

Original Research Article

Study of serum C-peptide levels in newly diagnosed diabetic mellitus subjects of North Gujarat region of India

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ABSTRACT

Background: Serum C-peptide has appeared as the chief clinical and practically adequate marker of β -cell function of pancreas. Serum insulin and C-peptide are concomitantly secreted into the blood circulation in equal amount. The aim of the study was to determine serum C-peptide levels in newly diagnosed diabetic mellitus subjects of North Gujarat region of India.

Methods: The present cross-sectional study was done on 50 subjects of recently diagnosed Diabetes mellitus (T2DM) and non-diabetic healthy controls at Banas Medical College and our trust-based hospital. All diabetics patients were further classified into two groups; normal FC group consist of subjects with FC level 0.5-3.2 ng/ml (N=14) and high FC group included subjects with FC>3.2 ng/ml (N=36). The patients' demographic and anthropometric parameters were recorded; detailed history and clinical examination were performed in the entire cases. All biochemical parameters were analyzed.

Results: Predominance of the T2DM subjects was in the age group of 41-50 years. Mean value for age ($p<0.01$), anthropometric ($p<0.01$), fasting plasma glucose ($p<0.001$), HbA1c ($p<0.01$), cholesterol ($p<0.01$), triglycerides ($p<0.001$) and C-peptide ($p<0.001$) were significantly higher in the T2DM subjects. The mean values of fasting plasma glucose ($p<0.001$) and HbA1c ($p<0.01$) are significantly higher in T2DM subject with high C-peptide level as compared to normal C-peptide level.

Conclusions: In our study, we conclude that elevated levels of fasting C-peptide in newly diagnosed T2DM. Therefore, we suggested that serum C-peptide levels are valuable as marker of endogenous insulin production from β -cell of pancreas.

Keywords: Diabetes mellitus, C-peptide, BMI, Endogenous insulin

INTRODUCTION

Diabetes mellitus (DM) is a cluster of metabolic syndrome or syndrome-X characterized by hyperglycemia ensuing from defects in insulin secretion from β -cell of pancreas, mechanism of insulin action, or can be together. More than ninety percent of individual with DM throughout globally have type 2 DM¹. India is capital of DM in the world. This is being reached to beneath ten crores diabetics by the year 2035.² Diabetes is one in the midst of the most monetarily draining

chronic non-communicable disease. The expenses for treatment increasing and the encumber it bears on family or entity finances and society makes it crucial to approach this disease in a more joint entirety.³ In India, more than 50% of patients have deprived glycemic control and have vascular complications. Thus, there is an imperative require to build up novel therapeutic agents of diabetes without the progress and progression of complications on safety.⁴ Estimation of C-peptide, which is co-secreted with insulin from beta cells of pancreas and gives an guidance of endogenous insulin secretion and

pancreatic beta cell function.⁵ Once DM is diagnosed, assay for C-peptide can be used to distinguish type 1 and type 2 DM and to differentiate those who necessitate insulin treatment from others who can be supervised by diet and physical activity.⁶ The lack of C-peptide in type 1 DM or its surplus in type 2 DM leads to the development of disorders in the cardiovascular, neurological, excretory function and other physiological systems.⁷ It is revealed that C-peptide within the physiological concentrations has anti-inflammatory, immune-modulatory and neuro-protective effects, so that it and its synthetic analogues can be broadly used to treat diabetic patients and to avert DM complications.⁸ The aim of the study was to know the serum C-peptide levels in newly detected diabetic patients in population of North Gujarat.

METHODS

The present cross-sectional study was carried out in the department of general medicine, General Hospitals associated with Banas Medical College and Research Institute Palanpur and our private trust-based Hospital in Banaskantha, Gujarat, India, over period of one year from July 2020 to June 2021. All newly diagnosed type 2 DM patients attending the OPD of the hospital during the study period were enrolled in the present study.

Total 50 newly diagnosed type 2 DM patients, age ranging 31 to 60 years, before commencement of any pharmacological treatment for DM, were selected for present study. 50 age and sex-matched healthy volunteers selected from the patient's entourage and health care professionals were incorporated in the control group. All diabetics patients were further classified into two groups depending on the Fasting serum C-peptide (FC) level, normal FC group consist of subjects with FC level 0.5-3.2 ng/ml (N=14) and high FC group included subjects with FC>3.2 ng/ml (N=36).

Subjects with any acute infirmity, any acute or complex chronic complications of DM were excluded from present study. The written informed consent was obtained from all participants before starts of study.

