

The effect of vitamin D replacement therapy on insulin resistance: a retrospective study

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ABSTRACT

Aims: This study retrospectively evaluated the effect of a 3-month vitamin D replacement therapy in patients diagnosed with insulin resistance (IR) and low vitamin D levels. The relationship between changes in vitamin D levels and IR was investigated.

Methods: A total of 98 patients with low serum vitamin D levels and HOMA-IR >2.5, who were admitted to the internal medicine outpatient clinic between January 1 and December 31, 2023, were included in this retrospective study. Sociodemographic characteristics and pre-and post-treatment biochemical parameters were obtained from medical records. Post-supplementation levels of vitamin D, glucose, insulin, and HOMA-IR were analyzed. Pre-and post-treatment values were compared using paired t-tests. The relationship between changes in vitamin D levels and HOMA-IR scores was assessed using Spearman correlation analysis.

Results: Of the 98 patients, 85.7% were female and 14.3% were male, with a mean age of 39.09±11.45 years. A significant reduction in HOMA-IR score was observed after vitamin D supplementation (pre: 4.54±2.05; post: 3.01±1.28; p<0.0001). A statistically significant negative correlation was found between the increase in vitamin D levels and the decrease in HOMA-IR scores (r=-0.298, p=0.0029). In addition, glucose and insulin levels significantly decreased after treatment, while no significant changes were observed in lipid profile or vitamin B12 levels.

Conclusion: The findings suggest that vitamin D replacement therapy may have a beneficial effect on IR. Vitamin D supplementation could be considered as a supportive approach in the management of IR, especially in individuals with vitamin D deficiency. The more pronounced improvement observed in female patients indicates the potential importance of considering sex-specific differences in future clinical assessments, but this should be interpreted cautiously due to the limited number of male participants.

Keywords: Vitamin D, insulin resistance, HOMA-IR, diabetes

INTRODUCTION

Insulin resistance (IR) is clinically characterized by impaired glucose uptake and utilization due to inadequate cellular response to endogenous or exogenous insulin.¹ Recognized as a precursor to type 2 diabetes, this pathological response in glucose metabolism has emerged as a growing global public health concern.² The reported prevalence of IR ranges from 15.5% to 46.5% in the literature,^{3,4} and it has been associated with all-cause mortality at rates of 20.6–25.3%.⁵

While IR is a component of metabolic syndrome, both genetic and environmental factors contribute to its etiology. Risk factors for IR include obesity, physical inactivity, aging, smoking, sedentary lifestyle, family history of diabetes, certain health conditions such as polycystic ovary syndrome (PCOS), and medications such as thiazide diuretics, β -adrenergic blockers, and glucocorticoids.⁶ As diminished insulin action has been shown to play a key role in the pathophysiology of

many diseases, identifying direct or indirect modulators of IR has gained significant importance. Accordingly, various metabolic conditions associated with IR have been widely studied.⁷ One such factor is vitamin D, which has long been recognized for its influence on insulin action and its association with IR.⁸

Vitamin D is a fat-soluble secosteroid hormone primarily involved in the regulation of calcium and phosphorus metabolism and bone mineralization.⁹ Beyond its classical roles, vitamin D has been shown to contribute to the prevention of various cancers, obesity, autoimmune, cardiovascular, and infectious diseases.¹⁰

In recent years, numerous studies have highlighted the relationship between vitamin D and IR. The notion that vitamin D deficiency may contribute to the development of

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IR and/or worsen the course of metabolic disorders related to IR has gained strong support. Although the mechanisms underlying the development of IR in the context of vitamin D deficiency remain unclear, several studies have suggested that the anti-inflammatory and antioxidant properties of vitamin D may be responsible. Deficiency may increase oxidative stress and promote a pro-inflammatory state in hepatocytes, contributing to IR.¹¹ Another study indicated that vitamin D deficiency impairs glucose-stimulated insulin secretion by downregulating the expression of peroxisome proliferator-activated receptor gamma (PPAR- γ).¹² In addition to its preventive role against IR and type 2 diabetes mellitus (T2DM), vitamin D supplementation has been associated with improved glycemic control in diabetic patients. Given that vitamin D deficiency is frequently encountered in outpatient settings, timely diagnosis and treatment have become increasingly important.^{13,14} The aim of this study is to retrospectively evaluate the effect of a 3-month vitamin D replacement therapy on IR in patients with low serum vitamin D levels.

