

Controlled and randomized clinical trial to compare the epidemiological and clinical-metabolic behavior of type 2 diabetes in the adult population of Añisok 2023/2024

Ensayo clínico controlado y aleatorio para comparar el comportamiento epidemiológico, clínico y metabólico de la diabetes tipo 2 en la población adulta de Añisok 2023/2024

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Abstract

Background: Type 2 diabetes constitutes a health problem with a 10.5% prevalence, presenting 537 million estimated at 783 million by 2045, 44.7% undiagnosed, and 70% deceased. **Objective:** Its epidemiological, clinical, and metabolic behavior was analyzed in the adult population of Añisok 2023/2024. **Material and methods:** This is an experimental design, randomized, double-blind clinical trial, quantitative, prospective, and cross-sectional approach. In a universe of 2,000 people, in the control group there were 1,500 participants with risk factors and in the experimental group 202 with low risk factors, with a total adult population aged 20 to 60 years, where 298 participants were excluded. Thirty were transferred to the country's capital, 10 had adverse effects, 98 refused to sign the consent form, 100 did not meet the eligibility criteria, 40 died and 20 dropped out. Variables are age, sex, education, occupation, glycated hemoglobin (HbA1c), blood glucose, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides. Excel, the Statistical Package for the Social Sciences, χ^2 , relative risk (RR), and interquartile ranges (IQR) were used. **Results:** Of the universe of 2,000, the sample was 1,702, of which 1,500 were from the control group and 202 from the experimental group. 88.1% ($n = 1500$), IQR = 750, 50% ($n = 850$) diabetic, 27% ($n = 460$) prediabetic, and 23% ($n = 190$) non-diabetic. 11.9% ($n = 202$), IQR=101, 2.3% ($n = 40$) diabetic, 1.7% ($n = 30$) prediabetic, 0.6% ($n = 10$) hypercholesterolemia, 4.1 % ($n = 70$) hyperglycemia, 1.5% ($n = 22$) hypertriglyceridemia, 1.7% ($n = 30$) no diabetics. Age 51-60 (49.3% and 5.8%), female (32.4% and 23.5%), primary level (38.2% and 26.4%), merchants (23.5% and 12.3%), officials (19.9% and 1.7%) and their work (17.7% and 3.5%). χ^2 statistically significant ($\alpha 0.05$), RR higher risk. **Conclusions:** The behavior was negative and related to obesity and hypertension, evidenced by high levels of HDL, LDL, triglycerides, HbA1c, and fasting blood glucose. Hepatic steatosis, penile necrosis, periodontitis, anguis-anger, and hypoxic-ischemic encephalopathy were reported.

Keywords: Type 2 diabetes. Lipid profile. Clinical trial. Glycated hemoglobin. Risk factors. Epidemiological behavior.

Resumen

Antecedentes: La diabetes tipo 2 constituye un problema de salud por 10,5% de prevalencia, presenta 537 millones estimados en 783 millones para 2045, 44,7% sin diagnóstico, 70% fallecidos. **Objetivo:** Se analizó su comportamiento epidemiológico, clínico y metabólico en la población adulta de Añisok 2023/2024. **Material y métodos:** Diseño experimental, ensayo clínico aleatorizado, doble ciego, enfoque cuantitativo, prospectivo y transversal. En un universo de 2,000 personas, en el

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grupo control hubo 1,500 participantes con factores de riesgos y en el grupo experimental 202 con bajos factores, con un total de población adulta de 20 a 60 años, donde se excluyeron 298 participantes. Se trasladaron a la capital del país 30, tuvieron efectos adversos 10, rehusaron firmar el consentimiento 98, no cumplieron criterios de elegibilidad 100, hubo 40 muertos y abandonaron 20. Variables: edad, sexo, instrucción, ocupación, HbA1c, glicemia, LDL, HDL y triglicéridos. Se utilizó Excel, SPSS, χ^2 , RR, IQR. **Resultados:** Del universo de 2,000, la muestra fue 1,702, de donde 1,500 fueron del grupo control y 202 experimental. El 88,1% ($n = 1500$), IQR = 750, 50% ($n = 850$) diabéticos, 27% ($n = 460$) prediabéticos y 23% ($n = 190$) no diabéticos. 11,9% ($n = 202$), IQR = 101, 2,3% ($n = 40$) diabéticos, 1,7% ($n = 30$) prediabéticos, 0,6% ($n = 10$) hipercolesterolemia, 4,1% ($n = 70$) hiperglicemia, 1,5% ($n = 22$) hipertrigliceridemia, 1,7% ($n = 30$) no diabéticos. Edad de 51-60 (49,3% y 5,8%), sexo femenino (32,4% y 23,5%), nivel primario (38,2% y 26,4%), comerciantes (23,5% y 12,3%), funcionarios (19,9% y 1,7%) y sus labores (17,7% y 3,5%). χ^2 estadísticamente significativa (alfa 0,05), RR mayor riesgo. **Conclusiones:** El comportamiento fue negativo y relacionado con obesidad e hipertensión, evidenciado por altos niveles de HDL, LDL, triglicéridos, HbA1c, glicemia en ayunas. Se reportó esteatosis hepática, necrosis del pene, periodontitis, angustia-ira y encefalopatía hipóxico-isquémica.

Palabras clave: Diabetes tipo 2. Perfil lipídico. Ensayo clínico. HbA1c. Factores de riesgos. Comportamiento epidemiológico.

