ORIGINAL ARTICLE

CONTENTS

The role of intraoperative debitometry in choosing the treatment strategy for patients with diabetes mellitus with stenotic-occlusive lesion of the tibial segment arteries

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ABSTRACT

Aim: To improve the results of surgical treatment of patients with ischemic form of diabetic foot syndrome (IF DFS) with stenotic-occlusive lesion (SOL) of the tibial segment arteries by creating an algorithm of diagnostic and treatment tactics.

Materials and Methods: An analysis of the surgical treatment outcomes of 137 patients with type 2 diabetes mellitus (DM2) and IF DFS with SOL of the tibial segment arteries, critical limb ischemia, and ischemic foot necrosis was conducted.

Results: According to the obtained indicators of the popliteal artery debit after performing balloon angioplasty (BAP) of the tibial segment arteries, the patients were divided into three groups. All patients, depending on the degree of increase in the popliteal artery debit after BAP (group A – <1,5 times; 1,5-2 times; >2 times), transcutaneous oxygen pressure (TcPO2) and the option of revascularization according to the angiosomal concept, were assigned a certain number of points and compared with the quality and timing of wound healing in the groups. It is considered that the calculation of quantitative changes in the popliteal artery debit after performing BAP accurately determines the prospects for healing of foot wounds after necrotectomy in patients with IF DFS and can be a criterion for formulating further treatment tactics.

Conclusions: Measuring TcPO2 and determining the revascularization option based on the results of BAP allow the DM2 patients in groups A, B, and C to be assigned the appropriate number of points, the sum of which shows the prognosis for healing of foot wounds and the timing of using other methods of revascularization or performing amputation.

KEY WORDS: diabetes mellitus, balloon angioplasty, debitometry, necrectomy

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INTRODUCTION

Diabetes mellitus remains one of the important problems of the healthcare system, and the prevalence of diabetes in different countries ranges from 1,5 to 6% and currently has a tendency to increase [1].

In people with diabetes for more than 20 years, the frequency of lower limb artery damage exceeds 80%. More than half of all non-traumatic lower limb amputations are performed in patients with diabetes, often repeatedly A feature of diabetic damage to the arterial bed is a multilevel stenotic-occlusive process in medium and small caliber arteries (popliteal, tibial and foot arteries) which leads to the development of chronic lower limb-threatening ischemia (CLLTI) [2]. The presence of CLLTI indicates an unfavorable prognosis, within a year after the manifestation of CLLTI, only 25% of patients recover, in 20% - symptoms persist; in 30% of patients the limb is amputated, and 25% - die [3].

In 2011, the International Working Group on the Diabetic Foot (IWGDF) adopted the following recommendation: "The goal of revascularization in these patients is to restore direct pulsatile blood flow to at least one artery in the foot, preferably the one supplying the anatomical site of the ulcer."This statement was the result of a number of studies that demonstrated the superiority of the angiosomal principle of revascularization [4].

AIM

The aim was to improve the results of surgical treatment of patients with ischemic form of diabetic foot (IF DFS) on the background of stenotic-occlusive lesions (SOL) of the tibial segment arteries by creating an algorithm of diagnostic and treatment tactics using intraoperative debitometry, microcirculation assessment using percutaneous measurement of transcutaneous oxygen pressure (TcPO2) in foot tissues and using the angiosomal concept.

MATERIALS AND METHODS

The results of surgical treatment of 137 patients with type 2 diabetes mellitus, with IF DFS on the background of SOL of the tibial arteries with threatening ischemia of the lower limb and ischemic genesis necrosis of the foot, who underwent treatment at the Center for Vascular Surgery of the Clinical Hospital «Feofaniya» State Administrative Department during 2014-2022 were analyzed. There were 86 men (62,8%), 51 women (37,2%). The age of the patients ranged from 58 to 78 years.

Inclusion criteria of patients in the study were:

1. Grade IV foot ischemia with the presence of necrotic tissue damage to the foot, which did not exclude the restoration of the supporting function of the limb;
2. SOL of the tibial segment arteries;
3. Patency of the superficial femoral vein (SFV), popliteal artery (PA), the presence of angiosome, or at least one passing artery of the foot.

Exclusion criteria were as follows:

1. Presence of acute coronary syndrome. Myocardial infarction, acute disruption of cerebral blood circulation within the last 6 months;
2. Predicted life expectancy up to 12 months;
3. Disseminated purulent-necrotic lesions of the foot, which required amputation;
4. Patients' unwillingness to perform the examination and treatment procedures.

