

**Deanship of Graduated Studies  
Al-Quds University**



**Diabetes Type-1;  
Protocols and Complications in Primary  
Health Care Centers in Ramallah District:  
Evaluation and Assessment**

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**Diabetes Type-1;**  
**Protocols and Complications in Primary Health Care Centers in**  
**Ramallah District: Evaluation and Assessment**

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## **Dedication**

**To my dear parents Issa and Nadia**

**To my dear wife Suha and my children Ro'a, Abrar and Maryam**

**Ziad Issa Muhmood Alkhdoor**

## **Declaration**

I certify that this thesis submitted for the degree of Master is the result of my own research, except where otherwise acknowledged, and that this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

Singed:

Ziad Issa Muhmood Alkhdoor

Date: 16/6/2007

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## Abstract

**Background/ Aim:** The purpose of this study is to describe the prevalence of macro and microvascular (heart disease, retinopathy, nephropathy and neuropathy) and acute diabetic complications, and to assess the nature of their treatment protocol by PHC, and the metabolic control status, in patients with type 1 diabetes mellitus at Ramallah district.

**Material/Methods:** We performed a cross-sectional population study evaluating all Type 1 diabetic patients (n=142) consecutively attending clinics for review of both MOH and UNRWA PHC in Ramallah district at the year 2006. Only 116 registered patients participated in the survey. However, 9 of the 116 patients did not have the objective testing, in particular the HbA1c, therefore, not included in the analysis. Therefore, 107 patients (92.2%) were included in the analysis. Of the approached patients, 80 patients (69%) have done the objective testing, i.e. HbA1c, fasting blood sugar (FBS), lipid profiling, and kidney functions testing, and blood pressure testing. Patients were referred to see an ophthalmologist, but only 63.8% did go (n=74 patients). Also, all these patients (n=107) were referred to consult with a diabetes specialist, but only 58.6 % (n=68) attended the consultations.

**Results:** The results of this study showed that the mean age at onset of disease was 15.5 (SD±7.4) years, the mean age of the patients was 23.5 (SD±10.4) years, and the mean duration of disease was 8.4 (SD±7.2). From our results we observed that 47.7% of patients were males, 66.4% were singles, and 53.3% were living in villages. 82.2% had less than 12 years of education, and 41.1% were students.

The mean HbA1c was 7.8 (SE±0.16), and 35.3% of the patients had a measurement >8.5%. The results of objective testing means were as follow: total cholesterol 191 (SE±5.1), triglyceride 146 (SE±11), FBS 203 (SE±9), LDL 123 (SE±4.7), urea was 28.2 (SE±1.4), creatinine was 0.9± (SE ±0.05), and HDL was 42 (SE±0.8).

Although complications associated with diabetes mellitus were under reported, 48.6% of the sample suffers from one or more of the common complications. Reported frequencies of chronic diabetic complications associated symptoms by patient themselves were as follows: diabetic retinopathy 36.4%, neuropathy 26.2%, nephropathy 7.5%, heart disease 3.7%, amputation 0.9% and diabetic foot syndrome 10.3% of the study patients.

The prevalence of diagnosed retinopathy was 33.8%, nephropathy was found in 7.4%, neuropathy was present in 16.2%.

Significant associations were found between diagnosed microvascular complications (retinopathy and clinical neuropathy) and HbA1c ( $p < 0.05$ ), disease duration ( $p < 0.05$ ), and sex ( $p < 0.05$ ) were observed.

The majority of patients were treated with insulin mixture with two daily insulin injections. Reported screening rates at primary health care in this study by the patients themselves were as follows: 24.3% had at least one HbA1c measurement per a year and 91.6% fasting blood glucose, 16.8% had a foot exam, 5.6% had electrocardiography test, 53.9% had a protein urine test, 43% had plasma urea test and 37.4% had creatinine test, 11.2% had an eye exam, 84.1% had a blood pressure reading and 51.1% received a fasting lipid profile. 85% had weight measured. Body mass index was greater than 25 kg/m<sup>2</sup> in 36.4% of patients.

The association of risk factors with diabetic complication (reported and evaluated) was also investigated. The basis of the risk estimation was control of blood glucose, lipid, pressure, and socio demographic data. Diabetes duration and age were the only common significant risk factors for development of both evaluated and reported retinopathy. For neuropathy, disease duration was the only common significant risk factors for the development of both evaluated and reported complications. However, when trying to develop the study multivariate models for the major complications (i.e. retinopathy, neuropathy and nephropathy) or glycemic control measurement, none of the above determinants were significantly associated with these outcome variables.

**Conclusions:** This is the first study in which the prevalence of diabetic type 1 complications is reported in a Palestinian community for patients registered in MOH and UNRWA. This cross-sectional study confirms that complications were common and mostly undiagnosed in a non-negligible percentage of patients. Treatment and control of diabetes by primary health care in this community is not optimal, and not achieving the level of complications intervention. Better continuing care and better education is needed for diabetic patients in these primary health care centers and for the health care professional to get a better care for these patients.

## ملخص الدراسة

**خلفية الدراسة:** هدفت هذه الدراسة إلى معرفة ووصف الوضع الصحي لدى مرضى السكري من النوع الأول من خلال معرفة نسبة المضاعفات المزمنة والتي تتمثل في مشاكل الأوعية القلبية، اعتلال الشبكية، اعتلال الكلى، و اعتلال الأعصاب وكذلك المضاعفات الحادة الناتجة عن المرض، بالإضافة إلى معرفة الخدمات التي يتلقاها المريض من خلال مراكز الرعاية الصحية الأولية التابعة لوزارة الصحة ووكالة الغوث الدولية في محافظة رام الله.

**منهجية الدراسة:** أجريت دراسة وصفية مقطعية في العام 2006 في مراكز الرعاية الصحية الأولية التابعة للأثروا ووزارة الصحة في محافظة رام الله شملت جميع مرضى النوع الأول من السكري والبالغ عددهم 142 . حيث شارك في الدراسة 116 مريض تم اعتماد 107 مريض أي ما نسبته 92.2% في التحليل الإحصائي ، بينما تم رفض 9 مرضى لعدم استيفائهم لشروط الدراسة من حيث عدم وجود نتيجة للسكر التراكمي لديهم ، كذلك تم عمل فحوصات دم مخبرية مثل فحص السكر التراكمي، سكر الصيام، فحص الشحميات ل 80 مريض (69%) ، كذلك تم عمل فحص عيون من قبل أخصائي ل 74 مريض (63.8%) في حين قام 68 مريض (58.6%) بالمعاينة من قبل أخصائي السكري.

**النتائج الرئيسية:** أظهرت نتائج هذه الدراسة أن متوسط أعمار المرضى وقت التشخيص 15.5 عاماً (انحراف معياري = 7.4) ، و كان متوسط عمر المرضى 23.5 عاماً (انحراف معياري = 10.4)، ومتوسط المدة الزمنية للمرض هي 8.4 عاماً (انحراف معياري = 7.2).

ومن نتائجنا عن الصورة العامة للمرضى تبين أن نسبة 47.7% من المرضى ذكور ، في حين كان 66.4% من المرضى غير متزوجين، وأفاد 53.3% بأنهم يسكنون في الأرياف، في حين كانت نسبة ممن لديهم تعليم أقل من 12 سنة هي 82.2% ، فيما كانت نسبة 41.1% من المرضى من الطلاب.

كما بينت النتائج أن معدل نسبة السكر التراكمي للمرضى هو  $0.16 \pm 7.8\%$  ، منهم 35.3% لديهم نسبة السكر التراكمي أعلى من 8.5%.

كما أظهرت نتائج فحوصات الدم المخبرية التي أجريت للمرضى أن معدل سكر الصيام (الريق) هو  $9 \pm 203$  ، ومعدل الدهون هو  $11.1 \pm 146$  ، ومعدل الكوليسترول هو  $5.1 \pm 191$  ، ويوريا الدم  $1.4 \pm 28.2$  ، ومعدل فحص الكرياتينين هو  $0.05 \pm 0.9$  ، ومعدل الدهون منخفض الكثافة (LDL) 123  $\pm 4.7$  ، ومعدل فحص الدهون عالي الكثافة (HDL) هو  $0.8 \pm 42$ .



وأبرزت هذه الدراسة نسبة 48.6% من عينة الدراسة يعانون على الأقل من واحد أو أكثر من مضاعفات هذا المرض وهذه النسبة أقل من الواقع، حيث كانت نسبة وجود المضاعفات بين المرض بناء على إجاباتهم هي كالتالي: مشاكل العيون المرطبة بالسكري (36.4%) ، اعتلال الأعصاب المرطب بالسكري (26.2%) ،مشاكل الكلى المرطبة بالسكري (7.5%)،بتر القدم المرطب بالسكري (0.9%) ،القدم السكري(10.4%).

بينما كانت نسبة المضاعفات المرضية(المشخصة) من خلال إجراء الفحوصات وتقييمها من قبل أخصائي السكري خلال الدراسة كالتالي: مشاكل العيون (33.8%) ، اعتلال الأعصاب (16.2%) ،مشاكل الكلى (7.4%) .

كما أظهرت النتائج وجود علاقة ايجابية وذات دلالة إحصائية بين مشاكل العيون و اعتلال الأعصاب التي تم تشخيصيهما من قبل الطبيب وكل من المدة المعروفة للمرض، الجنس، ونسبة السكر التراكمي حيث كانت قيمة الدالة الإحصائية أقل من 5% .

أفاد معظم المرضى أنهم يعالجون بالأنسولين المخلوط عن طريق الحقن بمعدل مرتين في اليوم. كما تم تقييم البروتوكول العلاجي المقدم من قبل خدمات الرعاية الصحية الأولية وذلك من خلال معدل الفحوصات ونوعها التي تقدم للمرضى حيث وجد أن معدل إجراء فحص السكر التراكمي للمرضى هو 24.3% ، ونسبة فحص سكر الصيام (الريق) هو 91.6%، ونسبة فحص القدمين هو 16.8% ، ونسبة إجراء فحص تخطيط القلب 5.6%، و نسبة معدل فحص البروتين في البول هو 53.6%، ونسبة معدل فحص يوريا الدم هو 43% ، ونسبة معدل فحص الكرياتينين هو 37.3% ، وفحص العيون هو 11.2% ، وقياس الضغط هو 84.1% ، وقياس مستويات الشحميات هو 51.1%، وقياس الوزن هو 85% ، كما أوجدت الدراسة أن مَنَسَبَ كتلة الجسم أكثر من 25 كغ/م<sup>2</sup> في 36.4% .

كما تم دراسة عوامل الخطر مع المضاعفات المرضية المسجلة من قبل المرضى أو المشخصة من قبل الطبيب، حيث أظهرت النتائج أن العمر الزمني للمريض والمدة المعروفة للمرض هما عاملي الخطر لكل من مشاكل اعتلال العين المكتوبة و المشخصة حيث كانت هناك علاقة ايجابية وذات دلالة إحصائية، بينما كان العمر الزمني للمريض هو عامل خطر لاعتلال الأعصاب المكتوبة و المشخصة حيث كانت هناك علاقة ايجابية وذات دلالة إحصائية.

**الاستنتاج:** من أهم ميزات هذه الدراسة أنها الأولى من نوعها التي درست الوضع الصحي لمرضى السكري من النوع الأول في المجتمع الفلسطيني، حيث كشفت هذه الدراسة وجود نسبة المضاعفات الناتجة عن المرض والتي لم يتم تشخيصها بعد في بعض الحالات. كما دلت الدراسة على أن التدبير العلاجي من قبل مراكز الرعاية الصحية الأولية للنمط الأول من السكري للمرضى ليس بالمستوى الأمثل، وأنه بحاجة إلى تحسين كي يمكن اتقاء المضاعفات المزمنة والحادة. لذا يجب أن يكون هناك عناية طبية مستمرة للمرضى وكذلك برامج تثقيف صحي لكل من المرضى والعاملين الصحيين من أجل العناية الجيدة لهؤلاء المرضى.

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## List of Abbreviations

ADA	-----	The American Diabetes Association
AER	-----	Albumin excretion rate
BMI	-----	Body Mass Index
CVD	-----	Cardiovascular disease
DCCT	-----	Diabetes Control and Complication Trial
DKA	-----	Diabetic ketoacidosis
DPN	-----	Diabetes Peripheral Neuropathy
ESRD	-----	End stage renal disease
FBS	-----	Fasting Blood Sugar
HDL	-----	High Density Lipoprotein
IGT	-----	Impaired Glucose Tolerance
LDL	-----	Low Density lipoprotein
MOH	-----	Ministry of Health
USA	-----	United States of America

## **Chapter one. Background and Significance**

**1.1** Background

**1.2** Study problem

**1.3** Study justification

**1.4** Study aim and objectives

**1.5** Study questions

**1.6** Study limitations

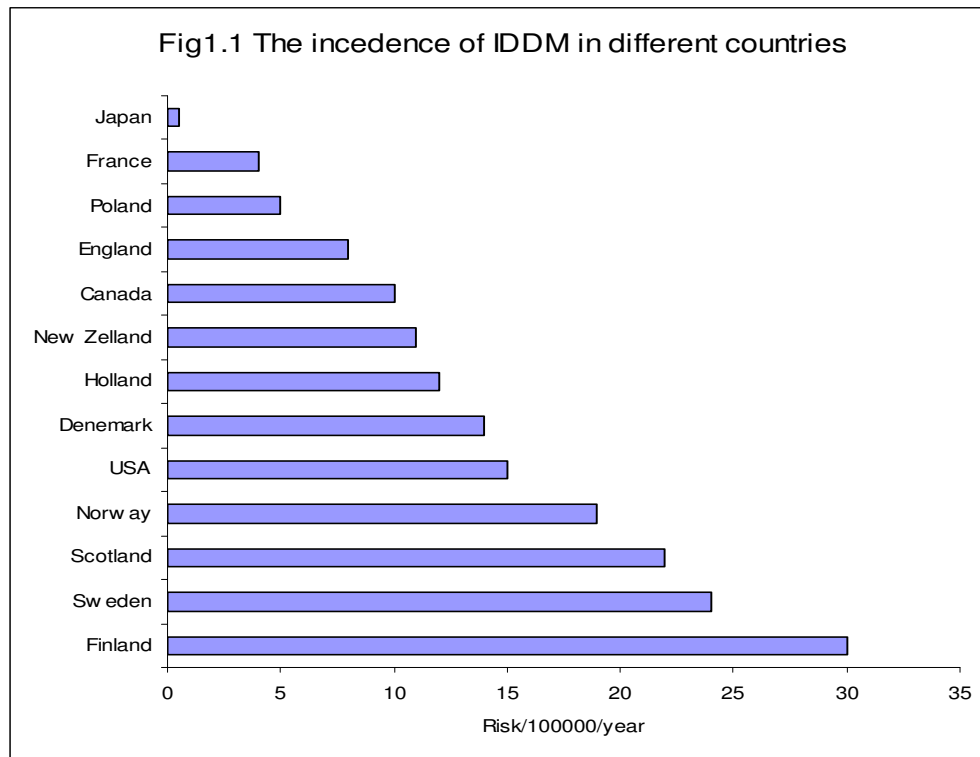
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## **1.1 Background**

Diabetes Mellitus is a complex; heterogeneous, and a metabolic disease that is characterized by abnormal blood glucose “sugar” concentration (WHO, 1991). This increase of blood sugar concentration is thought to result from reduction in insulin secretion in the pancreas or reduced sensitivity to insulin in the peripheral tissues (WHO, 1994). Therefore, two major types of diabetes are recognized. The first type is diabetes type 1 (Insulin Dependent Diabetes Mellitus, IDDM) which is characterized by severe reduction of insulin secretion that is due to destruction of the mass of Beta cells responsible for insulin secretion in the pancreas. The second type is diabetes mellitus type II (Non Insulin Dependent Diabetes Mellitus, NIDDM) which appears at older age than IDDM and represents 85% of diabetes (WHO, 1991). The onset and progress of type 2 is less acute compared to type-1 and its developments of complications are less aggressive. NIDDM developments are due to insulin resistant in the muscle tissue and consequently increase insulin secretion (Haffner, 1996).

## **1.2 Study problem**

Worldwide there is an increase of the incidence of childhood type-1 diabetes mellitus (Karvonen et al., 2000). This increase makes this disorder a major public health problem because of its high and rapidly increasing contribution of diabetes to the morbidity and mortality in the affected population. Type-1 diabetes mellitus occur in childhood and its peak of onset is early in puberty. Worldwide, it is the third most prevalent severe chronic disease of childhood after asthma and mental retardation (Rewers, 1997; Scherbaum, 2002). The incidence of childhood type-1 varies widely, since there is more than 350 fold difference between annual rates reported in the various countries, e.g. Finland annual rates (36.5/100000) compared with those for China (0.1/100000)(figure 1.1) (Watkins, 1996; Rewers, 1997).



**Figure 1.1: The incidence of IDDM in different countries (Watkins ,1996; Rewers ,1997).**

Globally 10-20 million people are affected by diabetes type-1. Its incidence continues to increase by 3-5 % per year (Rewers ,1997; Scherbaum ,2002), and in the Arab countries such as Jordan and Kuwait, the annual incidence among children is 3.6 and 15.4 per100,000 respectively (Punnose, 2002). This disorder development is thought to be due to complex of interactions between various environmental factors and the fact that the individual is genetically predisposed to the disorder. The possible environmental triggers are viral infections, e.g. Cocksackie's B virus, various dietary factors and stress (Davidson ,1991;Sharma ,1993). Studies in monozygotic twins suggest that the genetic component account for 30-40% of the total risk for having this disorder (Watkins, 1996).

The goal of the clinical management of all forms of diabetes is to control metabolic abnormalities in order to prevent acute (hyperglycemia and hypoglycemia) and long-term complications (retinopathy, nephropathy, neuropathy and cardiovascular disease) without negatively impacting on quality of life (Canton, 2004; Punnose et al 2002 and Laron-Kenet et

al., 2001).The appearance of these complications depends on the duration and severity of hyperglycemia and individual susceptibility (Punnose et al .,2002).

Patients with long standing diabetes might develop significant vascular complications. The appearance of these complications depends on the duration and severity of hyperglycemia and individual susceptibility (Scherbaum, 2002). These complications are related to blood vessel disease and are generally classified into small vessel disease such as those involving the eyes, kidneys and nerves (microvascular disease)( Scherbaum, 2002; Canton ,2004; Sharma ,1993 ; Devendra, 2004),and large vessel disease involving the heart and blood vessels (macrovascular disease ) (Watkins, 2003). The prevalence of micro- vascular complication in a patient with short-duration (<5 years) type-1 diabetes was found to be 25%, whereas for patient with long term disease (>14 years) could reach 72 %( Scherbaum, 2002) .The risk for development of micro vascular complications in patient with short-term could be increased by smoking and family history of hypertension. Long-term microvascular complications increased by poor glycemic control, and elevated serum lipids, which is the main causes of premature death are renal failure and coronary heart disease (Scherbaum, 2002; Punnose et al., 2002). For diabetic retinopathy, the prevalence of retinopathy is strongly related to the duration of diabetes (Punnose et al 2002, Strippoli 2003), for patients with short duration (<5 years), the prevalence of retinopathy was 25% and for long term disease (>14 years) was 72% (Punnose et al 2002). Kidney damage from diabetes results in hemodialysis, renal transplantation or death (Laron-Kenet et al., 2001; Rogus.John et al., 1998). The onset of nephropathy in type-1 detected by small amount of proteinuria after 7-10 years of diabetes, together with diabetic retinopathy but without evidence of other causes of renal disease urinary tract infection or heart failure (Leslie ,1989). Overt diabetic nephropathy occurs in 30-40% of type-1 diabetes patient, 20-25 years after disease onset (Strippoli, 2003).

Nerve damage in diabetes (neuropathy) is particularly a depilating complication of diabetes and account for significant morbidity by predisposing the foot to ulceration and lower extremity amputation (Gordois, 2003). Foot ulceration is a major complication of diabetes and consumes a major portion of the resources allocated for the treatment of diabetes (Pham Hau, 2000) It estimates show that foot ulceration may occur in up to 15% diabetic foot during their life time(Pham Hau, 2000).

Other factors, familiar and environmental factors also play a role in increasing the risk for having diabetes complications. For example, the risk for development of microvascular complications in patient with sort-term was increased by smoking and family history of hypertension and for long-term, microvascular complications increased by poor glycemic control, and elevated serum lipids (Punnose et al., 2002; Davidson ,1991).

### **1.3. Study Justification**

The Palestinian community is characterized as being in an epidemiological transition from communicable to non-communicable diseases. This made the community belonging to the two spectrum of health problems worldwide at the same time; i.e. the health problems of the developing countries such as infectious diseases and malnutrition, and the diseases of developed countries such as cardiovascular diseases, diabetes diseases, cancer diseases and hypertension. In the recent years the prevalence of non-communicable diseases has manifested a steep growth referred to the dramatic change in the lifestyles of the Palestinian community.

Diabetes is considered as one of the major health problem in the Palestinian community that is demonstrating an increased pattern due to different factors determining the occurrence of the disease (Shaar, 1998). Dietary change, physical inactivity, stress, and genetic factors are thought to affect the increase in the incidence of diabetes in Palestine (Shaar, 1998). Efficient diabetes care for Palestinian patients faces many problems. This “Western disease” and its care are totally lacking in a country under development “transition state”, where very few poorly equipped and staffed diabetes units are present. In fact diabetes care has a low profile as any other chronic disease, and is not in the government priority area. However, this perspective for chronic diseases primary and secondary prevention start to change lately.

In general, in Palestine, there is under-diagnosis and under reporting of diabetes mellitus (DM) as a leading cause of deaths. According to the Palestinian Ministry of Health (MOH) reports, DM is considered the 9th leading cause of death with a proportion of 4.1% of the total deaths (heart disease 2nd, renal failure 5th). DM prevalence rate is about 9% in 2000. By the end of 2003, there were 15,844 diabetic Palestinian refugee patients (including those with hypertension) under supervision of the United Nations for Refugees and Welfare Agency (UNRWA) in Gaza Strip. The estimated prevalence rate of diabetes mellitus among

Palestinian refugees aged 40 years and above was 4.3% in 2000 and 4.7% in 2001. The gap between the expected prevalence rates and cases under supervision requires special efforts to accelerate early case-finding activities in order to detect these diseases and meet the high cost of treating their complications and disabling consequences (MOH reports, 2003).

Most studies that have been concerned with diabetes focused on diabetes mellitus type II. No published study was neither concerned with the situation of diabetes type-1 patients, nor has evaluated the services provided for such life-time threatened kind of disease.

According to the experts of this disorder in Palestine, there is a high probability that the incidence of diabetes type-1 is increasing yearly, similarly to the rate of Jordan (i.e. 3.6 per 100,000 individuals). However, the reasons for such increase is not determined or proved yet. This probable increase in the morbidity severity and the raise up in the mortality rate could be due to the disease itself or its complications. This could eventually reflect in the enormous health care expenditures, made type-1 patients a primer target for secondary prevention, i.e. preventing its complications.

To have an overview of the services provided for type-1 diabetic patients in Ramallah district, we carried out several interviews with key persons at the central governmental primary health care centre in Ramallah and the major clinics operated by the United Nation for Refugees Welfare Agency (UNRWA). In addition, we visited the major private hospitals that could probably provide such services for these patients and several private internal medicine clinics in the district. From these interviews we found that the services offered to the diabetic patients of type-1 is mainly provided by both MOH and UNRWA, since they provide the insulin therapy for free for those patients. But, to a large extent, the follow up for these patients was bio-medically oriented, i.e. fasting blood sugar level which is measured monthly. However, other tests such as cholesterol, and triglyceride levels are measured yearly, but albumin, ECG, and eye and foot examinations are rarely done for these patients. HbA1C was not used by any means in any facility.

Therefore, as researchers we suspect that this mismanagement of this disorder is leading to serious complications for these patients and which could be lethal in many cases. Thus, we planned to carry out this baseline study in one of the big districts; i.e. Ramallah district (total population according to the PCBS at the mid year of 2004 was around 285,000)



In summary, there is no published study yet that is concerned with the situation of diabetes type-1 patients. No research was concerned with either to evaluate the disease itself or the services that is provided for such life-time threatened kind of disease, which if improved will improve the diabetic health care.

#### **1.4 Study aim and objectives**

We planned a study that covers all patients of diabetes type I they receive medical treatment by MOH and UNRWA in primary health care centers at Ramallah district, and investigated diabetes type I complications and therapeutic protocol. Moreover this study is planned to be used as a baseline survey for a study on type I diabetes and its complications in Palestine .Therefore, the study aims to assess and describe the situation of patients with diabetes type-1 in Ramallah district, which therefore will help us to assess the services provided and the complications of this disorder.

##### General Objective

To assess the health situation of patients with diabetes type-1 in Ramallah district

To highlight the possible determinants of diabetes type-1

To determine the appropriate method (s) for the follow up and management of type-1 disorder in Ramallah by the various care providers.

##### Specific objectives

To describe the various socio-demographic, physical and health condition, diabetes history of T1DM patients in this study.

To highlight the services provided to diabetic patients with T1DM.

To determine the prevalence of diabetes type-1 complications among the diabetics in Ramallah district.

To carry out blood testing, eye examination and examination by an endocrinologist to evaluate the present condition of these patients.

To determine the role of the various potential determinants for T1DM complications.

## **1.5 Research questions**

What are the complications that result from T1DM in Ramallah district?

What is the protocol used by the various health care providers in the treatment of T1DM to prevent or delay the occurrence of these complications?

Does self management among T1DM has an important role on managing the disease among these patients?

## **1.6 Study limitations**

Some patients could not be reached for the following reasons:

1- Some patient did not come to PHC centers by themselves to take the monthly insulin and having medical examination, instead a relative or a friend came to pick the medications so interview could not be done.

2- Due to the prevailing political condition and the continuous Israeli closer for areas, some patients could not be reached.

3- Lack of information in diabetic patient file like telephone numbers or exact address.

4- A number of patients were already dead and their families refused to fill in the questionnaires.

5- Some families refused their children participation in the survey.

6- Some families fill in the questionnaire but refused doing the testing.

7- Some families did the testing but refused seeing other physician than the one they see at the PHC.

## **1.7 Thesis chapters' description**

The thesis include six chapters starting from chapter one which discuss the aim, problem and the objectives of the study, also it include questions of the study and its limitations.

Chapter two include literature review of the previous studies that are related to the present study, the informations were taken from journals, books, and the internet.

Chapter three discusses the theoretical and conceptual frame works of the study. The theoretical include all types of diabetic complications and its risk factor plus the protocol of T1DM treatment.

Chapter four includes the methodology of the study, the way that was data collected; sample size, pilot study and statistical analysis of the data.

Chapters five and six, include the results of the study found in form of tables and figures. While chapter six discusses the result of the study and its finding. Finally the last chapter includes also the conclusion of the study and the research recommendations.

## **Chapter two. Literature Review**

### **2.1 Introduction**

### **2.2 Previous Studies**

#### **2.2.1 Diabetes type 1 situation worldwide**

#### **2.2.2 Epidemiological studies of type 1 IDDM, complications and its risk factors**

#### **2.2.3 The importance of glycemic control**

### **2.3 Summary**

## **2.1 Introduction:**

The literatures review in this chapter will focus on dependent and independent variables that are related to the study and this will include epidemiological studies of Diabetes type 1, complication and its risk factors of diabetes type 1, and finally the important of glyceimic control.

## **2.2 Previous studies**

The previous studies that are related to our study will be divided into:

- 2.2.1 Situation of diabetes type 1 worldwide
- 2.2.2 Epidemiological studies of type 1 IDDM, complications and its risk factors
- 2.2.3 Importance of Glycemic control

### **2.2.1 Diabetes Type 1 situation worldwide**

The term 'prevalence' of Type 1 diabetes usually refers to the estimated population of people who are managing Type 1 diabetes at any given time. The term 'incidence' of Type 1 diabetes refers to the annual diagnosis rate or the number of new cases of Type 1 diabetes diagnosed each year.

Several studies had been carried out in developed, developing and the Middle East countries. Epidemiological study of type 1 diabetes in children from 1990 to 1994 using a retrospective population-based registry in Philadelphia, PA, a city with large white, African-American, and Hispanic (Puerto Rican) populations in the USA. Found that the overall age-adjusted incidence rate in Philadelphia was 13.3/100,000/year (Terri et al., 2002). The incidence of insulin-dependent diabetes mellitus in children aged 0-17 years in Colorado from 1978 to 1988. Was 14.8/100,000 person-years. The rate was lower in individuals of Spanish origin (Hispanics) (8.7/100,000 person-years) compared with non-Hispanic individuals (15.5/100,000 person-years) .Incidence rates were higher in winter and lower in summer for children 5-17 years old. Children diagnosed before the age of 5 years showed no significant seasonal pattern, although peak incidences were observed in autumn and spring. No temporal

trend in diabetes incidence was observed overall or by ethnic group (Kostraba et al., 1992). The new cases of type 1 diabetes in children aged 0–14 years in the Mediterranean island of Sardinia were prospectively registered from 1989 to 1999 according to the EURODIAB ACE criteria show that A total of 1214 type 1 diabetic patients were registered yielding to an overall age- and sex-standardized incidence rate of 38.8/100000. There was a male excess with an overall male-to-female ratio of 1.4 (1.3-1.8). The increase of incidence during the 11 years analyzed was statistically significant (P = 0.002) with a yearly increasing rate of 2.8% (1.0-4.7). No evidence of an effect of age and sex on this trend has been found. (Casu et al., 2004). The highest annual incidence rate of childhood onset Type I diabetes in the world ever known was recorded in Finland in 1998 with 48.5 cases per 100 000 person-years (Podar et al., 2001). The crude annual incidence of Type 1 diabetes in children under 15 years in northern Thailand from 1991 to 1997 ranged from 0.31-0.56/100,000 per year, with an average incidence of 0.37/100,000 per year. This very low figure had raised 2.2 fold (over 100%) from that reported in 1984 (Unachak et al.,2001). The overall ascertainment-corrected IDDM incidence rate in China was 0.51 per 100,000, the lowest rate ever reported. There was a 12-fold geographic variation (0.13-1.61 per 100,000) (Yang et al., 1998).In the childhood age group, a highly variable incidence of IDDM is seen in many Arab countries. In the Sultanate of Oman, the incidence rates in the 0–14-year age group were 2.45 and 2.62/100 000 populations per year during 1993 and 1994, respectively (Soliman et al., 1996).Similar study was conducted in the same age group among Jordanian children aged 0-14 y during 1992-1996 , Data were obtained retrospectively for the years 1992-1994 and prospectively for the years 1995 and 1996, the study show that the incidence rate for the years (1992 through 1996) was 2.8, 2.9, 3.2, 3.6 and 3.6 per 100,000 populations, respectively (Ajlouni et al.,1999).Another study conducted in Kuwait show that the incidence rate of IDDM among Kuwaiti children aged 0- 14 years was 20.1/100000 during the period of 1991-1997(Shaltout et al.,2002).In Israel the incidence of IDDM between the ages 0-17 years in the year 1998 was 9.1/100000,this study show that the incidence were higher for Jews 9.5/100000 than for Arab 8.0/100000(IIRSG,2002).

The prevalence of insulin-dependent diabetes mellitus (IDDM) in the United States is estimated to be about 120,000 individuals' age less or equal 19 years and about 300,000-500,000 individuals of all ages (Ronald et al.,1994).While the prevalence of adult-onset insulin-dependent diabetes mellitus (IDDM) in a nationally representative sample of adults 30-

74 years of age of USA was 0.30% of the U.S. population 30-74 years of age and 7.4% of all diabetic patients diagnosed at 30-74 years of age ([Harris](#) and [Robbins](#), 1995). In England the prevalence is estimated to be about 166 000 persons which account 0.4% for all persons in England in 2001([Forouhi NG](#) et al 2006). The prevalence rates of IDDM among children aged from 0-14 years in Slovakia (per 1,000) were 0.28-0.50% in the 8-year period of 1985 to 1992 ([Michalkova](#) et al., 1995).

In southern Iran ([Karamizadeh et al.](#), 1996) a Middle Eastern country, a study among children (0-18 years of age) found that the prevalence of diabetes type 1 was 40.83 per 100,000 children (4/10,000). The annual incidence of diabetes in this age group was 4per 100,000 children with a higher frequency in females. A seasonal variation was noted in the onset of symptoms which was the highest during October and the lowest during August ([Karamizadeh et al.](#), 1996).

The prevalence data of IDDM in the Arab countries show different rates. A study in Kuwait ([Mohamed et al.](#), 2005) showed that IDDM was more prevalent in the age group 10-13 years 347.3 per 100,000 and lowest in the age group 6-9 years 182.6 per 100,000 individuals. During the study period from October 2000 to September 2002, the prevalence of IDDM was 269.9 per 100,000 with no significant between male and female. The mean age at onset was 9.2 and 8.1 years in male and female children, respectively, with no significant difference between regions of Kuwait.

Another household screening study in Saudi Arabia between years 1992-1996 of the adult population (more than 14 years), the prevalence of IDDM among male and female in the all different regions was 0 .23 and 0.3, respectively ([Warsy et al.](#),1999).

## **2.2.2 Epidemiology of Type 1 diabetes mellitus and its complications**

The epidemiology of diabetes type 1 and its complication were of great interest in the past 2 decades. Many researches and published work was concerned in studying the prevalence of microvascular disorders (retinopathy, nephropathy and neuropathy) and acute diabetic complications, and the metabolic control status.

Table 2.1 summarizes some of the most important studies that were concerned for both acute and chronic complications of T1DM.

