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POSSIBILITIES OF LASER AND PHOTODYNAMIC THERAPY IN THE TREATMENT OF PURULENT-NECROTIC PROCESSES OF THE LOWER EXTREMITIES IN PATIENTS WITH DIABETES MELLITUS

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Abstract:

The article presents the results of clinical studies on the possibility of using laser and photodynamic therapy in the treatment of purulent-necrotic processes of the lower extremities in patients with diabetes mellitus. To this end, the authors conducted clinical studies of 110 patients operated in the department of purulent-septic surgery of the ASMI clinic. Studies have shown that after the opening of the purulent-necrotic process of the lower extremities in patients with diabetes mellitus with the use of laser therapy in combination with photosensitization, accelerated regression of inflammatory infiltration, complete cessation of purulent-necrotic discharge, wound cleansing and activation of regeneration processes.

Keywords: Diabetic phlegmon, autopsy of the purulent-necrotic process, photosensitization, laser irradiation

RELEVANCE

Diabetes mellitus (DM) is an important public health problem, "affecting about 424.9 million people worldwide, a third of whom are over 65 years of age." Patients with DM have an increased susceptibility to infections with a negative evolutionary potential, leading to increased morbidity and mortality compared to the general population[3,5]. Infections localized in soft tissues (skin, fascia and aponeurosis, subcutaneous tissue, muscles) in patients with DM require a comprehensive medical and surgical approach, in which aggressive surgical treatment should be complemented by metabolic balancing and long-term antibacterial therapy. Among the various complications of DM, purulent processes of soft tissues belong to one of the most difficult categories [1,4,7]. Purulent processes (abscesses, phlegmons, boils, carbuncles, hydradenitis, etc.) develop in 10-25% of DM patients. The spread of the infectious process in DM can occur at lightning speed, when a small ulcer or wound can give rise to severe phlegmon and sepsis in a matter of days. Treatment of diabetic phlegmon should be carried out urgently and include the elimination of a purulent-necrotic focus and prevention of further spread of the inflammatory process [2,10]. The surgical method is aimed at achieving rapid healing by removing necrotic tissues, eliminating purulent congestion and creating conditions for adequate drainage. For the local treatment of extensive and long-term non-healing wounds, many methods and wound coverings have been developed[6,9]. Nevertheless, their wide variety indicates that there is currently no perfect method of treating extensive and long-term non-healing wounds in DM, and this determines the relevance of the search for new methods of treatment [2,8]. In this regard, clinical studies concerning the development of new methods of treatment of purulent-necrotic lesions of the soft tissues of the lower extremities in diabetes mellitus are the most relevant in purulent surgery and medicine in general.

The aim of the study is to improve the results of purulent-necrotic lesions of the lower extremities in patients with diabetes mellitus by using photodynamic therapy in combination with laser radiation.

MATERIAL AND METHODS.

The clinical study covered the period from 2020 to May 2023, a total of 110 patients operated on in the department of purulent septic surgery of the ASMI clinic were included for phlegmon of various localization on the lower extremities that developed against the background of DM. All patients were divided into two groups. The main group included 53 patients in whom, for the period from 2022 to May 2023, surgical treatment of phlegmon of the lower extremity was performed according to an improved method of treating purulent-necrotic processes of the lower extremities in patients with DM. The comparison group included 57 patients (2020-2021) whose surgical treatment was carried out according to the traditional method. Both groups were comparable in all major indicators: gender, age, localization and severity of the course of the purulent-necrotic process, etc.

The distribution of patients according to the localization of phlegmon on the lower limb showed that in the comparison group there were 24 (42.1%) patients with a purulent-necrotic process on the thigh and lower leg, in the remaining 9 (15.8%) cases the

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lesion was in the knee area. In the main group there were 22 (41.5%) patients with femoral phlegmon, 8 (15.1%) in the lower leg and 23 (43.4%) on the lower leg (Table 1).

Table 1
Distribution of patients by localization of phlegmon of the lower extremity

Localization	Comparison group		Main group		Total	
	Abs.	%	Abs.	%	Abs.	%
Phlegmon of the thigh	24	42,1%	22	41,5%	46	41,8%
Phlegmon of the knee area	9	15,8%	8	15,1%	17	15,5%
Lower leg phlegmon	24	42,1%	23	43,4%	47	42,7%
Total	57	100,0%	53	100,0%	110	100,0%

Men significantly prevailed in the groups and accounted for 73.7% (42 patients) in the comparison group and 69.8% (37 patients) in the main group. The age of the patients ranged from 18 to 70 years. In most cases, patients were between 40 and 70 years old – 82.5% (47 patients) in the comparison group and 81.1% (43 patients) in the main group.

