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ORIGINAL ARTICLE

The Implications of Cholecalciferol Supplement on Prevention of Preeclampsia in Past Preeclamptic Pregnant Women

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Abstract

Background: Preeclampsia (PE) is characterized by edema, proteinuria, and hypertension (≥ 0.3 g/24 h of protein in the urine (1+ dipstick) on two separate occasions, spaced greater than or equal to 6 h apart). It complicates 2%–8% of pregnancies and is a significant source of maternal and neonatal illness and death. Eclampsia, diffuse intravascular coagulation, and HELLP syndrome are among the side effects of PE. Fetal death and intrauterine growth restriction (IUGR) are risks to the fetus. Clinical research has linked low vitamin D (Vit D) levels to unfavorable pregnancy results because Vit D is crucial throughout pregnancy.

Aim: The study's objective is to assess the impact of cholecalciferol (Vit D3) supplementation on PE prevention in expecting mothers with a history of PE.

Patient and methods: The Department of Obstetrics and Gynecology, Air Force Hospital, and Al-Hussein Hospital, Al-Azhar University, conducted this research. The 200 pregnant participants in this research were split into two groups.

Results: Regarding PE Recurrence, there was a substantial variation between the two study groups. Regarding the measures of Vit D level, there was a very substantial variation between the two groups. Between the two study groups, there was no discernible change in the measures of serum ionized calcium.

Conclusion: Worldwide, there is a significant prevalence of Vit D insufficiency. Infants and pregnant women are more susceptible to Vit D insufficiency. Prenatal Vit D supplementation treatment may assist in lowering the prevalence of PE/gestational hypertension.

Keywords: Cholecalciferol, Preeclampsia, Vitamin D

1. Introduction

830 women pass away from pregnancy-related causes per day; the majority of illness burden is found in low- and middle-income nations (Peters and Flack, 2004). Pregnancy-related hypertensive diseases, such as gestational hypertension, pre-eclampsia (PE), and eclampsia, are among the main problems that cause 14% of maternal deaths.¹

Across 10% of all pregnancies around the globe are complicated by pregnancy-induced

hypertension, which is defined as blood pressure of more than 140/90 mmHg on two separate occasions that occur after 20 weeks of pregnancy and are at least greater than or equal to 6 h apart. PE is characterized by edema, proteinuria, and hypertension (protein in urine ≥ 0.3 g/24 h (1+ dipstick) on two occasions spaced ≥ 6 h apart).²

It complicates 2%-8% of conceptions and is a significant cause of maternal and neonatal illness and death. Eclampsia, which is the incidence of

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unexplained seizures, may develop in pregnant women who exhibit symptoms of PE or pregnancyinduced hypertension.³

Eclampsia, disseminated intravascular coagulation, and the HELLP syndrome (hemolytic anemia, enhanced liver enzymes, and low platelets) are among the side effects of PE. Fetal mortality and intrauterine growth restriction (IUGR) are risks to the fetus.⁴

Vit D is particularly crucial during pregnancy since inadequate maternal Vit D reserves may raise the risk of maternal comorbidities and issues like low birth weight and small for gestation age newborns.

With an incidence that varies from 18% to 84% based on the nation of residency, ethnicity, local dress habits, and nutritional consumption, Vit D insufficiency is a global pandemic.⁵ There are inconsistent findings from clinical research linking low Vit D levels to pregnancy complications such PE, gestational diabetes mellitus, low birth weight, premature labor, and caesarean section.

The study's objective was to assess the effects of cholecalciferol (Vit D3) supplementation on PE prevention in expecting mothers with a history of PE.

2. Patients and methods

Between April 2020 and April 2021, the Department of Obstetrics and Gynecology at the Air Force Hospital and the Al-Hussein Hospital of Al-Azhar University conducted prospective observation research.

2.1. Inclusion criteria

Age: 20–38 years old, pregnant women with past history of PE, singleton pregnancy in the first trimester, with low level of 25 hydroxy vit. D less than (20 ng/ml), with normal level of serum ionized calcium and gestational age: from first trimester.

