

1. Introduction and Literature Review

1.1 Diabetes mellitus

The term diabetes mellitus describes a metabolic disorder of multiple a etiology characterized by chronic hyper glycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The effects of diabetes mellitus include long-term damage, dysfunction and failure of various organs. ⁽¹⁾ Diabetes mellitus may present with characteristic symptoms such as thirst, polyuria, blurring of vision, and weight loss. In its most severe forms, keto acidosis or a non-kenotic hyper osmolar state may develop and lead to stupor, coma and, in absence of effective treatment, death. Often symptoms are not severe, or may be absent, and consequently hyperglycemia sufficient to cause pathological and functional changes may be present for a long time before the diagnosis is made. The long-term effects of diabetes mellitus include progressive development of the specific complications of retinopathy with potential blindness, nephropathy that may lead to renal failure, and/or neuropathy with risk of foot ulcers, amputation, Charcot joints, and features of autonomic dysfunction, including sexual dysfunction. People with diabetes are at increased risk of cardiovascular, peripheral vascular and cerebro vascular disease. ⁽¹⁾

1.1.1 Types of diabetes mellitus

1.1.1.2 Type 1 of diabetes mellitus

Type 1 indicates the processes of beta-cell destruction that may ultimately lead to diabetes mellitus in which “insulin is required for survival” to prevent the development of keto acidosis, coma and death. An individual with a Type 1 process may be metabolically normal before the disease is clinically manifest, but the process of beta-cell destruction can be detected. Type 1 is usually characterized by the presence of anti-GAD, islet cell or insulin antibodies which identify the autoimmune processes that lead to beta-cell destruction. In some subjects with this clinical form of Diabetes, particularly non-Caucasians, no evidence of an autoimmune disorder is demonstrable and these are classified as

“Type 1 idiopathic”. An etiological classification may be possible in some circumstances and not in others. thus, the an etiological Type 1 process can be identified and sub-categorized if appropriate antibody determinations are performed. It is recognized that such measurements may be available only in certain Centre's at the present time. If these measurements are performed, then the classification of individual patients should reflect this.⁽¹⁾

1.1.1.3 Type 2 of diabetes mellitus

Type 2 is the most common form of diabetes and is characterized by disorders of insulin action and insulin secretion, either of which may be the predominant feature. both are usually present at the time that this form of diabetics is clinically manifest. By definition, the specific reasons for the development of these abnormalities are not yet known. Diabetes mellitus of this type previously encompassed non-insulin-dependent diabetes, or adult-onset diabetes. It is a term used for individuals who have relative (rather than absolute) insulin deficiency. People with this type of diabetes frequently are resistant to the action of insulin^(2,3). At least initially, and often throughout their lifetime, these individuals do not need insulin treatment to survive. This form of diabetes is frequently undiagnosed for many years because the hyper glycaemia is often not severe enough to provoke noticeable symptoms of diabetes^(4,5). Nevertheless, such patients are at increased risk of developing macro vascular and micro vascular complications^(4,5). there are probably several different mechanisms which result in this form of diabetes, and it is likely that the number of people in this category will decrease in the future as identification of specific pathogenetic processes and genetic defects permits better differentiation and a more definitive classification with movement into “Other types ”. Although the specific a etiologies of this form of diabetes are not known, by definition autoimmune destruction of the pancreas does not occur and patients do not have other known specific causes of diabetes. The majority of patients with this form of diabetes are obese, and obesity itself causes or aggravates insulin resistance^(6,7). many of those who are not obese by

traditional weight criteria may have an increased percentage of body fat distributed predominantly in the abdominal region ⁽⁸⁾

1.1.1.4 Other specific types

Other specific types are currently less common causes of diabetes mellitus, but are those in which the underlying defect or disease process can be identified in a relatively specific manner. They include, for example, fibro calculus pancreatopathy, a form of diabetes, which was form early classified as one type of malnutrition-related diabetes mellitus⁽¹⁾. In patients with diabetes mellitus having vascular complications, control of blood glucose levels is a crucial factor in determining prognosis. The mechanisms that mediate vascular complications in diabetic patients are not at full understood. Etiology of diabetic vascular complications is multi factorial. Alteration of blood coagulation and fibrinolysis along with poor glycemic control in diabetes has also been implicated in the development of diabetic complications. Type 2 diabetes mellitus is a growing cause of disability and premature death, mainly because of cardiovascular diseases and chronic complications. ⁽⁹⁾the major complications resulting from T2DM are related to the micro vascular and macro vascular systems.^(10,11)

1.2 Obesity

Obesity is a cause of insulin resistance. Android obesity, which is characterized by a gross excess of adipose tissue within and around the abdomen, is the main type of obesity associated with type 2 diabetes and increased vascular risk ⁽⁴⁾. His adipose depot shows a high rate of turnover, possibly due to increased catecholamine-mediated b-adrenoceptor activity, with high activities of hormone-sensitive lipase as well as lipoprotein lipase. Adipose tissue turnover increases plasma free fatty acids and certain cytokines (e.g. TNF- and IL-6). Increased nutrient intake and decreased nutrient utilization due to low levels of physical activity will foster the vicious spiral of hyper in sulinemia and insulin resistance⁽¹⁾

1.3 Risk factor:

Genetic predisposition, environmental factors, age, pregnancy, family history and smoking ⁽¹²⁾.

