Current Status of Arterial Revascularization for the Treatment of Critical Limb Ischemia in Infrainguinal Atherosclerotic Disease

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Abstract

Keywords

- critical limb ischemia
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- overview
- management

Critical limb ischemia (CLI) is the most severe form of peripheral arterial disease (PAD) that may result in limb loss and even death; thus, the fast and proper treatment should be employed as earlier as possible to prevent these catastrophic consequences. Arterial revascularization is almost always an indispensable treatment option for CLI. Although both endovascular and surgical revascularization procedures have an important role, nowadays, the hybrid revascularization as a combination of these revascularization procedures has also gained increasing popularity in the treatment of patients with CLI. This review provides an update on the arterial revascularization strategies for the treatment of CLI.

Peripheral arterial disease (PAD) is a manifestation of systemic atherosclerosis which signifies an increased hazard of serious cardiovascular disorders. Although PAD affects 10 to 15% of the general population, it has often received less attention than other atherosclerotic diseases. Approximately half of patients with PAD are asymptomatic; leading to under-diagnosis and under-treatment.^{1–3} Critical limb ischemia (CLI) is a severe form of PAD, which frequently leads to the disabling symptoms of pain and may cause loss of the affected extremity. It is related to increased hazard of myocardial infarction, stroke, and even death from the cardiovascular diseases as well.^{4,5} Actually, CLI is not a common form of PAD and accounts for just 1 to 3% of all patients with PAD, but it is very important clinical condition because of its disabling and also lethal nature. Patients with CLI have a 1- and 10-year mortality rates of nearly 20% and 75%, respectively.⁶

CLI needs a multidisciplinary team approach due to its complex pathological process. This approach enhances a wider understanding of the disorder with a more extensive

use of medical, endovascular, and surgical options, and it favors collaboration over competition.⁷ The main objectives of the treatment of CLI are to relieve the patients' symptoms, such as ischemic pain and ulcer, prevent extremity loss, improve function and quality of life, and prolong survival.^{8,9} Modification of risk factors (smoking cessation, control of hypertension, and diabetes mellitus), pharmacological treatments (antiplatelet therapy with aspirin or clopidogrel alone, statins, and antihypertensive agents, such as angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers), wound healing therapies, and revascularization procedures (endovascular and surgical) constitute the items of CLI treatment. Although the efficiency of dual antiplatelet therapy (aspirin and clopidogrel) to reduce the risk of cardiovascular ischemic events is not established well in patients with symptomatic PAD, dual antiplatelet therapy can be reasonable to reduce the risk of limb-related events following arterial revascularization (Class IIb).¹ However, a recent meta-analysis has demonstrated that there is no significant

evidence for superiority of dual antiplatelet therapy compared with mono antiplatelet therapy following endovascular arterial revascularization.¹⁰ There are various evidences to support the use of hyperbaric oxygen, intermittent pneumatic compression, and angiogenic growth factors; however, these evidences are not considered to be sufficient to prove the real safety and efficiency in the treatment of CLI. Autologous stem cell therapy has been also used as an alternative option for the treatment of CLI for last years; however, the current literature on autologous stem cell therapy for CLI also could not demonstrate its significant benefit for overall survival, amputation-free survival, or amputation rates. Nevertheless, further well-designed large randomized controlled trials with low risk of bias are necessary to evaluate the actual outcomes of this therapeutic method and can prove its efficiency and safety for the treatment of CLI.^{1,9,11,12}

Arterial revascularization is accepted as the cornerstone of treatment to prevent extremity loss, and both open vascular surgery and endovascular therapy have a critical role in the treatment of patients with CLI.^{1,7,8,12–15} In this paper, the current literature was reviewed, and an overview of arterial revascularization for the treatment of CLI was made.

