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Research Article

**A RANDOMIZED CONTROL TRIAL TO DETERMINE THE  
ORALLY TAKEN VITAMIN-D GLYCATED HEMOGLOBIN  
AMONG PATIENTS OF T2DM**<sup>1</sup>Dr Aqsa Shaheen, <sup>2</sup>Dr Fatima Khawer, <sup>2</sup>Dr Sana Ijaz<sup>1</sup>Basic Health Unit Dharabi, Chakwal, <sup>2</sup>Tehsil Headquarter Hospital Sambrial, Sialkot.

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**Abstract:**

**Objective:** The main objective of the study was to determine the glycemic check of patients with type 2 diabetes by lessening glycated haemoglobin. It can be achieved by determining the efficiency of oral vitamin D.

**Methods:** The experimental study was carried out on an arbitrary basis at Sir Ganga Ram Hospital, Lahore from March 2017 to September 2018. It included patients suffering from type 2 diabetes mellitus. The average age of the patients included in the study ranges from 40 to 70. They were irregularly classified into two groups. Only metformin was given to patients included in group b. While the patients of group A were given the metformin as well as vitamin D. After three months the blood specimens of both groups were collected and analyzed to identify the variations during this period. For the measurement of data SPSS was used.

**Results:** Total of 140 persons were added in the study. These were classified into two groups on a random basis with 70 cases in every group. The average age of group-A patients were (54.40 ± 8.55). On the other hand, the average age for group-B was (58.40 ± 7.98). At the start of the study, no notable variation was identified levels of glycated haemoglobin. However, when this level was observed after 3 months of cure, a notable variation was examined.

**Conclusion:** The level of glycated haemoglobin in patients of diabetes can be reduced notably by the addition of vitamin D.

**Keywords:** Vitamin D, HbA1c, Diabetes Mellitus, Type 2 and Supplementation.

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**INTRODUCTION:**

Sunlight is necessary for the formation of vitamin D in the body. If our skin is masked to direct sunlight, we face the insufficiency of vitamin D [1]. Its main function is to play an essential role in muscles and bones. It also plays many other important functions [2, 3]. Out of the total individuals present in the whole world, 50% are suffering from an insufficiency of vitamin D [4]. These patients need to gain vitamin D to contest this shortage. There are various processes through which its deficiency can be minimized. There are many factors which affect the way to which vitamin D has been given to the patients. The fixed dosage of vitamin D cannot be suggested. Its supply varies with the conditions and time [6]. In addition to its role in muscles and bones, it is found that it also exerts many effects on tissues at various levels. Due to the identification of its function in this regard, it achieved more significance in the medical field [7]. It also exerts an important effect on the control of glucose homeostasis in diabetic patients. Its deficiency in blood also causes diabetes mellitus. Because its insufficiency resists the insulin and glucose level is increased in this way causing diabetes mellitus [8].

The release of insulin by body cells is affected by the level of vitamin D in the body [9]. A linkage was observed between hypovitaminosis D and IR by the investigators of the entire world. In patients of diabetes mellitus, a negative association was observed between haemoglobin and vitamin D level [10]. In vitamin D insufficient individuals when vitamin D is given to the patient from the outer environment it causes a decrease in fasting blood sugar and HBA1C levels in patients suffering from diabetes mellitus [11]. It was shown by another experiment which was conducted after 12 weeks that the supply of vitamin D to the diabetic patient maintains the HbA1c to about  $6.76 \pm 0.18\%$  in contrast with the level of metformin which was  $7.73 \pm 0.23\%$  [12]. However, another experiment declared that no variation was observed either vitamin D was given or not. If the only vitamin D was given to the patient its average HbA1c was maintained at 7.85. However, when the metformin was given to the patient its value was noticed too about 6.95 [13]. The insufficiency of vitamin D was noticed to be greatly present in diabetic patients. However, when vitamin D was achieved from an external source it maintains the glucose level in patients. Many studies were organized which exhibit different results. It was shown by literature that supplementation of vitamin D reduces the HbA1c level and controls the euglycemic position. To identify the confusing functions of vitamin D in diabetics the following

study was organized.

