RESEARCH PAPER

Effect of Vitamin D_3 Supplementation Along with Standard Treatment versus Standard Treatment Alone in the Management of Type 2 Diabetes Mellitus Among Patients with Vitamin D Insufficiency: A Prospective Observational Study

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ABSTRACT

Background: Vitamin D deficiency is highly prevalent among patients with Type 2 Diabetes Mellitus (T2DM) and has been implicated in impaired insulin secretion, reduced insulin sensitivity, and poor glycaemic control. Correction of Vitamin D insufficiency may improve metabolic outcomes; however, evidence regarding its clinical benefits remains inconsistent. **Aim:** To assess the effect of Vitamin D_3 supplementation along with standard antidiabetic therapy on glycaemic control in patients with Type 2 Diabetes Mellitus attending a tertiary care teaching hospital.**Methods:** A prospective, observational, comparative cohort study was conducted in 74 patients with Type 2 Diabetes Mellitus and serum Vitamin D_3 levels of 20–30 ng/mL. Patients were divided into two groups (n = 37 each): Group 1 received oral Vitamin D_3 supplementation with standard antidiabetic therapy, while Group 2 received standard therapy alone. Serum Vitamin D_3, HbA1c, FBS, and PPBS were assessed at baseline and after six months. **Results:** Following six months of treatment, Group 1 showed a significant increase in serum Vitamin D_3 levels from 24.4 ± 2.5 ng/mL to 37.9 ± 4.3 ng/mL ($p < 0.001$). Significant improvements were also observed in HbA1c (8.63 ± 0.78% to 7.91 ± 0.66%), FBS (169.2 ± 24.6 mg/dL to 145.8 ± 21.4 mg/dL), and PPBS (253.4 ± 37.5 mg/dL to 214.6 ± 32.1 mg/dL) ($p < 0.001$ for all), whereas only modest changes were observed in the control group. Baseline serum Vitamin D_3 levels demonstrated a moderate negative correlation with HbA1c reduction following supplementation ($r = –0.56$, $p < 0.001$), indicating that patients with lower baseline Vitamin D_3 levels experienced greater improvement in glycaemic control. **Conclusion:** Vitamin D_3 supplementation improved serum Vitamin D status and glycaemic control in patients with Type 2 Diabetes Mellitus. These findings support its use as an adjunct to standard antidiabetic therapy, particularly in Vitamin D-insufficient patients with T2DM.

Keywords: Vitamin D_3, Type 2 Diabetes Mellitus, Glycaemic Control, HbA1c, Fasting Blood Sugar, Postprandial Blood Sugar, Vitamin D Supplementation.

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INTRODUCTION

Vitamin D is traditionally recognized for its essential role in maintaining calcium and phosphate homeostasis and promoting bone mineralization. Following dietary intake, vitamin D undergoes hydroxylation in the liver to form 25-hydroxyvitamin D [25(OH)D], the principal circulating form, and is subsequently converted in the kidneys to its biologically active metabolite, 1,25-dihydroxyvitamin D [$1,25(OH)_2D$]. This active form enhances intestinal calcium absorption and contributes to normal skeletal growth and maintenance. Consequently, vitamin D deficiency is classically associated with rickets in children and osteomalacia in adults.

In recent years, interest in vitamin D has extended beyond skeletal health owing to its potential role in glucose metabolism and the pathogenesis of type 2 diabetes mellitus (T2DM). Vitamin D receptors are expressed in several tissues involved in glucose homeostasis, including pancreatic β-cells, skeletal muscle, adipose tissue, and the liver. Experimental and clinical evidence suggests that vitamin D may enhance insulin secretion by activating vitamin D receptors in pancreatic β-cells and improve insulin sensitivity by increasing insulin receptor expression and activating peroxisome proliferator-activated receptor-δ (PPAR-δ), thereby facilitating glucose uptake in peripheral tissues.

