بسم الله الرحمن الرحيم

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## Faculty of Health sciences

## Department of medical laboratory science

# Evaluation of PT and PTT among diabetes mellitus type2 patients in Atbara City during March to July 2018.

**Dissertation is submitted for partial fulfillment BSC honor in medical laboratory sciences.**

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# الآية

بِسْمِ ٱللَّهِ ٱلرَّحْمَٰنِ ٱلرَّحِيمِ

**قال تعالى :**

**(وأيوب إذ نادى ربه أني مسني الضر وأنت أرحم الراحمين۝**
**فاستجبنا له فكشفنا ما به من ضر وأتيناه أهله ومثلهم معهم رحمة**
**من عندنا وذكرى للعابدين۝)**

**سورة الأنبياء، الآية83-84**

# الاهداء

الى كل من اضاء بعلمه عقل غيره

او هدى بالجواب الصحيح حيرة سائليه

فاظهر بسماحته تواضع العلماء

و برحابته سماحة العارفين

الى الامهات والاباء

الى الاهل والعشيرة

الى الاساتذة الكرام

إلى الزملاء والزميلات

إلى الشموع التي تحترق لتضئ للأخرين

إلى كل من علمنا حرفا

نهدي هذا البحث المتواضع راجين من المولي عز وجل

القبول والنجاح

# الشكر والعرفان

امتثالا لقوله تعالى :(وإذ تأذن ربكم لئن شكرتم لأزيدنكم ولئن كفرتم إن عذابي لشديد) (ابراهيم 7).

وقوله ﷺ في الحديث الصحيح( لا يشكر الله من لا يشكر الناس)، اعترافا بالجميل نتقدم بالحمد والشكر لله اولا.

ونخص بالشكر اسرة قسم المختبرات الطبية وكلية العلوم الصحية بجامعة الشيخ عبد الله البدري التي إحتضنتنا طلابا فلها علينا ايادي بيضاء وفضل يذكر.

والشكر إلى / جمعية أصدقاء المرض السكري بمستشفي عطبرة التعليمي. و أسرة معمل لايف كير بمدينة عطبرة .

والشكرإلى / د. محمد هاشم

الذي أشرف علي هذا البحث.

# ABSTRACT

Diabetes mellitus is actually a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. To evaluation of PT and PTT among diabetes mellitus type 2 patients.

This is cross sectional study with control group based conducted in Atbara hospital during the period from March to July 2018.The patients were interviewed according to a questionnaire prepared for this purpose. A total of 50 samples from patients with type2 diabetes mellitus and 50 samples from healthy persons as control. PT and APTT were measured using semi-automated coagulometry (TECO- COATRON M1, GERMANY). The data was analyzed by SPSS software using independent t-test .The results show that the mean level of prothrombin time in type 2 diabetic patients was (16.64±3.09 Sec) and of control was(16.7±1.24 Sec), it was none significantly correlated (P value = 0.832) and the mean level activated partial thromboplastin time APTT in type 2 diabetic patients was (38.3±8.7)Sec and of control was( 36.2±2.7 Sec), it was none significantly correlated (P. value =0.111).Our study was concluded further that patients with type 2 diabetes mellitus had no hypercoagulable state due to PT and APTT. Other study with large sample size and many variables to reach to another facts.

# مستخلص البحث

مرض السكري في الحقيقة مجموعة من الأمراض الاستقلابية يتميز بزيادة سكر الدم ،ينتج عن خلل في انتاج الانسولين ، عمل الانسولين أو الأثنين معا. تقييم عوامل التجلط للاشخاص المصابين بمرض السكري( نوع الثاني).وهي دراسة وصفية مقطعية للمصابين بمرض السكري ومع مجموعة من الصحيين للمقارنة، وتمت الدراسة في مستشفي عطبرة خلال الفترة ما بين مارس-يوليو لعام ٢٠١٨م . وأجريت المقابلة مع المرضى وفقا للاستبيان المعد لهذا الغرض، جمعت ٥٠ عينة من المصابين للمرض السكري وكذالك ٥٠ عينة من الصحيين، وتم قياس زمن البروثرومبين وزمن الثرومبوبلاستين الجزئي النشط مستخدمين جهاز شبه الاوتوماتيكي كوترون م١ الألماني . تم تحليل البيانات بواسطه برنامج التحليل الاحصائي. أظهرت النتيجة أن متوسط زمن البروثرومبين في غير المصابين٣,٠٩ ± ١٦,٧ثانية. ومتوسط زمن البروثرومبين في مرضى السكري ١,٢٤±١٦,٦٤ثانية. متوسط زمن الثرومبوبلاستين الجزيئ النشط في مرضى السكري ٨,٧ ± ٣٨,٣ ثانية. متوسط زمن الثرومبوبلاستين الجزيئ النشط في غير المصابين ٢,٧ ± ٣٦,٢ثانية . أظهرت البيانات أن المرضى مع النوع الثاني من مرض السكري لا يعانو من فرط التجلط بمقتضي زمن البروثرمبين و الثرمبوبلاستين الجزيئ النشط .نوصي باجراء دراسة أخرى مع حجم كبير من العينات و العديد من المتغيرات لنصل لحقائق أخرى.

