

Comparison between Fasting Plasma Glucose and HbA1c in Glycemic Control of Type-2 Diabetic Patients

Israa Anwer Mohammed Jumaah

Medical Lab. Techniques Department /Technical College -Kirkuk

mezoosraa@gmail.com

Abstract

Glycosylated hemoglobin (HbA1c) in diabetic patients reflects the average blood glucose level, and will not be affected by variability in blood glucose in short time.

The aim of the study is to compare between fasting plasma glucose and HbA1c in determining the glycemic control and estimate blood pressure, body mass index(BMI),serum cholesterol and triglyceride in type 2 diabetic patients .

The study was carried out during the period from 1st July to 31st September 2014 in Kirkuk Azadi teaching Hospital . The study included 75 samples of type 2 diabetic patients their ages 21-71 years old were taken randomly and 40 samples of control subjects.The type 2 diabetes mellitus were diagnosed based on the family history and clinical examination of the patient . 4 ml of fasting venous blood samples were collected from each diabetic patients and control group. Serum glucose, cholesterol and triglyceride were determined by enzymatic method and HbA_{1c} was determined by quantitative colorimetric of glycohaemoglobin in whole blood measured spectrophotometrically .

The results showed the higher incidence of diabetic patients in female(82.6%) than male (17.4%) . The result illustrate the high occurrence of type 2 diabetes at age 61-70 and 51-60 years which recorded 22.6% and 21.3% in female group while in male group the higher incidence at age 51-60years followed by 41-50 years old with percentage 9.3%, 5.3% respectively . Statistical analysis showed significant increase in systolic pressure($p<0.05$) in diabetic patients . 38.6% of diabetic patients have overweight followed 32%are obese class-1-while only 4.6% have normal weight . Also the result showed increase in mean value of serum cholesterol and triglyceride which recorded 210 mg/dl and 176.5 mg /dl respectively compared to control group($p<0.01$) . 9.3% of diabetic patients have polycystic ovary and 17.3% of them have family history of diabetes .The present study revealed increase in fasting plasma sugar concentration (273.3mg/dl) and (HbA_{1c} 8.9%) in diabetic group compared to control group ($p<0.001$) .The sensitivity and specificity and positive predictive value of HbA_{1c} was reported 82%, 54% and 89% respectively. According to WHO classification of HbA_{1c} in diabetic patients , the results indicated 73.3% of diabetic patients were poor control ,17.3% fair control and 9.3% were good control .

Conclusion:. HbA_{1c} is not recommended as a diagnostic or a screening test while it is considered a marker of evaluation of long-term glycemic control in diabetic patients and predict risks for the development and progression of diabetic complications.

Keywords: Diabetes mellitus, Glycaemic Control, HbA_{1c}, fasting blood sugar.

الخلاصة

اختبار خضاب الدم السكري التراكمي (الهيموغلوبين الغلوكوزي) في مرضى السكري يعكس متوسط مستوى السكر في الدم، ولن يتأثر التباين في مستوى السكر في الدم في وقت قصير .

الهدف من هذه الدراسة هو المقارنة بين كلوكوز الدم الصيامي واختبار خضاب الدم السكري (HbA_{1c}) في تقدير الضبط السكري وتحديد ضغط الدم ومعامل كتلة الجسم والكوليسترول والدهون الثلاثية في مرضى النوع 2 من داء السكري.

أجريت الدراسة خلال الفترة من 1 يوليو - 31 سبتمبر 2014 في مستشفى آزادي التعليمي/ كركوك . شملت الدراسة (75) عينة من مرضى النوع 2 من داء السكري بأعمار تتراوح بين (21- 71) سنة والتي أخذت عشوائيا و 40 عينة من مجموعة السيطرة وتم تشخيص المرض على أساس الفحص السريري وتاريخ عائلي للمريض. أخذت عينة مقدارها 4 مل من الدم الوريدي من كل فرد في مجموعة المرض السكري والسيطرة. تم تحديد مصل الجلوكوز والكوليسترول والدهون الثلاثية بالطريقة الأنزيمية وتم تحديد نسبة HbA_{1c} في الدم الكامل بطريقة التحليل اللوني الكمي لهيموكلوبين السكري باستخدام التحليل الطيفي.

