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Assessment of Fasting Blood Glucose, HbA1c,Choleterol and Triglysrides in Patient with Skin Tags in Khartoum State

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Dedication

This thesis is dedicated to: The sake of ***Allah****, my Creator and my Master, My great teacher and messenger,* ***Mohammed*** *(May Allah blesses and grants him), who taught us the purpose of life*

I also dedicate my dissertation study to ***my family****. A special feeling of gratitude to my loving* ***parents, my husband Ahmed, my sons, DrAbdelwahab, My sisters and my brothers*** *Who have never left my side and are very special*

To friends *who encouraged and supportedme,****Heba, Walaa, Ebtihal,****and all the people in my life who touched my heart, I dedicate this research.*

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At the end of this thesis I would like to thank all those people who made this thesis possible. At the end of this thesis, it is a pleasant task to express my thanks to all those who contributed in many ways to the success of this study and made it an unforgettable experience for me.

At this moment of accomplishment, first of all I pay homage to my guide,

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*My heartfelt thanks and appreciation are due to all the staff of **Medical Laboratory Sciences, University oF Shendi**, who offered me the chance to do this research.*

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Abstract

Background: Skin tags (acrochordons) are the common small benign connective tissue tumor of the dermis that occurs in old subjects usually located on the neck and the major flexors .and the aim of this study to estimate the prevalence of Diabetes Mellitus and dyslipidemia among patients with Skin Tags in Khartoum state.

Materials and Methods: This is descriptive case control study and was conducted in period from March To July 2018,. In this study 50[28 (56%) male and 22(54%) female] patients with skin tags and 20[11(55%) male and 9(45%) female] healthy individual are randomly selected, blood samples were collected after fulfillment of questionnaire, fasting venous blood collected in fluoride oxalate container for fasting glucose, cholesterol and triglycerides and 2.5ml venous blood in EDTA for HbA1c, and were analysis by spectrophotometer for glucose cholesterol and triglycerides and ichroma for HbA1c,obtained results were analyzed statistically by using SPSS.

Results: the mean of fasting blood glucose,HbA1c,cholesterol and triglycerides of case is (111mg.dl, 5.6 %, 205mg.dl, 160mg.dl) respectively. and the mean of fasting blood glucose,HbA1c,cholesterol and triglycerides of healthy individual is (86mg.dl, 5.0%, 149mg.dl, 170mg.dl) respectively. 62.2% of male has (1-10 ST) ,38.5% of male has (11-20 ST) and 37.8% of female has (1-10 ST) ,61.5% has 11-20 ST. case aged 20-40 years (48.6% has 1-10 ST and 15.4% has 11-20 ST),case aged 41-80 years (51.4% has 1-10 ST and 84.6% has 11-20 ST).

Conclusion; There was significant correlation between number of skin tags and mean levels of fasting blood glucose, HbA1c, and fasting serum cholesterol levels, no significant correlation between gender and number of ST, significant correlation between age and number of ST.

المستخلص

المقدمة:الزوائد الجلدية تعتبر من الاورام الحميدة الشائعة ، تحدث عند الكبار وعادة تكون في العنق ومعظم الاعضاء.هنالك احتمال وجود علاقة بين هذه الزوائد والتغيير في استقلاب الكاربوهيدرات (الجلوكوز) واستقلاب الدهون.الهدف من هذه الدراسة تقدير انتشار مرض السكري وارتفاع نسبة الدهون لدي المرضي الذين لديهم زوائد جلدية ، في ولاية الخرطوم.

الطرق والادوات: هذه الدراسة دراسة مقارنة وصفية قمنا بها بالفترة من مارس الي يوليو2018 تم اختيار 50 مريض بشكل عشوائي { 28 (56%) رجال و22(54%) اناث } و20 ليس لهم زوائد للمقارنة {11 (55%) رجال و9(45%) اناث} . اخذت العينات بعد ملء الاستمارات ببينات المشاركين في البحث،وتم تحليل نسبة الجلكوز والهيموغلوبين السكري والكوليسترول والدهون الثلاثية في الدم. وحللت النتائج باستخدام برامج الحاسوب.

النتائج :نسبة متوسط الجلوكوز والهيموغلوبين السكري والكليسترول والدهون الثلاثية هي (111و5,8 و205 و160)علي التوالي للمرضي الذين لديهم زوائد جلدية، ونسبة متوسط الجلكوز والهيموغلوبين السكري والكليسترول والدهون الثلاثية هي (86 ،5.0 ،149 ، 170) علي التوالي للمشاركين الذين ليس لهم زوائد جلدية ،62.2 % من الرجال لديهم (1-10 زوائد جلدية) ،38.5% منهم لديهم (11-20 زوائد جلدية) ، و37,8% من النساء لديهن (1-10 زوائد جلدية) ،61,5% لديهن (11-20زوائد جلدية).المشاركين من عمر 20 الي 40 عام (48,6% لديهم 1-10 زوائد جلدية و15.4%لديهم 11-20 زوائد جلدية) ،والمشاركين من عم 40 الي 80 عام (51.4% لديهم 1-10 زوائد جلدية و84.6% لديهم 11-20 زوائد جلدية).

الخلاصة: وجدنا في الدراسة ان هنالك علاقة واضحة بين متوسط الجلوكوز والهيموغلبين السكري والكليسترول وبين عدد الزوائد الجلدية، وعلاقة طردية بين عدد الزوائد الجلدية والعمر، وليست هنالك علاقة بين الجنس وعدد الزوائد الجلدية.