**Table 2.1 Summary of studies that was concerned with type 1 diabetes complications**

Author, country of study	sample size	Study type, Patients age	testing	complications	Notes
EURODIAB IDDM Complications Study Europe	3250 IDDM patients	cross-sectional study	– <b>HbA1c</b> Normal=16%	– Retinopathy= 46% – Nephropathy=30.6% – Hypoglycemia=32.2% – Hospital adm =8.6% – Cardiovascular=19.3%	Mean (SD) duration of diabetes was 14.7 (9.3) years
ADA (1990)	657 IDDM patient diagnosed between 1950 and 1980 and currently aged 8-48 yr	cross-sectional study		– Retinopathy=70 % – Nephropathy= 84%(male) 59% (females) _ Cardiovascular= 11%(men) 30% (women)	after 30 yr duration
(Blanco et al 2004) Catalonia-spain	471 patients hospital records	Cross-section for patients diagnosed between 1987-1988	– <b>HbA1c</b> <7.5=48% >10=11.5%	– Retinopathy= 15% – Nephropathy=10.4% – Neuropathy=4.3% – Ketoacidosis=1.5% – Hypoglycemia=5.2% – Hospital adm =10.9%	After 10 yrs
Kozek et al (2003). Krakow-Poland	clinical data from 241 patients	Retrospective analysis	–	– Retinopathy= 41.5% – Nephropathy=17% – Neuropathy=29% – Hypoglycemia=32.2% – Cardiovascular=8.7% – Foot ulcer=8.3%	diabetes duration 10.00 +/- 8.6) in women, while in men 11.78 +/- 11.08 years



**Table 2.1.... continues**

Author, country of study	sample size	Study type, Patients age	testing	complications	Notes
(Olsen ,1999) Denemark	339 patients	Cohort follow-up study	– <b>HbA1C</b> <8=11%	– Retinopathy= 60% – Nephropathy=9% – Neuropathy=62%	median diabetes duration 13.2 years (range 8.9-24.5).
Nordwall et al (2006) Linkoping, Sweden	80 children and adolescents with DM1, age 7-22yrs	Cross-sectional	– <b>HbA1c</b> Mean HbA1c (SD)=8.4 (0.9)%	– Retinopathy= 27% – Nephropathy=5% – Neuropathy=59%	DM1 duration=13 years
(Agardh et al., 1997) Lund- Sweden	442 type 1 adult diabetic patients	follow-up study	– <b>HbA1C</b>  11 +/- 4%	– Retinopathy= 41%	After5 years
Fagulha A et al 2004 Coimbra- Portugal	1009 patients	Cross-section until 22 yr of age	– <b>HbA1c</b> -<7.5=12.5% - > or =7.5 and < 8%=11.3% - > or =8 and <9.5 = 33.5% ->9.5 =40.9%	– Retinopathy=1.4% – nephropathy= 6.4%	diabetes duration 5.2 yr+/-3.95

**Table 2.1.... continues**

Author, country of study	sample size	Study type, Patients age	testing	complications	Notes
Lievre M et al 2005 Lyon-France	562 children aged 10-16 and 1691 adults aged 16-	45cross-sectional study	– <b>HbA1c</b> -<7=15% Children and 26% adults.	– Retinopathy= Children (0.7%) Adults (28.3%) -micro-ormacro-albuminuria= children 10.2% adults 15.2%	After 2 years of type 1 diabetes or
Donaghue KC et al (2005) Westmead-Australia	209 patients	Cohort study children aged < 15 years diagnosed between 1990and 1992	–	– Retinopathy=24% – albumin excretion rate (AER) > or = 7.5 microg/min = 18% – albumin excretion rate (AER) > or = 20 microg/min =2%	After 6 yrs
Ramachandran A et al (2000) Chennai, India	617 Type 1 diabetic patients	Cross-sectional patients, aged < or =20 years at diagnosis of diabetes	–	– Retinopathy=13.4 % – Nephropathy=7.1% – Neuropathy=3% – IschaemicHeart disease=.5% -peripheral vascular disease in 0.5%	a minimum of 3 year follow-up
IDF (2003) Baku-Azerbaijan	69 type 1 medical document	Cross-sectional	–	– Hypoglycemia=1.4% – Retinopathy=1.4% – Eyes cataract=5.8% – Neuropathy=24.4% – Nephropathy=1.4%	Duration of disease3.5+/- .36 Age=10.2+/- .35 yrs

**Table 2.1.....continues**

<b>Author, country of study</b>	<b>sample size</b>	<b>Study type, Patients age</b>	<b>testing</b>	<b>complications</b>	<b>Notes</b>
Rahlenbeck & Gebre-Yohannes (1997) Gondar –Ethiopia	Type1 diabetic patients	Cross-sectional		– Nephropathy Microalbuminuria=33% Macroalbuminuria=23%	duration of disease more than 5 years
Kalter-Leibovici O(1991) Petah Tikva- Israel	231 young Jewish IDDM (Age range= 0.04-26.2 yr),	Cohort study		– Nephropathy Microalbuminuria=31% Macroalbuminuria=7% – Retinopathy Nonproliferative=44% Proliferative=12%	median duration of disease was 15.3 yr
(Ammari F 2004). Jeddah-Saudi Arabia	100 patients hospital files	Retrospective study	–	– Retinopathy= 7% – Nephropathy=2% – Neuropathy=6% – Hypoglycemia=32.2% – Cardiovascular=8.7% – Foot ulcer=8.3%	

### **2.2.3 Type 1 diabetes therapy and glycemic control:**

Several studies were done to compare the different ways of achieving tight glycemic control. One of the major studies was a 10-year study that compared intensive therapy versus conventional therapy conducted by the Diabetes Control and Complications Trial (DCCT) (DCCT, 1993). The DCCT included 1,441 subjects with type 1 diabetes, whom were randomly assigned either to intensive therapy or conventional therapy. Intensive therapy consisted of insulin administered either by continuous subcutaneous insulin infusion with an external insulin pump or multiple daily insulin injections (three or more injections per day). Insulin therapy was guided by self-monitoring of blood glucose (SMBG) three to four times daily, with additional specified samples, including a weekly overnight sample. It also included meticulous attention to diet and monthly visits to the treating clinic. Conventional therapy consisted of no more than two daily insulin injections; urine glucose monitoring or SMBG no more than twice daily; periodic diet review; and clinic visits every 2-3 months. The intensive group achieved median hemoglobin A<sub>1c</sub> (A1C) of 7.2% versus an A1C of 9.1% in the conventional group. Mean blood glucose was 155 mg/dl in the intensive group and 230 mg/dl in the conventional group. In the DCCT study, risk reductions for micro vascular and neurological end points were dramatic: > 70% for clinically important sustained retinopathy, 56% for laser photocoagulation, 60% for sustained microalbuminuria, 54% for clinical grade nephropathy, and 64% for confirmed clinical neuropathy. Macro vascular end points demonstrated trends in risk reduction—42% risk reduction for all macro vascular events combined and 78% risk reduction for cardiac events (DCCT, 1993).

Similar study was done at Alexandria University Children's Hospital, Egypt (Soliman et al., 2006). The 125 type 1 diabetic children were included in this study to compare glycemic control and insulin dosage in children with type 1 diabetes treated by a modified intensified insulin therapy (MII) using insulin pens (and premixed and regular insulin) with those on conventional insulin therapy. The result of the study show that in this study found that glycemic control is better during MII using insulin pens and premixed and regular insulin compared with conventional insulin therapy, without any significant change in insulin dose needed to achieve this level of control.

Another previous study done among children with type 1 diabetes diagnosed at 0–14 years in northern Sweden between 1981 and 1992. This survey study the impact of glycemic control (HbA<sub>1c</sub>) early in disease and age at onset on the occurrence of incipient diabetic

nephropathy (MA) and background retinopathy (RP) in childhood-onset type 1 diabetes. The result of the study shows that inadequate glycemic control, also during the first 5 years of diabetes, seems to accelerate time to occurrence of micro vascular complications (Svensson et al., 2004).

### **2.3 Summary**

In this chapter T1DM epidemiology and its various complications was discuss, Glycemic control and its role in delay and prevent diabetes complications was also discuss. From the previous study the researcher will determine sample size, statistical analysis, and to determine the hypothesis of the study.

Epidemiological studies show that the incidence rates gathered during the last years in people under 15 years of age confirm the vast geographic variation of IDDM incidence worldwide with rates (per 100,000) ranging from 0.6 in Thailand and China to 36 in Sardinia and Finland. This large variation was also observed in small areas of various countries such the Arabian Peninsula. Between continents the variation in incidence showed that the lowest rate was found in Asia, followed by Africa and South America; higher rates were recorded in Oceania (Australia and New Zealand) and North America, while the highest rates of all were recorded in Europe where the greatest intracontinental variation in incidence has been described.

From the review of the past studies that are done on both acute and chronic complications of T1DM and there risk factors, the researchers could summarize the most important results of these studies as follows:

- ♣ There is a significant relation ship between Duration of diabetes and the appearance of its complications.
- ♣ There is a significant relation ship between smoking habit and the appearance of diabetic complications.
- ♣ Onset of diabetes before puberty could be an additional risk factor for the appearance of diabetes complications.
- ♣ There is no difference between males and females in the appearance and frequency of diabetes complications.
- ♣ There is a significant relationship between poor glycemic control and the development of diabetes complications.
- ♣ Earlier use of intensive insulin treatment lowers HbA1c to normal value.

- ♣ There is a significant relationship between irregular home monitoring and the appearance of diabetes complications.

## **Chapter three. Theoretical and conceptual framework**

**3.10** Introduction

**3.11** Diabetes mellitus definition

**3.12** Types of diabetes

**3.13** Pathogenesis of type 1 diabetes mellitus

**3.14** Burden and complications of Diabetes Mellitus

**3.15** Diabetes diagnosis and services

**3.16** Management and follow up of type 1 diabetes

**3.17** Risk factors

**3.18** Summary

### 3.1 Introduction:

This chapter presents an overview of diabetes mellitus types, causes, diagnosis, and treatment protocols. In the chapter we will be discussing issues related to the under-treatment of diabetes type 1, the different types of insulin used by the diabetic patient, follow up mechanisms used by health the various care services, as well as its complications. Moreover, the risk factors for diabetes type 1 complications will be discussed. Diagram 3.1 presents the conceptual framework model of diabetes type 1 complications, as it is reflected in this thesis' objectives.

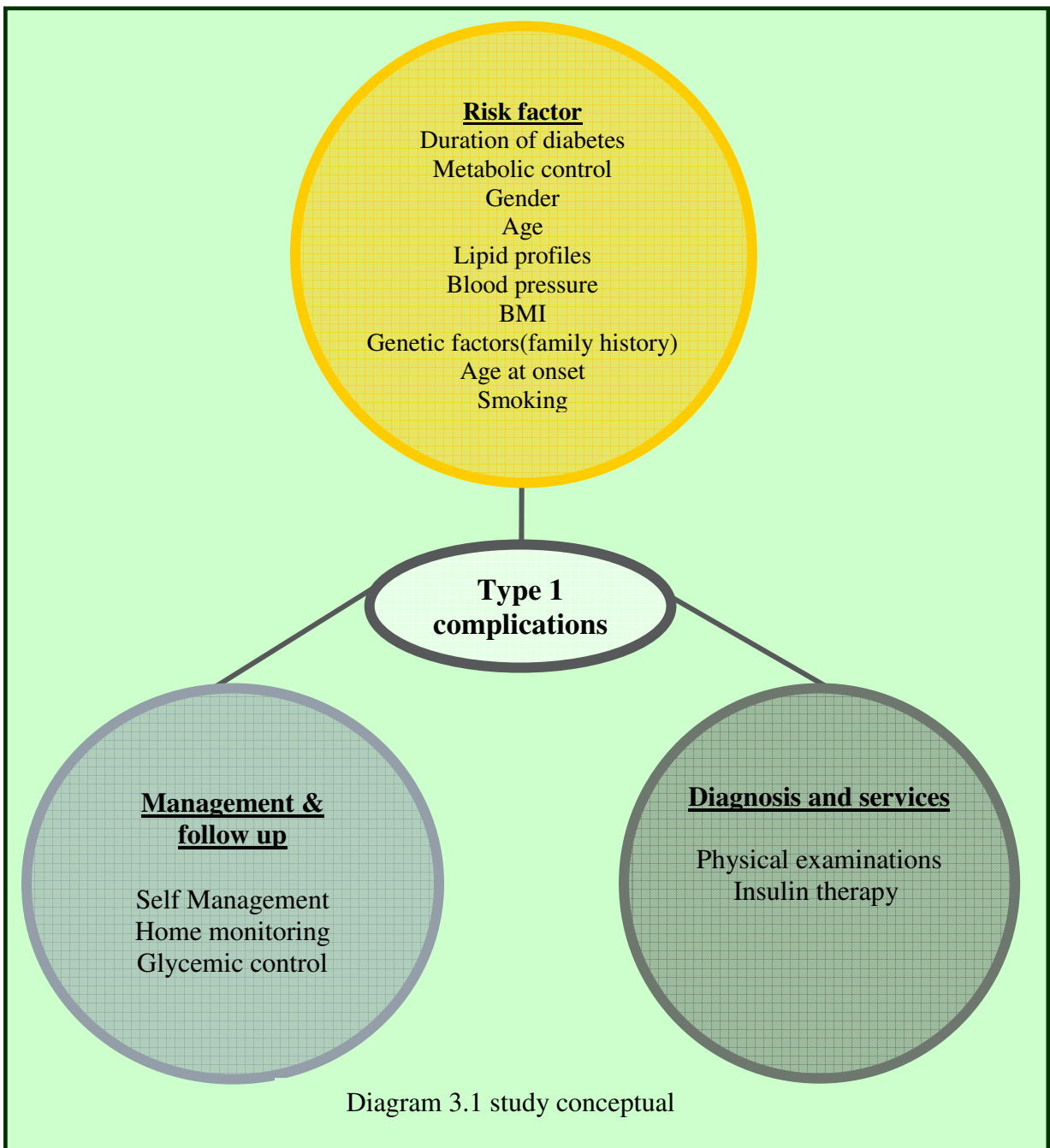


Diagram 3.1 study conceptual



### **3.2 Diabetes mellitus definition**

Diabetes mellitus is one of the oldest diseases that are in recorded history and which have been recognized in Egypt and India before Christianity (Halabi, 1996). However, even now relatively little is known about diabetes in developing countries, where the fight against communicable disease has attracted most attention (Halabi, 1996). Diabetes has been recognized since antiquity, as a wasting disease associated with frequent eating, urination and weight loss, despite frequent eating (Halabi, 1996).

The term Diabetes Mellitus describes a metabolic disorder of multiple etiologies. Davidson defined diabetes mellitus as a syndrome with metabolic, vascular, and neuropathic component that are interrelated. The metabolic syndromes characterize by alternation in carbohydrate, fat, and protein metabolism secondary to absent or insulin secretion or ineffective insulin actions (Davidson, 1991).

The World Health Organization defined diabetes mellitus as metabolic disorder of multiple aitiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protien metabolism resulting from defect in insulin secretion, insulin action or both (WHO, 1999). The effects of diabetes mellitus include long damage, dysfunction and failure of various organs, and it includes progressive development of the specific complications of retinopathy, with potential blindness, nephropathy, that may lead to renal failure, and neuropathy with risk of foot ulcers and amputation. In addition, the diabetes patient is at risk for cardiovascular, peripheral vascular and cerebrovascular diseases (WHO, 1999).

### **3.3 Types of diabetes**

Diabetes mellitus is a syndrome characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. An actual etiologic classification suggested by the American Diabetes Association. Table 3.1 presents this classification (Nordwall, 2006).

#### **I. Type 1 diabetes**

This is known as IDDM, or juvenile diabetes in which the pancreatic beta cell fail to produce the insulin hormone when the immune system attacks the insulin-producing beta cells in the pancreas and destroys them, about 5-10% of patients has type 1 diabetes mellitus. This type 1s usually developed in the children and young adults, but the disorder may appear at any age. Symptoms are; increased thirst and urination, constant hunger,

weight loss, blurred vision and extreme tiredness. The risk factor of type 1 diabetes includes auto immune, genetic and environmental (WHO, 1999; WHO, 2000; Davidson, 1991).

**Table 3.1: Etiological classification of diabetes mellitus**

<p>I Type 1 diabetes mellitus (beta cell destruction, leading to insulin deficiency)</p> <ul style="list-style-type: none"> <li>a. Immune mediated</li> <li>b. Idiopathic</li> </ul> <p>II Type 2 diabetes mellitus (different grades of insulin resistance with different grades of relative insulin deficiency)</p> <p>III Other specific types</p> <ul style="list-style-type: none"> <li>a. Genetic defects of beta cell function (e.g MODY Maturity Onset Diabetes of the Young)</li> <li>b. Genetic defects in insulin action</li> <li>c. Diseases of exocrine pancreas (e.g. pancreatitis, cystic fibrosis)</li> <li>d. Endocrinopathies (e.g. Cushing's syndrome)</li> <li>e. Drug- or chemical- induced (e.g. corticosteroids)</li> <li>f. Infections (e.g. congenital rubella)</li> <li>g. Uncommon form of immune-mediated diabetes mellitus</li> <li>h. Genetic syndromes associated with diabetes mellitus</li> </ul> <p>IV Gestational diabetes mellitus</p>
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Source: Adapted from Maria Nordwall master thesis, Linköping University, 2006

## **II. Type 2 diabetes**

This is known as non insulin-dependent diabetes mellitus or (NIDDM). It is the most common form of diabetes. About 90 to 95 percent of people with diabetes have type 2 diabetes. Usually it is developed in adults over the age of 40, and about 80 percent of people with type 2 diabetes are overweight. In this type of diabetes, the pancreas produces insulin, but for some reason the body cannot use the insulin effectively, which results in the unhealthy build up of glucose in the blood. The symptoms here are not noticeable as in type 1 diabetes. Symptoms include; feeling tired or ill, frequent urination, unusual thirst, weight loss, blurred vision, frequent infections, and slow healing of ulcers (WHO, 1999; WHO 2000; Davidson 1991).

### **III. Other specific type and secondary**

These conditions include diabetes and glucose intolerance that develop in association with disorders or factors such as pancreatic diseases, endocrinopathies, many genetic syndromes, and the diabetogenic effects of drugs, chemical agents, and toxins. The prevalence is ~1%-2% of all diabetes (Davidson, 1991).

### **IV. Gestational diabetes**

Is a (carbohydrate intolerance) resulting in hyperglycemia of variable severity with onset or first recognition during pregnancy, and usually disappears after the pregnancy is over, unless it was diabetes type 1. Diabetes in pregnancy may give rise to several adverse outcomes, including congenital malformations, increased birth weight and an elevated risk of prenatal mortality (WHO 1999; WHO 2000; Davidson, 1991).

#### **3.4 Pathogenesis of type 1 diabetes mellitus**

Type 1 diabetes is a disease characterized by “auto-destruction” of the pancreatic beta cells that produce insulin. Overtime, the body silently destroys these cells creating an insulin deficiency. Type 1 diabetes appears to stem from an inherited defect in the immune system, triggered by some environmental stimuli. The exact cause of the disease is still unknown; however, studies have isolated a few factors that may be related to development of the disease (Redondo et al., 2001).

Mainly, diabetes type 1 was seen as a combination of genetic susceptibility and environmental factors “*gene-environment interaction*” that leads to an autoimmune cellular and humoral mediated destruction of the beta cells in the pancreas. Genetically, a strong association was seen between certain HLA genes and risk for type 1 diabetes, , but the frequency of the high risk genotypes differs among children of different ages. Children with newly diagnosed diabetes have autoantibodies against glutamic acid decarboxylase (GADA), islet cells (ICA), insulin (IAA) or tyrosine phosphatase (IA - 2) in 85–98%, but the rate of antibody positivity varies among different age groups (Komulainen et al. 1999) (Fajardo et al., 2001). The major genetic risk factor for the development of type 1 diabetes is the human leukocyte antigen (HLA) genes located on the short arm of the sixth chromosome (Davidson,1991).

In the last decade, the rapid increase of type 1 diabetes incidence could not be explained by genetic changes in this short time perspective (Pundziute-Lycka, 2004). Studies in

monozygotic twins suggest that the genetic component account for 30-40% of the total risk (Peter, 1996; Rewers, 1997; Redondo et al., 2001; Kumar et al., 1993; Hyttinen et al., 2003). These factors speak in favor of the importance of environmental factors for the development of type 1 diabetes. In epidemiological studies several environmental factors has been associated with diabetes.

Evidence for a triggering role of environmental factors such as bovine albumin of milk or viral infection has also been postulated. The role of cow's milk related to T1DM is not clear; some suggestions that albumin has a section that is capable of reacting with "beta-cell specific surface proteins", which could contribute to islet cell dysfunction. (Karjalainen et al., 1992).

Several studies in humans suggest that persistent viral infection (e.g., Rubella virus, Coxsackie's B4, cytomegalovirus, Epstein-Barr, and so on) may be involved in some cases of IDDM (Wagenknecht et al., 1991). The role of viruses in the pathogenesis of IDDM is also supported by direct isolation of virus from pancreas of infant who died of diabetic ketoacidosis. (Draznin et al., 1994).

### **3.5 Burden and complications of Diabetes Mellitus**

The complications of diabetes can be classified as: Acute problem (Otherwise termed the diabetic medical emergencies) which include Diabetic ketoacidosis and hypoglycemia, or chronic complications which include Micro vascular and macro vascular complications. A round four million deaths every year are attributed to complications of diabetes mellitus (WHO,2003).

#### **3.5.1 Acute diabetic complications**

**I. Hypoglycemia** is defined as blood glucose less than 50 mg/dl . The main symptoms are headache, weakness, sweating, tremors, hunger, difficulty speaking, confusion, convulsion and coma. The eitiology of hypoglycemia in IDDM patient result from mismatch between insulin dose, carbohydrate ingestion and physical activity (Leslie et al., 1995). Hypoglycemia is classified as: i) mild hypoglycemia in which patients are able to treat themselves when the feel the symptoms such as tremors, palpitation, sweating and hunger; ii) severe hypoglycemia in which the symptoms include constipation, drowsiness, coma and seizure due to a very low blood glucose level and the patient is not able to treat themselves and needs help from others (MOH, 2004; WHO, 2002a).

## **II. Diabetic ketoacidosis:**

Diabetic ketoacidosis (DKA) is the most common hyperglycemic emergency in patients with diabetes mellitus. DKA most often occurs in patients with type 1 diabetes, but patients with type 2 diabetes are susceptible to DKA under stressful conditions, such as trauma, surgery, or infections. The incidence of ketoacidosis is about 1-5% in type 1 diabetics with a mortality of 3-9% (Berger, 1997).

DKA is reported to be responsible for more than 100 000 hospital admissions per year in the US, and accounts for 4-9% of all hospital discharge summaries among patients with diabetes. Treatment of patients with DKA uses significant healthcare resources and accounts for 1 out of every 4 healthcare dollars spent on direct medical care for adult patients with type 1 diabetes in the US (Umpierrez , 2003; Christaki et al, .2001).

### **3.5.2 Chronic complications**

Diabetes is associated several late stage complications that lead subsequent to mortality and morbidity. These late stage include microvascular and macrovascular complications. Microvascular diseases results from the impact of glucose intolerance on the smaller blood vessels and include retinopathy, nephropathy and neuropathy. Macrovascular disease involves the large blood vessels and is associated with atherosclerotic activity of these vessels (Davedson, 1991; ADA, 2004). Microvascular is more common complications in type 1 diabetes, although macrovascular complications are also increased. These complications are influence by several factors such as glycemic control, hypertension and hyperlipidmia. The primary risk factor for microvascular complications is hyperglycaemia, while other risk factors, such as hypertension and lipid control are the main for the development of macrovascular complications. Complications are therefore usually acquired after diagnosis (Bate and Jerums, 2003).

## **I. Microvascular complications**

### **1) Diabetic retinopathy:**

Diabetes is the most frequent cause of new cases of blindness among adults aged 20–74 year. (Donald, 2003). Diabetic retinopathy is the cause of blindness in approximately 2.5 million of the estimated 50 million blind people in the world (Viswanath et al., 2003). In economically developed societies, it is a major cause of visual disability in people aged 25 years or older (King et al., 1996; WHO, 1997). Blindness is 25 times more common in people with diabetes than people not having diabetes (Klein et al., 1995; Palm berg, 1977). It causes 12,000- 24,000 new cases of blindness each year (CDC, 2002), an estimated 63,000 cases of proliferative diabetic Retinopathy, 29,000 high risk proliferative diabetic retinopathy cases, 80,000 macular edma cases, 56,000 clinically significant macular edma cases, and 5,000 new cases of blindness occur each year as a result from diabetic retinopathy (Klein et al., 1995). In type 1 diabetes, background retinopathy is rare before 5 years of diabetes but its prevalence increases steadily thereafter to affect over 90 % of patients after 20 years. After several years of diabetes, the risk of proliferative changes is about 3% of patient per year, with cumulative total of over 60% after 40 years (Pickup et al., 1991).

The Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) which was a longitudinal study using a population based cohort of diabetes patient from Wisconsin found that PR is more prevalent in type 1 diabetes, also the study found that the 10 year follow up point, 30% of the younger onset group, 24% of older onset group taking insulin and 10% of older onset group not taking insulin developed retinopathy (Klein et al., 1994).

Diabetic retinopathy is any disease of the retina, usually associated with impairment of vision, distortion of objects and edema, and sometimes hemorrhages into the substance of the retina. Retinopathy is classified as background retinopathy, pre-proliferative retinopathy and proliferative retinopathy. Background retinopathy (shown in figure 3.1) is where there is partial occlusion of the small blood vessels in the retina which result in microaneurysms in the capillary wall. These microaneurysms are weak and capillary fluids leak out causing edema and intra retinal hemorrhages. pre-proliferative retinopathy indicated further destruction of retinal capillaries. Proliferative retinopathy (shown in figure 3.2) is the severe form and the capillaries become occluded, and new blood vessels

are formed to supply the retina with blood. It is caused by damage to the sensitive blood vessels in the eyes. (Pickup et al., 1991; Watkins, 2003; Sharma et al., 1993).



Figure 3.1: Moderate Non-Proliferative Diabetic retinopathy

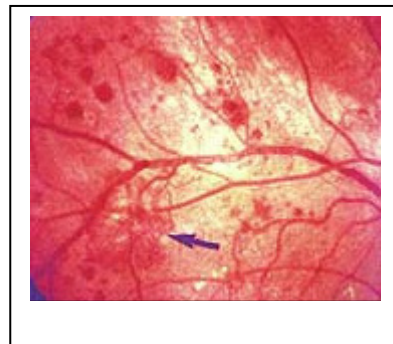


Figure 3.2: Proliferative diabetic retinopathy with neovascularisation elsewhere

There are many epidemiological studies that have established the various risk factors and provided guidelines for the management of diabetic retinopathy. Poor glycemic control is associated with retinopathy (Viswanath et al., 2003). The Diabetes Control and Complications Trial (DCCT) has shown that in Type 1 insulin dependent diabetes mellitus (IDDM), good control of metabolic status will reduce the risk of progression of diabetic retinopathy and delays the onset of retinopathy in patients who do not have retinal changes at the time of presentation (DCCT). The United Kingdom Prospective Diabetes Study (UKPDS) has confirmed that good glycaemic control in Type 2 non-insulin dependent diabetes mellitus is also beneficial and delays the onset of retinopathy (UKPDS). The duration of diabetes is probably the strongest predictor for development and progression of retinopathy (Donald et al., 2003). Hypertension reports have indicated that high diastolic blood pressure in young individuals and higher systolic blood pressures in older individuals can worsen the retinopathy (Viswanath et al., 2003). Pregnancy in women can be associated with worsening of the retinopathy (Viswanath et al., 2003). Elevated

triglyceride and low HDL-cholesterol (Chaturvedi et al.,2001;Chaturvedi et al., 2001) , and increased total and LDL-cholesterol (Watts et al.,1996) have been reported to predict diabetic retinopathy and diabetic nephropathy.

## **2) Diabetic Nephropathy:**

Diabetes is the leading cause of end-stage renal disease in the U.S. and Europe, accounting for 44% of new cases per a year. The majority of future ESRD cases from diabetic nephropathy are preventable (ADA, 2002a; CDC, 2002a). In 2001, 42,813 people with diabetes began treatment for end-stage renal disease. Also in 2001, a total of 142,963 people with end-stage renal disease due to diabetes were living on chronic dialysis or with a kidney transplant (CDC, 2002a). The cost for treatment of diabetic patients with ESRD in 1997 was in excess of \$15.6 billion (ADA,2002).About 20–30% of patients with type 1 or type 2 diabetes develop evidence of nephropathy, but in type 2 diabetes, a considerably smaller fraction of these progress to ESRD(ADA, 2002a ). End-stage renal disease (ESRD) develops in 50% of type 1 diabetic individuals with overt nephropathy within 10 years and in >75% by 20 years (ADA, 2002a).

Diabetic nephropathy is characterized by persistent albuminuria (albumin excretion rate >300 mg/24 h, declining glomerular filtration rate (GFR) and rising blood pressure. At its most severe, diabetic nephropathy results in end stage renal disease requiring dialysis or transplantation, but in the early stages overt disease is preceded by a phase known as incipient nephropathy (or microalbuminuria), in which the urine contains trace quantities of protein (not detectable by traditional dipstick testing). Microalbuminuria is defined as an albumin excretion rate of 20-300 mg/24 h or 20-200 µg/min in a timed collection and is highly predictive of overt diabetic nephropathy, especially in type 1 diabetes (Pickup et al. 1991; Watkins, 2003; Sharma et al., 1993).

The prevalence of microalbuminuria in patients with type 1 diabetes at 30 years disease duration is approximately 40% (SIGN, 2001). The prevalence of microalbuminuria and overt nephropathy in the “Pittsburgh Epidemiology of Diabetes Complications Study” was 84% (males) and 59% (females) at greater than or equal to 30 yr duration (Orchard et al., 1990a). Anderson et al found that the cumulative incidence of nephropathy in type 1 diabetes (Denmark) to be 41% at greater than 25 year of disease (Andersen ,1983).



The natural history of diabetic nephropathy is a process that progresses gradually over years. Early diabetes is heralded by glomerular hyperfiltration and an increase in GFR. This is thought to be related to increased cell growth and expansion in the kidney, possibly mediated by hyperglycemia itself. Microalbuminuria typically occurs after 5 years in type 1 diabetes. Overt nephropathy, with urinary protein excretion greater than 300 mg/day, often develops after 10 to 15 years. End-stage renal disease (ESRD) develops in 50% of type 1 diabetic, with overt nephropathy within 10 years' time (Pickup et al., 1991; Watkins, 2003; Sharma et al., 1993). There are several risk factors associated with nephropathy. Glycemic control is the major factor associated with disease risk. The Diabetes control and Complications Trial (DCCT) found that a reduction in mean HbA1c from 9.0% to 7.3% in people with Type 1 diabetes was associated with a 39% reduction in microalbuminuria and 54% reduction in proteinuria over 6.5 years. However, no clear benefit was seen in the treatment of established microalbuminuria in people with Type 1 diabetes (DCCT, 1993). Higher blood pressure and hypertension is associated with progression of diabetes renal disease (Krolewski et al., 1985). The 10-year incidence of proteinuria performed by a population-based study in southern Wisconsin of individuals with diabetes was significantly related to higher glycosylated hemoglobin level and diastolic blood pressure (Klein R & et al., 1995a). Cigarette smoking consider as a risk factors for diabetic nephropathy in type 1 diabetes (Scott et al, 2001). Elevated triglyceride and low HDL-cholesterol (Chaturvedi et al., 2001; Chaturvedi et al., 2001), and increased total and LDL-cholesterol (Watts et al., 1996) have been reported to predict diabetic nephropathy. Male sex and duration of disease are two independent risk factors for nephropathy and renal insufficiency (Orchard et al., 1990a).

### **3) Diabetic Neuropathy:**

Diabetic neuropathy (DN) is a common disorder and is defined as signs and symptoms of peripheral nerve dysfunction in a patient with diabetes mellitus (DM) in whom other causes of peripheral nerve dysfunction have been excluded (Bansal et al., 2006). It is a rarely cause of death, it is a major cause of morbidity. It causes clinical manifestations and disabilities of diverse spectrum and considerable severity. Both peripheral nerves (sensory and motor) and the autonomic nervous system can be affected (UNRWA, 2004). About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage. The results of such damage include impaired sensation or pain in the feet or hands, slowed

digestion of food in the stomach, carpal tunnel syndrome, and other nerve problems. Severe forms of diabetic nerve disease are a major contributing cause of lower-extremity amputations. (CDC, 2002a). One of the first study was to document the prevalence of neuropathy was the Rochester Diabetic Neuropathy Study ,which was a population-based cohort study of both type 1 and type 2 diabetes subjects ,in which Sixty-six percent of IDDM patients had some form of neuropathy; the frequencies of individual types were as follows: polyneuropathy, 54%; carpal tunnel syndrome, asymptomatic, 22%, and symptomatic, 11%; visceral autonomic neuropathy, 7%, and other varieties, 3%(Dyck et al.,1993). Diabetic neuropathy can be classified into four categories (Davidson, 1991) as shown in table 3.2.

**Table 3.2 Classification of diabetic neuropathy**

1	Peripheral neuropathy
2	Autonomic neuropathy
	a- Cardiovascular
	b-Gastrointestinal
	c-Genito-urinary
	d- Sudomotor
	e-Hypoglycemia unawareness
3	Acute-onset neuropathy
4	Neuropathic diabetic cachexia

Health behavior variables(recent medical contact, better control of dyslipidemia and blood pressure, regular glucose monitoring, lower glycated hemoglobin, physical activity in youth, and regular consumption (at least weekly) of alcohol) were more prevalent in subjects without complications. Using logistic regression, glycated hemoglobin level was the only independent predictor of complications after adjusting for health behavior Variables (Orchard, 1990b).

## **II. Macro vascular (Associated disease):**

**1) Cardio vascular disease:** Coronary artery, cerebrovascular, and peripheral vascular diseases are two to three times more common in people with diabetes than in general population (Davidson, 1991).Deaths from cardiovascular disease predominant in patients with diabetes of over 30 year's duration and in those diagnosed after 40 years of age (Pickup et al., 1991).Heart disease is the leading cause of diabetes-related deaths. Adults with diabetes have heart disease death rates about 2 to 4 times higher than adults without

diabetes. (CDC, 2002a). It accounts for approximately 50% of all deaths among people with diabetes in industrialized countries. (WHO, 2002), the risk for stroke is 2 to 4 times higher among people with diabetes, Risk factors for heart disease in people with diabetes include smoking, high blood pressure, high serum cholesterol and obesity( WHO 2002 ; Pickup J et al., 1991).The Pathogenesis of diabetic coronary heart and cardiovascular disease is not fully understood(Vinik and Flemmer, 2002). But it is likely that hyperglycemia promotes the reaction of glucose with components of the arterial wall to form advanced glycation products. These products cross-link with collagen, thereby increasing arterial stiffness (Bate and Jerums, 2003). In dyslipidaemia, increased levels of low-density lipoprotein (LDL) cholesterol, consisting mostly of small dense particles, promote atherogenesis. Hypertension promotes the development and progression of vascular disease (Bate and Jerums, 2003).

The major risk factors for coronary heart disease are increased level of serum cholesterol and elevated level of blood pressure.70-90% of diabetic people have dyslipidaemia (Fagot-Campagna et al., 2000).The UKPDS show that the risk of angina and myocardial infarction increase 1.57 fold time with an increase of 1mmol/L of LDL (Turner et al.,1998).Blood cholesterol was shown to be related to the coronary heart disease in the Steno clinic type 1 populations(Jensen et al.,1987).In the UKPDS men with hypertension show higher prevalence to develop coronary heart disease and non-fatal and fatal myocardial infarction (Turner et al.,1998). The prevalence of coronary heart disease in Pittsburgh Epidemiology diabetes complications study was associated with diabetes duration, hypertension, nephropathy and elevated TG (Maser et al., 1991).Among type 1 diabetic patient ,the WESDR study found that an significant association between HbA1c and four-year incidence of ischemic heart disease(Klein ,1995).There are many other risk factors that increase coronary heart disease .Microvascular complications increase the risk of coronary heart disease, microalbuminuria increase the risk for coronary heart disease in diabetic patients(Gall et al .,1995).

## **2) Diabetic foot:**

Foot ulceration, sepsis, and amputation in diabetic patient are almost present and increase with poor glycemic control and duration of diabetes, and this is a major cause of morbidity and disability of diabetic patient. Neuropathy and ischemia are the principal disorders

underlying foot problems. Figure 3.3 & figure 3.4 illustrate both ulcers how they are look in diabetic patient (Watkins, 2003).

In the United State more than 60% of nontraumatic lower-limb amputations occur among people with diabetes. In 2000-2001, about 82,000 nontraumatic lower-limb amputations were performed annually among people with diabetes (CDC, 2002). The cause of a diabetic foot is peripheral neuropathy with loss of sensation, peripheral vascular disease, callus, and foot bony deformity, and infection (WHO, 2002).



**Figure 3.3 Neuropathy ulcers in diabetic patient**



**Figure 3.4 Ischemic ulcers in diabetic patient**

### **3.6 Diabetes diagnosis and services**

#### **I. Diagnosis**

The American Diabetes Association criteria for the diagnosis of diabetes include symptoms of diabetes and a casual plasma glucose  $\geq 200$  mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss. The American Diabetes Association (ADA) recommends cutoff value for the diagnosis and classification of diabetes and for a fasting plasma glucose level indicative of diabetes mellitus. The

recommended cutoff point for the diagnosis of diabetes is now a fasting plasma glucose level of 126 mg/dl (7.0 mmol/L), versus the traditional value of 140 mg per dL (see table 3.3) (7.8 mmol/L). Table 3.3 presents the criteria for the diagnosis of diabetes (ADA, 2003; Peter, 2003).

Diagnosis of type 1 diabetes is usually straightforward and requires little or no specialized testing. Most children and adolescents with type 1 diabetes present with a several-week history of polyuria, polydipsia, polyphagia, and weight loss, with hyperglycemia, glycosuria, ketonemia, and ketonuria. Glycosuria alone, especially without ketonuria, may be caused by a low renal glucose threshold. Thus, an elevated blood glucose concentration must be documented to diagnose diabetes (ADA, 2005).