أظهرت النتائج ارتفاع النوع الثاني من الداء السكري في الإناث بنسبة (82.6%) مقارنة بالذكور (17.4%). تبين أن نسبة حدوث داء السكري في الإناث كانت أكبر في الفئة العمرية 61- 70 سنة تلتها الفئة العمرية 51- 60 سنة بنسبة (22.6% و 21.3%) على التوالي اما في الذكور فكانت النسبة أكبر في الفئة العمرية 51- 60 سنة تلتها الفئة العمرية 41- 50 سنة بنسبة

(9.3% و 5.3%) على التوالي. أظهر التحليل الإحصائي فرقا معنويا في ضغط الدم العالي فقط ($p < 0.05$) في مرضى السكري. 38.6% من مرضى السكري كانت لديهم زيادة في الوزن و 32% منهم يعانون من السمنة المفرطة من الدرجة الاولى في حين سجل الوزن الطبيعي 4.6 % فقط. كما أظهرت النتائج ارتفاعا معنويا في تركيز الكوليسترول في الدم والدهون الثلاثية والتي سجلت (210mg/dl و 176.5) على التوالي مقارنة بمجموعة السيطرة ($p < 0.01$). 9.3 % من اناث مرضى السكري لديهم تكيس المبايض و (17.3 %) منهم (ذكور واناث) لديهم تاريخ عائلي في مرض السكري. أظهرت الدراسة زيادة في تركيز سكر الدم الصيامي (273 mg/dl) وخضاب الدم السكري (8.9 %) في مجموعة مرضى السكري مقارنة بمجموعة السيطرة وبفرق معنوي ($p < 0.001$). سجلت الحساسية والخصوصية والقيمة التنبؤية الإيجابية في نسبة HbA1c فكانت 82%، 54% و 89% على التوالي. ووفقا لمنظمة الصحة العالمية لتقدير نسبة HbA1c في مرضى السكري سجلت لدينا 73.3% من المرضى السكري ضعف السيطرة ، والسيطرة المتوسطة 17.3% و 9.3% كانت سيطرة جيدة .

الاستنتاج: لا يوصى بفحص HbA1c في تشخيص داء السكري من النوع الثاني في حين يعتبر علامة لتقييم نسبة السكر في الدم على المدى الطويل في مرضى السكري بصورة دقيقة والتنبؤ بمخاطر مرض السكري ومضاعفاته. الكلمات المفتاحية: داء السكري، الضبط الكلوكوزي، خضاب الدم السكري ، سكر الدم الصيامي .

Introduction

Diabetes mellitus is a metabolic diseases characterized by high blood glucose level which is a result of a defects in insulin secretion, insulin action, or both. About 5% of all deaths around the world caused by diabetes. hyperglycemia results in this condition due to relative ineffective insulin . The chronic hyperglycemia of diabetes affect multiple organs resulting in long-term damage, dysfunction, and organs failure in which diabetic retinopathy and nephropathy (retina of the eyes and nephrons of the kidney) are most important and known complications , in addition to the effect on nerves, heart, and blood vessels (Vinod Mahato,2011) . The prevalence of diabetes mellitus around the world was estimated at 150 millions in 1995, and this is subjected to increase to 300 millions by 2025 (Adegate,2006) . Diabetes mellitus is a multifactorial disease in which the genetic in addition environmental and lifestyle factors (overweight, abdominal obesity and decrease physical activity) play an important factors in the development of the disease (Stumvoll,et al.2005).

Control of blood glucose level in diabetic patients is an important aspect in the management to prevent acute or chronic complications. Randomized and prospective clinical trials in type 1 and 2 diabetes have clearly shown that controlling or reducing hyperglycemia significantly decrease the microvascular complications of diabetes. There is 37% decrease in the risk of microvascular complications for each 1% reduction in haemoglobin A1c and 21% decrease in the risk of death or end point related to diabetes for each 1% reduction in HbA1c (Stratton,2000 and Rosediani,2006.,).

HbA1c test is commonly used to measure chronic hyperglycemia is. However, in some clinical conditions affect red cell life span or hemoglobinopathies can affect the result of the test and provide unreliable information . A straight relationship between HbA1c and blood glucose has been showed by many reports documented in the literature denoting (Mohammadi,2001., Rohlfing,2002., and Ghazanfari,2010.,) . However, this relationship has not been confirmed by others (Derakhshan,2001.,).The American Diabetes Association (ADA) started to make treatment recommendations based on HbA1C following publication of the results of the diabetes control and complication trial (DCCT) in the 1990s, the HbA1C has become the gold standard for the therapeutic management of diabetes mellitus in research and in the Clinical Setting American Society Of Health-System Pharmacist,2003) . The question is whether FBS or HbA1c is a better predictor of glycemic control . The aim of the present study is to compare between HbA1c and FBS in determining the glycemic

control and estimate blood pressure ,BMI, serum cholesterol, triglyceride in type 2 Diabetic patients.

