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CRITICAL LIMB ISCHEMIA. A LITERATURE REVIEW (PART 2)

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Abstract

Critical lower limb ischemia (CLI) is the final stage of peripheral arterial disease and occurs with chronic pain at rest, loss of tissue and limb. Despite the active development of new technologies, including endovascular and open surgical methods of treatment, and the development of various guidelines, CLI still remains an unresolved burden of vascular surgery around the world. The second part of the review describes large randomized trials, open and endovascular methods of lower limb revascularization in CLI. Also, the use of deep vein arterialization technology in No-option cases for conventional methods of revascularization.

Төменгі аяқтардың критикалық ишемиясы. Әдебиет шолуы (2-ші бөлім)

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Мүдделер қақтығысы:
Авторлар мүдделер қақтығысының жоқтығын мәлімдейді

Түйінді сөздер:
төменгі аяқтың критикалық ишемиясы, перифериялық артерия ауруы, қант диабеті, атеросклероз, ампутация

Тұжырым

Аяқтың критикалық ишемиясы перифериялық артерия ауруларының соңғы кезеңі болып табылады және қимылсыз созылмалы ауырсынумен, тіндердің және аяқтың жоғалуымен жүреді. Жаңа технологиялардың белсенді дамуына, соның ішінде эндоваскулярлық және ашық хирургиялық емдеу әдістеріне және әртүрлі нұсқаулардың дамуына қарамастан, аяқтың критикалық ишемиясы әлі күнге дейін бүкіл әлемде тамыр хирургиясының шешілмеген ауыртпалығы болып қала береді. Шолудың екінші бөлігінде үлкен рандомизацияланған сынақтар, аяқтың критикалық ишемиясы реваскуляризациясының ашық және эндоваскулярлық әдістері сипатталған. Сондай-ақ, реваскуляризацияның дәстүрлі әдістеріне жағдай болмаған жағдайда терең тамырларды артериализациялау технологиясын қолдануы жазылған.

Критическая ишемия нижних конечностей. Обзор литературы (часть 2)

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Аннотация

Критическая ишемия нижней конечности (КИНК) является финальной стадией заболеваний периферических артерий и протекает с хроническими болями в покое, потерей ткани и конечности. Несмотря на активное развитие новых технологий, включающие эндоваскулярные и открытые хирургические методы лечения, и, разработку различных методических рекомендаций, КИНК все еще остается нерешенным бременем сосудистой хирургии всего мира. Во второй части обзора описаны большие рандомизированные исследования, открытые и эндоваскулярные методы реваскуляризации нижних конечностей при КИНК. А также, применение технологии артериализации глубоких вен при отсутствии условий для общепринятых методов реваскуляризации.

Ключевые слова:
критическая ишемия нижних конечностей, заболевания периферических артерий, сахарный диабет, атеросклероз, КИНК, ЗПА, ампутация, артериализация глубоких вен

Critical limb ischemia (CLI) is the final stage of peripheral arterial disease (PAD) and occurs with chronic pain at rest, loss of tissue and limb.

PAD in diabetic patients is much more aggressive, with early involvement of large vessels with distal symmetrical neuropathy. The need for high amputation in diabetics occurs 5-10 times more often compared to non-diabetics. Sensory neuropathy with a decrease in resistance to the development of infectious complications also contributes to the increase in the frequency of amputations. Based on this evidence, the American Diabetes Association recommends screening patients with diabetes for PAD and measuring the ankle-brachial index every 5 years [1]. PAD of the arteries is 3 times more common in patients with diabetes. The percentage of occurrence in diabetic patients over 50 years of age is 29% [2,3].

Obliterating diseases of the arteries of the lower extremities associated with DM, for the most part, have lesions in the distal segments of the tibial arteries, which in turn requires shunting of the arteries of the dorsal foot, plantar artery, and more distal parts of the posterotibial artery [4]. The clinical manifestations of lesions of the arteries below the popliteal fossa for the most part manifest as critical ischemia of the lower extremities rather than intermittent claudication. Infrapopliteal arterial disease is more common in patients with diabetes and renal insufficiency [5]. The caliber of the arteries is smaller than the arteries above the knee, and the lesion of the arteries is of an extended nature [6]. The disease is characterized by calcification of the media or Mockenberg sclerosis, as a result of which the lumen of the vessel narrows, which is in contrast to isolated atherosclerosis, in which the pathological process occurs in the intimal layer of the vessel [7]. The arteries below the knee joint have a greater involvement in diabetic patients. It should be noted that the occurrence of trophic disorders of the lower extremities and life-threatening infections is more common in patients with diabetes [8,9].

