

Guideline for management of wounds in patients with lower extremity arterial disease.

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Overview

Guideline Objective

To provide evidence-based guidelines for the management of wounds in patients with lower extremity arterial disease (LEAD)

Patient Population

Patients with or at risk for wounds due to LEAD

Recommendations

Recommendation Statements

A. Comprehensive Patient Assessment

1. Prior to treatment, assess causative/contributive factors, and significant signs and symptoms to differentiate and determine the etiology of lower extremity (LE) wounds, which require a variety of treatments (refer to *Appendix A. Algorithm: Quick Guide to Determine Etiology of Lower-Extremity Wounds* in the [original guideline](#)). (**Level of Evidence = Task Force Consensus [TFC]; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = TFC**)
2. Review health history to identify risks, causative/contributing factors for LE arterial disease (LEAD), and coexisting diseases and comorbidities: tobacco use, diabetes mellitus (DM), peripheral neuropathic disease (ND), hypertension, dyslipidemia, renal insufficiency, and history of prescribed/self-prescribed medications. (**Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = TFC**)
3. Assess physical activity and functional status (e.g., ambulation, exercise capacity, frailty, use of mobility aids). (**Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion**)
4. Assess pain history.
 - a. Determine pain characteristics: onset (acute or chronic), duration, location, exacerbating and alleviating factors, effectiveness of analgesics, and the presence/absence of a painful wound.
 - b. Assess for characteristics of ischemic-related pain:
 - Intermittent claudication (IC) is reproducible cramping, aching, fatigue, weakness and/or frank pain in the buttock, thigh or calf muscles (rarely the foot) that occurs after exercise, and is typically relieved with 10 minutes rest.
 - Positional pain increases with elevation of the LE and decreases with dependency.
 - Resting pain indicates more severe ischemia. Pain occurs in forefoot/toes and might occur in the heel, but not the calf. Pain occurs in the absence of activity, typically at night when the legs are not in a dependent position. The patient dangles the leg over the side of the bed, walks, or sits to attempt to relieve the pain, and/or the pain can progress to a continuous state even with legs dependent.

- c. Differentiate LEAD-related ischemic pain from venous claudication, which is a tight bursting pain that involves the entire leg, and is worse in the calf. Venous pain occurs after exercise and subsides slowly; elevation helps relieve the pain; patient has history of deep vein thrombosis, edema, and/or LE venous disease.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

5. Assess history or signs of peripheral neuropathy. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)**

6. Assess the wound history.

- a. Description: location, onset, precipitating factors, course (e.g., improvement, regression, recurrence), and duration.

- b. Previous treatments and outcomes.

(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = TFC)

7. Review relevant laboratory test results warranted by the patient's medical history, risks, or treatments for coexisting conditions. **(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = TFC)**

B. Comprehensive, Bilateral LE Examination

1. Determine the perfusion status of each LE.

- a. Inspect/examine the LEs for ischemic skin changes and common indicators of LEAD: color changes (e.g., pallor with elevation, dependent rubor, cyanosis); skin feels cool to touch; atrophy of the skin, subcutaneous tissue, and muscle; shiny, taut, thin, dry, and fragile skin; hair loss; dystrophic nails; delayed capillary refill > 3 seconds indicates decreased arterial perfusion; paresthesia; and skin and tissue loss/nonhealing wounds. **(Level of Evidence = C;**

Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

- b. Determine presence or absence of LE pulses.

- Palpate both dorsalis pedis and posterior tibial pulses of each lower extremity. **Note:** Presence of palpable pedal pulses alone does not rule out LEAD, and an absent pulse alone is not a sensitive indicator of LEAD.