2.2. Exclusion criteria

Chronic hypertension, concurrent pulmonary, renal and cardiac disease, immunological diseases such as SLE and immigration or departing the study's site.

2.3. Study population

200 pregnant women who participated in this research and met the inclusion and exclusion criteria were split into two groups: group (A): Intervention group: 100 pregnant women administrated 'Cholecalciferol 5000 I.U'. [One capsule of vit. D3 125 mcg once daily at morning] till the end of the 37th weeks of pregnancy. Group (B): Control group: 100 pregnant women administrated one tablet 'placebo' daily till the end of the 37th weeks of gestation.

2.4. Methods

Every Patient was Submitted to:

2.5. Taking full history

Personal history as name, marital state, Age, address, Menstrual history, including age at menarche, menstrual disturbance, dysmenorrhea, and related symptoms, obstetric history, including parity and delivery method present history of chronic illnesses and medicines, past history of HTN, DM, family history of the condition or diabetes, history of medication allergy, and surgical history of operation, laparoscopic interference, and treatment of hirsutism by Lasik.

2.6. Examination

2.6.1. General assessment

Assessment of vital signs (Pulse, Bl. p, RR, and Temperature).

2.6.2. Technique of Bl.p measurement

Auscultatory technique (using calibrated aneroid or mercury sphygmomanometer) versus automated technique (using oscillometric devices), Korotkoff phase IV versus phase V to represent diastolic BP, Resting for at least 5 min from arrival at clinic prior to BP measurement versus immediate measurement on arrival in clinic, multiple measurements at one clinic visit versus one measurement at one clinic visit. Appropriately sized cuff versus universal cuff (cuff designed to be used in all women, regardless of arm circumference), systolic BP versus diastolic BP and systolic and/or diastolic BP versus mean arterial pressure measurement weight, height (BMI), Lower limb edema.

2.6.3. Clinical assessment of the abdomen and surrounding areas

To evaluate fundal level, gestation, any abdominal or pelvic disease that may be clinically detected, scars from prior operations, masses, pain, or stiffness. Adenex and uterus bimanually examined in the pelvis to look for any abnormalities in the female genitalia. Routine Transvaginal exam, ultrasound, and inspection for any lesions or secretions that are apparent.

2.7. Investigations

2.7.1. Laboratory investigations

Blood samples of all participants had been taken to analyze 25 hydroxy Vit D and serum ionized calcium level after 12 h fasting. A complete blood count will be performed via the BECKMAN COULTER DxH520-2019 device in order to calculate platelet values (platelet volume, median platelet volume, and breadth of the platelet distribution) using kits from BIO RAD/DiaMed. Urine analysis had been also done to detect proteinuria. Regular laboratory testing (checks on the liver and kidneys, blood type, Rhesus factor, and random blood sugar testing) will be performed.

2.8. Antenatal care every 2 weeks to all participants

2.8.1. Ethical considerations

The Ethical Committee of the Obstetrics and Gynecology Department of the Faculty of Medicine at AL Azhar University has submitted the study protocol for approval. Each participant in the research has given informed verbal and written permission after being informed of the purpose and methods of the investigation.

2.9. Statistical analysis

Microsoft Excel software was utilized to code, input, and analyze historical data, basic clinical examinations, laboratory investigations, and outcome measurements. The Statistical Package for the Social Sciences (SPSS version 21.0) program was then utilized to import the data and perform analysis. The following tests were used to determine the significance of variations in qualitative and quantitative data, which are represented by number, percentage, and mean \pm SD, respectively. Chi square test (χ^2) comparison and connection of qualitative variable. *t*-test comparisons between quantitative independent groups. *P* value was chosen at less than 0.001 for very substantial findings and less than 0.05 for outcomes that were substantial.

3. Results

Table 1 showed the age in the intervention group varied from 20 to 38, with a mean \pm SD = 30.68 \pm 4.81, whereas the age in the control group ranged from 20 to 38, with a mean \pm SD = 29.12 \pm 4.53, with a statistically substantial variation (*P* = 0.019) between the two groups.