## *Table of content:*



## *Chapter one*

## *Chapter two:*



## *Chapter three:*



## *Chapter four:*

# List of tables

# List of Figures

# List of abbreviations

| | |
|---|---|
| PT | Prothrombin time |
| APTT | Activated partial thromboplastin time |
| T2DM | Type two diabetes mellitus |
| IDDM | Insulin dependent diabetes mellitus |
| NIDDM | Non-insulin dependent diabetes mellitus |
| INR | International normalization ratio |

# Chapter one

# Introduction and Literature Review

# 1 INTRODUCTION

## 1.1 Diabetes mellitus:

Diabetes mellitus is actually a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Hyperglycemia is an increase in plasma glucose levels. In healthy patients, during a hyperglycemia state, insulin is secreted by the β- cells of the pancreatic islets of Langerhans. Insulin enhances membrane permeability to cells in the liver, muscle, and adipose tissue. It also alters the glucose metabolic pathways.[1] Hyperglycemia, or increased plasma glucose levels, is caused by an imbalance of hormones. An intermediate stage, in which the fasting glucose in increased above normal limits but not to the level of diabetes, has been named impaired fasting glucose. Use of the term impaired glucose tolerance to indicate glucose tolerance values above normal but below diabetes levels was retained. Also, the term gestational diabetes mellitus was retained for women who develop glucose intolerance during pregnancy.[1] 80% of patients with diabetes mellitus die a thrombotic death, 75% of these deaths are due to Cerebrovascular and peripheral vascular complications.[2] In Nigeria and the world at large, Diabetes is a major health problem with about 90% of diabetic patients having non-insulin type 2 while about 10% have insulin dependent [3].Diabetes is divided into two broad categories: type 1, insulin dependent diabetes mellitus (IDDM); and type 2, non–insulin-dependent diabetes mellitus (NIDDM).[1]Type 1 diabetes is characterized by inappropriate hyperglycemia primarily a result of pancreatic islet β-cell destruction and a tendency to ketoacidosis type 1 diabetes mellitus is a result of cellular mediated autoimmune destruction of the β cells of the pancreas,causing an

absolute deficiency of insulin secretion.[1]Upper limit of 110 mg/dL on the fasting plasma glucoseis designated as the upper limit of normal blood glucose.Type1constitutes only 10% to 20% of all cases of diabetes and commonly occurs in childhood and adolescence. This disease is usually initiated by an environmental factor or infection (usually a virus) in individuals with a genetic predisposition and causes the immune destruction of the β cells of the pancreas and, therefore, adecreased production of insulin.[1] Characteristics of type1diabetes include abrupt onset, insulin dependence, and ketosis tendency. This diabetic type is genetically related. One or more of the following markers are found in 85%to 90% of individuals with fasting hyperglycemia islet cell autoantibodies, insulin autoantibodies, glutamic acid decarboxylase autoantibodies, and tyrosine phosphatase IA-2 and IA-2B autoantibodies.[1] Signs and symptoms include polydipsia (excessive thirst), polyphagia (increased food intake), polyuria (excessive urine production), rapid weight loss, hyperventilation, mental confusion, and possible loss of consciousness (due to increased glucose to brain).[1]Type 2 diabetes mellitus is characterized by hyperglycemia as a result of an individual's resistance to insulin with an insulin secretory defect. This resistance results in a relative, not an absolute, insulin deficiency. Type 2 constitutes the majority of the diabetes cases. [1] Most patients in this type are obese or have an increased percentage of body fat distribution in the abdominal region. This type of diabetes often goes undiagnosed for many years and is associated with a strong genetic predisposition, with patients at increased risk with an increase in age, obesity, and lack of physical exercise.[1] Characteristics usually include adult onset of the disease and milder symptoms than in type 1, with ketoacidosis seldom occurring. However, these patients are more likely to

go into a hyperosmolar coma and are at an increased risk of developing macrovascular and microvascular complications.[1]Multiple mechanisms are found to be involved in it; but most likely mechanism is that of the insulin resistance syndrome may be central to the development of diabetic endothelial dysfunction. The hemostatic abnormality and endothelial dysfunction are responsible for the generation of hypercoagulable state in type 2 diabetes mellitus individuals. [2] Body of evidence suggest that certain haematological indices are altered in patients with diabetes mellitus.[4]In patient with diabetes mellitus, persistent hyperglycaemia exposes red blood cells (RBCs) to elevated glucose concentration, thus resulting in glycalation of haemoglobin, prothrombin, fibrinogen and other proteins involved in clotting mechanisms. [5] The glycation results in the incomplete activation and function of the clotting cascade. [6] Glycation of intrinsic and extrinsic clotting proteins will decrease the availability of these proteins which affect the clotting capacity.[7]

Complication of diabetes mellitus type 2 Microvascular complications such as (neuropathy, retinopathy, nephropathy) are strongly related to hemoglobin A1c Concomitant arthrosclerosis and occult macrovascular disease may follow an accelerated course in type 2 diabetes.[8]

