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The Effect of Ramadan Fasting on Anthropometric Measurements and some Biochemical Parameters among Type2 Diabetic Patients in Gaza Governorate

أثر صيام شهر رمضان المبارك على القياسات الجسمية وبعض التحاليل
البيوكيميائية لدى مرضى السكر النوع الثاني في محافظة غزة

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بِسْمِ اللّٰهِ الرَّحْمٰنِ الرَّحِیْمِ

قال تعالى { وَإِذَا نَسِيتُمْ عَلِيمًا } البقرة ١٨٤ "

In the name of Allah, Most Gracious, Most Merciful

{ *And that fast is better for you that you know* }"Holy Quran , Sura 2 , Aya 184"

Declaration

I certify that this thesis submitted for the fulfillment of the requirements for the award of the Master Degree of Medical Technology, Faculty of Science, Islamic University-Gaza, is wholly my own work, except otherwise Knowledge which was indicated to through references, and this thesis not been submitted for a higher degree in any another universities or academic institutions.

Signature -----

AKRAM M. AL - TAHER

Date: January 2012

Dedication

To my parents who have been supporting me.

To my wife who has helped me to accomplish this study.

To my mother in law.

To my beloved son, Baraa.

To my brothers and sisters.

To all of them I dedicate this work.

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Abstract

Background: Ramadan is the ninth month of the Islamic calendar where all Muslims compulsory must abstain from daily eat, drink, smoke and sexual relations from dawn to dusk. This holy month provides a unique opportunity to evaluate its impact on different biochemical parameters and anthropometric measurements among type 2 diabetes mellitus (T2DM) patients.

Objective: To assess the effect of Ramadan fasting on anthropometric measurements and some biochemical parameters among T2DM Patients in Gaza Governorate.

Materials and Methods: This study is a cross sectional. The study was carried out in Ramadan (late of July to August, 2011) in Gaza Governorate when the length of fasting was 16 hours a day. A total of 80 T2DM patients, aged 40 to 65 years, without history of diabetes complication or other diseases were treated with the same oral hypoglycemic drugs (OHD), were compared with 40 healthy individuals used as a normal control. During one week before Ramadan (Visit-1) and one week before its end (Visit-2), Anthropometric evaluation and biochemical detection for serum fasting blood glucose (FBG), glycated hemoglobin (HbA1c), total cholesterol (TC), triglycerides (TG), low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), urea and creatinine were carried out. FBG, TC, TG, urea and creatinine were detected using EIITech clinical kit by chemistry autoanalyzer (BS- 120). HDL-C was determined by precipitation method using EIITech clinical kit. LDL-C was estimated from quantitative measurement of TC, TG and HDL-C using Friedewald formula. HbA1c was determined by chromatography method using GLOBE DIAGNOSTIC kit. Data analysis were analyzed using SPSS version 14 following the process of data collection by interview questionnaire.

Results: There was statistically significant reduction in the mean of body weight ($p=0.038$ and $p=0.000$ respectively) and body mass index (BMI) ($p=0.001$ and $p=0.000$ respectively) at the end of Ramadan month among T2DM and controls as compared to pre-Ramadan. This study also found a statistically reduction in the mean \pm SD of serum FBG during Ramadan as compared to values before Ramadan in both groups ($p=0.000$ and $p=0.000$ respectively).

A statistically significant increase in the mean \pm SD of serum TG levels was observed at the end of fasting among diabetic group (p-value=0.000) while, a decreased among control group which was not statistically significant (p-value=0.69) at the end of Ramadan fasting month compared to pre-Ramadan mean. A among diabetic group, the mean \pm SD of HDL-C levels was showed significant reduction (P=0.000), while significant elevation in control group was observed (P=0.000) during Ramadan as compared to values before Ramadan. There was also statically significant elevation in the mean \pm SD of serum TC (p-value=0.000 in both groups) and LDL-C (p-value=0.000 in both groups) during the period of fasting by comparison at the period before fasting. In addition, during the two experimental periods, there were no statistical differences in the mean \pm SD of serum creatinine (p=0.0.193 and p=0.147 respectively) and urea levels (p=0.560 and p=0.143 respectively) in both groups. Concerning the HbA1c, the results also showed there were no statistical differences in the mean \pm SD of HbA1c levels (p=0.133 and p=0.905 respectively) in both groups.

Conclusions: Ramadan fasting is relatively safe and devoid of any serious complication among controlled diabetic patients. Furthermore patients should be properly educated about drug regimen adjustment, diet control, daily activities and possible complications that may suddenly occur and how to deal with them.

Keywords: Ramadan fasting, Biochemical parameters, Type 2 diabetes, Anthropometric measurement.

المستخلص

أثر صيام شهر رمضان المبارك على القياسات الجسمية وبعض المعايير البيوكيميائية لدى مرضى السكر النوع الثاني في محافظة غزة

مقدمة: رمضان هو الشهر التاسع في التقويم الإسلامي، حيث يتوجب على المسلمين الامتناع عن الطعام والشراب والتدخين والعلاقات الزوجية من طلوع الشمس حتى الغروب، ويعتبر هذا الشهر فرصة فريدة لتقييم آثار الصيام على المعايير المختلفة لدى مرضى السكر النوع الثاني.

الهدف: تهدف الدراسة إلى معرفة أثر صيام شهر رمضان على القياسات الجسمية وبعض التحاليل البيوكيميائية لدى مرضى السكر النوع الثاني في محافظة غزة.

الطرق والأدوات: تعتبر هذه الدراسة دراسة مقطعية تعتمد على مقارنة مجموعة ضابطة مع مجموعة تجريبية، وتم تنفيذها في مدينة غزة قبيل وخلال شهر رمضان (يوليو- أغسطس 2011) على ما مجموعه 80 متطوعاً من الذكور والإناث المصابين بمرض السكر النوع الثاني كمجموعة تجريبية حيث كانت تتراوح أعمارهم بين 40 إلى 65 عاماً، ولا يعانون من مضاعفات مرض السكري، ويأخذون نفس العلاج الخافض للسكر عن طريق الفم، بالإضافة إلى 40 متطوعاً من غير المصابين بمرض السكري كمجموعة ضابطة، كلا المجموعتين خضعوا لتقييم القياسات الجسمية والكيميائية قبل أسبوع واحد من شهر رمضان وفي نهاية الأسبوع الأخير من الشهر .

النتائج: عندما تم تحليل النتائج إحصائياً، كان هناك انخفاض ذو دلالة إحصائية في وزن الجسم ومؤشر كتلة الجسم في نهاية شهر رمضان، وجدت الدراسة أيضاً انخفاضاً ملحوظاً في نسبة جلوكوز الدم عند كل من المجموعة التجريبية والمجموعة الضابطة أثناء الصيام في نهاية شهر رمضان، لوحظ ارتفاع ذو دلالة إحصائية في مستويات الدهون الثلاثية عند المجموعة التجريبية خلال شهر رمضان لكن على النقيض لوحظ انخفاضاً في مستويات الدهون الثلاثية عند المجموعة الضابطة في نهايته، ولكن الفرق لم يكن ذو دلالة إحصائية، وأشارت النتائج إلى انخفاض ذو دلالة إحصائية في مستويات الكوليسترول عالي الكثافة عند المجموعة التجريبية في نهاية شهر رمضان بينما يرتفع ارتفاعاً ذو دلالة إحصائية عند المجموعة الضابطة في نهايته. أيضاً لوحظ ارتفاع ذو دلالة إحصائية في الكوليسترول الكلي والكوليسترول منخفض الكثافة عند كل من المجموعة التجريبية والمجموعة الضابطة خلال شهر رمضان، في حين أن كمية اليوريا والكرياتينين ونسبة مخزون السكر لم تتغير بشكل ملحوظ عند كل من المجموعتين خلال الشهر.

الاستنتاجات

صيام رمضان يعتبر أمن نسبياً وبلا مضاعفات سلبية بين مرضى السكر الذين يتلقون تعليمات صحيحة ومناسبة من الطبيب المختص حول جرعات العلاج الخافض للسكر و مراقبة النظام الغذائي بالإضافة إلى المضاعفات المحتمل حصوله فجأة وكيفية التعامل معها.

الكلمات المفتاحية: صيام رمضان، المعايير البيوكيميائية، مرض السكر من النوع الثاني، المقاييس الجسمانية، قطاع غزة.

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List of abbreviation

AHA	American Heart Association
ADA	American Diabetes Association
BMI	Body Mass Index
CVD	Cardiovascular disease
CAD	Coronary artery disease
CDC	Centers for Disease Control
CHD	Coronary Heart Disease
CHO	Carbohydrate
CVD	Cardiovascular Disease
DL	Deciliter
DM	Diabetes Mellitus
E.g.	For Example (exempli gratia)
EDTA	Ethylene Diamine Tetra Acetic Acid
Et al	And Others (et all)
FDA	Food& Drug Administration
FFQ	Food Frequency Questionnaire
FBG	Fasting Blood Glucose
HbA1c	Glycated Hemoglobin
HC	Hip Circumference
HDL-C	High Density Lipoprotein Cholesterol
LDL-C	Low Density Lipoprotein Cholesterol
MOH	Ministry Of Health
NCDs	Non-Communicable Diseases
NCEP	National Cholesterol Education Program
NGOs	Non- Governmental Organizations
NIDDM	Non- Insulin Dependent Diabetes Mellitus
NIS	New Israeli Shekel
OHD	Oral Hypoglycemic Drugs
PA	Physical Activity
PCBS	Palestinian Center Bureau of Statistics
PBUH	Peace Be Upon Him
PC	Personal Computer
SPSS	Statistical Package for Social Science
TG	Triglycerides
TC	Total cholesterol
WHO	World Health Organization
WHR	Waist to Hip Ratio
WC	Waist Circumference
UNRWA	United Nations Relief and Works Agency for Palestine Refugees
USD	United States Dollars

CHAPTER ONE

INTRODUCTION

1.1 Background

1.1.1 Ramadan month

Ramadan is the ninth month of the lunar calendar and is considered the holiest month for Muslims around the world and their fasting is obligatory (fard).

"O you who believe! Fasting is prescribed for you as it was prescribed for those before you, that you may become God-fearing" (Holy Qur'an, Al-Bakarah, 183).

Also this month has a special place for Muslims, because the first verses of the Qur'an, (Holy book of Islam) was revealed to Prophet Muhammad *"Ramadan is the (month) in which was sent down the Qur'an as a guide to mankind also clear (Signs) for guidance and judgment (between right and wrong)"* (Holy Qur'an, Al-Bakarah, 185), and the Muslims achieved important victories in the history of Islam in this month. During this month, all the adult Muslims abstain not only from eating, drinking, smoking and sexual relations but also from oral drug intake and intravenous injection from sunrise (dawn) to sunset (Meckel et al., 2008).

Ramadan month occurs 11 days earlier every year due to the difference between the solar and lunar years, and may occur in any of the four seasons (Sakr, 1975), making the length of fasting hours variable from 10-19 hours depending on the location of the country and the season in which the month of Ramadan falls (Altun et al., 2006), the fasting hours are longer in summer than in winter, and also harder and more difficult for Muslims. Ramadan fasting is commonly seen as beneficial for healthy individuals but among disabled individuals with acute or chronic diseases, certain diabetics can be exempted from this sacred obligation. Ramadan directly influences the control of diabetes because of the month-long changes in meal times, types of foods, use of medication and daily lifestyle (Rankin and Bhopal, 2001). During Ramadan Muslims have a meal after sunset, referred to as Iftar (breaking of the fast), and a smaller meal before dawn referred to as Sohor (pre-dawn).

The meal consumed before dawn usually consists of food that is usually eaten at breakfast and the meal consumed after sunset consists of variety of foods (dinner). Frequency and quantity of food and fluid intake are decreased and the dietary habits are changed to the consumption of foods that contain more carbohydrates and fats during Ramadan (Meckel et al., 2008). Muslims can eat all the food available to them during Ramadan, which are accustomed to eating during the other months. Unfortunately, most of the Muslim considered month of Ramadan as a festival of food and drink, in which all unhealthy dietary habits are applied. Ramadan is observed by all Muslims who spread across the globe and live under various geographical, climatic, social, cultural and economic conditions. This provides a unique opportunity to study the biochemical changes, eating habits, physical activity (PA) and the number of fasting hours in T2DM patients, and to get to the positive and negative impacts of the fast among T2DM patients as compared to healthy individuals over Ramadan time.

1.1.2 Diabetes mellitus

Diabetes mellitus (DM) is a metabolic disorder characterized by hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both (Wendy and Jean, 2007). DM is around 9% of population in Palestine, and the same ratio coexisted in Gaza strip (Ministry of Health (MOH), 2005b). The two major forms of diabetes are type 1 (insulin-dependent Diabetes mellitus, IDDM) resulting from autoimmune destructions of β cells lead to lack or severe reduction in insulin secretion and type 2 (non insulin-dependent Diabetes mellitus, NIDDM) resulting from both relative deficiency of insulin and insulin resistance (a disorder in which insulin can attach normally to receptors on liver and muscle cells but certain mechanisms prevent insulin from moving blood glucose into these cells) (Cohen, 2006). The most major risk factors for diabetes are overweight and obesity, Most of type 2 diabetic patients were found to be obese (Yassin et al., 2009). Sedentary lifestyle, poor diet, increased late age, and family history are from the other risk factors (Fujita, 2009). Type 1 and type 2 diabetes mellitus differ in their clinical presentation as well as their etiology. Type 1 diabetics are usually younger and thinner than type 2 diabetics.

Type 1 diabetics present with acute symptoms, while type 2 diabetes develops more slowly over time. Type 1 diabetics are more prone to develop ketoacidosis than type 2 diabetics. DM may present with symptoms such as thirst, polyuria, polyphagia, polydipsia, blurring of vision, and weight loss (Wendy and Jean, 2007). The long-term effects of DM (chronic hyperglycemia) include progressive development complications of nephropathy, neuropathy (Dyck et al., 2002), kidney damage, kidney failure (Maeda and Shiigai, 2007), vision problems, blindness, retinopathy (The National Eye Institute, 2006), sexual dysfunction, cardiovascular disease and increased risk of strokes (Marshall & Flyvbjerg, 2006). The tests which performed in Gaza for diagnosis, monitoring and prognosis of D.M. patients are fasting blood glucose, post prandial blood glucose, HBA1c, c-Peptide, and Insulin.

1.2 Research problem

During Ramadan month, T2DM patients are exposed to changes in meal times, types of foods, use of medication and daily lifestyle, these changes may affect their health. On the other hand, many unhealthy behavior have been observed among T2DM patients during Ramadan month such as decreasing physical activity (PA), eating much of sugary foods, eating high fat meals, eating high cholesterol meals, neglecting of sohor meals, and neglecting of oral hypoglycemic drug (OHD) regime which may lead to several diseases such as increase weight, cardiovascular disease (CVD), hypertriglyceridemia and hypercholesterolemia.

Physicians commonly face the difficult task of advising T2DM patients whether it is safe to fast, as well as recommending the dietary and drug regimens which diabetics should follow if they decided to fast. Lack of adequate literature on this subject makes it difficult to answer these questions. Unfortunately, no study has been undertaken about the effect of Ramadan fasting on T2DM patients in Palestine. Therefore, the question is whether Ramadan fasting, changes in lifestyle and ingestion unhealthy food during the Ramadan affect the anthropometric measurements and biochemical parameters of T2DM patients compared with healthy individuals in Gaza governorate?

1.3 Justification

The prevalence of DM disease in Palestine is about 9% and the mortality rate of DM diabetes was about 14.8/100,000 among Gaza strip population (MOH, 2005b). DM is constituted 3.1% of total Palestinians deaths (MOH, 2005b)

The few studies which reported in literature on the effect of Ramadan fasting on various blood components among T2DM patients were contradictory and inconsistent (Sulimani et al., 1991; Yarahmadi et al., 2003; Khatib et al., 2004; Khaled et al., 2006 and Khaled & Belbraouet, 2009).

Although, numerous studies were carried out on the effect of Ramadan fasting among different population categories, no study has been carried out in Gaza strip about the effect of this month fasting on anthropometric measurements and some biochemical parameters among T2DM patients.

1.4 Objectives

1.4.1 General objective

The main objective of this study is to investigate the effect of Ramadan fasting on the anthropometric measures and some biochemical parameters among T2DM patients in Gaza governorate. The study also aims to identify the effect of changes in food frequency and lifestyle on study subjects during this month.

1.4.2 Specific objectives

- 1- To study the effect of the change in lifestyle and dietary habits during Ramadan among the study subjects.
- 2- To evaluate the effect of Ramadan fasting on anthropometric measures among the study subjects.
- 3- To determine the effect of Ramadan fasting on serum lipid profile, HbA1c, blood glucose, creatinine & urea levels among the study subjects.

1.5 Hypotheses

- 1- There is a statistically significant difference among T2DM patients and healthy individuals according to dietary habits and lifestyle during Ramadan fasting.
- 2- There is a statistically significant difference between means \pm SD of weight and BMI among T2DM patients and healthy individuals at the end of Ramadan compared to pre-Ramadan means.
- 3- There is a statistically significant difference between means \pm SD of Lipid profile, FBG, HbA1c, urea and creatinine among T2DM patients and healthy individuals at the end of Ramadan compared to pre-Ramadan means.

1.6 Geography and demography of Palestine and Gaza Strip

Palestine is located in south-west Asia and is in the heart of the Middle East. To its north is Syria and Lebanon, to its south the Gulf of Aqaba and the Sinai Peninsula, and on its east is Jordan. The total area of Palestine is 27,008 square kilometers (Km²). The estimated global population of Palestinians at the end of 2011 was 11.2 million distributed as follows: 4.2 million in the Palestinian Territory (61.8% in the West Bank and 38.2% in Gaza Strip and both representing 37.7% of the global Palestinian population); 1.4 million (12.2%) in Israel; and 5.0 million (44.4%) in Arab countries (Palestinian Center Bureau of Statistics, PCBS, 2012). The number of Palestinians living in foreign countries was estimated to be 0.6 million (5.7%) of the global Palestinian population (Palestinian Center Bureau of Statistics (PCBS), 2012). The population density (Capita/Km²) at the end of 2011 was 703 in Palestinian Territory, 462 in West Bank and 4,429 in Gaza Strip (PCBS, 2012).

Gaza Strip lies on the eastern coast of the Mediterranean Sea. The Strip borders Egypt on the southwest and the occupied Palestinian territories land on the south, east and north. It is about 41 kilometers long, and between 6 and 12 kilometers wide, with a total area of 378 Km² and constitutes 6.1% of total area of Palestinian territory land. Gaza Strip takes its name from Gaza, its main city. The strategic location of Gaza Strip on the road between the continents of Asia and Africa make it coveted the invaders and occupiers throughout history.

In Gaza strip, the population number was 1,616,490 mainly concentrated in the cities, small village, and eight refugee camps that contain two thirds of the population of Gaza strip (PCBS, 2012).

1.7 Health services in Gaza Strip

Despite the small geographical area of the strip, there are a three main health providers offer health service in Gaza Strip, Ministry of Health (MOH), United Nations Relief and Works Agency (UNRWA) and Non Governmental Organizations (NGOs) accounts for 62%, 30% and 8.5% respectively. MOH covers most of these services because it takes over the responsibility in Gaza strip at 60 primary health care centers and 13 hospitals (MOH, 2006). Palestinian health care (PHC) system Consists of nine components, which are Primary Health Care, Laboratories and Blood Banks, Hospitals, Health Human Resources, Health Finance, Governmental Health Insurance, special treatment Abroad, Health Projects, and health information center (MOH, 2005a).

CHAPTER TWO

LITERATURE REVIEW

2.1 Diabetes Mellitus

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially eyes, kidneys, nerves, heart, and blood vessels (Wendy and Jean, 2007). Several pathogenic processes are involved in the development of diabetes. These range from autoimmune destruction of the β -cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action.

The basis of the abnormalities in carbohydrate, fat, and protein metabolism in diabetes is deficient action of insulin on target tissues. Deficient insulin action results from inadequate insulin secretion and/or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action. Impairment of insulin secretion and defects in insulin action frequently coexist in the same patient, and it is often unclear which abnormality, if either alone, is the primary cause of the hyperglycemia (Wendy and Jean, 2007).

Without insulin, the amount of glucose in the bloodstream is abnormally high, causing unquenchable thirst and frequent urination. The body's inability to store or use glucose causes hunger and weight loss (Chatrejee, 1992). Insulin deficiency causes excessive metabolization of free fatty acids; this may lead to a disorder in lipid metabolism. Insulin is a hypoglycemic hormone secreted from β -cell of the islet of pancreas. Insulin also has an effect on lipid metabolism (Godkar and Godkar 2003).

In diabetes mellitus abnormal increased levels of lipid, lipoprotein and lipid peroxides in plasma may be due to the abnormal lipid metabolism (Ronald and Krauss, 2004). Maximum increase in lipid peroxide was found in group of diabetes mellitus with complication. Elevated levels of lipid peroxide in diabetes mellitus may be due to the alteration of function of erythrocytes membrane.

This inhibits the activity of superoxide dismutase enzyme leading to accumulation of superoxide radicals which cause the maximum lipid peroxidation and tissue damage in diabetes (Mohsin et al., 2007). Diabetes mellitus can be linked to a diverse array of diseases like heart disease, stroke, high blood pressure, blindness, kidney disease, nervous system disease, amputations, dental disease, pregnancy complications, and others such as increased susceptibility to infectious diseases (Centers for Disease Control (CDC), 2007).

2.2 Classification of diabetes mellitus

2. 2.1 Type 1 Diabetes Mellitus

Type 1 diabetes mellitus (T1DM) is characterized by lack of insulin production and secretion by the beta cells of the pancreas. T1DM is approximately 10% of diabetics (Olefsky, 2001). One cause of the hyperglycemia of T1DM is an autoimmune destruction of the beta cells of the pancreas. The cell mediated response causes infiltration of the pancreas and reduction in the volume of beta cells (American Diabetes Association (ADA), 2005 and Wendy & Jean, 2007). As a protein hormone, insulin acts through chemical responses to receptors on the cells of target tissues. In the muscle, insulin stimulates glucose uptake into cells and enhances glycogenesis. In adipose tissue, insulin stimulates glucose uptake into cells and enhances lipogenesis. In the liver, insulin has a negative effect, inhibiting gluconeogenesis and glycogenolysis (Wendy and Jean, 2007).