All patients underwent ultrasound duplex scanning of the lower extremities arteries in the preoperative period using "Flex focus" made by "BK Medical" (Denmark). Angiography was performed by puncture of the SFV outfall under ultrasound control (Ukrainian Patent for Utility Model №. 114970) using "Euroampli ALIEN" angiographic system made by "EUROCOLUMBUS SRL" (Italy).

All 137 patients underwent enovascular interventions in the form of balloon angioplasty of the the lower leg segment arteries. The PA debit rate was measured using the following method: after installing a 6F introducer in the distal direction through the SFV outfall, a 0,035'' hydrophilic guidewire was passed into the PA, a 6F catheter was passed through it, and 20 ml of "Ultravist 370" contrast diluted with saline in a 1:1 ratio was injected into the catheter at a rate that excluded overflow of the SFV with contrast discharge into the deep femoral artery and branches of the common femoral artery. For X-ray control, the angiographic system "Euroampli ALIEN" made by "EUROCOLUMBUS SRL" (Italy) was used. The time during which all the contrast left the PA was determined and the PA debit was calculated for 1 minute.

After that, endovascular intervention was performed using the following technique: a hydrophilic J-shaped guidewire 0,035'' was inserted into the PA with support from a straight or J-shaped catheter 5F and led to the SOL zone. In the presence of SOL PA or tibioperoneal trunk (TPT), a hydrophilic guidewire 0,035'' was led beyond the SOL zone, and a dilation catheter with a balloon with a diameter of 3,5-5 mm was advanced through the affected area (depending on the diameter of the artery that was planned to be dilated). The balloon was inflated with a high-pressure syringe with a manometer, gradually increasing the pressure to 8-12 atm. Dilation was performed for 1-2 min with the introduction of 10 ml of a 1:200 heparin solution into the introducer and the balloon catheter channel. In the presence of residual stenoses in the balloon angioplasty (BAP) zone of more than 30%, the procedure was repeated 1-2 times until a satisfactory result was obtained.

The technique for performing the tibial and foot arteries BAP differed in that after passing the catheter with a 0,035'' guidewire into the PA, and entering the target tibial artery outfall, the 0,035'' hydrophilic guidewire was removed, and instead a 0,014'' straight guidewire was inserted through the catheter. A balloon dilation catheter with a 2,0-3,0 mm diameter and a 10-22 cm length was passed through the 0,014'' guidewire to the target tibial artery (depending on the artery diameter that was planned to be dilated and the length of the SOL zone), leaving the end of the guidewire 2-3 cm long free. Using the balloon catheter as a support for the guidewire, both were advanced simultaneously in the distal direction through the lesion area and BAP was performed according to the above technique.

In the foot, attempts were always made to restore the connection between the posterior and anterior tibial arteries by restoring patency of the external plantar artery, the deep plantar arch, and the deep plantar branch of the dorsalis pedis artery. After performing BAP, the balloon catheter and introducer were removed and manual compression was performed in the projection of the artery puncture for 30 minutes.