**PATIENTS AND METHODS:**

The experimental study was carried out on an arbitrary basis at Sir Ganga Ram Hospital, Lahore from March 2017 to September 2018. The patients with diabetes were selected for the analysis. The size of the specimen was measured with 95% self-assurance level, 80% will of inspection and taking the enormity of HbA1c as  $7.8 \pm 1.3\%$  with vitamin D and  $8.5 \pm 1.6\%$  with metformin diabetics. Only the patients suffering from diabetes mellitus and having the age limit between 40-70 years were added in the study. These patients were attaining only metformin and the range of HbA1c was about 7.5 to 9.0. Some patients were not included in the study those having lack of contribution, calcium level in blood  $>10.5$  mg/dl, medical proximal myopathy, ingestion of vitamin D, gaining omega 3 for about previous 3 months, effect on metabolism of vitamin D by some antibiotics, renal, hepatic and endocrinological diseases, sarcoma and use of insulin. Commencement of hypocalcaemia, hypersensitivity to cholecalciferol, the commencement of urolithiasis or any variation in hypoglycemic agents affects the removal criteria for impulsive execution.

The demographic knowledge, body mass index, time required for DM of the patients were assessed after getting permission from the patients or their close relatives. The permission from the King Edward Medical University, Lahore was also obtained to do all this. First of all, the blood of every patient was gained and HbA1c level was determined. After that patient was classified into two groups on random selection. Both vitamin D and metformin were given to the cases of group A. While only metformin was given to group B. Group A cases were asked for oral cholecalciferol 50,000 IU/week for about 3 months. After that patient was advised to visit the hospital regularly to give the HbA1c level by examining the blood samples. For the assessment of data SPSS was used. Age, BMI, time requirement of T2DM and HbA1c levels were shown as averages with standard deviation. Sexual status was analyzed by regularity and percentages. Autonomous sample examination was used to match the levels of HbA1c among patients. Consequence modifiers, such as age, masculinity, BMI and time requirement of DM were maintained by stratification. By putting the  $p \leq 0.05$  as important value sovereign specimen was practical.

**RESULTS:**

Total of 140 patients was included in the study. These were classified into two equal groups of 40 patients. The average age of patients in group A was  $54.80 \pm$

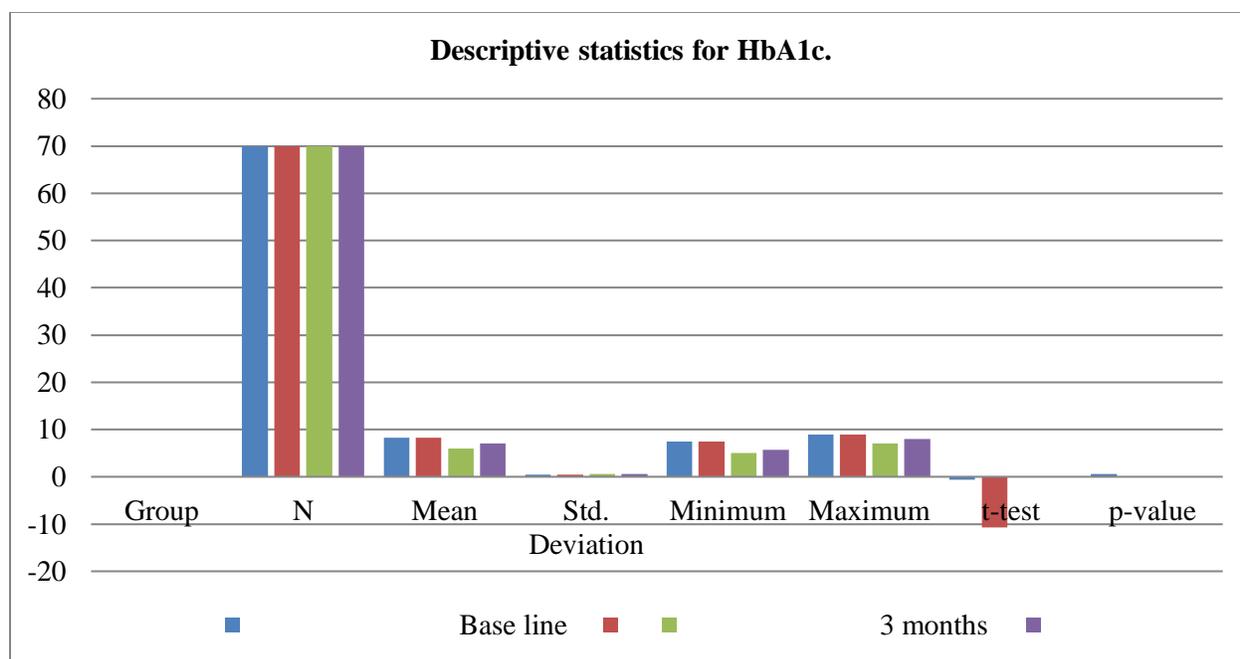
8.55. And the average age for group B was  $58.40 \pm 7.98$ . At the start of the study, the level of vitamin D was similar in both groups. After 12 weeks when patients of both groups were again examined, they showed a marked variation in the level of vitamin D. Various figures like BMI, T2DM interval, age and masculinity were determined at the start of the

