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Effect of Vitamin D Versus Placebo on Fetal Outcomes and Maternal Control in Pregnant Women with pre Gestational Diabetes Mellitus

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Abstract

Background: Diabetes mellitus (DM) is a prevalent global disease, with its occurrence steadily rising. Vitamin D insufficiency is globally acknowledged as a prevalent health issue.

Objective: To assess the impact of vitamin D on fetal outcomes and mother glycemic control in pregnant women with pre-gestational diabetes mellitus.

Patients and methods: This study is a prospective analysis involving 140 pregnant women who have already been diagnosed with pre-gestational diabetes mellitus. The patients were randomly assigned to two groups using a computer allocation process. The study was conducted at Bab El Sharia and Al-Hussein Al-Azhar University Hospitals. The patients recruited from the Inpatient and outpatient clinic.

Results: Regarding the maternal outcomes of the research groups. There was not any statistically significant distinction in the occurrence of pre-eclampsia between the two groups being examined ($p=0.154$). A notable disparity in Polyhydramnios was seen between both groups being examined, with a 0.005 significant p -value. There was a statistically significant difference in hospitalization between the two groups under investigation ($p=0.009$). Between the two groups under investigation, there was no statistically significant difference in preterm delivery ($p=0.245$). There was a significant difference in Macrosomia ($p=0.004$) between the two groups under investigation.

Conclusion: Pregnant women with GDM can benefit from vitamin D supplementation, which also lowers the risk of unfavourable pregnancy outcomes. It is important to remember that additional analysis and research on the amount and duration of vitamin D supplementation are still required to produce proof for avoiding negative effects in future, high-caliber studies.

Keywords: Vitamin D; Placebo; Pre-gestational diabetes mellitus; Fetal outcomes

1. Introduction

Globally, (DM) is a widespread illness whose prevalence is steadily rising.¹

Furthermore, recognized as a worldwide health issue, two vitamin D deficiency is associated with fractures and rickets.²

Furthermore, low D vitamin has now been linked to the development and course of mellitus with diabetes. There is mounting evidence that patients with diabetes mellitus frequently have inverted vitamin D levels.³

Moreover, a meta-analysis and other trials have confirmed the advantages of vitamin D administration in DM patients.⁴

When the body's immune system attacks and kills the pancreatic islet β -cells, insulin

production is completely stopped, resulting in type 1 diabetes. Type 1 diabetes is verified to be autoimmune due to auto-antibodies directed against islet β -cells and the infiltration of T, B, and macrophages into these cells. Studies have indicated that vitamin D has immunomodulatory characteristics. Multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, and systemic lupus erythematosus are just a few immune-suppressive conditions that have been linked to vitamin D deficiency. It is thought that type 1 diabetes and low vitamin D levels are related. Vitamin D may alter the Th1/Th2 cytokine profile, as evidenced by the expression of vitamin D receptors (VDR) in human T and B cells.

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Furthermore, there is a notion that vitamin D affects lymphocyte proliferation, which is linked to immune system function. Vitamin D-deficient non-obese diabetic (NOD) mice showed higher incidence and severity of diabetes. In NOD mice, 1,25(OH)₂D decreased effector T cell counts and ameliorated diabetic symptoms. 1,25-dihydroxy vitamin D (1,25(OH)₂D) was also discovered to block the activation of genes that control the death of human islet cells caused by cytokines in another investigation.⁵

The research aims to evaluate the effects of vitamin D on pregnancies with pre-gestational diabetes mellitus on mother glycemic control and fetal outcomes.

2. Patients and methods

In this prospective study, 140 expectant mothers who have already been diagnosed with pre-gestational diabetes mellitus are involved. Using a computerized allocation process, all patients were randomly split into two groups. The research was conducted from early February 2022 to February 2024 at the Bab El Sharia and Al-Hussein hospitals affiliated with Al-Azhar University.

Both inpatient and outpatient clinic patients were used to recruit the patients. Written informed consent was acquired from each pregnant diabetic woman participating in this study, and they all explained the study protocols.

Sample size calculation

The G*Power© software 3.1.0 (Institut für Experimentelle Psychologie, Heinrich Heine University, Düsseldorf, Germany) has been used to compute the necessary sample size.