Table 2 shows the reasons that led to the development of phlegmon on the lower limb. In more than a third of patients, the initial presence of acute inflammatory diseases of the skin and subcutaneous tissue (furuncle, carbuncle, pyodermitis) was noted, and in about 20% of patients, open and closed traumatic injuries of the skin and underlying tissues were the cause of phlegmon. Among other causes were acute diseases of the vascular and lymphatic system (acute thrombophlebitis, acute lymphadenitis, lymphangitis), microtrauma (wounds and abrasions, scratches, cracks), post-burn wounds (chemical, physical), as well as bitten wounds.

All patients at admission complained of the presence of febrile temperature, general intoxication, redness and swelling at the site of the purulent-necrotic process, as well as softening of the infiltrate with the development of a purulent cavity. In the comparison group, 42 (73.7%) and 45 (84.9) in the main group complained of chills, about 10% of patients noted an increase in lymph nodes (Table 3).

Table 2.
The main causes of the development of phlegmon of the lower extremities

Reasons	Comparison group (n=57)		Main group (n=53)	
	Amount	%	Amount	%
Acute inflammatory diseases of the skin and subcutaneous tissue (furuncle, carbuncle, pyoderma)	20	35,1%	20	37,7%
Acute diseases of the vascular and lymphatic system (acute thrombophlebitis, acute lymphadenitis, lymphangitis)	5	8,8%	5	9,4%
Open and closed traumatic injuries of the skin and underlying tissues	12	21,1%	10	18,9%
Microtrauma (wounds and abrasions, scratches, cracks)	6	10,5%	5	9,4%
Chronic diseases (trophic ulcers, dermatitis, eczema, psoriasis, mycosis)	3	5,3%	3	5,7%
Post-burn wounds (chemical, physical)	9	15,8%	7	13,2%
Bitten wounds	2	3,5%	3	5,7%
Total	57	100,0%	53	100,0%

Table 3
Clinical manifestations of purulent-necrotic process of soft tissues of the lower extremities in patients with diabetes mellitus

Clinical manifestations	Comparison group (n=57)		Main group (n=53)	
	Amount	%	Amount	%
T-body elevation (38-40 0S)	57	100,0%	53	100,0%
General intoxication: weakness, pallor, malaise, decreased appetite, nausea, sweating	57	100,0%	53	100,0%

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Chills, headache, thirst	42	73,7%	45	84,9%
Redness and sharp swelling of tissues at the site of the purulent-necrotic process	57	100,0%	53	100,0%
Enlarged lymph nodes	6	10,5%	5	9,4%
Softening of the infiltrate with the development of a purulent cavity	57	100,0%	53	100,0%

Depending on the type of phlegmon, the distribution showed the following. In the comparison group, 21 (36.8%) patients and in the main group, 17 (32.1%) had purulent phlegmon, serous in 6 (10.5%) and 4 (7.5%) patients, respectively, putrefactive in 7 (12.3%) and 7 (13.2%), necrotic in 13 (22.8%) and 16 (30.2%), anaerobic in 10 (17.5%) and 9 (17.0%) patients (Table 4).

Table 4
Distribution of patients with purulent-necrotic process of soft tissues of the lower extremities in patients with diabetes mellitus, depending on the type of phlegmon

Type of phlegmon	Comparison group (n=57)		Main group (n=53)	
	Amount	%	Amount	%
Serous	6	10,5%	4	7,5%
Purulent	21	36,8%	17	32,1%
Putrid	7	12,3%	7	13,2%
Necrotic	13	22,8%	16	30,2%
Anaerobic	10	17,5%	9	17,0%

After a short preoperative course of examination and preparation, all patients were operated on. An autopsy of a purulent-necrotic focus was performed, with necrectomy, while, as mentioned above, the wound management technique differed in the comparison groups.