1.4 Pathology:

Type 2 diabetes is more complex condition than type 1 diabetes because of insulin in liver and muscle together with impaired pancreatic B cell function leading to "relative " insulin deficiency. Insulin resistance appears to come first, and lead to elevated insulin secretion in order to maintain normal blood glucose levels. In susceptible individuals that pancreatic B cell are unable to sustain the increase demand for insulin a slowly progressive insulin deficiency develops ⁽¹²⁾.

1.5 Management:

The methods of treatment of diabetes are: dietary, life style modification, Oral Anti-Diabetic (OAD) agents and insulin by injection. In patients with suspected type 1 diabetes urgent therapy with insulin is required and prompt referral to a specialist is usually required. In patients with suspected type 2 diabetes, the first line of therapy involves advice about dietary and life style modification. OAD drugs are added only in those who do not achieve good glycaemic control with dietary modification alone , or who have more sever symptomatic hyperglycemia at diagnosis (e.g. HbA1c>10%) ⁽¹²⁾.

1.6 Complications:

Micro vascular ,Retinopathy ,cataract, Impaired vision due to Nephropathy ,Renal failure, Peripheral neuropathy Sensory loss pain and motor weakness, autonomic neuropathy , gastrointestinal problems (gastro paresis , altered bowel habit) , postural hypotension ,foot disease (ulceration , arthropathy) , macrovascula (coronary circulation) , myocardialischaemia \ infraction , cerebral circulation (transient ischemic attack , stroke) , peripheral circulation (claudication , ischemia)⁽¹²⁾

1.7 Uncontrolled diabetes:

Mean that patient is not on follow up, medication or patients have a lot of risk factor that increase HbA1c) ⁽¹²⁾ .

1.8 Literature Review

1.8.1 Prevalence of uncontrolled diabetes mellitus:

- In Brazilian at 2011 ,Lucian v Viana ,Cristiane B Leitao ,Caroline K Kramer ,Alessandra TN Zucatti ,Deborah L Jezini ,JoaFelicio ,Ana B Valverde ,Antonio R Chacra ,Mirala J Azevedo ,Jorge L Gross ,conducted poor glycaemic control patients with type2 diabetes attending the public health care system . The study aimed to describe the clinical profile of Brazilian patients with type 2 diabetes attending the public health care system and identify factors associated with poor glycaemic control .The study design was cross sectional ,total 5750 patients .The study conducted between Feb 2006 and April 2011.The informed obtained by standardized questionnaire .Ethnicity was self – reported .Data collection from person interview .The study conclude prevalence of un control diabetes among 66% female and 34% male .The study conclude significant glycaemic control ⁽¹³⁾ .

-prevalence of diabetes mellitus and impaired glucose regulation in Spain by F.Soriguer , A.Goday , A. Bosch-Comas , E. Bordiu , A.Calle-Pascual , R. Carmena , R.Casamitjana , L. Castano , C.Castell , M . Catala , E.Delgado , J.Franch , S.Gaztambide , J.Girbes , R.Gomis . The study aimed to examine the prevalence of diabetes mellitus and impaired glucose regulation. The diabetes study was cross-sectional study, population based survey conducted in 2009 - 2010. A cluster sampling design was used to select participants forming representative random sample of the Spanish population. A total sample 5,072 patients. The study was approved by the ethics and clinical investigation committee of Carlos Haya Hospital , and written informed consent was obtained from all participant . Over all prevalence of diabetes mellitus adjusted for age and sex was 13.8% ⁽¹⁴⁾.

-Gopinath B , Seri Sai Prasad M , Jayarama N ,Prabnakara K ,conducted the study of factors associated with poor glycaemic control in type 2 diabetic patients in India ,the study aimed to asses glycaemic control and association with risk factor ,it was descriptive study design ,total of 500 patients . The study was conducted from May 2011 to April 2012 , the study was approved by Seri

Devraj Urs medical college ethical committee , data collection was obtained through personal interview .The study concluded prevalence of uncontrol diabetes 36.2%female and 63.8%male .The study conclude significant glycaemic control⁽¹⁵⁾ .

