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ABSTRACT

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CLINICAL EVALUATION OF THE EFFECTIVENESS OF A COMPLEX OINTMENT PREPARATION WITH COLLAGENASE IN THE COURSE OF PURULENT NECROTIC PROCESSES OF SOFT TISSUES

Background. Traditional methods of treating purulent wounds in experimental and clinical surgery are often ineffective and there is a need to improve them and develop new methods and tools, including the use of drugs for biological cleansing of necrotic tissues in wounds.

The aim of the study was to conduct a clinical evaluation of gel agent "Iruksan" in the treatment of patients with infected, purulent wounds and necrotic processes of soft tissues.

Materials and methods. Seventy-eight patients with infected, purulent wounds and necrotic processes were observed. They were divided into the main group (37 patients, who received complex treatment with a collagenase-based therapeutic mixture (Iruksan)) and the comparison group (41 patients), who received treatment with Levomekol ointment. The average age of the patients was 52.3±17.1 years. Fifty-one patients (65.4% of the examined) were diagnosed with abscess, abscessing furuncle, carbuncle, or abscessing hidradenitis. Phlegmon was observed in 12 patients (15.4%), and 15 patients (19.3%) had suppurative and infected postoperative wounds after surgical interventions. In addition, an analysis of the use of Iruksan was conducted in obese patients who developed purulent-necrotic complications after abdominal surgery and in patients with necrotizing fasciitis.

Results. In the main group, pain syndrome resolved on average after 4.2±1.2 days, while in the comparison group, it resolved on average after 5.0±1.7 days (this difference is not statistically significant (p=0.094)), but the reduction in the duration of pain in the study group shows a positive trend.

The use of Iruxan allowed to cleanse the wound in 4.1±1.7 days in the main group, while in the comparison group, wound cleansing took 5.9±1.9 days (p=0.00012). Wound epithelialization in patients in the main group occurred after 7.8±2.1 days, and in patients in the comparison group – after 8.4±1.3 days (p=0.0187). Thus, it becomes clear that faster cleansing of the wound from dead tissue occurs due to collagenase, a proteolytic enzyme, which is a part of Iruxan.

Conclusions. A complex preparation containing collagenase (Iruxan) showed positive results when used to treat patients with purulent-necrotic processes in soft tissues, as well as in the treatment of patients with purulent-necrotic complications after surgical interventions on the abdominal organs in obese individuals, which, in turn, opens up prospects for further in-depth study and application of this drug in such patients. The use of Iruksan in combination with VAC therapy is also possible and makes it possible to significantly improve the treatment outcomes of patients with necrotizing fasciitis and purulent-necrotic pathology in patients with obesity.

Keywords: purulent soft tissue diseases, wounds, purulent necrotic processes, postoperative complications, collagenase, Iruksan, necrectomy, obesity, necrotizing fasciitis.

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РЕЗЮМЕ

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КЛІНІЧНА ОЦІНКА ЕФЕКТИВНОСТІ ЗАСТОСУВАННЯ КОМПЛЕКСНОГО МАЗЕВОГО ПРЕПАРАТУ З КОЛАГЕНАЗОЮ НА ПЕРЕБІГ ГНІЙНО-НЕКРОТИЧНИХ ПРОЦЕСІВ М'ЯКИХ ТКАНИН

Актуальність. Традиційні методи лікування гнійних ран в експериментальній та клінічній хірургії часто виявляються неефективними та існує потреба в їх удосконаленні та у розробці нових методів і засобів, в тому числі і використання препаратів для біологічного очищення ран від некротичних тканин.

Мета роботи – провести клінічну оцінку використання гелевого засобу «Іруксан» при лікуванні хворих з інфікованими, гнійними ранами та-некротичними процесами м'яких тканин..

Матеріали та методи. Під спостереженням знаходилось 78 хворих з інфікованими, гнійними ранами та некротичними процесами. Їх було розподілено на основну групу (37 пацієнтів, в комплексному лікуванні яких застосовувалася лікувальна суміш на основі колагенази («Іруксан»)) та групу порівняння (41 хворий), яка отримувала лікування із застосуванням мазі «Левомеколь». Середній вік пацієнтів становив 52,3±17,1 років. У 51 хворого (65,4% від обстежених) діагностували абсцес, абсцедуючий фурункул, карбункул, абсцедуючий гідраденіт. Флегмону спостерігали у 12 пацієнтів (15,4%) та у 15 осіб (19,3%) відзначали нагноєні й інфіковані післяопераційні рани. після хірургічних втручань. Крім того провели аналіз використання Іруксану у пацієнтів з ожирінням, у яких виявили гнійно-некротичні ускладнення після операцій на органах черевної порожнини та у пацієнтів з некротизуючим фасциїтом.

Результати. В основній групі зникнення больового синдрому спостерігали в середньому через 4,2±1,2 дні, хоча у групі порівняння

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– в середньому через 5,0±1,7 днів (ця різниця не є статистично достовірною (p=0.094)), однак скорочення часу «присутності болю у групі дослідження має позитивну динаміку.

