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Original Research Article

Study the effectiveness and safety of vitamin D as an additional treatment for type 2 diabetic patients using oral anti-diabetics at a tertiary care hospital

Fateen Shareef[1], Azha Fatima[2], Ananth Naik Banavathu[1], Abdul Wasay Mohammed[1], Venkata Anil Chandra Dronamraju[3]*, Syeda Ayesha Siddiqua[4]

[1]Intern, Deccan College of Medical Sciences, Santhosh Nagar, Hyderabad, Telangana, India
[2]MBBS Final year, Kamineni Academy of Medical Sciences and Research Center, LB Nagar, Hyderabad, Telangana, India
[3]Department of General Surgery, Gayatri Vidya Parishad Institute of Health Care and Medical Technology, Visakhapatnam, Andhra Pradesh, India
[4]Department of Pharmacology, Shadan Institute of Medical Sciences, Teaching Hospital and Research Center, Hyderabad, Telangana, India

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***Correspondence:**
Dr. Venkata Anil Chandra Dronamraju,
E-mail: dranildronamraju7@gmail.com

ABSTRACT

Background: The prevalence of type 2 DM is alarmingly rising on a global scale. Improved treatments for type 2 DM are still needed, in order to slow the disease's development. A role in the pathophysiology of type 2 DM has been suggested by the correlation between vitamin D insufficiency and several non-skeletal illnesses, including DM. The goal of the study was to determine if vitamin D supplementation may help type 2 DM patients whose glycemic status was uncontrolled even after using oral antidiabetics.
Methods: 60 individuals with type 2 DM and vitamin D insufficiency participated in this 12-week open-label, before-and-after study. For 12 weeks, in addition to oral anti-diabetic medications, these patients also received 60,000 IU of vitamin D_3 orally every week. HbA1c, FBS, and 25(OH)D levels parameters were included.
Results: The majority of the patients were from 41-50 years of age group (48.3%) with a male predominance (60%). Most of them were having >1 year of type 2 DM duration (78.3%) with a high family history of type 2 DM (70%). After 12 weeks, there was a substantial ($p<0.001$*) drop in FBG levels and a significant ($p<0.001$*) decrease in HbA1c. 25(OH)D levels showed a high rise ($p<0.001$*). None of the patients had any side effects.
Conclusions: Vitamin D treatment improves glycemic status, which slows the development of type 2 DM and its associated effects. As such, vitamin D supplementation is a safe and promising adjuvant treatment for individuals with type 2 diabetes who are low in vitamin D.

Keywords: FBS, HbA1c, Type 2 diabetes mellitus, Vitamin D supplementation

INTRODUCTION

Out of all non-communicable illnesses, diabetes mellitus (DM) is the most prevalent ailment worldwide. The diabetes pandemic is nowhere more severe than in India. By 2030, there will likely be 87 million people with diabetes worldwide, compared to the estimated 50.8 million who had the disease in 2010.[1] Nearly 90% of all incidents of diabetes are type 2 diabetes (DM), which is also the primary cause of the global diabetes epidemic.[2] Every country is experiencing an increase in type 2 DM incidence, with emerging nations accounting for 80% of

the disease's cases. This means that type 2 DM has escalated into a major public health issue that burdens every nation socioeconomically, with emerging nations like India bearing the brunt of the load.[3]

Even if treatments for type 2 diabetes and associated co-morbidity have improved over the last several decades, the effect of the disease has worsened, necessitating the development of new ideas for the prevention and management of the condition. There is sufficient data to conclude that vitamin D is important for numerous non-skeletal diseases, including type 2 diabetes.[4] On several processes connected to the pathophysiology of type 2 DM, vitamin D has been reported to have both direct and indirect impacts. There is potential for a new direction in type 2 DM care and prevention according to the findings.[5]

Numerous studies have shown that those with low vitamin D levels have a higher chance of developing type 2 diabetes and that supplementing with vitamin D increases insulin resistance and improves glucose tolerance.[6,7] Consequently, the goal of the current study was to determine how vitamin D supplementation affected the glycemic profile of type 2 DM patients who also had a vitamin D deficiency and whose glycemic status was uncontrolled while using oral antidiabetic medications.

METHODS

An open-labeled study was conducted on 60 patients of type 2 DM for 12 weeks from (August 2023 to October 2023) at the department of general medicine, in a tertiary care hospital, Hyderabad. The study comprised of subjects of either gender, aged between 30 to 60 years.

The institution's ethical committee gave its clearance before the study was carried out. Before the research study, all patients were asked for written informed permission and given a thorough explanation of the advantages and dangers in their native tongue. The following inclusion and exclusion criteria were used in the patient selection process.

