ANALYSIS OF THE EFFECTIVENESS OF OUTPATIENT TREATMENT OF PATIENTS WITH DIABETIC FOOT

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BACKGROUND: Diabetic foot syndrome is a late complication of diabetes mellitus and the main reason for non-traumatic amputations of the lower extremities in diabetic patients. Currently, standards of medical care have been developed and implemented for the treatment and prevention of this complication. At the same time, there is a lack of publications on the effectiveness of specialized care, especially at the pre-hospital stage.
AIM: To analyze the results of treatment of patients with diabetic foot on an outpatient basis in a specialized department and identify the factors affecting them.
MATERIALS AND METHODS: Medical records of patients with diabetic foot ulcers receiving specialized outpatient treatment in the diabetic foot department were analyzed. All patients underwent an assessment of the peripheral sensitivity and blood flow of low extremities during the initial examination. Treatment was prescribed in accordance with the presence and severity of infection and ischemia of the affected limb. The number of amputations at different levels, the percentage of healed and unhealed wounds during the year were analyzed. Predictors of high amputations and non healing during the year were identified.
RESULTS: Out of 503 patients with diabetic foot, neuropathic diabetic foot was diagnosed in 336 (67%) patients, neuro-ischemic in 167 (33%). Healing without amputations in the general cohort of patients was noted in 407 cases (81%). In 32 (7%) cases, amputations were required, of which: 23 (5%) within the foot, 3 above ankle (0.6%), 6 above knee (1.2%). Death occurred in 6 patients (1.2%), 2 of them after hip amputation. 61 patients (12%) continued to be treated at the end of the study. The predictors of high amputations in the general cohort of patients were age, impaired arterial blood flow in the arteries of the lower extremities, the depth of the Wagner ulcer and the level of glycated hemoglobin. Predictors of the non healing during the year were: the presence of impaired arterial blood flow and untimely treatment for specialized medical care.
CONCLUSION: The data obtained demonstrated the high effectiveness of specialized care for patients with diabetic foot ulcers at the prehospital stage

KEYWORDS: diabetic foot ulcers; neuropathic diabetic foot ulcers; neuroischemic diabetic foot ulcers; amputations of the lower extremities; healing; specialized care.

АНАЛИЗ ЭФФЕКТИВНОСТИ ЛЕЧЕНИЯ БОЛЬНЫХ С СИНДРОМОМ ДИАБЕТИЧЕСКОЙ СТОПЫ В АМБУЛАТОРНЫХ УСЛОВИЯХ

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ОБОСНОВАНИЕ. Синдром диабетической стопы (СДС) является поздним осложнением сахарного диабета (СД) и основной причиной выполнения нетравматических ампутаций нижних конечностей у больных СД. В настоящее время для лечения и профилактики данного осложнения разработаны и внедрены стандарты оказания медицинской помощи. При этом есть определенный дефицит опубликованных данных об эффективности специализированной помощи, особенно на догоспитальном этапе.
ЦЕЛЬ. Проанализировать исходы язвенных дефектов у больных СД с СДС, получающих лечение в амбулаторном режиме специализированного отделения, и выявить факторы, влияющих на них.
МАТЕРИАЛЫ И МЕТОДЫ. Были проанализированы медицинские карты пациентов с язвенными дефектами при СДС, получающих специализированное лечение в амбулаторном режиме в отделении диабетической стопы. Всем пациентам при первичном осмотре проводилась оценка состояния периферической чувствительности и магистрального кровотока. Лечение назначалось в соответствии с наличием и степенью выраженности инфекции и ишемии пораженной конечности. Анализировалось количество ампутаций на разных уровнях, процент заживших и незаживших ран в течение года. Выявлялись предикторы выполнения высоких ампутаций и отсутствия заживления в течение года.
РЕЗУЛЬТАТЫ. Из 503 пациентов с СДС нейропатическая форма была диагностирована у 336 (67%) пациентов, нейро-ишемическая — у 167 (33%). Заживление без выполнения высоких и малых ампутаций в общей когорте пациентов отмечено в 407 случаях (81%). В 32 (7%) случаях потребовалось выполнение ампутаций, из них: 23 (5%) — в пределах

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стопы, 3 — на уровне голени (0,6%), 6 — на уровне бедра (1,2%). Смерть констатирована у 6 пациентов (1,2%), из них у 2 после выполнения ампутации на уровне бедра. 61 пациент (12%) продолжал лечиться на момент окончания исследования. Предикторами выполнения высоких ампутаций в общей когорте больных стали возраст, нарушение магистрального кровотока в артериях нижних конечностей, глубина язвенного дефекта по Вагнеру и уровень гликированного гемоглобина. Значимыми предикторами отсутствия заживления на фоне консервативных мероприятий в течение года стали: наличие нарушенного магистрального кровотока и несвоевременное обращение за специализированной медицинской помощью.

