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A Descriptive Study of Cardiovascular Risk Profiles of Adults with Type 2 Diabetes from Hospitals in Urban Saudi Arabia

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MD, October 6th University (2009)

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ABSTRACT

OBJECTIVE: To determine the prevalence of Cardiovascular disease (CVD) risk factors among people with type 2 diabetes mellitus (T2DM) attending two different hospitals settings in Riyadh, Saudi Arabia, from 2008 -2012. To determine as well the percentage of patients achieving the recommended optimal levels of CVD risk factor control according to the American Diabetes Association (ADA) guidelines.

METHODS: This is a retrospective study that used outpatient data from King Fahad Madical City (KFMC) and Prince Salman Hospital (PSH) from 2008 to 2012. Data were extracted from medical records and frequencies of CVD risk factors (obesity [BMI ≥ 30 kg/m^2], hypertension [already diagnosed or patients with measured SBP ≥ 140 and DBP ≥ 90 mmHg], elevated cholesterol fractions) plus proportions achieving control targets (based on ADA guidelines) were reported. Frequencies and proportions were also compared across hospitals and gender.

RESULTS: Out of 422 patients with T2DM, 50.24% were women. The average age was 52 years. The prevalence of obesity among T2DM patients was 56%, and the prevalence of hypertension was 45% . In addition to being diabetic, 21% had two CVD risk factors, 31% had three risk factors, and 18% had four risk factors. The percentage of adults with T2DM that achieved the recommended HbA1c and BP levels was 8.93%, but it dropped to 3.57% when combined control of HbA1c, BP, and lipid profile (LDL, HDL, triglycerides, and total cholesterol) were examined.

CONCLUSION: The T2DM patients in two large health centers appear to be far from achieving evidence-based standards of medical care. The percentage of patients with poor glycemic, BP, and lipid control was high. This implies that major efforts are needed to improve these services in order to reduce the gap between the optimal level of risk factor control and what the current reality reflects.

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Chapter 1: Introduction and Literature Review

Diabetes

Diabetes mellitus (DM) is a rising global health problem. In 2000, the number of people with all types of diabetes was 171 million, with a worldwide prevalence of 2.8%[1]. The International Diabetes Federation (IDF) indicated that, in 2011, the number of people with diabetes jumped to 366 million and is projected to reach 552 million by 2030. [2] These alarmingly high numbers are due to a number of factors, but are most strongly related to aging of populations, the high prevalence of obesity, population growth, and lack of physical activity[3]. In most cases, complications from diabetes (such as blindness, limb amputation, stroke, heart disease, and kidney failure) are usually associated with high health care costs and are avoidable or can at least be delayed. It is evident that this disease is a global health problem that requires a high degree of attention for its detection, control, and maintenance at the international and local levels.

DM is a cluster of metabolic diseases characterized by hyperglycemia (high blood sugar levels) resulting from defects in insulin secretion, insulin action, or both. Chronic hyperglycemia from diabetes is associated with long-term damage, dysfunction, and the failure of various organs, particularly the eyes, kidneys, nerves, heart, and blood vessels. One of the main two categories of DM is Type 1 Diabetes (T1DM), which entails pancreatic cell destruction, usually leading to absolute insulin deficiency. This form of diabetes, which accounts for only 5–10% of the total cases globally, results from a cellular-mediated autoimmune destruction of the cells of the pancreas. It is also known as insulin- dependent diabetes, Type I Diabetes, and juvenile onset diabetes.

The second type is Type 2 Diabetes. This form of diabetes, which accounts for 90% to 95% of the total cases globally, encompasses individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency. It is commonly referred to as non-insulin-dependent diabetes, Type II Diabetes, or adult-onset diabetes. At least initially, and often throughout their lifetimes, these individuals do not need insulin treatment to survive. There are probably many different causes of this form of diabetes. The specific etiologies for T2DM are not known, but unlike T1DM, the autoimmune destruction of cells does not occur [4].

DM and Cardiovascular Disease

DM has been recognized to be an independent risk factor for vascular diseases. T2DM is associated with many microvascular and macrovascular complications that have devastating effects on quality of life, high mortality, and will lead to a heavy burden on healthcare systems.

Diabetic retinopathy has been diagnosed in 21% of those with T2DM [5] and is the leading cause of new blindness among adults aged 20–74 years, worldwide [6]. Additionally, high blood glucose levels can cause nerve damage, leading to such complications as loss of sensation, pain, and burning sensations, which are collectively called diabetic neuropathy [7]. Diabetic nephropathy (kidney damage) has been diagnosed in 18% of diabetic patients[8], and diabetes is also the leading cause of end-stage renal disease [9],[5],[10] and is a leading cause of non-traumatic lower extremity amputations [11]. Globally, it has been estimated that more than 50-70% of all non-traumatic limb amputations occur in diabetic patients [12]. Foot lesions in diabetic patients are usually the result of polyneuropathy, peripheral arterial problems, and

infections. For people with diabetes, insensitive feet are normally susceptible to trauma and may develop lesions that can become infected. Such lesions may often be painless and go undetected for a long period of time[13]. The risk of amputation in patients who have had diabetes for over 10 years is high, especially in males with poor glucose control and other complications, such as cardiovascular disease (CVD) and renal dysfunction [14].

DM patients have always had a higher risk of CVD complications than those without diabetes [15]. In the U.S., those with DM have a 2-4-fold increased risk of dying from coronary artery disease [16]. Adjusting for age, obesity, hypertension, dyslipidemia, and tobacco use, people with diabetes still have a 4-fold-greater risk of developing a CVD event than people without diabetes [17],[18]. The relative risk of CVD in women with T2DM is 3-4 fold greater than in women without diabetes [19],[20]. Additionally, T2DM shares an equivalent risk of having a myocardial infarction (MI) as non-diabetic people who have previously suffered an MI; T2DM patients are estimated to be at a 5-fold risk for developing their first MI compared to non-diabetics, and at a 2-fold greater risk for a recurrent MI compared to people who previously had an MI but do not have diabetes [21]. Patients with T2DM also have an increased risk of stroke [22].

In the United Kingdom Prospective Diabetes Study (UKPDS), 50% of individuals with diabetes already had some kind of complications at diagnosis [23]. The early detection and treatment of all types of diabetes is essential in order to reduce the impact of its serious complications.

Glycemic Control

The data from many different studies (The Diabetes Control and Complications Trial (DCCT), UKPDS [24], Kuanamoto [25], [26], The Collaborative AtoRvastatin Diabetes Study (CARDS*)* [27], The Scandinavian Simvastatin Survival Study (4S) [28], the Cholesterol Treatment Trialists Collaboration (CTT) [29] and the Blood Pressure Lowering Treatment Trialists' Collaboration [30]) showed that intensive control of blood glucose, blood pressure, and cholesterol levels reduces the high risk of vascular disease in DM patients. In the DCCT, the association between intensive and less intensive treatment for T2DM and the risk of complications showed that there was a relative reduction of approximately 60% in the risk of diabetic retinopathy, neuropathy, and nephropathy among those receiving the intensive treatment aimed to normalize the blood glucose [31].

The rationale for optimal glycemic control in T2DM patients has been confirmed in the UKPDS study; in that study, newly-diagnosed T2DM patients receiving intensive glucose control had an HbA1c level that was around 7%, compared to those receiving standard treatment, whose HbA1c level was 7.9%. After this treatment, the risk for those in the intensive group for any diabetes-related endpoint was reduced by 12%, and for micro-vascular endpoints, the risk was reduced by 25%. Additionally, the intensive treatment group had 16% lower risk of MI and sudden deaths compared to the normal treatment group [24],[32]. A ten-year follow-up study of the UKPDS showed a continued reduction in microvascular risk and MI [26]; the importance of glycemic control has also been confirmed in a Japanese study.