Materials &Methods

The collection of samples was conducted during the period from 1st July to 31st September 2014 in Kirkuk Azadi Teaching Hospital .Out of 75 patients type 2 diabetes mellitus with age range 20 to 72 years old were taken randomly , 62 of them were females and 13 of them were males .The samples selected were based on the history, clinical examination and questionnaire form. 4 ml of fasting venous blood samples were collected from each diabetic patient and control subject which consist of 40 healthy volunteers (24 females,16 males) with age range (20-70 years old). All volunteers were healthy and symptoms were free with no history of systemic diseases. Family history of them were normal.The blood samples were drawn via the needle of syringe with tourniquet and 2 ml of them were put in EDTA tube to assess HbA_{1C} and other 2 ml were put in serum tube and serum was separated to assess fasting blood sugar ,cholesterol and triglyceride. Serum cholesterol and triglyceride were estimated by enzymatic method (Tietz,1995) ,glucose was determined by (Teuscher,1971) and HbA_{1C} was determined by quantitative colorimetric of glycohaemoglobin in whole blood (Gabbay,1977).

Desirable cut-off points

According to WHO values An HbA_{1c} of 6.5% is recommended as the cut point for diagnosing diabetes. A value of less than 6.5% does not exclude diabetes diagnosed using glucose tests. (WHO,2011)

The WHO/ISH definition of arterial hypertension was used in this study: systolic blood pressure (SBP) $\geq$ 140 mmHg and/or a diastolic blood pressure (DBP) $\geq$ 90 mmHg (Guidelines Sub Committee,1999)

Questionnaire form and other measurements

Questionnaire form includes sex ,age ,family history of diabetes , blood pressure measurement for each patient as well as weight ,length were measured to calculate BMI .

Statistical analysis

Data were reported as proportions (%) for categorical variables and mean $\pm$ SD values. Comparisons of means between groups were made using the student t-test . A P value of ($p < 0.05$) was considered investigative of a statistically significant difference . the measured parameters were calculated using Microsoft Excell 2007 program.

Results

The result showed relationship of diabetes mellitus regarding to gender with high incidence in females which reveals (62) patients with percentage 82.6% in compare to males which recorded 13 patients with 17.3%(Table 1).

Table - 1- Association between type 2 diabetic patients and gender

Sex	no .of diabetic patients=75	%
Female	62	82.6
Male	13	17.3

The study showed distribution of diabetes mellitus regarding to age with high incidence in ages 61-70 followed 51-60 and 41-50 years in female group which recorded 22.6%,21.3% and 20% respectively ,while in male group the high occurrence at age (51-60) and (41-50)years with percentage (9.3%,5.3%) respectively. Table(2)

Table -2 -Distribution of diabetes mellitus according to age

Ages years	no. of patients(DM)=62 female	%	no of patients(DM)=13 male	%
21-30	3	4	1	1.3
31-40	7	9.3		
41-50	15	20	4	5.3
51-60	16	21.3	7	9.3
61-70	17	22.6	1	1.3
>71	4	5.3		

no: number DM: diabetes mellitus

The study demonstrated the relationship between systolic and diastolic pressure in diabetic mellitus patients that revealed increase in systolic and diastolic pressure in diabetic patients which recorded (136.4) and (84) compared to control group which reported (127.5) and (81.6) respectively, statistical analysis showed significant increase in systolic pressure. Table(3)

Table -3 -Relationship between diabetes mellitus and systolic , diastolic pressure

Parameter	DM Means $\pm$ SD mmHg	Control means $\pm$ SD mmHg
Systolic pressure	136.4 $\pm$ 17.6*	127.5 $\pm$ 7.4
Diastolic pressure	84 $\pm$ 10.7	81.6 $\pm$ 5

*(p<0.05)

Also the result showed 54.6% of diabetic patients have hypertension 45.3% in female and 9.3% in male.

Table -4- Change in number of diabetic patients with or without hypertension

Parameters	BP< 140/90 no. of diabetic patients	%	BP>140/90 no. of diabetic patients	%
Female	28	37.3	34	45.3
Male	6	8	7	9.3
Total	34	45.3	41	54.6

Cholesterol and triglyceride concentration in diabetic patients were recorded (210 mg/dl, 176.5 mg/dl) which are significantly higher than control group which recorded (155mg/dl, 143.5mg/dl) respectively. Table(5)

Table -5- Cholesterol and triglyceride concentration in diabetic patients and control group

Parameters	DM n=75 Means $\pm$ SD	Control n=40 Means $\pm$ SD
Cholesterol mg/dl	210 $\pm$ 29**	155 $\pm$ 18.5
Triglyceride mg/dl	176.5 $\pm$ 31**	143.5 $\pm$ 15.6

**($p < 0.01$)

80 % of diabetic patients(type 2) have BMI higher than 25 kg/m² and 20% have BMI between 18-24.9 (Table6).

