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ORIGINAL ARTICLE

Prevalence of limb amputations in a Roma population compared to Caucasians, in patients with diabetes mellitus

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Abstract

Introduction. Over the last few years, lower limb amputations have represented a prevalent worldwide burden in the evolution of diabetic patients, but at what extent this burden affects the Roma population compared to Caucasians in Romania still needs further comprehension.

Aim. The purpose of this study was to assess the prevalence of lower extremities amputations in a Roma population, compared to a Caucasian population, in the presence of diabetes mellitus (DM), as well as to identify the risk factors associated.

Materials and methods. We included 536 patients, of whom 257 Roma subjects and 279 Romanian Caucasians, with the following socio-demographic status: the Roma group included 123 women (48.1%) and 134 men (51.9%), aged between 18 and 86 years, while the Caucasian group registered 107 women (47.9%) and 172 men (61.6%), aged between 18 and 89 years.

Results. Analyzing the whole group, the prevalence of amputations was 5% (n=27). A greater proportion of amputations was found in Romanian Caucasians (n=21, 7.5%), where there were 17 men (9.9%) and 4 women (3.7%) affected, compared to the Roma population (n=6, 2.3%), where all amputations occurred in men. Noticeably, this complication is more predominantly afflicting men.

Conclusions. Non-traumatic lower extremity amputation remains a challenge today in the care of diabetic patients. In our study, higher rates of amputations were observed in Romanian Caucasians, in comparison with the Roma population. Apart from this, this condition was accompanied by many cardiovascular risk factors.

Keywords: lower limb amputations, Roma population, diabetes mellitus

Introduction

One of the most challenging clinical problems related to diabetes mellitus nowadays is lower limb amputation, holding a 10-20 fold higher incidence compared to non-diabetic patients [**1**]. As reported by the International Diabetes Federation (IDF) in the 9th edition of their atlas published in 2019, foot ulcers affect 2% of the people with diabetes every year. Of uttermost importance, it has been estimated that every 30 seconds a lower limb is lost as a consequence of diabetes worldwide [**2**]. Accordingly, 14 amputations in patients with diabetes are performed daily in Romania [**3**]. Between 2006 and 2010, data from all hospitals in Romania suggested that 16,873 non-traumatic diabetes related lower limb amputations were performed in diabetic patients over this 5-year period of time [**4**].

Nonetheless, there is less evidence of the incidence of lower limb amputations among Roma population, one of the largest minority ethnic groups in Romania. This minority consists of more than 600.000 Roma members, depicting around 3% of the population, but these findings could not be very accurate, as many Roma adults may not enlist their ethnic identity in the national census programs [**5**]. The Roma population minority is estimated at approximately 12 million people, being the largest in Europe, with almost 6 million living in the European Union in 2019 [**6**].

Aim

The purpose of this study was to compare the prevalence of limb amputations of diabetic Roma patients with the prevalence of a Caucasian population, in people with diabetes.

Materials and methods

Study design

This cross-sectional case-control trial was conducted between January and December 2019 in the Diabetes, Nutrition and Metabolic Diseases Department from "Nicolae Malaxa" Clinical Hospital in Bucharest, Romania. A written informed consent was obtained from all participants. The study was approved by the local Ethics Committee.

Participants

The studied population consisted of 536 patients: 257 Roma patients and 279 Romanian Caucasian patients.

On one hand, the inclusion criteria comprised Roma patients, as well as Caucasians, aged over 18 years old, with type 1 or type 2 diabetes mellitus, on the other hand, the exclusion criteria enclosed patients under 18 years old, pregnant or nursing women or patients who refused to accept and sign the informed consent notice.

Assessments

Patients were subjected to a complete medical evaluation, including medical history, clinical evaluation, as well as paraclinical evaluation including biochemical investigations, electrocardiogram (ECG), blood pressure, ankle-brachial index (ABI), eye fundus examination and diabetic neuropathy tests. The anthropometric parameters included height, weight, body-mass index (BMI) and abdominal circumference.

