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Clinical and Metabolic Particularities of a Roma Population with Diabetes- Considering Ethnic Disparities in Approaching Healthcare Management

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Abstract: The Roma population constitutes the largest ethnic minority in Europe, however, data regarding the prevalence of non- communicable diseases are still scarce in the medical literature. The aim of this study was to assess the clinical and metabolic particularities of a Roma population with diabetes, in comparison with a group of Romanian Caucasians. We conducted an observational, transversal study and evaluated 808 adult patients with diabetes mellitus, from a tertiary hospital providing diabetes care, aged between 18 and 89 years old, of whom the majority were men (52.84%). Most of them had type 2 diabetes mellitus (T2DM), reaching 95.1% the Caucasian group and 87.8% among the Roma patients. 81.1% of the Caucasian patients had hypertension, approximately 15% higher than the Roma group, while more than half of the patients in both groups had obesity. There were no differences concerning myocardial infarction, however, the number of patients with history of stroke was 2.1 times higher in the Roma group compared to Caucasians. Chronic kidney disease was present in 22.1% of the Roma patients, 33.25% had retinopathy, and 72.7% presented polyneuropathy. The prevalence of cardiovascular risk factors, cardiovascular disease and microvascular complications among the study Roma population are quite significant, underscoring the importance of ethnic disparities in approaching healthcare management strategies.

Keywords: clinical characteristics; metabolic particularities; anthropometric assessment; Roma population

1. Introduction

The Roma population constitutes the largest ethnic minority in Europe, estimated at 10–12 million. In countries with concentrated Roma members (Southern, Central, and Eastern Europe), limitations exist on collecting statistical data regarding health and its determinants based on ethnic status [1].

While the connection between extremely adverse socio-economic conditions and the poor health status among Roma is quite clear, the discrepancies noted in comparisons between the Roma population and the general population do not seem to be entirely explained by their inferior socio-economic status, recent research into the genetic basis of the high risk of various non-communicable diseases among Roma additionally supports the fact that the health status of them is influenced by a mix of different health-related factors [1].

It has been highlighted the elevated prevalence of communicable and non-communicable diseases among the Roma population, the health and living standards of this ethnic group in Central and Eastern Europe being reported as lower compared to the general population. Studies suggest a higher incidence of diseases like diabetes, coronary heart disease, and obesity within this minority group. Social determinants such as poverty, limited healthcare access, inadequate nutrition, and

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cultural traditions play significant roles in these disparities. Additionally, due to frequent consanguineous marriages within the Roma community, there's a heightened risk of genetically inherited illnesses emerging among them [1,2]. Therefore, research also indicates a reduced life expectancy among Roma compared to the majority population, their population pyramid typically showing a higher proportion of younger individuals and a lower concentration of elderly individuals, suggesting a predominantly progressive demographic trend [3].

For numerous years, this demographic has been notably overlooked in terms of health policy and research, with only recent developments beginning to address this issue. In response to emerging data concerning the health disparities faced by the Roma, the European Commission and other international entities have advocated the necessity for measures to narrow the health gap between the Roma and the broader population [1].

2. Materials and Methods

2.1. Study Design and Setting

We conducted an observational, transversal study during October 2022 and March 2024 and evaluated 808 adult patients with diabetes mellitus, aged between 18 and 89 years old, attending a tertiary hospital providing diabetes care, "Nicolae Malaxa" Clinical Hospital in Bucharest, Romania. The study was accomplished following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies [4]. All data were collected in adherence to the hospital's standard protocols for managing patients with diabetes. The study was approved by the Ethics Committee for Clinical Studies of the "Nicolae Malaxa" Clinical Hospital, with the approval number 75/2022. All participants involved in the study granted informed consent for the collection of data and the subsequent utilisation of medical information for research objectives.

2.2. Study Population

The study consisted of adult patients diagnosed with type 1 (T1DM) or type 2 diabetes mellitus (T2DM), who underwent consultations at the hospital's inpatient department throughout the study duration and agreed to participate and signed an Informed Consent. On the contrary, age less than 18 years, absence of diabetes, pregnant women and rejection of signing the Informed Consent represented exclusion criteria.