Blood Pressure Control

Over 11 million Americans have both diabetes and hypertension; this combination strongly predisposes those patients to renal failure and CVD [33]. There is non-disputable evidence that the coexistence of hypertension with diabetes increases the risk of microvascular complications, CVD incidence, and deaths. Specifically, any blood pressure greater than 115/75 mg Hg has been associated with increased CVD events and mortality in T2DM patients [34].

Since diabetes is defined by blood glucose levels, much of the attention in diabetes care focuses on the management of hyperglycemia. However, the causal link between hyperglycemia and micro vascular disease has been overstated [24, 35]; there is a need to consider controlling all the risk factors at the same time to reduce vascular complications of diabetes.

Studies of hypertension control in patients with diabetes have shown that improved control of blood pressure led to substantially reduced risks for cardiovascular events and death [36-38]. In addition, the literature suggests that aggressive hypertension control in diabetic patients also reduces the risk for microvascular events, including end-stage impairments (such as decreased visual acuity and end-stage renal disease) [39, 40]. The Hypertension Optimal Treatment (HOT) randomized trial showed that a four-point difference in diastolic blood pressure (85 mm Hg vs. 81 mm Hg) resulted in a 50% relative risk reduction for total cardiovascular events in patients with diabetes [38].

The drugs used to control blood pressure (i.e., angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers) have additional benefits in that they help

reduce the risk of kidney failure by 33%, and this is beneficial for diabetes patients because DM and hypertension together are leading risk factors for kidney failure [41].

The UKPDS study found that a reduction of 10/5 mmgHg units of blood pressure in T2DM patients reduced the incidence of microvascular complications by 37% and CVD incidence plus reduced deaths by 32%[34]. Recent data reveal that to preserve renal function and reduce CVD events, blood pressure must be reduced to a target level of 130/80 mmgHg to reduce the risk of CVD [33].

Lipid Control

To reduce the risk of CVD in diabetes patients, the strategy should include the assessment and treatment of Low-density lipoprotein (LDL) cholesterol. The aim is to reduce the LDL cholesterol to < 100 mg/dl. However, for a high-risk patient (someone with diabetes and pre-existing CVD), it is necessary to reduce LDL to < 70 mg/dL, along with addressing hypertension and glucose control [42, 43]. The borderline elevation of LDL cholesterol is common in diabetic patients and is associated with substantial cardiovascular risk since the LDL are small and dense cholesterol particles and more likely to perpetuate atherosclerosis within blood vessels. The mild elevation in the LDL cholesterol level will adversely impact other lipid abnormalities and increase the overall risk of Coronary Heart Disease (CHD). Studies show that an intensive LDL cholesterol control results in major reductions in cardiovascular morbidity and mortality [42-44]. The Scandinavia Simvastatin Survival Study (4S) showed a 55% reduction in major coronary events when Simvastatin was taken compared to placebo, and the total mortality was reduced when the cholesterol was reduced [45].

Diabetes in the Middle East

In Egypt, the crude prevalence of diabetes in 2008 was reported to be 4.07%, increasing with age to 19.8% among females 50 to 95 years old [46]. In 2010, another study from Egypt reported diabetes prevalence of 9.3% (affecting 7.5 million people), 40% of whom were undiagnosed [47]. Looking at the Gulf Cooperation Council (GCC) countries of the UAE and Bahrain, the prevalence of diabetes in the UAE in the adult population 20-79 years old was 18.7% in 2010 and 19.2% in 2011 [48]; in Bahrain, the prevalence was 19.9% overall [49]. A study indicated that diabetes prevalence in Bahrain was associated with ethnicity, that there was no association between diabetes and parental consanguinity, and that the obesity rate was inversely related to physical activity [50].

Diabetes in KSA

The prevalence of diabetes in the Kingdom of Saudi Arabia (KSA) has varied over time. Although the sample sizes of the following studies are different and so are the populations represented by them, there seems to be a powerful relationship between the factors above and the rising prevalence of diabetes in KSA.

Table 1: Summary of data regarding DM in KSA from 1982-2011

Year	Statistic and study type
1982	The prevalence of DM was 2.5%, based on a study of 1,385 male participants in the Al-Kharj area using the WHO criteria for screening[51]
1994	A report on the trends in non-communicable diseases by the Country Cooperation Strategies for the WHO and KSA showed that in 1994, the number of people with diabetes in the KSA was 1.09 million
1999	The prevalence of DM was 6%, based on a study of 14,660 male and female participants in a household screening survey program in five different regions [52]

2000	A community-based national epidemiological health survey study over a period of five years showed that the age adjusted DM prevalence in KSA in 2000 was 21.9%. DM was more prevalent in urban areas 25.5% compared to only 19.5% in rural areas. They concluded that despite the large and accessible health facilities in the Kingdom, 27.9% of diabetic patients were unaware of having diabetes [53].
2002	A report on the trends in non-communicable diseases by the Country Cooperation Strategies for the WHO and KSA showed that 1.59 million people were affected by diabetes in 2002, an increase of 500,000 cases since 1994 [54].
2004	The prevalence of DM was 24%. Based on a community-based national epidemiological health survey with 17,232 participants [53]
2004	The results of a study in 2004 conducted in the Eastern Province of KSA showed that the prevalence of DM was 17.2% and that it increased with age and was higher in women, widows, divorced persons and the unemployed [55]
2004	KSA had the third highest prevalence of DM in the world, 23.7% of the adult population, as reported in a community-based national epidemiological health survey[53]
2009	Among clinic-going patients, the prevalence is about 30%, which was reported in a cross-sectional study of 6,024 patients attending a primary care clinic in 2009 [56]
2010	A cohort study in Riyadh in 2010 revealed that the age-adjusted prevalence of diabetes in a total of 9,149 adult Saudis was 34.7% for males and 28.6% for females; the study also showed that the prevalence of obesity in females was higher than males, with an overall age-adjusted rate of 36.5% in females and 25.1% in males.

In light of all of these figures, it is no surprise that T2DM alone is the most costly medical disorder in KSA, exhausting 23% of the health care expenditures and 11% of all direct medical services [57]. One out of every five Saudi patients with diabetes develops nephropathy which can lead to end-stage renal disease (ESRD*)* The per-patient cost for dialysis in KSA is $1,400 per year, with a total cost burden for dialysis of $540 million [58]. Additionally, the approximate cost for managing one patient with an additional amputation is $40,000 to $75,000 per year [59], and 3,970 lower extremity amputations are performed in KSA each year [60].

The burden of the high prevalence of diabetes in KSA is well known at all governmental levels, and in particular in the Ministry of Health, where the Centers for

Diabetes Control and Maintenance has been established in all the major provinces. However, at the population level, awareness of the problem is very low, and the awareness of cardiovascular disease (CVD) risk among adults in 2009 was only 2.7% [55].

KSA: Background

Figure 1: KSA geographic map

Source:http://www.worldatlas.com/webimage/countrys/asia/lgcolor/sacolor.htm

The Kingdom of KSA (KSA) is 830,000 sq. miles, a quarter of the size of the United States. It is located in the Middle East, occupying 80% of the Arabian Peninsula. It is surrounded by the Red Sea on the west, the United Arab Emirates, Qatar, and the Arabian Gulf to the east, Jordan, Iraq, and Kuwait to the north, and Oman and Yemen to the south. The land is mostly desert, with some mountains on the west side. By far the

most precious resource in the KSA is oil. One of the world's largest oil reserves was discovered in 1938 in the eastern region, which produces approximately 10 million barrels per day. About 80% of the KSA's revenue comes from the oil industry, and this income has transformed Saudi society and contributed to a major shift in lifestyle.

One of these shifts can be seen in the demographic data. By 2004, the census showed that the population had reached 22.7 million, with 8 to 10 million of those migrant laborers [61]. Before the turn of the nineteenth century, diabetes was not heard of in KSA, most likely for simple reasons: the entire population was engaged in intensive labor-related physical activity, such as farming, fishing, pearl diving, and shepherding. Women participated in physical activities, including helping in the field, fetching water from long distances, and doing housework. Therefore, before the mid-20th century, very few members of the population were overweight or obese.