Використання Іруксану дозволило у пацієнтів основної групи очистити рану через 4,1±1,7 дні, тоді як у групі порівняння очищення проходило через 5,9±1,9 днів (p=0.00012). Епітелізація ран у пацієнтів основної групи наступала через 7,8±2,1 днів, а у пацієнтів групи порівняння через 8,4±1,3 дні (p=0.0187). Таким чином, стає зрозумілим те, що більш швидше очищення рани від змертвілих тканин відбувається завдяки колагеназі, протеолітичному ферменту що входить до складу Іруксану.

Відзначено також позитивний ефект застосування Іруксану при комплексному лікуванні гнійно-некротичних ускладнень після операцій на органах черевної порожнини у осіб з ожирінням та у пацієнтів з некротизуючим фасциїтом.

Висновки. Комплексний препарат з колагеназою (Іруксан) проявив позитивні ознаки при застосуванні його для лікування пацієнтів з гнійно-некротичними процесами м'яких тканин, а також при лікуванні хворих з гнійно-некротичними ускладненнях після хірургічних втручань на органах черевної порожнини у осіб з ожирінням, що, в свою чергу, складає перспективи для подальшого поглибленого вивчення та застосування цього препарату у таких пацієнтів. Використання Іруксану в комплексному лікуванні з ВАК-терапією також є можливим та дає можливість значно покращити результати лікування пацієнтів з некротизуючим фасциїтом та гнійно-некротичною патологією у пацієнтів на тлі ожиріння.

Ключові слова: гнійні захворювання м'яких тканин**,** рани, гнійно-некротичні процеси, післяопераційні ускладнення, колагеназа, Іруксан, некректомія, ожиріння, некротизуючий фасциїт.

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INTRODUCTION

It is known that various wounds are extremely common, and chronic wounds are even a silent epidemic that affects a significant proportion of the world's population and creates a significant economic burden on the health care system [1]. In contaminated wounds, the incidence of purulent-inflammatory postoperative complications increases significantly compared to conditionally clean wounds, and the length of hospital stay is three times longer than in patients whose postoperative wounds were not infected [2]. At the same time, the long history and widespread use of antibiotics have led to the emergence of resistant bacterial pathogens, which worsens the course of the wound process, increases morbidity and mortality [3]. It should also be noted that necrotizing soft tissue infections are becoming an increasingly common problem, often characterized by progressive and fatal soft tissue infection, which requires rapid, radical and often repeated surgical debridement of all affected tissues [4]. At the same time, traditional methods of treating purulent wounds in experimental and clinical surgery are often ineffective and there is a need to improve them and develop new methods and tools**.** Today, there are many methods to improve the results of purulent wound treatment, but none of them fully satisfy surgeons, and the very fact that there are numerous proposed methods indicates their lack of effectiveness and the absence of a single point of view on this problem [5]. Undoubtedly, an obligatory and key stage of treatment is adequate wound debridement, which is actually the basis for the process of re-epithelialization and tissue repair [6,7]. At the same time, one type of debridement is enzymatic, in which necrotic tissues in the wound bed are lysed by protease preparations of various origins applied to the wound bed. Currently, only collagenase is the only proteolytic enzyme preparation approved for use by the U.S. Food and Drug Administration (FDA) for debridement of both acute and chronic wounds [8]. Its advantage, which distinguishes collagenase from other proteases, is that

collagenase is sparing to viable tissues, i.e., it has a selective effect [9], and it has demonstrated not only its effectiveness in wound cleansing but also its influence on cell migration, which is a prerequisite for epithelialization in the healing process [10]. It is these properties of collagenase and the results of our own experimental studies that became the basis for a comprehensive clinical evaluation of the use of a drug with collagenase in the treatment of purulent necrotic processes of soft tissues.

The aim of the study was to conduct a clinical evaluation of the use of the gel agent "Iruksan" in the treatment of patients with infected, purulent wounds and necrotic processes of soft tissues.

MATERIALS AND METHODS

At the preliminary stage, we conducted a study on the morphological substantiation of the effectiveness of the use of the therapeutic mixture "Iruksan" in the experiment, where it demonstrated its effectiveness when used at different stages of the wound process, as evidenced by the better regenerative activity of tissues in the affected area, which was manifested in a faster reduction of inflammatory cell infiltration and clearing the wound of necrotic detritus and further accelerated formation and maturation of granulation tissue with a simultaneous active process of epithelialization. Also, the antimicrobial activity of the collagenase-based therapeutic mixture in the treatment of infected wounds was investigated in an experiment [11], where Iruksan showed a pronounced antimicrobial effect against clinical methicillin-resistant strains of S. aureus and somewhat lower activity against clinical strains of P. aeruginosa. Our data prompted us to study the morphological and functional features of the wound process during the treatment of purulent necrotic wounds in rats with antiseptics and collagenase. The results of histological studies demonstrated significantly faster dynamics of wound healing and achievement of complete epithelialization of the wound defect on the 10th day of the experiment in rats treated with collagenase, as opposed to groups of animals treated with other agents. This demonstrated the advantages and effectiveness of collagenase in the treatment of purulent wounds not only as an enzymatic debridement, but also as a drug that affects important aspects in the first and second phases of the wound process [12].