-In India at 2010 ,T.S. Sanal , N.S. Nair,P.Adhikari,conducted factors associated with poor control of type 2 diabetes mellitus .The aim of study was find the factors associated with poor control of diabetes systematic review and meta analysis was carried out .Over all 7,501 studies were identified from the initial search .The study conduct from 1980 to 2010 .The inform of consent from patients .Data collection obtained from personal interview .The study conclude prevalence of uncontrol diabetes among male was better than female .Experience with literature review showed that this area requires more attention of diabetes researchers⁽¹⁶⁾.

1.8.2Risk factor of Literature Review:

Prevalence of diabetes mellitus and impaired glucose regulation in Spain by F.Soriguer and et al, people with low educational level had risk factors closely associated with diabetes and a lower socioeconomic level had been associated.

Study of factors associated with poor glycaemic control in type 2 diabetic patients in India by Gopinath B and et al ,this study , male gender and hypertriglyceridemia were significantly associated with poor glycaemic control in type 2 diabetes patients ⁽¹⁴⁾ .

Factors associated with poor control of type 2 diabetes mellitus in India T.S Sanal and et al, life style modification and elderly patients(>60years) associated with poor control of diabetes ⁽¹⁵⁾.

The prevalence and determinants of poor glycaemic control among adult with type 2 diabetes mellitus in Saudi Arabia by, Riyadh A Alzaheb and et al, associated with glycaemic control as an outcome :patients family history , duration of diabetes , exercise levels and weight status⁽¹⁹⁾ .

The Poor glycaemic control in type 2 diabetes in the south of the Sahara issue of limited access to an HbA1c test ,by Alioune Camara and et al ,demographic

factors ,age under 65 years ,little education , clinical and behavioral factors , high diastolic blood pressure , absence of previous measure of HbA1c , diabetes duration >3 years , treatment with oral glucose control agents , insulin alone or with oral glucose control agents and normal weight were associated with poor glycaemic control ⁽²¹⁾.

Cross-sectional study of patients with type 2diabetes in OR tambo district ,south Africa, by Arosemena and et al This is worrisome given the health implications of un controlled (T2DM) ,poverty ,lack of diabetes education , sedentary lifestyle and dyslipidaemia are identified as the most important and independent determinants in setting⁽²²⁾.

1.9 Rationale (justification)

Diabetes Mellitus is a major health problem that results in significant morbidity and mortality from diverse complications. There is limited or non-published data in Sudan regarding the HbA1c level and prevalence of uncontrolled of diabetes mellitus in Atbara locality, 2018. Therefore, this study was conducted to determine the level of HbA1c among DM.

1.10 Objectives

1.10.1 General objective

To determine the prevalence of uncontrolled of diabetes mellitus in Atbara locality, 2018.

1.10.2 Specific objectives

1-To measure HbA1c level among diabetes mellitus patients type 2and 1 using I chroma™

2-To compare HbA1c level between type 2and 1 diabetes mellitus patients

3-To associate between HbA1c level, type of treatment, age, sex and duration of diabetes mellitus

2. Materials and Methods

2.1 Materials

2.1.1 Consumables

Table (2.1): Show the Consumables

Consumable	Manufacturer
EDTA container	Ningbo MF LAB-China
Vacutainar	Shangahi-China
Cotton	Pharmaplast -Egypt
Alcohol	Germany
Gloves	Malaysia
ichroma™kits	Chuncheon –si.Gang-won – do24398-.Korea

2.1.2 Instrument

2.1.2.1 Principle of ichroma™ HbA1c

Glycated protein is formed post-translationally through the slow, nonenzymatic reaction between glucose and amino groups on proteins. HbA1c is a clinically useful index of mean glycemia during the preceding 120 days, the average life span of erythrocytes. Carefully controlled studies have documented a close relationship between the concentrations of HbA1c and mean glycemia. HbA1c is considered as a more reliable parameter in monitoring glycemia over the glycemic reading with the conventional glucometer.

i-CHROMA™ HbA1c is based on the fluorescence immunoassay technology, specifically the competition immune-detection method. Whole blood is added to the mixture of hemolysis buffer and detection buffer, which results in hemolysis of red blood cells. The mixture containing HbA1c from the hemolyzed red blood cells and fluorescence-labeled HbA1c peptides from detection buffer is loaded onto the sample well of the Cartridge. The mixture then migrates through the nitrocellulose matrix of the test strip by capillary action. HbA1c from the blood competes with fluorescence-labeled HbA1c peptides for binding sites on HbA1c antibodies fixed on the nitrocellulose matrix. As a result, the higher

concentration of HbA1c produces a lower fluorescence signal from HbA1c-peptides. The signal is interpreted and the result displayed on *i*-CHROMATM Reader in units of percentage.



Show the Figure (2-1) of ichroma™

2.2 Methods:

2.2.1 Study Design:

Cross sectional study.

2.2.2 Study Area:

Atbara Teaching Hospital .

2.2.3 Study Period:

From April 2018 to July 2018 .

