly 8000-12,000 IU, continuous therapy c) Daily 2000 IU, continuous therapy d) Daily 400 IU, continuous therapy
Q9	For how long do you prescribe Vitamin D supplementation in pregnant women?
	a) <3 months b) 3-6 months c) Full term, up to 9 months d) Throughout pregnancy and lactation e) Lifelong, even after stopping lactation
Q10	In your opinion, what is the optimal dose of Vitamin D for daily therapy?
	a) 400 IU b) 800 IU c) 1200 IU d) 2000 IU
Q11	What percentage of pregnant women are aware of vitamin D deficiency and its implications on maternal and foetal health?
	a) <25% b) 25%-50% c) 50%-75% d) >75%
Q12	Are you aware of the ACOG, Canadian Pediatric Society, and Endocrine Society recommendations mentioning daily 1500-2000 IU vitamin D supplementation during pregnancy and lactation?
	a) Yes b) No
Q13	Do you think the ACOG, Canadian Pediatric Society, and Endocrine Society recommendations for vitamin D supplementation are relevant in the Indian scenario?
	a) Yes b) No

Q14	Do you have any concerns about using vitamin D 2000 IU per day in your pregnant patients?		
Q15	In your opinion, does vitamin D deficiency during pregnancy increase the risk of pregnancy-related complications like gestational diabetes, pre-eclampsia or preterm labour?		
	a) Yes	b) No	
Q16	In your opinion, does maternal vitamin D status have any impact on the health of the baby?		
	a) Yes, the development of bones and teeth may be impaired in the baby	b) Yes, in addition to (a), vitamin D deficiency may impair foetal neuro-development and increase the risk for asthma and other childhood-related illness	c) No, maternal vitamin D status has no impact on foetal health
Q17	Do you think the current Indian recommendations for vitamin D supplementation of IU/day during pregnancy should be revised?		
	a) Yes, the dose as per current recommendations is insufficient to meet the needs during pregnancy and lactation	b) No, the dose as per current recommendation is sufficient	
Q18	Are you concerned about the development of hypervitaminosis D in your patients, with use of 2000 IU vitamin D daily?		
	a) Yes	b) No	
Q19	Has the awareness level about the importance of vitamin D during pregnancy changed after the pandemic?		
	a) Increased	b) Decreased	c) Remained the same
Q20	How is the compliance of your pregnant patients to vitamin D supplementation?		
	a) Most patients adhere to the prescribed regimen	b) Patients tend to become irregular after 2-3 months of therapy	c) Patients do not take vitamin D regularly
Q21	Have you used vitamin D nano-formulations in your practice?		
	a) Yes	b) No	
Q22	In your opinion, is there any difference in efficacy between vitamin D nano-formulations and conventional preparations?		
	a) Yes, nano-formulations have better efficacy	b) Yes, conventional formulations are better	c) No difference between the two formulations
Q23	According to your experience, is the patient compliance to vitamin D therapy better with nano-formulations as compared to conventional preparations?		
	a) Yes, compliance to nano-formulations is better	b) No, conventional formulations have better compliance	c) No difference between the two formulations
Q24	Have you used the novel vitamin D 2K IU nano-formulation in your pregnant and lactating patients?		
	a) Yes	b) No	
Q25	What prompted you to prescribe the novel vitamin D 2K IU nano-formulation to your pregnant and lactating patients?		
	a) Unique novel delivery system that ensures accurate dose delivery	b) First-ever formulation with 2000 IU vitamin D in liquid nanotechnology	
	c) ACOG/RCOG recommendations regarding the usage of 2000 IU vitamin D during pregnancy	d) Any other	
Q26	How would you rate the novel delivery system on a scale of 1 to 5 (1 being the worst and 5 being the best)		
Q27	Do you think the novel delivery system offers dosing convenience to pregnant women during the daily administration of vitamin D?		
	a) Yes	b) No	
Q28	How would you rate the taste of the novel vitamin D 2K IU nano-formulation on a scale of 1 to 5 (1 is bad, 5 is good)?		
Q29	According to you what initiatives can help raise awareness		
Q30	Would you be interested in attending cross-specialty meetings on vitamin D involving endocrinologists, orthopaedic, and gynaecologists to get a complete perspective in managing Vitamin D deficiency?		