Laboratory findings

The laboratory findings included blood count, fasting glycemia, glycated hemoglobin (A1c), lipid profile: total cholesterol (TC), high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol fractions, triglycerides (TG); liver function tests, renal function tests (serum creatinine and urea; eGFR according to CKD-EPI equation, urinary albumin/ creatinine ratio (UACR).

Definitions

The classification of body-mass index (BMI) was defined by World Health Organization's (WHO) recommendation [**7**].

The abdominal obesity was characterized as waist circumference over 80 cm in women and over 94 cm in men, respectively [**8**].

High blood pressure was defined as a blood pressure ≥ 140/ 90 mmHg, as stated in the 2018 European Society of Cardiology (ESC)/ European Society of Hypertension (ESH) Guidelines [**9**].

The ankle-brachial index (ABI) test performed to assess the peripheral vascular disease (PVD) or peripheral arterial disease (PAD) compares the ankle blood pressure with the brachial blood pressure. The test result is defined by the ankle/ brachial blood pressure ratio. A value below 0.9 is useful in diagnosing PAD [**10,11**].

Chronic Kidney Disease (CKD) was categorized according to KDIGO classification, using estimated glomerular filtration rate (eGFR) and albuminuria [**11,12**].

Eye fundus examination included in the ophthalmological evaluation was used to assess diabetic retinopathy (DR), as reported by The Early Treatment for Diabetic Retinopathy Study [**13**].

Low-density lipoprotein cholesterol (LDL-c) concentration was obtained using the Friedewald formula [**14**].

Statistical analysis

Regarding the statistical research, data were collected using the Statistical Package for the Social Science (SPSS) 19 software. The set of data assay consists of numbers (percentage %), mean (± standard deviation) and median (interquartile range) values. The ANOVA (analysis of variance) model was used for quantitative variables and the Chi-squared test (χ^2 test) was used to validate categorial variables for both group comparisons. Statistical significance applies for 95% confidence interval.

Results

The prevalence of amputations among the group of patients studied was 5% (n=27), while the prevalence of PAD was 17.7% (n=95).

There were no statistically significant differences of mean age between the two groups included in the trial, with a mean age of 62.67 years in the Roma population, compared to 60.48 years in Romanian Caucasians who suffered a lower extremity amputation (**Table 1**).

Table 1. General characteristics of patients who underwent amputations, in Romanian Caucasians and Roma population

	Romanian Caucasians			Roma population			p#
Parameters	**Mean (Median)**	**Std. Deviation (IQR)**	**p***	**Mean**	**Std. Deviation**	**p***	
Age (years)	60.48	8.59	NS	62.67	8.35	NS	NS
Duration of diabetes (years) ##	12	11	NS	7	10	NS	NS
Height (cm)	171.6	7.68	NS	177	5.91	0.002	NS
Current weight (kg)	89.15	21.71	NS	87.4	8.08	NS	NS
BMI (kg/ m^2)	30.50	6.81	NS	28.01	3.44	NS	NS
AC (cm)	106.23	21.90	NS	107.6	4.87	NS	NS
HC (cm)	106.25	15.45	NS	103.75	7.13	NS	NS
SBP (mmHg)	128.33	19.32	NS	146.67	24.22	NS	NS
DBP (mmHg)	78.33	8.85	NS	84.17	11.14	NS	NS
A1c (%)	7.91	1.37	0.02	9.3	1.97	NS	NS
TC (mg/ dl)	168.62	45.83	NS	264.8	83.38	NS	NS

HDL-c (mg/ dl)	45.55	10.22	NS	38.8	6.76	NS	NS
LDL-c (mg/ dl)	91.23	32.32	NS	140	21.10	NS	0.009
Triglycerides (mg/ dl) ##	140.2	114	NS	211	150	0.013	0.022
Serum creatinine (mg/ dl)	1.46	1.63	0.007	1.15	0.21	NS	NS
eGFR (ml/ min/ 1.73m^2)	72.19	32.55	0.046	66.66	17.71	NS	NS
UACR (mg/ g) ##	23.2	128.1	NS	27	23	NS	NS