2.2.4 Study population:

Apparently healthy adult Sudanese male and females their age ranging from 18-80 years old .

2.2.5 Ethical consideration:

The individuals included in the study were notified well about the objective and the need of this study and they accept to give blood samples before the start of the collection process.

2.2.6 Sample Size:

Sample size of this study (209) subject DM patients.

2.2.7 Criteria of selection:

2.2.7.1 Inclusion criteria:

1. Atbara city apparently healthy male and females.
2. From 18 -80 years old.
3. Sudanese nationally.
4. Patients male and female diabetics mellitus type 1 and 2.

2.2.7.2 Exclusion criteria:

1. Age lower than 18 and above of 80 years old.
2. Patients with Liver disease, Malignancy

2.2.8 Data Collection:

The primary data was collected by a standard questionnaire and the secondary data was collected from lab work.

2.2.9 Blood sample collection and Preparation:

First, the donor identity has been checked, and found that it corresponds to the details on request form. Recommended that skin must be cleaned by 70% alcohol and allowed to dry before being punctured. Blood best withdrawn from antecubital vein or other visible vein in the forearm by either an evacuated tube. The tourniquet has been applied just above the venipuncture site and released as soon as the blood has been flown into evacuated tube. Anti coagulated specimen was mixed by harvesting the containers several times. After the blood was obtained, the needle was removed and then pressed applying pressure on the swab, Then the punctured site was covered with a small adhesive dressing⁽²⁵⁾.

Capillary blood and venous blood with or without anticoagulants (EDTA) can be used. The whole blood specimen must be at room temperature and be homogeneous before testing. Fresh blood samples are recommended for best results, and samples over 24 hours after collection are to be avoided, if possible. If the specimens appear to be hemolyzed, another specimen should be obtained for testing.

2.2.10 Test procedure

1. Transfer 10 μL of serum/plasma/control sample using a transfer pipette to a tube containing the detection buffer.
2. Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.).
3. Pipette out 75 μL of a sample mixture and dispense it into the sample well on the test cartridge.
4. Leave the sample-loaded test cartridge at room temperature for 12 minutes.
5. For scanning, insert it into the test cartridge holder of the ichroma™ Reader. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
6. Press ‘Select’ button on the ichroma™ Reader to start the scanning process.
7. ichroma™ Reader will start scanning the sample-loaded test cartridge immediately.
8. Read the test result on the display screen of the ichroma™ Reader.

2.2.11 Components of ichroma™

Test Cartridge Box:

- Sealed Test Cartridges 25
- ID Chip 1
- Package Insert1
- Box containing Detection Buffer Tube
- Detection Buffer Tubes25

2.2.11.1 Components and Reagents

***i*-CHROMATTMHbA1c**

consists of Cartridge, Detection Buffer and Hemolysis Buffer.

- Cartridge contains mouse monoclonal anti-HbA1c antibodies and rabbit IgG immobilized on the test and the control lines of the strip, respectively.
- Detection Buffer contains fluorescence-labeled HbA1c-peptide, fluorescence-labeled anti-rabbit IgG, BSA as a stabilizer and sodium azide as preservative in PBS.
- Hemolysis Buffer is pre-dispensed individually in a small tube and composed of cationic detergent.

2.2.12 Interpretation of Test Result

- IchromaTM Reader calculates the test result automatically .

Reference Range 4.5 ~ 6.5%

Measuring Unit %(HbA1c)

2.2.13 Data Analysis:

Data was analyzed using SPSS

3. Results

A total of (209) subject were enrolled in this study (176) subjects were DM type 2 patients and (33) type 1 DM groups for comparison, the patients type 2 and type 1 groups were selected according to inclusion criteria in Atbara locality . The mean age of both DM type 2 and type 1 patients were 51 years.

Table (3.1): show that distribution of participant base age group

Percentage	Frequency	Description	Variable			
			Mode	Median	Mean	Age
3.3%	7	Less than 20	4	5(51—60)	4.41	e
7.7%	16	21—30				
10%	21	31—40				
28.7%	60	41—50				
24.4%	51	51—60				
25.8%	54	More than 60				
100%	209	Total				

