

SURGERY

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The importance of use of endovascular methods in the provision of medical care to patients with critical limb ischemia*K. N. Movchan*^{1,3}, *V. K. Suhov*^{1,2}, *B. S. Artyushin*^{2,3},
*E. A. Shlojdo*², *V. V. Shlomin*^{1,2}, *Yu. M. Morozov*³, *A. A. Levina*¹¹ North-Western State Medical University named after I. I. Mechnikov,
41, ul. Kirochnaya, St. Petersburg, 191015, Russian Federation² St. Petersburg multidisciplinary hospital no. 2,
5, per. Uchebnyy, St. Petersburg, 194354, Russian Federation³ St. Petersburg Medical Informational and Analytical Centre,
30, ul. Shkapina, St. Petersburg, 198095, Russian Federation

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This paper contains general information concerning angiologists activity of St. Petersburg regional vascular centers at the period from 2011 to 2015. In particular specialists' activities assessment obtained by modeling of municipal multi-field hospitals medical assistance are provided for 403 patients with critical limb ischemia. All the patients' arterial beds were affected by atherosclerosis. Open reconstruction of arteries was performed for 278 patients, endovascular revascularization — for 51, and 15 patients underwent hybrid surgery. In 55 cases it was decided to abstain from the revascularization. In case of open surgical services endarterectomy loop formed by aortoiliac and femoropopliteal segments (190) as well as shunting arterial reconstructions (45) prevailed. In case of endoarterial treatment vascular correction was performed in femoropopliteal tibial segments (37 observations). In cases of refusal to reconstruct the arteries, amputation of lower limbs (15) and lumbar sympathectomy (14) was performed. Angiotropic therapy took place in 30 cases. In the early postoperative period, the complications of open surgical treatment were detected in 21.6% of cases; complications of endovascular surgical treatment — in 15% and complications of hybrid surgical treatment — in 13.3% of cases. Among the complications, the vascular thrombosis in the area of their reconstruction (35%) and the lack of blood supply to the limbs tissues in permeate vessels (19.7%) prevailed. No fatal cases were observed. In general, the use of

endovascular and hybrid reconstructions of the vascular bed at the specialized divisions of medical organizations for patients with critical limb ischemia and multifocal atherosclerosis justifies itself.

Keywords: atherosclerosis, critical ischemia, lower extremities, angiography, revascularization, vascular center, hybrid operations, endovascular surgery.

Introduction

Vascular diseases are one of the most frequent causes of death in Russia [1; 2]. In the structure of circulatory system diseases Lower Limbs (LL) amount from 15 to 16 % [3]. Indicators of critical ischemia (CI) development (i.e., pain in the legs at rest, and later the formation of trophic disturbances in LL) allow suspecting the manifestation of changes in the tissue structures of the lower limbs. Propagation of the latter is often possible to prevent only by LL amputation [4]. In Western European countries and in USA up to 30 lower limbs amputations (LLA) per 100 000 of population are annually performed (up to 70 % of total LLA are conditioned by CI) [4]. Forecast for life of diseased, subjected to LLA, are often appeared to be unfavorable. Particularly, indicators of perioperative lethality in case of LLA at the level above knee joint reaches 15–20 %, and in prolonged periods of observation (5 years and over) lethality level varies in the range 50–75 % [3]. In case of the LL CI, the need to restore the blood flow occurs in several arterial segments of the legs [5; 6]. In addition to the ultrasonic triplex scanning that is the most accessible method for evaluating the state of the vascular bed, the information obtained with the help of angiographic studies (direct, computer (CT) and magnetic resonance (MR) angiography) seemed to important and more reliable one. Their implementation ensures detection of the pathological changes in the aorta and its branches at the proper qualitative level [3; 5; 7]. A special role is assigned to angiography in the examination of patients who had previously undergone surgical treatment on arterial vessels. Based on the results of the assessment of the LL arterial status via angiography, decision of the choice of the method of leg revascularization is formed. However, the plurality of comorbidity in the older age group of patients and the repetition of implementation of multi-level surgical treatment on AV via so-called “traditional” (open) access to arterial vessels do not allow subjecting the older patients to another risky treatment without special preparation, and sometimes partial LL revascularization turns out to be insufficient to eliminate their CI. It is not always possible to perform the endovascular surgery with the extended occlusions of the LL arteries. If a success of angio reconstruction is doubtful, the so-called “hybrid” surgical treatment methods are used. They combine the advantages of both open and endovascular access to the zones of LL arterial revascularization [8]. The authors’ data on the results of hybrid surgical treatments application are ambiguous [5]. Therefore, the assessment of the place, role and results of endovascular methods used for examination and treatment of patients with LL CI is a topical area of scientific research for possibilities to increase effectiveness of surgical treatment of patients with multifocal atherosclerosis.

