Shapovalov Danylo Y., Hupalo Yurii M., Shaprynskyi Vasyl V., Shamrai-Sas Artem V., Kutsin Anton N., Gurianov Vitalii G. Wound-directed revascularisation in the Diabetic Foot patients. Journal of Education, Health and Sport. 2021;11(10):289-300. eISSN 2391-8306. DOI http://dx.doi.org/10.12775/JEHS.2021.11.10.027
https://apcz.umk.pl/JEHS/article/view/JEHS.2021.11.10.027
https://zenodo.org/record/5654971

The journal has had 5 points in Ministry of Science and Higher Education parametric evaluation. § 8. 2) and § 12. 1. 2) 22.02.2019.

Received: 30.09.2021. Revised: 12.10.2021. Accepted: 29.10.2021.

Wound-directed revascularisation in the Diabetic Foot patients

Danylo Y. Shapovalov, Yurii M. Hupalo, Vasyl V. Shaprynskyi, Artem V. Shamrai-Sas, Anton N. Kutsin, Vitalii G. Gurianov

State Institution of Science "Research and Practical Center of Preventive and Clinical Medicine", Kyiv, Ukraine

D. Shapovalov - MD, Vascular surgeon, Junior Researcher, State Institution of Sciense "Research and Practical Center of Preventive and Clinical Medicine" State Administrative Department, Kyiv, Ukraine, Email: pandanila.kiev@gmail.com, Phone number: +38 (067) 99 00 911, ORCID id:0000-0001-7419-9559
Y. Gupalo - MD., Phd, Leading Researcher, Vascular surgeon, State Institution of Science "Research and Practical Center of Preventive and Clinical Medicine" State Administrative Department, Kyiv, Ukraine, Email: uriy_gupalo@ukr.net, ORCID id:0000-0002-4273-5799
V. Shaprynskyi - MD., Phd, Senior Researcher, Vascular surgeon, State Institution of Science "Research and Practical Center of Preventive and Clinical Medicine" State Administrative Department, Kyiv, Ukraine, Email: vasyl.shaprynskyy@gmail.com, ORCID id:0000-0002-1437-7410
A. Shamray-Sas - MD., Phd, Senior Researcher, Vascular surgeon, Junior Researcher, State Institution of Science "Research and Practical Center of Preventive and Clinical Medicine" State Administrative Department, Kyiv, Ukraine, Email: sa-sha-art@bigmir.net, ORCID id:0000-0003-4099-3118
A. M. Kucyn - MD,Vascular surgeon, Postgraduate Student, Department of Minimally Invasive Surgery, State Institution of Science "Research and Practical Center of Preventive and Clinical Medicine" State Administrative Department, Kyiv, Ukraine, Email: kutsyn.anton@gmail.com, ORCID id:0000-0001-9421-8032
V. G. Gurianov - Phd, Associate Professor, Department of Public Health Service Management, Bogomolets National Medical University, Kyiv, Ukraine, Email:vggurianov1958@gmail.com, ORCID id:0000-0001-8509-6301

Conflict of interest: no conflicts

Contact information: no conflicts

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 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 metods: We analysed 98 revascularisations of arteries of 77 lower limbs in 74 ischemic diabetic foot patients for the period from 2017 to 2021**.** Angioplasties were performed in 71 cases (72,5%), open operations – in 21 (21,4%), hybrid operations – 6 (6,1%). According to angiosome theory we divided the revascularizations into two groups. I group – direct revascularizations (DR) – 57 cases, II group – indirect revascurizations (IR) – 21 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.

Key words: Diabetic foot; foot lesions; angiosome; revascularization; angioplasty.

Definitions:

Revascularization we defined as restoration of blood flow by surgery on 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.

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 deceases (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 [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 revascularisation 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-Threating Ichemia»[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.

Adherence to the angiosome theory allow to restore blood flow 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].

Dates of the meta-analysis prove greater efficiency of direct revascularization compared to indirect one [15, 16, 17].

