Original article:

Mini-invasive revascularization operations in the complex treatment of neuroischemic and ischemic forms of diabetic foot syndrome

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Abstract

Objective: Diabetic foot syndrome is the most dramatic complication of diabetes mellitus. The treatment success is impossible without improving blood circulation and the elimination of hemodynamic disorders in the affected limb.The study aim was to evaluate mini-invasive revascularization operations effectiveness on the lower limbs peripheral arteries in neuro-ischemic and ischemic diabetic foot syndrome forms. ***Materials and methods:*** The study enrolled 104 patients with purulent-necrotic complications of diabetic foot syndrome. 54 (51.9%) patients underwent stenting and balloon angioplasty (the main group). The comparison group included 50 (48.1%) patients, undergoing indirect revascularization surgeries in complex treatment. ***Results and discussion:***After endovascular interventions, the API index increased by 47.6% ($p<0.01$) after 20 days compared to the admission index, the average blood flow rate increased by 1.8 times ($p<0.01$), and the tPo2 value improved by 67.8% ($p<0.01$). In the control group, the tPo2 value increased by 40.3% after 20 days, and API – by 34.4%. In the main group, the swelling disappearance in the foot wounds area was by 3.7±0.5 days faster ($p<0.001$), wounds purification by 4.1 days ($p<0.001$), granulation appearance by 3.5±0.4 days ($p<0.001$), wound margins infiltration disappearance happened 3.3±0.9 days earlier ($p<0.001$), and the wound epithelization was 2.9 days earlier ($p<0.01$) than in the control group patients. ***Conclusion:*** Foot support function at discharge from hospital was preserved in 94.4% of the main group and in 84% of the control group.

Keywords: complex treatment; diabetes mellitus; diabetic foot syndrome; endovascular operations; purulent surgery.

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Introduction

Despite the great progress of medical science in recent decades, the treatment of patients with diabetic foot syndrome is still one of the timeless problems of purulent surgery. It is due to the steady increase in the number of patients suffering from diabetes mellitus.

Diabetic foot syndrome (DFS) is the most dramatic complication of diabetes mellitus, as, in half of the cases, it ends in amputation and leads to disability, causing significant socio-economic damage.[1-4]

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Diabetic foot (DF) develops in 80% of diabetic patients with a disease duration of more than 20 years and does not tend to decrease.[5-8] Diabetic foot syndrome requires inpatient treatment in 25% of cases exceeding, thus, other complications of diabetes by this indicator.

The development of gangrene in the limb is an indication of amputation, which is the most common surgical operation in the diabetic foot and is most often performed at the hip level. The mortality rate immediately after the operation reaches 25%, while within five years after the operation, the probability of corresponding changes in the other limb increases, accompanied by the mortality rate reaching 68%.[9-14]

Over the past 20 years, the attitude to amputations has changed towards the maximum possible preservation of limbs. Therefore, reducing the percentage of high amputations in patients with the diabetic foot is the main task in treating this pathology.

Based on the principles of the DFS pathogenesis, the treatment success is impossible without improving blood circulation and the elimination of hemodynamic disorders in the affected limb.

In the very first attempts to restore blood flow in the occluded arteries of the lower limbs, the method of direct removal of altered intima was used. For some period, this technique with its varieties provoked a mass enthusiasm. Afterward, with the appearance of new adequate plastic materials, the angio-surgery switched to shunting surgery.[6,8,15,16] However, the accumulated experience of using even the best varieties of vascular prostheses showed that the results of shunting, are very far from being perfect, especially in the delayed periods.[10,11,17,18]

Despite the achieved successes, unsatisfactory results in shunting operations reach 34%-63.5%.[3,19,20] From time to time, a need for repeated operations emerges, which presents certain difficulties in the use of any plastic material. A significant number of patients are generally denied in reconstructive surgery in case of diffuse lesions of the arterial bed of lower limbs with poor outflow paths, as well as due to the lack of adequate plastic material for distal reconstructions. The “multilayered” arterial bed lesion also requires “multilayered” reconstructions, which in the case of traditional shunting is associated with an increased volume of surgery and its traumatism.[21,22]

The peripheral vascular lesion, typical for diabetes mellitus patients, complicates the performance of distal shunting reconstructions on the vessels. In such cases, it is possible to eliminate ischemia when performing indirect revascularization.[3,18]

The latter includes the lumbar and periarterialsympathectomy, arterialization of the tibia venous system, tunneling of soft tissues of the lower limbs, microvascular transplantation of the greater omentum, etc. However, the appropriateness of these operations is a constant reason for discussion. And to date, no consensus among researchers is achieved to confirm or reject the effectiveness of indirect revascularization operations in DFS patients.

