

## CHOICE OF REVASCULARIZATION TECHNIQUE IN PATIENTS WITH ISCHEMIC DIABETIC FOOT

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### Summary

**Background.** Ischemic diabetic foot is determined by trophic disorders of the foot due to a combination of atherosclerosis of the arteries and diabetic lesions. In the United States and some European countries, among major non-traumatic amputations, amputations in patients with diabetes are 45-70%. The use of revascularization can significantly improve the results of treatment of patients with diabetic foot. Features of ischemic diabetic foot require a separate approach to revascularization. There are no generally accepted guidelines for revascularization in diabetic foot in the world today. The choice of revascularization technique remains an open question.

**The aim of the study.** To analyze the effectiveness of differentiated application of intervention techniques of revascularization for the treatment of ischemic diabetic foot.

**Steps of differentiated choice of revascularization.** We identified seven steps: determination of indications for revascularization, determination of the critical arterial segment, the level of hemodynamic compensation, determination of the feasibility of revascularization, the choice of revascularization technique, the perform revascularization, the active postoperative monitoring.

**Materials and methods.** Diabetic ischemic foot was diagnosed in 133 observations. 123 revascularizations of 94 lower extremities were performed in 91 patients with ischemic diabetic foot. Patients underwent angioplasty, surgical revascularization or hybrid intervention.

**Results.** Revascularization was performed in 92,4% of patients with ischemic diabetic foot. Amputation-free survival was noted in 85,4% of cases, wound-healing in 62,6%, preservation of foot support function in 79,7%, avoidance of repeated interventions in 78,9%. 5 (5,5%) patients died, 2 of them (2,2:%) within 30 days after revascularization.

**Conclusions:** Differentiated choice of revascularization technique allows to increase the number of patients to be revascularized 92,4%, to reach of the level amputation-free survival to 85,4%, to reach of the level wound-healing to 62,6%, to salvage of foot support function to 79,7%, to perform revascularizations in patients with a high probability of limb amputation.

**Key words:** peripheral arterial diseases, diabetic foot, revascularization, angioplasty, vascular surgery, endovascular treatment.

### INTRODUCTION

Peripheral arterial diseases (PAD) are frequent pathology that significantly impairs the quality of life and leads to disability of people over 50 years. In the study PARTNERS (2001p.) [1] 6,979 people over the age of 50 were examined. Peripheral arterial diseases (PAD) were found in 1865 (29%) patients. More than 80% of them had clinical signs, but only 49% were examined by their doctors and had a diagnosis.

The number of patients with diabetes, according to the WHO report for 2016 [2], in Ukraine is 9.1% and tends to increase, both in our country and around the world.

Diabetics are 2.7 times more prone to peripheral artery disease than people of the same age without diabetes [3]. Atherosclerosis of the arteries of the lower extremities in combination with diabetes remains the main cause of non-traumatic major amputations of the lower extremities [4]. The generally accepted probability of risk of diabetic foot ulcers is 25% [4], according to some studies can reach 34% [5].

According to the International Diabetes Federation, diabetic foot ulcers occur annually in 9.1 million of the world's 26.1 million diabetics. In the United States and some European countries, among major non-traumatic amputations, amputations in patients with diabetes are 45-70% [7,8,9,10].

Of these, the combination of diabetes and peripheral artery disease is 37-47% of all amputations, without diabetes – 16.2% – 22.1%. [10,11]. After major amputations, the average life expectancy is 50%, according to some data only 2 years [12], and 5-year mortality is 40-90% [13]. One recent study [14] reported the following: after major amputation for ischemic diabetic foot, survival for 1 year was 41.7%, for 5 years – 8.3%.

The use of revascularization can significantly improve the results of treatment of patients with diabetic foot. Limb salvage after revascularization for 1 year is 78-85% compared with 54% in patients treated conservatively [15].

Today there are two basic and two derivative methods of revascularization.

The basic ones include surgical revascularization (open vascular surgery, bypass surgery), endovascular revascularization (angioplasty). Combining endovascular and surgical techniques within a single procedure is called hybrid revascularization.

The use of endovascular technique for targeted administration of thrombolytic drugs – catheter-directed thrombolysis. The task of revascularization in a patient with diabetic foot is to restore blood flow to at least one of the arteries of the foot, preferably the one that supplies the affected area [16].

Targeted restoration of blood flow in the most damaged areas of the foot became possible due to the angiosomal concept [17,18]. Current clinical guidelines for the choice of revascularization technique are Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC-II) [19] and Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia (CLTI) [20].