ЗАКЛЮЧЕНИЕ. Полученные данные продемонстрировали высокую эффективность специализированной помощи больным с язвенными дефектами при СДС на догоспитальном этапе.

КЛЮЧЕВЫЕ СЛОВА: синдром диабетической стопы; нейропатические язвенные дефекты; нейроишемические язвенные дефекты; ампутации нижних конечностей; заживление; специализированная помощь.

BACKGROUND

Diabetic foot syndrome (DFS), a late complication of diabetes mellitus (DM), is the main cause of non-traumatic amputations of the lower extremities in patients with DM, their subsequent disability, persistent disability and reduced quality of life. The main causes of high amputations of the lower extremities in DFS include critical ischemia of the extremity, uncontrolled infection, critical ischemia in combination with infection [1]. Management of patients at risk of high amputations requires interdisciplinary interaction of endocrinologists, surgeon with specialization in purulent surgery, vascular surgeons, and orthopedists. To reduce the number of amputations above the ankle joint, their predictors are proposed: systolic pressure on the tibial arteries of the affected limb <50 mm Hg, ankle-brachial index (ABI) <0.5, pressure in the finger artery <30 mm Hg, transcutaneous oximetry <25 mm Hg. The presence of these signs in the patient indicates a high probability of amputation of the lower limb above the ankle joint and may necessitate revascularization as soon as possible [2]. Following these recommendations in real clinical practice has led to a decrease in the number of high amputations in many countries around the world. According to randomized trials in different countries, high amputations decreased by 3–85% in the period 1982–2011 [3]. According to the combined data for 21 countries, the proportion of high amputations in the general population decreased from 10.8 to 7.5 per 100,000 population (-30.6%). Eleven countries published figures on reducing high amputations from 1.83 to 1.28 per 1,000 patients with DM (-29.8%) [4]. In St. Petersburg, the number of high amputations per 1,000 patients with DM decreased from 2.53 in 2010 to 1.03 in 2021 [5]. It is crucially important that in the vast majority of publications, the reduction in high amputations was due to the implementation of a multidisciplinary approach to treating patients in an inpatient setting. Meanwhile, most patients with DFS receive care on an outpatient basis. In addition, in all countries, regardless of organization of medical care, DFS patients initially refer to an outpatient institution. Therefore, the number of emergency hospitalizations in advanced cases and, accordingly, the number of amputations will also depend on how care is organized at the prehospital stage. It should be taken into account that the contingents of patients receiving care in outpatient and inpatient settings differ. Therefore, the tasks to be solved by outpatient and inpatient institutions also have differences. For hospitals the key indicator of the effectiveness of care provided to patients is the number of high amputations and its dynamics. In the assessment of the effectiveness of outpatient care, along with the number of amputations, the healing time of ulcers and the frequency of their relapses are analyzed.

PURPOSE

To analyze the outcomes of ulcer defects in DM patients with DFS receiving treatment in outpatient settings (specialized department) and identify factors affecting the outcomes.

MATERIALS AND METHODS

Study site.

The study was conducted at the Endocrinological Dispensary, Moscow Department of Health.

Study period.

January 2014 – December 2019

Study populations (one or more).

The study involved patients who sought specialized help in the diabetic foot department.

Drawing samples from study population (or multiple samples from multiple study populations).

We analyzed outpatient records of patients who were treated in the diabetic foot department from 2014 to 2019 with an established diagnosis of DFS. The final analysis did not include data from patients who did not attend the department for three months or more. If the patient had several ulcer defects, in order to exclude possible distortion of the results, the analysis included data on one ulcer defect recorded last (Fig. 1).

Study design.

A retrospective observational single-center study.

Methods.

