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LONG-TERM RESULTS AFTER POPLITEAL-PEDAL BYPASS IN DIABETIC FOOT PATIENTS

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Purpose: The evaluation of the long-term results after popliteal-pedal bypass in diabetic foot patients.

Materials and methods. In this retrospective single-center study between January 2011 and June 2016 were selected diabetic patients Wifl 2–3, with chronic limb-threatening ischemia (CLTI) Rutherford III-IV category: men 27 (46,6%), women – 31 (53,4%); average age 68 year $\pm 5,6$ year ($n=58$).

Results. The mean preoperative ABPI was 0.4 to 1,2 and depend of Menkenbergs calcinosis. According to preoperative DUS in all patients were detected occlusive-stenotic lesion on BTK arteries, the type of Doppler spectrum curve on the foot arteries blood flow with lower peripheral resistance ($RI < 0.83$) in 31 (53.4%) patients, blood flow with high peripheral resistance ($RI = 1.0$) – in 19 (32.8%), pedal artery's lumen was detected – in 8 (13.8%). $TcPO_2$ on the foot was (11.2 ± 6.2) mm. Hg. The ABPI were used to evaluate the hemodynamic response after operation, was the good determinant technical success and clinical improvement, but we did not find any correlation with preoperative data. Wound healing after the intervention on the foot during 1–2 weeks occurred in 46 (79.3%), repeated intervention including autodermoplasty made wound healed within 1.5-2 months in 7 (12.1%) patients.

Conclusions. Limb salvage and CLTI patients survival after open surgery who were not performed major amputation after revascularization were comparable regardless of treatment method.

KEY WORDS: diabetic foot popliteal-pedal bypass; acute arterial thrombosis.

Introduction. Peripheral arterial disease (PAD) is a common pathology affecting the vessels of the lower extremities. This condition ranges from asymptomatic to intermittent claudication and, in severe cases, the development of critical limb ischaemia (CLI) [1–3]. PAD is closely associated with diabetes mellitus and atherosclerosis and, as a result, an increased risk of cardiovascular complications and mortality, and its prevalence is increasing annually [4; 5]. As of the early 2010s, PAD was confidently ranked third among the leading causes of cardiovascular disease, second only to coronary heart disease and stroke [6–8].

Recently, the number of studies focusing on improving the treatment of patients with intermittent claudication, the most common symptomatic manifestation of PAD, has increased significantly [9]. However, there is still no consensus on the optimal set of criteria that should be used to evaluate the results of such studies. The absence of a standardised approach makes it difficult to objectively compare the results of different studies and generalise findings for meta-analyses [10; 11]. Despite attempts to systematise and unify the data obtained in studies, in particular, the International Consortium of Vascular Registries consensus recommendations for

peripheral revascularisation registry data collection [12]. Current approaches and generalisations remain too fragmented. They show considerable variability in the proposed indicators and are limited to use in narrow clinical contexts.

According to the International Diabetes Federation, 9.1 million of the world's 26.1 million people suffer from trophic foot ulcers each year. The risk of trophic disorders with foot lesions, of all patients with diabetes is 25% of observations, and according to some studies can reach 34%. To compare on Diabetes WHO (World Health Organization) report 9,1% DM – 4 million persons in Ukraine and 15–25% of DM patients develops diabetic foot [13, 14].

The combination of diabetes mellitus and peripheral artery disease, the number of performed amputations reaches 37–47% of cases, without diabetes is 16.2–22.1%. After major amputations, the average life expectancy of 50% of diabetics is only 2 years, and the 5-year mortality rate is 40–90% of cases [15].

The use of revascularization allows to achieve limb preservation in diabetics with peripheral artery disease for 1 year in 78–85% of cases, and without revascularization in 54% [16].

The aim. The evaluation of the long-term results after popliteal-pedal bypass in diabetic foot patients.

Materials and methods. In this retrospective single-center study between January 2011 and June 2016 were selected diabetic patients Wifl 2–3, with chronic limb-threatening ischemia (CLTI) Rutherford III-IV category: men 27 (46,6%), women – 31 (53,4%); average age 68 year \pm 5,6 year (n=58).

The pre- and post-operation (before discharge, after 6, 12, and 24, 60 months) diagnostics included, in addition to a clinical examination, the Doppler occlusive pressure measurement (Heaco Sonoline C device), with a calculation of the ankle-brachial index (ABPI), Doppler ultrasound (DUS) using Mindray M5, oxygen pressure in the subcutaneous tissue (TcPO₂) using TCM 400 RADIOMETER COPENHAGEN and the determination of routine laboratory parameters or underwent diagnostic angiography using a Philips diagnost 76.

Patients were selected with adequate inflow to the popliteal artery – 50 (86.2%) as defined by presence of one of the following:

- palpable ipsilateral popliteal artery pulse;
- biphasic or triphasic Doppler waveform in the ipsilateral popliteal artery;
- normal radiographic appearance of ipsilateral common femoral and arteria profunda femoris or all detected lesions are < 50% severity stenosis.

