

MEDICAL SCIENCES

ISCHEMIC DIABETIC FOOT: WOUND-RELATED REVASCULARISATION

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Abstract

Introduction: Peripheral arterial diseases in patients with diabetic foot have significant features in pathogenesis, manifestations and course compared with peripheral arterial disease. These features require different approaches to treatment and the angiosome theory can help increase the effectiveness of revascularization in patients with diabetic foot.

The aim: Analyse the results of revascularisation of lower extremity arteries in the patients with ischemic diabetic foot ulcers according to the angiosome theory.

Materials and methods: We analysed 98 revascularisations of arteries of 77 lower limbs in 74 ischemic diabetic foot patients for the period from 2014 to 2019. Angioplasties were performed in 90 cases (73,2%), open operations – in 24 (19,5%), hybrid operations – 9 (7,3%). Results of endovascular interventions were combined with hybrid ones for correct statistical analysis. According to angiosome theory we divided the revascularizations into two groups. I group – direct revascularizations (DR) – 91 cases, II group – indirect revascularizations (IR) – 32 cases.

Results: Within 6 months foot lesions healing fixed in I group (DR) - 81.7%, in II group (IR) – 78.6%. Major amputations were the consequences of 17,1% revascularizations: DR group – 12,4%, IR group – 33,3%. Functional capacity of the lower extremity within one year was saved in 79,3% in DR group and in 57,9% in IR group. Repeated revascularizations accounted for 21,4% of cases: in DR group – 20,5%, in IR group – 25%.

The results of the statistical analysis revealed the dependence of the risk of amputation on adherence to angiosome theory during revascularization.

Conclusions: Angiosome-targeted revascularization in the area of foot lesions increases efficiency of the revascularization and improves immediate and long-term treatment results.

Keywords: Diabetic foot, foot lesions, angiosome, revascularization, angioplasty.

Definitions:

Revascularization we defined as restoration of blood flow by intervention in the arteries.

By "Ischemic diabetic foot" we meant as trophic changes of the foot and leg due to a combination of diabetes mellitus and peripheral arterial diseases.

Direct revascularization (DR) – restoring blood flow following the angiosome concept.

Indirect revascularization (IR) – restoring blood flow without following the angiosome concept.

INTRODUCTION

Diabetes, according to dates of WHO, has a tendency to increase in the whole world. In Ukraine the number of the diabetics was 9,1% in 2016 [1].

The diabetics have susceptibility to peripheral arterial diseases (PAD) 2,7 times more than people of the same age without diabetes [2]

Major amputations caused by PAD ranged from 54% to 70%, PAD with diabetes - 37-47% of them, PAD without diabetes – 16,2%-22,1% [3, 4]. Mortality after major amputations reaches 47% during 2 years [5] and 90% during 5 years [6].

Ischemic lesions of the foot and the leg because of combination PAD and diabetes currently remain an open problem and algorithm for its solution is constantly improved.

Application of revascularization allows significantly improve results of treatment of patients with ischemic diabetic foot. Limb salvage after revascularization is 78-85% during one year, it can be compared to

54% after conservative treatment [7]. The introduction of various methods of revascularisation allows to significantly reduce the risk of primary major amputation [8, 9].

However, revascularization in the patients with diabetic foot is used much less than there are indications for it. According to 14 European diabetic foot treatment centers, published in EURODIAL study, in the patients with ischemic diabetic foot angiography was made in the middle in 54% (14 - 86%), and revascularization - in 43% [10]. Main causes were the choice of the surgeon and patient's severe clinical condition.

According to an experience of the medical centres and institutions of all parts of the world in July 2019 approaches to the treatment of critical lower extremity ischemia were revised and new recommendations were issued – «Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia»[11].

Patients with diabetes actually were excluded from these recommendations “due to confusing manifestations of ischemia, neuropathy and infection”. Vascular surgeons usually use Fontain or Rutherford classifications, specialists in diabetic foot prefer WIFi, SINBAD and Wagner classifications. The use multiple classification systems has hindered the development of optimal treatment algorithms and has contributed to variability of care for all patients with chronic ischemia of the lower extremities [11].

Features of ischemic lesions of the arteries of the lower extremities in diabetes mellitus, as well as the development of X-rays endovascular surgery created conditions for the application of the angiosome theory for revascularization of the arteries of the leg and foot.

Angiosome theory [12] is the anatomical and physiological patterns of blood supply to areas skin and subcutaneous tissues through branches of the main arteries that perforate the superficial fascia of the body.

To restore blood flow, adherence to the angiosome theory, allow in areas with ischemic trophic lesions [13] – “wound-related revascularization”.

«During the revascularization in a patient with diabetic foot, you should try to restore blood flow to at

least one of the arteries of the foot, preferably the one that supplies the affected area». IWGDF Guideline 2019 [14].