All patients received a standard assessment of peripheral sensitivity and main blood flow during the initial treatment [6]. In accordance with the standards of medical care in the diagnosis of neuropathic ulcer defects, patient management was based on the following principles: unloading of the affected limb, antibacterial therapy (if necessary), local management of wounds using modern dressings and taking into account the wound healing stage. The unloading mode was provided in several versions: 1) shoes with unloading of the front or rear parts of the foot; 2) rigid immobilizing

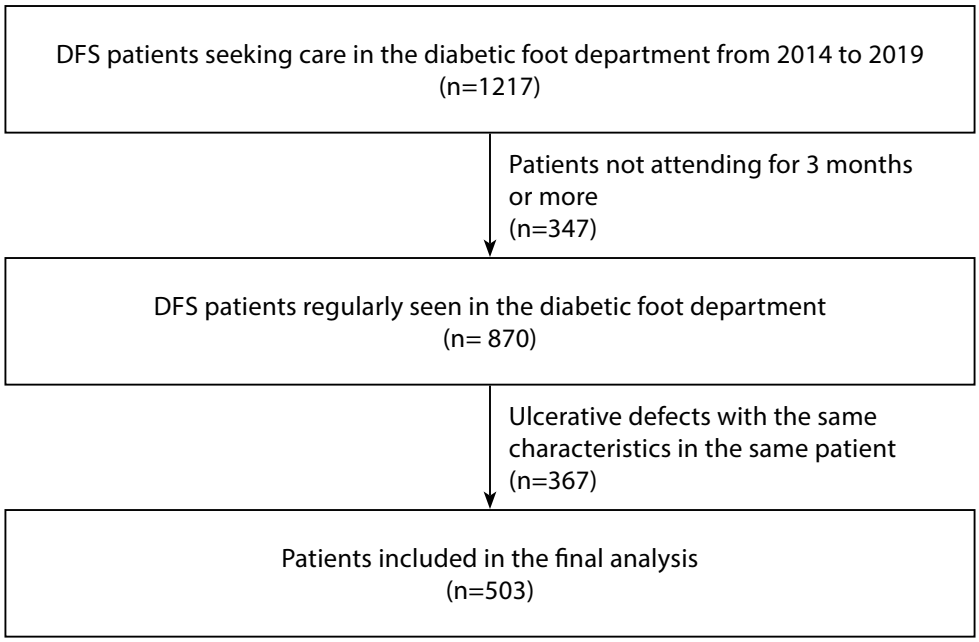

Figure 1. Cohort of patients with diabetic foot syndrome included in the final analysis.

Note: DFS, diabetic foot syndrome.

orthosis with ankle fixation; 3) individual unloading bandage (IRD) in removable or non-removable versions. IUB was applied during visit [6, 7].

Antibacterial therapy was prescribed in case of local or systemic signs of wound infection. The initial choice of the drug was carried out empirically on the basis of clinical and epidemiological data on the predominant pathogens, the severity of the infectious process, the presence and severity of nephropathy, neuropathy, allergic reactions, and previous hospitalizations. Preferences were given to broad-spectrum antibacterial agents: protected penicillins (amoxicillin/clavulanate, amoxicillin/sulbactam, ampicillin/sulbactam) and fluoroquinolones (levofloxacin, ciprofloxacin) in tablets. If treatment was ineffective, it was corrected taking into account the bacteriological study results [6, 8, 9].

Local treatment of wounds consisted of their cleansing, bathing, and dressing. Wound cleansing consisted of removing necrosis, areas of surrounding hyperkeratosis. The scope of the intervention was determined by the condition of the wound defect: necrotic tissues were removed with a scalpel and Volkmann spoon in one step or step-by-step. In order to remove foreign particles, surface nonviable layers and remnants of previous wound coverings, the wound was washed with an antiseptic solution (chlorhexidine 0.05%) or saline. At the final stage, a dressing was applied to the wound. The choice of dressing was based on the stage of the wound healing process and the level of exudation. Water-soluble multicomponent ointments, alginate dressings, and hydrofibers were used [6].

All patients with ulcer defects with comorbid decrease/or absence of main blood flow in the affected limb were consulted by a vascular surgeon, who determined the scope of additional examination and the need for hospitalization in the vascular surgery department. In preparation for hospitalization, patients received standard therapy for ulcer defects, taking into account the impairment of blood flow. It should be noted that only liquid antiseptic solutions were used as topical treatment. For limb unloading, mainly shoes with unloading of the forefoot or hindfoot were used, in some cases orthosis was used.

The frequency of visits to the clinic averaged 1 times every 7 days. If necessary, the frequency of visits increased to 1 time in 3 days.