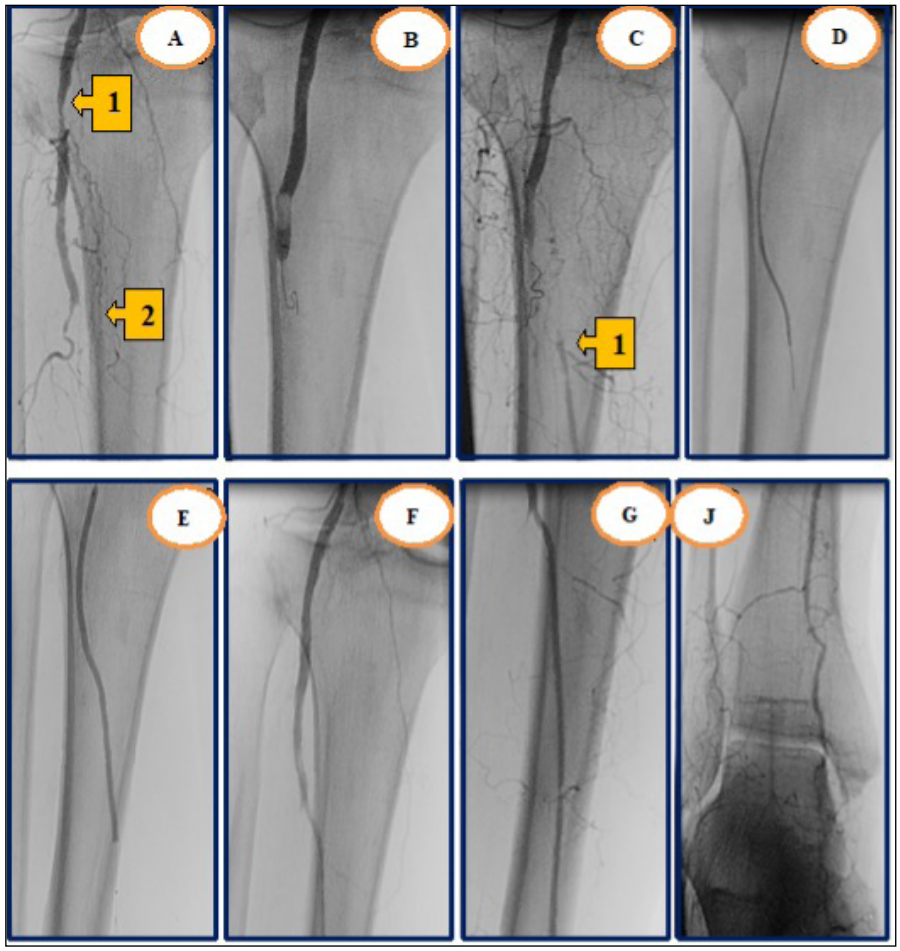

Fig. 1. Antegrade BAP of the arteries of the popliteal segment:
A – stenosis of the PA (1), occlusion of the branches of TPT (2);
B – PA BAP, 4,0 mm balloon;
C – restored patency of the PA, occlusion of the initial section of the posterior tibial artery (PTA) (1);
D – occlusion of the initial section of the PTA recanalized with a 0,035'' guidewire on a supporting catheter;
E – BAP of the initial section of the PTA, 2,5 mm balloon;
F, G, J – patency of the PTA restored up to its foot branches inclusive

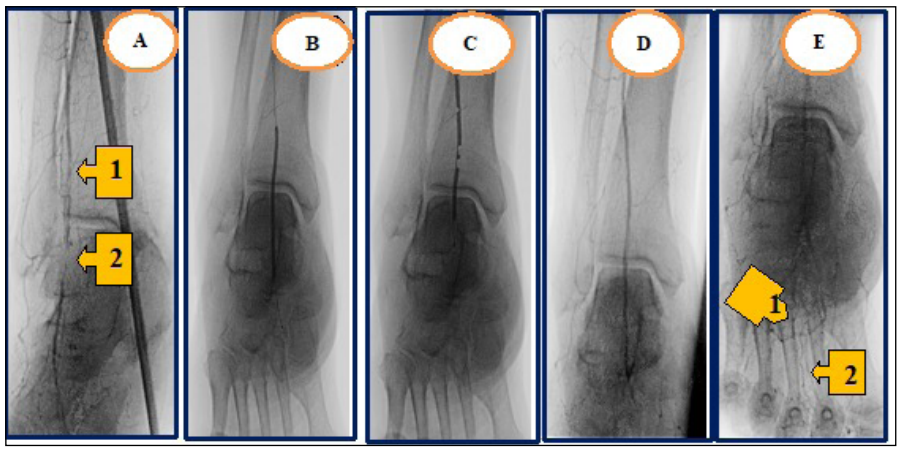

Fig. 2. BAP of the anterior tibial artery (ATA) and dorsalis pedis artery (DPA):
A – SOL of the distal third of ATA (1), the proximal third of DPA (2);
B, C – BAP of DPA and ATA;
D – restored patency of ATA and DPA;
E – contrasting of DPA branches: arcuate artery (1) and metatarsal arteries (2)