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These actions indicate that vitamin D may influence both insulin secretion and insulin action.[1,2]

A growing body of evidence has demonstrated an association between low vitamin D status and impaired glycemic control. Vitamin D deficiency has been linked to reduced insulin secretion, increased insulin resistance, and impaired glucose utilization, all of which contribute to the development and progression of T2DM. Epidemiological studies have reported that individuals with vitamin D deficiency have a significantly higher risk of developing prediabetes, with one meta-analysis estimating a 54% increased risk.[3] Furthermore, studies conducted in the Indian population have shown a high prevalence of vitamin D insufficiency among patients with T2DM, highlighting the coexistence of these two common health conditions.[4]

Several clinical studies and systematic reviews have also suggested that vitamin D supplementation may improve glycemic parameters, including fasting blood glucose and glycated hemoglobin (HbA1c), although the magnitude of benefit has varied across studies.[5,6] These inconsistent findings underscore the need for further research to clarify the clinical significance of vitamin D supplementation in diabetes management.

Given its low cost, favorable safety profile, and widespread availability, vitamin D supplementation has emerged as a potential adjunctive therapy for improving hypoglycemic control in patients with type 2 diabetes mellitus. Although several studies have investigated the association between vitamin D status and diabetes, the available evidence remains inconsistent, particularly in the Indian population. Therefore, further clinical research is needed to better understand its therapeutic role.

The present prospective observational study was undertaken to evaluate the effect of vitamin D_3 supplementation on glycemic parameters in patients with type 2 diabetes mellitus attending a tertiary care centre. The study aimed to assess changes in fasting blood glucose, postprandial blood glucose, glycated hemoglobin (HbA1c), and serum vitamin D levels following supplementation, thereby providing real-world evidence on the potential benefits of vitamin D_3 as an adjunct to standard antidiabetic therapy.

AIM OF THE STUDY

To assess the effect of Vitamin D_3 supplementation along with standard antidiabetic therapy on glycaemic control in patients with Type 2 Diabetes Mellitus attending a tertiary care teaching hospital.

OBJECTIVES

Primary Objective

To compare glycaemic control between patients receiving Vitamin D_3 supplementation along with standard antidiabetic therapy and those receiving standard antidiabetic therapy alone.

Secondary Objectives

1. To compare changes in HbA1c, fasting blood glucose (FBS) and postprandial blood glucose (PPBS) between the two groups.
2. To assess the correlation between baseline serum Vitamin D_3 levels and changes in glycaemic parameters following treatment.

METHODOLOGY

A prospective, observational, hospital-based comparative cohort study was conducted in the Department of Pharmacology at Dr. D. Y. Patil Medical College, Hospital and Research Centre after obtaining approval from the Institutional Ethics Committee (IEC approval number: **DYP/IECBH/2025/240**) prior to the commencement of the study. Adult patients with Type 2 Diabetes Mellitus attending the outpatient and inpatient departments of the hospital who fulfilled the inclusion and exclusion criteria were enrolled after obtaining written informed consent.

As this was an observational study, allocation of patients to either group was based solely on the treatment prescribed by the treating physician, and no intervention was made by the investigator. Patients were divided into two groups according to the prescribed treatment. Group 1 received oral Vitamin D_3 supplementation (cholecalciferol 60,000 IU once weekly for 8 weeks, followed by 60,000 IU once monthly for the subsequent 4 months) in addition to standard antidiabetic therapy, whereas Group 2 received standard antidiabetic therapy alone. Vitamin D_3 supplementation was prescribed by the treating physician in accordance with standard treatment guidelines.

Baseline demographic details and biochemical parameters, including serum 25-hydroxyvitamin D [25(OH)D], glycated haemoglobin (HbA1c), fasting blood sugar (FBS), and postprandial blood sugar (PPBS), were recorded before initiation of treatment. All patients were followed up for a period of six months, after which the same biochemical parameters were reassessed to evaluate the effect of Vitamin D_3 supplementation on glycaemic control.