In the study cohort, the following outcome options were evaluated: ulcer healing, limb amputation, ongoing treatment at the end of the study period, death. The study period was 12 months of follow-up. Healing was defined as complete epithelization of the ulcer defect and no recurrence within four weeks of healing. This group included patients in whom the healing of ulcer defects occurred as a result of conservative treatment measures, as well as after surgery without removing fingers or part of the foot. For amputations of the lower limb, their level was analyzed. High amputations include amputations above the ankle: at the level of the lower leg or thigh. Amputations of the toes or parts of the foot up to the ankle are classified as low or small.

Statistical analysis.

Descriptive statistics data are presented as mean with standard deviation (M ± SD) in the case of a normal data distribution, as median and 25th and 75th percentiles of the data set [Me (25; 75)] when the distribution is different from the normal. Frequency distribution of categorical variables was expressed as absolute number and percentage (n,%). Comparison of the two groups was carried out using contingency tables with the calculation of χ^2 for nominal variables and comparison of average values with the calculation of Student's t-test for continuous variables with normal data distribution. In case of uneven distribution of data, the Mann-Whitney method was used to compare two independent samples with the calculation of the U-test. Univariate ANOVA was used to compare multiple independent samples with the normal data distribution. A Tukey pairwise comparison was performed to determine which groups of the studied set of groups show statistically significant

differences. When the data were unevenly distributed, Kruskal-Wallace analysis of variance with H-test calculation was used to compare several independent samples. In such a situation, pairwise data comparison was not performed. The difference was considered significant at $p<0.05$.

The model for predicting the occurrence of an event (for example, performing a high amputation or healing of a chronic ulcer defect) was constructed in two stages. First, the odds ratio of event occurrence/non-occurrence was calculated to identify associations of each of the potential predictors of outcome. Second, taking into account the fact that in real clinical practice the outcome is influenced not by individual parameters, but by their combination, a logistic regression method was used to build a multidimensional model of simultaneous exposure to many independent factors, where the outcome for the ulcer defect was the dependent variable, namely, healing or amputation at any level. Correlation analysis was performed to identify possible significant interference of parameters. Pearson and Spearman correlation coefficients were applied. Statistical analyses were performed using SPSS software of version 17.0.

Ethical review

Taking into account the fact that the analyzed data were collected during routine work of the diabetic foot department, the ethical review of the study was considered inappropriate (Minutes No. 5 of 13.10.2023).

RESULTS

The final analysis included data from 503 patients with DFS. In 67% of cases, ulcer defects occurred with preserved main blood flow, in 33% of cases the main blood flow was decreased. During the study period, in the total cohort of DFS patients healing without high or small amputations was observed in 407 cases (80.9%). In 32 (6.3%) cases, amputations were required, of which: 23 (4.6%) – within the foot, 3 – at the lower leg level (0.6%), 6 – at the thigh level (1.2%). Death occurred in 6 patients (1.2%), of which 2 patients died after amputation at the hip level. At the end of study, 61 patients (12.1%) continued treatment (Figure 2).

Thus, in the vast majority of cases, healing of ulcer defects in DFS was achieved as a result of conservative therapeutic measures without amputations at any level.

Given the differences in the pathogenesis and prognosis of neuropathic and neuroischemic forms of DFS, the cohort was stratified by the presence or absence of ischemia of the affected limb. Patients with a neuroischemic form of the lesion were significantly older, they more often had CKD of stage 4 and 5, and were more likely to have necrosis of all skin layers (Grade 4 and 5 according to the Wagner's classification). Patients with neuropathic DFS were more likely to be diagnosed with proliferative stage diabetic retinopathy. According to such parameters as gender, type of diabetes, control of carbohydrate metabolism, the timeliness of seeking specialized medical care, location, size, and infection of the ulcer defect at the initial presentation, no differences were found between the forms of DFS.

Table 1 presents the outcomes of ulcer defects in various forms of DFS.

In patients with neuropathic form of DFS, healing within a year occurred in a significantly larger percentage of cases, while amputations at all levels, including small ones, were performed significantly less often than in patients with neuroischemic form of DFS. It should be noted that in patients with neuropathic ulcer defects no amputation at thigh level were performed. In addition, the small total number of high amputations over a 5-year period is important.

