

**COMPARATIVE CHARACTERISTICS OF CLINICAL AND LABORATORY
PARAMETERS OF PATIENTS OF THE DIABETIC FOOT DEPARTMENT,
DEPENDING ON THE PRESENCE OR ABSENCE OF DIABETES MELLITUS**

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Annotation: *Ulcerative defects, gangrene and occlusive atherosclerosis of the arteries of the lower extremities are the most common causes of hospitalization of patients in the foot rescue department. It is worth noting that most of these patients are people with diabetes mellitus (DM).*

Keywords: *Diabetic foot, diabetes mellitus.*

Diabetic foot syndrome (DFS) is one of the late severe complications of diabetes mellitus. This diagnosis occurs in 35% of cases among those hospitalized in the Department of endocrinology and in 80% of SDS is the cause of non-traumatic amputation of the lower limb. Due to the widespread late complication of diabetes and a significant decrease in the quality of life of patients with SDS, there is a negative dynamics in the economic aspect affecting the patient, his family and healthcare in general [1].

The foot is anatomically the most remote part of the lower limb, so there may be problems with its blood supply and innervation. The appearance of ulcers on the foot in people with diabetes mellitus is a sign of disease progression and, in the absence of adequate timely treatment, can lead to amputation [2]

The precursor of SDS is diabetic polyneuropathy, the risk factors for the development of which are: disorders of carbohydrate metabolism, dyslipidemia, micro- and macroangiopathy of peripheral nerves. A violation of the structure, permeability of the myelin sheath and changes in axonal flow in the nerve fiber also have a negative effect [3] The etiopathogenesis of SDS is multifactorial. The main causes of ulcers and tissue necrosis are 3 main factors: neuropathy, ischemia and infection [4]

In patients with type 2 diabetes, the need for amputations is 30-40 times higher than in patients without diabetes. Also, patients with DM have a high risk of mortality within 5 years after surgery and is equal to 39-68% [5]

According to the World Health Organization, about 250,000 amputations are performed annually in patients with diabetes in Europe. During 2010, approximately 71,000 patients in the United States with diabetes underwent amputation of a foot or lower limb [6]

The treatment of diabetic foot ulcers requires interdisciplinary collaboration in various fields of medicine. [7]

A multidisciplinary approach to the treatment of SDS in a group of patients with high risk of surgery reduces the likelihood of amputation of the lower limb by 50% [8]

THE PURPOSE OF THE STUDY

To evaluate the clinical and laboratory parameters of patients of the Department for the rescue of lower extremities (OAANK), depending on the presence/absence of diabetes

MATERIALS AND METHODS

A retrospective analysis of 902 case histories of patients (546 men and 356 women) who were hospitalized at the OSNK GKB named after V.P. Demikhov in the period from 2019 to 2020 was carried out. During the study, the patients were divided into two groups. Group I: n=759 - with DM (84.2%); Group II: n=143 - without DM (15.8%)

Statistical analysis was performed in the STATISTICA program. The normality of the distribution of quantitative features was checked using the Shapiro-Wilk criterion (with the number of subjects <50) or the Kolmogorov-Smirnov criterion (with the number of subjects >50). To describe the features with a normal distribution, an average value was used indicating a 95% confidence interval. When describing features with a distribution other than normal, a median was used indicating the interquartile range [25th and 75th percentiles]. Data from populations with a distribution other than normal were compared using the Mann-Whitney criterion. Data from populations with a normal distribution were compared using the Student's t-test. Qualitative data were compared using conjugacy tables based on Pearson's criterion χ^2 and Fisher's exact criterion. The differences were regarded as statistically significant at $p < 0.05$.

Result

Clinical characteristics of patients

2 groups were included in the study. 1 included patients with diabetes mellitus - n=759 - with diabetes mellitus (84.2%), 2 - without diabetes mellitus - n=143 - without diabetes mellitus (15.8%).