According to the IDF (International Diabetes Federation), the prevalence of DM among adults (20–79 years old) averages 5.1% (of which 90% is DM II) [10,11]. Approximately 10% of older diabetic patients have foot ulcers or gangrene. In the structure of ulcers in diabetic foot syndrome, 48% are neuroischemic and 7% are ischemic. Thus, 55% of ulcers in patients with DM develop against the background of critical lower limb ischemia (CLI) [12].

According to the international recommendations

TASC II, the incidence of critical lower limb ischemia is 500-1000 cases per 1 million population per year. In the structure of the incidence of critical ischemia of the lower extremities, the proportion of elderly and senile people is 80% [13].

Critical limb ischemia (CLI) is a severe form of peripheral arterial disease that results in reduced blood flow to the legs and feet, causing pain and potentially leading to amputation. It is caused by a buildup of plaque in the arteries that supply blood to the legs, causing them to narrow and restricting blood flow. Symptoms include pain while walking (claudication), open sores or wounds on the feet that won't heal, and changes in skin color or texture. Treatment for CLI aims to improve blood flow to the affected limb, relieve symptoms, and prevent progression to more severe stages of the disease. The specific treatment options for CLI depend on several factors, including the cause and extent of the blood flow restriction, the presence of other medical conditions, and the patient's overall health.

Today, there is a constant discussion of the methods of treating PAD: which method is better to apply in a particular case. The rapid development of the arsenal of interventional surgery does not detract from the results of open revascularization of peripheral arteries. What method of revascularization is acceptable for a particular patient still remains an urgent question. There are a sufficient number of studies on the methods of treatment of peripheral arterial diseases, however, the issue of saving the limb, preventing mortality, and improving the quality of life in such patients remains insufficiently studied [14].

Treatment options for CLI may include:

Lifestyle changes: This includes modifying risk factors such as smoking, controlling blood pressure and cholesterol levels, and engaging in regular physical activity.

Medications: This includes medications that improve blood flow, reduce pain, or prevent blood clots, among others.

Endovascular procedures: This includes angioplasty, in which a balloon is used to open up a blocked or narrowed artery, and stenting, in which a metal mesh is placed in the artery to keep it open.

Surgical procedures: This includes bypass surgery, in which a new blood vessel is created to bypass the blocked or narrowed artery, and amputation, in which the affected limb is removed, as a last resort.

Deep vein arterialization (DVA): A surgical procedure that uses a vein from the affected limb to bypass the blocked or damaged artery, restoring blood flow to the affected area.

Treatment for CLI should be individualized and tailored to the patient's specific needs, and is best determined by a healthcare professional. Early diagnosis and prompt treatment are important to prevent progression of the disease and avoid serious complications.

Lower limb revascularization is a surgical procedure performed to restore blood flow to the legs and feet in patients with peripheral arterial disease (PAD). It involves re-establishing blood flow to the affected limb by either bypassing the blocked artery with a graft or removing the blockage through angioplasty and stenting. The goal of lower limb revascularization is to relieve symptoms such as pain, improve wound healing, and prevent the progression of PAD, which can lead to amputation in severe cases. The type of procedure performed depends on the location and severity of the blockage, as well as the overall health of the patient. Lower limb revascularization is usually performed by a vascular surgeon and is done under general anesthesia.

There is no one "best" clinical trial for critical limb ischemia (CLI) as different trials may have different goals and evaluate different treatments or interventions. However, some well-known and widely cited trials in the field of CLI include:

BASIL Trial: The Bypass versus Angioplasty in Severe Ischaemia of the Leg Trial, which compared endovascular therapy (angioplasty) and surgical bypass in patients with CLI.

BEST-CLI Trial: The Bypass versus Angioplasty in Severe Ischemia of the Legs Trial, which compared endovascular therapy (angioplasty) and bypass surgery in patients with CLI.

