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Association between Socio-demographic Characteristics and Biochemical Profile of Type 2 Diabetic Patients Undergoing Vitamin D Supplementation

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Abstract

Background: Vitamin D deficiency is prevalent in type 2 diabetes and this vitamin may be related to insulin action which may facilitate insulin function by regulating its receptor expression, responsible for increasing insulin sensitivity. Therefore, the correction of vitamin D deficiency may result in improved glucose control as well has beneficial effects on complications of diabetes type 2. The principal aim of this study was to describe socio-demographic and biochemical profile of type 2 diabetic patient as well as to find out the effect of socio-demographic factors on different biochemical profiles of those diabetic persons. *Method:* The study was conducted on 45 type 2 diabetic patients (30 treatment group and 15 placebo group) undergoing vitamin D supplementation, who were recruited from specific health care center. Socio demographic data were collected using a structured pretested printed questionnaire by interviewing the subjects. Biochemical parameters were analyzed by spectroscopic methods using standard laboratory kits. SPSS software package version 21 was used to analyze the data. *Results:* Most of bio-chemical profiles were found to be improving following vitamin D supplementation Calcium and C-reactive protein become significantly changed (<0.005). Sex, age, education were significantly associated with CRP level (either on baseline or end line), whereas, Sex and BMI were found to be associated with HbA_1C at baseline, Calcium was associated with BMI at end line. *Conclusion:* We can conclude that socio demographic profile might have influence on the biochemical profile of type 2 diabetes.

Keywords

Socio Demography, Biochemical Profile, Type 2 Diabetes Mellitus, BMI

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1. Introduction

Diabetes mellitus (DM), characterized by hyperglycaemia or high blood glucose, is a leading cause of premature mortality and disability. Before the age of 70 years globally, almost half of all deaths are attributable to high blood glucose [1]. Worldwide the Indian subcontinent is more prominent of this growing burden which accounts for close to one-fifth of all diabetes cases [2]. In this region the prevalence of diabetes is projected to increase by 71% by 2035. In Bangladesh, according to the International Diabetes Federation in the next 15 years the prevalence of diabetes will increase to more than 50% [3].

The American Diabetes Association projects approximately 18.3% (8.6 million) of Americans with age of 60 and older have diabetes [3]. Diabetes is one of the four major types of non communicable diseases (NCDs) that make the largest contribution to morbidity and mortality in worldwide [4].

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A study in Bangladesh Institute of Research and Rehabilitation for Diabetes, Endocrine and Metabolic Disorders, Dhaka found that diabatic patients type 2 take both insulin and oral medication nearly about 15%and only 60% take oral medications [5]. The International Diabetes Federation estimated in Bangladesh 7.1 million people with diabetes and almost an equal number with undetected diabetes [5].

Vitamin D deficiency in pandemic, almost half of the world's population has got hypovitaminosis D [6]. Like elsewhere, which is highly prevalent in south Asian countries, in India the prevalence of vitamin D deficiency ranged from 40% to 99%, with most of the studies reporting a prevalence of 80%-90% [7]. Vitamin D has been found to aggravate the condition in diabetic patients by affecting insulin sensitivity and secretion [8]. Different socio economic status can also contribute to the diabetic parameters among patients. So, the present study aimed to estimate different biochemical profile of type 2 diabetic persons undergoing vitamin D supplementation as well as find out the influence of sociodemographic factors on certain biochemical profiles of those diabetic persons.

2. Methodology

2.1. Study Type

Cross-section observational study

2.2. Study Period

The study was conducted during April 2019 to August 2020

2.3. Study Participants

Total 45 (30 in treatment group and 15 were controlled group) diabetic patient aged between 30-70 years who attended at selected Health Center. Subjects who were on vitamin D supplement/ treatment, severe co-morbid conditions were excluded.

2.4. Sampling Technique

Samples were collected by Non-probability purposive sampling method. After collection data were checked to exclude any error or inconsistency.