The development of endovascular technologies with the use of antegrade and retrograde access helps to reduce the number of longer and more complicated shunting operations for a patient.[12,16,19,23]

Endovascular interventions on the arteries of the lower limbs in patients with diabetes mellitus are an effective and minimally invasive method of treating critical lower limb ischemia due to safety, low lethality, and cost-effectiveness.

The variety of methods to treat diabetic foot indicates that their effectiveness is low and insufficient. Therefore, improving the effectiveness of diabetic foot syndrome treatment is an urgent and socially relevant medical problem.

To date, the problem of treating DFS patients is far from being solved and requires further research to develop common principles of comprehensive treatment.

The study aimed to evaluate the effectiveness of mini-invasive vascularization surgeries on the peripheral arteries of the lower limbs in neuro-ischemic and ischemic forms of DFS.

Subjects and Methods

In the period from 2015 to 2019, 104 patients with purulent necrotic DFS lesions were treated at the Department of Purulent Surgery of Aktobe Medical Center. The research was approved by the local ethics committees of The Ministry of Health of the Republic of Kazakhstan “West Kazakhstan Marat Ospanov Medical University” (No. 545).

In all patients, comprehensive treatment began with small operations, namely, the sanitation of purulent focus on the foot, which included autopsy phlegmon, exarticulation, and necrotomy. Afterward, subsequent tactics of patient management depended on the course of the wounding process.

Conservative DF therapy was an obligatory

component of complex treatment for all patients that included insulin therapy, the antiaggregant, anticoagulant, antibacterial, and immunostimulant therapy, as well as prescription of drugs that improve the rheological properties of blood.

Out of 54 (51.9%) patients who comprised the main group, endovascular surgeries were used in the complex treatment. Thus, 31 patients underwent stenting and 23 – balloon dilatation of peripheral arteries of the lower limbs.

The comparison group included 50 (48.1%) patients who underwent indirect revascularization surgeries. It involved the combined periarterial sympathectomy, soft tissue tunneling of the lower limbs, osteoperforation, osteotrepanation of the tibia and feet.

Study design: Single-center randomized controlled trial. Both groups were comparable and homogeneous in age and sex. Randomization was performed randomly. Due to the specificity of the surgical procedures, "dazzling" or "masking" was not applied.

The criteria for inclusion into the study were: the presence of ischemic and neuro-ischemic forms of diabetic foot syndrome with purulent-necrotic complications, as well as the inability to perform direct vascular operations due to a multilayered vascular lesion, severe initial condition, and distal lesion of the vascular bed of the affected limb. Patients with neuropathic form were not included in the study due to pathogenesis peculiarities, as well as patients with wet or dry gangrene foot with the transition to the tibia, which required only high amputation (5th degree according to F. Wagner). The age composition of patients in the main and control groups was approximately the same (p=0.929). The age of patients ranged from 38 to 83 years. At the distribution of patients by age, it was revealed that the most numerous groups of patients were at the age of 51-60 and 61-70 years old - 29.8% and 31.7%, respectively. Persons younger than 40 years with diabetic foot syndrome made up only 4.8% (Table 1).

Insulin-independent (Type 2) DM occurred in 93 patients (89.4%), insulin- independent (Type 1) DM was present in 11 patients (10.6%). In 28 patients (26.9%), diabetes was diagnosed for the first time on admission to the hospital. The neuro-ischemic form of DFS was recorded in 64 patients (61.6%), and 40 patients had ischemic form (38.4%). The duration of diabetes ranged from several months to 32 years. Also, 69 patients (66.4%) suffered from DM for up to ten years, while 35 (33.6%) had a history of illness of more than ten years.

By the nature of the lesion of the vascular channel, the pathology of the femoral arteries was found in 15 patients, which amounted to 14.4% of the total number of patients, and lesions of the popliteal arteries were diagnosed in 25 (24.1%) patients. Occlusive lesions at the level of the femoral arteries were observed in 44 (42.3%) patients. A multilayered vascular lesion of the lower limbs was revealed in 20 patients (19.3%). The lesion of the arteries of the lower limbs was predominantly symmetrical. It corresponds to the data of other authors on the prevalence of tibia artery lesion among patients with diabetic foot syndrome, otherwise referred to in the literature as 'tibia artery disease'.[19,21]

The overwhelming majority of patients in both groups had a concomitant pathology of hypertension stage II and III, which was found in a total of 89 (85.5%) patients. The next most frequent concomitant pathology was CHD, and stable angina pectoris was found in 63 (60.5%) patients of the main and control groups. Besides, in 24 (23.1%) patients, these diseases occurred in combination. Other chronic diseases in the remission phase like bronchial asthma, chronic obstructive pulmonary disease, pancreatitis, cholecystitis, gastritis, and others were noted in 41 (39.4%) cases.

