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## The effect of vitamin D supplementation on glycaemic control in vitamin D deficient children with Type 1 Diabetes Mellitus at Pediatrics Department, Tanta University Hospital

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### Abstract

**Objectives:** The objective of this study is to assess the prevalence of vitamin D insufficiency in children with type 1 diabetes mellitus (T1DM) who are receiving care at the Endocrinology outpatient clinic at the Pediatrics Department of Tanta University Hospital. Additionally, the study aims to investigate the impact of vit D supplementation on the progression of T1DM.

**Methods:** The study was conducted as a prospective randomized and cross-sectional controlled trial at the "Endocrinology Outpatient Clinic" inside the Pediatrics Department of Tanta University Hospital. The research sample was composed of one hundred fifty-two children diagnosed with T1DM. The research methodology used many tools, which encompassed: Medical records are used to collect sociodemographic data. (2) Data associated with the relationship between food consumption and solar radiation exposure. (3). this research focuses on the variables associated with its insufficiency and the levels of vit D investigation. The participants in the research were children who had low vit D levels. These children were then categorized into two separate groups. The intervention group consisted of children who received standard care along with vit D supplementation. The control group consisted of youngsters who received just regular treatment. A further assessment was conducted after six months periods, whereby the previously mentioned examinations were performed for the children in both groups.

**Results:** Low vit. D levels were found in 78.3% of the studied children. Approximately 29.0% of them had insufficient vit. D level. Mild and moderate vit. D deficiency (VDD) were found among 25.7% and 23.7% of the studied children respectively. After receiving both vit. D and calcium (Ca) supplementations, Levels of vit. D, blood pH, Ca and Magnesium (Mg) increased, while levels of HbA1C, parathyroid hormone (PTH) and alkaline phosphatase (ALP) decreased.

**Conclusion:** Majority of children with T1DM have low vit. D levels. Bad dietary habits and lifestyles were more observed among children with low vit. D levels. Vit. D and Ca supplementations for at least six months added to the routine insulin dose proved their effectiveness in glycaemic control with increased levels of ionized Ca, blood pH and Mg level and decreased levels of PTH and ALP.

**Keywords:** Vitamin D, T1DM, Vit. D supplementations, vitamin D deficiency, glycaemia, dietary habits, Tanta

### Introduction

Vitamin D is a fat-soluble vitamin obtained from exposure to sun, eating certain foods and supplements. Vit. D is biologically inert and must undergo two hydroxylation in the body for activation. The first hydroxylation, which occurs in the liver, converts vit. D to 25-hydroxyvit D [25(OH) D], also known as "calcidiol." The second hydroxylation occurs primarily in the kidney and forms the physiologically active 1, 25-dihydroxyvit D [1,25(OH)2D], also known as "calcitriol" [1].

Vit. D has many functions in the human body. It promotes Ca absorption in the gut and maintains adequate serum Ca and phosphate concentrations to enable normal bone mineralization and prevent hypocalcemic tetany. It is also need for bone growth and bone remodeling by osteoblasts and osteoclasts. Other roles of vit. D includes reduction of inflammation, this also important for glucose metabolism as it promote synthesis and secretion of insulin and increase insulin sensitivity [2].

Vit. D deficiency (VDD) has been linked to many health problems including rickets, several types of cancer and metabolic syndromes as type 1 and type 2 diabetes mellitus [3]. Rickets is common among children with VDD, which is a disease characterized by a failure of bone tissue to become properly mineralized, resulting in soft bones and skeletal deformities. In addition to bone deformities and pain, severe rickets can cause failure to thrive, developmental delay, hypocalcemic seizures, tetanic spasms, cardiomyopathy, and dental abnormalities [4].

There is evidence that vit. D is closely related to the occurrence of autoimmune diseases. Vit. D can inhibit inflammation and immune reaction. Its deficiency has a potential influence on Type 1 Diabetes Mellitus (T1DM) incidence, complications and progression [5].

