

# Assessment of Baseline Biochemical Parameters and its Correlation with Clinical Outcomes in Type 2 Diabetics

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## Abstract

The aim of the study is to assess the different baseline biochemical parameters required for type 2 diabetics and to correlate the same with clinical outcomes. Nine hundred Type 2 diabetic subjects aged between 30-85 years of both the genders from 3 diabetic out-patient clinics in South Bangalore were selected for the study. All the study subjects gave their informed consent. All the subjects had clinical examination with anthropometric measurements and measurements of blood pressure. Pre- tested interview schedule was used to collect the information pertaining to socio-economic and duration of diabetes. Biochemical parameters with the laboratory methods done were collected and recorded in the schedule. Among the variables studied, fasting plasma glucose was above 131 mg/dl for 64% of diabetic subjects. Postprandial plasma glucose of >201mg/dl for 62% and poor to uncontrolled glycosylated hemoglobin (HbA1c) of greater than 8.1% were noted among 38% of the selected diabetic subjects. The individual lipid parameters were also assessed and the diabetic subjects showed higher total cholesterol (29%), triglycerides (33%), Low density Lipoprotein (59%), very Low Density Lipoprotein (15%) and lower High Density lipoprotein levels among 41% selected population. Similarly urine for microalbuminuria was noted in 71% and Albumin Creatinine Ratio (ACR) of >300 microgram/dl was found in 18% of the type 2 diabetic subjects. Also the different biochemical parameters were correlated with HbA1c and it was found that HbA1c was positively associated with all parameters except BMI and HDL at one per cent level ( $p \leq 0.001$ ). The parameters studied indicates that majority of the diabetic subjects are potential to develop diabetic related complications like diabetic nephropathy and underlying cardiovascular disorders. A strict glycemic control and a timely comprehensive evaluation of the biochemical parameters are considered as a potential marker to prevent diabetic prevalence to a certain level.

**Keywords:** Complications, Lipids, Plasma Glucose, Type 2 Diabetes

## 1. Introduction

Diabetes mellitus is the most common chronic diseases among adults [1]. In spite of well-defined treatment for type 2 diabetes, in majority of the people, disease is poorly controlled with existing therapies [2], [3]. Studies like UKPDS [4] and DCCT [5] have proven that poor glycaemic control (HbA1c>7%) is associated with increased risk for micro vascular complications [6]. Epidemiological

data over the past decades have shown that the pattern and profile of type 2 diabetes mellitus are very different in India compared to the West in their clinical and biochemical profile. These patients are neither related clinically or pathophysiologically [7]. Interpretation of diagnostic biochemical patterns requires an understanding of the pathological implications of abnormal results of the research. Together with normal results these form a pattern which reflects one or more underlying disease

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process. Investigative biochemical profiles are designed to provide all the data necessary for a broad investigation of internal disease [8].

One of the main goals of treating patients with type 2 diabetes mellitus is to produce near-normal glucose levels to prevent the development of diabetic complications [9]. The importance of protecting the body from hyperglycemia cannot be overstated; the direct and indirect effects on the human vascular tree are the major source of morbidity and mortality in both type 1 and type 2 diabetes. Generally, the injurious effects of hyperglycemia are separated into macrovascular complications (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy) [10].

Considering the tremendous economic and the human costs associated with diabetes and dyslipidemia, public health intervention programmes aiming at preventing the diabetic related cardiovascular events need to be addressed. With the above considerations, we studied the biochemical parameters of the type 2 diabetic subjects in South Bangalore and co-related the same with clinical outcomes.

## 2. Materials and Methods

This study follows an observational study of 900 type 2 diabetic patients of both the genders, aged between 30 and 85 years, who were registered with three diabetic outpatient clinics in South Bangalore and selected through purposive random sampling method.

A well informed written consent form was obtained from all the patients and the institutional research ethics committee approved the protocol. Patients were excluded from the study if they were below 30 years or above 85 years of age, gestational diabetics and type 1 diabetic patients. Any seriously ill patient whose sensorium and higher functions were altered were also excluded from the study.

### 2.1 Assessment of Anthropometric Measurements

Patient demographics including age, age during diagnosis was noted along with family and smoking history and details of medications in a pre-tested interview schedule. Anthropometric assessment was made individually for all the selected patients with respect to height, weight and

waist to hip ratio measurements. Height and weight measured from the most recent clinic visit were obtained to calculate BMI in  $\text{kg}/\text{m}^2$ .