Table 1. Initial characteristics of patients in the main and control groups

Variables		Number of patients		
		Main group (n-54)	Control group (n-50)	*p
Age	Under 40 years	3 (5.5%)	2 (4%)	p=0.929
	40-50 years	10 (18.5%)	10 (20%)	
	51-60 years	16 (29.6%)	15 (30%)	
	61-70 years	17 (31.4%)	16 (32%)	
	Older than 70 years	8 (14.8%)	7 (14%)	
Gender	Females	34 (62.9%)	32 (64%)	p=0.663
	Males	20 (37.1%)	18(36%)	
Type of diabetes	Type 1	6 (11.1%)	5 (10%)	p=0.855
	Type 2	48 (88.9%)	45 (90%)	
Form of DFS	Ischemic	21 (38.8%)	19 (38%)	p=0.617
	Neuro-ischemic	33 (61.2%)	31 (62%)	

Variables		Number of patients		
		Main group (n-54)	Control group (n-50)	*p
Duration	Under 10 years	36 (66.6%)	33(66%)	p=0.575
	More than 10 years	18(33.4%)	17(34%)	
Level of vascular channel lesion	Tibia arteries	23 (42.6%)	21 (42%)	p=0.989
	Popliteal arteries	14 (25.9%)	11 (22%)	
	Femoral arteries	7 (12.9%)	8(16%)	
	Multilayered lesion	10 (18.6%)	10 (20%)	

**p - the value was calculated using Pearson's Chi-square*

Purulent-necrotic foot lesions found in patients can be classified as ulcers, phlegmons, gangrene, and osteomyelitis of the foot bones. By the depth of destructive changes, the distribution of patients is shown in Table 2. The F. Wagner classification is considered as the most convenient in everyday surgery practice (Table 3) to determine the depth and prevalence of purulent-necrotic foot lesions. All patients were diagnosed with the lesion of II-IV degree. Patients with V-degree lesions required a primary high amputation and were not included in the study.

All patients with diabetes at admission were in a state of sub- and decompensation of a medium and severe degree, which was the reason for the transfer to insulin therapy of all patients who received outpatient oral sugar reduction drugs.

Table 2. Forms of purulent-necrotic lesions and their frequency

Purulent-necrotic feet lesions	Main group (n-54)		Control group (n-50)		Total(n-104)		*p
	abs.	%	abs.	%	abs.	%	
Foot fingers gangrene	11	20.3	9	18	20	19.2	p=0.466
Foot gangrene	10	18.5	7	14	17	16.4	p=0.613
Foot phlegmone	21	38.9	18	36	39	37.5	p=0.670
Foot bone osteomyelitis	4	7.4	2	4	6	5.9	p=0.452
No trophic disorders	0	0	1	2	1	0.9	p=0.319
Trophic ulcers	8	14.9	13	26	21	20.1	p=0.065

**p - the value was calculated using Pearson's Chi-square*

Table 3. Degrees of purulent - necrotic soft tissue lesion in diabetic foot syndrome (by F. Wagner).

Degree	Clinical Characteristics
0	No ulcer defect, but the skin is dry and beak-shaped deformation of fingers, protrusion of metatarsal bone heads, as well as other bone and joint anomalies are observed.
1	superficial ulcer without signs of infection
2	deep ulcer, usually infected but not involving the bone tissues into the process
3	deep ulcer with abscess formation and involvement of the bone tissues into the process
4	restricted gangrene (fingers or part of foot)
5	whole foot gangrene

Based on the value of oxygen stress in tissues ($TavO_2$), 29 patients (26.9%) had a compensated type of micro blood flow in the lower limbs, for 56 (54.8%) patients is was a sub-compensated, and in 19 (18.3%) patients, a decompensated type of micro blood flow was established (Table 4).

