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Predictors of complications of open surgery of the aorto-Iliac segment occlusion

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Abstract---Background: Peripheral artery disease is a complex and widespread pathology. Occlusive lesions of the aorto-iliac segment are combined with lesions of the arteries of vital organs such as heart, brain, kidneys, visceral organs. It is an additional challenge in the treatment of the pathology. The main aim: To develop comprehensive approach to improve the treatment of patients with occlusive aorto-iliac segment lesions using open surgical access. Materials and Methods: A prospective non-randomized clinical trial of the surgical treatment of 134 patients with occlusive aorto-iliac segment lesions was conducted. Patients were divided into 2 groups depending on the treatment tactics: the first group consisted of 70 patients with unstable aorto-iliac segment occlusion, and the second one - of 64 patients, who have got preliminary surgical vascular accompanying

pathology correction. Results: Complications in 30-day postoperative period in patients of the 1st group resulted in fatal outcome in 4 (5.7%) cases, in the 2nd group - in 1 (1.6%) case. The 5-year mortality in patients of the 1st group was in 5 (7.7%) cases, and in the 2nd group this rage was 2 (3.3%) cases. In the 30-day and postoperative period, the development of myocardial infarction depended on the correction of complication predictors. In a 5-year postoperative period, myocardial infarction development depended on the correction of complication predictors, acute renal failure on blood creatinine level, and chronic left-sided colon ischemia on internal iliac artery stenosis as well as its inclusion (antegrade or retrograde) into the main blood flow. Conclusion. An analysis of the endpoints of the study showed that 30-day and 5-year mortality was influenced by the correction of predictors of complications and the development of multiple organ failure.

***Keywords*---**occlusion of the aorta-iliac segment, complications predictors, open surgery, mortality, infarction, kidney failure.

Introduction

The treatment of occlusive lesions of the aorto-iliac segment is an important practical field in vascular surgery. According to the results of several large population studies, the incidence of such pathology is 0.9-7% and is age-dependent. Clinical manifestations can vary from a virtually asymptomatic course to the development of critical lower limb ischaemia [1-3]. Multifocal atherosclerotic lesions of lower limb arteries are typical for this localization and determine the features of clinical course, diagnosis and treatment [4,5]. The systemic nature of atherosclerosis determines the presence of simultaneous lesions of arteries of other localizations such as coronary, cerebral, visceral. Moreover, the combinations may be different [6,7].

The high risk of severe complications in critical limb ischaemia determines the need for highly traumatic emergency open-access surgical interventions. But even in elective surgical treatment, due to small access, stenting is possible only in 30-60% of cases [8,9]. Often, only open reconstructive surgery can be applied (due to anatomical features of stent seating and surgical access options). Evidence-based treatment approaches are vital for such group of patients.

The study purpose: To develop a comprehensive approach to improve the outcomes of patients with occlusive AIS lesions using open surgical access.

For solving this problem we have planned to solve the following tasks.

1. To determine the pattern of comorbid vascular disease in patients with occlusive aorto-iliac segment (AIS) lesions;

2. To identify predictors of postoperative complications at the hospital stage, 30-day mortality;

3. To determine the causes of complications in the long term of follow-up and the survival rate of patients for 5 years.

Materials and methods

The presented clinical trial is prospective and non-randomised. The study was conducted on the basis of the Department of Cardiovascular Surgery of the University Hospital of Semey Medical University (UH SMU) from 2010 to 2018.

We included 134 patients with occlusive AIS lesions confirmed according to the current Diagnostic and Treatment Protocol. The calculation of the patient sample size was performed with PASS 2000, version 12.0.4.
Inclusion criteria:

- occlusive AIS lesions,
- surgical intervention as a planned or emergency procedure,
- open reconstruction of the AIS.

Exclusion criteria:

- juxta- and interrenal AIS occlusions,
- abdominal aortic aneurysm,
- emergency surgeries,
- endovascular AIS prosthetics.

