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Comparative characteristics of postoperative outcomes of different treatment strategies of patients with intermittent claudication in combination with coronary arteries disease

Aim To compare in-hospital outcomes (severe cardiovascular complications, CVC) in patients with IIB stage chronic lower limb ischemia (CLLI) in combination with ischemic heart disease (IHD) in the following groups: stepwise percutaneous coronary intervention (PCI) and stenting and angioplasty of lower limb arteries (LLA) (group 1) and combination treatment, including PCI and open surgery on LLA (group 2).

Material and Methods Since 2019, the A. V. Vishnevsky National Medical Research Center of Surgery has performed a retrospective study that includes patients with stage IIB CLLI in combination with IHD. Patients were divided into 2 groups: group 1 (n=46), stepwise X-ray endovascular treatment (PCI and stenting and angioplasty of LLA); group 2 (n=46), stepwise combination treatment (PCI and open surgery on LLA). The endpoint included severe CVCs (death, acute myocardial infarction, acute cerebrovascular disease) and severe complications in the LLA area (stent thrombosis, repeated intervention on LLA, amputation).

Results In 198 surgeries, none of 92 patients had severe CVC, and no fatal outcomes were observed. In group 2, there was one (2.1%) severe complication on LLA during the early postoperative period, for which a successful additional intervention was performed.

Conclusion Individualized approach to care of each patient with LLA pathology in combination with IHD helps avoiding severe CVCs at the hospital stage. It was shown that X-ray endovascular and combination treatments are safe and effective in the absence of fatal outcomes and acute disorders of coronary circulation at the hospital stage.

Keywords Chronic lower limb ischemia; ischemic heart disease; cardiovascular complications

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Introduction

There is currently no consensus on how to treat patients with chronic lower limb ischemia (CLLI) stage IIB and concomitant hemodynamically significant coronary artery involvement. Both the available Russian and foreign publications present controversial opinions. Nevertheless, despite the controversy, authors highlight the need to conduct cardiovascular examination in patients with CLLI, since coronary artery disease (CAD) is the most common concomitant disease in these patients [1, 2].

According to the Swedish National Patient Register, the annual CLLI death rate is 1.9%, with one in three patients having CAD [3]. In the Russian Federation (RF), cardiovascular mortality is particularly high when compared to the European mean value (55.7% versus 46%, which translates to approximately 1 million deaths annually) [4].

The incidence of lower limb arterial pathologies rises as the number of risk factors for cardiovascular diseases grows [5]. According to the 2017 European Society of Cardiology (ESC) guideline, patients with lower limb arterial are likely to have clinically significant CAD in 25–72% of cases, while patients with CAD are likely to have lower limb atherosclerosis in 7–16% of cases [6].

Alekian et al. [7] presented the results of a study in 693 patients with aortic and peripheral arterial pathologies who underwent selective coronary angiography (CAG) at the A. V. Vishnevsky National Medical Research Center for Surgery in 2017–2018 (20 months). CLLI and critical limb ischemia (CLI) were found in 398 patients. Selective CAG

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revealed a more than 50% lesion of at least one coronary artery in 320 (80.4%) of patients. Lower limb artery and coronary artery revascularization was performed in 179 (55.9%) of 320 patients.

It is noteworthy that, in the absence of timely treatment, 21% of patients with CLLI develop CLI within 5 years, while 4–27% of patients undergo limb amputations [8]. The main treatment task in CLLI is reducing the risk of adverse cardiovascular events and improving the quality of life of patients, as well as preserving their limbs.

For many years, the only revascularization technique for patients with CLLI has been open vascular surgery. However, changes in the management of patients with CLLI taking place over the past decade have been possible mainly owing to the advances in endovascular surgery, increasing number of endovascular interventions and new treatment algorithms using the best possible drug therapy. According to Alekian et al. [9], the number of endovascular interventions has significantly increased in recent years in the Russian Federation. In 2008, 32,519 percutaneous coronary intervention (PCI) procedures and 3,590 lower limb endovascular surgeries were conducted in the Russian Federation, compared to 254,368 and 24,271, respectively, in 2019 [10].

Earlier, we published the direct results of X-ray endovascular interventions (step-by-step PCI and lower limb angioplasty and stenting) [11] and combined interventions (PCI and open lower limb arterial surgeries).

