

Anti-diabetics and glycemc control among type 2 Diabetic patients in out-patients clinics

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Abstract

The present study evaluates the anti-diabetics and glycemc control of type 2 diabetic patients attending the out-patients clinics Aden. It is a cross-sectional study carried out in Aden Diabetic Center at Al-Gamhouria General Modern Hospital, Aden. Thirty two type-2-patients attended the center during the period from 15 January to 15 February 2018, using anti-diabetic drugs for more than one year, were included. Data were collected through direct interviews using a structured questionnaire, including patients characteristics as well as medical and medications characteristics. Blood samples were drawn to measure glycated hemoglobin HbA1c. Data were analyzed by using SPSS. (Version 22). Thirty seven and a half percent were females and 62.5% males. The mean age of the participants was 55 ± 8.23 years. 56.2% of the patients showed good adherence to the exercise with the preponderance to the males, $p=0.043$. The mean BMI of the participants was 26.62 ± 3.89 Kg/m², with half of them considered overweight (25-29.9 Kg/m²), while almost one fifth of the samples were obese. Half of the patients had hypertension and high cholesterol as comorbid conditions. The most frequent antidiabetic classes utilized by the patients were sulfonylureas, 62.5% and biguanides 62.5%. There was a limited use of DPP-4 inhibitors, sitagliptin and alogliptin (6.2%). 53.1% of the studied patients utilized monotherapy, followed by a combination of oral antidiabetics 37.55%, and a combination of oral antidiabetics and insulin (9.3%). The mean value of HbA1c of the samples studied was $9.65 \pm 2.33\%$. Only 12.5% of the patients had good glycemc control and 87.5% of the participants had HbA1c of $\geq 7\%$. Almost forty percent of the patients with HbA1c $\geq 7\%$ had cardiovascular diseases such as hypertension and higher cholesterol ($p=0.019$). In conclusion, the most frequent antidiabetic classes utilized by type-2-patients who attended outpatients clinics were sulfonylureas and biguanides with a tendency to use combination regimens. The majority of patients had poor glycemc control associated with cardiovascular morbidity. Attention should be given on the treatment regimens and dosage.

Key words: Type 2 diabetes, Morbidity, Anti-diabetic drugs, Glycemc control

Introduction

Type-2-diabetes mellitus (type 2DM) is known as non-insulin dependent diabetes mellitus that is primarily associated with insulin secretory defects and/or insulin actions.⁵

Treatment of type-2-diabetes has witnessed a change due to deep understanding of its pathophysiology and introduction of new drugs. Many classes of antidiabetic agents have been emerged that expand the spectrum for medication selection. The indicator for the optimal treatment and proper blood glucose level is the glycosylated hemoglobin, called hemoglobin A1C (HbA1c), because it provides the most objective and reliable information about long-term glucose control (the level of the previous three months) in diabetic patients.^{21,28}

The American Diabetes Association (ADA) considered glycemc control as one of the important strategies for the management of DM, and determined HbA1c as the best measure of glycemc control to prevent the complications and to reduce mortality. HbA1c level less than 7% was taken as a goal of optimal blood glucose control.⁶

Treatment of type 2DM, based on assessment of HbA1c, is essential to reduce micro- and macro-complications and to improve the quality of life. Challenges have been done in many clinics and centers, including our local clinics, to bring about the diabetic patient to optimal glycemie status. A growing body of evidence has shown the benefit of intensive diabetes management in reducing diabetic complications, nevertheless, a high rate of patients remain poorly controlled. ^{4, 15, 16, 18, 22}

Studies have addressed the determinants to achieve good glycemie control such as adherence to controlled diet, exercise, medications, weight reduction, self-blood glucose monitoring and regular follow-up with health care providers. ^{2,7}

The present study aims at describing the medications (antidiabetic agents and drugs for comorbidities) and the present status of glycemie control including factors affecting its achievement among type2 diabetic patients attended outpatients clinics in Aden.

