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An Improved Method for Controlling Bleeding from The Bone Marrow Canal During Lower Limb Amputation in Patients with Diabetes Mellitus

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Abstract

Objective: To clinically evaluate the effectiveness of a new plastic form of the local hemostatic agent Hemoben for controlling bleeding from the medullary canal during lower limb amputation in patients with diabetes mellitus.

Methods: The study was conducted in patients who underwent lower limb amputation due to complications of diabetes mellitus. In the control group, intraoperative hemostasis was achieved using conventional techniques, including vessel



ligation, electrocautery, and standard local hemostatic agents. In the main group, a new plastic form of Hemoben was used to control bleeding from the medullary canal during femoral amputation. The plastic hemostatic material was prepared by mixing Hemoben powder with sterile physiological saline and combining it with a collagen hemostatic sponge. The prepared material was then placed into the medullary canal after transection of the femur. The following parameters were comparatively evaluated: time to achieve hemostasis, duration of surgery, intraoperative blood loss, incidence of postoperative local complications, wound healing time, and length of hospital stay.

Keywords: Diabetes mellitus, diabetic foot syndrome, lower limb amputation, hemostasis, medullary canal, Hemoben, plastic hemostatic agent, collagen hemostatic sponge.

1. Introduction

Diabetes mellitus is considered one of the most pressing medical and social problems of the 21st century. The year-on-year increase in the prevalence of the disease leads to high rates of disability and mortality associated with its chronic complications, specifically diabetic foot syndrome [1]. The combined development of diabetic micro- and macroangiopathy, peripheral neuropathy, and infectious-inflammatory processes leads to irreversible necrotic changes in the tissues of the lower extremities [2-3]. In such cases, the possibility of preserving the organ is limited, and leg amputation must be performed to save the patient's life [4]. Leg amputations are considered one of the most complex operations in general and purulent surgery. The functional outcome of the amputation depends not only on the degree of surgical intervention but also on how reliably hemostasis is maintained during the operation. One of the most important stages of the operation is the complete elimination of bleeding from soft tissues, muscles, and especially the bone marrow canal. Insufficient hemostasis increases the likelihood of hematoma, lymphorrhea, wound infection, buttock necrosis, late wound healing, and repeated surgical interventions in the postoperative period [5, 6]. Currently, ligation, electrocoagulation, bone wax, hemostatic sponges, and various local hemostatic drugs are widely used to stop bleeding. However, each of these methods has certain limitations [7,8]. Electrocoagulation can cause thermal necrosis in surrounding tissues, disrupt microcirculation, and slow down regeneration processes. Although the use of bone wax mechanically closes the bone marrow canal, its biological inertness can negatively affect the course of reparative processes. Therefore, in addition to reliably ensuring hemostasis, the development of new biomaterials that accelerate wound healing and reduce the local

inflammatory response remains one of the urgent tasks. In recent years, there has been a growing interest in biopolymer and biodegradable domestic hemostatic agents. Among them, hemostatic materials based on cellulose are of particular importance due to their good sorption properties, biocompatibility, local hemostatic activity, and compatibility with body tissues. Such materials are characterized by the fact that, while activating the blood coagulation process, they create a favorable environment in the wound area and stimulate reparative regeneration processes. In this regard, the use of a new plastic form of the hemostatic agent "Hemoben," developed on the basis of cellulose, is a promising direction in stopping bleeding from the bone marrow canal. The use of the hemostatic agent in combination with a collagen sponge allows for reliable filling of the bone marrow canal, eliminating bleeding in a short time, preventing excessive damage to surrounding tissues, and reducing the risk of developing postoperative hematoma and lymphorrhea. This can serve to accelerate wound healing, reduce postoperative complications, and shorten the rehabilitation period of patients. Diabetes mellitus is one of the most common chronic diseases worldwide, and diabetic foot syndrome holds a special place among its severe complications. The combined development of diabetic angiopathy, polyneuropathy, and infectious-inflammatory processes leads to tissue necrosis and gangrene in many patients. In such cases, when conservative treatment is ineffective, the only effective way to save the patient's life is to perform lower limb amputation. Lower limb amputations are accompanied by high surgical trauma, and one of the most critical stages of the operation is ensuring reliable hemostasis.