Based on the WHO guidelines, patients of either gender were classified as overweight if they had BMI between 25 to  $30 \text{ kg}/\text{m}^2$  and obese if the BMI was  $>30 \text{ kg}/\text{m}^2$ .

### 2.2 Laboratory Methods

The baseline biochemical parameters like fasting plasma glucose, post prandial plasma glucose and HbA1c (glycosylated haemoglobin) were obtained from the medical records along with the laboratory methods done for the same.

Plasma glucose estimations were performed by glucose oxidase peroxidase method. HbA1c level was known to be estimated by immunoturbidometric method. Fasting lipid profile was also recorded which was found to be determined through immunoturbidometric method. Urine for microalbuminuria and Albumin Creatinine Ratio (ACR) was quantitatively determined in undiluted urine by turbidimetric immunoassay method.

### 2.3 Analysis of data

Statistical Analysis through correlation was done using SPSS 17 version.

## 3. Results and Discussion

Age distributions of subjects selected for the study are categorized in Table 1.

A total of 900 type 2 diabetic subjects were studied, among whom 29.1 per cent fall between the age group of 50-59 and 27.2 per cent between 60-69 years of age. Around 19.7 per cent were found to have type 2 diabetes in the age range of 41-49 years, 12.5 per cent who were

**Table 1.** Age wise distribution of subjects (n=900)

Age in years	Number	%
30-40	113	12.56
41-49	178	19.78
50-59	262	29.11
60-69	245	27.22
70-79	92	10.22
80-85	10	1.11
Total	900	100

found to have diabetes between 30-40 years of age, 10.2 per cent between 70-79 years and only 1.11 per cent were above 80 years of age. This study results replicates the recent update given by the International Diabetes Federation (IDF) in which more than 382 million adults aged 20-79 years had diabetes in 2013 [11].

### 3.1 Body Mass Index (BMI)

Body Mass Index reflects the stage of obesity with respect to height and weight which is tabulated below.

Table 2 reveals that the prevalence of overweight (pre obese) was around 44 per cent whose BMI was between 25.1-29.9. Only 26.0 percent were found to have normal BMI between 18.5 & 24.9. It can be depicted from the study that 29.1 per cent were obese whose BMI ranged above or equal to 30.00. Obesity in type II diabetic patients is very common phenomenon and often termed as "Diabesity" [12]. Indians exhibit unique features of obesity: Excess body fat, abdominal adiposity, increased subcutaneous and intra-abdominal fat, and deposition of fat in ectopic sites (such as liver, muscle, and others). Obesity is a major driver for the widely prevalent metabolic syndrome and type-2 diabetes mellitus (T2DM) [13]. Similar prevalence was also noted in different studies [14].

## 3.2 Different Biochemical Parameters Evinces Clinical Outcomes

### 3.2.1 Fasting Plasma Glucose

The American Diabetes Association (ADA) has recognized the Fasting Plasma Glucose (FPG), instead of the 2-hour oral Glucose Tolerance Test (GTT), as the diagnostic test of choice [15]. The FPG is more consistent and reproducible than Postprandial Plasma Glucose (PPG) because there are more variables in the latter, such as timing and carbohydrate load [16]. The variables of food intake and exercise, for example, are much less of a factor at night preceding measurement of the FPG, and this may enable a more consistent pattern of values for FPG.

**Table 2.** Body Mass Index of the subjects (n=900)

BMI	Range	Number	%
Under weight	< 18.5	8	0.88
Normal range	18.5 - 24.99	234	26.00
Overweight:	> 25	658	73.11
Preobese	25.1 - 29.9	396	44.00
Obese	> 30	262	29.11

DeFronzo has noted that, in type 2 diabetic individuals, fasting glucose contributes approximately three-fourths and postprandial glucose approximately one-fourth of mean glycemia. Therefore, the phrase "fix the fasting first" has become an axiom of care for some practitioners [17].

It can be inferred from the Table 3 that 41.6 per cent of the selected diabetics' fasting blood sugars ranged between 131-200 mg/dl and was considered to be of average control in clinical parlance. Around 27.4 per cent of the samples maintained their FPG between 101-130 mg/dl, which was falling under accepted range. A significant number of diabetic populations of about 22.7 per cent had a very poor fasting range of > 201 mg/dl and only 8.1 per cent had a very good control of < 100 mg /dl of the fasting blood sugar.