Additional we include patients with acute thrombosis of popliteal artery – 8 (13.8%). Popliteal-pedal bypass was done in 58 (100%) patients.

The risk factors that affected the outcome of the procedure were previous intervention on the foot in 11 (18.9%) patients, previous vascular operation in 2 (3.4%) patients, arterial hypertension in 39 (67.2%) patients, myocardial infarction/angina in 43 (74.1%) patients, uncorrected diabetes during hospitalization in 22 (37.9%) patients, smoking in 28 (48.3%) patients, transient ischemic attacks or ischemic stroke in 14 (24.1%) patients, chronic lung disease in 17 (29.3%) patients, and chronic renal failure with a creatinine level of more than 150 μ mol/l in 7 (12.1%) patients.

According to urgent indications in case of secondary infection or moist gangrene of the distal part of the foot, preoperative debridement, incision and drainage with broad spectrum intravenous antibiotics for 5 days, next underwent popliteal-pedal bypass in 5 (8.6%) cases.

In case of non-infected dry necrosis of the fingers, simultaneous popliteal-pedal bypass and intervention on the foot where done in 18 (31.1%).

Indications for delayed intervention on the foot, after popliteal-pedal by were dry gangrene of the fingers with signs of infection, necrosis without demarcation line or infected open wound of the foot in 35 (60.3%).

The study was providing with compliance of Council of Europe Convention on Human Rights and

Biomedicine principles, World Medical Association Declaration of Helsinki on the ethical principles for medical research involving human subjects, and current regulations of the Ministry of Health of Ukraine. All patients signed an informed consent to participate in the study. The study protocol was approved by the local ethics committee.

To analyze the results of the study, when presenting qualitative data, the frequency of the characteristic was calculated in % and its standard error (\pm m), for quantitative characteristics, the mean value (\bar{x}) and standard deviation (\pm SD) were calculated. Fisher's exact test was used to compare the frequency of qualitative features. The risk ratio (RR) indicator was used to assess the clinical effect, and its 95% probability interval (95% PI) was calculated. The critical level of significance was chosen equal to 0.05.

The analysis was carried out in the statistical package MedCalc v. 18.0 (MedCalc Software, Belgium, 1993–2018).

The study performed as a fragment of the complex scientific projects of the Scientific Department of mini-invasive surgery (State Institution of Science "Research and Practical Center of Preventive and Clinical Medicine" State Administrative Department) "Optimization of the specialized and highly specialized surgical medical care provision based on "fast track surgery" principles for certain diseases of the thyroid and parathyroid glands, nasopharynx, abdominal internal and reproductive organs, vessels and joints using atomic forced microscopia and implant prelamination" (state registration number 0119U001046; term: 2019-2021) and "Surgical treatment optimization based on multimodal fast recovery program using nanobiosensoric technologies and anaesthesiological providing" (state registration number 0122U000233; term: 2022–2024).

Results. The mean preoperative ABPI was 0.8 ± 0.4 mm. Hg. and depend of Menkenbergs calcinosis.

According to preoperative DUS in all patients were detected occlusive-stenotic lesion on BTK arteries, the type of Doppler spectrum curve on the foot arteries blood flow with lower peripheral resistance ($RI < 0.83$) in 31 (53.4%) patients, blood flow with high peripheral resistance ($RI = 1.0$) – in 19 (32.8%), pedal artery's lumen was detected – in 8 (13.8%). TcPO₂ on the foot was 11.2 ± 6.2 mm. Hg.

Data on early/late major amputations and death data were retrospectively collected are depicted in Table 1.

The ABPI were used to evaluate the hemodynamic response after operation, was the good determinant technical success and clinical improvement, but we did not find any correlation with preoperative data (Table 2).

Wound healing after the intervention on the foot during 1–2 weeks occurred in 46 (79.3%), repeated

Table 1. Limb surviving following by-pass type

Type of operation	Number of patients, n=58 (100%)	1 year Limb surviving	2 year Limb surviving	5 year Limb surviving	Amputations	Death
Popliteal-dorsalis pedis	38 (63,3%)	38 (100%)	36 (94,7%)	26 (68,4%)	2 (5,3%)	8 (21,1%)
Poplitea-tibialis posterior	14 (23,3%)	12 (85,7%)	11 (78,6%)	1 (7,1%)	2 (14,3%)	5 (35,7%)
Popliteal thrombectomy	4 (6,7%)	4 (100%)	3 (75%)	2 (50%)	1 (25%)	2 (50%)
Thrombolysis	4 (6,7%)	4 (100%)	4 (100%)	4 (100%)	0	1 (25%)

Table 2. Clinical characteristics, intervention and post-operative investigation

Target artery DUS measurements		Initial TcPO2 A6c. (%±m%)	TcPO2 after revascularisation A6c. (%±m%)	1 year Limb survival A6c. (%±m%)	2 year Limb survival A6c. (%±m%)	5 year Limb survival A6c. (%±m%)
Low peripheral resistance (RI < 0.83), n=31 (53.4%)	Popliteal-dorsalis pedis	7.1 ± 2.1 mm. Hg.	28.2 ± 6.1 mm. Hg.	27 (87,1%)	24 (77,4%)	18 (58,1%)
	Poplitea-tibialis posterior					
High peripheral resistance (RI = 1.0) n=19 (32.8%)	Popliteal-dorsalis pedis	15.2 ± 3.1 mm. Hg.	20.1 ± 5.2 mm. Hg.	17 (89,5%)	10 (52,6%)	5 (26,3%)
	Popliteal-tibialis posterior					

intervention including autodermoplasty made wound healed within 1.5–2 months in 7 (12.1%) patients.