Inclusion Criteria

1. Adults aged 30–70 years diagnosed with Type 2 Diabetes Mellitus (as per ADA criteria).
2. Duration of Type 2 Diabetes Mellitus of more than six months.
3. HbA1c between 7% and 11% at baseline.
4. Serum 25-hydroxyvitamin D [25(OH)D] levels between 20 and 30 ng/mL.
5. Patients willing to provide written informed consent.

Exclusion Criteria

1. Type 1 Diabetes Mellitus.

2. Patients already on vitamin D or calcium supplementation within the last 3 months.
3. Chronic kidney disease (Stage 4 and above) or chronic liver disease.
4. Pregnant or lactating women.

The sample size was calculated using the method adopted by Banzal and Desai (2020), who evaluated the effect of Vitamin D₃ supplementation on glycemic control in patients with Type 2 Diabetes Mellitus. Based on a minimum expected difference in HbA1c of 0.65% between the two groups, a standard deviation (σ) of 1.0%, a significance level (α) of 0.05, and a study power of 80%, the required sample size was estimated to be 37 patients in each group. Accordingly, 74 patients were enrolled in the study.

Statistical Analysis

Data were analyzed using appropriate statistical methods. Continuous variables were expressed as **mean ± standard deviation (SD)**, while categorical variables were expressed as **frequencies and percentages**. Comparisons between the two groups were performed using the **Independent Student's *t*-test** for continuous variables and the **Chi-square test** for categorical variables. Within-group comparisons before and after follow-up were performed using the **Paired Student's *t*-test**. **Pearson's correlation analysis** was used to determine the relationship between baseline serum Vitamin D₃ levels and improvement in glycaemic parameters following supplementation. A **p-value < 0.05** was considered statistically significant. Statistical analysis was performed **using** using SPSS Version 26.0.

RESULTS

A total of 74 patients with Type 2 Diabetes Mellitus were included in the study and were divided into two groups of 37 patients each. The demographic and biochemical characteristics of the study participants were analyzed and compared at baseline, followed by assessment of changes in glycemic parameters after Vitamin D₃ supplementation.

Table 1: Comparison of Baseline Characteristics Between Group 1 and Group 2.

Characteristics	**Group 1 (n=37)**	**Group 2 (n=37)**	**P value**
Age (years) (Mean ± SD)	**55.6 ± 8.2**	**56.1 ± 7.9**	0.78
Gender			0.63
Male	21 (56.8%)	19 (51.4%)	
Female	16 (43.2%)	18 (48.6%)	
Socio-economic status			0.82
Lower	8 (21.6%)	9 (24.3%)	
Middle	22 (59.5%)	21 (56.8%)	
Upper	7 (18.9%)	7 (18.9%)	
Duration of diabetes (years) (Mean ± SD)	**7.8 ± 3.1**	**7.6 ± 3.4**	0.81
Dietary habits			0.74
Vegetarian	13 (35.1%)	15 (40.5%)	
Mixed	24 (64.9%)	22 (59.5%)	

Table 1 shows the comparison of baseline demographic characteristics between Group 1 and Group 2. There were no statistically significant differences between the two groups with respect to age, gender, socio-economic status, duration of diabetes, and dietary habits ($p > 0.05$), indicating that the groups were comparable at baseline.

Table 2. Comparison of Baseline Biochemical Parameters Between Group 1 and Group 2.

Parameter	**Group 1 (n = 37), n (%)**	**Group 2 (n = 37), n (%)**	**P value**
Vitamin D₃ (ng/mL)	24.4 ± 2.5	24.8 ± 2.6	0.49
HbA1c (%)	8.63 ± 0.78	8.57 ± 0.82	0.73
FBS (mg/dL)	169.2 ± 24.6	166.8 ± 25.9	0.68
PPBS (mg/dL)	253.4 ± 37.5	249.6 ± 39.2	0.66

Table 2 presents the comparison of baseline biochemical parameters between Group 1 and Group 2. The mean serum Vitamin D₃, HbA1c, fasting blood sugar (FBS), and postprandial blood sugar (PPBS) levels were comparable between the two groups, and no statistically significant differences were observed ($p > 0.05$).

