

## Type of Anti-Diabetic Treatment and Mortality Risk Factors in Type 2 Diabetics Attending Medical Out-Patient Clinic of a Teaching Hospital

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**ABSTRACT.** To study the different types of anti-diabetic treatment used in Type-2 diabetics attending King Abdulaziz University Hospital out-patient medical clinic and to determine their mortality risk factors, a random sample of 426 Type 2 diabetics was selected to participate in the study. Demographic data were collected as well as their nationality, duration of diabetes, degree of blood glucose control, type of antidiabetic treatment (oral hypoglycemic agents and their type, insulin or combined, presence of obesity, presence of hyperlipidemia, presence of hypertension, presence of ischemic heart disease, presence of renal failure, presence of stroke or transit ischemic attack, smoking (active or passive), and mortality. The mean age of the study group was 49 years with male:female ratio of 1.9:1. The mean duration of diabetes was 11 years. Oral hypoglycemic agents were the most frequently used antidiabetic treatment; 57% versus 36% insulin and 7% combined oral hypoglycaemic and insulin. Glibenclamide followed by metformin were the most common used oral hypoglycemic agents: 57% and 51%, respectively, while Repaglinide, rosiglitazone were used in 7% and 4%, respectively. On multiple regression analysis after adjustment to all factors and sex; presence of ischemic heart disease, hypertension, hyperlipidemia and poor glycaemic control were the most significant risk factors associated with mortality; O.R. 7.3, 2.07, 2.99, 2.76 (95% C.I. 2.1 -

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26.4, 1.15 - 3.71, 1.70 - 5.2, 1.1 - 6.7), and p value 0.002, 0.01, 0.001, 0.02, respectively. These are under use of new generations of oral hypoglycemic agents and insulin. Actions should be taken towards this. Free supply of medications might be of help.

**Keywords:** Oral hypoglycemic, Insulin, Type 2 diabetics, Mortality.

## Introduction

Worldwide, more than 100 million people have diabetes with the predictor this number will double over the next decade<sup>[1]</sup>. Many diabetics are not being identified sufficiently early to initiate the optimal care. At the time of the diagnosis about half of the patients with type 2 diabetes are already experiencing diabetes associated complications indicating that the disease is often present long before the patient receives a diagnosis<sup>[2]</sup>. Coronary heart disease prevalence in diabetics is at least twice that in the background population<sup>[3,4]</sup> and the life expectancy is reduced by one third from the age of diagnosis<sup>[5]</sup>. However, even those without complications at present are at increased risk of developing micro-vascular and macro-vascular complications. Poor glycemc control had been correlated with the development of these complications. Large-scale in-ventive trials have established the importance of tight glycemc control in reducing the risk of micro- and macro- vascular complications associated with diabetes<sup>[6-9]</sup>.

The aim of our work was to study the different types of anti-diabetic treatment used in type 2 diabetics attending King Abdulaziz University Hospital (KAUH) medical out-patient clinics and to determine their mortality risk factors.

The study was conducted at KAUH, a teaching hospital, which provided like other governmental hospitals and primary health care centers, medical services to the community in the western province of Saudi Arabia. Around 1,200-1,300 diabetics are seen in the medical out-patient clinics per year. Random sample of 426 type 2 diabetic patients were selected to participate in this study as they were seen regularly for follow-up at the medical out-patient clinics at KAUH during a one-year period (January, 2002 to January, 2003). Demographic data had been recorded as well as nationality, duration of diabetes, degree of blood glucose control (well control defined as Hb1c < 8%, and/or fasting blood glucose < 8 mmol/l and postprandial blood glucose < 10 mmol/l on more than one occasion), type of antidiabetic treatment (oral hypoglycemic agents(OHG) and their type, insulin or combined (OHG & insulin)), presence of obesity (defined as body mass index (BMI) > 30 kg/m<sup>2</sup>), presence of hyperlipidemia (defined as LDL-c > 2.6 and/or HDL-c < 1 mmol/l, triglyceride > 1.7 mmol/l), presence of hypertension (patient is known or had blood pressure > 140/90 mmHg on more than one occasion), presence of ischemic heart disease (defined as angina or

myocardial infarction by self report or by analysis of 12-leads electrocardiography), presence of renal failure (defined as high urea and creatinine on more than one occasion), presence of stroke or transient ischemic attack, smoking (active or passive), and mortality.

