PATTERN OF BIOCHEMICAL PARAMETERS IN OBESE AND NON-OBESE TYPE II DIABETIC PATIENTS ATTENDING MEDICINE OUTDOOR OF A TEACHING HOSPITAL IN KOLKATA: AN OBSERVATIONAL STUDY

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Abstract:

Introduction: The diagnostic parameters of diabetes in obese and non obese individuals might not be always same because the physiological basis of developing diabetes in them is not similar.

Objectives: The present study has been done to assess any significant difference in the Clinical and Biochemical parameters of diabetes like Glycosylated Haemoglobin (HbA1C), Fasting and Post prandial Blood Sugar (FBS and PPBS) among obese and non obese Type II Diabetes patients.

Methodology: The present study was undertaken in the Medicine Outdoor of Calcutta National Medical College during June to August 2018 among 100 Type II Diabetes Mellitus patients of both sexes and aged 18 or above prior to an informed consent. Any significant difference in the Clinical and Biochemical parameters of diabetes among different groups of Diabetic patients as per BMI and waist circumference was assessed. Data was analyzed by standard statistical software like SPSS version 20 with proportion and percentage and using parametric and non-parametric tests like Chi-squares and ANNOVA.

Result: The study reveals that 30% of the study population has BMI 25-29.99 kg/m², 9% has 30-34.99 kg/m² and 3% have BMI between 35-39.99 kg/m² and 83.67% of Males and 96.07% of females have increased Waist Circumference. Complications like Diabetic Nephropathy, Retinopathy, Neuropathy and Foot ulcer etc was found in 61% of the study population. There is significant difference in mean values of Glycosylated Haemoglobin, fasting blood sugar and post prandial blood sugar in the different groups of BMI. 32.78% of patients with complications of Diabetes Mellitus have BMI>24.99 and this association is statistically significant.

Conclusion: The present study has found significant difference of the mean values of diagnostic parameters of diabetes in different groups according to Body Mass Index. However the study was performed with the population who were already on treatment for some duration, so there can be a variation of findings in the present study from other studies done in different settings like primary care hospitals or with patients at onset of diabetes.

Key words: Diabetes, Glycosylated Haemoglobin, Fasting blood sugar, Post prandial blood sugar

Introduction

Epidemiological transition, changes in lifestyle, greater life-expectancy and increasing stress has led to increase in the prevalence of non communicable diseases (NCDs) in both developed and developing countries. Developing countries are now in a stage to face the epidemics of Non-Communicable Diseases (NCDs) in the coming years ¹ Among the Non-Communicable Diseases India leads the world with largest number of Diabetic subjects earning the dubious distinction of being termed the “**diabetes capital of the world**”. According to the Diabetes Atlas 2006 published by the International Diabetes

Federation, the number of people with diabetes in India currently around 40.9 million is expected to rise to 69.9 million by 2025 and among those Type 2 diabetes accounts for more than 90%.²

Central obesity is an important risk factor for diabetes as it reduces number of Insulin Receptors on target cells. Health Ministry India has reduced the diagnostic cut-off of BMI in case of Diabetes as 23 kg/m² as overweight and 25 kg/m² as obese (as opposed to 25kg/m² and 30kg/m² at the International level). Also according to guidelines, cut-offs for Waist Circumference for Indian men will now be 90 cm as opposed to 102 cm globally and 80 cm for Indian women as opposed to 88 cm globally ³

As the physiological basis of developing diabetes in obese and non obese individuals is not always similar, the diagnostic parameters of diabetes in obese and non obese individuals might not be always same. There are some published studies in different settings showing that the diagnostic parameters in obese and non obese persons are not always same. In Indian setup also there are very few published studies⁽⁴⁻⁶⁾.

In this background the present study has been performed in the Medicine Outdoor of a teaching hospital to assess any significant difference in the Clinical and Biochemical parameters of diabetes like Glycosylated Haemoglobin (HbA1C), Fasting and Post prandial Blood Sugar (FBS and PPBS) among obese and non obese Type II Diabetes patients.