What happened to this highly active and healthy population that has resulted in the high prevalence of diabetes, as well as other health issues? From the 1960's through the 1980's, KSA began to enjoy high revenues from the sale of its oil, bringing with it dramatic changes in the lifestyle and habits of all sectors of the population. In particular, there was and continues to be high migration from the rural and nomadic areas to the main cities (urbanization). People are now mainly engaged in office type work and military activities. Most physical labor, such as farming, fishing, and animal grazing, is now being done by the 8 to 10 million expatriates and migrant laborers. Women now have housemaids and drivers that do most of the housework and provide transportation; as a result, the obesity rate among women is higher than that of men [62].

Diets have changed drastically from the traditional simple unprocessed foods, to more processed oil-saturated food with a high proportion of carbohydrates. The most important factor has been the introduction of fast food (Western-style food), which was first introduced in the early 1970's [63]. The fast food market in KSA is expected to exceed $4.5 billion in gross sales by 2015, driven by growing demand from the population [64], [65]. In addition, it has been reported that KSA is the "third laziest nation" worldwide with 70% of the population not doing any type of exercise. In 2007, the prevalence of inactivity was estimated to be 96.1% according to a National Epidemiological Health Survey that included 17,395 participants, which is very high. The prevalence rate for females was even higher than for males: 98.1% compared to 93.9% [66].

CVD in KSA

Although there is no data on CVD risk factors (hypertension, dyslipidemia, and obesity) in the diabetes population in KSA, CVD risk factors are seen frequently, and these risk factors increase the risk of CVD and diabetes complications, as shown previously. According to data published by the Saudi Ministry Of Health (SMOH), CVD accounted for approximately 20% of the total deaths in 2005, 22% in 2006, and 19% in 2007 [67, 68]. A community-based study done in 2004 showed that the overall prevalence of CAD was 5.5%; among males, it was 6.6%, and among females, 4.4%. Moreover, the prevalence is higher among urban Saudis (6.2%) than rural Saudis (4%) [69].

Hypertension in KSA

Hypertension affects more than one-fourth of the adult Saudi population. In a community-based study done from 1995 to 2000, the prevalence of hypertension was estimated to be 26.1%; the prevalence of males with hypertension was 28.6%, while the prevalence of females with hypertension was somewhat lower, 23.9%. Additionally, the prevalence of CAD among hypertensive patients was 8.2% compared to 4.5% among patients without hypertension. The urban population has a higher rate of hypertension than the rural population: 27.9% of urban Saudis have hypertension, compared to 22.4% of rural Saudis. This might be due to the consequences of urbanization and the sedentary lifestyle that has accompanied it, the reduced levels of physical activity leading to major increases in the prevalence of obesity as well as hypertension [70, 71].

Hyperlipidemia in KSA

In 2008, a community-based study estimated a high prevalence of hypercholesterolemia: 54% among the general population, 54.9% among males, and 53.2% among females. The hypertriglyceridemia prevalence was 40.3% overall, 47.6% among males compared to 33.7% among females.

Obesity in KSA

Obesity is a factor that predisposes people to having high lipid levels as well as other CVD risk factors. In KSA, the overall obesity prevalence was 35.5% in 2005 (overweight is defined as having a body mass index [BMI] of 25 to 29.9 kg/m2, and obesity as having a BMI greater than or equal to 30 kg/m2) [72]. Another study showed significant regional variations in the distribution of obesity [73].

Study Significance

Several published studies of patients with diabetes have shown a significant reduction in cardiovascular morbidity and mortality when these patients closely control their glycemia and the main cardiovascular risk factors, such as hypertension and dyslipidemia [24, 74-76]. The UKPDS has shown a decrease in any DM-related complication as well in mortality with every 1% reduction in HbA1c [77]. The aggressive treatment of hypertension reduces macrovascular and microvascular events [34, 38], and the intensive treatment of dyslipidemia in T2DM similarly reduces CVD [78, 79].

A U.S. study was done in 2002 to estimate the control levels for CVD risk factors based on the American Diabetes Association ADA goals at two major urban medical centers in Brooklyn and Detroit. It found that only 3.2% of patients met the combined ADA goal for HbA1c, BP, and LDL cholesterol level [80]. Another study done in 2006 in Spain reported that optimal control of all CVD risk factors was found only in 7% of diabetic patients [81]. In light of these circumstances, this study aims to detect the proportion of control of HbA1c and other CVD risk factors (multifactorial control) in T2DM patients, using the ADA guidelines [82], in two different hospital settings in the Riyadh region of KSA. Since the literature also shows some variation in risk factor prevalence among men and women in KSA, we also examined risk factor prevalence and control among men and women separately.

Study Questions

1) What is the prevalence of CVD risk factors among people with T2DM attending two hospitals in Riyadh, KSA, from 2008 -2012?

2) What are the differences in T2DM control and management between secondary and tertiary health care facilities in Riyadh?
3) What percentage of patients is achieving the recommended optimal levels of their multiple CVD risks using the American Diabetes Association (ADA) guidelines?
4) What factors are associated with achievement of optimal control of CVD risk factors among diabetes patients?

Chapter 2: Methodology

Study Population

This study used data that were obtained from two accredited hospitals in the Riyadh region, in KSA: King Fahad Medical City's (KFMC) Diabetic Center and Prince Salman Hospital's (PSH) Al Shikh Diabetic Center, in collaboration with KSA's Ministry of Health (MOH). Data for the primary sample population was drawn from Diabetes Outpatient department's medical records. The study received approval for human subjects research from Emory Institutional Review Board (IRB) in the U.S. and KFMC Institutional Review Board in the KSA.

This study is a cross sectional study using retrospective medical chart review data. The study sample consisted of outpatients' files (30 to 79 years old), sample size (n=470) randomly selected, and only those with T2DM were included in the analysis (n=422). The inclusion criteria were Saudi nationality, diagnosed with T2DM, and without any history of cardiovascular disease. The exclusion criteria were non-Saudi nationality, pregnant women, and history of cardiovascular disease.

Sample selection. With regard to sampling, at Prince Salman Hospital, data were retrieved from the medical record rooms, where all the files were arranged on the shelves. Every third file on every shelf was selected, and if the patient's data fit the study criteria, then the information was taken from these files. If it did not fit the criteria, it was excluded and the next third file was taken.

At King Fahad Medical City, a random list of all patients diagnosed with T2DM was generated from the IT department using a software program. The same process of inclusion, exclusion, and replacement, based on the study criteria, was used at KFMC to arrive at medical files from T2DM patients.

Measurement

Data collection. All variables were collected from the patient medical records. The data collected were age, gender, height, weight, BMI, blood pressure, and lab test results for LDL, HDL, total cholesterol, triglyceride, and HbA1c.

Data categorization and definitions

- Age: ≥30 to ≤79 years old
- Age categorized as

  30-59y

  60y +
- Gender: Female and Male
- Height by Centimeter (cm)
- Weight by kilogram (KG)
- BMI was computed using =Mass (KG)/ (Height [m])2
- Blood pressure measurement at the last visit to the clinic and recorded in file
- LDL, HDL, total Cholesterol, triglyceride, and HbA1c: results of last test done and recorded in file.

Outcome variables.

Prevalence analysis definitions

- Hypertension: individuals were considered to have hypertension if the medical file reported HTN and/or the person was measured with a systolic blood pressure ≥ 140 mm/Hg and/or diastolic blood pressure ≥ 90 mm/Hg.
    - Diabetes: T2DM reported on the medical file
    - Lipids (using the ATP III guidelines [83]) : Elevated low-density lipoprotein (LDL): was defined as LDL >130 mg/dL (or >3.4 mmol/L). Low High-Density Lipoprotein-cholesterol (HDL): defined as HDL < 40 mg/dL (or < 1.00 mmol/L) for male and female.
    - Hypertriglyceridemia: defined as Triglyceride ≥ 200 mg/dL (or ≥ 2.26 mmol/L).
    - High total cholesterol: > 200 mg/dL (or > 5.172 mmol/L).
    - Obesity: individuals whose body mass index (BMI) was ≥30kg/m^2

Optimal control definitions. Optimal control of CVD risk factors among people with diabetes were defined using the American Diabetic Association (ADA) Standard of Care guidelines from 2013 [82].