Clinical studies were conducted on the basis of observation of 78 patients with various purulent necrotic diseases of soft tissues and wounds treated in surgical departments at the Department of General Surgery of the National Pirogov Memorial Medical University. Patients were divided into two groups: the main group consisted of 37 patients who received complex treatment with a collagenase-based therapeutic mixture (Iruksan); the comparison group (41 patients) received complex treatment with local use of traditional remedies (Levomekol ointments). The patients' age ranged from 22 to 85 years, with an average age of 52.3±17.1 years. There were 37 men and 41 women among the examined, which amounted to 47.0% and 53.0%, respectively.

The group of patients included patients with the following nosological diagnoses: abscess, abscessing furuncle, carbuncle, abscessing hydradenitis, which were diagnosed in 51 patients (65.4%), phlegmon - in 12 patients (15.4%) and 15 patients (19.3%) had suppurating and infected postoperative wounds (surgical site infection) after planned and urgent surgical interventions. Regarding the localization of the pathological process, it should be noted that there was a tendency for localization in the pelvic girdle and lower extremities to predominate. The proportion of such patients was 44.9% of cases. In 53 of the patients we examined (67.9%), concomitant diseases (mainly cardiovascular disease, diabetes mellitus, obesity, musculoskeletal disorders) were detected, which to some extent could have an impact on the course of the wound process, the duration and outcome of treatment.

The main group and the comparison group were representative in terms of gender, age, nosological structure and the presence of comorbidities.

All patients included in the study were treated according to the generally accepted methodology. Adequate surgical treatment of the purulent focus was performed, which included rational access, revision, elimination of purulent flooding, opening of "pockets", necrectomy, antiseptic washing, and "drying" of the abscess cavity. The surgeries were performed under regional anesthesia (46 patients) and intravenous anesthesia (32 patients). The surgical intervention was completed by drainage using rubber outlets and drainage tubes with side holes. At the end of the operation, an aseptic dressing with the appropriate study drug was applied. In 37 patients of the main group, the complex drug "Iruksan" was used (1 g of gel contains: collagenase, at least 70 ClA. Excipients: myramistin, polyethylene glycol 400, polyethylene glycol 1500, poloxamer 188, cetyl stearyl alcohol, purified water). Iruksan was injected in an amount of 2 to 10 ml (depending on the volume and configuration of the cavity) through drains, through counterperforations with a syringe with a nozzle. It was applied to the accessible areas of the wound surface in an amount of 2-4 cm3. In the comparison group (41 patients), the traditional ointment Levomecol was used (1 g of ointment contains chloramphenicol (levomycetin) 7.5 mg, methyluracil 40 mg). Excipients: polyethylene glycol 400, polyethylene glycol 1500).

In the postoperative period, daily dressings were performed, during which the wound was toileted, the

deep parts and pockets were washed with a 3% solution of hydrogen peroxide, 0.05% solution of chlorhexidine, 0.9% solution of sodium chloride in sequence. In patients of the main group, Iruksan was injected into the deep parts of the wound with a Luer-lock syringe and a subclavian catheter-type nozzle. The gel was heated to a temperature of 32-34°C before being filled into the syringe and injected. The application of Iruxan and drainage usually lasted up to 7-8 days. Later, they switched to other medications, applied secondary sutures, installed a VAC system, etc. In addition, some of the patients we examined received systemic antibiotic therapy, which was prescribed only in case of severe symptoms and risks of prolongation of infection according to treatment standards. In the comparison group, 28 (68.3%) patients received antibiotics, and in the main group - 24 patients (64.9%).

All patients underwent standard general clinical examinations, bacteriological monitoring of the wound process (identification of microflora, determination of its sensitivity to antibiotics), assessment of the intensity of the body's response to inflammation and the severity of intoxication by the pulse-leukocyte-temperature index of intoxication (PLTII) according to the formula of S.D. Khimich (1992), and evaluation of the dynamics of the wound process by conventional methods.

We also analyzed the treatment with Iruksan in 46 patients with different degrees of obesity, who had various postoperative purulent-necrotic complications after abdominal surgery, on the basis of the surgical departments of the University Hospital of the National Pirogov Memorial Medical University. Pirogov University Hospital and Bukovinian Clinical Oncology Center during 2023-2025, as well as an analysis of the effectiveness of Iruksan in the treatment of purulent necrotic processes in necrotizing fasciitis in patients at the medical bases of the Department of Surgical Diseases of Danylo Halytsky Lviv National Medical University.

The relevant scientific studies were approved by the Bioethics Committee of the National Pirogov Memorial Medical University (No. 3 of April 3, 2023).