Table 3.3 Criteria for the diagnosis of diabetes

- Symptoms of diabetes plus casual plasma glucose concentration 200 mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

Or

- FPG 126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.

Or

- 2-h PG 200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

In the absence of unequivocal hyperglycemia with acute metabolic decompensate, these criteria should be confirmed by repeat testing on a different day. The third measure (OGTT) is not recommended for routine clinical use. Adapted from the report of the expert committee on the diagnosis and classification of diabetes mellitus (ADA, 2003).

## 2) Insulin therapy and action

The patient with type 1 diabetes has lost the ability to produce insulin and is therefore dependent upon externally administered insulin without which they would die. The treatment of type 1 diabetes is therefore relatively straight forward; insulin, which act as a major tool in the treatment of type 1 diabetes in spite of the impossibility of giving it in a physiological way (Larsson , 1997). Factors such as onset, peak and duration of action can influence the ability of a particular insulin regimen to help control glucose levels. Patient factors, including individual variations in insulin absorption, levels of exercise and types of

meals consumed, also influence the effectiveness of an insulin regimen. (Hirsch, 1999; Raskin et al., 2000). The different types of insulin injection range from short-acting and intermediate to long-acting, the important characteristics of each type of insulin are: the onset (i.e. when it starts to work), the peak activity (i.e. when it works hardest), and the duration (i.e. how long it lasts). Table 3.4 summarizes the different kinds of human insulins and how they act.

**Table 3.4 Kinds of human insulin and how they act**

Type	Onset	Peaks	Duration
<b>Regular</b>	<b>30-60 minutes</b>	<b>2-3 hours</b>	<b>4-6 hours</b>
<b>NPH</b>	<b>2-4 hours</b>	<b>4-10 hours</b>	<b>14-18 hours</b>
<b>Lente</b>	<b>3-4 hours</b>	<b>4-12 hours</b>	<b>16-20 hours</b>
<b>Ultralente</b>	<b>6-10 hours</b>	<b>minimal peaking</b>	<b>20-30 hours</b>
<b>Lispro (Humalog)</b>	<b>Less than 15 minutes</b>	<b>30-90 minutes</b>	<b>Less than 5 hours</b>
<b>70/30</b>	<b>15-30 minutes</b>	<b>2-3 hours &amp; 8-12 hours</b>	<b>18-24 hours</b>

The major function of insulin is to counter the concerted action of a number of hyperglycemia-generating hormones and to maintain low blood glucose levels between 54-144 mg/dl (3-8 m mole/L). When food ingestion and absorption causes a rise in blood glucose which almost factors that stimulate insulin secretion from the beta cell of the pancreas which act to maintain a constant level of blood glucose by decreasing glucose output from the liver and increasing glucose intake and glycogen formation in the muscles. Insulin increases the conversion of glucose to glycogen in the liver, promotes the uptake and utilization of glucose by muscles and adipose tissue, and suppresses the production of glucose from fats and proteins in the liver. Insulin also stimulates entry of amino acids into cells, enhancing protein synthesis, enhances fat storage and prevents mobilization of fat for energy (lipolysis) (Alberti et al., 1997).

In developed countries the problem with insulin therapy lies not in access to insulin, syringes or blood glucose monitoring, as it does in developing countries, but in how to use them correctly to achieve near-normoglycaemia (King et al., 1999). In the EURODIAB IDDM Complications Study of Type 1 diabetic patients in 16 European countries, only 16% of patients had a normal HbA1c (EURODIAB IDDM Complications Study, 1994).

### **3.7 Management and follow up and control**

There is no known method to prevent type 1 diabetes according to diabetes control and prevention of WHO (WHO, 1994; Rewers, 1997). The high and increasing incidence, associated with severe morbidity, mortality and enormous health care expenditure, makes Insulin dependent diabetes Mellitus (IDDM) a prime target for prevention. The aim of treatment is to achieve glycemic control and to reduce and delay the appearance of diabetic complications. In treatment of type 1 diabetes, self-care and education, insulin therapy type and dose, health care provider, Screening for the long-term complications of diabetes, diet and home monitoring of glucose are considered to play a corner stone role in controlling the disease and in prevention or the delay of early and late complications (LeRoith et al., 2005; Dorey et al., 2006). Self-control led therapy is vital in the treatment of IDDM, allowing as it does, correct insulin therapy, a reduction in hospitalization and modification of therapy for individual needs in relation to various factors. Undoubtedly it is the responsibility of the diabetes team (doctors, nurses, dietician, psychologist and social assistant) to instruct the patient and help him /her in this new situation. (Lombardo et al., 2003).

#### **1) Monitoring and Glycemic Control Assessment:**

Glycemic control is fundamental to the management of diabetes. The goal of therapy is to achieve an HbA1c as close to normal as possible (representing normal fasting and postprandial glucose concentrations) in the absence of hypoglycemia. HbA1c is a measure of the non-enzymatic attachment of glucose to the  $\beta$  chain of hemoglobin and is expressed as the percentage of hemoglobin that is glycated. In the non-diabetic population this is approximately four to six per cent. Since the life-span of a red blood cell is approximately 120 days, HbA1c gives an indication of average glycaemia over a 60 day period (BMA, 2004). Although the relationship between HbA1c and plasma glucose is complex, the extensive data collected from the DCCT has been defined table 3.5.

**Table 3.5 Relationship between HbA1c and approximate mean plasma glucose levels**

<b>Percentage HbA1c</b>	<b>Approximate mean plasma glucose (mmol/l)</b>
<b>4</b>	<b>3.5</b>
<b>5</b>	<b>5.5</b>
<b>6</b>	<b>7.5</b>
<b>7</b>	<b>9.5</b>
<b>8</b>	<b>11.5</b>
<b>9</b>	<b>13.5</b>
<b>10</b>	<b>15.5</b>
<b>11</b>	<b>17.5</b>
<b>12</b>	<b>19.5</b>

Prospective randomized clinical trials such as the DCCT and the U.K. Prospective Diabetes Study (UKPDS) have shown that improved glycemic control is associated with sustained decreased rates of retinopathy, nephropathy, and neuropathy. In these trials, treatment regimens that reduced average A1C to  $\approx 7\%$  ( $\approx 1\%$  above the upper limits of normal) were associated with fewer long-term microvascular complications (DCCT, 1993; UKPDS, 1998).

## **2) Home monitoring and Self-care:**

Home blood glucose monitoring is one of the corner-stones in the management of type 1 diabetes (Blohme , 1983). Major clinical trials assessing the impact of glycemic control on diabetes complications have included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy (ADA, 2003). Good metabolic control was associated with numerous daily measurements of blood glucose whereas no independent connection was found between the form of treatment and the level of regulation (Wengler et al., 1989). The decrease in hemoglobin A1C concentration associated with increase number of reagent strips used (Josie et al., 1999).

Diabetic patients should be taught and encouraged to test their urine for glucose and ketones, although this is not as accurate as blood glucose monitoring, they need to be taught that the basis for urine glucose measurement is that glucosuria is correlated with hyperglycemia. Ketone testing is an important part of monitoring in type 1 diabetic patient, in pregnancy with pre-existing diabetes, and in gestational diabetes. The presence of



ketones may indicate impending or even established ketoacidosis, a condition that requires immediate medical attention. Patients with type 1 diabetes should test for ketones during acute illness or stress or when blood glucose levels are consistently elevated (e.g., >300 mg/dl [ $>16.7$  mmol/l]), during pregnancy, or when any symptoms of ketoacidosis, such as nausea, vomiting, or abdominal pain, are present (ADA, 2003, Bassili et al., 2001).

Home blood pressure monitoring is of value in the management and monitoring of diabetic children (Gompels and Savage, 1992). In general every 10 mmHg reduction in systolic blood pressure the risk of any complication related to diseases is reduced by 12%, and can reduce heart disease by approximately 33% to 50 % and can reduce micro vascular disease by approximately 33% (CDC, 2002 b).

### **3) Protocols of follow up of diabetes type-1 patients:**

Primary care providers are the main source of care for patients with chronic disease (Clancy et al., 1997). Studies examining the quality of care delivered by provider type (generalist or specialist physician) in chronic diseases have generally demonstrated that specialists adopt newer, more effective treatment techniques and may be more cost-effective when compared with generalists (Levetan et al., 1999). Attendance at diabetic clinics forms part of diabetic management. Diabetic patient should attend diabetic clinics monthly for check up or as indicate by health care providers. Diabetic clinics exist to review treatment and control blood glucose, to screen for early detection of complications and for ongoing health education. Poor glycemic control was found in diabetic patient who were attending diabetic clinic infrequently compared to those who attended regularly (Jacobson et al., 1997).

The recommended protocol for monitoring patients with diabetes according to American Diabetes Association include two basic guidelines physical assessment and lab examination as shown in table 3.6 (ADA, 2002).

**Table 3.6 ADA Protocols for diabetes diagnosis**

<b>Physical Assessment</b>	<b>Lab Exam</b>
<p><b>Blood Pressure, Weight</b> (for children, add height; plot on growth chart) Every visit. Blood pressure target goal &lt;130/80 mmHg (children &lt;90 pctl age standard).</p> <p>Children: normal weight for height (see standard growth chart).</p>	<p><b>HbA1c</b></p> <p>Quarterly, if treatment changes or is not meeting goals; 1-2 times /year if stable. Target goal &lt; 7%</p>
<p><b>Foot Exam</b></p> <p>Through visual inception every diabetes visit; pedal pulses , neurological exam annually.</p>	<p><b>Kidney Exam(Microalbuminuria)</b></p> <p>Albumin/Creatinine Ratio</p> <p>Type 1: 5 years post diagnosis, then every year until confirmed positive.</p>
<p><b>Eye Exams</b></p> <p>Type 1 diabetes: comprehensive eye examination by an ophthalmologist within 3-5 years after the onset of diabetes, then every year</p> <p>Pregnant women (diabetic) should have a comprehensive eye examination in the first trimester and follow up through pregnancy and for 1 year postpartum</p>	<p><b>Blood lipids</b></p> <p>In children &gt;2 years of age, perform a lipid profile after diagnosis of diabetes and when glucose control has been established. If values are considered low risk and there is no family history, assessments should be repeated every 5 years.</p>

### **3.8 Risk factors for diabetes type 1 and its complications**

Several risk factors have been suggested to be of importance for development of macro and microvascular complications in type 1 diabetes ( Table 3.7).Long-term glycemic control and diabetes duration are well-known risk factors for the development of microvascular complications in type 1 diabetes, and it has also been shown that intensive insulin treatment and improved glycemic control delays the onset and slows the progression of these complication, while the other association have been more controversial with partly

contradictory finding in different studies. The causal relationship between these factors and the development of complications is unclear and better term would be risk markers.

Table 3.7 Possible risk factors for long term diabetic complications

I.	Duration of diabetes
II.	Metabolic control
III.	Gender
IV.	Age at onset and Puberty
VI	Lipid profile
VII	Blood pressure
VIII.	BMI
IX.	Smoking
X.	Genetic factors
XI.	Insulin resistance

### **I. Duration of diabetes**

Practically all studies demonstrate increasing prevalence of severe complications after longer diabetes duration, but the pattern differs between nephropathy, retinopathy, and neuropathy.

By 25 years' duration of type 1 diabetes, 25–40% of patients will have developed renal complications. The incidence of diabetic nephropathy increases steeply after 10 years of disease and then declines once again after 30 years (Andersen et al., 1983; Rossing et al., 1995). The incidence peak of diabetic nephropathy occurs during the second decade of T1DM and declines thereafter (Andersen et al., 1983). While only a slight increase in the prevalence of microalbuminuria has been observed during the second decade of diabetes in young adult patients (Joner et al., 1992).

Most studies demonstrating a relationship between microalbuminuria and progression to diabetic nephropathy have included subjects with a mean duration of diabetes <17 years (Mathiesen et al., 1994)

The duration of diabetes may have less influence on diabetic nephropathy and microalbuminuria than on retinopathy. Prevalence of retinopathy increases with increasing duration of the disease, since one third of patients with duration between 10 and 12 years have retinopathy (Kernell et al., 1997), and nearly all of those with duration of 20 years or

over have it to some degree (Olsen et al., 2000; Kokkonen et al., 1994). Patients with type 1 diabetes diagnosed between 10 and 30 years of age may experience significant retinal changes within ten years thereafter (Joner et al., 1994), and proliferative retinopathy appears to 4% of those who have had diabetes for 10 years, 25% of those with 15 years of diabetes (Klein et al., 1984), and 30% of those who have had it for over 20 years (Kokkonen et al., 1994).

Most studies show that duration of diabetes in addition to poor diabetic glycaemic control have a negative impact on peripheral nerve function in children and adolescents with type 1 diabetes (Ziegler et al., 1991; DCCT, 1993).

Macrovascular complications developed in people who were older, and had longer duration of diabetes (Latika et al., 2006)

### **Metabolic control**

Several studies have demonstrated the effects of improved glycaemic control on microvascular, macrovascular, and neurological complications of diabetes. The rate of background retinopathy in the Berlin Retinopathy Study was found to increase with deteriorating glycaemic control, the greatest progression being observed in patients with long-term HbA1c within the highest quartile (Danne et al., 1994). The progression of diabetic retinopathy in adolescent patients with high HbA1c and long duration of diabetes was twice comparing to patients without these risk factors (Bonney et al., 1995). Javitt et al models predicted that 72% of patients with type 1 diabetes and inadequate metabolic control would develop proliferative retinopathy at some stage in their life-time (Javitt et al., 1989).

In patients with type 1 diabetes mellitus the progression of minimal albuminuria and the development of microalbuminuria are determined primarily by poor long term glycaemic control (Powrie et al., 1994), and poor control during the first years of diabetes in particular may later predispose to microalbuminuria (Rudberg et al., 1993).

Rossing et al reported that the relative risk for progression from normoalbuminuria to micro- or macroalbuminuria in a large prospective study from Denmark was 1.13 (95% confidence interval, CI 1.04–1.23) for patients with poor metabolic control (Rossing et al., 2002). Improvement of metabolic control will improve nerve conduction, which is slightly reduced at the time of diagnosis of type 1 diabetes, (Dahl-Jørgensen et al., 1986), and long-term normoglycaemia retards the development of peripheral nerve dysfunction (Amthor et al., 1994). The Oslo study show that decreases in motor and sensory nerve

conduction velocities along with deterioration of glycaemic control, independently of other parameters (Amthor et al., 1994). The role of chronic hyperglycemia for the development of Cardiovascular disease in type 1 diabetes is unknown (Nathan et al., 2003).

### **Gender**

The effect of sex on the risk of microvascular complications of type 1 diabetes is partly controversial. Men have a higher risk of nephropathy than women (Andersen et al., 1983), whereas no such clear relationship with sex has been demonstrated for elevated urinary AER or microalbuminuria (Canton et al., 2004; Ammari, 2004).

The risk of ESRD did not differ significantly between sexes (Finne, 2005). Retinopathy is more frequent in males (Pinto-Figueiredo et al., 1992). The EURODIAB Study reported moderate non-proliferative diabetic retinopathy to be significantly less frequent in women than in men, but mild nonproliferative and proliferative diabetic retinopathy did not differ between the sexes (Sjolie et al., 1997). Distal symmetrical polyneuropathy shows a constant rise with duration and is only marginally higher in men (Orchard et al., 1990).

coronary heart disease (CHD) incidence rate was slightly higher in males, while lower-extremity arterial disease (LEAD) incidence rate was slightly higher in females( Forrest et al., 2000),in other study the prevalence was the same in both sexes(9% in men and 10% in women) (Koivisto, 1996).

### **Age at onset and Puberty**

The observation that puberty is the watershed for the development of diabetic complications indicates that hormonal factors may be important.

The prevalence of early diabetic retinopathy in pubertal patients with type 1 diabetes was significantly greater than prepubertal subjects (Rogers et al., 1987), while it is extremely rare in children younger than 10 years, regardless of the duration of diabetes (McNally et al., 1993). In a Swedish multi center study, regardless of diabetic retinopathy stage, it was detected in 6% of the prepubertal patients compared with 18% of the post pubertal patients with a similar duration of diabetes (Kernell et al., 1997).

Prepubertal hyperglycemia in type 1 diabetes contribute to the risk of microalbuminuria during puberty and postpubertal(Schultz et al., 1999). Pubertal development seems to initiate or accelerate the progression of microalbuminuria or early kidney damage in type 1 diabetes (Schultz et al., 1999; Barkai et al., 1998).

Some studies have emphasized that microalbuminuria is more frequent in early than late puberty (Janner et al., 1994). The progression of AER and the risk of persistent

microalbuminuria are higher in pubertal patients than in prepubertal or postpubertal ones (Barkai et al., 1998), while if microalbuminuria is diagnosed at the end of puberty, it is more likely to progress than regress (Rudberg and Dahlquist , 1996).

### **Lipids and lipoproteins**

Elevated triglyceride and low HDL-cholesterol (Chaturvedi et al.,2001; Chaturvedi et al., 2001) , and increased total and LDL-cholesterol (Watts et al.,1996) have been reported to predict diabetic retinopathy and diabetic nephropathy. High density lipoprotein cholesterol predicts CVD in EURODIAB IDDM Complications Study, while triglycerides and hypertension predict CVD in the Pittsburgh Epidemiology of Diabetes Complications Study (EDC) (Orchard et al., 1998).

### **Blood pressure**

Numerous studies have demonstrated that increased systolic or diastolic blood pressure is a powerful predictor of microvascular complications. The 10-year incidence of proteinuria performed by a population-based study in southern Wisconsin of individuals with diabetes was significantly related to higher glycosylated hemoglobin level and diastolic blood pressure (Klein et al., 1995). Although hypertension is almost always associated with diabetic nephropathy in T1DM, elevations in routine office BP have not consistently been identified before the onset of MA (Schultz et al., 2001). However, one small study reported that an increased night to day ratio of arterial BP might precede the development of MA in which measured 24 hour ambulatory BP was measured (Poulsen et al., 1994), although BP may not be important in the initiation of diabetic retinopathy, a higher diastolic BP, even within the normal range, may increase the risk of progression of retinal lesions( Lloyd et al 1995). The presence of micro- or macroalbuminuria may also modify the effect of BP on the progression of retinopathy (Lloyd et al., 1995). Hypertension showed the greatest impact on the development of clinical neuropathy in adult patients with type 1 diabetes, in addition to other risk factors such as poor metabolic control, smoking, duration of diabetes and height(Forrest et al., 1997).

### **BMI**

Overweight (BMI  $\geq 25$  kg/m<sup>2</sup>) and obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) are becoming increasingly prevalent in the industrialized world, not only in type 2 but also in type 1 diabetic patients (Christophe et al., 2005). The role of body weight/BMI in the development of vascular complications of diabetes is unclear. However, information on the possible role of BMI on

retinopathy in type 1 diabetes is scarce. Zhang et al revisited data from the Diabetes Control and Complications Trial and observed that besides diabetes duration and metabolic control, BMI had a significant predictive value in developing retinopathy (Zhang et al., 2001). In Sweden, Henricsson et al observed that time to develop retinopathy among young adult people with diabetes was related to high HbA<sub>1c</sub> (A1C) and high BMI (Henricsson et al., 2003). Only one recent report suggested a role of BMI in neuropathy (Tesfaye et al., 2005). BMI above 30 kg/m<sup>2</sup> show significant relation ship with CVD (Ammari, 2004; Latika et al., 2006).

### **Smoking**

The evidence for cigarette smoking as a risk factor for diabetic nephropathy in type 1 diabetes has been inconsistent. Many studies have found significant association between cigarette smoking and advanced stages of diabetic nephropathy (Muhlhauser et al.,1986; Mühlhauser et al., 1996), but other study has not supported this association (Klein et al., 1995). The discrepancies might have resulted from increased mortality of those who smoked cigarettes. Significant association between the development of microalbuminuria and smoking was reported in a few studies (Chase et al., 1991, Chaturvedi et al., 1995), while other studies have not show like this association (DCCT, 1995).The connection between smoking and retinopathy is also controversial. Some authors have found clear association between progressions, prevalence and worsen of retinopathy and smoking (Muhlhauser et al., 1996, Chaturvedi et al., 1995; Chase et al., 1991), while other authors failed to demonstrate this connection (Moss et al., 1996). The diverging results could in part be explained by not adjusting for the possible confounding effect of metabolic control in some studies. Psychosocial factors could speculatively affect both smoking habits and the possibility to achieve a good metabolic control (Chaturvedi et al., 1995).

### **Genetic factors**

The risk of diabetic complications is most likely partly inherited. A family history of either diabetic nephropathy or retinopathy is associated with an increased risk of these complications in relatives with T1DM (DCCT, 1997). The risk of nephropathy is increased in patients who have siblings with type 1diabetes and nephropathy. This familial clustering suggests that genetic factors are important in the development of renal disease (Seaquist et al., 1989; Quinn et al., 1996). Furthermore, parental hypertension and parental type 2 diabetes are also associated with nephropathy risk in the offspring (Roglic et al., 1998;

Krolewski et al., 1988; Fagerudd et al., 1999). However, one study investigated parental factors in 300 young subjects and found that familial cardiovascular disease were associated with MA in the offspring(Rudberg et al., 1998).Thus family phenotypes may be useful markers of risk of microvascular disease.

### **Insulin resistance**

Is emergent risk factor for both macro- and microvascular complications in type 1 DM (Chaturvedi et al., 2001; Chaturvedi et al., 2001). but it is not clear if this phenomenon is mediated by associated risk factors (Porta et al .,2001)) or a common genetic determinant (De Cosmo et al .,2000 ;Lustman et al.,2000).

### **3.9 Summary**

As was shown in the conceptual framework diagram, this model content has been reflected in the questionnaire and the objective testing and physical examination that was done in this survey. This was done in the following matter:

In the questionnaire: Questions 1-13 reflects the demographic factor, questions 14-20 reflects physical measurement .questions 21-28 reflect diabetes history. Questions 29-30 reflect diabetes treatment, questions 31-41 reflect diabetes complications, questions 42-47 reflect self monitoring, and questions 48-55 reflect PHC services and physical and screening examinations.



## **Chapter Four. Study methodology**

**4.1** Introduction

**4.2** Study socio-demographic and geographic area description

**4.3** Health services in Ramallah District

**4.4** Study population

**4.5** Study design

**4.6** Study tools and equipment

**4.7** Data collection

**4.8** Ethical considerations

**4.9** Data analysis

**4.10** Operational Definitions

**4.11** Summary

## 4.1 Introduction

This study focuses on diabetic patients' type 1. The emphasis was on identifying the treatment and follow up protocols used for those patients and the prevalence of disease complications. In this chapter the research methodology: i.e. the study geographical area, study population, study design, and the sampling method are described. Study tool and the objective testing that were used to collect the data and testing those patients, in addition to statistical analysis method are also described.

## 4.2 Ramallah socio-demographic and geographic area description

Ramallah District is located in the middle part of the West Bank, extends from Jerusalem District in the south to Nablus District in the north and from Jericho District in the east to the 1948 cease-fire line between Israel and Jordan from the west (see figure 4.1A, and figure 4.1B).

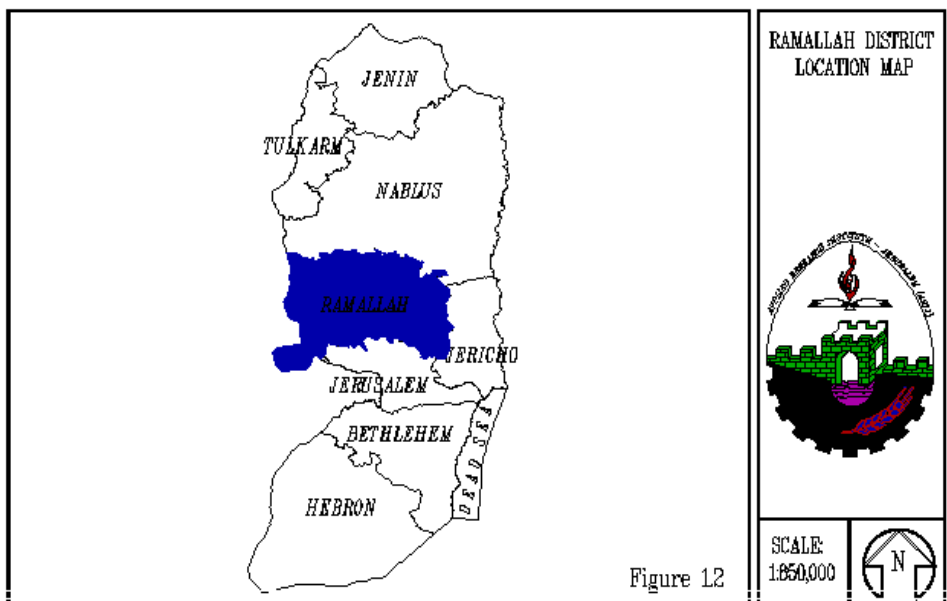
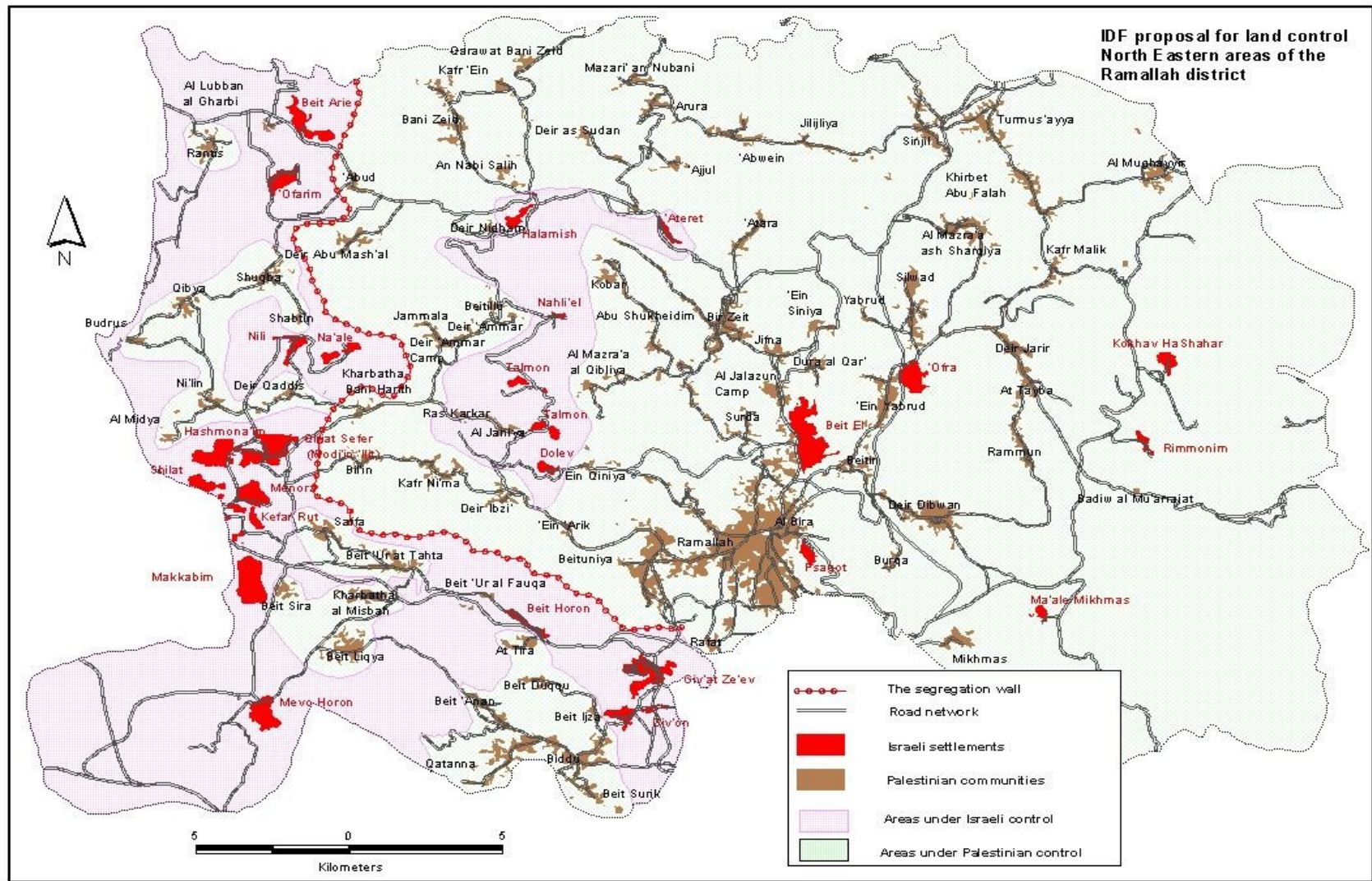


Figure 12

**Figure 4.1: Ramallah District location**



Figure(4.1B):Ramallah district

Demographic trends in Ramallah District, as is the case of other districts in the West Bank, have been closely related to the political situation. According to the population statistics estimated by the Palestinian Center Bureau of Statistics (PCBS), the mid year total population of 2004 was around 285,000 individuals, which includes the four refugee camps population. The population of Ramallah and Al-Bireh cities comprises approximately 26% of the total population of the district, while those living in rural areas present 65% of the total population. Approximately 9% (16,500) lives in the four refugee camps, i.e. Al-Ama'ri, Al-Jalazone, Qaddura and Deir A'mmar (PCBS, 1994; UNRWA Report, 1994). Ramallah District has a very young population with 58.4 % less than 18 years old, with a 1:1 male to female ratio.

The dominant economic activity in Ramallah District is the manufacturing industry. The major industrial activities are centered on food processing and the manufacture of pharmaceuticals (Center for Engineering and Planning, 1993). The economy of Ramallah District is affected by the political situation in the area. Approximately 63.2% of the working age population (16-59) is employed. Out of which 81.3% are permanently employed, 6.1% have seasonal employment, and 12.6% have part-time jobs. The unemployment rate is nearly 36.8% (PARC & Arab Thought Forum, 1994). A large number of people from Ramallah District have immigrated to other countries especially to the United States of America. Those people retain their strong relations with their families and their homeland and send money back to be invested in economic activities. With these added resources, Ramallah became the economic center in the West Bank. During the past two years, Ramallah city has developed at a high rate where many new commercial centers and housing projects have been constructed and many investors started their own businesses.

### **4.3 Health services in Ramallah District**

The Palestinian health care system is a mixture of governmental, non-governmental, United Nation Relief and Work Agency (UNRWA) and private (profit and non-profit) service delivery. These health providers are over lapping in services, and none of these sector can provide comprehensive health services.

### **A- Primary Health Care services**

There are approximately 55 primary health care clinics (PHC) in Ramallah District, 41 are sponsored by the Ministry of Health (MOH), 9 PHC clinics are operated by various non-governmental organizations, and UNRWA runs 5 PHC clinics serving the refugees (MOH-PHIC, 2004).

### **B- Secondary health care services:**

Five hospitals provide the secondary health care services to the residents of Ramallah District. In total, there are 186 hospital beds which are insufficient to provide satisfactory health services to more than 176,154 people in the district. The main governmental hospital is Ramallah hospital, which is always crowded and patients must wait several weeks for an appointment. While there are higher quality hospitals in Jerusalem, closure of Jerusalem greatly restricts people living in Ramallah District from using these facilities even though they are only few kilometers away (PCH ,1994).

### **C-Health care services provided for diabetic patients**

Two main health care providers provide health care for diabetes type I patients, i.e. the MOH and UNRWA PHC centers at Ramallah district. These two providers provide care and treatment especially insulin for type I diabetic patients. The Governmental health sector is providing special health services to diabetes patients through the clinics present in every PHC centers in all cities of the Palestine. The diabetes program of MOH is to a large extent biometrically oriented. Diabetic patients who are insulin dependent and have health insurance get their insulin free of charge. Similarly, the UNRWA provides services for the diabetic registered refugee patients free of charge and also provide them monthly with the needed insulin (personal communications, 2006).

## **4.4 Study population size**

It is well known that PHC centers are the main venues for regular and systematic care for diabetic patients. Management services for non-communicable diseases care are integrated within the PHC centers at MOH & UNRWA centers. For our study the source of data was found in one MOH clinic and three UNRWA clinics at different PHC centers at Ramallah district.

The study focus on type 1 diabetes mellitus patients receiving health care in the PHC centers of UNRWA and MOH at Ramallah district. The original sample consists of all patients of diabetes type 1 of both males and females in the different age groups. Information about these patients was extracted from their files that presented in the clinics and a prepared list was done to approach these patients when they come in their monthly visits to the clinics.

According to the registration's files of diabetic patients at primary health care centers of MOH and UNRWA at Ramallah district, the number of patients with type 1 diabetes was 142 patients, but only 116 were included in the study. The distributions and agreement to participate in this study is shown in table 4.1.

**Table 4.1: the distributions and participation of diabetic type I**

No of patient	Agree No (%)	No response No (%)
MOH 102 (71.8%)	81(57%)	21(14.8%)
UNRWA 40 (28.2%)	35(24.6%)	5 (3.6%)
Total number 142(100%)	116(81.7%)	26(18.3%)

#### 4.5 Study design

The study was cross-sectional . This design was chosen to meet the objective of the study, namely to determine the complications of diabetes and primary health care services for type 1 diabetic patients at Ramallah district. Information on complications, primary health care services, and other risk factors was collected at two levels, the first one included interview-only data and the second with objective testing( HbA1c testing, lipid profile ...etc) and physician's examination(Eye examination, neuropathy ...etc).

#### 4.6 Study tools and equipment

##### 4.6.1 The interview questionnaire

A pre-designed questionnaire was used by the researcher. Previously validated questionnaires were used to develop the study questionnaire. This questionnaire was selected from different previous studies (Abu Mousa, 1998; Siddiqui et al., 2003)

Questionnaire was developed for the study with the aim to cover the most important areas of interest regarding the patient s life and the services offered in the studied PHC centers.

**The study interview questionnaire was divided into the following sections:**

1. First part: demographic data such as sex, age, marital status, education completed, occupational history.
2. Second part: the vital measurement of people with diabetes such as present weight, height, blood pressure, HbA1c value.
3. Third part: the history of disease.
4. Fourth part: diabetes management through diet, and insulin medications.
5. Fifth part: clinical status and complications (history of cardiac disease, presence of neuropathy, presence of retinopathy, presence of nephropathy, presence of amputation, hypertension and hospitalization due to diabetes)
6. sixth part: primary health care therapy protocol e.g., blood glucose testing, insulin administration, number of visits to physicians, etc.
7. Seventh part: Includes questions on home monitoring (testing blood glucose, measure BP, and urine glucose and ketone test (see appendix 1).

**4.6.2 Questionnaire piloting and validation**

The questionnaire was piloted before using in the field. At initial stage of survey, a pilot test was provided on patients from the two settings of interest. Twenty patients of type II diabetic for pilot study were selected from those who attended the diabetic clinics of MOH and UNRWA. Interview was held in the clinic after the patient has been told about the study and its' aims, acceptance to participate in the study was noted in most patients.

The main aim of the pilot study was to examine the study instrument (the questionnaire) and to determine the ability of the study method to cover and efficiently lead to the desired goals .As a result of the pilot study, there were some necessary modifications on some questionnaire elements.

For questionnaire validation, the contents of the questionnaire were discussed with experts and specialists in the field of diabetes mellitus in governmental, UNRWA and NGOs to ensure that the core content is highly valid and reliable.

### 4.6.3 The objective testing:

All patients filling the questionnaire at the first stage were scheduled for having biomedical testing, blood pressure and ECG, ophthalmologist consultation and endocrinologist consultation.

#### a- Biochemical blood testing:

A fasting blood sample was taken by venipuncture; this sample was divided into two tubes. One tube has an EDTA anti coagulant used for measurement of HbA<sub>1c</sub>, the second tube which is an plane tube used for measurement of Glucose ,Urea ,Creatinine ,and Lipid profile.

1. **Glycohemoglobin HbA1-Test:** measurement of HbA<sub>1c</sub> using the Fast Ion-

Exchange Resin Separation method produced by Human Company which has a Batch no 10658. Normal and abnormal control was run with each set of analysis to insure internal quality control.