Autoantibodies are present in the circulation of many individuals with T1DM (Wendy and Jean, 2007). This appears to be a genetic susceptibility to development of autoantibodies, with certain histocompatibility antigens predominant in the T1DM population. T1DM is also related to environmental factors that are still poorly defined. The patients are rarely obese when they present with this type of diabetes (ADA, 2005). However, the development of disease is complex; triggering factors, such as rubella, mumps, and other viral infection, and chemical contact may be necessary for progression of disease (Dokhee, 1993).

2. 2.2 Type 2 Diabetes Mellitus

T2DM is characterized by decline in insulin action due to the resistance of tissue cells to the action of insulin or insulin secretion. The problem is intensified by the inability of the beta cells of the pancreas to produce enough insulin to counteract the resistance. Thus T2DM is a disorder of both insulin resistance and relative deficiency of insulin (Wendy and Jean, 2007).

Insulin resistance syndrome, also known as metabolic syndrome and syndrome X, affects the metabolism of many nutrients, including glucose, triglycerides, and high-density lipoprotein (HDL) cholesterol (Wendy and Jean, 2007). T2DM accounts for about 90-95% of all diagnosed cases of diabetes (Olefsky, 2001).

This form of diabetes frequently goes undiagnosed for many years because the hyperglycemia develops gradually and at earlier stages is often not severe enough for the patient to notice any of the classic symptoms of diabetes (ADA, 2005).

The etiology of T2DM is complex and multifaceted. There is evidence to show that there is an association of obesity with the development of T2DM. Most patients with this form of diabetes are obese, and obesity itself causes some degree of insulin resistance. Patients who are not obese by traditional weight criteria may have an increased percentage of body fat distributed predominantly in the abdominal region (ADA, 2005). Chronic obesity leads to increased insulin resistance that can develop into diabetes (Camastra & Ferrannini, 1999).

Other factors, such as family history of T2DM and lack of physical activity, have also been associated with the disorder. Previous diagnosis of gestational diabetes is a risk factor for T2DM, as are increasing age, hypertension, and dyslipidemia (Olefsky, 2001). Increased risk for developing the disease is also associated with membership in certain racial and ethnic groups (ADA, 2005).

2.2.3 Gestational Diabetes

Gestational diabetes is similar in etiology to T2DM; however, it is defined as diabetes that is diagnosed in pregnancy. Pregnancy is associated with increased tissue cell resistance to insulin.

Most pregnant women will compensate with increased secretion of insulin; those individuals who are unable to compensate may develop gestational diabetes. The hyperglycemia of gestational diabetes diminishes after delivery; however, the

individual who has developed gestational diabetes is at higher risk for the development of T2DM thereafter, 5-10% of women with gestational diabetes are found to have T2DM (Wendy and Jean, 2007).

2.2.4 Other specific causes of Diabetes Mellitus

The fourth form of diabetes is termed other specific causes of diabetes, and was previously called secondary diabetes. This form of hyperglycemia may be the secondary result of non-insulin-related events. Blood glucose levels are increased in endocrine disorders, such as Cushing's syndrome; in exocrine disorders, such as cystic fibrosis; and as a response to specific drugs, such as protease inhibitors and glucocorticoids (Wendy and Jean, 2007). Other causes of this form of diabetes are the result of genetic defects that affect pancreatic beta cells or the action of insulin (ADA, 2005).

2.3 Prevalence and Mortality rate of Diabetes Mellitus

Globally as of 2010 it is estimated that there are 285 million people diabetes with type 2 making up about 90% of the cases (Henry et al., 2011). Its incidence is increasing rapidly, and it is estimated that by 2030, this number will almost double (Wild et al., 2004). Diabetes mellitus occurs throughout the world, but is more common (especially T2DM) in the more developed countries. The greatest increase in prevalence is, however, expected to occur in Asia and Africa, where most patients will probably be found by 2030 (Wild et al., 2004). The increase in incidence of diabetes in developing countries follows the trend of urbanization and lifestyle changes, perhaps most importantly a "Western-style" diet. This has suggested an environmental (i.e., dietary) effect, but there is little understanding of the mechanism(s) at present, though there is much speculation, some of it most compellingly presented (Wild et al., 2004).

In United States (U.S.), about 25.8 million people, or 8.3% of population, have diabetes (Diagnosed: 18.8 million people, Undiagnosed: 7.0 million people) (CDC, 2011). DM is the sixth leading cause of death in the U.S, accounting for approximately 70,000 annual deaths (Murray et al., 2008).

According to the WHO global estimate, and on account of the epidemic nature of diabetes, prevalence of diabetes is expected to increase in Palestine. This was examined in a study conducted in 2000 in cooperation with Al-Quds University and the Ministry of Health. The preliminary results indicated that the prevalence of diabetes in Palestine was about 9% in 2000 (Abdeen, 2006 and MOH, 2004).

In 2001, the Union of Palestinian Medical Relief Committee screened 2,482 people through their mobile clinics for obesity, hypertension, diabetes and dyslipidaemia. The preliminary results showed that 77% of the population was overweight (BMI > 25); 47% was obese (BMI > 30); 31% had hypertension; 18% had diabetes; and 49% dyslipidaemia (Abdeen, 2006).

In another urban Palestinian population study of people between 35 and 65, Abdul-Rahim et al., (2001) found diabetes mellitus in 12% of the surveyed population. Diabetes mellitus constituted 3.6% of total population deaths. The average annual mortality rate of diabetes was 12.4 per 100,000 populations in the last 5 years (Abdul-Rahim et al., 2001 and MOH, 2005b).

2.4 Criteria for the diagnosis of Diabetes Mellitus

According to WHO, DM is characterized by recurrent or persistent hyperglycemia, and is diagnosed by demonstrating any one of the following (WHO, 1999):

- Classic symptoms of hyperglycemia (polyuria, polydipsia, Blurred vision, and unexplained weight loss) and casual plasma glucose ≥ 11.1 mmol/L (200 mg/dL). Casual is defined as any time of day without regard to time since last meal.
- Fasting plasma glucose level ≥ 7.0 mmol/L (126 mg/dL). Fasting is defined as no caloric intake for at least 8 hr.
- 2-hr postload glucose ≥ 200 mg/dl (11.1 mmol/l) during an Oral glucose tolerance test (OGTT). The test should be performed as described by WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in 250 ml of water.
- Glycated hemoglobin (Hb A1C) $\geq 6.5\%$ (ADA, 2010).

A positive result, in the absence of unequivocal hyperglycemia, should be confirmed by a repeat of any of the above-listed methods on a different day (ADA, 2005). According to the current definition, two fasting glucose measurements above 126 mg/dL (7.0 mmol/L) is considered diagnostic for diabetes mellitus.

2.5 Management of Diabetes Mellitus

Diabetes mellitus is a chronic disease which cannot be cured except in very specific situations. Management concentrates on keeping blood sugar levels as close to normal (Euglycemia) as possible, without causing hypoglycemia. Insulin replacement, diet management, and exercise have been shown to reduce the consequences of type 1 diabetes mellitus. Type 2 diabetes mellitus is best controlled by weight loss, diet management, and drug therapy. Insulin may be prescribed for type 2 diabetics who fail to achieve glycemic control with other measures (Wendy and Jean, 2007 and ADA, 2005).

Patient education, understanding, and participation is vital since the complications of diabetes are far less common and less severe in people who have well-managed blood sugar levels (Nathan et al., 2005). The therapeutic goal is an HbA1C level < 6.5% (Glycemic control) (National Institute for Health and Clinical Excellence (NIHCE), 2008). Attention is also paid to other health problems that may accelerate the deleterious effects of diabetes. These include smoking, elevated cholesterol levels, obesity, high blood pressure, and lack of regular exercise (NIHCE, 2008).

2.6 Obesity and T2DM patients

Obesity is a medical condition in which excess body fat has accumulated to the extent that it may have an adverse effect on health, leading to reduced life expectancy and/or increased health problems (Haslam et al., 2005). BMI is a measure of body fat based on a formula that calculates the ratio of body weight in Kg/height in meter square (WHO, 2000). Therefore, obesity is commonly defined as a BMI of 30 kg/m² or higher (WHO, 2012a). Obesity increases the likelihood of various diseases, particularly heart disease, T2DM, certain types of cancer, and osteoarthritis (WHO, 2000 and Haslam et al., 2005).

Globally, in 2008, approximately 1.5 billion adults were overweight and at least 400 million adults were obese. WHO reported that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese (WHO, 2012a). Obesity is most commonly caused by a combination of excessive food energy intake, lack of physical activity, and genetic susceptibility, although a few cases are caused primarily by genes, endocrine disorders, medications or psychiatric illness. Raised BMI is considered as a major risk factor for chronic diseases including T2DM (WHO, 2012a). About 55 percent of T2DM patients are obese (Eberhart et al., 2004). Camastra & Ferrannini, (1999) have reported that T2DM causes obesity as an effect of the changes in metabolism and other deranged cell behavior attendant on insulin resistance.

2.7 Ramadan Fasting and T2DM patients

It is estimated that there are 1.1–1.5 billion Muslims worldwide, comprising 18–25% of the world population (The Canadian Society of Muslims, 2000). Ramadan is month of obligatory daily fasting in Islam, the ninth month in the Islamic lunar calendar, The month begins 10 to 11 days earlier each year in the solar calendar and may occur during different seasons of the year, and their fasting is one of the five pillars on which Islam is built. The Prophet Mohammad Peace Be Upon Him (PBUH) said, *“Islam is built on five pillars: Certificate not to be worshiped except Allah and that Muhammad is the Messenger of Allah, to pay Zakat, to perform Hajj, and to fast during the month of Ramadan”*.

Muslims fast for the sake of Allah, Where they are refrain from eating, drinking, smoking and sex during daylight hours, and daily fasts begin at dawn and end with sunset. The month of Ramadan is a great opportunity to focus on bringing back a balanced and healthy lifestyle in people life.

Concerning diet during Ramadan, people usually eat two main meals rather than the usual three meals intake during the other months of the year, one before dawn (sohor) and one just after sunset (iftar). However, the Iftar meal is the main meal because it consists of a wide variety of foods, and also giving us the bulk of daily energy during fasting.

The sohor meal is a snack taken before sunrise but some Muslims omit this meal this may contribute to hypoglycaemia during the day. A study by Khaled and Belbraouet (2009) found that the iftar meal represented 76.49%, sohor meal represented 14.13%, and the snacks between the two meals counted only for 2.08% of the total energy consumed per day during Ramadan month. The fasting length per day may vary from 10 to 19 hr (Altun et al., 2006). In addition, sleep and physical activity habits are significantly reduced (Dill et al ., 1974). During the month of Ramadan, frequency and quantity of food and fluid intake are decreased and the dietary habits are changed to the consumption of foods that contain more carbohydrates, sugary foods, and salty foods (Meckel et al., 2008).

Modifying eating habits during Ramadan month and then significantly increasing one's intake after breaking the fast, could unbalance the metabolism of patients with diabetes and influence their nutritional intake and their anthropometric parameters (Yarahmadi et al., 2003; Khatib et al., 2004 and Khaled et al., 2006).

According to Islamic law, Ramadan fasting is fard (obligatory) on every muslims reached puberty, sane, capable of fast, and do not complain of disease makes him difficult to fast. Muslims who could threaten their health by fasting Such as sick patients, nursing women, pregnant women, menstruating and travelers can refrain from fasting until the end of their excuse.

“Fasting for a fixed number of days; but if any of you is ill or on a journey the prescribed number (should be made up) from days later” (Holy Quran, Al-Bakarah, 184). Patients with diabetes fall under this category because their chronic metabolic disorder may place them at high risk for various complications if the pattern and amount of their meal and fluid intake is markedly altered. This exemption represents *more* than a simple permission not to fast; the Prophet Mohammad PBUH said, *“Allah likes his permission to be fulfilled, as he likes his will to be executed”* .

Nevertheless, many patients with diabetes still prefer to fast during Ramadan, without medical guidance, exposing themselves to certain health risks as a direct consequence of fasting or because of a change in food and frequency of medication intake.

On the other hand, it has been shown that Ramadan fasting can be considered as an ideal hypo-caloric diet and a good opportunity to lose weight for patients with T2DM, particularly for those who are obese or overweight.

The Epidemiology of Diabetes and Ramadan (EPIDIAR) study showed (in 12,243 people with diabetes from 13 Islamic countries) that 43% of patients with type 1 diabetes and 79% of patients with type 2 diabetes fast during Ramadan (Salti et al., 2004) lead to the estimation that some 40–50 million people with diabetes worldwide fast during Ramadan. Although, the medical ramifications of fasting among patients with diabetes are largely unknown due to the limited literature information available from prospective or retrospective studies on the effects of fasting during Ramadan, It is therefore important that medical professionals be aware of potential risks that may be associated with fasting during Ramadan.

2.8 Pathophysiology of fasting among Diabetic patients

Carbohydrate metabolism, including glucose metabolism, is regulated by the action and counteraction of the endocrine system. Two hormones, insulin and glucagon, have predominant influence on the pathways of carbohydrate metabolism. The actions of these two hormones counteract each other (Wendy and Jean, 2007).

Insulin secretion in healthy individuals is stimulated with feeding, which promotes the storage of glucose in liver and muscle as glycogen. In contrast, during fasting, circulating glucose levels tend to fall, leading to decreased secretion of insulin. At the same time, levels of glucagon and catecholamines rise, stimulating the glycogenolysis (the breakdown of glycogen), while gluconeogenesis (the formation of glucose) is augmented (Cryer et al., 2003).

As fasting becomes protracted for more than several hours, glycogen stores become depleted, and the low levels of circulating insulin allow increased fatty acid release from adipocytes. Oxidation of fatty acids generates ketones that can be used as fuel by skeletal and cardiac muscle, liver, kidney, and adipose tissue, thus sparing glucose for continued utilization by brain and erythrocytes.

In individuals without diabetes, the processes described above are regulated by a delicate balance between circulating levels of insulin and counter regulatory hormones that help maintain glucose concentrations in the physiological range.

In patients with diabetes, however, insulin secretion is perturbed by the underlying pathophysiology and often by pharmacological agents designed to enhance or supplement insulin secretion.

In T1DM patients, glucagon secretion may fail to increase appropriately in response to hypoglycemia. Epinephrine secretion is also defective in some patients with T1DM due to a combination of autonomic neuropathy and defects associated with recurrent hypoglycemia (Cryer et al., 2003).

In patients with severe insulin deficiency, a prolonged fast in the absence of adequate insulin can lead to excessive glycogen breakdown and increased gluconeogenesis and ketogenesis, leading to hyperglycemia and ketoacidosis.

T2DM Patients may suffer similar perturbations in response to a prolonged fast; however, ketoacidosis is uncommon, and the severity of hyperglycemia depends on the extent of insulin resistance and/or deficiency (Botion and Green, 1999). T2DM is characterized by lack of insulin action and/or secretion that induces hepatic glucose output by inhibiting glycogen synthesis and stimulating glycogenolysis and gluconeogenesis then increased rates of hepatic glucose production result in the development of hyperglycemia, especially fasting hyperglycemia (Michael et al., 2000).

In such conditions, lipolysis in adipose tissue is promoted leading to elevated circulating levels of free fatty acids. Ketones are produced, and are found in large quantities in ketosis, the liver converts fat into fatty acids and ketone bodies which can be used by the body for energy (Botion and Green, 1999). In addition, excess fatty acids in serum of diabetics are converted into phospholipids and cholesterol in liver. These two substances along with excess triglycerides formed at the same time in liver may be discharged into blood in the form of lipoproteins (Jaworski et al., 2007). Some studies showed that cholesterol, triglycerides and LDL-C are elevated in diabetic patients (Saleh et al., 2004). In contrast, other studies documented that HDL-C was decreased (Al-tibi, 2007).

Higher insulin levels increase some anabolic ("building up") processes such as cell growth and duplication, protein synthesis, and fat storage. Insulin (or its lack) is the principal signal in converting many of the bidirectional processes of metabolism from a catabolic to an anabolic direction, and vice versa. In particular, a low insulin level is the trigger for entering or leaving ketosis (the fat burning metabolic phase) (Henry et al., 2011).

When the glucose concentration in the blood is raised beyond its renal threshold (about 10 mmol/L, although this may be altered in certain conditions, such as pregnancy), reabsorption of glucose in the proximal renal tubuli is incomplete, and part of the glucose remains in the urine (glycosuria). This increases the osmotic pressure of the urine and inhibits reabsorption of water by the kidney, resulting in increased urine production (polyuria) and increased fluid loss. Lost blood volume will be replaced osmotically from water held in body cells and other body compartments, causing dehydration and increased thirst (ADA, 2005).

Other hormones also affect carbohydrate metabolism. Epinephrine, a hormone that is released by the adrenal medulla at times of stress, inhibits insulin secretion and stimulates glycogenolysis and lipolysis. Glucocorticoids, such as cortisol, are released from the adrenal cortex to reduce blood glucose concentration by inhibiting gluconeogenesis the absorption of dietary glucose. Thyroxine, a thyroid hormone, increases glycogenolysis and gluconeogenesis and inhibits absorption of dietary glucose through the intestine (Wendy and Jean, 2007).

2.9 Risks associated with fasting Ramadan among Diabetic patients

The exact medical impact of fasting among people with diabetes is not well studied. However, most Muslim religious authorities accept that if a person is advised by a trusted doctor that fasting is harmful to his health, then that person is exempted from fasting (Beshyah et al., 2009). To minimize the risks of fasting Ramadan, the American diabetes Association (ADA) published a consensus statement on the management of diabetes during the month of Ramadan in 2005 (Al Arouj et al., 2005).

The major metabolic risks associated with fasting in people with diabetes are hypoglycaemia, hyperglycaemia and diabetic ketoacidosis and dehydration and thrombosis.

2.9.1 Hypoglycaemia

There is an increasing awareness of the risk for hypoglycaemia in people with diabetes. This risk is potentially higher during fasting Ramadan. A study conducted in London in 2007 on 111 persons with T2DM treated with oral hypoglycaemic agents showed that the incidence of any hypoglycaemic episode increased four-fold during Ramadan, compared with before fasting (Bravis et al., 2010).

The EPIDIAR study found that the change in eating patterns during Ramadan increased the risk of severe hypoglycaemia 4.7-fold in T1D and 7.5-fold in T2DM (Salti et al., 2004).

A small observational study (n=41) conducted in 1998 found an increase in symptomatic hypoglycaemia (Uysal et al., 1998), but other studies have not found a significant increase in the risk of hypoglycaemia during Ramadan in patients treated with oral hypoglycaemic medications or insulin (Cesur et al., 2007 and Bakiner et al., 2009).

2.9.2 Hyperglycaemia and diabetic ketoacidosis

Glycaemic control in patients with diabetes who fast during Ramadan has been reported to deteriorate, improve or show no change (Mafauzy et al., 1990; Belkhadir et al., 1993; Katibi et al., 2001 and Beckman et al., 2002).

In a study from London, there was no significant change in HbA1C before and after Ramadan (Bravis et al., 2010). Severe hyperglycaemia requiring hospitalisation increased five-fold during Ramadan in patients with T2DM diabetes and in T1D was approximately three-fold higher with or without ketoacidosis (Salti et al., 2004). The EPIDIAR study found a fivefold increase in the incidence of severe hyperglycaemia in T2DM patients during Ramadan (Salti et al., 2004).

2.9.3 Dehydration and thrombosis

Dehydration is a theoretical risk among individuals who perform hard physical labour during fasting hours. The decrease in endogenous anticoagulants, impaired fibrinolysis and the increase in clotting factors noted in some patients with diabetes could be a risk for thrombosis (Alghadyan, 1993). Retinal vein occlusion in people who fasted during Ramadan was increased in one study (Temizhan et al., 2000). However, there was no increase in hospitalisations due to thrombotic cardiac or cerebral conditions during Ramadan in the same group (Bravis et al., 2010).

2.10 Ramadan fasting and its effects on T2DM patients health

2.10.1 Dietary intake and anthropometric measurements

The aim of diet in patients with diabetes is to improve the stability of glycaemia and to reduce the risk of atherogenic complications. Modifying eating habits during Ramadan fasting and then significantly increasing one's intake after breaking the fast, could unbalance the metabolism of T2DM patients and influence their nutritional intake and their anthropometric parameters (Yarahmadi et al., 2003; Khatib et al., 2004 and Khaled et al., 2006).

Concerning diet during Ramadan, people usually eat two meals, one before dawn (Sohor) and one just after sunset (Iftar). Many studies and literature reviews on Ramadan reveal the controversial results concerning the effects of Ramadan fasting among T2DM patients according to anthropometric parameters and/or nutritional intake (Sulimani et al., 1991).

In several studies, the daily caloric and carbohydrates intake is said to decrease during Ramadan in T2DM patients (Bouguerra et al., 1997; Belkhadir et al., 1993 and Khaled et al., 2006). Studies in T2DM patients report that the decrease in carbohydrate intake is compensated for with an increase in fat intake without any change in the daily caloric intake (Chamakhi et al., 1991). However, an engorging after the breaking fast meal (Iftar) is usually observed. Indeed, it was reported in healthy subjects that 65% of the daily caloric intake was observed after this single meal (Gharbi et al., 2003).

Some authors observed a decrease in energy intake (103 Kcal/d), though not statistically significant, which is correlated with meal frequency (Mafauzy et al., 1990 and Bouguerra et al., 2003). However, in another study, the total daily energy intake (TEI) remained unchanged (Klocker et al., 1997).