Treatment of type 2 diabetes represents a challenge for the endocrinologists, including local doctors. Development of new anti-diabetic drugs extends the field of medication selection. Therefore, analyzing of the medications used and the evaluation of glycemie control may help understanding how effective are the drugs prescribed and how good is their practice and patients adherence. This study is done to get a social benefit too. The data of this study might be helpful in diabetic field.

Patients and methods

This is a cross-sectional study carried out in Aden Diabetic center at Al-Gamhouria General Modern Hospital, Aden, in the period from 15 January to 15 February 2018. The study was approved by the Medical Ethics Committee, University of Aden. Inclusion criteria for participation: 1-Known type 2 diabetic patients 2- aged more than 20 years and 3- using anti-diabetic drugs for more than one year and 4- accepted to participate in the study were included in the study. Exclusion criteria: Pregnant and lactating mothers, type 2 diabetic patients that could not perform the interview or who are treated for less than one year were excluded from the study.

32 male and female diabetic patients met the inclusion criteria who gave informed verbal consents were enrolled in the study. Venous blood was immediately drawn in non-fasting state and measured. All blood samples were measured by Cobas CIII- Roch diagnostic (a full automatic machine) at the center. The blood glucose level was measured with the glycosylated hemoglobin assay. Then patients were interviewed using a structured questionnaire including patients, medical and medications characteristics.

Analysis of data was performed by using SPSS. (Version 22). Mean and standard deviation, percentages and Chi-square for nominal variables were applied. P-value ≤ 0.05 was taken as significant. Ethical consideration: The interview with participants was conducted only after obtaining the verbal informed consent from each participant. For ethical purposes, every participant in the study was given sufficient information about the study objectives, the content of the questionnaire as well as the confidentiality of the information and was informed that their data will be used for research purpose only.

Results

1. Patients characteristics:

In the present study, the total diabetic patients were thirty two. 37.5% were females and 62.5% males. The mean age of the participants was 55 ± 8.23 years and the majority of them were in the age group 40-60 years, educated (62.5%), married (93.8%), nonsmokers (87.5%), and adhered to diet (50%), medication (87.5%) and exercise (56%), Table 1. The mean BMI of the participants was 26.62 ± 3.89 Kg/m² with half of them considered overweight (25-29.9 Kg/m²), while almost one fifth of the samples were obese.

Table 1: Characteristics of type 2 diabetic patients

	Frequency	%	n=32
Gender			
Male	20	62.5	
Female	12	37.5	
Mean age Mean ± SD (yrs.)	55 ±8.23		
Age groups (yrs.)			
40-50	11	34.4	
51-60	13	40.6	
61-70	08	25.0	
Education status:			
Educated	20	62.5	
Uneducated	12	37.5	
Marital status			
Married	30	93.8	
Widow	02	06.3	
Duration of diabetes (y) Mean ± SD	9.83±6.56		
Interval of diabetic duration (yrs.)			
1-8	16	50.0	
9-17	11	34.4	
18-26	05	15.6	

Table 2 shows the level of adherence of type 2 patients to the exercise. 56.2% of the patients showed good adherence to the exercise with the preponderance to the males. The difference is statistically significant.

Table 2: Adherence of participants to exercise

	Gender		Total	P value
	Male	Female		
Yes	14	4	18	0.043
% of Total	43.8%	12.5%	56.2%	
No	6	8	14	
% of Total	18.8%	25.0%	43.8%	
% of Total	62.5%	37.5%	100.0%	

Chi-Square Test

2. Medical characteristics:

Figure 1 illustrates that 90.6% of the participants reported the classic signs and symptoms of type 2 diabetes, while 9.4% did not experience them.