Table 2 showed, when the study began, the gestational age of the intervention group ranged from 2 to 12, with a mean \pm SD = 7.63 \pm 2.38, while the gestational age of the control group ranged from 3 to 12, with a mean \pm SD = 7.91 \pm 2.17, with no statistically substantial distinction (P = 0.386) between the two groups.

Table 3 showed Systolic blood pressure measures in the study groups. Between the two groups, there is no statistically substantial variation.

Table 4 showed Measurements of Diastolic blood pressure among the study groups. There is no statistical substantial variation between the two groups.

Table 5 showed Measurements of Fundal level at the time of termination among the study groups. Fundal level at the time of termination in Intervention group ranged from 36 to 40 with mean \pm SD = 38.05 \pm 0.9 while in Control group the Fundal level at the time of termination ranged from 36 to 40 with mean \pm SD = 37.89 \pm 0.91 with no statistical substantial variation (*P* = 0.213) between the two groups (Fig. 1).

Regarding the Termination of pregnancy, there was a substantial variation between the two study groups (P = 0.049).

Table 6 showed the Recurrence of PE among the study groups. Regarding PE, there was a substantial variation between the two study groups (P = 0.012).

Table 7 showed Measurements of Vit D level (ng/mL) among the study groups. Vit D level in the Intervention group ranged from 11 to 19 with mean \pm SD = 14.71 \pm 1.71 while in the Control group, the Vit D level ranged from 20 to 36 with mean \pm SD = 28.33 \pm 3.13 with highly statistical

Table 1. Characteristics of the research groups' demographics.

	Intervention group ($n = 100$)	Control group ($n = 100$)	Test of Significance	Р
Age (years) Mean \pm SD.	30.68 ± 4.81	29.12 ± 4.53	t = 2.361	0.019
Median (IQR)	31 (28–35)	29 (26-32)		
Range (Min-Max)	18 (20-38)	18 (20–38)		

IQR, interquartile range; SD, standard deviation; *t*, Independent *T* test.

p: P value for analyzing the groups under study.

P value greater than 0.05: Nonsubstantial; P-value less than 0.05: substantial; P value less than 0.001: Highly substantial.

Table 2. Age of gestation at the beginning of the research among the study groups.

	Intervention group $(n = 100)$	Control group $(n = 100)$	Test of Significance	Р
Gestational age at the start of the study Mean \pm SD.	7.63 ± 2.38	7.91 ± 2.17	t = -0.868	0.386
Median (IQR)	8 (6-9)	8 (6.75-10)		
Range (Min-Max)	10 (2-12)	9 (3–12)		

Table 3. Measurements of Systolic blood pressure among the study groups.

Systolic blood pressure (mmHg)	Intervention group ($n = 100$)	Control group ($n = 100$)	Test of Significance	Р
First trimester				
Mean \pm SD.	116.03 ± 14.53	113.99 ± 7.34	t = 1.253	0.212
Median (IQR)	115.5 (106.75-127)	114 (108–119)		
Range (Min-Max)	70 (86–156)	37 (97–134)		
Second trimester				
Mean \pm SD.	112.33 ± 15.62	111.92 ± 6.64	t = 242	0.809
Median (IQR)	114.5 (104.75-124)	110 (102–116)		
Range (Min-Max)	69 (84–151)	36 (96-131)		
Third trimester				
Mean \pm SD.	116.75 ± 14.93	114.23 ± 8.14	t = 830	0.407
Median (IQR)	116.5 (106.50-126)	115 (109–120)		
Range (Min-Max)	70 (85–157)	37 (95-130)		

Table 4. Measurements of Diastolic blood pressure among the study groups.