Introduction

Diabetes is associated with metabolic disorders that induce the presence of hyperglycemia, which is characterized by deficient insulin secretion. Complications of diabetes include neuropathy, nephropathy, retinopathy, heart disease, arteriopathies, cerebrovascular accidents, non-alcoholic fatty liver disease, and male erectile dysfunction, among others^{1,2}.

The World Health Organization estimates that 537 million adults have diabetes, with a prevalence of 10.5%, due to the increase in the prevalence of overweight and obesity³. Diabetes is a serious threat to the health of the population. In Brazil, 133.8 million people between 20 and 70 years of age suffer from this disease (8.7% and 41.7%). One complication of diabetes is diabetic foot (19.03%), which is damage to the foot characterized by orthopedic, infectious, vascular, and neurological alterations after necrotic ulcers fail to heal⁴.

The prevalence of diabetes in the United States is 34.2 million (10.5%), with 83,564 deaths attributed to diabetes. The prevalence of diabetes among adults is 34.1 million (13%). In Mexico, the prevalence of diabetes is 592 million (8.8%)⁵. In Latin American countries, the prevalence of diabetes is 9.2% among those aged 20-79 years owing to factors such as glucose intolerance, ignorance of the disease, and obesity⁶. Mortality ranges between 12.3% and 58% among individuals under 60 years of age. In 2017, the number of deaths reached 209,717, and common complications were stroke, ischemic heart disease, kidney failure, amputation, and blindness⁷. In Cuba, the prevalence of diabetes is 37.6% among women aged 20-29 years with a body mass index (BMI) > 25 kg/m²⁸. In Costa Rica, there are 3,227,930 people between 20 and 75 years old, and the

prevalence of diabetes is 6.78% in this age group, with 101,410 women and 117,400 men being affected⁹.

In Europe, among the population aged from 20 to 79 years, 59.3 million (8.9%) have diabetes, and 24.2 million of these individuals are without a diagnosis. The prevalence of diabetes is 9.3% in urban areas and 7.8% in rural areas¹⁰. The European countries most affected by diabetes are Germany (9.5 million), Russia (8.3 million), and Turkey 6.6 million. Among European individuals with diabetes, there were 465,900 (8.5%) deaths, 31.4% of which occurred in individuals younger than 60 years and 10.8% in individuals over 50 and 59 years. Fifty-nine percent of deaths due to diabetes occurred in Ukraine, Russia, and Turkey¹¹.

Regarding the number of deaths due to diabetes in Europe, 237,900 were in women and 228,000 were in men¹². In Spain, an estimated 90% of diabetes cases are confirmed, while 6% of cases are unknown. The risk factors for diabetes are a sedentary lifestyle, obesity, a high-sugar diet, no physical activity, and advanced age, all of which can be modified through lifestyle changes¹².

In Africa, 60% of cases of diabetes among the adult population aged 20-79 years are undiagnosed, and 64% of countries, except for Kenya, Uganda, and Ethiopia, lack data. The prevalence of diabetes among individuals over 65-69 years is 8.8%¹³. Among individuals with diabetes in African, 45.9% and 54.1% belong to low-income and middle-income countries, respectively¹⁴. In Africa, the majority of the adult population lives in urban areas 5.9% and the minority in rural areas 2.4%. The African countries with the highest prevalence of diabetes are South Africa (4.6 million inhabitants), at 12.7%; Seychelles and Comoros, 12.3%; Nigeria, 2.7%;

Ethiopia, 1.7%; and Congo, 1.8%, which accounts for 55.8% of all individuals with diabetes aged 20-79 years¹⁵.

The mortality rate is 9.1% among the population aged 30-39 years and 73.1% among those under 60 years of age. Mortality is directly proportional to country income, with the mortality rates for low- and middle-income countries being 41.8% and 58.2%, respectively. The African country most affected by diabetes in terms of mortality rate is South Africa (1.8%), with 131,700 and 234,500 deaths in men and women, respectively. The prevalence of type 2 diabetes is 0.8% and 2.2% in Rwanda, Mali, Benin, and others, with 85.75 throughout Africa. Approximately 70 to 85% of cases of diabetes are unknown, and 15% to 30% are due to lifestyle factors and various risk factors, such as a sedentary lifestyle, obesity, a family history, and genetic and hormonal factors¹⁶.

Equatorial Guinea has 1,225,442 inhabitants, and 209,000 (17.1%) are emigrants. The country presents growth rates of 2.54 and 59.3 in terms of life expectancy. The population under 15 years of age represents 47.3% of the overall population, while 2.7% of the population is over 60 years of age. The mortality rate is estimated to be in equal proportion to the birth rate¹⁷.

A historical, biomedical, social, and economic background related to diabetes is lacking. Epidemiological or statistical data are not available, which prevents estimations of the prevalence and incidence of the disease in relation to the entire population, sex, age, country of origin, ethnicity, and occupation.

According to the International Diabetes Federation Atlas, 39.9 (33.4-48.8) thousand adults aged 20-79 years have diabetes, with a prevalence of 5.5 to 7.6 (95% confidence interval [CI] = 4.5-6.7), and the age-adjusted comparison is 6.0 (95% CI = 5.1-7.4)¹⁸⁻²¹.

In this regard, the purpose of this research was to analyze the epidemiological, clinical, and metabolic characteristics of type 2 diabetes in the adult population aged 20-60 years residing in Añisok in 2023/2024.

General hypothesis

Is there an epidemiological and clinical-metabolic behavior of type 2 diabetes mellitus in the adult population aged 20-60 years?