2.3. Data Collection

Data collection included family history of diabetes, duration of diabetes, personal medical history of obesity, hypertension, heart failure, myocardial infarction, stable angina, stroke, hepatic steatosis, dyslipidemia, lower limb amputations, history of behaviours related to health (smoking and alcohol consumption), presence of microvascular diabetes-related complications (chronic kidney disease, peripheral neuropathy, orthostatic hypotension, retinopathy), socioeconomic and demographic factors (age, gender, place of residence), clinical measurements (anthropometric indicators), as well as paraclinical assessment

The place of residence was sorted by living in the urban or rural area.

Regarding the health-related behaviours, for smoking assessment, patients were classified as smokers (active or former smokers) and noon-smokers, depending on their self-evaluation responses, while for alcohol consumption evaluation, based on the participants´ self-assessment of their drinking habits, they were categorized as drinkers or non-drinkers.

2.4. Clinical Measurements

The following anthropometric indicators were assessed for each participant, including height (cm), weight (kg), maximum weight (kg), abdominal circumference (AC, cm), hip circumference (HC, cm), neck circumference (NC, cm) and body mass index (BMI, kg/m^2). AC and HC were determined using a measuring tape, following the standard procedures.

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2.5. Paraclinical Assessment

The laboratory parameters analysed were fasting plasmatic glycemia (FPG), HbA1c (glycated hemoglobin) level, serum creatinine, eGFR (estimated glomerular filtration rate), UACR (urinary albumin to creatinine ratio), uric acid, serum urea, AST (aspartate aminotransferase), ALT (alanine aminotransferase), GGT (gamma-glutamyl transferase), total cholesterol (TC), HDL (high-density lipoprotein)-cholesterol (HDL-c), LDL (low-density lipoprotein)- cholesterol (LDL-c) and triglycerides (TG).

HbA1c level was determined using the validated HPLC (high performance liquid chromatography) method [5].

eGFR was assessed using the 2021 CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) formula [6].

UACR was obtained using spot urine samples, calculated by dividing the total urinary albumin value in miligrams by creatinine concentration in grams.

LDL-c levels were derived either through calculation using the formula: total cholesterol minus HDL-cholesterol minus triglycerides/5 if triglyceride levels were below 400 mg/dl, or through direct laboratory measurement if triglycerides levels exceeded 400 mg/dl [7].

2.6. Definitions

Diabetes mellitus was defined according to the ADA (American Diabetes Association) guideline criteria [8].

Resting blood pressure was measured using the auscultatory method with the patient in a seated position. Hypertension was characterized by systolic blood pressure (SBP) exceeding 140 mm Hg, diastolic blood pressure (DBP) surpassing 90 mm Hg according to the AHA (American Heart Association) guidelines [9], current use of blood pressure-lowering medication, or a documented medical history of physician-diagnosed hypertension.

To classify the nutritional status according to BMI (body mass index), we used the definition of the World Health Organization (WHO): underweight was defined by a BMI <18.5 kg/ m^2, normal weight by a BMI between 18.5-24.9 kg/m^2, overweight as a BMI between 25-29.9 kg m^2, and obesity by a BMI over 30 kg/m^2 [10].

The diagnosis of hepatic steatosis was made either through imaging techniques, such as an abdominal ultrasound performed during the hospitalization or a medically recorded history of it.

Dyslipidemia was diagnosed by laboratory tests of the lipid profile according to present guidelines or current use of lipid-lowering medication [7].

The diagnosis of chronic kidney disease was established based on the KDIGO criteria, utilising estimated glomerular filtration rate and albuminuria [11].

Eye fundus examination, part of the ophthalmological evaluation, was employed to evaluate diabetic retinopathy, following the protocol outlined in The Early Treatment for Diabetic Retinopathy Study [12].

The ankle-brachial index test was conducted to evaluate peripheral arterial disease; the test outcome, determined by the ankle-to-brachial blood pressure ratio, with a value below 0.9 was indicative of the diagnosis [8].

2.7. Study Outcome

The primary endpoint was to assess the clinical and metabolic particularities of a sample Roma population in comparison with a corresponding group of Romanian Caucasians.

2.8. Statistical Analysis

The IBM SPSS 19th version was used for performing the statistical analysis. The continuous variables normally distributed were presented as mean± SD (standard deviation), non-normal variables were reported as median± IQR (interquartile range) while the categorical variables were presented as absolute counts and percentages. Normality tests employed included the Kolmogorov-

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Smirnov test with a Lilliefors correction for significance and the Shapiro-Wilk statistic. Statistical significance was set at a 95% confidence interval. For quantitative variables, analysis of variance (ANOVA) was used for comparisons among groups, while for categorical variables, the $\chi 2$ test.