## 1.2 Bleeding profile:

Coagulation tests like prothrombin time (PT) and the activated partial thromboplastin time (APTT) are global tests used to assess the coagulation system in a clinical setting. [9]Prothrombin time (PT) and activated partial thromboplastin time (APTT) are hematological indices that give an insight into the coagulation status of patients. [10] Divided into 3 pathways of intrinsic, extrinsic and common, these factors collectively play a central role

in arresting bleeding disorder. [11][12]The blood contains about a dozen clotting factors. [13] These factors are proteins that exist in the blood in an inactive state, but can be called into action when tissues or blood vessels are damaged. [13]Blood clotting is the transformation of liquid blood into a semisolid gel. Clots are made from fibers (polymers) of a protein called fibrin. Fibrin monomers come from an inactive precursor called fibrinogen. Also called Factor I, fibrinogen play critical role in blood viscosity. Increased concentration of fibrinogen (hyperfibrinogenemia) in uncontrolled NIDDM patients is implicated in vascular damage induction. [14]

### 1.2.1 Prothrombin time (PT):

The prothrombin time (PT) measures factors VII, X, V, prothrombin and fibrinogen. Tissue thromboplastin (a brain extract) and calcium are added to citrated plasma. The normal time for clotting is 10-14 seconds It may expressed as the international normalization ratio (INR). [15]

### 1.2.2Activated partial thromboplastin time (APTT):

The activated partial thromboplastin time measures factors VIII, IX, XI, XII, in addition to factors X, V, prothrombin and fibrinogen. Three substances phospholipids a surface activator (e.g. kaolin) and calcium are added to citrated plasma, The normal time for clotting approximately 30-40 seconds, prolonged clotting time in the PT and APTT. Because of factor deficiency are corrected by the addition of the normal plasma to the test plasma (50:50 mix).If there is no correction or incomplete correction with normal plasma, the presence of an inhibitor of coagulation is suspected. [15]PT and APTT can therefore be used to assess the risk of clotting complications in

patients with diabetes mellitus although modern coagulation diagnostic test are becoming more sophisticated, PT and APTT are still important basic examinations in clinical laboratories.[16]

## 1.3 Justification:

Diabetic patients has many chances to become affected many disease or risk factors, so this study will be carried out to investigate the effect of the bleeding profile to the diabetes mellitus type 2 patients, there was limited or none published data regarding the diabetes mellitus type 2 and the relationship of the PT and APTT therefore this study was conducted to evaluation of PT and PTT among diabetic mellitus type 2 patients.

## 1.4 Objectives:

### 1.4.1 General objectives

To evaluation of PT and PTT among diabetes mellitus type 2 patients in Atbara city.

### 1.4.2 Specific objectives

1- Prothrombin time (PT) in diabetic mellitus type 2 patients
2- Active partial thromboplastin time (APTT) in diabetic mellitus type 2 patients
3- To compare between PT and the APTT in the diabetes type 2 patients and healthy persons.
4- To correlate between the ages and PT and APTT in diabetes mellitus type 2 patients.
5- To correlate between exercises and the PT and APTT in diabetes mellitus type 2 patients.
6- To evaluate the effect of sex on coagulation profile in diabetic mellitus type 2 patients.

# 1.5 LITERATURE REVIEW

The study done by acang N1 jalil FD, University of andalas general hospital in 1993.Hypercoagulation in diabetes mellitus.That result was a significantly high fibrinogen and short PT and APTT in diabetic patients, especially those who suffered from diabetes for a long time and followed by chronic complications.[17] Another study done by Fayez karim, Qazi Shamima Akter and et al, Dhaka medical college Dhaka in July 2013 to June 2014.Coagulation impairment in type 2 diabetes mellitus. That result in this study PTand APTT were significantly ($P<0.001$) lower in diabetes mellitus than those of control group.[18]The study done by Fathelrahman Mahdi Hassan, AL-Jouf University, Saudi Arabia. Prothrombin time and activated partial thromboplastin time among type 2 noninsulin dependent diabetes mellitus. That results show that the mean level of prothrombin time type 2 diabetic patients was 12.0 Sec and of control was 11.1 Sec, it was significantly correlated (P value = 0.02) and the mean level activated partial thromboplastin time (APTT) was 30.7 Sec and of control was 31.2 Sec. This result was nonesignificant (P. value = 0.826) [19].Another study done by Amal S.elhassade, Omima Saeed Balha, Faculty of medical technology, Derna, Libya. Effect of diabetes mellitus type 2 on activated partial thromboplastin time and prothrombin time .That result show the mean value of APTT in T2DM individuals was significant lower (28.95 ±7.54) seconds as compare with control, (34.12±2.82) seconds (P = 0.06). The mean value of prothrombin time (PT) among T2DM individuals was (14.04 ±2.96) seconds and the mean value of PT among healthy individuals was (13.5 ± 1.54) seconds. There was no significant difference in PT of T2DM individuals $P \geq 0.05$.[20]

# Chapter tow

# Materials and Methods

## 2.1 MATERIALS AND METHOD:

### 2.1.1 Study design:

Cross sectional study with control group, prospective.