Data from several meta-analyzes prove greater efficiency of direct (angiosome) revascularization compared to indirect one. [15, 16, 17].

THE AIM

Make a comparative analysis of the results of direct and indirect revascularizations in patients with ischemic diabetic foot.

MATERIALS AND METHODS

Study design

We analysed 123 endovascular, open and hybrid revascularizations of 94 lower extremities in 91 patients with ischemic diabetic foot, operated from 2014 to 2020.

We choose revascularisations as object of the study for correct estimation, because one patient or one lower extremity could be operated more than one time. Revascularizations were divided in 2 groups according to the angiosome theory.

I group – direct revascularization. Blood flow in the angiosome was restored through appropriate artery that supplies this angiosome.

II group - indirect revascularization. Blood flow was restored in no-angiosome artery with supply through collateral arterial branches.

The monitoring period was 1 year.

Patients

All patients had ischemic foot lesions, in three of them on two lower extremities (4,1%), and underwent open, endovascular or hybrid revascularisation. Gender was dominated by males - 73 (59,3%), females - 50 (40,7%).

The average age of the patients was 68,5 years.

The localizations of lesions are presented in *Tab.1*

The toes were most often affected by ischemic lesions – in 45 cases (58,4%). Non-healing postoperative wounds were in 11 cases (14.3%).

Tab 1.

Localization of lesions.

Patients	91
Lower extremities	98
Revascularizations	123
Type of lesion	
- Necrosis	61 (49,5%)
- No-healing wound after minor operations	45 (36,7%)
- Ulcer	17 (13,8%)

Choice of the revascularization technique.

Features of arteries damages and possibility of using one of the method of revascularization we determined by Doppler ultrasound on the scanners Mindray 5 and Sonoace R3. Localization and elongation of the zone hemodynamically significant lesion were determined by dates of blood flow rate, resistance index and Doppler curve, determined the potential of the outflow arteries of the foot and the lower third of the leg.

If the date was not enough to choose the method of revascularization, we planned angiography with a

possible transition to revascularization. Angiographies were performed on the apparatus Philips Alura F920.

Based on the obtained data, was chosen the optimal method of revascularization for this case - endovascular technique (angioplasty), surgery or hybrid.

The feasibility of the chosen intervention in each patient was assessed according to the "risk / benefit" ratio. This approach is in line with the latest recommendations International Working Group on the Diabetic Foot [14].

Determining the risk-benefit ratio was based on the following data:

- estimation of probability of successful revascularization.
- assessment of the predicted probability of ischemia progression.
- trauma of the chosen technique for the patient.
- the forecast of preservation of basic function of foot.
- daily activity of the patient.
- individual needs of the patient to improve the quality of life.
- estimated timing of recovery of patient activity and improvement of quality of life.

First of all, we have always considered the possibility of angioplasty - "Angioplasty-first strategy". Other techniques were chosen with the predicted ineffectiveness of endovascular intervention.

Surgery revascularization were planned in case of inexpediency of angioplasty or in case of inefficiency of previous endovascular intervention.

Hybrid revascularization is a combination of open and endovascular techniques within a single intervention. Indications: the predicted inefficiency of one of the above methods, for example in the need to perform angioplasty after surgery thrombectomy or angioplasty in the outflow arteries during shunting.

After creating the revascularization plan patients were introduced of it. Patients who refused the proposed treatment were excluded from the study.

Exclusion group

The exclusion group consisted of the patients with pulsation of arteries of the foot, with intermittent claudication, which does not progress and does not significantly affect the quality of life, patients who refused surgical revascularization and patients with indications for primary amputation.

Such indications we considered this to be the condition of the limb, which precludes the possibility of maintaining the supporting function of the foot, even after successful revascularization. Mostly, these were changes at WiFi 5 clinical stage (unsalvageable foot), non-functioning limb at WiFi 4 clinical stage.

Revascularization technique

Angioplasty usually was performed according to standard technics.

A puncture of the common femoral artery in the distal direction was performed under ultrasound control, a 6 F introducer was installed, through which Ultravist 370 20 ml contrast was injected at a rate of 4-6 ml / s and arteriography was performed.

A hydrophilic guidewire 0.035 " was inserted, supported by a 5F catheter, into the occlusion zone. Passage of the occlusion zone was performed intralaminar with a 0.014" guidewire supported by a balloon catheter of appropriate size.

If it was impossible to pass with a balloon catheter, we used a microcatheter. The balloon catheter was inserted and positioned in the occlusion or stenosis zone after which angioplasty was performed. After removal of the catheter, control arteriography assessed the restoration of blood flow in the angiosome and the limb as a whole.

The main open interventions were endarterectomy, thrombectomy and bypass. Preference was given to an autovenous bypass, in the absence of an autovein we used a prosthesis or a combined bypass.