Many studies assess the prevalence of among Egyptian children and adolescents with T1DM. Hafez *et al.* found that 70% of them had VDD, 24% had vit. D insufficiency and only 6% were vit. D sufficient [6]. This high prevalence of VDD in patients with T1DM was previously reported in Cairo University; Hassan *et al.* concluded that 91.67% were vit. D deficient [7]. Similarly, in Menia and Zagazig, studies revealed that the prevalence of VDD was 84.9% and 75%, respectively [8,9].

From previous studies, VDD was estimated to be highly prevalent in Egypt and this deficiency is associated with many diseases. To make the picture clearer for the practicing physicians, and assure better prognosis of the course of the disease, assessment of vit. D levels among children with T1DM can guide early detection of VDD, hence managing it by adding vit. D supplementation as a part of the routine protocol of managing T1DM among children. Hopefully, vit. D supplementation will lead to better glycaemic control and avoidance of the known complications of diabetes mellitus in children.

## Materials and Methods

**Characteristics of research:** A non-blinded randomized controlled trial (RCT) and cross-sectional was conducted at the "Endocrinology Outpatient Clinic" inside the Pediatrics department. The research cohort composed of children who were diagnosed with T1DM who attended the "Endocrinology Outpatient Clinic" during the first phase of the trial, extending from November 2020 to August 2021. During the registration period, one hundred fifty-two children were registered in the research. A comprehensive assessment was conducted on all the children who were registered in the research in order to determine their blood levels of vit D, namely blood 25-hydroxyvit D (25(OH)D).

**Inclusion criteria of research:** The research included all children diagnosed with T1DM who had a diabetes duration exceeding one year. The inclusion of individuals with a history of T1DM) exceeding one year was implemented to prevent the enrollment of cases during the "honeymoon period." This phase typically starts around three months after the start of insulin therapy and is characterized by significant improvement in patients' condition.

**Exclusion criteria of research:** Children who suffer by malabsorption syndrome, as well as those with Ca disorders or other chronic systemic diseases. Participants who have previously used vit D or any medicines that are known to affect vit D metabolism during the three months before to the trial start, such as antibiotics, antiseizure medications, anticancer treatments, anti-inflammatory pharmaceuticals antifungal agents, antiretroviral drugs and herbal

supplement. Children are diagnosed with other autoimmune disorders or celiac disease.

## Tools of research

### A. Medical Records

Records from the Endocrinology outpatient clinic were accessed to get the following information: -

Sociodemographic details such as (name, age, gender, address)

### B. Questionnaire

#### Information like

- Parents' education level and employment were included.
- Modern anthropometrics (including weight, height, and Body Mass Index "BMI").

Underweight is defined as having a BMI less than the fifth percentile, normal weight is defined as having a BMI between the fifth and the eighty-fifth percentile, overweight is defined as having a BMI between the eighty-fifth and the ninety-fifth percentile, and obesity is defined as having a BMI greater than or equal to the ninety-fifth percentile. Information about vit D-rich foods to consume and sun exposure [Adapted from Amiri and colleagues, 2017] [11].

### C. Investigations

#### All the youngsters who participated in the research were given the following examinations

1. Level of glycated hemoglobin (HbA1c).
2. Serum 25-hydroxyvit D [25(OH) D] by Elisa kits.
3. The blood (potential of hydrogen) PH.
4. Mg, Ionized calcium, ALP and PTH blood level.

### D. vitamin D supplementation intervention

A simple random sample of children (n=one hundred and nineteen) with low vit D levels (30 ng/ml) was categorized into two groups with similar demographic characteristics:

Children in the intervention group (n=fifty and nine) also got vit D supplementation in addition to insulin dosing (as per clinic practice) and standard treatment. Children's vit D needs were determined by factoring in their weight and ages [12].

Standard group (n=sixty): children take routine insulin dose only and routine care.

Six months following enrollment, all children were monitored to see how they were doing in either group.

Each child in both groups got a Ca supplement tailored to his or her individual requirements throughout the research [12].

### E. Six months of monitoring following study registration

Regular interest, care and checkups, were offered for the following six months. The same screenings were given to both groups of children at the end of the six-month period.

