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Original Article

Risk Factors Related to Amputation in Diabetic Foot Patients: Single Center Outcomes

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Abstract

Aim: This study aimed at identifying factors that worsen the prognosis of diabetic foot, one of the most common complications seen in patients with diabetes.

Materials and patients: The sample included 230 patients treated in the Department of Surgery at Kaspela University Hospital in Plovdiv, Bulgaria, between January 2016 and May 2022. Of them, 55.65% were men, and 44.35% were women. The age of the patients ranged from 18 to 77 years, with a mean age of 44.4±14.7 years.

Results: Diabetic foot patients of grade ≥4 were 1.8 times more likely to be amputated than the rest of the patients (AOR=1.6; 95% CI: 1.504, 4.683). The utilization of inappropriate antibiotics was associated with a 9.47-fold increased risk of amputation (p<0.001). Subsequently, type 2 DM was found to have a 3.63-fold higher risk (p=0.002), poor glycemic control posed a 3-fold increased risk (p<0.001), a body mass index (BMI) greater than 29.5 was linked to a 2.66-fold raised risk (p=0.011), neuropathy was associated with a 2-fold increased risk (p=0.017), and alcohol consumption was linked to a 1.96-fold higher risk (p=0.024).

Conclusion: Our results contribute to clinical practice by identifying risk factors that should be considered in the early monitoring and education of patients with diabetes who are at risk for developing diabetic foot. To minimize the risk of developing diabetic foot ulcers, it is critical to optimize antibiotic therapy and prioritize the advantages of adopting a healthy lifestyle, which includes making informed dietary choices, weight management for reducing hyperglycemia, and refraining from harmful behaviors such as alcohol consumption.

Keywords

diabetic foot, foot ulcer, foot amputation, risk factors

INTRODUCTION

One of the major worldwide issues facing contemporary society is diabetes mellitus (DM), whose prevalence has been constantly rising for the past few decades. The World Health Organization reports that the number of persons with this disease was little over 30 million in 1985. By 2019, that number had risen to 463 million, and projections suggest that by 2050, that number would have doubled and, in a more dire prediction, may perhaps triple.[1,2] Diabetes is one of the leading causes of kidney failure and blindness due to retina damage, as well as a major factor in non-traumatic amputations of the lower limbs. The complications of diabetes carry a serious risk of disability and even fatal outcomes.[3] Diabetic foot is one of the most frequently observed complications in patients with DM. Usually, it begins as a diabetic ulcer, and this is actually an initial manifestation of the diabetic foot characterized by a lesion penetrating all layers of the dermis, located below the level of the ankle (according to the International Working Group on the Diabetic Foot).[4] The frequency of patients hospitalized due to diabetic foot is constantly increasing, reaching between 6% and 10% according to international statistics, and it is considered that the risk of developing diabetic foot in patients with DM reaches 25–30%.[5]

The most common predisposing factors for diabetic foot are: inadequate glycemic control, mechanical or thermal trauma to the lower limbs, increased pressure in the area of the foot, excess weight, which is often accompanied by metabolic syndrome, smoking, the patient's age, as well as the duration of the disease.[6-8]

Knowledge of the risk factors for the occurrence of a diabetic foot is important because, despite the applied preventive measures, many patients will develop it. In last year's debut of diabetes mellitus, the appearance of a diabetic foot due to unsolicited medical help was an important risk factor, indicating a severe course and rapid progression of the disease, threatening the patient's life.[9-11]

AIM

This study aimed at identifying factors that worsen the prognosis of diabetic foot, one of the most common complications seen in patients with diabetes.

MATERIALS AND METHODS

The study included patients seen in the Department of Surgery at Kaspela University Hospital, Plovdiv, Bulgaria, between January 2016 and May 2022. They were followed up retrospectively, focusing on the risk factors and complications of diabetic foot. The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Kaspela University Hospital, Plovdiv, Bulgaria (IRB No: 2021-01-04). Written informed consent was obtained from the patients who were included in the study. The severity of the diabetic foot was assessed utilizing the Wagner[12] classification system:

- grade 0 diabetic foot ulcer: No ulcer, but the foot is at risk for ulceration
- grade 1 diabetic foot ulcer: Superficial ulceration
- grade 2 diabetic foot ulcer: Ulcer with deep infection, but without involvement of the bone
- grade 3 diabetic foot ulcer: Ulcer with osteomyelitis
- grade 4 diabetic foot ulcer: Presence of localized gangrene on the foot
- grade 5 diabetic foot ulcer: Presence of gangrene of the whole foot.