2. **Fasting blood testing:** Glucose determination was done by GOD-PAP assay without deproteinisation produced by Randox Company which has batch no 057802. Semi micro procedure was used in which 10µl of serum sample, standard, and control were added to 1 ml of glucose reagent, then incubation at 37° C for the required time. Reading for the test tubes was taken by spectrophotometer and finally calculation was done to get the final result depending on the result of controls.

3. **Creatinine** was measured by colorimetric method (picric acid), produced by Randox company which has patch no 1040CR. Semi micro procedure was used in which 100µl of serum sample, standard, and control were added to 1 ml of working reagent of picric acid and sodium hydroxide, then incubation at 37° C for the required time. Reading for the test tubes was taken by spectrophotometer and finally calculation was done to get the final result depending on the result of controls.

4. **Urea, BUN:** Urease-modified Berthlot reaction was used in the determination of Urea. Kit which is used was produced by BioMerieux Company which has patched no 61912. 10µl of serum sample, standard, and control were added to 1 ml of working solution (urease added to color reagent), then incubation for 5 min at room temperature , after that 200 µl of alkaline reagent added to each test tubes then incubation for 10 min at room temperature. Reading for the test tubes was taken by spectrophotometer



and finally calculation was done to get the final result taking in the consideration the result of controls.

**5. Cholesterol measurement:** was done by Enzymatic Endpoint Method manual method. Kit which is used was produced by Randox Company which has patch no 054457. 10 $\mu$ l of serum sample, standard, and control were added to 1 ml of cholesterol reagent, then incubation at 37° C for the required time. Reading for the test tubes was taken by spectrophotometer and finally calculation depending on the following equation was done to get the final result taking into consideration the result of controls.

$$\text{Conc. Of cholesterol in sample} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times \text{conc. standard}$$

**6. HDL-cholesterol:** was determined by precipitant manual method. Kit which is used was produced by Randox Company which has patched no 055408. Macro procedure was used in which 0.5 ml of serum sample, standard, and control were added to 1 ml of precipitant reagent, then incubation for 10 min at room temperature. Separation off the clear supernatant within tow hours and determine the cholesterol content by the CHOD-PAP method by adding 100 $\mu$ l of serum sample, standard, and control to 1 ml of cholesterol reagent, then incubation at 37° C for 5 min. Reading for the test tubes was taken by spectrophotometer and finally calculation depending on the following equation was done to get the final result taking into consideration the result of controls.

$$\text{Conc. Of HDL- cholesterol in sample} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times \text{conc. standard}$$

**7. LDL cholesterol:** the following equation was used for determination of LDL LDL-Cholesterol=Total cholesterol-Triglyceride/5-HDL cholesterol

**8. Triglyceride measurement:** was determined by GPO-PAP method. Kit which is used was produced by Randox company which has patch no 760TR. 10 $\mu$ l of serum sample, standard, and control were added to 1 ml of TG reagent, then incubation at 37° C for the required time. Reading for the test tubes was taken by spectrophotometer and finally calculation depending on the following equation was done to get the final result taking into consideration the result of controls.

$$\text{Conc. Of TG in sample} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times \text{conc. standard}$$

**Quality control Sera :** were used to achieve internal quality control for each test, this control was manufacture by Randox Company which is the same company that the kit was

used for Biochemistry test except for Urea test which used another control. Duplication and repeat the tests was done to check the accuracy of results.

#### **b- Blood pressure and electro-cardio gram (ECG) examination**

Each patient was scheduled to have an ECG testing and Blood pressure measurement at the day of having an endocrinologist consultation.

#### **c- Ophthalmic examination**

The procedure for eye examination at ophthalmologist clinic include the following ;

Vision examination was done by Snellen's chart first without glasses then with glasses and refraction is done to each patient for the best corrected visual acuity.

Intra ocular pressure is done by applanation Goldman Tonometer.

Each patient his fund was examined after pupillary dilation with tropic amide (0.5% Mydramide) two to three drops for at least 30 min, and then funds are examined.

Classification of diabetic retinopathy was done according to American Academy of Ophthalmology.

Patient who is at higher risk where asked to be checked closely .While patients with poor visions which can not be explained by diabetic retinopathy were underwent more ophthalmic examinations to diagnose there poor vision (see appendix 2).

#### **D-Diabetes specialist evaluation criteria**

The evaluation of diabetic patient situation was done by an expert in the field of this disease depending on laboratory tests, ECG reading , Blood pressure measurement, patient examination ,previous history finding of patient, and the result of eye examination which done by an ophthalmologist.

### **4.7 Data Collection**

#### **I) Questionnaire:**

For the interview questionnaire, patients who were registered in the pre-prepared lists in the two main centers, i.e. Ramallah PHC center and Al-Ama'ri, Al-Jalazone and Qalandia PHC centers were approached at the day of their visit to fill in the questionnaire. The questionnaire was answered by the patients themselves or by their parents in case of being a child. After signing the informed consent and understanding the aim and objectives of this study, a pre-trained nurse and the research himself asked the questions and filled in the answers as reported by the patients or their guardian.

The participants were not obligated and they had the right to refuse or take part in this study. However, when the patient refused to participate, because he/she was in hurry or not feeling well or did not have an interest to survey, they were approached again in the following month. Also those patients were given the researcher phone number in case they change their decision. Also, they were given a copy of the questionnaire in case they decided to fill it by themselves at their houses.

## **II) The objective testing and seeing the consultants**

After finishing the questionnaire filling, patients fill in a form of acceptance to participate in the following part of the survey, i.e. attending the physicians' consultations and doing the objective testing. They were asked for a phone number through which they will be invited to do the testing. Patients were invited by a telephone call to do objective testing freely. In case of not responding to do objective testing, they were called again for a coupled of times at different dates. In a third call, if they did not show up, they were called to ask for a confirmation that this is the last chance, and if they apologized, they were considered as no response.

## **III) Protocol and forms of organizing the survey**

Special forms were prepared and were presented at the study laboratory (see appendix3). Patients were given the address of the laboratory. As they arrive to the laboratory, the technician explained the nature of tests he/she will go through, took a blood sample and gave them appointments for the ophthalmologist and the diabetes specialist. Table 4.2 shows the response rate for every type of examination and testing.

**Table 4.2 Response rate for every type of examination and testing**

Type of test	Number of patients N=142	percent
Questionnaire filling	116	81.7%
Laboratory testing	80	56%
Ophthalmic evaluation	74	52%
ECG examination	68	48%
Diabetes evaluation	68	48%

All results were then collected from the laboratory and the ophthalmologist and referred to the endocrinologist for evaluating their diabetes condition. At the day of consultations, patients ECG and blood pressure were measured. Finally the overall results of the previous tests were evaluated by an expert of diabetes plus direct examination of the patient by this expert.

#### **4.8 Ethical considerations:**

The conducting of research requires not only expertise and diligence but also honesty and integrity. This is done to recognize and protect human subject right. To render the study ethical, the right to self-determinations, anonymity, confidentiality and informal consent were done.

Before the permission to conduct the interviews with the patients at the clinic of PHC centers, we had arranged for a meeting personally with the two different

People who are responsible or director of the PHC centers of the two both health provider MOH and UNRWA. . The first meeting was with the doctor responsible for the health program at the UNRWA. The second meeting was with the doctor responsible for treating the diabetic patients at the Palestinian Ministry of Health after sending a letter to the director of PHC centers of the ministry. In these two interview a good idea of the health system in general and diabetes in specific was obtained. As well as the location of different clinics that provide care for type I diabetes especially UNRWA. We contacted the clinics through these people. In addition a letter was sent from Al-Quds University to these clinics, in which the study was explained and an official permission has been asked for the researcher to visit the clinics and to conduct the interviews. The clinics were visited before interviewing the patients started, in order to get to know the place, to introduce the researcher, to ask the staff about the working hours. After that, the place where the researcher could meet with the patient, privately without disturbances was discussed. Before starting with the data collection, the researcher made sure to show responsibility to the informants. It was explained that there is no financial benefit for them after finishing the study. But explained briefly what the purpose of the study is, and what the results will be used for. Nothing was promised which could not be kept.

Protection of the informants' rights had been taken into account. To insure confidentiality, mentioning the right to stop or withdraw, considering the consequences of the information, and to make sure not to harm the informants.

A short but fair introduction about the research has been given to the informants. He/she will be the person with diabetes, and he/she will be the same person who is going to be interviewed. The information will be written on a paper, in Arabic language, and a special informed consent to be signed by the participants or their guardians. In case of difficulties in getting a signature of the participants, and this is understood due to the current sensitive political situation, the signature of the researcher after telling all the information about the study had been considered enough (see appendix (4) for the two form).

#### **4.9 Data analysis**

The collected data was entered and analyzed by using the statistical package for the social sciences (SPSS version 11.5). The analysis process divided into different stages.

First stage include calculations of frequencies of all variable, then univariate analysis was done to compare metabolic control(HbA1c) with all other variable (demography, diabetes history, vital measurement, diabetes complications, PHC services and home monitoring) using Person chi-square test of significance at 5% significance level .

Second stage include univariate analysis was done to compare metabolic control with objective testing, and evaluated complications. Using Person chi-square test of significance at 5% significance level.

Third stages of analysis which will present in the next chapter include: Part a Univariate analysis comparing relationship between demographic data with objective testing, evaluated complications, and reported complications. Part B includes Univariate analysis comparing relationship between objective testing with evaluated complications, and reported complications.

#### **4.10 Operational Definition of Variables:**

**Age:** The age of the participant (in completed years at the time of conducting the survey).

**Age categories:** composed of three catagoreis

A- Children: all children less than 16 years of age

B-Adult: individual between 16-30 years of age

C-Older adult: individual who are above 30 years age?

Gender: Male or female of the participant

**Marital status:** In terms of legal status at the time of the interview. The scale of it was divided into two scales single and married.

**Place of residence:** Place in which participant lives (City, Rural and Camp)

**Educational Level:** Years of education of the participant.

**Education categories:** composed of two categories

A -0-12 years

B- 13 years and above

**Occupation: Composed** of three categories

A. Worker

B.Student

C. Non worker

**Body Mass Index (BMI):** depend on the calculation of BMI was weight (kilograms) divided by the square of height (meters). BMI divided into three categories

A. Under weight in which BMI <20

B. Normal where BMI 20-25

C. Over weight and obese >25

**Type-1 diabetes:** Insulin dependent diabetes mellitus diagnosed in participant below age 30 year.

**Diabetes type-1 reported complications**

**Reported retinopathy:** Patient was asked if the diabetes affect his eye.

**Reported nephropathy:** Patient was asked if the diabetes affect his kidney.

**Reported neuropathy:** Patient was asked if the diabetes affect his nerves.

**Reported cardiovascular disease:** Patient was asked if the diabetes affect his cardiac .

**Reported diabetic foot:** It was considered by asking patients if he had ulcer in his foot.

**Reported amputation:** If patients had previously amputation due to gangrene.

### **Diabetes type-1 evaluated complications**

**Retinopathy:** The presence of retinopathy was calculated on the basis of examinations performed by an ophthalmologist through this study. Two different levels of retinopathy were defined: no retinopathy, and retinopathy.

**Nephropathy:** Patient was considering having nephropathy as evaluated by the endocrinologist depending on laboratory tests, or by previous history of nephropathy.

**Neuropathy:** Patient was considering having neuropathy as evaluated by the endocrinologist.

**Cardiovascular disease:** Patient was considering having CVD as evaluated by the endocrinologist depending on ECG test or previous history of CVD.

**Metabolic control:** The value of HbA1c during the last 6 months. Two categories of metabolic control

A-Good metabolic or controlled diabetes when the value less than 8.5%.

b- Uncontrolled diabetes when the value equal or greater than 8.5%.

**Self-monitoring of blood glucose:** SMBG was defined as self-monitoring of blood glucose at least once per day at home.

### **4.11 Summary**

This study is a cross-sectional study of complications in type 1 diabetes and therapy protocol, it is comprised of two levels (level 1 includes survey only and level 2 includes examination). All participants were diagnosed at <30 years of age. All complications were assessed by consultation or self-report. The validity and reliability of the questionnaire was tested by pilot study, after that this questionnaire was used in collection of data (Level 1).

Study protocol of examination (level 2) for participant's patients includes four stages:

Stage 1 laboratory testing, stage 2 include ophthalmic examination, stage 3 include ECG measurement for adult and blood pressure, and finally evolutions for patients depending on the result of the previous stages by endocrinologist.

Univariate analysis was done to compare the relationship between complications of diabetes (micro and Macrovascular) and the metabolic control (HbA1c), demographic variable, and objective testing, using Pearson chi-square test of significance at 5% significance level

Examinations results were statistically analysis, frequencies were done for each test, and then univariate analysis was done to compare the relationship between objective testing

and complications of diabetes (evaluated and reported), using Person chi-square test of significance at 5% significance level.



## **Chapter Five. Results**

### **5.1 Introduction**

This study has been conducted to identify diabetes complications among diabetic patients' type 1 and the therapeutic protocol used in their treatment at Ramallah district, at the primary health care (PHC) of both the MOH and the UNRWA.

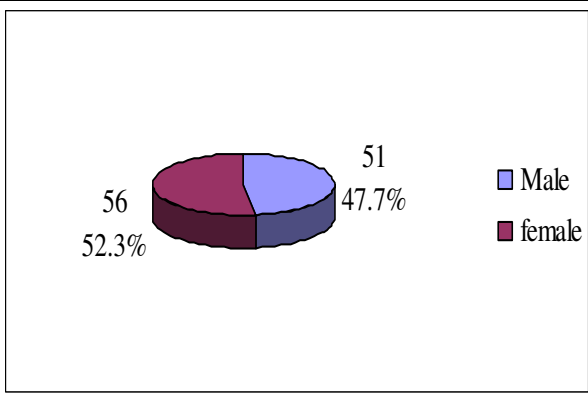
The first part of the results presents the diabetic patients' socio-demographic, physical and health condition, diabetes history as reported by patients themselves in the interview. The second part shows the univariate analysis between the various determinants and the reported complications by the patients. Third part presents the relationships between the objective-testing with the various determinants as seen by the questionnaire data. The fourth part presents of diabetic patient diagnosed complications and self care. The fifth part presents the management protocols by the various health care providers. At the end of results, multivariate analysis was done for the major complications including glycemic controls determinants.

### **5.2 Part 1 results**

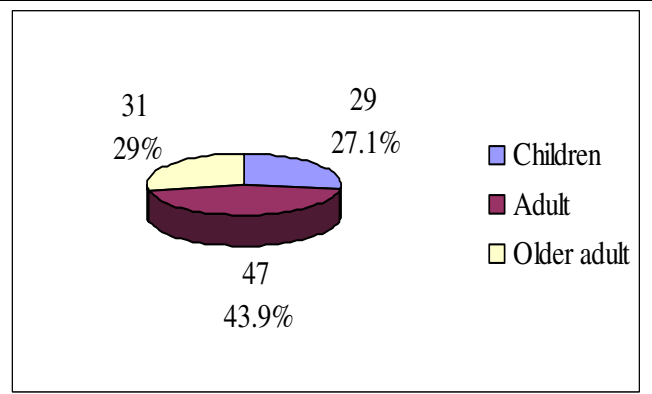
#### **5.2.1 Study population socio-demographic characteristic**

The response rate of the study was 81.7%. The number of diabetic patients type 1, as presented in the filing system of the MOH and UNRWA was 142 patients. Only 116 registered patients participated in the survey. However, 9 of the 116 patients did not do the objective testing, in particular the HbA1c, therefore, not included in the analysis. Therefore, 107 patients (92.2%) were included in the analysis. All the 107 patients filled in the study questionnaire and have been tested for at least HbA1c.

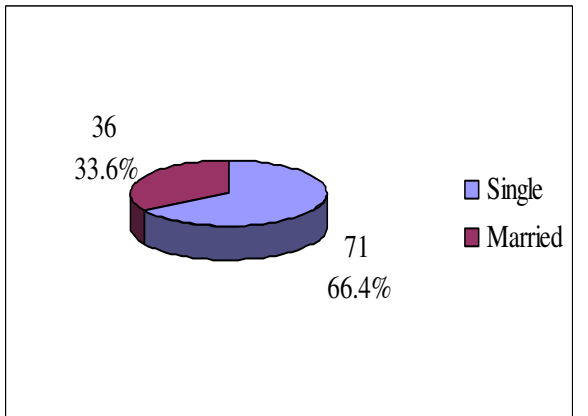
In the study, 47.7% of the study population were males (see Figure 5.1). The mean age of the group was  $23.5 \pm 10.4$  (mean+ S.D) (see figure 5.2). Two third of the study population were singles (n=71 patients, 66.4%, see figure 5.3), and 53.3% lived in villages (see figure 5.4). Of the study population, 82.2% had less than 12 years of education (see figure 5.5), and 41.1% were students (see figure 5.6).



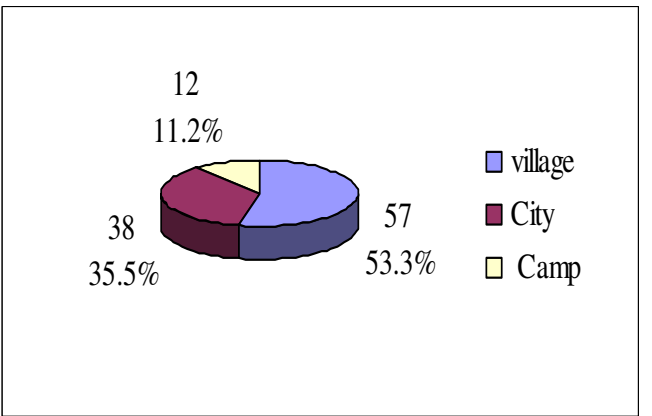
**Figure 5.1: Distribution of Study population by gender**



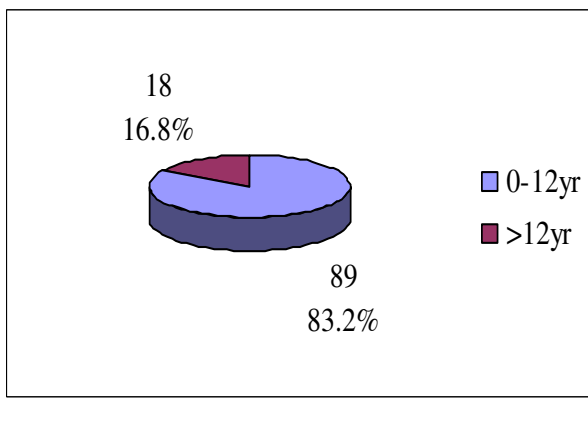
**Figure 5.2: Distribution of study population by age group.**



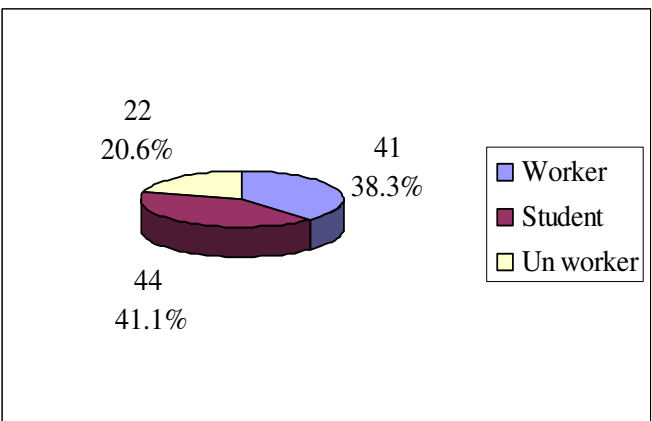
**Figure 5.3: Distribution of study population by marital status**



**Figure 5.4: Distribution of study population by place of residency**



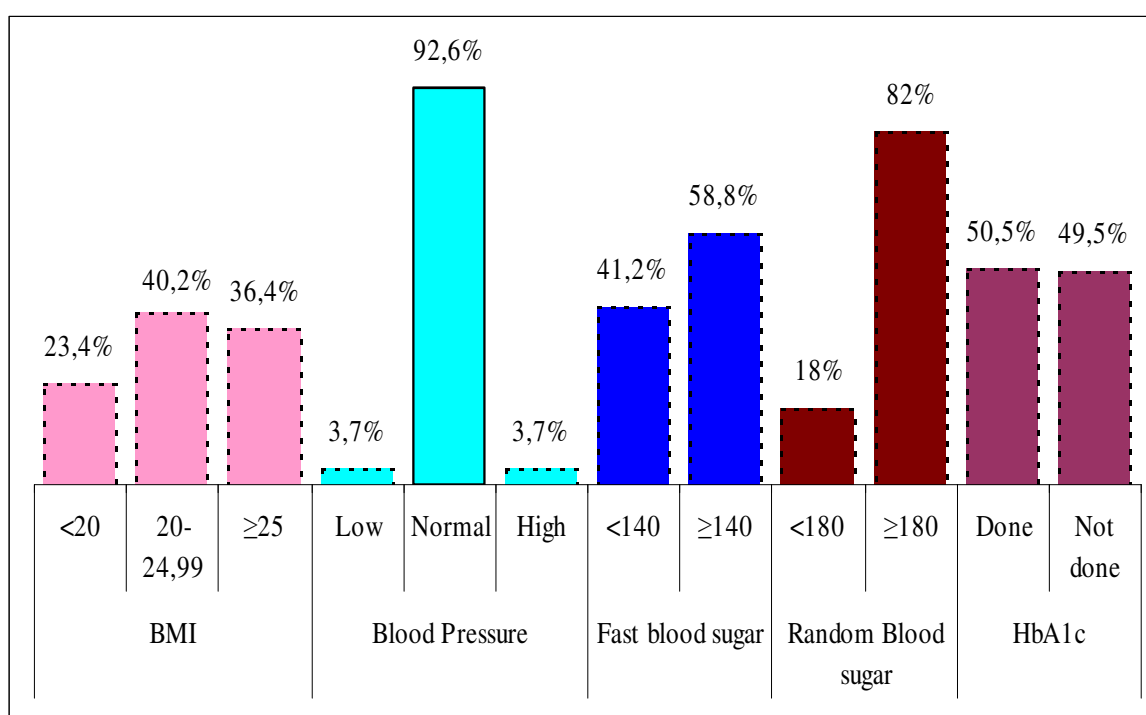
**Figure 5.5: Distribution of study population by years of education**



**Figure 5.6: Distribution of study population by type of occupation**

## 5.2.2 Study population physical and health condition characteristics

We calculated the Body Mass Index (BMI) for each patient as reported in the questionnaire. The calculated index in figure 5.7 shows that 36.4% were overweight and obese (BMI  $\geq 25$ ) and 23.4% were under-weight (BMI  $< 20$ ). Mainly all study had normal blood pressure, but 58.8% had fasting blood sugar  $\geq 140$  mg/dl, and 82 % had high random blood sugar testing. Of the study population, 50% reporting having HbA1c testing (see figure 5.7), and did not remember its normality.

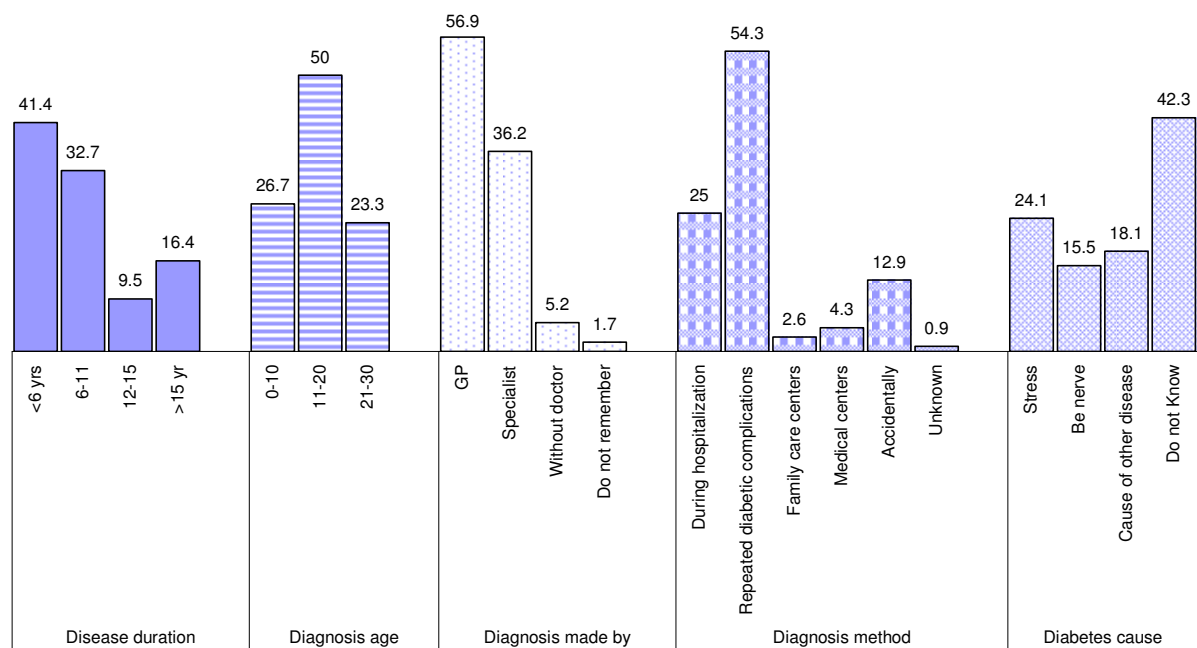


**Figure 5.7: Study population physical and health condition characteristics**

## 5.2.3 Diabetes history among study population as reported by patients themselves

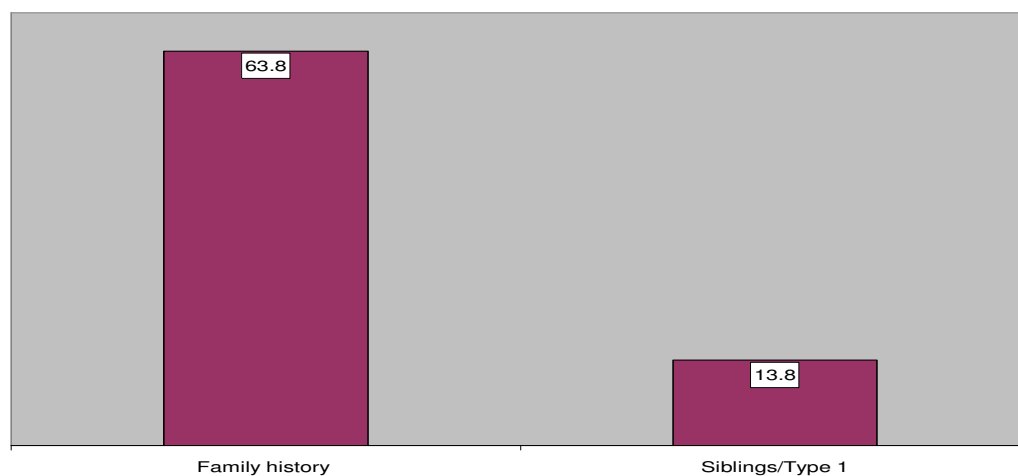
As shown in figure 5.8, the duration of diabetes illness of the study population varied between 5-15 years, where 16.8 % of the registered patients have been registered for more than 15 years. The peak incidence of diabetes type 1 patient ranged 10-15 years of age, where 48.6% of patients were diagnosed between 10-20 years of age. More than half of the patients were diagnosed by general practitioners, and 5% found that themselves. Also, 53% were diagnosed due to the repeated symptoms of diabetes itself, and 25% during hospitalized for some other reasons than diabetes itself. When diabetes was detected most

Patients did not know why they got diabetes, but 25% thought it might be due to stress (see figure 5.8).



**Figure 5.8: Distribution of Diabetes history among study population**

Interestingly, 64% of the study population reported a family history of diabetes and 13.8% reported having at least one of their siblings with diabetes type 1 (see figure 5.9).



**Figure 5.9: Distribution of study population by their family history of diabetes**

## **5.3 Part 2 results**

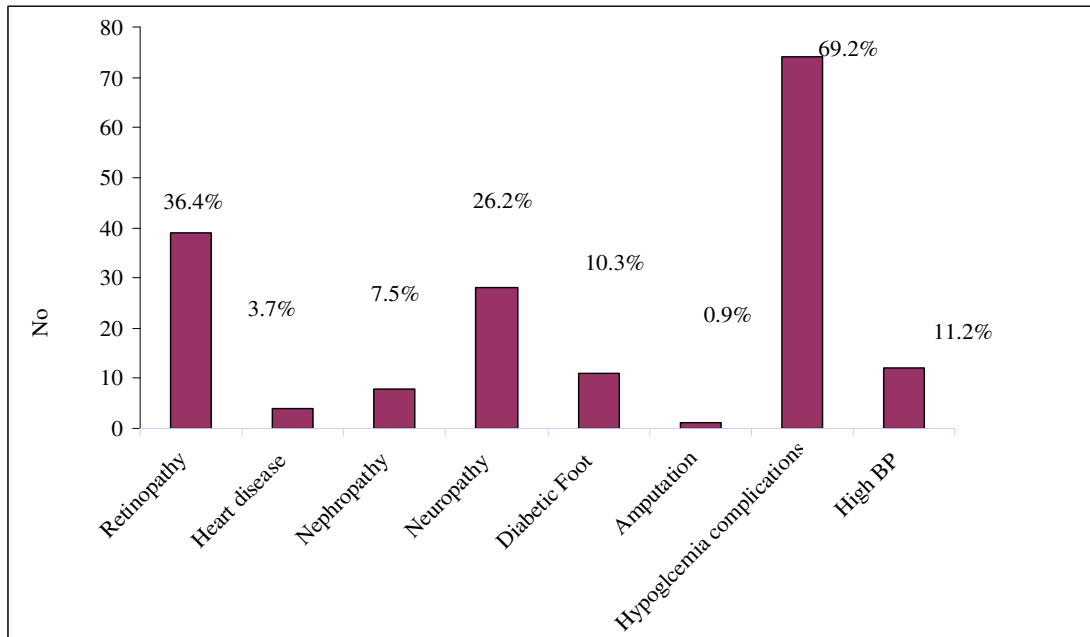
### **5.3.1 Association between reported diabetes-related complications and demographic variables**

Of the study population, 48.5% reported having one or more of the common chronic diabetes-related complications. These diabetes-related complications included symptoms of cardiovascular diseases, retinopathy-related symptoms, nephropathy-related symptoms, neuropathy-related symptoms and diabetic foot-related symptoms. Of these patients, 39 patients (36.4%) reported a retinopathy problems, 4 patients (3.7%) reported heart diseases symptoms, 8 patients (7.5%) reported a nephropathy-associated symptoms, 28 patients (26.2%) a neuropathy-associated symptoms, 11 patients (10.3%) reported having diabetic foot, one patient (0.9%) reported an amputation, 74 patients (69.2%) reported suffering from hypoglycemia complications, and 12 patients (11.2%) reported a high blood pressure (see figure 5.10).

A significant difference was found between the frequency of retinopathy-associated symptoms with the type of occupation ( $P < 0.05$ , see Table 5.1). No association was found between the presence of retinopathy-associated symptoms with place of residency, with patient educational level, or with age of patient at diagnosis of disease ( $P > 0.05$ , see Table 5.1). A significant association was found between neuropathy-associated symptoms with patients' occupation and with age ( $P < 0.05$ , see Table 5.2), but no association was found with sex, and educational level ( $P > 0.05$ ).

Table 5.3 presents the associations between hypoglycemia complications with the various demographic variables, however, only a significant association was found with age ( $P < 0.05$ ).

Number of patients with diabetic foot-related symptoms, heart diseases-associated symptoms, and nephropathy-related symptoms according to possible determinants for diabetes were less than 11 patients (see appendix 5, table 5.1).



**Figure 5.10: Complications reported by diabetic patients**

**Table 5.1: The distribution of reported retinopathy-associated symptoms with the various demographic variables for the 107 patients in Ramallah district**

Variable	Retinopathy-associated symptoms No: 39 (36.4%)	No-retinopathy associated symptoms No: 68 (63.6%)	Total N=107(100%)	P value
<b>Age</b>				
Children (0-16 yr)	4 (3.7%)	25 (23.4%)	29 (27.1%)	<b>&lt;0.05</b>
Adult (16-30 yr)	21 (19.6%)	26 (24.3%)	47 (43.9%)	
Older adult (>30 yr)	14 (13.1%)	17 (15.9%)	31 (29%)	
<b>Gender</b>				
Male	22 (20.5%)	29 (27.1%)	51 (47.6%)	<b>&gt;0.05</b>
Female	17 (15.9%)	39 (36.5%)	56 (52.4%)	
<b>Occupation</b>				
Working	19 (17.7%)	22 (20.6%)	41 (38.3%)	<b>&lt;0.05</b>
Not working	11 (10.3%)	11 (10.3%)	22 (20.6%)	
Student	10 (9.4%)	34 (31.7%)	44 (41.1%)	
<b>Marital status</b>				
Single	23 (21.5%)	48 (44.9%)	71 (66.4%)	<b>&gt;0.05</b>
Married	16 (14.9%)	20 (18.7%)	36 (33.6%)	
<b>Residency</b>				
City	15 (14%)	23 (21.6%)	38 (35.6%)	<b>&gt;0.05</b>
Village	19 (17.7%)	38 (35.5%)	57 (53.2%)	
Camp	5 (4.7%)	7 (6.5%)	12 (11.2%)	
<b>Educational level</b>				
0-12 year	33 (30.8%)	56 (52.4%)	89 (83.2%)	<b>&gt;0.05</b>
>12 year	6 (5.6%)	12 (11.2%)	18 (16.8%)	

**Table 5.2: The distribution of neuropathy-associated symptoms with the various demographic variables for the 107 patients in Ramallah district**

<b>Variable</b>	<b>Neuropathy-associated symptoms N=28 (26.2%)</b>	<b>No-neuropathy-associated symptoms N=79 (73.8%)</b>	<b>Total N=107 (100%)</b>	<b>P value</b>
<b>Age</b>				
Children (0-16)	1 (0.9%)	28 (26.2%)	<b>29 (27.1%)</b>	<b>&lt;0.05</b>
Adult (16-30)	14 (13.1%)	33 (30.8%)	<b>47 (43.9%)</b>	
Older adult (>30)	13 (12.2%)	18 (16.8%)	<b>31 (29%)</b>	
<b>Gender</b>				
Male	17 (15.9%)	34 (27.1%)	<b>51 (47.6%)</b>	<b>&gt;0.05</b>
Female	11 (10.3%)	45 (36.5%)	<b>56 (52.4%)</b>	
<b>Occupation</b>				
Work	14 (13.1%)	27 (25.2%)	<b>41 (38.3%)</b>	<b>&lt;0.05</b>
Not working	11 (10.3%)	11 (10.3%)	<b>22 (20.6%)</b>	
Student	3 (2.8%)	41 (38.3%)	<b>44 (41.1%)</b>	
<b>Marital status</b>				
Single	15 (14%)	56 (52.4%)	<b>71 (66.4%)</b>	<b>&gt;0.05</b>
Married	13 (12.2%)	23 (21.4%)	<b>36 (33.6%)</b>	
<b>Residency</b>				
City	11 (10.3%)	27 (25.3%)	<b>38 (35.6%)</b>	*
Village	14 (13.1%)	43 (40.1%)	<b>57 (53.2%)</b>	
Camp	3 (2.8%)	9 (8.4%)	<b>12 (11.2%)</b>	
<b>Educational level</b>				
0-12 year	23 (21.5%)	66 (61.7%)	<b>88 (83.2%)</b>	*
>12 year	5 (4.7%)	13 (12.1%)	<b>19 (16.8%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.3: The distribution of Hypoglycemia complications with the various demographic variables for the 107 patients in Ramallah district**

<b>Variable</b>	<b>Hypoglycemia N=74 No (%)</b>	<b>No- Hypoglycemia N=33 No (%)</b>	<b>Total N=107 No (%)</b>	<b>P value</b>
<b>Age</b>				
Children (0-16)	14 (13.1%)	15 (14%)	<b>29 (27.1%)</b>	<b>&lt;0.05</b>
Adult (16-30)	37 (34.6%)	10 (9.4%)	<b>47 (43.9%)</b>	
Older adult (>30)	23 (21.5%)	8 (7.5%)	<b>31 (29%)</b>	
<b>Gender</b>				
Male	39 (36.4%)	12 (11.2%)	<b>51 (47.6%)</b>	<b>&gt;0.05</b>
Female	35 (32.8%)	21 (19.6%)	<b>56 (52.4%)</b>	
<b>Marital status</b>				
Single	46 (43%)	25 (23.4%)	<b>71 (66.4%)</b>	<b>&gt;0.05</b>
Married	28 (26.2%)	8 (7.4%)	<b>36 (33.6%)</b>	
<b>Occupation</b>				
Work	32 (29.9%)	9 (8.4%)	<b>41 (38.3%)</b>	*
Not working	18 (16.8%)	4 (3.8%)	<b>22 (20.6%)</b>	
Student	24 (22.5%)	20 (18.6%)	<b>44 (41.1%)</b>	
<b>Educational level</b>				
0-12 year	59 (55.2%)	30 (28%)	<b>89 (83.2%)</b>	<b>&gt;0.05</b>
>12 year	15 (14%)	3 (2.8%)	<b>18 (16.8%)</b>	
<b>Residency</b>				
City	29 (27.1%)	9 (8.5%)	<b>38 (35.6%)</b>	*
Village	38 (35.6%)	19 (17.6%)	<b>57 (53.2%)</b>	
Camp	7 (6.5%)	5 (4.7%)	<b>12 (11.2%)</b>	

\*Chi square not calculated since expected count in one cell less than 5



### **5.3.2 Association between reported diabetes-related complications and the various possible determinants for diabetes**

We studied the relationship between diabetes-related complication and some determinant that affect these complications (i.e. family size, family history, smoking status, duration of disease, age at diagnosis, and diagnosis cause).