Materials and methods

Medical Information and Analytical Center databases with the data of activities directed on Regional Vascular Centers (RVC) organization in St. Petersburg since 2002 provided the basis for performed study. By 2009, an innovative system of specialized Medical

Care (MC) for patients with circulatory system diseases (mainly, with acute myocardial infarction and acute cerebrovascular disease) was organized in our city. In 2016 35,367 patients at 1,294 beds received medical care in eight regional vascular centers in St. Petersburg (2,888 observations with 8.1% of nosocomial lethality), and 4,988 patients in six primary vascular departments. Particular results of endovascular methods application for treatment patients with LL CI were studied on the basis of the analysis of patient data received from St. Petersburg State Budgetary Healthcare Institution Municipal Multi-Field Hospital no. 2 where there were 383 patients (77% of which are men) on examination and treatment for LL CI from 2013 to 2015. Ratio of patients older than 61 years constituted 70%. Primarily, patients with LL CI diseases seek for medical care for 403 times. In 320 cases patients were hospitalized once, 46 patients were hospitalized twice, 11 patients were hospitalized three times and 5 patients were hospitalized more than 5 times. Repeated hospitalizations were caused by relapses of the CI condition in the treated or contralateral LL. The signs of both lower limbs ischemia were ascertained in case of 19 patients out of 383. Pain in legs without movement mostly disturbed patients in absence of effect when trying to eliminate the pain syndrome with narcotic analgesics. Some patients with such obvious signs of stage III and stage IV lower limbs ischemia as trophic changes in the LL [3] according to Anatoly Pokrovsky were revealed. Cases of stage III lower limbs ischemia were verified in case of patients during 188 hospitalizations with the detection of LL trophic changes (stage IV) in 215 cases (Table 1).

Table 1. Distribution of patients with stage III-IV ischemia of the LL according to Pokrovsky-Fontaine accounting for gender characteristics

Gender groups of patients	Number of patients with LL ischemia		Total
	stage III	stage IV	
men (n-295)	146	164	310
women (n-88)	42	51	93
Total	188	215	403

Necrotic lesions of one of the toes were detected in 37% of cases. In 19% of cases examination revealed the necrosis of two or more toes. Necrosis of all fingers and distal of third part of the feet were detected in 3% of cases with stage IV chronic arterial insufficiency. In 57% of cases duration of the disease did not exceed half a year. Over the time in 70% of cases area of trophic changes in LL of patients significantly increased. Disturbances of trophism of LL tissue for a long time remained unchanged in shape and size in 26% of cases. Among the concomitant pathology for the patients of Municipal Multi-Field Hospital no. 2 on background of CI LL more recently diseases of circulation system were revealed. Ischaemic heart diseases were verified in 68% of all hospitalized patients, myocardial infarction at that undergo one in five (21%) patients. Cerebrovascular disease was observed in 28% of cases, acute cerebrovascular disorder in anamnesis diseased tolerated in 22% of observations. Pancreatic diabetes of the second type was revealed in 23% of cases. Chronic bronchitis and chronic obstructive lung disease were verified in 20% of observations. Laboratory and instrumental studies were carried out in different ways considering the nature of the main and concomitant diseases of patients, and also considering the type of planned surgical treatment. Clinical blood and urine analysis, biochemical

