Coll. Antropol. **44** (2020) 3: 147–153
Original scientific paper

Incidence of Lower Limb Amputation in Diabetic Patients in Osijek-Baranja County

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ABSTRACT

Amputation of the lower limb (LLA) is one of the most feared adverse outcomes among diabetic patients. Our aim was to determine the incidence of amputation in diabetic patients in Osijek-Baranja County and to examine the possible correlation between clinical characteristics of the patients and the time elapsed before the first amputation. This was a tertiary-care-based retrospective study and included 925 diabetic patients who underwent non-traumatic lower limb amputation in the University Hospital Osijek from January 1st 2008 to December 31st 2018. Data on associated cardiovascular risk factors and clinical characteristics of the patients were collected from diabetic registry of the Department of diabetes and endocrinology. A total of 278 patients had all data for further analysis. There were 1551 LLAs over a ten year period. The incidence was 6.14 per 1,000 adults with diabetes. LLA rates per 1,000 adults with diabetes decreased by 29% between 2010 and 2013 and then increased by 76% between 2014 and 2018. In ten year period incidence of amputation in diabetic patients varied from 4 to 7.8 per 1000 persons-year. We observed the same pattern in both minor and major LLA but rates of amputation above knee steadily increased 2.7 times between 2010 and 2018 (from 0.69 to 1.83 per 1000 patients-year). The mean age of patients with LLA was 67.2 years, 66% were male, mean BMI was 29.6±4.8 kg/m² and the mean duration of diabetes was 14.7±8.2 years. There was no association between smoking, arterial hypertension and hyperlipemia, ACE inhibitor use, statin use, antiplatelet use, CVD, neuropathy and duration of diabetes before first amputation. Only sulphonylurea and insulin therapy significantly prolonged the time before the first amputation (p = 0.00001, for each). In conclusion, our study confirmed high rate of lower limb amputation in diabetic patients in Osijek-Baranja County. Incidence rates of LLA in our population are important for further improvements in diabetes care and decisions in health care policy.

Key words: *diabetes mellitus, peripheral artery disease, lower limb amputation, risk factors, Osijek-Baranja County*

Introduction

Diabetes mellitus (DM) is a major risk factor for all forms of cardiovascular disease, which is the most common cause of death for patients with diabetes[1]. DM is also a strong risk factor for peripheral artery disease (PAD), defined as atherosclerosis in lower extremity arteries or LEAD[2]. PAD is an important predictor of ulceration of the foot and limb loss in diabetic patients[2]. It is present in 50% of patients with diabetic foot ulceration a proportion which may be increasing[2,3]. Patients with diabetes and PAD have an increased risk of adverse cardiac and limb events[3,4]. Lower extremity amputation (LEA) is one of the most devastating consequences of PAD and diabetic foot ulceration.

Received for publication August 15, 2020

LEAs reduce the quality of life[5] and increase mortality[6] as well as medical costs[7].

USA National surveillance data showed that rates of non-traumatic LEA declined by about half between 1990 and 2010 mainly by improving diabetes control, screening and detection of vascular disease and revascularization techniques thus minimizing the onset of complications such as PAD and neuropathy[8,9]. However, the most recent trends in USA showed the increase in rates of total, major, and minor amputations which were most pronounced in young and middle-aged adults and may indicate a reversal in the progress of diabetes care[10].

There are significant geographic variations in the rates of LLA between different countries[11] and across the USA and UK[12]. To our knowledge there is no data about LLA incidence in Croatia either in diabetics or in non-diabetics. Our aim was to determine the incidence of amputation in patients with diabetes mellitus in Osijek-Baranja County and to examine the possible correlation between cardiovascular risk factors and other specific clinical and general characteristics of the patients and the time elapsed before the first amputation.