Inclusion Criteria: Age range: 18-35; one cesarean section prior; one pregnancy; Index of body mass (BMI): 18-30 kg/m², Using FBS, PPS, and HBA1C measurements, individuals with normal vitamin D levels and women with confirmed diabetes.

Exclusion Criteria: Endocrinopathy, such as hypocalcaemia, thyroid dysfunction, etc. Patients with more than cesarean section, Primigravida, Chronic illness like active liver diseases, chronic kidney disease, hypertension, Local diseases such as uterine anomalies, Patients with a history of bad obstetric history like FGR, PPRM, Multiple gestations and Patients with threatened miscarriage.

Group A: includes 70 patients who are pregnant women with pre gestational diabetes mellitus. Patients will take 100 mg of vitamin D of the drug daily for the rest of pregnancy, starting from 1st day of pregnancy.

Group B: includes 70 patients who are pregnant women with pre-gestational diabetes mellitus. Patients will take a placebo of one tablet daily for the rest of the pregnancy, starting from the first day.

The following will be applied to every patient:

History: A thorough history will be recorded. Age, obstetric history, date of first day of LMP, menstrual history, diabetes symptoms and signs, if any, history of chronic diseases, including hypertension and chronic kidney disease, surgical history, and family history are all included.

Physical examination: A general examination measures temperature, respiration rate, blood pressure, pulse, and obesity. Vaginal examination only when required, and an examination of the abdomen to determine the fundal height scars from surgeries.

Investigations: FBS, PPS and HBA1C. Ultrasound in 1stANC visits to confirm pregnancy, location, dating and viability, then an ultrasound scan every three weeks till 24 weeks, then every two weeks till 36 weeks, then hospital admission till labour; for each scan, we will comment on viability; gestational age, liquor, placenta, any structural abnormality and fetoplacental blood flow and Serum vitamin D. 4D anomaly scan at 18/22 weeks, Pelviabdomen Ultrasound to assess kidney affection, Liver enzymes, serum creatinine, complete blood count and Fundus examination every trimester to exclude diabetic retinopathy.

Primary outcome: Fetal outcomes regarding growth disorders, prelabor preterm rupture of membranes, intrauterine fetal death and Maternal glycemic control.

Statistical methods

All the data were collected, tabulated, and statistically analyzed using SPSS 26.0 for Windows (SPSS et al., USA). Utilizing percentages and numbers, the qualitative data was described. Quantitative data were described using the phrases range (minimum and maximum), mean, standard deviation, and median. Every statistical comparison was regarded as significant if it had two tails. A level of P-value ≤0.05 indicates a significant difference, a highly significant difference is shown by p<0.001, and a non-significant difference is indicated by P>0.05. To compare the proportions of the qualitative markers, the chi-square (X²) test was utilized to determine its significance. Two independent groups' parametric quantitative data were compared using the independent T-test.

3. Results

Table 1. Maternal and gestational age among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
MATERNAL AGE			T= - 1.284	0.201
MEAN±SD.	26.67 ± 3.42	27.37±3.02		
MEDIAN (IQR)	26.5 (25-29)	27 (26-29)		
RANGE (MIN-MAX)	18 (18-36)	14 (21-35)		
GESTATIONAL AGE			T= 0.237	0.813
MEAN±SD.	26.11±3.21	25.99 ±3.2		
MEDIAN (IQR)	26 (24-28)	26.5 (24-28)		
RANGE (MIN-MAX)	16 (19-35)	14 (19-33)		

t=Test of Independence. SD stands for standard deviation. Interquartile range, or IQR. p:p value for comparing the groups under study. P>0.05 indicates non-significant; P<0.05 indicates significant; and P<0.001 indicates highly significant.

The Vitamin D group's mean maternal age ranged from 18 to 36, whereas the Placebo group's mean maternal age ranged from 21 to 35, with a standard deviation of 27.37±3.02. There was not a statistically significant distinction (p=0.201) between the two groups. The Vitamin D group had a mean±SD of 26.11±3.21 for Gestational Age, ranging from 19 to 35. In the Placebo group, the Gestational Age varied from 19 to 33 with a mean±SD of 25.99±3.2. There was not a statistically significant distinction (p=0.813) between both groups.

