

FARGALS IN THE TREATMENT OF NECROTIC INFECTIONS OF SOFT TISSUES ON THE BACKGROUND OF DIABETES MELLITUS

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Abstract

One of the most difficult areas of purulent surgery is the development of a surgical infection of soft tissues against the background of diabetes mellitus, when necrotic changes dominate. To accelerate the process of cleansing and subsequent healing of soft tissue wounds in patients with diabetes mellitus, antibacterial drugs, proteolytic enzymes, as well as ointment dressings are used, depending on the stage of the wound process using methods physical impact. In this regard, the purpose of this study is: to study the antibacterial and anti-inflammatory effect of the drug FarGALS in necrotic infections of soft tissues against the background of diabetes mellitus. Studies were conducted in 103 patients with purulent-inflammatory diseases who were on inpatient treatment at the Republican Center for Purulent Surgery and Surgical Complications of Diabetes Mellitus.

Keywords: purulent wound; necrotizing infection, anti-inflammatory activity; wound area; FarGALS, diabetes mellitus.

Under Management

The search for methods to combat wound infection has a long history. Over the centuries, mankind has been developing various methods of wound treatment, strictly focusing on the stages of the wound process, especially infectious complications caused by various microorganisms [1, 16]. Many difficulties arise in the treatment of wounds with an attached infection, while the "dormant" infection is of particular danger, the aggressiveness of which is due to the variability of microflora and reactivity of the body [1 4, 15, 17, 18, 19].



The problem of treating purulent wounds remains relevant. There are 3 phases of the course of the wound process: the first period is the phase of inflammation (hydration); the second is the phase of regeneration (dehydration); the third is the phase of scar reorganization and epithelialization [7, 8, 13].

In the first phase, it is necessary to distinguish the process, cleanse the wound from dead and non-viable tissues, create conditions for the outflow of wound exudate, suppress the vital activity of the wound microflora, for which ointments on a water-soluble polyethylene oxide basis "Levosin", "Levomekol", which include chloramphenicol and methyluracil, are used.

In phase II, it is necessary to create conditions for the growth of granulation. Acceleration of regeneration is possible with the use of creams and ointments "Solcoseryl", "Bepanten", "Actovegin". The composition of "Solcoseryl" and "Actovegin" contains a natural biological component - hemoderivate, which has the ability to accelerate woundhealing by stimulating cell growth and collagen synthesis [2, 3, 21].

In the III phase of scar maturation and epithelialization, funds based on dexapanthenol ("Bepanten", "Panthenol"), "Actovegin" in any dosage form for external use are widely used [5, 9, 11].

The principle of selecting drugs and applying treatment methods that are effective in a particular phase of the wound process has been practically worked out and has not traditionally been revised for a long time [4, 6, 10, 12, 20]. All this will indicate that the combination of diabetes mellitus and surgical infection forms a vicious circle in which the infection negatively affects the metabolic processes, increasing insulin deficiency, effortacidosis. In this regard, the purpose of the current study is: to study the antibacterial and anti-inflammatory effect of the drug FarGALS in purulent-inflammatory diseases on the background of diabetes mellitus.

To achieve this goal, it is planned to conduct a comparative assessment of the effectiveness of the drug FarGALS in clinical settings among the two groups. Against the background of general treatment in both studied groups, a distinctive feature of each was the fact that after sanitation and emptying of the pathological focus in patients of the main group, the drug FarGALS was used, while in the control group, after the therapeutic measures taken, Levomekol ointment was applied locally, which has hyperosmolar properties and allows to limit the inflammatory process. The main condition was the presence of a background disease - diabetes mellitus.



Research Methods

103 patients with purulent-inflammatory diseases who were on inpatient treatment at the Republican Center for Purulent Surgery and Surgical Complications of Diabetes Mellitus were examined. The original wound-healing drug FarGALS was used as the object of the study. The drug Levomekol (Nizhpharm, Russia), which includes chloramphenicol and methyluracil, was used as a comparison drug. All patients were divided into 2 groups: the control group is represented by 45 (43.7%) patients who were treated for purulent wounds using Levomekol ointment. The main group included 58 (56.3%) patients who were treated with purulent-inflammatory diseases using the drug FarGALS.

In terms of age and sex, the compared groups were as follows: there were 41 men (39.8%), women - 62 (60.2%). By age, the patients were distributed as follows: from 20 to 40 years there were 9 patients, which was 8.7%, from 41 to 50 years - 16 (15.5%), from 51 to 60 - 47 (45.6%) patients and over 61 years - 31 patients, who made up 30.1%, of their total.