At the stage of preoperative examination, the following methods were mainly carried out: Standard clinical research methods; clinical and laboratory methods; instrumental methods (ultrasound, ultrasound and tomographic methods according to indications); determination of the degree of intoxication; assessment of local status; sowing of wound discharge on microflora; bacteriological determination of sensitivity to antibiotics; radiography of the affected area according to indications; indications of CT, MRI of soft tissues; according to indications, other additional methods of investigation

RESULTS AND DISCUSSION

Assessment of the dynamics of the wound process after surgery

In both groups, the autopsy and sanitation of the hearth were identical in technical terms. The differences were in addition in the main group of methods of physical impact on the wound, that is, laser irradiation and the photodynamic effect of methylene blue.

The technique of wound rehabilitation using laser therapy in combination with photosensitization

The following task is set – to increase the antibacterial effectiveness and reduce the duration of treatment of purulent-necrotic processes of the lower extremities in patients with diabetes mellitus.

The task is solved by the fact that in the method of surgical treatment of purulent-necrotic processes of the lower extremities in patients with diabetes mellitus, including excision and sanitation of necrotic tissues, the establishment of two-light drains, sealing the wound from the external environment with a sterile polyethylene self-adhesive film (film for dressings) and subsequent antiseptic measures, as antiseptic measures in the postoperative period, drip washing of the wound cavity is carried out through the established drainage with a 0.1% solution of methylene blue for 1 hour under a pressure of at least 500 mm of water.st. at a rate of 60 drops per minute, then, 30 minutes after the start of washing, through a film fixed over the wound, the wound area is irradiated with an Vostok-2 laser device in a defocused continuous mode, in the range of 630-660 nm, with a power of 120 MW, for 1 minute for each on 2.5-3.0 cm2 of the irradiated surface, while washing with methylene blue and laser irradiation with the above parameters is carried out 3-4 times a day for 3-5 days, then 2 times a day for 2-3 days, then 1 time a day for 2-3 days.

Advantages of the method:

- requires less bandages, is not burdensome and painless for the patient;

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- constant irrigation of the wound leads to the leaching of necrotic tissues and pus;

- methylene blue, being an antiseptic, under the action of laser radiation becomes a donator of oxygen radicals, providing a photodynamic effect that is detrimental to all types of pathogenic microflora.

The method includes the following steps:

- dissection of tissues and sanitation of purulent congestion, excision of necrotic tissues with the leaving of two-light transparent drainage tubes in pockets and cavities;

- after removing the drains, the open wound is closed with a sterile polyethylene self-adhesive film, namely, a sterile Hydrofilm Hartmann adhesive film is glued in such a way that the film overlaps on the edges of the unchanged skin, with the sticky side to the wound, to create tightness;

- then, in the postoperative period, drip washing of the wound cavity is carried out through the installed drainage with 0.1% methylene blue solution for 1 hour under a pressure of at least 500 mm of water at a rate of 60 drops per minute, and 30 minutes after the start of washing through a film fixed over the wound, the wound area is irradiated with an Vostok-2 laser device in unfocused continuous mode, in the range of 630-660 nm, with a power of 120 MW, for 1 minute for each 2.5-3.0 cm2;

- this procedure is carried out 3-4 times a day for 3-5 days;

- after the acute purulent inflammation subsides, on average after 3-5 days, the procedure is carried out 2 times a day for 2-3 days and then 1 time a day for another 2-3 days.

On average, laser irradiation with washing is carried out daily until the wound is completely cleaned, the appearance of granulation tissue (on average, the course is 7-10 days, during which 17-25 procedures are performed).

In the early postoperative period, all types of possible complications were taken into account. Their total frequency in the comparison group was 66.7% (in 38 out of 57 patients), while in the main group 24.5% of cases of complicated course were verified (in 13 out of 53 patients), which turned out to be significantly less than in the comparison group ($\chi 2=19.610$; df=1; $p<0.001$). The nature of the lesion determined the possibility of its spread after autopsy and rehabilitation, which was noted in both groups, but at the same time, additional exposure to the wound in the main group actually reduced the risk of developing this complication by 4 times. Thus, in the comparison group, the spread of the inflammatory process to neighboring tissues was noted in 21 (36.8%) patients, and in the main group in 5 (9.4%). Marginal necrosis of the wound developed in 15 (26.3%) and 6 (11.3%) patients, respectively. Other frequent complications in the comparison group were hemorrhage from the wound and infiltration – in 9 (15.8%) patients, while in the main group, the development of the infiltrative process was noted only in 3 (5.7%) patients. The phenomena of acute lymphangitis were registered in 6 (10.5%) and 2 (3.8%) patients (Table 5).