Inclusion criteria

Type 2 diabetics who take frequent oral anti-diabetic medications and have an HbA1c of more than 7% and with less than 30 ng/ml of vitamin D.

Exclusion criteria

The study excluded patients with a history of type 1 DM, and metabolic disorders, gastrointestinal, cardiovascular, renal, and liver disorders, as well as those who were already taking vitamin D supplements. Additionally, patients with hypersensitivity to vitamin D, and females who were pregnant or nursing were not included in the study.

Diabetic profile as per WHO guidelines is: FBS: ≥126 mg/dl, PPBS: >200 mg/dl, HbA1c: ≥6 mg/dl.[10]

Vitamin D profile as per WHO guidelines is <30 ng/dl.

Statistical analysis

Data was analyzed using SPSS software. Data were expressed as Mean±SD and p value <0.001* was considered statistically significant.

RESULTS

A total of 60 type 2 DM patients of either gender aged between 30 to 60 years participated in the present study. Most of the patients were from the age group of 41 to 50 years (n=29, 48.3%) with male patients in the majority (n=36, 60%). More than 1 year of duration of type 2 DM was observed in a high number of patients (n=47, 78.3%). There existed a family history of type 2 DM in a wide number of study participants (n= 42, 70%) (Table 1).

Table 1: Demographic characteristics of study subjects.

Demographic parameters		Frequency (n=60)	Percentage
Age (30-60 years)	30 to 40	22	36.7
	41 to 50	29	48.3
	51 to 60	09	15
Gender (male/female)	Male	36	60
	Female	24	40
Duration of type 2 DM	<1 year	13	21.7
	>1 year	47	78.3
Family history of type 2 DM	With family history	42	70
	Without family history	18	30

Data represented as Mean±SD, DM- diabetes mellitus

With supplementation of vitamin D mean FBS values and HbA1c values showed a reduction from baseline to 6-week period but a very potential improvement was observed over 12-week period. The baseline value of FBS (162.51±51.86) has comparatively reduced after 6 weeks (144.21±48.34) and after 12 weeks (132.01±54.78) there was a noticeable significant reduction (p<0.001*). In comparison with mean baseline HbA1c values (9.01±1.49), there was a significant reduction after 6 weeks (8.12±1.57), whereas after 12 weeks of vitamin D supplementation difference in mean HbA1c values was highly significant (p<0.001*). After 12 weeks of supplementation, patients achieved adequate levels of 25(OH)D, with mean levels (43.56±11.92) showing a highly significant (p<0.001*) rise from baseline (18.62±6.03) (Tables 2 and 3).

Table 2: Effects of vitamin D supplementation on study subjects from baseline to 6 weeks.

Biochemical parameters	Baseline (Mean±SD)	After 6 weeks (Mean±SD)	P value
FBS (mg/dl)	162.51±51.86	144.21±48.34	0.001*
HbA1c (%)	9.01±1.49	8.12±1.57	0.001*
25(OH)D (mg/dl)	18.62±6.03	38.02±10.54	0.001*

Table 3: Effects of vitamin D supplementation on study subjects from 6 weeks to 12 weeks.

Biochemical parameters	After 6 weeks (Mean±SD)	After 12 weeks (Mean±SD)	p value
FBS (mg/dl)	144.21±48.34	132.01±54.78	0.001*
HbA1c (%)	8.12±1.57	7.20±1.73	0.001*
25(OH)D (mg/dl)	38.02±10.54	43.56±11.92	0.001*

In Figure 1, a significant (p<0.001*) increase of mean 25(OH)D values can be observed with the vitamin D supplementation at baseline (18.62±6.03), after 6 weeks (38.02±10.54) and after 12 weeks (43.56±11.92), respectively.

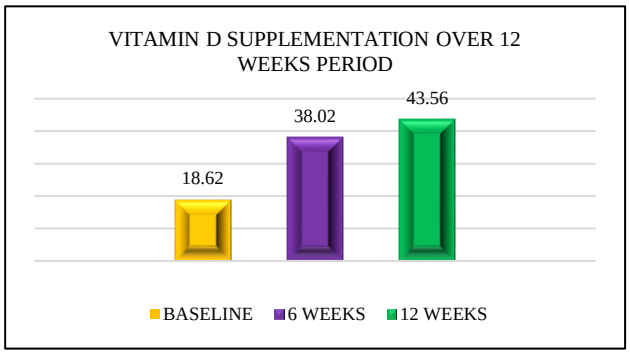

Figure 1: Vitamin D supplementation over 12 weeks period.

Figure 2 depicts that, there are no side effects with vitamin D supplementation in the study participants, and it is very safe to use in type 2 DM patients.

