Research Article

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Endovascular Stent Thrombectomy in Patients With Acute Lower Limb Arterial Thrombosis on the Background of COVID-19

I.S. Semyin[1], A.N. Ivanenko[1], A.S. Zharova[2], V.A. Pyatkov[1], I.L. Bakhtin[1], G.A. Sobolev[1], A.D. Kiselev[1], A.V. Korotkikh[3], A.N. Kazantsev[4] ✉, K.P. Chernykh[4]

Department of Cardiovascular Surgery
[1] Arkhangelsk Regional Clinical Hospital
292, Lomonosov Ave., 136045, Oktyabrsky District, Arkhangelsk, Russian Federation
[2] I.I. Mechnikov North-Western State Medical University
41, Kirochnaya Str., 191015, Str. Petersburg, Russian Federation
[3] Amur State Medical Academy
95, Gorkogo Str., 675000, Blagoveshchensk, Russian Federation
[4] City Alexandrovskaya Hospital
4, Solidarnosty Ave., 193312, Str. Petersburg, Russian Federation

✉ **Contacts:** Anton N. Kazantsev, Cardiovascular Surgeon, Department of Cardiovascular Surgery, Alexander City Hospital. Email: dr.antonio.kazantsev@mail.ru

AIM Analysis of the outcomes of endovascular stent thrombectomy in patients with acute arterial thrombosis of the lower extremities on the background of COVID-19.

MATERIAL AND METHODS This retrospective study for the period from January 1, 2020 to March 1, 2022 included 34 patients with acute lower limb ischemia who were diagnosed with the novel coronavirus infection SARS-COV-2. Endovascular stent thrombectomy was performed according to the standard technique using a Destination 8F guiding sheath (Terumo), an Advantage 0.014`` guidewire (Terumo), and a Casper stent (Microvention, Terumo) as a stent retriever. In case of fragmentation of thrombotic masses in the guide sheath, manual aspiration of thrombi was performed using a standard 50,0 ml syringe. Self-expanding nitinol stents were implanted in 11 clinical cases.

RESULTS Intraoperative bleeding from the puncture site of the artery developed in 14.7% of cases, which required additional manipulation to achieve hemostasis. Every tenth (11.8%) patient developed myocardial infarction, in 2.9% of cases — ischemic stroke. In the hospital postoperative period during the first hours after surgery, 26.5% of patients developed rethrombosis which required re-intervention. In 8.8% of cases, retrombectomy was unsuccessful, and limb amputation was performed. A fatal outcome occurred in 67.6% of cases, which was due to an increase in multiple organ failure and the development of sepsis.

CONCLUSION Endovascular stent thrombectomy is characterized by a low risk of rethrombosis and amputation in the context of COVID-19.

Keywords: thrombosis, arterial thrombosis, thrombectomy, acute thrombosis, acute ischemia, COVID-19, coronavirus, SARS-COV-2, stent thrombectomy, stent retriever

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Affiliations

Igor S. Semyin	Endovascular Surgeon, Arkhangelsk Regional Clinical Hospital; https://orcid.org/0000-0001-5762-4883, kor01777@yandex.ru; 20%, article writing
Alexander N. Ivanenko	Endovascular Surgeon, Arkhangelsk Regional Clinical Hospital; https://orcid.org/0000-0001-6839-207X, best_angiosurgery@mail.ru; 10%, literature review
Alina S. Zharova	Student, I.I. Mechnikov North-Western State Medical University; https://orcid.org/0000-0001-9474-4972, zharova.alina2018@yandex.ru; 12%, text editing
Vasily A. Pyatkov	Endovascular Surgeon, Arkhangelsk Regional Clinical Hospital; https://orcid.org/0000-0001-6839-207X, best_angiosurgery@mail.ru; 10%, literature review
Igor L. Bakhtin	Candidate of Medical Sciences, endovascular surgeon, Arkhangelsk Regional Clinical Hospital; https://orcid.org/0000-0003-0195-6082, aaapppmmmooo@gmail.com; 9%, text editing