Regarding anthropometric measurements, in one group of studies, T2DM patients had an increase in their weight during fasting (Klocker et al., 1997 and Khatib et al., 2004). In another group, there was no change (Sulimani et al., 1991 and Uysal et al., 1997) or a decrease (Khatib et al., 1997; Yarahmadi., 2003 and Khaled et al., 2006) in body weight during fasting. While no food or drink is consumed between dawn and sunset during the month of Ramadan, there is no restriction on the amount or type of food consumed at night (Laajam et al., 1990). Furthermore, most diabetics reduce their daily activities during this period in fear of hypoglycemia. (Ewis et al., 1997). However, the decrease in weight is related to decrease in energy intake, while a food excess intake and reduction of exercise leads to the increase in body weight.

A study by Méghit et al. (2005) was designed to assess the effect of diet during Ramadan fasting on body weight and on serum lipid components in type 2 diabetic obese women. During Ramadan of 2005, 89 diabetic women receiving oral treatment, aged 52 (± 5 years), were selected. The study was carried out over 3 periods-, before (T1: pre-fasting), during (T2: fasting), and after (T3: post-fasting) Ramadan-in Sidi-bel-Abbes city. The result showed that there was a significant weight loss in diabetic women during T2, correlated with a decrease in meal frequency ($p < 0.01$). Similarly, in another before-after study by the same authors on 276 diabetic obese women reported significant weight loss, a decrease in meal frequency, and in energy intake but an increase in dietary fat and cholesterol consumption (Khaled & Belbraouet, 2009).

Other study by Ait Saada et al. (2008) was carried out (during and before the month of Ramadan fasting) to evaluate the effect of some anthropometric and biochemical parameters in men and women who suffering from the diabetes of the type 2, old from 45 to 55 years and treated with oral antidiabetics constituted of a mixture (Biguanides and Sulphamides). This study found that the BMI remains practically stable ($P > 0.05$) during the Ramadan among the diabetic patients. However, the women recorded results of BMI significantly ($P < 0.01$) higher than those of the men.

On other hand, many studies have been published on the effect of Ramadan fasting on anthropometric parameters and/or nutritional intake among healthy individuals, and reported a decrease (Sweileh et al. 1992 and Al-Numair, 2006), no change (El-Ati et al., 1995) and an increase in energy intake (Frost and Pirani, 1987) at the end of Ramadan fasting.

Food composition has been reported to shift toward consuming more fat and less CHO during Ramadan month (Khaled and Belbraouet, 2009).

Regarding BMI and body weight, Weight losses of 1.7 kg (Azizi, 1978), 1.8 kg (Sajid et al., 1991), 2.0 kg (Takruri, 1991), and 3.8 kg (Sulimani, 1988) have been reported in normal weight individuals after they have fasted for the month of Ramadan. In one study that was overrepresented by females, no change in body weight was seen (Shoukry, 1986). It has also been reported that overweight persons lose more weight than normal or underweight subjects (Takruri, 1991). Some studies show weight gain instead of loss (Frost and Pirani, 1987 and Rashed, 1992).

2.10. 2 Lipid profile

In diabetes many factors may affect blood lipid levels, this is because carbohydrates and lipid metabolism are interrelated to each other if there is any disorder in carbohydrate metabolism it also leads disorder in lipid metabolism. Insulin affects many sites of mammalian lipid metabolism. It stimulates synthesis of fatty acid in liver adipose tissue and in the intestine. The insulin has also been reported to increase the cholesterol synthesis. The activity of lipoprotein lipase in white adipose is also increased (Suryawanshi et al., 2006).

In diabetic subjects sex plays a significant effect on risk of coronary artery disease. The males have marginally high serum lipid levels as compared to diabetic females because sex hormones play unique role for lipid metabolism (Salonen et al., 1981).

Experts recommend that men aged 35 and older and women aged 45 and older should be frequently screen lipid disorders (ADA, 2007). The screening test that is usually performed is a blood test called a lipid profile. The lipoprotein profile includes:

Cholesterol, LDL-C (low-density lipoprotein cholesterol, also called "bad" cholesterol), HDL-C (high-density lipoprotein cholesterol, also called "good" cholesterol) and Triglycerides (fats carried in the blood from the food eating, Excess calories, alcohol, and sugar in the body are converted into triglycerides and stored in fat cells throughout the body). lipid profile used to diagnostic of coronary heart diseases and other diseases (MOH, 2005c).

2.10.2.1 Serum total cholesterol

Cholesterol is an unsaturated steroid alcohol – amphipathic- compound composed of four ring structures (A, B, C, D) with single side R chain. Cholesterol is synthesized in the liver from dietary fats and within the cells. It presents in all body tissue and it is the major component of LDL-C, cell membrane, brain, several essential hormones and vitamin D. Most cholesterol in the body is synthesized from acetyl CoA and also from ingested dietary meat, egg, or dairy products. Cholesterol is oxidized in the liver into bile acids (Shepherd, 2001). Lifestyle habits like eating unhealthy, excessive drinking, smoking, and inactivity can raise cholesterol levels. Elevated blood cholesterol level (Hypercholesterolemia) with low HDL increase the risk of arteriosclerosis and coronary artery diseases (Kerenyi et al., 2006). Cholesterol and other fats are transported through the blood stream in the form of round particles called lipoproteins. The two most commonly known lipoproteins are low-density lipoproteins cholesterol (LDL-c) and high-density lipoproteins (HDL-c). The majority of the cholesterol in the blood is packaged as LDL, and only a relatively small proportion is from HDL cholesterol. According to the American Heart Association (AHA), Serum Cholesterol Level is commonly divided into four categorical as the values listed below (AHA , 2011).

Total Cholesterol Level	Category
Less than 200 mg/dL	Desirable level that lower risk of coronary heart disease.
200 to 239 mg/dL	Borderline high
240 mg/dL and above	High blood cholesterol.

A person with 240 mg/dL and above level has more than twice the risk of coronary heart disease as someone whose cholesterol is below 200 mg/dL (AHA , 2011).

2.10.2.2 Serum triglycerides (Triacylglycerols)

Triglycerides are compounds consisting of fatty acids/ glycerol esters that comprise a major part of very low density lipoprotein cholesterol (< 10%). Most of the fat carried through body and stored in the form of TG. Dietary TG are carried as a part of chylomicrons (up to 90%) through the lymphatic system and blood stream to adipose tissue. It is synthesized in liver from protein, fatty acids and glucose above the body's current needs. Insulin promotes TG synthesis by converting glucose to fatty acids. During absence of glucose in certain conditions, TG hydrolyzed into fatty acids.

Usually, TG levels increase after meals. It is derived from fats eaten in foods and the body can make it from other energy sources such as CHOs since the energy consumed and not used immediately by the body tissues is converted to TG and stored in adipose tissue (AHA, 2011).

Elevated serum TG levels (Triglyceridemia) may be caused by medical conditions such as diabetes, hypothyroidism, kidney disease, or liver disease. Dietary causes of elevated TG levels may include obesity and high intakes of fat, alcohol, and concentrated sweets.

Triglyceridemia has been associated with increased risk of coronary heart disease both in non diabetic and type 2 diabetic subjects (Frank et al., 2002). TG levels were identified as an independent risk factor for IHD (Assmann et al., 1998). Serum TG Level is commonly divided into four categorical as the values listed below (American Heart Association (AHA), 2011).

Triglyceride Level	Category
Less than 150 mg/dL	Normal
150–199 mg/dL	Borderline high
200–499 mg/dL	High
500 mg/dL and above	Very high

2.10.2.3 Serum high -density lipoprotein cholesterol

High-density lipoproteins (HDL-C), or alpha lipoproteins, which are the smallest and most dense of lipoproteins. also known as good cholesterol. HDL-C contains about 17% to 20% cholesterol and 1% to 7% TG.

HDL-C levels is protective because it picks up about 1/3 to 1/4 of blood cholesterol and triglycerides from the body cells of membranes and carries them back to the liver, where they are metabolized and then excreted. It is either taken up by the liver, or is incorporated into intermediate density lipoprotein cholesterol resulting in the mature LDL-C. This transport mechanism prevents the accumulation of lipids in the arterial walls, thereby providing protection against the development of coronary artery disease (Sherlock and Dooley, 2002).

High levels of HDL-C can lower an individual's risk of developing CHD (Mchenry, 1992). High levels of HDL-C may protect against CVDs, while low HDL-C levels increase the risk of it (AHA, 2009a). High TG levels, physical inactivity, being overweight, obese, smoking, high carbohydrate intakes, T2DM, some medications as well as genetic factors can contribute to low HDL cholesterol levels (Toth, 2005). Serum HDL Cholesterol Level is divided as the values listed below (AHA, 2011).

HDL Cholesterol Level	Category
Less than 40 mg/dL (for men) Less than 50 mg/dL (for women)	Low HDL cholesterol. A major risk factor for heart disease.
40–59 mg/dL	Medium HDL cholesterol
60 mg/dL and above	High HDL cholesterol. An HDL of 60 mg/dL and above is considered protective against heart disease.

2.10.2.4 Serum low-density lipoprotein cholesterol

Low-density lipoproteins (LDL-C), or beta lipoproteins, also known as bad cholesterol, which is rich in cholesterol and transports it from liver to other body tissue. They consist of 40% to 50% cholesterol and 7% to 10% triglycerides.

When LDL-C levels are too high, the LDL lipoprotein tends to stick the lining of the blood vessels, which helps to stimulate atherosclerosis. So, an elevated LDL-C level is a major risk factor for CHD and stroke (Law et al., 1994).

LDL-C is often determined in clinical laboratories by calculation by Fried Wald's formula¹. This calculation not valid when TG over 400mg/dl. TC and LDL-C is related to life style factors such as diet and exercise. High levels of saturated fats in the diet can result in an increase in TC and LDL-C, and substitution of monounsaturated and polyunsaturated for saturated fats can lead to a reduction in TC and LDL-C (Brody, 1999).

LDL-C is commonly categorical as the values listed below (AHA , 2011).

LDL Cholesterol Level	Category
Less than 100 mg/dL	Optimal
100 to 129 mg/dL	Near or above optimal
130 to 159 mg/dL	Borderline high
160 to 189 mg/dL	High
190 mg/dL and above	Very high

Regarding the effect of fasting during Ramadan on the diabetic lipid profile, Many previous studies showed that Ramadan fasting doesn't affect TGs, LDL-c and HDL-c rates (Bouguerra et al., 2003 and Khatib, 2004). Similar result was reported by the other studies, where they showed that, there is no change or a slight decrease in serum concentrations of TC and TG among T2DM at the end of Ramadan fasting month when compared with pre-Ramadan (Klocker et al.,1997; Khatib, 1997; Bouguerra et al.,1997 and Uysal et al.,1998).

¹Fried Wald's formula: $[\text{LDL-C} = \text{TC} - (\text{HDL-C}) - \text{TG}/5(\text{mg/dl})]$.

However, a decrease in TGs has been noticed during fasting (Sadr et al., 2001 and Sari et al., 2004), when TC (Yarahmadi et al., 2003) HDL-c (Khatib, 1997) and LDL-c (Bouguerra et al., 2003 and Khaled et al., 2006) rose. A decrease of HDL-c rate was seldom observed (Khaled et al., 2006). Unlike the previous studies, two studies found a statistically significant increase in TC levels during Ramadan month among T2DM (Laajam, 1990; Yarahmadi et al., 2003) as in healthy persons (Maislos et al., 1993 and Adlouni et al., 1997).

Few studies have reported increases in HDL-C among T2DM at the end of Ramadan month fasting when compared with pre-Ramadan (Khatib, 1997; Uysal et al., 1997 and Uysal et al., 1998). One report indicates an increase in LDL-C and a decrease in HDL-C among T2DM at the end of Ramadan month fasting when compared with pre-Ramadan (Bouguerra et al., 1997). In another study on 60 obese women with type 2 diabetes in Algeria, fasting resulted in significant improvement in glucose homeostasis, although the TC, TG and LDL levels also increased significantly (Khaled et al., 2006).

Another study done by Ait Saada et al. (2008) evaluated the effect of some parameters anthropometric and biochemical in men and women who suffering from the diabetes of the type 2, old from 45 to 55 years and treated with oral antidiabetics constituted of a mixture (Biguanides and Sulphamides). This study reported the rates of plasmatic TG and of HDL-C decreased significantly ($P < 0.01$) with fasting; on the contrary, rates of LDL-C and of TC increased slightly ($P > 0.05$).

A study conducted on T2DM patients (31 male and 22 female) and 56 (21 male 35 female) healthy volunteers as controls. The study revealed that, TC, TG and LDL-C did not show any significant changes before and during Ramadan. There was statistically significant increase in TC and TG among healthy volunteers (control group) during fasting (Yousuf et al., 2000).

Regarding to effect of fasting on lipid profile among healthy individual, Maislos et al. (1993) observed a rise in HDL-C, and no significant difference in serum TG and TC and LDL-C with fasting. Another study observed a significant elevation in plasma HDL-C, while, TC, TG, LDL-C and VLDL-C were not change significantly after Ramadan fasting when compared with pre-Ramadan (Maisols et al., 2007).

A before-after study was conducted to estimate the effect of Ramadan fasting on 103 obese individuals in Egypt, it showed that there was a significant improvement in TC, TG, HDL, LDL, TC/HDL ratio and LDL/HDL ratio at the end of Ramadan fasting (Saleh et al., 2004). Nagra & Rahman (1998) reported a significant decrease in TC and LDL-C, but there were non-significant increases in HDL-C, serum TG and VLDL-C in a study conducted on 26 healthy females.

Another study found a decrease in LDL-C and HDL-C but no change in the TC with fasting (Hallak et al., 1988). This study also reported that the TG level at the 14th day of Ramadan correlated positively with sugar intake (gram/day) during this month. The increase in blood triglycerides with high sucrose intake was also observed (Albrink et al., 1986). A study conducted on 26 healthy females reported a significant decrease in TC and LDL-C but there were non-significant increase in HDL-C, TG and VLDL-C (Ziaee et al., 2006).

A study by Mahboob et al. (1999) was conducted on hyperlipidemic male subjects to investigate the effect of Ramadan fasting on lipid profile and the results showed a significant decrease in serum TC, TG and LDL-C levels during Ramadan fasting. Similar results were reported by other studies, where they showed a significant reduction in TC and TG levels during Ramadan (Asgary et al., 2000). Qujeq et al. (2002) found a significant reduction of the LDL-C concentration in mid and end of Ramadan, also significant elevation in the HDL-C concentration compared to concentration levels before Ramadan.

Saleh et al. (2005) conducted on 60 healthy Kuwaiti male and female and found a significant reduction in TC and LDL-C in male group at the end of fasting, and serum TG, VLDL-C and HDL-C were not significantly increased, while in female group, TC, TG, LDL-C and VLDL-C, were not significantly decreased, and HDL-C of women was decreased compared to pre-fasting, but the difference was not significant. In addition, Mansi et al. (2007) observed significant increase in serum HDL-C during Ramadan in both, male and female, a significant reduction in LDL-C, non-significant rise in TG, and non-significant reduction in the average TC at the end of fasting. Furuncuoglu et al. (2007) showed a significant reduction in TG and TC, but no change in HDL-C was reported in this study.

It's seen that the findings reported in the literature of the effects of Ramadan fasting on blood lipids are inconsistent and contradictory. These variations and contradictions were partly attributed to the fact that Ramadan fasting follows the lunar cycle rather than the solar cycle, hence the duration of fasting, which is limited during day light hours, varies from country to country and from year to year depending on whether Ramadan falls during long hot summer days or short cold winter days (Asgary et al., 2000). Also the diverse social and economic differences between different ethnic groups may have influenced by dietary patterns (Saleh et al., 2005; Furuncuoglu et al., 2007). Until there is a standardization of the research on the three fundamental factors affecting diabetes in Ramadan (hypoglycemic drug regimens, diet control, and daily activity), the beneficial or hazardous effects of Ramadan fasting on the serum lipids of diabetics will remain unclear.

2.10.3 Other biochemical parameters

2.10.3.1 Blood glucose

Glucose is the main simple sugar (monosaccharide) in the body, and it is carried through the blood stream to provide energy to all cells in the body. Glucose is derived from digestion of dietary carbohydrates, breakdown of glycogen in the liver (glycogenolysis) and production of glucose from amino acid precursors in the liver (gluconeogenesis). Glucose is transported from the intestines or liver to body cells via blood stream, and is made available for cell absorption via the hormone insulin. Blood glucose level is the amount of glucose (sugar) present in the blood of a human. It is also known as plasma glucose. Normally in human, the body maintains the blood glucose level at a reference range between about 3.6 and 5.8 mM (mmol/L, i.e., millimoles/liter), or 64.8 and 104.4 mg/dL. But they are higher after meals and usually lowest in the morning. (WHO, 1999).

Blood glucose levels outside the normal range may be an indicator of a medical condition. High level is referred to as hyperglycemia; low levels are referred to as hypoglycemia.

DM is characterized by persistent hyperglycemia from any of several causes, and is the most prominent disease related to failure of blood sugar regulation. A temporarily elevated blood sugar level may also result from severe stress, such as trauma, stroke, myocardial infarction, surgery, or illness (ADA, 2010).

The human body naturally tightly regulates blood glucose levels as a part of metabolic homeostasis. The homeostatic mechanism keeps blood glucose levels within a narrow range. FBG level is considered as a good indicator for the overall glucose hemostasis and commonly used for the diagnosis of DM (Champe et al., 2005). There are two types of mutually antagonistic metabolic hormones affecting blood glucose levels: catabolic hormones (such as glucagon) which increase blood glucose and anabolic hormone (insulin), which decreases blood glucose. These hormones affect glucose concentrations by modifying glucose uptake by cells (for energy production), promoting or inhibiting gluconeogenesis, or affecting glycogenesis (glycogen production) and glycogenolysis. The table below summarizes the effects of these different major hormones on physiologic processes that affect blood glucose concentrations.

Hormone	Glycogen	Gluconeogenesis	Glucose uptake	Glucose
Insulin	Synthesis	Decrease	Stimulates	Decrease
Glucagon	Breakdown	Increase	No effect	Increase
Catecholamines	Breakdown	Increase (indirect by insulin inhibition)	Decrease (indirect through GH/insulin inhibition)	Transient increase
Growth hormone	Breakdown		Decrease	Increase
Corticosteroids	Synthesis	Increase	Decrease	Increase

2.10.3.2 Glycated hemoglobin

HbA1c is the compound produced by the chemical reaction between haemoglobin and glucose in the blood. HbA1c is also called glycated haemoglobin. Normal levels of glucose produce a normal amount of HbA1c. As the average amount of plasma glucose increases, the fraction of HbA1c increases in a predictable way. HbA1c is used to assess the effectiveness of therapy by monitoring long-term serum glucose regulation among diabetic patients. The HbA1c level is proportional to average blood glucose concentration over the previous four weeks to three months (Peterson et al., 1998). HbA1c is a more comprehensive measure of total glycaemic exposure than FPG due to the representation of blood glucose in the postprandial state in addition to the fasting state (Rohlfing et al., 2000). In diabetes mellitus, any increase in the HbA1c level indicates poorer control blood glucose levels, have been associated with CVD, nephropathy, and retinopathy (Khaw et al., 2001).

The United Kingdom Prospective Diabetes Study Group (UKPDS) was a 20-year-long research trial in diabetes. It showed that for every 1 per cent rise in HbA1c, a person with Type 2 diabetes is 30 per cent more likely to develop late-stage complications arising from damage to the small blood vessels (Home et al., 2008). According to ADA, Diabetes may be defined as having an HbA1c ≥ 48 mmol/l ($\geq 6.5\%$) (ADA, 2010b). So, (HbA1c $>6.5\%$ is consider diabetic, $<6.0\%$ is consider non diabetic, in 6.0-6.5 is consider 'pre-diabetes' or 'at risk of diabetes. Clinical and population studies have found racial, ethnic, and age disparities in HbA1c levels (Saaddine et al., 2002 and Kirk et al., 2006).

2.10.3.3 Serum creatinine

Creatinine is a break-down product of creatine phosphate in muscle, and is usually produced at a fairly constant rate by the body and its production is continuous and proportional to muscle mass (Hofso et al., 2009). Creatinine is freely filtered and therefore the serum creatinine level depends on the Glomerular Filtration Rate (GFR).

Serum creatinine is commonly used as a screening measure of GFR (Landry and Bazari, 2011). If the serum creatinine level doubles, the GFR is considered to have been halved. A threefold increase is considered to reflect a 75% loss of kidney function. Increased serum creatinine levels are seen in: impaired renal function, chronic nephritis, urinary tract obstruction, muscle diseases such as gigantism and congestive heart failure. Decreased creatinine levels may be seen in: the elderly, decreased muscle mass, or inadequate dietary protein (Fischbach and Dunning, 2009).

Skeletal muscle is the most important site of insulin resistance and accounts for approximately 90% of overall glucose disposal after glucose infusion (Ferrannini et al., 1985). Muscle mass has been shown to be inversely associated with insulin resistance (Volpi et al., 2004). Low serum creatinine levels were associated with a higher risk of T2DM in a recent study of non-obese middle-aged Japanese men (Harita et al., 2009). In addition, glomerular hyperfiltration, which is associated with lower serum creatinine levels, may be associated with future diabetes (Lorenzo et al., 2009).

The normal serum creatinine level is 0.7-1.3 mg/dL for males (values are slightly higher in males due to larger muscle mass), 0.6-1.1mg/dL for females and 0.2-1.0 for children (values are slight increases with age because values are proportional to body mass) (Landry and Bazari 2011).

2.10.3.4 Serum urea

Urea is the major end product of nitrogen metabolism in humans and mammals. Urea is formed solely in the liver from the catabolism of amino acids and is the main excretion product of protein metabolism. If kidney fails, blood urea conc. increase to high level and toxic condition known as (Uremia) will result. In uremia, urea must be removed from the blood by clinical procedure called "Blood Dialysis". High urea levels suggest poor kidney function (Sakami and Harrington, 1963). This may be due to acute or chronic kidney disease. However, there are many things besides kidney disease that can affect urea levels such as decreased blood flow to

the kidneys as in congestive heart failure, shock, stress, recent heart attack or severe burns; bleeding from the gastrointestinal tract; conditions that cause obstruction of urine flow; or dehydration. Low urea levels are not common and are not usually a cause for concern. They can be seen in severe liver disease or malnutrition but are not used to diagnose or monitor these conditions. Low urea levels are also seen in normal pregnancy.