Arterial Revascularization

Numerous scientific data are available in the literature to report the efficiency of arterial revascularization procedures especially in terms of limb salvage.^{1,7,8,12–17} Without arterial revascularization, up to 40% of patients with CLI will require extremity amputation by 1 year.¹⁸ Moreover, following an index amputation, an important number of patients will require contralateral amputation (5.7% and 11.5% at the first and fifth years after first amputation, respectively), have ischemic ulcers recurrences, or die.^{18,19} Each intervention should be performed to offer the most efficient, safe, timely, and cost-effective form of revascularization to the patients with CLI.^{7,20} Options for revascularization include endovascular and surgical revascularization and hybrid revascularization as a combination of endovascular and surgical interventions. Nowadays, there is a significant trend toward “endovascular first” approach in the treatment of CLI, given consideration to the more invasiveness, the risks of morbidity and mortality associated with surgical revascularization, and the significant technological advances in endovascular area.⁷

Endovascular Revascularization

For many cardiovascular atherosclerotic diseases, both diagnostic and therapeutic endovascular approaches have advanced remarkably and have gained an increased popularity over last 2 decades. As a result of this process, therapeutic endovascular interventions have been applied successfully for the treatment of CLI as well.²¹ After published several case series with relatively small and selected patient populations, the first landmark trial of endovascular versus surgical revascularization for CLI, Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial, was published in 2005.²² In this multicenter prospective randomized controlled trial, a total of 452 enrolled patients were divided into two groups

according to their revascularization procedures, and a comparison between patients treated with bypass surgery-first ($n = 228$) and balloon angioplasty-first ($n = 224$) was performed. This study showed no significant difference between the treatment groups with respect to health-related quality of life and amputation-free survival at the first and third years of follow-up; however, for the first year, the hospital costs related to surgery were higher than those to angioplasty procedure. Long-term follow-up and subgroup analysis revealed that the surgery was still the best therapeutic option for suitable patients with sufficient venous graft for bypass procedure despite the decrease in the numbers of operative procedures because of improved medical and endovascular interventions.²³

A prospective study by Faglia et al²⁴ on 993 consecutive patients assessed the angioplasty procedure as the first-choice revascularization in diabetic patients with CLI. In this study population, 61.4% had lesions in the femoropopliteal and infrapopliteal regions, and 31.8% had lesions in the infrapopliteal region alone. Majority of patients underwent balloon angioplasty of multiple vessels with success rates for angioplasty of popliteal and proximal arteries being significantly higher than for angioplasty of infrapopliteal arteries. Primary patency rate of successfully treated arteries at 5 years was 88%, and limb salvage was provided in almost all of patients.

A meta-analysis of 30 studies by Romiti et al²⁵ evaluated the technical success, primary and secondary patency, limb salvage, and survival for patients treated with infrapopliteal percutaneous transluminal angioplasty (PTA). These were compared with similar end-points for patients treated surgically using with vein bypass grafts, and it was found a significant difference in primary patency rates between vein bypass and PTA, but limb salvage rates were similar at the first month and the first and third years of follow-up. Additionally, the meta-analysis demonstrated that the limb loss and diabetes mellitus were associated with the poor outcomes ($p < 0.002$).

Surgical Revascularization

Recent studies have shown a decrease in the numbers of surgical revascularization procedures on account of improved medical therapy and endovascular intervention.²⁶ Nevertheless, it has been demonstrated that open surgery provides the best long-term patency rates with the use of autologous saphenous vein grafts serving as the “gold standard therapy” for patients with CLI.²³ Open surgical revascularization should be preferred in patients with CLI who are relatively suitable, active, younger, and have a life expectancy >2 years, and may withstand the rigors of an open surgery.^{12,17}

Aortoiliofemoral occlusive disease can be treated with anatomic or extra-anatomic bypass (e.g., aortobifemoral, femoropopliteal, axillobifemoral, or femorofemoral crossover bypass) with satisfactory patency rates. Patients who undergo extra-anatomic bypass are generally older and are more likely to have a history of prior aortofemoral inflow operation, advanced preoperative extremity ischemia, and severe chronic obstructive pulmonary disease.²⁷ Because of its higher patency rates, great saphenous vein is the optimal and most preferred conduit for infrainguinal bypass if its usable adequate length

is available. Alternative vascular grafts are spliced arm and leg veins and prosthetic polytetrafluoroethylene with or without heparin bonding.²⁸⁻³² Due to the fact that an important majority of technical issues with prosthetic bypass grafts seems to occur at the distal anastomosis region, several alternative approaches (e.g., distal vein patch technique) have been described,^{33,34} but no single modification has demonstrated superiority in large-scale studies.³⁵ Generally, femoropopliteal bypass grafts to the above-knee popliteal artery target have the highest patency rates, and patency rate decreases when the distal target is the below-knee popliteal or tibial artery.^{7,28,35-37}