The recommendations of TASK-II (2007) do not currently take into account the current possibilities of endovascular revascularization.

The CLTI guidelines have specifically highlighted the limitations of using these guidelines in patients with diabetes due to the large difference between peripheral artery disease and ischemic diabetic foot [20].

A careful study of the studies on which these recommendations are based reveals a significant difference in the results of open, endovascular, and hybrid revascularizations, depending on the authors, clinics, and countries. The result of revascularization is obviously influenced by the experience of specialists, organizational and economic factors, both within the clinic and within the country.

## THE AIM OF THE STUDY

To analyze the effectiveness of differentiated application of intervention techniques of revascularization for the treatment of ischemic diabetic foot.

We defined the goal of revascularization as improving the quality of life by preserving the limb. Tasks of revascularization are reduction of pain, avoidance of large amputation, healing of trophic disorders, preservation of functional capacity (support function) of the foot, sufficient for comfortable daily activity.

## STAGES OF DIFFERENTIATED REVASCULARIZATION ALGORITHM

Step 1. Determination of indications for revascularization. Indication for revascularization is the presence of the ischemic diabetic foot.

Step 2. Determination of the critical arterial segment. The critical arterial segment, we considered the affected arterial area, which most changes the hemodynamics in the limb. The second necessary task was to determine the functional capacity of inflow arteries and outflow arteries.

Step 3. The level of hemodynamic compensation. Hemodynamic compensation was defined as the ratio of occlusive-stenotic arterial lesions and ischemia of foot scans.

Step 4. Determination of the feasibility of revascularization. Probability of successful revascularization. The feasibility of revascularization was determined by the risk-benefit ratio. We took into account: the probability of successful revascularization, the probability of progression of ischemia, trauma of the chosen technique, the forecast of preservation of functional ability of foot, daily activity of the patient.

the patient's needs for quality of life, predicted timing of recovery of patient activity.

Step 5. The choice of revascularization technique. First of all, we have always considered the possibility of angioplasty – «Angioplasty is the first strategy». When performing angioplasty, we tried to adhere to the angiosomal concept. Surgical revascularization was chosen in prolonged resistant occlusions with capable outflow arteries, local short occlusions of the bifurcation zone of the common femoral artery, Lerich's syndrome, ineffectiveness of previous endovascular intervention.

Step 6. Perform revascularization.

Step 7. Active postoperative monitoring. The monitoring period lasted one year. The monitoring consisted of follow-up with ultrasound examinations, debridement, infection control, off-loading, daily walking and drug support

## RESEARCH DESIGN

Indications for revascularization.

Indications for revascularization were considered to be the presence of diabetic ischemic foot.

Exclusion group.

- patients with palpatory pulsation of the arteries of the foot,
- patients with intermittent claudication that has not progressed or has not significantly affected quality of life,
- patients with diabetes mellitus and peripheral arterial diseases without trophic disorders,
- patients who refused revascularization or went to another institution.

Indications for primary major amputation: the condition of the limb, which eliminates the possibility of maintaining the supporting function of the foot even after successful revascularization.

Clinical data. Preliminary planning of the method of intervention during the initial examination was based on the somatic condition of the patient, the local status of the lower extremity, palpation of the arteries of the lower extremities.

## ADDITIONAL EXAMINATIONS

Ultrasound of the arteries of the lower extremities is a mandatory examination performed during the general examination for signs of ischemia.

CT angiography of the lower extremities. It was used mainly for lesions of the arteries of the 1st and 2nd order, when it is necessary to determine the exact size of the affected area (eg, aneurysm) or if the patient has the results of the examination at the first examination.

Angiography was planned to obtain additional information with the subsequent transition to the revascularization procedure according to one of the methods according to the obtained data.

## CRITERIA FOR EVALUATING THE RESULTS

The following were chosen as criteria for evaluating the results: avoidance of major amputation, healing of trophic disorders, preservation of the supporting function of the foot, repeated surgical interventions.

Terms of evaluation of results.

The monitoring period was 12 months.

## MATERIALS AND METHODS

Diabetic ischemic foot was diagnosed in 133 observations. Revascularization was considered inexpedient at the stage of the initial examination in 3 observations.

In 5 observations after angiography revascularization by any method was considered impossible

Attempts at revascularization were unsuccessful in 2 observations.

123 revascularizations of 94 lower extremities were performed in 91 patients with ischemic diabetic foot.