- Controlled blood pressure < 130/80 mmHg.
- Optimal level of HbA1c ≤ 7.0%.
- Optimal LDL <100 mg/dl (or < 2.6 mmol/L).
- Optimal level HDL > 40 mg/dl (or 1.00 mmol/L) for male, > 50 mg/dl (or > 1.3 mmol/L) for female.
- Optimal triglyceride <150 mg/dl (or <1.7 mmol/L).
- Optimal total cholesterol < 200 mg/dl (or <5.172mmol/L).

Statistical Analyses

Exploratory analyses of the data were done to produce summary statistics for all

demographic, clinical, and metabolic variables as appropriate. Continuous variables were summarized with descriptive statistics (n, mean, standard deviation, range, and median). Frequency counts and percentage of subjects within each category were summarized for categorical data. Outliers and influential or extreme points in the design space were examined graphically with boxplots, histograms, scatterplots, and quantitatively with residual analyses. A Crosstab association analysis of demographic, clinical and metabolic features between KFMC vs. PSH was conducted using a Chi-Square test. Instances when the sample size distributions for categories of these variables were skewed and/or small, Exact Fischer test was conducted. The resulting p-values using Fisher's exact test for these analyses did not contradict the results from the Chi-square test and did not change greater than 10% in any direction from the Chi square p-value. This indicated the Chi-square test provided a good approximation to the exact results and therefore subsequent association analyses were conducted using Chi-Square. A chi-square analysis of metabolic and clinical features between the hospitals was conducted to test for an association between these features in subjects with hypertension. We also compared data from all patients in the full sample (n=422) and those patients with complete data only (n=168). This was to explore if there were biases or major differences in those without complete data. It gave us an opportunity to examine the robustness of the data and report our findings with confidence.

Chapter 3: Results

Data from 470 people were extracted from medical records from KFMC and PSH, of which data from 422 patients were included in the analysis with T2DM after excluding 70 patients whose data did not fit the inclusion criteria. These data represent patient visits to the hospitals during the period from 2008 to 2012. Descriptive demographic statistics are displayed in Table 2. Of these 422 patients, 50.24% were women (n = 212) and the average age was 52 years (n=422); there was no significant difference in age between men and women. In KFMC, 64% (n=146) were women, while in PSH, 34% (n=66) were women. The CVD risk profile shows that of the total (n=415), 56% were obese (BMI ≥ 30kg/m^2), with a mean BMI of 31 kg/m^2 (SD=7.9) (see Tables 3 and 4).

The proportion of patients diagnosed with HTN and/or having SBP≥140 and DBP ≥80 reached 45% (of the total n=422), of whom 57% were female and 70% were patients in KFMC. The mean DBP was 77 mmHg (SD=10), and the mean SBP was 131 mmHg (SD=18). The mean percentage for HbA1c was high, at 9% (SD=2.15). The proportion of those who had LDL levels greater than 3.4 mmol/L was 77% (of the total n=363), with a mean of 2.75 mmol/L (SD=0.94) (see Tables 3 and 4).

The prevalence of CVD risk factors among T2DM patients using the patients with complete data profiles only (n=168) showed that the prevalence of HbA1c was 88% and the prevalence of obesity (BMI≥30) among T2DM patients was 68%. The prevalence of HTN in T2DM patients was 100% (diagnosed and/or having SBP ≥ 140, and DBP≥80). The prevalence of hyperlipidemia (LDL) among T2DM patients was 15% (LDL >3.4 mmol/L) (see Table 5).

Among T2DM patients with complete data (n=168), only a minority had optimal control of any CVD risk factor except LDL: 19% reached a desirable level of HbA1c (<7%), only 27%

reached the optimal control level of their BP <130/80 mmHg, and 62% reached the optimal control of their LDL level (<2.6 mmol.L).We can see that 31% of the T2DM patients had three CVD risk factors, 18% had four CVD risk factors, and 14% had five CVD risk factors; only 4% had six CVD risk factors (Table 6).

The risk factors (Hb1Ac, LDL, and HTN) were stratified by age and gender. When HbA1c was stratified by gender, it was the only stratification that showed a statistically significant difference (p=0.021). The female patients at KFMC had better optimal control of their HbA1C: 5.8% had controlled levels, compared to 2.6% in PSH. It was the opposite for males: 4.8% of them had optimal levels of HbA1c in KFMC compared to 6.7% of them in PSH (Table 7).

Among diabetics with CVD risk factors, 21% had two CVD risk factors, 31% had three risk factors, and 18% had four risk factors (Table 8).

Overall, the percentage of adults with T2DM that achieved the recommended HbA1c level and BP levels was 8.93%, but it dropped to 3.57% when the optimal lipids profiles were combined with optimal HbA1c and BP rates (Table 9).

Chapter 4: Discussion

We found a high prevalence of CVD risk factors among patients with diabetes in urban KSA, and a large proportion of these were not well controlled. We will explore the factors associated with this prevalence and lack of control of CVD risks in KSA and propose some recommended actions.

Cross-Study Comparisons

This study showed a similarity to other studies in the low control over glycaemia, BP, and lipid levels in KSA and other Gulf Cooperation Council (GCC) countries. For example, a UAE retrospective cohort study with 382 DM patients showed that 41% reached the optimal level in their glycated hemoglobin (HbA1c), 47% reached the target level in SBP, 73% reached the optimal level of DBP, and 72% reached the target LDL level [84-86]. In Lebanon, a National Health Service Registry study found that just over half of the participants had an HbA1c level of less than 8%, and fewer than half of the participants had a total cholesterol <5.0 mmol/l [87, 88]. In Egypt, in a retrospective cohort study with 137 DM patients, 89.2% did not reach the optimal level of fasting blood glucose of < 130 mg/dl. A total of 40.2% did not meet the optimal goal of 130 mmHg for SBP, and 46.7% did not meet the goal of 80 mmHg for DBP. Over half (59%) did not meet the goal of total cholesterol level of <200 mg/dl, and 76.4% did not reached the triglycerides level of <150 mg /dl [89, 90].

CVD Risk Factors

The majority of patients in this study had levels of HbA1c that were higher than 7% (mean 9%, SD 2.15), far from the current ADA-recommended goal of <7% to reduce

the CVD complications. For every 1% increase in the HbA1c level, there is a 25% increase in the risk of CVD events or death [82]. Studies show that vigorous control of glycemic level delays the onset of retinopathy, neuropathy, and nephropathy too [91] [24]. Based on this and other studies, there is an urgent need to aggressively control HbA1c levels and reduce them to under 7%, while also considering individualized recommendations for patients at high risk [92]. The proportion of patients with T2DM in this study having the ADA-recommended level of HbA1c was 19%, and this is in the same range of findings as another study done in 2010 in the Riyadh region, in which 21.8% of the participants had the recommended HbA1c level in an observational, cross-sectional, retrospective study with a 1,188 patients [93]. In the UPKDS, after the nine-year follow up study, less than 25% of those patients continued with good levels of glycemic control. This is closer to our finding [94].

There were differences in the demographic characteristics of the T2DM populations who were tracked at the two different urban hospitals. Patients in KFMC had higher rates of obesity and higher blood pressure rates than those in PSH (Table.4). These observations may reflect the strong relationship between hypertension and obesity [95]. Additionally, KFMC is a tertiary hospital that accepts referrals from all over the country, and some of the patients might have been referred there for bariatric surgery.

