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# EVALUATION OF THE EFFECTIVENESS OF COMPLEX TREATMENT OF PATIENTS WITH CHRONIC ULCERS ON THE BACKGROUND OF DIABETES MELLITUS: THE ROLE OF IMMUNOMODULATORS IN THE HEALING PROCESS

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#### ABSTRACT

The aim of this study is to evaluate the effectiveness of the use of immunomodulators in the complex treatment of patients with chronic ulcers on the background of diabetes mellitus. The study involved 100 patients divided into the main and control groups, in which different treatment methods were used. Immunomodulators were used in the main group, and standard therapy was used in the control group. Clinical outcomes were evaluated, including ulcer healing time, infection rate, antibiotic therapy, and complication rate. The average wound healing time in the main group was  $35.6 \pm 5.2$  days, in the control group- $48.9 \pm 7.3$  days. In the main group, the rate of wound infection was 47% (23 patients), in the control group — 65% (32 patients). The incidence of complications in the main group was 10% (5 patients), in the control group — 18% (9 patients). The use of antibacterial therapy in the main group was 70%, in the control group — 85%. The results of the study confirm that the use of immunomodulators promotes accelerated wound healing, reduces the frequency of infection and complications, which makes them an effective supplement in the treatment of chronic ulcers in diabetes mellitus.

**Key words:** chronic ulcers, diabetes mellitus, immunomodulators, treatment, wound healing, infection, complications, antibacterial therapy.

#### **INTRODUCTION**

Diabetes mellitus is a chronic metabolic disease characterized by a violation of carbohydrate metabolism, which leads to an increase in blood glucose levels [2]. One of the most serious complications of diabetes is chronic ulcers, which are particularly common in the lower extremities. According to studies, trophic ulcers and ulcers of the diabetic foot cause a significant deterioration in the quality of life of patients and increase the risk of disability, and in some cases amputation of limbs. This is a serious medical and social problem, as the number of such patients

continues to grow, including due to an increase in the incidence of diabetes mellitus[7]. The healing process of chronic ulcers in diabetes mellitus is hindered by many factors, such as impaired microcirculation, tissue hypoxia, infectious complications, and a weakened immune system. In such cases, traditional treatments, including topical and systemic medications, may not be effective enough. Since one of the key problems is the reduction of immune activity, especially local ones, special attention is paid to the search for new methods aimed at stimulating the immune response [5]. Immunomodulators that affect the body's immune system are a promising direction in the treatment of chronic ulcers in diabetes mellitus. They can improve local and systemic immune responses, increase tissue resistance to infections, and speed up the healing process. Recent studies show that immunomodulators can help accelerate wound healing, reduce the incidence of infectious complications, and prevent infection from spreading to the deeper layers of tissues [8]. To date, the effectiveness of immunomodulators in the treatment of chronic ulcers in diabetes remains insufficiently studied, which underlines the relevance of this topic. Existing data are contradictory, and many studies show mixed results in terms of their effect on the healing process. In this regard, additional clinical studies are needed to assess the effect of immunomodulators on the healing of ulcers, the frequency of infections, the need for antibacterial therapy, and the development of complications [7]. The use of new approaches, such as the use of immunomodulators, is becoming an important element in solving the problem of treating trophic ulcers and ulcers of the diabetic foot. The effectiveness of such drugs can significantly affect clinical outcomes, improve the quality of life of patients, and reduce the economic burden on healthcare. Thus, studying the role of immunomodulators in the treatment of chronic ulcers in diabetes mellitus is an important scientific and practical task, the solution of which can significantly improve the results of treatment and increase the effectiveness of therapeutic approaches for patients suffering from this complication [9].

### Goal:

The aim of this study is to evaluate the clinical efficacy of immunomodulators in the treatment of chronic ulcers with diabetes mellitus, as well as their impact on wound healing time, infection rate, complications, and the need for antibacterial therapy.