### Sample Size and Statistical Analysis

The study comprised children who were diagnosed with T1DM within the trial first few months, namely from November 2020 to August 2021. These children were observed at the "Endocrinology Outpatient Clinic." One hundred and fifty two children were born consequently. The findings were recorded using Microsoft Excel. The data were recorded and gathered in a Microsoft Excel spreadsheet. The statistical analysis was conducted using the SPSS Package 25 for Microsoft Windows. The Shapiro-Wilk test was conducted to assess the quantitative data

normality. The nonparametric quantitative data were reported using measures such as the Interquartile Range (IQR) and median, whereas the qualitative data were given in terms of the percentage and number. The Mann Whitney U test was used to compare two independent groups in terms of nonparametric quantitative variables. The Wilcoxon signed ranks test was conducted to examine the differences between two dependent groups of nonparametric quantitative variables, specifically the pre and post intervention measurements. The research of qualitative variables involved the Chi-square test utilization. In instances where the Chi-square test was considered unsuitable, it was substituted by the Monte Carlo exact test. A P value more than 0.05 was deemed not statistically important, whilst a P value less than 0.05 was thought to be statistically important. Furthermore, a P value less than 0.001 was regarded as very important.

**Results**

**Table One:** Illustrates that a proportion of 21.7% of the children under study had normal levels of vit D. A significant proportion of the children included in the study (78.3%) exhibited low levels of vit D. Among these children, 28.9% had inadequate levels of vit D, while 49.9% had a deficiency in vit D. A prevalence of 25.7% and 23.7% was observed for mild and moderate vit D insufficiency, respectively, among the children included in the investigation.

**Table Two:** Illustrates that the median age was about same in both the low and normal vit D deficient groups, with no statistically important distinction observed between the two groups. In relation to sexual characteristics, it was observed that a deficiency in vit D was present in 78.5% of men and 78.0% of females. However, no statistically important correlation existed between these two groups. In relation to residence location, it was observed that a important proportion of individuals residing in regions of rural (66.3%) and areas of urban (89.2%) exhibited inadequate vit D levels. In relation to the educational background of parents, it was observed that all children (hundred %) whose parents had attained a university education exhibited low of vit D levels. In relation to the parent’s occupation, an important proportion of children whose parents were

engaged in had their own businesses or professional occupations exhibited low vit D levels. A statistically significant relationship was observed between vit D level residence and parents' criterion ( $p < 0.001$ ).

**Table Three:** The data indicates that children with levels of low vitD had higher median values for weight, BMI and height. Specifically, the median weight was fourty and nine and half kg (with a range of 41.0 - 56.7 kg), the median height was 1.54 m (with a range of 1.46 - 1.6 m), and the median BMI was 20.1 (with a range of 17.8 - 23.7). The obesity and overweight prevalence was higher in children with low vit D levels (93.9% and 100% respectively), and there was a statistically significant relationship observed between BMI, weight, BMI categories and vit D status ( $p < 0.001$ ).

**Table Four** the research demonstrates that children with vit D deficiency had higher median height, BMI and weight compared to those who seldom consumed fortified milk, had limited direct sun exposure and fish. A statistically important correlation was observed between dietary behaviors, sun exposure practices and vitamin D level ( $p < 0.001$ ).

**Table Five:** The findings demonstrate that there was no statistically important variance observed between the two groups in baseline investigations terms. Following a intervention six months period, it was observed that the levels of, vit D, blood pH and mg and Ca were considerably higher in the group that received both Ca supplements and vit D ( $p < 0.001$ ). The group that received both Ca supplements and vit D had substantially lower PTH and HbA1c levels compared to the other group ( $p < 0.001$ ). The group that received both Ca supplements and vit D exhibited a lower ALP level. In the intervention group: Median vit. D level, ionized Ca and Mg, blood pH level increased after six months of treatment with statistically important significant between pre and post intervention ( $p < 0.001$ ). Levels of HbA1c, ALP and PTH declined after six months of treatment ( $p < 0.001$ ).

In control group: Slightly change in all investigations after 6 months.