### 2.1.2 Study area:

Atbara city.

### 2.1.3 Study duration:

From March to July 2018.

### 2.1.4 Study population:

Diabetes type 2 patients in Atbara city.

### 2.1.5 Sample size:

100 samples were collected, 50 of them were collected from diabetes mellitus type 2 patients, and the other 50 were collected from healthy persons as a control.

### 2.1.6 Data collection:

The data was collected by using a questioners, and will be excluded the patients use anticoagulant drugs and other drugs effect bleeding profile, those who have liver and kidney disease and other diseases those can affect the bleeding profile in the diabetic mellitus type 2 patients.

### 2.1.7 Sampling:

50 samples of diabetes mellitus type 2 patients and 50 samples of healthy persons were collected in a trisodium citrate tubes.

### 2.1.8 Sample processing:

The samples those who collected from the diabetes type 2 patients and healthy persons were centrifuged and assessed the prothrombin time (PT), and activated partial thromboplastin time (APTT).

## 2.2 Test procedure:

The COATRON M1 is designed to carry out coagulometric tests such as PT, PTT, TT, fibrinogen, single factor tests, chromogenic and immune-turbidimetric tests (for instance antithrombin III D -dimer etc.).Use only citrated plasma for test analysis runs: mix 9 parts venous blood with 1 part 3.2 %( 0.105m) sodium citrate and centrifuge the mixture at 1500g for approx 10 minutes, plasma must be used within 4h. All tests are performed with a quarter of the regular volumes .the micro cuvette can be run with a minimum of 75 µl = 25µl sample +50µl thromboplastin for PT. Incubation area for 6 sample and 2 reagent positions .The COATRON M1 needs 3-5 min to warm up to 37.0 C .A green signal light indicates the correct temperature .Automatic start at reagent addition.[21]

COATRON M1 FIGURE (2 -1)

### 2.2.1 Theory of operation:

The COATRON M1 is a highly sensitive single channel photometer. A very intensive laser LED-Optic at 400 nm ensures accurate and precise results, even when icteric or lipemic samples are used. The receiver signal is detected and converted to an electrical current. During the actual test the system is searching for the best amplification. The software algorithms are based on optical density (extinction), which absorbs outside light effects.[21]

### 2.2.2 Detection principle:

Plasma /blood and reagent absorb the transmitted laser light. The rate of absorbance is obtained by the detector and sent to the micro controller. Here a program analyses the signal and send the result to the display and printer (optional).[21]

### 2.2.3 Test selection:

To alternate between the tests, press key “TEST” to activate selection, cursor keys to change and key ENTER to confirm.[21]

### 2.2.4 Stopwatch:

A stopwatch function helps the operator to control the correct incubation times the timer stops after 999s automatically, to start the stopwatch press key “TIMER”, to stop and rest press key “TIMER” again. [21]

### 2.2.5 Measurement:

Before activating the channel the cuvette must be inserted into the measurement position and ready to add the start reagent .press key “OPTIC” to activate the channel message “WAIT” indicates that the measurement calibrates the optic to the actual optical value. If “ACTIVE” is displayed on

the screen the measurement is ready to start. The actual result ID is also displayed. If the optical value changes from the "TRIGGER" value (e.g. by adding reagent), the measurement will start .The start can be also triggered by pressing the key "OPTIC". Once started a small Deeping noise is followed by scrolling arrow. The current light absorbance (OD) can be read on the display. Avoid contact with the cuvette while this message is shown. A Deeping noise will sound again when a clot reaction was detected and the result will be displayed. If the clot reaction needs more than the maximum reading time of 300s the optic will stop and display "+++. +", which means "no clot detected".[21]

### 2.2.6 PT Determination:

#### 2.2.6.1 Principle:

The one stage prothrombin time measures the clotting time of test plasma after the addition of thromboplastin reagent containing calcium chloride. The reagents supply a source of "tissue thromboplastin", activating factor seven VII, and is therefore sensitive to all stage 2 and 3 factors. Deficiencies of stage1 factors (VIII, IX, XI, and XII) are not detected by the test. INR = patient PT (s) divided by normal PT (s) squared ISI.[21]

#### 2.2.6.2 Preparation:

Buffered sodium citrate, 3.8% or 3.2 % were used as anticoagulant venous blood was obtained from the participants by clean venipuncture. Immediately 9 parts of blood were mixed with 1 part of anticoagulant. The specimen is centrifuged at 1000 RCF for 15 min. The plasma is removed from the tube within 60 min, using a plastic pipette and stored in a plastic tube. [21]

### 2.2.7 COATRON M1 preparation:

Turn on instrument and wait until the ready light is lighting, turn on PT as an active test, check calibration, and allow reagent to prewarm at least 5 min.[21]