Table 1.

Distribution of patients with purulent surgical diseases of various localization according to nosology

Nosology	Control group		Main group	
	Cole's	%	Cole's	%
Phlegmons of different localization	13	29,0	19	32,8
Abscess of various localization	9	20,0	10	17,2
Carbuncles of different localization	6	13,3	7	12,1
Boils of various localization	4	8,9	4	6,9
Acute paraproctitis	4	8,9	2	3,4
Erysipelas n/k	2	4,4	2	3,4
Suppuration of postoperative wounds	1	2,2	2	3,4
Purulent-necrotic wound	2	4,4	7	12,1
Suppurating coccyx cyst	1	2,2	1	1,7
Hydradenitis	1	2,2	2	3,4
Whitlow	2	4,4	2	3,4
Altogether	45	100,0	58	100,0



The structure of purulent-inflammatory diseases of soft tissues was different. As can be seen from Table 1, the most common were phlegmons and abscesses of various localizations, which were noted in 31.1% and 18.4% of cases, respectively. Less common were carbuncles (8.7%), boils of various localization in 7.8% of cases. In all patients, the purulent-inflammatory process of soft tissues developed against the background of diabetes mellitus (Table. 1.).

In total, 144 surgical methods of treatment were carried out for patients of the control and main groups. The main share of operations was necrectomy 55 (38.2%) and the opening of e purulent foci 89 (61.8%). The total number of surgical operations in the control group of patients was 65 (45.1%), and in the main, respectively- 79 (54.9%). Process with the defeat of structures, necrectomy was performed, the proportion of which, respectively, was high 55 (38.2%). I would like to note that with the defeat of soft tissues by a purulent-inflammatory process, this operation was mandatory, because locally necrotic changes dominate. In the postoperative period, wounds were bandaged daily using Levomekol ointment in the control group, and in the main domestic druga FarGALS, while staged necrectomy was performed in both groups. . In all cases, the wounds healed by secondary tension.

Upon admission after a preliminary examination, all patients were examined by an endocrinologist, followed by daily observation, while preference was given to the transfer of patients to insulin therapy, using short-acting insulin. On the day of admission, patients were prescribed antibiotic therapy, using an empirical approach. Combinations of cephalosporins (ceftazidime, ceftriaxone), aminoglycosides (netromycin, amikacin) and metronidazole were used. In the future, antibiotics changed depending on the sensitivity of the detected microorganisms. If fungi were detected, fluconazole was added to the treatment.

The control group of patients is represented by 45 (43.7%) patients with necrotic infections of soft tissues of various localization. All of them had a surgical infection developed against the background of diabetes mellitus, the experience of which varied from 3 to 25 years, type II diabetes mellitus dominated. I would like to note that the main contingent of patients was secondary, i.e. primary treatment was provided to them at the place of residence. By age, the control group was dominated by older people and at the age of 51-60 years there were 40.0% of patients, and at the age of persons older than 61-35.5%. Young and middle-aged people were less common, which indicates the prevalence of diabetes among older people. The sex difference



indicated the dominance of women, of which there were 28 patients, which corresponds to 62% (Table. 2).

Table 2.

***Distribution of patients with purulent surgical diseases
different localization by sex and age***

Age (years)	Control group					
	Husband.		Wives.		Altogether	
	Abs	%	Abs	%	Abs	%
20-40	2	4,4	2	4,4	4	8,9
41-50	4	8,9	3	6,7	7	15,6
51-60	5	11,1	13	28,9	18	40,0
61 and older	6	13,3	10	22,2	16	35,6
Altogether:	17	37,8	28	62,2	45	100,0

Studying the severity of the course of the wound process on a point scale, it was revealed that the main contingent of patients were patients with moderate severity of the wound process, which was noted in 29 patients, which corresponded to 64.4%. A severe course of the wound process was noted in 16 patients.

Table 3.

Severity of the wound process

Heaviness	Cole's	Point
Easy	-	-
Average	29	12±0,4
Grind	16	26±1,3

At the time of admission of patients with a mild degree of severity, the wound process was not detected (Table 3).

The essence of the therapeutic measures carried out was as follows: upon admission, after short-term preoperative preparation, patients underwent surgical intervention aimed at opening the pathological focus, its adequate necrectomy within healthy tissues and, if necessary, the cavity was drained, but in most cases the wounds remained open, which made it possible to assess the effectiveness of local changes, against the background of the treatment. So, in the control group, a high proportion accounted for the opening of phlegmon, which was performed in 23.1% of patients. In second place were the autopsy of abscesses of various localizations, which were performed in 9 patients, amounting to 13.8%. I would like to note that the most commonly performed necrectomy, the proportion of which was 38.4%. This is due to the fact that this

operation is performed during the primary surgical intervention and in the future, as necrotic tissues appear, during local treatment (tabl. 4).