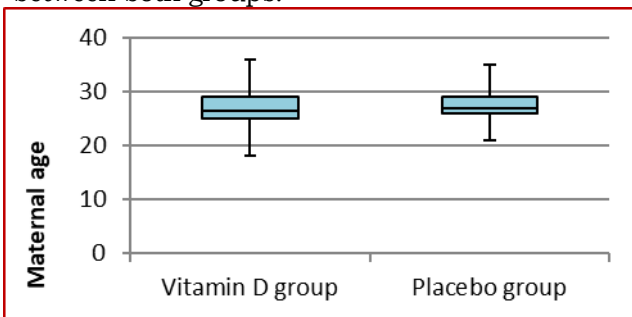


Figure 1. Box-plot illustrating the age difference between the research groups' mothers.

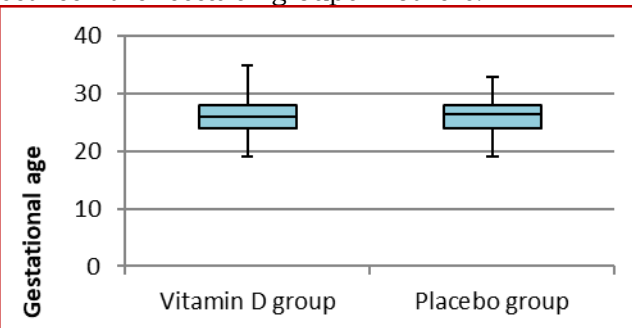


Figure 2. Box-plot illustrating the variations in

gestational age between the research groups

Table 2. Height measurements among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
HEIGHT MEAN±SD.	160.44 ± 19.44	163.09 ± 19.78	t= - 0.797	0.427
MEDIAN (IQR)	160.5 (148.5-173)	162 (150-176.75)		
RANGE (MIN-MAX)	88 (122-210)	89 (115-204)		

t=Test of Independence. Standard deviation, or SD Interquartile range, or IQR. p:p value for comparing the groups under study. P>0.05 indicates non-significance, P<0.05 indicates significance, while P<0.001 indicates highly significance.

The height varied from 122 to 210 in the Vitamin D group, with a mean±SD of 60.44 ±19.44, and from 115 to 204 in the Placebo group, with a mean±SD of 163.09±19.78. Between the two groups, there was not a statistically significant distinction (p=0.427).

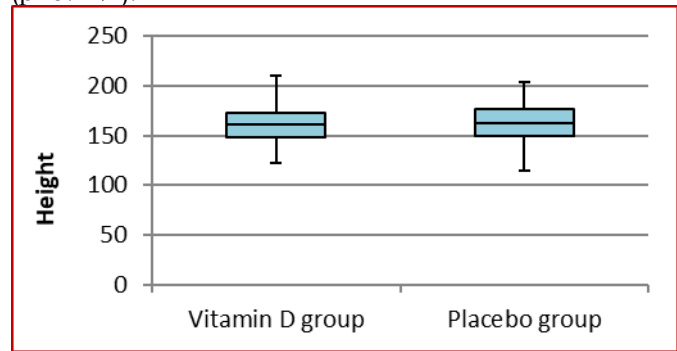


Figure 3. Box-plot illustrating the height differences between the research groups.

Table 3. Weight measurements among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
BASELINE WEIGHT			T= - 2.851	0.005
MEAN±SD.	75.39±9.09	79.91±9.7		
MEDIAN (IQR)	75.5 (69-81.5)	80 (73-86.75)		
RANGE (MIN-MAX)	45 (49-94)	40 (5-99)		
END OF TRIAL WEIGHT			T= - 2.816	0.006
MEAN±SD.	77.14±9.29	81.71±9.91		
MEDIAN (IQR)	76.5 (71-83)	82 (74-87.75)		
RANGE (MIN-MAX)	51 (53-104)	46 (61-107)		

t=Test of Independence. Standard deviation, or SD. Interquartile range, or IQR. p:p value for comparing the groups under study. P-values >0.05 indicate non-significance, <0.05 indicate significance, and <0.001 indicate highly significant

The vitamin D group and placebo groups had baseline weights of 49 to 94 and 75.39±9.09,

accordingly. Between the two groups, there was a statistically significant difference ($p=0.005$) in the Baseline Weights, with a mean±SD=79.91± 9.7 and a range of 59 to 99, respectively. The Vitamin D group and the Placebo group had end-of-trial weights of 53 to 104 and 77.14±9.29 and 81.71±9.91, respectively. A statistically significant difference ($p=0.006$) existed between the two groups.

