Review

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Sympathectomy and Neuromodulation in the Treatment of Critical Lower Limb Ischemia

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INTRODUCTION Critical lower limb ischemia is a widespread disease that occurs due to atherosclerotic lesions of the arteries with progressive narrowing of their lumen. Clinically critical ischemia is manifested by pain at rest, resistant to narcotic analgesics, and/or ulcerative necrotic process on the legs. In the absence of treatment, patients undergo amputation of the lower limb. Almost all patients die 10 years after amputation of the lower limb at the level of the thigh. Currently, there are following methods of treatment of critical ischemia: conservative therapy, direct revascularization, lumbar sympathectomy and neurostimulation.

AIM OF STUDY To present the data of modern scientific literature on the use of lumbar sympathectomy and epidural spinal cord stimulation in the treatment of critical lower limb ischemia.

MATERIAL AND METHODS This review presents the latest data obtained as a result of studying domestic and foreign literature on the treatment of critical lower limb ischemia with lumbar sympathectomy and epidural spinal cord stimulation. Currently, lumbar sympathectomy is performed by surgical (open, mini-access and endoscopic) and percutaneous (chemical or radiofrequency) methods. Percutaneous access is becoming widespread due to its minimally invasiveness, maximum accessibility, ease of performance and low cost. Epidural spinal cord stimulation is performed for resistant pain syndrome. The mechanism of action of spinal stimulation is to block the transmission of nerve impulses at the level of the gelatinous substance of the posterior horns of the spinal cord during stimulation of afferent fibers of a larger diameter (type A-alpha and A-beta fibers).

CONCLUSION Spinal neurostimulation and lumbar sympathectomy are promising methods of treatment for critical lower limb ischemia in case of impossibility of direct revascularization. Lumbar sympathectomy can reduce the intensity of pain and improve the quality of life of patients. According to a number of studies, epidural spinal cord stimulation significantly reduces the likelihood of amputation of the lower limb, and also reduces the intensity of pain in patients refractory to conservative therapy, as well as in those who are not indicated for direct revascularization of the arteries of the lower extremities. More large-scale studies are needed to determine the indications for the above methods.

Keywords: lumbar sympathectomy, critical lower limb ischemia, spinal neurostimulation, limb preservation, chronic pain syndrome, sympathetic ganglion

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ACVA – acute cerebrovascular accident
CLLI – critical lower limbs ischemia
PS – pain syndrome
LE – lower extremities
LS – lumbar sympathectomy
PE – pulmonary embolism
PAD – chronic arterial occlusive disease of the lower extremities
QOL – quality of life
SCS – spinal cord stimulation
VAS – visual analogue scale

INTRODUCTION

Critical lower limb ischemia (CLLI) is a disease characterized by decompensation of chronic arterial insufficiency of the lower extremities (LE) [1, 2]. The leading clinical signs of CLLI are pain syndrome (PS) at rest, intractable with opioid analgesics, and/or ulcerative-necrotic process of LE, lasting more than 2 weeks [3]. The prevalence of CLLI in the United States and Western Europe is gaining 50-100 cases per 100 000 population annually [1]. In the United States, more than 400 000 patients are hospitalized annually with chronic arterial occlusive disease of the lower extremities (PAD). At the same time, 50 000 angioplasties, 110 000 bypass operations and 69 000 foot and LE amputations are performed per year [4]. After verification of CLLI, the mortality rate is 8–33%; and 16–34% of patients undergo LE amputation within 1 year of follow-up [1, 5]. Patients who underwent LE amputation had a 1.8-fold higher risk of death within 2 years after CLLI verification than those who managed to keep it. Terrible complications (stroke, myocardial infarction, infection, pneumonia, pulmonary embolism) occur after this operation in 20–37% of patients, and mortality after amputation is gaining 8.5% [1].