Table- 6- Number of diabetic patients according to BMI

Parameters	Normal(18-24.9kg/m ²)	%	Abnormal(>25kg/m ²)	%
Female	14	18.7	48	64
Male	1	1.3	12	16

The study proved most of diabetic patients were overweight followed obese class (1) which represented (38.6% , 32%) and only 14.6% of them were normal.

Table -7 -Percentage distribution of type 2 diabetes on the basis of BMI

BMI category	BMI range kg/m ²	Number	%
Normal	18.5-24.9	11	14.6
Overweight	25-29.9	29	38.6
Obese class 1	30-34.9	24	32
Obese class 2	35-39.9	10	13.3
Obese class 3	Over 40	1	1.3

Concentration of FBG and HbA1c recorded significant increase (273.3mg/dl and 8.9%) in diabetic patients ($p<0.001$) than control group which reported (93.2mg/dl and 4.7%) for both sexes respectively.

Table -8- Concentration of FBG and HbA1c in diabetic patients compared it to control group

Parameter	No. of diabetic patients=74 Means $\pm$ SD	Control=40 Means $\pm$ SD
FPG mg/dl	273.3 $\pm$ 29***	93.2 $\pm$ 7
HbA1c%	8.9 $\pm$ 1.8***	4.7 $\pm$ 0.5

***($p<0.001$)

Table- 9- Comparison between HbA1c and FPG according to sex in assessing diabetes mellitus.

parameter	Diabetic female Means $\pm$ SD	Female control Means $\pm$ SD	Diabetic male Means $\pm$ SD	Male control Means $\pm$ SD
HbA1c	9 $\pm$ 1.9**	4.7 $\pm$ 0.56	8.1 $\pm$ 1.2**	4.7 $\pm$ 0.6
FPG	250 $\pm$ 94.2**	93.7 $\pm$ 8.9	189.5 $\pm$ 75.8**	92.5 $\pm$ 6.1

**($p<0.01$)

The result showed high sensitivity of HbA1c (82%) , specificity(54%) and positive predictive value(89%).

Table -10 –Sensitivity, specificity and positive predictive value (PPV) of HbA1c in predicting good glycaemic control of diabetic patients.

Parameter	HbA1c
Sensitivity %	82%
Specificity%	54%
Positive predictive value(PPV)	89%

HbA1c were classified into three limits, $\leq 6.5\%$, $6.5\% - 7.4\%$ and $\geq 7.5\%$ were used to assess the diabetic control of patients and to classify them into good, fair and poor control categories respectively, our result revealed most diabetic patients are poor control with percentage 73.3% .

Table -11- Changes of HbA1C in diabetic patients (HbA1C%) according to WHO values in predicting glycaemic control .

parameter	≥ 6.4 HbA1c Good control	$6.5-7.4$ HbA1c Fair control	$7.5 \leq$ HbA1c Poor control
HbA1c	(7) 9.3%	(13) 17.3%	(55) 73.3%

Also the results revealed 9.3% of diabetic patients have polycystic ovary and 17.3% have family history for diabetes mellitus .

Table-12-Distribution of polycystic ovary and family history of diabetes in type 2 diabetic patients

Parameter	No. of patients	%
Polycystic ovary	7	9.3
Family history of diabetes	13	17.3

Discussion

Diabetes mellitus is a chronic disease that requires medical care, patient education, self management and support to prevent acute complications and to reduce the risk of long-term complications . Control of blood glucose level can be assessed by several methods in patients with diabetes . The glycated haemoglobin level is the gold standard for assessment of glycaemic control at follow up (Ghazanfari,2010). Although diabetes mellitus is associated with many complication, but it's control lead to decrease morbidity and mortality in addition to decrease economic burden of the disease (Ahmed,2001). Regular measurement of HbA1C is a good marker of long-term glycemic control as a part of the patient's follow-up once of every 3-4 months (Razzak,2003and Marcus,2008).

The present study showed that patients with type 2 diabetes among females were about 82.6% while in males were about 17.3%, this indicated that patients with type2 diabetes are more common among females than males.

This result is compatible with data collected on 3500 randomly selected civil servants showed that prevalence of type2 diabetes was significantly higher in females than males (King,2003). Other studies recorded the prevalence of type 2 diabetes was higher among men (Geer,2009 and Wild,2004.,). The sex differences are attributed to body fat distribution are closely related to sex differences in insulin resistance (Geer,2009) or may be due to changes in body composition , the strength and bulk of skeletal muscle, a major tissue involved in glucose metabolism, also declines leading to muscle weakness and a reduction in physical activity. These changes lead to marked reduction in energy expenditure and abdominal fat accumulation causing insulin resistance (Mansour,2014).