Diabetes is now the major cause of end stage kidney failure throughout the world in both developed and emerging nations. The rise in prevalence, progression and complications of chronic kidney disease is probably attributable to a progressively aging population, duration of diabetes and presence of hypertension (Norris and Nissenson, 2008). T2DM patients are at an increased risk of developing specific complications including: nephropathy, retinopathy, neuropathy and atherosclerosis (Rehman et al., 2005). Urea is routinely measured in the blood as: Blood Urea Nitrogen (BUN). BUN can be convert to urea in mg/dL by using following formula: $\text{Urea [mg/dL]} = \text{BUN [mg/dL]} * 2.14$. A normal serum level of urea for adults mg/dl is (15-50) and normal serum BUN level is (5- 25) mg/dl (Landry and Bazari 2011).

Only few studies concerning the effect of Ramadan fasting on FBG, HbA1c creatinine and urea among T2DM and healthy individual. Regarding to the effect of fasting on biochemical parameters other than lipid profile among T2DM patients, Most patients show no significant change in their serum glucose concentration (Mahboob et al., 1999; Asgary et al., 2000 and Saleh et al., 2005). In some patients, serum glucose concentration may fall or rise. (Mansi et al., 2007 and Furuncuoglu et al., 2007). This variation may be due to the amount or type of food consumption, regularity of taking medications, engorging after the fast is broken, or decreased physical activity. In most cases, no episode of acute complications (hypoglycemic or hyperglycemic types) occurs in patients under medical management (Al Nakhi et al., 1997 and Adlouni et al., 1997).

A study was carried out in the month of Ramadan on 89 Algerian type 2 diabetic obese women. It was found there was a significant decrease in blood sugar values at the end of fasting (Méghit et al., 2005). In another study on 60 obese women with type 2 diabetes in Algeria, fasting resulted in significant improvement in glucose homeostasis (Khaled et al., 2006).

In general, HbA1c values show no change or even improvement during Ramadan. (Nagra et al., 1998; Mahboob et al., 1999; and Saleh et al., 2005). Few studies have reported slight increases in HbA1c levels (Hallak et al., 1988 and Belkhadir et al., 1993). However, one report has emphasized the same increase in nonfasting patients as in fasting ones (Belkhadir et al., 1993) while another has shown a return to initial levels immediately after the month of Ramadan (Hallak et al., 1988).

Concerning the serum creatinine and urea, most studies showed that serum creatinine, uric acid and blood urea nitrogen do not show significant changes among T2DM patients during fasting periods (Maisols et al., 1993; Al-Hader et al., 1994 and Ewis et al., 1997). A study by Ait Saada et al. (2008) was carried out (during and before the month of Ramadan fasting) to evaluate the effect of some anthropometric and biochemical parameters in men and women aged 45 to 55 years who were suffering from type 2 diabetes and treated with oral antidiabetics consisting of a mixture (Biguanides and Sulphamides). This study reported the rates of serum urea and creatinine to be practically stable ($P > 0.05$) among the women and the men diabetic during all the experimental periods.

Regarding the effect of fasting on biochemical parameters other than lipid profile among healthy individuals, a study was carried out in the month of Ramadan on Jordanian students. It was found there was no significant rise in blood sugar values at the end of fasting (Mansi, 2007). Similarly, a study performed in Kuwait in 2003 found no significant rise in blood sugar value at the end of Ramadan (Asgary et al., 2000). Saleh et al. (2005) performed a study on 60 healthy Kuwaiti males and females and reported a non-significant decrease in blood glucose of females at the end of Ramadan fasting, while blood glucose levels were not affected significantly in males. Méghit et al. (2005) found a significant decrease in FBG ($p < 0.01$) and a decrease in HbA1c but not statistically significant.

Many previous studies have been published on the effect of Ramadan fasting on serum creatinine and urea in healthy individuals and reported small changes that were statistically not significant (Sliman and Khatib, 1988 and Mafauzy et al., 1990). One study was carried out in Turkey on thirty nine healthy subjects (32 women and 7 men) showed a significant reduction creatinine level during Ramadan than it was before Ramadan, this study also showed no change in serum urea and uric acid levels at the end of Ramadan (Furuncuoglu et al., 2007).

Ibrahim et al. (2008) also reported no significant change in serum urea and serum uric acid level at the end of Ramadan in a study conducted on 14 healthy subjects (9 men and 5 women) But in some of other previous studies, it has been reported that uric acid levels might change (Hallak, 1988). Roky et al. (1997) showed an increase in serum urea and uric acid levels during Ramadan which attributed to dehydration during this month.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study design

It is a cross sectional study.

3.2 Target population

The study population was consisted of T2DM patients aged between 40- 65 years who had no history of diabetic complication or other diseases.

3.3 Setting and sampling procedure

The subjects of this study were chosen from diabetology services, Palestinian Medical Relief Society laboratories. Convenience sampling technique was used to select the study T2DM patients who were attending to the health center with well controlled dietary instructions and the same Oral Hypoglycemic Drug (OHD).

3.4 Period of the study

The study was carried out in the previous Ramadan (late of July to August, 2011) at two points of time; one week before Ramadan (visit- 1) and one week before its end (visit- 2). The aim of pre-Ramadan visit (visit1) was to assess the physical well being of patients and to assess their diabetic control. They were also educated about the warning symptoms of hypoglycemia, dehydration, and any other possible complications. They were advised to break fast as soon as any such complication was noted. However they were instructed to carry on with their usual living habits and physical activity. Blood samples were also collected for baseline blood levels. They were told to revert back to prior schedule after end of Ramadan The aim of Ramadan visit (visit 2) was to collect blood sample for final analysis. Noteworthy that, after the second visit, the study participants have been telling about the results of the study in addition to overall impact of fasting on their health and how they could maintain better diabetic control in future. Results delivered to T2DM patients and healthy individuals through printed reports.

3.5 Sample size and response rate

The sample size of the study was calculated by using the Epi_Info program version 16 with 95.0 % confidence interval, 3% standard error and 9 % prevalence of DM based on previous studies that carried out in Palestine (MOH, 2002 and MOH 2005a). The sample size was 108 T2DM patients. The response rate of cases was 75% and hence the actual total sample size was 80 T2DM patients.

3.6 Selection criteria

Subjects who were eligible to participate in the study are those met the following criteria.

3.6.1 Inclusion criteria

A: Cases

Inclusion criteria included T2DM patients (40 males & 40 females) aged 40-65 years whose diabetes was identified maximum 3 years ago, treated the same OHD, presented no diabetic complications or other diseases and live in Gaza city.

B: Healthy individuals (controls)

Controls are healthy individuals (20 males & 20 females) aged 40-65 years in average they match the cases in age, weight and were selected from the same area.

3.6.2 Exclusion criteria (for cases and controls)

Exclusion criteria were included: T2DM patients or healthy individuals aged less than 40 years or more than 65 years, and T2DM patients with diabetic complications or other diseases.

3.7 Ethical Consideration

1. All formal letter of approval to conduct the study was obtained from the graduate committee of The Islamic University.
2. An official letter of approval to conduct the study was obtained from the Helsinki Committee (Ethical committee in the Gaza Strip) to conduct the study and to make the necessary analysis (annex, 1).

3. An official approval letter from Palestinian Medical Relief Society to conduct the study and to make the needed biochemical analyses in their laboratory (Annex, 2).
4. Every subject in the study was given a consent form about the study. This form included the purpose of the research, confidentiality of information, funding and so on. Interviewer read for each subject (Annex, 3).
5. All study participants received the report of the results of their biochemical examinations after the end of the study (Annex, 4).

3.8 Operational definitions

3.8.1 Body mass index

BMI is a statistical measurement derived from individual's height and weight used as an indicator for human body fat ($BMI = \text{weight (kg)} / \text{height (m}^2\text{)}$), and consequently a degree of over- or underweightness. Although it is considered to be a useful way to estimate healthy body weight, it does not measure the percentage of body fat. BMI is commonly categorical as the values listed below (World Health Organization (WHO), 2000 and WHO, 2012a).

BMI	Weight Classifications
Below 18.5 kg/m ²	Underweight
18.5-24.9 kg/m ²	Normal weight
25-29.9 kg/m ²	Overweight
30-34.9 kg/m ²	Obesity (class 1)
35-39.9 kg/m ²	Obesity (class 2)
40 kg/m ² & above	Extreme obesity (class 3)

The reduction in BMI is associated with lower risk of obesity-related diseases such as CVDs, DM, and certain types of cancers e.g. breast cancer, colon cancer (Haslam and James, 2005).

3.8.2 Physical activity

Physical activity (PA) is any bodily movement produced by skeletal muscles and requires more energy than resting (WHO, 2012b). Aerobic PA greatly decreases the risk of developing diseases of affluence such as T2DM and cardiovascular disease (Skerrett and Manson, 2002). Experts recommend that adults get 30-60 minutes/day of moderate-intensity physical activity on a regular basis. The physical activity level (PAL) is a way to express a person's daily physical activity as a number, and is used to estimate a person's total energy expenditure. The following table shows the indicative numbers for the Physical activity level for several lifestyles (Food and Agriculture Organization of the United Nations, 2004)

Lifestyle	Example	PAL
Extremely inactive	Patient cerebral palsy	<1.40
Sedentary active	Office worker, Reading, Typing	1.40-1.69
Moderately active	Construction worker, running one hour daily, Shopping, Nursing	1.70-1.99
Vigorously active	Agricultural worker, Football, running, person swimming two hours daily	2.00-2.40
Extremely active	Competitive cyclist	>2.40

3.9 Data collection

Data was collected by the researcher and his qualified team through direct and indirect methods. The indirect method included a structured interviewed questionnaire. While the direct method included measurements of anthropometric measurements (measurement of weight and height) and biomedical parameters (measurement of lipid profile, FBG, HbA1c, urea and creatinine).

3.9.1 The indirect method

It was designed to be face-to-face interviewed questionnaire. The questionnaire consisted of the following three parts (Annex, 5):

- Part one included personal data, demographic data and some characteristics of the study population (age, address, telephone number, marital status, educational level, monthly income and so on).
- Part two included physical activity related data (level of exercise before and during Ramadan month) in addition to dietary habits and lifestyle during Ramadan (smoking status, sleeping pattern, Television (TV) or Personal Computer (PC) watching after Iftar meal, and Taraweh praying).
- Part three included a Food Frequency Questionnaire (FFQ), which was used to cover the most common foods that consumed during Ramadan month (dairy products, red and white meats, eggs, liver, sugary foods and so on).

3.9.2 The direct method

3.9.2.1 Anthropometric data

Standard techniques were adopted for obtaining anthropometric measurements, The anthropometric data were measured at the two period of the study, one week before Ramadan fasting and one week before its end. The participant weighed in light cloths without shoes to the nearest 0.1 Kg by an electronic weighing scale, the height measured by a stadiometer to the nearest 1.0 cm, the subjects was instructed to stand bare feet with their head in an upright position. Body mass index (BMI) was calculated by dividing the weight in kilograms by the square of the height in meters.

3.9.2.2 Specimen collection and biochemical analysis

During one week before Ramadan month and one week before its end, About 5 ml blood sample in a fasting state was withdrawn from 80 T2DM patients and 40 controls after 12- 14 hours (h) fasting by venipuncture into tubes as the following:

Three milliliters of the blood were taken and placed into a plain tube (without anticoagulation) and samples were allowed to clot and the serum centrifuged at room temperature by Fuhua 80-1 centrifuge, China at 4000 round/minute for 10 minutes.

Serum was stored at -18°C until analyzed. Serum was used to determine TC, TGs, HDL-C, creatinine, urea, and blood glucose level. LDL-C in mg/dL was measured by using Fried Wald's formula which mentioned before (Friedewald et al., 1972 and MOH, 2005c).

Two milliliters of blood was collected into Ethylene Diamine Tetra Acetic Acid (EDTA) tube for determination of HbA1c percent.

Serum glucose, urea, creatinine, TC, TG were analysed by Chemistry Autoanalyzer (BS-120, Guangdong, China (Mainland)) in El Arabi medical Laboratory. Quality assurance program was carried out. Colorimetric calculations of glucose, urea, creatinine, TC, TGs were obtained automatically from autoanalyzer depending on beer's law.

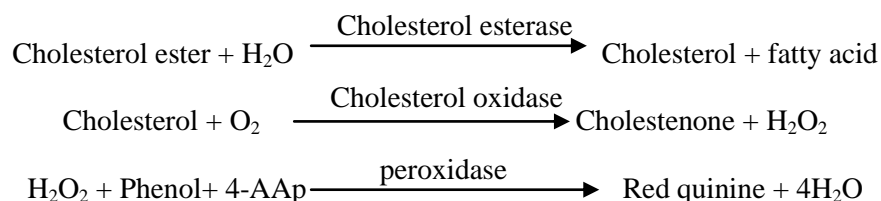
The colorimetric concentration = Absorbance of Test x Concentration of Standard / Absorbance of Standard

Serum high density lipoprotein cholesterol (HDL-C) was measured using spectrophotometer whereas low density lipoprotein cholesterol (LDL-C) was calculated using Friedewald empirical equation (Friedewald et al., 1972).

3.9.2.2.1 Determination of serum cholesterol

Principle

Enzymatic colorimetric determination of serum total cholesterol (using EITech clinical kit, France) according to the following reactions (Allain et al., 1974):



Reagents composition

Reagents	Component	Concentration
Reagent-1	Pipes buffer	50 mmol/L
	Phenol	24 mmol/L
	Sodium cholate	5 mmol/L
	4-Aminoantipyrine	0.5 mmol/L
	Cholesterol esterase	180 U/L
	Cholesterol oxidase	200 U/L
	Peroxidase	1000 U/L
	pH	6.7
Standard :	Cholesterol	200 mg/dL

Procedure

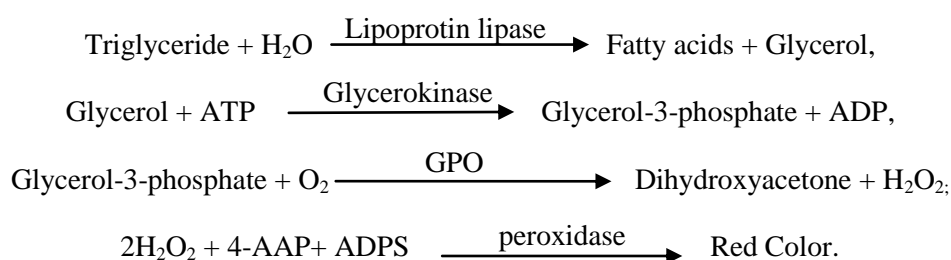
About 0.5 ml of serum was transferred to the Chemistry Autoanalyzer (BS-120), to perform the test according to these parameters:

Parameter	Value
Reaction type	End point
Pri- wave (nm)	510
Sec- wave (nm)	-
Direction	Increase
Reaction time	0 -17
Incu- time (sec)	180
Unit	(mg/dl)
Precision	0.1
R1 volume (µl)	300
R2 volume (µl)	-
Sample volume (µl)	3
Calibrator type	Linear

3.9.2.2.2 Determination of serum triglycerides

Principle

Enzymatic colorimetric determination of serum triglycerides (using EIITech clinical kit, France) according to the following reactions (Fossati and Prencipe 1982):



Reagent composition

Reagents	Component	Concentration
Reagent-1	Pipes buffer	50 mmol/L
	Mg ²⁺	14.8 mmol/L
	p-Chlorophenol	2.7 mmol/L
	ATP	3.15 mmol/L
	Potassium ferrocyanide	10 mmol/L
	Amino-4-antipyrine	0.31 mmol/L
	Lipoprotein lipase	≥ 2000 U/L
	Glycerol kinase	≥ 500 U/L
	Glycerol-3-phosphate oxidase	≥ 4 000
	Peroxidase	500 U/L
pH	7	
Standard :	Glycerol (triglycerides equivalent)	200 mg/dL

Procedure

About 0.5 ml of serum was transferred to the Chemistry Autoanalyzer (BS-120), to perform the test according to these parameters:

Parameter	Value
Reaction type	End point
Pri- wave (nm)	510
Sec- wave (nm)	-
Direction	Increase
Reaction time	0 -17
Incu- time (sec)	180
Unit	(mg/dl)
Precision	0.1
R1 volume (µl)	300
Sample volume (µl)	3
Calibrator type	Linear

3.9.2.2.3 Determination of serum high density lipoproteins (HDL-C)

HDL-C was determined by precipitating method using ELITech clinical kit, France (Burstein et al., 1970).

Principle

Chylomicrons, Very Low Density Lipoproteins (VLDL) and Low Density Lipoproteins (LDL) of serum are precipitated by Phosphotungstic acid and Magnesium ions. After centrifugation, High Density Lipoproteins (HDL) are in the supernatant. Cholesterol included in this phase, is measured by an enzymatic method.

Reagents composition

Reagents	Component	Concentration
Reagent-1	Phosphotungstic aci	14 mmol/L
Reagent-2	Magnesium chloride	2 mmol/L
Standard : Std	Cholesterol	50 mg/dL

Procedure

1) Precipitating reagent preparation

- Mix 4 volumes of the reagent R1 with 1 volume of the reagent R2.

2) Sample preparation

- Add to 500 µL of sample, 50 µL of precipitating reagent. Mix, wait for 10 minutes and centrifuge at 5 000 r.p.m. for 15 minutes.

- The supernatant is collected for HDL determination.

3) HDL determination

- The cholesterol kit is used for HDL cholesterol determination.

- Pipette into centrifuge tube 1 ml cholesterol reagent and 10 µl of the supernatant. -

- Mix well. Allow to stand for 10 minutes at room temperature.

- Set the unicam spectrophotometer, United Kingdom, at 500 nm and adjust it to zero with blank reagent. Read the Absorbance (A) of the test, and standard against reagent blank.

4) Calculation:

$$HDL\ Concentration = (A)\ Test \times (C)\ Standard / (A)\ Standard$$

3.9.2.2.4 Determination of serum low density lipoproteins (LDL-C)

Principle

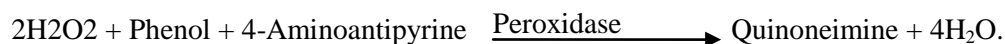
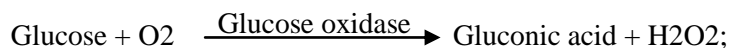
LDL-C was estimated from quantitative measurements of TC and HDL-C and TG using Friedewald formula (Friedewald et al., 1972).

$$\text{The Equation } \{ LDL-C = Total\ Cholesterol - HDL-C - TG/5 \}$$

3.9.2.2.5 Determination of serum glucose

Principle

Enzymatic determination of serum glucose (using Elitech clinical kit, France) according to the following reactions (Trinder, 1969):



Reagents composition

Reagents	Component	Concentration
Reagent-1	Phosphate buffer	13.8 mmol/L
	Phenol	10 mmol/L
	4-Aminoantipyrine	0.3 mmol/L
	Glucose oxidase	$\geq 10\,000$ U/L
	Peroxidase	≥ 700 U/L
	pH	7.4
Standard : Std	D-Glucose	100 mg/dL

Procedure

About 0.5 ml of serum was transferred to the Chemistry Autoanalyzer (BS-120), to perform the test according to these parameters:

Parameter	Value
Reaction type	End point
Pri- wave (nm)	510
Sec- wave (nm)	-
Direction	Increase
Reaction time	0 -33
Incu- time (sec)	180
Unit	(mg/dl)
Precision	0.1
R1 volume (μ l)	300
R2 volume (μ l)	-
Sample volume (μ l)	3
Calibrator type	Linear

3.9.2.2.6 Determination of Hemoglobin A1c

HbA1c was determined by Chromatographic in tube with pre weighted resin of Hemoglobin A1c in blood. Using GLOBE DIAGNOSTICS srl kit, ITALY.

Principle

The present procedure utilizes a weak binding cationexchange resin for the rapid separation of glycated hemoglobin A1c from all the other hemoglobins.

A hemolyzed preparation of the whole blood is mixed continuously for 5 minutes with a weak binding cationexchange resin. During this time, HbA0 binds to the resin. HbA0 consist of all the other hemoglobins except A1c which remains in solution. After the mixing period, a filter is used to separate the supernatant containing the A1c from the resin. The percent glycohemoglobin is determined by measuring the absorbance at 415 nm of the A1c fraction and the total hemoglobin fraction. The ratio of the two absorbances gives the percent of HbA1c.

Reagents composition

Reagent A:

-Resin reagent: 8 mg/ml Cation-exchange resin, Resin buffered at pH 6.9. ready to use and Preweighted in tube.

Reagent B:

- **Lysing reagent:** Potassium cyanide 10 mM, surfactant added.
- **Glycohemoglobin Standard:**Lyophilized, Glycohemoglobin A1c 10%.
- **Filter Separators**

Procedure

I- Hemolysate Preparation:

1. Dispense 500 µl Lysing Reagent (Reagent B) into tubes labelled: Standard, Control, Sample 1, etc.
2. Place 100 µl of the well-mixed blood sample, standard or control into the appropriately labelled tube. Mix well and allow standing for 5 minutes.

II- Glycohemoglobin preparation:

1. Add 70 µl of the hemolysate in the resin tube (RA).
2. Position the Filter Separators in the tubes so that the rubber sleeve is approximately 1 cm above the liquid level.
3. Place the tubes on the rocker or rotator and mix continuously for 5 minutes.
4. Remove the tubes from the rocker or rotator.
5. Push the Filter Separator into the tubes until the resin is firmly packed.
6. The supernatant may be poured into another tube or directly into a cuvette for absorbance measurement.
7. Adjust the instrument to zero absorbance at 415 nm with deionized water as the blank. (Wavelength range: 390-420).
8. Read and record the absorbance values for Standard, Control, Sample 1, etc. These readings are for glycohemoglobin.

