The impact of vitamin D3 supplementation on glycemic control in type-2 diabetes mellitus at a tertiary care hospital

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ABSTRACT

Background: It has been estimated that at least one billion people worldwide have vitamin D3 deficiency. Type 2 diabetes mellitus has consistently been shown to be prevalent in individuals with vitamin D3 deficiency. This study focuses on exploring if there is any association between vitamin D3 deficiency, type 2 diabetes mellitus and glycemic control, by measuring HbA1c levels, after vitamin D3 supplementation.

Methods: 77 patients with confirmed type II diabetes mellitus were enrolled during the study. Pre and post treatment (after 3 month) laboratory investigations - FBS, PPBS, HbA1c and serum vitamin D3 levels were done in all the patients. Patients were classified into two groups. Group 1 - vitamin D3 < 30 ng/ml (n=41) and group 2 - vitamin D3 ≥30 ng/ml (n=36). Group 1 was given 60,000 IU of calcitriol sachet weekly for 8 weeks followed by 60,000 IU once a month. No vitamin D3 supplementation was given to group 2.

Results: Vitamin D3 supplementation in group 1, has resulted in number of patients with control on HbA1c (< 7%) increased from 8 to 17 (a more than 100% increase). Number of patients with control on FBS (<130 mg/dl) increased from 14 to 23 (64% increase).

Conclusions: There is a positive association between vitamin D3 status and glycemic control in type 2 diabetic mellitus patients. Vitamin D3 supplementation in deficient group has resulted in significant reduction in HbA1c level (p<0.001).

Keywords: Vitamin D deficiency, Type 2 diabetes, Glycemic control, HbA1c, FBS, PPBS

INTRODUCTION

Vitamin D3 deficiency and diabetes mellitus are two common conditions that are widely prevalent across people of all ages, races, geographical regions, and socioeconomic classes. A lot of current focus is on the role of vitamin D3 deficiency in the pathogenesis and development of type 2 diabetes. Inadequate exposure to sunlight and inadequate dietary intake of vitamin D3 are leading to a widespread deficiency in all ages.1

Vitamin D3 plays an important part in the regulation of calcium. Calcium besides having multiple functions in our body systems also helps to facilitate the release of insulin, so a decrease in calcium has a negative effect on beta cell function, which may affect normal insulin release. Type 2 diabetes mellitus has consistently been shown to be prevalent in individuals with vitamin D3 deficiency. The condition is characterized by insulin resistance and altered insulin secretion, associated with defects in pancreatic beta cell function.

It has been reported through various animal and human studies that vitamin D has a role in controlling glucose metabolism besides having a role in skeletal functions. There has been increasing evidence to suggest that vitamin D may be important in modifying risk of type 2 diabetes. Vitamin D is supposed to have an effect on both
direct (through activation of the vitamin D receptor) and indirect (via regulation of calcium homeostasis) mechanisms related to the pathophysiology of type 2 diabetes. The effect of vitamin D is also seen on pancreatic beta-cell dysfunction, impaired insulin action, and systemic inflammation. The evidence comes from cross-sectional and a few prospective observational human studies showing an inverse association between vitamin D status and prevalence or incidence of type 2 diabetes. Vitamin D₃ replenishment may improve glycemic control and insulin secretion in patients with type 2 diabetes mellitus with established hypovitaminosis D₃, thereby suggesting a role for vitamin D₃ in pathogenesis of diabetes mellitus.

There has been a lack of conclusive evidence to establish the role of vitamin D₃ in prevention or treatment of type 2 diabetes.

The objective of this study was to explore if there is any association between vitamin D₃ deficiency, type 2 diabetes mellitus and glycemic control, by measuring HbA₁c levels after vitamin D₃ supplementation.

METHODS

This was an observational study carried out at departments of pharmacology and medicine at a tertiary care hospital Surat Municipal Institute of Medical Education and Research (SMIMER), Surat. In this study, patients attending medicine OPD and diagnosed with confirmed type II diabetes mellitus for more than six months were included. The permission of the ethics committee of the institute was taken prior to the commencement of the study.

Sample size calculation

Sample size (n) was calculated by using the following formula,

\[ n = \frac{(Z\alpha/2) \times (Z\alpha/2) \times p \times q}{L \times L} \]

Where \( p \) is the proportion of diabetic patients attending medicine OPD. It was obtained by one-month pilot survey and was found to be 7.5%. \( q \) is the proportion of non-diabetic population attending the medicine OPD, which is 1-p i.e. 92.5%. \( Z\alpha \) is standard normal variate, at the level of significance 95% \( (p<0.05) = 1.96 \).

\[ n = \frac{1.96 \times 1.96 \times 0.075 \times 0.925}{0.06 \times 0.06} \]

Grouping of patients

According to level of vitamin D₃, 77 patients were classified as two groups.