METHODS

Ethics

This study was conducted as a retrospective analysis. Ethical approval was obtained from the Clinical Researches Ethics Committee of Kartal Dr. Lütfi Kırdar City Hospital (Date: 27.09.2023, Decision No: 2023/514/258/1). The study was carried out at Kartal Dr. Lütfi Kırdar City Hospital in accordance with the principles of the Declaration of Helsinki.

Study Population

The study was conducted with patients who were diagnosed with IR and vitamin D deficiency and met the inclusion criteria at the internal medicine outpatient clinic of Kartal Dr. Lütfi Kırdar City Hospital between January 1, 2023 and December 31, 2023.

Inclusion Criteria

- Patients diagnosed with IR at the internal medicine outpatient clinic between 01/01/2023 and 31/12/2023, followed up by a single clinician
- Patients not using any pharmacological treatment for IR
- Aged between 18 and 65 years
- No diagnosis of diabetes mellitus
- Serum 25-hydroxy vitamin D (25-OH-D) levels <20 ng/ml
- Received vitamin D replacement therapy for 3 months following the diagnosis of vitamin D deficiency, applied under the same treatment algorithm and supervised by the clinician

Exclusion Criteria

- Patients using medications for IR (e.g., metformin, pioglitazone)
- Diagnosed with diabetes mellitus

- Serum 25-OH-D vitamin levels >20 ng/ml
- Age >65 or <18 years
- Patients with terminal-stage malignancies
- Patients with advanced neurological or psychiatric disorders
- Pregnant women

Parameters Evaluated at Baseline and After 3-Month Vitamin D Supplementation

- Age
- Vitamin D
- Glucose
- Insulin
- Vitamin B12
- HbA1c
- HDL cholesterol
- LDL cholesterol
- Triglycerides
- Total cholesterol

Calculation of HOMA-IR

The homeostatic model assessment (HOMA) is a mathematical model used to evaluate IR based on fasting glucose and insulin concentrations.¹⁵ In this study, IR was defined as a HOMA-IR score greater than 2.5, calculated using the following formula:

$$\text{HOMA-IR score} = (\text{fasting glucose} \times \text{fasting insulin}) / 405$$

Statistical Analysis

The data analyses of the patient data collected in this study were performed using GraphPad Prism version 8.0 software. Continuous variables were evaluated using descriptive statistics and expressed as mean $\pm$ standard deviation (mean $\pm$ SD). Paired t-test or Wilcoxon signed-rank test was used to compare clinical and biochemical parameters before and after vitamin D supplementation. Paired t-test was specifically used for evaluating changes in HOMA-IR scores. To assess the relationship between the change in vitamin D levels and the change in HOMA-IR scores, Spearman correlation analysis was conducted. A p-value less than 0.05 was considered statistically significant.

RESULTS

Among the 98 patients included in the study, 14.3% (n=14) were male and 85.7% (n=84) were female. The mean age of the patients was 39.09 ± 11.45 years (range: 20–65), with males having a mean age of 34.57 ± 12.4 years (range: 20–65) and females 38.03 ± 11.21 years (range: 20–60).

At the time of the initial visit, the patients' clinical and biochemical parameters were as follows: mean serum vitamin D level was 11 ± 3.94 ng/ml, vitamin B12 level was 280 ± 129.6 pg/ml, glucose level was 94.17 ± 9.82 mg/dl, HbA1c level was $5.54 \pm 0.34\%$, insulin level was 19.52 ± 8.27 μ IU/ml, HDL

cholesterol was 50.59 ± 10.83 mg/dl, LDL cholesterol was 114.36 ± 30.64 mg/dl, triglycerides were 138.69 ± 71.5 mg/dl, and total cholesterol was 193.37 ± 38.57 mg/dl (**Table 1**).