III- Total Hemoglobin Fraction:

1. Dispense 5.0 ml deionized water into tubes labelled: Standard, Control, Sample 1, etc.
2. Place 20 µl of the hemolysate into the appropriately labelled tube. Mix.
3. Adjust the instrument to zero absorbance at 415 nm with deionized water as the blank.
4. Read and record the absorbance values for Standard, Control, Sample 1, etc. These readings are for total hemoglobin.

IV- Calculation of results

Results should be determined as follows:

$$\%HbA1c \text{ (unknown)} = (R \text{ (unknown)} / R \text{ (standard)}) \times \text{standard conc}$$

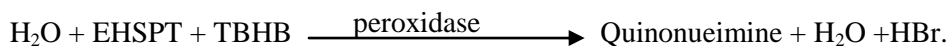
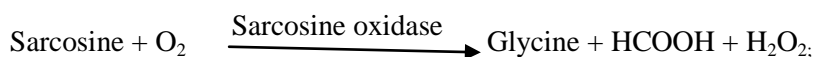
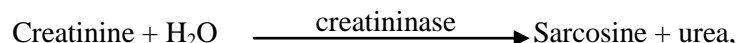
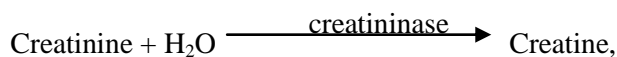
$$R \text{ (unknown)} = \text{Ratio (unknown)} = (\text{Abs of HbA1c (unknown)} / \text{Abs of Hb Tot (unknown)})$$

$$R \text{ (standard)} = \text{Ratio (standard)} = (\text{Abs of HbA1c (standard)} / \text{Abs of Hb Tot (standard)})$$

3.9.2.2.7 Determination of serum creatinine

Principle

Enzymatic colorimetric determination of serum creatinine (using EIITech clinical kit, France) according to the following reactions: (Fossati et al., 1983).



Reagents composition

Reagents	Component	Concentration
Reagent-1	EHSPT	0.4 mmol/L
	Creatinase	$\geq 10\,000$ U/L
	Sarcosine Oxidase	≥ 3500 U/L
	Ascorbate Oxidase	≥ 1000 U/L
Reagent-2	Amino-4-Antipyrine	2.92 mmol/L
	Creatininase	150 000 U/L
	Peroxidase	4 000 U/L

Procedure

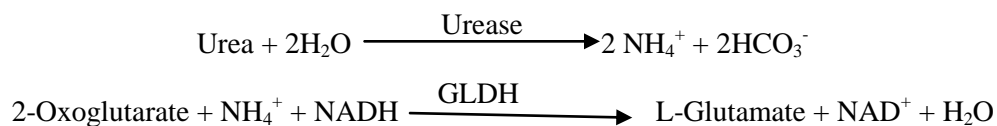
About 0.5 ml of serum was transferred to the Chemistry Autoanalyzer (BS-120), to perform the test according to these parameters:

Parameter	Value
Reaction type	Fixed time
Pri- wave (nm)	510
Sec- wave (nm)	-
Direction	Increase
Reaction time	2-9
Incu- time (sec)	60
Unit	(mg/dl)
Precision	0.1
R1 volume (μl)	200
R2 volume (μl)	200
Sample volume (μl)	40
Calibrator type	Linear

3.9.2.2.8 Determination of serum Urea

Principle

Enzymatic colorimetric determination of serum urea (using ElITech clinical kit, France) according to the following reactions: (Fossati et al., 1983).



Reagents composition

Reagents	Component	Concentration
Reagent-1	ADP	0.7 mmol/L
	GIDH	≥ 1000 U/L
	Urease	≥ 30 000 U/L
	NADH	0.3 mmol/L
	Ketoglutarate	9 mmol/L
	pH	7.4
Reagent-2	Tris buffer	100 mmol/L
	pH	7.7
Standard : Std	Urea	50 mg/dL

Procedure

About 0.5 ml of serum was transferred to the Chemistry Autoanalyzer (BS-120), to perform the test according to these parameters:

Parameter	Value
Reaction type	kinetic
Pri- wave (nm)	340
Sec- wave (nm)	-
Direction	Increase
Reaction time	2-9
Incu- time (sec)	60
Unit	(mg/dl)
Precision	0.1
R1 volume (µl)	200
R2 volume (µl)	50
Sample volume (µl)	3
Calibrator type	Linear

3.10 Data analysis

Data were analyzed using Statistical Package of Social Sciences (SPSS) system (version 14.0). The following statistical tests were applied:

- Frequency distributions
- Chi – Square Test
- Pairs samples t-test

Probability values (p) were obtained from 't' student's table and Chi-square test at significance $p < 0.05$.

3.11 Limitations of the study

- The continuous and frequent outages of electricity.
- Lack of commitment by some patients and controls to participate in the second phase of the study, which was in the last week of the month of Ramadan.
- Lack of commitment by some patients to take OHD according to the recommendations of the physician supervisor to them during the days of the month, forcing the researcher to be excluded from the study.
- High cost of biochemical tests and tools.

CHAPTER FOUR

RESULTS

4.1 General characteristics of the study subjects

4.1.1 Gender

Table and figure 4.1, shows that female cases represented 52.5% of the study subjects, while male cases represent 47.5%; whereas female controls represent 50.0% of the study subjects while male controls represent 50.0%.

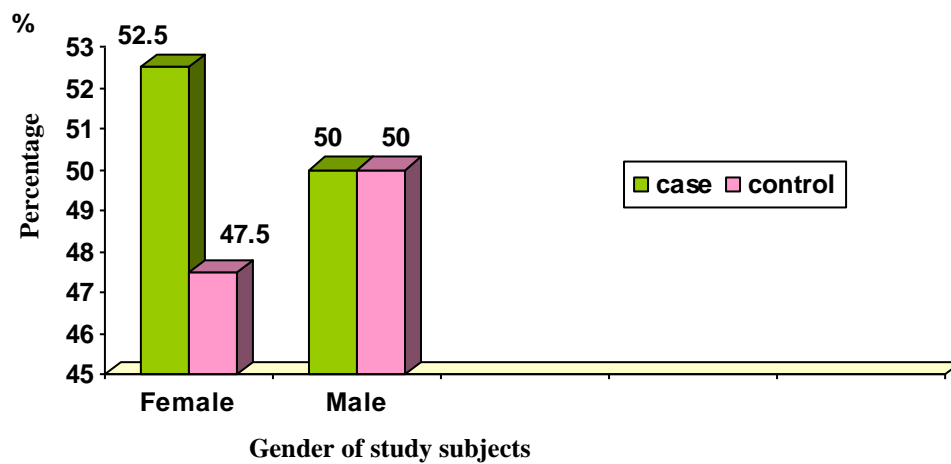


Figure 4.1: Percentage distribution of the study subjects according to gender

4.1.2 Age

Figure 4.2, shows that the mean ages of the study subjects were 53.21 (\pm 7.459) years and 54.84 (\pm 6.798) years for cases and controls respectively ($P=0.966$). The age of the study subjects ranged from 40 to 65 years and grouped into three. The highest percentage among cases was recorded among the age group 50-59 years followed by the age group 40-49 years. The lowest percentage was noticed in the age group 60-65 years (table 4.1). However, there was no statistically difference between the study subjects with respect to age ($P=0.966$).

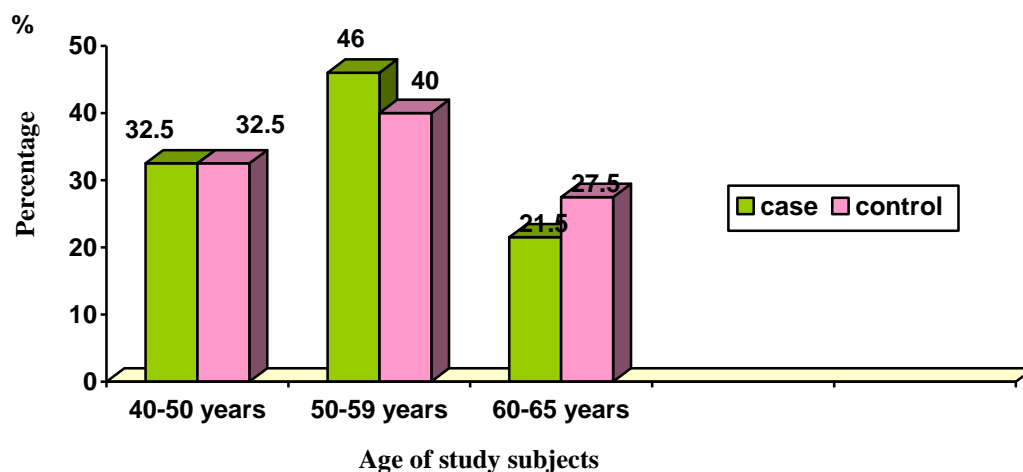


Figure 4.2: Percentage distribution of the study subjects according to age

Table 4.1: General characteristics of the study subjects

Item	Diabetic		Control		Chi-Square Test	P-Value	
	N (N=80)	%	N (N=40)	%			
Gender						0.050	0.823
Male	41	52.5	20	50.0			
Female	39	47.5	20	50.0			
Age (years)						16.759	0.966
40 - 49	26	32.5	13	32.5			
50 - 59	37	46.0	16	40.0			
60 - 65	17	21.5	11	27.5			
Level of education						1.169	0.883
Illiterate	5	6.3	4	10.0			
Primary	13	16.1	5	12.5			
Preparatory	25	31.3	11	27.5			
Secondary	27	33.8	14	35.0			
Undergraduate or more	10	12.5	6	15.0			
Monthly income(NIS)						0.600	0.741
Less 1000	37	46.3	18	45.0			
1000 -2000	27	33.7	15	37.5			
> 2000	16	20.0	7	17.5			
Going on diet						81.852	0.000**
Yes	72	90.0	7	17.5			
No	8	10.0	33	82.5			

P < 0.05: Significant

4.1.3 Level of education

As indicated in Table 4.1, The percentage of cases who had secondary educational level was 33.8% for cases Vs. 35.0% for controls, and 31.3% of the study cases Vs. 27.5% controls had preparatory education. However, there was no statistically difference among study subjects with respect to education level ($P=0.883$) (Figure 4.3).

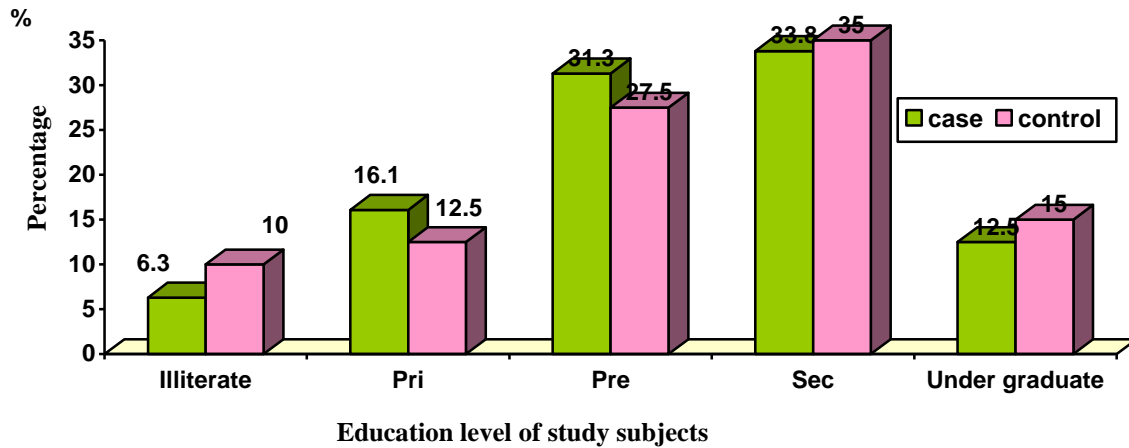


Figure 4.3: Percentage distribution of the study subjects with respect to their level of education

4.1.4 Monthly income

As shown in table 4.1, the percentage of subjects with monthly income less than 1000 New Israeli Shekel (NIS)/month was 46.3% among cases Vs. 45.4% among controls; the percentage of subjects with monthly income more than 2000 NIS/month was 20.0% among cases Vs. 17.5 among controls. There was no statistically significant difference among study subjects with respect to monthly income (salary) ($P=0.741$) (Figure 4.4).

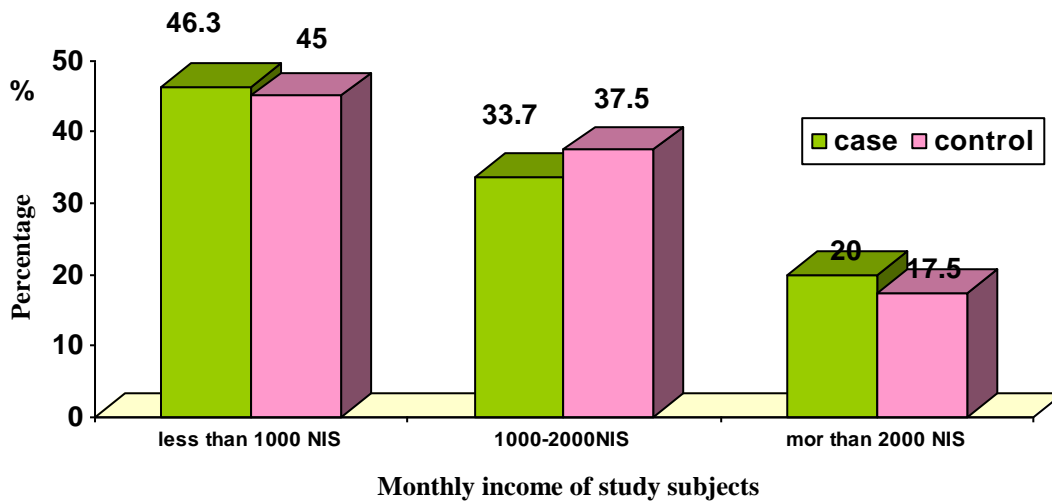


Figure 4.4: Percentage distribution of the study subjects by monthly income

4.1.5 Going on diet before Ramadan fasting

Table 4.1 and figure 4.5 reveals that, 90.0% of the cases Vs. 17.5% of the controls were going on diet whereas 10.0% of the cases Vs. 82.5% of the controls were not going on diet. However, there was a statistically difference among study subjects with respect to going on diet ($P=0.000$).

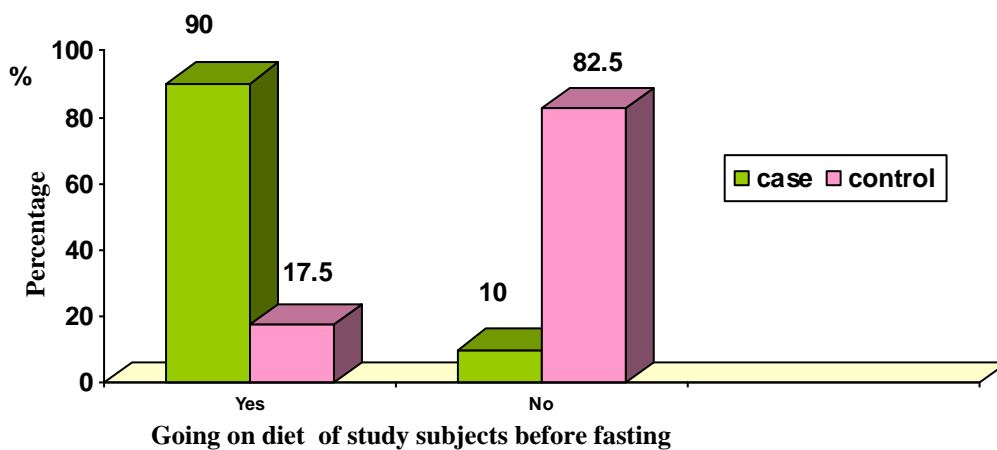


Figure 4.5: Percentage distribution of the study subjects according to their going on diet before Ramadan fasting

It should be mentioned that, the general characteristics were not significantly different among the study cases and the study controls with respect to gender (data are not shown).

4.2 Physical activity and BMI among the study subjects before fasting

4.2.1 Physical activity (PA)

The study subjects were classified into four groups according to PA before fasting as shown in the table 4.2. Only 47.5% of the cases Vs. 50.0% of the controls there works required light effort (light PA), followed by 40% of the case Vs. 27.5% of controls were exert no effort at work (Sedentary PA). Moreover, 10.0% of the case Vs. 17.5% of the controls were moderately active and those whose work demands a vigorous physical activity represented 2.5% of the cases Vs 5% of the controls. However, there was no a statistically difference among the study subjects with respect to PA before Ramadan month (P=0.339) (figure 4.6).

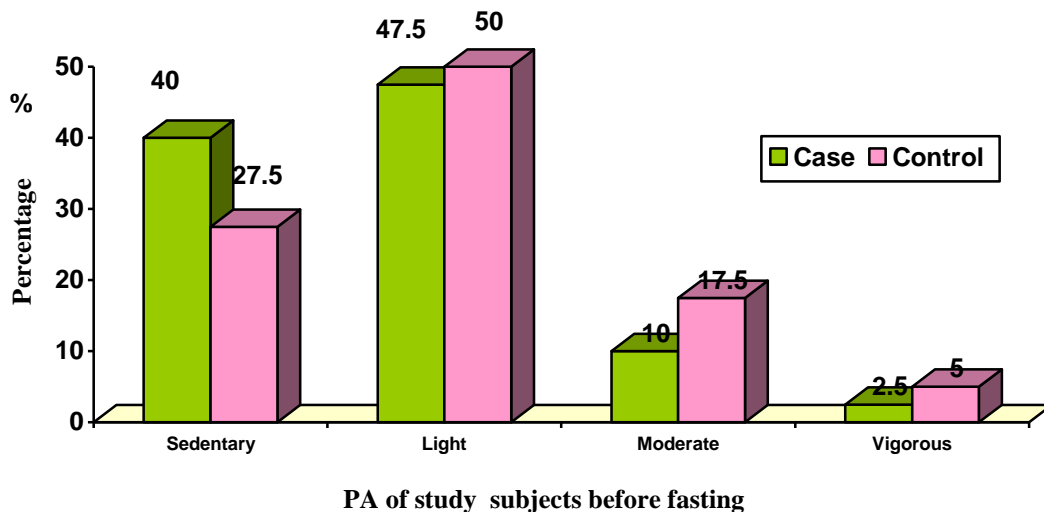


Figure 4.6: Percentage distribution of the study subjects with respect to their PA before fasting

4.2.2 Body mass index

Regarding BMI before fasting, table 4.2 and figure 4.7 illustrated that, the majority of the study cases 90.0% Vs. 80.0% of the controls were obese at the last week of Shaban month just before advent Ramadan month, whereas 10.0% of the cases Vs 20.0% of the controls had ideal weight. The mean (\pm SD) of BMI among cases were (30.85 \pm 6.11) kg/m² Vs. (31.40 \pm 5.12) kg/m² among controls (P=0.120).

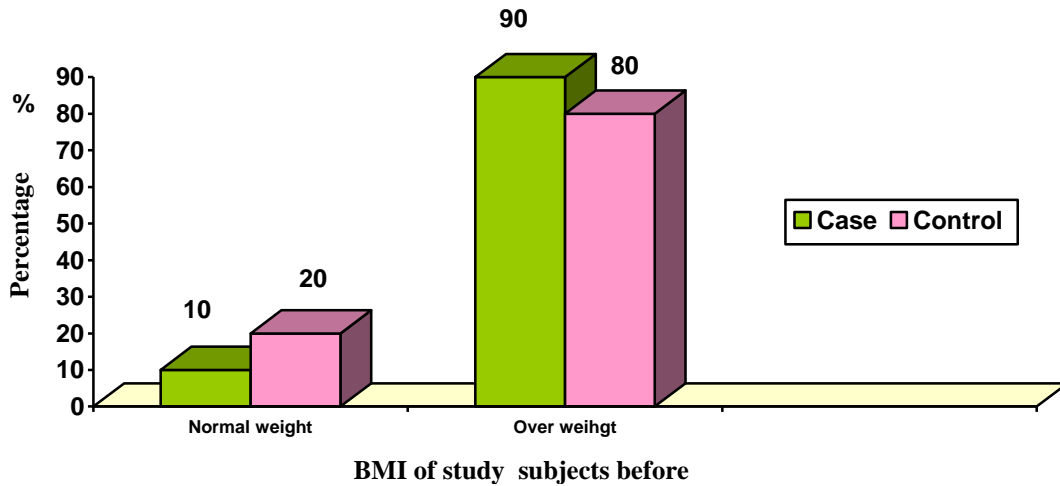


Figure 4.7: Percentage distribution of the study subjects according to their BMI before fasting

Table 4.2: Physical activity and BMI among the study subjects before fasting

Item	Diabetic		Control		Chi-Square Test	P-Value	
	N (N=80)	%	N (N=40)	%			
BMI						3.137	0.120
Ideal weight	8	10.0	8	20.0			
Overweight	72	90.0	32	80.0			
Physical activity						3.360	0.339
Sedentary	32	40.0	11	27.5			
Light	38	47.5	20	50.0			
Moderate	8	10.0	7	17.5			
Vigorous	2	2.5	2	5.0			

P < 0.05: Significant

4.3 Lifestyle characteristics of the study subjects during Ramadan

4.3.1 Taraweh praying

As shown in table 4.3, the majority of the study subjects 87.4% of the cases Vs. 87.5% of the controls were accustomed to pray Taraweh during Ramadan month whereas, 6.3% of the cases Vs. 7.5% of the controls were not accustomed to pray of Taraweh (p=0.904).

4.3.2 Physical activity during Ramadan fasting

As indicated in Table 4.3, the study subjects classified in to four groups according to PA during Ramadan fasting. The PA exerted by about sixty percent (58.8%) of the case Vs. 52.5% of controls was sedentary and the activity exerted by 43.7% of the cases Vs. 40.0% of the controls during daily work was light.

Moreover, 6.2% of the case Vs. 5.0% of the controls were moderately active before Ramadan month and those whose work was require a vigorous PA represented 1.3% of the cases Vs 2.5% of the controls (figure 4.8) (P=0.876).

