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Immediate and Long-term Results of Revascularizing Osteotrepanasion and Lumbar Sympatectomy in Patients with Critical Ischemia of The Lower Extremities (Correlation and Statistical Analysis)

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Abstract

Objective: To study the immediate and long-term results of revascularizing osteotrepanation and lumbar sympathectomy in patients with critical ischemia of the lower extremities (CILE) on the background of distal arterial steno-occlusion.

Material and methods: The results of standard treatment and the use of various types of indirect revascularization in 171 patients with CILE against the background of distal arterial steno-occlusion were analyzed. The etiological factors of CILE were obliterating atherosclerosis (115 patients) and thromboangiitis obliterans (56 patients). The level of arterial damage: femoro-popliteal segment -26 (15.2%), popliteal-tibial segment -56 (32.7%), tibial-foot segment -50 (29.2%), foot - 25 (14.6%), multilevel lesion -14 (8.2%). To establish a diagnosis and assess the results of treatment, changes in the clinical status of patients were traced, Doppler ultrasound with angioscanning, multispiral computer-tomographic angiography, rheovasography were performed, and skin oxygen saturations were determined. The immediate results of treatment were assessed by the Rutherford

R.B. et al. (1997) scale.

Results: 48 patients (control group) underwent standard treatment. The following types of indirect revascularization were performed to stimulate regional circulation: revascularizing osteotrepanation (ROT) in 64 patients, lumbar sympathectomy (LSE) in 59 patients. In patients with CILE against the background of distal arterial steno-occlusion, ROT and LSE improve the immediate and long-term results of surgical treatment, make it possible to preserve the supporting function of the limb, reduce the frequency of rehospitalization, and continue an active lifestyle.

Conclusions: Correlation and statistical analysis revealed a significant dependence of the results obtained on the method of revascularization. The technical simplicity of performing the operation of ROT and LSE creates the prerequisites for the introduction of surgical departments of multidisciplinary clinics in daily practice.

Keywords: distal occlusion of the arteries; critical ischemia of the lower extremities; revascularizing osteotrepanation; lumbar sympathectomy

Introduction

The issues of diagnosis, determination of indications for surgery, optimization of the results of surgical and conservative treatment of patients with lower limb critical ischaemia (CILE) with distal lesions of ischemic arteries remain an unsolved problem of modern angiology and vascular surgery. The results of reconstructive operations on the arteries of the lower extremities at the stage of critical ischemia are not always satisfactory, since in 5.8-16.5% of cases there are unfavorable outcomes [1, 2], and in 8.8-20.4% of cases there are major amputations [1, 3, 4]. Despite certain advantages of rentgeno-endovascular surgery, it does not provide adequate revascularization of the limb in all patients [5-8]. Patients and surgeons are also not always satisfied with the results of hybrid operations for CILE against the background of distal arterial steno-occlusion [9]. Given the ineffectiveness of conservative therapy, as an alternative to cripple operations – amputations, genetically engineered drugs are used to stimulate regional blood flow [10, 11] and various methods of indirect revascularization are used, including revascularizing osteotrepanation (ROT), lumbar sympathectomy (LSE) [12-17]. In the literature available to us and on the Internet, we have not come across materials in which, on the basis of correlation and statistical analysis, the dependence of short-term and long-term results on the methods of indirect revascularization has been studied.

Purpose of the study

To study the immediate and long-term results of ROT and LSE operations in patients with CILE on the background of distal arterial stenoocclusion.

Material and Methods

A prospective controlled clinical trial was conducted. Permission was obtained from the Ethics Committee of the Scientific Center of Surgery named after acad. M.A. Topchubashov. All patients were familiarized with all aspects of surgical treatment before starting treatment and signed the appropriate information consent.

The immediate and long-term results of complex conservative and surgical treatment of 171 patients with CILE against the background of distal arterial steno-occlusion aged 28 to 74 years were analyzed. 119 (69.6%) males and 52 (30.4%) females were CILE obliterating atherosclerosis (115 patients) and thromboangiitis obliterans (56 patients). In 48 patients, due to the impossibility of carrying out the level of arterial damage, the femoro-popliteal segment -26 (15.2%), the popliteal-tibial segment -56 (32.7%), the tibial-foot segment -50 (29.2%), the foot-25 (14.6%), and the multilevel lesion -14 (8.2%). In 48 patients, due to the impossibility of direct revascularization and in the presence of contraindications to indirect revascularization, conventional conservative treatment (control group) was carried out. After preoperative preparation for 4-5 days with the use of long-term epidural blockade in the perioperative

period, intravenous laser therapy to stimulate regional circulation, the following types of indirect revascularization surgery were performed: revascularizing osteotrepanation (ROT) in 64 patients (group I); lumbar sympathectomy (LSE) in 59 patients (group II).