The aim

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

Materials and methods

Study design

We analysed 98 endovascular, open and hybrid revascularizations of 77 lower extremities in 74 patients with ischemic diabetic foot, operated from 2017 to 2021.

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. Revascularizions 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.

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 - 47 (59,5%), females - 30 (40,5%). The average age of the patients was 68,4 years. The localizations of lesions are presented in *Tab.1*.

Table 1. Localization of lesions

Patients	74
Lower extremities	77
Wound location	
- Toes	45 (58,4%)
- Foot - No-healing wound after minor operations	32 (41,6%) 11 (14,3%)
- Leg	4 (5,2%)

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

Revascularization method

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 - angioplasty (X-ray endovascular technique), open 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].

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.

Open vascular operations were planned in case of inexpediency of angioplasty or in case of inefficiency of previous endovascular intervention.

Hybrid interventions were preferred in stenoses and occlusions of the tibial and foot arteries complicated by proximal or distal thrombosis.

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 common purulent-necrotic changes of the leg and foot - WIFi 5 clinical stage (unsalvageable foot), forced position of the limb with a lesion of the foot WIFi 4 clinical stages (High risk amputation).

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.

Results

98 revascularization was performed on 77 affected limbs in 74 patients with diabetes. In two cases (2%) revascularization attempts were technically unsuccessful. Both cases are endovascular attempts to restore blood flow by occlusion of all tibial arteries.

Distribution of interventions by types of revascularization are presented in the *Tab. 2*

Table 2. Types of revascularizations

Revascularization	Cases
Angioplasties	71 (72,5%)
Opens	21 (21,4%)
Hybrids	6 (6,1%)
Re-operations	21 (21,4%)
Angioplasties	11 (11,2%)
Opens	6 (6,1%)
Hybrids	4 (4,1%)

Results by study groups.

I – direct revascularizations:

patients - 55 (74,3%), operated limbs – 58 (75,3%), revascularizations – 73 (74,5%).

II – indirect revascularizations:

patients – 19 (25,7%), operated limbs – 19 (24,7%), revascularizations – 24 (25,5%).

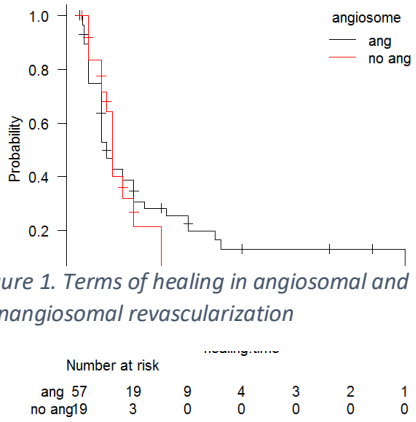

Figure 1. Terms of healing in angiosomal and nonangiosomal revascularization

Wound-healing

The median healing is 3 months (0.2-0.5 CI 95%) in the I group and 4 months (0.2-0.5 CI 95%) in the II group.

During 6 months, healing of the trophic lesions was noted in the I group - 81.7%, in the II group - 78.6%. No statistically significant differences in terms of healing between two groups were found (p=0.937). (*Figure 1.*)

Major amputation of the lower extremity

Major amputation, according to the accepted definition, we considered the level of amputation above the ankle [16] (*Fig. 2)*

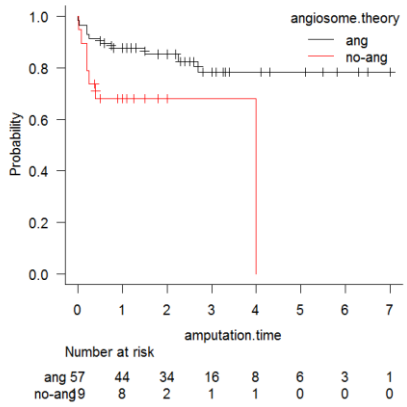

Figure 2. Avoidance of amputations in angiosomal and non-angiosomal revascularization.