H_0 = The epidemiological and clinical-metabolic behavior of type 2 diabetes mellitus is independent of associated risk factors (BMI > 30 kg/m² and blood pressure [BP] > or = 140/90 mmHg).

H_1 = The epidemiological and clinical-metabolic behavior of type 2 diabetes mellitus depends on associated risk factors (BMI > 30 kg/m² and BP > or = 140/90 mmHg).

Material and methods

- The design was an experimental clinical trial that was controlled and randomized. There was double-blind masking. The approach was quantitative, prospective, and cross-sectional.
- The study subjects were individuals of both sexes who were 20-60 years of age, lived in the district of Añisok, and met the eligibility criteria.
- The sampling method was random, and the randomization units were towns, village councils, and neighborhood communities. The random assignment criteria were even days of the week, excluding Sundays (Tuesday, Thursday, and Saturday), for the control group and odd days of the week (Monday, Wednesday, and Friday) for the experimental group.
- Sample size: the aspects that guaranteed the absence of bias in the selection of the sample were age (20-30, 31-40, 41-50, or 51-60 years), sex (male or female), occupation (subjects' jobs; merchant, student, civil servant, or other level), and education level (primary, secondary, baccalaureate, university or other). Weight and height were used to calculate the BMI through the following formula: BMI = weight/height². Then, BP was measured to determine the control group (BP > 140/90 mmHg + BMI > 30 kg/m²) and the experimental group (BP < 140/90 mmHg + BMI < 30 kg/m²). Blood samples were collected to classify subjects as having prediabetes, diabetes, or no diabetes according to criteria based on the levels of glucose, glycated hemoglobin (HbA1c), triglycerides, high-density lipoprotein (HDL), and low-density lipoprotein (LDL). The sample included 1,702 people, 1,500 in the control group, and 202 in the experimental group.
- Population: Equatorial Guinea has 1,634,466 inhabitants, with 47.18% of the population being female and 52.83% being male. Residents have a life expectancy of 60.59 years, with a typical pyramid of third-world countries of a low life expectancy (0-14 years, 38.77%; 15-64 years, 58.09%; and > 64 years, 3.15%) and high birth rates. The number of residents in Añisok aged 20-60 years was 2,000 people.
- Variables: the following variables were evaluated in this study: age, sex, occupation, education level, HbA1c level, fasting blood glucose level, LDL cholesterol level, HDL cholesterol level, and triglyceride level.

Statistical analysis

Sample size: The sample size was large, and the clinical trial generated high costs for data processing.

Descriptive analysis

Variables with a non-normal distribution (BP, BMI, HbA1c level, triglyceride level, HDL level, LDL level, and fasting blood glucose level) are presented as interquartile ranges (IQRs); variables with a normal distribution (occupation, education level, age, and sex) are presented as the absolute frequencies and percentages.

Comparative analysis

χ^2 depended on the sample group (control and experimental). The null hypothesis (H_0) supported the independence of diabetes from risk factors, and the alternative hypothesis (H_1) supported the association of diabetes with categorical variables in statistical tests.

The χ^2 test was used to determine whether a significant difference existed between the observed and expected results in one or more categories. We used a 95% CI, a significance level of 0.05, and a precision between zero and one. The relative risk (RR) was a relative measure of effect. Microsoft Excel 2016 and the Statistical Package for the Social Sciences, version 23, were used. The diagnostic criteria for diabetes used were the 2023 American Diabetes Association criteria. Ethical considerations: This study was approved by the UCAM Ethics Committee (Code CEO52310, Registry 8289/29/05/023). The results were protected according to European Union Regulation 2016/679 of the European Parliament. Informed consent forms were given to the participants²²⁻²⁴.

Results

Among the sample of 1,702 adults from Equatorial Guinea aged 20-60 years, 88.1% ($n = 1500$), IQR = 750, presented risk factors associated with type 2 diabetes (BP > 140/90 mmHg + BMI > 30 kg/m²) and constituted the control group; 50% ($n = 850$) were diabetic, 27% ($n = 460$) were prediabetic, and 23% ($n = 190$) were non-diabetic. In contrast, 11.9% ($n = 202$) of participants belonged to the experimental group or people with low-risk factors (BP < 140/90 mmHg + BMI < 30 kg/m²); IQR = 101, of which 2.4% ($n = 40$) were diabetic, 1.7% ($n = 30$) were prediabetic, 0.6% ($n = 10$)

had hypercholesterolemia, 4.1% ($n = 70$) had hyperglycemia, 1.5% ($n = 22$) had hypertriglyceridemia, and 1.7% ($n = 30$) had no diabetes. Overall ($n = 1,702$) (control group and experimental group), 52.3% ($n = 890$) of participants were diabetic, 28.7% ($n = 490$) were prediabetic, and 24.7% ($n = 220$) were non-diabetic (Tables 1 and 2).

In the analysis of age, sex, education level, and occupation in both groups (control and experimental), the majority of individuals in the control group ranged in age from 51 to 60 years, with 49.3% ($n = 240$) having diabetes and 5.8% ($n = 100$) having prediabetes. In the experimental group, 2.4% ($n = 40$) had diabetes and 1.7% ($n = 30$) had prediabetes. Among the control group females, 32.4% ($n = 550$) had diabetes and 23.5% ($n = 400$) had prediabetes. Among the experimental group, 1.4% of males ($n = 25$) had diabetes and 1.7% ($n = 30$) had prediabetes. Among the control group subjects with a primary education level, 38.2% ($n = 650$) had diabetes and 26.4% ($n = 450$) had prediabetes, while 2.4% ($n = 40$) of subjects in the experimental group with a primary education level had diabetes. Among merchants in the control group, 12.3% ($n = 210$) had diabetes and 23.5% ($n = 400$) had prediabetes, while 2.4% ($n = 40$) of subjects who were merchants in the experimental group had diabetes. Among officials, 19.9% ($n = 340$) in the control group had diabetes, and 1.7% ($n = 30$) of officials in the experimental group had prediabetes. Among people who were self-employed, in the control group, 17.7% ($n = 300$) had diabetes and 3.5% ($n = 60$) had prediabetes (Tables 3 and 4).