In particular, the complete cessation of bleeding from the bone marrow canal after a femoral amputation remains a pressing issue in practice. The widely used electrocoagulation method can cause thermal damage to soft tissues, disrupt local microcirculation, and slow wound healing. This increases the risk of postoperative hematoma, lymphorrhea, infectious-inflammatory complications, and repeated surgical interventions. In this regard, the development and implementation into clinical practice of new domestic hemostatic agents that allow for the rapid, reliable, and minimal damage to the surrounding tissues of bone marrow bleeding is of great importance. One such promising local hemostasis method is the new plastic form of the "Hemoben" hemostatic agent developed on the basis of cellulose.

It serves to hermetically close the bone marrow canal, stop bleeding in a short time, and create favorable conditions for wound healing. The aim of this study is to evaluate the clinical efficacy of using a new plastic form of the hemostatic agent "Hemoben" to stop bleeding from the bone marrow canal during



lower limb amputations in patients with diabetes mellitus and to determine its effect on the results of surgery and the postoperative period.

2. Methods

Hip amputations in patients with diabetic foot syndrome are considered one of the most pressing and important problems in modern surgery. Amputation is one of the most effective methods for preventing complications of severe circulatory disorders, diabetic gangrene, phlegmon, purulent-necrotic lesions, and other severe pathological conditions in patients with diabetes mellitus. This is often the only way to save the lives of patients.

During surgery, the incision of soft tissues, muscles, and large small main blood vessels significantly increases the risk of blood loss in patients. Therefore, establishing immediate and reliable hemostasis at every stage of the operation is one of the primary duties of the surgeon. In cases where the applied hemostasis is ineffective, the volume of intraoperative bleeding increases, leading to the formation of postoperative hematomas, which exacerbates inflammatory processes in the wound area and slows the healing of the abscess.

In both groups, the amputation and sanitation of the femoral region were technically identical. The differences were in the completeness of the main group of methods of physical impact on the wound, i.e., under the influence of the new plastic form of the hemostatic agent "Hemoben." All types of complications that may occur during surgery and in the early period were taken into account. Their overall frequency in the comparison group was 50.9% (in 28 out of 55 patients), while in the study group, 18.37% of cases with a complicated course were confirmed (in 9 out of 49 patients), which was significantly lower than in the comparison group ($\chi^2 = 12.07$; $df = 1$; $p < 0.001$). The nature of intraoperative wound bleeding was studied, and the probability of bleeding after sanitization was determined, which was noted in both groups; however, wound bleeding in the primary group allowed for a practically complete reduction in the risk of developing this complication. Thus, wound bleeding was noted in 7 (12.7%) patients in the comparison group and in 0 (0.0%) patients in the study group. Hematomas in the wound area developed in 16 (29.1%) and 1 (2.04%) patients, respectively. Other frequent complications in the comparison group included limited fluid accumulation in the wound area—11 (20.0%) patients; in the study group, this indicator was noted in only 3 (6.12%) patients. Lymphorrhagic processes were noted in 3 (5.5%) and 0 (0.0%) patients, respectively (Table 1).

Table 1

Frequency of early complications following hip amputation in the study groups.

Slavery	Comparison group		Main group	
	Abs.	%	Abs.	%
Wound bleeding	7.	12.7%	0	0.00%
Haematoma at surgical site	16	29.1%	1.	2.04%
Lymphorrhoea	3.	5.5%	0	0.00%
Limited fluid accumulation at the surgical site	11.	20.0%	3.	6.12%
Wound suppuration	16	29.1%	7.	14.2%



Complicated patients	28	50.9%	9.	18.37%
Difference reliability	$\chi^2 = 12.07; df = 1; p < 0.001;$			

Overall, additional invasive interventions were performed in 19 (34.5%) patients in the comparison group, compared to only 7 (14.3%) in the study group ($\chi^2 = 5.57; df = 1; p = 0.018$). Reopening of the inflammatory focus was performed in 5 (9.1%) and 2 (4.1%) patients, respectively, and in

another 6 (10.9%) and 1 (2%) cases, this manipulation involved the removal and reopening of necrotic tissues. In 8 (14.5%) and 4 (8.2%) cases, the intervention was limited to the removal of necrotic tissues (Fig. 1).