There was a statistically significant difference in the number of amputations after angiosome and non-angiosome revascularizations (p = 0.0159). Avoidance of major amputations during one year was noted in group I (PR) - 87.6% and in group II (HP) - 66.7%.

A total of 17 amputations were performed (17.3%): in the first group - 10 (12.4%), in the second group - 7 (36.8%).

According to multifactor statistical analysis by Cox, the probability of major amputation in group II is higher (p=0,0173).

No significant influence of other factors on the probability of amputation was detected.

There was no statistically significant difference in the healing of trophic disorders in I groups and II group (*Tab.3)*. The influence of revascularization technique on the healing of trophic changes and the probability of amputation is also undetected (*Tab.3).*

Table. 3. Statistical analysis of revascularization results

Factor	Major amputation		Healing	
	Hazard ratio	p.value	Hazard ratio	p.value
Age	0.9795	0.4918	0.9964	0.8152
Sex	0.4221	0.1462	0.2270	0.4777
Method of revascularization	2.7870	0.06796	0.7748	0.5098
Depending on the angiosome theory	3.3210	0.01735	1.0100	0.9769

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

All re-operations were performed 21 (21,4% from all interventions). In the I group – 15 (20.5%), in the II group – 6 (25%). There was no statistically significant difference in the proportion of re-operations between DR and IR (p = 0.845). *Figure 3.*

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 46 (79,3%) patients in the 1 group and in 11 (57,9%) patients in the II group (*Figure 4.*).

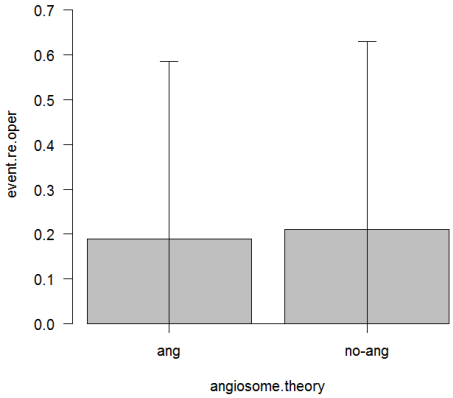

Figure 3. Re-operations in angiosome and no-angiosome groups.

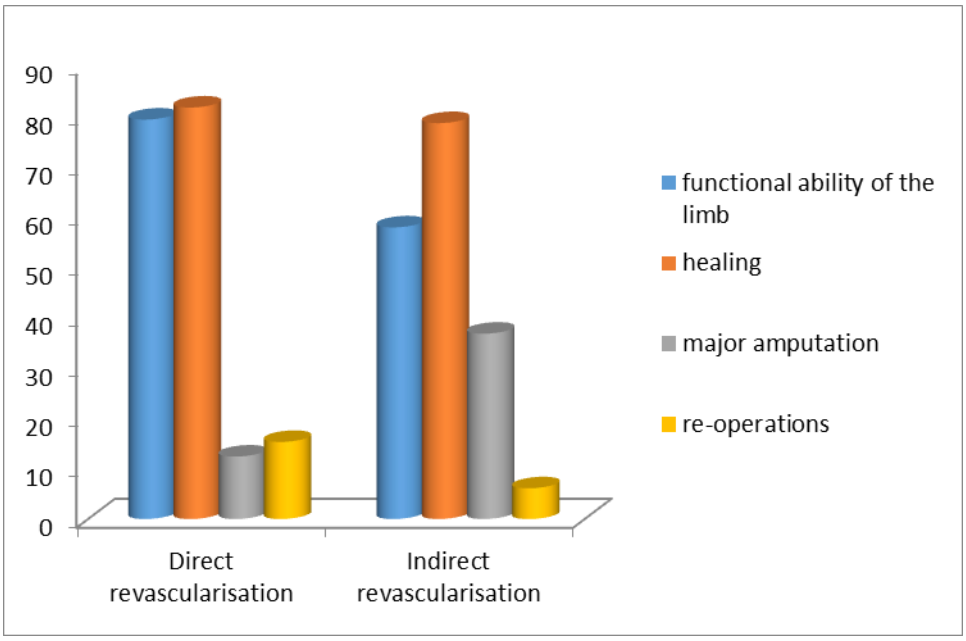

Figure 4. The results of revascularization according to the main criteria

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 82,9%. The rate of avoidance of high amputations within one year according to the results of multicenter studies SPINACH and CRITISH was 73-78%. According to some studies the best results of amputation-free survival during the year were - 89% after angioplasty and 90% after open vascular surgery.