Both groups were dominated by men: women in group I were 41.24% (313 out of 759), 58.7% of men (446 out of 759), and in group II - 31.47% (45 out of 143) women and 68.53% (98 out of 143) men ($p < 0.05$).

More than half of the patients in the first group had diabetes experience of more than 10 years – 52.3%, and more than 20 years -15.54%

Patients with DM were younger than patients without DM: the average age in group I was 65.52 ± 0.39 (95% CI 64.76 - 66.28) years, and in group II - 70.07 ± 1.0 (95% CI 68.09 - 72.05) years ($p < 0.01$).

Patients with DM compared with patients without DM in a larger percentage of cases had a moderate and severe degree of severity upon admission: severe (group I - 3.03% vs group II – 1.4%, $p < 0.05$), average (group I - 94.99% vs group II – 92.31%, $p < 0.05$). At the same time, the mild severity at admission was significantly higher in the group without diabetes: group I - 1.98% vs group II – 5.59% ($p < 0.05$).

With regard to body mass index, it was found that patients with DM had a higher body mass index compared with patients without DM: in group I it was 31.34 ± 0.44 (95% CI 30.48 - 32.21) kg/m², and in II it was 27.8 ± 2.06 (95% CI 22.76 - 32.85) kg/m² ($p < 0.01$), but it was calculated only in 9.53% (86 out of 902) of the total number of patients, which indicates an insufficient diagnosis of patients in the department. It is possible that the patients had obesity, which in turn is, firstly, a risk factor for the development of diabetes mellitus, and secondly, determines therapeutic tactics and preventive measures.

There was no difference in the duration of hospitalization: in the first group it was 13.90 beds/days (k/d), and in the second 13.0 k/d ($p > 0.05$)

Concomitant pathology:

Patients have a number of concomitant diseases, which we analyzed in the study groups and calculated the percentage of occurrence:

The incidence of concomitant diseases was also assessed and it was found that in the group of patients with diabetes the most common were: arterial hypertension in the first group was noted in 88.01% of cases (668 out of 759), and in the second - 81.82% (117 out of 143) ($p < 0.05$), CKD (GFR < 60 ml/min/1,73m²) in group I - 43.74%, and in group II - 34.27% ($p < 0.05$), and in the group of patients without diabetes, the most common were: atherosclerosis of the arteries of the lower extremities in the first group - 74.7% (567 out of 759, in the second group - 97.90% (140 out of 143) ($p < 0,01$). Despite the fact that patients with DM2 were more likely to suffer from coronary heart disease, there was no statistically significant relationship between the study groups: in the first group - 61.92% (470 out of 759), in the second group - 59.44% (85 out of 143). However, the incidence of MI and ONMC was higher in patients without diabetes, but no statistically significant relationship was found in the studied groups: myocardial infarction accounted for 19.76% (150 out of 759) in the first group, and 20.28% (29 out of 143) in the second group ($p > 0.05$) and in relation to ONMC in the first group corresponds to 16.34% of cases (124 out of 759), and in 17.48% (25 out of 143) in the second group ($p > 0.05$). In general, cardiovascular diseases predominate among the identified pathologies in both groups.

The structure of the diagnosis:

When we analyzed the diagnoses at admission, we found that the majority of patients with DM had purulent necrotic lesions of the lower extremities: phlegmon (group I - 17.26% vs group II - 3.5%, $p < 0.05$), abscess (group I - 6.85% vs group II - 0.7%, $p < 0.05$), osteomyelitis (group I - 8.43% vs group II - 0.7%, $p < 0.05$) and Arthritis: purulent, destructive, purulent- destructive (group I - 17.92% vs group II - 5.59% ($p < 0.05$) in contrast to patients without diabetes, who more often had atherosclerotic lesions of the arteries of the lower extremities: critical ischemia (group I - 17.79 % vs group II - 30.07%, $p < 0.05$).