All information was collected from all subjects by semi structured questionnaire. A detailed clinical history was taken such as age and sex, symptomatic, past history of hypertension and other endocrine disorders, any family history of diabetes, hypertension, dyslipidemia, liver disease, history of smoking, and history of alcohol consumption. Clinical examination was also performed, anthropometric measurement including height, weight, BMI, waist circumference, hip circumference, and waist to hip ratio were also measured. The waist circumference was measured at the mid-point between the lower border of the rib cage and the iliac crest, whereas the hip circumference was recorded at the widest point between the hip and buttock.

The biochemical parameters like Fasting blood glucose (FBG), total cholesterol, Triglycerides (TG), and High-density lipoprotein cholesterol (HDL-C) levels were determined by enzymatic method using commercial available diagnostic kit on fully automated biochemical analyzer. Low density lipoproteins cholesterol (LDL-C) was determined by using Friedwald formula. Serum c-peptide was estimated by quantitative Enzyme-linked immunoassay (ELISA) method. HbA1c was estimated by immune-fluorescence technique on quantitative immunoassay analyzer using a commercially available diagnostic kit. The study protocol was approved by Institutional ethics committee human (IEC-H).

Statistical analysis

Data was analyzed using Statistical Package for Social Sciences, version 20 (SPSS Inc., Chicago, IL). Results for continuous variables are presented as mean±standard deviation, and unpaired student's test was used for significant difference between two variables. Chi-square test and Fischer's exact Chi square test were used for the comparison of categorical variables and presented as percentage. The level $p<0.05$ was considered as significance.

RESULTS

Demographic characteristics are presented in Table 1 and 2. The total of 100 subjects was included in this study. Study group (T2DM) consist of 50 subjects (14 female, 36 male, mean age 48.56 ± 5.25) and control group included 50 subjects (10 female and 40 male, mean age 40.62 ± 2.75). Total male subjects are 76 (76%) and female subjects are 24 (24%) in both groups

In our study, preponderance of the T2DM subjects was in the age group of 41-50 years.

Out of 50 subjects, 5 subjects are 31-40 years (10%), 25 subjects are 41-50 years (50%), 15 subjects are 51-60 years (30%) and 5 subjects are >60 years (10%).

Table 3 shows the anthropometric and biochemical variables of the study population. Differences between anthropometric and biochemical variables between subjects with T2DM and healthy control, were tested by Student independent t-test. Mean value for age ($p<0.01$), body mass index ($p<0.01$), waist-hip ratio ($p<0.05$), fasting plasma glucose ($p<0.001$), HbA1c ($p<0.01$), total cholesterol ($p<0.01$), triglycerides ($p<0.001$) and C-peptide ($p<0.001$) were significantly higher in the T2DM subjects as compared to control subject. HDL-C levels were significantly lower in the T2DM subjects when compared to control healthy subjects ($p<0.01$). The mean value of LDL-C was slightly higher in T2DM patients as compared to healthy control subjects but this difference was statistically non-significant ($p>0.05$).

The comparison of obesity and diabetic profile markers among T2DM subjects between normal and high c-peptide level are illustrated in Table 4. The mean values of fasting plasma glucose (p<0.001) and HbA1c (p<0.01)

are significantly higher in T2DM subject with high C-peptide level as compared to normal C-peptide level where as not significantly difference found with respect to body mass index (p>0.05).

Table 1: Age wise distribution of subjects in both groups.

Age group (years)	Cases (T2DM) (N=50)	Control (N=50)	Level of significance
31-40	05 (10%)	10 (20%)	P<0.001 As per Chi-square test
41-50	25 (50%)	20 (40%)	
51-60	15 (30%)	10 (20%)	
>60	05 (10%)	10 (20%)	
Total	50 (100%)	50 (100%)	

Note: Two side p values are<0.05, considered significant. The row/column variables are significantly associated.

Table 2: Distribution of subjects according to gender.

Gender	Cases (T2DM) (N=50)	Control (N=50)	Total (N=100)	Level of significance
Male	36 (72%)	40 (80%)	76 (76%)	P<0.05 as per Chi square test
Female	14 (28%)	10 (20%)	24 (24%)	
Total	50 (100%)	50 (100%)	100 (100%)	

Note: Two side p values are<0.05, considered significant. The row/column variables are significantly associated.

