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SPECIFICITY OF TREATMENT IN PATIENTS WITH PURULENT-NECROTIC COMPLICATIONS OF DIABETIC HEEL SYNDROME

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ABSTRACT

This article covers the prevalence of diabetes mellitus, the epidemic scale of diabetic heel syndrome, a significant increase in the number of patients, an increase in the life expectancy of patients with diabetes due to the creation of effective means and methods of treatment, an increase in the number of late complications of the disease, problems of patient disability, optimal methods of treatment.

Keywords

Kandli diabetes, diabetic retinopathy, polyneuroangiopathy, nephropathy, hyperglycemia, atherosclerosis.

The problem of treating patients with the neuropathic form of diabetic foot syndrome (DFS) is becoming increasingly relevant for clinical surgery, as the number of late purulent necrotic complications increases against the background of a widespread increase in the incidence of diabetes mellitus (DM) [1-4]. Currently, 15-25% of DM patients have ulcerative necrotic changes in the tissues of the foot, while at least 27-44.2% of the SDS structure accounts for the neuropathic infected form [1,5].

Despite significant advances in the study of the etiology and pathogenesis of SDS, improvement of diagnostic and treatment methods, statistics on the frequency and outcome of purulent necrotic lesions of the lower extremities still remain disappointing. To date, among all non-traumatic amputations of the lower extremities, 40-60% are performed in patients with diabetes due to the development of purulent-necrotic complications, and in 6-22% they cause deaths [6, 9].

The modern concept of complex multidisciplinary treatment of purulent-necrotic complications of the neuropathic form of SDS is based on the following principles: complete unloading of the affected limb; radical surgical treatment of a purulent focus; local treatment and control of wound infection; rational antibacterial therapy; hypoglycemic and metabolic therapy; if necessary, early plastic closure of the wound (plastic reconstruction of the foot) with the utmost possible preservation functions of the affected limb [14-16]. At the same time, the

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insufficient effectiveness of treatment for purulent-necrotic complications of SDS is largely due to a significant decrease in antiinfection resistance in this category of patients, which is facilitated by a violation of local tissue reactions, inhibition of immune mechanisms regulating the wound reparative process, including cytokine imbalance, high microbial contamination of the wound surface [1,6]. At the same time, one of the problems of treating patients with SDS is directly related to the insufficiently high effectiveness of antibacterial therapy due to the presence of bacterial infections associated with biofilms in purulent-necrotic wounds, which reduces the sensitivity of bacteria to anti-bacterial agents by 100-1000 times [1,5].

Currently, the prospects for successful treatment of purulent-necrotic complications in patients with SDS are associated with the use of new adjuvant wound treatment methods, in particular Negative pressure wound treatment (NPWT) [2,5], the use of targeted immunocorrection [3], as well as with an increase in the effectiveness of systemic antibacterial therapy [7].

Regarding the issue of increasing the effectiveness of antibacterial therapy, taking into account the polymicrobial nature of the purulent focus in patients with SDS [1], we drew attention to the combined drug "Tsifran ST", intended for the treatment of infections caused by aerobic and anaerobic microorganisms. It contains ciprofloxacin hydrochloride and tinidazole. Ciprofloxacin is a broad—spectrum antibiotic, active against most aerobic gram-positive and Gram-negative microorganisms, such as Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus haemolyticus, Klebsiella spp., Proteus vulgalis, Proteus mirabilis, Pseudomonas aeruginosa, Citrobacter spp., Enterococcus spp. et al. Tinidazole is effective against anaerobic microorganisms (Bacteroides fragilis, Peptococcus spp., Peptostreptococcus anaerobius, Clostridium spp.).

At the same time, a number of researchers point to the high clinical and bacteriological effectiveness of the drug "Tsifran ST" in the treatment of patients with purulent wounds of the skin and soft tissues of aerobic and anaerobic etiology, including those with SDS [4]. In addition, according to recent data, ciprofloxacin (especially in combination with other antibacterial drugs) reduces the adhesion and mobility of biofilm forms of bacteria on biological surfaces, thereby reducing the degree of colonization and contributing to the destruction of biofilms [5].

The aim of the study was to improve the results of treatment of patients with purulent—necrotic complications of SDS by including NPWT therapy in a comprehensive treatment program in combination with the use of the combined antibacterial drug "Tsifran ST" and immunocorrective therapy.

Material and methods

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A prospective multicenter study was conducted at the clinical bases of Rostov State Medical University and Kuban State Medical University (City Hospital No. 7 and City Hospital No. 1 named after N.A. Semashko, Rostov-on-Don, Krasnodar Regional Clinical Hospital No. 1 named after Prof. S.V. Ochapovsky) for the period from 2015 to 2018. The results of treatment of 184 patients with a neuropathic form of SDS complicated by the development of a purulent necrotic process were analyzed. Among the patients included in the study were 78 (42.4%) men and 106 (57.6%) women. The average age of the patients was 59.7±4.5 years. At the time of admission, the average level of glycated hemoglobin in the blood of patients was 11.3± 1.5%. According to the Wagner classification, grade II foot tissue damage was diagnosed in 19 (10.3%) patients, grade III in 118 (64.1%) and grade IV in 47 (25.5%). Patients with hemodynamically significant lesion of the main arteries of the lower extremities, which was revealed by the results of ultrasound duplex scanning, were excluded from the study.

In 135 (73.4%) patients, purulent-necrotic tissue changes were localized in the area of the plantar surface of the foot. At the same time, 115 (62.5%) patients were diagnosed with subaponeurotic or deep (subcutaneous) phlegmon of the plantar surface of the foot. Subfascial phlegmons of the back of the foot were observed in 48 (26.1%) patients.

