RESEARCH ARTICLE

LEVEL OF GLYCAEMIC CONTROL IN TYPE 2 DIABETES MELLITUS IN BAREILLY REGION (INDIA)

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ABSTRACT

Background: Diabetes mellitus has emerged as a major health care problem of India. The real burden of diabetes is due to its associated complications which lead to increased morbidity and mortality. An accurate diagnosis of diabetes and level of glycaemic control in known diabetics is recommended for the treatment and prevention of complication in the population.

Aims & Objective: To identify the pattern of glycaemic control in type 2 diabetes mellitus using glycosylated haemoglobin (HbA1C) in Bareilly region, India.

Material and Methods: The present cross sectional study was conducted in one of the tertiary care hospital of Bareilly district. The respondents were the 1000 type 2 diabetics of 35 to 60 years of age group. Glycosylated haemoglobin A1C (HbA1C) was done in all subjects by ion exchange chromatography and results were categorized as normal, good, average and poor diabetes control. The statistical analysis was Analysis of variance (ANOVA) using SPSS software.

Results: Out of 1000 individuals, 120 had good, 469 had fair and 411 had poor glycaemic control on the basis of their HbA1C status. Age was similar for all 3 groups and was insignificantly related to glycaemic control (p-0.663). Out of 1000 individuals, 703(70.30%) had normal BMI while 297 (29.7%) were overweight.

Conclusion: Measurement of glycosylated haemoglobin levels should be used in monitoring the treatment and long term glycaemic control of diabetes in a population and the assessment of body mass index should be done for the need of life style intervention in a population.

KEY-WORDS: Type 2 Diabetes Mellitus; Glycosylated Haemoglobin A1C (HbA1C); Glycaemic Control; Body Mass Index (BMI)

Introduction

Type 2 diabetes mellitus is characterized by high blood glucose in the context of insulin resistance and relative insulin deficiency.[1] The World Health Organization definition of diabetes mellitus (both type 1 and type 2) is for a single raised glucose reading with symptoms, otherwise raised values on two occasions, of either[2]: fasting plasma glucose ≥ 7.0 mmol/L (126 mg/dl) or with a glucose tolerance test, two hours after the oral dose a plasma glucose ≥ 11.1 mmol/L (200 mg/dL). A random blood sugar of greater than 11.1 mmol/L (200 mg/dL) in association with typical symptoms[3] or a glycated haemoglobin (HbA1C) of greater than 6.5% is another method of diagnosing diabetes[4]. In 2009 an International Expert Committee that included representatives of the American Diabetes Association (ADA), the International Diabetes Federation (IDF), and the European Association for the Study of Diabetes (EASD) recommended that a threshold of ≥6.5% HbA1C should be used to diagnose diabetes. This recommendation was adopted by the American Diabetes Association in 2010.[5] Positive tests have to repeated unless the person presents with typical symptoms and blood sugars >11.1 mmol/L (>200 mg/dL).[6]

According to WHO regional office for south-east Asia, the percentage of diabetic in urban areas will increase from 54% in 1995 to 73% by the year 2025.The risk of complications are also on a rise, so it is important to intervene at right time to decrease the associated morbidity.[7] According to WHO, the estimation of fasting blood glucose is the highly effective method for diagnosing diabetes mellitus. Measurements of fasting blood glucose levels provide a short-term picture of control. When plasma glucose is consistently

elevated, there is an increase in non-enzymatic glycosylation of haemoglobin, and this alteration reflects glycaemic control of the past 2-3 months as red blood cells have a lifespan of 120 days. Thus, glycosylated haemoglobin levels are used to diagnose diabetes mellitus.[8] The correlation of development and progression of the microvascular and neuropathic complications of diabetes was proved in the diabetes control and complications trial (DCCT)[9] for type1 diabetes as well as in the Pima Indian and Japanese[10] populations for type 2 diabetes. There is a need of population based awareness and screening programs to identify and treatment of diabetes and its complications. The present study had been conducted with the objective to identify the pattern of glycaemic control using glycosylated haemoglobin in type 2 diabetics attending the tertiary care centre in Bareilly region of Uttar Pradesh (India), as no such study is available in context of Bareilly region.