- **Group 1**: 41 patients with vitamin D₃<30 ng/ml referred as vitamin D₃ deficient group or simply Gp1.
- **Group 2**: 36 patients with vitamin D₃>30 ng/ml referred as vitamin D₃ sufficient group or Gp2.

Accordingly, 77 patients with confirmed type II diabetes mellitus meeting the above criteria were eventually taken for study. Informed written consent was taken from the patients for using their clinical data for the study purpose. Laboratory investigations like FBS, PPBS, HbA₁c and serum vitamin D₃ were carried out in all the patients. Serum vitamin D₃ was measured by the method of electrochemiluminescence immunoassay (ELCIA). These parameters were recorded and noted as “pre-treatment” levels.

Gp1 patients were given 60,000 IU of calcitriol sachet weekly for 8 weeks followed by 60,000 IU once a month, along with prescribed medication by physician. Patients were telephonically reminded for compliance and follow up. Gp2 patients were asked to continue treatment of physician only. No vitamin D₃ supplementation was given to this group.

All the patients were given dietary and lifestyle modification advice. Patients were asked regarding general wellbeing or any problems during the study period. After a gap of 3 months, repeat investigation for FBS, PPBS, HbA₁c and serum vitamin D₃ were carried out in all the patients (Gp1 and Gp2) to get the data for analysis. These levels were recorded and noted as “post treatment” levels. OPD patients of age more than 18 years attending the department of medicine having history of diabetes mellitus type II for more than 6 months were included. Patients having history of liver disease, chronic heart disease or any other chronic illness, patients with nephropathy or renal failure, pregnant woman and patients of history of calcium supplementation or history of vitamin D₃ supplementation in last three months were excluded from the study.

Statistical analysis

The data was analysed by descriptive statistics such as mean, SD (standard deviation), bar graphs, paired t-test, independent t-test were applied to know the effectiveness of pre and post comparison of variables. Statistical analysis was done by SPSS20.

Ethical approval

The permission of the ethics committee of the institute was taken prior to the commencement of the study.
**RESULTS**

Pre-treatment values refer to values of parameters (vitamin D₃, HbA1c, FBS, PPBS) recorded in all subjects (Gp1 and Gp2) at the beginning of the study.

Post-treatment values refer to values of parameters (vitamin D₃, HbA1c, FBS, PPBS) recorded after vitamin D₃ supplementation in Gp1 patients and without vitamin D₃ supplementation in Gp2 patients after three months of follow up.

The study population constituted of predominantly male patients. There were 55 (71%) males and 22 females in the study population. The proportion of female was 41.5% in vitamin D₃ deficient group as compared to vitamin D₃ sufficient group in which it was 13.9%. There were more patients 74% in the age group of more than or equal to 50 years in the study population.

**Table 1: Demographic data.**

| Parameters                      | Gp1 (n=41) | Gp2 (n=36) |
|--------------------------------|------------|------------|
| Gender                         |            |            |
| M: 24 (58.5)                   | M: 31 (86.1) |
| F: 17 (41.5)                   | F: 5 (13.9)  |
| Age                            |            |            |
| <50 years: 14 (34.1)           | <50 years: 06 (16.7) |
| ≥50 years: 27 (65.9)           | ≥50 years: 30 (83.3) |
| Socio-economic status          |            |            |
| ≤4.2 L/year: 36 (87.8)         | ≤4.2 L/year: 29 (80.6) |
| >4.2 L/year: 05 (12.2)         | >4.2 L/year: 07 (19.4) |
| Duration of diabetes           |            |            |
| 2 to 10 years: 31 (75.6)       | 2 to 10 years: 26 (72.2) |
| >10 years: 10 (24.4)           | >10 years: 10 (27.8) |
| Dietary habits                 |            |            |
| Vegetarian: 27 (65.9)          | Vegetarian: 20 (55.6) |
| Non veg: 14 (34.1)             | Non veg: 16 (44.4) |

**Drug utilization pattern in study population**

Most of the patients 94.8% were on multi-drug therapy. The drug which was used by all the patients was metformin (100%) followed by glibipiride (94.8%), voglibose (27.3%) and pioglitazone (1.3%) mainly through combination therapy. The Figure 1, below depicts the drugs utilization pattern in the treatment of type 2 diabetes mellitus.