Table 4. Types of microcirculation disorders of the lower limbs in patients on admission

Types of microcirculation	Indicators of $TavO_2$	Number of patients	
		Main group	Control group
Compensated	> 30 mm Hg	15(27.8%)	14(28%)
Subcompensated	20 - 30 mm Hg	29(53.7%)	27(54%)
Decompensated	< 20 mm Hg	10(18.5%)	9(18%)
TOTAL		54 (100%)	50(100%)

The existing pattern of lower limb vascular lesions in DFS patients of both clinical groups significantly limited the use of shunting and prosthetic surgery.

To directly assess the effectiveness of the applied operational interventions, the following clinical and

instrumental research methods were used.

1. The clinical trial included studying the dynamics of the wounding process and determining the wound healing rate (WHR) by Popova L.N. formula (1942);
2. Ultrasound of the lower limb vessels with the determination of blood flow rate in the arteries (Vav), resistance (iR) and pulsation (Pi) indices, as well as an ankle-brachial index (ABI). Studies were performed on the popliteal artery (PA), the posterior tibial artery (PTA), and arteria dorsalis pedis (ADP);

The oxygen stress in tissues (tPo_2) was measured with the help of TCM-222 device of RADIOMETER company (Denmark).

The research was conducted on admission, on the 10th and 20th day after the operative interventions.

The main criteria to evaluate the effectiveness of complex treatment with operative interventions were the following:

1. The frequency reduction of high amputations of the lower limbs;
2. An increase in the number of patients with a preserved functioning foot.

Revascularization operations in the complex treatment of diabetic foot were performed after adequate local surgical rehabilitation of the purulent focus after 2-3 days.

Statistical data processing was performed using the STATISTICA 10.0 software package. The null hypothesis about the absence of differences between the observed distribution of feature and the theoretical expected normal distribution was tested using Shapiro-Wilk's W-test. Differences between samples of qualitative indicators for comparison were estimated by Pearson's Chi-square criterion. Comparative analysis for two independent groups was conducted using the Mann-Whitney statistical significance level - $p<0.05$.

Results

After application of minimally invasive endovascular interventions, namely, the stenting and cylinder dilatation of peripheral arteries of the lower limbs in the complex treatment of ischemic and neuro-ischemic forms of DFS, a significant positive and statistically significant dynamics of rheogemodynamic indices, as well as improvement of the wound process course was observed in comparison with combined indirect revascularization operations. According to ultrasound examination data in the main group, the largest changes in the studied parameters were observed in ADP (Table 5).

Table 5. Indicators of blood flow rate, resistance index, and pulsation index in patients of the main and control groups

Indicators	Clinical groups	On admission			10 days			20 days		
		PA***	PTA	ADP	PA	PTA	ADP	PA	PTA	ADP
Vcp, cm/s	Main	24.86± 0.53	13.21± 0.42	11.31± 0.42	30.69± 0.54*	20.32± 0.55*	18.75± 0.59*	34.63± 0.49**	24.21± 0.61**	20.85± 0.61**
	Control	25.51± 0.51	14.11± 0.47	10.12± 0.49	27.72± 0.56	16.42± 0.65*	13.68± 0.62	28.73± 0.52**	17.33± 0.68**	14.95± 0.59**
iR	Main	1.32± 0.03	0.59± 0.03	0.56± 0.02	1.48± 0.04*	0.99± 0.03*	0.81± 0.03*	1.54± 0.04**	1.42± 0.03**	0.98± 0.02**
	Control	1.19± 0.03	0.64± 0.02	0.53± 0.03	1.35± 0.03	0.84± 0.04*	0.71± 0.02	1.44± 0.03**	0.99± 0.02**	0.85± 0.03**
Pi	Main	3.4± 0.52	2.28± 0.23	1.62± 0.3	5.8± 0.59	3.9± 0.3*	3.2± 0.15*	6.3± 0.59**	4.3± 0.21**	3.3± 0.22**
	Control	3.2± 0.56	2.41± 0.24	1.71± 0.3	4.5± 0.64	3.13± 0.23*	2.81± 0.18	5.2± 0.62**	3.7± 0.19**	3.1± 0.21**

Notes

*1 - * significance of difference ($p<0.05$) with indicators on admission;*

*2 - ** significance of difference ($p<0.01$) with indicators on admission;*

*3 -*** PA – popliteal arteria; PTA – posterior tibial arteria; ADP – arteria dorsalis pedis.*

At the indicated artery, the average blood flow rate increased by 1.8 times ($p<0.01$) after 20 days of the study as compared to the value on admission, the resistance index increased by 1.75 times, and the pulsation index raised twice ($p<0.01$), while in the control group that indicators showed an increase by 1.5, 1.6, and 1.8 times, respectively.