The patients were divided into groups according to treatment tactics. The first group consisted of 70 patients with critical limb ischemia and high risk of irreversible trophic disorders, infectious complications up to gangrene. It was an indication for urgent surgical interventions without taking into account the presence of potential lesions of the arterial bed in other basins.

The second group included 64 patients, who, in addition to the correction of AIS, in the presence of indications, underwent surgical correction of the pathology of hemodynamics of the coronary and cerebral bed, revascularization of the pelvic basin, correction of renal failure.

Clinical follow-up was performed within 30 days after the intervention, prospective follow-up for 5 years with mandatory examination every 6 months. All patients were between 49 and 77 years of age. The mean age for all patients examined was 64.3 years (Me = 65, Q_1 = 58, Q_3 = 70); the 1st group was 64.2 years (Me = 65; Q_1 = 59; Q_3 = 69), the 2nd group was 64 years (Me = 65; Q_1 = 58; Q_3 = 71). Male patients were 64 (91.4%) in the 1st group and 60 (93.8%) in the 2nd group; female patients were 6 (8.6%) and 4 (6.2%), respectively.

In the preoperative period, along with physical examination, determination of angiological status and laboratory analyses, instrumental examination was carried out. They are electrocardiography (ECG), echocardiological examination (EchoCG), ultrasound dopplerography and duplex scanning, multispiral computed tomography angiography (MSCT-angiography), coronarography, transcranial Doppler if required. Targeted attention was paid to the identification of comorbidities and associated lesions in other vascular basins.

The criteria for evaluation in the immediate 30-day postoperative period were: restoration of blood flow in the lower extremities; absence of circulatory disturbances in the intervention-related areas, status of vital organs in the dynamics, restoration of intestinal peristalsis, consistency and dynamics towards healing of postoperative wounds.

Statistical processing was carried out using the SPSS Statistical Software Package, version 20. Two-sided Fisher's exact test was used to compare the relative measures. Analysis of predictors of complications and lethality in the 30-day period was performed by logistic regression technique, determining odds ratio (OR) and 95% confidence interval (CI). And in the 5-year postoperative period by Cox regression with hazard ratio (HR) and 95% CI, respectively. Survival analysis was performed using the Log-Rank statistical criterion [10].

Boundary criterion for rejecting the null hypothesis was significance level of differences<0.05.

Results

The analysis of preoperative data allowed us to conclude that atherosclerosis was the cause of AIS occlusion in all patients.

The majority of patients in both groups had various concomitant pathologies, including arterial lesions of other localizations (Table 1).

Coronographic studies were performed in the patients of the 2nd group in 51 cases (79.7%). According to its results there were no surgically significant stenoses in 33.3% of cases (17 patients), one-vessel lesion was detected in 6 cases (11.8%), two-vessel lesion in 16 patients (31.4%), three-vessel lesion in 23.5% cases (12 patients).

The presence of multifocal vascular lesions detected during the examination determined the appropriateness of staged interventions. The order in which they were performed depended on the features of the clinical course and the degree of hemodynamically significant lesions in different basins. At first, surgical correction of coronary or carotid lesions was usually performed; then, after the recovery period, AIS reconstruction was performed (Table 2).

Reconstructive interventions in the AIS were performed in both occlusion-related groups (Table 3).

Analysis of the performed surgical interventions

The immediate results of the patients treatment were analysed within 30 days after the intervention. Complications in the 30-day postoperative period were observed in both groups (Table 4). In several cases they were fatal.

In the first group the mortality rate was 5.7% (4 cases), including acute myocardial infarction which was observed in 1 case out of (1.4%), acute cerebrovascular failure in 1 case (1.4%), acute renal failure in 1 case (1.4%) and multiple organ failure in 1 case (1.4%). In the second group, progressive multiple organ failure was the cause of death of 1 patient (1.6%) after the intervention.

