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Peer Reviewer of *World Journal of Clinical Cases*, Suman Baral, MD, Assistant Professor, Department of Surgery, Mediplus Hospital and Trauma Center, Pokhara 33700, Nepal. brylsuman.sur@gmail.com

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Advances in the management of arteriosclerosis of the lower extremity: Integrating Western and Chinese medicine approaches

Sha Cheng, Jia-Xin Xu, Wen-Jie Long

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Sha Cheng, Jia-Xin Xu, Department of Cardiovascular, The Affiliated Traditional Chinese Medicine Hospital, Guangzhou Medical University, Guangzhou 510000, Guangdong Province, China

Wen-Jie Long, Department of Geriatrics, The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou 510006, Guangdong Province, China

Co-first authors: Sha Cheng and Jia-Xin Xu.

Corresponding author: Wen-Jie Long, MD, PhD, Attending Doctor, Department of Geriatrics, The First Affiliated Hospital of Guangzhou University of Chinese Medicine, No. 16 Jichang Road, Guangzhou 510006, Guangdong Province, China. derek1626@163.com

Abstract

This editorial provides a commentary on the recent article. The paper reviews current literature and explores innovative treatment strategies for lower extremity arteriosclerosis obliterans (LEASO) through an integrative approach. It highlights the effectiveness of combination therapies that merge traditional Chinese medicine (TCM) with Western medical practices, suggesting that such integrative methods may improve patient compliance and outcomes through personalized care. This paper stresses the importance of rigorous clinical trials to evaluate the efficacy and safety of TCM interventions within LEASO treatment protocols, advocating for evidence-based validation of these combined therapies. Our recommendations emphasize accurate diagnosis, appropriate pharmacological interventions, the use of advanced surgical and endovascular techniques, and the inclusion of TCM to address underlying dysfunctions. Additionally, continuous monitoring, patient education, and lifestyle modifications are essential to slow disease progression and achieve optimal patient outcomes. The paper concludes by calling for further research to develop standardized treatment protocols that effectively integrate both Western and Chinese medical approaches in managing LEASO.

Key Words: Lower extremity arteriosclerosis obliterans; Traditional Chinese medicine; Integrative healthcare; Vascular therapy; Combination therapies

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Core Tip: Lower extremity arteriosclerosis obliterans (LEASO), a condition primarily influenced by smoking and diabetes, significantly increases the risks of limb ischemia and amputation. Current treatments, such as pharmacological and surgical interventions, provide limited relief. Integrative approaches that combine traditional Chinese medicine with Western medical practices offer holistic and personalized treatment strategy that focuses on addressing the root cause as well as managing symptoms. To establish the efficacy and safety of this combined approach, extensive randomized controlled trials are essential. Such evidence-based research is crucial for developing protocols that can improve patient outcomes in managing LEASO.

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INTRODUCTION

Lower extremity arteriosclerosis obliterans (LEASO) is a common vascular condition characterized by the obstruction of arterial blood flow due to atherosclerotic changes. This leads to limb ischemia and increases the risk of amputation. The development of LEASO involves a complex interplay of genetic, environmental, and lifestyle factors, with smoking and diabetes mellitus being particularly significant contributors. Smoking contributes to LEASO by inducing vasospasm and promoting a hypercoagulable state.

Despite over a century of research, the precise pathogenesis and optimal therapeutic strategies for LEASO remain unclear. According to a 2021 paper published in the *Chinese Journal of Surgery*, the incidence of LEASO is rising in China, potentially affecting up to 45.3 million individuals[1]. Despite advancements in Western medicine, such as endovascular treatments and surgical interventions, there is increasing interest in integrating Chinese medicine to offer a more personalized and holistic approach to managing LEASO.

Current treatment strategies for LEASO include pharmacological management with antiplatelet agents, statins, and prostanoid therapies, as well as surgical revascularization techniques like bypass grafting and endovascular procedures. The Global Vascular Guidelines published in 2019 provide comprehensive recommendations for diagnosis and treatment of critical limb-threatening ischemia (CLTI)[2]. However, the implementation of these guidelines has been inconsistent, with many patients not receiving standardized drug therapy. While Western treatments for LEASO are effective, they have limitations. High-quality clinical studies are needed to provide objective evidence for treatment decisions, particularly in anticipation of results from studies like the Best Endovascular Versus Best Surgical Therapy for Patients with Critical Limb Ischemia trial.