Table 5.4 presents the relationship between retinopathy-associated symptoms and the various possible determinants of diabetes type 1. Significant associations were seen between retinopathy-associated symptoms and family size, duration of disease and age at diagnosis. Significant associations were seen between neuropathy-associated symptoms and family history of diabetes, duration of disease and age at diagnosis (see Table 5.5). Number of patients with diabetic foot-related symptoms, heart diseases-associated symptoms, and nephropathy-related symptoms according to possible determinants for diabetes were less than 11 patients (see appendix 5, table5. 2).

**Table 5.4: The distribution of retinopathy-associated symptoms with the various possible determinants for the 107 patients in Ramallah district**

<b>Variable</b>	<b>Retinopathy-associated symptoms N=39 No (%)</b>	<b>No-retinopathy-associated symptoms N=68 No (%)</b>	<b>Total N=107 No (%)</b>	<b>P value</b>
<b>Family size people at household</b>				
≤ 4	13(12.1%)	9(8.4%)	<b>22(20.5%)</b>	<b>&lt;0.05</b>
>4	26(24.3%)	59(55.2%)	<b>85(79.5%)</b>	
<b>Number of children*</b>				
≤3	7(19.4%)	14(38.9%)	<b>21(58.3%)</b>	<b>&gt;0.05</b>
>3	8(22.2%)	7(19.4%)	<b>14(41.7%)</b>	
<b>Family history of diabetes</b>				
Yes	26(24.3%)	41(38.3%)	<b>67(62.6%)</b>	<b>&gt;0.05</b>
No	13(12.1%)	27(25.3%)	<b>40(37.4%)</b>	
<b>A sibling with diabetes</b>				
Yes	8(7.5%)	6(5.6%)	<b>14(13.1%)</b>	<b>&gt;0.05</b>
No	31(28.9%)	62(58%)	<b>93(86.9%)</b>	
<b>Smoking now</b>				
Yes	13(12.1%)	15(14%)	<b>28(26.1%)</b>	<b>&gt;0.05</b>
No	26(24.3%)	53(49.6%)	<b>79(73.9%)</b>	
<b>Disease duration</b>				
≤5	8(7.4%)	38(35.5%)	<b>46(42.9%)</b>	<b>&lt;0.05</b>
>5	31(29%)	30(28.1%)	<b>61(57.1%)</b>	
<b>Diagnosis age</b>				
<10	9(8.4%)	20(18.7%)	<b>29(27.1%)</b>	<b>&gt;0.05</b>
10-20	18(16.8%)	34(31.8%)	<b>52(48.6%)</b>	
>20	12(11.2%)	14(13.1%)	<b>26(24.3%)</b>	
<b>Diagnosis cause</b>				
Psychological stress	12(11.2%)	14(13.1%)	<b>26(24.3%)</b>	<b>&gt;0.05</b>
Neurological stress other disease causes	6(5.6%)	10(9.4%)	<b>16(15%)</b>	
	6(5.6%)	13(12.1%)	<b>19(17.7%)</b>	
Do not know	15(14%)	31(29%)	<b>46(43%)</b>	

**Table 5.5: The distribution of neuropathy-associated symptoms with the various possible determinants for the 107 patients in Ramallah district**

<b>Variable</b>	<b>Neuropathy-associated symptoms N=28 No (%)</b>	<b>No-neuropathy-associated symptoms N=79 No (%)</b>	<b>Total N=107 No (%)</b>	<b>P value</b>
<b>Family size: people at household</b>				
≤ 4	9(8.4%)	13(12.1%)	<b>22(20.5%)</b>	<b>&gt;0.05</b>
>4	19(17.8%)	66(38.3%)	<b>85(79.5%)</b>	
<b>Number of children*</b>				
≤3	6(16.7%)	15(41.7%)	<b>21(58.4%)</b>	<b>&gt;0.05</b>
>3	6(16.7%)	9(24.9%)	<b>15(41.6%)</b>	
<b>Family history of diabetes</b>				
Yes	22(20.5%)	45(42.1)	<b>67(62.6%)</b>	<b>&lt;0.05</b>
No	6(5.7%)	34(31.7%)	<b>40(37.4%)</b>	
<b>Smoking now</b>				
Yes	9(8.4%)	19(17.8%)	<b>28(26.2%)</b>	<b>&gt;0.05</b>
No	19(17.8%)	60(56%)	<b>79(73.8%)</b>	
<b>Disease duration</b>				
≤5	5(4.7%)	41(37.4%)	<b>45(42.1%)</b>	<b>&lt;0.05</b>
>5	23(21.5%)	38(35.5%)	<b>44(41%)</b>	
<b>Diagnosis age</b>				
<10	4(3.7%)	25(23.4%)	<b>29(27.1%)</b>	<b>&gt;0.05</b>
10-20	16(15%)	36(33.6%)	<b>52(48.6%)</b>	
>20	8(7.5%)	18(16.8%)	<b>26(24.3%)</b>	
<b>Diagnosis cause</b>				
Psychological stress	8(7.5%)	18(16.8%)	<b>26(24.3%)</b>	<b>&gt;0.05</b>
Neurological stress other	8(7.5%)	8(7.5%)	<b>16(15%)</b>	
disease causes	4(3.7%)	15(14%)	<b>19(17.7%)</b>	
Do not know	8(7.5%)	38(35.5%)	<b>46(43%)</b>	

## 5.4 Part 3 results

The distribution of the objective testing by the various demographic variables is presented in appendix number 5 (table 5.3, 5.4A, 5.4B, and 5.4C). Also, the associations between the objective testing and the various demographic variables are presented in appendix 5 (table 5.5, 5.6, 5.7, and 5.8).

When Comparing the reported complications with the diagnosed complications, data showed that 20.5% (9 of 46 patients reported no retinopathy) who reported that they never had retinopathy was diagnosed with it. Also 8 patients who reported having retinopathy were not diagnosed with this disorder. But only 2 patients (one was found without the disease although he reported it and the other was the opposite) did not report correctly having or not having nephropathy. Also, for neuropathy, one patient was not diagnosed, but 7 patients (41%) were reported having it but blood testing did not show it. Therefore, Cronbach Alpha for reliability agreement beyond chance between reported and diagnosed was 0.61 for retinopathy, 0.85 for nephropathy, and was for neuropathy. This means that retinopathy is the most under-diagnosed complications among diabetic patients.

In the following sections diagnosed and reported complications associations with the study demographic variables, objective testing will be presented.

### 5.4.1 Associations between diagnosed complications by consultations in relation with all demographic variables

Table 5.6, 5.7, and appendix table 5.9, and appendix table 5.10. present data for the 68 patients who did the full consultations with ophthalmologist, endocrinologist and did all the laboratory testing. As diagnosed by the ophthalmologist, retinopathy was found in 33.8% of the patients (n=23). Males showed a higher possibility to developed retinopathy compared to females ( $P < 0.05$ ). Significant difference in the frequency of retinopathy was seen in different age group among patients ( $P < 0.05$ ). Married cases showed a higher possibility to developed retinopathy compared to single cases ( $P < 0.05$ , see table 5.6). Nephropathy was found in 7.4% of the patients (n=5). Since the number of nephropathy cases was small the univariate analysis is not presented (see appendix 5, table 5.9). Clinical neuropathy was present in 16.2% of patients (n=11). Significant association with sex was observed ( $P < 0.05$ , see appendix 5, table 5.10).

#### **5.4.2 Association between the diagnosed complications by consultations in relation with the various possible associated determinants**

Table 5.7 present data for the relationship between diagnosed retinopathy of 68 patients who did the full consultations with ophthalmologist, endocrinologist and did all the laboratory testing with various possible associated determinants. Family size showed no significant association with developing retinopathy ( $P > 0.05$ ). Patient with more diabetes duration showed a higher possibility to developed retinopathy compared to diabetic patient with less disease duration ( $P < 0.05$ ). Age of diagnosed diabetic patients shows a significant association with developing retinopathy ( $P$  value  $< 0.05$ ). People who used to smoke cigarette show also a higher possibility to developed retinopathy compared to diabetic patient who did not smoke ( $P < 0.05$ ). Patient with more diabetes duration showed a higher possibility to developed neuropathy compared to diabetic patient with less disease duration ( $P < 0.05$ , see appendix 5, table 10).

#### **5.4.3 Association between objective testing and diagnosed complications by consultation.**

Significant associations were found between having retinopathy and metabolic control (HbA1c) and lipid profile tests (Cholesterol, triglyceride and LDL) ( $P < 0.05$ ). No association found between HDL and retinopathy ( $P > 0.05$ , see table 5.8). Significant associations were found between clinical neuropathy and triglyceride ( $P < 0.05$ , see table 5.9).

#### **5.4.4 Association between objective and diagnostic testing and patients' reported complications.**

In this part of results, the association between reported complications (retinopathy, neuropathy, nephropathy, and macro vascular disease) with objective testing and diagnostic testing will be presented. Reported retinopathy-associated symptoms showed no significant association with any of the objective or diagnostic testing ( $P > 0.05$ ) (Table 5.10). While reported neuropathy-associated symptoms showed significant associations with lipid profile testing ( $P < 0.05$ , see Table 5.11).

**Table 5.6: The distribution of the diagnostic retinopathy with demographic variables for the 68 patients in Ramallah district**

<b>Variable</b>	<b>Diagnosed Retinopathy N=23 No (%)</b>	<b>No retinopathy N= 45 No (%)</b>	<b>Total N=68 No (%)</b>	<b>P value</b>
<b>Age Mean ± SE (yrs)</b>	31.96±2	17.7±1.2	<b>23.54±0.96</b>	<b>P&lt;0.05</b>
<b>Age</b>				
Child	2(2.9%)	19(27.9%)	<b>21(30.8%)</b>	
Adults	6(8.8%)	22(32.3%)	<b>28(41.2%)</b>	<b>P&lt;0.05</b>
Older adults	15(22.1%)	4(5.9%)	<b>19(28%)</b>	
<b>Sex</b>				
Male	15 (22.1%)	17 (25%)	<b>32 (47%)</b>	
Female	8 (11.7%)	28 (41.2%)	<b>36 (53%)</b>	<b>P&lt;0.05</b>
<b>Marital status</b>				
Single	8 (11.7%)	37 (54.4%)	<b>45 (66.2)</b>	
Married	15 (22.1%)	8 (11.7%)	<b>23 (33.8)</b>	<b>P&lt;0.05</b>
<b>Occupation</b>				
Work	16 (23.4%)	11 (16.2%)	<b>27 (39.6%)</b>	
Not working	5 (7.4%)	5 (7.4%)	<b>10 (14.8%)</b>	*
Student	2 (3%)	29 (42.6%)	<b>31 (45.6%)</b>	
<b>Place of residency</b>				
City	8 (11.8%)	14 (20.6%)	<b>22 (32.4%)</b>	
Village	10 (14.7%)	25 (36.7%)	<b>35 (51.4%)</b>	*
Camp	5 (7.4%)	6 (8.8%)	<b>11 (16.2%)</b>	
<b>Education level</b>				
0-12 year	20 (29.4%)	40 (58.8%)	<b>60 (88.2%)</b>	
>12 year	3 (4.4%)	5 (7.4%)	<b>8 (11.8%)</b>	*

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.7: The distribution of the diagnostic retinopathy with various possible associated determinants for the 68 patients in Ramallah district.**

<b>Variable</b>	<b>Diagnosed Retinopathy N=23 No (%)</b>	<b>No Retinopathy N=45 No (%)</b>	<b>Total N=68 No (%)</b>	<b>P value</b>
<b>Family history of diabetes</b>				
Yes	16(23.5%)	27(39.7%)	<b>43(63.2%)</b>	<b>&gt;0.05</b>
No	7(10.3%)	18(26.5%)	<b>25(36.8%)</b>	
<b>Current Smoking</b>				
Yes	9(13.3%)	8(11.8%)	<b>17(25.1%)</b>	<b>&lt;0.05</b>
No	14(23.5%)	37(51.4%)	<b>51(74.9%)</b>	
<b>BMI</b>				
Underweight	3(4.4%)	14(20.5%)	<b>17(24.9%)</b>	<b>&gt;0.05</b>
Normal	10(14.7%)	19(28%)	<b>29(42.7%)</b>	
Over weight and obese	10(14.7%)	12(17.7%)	<b>22(32.4%)</b>	
<b>Disease duration</b>				
≤5	1(1.5%)	32(47.1%)	<b>33(48.6%)</b>	<b>&lt;0.05</b>
>5	22(35.3%)	13(19.1%)	<b>35(54.6%)</b>	
<b>Diagnosis age</b>				
<10	4(5.9%)	17(25%)	<b>21(30.9%)</b>	<b>&lt;0.05</b>
10-20	11(16.2%)	20(29.5%)	<b>31(45.6%)</b>	
>20	8(11.7%)	8(11.7%)	<b>16(23.5%)</b>	

**Table 5.8: The distribution of diagnostic retinopathy and the objective testing for the 68 patients in Ramallah district**

<b>Variable</b>	<b>Diagnosed Retinopathy N=23 No (%)</b>	<b>No-retinopathy N=45 No (%)</b>	<b>Total N=68 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b>				
HbA1c <8.5	11 (16.2%)	33 (48.6%)	<b>44 (64.8%)</b>	<b>&lt;0.05</b>
HbA1c ≥8.5	12 (17.6%)	12 (17.6%)	<b>24 (35.2%)</b>	
<b>Sugar (mg/dl)</b>				*
<140	1(1.5%)	22(32.3%)	<b>23(33.8%)</b>	
≥140	22(32.3%)	37(33.9%)	<b>45(66.2%)</b>	
<b>Urea (mg/dl)</b>				*
<45	19(27.9%)	45(66.2%)	<b>64(94.1%)</b>	
≥45	4(5.9%)	—	<b>4(5.9%)</b>	
<b>Creatinine (mg/dl)</b>				*
<1.4	16(23.5%)	42(61.8%)	<b>58(85.3%)</b>	
≥1.4	7(10.3%)	3(4.4%)	<b>10(14.7%)</b>	
<b>Cholesterol (mg/dl)</b>				
<200	7 (10.3%)	32 (47.1%)	<b>39 (57.4%)</b>	<b>&lt;0.05</b>
≥200	16 (23.5%)	13 (19.1%)	<b>29 (42.6%)</b>	
<b>Triglyceride (mg/dl)</b>				
<150	6 (8.8%)	30 (44.1%)	<b>36 (52.9%)</b>	<b>&lt;0.05</b>
≥150	17 (25%)	15 (22.1%)	<b>32 (47.1%)</b>	
<b>LDL (mg/dl)</b>				
<100	3 (4.4%)	19 (28%)	<b>22 (32.4%)</b>	<b>&lt;0.05</b>
≥100	20 (29.4%)	26 (38.2%)	<b>46 (67.6%)</b>	
<b>HDL (mg/dl)</b>				
<40	12(17.6%)	20 (29.5%)	<b>32 (47.1%)</b>	<b>&gt;0.05</b>
≥40	11 (16.2%)	25 (36.7%)	<b>36 (52.9%)</b>	

\*Chi square not calculated since expected count in one cell less than 5



**Table 5.9: The distribution of diagnostic neuropathy and the objective testing for the 68 patients in Ramallah district**

<b>Variable</b>	<b>Diagnosed Neuropathy N=11 No (%)</b>	<b>No-Neuropathy N=57 No (%)</b>	<b>Total N=68 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b>				*
HbA1c <8.5	6(8.8%)	38(55.8%)	<b>44(64.6%)</b>	
HbA1c ≥8.5	5(7.4%)	19(28%)	<b>24(35.4%)</b>	
<b>Sugar (mg/dl)</b>				*
<140	0	9 (13.3%)	<b>9 (13.3%)</b>	
≥140	11 (16.2%)	48 (70.5%)	<b>59 (86.7%)</b>	
<b>Urea (mg/dl)</b>				*
<45	10 (14.7%)	54 (79.4%)	<b>64 (94.1%)</b>	
≥45	1 (1.5%)	3 (4.4%)	<b>4 (5.9%)</b>	
<b>Creatinine (mg/dl)</b>				*
<1.4	7(10.3%)	51(75%)	<b>58(85.3%)</b>	
≥1.4	4(5.9%)	6(8.8%)	<b>10(14.7%)</b>	
<b>Triglyceride (mg/dl)</b>				<b>&lt;0.05</b>
<150	1 (1.5%)	35 (51.4%)	<b>36 (52.9%)</b>	
≥150	10 (14.7%)	22 (32.4%)	<b>32 (47.1%)</b>	
<b>Cholesterol (mg/dl)</b>				*
<200	0	39 (57.4%)	<b>39 (57.4%)</b>	
≥200	11 (16.2%)	18 (26.4%)	<b>29 (42.6%)</b>	
<b>LDL (mg/dl)</b>				*
<100	1 (1.5%)	21 (30.9%)	<b>22 (32.4%)</b>	
≥100	10 (14.7%)	36 (52.9%)	<b>46 (67.6%)</b>	
<b>HDL (mg/dl)</b>				<b>&gt;0.05</b>
<40	6 (8.8%)	30 (44.1%)	<b>36 (52.9%)</b>	
≥40	5 (7.4%)	27 (39.7%)	<b>32 (47.1%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.10: The distribution of the objective testing and patients reported retinopathy for the 80 patients in Ramallah district**

<b>Variable</b>	<b>Reported retinopathy N=30 No (%)</b>	<b>Normal Reported-retina N=50 No (%)</b>	<b>Total N=80 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b>				
<8.5	19 (23.8%)	35 (43.8%)	<b>54 (67.6%)</b>	<b>&gt;0.05</b>
≥8.5	11 (13.7%)	15(18.7%)	<b>26 (32.4%)</b>	
<b>Sugar (mg/dl)</b>				*
<140	1 (1.3%)	9 (13.2%)	<b>10 (12.5%)</b>	
≥140	29 (26.2%)	49(61.3%)	<b>70 (87.5%)</b>	
<b>Urea (mg/dl)</b>				*
<45	27 (33.7%)	49 (61.3%)	<b>76 (95%)</b>	
≥45	3 (3.8%)	1 (1.2%)	<b>4 (5%)</b>	
<b>Creatinine (mg/dl)</b>				*
<1.1	24(30%)	44(55%)	<b>68(85%)</b>	
≥1.1	6(7.5%)	6(7.5%)	<b>12(15%)</b>	
<b>Cholesterol (mg/dl)</b>				
<200	16 (20%)	31 (38.8%)	<b>47 (58.8%)</b>	<b>&gt;0.05</b>
≥200	14 (17.5%)	19 (23.7%)	<b>33 (41.2%)</b>	
<b>Triglyceride (mg/dl)</b>				
<150	13 (16.3%)	29 (36.2%)	<b>42 (52.5%)</b>	<b>&gt;0.05</b>
≥150	17 (21.2%)	21 (26.3%)	<b>38 (47.5%)</b>	
<b>LDL (mg/dl)</b>				
<100	7 (8.8%)	17 (21.2%)	<b>24 (30%)</b>	<b>&gt;0.05</b>
≥100	23 (28.7%)	33 (41.3%)	<b>56 (70%)</b>	
<b>HDL (mg/dl)</b>				
<40	14 (17.5%)	25 (31.25%)	<b>39 (48.75%)</b>	<b>&gt;0.05</b>
≥40	16 (20%)	25(31.25%)	<b>41 (51.25%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.11: The distribution of reported neuropathy and the objective testing for the 80 patients in Ramallah district**

<b>Variable</b>	<b>Diagnosed Neuropathy N=21 No (%)</b>	<b>No-neuropathy N=59 No (%)</b>	<b>Total N=80 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b>				
HbA1c <8.5	11 (13.7%)	43(53.8%)	<b>54 (67.5%)</b>	<b>&gt;0.05</b>
HbA1c ≥8.5	10 (12.5%)	16(20%)	<b>26 (32.5%)</b>	
<b>Sugar (mg/dl)</b>				*
<140	0 (0%)	10 (12.5%)	<b>10 (12.5%)</b>	
≥140	21 (26.2%)	49 (61.3%)	<b>70 (87.5%)</b>	
<b>Urea (mg/dl)</b>				*
<45	18 (22.5%)	58 (72.5%)	<b>76 (95%)</b>	
≥45	3 (3.8%)	1 (1.2%)	<b>4 (5%)</b>	
<b>Creatinine (mg/dl)</b>				*
<1.1	14(17.5%)	54(67.5%)	<b>68(85%)</b>	
≥1.1	7(8.8%)	5(6.2%)	<b>12(15%)</b>	
<b>Cholesterol (mg/dl)</b>				
<200	7 (8.8%)	40 (50%)	<b>47 (58.8%)</b>	<b>&lt;0.05</b>
≥200	14 (17.5%)	19 (23.7%)	<b>33 (41.2%)</b>	
<b>Triglyceride (mg/dl)</b>				
<150	6 (7.5%)	36 (45%)	<b>42 (52.5%)</b>	<b>&lt;0.05</b>
≥150	15 (18.8%)	23 (28.7%)	<b>35 (47.5%)</b>	
<b>LDL (mg/dl)</b>				
<100	2 (2.5%)	22 (27.5%)	<b>24 (30%)</b>	<b>&lt;0.05</b>
≥100	19 (23.7%)	37 (46.3%)	<b>51 (70%)</b>	
<b>HDL (mg/dl)</b>				
<40	11 (13.8%)	28 (35%)	<b>39 (48.8%)</b>	<b>&gt;0.05</b>
≥40	10 (12.5%)	31 (38.7%)	<b>41 (51.2%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

## 5.5 Part 4 results

### 5.5.1 Associations between diagnosed complications and home monitoring and self-care assessment as reported by patients themselves

Self-monitoring of blood glucose (SMBG) is an important component of modern therapy for diabetes mellitus. SMBG has been recommended for people with Insulin treated diabetes and their health care professionals in order to achieve a specific level of glycemic control and to prevent hypoglycemia. In this part of results, the association between SMBG and the frequency of blood glucose measurement at home, and blood pressure measurement at home with glycemic control (HbA1c) are presented. As shown in table 5.12, no significant associations were seen between home monitoring and glycemic control (HbA1c) ( $P > 0.05$ ). Also, patients without diagnosed retinopathy did not show a significant difference in using any practice method of home monitoring compared to diagnosed patients ( $P > 0.05$ , see table 5.13). For diagnostic neuropathy univariate analysis was not done (see table 5.14). Similarly, those who reported having retinopathy and neuropathy-associated symptoms showed no significant association with any practice method of home monitoring ( $P > 0.05$ , see tables 5.15, and 5.16)

**Table 5.12: Association between home monitoring with glycemic control**

Variable	HbA1c $\geq 8.5$ N=41 No (%)	HbA1c $< 8.5$ N=66 No (%)	Total N=107 No (%)	P value
<b>Blood Pressure Device</b>				
Yes	14 (13.1%)	14 (13.1%)	<b>28 (26.2%)</b>	<b>&gt;0.05</b>
No	27 (25.2%)	52 (48.6%)	<b>79 (73.8%)</b>	
<b>Glucose measurement</b>				
Yes	26 (24.3%)	48 (44.9%)	<b>74 (69.2%)</b>	<b>&gt;0.05</b>
No	15 (14.1%)	18 (16.8%)	<b>33 (30.8%)</b>	
<b>Glucose frequency testing</b>				
Daily	21 (28.4%)	27 (36.5%)	<b>48 (64.9%)</b>	<b>&gt;0.05</b>
Not Daily	10 (13.5%)	16 (21.6%)	<b>26 (35.1%)</b>	
<b>Glucose in urine</b>				
Yes	1 (0.9%)	2 (1.9%)	<b>3 (2.8%)</b>	*
No	40 (37.4%)	64 (59.8%)	<b>104 (97.2%)</b>	
<b>Ketone in Urine</b>				
Yes	—	1 (0.9%)	<b>1 (0.9%)</b>	*
No	41 (38.3%)	65 (60.8%)	<b>106 (99.1%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.13: The distribution of diagnostic retinopathy and the Home monitoring for the 68 patients in Ramallah district**

<b>Variable</b>	<b>Diagnosed Retinopathy N=23 No (%)</b>	<b>No-retinopathy N=45 No (%)</b>	<b>Total N=68 No (%)</b>	<b>P value</b>
<b>Blood Pressure Device</b>				
Yes	7 (10.3%)	15 (22.1%)	<b>22 (32.4%)</b>	<b>&gt;0.05</b>
No	16 (23.5 %)	30 (44.1%)	<b>46 (67.6%)</b>	
<b>Glucose measurement</b>				*
Yes	15(22.1%)	39(57.4%)	<b>54(72.2%)</b>	
No	8(11.7%)	6(8.8%)	<b>14(27.8%)</b>	
<b>Glucose frequency</b>				
Daily	8(14.8%0	23(42.6%)	<b>31(57.4%)</b>	<b>&gt;0.05</b>
Not daily	7(13%)	16(29.6%)	<b>23(42.6%)</b>	
<b>Glucose in urine</b>				*
Yes	-----	3(4.4%)	<b>3(4.4%)</b>	
No	23(33.8%)	42(61.8%)	<b>65(95.6%)</b>	
<b>Ketone in Urine</b>				*
Yes	-----	1(1.5%)	<b>1(1.5%)</b>	
No	23(33.8%)	44(64.7%)	<b>67(98.5%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.14: The distribution of diagnosed neuropathy and the Home monitoring for the 68 patients in Ramallah district**

<b>Variable</b>	<b>Diagnosed Neuropathy N=11 No (%)</b>	<b>No-neuropathy N=57 No (%)</b>	<b>Total N=68 No (%)</b>	<b>P value</b>
<b>Blood Pressure Device</b>				
Yes	2 (3%)	20 (29.4%)	<b>22 (32.4%)</b>	*
No	9 (13.2 %)	37(54.4%)	<b>46 (67.6%)</b>	
<b>Glucose measurement</b>				*
Yes	8 (11.8%)	46 (67.6%)	<b>54(79.4%)</b>	
No	3(4.4%)	11 (16.2%)	<b>14 (20.6%)</b>	
<b>Glucose frequency*</b>				*
Daily	4 (7.4%)	27 (49.9%)	<b>31 (57.3%)</b>	
Not daily	4(7.4%)	19(35.3%)	<b>23 (42.7%)</b>	
<b>Glucose in urine</b>				*
Yes	0	3 (5.5%)	<b>3 (5.5%)</b>	
No	11(16.2%)	54(78.3%)	<b>65(94.5%)</b>	
<b>Ketone in Urine</b>				*
Yes	0	1 (1.5%)	<b>1 (1.5%)</b>	
No	11 (16.2)%	56 (82.3%)	<b>67(98.5%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.15: The distribution of reported retinopathy and the Home monitoring for the 107 patients in Ramallah district**

<b>Variable</b>	<b>Reported retinopathy N=39 No (%)</b>	<b>Normal reported retina N=68 No (%)</b>	<b>Total N=107 No (%)</b>	<b>P value</b>
<b>Blood Pressure Device</b>				
Yes	13 (12.1%)	15(14.1%)	<b>28 (26.2%)</b>	<b>&gt;0.05</b>
No	26 (24.3 %)	53 (49.5%)	<b>79 (73.8%)</b>	
<b>Glucose measurement</b>				
Yes	24 (22.4%)	50 (44.2%)	<b>74 (68.2%)</b>	<b>&gt;0.05</b>
No	15 (14%)	18 (17.8%)	<b>33 (31.8%)</b>	
<b>Glucose frequency</b>				
Daily	10 (13.6%)	33(44.6%)	<b>43 (58.2%)</b>	<b>&lt;0.05</b>
Not a daily	14 (19%)	17 (22.8%)	<b>31 (41.8%)</b>	
<b>Urine glucose measurement</b>				
Yes	0	3 (0.9%)	<b>3 (2.8%)</b>	*
No	39 (36.4%)	65 (60.8%)	<b>104(97.2%)</b>	
<b>Ketones measurement (urine)</b>				
Yes	0	1 (0.9%)	<b>1 (0.9%)</b>	*
No	39 (36.4)%	67 (62.7%)	<b>106(99.1%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.16: The distribution of reported neuropathy and the Home monitoring for the 107 patients in Ramallah district**

<b>Variable</b>	<b>Reported neuropathy N=28 No (%)</b>	<b>No- reported neuropathy N=79 No (%)</b>	<b>Total N=107 No (%)</b>	<b>P value</b>
<b>Blood Pressure Device</b>				
Yes	9 (8.4%)	19(17.8%)	<b>28 (26.2%)</b>	<b>&gt;0.05</b>
No	19(17.8 %)	60 (56%)	<b>79 (73.8%)</b>	
<b>Glucose measurement</b>				
Yes	17 (15.9%)	57 (52.3%)	<b>74 (68.2%)</b>	<b>&gt;0.05</b>
No	11 (10.3%)	22 (21.5%)	<b>33 (31.8%)</b>	
<b>Glucose frequency *</b>				
Daily	10 (13.5%)	33(44.6%)	<b>43 (58.1%)</b>	<b>&gt;0.05</b>
Not daily	7 (9.5%)	24(32.4%)	<b>31 (41.9%)</b>	
<b>Glucose in urine</b>				
Yes	0	3 (2.8%)	<b>3 (2.8%)</b>	*
No	28 (26.2%)	76 (71%)	<b>104(97.2%)</b>	
<b>Ketone in Urine</b>				
Yes	0	1 (0.9%)	<b>1 (0.9%)</b>	*
No	28(26.2)%	78 (72.9%)	<b>106(99.1%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

## **5.6 Part five results**

### **5.6.1 Patients follow up and treatment by PHC centers**

Primary health care centers are the main source of care for patients with diabetes type 1 at Ramallah district. The purpose of these services is to prevent complications and control the main precursors of these complications (i.e. poor blood glucose, blood pressure and blood lipid). The impact of these conditions can be moderate or prevented through appropriate treatment and screening. In our study we consider physical examinations, fundus examination, blood glucose measurement and control, blood chemistry tests (i.e. lipid profile, kidney function, and enzymatic test), ECG, weight, height measurement, specialist consultations and blood pressure measurement and control as screening test and indicators for assessment of PHC services. Figures 5.11, 5.12A, and 5.12B summarize the percent of screening tests among diabetic patients that receive from the PHC centers as they reported by themselves.

#### **A-Diet regiment**

It was proposed that food habits are a basic factor in diabetes. In this study, patients were asked if they follow the recommended diet regiment for diabetic patients. Of the 107 patients, only 60 patients (56.1%) reported following a diet regiment. However no statistical significant association was found between diet regiment and good glycemic control ( $P > 0.05$ , see table 5.17).

#### **B. Management according to insulin therapy type**

Of the study population, 77.6% reported using insulin mixture in their treatment at time of interview. No statistical significant relationship between Insulin type used by diabetic patients and glycemic control, and reported complications ( $P > 0.05$ , see Table 5.17).

#### **C. Availability of health insurance**

A 51.7% of study population reported having governmental health insurance, 12% were UNRWA health insurance, 36.3% had private health insurance,. However, no statistical significant association was found between health insurance and glycemic control ( $P > 0.05$ , see table 5.17).

#### **D. Management according to place of care**

During interview the patients were asked about the place from which they used to receive their management services including insulin and laboratory test: 62.6% receive care at MOH, PHC centers only. 30.1% from UNRWA, PHC centers only, while the rest from more than one place, which could be considered as duplication of service. No statistical

significant relationship between existing place of care and glycemic control ( $P > 0.05$ , see table 5.17).

**Table 5.17: Association between diabetes management according to diet regimen and health insurance with glycemic control in the 107 patients in Ramallah district**

<b>Variable</b>	<b>HbA1c <math>\geq 8.5</math> N=41 No (%)</b>	<b>HbA1c <math>&lt; 8.5</math> N=66 No (%)</b>	<b>Total N=107 No (%)</b>	<b>P value</b>
<b>Diet regimen</b>				
Yes	23 (21.6%)	37 (34.5%)	<b>60 (56.1%)</b>	<b>&gt;0.05</b>
No	18(16.8%)	29 (27.1%)	<b>47 (43.9%)</b>	
<b>Health insurance type</b>				
Governmental	17 (15.9%)	37 (34.5%)	<b>54 (50.4%)</b>	<b>&gt;0.05</b>
UNRWA	8(7.5%)	5 (4.7%)	<b>13 (12.2%)</b>	
Private	16(15%)	24(22.4%)	<b>40(37.4%)</b>	
<b>Insulin therapy type*</b>				
Rapid	6(12.1%)	12 (4.7%)	<b>18 (16.8%)</b>	<b>&gt;0.05</b>
Mixture	34(64.5%)	49 (13.1%)	<b>83 (77.6%)</b>	
<b>First source of treatment</b>				
MOH	34 (31.8%)	8 (7.5%)	<b>42 (39.3%)</b>	<b>&gt;0.05</b>
UNRWA	21 (19.6%)	4 (3.7%)	<b>25 (23.3%)</b>	
Private	21 (19.6%)	6 (5.6%)	<b>27 (25.2%)</b>	
More than one source	11 (10.3%)	2 (1.9%)	<b>13 (12.2%)</b>	
<b>Source of treatment</b>				
MOH	24 (24.5%)	43 (43.8%)	<b>67 (68.3%)</b>	<b>&gt;0.05</b>
UNRWA	13(13.3%)	18 (18.4%)	<b>31 (31.7%)</b>	

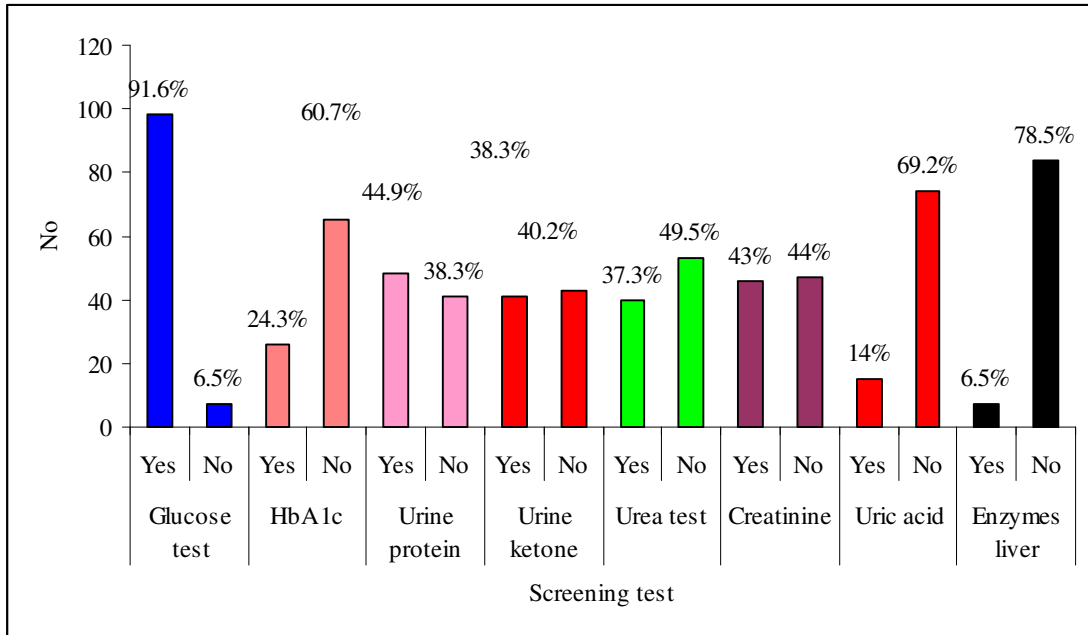
### 5.6.2 Management according to screening test

24.3% of the patients reported that they were tested for HbA1c at PHC, 5.6% reported that they were tested for ECG, 2.8% reported that they were tested for chest X-ray, 6.5% reported that they were tested for liver enzymes, 43.6% reported that were tested for triglyceride and cholesterol, 84.1% reported that they were tested for blood pressure see figure 5.11A, and figure 5.11B. No significant association was seen between screening tests and its frequency with glycemic control ( $P > 0.05$ , see table 5.18, and table 5.19): however protein test frequency in urine show significant association with HbA1c ( $P$  value  $< 0.05$ ).