A 30-day complication analysis showed an association between 30-day mortality and correction of predictors of complications (OR 0.041; 95% CI 0.003-0.513; p=0.013) and multiple organ failure (OR 6.458; 95% CI 3.551-11.569; p=0.001). Myocardial infarction was influenced by corrected predictors (OR 0.068; 95% CI 0.005-0.443; p=0.004) and ejection fraction (OR 0.911; 95% CI 0.859-0.965; p=0.003). Acute renal failure was associated with blood creatinine levels (OR 0.076; 95% CI 0.024-0.352; p=0.003). Analysis of other complications at 30 days postoperatively showed no association with possible risk factors.

Analysis of the performed surgical interventions results in the long term

In the long-term period, the condition of the vascular prosthesis and the level of blood supply to the lower extremities, anastomosis health, and blood flow indicators in the vital organs' arterial basins were studied. 65 patients from the 1st group (92.9%) and 61 patients from the 2nd group (95.3%) were included in the long-term outcome analysis (Table 5).

The causes of lethal outcomes were recorded in 5 cases (7.7%) in patients of the 1st group, with myocardial infarction in 2 cases (3.1%), stroke, cancer pathology and advanced renal failure in 1 case each (1.5%). The 2nd group had 2 deaths (3.3%) during the same period. The causes were myocardial infarction in 1 case (1.6%), and acute renal failure in 1 case (1.6%) respectively.

Survival of patients at 5 years was 56.1 (95% CI 52.7-59.5) months in the 1st group of patients, and 58.4 (95% CI 56.3-60.0) months in the 2nd group (Log Rank=0.834; p=0.361).

Survival of patients at follow-up up to 5 years depended on the presence of correction of predictors of complications (HR 0.146; 95% CI 0.108-0.456; p=0.034).

Myocardial infarction (HR 3.509; 95% CI 1.153-5.945; p=0.005) and acute renal failure (HR 5.731; 95% CI 2.371-10.964; p=0.001) were significant predictors of complications. The risk of myocardial infarction during this period depended on correcting predictors of complications (HR 1.145; 95% CI 1.052-1.246; p=0.002), the risk of ARF on blood creatinine content (HR 3. 017; 95% CI 1.921-8.739; p=0.001), and likelihood of chronic left-sided colon ischaemia from the presence of internal iliac artery (IIA) stenosis (HR 1. 012; 95% CI 1.003-1.019; p=0.018),

antegrade (HR 0.060; 95% CI 0.017-0.218; p=0.001) or retrograde (HR 0.201; 95% CI 0.067-0.666; p=0.010) implementation of IIA inclusion in the main blood flow during reconstructive surgery.

Discussion

The development of any diseases or their complications is in one way or another associated with certain causes (predictors). In our study, we intended to analyse the causal relationship between certain predictors and the development of complications in patients after open surgery for AIS occlusion. Appropriate predictors were identified for each complication according to its pathogenesis and literature data [11-12]. Nowadays, specialists are talking about the need to create a database of patients with chronic diseases, which can significantly improve and facilitate the process of emergency medical care in cases where complete, including instrumental examination, for some reason is not possible [13-14]. Such suggestions are particularly important in view of the research that shows a genetic predisposition of members of the same family to certain pathologies. Cardiovascular diseases are included in such a list [15].

The analysis of the results of surgical treatment of patients with occlusive lesions in the AIS shows that early and late outcomes largely depend on the presence and severity of combined lesions in other major arterial basins (coronary, cerebral, renal). An adequately performed intervention in the AIS can be ineffective due to the development of acute circulatory disturbances in the coronary or cerebral basin, which will cause a fatal outcome [16]. In this regard, improving surgical management of AIS occlusion in combination with other circulatory disorders is an urgent issue for modern angiosurgery [17].

The patients included in our study and divided into two groups were comparable in terms of the frequency and structure of concomitant pathology, including the presence of CHD, cerebral artery lesions, history of heart attacks and strokes, arterial blood supply and renal function disorders. The patients of the 1st group had a clinical picture of critical ischemia and a threat of the development of irreversible trophic disorders due to the unstable course of the occlusion. It was an indication for urgent surgical intervention [18-19].