All patients (100%) had trophic ischemic lesions of the foot, in three cases both lower extremities were affected (2.4%).

All patients underwent angioplasty, surgical revascularization or hybrid intervention.

Sex. 73 revascularizations were performed in men (59.4%), 50 in women (40.6%). Age. By age, patients were divided into 2 groups: I – up to 65 years, II – 65 years and older, the distribution by groups was 37 (30.8%) and 83 (69.2%), respectively. Ураження стопи.

There are three characteristics of foot lesions:

- WiFi classification category,
- type of ischemic lesion,
- localization of the lesion.

Patients with category 0 foot lesions (rest pain, no skin damage) were excluded from the study design.

## REVASCULARIZATION TECHNIQUE

Revascularization techniques were divided into 3 groups: X-ray endovascular, surgical and hybrid. Endovascular revascularizations were performed 90 (73.2%), surgical – 24 (19.5%), hybrid – 9 (7.3%).

To statistically accurately evaluate the results of revascularizations, it was decided to combine hybrid interventions with X-ray interventions, given their relatively small number.

Catheter-directed thrombolysis was considered as a derivative of X-ray endovascular technique.

In the study group of patients as a separate method of treatment catheter-directed thrombolysis was not used, it was part of the staged treatment according to the scheme «thrombolysis-angioplasty».

## RESULTS

Diabetic ischemic foot was diagnosed in 133 cases. Revascularization was considered inexpedient at the stage of the initial examination in 3 observations.

In 5 observations after angiography, revascularization by any method was considered impossible due to total occlusion of the main arteries of the leg and foot and underdeveloped collateral arteries.

123 revascularizations of 94 lower extremities were performed in 91 patients with ischemic diabetic foot. Attempts at revascularization were unsuccessful in 2 observations.

The analysis of long-term results within 1 year after revascularization was performed.

Total number: 123 revascularizations	Number	percents
Amputation-free survival	101	85,40%
Wound-healing	77	62,60%
Avoidance of repeated revascularization	97	78,90%
Functional capacity of the foot	98	79,70%

Amputation-free survival was noted in 85.4% of cases, wound-healing in 62.6%, preservation of foot support function in 79.7%, avoidance of repeated interventions in 78.9%.

5 (5.5%) patients died, 2 of them (2.2:%) within 30 days after revascularization.

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### EVALUATION OF RESULTS

The results of revascularization were evaluated according to the following criteria: amputation-free survival, healing of trophic lesions, repeated revascularization; preservation of the supporting function of the foot.

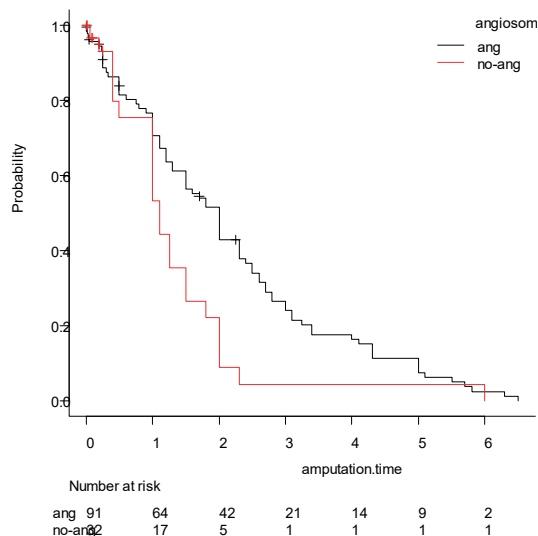
### STATISTICAL ANALYSIS

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].

#### Method of revascularization

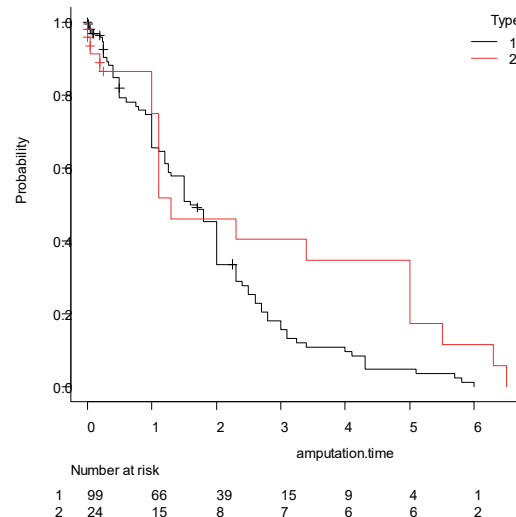
A statistically significant difference ( $p$ .value = 0.046) in the effectiveness of different revascularization techniques was revealed.