3. Results

3.1. General Characteristics of the Patients

The general characteristics of the patients are summarised in Table 1. The study included 458 Roma patients and 350 Caucasian participants, of which the majority were men (54.6% and 51.5%, respectively). In both groups, most of the patients included had T2DM, reaching 95.1% the Caucasian group and 87.8% among the Roma patients. More than half of the participants from both groups did not have a family history of diabetes.

Regarding the place of residence, irrespective of their ethnicity, most of the patients lived in the urban area (65.1% of the Caucasian patients and 52.2% of the Roma patients).

A large proportion of Caucasian patients were non-smokers (73.7%), compared to the corresponding group where the majority of the Roma were smokers (both former or active smokers, 50.4%). Alcohol consumption accounted for 26.9% in the Roma group, while in the Caucasian group, slightly less patients (25.1%) were alcohol users.

Table 1. General characteristics of the patients.

Variables		Caucasian patients (n=350)	Roma patients (n=458)	p-value
Gender	Men	54.6% (n=191)	51.5% (n=236)	0.391
	Women	45.4%(n=159)	48.5% (n=222)	
Place of residence	Urban area	65.1% (n=228)	52.2% (n=239)	0.0001
	Rural area	34.9% (n=122)	47.8% (n=219)	
Type of diabetes	T1DM	4.9% (n=17)	12.2% (n=56)	0.0001
	T2DM	95.1% (n=333)	87.8% (n=402)	
Family history of diabetes	Yes	47.1% (n=165)	45.4% (n=208)	0.625
Smoking (former or active smokers)	Yes	26.3% (n=92)	50.4% (n=231)	0.0001
Alcohol consumption	Yes	25.1% (n=88)	26.9% (n=123)	0.583

3.2. Prevalence of Comorbidities

Regarding the associated diseases, a significant percentage of the Caucasian patients had hypertension (81.1%), approximately 15% higher than the Roma group (67.7%). There were slight differences regarding dyslipidemia, with 78.5% among the Caucasians, and 76.7% among the Roma. Analysing the prevalence of cardiovascular disease, there were no differences concerning the personal history of myocardial infarction, approximately 12% of the patients from each group associating it; however, the number of patients with history of stroke was 2.1 times higher in the Roma group compared to Caucasians (42 versus 20 patients, p=0.067). The prevalence of stable angina and heart failure was significantly lower in the Caucasian group (p=0.0001). Peripheral artery disease was significantly more frequent in the Caucasian group compared to the Roma (21.7% versus 9.6%). A modest percentage of patients suffered from lower limb amputations, with no differences observed between the two groups (Table 2).

Apart from this, a predominance of obesity was noticed, with more than half of the patients in both groups (62.2% in the Roma group and 50.3% in the Caucasian group). Hepatic steatosis was present in 55.3% of the Caucasian participants and 48.5% in the Roma subjects (Table 2).

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Table 2. Prevalence of the patients' comorbidities according to their ethnicity.

Comorbidities	Caucasian patients (n=350)	Roma patients (n=458)	p-value
Hypertension	81.1% (n=287)	67.7% (n=310)	0.0001
Myocardial infarction	12.6% (n=44)	12.0% (n=55)	0.809
Stroke	5.7% (n=20)	9.2% (n=42)	0.067
Stable angina	13.4% (n=47)	29.5% (n=135)	0.0001
Lower limb amputation	3.4% (n=12)	3.5% (n=16)	0.960
Heart failure	5.1% (n=18)	19.0% (n=87)	0.0001
Peripheral artery disease	21.7% (n=76)	9.6% (n=44)	0.0001
Obesity	50.3% (n=176)	62.2% (n=285)	0.003
Dyslipidemia	78.5% (n=275)	76.7% (n=351)	0.0001
Hepatic steatosis	55.3% (n=83)	48.5% (n=214)	0.150

3.3. Prevalence of Diabetic Complications

In the Roma population, chronic kidney disease was present in 22.1% of the patients, while in the Caucasian group, nearly 35% associated this complication. Apart from this, almost a third of the participants from both groups associated diabetic retinopathy, a slightly higher percentage being observed among the Caucasian patients (38.3% versus 33.25%). Orthostatic hypotension was was more prevalent in the Roma population compared to the corresponding group, accounting for 14.6%. The most prevalent microvascular complication was peripheral polyneuropathy, exceeding 70% in both groups (Table 3).