Figure 1. Comparison of Pre- and Post-treatment Serum Vitamin D₃ Levels Between Group 1 and Group 2.

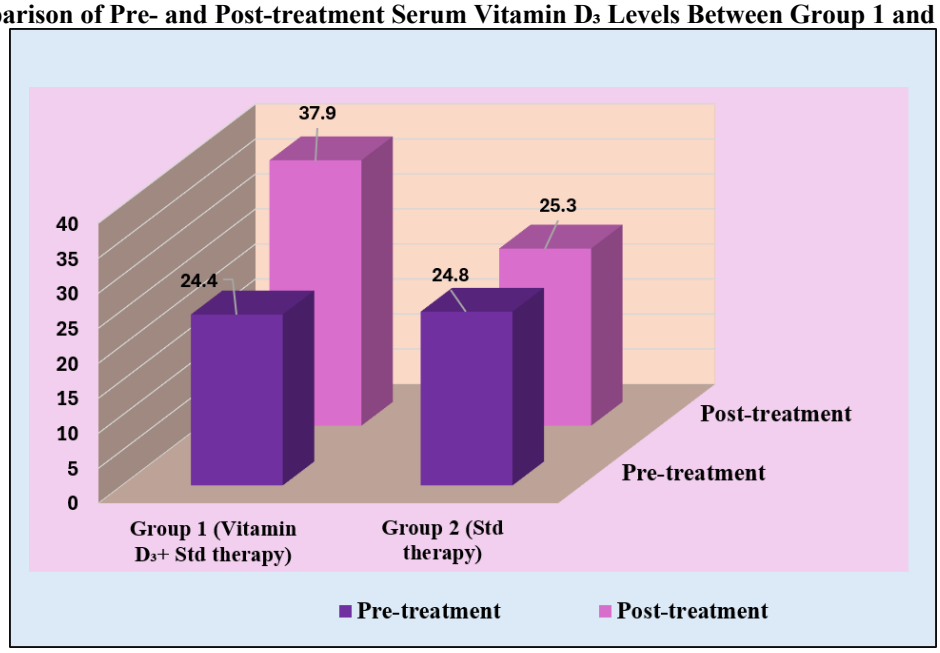


Figure 1 shows the comparison of mean serum Vitamin D₃ levels before and after treatment in Group 1 and Group 2. A significant increase in mean serum Vitamin D₃ levels was observed in Group 1 following Vitamin D₃ supplementation, whereas no significant change was observed in Group 2.

Table 3. Comparison of Pre- and Post-treatment Serum Vitamin D₃ Levels in Group 1 (n = 37)

Assessment	Sample Size (n)	Mean (ng/mL)	SD	P value
Pre-treatment	37	24.4	2.5	<0.001
Post-treatment	37	37.9	4.3	

Table 3 compares the pre-treatment and post-treatment mean serum Vitamin D₃ levels in Group 1. Following Vitamin D₃ supplementation, a significant increase in mean serum Vitamin D₃ levels was observed compared with baseline (**$p < 0.001$**).

Figure 2. Comparison of Pre- and Post-treatment HbA1c Levels Between Group 1 and Group 2.