Gleb A. Sobolev	Endovascular Surgeon, Arkhangelsk Regional Clinical Hospital; https://orcid.org/0000-0002-4826-0501, gibgrid@mail.ru; 8%, writing part of the article
Andrey D. Kiselev	Endovascular Surgeon, Arkhangelsk Regional Clinical Hospital; https://orcid.org/0000-0002-2603-9902, givchikov8@gmail.com; 7%, literature review
Alexander V. Korotkikh	Chief Physician, Clinic of Cardiac Surgery, Amur State Medical Academy; https://orcid.org/0000-0002-9709-1097, ssemioo@rambler.ru; 7%, statistical analysis
Anton N. Kazantsev	Cardiovascular Surgeon, Department of Cardiovascular Surgery, City Alexandrovskaya Hospital; https://orcid.org/0000-0002-1115-609X, dr.antonio.kazantsev@mail.ru; 6%, article writing
Konstantin P. Chernykh	Cardiovascular Surgeon, Department of Cardiovascular Surgery, City Alexandrovskaya Hospital; https://orcid.org/0000-0002-5089-5549, cvs.doc@yandex.ru; 6%, approval of the final version of the article

AAI - acute arterial insufficiency
ACVA - acute cerebrovascular accident
ATA - anterior tibial artery
CABG - coronary artery bypass grafting
CDS - color duplex scanning
CEA - carotid endarterectomy
CFA - common femoral artery
CIA - common iliac artery
CKD - chronic kidney disease
COPD - chronic obstructive pulmonary disease
CT - computed tomography
EIA - external iliac artery
DM - diabetes mellitus
DPA –dorsalis pedis artery
i / v – intravenously
PTA - posterior tibial artery
PA - peroneal artery
MI - myocardial infarction
MSCT - multislice computed tomography
PCI - percutaneous coronary intervention
PopA - popliteal artery
PCR - polymerase chain reaction
RNA - ribonucleic acid
SFA - superficial femoral artery
TIA - transient ischemic attack
TPT – tibioperoneal trunk

INTRODUCTION

The COVID-19 pandemic has changed the understanding of the medical community about the genesis of arterial thrombosis. SARS-COV-2 causes three pathological processes: coagulopathy, endothelitis, and systemic inflammation [1–5]. A gradual increase in the severity of the disease can lead to arterial thrombosis of various localizations [1–5]. Available publications report the low efficiency of existing revascularization techniques under these conditions and the high risk of recurrent thrombosis and limb amputation [6–10].

Currently, data on the outcomes of various methods of thrombectomy is not enough to make a final conclusion about the greater efficiency of a particular reperfusion technique. The most current recommendations for acute limb ischemia (European Society for Vascular Surgery (ESVS) 2020) refer to the use of puncture mechanical thrombectomy (class of recommendations IIA, level of evidence B) in acute lower limb ischemia, which includes, among other things, endovascular stent thrombectomy [11].

The aim of this study is to analyze the outcomes of endovascular stent thrombectomy in patients with acute lower extremity arterial embolism on the background of COVID-19.

MATERIAL AND METHODS

This retrospective study for the period from January 1, 2020 to March 1, 2022 included 34 patients with acute lower limb ischemia who were diagnosed with the novel coronavirus infection SARS-COV-2. Thrombosis was visualized using color duplex scanning (CDS), a number of patients were assessed utilizing multislice computed tomography (MSCT) with intravenous (IV) contrast enhancement. All the patients underwent endovascular stent thrombectomy.

The choice of the endovascular approach in the treatment of this category of patients was due to less invasiveness, a decrease in the need for general anesthesia and earlier activation in the postoperative period compared to traditional intervention.