treatment and after the 3 months of the treatment in both the groups to compare the level of HbA1c.

The decrease in HbA1c level and enhancement in the maintenance of glucose level were noticed in group A.

**Table – I:** Descriptive statistics for HbA1c.

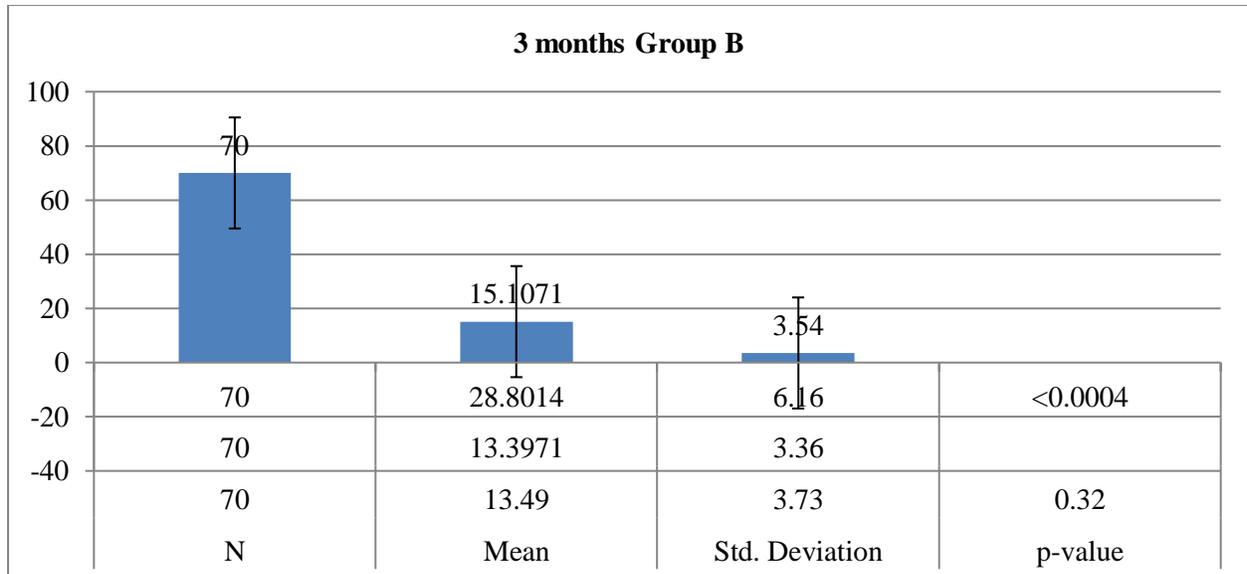
Group	Baseline		3 months	
	A	B	A	B
N	70	70	70	70
Mean	8.21	8.25	5.93	7.02
Std. Deviation	0.44	0.47	0.61	0.59
Minimum	7.5	7.5	5.0	5.7
Maximum	9.0	9.0	7.0	8.0
t-test	-0.590	-10.66		
p-value	0.56	0.000		



Group A: Vitamin D with Metformin Group B: Metformin only  
HbA1c: Hemoglobin A1C.