blood analysis were performed in 386, 379 and 384 cases (96, 94 and 95 % from 403 hospitalizations) respectively. Analysis of specified indicator in postoperative period constituted 85, 71 and 76 % respectively. Electrocardiogram control before and after operation constituted 94 and 71 % respectively. Thoracic organs radiography before operation was carried out in 62 % cases. Ray-tracing methods directed on vascular bed visualization for estimate of its passability — direct angiography and computer / magnetic resonance imaging in vascular mode — were performed in 171 and 150 cases (42 and 37 %) respectively. To assess arteries condition of carotid system in 175 cases (43 %) its duplex ultrasonography was performed. Fibrogastroduodenoscopy was performed in 176 observations (43 %).

Blood flow restoration was conducted for 85 and 104 patients of Municipal Multi-Field Hospital no. 2 with a personal history of contralateral and ipsilateral LL respectively. The type of the received surgical treatment was considered in assessing general condition of the LL arterial bed and in choosing appropriate surgical treatment in current hospital admission at a given medical organization. Table 2 and Table 3 presents treatments of contralateral and ipsilateral LL.

Table 2. Distribution of surgical interventions performed on the contralateral LL before patients treatment in Municipal Multi-Field Hospital no. 2 regarding CI

Operations	Number of cases (n-85)
aorto-femoral artery bypass: bilateral/unilateral	19/1
iliac artery semi-closed loop endarterectomy (SCLE)	9
femoral artery SCLE	15
autovenous/prosthesis/combined/ without specifying femoropopliteal bypass	4/4/1/3
prosthesis distal bypass	1
femoroprofundoplasty	1
iliac artery SCLE + femoral artery SCLE	3
iliac artery SCLE + femoropopliteal bypass	1
thrombectomy: primary/secondary	5/2
repeated surgical interventions of the femoropopliteal segment	1
iliac artery endovascular therapy	1
two-level endovascular reconstructions	2
above-knee amputation: primary/secondary	2/10
primary below-knee amputation	1
lumbar sympathectomy	5
other	29
Total	128

On the base of accompanying pathology and general patient condition as well as of planned volume of surgical intervention assessment of anesthetic and surgical risk was performed, which permitted to select optimal anesthetic support. Assessment of surgical intervention risk was carried out in accordance with American society of anesthesiologists (ASA): part of patients with severe systemic disturbances which considerably disturb

Table 3. Distribution of surgical interventions performed on the ipsilateral LL before patients treatment in Municipal Multi-Field Hospital no. 2 regarding CI

Operations	Number of cases (n-104)
open on segments:	
<i>aortoiliac</i>	
aorto-femoral artery bypass: bilateral/unilateral	19/2
iliac artery semi-closed loop endarterectomy	11
without specifying	2
other reconstructions of the aortoiliac segment	4
<i>femoropopliteal</i>	
semi-closed loop endarterectomy (SCLE)	23
autovenous/prosthesis femoropopliteal bypass	
above-knee	1/8
below-knee	4/6
autovenous/prosthesis distal bypass	3/2
prosthetics of the superficial femoral artery	3
without specifying	7
other reconstructions of the femoropopliteal segment	3
two — level vascular reconstructions:	
aorto-femoral artery bypass + femoropopliteal bypass	1
iliac artery SCLE + femoral artery SCLE	2
iliac artery SCLE + femoropopliteal bypass	4
extra — anatomic bypass:	
femoro-femoral crossover bypass	2
extra-anatomic prosthetic-femoral bypass	1
thrombectomy: primary/secondary	3/7
repeated surgical interventions:	
femoropopliteal segment	1
reconstruction of distal anastomosis	1
elimination of reconstruction complications	1
without specifying	1
multiple	5
endovascular on segments:	
<i>aortoiliac</i>	1
<i>femoropopliteal</i>	2
hybrid:	
iliac artery stenting + femoropopliteal bypass above-knee	1
другие	
lumbar sympathectomy	6
secondary below — knee amputation	1
Total	138

