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FEATURES OF ORGAN-SAVING FOOT AMPUTATION ASSOCIATED WITH OZONE THERAPY, LOCAL APPLICATION OF AUTOLOGOUS PLATELET-RICH PLASMA AND VACUUM SANITIZATION OF POSTOPERATIVE WOUND IN PATIENTS WITH ISCHEMIC-GANGRENOUS FORM OF DIABETIC FOOT SYNDROME

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Abstract

Improvement of reparative process of the chronic wounds with the insufficiency of peripheral blood suppling in patients suffering from diabetes mellitus is an important issue requiring further investigation. An optimal choice of surgery, effective renewal of blood supply and active stimulation of tissue repair on the cellular level are essential components of success treatment of this problem.

Objective of research: From 2017 to 2020, the efficiency of one of the variants of organ-saving surgery performed on 210 patients with an ischemic-gangrenous form of diabetic foot syndrome was studied.

Materials and methods. Control group included 104 patients (49.52%), were the treatment carried out in accordance with the standard scheme. The main group (106 patients - 50.47%) in addition to the standard therapy have used regional ozone therapy, vacuum sanitization and local application of autologous platelet-rich plasma (APRP).

Results. These proposed measures reduced the period of clinical treatment to 24±1,2 days in the main group compared to 37±2,4 in the control one. 2 years later, patients of the main group confirmed the formation of a foot stump functionally adapted for walking with angular dislocation of fragments of the cuboid and scaphoid bones.

Two years after foot amputation due to the ischemic-gangrenous form of diabetic foot syndrome (DFS), the amount of repeated above knee amputations was 1.8 times higher in the control group in comparison with the main group, which is indicative of a reasonable use of the complex of activate a reparative process in the wound.

Conclusions: The suggested modification of the organ-saving and partial foot amputation in patients with IV degree of ischemia and DFS is indicative of a possibility to perform such kind of surgery as a variant of choice.

The complex of proposed additional measures including regional ozone therapy, vacuum sanitization and local administration of autologous platelet-rich plasma activates a reparative process of a chronic foot wound and promotes an effective treatment of patients with ischemic-gangrenous form of DFS.

Key words: diabetic foot syndrome; ozone therapy; vacuum therapy; autologous platelet-rich plasma.

Introduction. Searching possibilities to activate a reparative process in the wound with chronic disturbances of the peripheral blood supply in the limbs is an issue requiring further investigation [2, 5, 8, 9, 10, 11, 12]. First of all, it concerns patients suffering from type 2 diabetes mellitus with signs of macro- and micro-angiopathy of the lower limbs. This process is manifested by critical ischemia with necrosis of the soft tissues at the final stage of its development [5, 10]. An optimal choice of surgery, effective renewal of blood supply and active stimulation of tissue restoration process on the cellular level are essential components of success in the treatment of this problem [1, 2, 5, 6, 8, 9, 11, 12].

Objective: to study efficiency of the suggested organ-saving variant of surgery combined with the use of a complex of auxiliary factors activating a reparative process in the wound including regional ozone therapy, vacuum sanitization and local application of autologous platelet-rich plasma (APRP) [1, 2, 6, 7, 10, 11, 13]. The efficiency of the suggested complex of therapeutic measures was analyzed on the clinical material obtained.

Materials and methods. During the period from 2017 to 2020 210 patients with gangrene of the distal third of the foot with ischemic-gangrenous form of diabetic foot syndrome (DFS) stayed in the clinic “Surgery-2, BSMU”, including 124 men (59,04%), and 86 women (40,95 %). The majority of patients (168) were at the age of 65-67 (80 %). All the examined patients suffered

from type 2 diabetes mellitus (DM). Distribution of patients according to the quantitative content and age was identical and did not differ reliably (p>0,05) (Table 1). The patients were divided into the two groups. The main one included 106 (50,47%) patients, and the control group – 104 (49,52%).

A standard, common complex of treatment applied in case of DFS was used for the patients from the control group [5, 10]. The parameters to identify ischemia of the lower limbs were similar in both groups. The complication of the disease was classified as IV degree according to Meggitt-Wagner classification in all the hospitalized patients in the clinic from both the main and the control groups.

Table 1 - Distribution of patients from the main and control groups

Group of patients	Number of patients (n)	Age (M±m)
Main	106	67±1,2
Control	104	65±1,4
P	> 0,05	

Note: p – statistical probability

In addition to the standard complex of therapeutic measures similar to that of the control group, all the patients from the main group (106 individuals – 50,47%) underwent an intravenous injection of ozonized physiological solution (OPS), a programmed sanitization of the wounds with ozone-contained physiological solution and regional vacuum therapy (Fig. 1) [1, 6, 7].

