

INJECTING MATERIAL FOR SKIN REGENERATION LACERTA® APPLICATION IN TREATMENT OF TROPHIC ULCERS IN PATIENTS WITH DIABETIC FOOT SYNDROME

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Abstract

Examined 22 patients with diabetes mellitus (DM) type II of neuropathic form of diabetic foot syndrome (DFS). In 12 patients (comparison group) local povidone—iodine was used main in 10 (study group), except povidone—iodine, in the phase of exudation used tyrothricin in gel form, the granulation and epithelization phase, after cleaning the wounds, were injected intradermally 1 ml of injecting material for skin regeneration Lacerta®. Trophic defects in 9 (90 %) patients of the main group during the observation period healed completely, in the comparison group complete healing of the ulcer reached in 2 (16.7 %) patients, the rest — wounds, although purified, however, were lethargic granulation, epithelization occurred very slowly. Consequently, the use of the proposed method allows to achieve more rapid healing of trophic ulcers that do not heal continued in patients of neuropathic forms of DFS.

Key words: diabetic foot syndrome; trophic ulcer; local treatment; Lacerta®.

Diabetic foot syndrome (DFS) is one of the most common and severe complications of the DM [1–3]. It complicates the course of the DM almost in 25 % of the patients. Such patients have 20-fold higher risk of gangrene of lower extremities, than the general population [4]. 55 lower extremity amputations with the DFS are performed every hour in the world. Only in the U.S. annually almost 50 thousand operations of high and low amputation are performed in patients with DM, and in Germany — more than 20 thousand. In Ukraine in 2006, gangrene of lower extremities has occurred in 7842 patients, in 70% of which – as a result of DM type II [5]. The frequency of postoperative complications is high enough (30–37 %), postoperative lethality is 9–26 % [6, 7]. The most common form of DFS is neuropathic [8]. Trophic ulcers in such patients exist during a long term in typical areas (soles, heels). They are rarely and slowly healed or recur after restorative surgeries [9, 10].

Objective of the research: to improve the results of local treatment of patients with neuropathic form of DFS.

MATERIALS AND METHODS OF THE RESEARCH

22 patients with DM type II with neuropathic form of DFS were treated in 2013-2014 On the basis of the Chernivtsi regional endocrinology centre (CREC). Males - 14, females - 8, average age of patients (57.3 ± 5.6). Deep ulcerous defects on the foot were detected in all patients (category 4A and 4B - according to the classification of the University of Texas, or stage II A and II B - according to the Meggitt-Wagner classification), duration of their existence from 3 weeks to 2 years. Diagnostic measures were conducted in all patients to confirm diabetic neuropathy (determination of temperature, pain, vibration and tactile sensitivity, evaluation of the tendon reflexes, neuromyography) and to exclude diabetic macroangiopathy (examination of arteries of lower extremities, measurement of the ankle-brachial index, doppler echocardiography of the vessels of lower extremities, nailfold capillaroscopy, pulse oximetry of the lower extremities, photodocumentation). Treatment was performed according to the generally accepted standards: glucose-lowering therapy (insulin therapy), α -lipoic acid drugs, B vitamins, system antibacterial therapy (according to the results of antibioticogram), hemoderivatives of cattle. Patients were divided into two groups by method of local treatment. In 12 patients (comparison group) povidon-iodine was applied twice a day; in 10 (the main group), except povidon-iodine, in the phase of exudation tyrothricin gel was applied, in the phase of granulation and epithelization, after wound purification, once a week 1 ml of injection material was administered intradermally for skin generation (Lacerta®, "Yuria-Pharm", Ukraine) for 4 - 5 weeks. During the treatment patients

were prescribed unloading therapy (crutches, plaster splints, and orthopedic shoes). A side effect of medicines was not detected.

