# CLINICAL PROFILE OF PATIENTS CARED FOR TYPE 2 DIABETES IN A REVERSION PROGRAM

PERFIL CLÍNICO DE PACIENTES ATENDIDOS CON DIABETES MELLITUS TIPO 2 EN UN PROGRAMA DE REVERSIÓN

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#### **ABSTRACT**

Diabetes is a chronic disease, where the pancreas does not produce enough insulin or is not used effectively, when not controlled, it can damage many organs. The objective was to describe the clinical profile of patients diagnosed with type 2 diabetes mellitus. We conducted a descriptive, observational, retrospective study between January and December 2019 in the area of consultation specialized in Integral Medicine IPS (Cartagena, Colombia). Of the 23 patients studied, 47.8% were women and 52% were men. 39.1% of the population were between 50 and 59 years old, and 26.1% were overweight. It is concluded that, most diabetic patients have a good control of their disease. However, they have a high comorbidity and a high risk of Chronic Renal Disease and a high percentage of patients whose life expectancy does not exceed 10 years, according to the Charlson Index.

Key words: Diabetes Mellitus Type 2; Comorbidity; Risk Factors; Glycated Hemoglobin A (HbA1c) (source: MeSH NLM).

### **RESUMEN**

La diabetes es una enfermedad crónica, donde el páncreas no produce insulina suficiente o no es utilizado eficazmente, cuando no se controla, puede dañar muchos órganos. El objetivo fue describir el perfil clínico de los pacientes diagnosticados con diabetes mellitus tipo 2. Realizamos un estudio descriptivo, observacional, retrospectivo, entre enero y diciembre del 2019 en el área de consulta especializada en Medicina Integral IPS (Cartagena, Colombia). De los 23 pacientes estudiados, el 47,8% era mujeres y el 52,1% hombres. El 39,1% de la población tenían una edad comprendida entre 50-59 años, y el 26% presentaban sobrepeso. Se concluye que, la mayoría de los pacientes diabéticos tienen un buen control de su enfermedad. Sin embargo, presentan una alta comorbilidad y un elevado riesgo de Enfermedad Renal Crónica y un alto porcentaje de pacientes cuya expectativa de vida no supera los 10 años, según el Índice de Charlson.

Palabras clave: Diabetes Mellitus Tipo 2; Comorbilidad; Factores de Riesgo; Hemoglobina A Glicada (HbA1c) (fuente: DeCS BIREME).

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# ORIGINAL SHORT

# INTRODUCTION

Diabetes Mellitus (DM) is currently one of the biggest public health problems worldwide. According to the World Health Organization (WHO), globally, from 1995 to the present, the patients diagnosed with diabetes increased considerably, with the most recent estimate of 347 million affected patients<sup>(1)</sup>. According to the International Diabetes Federation (IDF), India, Brazil, China, Russia, the United States and Mexico are the nations with the highest proportions of patients with diabetes<sup>(2)</sup>.

Diabetes is a chronic disease that occurs when the pancreas produces insufficient insulin or is used ineffectively. Manifesting clinically as hyperglycemia (increased blood sugar), which over the years causes serious damage to organs and systems, especially nerves and blood vessels<sup>(3)</sup>.

The IDF establishes that almost 10% of the global population suffers from DM (382 million people), and it is estimated that it increases to more than 590 million patients in a period of less than 25 years, increasing by 55% (having into account that there are at least 175 million sick people who have not yet been diagnosed)<sup>(4)</sup>.

In Colombia, during 2019, 186,568 new cases of DM were diagnosed, 73,630 more than in 2018, of these 56.6% (n = 105,597) were female. Being the average age of 61.84 years (SD  $\pm$  13.8), it was also observed that 80.4% were between 50 and 75 years old and 3.6% were under 35 years old. Antioquia was the territory that reported the highest incidence of DM (n = 76 44, IA = 10.7), followed by Bogotá, D.C. (n = 76 44, IA = 10.7)54,551, IA = 5.7) and Valle del Cauca (n = 40,943, IA = 7.8). 80.4% of the new cases of DM were reported by the entities of the contributory regime and 19.3% by the entities of the subsidized regime, the E.P.S. Sanitas reported the highest number of cases (n = 34650 IA = 14.42) together with the E.P.S. Famisanar (n = 28 840 IA = 18.2), the EPS Suramericana (n = 22 477 IA = 8.5) and Salud Total E.P.S. (n = 22 029  $IA = 11.3^{(5)}$ .