### 3.2.2 Postprandial Plasma Glucose (PPG)

The word postprandial means after a meal; therefore, PPG concentrations refer to plasma glucose concentrations after eating. The magnitude and time of the peak plasma glucose concentration depend on a variety of factors, including the timing, quantity, and composition of the meal [18].

Table 4 clearly indicates that 40.7 per cent of the samples had postprandial plasma glucose ranging between 201-300 mg/dl, 28.7 per cent between 141-200 mg/dl, 21.2 per cent > 300 mg/dl reflecting poor control and surprisingly only 9.4 per cent recorded <140 mg/dl. It is reported in the guidelines for management of post meal

**Table 3.** Fasting Plasma Glucose values (n=900)

FPG (mg/dl)	number	%
<100	73	8.11
101-130	247	27.44
131-200	375	41.67
>201	205	22.78
Total	900	100

**Table 4.** Postprandial Plasma Glucose values (n=900)

PPG (mg/dl)	Number	%
<140	85	9.44
141-200	258	28.67
201-300	366	40.67
>301	191	21.22
Total	900	100

glucose that in a cross sectional study of 443 individuals with type 2 diabetes 71 per cent of those studied had mean two hour post meal plasma glucose of >252mg/dl which correlates with the present findings [19].

### 3.2.3 Glycosylated Hemoglobin

Table 5 depicts the values of glycosylated hemoglobin which is denoted as HbA1c

From table 5, it can be depicted that 35.5 per cent of the selected type 2 diabetics had a average control between 7.1-8 per cent. A significant (around 29 per cent) population was found to have poor glycemic control ranging between 8.1-10 per cent and with 24.4 per cent had between 6.1-7 per cent which reflects good glycemic control and 9 per cent of the samples fall under the uncontrolled range of > 10 .1 per cent. Only a bare minimum of 2 per cent of the population was under the 6 per cent category of very good glycemic control. Yaffe [20] points from his study that higher A1c levels are associated with lower cognitive function in individuals with diabetes. New clinical practice recommendations from the American Diabetes Association advocate the use of glycated hemoglobin, largely on the basis of the established association between glycated hemoglobin and microvascular disease [21]. Long-term prognostic data are also useful for informing diagnostic cutoff points for asymptomatic conditions, and there is evidence that elevated glycated hemoglobin values may be a risk factor for macrovascular disease [22].

### 3.2.4 Lipid Profile

Diabetic patients with accompanied (but often unnoticed) dyslipidemia are soft targets of cardiovascular deaths. Patients with type 2 diabetes often exhibit an atherogenic lipid profile, which greatly increases their risk of Cardiovascular Disorders (CVD) compared with people without diabetes [23].

**Table 5.** Glycosylated Hemoglobin values (n=900)

HbA1c (%)	Number	%
<6	18	2.00
6.1 - 7	220	24.44
7.1 - 8	320	35.56
8.1 - 10	260	28.89
>10.1	82	9.11
Total	900	100

From the Table 6 it is evident that 44 per cent of the diabetics had total cholesterol ranging between 151-200 mg/dl showing moderate level, 28.9 per cent had as high as >200 mg/dl indicating a risk factor for heart ailment and only 27.1 per cent samples maintained a safe level of <150 mg/dl.

It can be inferred from the above table that 67.2 per cent of the selected subjects maintained their triglycerides level below 150 mg/dl mark, whereas 17.4 per cent had between 151-200 mg/dl indicating high borderline and 15.3 per cent showed very high levels of above 200mg /dl.

Details on HDL-C levels were encouraging which was found that 55 per cent of the subjects had better HDL ranges between 40-60mg/dl, 41.4 per cent showed poor control of <40 mg /dl, and 3.6 per cent maintained the desirable range of >60 mg/dl .

**Table 6.** Lipid Profile values (n=900)

Sl No	Lipid Parameters (mg/dl)	n	%
1	Total Cholesterol (TC)		
	< 150	244	27.11
	151-200	396	44.00
	>201	260	28.89
2	Triglycerides (TGL)		
	<150	605	67.22
	151-200	157	17.44
	>201	138	15.33
3	High Density Lipoprotein (HDL)		
	< 40	373	41.40
	41-60	495	55.00
	>61	32	3.60
4	Low Density Lipoprotein Cholesterol (LDL -C)		
	<100	367	40.80
	101-200	525	58.30
	>201	8	0.90
5	Very Low Density Lipoprotein Cholesterol (VLDL -C)		
	<40	764	84.80
	41-80	122	13.60
	>81	14	1.60
6	Ratio		
	<4.4	526	58.44
	4.5-11	374	41.56
	Total	900	100.00

From the above table with regard to LDL –C levels it can be showed that 58.3 per cent had LDL ranging between 100-200 mg/dl falling under risk category for development of CVD, 40.8 per cent who had a desirable range below 100 mg/dl and 0.9 per cent of the type 2 diabetics whose LDL were dangerously high above 200 mg/dl highlighting immediate treatment.

