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VITAMIN D ROLE IN CONTROL TYPE II DIABETES MELLITUS. A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Vitamin D is a hormone that affects bone integrity. Extra-skeletal Vitamin D effects have recently gained significant attention. Vitamin D deficiency may lead to type 2 diabetes. Vitamin D may improve insulin action by modulating receptor expression, potentially increasing insulin sensitivity. Vitamin D anti-inflammatory properties are crucial for insulin production and sensitivity, as inflammation is a leading cause of insulin resistance (IR), metabolic syndrome (MetS), diabetes, and associated complications. **Objectives:** Is to investigate the effect of vitamin D supplementation on glucose management, insulin sensitivity, and lipid profile in type 2 diabetes patients. **Methods:** This is a randomized, placebo-controlled, and double-blind. The study included adults aged 30 to 65 with type II diabetes, normal renal function, HbA1c ≥ 6 (42 mmol/mol), hypovitaminosis D (serum 25(OH)D < 20 ng/mL), and insulin resistance (HOMA-IR ≥ 2). Participants were assessed at consultation clinic of Al-Tuz General Hospital from January 2024 to April 2025. The questionnaire includes three sections, section one for demographic information, section two for the patients' anthropometric measurements, section three for the investigation results. **Results:** The study included 50 patients, distributed into 2 groups (25 patients received Vitamin D and another 25 patients received placebo). Among those who received Vitamin D, 14 patients were males and 11 were females, while among those who received placebo 13 patients were males and 12 patients were females. The mean age ± standard deviation of the study participants was 51.24 ± 5.63 years. No statistically significant difference between the two groups regarding their gender (P value = 0.649) and age (P value = 0.389). Moreover, no statistically significant difference between them regarding their BMI, waist circumference, hip circumference, waist to hip ratio and duration of diabetes (P value > 0.05) for all of them. On the other hand, statistically significant difference was shown with regard to post intervention glycated hemoglobin and insulin level (P value <0.001) for both of them. Furthermore; within the same group, statistically significant difference between the two groups regarding baseline and post intervention levels of HDL, glycated hemoglobin and insulin (P value <0.001) for all of them. **Conclusion:** In patients with type 2 diabetes, Vitamin D supplementing may regulate blood sugar levels; however, there was no positive effect in the lipid profile, with the exception of HDL-C concentration.

KEYWORDS: Diabetes, Effect, Regulation, Vitamin D.

1- INTRODUCTION

Vitamin D is a hormone that affects bone integrity.[1-2] Extra-skeletal Vitamin D effects have recently gained significant attention. Vitamin D deficiency may lead to type 2 diabetes.[3] Mild to severe vitamin D deficiency has been identified as a risk factor for type 2 diabetes. In high-risk individuals, higher plasma vitamin D levels have been linked to a decreased chance of developing diabetes mellitus.[4] Vitamin D insufficiency has been linked to metabolic syndrome components, including

certain vitamin D receptor gene variants.[5] Additionally, Vitamin D deficiency may raise the chance of developing gestational diabetes, due to the negative correlation between Vitamin D and the glycosylated hemoglobin levels in diabetic pregnant ladies, suggesting an impact on glucose homeostasis.[6-7]

Diabetes type 2 is a global illness that is expected to affect over 550 million people by the end of 2030.[8] Vitamin D may improve insulin action by modulating receptor expression, potentially increasing insulin sensitivity.[5,9] Vitamin D anti-inflammatory properties are crucial for insulin production and sensitivity, as inflammation is a leading cause of insulin resistance (IR), metabolic syndrome (MetS), diabetes, and associated complications. Vitamin D may control glucose levels by increasing insulin secretion from pancreatic B-cells.[5, 10]

Correcting vitamin D insufficiency can improve glucose control and reduce complications of diabetes type 2.[11] Diabetics with low calcidiol levels have a higher risk of coronary artery disease. Supplementing with vitamin D dramatically improves insulin sensitivity in impaired glucose tolerance patients.[12]

This study aimed to investigate the effect of vitamin D supplementation on glucose management, insulin sensitivity, and lipid profile in type 2 diabetes patients.