Table 3. Prevalence of diabetic complications according to ethnicity.

Diabetic complications	Caucasian patients (n=350)	Roma patients (n=458)	p-value
Chronic kidney disease	34.9% (n=122)	22.1% (n=101)	0.0001
Peripheral polyneuropathy	78.9% (n=276)	72.7% (n=333)	0.044
Orthostatic hypotension	9.4% (n=33)	14.6% (n=67)	0.026
Retinopathy	38.3% (n=134)	33.2% (n=152)	0.133

3.4. Clinical and Paraclinical Assessments

Comparing the Roma population with the Caucasian group, the mean age was lower in the Roma group (55.62 ±11.55 versus 62.06 ±10.6 years); moreover, the median duration of diabetes was significantly lower (6.00 ±6.89 versus 11.00±8.18 years, p-value=0.0001).

Analysing the anthropometric measurements, the average height of the Caucasian patients was slightly higher compared to the opposite group (166.83±9.68 cm versus 164.54±9.27 cm), but the average weight, abdominal circumference and hip circumference, however, were higher among the Roma patients (87.51±20.12 kg versus 84.81±17.82 kg, 110±15.87 cm versus 103.73±14.70 cm, and 108.61±14.40 cm versus 104.82±14.02 cm, respectively); concerning the mean BMI, the same trend was observed (32.28±7.03 kg/m^2 versus 30.41±5.06 kg/m^2).

Regarding the paraclinical assessments, the Roma patients had a slightly higher mean HbA1c level compared to the Caucasians (9.91±2.45% versus 9.07±2.09%); apart from this, the mean values of the lipid profile were as well significantly higher in this ethnic group, with the exception of the mean value of HDL-c, which was higher among the Caucasian patients. The mean values of the renal profile parameters (creatinine level and uric acid level, respectively) were higher among the Roma patients, but there were no differences regarding the mean urea level. However, the median value of the eGFR level was lower among the Roma patients (80.00± 41.00 ml/min/1.73m^2 versus 83.00± 45.00 ml/min/1.73m^2), but the median value of the urinary albumin to creatinine ratio was quite similar

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(25.00±31.28 mg/g versus 25.13± 104.27 mg/g, respectively). The mean values of the hepatic enzimes were higher among the Roma population compared to the corresponding group.

Table 4. Mean values of the analysed parameters according to ethnicity.

Parameters	Caucasian patients (n=350)		Roma patients (n=458)		Total (n=808)		p-value
	Mean	SD	Mean	SD	Mean	SD	
Age (years)	62.06	10.6	55.62	11.55	58.41	11.59	0.0001
Duration of diabetes (years)	11.00*	8.18	6.00*	6.89	9.00*	7.77	0.0001
Height (cm)	166.83	9.68	164.54	9.273	165.67	9.54	0.001
Weight (kg)	84.81	17.82	87.51	20.12	86.19	19.06	0.059
AC (cm)	103.73	14.70	110.00	15.87	107.08	15.64	0.0001
HC (cm)	104.82	14.02	108.61	14.40	107.20	14.36	0.011
BMI (kg/m^2)	30.41	5.60	32.28	7.03	31.36	6.43	0.0001
HbA1c (%)	9.07	2.09	9.91	2.45	9.53	2.33	0.0001
FPG (mg/dl)	226.35	87.96	232.00*	117.42	243.59	106.46	0.0001
TC (mg/dl)	192.66	65.29	217.12	63.41	205.67	65.40	0.0001
HDL-c (mg/dl)	49.40	14.09	45.57	9.91	47.38	12.20	0.0001
TG (mg/dl)	192.06	138.62	234.39	123.45	214.54	132.39	0.0001
LDL-c (mg/dl)	103.64	48.67	123.11	52.59	113.79	51.64	0.0001
Creatinine (mg/dl)	0.96	0.373	1.04	0.43	1.00	0.407	0.010
eGFR (ml/min/1.73 m^2)	83.00*	45.00	80.00*	41.00	83.00*	41.00	0.255
Urea (mg/dl)	44.56	20.08	44.34	18.49	44.43	19.16	0.904
Uric acid (mg/dl)	5.99	1.98	6.16	2.36	6.06	2.15	0.578
UACR (mg/g)	25.13*	104.27	25.00*	31.28	24.14*	65.7	0.003
AST (UI/l)	20.00*	22.66	23.00*	25.88	22.00*	13.18	0.086
ALT (UI/l)	24.00*	27.31	29.00*	28.75	27.00*	23.00	0.002
GGT (UI/l)	33.35*	102.97	44.00*	47.58	42.00*	38.00	0.081