Mortality and major morbidity of open surgical revascularization for CLI were documented well owing to the PREVENT III trial. According to this prospective randomized multicenter trial of 1404 CLI patients who were treated with vein bypass from 2001 to 2003, the rates of perioperative mortality, postoperative myocardial infarction, and early graft occlusion were 2.7%, 4.7% and 5.2%, respectively.³⁸ In another study, it has been indicated that postoperative wound healing is problematic in 15 to 25% of patients, the rate of bypass infections is 1 to 3% (especially higher in prosthetic grafts), and the rates of early perioperative and 1-year mortality are 1 to 2% and 10%, respectively.³⁹

Venous arterialization can be considered as last resort for limb salvage in CLI patients with no revascularization options. It is a unique surgical procedure in which the venous bed is used as an alternative conduit for perfusion of peripheral tissues. According to the data of a recent systematic review and meta-analysis study, venous arterialization has been still seemed to be a valued alternative therapeutic option with 75% limb salvage rate at 12 months for patients facing amputation of the affected extremity; nevertheless, the existing evidence is not of high quality.⁴⁰

Hybrid Revascularization

Open surgery and endovascular interventions may be combined in cases of multilevel disease; thus, the blood flow into or out of a bypass graft may be improved by interventional means at a single session. A significant number of patients with CLI nowadays have received the hybrid therapies to achieve complete revascularization with a less extensive operative procedure, shorter duration of operation, and decreased risk of perioperative complications. Hybrid procedure enables an attractive revascularization option in patients who are older, frail, or have limited autologous graft for bypass surgery.^{12,16,41}

Most of the studies on this issue in the literature present PTA of the aortoiliac segment together with a simultaneous surgical intervention of the femoropopliteal segment. Early term outcomes of these procedures appear to be good with excellent limb salvage and reduced morbidity rates.⁴¹⁻⁴⁴ Several studies demonstrating outcomes of infrainguinal PTA of the femoropopliteal segment together with simultaneous ultra-distal bypass have been published as well, with the reported data showing satisfactory early term and long-term outcomes (the 5-year limb salvage and survival rates of 70 to 86% and 35 to 65%, respectively).⁴⁵⁻⁴⁸

Outcomes of Comparative Analysis of Arterial Revascularization Procedures

Current investigations have been focused on an ongoing debate: endovascular versus surgical therapy for CLI treatment. Many comparative studies have been conducted on this issue, and the evidence of whether endovascular or surgical therapy is superior for patients with CLI has been sought for last years.^{22,23,49-53} The first report of the BASIL trial revealed that amputation-free survival and quality-of-life rates were similar in both endovascular and open surgery groups at 6 months.²² In the long-term, nevertheless, open bypass surgery has provided a significantly increased overall survival benefit of nearly 7 months for patients who survived over 2 years.⁴⁹ Although the option of open surgery has better outcomes, it remains limited to a selected patient population healthy enough to withstand an invasive intervention. Based upon this study of operable cases, just those patients with life expectancies higher than 2 years are likely to realize a survival benefit from surgery compared with endovascular option.^{49,50,54}

Taha et al⁵¹ evaluated the comparative effectiveness of endovascular versus surgical revascularization for acute lower extremity ischemia, and they found similar limb salvage rates between the groups while significantly higher mortality rates in the open surgical revascularization group. Ohmine et al assessed the comparative efficacy and durability of endovascular therapy or bypass surgery as a first approach for the treatment of CLI due to infragenicular lesions, and they concluded that the endovascular therapy-first option was more effective and durable especially for patients who were in poor general condition or whose saphenous veins were in poor condition. Another recent intriguing study comparing the results of infrageniculate bypass surgery and endovascular intervention for occlusive disease at and below the knee in patients with CLI has just been published. In this study, which includes a total of 2,566 cases, authors compared the procedures in terms of the rates of 1-year primary patency, major amputation, and mortality, and they found lower 1-year primary patency rate in bypass surgery patients while similar major amputation and mortality rates of both revascularization procedures.⁵³