RESULTS OF THE STUDY

During the treatment, the course of the wound process in patients of both groups was assessed on the basis of clinical data: the rate of wound cleansing from dead tissue, fibrin and pus, the time of granulation, the rate of regression of pain and swelling of the tissues around the wound, the onset of peripheral epithelialization, and the restoration of the function of the affected area.

In patients in the comparison group, the disappearance of pain was noted in 5.0±1.7 days, wound cleansing from necrotic tissue lasted on average 5.9±1.9 days, the appearance of granulations was noted on average on 6.1±1.5 days, and the onset of epithelialization – in 8.4±1.3 days. It should be emphasized that in patients of this group, during the first phase of the wound process, a thick, viscous exudate was noted, which made it difficult to drain.

As an indicator of intoxication, PLTII in patients of the comparison group ranged from about 2.6 ± 1.4 units, which indicated the presence of a mild to moderate intoxication syndrome.

In 32 patients out of 41 in the comparison group, microbial pathogens were identified from the inflammatory focus: St. aureus - in 19 (59.4%) cases, St. haemoliticus - in 7 (21.9%), Ps. aeruginosa - in 4 (12.5%) and E. coli - in 2 (6.3%). It should also be noted that during the treatment, even on day 5-6, patients in this group retained signs of destructive and inflammatory nature with remnants of purulent-necrotic contents and unstructured masses (tissue detritus). In general, the duration of treatment in patients of the comparison group was on average 9.3 ± 3.6 days.

During the observation of patients in the main group, the disappearance of pain was noted in an average of 4.2±1.2 days, wound cleansing from necrotic tissue occurred in an average of 4.1±1.7 days, the appearance of granulations was observed in 5.4±1.8 days, and the onset of epithelialization - in 7.8±2.1 days. As evidenced by the above data, patients in the main group had a more favorable, dynamic course of the wound process. In general, there was a fairly rapid regression of inflammatory phenomena, clearing of the wound from necrotic tissue, and the appearance of granulations. During the first phase of the wound process, the exudate in patients of the main group was fluid, “mobile”, and well drained. Inflammatory phenomena decreased on the 3rd-7th day. Due to the rapid cleansing of the wound from necrotic tissue, appropriate conditions for full epithelialization of the wound arose earlier. The “transitional” period (the period during which granulations had already appeared, but the wound was not completely cleared of necrotic tissue, pus and fibrin) in patients of this group averaged 1.5 days.

The macroscopic picture on days 7-9 was characteristic of the regenerative-inflammatory type with the absence of unstructured masses (tissue detritus). The duration of treatment in patients of the main group was on average 6.6 ± 4.7 days. It is also noteworthy that patients in the main group who received complex treatment with Iruksan, which contains the enzyme collagenase, had a favorable course of the wound process.

DISCUSSION OF RESULTS

From a clinical point of view, patients in both groups had a relatively minor intoxication syndrome and only in some cases the indicators corresponded to pronounced signs of intoxication. As mentioned above, in the patients of the comparison group, the PLTII ranged

from 2.6 ± 1.4 units, indicating the presence of a mild to moderate intoxication syndrome, while the PLTII in the main group averaged 2.3 ± 1.1 units (p≥0.05).

The disappearance of pain in the main group was recorded in an average of 4.2±1.2 days, and in the comparison group - in 5.0±1.7 days. And although the difference in the indicators is not statistically significant (p=0.094), the reduction in the time of "pain presence" in the study group is a positive trend.

In our opinion, the time of wound cleansing from necrotic tissue is of paramount importance for the entire course of the wound process. After all, the removal of foreign bodies, necrotic tissues, senescent cells that are unable to migrate, bacteria that prevent the migration of keratinocytes along the wound bed ultimately contribute to re-epithelialization and tissue repair, i.e. wound healing [6].

The use of a complex preparation with collagenase allowed the main group to clean the wound slightly faster – in 4.1±1.7 days, while in the comparison group this indicator was 5.9±1.9 days (p=0.00012). Accordingly, this further contributed to earlier wound epithelialization in patients in the main group (7.8±2.1 days) compared to patients in the comparison group (8.4±1.3 days) (p=0.0187). It is obvious that this effect of faster wound cleansing from dead tissue is due to the presence of the proteolytic enzyme collagenase in Iruxan. The data obtained give us grounds for recommending the inclusion of pathological conditions such as infected and purulent wounds and purulent-necrotic processes of soft tissues in the instructions for use of Iruxan.

Here is a clinical example. Patient M., 65 years old. He has been ill for about 8-10 days. He did not treat himself. Without severe concomitant pathology (coronary artery disease, hypertension IIst. 2 st., HF 0). WBC 12.7 × 10^9. Diagnosis - carbuncle of the back. Under intravenous anesthesia, the pathological process was opened, partial necrectomy and drainage were performed. The bacteriological examination revealed Staphylococcus aureus 10^5 CFU/ml (Fig. 1-4).