Though the study has been performed on a limited population, but if performed on a larger population or in the field setting it might give us an idea regarding modifications of the biochemical parameters among obese and non-obese Type II diabetic patients and to help develop an insight into the need for modifying management strategies in obese and non-obese Diabetes Mellitus patients in the context of prevention morbidity and mortality.

MATERIALS AND METHODS:

The present study was undertaken in the Medicine Outdoor of Calcutta National Medical College during June to August 2018. All the patients with Type II Diabetes Mellitus, attending the Medicine Outdoor of Calcutta National Medical College & Hospital during the study period were included as study population. Patients of both sexes aged 18 or above were included prior to an informed consent. BMI of all those patients were recorded and accordingly they were classified into different groups. The seriously ill or unconscious patients, patients suffering from acute myocardial infarction, renal failure, liver disease, tuberculosis, carcinoma or any severe infection and women with Gestational Diabetes Mellitus were excluded from the study.

From the previous hospital records of prior 2 years, it was found that the number of patients satisfying the above criterion attending the Medicine OPD in three months is approximately four hundred. Considering the feasibility, 25% of those patients, i.e. 100 were included in the study.

The study was conducted after obtaining necessary approval from the Institutional Ethics Committee, Calcutta National Medical College. Informed written

consent in vernacular was obtained from each patient before inclusion in the study. The consent form was also approved by Institutional Ethics Committee.

The study subjects were interviewed with a pre-designed, pre-tested, semi-structured schedule about some socio-demographic Factors like age, sex, residence, some life style and clinical factors related to diabetes like family history of diabetes, history of smoking and alcohol addiction, history of regularity of exercise and age of onset of diabetes. They were clinically examined for BMI and Waist circumference. Presence of any complication of diabetes was assessed with the guidance of doctors of Medicine Department, Calcutta National Medical College.

Biochemical examination of blood was done to assess Fasting and Post Prandial blood glucose, Glycosylated Haemoglobin, Serum Triglycerides, total Cholesterol and LDL, HDL, VLDL Cholesterol in the Biochemistry department of Calcutta National Medical College.

Fasting and Post-Prandial plasma glucose was determined by Glucose oxidase and peroxidase (GOD/POD) method (CREST biosystems)⁽⁷⁾. Glycosylated Haemoglobin was estimated by Micromat II (Biorad) instrument based on Boronate Affinity Chromatography⁽⁸⁾. Cholesterol was determined by CHOD/PAP method (Crest biosystems).^(7, 9) Triglycerides was determined by GPO/PAP method (Crest biosystems).^(7, 10) LDL was determined by ERBA diagnostics.⁽¹¹⁾ HDL is determined by PEG Precipitation method.^(7, 9, 12) VLDL was estimated from the levels of Total cholesterol and HDL and LDL cholesterol.

As per the results of above clinical and biochemical examination, the patients were grouped according to their BMI and waist-hip ratio. The cut-offs for Waist Circumference was taken as 90 cm for men and 80 cm for women³. The mean value of age of onset of diabetes, fasting and post prandial blood sugar and glycosylated haemoglobin was obtained and the distribution of these mean values were assessed among different groups of BMI. The study subjects were classified as hyperlipidemic if their Total Cholesterol was >200mg/dl, or LDL Cholesterol was >130 mg/dl, or HDL Cholesterol was <35 mg/dl, or Triglycerides was >150 mg/dl.¹³

Data was tabulated in MS Excel and analyzed by standard statistical software like SPSS version 20 with

proportion and percentage and using parametric and non-parametric tests like Chi-squares and ANNOVA.