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List of abbreviations

Abbreviation	Meaning
Dl	Deciliter
DM	Diabetic mellitus
FBS	Fasting blood sugar
L	Litter
Mg	Milligram
Mm	Millimeter
Nm	Nanometer
ST	Skin Tag

Chapter One

1.1 Introduction

Skin tags: Skin tags (acrochordons) are the common small benign connective tissue tumor of the dermis, most are minute 1 to 5 mm in the length, flesh colored to hyper pigmented pedunculated papilloma.[1] Characteristically attached by short, thin stalk. They are most common on the neck, axilla and skin folds.[2]They are also name soft fibromas, fibro epithelial polyps.[3]These lesions are extremely common in adult population over 40 year of age and increase incidence in the elderly.[4]Acrochordons are most frequent in obesity[5], hormonal imbalance[6] metabolic syndrome[7] and other condition have been reported as contributing factors. Histological, Skin tags classify as fibromas with hyperplasic epidermis connected to the skin on connective tissue stalk.[8]The over lining epidermis is essentially normal. The skin tags appear as an outgrowth of skin. The dermis appear normal and there is a minimal inflammatory infiltrate present.[1]Skin tags remain asymptomatic and are usually not painful unless they become inflamed or irritated.[9]Most patients with skin tags consult a doctor for cosmetic reasons. Multiple STs are frequently associated with non- insulin dependent diabetes mellitus and obesity.[5]

Clinical findings: Skin tags can be found throughout the adult population. They have no sex or race predilection. They are completely benign skin growth that has no malignant potential. Skin tags are almost never seen in children. Most skin tags are minute 1 to 5 mm in length, with a skin-colored to slightly hyper pigmented appearance .[10]The lesion develop on the skin surface that rub together or that chronically rub against clothes.[11]

Histology: Skin tag histological classifies as fibromas with hyperplasic epidermis connected to the skin on connective tissue stalk [(11)].The overlying epidermis is essentially normal. The skin tag appears as an outgrowth of the skin. The dermis appears normal, and there is a minimal inflammatory infiltrate present. [(10)]

1.2Rationale

- Skin is the system in the body that can reflect many metabolic disorders; so can assist early diagnosis.
- Most Sudanese people don’t aware about skin tags because it is harmless and painless unless its inflamed or irritated, but others consider it as ugly singes and removed only for cosmetic purpose regardless of the causes of their appearance.
- This study can assist dermatologist to evaluate the patients with acrochordons for the presence of diabetes mellitus and dyslipidemas.

1.3 Objectives:

3.1.1 General objective:

To assess Fasting Blood Glucose (FBG),HbA1c ,cholesterol and triglycerides among skin tags patient in Khartoum state.

3.1.2 Specific objectives:

- To measure FBG,HbA1c ,cholesterol and triglyceridesin case and control group.
- To compare betweenmeans of fasting blood glucose ,HbA1c ,serum cholesterol and serum triglycerides in patients with skin tags and in healthy individuals.
- To compere between the mean of FBS ,HbA1c ,S.Ch and TG in patients with different number of skin tags.
- To compare between the frequency and percentage of gender and number of skin tags.
- To compare between the frequency and percentage of age and number of skin tags.

Chapter Two

2. Literature Review

2.1 Skin manifestation of diabetes mellitus:

The human skin is the outer covering of the body. In humans, it is the largest organ of the integumentary system. The skin has multiple layers of ectodermaltissue and guards the underlying muscles, bones, ligaments and internal organs.[12]

Diabetes can affect every part of the body, including the skin. As many as 33 percent of people with diabetes will have a skin disorder caused or affected by diabetes at some time in their lives. In fact, such problems are sometimes the first sign that a person has diabetes. Luckily, most skin conditions can be prevented or easily treated if caught early. [13]

Coetaneous manifestations in the setting of diabetes can be classified to non infectious, Infectious, Related to complication because of vasculopathy and Related to complication of diabetes treatment.[14]

Insulin signaling supports normal skin proliferation, differentiation, and maintenance so in Diabetes mellitus there are a variety of coetaneous manifestations. Good metabolic control may prevent some of these manifestations and may support cure. Unfortunately, most glucose-lowering drugs also have coetaneous side effects.[15]

2.1.1 Non infectious skin manifestation: Common Non infectious skin finding in diabetes included: acanthosisnegregcan (AN), skin tag, and vitiligo, and necrobiosislipodica, diabetic dermopathy. [16]Diabetes Mellitus (DM): is group of metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both.[14]

2.1.2 Pathophysiology of Skin Tags: Both insulin and IGF-1 stimulate the synthesis of androgens in the ovaries and testis and both inhibit hepatic synthesis of sex hormone binding globulin (SHBG) , allowing for

higher level of free biologically active androgens , which directly contribute to the pathophysiology of (coetaneous papilloma (skin tag).[17]Skin Tags are characterized by hyper keratinization chronic hyperinsulinemia leads to chronic elevation of non-stratified FFAs, which causes increased production of epidermal growth factor and decrease in production of IGFBP-3 locally, allowing an increase in free IGF-1 that promotes the proliferation of keratinocytes , furthermore, decrease IGFBP-3 reduces the binding affinity of retinoic acid for its receptors , thus reducing the normal inhibition of cellular proliferation.[17]

2.2 Diagnostic criteria of Diabetes Mellitus

The diagnostic criteria for diabetes mellitus were modified by the expert committee to allow for earlier detection of the disease. Diagnostic criteria are fallowing [18]:

- Random plasma glucose > = 200 mg/dl (11.1 mmol/L)+ symptoms of diabetes
- Fasting plasma glucose > = 126mg/dl (7.0mmol/L)
- Two-hour plasma glucose > = 200 mg/dl (11.1mmo/L) during an OGTT (75-g glucose load)

An intermediate group who did not meet the criteria of diabetes mellitus but who had glucose level above normal was defined by two methods :[18]

- Fasting glucose levels >= 110 mg/dl but < 126 mg/dl were called the impaired fasting glucose group
- Patients who had 2-hour OGTT levels of > = 140 mg/dl but < 200 mg/dl was defined as impaired glucose tolerance
- Hemoglobin **A1C** is a widely used marker of chronic glycemia, reflecting average blood glucose levels over a 2- to 3-month period of time. The test plays a critical role in the management of the patient with diabetes.[19]

2.2.1 HbA1c testing in diagnosing diabetes

The World Health Organization (WHO) suggests the following diagnostic guidelines for diabetes:

HbA1c below 42 mmol/mol **(6.0%):** Non-diabetic

HbA1c between 42 and 47 mmol/mol **(6.0–6.4%):** Impaired glucose regulation (IGR) or Prediabetes.

HbA1c of 48 mmol/mol (6.5%) or over: Type 2 diabetes

2.3 Dyslipidemias

Dyslipidemias are disorders of lipoprotein metabolism, including lipoprotein overproduction and deficiency. These disorders may be manifested by elevation of the serum total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglyceride concentrations, and a decrease in the high-density lipoprotein (HDL) cholesterol concentration. Abnormal blood lipids are an increasing health problem in the world. Studies from India have shown upward trend in the prevalence of dyslipidemia, even among the young adult population.