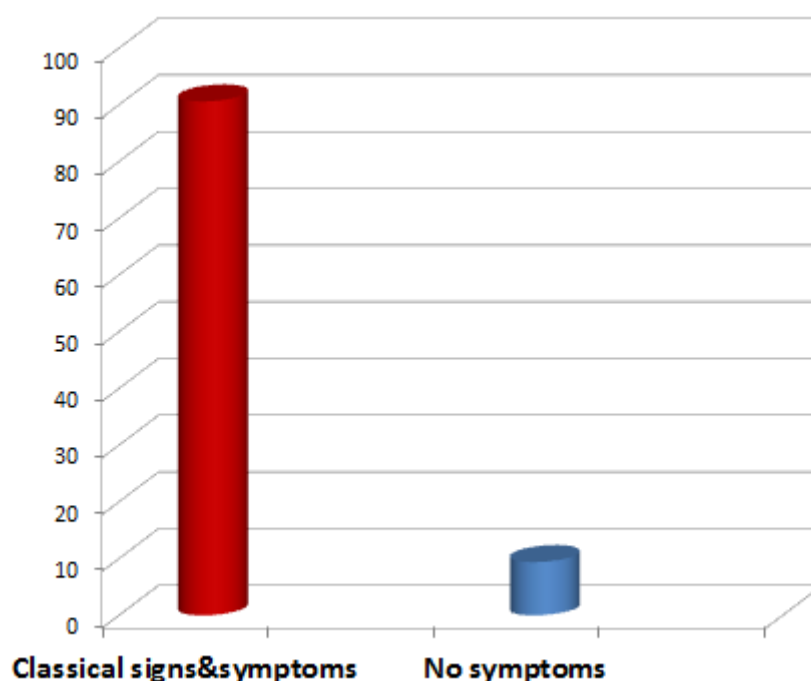


Figure 1: Classical signs and symptoms of diabetic patients

Figure 2 shows comorbid conditions accompanying diabetes patients. Half of the patients have hypertension and high cholesterol (50%) as comorbid conditions, while 37.5% of the patients without accompanying diseases. The rest showed anemia, heart failure and kidney diseases (12.5%), Figure 2.

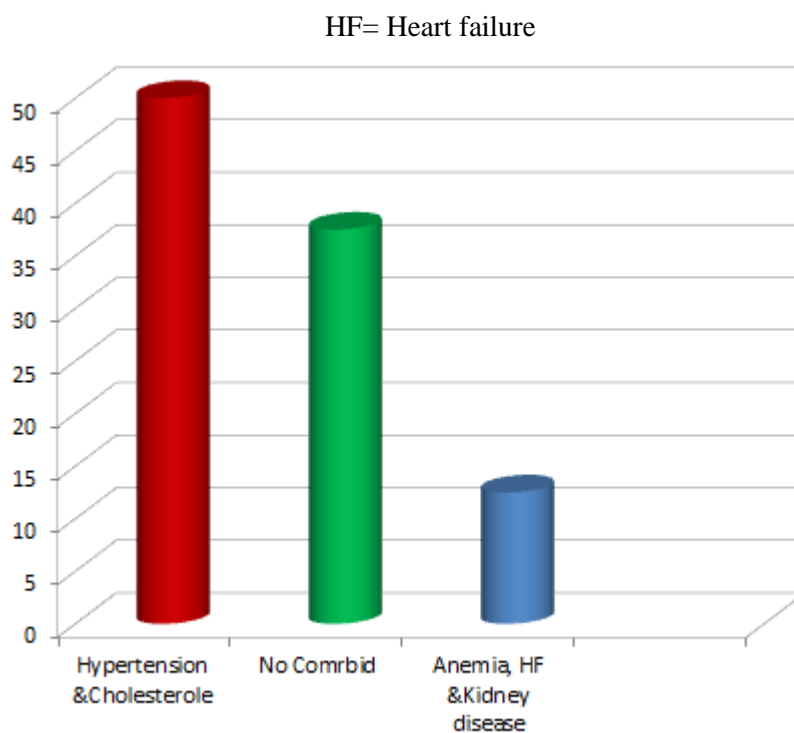


Figure 2: Comorbid conditions accompanying diabetes patients

Table 3: Distribution of anti-diabetic classes utilized by the patients related to gender