Statistical analysis was done using SPSS 10.1. Different types of statistical methods were used when appropriate. Mean  $\pm$  SD was determined for quantitative data and frequency for categorical variables. Independent *t*-test was performed in all continuous variables. Normal distribution of the data was checked before any *t*-test. Chi-square was used to analyze group difference for categorical variables. In logistic regression models, sex was adjusted for the estimation of all the independent effects of different factors on mortality. The goodness-of-fit of the logistic regression model was assessed using the test described by Hosmer and Lemeshow and adequate fit was obtained for all models used in this study. A *p* value  $< 0.05$  was considered significant.

## Results

A total of 426 type 2 diabetics were included in the study. General characteristics of this study group are shown in Table 1. Oral hypoglycemic agents (OHG) were the most frequently used antidiabetic treatment; 242 (57%) versus 153 (36%) were on human insulin and 31 (7%) on combined OHG and human insulin. Sulfonylurea was the most frequently used OHG followed by metformin and there was under use of the new generation of OHG (Table 2).

TABLE 1. Showing general characteristics of the study group.

Variables	
Age in yrs. (mean $\pm$ SD)	49.0 $\pm$ 19.4
Sex (male : female)	1.9 : 1
Nationality (Saudi : Non-Saudi)	1 : 1.5
Duration of Diabetes in yrs. (mean $\pm$ SD)	11.4 $\pm$ 7.9
Poor Glycaemic Control N (%)	345 (81)
Obesity (BMI $> 30$ kg/m <sup>2</sup> ) N (%)	107 (25)
Hypertension N (%)	187 (44)
Hyperlipidemia N (%)	153 (36)
Smoking N (%)	128 (30)
Ischemic Heart Disease N (%)	156 (37)
Renal Failure N (%)	117 (28)
Stroke N (%)	51 (12)

BMI = body mass index

**TABLE 2.** Types of oral hypoglycemic agent used\*.

Oral Hypoglycemic Agent	Total = 242 N (%)
Glibenclamide	139 (57)
Glipizide	15 (6)
Glimepiride	33 (14)
Gliclazide	73 (30)
Metformin	124 (51)
Repaglinide	17 (7)
Acarbose	15 (6)
Rosiglitazone	10 (4)

\*More than one agent can be used by one patient.

No significant relation was found between the use of different antidiabetic treatment and sex of degree of blood glucose control; however, non-Saudis were more significantly using OHG than insulin were significantly younger in age compared to those on OHG. Patients with ischemic heart disease were less likely to be on insulin compared to those without ischemic heart disease and patients with renal failure were less frequently treated with OHG compared to those without renal failure (Table 3). mortality was reported in 57 (13%). On multiple regression analysis after adjusting to all factors and sex; presence of IHD, poor glycemic control, high blood pressure and hyperlipidemias were risk factors for high mortality (Table 4). We didn't study the effect of each OHG agent on mortality as it is beyond the scope of our aim, but there was no significant relation between mortality and antidiabetic treatment with OHG or insulin.

**TABLE 3.** Relation of antidiabetic treatment to different variables.

Variables	OHG Total No. = 242	Insulin Total No. = 153	P Value
Age in years (mean ± SD)	59.5 ± 13.2	49.9 ± 10.5	0.03
Sex (%)			
Male	55	39	0.40
Female	52	38	
Nationality (%)			
Saudi	46	46	0.03
Non-Saudi	60	34	
Duration Diabetes in Years (mean ± SD)	9.8 ± 7.2	12.5 ± 8.1	0.10
Glucose Control (%)			
Poor	56	75	0.10
Well	44	48	

TABLE 3. Contd.

Variables	OHG Total No. = 242	Insulin Total No. = 153	P Value
Ischemic Heart Disease N (%)			
Yes	59	31	0.01
No	51	44	
Renal Failure N (%)			
Yes	48	48	0.05
No	56	36	

OHG = oral hypoglycemic agents

TABLE 4. Multiple logistic regression of mortality with different variables after sex adjustment.