2- PATIENT AND METHODS

This is a randomized, placebo-controlled, and double-blind. The study included adults aged 30 to 65 with type II diabetes, normal renal function, HbA1c ≥ 6 (42 mmol/mol), hypovitaminosis D (serum 25(OH)D < 20 ng/mL), and insulin resistance (HOMA-IR ≥ 2). Participants were assessed at consultation clinic of Al-Tuz General Hospital from January 2024 to April 2025. Patients on a stable oral hypoglycemic medication regimen for at least 30 days prior to screening were recruited. Individuals using lipid-lowering or antihypertensive medications should have maintained a steady regimen for at least 30 days. Patients with chronic liver disease, proteinuria (> 3.5 g/24 hours), autoimmune or inflammatory diseases, myocardial infarction within the previous six months, congestive heart failure, cerebrovascular accidents, gastrointestinal malabsorption disorders, hypercalcemia (serum Ca2+ > 10.2 mg/dL), primary parathyroid disorder or using active vitamin D analogs, nutritional vitamin D agents > 800 IU/day, glucocorticoids, carbamazepine, digoxin, cholestyramine, orlistat were excluded. To avoid any interference with the HOMA model, the study excluded those who used insulin. A total of 30 patients were randomly divided to receive cholecalciferol (5000 IU/day) or placebo for 12 weeks using a computer-generated randomization list. The placebo capsules had the same shape, size, and color as the cholecalciferol capsules. Both the investigators and the patients were unaware of the therapy allocation. Patients were instructed not to change their drug type or dose during the course of the study.

There were three follow up visits for each patient over the 12-week therapy period. At each visit, patients did blood tests and anthropometric measures. Until the day of analysis, the samples were stored at -80°C. Height, hip, and waist circumferences were measured to the closest centimeter, and weight to the nearest kilogram. BMI was calculated by dividing weight by height squared. Blood samples were collected at the start and end of the trial following a 12-14 hour fast. Serums were centrifuged and kept at -80 C until serum lipid profile, and insulin concentrations were measured. HPLC columns were used to assess HbA1c, a long-term glucose management marker. The human insulin ELISA kit (Diametra, Italy) was used to test serum insulin with a sensitivity of 0.25 mcIU/ml and an intraassay and interassay range of ≤5% and ≤10%, respectively. HOMA-IR was determined by multiplying fasting glucose (mmol/L) with fasting insulin (μIU/mL) and dividing by 22.5.

The Kolmogorov-Smirnoff test was used to assess parameter normality, while the Wilcoxon and Mann-Whitney tests were utilized to analyze non-normal distribution variables within and across groups. Independent and paired t-tests to compare pre- and post-supplementation groups, as well as within-group analyses of normal distribution variables. P value of less than 0.05 was considered statistically significant.

3-RESULTS

The study included 50 patients, distributed into 2 groups (25 patients received Vitamin D and another 25 patients received placebo). Among those who received Vitamin D, 14 patients were males and 11 were females, while among those who received placebo 13 patients were males and 12 patients were females. The mean age ± standard deviation of the study participants was 51.24 ± 5.63 years. No statistically significant difference between the two groups regarding their gender (P value = 0.649) and age (P value = 0.389). As shown in table 1.

Table 1: Comparison between patients who received Vitamin D and those who received placebo drug (number = 50).

Variable	Vitamin D group = 25		Placebo group = 25		P value
	Number	Percent	Number	Percent	
Gender: -Male -Female	 14 11	 56% 44%	 13 12	 52% 48%	0.649
Mean age ± standard deviation	50.79 ± 6.02		51.79 ± 5.94		0.389

Table 2 shows comparison between the two groups regarding their anthropometric measures and duration of diabetes. No statistically significant difference between them regarding their BMI, waist circumference, hip circumference, waist to hip ratio and duration of diabetes (P value > 0.05) for all of them.

Table 2: Comparison between the two groups regarding their anthropometric measures and duration of diabetes (number = 50).

Variable	Vitamin D group = 25	Placebo group = 25	P value
BMI (kg/m^2), mean ± standard deviation	27.12 ± 0.79	28.27 ± 0.89	0.219
Waist circumference (cm), mean ± standard deviation	94.52 ± 2.23	93.33 ± 2.40	0.331
Hip circumference (cm), mean ± standard deviation	102.45 ± 1.79	104.12 ± 2.11	0.721
Waist to hip ratio, mean ± standard deviation	0.91 ± 0.03	0.92 ± 0.04	0.320
Duration of diabetes (year), mean ± standard deviation	5.71 ± 0.86	6.02 ± 0.91	0.451

Table 3 shows comparison between the study groups regarding their different biochemical variables. Statistically significant difference was shown with regard to post intervention glycated hemoglobin and insulin level (P value <0.001) for both of them. Furthermore; within the same group, statistically significant difference between the two groups regarding baseline and post intervention levels of HDL, glycated hemoglobin and insulin (P value <0.001) for all of them.