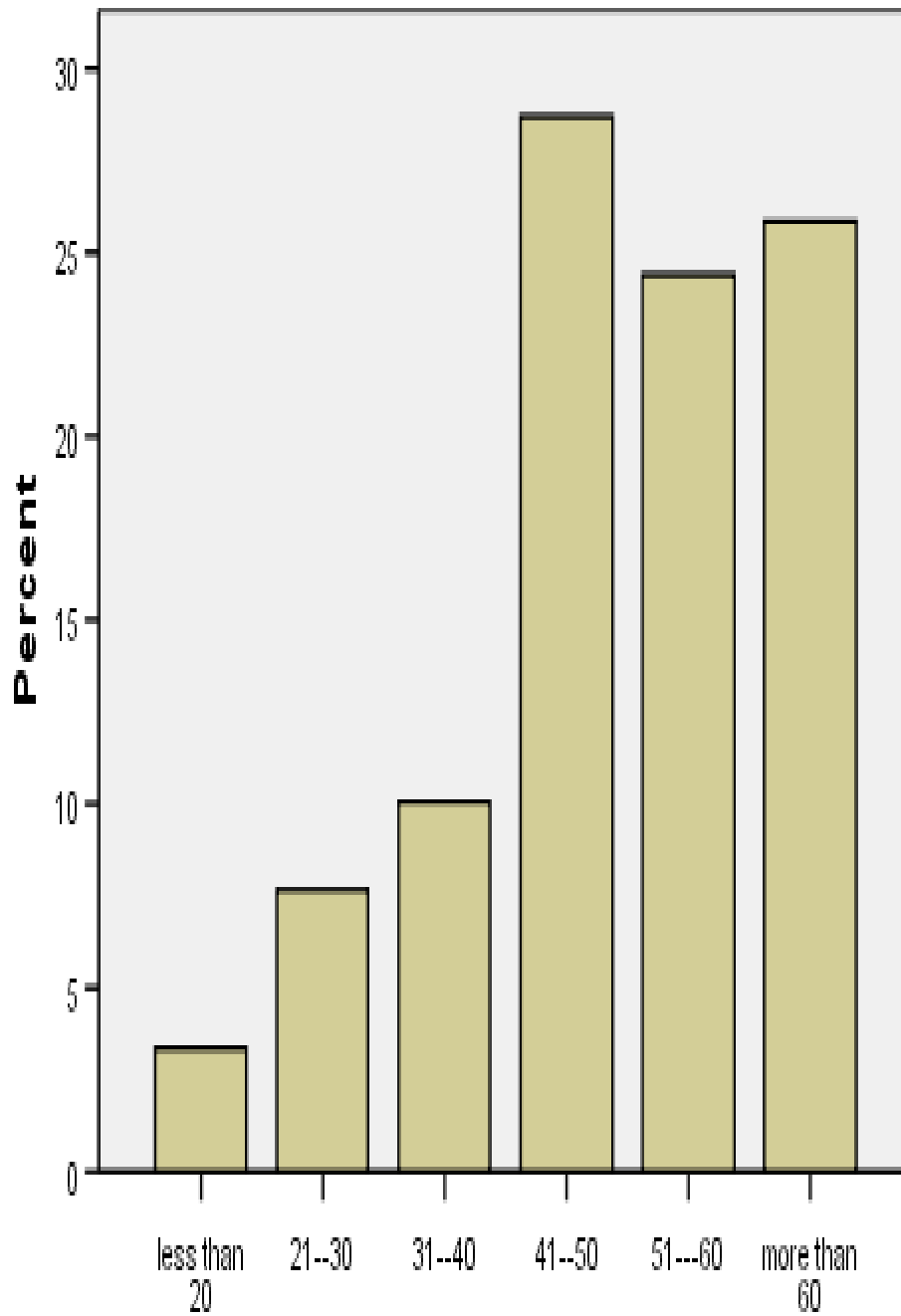


Figure (3.1): show that distribution of participant according to age

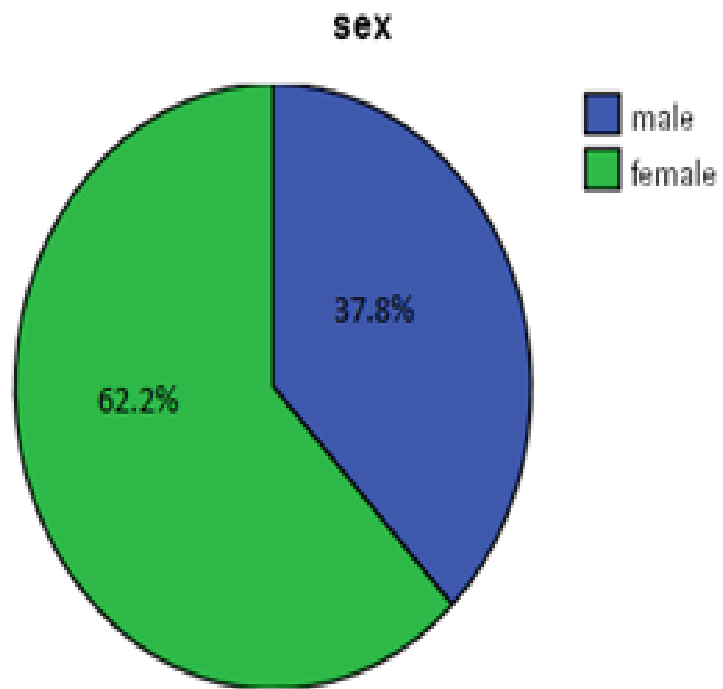


Figure (3.2): show distribution of participant base at gender

Table (3.2):Show The mean of control type 1 DM

N	Valid	7
	Missin	15
Mean		5.1143
Median		5.4000
Mode		5.60
Variance		.865
Range		2.80
Minimum		3.40
Maximum		6.20
Percentil es	20	4.0000

Table (3.3):Show the mean of uncontrolled type 1 DM.