The significant relationships between the groups were as follows: $\alpha = 0.05$; type I error of 5%; 95% confidence level; degrees of freedom, 2; critical value, 5,991; $\chi^2 = 8.05$; accuracy = 0.01783.

$\chi^2 > \text{critical value}$ = statistically significant at the α level of 0.05. The null hypothesis (H_0) was rejected, and the alternative (H_1) was accepted. It was confirmed that the epidemiological, clinical, and metabolic characteristics of type 2 diabetes depend on the associated risk factors: BP > 140/90 mmHg and BMI > 30 kg/m².

Since the precision value 0.01783 is lower than the significance level 0.05, the null hypothesis (H_0) is rejected and the significant statistical association between the variables is confirmed.

Population with risk factor = 0.873

Population without risk factor = 0.346

RR = 2.52 > 1; association between type 2 diabetes and risk factors

RR > 1 = increased risk (Table 5).

Table 1. Lipid profile of type 2 diabetes patients in the adult population aged 20-60 years

Variables and categories	Baseline fasting blood glucose									
	No diabetes				Prediabetes		Diabetes			
	Normoglycemia		Hyperglycemia		110 a 126 mg/dL	Percentage	> 126 mg/dL	Percentage	Total	QRI
	70 a 110 mg/dL	Percentage	110 a 130 mg/dL	Percentage						
Control group (n = 1500)	190	11,2	-	-	460	27	850	50	1500	750
Experimental group (n = 202)	62	3,7	70	4,1	30	1,7	40	2,3	202	101
Total	252	14,9	70	4,1	490	28,7	890	52,3	1702	851
QRI	120	-	35	-	245	-	445	-	851	-
HDL										
Variables and categories	No diabetes				Prediabetes		Diabetes			
	Normal		Hypercholesterolemia		40 mg/dL	Percentage	< 40 mg/dL	Percentage	Total	QRI
	Ø 35 mg/dL	Percentage	Ø 40 mg/dL	Percentage						
	190	11,2	-	-	460	27	850	50	1500	750
Control group (n = 1500)	190	11,2	-	-	460	27	850	50	1500	750
Experimental group (n = 202)	110	6,4	22	1,5	30	1,7	40	2,3	202	101
Total	300	17,6	22	1,5	490	28,7	890	52,3	1702	851
QRI	150	-	11	-	245	-	445	-	851	-
LDL										
Variables and categories	No diabetes				Prediabetes		Diabetes			
	< 200 mg/dL		200 mg/dL		Ø 200 mg/dL	Percentage	Total	QRI		
	Percentage	Percentage	Percentage	Percentage						
	190	11,2	460	27	850	50	1500	750		
Control group (n = 1500)	190	11,2	460	27	850	50	1500	750		
Experimental group (n = 202)	132	7,8	30	1,7	40	2,3	202	101		
Total	322	19	490	28,7	890	52,3	1702	851		
QRI	161	-	245	-	445	-	851	-		

(Continues)

Table 1. Lipid profile of type 2 diabetes patients in the adult population aged 20-60 years (continued)

Variables and categories	Triglycerides							
	No diabetes				Prediabetes		Diabetes	
	Normal		Hypertriglyceridemia		150-250 mg/dL	Percentage	Ø 250 mg/dL	Percentage
	10-150 mg/dL	Percentage	Ø 150 mg/dL	Percentage				
Control group (n = 1500)	190	11,2	-	-	460	27	850	50
Experimental group (n = 202)	122	7,2	10	0,6	30	1,7	40	2,3
Total	312	18,4	10	0,6	490	28,7	890	52,3
QRI	156	-	5	-	245	-	445	-

IQR: interquartile range=03-01.
Source: Randomized controlled clinical trial.

Clinical aspects included necrosis in the penis, hepatic steatosis, periodontitis, anguis-anger, and hypoxic ischemic encephalopathy.

Discussion

Taking into account the findings of this research, the general hypothesis that the epidemiological, clinical, and metabolic characteristics of type 2 diabetes in the adult population between 20 and 60 years of age in the district of Añisok in the Republic of Equatorial Guinea in 2023/2024 was confirmed. These results are similar to those reported by Calie et al. (2023) since there is a high rate of development of type 2 diabetes in people with risk factors¹⁴. Vera-Rodriguez et al. (2022) reported that 63% of individuals were obese and 35.5% had diabetes, and a statistically significant association was found between the conditions, while the performance of physical activity was a protective factor for the conditions¹⁵. In contrast to the previous results, Mejía-Álvarez et al. (2021) reported that 85% of individuals had associated risk factors, such as lack of physical activity, lack of access to healthy food, and lack of educational programmes¹⁶. Represas-Carrera et al. (2021) studied 694 diabetic patients, 356 of whom were in the control group and 338 of whom were in the experimental group; 37.64% of the women aged 60 years or more were in the control group, while 37.87% were in the experimental group. HbA1c and HDL levels were significantly influencing variables¹⁷. Baque-Pin et al. (2023) reported that 25% to 35% of adults develop sadness, depression, a lack of interest in life, alterations in appetite, insulin resistance, and alterations in pancreatic cells¹⁸.

