



## Original Research Article

# A CROSS-SECTIONAL STUDY TO ASSESS THE CORRELATION BETWEEN SERUM 25-(OH)VITAMIN D AND INSULIN LEVELS IN TYPE II DIABETES MELLITUS PATIENTS VISITING TERTIARY CARE CENTER IN KALABURAGI

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**ABSTRACT**

**Background:** Indians outstand in the prevalence of both vitamin D deficiency and diabetes. Studies have shown that the vitamin D level is inversely proportional to the level of FBS and HbA1c. Type II diabetics have lower vitamin D levels than healthy people. The objective of the study is to find out prevalence of vitamin D deficiency in diabetic persons and then to find out if there is any correlation between serum vitamin D levels with FBS, HbA1c, insulin and insulin resistance.

**Materials and Methods:** This study was a hospital based cross sectional study. A total of 85 participants having type II DM aged 35-75 years were recruited from OPD patients attending Non-Communicable Disease (NCD) clinic. Estimation of serum levels of 25-(OH) vitamin D with FBS, HbA1C, insulin levels and HOMA-IR in type II DM patients was done to find out the correlation. **Results:** Mean BMI was found to be higher in females compared to males. Mean FBS and HbA1c were found higher than standard reference range in all study participants. HOMA-IR value was found to be higher indicating insulin resistance across overall study population. It was noted that 25(OH) vitamin D levels were significantly reduced compared to normal standard range.

**Conclusion:** Negative correlation between vitamin D with FBS and HbA1c levels was observed. Therefore, lower the vitamin D levels higher will be the levels of FBS & HbA1c. Hence, vitamin D supplementation should be considered in patients with type 2 diabetes for better glycemic control.

**Keywords:** Type II Diabetes, Vitamin D, Correlation, Glycemic control.

**INTRODUCTION**

Diabetes mellitus (DM) is a group of metabolic disorders characterized by long-term hyperglycemia resulting from defects in insulin action, insulin secretion, or both.<sup>[1]</sup> Being diagnosed with and managing diabetes often affects an individual's quality of life and is also the leading cause of significant morbidity and premature mortality, as

well as a major risk factor for adverse complications such as blindness, stroke, heart attack, amputation, and kidney failure.<sup>[2]</sup> The burden of diabetes is high and increasing globally. According to the international diabetes federation (IDF), data released in 2021 showed that 537 million adults live with diabetes worldwide. The total number is predicted to rise to 643 million by 2030 and to 783 million by 2045.<sup>[3]</sup>

Indians outstand in the prevalence of both vitamin D deficiency and diabetes. To prevent long-term micro- and macro-vascular complications, patients with DM are required to have adequate glycemic control, which is routinely assessed by measuring glycosylated haemoglobin (HbA1c) and fasting blood sugar (FBS) levels.<sup>[4]</sup>

Despite being classified as a micronutrient, vitamin D has been noted to serve several hormonal functions through vitamin D receptors (VDRs), which are ubiquitously expressed on various cell types including human skeletal muscle and adipose tissue and serve a role in peripheral insulin sensitivity as they are responsible for glucose uptake in these cells in response to insulin secretion.<sup>[5,6]</sup> Hence, low vitamin D levels play important role in the development of diabetes.

Several studies have shown that the vitamin D level is inversely proportional to the level of FBS and HbA1c.<sup>[7,8]</sup> Type II diabetics have lower vitamin D levels than healthy people.<sup>[9]</sup> Also, there was a significant improvement in FBS and insulin after treatment with vitamin D, suggesting that vitamin D supplementation could reduce insulin resistance in them.<sup>[10,11]</sup>

Study findings differ across geographical regions and are inconsistent and the issue is still under debate. At present, very few research studies have addressed the correlation between vitamin D deficiency with glycemic control and insulin resistance in type II diabetes in India. Therefore, this study was conducted for the population of Kalaburagi having type II diabetes visiting tertiary care center with the main objective to find out prevalence of vitamin D deficiency in them and then to find out if there is any correlation between serum vitamin D levels with FBS, HbA1c, insulin and insulin resistance using homeostatic model assessment for insulin resistance (HOMA-IR) index.<sup>[12,13]</sup>

## MATERIALS AND METHODS

This study was a hospital based cross sectional observational study. A total of 85 participants having type II DM aged 35-75 years were recruited from OPD patients attending Non-Communicable Disease (NCD) clinic, and Department of General medicine in Gulbarga Institute of Medical Sciences, Kalaburagi. The study was done over a period of 6 months from February 2025 to August 2025. Institutional Ethics Committee permission was taken

before the conduct of the study. Written informed consent was obtained from all the subjects before their participation.