Parameters	Total (n=98)	Male (n=14)	Female (n=84)
Year	39.09±11.45	34.57±12.4	38.03±11.21
Vitamin D (ng/ml)	11±3.94	12.97±3.55	10.67±3.92
Glucose (mg/dl)	94.17±9.82	95.71±8.07	93.91±10.1
Insulin (μIU/ml)	19.52±8.27	17.2±5.25	19.91±8.63
Vitamin B12 (pg/ml)	280±129.6	287.78±85.87	278.7±135.88
HbA1c (%)	5.54±0.34	5.61±0.23	5.53±0.35
HDL (mg/dl)	50.59±10.83	44.21±7.47	51.65±10.97
LDL (mg/dl)	114.36±30.64	119.5±19.8	113.49±32.12
Triglycerides (mg/dl)	138.69±71.5	136.71±49.71	139.02±74.74
Total cholesterol (mg/dl)	193.37±38.57	190.92±22.43	193.78±40.73

HDL: High-density lipoprotein, LDL: Low density lipoprotein

The mean HOMA-IR score, calculated using fasting glucose and insulin levels of the 98 patients included in the study, was 4.54 ± 2.05 at the initial visit. Following vitamin D supplementation, the mean HOMA-IR score was found to be 3.01 ± 1.28 based on the blood samples obtained at follow-up visits. When the same analysis was performed based on gender, a significant reduction was observed in both sexes; however, this reduction was more pronounced in female patients ([Female HOMA-IR score before: 4.62 ± 2.15 , after: 2.97 ± 1.35 , $p < 0.0001$]; [Male HOMA-IR score before: 4.05 ± 1.19 , after: 3.21 ± 0.83 , $p = 0.0011$]). The comparison of HOMA-IR scores before and after vitamin D supplementation revealed a statistically significant decrease in HOMA-IR levels ($p < 0.0001$) (**Figure 1**). The mean difference was -1.53 , which was statistically significant ($t(97) = 11.87$, $p < 0.0001$, 95% CI: -1.789 to -1.277). The pairing was strong and significant ($r = 0.80$).

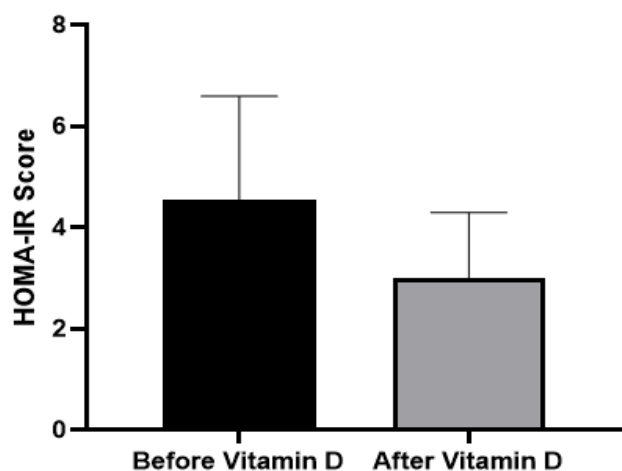


Figure 1. Comparison of HOMA-IR scores before and after vitamin D supplementation (n=98; mean difference= -1.53 ; $p < 0.0001$)
HOMA-IR: Homeostatic model assessment-insulin resistance

Additionally, the proportion of patients whose HOMA-IR score dropped below 2.5 following vitamin D supplementation was also evaluated. Among the 98 patients with pre-treatment

HOMA-IR ≥ 2.5 , post-treatment values fell below 2.5 in 39 patients (39.8%), which was found to be statistically significant ($p < 0.0001$). In the gender-based analysis, this reduction remained statistically significant in females ($p < 0.0001$); however, due to the limited number of male patients whose HOMA-IR score dropped below 2.5, the difference was not statistically significant in males ($p = 1.00$) (**Table 2**).

Group	HOMA-IR before (mean±SD)	HOMA-IR after (mean±SD)	p-value	Patients with HOMA-IR <2.5 (n, %)	p-value (Drop <2.5)
Total	4.54±2.05	3.01±1.28	$p < 0.0001$	39 (39.8%)	$p < 0.0001$
Female	4.62±2.15	2.97±1.35	$p < 0.0001$	38 (45.2%)	$p < 0.0001$
Male	4.05±1.19	3.21±0.83	$p = 0.0011$	1 (6.6%)	$p = 1.00$

Vitamin D replacement therapy the rate of patients with a HOMA-IR score below 2.5 was found to be 39.8% overall, 6.6% in men, and 45.2% in women. HOMA-IR: Homeostatic model assessment-insulin resistance, SD: Standard deviation

A statistically significant negative correlation was found between the change in vitamin D levels and the change in HOMA-IR scores in patients (Spearman $r = -0.298$, $p = 0.0029$) (**Figure 2**).

