



## ANALYSIS OF OUTPATIENT TREATMENT OF COMPLICATIONS OF DIABETES MELLITUS - TROPHIC ULCERS

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### Abstract:

According to the World Health Organization, over the past 40 years, the number of adults with diabetes mellitus (DM) has increased from 108 million to more than 500 million. Diabetes disease and its prevalence have been growing sharply over the past decades. Diabetes mellitus is one of the ten leading causes of death worldwide and the number of its complications is steadily increasing. One of the main complications of diabetes mellitus is diabetic foot syndrome (DFS), a cause of non-traumatic amputations of the lower extremities. According to data, in 2020, diabetic foot syndrome develops in 6.3% of the total number of patients with diabetes. Due to the advent of new, modern methods of surgical and endovascular revascularization in developed countries, there has been a tendency to reduce the number of high amputations in patients with DFS, despite this, the relative number of other causes of amputation, primarily due to surgical infection of soft tissues, is increasing due to the development of various forms DDS - neuropathic, neuro-ischemic. In a large number of studies, the authors note late or insufficient diagnosis of this condition in patients with pathological changes in the foot due to diabetes, which leads to severe complications and is accompanied by a high risk of high limb amputation. In some sources, trophic ulcers complicate the course of the disease in 15%, in other sources, the authors note that trophic ulcers are the most common complication of diabetic foot syndrome, occurring in 50 - 60% of cases

**Keywords:** Diabetes mellitus, wound infection, ischemia, neuropathy, trophic ulcer.

### INTRODUCTION

Neuropathy and/or ischemia play a major role in the development of diabetic foot infection. Emerging ulcerative defects become a constant source of infection in complicated DFS, which, with a long-term existence of first a superficial ulcer, then a deep one, can subsequently be complicated by phlegmon, osteomyelitis, gangrene, which can subsequently lead to amputation at various levels. Trophic ulcers in DFS are chronic wounds and differ from ordinary wounds in the duration of their course and, most often, in extremely rare healing. The literature describes this as a complex process of restructuring of the extracellular matrix and tissue remodeling with a sharp slowdown in collagen formation. The time threshold of existence is associated with the phenomena of peripheral neuropathy, changes in macro and microcirculation, often accompanied by osteoarthropathy. The healing time for these chronic wounds is very long and most often recur[.]. A favorable success factor in the treatment of trophic ulcers in diabetes is following the modern protocol for patient management and individual selection of local effects on the ulcer in

accordance with the stages of the wound process. This pathology is usually very difficult to treat and it is important to know the bacterial flora for adequate antibacterial therapy. Despite the progress of medicine and significant progress in the treatment of various complications of diabetes mellitus, the problem of treating patients with purulent-necrotic lesions of the lower extremities still remains unresolved [1]. The widespread introduction of endovascular and non-traditional revascularization operations, the creation of new drugs, significantly improved the results of the treatment of diabetic foot syndrome, however, many aspects remain unresolved [2]. In Russia, 5 out of 6 amputations not associated with trauma and oncological diseases are performed in patients with purulent-necrotic complications of the diabetic foot syndrome [1,5,9,13]. In this case, the most common level of amputation is the upper third of the lower leg or thigh. In the structure of the causes of all non-traumatic amputations of the lower extremities, patients with diabetes mellitus account for 50-70% [4]. Studies have shown that even one year after diagnosis of diabetic foot infection, 55% of patients still have



infection, and 15% have undergone amputation. In view of this, the treatment of this disease represents a complex clinical problem.

**PURPOSE OF THE STUDY:** to analyze the results of outpatient observation and treatment of patients with trophic foot ulcers due to diabetes mellitus using modern principles of general and differentiated local treatment.

#### MATERIALS AND METHODS:

An analysis was conducted of patients with diabetic foot syndrome (DFS) who attended a consultation and received outpatient treatment in 2021–2022. Over 2 years, 1070 patients underwent outpatient visits: women – 526 (49.1%) (average age 63.9 years); men – 544 (52.9%) (average age 59.3 years). Patients were divided according to the form of DFS into neuropathic – 535 (50.0%) and neuroischemic – 535 (50.0%). They were then all classified into degrees according to the University of Texas classification (Ralph de Fronzo 1988).