N=32	Gender		Total
	Male	Female	
Sulfonylureas	5	3	8
% of Total	15.6%	9.4%	25.0%
Biguanides	4	1	5
% of Total	12.5%	3.1%	15.6%
FDC-metformin +DPP-4 inhibitors	1	0	1
% of Total	3.1%	0.0%	3.1%
FDC-sulfonylureas + biguanides	4	4	8
% of Total	12.5%	12.5%	25.0%
Insulin	2	2	4
% of Total	6.3%	6.3%	12.5%
Biguanides and sulfonylureas	1	2	3
% of Total	3.1%	6.3%	9.4%
Insulin and FDC-sulfonylureas +biguanides	1	0	1
% of Total	3.1%	0.0%	3.1%
Insulin and FDC-Metformin+Alogliptin	1	0	1
% of Total	3.1%	0.0%	3.1%
Insulin and biguanides	1	0	1
% of Total	3.1%	0.0%	3.1%
Total	20	12	32
% of Total	62.5%	37.5%	100.0%

Chi square test P= 0.667

3. Medications characteristics:

Table 3 shows the distribution of anti-diabetic classes utilized by the patients related to gender. The most frequent antidiabetic classes, utilized by the patients, were sulfonylureas (either alone or in combinations), 62.5%, and biguanides 62.5%, followed by insulin 21.8% Table 3. There is a limited use of DPP-4 inhibitors, Sitagliptin and Alogliptin (6.2%). 53.1% of the studied patients utilized monotherapy, followed by a combination of oral antidiabetics (37.55%) and a combination of oral antidiabetics and insulin (9.3%) . Metformin is prescribed for 62.5% of the studied patients.

Figure 3 displays the percentage of oral hypoglycemic agents and insulin utilized by the type 2 diabetic patients. The participants utilized 38 anti-diabetic preparations with an average of 1.2 anti-diabetics per patient. Out of 38 anti-diabetic preparations utilized, 18.4 % were insulin and 81.6 % were oral hypoglycemic preparations.

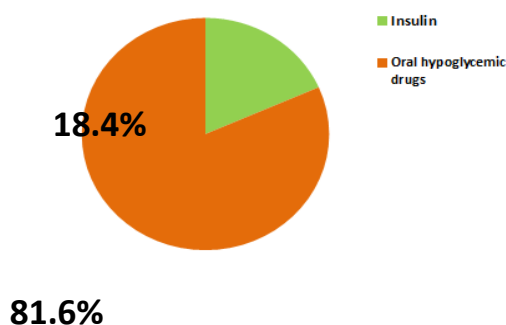


Figure 3: Percentage of oral hypoglycemic and insulin utilized by diabetic patients

Table 4 displays the total drugs utilized by the participants. In the present study, the total number of antidiabetics and drugs for comorbidity was 85. Out of them, **44.7%** were antidiabetic drugs and **55.3 %** were drugs for comorbid conditions. The most frequent drugs utilized for comorbidity were antihypertensives and hypolipoproteinemic drugs. (Table 4).

Table 4: Total drugs utilized by the participants

n=85		Frequency	No of drugs	Percentage*
Antidiabetics n= 38 (44.7%)				
<i>Sulfonylureas</i>		08		21.1
	Glibenclimide		2	
	Gliclazide		2	
	Glimberide		4	
<i>Biguanides</i>		05		13.2
	Metformin		5	
<i>Fixed dose combinations</i>		09		23.7
	Metformin+Glibenclimide		7	
	Metformin+Gliclazide		1	
	Metformin+Sitagliptin		1	
<i>Two drugs combinations</i>		12		31.6
	Metformin &Glimibride		4	
	Metformin & Dliclazide		2	
	Insulin & Metformin		2	
	Insulin& FDC- Metformin+Alogliptin		2	
	Insulin& FDC-Metformin+Glibenclimide		2	
<i>Insulin</i>		04		10.5
Drugs for comorbidity n= 47 (55.3%)				
<i>Cardiovascular drugs</i>		33		70.21
	Lisinopril		5	
	Ramipril		1	
	Enalapril		1	
	Candesartan		1	
	Amlodipine		3	
	Bisoprolol		4	
	Isosorbide dinitrate		2	
	Furosemide+spironolactone		1	
	Atorvastatine		9	
	Rosuvstatine		1	
	Aspirin		5	
<i>Others</i>		14		29.79
	Folic acid		3	
	Neuropion		5	
	Methylcoalamine+alpha-lipoic acid		4	
	B-complex vitamin		1	
	Herbal remedy		1	