**Inclusion Criteria:** Individuals aged 35-75 years, inclusive of both genders, diagnosed with type II DM were recruited.

**Exclusion Criteria:** Patients with history of liver disease, kidney diseases, thyroid disorders, malignancy, type I DM, type II DM patients on insulin therapy, patients on vitamin D supplements, pregnant and lactating mothers, patients on steroid therapy, patients on addictive drugs were excluded.

Sample size was calculated by using formula  $n=4PQ/D^2$ , where n is sample size, P is prevalence, Q is (100-P), D is margin of error. According to previous study done by National Family Health Survey-5 (NFHS-5),<sup>[14]</sup> conducted in 2019-21, the prevalence rate of people residing in urban area with type II DM was 8.5. We had kept allowable margin of error as 6%. We calculated the sample size, which came out to be 85. Hence, we decided to include 85 participants in our study.

General information such as age, gender, occupation, literacy status, smoking status and socio-economic status were collected. Detailed clinical & biochemical examinations was performed for all patients. Body mass index (BMI) was calculated using standard methods and equipment.

1. Determination of fasting blood sugar and HbA1c was done by Automatic Biochemistry Analyzer.
2. Determination of 25-(OH) vitamin D and fasting insulin was done using commercially available ELISA kit. All kit measurements were according to instructions.

The level of  $\leq 20$  ng/mL was considered to be the level of vitamin D deficiency.<sup>[15]</sup> Normal fasting serum insulin levels range from 5 to 15 mIU/L (30-90 pmol/L). Insulin resistance was assessed by HOMA-IR index using the following formula.<sup>[12,13]</sup>

$$\frac{\text{Fasting Insulin } (\mu\text{IU/mL}) \times \text{Fasting Serum Glucose}(\text{mg/dL})}{405}$$

The data was compiled and analysed with the Jamovi 2.0, a statistical tool. The quantitative variables were expressed as mean and standard deviation and for describing the qualitative variables, number and percentage were applied. Pearson correlation and regression analysis was performed for correlation between variables. Independent Sample T test was used for comparison between subgroups for clinical parameters.  $P < 0.05$  was regarded as significant.

## RESULTS

**Table 1: Clinical characteristics of the study population**

Parameters	Total (n=85) Mean±SD	Males (n=43) 50.59% Mean±SD	Females (n=42) 49.41% Mean±SD	P value
Age (years)	52.1±10.2	54.5 ± 11.6	49.8 ± 8.03	0.043
BMI (kg/m <sup>2</sup> )	26.2±4.48	25.0 ± 3.57	27.04 ± 5.01	0.013*
FBS (mg/dL)	184±94.9	176 ± 89.1	192 ± 101	0.429
HbA1c (%)	9.74±2.21	9.60 ± 2.24	9.88 ± 2.21	0.559
Fasting Insulin ((μIU/mL))	7.25±8.18	7.54 ± 8.10	6.96 ± 8.34	0.748
HOMA-IR	3.49±4.47	3.21 ± 3.76	3.78 ± 5.13	0.566
25(OH)Vit D (ng/mL)	8.52±1.85	8.66 ± 1.95	8.39 ± 1.75	0.505

The mean age of total study population was 52.1±10.2 years and that of males and females were 54.5 ± 11.6 and 49.8 ± 8.03 respectively. Mean BMI was 26.2±4.48 in total study group showing obesity according to the Asian standards of BMI classification, which was comparatively higher in females (27.04±5.01) than males (25.0 ± 3.57). Mean FBS and HbA1c were higher than standard reference range in all categories. Mean total FBS was 184±94.9; and it was 176 ± 89.1 and 192 ± 101 in males and females respectively. HbA1c levels were higher in all groups. Mean total HbA1C was

9.74±2.21 and that in males and females were 9.60 ± 2.24 and 9.88 ± 2.21 respectively. Mean total fasting insulin was 7.25±8.18 with 7.54 ± 8.10 in males and 6.96 ± 8.34 in females, all within normal range. HOMA-IR value was found to be higher indicating insulin resistance with total mean 3.49±4.47 and that in males and females were 3.21 ± 3.76 and 3.78 ± 5.13 respectively. It was noted that 25(OH) vitamin D levels were significantly reduced compared to normal standard range. It was 8.52±1.85 in total study group; 8.66 ± 1.95 and 8.39 ± 1.75 in males and females respectively.