Table 5

The frequency of complications after the autopsy of the purulent-necrotic process of the lower extremities in patients with diabetes mellitus in the study groups

Complication	Comparison group		Main group	
	Abs.	%	Abs.	%
Hemorrhage from the wound	9	15,8%	0	0,0%
The spread of inflammatory purulent process	21	36,8%	5	9,4%
Postoperative wound infiltration	9	15,8%	3	5,7%
Necrosis of the wound edges	15	26,3%	6	11,3%
Acute lymphangitis	6	10,5%	2	3,8%
Patients with complications	38	66,7%	13	24,5%
Reliability of differences	$\chi^2=19,610$; df=1; p<0,001			

The development of complications after the autopsy of the purulent-necrotic process on the lower extremities in patients with diabetes mellitus required appropriate additional measures. In cases of complications in the form of hemorrhage from an operating wound, tamponade with a hemostatic sponge and the appointment of hemostatic agents were limited,

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mainly these complications developed 1-2 days after surgery.

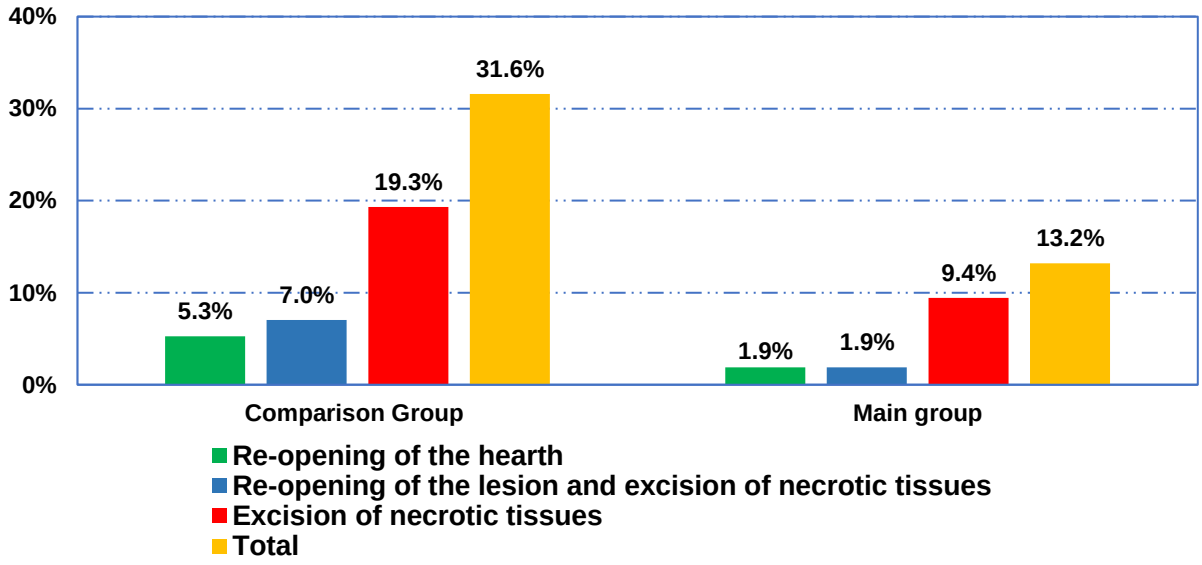
In cases of the spread of the purulent process (purulent congestion), additional interventions were undertaken (opening and drainage of purulent congestion). The patients underwent secondary surgical treatment of the wound from an additional incision. As a rule, these complications occurred 2-3 days after surgery.

In case of infiltration of a postoperative wound, conservative measures were carried out, including physiotherapy procedures, anti-inflammatory and local treatment. These complications occurred in the early postoperative period on 5-7 days.

In cases of complications in the form of necrosis of the wound edges, excision of necrotic tissues was limited.

In cases of acute lymphangitis, complex conservative measures were carried out, including anti-inflammatory, antibacterial drugs, antihistamines, physiotherapy procedures (ultraviolet rays). These complications occurred at the height of the inflammatory process with phlegmon of the lower extremities and persisted in the early postoperative period.