Dyslipidemia plays a crucial role in the development of cardiovascular diseases, which has become the leading cause of death in most developed as well as in developing countries. It is now known that dermatological disorders, such as psoriasis are associated with dyslipidemias.[20]

2.3.1 Dyslipidemia and skin: Many dermatological disorders are known to be associated with dyslipidemia. Most of these are chronic inflammation diseases, and underlying mechanism may involve secretion of pro inflammatory cytokines. Studies have shown an increased occurrence of dyslipidemia in skin disorders like psoriasis, lichen planus,

pemphigus, granuloma annulare, histiocytosis, and connective tissues diseases like lupus erythematosus.[20]

2.3.2 Lipid Profile

This group of tests measures the amount of cholesterol and other fats in your blood.[18]

- Total cholesterol
- Triglycerides, another type of fat that causes hardening of the arteries.
- Test results may vary depending on age, gender, health history, the method used for the test, and other things. test results may not mean have a problem.

Results are given in milligrams per deciliter (mg/dl). Here are the ranges for total cholesterol in adults: [18]

- Normal: Less than 200 mg/dl
- Borderline high: 200 to 239 mg/dl
- High: At or above 240 mg/dl

The above numbers are general guidelines, because actual goals depend on the number of risk factors you have for heart disease.

- High levels of triglycerides are linked with a higher heart disease risk. Here are the adult ranges: [18]
  - Normal: Less than 150 mg/dl
  - Borderline high: 150 to 199 mg/dl
  - High: 200 to 499 mg/dl
  - Very high: Above 500 mg/dl

2.4 Previous studies

Many current researches and studies in different countries and nations assessing the association between the skin tags and (Diabetes Mellitus and dyslipidemias)

In Europe 1987 there is study was conducted BY .Kahana M, Grossman E, Feinstein A, Ronnen M, Cohen M, Millet MS in which the skin tag serve as marker for DM .which Two hundred and sixteen non hospitalized patients with skin tags (ST) were studied for the presence of diabetes mellitus (DM) and obesity. Overt DM was found in 57 (26.3%) patients and impaired glucose tolerance test was found in 17 (7.9%) patients. Sixteen new cases of DM (6%) were found among this group. All the diabetic patients in the study population had non-insulin dependent DM. Sixty-two (28.7%) of the patients were obese. No correlation was found between the localization, size, color and number of the ST and the presence of DM. this study indicates that ST are not associated with increased incidence of obesity compared to the general population. On the other hand, ST are associated with impaired carbohydrate metabolism, and may serve as means for identifying patients at increasing risk of having DM.[21]

In an Epidemiological study in India by DM Thappa :22-oct-1995 where 35 patients with ST were screened out of 5000 consecutive patients visiting dermatology clinic to ascertain whether skin tags (ST) are associated with a higher risk for diabetes mellitus (DM). The study group ranged in age from 35 to 73 years, of the cases, 62.8% (22 patients) had DM. Four new cases of DM (11.4%) were found among this group. All the diabetic patients in this study population had noninsulin dependent DM, The frequency of DM in ST patients was found to increase with age; however, it was statistically insignificant. No correlation was found

between localization, size, color, or number of ST and the presence of DM. This study confirmed that the frequency with which ST had been found to co-exist with DM in this population is significant, and ST may serve as a marker for DM.[22]

In turkey at June 2002 there was other study by S. Demir.Y, evaluated 120 patients with acrochordon for the presence of impaired carbohydrate metabolism. Overt diabetes mellitus (DM) was found in (73.3%) 88 patients, glucose intolerance was detected in(5%) 6 patients and (3.3%) 4 patients had reactive hypoglycemia. concluded that acrochordons may be skin markers of underlying impaired carbohydrate metabolism and the patients with acrochordon should be evaluated for the presence of diabetes mellitus .[23]

In Tehran, Iran at nov.2007 A case-control study was conducted by AbbasRasi MD, RaziehSoltani-Arabshahi MD, NasimShahbazi MD in individuals over 15 years old , comparing cases (n = 104) with at least three skin tags and age-, sex-, and body mass index (BMI)-matched controls (n = 94) without skin tag. Cases and controls were recruited from patients consecutively seen at an academic outpatient dermatology clinic. All patients underwent a standard 2-h oral glucose tolerance test with 75 g glucose. The result of this study was that Patients with skin tag had higher frequency of diabetes than the control group (23.07% vs. 8.51 %,). The difference in the frequency of IGT was not significant (13.46% vs. 10.63%), there was a positive correlation between the total number of skin tags and the mean fasting plasma glucose, and patients with more than 30 skin tags were particularly at an increased risk of diabetes (52.0%). No correlation was found between the number of skin tags and BMI. We did not find any correlation between the anatomical localization of skin tags and impaired carbohydrate metabolism, except for skin tags

under the breast in women. These results show an increased risk of diabetes mellitus in patients with multiple skin tags. With regard to the importance of early diagnosis of diabetes, we recommend a high level of suspicion for impaired carbohydrate metabolism in patients with skin tag.[24]

In Germany 2008 there was other study by .Sudy E, Urbina F, Maliqueo M, Sir T involved the fallowing , Clinical and metabolic glucose/insulin characteristics of men with multiple (8 or more) skin tags on the neck were compared with a control group with few or none. Both groups were divided in two subgroups according to normal or abnormal laboratory findings. In the study subgroup with normal laboratory findings the number of skin tags varied from 8-33, whereas in those with abnormal laboratory findings the range was 9-65. Eight or more skin tags were related with statistically significant laboratory glucose/insulin abnormalities: basal hyperinsulinemia ($p<0.002$), postprandial hyperinsulinemia ($p<0.003$), and postprandial hyperglycemia ($p<0.01$). In the multiple skin tag group 77 % had diverse laboratory abnormalities, including insulin resistance, basal hyperinsulinemia, postprandial hyperinsulinemia, glucose intolerance or type 2 diabetes, in contrast with the control group, where only 33 % showed laboratory abnormalities. One-third of the study group had acanthosisnigricans. Only 15 % of patients with metabolic abnormalities did not show any cutaneous expression of glucose/insulin alterations (9 or more skin tags on the neck, acanthosisnigricans, or waist circumference greater than 95 cm). Multiple skin tags were more sensitive than acanthosisnigricans in identifying those with alterations in the glucose/insulin metabolism (77 vs. 32 % respectively), although less specific (68 vs.100%). Multiple skin tags should raise suspicion of insulin resistance or hyperinsulinemia. [25]

