

Dose of the vitamin D in prenatal supplements and the current prevention its deficiency at mothers and newborns

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Summary

Introduction. Because of widespread deficiencies of vitamin D in the human body there is a need of supplementation large amount of vitamin D during pregnancy - in the dose of 37,5 - 50 µg per day.

The aim. The aim of this study was evaluation of the dose of vitamin D in vitamin-mineral prenatal supplements in the context of actual prevention its deficiency at mother and newborn.

Material and methods. The assortment of preparations was collected in 10 pharmacies in Warsaw in 2014. The content of vitamin D was estimated based on the information on the package of preparations.

Results. The content of vitamin D in vitamin-mineral prenatal supplements was diversified (5-50 µg per tablet/capsule), but 85% of them contained small dose of vitamin D (5-10 µg).

Conclusions. Prenatal supplements are not able to provide good prevention of vitamin D deficiency at mother and newborn, therefore adjusting their composition to actual recommendations is needed.

Key words: vitamin D; over the counter drug; supplementation; pregnancy; newborns

INTRODUCTION

In the past decade, the world academic literature has been unanimously stressing the commonness of vitamin D deficiency in the population, including pregnant women. The problem also concerns the regions of considerable sunshine, which is referred to as the "Mediterranean paradox". Although vitamin D deficiencies in pregnant women were detected as early as in the 1980s, this problem has started to evoke widespread discussion only recently, which is dictated by factors that increase the deficit. These factors include obesity in women of child-bearing age and during pregnancy, which is associated with lower vitamin D level in the organism, and lifestyle changes, such as staying indoors for longer periods of time and using sunscreens [1–5].

Vitamin D deficiency in pregnant women leads to fetal deficiencies and increases the risk of abnormal pregnancy [1,6–8]. A proper vitamin D level during pregnancy is also necessary for the physiological growth of calcium absorption. Thanks to this, dietary calcium requirement is not increased during pregnancy despite its important role in this period [1,9–10]. Serum concentration of 25-hydroxyvitamin D 25(OH)D is the best indicator of vitamin D status. Nevertheless, the definition of the optimal concentration of this metabolite is still being discussed [1,7,11–13].

Currently, experts agree that increased dietary vitamin D supplementation in pregnant women is important. The guidelines of 2013 for Central Europe, including Poland, recommend pregnant women to take 1,500–2,000 IU (37.5–50 µg) of vitamin D starting from at

least the second trimester, irrespective of the season [14]. The latest recommendations issued in 2014 by the Polish Gynecological Society significantly increased the previous recommended dose from 800–1,000 IU (20–25 µg) to 2,000 IU (50 µg) daily in women who plan pregnancy, are pregnant or breast-feed [15–17].

Research shows that most pregnant women take combined vitamin and mineral preparations (multivitamins) [18–19]. Since the level of nutrients in such products is not legally regulated, their content can vary considerably. In the light of the current recommendations, it is necessary to determine vitamin D content in the products available on the market in terms of their efficacy in deficiency prevention. This can lead to the preparation of recommendations concerning the composition of products intended for pregnant women.

AIM

The aim of the paper was to assess vitamin D content in vitamin and mineral supplements intended for pregnant women and in single-component vitamin D preparations for adults. Furthermore, the authors analyzed these doses with respect to the current recommendations concerning vitamin D deficiency prophylaxis in the mother and neonate.

MATERIAL AND METHODS

Preparations were obtained from 10 pharmacies in 5 Warsaw districts (Śródmieście, Wola, Praga Północ,

Mokotów and Ursus) in July–August 2014. Vitamin D content, its chemical forms and other essential data were obtained from labels of unit packages.

RESULTS

Multivitamins/minerals

Twenty vitamin and mineral preparations for pregnant women were found in pharmacies. Depending on the size of a pharmacy, the offer was diversified: from 3 to 14 preparations. Most of them (70%) were dietary supplements. Vitamin D content ranged from 5 to 50 µg per tablet/capsule, but usually the dose was 5–10 µg. Two products for women planning pregnancy and in the first trimester of gestation did not contain vitamin D. This nutrient was found in the form of cholecalciferol, called vitamin D₃, in all products. Vitamin D content stated on the label of dietary supplements was expressed in µg, and on the packages of products registered as dietary foods for special medical purposes or medicinal products – in IU. To facilitate the interpretation of this study, the content has been presented in both units (Tab. 1).