(Level of Evidence = B; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Low)

- Palpation of pulses is subjective; determining the presence or absence of Doppler arterial signals is more reliable. **(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = TFC)**
- Auscultate femoral/popliteal arteries for bruits. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)**

2. Determine the presence/absence of the indicators of chronic limb-threatening ischemia (CLTI), which is the most severe form of LEAD due to atherosclerosis with rest pain and/or tissue loss from ischemia that is confirmed with objective hemodynamic tests. Indicators of CLTI include:

- a. Ischemic rest pain, typically in the forefoot, ≥ 2 weeks.
- b. A nonhealing limb or foot ulcer ≥ 2 weeks, a diabetic foot ulcer (DFU), or gangrene of the foot or LE.
- c. One or more abnormal findings from hemodynamic tests (i.e., ankle brachial index [ABI] < 0.40 ; ankle pressure < 50 mmHg; toe pressure < 30 mmHg; transcutaneous oxygen tension/pressure [TCPO₂] < 30 mmHg; flat or minimally pulsatile pulse volume recording [PVR] waveforms).

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

3. Differentiate acute limb ischemia (ALI) from CLTI. ALI is a rapid or sudden decrease in limb perfusion, which threatens tissue and limb viability due to occlusion from a thrombus, embolism, or trauma. The hallmark signs of ALI include the sudden onset of pain, pulselessness, pallor, paresthesia, paralysis, polar/coldness, and a purplish or cyanotic color of the limb/foot may be seen. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)**

4. Examine the neurosensory status of the feet.

- a. Observe for signs of peripheral neuropathy: numbness, decreased or abnormal sensations (paresthesia), muscle weakness/atrophy, foot/toe deformities (e.g., claw toes, hammer toes, foot drop, Charcot deformity), gait abnormalities, and increased or absent sweating of the feet.

b. Test for loss of protective sensation (LOPS) with a 10-g monofilament at 3 to 10 sites on both feet, plus at least one other assessment of vibratory perception or ankle reflexes.

- Test ability to perceive vibration on the dorsum of the great toe/hallux with a 128-Hz tuning fork, or test ankle reflexes with a reflex/percussion hammer.
- Use the Ipswich Touch test (light touch test) in the absence of a monofilament to assess if the patient can feel 1–2 seconds of light touch from an examiner's index finger on the tips of the first, third, and fifth toes.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

C. Vascular Assessment/Tests of Perfusion

1. Assess all patients with ischemic rest pain or a nonhealing limb or foot wound ≥ 2 weeks, DFU, or gangrene of a limb or foot for objective indicators of CLTI with noninvasive hemodynamic tests. **(Level of Evidence = C;**

Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

2. Measure an ABI to assess arterial blood flow in both legs, or refer the patient to a vascular laboratory to obtain an ABI. **(Level of Evidence = C;**

Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

a. Doppler technique with a sphygmomanometer is the preferred method for measuring arm and ankle pressures for the ABI. **(Level of Evidence = B; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Low)**

b. Calculate ABI for each leg using the higher of the ankle pressures (dorsalis pedis or posterior tibial) divided by the higher of the brachial pressures from the right or left arm. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Low)**

c. Interpret the ABI taking into consideration the overall results of the clinical exam:

- ABI values: normal (≥ 1.00); LEAD (≤ 0.90); borderline perfusion (≤ 0.60 – 0.80); severe ischemia (≤ 0.50); CLTI (≤ 0.40).
- The ABI can be elevated (> 1.30) in individuals with DM, renal failure, or arthritis due to calcification of the ankle arteries.

- The ABI can also be undeterminable due to noncompressible arteries due to calcification (i.e., unable to obliterate the Doppler arterial signal at a cuff inflation pressure > 250 mmHg).

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)

d. Recheck the ABI periodically (every 3 months) for patients with nonhealing, LE wounds, unless prior ABI tests have shown noncompressible arteries, which would not provide a reliable ABI. **(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = TFC)**

e. Refer patients who have symptoms of LEAD but a normal, resting ABI to a vascular laboratory for a postexercise ABI test, or other vascular testing. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Low)**

3. Measure toe pressures/toe-brachial index (TBIs) of patients with suspected LEAD, DM, renal disease/kidney failure, noncompressible arteries/undeterminable ABI, an unmeasurable ABI due to an amputation or wound, or an ABI > 1.30; or refer the patient to a vascular laboratory for the test. Most commonly, toe pressure is measured with photoplethysmography. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Low)**

a. TBI < 0.70 indicates LEAD.