RESULT

From the study, it was observed that 76% of the study population was above 50 years of age. 51% of them are female while 49% are male. Among study population in 38%, the age of onset of Diabetes Mellitus is between 46-55 years and in 77% the age of onset is below 55 years (Table 1). The study reveals that 30% of the study population has BMI 25-29.99 kg/m², 9% has 30-34.99 kg/m² and 3% have BMI between 35-39.99 kg/m² and 83.67% of Males and 96.07% of females have increased Waist Circumference (> 90 cm in males and >85 cm in females) (Table 1). Complications like Diabetic Nephropathy, Retinopathy, Neuropathy, Foot ulcer etc was found in 61% of the study population (Table 1). Among the biochemical examinations it was observed that 32% study subjects were hyperlipidemic, 75% of the study population has Glycosylated Haemoglobin (HbA_{1c}) values $\geq 6.5\%$. 64% have Fasting blood sugar >126 mg/dl and 63% have post prandial blood sugar ≥ 200 mg/dl (Table 1).

Table 1: Distribution of study population according to Age, Sex, Age of onset of diabetes, BMI, Increased waist circumference, Hyperlipidemia, Presence of complications and Biochemical parameters of diabetes. (n=100)

Variables	Frequency	Percentage
Age(year)		
31-40		
41-50	9	9
51-60	15	15
61-70	37	37
71-80	19	19
	20	20
Sex		
Male	49	49
Female	51	51
Age of onset(year)		
26-35	10	10
36-45	29	29
46-55	38	38
56-65	11	11
66-75	1	1
>75	11	11
BMI		
15-17.99	2	2
18-24.99	56	56
25-29.99	30	30
30-34.99	9	9
35-39.99	3	3
Increased Waist circumference(n=90)		
Male(n=49)	49	83.67
Female(n=51)		96.07

Complications Present	61	61
Complications Absent	39	39
Hyperlipidemia		
Hyperlipidemia Present	32	32
Hyperlipidemia Absent	68	68
HbA_{1c}		
<6.5%	25	25
$\geq 6.5\%$	75	75
FBS		
<126 mg/dl	36	36
≥ 126 mg/dl	64	64
PPBS		
<200 mg/dl	37	37
≥ 200 mg/dl	63	63

It has been found that mean age of onset of diabetes among the study population is 49.43 years and the mean age of onset were studied in different groups according to BMI and it was revealed that the difference in mean age of onset in these groups was not statistically significant as tested by Annova(p=0.923)

(Table 2). The study also assessed the mean value of Glycosylated Haemoglobin, Fasting blood sugar and Post prandial blood sugar in different groups of BMI. It was found that difference in mean values of Glycosylated Haemoglobin in the different groups of BMI was statistically significant with p=0.012 (Table 2). Significant statistical association was also observed in the difference in mean value of fasting blood sugar with p=0.014 and of post prandial blood sugar with p=0.027 (Table 2).

Table 2: DISTRIBUTION OF STUDY POPULATION ACCORDING TO DISTRIBUTION OF MEAN HbA_{1c}, FBS, PPBS AMONG DIFFERENT GROUPS OF BODY MASS INDEX (BMI) N=100

Body Mass Index (BMI)	MEAN AGE OF ONSET(year)	MEAN VALUE OF HbA _{1c}	MEAN VALUE OF FBS	MEAN VALUE OF PPBS
15-17.99 (n=2)	41.50 $\pm$ 6.364	6.10 $\pm$ 0.70	91.00 $\pm$ 19.799	125.00 $\pm$ 21.213
18-24.99 (n=56)	49.21 $\pm$ 13.602	6.83 $\pm$ 1.24	126.27 $\pm$ 35.243	195.41 $\pm$ 62.126
25-29.99 (n=30)	50.27 $\pm$ 13.635	7.17 $\pm$ 0.726	138.60 $\pm$ 43.287	210.83 $\pm$ 58.109
30-34.99 (n=9)	50.44 $\pm$ 17.372	7.72 $\pm$ 0.664	138.89 $\pm$ 34.130	227.67 $\pm$ 55.767
35-39.99 (n=3)	47.33 $\pm$ 5.508	8.46 $\pm$ 0.404	197.00 $\pm$ 67.506	278.00 $\pm$ 79.674

Complications like Diabetic Nephropathy, Retinopathy, Neuropathy, Foot ulcer etc was found in 61% of the study population and 32.78% of patients with complications of Diabetes Mellitus have

BMI>24.99 and the association of BMI with presence of complications in Diabetes Mellitus is statistically significant ($p=0.003$) (Table 3). The study has observed that 43.75% of the Hyperlipidemic patients have complications due to Diabetes Mellitus and this association is statistically significant ($p=0.015$) (Table 3).