**Table 2: Frequency distribution of 25(OH) vitamin D along with clinical parameters**

Parameters	25(OH) Vit D 10 -20 ng/mL (n=17) 80% Mean±SD	25(OH) Vit D < 10 ng/mL (n=68) 20% Mean±SD	P value
Age	57.2 ± 12.2	50.8 ± 9.52	0.022
BMI	24.5 ± 3.97	26.6 ± 4.53	0.083
FBS	152 ± 60.3	192 ± 100	0.122
HbA1c	9.54 ± 1.82	9.79 ± 2.31	0.680
Fasting Insulin	7.18 ± 9.36	7.27 ± 7.93	0.965
HOMA-IR	3.28 ± 4.17	3.54 ± 4.57	0.828

Table 2 shows categorization of the participants, based on serum 25(OH) vitamin D levels as deficiency group with levels 10-20 ng/mL and severe deficiency group with levels <10 ng/mL. It was noted that majority of participants (80%) were having severe deficiency, whereas remaining 20% of participants were having deficiency. No participant had levels above >20ng/mL with minimum and

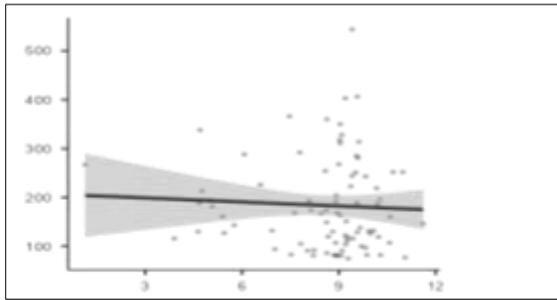
maximum observed levels being 1.14 ng/mL and 11.6 ng/mL respectively. All clinical parameters were analyzed once again in these two subgroups. It was noted that mean BMI, FBS, HbA1c, fasting insulin and HOMA-IR were higher in group with severe deficiency but was not statistically significant as per Independent Sample T Test.

**Table 3: Correlation between 25(OH) vitamin D with various diabetic parameters (n=85)**

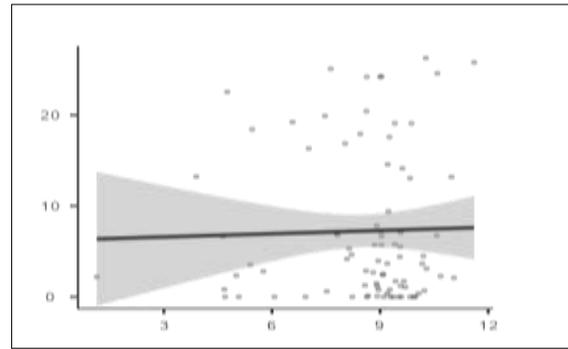
Correlation between	Pearson correlation value (r)
25(OH) Vitamin D and FBS	-0.054
25(OH) Vitamin D and HbA1c	-0.104
25(OH) Vitamin D and fasting insulin	0.027
25(OH) Vitamin D and HOMA-IR	0.027

We performed Pearson's correlation to investigate relation between 25(OH) vitamin D with various diabetic parameters. Table 3 represents correlation of 25(OH) vitamin D with FBS, HbA1c, fasting insulin and HOMA-IR. The 'r' value between 25(OH) vitamin D and FBS was - 0.054 suggesting a very weak negative/inverse linear relationship between two parameters. There was also an inverse correlation between 25(OH) vitamin D and HbA1c with 'r' value being -0.104. This indicates that lower the vitamin D level, higher will be FBS & HbA1c values and vice

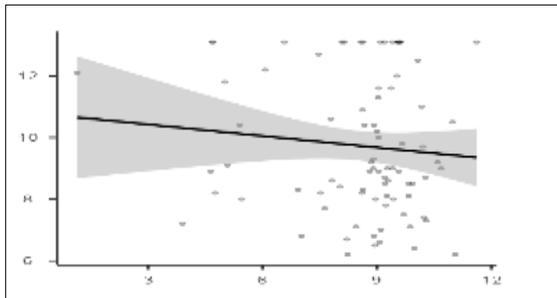
versa. However, when we analyzed vitamin D with fasting insulin and HOMA-IR, 'r' values were 0.027 suggesting very weak, essentially non-existent relationship between two variables.