By the end of the 2nd year after amputation, 34-50% of patients die, 76% of patients survive 1 year after amputation of the LE at the level of the thigh, 51-56% die in 3 years, 34-36% die in 5 years, almost everyone dies in 10 years [4]. Deterioration in the quality of life (QoL) of patients occurs due to PS, ulcers, and limited mobility. In CLLI, incompletely oxidized metabolic products accumulate in soft tissues and muscles and metabolic acidosis develops, which causes LE edema and irritation of nerve endings [6, 7]. Clinically, this is manifested by PS in CLLI, a vicious circle is formed: PS reduces the patient's motor activity, which leads to deterioration in venous outflow and a reduction in the blood supply to LE tissues [8, 9]. In the treatment of CLLI, the main components are elimination or reduction of PS, healing of ulcerative necrotic processes, increase in motor activity, preservation of LE and improvement in QOL [1, 10]. To achieve these goals, the following main approaches are used: conservative, reconstruction of the LE arteries, destructive operations (sympathectomy) and neurostimulation.

Conservative treatment of CLLI includes [11–13]:

1. Antispasmodics (drotaverine, no-shpa, benziklan fumarate, buflomedil, platifillin, nicergoline, nikospan, papaverine hydrochloride).
2. Metabolites (solcoseryl, actovegin).
3. Lipid-lowering drugs (statins, ezetimibe, fibrates).
4. Angioprotectors (pentoxifylline, ginkgo biloba, xanthinol nicotinate, naftidrofuryl, nicergoline, troxerutin).
5. Antiplatelets (acetylsalicylic acid, ticlopidine, sulodexide, dipyridamole, clopidogrel, cilostazol, ticagrelor, prasugrel, selexipag).
6. Rheological preparations (dextran, pentoxifylline, L-arginine).
7. Antioxidants (tocopherol acetate, ascorbic acid, ethylmethylhydroxypyridine succinate, taurine, methylethylpyridinol hydrochloride, alpha-lipoic and thioctic acid preparations).
8. Immunostimulants (immunofan, azoxymer bromide, T-activin).
9. Anticoagulants (nadroparin calcium, enoxaparin sodium, warfarin, dalteparin sodium, dabigatran etexil, rivaroxaban, apixaban, bemiparin sodium, phenindione, parnaparin sodium, acenocoumarol, sulodexide, fondaparinux sodium).
10. Venotonics (diosmin, troxerutin, hesperidin + diosmin)
11. Prostaglandins (alprostadil, iloprost)

It is also necessary to perform therapeutic exercises: dosed training walking (45-60 minutes per day). It is aimed at the development of collateral vessels, improvement of microcirculation and venous outflow, contributing to the improvement of blood supply in ischemic LE tissues [14]. Hyperbaric oxygenation has a positive effect on the state of the blood coagulation system and microcirculation.

The effectiveness of drug treatment of CLLI has increased recently due to the development of new drugs and treatment regimens. Despite the advances in pharmacology, CLLI is progressing and the prognosis regarding the preservation of LE remains unfavorable (during the 1st year, 20–30 % of individuals lose one LE, and in the next 2–3 years, two LEs) [1]. In this regard, patients undergo direct revascularization whenever possible. For this, open (bypass, prosthetics, endarterectomy, arterialization of the venous bloodflow) and endovascular (angioplasty, stenting) interventions on the LE arteries are used [1, 15].

Bypass surgery and endarterectomy are the most commonly used. Arterialization of the venous bloodflow is possible only if the distal LE is affected and leads to a fairly large number of complications [8]. It should be remembered that in 40% of cases, reconstructive surgery in patients with CLLI is impossible due to the prevalence of the atherosclerotic process, LE angioarchitectonics, the risk of complications associated with comorbidities, age, and lesions of several arterial systems [6].

Lumbar sympathectomy (LS) appears to be the most common palliative surgical treatment for CLLI [16–18]. LS was first performed in 1924 by the Argentine surgeon J. Diez [19–21]. Currently, LS is performed by several methods: surgical (open, mini-access and endoscopic), percutaneous (chemical or radiofrequency) [22-24]. LS seems to be the most widely used method for stimulating collateral blood flow, developing vasodilation, and in order to reduce BP in the absence of the effect of conservative therapy and the impossibility of direct revascularization [25–27]. LS involves the removal or destruction of the 2nd, 3rd, and 4th lumbar sympathetic ganglia (Fig. 1) [28–30].

