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Does Vitamin D Supplementation Affect Postpartum Anthropometric Measurements in Gestational Diabetes? A Randomized Controlled Clinical Trial

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ABSTRACT

Introduction: We know mothers with gestational diabetes mellitus (GDM) are in the higher postpartum risk of spare weight gain and type 2 diabetes. Excessive postpartum weight gains also lead to low maternal vitamin D levels. So, we decided to evaluate the result of a single mega dose of injectable vitamin D in postpartum weight gain and other anthropometric measurements in the new cases of GDM.

Methods: This is a randomized clinical trial study with the follow-up time of 3 months. Totally 45 people were randomly allocated into control and intervention groups. The intervention group got only one IM injection of 300,000 IU of vitamin D whereas controls did not. The body mass index (BMI), waist circumference, hip circumference and waist to hip ratio were quantitated.

Results: 24 mothers with an average age of 30.7±6.2 in the intervention group and 21 mothers with an average age of 29.5±4.0 in the control group took part in the study. Waist circumference and hip circumference reduced in the intervention group in compared to the control group (P value= 0.006), significantly. Changes of BMI were not significant after intervention (P value= 0.9).

Conclusions: Only one single 300,000 IU dose of vitamin D decreased waist and hip circumference in postpartum of GDM women, but it did not find any significant effect on BMI. Further prospective studies with longer follow up period are necessary.

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Introduction

Gestational diabetes mellitus (GDM) that is the most important metabolic problem in pregnancy is determined by glucose intolerance with the first discernment in pregnancy (1). Researchers found that GDM has been related to postpartum problems comprising increased risk of developing type 2 diabetes mellitus, obesity and cardiovascular disease (2).

Understanding the association between GDM and maternal obesity revealed an increased prevalence of GDM among obese women compared to those of normal weight (3). The prevalence of obesity as the most common nutritional problem has increased in the last two decades (4-6) about 63% and 50% in the reproductive age (7) and pregnant women (8) respectively. Vitamin D deficiency is one other prevalent public health concern in developed (9-11) and developing countries (12). Moreover, obesity as one of the most important causes of diabetes (13) is associated with low plasma 25-hydroxyvitamin D concentration (14). Some studies revealed that vitamin D supplementation might be effective in weight loss (15) but another not (16).

Low vitamin D concentration has been related to altered glucose homeostasis in both in vitro (17) and observational studies (18). At the same time some clinical trials found significant benefit of vitamin D supplementation in associated with the risk of gestational diabetes (19-21). In addition a meta-analysis found an inverse significant relation between 25 OHD and incidence of GDM in cross-sectional studies (22). However, the meta-analysis of randomized controlled trials showed that the actual benefit of vitamin D supplement in pregnancy remains vague (23). Most of the studies evaluating the

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effect of vitamin D have been done in GDM with daily or weekly doses of vitamin D that might have little compliances.

To the best of our knowledge there is not any data about the effect of one injectable mega dose of vitamin D on anthropometric measurements in postpartum of women with GDM. Women have higher risk of glucose intolerance and also type two diabetes in their life (24), which might be inversely related to serum 25-(OH)D and anthropometric parameters (25). So, the study was designed to explore the effect of an injectable mega dose of vitamin D on anthropometric indexes in postpartum of GDM.

Material and Methods

Design and Population

This is a parallel randomized clinical trial with a 3-month follow-up duration with trial registration code IRCT138902113840N1. Mothers with the first diagnosis for GDM in 24-28 weeks of conception on the basis of Carpenter and Coustan ratio (26) participated in our study. The sample size, inclusion criteria, simple random allocation into intervention (IG) and control groups (CG), study setting, blinding and spare details was explained in another publication of the study (27). This study talks over about anthropometric measurements which have not yet been discussed.

Patients who volunteered for the study were informed that they could withdraw from the study at any time. Written informed consent was gotten from each subject before the study. In addition, the study proposal had been approved by Ethics-in-Research Commission in Shahid Sadoughi University of Medical Sciences (SSUMS).

Measurements

We measured the participants' weights using Seca scale (Germany Seca) with the accuracy of 0.1 kg. Also, the participants' heights were measured by Seca scale with the accuracy of 0.5 cm and then we calculated BMI. We measured waist and hips circumference with one narrow strip for calculating waist to hip ratio. In addition, mothers were interviewed to obtain general information about them. Moreover, patients were asked not to change their normal diet and their physical activity.

We measured serum 25(OH)D with ELISA and using kit of immunodiagnostic systems Ltd Nyco card equipment (Nyco corporation, Norway), with a sensitivity of 2 nmol/ml.

Administration Dose and Follow-up

300,000 mega doses supplements of Vitamin D intramuscular injection form were made by Iran Hormon Corp (Iran, Tehran). We kept ampoules far away light or kept at 15-30 °C. 12 weeks after injecting vitamin D, blood sampling was again implemented and the same variable was scanned in the same way as for the baseline samples.