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 surgical revascularization of the leg and foot arteries in patients with ischemic diabetic foot is to increase the volume of blood flow in the lower extremity.

Angiosome-targeted revascularization increases the efficiency of revascularization and improves immediate and long-term treatment outcomes.
The possibility of choosing open and endovascular methods of revascularization or their combination increases the effectiveness of treatment of the lower leg and foot in patients with diabetes.

References:

1. Gojka R. WHO Global report on diabetes: A summary. Int J Noncommun Dis Jan 2016; 1 (1): 3-8. doi:10.4103/2468-8827.184853. https://www.ijncd.org/article.asp?issn=2468-8827

2. National diabetes audit executive summary 2009-10. The NHS Information Centre 2011 https://digital.nhs.uk/data-and-information/ publications/ statistical/ national-diabetes-audit/national-diabetes-audit-2009-10

3. Spoden M, Nimptsch U, Mansky T. Amputation rates of the lower limb by amputation level - observational study using German national hospital discharge data

from 2005 to 2015. BMC Health Serv Res. 2019 Jan 6; 19(1): 8. doi: 10.1186/s12913-018-3759-5..PMID: 30612550. https://pubmed.ncbi.nlm.nih.gov/30612550/

4. Ziegler-Graham K, MacKenzie E, Ephraim P. et al. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. Arch Phys Med Rehabil. 2008 Mar; 89(3): 422-9. doi: 10.1016/j.apmr.2007.11.005. https://pubmed.ncbi.nlm.nih.gov/18295618/

5. Carmona G, Hoffmeyer P, Herrmann F. et al. Major lower limb amputations in the elderly observed over ten years: the role of diabetes and peripheral arterial disease. Diabetes Metab. 2005; 31(5): 449–454. PMID: 16357788 doi: 10.1016/s1262-3636(07)70215-x. https://pubmed.ncbi.nlm.nih.gov/16357788/

6. Thorud JC, Plemmons B, Buckley CJ et al. Mortality After Nontraumatic Major Amputation Among Patients With Diabetes and Peripheral Vascular Disease: A Systematic Review. J Foot Ankle Surg. 2016; 55(3): 591-9 PMID: 26898398 doi: 10.1053/j.jfas.2016.01.012. https://pubmed.ncbi.nlm.nih.gov/26898398/

7. Lepäntalo M, Mätzke S. Outcome of unreconstructed chronic critical leg ischaemia. Eur J Vasc Endovasc Surg. 1996; 11(2):153-7. PMID: 8616645 DOI: 10.1016/s1078-5884(96)80044-x. https://pubmed.ncbi.nlm.nih.gov/8616645/

8. Londero L, Høgh A, Houlind K. et al. Prevalence of Major Lower Limb Amputation Across Denmark and Its Relationship with Revascularization, Demography and Disease Risk Factors. Eur J Vasc Endovasc Surg. 2019; 57(1):111-120. doi: https://doi.org/10.1016/j.ejvs.2016.07.059. https://pubmed.ncbi.nlm.nih.gov/30293885/

9. Ebskov L, Schroeder T, Holstein P. Epidemiology of leg amputation: the influence of vascular surgery. Br J Surg. 1994 Nov; 81(11):1600-3. PMID: 7827881 DOI: 10.1002/bjs.1800811111 https://pubmed.ncbi.nlm.nih.gov/7827881/