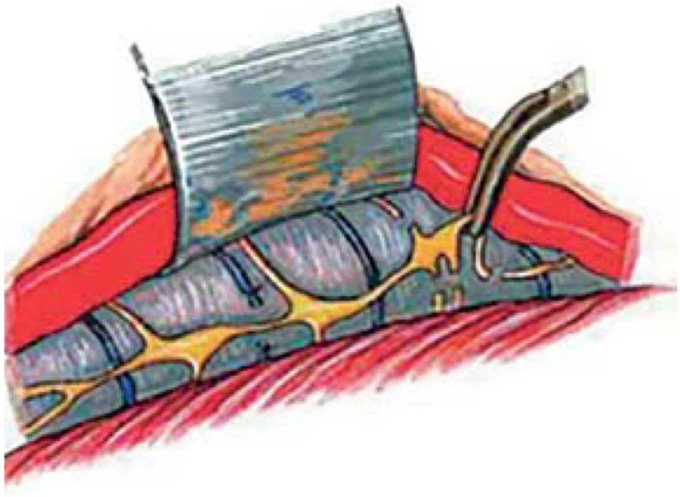

Fig. 1. Scheme of lumbar sympathectomy

The lumbar sympathetic ganglia are located on the ventral surface of the lumbar vertebral bodies [31]. The advantages of LS include minimally invasiveness, maximum accessibility, ease of execution, and low cost [32–34]. Improvement in subjective well-being after LS was recorded in more than 60% of patients, which makes it possible to recommend it as an alleviation of the symptoms of CLLI [35].

The open LS technique causes weakness of the muscles of the anterior abdominal wall on the access side and an increase in the duration of hospitalization, which slows down most surgeons before performing it [36–38]. With the development of modern technologies, LS has recently been developed using transcutaneous technologies and neuroimaging methods (X-ray or computed tomography (CT) guidance). Under X-ray guidance (anterior - posterior, oblique with an angle of 15–25°, lateral projection) and under local anesthesia (lidocaine, ropivacaine, marcaine, etc.), 2–5 ml of solution at each level on the side of the spine, lateral to the midline, a stylet is inserted to the ventral-lateral surface of the vertebral bodies L2, L3, L4 in accordance with the side of the CLLI (Fig. 2) [9, 39].

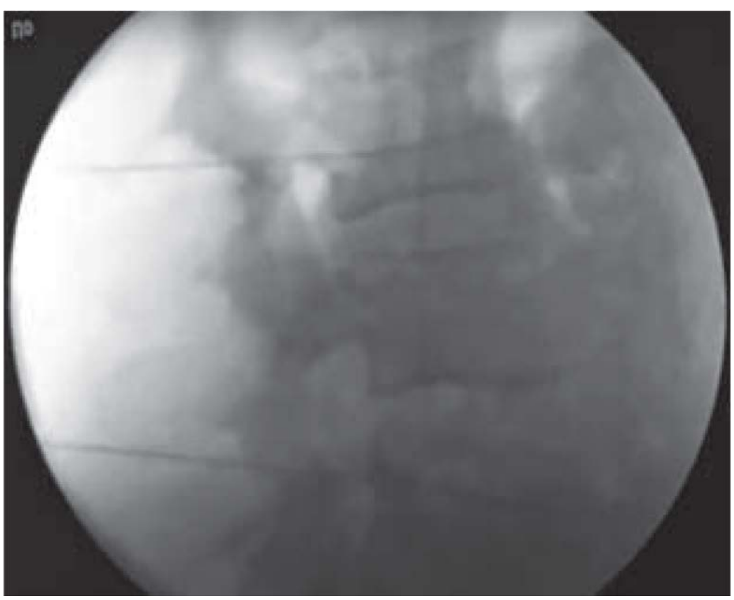

Fig. 2. X-ray guided (lateral projection) needle placement for chemical lumbar sympathectomy

Next, 0.5 ml of a contrast agent (yopamiscan, omnipaque, iodiscan, yohexol, ultravist, etc.) is injected to exclude the intradural, intraorganic, or intravasal location of the electrode (Fig. 3).