IN.PACT SFA Trial: The IN.PACT SFA trial, which evaluated the safety and efficacy of the paclitaxel-coated balloon for the treatment of peripheral artery disease in the superficial femoral artery.

Ultimately, the "best" trial for a particular patient depends on many factors, including their individual clinical characteristics and the goals of treatment. Patients should discuss the risks and benefits of each trial with their doctor before making a decision.

Prior to the publication of the American College of Cardiology/American Heart Association guidelines in 2011, there was no clear recommendation for the use of revascularization techniques. This publication referred to the single-center randomized trial The Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL), which reported similar outcomes in patients with critical limb ischemia after endovascular and open surgery [15].

The 2007 Inter-Society Consensus on the Management of PAD (TASC II) and the 2012 National Institute for Health and Clinical Excellence (NICE) have published guidelines for the diagnosis and treatment of peripheral arterial disease. But, in the proposed recommendation, there is not enough data on the management of patients with PAD, with concomitant diabetes [16,17].

BASIL trial

According to the literature, there are a sufficient number of studies comparing various treatments. So, in the randomized clinical trial BASIL, initiated by the UK, 452 patients with damage to the arteries of the lower extremities took part. This study compared two treatments: endovascular treatment, surgical

treatment in patients with lesions of the infrainguinal arteries, where one third of patients underwent bypass surgery on the arteries of the lower leg and 62% of patients underwent balloon angioplasty of the superficial femoral artery. Separate evaluation of the results in the subgroup with infrapopliteal arterial disease was not carried out [18]. The worst outcome and high probability of high amputation is observed in patients with diabetes and concomitant PAD [19]. Despite the constantly improving technique of minimally invasive endovascular procedures, bypass surgery for patients with PAD is still in demand [20].

BEST-CLI trial

Another large randomized trial comparing endovascular and open treatments is BEST-CLI, which includes 1830 patients. Patients ultimately were randomized into 1 of 2 treatment cohorts. A total of 1,434 patients were assigned to Cohort 1, of whom 718 (50.1%) received surgical revascularization and 716 (49.9%) underwent endovascular intervention. Median follow-up after open revascularization was 2.7 years (IQR 1.6-4.0), and after endovascular revascularization was 2.7 years (IQR 1.6-4.1). The mean time to the index procedure before surgical revascularization was 4 days (IQR 1-11), and before endovascular revascularization was 1 day (IQR 0-7)

In the face of increasing incidence of endovascular and hybrid interventions for the treatment of CTLI, the BEST-CLI trial aimed to compare the 2 most popular revascularization methods available: open bypass surgery versus endovascular intervention. In summary, the findings reported that when an autologous (GSV) graft is available, surgical revascularization offered a 32% decreased risk of major adverse limb events or all-cause mortality [21].

The results of this trial indicate that among patients with CLTI in whom both surgical and endovascular interventions were feasible, surgical revascularization with a great saphenous venous conduit was superior to endovascular intervention in reducing major adverse limb events (including above-ankle amputations) or death, primarily driven by a reduction in major adverse limb events. When a great saphenous vein conduit was not available, outcomes were similar between surgery and endovascular therapies. Baseline health-related quality of life was quite poor in these patients, with greater improvements among patients undergoing endovascular intervention compared with surgery. Taken together, these results emphasize the role of pre-procedure planning (primarily by means of venous ultrasound to identify suitable venous conduit availability) as well as the need to include surgical candidacy and patient wishes/quality of life in the decision making [22].

IN.PACT SFA trial

Еще одно исследование, sought to investigate the longer-term outcomes of a paclitaxel-eluting DCB compared to PTA for femoropopliteal lesions. 331 patients with symptomatic (Rutherford 2 to 4) femoropopliteal lesions up to 18 cm in length were enrolled. Patients were randomly assigned in a 2:1 ratio to treatment with DCB or PTA. The 24-month assessments included primary patency, freedom from clinically driven target lesion revascularization (CD-TLR), major adverse events, and quality of life and functional outcomes as assessed by the EuroQOL-5D quality-of-life questionnaire, walking impairment questionnaire, and 6-min walk test. At 24 months, patients treated with DCB showed significantly higher primary patency when compared with PTA (78.9% vs. 50.1%; $p < 0.001$). The rates of CD-TLR were 9.1% and 28.3% ($p < 0.001$) for the DCB and PTA groups, respectively. The overall mortality rate in the DCB group was 8.1% versus 0.9% in the PTA group ($p = 0.008$). There were no device- or procedure-related deaths and no major amputations in either group through 24-month follow-up. The rate of vessel thrombosis was low (1.5% DCB vs. 3.8% PTA; $p = 0.243$), with no new events reported between 1 and 2 years. Both groups showed similar functional improvement at 2 years, although DCB patients achieved this level of function with 58% fewer reinterventions [23].