Objective

To perform comparative analysis of hospital outcomes (severe adverse cardiovascular events) in the following patient groups: step-by-step PCI, lower limb angioplasty and stenting (Group 1) and combination of PCI and open lower limb arterial surgeries (Group 2).

Material and Methods

92 patients with CLLI stage IIB and CAD were treated in A.V. Vishnevsky National Medical Research Center for Surgery between January 2017 and December 2020. Treatment tactics in the study group of patients was determined by the cardiovascular team of the Center.

Inclusion criteria comprised: combined hemodynamically significant lower limb arterial pathologies stage IIB (according to the Fontaine-Pokrovsky classification) and coronary artery involvement in patients who underwent step-by-step interventions in two vascular systems using different surgical techniques; the absence of a positive effect of the best possible drug therapy, such as increased pain-free walking distance; informed consent to take part in the study signed by the patient or the patient's legal representative.

Exclusion criteria comprised: isolated coronary artery anomalies or only CLLI; contraindications to dual antiplatelet therapy; acute coronary syndrome at the time of hospitalization.

Two groups of patients were formed depending on the chosen treatment tactics: Group 1 (n=46, or 50%) – step-by-step X-ray endovascular treatment: PCI and lower limb angioplasty and stenting; Group 2 (n=46, or 50%) – step-by-step combination treatment: PCI and open lower limb arterial surgery. The study was approved by the ethics committee of the Center. Patients signed informed consent.

The following factors were taken into consideration when selecting a coronary revascularization technique: functional class of angina according to the Canadian Cardiovascular Society classification; anatomy of the coronary anomaly; left ventricular ejection fraction; the presence/absence of valvular pathology; a history of acute myocardial infarction (MI); the presence of other peripheral artery pathologies; age; body mass index.

The choice of technique for lower limb arterial revascularization was informed by the 2017 ESC Guideline on the treatment of lower limb arterial pathology, according to which the treatment strategy is determined based on the length of arterial lesions. However, it should be noted that endovascular intervention can also be considered in some patients for whom open surgery is contraindicated (class IIb, level C).

All patients underwent the following non-invasive diagnosis: multi-slice computed tomography; echocardiography; duplex scanning. Among 92 patients, 70 (76%) were male, while 22 (24%) were female. The mean age of patients was 65.7±7.7 years (median 66 years; 95% confidence interval (CI) 64–67): 22 (47.8%) patients were aged from 45 to 59 years old, 58 (63.0%) patients were aged from 60 to 74 years, while 12 (13.0%) patients were between 75 and 85 years old. Exertional angina functional class (FC) II–III (CCS) and painless myocardial ischemia were detected in 72 (78.2%) and 20 (21.8%) patients, respectively. A history of MI was reported in 26 (28.2%) patients. Single-vessel coronary lesion (more than 50% narrowing) was diagnosed in 23 (25%) patients, while two-vessel and three-vessel coronary lesions were identified in 34 (36.9%) and 35 (38%) patients, respectively. Only 2 (2.1%) patients had undergone coronary artery bypass grafting (CABG).

Unilateral and bilateral lower limb arterial pathologies were found in 72 (78.2%) and 20 (21.7%) patients, respectively.

In the two groups, 45 (48.9%) of 92 patients had concomitant aortic and other peripheral atherosclerosis (Table 1). In this regard, 1 (2.2%) patient underwent subclavian and common carotid artery stenting. Subclavian artery stenting was performed in 2 (2.2%) patients, internal carotid artery stenting was carried out in 4 (8.8%) patients, carotid endarterectomy – in 8 (17.7%) patients, while 3 (6.6%) patients received renal artery stenting.

A total of 198 surgeries were performed in 92 patients (a mean of 2.1 interventions per patient): 106 lower limb arterial surgeries comprising 53 open surgeries and 53 endovascular interventions (Table 2) and 92 PCI procedures. Myocardial revascularization was carried out in 92 patients. Figure 1 details the interventions performed.

Promus Element Plus, Xience Xpedition and Resolute Integrity drug-eluting stents were implanted. Blood vessel prosthetics Sever and Ekoflon were used in the lower limb artery surgeries.

The data obtained were analyzed in Statistica 7.0. The database was created in Microsoft Office Excel 2016.