The epidemiological characteristics of type 2 diabetes according to age, sex, education level, and occupation in both groups (control and experimental) were identified. Sánchez-Delgado and Sánchez-Lara (2022) reported results similar to ours, where the most relevant age group was from 60 to 69 years (29.6%), females were the most affected sex (55.5%), and the percentage of patients with risk factors for obesity was 64.19%; 80.2% had an inadequate diet, and 54.3% had a family history of dyslipidemia¹⁹. Russo et al. (2022) found that 15.7% of residents of Equatorial Guinea between 65 and 80 years of age had diabetes, 52% of females had diabetes, 74% had concomitant risk factors for arterial hypertension, 55% were obese, and 88% had dyslipidemia²⁰. Reynoso-Vázquez et al. (2020) found that among individuals with diabetes from 45 to 60 years old, 55% were male, 81% had a secondary education

Table 2. Clinical characterization of type 2 diabetes in the adult population aged 20-60 years

Variables and categories	Clinical characterization of the population (HbA1c)							
Diagnosis	No diabetes		Prediabetes		Diabetes			
HbA1C	< 5%	Percentage	5,7-6,4%	Percentage	7-8%	Percentage	Total	QRI
Control group (n = 1500)	190	11,2	460	27	850	50	1500	750
Experimental group (n = 202)	132	7,8	30	1,7	40	2,3	202	101
Total	322	19	490	28,7	890	52,3	1702	851
QRI	161	-	245	-	445	-	851	-

HbA1c: glycated hemoglobin; IQR: interquartile range = Q3-Q1.
 Source: Randomized controlled clinical trial.

level, 60% were merchants, and 40% were self-employed²¹. Fernández and Bello (2021) reported that, among 587 individuals with diabetes, 46.5% were female and 53.5% were male; these results were similar to ours²². García (2020) found that the average age was from 51 to 55 years (19.8%), 68% were female, 70.8% had a primary education level, and 66% were self-employed²³. Hernández (2023) found 54% (n = 56) in the age group, 65% in the female sex, 38% in the male sex, and 66% in the primary level²⁴. Alcocer-Díaz et al. (2023) reported a prevalence of diabetes of 66.9%, with associated risk factors such as obesity (48.2%), overweight (68.5%), dietary patterns, and inadequate nutrition²⁵. Quiroz, Guacho and Rodríguez (2023) reported that, in adults, the prevalence of dyslipidemia is high, and there are associated risk factors such as a sedentary lifestyle, tobacco use, alcohol use, unhealthy eating habits, obesity, and overweight (37.5%)²⁶. Zavala-Hoppe et al. (2024) reported that overweight, obesity, a sedentary lifestyle, smoking, alcohol use, and high BP were risk factors for diabetes²⁷. Castillo et al. (2024) reported a high prevalence of type 2 diabetes (35.5%) and percentage of individuals with low risk factors of 64.5%²⁸. Toala-León et al. (2023) determined the existence of factors associated with type 2 diabetes, such as sex, age, nutritional status, sedentary lifestyle, family history, physical inactivity, and overweight/obesity²⁹. Montero et al. (2024), in a sample of 1,751 adults, reported a high prevalence of periodontitis, characterized by destruction of the tissue supporting teeth, which significantly and negatively affects glycemic control. Among the 8.2% (n = 144) of individuals with diabetes and 59.0% with periodontitis, 68.8% had risk factors such as sex, age, BMI, smoking, hypertension, education level, dyslipidemia, a family history, and physical inactivity (RR = 4.9, 95% CI = 22-10.7,

p = 0.001)³⁰. Linares-Pineda et al. (2024) reported similar characteristics under both conditions, such as increased insulin resistance, increased blood glucose levels and genetic predispositions, and changes in gene expression but not in DNA sequence; all of these characteristics are influenced by environmental factors. In fact, of the 312 European women, 73 had gestational diabetes; of the 168 South African women, 68 had gestational diabetes; and of the 32 North American women, 16 had gestational diabetes. Among the 850,000 gene mutation sites, 42 were associated with type 2 diabetes mellitus and gestational and fasting glucose levels³¹. Rivas-Carro (2024) reported that providing information to people with diabetes about changes in attitudes through communication and structured educational programs is pertinent³².

With respect to the clinical characterization of type 2 diabetes, Toala Muñoz and Quimis (2022) reported HbA1c values > 6.5%, with clinical manifestations such as weight loss, blurred vision, polyuria, depression, fatigue, strong appetite, and drowsiness, among others³³. In contrast, García-Ardanaz et al. (2023) reported a significant reduction in HbA1c values to below 6.5% in individuals with diabetes who performed resistance exercise in combination with aerobic exercise³⁴. López-González et al. (2023) reported simultaneous considerable decreases in the lipid profile, glucose, and BP when HbA1c levels were reduced by 1%, corresponding to a 25% reduction in cardiovascular complications and a 10% reduction in deaths³⁵. Correia et al. (2021) reported statistically significant differences related to HbA1c (n = 7,703, CI = 95%, I² = 86.70%) and baseline fasting blood glucose (n = 5524, I² = 64.28%, CI = 95%) but not BMI (n = 5957, I² = 35.94%, CI = 95%), triglycerides (CI = 95%, n = 2360, I² = 0%), or total cholesterol (CI = 95%, n = 5381, I² = 59.93%); these