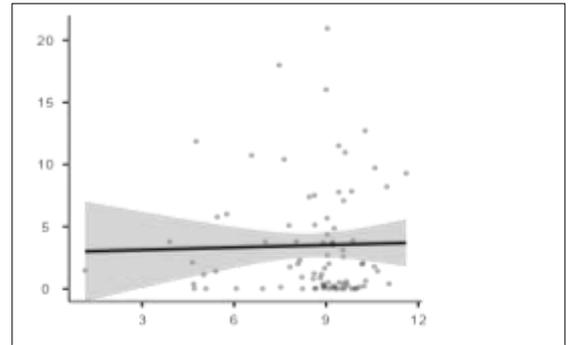
**Figure 1: Correlation between 25(OH) Vit D with FBS**



**Figure 3: Correlation between 25(OH) Vit D with insulin**



**Figure 2: Correlation between 25(OH) Vit D with HbA1c**



**Figure 4: Correlation between 25(OH) Vit D with HOMA-IR**

**Table 4: Frequency distribution of glycemic control along with clinical parameters**

Parameters	Well controlled diabetes HbA1c ≤ 7% (n=9) 10.59% Mean ± SD	Poorly controlled diabetes HbA1c > 7% (n=76) 89.41% Mean ± SD	P value
Age (Years)	54 ± 7.79	51.8 ± 10.6	0.555
BMI (kg/m <sup>2</sup> )	26.5 ± 4.64	26.1 ± 4.49	0.820
FBS (mg/dL)	99.0 ± 29.8	194 ± 95	0.004*
Insulin (μIU/mL)	3.42 ± 5.13	7.71 ± 8.37	0.138
HOMA-IR	0.836 ± 1.23	3.81 ± 4.61	0.059
25(OH)Vit D (ng/mL)	8.95 ± 1.13	8.47 ± 1.91	0.471

An attempt was made to further analyze the study population by regrouping them on the basis of HbA1c level. As per ADA guidelines the target in diabetic patients is to achieve an HbA1c of ≤ 7 % which is considered as well controlled. Table 4 shows categorization of participants as; well controlled diabetes group with HbA1c ≤ 7% and poorly controlled diabetes group with HbA1c > 7%. It was observed that majority of participants (89.41%, n=76) were having poorly controlled diabetes and

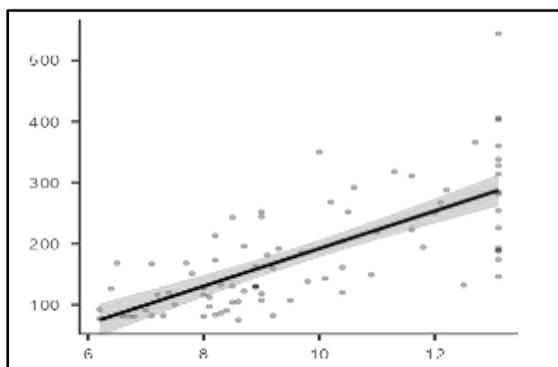
only 9 participants (10.59%) were having well controlled diabetes. Mean FBS was significantly higher in poorly controlled group with p value 0.004. Fasting insulin levels were higher in poorly controlled diabetes group but not statistically significant. It was also noted that HOMA-IR values were much higher in poorly controlled group in comparison with well controlled diabetes group. However, 25(OH) vitamin D levels did not show much difference between two groups.

**Table 5: Correlation between HbA1c with various clinical parameters (n=85)**

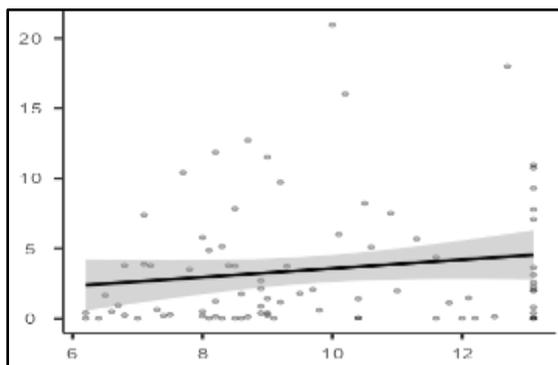
	Pearson correlation value (r)
HbA1c and FBS	0.719
HbA1c and 25(OH) Vitamin D	-0.104
HbA1c and fasting insulin	-0.064
HbA1c and HOMA-IR	0.155

Table 5 shows correlation between HbA1c with various clinical parameters. Correlation between HbA1c with FBS was strong positive with 'r' value being 0.719; whereas that with HOMA-IR was 0.155 showing weak positive relationship. However, 'r' value for Pearson correlation was -0.064 between

HbA1c and fasting insulin indicating no relationship between them.