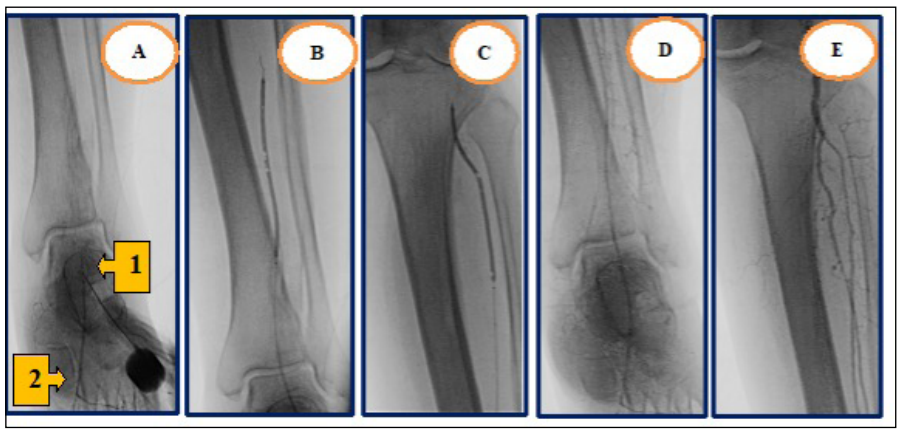

Fig. 3. Retrograde BAP of ATA:
A – retrograde puncture and contrast of the DPA (1) and arcuate artery (2);
B, C – retrograde BAP of the ATA;
D, E – restored patency of the ATA

If it was not possible to pass the guidewire in the tibial segment artery antegradely, retrograde puncture of the distal segment of the tibial artery in the lower third of the tibia or the corresponding foot artery was performed with a 22G needle and a microcatheter of the appropriate diameter was installed under ultrasound guidance. If percutaneous puncture was impossible, open surgical access to the target artery was performed. A straight 0,014'' guidewire was inserted through the microcatheter and a balloon dilation catheter with 2,0-2,5 mm diameter and 10-22 cm length was passed through it. The SOL zone was passed and BAP was performed according to the above method. BAP was considered successful if residual stenosis was <30%. If residual stenosis was >30%, dilation was repeated using a balloon catheter with a 0,5 mm larger diameter. If surgical access to the tibial or foot artery was performed, the introducer was removed after completed intervention, the hole in the artery was sutured with atraumatic Prolene 6-0 suture. The wound was sutured with drainage. An aseptic bandage was applied.

Angiograms of performing BAP of the popliteal-ankle-foot segment arteries are shown in Fig. 1, Fig. 2, Fig. 3.

Immediately after performing the BAP, the PA debit was determined using the above method, after which the introducer was removed, manual compression of the puncture area of the PA outfall was performed, and a compression bandage was applied for 1 day.

In all patients, 3 days after BAP, TcPO2 was measured using "TSM 4 Series" device, made by "Radiometer Copenhagen" (Denmark) near the necrotic lesion area, but in the area of viable tissues. Measurements were performed over an area with a uniform capillary bed without large arteries and veins, skin defects, and hair cover. Placing the electrode directly over the bone may lead to inaccurate results, especially if a change in body position causes the skin to be stretched by the protruding bone. Significant swelling in the examination area can also lead to inaccurate results.

During the examination, the patient was in a horizontal position, was in comfortable conditions and in a calm psycho-emotional state. Before the start of the examination, the electrode was calibrated with atmospheric air. The electrode was installed in a fixing ring on the skin. The cavity of the fixing ring was previously filled with 2-3 drops of electrolyte solution.

Three-five days after performing BAP, necrotectomy was performed on the foot within viable tissues, vacuum therapy methods were used, and a Tirsch or Reverden free split-cutaneous perforator flaps was transplanted.

The end point of the study was considered to be the healing of the foot wound after 1 and 3 months: complete, partial, or absent.

The study was carried out in accordance with the fundamental principles outlined in the Council of Europe Convention on Human Rights and Biomedicine, the Declaration of Helsinki adopted by the World Medical Association regarding ethical standards for medical research involving human participants, as well as current national legislation. The study protocol received approval from the local ethics committee, and written informed consent was obtained from all participants.

RESULTS

According to the obtained indicators of PA debit after performing BAP of the tibial segment arteries, patients were divided into three groups. Group A included 29 patients in whom PA debit after BAP of the tibial segment arteries increased up to 1,5 times. Group B included 44 patients in whom PA debit after BAP of the tibial segment arteries increased by 1,5–2 times. Group C included 64 patients in whom PA debit after BAP of the tibial segment arteries increased by more than 2 times. According to the degree of increase in PA debit after of the tibial segment arteries, patients in group A were assigned 0 points, group B – 1 point, group C – 2 points.