Diastolic blood pressure (mmHg)	Intervention group ($n = 100$)	Control group ($n = 100$)	Test of Significance	Р
First trimester				
Mean \pm SD.	74.06 ± 4.95	73.95 ± 6.42	t = 0.136	0.892
Median (IQR)	74 (71–77.25)	74 (70-78.25)		
Range (Min-Max)	21 (64-85)	34 (58–92)		
Second trimester				
Mean \pm SD.	72.16 ± 5.22	72.85 ± 6.83	t = 0.805	0.422
Median (IQR)	72 (68-73.25)	72 (71-75.5)		
Range (Min-Max)	20 (62-83)	32 (55-90)		
Third trimester				
Mean \pm SD.	75.12 ± 5.15	73.95 ± 6.42	t = 0.422	0.157
Median (IQR)	74 (72–77.75)	74 (71–77.5)		
Range (Min-Max)	21 (65-86)	34 (57-91)		

Table 5. Measurements of Fundal level at the time of termination among the study groups.

	Intervention group $(n = 100)$	Control group $(n = 100)$	Test of Significance	Р
Fundal level at the time of termination (cm)			t = 1.249	0.213
Mean \pm SD.	38.05 ± 0.9	37.89 ± 0.91		
Median (IQR)	38 (37.75-39)	38 (37-38)		
Range (Min-Max)	4 (36–40)	4 (36-40)		

substantial variation (P = < 0.001) between the two groups. However, there is no statistically substantial variation in Vit D (P = 0.306) between the two groups at labor (Fig. 2).

Measurements of Serum ionized Calcium (mg/dL) among the study groups. Serum ionized Calcium in Intervention group ranging from 4.2 to 5.3 with mean \pm SD = 4.81 \pm 0.2 while in Control group the

Serum ionized Calcium ranging from 4.3 to 5.3 with mean \pm SD=4.8 \pm 0.23 with no statistical substantial variation (P = 0.649) between the two groups.

4. Discussion

Contradictory results have been found in clinical studies examining the relationship between low Vit

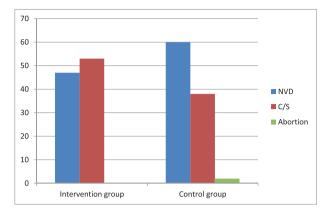


Fig. 1. A bar chart comparing the research groups' conclusions of pregnancy termination.

D and undesirable pregnancy outcomes, including PE, gestational diabetes mellitus, low birth weight, early labor, and cesarean delivery Arora and colleagues.⁶

This study's major objective was to assess how cholecalciferol (Vit D3) supplementation affected pregnant women with a history of PE in terms of PE prevention.

This case-control research was conducted between April 2020 and April 2021 at the Department of Obstetrics and Gynecology, Air Force Hospital, and Al-Hussein Hospital, Al-Azhar University. 200 pregnant women participated in the research, and they were split into two groups: group (A): Intervention group: 100 pregnant women administrated 'Cholecalciferol 5000 I.U'. [One capsule of vit. D3 125 mcg once daily] till the end of the 37th weeks of pregnancy. Group (B): Control group: 100 pregnant women administrated one tablet 'placebo' daily till the end of the 37th weeks of gestation.

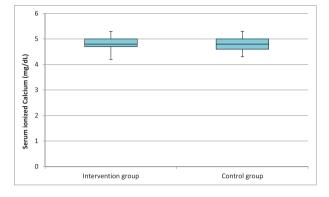


Fig. 2. Comparative box-plot of the research groups' serum ionized calcium levels. Measurements of Serum ionized Calcium (mg/dL) among the study groups. Serum ionized Calcium in Intervention group ranging from 4.2 to 5.3 with mean \pm SD = 4.81 \pm 0.2 while in Control group the Serum ionized Calcium ranging from 4.3 to 5.3 with mean \pm SD = 4.8 \pm 0.23 with no statistical substantial variation (*P* = 0.649) between the two groups.

Regarding demographic details of the research groups. The average age in the intervention group was 20–38 with a mean \pm SD = 30.68 \pm 4.81, whereas the average age in the control group was 20–38 with a mean \pm SD = 29.12 \pm 4.53, with a statistically substantial variation (*P* = 0.019) between the two groups. When the study began, the gestation period of the intervention group varied from 2 to 12, with a mean \pm SD = 7.63 \pm 2.38, while the gestational age of the control group varied from 3 to 12, with a mean \pm SD = 7.91 \pm 2.17, with no statistically substantial variation (*P* = 0.386) between the two groups. Between the two study groups, there was no discernible change in BMI (*P* = 0.101).