Single-component preparations

Pharmacies offer a broad selection of single-component vitamin D preparations for adults in the form of 14 products (Tab. 2.). Vitamin D content ranged from 10–50 µg, but 10 products (71%) contained at least 25 µg of this vitamin. All preparations were registered as

Tab. 1. Characteristics of prenatal preparations available in pharmacies in Warsaw (as of August 2014)

Name	Type	Vitamin D content in a unit (tablet/capsule)	Recommended daily dose
Centrum Materna	dietary supplement	5 µg (200 IU)	1 tablet
Doppelherz aktiv Mama	dietary supplement	2.5 µg (100 IU)	2 capsules
Elevit Pronatal	medicinal product	500 IU (12.5 µg)	1 tablet
Falvit mama	dietary supplement	5 µg (200 IU)	1 tablet
Femibion Natal 1	dietary supplement	no vitamin D	1 tablet
Femibion Natal 2	dietary supplement	10 µg (400 IU)	1 tablet
Feminatal 800 Metafolin	dietary supplement	no vitamin D	1 tablet
Ladee Vit	dietary supplement	10 µg (400 IU)	1 capsule
Matruelle	dietary supplement	5 µg (200 IU)	1 capsule
Omegamed optima	dietary food for special medical purposes	20 µg (800 IU)	1 capsule
Omegamed optima Forte	dietary food for special medical purposes	37.5 µg (1,500 IU)	1 capsule
Pregna plus	dietary supplement	37.5 µg (1,500 IU)	1 capsule
Pregnaker original	dietary supplement	5 µg (200 IU)	1 tablet
Prenalen MultiVit	dietary supplement	5 µg (200 IU)	1 tablet
Prenalen MultiVit + DHA	dietary supplement	5 µg (200 IU)	1 tablet
Prenatal Complex	dietary food for special medical purposes	10 µg (400 IU)	1 capsule
Prenatal Duo	dietary food for special medical purposes	20 µg (800 IU)	1 tablet
Prenatal Classic	dietary food for special medical purposes	50 µg (2,000 IU)	1 tablet
Vita-miner Prenatal	dietary supplement	10 µg (400 IU)	1 tablet
Vita-min plus Mama	dietary supplement	5 µg (200 IU)	1 capsule

foods: 8 of them (57%) as dietary foods for special medical purposes and 6 (43%) as dietary supplements. As with the prenatal multivitamins, the chemical form of vitamin D in all the preparations was cholecalciferol.

DISCUSSION

Only 3 of 18 preparations intended for the entire pregnancy contained the currently recommended vitamin D dose at the level of 37.5–50 µg. At the same time, only 5 preparations (25%) met the previous criteria concerning vitamin D supplementation at a dose of 20–25 µg. Most products (60%) contained a low dose of vitamin D (5–10 µg). The currently recommended dose of this nutrient in preparations has doubled which results from the state-of-the-art concerning low efficacy of low-dose supplementation. It is of note that publications from several years ago mention the lack of data that would indicate increased vitamin D requirement during pregnancy. Moreover, the level that used to be considered normal during pregnancy is now interpreted as a considerable deficiency [20–21]. At the same time, some experts are of the opinion that the vitamin D requirement in pregnant women is difficult to define considering its low safety level as well as high and dangerous risk of overdose [20]. The latest publications more and more frequently stress the fact that vitamin D doses during pregnancy should depend on its serum concentration. However, since there are various recommendations, its optimal concentration is not uniform [1]. The American Academy of Pediatrics is considering introducing 25(OH)D assay in pregnant women in order to

select the dose that will ensure its concentration at the level exceeding 32 ng/ml. Other experts believe that normal vitamin D level in a neonate can be achieved when maternal concentrations are above 20 ng/ml [22]. In the light of the recent guidelines for pregnant women in Poland, the target serum 25(OH)D concentration should range from 30–50 ng/ml [14]. Such levels require the usage of large doses. Vitamin D content in most of the prenatal preparations is therefore still too low despite the fact that the inefficacy of such supplementation has been indicated for a long time. In 2004, Laskowska-Klita et al. demonstrated that the intake of multivitamin/mineral products increases vitamin D concentration by merely 10%, and in 2011, Skowrońska-Jóźwiak et al. found that serum vitamin D concentration in women using such preparations was too low in over 46% of cases, which resulted from too low content of this vitamin in these products [6,21]. Authors agree that a dose of 5–10 µg (200–400 IU) does not cause a significant improvement in the saturation with vitamin D. Only 50 µg (2,000 IU) can ensure its appropriate level [3,6–7,11].