Table 3. Epidemiological characteristics of type 2 diabetes according to age, sex, education level, and occupation level of the population in relation to associated risk factors

Variables and categories	Blood pressure > 140/90 mmHg (n = 200) (11,7%) IQR = 100 Characteristics							BMI > 30 kg/m ² (n = 300) (17,6%) IQR = 150 Characteristics		
Age group (years)	Diabetes	Percentage	Prediabetes	Percentage	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage
20-30	-	-	-	-	80	4,8	-	-	-	-
31-40	-	-	10	0,6	-	-	-	-	-	-
41-50	10	0,6	-	-	-	-	-	-	50	50
51-60	-	-	100	5,8	-	-	240	14,1	-	-
TOTAL	10	0,6	110	6,4	80	4,8	240	14,1	-	50
Variables and categories	BMI > 30 kg/m ² (n = 300) (17,6%) IQR = 150 Characteristics									
Age group (years)	%	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage	No diabetes		
20-30	-	-	-	-	-	-	-	30		
31-40	-	10	0,6	-	-	-	-	70		
41-50	2,9	-	-	-	-	300	17,7	-		
51-60	-	-	-	600	35,2	-	-	-		
TOTAL	2,9	10	0,6	600	35,2	300	17,7	100		
Variables and categories	Risk factors associated with type 2 diabetes Control group (n = 1500) (88,1%)									
	Blood pressure > 140/90 mmHg (n = 200) (11,7%) IQR = 100 Characteristics							BMI > 30 kg/m ² (n = 300) (17,6%) IQR = 150 Characteristics		
Sex	Diabetes	Percentage	Prediabetes	Percentage	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage
Female	10	0,6	70	4,1	80	4,8	140	8,3	30	1,7
Male	-	-	40	2,3	-	-	100	5,8	20	1,2
Total	10	0,6	110	6,4	80	4,8	240	14,1	50	2,9

(Continues)

Table 3. Epidemiological characteristics of type 2 diabetes according to age, sex, education level, and occupation level of the population in relation to associated risk factors *(continued)*

Variables and categories	Risk factors associated with type 2 diabetes Control group (n = 1500) (88.1%)									
	BMI > 30 kg/m ² (n = 300) (17,6%) IOR = 150 Characteristics		Blood pressure > 140/90 con BMI > 30 kg/m ² (n = 1000) (58,7%) IOR = 500 Characteristics							
Sex	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage	No diabetes	Percentage	Percentage	Percentage
Female	-	-	400	23,5	300	17,7	-	-	-	-
Male	10	0,6	200	11,7	-	-	100	-	5,8	5,8
Total	10	0,6	600	35,2	300	17,7	100	-	5,8	5,8
Variables and categories	Risk factors associated with type 2 diabetes Control group (n = 1500) (88.1%)									
	Blood pressure > 140/90 mmHg (n = 200) (11,7%) IOR = 100 Characteristics					BMI > 30 kg/m ² (n = 300) (17,6%) IOR = 150 Characteristics				
Education level	Diabetes	Percentage	Prediabetes	Percentage	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage
Primary	10	0,6	100	5,8	-	-	240	14,1	50	2,9
Secondary	-	-	10	0,6	-	-	-	-	-	-
Baccalaureate	-	-	-	-	80	4,8	-	-	-	-
TOTAL	10	0,6	110	6,4	80	4,8	240	14,1	50	2,9
Variables and categories	Risk factors associated with type 2 diabetes Control group (n = 1500) (88.1%)									
	BMI > 30 kg/m ² (n = 300) (17,6%) IOR = 150 Characteristics		Blood pressure > 140/90 mmHg with BMI>30 kg/m ² (n = 1000) (58,7%) IOR = 500 Characteristics							
Education level	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage	No diabetes	Percentage	Percentage	Percentage
Primary	-	-	400	23,5	300	17,7	-	-	-	-
Secondary	-	-	200	11,7	-	-	30	-	1,7	1,7
Baccalaureate	10	0,6	-	-	-	-	70	-	4,1	4,1
TOTAL	10	0,6	600	35,2	300	17,7	100	-	5,8	5,8

(Continues)

Table 3. Epidemiological characteristics of type 2 diabetes according to age, sex, education level, and occupation level of the population in relation to associated risk factors (*continued*)

Variables and categories	Risk factors associated with type 2 diabetes control group (n = 1500) (88.1%)									
	Blood pressure > 140/90 mmHg (n = 200) (11.7%) Characteristics					BMI > 30 kg/m ² (n = 300) (17.6%) Characteristics				
Occupational level	Diabetes	Percentage	Prediabetes	Percentage	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage
Merchants	10	0,6	70	4,1	-	-	-	-	30	1,7
Officials	-	-	-	-	80	4,8	240	14,1	-	-
Self-employed	-	-	40	2,3	-	-	-	-	20	1,2
Total	10	0,6	110	6,4	80	4,8	240	14,1	50	2,9
Variables and categories	Risk factors associated with type 2 diabetes control group (n = 1500) (88.1%)									
	BMI > 30 kg/m ² (n = 300) (17,6%) Characteristics					Blood pressure > 140/90 mmHg con BMI>30 kg/m ² (n = 1000) (58,7%) Characteristics				
Occupational level	No diabetes	Percentage	Diabetes	Percentage	Prediabetes	Percentage	No diabetes	Percentage	Prediabetes	Percentage
Merchants	-	-	200	11,7	300	17,7	20	1,1	-	-
Officials	-	-	100	5,8	-	-	80	4,7	-	-
Self-employed	10	0,6	300	17,7	-	-	-	-	-	-
Total	10	0,6	600	35,2	300	17,7	100	5,8	-	-

BMI: body mass index; HT: arterial hypertension; IQR: interquartile range=Q3-Q1.
Source: Randomized controlled clinical trial.