Table 3: Biochemical variables of the study participants

Biochemical variables	Cases (T2DM) (N=50) (mean±SD)	Control (N=50) (mean±SD)	Level of significance
Age (years)	48.56±5.25	40.62±2.75	P<0.01
BMI (kg/m ²)	27.58±2.56	23.76±1.20	P<0.01
Waist-hip ratio	0.99±0.04	0.92±0.02	P<0.05
Fasting plasma glucose (mg/dl)	168.91±53.72	90.47±7.12	P<0.001
HbA1c (%)	9.12±2.13	4.98±0.25	P<0.01
Total cholesterol (mg/dl)	195.20±26.52	179.10±21.15	P<0.01
Triglyceride (mg/dl)	199.40±70.76	180.40±62.27	P<0.01
LDL-cholesterol (mg/dl)	114.14±20.24	113.07±20.24	P>0.05
HDL-cholesterol (mg/dl)	36.82±2.48	42.52±2.98	P<0.01
C-peptide (ng/ml)	9.89±4.28	1.24±0.21	P<0.001

Table 4: Comparison of obesity and diabetic profile markers in T2DM subjects between normal and high C-peptide.

Variables	Normal C-peptide (0.5-3.2 ng/ml) (N=14) (mean±SD)	High C-peptide (>3.2 ng/ml) (N=36) (mean±SD)	Level of significance
BMI (kg/m ²)	28.41±2.68	27.60±2.32	P>0.05
Fasting plasma glucose (mg/dl)	136.89±31.24	189.48±78.27	P<0.001
HbA1c (%)	7.94±1.35	10.49±2.64	P<0.01

DISCUSSION

T2DM is one of the foremost causes of morbidity and mortality worldwide. In this cross-sectional study, population of 50 patients of newly diagnosed DM 2 type, 36 (72%) patients were males and 14 (28%) patients were females. The mean age of the T2DM patients is 48.56±5.25 years (range 31-60). The globe figures show that general age of detecting Type 2 diabetes is 40-45 years.⁹ The Asian (Indian) data show that it is 5-10 years

earlier than that of globe figures. In our study also the age group with most patients is 30-60 years.¹⁰

In our study evaluated the endogenous insulin secretory ability of the study participants by assessing fasting serum c-peptide. Not single newly diagnosed T2DM patients had a c-peptide level beneath the normal range. C-peptide was elevated in new T2DM subjects in comparison to the non-diabetic healthy controls (9.89±4.28 vs 1.24±0.21 ng/ml, p<0.001). This point out

that the T2DM subjects had no complete drops in insulin secretion; there was a compensatory raise in insulin secretion in numerous to conquer the insulin resistance which was not estimated in our study. Only a few studies have evaluated C-peptide status in T2DM, particularly in newly detected T2DM. Neha et al in their study, reported new T2DM subjects to have higher C-peptide levels than healthy controls.¹¹

In our study, 36 (72%) of the T2DM subjects had increased (>3.2 ng/ml) fasting C-peptide level and the rest 14 (28%) had normal level (0.5-3.2 ng/ml) of C-peptide. Elevated level of c-peptide suggested the potential excellent response to insulin sensitizers and other oral anti-diabetic drugs.¹² In this study mean HbA1c level significantly higher in T2DM subject with higher C-peptide level and it was 10.49 ± 2.64 . A study done by Hasan et al observed the higher HbA1c ($10.69\% \pm 2.64$) in newly diagnosed Bangladeshi T2DM subjects which was similar to our study.¹³ The HbA1c level of this study subjects point out that their diabetes can be controlled by metformin plus another second line oral anti-diabetes drug without insulin use.¹² In our study, the high c-peptide group of the T2DM subjects had significantly higher levels of fasting plasma glucose and HbA1c than the normal c-peptide group. In the early period of T2DM, when blood glucose rises there is a compensatory increase of insulin secretion in a proportion manner to maintain the blood glucose within the normal range. If embroidered insulin secretion cannot conquer the insulin resistance, hyperglycemia occurs.¹⁴ elevated glycemic index in elevated C-peptide T2DM subjects equal the pathophysiology of T2DM.

In our study, no difference was reported in BMI between T2DM subjects with high c-peptide level and normal C-peptide level, a significant positive relationship was reported between c-peptide and BMI in the studied T2DM subjects. Obesity is connected with insulin resistance and more insulin secretion is needed to conquer the higher level of insulin resistance in obese subjects. Mariyam et al had similar observations to our findings.¹⁵

Limitations

In present study, sample size was small and randomization of sampling was not performed. This study was a single district level hospital based not a multi-centric study therefore findings may not reflect the entire society. In addition, insulin resistance was not estimated thus relative insulin deficiency could not be established in our study.

CONCLUSION

In our study, we conclude that elevated levels of fasting C-peptide in newly diagnosed T2DM. Therefore, we suggested that serum C-peptide levels are valuable as marker of endogenous insulin production from β cell of

pancreas. Further study can be investigating the exact role of insulin resistance and insulin secretary defects in this field.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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