Between July 2018 and June 2019, 1,294,940 people diagnosed with DM were reported, meaning a prevalence rate of 2.58 cases per 100 inhabitants, which is equivalent to 85,462 more people than the previous period. Of the total with DM diagnosis, 59.5% were women<sup>(5)</sup>. During the time that the study lasted, 27 656 deceased people diagnosed with DM were reported, of all of them 55.1% (n = 15 238) were women. The mortality rate for DM was estimated at 55.2 deaths per 100 000 inhabitants, being more in

females (60.0) than in males (50.2) and the average age of 76.26 years (SD  $\pm$  12, 2)<sup>(5)</sup>.

Type 2 DM (DM2) is the main cause of various conditions in adults who suffer from it, such as loss of vision, kidney failure or diabetic foot, which can cause the loss of the lower limbs<sup>(6)</sup>. The increased risk of cardiovascular problems is due to its pathophysiology. A correct tertiary prevention based on maintaining adequate metabolic control has a close correlation with the reduction and delay in the appearance of complications<sup>(7)</sup>. DM2 is potentially reversible; and even more so in the first years after diagnosis<sup>(8)</sup>. A research study in the United Kingdom with people suffering from DM2 after a follow-up of ten years, indicated a 37% decrease in the incidence of microvascular complications, per percentage point reduced in HbA1c<sup>(9)</sup>. However, in other studies this association was deficient(10,11).

The objective of this study was to describe the clinical profile of patients cared for type 2 diabetes mellitus in a reversion program.

#### THE STUDY

We carried out a retrospective descriptive observational study, between January and December 2019, in patient care, in the specialized consulting office in Medicina Integral IPS (Cartagena, Colombia).

Patients aged 18 years or more were included, having received medical care in Medicina Integral IPS, diabetes program, having registered consultations on 01/01/2019 - 12/31/2019 with a diagnosis of DM2 in their clinical history (CH), with the code CIE10 E11, and having registered at least once the HbA1c value in the CH in the year to the date of recording the data. Disenrolled persons were excluded before the study began and while it was running.

Regarding the sampling, work was carried out with a sample with replacement, until reaching the number of patients calculated. The number of sample was calculated from patients aged 18 years or older cared with a diagnosis of DM2 during 2019, which was 2,738 people, recorded with the CIE10 E11 coding in the CH. The number of patients required with a diagnosis of DM2 to estimate a statistical inference was 24 patients. To make this estimate, work was carried out with a confidence level of 95%, an expected prevalence of people with DM2, with HbA1c less than 7%, of 15% (2,4,5,9-11); and with an accuracy of  $\pm$  5%.

Later date records of all characteristics evaluated were gathered solely from the Fomplus electronic medical record (EHR), individual service delivery records, and the Diabetes Cartagena model feedback database.

Between January and December 2019, the participants were enrolled by communication via telephone and in control of specialized medical consultation appointments, where the objective of the diabetes reversal program was explained and a face-to-face appointment was arranged at the headquarters of Medicina Integral IPS, Cartagena, Colombia. Subsequently, the individual records and the EHR of each participant were reviewed to collect the last records of the study variables.

Sociodemographic characteristics were collected, such as age and sex; and anthropometric, such as weight and height and, based on these, the body mass index (BMI).

For adequate metabolic control, were considered the indicators proposed as cardiovascular risk factors (CVRF) according to the American Diabetes Association (ADA)<sup>(11)</sup>; which were total cholesterol (TC) <185mg / dL, triglycerides (TG) <150md / dL, HDL cholesterol > 40mg / dL in men and > 50mg / dL in women, LDL cholesterol <100mg / dL, HbA1c <7%

, blood pressure (BP) <140 / 90mmHg, systolic blood pressure (SBP) <140mmHg, and diastolic blood pressure (DBP) <90mmHg.

Comorbidities were measured using the Charlson index<sup>(12)</sup>. Likewise, records of arterial hypertension (AHT) and progression of CKD (kidney disease) were collected, since they are highly relevant when evaluating the level of metabolic control in patients with DM2.

For the statistical analysis, a descriptive analysis was performed; to describe the quantitative variables, means were used and for the qualitative variables, the proportions; both with their respective 95% confidence intervals. The Shapiro-Wilk test was used to evaluate the distribution of normality. Statistical analysis was performed with R software (https://cran.r-project.org/).

# **FINDINGS**

24 patients were listed, of which 1 is disenrolled during the course of the study. Of the 23 participants, 47.8 were female and 52.1% male. 39.1% of the sample were between 50-59 years old, and 26.1% were overweight. The other characteristics are shown in table 1.