Fig. 1. The first day after surgery. The bottom and walls of the wound are covered with dense purulent-necrotic layers. A partial necrectomy was performed. Iruksan was injected into the wound

Fig. 2. Third day after surgery. The wound is significantly cleared. There are remnants of necrotic tissues, traces of layering on the wound walls, moderate perifocal edema

Fig. 3. Fifth day after surgical treatment. There is no swelling and cyanosis around the wound. Necrotic tissue and purulent layers were lysed and removed from the wound. The wound cleared. The wound volume decreased significantly

Fig. 4. Seventh day after surgery and local treatment. "Young" granulation tissue is actively developing in the wound, filling the defect, and marginal epithelialization is noted on all sides

Wound healing is a complex, highly regulated process that is crucial for maintaining the barrier function of the skin. Numerous diseases can disrupt the cascade of events associated with wound healing, leading to chronic non-healing wounds that cause significant discomfort and suffering to the patient, draining the medical system of a huge amount of resources. Superficial wound healing requires many factors working in concert, and wound dressings and treatments have evolved significantly to address potential barriers to wound healing, ranging from infection to hypoxia [13]. This also applies to obese patients. Since the postoperative wound process in obese people often suffers not only from surgical procedures, but also from excessive contamination of the skin with microorganisms (with the bacterial activity of the skin decreasing with increasing obesity) [14, 15], such patients can often develop various postoperative purulent-necrotic complications of soft tissues, which cause many difficulties in the complex treatment of surgical and oncological patients with obesity, because the

consequences of treatment often depend on the technical difficulties of surgical procedures in patients with obesity [16].

According to our data and the literature, people with an increasing degree of obesity have an increased risk of purulent necrotic complications (after "conditionally clean" abdominal surgery) as a result of increased tissue trauma, impaired microcirculation, significant lymphorrhea, and inadequate methods of suturing and drainage of postoperative wounds. However, if in 34 patients (about 2/3 of patients) due to various conservative measures (gradual partial early removal of sutures, semi-alcoholic compresses, physical therapy, etc.) it was possible to avoid wound suppuration, then in 16 patients rapid wound suppuration with necrotic changes was observed (Fig. 5).

In the presence of purulent-necrotic complications in obese patients that occurred after abdominal surgery, the treatment consisted of the following. Sutures were partially removed from the skin and subcutaneous tissue. Necrotic tissue from subcutaneous fat was partially excised to the muscle aponeurosis. In the presence of necrotic changes on the aponeurosis, necrotic tissues were removed only those that were easily washed out with antiseptics, and the sutures were not removed because of the high risk of further evolution (Fig. 6).

As can be seen from Figures 6-10, in purulent-necrotic processes in obese people, Iruksan showed significant effectiveness, and in this situation, priority was given to a biological antiseptic rather than a mechanical one. By applying Iruksan to the wound, a gentle biological debridement of the wound was applied, because after 3-5 days, through the lysis of necrotic tissues, the wounds began to cleanse significantly. Later, secondary sutures and aseptic dressings were applied to the wounds.

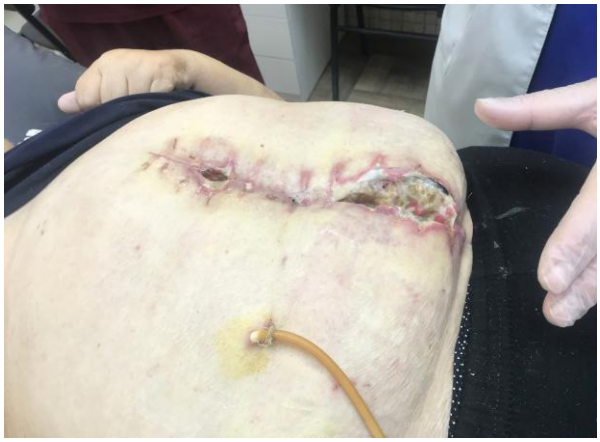

Fig. 5. Patient M., 68 years old. Obesity of the third degree, BMI 40.5. Day 7 after biliary surgery with biliodigestive anastomosis. Purulent necrotic complication in the laparotomy wound

Fig. 6. Patient M., 68 years old. Obesity of the third degree, BMI 40.5. Day 7 after surgery. Mechanical necrectomy was performed

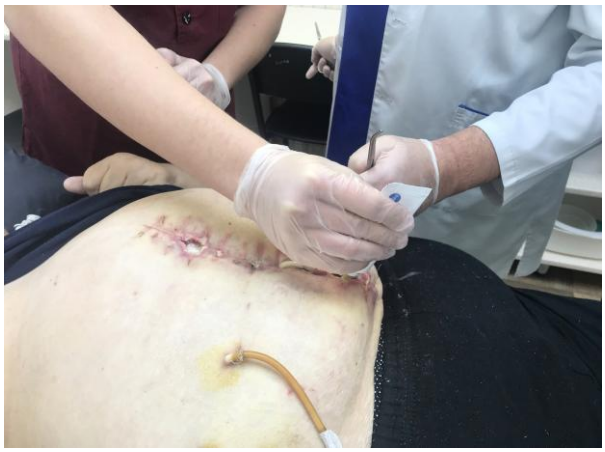

Fig. 7. Patient M., 68 years old. Obesity of the third degree, BMI 40.5. Day 8 after surgery on the biliary system with biliodigestive anastomosis. Purulent-necrotic complication of the laparotomy wound. Iruksan is injected into the postoperative wound cavity