The inclusion criteria for the study were as follows:

1. The presence of acute limb ischemia due to thrombosis or thromboembolism of the arteries of the lower extremities;
2. Viable lower limb: the presence of venous blood flow during CDS.
3. Positive result of the polymerase chain reaction for the presence of SARS-CoV-2;
4. Viral pneumonia according to MSCT of the chest organs.

Criteria for exclusion from the study:

1. The terminal state of the patient.
2. Contraindications for the prescription of anticoagulant and antiplatelet therapy.
3. Irreversible lower limb ischemia.

The treatment regimen (initial therapy) of the patient was determined according to the recommendations of the leading scientific communities which basically included heparin therapy, acetylsalicylic acid and clopidogrel. If clopidogrel proved ineffective, it was replaced with ticagrelor therapy, a single loading dose of 180 mg. Also, ticagrelor was prescribed on a baseline basis when antiplatelet therapy was not performed preoperatively. If there were indications for anticoagulant therapy, acetylsalicylic acid was canceled and apixaban was administered.

Endovascular stent thrombectomy was performed according to the standard technique using a Destination 8F guiding sheath (Terumo), an Advantage 0.014`` guidewire (Terumo), and a Casper stent (Microvention, Terumo) as the stent retriever. In case of fragmentation of thrombotic masses in the guide sheath, manual aspiration of thrombi was performed using a standard 50,0 ml syringe.

Self-expanding nitinol stents were implanted in 11 clinical cases.

The indications for implantation were as follows:

- the presence of residual thrombotic mass, flow-limiting dissection of the intima;
- the presence of an atherosclerotic lesion of the iliac segment subject to stenting;
- unsatisfactory result of balloon angioplasty of the arteries of the femoral-popliteal segment.

The hospital postoperative period in the total sample was 23.5±6.5 days. The primary endpoints were: death, rethrombosis, re-thrombosis after rethrombectomy, amputation, secondary myocardial infarction (MI), acute cerebrovascular accident (ACVA), bleeding of various localization requiring transfusion.

All patients signed a written consent to participate in the study, as well as a voluntary informed consent of a citizen to use the tools "outside the instructions" ("off-label"). The work was performed in accordance with the Good Clinical Practice standards and the principles of the Declaration of Helsinki; it did not contradict the Federal Law of the Russian Federation dated November 21, 2011 No. 323-FZ "On the Basics of Protecting the Health of Citizens in the Russian Federation", Order of the Ministry of Health of the Russian Federation dared April 1, 2016 No 200n "On Approval of the Rules of Good Clinical Practice".

The majority of patients in the sample were predominantly elderly and male. Most often acute ischemia class I and IIa (the Rutherford Classification for Acute Limb Ischemia) were registered. All the patients with acute ischemia class IIb (the Rutherford Classification) underwent fasciotomy. Less than half of the patients suffered from diabetes mellitus (DM). Every tenth patient had a history of ischemic stroke or myocardial revascularization (Table 1).

Table 1

Clinical and anamnestic indicators

Indicator	*n*=34
Age, M±m, years	69,32±9,12
Male sex, n (%)	21 (60,4)
The Rutherford Classification for AAI, n (%):	
I	16 (47)
IIA	11 (32,4)
IIB	7 (20,6)

DM, n (%)	13 (38,2)
COPD, n (%)	1 (2,9)
CKD, n (%)	2 (5,9)
PCI in history, n (%)	4 (11,8)
CABG in history, n (%)	2 (5,9)
ACVA/TIA in history, n (%)	4 (11,8)
CEA in history, n (%)	1 (2,9)
The content of oxygen in the blood, M±m, %	93,05±4,61
Mechanical ventilation, n (%)	4 (11,8)
Intraoperative indicators	
Operation duration, M±m, min	98,91±45,48
General anesthesia, n (%)	6 (17,6)
Volume of contrast medium, M±m, ml	358,82±105.5
Stent implantation, n (%):	11 (32,4)
Casper (Terumo)	6
Smartflex (Cordis)	1
Easy HiFlype (ALVIMEDICA)	4

Notes: CABG — coronary artery bypass graft; CEA - carotid endarterectomy; AAI - acute arterial insufficiency; ACVA - acute cerebrovascular accident; DM - diabetes mellitus; TIA - transient ischemic attack; CKD - chronic kidney disease; COPD - chronic obstructive pulmonary disease; PCI - percutaneous coronary intervention

The duration of surgery in most cases did not exceed 2 hours. Every fifth patient underwent general anesthesia. Stent implantation was performed in one third of the cases (see Table 1).