#### 2.2.7.1 Procedure on COATRON M1:

Pipette 25µl plasma into cuvette ,prewarm plasma for 1 min ,transfer cuvette to measuring position ,activate optic ,add 50 µl pre-warmed thromboplastin and simultaneously start the optic , the instrument will read maximal 300 seconds ,if clot is not detected the display will read "+++,+" , the result is displayed in seconds and INR.[21]

#### 2.2.7.2 Quality control:

Control plasma should be tested in conjunction with patient sample, it is recommended that at least one normal and one Subnormal be run at least each shift and a minimum of once per 20 patient samples. A control range should be established by the laboratory to determine the allowable variation in day to day performance on each control plasma.[21]

### 2.2.8 PTT Determination:

The APTT test measures the clotting of test plasma after the addition the APTT reagent .then allowing an "activation time", followed by the addition of calcium chloride, deficiencies of approximately 40% and lower of factors VIII, IX, XI, and XII will result in a prolonged APTT .Heparin in the presence of adequate amounts of anti-thrombin III will also result in a prolonged APTT.[21]

### 2.2.8.1 Reagent:

APTT reagent

Calcium chloride

Specimen collection

Buffered sodium citrate, 3.8% or 3.2 % were used as anticoagulant.

Venous blood was obtained from the participants by clean venipuncture.

Immediately 9 parts of blood were mixed with 1 part of anticoagulant.

The specimen is centrifuged at 1000 RCF for 15 min.

The plasma is removed from the tube within 60 min, using a plastic pipette and stored in a plastic tube.[21]

### 2.2.8.2 COATRON M1 preparation:

Turn on instrument and wait until the ready light is lighting, turn on PTT as an active test, check calibration, and allow cacl2 to pre-warm at least 5 min.[21]

### 2.2.8.3 Procedure on COATRON M1:

Pipette 25µl plasma into cuvette ,add 25µl APTT to plasma, incubate exactly for 5 min ,transfer cuvette to measuring position ,activate optic ,add 25 µl pre-warmed calcium chloride and simultaneously start the optic , the instrument will read maximal 300 seconds ,if clot is not detected the display will read "+++,+" , the result is displayed in seconds and ratio.[21]

### 2.2.8.4 Quality control:

Control plasma should be tested in conjunction with patient sample. It is recommended that at least one normal and one abnormal be run at least each shift and a minimum of once per 20 patient samples. A control range should be established by the laboratory to determine the allowable variation in day to day performance on each control plasma.[21]

## 2.3 Data analysis:

Data was analyzed by SPSS version 22 using [a]Independent T-test.

## 2.4 Ethical considerations:

Permission to carry out the study was obtained from the collage of health, Elshaikh Abdallah Elbadri University and permission of ministry of health. All blood samples were examined informed for the purpose of the study before collection of the sample and verbal consent was taken from them.

# Chapter three

# Results

# 3 RESULTS AND DESCRIPTION:

**This is a descriptive cross sectional study that conducted in Atbara hospital during the period from March to July 2018.**

**Table (4-1) Distribution: Sex**

| | Frequency | Percent% |
|---|---|---|
| Male | 23 | 46.0 |
| Female | 27 | 54.0 |
| Total | 50 | 100.0 |

**Table (4-2) Distribution: age**

| | Frequency | Percent% |
|---|---|---|
| Less than 30 Years | 3 | 6.0 |
| 30__40 Years | 3 | 6.0 |
| 40__50 Years | 12 | 24.0 |
| 50__60 Years | 10 | 20.0 |
| 60__70 Years | 14 | 28.0 |
| 70__80 Years | 8 | 16.0 |
| Total | 50 | 100.0 |

**50 samples were collected from diabetic patients in which there were 2 (4%) yes and 48 (96%) No, this is shown in fig (1).**