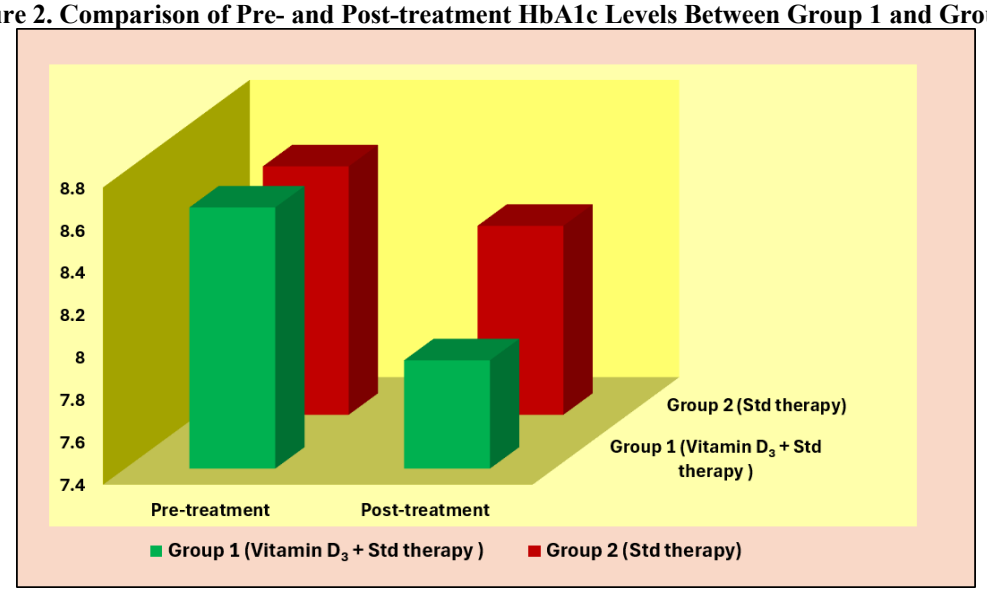


Figure 2 illustrates the comparison of mean HbA1c levels before and after treatment in Group 1 and Group 2. A greater reduction in mean HbA1c levels was observed in Group 1 following Vitamin D₃ supplementation compared with Group 2.

Table 4. Comparison of Pre- and Post-treatment HbA1c, Fasting Blood Sugar (FBS), and Postprandial Blood Sugar (PPBS) Levels Between Group 1 and Group 2

Parameter	Assessment	Group 1 (Vitamin D₃) Mean ± SD	Group 2 (Control) Mean ± SD	P value
HbA1c (%)	Pre-treatment	8.63 ± 0.78	8.57 ± 0.74	0.721
	Post-treatment	7.91 ± 0.66	8.29 ± 0.69	<0.001
FBS (mg/dL)	Pre-treatment	169.2 ± 24.6	167.8 ± 23.9	0.806
	Post-treatment	145.8 ± 21.4	156.4 ± 22.7	0.036
PPBS (mg/dL)	Pre-treatment	253.4 ± 37.5	251.8 ± 36.9	0.851
	Post-treatment	214.6 ± 32.1	232.7 ± 34.8	0.018

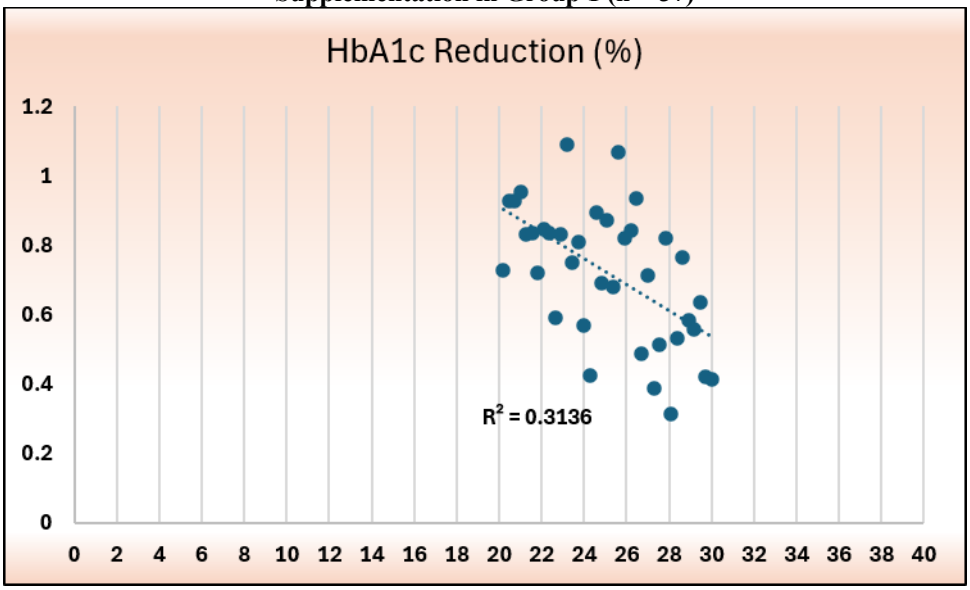
Table 4 compares the pre- and post-treatment HbA1c, fasting blood sugar (FBS), and postprandial blood sugar (PPBS) levels between Group 1 and Group 2. At baseline, there were no statistically significant differences in HbA1c, FBS, and PPBS levels between the two groups ($p > 0.05$), indicating comparable glycaemic status. Following treatment, Group 1 showed a significantly greater reduction in HbA1c, FBS, and PPBS levels compared with Group 2 ($p < 0.05$), demonstrating improved glycaemic control among patients receiving Vitamin D₃ supplementation.