We conducted a variety of surgical procedures, including necrectomy, toe amputation, transmetatarsal amputation, and Chopart amputation (all of which are currently combined under the term minor amputation in the western literature) based on the aforementioned classification and taking the patient's overall health into consideration. Unfortunately, we also had major amputations located above the ankle joint, and in a large part of this group, amputations were performed at the level of the thigh, mainly in neglected cases with a severe septic condition and a life-threatening soft tissue infection

Statistical analysis

The SPSS 22.0 software was used for the data analysis. The primary variables were categorical and presented as numbers and percentages. The Fisher's exact test was employed to compare the incidence of risk factors in the patients with and without amputation. A subsequent analysis involved computing odds ratios, 95% confidence intervals for the odds ratios, z-statistics, and corresponding p-values. All statistical tests were two-tailed, and the type I error was set at 0.05 ($p<0.05$).

RESULTS

The study included 230 patients who were treated in the Department of Surgery at Kaspela University Hospital, Plovdiv, Bulgaria, in the period from January 2016 to May 2022. Of them, 128 (55.65%) were men, and 102 (44.35%) were women. The age of the patients ranged from 18 to 77 years, with a mean age of 44.4±14.7 years. The mean BMA was 24.94±3.69 kg/m^2, with 29.60% of the patients having a very high BMA and 13.91% being obese. The patients were almost equally distributed by their residence, whether urban or rural.

One hundred and sixteen (50.4%) patients had comorbidities, with the most common ones being arterial hypertension (48.7%), retinopathy (47.76%), and neuropathy (45.20%). Sixty (26.10%) were smokers, and 72 (33.00%) reported using alcohol every day **(Table 1)**.

It is crucial to initiate antibiotic therapy for diabetic foot

Table 1. Comorbidity in our patients

Variables		Patients (n)	%
Co-morbidity	Nephropathy	92	40.00
	Neuropathy	104	45.20
	Arterial hypertension	112	48.79
	Retinopathy	110	47.76
	Vascular problems	84	36.50
	Heart problems/ angina pectoris/ myocardial infraction	82	35.50
	Dyslipidemia	80	34.68
Smoking and alcohol use	Daily alcohol consumption	76	33.03
	Smokers	60	26.06

patients for a duration of 36–72 hours, until microbiology results are obtained. The therapy was determined in view of the severity of the infection as well as the likely etiologic agent. The initial antibiotic treatment for a mild soft tissue infection was administered for about 7 days, whereas for moderate-to-severe cases, it lasted between 14 and 21 days. The therapy also included low-molecular-weight heparin, antiplatelet drugs, vasodilators, insulin, electrolytes, and IV fluids.

Clindamycin (34.15%) was the most commonly prescribed antibiotic for the treatment, followed by metronidazole (26.22%) and ceftriaxone (20.12%) **(Table 2)**.

Table 2. Antibiotics used to treat diabetic foot patients

Antibiotics	Use	Total %
Clindamycin	112	34.15
Metronidazole	86	26.22
Ceftriaxone	66	20.12
Ampicillin	18	5.49
Vancomycin	20	6.00
Gentamycin	10	3.05
Ceftazidime	8	2.44
Ciprofloxacin	6	1.83
Amoxicillin	2	0.61

Conservative treatment (necrectomy) was applied in 160 (69.60%) of the patients with diabetic foot, whereas 70 (30.40%) had amputation. Of the latter, 40 (57.1%) underwent minor and 30 (42.9%) major amputations. Of the patients with major amputations, 18 (60%) were below the knee and 12 (40%) above the knee **(Table 3)**.