To establish a diagnosis and assess the results of treatment, changes in the patient's clinical status were traced, Doppler ultrasound and duplex angioscanning with the determination of the ankle-brachial index and linear blood flow velocity, multispiral computer-tomographic angiography, rheovasography with the determination of the rheographic index were performed, and oxygen saturation of the skin was determined. The immediate results of conservative and surgical treatment were evaluated according to the Rutherford R.B. et al. (1997) scale [18].

The obtained immediate and long-term results were processed by the method of nonparametric statistics with the calculation of the Pearson agreement criterion ($\chi 2$) at the confidence level P=0.95 ($p<0.05$).

Results and Discussion

In the control group (standard treatment), 16 (33.3%) patients were diagnosed with stage III chronic ischaemia without trophic changes in group I, 20 (31.3%) patients in group I, and 17 (28.8%) patients in group II. The IY degree of chronic ischaemia was diagnosed in 32 (66.7%) patients in the control group, in 45 (68.2%) patients in group I, and in 41 (62.5%) patients in group II. Semiotics of trophic disorders was characterized as follows: necrotic soft tissue ulcer in 18 (15.3%) patients, necrotizing ulcer on the fingers in 23 (19.5%) patients, dry gangrene of 1-2 fingers in 21 (17.8%) patients, dry gangrene of 3 and more fingers in 19 (16.1%) patients, wet gangrene of 1-2 toes in 13 (11.0%) patients, non-healing wound of the foot after early surgery in 24 (20.3%) patients.

Upon admission to the hospital, the clinical condition of the patients was assessed as severe or moderate. Non-invasive instrumental methods of examination revealed a sharp violation of regional macro- and microhemodynamics with a significant decrease in skin oxygen saturation. As a result of stimulation of peripheral blood flow by indirect methods of revascularization, along with clinical improvement, an increase in total blood flow, a decrease in peripheral vascular resistance and an increase in oxygen supply to tissues in the ischemic limb were stated.

At the end of the course of standard treatment, the patients observed a certain positive dynamics in the clinical status. In the majority of patients who underwent indirect revascularization operations (ROT, LSE), on the 2nd or 3rd day after surgery, ischemic pain was relieved, the patients became more active, began to walk actively, and took care of themselves. Warming of the limb, subsiding and limitation of aseptic and infectious inflammatory reactions were also observed. In the control group, 9 (28.1%), in group I in 16 (35.6%), and in group II, in 13 (31.7%) patients, healing of the necrotic wound was observed. Types of surgery performed in the lower extremities are presented in Table 1.

Research Groups / ***Results of the study***	***Standard treatment*** ***n=48***	***Revascularization methods***	
		ROT ***n=64***	***LSE*** ***n=59***
Finger amputation	1	2	1
Disarticulation of 1-2 toes with resection of the metatarsal head	2	9	9
Disarticulation of all fingers with resection of the metatarsal head	3	6	5
Transmetatarsal foot amputation	3	4	4
Transmetatarsal Foot Amputation Due to Aggravation of Ischemia	6	5	5
Major amputation due to aggravation of ischemia	8	3	4

Notes: ROT - *Revascularizing osteotrepanation*; LSE - *lumbar sympathectomy*.

Table 1: Types of surgical interventions in the lower extremities in patients with CILE with distal lesions of the arteries.

As can be seen from the table, due to the aggravation of chronic ischemia in the lower extremities, 6 patients in the control group underwent minor (transmetatarsal) amputation, and 8 patients underwent major (at the level of the tibia) amputation. Due to the increase in ischemia, minor amputation was performed in 5 patients in group I and in 5 patients in group II. For the same reason, major amputation was performed in group I in 3 patients, and in group II in 4 patients. The dependence of the total number of "mayor+minor" amputations performed in connection with the aggravation of critical ischemia on the method of indirect revascularization was studied and it was established that in patients who underwent ROT and LSE operations, such a dependence is significant. ($\chi 2 = 4.827$; p=0.029 and $\chi 2=3.947$; p=0.047, respectively).

The clinical efficacy of indirect revascularization methods for stimulating peripheral circulation in patients with CILE with distal arterial steno-occlusion is consistent with the results of other authors [4, 8, 11, 13].

Assessing the immediate results after conservative therapy and surgical treatment with indirect revascularization according to the Rutherford R.B. et al. (1997) scale, we found that while in the control group 21 (43.8%) patients showed significant, moderate and insignificant improvement, then in groups I and II, respectively, 42 (65.6%) and 39 (66.1%) patients showed improvement. Immediate results of treatment of the examined patients according to the Rutherford scale R.B.et al. (1997). are presented in Table 2.

Research Groups / ***Results of the study***		***Standard treatment***	***Revascularization methods***	
			n=48 ROT n=64	***P LSE n=59***
+3	Significant improvement	5	13	12
+2	Moderate improvement	9	17	15
+1	Minor improvement	7	12	12
0	No change	7	8	6
-1	Slight deterioration	6	6	6
-2	Moderate deterioration	6	5	4
-3	Significant deterioration	8	3	4

Notes: ROT - *Revascularizing osteotrepanation*; LSE - *lumbar sympathectomy*.