*= percentage of the group

4. Outcomes of the therapy:

Table 5 illustrates the levels of HbA1c by gender. The mean value of HbA1c of the samples studied was **9.65 ±2.33%**. Twelve and half percent of the patients had good glycemc control and **87.5%** of the participants showed HbA1c levels of $\geq 7\%$. Two thirds of patients (75%) showed HbA1c values more than 8% with the preponderance to the males (Table 5).

Table 5: Groups HbA1c by gender

			Gender		Total
			male	Female	
Groups HbA1c	less than 7%	Count	3	1	4
		% of Total	9.4%	3.1%	12.5%
	7.-7.4%	Count	2	0	2
		% of Total	6.3%	0.0%	6.3%
	7.5-8%	Count	2	0	2
		% of Total	6.3%	0.0%	6.3%
	more than 8%	Count	13	11	24
		% of Total	40.6%	34.4%	75.0%
Total	Count	20	12	32	
	% of Total	62.5%	37.5%	100.0%	

Chi –square test P=0.337

Table 6: Factors associated with levels of HbA1c

n=32	< 7%		≥7%		p
	Frequency	%	Frequency	%	
Family history of DM					
Yes	1	3.1	18	56.3	0.171
No	3	9.4	10	31.3	
Adherence to medication					
Yes	4	12.5	24	75.0	0.569
No	0	00	04	12.5	
Adherence to diet					
Yes	3	9.4	13	40.6	0.300
No	1	3.1	15	46.9	
Adherence to exercise					
Yes	3	9.4	15	46.9	0.403
No	1	3.1	13	40.6	
Body mass index					
18.5-24.9	1	3.1	10	31.3	0.627
25-29.9	3	9.4	12	37.5	
30-34.9	0	0.0	05	15.6	
≥35	0	0.0	01	3.1	
Smoking					
Yes	0	0.0	4	12.5	0.569
No	4	12.5	24	75.0	
Diabetic duration intervals					
1- 8 y	3	9.4	13	40.6	0.301
9-17	0	0.0	11	34.4	
18-26	1	3.1	04	12.5	

Comorbidities	3	9.4	13	40.6	0.019
Cardiovascular diseases	1	3.1	02	06.3	
Kidney disease	0	0.0	01	03.1	
Anemia	0	0.0	12	37.5	
No comorbidity					
Reported improvement	4	12.5	19	59.4	0.246
Yes	0	0.0	09	28.1	
No					

Chi –square test

Table 6 shows the factors associated with levels of HbA1c. Half of the patients with higher HbA1c had family history of DM, adhered to exercise and were overweight /obese, while two thirds were adhered to medications and one quarter were smokers (Table 6). 40.6% of the patients with HbA1c $\geq 7\%$ had cardiovascular diseases such as hypertension and dyslipidemia which is statistically significant , p=0.019.

Discussion

The present study is designed to evaluate the utilization of antidiabetic medications for th treatment of patients with type 2 DM and the glycemie control. The results revealed that the most frequent antidiabetic classes, utilized by type 2 patients, were Sulfonylureas and Biguanides (either alone or in combination), followed by Insulin. This finding is dissimilar to the study of Moradi and Mousavi in which Metformin is the most prescribed antidiabetic agent, followed by Sulfonylurea²⁰, and Oestgren et al in which the higher utilization of antidiabetics was Metformin (58.5%), followed by Sulfonylurea (31.3%).²³ In our study, there is a limited utilization of DPP-4 inhibitors(6%) which is higher than that found by Oestgren et al (0.1%). This might be due to a small sample size.