Methods

This was a tertiary-care-based retrospective study involving adult patients in whom amputation were performed for reasons relating to complication of PAD and/or diabetes in the Department of vascular surgery, University Hospital Centre Osijek from 1st January 2008 to 31st December 2018. This study complied with the Declaration of Helsinki and was approved by ethics committee of University Hospital Osijek. Informed and written consent was not required by the ethics committee, this waiver was due to the retrospective nature of our study. No personal data that could be linked to a patient were used. Patient with diabetes were defined as those with discharged diagnosis diabetes mellitus or code E10-13. LLAs were categorized by level of amputation as follows: minor amputation (toe and foot) and major amputation (above foot and below knee, and above knee). If there was more than one operation during a single admission, only one (the highest) was counted, but when amputations occurred during separate admissions they were counted as separate episodes. We calculated LLA rates using estimates of the population with diabetes derived from CroDiab registry and Croatian Institute for Public Health for our county. Data on associated cardiovascular risk factors (arterial hypertension, hyperlipidemia, smoking) and other clinical characteristics (age, gender, type of diabetes, duration of diabetes, diabetic therapy, complications of diabetes) of the patients were collected from diabetic registry of the Department of diabetes and endocrinology. A total of 278 patients had all data for further analysis.

Statistical analysis

We described data using means and medians and compared them using either the Student t-test or Mann Whitney U-test for paired comparisons depending on whether the variables were parametric or non-parametric. We tested differences in frequencies for significance using the Chi-square test or Fishers Exact tests. Association between the time elapsed before the first amputation and smoking, diabetic therapy and other clinical characteristics were analyzed using Spearman's rank correlation coefficient. We created Cox proportional hazard regression analysis models to determine factors that predicted the time elapsed before the first amputation.

Results

There were 1551 LLAs in ten year period. Smaller proportion of amputations were major amputations i.e. above foot (49.3% vs. 59.3%). The incidence was 6.14 for 1,000 adults with diabetes. LLA rates per 1,000 adults with diabetes per year decreased by 29% between 2010 and 2013 and then increased by 76% between 2014 and 2018 (Figure 1). In ten year period incidence of amputation in diabetic patients varied from 4 to 7.8 per 1000 patients-year with increasing trend from 2014 to 2018. We observed the same pattern in both minor and major LLA but rates of amputation above knee steadily increased 2.65 times between 2010 and 2018 (from 0.69 to 1.83 per 1000 patients-year).

Among 925 diabetic patients with LLA we identified a group of 278 patients with complete clinical data for further analysis. Their characteristics are shown in Table 1. The mean age of patients with LLA was 67.2 years, 66% were male, almost all diabetes-related LLA occurred in

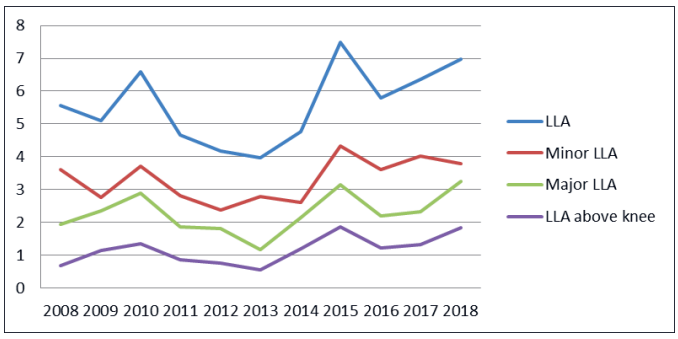

Fig. 1. Total, minor and major lower limb amputation incidence per 1,000 diabetic patient per year

TABLE 1

BASELINE CHARACTERISTICS OF PARTICIPANTS

		Number of participants (N)	Percentage (%)	Mean	SD	Median	IQR
Gender	Females	94	34				
	Males	184	66				
Age (years)				67.24	10.39	68.00	60.00–75.00
Type of diabetes	1	13	5				
	2	262	94				
	NK	3	1				
Duration of diabetes (years)				14.73	8.19	15.00	9.00–20.00
HbA1c				9.12	1.86	9.30	7.70–10.40
BMI (kg/m^2)				29.63	4.76	29.10	26.40–32.10

HbA1c – glycated hemoglobin, BMI – body mass index, SD – standard deviation, IQR – interquartile range, NK – not known

type 2 diabetes patients (94%) and the mean duration of diabetes was 14.7±8.2 years. Metabolic control was poor (HbA1c 9.1±1.9%), and they were overweight and/or obese (BMI 29.6±4.8 kg/m^2).