Table 4. The nature of the surgical interventions performed in patients of the control group

Type of operation	Control group	
	Cole's	%
Opening of the boil	4	6,2
Autopsy of the carbuncle	6	9,2
Dissection of abscess	9	13,8
Dissection of phlegmon	13	20,1
Necrectomy	27	38,4
Dissection of paraproctitis	4	6,2
Dissection of hydroadenitis	1	1,5
Opening of the coccyx cyst	1	1,5
Dissection of panaritium	2	3,1
Total	65	100

When studying the clinical and biochemical parameters on the day of admission, it was revealed that all patients showed signs of severe intoxication and sepsis, manifested in a sharp tachycardia of 1082.8 beats / min, tachypnea 282.0 times per minute, an increase in systolic blood pressure to 1408.0 mm Hg. art., hyperthermia 38,80,4±±±±0°C and leukocytosis (15,10,9·10±⁹), LII reached the level of 4,80,6±. Against the background of high toxemia (OSM 3228.7), patients showed signs of hypoproteinemia 54±± 3.2 g / l. On the day of admission in patients, glycemia was at the level of 13.31.9 mmol / L. According to other parameters, no special deviations were observed (Table±. 5).

Table 5. Dynamics of changes in clinical and biochemical parameters of blood in patients of the control group

Index	Term of observationI			
	1-сутка	3-day	7-day	14-day
Pulse, oud. in min.	1082,8±	1022,±6	102±2,0	981,5**±
NHD	28 2,0±	261,9±	231,6±	201,1**±
Systolic blood pressure, mm Hg.	1408,0±	1408,0±	1304,5±	1303,8±
JSC diastolic, mm rt.st.	906,0±	906,0±	80±5,0	803,5±
Temperature, °C	39,10,8±	38,50,±4	38,00,2±	37,00,±2
Leukocytosis ×10 ⁹ / l	15,10,9±	12,7±0,7*	11,50,±6**	8,20,±4***
ESR, mm/h	481,8±	451,8±	281,4***±	181,2***±
OSM	3228,7±	286±7,1**	2306,4***±	2175,2***±
LEE	4,80,6±	4,00,±5	2,70,±5*	1,80,±4***
Total protein, g/l	54±3,2	46,13,±0	512,8±	561,9±
Blood sugar, mmol/ l	13,31,9±	14,11,±5	10,30,8±	8,40,7*±

Note: * - различия относительно данных группы на 1 сутки значимы (* - P<0.05, ** - P<0.01, *** - P<0.001)



Thus, the treatment of purulent-inflammatory diseases of soft tissues with the use of Levomekol ointment in a control group of patients has an antibacterial effect. Its effective effect is manifested only in the adsorption of exudate and a slight decrease and activity of inflammatory-destructive changes, while diffuse inflammatory changes remain in the deep layers of the dermis and in the subcutaneous tissue and necrotic phenomena, which leads to a lengthening of the treatment of patients with this pathology.

Results and their Discussion

Based on the results of the research, we conducted a comparative analysis in both groups and at the same time it (and the analysis) showed that the severity of the wound process in both groups was the same. Patients with mild severity and the course of the wound process in the studied groups were not detected, with moderate and severe degrees there were more in the main group (Table. 6).

Table 6.

Severity of the wound process in both groups

Heaviness	Cole's				Point	
	Control group		Main group		Control group	Main group
	Abs	%	Abs	%		
Easy	0	0	0	0,0		
Average	29	64,4	35	60,3	12±0,4	12±0,8
Grind	16	35,6	23	39,7	26±1,3	27±1,2
Altogether	45	100,0	58	100,0		

The study of the dynamics of changes in clinical and biochemical parameters in both groups showed that with initially identical indicators, the phenomena of intoxication in the main group progressively decreased against the background of the treatment and by 3 days of treatment were close to normal values. Thus, the LII in the main group was 3,70,3, while in the control group it remained high, amounting to 4,00,5. By the 14th day of treatment, in the main group it was within the normal range of 1,40,2, and in the control group 1,80,4±±±±. One of the important diagnostic criteria for the course of the pathological process is the temperature reaction, which on day 1 was high in patients of both the main and control groups and amounted respectively to 39.10.8 ° C and 39.20.6 ° C. This indicator against the background of the treatment was evenly reduced in both groups, however, in the control group by the 3rd day of treatment, it was 3±± 7.8 ±0.4 ° C, which indicates the preservation of inflammatory phenomena in the



area of the pathological process. Only on the 7th day there is a normalization of the temperature reaction, which was observed on the 14th day.