The patients who underwent amputation were compared with those who were treated conservatively regarding potential risk factors. The following factors showed significantly higher proportions among the patients with amputations: alcohol consumption (p=0.026), type 2 diabetes (p=0.014), neuropathy (p=0.021), obesity (p=0.013), poor glycemic control (p=0.021), ulcers of size 1 to 5 cm^2, and inappropriate use of antibiotics (p<0.001).

On the other hand, the patients who did not need to have amputations and were treated conservatively showed higher proportions of those categorized with a BMI <24 (p=0.005) and ulcer wounds of size <1 cm^2 (p=0.021). The remaining risk factors did not show significant differences between the two groups **(Table 4)**.

Odds ratios were computed based on the risk factors that exhibited a significantly higher incidence among the patients who had undergone amputation.

The utilization of inappropriate antibiotics was associated with a 9.47-fold increased risk of amputation (p<0.001). Subsequently, type 2 DM was found to have a 3.63-fold higher risk (p=0.002), poor glycemic control posed a 3-fold increased risk (p<0.001), a body mass index (BMI) greater

Table 3. Surgical procedures and level of amputation

Location of diabetic ulcer/gangrene	Amputation n (%)	Necrectomy (sharp dissection) n (%)	Total n (%)
Inter digital toes	18 (7.83)	44 (19.13)	62 (26.96)
Forefoot/mid foot/ hind foot	22 (9.57)	52 (22.60)	74 (32.17)
Toes	12 (5.22)	48 (20.87)	60 (26.09)
Foot dorsal part	10 (4.35)	8 (3.48)	18 (7.83)
Heel	8 (3.48)	8 (3.48)	16 (6.96)
Total	70 (30.40)	160 (69.60)	230 (100%)

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Table 4. Comparison of the patients with and without amputations on potential risk factors

Potential risk factors		Amputation		*p*-value
		YES n (%)	NO n (%)	
Residence	Rural	34 (29.81)	80 (50.00)	0.842
	Urban	36 (31.00)	80 (68.90)	
Patients sex	Male	38 (54.30)	90 (56.25)	0.885
	Female	32 (45.70)	70 (43.75)	
Alcohol consumption	Yes	34 (48.60)	52 (32.50)	**0.026**
	No	44 (51.40)	108 (67.50)	
Smoking count	Yes	24 (34.00)	36 (22.50)	0.073
	No	46 (66.00)	124 (77.50)	
Ulcer/Wound before	Yes	32 (45.70)	72 (45.00)	1.000
	No	38 (54.30)	94 (55.00)	
Diabetes type	Type 2 DM	46 (66.00)	76 (47.50)	**0.014**
	Type 1 DM	24 (34.00)	84 (52.50)	
Arterial hypertension	Yes	32 (45.70)	80 (50.00)	0.569
	No	38 (54.30)	80 (50.00)	
Ischemic heart disease	Yes	28 (40.00)	54 (33.70)	0.373
	No	42 (60.00)	106 (66.30)	
Dyslipidemia	Yes	26 (37.00)	54 (33.70)	0.653
	No	44 (63.00)	106 (66.30)	
Retinopathy	Yes	34 (48.50)	76 (47.50)	0.887
	No	36 (51.50)	84 (52.50)	
Neuropathy	Yes	40 (57.00)	64 (40.00)	**0.021***
	No	30 (43.00)	96 (60.00)	
Coronary heart disease	Yes	18 (25.70)	36 (22.50)	0.615
	No	52 (74.30)	124 (77.50)	
Peripheral vascular disease	Yes	26 (37.00)	58 (36.00)	1.000
	No	44 (63.00)	102 (64.00)	
Body mass index	<24	30 (42.00)	100 (62.50)	**0.005**
	24.5–29.5	24 (35.00)	44 (27.50)	0.347
	>29.5	16 (23.00)	16 (10.00)	**0.013**
Glycemic Control	Poor	40 (57.00)	64 (40.00)	**0.021**
	Good	28 (43.00)	96 (60.00)	
Duration of diabetes	<5 years	28 (40.00)	56 (35.00)	0.552
	5–10 years	28 (40.00)	66 (41.00)	0.885
	> 10 years	14 (20.00)	38 (24.00)	0.609
Size of ulcer (wound)	<1 cm^2	32 (46.00)	100 (63.00)	**0.021**
	1–5 cm^2	22 (31.00)	30 (18.50)	**0.040**
	>5 cm^2	16 (23.00)	30 (18.50)	0.475
Antibiotics	Inappropriate	44 (63.00)	36 (23.00)	**<0.001**