Apart from the prophylaxis and elimination of vitamin D deficiency, the safety of using higher vitamin D doses is a separate issue. It must be emphasized that in 2012 the European Food Safety Authority (EFSA) introduced significant changes concerning the tolerable upper intake level of vitamin D (UL) for adults, including pregnant and breast-feeding women, from 50 µg daily to 100 µg daily [23]. Other experts are of the opinion that the safe level of vitamin D intake is much

Tab. 2. Characteristics of vitamin D preparations available in pharmacies in Warsaw (as of August 2014)

Name	Type	Vitamin D content in a unit (tablet/capsule)	Recommended daily dose
Bio-Witamina D ₃	dietary supplement	20 µg (800 IU)	1 capsule
D-Vitum forte	dietary food for special medical purposes	25 µg (1,000 IU)	1 capsule
Naturalna Witamina D ₃	dietary supplement	25 µg (1,000 IU)	1 capsule
Protego Witamina D	dietary supplement	25 µg (1,000 IU)	1 capsule
VitaDerol forte	dietary food for special medical purposes	37.5 µg (1,500 IU)	1 capsule
Vitamin D ₃	dietary food for special medical purposes	25 µg (1,000 IU)	1 capsule
Vitrum D ₃	dietary food for special medical purposes	25 µg (1,000 IU)	1 capsule
Vitrum D ₃ forte	dietary food for special medical purposes	50 µg (2,000 IU)	1 capsule
Witamin D-3	dietary supplement	10 µg (400 IU)	1 capsule
Witamina D	dietary food for special medical purposes	10 µg (400 IU)	1 capsule
Witamina D	dietary supplement	20 µg (800 IU)	1 capsule
Witamina D 2000	dietary food for special medical purposes	50 µg (2,000 IU)	1 capsule
Witamina D ₃	dietary supplement	50 µg (2,000 IU)	1 capsule
Witaminum D 2000	dietary food for special medical purposes	50 µg (2,000 IU)	1 capsule

higher, even 250 µg. A toxic dose is thought to be greater than 750 µg daily for more than 3 months [24].

Epidemiological studies concerning vitamin D intake in pregnant women, conducted over several years in Poland, indicate that it is still low and does not change over time. In 2000, Szponar et al. demonstrated that mean intake was 2.8 µg daily and constituted only 56% of the recommended normal dose. The situation in non-pregnant women was not much better. In this case, mean daily intake was 3.4 µg. Only 15% of Polish women covered the recommended mean intake [25]. The same tendency was indicated by a study of Lebedzińska et al. conducted in 2008–2009. Vitamin D intake was 2.4 µg daily in women of optimal child-bearing age [26]. A similar alarming situation can be observed in other European countries. In Great Britain, vitamin D intake by young women is estimated at 3 µg daily, and only 1% of women consume more than 10 µg of this vitamin per day [7]. Bearing in mind low vitamin D intake in women of child-bearing age, including pregnant individuals (2.4–3.4 µg daily), and the recommended dose of this vitamin in preparations (37.5–50 µg daily), its estimated intake from both sources will be well below the safe intake level (100 µg). The composition of prenatal multivitamin products should be therefore modified in order to ensure an optimal vitamin D level in the organism of the mother and the fetus. In most preparations, a dose of vitamin

D has not changed for years even though expert recommendations have indicated its increased requirement during pregnancy. Currently, when experts have agreed that the safe vitamin D level (UL) can be doubled, increasing its dose in vitamin preparations does not carry a risk of reaching the tolerable upper intake level. Until such a modification is introduced, physicians should inform their patients about the need for an optimal vitamin D supplementation, which, in most cases, is associated with the necessity to use additional preparations, preferably single-component products of an adjusted vitamin D content so as to avoid excessive intake of this vitamin and of other components that can be potentially present in the two preparations used. Such supplementation can be problematic for women, and therefore it should be supervised by a physician.

CONCLUSIONS

1. Most vitamin and mineral preparations intended for pregnant women do not contain a recommended dose of vitamin D.
2. Optimal vitamin D intake in pregnant women necessitates additional dietary supplementation with a product selected in terms of vitamin D content.
3. Product manufacturers and marketing authorization bodies should be aware of the fact that the composition of these products ought to be adjusted to the current recommendations.

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