Table 3: Comparison between the two groups regarding their anthropometric measures and duration of diabetes (number = 50).

Variable	Vitamin D group = 25	Placebo group = 25	P value
Fasting blood sugar (mg/dl): -Baseline - Post-intervention -P value*	 146.37 ± 11.25 146.49 ± 10.99 0.542	 144.54 ± 11.33 149.20 ± 10.88 0.092	 0.389
Triglyceride (mg/dl): -Baseline - Post-intervention -P value*	 156.05 ± 14.91 149.22 ± 13.22 0.212	 167.11 ± 16.78 172.14 ± 14.33 0.190	 0.102 0.079
Total cholesterol (mg/dl): -Baseline - Post-intervention -P value*	 193.29 ± 14.91 188.33 ± 13.53 0.450	 200.21 ± 16.32 196.68 ± 15.24 0.679	 0.096 0.398
High density lipoprotein (mg/dl): -Baseline - Post-intervention -P value*	 42.12 ± 1.81 49.82 ± 1.79 **0.039**	 43.39 ± 1.92 45.23 ± 1.89 0.479	 0.789 0.394
Low density lipoprotein (mg/dl): -Baseline - Post-intervention -P value*	 86.73 ± 9.39 87.42 ± 8.93 0.839	 85.98 ± 10.21 87.46 ± 10.01 0.910	 0.692 0.891

Glycated hemoglobin (%): -Baseline - Post-intervention -P value*	 7.59 ± 0.31 6.39 ± 0.29 **<0.001**	 7.53 ± 0.30 7.42 ± 0.31 0.920	 0.792 **<0.001**
Insulin (µIU/mL): -Baseline - Post-intervention -P value*	 8.19 ± 0.93 6.89 ± 0.98 **<0.001**	 8.41 ± 0.83 8.34 ± 0.87 0.481	 0.249 **<0.001**
HOMA-IR: -Baseline - Post-intervention -P value*	 2.53 ± 0.22 2.39 ± 0.19 0.277	 2.59 ± 0.23 2.61 ± 0.25 0.590	 0.401 0.097

4-DISCUSSION

The results of this study showed that vitamin D supplementation decreased serum insulin concentration and had beneficial effects in decreasing HbA1c in diabetic type 2 patients. There are several studies with similar results supporting this idea that vitamin D is an important nutrient in control of glucose homeostasis.[13, 14] Vitamin D intake decreased prevalence of diabetes type 2 in long-time.[15] This indicates that Vitamin D plays a role in glucose homeostasis, making it a potential complementary therapy for type 2 diabetes as Vitamin D can promote insulin receptor gene expression and improve glucose transfer from the gut.[16] Additionally, Vitamin D has a role in calcium absorption from the stomach, which is required for insulin release from beta cells.[17] Furthermore, the study found no significant effect of Vitamin D on Fasting blood sugar and insulin resistance (HOMA-IR), which runs with Rad et al study findings.[18]

On the other hand, the study found that Vitamin D supplementation had no effect on lipid except for high density lipoprotein. There are conflicting and varied results regarding its effects on the full lipid profile. While some meta-analyses suggest that vitamin D supplementation can lead to an increase in high density lipoprotein levels[19], others have found no significant effect on high density lipoprotein.[20-21] Anyhow, the impact of vitamin D supplementation on lipids (total cholesterol, LDL-C, HDL-C, and triglycerides) varies across studies due to differences in dosage, duration, the health status of participants (e.g., presence of vitamin D deficiency, obesity, or polycystic ovary syndrome), and baseline lipid levels.

The study limitations are; as the study findings were based solely on the population of Tuz Khurmatu city in Iraq, it is yet unknown whether researchers would find the same outcomes in a different ethnic group. Additionally, the study did not evaluate patients' housing situation regarding sun exposure and dietary patterns. Which might affect the study results.

4- CONCLUSION AND RECOMMENDATION

In patients with type 2 diabetes, supplementing of the international recommended dosage of vitamin D may regulate blood sugar levels; however, there was no positive effect in the lipid profile, with the exception of HDL-C concentration. Thus, it appears that vitamin D administration might be a tactic for managing glucose levels in type 2 diabetic patients.

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Conflict of intertest

About this study, the authors disclose no conflicts of interest.

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