The nature of the surgical intervention

In patients with DM, compared with patients without DM, there was a higher risk of amputations, which is associated with frequent ulcerative necrotic processes in this group. Thus, in the group of patients with DM amputations 50.46% of cases, without DM 38.46%, ($p < 0.05$). At the same time, high amputations were performed more often in patients without DM, compared with patients with DM: 36.36% vs. 9.66%, ($p < 0.01$), which is an indicator of atherosclerosis in patients without DM, and low amputations prevailed in patients with DM: 90.34% vs. 63.64%, ($p < 0.01$), which is associated with microangiopathy and polyneuropathy. Revascularization was more often performed in patients without DM, due to the fact that critical ischemia was just observed in patients without DM, although these bottom-line were not clinically significant: without DM - 20.28% vs. 15.55%, ($p > 0.05$).

It is worth noting that a large number of patients of both groups have a history of there were revascularizations and amputations, which aggravates the course: revascularization in patients with DM - 22.27%, and without DM - 30.77% ($p < 0.05$), amputation in patients with DM - 39%, and without DM - 24.48% ($p < 0.01$).

Laboratory parameters that have not been adequately evaluated:

In order to choose treatment tactics and for further prevention, it is very important for us to assess the lipid spectrum, inflammatory status, blood clotting indices, and blood carbohydrate indices. In our case, many and at the same time very necessary analyses were not carried out, which makes it difficult to conduct a full-fledged analysis of our study. But the most important thing is that it can lead to an erroneous choice of treatment tactics and a lack of preventive measures.

The following lipid profile analyses were not fully evaluated: LDL in patients with DM - 99.34%, and without DM - 100% of cases, TG in patients with DM - 95.52%, and without DM - 93%, total cholesterol in patients with DM - 68.7%, and without DM - 80.4%, as well There are no data reflecting the metabolic profile of patients (BMI) in the first group at 72.46%, in the second group at 95.10%.

And among patients with diabetes, 13.97% did not evaluate glycated hemoglobin, which is necessary for the selection of hypoglycemic therapy

Patients who did not receive proper drug therapy:

If indicated, more than half of the patients did not receive statins: in 61.71% of cases in the group with DM and with a frequency of 65.96% among patients without DM. A smaller number of patients with a history of atherosclerosis, coronary heart disease, revascularization or amputation were prescribed antiplatelet agents: in groups 1 and 2 of patients in 17% of cases. In the presence of arterial hypertension, antihypertensive therapy was not prescribed: 9.43% (63 out of 668) in the group of patients with DM compared with 19.66% (23 out of 117) in the group of patients without DM

Conclusion

Patients with DM, unlike patients without DM, have more pronounced hyperglycemia and dyslipidemia, as well as a higher percentage of hypertension. It is worth noting that this triad is key in relation to the risks of developing atherosclerotic and polyneuropathic lesions of the lower extremities.

DM significantly increased the risk of hospitalization in the department.

Patients without diabetes had early disorders of carbohydrate metabolism, therefore, they had a comparable hyperglycemic risk of developing lower limb lesions compared with patients with diabetes. Nevertheless, the percentage of dyslipidemia and hypertension in patients without DM was lower compared to patients with DM.

An assessment of the incidence structure shows that the most common pathology of patients without DM was the presence of atherosclerotic lesions of the arteries of the lower extremities, while patients with DM2 were characterized by the presence of polyneuropathy and the development of an infectious process.

The frequency of lower limb amputation is higher in patients with DM, while high amputations are more typical for patients without DM, and low amputations for patients with DM. But in most cases, the prognosis of the disease is influenced not only by the presence of diabetes, but by the burden of comorbid somatic pathology in general.

Additional information

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The participation of the authors.

All authors approved the final version of the article before publication, and agreed to be responsible for all aspects of the work, implying proper study and resolution of issues related to the accuracy or integrity of any part of the work.

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