2.5. Sampling Tool

A pretested structured questionnaire was used to collect the socio demographic including anthropometric data by direct interview of the diabetic patients. Well trained enumerators collected and recorded the information in the questionnaire, which was then checked and used for entry into computer.

2.6. Biochemical Sample Collection

A 10 ml fasting venous blood was collected aseptically from the antecubital vein of each of the participating diabetes in heparin tube and was placed in cool box. Blood sample was processed immediately to separate plasma, aliquot of which was then taken into Eppendorf and stored at e -40°C for analysis of biochemical profile [9].

2.7. Estimation of Biochemical Parameter

The plasma collected was analyzed for the biochemical tests. The method and kit employed for are briefed as:

3. Biochemical Investigations

All subjects will be investigated for serum biochemical parameters.

Table 1. Test of Biochemical Parameters among study subjects

Biochemicals	Method	Reagent(Kit)	Machine used	Procedure	Reference
Plasma Fasting blood sugar	Enzymatic method (Hexokinase-mediated reaction)	Hexokinase (Roche Diagnostics, Switzerland)	Roche/Hitachi Cobas c 311/501 Analyzer	Specimens must be transferred to a centrifuge tube for 10Minutes of 3000 RCF before testing. Dispenses R1: 28 µL + Diluent (H_2O): 141 µL into a Reaction Cuvette, then dispense sample: 2 µL and R2: 10 µL + Diluent (H_2O): 141 µL Incubation at 37°C after 10 minutes.	[10]
Serum Calcium	Photometric estimation	The Calcium Gen. 2 test system	Roche/Hitachi Cobas C Analyzer	Specimens must be transferred to a centrifuge tube for 10Minutes of 3000 RCF before testing. Dispenses R1: 20 µL + Diluent (H_2O) into a Reaction Cuvette, then dispense sample: 3 µL and R2: 20 µL. Incubation at 37°C after 10 minutes.	[11]
Serum Vitamin D	Chemiluminescence Microparticle Immunoassay (CMIA)	ARCHITECT (Abbott Laboratories, Lake Forest, IL, USA)	Architec4100	Allow blood samples to clot adequately before centrifugation. Specimens must be transferred to a centrifuge tube and centrifuged for 10Minutes of 3000 RCF before testing. Dispenses 60 µL of a sample into a RV(Reaction Vessels)	[12]
Serum Fasting Insulin	Chemiluminescence Microparticle Immunoassay (CMIA)	8K41 ARCHITECT Insulin Reagent Kit.(Brand Architect TM, Abbott	Architect 4100	Allow blood samples to clot adequately before c entrifugation for 10Minutes of 3000 RCF before testing. Dispenses 150 µL of a sample into a RV (Reaction Vessels. 100 µL Pre-Trigger and 300µL Trigger Solutions are added to the reaction mixture.	[13]

Biochemicals	Method	Reagent(Kit)	Machine used	Procedure	Reference
		Laboratories, Japan)			
Serum HbA1c	Ion-exchange high performance liquid chromatographic (HPLC) method	Bio-Rad D-10TM Hemoglobin A1c (Bio-Rad Laboratories, USA	HPLC Analyzer (fully automated)	Samples were stored as 1 day at room temperature (15-30°C), 7 days at 2-8°C. Before analysis sample on Variant II Turbo quality control was performed. After separated hemoglobin then pass through the flow cell of filter photometer, where changes in the absorbance at 415 nm are measured. An additional filter at 690 nm corrects for background absorbance.	[14]
Serum C-reactive protein (CRP)	Immunoturbidimetric assay	CRPHS reagent kit (Cat. No. 04628918190, Roche Diagnostics, Switzerland)	Roche/Hitachi Cobas C systems	Specimens were mixed well, allowed clot to fully form and centrifuged 10 minutes at 2000 x g before use. A liquot a minimum of 0.1 mL was taken.	[15]

3.1. Statistical Analysis

SPSS software package (version 21.0 SPSS Inc, Chicago, IL, USA) was used to analyze the data. Descriptive statistics were employed to analyze all variables. Values were expressed as frequency, percentage, mean and standard deviation as and where necessary. Association of sociodemographic and biochemical profile was performed by chi-square test.