Abbreviations: AC (cm)- abdominal circumference, HC (cm)- hip circumference, BMI (kg/m^2)- body mass index, HbA1c (%)- glycated hemoglobin, FPG (mg/dl)- fasting plasmatic glycemia, TC (mg/dl)- total cholesterol, HDL-c (mg/dl)- high-density lipoprotein-cholesterol, LDL-c (mg/dl)- low-density lipoprotein-cholesterol, TG (mg/dl)- triglycerides, eGFR (ml/min/1.73m^2)- estimated glomerular filtration rate, UACR (mg/g)- urinary albumin to creatinine ratio, AST (UI/l)- aspartate aminotransferase, ALT (UI/l)- alanine aminotransferase, GGT (UI/l)- gamma-glutamyl transferase.The data has been represented as mean±SD (standard deviation) and median±IQR (marked with "*", IQR- interquartile range). The statistical significance was considered at a p-value<0.05.

4. Discussion

The data that we used is from a Romanian sample of adults, among whom T2DM was predominant. We analysed the clinical and metabolic particularities of a Roma population compared to a corresponding group of Caucasians, including the prevalence of cardiovascular risk factors, cardiovascular disease, health-related behaviours, anthropometric and paraclinical measurements.

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Regarding the prevalence of cardiovascular risk factors, the most frequent factors identified in our study were hypertension, obesity, dyslipidemia, smoking and alcohol consumption. Our findings are comparable with the results from a paper of Enache et al. that analysed a group of Roma patients from Călărași County, Romania, the prevalence of obesity in our study being likewise higher among the Roma patients, however, greater rates being observed, with approximately 60% in the Roma group and 50% in the Caucasian group versus 45.2% and 43.9%, respectively. Hypertension and dyslipidemia were also significantly prevalent among both groups, but the rates were correspondingly higher among the Caucasian participants [13]. Nevertheless, data from another study that compared Roma patients from Călărași County with the general population showed higher percentages regarding the prevalence of obesity, but even so, lower rates than the results in our paper, obesity being present in 43.2% of the Caucasians and 43.3% of the Roma. What should be mentioned is that diabetes (known and newly diagnosed) was present in only 10% and 13.6% of the Roma patients, respectively [14].

Weiss et al. implied a prevalence of 33% of obesity, 33.62% of hypertension, 26.92% of dyslipidemia and 42.55% of smoking among the analysed Roma patients, suggesting lower rates compared to our study; nonetheless, only 15.13% of the patients had diabetes mellitus [15].

In the Predatorr study, a representative research in Romania that included more than 2500 patients, aged between 20 and 79 years old, the prevalence of obesity was 56.4% in patients with known diabetes and 52.3% in patients with unknown diabetes, similar rates being observed only among the Caucasians, the prevalence of obesity among the Roma being higher; however, the prevalence of hypertension was around 64% in patients with both known or unknown diabetes, similar rates being observed only among the Roma; concerning the smoking status, the prevalence was around 50% in patients with both known or unknown diabetes, our paper identifying the same rate among the Roma, a lower rate being observed among the Caucasians [16].

Analysing our results in comparison with those from a Roma population in Serbia, among whom the prevalence of previously diagnosed diabetes was 5.9% and newly diagnosed T2DM was 5.2%, only a third of the patients presented a family history of diabetes; our findings, however, suggested a higher percentage of positive family history of diabetes (45.4%) [17].