Indirect comparisons of endovascular interventions^{25,55} and bypass surgery using a venous conduit⁵⁶ demonstrated similar outcomes with respect to 1-year limb salvage and mortality rates in the treatment of CLI, both ranging from 85 to 90%, however, a higher requirement of re-interventions following endovascular treatment.⁵⁷ This increased rate of re-intervention is associated with an increase in the number of endovascular interventions in case of both intermittent claudication and CLI over the years, which outnumbers the decrease in open surgical procedures. In another study by Goodney et al,⁵⁸ it was reported that over three endovascular interventions were applied for every one procedure declined in lower extremity bypass surgery. It is not probable that the increase in endovascular procedures is only an outcome of more applied re-interventions following endovascular intervention. It can also be because of a lowering threshold for endovascular procedures as reflected by an increase in hospital admissions for endovascular procedures for intermittent claudication (i.e., the increase

from 10–31% to 26–43% of the PAD-related hospital admissions in 2001 and 2008, respectively).⁵⁹

Moreover, several systematic review studies evaluating comparative effectiveness of revascularization procedures have been recently published consecutively, and it has been reported that there are no significant differences in terms of clinical outcomes including major amputation and mortality rates for patients with CLI treated with endovascular or surgical revascularization.^{60–62}

Bisdas et al⁶³ performed the second prospective multicenter randomized controlled trial in the literature (following the BASIL trial) on 1,200 patients to compare both revascularization strategies as the first-line treatment for CLI, and they presented the interim analysis report. According to this report, the endovascular-first approach has a non-inferior amputation-free survival rate compared with open surgery-first approach when physicians are free to individualize therapy to CLI patients. Lastly, a newly designed BEST-CLI trial, as a multicenter prospective randomized controlled trial that compares best endovascular therapy with best open surgical treatment in patients eligible for both treatments, is a timely and much-needed study. It is hoped that this trial will help in describing the best clinical practice and enabling a basis in the decision and implementation of current and further therapeutic approaches for CLI patients.⁶⁴

Primary Parameters Involved in the Selection of Revascularization Procedure

The selection of revascularization procedure in the treatment of CLI varies by different parameters, such as the length, degree, and localization of stenotic lesions; the difficulty, risks, and expected outcomes of each procedure; the condition of autogenous grafts; and life expectancy and general and comorbid clinical status of each patient. Among them, general clinical status and life expectancy of patients are foremost key factors. Patients with severe comorbidities cannot be appropriate for surgical revascularization or general anesthesia. Endovascular procedures or even conservative management can be most appropriate approach in frail, debile, and immobile patients.¹⁷ Main eligibility criteria involved in selecting the revascularization procedures are listed in ►Table 1.

Table 1 Main parameters taken into account in the selection of revascularization procedure

	Endovascular	Surgery
General clinical status	Poor	Good
Life expectancy	<2 years	>2 years
Perioperative mortality risk	High	Average (<5%)
Severity of disease	Mild/moderate	Severe/moderate
Autogenous graft condition	Inadequate	Adequate and good quality
Anatomical condition	Single level; TASC A/B/C	Multilevel; TASC C/D

Abbreviation: TASC, Trans-Atlantic Inter-Society Consensus.

Differences of this Present Review from Other Recent Reviews of CLI

When we look at the other recent reviews of CLI in the available literature, these reviews seem to analyze almost all aspects of CLI, such as medical treatment, non-invasive and minimally invasive therapeutic options, arterial revascularization strategies, and recommendations for future.^{7,13,26} On the other hand, this present paper specifically focuses on the current status of arterial revascularization in the treatment of CLI and reviews this issue more comprehensively and systematically.

Conclusions

Arterial revascularization is the most important item of CLI treatment. However, the reply of the question, “Which arterial revascularization procedure is superior in CLI treatment, endovascular or surgical revascularization?” is controversial. Numerous comparative study investigating this issue has been conducted in recent years, but there is yet no consensus on this issue according to the available literature. Generally, it can be expressed that the reply of this question depends on various patient characteristics. Hence, it should be given consideration an individualized approach in selecting the best revascularization option. For last years, hybrid revascularization strategies have gained increased popularity and have been widely used in selected patients. Endovascular and surgical revascularization procedures, in fact, should be considered as complementary treatment modalities rather than competing strategies for CLI. The treatment decision in patients with CLI should be given by the multidisciplinary teams.

Conflict of Interest

None.

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