Significant predictors of high amputations were identified only in patients with neuroischemic DFS. In this group, the risk of high amputations increased 3.2-fold with increasing age for every 10 years; 1.69 times – with an increase in the level of HbA_{1c} by 1%; 7.53 times – with involvement of bones, tendons and deep tissues in the process. Analysis of a group of patients with preserved main blood flow did not reveal objective predictors for high amputations (Fig. 3).

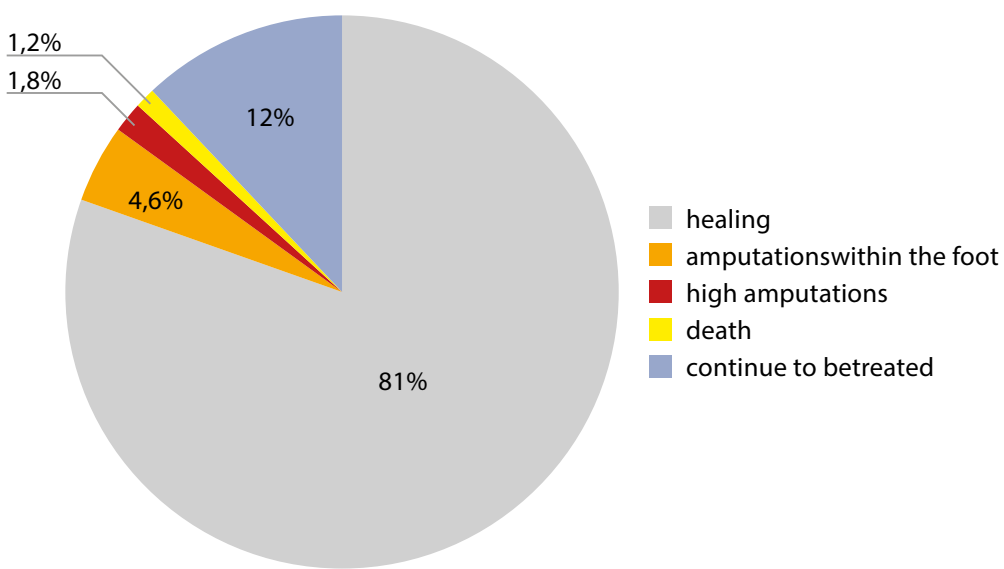

Figure 2. Outcomes of ulcer defects in diabetic foot syndrome in a cohort of patients followed up in the diabetic foot department from 2014 to 2019.

Table 1. Outcomes of ulcer defects in neuropathic (DFSn) and neuroischemic (DFSni) forms of diabetic foot syndrome

Outcome	Neuropathic DFS (n=336)	Neuroischemic DFS (n=167)	p
Healing within 12-month, n (%)	294 (87.2)	113 (67.7)	0.0001
Ongoing, n (%)	31 (9.2)	30 (18)	0.004
Death, n (%)	2 (0.6)	2 (1.2)	0.405
Amputations, total	10 (3)	22 (13.2)	
at foot level, n (%)	9 (2.6)	14 (8.4)	0.005
at ankle level, n (%)	1 (0.3)	2 (1.2)	0.538
at thigh level, n (%)	0	6 (3.6)	0.01

Note: Numerical data are presented as absolute number and percentage (n,%).
DFS, diabetic foot syndrome.

According to our data, parameters related to the patient's characteristics, such as sex, DM type, type of glucose-lowering treatment, and presence and severity of DM complications, do not significantly affect the frequency of high amputations.

At the next stage, we identified factors affecting the healing and absence of healing of ulcer defects as a result of conservative measures during the year.

Patients with healed and non-healed ulcer defects differed in the duration of the ulcer defect before seeking specialized care. Among the healed wounds, there were significantly more which existed less than 30 days. Among the unhealed wounds, there were more of those that formed as a result of surgery and with impaired main blood flow. For other parameters related to both the patient and the ulcer defect, there were no differences between the groups.

A binary logistic regression method was used to identify parameters simultaneously affecting and influencing the outcome (healing or non-healing during the year). Significant predictors of non-healing with conservative treatment during the year included impaired main blood flow and untimely seeking specialized medical care (Table 2).