**Pre-treatment lab test data**

Vitamin D₃, HbA1c, FBS, PPBS were done for all patients and the data recorded for each group (Table 2).

For HbA1c the division was made considering ADA guidelines which recommend the target level of HbA1c as 7% for the management of HbA1c in most diabetic patients. In the study, when we consider Gp1 patients, the target level of HbA1c<7% was achieved by 20% patients and in Gp2, 42% patients had their HbA1c<7%.

**Table 2: Pre-treatment lab reports data.**

| Test          | Criteria          | Gp1 (n=41) | Gp2 (n=36) |
|---------------|-------------------|------------|------------|
| Vitamin D₃ (ng/ml) | ≤ 30              | 41 (98%)   | 36 (89%)   |
|               | ≥30               |            |            |
| HbA1C (%)     | < 7               | 8 (20%)    | 15 (42%)   |
|               | ≥7 and <10        | 26 (63%)   | 18 (50%)   |
|               | ≥10               | 7 (17%)    | 3 (8%)     |
| FBS (mg/dl)   | <130              | 14 (34%)   | 16 (44%)   |
|               | ≥130              | 27 (66%)   | 20 (56%)   |
| PPBS (mg/dl)  | ≤180              | 12 (29%)   | 19 (53%)   |
|               | ≥180              | 29 (71%)   | 17 (47%)   |

As per ADA guidelines FBS target level for diabetes mellitus patients is recommended to be less than 130 mg/dl. Further in Gp1, 34% of the population was in target range in comparison to 44% population in Gp2. As per American diabetes association guideline, the target range recommended for PPBS levels is less than 180 mg/dl. Accordingly, it is observed that the target level was achieved in 40% of the patients. If we look within Gp1 and Gp2, it is observed that Gp2 had more population under control with 53% in comparison to 29% in Gp1.
Table 3: Pre-treatment mean vitamin D3, HbA1c, FBS, PPBS level in Gp1 (n=41) and Gp2 (n=36) patients.

| Parameters       | Gp1  | Mean  | SD   | P value | Significance |
|------------------|------|-------|------|---------|--------------|
| Vitamin D3 (ng/ml) |      |       |      | <0.001  | Highly significant |
| Gp1              | 17.3 | 5.9   |      |         |              |
| Gp2              | 40.1 | 8.5   |      |         |              |
| HbA1c (%)        |      |       |      | 0.063   | Not significant |
| Gp1              | 8.5  | 2.5   |      |         |              |
| Gp2              | 7.6  | 1.5   |      |         |              |
| FBS (mg/dl)      |      |       |      | 0.488   | Not significant |
| Gp1              | 146  | 39    |      |         |              |
| Gp2              | 139.5| 42.9  |      |         |              |
| PPBS (mg/dl)     |      |       |      | 0.351   | Not significant |
| Gp1              | 207.4| 68    |      |         |              |
| Gp2              | 192.9| 67.2  |      |         |              |

Table 4: Pre-treatment and post treatment mean vitamin D3, HbA1c, FBS and PPBS levels in Gp1.

| Parameters       | Sample size | Mean  | SD   | P value | Significance |
|------------------|-------------|-------|------|---------|--------------|
| Vitamin D3 (ng/ml) |             |       |      | <0.001  | Highly significant |
| Pre              | 17.3        | 5.9   |      |         |              |
| Post             | 30.7        | 12.3  |      |         |              |
| HbA1c (%)        |             |       |      | 0.005   | Significant |
| Pre              | 8.5         | 2.5   |      |         |              |
| Post             | 7.6         | 1.9   |      |         |              |
| FBS (mg/dl)      |             |       |      | 0.007   | Significant |
| Pre              | 146         | 39    |      |         |              |
| Post             | 139.5       | 42.9  |      |         |              |
| PPBS (mg/dl)     |             |       |      | 0.001   | Highly significant |
| Pre              | 207.4       | 68    |      |         |              |
| Post             | 177         | 61.3  |      |         |              |

Table 5: Post treatment mean vitamin D3, HbA1c, FBS and PPBS levels in Gp1 and Gp2 patients.

| Parameters       | Sample size | Mean  | SD   | P value | Significance |
|------------------|-------------|-------|------|---------|--------------|
| Vitamin D3 (ng/ml) |             |       |      | 0.0008  | Highly significant |
| Gp1              | 30.7        | 12.3  |      |         |              |
| Gp2              | 39.4        | 7.1   |      |         |              |
| HbA1c (%)        |             |       |      | 0.264   | Not significant |
| Gp1              | 7.6         | 1.9   |      |         |              |
| Gp2              | 7.1         | 1.3   |      |         |              |
| FBS (mg/dl)      |             |       |      | 0.952   | Not significant |
| Gp1              | 129.5       | 42.9  |      |         |              |
| Gp2              | 128.9       | 30.4  |      |         |              |
| PPBS (mg/dl)     |             |       |      | 0.307   | Not Significant |
| Gp1              | 177.0       | 61.3  |      |         |              |
| Gp2              | 164.7       | 40.6  |      |         |              |