Significance of differences in indicators of the main group on ADP was noted already by the 10th day of the postoperative period ($p<0.05$), while in the control group that was only by the 20th day.

The described changes manifested clinically, first of all, as a decrease in the intensity of pain in the affected limb, the appearance/increase in arteries pulsation, primarily in the foot, and an increase in skin temperature on the foot. In the main group, these signs were observed already by 5-8 days, while in the control group, only by 18-20 days and more of the postoperative period.

The increase of ABI values by 20 days after stenting and cylinder dilatation of peripheral arteries of the lower limbs was 47.6% ($p<0.01$), while in the control group, it was 34.4% (Table 6).

Table 6. API indices in patients of the main and control groups

Clinical groups	Definition periods		
	On admission	After 10 days	After 20 days
Main	0.63±0.07	0.89±0.05*	0.93±0.04**
Control	0.61±0.05	0.78±0.04*	0.82±0.06*

Notes

*1 - * significance of differences ($p < 0.05$) with indicators on admission;*

*2 - ** reliability of differences ($p < 0.01$) with indicators on admission.*

The index of oxygen tension in tissues (tPo_2) of limbs increased in the main group by 67.8% ($p<0.01$) after 20 days, while in the control group - by 40.3% (Figure 1).

Since patients with DF addressed with purulent-necrotic foot lesion, the dynamics of the wound process was an essential criterion to evaluate the result of complex treatment with endovascular and indirect revascularization operations, which revealed the benefits of endovascular interventions. As shown in Table 7, infiltration of the wound margins after stenting and balloon dilatation of the lower limb arteries was resolved faster, i.e., by 9.6±1.8 days in the main group and by 12.9±2.7 days in the control group, that is, by 3.3±0.9 days earlier on the average ($p<0.001$).

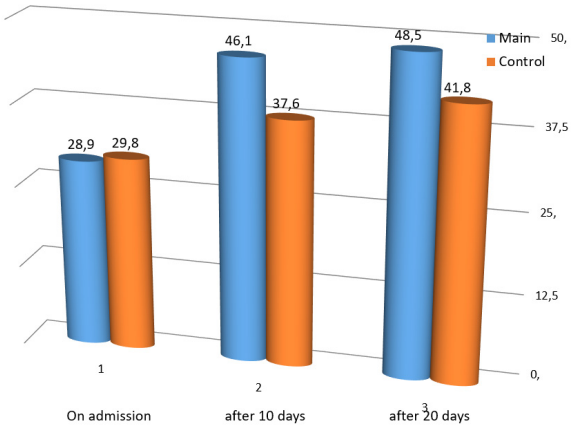

Figure 1. Tissue oxygen tension indices (tPo_2, mmHg) in patients of the main and control groups.

Besides, a rapid appearance of granulations in the wound occurred, by 8.3±2.0 days in the main group and 11.8±1.63 days in the control group, i.e., by 3.5±0.4 days ($p<0.001$) on the average. A decrease in foot edema was observed in the main group by 6.6±1.9 days, and in the control group only by 10.3±2.4 days, i.e., by 3.7±0.5 days faster ($p<0.001$) than in the control group. Also, epithelialization of the wound occurred on 15±2.0 days in the main group, while in the control group, only by 17.9±2 days ($p<0.001$).

Table 7. Dynamics of the wound process in the main and control groups

Indicators	Main group (n-54)	Control group (n-50)	*p
Disappearance of wound margins infiltration (day)	9.6±1.8	12.9±2.7	p<0.001
Foot edema disappearance (day)	6.6±1.9	10.3±2.4	p<0.001
Time limits for cleaning wounds (24 hours)	6.7±1.6	10.8±1.8	p<0.001
Time of granulation occurrence (day)	8.3±2.0	11.8±1.63	p<0.001
Time of epithelization appearance (day)	15.0±2.0	17.9±2	p<0.001

**p - the value was calculated using the Mann-Whitney U-criterion*

By the 20th day of the study, the WHR index significantly increased by 69.2% compared to the 10-days value, while in the control group, it increased by 56%. At that, a decrease of the wound area by more than 3.3 times ($p<0.05$) in the main group and only by 2.3 times in the control group was reported (Figure 2).