Table 5. Correlation Between Baseline Serum Vitamin D₃ Levels and Improvement in Glycaemic Parameters in Group 1 (n = 37)

Parameter	Pearson correlation (r)	P value	Interpretation
HbA1c (%)	-0.56	<0.001	Moderate negative correlation
FBS (mg/dL)	-0.48	0.003	Moderate negative correlation

The correlation analysis demonstrated a **significant negative correlation** between baseline serum Vitamin D₃ levels and improvements in HbA1c, fasting blood sugar (FBS), and postprandial blood sugar (PPBS). Patients with lower baseline Vitamin D₃ levels showed greater improvement in glycaemic parameters following Vitamin D₃ supplementation.

Figure 3.Correlation Between Baseline Serum Vitamin D₃ Levels and Reduction in HbA1c Following Vitamin D₃ Supplementation in Group 1 (n = 37)



Pearson's correlation analysis demonstrated a moderate negative correlation between baseline serum Vitamin D₃ levels and reduction in HbA1c (**$r = -0.56$, $p < 0.001$**). The coefficient of determination (**$R^2 = 0.3136$**) indicated that baseline serum Vitamin D₃ levels explained approximately **31.36%** of the variation in HbA1c reduction following supplementation.

DISCUSSION

The present prospective observational comparative cohort study was conducted to evaluate the effect of Vitamin D₃ supplementation on glycaemic control in patients with Type 2 Diabetes Mellitus attending a tertiary care teaching hospital. A total of 74 patients were included and equally allocated into two groups based on the treatment prescribed by the treating physician. The effect of Vitamin D₃ supplementation was assessed using serum 25-hydroxyvitamin D [25(OH)D], glycated haemoglobin (HbA1c), fasting blood sugar (FBS), and postprandial blood sugar (PPBS).

The baseline demographic and biochemical characteristics were comparable between the two groups, indicating that both groups were well matched before treatment. Similar observations have been reported in previous studies **(6–8)**, supporting the comparability of study groups and minimizing the influence of baseline confounding factors.

Serum Vitamin D_3 Levels

Vitamin D_3 supplementation effectively corrected Vitamin D insufficiency in Group 1, whereas only minimal changes were observed in Group 2. Similar improvements in serum Vitamin D levels following supplementation have been consistently reported in clinical studies **(6,7,9)**. Recent systematic reviews and meta-analyses have also confirmed that Vitamin D supplementation effectively restores serum Vitamin D status and may improve glycaemic outcomes, particularly in individuals with Vitamin D insufficiency **(10,11)**. The improvement observed in the present study may be attributed to adequate supplementation, good treatment adherence, and regular follow-up.