***Abbreviations**: BMI = Body Mass Index; AC = abdominal circumference; HC = hip circumference; SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; A1c = glycated hemoglobin fraction; TC = total cholesterol; HDL-c = high density lipoprotein cholesterol;*
LDL-c = low density lipoprotein cholesterol; TG = triglycerides; eGFR = estimated glomerular filtration rate; UACR = urinary albumin/ creatinine ratio
p* difference among the group, in Romanian Caucasians and Roma population, respectively, in patients who underwent amputations
p# difference between Romanian Caucasians and Roma population in patients who underwent amputations
data are expressed as median and interquartile range

As presented in **Fig. 1**, the majority of the patients with lower limb amputations were between 50 and 59 years old in Romanian Caucasians, while most Roma patients with this complication were more than 60 years old.

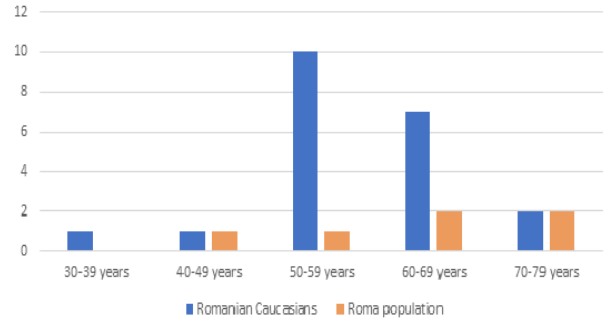

Fig. 1 Rates of amputation in various age groups in Romanian Caucasians and Roma population

The duration of diabetes was slightly higher in Romanian Caucasians versus Roma patients, but with no statistically significant association was noted between the groups. Moreover, in contrast with the Roma population, no differences regarding BMI or metabolic circumferences (abdominal and hip circumferences) were observed in the Romanian Caucasians (**Table 1**).

Concerning the glycemic control, A1c value was above target in both groups, but considerably higher in the group of Roma subjects, with a mean value of 9.3%, in comparison with 7.91% in the group of Romanian Caucasians with a history of amputation. The differences between the two groups included were not significant statistically.

Regarding the lipid profile, LDL-c and triglycerides were statistically significantly higher in the Roma population (all $p<0.005$).

The Roma population with lower limb amputations evaluated in the trial appeared to have a more impaired renal function profile, with a relatively more decreased eGFR mean value of 66.66 ml/ min/ 1,73m^2, compared to 72.19 ml/ min/ 1,73 m^2 in the opposed group (**Table 1**).

A greater proportion of amputations was found in the Romanian Caucasians (n=21, 7.5%), where there were 17 men (9.9%) and 4 women (3.7%) affected, compared to the Roma population (n=6, 2.3%), in which all amputations occurred in men.

Regarding the group of patients who underwent an amputation, in the Romanian Caucasians (n=21, 7.5%) there were 17 men (9.9%) and 4 women (3.7%) affected, compared to the Roma population, in which all the amputations occurred in men (n=6; 2.3%).

All the patients found in the Roma population had type 2 diabetes mellitus, while the majority of Romanian Caucasians with amputations had this type of diabetes (n=19; 90.5%) (**Table 2**).

Table 2. Cardiovascular risk factors and target organ damage related to DM, in Caucasians and Roma patients who underwent lower-limb amputations