	Valid	26
N	Missin g	0
Mean		12.7577
Median		9.9000
Mode		10.30
Variance		208.507
Range		75.50
Minimum		7.50
Maximum		83.00
Percentil es	20	8.2000

Table (3.4):Show the mean of controlled type 2 DM

N	Valid	41
	Missin g	93
Mean		5.6683
Median		6.0000
Mode		5.20 ^a
Std. Deviation		1.0085
Variance		7
Range		1.017
Minimum		3.90
Maximum		3.00
Percentiles	20	6.90
		4.8000

Table (3.5):Show the mean of uncontrolled type 2 DM.

N	Valid	134
	Missing	0
Mean		9.8231
Median		8.7500
Mode		9.00
Std. Deviation		7.22441
Variance		52.192
Range		88.40
Minimum		1.00
Maximum		89.40
Percentil es	20	7.5000

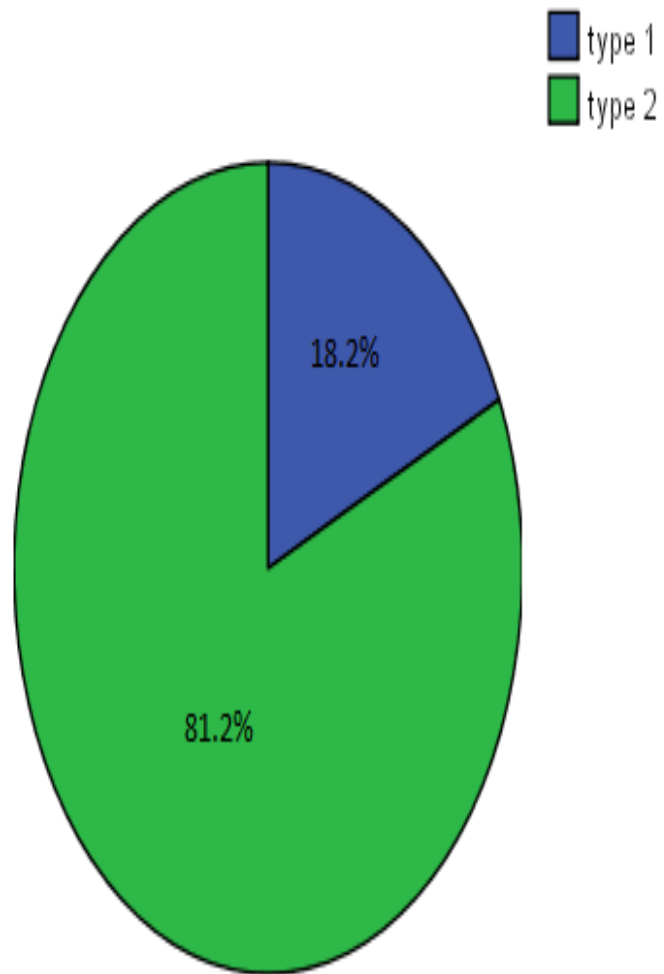


Figure (3.3): show that distribution of participant base at type of diabetes

Table (3.6): show that distribution of participant according to HbA1c

Percentage	frequencies	Description	Variable
26.3%	56	Control	Hba1c
73.3%	153	Un-control	
100%	209	Total	