At the time of amputation 46% of diabetic patients were taking oral diabetic drugs (Table 2), mostly sulfonylureas (80%), only 33% were taking metformin. At the time of amputation 51% of patients were on insulin therapy. ACE

TABLE 2

ORAL ANTIHYPERGLICEMIC THERAPY

		Number of participants (N)	Percentage(%)	Mean	SD	Median	IQR
Oral antidiabetics at the time of amputation	Yes	127	46				
	No	100	36				
	NK	51	18				
Sulfonylurea	Yes	223	80				
	No	20	7				
	NK	35	13				
Duration (years)				7.13	6.36	6.00	2.00–11.00
Metformin	Yes	91	33				
	No	152	55				
	NK	35	12				
Duration (years)				1.27	2.8	0.00	0.00–0.75
Insulin therapy	Yes	42	15				
	No	200	72				
	NK	36	13				
Duration (years)				4.43	6.79	1.00	0.00–7.00
ACE inhibitors	Yes	112	40				
	No	132	48				
	NK	34	12				
Statins	Yes	148	53				
	No	98	35				
	NK	32	12				
Antiplatelet therapy	Yes	75	27				
	No	169	61				
	NK	34	12				

NK – not known

TABLE 3

CVD AND DIABETIC COMPLICATIONS

		Number of participants (N)	Percentage (%)
Hystory of myocardial infarction	Yes	35	13
	No	218	78
	NK	25	9
Hystory of ishemic stroke	Yes	41	15
	No	212	76
	NK	25	9
Diabetic polyneuropathy	Yes	87	59
	No	165	32
	NK	26	9

inhibitors had 40%, statin had 53% and antiplatelet therapy 27% of patients.

Tables 3 and 4 show CVD, CVD risk factors and diabetic complications at time of amputation. There was no association between smoking, arterial hypertension and hyperlipidemia and duration of diabetes before the first amputation (Table 4). Also, there was no association between ACE inhibitor use, statin use, antiplatelet use and diabetes duration before first amputation (Table 5). CVD and neuropathy had no impact on the time elapsed before the first amputation.

When we look at the association between oral diabetic drug and the time elapsed before the first amputation (Table 6), only sulfonylurea and insulin therapy significantly prolonged the time before the first amputation (p=0.00001, for each). For DPP4 inhibitors there was non-significant association (p=0.06) probably due to a small number of patients (only 19 or 7% of patients).

Discussion

Our study confirmed high rate of lower limb amputation in diabetic patients in Osijek-Baranja County. In ten year period there were 1551 lower limb amputations in 925 patients. The incidence was 6.14 for 1,000 adults with diabetes. After a decreasing trend in overall LLA incidence, from 2014 to 2018 amputations increased again,

TABLE 4

ASSOCIATION BETWEEN RISK FACTORS AND DURATION OF DIABETES AT THE TIME OF FIRST AMPUTATION

		Duration of diabetes (years)						
		Number of participants (N)	Percentage (%)	Mean	SD	Median	IQR	p
Arterial hypertension	Yes	219	14.82	8.54	15.00	8.00–20.00	8.00–20.00	0.74
	No	59	14.42	7.22	14.00	9.00–19.00	9.00–19.00	
Hyperlipidemia	Yes	158	13.88	7.05	15.00	8.00–19.00	8.00–19.00	0.06
	No	118	15.70	9.38	14.50	9.00–21.00	9.00–21.00	
Smoking	Yes	45	13.80	8.07	16.00	10.00–17.00	10.00–17.00	0.16

SD – standard deviation, IQR – interquartile range, NK – not known

TABLE 5

ASSOCIATION BETWEEN CONCOMITANT THERAPY AND DIABETES DURATION AT THE TIME OF FIRST AMPUTATION

		Duration of diabetes (years)					
		Number of participants	Mean	Number of participants	Medijan	IQR	p
Statins	Yes	148	14.59	7.99	15.00	8.00–19.50	0.72
	No	98	14.22	8.23	14.00	9.00–20.00	
ACE-inhibitors	Yes	112	14.67	9.03	14.00	8.50–20.00	0.67
	No	132	14.23	7.15	14.00	8.50–19.00	
Anti platelet therapy	Yes	75	14.12	6.80	14.00	10.00–19.00	0.66