**Table 1:** The studied children Vit D status (n = one hundred and fifty two)

Vit. D status	No.	%
Normal vit. D level ( $\geq 30$ ng/ml)	Thirty three	21.7%
Deficient vit. D level	Hundred and nineteen	78.3%
• Insufficiency (20-29 ng/ml)	Forty and four	28.9%
• Mild deficiency (10- <20 ng/ml)	Thirty and nine	25.7%
• Moderate deficiency (5- <10 ng/ml)	Thirty and six	23.7%
Total	One hundred and fifty two	100.0%

**Table 2:** Distribution of the studied children according to their sociodemographic features

Sociodemographic characteristics	Normal (n=Thirty three)	Low vit. D level (n= 119)	Test of sig.	p
<b>Age</b>				
Median (IQR)	10.75 (9.0 – 12.9)	10.75 (8.0 – 12.5)	U 1738.5	0.314
<b>Gender</b>				
Male (n = 93)	20 (21.5%)	73 (78.5%)	$\chi^2$ 0.006	0.939
Female (n = 59)	13 (22.0)	46 (78.0%)		
<b>Residence</b>				
Rural (n = 95)	32 (33.7%)	63 (66.3%)	$\chi^2$ 21.369	<0.001*
Urban (n = 57)	1 (1.8%)	56 (98.2%)		
<b>Father education</b>				
Illiterate (n = 30)	30 (100.0%)	0 (0.0%)	$\chi^2$ 135.893	<0.001*
Primary (n = 16)	2 (12.5%)	14 (87.5%)		

Secondary (n = 81)	1 (1.2%)	80 (98.8%)	$\chi^2$ 120.563	<0.001*
University (n = 25)	0 (0.0%)	25 (100.0%)		
<b>Mother education</b>				
Illiterate (n = 27)	27 (100.0%)	0 (0.0%)		
Primary (n = 38)	5 (13.2%)	33 (86.8%)		
Secondary (n = 71)	1 (1.4%)	70 (98.6%)	$\chi^2$ 49.233	<0.001*
University (n = 16)	0 (0.0%)	16 (100.0%)		
<b>Father occupation</b>				
Unemployed or Manual worker (n = 66)	32 (48.5%)	34 (51.5%)		
Governmental employee or Professional (n = 57)	1 (1.8%)	56 (98.2%)		
Private work (n = 29)	0 (0.0%)	29 (100.0%)	$\chi^2$ 31.492	<0.001*
<b>Mother occupation</b>				
Unemployed or Manual worker (n = 87)	33 (37.9%)	54 (62.1%)		
Governmental employee or Professional (n = 55)	0 (0.0%)	55 (100.0%)		
Private work (n = 10)	0 (0.0%)	10 (100.0%)		

IQR: Interquartile range, U: Mann Whitney U test,  $\chi^2$ : Chi square test, \*p≤ 0.05 (Statistically significant)

**Table 3:** Vitamin D status of the studied children according to their nutritional status and anthropometric measures.

Anthropometric measures	Normal (n=thirty three)	Low vit. D level (n=one hundred and nineteen)	Test of sig.	p
<b>Weight (Kg)</b>			U	<0.001*
Median (IQR)	40.2 (34.65 - 44.7)	49.5 (41.0 - 56.7)	1138.0	
<b>Height (m)</b>			U	0.392
Median (IQR)	1.52 (1.49 - 1.53)	1.54 (1.46 - 1.6)	1772.0	
<b>BMI</b>			U	<0.001*
Median (IQR)	17.9 (16.4 - 19.6)	20.1 (17.8 - 23.7)	1102.0	
<b>BMI categories</b>			MC	<0.001*
Underweight (n = 7)	7 (100.0%)	0 (0.0%)		
Normal weight (n = 95)	24 (25.3%)	71 (74.7%)		
Overweight (n = 33)	2 (6.1%)	31 (93.9%)		
Obese (n = 17)	0 (0.0%)	17 (100.0%)		

IQR: Interquartile range, U: Mann Whitney U test MC: Monte Carlo Exact test \*p≤ 0.05 (Statistically significant)