than 29.5 was linked to a 2.66-fold raised risk (p=0.011), neuropathy was associated with a 2-fold increased risk (p=0.017), and alcohol consumption was linked to a 1.96-fold higher risk (p=0.024) **(Table 5)**.

DISCUSSION

Many authors tried to evaluate the predictive value for amputation of the Wagner ulcer classification.[13,14] In our study, patients with a Wagner score of ≥3 had a 1.5-fold higher risk of amputation than the others with a lower score. This result was consistent with multiple trials and meta-analyses worldwide.[14,15]

Most of our patients with advanced Wagner grade (3-5) usually had poorly managed diabetes, severe neuropathy, and peripheral vasculopathy.[15,16] In our study, diabetic neuropathy and vasculopathy were seen more in cases with increased HbA1c, advanced age, increased blood sugar levels, and duration of diabetes, all of which are in-

Table 5. Factors showing increased risk for amputation

Risk factors	Odds ratio 95% CI	z statistic	*p*-value
Inappropriate antibiotics	9.47; 4.79 to 18.73	6.46	<0.001
Type 2 DM	3.63; 1.85 to 7.12	3.75	<0.001
Poor glycemic control	3.00; 1.60 to 5.59	3.45	<0.001
BMI >29.5	2.66; 1.24 to 5.70	2.53	0.011
Neuropathy	2.00; 1.13 to 3.53	2.38	0.017
Alcohol consumption	1.96; 1.10 to 3.48	2.30	0.024

creasing the amputation risk. Farooque et al. reported that 26.1% of their patients showed foot ulcerations with nephropathy, which was considered another predictive factor of amputation in diabetic foot patients.[17]

In our study, neuropathy increased the risk of amputation more than 1.5 times, and this result is in agreement with Manada et al.[18] Peripheral arterial disease and arterial insufficiency usually result in prolonged healing when ulceration develops, increasing the significantly increased risk of amputation.[19] Additionally, attempts to control bacterial infections will be impaired due to the impossibility of delivering antibiotics to the infection site. Therefore, early recognition and aggressive treatment of lower extremity ischemia are vital to lowering limb salvage.[20,21]

The most commonly prescribed antibiotics in our study patients were clindamycin (34.1%), followed by metronidazole (26.2%) and ceftriaxone (20.1%). A study by Selva et al. found that the most commonly used antibiotics were clindamycin and ciprofloxacin.[22] However, in a Swedish study, metronidazole (56%) and ciprofloxacin (54%) were the most commonly used, followed by flucloxacillin (40%) and cefadroxil (31%). Additionally, Chismann et al. also showed that the most commonly prescribed antibiotic therapy included semi-synthetic penicillin and third-generation cephalosporins or fluoroquinolones.[23] The variety of prescribed antibiotics can be attributed to differences in the bacterial agents, patients' conditions, the availability of the drugs, and the personal preference of the physicians.

The outcome of diabetic foot patients was associated with antibiotics given for the treatment of diabetic foot infections. Patients with empiric inappropriate antibiotic therapy showed two times more risk of being amputated. Our result was in agreement with the UK study, in which the amputation rate dropped from about 70% to about 30% with appropriate antibiotic therapy.[24] In our study, more than 3/4 of the antibiotics were prescribed appropriately. Inappropriate antibiotic treatment increases the risk of developing resistant pathogens.[25]

The duration of diabetes prior to its appearance does not affect the outcome of diabetic foot ulcers. Previous studies from Germany, Pakistan, and the UK have demonstrated the inhibiting effects of diabetes on wound healing, but the duration of the disease is not as important as overall blood glucose control (which was not looked at in this study).[26,27]