Abd Moain Abu Dabrh MBBCh, MS, together with co-authors, conducted a systematic review on the topic: Distal shunting versus endovascular interventions in critical lower limb ischemia, where 9 studies were included, 3 of which were randomized clinical trials and 6 cohort studies. The conclusion of this review is that there is an identical effect on mortality and major amputations no matter what type of intervention was used. However, primary patency is higher when performing open surgery. However, further research is needed to include additional endpoints [24]. Endovascular interventions are considered safer in terms of morbidity and mortality, but the risk of interventional failure may be higher compared to distal shunting [25]. The Intersociety Transatlantic Consensus Document (TASC II) recommends arterial revascularization as the most appropriate treatment option, but the method of revascularization remains controversial [26].

Nasser M. Malyar and co-authors, in their study, evaluated the immediate and long-term results in patients with diabetes mellitus, complicated lesions of the arterial basin of the lower extremities and diabetic foot in Germany. The authors divided the patients, whose number reached 40,335, into 3 groups: patients with diabetic foot, patients with DM and with PAD, patients with PAD without DM. Major amputation was more common in patients with diabetic foot than in the group of DM in combination with PAD and isolated lesions of the arteries of the lower extremities (31.9% vs. 11.1% vs. 6%). Also in the issue of 4-year survival (57.4%, 60.8% and 70.0%) and limb preservation (45.4%, 74.4% and 86.5%), a group of patients with diabetic foot and DM, in combination with damage to the arteries of the lower extremities, had the worst results. In conclusion, the authors summarized the need to study the factors affecting the prognosis in patients with DM and PAD [27].

A study by Yisu Gu et al. evaluated the results of conservative treatment and various types of revascularization in patients with DM, where there was no significant difference in limb salvage after 1 year of follow-up. But, in the future, after 5 years of observation, in patients after revascularization, the chances of saving the limb were higher, mortality was lower, in comparison with the group where drug therapy was carried out [28].

D. W. Good et al conducted a study in which 24 patients, 19 of whom had diabetes, underwent popliteal-pedal autovenous shunting. For 5 years, the observation was carried out, in which the frequency of saving the limb reached 81.8% after 1, 3, 5 years. All 3 amputations were performed within the first 3 months. In conclusion, the authors consider distal shunting - popliteal-pedal autovenous shunting as an effective treatment. However, a randomized trial is required to compare endovascular treatment [29].

Lee MS et al evaluated the clinical outcome in PAD patients with and without DM who underwent balloon angioplasty. After two years of follow-up, it was found that the frequency of restenoses and amputations is higher in the group of patients with DM [30].

DEEP VEIN ARTERIALIZATION

When the disease progresses with damage and occlusion of the arteries of the foot, distal bypass or balloon angioplasty is usually used, however, in the vast majority of cases, these attempts end in a major amputation (above the knee) [31].

This is due to multi-vessel and multi-level arterial disease and the absence of a receiving bed, which is called "critical limb ischemia without options" (no-option-CLI or NOP-CLI). In such situations, connection of the venous bed into the bloodstream and nutrition of the limb due to the reverse flow through the venous vessels (vein arterialization) can be applied. There are several rationales that explain the success that can be achieved with venous arterialization, such as maximizing tissue perfusion through the capillary bed, improving venous return in the remaining vessels, and enhancing angiogenesis [32].

In 1977, a group of authors Sheil et al first described the then modern procedure. The great saphenous vein was anastomosed to the dorsal venous arch of the foot in six patients with critical limb ischemia, with pain resolution at rest and wound healing in five of six patients [33]. Numerous series of cases of this procedure have since been published.