#### Amputation-free survival



The probability of amputation-free survival for 1 year with endovascular or hybrid techniques – 87.9%, with vascular surgery – 75.0%.

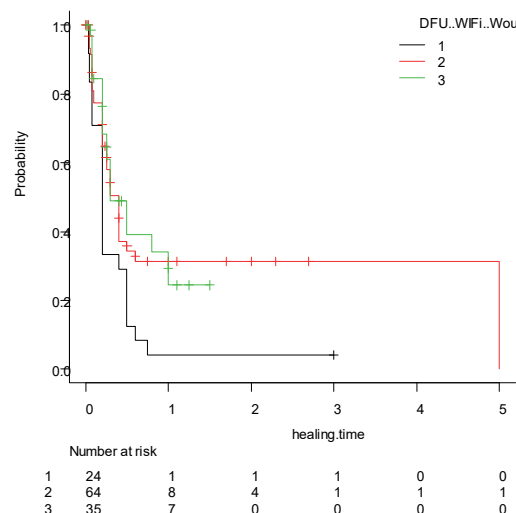
#### Angiosomal concept.



There was also a statistically significant difference in adherence to the angiosomal concept in revascularization of the foot and leg ( $p$ .value = 0.018).

The probability of amputation-free survival within 1 year in angiosomal revascularization (direct revascularization) – 91.9%, in indirect (indirect revascularization) – 71.9%.

#### Wound healing



There was a statistically significant difference ( $p$ .value = 0.015) of healing from the category of foot tissue lesions by WiFi. Healing during the year with lesions of 1 cat. noted in 95.8% of observations, 2 cat in 54.0%, 3 cat. in 55.6%.

There was no statistically significant dependence on the method of intervention ( $p$ -value = 0.086). The median healing was 0.25 for X-ray endovascular and 0.6 for surgical revascularization. On the basis of the received statistical data it is possible to assume a tendency to the best healing at endovascular interventions.

### Repeated revascularization.

There was no statistically significant dependence of the risk of re-intervention on the chosen method, adherence to the angiosomal concept, localization of arterial lesions and features of trophic changes.

There was no statistically significant difference between primary and repeated revascularizations in terms of amputation avoidance ( $p$ -value = 0.301) and healing ( $p$ -value = 0.119). It is possible to note a tendency to the best healing after primary revascularizations.

## CONCLUSIONS

Differentiated choice of revascularization technique allows to increase the number of patients to be revascularized to 92,4%, to reach of the level amputation-free survival to 85,4%, to reach of the level wound-healing to 62,6%, to salvage of foot support function to 79,7%, perform interventions in patients with a high probability of limb amputation.

Differentiated choice of revascularization technique allows:

- the number of patients to be revascularized can be increased to 92,4%.
- the level amputation-free survival can be reach to 85,4%,
- the level wound-healing can be reach to 62,6%,
- the foot support function can be salvage in 79,7%,

- revascularization can be performed in patients with a high probability of high limb amputation.

The angiosomal concept when performing endovascular techniques of revascularization makes possible effective targeted restoration of blood flow in the area of trophic lesions.

Arterial lesions, in which one of the methods is predicted to be ineffective, are indications for a combination of techniques – hybrid revascularization.

Repeated revascularization can be an effective way to prolong the life of the limb in the postoperative period.

## KEYWORDS

Diabetic foot, ischemia, diabetes mellitus, revascularization, peripheral artery disease, amputation,

## FINANCING

The work was performed in accordance with the dissertation research of the applicant D. Shapovalov.

The authors did not receive financial support from companies producing drugs and medical devices.

## CONFLICT OF INTEREST

The authors state that there is no conflict of interest.

## APPROVAL OF THE ETHICS COMMITTEE

The clinical study was approved at a meeting of the commission on ethics of DNU «Scientific and Practical Center for Preventive and Clinical Medicine» DUS, from 29.01.2018.