In Slovakia, a sample from the Roma population had a BMI above 25 kg/m^2 (55.8% of the Roma men, and 53.4% of the Roma women, respectively), while a significant proportion of them had a BMI higher than 30 kg/m^2 (28,8% of the Roma men and 26.2% of the Roma women, respectively), with a mean waist circumference higher in women than in men [18]. In our study, we analysed the Roma in comparison with a corresponding group of non-Roma and identified a higher mean BMI value among them (32.28 kg/m^2 versus 30.4kg/m^2), as well as higher mean abdominal and hip circumferences (110.00 cm versus 103.73 cm, and 108.61 cm versus 104.82 cm, respectively). It would be intriguing to investigate potential disparities between genders.

In Hungary, data from a sample of Roma people implied that, regarding the anthropometric parameters, they had a lower mean height and weight, but with no differences regarding the average BMI compared to the general population; in our study, only the average weight was higher among the Roma group compared to the Romanian Caucasians, while concerning the mean BMI, there were as well slight differences between the two groups [1].

Although the high frequency of communicable diseases among the Roma is firmly highlighted by the current medical literature, data regarding the prevalence of non-communicable diseases, including cardiovascular disease are still modest. The prevalence of heart disease among the adult Roma population is considered to be around 10% [19]. However, it remains the main cause of premature mortality among this ethnic group, according to a paper from Slovakia [20]. Our study revealed corresponding results, 12% of the Roma participants associating myocardial infarction and 9.2% having a history of stroke. Nonetheless, higher rates were observed concerning stable angina and heart failure, 29.5% of the Roma patients, and 19% of them, respectively.

Concerning the paraclinical examination, a study from Bulgaria revealed higher mean values of the total cholesterol, triglycerides and LDL-c among a Roma population compared to the non-Roma

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group, but a higher average HDL-c level among the latter [21]. These results are in concordance with our findings.

Regarding the prevalence of diabetic microvascular complications among the Roma population, data from the medical literature are scarce. Of the general population with T2DM, chronic kidney disease is considered to affect 25% of the patients, retinopathy is considered to be present in 21% of the patients, while approximately more than 50% of the patients associate polyneuropathy [22]. Our study revealed corresponding data regarding the prevalence of chronic kidney disease among the Roma, but with higher rates observed with reference to peripheral neuropathy and retinopathy. A paper of Weiss et al identified that retinopathy affected 12.5% of the Roma diabetic patients [15].

As regards the prevalence of amputations, a recent study from Romania suggested that 51.2% of the total number of non-traumatic amputations were in patients with diabetes [23]. Other papers indicated a prevalence of 3.6% in the general Romanian population, while a comparison between Romanian Caucasians and Roma patients implied a higher prevalence among the former group (7.5% versus 2.3%) [24,25]. Our study identified a percentage around 3.5% among both groups.

Limitations of the Study

In addressing the constraints of our research, participant recruitment was confined to a single tertiary care hospital amid the COVID-19 pandemic, which may not be representative of the general Roma and non-Roma populations with diabetes, although the sample size is reasonable. Moreover, our study relied on self-reported data for health behaviours like smoking and alcohol consumption, which can be inaccurate due to social desirability bias (people under-reporting unhealthy behaviours).

While our findings align with larger studies comparing the general population to ethnic minorities, there's a scarcity of data on Roma patients. Consequently, we acknowledge the imperative for additional research in this area, with a more in-depth analysis to identify the specific genetic and environmental factors contributing to the higher cardiovascular risk in the Roma population. Considering conducting a longitudinal study to investigate cause-and-effect relationships between observed factors and health outcomes by partnering with community leaders and healthcare professionals from the Roma community could contribute significantly to improving cardiovascular health outcomes and reducing ethnic disparities in healthcare for the Roma population.

5. Conclusions

Taking the above into consideration, the prevalence of cardiovascular risk factors, cardiovascular disease and microvascular complications among the study Roma population are quite significant, underscoring the importance of considering ethnic disparities in approaching healthcare management strategies. As regards the anthropometric and paraclinical assessments, our data demonstrated different characteristics of the Roma in comparison to a corresponding group of Caucasians, which highlight the importance of tailoring healthcare interventions to the specific needs and cultural context of this ethnic minority. Further research is warranted to explore the underlying factors contributing to these differences, potential genetic or environmental factors, and to develop targeted interventions in high- risk populations.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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Data Availability Statement: The data presented in this study are available on request from the corresponding author.

The data are not publicly available due to the hospital's privacy policy.

Conflicts of Interest: The authors declare no conflicts of interest.

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