**Table 4:** Relation between its level in bodies of the studied children and dietary consumption of vitamin D

	Normal (n=thirty)	Low vit. D level (n=one hundred nineteen)	Test of sig.	p
<b>Consumption of milk fortified with vit. D</b>			$\chi^2$ 54.249	<0.001*
Rarely (n=39)	0 (0.0%)	39 (100.0%)		
Sometimes (n=67)	6 (9.0%)	61 (91.0%)		
Usually (n=46)	27 (58.7%)	19 (41.3%)		
<b>Consumption of food rich in vit. D at least twice a week</b>			$\chi^2$ 23.145	<0.001*
Rarely (n=73)	6 (8.2%)	67 (91.8%)		
Sometimes (n=55)	14 (25.5%)	41 (74.5%)		
Usually (n=24)	13 (54.2%)	11 (45.8%)		
<b>Direct sun exposure (at least 10 minutes/day)</b>			$\chi^2$ 37.938	<0.001*
Rarely (n=35)	0 (0.0%)	35 (100.0%)		
Sometimes (n=50)	3 (6.0%)	47 (94.0%)		
Usually (n=67)	30 (44.8%)	37 (55.2%)		

$\chi^2$ : Chi square test, \*p ≤ 0.05 (Statistically significant)

**Table 5:** Baseline and after 6 months of intervention values of some laboratory investigations in the control and intervention groups (n=119)

	Intervention group (Receive Ca & vit. D) (n=fifty nine)		Control group (Receive Ca only) (n=sixty)		Up	
	Baseline	After six months	Baseline	After six months	Baseline	After six months
<b>25 (OH) vit. D (ng/ml)</b>						
Median (IQR)	13.3 (8.8-22.3)	40.0 (32.6-45.9)	16.1 (9.0-23.0)	16.0 (9.0-23.1)	1626.5	8.0
z (p)	6.736 (<0.001*)		1.127 (0.260)		0.445	<0.001*
<b>HbA1c</b>						
Median (IQR)	8.8 (8.3-9.7)	8.5 (8.0-9.4)	9.5 (8.5-9.5)	9.4 (8.5-9.6)	1514.5	1124.0
z (p)	6.800 (<0.001*)		0.535 (0.592)		0.170	<0.001*
<b>pH</b>						
Median (IQR)	7.32 (7.3-7.35)	7.37 (7.35-7.39)	7.32 (7.29-7.35)	7.3 (7.3-7.35)	1764.0	673.0
z (p)	6.494 (<0.001*)		1.107 (0.268)		0.974	<0.001*
<b>Ionized Ca (millimol/L)</b>						
Median (IQR)	1.2 (1.03-1.3)	1.28 (1.23-1.36)	1.2 (1.05-1.3)	1.23 (1.1-1.3)	1738.0	1099.0
z (p)	6.742 (<0.001*)		1.667 (0.096)		0.864	<0.001*
<b>Mg (mg/dl)</b>						
Median (IQR)	1.4 (1.2-1.6)	1.9 (1.73-2.11)	1.4 (1.2-1.6)	1.4 (1.1-1.6)	1690.5	354.5
z (p)	6.738 (<0.001*)		0.885 (0.376)		0.670	<0.001*
<b>PTH (pg/ml)</b>						
Median (IQR)	77.0 (50.0-82.0)	51.0 (45.3-54.0)	66.0 (50.0-80.0)	65.0 (50.0-80.0)	1673.5	849.5



z (p)	6.741 (<0.001*)		1.633 (0.102)		0.608	<0.001*
<b>ALP (IU/L)</b>						
Median (IQR)	290.0 (220.0-370.0)	283.5 (216.5-364.3)	310.0 (235.0-390.0)	308.0 (233.0-387.0)	1559.5	1469.0
z (p)	6.693 (<0.001*)		0.577 (0.564)		0.263	0.110

z: Wilcoxon signed ranks (z) test U:Mann Whitney U test \* $p \leq 0.05$  (Statistically significant)