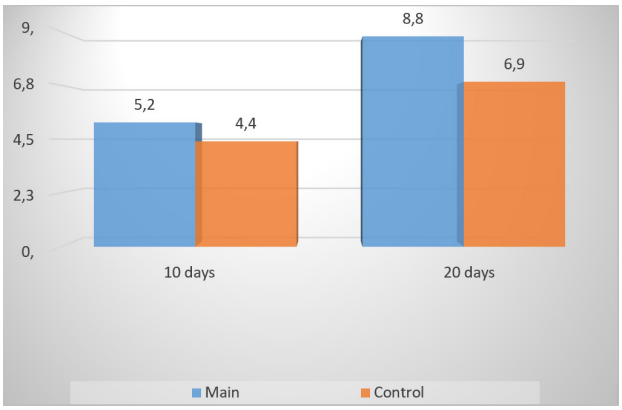

Figure 2. Dynamics of WHR indices in patients of the main and control groups.

The study results obtained in both compared groups were consistent with the outcomes of treatment tactics (Table 8). As mentioned earlier, the main criteria for the effectiveness of complex treatment were the reduction of the frequency of high amputations of the lower limbs and an increase in the number of patients with the preserved functioning foot.

Table 8. Treatment outcomes in the main and control groups

Criteria for treatment effectiveness	Main group (n-54)	Control Group (n-50)
Small repeated operations	5 (9.3%)	6(12%)
Small amputations	3 (5.6%)	5(10%)
Amputations on the lower leg	2 (3.7%)	4(8%)
Amputations on the thigh	0	2(4%)
Preserved functioning foot	51(94.4%)	42(84%)
Lethality	1(1.8%)	2(4%)

Amputations due to the progressive purulent-necrotic process and gangrene of the limbs were performed on the lower legs of 2 patients (3.7%) in the main group and 4 patients (8%) in the control one. Amputation at the level of the upper third of the lower leg allowed preserving the knee joint, which provided more physiological prosthetics in the future. Amputations at the thigh level were performed only in 2 patients (4%) of the control group.

As a result of treatment, foot function was preserved in 51 patients (94.4%) of the main and 42 patients (84%) of the control groups. Lethality was 1.8% in the main group (1 case of pulmonary artery thromboembolism) and 4% in the control group (2 cases of myocardial transmural infarction).

Thus, in patients of the main group, the number of amputations on the lower limbs reduced twice and lethality by 2.2 times compared to the control group ($p<0.01$).

Discussion

The main purpose of the surgical treatment of purulent and necrotic manifestations of diabetic foot syndrome is to preserve the limb and life of the patient. The complexity of surgical interventions on the main arteries of the lower limbs in patients with DM with purulent necrotic foot lesions is associated with decompensation of DM, the presence of associated diseases in elderly patients, and a high incidence of postoperative complications.[2,4,14]

In this study, positive dynamics were observed in the clinical evaluation of the wound process after surgical methods of correction. It was expressed in early normalization of skin color, foot-warming, elimination of perifocal inflammation in the form of disappearing foot edema and tissue infiltration, the appearance of a clear demarcation line, granulation and epithelization of the wound surface. It indicated an improvement in regional blood flow and was consistent with earlier examinations of other authors.[10,12,19]

As presented, the obtained results indicate the best dynamics in the treatment of patients with purulent necrotic foot lesions in the diabetic foot with mini-invasive endovascular methods of surgical intervention. It can be attributed to the fact that one-stage direct surgical improvement of adequate arterial inflow with a maximum opening of the distal channel by installing a permanent stent and mechanical expansion of the vascular lumen rather provides a reduction of ischemia and restoration of soft tissue defects unlike to indirect methods of revascularization. In this case, the obtained effect in the group after stenting and cylinder angioplasty is faster, the improvement of blood flow is observed immediately after surgery, while against the background of indirect revascularization operations, the effect is expressed after a longer period.

In the compared groups, the most significant differences were revealed in tissue oxygenation,

indicators of peripheral blood circulation, and treatment outcomes. Oxygenation of foot skin was low in all patients on admission, which indicated critical ischemia. After surgical interventions, a good corrective effect of the proposed treatment method was stated. Thus, by the 20th days of treatment, the index of tPo_2 in the extremity increased by 67.8% ($p<0.01$) in the main group and 40.3% ($p<0.01$) in the control one.

In the main group, significant changes in the peripheral circulation of the lower limbs directly resulted from applying stenting and endovascular balloon dilatation of the peripheral arteries, which affected the pathologically altered vessels and improved blood circulation in contrast to indirect revascularization operations, the effect of which was achieved over the time.