All patients underwent radical surgical treatment of a purulent necrotic lesion upon admission to the hospital. If necessary, bone resection was performed during surgery (most often the heads of the metatarsal bones). Subsequently, patients underwent generally accepted complex multicomponent therapy, including complete foot unloading, insulin therapy under control of glycemia levels, systemic antibacterial therapy, detoxification, metabolic and anticoagulant therapy taking into account hemostasiogram indicators, as well as local wound treatment. After the appearance of granulations and marginal epithelialization in the wound, plastic closure of the wound was performed with local tissues or a free perforated skin flap.

Depending on the choice of treatment methods in the postoperative period, all patients are divided into two groups. The first group (comparison) consisted of 95 patients in whom modern iodine-containing ointments based on polyethylene glycol (Stellanin-PEG 3%, Betadine) were used for the local treatment of purulent foot wounds. In the postoperative period, for 2-4 weeks, patients underwent systemic antibacterial therapy with drugs selected according to the results of an antibioticogram. Antibacterial drugs were administered intravenously or intramuscularly.

The 2nd (main) group included 89 patients in whom, after surgical treatment of purulent-necrotic foci in the postoperative period, negative variable pressure

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therapy was used for wound treatment using a VivanoTec S 042 NPWT vacuum apparatus and a VivanoMed dressing kit (Paul Hartmann, Germany). NPWT therapy was performed in an intermittent mode (125 mmHg / 5 min — 20 mmHg / 2 min). In the 2nd group of patients, antibacterial therapy was combined. After surgery, in addition to parenteral antimicrobial therapy, patients were additionally orally prescribed the combined drug "Tsifran ST" (500 mg 2 times a day for 10-14 days). At the same time, the total duration of systemic combined antibacterial therapy did not exceed 14 days. In addition, early after surgery, group 2 patients underwent immunocorrective therapy aimed at eliminating cytokine imbalance. For this purpose, during the first 5-7 days after surgery, patients were injected with the drug "Leukinferon" (a combination of natural leukocyte interferons and other cytokines of the first phase of the immune response). The drug was diluted in 50 ml of 0.9% sodium chloride solution (10,000 IU) and administered intravenously.

The analysis of the dynamics of the wound process was carried out according to the clinical picture (the presence of signs of inflammation in the wound, the appearance of granulation tissue, the onset of wound epithelialization) and the results of cytological, bacteriological and immunological studies of wound material obtained during surgery and on the 5th, 10th, 15th and 20th days after surgery.

Cytological examination included taking smear prints from the wound surface according to the method of M.P. Pokrovskaya and M.S. Makarov, followed by staining of preparations according to Romanovsky-Gimza. Cytological preparations were studied at a magnification of 900 times using immersion microscopy. When interpreting the results of cytological examination, the type of cytogram was evaluated [7], and the regenerative degenerative index (RDI) was calculated [2]. The bacteriological study included qualitative and quantitative analysis of the microflora in the foci of infection using standard methods. In addition, the content of proinflammatory and anti-inflammatory cytokines, interleukin (IL) 1β, 4, 6 and 10, was determined in patients during treatment in the wound discharge. To determine the cytokine content in the wound discharge, the method of solid-phase enzyme immunoassay was used using appropriate test kits.

The research results were processed on a personal computer using Microsoft Excel 2016 software and the R statistical program (version 3.2, R Foundation for Statistical Computing, Vienna, Austria). At the same time, conjugacy tables were built, the mean, standard deviation, median, mode, interquartile range (25th and 75th quartiles), chance, absolute and relative risks, the Wilcoxon-Mann-Whitney U-test, Pearson's criterion for comparing distributions -2, and Fisher's exact criterion were calculated. The differences were recognized as statistically significant at $p<0.05$.

Results and discussion

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A comparative clinical assessment of the dynamics of the course of the wound process after surgery in the studied groups of patients showed that in the conditions of complex treatment in patients of the 2nd group, the elimination of inflammatory changes (edema, hyperemia), cleansing of the wound from purulent necrotic tissues, the initial appearance of granulations and their execution of a wound defect were noted at a much earlier time (Table 1). Thus, in patients of group 1, only on day 21.1±0.8, the wound was performed with healthy fine-grained granulations and foci of marginal epithelialization appeared. In patients of the 2nd group, the course of the wound process was clinically noted to be close to the normal course with the transition from phase I to phase II on the 12th-16th day (on average, 14.2± 0.9 days). At the same time, in patients of group 2, wound epithelialization after surgery (if plastic wound closure was not performed) occurred on average 6.8 days earlier (18.6± 1.7 days) than in patients of group 1 — 25.4± 0.9 days.

The dynamics of changes in the content of proinflammatory and anti-inflammatory cytokines in wound exudate in patients of groups 1 and 2 during treatment is shown in Fig. 3. From these data, it follows that in patients of the 2nd group in the postoperative period, a more pronounced regression of the level of all studied cytokines was observed compared with patients of the 1st group. Thus, in patients of group 2 after surgery on day 5, the content of IL-1ß in the wound discharge was 12.2% lower (216±3.2 pg/ml versus 246±4.9 pg/ml in group 1), IL-6 was 10.0% lower (217±3.1 pg/ml vs. 241±4.5 pg/ml), IL-4 — by 17.8% (152±2.7 pg/ml vs. 185±7.3 pg/ml), IL-10 — by 13.3% (215±3.4 pg/ml vs. 248±3.6 pg/ml) ($p<0.05$). In the subsequent periods of observation, this trend continued. At the same time, the most distinct difference in cytokine content in patients of groups 1 and 2 was noted for IL-1β and IL-6 on the 15th day after surgery, when it amounted to 45.2 and 39.5%, respectively, and for IL-4 and IL-10 on the 20th day, respectively 34 and 18.3% ($p<0.05$).

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