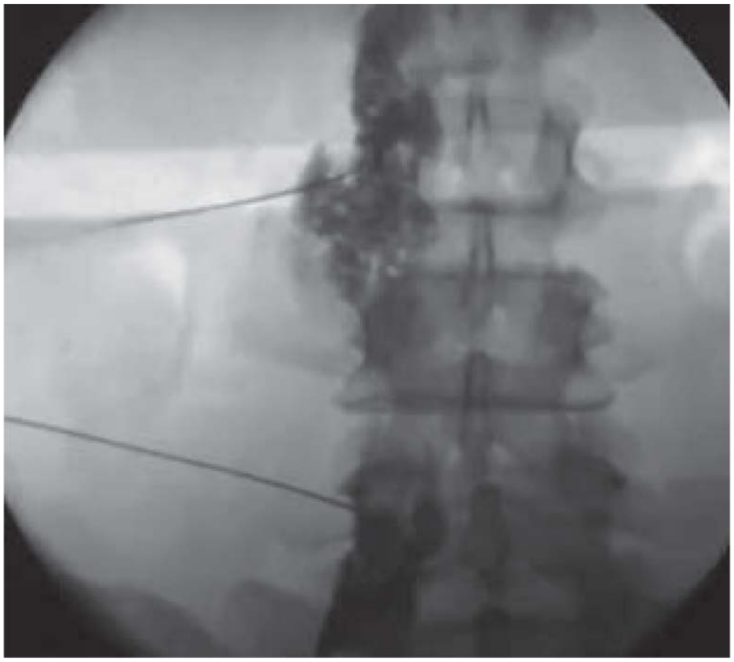

Fig. 3. Introduction of a radiopaque agent to exclude intradural and intravasal position

The spread of the contrast agent along the lumbar vertebral bodies confirms the correct position of the needle tip (Fig. 4).

Fig. 4. X-ray contrast agent spreads along the lumbar vertebrae, which indicates the correct placement of the needles

Next, the mandrin is replaced with a radiofrequency thermocouple electrode and radiofrequency ablation is performed. In chemical LS, after the preliminary injection of a local anesthetic, 2–3 ml of 95% ethyl alcohol is injected [20].

The results of the study demonstrated that LS does not increase muscle blood flow, but causes the development of arteriovenous bypass [40]. The opening of arteriovenous bypasses leads to the discharge of blood from those areas of soft tissues and skin that need it most, which is also described in studies where the productivity of LS was assessed by scintigraphy. V.P. Kokhan and O.V. Pinchuk (1997). According to the results of the study of blood flow in the LE by dynamic scintigraphy (Tmax /T1/2) showed that its parameters in the terminal stage of CLLI changed from 17.37±2.03 and 207.47±62.48 to 10.0±0, 9 and 178.3±31.6 ($0.2 < p < 0.4$ and $0.2 < p < 0.4$) [41]. On the contrary, W.S. Moore , A.D. Hall (1973) found that LS increased capillary skin blood flow, as shown by an increase in xenon clearance in the LE on the side of the LS, in addition, an increase in blood flow in the skin was regulated with clinical improvement [42].

In the work of Yu.M. Polous and R.Ya. Kushnir (1991), where out of 63 patients with 2 degree after LS in 11 patients with PAD and obliterating endarteritis developed PS at rest appeared and subsequently trophic changes developed [43]. They demonstrated the presence of steal syndrome after LS and announced the possibility of predicting LS using drug ganglionectomy with the study of the p02 level of muscles (partial pressure of oxygen in the gas phase) and the subcutaneous basis of LE.

A study by W. C. Johnson et. al. (1998) assessed LS productivity by transcutaneous oxygen tension, where an increase in this indicator after LS was shown in 50% of individuals [44]. The duration of recovery of the vasomotor reaction after LS ranges from 2 weeks to 6 months. However, the experience of using LS by V.P. Kokhan proved the possibility of a sustained effect after LS for several years (sometimes >10 years).