In Brazil 2010 a cross-sectional study involving adult patients receiving care at a university teaching hospital was conducted by Tamega Ade A, Aranha AM, Guiotoku MM, Miot LD, Miot HA to evaluate the association between skin tags in the neck or axillary regions and insulin resistance. Cases were defined as patients with > 5 skin tags in the neck region and/or axilla. Insulin resistance was estimated using the HOMA-IR index. Results were adjusted for the other known covariates of risk for insulin resistance using a multiple logistic regression model. Ninety-eight cases and 103 controls were evaluated. There was no difference between the groups with respect to age or gender. Skin tags were directly associated with HOMA-IR values (odds ratio = 1.4), hypertriglyceridemia and body mass index, irrespective of adjustment for diabetes mellitus, age, skin phototype, gender, family history of diabetes mellitus or hip/waist ratio. Qualitatively elevated HOMA-IR levels (>3.8) were also significantly associated (odds ratio = 7.5). The presence of multiple skin tags was strongly associated with insulin resistance irrespective of other risk factors.[26]

In Iran 2012 other study by Ramin Taheri, BatoolOodi , RahebGhorbani in the same task in whether there is association between skin tag and diabetes mellitus. This study was carried out on 80 patients with skin tags as a case group and 80 patients without skin tags as a control group that they were referred to Semnan dermatological clinics. Then fasting blood sugar (FBS) were checked out in both two groups. In addition, height and weight were measured in all patients and body mass index (BMI) calculated for each of the patient. Results: 43.8% and 55% of patients were respectively female in the case group and the control group. Age mean (± SD) was 44.3±16.6 and 37.3±18.9 years in the case and control group, respectively. BMI mean (±SD) index was 28.0±4.3kg/m2 in the patients with skin tag, whereas, it was 25.5±5.1 kg/m² in the patients

without skin tag (P=0.001). Patients with skin tag had higher frequency of diabetes than patients in the control group (27.5% vs. 5%) and also the case group showed a higher frequency of pre diabetes than the control group (20% vs. 15%). The probability of presence of diabetes mellitus in the patients with skin tag was 6.82 times more than the patients in the control group (Odds ratio=6.82, 95% Confidence interval: 2.06-22.56, P=0.002). These data suggest that there was an association between skin tag and diabetes mellitus. Therefore, screening of patients with skin tag is recommended for early diagnosis diabetes mellitus.[27]

This study done by Guy's, St Thomas's, report details four patients who had skin tags, mainly on their torso, neck, and axillae, and who also displayed an abnormal lipid profile. All showed an increased serum triglyceride (fasting > 1.70 mmol/litre) and decreased highdensity lipoprotein (HDL) cholesterol (< 1.1 mmol/litre inwomen and 1.0 mmol/litre for men) concentration. The displayed lipid profile is also known as the atherogenic profileand is associated with insulin resistance, type 2 diabetes mellitus, and an increased risk of cardiovascular disease. Two of the patients had impaired glucose tolerance and one had type 2 diabetes mellitus. Three of the individuals had coronary artery disease. Skin tags might be a useful clinical sign that could alert clinicians to screen such individuals for abnormal lipids, type 2 diabetes mellitus, and cardiovascular disease.[28]

A comparison study of lipid profile levels between skin tags affected people and normal population in Tehran done by Abbas Rasi,[1] Alireza Faghihi,[2] Yaser Rahmanzadeh,[1] and Habib Hassannejad, Iran from April 2009 to June 2011, 168 patients enrolled the study:Sixteen patients were lost to follow-up for reasons unrelated to the study. Among the remaining 152 patients, there were 89 females (58.5%) and 63 males (%41.5). The

age ranged between 18 and 73 years (mean age, 49.6 years).Based on the TLGS study, 136 men and 220 women enrolled the control group of the study. The mean age was 28.4 years. No clinically significant differences were found in demographic variables between cases and control group.Mean skin tag number was 12.6 per subject. In 56 patients (36.8%), skin tag number was low (<10). In 75 subjects (51.9%) it was moderate (between 10 to 30) and finally in 17 patients (11.1%), total body skin tags number was high (≥30). Statistical analysis showed no significant differences between skin tag number and hypertriglyceridemia or hypercholesterolemia.[29]

Chapter Three

3. Materials and Methods

3.1 Study design:

This is comparativecase control study.

3.2 Study area:

The study was conducted at Khartoum state(Alanood hospital).

3.3 Study duration:

The study was conducted during the period from March to July 2018.

3.4 Study population and sample size:

All population with skin tags (at least three skin tags) in different age and gender selected randomly (50 patients with skin tags (28 male and 22 female)) and (20 healthy individual (11 male and 9 female)).

3.5 Inclusion criteria:

Patient with at least three benign diagnosed skin tags.

3.6 Exclusion criteria:

Pregnant women, acromegaly, poly cystic ovary syndrome, insulinoma, drugs that induced hyperinsulinemia and hereditary skin tags were excluded.

3.7Tool of data collection: Questionnaire: data were collected using well structured questionnaire make with patient face to face (age, gender, number of skin tags, location of skin tags, medical history).

3.9 Ethical clearance: All participants in the study had to sign consent for participation and the results of investigations were to be conveyed to their treating doctors who will discuss results with them and provide the necessary treatment.

3.10 Samples collection: Under a septic condition Fasting Venous blood(2.5 ml) were be collected in fluoride oxalate container for fasting blood glucose , cholesterol and triglycerides and 2.5 ml venous blood in EDTA for HbA1c.

3.11 Methodology

3.11.1 Glucose method

Principle of the method;Glucose oxidase peroxidase

Glucose in the sample originate, by means of coupled reaction, acoloured complex that can be measured by spectrophotometry.

Procedure

1. Reagent were brought to room temperature.
2. Were pipetted into test tubes.
3. Mixed thoroughly and incubated the tube for 10 minutes at room temperature.
4. The absorbance of the standard and sample were measured at 500 nm against the blank.

3.11.2 HbA1c:

Principle

The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigens in sample forms the more antigen-antibody complex and lead to stronger intensity of fluorescence signal on detector antibody. Instrument for ichroma tests displays the content of glycated hemoglobin in terms of percent of the total hemoglobin in blood.

Procedure

1. .1 ml of hemolysis buffer were drawn and transferred it into detection buffer tube.
2. .005 ml of blood were drawn using capillary tube and was putting it into detection buffer tube.