In our study, only 12% of patients had acceptable BP measurements (of the patients with complete data (n=168)) (Table 6). This finding is much lower than what was reported in a study done in 2010 in The King Fahad National Guard Hospital, King Abdulaziz Medical City, with participants in the exact same age group, which indicated that 39.0% of patients were at optimal control for SBP and 40.6%

were at optimal control for DBP [93]. In comparison to the UKPDS, we are achieving lower BP control rates; notably, they achieved a 56% BP control rate for patients in the group with tighter controls (< 150/85 mm Hg), compared to a 37% BP control rate in the less tightly-controlled group (<180/105 mm Hg) [34]. High BP is of great concern due to the fact that this factor increased inpatients' rates of cardiovascular disease and stroke complications. Studies confirmed that with tight blood pressure control, fatal and nonfatal microvascular and macrovascular complications were reduced, and so was the relative risk of fatal or nonfatal strokes [24, 34]. This gives us an indication to go further in our efforts to reduce BP in diabetic patients.

In regard to the lipids in those patients with complete data (n=168), 82% reached the optimal total cholesterol level, 63% were in the optimal control zone for triglyceride, and 62% reached the optimal LDL level (Table.6), which is slightly better than the percentage in another study in KSA, in which 55.5% of the participants reached the optimal LDL level [93]. Participants in this study achieved the same level of the optimal control of LDL as the participants in a U.S. study conducted in 2005 (62.2%) [96], and in Australia, a study from 2006 showed that 60% of participants had optimal LDL levels [97]. Overall, only 44% of males and females reached the optimal level of HDL. These percentages show that there is room to do more in controlling lipids profiles in KSA. The Cholesterol and Recurrent Events (CARE) trial and the diabetic subset of the Scandinavian Simvastatin Survival Study (4S) revealed a striking decrease in the CVD risk when the participants aimed for the optimal level zone [45, 79].

Obesity was added to the major risk factors for CHD by the American Heart Association [98]. In this study, 68% of T2DM patients were obese, defined as having a

BMI ≥ 30 (Table.6). Having a high BMI is related to being at an increased risk of CHD [99-102]. Those with a BMI over 30 have a 50% to 100% increased risk of death from all causes compared with individuals with a BMI of 20 to 25. The increased risk of mortality is mainly attributed to CVD causes [103-105]. The problem with obesity in T2DM patients is that it is usually associated with atherogenic changes in lipids and lipoproteins, which increases the risk for CHD [106].

In most all of the literature reviewed, diabetes was associated with obesity; however, a significant study on this connection spanning from 1979 to 2001 by Sui et al. showed that fitness and adiposity is a mortality predictor in older adults. Death rates for older adults with higher fitness, independent of their abdominal adiposity, were less than half the rates for those who were unfit. This study clearly indicates that fitness, rather than obesity, is the major factor of association. Fit people are those who are regularly engaged in relatively moderate physical activity (fitness was defined in this study as achieving at least 85% of maximal heart rate age predicted for of (-220) in the maximal treadmill exercise test that minus age) [107]. Given that almost 70% of the Saudi population do not engage in any physical exercise [108] and more than 40% are obese [109] with a very high prevalence of diabetes, there is no doubt that prevention and control of diabetes in the long term must be a high priority in the public health sector.

Multiple CVD Risk Factors

Most of the T2DM patients in our study have more than three CVD risk factors (31% of them have three risk factors and 18% have four risk factors) (Table 8). The associated morbidities of having multiple risk factors are multiplicative rather than additive. It is imperative that comprehensive assessments are used to identify the

coexisting risks of target specific organ complications and that early treatment and monitoring should be instituted to help prevent these [110, 111]. According to the ADA guidelines, comprehensive diabetic care involves more than just CVD risk factor control. Good diabetic care controls all other risk factors for their patients, and requires that these patients come back for annual examinations (foot exam, urine exam, kidney, and dental check-ups); the rate of complications in clinics providing good total care is found to be low [82].

The high prevalence of having multiple CVD risk factors need to be studied further, in particular reference to whether there is a social gradient. In a 2006 study, the combination of risk factors like HTN, smoking, high serum cholesterol, and high blood glucose were found to account for less than one third of the social gradient in the CHD mortality with the implication that stress linked to low social states is more strongly to blame [112-114]. Similarly, in a study in KSA showed the prevalence of DM was higher with older age and was higher in women, widows, divorced persons, and the unemployed [55]

Our study showed that 7.14% reached optimal control levels of HbA1c, BP, and LDL, together (Table 9). A similar finding (7.3%) for controlling the same risk factors was found in a national study in the U.S. using the Third National Health and Nutrition Examination Survey (NHANES III).[115] Another cross-sectional study with 1107 participants studied in KSA, with the same age group; found to be that 4.5% achieved all optimal levels in glucose, BP, and LDL cholesterol control.[116] Given that only 3.57% are reaching the optimal level in HbA1c, BP, and all lipids profile (LDL, HDL, triglyceride and total cholesterol) in this study, there is an urgent need to investigate the

low proportion of T2DM reaching optimal control of combined CVD risk factors. Additionally, this percentage will go lower if we add the obesity and the smoking as additional risk factors. In 2001, in the U.S. a prospective observational study done with 235 diabetic patients, and the results showed only one patient (0.4%) had an optimal control of all the modifiable risk factors [117]. In a national cross-sectional French study published in 2005 with 2,346 T2DM patients, 0.3% of the patients met the optimal control of all the modifiable risk factors [118].

As we have shown, the percentage of controlled CVD risk factors for diabetic patients was very low in this study. Some of the reasons behind this figure could be attributed to physician-patient barriers and to patients' lack of compliance to their medications.

Health Care Provider and Patient Barriers

The issue of barriers between health care providers and patients can be addressed in different ways. A WHO report in 2006 indicated that in 2004, KSA had 1.30 physicians per 1,000 patients (ranked 77), 0.22 pharmacists per 1,000 patients (ranked 78), and 2.97 nurses per 1,000 patients (ranked 88) [119]. This gives us a broad picture of the problem that health providers face in KSA. There is not enough staff and no sufficient time to spend with the patients in order to take a full history, make complete examinations, or explain things to the patients. Added to this is the lack of multidisciplinary care teams. For these reasons, physicians are constrained from improving the skills that they need and finding the required time to teach patients behavioral strategies for controlling CVD risk factors and decreasing their risk [120].

Another factor can attributed to this barrier is the lack of organizational support and information systems to track patient care and health outcomes, as was seen in both hospitals which used paper-based files without the capacity to track patients and follow up [121].

Another barrier could be cultural differences between health providers and patients. According to 2010 SMOH statistics, only 21% of the physicians who work in the MOH are Saudi nationals; with the 79% of physicians being non-Saudi, patients and doctors may not be able to communicate effectively [122].

In addition to these barriers, poor reading skills and low health literacy have been associated with a range of adverse health outcomes and increased risk of hospitalization and mortality. In light of this, the health care providers need to know the level of health literacy of each patient, which should be documented clearly in his or her medical file so that they can manage each patient individually with their needs [123, 124].

Medication Adherence

Different studies show that patients with T2DM usually do not adhere to treatment, which has been linked to increases in morbidity, mortality, and health care costs. The adherence range in a retrospective study reviewing literature from 1966-2003 was from 62% to 64%.REF A high adherence rate contributes greatly to the achievement of optimal levels for multiple CVD risk factors. Adherence can be improved by using electronic monitoring systems for all diabetic patients. The first step in improving adherence is to identify those patients who are not adhering to their prescribed medications and then to distinguish between poor glycemic control due to poor adherence

and the failure of the type of medication prescribed, and finally, to address their individual need [125, 126].

Strengths

To our knowledge, this is the first Saudi study that used two different hospital settings that are supported by the MOH to evaluate T2DM care and whether ADA guidelines were being met. Both hospitals are accredited and KFMC is a tertiary hospital that accepts referrals from all over the country. So, both hospitals have a very broad and comprehensive patient base. Additionally, only Saudi citizen data was used in this study. Citizens have a very similar cultural and genetic background; they also share the same cuisine, eating habits, and lifestyle behaviors. Many Saudis have widespread familial connections due to the tradition of interfamilial marriage.