**Table 1.** Sociodemographic and anthropometric characteristics of the population. Integral Medicine, Cartagena, 2019.

Variable		n	Value	95% CI
Sex	Woman (%)	11	47.8	42.8-56.7
	Man (%)	12	52.1	43.3-57.2
Age (years)	Mean	23	57.7	68.1-71.5
	<50 years (%)	4	17.4	
	50 – 59 years (%)	9	39.1	
	60 – 69 years (%)	7	30.4	
	70 – 79 years (%)	2	8.7	
	≥80 years (%)	1	4.3	
Height cm (mean)		23	161.1	160.4-163.2
Weight kg (mean)		23	81.5	78.3-83.2
	Mean	23	28.6	29.9-31.5
BMI kg/m²	Underweight (%)	1	4.3	<15-18.4
	Normal weight (%)	8	34.8	18.5-24.9
	Overweight (%)	6	26.1	25-29.9
	Obesity class I (%)	5	21.7	30-34.9
	Obesity class II (%)	2	8.7	35-39.9
	Morbid obesity (%)	1	4.3	>40

BMI: Body Mass Index

95.7% of the participants had an HbA1c value lower than 7.0%. 78.3% had a diagnosis of hypertension (95% CI 66.7-79.0), and 45% dyslipidemia (DLP)

(95% CI 60.8-73.9). Table 2 shows the characteristics related to comorbidities and metabolic control.

**Table 2.** Metabolic control and comorbidity of the population. Integral Medicine, Cartagena, 2019.

Variable		n	Value	95% CI
Arterial Blood Pressure	SBP mmHg (media)	23	120.9	122.1-136.8
	DBP mmHg (media)	23	73.1	75.5-78.3
	BP < 140/90 mmHg (%)	23	100.0	
Glycated hemoglobin percentage	Mean	23	6.1	6.8-7.1
	HbA1c < 7,0% (%)	22	95.7	
	HbA1c < 7,5% (%)	1	4.3	
LDL cholesterol	Mean (mg/dL)	20	174.3	100.2-109.9
	< 100 mg/dL (%)	9	45.0	
HDL cholesterol	Mean (mg/dL)	21	105.1	49.6-53.1
	Men (media)	11	52.4	44.1-48.7
	Women (media)	10	47.6	54.2-58.7
Triglycerides	Mean (mg/dL)	15	47.9	129.1-152.2
	< 150 mg/dL (%)	0	0.0	
AHT (%Si)		18	78.3	66.7-79.0
Charlson comorbidity index	Points (mean)	23	4.4	2.6-3.0
	Charlson index (mean)	23	32.0	
	Absence of comorbidity (%)	0	0.00	
	Low comorbidity (%)	4	17.4	
	High comorbidity (%)	19	82.6	

## **DISCUSSION**

As observed in this study, although most of the participants have adequate control of DM2's glucose and values of cholesterol and triglycerides in the blood, a large percentage have a very high risk of chronic renal disease progression.

The results of the social and demographic data are similar to those found by other researchers who use very similar variables<sup>(7,11)</sup>. It could be explained, in a general way, because in patients with DM2, the programs are aimed at typical patients, whose characteristics include an age close to 50 years of age and the presence of other diseases, such as hypertension, dyslipidemia, etc.

Regarding the control of serum glucose by estimating HbA1c, the ADA urges, for adequate control, trying to maintain values below 7.0%<sup>(12)</sup>. Emphasizing that the majority of the population of the Diabetes Reversion Program would be showing, according to the ADA guidelines, adequate metabolic control.

In this group of patients, more than half of the study subjects have obesity. For this reason, the diabetes reversal program is focused on lifestyle modifications so that, pathophysiologically, aging decreases by increasing physical activity and favoring changes in diet, reducing the consumption of saturated fat and simple carbohydrates<sup>(13)</sup>. Therefore, following the suggestions of the ADA 2016, it is essential to face obesity to have better glycemic control<sup>(12)</sup>.

It might be said that the study's patients have good

control over their blood pressure values, according to the suggestions of the ADA 2016<sup>(12)</sup>, which advises having values below 140 mmHg of SBP and below 90 mmHg of DBP. Regarding the control of triglycerides and total cholesterol, more than 50% of the participants had good control; while less than 50% reached an LDL cholesterol value lower than 100mg / dL, however, the mean of the HDL cholesterol values exceeds the mean in the suggested limits (>40 mg /dL in men and >50mg /dL in women).

Adequate control of DM2 must adhere to the particular goals of HbA1c values in each person, to avoid treatments that do not show significant progress. It is preferable that the personalization of the metabolic control objectives be taken into account, according to the specific and individual conditions of each patient, such as age, comorbidities, time of illness, risk of cardiovascular disease or kidney disease. Also in future research, a larger study population will be necessary to address and better understand the degree of individual control of HbA1c. Within the limitations of the present study, a limited sample size was shown.

#### CONCLUSION

Most diabetic patients have adequate control of their disease. However, they present a high comorbidity, a high risk of Chronic Kidney Disease and a high percentage of patients whose life expectancy does not exceed 10 years, following the Charlson Index method.



**ORIGINAL SHORT** 

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