SD – standard deviation, IQR – interquartile range, NK – not known

TABLE 6

ASSOCIATION BETWEEN ANTIDIABETIC THERAPY AND DIABETES DURATION AT THE TIME OF FIRST AMPUTATION

		Duration of diabetes (years)					
Antidiabetic therapy		Number of participants (N)	Mean	SD	Median	IQR	p
Oral antidiabetics at the time of amputation	Yes	127	12.04	6.98	11.00	6.00–17.00	0.000009
	No	100	16.94	8.79	16.50	11.50–21.00	
Sulfonylurea	Yes	223	15.06	7.69	15.00	10.00–20.00	0.00001
	No	20	8.25	6.54	7.00	3.00–12.00	
Metformin	Yes	91	14.34	7.04	14.00	10.00–19.00	0.81
	No	152	14.59	8.26	15.00	8.00–20.00	
Meglitinides	Yes	42	15.33	7.29	15.00	9.00–22.00	0.45
	No	200	14.34	7.85	14.50	8.50–19.50	
Alfa Glukozidase inhibitors	Yes	27	16.88	6.50	17.00	13.00–20.00	0.08
	No	216	14.20	7.93	14.00	8.00–20.00	
DPP – 4 inhibitori	Yes	19	11.36	7.08	11.00	5.00–16.00	0.06
	No	218	14.72	7.88	15.00	9.00–20 00	
Insulin at the time of amputation	Yes	142	16.30	8.07	16.00	11.00–21.00	0.00001
	No	99	11.66	7.65	10.00	5.00–17.00	

SD – standard deviation, IQR – interquartile range

with LLA rates from 4 to 7.8 per 1000 persons-year. The same pattern was observed for both minor and major amputations. However, the rates of amputations above knee steadily increased from 0.69 to 1.83 per 1000 persons-year, 2.7 times in ten years period. The rate of LLA has been considered as an indicator of the quality of diabetic foot care reflecting delayed management of diabetic foot and diabetic foot complication as well as difficulties in diagnosis and treatment of PAD[2]. In our study there were more minor than major amputations. The increase in minor amputations may reflect a more aggressive clinical approach, since earlier toe amputations may prevent more serious amputations. Therefore, in our study there was considerable increase in minor amputations from 2013 to 2018.

In a large international survey of 12 European countries and New Zealand on amputation rates for PAD from 2010 to 2014, significant differences were identified between countries, with the mean incidence of major amputation being highest in Hungary (41.4/100,000) and lowest in New Zealand (7.2/100,000) with an overall declining trend for major amputations, except for Slovakia[11]. In a recent meta-analysis of population-based studies on incidence, relative risks and changes of amputation rates over time in diabetic and non-diabetic population considerable differences between studies were recorded[13]. The incidence of LLA in the diabetic population ranged from 78 to 704 per 100,000 person-years and the relative risks between diabetic and non-diabetic patients varied between 7.4 and 41.3[13]. In England the incidence of LLA was 2.51 per 1,000 person-years in people with diabetes[12]. Moreover, there was considerable regional variation within country, and the incidence varied tenfold–both for major (range 0.22–2.20 per 1,000 person-years) and minor ones (range 0.30–3.25 per 1,000 person-years)[12]. USA National surveillance data showed that rates of LLAs declined by about half between 1990 and 2010 mainly by improving access to effective primary care, with improved control of blood sugar and interventions to minimize the onset of complications such as peripheral arterial disease and neuropathy[13,14]. However, the most recent trends in USA for 2000-2015 showed that LLA incidence decreased 45% from 2000-2009, but then rebounded by 50% between 2009 and 2015[10]. The reversal in amputation rates was driven primarily by increases in younger and middle-aged adults and men and may indicate a reversal in the progress of diabetes care[10]. In our study, increase in LLA incidence from 2014-2018 may indicate that after improvement in previous years (2008-2013) amputation rates in diabetic patients again began to increase. Reasons for that reversal trend are unclear. It can be due to failures in the prevention of major lower-extremity disease, delayed diagnosis and treatment of PAD, poor management of CVD risk factors and poor glycemic control. It is also possible that changes in health policy and organization of diabetes care in 2013 and changes in access to effective diabetic care in Croatia together with socio-economic factors could have affected trends of LLA.

There are a number of studies in different countries that have shown that it is possible to reduce the incidence of amputation in diabetes by implementing changes to the structure of diabetes foot ulcer care and after introduction

of multidisciplinary team for diabetic foot[15,16]. However, despite the implementation of a care plan for patients with diabetes, the incidence of LLA has not fallen in Andalusia in recent years[17].