In general, in the comparison group, additional invasive interventions were performed in 18 (31.6%) patients, while in the main group only in 7 (13.2%) ($\chi 2=5,278$; df=1; p=0.022). Repeated opening of the focus during the spread of inflammation was performed in 3 (5.3%) and 1 (1.9%) patients, respectively, in 4 (7.0%) and 1 (1,%) cases, this manipulation was supplemented by excision of necrotic tissues. In 11 (19.3%) and 5 (9.4%) cases, the intervention was limited to excision of necrotic tissues (Pic. 1).



Pic. 1. The number of patients with repeated interventions on the wound

In the early postoperative period in patients after the opening of the purulent-necrotic process, the assessment of the local status in dynamics was carried out according to the condition of the skin around the wound, its color, the presence of edema, hyperemia, purulent swelling or necrotic tissue, local temperature, as well as the nature and size of the wound defect.

First of all, we present data on the dynamics of leukocytosis. In both groups, a regression of leukocytosis was noted in the early period. Thus, in the comparison group, the leukocyte level before surgery was 13.7±3.7 x 109/l, on day 3 the indicator decreased to 11.6±3.5 x 109/l (t=16.08; p<0.05), and on day 7 to 10.3±3.1 x 109/l (t=10.05; p<0.05). In turn, in the main group, the leukocyte level before surgery was 14.2±2.8 x 109/l, on the 3rd day the indicator decreased to 10.1±2.6 x 109/l (t=20.14; p<0.05), and on the 7th day to 8.8±2.1 x 109/l (t=10.07; p<0.05), while the indicators between the groups significantly differed both on day 3 (t=2.63; p<0.05) and on day 7 (t=2.96; p<0.05) (Pic. 2).

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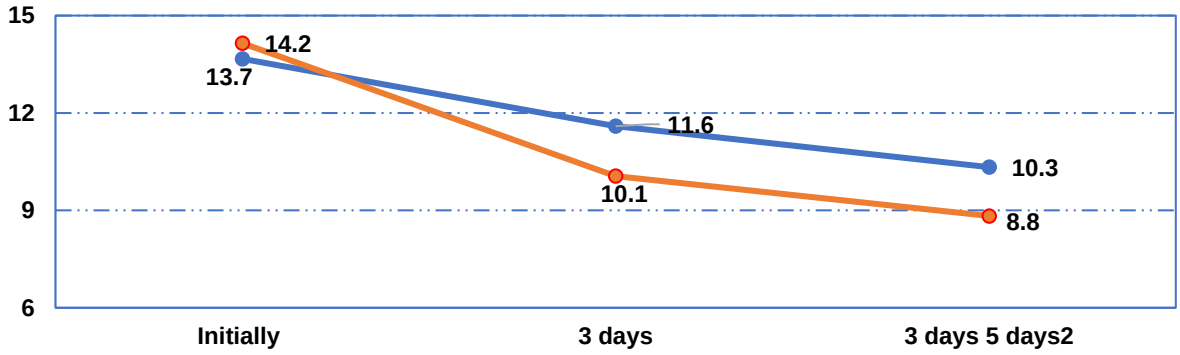
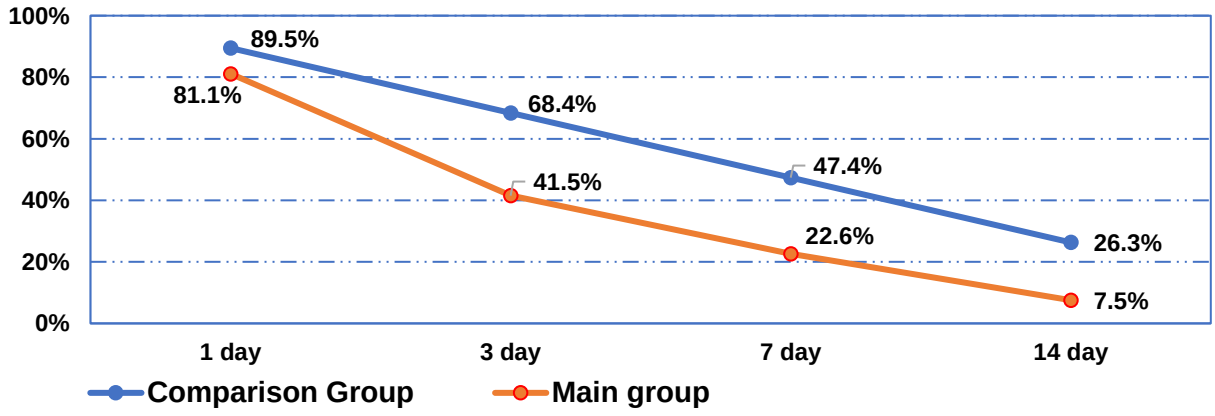