Table 1

Patients with neuropathic form of SDS (n=535)

Table 1

	0	I	II	III
A(-)infection	21,7%	34,8%	6,0%	
B(+) infection	-	8,2%	7,5%	21,8%

Table 2

Patients with neuroischemic form of DFS (n=535)

	0	I	II	III
C (+) ischemia	-	36,0%	8,3%	16,0%
D (+) ischemia+infection	-	2,1%	3,8%	33,8%

The diagnostic protocol at the specialized stage includes in the algorithm: clinical data, thermometry of the feet (infrared thermometry), rheovasography, ultrasound of the peripheral arteries of the lower extremities, MSCT with contrast according to indications, radiography of the feet in 2 projections, MRI if osteoarthropathy is suspected. During the purulent-destructive process, clinical (localization of ulcerative defects, wound depth, bone probing) and laboratory studies (leukocytosis, C-reactive protein, ESR) were carried out. The tactics and principles of outpatient and inpatient management were based on modern national and foreign recommendations. Based on the stage of the process, patients with the neuropathic form (grades AII, BII, BIII) and the neuroischemic form (grades CIII and DIII) were sent for treatment to a specialized surgical hospital. Other

patients were treated on an outpatient basis. 616 people were treated outpatiently. There were 388 patients with the neuropathic form, of which diabetic osteoarthropathy was diagnosed in 194 (grade A0 = 63). Of this group, 262 had trophic foot ulcers (AI – 200, BI – 62). Trophic ulcers + Osteoarthropathy in 68 patients. With the neuroischemic form - 228, all of them had trophic ulcers (CI - 201, DI - 27). During the combined outpatient treatment of patients with trophic ulcers, blood glucose was corrected, and the basic principles of local treatment of trophic ulcers, which were defined in consent documents, were implemented.

- Unloading of the affected area of the limb (evidence level 2B);
- Sanitation of a wound defect (level of evidence 1A);
- The use of modern dressings and the creation of a moist environment (evidence level 3A) and mandatory control of exudation (evidence level 1A);
- antibacterial therapy depending on the results of microbiological testing (level of evidence 2C).

Outpatient visits to a specialized specialist were carried out and depended on the presence and severity of the purulent process. Patients with infected ulcers were observed on an outpatient basis up to 2–3 times a month, without infection – once a month. The results of treatment were assessed within 1 year of observation of groups of patients in accordance with the initial degrees of damage; patients who were operated on in the purulent surgery department were also treated on an outpatient basis. These patients were observed as in the outpatient group, but we did not include them in the statistics. The material of the article was processed using standard statistical methods in the Biostat program.

**RESULTS AND DISCUSSION:** When analyzing the patient's medical record, it was revealed that 78% with DDS had target glycemic values (the average glycated hemoglobin (HbA1c) was 13.7% with normal values (7.0–7.5%), which required connection to the treatment of an endocrinologist. The regimen of glucose-lowering therapy was changed. Most often, basal insulin was added to oral glucose-lowering therapy or the patient was transferred to a basal-bolus insulin therapy regimen. For outpatient treatment, limb unloading was recommended for all patients. For trophic ulcers, "Total contact cast" was used (TSS) + unloading shoe; for osteoarthropathy with a trophic ulcer (TCC). The average time for unloading a limb for patients with osteoarthritis is 4-12 months, for patients with a trophic ulcer until complete epithelization of the ulcer, most often up to 4 months. PSO (surgical debridement of the wound), was carried out by a surgeon without anesthesia, the goal of which is the most complete removal of necrotic and non-viable



tissue in patients without critical ischemia in order to convert a chronic wound into an acute one. The wound was treated with sterile saline or 0.05% aqueous solution of chlorhexidine digluconate. For local treatment, according to indications, various wound coverings were used, such as (Inadin, Mepitel NA-dressing, Branolind N, Atrauman Ag, Voskopran, Parapran); hydrogels (Normgel, Hypergel, Hydrosorb, Askina Gel); hydrocolloids ("Askina hydro", "Kutinova hydro", "Hydrocoll"); hydrocellular polyurethane dressings ("Mepilex", "Tielle", "Alevin", "Askina Foam"); exudate and odor absorbers ("Actisorb", "AskinaCarbosorb"); alginates ("Sorbagon", "Melgisorb", "Askina sorb", "Algisayt M"); film coatings ("Hydrofilm"); lipid colloid sponge coatings ("Permafoam", "Urgotul"), biofilms ("Kolost", "G-Derm"). We consider the advantages of these dressings to be non-traumatic and hypoallergenic, the ability to allow air and water vapor to pass through, as well as maintaining a constant pH in the wound. Treatment was carried out in accordance with the stages of the wound process, taking into account the area and depth of necrotic tissue damage, the amount and nature of exudate, changes in the edges of the wound. In our practice, atraumatic mesh dressings were more often used. Their advantage is the possibility of use at any stage of the wound process. Infected wounds were preferred to be treated with dressings with ions silver. Depending on the degree of wetness, the dressing was changed; if there was slight exudation on the wound, the dressing was left in place for up to 5-7 days. Priority was given to the "Atrauman Ag" and "Branolind N" dressings - the dressings are very soft and flexible and do not injure the wound. At the stage of necrotic rejection and exudation, together with atraumatic dressings, antiseptics were used (preference was given to the drug povidone-iodine, iodopirone, betadine) or enzymes, as well as water-soluble ointments. For flat ulcers with heavy or moderate exudation, polyurethane foam sponges were prescribed. Most often, dressings with silver ions (Mepilex Ag, AskinaCalgitrol) were used to treat infected wounds. For moderately exuding ulcers, preference was given to sponge dressings with a hydrogel mesh layer. They absorb wound exudate well, but do not dry the wound; they create a physiological moist environment for healing, which stimulates the growth of granulation and epithelization (HydroTak dressing). Sponge dressings were used for flat ulcers, which facilitates their tighter adherence to the wound surface. In the case of deep, profusely exuding ulcers, sponge dressings were used as secondary dressings, after alginate ones, since they perfectly absorb excess exudate. For significant amounts of exudate and deep ulcers, absorbent alginate wound coverings with high absorbency and