## Discussion

The potential impact of Vit D on the autoimmune pathology of T1DM is attributed to its immune-modulatory properties and anti-inflammatory. The current investigation comprised a cohort of one hundred and fifty two children diagnosed with T1DM. The findings of this research revealed that a significant proportion of the examined children exhibited a deficiency in vit D, with 78.3% of the participants falling into this category. Ragab and colleagues (2021) [13] showed a greater T1DM incidence among youngsters in Egypt compared to the prevalence observed in the present investigation. The research comprised a sample of sixty individuals diagnosed with T1DM, ranging in age from six to fourteen years old. These patients were selected from the Adolescents and Pediatric Diabetes Clinic at Children's Hospital, University of Ain Shams. The research revealed that out of the whole sample size, twenty-four patients (53.3%) exhibited a deficit in vitD, while sixteen patients (35.6%) shown insufficient vitD levels. Conversely, only five patients (11.11%) exhibited vit D blood levels that were considered sufficient. The notable vitD insufficiency occurrence in Egypt, despite the abundance of favorable weather and sunlight conditions throughout most of the year, may be ascribed to many variables. These factors encompass insufficient exposure to sunlight and the timing of the research, which took place during the fall and winter seasons characterized by the lowest ultraviolet index (UVI) values. Another potential factor to consider is that individuals with pigmented skin may exhibit lower sensitivity compared to those with lighter skin in relation to the vit D manufacturing process [13]. In a research done in Egypt in 2017, Mona Hafez *et al.* found that a important proportion of patients had vit D deficiency (seventy %) and insufficiency (twenty and four %). The objective of this research was to assess the vit D incidence insufficiency among a cohort of Egyptian adolescents and children diagnosed with (T1DM) (n = fifty). Additionally, the research intended to investigate the impact of vit D supplementation on their glycemic control [6]. In a research conducted by Sharma *et al.* (2017) in South India, a RCT revealed that 63.5% of children diagnosed with T1DM were found to have a deficiency in vit D. This deficiency was determined by measuring levels of blood 25-hydroxy vit D, with a threshold of less than twenty ng/mL. The research included fifty-two children, of which thirty three were identified as vit D deficient. This finding was reported in reference fourteen of the research. Nevertheless, the research conducted by Hassan *et al.* (2016) in Egypt revealed much lower prevalence of vitD rates insufficiency compared to the findings presented in the current research. Their study enrolled 60 children and adolescents with T1DM. They assessed their Vit. D levels and concluded that 91.67% were Vit. D deficient [7]. The prevalence rates reported in the research conducted in Menia and Zagazig by Soliman *et al.* (2015) and Abd-Allah *et al.* (2014) were found to be 84.9% and seventy five%, respectively [8]. The notable vitD insufficiency occurrence in Egypt, despite the favorable weather conditions and sunlight abundance during the year majority, may be readily ascribed to cultural factors that limit skin exposure. In a research conducted by Mohammadian *et al.* (2015) in Iran, a greater vitD insufficiency incidence was demonstrated compared to the

findings presented in the current research. The study conducted in Iran revealed that out of the total cases examined, three instances (5.66%) exhibited sufficient vit D levels, however the majority of cases, fifty (94.3%), were found to be deficient in vitD. Specifically, forty seven cases were classified as vit D deficient, while three cases were categorized as vit D insufficient. All of the individuals in this research were under the age of seventeen. The elevated frequency of this condition can be attributed to the prevailing wet climate in Iran, which results in restricted opportunities for sun exposure over the majority of the year. [15].