Combinations of Metformin and Insulin secretagogues can reduce HbA1c between 1.5% to 2.2% in patients sub-optimally controlled by life style modification.⁹ Moreover, the combination of Metformin and DPP-4 inhibitors can achieve adequate glycemie control²⁵ because, first DPP-4 inhibitors prolong the duration of endogenous active glucagon-like peptide 1 (GLP-1) by inhibiting DPP-4 peptidase leading to enhancement of insulin secretion as a physiological response to feeding and second Metformin also increases GLP-1 levels leading to reduction of food intake and weight loss.¹⁹ In this study, combination regimens of Metformin and Sulfonylureas, or DPP-4 inhibitors (Sitagliptin and Alogliptin), were utilized by almost half of the studied patients. This tendency towards using combination patterns has been also reported by Moradi and Mousavi.²⁰ Studies on the combinations of Metformin and Sitagliptin¹¹ or Metformin and Alogliptin³² revealed improvement in glycemie control but there is not statistically significant differences in rates of major cardiovascular events between treatment and placebo groups. Furthermore, the U.S. Food and Drug Administration (FDA) warned that Saxagliptin and Alogliptin may increase the risk for heart failure, especially in patients with preexisting heart failure or renal impairment.³¹

Glycated hemoglobin which is known as hemoglobin A1c, HbA1c, or A1C is an accurate and objective measure to assess glycemie control and to diagnose new cases of diabetes.²⁹ Increment in its values is indicative of uncontrolled blood glucose levels and of excessive formation of glycation products that result in diabetic complications.^{1, 10, 12} Measuring of HbA1c is not a routine regimen in our local clinics; but, nowadays, a tendency to use it is noted. The mean value of HbA1c of the samples studied was **9.65% \pm 2.33%**. This is more than that found by Ahmed et al who reported the mean of HbA1c about 8.04%.² In addition, 23.0% of their study samples showed good glycemie control, and this is almost double than that found in the present study (12.5%). Moreover, our finding is almost similar to Fikree et al, 2006 from Bahrain in which 11.2% of the participants had good glycemie control.⁸

In the present study, the majority of the studied diabetic patients showed poor glycemc control with HbA1c more than 7%. This outcome was comparable to those obtained in the study of Samara et al²⁶ and Kassahun et al¹⁴ in which two thirds of the participants showed poor blood glucose control. Our finding is also consistent with the studies of Nouredine et al²² and Radwan et al²⁴ in which four fifths of the participants had poor glycemc control with a mean HbA1c of 8.97±2.02%. On the other hand, this finding is different from that reported by Islam from Bangladesh in which only 16.7% of the samples had poor glycemc control.¹³

In this study, the factors associated with higher HbA1c values were family history of diabetes, higher BMI (overweight and obesity), comorbidity like hypertension and high cholesterol (p=0.019), and non-adherence to diet. Concerning age and duration of diabetes, there is no characteristic relation with higher HbA1c values. Conflicting results on factors associated with poor glycemc control have been reported in different studies. This may be explained by the differences in study designs, characteristics of the study populations such as race and ethnicity, dosage for oral medications or insulin, compliance with regimens and the types of treatment facilities.³

It is surprising to find that the majority of the patients who adhere to medications and who do not smoke had uncontrolled blood glucose levels. In addition, the patients showed good adherence to the exercises with the preponderance to males. Although these patients reported improvement in signs and symptoms after the treatment, their measured blood levels showed HbA1c values higher than 7%. In spite of the expansion of antidiabetic agents and well-defined treatment for type 2 diabetes, the majority of the patients are poorly controlled. In this study, inappropriate treatment (may include not reaching to maximum tolerated daily dose or higher cost of the indicative drug) and comorbid conditions might also stand behind this higher figure of poorly controlled patients.

In a meta-analysis, it has been shown that elderly patients (> 60 years), being males or patients having normal BMI had better control on diabetes, while younger diabetics did not care about the disease control.²⁷ In contrast to this, in this study, elderly people and being male patients were frequent with uncontrolled diabetes.