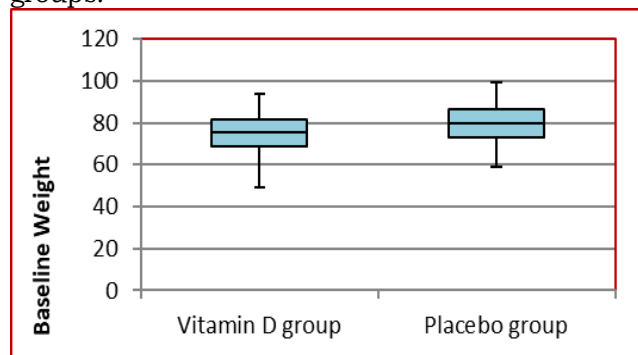


Figure 4. Box-plot illustrating how the research groups' baseline weights varied.

Table 4. BMI results among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
BASILINE BMI			t= - 1.773	0.078
MEAN±SD.	29.96±3.63	31.06±3.74		
MEDIAN (IQR)	29.9 (27.1-32.6)	31.55 (28.72-33.5)		
RANGE (MIN-MAX)	15.8 (22.7-38.5)	18.6 (20.2-38.8)		
END OF TRIAL BMI			t= - 1.632	0.105
MEAN±SD.	30.69±3.72	31.74±3.85		
MEDIAN (IQR)	30.45 (28.15-32.78)	31.9 (29.02-34.15)		
RANGE (MIN-MAX)	21.2 (22.2-43.4)	19.8 (23-42.8)		

t=Test of Independence. Standard deviation, or SD. Interquartile range, or IQR. p:p value for comparing the groups under study. P-values >0.05 indicate non-significance, <0.05 indicate significance, and <0.001 indicate highly significant.

The baseline BMI varied from 22.7 to 38.5 in the vitamin D group, with a mean±SD of 29.96±3.63, while it ranged from 20.2 to 38.8 in the placebo group, with a mean±SD of 31.06±3.74. Between the two groups, there was no statistically significant difference ($p=0.078$). The vitamin D group's trial end BMI ranged from 22.2 to 43.4, with a mean±SD of 30.69±3.72, whereas the placebo group's trial end BMI ranged from 23 to 42.8, with a mean±SD of 31.74±3.85. No statistically significant difference ($p=0.105$) was seen between the two groups.

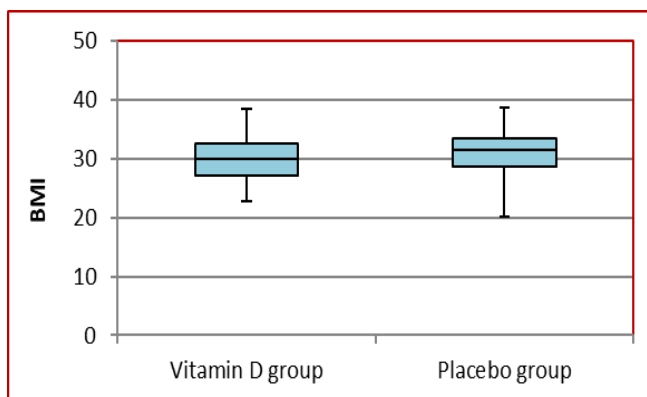


Figure 5. Box-plot displaying the baseline BMI differences across the research groups.

Table 5. Ca level among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
BASILINE CA			t= - 0.597	0.551
MEAN±SD.	8.26±1	8.36±1.01		
MEDIAN (IQR)	8.4 (7.6-8.88)	8.3 (7.7-9.17)		
RANGE (MIN-MAX)	5.2 (5.2-10.4)	4.8 (5.9-10.7)		
END OF TRIAL CA			t= 3.532	0.001
MEAN±SD.	8.9±1.07	8.29±1		
MEDIAN (IQR)	8.95 (8.1-9.8)	8.3 (7.62-8.98)		
RANGE (MIN-MAX)	4.8 (6.5-11.3)	4.4 (5.7-10.1)		

t=Test of Independence. Standard deviation, or SD. Interquartile range, or IQR. p:p value for comparing the groups under study. P-values >0.05 indicate non-significance, <0.05 indicate significance, and <0.001 indicate highly significant.