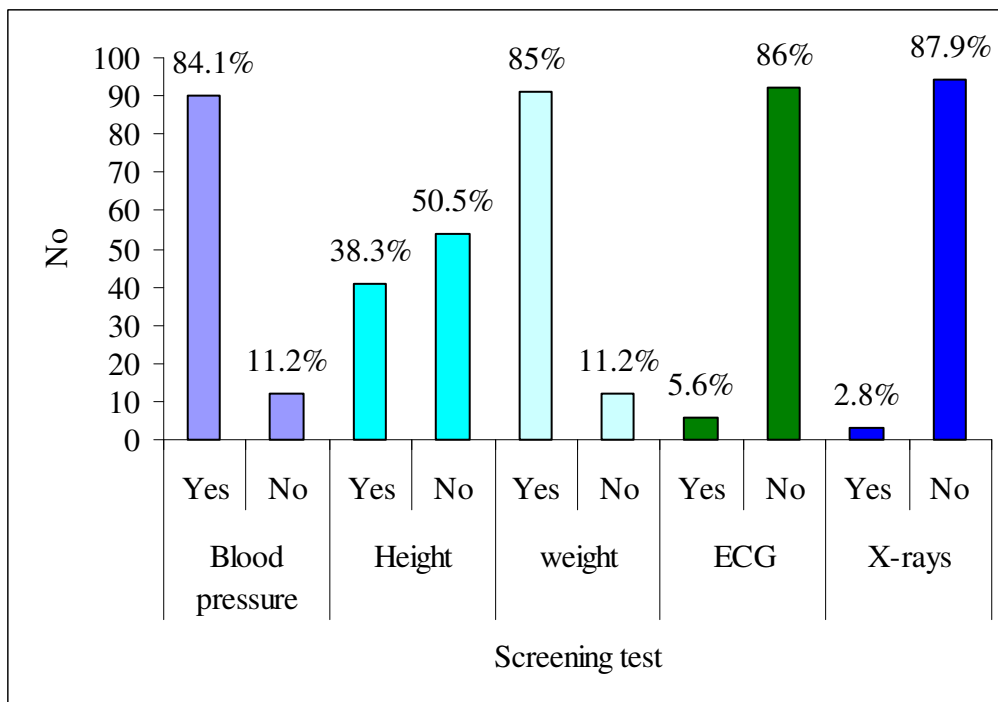
Ninety three patients (86.9%) have not been examined for retinopathy, 66% of them have been diagnosed with diabetes before 5 years.3.7% of the patients have been examined by



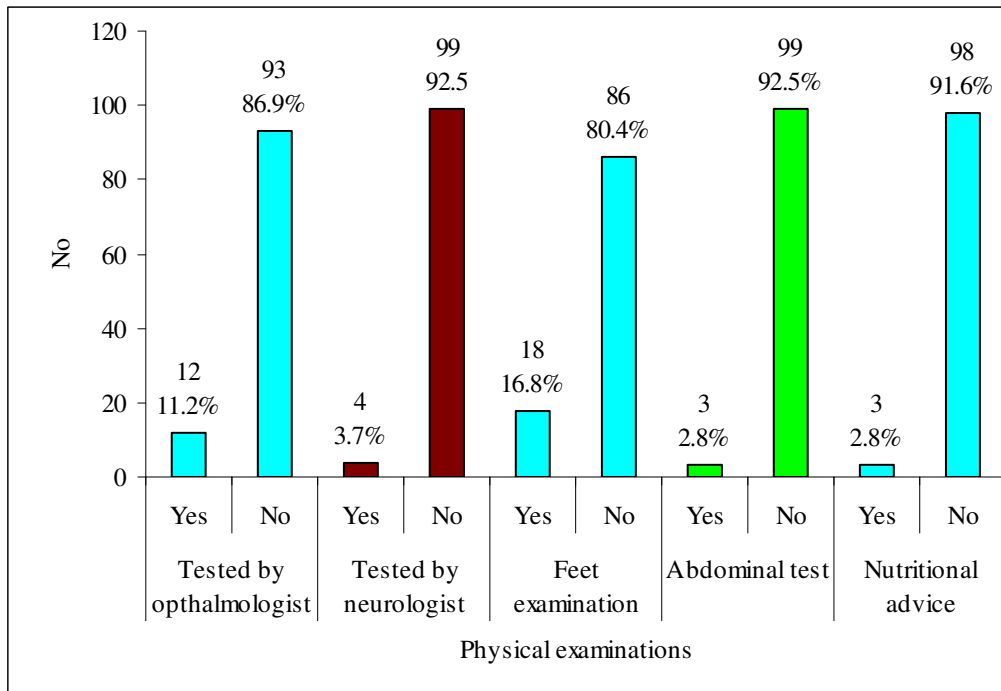
neurologist, 80.4% of the patients have not been examined for diabetic foot. 2.8% of the patient reported that they were tested by nutrients (figure 5.12).



**Figure 5.11A: The distribution of screening tests for the 107 patients in Ramallah district**



**Figure 5.11B: The distribution of screening tests for the 107 patients in Ramallah district**



**Figure 5.12: The distribution of physical examination tests for the 107 patients in Ramallah district**

**Table 5.18 : Association between laboratory screening tests with glycemic control**

<b>Variable</b>	<b>HbA1c &lt;8.5 N=57 (%)</b>	<b>HbA1c ≥8.5 N=34 (%)</b>	<b>Total N=107 (%)</b>	<b>P value</b>
<b>HbA1c*</b>				
Yes	18 (19.8%)	8 (8.8%)	<b>26(28.6%)</b>	<b>&gt;0.05</b>
No	39 (42.9%)	26 (28.5%)	<b>65 (71.4%)</b>	
<b>Urine protein*</b>				
Yes	27 (30.3%)	21 (23.6%)	<b>48 (53.9%)</b>	<b>&gt;0.05</b>
No	29 (32.6%)	12 (13.5%)	<b>41 (46.1%)</b>	
<b>triglyceride &amp; Cholesterol*</b>				
Yes	29 (31.5%)	18 (19.6%)	<b>47 (51.1%)</b>	<b>&gt;0.05</b>
No	29 (31.5%)	16 (17.4%)	<b>45 (48.9%)</b>	
<b>Urea</b>				
Yes	24 (25.8%)	16 (17.3%)	<b>40 (43.1%)</b>	<b>&gt;0.05</b>
No	34 (36.6%)	19 (19.3%)	<b>53 (56.9%)</b>	
<b>Creatinine</b>				
Yes	26 (28%)	20 (21.5%)	<b>46 (49.5%)</b>	<b>&gt;0.05</b>
No	32 (35.4%)	15 (15.1%)	<b>47 (50.5%)</b>	
<b>Uric Acid*</b>				
Yes	8 (9%)	7 (7.8%)	<b>15 (16.8%)</b>	<b>&gt;0.05</b>
No	47 (52.8%)	27 (30.4%)	<b>74 (83.2%)</b>	
<b>Urine ketones*</b>				
Yes	23 (27.4%)	18 (21.4%)	<b>41 (48.8%)</b>	<b>&gt;0.05</b>
No	29 (34.5%)	14(16.7%)	<b>43 (51.2%)</b>	
<b>Height*</b>				
Yes	23 (24.3%)	18 (18.9%)	<b>41 (43.1%)</b>	<b>&gt;0.05</b>
No	36 (37.9%)	18 (18.9%)	<b>54 (56.9%)</b>	
<b>BMI*</b>				
Yes	22 (21.2%)	17 (16.6%)	<b>39 (37.8%)</b>	<b>&gt;0.05</b>
No	42 (41%)	22 (21.2%)	<b>64 (62.2%)</b>	

\*Some cases were excluded from the analysis since answer not remember or missing data.

**Table 5.19 : Association between frequencies of laboratory screening tests with Glycemic control**

<b>Variable</b>	<b>HbA1c ≥8.5 N= No (%)</b>	<b>HbA1c &lt;8.5 N= No (%)</b>	<b>Total N= No (%)</b>	<b>P value</b>
<b>HbA1c</b> Once every six month Once a year Do not do	4(4%) 5(5%) 27(27%)	11 (11) 9(9%) 44(44%)	<b>15 (15%)</b> <b>14(14%)</b> <b>71(71%)</b>	<b>&gt;0.05</b>
<b>Urine protein</b> Once every six month Once a year Do not do	11(11.8%) 21 (22.6%) 24(25.8%)	10 (10.8%) 5 (5.4%) 22(23.6%)	<b>21 (22.6%)</b> <b>26(28%)</b> <b>46 (49.4%)</b>	<b>&lt;0.05</b>
<b>Ketone test</b> Once every six month Once a year Do not do	12(14%) 16 (18.6%) 25(29%)	5 (5.8%) 4 (4.7%) 24(27.9%)	<b>17 (19.8%)</b> <b>20(23.3%)</b> <b>49 (56.9%)</b>	<b>&gt;0.05</b>
<b>triglyceride&amp; Cholesterol</b> Once every six month Once a year Do not do	9(9.7%) 19 (20.4%) 30(32.3%)	12 (12.9%) 12 (12.9%) 11(11.8%)	<b>21 (22.6%)</b> <b>31(33.3%)</b> <b>31 (44.1%)</b>	<b>&gt;0.05</b>
<b>Creatinine test</b> Once every six month Once a year Do not do	7(7.1%) 23 (23.6%) 31(31.6%)	7 (7.1%) 11 (11. 2%) 19(19.4%)	<b>14 (14.2%)</b> <b>34(34.8%)</b> <b>50 (56.9%)</b>	<b>&gt;0.05</b>

### **5.6.3 Association between frequencies of laboratory screening tests with diagnostic complications**

We studied the association between diagnostic retinopathy and neuropathy with screening tests done for patients at PHC centers. Triglyceride and cholesterol show no significant association with diagnostic retinopathy (P value >0.05) (table 5.20and 5.21).While other association can not be done since chi square can not be calculated.

**Table 5.20 : Association between frequencies of laboratory screening tests with reported retinopathy**

<b>Variable</b>	<b>Diagnosed Retinopathy No (%)</b>	<b>No-retinopathy No (%)</b>	<b>Total No (%)</b>	<b>P value</b>
<b>HbA1c</b>				*
Once every six month	2(3.2%)	6(9.7%)	<b>8(12.9%)</b>	
Once a year	4(6.5%)	6(9.7%)	<b>10(16.2%)</b>	
Do not do	14(22.6%)	30(48.3%)	<b>44(70.9%)</b>	
<b>Urine protein</b>				*
Once every six month	11(20%)	6(10.9%)	<b>17(30.9%)</b>	
Once a year	2(3.6%)	10(18.2%)	<b>12(21.8%)</b>	
Do not do	6(10.9%)	20(36.4%)	<b>26(47.3%)</b>	
<b>Ketone test</b>				*
Once every six month	7(13.5%)	5(9.6%)	<b>12(23.1%)</b>	
Once a year	2(3.8%)	8(15.4%)	<b>10(19.2%)</b>	
Do not do	9(17.3%)	21(40.4%)	<b>30(57.7%)</b>	
<b>triglyceride &amp; Cholesterol</b>				>0.05
Once every six month	8(15.1%)	7(13.2%)	<b>15(28.3%)</b>	
Once a year	8(15.1%)	10(18.7%)	<b>18(33.8%)</b>	
Do not do	5(9.4%)	20(28.5%)	<b>20(37.9%)</b>	
<b>Creatinine test</b>				*
Once every six month	4(8%)	5(10%)	<b>9(18%)</b>	
Once a year	7(14%)	12(24%)	<b>19(38%)</b>	
Do not do	9(18%)	23(46%)	<b>32(64%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.21 :Association between frequencies of laboratory screening tests with reported neuropathy**

<b>Variable</b>	<b>Diagnosed neuropathy N= No (%)</b>	<b>No-neuropathy N= No (%)</b>	<b>Total No (%)</b>	<b>P value</b>
<b>HbA1c</b> Once every six month Once a year Do not do	1(1.6%) 3(4.8%) 6(9.7%)	7(11.3%) 7(11.3%) 38(61.3%)	<b>8(12.9%)</b> <b>10(16.1%)</b> <b>44(71%)</b>	*
<b>Urine protein</b> Once every six month Once a year Do not do	4(7.3%) 1(1.8%) 5(9.1%)	13(23.6%) 11(20%) 21(38.2%)	<b>17(30.9%)</b> <b>12(21.8%)</b> <b>26(47.3%)</b>	*
<b>Ketone test</b> Once every six month Once a year Do not do	2(3.8%) 1(1.9%) 6(11.5%)	10(19.2%) 9(17.3%) 24(46.3%)	<b>12(23%)</b> <b>10(19.2%)</b> <b>30(57.8%)</b>	*
<b>triglyceride&amp; Cholesterol</b> Once every six month Once a year Do not do	3(5.2%) 5(8.6%) 3(5.2%)	12(20.7%) 13(22.4%) 22(37.9%)	<b>15(25.9%)</b> <b>18(31%)</b> <b>25(43.1%)</b>	*
<b>Creatinine test</b> Once every six month Once a year Do not do	2(4%) 4(8%) 4(8%)	7(14%) 15(30%) 28(56%)	<b>9(18%)</b> <b>19(38%)</b> <b>32(64%)</b>	*

\*Chi square not calculated since expected count in one cell less than 5

## Part 6

### 5.7: Multivariate analysis

According to the results above, multivariate models for the major complications, i.e. retinopathy, neuropathy, nephropathy and HbA1C, with the significant above associations were investigated in multivariate models. However, due to the small numbers of patients (<68 patients in total) and the number of patients having the disorder, none of the models were significant to be presented in this data analysis.

## **Chapter six. Discussion& Conclusion**

- 6.1 Summary of study findings**
- 6.2 Socio-demographic factors**
- 6.3 Study population physical and health characteristic**
- 6.4 Diabetes history among study population**
- 6.5 Evaluated of reported complications and demographic variables**
- 6.6 Evaluation of objective testing by the various demographic variables**
- 6.7 Evaluated of diagnosed complications and demographic variables**
- 6.8 Home monitoring and self-care assessment as reported by patients**
- 6.9 Patients follow up and treatment by PHC centers**
- 6.10 Methodological aspects**
- 6.11 Conclusions**
- 6.12 Recommendations**

The distinguishing feature of this study is that it is the first to investigate in T1DM in Palestine. This study provides a baseline for further studies to improve diabetes health care and self-management, which therefore affects its complications.

The study was performed in primary health care centers that belong to the MOH and UNRWA health services in Ramallah district. It is an explorative study, which was used to identify possible complications among diabetic patients and problems in diabetes services from these primary health care centers.

### **6.1 Summary of study findings**

The response rate of the study was 81.7%. The number of diabetic patients type 1, as presented in the filing system of the MOH and UNRWA, was 142 patients. Only 116 registered patients participated in the survey. However, 9 of the 116 patients did not do the objective testing, in particular the HbA1c and were not included in the analysis. Therefore, 107 patients (92.2%) were included in the analysis. All the 107 patients filled in the study questionnaire and have been tested for at least HbA1c. Several reasons played a role in this response rate (81.7%). The most probable reasons for were that patients were very afraid that anyone might find out about their children diabetes so refused to appear in the study clinic, or some informed the investigators that their family doctors did not encourage them to engage with this research, and others did not have the interest to be part of any research.

In describing the study population, T1DM was more prevalent in the age group 10-20 years with a mean age 23.6 (SD  $\pm$ 10.5 years) and with no difference between males and females. The mean disease duration was 8.4 years (SD $\pm$ 7.2 years) and ranges 5-15 years. One third of these patients were obese and 23% were under weight. A 63.8% reported a family history of diabetes and 13.8% reported having at least one of their siblings with diabetes type 1.

Results showed the frequency of screening test for T1DM by PHC centers. Most patients did not have at least one of the needed tests to follow up these patients, as recommended by the international guidelines for T1DM. For example, neither any of them had physical eye examination nor had HbA1c level since a year or more.

In describing the complications among these T1DM patients, either as reported by patients themselves or as evaluated by the study consultants, early micro-vascular complication was



found to be very common among a population of young adults with mean 8.4 years of diabetes duration. The prevalence of retinopathy and nephropathy were similar by reported symptoms and by evaluation. However, clinical neuropathy was reported symptoms more by the patients themselves compared to evaluation.

The association between of risk factors with diabetic complication (reported and evaluated) was also investigated. The basis of the risk estimation was control of blood glucose, lipid, pressure, and socio demographic data. Diabetes duration and age were the only common significant risk factors for development of both evaluated and reported retinopathy. For neuropathy, duration, HbA1c and age were the only common significant risk factors for the development of both evaluated and reported complications.

The gap and variations of results between evaluated and reported complications could be due to one or more of the following reasons:

- Some patients were not tested by an ophthalmologist since the onset of their diabetes.
- Lack of interest among physicians regarding early detection of complications.
- Poor feedback and reporting system at the level of PHC centers.
- Socioeconomic and cultural factors affect negatively the compliance of patients to do the testing either due to its availability, access at the health service, or if not covered by insurance could be expensive.
- Many patients or their families hid the fact that they have such a disease. Therefore, did not do the testing since their families used to bring them their medication, so physically never attend the PHC for any follow up. This was clearly seen with the low compliance of these patients to do the testing and consultations in this study, although it was free of charge.
- Lack of enough and appropriate comprehensive services and this may due to its high cost.
- Lack of professional's skills among the health staff working at the PHC centers to link the complication with risk factors.
- Lack of appropriate specialists' consultations at the level of PHC centers.

In the coming sections the study results will be discussed and compared to the present literature in details.

## 6.2 Socio-demographic factors

Age, sex, marital status, place of residence, occupation type and educational level were the main socio-demographic factors that were of concern in this study conceptual model. The mean age of the study group was  $23.5 \pm 10.4$  years, and only 27% were children less than 16 years of age. Since this study was concerned with T1DM patients, it was expected that the studied group would represent a younger population. Studies around the world showed a younger T1DM patients (Fagulha et al., 2004, and Donaghue et al., 2005), while other studies showed a more older patients (Lievre et al., 2005). But, this study results were similar to others (Orchard et al., 1997) which showed that the mean age of population in a study conducted in USA was 27.9 years. Also, in the Spanish population, Blanco showed that the mean age of T1DM was  $24.8 \pm 6.7$  (Blanco et al., 2004), while in the Saudi Arabia the mean age group of patients was  $43.1 \pm 15.5$  (Ammari, 2004). Taking into consideration that our study is cross-sectional study, the result where the mean age of diabetic patients increase might be explained by the increase in the survival rate, so the survival rate among T1DM in our community is very low.

In general, males and females have similar risk of type 1 diabetes (Gale, and Gillespie, 2001). Our results showed that there was no difference in the overall prevalence of T1DM between males and females (47.7% vs. 52.3%). Similar findings were seen in other countries such as Kuwait, Lebanon, and United Arab Emirates (Mohamed et al., 2005; Yusef, 2000; and Punnose et al., 2002). However, in other studies conducted on the diabetes type 1 population, T1DM was prevalent more among females in Poland where 66% of the study population were females (Kozek et al., 2003), and was 62% females among the T1DM in Saudi Arabia (Ammari, 2004). The possible explanation for this finding is that the overall sex ratio is roughly equal in children diagnosed under the age of 15 years, while populations with the highest incidence ( $>20/100,000$ ) all showed it to be higher among males, the lowest risk populations studied ( $<4.5/100,000$ ), mostly of non-European origin, characteristically showed a female bias (Gale, and Gillespie, 2001).

Although the majority of cases in our study were singles, marital status was considered as a risk factor for T1DM complications. The percent of married cases in our sample populations was 33.6%. Similar findings were seen in other countries such as a study conducted by Ammari at Saudi Arabia in which married cases were 27% (Ammari, 2004).

In our study significant association was found between marital status and retinopathy, but El-Shazly from Egypt found that there was no association between diabetic retinopathy and marital status (El-Shazly et.al, 2000).

In developing countries the prevalence of diabetes mellitus is reported to be lower in rural areas compared to urban areas. This difference has been attributed to lifestyle factors associated with the higher socio-economic status of those living in urban areas (Mennen et. al., 2000; and Sobngwi and colleagues, 2002). However, in this study the prevalence of diabetes according to residency place showed that only 35.5% of diabetic population lived in cities. This is attributable to lifestyle changes of Palestinian community associated with urbanization and westernization. Rural lifestyle in Palestine is characterized by changes in dietary habits involving an increase in the consumption of refined sugars and saturated fat and a reduction in fiber intake, obesity and more stress due to social, cultural, political and economic environment.

Education has been shown to be a powerful and unique predictor of health outcomes - lower levels of education are associated with poor health and higher levels of education are associated with better health. This study showed that 83.2% of the participants did not finish high school. They were either illiterate, student, or did not finish the 12 years of basic education. When looking at different demographic groups participating in the study, big differences in the attended school years were detected.

Refugee camps residents had the lowest educational level in this study, whereas village's and city's populations had the same percent of high educational level. No significant difference was seen between male and female, both have the same percent of low and high education. Nicolucci found that educational level can determine a complication risk not dissimilar from hard clinical variables, such as hypertension and diabetes duration (Nicolucci et. al., 1998). Chaturvedi in his study found that healthy lifestyles are more prevalent in better educated men and women with IDDM, but these are not reflected in heart disease prevalence in men. The lower prevalence of severe micro vascular complications was seen in better educated men (Chaturvedi et al., 1996). Whereas El-Shazly from Egypt found that there was no significant association between the development of eye complications and educational level of diabetic patients (El-Shazly et al., 2000). In this study, education appears to have no affect on diabetes prognosis. A

possible explanation for this study finding might be related to the low understanding of the illness and therefore low commitment of self care. In this study, in spite of a longer mean duration of diabetes, those with a college education had the same complication rate as less educated (complication rate 38% vs. 33% for less educated).

The study showed that 38.3% of the participants are worker, i.e. employed, marcher, unskilled worker (cleaner) etc. Patients who are currently employed or working had higher diagnostic retinopathy (23.4%) as compared to those not working (7.4%) or student (3%). In other studies they found no significant association between the development of eye complications and occupation of diabetic patients (El-Shazly et. al., 2000)

### **6.3 Study population physical and health characteristic**

Overweight (BMI  $\geq 25$  kg/m<sup>2</sup>) and obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) are becoming increasingly prevalent in the industrialized world, not only in type 2 but also in type 1 diabetic patients. The role of body weight/BMI in the development of vascular complications of T1DM is unclear. A study conducted in Belgium by Christophe found that BMI above  $\geq 25$  kg/m<sup>2</sup> was 47 % among type 1 diabetic patients ( Christophe et. al., 2005). In Saudi Arabia, Ammari found that the BMI  $>30$  was 61 % among T1DM patients ( Ammari ,2004). While Punnose in his study at United Arab Emirates found that obesity present in 12.5% of diabetic patients and super-obesity found in 9% (Punnose et. al .,2002). In the studied population, 36.4% of the participant had BMI over 25, which means that this proportion of the sample is categorized in the obese group.

Intensive insulin therapy, as shown in the Diabetes Control and Complications Trial, is associated with an increase in body weight (DCCT, 1993). Possible explanations for weight gain with improvement of glycemic control include elimination of caloric loss from glycosuria, shift in fuel use from fatty acids to glucose, and an insulin-induced increase in appetite (Carlson, and Campbell., 1993). However, this could not be observed in the present study. Overweight and non-overweight subjects injected a similar insulin dose/kilogram body weight. Theoretically, insulin resistance could contribute to the development of chronic diabetes complications. Recent studies of type 1 diabetic patients have shown that a higher BMI is associated with hypertension and an atherogenic lipid profile as part of the insulin resistance syndrome. The adverse lipid profile consists of

higher triglyceride and LDL cholesterol levels and lower HDL cholesterol levels (Purnell et al., 1998). Christophe in his study observed a positive correlation between BMI and total cholesterol, LDL cholesterol, and non-HDL cholesterol in men but not in women. Overweight men had a more unfavorable risk profile than overweight women, with higher blood pressure and worse lipid profile. In our study men with BMI  $\geq 25$  kg/m<sup>2</sup> have higher average of cholesterol and Triglyceride compared with women in the same categories (210 and 195 vs. 181 and 141).

For blood pressure diagnosis, the MOH and UNRWA considered patients to be diagnosed with high blood pressure if he had blood pressure persistently  $\geq 140$  mm Hg systolic or  $\geq 90$  mmHg diastolic. Using this cut-off level in our study, 3.7 % of participant only had reported having high blood pressure. In comparison, 4.4% were diagnosed to suffer from hypertension through objective testing when patients were consulting with endocrinologist. The EURODIAB IDDM Complications Study examined 3250 randomly selected Type 1 diabetic patients with a mean duration of diabetes of  $14.7 \pm 9.3$ , of whom 24% patients reported having hypertension (Collado-Mesa, 1999). Blanco in his study found that was 20.4% of T1DM had hypertension (Blanco et al., 2004), while Ammari found that the prevalence of hypertension was 25% among Saudi diabetic patients (Ammari, 2004). The low percent of high blood pressure in our study might be due to that most patients are young in age and have not long period of disease duration. Many studies have convincingly demonstrated the valuable effect of blood pressure level as a risk factor for the initial development of diabetic retinopathy and nephropathy (Chaturvedi et al., 2001; Olsen et al., 1999; and Schultz et al., 2001), perhaps partly explained by not adjusting for the confounding effect of metabolic control, diabetes duration and early stages of nephropathy. Since the number of patients diagnosed with hypertension was very low, our study does not support the importance of higher blood pressure levels for the development of microvascular complications. However, the role of blood pressure levels must still be considered unclear and intervention studies with early antihypertensive therapy and long follow up are necessary to eventually investigate the clinical importance and create guidelines for clinical practice.

For blood glucose monitoring, UNRWA health centers use two hours postprandial blood glucose values for monitoring of blood glucose, therefore, a blood glucose  $< 180$  mg/ml considered controlled blood glucose. MOH use fasting blood glucose (FBG) for 8 hours,

therefore, FBG <140 mg/ml considered controlled blood glucose. According to the last blood glucose readings reported by patients, 58.8% of the sample were considered to have uncontrolled fast blood glucose. While 82% of the sample were considered to have uncontrolled random blood glucose. This high result of uncontrolled blood glucose will accelerate the development of diabetes complications. The mean postprandial blood glucose level (mg/dl  $\pm$  SE) in our study was 225 $\pm$ 10.6. This finding is much higher compared with a multicenter randomized open label 6-month study conducted by Raskin at USA and Canada include subjects with type 1 diabetes found that the mean postprandial blood glucose levels (mg/dl  $\pm$  SEM) were significantly lower for subjects in the IAsp group compared with subjects in the HI group after breakfast (156  $\pm$  3.4 vs. 185  $\pm$  4.7) (Raskin et al., 2000).

Several studies such as the DCCT and the United Kingdom Prospective Diabetes Study (UKPDS) had clearly demonstrated that improved glycemic control (HbA1c) reduces the development and progression of several micro- and macrovascular complications in both type 1 and type 2 diabetes mellitus. UNRWA does not include HbA1c in its routinely screening test for diabetic patients, However MOH newly entered HbA1c in its services depending on its availability at PHC centers. In the studied population, there were 50 % of participant who reported having been tested for HbA1c during the last six months. This percent give us a clear idea about diabetes monitoring. This finding is similar compared with a Retrospective cohort study conducted by Christaki at USA that include subjects with type 1 diabetes found that only 54% in the year 1997 had their HgA1c checked by PHC (Christaki et al., 2001).

Smoking is a serious health problem, and in diabetic patients it adds to the increased risk of coronary artery disease and micro vascular disease. In our study 26.2% of diabetics patients reporting being smokers compared with 33.2% reported by Blanco (Blanco et al., 2004).Where Chaturvedi found that the prevalence of smoking was 35% in men and 29% in women (Chaturvedi et al., 1995). It was suggested that smoking which is a major main variable in diabetes and can affect glycemic control .How ever, there was no significant relationship between smoking and glycemic control in our study. This could be explained by that poorer glycemic control can account for some of the increased risk of complications in smokers, and that quitting smoking would be effective in reducing the incidence of complications (Chaturvedi et al., 1995).

#### **6.4 Diabetes history among study population**

In this study, 57.1% of patients had diabetes for more than five year (mean duration of the disease was 8.3 years. This study finding is higher than the duration of disease found by a study conducted at Portugal by Fagulha in which disease duration was 5.2 yr $\pm$ 3.95 .another study conducted at Azerbaijan has duration of disease 3.5 $\pm$  .36yr (IDF, 2003). While the mean duration of disease in EURODIAB IDDM Complications Study was 14.7 $\pm$ 9.3 (The EURODIAB IDDM Complications Study, 1994). Olsen in his study at Denmark found median diabetes duration 13.2 years (range 8.9-24.5) (Olsen, 1999).

As shown in literature, patients having diabetes for more than 5 years need a regular physical eye examination. However 25.9 % of the registered study patients have been registered as T1DM for more than 10 years in The UNRWA and MOH. These patients are likely to have various diabetes mellitus complications and they are in bad need for comprehensive care to avoid irreversible severe complications that may lead to early disability, morbidity and mortality. Not unexpectedly, duration of diabetes in our study was a significant independent risk factor for both reported and evaluated retinopathy, and also between reported and evaluated neuropathy, which is also in concordance with other studies. Since blood pressure, BMI, lipid values and prevalence of history of CVD and smoking increase with age, this of course highly correlates with diabetes duration.

The hormonal changes and rapid growth that take place during puberty usually have an unfavorable effect on the metabolic balance in T1DM. Together with psychological changes and poor compliance, these events form a challenging equation in the clinical care of adolescent patients with this disease. Based on age at time of diagnosis, 48.6% of the sample was diagnosed between 10-20 years of age, which concordance with other studies finding and the literature about the peak incidence of DT1 occurrence between ages 10-15 years. The results show that the mean age at diagnosis was 15.5 $\pm$ 7.4 yr (range 1-30 year), this is congruent with the result of Blanco (Balnco et al. 2004) that showed a mean age at diagnosis of 13.8 $\pm$ 6.9 years. While Punnose in his study at United Arab Emirates found mean age of onset of Type 1 DM 9.2 $\pm$ 4.1 years with the peak incidence being in the 10–14-year age group (Punnose et al . 2002).

In this study, 56.9% of the sample population were diagnosed by general practitioners who run the PHC centers. This segment of doctors who are the most important link in early

diagnosis and guiding the patient properly, but are often not well trained to handle diabetes related issues, unaware of the latest trends, or unable to devote time to diabetes due to their busy practice. This study is consistent with the study of Abu Mousa (1998), which shows that 73.4% were diagnosed by general practitioners. Rayappa from India found in his study that most of the respondents (type1 and type 2), over 91%, initially visited a non specialist for diagnosis (Rayappa, 1999). Punnose in his study at United Arab Emirates show that all patients in his study had a diagnosis of diabetes mellitus at the Al-Ain hospital(Punnose et al ., 2002).

Most patient who develop T1DM can not tolerate having diabetes without treatment and daily insulin injection, while patient with type 2 diabetes can live years without diagnosis. So the diagnosis of T1DM will be after the appearance of symptoms directly within few days. Each patients was asked about the circumstances or health events led to diagnosis of diabetes. 53% of the sample population were diagnosed following appearance of classical symptoms of diabetes mellitus; weight loss, polyuria, polydepsia, general tiredness and easy fatigability, polyphagia, blurred vision and repeated infections. Abu Mousa (1998) in his study found that 35.1% of the sample population was diagnosed following appearance of classical symptoms of diabetes mellitus.Punnose in his study at United Arab Emirates found 94.2% of the type 1 diabetic patients had glycaemic symptoms for several days prior to the diagnosis and 60% of them were symptomatic for 15 days ( Punnose et al.,2002).

The exact cause of the disease is still unknown which make it to be considering as idiopathic disease. However, our study showed that most cases reported that they do not know the cause of their disease. Genes that are responsible for transmitting the diabetes disease determine opportunities for health and susceptibility to diseases, while environmental factors determine which susceptible persons will develop illnesses. In this study the prevalence of positive family of diabetes i.e. mother, father ...etc was 64%, this seems that genetic and hereditary factors may play a role in the development of diabetes type 1. The result of this study is consist with that done by Punnose in United Arab Emirates (2002), which found the family history of T2DM was obtained in 57% and Type 1 DM in 6% patients (Punnose et al .,2002). However our results is higher than that done by Ammari in Saudi Arabia which found 33% of patients had positive family of diabetes (Ammari, 2004).



## 6.5 Evaluation of Diabetes-Related Complications

48.5% reported having one or more of the common chronic diabetes-related complications. This is a striking finding reflecting the extremely high prevalence of complications in the Palestinian diabetic type 1 population. Knowing that only 18.7% of the studied population had HbA1c less than 7%, and that 38.3% had HbA1c above 8.5%, there is reason to think that the studied population is at risk regarding the development of serious diabetes complications. The most common reported complication of diabetes in this study was found to be retinopathy (36.4%).

The result of this study is consistent with a study in USA Siddiqui et al (2001) in which eye problem related to diabetes was 43.4% . Similar finding was seen by a study conducted by (Feleke1 and Enquesselassie, 2005) in Ethiopia in which diabetes related eye disease was 33%.

The prevalence of retinopathy is strongly related to the duration of diabetes, but prolonged hyperglycemia might accelerate early development of retinopathy due to early and progressive changes in the retinal capillary bed (Pickup et al., 1991, and Viswanath et al., 2003). In our study both duration and age of diabetic patients showed a significant association with reported retinopathy while glycemic control did not. This could be due that some patient reported not to have retinopathy but when they are tested by ophthalmologist was found to have one of retinopathy classification. The under-diagnosis of retinopathy was found in 10 patients (13.2%) who did not report that when interviewed.

A 26.2% of the sample reported neuropathy complications which were considered positive by having a reported positive answer to any of these symptoms: having pain at the site of peripheral nerves, loss of sensation, numbness, burning sensation, muscular weakness, impotence and bladder dysfunction, postural hypotension, dizziness chronic headache. The DiaComp study which is a multinational (17 countries) cross-sectional study examining 892 T1DM patients diagnosed at age <15 year with diabetes duration of 5–24 years found that reported neuropathy by patients in Lithuania was 22.1% vs. 12.4% when tested by Michigan Neuropathy Screening Instrument exam for neuropathy, while in Slovakia (Martin) reported neuropathy was 10% vs. 6.9% for examined (ADA, 2004). Patients with peripheral neuropathy need visual perception to normalize gait, avoid injury, and detect emerging foot ulcerations.