Limitations

Due to the limited timeframe, the sample size was small. Another limitation is the hospital's use of paper medical records, which may have resulted in some inaccuracies in data entry on the part of the health providers and may have limited the quality of our findings. So, some of the data retrieved may not reflect the actual T2DM management delivered or the treatment outcomes.

Although smoking is a great predictor of mortality and is possibly the single most preventable risk factor for CHD, we lacked data on smoking in our study [127]. There is a 2-fold increase in the relative risk for all cause of mortality in smoking diabetic patients versus non- smoking diabetic patients [128], but unfortunately, data on patient smoking status was not included in the statistical analysis because the smoking status was not an included as a variable on the patient history data sheet. So, the smoking status was only

noted if the health provider requested the information and thus could not be included for use in this study.

Implications of the study

This study provides useful baseline data about whether diabetes patients reach the ADA's optimal target controls of T2DM management in two different diabetes centers, one a tertiary healthcare setting (KFMC) and the other a secondary hospital in Riyadh (PSH). The results of this study reveal that a strategic in-depth study and assessment of the management of care and control of T2DM are needed to achieve further improvements.

We did not identify any differences between the diabetes optimal control provided by the tertiary and secondary hospitals. The findings in this study can assist healthcare professionals and policymakers in addressing the issue and planning for quality improvement enterprises. It is worrying that a great majority of Saudi citizens with T2DM in this study had poor levels of glycemic control given that the risk for both micro vascular and macrovascular complications over a long period of time is great under these conditions.

At the level of different diabetes care centers; there is a need to establish a system for monitoring and evaluation of the country's total diabetes care management. As more than 34% of the KSA population are T2DM, composed of all regions in the Kingdom, a regular surveillance system is recommended, with an objective to follow optimal control and quality of care over time in different hospital settings and to study reasons behind the big gap between guidelines and practice.

Chapter 5: Recommendations and Conclusion

Despite the complexity of managing diabetes and following all of the international guidelines, it can be done successfully and to the benefit of many patients. The findings in this study indicate gaps in management and care; we recommend specific actions that will be important for improving the risk profile of people with diabetes in KSA.

Review Current T2DM Management Program

All centers caring for people with diabetes should review their current T2DM management program (treatment, diet control, physical activity) at the central and regional levels. In addition, more accurate reporting is needed. We recommend that the physical history sheet should be revised to include: (FORMAT LIST BETTER)

- Smoking status, type of tobacco, tobacco consumption amount, smoking cessation status
- Use of the patient's Date of Birth instead of age, as it is more likely to be accurate.
    - The literacy level [123]
    - Waist measurement (as abdominal obesity is an important risk factor in the development of T2DM and CVD)[129]
    - Activity level
    - Blood pressure measurements should be standardized to be taken three times with rest period [130, 131]

Create a National Diabetes Committee

Creating a national diabetes committee composed of public health and medical professionals will help to address a complete review of the burden of diabetes and to produce creative and practical plans and procedures to control diabetes progression.

From the national committees, subcommittees should be created to work in each province with the same aim and objectives.

The national and regional committees need to increase the awareness of diabetes and CVD risk among the general public. There should be a focus on conveying the seriousness and preventability of diabetes in all ages. This can be approached with using social marketing and with the combination of educational programs that consider age, motivation, and literacy level.

The national and regional committees need to coordinate with the ministry of education to introduce a new subject, Health Promotion, in the current education curriculum for non-communicable disease, with important reference to diabetes. Health promotion at school has been strongly recommended by the WHO and is being implemented in many countries throughout the world; since 1996, their Health Promoting Schools Framework has been promoting the health and well-being of students, teachers, staff, administrators and community. This shows how much the WHO values health promotion in schools [132].

The National Diabetes Committee should work very closely with the Ministry of Culture and Information (the government media) in the context of social marketing in public health to produce and disseminate practical awareness information related to

diabetes on a regular and continuous basis throughout the year, rather than in a single campaign. This should include TV, radio, newspaper, and social media networks [133].

The National Diabetes Committee should work with the Communications and Information Technology Commission (CITC) to reach all people with registered diabetes through their mobile phone numbers to receive a weekly diabetes health educational message. Studies have shown that text messaging is more effective than distributing pamphlets in improving the knowledge, practices, and attitudes among people who received them, and that people were more likely to adhere to the messages that they received [134, 135].

The National Diabetes Committee will work with the General Presidency of Youth Welfare (GPYW*)* to develop diabetes awareness messages to be produced and disseminated in sports clubs, on entry tickets, bulletin boards, and stadium display screens, given the fact that football matches are one of the most popular outdoor activities in the country and likely to be attended by the majority of males of all ages.

Develop a Public Awareness Program

Given that none of the schools in the Kingdom is in use after 3:00 pm daily and all schools are completely closed from the beginning of May until the end of August, it will be an ideal opportunity for the Ministry of Health (the primary health care centers) and Ministry of Education, with the cooperation of the regional municipal councils, to develop a health program for all adult population in the Kingdom to raise the level and public health awareness that will take place in these schools.

Increase the Level of Physical Activity in the Kingdom

Of particular importance, great attention should be put on raising consciousness for the need for physical activity and how to engage it. MOH should open a new position in the name of physical activity consultant, so clinicians can refer patient to them. They should also open more positions to clinical dietitians so they can assist patients in planning and monitoring their diet.

Conclusion

The quality of management and care provided to T2DM patients in our centers appears to be far from the evidence-based standards of medical care. The percentage of patients with poor glycemic, BP, and lipid control was high, nearly the same as that reported in other countries. This implies that our centers need to make major efforts to improve these services in order to reduce the gap between the optimal levels and what the current reality reflects.

Appendix: Tables and Figures

Table 2: Demographic Characteristics of the Participants

	Total T2DM	**T2DM Females**	**T2DM Males**
Frequency (Percent)			
Gender *(n-422)*			
		212 (50.24%)	210 (49.76%)
Age (Cat.) *(n=422)*			
30 - 59 Years Old	322 (76.30%)	171 (40.52%)	151 (35.78%)
60 Years Old and Above	100 (23.70%)	41(9.72%)	59(13.98%)
Hospital (Cat.) *(n=421)*			
KFMC	228 (54.03%)	146 (34.60%)	82 (19.43%)
PSH	194 (45.97%)	66 (15.64%)	128 (30.33%)

Abbreviations: T2DM*:* Type 2 Diabetes Mellitus, KFMC*:* King Fahd Medical City, PSH: Prince Salman Hospital, F: female, M: male

Table 3: Distribution of the Cardiovascular Risk Factors by Genders

	Total T2DM	**T2DM Females**	**T2DM Males**
Age (n=422) Mean, ±SD	52.0, ±10.26	51.31, ± 9.49	52.79, ± 10.95
HbA1c (Cat.) *(n-375)*			
Mean, ±SD	9, ± 2.15	9.22, ± 2.09	8.76, ± 2.19
HbA1c < 6.5 %	43 (11.47)	19 (5.07)	24 (6.40)
HbA1c ≥ 6.5 %	332 (88.53)	177 (47.20	155 (41.33)
BMI *(n-415)*			
Mean, ±SD	31.67, ± 7.9	33.95, ± 9.06	29.37, ± 5.68
Obese (BMI ≥ 30)	235 (56.63)	147 (35.42)	88 (21.20)
Hypertension *(n-422)*			
Mean, ±SD - DBP	77.15 ± 10.86	75.62 ± 10.98	78.69± 10.54
Mean, ±SD - SBP	131.61 ± 18.25	132.82 ± 19.23	130.39± 17.15
Hypertension Diagnosis with and without Systolic BP ≥ 140 and Diastolic BP ≥ 80	190 (45.02)	109 (25.83)	81 (19.19)
Cholesterol *(n-418)*			
Mean, ±SD	4.65 ± 1.21	4.65 ± 1.16	4.65 ± 1.25
Cholesterol > 5.18 mmol/L	125 (29.90)	61 (14.59)	64 (15.31)
HDL *(n-373)*			
Mean, ±SD	1.17 ± 0.41	1.25 ± 0.44	1.08 ± 0.36
HDL < 1.0 mmol/L	137 (36.73)	53 (14.21)	84 (22.52)
LDL *(n-363*			
Mean, ±SD	2.75 ± 0.94	2.78 ± 0.9	2.73 ± 0.99
LDL > 3.4 mmol/L	77 (21.21)	40 (11.02)	37 (10.19)
Triglyceride *(n-416)*			
Mean, ±SD	1.74 ± 1.16	1.6 ± 0.97	1.9 ± 1.32
Triglycerides ≥ 2.26 mmol/L	86 (20.67	35 (8.41)	51 (12.26)