Hybrid interventions usually began with an open stage, thrombectomy or endarterectomy, then performed angioplasty, at the end of the operation did a control angiography.

Starting point

Starting point of limb salvage (amputation-free survival), wound-healing and preservation of a functional foot was defined as date of the first revascularization procedure.

Follow-up

Follow-up period was 1 year, control was performed 2 hours after revascularization, 1 day, 7 days, 2 months, 6 months and 1 year. The revascularization effectiveness was evaluated according to the patient's complaints, clinical changes, by blood flow parameters according to ultrasound scanning.

Final point

Direct revascularization we considered the restoration of blood flow in the angiosome's main artery, regardless of the location of vascular lesions and the applied technique of surgery.

The result of revascularization was evaluated by healing of trophic disorders, avoidance of high amputations, repeated surgery, functional capacity of the foot.

Criteria for evaluating the results:

The following were selected as evaluation criteria:

- amputation-free survival.
- wound-healing.
- salvage of the functional capacity of the foot.
- repeated revascularization.

The monitoring period was 12 months

Results

123 revascularization was performed on 94 affected limbs in 91 patients with diabetes. Results of interventions are presented in the *Tab. 2*

Tab.2

Results of revascularizations

N=123	Number	percents
Amputation-free survival	101	85,40%
Wound-healing	77	62,60%
Without repeated revascularization	97	78,90%
Salvage of the functioncapacity of the foot	98	79,70%

Results by study groups are presented in the *Tab. 2*

Tab.2

Direct and Indirect revascularizations.

Criteria		Number of re-vascul	Amp-free survival				healing			
			amp-free	percents	p.value	mediana survival	healing	percents	mediana survival	p.value
angiosome concept	direct revascularization	92	83	90,2%	0,023	2,00	61	67,0%	0,30	0,548
	indirect revascularization	31	22	71,0%		1,10	16	51,6%	0,30	

Statistical analysys

Statistical analysis was performed using the statistical open access package EZR v. 1.54 (graphical user interface for R statistical software version 4.0.3, R Foundation for Statistical Computing, Vienna, Austria) [21].

Wound-healing.

The median healing is 3 months (0.2-0.5 CI 95%) in the I group and 3 months (0.2-0.75 CI 95%) in the II group.

No statistically significant differences in terms of healing between two groups were found (p=0.548). (Figure 1.)

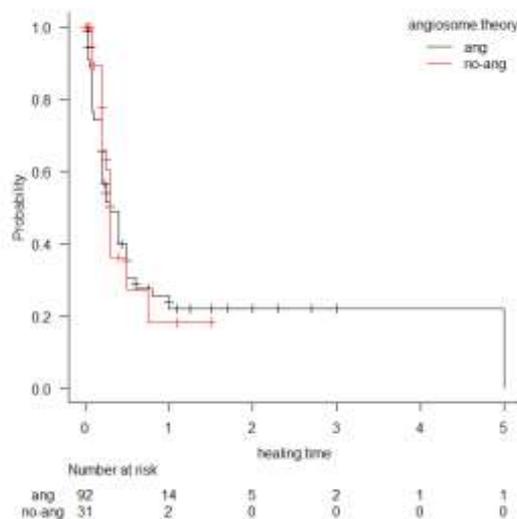


Figure 1. Terms of healing in angiosomal and nonangiosomal revascularization

Amputation-free survival. Major amputation, according to the accepted definition, we considered the level of amputation above the ankle [16].

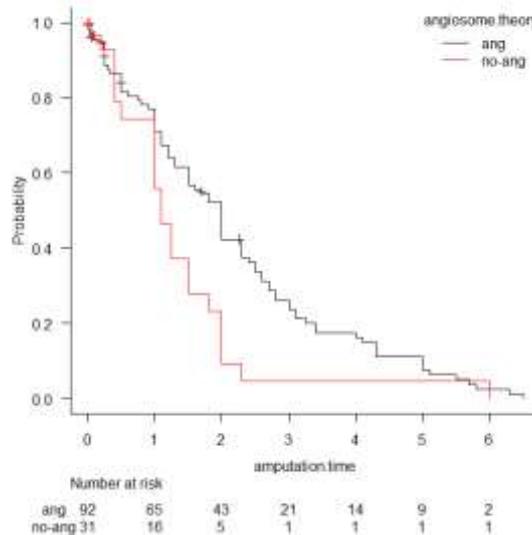


Figure 2. Avoidance of amputations in angiosomal and non-angiosomal revascularization.

The median of amputation-free survival is 24 months (1,5-2,3 CI 95%) in the I group and 13 months (1,1-1,5 CI 95%) in the II group.

There was a statistically significant difference in the number of amputations after angiosome and non-angiosome revascularizations ($p = 0.023$). Amputation-free survival during one year was noted in group I (PR) - 90.2% and in group II (HP) - 71.0%.