Table 4. Epidemiological characteristics of type 2 diabetes according to age, sex, education level, and occupation of the population in relation to associated risk factors

Variables and categories	Risk factors not associated with type 2 diabetes Blood pressure < 140/90 mmHg BMI < 30 kg/m ² Experimental group (n = 202) (11.9%) IOR = 101												
Age group (years)	Hypercholesterolemia	Percentage	Hyperglycemia	Percentage	Hypertriglyceridemia	Percentage	No diabetes	Percentage	Prediabetes	Percentage	Diabetes	Percentage	
20-30	-		10	0,6	-		-		-		-		
31-40	-		-		-		30	1,7	-		-		
41-50	22	1,5	20	1,2	10	0,6	-		-		-		
51-60	-		40	2,3	-		-		30	1,7	40	2,3	
Total	22	1,5	70	4,1	10	0,6	30	1,7	30	1,7	40	2,3	
Variables and categories	Risk factors not associated with type 2 diabetes Blood pressure < 140/90 mmHg BMI < 30 kg/m ² Experimental Group (n = 202) (11.9%) IOR = 101												
Sex	Hypercholesterolemia	Percentage	Hyperglycemia	Percentage	Hypertriglyceridemia	Percentage	No diabetes	Percentage	Prediabetes	Percentage	Diabetes	Percentage	
Female	-	-	-	-	-		30	1,7	-	-	15	0,9	
Male	22	1,5	70	4,1	10	0,6	-	-	30	1,7	25	1,4	
Total	22	1,5	70	4,1	10	0,6	30	1,7	30	1,7	40	2,3	
Variables and categories	Risk factors not associated with type 2 diabetes Blood pressure < 140/90 mmHg BMI < 30 kg/m ² Experimental group (n = 202) (11.9%) IOR = 101												
Education level	Hypercholesterolemia	Percentage	Hyperglycemia	Percentage	Hypertriglyceridemia	Percentage	No diabetes	Percentage	Prediabetes	Percentage	Diabetes	Percentage	
Primary	-	-	70	4,1	-		-	-	-		40	2,3	
Secondary	-	-	-	-	-		-	-	30	1,7	-	-	
Baccalaureate	22	1,5	-	-	10	0,6	30	1,7	-	-	-	-	
Total	22	1,5	70	4,1	10	0,6	30	1,7	30	1,7	40	2,3	

(Continues)

Table 4. Epidemiological characteristics of type 2 diabetes according to age, sex, education level, and occupation of the population in relation to associated risk factors (*continued*)

Variables and categories	Risk factors not associated with type 2 diabetes Blood pressure < 140/90 mmHg BMI < 30 kg/m ² Experimental Group (n = 202) (11.9%) IOR = 101									
	Hypercholesterolemia	Percentage	Hyperglycemia	Percentage	Hypertriglyceridemia	Percentage	No diabetes	Percentage	Prediabetes	Percentage
Merchants	22	1,5	-	-	-	-	-	-	-	40
Officials	-	-	-	-	-	-	-	-	30	1,7
Self-employed	-	-	70	4,1	10	0,6	30	1,7	-	-
Total	22	1,5	70	4,1	10	0,6	30	1,7	30	1,7
										40
										2,3
										-
										-
										2,3

IOR: interquartile range=03-01; BMI: body mass index.
Source: Randomized controlled clinical trial.

findings are not consistent with our research³⁶. Millan-Ferro et al. (2020) reported that among those aged between 20 and 75 years, a significant reduction in HbA1c values (> 0.5%) was found (from 8.6% to 8%; $p = 0.0001$) among individuals who performed regular physical activity and had a healthy diet (53.2% to 35.2%, $p = 0.03$). In terms of BP, systolic BP decreased from 136.2 to 129.3 mmHg ($p = 0.008$), and diastolic BP decreased from 79.7 to 75.2 mmHg ($p = 0.004$). In terms of BMI, no significant differences were found³⁷. Alvarado-Cruz et al. (2023) reported that, among 158 patients, the mean age was 57 years, with a female predominance (55.1%); HbA1c levels were not controlled in 63.9% of patients (95% CI = 8.645 and 9.67%), and 53.8% had glucose levels > 130 mg/dL. A significant correlation of 0.722 (sig. = 0.001) between baseline blood glucose levels and HbA1c levels was confirmed³⁸. Lima et al. (2023) found that glucose levels of 70-180 mg/dL were negatively correlated with HbA1c over time, but at values higher than 180 mg/dL, the correlation with HbA1c was positive³⁹.