10. Prompers L, Huijberts M, Apelqvist J et al. Delivery of care to diabetic patients with foot ulcers in daily practice: results of the Eurodiale Study, a prospective cohort study. Diabetic Medicine Volume 25, Issue 6 June 2008 Pages 700-707 https://doi.org/10.1111/j.1464-5491.2008.02445.x

11. Conte MS, Bradbury AW, Kohl Ph. et al. GVG Writing Group for the Joint Guidelines of the Society for Vascular Surgery (SVS), European Society for Vascular Surgery (ESVS), and World Federation of Vascular Societies (WFVS). Global Vascular Guidelines on the Management of Chronic Limb-Threating Ichemia Eur J Vasc Endovasc Surg. 2019; 58(1S):S1-S109. doi: 10.1016/j.ejvs.2019.05.006. Epub 2019 Jun 8. https://pubmed.ncbi.nlm.nih.gov/31182334/

12. Taylor GI The angiosomes of the body and their supply to perforator flaps. Clin Plast Surg. 2003; 30(3): 331-42, v. PMID: 12916590. doi: 10.1016/s0094-1298(03)00034-8. https://pubmed.ncbi.nlm.nih.gov/12916590/

13. Manzi M, Cester G, Palena LM et al. Vascular imaging of the foot: the first step toward endovascular recanalization. Radiographics. 2011; 31(6):1623-36. doi: 10.1148/rg.316115511. https://pubmed.ncbi.nlm.nih.gov/21997985/

14. Nicolaas C. Schaper (chair), Jaap J. Van Netten, Jan Apelqvist et al. IWGDF Guidelines on the prevention and management of diabetic foot disease Diabetes Metab Res Rev. 2020; 36 (1): e3266. doi: 10.1002/dmrr.3266. https://pubmed.ncbi.nlm.nih.gov/32176447/

15. Marco Manzi, Luis M. Palena. Treating Calf and Pedal Vessel Disease: The Extremes of Intervention Semin Intervent Radiol. 2014;31(4):313-9. doi: 10.1055/s-0034-1393967. PMID: 25435656 PMCID:PMC4232433. https://pubmed.ncbi.nlm.nih.gov/25435656/

16. Huang TY, Huang TS, Wang YC et al. Direct Revascularization With the Angiosome Concept for Lower Limb Ischemia: A Systematic Review and Meta-Analysis Medicine (Baltimore). 2015; 94(34):e1427. doi: 10.1097/MD.0000000000001427. https://pubmed.ncbi.nlm.nih.gov/26313796/

17. Jongsma H., Bekken J.A., Akkersdijk G.P. et al. Angiosome-directed revascularization in patients with critical limb ischemia J Vasc Surg. 2017; 65(4):1208-1219. doi: 10.1016/j.jvs.2016.10.100. https://pubmed.ncbi.nlm.nih.gov/28342514/

18. Tefera G, Hoch J, Turnipseed WD. Limb-salvage angioplasty in vascular surgery practice. J Vasc Surg. 2005;41(6):988-93. PMID: 15944598 DOI: 10.1016/j.jvs.2005.03.018. https://pubmed.ncbi.nlm.nih.gov/15944598/

19. Osamu Iida, Mitsuyoshi Takahara,Yoshimitsu Soga et al. Three-Year Outcomes of Surgical Versus Endovascular Revascularization for Critical Limb Ischemia The SPINACH Study (Surgical Reconstruction Versus Peripheral Intervention in Patients With Critical Limb Ischemia) on behalf of the SPINACH Investigators (*Circ Cardiovasc Interv*. 2017;10:e005531. DOI 10.1161/CIRCINTERVENTIONS.117.005531.) https://pubmed.ncbi.nlm.nih.gov/29246911/

20. Stavroulakis K, Borowski M, Torsello G. One-Year Results of First-Line Treatment Strategies in Patients With Critical Limb Ischemia (CRITISCH Registry). J Endovasc Ther. 2018; 25(3):320-329. doi: 10.1177/1526602818771383. https://pubmed.ncbi.nlm.nih.gov/29968501/