3.2. Ethical Approval

Informed consent was taken from each subject before the beginning of the study. The study protocol was reviewed and approved by The Ethical Board of the Faculty of Biological Science, University of Dhaka.

4. Results

Socio-demography of type-2 diabetic patients is described in Table 2. Mean age of the diabetic patients was 44.17 ± 9.95 years, more than half of the study subject were female (56.7%) and all were married. More than two fifth (42.11%) were illiterate, only 26.32% have secondary level education. Among female about 47% subjects were involved in household works and 63.3% have had low-middle income between (USD 250-375). However, more than half of them (53.33%) were overweight, which is one of the risk factors for diabetes.

Table 2. Socio-demography and nutritional status of type 2 diabetic patients undergoing Vitamin D supplementation.

Socio-demography and nutritional status		N (%)
Age in years	<40	9(30)
	40-50	16(53.33)
	>50	5(16.66)
Sex	Female	17(56.7)
	Male	13(43.3)
Education	Illiterate	10(33.4)
	Up to Primary	9(30)
	Up to Secondary	11(36.6)
Occupation	Service	7(23.3)
	Business	3(10)
	Housewife	8(26.7)
	Unemployment	2(6.7)
	Others	10(33.3)
Income	<20,000	10(33.4)
	>20,000	20(66.6)
Religion	Hindu	3(10)
	Muslim	27(90)
Family Diabetes	Yes	17(56.7)
	No	13(43.3)
Duration DM	<5 years	18(60)
	≥5 years	12(40)
BMI(Kg/m^2)	18.5-24.9	14(46.66)
	25-29.9	16(53.33)

Table 3 depicts a comparison on certain biochemical profiles measured at baseline and end line of the study. Significance changes were found in biochemical profile calcium and c reactive protein upon Vitamin D supplementation.

Chi-square analysis indicated that, at baseline HbA_1C was significantly related to sex and BMI, and Education level was related to CRP level (Table 4). At End line Calcium level was found to be significantly related to BMI and CRP was

significantly associated with sex and age of the participants (Table 5).

Table 3. Biochemical profile of type 2 diabetic patients undergoing Vitamin D supplementation.

Biochemical parameters (n=30)	Timeline		P value
	Baseline	End line	
HbA_1C	9.11 ± 2.19	8.63 ± 1.86	.093
Fasting Blood Sugar	10.53 ± 3.34	9.85 ± 3.27	.207
Calcium	9.68 ± 0.62	9.99 ± 0.41	.008
C-reactive protein	8.56 ± 7.56	6.34 ± 4.99	.005
Fasting Insulin	9.03 ± 5.22	15.99 ± 32.45	.264

HbA_1C (Glycated Haemoglobulin); Paired sample t-test; * P<0.05.

Table 4. Influence of socio demographic factors and nutritional status on Baseline biochemical profile of type 2 diabetic patients undergoing Vitamin D supplementation.

Socio demographic factors and nutritional status		Biochemical Profile				
		HbA1C (<7.8, >7.8)	FBS (<11.5, >11.5)	Calcium (<9.5, >9.5)	CRP (<3, >3)	Fasting Insulin (<12, >12)
Sex	Female	x^2=4.344	x^2= 0.072	x^2= 0.003	x^2= 0.39	x^2= 0.574
	Male	p=0.03	P= 0.78	P= 0.95	P= 0.42	P= 0.45
Age	<40	x^2=.287	x^2= 0.271	x^2= 0.151	x^2= 0.197	x^2= 2.172
	>40	P= 0.59	P= 0.60	P= 0.69	P= 0.65	P= 0.14
Education	Illiterate	x^2 =.075[a]	x^2= 3.18	x^2= 1.405	x^2= 5.67	x^2= 4.091
	Up to Primary	P= 0.78	P= 0.2	P= 0.49	P= 0.05	P= 0.13
	Secondary or above					
Income	<20K	x^2=.075	x^2= 0.300	x^2= 0.085	x^2= 0.341	x^2=0.00
	>20K	p=0.78	P= 0.58	P= 0.77	P= 0.56	P= 1.00
BMI	<25	x^2= 4.34	x^2= 0.067	x^2=1.099	x^2=3.68	x^2= 2.71
	>25	p=0.03	P= 0.79	P= 0.29	P= 0.54	P= 0.10

Table 5. Influence of socio demographic factors and nutritional status on End line biochemical profile of type 2 diabetic patients undergoing Vitamin D supplementation.