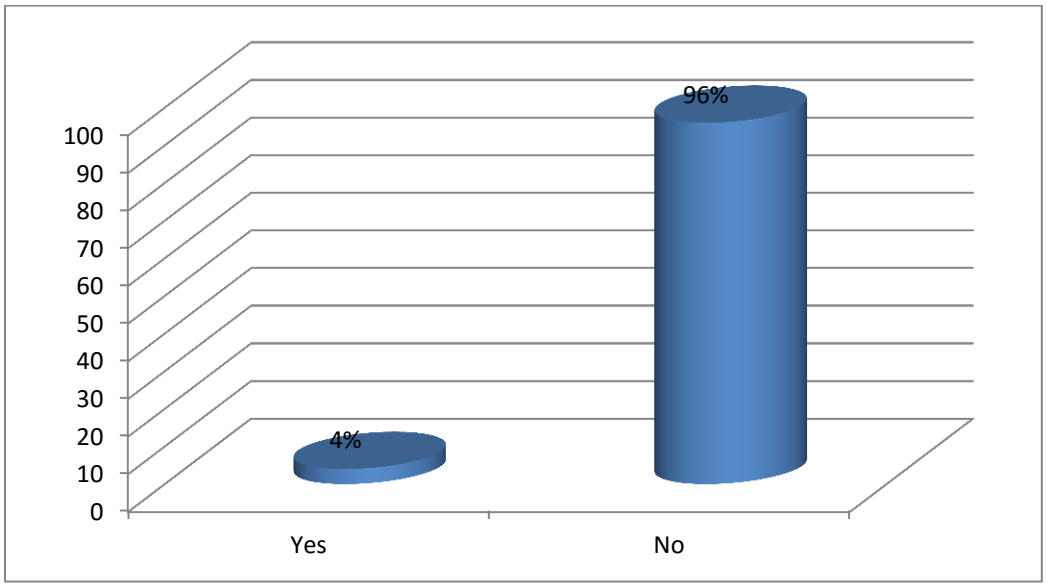


**Figure :( 4-1) Smoking in diabetic patients**

**Table (4-3) Distribution: Exercise**

| | Frequency | Percent% |
|---|---|---|
| Yes | 21 | 42.0 |
| No | 29 | 58.0 |
| Total | 50 | 100.0 |

**50 samples were collected from diabetic patients in which there were 7 (14%) yes and 43 (86%) No, this is shown in fig (2).**

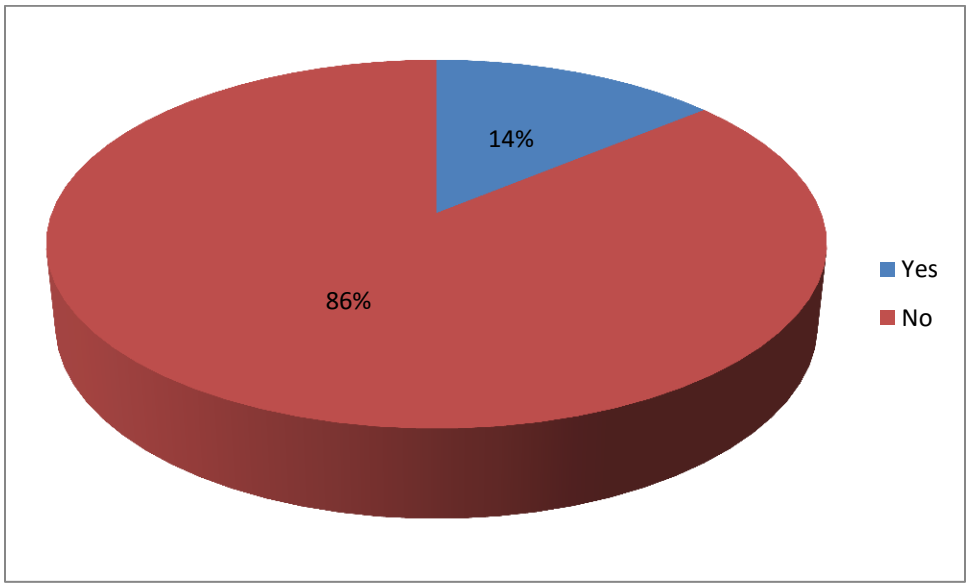


**Figure :( 4-2) History in diabetic patients**

**Table (4-4) Distribution: duration**

| | Frequency | Percent% |
|---|---|---|
| 1__5 Years | 22 | 44.0 |
| 5__10 Years | 15 | 30.0 |
| 10__15 Years | 8 | 16.0 |
| 15__20 Years | 2 | 4.0 |
| 20__25 Years | 3 | 6.0 |
| Total | 50 | 100.0 |

**Table (4-5): Comparison of means of PT, APTT and INR in healthy individuals' and diabetic patients**

| Variable | healthy individuals N=50 | Diabetic patients N=50 | P value |
|---|---|---|---|
| PT | 16.7 ± 1.24 (14.6 - 19.2) | 16.64 ± 3.09 (12.9 - 28.1) | = 0.832 |
| APTT | 36.2± 2.7 (30 – 42) | 38.3±8.7 (26.– 61) | =.111 |
| INR | 1.158± .091 (1 – 1.34) | 1.15± .227 (.88 – 2) | =.844 |

- The table shows the mean ± SD (mini - max) and probability (P)
- T-test was used for comparison.
- P value ≤ 0.05 was considered significant.

**Table (4-6): Comparison between exercise and PT, APTT, INR in diabetic patients**

| Variable | Yes N=21 | NO N=29 | P value |
|---|---|---|---|
| PT | 16.9± 3.5 | 16.4 ± 2.8 | = 0.609 |
| APTT | 38.21± 9.4 | 38.3±8.35 | =.956 |
| INR | 1.1695± .25814 | 1.1379± .20555 | =.632 |

- The table shows the mean ± SD (mini - max) and probability (P)
- T-test was used for comparison.
- P value ≤ 0.05 was considered significant

**Table (4-7): Comparison between age and PT, APTT, INR in diabetic patients**

| | | Sum of Squares | Df | Mean Square | F | Sig. |
|---|---|---|---|---|---|---|
| PT | Between Groups | 22.977 | 5 | 4.595 | .453 | .808 |
| | Within Groups | 445.901 | 44 | 10.134 | | |
| | Total | 468.878 | 49 | | | |
| INR | Between Groups | .125 | 5 | .025 | .458 | .805 |
| | Within Groups | 2.403 | 44 | .055 | | |
| | Total | 2.528 | 49 | | | |
| PTT | Between Groups | 133.373 | 5 | 26.675 | .326 | .895 |
| | Within Groups | 3605.507 | 44 | 81.943 | | |
| | Total | 3738.880 | 49 | | | |