**Figure 5: Correlation between HbA1c and FBS**



**Figure 6: Correlation between HbA1c and HOMA-IR**

## DISCUSSION

We observed low 25 (OH) vitamin D levels in all 85 type 2 DM patients showing 100% prevalence. It was noted that mean 25(OH) vitamin D level was  $8.52 \pm 1.85$  in total study group;  $8.66 \pm 1.95$  and  $8.39 \pm 1.75$  in males and females respectively, showing significant reduction compared to normal standard range. We observed that no participant had levels above  $>20\text{ng/mL}$ , with minimum and maximum recorded levels being  $1.14\text{ ng/mL}$  and  $11.6\text{ ng/mL}$  respectively. High prevalence of low vitamin D levels in type 2 DM patients has been reported by several studies.<sup>[15-19]</sup>

In the research conducted in Saudi Arabia by Al Ghadeer HA et al,<sup>[15]</sup> it was noted that majority of individuals who had type 2 DM had vitamin D levels below normal range, which demonstrated a similar pattern to the current study. Vijay G S et al,<sup>[16]</sup> conducted a cross-sectional study on 116 type 2 DM patients for vitamin D deficiency and found prevalence of 74.14%. In a study done in the southern part of India by Palazhy S et al,<sup>[17]</sup> among the diabetic population which included 4628 subjects, 71.4% were vitamin D deficient, 15% were vitamin D insufficient and 13.6% had normal vitamin D levels. Daga RA et al,<sup>[18]</sup> conducted a study in the northern states of India and found that vitamin D deficiency was 91.1% in subjects with diabetes. In another study conducted by Prasad BNR et al,<sup>[19]</sup> among the diabetic population residing in Karnataka, India, 78.2% prevalence has been reported. The variation in findings from other studies may be due to different

food habits, varying sun exposure due to geographical location may also contribute.

In our study, out 85 total study participants, 50.59% (n=43) were males and 49.41% (n=42) were females. There was no statistically significant difference noted in vitamin D levels according to gender of the participants in our study. Similar observation was reported by Palazhy S et al.<sup>[17]</sup> Gender and vitamin D levels have not been proven to be significantly correlated.

Mean BMI of total participants in our study was  $26.2 \pm 4.48$ . Hence, they belong to the obese category according to the Asian standards of BMI classification.<sup>[20]</sup> A strong link between vitamin D deficiency and obesity has been reported by other studies.<sup>[8,21]</sup>

On categorizing the participants based on serum 25(OH) vitamin D levels as deficiency group ( $10\text{-}20\text{ ng/mL}$ ) and severe deficiency group ( $<10\text{ ng/mL}$ ), it was noted that majority of participants (80%, n=68) were having severe deficiency, whereas remaining 20% (n=17) of participants were having deficiency. After analyzing all clinical parameters between these groups, it was noted that mean BMI, FBS, HbA1c, fasting insulin and HOMA-IR were higher in severe deficiency group, but were not statistically significant. Similar way of analysis by categorization has been reported by other studies.<sup>[22-23]</sup> Kostoglou-Athanassiou I et al,<sup>[22]</sup> analyzed percentage of subjects with vitamin D deficiency and insufficiency in the patient and control groups. In the group of type 2 DM patients, 17.5% as opposed to 5.8% in the control group had vitamin D deficiency; in the group of type 2 DM patients, 63.3% as opposed to 23.3% in the control group had vitamin D insufficiency in their study. However, we did not include control group in our study for such comparison. Zhao H et al,<sup>[23]</sup> divided type 2 DM patients into no vitamin D deficiency group [25(OH) D  $>20\text{ ng/mL}$ ] and vitamin D deficiency group [25(OH) D  $<20\text{ ng/mL}$ ] and observed that HbA1c levels in the vitamin D deficiency group were significantly higher.