b. Systolic toe pressure < 30 mmHg indicates CLTI.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)

4. Refer patients to a vascular laboratory for additional noninvasive tests if the ABI and toe pressures/TBIs are inconclusive, inconsistent, or unmeasurable due to an amputation or wound; if the ABI is > 1.30; or if arteries are noncompressible and ABI is undeterminable.

a. PVR and waveform analysis.

b. Skin perfusion pressures.

c. Consider TcPO₂ if a wound is not healing and the ABI is < 0.90, toe pressure is < 30 mmHg, or if unable to perform an ABI or toe pressure/TBI. TcPO₂ < 40 mmHg is considered hypoxic, and is associated with impaired wound healing.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Low)

5. Refer patients to a vascular laboratory for additional imaging studies if CLTI is suspected, or to select revascularization (surgical or endovascular) candidates.
 - a. Duplex ultrasound.
 - b. Computed tomographic angiography.

(Level of Evidence = B; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Moderate)

- c. Magnetic resonance angiography (MRA).
 - d. Multidetector computed tomographic angiography (MDCTA).

(Level of Evidence = A; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Moderate)

6. Refer patients to interventional radiology for invasive studies such as contrast catheter angiography or digital subtraction angiography (if MRA or MDCTA are contraindicated or inconclusive) to definitively determine the anatomic location of LEAD when surgery is planned. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)**

D. Comprehensive Wound Examination

1. Perform a comprehensive examination of the wound.
 - a. Determine and document wound and periwound characteristics at each dressing change: location; shape; size; color of wound base and type tissue; wound edges; periwound skin; exudate; presence/absence of odor, necrosis, or eschar; and presence/type wound pain;
 - b. Assess for wound complications: infection, cellulitis, gangrene, or osteomyelitis.
 - c. Determine if wound is atypical in appearance and/or location.

(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = TFC)

2. Determine presence of mixed etiology. (**Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Low**)

E. Quality of Life Assessment

1. Assess quality of life in patients with symptomatic LEAD.
2. Assess for depression and anxiety in patients with symptomatic LEAD.

(**Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low**)

F. Indications for Referral for Further Evaluation, Testing, and/or Treatment (e.g., Vascular, Surgical, Infectious Disease, and/or Other Specialists)

1. Refer patients with the following symptoms, conditions/complications, or assessment findings for further evaluation, testing, and/or treatment.
 - a. Wound complications:
 - Clinical signs of infection, cellulitis, or suspected osteomyelitis.
 - Uncertain etiology; inconsistent findings between assessment and wound characteristics.
 - Atypical wound or location.
 - Nonhealing wound; deteriorates or fails to improve after 2–4 weeks of appropriate care.
 - Wound with mixed etiology; wound and/or edema in mixed arterial/venous disease that fails to respond to compression therapy or worsens.
 - b. IC, rest pain, or intractable pain.
 - c. Comorbidities/conditions or specialized treatment needs that require additional interdisciplinary management including, but not limited to, occupational therapy, physical therapy, social services, or mental health services.
 - d. Findings from physical assessment and/or noninvasive vascular tests:

- Absence of palpable dorsalis pedis and posterior tibial pulses, or absence of dorsalis pedis and posterior tibial Doppler arterial signals.
- Inconsistent findings from noninvasive vascular tests.
- ABI < 0.90; ankle pressure < 50 mmHg.
- ABI > 1.30, or undeterminable ABI due to noncompressible vessels and unable to obliterate the Doppler arterial signal at cuff pressures greater than 250 mmHg.
- TBI < 0.70; toe pressure < 30 mmHg.
- TcPO₂ < 30 mmHg.