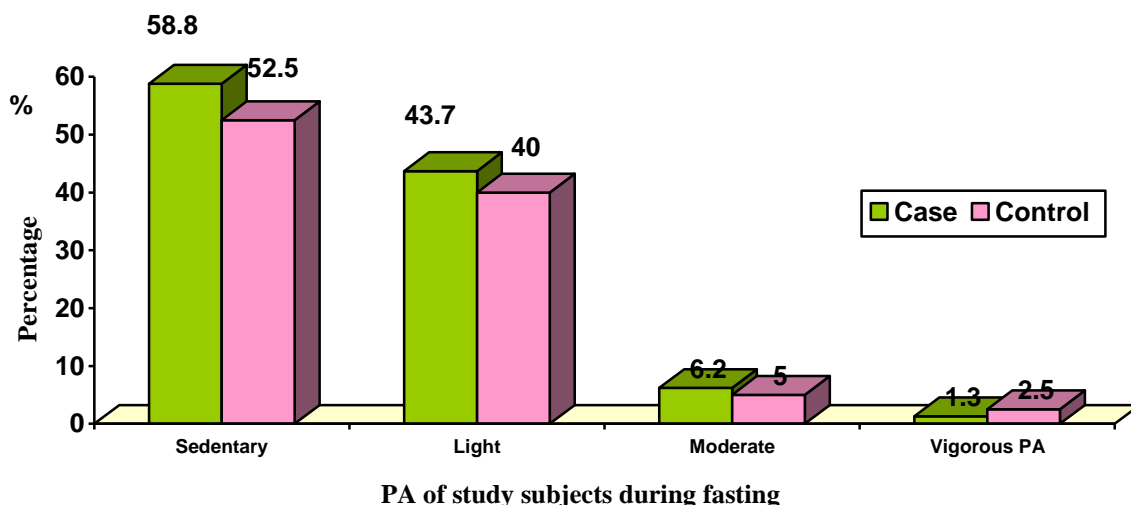


Figure 4.8: Percentage distribution of the study subjects with respect to their PA during fasting

4.3.3 Smoking status

The findings also showed that, 16.5% of the cases were found to be smokers compared to 25.0% of the controls, whereas 83.5% of the cases Vs. 75.0% of the controls were non-smokers during Ramadan (table 4.3) (P=0.246).

4.3.4 Watching TV or Personal computer (PC) after Iftar meal

Table 4.3 reveals that, the majority of the study cases (81.3%) Vs. 80.0% of the controls were accustomed to watch TV or PC after Iftar meal during Ramadan month, whereas 18.7% of the cases Vs 20.0% of the controls were neither watched TV nor PC after Iftar meal (P=1.000).

Table 4.3: Lifestyle characteristics among the study subjects during Ramadan

Item	Diabetic		Control		Chi-Square Test	P-Value
	N (N=80)	%	N (N=40)	%		
Taraweh praying					0.202	0.904
Never	5	6.3	3	7.5		
Sometimes	5	6.3	2	5.0		
Always	70	87.4	35	87.5		
Physical activity					0.690	0.876
Sedentary	39	58.8	21	52.5		
Light	35	43.7	16	40.0		
Moderate	5	6.2	2	5.0		
Vigorous	1	1.3	1	2.5		
Smoking status					1.345	0.246
Yes	13	16.5	10	25.0		
No	66	83.5	30	75.0		
Watching TV or PC after Iftar meal					0.000	1.000
Yes	65	81.3	32	80.0		
No	15	18.7	8	20.0		

P < 0.05: Significant

4.4 Frequency of dietary intake during Ramadan month

Table 4.4. describes frequency of dietary intake of the study subjects during Ramadan

4.4.1 Eggs and Liver consumption

The results showed that percentage of cases who ate eggs daily was 6.3% Vs. 18.8% of control, and 31.2% of the cases Vs. 32.5% of control did not eat eggs during Ramadan month (P=0.099). The findings also showed that 2.5% of controls were ate livers 3-5 times a week, whereas 86.3% of the cases Vs. 90.0% of control did not consumed livers during this month (P=0.308).

4.4.2 Red meats consumption

It was shown that 25.0% of the cases Vs. 17.5% of controls ate red meat daily during Ramadan month. In contrast, 6.3% of the cases Vs. 7.5% of controls did not ate red meat throughout the fasting (P=0.167).

4.4.3 White meat (chickens and fish) consumption

The findings showed that 3.8% of the cases Vs. 2.5% of controls ate chickens once daily, and 3.0% of the cases Vs. 3.8% of controls did not consumed chickens during Ramadan month (P=0.371). The results also showed that participants who ate fish once a day were 11.3% of the cases Vs. 10.0% of controls, While 25.0% of the cases Vs. 25% of controls did not consumed fish during this holy month (P=0.701).

4.4.4 Fruits and Vegetables consumption

The study showed that 52.5% of the cases Vs. same percent of controls ate fruits 3-5 weekly, whereas 1.3% of the cases Vs. 2.5% of controls did not consumed fruits during Ramadan month (P=1.000). On the other hand, the study also found that percentage of cases who ate vegetables daily was 38.0 % Vs. 30.0% of controls, and 3.5% of the cases did not consumed vegetables (P=0.387).

4.4.5 Legumes consumption

It was shown that 25.0% of the cases Vs. same percent of controls were ate legumes daily during Ramadan month, while 22.5% of cases Vs. 27.5% of the controls did not eat legumes throughout the holy month (P=0.372).

Table 4.4: Frequency of dietary intake during Ramadan month

Food consumption items		Once daily		3-5 Weekly		Once Weekly		Once every 2 Weeks		None		P-Value
		No	%	No	%	No	%	No	%	No	%	
Eggs	Case	5	6.3	15	18.7	30	37.5	5	6.3	25	31.2	0.099
	Control	4	18.8	7	17.5	9	22.5	4	8.8	13	32.5	
Red meats	Case	20	25.0	40	50.0	14	17.5	1	1.3	5	6.3	0.167
	Control	7	17.5	22	55.0	7	17.5	1	1.3	2.5	7.5	
Chickens	Case	3	3.8	29	36.3	42	52.0	4	5.0	2	3.0	0.371
	Control	1	2.5	20	50.0	15	37.5	4	6.3	2	3.8	
Liver	Case	0	0.0	0	0.0	3	10.0	3	3.8	69	86.3	0.308
	Control	0	0.0	1	2.5	2	5.0	1	2.5	36	90.0	
Fish	Case	9	11.3	16	20.0	23	28.8	12	15.0	20	25.0	0.701
	Control	4	10.0	8	20.0	10	25.0	8	20.0	10	25.0	
Legumes	Case	20	25.0	14	17.5	20	25.0	8	10.0	18	22.5	0.372
	Control	10	25.0	6	15.0	8	20.0	5	12.5	11	27.5	
Vegetables	Case	30	38.0	40	50.0	4	5.0	3	3.5	3	3.5	0.387
	Control	12	30.0	25	62.5	2	5.0	1	2.5	0	0.0	
Fruits	Case	23	28.8	42	52.5	10	12.5	4	5.0	1	1.3	1.000
	Control	11	27.5	21	52.5	5	12.5	2	5.0	1	2.5	
Salty foods	Case	5	6.2	10	12.5	20	25.0	20	25.0	25	31.3	0.104
	Control	5	12.5	10	25	5	12.5	8	20.0	12	30.0	
Vegetables oil	Case	78	97.5	2	2.5	0	0.0	0	0.0	0	0.0	0.341
	Control	38	95.0	2	5.0	0	0.0	0	0.0	0	0.0	

P < 0.05: Significant

4.4.6 Salty foods consumption

The study showed that percentage of cases who ate salty foods daily was 6.2% Vs. 12.5% of control. In contrast, 31.3% of the cases Vs. 30.0% of control did not ate Salty foods during Ramadan month (P=0.104).

4.4.7 Vegetables oil (olive and corn oil) consumption

The findings also shows that 97.5 % of the cases Vs. 95.0% of controls were ate vegetables oil daily during Ramadan month, while 2.5% of the cases Vs. 5.0% of controls were ate vegetables oil 3-5 Weekly during this month (P=0.341).

However, food frequency intake among the study population was not significantly different for all mentioned food items (P>0.05) (table 4.4).

4.5 Food habits in Iftar meal during Ramadan fasting

4.5.1 Number of Iftar Stages

The findings showed that, 82.5% of the cases Vs. the same percent of controls had their Iftar meal at one stage, whereas, 17.5% of the cases Vs. (17.5%) of control had their Iftar meal at two stages (P=1.000) (table 4.5).

4.5.2 Having snacks beyond Iftar meal

As shown in table 4.5, about (35.0%) of the cases Vs. 30.0% of controls did not have snacks beyond Iftar meal during Ramadan month, and 37.5% of the cases Vs. 50.0% of control were sometimes have snacks beyond Iftar meal. While 27.5% of the cases Vs. 20.0% of controls were always have snacks beyond Iftar meal during the month of fasting (P=0.208).

4.5.3 Sweets eating

Moreover, 11.2% of the cases Vs. 27.5% of controls regularly ate sweets during Ramadan month, and 22.5% of the cases Vs. 7.5% of control were not ate sweets during Ramadan month (P=0.003) (table 4.5).

4.5.4 Juices & water drinking

The finding showed that, the percentage of cases who drank from 6 to 8 cups of water daily were 38.7% Vs. 32.5% of control, and 21.3% of the cases Vs. 22.5 % of controls drank less than 6 cups daily (P=0.596).

Table 4.5: Food habits in Iftar meal during Ramadan fasting

Item	Diabetic		Control		Chi-Square Test	P-Value
	N (N=80)	%	N (N=40)	%		
Number of Iftar Stages					0.000	1.000
One Stage	66	82.5	33	82.5		
Two Stage	14	17.5	7	17.5		
Having snacks beyond Iftar meal					3.142	0.208
Never	28	35.0	12	30.0		
Sometimes	30	37.5	20	50.0		
Always	22	27.5	8	20.0		
Sweets eating					11.461	0.003*
Never	18	22.5	3	7.5		
Sometimes	53	66.3	26	65.0		
Always	9	11.2	11	27.5		
Drinking of Juice & Water /day					1.034	0.596
< 6 Cups	17	21.3	9	22.5		
6 – 8 Cups	31	38.7	13	32.5		
> 8 Cups	32	40.0	18	45		
Tea drinking/day					2.072	0.558
Non	21	26.2	9	22.5		
1 Cup	40	50.0	17	42.5		
2 – 3 Cups	11	13.2	9	22.5		
> 3 Cups	8	10.0	5	12.5		
Coffee drinking/day					0.825	0.843
Non	37	46.3	21	52.5		
1 Cup	18	22.5	8	20.0		
2 – 3 Cups	13	16.3	5	12.5		
Soft drinks drinking					3.143	0.208
Never	29	36.3	10	25.0		
Sometimes	44	55.0	24	60.0		
Always	7	8.7	6	15.0		

P < 0.05: Significant

4.5.5 Tea drinking

The findings showed that, 26.2% of the cases Vs. 22.5% of controls did not drink tea during Ramadan month, and 10.0% of the cases Vs. 12.5% of controls were drank more than three cups of tea daily during Ramadan month (P=0.558) (table 4.5).

4.5.6 Coffee drinking

Table 4.5 also shows that, the majority of the (46.3%) cases Vs. 52.5% of controls did not drink coffee during Ramadan, while 15.0% of the cases Vs. same percent of controls drank more than three cups of tea daily during Ramadan month (P=0.843).

4.5.7 Soft drinks

Table 4.5 also shows that, 8.7% of the cases Vs. 15.0% of controls regularly had soft drinks during Ramadan month, and 36.3% of the cases Vs. 25.0% of controls did not had soft drinks during Ramadan (P=0.208).

4.6 Food consumed on Sohor meal during Ramadan fasting

4.6.1 Sohor meal ingestion

As indicated in table 4.6 and figure 4.9, the percentage of cases who had Sohor meal regularly during Ramadan month was 70.0% for cases Vs. 72.5% for controls, and the percentage of cases who had Sohor meal irregularly was 23.7% of the cases Vs. 20.0% of controls (P=0.826).

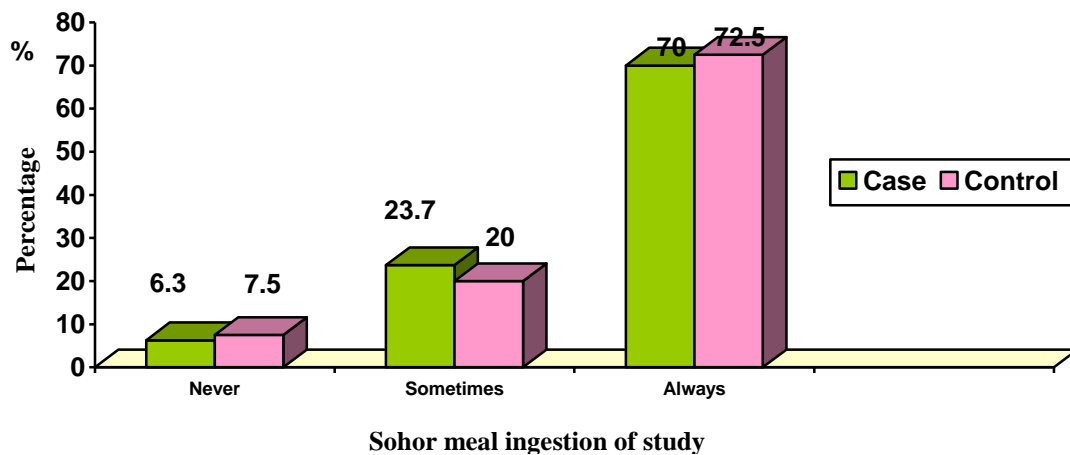


Figure 4.9: Percentage distribution of the study subjects with respect to sohor meal ingestion

4.6.2 Sugary foods consumption

Table 4.6 and figure 4.10 and 4.11 illustrates that, the percentage of cases (6.3%) who consumed sugary foods on Sohor meal was lower than controls (30.0%).

However the results reflected a positive statistically significant difference with respect to sugary foods consumption on Sohor meal among the study population (P=0.000).

4.6.3 Salty foods consumption

Table 4.6 also showed that, the percentage of cases (26.2%) who consumed salty foods on Sohor meal during Ramadan was lower than controls (52.5%) (figure 4.10 and 4.11).

However the results reflected a positive statistically significant difference with respect to Salty foods consumption on Sohor meal among the study population (P=0.001).

4.6.4 Legumes consumption

The finding showed that, the percentage of cases who consumed legumes on Sohor meal was 42.5% Vs. 40.0% for control, whereas 57.5% of the cases Vs. 60.0% of controls did not eat salty foods (P=0.177) (table 4.6 and figure 4.10 and 4.11).

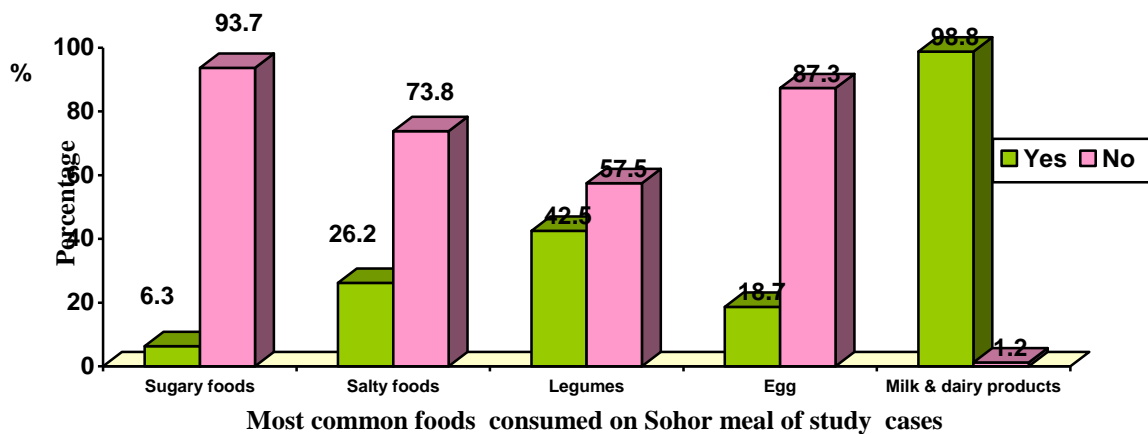


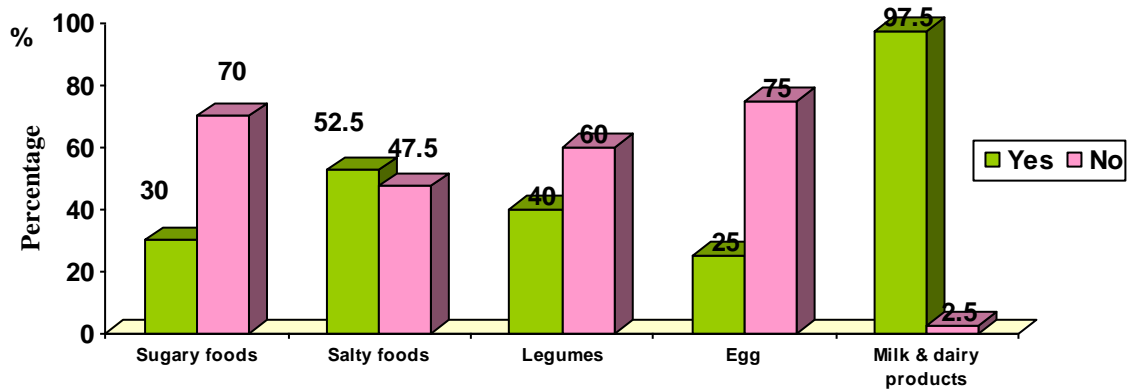
Figure 4.10: Percentage distribution of the study cases with respect to the most common foods consumed on Sohor meal

4.6.5 Eggs consumption

As shown in table 4.6, most of the cases (87.5%) of the Vs. 57.5% of controls did not eat eggs on Sohor meal, whereas 18.7% of the cases Vs. 25.0% of controls ate eggs on Sohor meal (P=0.084) (figure 4.10 and 4.11).

4.6.6 Milk and dairy products consumption

As shown in table 4.6, the majority of the study population (98.8%) of the cases Vs. 97.5% of controls consumed milk and dairy products on Sohor meal, whereas 1.2% of the cases Vs. 2.5% of controls did not consume milk and dairy products on Sohor meal during Ramadan month (P=0.560) (figure 4.10 and 4.11).



Most common foods consumed on Sohor meal of study controls

Figure 4.11: Percentage distribution of the study controls with respect to the most common foods consumed on Sohor meal

Table 4.6: Most common foods consumed on Sohor meal

Item	Diabetic		Control		Chi-Square Test	P-Value	
	N (N=80)	%	N (N=40)	%			
Sohor meal ingestion						0.383	0.826
Never	5	6.3	3	7.5			
Sometimes	19	23.7	8	20.0			
Always	56	70.0	29	72.5			
Sugary foods						15.204	0.000**
Yes	5	6.3	12	30.0			
No	75	93.7	28	70.0			
Salty foods						11.546	0.001*
Yes	21	26.2	21	52.5			
No	59	73.8	19	47.5			
Legumes						1.823	0.177
Yes	34	42.5	16	40.0			
No	46	57.5	22	60.0			
Eggs						5.161	0.084
Yes	15	18.7	10	25.0			
No	65	87.3	30	75.0			
Milk and dairy products						0.340	0.560
Yes	79	98.8	39	97.5			
No	1	1.2	1	2.5			

P < 0.05: Significant

4.7 Anthropometric and Biochemical Investigation

Anthropometric and biochemical investigations were carried out for a total of 120 volunteers 40 T2DM men, 40 T2DM women & their controls (40 normal patient). Paired student's t-test were used to analyze the differences between study variables, the variables were expressed as mean and standard deviation (mean \pm SD), and the differences between the study variables were considered statistically significant at p-value less than 0.05.

4.7.1 Effect of fasting on anthropometric measurements

4.7.1.1 Body weight and BMI

As indicated in table 4.7, there is statistically significant reduction in the means of body weight and BMI at the end of Ramadan month as compared to pre-Ramadan in both groups (p=0.038, p=0.001 and p=0.000 and p=0.000 respectively).

Table 4.7: Effect of fasting on anthropometric variables among the study subjects before fasting (Visit 1) and during Ramadan (Visit 2)

Variable	T2DM patients n=80			controls n=40		
	Visit 1 Mean \pm SD	Visit 2 Mean \pm SD	P-value	Visit 1 Mean \pm SD	Visit 2 Mean \pm SD	P-value
Body weight (Kg)	83.5 \pm 18.3	82.9 \pm 17.8	0.038*	85.9 \pm 12.8	84.6 \pm 12.5	0.000**
BMI (Kg m²-)	30.8 \pm 6.1	30.4 \pm 5.9	0.001*	31.4 \pm 5.1	30.9 \pm 4.9	0.000**

P < 0.05: Significant

4.7.2 Effect of fasting on biochemical parameters

4.7.2.1 Fasting blood glucose

As indicated in table 4.8, there was a significant decrease in serum FBG mean during Ramadan as compared to values before Ramadan in both groups ($p=0.000$ and $p=0.000$ respectively).

4.7.2.2 Total cholesterol

The findings showed a significant increases in means of serum TC among both groups at the end of Ramadan month ($p\text{-value}=0.038$ for both groups) (table 4.8).

4.7.2.3 Triglyceride

Table 4.8 illustrates that, the mean of serum TG levels was increased significantly ($p\text{-value}=0.000$) among cases, while decreased non-significantly among control group ($p\text{-value}=0.69$).

4.7.2.4 HDL-C

The table 4.8 also shows that, among diabetic group HDL-C levels showed significant reduction ($P=0.000$), while significant elevation in control group ($P=0.000$) during Ramadan as compared to values before Ramadan.