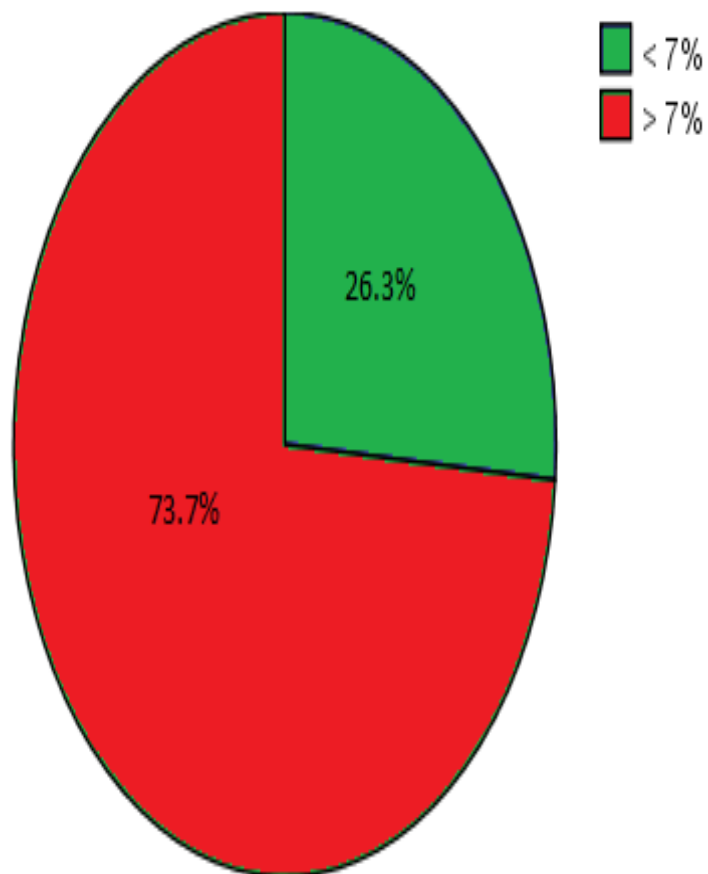


Figure (3.4): show that distribution of participant base of HbA1c

Table (3.7): Show the relationship between uncontrolled type 2 and long duration .

Mode 1	R	R Square	Std. Error of the Estimate
1	.053 ^a	.003	2.78230

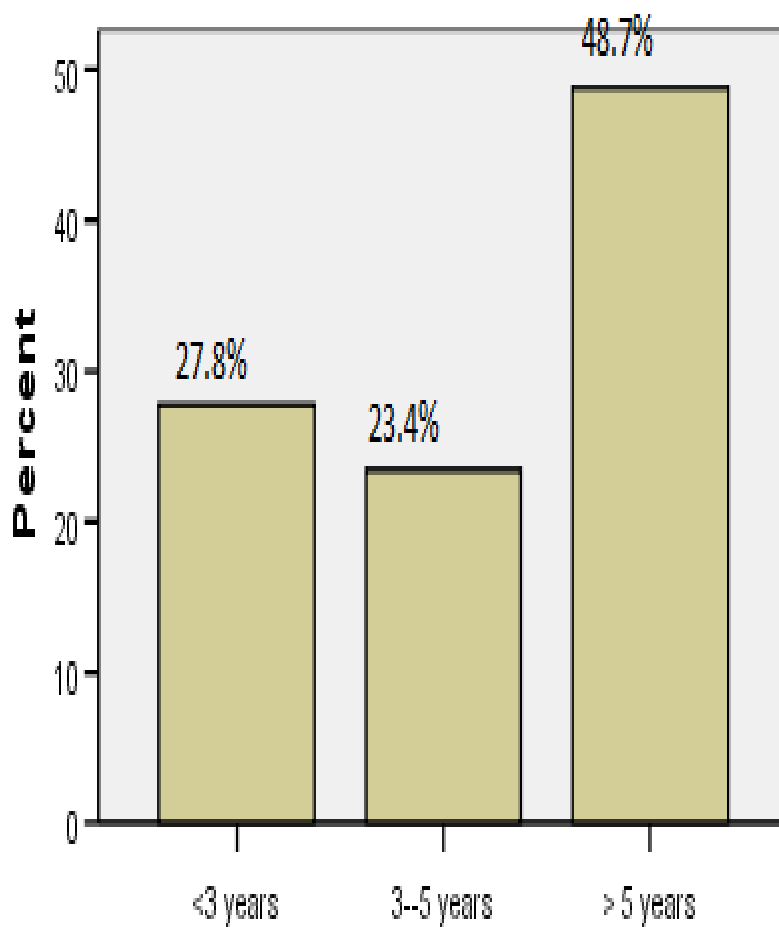


Figure (3.5): show that distribution of participant according to duration of disease

Table (3.8): show the relationship between uncontrolled type 2 DM and Oral anti-diabetic.

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.62 ^a	.628	..620	2.91905

Table (3.9): Show the relationship between uncontrolled type 2 DM and insulin .

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	.039 ^a	.408	.040	2.91905	Sig. F Change .231