2. Make an urgent vascular and/or surgical referral for patients with signs/symptoms of ALI, ABI < 0.40, suspected CLTI or signs/symptoms of CLTI, or gangrene.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

G. Wound Management/Interventions

1. Recommend patients with wounds and LEAD seek care guided by a wound care expert. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)**
2. Use baseline and ongoing assessment data to establish goals and evaluate treatment outcomes.
3. Use basic principles of wound management as a guide for treatment of ischemic wounds: Identify and manage infection, necrotic tissue, exudate, and closed wound edges; and protect the wound and periwound skin.
4. Determine interventions/treatments based on adequacy of perfusion.

(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = TFC)

5. Protect ischemic limbs and completely off-load heels of patients who are confined to a bed or wheelchair/chair who are immobile, nonambulatory or have limited ambulation, and who have/ or are at risk for pressure injuries with products specifically designed to eliminate/redistribute heel pressure.

6. Maintain dry, stable eschar/blisters in noninfected ischemic wounds.
(**Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Expert Opinion**)

Wound Debridement

7. Determine perfusion status prior to debridement of necrotic tissue to determine if the wound has an adequate blood supply for healing. (**Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = TFC**)
8. Do not debride wounds with stable, black eschars until perfusion status is determined.
9. If blood supply is adequate, consider debridement of necrotic tissue taking into account the overall clinical situation: patient's goals of care and prognosis; setting; wound location, type and amount of necrotic tissue; presence/absence infection; comorbidities; anticoagulant use; mobility; and skill/capability and scope of practice/licensure of the health-care provider.
10. Refer patients with an infected necrotic wound on an ischemic LE for an evaluation for revascularization and surgical removal of the necrotic tissue, which is the treatment of choice for limb salvage.
11. Closely monitor autolytic or enzymatic debridement if used for open, draining ischemic wounds with necrotic tissue.

(**Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Expert Opinion**)

12. Do not use mechanical, nonselective debridement methods in ischemic wounds.
(**Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = TFC**)

Topical Therapy/Dressings

13. Cleanse wounds with noncytotoxic cleansers.
14. Select dressings and topical agents based on assessment of the goals of care, characteristics of the wound and periwound skin, amount of exudate; and patient needs such as comfort, cost, and ease of application, and availability of dressings.

15. Choose dressings for ischemic wounds that permit frequent visualization and inspection of the wound.

16. Do not use hydrocolloid dressings for infected wounds.

(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = TFC)

17. Conduct a carefully monitored trial of moist dressings for ischemic open and draining wounds with soft slough/necrotic material or exposed bones or tendons.

Note: Wet-to-dry dressings provide mechanical debridement and should not be confused with moisture- retentive dressings. **(Level of Evidence = C;**

Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Expert Opinion)

Wound Infection

18. Monitor ischemic wounds closely for signs/symptoms of infection, which can be subtle because of reduced blood flow.

19. Assess the severity of infection based on the presence of local and systemic signs/symptoms of infection. Infection is graded 0–3 (no infection to severe/limb and/or limb-threatening infection) according to presence/absence of symptoms/signs of infection, depth/extent of infection (i.e., infection localized to skin and subcutaneous tissue, or infection extends to surrounding tissues or deeper structures), and the presence/absence of systemic inflammatory response signs.

20. For clinically infected wounds, to identify the type and number of infecting organisms and guide antibiotic therapy, collect an appropriate culture: a tissue specimen is considered the gold standard (e.g., curettage, biopsy, needle biopsy); a swab culture using the Levine technique; and/or a blood culture if systemic signs of infection are present.

21. Do not culture wounds indiscriminately in the absence of clinical signs of infection.

22. Refer patients with infected, ischemic wounds, which are limb threatening, for immediate evaluation, culture-guided antibiotic therapy, and assessment of perfusion status and need for surgical intervention.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Expert Opinion)

Antimicrobial/Antibiotic Therapy

23. Determine appropriate antibiotic/antimicrobial therapy for infected wounds.

- a. Limit use of antiseptics in open wounds to a short period of 2 weeks, or up to 4 weeks if biofilm is suspected or is being treated.
- b. Do not rely solely on topical antibiotics to treat infected, ischemic wounds.
- c. Promptly institute culture-guided, systemic antibiotics for patients with LEAD/CLTI and evidence of limb/wound infection or cellulitis.