3. The lid of the detection buffer tube were closed and was mixxing the sample thoroughly by shaking it about 15 times.
4. .075 ml of the sample mixture was pipetted and loaded into sample well in the test cartridge.
5. Wait till sample mixture flow appears in the windows (about 10 seconds).
6. The cartridge wasinserted in to i-chamber slot.
7. The cartridge was leaved into i-chamber for 12 minutes before removing. Scan the sample-loaded cartridge immediately when the incubation time is over.
8. The test result was red on the display screen of the instrument for ichroma test.

3.11.3 Cholesterol method;

Cholesterol oxidase\peroxidase (Bio Systems)

Principle

Free and esterified cholesterol in the sample originates by means of the coupled reactions, a coloured complex that can be measured by spectrophotometry.

Procedure

1. Reagent were brought to room temperature.
2. The reagent were pipetted in to labelled test tubes.
3. The tube was mixed thoroughly and incubated for 10 minutes.
4. The absorbance of the standard and sample were measured at 500nm against a blank.
5.

3.11.4 Triglycerides method

Glycerol phosphate oxidase\peroxidase (Bio Systems)

Principle of the method

Triglycerides in the sample originates, by means of the coupled reactions, coloured complex that can be measured by spectrophotometry.

Procedure

1. The reagent were brought to room temperature.

2. Reagent were pipetted into labelled test tube.

3. The tube was mixed thoroughly and incubated for 10 minutes.

4. The absorbance of the standard and sample were measured at500nm against blank.

3.12 Data Analysis:

Data were analyzed using computerized program SPSS (T test).

Chapter Four

4. Results

Table (4.1) Comparison between the mean of fasting glucose, HbA1c, Cholesterol and Triglycerides in patient with skin tags and in healthy idivduals.

Parameters	Study groups	No	Mean	Std. Deviation	p.value
Glucose Mg dl	Case	50	111	16.1	0.00
	Control	20	86	11.5	
HbA1c %	Case	50	5.8	0.6	0.00
	control	20	5.0	0.6	
Cholesterol Mg dl	Case	50	205	27.8	0.00
	control	20	149	48.7	
Triglycerides Mg dl	Case	50	160	34.0	0.2
	control	20	170	34.3	

Table (4.2) Comparison between themean of fasting glucose, HbA1c, Cholesterol and Triglycerides withdifferent number of skin tags.

Parameters	No of skin tag	Mean	Std. Deviation	p.value
Glucose Mg dl	1-10	108	14.0	0.01
	11-20	121	18.4	
HbA1c %	1-10	5.6	0.4	0.00
	11-20	6.2	0.9	
Cholesterol Mg dl	1-10	200	29.3	0.03
	11-20	219	17.0	
Triglycerides Mg dl	1-10	161	35.2	0.8
	11-20	159	31.9	

Table (4.3) comparison between the frequency and percentage of gender and number of skin tag.

			No of skin tag		p.value
			1-10	11-20	
Gender	Male	**Frequency**	23	5	0.1
		Percentage	62.2%	38.5%	
	Female	**Frequency**	14	8	
		Percentage	37.8%	61.5%	

Table (4.4) comparison betweenthe frequency and percentage of age and number of skin .

			No of skin tag		p.value
			1-10	11-20	
Age	20–40 years	**Frequency**	18	2	0.03
		Percentage	48.6%	15.4%	
	41–80 years	**Frequency**	19	11	
		Percentage	51.4%	84.6%	

Chapter Five

5.1Discussion

A total of 50 cases: [28 (56%) male and 22(54%)female] and a total of 20 healthy control [11(55%)male and 9(45%)female].All the results were expressed as mean+ or – SD value .The fasting blood glucose was higher in patients with skin tags and was statistically significant [p value <0.05] shows in table 1,The mean of case(111mg/dl) is higher than mean of control (89mg/dl). The overall patients [34(69%)] were impaired FBG according to WHO criteria.

The HbA1c in case was higher in patients with skin tags and was statistically significant [p value <0.05] shows in table 1, the mean of case (5.8%) is higher than mean of control (5%).

These results of FBG and HbA1c go in accordance with the finding of other study which has found a relationship between Skin Tags and diabetes mellitus.[22, 23, 24, and 25)]

The total cholesterol in case is higher in patients and was statistically significant [p value <0.05], the triglycerides in case is less than control and was not statistically significant [p value >0.05] shows in table (4.1), these result go accordance of other study which found relationship between Skin Tags and dyslipidemia [(28)] and discordance of study which found no relationship between Skin Tags and dyslipidemia. [(29)]

There wasstatistically significant correlation between mean of FBG, HbA1c and total cholesterol with number of Skin Tags, and no significant correlation between triglycerides and number of Skin Tags, as shown in table (4.2).There was statistically significant correlation between gender and number of skin tags, as shown in table (4.3).There is no significant correlation between age and number of Skin Tags, as shown in table (4.4).

The most frequent localization of acrochordon was face and neck.

5.2 Conclusion

This study concludes that;

- There was statistically significant association between Skin Tags with glucose, HbA1c and cholesterol levels.
- There was statistically significant association between number of Skin Tags with glucose, HbA1c and cholesterol level.
- There was statistically significant correlation between gender and number of skin tags

5.3Recommendation

This study recommendes that**:**

- Patients with Skin Tags need suitable interventions like change in dietary habits.
- Patients with Skin Tags should have been screened for the presence of Diabetes Mellitus and Dyslipidemia.
- Others studies should be done with large sample size to approve this relationship.

Chapter Six

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6.2 Appendixes

Appendix I

بسم الله الرحمن الرحيم

Ministry of Higher Education and Scientific Research

University of Shendi

Faculty of Graduate studies and Scientific Research

Assessment of Fasting Blood Glucose, HbA1c and Lipid profile in Patients with Skin Tags at Khartoum state

Questionnaire

Patient …… Lab No ……..

Age……

Gender Male ( ) female ( )

Numbers of Skin Tags ……

Locations of Skin Tags ……..

Previously diagnosed with …. Diabetes ( ) prediabetes ( ) none ( )

Type …….