No significant statistical difference was seen ($p=0.551$) between both groups. The baseline calcium in the vitamin D group varied from 5.2 to 10.4 with mean±SD=8.26±1, whereas the baseline calcium in the placebo group ranged from 5.9 to 10.7 with mean±SD=8.36±1.01. The trial's end Ca varied from 6.5 to 11.3 in the vitamin D group, with a mean±SD of 8.9±1.07, and from 5.7 to 10.1 in the placebo group, with a mean±SD of 8.29±1, showing a statistically significant distinction ($p=0.001$) between both groups.

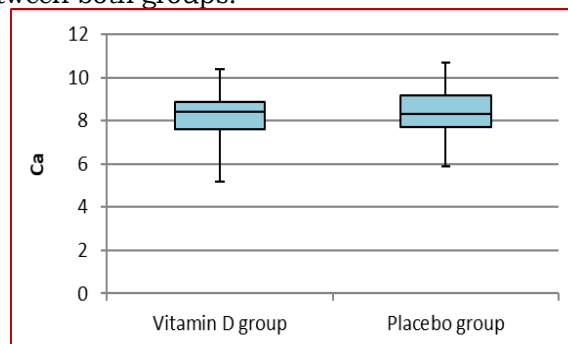


Figure 6. Box-plot illustrating the variations in Baseline Ca between the research groups.

Table 6. Vitamin D level among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
BASILINE VITAMIN D			t= - 9.109	<0.001
MEAN±SD.	17.56±2.05	21.2±2.64		
MEDIAN (IQR)	17.5 (16-19)	21 (20-22.75)		
RANGE (MIN-MAX)	10 (13-23)	16 (13-29)		
END OF TRIAL VITAMIN D			t= - 0.614	0.54
MEAN±SD.	21.53±2.61	21.8±2.62		
MEDIAN (IQR)	21 (20-24)	22 (20-24)		
RANGE (MIN-MAX)	12 (15-27)	15 (15-30)		

t=Test of Independence. Standard deviation, or SD. Interquartile range, or IQR. p:p value for comparing the groups under study. P-values >0.05 indicate non-significance, <0.05 indicate significance, and <0.001 indicate highly significant.

With a mean±SD=17.56±2.05, the baseline Vitamin D in the Vitamin D group varied from 13 to 23, whereas in the Placebo group, it ranged from 13 to 29 with a mean±SD=21.2±2.64, indicating a highly significant difference (p=<.001) between both groups. No significant statistical difference was seen (p=0.54) between both groups when it came to the End of Trial Vitamin D levels. In the Vitamin D group, the range was from 15 to 27, with a mean±SD=21.53±2.61, whereas in the Placebo group, the range was from 15 to 30 with a mean±SD=21.8±2.62.

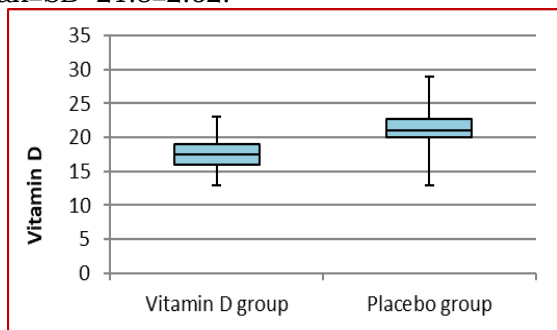


Figure 8. Box-plot depicting the fluctuations in the baseline. The levels of D vitamin among the research groups.

Table 7. Maternal outcomes among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
MATERNAL PRE-ECLAMPSIA -YES	0 (0.00%)	2 (2.86%)	X ² =2.029	0.154
-NO	70 (100.00%)	68 (97.14%)		
MATERNAL POLYHYDRAMINOS -YES	2 (2.86%)	12 (17.14%)	X ² =7.937	0.005
-NO	68 (97.14%)	58 (82.86%)		
MATERNAL HOSPITALIZATION -YES	1 (1.43%)	9 (12.86%)	X ² =6.892	0.009
-NO	69 (98.57%)	61 (87.14%)		

Chi-square test, or x². p:p value for comparing the groups under study.

P-values >0.05 indicate non-significance, <0.05 indicate significance, and <0.001 indicate highly significant.