Table 2: The most important results of standard treatment and the use of indirect revascularization of patients with CILE according to the Rutherford scale R.B.et al. (1997).

As can be seen from the table, despite conservative therapy, the clinical status of patients in this group remained unchanged in 27 (56.2%) cases or negative dynamics to varying degrees was observed. Such a clinical situation was observed in group I in 22 (34.4%) patients, and in group II – in 20 (33.9%) patients. We analyzed the dependence of short-term results on the tactics of indirect revascularization in individual groups. In comparison with the control group, the improvement of the immediate results of various degrees in patients of groups I and II turned out to be significant ($\chi 2 = 5.333$; $p = 0.021$ and $\chi 2 = 5.368$; $p = 0.021$, respectively). Taking into account the effectiveness and less traumatic nature, in the presence of contraindications to LSE, in patients with CILE with distal arterial steno-occlusion, ROT surgery can be used.

Long-term results were observed within 6 months to 5 years in 155 patients. In the remote period, the following indicators were analyzed: rehospitalization, the number of major and minor amputations, and the preservation of the supporting function of the limb. The results of the long-term results for the above indicators are presented in Table 3.

Research Groups / *Results of the study*	*Standard treatment* *n=43*	*Revascularization methods*	
		ROT *n=59*	*LSE* *n= 53*
Readmissions	36(83,7%)	34(57,6%)	32(62,3%)
Major amputation	22(51,2%)	14(23,7%)	13(24,5%)
Minor amputation	10(23,3%)	13(22,0%)	12(22,6%)
Preservation of the support function of the limb	21(48,8%)	45(76,5%)	34(73,9%)

Notes: ROT - *Revascularizing osteotrepanation*; LSE - *lumbar sympathectomy*.

Table 3: Long-term results of standard and surgical treatment by indirect revascularization of patients with CILE in distal arterial lesions.

A statistical analysis of the dependence of long-term results (rehospitalization, preservation of the supporting function of the limb) on the tactics of indirect revascularization in selected groups was carried out. In comparison with the control group, patients of groups I and II showed a decrease in the frequency of readmission ($\chi2=7.866$; $p=0.006$ and $\chi2=6.262$; $p=0.013$, respectively). The frequency of "major and minor" amputation in the remote period was also significantly reduced depending on the methods of indirect revascularization ($\chi2 = 8.376$; $p = 0.004$ and $\chi2 = 8.376$; $p = 0.004$, respectively). In the remote period, if in the control group the support function was retained in 21 (48.8%) patients, then in group I patients in 45 (76.3%) patients, in group II in 40 (75.5%) patients, it was possible to preserve the supporting function of the limb ($\chi2 = 8.197$; $p = 0.005$ and $\chi2 = 7.270$; $p = 0.008$, respectively).

The analysis of the obtained short-term and long-term results showed that in CILE against the background of distal steno-occlusion of the arteries, due to the impossibility of performing open, endovascular and hybrid revascularizations, the low effectiveness of conservative therapy, the high cost and low availability of drugs for stimulating blood flow of genetic engineering for many patients, in order to preserve the supporting function of the limb and continue an active lifestyle in such a severe category of patients, ROT and the LSE are justified. The technical performance of these operations is not difficult, does not require special, complex, expensive technologies and tools. In case of recurrence of critical ischemia in the remote period, repeated ROT surgery does not cause any difficulties. Considering these factors, ROT surgery can be performed by general surgeons.

Findings

1. The use of indirect revascularization operations – ROT and LSE in CILE against the background of distal arterial lesions makes it possible to achieve a significant, moderate and insignificant improvement in the immediate results in patients of groups I and II in 65.6% and 66.1%, respectively, against 43.8% of cases in the control group ($\chi2 = 5.333$; $p = 0.021$ and $\chi2 = 5.368$; $p = 0.021$, respectively).
2. The frequency of "major + minor" amputations due to aggravation of critical ischaemia in patients of groups I and II is 12.5% and 15.3% respectively against 29.2% of cases in the control group and significantly depends on the operation of ROT and LSE. ($\chi2 = 4.827$; $p=0.029$ and $\chi2=3.947$; $p=0.047$, respectively).
3. The rate of long-term readmission in patients I and II was 57.6% and 62.3% of cases, respectively, versus 83.7% of cases in the control group ($\chi2=8.376$; $p=0.004$ and $\chi2 = 8.376$; $p=0.004$, respectively).
4. In patients with non-shuntable occlusive-stenotic lesions of the distal arteries of the lower extremity, as an alternative to amputation, ROT and LSE make it possible to preserve the supporting function of the limb in the majority of patients of groups I and II in 76.3% and 75.5% of cases, respectively, against 48.8% of cases in the control group. ($\chi2 = 8.197$; $p = 0.005$ and $\chi2 = 7.270$; $p = 0.008$, respectively).
5. The simplicity of performance, the possibility of repeated performance, the absence of the need for special high-tech instruments make it possible to recommend the operation of ROT and PSE for implementation in surgical practice in the departments of

multidisciplinary hospitals.

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