OUTCOMES

According to laboratory parameters, an inflammatory syndrome (leukocytosis, elevated C-reactive protein, elevated ferritin), coagulopathy (elevated D-dimer) were noted (Table 2).

Table 2

Laboratory parameters

Indicator	*n*=34
Leukocytes, M±m, x109/L	14.04±5.61
Platelets, M±m, x109/L	242.19±105.71
Ferritin, M±m, ng/mL	643.40±300.20
D-dimer, M±m, ng/mL	166.85±9.08
C-reactive protein, M±m, mg/L	87.06±69.02

Most often thrombosis (41.2%) was localized in the popliteal segment, in every fifth patient – in the common iliac artery (CIA) or superficial femoral artery (SFA) (Table 3).

Table 3

Localization of occlusion

Localization	*n*=34
CIA, n (%)	6 (17.7)
EIA	4 (11.8)
CFA	2 (5.9)
SFA	8 (23.5)
Popliteal segment	14 (41.2)

Notes: EIA — external iliac artery; CFA - common femoral artery; CIA - common iliac artery; SFA - superficial femoral artery

Intraoperative bleeding from the puncture site of the artery developed in 14.7% of cases, which required additional manipulation to achieve hemostasis. Every tenth patient (11.8%) developed MI, and 2.9% developed ischemic stroke (Table 4).

Table 4

Complications throughout the procedures

Indicator	*n*=10
MI, n (%)	4 (11.8)
ACVA, n (%)	1 (2.9)
Bleeding requiring transfusion, n (%)	5 (14.7)

Notes: ИМ — myocardial infarction, ОНМК — acute cerebrovascular accident;

In the hospital postoperative period during the first hours after surgery, 26.5% of patients developed rethrombosis which required repeated intervention. In 8.8% of cases, retrombectomy was unsuccessful, limb amputation was performed. A fatal outcome developed in 67.6% of cases, which was due to an increase in multiple organ failure and the development of sepsis (Table 5).

Table 5

Procedural success and failure

Indicator	*n*=34
Retrombosis requiring unplanned revascularization, n (%)	9 (26,5)
Lethal outcome, n (%)	23 (67,6)
Thrombosis after retrombectomy, n (%)	6 (17,6)
Amputation, n (%)	3 (8,8)

Case Study #1

Patient K., 80 years old, was admitted to the department for the treatment of patients with the novel coronavirus infection on March 1, 2021 with complaints of right lower limb pain in the region of the lower leg and foot at rest. From the anamnesis: fell ill on February 16, 2021, noted an increase in body temperature to 38 ° C, the presence of catarrhal phenomena in the nasopharynx. Examined at home by a local therapist, a PCR study of a smear from the nasopharyngeal mucosa was performed, RNA+ dated February 18. On February 21, 2021 the patient was hospitalized to the central district hospital at the place of residence. CT examination of the chest detected bilateral polysegmental viral pneumonia. As a result of the treatment, the body temperature returned to normal. On February 28, 21, pain suddenly appeared in the right shin. On March 1, 21, the patient was examined by a surgeon, color duplex scanning (CDS) of the lower limb arteries revealed occlusion of the popliteal artery and the main arteries of the shin. The patient was examined by a vascular surgeon, the diagnosis was verified: acute thrombosis of the popliteal artery (PopA), tibial arteries of the right lower limb. The Rutherford class I right lower limb acute ischemia. A decision was made to perform endovascular stent thrombectomy, heparin therapy was started (7500 IU of unfractionated heparin i.v. bolus), 125 mg of acetysalicylic acid and 300 mg of clopidogrel were administered orally. On March 2, 2021, the patient was taken to the X-ray operating room.