Parameters	Romanian Caucasians (n=21)		p*	Roma population (n=6)		p*	p#
Gender	Men	Women	NS	Men	Women	0.018	NS
	17 (81%)	4 (19%)		6 (100%)	0 (0%)		
Smoking	2 (9.5%)		NS	3 (50%)		NS	0.024
Type 2 diabetes	19 (90.5%)		NS	6 (100%)		NS	NS
HBP (mmHg)	15 (71.4%)		NS	5 (83.3%)		NS	NS
Obesity	11 (52.4%)		NS	1 (16.7%)		NS	NS
Hypercholesterolemia	7 (33.3%)		NS	6 (100%)		NS	0.004
Hypertriglyceridemia	7 (33.3%)		NS	5 (83.3%)		NS	0.03
LDL-c >100 mg/ dl	8 (38.1%)		NS	6 (100%)		NS	0.007
A1c > 8%	9 (42.9%)		NS	4 (66.7%)		NS	NS
CKD	13 (61.9%)		0.041	4 (66.7%)		NS	NS
DR	13 (61.9%)		0.001	2 (33.3%)		NS	NS
DN	19 (90.5%)		NS	6 (100%)		NS	NS
IHD	21 (100%)		0.001	5 (83.3%)		NS	NS
MI	1 (5%)		NS	0 (0%)		NS	NS
AP	11 (55%)		< 0.001	0 (0%)		NS	0.021
Stroke	5 (25%)		< 0.001	1 (16.7%)		NS	NS

Abbreviations: *HBP = High Blood Pressure; LDL-c = low density lipoprotein cholesterol; A1c = glycated hemoglobin fraction; CKD = chronic kidney disease; DR = diabetic retinopathy; DN = diabetic neuropathy; IHD = ischemic heart disease; MI = myocardial infarction; AP= angina pectoris;*

p* difference among the group, in Romanian Caucasians and Roma population, respectively in patients who underwent amputations

p# difference between Romanian Caucasians and Roma population in patients who underwent amputations

With respect to PAD, in the Caucasian group of patients, there were 18 women (28.6%) and two and a half more men (n=45; 71.4%) diagnosed, while in the Roma population, 9 women (28.1%) and 23 men (71.9%) were identified with this condition.

These results depict not only a higher prevalence of lower limb amputations, but also a predominance of PAD in men (**Table 2**).

Cardiovascular risk factors and lower-limb amputation

Among the patients who suffered an amputation, we found that 9.5% of the Caucasians (n=2) and 50% of the Roma patients were smokers. Moreover, our findings suggested that smoking was more frequent in Roma patients who suffered an amputation. High Blood Pressure (HBP) was found in 71.4% of the Romanian Caucasians (n=15) and in 83.3% of the Roma population (n=5). Prevalence of obesity was 3 times higher in the amputated-Caucasians group (52.4%, n=11) compared to the Roma patients (16.7%, n=5), although the prevalence of obesity was higher among the Roma population (**Table 2**).

Lipid profile

The lipid panel measures, including total cholesterol, triglycerides and LDL-c fraction were higher in the Roma population (all p<0.005; **Table 2**).

Glycemic imbalance and lower-limb amputation

A poor glycemic control, with A1c hemoglobin fraction above 8% was observed in less than a half of the Romanian Caucasians who had a lower extremity amputation (n=9; 42.9%), compared to the Roma population, in which our findings reflected that 4 out of 6 (66.7%) had this modification (**Table 2**). This parameter did not show statistical relevance. However, it is of utmost importance for people with diabetes to achieve optimal blood glucose levels in order to prevent long-term infirmities.

Chronic complications of DM and lower-limb amputation

61.9% (n=13) of the Romanian Caucasians who underwent an amputation had diabetic retinopathy, while only 33.3% (n=2) of the Roma group presented DR. Concerning the diabetic neuropathy, in the amputated-Roma group, all the participants were affected (100%, n=6) compared to 90.5% (n=19) of the amputated – Romanian Caucasians group (**Table 2**).

Target organ damage related to DM and lower-limb amputation

Angina pectoris and myocardial infarction were found in 55% (n=11) and 5% (n=1) of the Romanian Caucasians, while no patient of the Roma group presented these target organ damages. A higher prevalence of stroke was also found in Romanian Caucasians, in whom 25% (n=5) were affected, compared to 16.7% (n=1) of Roma patients. In the studied groups, all the Caucasians had ischemic heart disease (100%, n=21) compared to only 83.3% (n=5) among the Roma population (**Table 2**).