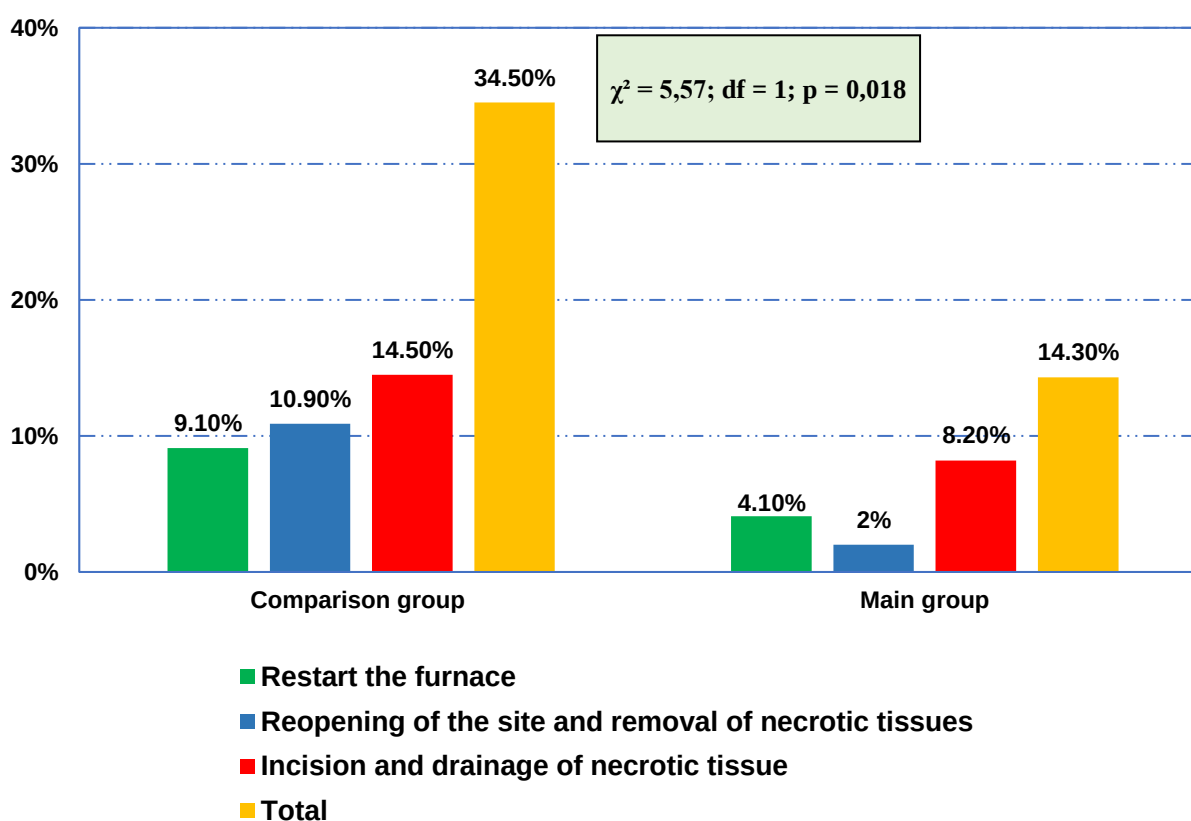


Figure 1. Number of patients with repeated postoperative interventions

In the early postoperative period, after the opening of the purulent-necrotic process, an assessment of the local condition in patients was conducted in dynamics based on the condition of the skin around the wound, its color, edema, hyperemia, the presence of purulent foci or necrotic tissues, local temperature, as well as the nature and size of the wound defect.