Reported neuropathy show high prevalence than evaluated neuropathy by consultation, this may be due to that patient consider lipodystrophy as a neuropathy complication.

7.5% of the sample population reported nephropathy complications. Most of these patients who reported having diabetic nephropathy have undergone kidney dialysis or past diagnosed with renal disease, so the exact prevalence of nephropathy might be higher than the reported nephropathy. This might be due to the fact that the PHC centers of both UNRWA and MOH do not test patients for micro and macroalbuminuria in their routine screening tests which is an early detection for nephropathy. The DiaComp study found that reported nephropathy by patients in Japan was 4.3% vs. 23.1% when tested for microalbuminuria (MA), while in UK was 8.1% vs. 23.1% (ADA,2004).

4 (3.7%) of the sample reported cardiovascular complication. This low prevalence might be due to the fact that macrovascular diseases are more common among patients with diabetes type 2 than T1DM. As known, uncontrolled blood glucose might lead to accelerated heart disease by increasing arterial stiffness (Bate and Jerums, 2003). In our study the average value for HbA1c of the patients that reported heart disease was 9.2 (standard error  $\pm 0.8$ ). Other risk factor for developing heart disease could be duration of disease (Latika et al., 2006). In this study, the average duration of disease for patient that reported heart disease ( $X \pm SE$ ) was  $12.0 \pm 4.2$  year.

Poor glycemic control and duration of diabetes was shown to increase the occurrence of diabetic foot (Watkins, 2003). 11 (10.3%) of the sample reported having diabetic foot complication, and the average HbA1c for these patients was 8.2 ( $SE \pm 0.4$ ). This increase in HbA1c value may play as risk factors for developing diabetic foot. Other risk factors could be the duration of disease, the average duration for diabetic patients with reported diabetic foot was 11 ( $SE \pm 2.2$ ).

## **6.6 Evaluation of objective testing by the various demographic variables**

### **A: Glycemic control**

The present data suggested a lack of public awareness about T1DM in the Palestinian community. This study's patients had a delayed presentation as evidenced by very high mean plasma glucose  $203 \pm 9$  mg/dl (range: 37-510). This result is much higher than the normal range for glucose or the recommended value for diabetic patient according to ADA. This could be explained by the effect of low insulin dose in monitoring blood glucose. The ADA recommends that the goal of therapy should be an HbA1c concentration  $<7\%$  and that treatment regimens should be reevaluated if HbA1c values are consistently  $>8\%$ . Similar finding to this study results was shown by the DCCT study in which the mean blood glucose was 230 mg/dl in the conventional group, while it is 155 mg/dl in the intensive group (DCCT, 1994). Also, in a study in United Arab Emirates, the mean plasma glucose among the investigated patients was  $497 \pm 198$  mg/dl (Punnose 2002).

The normal range as recommended by the ADA for HbA1c is 4.5-7% (ADA, 2004). In this study the average of objective HbA1c was 7.8 (SE  $\pm 0.16$ ). According to this result this study diabetic patient are at the risk range or above the recommended value of HbA1c. In relation to metabolic control result, this study's patients had lower HbA1c than other groups (Nordwall et al., 2006). This could be explained by the younger age of the patients included in the previous study, with a higher percentage of children and adolescents, in whom metabolic control is more difficult. The results presented herein are quite similar to the data reported in Spanish population (Blanco et al., 2004).

### **B: Kidney function testing**

In this study, investigators used urea and creatinine to test the kidney function. The mean serum urea was 28.2 mg/dl (SE  $\pm 1.4$ , range: 6-88). The mean serum creatinine was 0.9 mg/dl (SE  $\pm 0.05$ , range: 0.4-4.1). These results are within the normal range of blood urea and creatinine, which are similar to Blanco et al study results in Spain (Blanco et al., 2004). Patient classification according to demographic data show normal value for urea. This finding could be explained by the high result of urea only found in patient with diagnosed nephropathy in which the average urea was 61 (SE  $\pm 11.4$ ) compared to 27 (SE  $\pm 1$ ) in patient without nephropathy. Rehman and Hamayun in there study that was conducted in Pakistan found that the mean blood urea for T1DM patients with nephropathy was 158 (SE  $\pm 1.93$ ) (Rehman and Hamayun, 2004).

Patient's classification according to demographic data show high value for creatinine among the non worker. This finding could be explained by the high result of creatinine only found in patient with diagnosed nephropathy and most of them have kidney dialysis which makes them unable to work. In our study the average of creatinine for patients diagnosed with nephropathy was 2.3 (SE±.56) which lower than that found by Rehman and Hamayun (2004) among Pakistani patients diagnosed with nephropathy where mean blood creatinine was 6.94 (SE±0.07) ( Rehman and Hamayun,2004).

### **C: Lipid profiling**

Recent studies of type 1 diabetic patients have shown that a higher BMI is associated with hypertension and an atherogenic lipid profile as part of the insulin resistance syndrome. The adverse lipid profile consists of higher triglyceride and LDL cholesterol levels and lower HDL cholesterol levels. HbA1C correlated positively with total and LDL cholesterol and triglyceride in men.

In this study total cholesterol was 191 mg/dl (SE ±5.1). Yusef in his study that conducted at UNRWA primary health care facilities in Lebanon found that mean cholesterol level (185 ± 52 mg/dL) (Yusef, 2000). Similar result was found in a study conducted by Blanco (2004) in Spanish patients in which total cholesterol was 182.6±35.6. In our patients, triglyceride concentration was higher (142 ±11.1 vs. 70.4±47.7), serum LDL cholesterol concentration was significantly higher (123±4.7 mg/dl vs. 109.1±31.3 mg/dl) and HDL concentration significantly lower (42±0.8 mg/l vs. 58.5±14.5 mg/dl) comparison with Spanish diabetic patients at Blanco study (Blanco et al ., 2004) .While Yusef in his study conducted at UNRWA primary health care facilities in Lebanon found the mean triglyceride level (170 ± 154 mg/dL) for type 1 diabetes patients (Yusef,2000).

Serum lipid profile i.e. triglyceride, cholesterol were higher in older male who are worker than in the other demographical categories of patients, and were even higher in patients with poor metabolic control. This result is similar with that done by Yusef in Lebanon (2000). Since increased serum triglyceride concentrations and a high waist to hip ratio were found in the EURODIAB Study to be risk factors for retinopathy (Porta et al., 2001) and persistent microalbuminuria (Chaturvedi et al.,2001) we cannot rule out the possibility that these patients in this particular study had a greater risk of microvascular complications. Yusef in his study conducted at UNRWA primary health care in Lebanon found that there is a difference between the means for both sexes was statistically

significant for triglycerides but not significant for cholesterol (Yusef, 2000). However, in our study significant association for both mean of cholesterol and triglyceride with sex was found.

## **6.7 Diagnosed T1DM complications**

### **6.7.1 Retinopathy**

There is a paucity of information about the prevalence of retinopathy in T1DM in Palestine. Some reports refer to diabetic patients as a whole, not only T1DM (Abu Mousa, 1998). The present study has revealed a relatively high prevalence of diabetic retinopathy among T1DM in Ramallah district. Our results are similar to those of some studies (Agardh et al., 1997; Kozek et al., 2003) but much higher than those of others (Blanco et al., 2004; Nordwall et al., 2006; Donaghue et al., 2005). This may be due to better diabetic control. Patients with retinopathy had higher HbA1c compared to patients without retinopathy. The present study has revealed that retinopathy is more frequent in males than female. Our results are similar to those of some studies (Pinto-Figueiredo et al., 1992). This difference may be attributed to that finding by the EURODIAB Study which reported that moderate non-proliferative diabetic retinopathy to be significantly less frequent in women than in men, but mild nonproliferative and proliferative diabetic retinopathy did not differ between the sexes (Sjolie et al., 1997). Our study shows that there is a significant relationship between age and development of diabetic retinopathy, this is similar to previous findings by other studies (Lievre et al., 2005; Klein et al., 1984). The present study has revealed a significant relationship between retinopathy with marital status. This is not similar as other studies (El-Shazly et al., 2000; Zhang et al., 2001). This finding may be attributed to that most people who are married are older in age. Our study showed that there is a significant relationship between smoking habit and development of diabetic retinopathy, these findings are consistent with other studies from different parts of the world (Muhlhauser et al., 1996; Chaturvedi et al., 1995; Chase et al., 1991). While this finding is different from other studies (Blanco et al., 2004; Ammari, 2004). The diverging results could in part be explained by not adjusting for the possible confounding effect of metabolic control in some studies. The duration of diabetes is probably the strongest predictor for development and progression of retinopathy, long duration of diabetes is shown among patients with retinopathy compared to patients without retinopathy in this study. This finding is similar as reported in different previous studies (Blanco et al., 2004; Ammari, 2004). The prevalence

of retinopathy in our study in patient diagnosed with T1DM post pubertal was significantly greater than prepubertal diagnosed subjects. This significant association finding is similar as reported in previous studies in which age at diagnosis and puberty play a major role in developing retinopathy (Kernell et al., 1997).

The Diabetes Control and Complications Trial Research Group have shown that intensive insulin therapy aiming at glycemia levels as close to the non-diabetic range as possible is effective in delaying the onset and slowing the progression of diabetic retinopathy (DCCT,1993).Patients with retinopathy had higher HbA1c compared to patients without retinopathy. This study further showed a direct association between poor metabolic control and retinopathy, as also has been observed in several other previous studies (Blanco et al., 2004; Ammari, 2004; Danne et al., 1994). We used only the result of determinations of HbA1c performed in the objective testing of the study; in that case, the value of the analysis of the relationship between glycemic control and the prevalence of complications is limited. We think, however, that it probably reflects the metabolic control for a particular patient during a longer period. In this sense, Aghard et al., in a 5-year follow-up study of 442 adults type 1 diabetic patients under routine care, showed that the individual levels of glycemic control and blood pressure can be kept fairly constant.

Significant relationship between microalbuminuria and diabetic retinopathy was shown in previous studies (Danne et al., 1994) .In our study patients with retinopathy show high average results of kidney function tests i.e, creatinine and urea. In this study significant association was shown between Triglyceride, cholesterol and LDL-cholesterol, as also has been observed in several other previous studies (Chaturvedi et al., 2001; Watts et al., 1996).

### **6.7.2 Nephropathy**

About 7.4% of the patients in this study had nephropathy. This finding is similar to other finding by previous studies (Fagulha et al., 2004; Olsen, 1999). Our prevalence is much lower than that reported by some authors (Rahlenbeck & Gebre-Yohannes 1997; Andersen et al 1983), which may be due to types of studies used. The low prevalence of nephropathy in this study may come from our evaluation since it depends only on creatinine and urea measurement which give an indicative for the last stage of nephropathy and not the beginning stage. As a consequence of the rather low prevalence of nephropathy and the cross sectional nature of the present study, and a rather limited number of patients in the

various demographical data, this study does not allow to assess the impact of demographical variable on nephropathy any further. However, other series have shown that demographical data is associated with an increase in nephropathy (Andersen et al 1983).

Some studies showed that adult men with T1DM have a higher risk of diabetic nephropathy than women (Andersen et al 1983). These studies also showed that the relationship between sex and increased microalbuminuria is not straightforward (Canton et al., 2004; Ammari, 2004). In this respect our finding of nephropathy shows that both adult male and female have the same percent value to develop nephropathy.

Rossing and colleagues showed that the duration of diabetes has a role as risk factor in developing nephropathy (Rossing et al., 1995). In this respect our finding shows that the mean duration of diabetes among patient who develops nephropathy was higher than those who did not have nephropathy ( $18.6\pm 3.5$  vs.  $6.9\pm 0.9$ ).

Poor long term glycemic control, and poor control during the first years of diabetes in particular may later predispose to microalbuminuria (Powrie et al 1994, Rudberg et al., 1993). In keeping with the previous findings the patients with nephropathy in the present series had higher HbA1c than those without nephropathy ( $9.3\pm 0.6$  vs.  $7.7\pm 0.2$ ).

The mean average for cholesterol, triglyceride, and LDL was much higher than those with out nephropathy ( $223\pm 20, 175\pm 20, 158\pm 23$  vs.  $189\pm 5.8, 145\pm 14, \text{ and } 118\pm 4.9$ ). These results are consistent with those described previously in the Spanish population (Blanco et al., 2004) suggesting that patients who develop nephropathy have a worse lipid profile.

### **6.7.3 Neuropathy**

20.6% of the patients in the present study had clinical neuropathy with significant difference according to sex. This finding is similar to other finding by previous studies (IDF, 2003; Kokez et al., 2003). This study show lower prevalence of neuropathy than previous reports from Denmark and Sweden (Olsen, 1999; Nordwall et al., 2006). The discrepancy between the percentages of neuropathy prevalence in our study and these two studies is probably due to the slightly higher duration of diabetes, although some other factors could be involved, including some methodological issues.

Poor metabolic control is one of the most important prognostic factors on peripheral nerve function in children and adolescents with T1DM (Dahl-Jørgensen et al 1986; Amthor et al., 1994), while duration of diabetes may become increasingly important for the

progression of nerve dysfunction later in the course of diabetes (Ziegler et al 1991; DCCT, 1993). In keeping with the previous findings the patients with neuropathy in our study not only had higher HbA1c than those without neuropathy but also a longer duration of diabetes.

## **6.8: Home monitoring and self-care assessment as reported by patients themselves**

### **A: Self assessment**

It was important to know how the diabetic patients deal with their diabetes, and how does he/she consider his/her life-long visitor that will live with him for the rest of his life. Therefore, self-management of diabetes is the ultimate goal for all patients with diabetes, with insulin dosing decisions based on interpretation of blood glucose results. Self-monitoring of blood glucose (SMBG) allows people with diabetes and their families to measure blood glucose levels rapidly and accurately. All basal/bolus diabetes management regimens of insulin and all self-management skills rely on frequent SMBG.

In the present study, the self-monitoring of blood glucose was reported by 68.2% of the study sample at home by using glucometers. However, only 24.3% reported to test their blood glucose more than one time per a day. The DiaComp study which is a substudy of the WHO DiaMond study of type 1 diabetes incidence, it comprised 25 centers world wide found different results of daily SMBG as reported by participants. In Puerto Rico, Romania, and Sweden the percentage of daily SMBG was 30%, 27.8%, and 23.5% respectively. While in Israel, Italy, and U.K the percentage of daily SMBG was 67.3%, 92.2%, and 79.5% respectively (ADA, 2004). Punnose in his study conducted in United Arab emirates found that (57%) had regular blood glucose monitoring (daily fasting and 2–3 post prandial values) at home (Punnose et al., 2002).

In our study Glucose measurement at home show no significant association with glycemic control. This could be explained that most patients lack good interpretation of blood glucose monitoring results and how to use these results for insulin dose calculations. The low percentage of glucose measurement at home could be due to economic factors (i.e. price of strip), and lack of reinforcing and follow up possibilities.

The findings about self-monitoring show that 2.8% of our patients used urine sticks for testing glucose and the same percent was seen for ketone test in urine. The result of this



study is much lower than that done by Bassili at Egypt in which checking glucosuria at home was 45.2% of insured children compared to 34.0% of uninsured children (Bassili et al., 2001). This low percent of finding indicate that patients at the risk of establishing ketoacidosis, a condition that requires immediate medical attention.

Home blood pressure monitoring may be useful in the management of many patients with hypertension and diabetes. The United Kingdom Prospective Diabetes Study (UKPDS) clearly demonstrated the need for tight control of blood pressure in persons with diabetes (UKPDS, 1998). In this study, “tight” blood pressure control reduced the risk of multiple diabetes endpoints: 32% decrease in deaths related to diabetes; 44% decreased risk of stroke; and 34% decrease in risk of all macrovascular diseases, as well as a significant decrease in the development of retinopathy and proteinuria. In this study only 26% of the diabetic patients reported that they measure their blood pressure at home. Jilleh in his study at Palestine found that 85.5% of diabetic patients check their blood pressure regularly and 80% check it every month (Jilleh, 2002).

### **B: Diet regiment**

In the study sample, 60 patients (56%) reported that they had follow diet regiment. Roaeid in his study conducted at Libyan Arab Jamahiriya found that among both type 1 and type 2 only 2.7% of them were on diet control (Roaeid R, and Kablan A.,2007).

However, no statistical significant found between diet regiment and glycemic control. This could be explained by that most patients do not consult with a dietitian to develop/discuss their medical nutrition plan. Another reason could be due to incorrect dose of insulin. Patients do not consider height, weight, and BMI in diet regimen and this mainly to less educated program about management of diabetes.

### **6.9 Patients follow up and treatment by PHC centers**

It is universally accepted that a number of services are supposed to be provided in the diabetes health care facilities. These core services are recognized as the components of optimal diabetes care (Hiss, 1996, and ADA, 2006). They include: Consultation with general pediatrician (GPs), consultation with dietitian, ophthalmologic examination service, neurological examination, provision of health education program, evaluation of the previous treatment and the past and present degrees of glycemic control, and having

laboratory testing (HbA1c, lipid profile, microalbuminuria, serum creatinine) and heart echogram (ECG).

#### **A: Services in PHC**

Another important determinant for T1DM disorder complications is the provision of certain services, as shown in the study conceptual framework. In our study, clinical services were identified as the most important services to be offered to the diabetic patients in the health care setting. A 62.6% of the study population receives care at MOH, PHC centers only, while 30.1% receive their whole treatment from UNRWA, PHC centers only. The results of this study differ from that conducted by Abu Mousa (1999) in which 49.3% receive care at UNRWA, PHC centers, and only 31.1% from MOH (Abu Mousa, 1999). However, place of care showed no significant association with glycemic control. This could be explained that both UNRWA and MOH have nearly the same services offered to diabetic patients.

#### **B: Availability of health insurance**

Another important determinant for services provided for T1Dm patients is having health insurance, as shown in the study conceptual framework. Most study populations have health insurance. However, no statistical significant relationship between health insurance and glycemic control. This could be due to that most these health insurance does not cover all treatment of diabetes, and it is just for receiving insulin and cover test available at PHC only. El-Shazly in his study that conducted in Egypt found no significant association could be detected between being health insured and the development of retinopathy(El-Shazly et al ., 2000).

#### **C: Management according to insulin therapy type**

Insulin therapy of type 1 diabetic patients aims at insuring both a good quality of life, especially avoiding severe hypoglycemia, and a good metabolic control in order to prevent diabetic complications. The most appropriate insulin scheme comprises the injection of short-acting insulin before each meal, to control postprandial hyperglycemia, and one (or possibly two) injection of a long-acting insulin, to maintain adequate plasma glucose levels

between meals and at time bed (Philips, and Radermecker, 2005). A 77.6 % of the participants reported using insulin mixture in there treatment at time of interview. This could be explained that this type of insulin is the most available at both MOH and UNRWA. Most of the diabetic participants use two injections daily. Mortensen et al in there study found that 60% of the children used two daily insulin injections while 37% used three or more. Of those on two or three injections daily, 37% used pre-mixed insulins, either alone or in combination with short- and intermediate-acting insulin (Mortensen et al., 1998). In United Arab Emirates Punnose in his study found that 68.6% of patients were managed with NPH insulin, 17.1% of patients with premixed NPH/regular insulin (70/30) and in 14.3% of patients regular insulin was added to NPH insulin. Of these patients 91% had two times daily insulin injection ( Punnose et al ., 2002).In this study no significant association between glycemic control and insulin therapy type this could be explained to Insulin type characteristic and patients' factors, in which both these two factors seem to be influence the effectiveness of an insulin regimen (Hirsch, 1999).

#### **D: Management according to screening test**

Screening for the long-term complications of diabetes is a critical component of diabetes management; however, evidence in this study demonstrates that screening rates for some tests in diabetes populations are not suboptimal.

The type of screening tests and its frequencies have been described .The association between screening test with glycemic control and diabetic complications were also investigated.

Reported screening rates in this study were as follows: 24.3% had at least one HbA1c measurement per a year, 16.8% had a foot exam, 53.9% had a protein urine test, 11.2% had an eye exam, 84.1% had a blood pressure reading and 51.1% received a fasting lipid profile. Within this group, 9.4% of subjects reported undergoing all five tests (optimal screening).However our result is much lower than found in a study conducted at Pittsburgh, Pennsylvania by Dorsey et al (2006) in which rates for screening tests i.e. HbA1c, foot exam, spot urine test, eye exam, blood pressure, and fasting lipid profile were 87.9%, 63%, 73.3%, 81.9%, and 68.7% respectively. 37.7% patients reported undergoing all five tests (optimal screening) (Doresy et al., 2006).

In this study, glycemic control show no significant association with any screening test. This finding could be explained that frequencies of tests play a role in glycemic control.

## **6.10 Methodological aspects**

A cross-sectional study design was used to collect information from diabetes patients themselves about their health care services, diabetes complications, and means of self-management they practiced in their daily life. The patients described herein are those in regular follow-up by PHC as previously stated. Of the patients, 75% were allocated and had all medical data needed for the purpose of the study, but others could not be traced (18.3%) and data for 6.3% were insufficient to be included in the analysis. These patients correspond mainly to subjects followed by private practice, primary health care, or under irregular follow-up. However, they were not different in terms of age, sex and age at onset in comparison to those who were followed up. However, this non-response rate still might cause bias in this study, which is also a bias in any research.

Only intervention studies can give a definite answer whether associations between risk factors are causal. In this type of descriptive study, there is a complex interrelationship between different risk factors and it is necessary to use statistical methods such as logistic regression models to adjust for confounding factors. However, introduction of several variables in the analysis can diminish the possibility to really discover significant associations, especially if the population is quite small as in our study in which numbers of cases are very small. We can't exclude that lack of association in some cases could partly be explained by too low statistical power.

The present study was based on examination tests for participant patients, which was one of the strengths of the study. These tests include funds examination by ophthalmologist, ECG, nerves evaluations by specialist. The relationship between metabolic control, lipid profile, kidney function testing and the development of macro and microvascular complications in type 1 diabetes was based on objective testing for participant patients, which gave strengths to the study.

This study is associated with several limitation that must be consider when interpretation our finding. First, with exception of objective tests and complication evaluation by consultation, all data are self reported, which could result in recall bias. Validation studies surrounding self-report of diabetes preventive care services, found that patients tend to over- report screening test for diabetes complications (Fowles et al., 1999). Thus, it is possible for the reported screening tests frequency rates to be higher than actually they are .Second, the finding from this study come from cross-sectional design.

## Conclusions

This study described, for the first time in Palestine, the situation of patients with type 1 diabetes mellitus. We evaluated the prevalence of macro and microvascular complications and the treatment protocol offered by PHC centers. The conclusion of the study would answer the present questions, objectives and hypothesis of this research.

Diabetes is a growing public health problem in the Palestinian community. This is the result of the epidemiological transition experiences in the community with rapid reform towards the westernized lifestyle. According to our sample population we could estimate the prevalence of T1DM to be 0.05%, with no discrepancy between male and female.

Positive clinical outcome such as glycemic control is not achieved in a large part of the studied population. To a large extent, these studied populations are affected by one or more of the early or late complications associated with diabetes. Diabetic patient in this study reported to have 36.4% retinopathy problems, 3.7% heart diseases symptoms, 7.5% nephropathy-associated symptoms, 26.2% neuropathy-associated symptoms, 10.3% reported having diabetic foot, and 0.9% amputation.

After evaluation of diabetic patients through ophthalmologist test and endocrinologist, we found that 33.8% have diabetic retinopathy, 7.4% nephropathy and 16.2% clinical polyneuropathy. The mean HbA1c was 7.8 (SE±0.16).

A number of risk factors have been positively associated with the development of diabetes complications among the Ramallah district population were identified, these include Glycemic control, sex, age, marital status, disease duration, age at diagnosis, hyperlipidemia, and smoking. Glycemic control and disease duration were the most important factors to develop macro and microvascular complications. There was significant association between glycemic control and disease duration with neuropathy and retinopathy. Retinopathy and neuropathy were highly prevalent among male, there was significant association between sex with retinopathy and neuropathy. Smoking was highly prevalent among males, and there was significant association between smoking and retinopathy.

Patients with diabetic complication are older than those without complications; there was significant association between age and retinopathy. Patient who had diagnosed with diabetes during puberty and post pubertal had higher prevalence of diabetic complication compared with those diagnosed with diabetes during prepuberty stage; there was significant association between age at diagnosis with retinopathy and neuropathy.

Hyperlipidemia is more prevalent in older male who are worker and married than other group; there was significant association between high cholesterol and triglyceride with retinopathy, while significant association was found between high triglyceride with neuropathy.

Clinical status of the patients is not affected by the services offered to them from either MOH or UNRWA or by the self care practice of these patients. Services offered to diabetic patients in MOH and UNRWA health care setting are to a large extent biomedical oriented. Clinical services offered to diabetic patients were found to have no or minimal effect in delay or prevent the development of disease complications in the studied population.

People with diabetes in Ramallah district are not receiving all what can be offered to them of diabetes screening tests. The frequencies of screening tests doing to them are not sufficient to meet their needs as diabetics.

The results indicate that home blood pressure and home blood glucose monitoring is not of value in the management of diabetic patients.

## **6.12 Recommendations**

The major concern in setting any control program is to define plans of action. The goal of the program is to be able to have a marked reduction in type 1 diabetes complications prevalence and to have an acceptable impact in decreasing morbidity and mortality-related diseases. Therefore, the following is recommended:

- 1- Fundus examination, blood pressure check-up and urine testing should form the corner stone of diabetes care. Patients should be provided with glucometers for self-monitoring of blood glucose. Laboratory facilities should include estimation of HbA1c, lipid profile and urine for micro- and macroproteinuria.
- 2- Patients should be educated about the nature of the disease, importance of treatment compliance, foot care, exercise, symptoms and treatment of hypoglycaemia, and dangers of smoking on developing complications. There should be visual demonstrations on how to inject insulin, feet check-ups.
- 3- Patients should be educated about the important of making good interpretation of blood glucose monitoring results and how to use these result for dose calculations for achieving good metabolic control.
- 4- A dietician, preferably someone knowledgeable about Palestinian food and eating habits, should be available daily in the PHC clinics. A chiropodist and full-time

ophthalmologist are necessary. Health care providers (doctors, nurses, and other medical personnel) should be trained both locally and abroad on diabetes health care.

- 5- Annual screening for microalbuminuria should be initiated once the child is 10 years of age and has had diabetes for 5 years; more frequent testing is indicated if values are increasing.
- 6- Ophthalmological screening evaluations should be reviewed and regular examinations scheduled with an eye care professional skilled in the care of children and adolescents with diabetes. The first ophthalmologic examination should be obtained once the child is  $\geq 10$  years of age and has had diabetes for 3–5 years. After the initial examination, annual routine follow-up is generally recommended.
- 7- Behavioral interventions that enhance the ability of youth and families to self-manage diabetes should be incorporated into routine care.
- 8- Routine screening of psychosocial functioning, especially depression and family coping should be performed.
- 9- Cooperation between the various health care providers to set up a national care strategy for T1DM.
- 10- To set up professional education programs that are based on research findings this will help professional to set up a Palestinian national program for T1DM patients.
- 11- From a research point of view, a national survey should be set to have a data bank of all these patients. This will help T1DM to have a follow up program, regardless of the implementing body, such as supporting their medication, examination programs, education programs, and also for research programs.
- 12- Focusing research on the identification of associated risk factors could help us to prevent, or at least delay, the incidence of diabetic complications

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## Appendix (1)

الرقم المتسلسل    (آخر ثلاث أرقام من الهوية إذا أمكن)  
أخي/أختي المشارك/ة: عند الإجابة على أسئلة الاستبيان الرجاء وضع رقم الجواب الصحيح في المربع

القسم الأول: المعلومات الديموغرافية

1- الاسم الثلاثي (إذا رغبت)		الاسم الأول	الثاني	العائلة
2- الجنس:	1. ذكر	2. أنثى		
3- العمر:	(سنوات)			
4- عنوان السكن:				
5- التلفون	6- الجوال			
7- الديانة:	1. مسلم	2. مسيحي	3. غيره	
8- الحالة الاجتماعية:	1. أعزب	2. متزوج/ة	3. خاطب	
	4. أرمل/ه	5. مطلق/ة		
9- عدد أفراد الأسرة (أي شخص يسكن في البيت):				
10- إذا كنت متزوج فما هو عدد الأولاد:				
11- مكان الإقامة:	1. مدينة	2. قرية	3. مخيم لاجئين	
	4. غير ذلك، أذكر			
12- المستوى التعليمي	1. مرحلة ابتدائية (0-6 سنوات مدرسية)			
	2. مرحلة إعدادية (7-9 سنوات مدرسية)			
	3. مرحلة ثانوية (10-12 سنوات مدرسية)			
	4. مرحلة جامعية (13-16 سنوات جامعية)			
13- المهنة:				

القسم الثاني: القياسات الحيوية يوم الدراسة  
الرجاء وضع رقم الجواب الصحيح في المربع

14- ما هو وزنك الحالي؟ \_\_\_\_\_ (كغم)

15- ما هو طولك؟ \_\_\_\_\_ (سم)

16- ما هي قيمة آخر قياس للضغط لديك؟	1. عالي	2. واطي	3. طبيعي
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17- ما هي نتيجة آخر مستوى للسكري لديك؟ قبل الأكل \_\_\_\_\_ وبعد الأكل \_\_\_\_\_

18- ما هي نتيجة آخر فحص لمستوى السكر التراكمي أو سكري الثلاث شهور لديك (هيموجلوبين A1c)؟ \_\_\_\_\_

19- هل تدخن السجائر حالياً؟  
إذا نعم، ما هي عدد السجائر؟ \_\_\_\_\_ (يومياً)

1. نعم  
2. لا

20- هل كنت تدخن وتوقفت عن التدخين؟  
إذا نعم، منذ متى توقفت عن التدخين؟ \_\_\_\_\_ (سنوات)  
ما عدد السنوات التي دخنتها؟ \_\_\_\_\_ (سنوات)

1. نعم  
2. لا

القسم الثالث: التاريخ المرضي

21- متى تم تشخيصك بمرض السكري؟ \_\_\_\_\_ (سنوات)

22- كم كان عمرك عند تشخيصك بالمرض؟ _____ (سنوات)
--

23- من قام بتشخيصك بالمرض؟	1. طبيب عام	2. طبيب أخصائي
	3. بدون طبيب	4. لا أذكر

24- كيف تم تشخيصك بمرض السكري؟	1. من خلال إجراء فحوصات طبية في المستشفى
	2. مراجعة للطبيب بسبب ظهور أعراض المرض
	3. خلال عيادة الأمومة والطفولة
	4. في العيادة بسبب مرض آخر
	5. بالصدفة
	6. بعد عملية جراحية
	7. لا أذكر

25- ما سبب ظهور السكري لديك باعتقادك؟	1. بسبب ضغط نفسي	2. بسبب ضغط عصبي
	3. أثناء الحمل	4. بسبب مرض آخر، حدد ----
	5. لا أعلم	

26- إذا كان سكري حمل، هل استمر السكري بالظهور معك بعد انتهاء	1. نعم	2. لا
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فترة الحمل؟ (لل سيدات)		
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27- هل لدى أحد أفراد عائلتك مرض السكري؟	1. نعم	2. لا
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28- أرجو تعبئة الجدول التالي لأي فرد من أفراد الأسرة ممن يعيشون معكم في نفس البيت مصابون بمرض السكري؟

الرقم	الاسم	العمر	الجنس	صلة القرابة	نوع السكري (الأول، الثاني)
28.1					
28.2					
28.3					
28.4					
28.5					
28.6					
28.7					
28.8					
28.9					

القسم الرابع: العلاج المستخدم للمريض  
الرجاء وضع رقم الجواب الصحيح في المربع

29- هل تستخدم نظام حماية معينة بالإضافة للأنسولين ؟	1. نعم	2. لا
---	--------	-------

30- ما هو نوع الأنسولين الذي تستخدمه/تستخدميه ؟	نوع الأنسولين (الرجاء ضع دائرة)	كمية الجرعة في الصباح	كمية الجرعة في المساء
	1. السريع (الأصفر أو الصافي)	_____	_____
	2. الأنسولين المتوسط (الأخضر أو البني)	_____	_____
	3. الأنسولين المخلوط (البني)	_____	_____

31- عند بداية السكري، من أين كنت تحصل على الدواء ؟	1. وزارة الصحة	2. وكالة الغوث
	3. قطاع طبي خاص	4. أكثر من مصدر
	5. لا أذكر	

32- ما هو المصدر الحالي الذي يتم الحصول على الدواء من خلاله ؟	1. وزارة الصحة	2. وكالة الغوث
	3. قطاع طبي خاص	4. أكثر من مصدر

33- هل لديك تأمين صحي ؟	1. نعم	2. لا
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34- إذا كان الجواب نعم فما هو نوع التأمين ؟	1. حكومة	2. وكالة	3. خاص
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35- هل التأمين الصحي يقوم بتغطية جميع العلاج اللازم لمرض السكري ؟	1. نعم	2. لا
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36- ما أنواع الفحوصات التي يغطيها التأمين، الرجاء التحديد؟ _____
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القسم الخامس: المضاعفات المرضية			
37- هل تعاني أو أصبت بإحدى المشاكل الصحية الآتية بسبب مرض السكري؟ (الرجاء وضع إشارة صح في المكان المناسب)			
لا	لا	1.نعم	
3.لا	لا	لا	أذكر
			37.1- مشاكل في العينين؟
			37.2- إصابة بنوبة قلبية؟
			37.3- مشاكل في الكلى؟
			39.4- تاثير للسكري على الأعصاب مثل الأطراف؟
			37.5- تقرحات في القدمين؟
			37.6- قيام الأطباء ببتنر أي جزء من أصابعك بسبب السكري؟
			37.7- الإصابة بأعراض هبوط السكري: (التعرق، الرجفة، التهيج، ألم الرأس)
			37.8- تشخيصك بأن ضغط الدم مرتفع

38- هل أدخلت المستشفى بسبب السكري؟	1.نعم	لا	3.لا	أذكر
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39- إذا كان الجواب نعم، فكم مرة (أذكر) _____
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40- ماذا كان السبب في دخولك للمستشفى؟	1. دوخة، غميان	2. هبوط حاد في السكر
	3.جلطة	4.خلل في الأعصاب
	5.ارتفاع ضغط الدم	6.ارتفاع في السكر

7. أسباب أخرى، حدد \_\_\_\_\_

41- هل كنت تعاني من إحدى الأمراض التالية قبل تشخيصك بمرض السكري؟ (الرجاء وضع إشارة صح في المكان المناسب)			
لا	لا	1.نعم	
3.لا	لا	لا	أذكر
			41.1-الضغط
			41.2-مشاكل في القلب
			41.3-مشاكل في العينين
			41.4-مشاكل في الكلى
			41.5-مشاكل في الرئتين (أزمة، ضيق نفس)
			41.6-أمراض نتيجة للالتهابات الفيروسية مثلا
			41.7-أمراض في الدم
			41.8-أورام سرطانية
			41.9-مشاكل في الأعصاب
			41.10-غير ذلك، حدد

القسم السادس: المراقبة الذاتية في البيوت من المريض نفسه  
(الرجاء وضع رقم الجواب الصحيح في المربع)

42- هل لديك جهاز في البيت لقياس الضغط ؟ 1.نعم 2.لا

43- هل تقوم بقياس نسبة السكر بالدم في البيت ؟ 1.نعم 2.لا

44- إذا كان الجواب نعم فما هي عدد المرات التي تقيسه غالبا ؟	1.أكثر من مرة في اليوم	2. مرة في اليوم
	3. مرة في الأسبوع	4. مرة في الشهر