Note: Total cholesterol= < 200mg (or < 5.172 mmol/L, LDL= >130 mg/dl (or >3.4 mmol/L), HDL=< 40 mg/dl for both (or < 1.00 mmol/L for both), Triglyceride=≥ 200 mg/dl (or ≥ 2.26 mmol/L).
Abbreviations: T2DM*: Type 2 Diabetes* Mellitus, KFMC*:* King Fahd Medical City, PSH: Prince Salman Hospital, BMI: body mass index

Table 4: Distribution Cardiovascular Risk Factors by Hospitals

	Total T2DM	**T2DM KFMC**	**T2DM PSH**
Age (n= 422) Mean, ±SD	52.05 ± 10.26	52.01 ± 10.53	52.09 ± 9.95
HbA1c *(n-375)*			
Mean, ±SD	9 ± 2.15	9.02 ± 2.1	8.97 ± 2.23
HbA1c < 6.5 %	43 (11.47)	24 (6.40)	19 (5.07)
HbA1c ≥ 6.5 %	332 (88.53)	201 (53.60)	131 (34.93)
BMI *(n-415)*			
Mean, ±SD	31.67 ± 7.9	33.15 ± 9.35	29.92 ± 5.23
Obese (BMI ≥ 30)	235 (56.63)	144 (34.70)	91 (21.93)
Hypertension *(n-422)*			
Mean, ±SD DBP	77.15±10.86	75.81± 10.54	78.73± 11.05
SBP	131.61 ± 18.25	130.77± 16.71	132.61± 19.91
Hypertension Diagnosis with and without Systolic BP ≥ 140 and Diastolic BP ≥ 80	190 (45.02)	133 (31.52)	57 (13.51)
Cholesterol *(n-418)*			
Mean, ±SD	4.65 ± 1.21	4.34 ± 1.17	5.02 ± 1.15
Cholesterol > 5.18 mmol/L	125 (29.90)	50 (11.96)	75 (17.94)
HDL *(n-373)*			
Mean, ±SD	1.17 ± 0.41	1.19 ± 0.44	1.13 ± 0.37
HDL < 1.0 mmol/L	137 (36.73)	77 (20.64)	60 (16.09)
LDL *(n-363)*			
Mean, ±SD	2.75 ± 0.94	2.64 ± 0.92	2.95 ± 0.95
LDL > 3.4 mmol/L	77 (21.21)	36 (9.92)	41 (11.29)
Triglyceride *(n-416)*			
Mean, ±SD	1.74 ± 1.16	1.58 ± 0.99	1.94 ± 1.32
Triglycerides ≥ 2.26 mmol/L	86 (20.67	39 (9.38)	47(11.30)

Note: Total cholesterol= < 200mg (or < 5.172 mmol/L, LDL= >130 mg/dl (or >3.4 mmol/L), HDL=< 40 mg/dl for both (or < 1.00 mmol/L for both), Triglyceride=≥ 200 mg/dl (or ≥ 2.26 mmol/L).
Abbreviations: T2DM: Type 2 Diabetes Mellitus, KFMC: King Fahd Medical City, PSH: Prince Salman Hospital, BMI: body mass index

Table 5: Prevalence of the Cardiovascular Risks in the Study

	Total T2DM Population	**Complete Cases T2DM Population (n=168)**
	Frequency (Percent)	**Frequency (Percent)**
BMI (Cat.) *(n=415)*		
Not Obese (BMI < 30)	180 (43.37)	53 (31.55)
Obese (BMI ≥ 30)	235 (56.63)	115 (68.45)
Hypertension	*(n=422)*	
No Hypertension Diagnosis	232 (54.98)	
Hypertension Diagnosis with and without SBP ≥ 140 and DBP ≥ 80	190 (45.02)	168 (100.00)
Cholesterol (Cat.) *(n=418)*		
Cholesterol ≤ 5.18 mmol/L	293 (70.10)	138 (82.14)
Cholesterol > 5.18 mmol/L	125 (29.90)	30 (17.86)
HDL (Cat.) *(n=373)*		
HDL ≥ 1.0 mmol/L	236 (63.27)	110 (65.48)
HDL < 1.0 mmol/L	137 (36.73)	58 (34.52)
HbA1c (Cat.) *(n=375)*		
HbA1c < 6.5 %	43 (11.47)	20 (11.90)
HbA1c ≥ 6.5 %	332 (88.53)	148 (88.10)
LDL (Cat.)	*(n=363)*	
LDL ≤ 3.4 mmol/L	286 (78.79)	142 (84.52)
LDL > 3.4 mmol/L	77 (21.21)	26 (15.48)
Triglyceride (Cat.) *(n=416)*		
Triglycerides < 2.26 mmol/L	330 (79.33)	135 (80.36)
Triglycerides ≥ 2.26 mmol/L	86 (20.67)	33 (19.64)

Note: (n=168) patients with complete data with all the variables
-Total cholesterol= > 200mg (or > 5.172 mmol/L, LDL= >130 mg/dl (or >3.4 mmol/L), HDL=< 40 mg/dl for both (or < 1.00 mmol/L for both), Triglyceride=≥ 200 mg/dl (or ≥ 2.26 mmol/L).
Abbreviations: T2DM*:* Type 2 Diabetes Mellitus, KFMC*:* King Fahd Medical City, PSH: Prince Salman Hospital, BMI: body mass index, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure

Table 6: Patients with Optimal control level Using the ADA Guidelines

	Total DM2 Population	**Complete Cases DM2 Population (n=168)**
Variables	**Frequency (Percent)**	**Frequency (Percent)**
BMI (Cat.) *(n=415)*		
Not Obese (BMI < 30)	180 (43.37)	53 (31.55)
Obese (BMI ≥ 30)	235 (56.63)	115 (68.45)
Hypertension *(n=422)*		
Not Optimal Control: Hypertension Diagnosis with Systolic BP ≥ 130 and Diastolic BP ≥ 80	369 (87.44)	122 (72.62)
Optimal Control: Hypertension Diagnosis with SBP < 130 and DBP < 80	53 (12.56)	46 (27.38)
Cholesterol (Cat.) *(n=418)*		
Not Optimal Control: Cholesterol ≥ 5.172 mmol/L	125 (29.90)	30 (17.86)
Optimal Control: Cholesterol < 5.172 mmol/L	293 (70.10)	138 (82.14)
HDL (Cat.) *(n=373)*		
Not Optimal Control: HDL ≤ 1.0 mmol/L (M) or ≤ 1.3 mmol/L (F)	205 (54.96)	93 (55.36)
Optimal Control: HDL > 1.0 mmol/L (M) or > 1.3 mmol/L (F)	168 (45.04)	75 (44.64)
HbA1c (Cat.) *(n=375)*		
Not Optimal Control: HbA1c ≥ 7.0 %	300 (80.00)	136 (80.95)
Optimal Control: HbA1c < 7.0 %	75 (20.00)	32 (19.05)
LDL (Cat.) *(n=363)*		
Not Optimal Control: LDL ≤ 2.6 mmol/L	186 (51.24)	63 (37.50)
Optimal Control: LDL < 2.6 mmol/L	177 (48.76)	105 (62.50)
Triglyceride (Cat.) *(n=416)*		

Not Optimal Control: Triglycerides ≥ 1.7 mmol/L	159 (38.22)	61 (36.31)
Optimal Control: Triglycerides < 1.7 mmol/L	257 (20.78)	107 (63.69)

Note: (n=168) patients with complete data with all the variables
-Total cholesterol= < 200mg (or < 5.172 mmol/L, LDL= <100 mg/dl or < 2.6 mmol/L, HDL=> 40 mg/dl (or 1.00 mmol/l) for men, > 50 mg/dl (or > 1.3 mmol/L) for women ,Triglyceride=<150 mg/dl (or 1.7 mmol/L).
Abbreviations: ADA: American Diabetes Association T2Dm: Type 2 Diabetes Mellitus, KFMC: King Fahd Medical City, PSH: Prince Salman Hospital, BMI: body mass index, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, LDL: Low-density lipoprotein, HDL: High-density lipoprotein.