Three days after BAP, TcPO2 measurements were performed according to the above method. In group A, the TcPO2 index ranged from 0 to 20 mm Hg in 19 patients, from 20 to 40 mm Hg in 8 patients, and from 40 to 60 mm Hg in 2 patients. In group B, the TcPO2 index ranged from 0 to 20 mm Hg in 2 patients, from 20 to 40 mm Hg in 32 patients, and from 40 to 60 mm Hg in 10 patients. In group C, the TcPO2 index ranged from 0 to 20 mm Hg in 1 patient, from 20 to 40 mm Hg in 20 patients, and from 40 to 60 mm Hg in 43 patients. Patients with a TcPO2 index of 0–20 mm Hg were assigned 0 points, 20–40 mm Hg – 1 point, and 40–60 mm Hg – 2 points.

The analysis of the results of BAP was carried out according to the angiosomal concept. Restoration of blood supply to the necrotic area of the foot through the angiosomal artery - this option of revascularization was considered as direct (DR). Restoration of blood supply to the necrotic area of the foot not through the angiosomal artery, but through the artery that has the most developed anatomical connections with the angiosomal artery - collateral revascularization (CR). If no visible collateral branches to the necrotic area were found, this option of revascularization was considered as indirect (IR). In group A - the DR option was not performed in any patient; CR - 5 patients; IR - 24 patients. In group B - DR was performed in 16 patients; CR - 22

Table 1. Management of diabetes mellitus patients with SOL of the tibial segment arteries*

Group of patients	The increase of PA debit after BAP of the tibial segment arteries	Principles of management
A	<1,5 times	Bypass in the artery of the talocrural segment or amputation of the limb at the optimal level for further prosthetics
B	1,5–2 times	Treatment of foot wounds for 1-3 months, in the absence of at least partial healing of foot wounds - bypass in the artery of the talocrural segment or amputation of the limb at the optimal level for further prosthetics
C	>2 times	Treatment of foot wounds for up to 3 months, in the absence of at least partial healing of foot wounds – bypass surgery in the artery of the talocrural segment or amputation of the limb at the optimal level for further prosthetics

Note: * — in the absence of the possibility of determining TcPO2

patients; IR - 6 patients. In group C - DR was performed in 54 patients; CR - 8 patients; IR - 2 patients. If there was a DR variant, the patient was awarded 2 points; CR – 1 point; IR – 0 points.

In group A, 1 month after BAP and relevant foot operations, complete healing of foot wounds was not achieved in any patient, partial healing – 4 patients, no healing – 25 patients; after 3 months: complete healing of foot wounds in 1 patient, partial healing – 3 patients, no healing – 25 patients.

In group B, 1 month after BAP and relevant foot operations, complete healing of foot wounds occurred in 12 patients, partial healing – 15 patients, no healing – 17 patients; after 3 months: complete healing of foot wounds in 22 patients, partial healing – 12 patients, no healing – 10 patients.

In group C, 1 month after BAP and relevant foot surgeries, complete healing of foot wounds occurred in 45 patients, partial healing – 10 patients, no healing – 9 patients; after 3 months: 53 patients had complete healing of foot wounds, 6 patients had partial healing, and 5 patients had no healing.

An example of calculating the number of points scored by a random patient from group A: belonging to group A gives "0" points, TcPO2 within 20 – 40 mm Hg gives "1" point, the variant of BAP – CR gives "1" point. Thus, the sum of points = 2. The maximum sum of points for a patient from group A = 3. In total, all 29 patients from group A scored 17 points. The average number of points per 1 patient in group A = 17/29 = 0,59.

An example of calculating the number of points scored by a random patient from group B: belonging to group B gives a "1" point, TcPO2 within 40 – 60 mm Hg gives "2" points, the variant of BAP – CR gives a "1" point. Thus the sum of points = 4. The maximum sum of points for a patient from group B = 5. In total, all 44 patients from group B scored 150 points. The average number of points per 1 patient in group B = 150/44 = 3,41.

Here is an example of calculating the number of points scored by a random patient from group B: belonging to group C gives a "2" point, TcPO2 within 20 – 40 mm Hg gives "1" point, the variant of BAP – PR gives "2" points. Thus, the sum of the points = 5. The maximum sum of the points for a patient from group B = 6. In total, all 64 patients from group B scored 350 points. The average number of points per 1 patient in group B = 350/64 = 5,47.