patients' organism functionality (3 points on ASA scale) constituted 67.6 %; patients with severe systemic disturbances, producing severe danger for life (4 points on ASA scale) — 20 %. In 7.5 % of observations (in a greater degree, in case of endovascular interventions) risk of anesthesia was not evaluated. Open vascular reconstruction of lower limbs arteries was carried out mainly under general and epidural anesthesia — 53 and 37 % respectively; endovascular surgical interventions in 100 % of cases were performed under local anesthesia. 73 % of hybrid procedures were performed under epidural anesthesia.

Table 4 and Table 5 presents anesthesia risk assessment during surgical treatment of patients with LL CI.

Table 4. Distribution of surgical interventions carried out in Municipal Multi-Field Hospital no. 2, considering risks of anesthesia regarding LL CI

Risk of anesthesia	Number of performed operations					LSE*
	open	endovascular	hybrid	LL amputation		
				below-knee	above-knee	
not evaluated	—	26	2	—	—	—
II/2	2	8	1	—	—	7
III/2	1	2	—	—	1	2
III/3	211	8	9	4	9	5
IV/4	64	3	3	—	1	—
IV/3	4	—	—	—	—	—

* LSE — lumbar sympathectomy

Table 5. Distribution of anesthesia observations accompanying operations accounting for their type in LL CI cases

Type of anesthesia	Number of performed operations					LSE*
	open	endovascular	hybrid	LL amputation		
				below-knee	above-knee	
general	104	—	3	1	4	9
epidural	151	—	11	2	4	3
combined	23	—	—	—	—	—
spinal	4	—	—	1	3	2
local	—	47	1	—	—	—

* LSE — lumbar sympathectomy

In general case, surgery was performed on LL arteries for 328 patients (Table 6). Over the next three years 16 patients required revascularization of LL CI and 2 patients required amputation of contralateral LL. In 278 cases surgical treatment was performed using open method, which in 51 cases was performed using endovascular method and in 15 cases — using hybrid method. While examining 59 patients there were no anatomical substrate for the revascularization, therefore 14 patients underwent the lumbar sympathectomy and 30 patients had a strictly conservative treatment. In 15 cases patient treatment was com-

Table 6. Distribution of operations performed for patients at Municipal Multi-Field Hospital no. 2 in connection with LL CI in 2013–2015.

Surgical interventions	Number of cases (n-387)
open on segments:	282
<i>aortoiliac</i>	
aorto-femoral artery bypass: bilateral/unilateral	10/3
semi-closed loop endarterectomy (SCLE)	40
bilateral SCLE	2
aortoiliac segments open endarterectomy	12
other reconstructions of the aortoiliac segment	5
<i>femoropopliteal</i>	
semi-closed loop endarterectomy	90
autovenous/prosthesis femoropopliteal bypass:	above-knee 2/4
	below-knee 2/3
autovenous/prosthesis distal bypass	5/6
endarterectomy from the common, deep femoral artery, profundoplasty	11
SCLE + femoropopliteal bypass below-knee	18
other reconstructions of the femoropopliteal segment	11
two – level vascular reconstructions	
iliac artery SCLE + femoral artery SCLE	28
iliac artery SCLE + femoropopliteal bypass	3
other reconstructions	1
primary / secondary thrombectomy	3/14
repeated surgical interventions	6
simultaneous operations:	
femoral artery SCLE + carotid endarterectomy	1
other surgical interventions:	2
endovascular on segments:	47
<i>aortoiliac</i>	6
<i>femoropopliteal</i>	37
two – level vascular reconstructions	4
hybrid	15
aortoiliac endovascular therapy + femoropopliteal segment open surgery	4
+ distal endovascular therapy	6
aortoiliac open surgery + femoral artery endovascular therapy	2
femoropopliteal segment open surgery + distal endovascular therapy	3
Total	344

pleted by the primary lower limb amputation — 11 cases at the hip level and 4 cases within the shins.