In contrast, Chinese medicine focuses on maintaining the equilibrium of 'Yin' and 'Yang' and ensuring the harmonious circulation of 'Qi' and blood. It employs various therapeutic modalities, including herbal remedies, acupuncture, and dietary therapy, which are believed to have fewer side effects and offer long-term sustainability. Chinese medicine's emphasis on syndrome differentiation allows for a more individualized treatment approach, potentially complementing the more generalized methods of Western medicine.

Recently, there has been growing interest in alternative therapies, particularly traditional Chinese medicine (TCM), due to its observed anti-atherosclerotic, anti-inflammatory, and wound-healing properties. However, scientific evidence supporting the efficacy and safety of these therapies is still limited, emphasizing the need for further research to establish their clinical relevance. This introduction sets the stage for a detailed exploration of how the strengths of both Western and Chinese medicine can be integrated to optimize patient outcomes in the management of LEASO.

LEASO STAGES

The ankle-brachial index (ABI), which measures the ratio of ankle-to-brachial systolic blood pressure, is the primary noninvasive diagnostic method for LEASO and requires standardized measurement techniques[3]. An ABI value of ≤ 0.90 is indicative of LEASO. Normal ABI values range from 1.00 to 1.40, with ≤ 0.90 considered abnormal, 0.91 to 0.99 critically abnormal, and > 1.40 suggesting severe vessel calcification or reduced elasticity[4]. Fontaine's classification stages LEASO [5] as follows: (1) Stage I: Mild symptoms, with most patients either asymptomatic or experiencing mild symptoms; (2) Stage IIa: Intermittent claudication with an absolute claudication distance > 200 m; (3) Stage IIb: Intermittent claudication with an absolute claudication distance ≤ 200 m; (4) Stage III: Resting pain; and (5) Stage IV: Ulceration and gangrene.

WESTERN MEDICINE FOR THE TREATMENT OF LEASO

Drug-coated balloons

Drug-coated balloons (DCBs) use carriers like paclitaxel or rapamycin to inhibit intima-media myocyte proliferation, thereby reducing restenosis due to intimal hyperplasia after treatment. Evidence supports the efficacy of drug-carrying

devices in femoropopliteal arteries, particularly DCBs, making them an important treatment option for lower extremity arterial disease[6]. Despite their advantages in reducing postoperative restenosis and the need for stenting, DCBs do not entirely eliminate undesirable dilatation effects such as elastic retraction and flow-limiting entrapment, necessitating remedial stenting when required. Additionally, DCBs face challenges including lower rates of distant patency, the presence of a pressure differential across the lesion, residual stenosis > 50%, and issues related to flow-limiting entrapment[7].

Surgical revascularization

Surgical revascularization involves the direct reconstruction or repair of diseased vessels to restore blood flow, rapidly alleviating ischemia, pain, and related symptoms[8]. For patients with severe vascular stenosis or occlusion, surgical revascularization often yields superior therapeutic results and significantly enhances quality of life. Compared to medical treatments, surgical revascularization offers more durable outcomes and maintains vascular patency over the long term. It is particularly beneficial for complex vascular lesions, such as multiple stenoses or occlusions, providing a more comprehensive solution.

However, vascular revascularization surgery carries inherent risks, including infection, bleeding, thrombosis, and other complications. The procedure is invasive, resulting in greater trauma and longer postoperative recovery times. Not all patients are suitable candidates for surgery; factors such as advanced age, poor physical condition, and other severe health conditions may preclude some individuals from undergoing these procedures. Additionally, surgical revascularization requires specialized equipment and technical expertise, which can be costly and impose a financial burden on patients.

TCM may complement surgical revascularization by improving overall health, enhancing bodily resistance, and facilitating postoperative recovery through practices such as acupuncture, massage, and herbal treatments. TCM emphasizes overall conditioning and syndrome differentiation, aiming to prevent recurrence of vascular diseases by regulating bodily functions and balancing qi and blood. While TCM does not replace surgical revascularization as a standalone treatment, it can serve as an effective adjunct therapy. By integrating TCM during the perioperative period, it may enhance surgical outcomes and improve patients' quality of life, offering a more comprehensive treatment approach.