Pregnant ( )

Acromegaly ( ) hereditary skin tags ( )insulinoma ( )

Drugs;

Telephone NO ……Signature ……

Parameters

FBS = …….. mg/dl

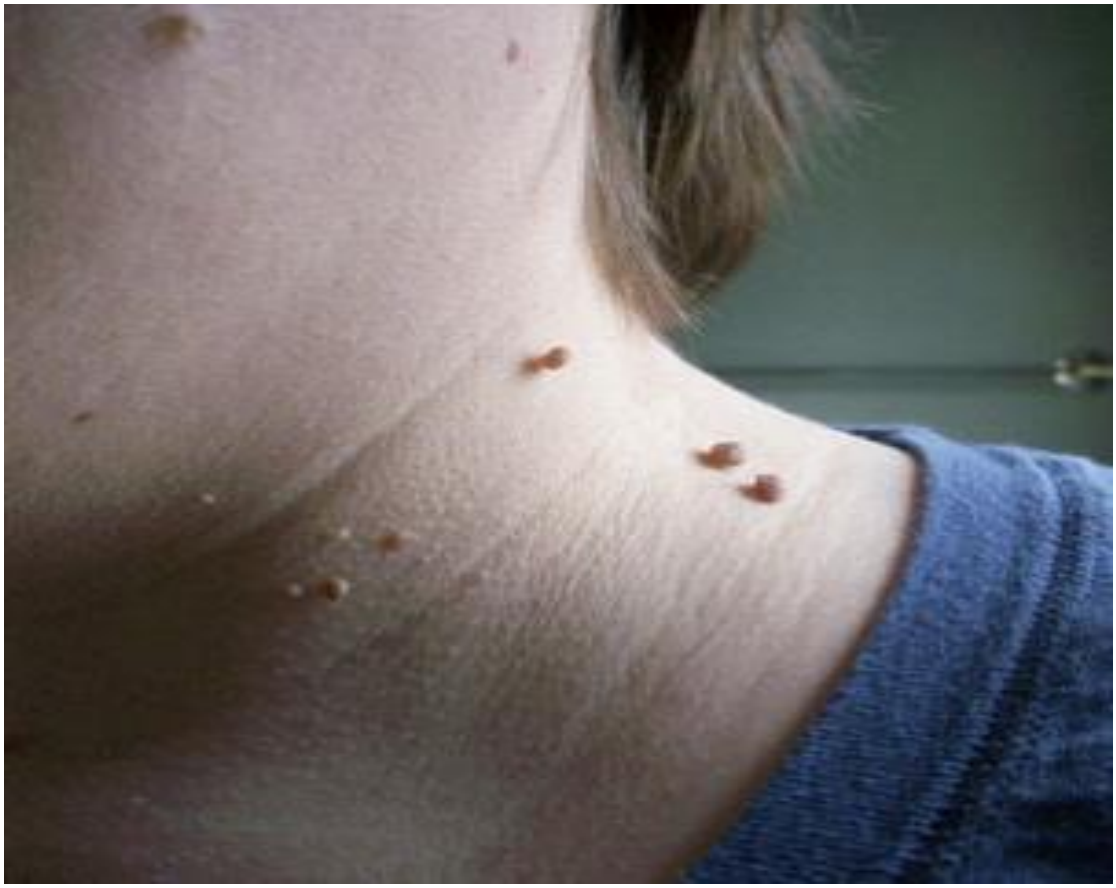
HbA1c = …… %

Cholesterol= ……. mg/dl

Triglycerides = ……. mg/dl

Appendixes II:

Acrochordons (skin tags)



COD 11828	COD 11528	COD 11529
1 x 50 mL	4 x 50 mL	2 x 250 mL
STORE AT 2-8°C		
Reagents for measurement of triglycerides concentration Only for *in vitro* use in the clinical laboratory		

TRIGLYCERIDES

BioSystems
REAGENTS & INSTRUMENTS

CE

TRIGLYCERIDES
GLYCEROL PHOSPHATE OXIDASE/PEROXIDASE

PRINCIPLE OF THE METHOD

Triglycerides in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry[1,2].

$$\text{Triglycerides} + H_2O \xrightarrow{\text{lipase}} \text{Glycerol} + \text{Fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{glycerol kinase}} \text{Glycerol} - 3 - P + \text{ADP}$$

$$\text{Glycerol} - 3 - P + O_2 \xrightarrow{\text{G-3-P-oxidase}} \text{Dihidroxyacetone} - P + H_2O_2$$

$$2\ H_2O_2 + 4 - \text{Aminoantipyrine} + 4 - \text{Chlorophenol} \xrightarrow{\text{peroxidase}} \text{Quinoneimine} + 4\ H_2O$$

CONTENTS

	COD 11828	COD 11528	COD 11529
A. Reagent S. Standard	1 x 50 mL 1 x 5 mL	4 x 50 mL 1 x 5 mL	2 x 250 mL 1 x 5 mL

COMPOSITION

A. Reagent: Pipes 45 mmol/L, magnesium chloride 5 mmol/L, 4-chlorophenol 6 mmol/L, lipase > 100 U/mL, glycerol kinase > 1.5 U/mL, glycerol-3-phosphate oxidase > 4 U/mL, peroxidase > 0.8 U/mL,4-aminoantipyrine 0.75 mmol/L, ATP 0.9 mmol/L, pH 7.0.

S. Triglycerides Standard: Glycerol equivalent to 200 mg/dL (2.26 mmol/L) triolein. Aqueous primary standard.

STORAGE

Store at 2-8°C.

Reagent and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

- Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.150 at 500 nm (1 cm cuvette).
- Standard: Presence of particulate material, turbidity.

REAGENT PREPARATION

Reagents are ready provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37°C.
- Analyzer, spectrophotometer or photometer able to read at 500 ± 20 nm.

SAMPLES

Serum or plasma collected by standard procedures.

Triglycerides in serum or plasma are stable for 5 days at 2-8°C. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

PROCEDURE

1. Bring the Reagent to room temperature.
2. Pipette into labelled test tubes: (Note 1)

	Blank	Standard	Sample
Triglycerides Standard (S)	—	10 µL	—
Sample	—	—	10 µL
Reagent (A)	1.0 mL	1.0 mL	1.0 mL

3. Mix thoroughly and incubate the tubes for 15 minutes at room temperature (16-25°C) or for 5 minutes at 37°C.
4. Measure the absorbance (A) of the Standard and Sample at 500 nm against the Blank. The colour is stable for at least 2 hours.

CALCULATIONS

The triglycerides concentration in the sample is calculated using the following general formula:

$$\frac{A_{Sample}}{A_{Standard}} \times C_{Standard} = C_{Sample}$$

If the Triglycerides Standard provided has been used to calibrate (Note 2):

$\frac{A_{Sample}}{A_{Standard}}$	x 200 = mg/dL triglycerides x 2.26 = mmol/L triglycerides

REFERENCE VALUES

The following uniform cut-off points have been established by the US National Institutes of Health and have also been adopted in many other countries for the evaluation of risk[3].