Variables	Mortality N = 57		
	O.R.	95% C.I.	P
Ischemic Heart Disease	7.30	2.10 - 26.40	0.002
Hypertension	2.07	1.15 - 3.71	0.01
Hyperlipidemia	2.99	1.70 - 5.20	0.001
Obesity	1.50	0.80 - 2.83	0.2
Smoking	0.49	0.10 - 1.20	0.1
Renal Failure	0.59	0.20 - 1.40	0.2
Stroke	0.42	0.10 - 1.30	0.1
Poor Glycemic Control	2.76	1.10 - 6.70	0.02
Oral Hypoglycemic Agents	0.01	0.01 - 1.10	0.7
Insulin	0.01	0.01 - 1.30	0.6

## Discussion

The overall goal of treating patients with diabetes is to achieve blood glucose level as low as possible without increasing the risk of hypoglycemia in order to decrease the frequency of complications. The American Diabetes Association (ADA) recommend therapeutic goal of  $< 7.2$  mmol/l for fasting blood glucose and  $< 7\%$  for HbA1c<sup>[10]</sup>. Several studies suggest that postprandial blood glucose excursion is an important determinant of HbA1c and may better predict overall glycemic control and the risk of micro-vascular and macro-vascular complications than do fasting blood glucose<sup>[11-13]</sup>.

Major clinical trials have shown that intensive treatment significantly reduces the risk of complications associated with type 2 diabetes such as cardiovascular disease, retinopathy, neuropathy and nephropathy<sup>[7,8]</sup>. People with type 2 di-

abetes usually demonstrate both insulin resistance and deficient insulin secretion. The insulin resistance usually manifested by over production of glucose by the liver, impaired ability to deposit glucose in the muscle and increase breakdown of fat leading to high level of free fatty acid<sup>[14,15]</sup>.

Treatment of diabetic patients is complex because of the progressive nature of the disease and the multifaceted physiological defects<sup>[14]</sup>. The availability of different types of antidiabetic treatment will offer physicians and patients with more options for achieving glycemic control and allow treatment to be tailored to the individual needs of each patient.

Five distinctive oral hypoglycemic drugs are available for treatment of type 2 diabetics in addition to insulin. Sulfonylurea is one of the two classes of insulin secretagogues. They have been available for a long time; between 1970 and 1995. they were only oral antidiabetic agents available in the United States. Generally, they are the most commonly used, which also was noticed in our study. Sulfonylurea increases insulin secretion regardless of level of the circulating blood glucose and it has no effect on blood pressure or lipid<sup>[16]</sup>. Glibenclamide, glipizide, glimepiride are examples of them. Although many patients achieve adequate glycemic control using such drugs, around 30% have a poor response and in the remaining 70% the subsequent failure is 4-5% per year<sup>[17]</sup>.

An early prospective studies which examined the effect of glycemic control with various agents on coronary heart disease showed excess cardiovascular mortality in the group receiving Sulfonylurea due to inhibition of ATP-sensitive potassium channels in the heart<sup>[18]</sup>. Most recently glimepiride (new generation of Sulfonylurea) appear to be safe as it maintains myocardial preconditioning due to some differences in it's pharmacodynamics<sup>[19-20]</sup>. The second insulin secretagogue (non-sulfonylurea) is the meglitinides group, which includes repaglinide and nateglinide. It binds to a different site on the beta cell than do Sulfonylurea<sup>[21]</sup>. It has short onset and duration of action. It's short half-life makes it suitable for use in older patients with impaired renal function<sup>[22]</sup>. It acts mainly on the postprandial blood glucose. Alpha-glucosidase inhibitors including acarbose and miglitol, these agents slow the rate of carbohydrate absorption and reduce postprandial blood glucose<sup>[15]</sup>.

Several long-term trials have also reported a decrease in fasting blood glucose and HBA1c<sup>[23-26]</sup>. Reports had shown a lower rate of cardiovascular disease and all-cause mortality with the use of meglitinide and alpha-glucosidase inhibitors due to their effect on postprandial hyperglycemia<sup>[27]</sup>. The second class of OHG is the insulin sensitizer; including biguanide and glitazone group. Metformin (from the biguanide group) is the second most commonly prescribed OHG in Europe where it is taken on monotherapy in 40% of patients<sup>[28]</sup>.

Our study also showed that it is the second most commonly used in our patients after Sulfonylurea. It reduces endogenous glucose output by improving hepatic insulin sensitivity. It also improves insulin sensitivity in peripheral tissues<sup>[29,30]</sup>. Outcome studies suggest that metformin may prevent cardiovascular disease<sup>[29]</sup>. The UKPDS, demonstrated a significant reduction in diabetes-related mortality and myocardial infarction as a result of associated beneficial changes in lipids, blood pressure, procoagulant factors and body weight<sup>[7,8,29]</sup>. Glitazone group is new insulin sensitizer; rosiglitazone and pioglitazone are examples of them. They target insulin resistance which is thought to play a central role in type 2 diabetes and the associated metabolic syndrome, (characterized by central obesity, hypertension, dyslipidemia, and hypercoagulability), all leading to increased cardiovascular morbidity and mortality. As a result the glitazone group have the potential to improve other conditions associated with the metabolic syndrome in addition to their glycemic action<sup>[31]</sup>.