Limitations of Western medicine treatment

Western medicine treatment for LEASO includes drug therapy, interventional procedures (such as balloon angioplasty and stent implantation), and surgical treatments (such as arterial bypass grafting)[9]. Despite significant advances, these treatments have notable limitations. First, for severe or widespread lesions, Western medicine often provides only partial relief, addressing symptoms or improving blood flow temporarily rather than resolving long-term issues. Second, drug therapies can cause adverse reactions like liver and kidney damage or bleeding tendencies, while interventional and surgical options carry risks such as infection, thrombosis, aneurysm, and restenosis, which can exacerbate the condition. Third, these treatments are influenced by patient-specific factors, such as age and overall health, and their effectiveness can be limited by the suitability of the lesion site and the patient's ability to tolerate the procedure[10]. Fourth, the high cost of these treatments adds a financial burden that can affect patient access and adherence. Fifth, Western medicine alone may not fully prevent disease recurrence due to individual differences, disease progression, or poor lifestyle habits. Therefore, a comprehensive approach that includes tailored treatment plans, health education, and follow-up management is crucial to improve outcomes and quality of life for patients.

Advantages of TCM for the treatment of LEASO

Multi-target therapeutic effect: TCM employs a multi-target therapeutic approach, using various active ingredients to synergistically regulate physiological functions, promote blood circulation, remove blood stasis, relax tendons, and improve microcirculation, thereby alleviating ischemic symptoms.

Overall conditioning: Emphasizing a holistic view, TCM addresses LEASO by considering the dysfunction of zang-fu organs, qi stagnation, and blood stasis[11], and works to enhance overall physical health and resistance, rather than focusing solely on the affected area.

Symptom relief: TCM also effectively relieves symptoms such as limb pain, numbness, and chills, and can reduce the need for opioid pain management, improving patients' quality of life.

Fewer side effects and complications: TCM has relatively fewer side effects compared to Western medicine, making it suitable for long-term use without significant risk of drug resistance or damage to liver and kidney function.

Comprehensive treatment: When used as an adjunct to Western medical treatments, TCM can enhance therapeutic efficacy, reduce adverse effects, and support perioperative care by preventing infection, promoting wound healing, and improving blood circulation. Moreover, TCM helps improve lifestyle and psychological conditions, further enhancing the overall quality of life for patients.

Innovation and limitations of research design

Li *et al*[12] study represents a novel approach by integrating TCM techniques, specifically auricular acupoint embedding, with the Wenjing Sanhan prescription for treating patients with arteriosclerosis obliterans (ASO). This integrated approach demonstrates a significantly higher clinical efficacy compared to the control group, which received only the warming meridian and cold-dispersing formula. However, the study has notable limitations, including a relatively small

sample size, which may affect the generalizability of the results. A small sample size can lead to larger sampling errors and may not accurately reflect the broader population, potentially impacting the validity of the findings[13]. Additionally, a small sample size may lack sufficient statistical power to support or refute the research hypothesis, with observed associations possibly being due to random effects rather than true effects. Furthermore, small sample sizes are more susceptible to selection bias and information bias, which can further skew the authenticity of the results. Proper sample size determination typically involves using statistical software or formulas, such as Statistical Package for the Social Sciences or G Power[14]. For accurate results, the sample size must be calculated to ensure the generalizability of the findings. The formula used in cross-sectional studies is: $N = [(Z_{\alpha/2} \times \sigma) \div \delta] \times 2$, where σ represents the overall standard deviation (often estimated by the sample standard deviation s), δ is the allowable error (the difference between sample mean and population mean), and α is set at 0.05. Cohen provides a comprehensive discussion on statistical power analysis and sample size determination, offering a theoretical and practical framework for researchers[15]. Additionally, the study lacks long-term follow-up to evaluate the sustainability and durability of the therapeutic effects. Despite these limitations, the research offers valuable insights into the potential role of TCM in treating ASO.

Integrated traditional Chinese and Western medicine vs Western medicine alone

Integrating TCM with western medical approaches presents a promising strategy for the comprehensive management of LEASO. This section explores the advantages and limitations of both modalities, drawing on recent literature and shared insights.