While in the study of Khalifa and colleagues,⁷ Women were divided into two groups; group I got

Table 6. Recurrence of Preeclampsia among the study groups.

 31.79 ± 3.82

30 (27-34)

18 (25-36)

Mean \pm SD.

Median (IQR)

Range (Min-Max)

	Intervention group ($n = 100$) n (%)	(%) Control group $(n = 100) n$ (%)	Test of Significance	Р
Preeclampsia			$\chi^2 = 6.258$	0.012
Preeclampsia				
n (%)	16 (16%)	31 (31%)		
Nonpreeclampsia				
n (%)	84 (84%)	69 (69%)		
	ts of Vit D level (ng/mL) among the s	luuy 310ups.		
Vit D level (ng/mL)	, 8 8	Control group ($n = 100$)	Test of Significance	Р
Vit D level (ng/mL) During pregnancy	Intervention group	56 1	Test of Significance $t = -38.197$	P <0.001
	Intervention group	56 1		_
During pregnancy	Intervention group $(n = 100)$	Control group ($n = 100$)		_
During pregnancy Mean ± SD.	Intervention group ($n = 100$) 14.71 \pm 1.71 15 (13-16)	Control group ($n = 100$) 28.33 ± 3.13		_

 32.37 ± 4.16

31 (29-37)

17 (28-38)

supplements containing 25-hydroxyvitamin D, whereas group II got a placebo. The mean age (years) was 29.52 years \pm 3.75 years and 30.72 years \pm 3.48 years for group I and II respectively; (P = 0.247) while the mean gestational age (weeks) was 12.64 \pm 2.12 and 12.48 \pm 1.92, respectively; (P = 0.781) and the mean BMI (kg/m²) was 28.65 \pm 2.14 and 28.57 \pm 1.88, respectively; (P = 0.889). Regarding demographic information, there were no notable statistical variations between the two groups that were examined.

Similarly, Behjat Sasan and colleagues,⁴ revealed that there were 142 people in all who met the inclusion criteria for the research. The participants were divided into the intervention group (Vit D) and the control group at random. As a result, 72 patients were assigned to the control group and 70 patients to the intervention group. Regarding demographic information, there were no notable statistical variations between the two groups that were examined.

The present study showed that as regard number of previous pregnancies among the study groups. Number of previous pregnancies in Intervention group varied from 1 to 6 with mean \pm SD = 3.04 \pm 1.14 while in the Control group the Number of previous pregnancies varied from 1 to 5 with mean \pm SD = 2.92 \pm 0.91 with no statistically substantial variations (*P* = 0.41) between the two groups.

In accordance with our results study of Behjat Sasan and colleagues,⁴ revealed that Regarding the number of prior pregnancies, there were no substantial statistical variations between the two study groups.

According to assessments of systolic blood pressure among the research groups, the present study demonstrated that Systolic blood pressure in the Intervention group ranged from 86 to 156 with mean \pm SD = 116.03 \pm 14.53 while in the Control group the Systolic blood pressure ranged from 97 to 134 with mean \pm SD = 113.99 \pm 7.34 with no statistically substantial variation (P = 0.212) between the two groups. As regard measurements of diastolic blood pressure among the study groups. Diastolic blood pressure in the Intervention group ranged from 64 to 85 with mean \pm SD = 74.06 \pm 4.95 while in the Control group the Diastolic blood pressure varied from 58 to 92 with mean \pm SD = 73.95 \pm 6.42 with no statistically substantial variation (P = 0.892) between the two groups.

Our results were in line with research of Khalifa and colleagues,⁷ revealed that the mean systolic blood pressure was 118.0 mmHg \pm 5.92 mmHg and 119.7 mmHg \pm 5.68 mmHg for group I and II, respectively (*P* = 0.300) while the mean diastolic

pressure was 80.96 mmHg \pm 3.76 and 80.16 mmHg \pm 3.93, respectively (P = 0.446). According to BP, there were no substantial statistical variations between the two groups under investigation.