Glycated Haemoglobin (HbA1c)

Improvement in HbA1c following Vitamin D_3 supplementation suggests that correction of Vitamin D insufficiency may enhance long-term glycaemic control when used as an adjunct to standard antidiabetic therapy. Comparable findings have been reported in clinical studies and systematic reviews **(6–8,10,12)**. However, a few studies have shown limited or no improvement in HbA1c, possibly because of differences in baseline Vitamin D status, supplementation regimen, study duration, sample size, and concomitant antidiabetic therapy. Nevertheless, the present findings support the growing evidence that Vitamin D supplementation may contribute to better long-term glycaemic control in patients with Type 2 Diabetes Mellitus.

Fasting Blood Sugar (FBS)

Vitamin D_3 supplementation was associated with improved fasting glycaemic control. Similar reductions in fasting blood glucose have been demonstrated in clinical studies and meta-analyses **(9–12)**. Variations in the magnitude of improvement across studies may be related to differences in baseline Vitamin D levels, duration of diabetes, treatment duration, and patient characteristics.

Postprandial Blood Sugar (PPBS)

Vitamin D_3 supplementation also contributed to improved postprandial glycaemic control. Comparable findings have been reported in previous clinical studies **(6,7)**. Although evidence regarding postprandial glucose is relatively limited compared with HbA1c and fasting glucose, available studies suggest that restoration of adequate Vitamin D levels may improve insulin secretion and peripheral glucose utilization during the postprandial period.

Correlation between Baseline Serum Vitamin D_3 Levels and Improvement in Glycaemic Control

The correlation analysis demonstrated that lower baseline serum Vitamin D_3 levels were associated with greater improvement in HbA1c following supplementation. Similar inverse associations between baseline Vitamin D status and glycaemic parameters have been reported previously **(3,5)**. Furthermore, systematic reviews and meta-analyses have shown that the glycaemic benefits of Vitamin D supplementation are more pronounced among individuals with Vitamin D deficiency or insufficiency **(8,10–12)**. These findings suggest that baseline Vitamin D status may influence the magnitude of response to supplementation.

Possible Mechanisms

The beneficial effects of Vitamin D_3 supplementation may be explained by several biological mechanisms. Vitamin D receptors are expressed in pancreatic β-cells, skeletal muscle, adipose tissue, and other insulin-responsive tissues. Activation of these receptors enhances insulin secretion, improves insulin sensitivity, regulates intracellular calcium homeostasis, and reduces chronic low-grade inflammation **(2)**. Experimental studies have also demonstrated that Vitamin D modulates inflammatory cytokines, improves β-cell survival, and influences insulin receptor gene expression, thereby contributing to improved glucose metabolism.

Strengths of the Study

The present study has several strengths. It was conducted prospectively in a tertiary care teaching hospital under real-world clinical conditions. Both Vitamin D status and important glycaemic parameters, including HbA1c, FBS, and PPBS, were evaluated over a six-month follow-up period. The inclusion of a comparison group receiving standard antidiabetic therapy without Vitamin D_3 supplementation enabled a better assessment of the additional effect of Vitamin D_3 on glycaemic control.

Limitations of the Study

Despite these strengths, the study has certain limitations. It was conducted at a single tertiary care centre with a relatively small sample size, which may limit the generalizability of the findings. Since the study was observational, treatment allocation depended on the treating physician rather than randomization, making it susceptible to selection bias and residual confounding. In addition, factors such as dietary intake, sunlight exposure, physical activity, seasonal variation, and medication adherence were not completely controlled and could have influenced Vitamin D status and glycaemic outcomes.

CONCLUSION

The findings of the present study demonstrate that oral Vitamin D_3 supplementation effectively improved

serum Vitamin D levels and was associated with significant improvements in HbA1c, fasting blood sugar, and postprandial blood sugar in patients with Type 2 Diabetes Mellitus. The results are in agreement with several clinical studies and recent systematic reviews, supporting the role of Vitamin D_3 as a useful adjunct to conventional antidiabetic therapy, particularly in patients with Vitamin D insufficiency or deficiency. Nevertheless, larger multicentre randomized controlled trials with longer follow-up are required to establish the optimal dose, duration, and long-term clinical benefits of Vitamin D_3 supplementation in the management of Type 2 Diabetes Mellitus.

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