Western medicine for LEASO includes pharmacological interventions, endovascular techniques, and surgical revascularization. According to the 2021 study published in the *Chinese Journal of Surgery*, DCBs have significantly advanced endovascular treatment, improving limb salvage and graft patency rates for femoropopliteal and infra-popliteal artery occlusive disease[1]. However, concerns about the long-term safety of DCBs persist, with a 2018 meta-analysis suggesting a potential increase in mortality risk, sparking considerable debate[16]. Surgical revascularization remains effective but requires ongoing education and monitoring to maintain its efficacy. Inframalleolar bypass is noted for good graft patency and limb salvage rates CLTI patients, but the choice between regional and general anesthesia adds complexity to treatment decisions.

In contrast, TCM offers a holistic approach, focusing on syndrome differentiation and treatment. It emphasizes herbal formulas, acupuncture, and lifestyle modifications to address the root causes of LEASO, aiming to promote vascular regeneration and improve blood circulation. Compounds such as Dan Hong Injection and Gubuci Capsule have shown potential in enhancing clinical outcomes. The integrative approach combining Western medicine with TCM's holistic strategies offers significant promise. This synergy could potentially reduce amputation rates and improve limb salvage rates by tailoring treatment plans to individual patient needs, as highlighted in systematic reviews of randomized controlled trials.

Moreover, clinical markers like the ABI are crucial for assessing treatment efficacy in LEASO. Both Western and Chinese medicine recognize ABI's importance in monitoring disease progression and response to treatment. The integrative approach also includes other clinical markers such as high-density lipoprotein and low-density lipoprotein levels, essential for evaluating overall cardiovascular health. This approach addresses the limitations of Western treatments; for example, the bleeding risks associated with certain medications may be mitigated by incorporating Chinese herbal medicine, which may offer a more favorable safety profile. Additionally, the holistic care provided by TCM, including dietary and lifestyle modifications, complements the targeted interventions of Western medicine.

In conclusion, combining Western and Chinese medicine in treating LEASO leverages the strengths of both systems. While Western medicine provides evidence-based solutions for immediate symptom relief and disease management, Chinese medicine enhances overall well-being and addresses underlying imbalances contributing to the disease. Future research should focus on optimizing this integrative approach, standardizing treatment protocols, and conducting robust clinical trials to validate the efficacy and safety of combined therapies for LEASO management.

Comprehensive management of LEASO: Diagnosis, treatment, and integration

Diagnosis and staging: Accurate diagnosis and staging of LEASO are critical for determining the most effective treatment strategies. The ABI and other clinical markers should be employed to evaluate disease severity and guide management decisions.

Pharmacological interventions: Antiplatelet agents, statins, and other Western pharmaceuticals should be prescribed based on established clinical guidelines. Individual patient risk factors and medication contraindications must be considered to tailor treatment effectively.

Endovascular and surgical treatments: For patients with advanced LEASO, DCBs and surgical revascularization are viable options. The choice of procedure should be guided by the patient's anatomical and clinical profile, as well as the availability of expertise and resources.

TCM integration: TCM therapies, including herbal medicine and acupuncture, should be integrated into the treatment plan to address underlying imbalances and enhance overall health. Collaboration with TCM practitioners is essential to ensure safety and efficacy.

Lifestyle modifications: Patients should receive guidance on lifestyle changes such as diet, exercise, and smoking cessation to complement medical interventions and slow disease progression.

Continuous monitoring and follow-up: Regular follow-up is crucial to assess disease progression and treatment response. The treatment plan should be adjusted based on clinical outcomes and patient feedback to ensure ongoing effectiveness.

Patient education: Educating patients about the disease, available treatment options, and self-care practices is vital for empowerment and adherence to treatment plans, ultimately improving health outcomes.

CONCLUSION

LEAO remains a challenging condition to manage, with limited therapeutic options and high recurrence rates. TCM offers potential as a complementary therapeutic modality due to its anti-atherosclerotic, anti-inflammatory, and reparative properties. However, current scientific evidence on the efficacy and safety of TCM for LEAO remains inadequate, highlighting the need for further research. Large-scale, randomized controlled trials are essential to evaluate TCM formulations' effectiveness and safety, elucidate their clinical benefits, and determine optimal formulations and dosages. Continued research and clinical trials are crucial for establishing TCM as a viable alternative therapy, with the potential to improve patient outcomes in LEAO management.

FOOTNOTES

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Country of origin: China

ORCID number: Wen-Jie Long [0000-0002-9849-5077](https://orcid.org/0000-0002-9849-5077).

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