V.P. Kokhan and O.V. Pinchuk (1997) note that a better effect is observed in persons with hyperhidrosis and COD than in those with Buerger's disease [41].

F. W. Cross , L. T. Cotton (1995) announced the results of a prospective, randomized, controlled, 2nd blind study of chemical LS versus placebo (bupivacaine). BP at rest was reduced in 83.5% of subjects (in placebo in 23.5%, p <0.002), 66% of patients did not have resting BP within 6 months, and hemodynamic changes after LS were not observed [45].

Conclusions of a survey of specialists in angiosurgery and associated specialties in the UK and Ireland on the use of chemical LS in the treatment of patients with CLLI when revascularization is not possible, published in International Journal of Surgery in 2009 (242 responses received out of 490 requests) follow-up: 183 physicians (75%) use LS for CLLI [46].

In a literature review by M. Pekař et. al. (2016), demonstrated a significant efficacy of LS (based on 3 studies), which reached 63.6–93.4% in patients with CLLI [47].

The results of the use of LS in various diseases are presented in Table 1.

Table 1

Results of lumbar sympathectomy

Bibliography	Best	Acceptable	Contraindications
W.S. Moore Vascular and Endovascular Surgery a comprehensive review. 8 ed. Philadelphia: Elsevier Saunders . 2013; 1087. [34]	Hyperhidrosis; causalgia; frostbite; Buerger's disease; atheroembolism	Impossibility of revascularization in case of Buerger's disease or PAD with a minimum tissue loss; PS at rest in non-diabetics with damage to small-caliber arteries with or without Raynaud's syndrome	Intermittent lameness; diabetes mellitus with polyneuropathy
	Excellent	Good to fair	Poor
R.B. Rutherford Vascular surgery. 6th ed. Philadelphia: Elsevier Saunders. 2005; 1; 1825–1846. [35] Haimovici's Vascular Surgery, 6th Edition. Edited by Enrico Ascher. 2012; 1342. [36]	Causalgia; hyperhidrosis; vasospastic diseases complicated by ulcers on the fingers	The impossibility of revascularization in PAD with the presence of PS at rest or limited necrosis; Buerger's disease	Intermittent lameness; diabetic polyneuropathy

Notes: БС — pain syndrome; ХОЗАНК — peripheral occlusive arterial disease of the lower extremities

I.N. Staroverov and O.M. Lonchakova (2014) compared the results of open (n =38) and chemical (n =26) LS. Immediate results showed the comparability of the obtained data (good outcomes — χ^2=0.04, p =0.8; satisfactory and unsatisfactory outcomes — χ^2=0.01, p =0.9). In the postoperative period, weakness of the anterior abdominal wall was observed in 32% of patients (12/38) on the side of LS, and there were no complications in percutaneous LS [36].

According to A.V. Pokrovsky LS brings a temporary insignificant effect no longer than 3–4 years in patients with stage 2 PAD, and in patients with stage 3–4 it is almost always ineffective [11]. In a comparative analysis of direct, combined and reduced revascularizations, the best results were obtained when direct revascularizations were combined with LS [12, 48].

Neurostimulation. Persistent PS in CLLI leads to a pronounced limitation of mobility and a sharp decrease in QoL [2]. Analgesic effect Spinal Cord Stimulation (SCS) helps improve the quality of life of patients by reducing BP and increasing physical activity [9]. Mechanisms of PS reduction in SCS are also diverse and include influences both at the peripheral and central levels with the involvement of neurotransmitter systems [49–51]. PS impulses can be blocked at the level of the gelatinous substance of the dorsal horns of the spinal cord upon stimulation of larger diameter afferent fibers (types A-alpha and A-beta) [52]. SCS induces functional LS and vasodilation, which has positive trophic and antinociceptive effects [53].

Candidates for SCS must be PS associated with CLLI, insensitive to drug therapy, the lack of the possibility of direct revascularization and the expected longevity. With test SCS, paresthesia in the PS areas and its significant reduction should be obtained. In the presence of ulcers on the LE, their diameter should be less than 2 cm, and they themselves are not buried in the dermis; gangrene should not be dry and have parameters not exceeding those indicated for ulcers. The main response features for the test SCS are a reduction in BP on the visual analog scale (VAS) and an increase in walking distance.