- T-test was used for comparison.
- P value $\leq 0.05$ was considered significant

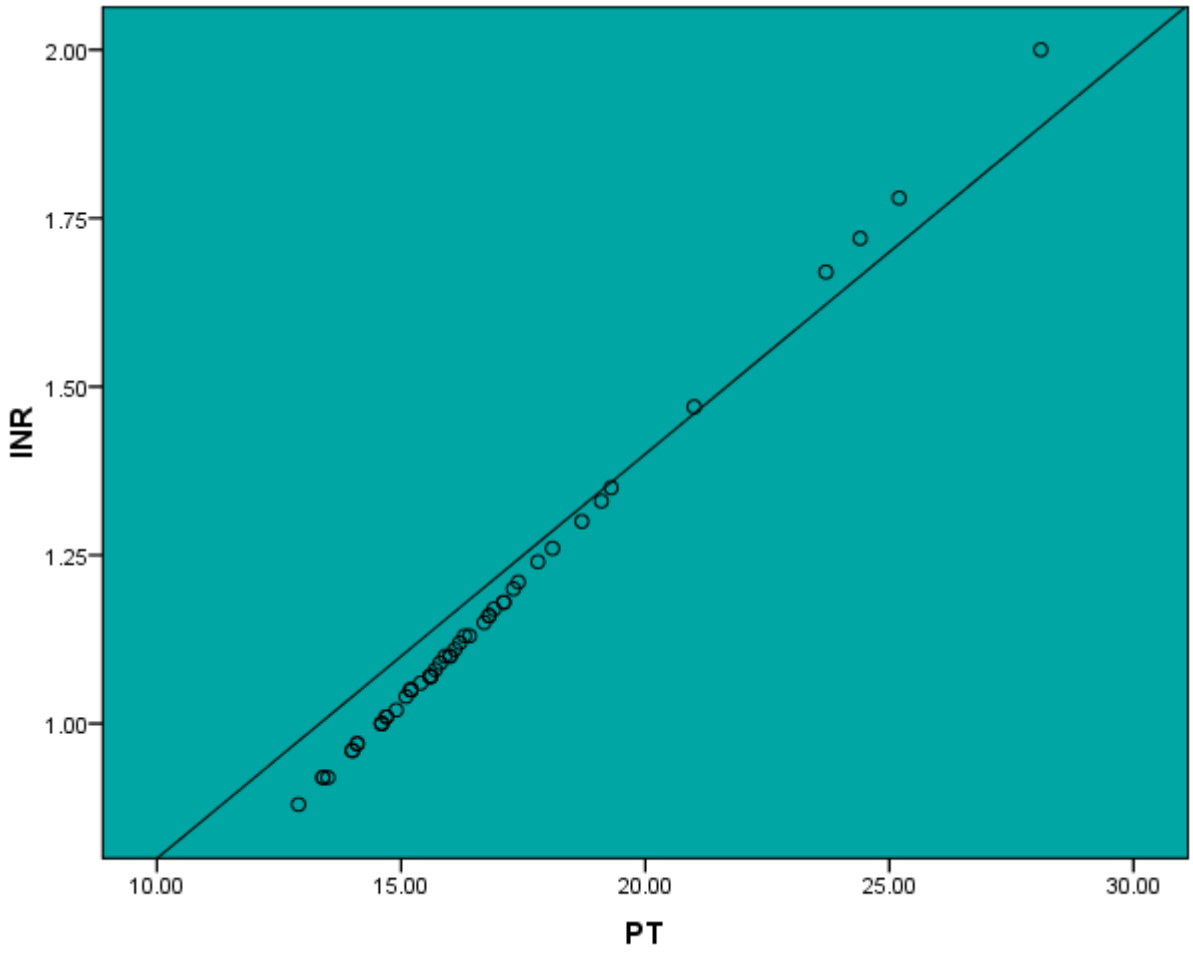


**Fig. (4-3): Ascatter plot shows the relationship between PT&INR of the diabetic patients (r=%65, P= 0.000)**

# Chapter four

## Discussion, Conclusion and Recommendations

# 4.1 DISCUSSION:

Diabetes mellitus is associated with increased risk of atherosclerosis, so diabetes is a procoagulant state. Is characterized by high risk of athero-thrombotic complications affecting the coronary, cerebral and peripheral arterial trees. It is a syndrome characterized by presence of chronic hyperglycemia due to defective insulin secretion, insulin action or both affecting metabolism of various compounds including carbohydrate, lipids, and proteins and it also impairs various biological processes such as coagulation and fibrinolytic alteration. Therefore in the present study were evaluated some of Bleeding profile tests in diabetes mellitus type2 individuals. The results show that the mean level of prothrombin time type 2 diabetic patients was 16.64±3.09 Sec and of control was 16.7±1.24 Sec, it was none significantly correlated (P value = 0.832) and the mean value of APTT in diabetes mellitus type2 was 38.3±8.7 seconds while in healthy individuals it was 36.2±2.7 seconds, no significant difference in APTT was found in the diabetes mellitus type2 and healthy individuals (P value as 0.111). The study done by acang N1 jalil FD, University of andalas general hospital in 1993.Hypercoagulation in diabetes mellitus. That result was a significantly high fibrinogen and short PT and APTT in diabetic patients which disagree with our study. [17] Another study done by Fayez Karim, et al, in July 2013 to June 2014.Coagulation impairment in type 2 diabetes mellitus. That result in this study PT and APTT were significantly ($P<0.001$) lower in diabetes mellitus than those of control group, which disagree with our study[18].The study done by Fathelrahman Mahdi Hassan, Prothrombin time and activated partial thromboplastin time among type 2 noninsulin dependent diabetes mellitus that results show that the mean level of

prothrombin time type 2 diabetic patients was 12.0 Sec and of control was 11.1 Sec, it was significantly correlated (P value = 0.02) and the mean level activated partial thromboplastin time (APTT) was 30.7 Sec and of control was 31.2 Sec. This result was none significant (P. value = 0.826), which disagree PT in our study, however the APTT agree with our study[19].Another study done by Amal S. elhassadel et al, effect of diabetes mellitus type 2 on activated partial thromboplastin time and prothrombin time .That result show the mean value of APTT in diabetes mellitus type2 individuals was significant lower (28.95 ±7.54) seconds as compare with control, (34.12±2.82) seconds (P = 0.06). The mean value of prothrombin time (PT) among T2DM individuals was (14.04 ±2.96) seconds and the mean value of PT among healthy individuals was (13.5 ± 1.54) seconds. There was no significant difference in PT of diabetes mellitus type2 individuals $P \geq 0.05$which the APPT of their study disagree with our study, however the PT of their study agree with our study.[20]