Since both endovascular and indirect revascularization operations belong to 'pure' interventions, the question of purulent complications development from surgical wounds and vessels on the background of the initially existing purulent necrotic process due to DM complications is quite natural. It should be noted that not a single case of postoperative wound suppuration both after endovascular and tunneling operations was registered. It is probably since the surgical interventions were carried out against the background of the already conducted conservative therapy, which included, among other measures, correction of glycemic level and antibacterial therapy. After all, patients were assigned to surgical interventions only after the correction of glycemic status, i.e., reduction of blood glucose level to not more than 11 mmol/l, as well as after the transfer of patients from the state of diabetes decompensation to that of compensation. Also, a full mandatory surgical rehabilitation of the purulent focus on the foot – phlegmon autopsy, necrotomy, disarticulation of the toes, and distal amputations before the prescription of mini-invasive interventions was the factor that excluded the suppuration of postoperative wounds and arterial lesions.

The dynamics of the wound process on the foot and the possibility of maintaining its function were chosen as the main criteria for assessing the treatment effectiveness in patients with purulent and necrotic complications of the diabetic foot. These are the indicators that prevail in the clinical picture of the disease and worry the patient being capable to be visually observed by the patient himself. As can be seen from the data presented in the main group, foot support function was preserved in 94.4% of patients, while a similar result was achieved in 84% of patients in the control group.

This study analyzed the results of treatment in patients that were received only for the period of patients' stay in the hospital immediately after surgical intervention. According to the results of previous studies, the effect of revascularization surgeries develops gradually over time, and the full effect is pronounced over a longer period than inpatient surgery.[24,25] Thus, to study the distant results of revascularization operations in complex treatment of patients with purulent-necrotic complications of diabetic foot syndrome, further observation of patients during 4-5 years is assumed. In this case, patients will be actively summoned for control examination 6 and 12 months after discharge, and then annually.

Conclusions

1. Treatment outcomes of patients with diabetic foot syndrome showed that endovascular dilatation and stenting of peripheral arteries of the lower limbs have clear advantages over indirect revascularization operations (osteo-perforation of bones of the foot or tibia in combination with tunneling of soft tissues of the thigh and tibia).
2. The use of mini-invasive revascularizing operations on the lower limbs in the complex treatment of purulent-necrotic complications of DFS helps to improve macro- and microcirculation in the affected foot, reduce the time of purulent-necrotic wounds purification by 1.4 times and the frequency of amputations on the lower limbs by 3.2 times, as well as preserve the leg capacity in 94.4% of patients.

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Data Availability. Data will be available on request.