Statistical Analysis

Kolmogorov–Smirnov test was used to describe normal distribution variables. Paired t-test was used for comparing means of normal distribution variables in the beginning and the end of the study for both groups. Student t-test was used to compare the mean of variables between the two groups. In addition, Wilcoxon test was carried out for comparing the covariates without normal distribution in each group and between the two groups. Mann–Whitney U test was also used for comparing data from the two groups. Fisher's exact test and Chi-square were used to compare of qualitative variables between the two groups. The approach of the analysis was intention to treat. The results of the quantitative data with normal distribution were described as mean ± SD. Significance level was considered in P-value ≤ 0.05 and β was 0.2.

Results

It should be noted that three people withdrew from the intervention group. Therefore, we analyzed the data of 45 participants who really continued the study period including 24 with the age average of 30.7±6.2 in the IG and 21 with the age average of 29.5±4.0 in the CG. The analysis approach was as per the protocol and was performed only for people who completed the study period.

Table 1 demonstrates information before intervention. Body mass index (BMI) between the 2 groups was not statistically significant before intervention (P_{value}= 0.9). Also with the classification of the BMI on the basis of World Health Organization, overweight classified by BMI was in the range of 25-30 kg/m2 were 58.3% in the IG and 57.1% in the CG that was not statistically significant, too. Also the frequency of the subjects on the basis of this classification between the two groups at the

beginning of the intervention was not significant ($P_{value} \geq 0.2$). However, differences of BMI before and after intervention were not significant in both groups.

The average of waist circumference before intervention was not significant between two groups ($P_{value} = 0.9$). After vitamin D supplementation, it decreased significantly in IG ($P_{value} = 0.006$) but not in CG ($P_{value} = 0.07$). The mean of Hip circumference after intervention was not significantly different before treatment in the two groups, however it decreased significantly in IG ($P_{value} = 0.006$) but not CG.

Table 1. The comparison of means and percentage of the variables under the study in the intervention and control groups before intervention

Variables	Intervention Group (N=24)	Control Group (N=21)	P-value
Age (year)	30.7±6.2	29.5±4	0.4
Pregnancy month for diagnosing GDM	5.1±2.3	4.7±2.2	0.6
Weight (kg)	70.2±12.5	69.9±11	0.9
Height (cm)	155.6±5	157.9±4.4	0.4
BMI* (kg/m2)	28.9±4.8	27.9±3.6	0.9

*Body Mass Index

Table2. The comparing of 25(OH) D3 and anthropometrics measurements between and within the two groups

variables/Groups	Control group(n:21) Mean ± SD	Intervention group(n:24) Mean ± SD	P value [b]
25(OH)D3 (nmol/l)			
Before	25.30(12.8-137.2) [a]	24.25(13.3-202.4)	0.44
After	24.10(18.0-191.7)	62.10(31.7-278.9)	<0.001
P value [c]	0.020	**< 0.001**[c]	
BMI (kg/m^2)			
Before	28.9±3.6	29.15±5	0.4
after	27.4±3.7	29.85±6	0.1
P value	0.25	0.35	
Waist circumference			
Before	88.3±7.2	90±8.7	0.9
after	88.1±9.4	85.5±9.6	0.8
P value	0.07	***0.006****	
Hip circumference			
Before	107.8±8.8	110.3±10.3	0.5
after	106.2±10.3	107.3±9.1	0.7
P value	0.10	***0.006****	

a: Median (Min-Max); **b:** Mann-Whitney U test has been used for 25-(OH) D3 and Student t-test for others; **c:** Wilcoxon test has been used for 25-(OH) D3 and Paired t-test for other cases.

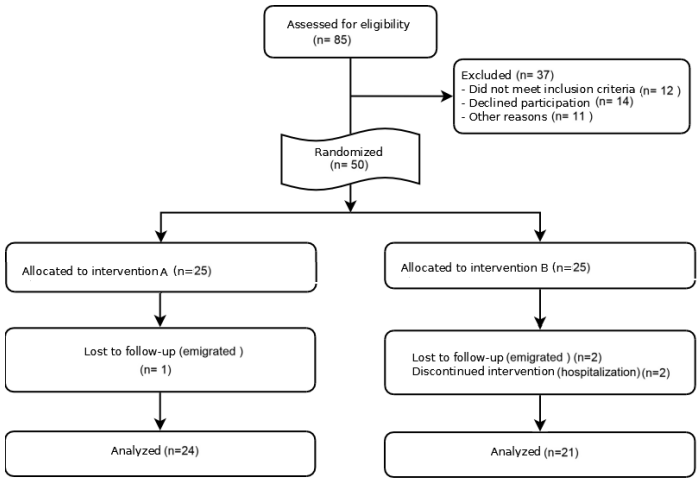

Fig. 1. Flowchart of the study procedure.

Discussion

In this study the mega doses vitamin D supplementation presented higher plasma 25-(OH) D after 3 months in the IG. After the intervention of vitamin D and after 12 weeks, hip and waist circumferences significantly

decreased while there was no difference on BMI. It is necessary to mention that the used dose has had efficacy and safety (28) and we did not watch any side effects.