Quantitative parameters were described using variation series, as well as means and standard deviations (M±SD). Nominal data were expressed with the absolute values and percentages. Non-normally distributed independent variables were compared using the Mann-Whitney U-test. Nominal data were compared using Pearson's chi-squared test. When

Table 1. Clinical characteristics of patients with CLLI and CAD

Parameter	Group 1 (n=46)		Group 2 (n=46)		p
	n	%	n	%	
Male	30	65.2	40	86.9	0.01
Female	16	34.7	6	13	
BMI ≥ 30 kg/m²	28.65±4.69	—	26.52±3.46	—	0.02
Postinfarction cardiosclerosis	13	28.2	13	28.2	0.81
Hypertensive heart disease	46	100	46	100	
Diabetes mellitus	14	30.4	4	8.7	0.01
COPD	4	8.7	1	2.1	0.35
Chronic kidney disease, GFR ≤ 59 mL/min/1.73 m²	3	6.5	2	4.3	0.64
Angina FC II-III	35	76.0	37	80.4	0.80
painless	11	23.9	9	19.6	
Coronary artery involvement >50%					
• Single-vessel	8	17.4	15	32.6	0.09
• Two-vessel	16	34.7	18	39.1	0.66
• Three-vessel	22	47.8	13	28.2	0.05
Heart rhythm disorders	7	15.2	3	6.5	0.31
Lower limb artery disease					
• Unilateral	34	74	38	82.6	0.31
• Bilateral	12	26	8	17.4	
Involvement of other arterial systems	22	47.8	22	47.8	1.0
• Carotid arteries >30%	15	32.6	20	43.4	0.28
• Subclavian arteries >50%	2	4.3	1	2.17	0.55
• Renal arteries>50%	5	10.8	1	2.17	0.09

CLLI – chronic lower limb ischemia; BMI – body mass index; COPD – chronic obstructive pulmonary disease; GFR – glomerular filtration rate; FC – functional class.

Table 2. Primary surgeries on lower limb arteries (n=92)

Intervention	n	%
CIA angioplasty and stenting	17	18.4
EIA angioplasty and stenting	8	8.7
SFA angioplasty and stenting	15	16.3
PA, SFA angioplasty and stenting	5	5.4
PA, tibial artery angioplasty and stenting	3	3.2
SFA, tibial artery angioplasty and stenting	5	5.4
Femoral popliteal bypass surgery	17	18.4
Iliofemoral bypass surgery	15	16.3
• including resection of abdominal aortic aneurysm	2	2.1
Femoral tibial bypass surgery	4	4.3
Resection of abdominal aortic aneurysm and aorto-bi-iliac grafting	2	2.1
Femorofemoral cross bypass grafting	1	1.0
Aortic femoral bypass grafting	14	15.2

CIA, common iliac arteries; EIA, external iliac arteries; SFA, superficial femoral arteries; PA, popliteal arteries