45- ما نوع الجهاز الذي تستخدمه في عملية القياس \_\_\_\_\_

46- هل تقوم بقياس نسبة السكر في البول في البيت ؟ 1.نعم 2.لا

47- هل تقوم بفحص الكيتونات في البول في البيت؟ 1.نعم 2.لا

القسم السابع: المراقبة للمرضى في مراكز الرعاية الصحية  
(الرجاء وضع رقم الجواب الصحيح في المربع)

48- هل تقوم باستشارة طبيبك العام؟	1. على الأقل مرة في الأسبوع	2. على الأقل مرة في الشهر
	3. كل ثلاث شهور	4. كل ستة أشهر
	5. كل تسعة أشهر	6. على الأقل مرة في السنة
	7. لا أقوم بذلك	

49- في أي المراكز تقوم/ي بمراجعة طبيبك الخاص؟	1. وزارة الصحة	2. وكالة الغوث
	3. قطاع طبي خاص	4. أكثر من مصدر: حدد: _____

50- هل يقوم طبيبك بفحصك كل مرة تذهب/ي للعلاج في مراكز الرعاية الأولية؟ 1.نعم 2.لا

51- هل يوجد لدى الطبيب ملف خاص بك يشمل على معلومات عن سير المرض لديك؟ 1.نعم 2.لا

52- هل تجرى لك الفحوصات الدورية التالية في مراكز الرعاية الأولية التي تتلقى فيها الخدمات الصحية؟ (الرجاء وضع إشارة صح في المكان المناسب )			
لا أذكر	لا	1.نعم	
			52.1- فحص السكري
			52.2- فحص هيموجلوبين A1c
			52.3- فحص البروتينات(الزلال) في البول
			52.4- فحص الضغط
			52.5- فحص الكيتونات في البول
			52.6- فحص الدهون والكوليسترول في الدم
			52.7- فحص الطول
			52.8- فحص الوزن
			52.9- فحص تخطيط القلب (ECG)
			52.10- صورة أشعة للصدر
			52.11- فحص الكلى من خلال فحص اليوريا
			52.12- فحص الكلى من خلال فحص الكرياتينين
			52.13- فحص الكلى من خلال فحص حامض اليوريك
			52.14- فحص أنزيمات الكبد المخبرية

53- ما هي عدد المرات التي تجرى لك الفحوصات المخبرية التالية في مراكز الرعاية الأولية التي تتلقى فيها الخدمات الصحية؟ (الرجاء وضع إشارة صح في المكان المناسب)							
لا	6.على الأقل مرة في السنة	5.كل تسعة أشهر	4.كل ستة أشهر	3.كل ثلاث شهور	2.على الأقل مرة في الشهر	1.على الأقل مرة في الأسبوع	
							1-فحص السكري
							2-فحص هيموجلوبين A1c
							3-فحص البروتينات في البول
							4-فحص الضغط
							5-فحص الكيتونات في البول
							6-فحص الدهون والكوليسترول في الدم
							7-فحص الطول
							8-فحص الوزن
							9-فحص تخطيط القلب (ECG)
							10-صورة أشعة للصدر
							11-فحص الكلى من خلال فحص اليوريا
							12-فحص الكلى من خلال

							فحص الكرياتينين
							13-فحص الكلى من خلال فحص حامض اليوريك
							14-فحص أنزيمات الكبد المخبرية

<b>الفحوصات الجسمية لمرضى السكري:</b>			
54- هل تجرى لك الفحوصات التالية؟ (الرجاء وضع إشارة صح في المكان المناسب)			
	1.نعم	2.لا	3.لا أعلم
			54.1- فحص العيون لدى أخصائي
			54.2- الفحص من قبل أخصائي الأعصاب
			54.3- القيام بالفحص لدى أخصائي أمراض باطنية
			54.4- القيام بفحص القدمين
			54.5- الاستشارة لدى أخصائي تغذية

55- ما هي عدد المرات التي تجرى لك الفحوصات الجسمية التالية في مراكز الرعاية الأولية التي تتلقى فيها الخدمات الصحية؟ (الرجاء وضع إشارة صح في المكان المناسب)							
	1.على الأقل مرة في الأسبوع	2.على الأقل مرة في الشهر	3.كل ثلاث شهور	4.كل سنة أشهر	5.كل تسعة أشهر	6.على الأقل مرة في السنة	7.لا أقوم بذلك
							55.1-فحص العيون لدى أخصائي
							55.2-الفحص من قبل أخصائي الأعصاب
							55.3-القيام بالفحص لدى أخصائي أمراض باطنية
							55.4-القيام بفحص القدمين
							55.5-الاستشارة لدى أخصائي تغذية

**Appendix (2)**

Patient name \_\_\_\_\_  
 Address \_\_\_\_\_

Age \_\_\_\_\_  
 Telephone \_\_\_\_\_

Onset of diabetes: -----

Past ocular :-----  
 -----

Ocular medication:-----  
 -----

Ocular complaint if any-----  
 -----

Visual acuity-----

	Unaided	Aided	Power of Eye glass
Right Eye			
Left Eye			

External ocular exam: -----  
 -----

Extra ocular motility:-----  
 -----

Pupil reaction:-----

segment exam :-----Anterior  
 -----

Intra ocular pressure :-----  
 -----

Findus exam with dilating drops: -----  
 -----

	Right eye	Left eye
1-Normal		
2- Simple back diabetic retinopathy		
3- Diabetic Maculopathy		
4-Preproliferative diabetic retinopathy		
5-Proliferative diabetic retinopathy		
6-Previous laser therapy		
7-No of sessions and date		
8-Does he need laser therapy now		

Date of follow up: -----

### Appendix (3)

#### ملتقى الصحة في فلسطين و جامعة القدس

#### جدول مواعيد الأطباء لمرضى السكري النوع الأول

اسم المريض	العمر
العنوان	الهاتف

**عيادة أخصائي العيون الدكتور هاني عوض**  
المكان رام الله-دوار الساعة-شارع المعاهد-مجمع رمون التجاري-الطابق الرابع  
تلفون العيادة: 02/2987047  
أوقات المراجعة: يومي السبت و الأربعاء **فقط** من الساعة الثامنة حتى الرابعة (8صباحا-4مساء)

**عيادة تخطيط القلب**  
المكان: عيادة ملتقى الصحة في فلسطين-رام الله-شارع الإرسال-مركز البزار التجاري-بجانب فندق بست ايسترن  
تلفون عيادة الملتقى: 02/2974402  
أوقات المراجعة: أيام الخميس **فقط** من الساعة الواحدة ظهرا حتى الثالثة مساء (1-3)  
ملاحظة هامة: يجب عمل تخطيط القلب قبل مراجعة دكتور راند العلمي (أخصائي السكري)

**عيادة أخصائي السكري الدكتور راند العلمي**  
المكان: عيادة ملتقى الصحة في فلسطين-رام الله-شارع الإرسال-مركز البزار التجاري-بجانب فندق بست ايسترن  
تلفون عيادة الملتقى: 02/2974402  
أوقات المراجعة: أيام الخميس **فقط** من الساعة الثانية ظهرا حتى السادسة مساء (3-6)

**مختبر سحب الدم**  
المكان: مختبر دكتور لاب الطبي -مركز الخطيب التجاري- شارع مستشفى رام الله  
تلفون المختبر: 02/2950160  
أوقات سحب الدم: أيام السبت إلى الثلاثاء صباحا  
ملاحظة هامة: يشترط أن يكون المريض أو المريضة صائم على الأقل 8 ساعات

#### Appendix (4)

بسم الله الرحمن الرحيم



جامعة القدس/ كلية الصحة العامة

بحث كمتطلب لماجستير الصحة العامة

اسم الطالب: زياد الخضور

يعتبر مرض السكري من أكثر الأمراض المنتشرة في فلسطين، حيث يقسم المرض الى نوعين ،نوع يصيب الكبار ويطلق عليه النوع الثاني، ونوع يصيب الأطفال والشباب وهو النوع الأول من المرض وهو ناتج عن انعدام إفراز الأنسولين الذي ينظم نسبة السكر في الدم مما يؤدي إلى ظهور أعراض ومضاعفات هذا المرض كضعف البصر ومشاكل في الكلى.

من المتوقع أن تكون نسبة انتشار مرض السكري من النوع الأول في فلسطين كباقي الدول المجاورة حيث تتراوح النسبة ما بين 0.5 الى 1%، لذلك ستجرى هذه الدراسة في محافظة رام الله كعينة أولية حيث من المتوقع أن يكون عدد المرضى مئة وخمسون مريضاً. يهدف هذا البحث إلى معرفة الوضع الصحي لدى مرضى السكري من النوع الأول، والخدمات التي يتلقاها المريض من خلال مراكز الرعاية الأولية التابعة لوزارة الصحة ووكالة الغوث في محافظة رام الله من أجل العمل على الوقاية والحد من انتشار مضاعفات هذا المرض عند هؤلاء المرضى، وبالتالي تقليل نسبة الوفيات الناتجة عنه. لذا سيتم مقابلة جميع مرضى السكري من النوع الأول في محافظة رام الله دون استثناء.

لقد قمنا بتجهيز استبيانة تحتوى على أسئلة خاصة بأهداف الدراسة، لذا نرجو منكم الإجابة على الاستبانة من قبل المشاركين، وأملين من حضرتكم إجابة كافة الأسئلة بموضوعيه تامة بقراءة كل فقره بتمعن والاستجابة عليها حسب التعليمات الواردة قبل كل فقره، علما أن المعلومات الواردة في الاستبانة ستستعمل لأغراض البحث فقط، ونضمن لكم السرية التامة في المعلومات التي ستدلون بها. لذا نرجو منكم التوقيع بالموافقة على المشاركة لإتمام أهداف هذه الدراسة.

شاكرين لكم حسن تعاونكم

الباحث: زياد الخضور



لقد قمت بدراسة جميع التعليمات الواردة في هذا الاستبيان وعليه قررت المشاركة في هذه الدراسة،  
وأن وجود اسمي وتوقيعي هو دليل على قبولي للمشاركة في هذه الدراسة.

التاريخ:

الوقت:

اسم المشارك:

اسم الباحث: زياد الخضور

التوقيع

التوقيع

## Appendix(5)

**Table 5.1 : The distribution of Nephropathy-associated symptoms, Diabetic foot, Heart diseases-associated symptoms with the various demographic variables in Ramallah district**

<b>Variable</b>	<b>Nephropathy-associated symptoms N=8</b>	<b>Diabetic foot N=11</b>	<b>Heart diseases-associated symptoms N=4</b>
Disease duration Average $\pm$ SE	12.1 $\pm$ 3.7 range (0.5-31)	11 $\pm$ 2.2 range (0.1-22)	12 $\pm$ 4.3 range (2-22)
Diagnosis age Average $\pm$ SE	14 $\pm$ 1.1 range (10-19)	14.9 $\pm$ 1.6 range (6-25)	13.8 $\pm$ 3.8 range (5-20)
<b>Age</b>			
Children (0-16)	1(12.5%)	1(9.1%)	1(25%)
Adult (16-30)	4(50%)	7(63.7%)	1(25%)
Older adult (>30)	3(37.5%)	3(27.3%)	2(50%)
<b>Gender</b>			
Male	3(37.5%)	5(45.5%)	3(75%)
Female	5(62.5%)	6(54.5%)	1(25%)
<b>Occupation</b>			
Work	2(25%)	3(27.3%)	2(50%)
Not working	4(50%)	7(63.6%)	
Student	2(25%)	1(9.1%)	2(50%)
<b>Marital status</b>			
Single	7(87.5%)	7(63.6%)	2(50%)
Married	1(12.5%)	4(36.4%)	2(50%)
<b>Residency</b>			
City	4(50%)	2(18.2%)	2(50%)
Village	3(37.5%)	8(72.7%)	2(50%)
Camp	1(12.5%)	1(9.1%)	
<b>Educational level</b>			
0-12 year	7(87.5%)	11(100%)	3(75%)
>12 year	1(12.5%)	-----	1(25%)

**Note: all association can not be done since expected value <5**

**Table 5.2: Frequencies and percentage of Diabetic foot-related symptoms, Heart diseases-associated symptoms, and nephropathy-related symptoms according to possible determinants for diabetes**

<b>Variable</b>	<b>Nephropathy-associated symptoms N=8</b>	<b>Diabetic foot N=11</b>	<b>Heart diseases-associated symptoms N=4</b>
Disease duration Average $\pm$ SE	12.1 $\pm$ 3.7	11 $\pm$ 2.2	12 $\pm$ 4.3
Diagnosis age Average $\pm$ SE	14 $\pm$ 1.1	14.9 $\pm$ 1.6	13.8 $\pm$ 3.8
Diagnosis made by GP Specialist Without doctor Do not remember	6(75%) 2(25%) _____ _____	5(45.5%) 6(54.5%) _____ _____	3(75.0%) 1(25.0%) _____ _____
Diagnosis method During hospitalization Repeated diabetic complications MCH clinic At clinic for other disease Accidentally Unknown	2(25%) 4(50%) _____ _____ 2(25) _____	3(27.3%) 7(63.6%) _____ _____ 1(9.1%) _____	1(25%) 1(25%) _____ 1(25%) 1(25%) _____
Diagnosis cause Psychological stress Neurological stress Cause of other disease & Hereditary Do not know	_____ 3(37.5%) 1(12.5%) 4(50.0%)	2(18.2%) 3(27.3%) _____ 6(54.5%)	_____ 1(25.0%) 2(50.0%) 1(25.0%)

#### **5.4.1 Distribution of the objective testing by the various demographic variables**

Of the approached patients, 80 patients (69%) have done the objective testing, i.e. HbA1c, fasting blood sugar (FBS), lipid profiling, and kidney functions testing, and blood pressure testing. Patients were referred to see an ophthalmologist, but only 63.8% did go (n=74 patients). Also, all these patients (n=107) were referred to consult with a diabetes specialist, but only 58.6 % (n=68) attended the consultations.

The normal ranges for each test in this survey were used according to the ADA values (table 5.3). Table 5.4A, 5.4B, and 5.4C summarize the average and standard error ( $X \pm SE$ ) and range for objective testing (HbA1c, FBS, Urea, Creatinine, Cholesterol, triglyceride, LDL, and HDL) and their distribution according to patients demographic variable. The average and standard error ( $X \pm SE$ ) of HbA1c was  $7.8 \pm 0.16$ . Both male and female show higher result of HbA1c than normal value. Older adults show the highest average of HbA1c among the rest age group. There was no difference in the average value of HbA1c among patients according to the patient's residency place; however, patients who live in camp had higher average value of HbA1c than other. Both single and married patients had average HbA1c value above the normal range. The mean value for HbA1c still higher among patients sample according to their occupations; however patients who are non worker had the highest value than other. Both educated and less educated patients had average HbA1c value above the normal range. The average and standard error ( $X \pm SE$ ) of FBS was  $203 \pm 9$ . The average value of both male and female of FBS was higher than normal range of FBS and much higher than the recommended value for diabetic patients. All age group had higher value of FBS: however child had the heist value of FBS. The result of FBS was higher than normal range in patients according to the patient's residency place; however patients who live in camp had higher result of FBS than other. Single and married patient had both high results of FBS with no difference in the result of FBS in both group. All occupation and educational level group categories had high average result of FBS; however student and less educated patient had the highest result among these categories. The average and standard error ( $X \pm SE$ ) of Urea was  $28.2 \pm 1.4$ , all demography categories for patients had an average result for urea in the normal value. The average and standard error ( $X \pm SE$ ) of creatinine was  $0.9 \pm 0.05$ . Both male and female had normal average value of creatinine, Child and adult had normal average value of creatinine:

however old adult show average means of creatinine above the normal range. All occupation group, marital status, residency place and educational level categories had normal value of creatinine. The average and standard error ( $X \pm SE$ ) of cholesterol was  $191 \pm 5.1$ . Male had an average result of cholesterol in the border line comparing with normal value; however female had normal average of cholesterol. Adult and older adult had an average result in the border line while child had normal value of cholesterol. All residency categories had normal average of cholesterol, while married patients had an average result which is at the border line. Worker patients had a average cholesterol in the border line while other occupation categories had normal average cholesterol. Educated patients show higher cholesterol mean than less educated. The average and standard error ( $X \pm SE$ ) of triglyceride was  $146 \pm 11.1$ . Older age and male patients had triglyceride above the normal range. All residency categories had an average normal triglyceride value. Married patients had an average triglyceride result above the normal range, while single patients had normal triglyceride result. Worker and student had triglyceride value above normal range. Educated patients had abnormal value of triglyceride. The average and standard error ( $X \pm SE$ ) of HDL was  $42 \pm 0.8$ . All HDL average results of patients distributed according to demographic variable showed normal value.

**Table 5.3 Normal range and target value for laboratory test done for diabetic patients at this study**

<b>Test</b>	<b>Normal range</b>	<b>Target value</b>
<b>HbA1c %</b>	4.5-7 Well control diabetes ≥8.5 Uncontrolled diabetes	<7
<b>Glucose (mg/dl)</b>	75-115	<140
<b>Urea (mg/dl)</b>	6-18 Infant 15-33 Children 15-45 Adults	<45
<b>Creatinine (mg/dl)</b>	0.6-1.1 Men 0.5-0.9 Women	<1.4
<b>Cholesterol (mg/dl)</b>	<200 Desirable 200-239 Borderline 240 High	<200
<b>Triglyceride (mg/dl)</b>	40-150 Men 35-135 Women	<150
<b>LDL (mg/dl)</b>	Up to 150	<100
<b>HDL (mg/dl)</b>	<40 Low ≥60 High	≥40

**Table 5.4A: Mean and standard error (X± SE) and range of the objective testing by the various demographic variables of the 68 patients in Ramallah district**

Testing	Gender		Age group			Total X± SE
	Male X± SE Range	Female X± SE Range	Child X± SE Range	Adult X± SE Range	Older adults X± SE Range	
<b>HbA1c %</b>	7.5±0.23 5.7-11	7.9±0.2 5.6-11	7.6±.28 5.6-11	7.6±.23 5.7-11	8.2±.3 5.9-11	7.8±.16 5.6-11
<b>FBS</b> (mg/dl)	190±9.5 70-397	215±15 37-510	222±18.5 60-406	192±14.5 37-510	201± 13 79-397	203±9 37-510
<b>Urea</b> (mg/dl)	29.5±1.6 6-60	26.9±2.3 7-88	21.7±1.4 6-32	29±1.3 16-40	33.4±4 9-88	28.2±1.4 6-88
<b>Creatinine</b> (mg/dl)	1±.06 .5-3	0.9±.09 04-4.1	0.8±.03 05-1.1	0.9±.03 .4-1.3	1.2±.17 0.6-4.1	.9±.05 .4-4.1
<b>Cholesterol</b> (mg/dl)	207±7.1 116-306	175±6.5 95-273	158±8.1 95-243	202±6.4 130-273	208±10 107-306	191±5.1 95-306
<b>Triglyceride</b> (mg/dl)	169±16.2 38-605	124±14.6 24-582	90±10.7 24-248	143±10.3 38-256	208±29.7 38-605	146±11.1 24-605
<b>LDL</b> (mg/dl)	135±7.2 33-243	112±5.4 46-208	101±8.3 46-243	132±6.1 67-208	134±9.3 33-230	123±4.7 33-243
<b>HDL</b> (mg/dl)	43±1.3 29-75	41±1 32-64	42±1.9 29-75	42±1.3 33-65	41±.93 32-50	42±.8 29-75

**Table 5.4B: Mean and standard error (X± SE) and range of the objective testing by the various demographic variables of the 68 patients in Ramallah district**

Testing	Residency			Marital status		Total X± SE
	City X± SE Range	Village X± SE Range	Camp X± SE Range	Single X± SE Range	Married X± SE Range	
<b>HbA1c %</b>	7.9±3 5.7-11	7.5±0.16 5.6-10	8.2±0.5 5.9-11	7.8±0.19 5.7-11	7.6±.27 5.6-11	7.8±.16 5.6-11
<b>FBS</b> (mg/dl)	190±13.8 74-406	197±10.4 37-386	235±35.5 70-510	205±12.1 37-510	198±12.7 74-397	203±9 37-510
<b>Urea</b> (mg/dl)	29.9±3.5 7-88	27.9±1.4 6-60	25.5±2.6 17-48	27.6±1.9 6-88	29.2±1.9 9-60	28.2±1.4 6-88
<b>Creatinine</b> (mg/dl)	1±.13 0.5-4.1	0.9±.05 0.5-3	0.9±.08 0.5-1.5	.9±.07 .4-4.1	1±.08 .6-3	.9±.05 .4-4.1
<b>Cholesterol</b> (mg/dl)	193±7.9 107-260	192±6.9 109-273	180±17.3 95-306	182±6.1 95-273	208±8.5 107-306	191±5.1 95-306
<b>Triglyceride</b> (mg/dl)	153±19.9 49-582	138±11.7 24-391	159±54.7 38-605	127±12.3 24-542	182±20.8 38-605	146±11.1 24-605
<b>LDL</b> (mg/dl)	124±5.5 76-187	138±11.6 33-243	109±14.7 46-230	115±5.3 46-243	139±8.2 33-208	123±4.7 33-243
<b>HDL</b> (mg/dl)	43-1.2 35-65	42±1.2 29-75	41±2.5 33-64	42±1.1 29-75	42±.9 32-50	42±.8 29-75



**Table 5.4C: Mean and standard error (X± SE) and range of the objective testing by the various demographic variables of the 68 patients in Ramallah district**

Testing	Occupation			Educational level		Total X± SE
	Worker X± SE Range	Non worker X± SE Range	Student X± SE Range	≤12yr X± SE Range	>12yr X± SE Range	
<b>HbA1c %</b>	7.5±.24 5.6-11	8.4±.37 5.9-11	7.7±.23 5.7-11	7.8±0.17 5.7-11	7.4±.24 5.6-11	7.8±.16 5.6-11
<b>FBS</b> (mg/dl)	187±12.5 70-397	205±13.8 150-325	217±16.8 37-510	209±9.9 37-510	160±15 70-201	203±9 37-510
<b>Urea</b> (mg/dl)	30.7±1.6 16-60	34.7±6 9-88	22.9±1.3 6-39	27.9±1.6 6-88	29±2.7 16-40	28.2±1.4 6-88
<b>Creatinine</b> (mg/dl)	1±.07 0.4-3	1.2±.24 0.6-4.1	.8±.02 0.5-.9	.9±.06 .5-4.1	0.9±.06 0.4-1.1	.9±.05 .4-4.1
<b>Cholesterol</b> (mg/dl)	212±7.1 130-306	184±10.4 107-260	173±7.8 95-273	188±5.5 95-306	209±13.5 150-260	191±5.1 95-306
<b>Triglyceride</b> (mg/dl)	212±22.1 38-605	142±13.5 76-241	208±29.7 24-256	140±10.7 24-605	186±47 38-582	146±11.1 24-605
<b>LDL</b> (mg/dl)	136±7.2 33-230	120±8.8 67-174	112±7.4 46-243	122±5.0 33-243	134±13 80-197	123±4.7 33-243
<b>HDL</b> (mg/dl)	42±1 32-64	43.2±2 37-65	41.7±1.4 29-75	42±0.8 29-75	44±2.6 37-64	42±.8 29-75

#### **5.4.2 Association between the objective testing and the various demographic variables**

A significant association was seen between sex and lipids testing, i.e. triglyceride and cholesterol (P value <0.05, see table 5.5). No significant association was seen between metabolic control (HbA1c), FBS, and HDL results by gender. Age categories had significant association with metabolic control (HbA1c) and lipids testing (P value <0.05, see table 5.6). A significant association was seen between marital status and lipids testing (see table 5.7). No association was found between triglyceride and HDL testing by the various educational levels of the patients (P value <0.05). A significant association was seen between patients' occupation type and lipids testing (P value <0.05 see table 5.8). Since most of the study populations were Moslems (only 3.7% were Christians), therefore, no uni-variate analysis was done.

**Table 5.5: The distribution of the various objective testing by gender for the 80 patients who did the testing in Ramallah district**

<b>Variable</b>	<b>Male N=39 No (%)</b>	<b>Female N=41 No (%)</b>	<b>Total N=80 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b>				
<8.5	11 (13.8%)	7 (8.7%)	<b>18 (22.5%)</b>	<b>&gt;0.05</b>
≥8.5	28 (35%)	34 (42.5%)	<b>62 (77.5%)</b>	
<b>Sugar (mg/dl)</b>				
<140	5 (6.25%)	5 (6.25%)	<b>10 (12.5%)</b>	<b>&gt;0.05</b>
≥140	34 (42.5%)	36 (45%)	<b>70 (87.5%)</b>	
<b>Urea (mg/dl)</b>				
<45	37 (46.3%)	39 (48.7%)	<b>76 (95%)</b>	<b>*</b>
≥45	2 (2.5%)	2 (2.5%)	<b>4 (5%)</b>	
<b>Creatinine (mg/dl)</b>				
<1.1	29 (36.3%)	39 (48.7%)	<b>39(48.8%)</b>	<b>&lt;0.05</b>
≥1.1	10 (12.5%)	2 (2.5%)	<b>41 (51.2%)</b>	
<b>Cholesterol (mg/dl)</b>				
<200	14 (17.5%)	33 (41.3%)	<b>47 (58.8%)</b>	<b>&lt;0.05</b>
≥200	25 (31.2%)	8 (10%)	<b>33 (41.2%)</b>	
<b>Triglyceride (mg/dl)</b>				
<150	13 (16.3%)	29 (36.2%)	<b>42 (52.5%)</b>	<b>&lt;0.05</b>
≥150	26 (32.5%)	12 (15%)	<b>38 (47.5%)</b>	
<b>LDL (mg/dl)</b>				
<100	11 (13.8%)	13 (16.2%)	<b>24 (30%)</b>	<b>&gt;0.05</b>
≥100	28 (35%)	28 (35%)	<b>56 (70%)</b>	
<b>HDL (mg/dl)</b>				
<40	20 (25%)	19 (23.75%)	<b>39 (48.75%)</b>	<b>&gt;0.05</b>
≥40	19 (23.75%)	22 (27.5%)	<b>41 (51.15%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.6: The distribution of the various objective testing and age categories for the 80 patients who did the testing in Ramallah district**

<b>Variable</b>	<b>Child N=23 No (%)</b>	<b>Adult N=34 No (%)</b>	<b>Older adults N=23 No (%)</b>	<b>Total N=80 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b>					
<8.5	15 (18.8%)	28 (35%)	11(13.7%)	<b>54 (67.5%)</b>	<b>&lt;0.05</b>
≥8.5	8 (10%)	6(7.5%)	12 (15%)	<b>26(32.5%)</b>	
<b>Sugar (mg/dl)</b>					*
<140	4 (5%)	5 (6.3%)	1 (1.2%)	<b>10 (12.5%)</b>	
≥140	19(23.8%)	29 (36.2%)	22 (27.5%)	<b>70 (87.5%)</b>	
<b>Urea (mg/dl)</b>					*
<45	23 (28.8%)	34 (42.5%)	19 (23.7%)	<b>76 (95%)</b>	
≥45	0 (0%)	0 (0%)	4 (5 %)	<b>4 (5%)</b>	
<b>Creatinine (mg/dl)</b>					*
<1.1	23 (28.8%)	27 (33.75%)	18(22.5%)	<b>68 (85%)</b>	
≥1.1	—	7 (8.75%)	5 (6.25 %)	<b>12 (15%)</b>	
<b>Cholesterol (mg/dl)</b>					<0.05
<200	20 (25%)	18 (22.5%)	9 (11.2%)	<b>47 (58.7%)</b>	
≥200	3 (3.8%)	16 (20%)	14 (17.5%)	<b>33 (41.3%)</b>	
<b>Triglyceride (mg/dl)</b>					<0.05
<150	18 (22.5%)	16 (20%)	8 (10%)	<b>42 (52.5%)</b>	
≥150	5 (6.2%)	18 (22.5%)	15 (18.8%)	<b>38 (47.5%)</b>	
<b>LDL (mg/dl)</b>					<0.05
<100	13 (16.2%)	7 (8.8%)	4 (5%)	<b>24 (30%)</b>	
≥100	10 (12.5%)	27 (33.8%)	19 (23.7%)	<b>56 (70%)</b>	
<b>HDL (mg/dl)</b>					>0.05
<40	10 (12.5%)	18 (22.5%)	11 (13.8%)	<b>39 (48.8%)</b>	
≥40	13 (16.2%)	16 (20%)	12 (15%)	<b>41 (51.2%)</b>	

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.7: The distribution of the various objective testing and marital status for the 80 patients who did the testing in Ramallah district**

<b>Variable</b>	<b>Single N=52 No (%)</b>	<b>Married N=28 No (%)</b>	<b>Total N=80 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b> <8.5 ≥8.5	35 (44%) 17(21%)	19 (23.8%) 9 (11.2%)	<b>54 (67.8%)</b> <b>26 (32.2%)</b>	<b>&gt;0.05</b>
<b>Sugar (mg/dl)</b> <140 ≥140	9 (12.1%) 43 (52.7%)	1 (1.4%) 27 (33.8%)	<b>10 (13.5%)</b> <b>64 (86.5%)</b>	*
<b>Urea (mg/dl)</b> <45 ≥45	50 (62.5%) 2 (2.5%)	26 (32.5%) 2 (2.5%)	<b>76 (95%)</b> <b>4 (5%)</b>	*
<b>Creatinine (mg/dl)</b> <1.1 ≥1.1	46 (57.5%) 6 (7.5%)	26 (37.5%) 6 (7.5%)	<b>68 (85%)</b> <b>12 (15%)</b>	*
<b>Cholesterol (mg/dl)</b> <200 ≥200	37 (46.2%) 15 (18.8%)	10 (12.5%) 18 (22.5%)	<b>47 (58.7%)</b> <b>33 (41.3%)</b>	<b>&lt;0.05</b>
<b>Triglyceride (mg/dl)</b> <150 ≥150	32 (40%) 20 (25%)	10 (12.5%) 18 (22.5%)	<b>42 (52.5%)</b> <b>38 (47.5%)</b>	<b>&lt;0.05</b>
<b>LDL (mg/dl)</b> <100 ≥100	18 (22.5%) 34 (42.5%)	6 (7.5%) 22 (27.5%)	<b>24 (30%)</b> <b>56 (70%)</b>	<b>&gt;0.05</b>
<b>HDL (mg/dl)</b> <40 ≥40	24 (29.8%) 28 (33.8%)	15 (18.8%) 13 (17.6%)	<b>39 (48.6%)</b> <b>41 (51.4%)</b>	<b>&gt;0.05</b>

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.8: The distribution of the various objective testing and type of occupation for the 80 patients in Ramallah district**

<b>Variable</b>	<b>Work N=33 No (%)</b>	<b>Not working N=14 No (%)</b>	<b>Student N=33 No (%)</b>	<b>Total N=80 No (%)</b>	<b>P value</b>
<b>HbA1c (%)</b> <8.5 ≥8.5	25 (31.25%) 8(10%)	7 (8.75%) 7 (8.75%)	22 (27.5%) 11(13.75%)	<b>54 (67.5%)</b> <b>26 (32.5%)</b>	*
<b>Sugar (mg/dl)</b> <140 ≥140	5 (6.2%) 28 (35%)	0 14 (17.5%)	5 (6.3%) 28 (35%)	<b>10 (12.5%)</b> <b>70 (87.5%)</b>	*
<b>Urea (mg/dl)</b> <45 ≥45	31 (38.7%) 2 (2.5%)	12(15%) 2 (2.5%)	33 (41.3%) 0	<b>76 (95%)</b> <b>4 (5%)</b>	*
<b>Creatinine (mg/dl)</b> <1.1 ≥1.1	23 (28.75%) 10 (12.5%)	12(15%) 2 (2.5%)	33 (41.3%) 0	<b>68 (85%)</b> <b>12 (15%)</b>	*
<b>Cholesterol (mg/dl)</b> <200 ≥200	11 (13.7%) 22 (27.5%)	10 (12.5%) 4 (5%)	26 (32.5%) 7 (8.8%)	<b>47 (58.7%)</b> <b>33 (41.3%)</b>	<b>&lt;0.05</b>
<b>Triglyceride (mg/dl)</b> <150 ≥150	10 (12.5%) 23 (28.7%)	9 (11.2%) 5 (6.3%)	23 (28.8%) 10 (12.5%)	<b>42 (52.5%)</b> <b>38 (47.5%)</b>	<b>&lt;0.05</b>
<b>HDL (mg/dl)</b> <40 ≥40	17 (21.2%) 16 (20%)	9 (11.3%) 5 (6.2%)	13 (16.3%) 20 (25%)	<b>39 (48.8%)</b> <b>41 (51.2%)</b>	<b>&gt;0.05</b>
<b>LDL (mg/dl)</b> <100 ≥100	7 (8.7%) 26 (32.5%)	3 (3.7%) 11 (13.8%)	14 (17.6%) 19 (23.7%)	<b>24 (30%)</b> <b>56 (70%)</b>	*

\*Chi square not calculated since expected count in one cell less than 5

**Table 5.9: The distribution of the diagnostic nephropathy with demographic variables for the 68 patients in Ramallah district**

Risk factor	Diagnosed Nephropathy N=5 No (%)	No-Nephropathy N=63 No (%)	Total N=68 No (%)	Significance
Age Mean $\pm$ SE (yrs)	35.8 $\pm$ 2.89	21.5 $\pm$ 1.34	22.53 $\pm$ 1.34	*
Age				
Child	0	21(30.9%)	21(30.9%)	*
Adults	0	28(41.2%)	28(41.2%)	
Older adults	5(7.4%)	14(20.5%)	19(27.9%)	
Sex				
male	3 (4.4%)	29 (42.6%)	32 (47%)	
female	2 (3%)	34 (50%)	36 (53.0%)	*
Marital status				
Single	2 (3%)	42 (61.8%)	44 (64.8%)	
Married	3 (4.4%)	21 (30.9%)	24 (35.2%)	*
Occupation				
Work	3 (4.4%)	24 (35.3%)	27 (39.7%)	
Not working	2 (3%)	8 (11.7%)	10 (14.7%)	*
Student	0	31 (45.6%)	31 (45.6%)	
Place of residency				
City	2 (3%)	20 (29.4%)	22 (32.4%)	
Village	2 (3%)	33 (48.4%)	35 (51.4%)	*
Camp	1 (1.4%)	10 (14.8%)	11 (16.2%)	
Education level				
0-12 year	5 (7.4%)	54 (79.4%)	59 (86.8%)	
>12 year	0	9 (13.2%)	9 (13.2%)	*

**Table 5.10: The distribution of the diagnostic neuropathy with demographic variables for the 68 patients in Ramallah district**

Risk factor	Diagnosed Neuropathy N=11 No (%)	Non Neuropathy N=57 No (%)	Total N=68 No (%)	P value
Age Mean±SE (yrs)	35.91±2.58	19.95±1.26		
Age				
Child	0	21(30.9%)	21(30.9%)	
Adults	3(4.4%)	25(36.8%)	28(41.2%)	*
Older adult	8(11.8%)	11(16.1%)	19(27.9%)	
Sex				
male	11 (16.2%)	21 (30.9%)	32 (47%)	
female	0	36 (53%)	36 (53%)	P<0.05
Marital status				
Single	2 (3%)	43 (63.2%)	45 (66.2%)	*
Married	9 (13.2%)	14 (20.6%)	23 (33.8%)	
Work	10 (14.7%)	Occupation	27 (39.7%)	
Not working	1 (1.5%)	17 (25%)	10 (14.7%)	*
Student	0 (0%)	9 (13.2%)	31 (45.6%)	
Place of residency		31 (45.6%)		
City	3 (4.4%)		22 (32.4%)	*
Village	6 (8.8%)	19 (28%)	35 (51.4%)	
Camp	2 (3%)	29 (42.6%)	11 (16.2%)	
Education level		9 (13.2%)		
0-12 year	10 (14.7%)		59 (86.8%)	*
>12 year	1 (1.5%)	49 (72.1%)	9 (13.2%)	
		8 (11.7%)		

\* Chi square was not calculated since expected count in one cell less than 5