Materials and Methods

The present study was done in tertiary care centre of Bareilly region of Uttar Pradesh (India) in 1000 type 2 diabetics (newly diagnosed as well as previously diagnosed) of 35 to 60 years of age group with ethical approval from institute ethical committee and informed consent with each subject between year 2009 to 2010. Type 1 diabetics, pregnant and lactating females were excluded from study. All subjects were verified for diabetic status and duration since diagnosis through their previous record. Each patient was subjected to routine blood investigation, random blood sugar, serum creatinine, serum urea and glycosylated haemoglobin A1C (HbA1C). Fasting blood sugar and lipid profile was done in selected cases that came with minimum eight hours of fasting.

Glycosylated haemoglobin A1C (HbA1C) was done in all subjects by ion exchange chromatography, the method described by Cohen et al.[11] Intravenous blood was drawn from ante-cubital fossa of the patient and stored in EDTA coated vials. The sample was sent for estimation of HbA1C. A simple three step procedure was followed. Step A: 50µl of blood sample was added in 250µl of lysing agent and properly mixed for 1-2 minutes till lysis was evident. Later, this hemolysate was allowed to stand for 5 minutes. Step B: 100 µl of hemolysate obtained from step A was added to the ion exchange resin tube (R1). Resin separator (R3) was then inserted to the point it was above the level of resin suspension liquid (R1). The tube was kept on vortex mixer for 5 minutes. After vortexing, tube was allowed to stand for a minute and resin separator (R3) was pushed until the resin was firmly packed at the bottom of the tube (R1). The supernatant thus collected in resin separator (R3), was transferred and its absorbance was compared with absorbance of distilled water at 460 nm. Step C: To calculate total haemoglobin fraction, 20µl of hemolysate from step A was added in 5 ml of distilled water and its absorbance was read against the absorbance of distilled water. Final calculation of glycosylated haemoglobin percentage (GHb %) was calculated by,

$$\textbf{GHb } \% = \frac{\textbf{Glycosylated Hb} \times \textbf{4.61 (Assay Factor)}}{\textbf{Total Haemoglobin}}$$

By the values of GHb %, corresponding value of HbA1C was calculated by the table provided with test kit.

According to Laboratory Evaluation of Diabetes Control (American Diabetes Association Guidelines) for HbA1C, the population were categorized[12] as normal (4-6%), good diabetes control (<7%), average diabetes control (7-8%) and poor diabetes control (>8%).

Data Analysis

The data was computerized in specific programme developed on Microsoft excel 2007 software and it was analyzed with the help of SPSS statistical software and the results were transferred to predesigned classified tables prepared according to the aims and objective of the study and the inferences were drawn and the results were discussed studies. Analysis of Variance test was applied as a test of significance. Level of significance was taken as 0.05.

Results

The present study was done in tertiary care centre of Bareilly region of Uttar Pradesh (India) in 1000

type 2 diabetics of 35 to 60 years of age group with ethical approval from institute ethical committee and informed consent with each subject between years 2009 to 2010. The present epidemiological study of 1000 type 2 diabetic had 477 males and 523 females. 360 (36%) patients had less than 5 years and 640(64%) had more than 5 years of duration of diabetes mellitus since diagnosis.