Of our diabetic foot patients, 30.43% were amputated. Of them, 57.14% had minor amputations, and 42.86% had major amputations. These results are in accordance with those of other authors worldwide, such as Acar et al.[28] and Kow et al.[29] There are also studies that show a lower rate of amputations caused by diabetes.[30,31] Perhaps the variations in the standard of care for diabetic feet and the challenge of establishing precise standards for major and minor amputations contributed to these disparities.[32] This disparity may also be attributable to individual choices. Some individuals hold the view that amputation is preferable to death, particularly in less developed nations, and they are vehemently opposed to the procedure. Consequently, it follows that the incidence of amputations would be lower in these countries.

The study's findings hold practical significance as they have the potential to inform clinical practice and contribute to related research. The absence of antibiotic therapy guidelines for patients with diabetic foot complications in our country is one of the limitations. Consequently, we typically initiate empiric treatment in our clinic on the basis of our experience. Another constraint is that the follow-up was conducted by telephone, which may reduce the reliability of the data.

CONCLUSIONS

According to our results, overweight, uncontrolled diabetes, neuropathy, inappropriate antibiotic treatment, alcohol consumption and advanced grades of diabetic foot ulcers were important factors that predicted a high risk for amputation in diabetic foot patients. Comprehension of their impact on amputations is necessary to create risk assessment, management, and treatment protocols for diabetic foot patients.

Author contributions

Conceptualization: R.D.; methodology: R.D., M.D., and G.K.; software: G.A., L.D., and B.H.; validation; R.D. and G.K.; formal analysis: M.D., L.D., and B.H.; writing – original draft preparation: R.D., M.D., and G.K.; writing – review and editing: G.A. and B.N. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Kaspela University Hospital, Plovdiv, Bulgaria (IRB No: 2021-01-04), for studies involving humans.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study. Written informed consent was obtained from the patients regarding using the data for academic publications.

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 institutional restrictions.

Conflicts of Interest

The authors declare no conflict of interest.

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Факторы риска, связанные с ампутацией у пациентов с диабетической стопой: результаты одного центра

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Резюме

Цели: Целью данного исследования было выявление факторов, ухудшающих прогноз диабетической стопы, одного из наиболее распространённых осложнений, наблюдаемых у пациентов с диабетом.

Материалы и пациенты: Выборка включала 230 пациентов, проходивших лечение в хирургическом отделении университетской больницы „Каспела“ в Пловдиве, Болгария, в период с января 2016 года по май 2022 года. Из них 55.65% были мужчинами и 44.35% женщинами. Возраст пациентов варьировался от 18 до 77 лет, средний возраст составил 44.4±14.7 года.

Результаты: Пациенты с диабетической стопой ≥ 4 степени имели в 1.8 раза большую вероятность ампутации, чем остальные пациенты (AOR=1.6; 95% CI: 1.504, 4.683). Использование неподходящих антибиотиков было связано с 9.47-кратным увели-

чением риска ампутации (p<0.001). Впоследствии было обнаружено, что СД 2 типа имеет в 3.63 раза более высокий риск (p = 0.002), плохой гликемический контроль представляет собой 3-кратный повышенный риск (p < 0.001), индекс массы тела (ИМТ) более 29.5 был связан с 2.66-кратным повышенным риском (p = 0.011), невропатия была связана с 2-кратным повышенным риском (p = 0.017), а употребление алкоголя было связано с 1.96-кратным повышенным риском (p = 0.024).

Заключение: Наши результаты вносят вклад в клиническую практику, определяя факторы риска, которые следует учитывать при раннем мониторинге и обучении пациентов с диабетом, которые подвержены риску развития диабетической стопы. Чтобы минимизировать риск развития диабетических язв стопы, крайне важно оптимизировать антибактериальную терапию и расставить приоритеты преимуществ принятия здорового образа жизни, который включает в себя осознанный выбор диеты, контроль веса для снижения гипергликемии и воздержание от вредного поведения, такого как употребление алкоголя.

Ключевые слова

диабетическая стопа, язва стопы, ампутация стопы, факторы риска