Our study shows negative correlation between vitamin D with FBS and HbA1c levels but was not statistically significant. 'r' value between 25(OH) vitamin D and FBS was -0.054 and that between 25(OH) vitamin D and HbA1c was -0.104 indicating very weak negative linear relationship between two variables. Our observation is supported by other studies.<sup>[7,12,23]</sup> Ghavam S et al,<sup>[8]</sup> reported similar weak inverse linear relationship between vitamin D with FBS and HbA1C with 'r' value being -0.047 and -0.088 respectively. Raj V et al,<sup>[12]</sup> noted 'r' values of -0.097 and -0.175 between vitamin D with FBS and HbA1c levels respectively. Similar observation has been reported by Zhao H et al,<sup>[23]</sup> and Mehta N et al,<sup>[24]</sup> However, Abdo B et al<sup>[25]</sup> noted a statistically significant negative correlation between the vitamin D level and HbA1c (correlation coefficient r: -0.5452; 95% CI: -0.6109 to -0.4720,  $p < 0.0001$ ) implying a moderate linear relationship between two variables.

In our study HOMA-IR value was found to be higher with total mean  $3.49 \pm 4.47$  which suggests significant insulin resistance. HOMA-IR is widely used as the measure of insulin resistance and defined as an increase in insulin secretion necessary for the maintenance of glycemic homeostasis.<sup>[26]</sup> Various studies have been conducted in different countries to define insulin resistance and reported HOMA-IR cut-offs.<sup>[13,27,28]</sup> Masoodian SM et al,<sup>[13]</sup> reported mean value of  $2.11 \pm 0.99$  for HOMA-IR in the Iranian healthy population. Schrank Y et al,<sup>[27]</sup> suggested the Reference Intervals (RIs) of 0.39-2.86 for the HOMA-IR index for normal adults in Brazilian population. Lee CH et al,<sup>[28]</sup> reported HOMA-IR cut-offs of 1.4 and 2.0 to discriminate dysglycemia and type II DM respectively in Southern China.

When we analyzed correlation between vitamin D with fasting insulin and HOMA-IR we found very weak, essentially non-existent relationship with 'r' value being 0.027. This is in contrary with other studies.<sup>[26,29,30]</sup> Rafiq S et al,<sup>[26]</sup> Lu L,<sup>[29]</sup> et al and Bachali S et al<sup>30</sup> observed inverse associations of vitamin D with fasting insulin and HOMA-IR. Bachali S et al,<sup>[30]</sup> divided type 2 DM patients into group 1 with 25(OH) vitamin D  $\leq 20$  ng/mL and group 2 with 25(OH) vitamin D  $>20$  ng/mL and observed that, HOMA-IR was more in group 1 than in group 2 with p value of 0.037. However, in our study we divided participants into deficiency group (10-20 ng/mL) and severe deficiency group ( $<10$  ng/mL). Mean HOMA-IR was high in severe deficiency group but was not statistically significant (p value=0.828).

As per ADA guidelines, the target in diabetic patients is to achieve an HbA1c of  $\leq 7\%$  which is considered as well controlled.<sup>[31]</sup> Considering this, we further analyzed the study population by stratifying them on the basis of glycemic control as, a well-controlled diabetes group with HbA1c  $\leq 7\%$  and a poorly controlled diabetes group with HbA1c  $>7\%$ .<sup>[24,32]</sup>

It was observed that majority of participants (89.41%, n=76) were having poorly controlled diabetes and only 9 participants (10.59%) were having well controlled diabetes. Mean FBS was significantly higher in poorly controlled group (p value=0.004). Higher HOMA-IR and elevated fasting insulin levels in poorly controlled diabetic group are other notable observations.<sup>[25]</sup> (OH) vitamin D levels were lower in poorly controlled but not statistically significant. We also observed a strong positive linear relationship between HbA1c with FBS ( $r=0.719$ ) which is similar to other studies.<sup>[8]</sup> However, a weak positive correlation was noted between HbA1c with HOMA-IR ( $r=0.155$ ).

## CONCLUSION

In our study 100% prevalence of low vitamin D levels was noted in type 2 diabetic patient population in Kalaburagi with majority falling into severe deficiency category. Mean FBS, HbA1c and HOMA-

IR were higher than standard reference range. Mean total fasting insulin was within normal range. Negative correlation between vitamin D with FBS and HbA1c levels was observed. Therefore, lower the vitamin D levels higher will be the levels of FBS & HbA1c. Hence, vitamin D supplementation should be considered in patients with type 2 diabetes for better glycemic control. Vitamin D fortified diabetic diets may be of additional help. With the high prevalence of vitamin D deficiency in patients with diabetes and putative mechanisms linking vitamin D deficiency to diabetic complications, there is a compelling argument for undertaking large well-designed randomized controlled trials of vitamin D supplementation.

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