Under local anesthesia, an antegrade puncture of the right common femoral artery was performed, an introducer sheath (6F Terumo Destination) was inserted. According to the performed angiography (Fig. 1A), occlusion of the proximal PopA was revealed, filling of the collateral branches was noted distally, the main arteries of the shin were not visualized.

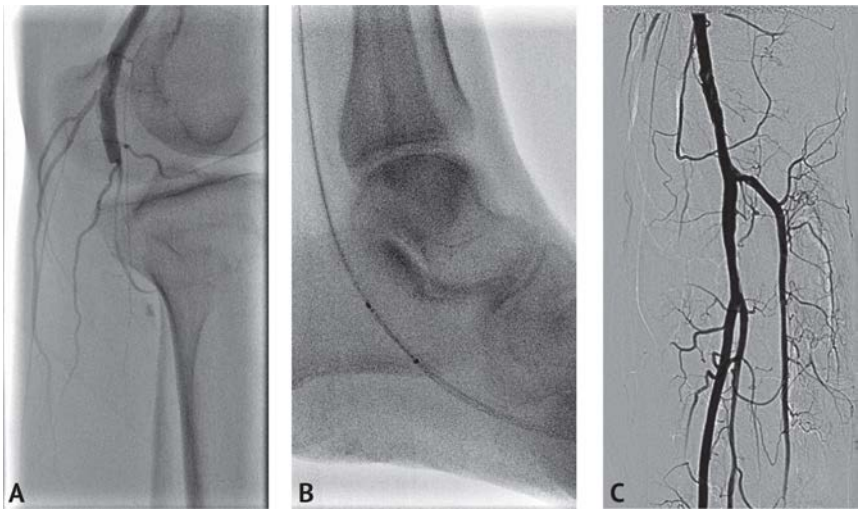

Fig. 1. Angiograms during the intervention: A — popliteal artery embolic occlusion; B — partially released stent retriever in the lateral plantar artery; C — final angiographic result in the projection of the bifurcation of the popliteal artery

The endovascular treatment strategy was chosen taking into account the possibility of controlled manipulation into all affected arteries using various endovascular technologies. The introducer sheath was replaced with a guiding catheter 8F 65 cm, its tip was placed in the proximal part of the thrombus. An Advantage 0.014`` guidewire (Terumo) was passed through thrombotic occlusion of the PopA, tibeoperitoneal trunk (TPT) into the distal posterior tibial artery (PTA). A Casper stent was inserted into the lateral plantar artery (Fig. 1B), its partial release was performed, followed by traction. A similar manipulation was performed in the basins of the anterior tibial (ATA) and peroneal arteries (PA). During control contrasting: the lumen of the main arteries of the right lower limb was restored, the blood flow was satisfactory (Fig. 1C). All catheters and introducers were removed. Hemostasis was performed using an AngioSeal hemostatic puncture closure device. A pressure aseptic bandage was applied.

On the 4th day, the patient's condition showed significantly positive dynamics: the skin of the right lower limb was warm, pale pink, movements and sensitivity restored in full. After a negative PCR test for the novel coronavirus infection, the patient was transferred to the central district hospital at the place of residence.

Case Study #2

Patient K., 70 years old, was taken to the emergency department on 11/27/2021 with complaints of first-time sharp pains in the right lower limb; on 11/26/2021, its coldness and decreased sensitivity. CDS of the right lower limb arteries revealed occlusion of the distal segment of the SFA. Express testing for the novel coronavirus infection gave a positive result. In the conditions of the emergency department, heparin therapy was started (7500 IU of unfractionated heparin i.v. bolus), 300 mg of clopidogrel and 125 mg of acetylsalicylic acid were administered orally, the patient was taken to the X-ray operating room for revascularization of the right lower limb.