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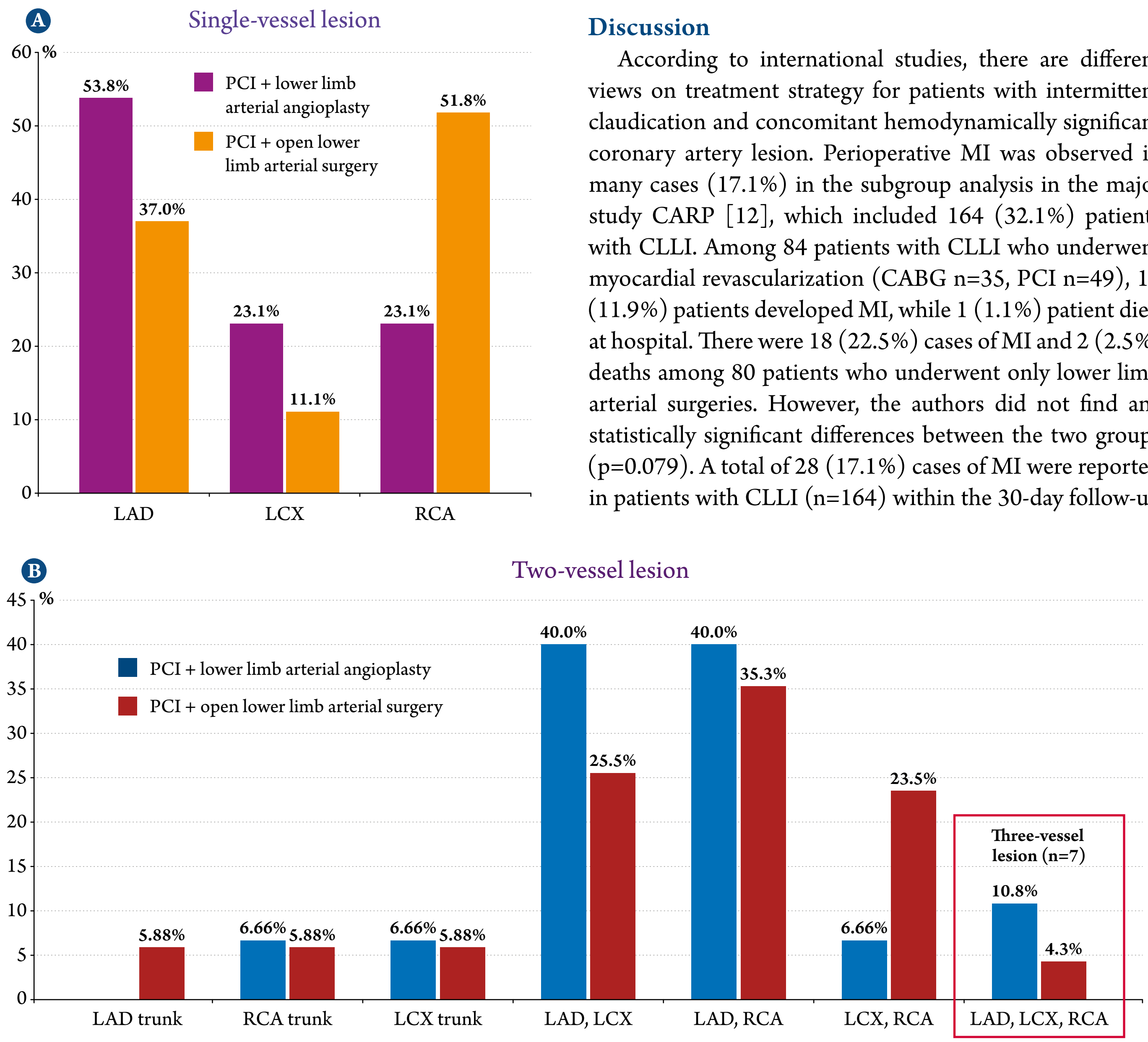
the number of expected observations was less than 5, the significance level of differences was estimated using Fisher's exact test. The differences were statistically significant with p value less than 0.05.

Results

Table 3 presents in-hospital outcomes assessed by the frequency of severe adverse cardiovascular events (death, acute MI, cerebrovascular accident (CVA)) and severe adverse lower limb arterial events (graft thrombosis, repeated lower limb arterial interventions, amputations), as well as non-severe adverse events.

Figures 1. PCI procedures



PCI – percutaneous coronary intervention; LCA – left coronary artery; LAD – left anterior descending artery; LCX – left circumflex artery; RCA – right coronary artery.

None of the 92 patients who underwent a total of 198 surgeries had any severe adverse cardiovascular events. Non-severe adverse events were treated conservatively. Hematoma at the common femoral artery access site was reported in 1 (2.1%) patient. In this case, the hematoma was removed following revision of the retroperitoneal space. There was 1 (2.1%) lower limb arterial adverse event in the early postoperative period in a 71-year-old patient. After removing an external iliac popliteal bypass graft due to thrombosis, the patient's condition stabilized in 9 days; subsequently, he was discharged from the Center.

All patients were discharged in satisfactory condition to be followed up at the local outpatient clinics. The mean number of days at hospital following surgery is provided in Table 4.

Discussion

According to international studies, there are different views on treatment strategy for patients with intermittent claudication and concomitant hemodynamically significant coronary artery lesion. Perioperative MI was observed in many cases (17.1%) in the subgroup analysis in the major study CARP [12], which included 164 (32.1%) patients with CLLI. Among 84 patients with CLLI who underwent myocardial revascularization (CABG n=35, PCI n=49), 10 (11.9%) patients developed MI, while 1 (1.1%) patient died at hospital. There were 18 (22.5%) cases of MI and 2 (2.5%) deaths among 80 patients who underwent only lower limb arterial surgeries. However, the authors did not find any statistically significant differences between the two groups (p=0.079). A total of 28 (17.1%) cases of MI were reported in patients with CLLI (n=164) within the 30-day follow-up period. MI was specified as the main cause of death in those patients. There were no cases of in-hospital MI or death after 198 open surgeries and X-ray endovascular interventions in 92 patients.