Fig. 1 - Patient B. with ischemic-gangrenous form of DFS after local vacuum therapy performed according to one of the variants

The above complex of therapeutic measures was supplied with the ozonation method of the wound surface due to the “ozone boot” (Fig. 2) and local administration of APRP from 5 to 6 procedures [2, 12, 13].

Fig. 2 - The use of "ozone boot" in patients with ischemic-gangrenous form of DFS

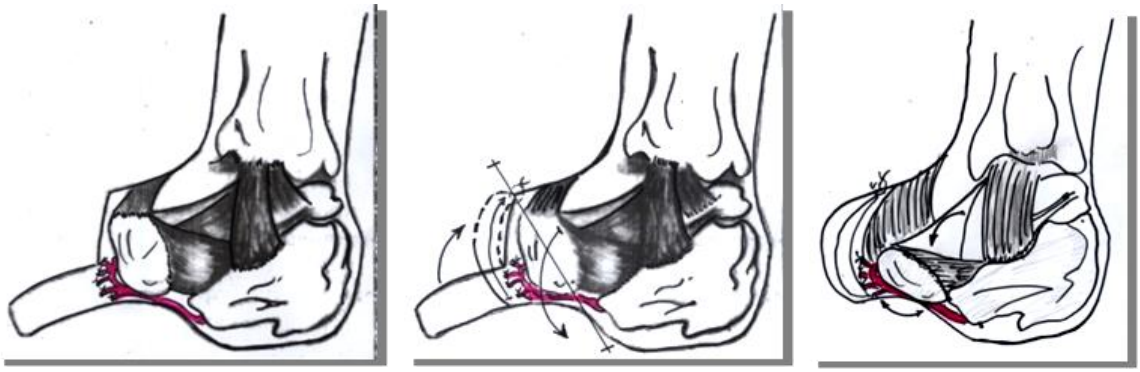
Method to obtain APRP. The criterion to use APRP in the treatment of chronic wounds is consideration of physiological parameters of platelets in the blood of patients from the main group. For this purpose, platelets were calculated according to the standard method [3]. To get APRP the blood was taken from the peripheral vein of a patient into 2 sterile heparinized tubes 8 ml each. They contained 14-20 units of heparin per 1 ml of blood [2, 3, 11, 12, 13]. The obtained APRP was injected by means of a syringe along the peripheral surface and bottom of the wound (when APRP was injected by means of an “open” method 15 injections 0,5 ml each were given). The interval between the points of injections was 1 cm. A part of remaining APRP was applied onto the wound defect and covered with a dry sterile dressing for 24 hours.

The method to perform surgery. All the necrotized tissues within the visual healthy tissue were removed during surgery. The tendons and fasciae were removed as well within the wound limits together with excessive amount of the adipose tissue. At the same time, viable healthy tissues were carefully treated and their additional damage was prevented, such as the vessels of the plantar area in particular.

Hemostasis was performed by means of the bipolar electrocoagulation method and biological repair method of tissues by means of the electric surgical generator "CovidienValleylab – LS10". Ligatures were applied on the points of location of the deep arterial arch in the plantar foot areas only, with its maximal possible retaining and local single injection of 5000 UN of heparin into the perivascular space with compulsory retention of r. plantaris profundus a. dorsalis pedis (Fig. 3a).

The foot was amputated with a half saw cut of the middle portion of the cuboid and scaphoid bones. Such amputation preserves the possibility of the angular dislocation of the saw cut and

formation of the scar tissue closely connected with the soft tissues of the distal portion of the formed stump (Fig. 3.b, c). The above variant of surgery creates conditions for maintenance of a supporting function of the operated foot (Fig. 3, 4, 5).



a **b** **c**

Fig. 3 - The scheme of performing the suggested variant of foot amputation with retaining r. plantarisp rofundus a. dorsalis pedis.

Fig. 4 - Typical variant of the stump 2 years after amputation (the main group)

Fig. 5 - Angular dislocation of the saw cut of the cuboid and scaphoid bones in the position functionally advantageous for supporting load (the main group, 2 years after surgery)

Ozonized physiological solution (OPS) was infused or introduced intravenously drop-by-drop. Ozone concentration in 200 ml of physiological solution was 2,0 – 2,5 mg/L. It was injected at the rate of 40-60 drops per 1 minute. About 6 procedures were performed for the patients at the

early postoperative period. It depended on the dynamics of the disease development and local changes in the place of foot affliction.