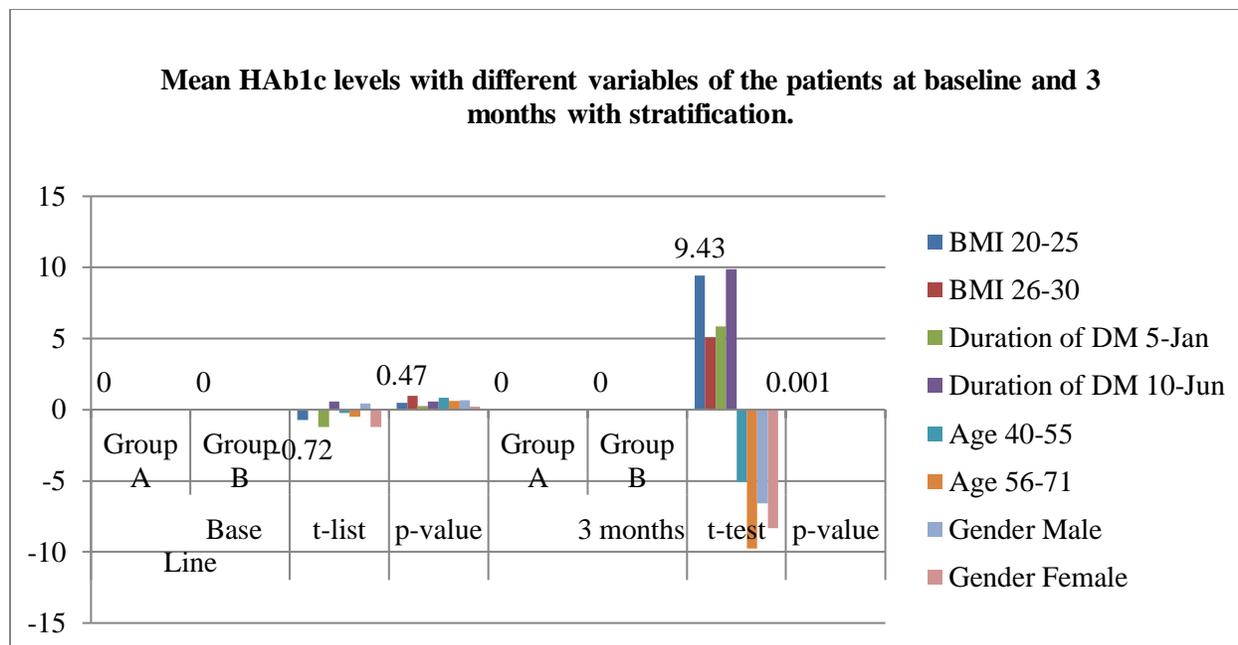
**Table – II:** Average vitamin D levels between both groups

VITAMIN D LEVELS					
	Group	N	Mean	Std. Deviation	p-value
Baseline	Group A	70	13.4900	3.73	.320
	Group B	70	13.3971	3.36	
3 months	Group A	70	28.8014	6.16	<0.0004
	Group B	70	15.1071	3.54	



**Table – III:** Mean HbA1c levels with different variables of the patients at baseline and 3 months with stratification

		Base Line		t-list	P-value	3 months		t-test	P-value
		Group A	Group B			Group A	Group B		
<b>BMI</b>	20-25	8.20±0.42	8.27±0.45	-0.72	0.47	5.96±0.62	7.08±0.54	9.43	0.001
	26-30	8.21±0.48	8.21±0.53	-0.004	0.99	5.84±0.60	6.88±0.69	5.11	0.001
<b>Duration of DM</b>	1-5	8.15±0.46	8.28±0.52	-1.21	0.27	5.96±0.65	6.85±0.64	5.87	0.001
	6-10	8.29±0.40	8.23±0.41	0.57	0.56	5.87±0.56	7.18±0.50	9.89	0.001
<b>Age</b>	40-55	8.20±0.43	8.23±0.48	-0.223	0.824	6.02±0.64	6.89±0.65	-5.08	0.000
	56-71	8.21±0.45	8.26±0.47	-0.500	0.618	5.82±0.57	7.08±0.55	-9.78	0.000
<b>Gender</b>	Male	8.21±0.46	8.16±0.50	0.428	0.670	5.95±0.61	6.96±0.57	-6.59	0.000
	Female	8.20±0.43	8.32±0.44	-1.22	0.225	5.91±0.63	7.06±0.61	-8.313	0.000



HbA1c: Hemoglobin A1C

BMI: Body Mass Index

DM: Diabetes Mellitus.