With respect to the lipid profile of individuals with type 2 diabetes, in line with our findings, Alfieri-Pappalard (2021) reported that among 74% (n = 148) of adults with type 2 diabetes, 57% (n = 85) had alterations in the blood lipid profile, with a significant association with obesity⁴⁰. Aquino et al. (2022) reported greater effectiveness of a combined dietary plan and exercise program, which reduced lipid levels, risk factors, and cardiovascular disease incidence in adults aged 18-24 years⁴¹. Among individuals with diabetes, Palacios-Sedam (2021) reported a male predominance of 54.8% with a mean age of 65.46 years and 18-39.7% having dyslipidemia, with 39.9% having decreased HDL levels, 3.5% having increased LDL levels, and 339.7% having high triglyceride levels; the authors concluded that the prevalence of an abnormal lipid profile depends on the degree of dyslipidemia⁴². Guevara-Tirado et al. (2021) found that 15.90% of patients in their sample had prediabetes and 15.10% had diabetes; they also reported correlation coefficients of 0.145 for the association between cholesterol and glucose, 0.255 for the association between triglycerides and glucose, and 0.405 for the association between cholesterol and triglycerides. The authors concluded that cholesterol and glucose levels are regulated by various physiological and genetic factors⁴³. Romero-Rojas et al. (2023) reported that metabolic syndrome has a significant effect on cardiovascular risk due to the high triglyceride levels, decreased HDL levels, and associated factors such as smoking habits, BMI, and BP; among the

Table 5. Relationships between variables: X_2 statistical test. Relative risk test

X_2 diagnosis	No diabetes	Prediabetes	Diabetes	Total
Population with risk factors (CG)	190 283,78 0,66	460 431,84 0,13	850 784,37 0,16	1500
Population without risk factors (EG)	132 38,21 4,90	30 58,15 0,96	40 105,62 1,24	202
Total	322	490	890	1702
Relative risk	Prediabetes/diabetes	No diabetes	Total	
Population with risk factors (CG)	A 1310	B 190	A + B 1500	
(EG)	C 70	D 132	C + D 202	
Total	A + C 1380	B + D 322	1702	

CG: control group; EG: experimental group.
Source: Randomized controlled clinical trial.

12.1% ($n = 17$) of those with diabetes in their study sample, 84.3% ($n = 118$) had low HDL levels, 42.9% ($n = 60$) had high triglyceride levels, 62.9% ($n = 88$) had a high BMI, 12.9% ($n = 18$) smoked, and 18.6% ($n = 26$) had high BP⁴⁴. Among their sample of 75 people (average age, 60 years; 37.3% women), Alcázar et al. (2022) found that the most common risk factors for diabetes (prevalence, 22.7%) were hypertension (49.3%), dyslipidemia (48%), smoking habits (32%), and cardiovascular risk (58.7%). LDL was 84.3 mg/dL; triglycerides were 133 mg/dL; and HDL was 110 mg/dL⁴⁵. In a sample composed of 56% females and 44% males with an average BMI of 22.62 kg/m², glucose of 89.48 mg/dL, Vega-Cárdenas et al. (2022) found an average insulin level of 6.62 μ mol/mL and a triglyceride level of 95.64 mg/dL. The prevalence of insulin resistance was 28.2%, with a sensitivity of 66% and a specificity of 53%; from where the resistance was 47%, 19.3% in men, and 28.5% in women⁴⁶. Flores et al. (2023) reported the prevalence of the following risk factors associated with atherosclerosis: arterial hypertension, 87.23%; high levels of LDL, 81.25%; obesity, 12.50%; smoking, 41.1%; and high BMI, 18.8%⁴⁷. Murillo et al. (2023) evaluated the prevalence of cholesterol levels > 200 mg/dL, triglycerides > 150 mg/dL, LDL > 120 mg/dL, and HDL < 219 mg/dL. They concluded that the risk factors for patients with cardiovascular diseases are obesity, dyslipidemia, and diabetes⁴⁸. Checa-Huilcatoma and Durán Cañarte (2023) reported a prevalence between 15% and 30%, with dyslipidemia, insulin resistance, and cardiovascular events being important factors⁴⁹. Cuevas-Fernández et al. (2021), found that,

among 587 people with diabetes, 46.5% were women, 4.1% did not adhere to treatment, 13.8% had treatment inertia, 23.7% had poor glucose control, men with 65 years, inadequate diet, diabetes > 0.5 years, metabolic syndrome, HDL/triglycerides ratio > 3, medical visits < 3 years with lack of ECG, and increase in medical prescription with antidiabetics²².

Conclusion

The epidemiological characteristics of type 2 diabetes were negative in the adult population aged 20-60 years in a large sample; in a randomized clinical trial, it has high efficacy and reliability. The incidence of diabetes is increasing in the population because of the high blood levels of lipids, which are associated with negative clinical implications with systemic involvement and an increase in the number of comorbidities related to the condition. In fact, it is important to implement early detection mechanisms and promote sustainable preventive interventions, as well as case monitoring and follow-up systems, to reduce complications. Older age and female sex are two fundamental predisposing factors for the development of type 2 diabetes. Dietary assessment can identify factors to prevent the development of diabetes as well as the complications derived from ageing. In the context of risk factors such as obesity and high BP, exhaustive dietary control is required in the healthy plan, and aerobic and anaerobic exercises are required to delay the macro/microvascular complications associated with diabetes.

Diabetes constitutes a population health problem due to its negative impact and associated events.

Future research on diabetes should involve different approaches and designs, with a focus on addressing the analytical and clinical variables identified in this study, such as necrosis of the penis, periodontitis, hypoxic ischemic encephalopathy, hepatic steatosis, and mood disorders, to foster new clinical and metabolic assessment methods in clinical practice and to improve the quality of life in people.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that the procedures followed complied with the ethical standards of the responsible human experimentation committee and adhered to the World Medical Association and the Declaration of Helsinki. The procedures were approved by the institutional Ethics Committee.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from patients, and received approval from the Ethics Committee. The SAGER guidelines were followed according to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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