Out of 1000 individuals, 120 had good, 469 had fair and 411 had poor glycaemic control on the basis of their HbA1C status. Age was similar for all 3 groups and was insignificantly related to glycaemic control (p-0.663). Male to female ratio in good glycaemic control group was 65:55, in average glycaemic control group was 251:218 and in poor glycaemic control group was 207:204. Thus, gender was found to be insignificantly related to glycaemic status (p-0.588). (Table 1)

Out of 1000 individuals, 703 (70.30%) had normal BMI while 297 (29.7%) were overweight. In good glycaemic control group 64.2% had normal BMI, in average glycaemic control group 69.9% had normal BMI and in poor glycaemic control group 72.5% had normal BMI. Thus, BMI was insignificantly related to glycaemic control (p-0.207). (Table 2)

Table-1: Demographic Characteristics of the Population under Study

Variable	Good Control (n=120)	Fair Control (n=469)	Poor Control (n=411)	Statistical Significance	
				X^2/F	p
Age (Mean ± SD)	42.58 ± 6.06	43.15 ± 6.43	43.15 ± 6.45	0.411	0.663
Gender Male/Female	65/55	251/218	207/204	1.063	0.588

Table-2: Categorization of Glycaemic Control with BMI

BMI	Good Control (n=120) N (%)	Fair Control (n=469) N (%)	Poor Control (n=411) N (%)
18.5 – 24.9	77 (64.2)	328 (69.9)	298 (72.5)
>25	43 (35.8)	141 (30.1)	113 (27.5)

Discussion

The prevalence of diabetes is rapidly rising in the world at an alarming rate.[13] The International Diabetes Federation (IDF) estimates that the total number of diabetic subjects in India will rise to 69.9 million by the year 2025.[14] Chronic course and poor glycaemic control in diabetes mellitus lead to secondary complications such as coronary artery disease, neuropathy, nephropathy, retinopathy, hypertension, and diabetic foot as a result of persistent hyperglycaemia. The surveillance of glycaemic control in diabetes has improved to a great extent after the introduction of measurement of HbA1C level. Measurement of HbA1C is utilized safely as diagnostic tool and can be a great help in therapeutic management of the diabetic patients. The study conducted in Malaysia suggested that an HbA1C value of 6.5% is an adequate marker to diagnose diabetes because of its high specificity. A borderline (5.6-6.4%) or high (≥ 6.5%) level of HbA1C strongly predicted future pharmacotherapy for diabetes.[15] The other important study suggested that HbA1C is not only important for diagnosis but it is also as an effective marker indicating the need for acute intervention.[16]

The present study had shown that out of 1000 type 2 diabetics, 120 had good, 469 had fair and 411 had poor glycaemic control on the basis of their HbA1C status. This suggests that about half of type 2 diabetics were not taking adequate dietary measure or life style interventions or drug therapy in this region. There should be community based program especially for rural Indian about the awareness of diabetes. Out of 1000 individuals, 703 (70.30%) had normal BMI while 297 (29.7%) were overweight. The data suggest that about 30% of type 2 diabetics need urgent life style intervention as obesity is an important modifiable risk factor for type 2 diabetes[17] and associated with poor control of blood glucose, blood pressure and cholesterol leading to higher risk for both cardiovascular and microvascular disease[18]. Obesity is commonly present in of type 2 diabetes patients attending a diabetes clinic. This is similar to the association between obesity and diabetes shown in other studies.[19,20] Several prospective studies have shown that measures of lifestyle modification help in preventing the onset of diabetes. The Indian Diabetes Prevention Program (IDPP), a preventive study done in India based has clearly documented the importance of physical activity in the prevention of diabetes.[21]

There are certain limitations that may have influenced the outcomes of the whole study. HbA1C levels may vary with some intrinsic or extrinsic factors. Iron deficiency anaemia may lead to rises in the levels of HbA1C which is reversible on treatment with iron. Another factor which may alter the levels of HbA1C is a high dose of aspirin, which can falsely raise HbA1C due to formation of acetylated haemoglobin. Disorders like renal failure, haemoglobinopathies (like sickle cell anaemia, spherocytosis etc.) may also give false value of HbA1C.[22] The study population involved patients who reached hospital. There is a need of door to door epidemiological study to know the actual status of the diabetes in Bareilly population.

Conclusion

The findings from this study provide further evidence for HbA1C as an indicator of future health. Measurement of glycosylated hemoglobin levels should be used in monitoring the treatment and long term glycaemic control of diabetes in a population .The assessment of body mass index should be done for the need of life style intervention in a population.

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