In the second group, the clinical situation was stable with a positive immediate prognosis without intervention, which allowed us to compare the two tactics for open surgical treatment of AIS occlusion. To identify the influence of the patient group on the analysed case or mortality, a variable "Predictor Correction" was created to distinguish patients of the 2nd group.

During surgical interventions on AIS in patients of the second group, the focus was on the improvement of blood supply to the pelvic organs and the left half of the colon (by IIA). Thus, in 6 cases (9.4%) the revascularization of the IIA was carried out according to the method of the Clinic of Hospital Surgery of UH SMU, in 7 cases (10.9%) antegrade blood flow through the IIA was achieved by aorto-iliac-femoral reconstruction. The performed interventions reduced the incidence of chronic ischemic colitis from 4.6% to 1.6% (p=0.257), which corresponds to the literature data on the direction and degree of dynamics [20].

It should be noted that in the 2nd group of patients in the 30-day postoperative period, we managed to prevent the development of stroke, reduce the number of myocardial infarctions, complications from the kidneys, lungs, manifestations of multiple organ failure, in comparison with the 1st group. In general, the set of obtained data is consistent with the results of several studies conducted by different teams of authors in recent years. Thus, a significantly higher incidence of complications was found in emergency surgical treatment compared to planned [21-22]. Individual systemic complications had a relatively low incidence, and no significant differences were found in pairwise comparisons. However, when the frequency rates at 30 days postoperatively were combined, the number of complications was significantly higher in the 1st group of patients in comparison with the 2nd group of patients (p=0.004). Also the lethality rate in the early period was lower in the 2nd group of patients (Log Rank=7.823; p=0.043). These data are consistent with those obtained by foreign authors, who performed staged treatment of atherosclerotic lesions of the main arteries. A number of studies have shown a reduction in the incidence of acute vascular events and overall mortality after intervention [23-24].

In the long-term postoperative period, the number of systemic complications was also greater in the 1st group of patients than in the 2nd group (p=0.011), but no difference in 5-year survival was found (Log Rank=0.834; p=0.361).

Conclusion

A comparative analysis of the endpoints of different open surgical treatment tactics for occlusive AIS lesions with concomitant atherosclerosis of other localisations led to the following conclusions:

1) the leading factors influencing mortality in the early postoperative period were correction of predictors of complications and the development of multiple organ failure;

2) the main factors of myocardial infarction development were correction of predictors of complications and ejection fraction level and for acute renal failure it was preceding blood creatinine level;

3) at 5-year postoperative period the risk of myocardial infarction was more dependent on the correction of predictors of complications and the risk of acute renal failure was dependent on the blood creatinine level. As for the risk of the chronic left-sided colon ischemia, so it was dependent on the presence of IIA stenosis, antegrade or retrograde IIA inclusion in the main blood flow during AIS reconstruction;

4) the 5-year survival rate of patients was influenced by correction of predictors of complications and development of such conditions as myocardial infarction and acute renal failure.

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Abbreviations

ACB – aorto-coronary bypass

AIS - aorto-iliac segment

CE – carotid endarterectomy

CI - confidence interval

ECG – electrocardiography

EchoCG - echocardiological examination

HR - hazard ratio

ICA – internal carotid artery.