First, let's provide data on the dynamics of leukocytosis. Regression of leukocytosis in the early period was noted in both groups. Thus, in the comparison group, the leukocyte level before

surgery was $14.2 \pm 3.7 \times 10^9/L$; on the 3rd day, the indicator decreased to $11.6 \pm 3.3 \times 10^9/L$ ($t=4.49; p < 0.001$), and on the 7th day, it decreased again to $10 \pm 3.1 \times 10^9/L$ ($t=6.97; p < 0.001$). In turn, in the main group, the leukocyte level before surgery was $14.2 \pm 2.9 \times 10^9/L$; on the 3rd day, the indicator decreased to $9.8 \pm 2.5 \times 10^9/L$ ($t=8.22; p < 0.001$), and on the 7th day, it decreased again to $8.3 \pm 2.1 \times 10^9/L$ ($t=11.75; p < 0.001$), while the indicators between the groups differed significantly on both the 3rd day ($t=8.22; p < 0.001$) and the 7th day ($t=11.75; p < 0.001$) (Fig. 2).

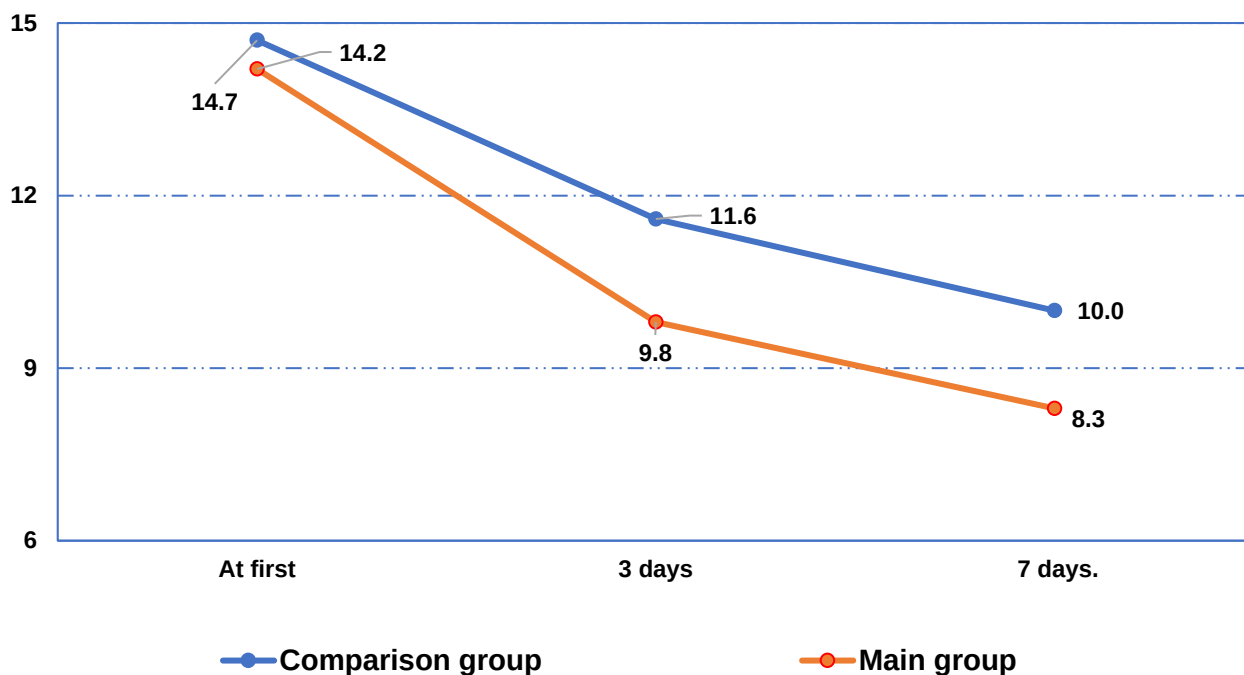


Figure 2. Dynamics of blood leukocyte indicators in the comparison groups (x10⁹/l) (M±δ).

The reduction in the time required to achieve intraoperative hemostasis also had a positive effect on the overall duration of the operation. Compared to the comparison group using traditional hemostasis methods, a significant reduction in the duration of surgical intervention was achieved in the primary group using the new plastic form of "Hemoben."

The results of the analysis showed that achieving intraoperative hemostasis allowed for a reduction in time from 7.8±1.1 to 2.3±0.3 minutes ($t = 33.9$; $df \approx 56$; $p < 0.001$). While the average duration of surgery in the comparison group was 54.1±7.8 minutes, in the study group this indicator decreased to 42.5±2.3 minutes ($t = 10.03$; $df \approx 59$; $p < 0.001$). (Fig. 3).