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*Резюме***ВИБІР МЕТОДИКИ РЕВАСКУЛЯРИЗАЦІЇ У ХВОРИХ НА ІШЕМІЧНУ ДІАБЕТИЧНУ СТОПУ****Д. Ю. Шаповалов**

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**Вступ.** Ішемічна діабетична стопа визначається трофічними розладами стопи внаслідок поєднання атеросклерозу артерій та діабетичних уражень. Особливості ішемічної діабетичної стопи вимагають окремого підходу до реваскуляризації. Сьогодні у світі немає загальноприйнятих рекомендацій щодо реваскуляризації діабетичної стопи. Вибір техніки реваскуляризації залишається відкритим питанням.

**Мета дослідження.** Проаналізувати ефективність диференційованого застосування методів втручання реваскуляризації для лікування ішемічної діабетичної стопи.

**Етапи диференційованого вибору реваскуляризації.** Ми визначили сім кроків: визначення показань до реваскуляризації, визначення критичного артеріального сегмента, оцінка гемодинамічної компенсації, визначення доцільності реваскуляризації, вибір техніки реваскуляризації, виконання реваскуляризації, активний післяопераційний моніторинг.

**Матеріали та методи.** Діабетична ішемічна стопа була діагностована в 133 спостереженнях. Було проведено 123 реваскуляризації 94 нижніх кінцівок у 91 пацієнта з ішемічною діабетичною стопою. Пацієнтам виконували ендovasкулярну, хірургічну або гібридну реваскуляризацію.

**Результати.** Реваскуляризацію виконали у 92,4% пацієнтів з ішемічною діабетичною стопою. Виживання без ампутації відзначалося у 85,4% випадків, загоєння ран -у 62,6%, збереження опорної функції стопи – у 79,7%, уникнення повторних втручань-у 78,9%. Померло 5,5% пацієнтів, 2,2% з них впродовж 30 днів після реваскуляризації.

**Висновки.** Диференційований вибір техніки реваскуляризації дозволяє досягти кількості пацієнтів, які підлягають реваскуляризації, до 92,4%, досягти рівня виживання без ампутації 85,4%, досягти рівня загоєння ран 62,6%, зберегти функцію підтримки стопи в 79,7%, а також виконувати втручання пацієнтам з високою ймовірністю ампутації високої кінцівки.

**Ключові слова:** захворювання периферичних артерій, діабетична стопа, реваскуляризація, ангіопластика, хірургія судин, ендovasкулярне лікування.



**Резюме****Д. Ю. ШАПОВАЛОВ****Выбор методики реваскуляризации у пациентов с ишемической диабетической стопой**

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**Вступление.** Ишемическая диабетическая стопа определяется трофическими расстройствами стопы вследствие сочетания атеросклероза артерий и диабетических поражений. Особенности ишемической диабетической стопы требуют отдельного подхода к реваскуляризации. Сегодня в мире нет общепринятых рекомендаций по реваскуляризации диабетической стопы. Выбор техники реваскуляризации остается открытым вопросом.

**Цель исследования.** Проанализировать эффективность дифференцированного применения методов вмешательства реваскуляризации для лечения ишемической диабетической стопы.

**Этапы дифференцированного выбора реваскуляризации.** Мы определили семь шагов: определение показаний к реваскуляризации, определения критического артериального сегмента, оценка гемодинамической компенсации, определение целесообразности реваскуляризации, выбор техники реваскуляризации, выполнение реваскуляризации, активный послеоперационный мониторинг.

**Материалы и методы.** Диабетическая ишемическая стопа была диагностирована в 133 наблюдениях. Было проведено 123 реваскуляризации 94 нижних конечностей у 91 пациента с ишемической диабетической стопой. Пациентам выполняли эндоваскулярную, хирургическую или гибридную реваскуляризацию.

**Результаты.** Реваскуляризацию выполнили у 92,4% пациентов с ишемической диабетической стопой. Выживаемость без ампутации отмечалась в 85,4% случаев, заживление ран – в 62,6%, сохранение опорной функции стопы – в 79,7%, избежание повторных вмешательств – в 78,9%. Умерло 5,5% пациентов, 2,2% из них в течение 30 дней после реваскуляризации.

**Выводы.** Дифференцированный выбор техники реваскуляризации позволяет достичь количества пациентов, которые подлежат реваскуляризации, в 92,4%, достичь уровня выживаемости без ампутации 85,4%, достичь уровня заживления ран 62,6%, сохранить функцию поддержки стопы в 79,7%, а также выполнять вмешательства пациентам с высокой вероятностью ампутации высокой конечности.

**Ключевые слова:** заболевания периферических артерий, диабетическая стопа, реваскуляризация, ангиопластика, сосудистая хирургия, эндоваскулярное лечение.

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