Discussions

Diabetes mellitus alongside with smoking are the strongest risk factors for peripheral arterial disease and furthermore for systemic atherosclerotic disease, whose course is accelerated by the presence of DM [**15**]. PAD is associated with increased risk of lower extremity amputation, causing significant long-term disability in diabetic patients. Previous studies have shown that 20-30% of the patients with PAD have DM and more than 50% of the patients with critical limb ischemia (CLI) also have DM [**16**]. The prevalence of major amputation in patients with DM ranges in different studies from 5 to 15 times greater than nondiabetic patients [**17**]. 50-70% of the non-traumatic amputations are performed in diabetics and up to 90% of these amputations are preventable if an aggressive, prompt and correct line of treatment is followed [**18**].

With respect to lower extremities amputations, one study conducted in Romania revealed a prevalence of 3,5% among adult diabetic patients [**19**]. Our results are accordingly, with a 5% history of amputations in the participants studied. Amputation rates increase with age, as various studies in the medical literature assert, and are found more frequently in active subjects, aged between 20 and 60 years old [**4,19**]. However, there is great variability worldwide in the incidence of lower extremity amputation in patients with diabetes, depending on their ethnicity and social discrimination [**20**]. Our findings regarding the fact that men are more likely to undergo diabetes-related lower limb amputation are consistent with other studies conducted in different populations [**21,22**]. These gender differences persisted among both ethnic groups, Romanian Caucasians and Roma.

There is a lack of evidence in literature about the prevalence of diabetes-related lower limb amputations in the Roma population. Results of our study showed a lower prevalence of this complication (2.3%), but further studies are needed to sustain these findings.

The most common cardiovascular risk factors among Roma patients were dyslipidemia, with high levels of LDL-cholesterol, followed by a personal history of active heavy smoking status and an increased abdominal circumference [**23-25**]. Hypertension is also a prevalent condition among Roma patients [**23**]. These markers increase the risk of amputation, and data from our study revealed complementary findings in Roma patients: they have higher mean SBP and DBP, higher mean values of LDL-c and TG and lower HDL-c fraction, compared to the Romanian Caucasians group. Several studies found that age, duration of diabetes and peripheral neuropathy are associated with an increased risk of PAD and therefore of lower limb amputations in patients with DM [**26**]. Interestingly, in our Roma studied

group, when compared to the Romanian Caucasians population who underwent an amputation, we found that they were older (mean age = 62.67 vs. 60.48), had a shorter duration of DM (mean duration of DM was 12.67 vs. 15.49 years) and a higher prevalence of DN (n=6, 100%) versus 19 (90.5%). Roma patients were also found to have higher rates of smoking (50% versus 9.5%), enhancing the major impact of socio-economic factors in the health status of this ethnic group [**27**].

Limitations of the study

We consider that one of the limitations of this cross-sectional case-control study that can be noted is the fact that we included exclusively hospitalized patients, and the data might not be valid for the entire population of Roma, and Caucasians, respectively. For this reason, our findings might not be representative for a larger population with diabetes. Apart from this, low prevalence of several diseases among Roma population might be related to a more limited access to healthcare delivery, that leads to an underestimation of rates.

Conclusions

Considering the studies reviewed, non-traumatic lower limb amputations are quite a prevalent complication of diabetes in patients with several cardiovascular risk factors associated, including hypertension, dyslipidemia with abdominal obesity and smoking, particularly affecting men, and our study fortified these findings. When comparing amputation rates in Caucasians with the Roma population in Romania, they were higher in the first group. Apart from this, our findings suggested that Roma participants had more elevated blood glucose and A1c levels than the Romanian Caucasians, although rates of amputation were higher in the last category. Nonetheless, tight glycemic control is the essential element in the management of diabetes complicated by lower limb amputations.

Non-traumatic lower extremity amputation remains a challenge today in the care of diabetic patients, and still needs thorough improvement in order to reduce fatal consequences.

Conflict of Interest statements

Authors state no conflict of interest.

Informed Consent and Human and Animal Rights statements

Informed consent has been obtained from all individuals included in this study.

Authorization for the use of human subjects

Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies, is in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent commitee.

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