Regarding VLDL–C it can be depicted that a majority of 84.8 per cent of the sample had a desirable levels of <40 mg/dl, 13.6 per cent between 41–80 mg/dl showing a poor level where the co morbidities related to diabetes are greater and 1.6 per cent had very poor levels of >80 mg/dl putting them in vulnerable category for development of CVD.

The above table on ratio shows that 58.4 per cent of the subjects had a desirable ratio below 4.4 and 41.6 per cent whose ratio was within 4.4 to 11.1 where emphasis should be given for a dietary and a lifestyle modification.

### 3.2.5 Urine Albumin Creatinine Ratio (UACR)

Microalbuminuria is defined as levels of albumin ranging from 30 to 300 mg in a 24-h urine collection. Overt albuminuria, macroalbuminuria, or proteinuria is defined as a urinary albumin excretion of  $\geq 300$  mg/24 h. Urinary albuminuria comprises 20–70% or urinary total protein excretion [24]. Clinical guidelines recommend regular screening for microalbuminuria because it is common, is known to be associated with adverse renal and cardiovascular outcomes. The Diabetes Control and Complications Trial (DCCT) demonstrated that hyperglycemia is a risk factor for developing microalbuminuria and that intensive diabetes therapy can prevent or delay the development of microalbuminuria [25].

Per cent distribution of samples based on UACR values (Table 7) shows that a majority of 70.8 per cent of the population had micro albuminuria indicating proteinuria and 17.7 per cent whose renal function were above 300 microgram /dl depicting underlying nephropathy condition and only 11.3 per cent of the diabetic samples had normal renal function. Varghese et al. [26] showed that

**Table 7.** UACR values

UACR ( $\mu\text{g}/\text{dl}$ )	Number	%
<30	102	11.33
30.1-300	638	70.89
$\geq 300.1$	160	17.78
Total	900	100

the overall prevalence of microalbuminuria was 36.3% in type2 diabetes mellitus at a diabetes centre in Southern India. Also work done by Maharjan [27] described that the overall prevalence of albuminuria in type2 diabetes in the study was high and there was significantly higher macroalbuminuria in Jyapu compared with Brahmin.

### 3.3 Correlation between BMI, Plasma Glucose and Lipid Parameters with HbA1c

The efficacy of HbA1c in detection of diabetes, it is an important marker to assess the microvascular complications and plasma glucose. The relationship between HbA1c and blood glucose is well documented in literature denoting a straight relationship (Table 8).

In this study, the role of Biochemical parameters like Glycosylated Hemoglobin, fasting plasma glucose, post-prandial plasma glucose, total cholesterol, triglycerides, low density lipoprotein, very low density lipoprotein and urine albumin creatinine ratio were found to be significant at one per cent level in the prediction of microvascular complications in diabetic populations since there was a significant association of all the biochemical parameters with HbA1c. It can be interpreted from the study that since HbA1c is positively associated with most of the biochemical parameters, controlling and keeping HbA1c within accepted range will lower the risk of developing diabetic related complications. The results of the study replicates the study done by Ghazhanfari et al. [28] for fasting blood sugars and Haddadinezhad and Ghazaleh [29] for postprandial blood sugars who showed a significant association with glycosylated hemoglobin levels. A

**Table 8.** Correlation between HbA1c and different biochemical parameters

Parameter	r	P-Value
BMI	-0.027	0.420
FPG	0.729	<0.001*
PPG	0.735	<0.001*
Total Cholesterol	0.162	<0.001*
TGL	0.199	<0.001*
HDL	0.019	0.563
LDL	0.105	0.002*
VLDL	0.172	<0.001*
UACR	0.192	<0.001*

\* Significance at one percent level.

significant correlation between HbA1c and serum lipid profile is in agreement with the reports of the study done by Ramona et al. [30]. Samatha et al. [31] has also reported a similar result.

## 4. Conclusion

The present study indicates the significance of estimating glycosylated haemoglobin levels. Controlling its level in blood will lower the risk in type 2 diabetics.

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