The aortoiliac segment revascularization was performed in 72 cases, the reconstruction of femoropopliteal tibial segments — in 152 cases, and two-level vascular reconstructions — in 32 cases. The thrombendarterectomy and repeated surgical treatments were performed for 26 patients. Treatment performed using wide access semi-closed loop endarterectomy was performed in most cases (190 cases). The shunt surgical treatments were performed in 45 cases.

Different types of thrombendarterectomy were performed for 17 patients. Nonstandard reconstructive treatments on previously treated vessels were performed for 9 patients. In 47 cases vascular reconstructions were performed endovascularly: on aortoiliac and femoropopliteal tibial segments in 6 and 37 cases, respectively; two-level revascularization was performed in 4 cases; stent implantation was performed in 18 cases; and balloon angioplasty was performed in 29 cases. Hybrid treatment through the common femoral artery was performed in 15 cases with the aim to correct arterial inflow and outflow channel. Permeability of aortoiliac region was restored by means of endovascular repair in 10 cases, and in 2 cases it was restored by means of Vollmar ring. Open endarterectomy from common femoral artery was performed in 3 cases. Reconstruction of arteries' distal sections was performed by means of endovascular and open endovascular repair.

Necrectomy at the stage of hospitalization was performed for 64 patients with stage IV lower limbs chronic ischemia. Feasibility of waiting till distinct demarcation line of necrosis will be formed with repeated hospitalization of patients in order to undertake the surgical treatment conditioned abandoned intent to perform necrectomy (in case of trophic changes presence) for 112 cases. The total number of lower limb amputation constituted 30 (Table 7).

Table 7. Distribution of trophic changes in LL observations, taking into account the volume of operations performed in Municipal Multi-Field Hospital no. 2

Volume of operations	Number of operations
above-/below-knee amputation	21/9
surgical treatment of foot necrosis	64
necrotomy not performed	112
trophic changes were not detected	188
data not available	9

Obtained results and their discussion. Regional vascular centers and primary angio suites bed capacity at St. Petersburg for review period increased from 907 to 1,493. At that, the scope of the medical care provision increased from 21,171 to 40,355 observations, i.e. doubled, and mortality rate has decreased from 10% to 6.8%. Since 2012, on the basis of Municipal Multi-Field Hospital no. 2 five primary angio suites were deployed and authorized department of X-ray surgical methods of diagnosis and treatment. In 2016 they were reorganized into the RVCs. In the period from 2012 to 2016 medical care was provided for 21,814 patients at RVC and primary vascular departments of Municipal Multi-Field Hospital no. 2. Mortality rate ranged from 3.5 to 4.7%, i.e., it appeared to be substantially lower than the similar average parameter for the whole St. Petersburg (Table 8).

Table 8. Parameters of regional vascular center activity at Municipal Multi-Field Hospital no. 2 in the field of cardiology in 2012–2016

Parameters of activity	Quantitative parameters of performance in				
	2012	2013	2014	2015	2016
bed fund	200	200	200	185	150
hospitalized patients	4 115	3 881	4 042	4 297	5 479
of them died	148	162	163	158	260
including in the first 24 hours	27	24	28	38	59
total bed-day	54 592	52 199	51 110	48 332	56 575

Therefore, experience of specialists at regional vascular center of Municipal Multi-Field Hospital no. 2 deserves a special attention. Regional vascular center activity directed at medical care provision for patients with acute myocardial infarction and acute cerebrovascular diseases is prioritized one. Moreover, most large hospitals at St. Petersburg have specialized vascular surgery departments for patients with peripheral arterial pathology, including LL CI. The current level of knowledge in vascular surgery involves application of endovascular technologies for patients with LL CI. For this purpose it is necessary to equip appropriately medical treatment and preventive care institutions with specialized X-ray or so-called “hybrid” operating rooms. Despite the fact that one or two X-ray operating rooms are usually deployed at the hospital, the provision of medical care to patients with peripheral arterial diseases is often carried out by so called leftover principle. Such negative aspects can be surely eliminated with the proper arrangement of medical treatment and preventive care institutions that was proved by experience of medical care provided for patients with LL CI at Municipal Multi-Field Hospital no. 2.