### DISCUSSION:

Diabetic patients are present in the entire world. Their number is growing day by day [14]. According to the recent reports 280 million diabetics were recorded all over the world. It is expected that their number will reach up to 438 million at the end of the year 2030. Various results were obtained about the connection between the less vitamin D and progression of diabetes. Although a strong association was found between impaired glucose acceptance and hypovitaminosis according to the epidemiological studies [15]. An association between less vitamin D and microvascular diabetic complexities was also found according to some epidemiological researches [16]. In addition, 125 dihydroxycholecalciferol exerts its role in controlling the euglycaemic atmosphere in many ways. The insulin receptor gene appearance can be articulated by the exploit of vitamin D on beta cells of the pancreas [17]. Calcium level in the blood also increased due to the commencement of vitamin D. The level of vitamin D can be increased by its less absorption in the intestine. Calcium is the precondition for the insulin release from beta cells of the pancreas.

In the near past, beta cells were analyzed completely. It was identified that beta cells contain special cells for energetic vitamin D. These cells can transform the dormant form of vitamin D into the energetic form [18]. Investigators examined the function of vitamin

D on the homeostasis of glucose and IR in diabetic patients. It has been identified by research that HbA1c decreases as a result of the substitution of vitamin D [12]. The consequences obtained during our trials were comparable with that report. It was shown by another study that there is no variation in the HbA1c in both groups [13]. The effects on both groups by the supply of vitamin D were not clearly shown in the first 6 months [19]. Another similar study was carried out in Korea on 129 patients. No significant role of vitamin D supply was found on the maintenance of HbA1c [20].

A group of investigators perform a meta-analysis. Their purpose was to look out the consequences of supply of vitamin D to the blood and IR in diabetic patients. It was identified that the small amount of vitamin D is when given to the patient; it decreases the attaching blood glucose, HbA1c, and homeostatic model judgment. It also plays its role in maintaining glycaemic reaction and perk up insulin compassion in patients of diabetes [21]. These confusing consequences challenged more trials in this respect. There is no perfect indication of the role of vitamin D in the medical or therapeutic treatment of diabetic patient [22].

On the other hand, many experiments were carried out impaired glucose acceptance and hypovitaminosis. Many recent studies identified that

decreased level of vitamin D can cause the diabetes mellitus [23]. As vitamin D and IR were found to be clearly present in diabetic patients so these are considered as the possible causes of diabetes.

There are many possible causes of such a great variety of results in different studies. The variables of various studies are different from each other. In addition, the follow-ups and the time required to induce consequences are also varying. The amount of vitamin D supplied, its administration and sample size are responsible for variations in consequences. These unclear and confusing results should be made clear by further investigations. The consequences obtained from the recent study should be generalized to the common masses suffering from diabetes having less amount of vitamin in the body on metformin by examining its sample size, related processes and mathematical investigation. Even if the consequences can be made common among type 1 diabetic patients or the persons utilizing many medicines for treatment, it is necessary to improve their results by further investigation. There are also some shortcomings in the following study. The first limitation of the study is that it is a single centre experiment. Its sample size is small. Specimens of the diabetic patients were not heterogeneous. It is necessary to organize further trials to eliminate all these shortcomings.

### CONCLUSION:

If vitamin D and specific anti-diabetic drugs are given to the patients their glycaemic position and level of HbA1c can be maintained. Total of 140 patients were included in the study. These were classified into two equal groups of 40 patients. The average age of patients in group A was  $54.80 \pm 8.55$ . And the average age for group B was  $58.40 \pm 7.98$ . At the start of the study, the level of vitamin D was similar in both groups. After 12 weeks when patients of both groups were again examined they showed a marked variation in the level of vitamin D. Various figures like BMI, T2DM interval, age and masculinity were determined at the start of the treatment and after the 3 months of the treatment in both the groups to compare the level of HbA1c.

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