No significant statistical difference was seen (p=0.154) in pre-eclampsia between the two groups under study. Between the two groups under study, there was a substantial distinction in terms of Polyhydraminos (p=0.005). There was a significant difference (p=0.009) in hospitalization between the two groups under study.

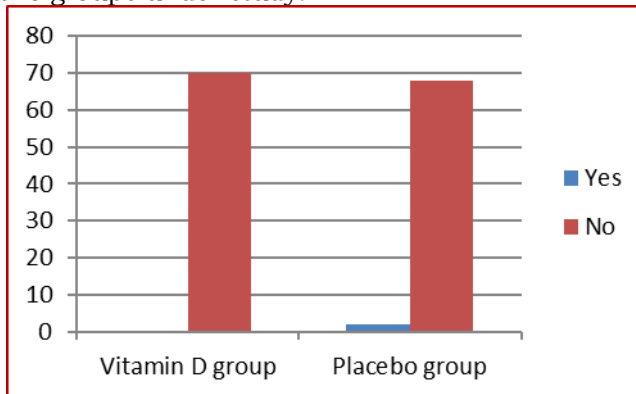


Figure 9. Bar graph comparing the pre-eclampsia levels of the study groups.

Table 8. Neonatal outcomes among the study groups.

	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	TEST OF SIG.	P
NEONATAL HYPERBILIRUBINEMIA YES	5 (7.14%)	18 (25.71%)	X ² =8.792	0.003
NO	65 (92.86%)	52 (74.29%)		
NEONATAL HOSPITALIZATION YES	6 (8.57%)	17 (24.29%)	X ² =6.295	0.012
NO	64 (91.43%)	53 (75.71%)		
NEONATAL HYPOGLYCEMIA YES	0 (0.00%)	1 (1.43%)	X ² =1.007	0.316
NO	70 (100.00%)	69 (98.57%)		

x²: Chi- Square test p: p value for comparing between the studied groups P-value>0.05: Non-significant; P-value<0.05: Significant; P-value<0.001: Highly significant

There was a significant difference between the two studied groups (p=0.003). Regarding Neonatal Hospitalization, there was a significant difference between the two studied groups (p=0.012). Regarding Neonatal Hypoglycemia, there was no statistically significant difference between the two studied groups (p=0.316).

Table 9. Adverse pregnancy outcomes among the study groups.

PARAMETER (VARIABLE)	VITAMIN D GROUP (N=70)	PLACEBO GROUP (N=70)	P
MODE OF DELIVERY			0.1
CESAREAN SECTION	69(98.5%)	69(98.5%)	
VAGINAL	1(1.5%)	1(1.5%)	

DELIVERY PROM	2 (2.85%)	4 (5.71%)	0.5
ADMISSION TO NICU (P)	6 (8.57%)	17 (24.29%)	0.012
FETAL BIRTH WEIGHT (GM)	3335.1±644.9	3718.9±211.7	0.016

The overall adverse pregnancy outcomes were significantly higher in women not receiving vitamin D.

4. Discussion

Our findings were corroborated by research by Zhang et al.,⁶ The patients (n=133) were then randomly divided into four groups per their study. Twenty people were placed in the control group and given a daily placebo as one sugar granule. A total of 37 participants were given a dosage of 50,000 IU every two weeks, equivalent to a daily dosage of 4,000 IU for 12.5 days. In other places, 38 individuals received the low dosage group's recommended intake of 200 IU of vitamin D (calciferol; Costco Wholesale Corporation, Issaquah, WA, USA). 38 individuals received 50,000 IU monthly (2,000 IU daily for 25 days). Furthermore, the 37 participants in the high-dosage group were given the same medication every two weeks. There was no discernible difference in mother age across the groups under investigation.

Similarly, Yazdchi et al.,⁷ indicated that 72 of the 76 participants-36 in the vitamin D group and 36 in the placebo group completed the trial. There was no significant distinction among the groups under investigation regarding mother age.

The current study's results indicate no appreciable variation in height across the study groups regarding the weight measurements in every study group. The vitamin D group's baseline weight ranged from 49 to 94, with a mean±SD of 75.39±9.09, while the placebo group's baseline weight ranged from 59 to 99, with a mean±SD of 79.91±9.7. A statistically significant difference (p=0.005) was observed between the two groups. After the trial, the two groups had a statistically significant difference (p=0.006). The trial weight for the vitamin D group ended up ranging from 53 to 104 with mean±SD=77.14±9.29, while the trial weight for the placebo group ended up ranging from 61 to 107 with mean±SD=81.71±9.91. There was no appreciable difference in BMI between the groups that were being studied.