DISCUSSION

This paper presents a study of the outcomes of treatment of 503 DFS patients with ulcer defects receiving specialized outpatient care. Given the possible impact of COVID19 on the structure of nosologies, the number of patients, their ability to follow the prescribed regimen and visit the clinic, it was decided to analyze the data for 5 years preceding the pandemic, from 2014 to 2019. Most of the ulcer defects in DFS patients treated on an outpatient basis occur with the adequate main blood flow (67%). The number of high amputations during the study period (2014-2019) in the overall group was 1.8%. The main risk factor for high amputations was an impairment of the main blood flow in the affected limb. After stratifying the group according

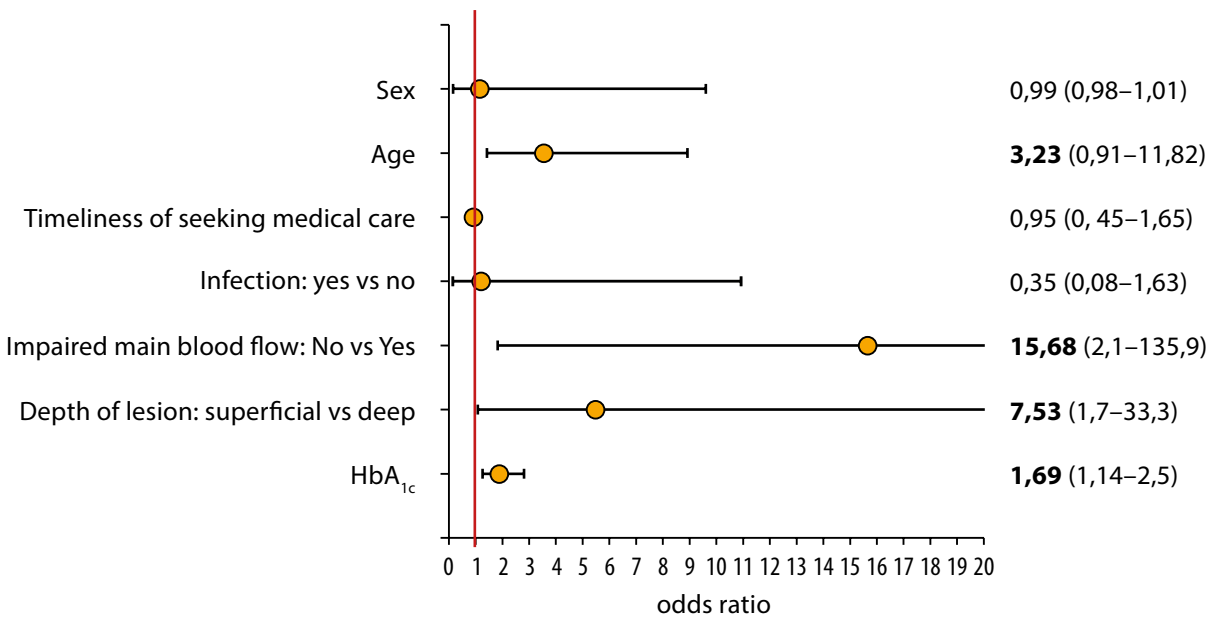

Figure 3. Predictors of the need for high amputations in patients with neuroischemic DFS.

Note: On the right: numerical values of the odds ratio, confidence interval in brackets. Statistically significant predictors are those which range does not cross the line corresponding to 1: age (p=0.006), impaired main blood flow (p=0.001), depth of lesion according to Wagner's classification (p=0.003), HbA_{1c} (p=0.001).
HbA_{1c}, glycated hemoglobin.

Table 2. Predictors of non-healing of ulcer defects with conservative treatment in a cohort of DFS patients receiving specialized outpatient care

Predictor	Overall DFS cohort (n=503)		
	OR	95% CI	P
Age, per 10 years of age increase*	1.19	0.67–1.27	0.25
Sex (M vs F)	0.59	0.33–1.07	0.88
Wound size: >1 cm^2 vs ≥1 cm^2	1.44	0.75–2.74	0.29
Seeking specialist care, 1 month increase	1.07	1.03–1.11	0.001
HbA_{1c}, 1% increase	0.95	0.79–1.16	0.71
Localization: plantar vs rear	0.966	0.44–1.88	0.53
Infection: yes vs not	1.15	0.65–2.02	0.67
Wound depth: superficial vs deep	0.92	0.47–1.88	0.48
Main blood flow impairment: no vs yes	2.01	1.18–3.43	0.014

Note: OR, odds ratio of the event (no healing during the year); CI, confidence interval; DFS, diabetic foot syndrome; M, male; F, female; HbA_{1c}, glycated hemoglobin.