However, Monaco et al. [13] showed in their prospective randomized trial, which included 208 patients suffering from aortoiliac obstruction and aortic aneurysms, that CAG and myocardial revascularization had beneficial long-term effects. Patients were divided into two groups. In Group 1 (n=103; 49.5%), patients underwent a stress test, after which CAG was CAG was conducted. Group 2 included 105 (50.4%) patients who underwent CAG prior to the vascular surgery. Following positive stress tests, 47 (45.6%) of the 103 patients in Group 1 were referred for selective CAG, which showed that 46 (97.8%) of patients in this group had hemodynamically significant stenosis. Myocardial revascularization was performed in 42 (91.3%) of 46 patients, while 1 (2.4%) patient died of cardiogenic shock. Subsequently, 3 (7.1%) of 42 patients did not undergo vascular surgery. A fatal outcome was reported in 1 (2.4%) of 42 patients prior to lower limb arterial surgery for cardiac adverse event, while 2 (4.7%) patients refused vascular surgery. Within 2 months, elective lower limb arterial surgery was performed in 38 (90.5%) of 42 patients who had undergone myocardial revascularization. There were no fatal outcomes. The remaining 61 (59.2%) of 103 patients with a negative stress test and without angiographically significant stenosis underwent elective vascular surgery. In this subgroup, there were 5 (8.2%) fatal outcomes of surgery-related adverse cardiovascular events.

In Group 2 (n=105; 50.4%), 65 (61.9%) of all patients who underwent CAG had hemodynamically significant coronary involvement. There were no major adverse events related to CAG. Myocardial revascularization was carried out in 61 (93.8%) of 65 patients. The overall incidence of severe adverse cardiovascular events, including death, was higher in Group 1 (n=12; 11.6%) than in Group 2 (n=5; 4.7%; p=0.1). There were no adverse cardiovascular events within 4 years of follow-up in 69.6±4.7% of cases in Group 1 and 86.6±3.6% of cases in Group 2; the absolute risk decreased by 16.7%, which corresponds to a decreased in odds ratio (OR) by 59.4% (95% confidence interval (CI) 1.4–6.8; p=0.04). There were no adverse cardiovascular events within 8 years of follow-up in 53.5±6.3% of cases in Group 1 and 77.5±4.8% of cases in Group 2; the absolute risk decreased by 19.8%, which corresponds to a decreased in odds ratio (OR) by 53.6% (95% confidence interval (CI) 1.4–5.7; p=0.002). The authors concluded that CAG with subsequent myocardial revascularization significantly reduced the risk of adverse cardiovascular events in that group of patients.

Table 3. Severe adverse cardiovascular events and non-severe adverse events (n=92)

Severe adverse events	Group 1 (n=46)		Group 2 (n=46)		p
	абс.	%	абс.	%	
Death	0	0	0	0	—
MACE	0	0	0	0	—
• Myocardial infarction	0	0	0	0	—
• CVA	0	0	0	0	—
MALE					
• Bypass thrombosis	—			2.1	—
• Amputation	0			0	—
• Repeat intervention	0	0	1	2.1	—
Minor adverse events					
• Bradycardia, hypotension	1	2.1	0	0	0.31
• Hematoma at the puncture site	1	2.1	—	—	—
Total	**2**	**4.2**	**2**	**4.2**	—

MACE – major adverse cardiac events;
CVA – cerebrovascular accident;
MALE – major adverse events in the lower limb arteries.

Table 4. Mean number of days in hospital after surgery in Group 1 and Group 2

Parameter	Group 1	Group 2
Mean number of days in ICU after lower limb arterial surgery	0,19±0,7	1,5±1,7
Mean number of days in ICU after PCI	0,10±0,3	0,04±0,2
Mean number of days after lower limb arterial surgery	2,78±1,5	8,98±5,6
Mean number of days after PCI	2,84±3,2	3,26±2,8

ICU – intensive care unit;
PCI – percutaneous coronary intervention.