Table 7: Optimal Control of CVD Risk Factors Between KFMC and PSH Stratified by Age and Gender

- Table A: optimal control of BP among KFMC and PSH stratified by age and gender

Optimal Control: Hypertension Diagnosis with Systolic BP < 130 and Diastolic BP < 80	KFMC		PSH		Total		P value
Female	24	(12.63%)	4	(2.11%)	28	(14.74%)	<0.0165
Male	14	(7.37%)	11	(5.79%)	25	(13.16%)	
Total	38	(20.00%)	15	(7.89%)	190	(27.89%)	

Optimal Control: Hypertension Diagnosis with SBP < 130 and DBP < 80	KFMC		PSH		Total		P value
Age: 30 - 59	25	(13.16%)	10	(5.26%)	35	(18.42%)	0.9516
Age: 60+	13	(6.84%)	5	(2.63%)	18	(9.47%)	
Total	38	(20.00%)	15	(7.89%)	190	(27.89%)	

- Table B: Optimal control of HbA1c among KFMC and PSH stratified by age and gender

Optimal Control: HbA1c < 7.0 %	KFMC		PSH		Total		P value
Female	22	(5.87%)	10	(2.67%)	32	(8.53%)	0.0210
Male	18	(4.80%)	25	(6.67%)	43	(11.47%)	
Total	40	(10.67%)	35	(9.33%)	375	(20.00%)	

Optimal Control: HbA1c < 7.0 mmol/L	KFMC		PSH		Total		P value
Age: 30 – 59	25	(6.67%)	26	(6.93%)	51	(13.60%)	0.2750
Age: 60+	15	(4.00%)	9	(2.40%)	24	(6.40%)	
Total	40	(10.67%)	35	(9.33%)	375	(20.00%)	

- Table C: optimal control of LDL level among KFMC and PSH stratified by age and gender

Optimal Control: LDL < 2.6 mmol/L	KFMC		PSH		Total		P value
Age: 30 - 59	92	(25.34%)	35	(9.64%)	127	(34.99%)	0.8336
Age: 60+	37	(10.19%)	13	(3.58%)	50	(13.77%)	
Total	129	(35.54%)	48	(13.22%)	363	(48.76%)	

Optimal Control: LDL < 2.6 mmol/L	KFMC		PSH		Total		P value
Female	75	(20.66%)	22	(6.06%)	97	(26.72%)	0.1436
Male	54	(14.88%)	26	(7.16%)	80	(22.04%)	
Total	129	(35.54%)	48	(13.22%)	363	(48.76%)	

Note: Stratification done with those only reached the optimal level; patients with diagnosed Hypertension only were used. LDL= <100 mg/dl (or < 2.6 mmol/L)
Abbreviations: CVD: Cardiovascular disease, T2DM*:* Type 2 Diabetes Mellitus, KFMC*:* King Fahd Medical City, PSH: Prince Salman Hospital, LDL: Low-density lipoprotein

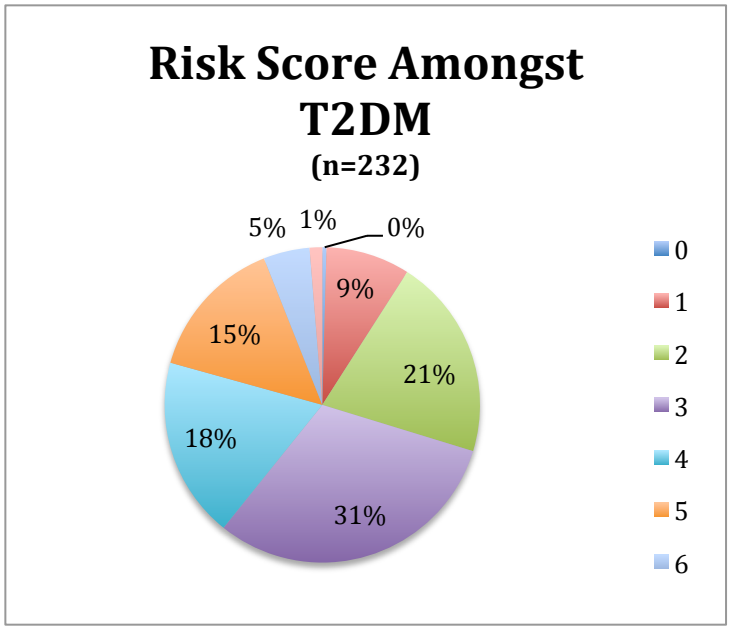
Table 8: Number of Cardiovascular Risks Among People with T2DM, n=232

Number of Positive Risk Factors		
Risk Score	**Frequency**	**Percent**
0	1	0.43
1	20	8.62
2	48	20.69
3	72	31.03
4	43	18.53
5	34	14.66
6	11	4.74
7	3	1.29

Note: The CVD risk factors was used to collect the risk score are: - HbA1c= ≥ 7%, SBP ≥ 140, DBP ≥80, Total cholesterol >200mg (or > 5.172 mmol/L, LDL= >130 mg/dl (or >3.4 mmol/L), HDL < 40 mg/dl for male and female (or < 1.00 mmol/L for male and female), Triglyceride≥ 200 mg/dl (or ≥ 2.26 mmol/L), BMI ≥30

- Zero score = to the patient having 2TDM only, score one= patients having 2TDM and one other risk factor.

Figure 2: Number of Cardiovascular Risks Among People with T2DM



Note: The CVD risk factors was used to collect the risk score are: - HbA1c= ≥ 7%, SBP ≥ 140, DBP ≥80, Total cholesterol >200mg (or > 5.172 mmol/L, LDL= >130 mg/dl (or >3.4 mmol/L), HDL < 40 mg/dl for male and female (or < 1.00 mmol/L for male and female), Triglyceride≥ 200 mg/dl (or ≥ 2.26 mmol/L), BMI ≥30

- Zero score = to the patient having 2TDM only, score one= patients having 2TDM and one other risk factor.

Table 9: Proportion of T2DM achieving combined optimal level control of CVD risk factors using the ADA.

CVD risk factors	Percentage
HbA1C and BP	(n=15) 8.93 %
A1C and LDL	(n=21) 12.50%
A1c and BP+LDL	(n=12) 7.14 %
A1C, LDL, HDL, TG and Total Cholesterol	(n=10) 5.95 %
HbA1c and BP+ All lipids	(n=6) 3.57%

Note: -using the ADA guide line, HbA1c <7, BP <130/80, LDL <100 mg/dl (or < 2.6 mmol/L), HDL=> 40 mg/dl (or 1.00 mmol/l) for male, > 50 mg/dl (or > 1.3 mmol/L) for female, Total cholesterol= < 200mg (or < 5.172 mmol/L)., Triglyceride=<150 mg/dl (or 1.7 mmol/L).Abbreviations: BP: Blood Pressure, LDL: Low-density lipoprotein, HDL: High-density lipoprotein, TG: Triglyceride, ALL lipids: LDL, HDL, Triglyceride and total Cholesterol

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