to the state of blood flow, the number of high amputations was 0.3% in the group with neuropathic ulcer defects, and 8% in the group with neuroischemic defects. The rates we obtained are comparable to those published in the literature regarding high limb amputations among patients receiving care on an outpatient basis. For example, according to the largest prospective multicenter study EURODIALE, the proportion of high amputations was 5% among all patients with DFS and 8% among patients with neuroischemic DFS [10]. In Nottingham (UK), high amputations were performed in 5% of patients with DFS [11], and in a cohort study conducted in Germany – in 3% of patients [12]. In these two studies, the group was not stratified by the main blood flow. At the same time, according to our data, the risk of high amputations in patients with ischemia of the limb increases by 3.2 times for every 10 years of age increase, by 7.5 times with an increase in the depth of damage per every grade according to Wagner's classification, and by 1.7 times per 1% increase in HbA_{1c} level. It should be noted that the data on the effect of carbohydrate metabolism control on the likelihood of high amputations in patients with neuroischemic form of DFS were obtained for the first time. The results of a study were published that involved patients with SD1 without specifying the state of the main blood flow, where the relative risk of high amputations increased by 1.68 times per 1% increase in HbA_{1c} [13]. There are also indications that at HbA_{1c} >7%, the relative risk of amputations at any level doubles [14]. Considering that reducing blood glucose to target values is a modifiable parameter, the normalization of carbohydrate metabolism can be considered as an essential component of reducing the number of high amputations in DM patients with impaired main blood flow in the arteries of the lower extremities.

Healing without performing high and small amputations in the total cohort of patients with DFS was achieved in 406 cases (80.7%). The data on the number of wounds healed during the year are comparable to the published data in a number of European clinics. For example, in the EURODIALE study, healing of ulcer defects in DFS was achieved in 77% [15]. According to a prospective study of German colleagues, the healing rate of ulcer defects in DFS was 57% in complicated forms of DFS, including a decrease in blood flow in the affected limb, infection, osteomyelitis, and up to 93% in uncomplicated forms. It should be noted that this study does not indicate the time frame at which the above result was achieved. The percentage of high amputations was 3% in the overall group of patients with DFS [12].

Significant predictors of non-healing with conservative treatment during the year were impaired main blood flow and untimely seeking specialized medical care. When stratifying the cohort according to the state of the main blood flow, the predictor of non-healing was untimely seeking specialized medical care and lesion size exceeding 1 cm^2 in the neuropathic form of DFS. No evidence of any effect on the outcome was found for of demographic parameters (age, sex) and clinical parameters (DM type, HbA_{1c}, location of the ulcer defect, its depth, infection at the initial treatment). These results differ from published results from cohort studies. For example, in the EURODIALE study, predictors of non-healing in the general group of patients with DFS were age, male sex, heart failure, end-stage chronic

kidney disease, large size of ulcer defect, impaired main blood flow, and peripheral neuropathy. The parameter determining the non-healing in patients with impaired main blood flow was infection [15]. In our study, no effect of infection on the outcome of ulcer defect during the year was identified. One possible explanation for this is the mandatory prescription of antibacterial drugs when signs of infection are detected during initial presentation, adequate surgical treatment of the wound and more frequent visits to the department (2–3 visits a week) for wound care.

Special attention should be paid to such an indicator as the timeliness of seeking specialized medical care. This parameter is one of the key ones in terms of preventing high amputations, but experts rightly note that this recommendation is based on theoretical assumptions rather than on real numbers [10]. In our study, we obtained first objective data confirming the great importance of seeking specialized care as quickly as possible.

CONCLUSION

In conclusion, restoration of the main blood flow in the affected limb, control of infection and compliance with the unloading regimen are able to minimize the number of high amputations and achieve healing of ulcer defects in the majority of cases. Our cohort analysis demonstrated the high efficiency of specialized care for this category of patients at the pre-hospital stage. In this regard, the organization of outpatient rooms for diabetic foot patients is of fundamental importance both in relation to the prevention of high amputations of the lower extremities in DM patients, and the healing of chronic ulcer defects of the feet.

FURTHER INFORMATION

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Contributions of authors. E.Yu. Komelyagina – study concept and design, collection of clinical data, selection of patients, review of relevant publications, processing and analysis of the data, writing the text; M.B. Antsiferov – study concept and design, editing, final approval of the manuscript. All authors approved the final version of the manuscript before publication, agreed to be responsible for all aspects of the manuscript, ensuring proper investigation and resolution of issues related to the accuracy or fidelity of any part of the manuscript.

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