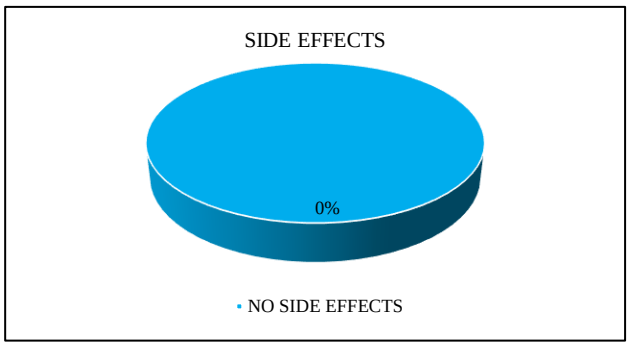

Figure 2: Side effects with Vitamin D supplementation.

DISCUSSION

The purpose of the current study was to examine the safety and effectiveness of vitamin D when taken in addition to oral antidiabetic medications by measuring glycaemic control in sixty individuals with type 2 diabetes mellitus. Included in the study were patients with type 2 diabetes who were on different oral antidiabetic medications and had a vitamin D deficiency. Glycemic status was then compared with baseline results after they received a weekly oral 60,000 IU vitamin D_3 sachet for 12 weeks.

The present study showed that most of the patients were from the age group of 41 to 50 years (n=29, 48.3%) with male patients in the majority (n=36, 60%). In a similar 18-month study done by Al-Daghri et al, on vitamin D supplementation as adjuvant therapy for T2DM patients, the study population was around 50 years but unlike our study the female population was predominant.[8] It was also noticed that >1 year of duration of type 2 DM was observed in a high number of patients (n=47, 78.3%) and there existed a family history of type 2 DM in a wide number of study participants (n=42, 70%). This is as per a cross-sectional study on the prevalence of vitamin D deficiency in type 2 diabetes mellitus patients done by Vijay et al, where diabetes mellitus duration was >1 year with a high family history of the ailment.[9]

In the current study, the vitamin D supplementation resulted in a decrease in mean FBS and HbA1c values from baseline to the 6-week period, although a highly promising improvement was shown at the 12-week period. The baseline value of FBS (162.51±51.86) has comparatively reduced after 6 weeks (144.21±48.34) and after 12 weeks (132.01±54.78) there was a noticeable significant reduction (p<0.001*). In comparison with mean baseline HbA1c values (9.01±1.49), there was a significant reduction after 6 weeks (8.12±1.57), whereas after 12 weeks of vitamin D supplementation difference in mean HbA1c values was highly significant (p<0.001*). The results are consistent with abundant studied done in past in which vitamin D supplementation improved FBS and HbA1C, respectively. Nasri et al, conducted a similar study in 2014, in which vitamin D supplementation improved glycaemic parameters in patients with type 2 diabetes mellitus.[10] In parallel studies done by Lalitha et al and Talaei et al, type 2 diabetics deficient in vitamin D who received vitamin D treatment had significantly lower FBS and HbA1C values than those who did not receive vitamin D supplements.[11,12]

After 12 weeks of vitamin D supplementation, patients achieved adequate levels of 25(OH)D, with mean levels (43.56±11.92) showing a highly significant (p<0.001*) rise from baseline (18.62±6.03), a significant (p<0.001*) increase of mean 25(OH)D values can be observed with the vitamin D supplementation at baseline (18.62±6.03), after 6 weeks (38.02±10.54) and after 12 weeks (43.56±11.92), respectively. Heshmat et al, Patel et al and

Al-Daghri et al, in their respective comparable studies showed highly significant change in 25(OH)D levels in T2DM patients after vitamin D supplementation.[13-15] Heshmat et al in their respective comparable studies showed highly significant change in 25 (OH) D levels in T2DM patients after vitamin D supplementation.[13,14]

Regarding the safety and tolerability of vitamin D, in patients with type 2 diabetes, neither unfavourable side effects nor indications of vitamin D toxicity were noted during or after vitamin D supplementation.[16]

The small sample size and short duration were the major limitations. The study only included participants from tertiary care hospitals; no participants from peripheral health care centers were included. Additional research is necessary to validate our observations, which was not feasible in the given restricted sources and setup.

CONCLUSION

It indicates that vitamin D therapy increases glycemic control, which in turn slows down the development and, ultimately, the consequences of type 2 DM in individuals with low vitamin D levels. For these patients, vitamin D supplementation is a promising adjuvant therapy. Vitamin D supplementation must be a part of the therapy of type 2 diabetes mellitus patients since doses of 60,000 IU taken orally every week for 12 weeks are fairly safe in those with low vitamin D levels.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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