Table 3: DISTRIBUTION OF STUDY POPULATION ACCORDING TO PRESENCE OF COMPLICATIONS OF DIABETES MELLITUS WITH BMI AND HYPERLIPIDEMIA

VARIABLE	COMPLICATIONS OF DIABETES MELLITUS		Chi-square	p value
HYPERLIPIDEMIA				
	Present	Absent		
Present(n=32)	(n=61)	(n=39)	5.886;d.f=1	0.015
	14(43.75)	18(56.25)		
Absent(n=68)	47(69)	21(31)		
BMI				
15-17.99(n=2)	2(3.2)	0	15.673 ;	0.003
18-24.99(n=56)	39(63.9)	17(43.6)	d.f=4	
25-29.99(n=30)	10(16.5)	20(51.3)		
30-34.99(n=9)	7(11.5)	2(5.1)		
35-39.99(n=3)	3(4.9)	0		

In the present study, it has been observed that 83.67% of Males and 96.07% of females have increased Waist Circumference (> 90 cm in males and >85 cm in females) but the correlation of Waist Circumference with Glycosylated Haemoglobin (HbA_{1c}) [$p=0.065$], Fasting Blood Sugar [$p=0.984$] and Post Prandial Blood Sugar [$p=0.708$] is not statistically significant (Table 4).

Table 4: ESTIMATION OF CORRELATION OF WAIST CRICUMFERENCE WITH HbA_{1c}, FASTING BLOOD SUGAR, POST PRANDIAL BLOOD SUGAR

N=100

WAIST CIRCUMFERENCE	PEARSON CORRELATION	p value
HbA _{1c}	0.186	0.065
FBS	0.002	0.984
PPBS	0.038	0.708

DISCUSSIONS:

In the present study, 100 Type 2 Diabetic patients with history of IHD were interviewed, clinically examined and tested for biochemical profile. The patients were physically examined for estimation of BMI and waist circumference and the biochemical profile included are Glycosylated Haemoglobin (HbA_{1c}), Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS) and Lipid profile. From the study, it was observed that 76% of the study population was

above 50 years of age. 51% of them are female while 49% are male. In the study performed by Patil SP. et al the mean age of men was observed to be 59 years while that of females was 56 years.⁽³⁾ While in the study performed by K.Murugan subjects belonging to age group 30-70 years were included.⁽¹⁴⁾ 56%, 42% and 42% of the study population has family history of Obesity, Diabetes and Ischemic Heart Disease respectively. Among the study population, 43% and 33% of the study population has addiction for smoking and alcohol, while only 13%, 20%, 6% and 20% has regular habit of Brisk Walking, Jogging, Cycling and Domestic Work respectively.

It was observed that 30% of the study population has BMI 25-29.99 kg/m², 9% has 30-34.99 kg/m² and 3% have BMI between 35-39.99 kg/ m². In the study done by Patil SP. et al, 19% of the population were between 18-22.9, 58% between 23-24.9% and 23% above 25.⁽³⁾ In this study, both diabetic and non diabetic patients were included and as Type 2 diabetes has a strong association with obesity, this might be a cause for this difference. No significant statistical association was found in the mean age of onset in different groups according to BMI. In the study done by Hillier TA, Pedula KL⁽¹⁵⁾ it was observed that the more obese patients had an earlier onset of diabetes and they found this association to be statistically significant. The present study has been performed in a developing country with patients of lower socio-economic groups, there might have been delay in diagnosis after onset and hence when compared to the study⁽¹⁵⁾ which was done in a developed country where there is no such delay in diagnosis after the onset and this difference in study setting might be a cause for this difference.