24 hours later after all the complex of the suggested measures was carried out, APRP was injected locally in the amount of 5 ml distributed in doses of 0,5 ml subcutaneously and 2,5 ml in the form of local injection into the wound surface in case of its “open” introduction. The efficacy of a comprehensive treatment suggested was assessed clinically by the results of surgical treatment which was focused on the maximal sparing variants of surgery performed.

With the aim to objectify the investigations conducted, the dynamics of changes of sugar level in the blood before and after intravenous injection of OPS was examined in the patients of the main and control groups.

Blood sugar level before the beginning of the procedure was practically similar and did not differ much in the patients from the main and control groups. 10-12 hours after intravenous injection of the above dose of OPS the patients from the main group (up to 18 hours) developed a reliable difference between these parameters (< 0,05) (Table 2).

Table 2 - Dynamics of blood sugar changes after intravenous injection of OPS given (up to 18 hours) since the first day of the postoperative treatment of patients with DFS

Distribution of blood sugar in the groups of patients by hours	8 hours	14 hours	18 hours
Main group	9,4±2,1 mmol/L	9,3±2,8 mmol/L	8,9±1,0 mmol/L
Control group	9,1±2,4 mmol/L	9,5±3,0 mmol/L	9,6±2,3 mmol/L
p	>0,05	>0,05	<0,05

Note: p – statistical probability

The results of clinical observation identified that on the 4-6th days of the postoperative period the patients of the main group developed much quicker decrease of swelling, infiltration and hyperemia round the wound. These parameters stabilized in the control group on the 12-14th day after surgery. The use of the whole complex of the therapeutic measures in the main group enabled to reduce the period of treatment of patients in the hospital 23±1,3, days in the main group compared to 34±1,4 in the control one (Table 3).

Table 3 - Periods of in-patient treatment of the main and control groups

Group of patients	Number of patients (n)	Periods of in-patient treatment (M±m)
Main group	106	23±1,3
Control group	104	34±1,4
p	<0,05	

Note: p – statistical probability

2 years later 95 patients (45,46 %) of the main group who underwent organ-saving foot amputation (106 – 50,47% out of the whole number of patients - 210), admitted the formation of the foot stump functionally able to walk with optimal angular dislocation of the saw cut of the cuboid and scaphoid bones in the position functionally suitable for supporting load (Fig. 4, 5).

For this period of time sclerotic changes prevailed in the osseous structures of the formed stumps in patients from the control group (104 patients – 49,52% out of the total number) (Fig. 6). Formation of the stump functionally adapted for walking with the necessary angular dislocation of the saw cut of the cuboid and scaphoid bones in the control group was found 69 patients (32,85 %), which is 12,61% less as compared to the similar results in the main group (Fig. 7).

Fig. 6 - Clinical observation 2 years after foot amputation in the suggested variant on the level of Chopart joint with retention of r. plantaris profundus a. dorsalis pedis (the control group of patients)

Fig. 7 - Clinical observation 2 years after foot amputation in the suggested variant on the level of Chopart joint with retention of r. plantaris profundus a. dorsalis pedis (the control group of patients)

At the same period of time, due to advanced course of the disease, 10 patients from the main group (4,76% from the total number of 210), and 18 patients (8,57 % from the total number of 210) from the control group underwent “high” amputation of the lower limb. The number of repeated amputations in the patients from the control group was 1,8 times higher than that of the main group.

Conclusions:

1. The suggested modification of the organ-saving and partial foot amputation in patients with IV degree of ischemia and DFS is indicative of a possibility to perform such kind of surgery as a variant of choice for patients with ischemic-gangrenous form of diabetic foot syndrome.

2. The complex of auxiliary measures including regional ozone therapy, vacuum sanitization and local administration of APRP, activates a reparative process of healing of a chronic foot wound and promotes an effective treatment of patients with ischemic-gangrenous form of diabetic foot syndrome.

3. The above complex of therapeutic measures enables to make the period of hospital stay for patients shorter – to 24±1,2 days in the main group as compared to 37±2,4 days in the control one.

4. Clinical observation of a remote postoperative period (2 years later) confirm a possibility to form a foot stump functionally adapted for walking with angular dislocation of fragments of the cuboid and scaphoid bones, functionally advantageous for supporting load.

5. Two years after amputation of the foot due to ischemic-gangrenous form of DFS, the amount of repeated above knee amputations was 1.8 times higher in the control group in comparison with the similar parameter in the main group, which is indicative of a reasonable use of the complex of auxiliary factors to activate a reparative process in the wound in the main group of the examined patients.

Prospects for further research. In the future, it is advisable to consider changes in local blood flow after the proposed complex of treatment, the quality of recovery of collateral blood flow and the duration of the effect of this treatment.

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