cleansing ability were used. They effectively remove wound contents and prevent skin maceration. In case of concomitant infection or the presence of high-risk factors for its development, we used dressings with silver ions. For deep trophic ulcers, necrolytic drugs (trypsin, chymotrypsin, ribonuclease, etc.) in powder form were used to cleanse the wound. During the exudation stage, the dressings were changed as they got wet. Maximum fixation of the bandage on the wound was carried out using self-fixing bandages, for minimal trauma, using classic dressing material. For superficial ulcers with dry necrosis, dressings with hydrogels were used to cleanse the wound by hydrating it and stimulating tissue necrolysis. In the case of deep ulcers with the presence of necrotic tissue and moderate exudation (only for the neuropathic type), "smart" dressings were used, such as HydroClean plus, which simultaneously stimulate the rejection of necrosis and absorb wound exudate, ensuring wound cleansing. In case of polyinfection, systemic antibacterial therapy was carried out in accordance with the qualitative composition of the microflora, selectively analyzed in 200 patients. From our results it is clear that the microflora of the wounds contained G (+) - aerobes - 58% of the crops. G (-) - aerobes, anaerobes and fungi of the genus *Candida* accounted for the second half of the cases. MRSA was found in 14% of cases, *Pseudomonas aeruginosa* in 4% of studies. The drugs of choice for antibacterial therapy were fluoroquinolones (levofloxacin, moxifloxacin), inhibitor-protected penicillins (amoxicillin + clavulanic acid). Before prescribing antibacterial therapy, the patient's renal excretory function must be examined.

A trophic ulcer, cleared of necrotic tissue, fibrin, subsidence of perifocal inflammation, decreased exudation and formation of granulations, created conditions for optimal regeneration and mechanical protection of young granulation tissue. For neuropathic ulcers, sponge hydropolymer dressings were used to heal the wound in a moist environment. In the neuroischemic form, antiseptics were used at this stage. (solutions of dioxidine, povidone-iodine, betadine, iodopirone) and atraumatic dressings with antiseptics (povidone-iodine, ionized silver), in stage II the dressings were changed after 5-7 days. During the epithelization stage, liquid antiseptics, neutral atraumatic dressings, and sometimes transparent semi-permeable dressings were used to avoid trauma to the growing epithelial tissue and the developing scar and for visual control of the wound process. Dressings were changed 3-5 times a week. The healing time of extensive defects was reduced through the use of wound coverings (bioresorbable implants) based on collagen ("Collost" in the form of 7% gel and membranes, G-Derm membrane), promoting migration

and proliferation of fibroblasts, creating physiological conditions for wound healing. Based on the results obtained, differentiated treatment of trophic ulcers and constant monitoring of the patient by a surgeon and endocrinologist contribute to fairly satisfactory results in both forms of DFS. Of the 186 patients with the neuropathic form, who were regularly observed and treated by specialized specialists, healing was achieved in 130 (78.3%). Others continue to be observed and receive the necessary treatment. Based on the study, it can be said that trophic ulcers tend to sluggish granulation and prolonged epithelization. In the neuroischemic form, out of 206 patients regularly observed by a surgeon and endocrinologist, epithelization was achieved in 152 (73.8%), trophic ulcers were non-epithelialized in 38 patients (18.4%), minor and high amputations were performed, respectively, in 3.9 and 3.9% cases. Preservation of the supporting limb was achieved in 96.1% of cases. In general, in the outpatient group of patients with ulcers due to diabetes mellitus, the number of high amputations of the lower extremities during 2 years of observation was minimal - 4 (1.63%).

**CONCLUSION:** As a result of the observation, it was revealed that: implementation of the standard modern protocol for the management of patients with trophic foot ulcers that complicated the course of diabetes mellitus, individual use of a wide range of modern dressings for local treatment and dynamic observation by specialized specialists, made it possible to reduce the number of high limb amputations in over 2 years of observation to minimum values. The use of cellular technologies and modern bioabsorbable collagen-based materials has significant prospects for improving treatment results and accelerating the healing of trophic ulcers against the background of diabetes mellitus.

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