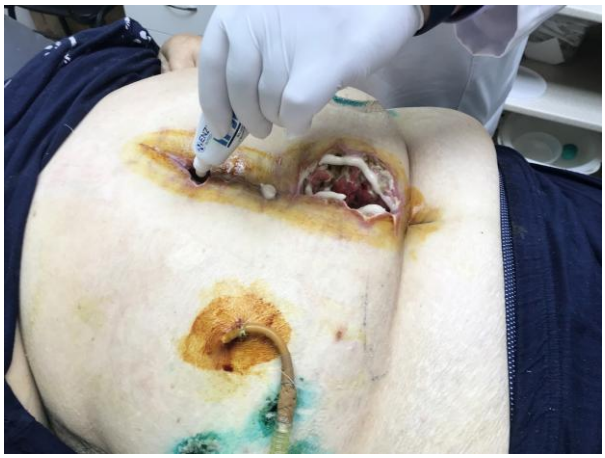

Fig. 8. Patient M., 68 years old. Obesity of the third degree, BMI 40.5. Day 10 after biliary surgery with biliodigestive anastomosis. Purulent-necrotic complication of the laparotomy wound. The wound has partially cleared. Iruksan is still being used

Fig. 9. Patient M., 68 years old. Obesity of the third degree, BMI 40.5. Day 12 after biliary surgery with biliodigestive anastomosis. Purulent-necrotic complication of the laparotomy wound. The wound was completely cleared and reduced in volume

We have also successfully used Iruksan for necrotizing fasciitis. For example, here is the case of a patient who developed post-injection abscesses of both buttocks and thighs on the basis of injection drug addiction. He injected an unknown drug intramuscularly. In addition to the suppurative process, there was extensive necrosis of the subcutaneous fascia and tissue as in fasciitis, with the formation of skin necrosis in the center (Fig. 11).

In order to improve the “biological debridement”, i.e. to accelerate the cleansing of the wound from necrotic tissue, we first proposed the simultaneous use

Fig. 11 Significant defect of the skin and other soft tissues with necrotizing fasciitis. For the purpose of “biological debridement” Iruksan was applied to the wound

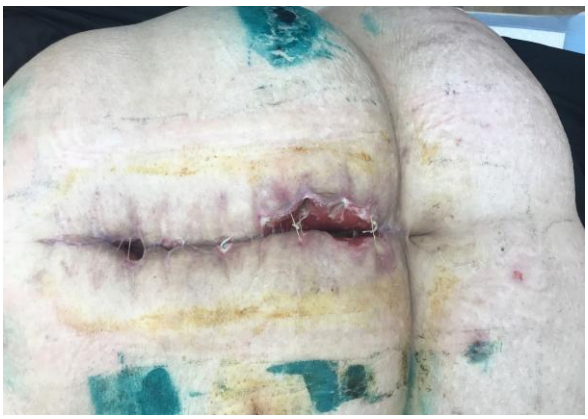

Fig. 10. Patient M., 68 years old. Obesity of the third degree, BMI 40.5. Day 14 after biliary surgery with biliodigestive anastomosis. Purulent-necrotic complication of a laparotomy wound. The wound was completely cleared and significantly reduced in volume. The granulation tissue with “fibrin threads falling out” is actively developing

of Iruksan and VAC therapy. It turned out that in this combination, Iruksan “helps VAC therapy” by significantly lysing necrotic tissues and better removing them. In turn, "VAC therapy assists Iruksan by continuously removing necrotic tissue and accessing other pathologically altered tissues (Fig. 12).

Fig. 12. VAC system applied to purulent necrotic wound with Iruksan injected

Another case. Patient G, 26 years old. Transferred from a district hospital to the Department of Thermal Trauma and Reconstructive Surgery on an emergency basis with a diagnosis of: “Necrotizing fasciitis of the left thigh, sepsis?” His medical history revealed that 2 months before, he had fallen down a ladder, suffered extensive soft tissue contusion of the lateral thigh surface and a small thigh hematoma, which was opened and drained. The wound was sutured and healed with primary tension. The patient returned to physical activity.

After 6 weeks, he developed a compaction and pain in the area. He went back to the district hospital, where

under local anesthesia the soft tissue was dissected to the fascia and drainage was installed. The surgery did not bring any relief, and the patient's condition progressively deteriorated. After hospitalization in one of the clinical bases of the Department of Surgery of Danylo Halytskyi Lviv National Medical University on October 19, 2023, the wound was urgently examined. An extensive purulent-necrotic process was noted at the level of the subcutaneous and deep fascia of the thigh at the site of the postoperative scar, the tensor fasciae of the broad thigh (Fig. 13).