Under local anesthesia, an antegrade puncture of the right common femoral artery (CFA) was performed, an introducer sheath (6F Terumo Destination) was inserted. Angiography revealed occlusion from the level of the proximal PopA with no filling of the distal sections of the main arteries of the shin (Fig. 2A).

Fig. 2. Angiograms during the intervention. A — primary angiography: popliteal artery embolic occlusion; B — partially released stent retriever in the dorsalis pedis artery; C — angiography of the dorsalis pedis artery; D — final angiography of the foot

The introducer sheath was replaced with a guiding catheter 8F 65 cm. An Advantage 0.014`` guidewire (Terumo) was passed through thrombotic occlusion of the PopA, TPT into the distal posterior tibial artery (PTA). A Casper stent was inserted into the lateral plantar artery, its partial release was performed, followed by traction. A similar manipulation was performed in the basins of the anterior tibial (ATA) (Fig. 2B) and peroneal (PA) arteries. The Advantage 0.014`` guidewire (Terumo) was re-inserted from the ATA through the plantar arch into the PTA, a Coyote OTW 2.0x150 mm balloon catheter was delivered through it, dilatation was performed at a pressure of 6 atm., exposure for 120s. The ATA and PTA were dilated throughout the entire length with a balloon catheter Coyote OTW (Boston Scientific) 3.0x220 mm. Selective angiography of the arteries of the foot was performed: DPA, plantar arch and lateral plantar artery were patent (Fig. 2C). Control angiography revealed that blood flow to the artery of the shin and foot was restored without residual stenoses and intimal dissections (Fig. 2D).

The early postoperative period was uneventful in the conditions of the infectious disease department for patients with the novel coronavirus infection, heparin therapy was performed under the control of activated partial thromboplastin time (77.5 from 11/28/2021).

At 14.20 on November 29, 2021, complaints of pain and numbness of the right lower limb appeared. Performed CDS revealed rethrombosis of the right lower limb arteries at the level of the proximal RCA. Clopidogrel was canceled, 180 mg of ticagrelor was administered orally, the patient was taken to the X-ray operating room.

Under local anesthesia, an antegrade puncture of the right CFA was performed, an introducer sheath (6F Terumo Destination) was installed. Angiography revealed PopA reocclusion (Fig. 3A).