In our study we have analyzed characteristics of patients which could influence greater amputation risk. The mean age of our diabetic patients was over 65 years and 66% were male. Despite a high prevalence of uncontrolled vascular risk factors such as hypertension, hyperlipidemia and diabetes, only 54%, 40% and 27% of those with LLA were on lipid-lowering, ACE inhibitor and antiplatelet therapy. Male gender was previously identified as a risk factor for PAD and some studies found higher incidence of LLA among men than women in both the diabetic and the non-diabetic population[13]. Moreover, men were younger at the time of LLA then women[17]. The increased amputation rates among men may be explained by environmental factors such as smoking as well as by a higher prevalence of peripheral vascular disease, peripheral neuropathy and diabetic foot ulceration. Our diabetic patients had poor metabolic control with high HbA1c which could reflect serious condition before amputation, with inflammation and/or sepsis. Good metabolic control and diabetes management is very important in delaying amputation. In our study only sulfonylurea and insulin treatment significantly prolonged time to first amputation. Therefore, improvement in diabetes management and care, management of CVD risk factors, good foot care and early detection of PAD are warranted to reduce diabetic complications and prevent amputations in diabetic patients.

In conclusion**,** our study confirmed a high rate of lower limb amputation in diabetic patients in Osijek-Baranja County which is representative for east Croatia region. Regular evaluation of incidence rates of lower limb amputation in our population are of crucial importance for health policy decision makers and for further improvements in diabetes care.

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INCIDENCIJA AMPUTACIJA DONJIH EKSTREMITETA U DIJABETIČKIH BOLESNIKA OD 2010. DO 2018. GODINE U OSJEČKO-BARANJSKOJ ŽUPANIJI

SAŽETAK

Amputacija donjih ekstremiteta za dijabetičke bolesnike predstavlja neželjeni ishod kojeg se najviše boje.Cilj našeg ispitivanja bio je odrediti kretanje godišnje stope amputacija donjih ekstremiteta u dijabetičkih bolesnika te ispitati povezanost između kliničkih značajki bolesnika i trajanja dijabetesa do prve amputacije. Ovo je presiječno retrospe-

ktivno ispitivanje u tercijarnom centru obuhvatilo 925 dijabetičkih bolesnika kojima je učinjena netraumatska amputacija donjih ekstremiteta u razdoblju od 2008. do 2018.g u KBC Osijek. Prikupljeni su podaci iz registra Zavoda za endokrinologiju o kardiovaskularnim rizičnim čimbenicima i drugim kliničkim značajkama bolesnika. Za dodatne analize izdvojena je skupina od 278 pacijenata koji su imali podatke za daljnju analizu. U desetogodišnjem razdoblju bilo je 1551 amputacija donjih ekstremiteta. Incidencija stope amputacija iznosila je 6,14 na 1000 pacijent-godina. Stopa amputacija na 1000 pacijent-godina smanjila se za 29% između 2010.i 2013. godine te ponovo porasla na 76% od 2014.–2018. Godišnja stopa varirala je od 4,0–7,8 amputacija na 1000 pacijent-godina. Isti obrazac registrirali smo za manje i veće amputacije, ali stopa amputacija iznad nivoa koljena postojano je rasla i od 2010. do 2018. g. povećala se 2,7 puta (od 0,69 na 1,83 amputacijana 1000 pacijent-godina). Prosječna dob pacijenata bila je 67,2 g, a 66% su činili muškarci, s prosječnim ITM 29,6±4,8 kg/m^2 i trajanjem dijabetesa od 14,7±8,2 g. Nije ustanovljena povezanost između pušenja, arterijske hipertenzije, hiperlipidemije, terapije ACE inhibitorima i statinima, antiagregacijske terapije, KVB, te neuropatije i trajanja dijabetesa do prve amputacije. Samo prethodno liječenje sulfonilurejom i inzulinom značajno je produljilo vrijeme do prve amputacije (p=0,00001, za obje terapije). U zaključku, godišnje stope amputacija donjih ekstremiteta u oboljelih od šećerne bolesti su visoke u našoj županiji. Poznavanje stopa amputacija donjih ekstremiteta za regiju važna je zbog unaprijeđivanja skrbi dijabetičkih bolesnika te planiranja zdravstvene politike.