In the study of Yazdchi et al.,⁷ they stated that there was no discernible change in height, weight, or BMI between the groups under study.

According to the results of the current investigation, the study groups' Ca levels varied. There was no statistically significant distinction (p=0.551) between both groups. The baseline

calcium varied from 5.9 to 10.7 in the placebo group and from 5.2 to 10.4 in the vitamin D group, with a mean±SD of 8.26±1. The trial's end Ca varied from 6.5 to 11.3 in the vitamin D group, with a mean±SD of 8.9±1.07, and from 5.7 to 10.1 in the placebo group, with a mean±SD of 8.29±1, showing a statistically significant distinction (p=0.001) between both groups.

Research by Hosseinzadeh-Shamsi-Anar et al.,⁸ corroborated our findings, as they demonstrated no change in the IG and CG's serum Ca concentrations before or after the intervention. There was no discernible difference in the blood concentration of Ca in the CG before and after the intervention. However, the CG was much more significant after the intervention than after the previous therapy.

However, in the study of Zhang et al.⁶ The control group's mean calcium levels were comparable to those in every treatment group (P>0.05).

About the vitamin D levels in the study groups under investigation. There was a very statistically significant differential (p<.001) between both groups for Baseline Vitamin D. In the Vitamin D group, it varied from 13 to 23 with a mean±SD=17.56±2.05. In contrast, the Placebo group ranged from 13 to 29 with a mean±SD=21.2±2.64. The vitamin D end-of-trial ranged from 15 to 27 in the vitamin D group, with a mean±SD=21.53 ± 2.61, and from 15 to 30 in the placebo group, with a mean±SD=21.8±2.62, showing no statistically significant distinction (p=0.54) between both groups.

Research by Zhang et al.⁶ corroborated our findings since they stated that each treatment group's mean vitamin D levels were comparable to those of the control group (P>0.05).

In the study of Ali et al.⁹ There was a substantial difference in the vitamin D level among the GDM and control groups. The GDM group had significantly decreased Vitamin D levels compared to the control group. Approximately one-third of persons in the GDM groups, specifically 7.7%, 9.7%, and 13.5%, had adequate vitamin D. Conversely, nearly two-thirds had insufficient levels.

Our findings were corroborated by research by Wang et al.,¹⁰ since they found that vitamin D supplementation significantly decreased the risk of adverse Maternal outcomes in pregnant women with gestational diabetes mellitus (GDM), including a reduced likelihood of needing a cesarean section (relative risk [RR]: 0.75, 95% confidence interval [CI]: 0.63 to 0.89), decreased chances of hospitalization for the mother (RR: 0.13, 95% CI: 0.02 to 0.98), and a potential decrease in the occurrence of postpartum haemorrhage (RR: 0.47, 95% CI: 0.22 to 1.00).

Our findings revealed that the newborn

outcomes of the research groups were closely linked. A statistically significant difference ($p=0.003$) in Neonatal Hyperbilirubinemia was observed between the two studied groups. The rates of neonatal hospitalization between the two study groups showed a notable disparity ($p=0.012$). No statistically significant difference was observed between the two study groups about newborn hypoglycemia ($p=0.316$).

Our results were supported by a meta-analysis conducted by Wu et al.¹¹. In all, 20 randomized controlled trials (RCTs) involving 1682 individuals with gestational diabetes mellitus (GDM) included 837 who got vitamin D therapy. It was discovered that vitamin D supplementation significantly reduced the likelihood of hyperbilirubinemia (OR=0.38, 95% CI: (0.25, 0.58), premature birth (OR=0.37, 95% CI: (0.22, 0.62)), and neonatal hospitalization (OR=0.38, 95% CI: (0.25, 0.58)) in neonates (all $P<0.05$). The combined data showed no discernible evidence of publication bias (all $P>0.05$).

4. Conclusion

Supplementing with vitamin D lowers the risk of adverse pregnancy outcomes and is beneficial for women with GDM who are pregnant. It is crucial to remember that more investigation and study into the quantity and duration of vitamin D supplements are still needed to provide evidence for preventing long-term adverse effects. superior quality research.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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