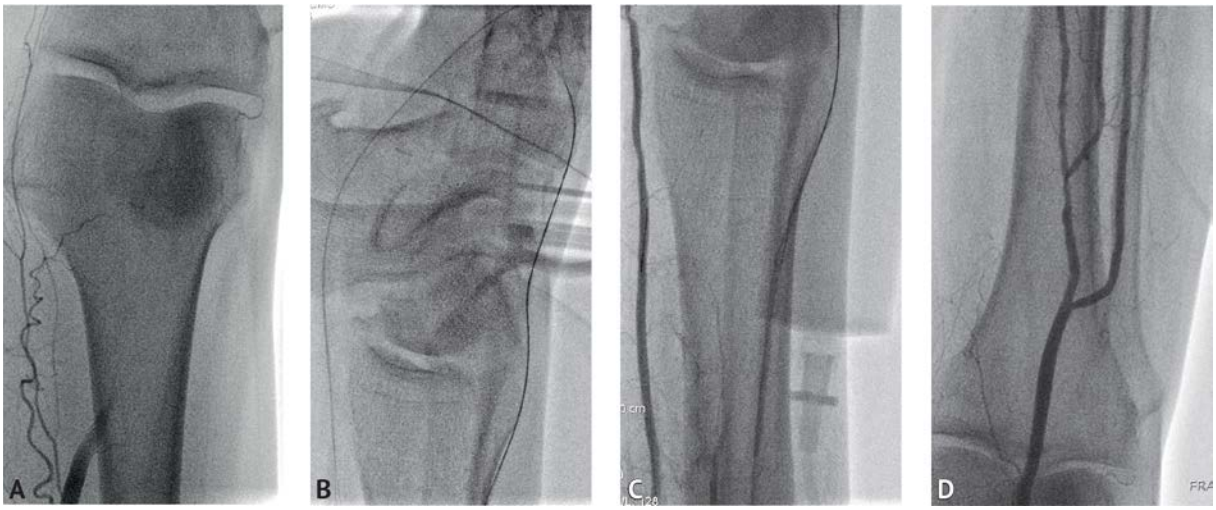

Fig. 3. Angiograms during re-intervention for lower limb arterial retrombosis. A — rethrombosis of the popliteal artery; B — a guide carried out from the posterior tibial artery through the plantar arch in the dorsalis pedis artery; C — angiography of the tarsal arteries; D — final outcome

The introducer sheath was replaced with a guiding catheter 8F 65 cm. Recanalization of the thrombosis zone was performed with an Advantage 0.014`` guidewire (Terumo), stent thrombectomy was performed alternately from the PopA, TPT, PA, PTA, and ATA basins, and thrombotic material was obtained (Fig. 4).

Fig. 4. Intraoperative photo: Thrombotic substrate of acute limb ischemia extracted using a Casper stent (Microvention, Terumo) and a Destination 8F guiding sheath (Terumo)

The guidewire from the ATA through the dorsalis pedis arteries (DPA) was retrogradely re-inserted into the distal part of the PTA (Fig. 3B), a Coyote OTW 2.0x150 mm balloon catheter was delivered through it, dilatation was performed with a pressure of 6 atm., exposure for 120 sec. Control angiography revealed that blood flow to the arteries of the shin and foot was restored without residual stenoses and intima dissections (Fig. 3C, D).

The postoperative period was uneventful, during the day heparin was administered intravenously using a microfluidic device, then the patient was transferred to oral administration of apixaban, acetylsalicylic acid was canceled.

Control CDS on 12/01/2021. The study was carried out in the ward, on a portable apparatus. Condition after endovascular stent thromboextraction on the right lower limb arteries. The iliac arteries, CFA, SFA, DFA, PopA, PTA, ATA, DPA are passable, artery walls are thickened, increased echogenicity, no obstruction to blood flow was detected in their projection, the main type of blood flow is recorded.

12/02/2022 and 12/03/2022 — a negative PCR test for the novel coronavirus infection, but the fever persisted up to 38°C. Chest CT scan revealed bilateral viral pneumonia, the patient received antiviral and antibiotic therapy, was under the supervision of a general practitioner and a vascular surgeon, and discharged on December 10, 2021 in a satisfactory condition for outpatient treatment by a general practitioner at the place of residence.

DISCUSSION

In Russia, the most common revascularization strategy for acute limb ischemia today is Fogarty catheter thrombectomy [12–16]. However, studies on the use of this method against the background of COVID-19 reflect low efficacy and safety. In particular, the vast majority of domestic publications demonstrate the incidence of rethrombosis reaching 90% after open surgical thrombectomy [5–8, 10]. The results of our study using the endovascular technique showed more optimal outcomes of revascularization. This is most likely due to several factors. Firstly, this procedure is not as invasive as the open surgery, which excludes the progression of the inflammatory syndrome caused by surgical exposure. Secondly, the ability to intraoperatively monitor the state of the peripheral bloodstream and the quality of the implemented revascularization makes it possible to achieve a more convincing outcome, which cannot be achieved with the "blind" insertion of the Fogarty catheter during open thrombectomy. Thus, the presented data prove the high efficiency of the endovascular treatment strategy for acute thrombosis of the lower limb arteries against the background of COVID-19, which is of high practical importance for the medical community in the present conditions.

CONCLUSION

Endovascular stent thrombectomy is characterized by a low risk of retrombosis and the need for amputation in the context of COVID-19.

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