Up to 150 mg/dL = 1.7 mmol/L	Normal
150-199 mg/dL = 1.70-2.25 mmol/L	Borderline-high
200-499 mg/dL = 2.26-5.64 mmol/L	High
> 500 mg/dL = > 5.65 mmol/L	Very high

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 1.6 mg/dL = 0.018 mmol/L
- Linearity limit: 600 mg/dL = 6.78 mmol/L. For higher values dilute sample 1/ 4 with distilled water and repeat measurement.
- Repeatibility (within run):

Mean Concentration	CV	n
100 mg/dL = 1.13 mmol/L	1.7 %	20
245 mg/dL = 2.77 mmol/L	0.7 %	20

- Reproducibility (run to run):

Mean Concentration	CV	n
100 mg/dL = 1.13 mmol/L	2.6 %	25
245 mg/dL = 2.77 mmol/L	1.7 %	25

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents (Note 2). Details of the comparison experiments are available on request.
- Interferences: Hemoglobin (10 g/L) does not interfere. Bilirubin (2.5 mg/dL) may intefere. Other drugs and substances may interfere[4].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

Triglycerides are esters of glycerol and fatty acids coming from the diet or obtained by synthesis mainly in the liver. Triglycerides are transported in plasma by lipoproteins and used by adipose tissue, muscle and other. Their primary function is to provide energy to the cell.

Elevated serum triglycerides levels can be caused by liver disease, diabetes mellitus, nephrosis, hypothyroididsm, alcoholism, familial hyperlipoproteinemia IV and V, and other[3,5].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. This reagent may be used in several automatic analysers. Instructions for many of them are available on request.
2. Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analyzers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18011 and 18044).

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COD 11805 1 x 50 mL	COD 11505 1 x 200 mL	COD 11506 1 x 500 mL	COD 11539 1 x 1 L
STORE AT 2-8ºC			
Reagents for measurement of cholesterol concentration Only for *in vitro* use in the clinical laboratory			

CHOLESTEROL

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REAGENTS & INSTRUMENTS

CE

CHOLESTEROL
CHOLESTEROL OXIDASE/PEROXIDASE

PRINCIPLE OF THE METHOD

Free and esterified cholesterol in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry[1,2].

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{chol. esterase}} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + \tfrac{1}{2}\,O_2 + H_2O \xrightarrow{\text{chol. oxidase}} \text{Cholestenone} + H_2O_2$$

$$2\,H_2O_2 + 4\text{-Aminoantipyrine} + \text{Phenol} \xrightarrow{\text{peroxidase}} \text{Quinoneimine} + 4\,H_2O$$

CONTENTS

	COD 11805	COD 11505	COD 11506	COD 11539
A. Reagent S. Standard	1 x 50 mL 1 x 5 mL	1 x 200 mL 1 x 5 mL	1 x 500 mL 1 x 5 mL	1 x 1 L 1 x 5 mL

COMPOSITION

A. Reagent. Pipes 35 mmol/L, sodium cholate 0.5 mmol/L, phenol 28 mmol/L, cholesterol esterase > 0.2 U/mL, cholesterol oxidase > 0.1 U/mL, peroxidase > 0.8 U/mL, 4-aminoantipyrine 0.5 mmol/L, pH 7.0.

S. Cholesterol Standard. Cholesterol 200 mg/dL (5,18 mmol/L). Aqueous primary standard.

STORAGE

Store at 2-8ºC.

Reagent and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

- Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.200 at 500 nm (1 cm cuvette).
- Standard: Presence of particulate material, turbidity.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37ºC
- Analyzer, spectrophotometer or photometer able to read at 500 ± 20 nm

SAMPLES

Serum or plasma collected by standard procedures.

Cholesterol is stable for 7 days at 2-8ºC. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

PROCEDURE

1. Bring the Reagent to room temperature.
2. Pipette into labelled test tubes: (Note 1)

	Blank	Standard	Sample
Cholesterol Standard (S)	—	10 µL	—
Sample	—	—	10 µL
Reagent (A)	1.0 mL	1.0 mL	1.0 mL

3. Mix thoroughly and incubate the tubes for 10 minutes at room temperature (16-25ºC) or for 5 minutes at 37ºC.
4. Measure the absorbance (A) of the Standard and Sample at 500 nm against the Blank. The colour is stable for at least 2 hours.

CALCULATIONS

The cholesterol concentration in the sample is calculated using the following general formula:

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times C_{\text{Standard}} = C_{\text{Sample}}$$

If the Cholesterol Standard provided has been used to calibrate (Note 2):

$\frac{A_{\text{Sample}}}{A_{\text{Standard}}}$	x 200 = mg/dL cholesterol x 5.16 = mmol/L cholesterol

REFERENCE VALUES

The following uniform cut-off points have been established by the US National Cholesterol Education Program and have also been adopted in many other countries for the evaluation of coronary artery disease risk[3].

Up to 200 mg/dL = 5.2 mmol/L	Desirable
200-239 mg/dL = 5.2-6.21 mmol/L	Borderline High
> 240 mg/dL = > 6.24 mmol/L	High

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 0.3 mg/dL = 0.008 mmol/L
- Linearity limit: 1000 mg/dL = 26 mmol/L. For higher values dilute sample 1/2 with distilled water and repeat measurement.
- Repeatability (within run):

Mean Concentration	CV	n
121 mg/dL = 3.13 mmol/L	1.1 %	20
257 mg/dL = 6.66 mmol/L	0.9 %	20

- Reproducibility (run to run):

Mean Concentration	CV	n
121 mg/dL = 3.13 mmol/L	1.9 %	25
257 mg/dL= 6.66 mmol/L	1.0 %	25

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents (Note 2). Details of the comparison experiments are available on request.
- Interferences: Lipemia (triglycerides 10 g/L) does not interfere. Bilirubin (>10 mg/dL) and hemoglobin (>5 g/L) may affect the results. Other drugs and substances may interfere[4].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

Cholesterol is a steroid of high molecular weight and possesses the cyclopentanophenanthrene skeleton. Dietary cholesterol is partially absorbed and it is also synthesized by the liver and other tissues. Cholesterol is transported in plasma by lipoproteins. It is excreted unchanged into bile or after transformation to bile acids.