Vitamin D concentration in pregnant women has been studied extensively (29-33). Studies revealed that vitamin D deficiency has been related to several adverse gestation outcomes including cesarean section (34), preeclampsia (35), GDM (36), LBW or low birth weight(37), and increased rates of SGA or small for gestational age (38). We found vitamin D supplementation improved waist and hip circumferences significantly. Another study has found a 1 cm rise in waist circumference in obese participants for a fall of 0.29 nmol/L ($p = 0.01$) in vitamin D (39). Framingham heart study showed that vitamin D concentration inversely related to waist circumference in 3890 population (40). Some experimental studies show that moderate to severe vitamin D deficiency directs to increased parathyroid hormone, which it may stimulate calcium influx into adipocytes and thereby increase biogenesis and promote greater adiposity. (41).

In contrast with our result, Rosenblum found the fortification with calcium and 100 IU vitamin D did not have any significant effect on waist circumference after adjustment for total abdominal fat, however the reduction in visceral adipose tissue was higher in IG compared with CG significantly (42), maybe because of a low dose of juice fortification with vitamin D or calcium. Additionally, another study that has investigated the effect of 4000IU vitamin D supplementation in healthy overweight and obese women, found that vitamin D3 supplementation caused body fat mass and waist to hip ratio reduction. However, waist circumference and body weight were not significantly different in the study. (43). The mechanisms by which vitamin D may affect obesity are unclear, and the probable justifications are theoretical. In vitro experiments have been suggested that vitamin D may affect the risk of obesity via modulating the catabolic (44, 45) and anabolic (46, 47) activity of adipocytes.

This study showed the injection of only one mega dose of vitamin D had no effect on body mass index. In line with our results, a 100 µg (4000 IU) supplementation with vitamin D showed no statistically significant effect on vitamin D in body mass index (48). Also another study with 50,000 IU vitamin D_3 supplementation 2 times throughout the study (at baseline and at day 21 of the intervention) showed no significant effect of vitamin D in body mass index and weight (19). In addition a vitamin D-calcium co-supplementation study found that mean differences of weight and BMI are not statistically significant (49). Another study showed that no significant reduction in weight, BMI, waist and waist to hip circumference caused by vitamin D supplementation (50). The opposite results in a study found that BMI significantly decreased after daily supplementation of 400IU vitamin D (51). Differences between studies may be due to differences in doses, duration of supplementation, or race. Vitamin D could balence body weight and energy expenditure through calcium regulation. Some studies have shown that intracellular calcium concentration modulates lipolytic activity in isolated human adipocytes (41) and other studies have shown that vitamin D could prevent the function of adipogenic transcription factors (52).

Based on a study body fat mass was associated with 25(OH) D in pregnancy, inversely (53); however, Looker (54) found that the association between vitamin D and body fat mass was stronger in white women and was significant in black women just for younger than 50 years. I n the study of Young et al (55) BMI and adiposity that measured by visceral and subcutaneous adipose tissue, were associated with 25(OH) D, in reverse.

Studies display the risk of vitamin D insufficiency and deficiency increase in obese or overweight people with ethnic differences, but it depends on the kind of variable that used to measure of adiposity. In other words, the accumulation of vitamin D in it makes it less available. (56). Because, decreased bioavailability can lead to vitamin D deficiency and excessed fat stores in the body. In other words, the accumulation of vitamin D in fat mass makes it less available (57, 58).

The possible strengths of the study are the presence of a control group that follow up parallel with intervention group for disappearing time trend effects. Also, we randomized IG and CG well, because covariates were not deferent significantly between 2 groups on the baseline. The limitation is that we did not have information about spending times outdoors or exposure on sun. Also, the results of

our study is not generalizable to all age or ethnic groups, because our sample was white and adult Asian women. and we did not do sampling randomly. It seems that the duration of this study was short, by doing the research in a longer period, the better control on the efficacy of a mega dose of vitamin D was possible. The ethics committee did not allow injections for control group. So, they did not blind. Finally, more clinical trials with different doses of vitamin D and in longer duration are recommended in postpartum of GDM.

Conclusion

This study showed that supplementation with only one high dose of vitamin D injection can significantly decrease waist and hip circumference in postpartum of GDM women, but it did not find any significant effect on BMI.

***Abbreviations*:**
GDM: Gestational diabetes mellitus
IM: Intra muscular
BMI: Body mass index
25(OH) D: 25 Hydroxyl vitamin D
IU: International unit
µg: Micro gram
VDD: Vitamin D deficiency
VDI: Vitamin D insufficiency
IG: Intervention group
CG: Control group
SSUMS: Shahid Sadoughi University of Medical Sciences

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Conflicts of Interest

Not all authors have a conflict of interest.

Authors Contributions

MH has made substantial contributions to conception and design, recruitment, biochemical analysis, and the drafting of the manuscript. HMK has made substantial contributions to conception and interpretation of data. ESh has made substantial contributions to recruitment and biochemical analysis. MKh has made substantial contributions to drafting and finalizing of the manuscript. All authors have given final approval of the version to submit.

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