Discussion. The reasoning for the present study is the assumption that diabetic patients Wfl 2–3 with chronic limb-threatening ischemia (CLTI) Rutherford V–VI category must go revascularization of the foot arteries (popliteal-pedal bypass) to heal the wound.

Its important of visualizing foot vessels in diabetic patients with limb-threatening ischemia use digital subtraction angiography, since it gives good visualization with a minimum of contrast and patient discomfort [17]. We provide DUS detection of pedal artery's lumen or fine needle angiography by popliteal artery puncture [18].

The optimal revascularization strategy is autogenous vein for open bypass surgery [19]. We use reversible grate saphenous vein (GSV) taken above the knee in 34 (58,7%) case, below – in 24 (41,3%).

For prevention of wound complications at the site of the pedal incision we plane incision 30 mm more proximally to the foot wound.

Wound complications at the site of the distal (pedal) incision have been observed with a incidence of up to 10%, especially in diabetic patients of older age [20, 21].

Also, in our retrospective study where included 8 cases of acute popliteal thrombosis with critical limb ischemia (CLI) threat by open thrombectomy from

popliteal artery next going to popliteal-pedal bypass – 4 (7%) cases; catheter directed thrombolysis [CDT] and within 3–4 days delay popliteal-pedal bypassing – 4 (7%). Catheter-directed thrombolysis (CDT) using urokinase was performed as a below-the-knee revascularization method. During the procedure, a 4F introducer was inserted into the SFA by Seldinger method followed by ultrasound navigation with additional heparinization.

The both treating methods in eight cases received regression of ischemia and good long term results of revascularization.

Conclusions. Limb salvage and CLTI patients' survival after open surgery who were not performed major amputation after revascularization were comparable regardless of treatment method.

Prospects for further research. Future studies should analyze the impact of patient-specific factors, such as comorbidities and glycemic control, on postoperative complications and the percentage of limbs preserved. A comparative analysis of alternative methods of revascularization, including endovascular interventions, can provide valuable information about the most effective treatment strategies. In addition, the development of standardized postoperative care protocols and rehabilitation programs adapted for patients with diabetic foot remains an important area for further research.

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ВІДДАЛЕНІ РЕЗУЛЬТАТИ ПІДКОЛІННО-ГОМІЛКОВОГО ШУНТУВАННЯ В ПАЦІЄНТІВ З ДІАБЕТИЧНОЮ СТОПОЮ

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Мета: оцінювання віддалених результатів після підколінно-гомількового шунтування у хворих на діабетичну стопу.

Матеріали і методи. У ретроспективне одноцентрове дослідження в період із січня 2011 р. по червень 2016 р. були відібрані пацієнти з цукровим діабетом Wfl 2–3, з хронічною ішемією, що загрожує кінцівкам, III–IV ФК за Резерфордом: чоловіків – 27 (46,6%), жінок – 31 (53,4%); середній вік 68 років \pm 5,6 року (n=58).

Результати. Середній передопераційний показник ультразвукової доплерографії становив від 0,4 до 1,2 і залежав від наявності кальцинозу Менкенберга. За даними передопераційної УЗДГ у всіх пацієнтів виявлено оклюзійно-стенотичне ураження артерій гомілки, тип доплерівської спектральної кривої на артеріях стопи – кровотік із низьким периферичним опором ($RI < 0,83$) у 31 (53,4%) пацієнта, кровотік із високим периферичним опором ($RI = 1,0$) – у 19 (32,8%), просвіт гомілкової артерії виявлено у 8 (13,8%). ТсРО2 на стопі становив $(11,2 \pm 6,2)$ мм рт. ст. Показники кістково-плечового індексу, які були використані для оцінювання гемодинамічної відповіді після операції, виявилися гарною детермінантою технічного успіху та клінічного покращення, проте ми не виявили кореляції з передопераційними даними. Загоєння рани після втручання на стопі протягом 1–2 тижнів відбулося у 46 (79,3%), повторне втручання, що включало аутодермопластику, призвело до загоєння рани протягом 1,5–2 місяців у 7 (12,1%) пацієнтів.

Висновки. Збереження кінцівки та виживання пацієнтів із хронічною ішемією, що загрожує кінцівкам після відкритого хірургічного втручання, яким не виконували велику ампутацію після ревазуляризації, були порівнянними незалежно від методу лікування.

КЛЮЧОВІ СЛОВА: діабетична стопа; підколінно-гомілкове шунтування; гострий артеріальний тромбоз.

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