To date, methods of vein arterialization are divided into open, endovascular and hybrid with various modifications and technologies. However, in the current literature there are no large studies comparing the safety and efficacy of these methods in the near and long term. Deep vein arterialization (DVA) is a surgical procedure that is used to treat critical limb ischemia (CLI), a severe form of peripheral arterial disease (PAD) that results in reduced blood flow to the legs and feet. In DVA, a vein from the affected limb is used to bypass the blocked or damaged artery, restoring blood flow to the affected area. The procedure involves disconnecting the vein from the deep venous system and connecting it to the arterial system, thereby creating a new "arterial" vessel.

DVA is typically used in patients with CLI who are not candidates for conventional revascularization techniques such as bypass surgery or angioplasty. The procedure is performed by a vascular surgeon and is done under general anesthesia. The goal of DVA is to improve blood flow to the affected limb, relieve symptoms such as pain, and prevent the progression of CLI, which can lead to amputation in severe cases.

The results of DVA are generally good, with improved blood flow and reduced pain in most patients. However, as with any surgical procedure, there are risks and potential complications associated with DVA, including infection, wound healing problems, and vein occlusion. Patients should discuss the risks and benefits of DVA with their doctor before deciding if the procedure is right for them.

One of the newest methods of arterialization is percutaneous (endovascular) arterialization of deep veins, (percutaneous Deep vein arterialization), developed by doctors from Paris (France). A feature of this technology is the formation of an arteriovenous fistula proximal to the site of arterial occlusion and at the closest distance to the nearest deep vein using percutaneous technologies and achieving optimal blood circulation in the distal ischemic area of the tissue or limb. Hypothetically, this technology should reduce the traumatization of an already ischemic limb and can be considered as more promising. However, very little information has been reported in the literature regarding this technology and there are several case series in which it is difficult to thoroughly study efficacy and safety issues.

Thus, the author of Kum et al describes a case series of 7 patients with critical ischemia and the threat of limb loss, who were first treated with percutaneous deep vein arterialization (pDVA) [34]. Primary safety was 100% with no mortality, no above-the-knee amputations, and no major reintervention within 30 days, but two patients had heart attacks. In addition, the technical success of the procedure was achieved in 100% of patients. All patients showed an improvement in symptoms in the form of the formation of granulating tissue at the wound site and a decrease in pain at rest. Complete wound healing was achieved in 4 of 7 patients (57.1%) within 6 months and in 5 of 7 patients (71.4%) within 12 months with a median healing time of 138 days (95% CI, 84-192 days).

When assessing transcutaneous oxygenation (TCO) after the procedure, the maximum value was 61.5 mm Hg compared to 8 mm Hg before the procedure. Within 12 months, one patient underwent amputation above the knee due to the spread of the focus of infection, as well as in one patient above the

knee due to thrombosis of the peripheral stent graft. The percentage of limb salvage for the first time at 6 months was 85.7% and 68.6% within 12 months. Mortality at 12 months was 42.9%, but the cause of death was not related to the procedure or devices used [34]. The PROMISE multicentre trial is currently under investigation [35].

CONCLUSION

Thus, with the development of modern technologies and methods of percutaneous and open revascularization, as well as with the improvement of blood glucose control approaches, patients will be older and have more comorbidities. All these factors will limit the current possibilities of revascularization and patients with CLI and the risk of limb loss will increase.

The end point of the available methods in stopping the signs of ischemia, by restoring blood circulation in the basin of the lower extremities. The arsenal for endovascular interventions is inexorably increasing, which expands the field of activity for revascularization of the affected arteries. But, open surgery also does not stand still. If earlier, arterial lesions immediately under trifurcation were considered unacceptable for the reconstruction of the arterial bed, and treatment was limited to palliative or drug therapy, then today revascularization of the arteries of the lower leg and foot by the surgical method has become possible. Percutaneous deep vein arterialization (pDVA) in these patients may be a promising alternative and minimally invasive limb-sparing technique for CLI with threatened limb loss. However, to date, in order to obtain a reliably significant number of patients and long-term results, this method requires further study. Based on the foregoing, there remains an open question about the most optimal way to treat PAD with concomitant DM.

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