In general, results of endovascular methods application in treatment patients with LL CI and revascularization of the LL arteries at regional vascular center of Municipal Multi-Field Hospital no. 2 in most cases were positive. Carrying out of angiographic control before operation and intraoperatively, as well as scrupulous planning and adherence to the technique of surgical treatment make it possible to achieve success in open vascular reconstructions of the LL arteries in 221 cases (78.4%). Successful LL revascularization using the endovascular methods was detected in 40 cases (85%) and in 13 cases using the hybrid technologies (86.7%). Complications of the surgical restoration of blood flow in the LL arteries in the early postoperative period were ascertained for 70 patients of Municipal Multi-Field Hospital no. 2, along with 91 complications in total (Table 9).

High frequency of postoperative complications for most patients is largely due to a significant incidence of atherosclerotic vascular bed, as well as a pronounced comorbide background of elder and senile patients constituting the large group. The elimination of postoperative complications and their consequences through repeated surgical treatment was performed in 48 cases (Table 10).

For 22 patients complications were mitigated by means of conservative treatment. No fatalities were observed.

Table 9. Distribution of legs revascularization complications due to their LL CI for patients at Municipal Multi-Field Hospital no. 2 in the early postoperative period in 2011–2013

Complications developed in the early postoperative period in the area of vascular reconstruction	Types of surgical interventions (n-70)*		
	open	endovascular	hybrid
	51	6	1
in the areas of postoperative wounds	11	3	1
in abdominal cavity	2	—	—
general medical profile	10	6	—

*70 people, 91 complications

Table 10. Surgical interventions to eliminate postoperative complications of vascular reconstructions

Surgical operations performed on the complications of	Number of attempts to correct complications of vascular reconstructions		
	1 st	2 nd	3 rd and more
open vascular reconstructions	42	11	2
endovascular technologies	5	1	2
hybrid vascular methods	1	—	—
Total	26	29	4

Conclusion

Increased quality level of cardiologic and cardiosurgery assistance provided for Russian population permitted considerably reduce rate of fatal cases within patients with cardiovascular system pathology. Equipment of medical institutions in the period of the national “Health” project measures implementation, within the program of regional health care institutions modernization, as well as increased professionalism of doctors, which obtained possibility to use modern high-technology equipment and opportunity for purposeful training endovascular methods, made it possible to provide medical assistance for patients with LL CI at qualitatively new level. Angiography data used at regional vascular center before and during surgery for the patients with LL CI allow focusing on the state of LL arterial vessels of patients by providing information required for differential selection of LL revascularization method. Performing endovascular and hybrid operations for patients with multifocal atherosclerosis, especially in cases of multiple concomitant pathologies at the stage of decompensation, reliably prevents the possible postoperative complications and creates new opportunities for improving of long-term results of treatment patients with LL CI at regional vascular centers.

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Author's information:

Konstantin N. Movchan — MD, Prof.; movchank@miac.zdrav.spb.ru
Valentin K. Sukhov — MD, Prof.; suhov_vk@mail.ru
Boris S. Artyushin — PhD, Assoc. Prof.; artyushin_boris@mail.ru
Evgeny A. Shlojdo — PhD; shl_evan@mail.ru
Vladimir V. Shlomin — PhD; shlominv@gmail.com
Yury M. Morozov — MD, Prof.; morozovyun@miac.zdrav.spb.ru
Aleksandra A. Levina — post-graduate student; Levina_AlAn@mail.ru