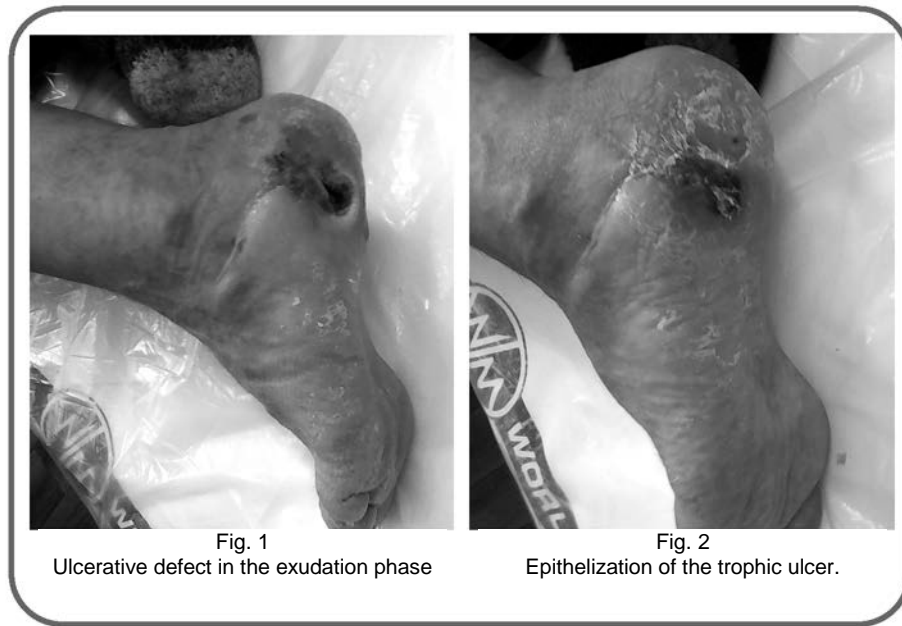


Fig. 1
Ulcerative defect in the exudation phase

Fig. 2
Epithelization of the trophic ulcer.

RESULTS AND THEIR DISCUSSION

Clinical manifestations of the neuropathy were disturbance of the lower extremities sensitivity, saving of pulsation on arteries of the foot and lower leg, the availability of hyperkeratosis on sole, specific deformation of fingers and foot [11, 12]. Trophic ulcers were located in areas of excessive pressure on the sole - heel area, head of the metatarsal bones, lateral surface of the foot. According to electroneuromyography data diagnosis was confirmed in all patients.

The results of wounds treatment were evaluated for clinical efficiency of the local drugs application. The results of treatment in movement were evaluated by the weekly measuring of the ulcerative defects sizes, permitting to correct the treatment, using tape and photographing wounds with following processing using computer programs. The treatment was performed in the outpatient and hospital conditions, that confirm simple using of the developed method, not requiring additional instruments, specialized operating theatre, anaesthesia.

Trophic defects in 9 (90 %) patients of the main group were healed completely during the observation period. In 1 (10 %) patient ulcerative defect was healed not completely, after 5 weeks of treatment callous brims of ulcer appeared, which were conditioned by the patient's refusal from unloading therapy (removed plaster splints without permission).

In comparison group full healing of the ulcerative defect was achieved only in 2 (16,7 %) patients, in rest - wounds although were purified, however, granulations were inert, and epithelization was extremely slow. Here are clinical observations.

Patient G, 45 years old, was treated in outpatient conditions in November-December 2014 in CREC with the diagnosis: DM type II in subcompensation stage, severe form, complicated with non-proliferative diabetic retinopathy, microangiopathy of the lower extremities, sensory diabetic polyneuropathy, DFS, neuropathic form, trophic ulcer of the right foot. He complained about availability of durable (for almost 2 years) trophic ulcer in lateral edge of the right heel, paraesthesia, reduction of the tactile sensitivity of lower extremities, hot pain in both shanks and footsteps, cold footsteps.

DM exists for 8 years, gets insulin. The temperature on both lower extremities is normal, skin is significantly dry, peripheral sensivity is reduced, pulse on both feet and shanks is satisfactory, on the lateral edge of the right heel the trophic ulcerative defect has sizes of 3.5 x 2 cm with callous edges and hyperkeratosis around. Defect sanitation was performed,

hyperkeratosis areas was carved, bandage with povidon-iodine was applied. In the exudation phase povidon-iodine and tyrothricin gel around wound were applied (*Fig. 1*).

Course of the injectible material administration was initiated for skin regeneration Lacerta®. In the conditions of applying bandage, ulcerative defect area was treated with decasan solution, necrotomy was performed. Sizes of the defect before the therapy were determined using measuring tape. Material Lacerta® was injected intradermally, departing 0.5 cm from the edge of ulcer, 0,1 - 0,2 ml in single dose using retrograde tunneling method (with total amount of 1 ml of the drug). The intervals between injections are 0.5 cm. Sterile gauze bandage was applied on the wound defect. The procedure was repeated once a week with obligatory sizes measuring of ulcerative defect and its photographing. In the intervals between use of material bandages were applied 1 - 2 times a day with using povidon-iodine. Treatment Course was 4 weeks. Unloading therapy was performed during the whole period of treatment.

Complete epithelization of trophic ulcers was observed after course of treatment. The patient was recommended to wear protective gauze bandage and to undergo unloading therapy of foot (orthopedic shoes, crutches) for 4 week (*Fig.2*). Consequently, the use of the proposed treatment plan, which included topical antibacterial drugs and skin repair booster – injection material for skin regeneration Lacerta®, contributed to more rapid healing of the trophic ulcers, which were not healed for a long time, in patients with neuropathic form of DFS.

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