In the SCS-E study, PO S W. Amann et. al. (2003) selected patients depending on microcirculation data. The experimental group included patients with moderately reduced local oxygenation (within 10–30 mm Hg) and very low oxygenation (<10 mm Hg), in whom the increase in test SCS was at least 20 mm Hg. In the SCS group, when revascularization was impossible, the highest results of LE preservation were shown in comparison with conservative treatment [54].

Y. Tshomba et. al. (2014), after analyzing the long-term results of SCS in 274 individuals, proved that the main predictor of success (the ability to walk at least 30 meters without the appearance of PS) seems to be the early onset of SCS - 2–5 months after the onset of ulcers on the LE, and at the onset of SCS 12-15 months after the formation of ulcers, there was no effect [55].

In a study by J.T. Liu et. al. (2018) included 78 patients with CLLI. Before SCS, walking distance was 64.86±40.80 meters, walking time was 2.65±1.64 min, and sleep quality was 1.70±0.78. Twelve months after SCS, walking distance was 1 595.00±483.60 m, walking time was 48.92±14.10 minutes, and sleep quality was 4.65±0.92. PS according to the VAS scale in a week — 8.63±0.54 and in a year — 2.35±0.62 [56].

The work of A.A. Ashurkova et al. (2019) included 38 patients with CLLI (10 women, 28 men, mean age 39–83 years) operated on in 2012–2016. Patients' QoL was assessed using the SF -36 questionnaire before and after 30–60 months of SCS. In addition, the dynamics of patient mortality, the number and level of amputations were analyzed [8]. Prior to SCS, mean scores of 3 of the 4 physical well-being scales in the patient group were significantly low compared to population norms ($p < 0.001$).

Indicators of scales of psychological well-being were closer to the average level. The total indicator of physical well-being was below the normal range (score 37.9±9.2), the indicator of psychological well-being had average values (48.1 ± 8.3 points). When monitoring for 30–60 months after SCS, it was not possible to contact 5 patients, 12 patients died, 3 patients underwent amputation at the level of the lower leg; the supporting function of the LE was preserved in 16 patients, in 2 of them the amputation of the toe took place. In 3 cases, the system failed. Questionnaire SF-36 30–60 months after SCS was filled in by patients with preserved LE supporting function. An increase in all QOL parameters was noted, the average total indicator of physical well-being approached the population norm (46.3±10.6 score, $p=0.050$ when compared to the preoperative value), and the total indicator of psychological well-being became higher than the average population level (57.9±3.8 score, $p = 0.041$). SCS does not reduce the mortality rate in patients with CLLI compared with mortality data with conservative treatment, however, it reduces the percentage of LE amputations in surviving patients.

Neuromodulation Appropriateness Consensus Committee (NACC) concluded that SCS may reduce the risk of LE amputation and the intensity of PS in individuals with CLLI when direct revascularization is not possible and refractory to conservative treatment (level of evidence B) [1, 8, 57].

CONCLUSION

In patients with severe pain syndrome, it is advisable to perform lumbar sympathectomy for the relief of critical ischemia of the lower extremities at the first stage. Percutaneous (chemical or radiofrequency) lumbar sympathectomy is the operation of choice that meets the criterion of the ratio of the concepts of "cost-risk-benefit".

SCS is a relatively new treatment for critical lower limb ischemia. It is necessary to conduct large-scale studies to determine the exact indications of SCS in critical lower limb ischemia, taking into account: the degree of chronic lower limb ischemia, age, microcirculation data (transcutaneous oxygen tension, linear blood flow velocity, ankle-brachial index, etc.) and angiography of lower limb arteries, concomitant pathology, the prevalence of atherosclerosis, the level of pain syndrome and its location, the presence of ulcerative-necrotic processes in the lower extremities and the distance of pain-free walking. A wider introduction of SCS and lumbar sympathectomy techniques in the treatment of critical lower limb ischemia is needed.

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