A comparative analysis of the microbial contamination of purulent wounds among aerobes and anaerobes, on the day of admission, showed that their content in the study groups was the same. Thus, the concentration of anaerobes in the control group was at the level of 7.6 ± 0.6 lgKOE / ml, and in the main 8.4 ± 0.3 lgCOE / ml. The microbial contamination of anaerobes on the day of admission was 8.4 ± 0.5 lgCOE / ml in the control and 8.1 ± 0.4 lgCOE / ml in the main. Against the background of the treatment in both groups, by the 3 days of treatment, their significant decrease was noted, for aerobes in the main group 5.0 ± 0.3 lgCOE / ml, and in the control group 6.0 ± 0.4 lgCOE / ml. The concentration of anaerobes at this time was almost the same (5.1 ± 0.3 lgCOE / ml and 5.2 ± 0.4 lgCOE / ml). A significant decrease was observed on the 7th day, when the level of aerobes in the main group reached 3.2 ± 0.2 lgCOE / ml, which is an indicator of concentration below the critical, while in the control group this indicator remained at the level of 4.3 ± 0.3 lgCOE / ml. The picture of anaerobic contamination was for aerobes in the main 3.0 ± 0.2 lgCOE / ml, and in the control group 4.0 ± 0.3 lgKOE / ml. The above indicates a pronounced antibacterial effect, provided with topical application of the drug FarGALS, in comparison with Levomekol ointment.

The results of treatment of both groups showed that good results prevailed in patients of the main group, which were noted in 26 patients, in comparison with the control group, where this indicator was noted in 12 patients. Among the satisfactory treatment results in the control group, they were noted among 53.3%, in the main group it was 48.3%.

According to unsatisfactory treatment results, when the necrotic process was preserved in the wound, in the control group it was detected in 9 patients, while in the main this indicator was noted only in 7% of patients. 7).

Table 7.

The result of treatment of patients

Result	Control group		Core group	
	n	%	n	%
Good	12	26,7	26	44,8
Satisfactory	24	53,3	28	48,3
Unsatisfactory	9	20,0	4	6,9
Lethality	-	-	-	-
Altogether	45	100	58	100



A comparative assessment of the timing of wound cleansing in the study groups showed a significant reduction in the duration of the I and II phases of the course of the wound process, while the duration of the first phase of the purulent-inflammatory process was reduced by 2.2 ± 0.6 days, phase II by 1.2 ± 0.4 days, compared with the control (tabl. 8).

Table 8.

Timing of wound healing

Group	Cole's	Medium term				
		I фаза	II фаза	III фаза	Bed-day	Amb-no
Control	45	$5,8 \pm 1,1$	$7,1 \pm 1,2$	$10,6 \pm 0,4$	$12,5 \pm 2,1$	$24,2 \pm 0,3$
Main	58	$2,6 \pm 0,5^{**}$	$5,9 \pm 0,3$	$9,1 \pm 0,6^*$	$10,3 \pm 0,7$	$24,3 \pm 0,6$

Note:

* - различия относительно данных контрольной группы значимы (* - $P < 0.05$, ** - $P < 0.01$)

Thus, the differentiated use of FarGALS in patients of the main group allows to reduce the duration of the wound process, due to the relief of the inflammatory process in the deep layers of the affected area, with the creation of dry necrosis and rapid cleaning of the wound.

1. The use of FarGALS in patients with purulent-inflammatory diseases on the background of diabetes mellitus can reduce microbial contamination by 7 days of treatment to 3.2 ± 0.2 lgCOE / ml for aerobes and 3.0 ± 0.4 lgCOE / ml for anaerobes. By this time, clinical and biochemical parameters are normalized, with the relief of phase I to 2.6 ± 0.5 , II phase to 5.9 ± 0.3 and III phase to 9.1 ± 0.6 days of treatment, respectively;
2. A comparative analysis of the effectiveness of the drug FarGALS and Levomekol ointment made it possible to identify by 7 days a significant decrease in the concentration of aerobes by 1.1 ± 0.4 lgCOE / ml and anaerobes by 1.2 ± 0.3 lgCOE / ml. At the same time, the duration of the I phase of the purulent-inflammatory process was reduced by 2.2 ± 0.6 days, phase II by 1.2 ± 0.4 days, compared with the control.



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