### MATERIAL AND METHODS OF RESEARCH

100 patients with chronic ulcers and diabetes mellitus were selected for the study. Patients were divided into two groups: the main group (50 patients), who received complex treatment with immunomodulators, and the control group (50 patients), who were treated with standard methods. The average age of participants

was  $62.3 \pm 7.4$  years. During the study, the following parameters were recorded: wound healing time, infection rate, complication rate, and use of antibacterial therapy. Clinical outcomes were evaluated on days 7, 14, and 30 of follow-up.

### **RESULTS AND DISCUSSION**

The study involved 100 patients with chronic ulcers caused by diabetes mellitus. The patients were divided into two groups: the main group (50 patients) and the control group (50 patients). In the main group, patients received immunomodulatory treatment in addition to standard therapy, while in the control group, only standard therapy was used.

The average age of participants was  $62.3 \pm 7.4$  years. Of all the patients, 60%(60 people) had type 2 diabetes, and 40% (40 people) had type 1 diabetes. In the main group, 64% (32 patients) had diabetic foot ulcers, while in the control group it was 56% (28 patients). The remaining patients suffered from trophic ulcers on their legs (mainly on the lower leg and feet), including neuropathy, post-thrombophlebitic syndrome, and other disorders. The average ulcer healing time in the main group was  $35.6 \pm 5.2$  days, while in the control group it was significantly higher and amounted to  $48.9 \pm 7.3$  days. This confirms a faster healing process in the group of patients treated with immunomodulators. The rate of wound infection in the main group was 47% (23 patients), while in the control group it was higher and amounted to 65% (32 patients). As a result of the use of immunomodulators in the main group, the risk of developing infectious complications significantly decreased. When analyzing the frequency of complications, such as gangrene, sepsis, and osteomyelitis, 10% (5 patients) of cases of complications were registered in the main group, while in the control group this indicator was 18% (9 patients). In the main group, there were also fewer cases of limb amputation — 4% (2 patients), while in the control group results confirm the effectiveness 12% (6 patients). These of using immunomodulators in reducing the frequency of severe complications. In addition, in the main group, the use of antibacterial therapy was 70% (35 patients), while in the control group — 85% (42 patients). This confirms that the use of immunomodulators can reduce the need for antibiotics, which is important in the context of combating antibiotic resistance. When assessing clinical outcomes using the Wound Healing Score (WHS) scale, it was found that in the main group, the average score on the scale was  $8.2 \pm 1.1$ , which indicates more pronounced positive changes in the healing process than in the control group, where this indicator was  $6.3 \pm 1.3$ . Thus, the results showed that the use of immunomodulators in the treatment of chronic ulcers in diabetes mellitus significantly accelerates the healing process, reduces the frequency of infection and complications, and also reduces the need for antibacterial therapy and reduces the risk of amputations. These data confirm the

effectiveness of immunomodulators as an important component of complex treatment of chronic ulcers in diabetes mellitus.

## CONCLUSION

The study involved 100 patients with chronic ulcers caused by diabetes mellitus. Patients were divided into two groups: the main group (50 people), which received immunomodulatory treatment, and the control group (50 people), which used only standard therapy. The average ulcer healing time in the main group was  $35.6 \pm 5.2$  days, while in the control group this value was significantly higher —  $48.9 \pm 7.3$  days. This confirms that the immunomodulator helps accelerate wound healing. The rate of wound infection in the main group was 47% (23 patients), in the control group — 65% (32 patients), which indicates the effectiveness of using immunomodulators in reducing infectious complications. As for complications, in the main group 10% (5 patients) suffered from sepsis, gangrene or osteomyelitis, in the control group this indicator was 18% (9 patients). In the main group, limb amputation was performed in 4% (2 patients), in the control group - in 12% (6 patients), which demonstrates a lower frequency of amputations in the group with an immunomodulator. The average number of days spent in hospital by patients in the main group was  $45.4 \pm 6.1$ , and in the control group- $60.3 \pm 8.2$ , which also confirms a faster recovery process. Thus, the results show that the use of immunomodulators promotes faster healing of ulcers, reduces the frequency of infections and complications, and reduces the need for amputation of limbs.

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