Significant statistical association was found in the distribution of mean Glycosylated Haemoglobin, Fasting blood sugar and post prandial blood sugar in different groups of BMI. This finding was supported by the study done by AL-Auqbi TF, Mustafa MA et al⁽¹⁶⁾, where a strong positive correlation exists between the BMI and biochemical parameters like fasting blood Sugar (FBS) and mean values of HbA_{1c} with the coefficient correlation $r=0.866$. Similarly in various studies, done in different settings^(3,14,17-20), a significant positive correlation has been observed between BMI and biochemical parameters like HbA_{1c}, Fasting Blood Sugar and Post Prandial Blood Sugar.

In certain other studies, notably by Anwar Basha Dudekula ⁽²¹⁾, and V.Mohan et al ⁽²²⁾ it has been demonstrated that the Fasting, Post Prandial Blood Sugar and Glycosylated Haemoglobin are higher among the lean diabetics than among the obese. This is contradictory to the findings of the present study where the lean diabetics have better glycaemic control than overweight and obese groups. The reason for poor glycemic control among the lean diabetics in the study by Anwar Basha Dudekula ⁽²¹⁾ might be that the lean diabetics were treated with Oral Hypoglycemic Agents (OHA). According to studies conducted by Yajnik et al ⁽²³⁾ there can be secondary failure to OHA in lean diabetics which is related to decreased insulin secretion. In the present study, all the study subjects were already on treatment in a tertiary care hospital, with both Insulin and OHA, as per requirement. Due to higher costs of OHA and a better supply of insulin in the hospital and its cheap availability, insulin is the preferred mode of treatment in majority of these subjects. Hence, secondary failure is reduced in these subjects and obesity is the principal factor for insulin resistance and elevated biochemical parameters of glycemic control and this might be the cause of contradictory findings in the levels of Biochemical parameters found in those studies ⁽²¹⁾.

Mohan et al ⁽²²⁾, performed the study on the patients at the time of first registration at their centre before optimal regulation of diabetes had been achieved. Therefore, the patients classified as lean in their study might have had weight loss due to poor initial glycemic control. Similarly, the patients classified as obese might have better glycemic control as reflected in low level of HbA1c (which indicates the long term control of diabetes) in them. As in the study ⁽²²⁾ the follow up of the biochemical parameters after initiation of the treatment was not done, so it could not be commented whether the increased levels of parameters of glycemic control would be reversed after treatment or not.

The present study revealed significant statistical association of BMI with presence of complications in Diabetes Mellitus ($p=0.003$). In the study by Jumah NA, Al-Hajeri SS, Al-Al KA, Ismaiel AE, Kamel MI 31.2% of subjects had Cardiovascular complications, 11.5% nephropathy, 32.4% from peripheral neuropathy, 32.1% in retinopathy and 43.6% vascular limb complications ⁽²⁴⁾. This study has observed a relatively less number of complications

among the study populations as they have performed the study in a Primary health care setting and the present study has been done in a tertiary care hospital. The study has observed that 43.75% of the Hyperlipidemic patients have complications due to Diabetes Mellitus and this association is statistically significant.

In the present study, it has been observed that the correlation of Waist Circumference with Glycosylated Haemoglobin (HbA_{1c}) [$p=0.065$], Fasting Blood Sugar [$p=0.984$] and Post Prandial Blood Sugar [$p=0.708$] is not statistically significant. In the study done by Smita et al ⁽³⁾, it was found that a positive statistically significant correlation existed between Fasting Blood Glucose and Waist Circumference ($p<0.01$). That study was performed on both diabetics and non-diabetics and this difference in study design might be the cause of the variation. Similarly difference in study setting might be the cause of different result when compared to the study done by Gupta R, Rastogi P ⁽²⁰⁾.

CONCLUSIONS:

The present study has found significant difference of the mean values of glycosylated haemoglobin, fasting blood sugar and post prandial blood sugar in different groups according to Body Mass Index but no significant correlation of those parameters with waist circumference was found in the study.

Presence of complications due to diabetes is also significantly associated with different groups according to BMI and with presence of hyperlipidemia.

However the study was performed in a tertiary care hospital with the population who were already on treatment for some duration, so there can be a variation of findings in the present study from other studies done in different settings like primary care hospitals or with patients at onset of diabetes

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