4.7.2.5 LDL-C

The findings also showed that, there was statistically significant increase in serum LDL-C mean among healthy volunteers (control group) and T2DM patients during Ramadan as compared to values before Ramadan ($p=0.000$ and $p=0.000$ respectively) (table 4.8).

4.7.2.6 HbA1c

Regarding the HbA1c, the results also showed no statistical differences in the mean of HbA1c levels in both groups at the end of Ramadan fasting month compared to pre-Ramadan mean ($p=0.133$ and $p=0.905$ respectively) (table 4.8).

2.4.2.7 Urea

The results reflected that there were no significant differences in mean of serum urea among both groups at the end of Ramadan month (p=0.560 and p=0.143 respectively) (table 4.8).

2.4.2.8 Creatinine

Similarly, the results also reflected that there were no statistical differences in the mean of serum creatinine before and at end Ramadan between these 2 groups (p=0.0.193 and p=0.147 respectively) (table 4.8).

Table 4.8: Biochemical parameters laboratory values tested among the study subjects before fasting (Visit 1) and during Ramadan (Visit 2)

Variable	T2DM patients n=80			controls n=40		
	Visit 1	Visit 2	P- value	Visit 1	Visit 2	P- value
	Mean ±SD	Mean ±SD		Mean ±SD	Mean ±SD	
Total cholesterol (mg/dL)	184.0±38.2	215.7± 39.9	0.038*	149.5±25.2	182.1±23.0	0.000**
Triglyceride (mg/dL)	165.3±66.0	190.1±62.3	0.001*	143.8±35.2	139.8±38.7	0.690
HDL-C (mg/dL)	53.0±13.3	51.4±12.9	0.000**	45.2±9.1	46.9±9.1	0.000**
LDL-C (mg/dL)	100.8±38.0	125.3±36.9	0.000**	84.2±23.6	110.4±21.8	0.000**
Fasting blood glucose (mg/dL)	192.3±66.8	156.0±60.4	0.000**	99.4±9.1	81.0±13.9	0.000**
HbA1c (%)	7.0±0.8	7.0±0.8	0.133	4.9±0.5	4.9±0.5	0.905
Urea (mg/dL)	30.2±4.5	30.4±5.0	0.560	31.8±5.5	31.5±5.5	0.143
Creatinine (mg/dL)	0.93±0.18	0.94±0.18	0.193	0.92±0.15	0.89±0.18	0.147

P < 0.05: Significant

CHAPTER FIVE

DISCUSSTION

5.1 Dietary intake and anthropometric measurements

During Ramadan fasting it has been noted that there is a decreased in physical activity and a tendency to overeat when the fast is broken. During Ramadan more foods are prepared than other days plus many families inviting guests to eat with them. This may lead to increased food intake. It is also thought that T2DM patients with the fear of hypoglycemia avoid exercising which leads to minimal or no decrease in body weight or even increase in body weight despite the fast (Frost et al., 1987). On the other hand, some studies have reported a decrease in body weight during the month of Ramadan has been attributed mainly to decline in the number of meals among both T2DM patients and controls as well as commitment of diabetes in diet during Ramadan in fear of hyperglycemia (Dennis, 1993). This controversy in body weights has been noted when a review of the literature on weight changes in diabetics was done (Azizi and Siahkollah, 1998).

The results of the present findings found that, both T2DM patients and control group showed significant reduction in body weight and BMI during Ramadan as compared to before Ramadan ($P < .001$). This reduction probably may be due to two reasons: the first reason, a decrease in the number of meals (two meals instead of three meals) that significantly contributed to reduce the amount of calories intake in both groups during Ramadan as compared to values before Ramadan. The second reason, Loss of the midday meal (lunch), especially at this time that the body is metabolically active which also led to calorie intake reduction during the Ramadan.

This loss in body weight and BMI among the study populations was in line with the majority of previous studies that found statistically significant lose in weight and BMI among T2DM patients (Még hit et al., 2005; Khaled et al., 2006 and Khaled and Belbraouet, 2009) and healthy individual (Adlouni et al., 1997 and Ziaee et al., 2006) at the end of Ramadan month.

In other previous studies weight reduction has been shown among controls but not in diabetics (Sulimani, 1988 and Sajid et al., 1991). Dattilo (1992) and Dennis (1993) reported that the reduction of the BMI among diabetic patients is clearly associated to reduction in the cholesterol plasmatic concentrations; to this subject, it appears that the consumption of a food containing a low content of animal grease generates a substantial decrease of the cholesterol plasmatic accompanied by loss of body weight (Lichtenstein, 1994).

The decrease in body weight among healthy individuals was attributed to efficient utilization of body fat during fasting (ElAti et al., 1995). Khaled and Belbraouet, (2009) also reported that the weight loss among healthy individual during Ramadan month was correlated with the decrease in the number of meals and energy intake. Whereas, the weight reduction during Ramadan month was explained by Shariatpanahi et al. (2008) to be a result of the absence of the mid-day meal.

In contrast, the present study findings were inconsistent with some of the previous studies that reported no change in the mean of body weight and BMI among T2DM patients (Ewis et al.,1997; Uysal et al.,1997 and Maislos et al., 1998) and healthy individual (Yucel et al., 2004 and Furuncuoglu et al., 2007) during Ramadan month fasting. The reduction in the insulin concentration during the fasting can be an adaptive mechanism able to explain the maintenance of a normal weight among diabetic patients (Yarahmadi et al., 2003).

Moreover, few studies reported a statistically significant increase in the energy intake during Ramadan than post-Ramadan period that associated with a significant weight gain among T2DM patients (Klocker et al., 1997; Aldouni et al., 1998 and Khatib et al., 2004) and healthy individual (Maislos et al., 1998). However, the decrease in weight is related to decrease in energy intake, while a food excess intake and reduction of exercise leads to the increase in body weight.

Ait Saada et al.,(2008) reported that, the light rise in the weight and BMI noted during the fasting among T2DM patients could be allocated to the consistency of the diet ingested during this period of abundance; but also undoubtedly to the reduced PA of the fasters whose the schedules of work during the Ramadan are often lowered from at least 1 hour by comparison in the other months of the year.

Although this study explained that calorie intake is reduction may be the cause of weight reduction among the study subjects at the end of Ramadan month, Nevertheless, PA reduction was observed among both groups, especially among the diabetes in fear of hypoglycemia. Moreover, both groups was trend toward sedentary lifestyle during Ramadan month (58.8% of the case Vs. 52.5% of controls) also the majority of the study populations (81.3% of the case Vs. 80% of controls) were used to watch TV or PC after Iftar meal. and thus minimized the beneficial effect of fasting on the body weight, which could have a greater benefit if PA persisted during Ramadan month. Most diabetics reduced their daily activities during fasting period in fear of hypoglycemia (Laajam et al., 1990 and Ewis et al.,1997).

These findings are in accordance with those obtained by the EPIDIAR study carried out in 13 Muslim countries over 11000 patients with T2DMM, whose daily physical activity was considered as light to moderate for 94% of the studied population and remained unchanged in approximately half of them (Salti et al., 2004).

Normal levels of PA may be maintained among T2DM patients during Ramadan. However, excessive PA may lead to higher risk of hypoglycemia and should be avoided, particularly during the few hours before the Iftar meal. If Tarawaih prayer (multiple prayers after the sunset meal) is performed, then it should be considered a part of the daily exercise program (Monira Al-Arouj et al., 2009).

The daily energy intake during Ramadan varies according to the food habits in different Islamic countries. Many physiological and psychological changes are observed during Ramadan. It has been established that these changes occur at the end of the first week and adaptations require at least 10 days and remain the same for at least 10 days after Ramadan (Aksungar et al., 2005).

The quality of ingested nutrients can also differ during Ramadan compared with the rest of the year, with a tendency to consume foods that are richer in carbohydrate and lipids (Lamri- Senhadji et al., 2009). Ramadan fasting could be considered as an ideal hypo-caloric diet for the obese T2DM patients. It is important to note that during Ramadan there is a major change in dietary patterns. People may fast from dawn to sunset, but they take substantial quantities of sugary fluids (juice and

carbonated drinks) together with fried foods and carbohydrate rich meals during non fasting hours. Sweet foods, moreover, are specially prepared for Ramadan. These traditionally rich foods associated with Ramadan may present a risk of hyperglycaemia and weight gain for Muslim diabetic patients (Rashed et al., 1992).

T2DM patients can avoid high BMI in addition to the diseases related to them through achieve energy balance and a healthy weight by limit energy intake from total fats and shift toward consumption of unsaturated fats instead of saturated fats; increase consumption of fruit and vegetables, legumes, whole grains and nuts. Whereas limit the intake of sugary food; and increase PA- at least 30 minutes per day during Ramadan (Debra, 2008).

The distribution of calories from fat and carbohydrate varies from one individual to another depending on the nutrition evaluation and objectives of treatment (ADA, 2000). The benefits of Ramadan fasting will only occur in both patients and healthy individuals especially in overweight diabetics, who maintain their appropriate diets and daily activities (Tang and Rolfe, 1989).

Concerning the drug intake during Ramadan, no signs or symptoms of hypoglycaemia were observed among the diabetic participating in the study. Some authors suggested that the modification of lifestyle and food intakes which occur during Ramadan, should take in to account an appropriate OHD (Zargar et al., 2005).

5.2 Lipid profile measurements:

Fasting in Muslims differs from other fasting or diet plans where persons are subjected to fixe or select meal plans and prescribed certain physical activity. In diabetes, many factors may affect blood lipid levels, this is because carbohydrates and lipid metabolism are interrelated to each other if there is any disorder in carbohydrate metabolism it also leads disorder in lipid metabolism (Ononogbu, 1988).

Insulin deficiency causes excessive mobilization of free fatty acids; this may lead to a disorder in lipid metabolism. Insulin also has an effect on lipid metabolism (Godkar & Godkar, 2003).

Many studies observed that increases and decreases in serum lipid profile associated with Diabetes mellitus (Adedeji et al., 1990 and Sccopola et al., 1995). Talat et al. (2004) found that duration of diabetes was associated with higher incidence of dyslipidemia. In that study they found elevated total cholesterol, low density lipoprotein and triglycerides but normal HDL. The Patients with diabetes have a higher degree of atherosclerosis burden and CVD due to dyslipidemia than people without diabetes (Mohsin et al., 2007).

5.2.1 Serum total cholesterol

As well known previously, the risk of coronary artery disease (CAD) rises when blood cholesterol levels increase. when other risk factors (such as high blood pressure and smoking) are present, this risk increases even more. Age, sex, heredity and diet also affect a person's cholesterol level. In both normal persons and diabetics there have been conflicting results on the effect of dietary fat on changes in serum TC levels.

The results of the present finding observed a statistically significant increase in the mean of TC levels during both periods of the study in both groups. This increase is attributed to higher consumption of dietary fat, especially the saturated fatty acids and dietary cholesterol during the month. When compared with healthy people, T2DM patients present a higher cholesterol synthesis (Simonen et al., 2002). T2DM patients are already at risk of having high blood cholesterol levels as one of the complications of diabetes, despite those patients who participated in this study were chosen without any complications of diabetes. A previous study conducted by Khaled and Belbraouet, (2009) also reported that dietary fat, particularly saturated fat, was higher in the diet during Ramadan month.

Similar findings were found by other researchers, where they found an increase in TC levels during Ramadan month among T2DM patients (Yarahmadi et al., 2003; Khaled et al., 2006 and Khaled and Belbraouet, 2009) and healthy individuals (Dwivedi et al., 1996 and Saleh et al., 2004).

Two previous studies were conducted to observe influence of high fat diet on TC among T2DM patients and healthy individuals respectively. The first study carried out by Iacano and Daugherty, (1991) proved that the ingestion of the unsaturated fatty acids can reduce plasmatic total cholesterol. The second study by Hallak and Nomani, (1988) found that significantly increased in TC levels with the high fat diet compared to the levels obtained after the high CHO diet. Some studies have reported raised concentrations of cholesterol, which may be related to weight loss during the Ramadan fast (Shoukry, 1986 and Nomani et al., 1992). Hallak and Nomani, (1988) also noticed an increased TC level with weight loss and BMI during the fasting month of Ramadan.

The result of the present finding was not in agreement with the majority of the previous studies that reported no change in TC levels during Ramadan month among T2DM patients (Maisols et al., 1993, Uysal et al., 1997; Bouguerra et al., 1997 and Uysal et al., 1998) and healthy individuals (Hallak & Nomani, 1988; Mansi, 2007 and Ibrahim et al., 2008).

In contrast to the present finding, other researchers found a significant decrease in TC levels among T2DM patients (Asgary, et al., 2000 and Fakhrazadeh et al., 2003) and healthy individuals with Ramadan fasting (Nagra and Rahman, 1998 and Furuncuoglu et al., 2007). This decrease was interpreted by most previous studies that due to the change in the dietary habits during Ramadan where total fat intake, (especially saturated fat) significantly decreased whereas, CHO and protein intake increased compared to usual diet through the other months of the year.

5.2.2 Serum triglycerides

Triglycerides are another type of fat in the blood that is associated with an increased risk of heart disease. Washio et al. (2001) indicated that elevated fasting triglycerides level is a risk factor for CAD and CVD. The results of the present findings found that a significantly elevated in the mean of serum TG levels at the end of Ramadan month among T2DM patients whereas; a non statistically significant reduction among healthy individuals was observed. The mean of blood TG levels among T2DM patients fell within that borderline range. However, the fact that the serum TG levels of T2DM patients were within the borderline range is not surprising because of most diabetic (90%) who participated in this study were overweight. Accordingly, T2DM patients with overweight in addition to physically inactive tend to have elevated TG levels. High CHO intake, high fat intake, and certain drugs such as corticosteroids considered as other factors that may contribute to an elevated blood TGs level (NCEP, 2002).

Similar findings were found by other researchers, where they found a significant increase in blood TG during Ramadan month among T2DM patients (Nagra et al., 1998 and Khaled et al., 2006) and a non-significant change or slightly increase in blood TG during Ramadan month among healthy individuals (Saleh et al., 2004 and Rahman et al., 2004).

The elevation in blood TG in this study among T2DM patients explained by the researcher as a result of an increased in the lipolytic effect considerable of fat tissues during Ramadan month. This interpretation is supported by studies done by Gumaa et al. (1978) and Nagra et al. (1998) which announced an increase of TG levels consequently to the lipolytic effect considerable of fat tissues during the Ramadan fasting.

There is another interpretation of the researcher for this rise in TG levels during Ramadan, This interpretation suggests that insulin concentrations decreased during energy restriction (fasting hours) because of the low availability of glucose during fasting hours (Dubuc et al., 1998). This decreasing in insulin concentration with fasting in T2DM patients lead to more deficiency in adipose tissue lipoprotein lipase function which result in elevating of TG level among these patients.

Insulin deficiency causes excessive mobilization of free fatty acids from adipose tissue; this may lead to a disorder in lipid metabolism (Godkar and Godkar, 2003). Other study conducted on 84 T2DM patients (42 men and 42 women) to evaluate effect of fasting on insulin level during Ramadan month. This study reported a significant decrease in insulin rates ($p < 0.05$) during the fourth week of Ramadan (Ait Saada et al., 2008).

The non statistically significant reduction in the mean of blood TG levels in the present study with fasting among healthy individuals attributed by the researcher to decreased in the number of meals which led to reduction in total calories intake during Ramadan month.

In contrast, other studies have reported a statistically significant decrease in blood TG levels during the month of Ramadan among T2DM patients (Athar & Habib, 1994 and Yarahmadi et al., 2003) and healthy individuals (Ibrahim et al., 2008). The reduction in blood TG levels was accompanied by a significant decrease in total energy intake as well as CHO, protein, and fat intake during Ramadan month (Al-Numair, 2006). Mahboob et al. (1999) and Asgary et al. (2000) found a significant decrease in serum TG levels after mid of Ramadan and interpreted this decline as a result of changes in fat, CHO and protein intake or inherent metabolic changes during Ramadan.

In previous report by Al Hourani & Atoum, (2007) reported that fat intake during Ramadan was similar to pre Ramadan in healthy young Jordanian females. Therefore, this result supports the fact that inherited metabolic changes during Ramadan may lower serum TG levels.

On the other hand, more than one study have found a significant elevation in the mean of blood TG levels during fasting among healthy individuals (Gumaa et al., 1978 and Khaled et al., 2006). In these studies, the rise was attributed to high CHO rich food in spite of tendency to eat high fat rich food among this study population during Ramadan. However, many studies tied between the increase in carbohydrate intake and high TG (Hallak & Nomani, 1988 and Khaled et al., 2006).

5.2.3 Serum HDL cholesterol

HDL cholesterol is important for transporting less-healthy cholesterol away from the heart, thereby preventing the buildup of unhealthy cholesterol in coronary arteries. Low levels of HDL-C increase risk of CHD while high levels of HDL-C reduce the potential risk for developing CVD (Mchenry and salerno, 1992).

The results of the present findings found a statistically significant decrease in the mean of HDL-C levels among T2DM patients whereas a statistically significant increase among healthy individual at the end of Ramadan month as compared to before Ramadan levels. This decrease, which happened in HDL-C levels during fasting among diabetics attributed by the researcher to two reasons. The first causative was due to decline in PA among patients during the month of Ramadan. PA reduction was observed among both groups, especially among the diabetes in fear of hypoglycemia. Moreover, both groups was trend toward sedentary lifestyle

during Ramadan month (58.8% of the case Vs. 52.5% of controls). Toth, (2005) reported that sedentary lifestyle may lead to the low HDL-C levels. and the second causative was attributed to high CHO rich food in spite of tendency to eat high fat rich food.

On the other hand, the rise in HDL-C levels observed in this study among healthy individuals attributed by the researcher to weight loss that occurred with fasting, in addition to increased in the dietary fat intake that observed during Ramadan month. Mansi, (2007) reported that the increase in HDL-C level during Ramadan month was positively associated with fat intake.

The finding of present study was in line with the most previous studies that found a statistically significant reduction in HDL-C levels during Ramadan fasting among T2DM patients (Bouguerra et al., 1997; Avignon, 2001 and Ait Saada et al. 2008) and statistically significant increase in HDL-C levels among healthy individuals with Ramadan fasting (Maislos et al. 1998; Rahman et al., 2004 and Akhund et al., 2007).

The present study findings were also inconsistent with the previous reports that showed a significant increase in HDL-C levels during Ramadan month among T2DM patients (Dehghan et al., 1994; Khatib, 1997 and Uysal et al.,1998) and statistically significant decreased in HDL-C levels among healthy individuals (Ziaee et al., 2006 and Khaled et al., 2006).

On other hand, few studies observed no change in HDL-C among T2DM patients (Sadr et al., 2001; Bouguerra et al., 2003 and Yarahmadi. et al., 2003) and healthy individuals (Saleh et al., 2005 and Furuncuoglu et al., 2007).

In two separate previous studies, Leenen et al. (1993) and Avignon, (2001) found a significantly reduction in HDL-C levels during Ramadan month among T2DM patients. They explained it to the slowing of metabolic hydrolysis of the VLDL and, to the richness of the diet in carbohydrates which can to cause an appreciable reduction of the concentrations in lipoproteins plasmatic.

The rise in the rate of HDL-c often coincides with the reduction in the rates of VLDL; this supposes that the increased hepatic hydrolysis of the VLDL supports an important synthesis of HDL among these patients (Basdevant, 1979).

On the other hand, a non-Ramadan study was done by Dattilo et al. (1992) to examine the correlation between HDL-C levels and body weight, and found that the average HDL-C levels is inversely proportional to the average body weight. Thus, it be declared that the rise in HDL-C levels that was observed in healthy individuals in this work may be due to the weight loss that occurred with fasting.

A non-Ramadan study was also done by Asztalos et al. (2000) to determine the effect of low-fat diet on low and normal HDL-C subjects. They observed that low-fat diet resulted in lower HDL-C levels of both groups. This observation was confirmed by Rahman et al. (2004) and Mansi, (2007) who reported that the increase in HDL-C level during Ramadan month was positively associated with fat intake. However, the rise in the level of HDL-C that observed among the healthy individuals in this study might be caused by high fat intake during Ramadan month Because of the current study lacked information about the composition of food for all participants.

5.2.4 Serum LDL cholesterol

Elevated serum LDL-C is the major cholesterol-carrying lipoprotein and it is highly associated with CHD. An elevated LDL-C level is a major risk factor for CHD and stroke (Law et al., 1994). The results of the present findings revealed that during the both periods of the study, there is a statistically significant rise in mean of LDL-C levels in both groups. This elevation in LDL-C levels observed in the present study was attributed to higher consumption of dietary fat, especially the saturated fatty acids and dietary cholesterol during the holy month. The same finding were reported in literature studies among T2DM (Nagra et al., 1998; Yarahmadi et al., 2003 and Khaled et al., 2006) and healthy individuals (Saleh et al., 2004 and Khaled and Belbraouet, 2009).

Nevertheless, this result was not inconsistent with the majority of the studies reported in literature that showed no significance difference in LDL-C levels with fasting among T2DM patients (Klocker et al.,1997; Khatib, 1997 and Uysal et al., 1997) and healthy individuals (Maislos et al., 1993; Rahman et al., 2004 and Aksungar, et al., 2005).

Many studies have also reported a significant decrease in the LDL-C levels during Ramadan fasting month among T2DM patients (Adlouni et al., 1997 and Fakhrazadeh et al., 2003) and healthy individuals (Nagra & Rahman, 1998; Adlouni et al., 1997 and Akhund et al., 2007). The reduction in LDL-C levels observed in these previous studies was attributed to the change in the dietary habits during Ramadan month, in which CHO and protein intake increased and total fat intake (particularly saturated fat) decreased significantly compared to usual diet through the other months of the year.

A cross-sectional survey was conducted by Fornes et al. (2006) to identify the association between food group consumption frequency and serum lipoprotein levels among adults. This survey has indicated that consumption of fatty meat, chicken, eggs and dairy foods were each positively and significantly correlated with LDL-C, whereas, the intake of vegetable and fruits showed an inverse correlation.