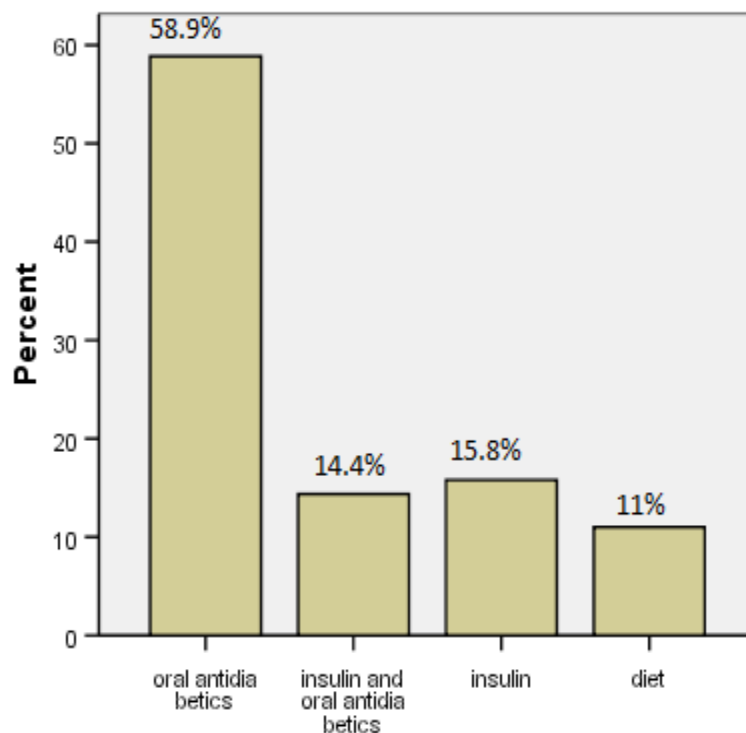


Figure (3.6): show that distribution of participant according to type of treatment

4.1 Discussion

Diabetes Mellitus is a major health problem that results in significant morbidity and mortality from diverse complications., the mean age of both DM patients was 51 years old .There were significant means differences of HbA1c level of type 1 and type 2 of DM (12.7) and (9.8) respectively. This result reflects that the effect of DM on HbA1c level. There was positive association between HbA1c level and duration of DM $r^2(0.003)$. which indicate there were relationship between HbA1c level and duration of the disease

that prevalence of this study of uncontrolled DM patients was 73.7%

Our result of the study compare with other studies we were found that prevalence of study fourfold of Spain study by F.Soriguer and et al, In Indian study by Gopinath and et al is slightly higher than our study due to elderly age and longer duration of diabetes .

Our study was agree with other studies done by Ngowoguko, et al and Alioune Camara and et al in Nigeria and South of Sahara respectively .

Our study determine poor glycaemic control in type 2 DM agree with other study

In Sudia Arabia in 2017 ,Riyadh A Alzaheb and Abdullah H Alteman . The prevalence and determinants of poor glycaemic control among adult with type 2 diabetes mellitus. The study aim to investigated glycaemic control status and the factors influencing poor glycaemic control among adult type 2 diabetes mellitus patients in Tabuk. The study was cross sectional observational study of adult out patients attending diabetes clinic at diabetic center in Tabuk .The study conduct from September 2016 t0 July 2017 . The ideal total sample size was therefore calculated as 385 patients. After additional 20% to account for non respondents the

final sample size 460 patients . Data were collected during direct encounters between trained investigators and participating patients .Via four parts questionnaire specially designed for the research. The result of the analysis indicated that 74.9% of the study sample of patients with type 2 diabetes mellitus suffered from poor glycaemic control . The high prevalence of un controlled type 2 diabetes mellitus reported in this research ⁽¹⁹⁾.

Ngwoguko ,MbaI.EK,NgwoguA.C, conducted glycaemic control amongst diabetic mellitus patients in UmuhiaMetropolliis , Abia state , Nigeria . The study aim to determine the level of glycaemic control among diabetic patients and to assess the relative association with some diabetic complication . The study was cross sectional study design participant 120 confirmed diabetic mellitus subject 55 males and 65 females were involved in this study. The study was conducted from June to December 2010. All the subject who gave consent. Data collection was obtained through personal interview. The study conclude prevalence of un control diabetes among 55 males and 65 females. The study conclude 38% had good glycaemic control while 62% had poor glycaemic control⁽²⁰⁾.

Glyceamic control and its associated factors in type 2 diabetic patients in Amman, Jordan,byM.Adham and et al ,related to a number of factors including sex, duration of DM ,body mass index (BMI), dyslipidaemia and treatment modality The study of oral manifestation in controlled and un controlled diabetes patients in Jordan,byShamikh and et al ,enlargement of parotid glands been unquestionably associated with diabetic patients⁽¹⁷⁾.

Prevalence Of Uncontrol Diabetes Mellitus Sufiank.noor and etal do study in glycaemic control in Sudanese individuale with type 2diabetes

mellitus Factor significantly associated with un controlled diabetes were the prolonged duration of diabetes ($p=0.02$)was similar to this study ⁽²⁴⁾.

4.2 Conclusion

This study concluded that the HbA1C level was higher among type II diabetes mellitus patients compared to the Type 1, the HbA1c level has appositive s association with duration of diabetes mellitus and type of treatment .

4.3 Recommendation

- The HbA1c should be measured regularly for DM patients.
- Other study with large sample size should be done.

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Appendix

Questionnaire:

Age: -----

Sex:----- male female

1-Are you on any medication of diabetes ?

Yes No

If yes please identify

2-What types of DM ?

1 : 2.....

3-What is time of diabetes duration?.....

4-HbA1c:----- <7.....or >7.....