Repeated operation
Repeated revascularization was defined as next revascularization on the same limb for 1 year.

Criterion	Type of criterion	Revascularizations ;	Re-revascularizations	% no-reoper	p.valu e
		N=123	N=26		
angiosome concept	ang	91	18	80,2%	0,842
	no-ang	32	8	75,0%	

All re-operations were performed 26 (21,1% from all interventions). In the I group - 18 (19.8%), in the II group - 8 (25%). There was no statistically significant

difference in the proportion of re-revascularizations between direct and indirect revascularizations ($p = 0.842$).

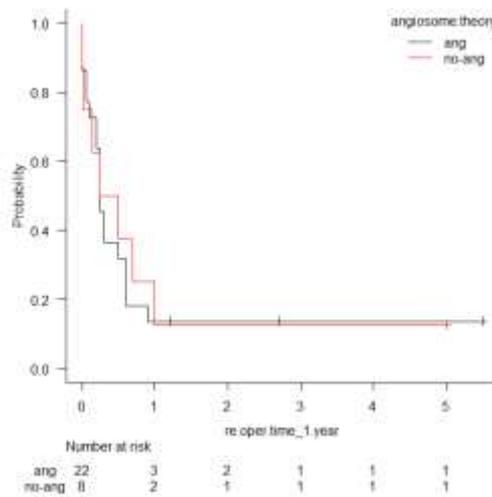


Figure 3. Repeated revascularizations in 1 year.

Functional ability of the limb

Functional ability of the limb we defined as saving of the supporting function of the foot when walking independently without the need for prosthetics and aids (crutches, wheelchairs, etc.). In the world literature, this

corresponds to the definition of Tefera et al. [18]. Functional ability of the limb was saved for a year in 76 (77,2%) patients in the 1 group and in 19 (61,3%) patients in the II group (Figure 4).

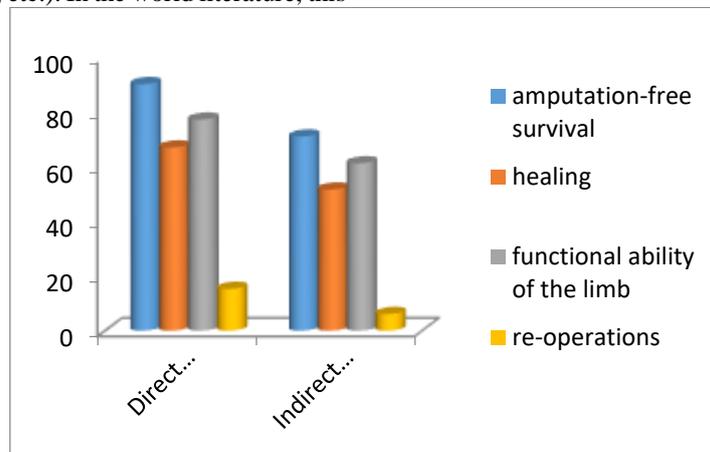


Figure 4. The results of revascularization according to the main criteria

Discussion.

In 2017 SPINACH multicenter study on revascularization in patients with diabetes mellitus was published [19]. Open and endovascular revascularizations were performed mainly in different clinics. Results of amputation-free survival after open and endovascular revascularizations during the year were 75% and 78%, respectively. Data from the CRITISCH multicenter study (Germany, 2015) were almost identical - 73% for open and 75% - for endovascular revascularizations [20]

Amputation-free survival during one year according to our data amounted to 85,4%.

The rate of amputation-free survival within one year according to the results of multicenter studies SPINACH and CRITISCH was 73-78%. According to some studies the best results of amputation-free survival during the year were - 89% after angioplasty and 90% after surgical revascularization.

In our opinion, the difference in results are due to significant differences in the definition of indications for revascularization and the choice of surgical technique depending on the capabilities of the clinic and the experience of surgeons in the use of different methods of revascularization. The possibility of one team to use open or endovascular methods, depending on the clinical situation and the actual assessment of their own capabilities, gives an advantage even with the relative technical imperfection in each of the methods separately.

The priority direction of revascularization is the restoration of blood flow along the main angiosome artery of the leg with the filling of the angiosome (Direct Revascularization). In the absence of conditions - revascularization of the non-angiosomal main artery (Indirect Revascularization), preferably together with the branch to the affected angiosome (wound-direct) artery.

Conclusions:

The main task of revascularization of the leg and foot arteries in patients with ischemic diabetic foot is improve the quality of life of patients with ischemic diabetic foot.

Angiosome-targeted revascularization increases the efficiency of revascularization and improves immediate and long-term treatment outcomes.

The possibility of choosing surgical and endovascular methods of revascularization or their combination increases the effectiveness of treatment of the lower leg and foot in patients with diabetes.

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