The present investigation revealed a notable disparity in levels of vit D between children residing in urban regions, who exhibited a much higher prevalence of vit D insufficiency, and those with normal vitD levels. The observed phenomenon might potentially be linked to limited exposure to sunlight and less engagement in outdoor activities. In the case of older male children, it may be associated with prolonged duration of diabetes mellitus and insufficient dietary intake of vit D, which can impact levels of vit D. In a research done by Akkermans *et al.* (2016) in Germany, the Netherlands, and the United Kingdom from 2012 to 2014, it was shown that there was a notable disparity in vit D insufficiency across genders, with males exhibiting a higher prevalence [15]. The current investigation findings exhibited similarity to the outcomes obtained in the research done by Ragab *et al.* (2021) [13] within the geographical context of Egypt. The study conducted by Ragab composed of a sample size of sixty individuals diagnosed with TDM1, ranging in age from six to fourteen years. The research findings indicated that there were no statistically important variations in levels of vit D between females and men as well as between and older children (above twelve years) and younger children (below twelve years) [13]. Furthermore, a research conducted by Hafez *et al.* (2017) in Egypt revealed that a significant proportion of females (91.3%) had vit D insufficiency, but only 51.9% of men were found to have this deficiency. This finding contrasts with the findings obtained in the current research [13]. In contrast, a research conducted by Janner *et al.* (2010) in Switzerland examined a cohort of one hundred twenty nine adolescents and children diagnosed with (T1DM). The findings of this study indicated that there were no statistically important variations in the patients' features among various groups based on their vit D status [16]. In the present research, a higher prevalence of obesity and overweight was demonstrated among children exhibiting low vit D levels. The findings of the current research are consistent with those of Shih *et al.* (2016), which demonstrated that the group with vit D deficiency had a higher proportion of obese and overweight persons (40%) compared to the group with appropriate levels of vit D (13.2%) [17]. among our research, we observed a higher prevalence of vit D deficiency among children who seldom consumed fish, fortified milky and had little exposure of direct sun exposure. In a similar vein, Bener *et al.* (2009) shown that both diabetes and non-diabetic toddlers had a notably restricted level of solar exposure [18]. Following a period of six months of intervention, it was discovered that the group taking both Ca supplements and vit D had considerably higher levels of blood pH, mg, vit D and

calcium. The group receiving both Ca supplements and vitamin D and had lower levels of HbA1c, ALP and PTH compared to the other group. In line with previous research conducted by Sharma *et al.* (2017), the findings of the present study indicate that a six-month supplementation of vit D resulted in a notable increase in serum levels of vit D, reaching a sufficient range within the intervention group. Furthermore, a significant disparity was observed between the control groups and intervention in terms of both HbA1c levels and vitD<sup>[14]</sup>. Furthermore, the research conducted by Madar *et al.* (2014) demonstrated a significant elevation in 25-hydroxyvitD<sup>[25]</sup> (OH) D levels following the intervention, whereas the placebo group saw no alterations<sup>[19]</sup>. In the current research, the intervention group exhibited a statistically important increase in median vit D levels, ionized calcium, blood pH and mg levels following a six-month treatment period, as compared to the pre-intervention measurements. After a of six months period of therapy, there was a decline observed in fasting blood glucose, two-hour postprandial blood glucose, HbA1c, ALP and PTH levels. The findings of the present research were consistent with those of Mohammadian *et al.* (2015), who reported a significant shift in vit D status from 93.2% deficient and 6.8% insufficient prior to intervention, to 34.1% deficient, 47.7% insufficient, and 18.2% sufficient following intervention<sup>[15]</sup> group<sup>[19]</sup>.

### Conclusion

Majority of children with T1DM have low vit. D levels. Bad dietary habits and lifestyles were more observed among children with low vit. D levels. Vit. D and Ca supplementations for at least six months added to the routine insulin dose proved their effectiveness in glycemic control with increased levels of ionized Ca, blood pH and Mg level and decreased levels of PTH and ALP.

### Declaration

**Ethical Standards Disclosure:** This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving research study participants were approved by the [ethics committee of Tanta university], (approval number 33745/3/20). Formal consent was obtained from all subjects/patients.

**Consent for publication:** "None." As my manuscript does not contains any individual person's data in any form.

**Data availability:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Conflict of Interest:** None.

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**Authorship:** [Aya Mohamed Rabie: Conceptualization, methodology, data analysis and writing the original draft.

**Shymaa Mohamad Elrifay:** Reviewed the findings and the original draft.

**Asmaa Abdel-Reheem Atalla:** revision of the final manuscript for submission.

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