IIA - internal iliac artery

MSCT - multispiral computed tomography

OR - odds ratio

PTA – percutaneous transluminal angioplasty

PTCA – percutaneous transluminal coronary angioplasty

RCA – right coronary artery

SPSS - Statistical Software Package

UH SMU - University Hospital of Semey Medical University

Tables

Table 1. Concomitant pathology in patients in the study groups

Concomitant pathology	st group =70		nd group =64		
		%		%	
Coronary heart disease	9	4.3	2	1.3	.815
Postinfarction cardiosclerosis	0	4.3	5	3.4	.139
Cerebral circulation disorders	6	1.4	3	1.6	.922
History of acute cerebral circulation disorder		.6		0.9	.655
Chronic obstructive pulmonary diseases	2	1.4	8	8.1	.696
Arterial hypertension	6	0.0	8	5.0	.688
Chronic gastritis	0	7.1	6	6.3	.925
Prostate adenoma	1	0.0	8	8.1	.793
Chronic kidney disease	9	1.4	4	7.5	.736
Chronic cholecystitis	2	7.1	0	5.6	.862
Diabetes		1.4		.4	.655
Other illnesses	2	0.0	6	6.3	.710

Table 2. Analysis of surgeries performed in the 2nd group of patients

Stages of surgeries	Completed surgeries, n=64	
	A total number	%
One-stage	**27**	**42.2**
Reconstruction of the AIS	27	42.2
Two-stage	**35**	**54.7**
ACB → AIS reconstruction	21	32.8
PTCA со стентированием → AIS reconstruction	10	15.6
CE → AIS reconstruction	3	4.7
PTCA with RCA stening, PTA with ICA stening → AIS reconstuction	1	1.6
Three-stage	**2**	**3.1**
PTA with ICA stening→ ACB → AIS reconstruction	1	1.6
ACB → CE → AIS reconstruction	1	1.6

Note:
AIS– aorto-iliac segment
ACB – aorto-coronary bypass
PTCA – percutaneous transluminal coronary angioplasty
CE – carotid endarterectomy
RCA – right coronary artery
PTA – percutaneous transluminal angioplasty
ICA – internal carotid artery.

Table 3. Comparative analysis of reconstructive surgeries in the AIS by groups

Reconstruction type	1st group, n=70		2-nd group, n=64		p
	A total number	%	A total number	%	
Bifurcation aorto-femoral bypass	59	84.3	44	68.8	0.225
Bifurcation aorto-femoral bypass with internal iliac artery revascularisation	-		6	9.4	-
Linear aorto-femoral bypass	11	15.7	7	10.9	0.336
Bifurcation aorto-iliac femoral bypass	-		7	10.9	-

Table 4. Post-operative complications identified during the early post-operative period

Type of complication	1st group, n=70		2nd group, n=64		p
	A total number	%	A total number	%	
Systemic					
Myocardial infarction	3	4.3	1	1.6	0.414
Acute cerebral circulation disorder	2	2.9	-		-
Acute renal failure	4	5.7	1	1.6	0.157
Pneumonia	2	2.9	1	1.6	0.655
Multiple organ failure	2	2.9	1	1.6	0.655
TOTAL	13	18.6	3	4.7	0.004
Local					
Prosthetic jaw thrombosis	2	2.9	1	1.6	0.655
Gangrene of the pelvic limb	2	2.9	1	1.6	0.655
Eventration of abdominal organs, relaparotomy	1	1.4	-		-
Lymphorrhea	3	4.3	2	3.1	0.705
TOTAL	8	11.4	4	6.3	0.225

Table 5. Long-term analysis of post-operative complications*

Type of complication	1st group, n=65		2nd group, n=61		p
	A total number	%	A total number	%	
Systemic					
Myocardial infarction	2	3.1	1	1.6	0.257
Acute cerebral circulation disorder	2	3.1	1	1.6	0.655
Acute renal failure	3	4.6	2	3.3	0.480
Cancer pathology	1	1.5	-		
Multiple organ failure	2	3.1	1	1.6	0.655
Chronic ischaemic colitis	3	4.6	1	1.6	0.257
TOTAL	14	21.5	5	8.2	0.035
Local					
Failure of aorto-pelvic anastomosis with false aneurysm	4	6.2	2	3.3	0.317
Postoperative ventral hernia	2	3.1	1	1.6	0.655
Adhesive intestinal obstruction	2	3.1	1	1.6	0.655
TOTAL	8	12.3	4	6.6	0.431

*Fisher's test was used