Meaning	Initially		3 day 7 day		7 day	
Difference (Md±δd) in the comparison group	-	-	2,1±1,0		1,3±0,9	
The difference (Md±δd) in the main group	-	-	4,1±1,5		1,2±0,9	
t-criterion in the comparison group	-	-	16,08	<0,05	10,05	<0,05
t-criterion in the main group	-	-	20,14	<0,05	10,07	<0,05
t-criterion between groups	-0,77	>0,05	2,63	<0,05	2,96	<0,05

Pic. 2. Dynamics of blood leukocyte indices (x109/l) in comparison groups (M±δ)

The next factor in assessing the quality of the course of the wound process was the regression of local swelling. On the first day, swelling in the wound area persisted in 51 (89.5%) patients in the comparison group and 43 (81.1%) in the main group (χ2=1.537; df=1; p=0.216). On day 3, this factor was determined in 39 (68.4%) and 22 (41.5%) patients, respectively, while the indicators significantly differed in the main group (χ2=8,052; df=1; p=0.005). On day 7, swelling persisted in 27 (47.4%) patients in the comparison group and only in 12 (22.6%) patients in the main group (χ2=7,338; df=1; p=0.007), and on day 14 in 15 (26.3%) and 4 (7.5%) patients (χ2=6,770; df=1; p=0.010) (Pic. 3).

Next, we present data on the regression of hyperemia. On the first day, hyperemia in the wound area was in 54 (94.7%) patients in the comparison group and 49 (92.5%) in the main group (χ2=0.240; df=1; p=0.624). On day 3, this factor was determined in 43 (75.4%) and 27 (50.9%) patients, respectively, while the indicators significantly differed in the main group (χ2=7,121; df=1; p=0.008). On day 7, hyperemia persisted in 21 (36.8%) patients in the comparison group and only in 8 (15.1%) patients in the main group (χ2=6.691; df=1; p=0.010), and on day 14 in 12 (21.1%) and 3 (5.7%) patients (χ2=5,525; df=1; p=0.019) (Pic. 4).



Pic. 3. Dynamics of the presence of local swelling in the wound area

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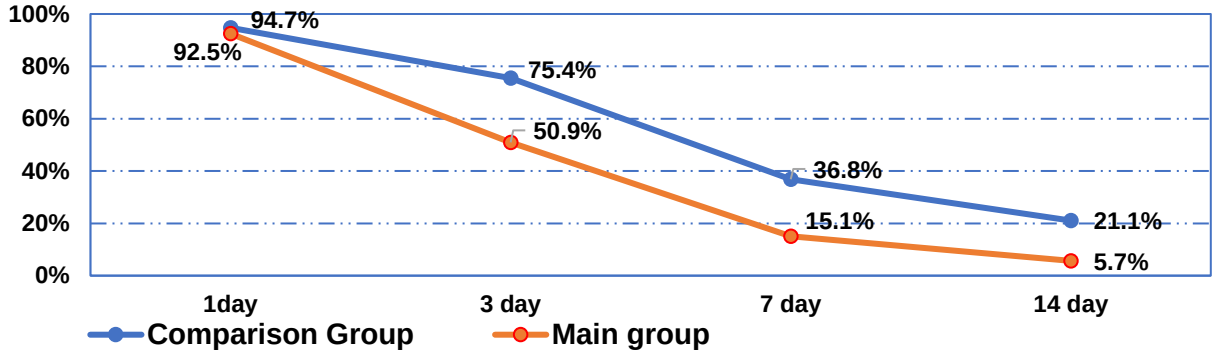
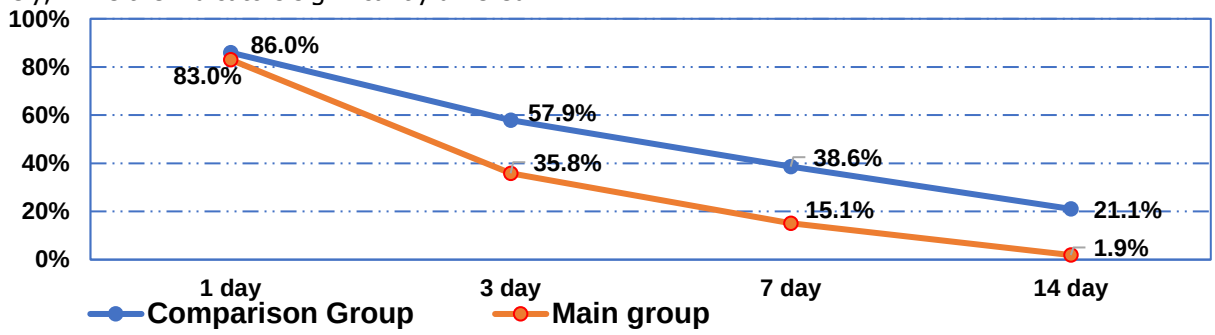