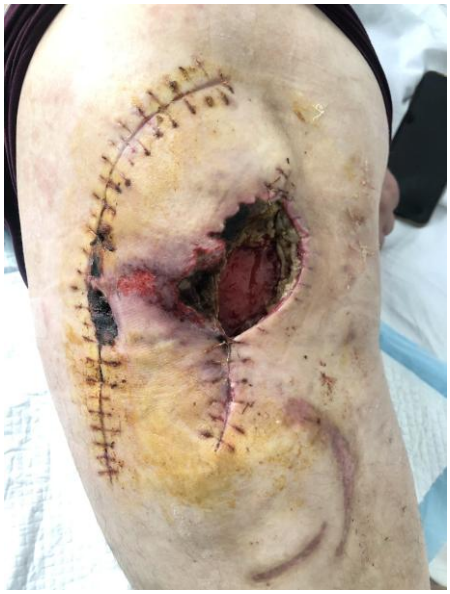

Fig. 13. Patient G., 26 years old. An extensive purulent-necrotic process is seen at the level of the subcutaneous and deep fascia of the left thigh at the site of the postoperative scar, the tensor digitorum major muscle

The patient underwent a radical necrectomy of the entire mass of necrotic tissue to the border of fascia separation, and received VAC therapy twice for 3 days (Fig. 14).

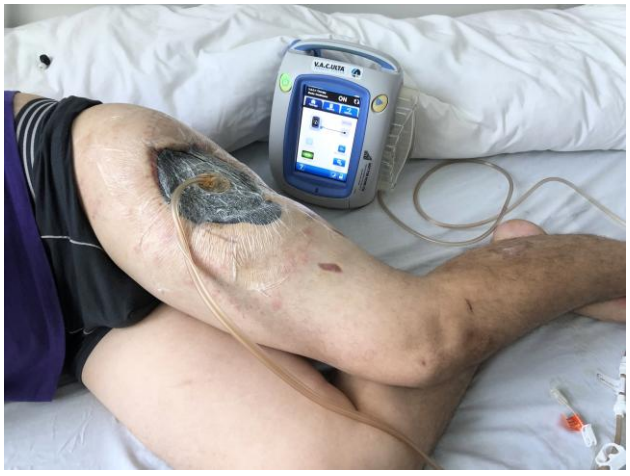

Fig. 14: The use of VAC therapy with Iruksan

The patient's condition was stabilised and he was transferred from the intensive care unit to a regular ward. After the discontinuation of the LAC therapy, the wound was treated exclusively with Iruksan ointment dressings for 8 days, as residual necrosis was noted around the wound perimeter (Fig. 15). After wound debridement, free autodermoplasty was performed, the wound healed, and the patient was discharged on day 28.

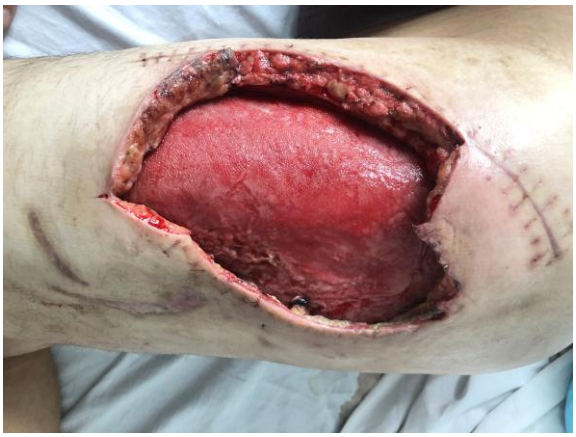

Fig. 15. The condition of the cleared wound from necrotic conditions after the use of LAC therapy and Iruksan. The wound is completely cleaned and prepared for autodermoplasty

In our opinion, it is also worth noting that Iruksan has been successfully used in purulent necrotic processes in patients with diabetes mellitus. Here is another example. Patient K, 66 years old, was admitted on 19.12.2022 with a diagnosis of "Diabetes mellitus, type II, severe course, in the stage of decompensation. Diabetic neuroangiopathy, nephropathy, angiopathy. Diabetic foot syndrome, grade 4 foot ulcer (according to Meggitt-Wagner) in the projection of the 1st metatarsophalangeal joint of the right big toe, gangrene of the right big toe."

The patient was operated on in an urgent manner. Amputation of the right big toe with transmetatarsal amputation of the 1st metatarsal bone was performed. Subsequently, staged necrectomies were performed during dressings and ointment dressings with Iruksan were used for 2 weeks (Fig. 16, 17, 18).

After cleaning the wound, the skin edges were partially sutured with secondary skin sutures and a skin flap of the dorsal-medial part of the main phalanx of the finger, which was rotated and closed part of the wound; the residual wound on the medial surface was healed with secondary tension until complete epithelialisation. The function of the foot was preserved due to the preservation of a skin flap of the dorsal-medial part of the main phalanx of the finger. The patient also underwent the manufacture of individual footwear (Fig. 19).