Socio-demography and Nutritional Status		Biochemical profiles				
		HbA1c (≤7.8, >7.8)	FBS (≤11.5, >11.5)	Calcium (≤9.5, >9.5)	CRP (≤3, >3)	Fasting Insulin (≤12, >12)
Sex	Female	x^2= 1.033	x^2= 0.574	x^2= 0.016	x2= 4.474	x^2= 2.391
	Male	p= 0.31	p= 0.45	p= 0.9	p= 0.03	p= 0.12
Age	<40	x2= 0.889	x^2= 2.172	x^2= 0.739	x2= 6.27	x^2= 1.824
	>40	p=0.24	p= 0.14	p= 0.39	p= 0.01	p= 0.18
Education	Illiterate	x^2 = 1.292	x^2= 1.092	x^2= 0.022	x^2= 1.292	x^2= 0.600
	Up to Primary	p= 0.52	p= 0.58	p= 0.99	p= 0.52	p= 0.74
	Secondary or above					
Income	<20K	x^2= 1.086	x^2= 0.938	x^2= 1.667	x^2= 0.068	x^2= 0.287
	>20K	P=0.29	P= 0.33	P= 0.19	P= 0.79	P= 0.59
BMI	<25	x^2=1.033	x^2= 0.033	x^2=2.917	x^2=0.475	x^2=2.63
	>25	P=0.31	P= 0.83	P= 0.08	P= 0.49	P= 0.1

5. Discussion

Diabetes is often the consequence of insulin resistance and Vitamin D deficiency has been found to be associated with impaired β cell function and insulin resistance [16].

In the present study, the mean age of the diabetic patients was 44.17 years, more than half of the study subjects were female and all were married. More than two fifths were illiterate. However, more than half were overweight, which is one of the risk factors for diabetes.

Results of this study showed, upon vitamin D supplementation, serum insulin concentration was increased and had beneficial effects in decreasing HbA1c in diabetic type 2 patients. Also, there was a study in Nigeria presented vitamin D may indirectly affect insulin secretion via regulation of calcium-mediated insulin release by regulating calcium influx through the cell membrane [17].

In our study, serum calcium level and C reactive protein ($p<0.05$) changed in diabetic patients significantly upon Vitamin D supplementation. Vitamin D increase was found to be associated with CRP decrease among patients with inflammatory diseases in a study [18]. Upon supplementation, the levels of HbA1c and FBS were decreased though they were insignificant.

In the demographic analysis, HbA_1c was found to be associated with age and BMI in this study. In one study it has been found that obese adults are predisposed to diabetes

sooner than adults with normal weight [19]. Serum calcium level was also associated with BMI. Age and Sex were found to be related with CRP levels. A previous study also found sex differences in CRP levels and found it higher in girls [20]. In present study, CRP level was found to be associated with educational levels. The finding is parallel with other studies, which suggests low educational qualification related to low income can be the underlying reason for high CRP [21].

One of the limitations is small patients participated in the study.

6. Conclusion

This study was done to determine the association of vitamin D supplementation and the socio demographic factors that might influence the diabetic parameters. According to the findings of present study Vitamin D supplementation significantly decreased CRP level and increased mean calcium level. Among demographic factors BMI was significantly associated with HbA1c and calcium. CRP level was significantly associated with age, gender and educational levels among the diabetic patients. Further large investigation is needed to identify the underlying pathways of such association.

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Conflict of Interest

There was no conflict of interest among the authors in any part of the study.

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