The percentage of complete healing of foot wounds in group A was 0 % after 1 month and 3,5% after 3 months; in group B – 27,3% after 1 month and 50% after 3 months; in group C – 70,3% after 1 month and 82,8% after 3 months. Given this, we concluded: with a patient's score of «5-6» - the probability of healing of foot wounds is very high, in such patients it is advisable to focus on local wound treatment. With a score of «4» in the patient, the probability of healing of foot wounds is moderate. In such patients, it is advisable to focus on local wound treatment using more modern and expensive materials (adhesive bandages, sorbents, gel patches, polymer coatings, etc.) and the use of Prostaglandin E1, deproteinized hemoderivative of calf blood, alpha-lipoic acid, vitamin complexes, etc. With a score of «3» in the patient, the probability of healing of foot wounds is low. If such patients do not have at least partial healing of foot wounds after 1 month, it is necessary to consider the possibility of performing bypass surgery in the artery of the talocrural segment or amputation of the limb at the optimal level for further prosthetics. If the patient's score is «1-2», there is no chance of healing the foot wounds. In such patients, the question of the possibility of performing bypass surgery in the artery of the talocrural segment or amputation of the limb at the optimal level for further prosthetics should be immediately raised.

Considering the average number of points per patient in the selected groups: A – 0,59, B – 3,41, C – 5,47, we believe that the determination of quantitative changes in the PA debit after performing BAP sufficiently accurately determines the prospects for healing of foot wounds after necrotectomy in patients with diabetes mellitus

with grade IV foot ischemia and, in the absence of the possibility of determining TcPO2, may be a criterion for formulating the further tactics, being proposed in Table 1.

DISCUSSION

The concept of improving the quality of life dictates the need to preserve the supporting function of the lower limb in all possible ways when treating patients with IF DFS, since in the case of high amputation, numerous studies have proven a significant decrease in the quality of life [5, 6].

It should be noted that despite the widespread implementation of endovascular methods for the treatment of SOL of the lower limb arteries, a generally accepted algorithm for diagnostic and treatment tactics in patients with IF DFS with SOL of the tibial segment arteries still does not exist [7, 8].

The current literature has not yet fully addressed the issue of the informativeness of intraoperative debitometry, determination of TcPO2 in foot tissues, and the value of the angiosomal concept in making decisions about the tactics of endovascular revascularization [9-11]. The treatment of foot wounds after necrectomy in patients with IF DFS with SOL of the lower leg segment arteries after BAP is carried out without clear criteria for how long such treatment should last and when to switch to more radical treatment methods. This leads to an unjustified burden on budgetary and extra-budgetary sources of funding, because the cost-effectiveness of medical interventions is an important component of organizing the provision of medical care to patients with diabetes [12].

In this context, the issue of choosing the optimal method of limb revascularization in patients with diabetes mellitus and CLLTI due to damage to the arteries of the popliteal-ankle-foot segment remains relevant. Existing approaches require further improvement and clarification of indications for their use. In addition, the issue of choosing the optimal treatment tactics in patients with high surgical risk and in the absence of the technical possibility of performing revascularization remains insufficiently developed.

CONCLUSIONS

Measurement of TcPO2 and determination of the revascularization option (DR, CR and IR) based on the results of BAP allows to assign to patients of groups A, B and C the appropriate number of points, the sum of which shows the prognosis of healing of foot wounds and the timing of application of other methods of revascularization or amputation. The average number of points per patient in the selected groups: A – 0,59, B – 3,41, C – 5,47. The probability of healing of foot wounds: 5-6 points – high, 4 points – moderate, 3 points – low, less than 3 points – absent.

The division of patients into groups A, B and C, according to the increase in the PA debit after BAP of the tibial arteries, allows us to determine the tactics and timing of treatment of foot wounds in groups: A – there is almost no prospect of healing of foot wounds (1 month – 0 %, 3 months – 3,5 %), urgent bypass in the artery of the talocrural segment or amputation of the limb at the optimal level for further prosthetics is indicated; B - the prospects of healing of foot wounds are doubtful (1 month – 27,3 %, 3 months – 50,0 %), treatment of foot wounds is indicated within 1 month, in the absence of at least partial healing of foot wounds - bypass in the artery of talocrural segment or amputation; C – the prospects for healing of foot wounds are good (1 month – 70,3 %, 3 months – 82,8 %), treatment of foot wounds for up to 3 months is indicated, in the absence of at least partial healing of foot wounds - bypass surgery in the artery of the talocrural segment or amputation.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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