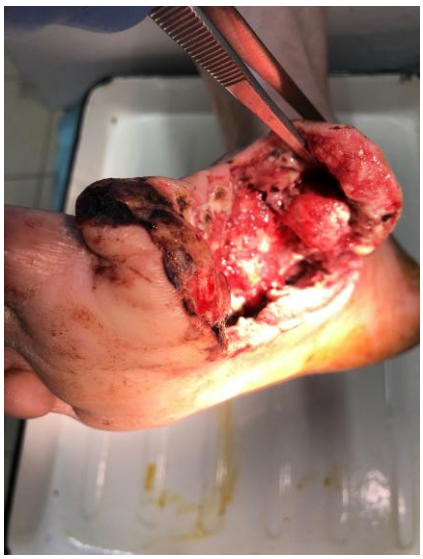

Fig. 16. Wound condition after surgical intervention

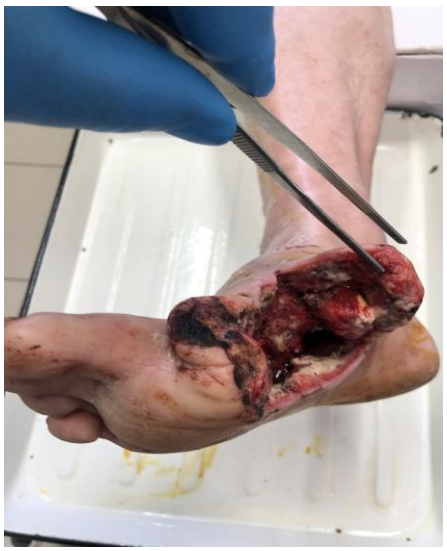

Fig. 17. Wound condition five days after staged necrectomy

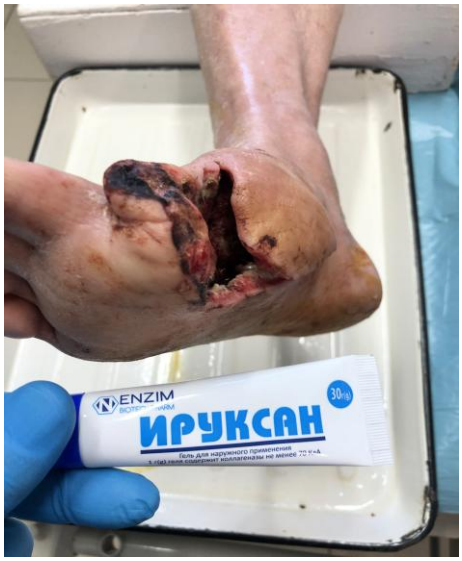

Fig. 18. The wound is cleared with Iruksan and significantly reduced in volume

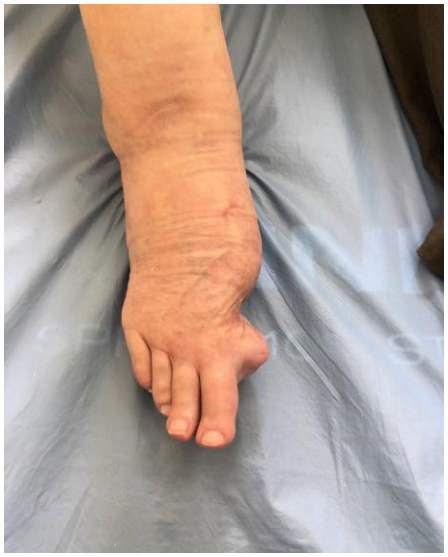

Fig. 19. Healed wound with restoration of supportive function. - six months after rehabilitation surgery

CONCLUSIONS

1. Iruksan, which is a complex preparation containing collagenase, demonstrates significantly better results in the treatment of purulent necrotic processes in soft tissues than Levomekol ointment in terms of wound cleansing speed.

2. Positive results have been noted in the use of Iruksan for purulent-necrotic complications after abdominal surgery in obese patients, which opens up opportunities for further in-depth study and application of this drug in such patients.

3. The use of Iruksan in the complex treatment with other methods, including LAD therapy, made it possible to significantly improve the results of treatment of patients with necrotising fasciitis and purulent necrotic pathology in patients with obesity.

PROSPECTS FOR FUTURE RESEARCH

The data obtained inspire further research on the effectiveness of Iruksan in obese patients and patients with impaired immunological status (e.g., purulent necrotic processes in HIV/AIDS patients or post-COVID patients).

AUTHOR CONTRIBUTIONS

All authors substantively contributed to the drafting of the initial and revised versions of this paper. They take full responsibility for the integrity of all aspects of the work.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ARTIFICIAL INTELLIGENCE DISCLOSURE

No artificial intelligence (AI) technology was used in the writing or editing of this manuscript.

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