References

1. Burleva EP, BabushkinaYuV, Galimzyanov FV andFominykh AN. The results of differentiated treatment of patients with diabetic foot syndrome at the stage of specialized surgical aid. *Pirogov Chirurgiya J* 2019; **5**:42-51. https://doi.org/10.17116/hirurgia201905142
2. Styazhkina SN, Tretyakov DA andKhuzin GA. Diabetic foot syndrome in surgery, peculiarities of process and therapy. *Central Sci J* 2017; **2**:45.
3. Barkhatova NA. Effect of therapy and indirect angiotropy limb revascularization on the course and prognosis in diabetic foot syndrome. *Int Res J* 2014; **4**:9-12.
4. Bus SA. Offloading the diabetic foot: the evolution of an integrated strategy. In The diabetic foot syndrome. Karger Publishers, Basel, 2018, Vol. 26: 97-106. https://doi.org/10.1159/000480056
5. Krivoshchekov EP, Boklin AA, Elshin EB, Dmitrieva IA. Complex treatment of patients with purulent-necrotic forms of diabetic foot syndrome. *FundamIssledov* 2015;**1**(5): 975-9.
6. Kislyakov VA, Obolenskiy VN, Yusupov IA. Diabetic foot syndrome: a complex approach to treatment. *Russian Med J* 2016;**12**:768-70.
7. Andrews KL, Houdek MT, Kiemele LJ. Wound management of chronic diabetic footulcers: From the basics to regenerative medicine. *Prosthet OrthotInt* 2015;**39**(1):29-39. https://doi.org/10.1177/0309364614534296
8. Davidenko OP. Syndrome of diabetic foot: its role and place in modern diabetology (of literature review). Med EducSibiria 2014;5:45-47.
9. Obolensky VN. A new approach to unloading the diabetic foot. *Chirurgia* 2017;**3**:48-53.
10. Stupin VA. Evaluation of the dynamics of wound area and frequency of complete epithelization in the treatment of diabetic foot syndrome (results of multi-center study. Surgery. Journal after V.A Stupin. N. I. *Pirogov Journa*l 2017;**3**:55-60. https://doi.org/10.17116/hirurgia2017355-60
11. Belozertseva YP, Kurlaev PP, Esipov VK, Gritsenko VA. Experience in the treatment of purulent-necrotic complications of diabetic foot syndrome with the using of the original surgical method in the combination with a targeted antibiotic therapy. *Creative Surg Onco*l 2014;**3**:67-9.
12. Butt T, Lilja E, Elgzyri T, Apelqvist J, Gottsäter A, Engström G.et al. Amputation-free survival in patients with diabetic foot ulcer and peripheral arterial disease: endovascular versus open surgery in a propensity score adjustedanalysis.*JDiabetesComplic*2020;**34**(5):107551. https://doi.org/10.1016/j.jdiacomp.2020.107551
13. Bensman VM. Surgery of purulent-necrotic complications of diabetic foot. Guide for doctors. Second processed and supplemented edition. Moscow: Medical Practice; 2015.
14. Veresiu IA, Iancu SS, Bondor C. Trends in diabetes-related lower extremities amputations in Romania - a five year nationwide evaluation. *Diabetes Res Clin Pract* 2015;**109**:293-8. https://doi.org/10.1016/j.diabres.2015.05.020
15. Ahmad J. The diabetic foot. *Diabetes Metab Syndr* 2016;**10**(1):48-60. https://doi.org/10.1016/j.dsx.2015.04.002
16. Rajendran S, Thottiyil SM, Karatparambil AA, Nadakkavil MR, Thamaran R, Kattoor TT. Evaluation of angiosome based revascularization in diabetic foot ulcers. *Int Surg J* 2016;**3**:721-8. https://doi.org/10.18203/2349-2902.isj20161147
17. Grigorev AA. Diabetic foot. Successful treatment arranging process. Deputy CMO Treat Med Expert 2017;6:98-108.
18. Kallio M, Vikatmaa P, Kantonen I, Lepäntalo M, Venermo M, Tukiainen E. Strategies for free flap transfer and revascularisation with long-term outcome in the treatment of large diabetic foot lesions. *Eur J Vasc Endovasc Surg* 2015;**50**:223-30. https://doi.org/10.1016/j.ejvs.2015.04.004
19. Fareed A, Zaid N, Alkhateep Y. Predictive value of angiographic characteristics for endovascular revascularization of the ischemic diabetic foot. *Egypt J Surg* 2018;**37**(3):294-303. https://doi.org/10.4103/ejs.ejs_123_17
20. International Working Group on the Diabetic Foot 2015. International consensus on the diabetic foot and guidance on the management and prevention of the diabetic foot. The Hague, 2015. www.iwgdf.org
21. Galstyan GR, Tokmakova AY, Egorova DN, Mitish VA, Paskhalova YS, Antsiferovet MB.et al. Clinical guidelines for diagnosis and treatment of diabetic foot syndrome. Wounds and Wound Infections the Prof. B.M. *Kostyuchenok Journal* 2015; **3**:63-83. https://doi.org/10.17650/2408-9613-2015-2-3-63-83
22. Lavery LA, Higgins KR, La Fontaine J, Zamorano RG, Constantinides GP, Kim PJ. Randomised clinical trial to compare total contact casts, healing sandals and a shear-reducing removable boot to heal diabetic foot ulcers. *Int Wound J* 2014;**12**(6):710-5. https://doi.org/10.1111/iwj.12213
23. Ivanova YV, Klimova OM, Prasol VO, Korobov AM, Mushenko YV, Kiriienkoet DO.et al. Plastic closure of wounds in patients with ischemic form of diabetic foot syndrome. *Medicni Perspektivi* 2018;**23**(4):71-5. https://doi.org/10.26641/2307-0404.2018.4(part1).145669
24. Katelnitskiy II, Livadnyaya ES. Methods of treatment of patients with obliterate atherosclerosis at a critical ischemia of lower limb. *Modern Probl Sci Educ* 2014;**3**:463.
25. Wukich DK, Armstrong DG, Attinger CE, Boulton AJM, Burnset PR, Frykberg RG.et al. Inpatient management of diabetic foot disorders: a clinical guide. *Diabetes Care* 2013;**36**(9):2862-71. https://doi.org/10.2337/dc12-2712