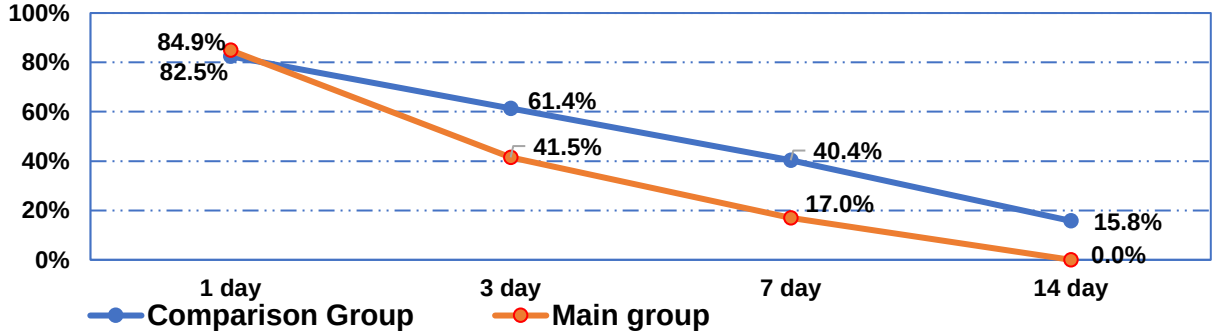
Pic. 4. Dynamics of hyperemia regression in the wound area

Next, we present data on the regression of wound infiltration. On the first day, infiltration in the wound area was in 49 (86.0%) patients in the comparison group and 44 (83.0%) in the main group (χ2=0.182; df=1; p=0.624).On day 3, this factor was determined in 33 (57.9%) and 19 (35.8%) patients, respectively, while the indicators significantly differed in the main group (χ2=5,355; df=1; p=0.021).On day 7, infiltration persisted in 22 (38.6%) patients in the comparison group and only in 8 (15.1%) patients in the main group (χ2=7,648; df=1; p=0.006), and on day 14 in 12 (21.1%) and 1 (1.9%) patients (χ2=9.680; df=1; p=0.002) (Pic. 5).



Pic. 5. Dynamics of infiltrate regression in the wound area

On the first day, purulent wound discharge from the wound was in 47 (82.5%) patients in the comparison group and 45 (84.5%) in the main group (χ2=0.120; df=1; p=0.729).On day 3, this factor was determined in 35 (61.4%) and 22 (41.5%) patients, respectively, while the indicators significantly differed in the main group (χ2=4,354; df=1; p=0.037).On day 7, the discharge was in 23 (40.4%) patients in the comparison group and only in 9 (17.0%) patients in the main group (χ2=7,271; df=1; p=0.008), and on day 14 in 9 (15.8%) and was absent in patients in the main group (χ2=9,114; df=1; p=0.003) (fig. 6).