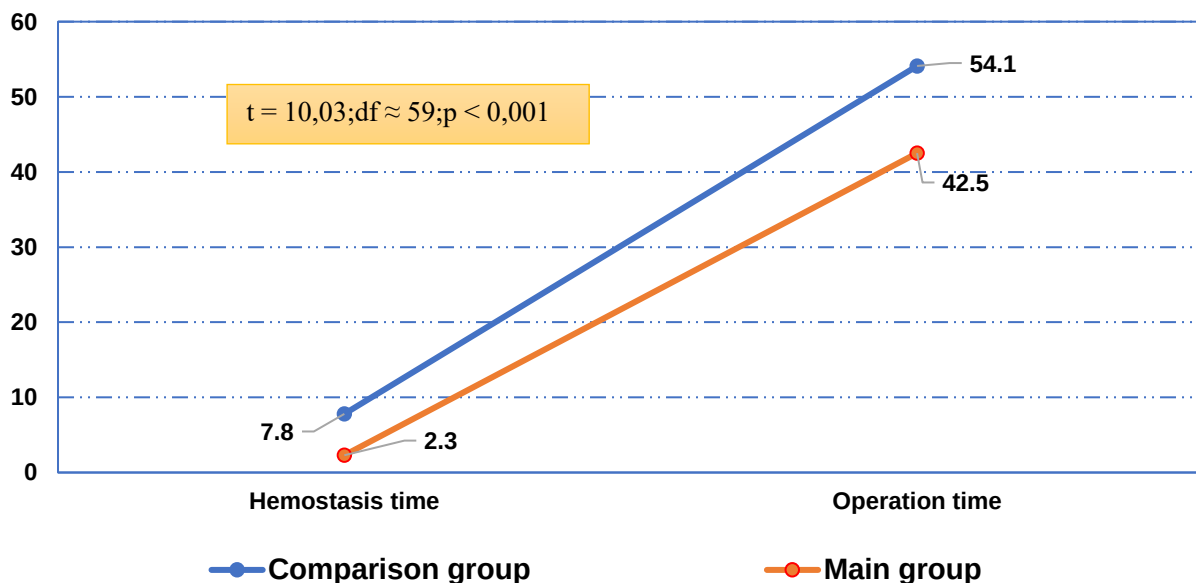


Figure 3. Intraoperative hemostasis and total duration of surgery (minutes, M±δ)



The results obtained confirmed the high hemostatic efficacy of the new "Hemoben" plastic form, its ability to quickly stop and reliably control intraoperative bleeding, reduce surgical time, and improve the effectiveness of amputation interventions.

3. Conclusion

The introduction of a new treatment method using a new plastic form of the hemostatic agent "Hemoben" during leg amputation surgeries in patients with diabetes mellitus reduced the frequency of postoperative complications from 50.9% (in 28 out of 55 patients in the comparison group) to 18.37% (in 9 out of 49 patients in the main group; $\chi^2 = 11.95$; $df = 1$; $p = 0.001$), while the need for repeated interventions ranged from 34.5% (19 patients in the comparison group) to 14.4% (7 patients in the main group; $\chi^2 = 5.57$; $df = 1$; $p = 0.018$). Stimulating the etiopathogenetic mechanisms of postoperative wound healing allowed for a significant acceleration in the regression of the wound process; specifically, a significant decrease in leukocytosis levels was noted by day 3 (from 14.7 ± 3.7 to $11.6 \pm 3.3 \times 10^9/L$ in the comparison group and from 14.2 ± 2.9 to $9.8 \pm 2.5 \times 10^9/L$ in the study group; $t = 8.22$; $p < 0.001$), which, in turn, allowed for a reduction in the time to achieve intraoperative hemostasis to 7.8 ± 1.1 minutes in the comparison group and 2.3 ± 0.3 minutes in the study group ($t = 33.9$; $df \approx 56$; $p < 0.001$). While the average duration of surgery in the comparison group was 54.1 ± 7.8 minutes, in the study group this indicator decreased to 42.5 ± 2.3 minutes ($t = 10.03$; $df \approx 59$; $p < 0.001$).

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