Increased total cholesterol values are associated with a progressively escalating risk of atherosclerosis and coronary artery disease[5,6].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. This reagent may be used in several automatic analysers. Instructions for many of them are available on request.
2. Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analyzers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18011 and 18044).

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Diabetes

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INTENDED USE

INTRODUCTION

PRINCIPLE

COMPONENTS

STORAGE AND STABILITY

LIMITATIONS OF THE TEST SYSTEM

SAMPLE COLLECTION AND PROCESSING

TEST SETUP

TEST PROCEDURE

PERFORMANCE CHARACTERISTICS

COD 11803	COD 11503	COD 11504	COD 11538
1 x 50 mL	1 x 200 mL	1 x 500 mL	1 x 1 L
STORE AT 2-8°C			
Reagents for measurement of glucose concentration Only for *in vitro* use in the clinical laboratory			

GLUCOSE

BioSystems
REAGENTS & INSTRUMENTS

CE

GLUCOSE
GLUCOSE OXIDASE/PEROXIDASE

PRINCIPLE OF THE METHOD

Glucose in the sample originates, by means of the coupled reactions described below, a coloured complex that can be measured by spectrophotometry[1].

$$\text{Glucose} + \tfrac{1}{2}\,O_2 + H_2O \xrightarrow{\text{glucose oxidase}} \text{Gluconate} + H_2O_2$$

$$2\,H_2O_2 + 4\text{-Aminoantipyrine} + \text{Phenol} \xrightarrow{\text{peroxidase}} \text{Quinoneimine} + 4\,H_2O$$

CONTENTS

	COD 11803	COD 11503	COD 11504	COD 11538
A: Reagent S: Standard	1 x 50 mL 1 x 5 mL	1 x 200 mL 1 x 5 mL	1 x 500 mL 1 x 5 mL	1 x 1 L 1 x 5 mL

COMPOSITION

A. Reagent: Phosphate 100 mmol/L, phenol 5 mmol/L, glucose oxidase > 10 U/mL, peroxidase > 1 U/mL, 4-aminoantipyrine 0.4 mmol/L, pH 7.5

S. Glucose/Urea/Creatinine Standard. Glucose 100 mg/dL (5.55 mmol/L), urea 50 mg/dL, creatinine 2 mg/dL. Aqueous primary standard.

STORAGE

Store at 2-8°C.

Reagent and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

- Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.150 at 500 nm (1 cm cuvette).
- Standard: Presence of particulate material, turbidity.

REAGENT PREPARATION

Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37°C
- Analyzer, spectrophotometer or photometer able to read at 500 ± 20 nm

SAMPLES

Serum or plasma collected by standard procedures. Serum or plasma must be separated from the red cells promptly to prevent glycolysis. The addition of sodium fluoride to the blood sample prevent glycolysis.

Glucose in serum or plasma is stable for 5 days at 2-8°C. Heparin, EDTA, oxalate and fluoride may be used as anticoagulants.

Cerebrospinal fluid collected by standard procedures. Cerebrospinal fluid may be contaminated with bacteria or other cells and should therefore be analyzed for glucose immediately.

PROCEDURE

1. Bring the Reagent to room temperature.
2. Pipette into labelled test tubes: (Note 1)

	Blank	Standard	Sample
Glucose Standard (S)	—	10 µL	—
Sample	—	—	10 µL
Reagent (A)	1.0 mL	1.0 mL	1.0 mL

3. Mix thoroughly and incubate the tubes for 10 minutes at room temperature (16-25°C) or for 5 minutes at 37°C.
4. Measure the absorbance (A) of the Standard and the Sample at 500 nm against the Blank. The colour is stable for at least 2 hours.

CALCULATIONS

The glucose concentration in the sample is calculated using the following general formula:

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times C_{\text{Standard}} = C_{\text{Sample}}$$

If the Glucose Standard provided has been used to calibrate (Note 2):

$\frac{A_{\text{Sample}}}{A_{\text{Standard}}}$	x 100 = mg/dL glucose x 5.55 = mmol/L glucose

REFERENCE VALUES

Serum and plasma[2]:

Newborn, premature	25-80 mg/dL = 1.39-4.44 mmol/L
Newborn, term	30-90 mg/dL = 1.67-5.00 mmol/L
Children, adult	70-105 mg/dL = 3.89-5.83 mmol/L

Cerebrospinal fluid[2]:

Children	60-80 mg/dL = 3.33-4.44 mmol/L
Adult	40-70 mg/dL = 2.22-3.89 mmol/L

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

According to the National Diabetes Data Group (US)[3], elevation of fasting plasma glucose values over 140 mg/dL (7.77 mmol/L) on more than one occasion is diagnostic of diabetes mellitus.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 0,23 mg/dL = 0,0126 mmol/L
- Linearity limit: 500 mg/dL = 27.5 mmol/L. For higher values dilute sample 1/4 with distilled water and repeat measurement.
- Repeatibility (within run):

Mean Concentration	CV	n
88 mg/dL = 4.84 mmol/L	1.2 %	20
326 mg/dL = 17.93 mmol/L	0.9 %	20

- Reproducibility (run to run):

Mean Concentration	CV	n
88 mg/dL = 4.84 mmol/L	2.7 %	25
326 mg/dL = 17.93 mmol/L	1.9 %	25

- Sensitivity: 4 mA·dL/mg = 0.22 mA·L/mmol
- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents (Note 2). Details of the comparison experiments are available on request.
- Interferences: Hemoglobin (> 3 g/L), lipemia (triglycerides > 1.25 g/L) and bilirubin (10 mg/dL) may interfere. Other drugs and substances may interfere[4].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

Glucose is the major source of energy in the body. Insulin, produced by islet cells in the pancreas, facilitates glucose entry into the tissue cells. A deficiency of insulin or a decrease of its effectiveness increases blood glucose.

Elevated serum or plasma glucose concentration is found in diabetes mellitus (insulin dependent, non-insulin dependent) and in other conditions and syndromes[2,3].

Hypoglycemia can occur in response to fasting, or it may be due to drugs, poisons, inborn errors of metabolism or previous gastrectomy[2,3].

Clinical dianosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. These reagents may be used in several automatic analysers. Specific instructions for application in many of them are available on request.
2. Calibration with the provided aqueous standard may cause a matrix related bias, specially in some analyzers. In these cases, it is recommended to calibrate using a serum based standard (Biochemistry Calibrator, cod. 18011 and 18044).

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