The results showed most of diabetic patients have hypertension ,the statistical analysis showed significant difference in systolic pressure .

Nilsson *et al*, 2011 reported hypertension is present in more than 60% of type 2 diabetes mellitus patients . This result is agree with Ostchega, 2007 who showed that patients with diabetes were less likely to have controlled blood pressure compared to individuals without diabetes. Other studies recorded the prevalence of hypertension, the frequencies of undiagnosed hypertension and uncontrolled hypertension among Moroccan patients with type 2 diabetes were very high (Mubarak,2008) .Data obtained from death certificates showed that hypertensive disease has been implicated in 4.4% of deaths coded to diabetes, and diabetes was involved in 10% of deaths coded to hypertensive disease (Epstein,1992) .

The results revealed increase in serum cholesterol, triglyceride compared to control group .This elevation is attributed to increased free fatty acid flux secondary to insulin resistance and impaired insulin-mediated skeletal muscle uptake of free fatty acids increase fatty acid flux to the liver (Arshag,2009 and Mooradian,2009.,) . Other studies were compatible with this result who recorded the diabetic patients had a higher prevalence of high serum cholesterol, triacylglycerol than the controls (Bhalodkar,2006.,Albrki ,2007.,Mooradian,2008.,), indicating that diabetic patients were more liable to cardiovascular diseases (Albrki ,2007.,). Another study was done in Pakistan reported raised levels of total cholesterol as the main finding in type2 diabetes(Naheed,2003).

The study showed most of type2 diabetes patients were overweight with percentage 38.6% followed obese class1 with percentage 32% . Our results are compatible with Sluik, *et al* (2011).Other studies strongly support this close association, identifying obesity as one of the most important risk factors for type 2 diabetes (Lloret,2008). Another studies suggest that around 80–90% of patients with type 2 diabetes are overweight or obese (Norris,2005).

The results in table 8 is compatible with Mohan,*et al* (2006) who recorded fasting blood sugar levels were significantly increased in diabetics when compared to those in the controls. HbA1c is directly associated with the risk of diabetic complications (Nathan ,2005). Other studies had comparable results, suggesting that HbA1C and FPG are similarly useful in the detection of diabetes mellitus (Bennett,2007). Buell, *et al* (2007) ,proposed that those individuals with HbA1C $\geq 5.8\%$ return for a fasting plasma glucose test for confirmation of the diagnosis(Buell,1999

The present study indicated that most patients with type 2 diabetes were poor HbA1c control with percentage 73.3% . Other studies reported 27% of type2 diabetics had elevated plasma HbA1c levels representing poor long-term glycemic

control, this may be an indication of poor adherence to dietary and can predispose patients to developing long-term complications of diabetes mellitus (Buritis, 2008). Another study was conducted in Jordan that 65.1% of patients type 2 diabetes had poor glycemic control (Khattab, 2010). Patients with type 2 diabetes mellitus with HbA1c levels > 7.5% have a 2.5- to 5-fold greater relative risk of developing microvascular complications (Heine, 2004). A study is done on diabetes in individuals with A1C levels between 5.5% and 6.4%, population studies demonstrate that A1C levels of 6.0% to 6.4% are associated with a higher risk for diabetes compared to levels between 5.5% and 6.0% (Zhang, 2010).

Glycosylated hemoglobin (HbA1c) is a marker of evaluation of long-term glycemic control in diabetic patients and predict risks for the progression of diabetic complications. (Lorenza, 2005), previous studies who focused upon the inconvenience caused to diabetic patients, due to overnight fasting when used FPG (Weeraratne, 2006). HbA1c is not recommended as a diagnostic or a screening test because it is inferior to FPG at predicting type 2 diabetes and this is due to presence of hemoglobin or red cell abnormalities can increase the variability of HbA1c values (Janghorbani, 2009).

HbA1c remains the gold standard in the assessment of glycemic control with availability of standardized methods. The diabetic patients need to be educated regarding the importance of achieving good glycemic control (To achieve HbA1c < 7%) to reduce the morbidity & mortality due to various complications of diabetes mellitus (Swetha, 2014).

The results recorded 9.3% of type 2 diabetic patients with polycystic ovary, both type 2 diabetic and polycystic ovary syndrome are obesity-related conditions that share epidemiological and pathophysiological factors. Insulin resistance is a key factor whereby obesity influences the expression of each conditions (Barber, 2012) and this result was compatible with (De Leo, 2004.,).

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