It is further believed that patients with CLLI stage IIB should be treated using the best possible drug therapy and special physical exercises to increase painless walking distance. The authors of the IRONIC study published in 2014 [14] concluded that lower limb arterial revascularization in patients with intermittent claudication was no more beneficial than the best possible drug therapy and did not improve the long term the quality of life. However, the study had several restrictions. Patients over 80 years old with a history of two lower limb arterial surgical interventions were excluded. The effect of each treatment was not assessed based on measuring the length of the vascular segment involved. Since the single-center study lacked a detailed characterization of patients, the outcomes of this treatment cannot be extended to all patients with CLLI.

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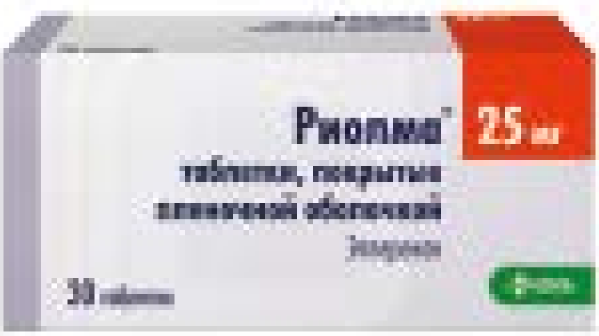

НАЙТИ В АПТЕКАХ
ВАШЕГО ГОРОДА

KRKA

According to the 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease, the condition of 10–15% of patients with CLLI worsens within 5 years in the absence of improvements during the best possible drug therapy, which can lead to the development of CLI [15]. All patients taking part in our study, who received the best possible drug therapy prior to the admission to the Center, experienced no improvements as a result.

In 2020, Tang et al. [16] published a meta-analysis comparing the results of open surgeries and endovascular interventions on lower limb arteries. Fatal outcomes were significantly more frequent in the open surgery group than in the endovascular intervention group: 10.86% and 7.54%, respectively (95% CI 0.73 [0.61–0.86]; $p<0.05$). A meta-analysis showed that there were significantly fewer adverse events in the endovascular intervention group than the open surgery group ($p<0.05$). Although there were no statistically significant differences, the annual survival rate was 70.6% and 73.9% in the endovascular intervention group and open surgery group, respectively ($I2=49\%$; 95% CI 0.97 [0.87–1.07]; $p>0.05$) [16].

In our opinion, taking the analyzed publications into account, the findings of this study may be attributable to the subclinical course of CAD in the included patients, which was not detected prior to lower limb interventions.

In our study, 1 (2.1%; $p=0.31$) bypass graft thrombosis was reported (Group 2) in the hospital period, for which iliac popliteal bypass thrombectomy was performed. The fact that there were no fatalities in the two groups indicates the optimal performance of the multidisciplinary team and the low risk of the chosen treatment strategy in patients with CLLI and CAD. CLI develops in every third patient with CLLI without lower limb arterial revascularization within a 5-year period, while 5% of patients are subjected subsequently to amputation [17]. Timely revascularization prevents possible cardiac and lower limb adverse events.

The attention drawn to many adverse cardiovascular events in the mentioned studies underlines the need to perform a thorough preoperative examination of patients with CLLI. Given these points and the contradictory conclusions of major studies, we recognize the need for further research into the immediate and long-term treatment outcomes in patients with CLLI and CAD.

Conclusions

1. The personalized approach of the multidisciplinary cardiovascular team to each patient with lower limb arterial pathologies and coronary artery disease informs the prevention of severe cardiovascular adverse events during hospital stay.
2. X-ray endovascular procedures (percutaneous coronary intervention + lower limb arterial angioplasty and stenting) and combined treatment strategy (percutaneous coronary intervention + open lower limb arterial surgery) in patients with chronic lower limb ischemia combined with coronary artery disease during hospital stay were shown to be safe and effective, allowing fatal outcomes and acute coronary disorders to be avoided.
3. There were no severe cardiovascular adverse events after 198 open and X-ray endovascular surgeries in 92 patients (a mean of 2.1 interventions per patient). We assume that timely percutaneous coronary interventions in patients with chronic lower limb ischemia helps to prevent severe cardiovascular adverse events during hospital stay.
4. As compared to open surgery, X-ray endovascular interventions in patients with lower limb arterial pathologies reduces the time after surgery in intensive care from 1.5±1.7 days to 0.19±0.7 days ($p<0.05$) and from 8.9±5.6 days to 2.7±1.5 days in hospital ($p<0.05$).

No conflict of interest is reported.

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