## 4.2 CONCLUSION:

Our data was concluded further that patients with type 2 diabetes mellitus had no hypercoagulable state due to PT and APTT.

## 4.3 RECOMMENDATION:

Other study with large sample size and many variables to reach to another facts.

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**21.** Operation Manual Coatron M1- software C1.20

# Appendix

## Questionnaire

Patient name ----------

Sex----------

Age----------

The age you get the disease----------

Do you take anticoagulant drug: Yes---------- No ----------

Do you get before bleeding disorder: Yes----------No----------

Family history of bleeding disorder: Yes----------No ----------

Are you suffering from renal or liver disease: Yes---------- No----------

Do you smoker: Yes---------- No----------

Do you do exercise: Yes---------- No----------

## INFORMED CONSENT FOR COLLECTION OF BLOOD SAMPLES FOR REASEARCH

This sample is being collected solely for purpose of research .The research evaluation of PT and PTT among diabetes mellitus type2 patients with control group for comparison between them on Atbara people. The procedure for sample collection involves only the withdrawal of 2-3 ml of blood. It is such a harmless process .The results of the study may not be of immediate benefit to the patient. Complete confidentiality will be maintained in the handling and processing of samples. The above statement has been read out or explained to me, and having understood the same, I put my signature or thumb impression. I hereby consent to collection of the blood sample of myself.

Patient name: Phone number:

Address: signature/ left thumb impression of patient:

Date:

## استمارة موافقة للأشخاص المشاركين في الدراسة

هذه الدراسة لغرض البحث العلمي فقط وهى بغرض مقارنه عوامل التجلط بين المصابين بمرض السكري النوع الثاني وغير المصابين بالمرض في سكان مدينه عطبره. وتتطلب اخذ 2-3 مل من الدم ولا يوجد أذى أو خطورة تنتج منها عليك و حال موافقتك على المشاركة في هذه الدراسة سيبقى اسمك قيد الكتمان كما لا يوجد اى تعويض مالى. لقد اطلعت على استمارة الموافقه وادركت مضمونها واطلعنى الباحث عن فوائد بحثه واهميته العلميه والعملية وبناء عليه فانى حرا مختارا وبمحض ارادتى اوافق على المشاركه فى هذه الدراسه كما اوضح بان مشاركتى فيها طوعا منى ، وان باستطاعتى رفض المشاركه كما ان بامكانى ان لا اجيب على اى سؤال لا ارغب فى اجابته ، كما تم اعلامى بان مشاركتى بالبحث لن تحملنى اى نفقات او مسائله من شانها الضرر بمهنتى او شخصى . وان المعلومات الناتجه عن مشاركتى سوف تعامل بسريه تامه ولن يطلع عليها اى شخص غير معنى بالبحث وان هذه المعلومات ونتائجها هى لاغراض علميه فقط ولن تكون هنالك اشاره الى شخص او عائلتى فى اى منشور عن هذه الدراسه ولااجل هذا فانى اوافق بى مشاركتى فى هذه الدراسه.

اسم المشارك: رقم التلفون:

التوقيع: العنوان:

التاريخ :