It seems that the month of Ramadan induces an increase in the plasmatic rate of LDL-C particularly among diabetic patients and healthy individuals. Streicher et al. (1996) showed that the insulin which decreases during the fasting increases the expression of genes of the hepatic receptors of LDL-C. In addition, Matisson & Gundy (1985) explained the diminutions of the levels of LDL-C during the fasting at the nature of the greases ingested by the patients whose composition noted during this period is richer in unsaturated mono fatty acids and in poly unsaturated fatty acids. Thus, the high take of saturated fatty acids is at the probable origin of the rise in the rates of LDL-c noticed among the study subject. Iacano and Daugherty, (1991) also confirmed that the ingestion of a diet rich in fatty acids poly unsaturated induced a notable reduction of the plasmatic levels of LDL-C.

5.3 Other biochemical parameters

5.3.1 Fasting blood glucose

Fasting blood glucose is a test to determine how much glucose (sugar) is in a blood sample after an overnight fast (at least eight hours). It is often the first test done to check for pre-diabetes and diabetes. Recent data from the United Kingdom Prospective Diabetes Study (UKPDS), has demonstrated that maintaining normal plasma glucose levels substantially reduces the risk of developing diabetic complications (UKPDS, 1998).

From the period before the fasting to Ramadan period, the study results showed a significant reduction in FBG levels among T2DM patients and healthy individuals. This decrease that has been observed attributed to the decrease in the number of meals (Two meals instead of three meals) during Ramadan. This condition in turn led to low calorie intake within the body and the consequent depletion in glycogen stores. In addition, during Ramadan month, healthy individuals tend to eat low simple sugar foods which may contribute to low blood glucose level.

More than one study supported this interpretation. One of this study carried out by Nomani et al. (1989) and suggested that the FBG and HbA1c values depend on diet composition, energy metabolism, and energy intake regulation. Other studies by Al-Numair, (2006) found that the decreased in FBG levels correlate positively with the decreased in total energy intake during Ramadan month. Jamil-ur-Rehman et al. (2000) also found a rise in FBG levels after Ramadan compared to levels during the month and attributed to the change in the dietary habits after Ramadan month and the increase in calorie consumption. This finding of the present study coincided with the literature studies that reported a statistically significant reduction in FBG at the end of Ramadan month compared to pre-Ramadan among T2DM patients (Larijani et al., 2003; Méghit et al., 2005 and Khaled et al., 2006) and healthy individuals (Ibrahim et al., 2008 and Shariatpanahi et al., 2008).

However, this result was not in agreement with other few studies that showed no statistically significance differences in FBG levels at the end of Ramadan when compared with pre-Ramadan levels among T2DM patients (Mahboob et al., 1999 and Saleh et al., 2005) and healthy individuals (Saleh Mansi, 2007 and Hordern et al., 2008). The present study findings were also inconsistent with the studies that showed a statistically significant elevation in FBG levels during Ramadan month among T2DM patients (Shepherd & Kahn, 1999 and Avignon, 2001) and healthy individuals (Larijani et al., 2003). Clore et al. (1992) noted an increase in levels of glucose during the fasting. This increase result from an activation of the gluconeogenesis. In addition, the significant rise in the circulating free fatty acids can contribute to the increase in the plasmatic concentration of glucose newly formed particularly at the diabetic ones showing an insulin resistance (Shepherd & Kahn, 1999).

These controversial data regarding the impact of fasting on FBG can be due to a quantitative and qualitative food diversity consumed by the patients during the period of fasting; but also to the difference in the eating habit of the studied populations. Other factors such as the regular taking of medicines (Azizi & Siahkollah, 2003), the daily length of fasting, the individual variations in the quantity of blood glucose and the lack of physical exercise were also found to influence the outcome (Larijani et al., 2003).

During Ramadan month, The finding reported a significant decrease in the amount of carbohydrates (especially simple sugar) among T2DM patients compared to control ($p=0.003$) who tried following their physician's advice to abstain from eating sweet, in order to reduce calorie intake. This contributed greatly in improving their glucose control during fasting and consequently, to attenuate their hunger by consumption more fatty foods ($P = 0.003$). On other hand, the percentage of cases (6.3%) who consumed sugary foods on sohor meal during Ramadan was lower than controls (30.0%) ($P = 0.000$).

The fact that obesity increases the risk of cardiovascular complications and insulin resistance, and consequently complicates management among T2DM patients. However, This finding illustrates that, The majority of the study cases 90.0% Vs. 80.0% of the controls were obese at the last week of shaban month just before advent Ramadan month. There are three important goals for overweight and obese people (particularly for T2DM patients) are: a moderate weight loss of about 5%, a lifestyle modification with reduction of energy intake, and an increase in PA (Abraira et al., 2003). These factors improve glycaemia and blood pressure control, improve insulin action, decrease FBG concentrations, reduce the need for diabetes medications, as well as improve serum lipid concentrations (Lipscombe & Hux, 2007).

5.3.2 Glycated hemoglobin

The HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. The rate of HbA1c is directly proportional to the concentration of glucose in blood. It is independent of the variations daily of the glycemia and is not affected by the physical exercise, the fasting or the recent ingestion of sugar. Its dosage among patients does not require 12 hours of fasting. Recent data from the (UK Prospective Diabetes Study Group (UKPDS), 1998) has demonstrated that maintaining normal plasma glucose levels substantially reduces the risk of developing diabetic complications. It is well established that a well balanced diet is essential to achieve optimal diabetes control.

The UKPDS, (1998) also noted clearly the clinical benefit which can bring back significantly each plasmatic reduction of 1% of HbA1c in terms of reduction of the risk of micro and macro vascular complications among T2DM patients. It has been proven that for every 1% decrease in HbA1c, there is a 35% decrease in the risk of micro vascular complication (Abraira et al., 2003).

However, the present study showed that there were no statistical differences in the mean (\pm SD) of HbA1c levels at the end of Ramadan month among T2DM patients and healthy individuals when compared with pre-Ramadan values. The finding was consistent with the most studies reported in literature that found no significant change in blood HbA1c levels during Ramadan month among T2DM patients (Athar et al., 1994; Azizi et al., 2003 and Sari et al., 2004).

On the other hand, other research studies have reported a statistically significant decrease in blood HbA1c levels during the month of Ramadan among T2DM patients (Mufauzy et al., 1990; Sulimani et al., 1991; Gustaviani et al., 2004). The reduction in the rate of HbA1c is a proof justifying the beneficial effect of the medicinal treatment taken during the fasting of Ramadan (Sulimani et al., 1991). Abraira et al. (2003) reported that improvement of glucose homeostasis during Ramadan was marked by a significant decrease in FBG and HbA1c. The decrease in HbA1c level was correlated with the decrease in total energy intake (Mufauzy et al., 1990) whereas; Gustaviani et al. (2004) attributed this improvement in HbA1c to the decrease in the number of meals and not to a change in the total amount of calories

ingested. In contrast, few studies have reported slight increases in glycosylated hemoglobin levels (Belkhadir et al., 1993 and Uysal et al., 1997). However, one report has emphasized the same increase in non fasting patients as in fasting ones (Belkhadir et al., 1993) while another has shown a return to initial levels immediately after the month of Ramadan (Uysal et al., 1997).

5.3.3 Serum creatinine

In general, serum creatinine levels can reflect kidney function of patients with kidney diseases. Higher serum creatinine level often suggests severe kidney damage; on the other hand, severe kidney damage can lead to increasing serum creatinine level.

The results of the present findings found that serum creatinine levels did not show any significant change in either group as compared to before Ramadan. Most of the previous showed that, Ramadan fasting was associated with no statistically significant change in serum creatinine levels among T2DM patients (Maisols et al 1993; Al-Hader et al.,1994; Klocker et al., 1997 and Ewis et al.,1997) and healthy individuals (El-Ati et al., 1995 and Al-Hourani et al., 2009). These studies agree with our study.

In contrast, the result of the present study was not in agreement with others that a statistically significant increase in serum creatinine levels among T2DM patients (Ait Saada et al., 2008) and healthy individuals (Schmahl et al., 1991). This elevated in creatinine levels that was observed in these two studies attributed to the severe dehydration that was observed among the studies participants during the month of Ramadan.

As it is known that the levels of serum creatinine is proportional to the lean muscle mass whereas is not dependent on type of food or dietary habits. Thus, the finding that serum creatinine levels did not show any significant change in either group in this study is acceptable particularly as diabetics who were chosen in this study did not complain of diabetic complications.

5.3.4 Serum urea

Urea levels are used to evaluate how well the kidney is working and to monitor patients with kidneys that are diseased or those receiving kidney dialysis.

Regarding serum urea, the present finding observed no statistical differences in the mean of urea levels at the end of Ramadan month among T2DM patients and healthy individuals compared to pre-Ramadan values.

Few studies were carried out to investigate the effect of Ramadan fasting on blood urea, most of these in accord with the present finding showing no change in serum urea levels during Ramadan month among T2DM patients (Mafauzy et al. 1990; Maisols et al 1993 and Klocker et al., 1997) and healthy individuals (El-Hazmi et al. 1987; Chamsi-Pasha et al., 2004 and Al-Hourani et al., 2009).

In contrast to the study findings, Sulimani et al. (1998) noticed a significant rise of the urea rate which results according to the same author from a bad glomerular filtration among T2DM patients. Other authors explained the increase in the values among diabetic patients with the dehydration caused by the food restriction liquids during fasting period (Raza et al., 1994). Indeed, according to Bonneau et al. (2001) the dehydration prolonged during fasting can induce a fall of the diuresis and in consequence can cause an increase in uraemia.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusion

Based on these findings, it was concluded that fasting during the month of Ramadan is relatively safe and devoid of any serious complications among stable T2DM patients provided they should be properly educated about drug regimen adjustment, diet control, daily activities and possible complications that might be happen. However, according to the present finding, one can conclude the following:

- 1- Ramadan fasting induces weight and BMI loss, which was correlated with a decrease in the number of meals and calorie intake.
- 2- The total daily energy intake decreases during Ramadan, whereas the dietary fat consumption increases because of the excessive use of vegetable oil and the high consumption of fried food
- 3- The increase in serum TC levels among T2DM patients and healthy individuals seemed to be a result of the dietary mismanagement during Ramadan month.
- 4- The increase in serum LDL-C levels during Ramadan month among T2DM and healthy individual seemed to be a result of fat consumption (especially saturated fat) during Ramadan.
- 5- The increase in HDL-C levels during Ramadan month among healthy individuals presents a definite advantage of Ramadan fasting, but the reduction of HDL-C levels among T2DM patient is disadvantage.
- 6- Serum TG levels of T2DM patients increased significantly, that might be due to high CHO intake, high fat intake and physically inactivity during Ramadan.

7- Ramadan Fasting is beneficial in improvement serum glucose levels in T2DM patients and healthy individual. This reduction in blood glucose level was found to correlate positively with the reduction in total energy intake during Ramadan month.

6.2 Recommendations

- T2DM patients are advised to exploit the fast during Ramadan as an opportunity to change unhealthy dietary habits as well as to lose excess weight.
- Benefits of Ramadan fasting appear only in patients who maintain their appropriate diets and committed to adjust the OHD. Thus, diabetics must be reminded to abstain from high-calorie and highly-refined foods prepared during this month.
- T2DM patients are advised to eat a well balanced diet that is higher in complex CHO and dietary fibers which has hypocholesterolemic effect whereas, low in cholesterol and saturated fat.
- Health education regarding healthy diet and eating habits, and PA during Ramadan should be encouraged and reinforced to reduce serum cholesterol, increasing HDL-C levels and management of body weight, which in turn reduce the risk of diabetes complications.
- Normal levels of PA may be maintained among T2DM patients. However, excessive PA may lead to higher risk of hypoglycemia and should be avoided. If Taraweh prayer is performed, then it should be considered a part of the daily exercise program.
- Islamic rules allow patients to not fast. However, if T2DM patients wish to fast, it is necessary to advise them to undertake glycaemia control several times a day, to prevent hypoglycemia risks during daytime fasting or hyperglycaemia during the night.
- T2DM patients also advised to not to miss a meal at Sohor, not to overeat at Iftar, not to attempt self-reduction or omission of treatment and regularly monitor blood glucose during the fast.

- T2DM patients should break the fast if hypoglycemia (blood glucose of <60 mg/dl [3.3 mmol/l]) occurs and if blood glucose exceeds 300 mg/dl (16.7 mmol/l).
- A large – scale coordinated studies with standardization of research methods regarding the season, gender, food habits, and ethnic background of the subjects and other important physiologic and pathologic conditions are recommended, to explore the issue more comprehensively.
- Further studies are needed to assess the hormonal status during Ramadan month among T2DM patients.

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Annex (1): An official approval letter from Helsinki committee

Palestinian National Authority
Ministry of Health
Helsinki Committee



السلطة الوطنية الفلسطينية
وزارة الصحة
لجنة هلسنكي

التاريخ 5/3/2012

Name:

الاسم: أكرم الطاهر

نفيدكم علماً بأن اللجنة قد ناقشت مقترح دراستكم

حول:-

I would like to inform you that the committee has discussed your application about:

“Effect of Ramadan Fasting on Anthropometric Measures and some Biochemical Parameters among Type 2 Diabetic Patient in Gaza Governorate, Gaza Strip.”

In its meeting on **March** 2012

و ذلك في جلستها المنعقدة لشهر 3 2012

and decided the Following:-

و قد قررت ما يلي:-

To approve the above mention research study.

الموافقة على البحث المذكور عاليه.

Signature

توقيع

Member

Member

Chairperson

عضو



عضو

Conditions:-

- ❖ Valid for 2 years from the date of approval to start.
- ❖ It is necessary to notify the committee in any change in the admitted study protocol.
- ❖ The committee appreciate receiving one copy of your final research when it is completed.

Annex (2): An official approval letter to Palestinian Medical Relief Society



الجامعة الإسلامية - غزة كلية العلوم

The Islamic University of Gaza

منسق برنامج ماجستير العلوم الحياتية

التاريخ / 2011/7/9م

الأخ/ د. عائد ياغي مدير عام الإغاثة الطبية حفظه الله ،،

السلام عليكم ورحمة الله وبركاته ،،

الموضوع / تسهيل مهمة باحث

تشهد إدارة ماجستير العلوم الحياتية بالجامعة الإسلامية أن الطالب: **أكرم محمد رفعت الطاهر** طالب

في ماجستير العلوم الحياتية تخصص - **تحاليل طبية** يقوم بإجراء البحث النهائي في برنامج

الماجستير والذي بعنوان:

The effect of Ramadan fasting on type 2 diabetic patients

الباحث بحاجة للحصول علي المعلومات والعينات من مختبرات الاغاثة الطبية.

لذا نرجو من سيادتكم مساعدة الباحث في الحصول علي المعلومات والعينات.

ولكم منا جزيل الشكر والتقدير ،،

منسق برنامج ماجستير العلوم الحياتية

د. طارق البشيتي

Annex (3): Consent Form

نموذج موافقة للمشاركة في البحث

تأثير صيام شهر رمضان على القياسات البشرية و بعض التحاليل المخبرية عند الرجال البالغين الذين يعانون من مرض السكر النوع الثاني

عزيزي المشارك :

أنا أكرم رفعت الطاهر، باحث في ماجستير العلوم الحياتية قسم التحاليل الطبية في الجامعة الإسلامية بغزة، أدعوك للمشاركة في البحث المذكور أعلاه، حيث أن هذا البحث هو جزء من متطلبات التخرج من برنامج ماجستير العلوم الحياتية التابع لكلية الدراسات العليا بالجامعة الإسلامية بغزة، ويهدف هذا البحث إلي التعرف علي مدي تأثير الصيام في شهر رمضان المبارك علي القياسات الجسمية و بعض التحاليل البيوكيميائية لدى مرضى السكر النوع الثاني في محافظة غزة.

ويتطلب إجراء البحث الإجابة على بعض الأسئلة القصيرة الموضحة في الاستبيان التالي والتي تتضمن النمط الغذائي والحياتي لك خلال شهر رمضان، كما و يتطلب أخذ عينات دم وبعض القياسات كالتطول والوزن ، قبل شهر رمضان بأسبوع وفي الأسبوع الأخير من شهر رمضان وذلك لمعرفة آثار الصيام علي صحة الأفراد، وسوف يستغرق ملء هذا الاستبيان نحو عشرة دقائق.

وتعتبر مشاركتك في هذا البحث طوعية، كما انه لديك الحق في رفض الإجابة عن أي من الأسئلة التي سوف تطرح عليك. كما أن المعلومات التي سوف تعطيها ستبقي سرية وطي الكتمان ولن يطلع عليها أحدا باستثناء فريق البحث.

ولكم جزيل الشكر علي تعاونكم

الباحث / أكرم الطاهر

Annex (4): Clinical chemistry report

The Islamic University-Gaza
Deanery of Higher Education
Faculty of Science
Department of Biological Sciences
Medical Technology



الجامعة الإسلامية - غزة
عمادة الدراسات العليا
كلية العلوم
ماجستير العلوم الحياتية
تخصص التحاليل الطبية

الاسم	الجنس		العمر	عام
الطبيب المعالج	د. /	تاريخ سحب العينة			

Clinical Chemistry Report

Test	Result	Normal Range
<i>Glucose (Fasting 6-8 hr)</i>		Adult : 70 -126 mg/d L, Child : 60 -100 mg/dL
<i>Urea</i>		Infant and child : 10 -38 mg /dL Adult 18 -60 yrs : 13 -43 mg/dL
<i>Creatinine</i>		Child : 0.3 - 0.7 mg /dL Male : 0.9 - 1.3 mg /dL Female : 0.6 - 1.1 mg /dL
<i>Cholesterol (Total)</i>		Desirable < 220 mg/dL
<i>HDL</i>		Male : 35 - 65 mg/dL female: 35 -80 mg/dL
<i>LDL</i>		Desirable < 130 mg/dL
<i>Triglycerides (Fasting 14 hr)</i>		Desirable < 200 mg/dL
<i>HbA1c</i>		Borderline 6.5 -8.0 % Excellent control : < 7.0 %

A thesis submitted tests is a part of the requirements for the degree of master
of biological sciences/ Medical Technology

Researcher: Akram M. Al-Taher

Signature.....

Internal supervisor: Prof.Dr.Baker M. Zabut

External supervisor: Dr Samy El-Esawy

Annex (5): Interview Questionnaire

Parts one and two: personal and physical activity related data

1. Name
2. Code number.....
3. Telephone number
4. Age in years.....
5. Address.....
6. Subject: a. Case b. Control
7. Sex a. Male b. Female
8. Marital status a. Single b. Married
 c. Widowed d. Divorced
9. Do you smoke cigarettes now? a. Yes b. No
10. Years of educationyears
11. Level of education status a. Illiterate b. Primary
 c. Preparatory d. Secondary e. Undergraduate or more
12. What is the average household income per month (shekel)?
 a. Less than 1000 b. 1000-2000 c. More than 2000
13. Do you follow any particular diet? a. Yes b. No
14. If yes, specify the following: a. Low fat b. Few salts c. Special food for DM d.
 Special food for weight loss e. Vegetarian only
15. Type of physical activity before Ramadan fasting.
 a. Sedentary PA (e.g. Reading, Typing, etc.)
 b. Light PA (e.g. Cooking food, Teaching, etc.)
 c. Moderate PA (e.g. Shopping, Nursing, etc.)
 d. Vigorous PA (e.g. Football, running, etc.)
- 16- Which of the following activities have been practiced during Ramadan ?
 a. Walking b. Cycling c. Football
 d. Other activities, Mention them..... e. Does not practice any sport
- 17- If you exercise a previous activities What is the average daily activity for you?
 a. light (half hour) b. Moderate (less than an hour) c. severe (more than an hour)
- 18- Do you continue to exercise during Ramadan? a. Yes b. No
- 19- If the answer is yes in the question (18) what is the rate of this activity?
 a. light (half hour) b. Moderate (less than an hour) c. severe (more than an hour)

20- How would you describe your usual walking pace during Ramadan month?

- a. Slow pace b. Steady average pace c. Brisk pace d. Fast pace

21- How many hours does it take in watch TV or your computer after breakfast during Ramadan?

- a. less than an hour b. than an hour to two hours
c. more than two hours d. more than two hours

22- Do you strive to pray Taraweh during Ramadan?

- a. Yes b. No c. Sometimes

23. Do you take tea after breakfast?

- a. Constantly b. Sometimes

24. If yes, how much glass of tea you drink every day?

- a. one cup b. 2 - 3 cups c. > 3 Cups d. I do not take tea

25. Do you take Coffee after breakfast?

- a. Constantly b. Sometimes

26. If yes, how much glass of Coffee you drink every day?

- a. one cup b. 2 - 3 cups c. > 3 Cups d. I do not take coffee

27. Do you take Juice & Water after breakfast?

- a. Constantly b. Sometimes

28. If yes, how much glass of Juice & Water you drink every day?

- a. < 6 Cups b. 6 – 8 Cups c. > 8 Cups

29. Do you feel thirsty during the fast?

- a. Yes b. No c. Sometimes

30. What are the foods that frequently addressed at breakfast?

- a- Protein b-Fat c- Carbohydrates d - All of the above

31. What is the number of Breakfast (Iftar) stages?

- a. One Stage b. Two Stage

32. Do you eat snacks after Iftar meal?

- a. Always b. Never c. Sometimes

33. Do you eat Sweets after Iftar meal?

- a. Always b. Never c. Sometimes

34. Do you drink Soft drink after Iftar meal?

- a. Always b. Never c. Sometimes

35. Sohor meal ingestion

- a. Always b. Never c. Sometimes

36. Favorite foods during Sohor meal

- a- Sugary foods b-Salty foods c-Legumes d-Egg
 e- Milk and dairy products f-other

Part three: Food Frequency Questionnaire (FFQ) of participants

	How often do you eat the following foods	Once daily or more	3-5 times weekly	Once weekly	Once per two weeks	None
1-	Eggs					
2-	Red meats					
3-	Chickens					
4-	Liver					
5-	Fish					
7-	Legumes					
7-	Vegetables					
8-	Fruits					
9-	Salty foods					
10-	Vegetables oil					