Similarly, Behjat Sasan and colleagues,⁴ demonstrated that Systolic and diastolic blood pressure did not statistically vary significantly between the two groups under investigation.

In the research in our hands, as regard measurements of fundal level at the time of termination among the study groups. Fundal level at the time of termination in Intervention group ranged from 36 to 40 with mean \pm SD = 38.05 \pm 0.9 while in Control group the Fundal level at the time of termination varied from 36 to 40 with mean \pm SD = 37.89 \pm 0.91 with no statistically substantial variation (*P* = 0.213) between the study groups.

Regarding Termination of pregnancy, there was a substantial variation between the two studied groups (P = 0.049).

In contrary to our results the research of Behjat Sasan and colleagues,⁴ revealed that There was no discernible variation between the two groups when it came to the method of pregnancy termination—normal vaginal birth, cesarean delivery, or abortion.

The present study showed that as regard the recurrence of PE across the study groups. Regarding PE, there was a substantial variation between the two studied groups (P = 0.012).

Our findings were consistent with research by Behjat Sasan and colleagues,⁴ which revealed that PE relapse in the intervention group and control group was the study's final finding. Study participants had a considerably decreased chance of developing PE than those in the control group (P value = 0.036).

Our results were matched to the findings of metanalysis conducted by Fogacci and colleagues,⁸ as they revealed that Data from 27 RCTs with 59 arms and a total of 4777 individuals were merged. Of these, 2487 were in the Vit D-treated arm and 2290 were in the control arm. PE risk was lower when women received Vit D throughout pregnancy (95% confidence interval [CI]: 0.26 to 0.52; odd ratio [OR] of 0.37; I2 = 0%).

While in the study of Khalifa and colleagues,⁷ the frequency of PE and Vit D levels did not significantly correlate. Additionally, PE occurred more often in individuals who did not take Vit D supplements, although this variation was not substantial.

According to assessments of Vit D levels (ng/mL) across the research groups, the present investigation

demonstrated that. Vit D levels varied from 11 to 19 group in the intervention with а mean \pm SD = 14.71 \pm 1.71, while they varied from 20 group control 36 in with to the а mean \pm SD = 28.33 \pm 3.13, with a strongly statistically substantial distinction (P = < 0.001) between the two groups.

In contrary to our results study of Khalifa and colleagues,⁷ revealed that the mean 25- hydroxy Vit D plasma concentration was 26.72 ng/ml \pm 7.31 and 26.40 ng/ml \pm 7.88 for group I and II respectively (*P* = 0.882). Regarding the levels of Vit D, there were no statistically substantial variations between the two groups. The difference may be different sample size and duration of study.

Our results showed that as regard measurements of Serum ionized Calcium (mg/dL) among the study groups. Serum ionized Calcium in the Intervention group varied from 4.2 to 5.3 with median \pm SD = 4.81 \pm 0.2 while in the Control group, the Serum ionized Calcium ranged from 4.3 to 5.3 with median \pm SD = 4.8 \pm 0.23 with no statistically substantial distinction (*P* = 0.649) between the two groups.

Women having a history of PE have a higher chance of developing the condition again. Compared with the first episode, maternal and newborn problems are more frequent in instances with recurrent PE. Testing the efficacy and safety of Vit D, a good contender for preventing PE requires well-controlled randomized studies very away.

A prospective cohort design and the random inclusion of women with a history of PE were two of the study's many strengths. The fact that the end data were based on vital signs rather than a clinical diagnosis, as in several of the examined studies, is another strength. Finally, we acquired comprehensive data on a number of possible confounding factors. The primary, and maybe the only, restriction was the very small size of the material under study, which could affect the strength of the data we provide, in addition to the restricted variation in Vit D levels and PE classifications.

4.1. Conclusion

Worldwide, there is a significant prevalence of Vit D insufficiency. Vit D supplementation treatment

during pregnancy may assist to lower the prevalence of gestational hypertension/PE since pregnant women and newborns are more susceptible to Vit D insufficiency.

Authorship

All authors have a substantial contribution to the article.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

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Conflicts of interest

The authors declared that there were NO conflicts of Interest.

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