Comparative data of pre-treatment levels of vitamin D3, HbA1c, FBS and PPBS between Gp1 and Gp2

It is observed that between the two groups, the difference in vitamin D3 levels were statistically significant. An inverse relationship is observed between the high vitamin D3 level and HbA1c parameters between the two groups. However, the HbA1c levels between the groups were not statistically significant. FBS and PPBS values observed in Gp2 are less than the values observed in Gp1. However, these values are statistically not significant (Table 3).

Comparative data of vitamin D3, HbA1c, FBS and PPBS in Gp1 - pre and post supplementation of vitamin D3

Gp1 patients were given the vitamin D3 supplementation of 60,000 IU for 8 weeks and once a month thereafter and the reading of vitamin D3, HbA1c, FBS and PPBS were taken after 3 months from the first dose of supplementation. The following are the observations of the parameters before and after the treatment was given to Gp1. It can be seen that all the parameters had significant change in their values (Table 4).

Comparative data on post treatment levels of vitamin D3, HbA1c, FBS and PPBS between Gp1 and Gp2

The comparison of vitamin D3, HbA1c, FBS and PPBS mean levels is made between Gp1 and Gp2, after vitamin D3 supplements were given to Gp1. It was observed that Gp2 vitamin D3 mean level was higher than the level of Gp1. The independent ‘t’ test showed that the difference of vitamin D3 levels was statistically significant.

The HbA1c level between the two groups was not found to be statistically significant. The values in the Gp2 were on the lower side. This also shows the inverse relationship between vitamin D3 level and HbA1c levels (Table 5).
DISCUSSION

The mean age in the present study was 55.2±9.2 (n=77) years. This is similar to the study carried out by Hamid et al in which the mean age was 55±10.7 (n=60) and also similar to the study carried out by Ohk et al in 2014 in which mean age was 54.8±7.6 (n=64). The mean age in most of the studies carried out on type 2 diabetic patients is around 55 years. In the age group below 50 years, it is evident that there was a higher prevalence (34.1%) of diabetes mellitus in the Gp1 than in the Gp2 (16.7%). This indicates an association of early onset of type 2 diabetes in vitamin D deficient subjects. This finding is similar to the finding in the study carried out by Harish et al in 2015 on correlation of vitamin D level with glycemic control in type 2 diabetes mellitus (n=50) in which he observed that there were 44% patients in vitamin D deficient group (D<30 ng/ml) in comparison to only 14% in vitamin D sufficient group in the age group below 45 years.7

In the present study, the duration of diabetes mean was 6.1 years. This is similar to the mean duration observed in the study carried out by Krul et al in a study as 6 years.8 The percentage of patients with a non-vegetarian diet were 39%, comparable to the study of Krul et al 35%.8 It was also noted that the subjects with vegetarian diet were on a higher side (66%) in the vitamin D3 deficient group in comparison to the non-vegetarian diet patients (34%).

It was observed that all patients were on multi drug therapy. All (100%) have been prescribed metformin and 94.8%, sulfonyl urea group drug glimipride, alpha-glucosidase inhibitor voglibose (27.3%), pioglitazone (in 1.3%) are given in combination with metformin. This is comparable with the study carried out by Ohk et al on Korean subjects in which 88.6% were given metformin, followed by 78.5% sulfonyl urea group, 34.2% acarbose group and 15.4% pioglitazone.6

In the present study the number of patients having better glycemic control (HbA1c <7% as per ADA guidelines) were 20% in Gp1 in comparison to 42% in Gp2, implying an improvement in glycemic control with sufficient vitamin D3 levels.4 Similarly, in our study the FBS target level (<130 mg/dl as per ADA) was achieved in 34% patients in Gp1 in comparison to 44% in Gp2.4

Our study has noted the similar inverse relationship on PPBS and vitamin D3 levels in achieving the target level of 180 mg/dl. Our results match with the findings of Pittas et al in which the author has noted improvement in glycemic control with high level of vitamin D3.9 The finding is also similar to the finding of Brijesch et al in which author noted an inverse correlation through linear regression between vitamin D3 levels and HbA1c levels.10 The same is supported by the finding of Harish et al in which he noted a significant inverse relationship with the vitamin D3 level and HbA1c (p=0.006).7

In the present study, the vitamin D3 level increased in both the genders significantly (p<0.001). The result of our study matches with the study carried out Ohk et al, Krul et al and Sabherwal et al.6,8,11 In the present study Gp1 patients treated with vitamin D3 supplementation show significant improvement in vitamin D3 level along with significant improvement in the HbA1c (p=0.005), FBS (p=0.007) and PPBS (p=0.001) levels. This suggests a positive relationship between glycemic control and vitamin D3.