Pic. 6. Dynamics of regression of wound discharge from the wound

One of the main criteria is the timing of complete cleansing of the wound. This factor was determined on day 3 in 11 (20.8%) patients in the main group (χ2=13.145; df=1; p<0.001).By day 7, the wound was

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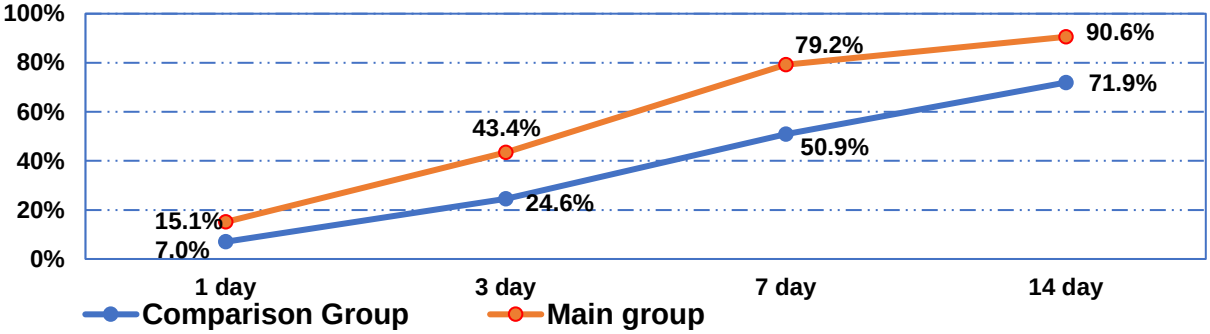
cleared in 14 (24.6%) patients in the comparison group and in 29 (54.7%) patients in the main group (χ2=10.489; df=1; p=0.002), and on day 14 in 36 (63.2%) and 48 (90.6%) patients, respectively (χ2=9,196; df=1; p=0.003) (Pic. 7).



Pic. 7. The proportion of patients with wound cleansing in dynamics

Thus, the introduction of a new method for the treatment of purulent-necrotic processes of the lower extremities in patients with diabetes mellitus allowed to reduce the frequency of postoperative complications from 66.7% (in 38 of 57 patients from the comparison group) to 24.5% (in 13 of 53 patients in the main group; χ2=19.610; df=1; p<0.001), thereby reducing the need for repeated interventions from 31.6% (18 patients in the comparison group) to 13.2% (7 patients in the main group; χ2=5,278; df=1; p=0.022). Stimulation of the etio-pathogenetic mechanisms of healing of purulent wounds made it possible to significantly accelerate the regression of the wound process, in particular, by the 3rd day there was a significant decrease in the level of leukocytosis (from 13.7±3.7 to 11.6±3.5 x109/l in the comparison group and from 14.2±2.8 to 10.1±2.6 x109/l in the main group; t=2.63; p<0.05), in turn, the presence of wound edema by 7 days persisted in 36.8% (21 patients) in the comparison group and in 15.1% (8) in the main group (χ2=6.691; df=1; p=0.010), infiltration in 38.6% (22) vs. 15.1% (8) (χ2=7,648; df=1; p=0.006), respectively, of wound discharge in 40.4% (23) vs. 17.0% (9) (χ2=7,2,71; df=1; p=0.008), with complete wound cleansing in these terms in 50.9% (29) vs. 79.2% (42) (χ2=9,658; df=1; p=0.002) and the appearance of granulation tissue in 24.6% (14) versus 54.7% (29) (χ2=10.489; df=1; p=0.002).

CONCLUSIONS

1. The introduction of a new method for the treatment of purulent-necrotic processes of the lower extremities in patients with diabetes mellitus allowed to reduce the frequency of postoperative complications from 66.7% to 24.5% (p<0.001), thereby reducing the need for repeated interventions from 31.6% to 13.2% (p=0.022), while on the 7th day more than significant decrease in leukocytosis (10.3±3.1 vs. 8.8±2.1 x109/l; p<0.05), the proportion of patients with preserved edema from 36.8% to 15.1% (p=0.010), infiltration from 38.6% to 15.1% (p=0.006), wound discharge from 40.4% to 17.0% (p=0.008), as well as an increase in patients with complete wound cleansing from 50.9% up to 79.2% (p=0.002) and the appearance of granulation tissue from 24.6% to 54.7% (p=0.002).

2. Stimulation of the etio-pathogenetic mechanisms of healing of purulent wounds allowed to significantly accelerate the regression of the wound process, with an increase in the frequency of complete epithelization of the wound by 14 days of treatment from 36.8% to 69.8% (p<0.002), significantly higher rates of reduction of the wound surface area (p<0.05), a reduction in the average time of complete wound healing with 19.1±10.3 to 12.5±6.3 days (p<0.05), as well as the duration of hospitalization from 11.2±4.1 to 8.3±2.7 days (p<0.05).

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