Review of 20 therapeutic trials published in the year 1997-1999 that evaluate the new insulin sensitizer; glitazone group (rosiglitazone and pioglitazone) and new insulin secretagogue; meglitinide group (repaglinide), showed that they have been appropriate for both mono and combined therapy and have comparable blood glucose potential to older antidiabetic drugs<sup>[32]</sup>.

Since 1920, insulin has been the mainstay of treatment for type-1 diabetes. It has been used more and more in type 2 diabetics for more aggressive strategy to achieve glycemic control. The recent introduction of insulin analogues (insulin lispro, insulin aspart, and insulin glargine) provided better physiological events than human insulin<sup>[33-35]</sup>. There is under use of insulin in our patients either alone or in combination with OHG and there are a high proportion of poorly controlled diabetics who might be helped by the addition of insulin to their treatment. It is well known that ischemic heart disease is the major cause of death in patients with diabetes<sup>[36]</sup>, which is in agreement with our findings. Direct intervention targeted at the metabolic disorder in ischemic heart disease has only been investigated in the DIGAMI study. Where glucose/insulin treatment followed by long-term treatment with insulin was compared to conventional treatment. The mortality was lower in the insulin treated group after one to four years of follow-up<sup>[37]</sup>.

We conclude that most of our patients are using OHG - glibenclamide and metformin were the most commonly used. There is under use of the new agents like meglitinide and glitazone group and insulin in spite of their reported benefit. This could be related to either to the lack of physician's knowledge about their benefit or due to their cost. The hospital of the study is a government hospital which provides care to a certain sector of the population, most of them can't afford buying expensive medications and they may be using more than

one medication. One of the major challenges in diabetes treatment is to ensure adequate resources to allow optimization of treatment for the increasing number of diabetic patients so free supply of medications may be of help.

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## نوع العقاقير المستخدمة لعلاج مرض السكري والعوامل المؤثرة على الوفاة لدى مرضى السكري في النوع الثاني الذين يراجعون عيادة الباطنة في مستشفى تعليمي

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المستخلص. تهدف الدراسة إلى معرفة نوع العقاقير المستخدمة لعلاج مرض السكري والعوامل المؤثرة على الوفاة لدى مرضى السكري النوع الثاني، الذين يراجعون في العيادة الباطنية في مستشفى جامعة الملك عبد العزيز. تمت دراسة ٤٢٦ مريضاً مصاباً بالسكري من النوع الثاني الذين يراجعون عيادة الباطنية في الفترة بين يناير ٢٠٠٢ ويناير ٢٠٠٣، وتدوين المعلومات التالية: مدة الإصابة بمرض السكري، معدل انتظام السكر في الدم، نوع علاج السكري المستخدم (حبوب، أنسولين، أو حبوب وأنسولين)، ووجود السمنة، وارتفاع ضغط الدم، وارتفاع الدهون في الدم، ووجود قصور شرايين القلب، وفشل كلوي، وسكتة دماغية، ونسبة التدخين، والوفاة. كان متوسط العمر في العينة التي تمت دراستها ٤٩ سنة وكانت نسبة الذكور والإناث ٩، ١ : ١. أما متوسط مدة الإصابة بمرض السكري فكانت ١١ سنة. الحبوب كانت أكثر استخداماً من الأنسولين وكانت النسبة ٥٧٪ إلى ٣٦٪ وقد وجد أن ٧٪ استخدموا الحبوب والأنسولين. الجليبينكلاميد والميتفورمين كانت أكثر أنواع الحبوب استخداماً. وقد وجد أن وجود قصور في شرايين القلب، وارتفاع ضغط الدم، والدهون في الدم، وعدم انتظام السكر في الدم، من العوامل الخطرة التي تزيد نسبة الوفاة. أظهرت الدراسة قلة استخدام أنواع العقاقير الحديثة والأنسولين في علاج مرض السكري. وأن إمكانية توفير العلاج بالمجان قد يساعد في حل المشكلة.