The present study also observed that after the vitamin D3 supplementation the number of patients with control on HbA1c (<7% as per ADA guidelines) increased from 8 to 17, a more than 100% increase.4 Similarly the number of patients with FBS<130 mg/dl considered under control as ADA increased from 14 to 23, an increase of 64%, and number of patients with PPBS<180 mg/dl increased from 19 to 27, an increase of 42%. This shows an improvement in glycemic control with an increase in vitamin D3 levels.

Our study results match with the study carried out by Sabherwal et al who noted that vitamin D3 and calcium replacement therapy in South Asian patients with type 2 diabetes mellitus produced a significant decrease in both HbA1c (p<0.001) and weight, which might be due to the increase in vitamin D3 levels post treatment.11 Krul et al also noted a significant (p=0.02) inverse relationship between HbA1c and vitamin D3 level in a sub group of vitamin D3 deficient subjects.8

However, the study carried out by Ohk et al did not find any significant change in the HbA1C, FBS with an increase in vitamin D3 levels.6 This supports the hypothesis that glycemic control depends on multiple factors and vitamin D3 level is not the only governing factor. The above studies support the findings of the present study that the vitamin D3 levels can have a role in glycemic control on type 2 diabetes mellitus patients.

Based on above results it can be assumed that it would be advisable to correct the vitamin D3 level in all patients suffering from type 2 diabetes. Accordingly, vitamin D3 has been administered to patients with diabetes mellitus type 2.12

In a study carried out Hamid et al in 2014 to assess the efficacy of supplementation of vitamin D on improvement on glycemic parameters in patients having type 2 DM in a randomized double blind clinical trial, the authors noted that that significant improvement in glycemic control was observed only in the male subjects (p=0.0068).5 However in our study improvement in glycemic control was observed in both the genders.

The present study observed that in Gp2 also HbA1c, FBS and PP2BS significantly improved (p<0.05) though there was no supplementation of vitamin D3 in this group, however, the vitamin D3 levels were maintained and mean (39.4 ng/ml) was higher than in the Gp1 (30.7...
ng/ml). Advice and counselling about the dietary modification and lifestyle changes of patients might have been a probable factor for this improvement.13,15 This also suggests that glucose homeostasis in type 2 diabetes mellitus is affected by multiple factors.

The present study shows that in type 2 diabetic patients, vitamin D₃ levels were found to be negatively correlated with glycosylated hemoglobin levels. The present study noted that in type 2 diabetes subjects having vitamin D₃ deficiency (Gp1), there is a significant improvement in HbA1c levels post vitamin D₃ supplementation. There is also a significant improvement in glucose homeostasis in this group.

Based on above results, it would be physiologically correct to recommend vitamin D₃ supplementation to improve glucose control in type 2 diabetes mellitus patients along with counseling for dietary modification and lifestyle changes.

Limitations

Study assumed that the subjects kept their medication doses constant. Study also assumed that subjects had complied with the vitamin D₃ doses prescribed during the study. Study may not represent the whole population. Study did not account for vitamin D₃ variation with change in season during the period of the study.

Implications of research

In patients of type 2 diabetes with vitamin D₃ deficiency, supplementation of vitamin D₃ may be advised in order to enable better glycemic control and improvement in clinical outcome. This may also help in prevention of other complications associated with un-controlled blood sugar levels in patients with type 2 diabetes mellitus.

CONCLUSION

On the basis of our study, we observed that those having vitamin D₃ deficiency are likely to have an early onset of diabetes mellitus and we found a positive association between vitamin D₃ status and glycemic control in type 2 diabetic mellitus patients. Moreover, it was also noted that type 2 DM is a multi-factorial disease and it is unlikely that vitamin D₃ deficiency alone would be a major cause of disease or a major therapeutic target. However, vitamin D₃ supplementation may have a role in glycemic control and it is recommended to correct the deficient patients by supplementing vitamin D₃ adequately.

Further randomized controlled trials for longer duration and large cross section of the population is recommended to better define the clinical role of vitamin D₃ as potential intervention for prevention and management of type 2 diabetes.

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