Limitation: The total number of the diabetic patients was lower because of the higher cost of glycated hemoglobin measuring and therefore, the sample size was small.

In conclusion, the most frequent antidiabetic classes utilized by type 2 patients attending outpatient's clinics were Sulfonylurea and Biguanides, with a tendency to use combination regimens. The majority of patients had poor glycemc control that is associated with cardiovascular morbidity. Attention should be given on the treatment regimens and dosage.

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عقاقير لعلاج مرض السكري وضبط السكر في الدم لمرضى السكري من النوع الثاني

في عيادات خارجيه للمرضى

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الملخص

تهدف الدراسة إلى تقييم أدوية علاج السكري ومستوى ضبط السكر في الدم لمرضى السكري النوع الثاني الذين يترددون على عيادات المرضى الخارجيين. هذه دراسة مقطعية أجريت في عيادات المرضى الخارجيين ومركز (السكري عدن) في هيئة مستشفى الجمهورية العام، عدن، خلال الفترة من 15 كانون الثاني/يناير إلى 15 فبراير 2018. تم جمع البيانات من خلال المقابلات المباشرة لعدد 32 من المرضى باستخدام استبيان منظم يتضمن خصائص المرض والأدوية. وقد أخذت عينات الدم لقياس نسبة السكر التراكمي في الدم HbA1c. تم تحليل البيانات باستخدام SPSS (إصدار 22). وأظهرت النتائج أن 53.5% في المائة كانوا من الإناث و 62.5 في المائة من الذكور. وكان متوسط عمر المشاركين 55 ± 8.23 سنة. 56.2 في المائة من المرضى الذين أظهروا التمسك بممارسة جيدة للرياضة مع الرجحان للذكور، ($p = 0.043$). كان متوسط BMI للمشاركين 26.62 ± 3.89 كجم/م² وأظهر نصفهم زيادة في الوزن، في حين أن قرابة خمس العينة كانوا يعانون من السمنة المفرطة (BMI يساوي أو أكثر من 30 كجم/م²). نصف المرضى يعانون من ارتفاع ضغط الدم وارتفاع نسبة الكوليسترول في الدم (50%، 16/32). الأدوية الأكثر شيوعاً التي يستخدمها المرضى كانت السلفونيل يوريا 62.5% والبيجوانايدز 62.5%. هناك استخدام محدود لمثبطات DPP-4، سيتاجليبتين والوجلبيبتين، 6.2%. 53.1% من المرضى استخدموا العلاجات الأحادية، متبوعاً بأدوية ممزوجة من مضادات السكري عن طريق الفم 37.55، ويليهما الأدوية الممزوجة عن طريق الفم مع الأنسولين 9.3 في المائة. وكان متوسط قيمة HbA1c في عينة الدراسة 9.65 ± 2.33 %. 12.5 في المائة فقط من المرضى الذين أظهروا تحكماً جيداً في نسبة السكر في الدم. 87.5 من المرضى لديهم HbA1c يساوي أو أكثر من 7%. تقريباً 40.6 في المائة من المرضى ذوي ($HbA1c \geq 7\%$) لديهم أمراض القلب والأوعية الدموية مثل ارتفاع ضغط الدم وارتفاع نسبة الكوليسترول في الدم ($p = 0,019$). تستنتج الدراسة ان مضادات السكري سولفونيل يوريا و البيجوانايدز هي الأكثر شيوعاً واستخداماً لمرضى السكري من النوع الثاني في عيادات المرضى الخارجيين مع ميل إلى استخدام العلاجات المركبة. الغالبية العظمى من المرضى لديهم عدم انضباط في نسبة مستوى السكر في الدم ومرتبطين بأمراض القلب والأوعية الدموية. ينبغي إيلاء الاهتمام بالأنظمة العلاجية والجرعات.

الكلمات المفتاحية: مرض السكري نوع 2، الاعتلال، أدوية السكري، مراقبة نسبة السكر في الدم.