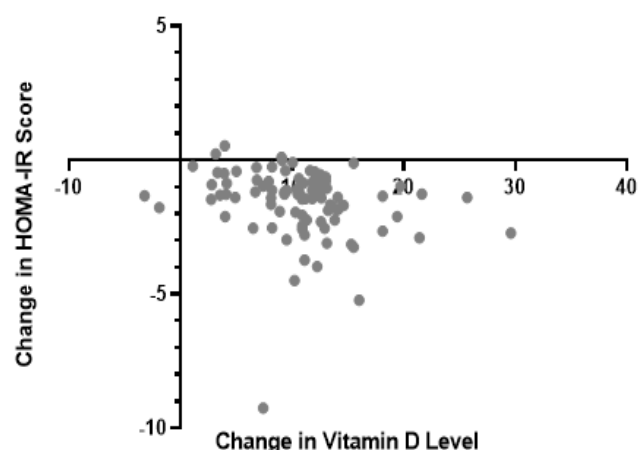


Figure 2. Correlation between the change in vitamin D levels and the change in HOMA-IR scores (Spearman $r = -0.298$, $p = 0.0029$)
HOMA-IR: Homeostatic model assessment-insulin resistance

Following 3 months of vitamin D supplementation, the patients' mean vitamin D level increased significantly, indicating the effectiveness of the treatment (pre-treatment: 11 ± 3.94 ng/ml, post-treatment: 21.68 ± 6.18 ng/ml; $p < 0.0001$). A significant decrease was also observed in glucose and insulin levels after supplementation. However, no statistically significant changes were found in B12, HbA1c, HDL, LDL, triglycerides, or total cholesterol levels (**Table 3**).

DISCUSSION

IR is a reduced biological response to exogenous or endogenous insulin and a major public health problem linked to multiple comorbidities.² It is influenced by genetics, perinatal factors, sex, ethnicity, puberty, medications, obesity, lifestyle and nutrition.^{6,16,17} One of the factors affecting IR, vitamin D has been widely studied for its potential role in glucose metabolism. It is known to enhance insulin production and insulin

Table 3. Comparison of biochemical parameters before and after vitamin D supplementation

Parameters	Before (mean±SD)	After (mean±SD)	p-value
Vitamin D	11±3.94	21.68±6.18	<0.0001
Glucose	94.17±9.82	91.42±8.68	0.0001
Insulin	19.52±8.27	13.28±5.30	<0.0001
Vitamin B12	280±129.60	275.03±120.15	0.7442
HbA1c	5.54±0.34	5.55±0.31	0.6427
HDL	50.59±10.83	51.14±10.48	0.3484
LDL	114.36±30.64	116.9±27.33	0.3121
Triglycerides	138.69±71.5	137.78±55.69	0.8290
Total cholesterol	193.37±38.57	195.74±34.63	0.2552

SD: Standard deviation, HDL: High-density lipoprotein, LDL: Low density lipoprotein

receptor expression, while also reducing proinflammatory cytokine levels.¹⁸ The important roles of vitamin D in glucose metabolism are known, and the pathways involved are still under investigation.^{8,19}

In this study, which aimed to investigate IR and various clinical and biochemical parameters before and after vitamin D treatment in patients diagnosed with IR, 14.3% (n=14) of the 98 included patients were male and 85.7% (n=84) were female. The high prevalence of IR among female patients is consistent with literature data showing that women tend to have more than men.²⁰ This can be explained by certain biological disadvantages in women that play a role in the pathophysiology of IR, including gender hormones, environmental and lifestyle factors, differences in body fat and muscle mass distribution and function, and genetic variations, particularly prominent during menopause.²¹ Among other sociodemographic data examined in our study, the mean age was 39.09±11.45 years (range 20–65), with 34.57±12.4 in males (range 20–65) and 38.03±11.21 in females (range 20–60). This is consistent with the age data reported by Özdin et al.²² in 2021.

In line with our study aim, the mean HOMA-IR score was calculated using fasting glucose and insulin levels of the 98 patients at initial admission was 4.54±2.05. After 3 months of vitamin D supplementation, the mean HOMA-IR score was found to be 3.01±1.28, and the difference between the pre- and post-treatment scores was statistically significant (p<0.0001). A statistically significant negative correlation was found between the change in vitamin D levels and the change in HOMA-IR scores. In a study conducted in Japan, a comparison between a group receiving vitamin D supplementation and a placebo group showed a significant decrease in HOMA-IR levels in the supplementation group after one year.²³ Another noteworthy study reported a 60% improvement in insulin sensitivity after one year of vitamin D treatment, suggesting that this treatment may be more effective than troglitazone or metformin.²⁴ In a 4-year randomized controlled trial at the Medical University of Graz, Austria, 150 healthy premenopausal women with 25(OH)D levels <75 nmol/L received 20,000 IU vitamin D once weekly for 24 weeks. Importantly, this shorter-term intervention, similar in duration to our study, showed significant improvements in HOMA-IR, supporting our findings.²⁵

In our study, it was found that only three months of vitamin D replacement therapy the rate of patients with a HOMA-IR score below 2.5 was found to be 39.8% overall, 6.6% in men, and 45.2% in women. It is noteworthy that vitamin D supplementation significantly reduced HOMA-IR scores more pronounced effect in women. Several studies suggest that vitamin D supplementation may exert a stronger protective effect against IR in women. Von Hurst et al.²⁶ reported improved insulin sensitivity following vitamin D supplementation in insulin-resistant women. Additionally, evidence from another study indicated that found sex-specific associations between vitamin D status and prediabetes, with lower vitamin D levels linked to increased risk in men but not in women.²⁷ A narrative review published in 2023 further highlights potential synergistic interactions between vitamin D and estrogen, which may enhance the hormone's efficacy in improving insulin metabolism in women.²⁸ The more pronounced reduction in HOMA-IR observed in women may be explained by potential synergistic interactions between vitamin D and estrogen, which enhance β -cell function and insulin sensitivity. Additionally, vitamin D may reduce proinflammatory cytokine levels, preserving insulin signaling pathways. These mechanisms may account for the sex-specific differences observed in our study.

Limitations

An important limitation of our study is its retrospective design, which precludes full control over variables such as vitamin D dosage. In addition, data regarding potential weight changes, dietary interventions, physical activity, lifestyle modifications and concomitant medication use during the 3-month follow-up period were not available. However, based on clinical follow-up notes, no obvious weight loss was noted in these patients. Notably, all patients included in this study were followed by a single clinician, and vitamin D replacement therapy was applied under a consistent treatment algorithm. This consistency enhances the reliability of the follow-up data and reduces variability that could arise from different clinical practices.

Moreover, the 3-month follow-up period might seem short, but in clinical practice, patients receiving vitamin D supplementation are typically re-evaluated after 3 months. In this context, the relatively short follow-up period can actually be advantageous, as it minimizes the potential influence of confounding factors such as lifestyle changes, weight variations, diet, and physical activity. Importantly, even within this 3-month period, a significant reduction in HOMA-IR was observed.

Nevertheless, the short duration still limits assessment of the long-term sustainability of the observed effects. Therefore, to clarify the causal relationship between vitamin D and IR, particularly in women, for whom this condition is a major public health concern and to elucidate the mechanisms underlying the more pronounced effectiveness of vitamin D in women, larger prospective and randomized controlled studies are needed.

CONCLUSION

As a result, this study clearly demonstrates that vitamin D therapy may have a beneficial effect on IR. Therefore, vitamin D supplementation could be considered as an adjunctive option in the management of patients diagnosed with IR. The more pronounced improvement observed in female patients should be interpreted cautiously and may indicate the potential importance of considering sex-specific differences in treatment planning, given the small number of male participants.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was initiated with the approval of the Kartal Dr. Lütfi Kırdar City Hospital Clinical Researches Ethics Committee (Date: 27.09.2023, Decision No: 2023/514/258/1).

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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