24. Collaborate/consult with an infectious disease specialist for complex cases, nonresponsive infections, and/or patients with multiple organisms involved.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Expert Opinion)

H. Nutritional Interventions

1. Assess the nutrition/hydration status of patients with LEAD/CLTI and wounds.
2. Advise patients to maintain adequate nutrition and a healthy diet (e.g., Mediterranean diet or other healthy eating patterns).
3. Refer patients with LEAD and wounds to a dietitian for evaluation, identification of nutritional and vitamin deficiencies that warrant intervention, and dietary counselling as indicated.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)

I. Pain Management

1. Recommend supervised exercise therapy (SET) 30 to 45 minutes, 3 times per week for a minimum of 2 weeks for medically stable patients with IC.
2. Recommend organized home-based exercise/walking programs for patients who are unwilling or unable to participate in SET programs.

(Level of Evidence = A; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Moderate)

3. Recommend any self-directed walking program for patients that are unwilling or unable to participate in supervised/organized walking programs. **(Level of Evidence**

= C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)

4. Consider the need for appropriate analgesics/premedication prior to wound care, and/or for management of IC or rest pain.
5. Refer patients with chronic severe or intractable pain for an evaluation for revascularization.
6. Refer patients who are not candidates for revascularization to pain management specialists.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

7. Consider referral of patients who are unsuitable for revascularization and have chronic severe/intractable pain and CLTI for spinal cord stimulation. **(Level of Evidence = A; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)**

J. Compression Therapy

1. Use a reduced level of compression (23–30 mmHg at the ankle) for patients with mixed arterial/venous disease ($ABI < 0.80$ and > 0.50), wounds, and edema; and closely supervise the patient for complications.
2. Avoid compression if $ABI < 0.50$, ankle pressure < 70 mmHg, or toe pressure < 50 mmHg.
3. If the patient is revascularized, consider compression to manage the edema due to the venous disease.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)

6. Carefully monitor patients with neuropathy if compression is provided because they may not sense pain or discomfort from compression that is too tight. **(Level of Evidence = TFC; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = TFC)**
7. Consider use of graduated, compression stockings (18–30 mmHg) to manage postoperative edema after LE bypass surgery. **(Level of Evidence = B; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)**
8. If LEAD is present ($ABI \leq 0.90$), prior to the use of antiembolism compression stockings (AECS) or mechanical devices, consult with the primary health-care provider to determine if AECS or mechanical devices are indicated and safe, or if

other interventions are warranted. (**Level of Evidence = TFC;**
Benefit/Effectiveness/Harm = Class II; Quality of Evidence = TFC)

K. Risk Reduction and Pharmacotherapy

1. Consider pharmacotherapy to reduce cardiovascular risks and improve limb outcomes for patients with symptomatic LEAD taking into consideration the benefits versus risks and side effects of the medications (e.g., bleeding risk with antithrombotics).

- a. Statin therapy: provides lipid control, and reduces cardiovascular mortality and morbidity.
- b. Angiotensin-converting enzyme inhibitors (Ramipril): reduces cardiovascular events, and improve pain-free walking.

(Level of Evidence = A; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)

- c. Antiplatelet therapy for symptomatic patients:

- Clopidogrel: decreases cardiovascular risk, adverse limb events, and mortality.
- Cilostazol: improves symptoms and walking distance in patients with IC, but is contraindicated in patients with heart failure.
- Aspirin: decreases vascular events/stroke.

(Level of Evidence = A; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)

2. Consider a trial of prostanoids, which have shown some benefit in pain relief and wound healing for patients with CLTI. (**Level of Evidence = A;**
Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Moderate)

L. Surgical Interventions

1. Refer patients with the following conditions that warrant evaluation for surgical/vascular interventions:

- a. Lifestyle-limiting IC and poor response to/or failure of medical therapy.
- b. Intractable pain.
- c. CLTI.
- d. Nonhealing wounds despite appropriate care.
- e. Infection; sepsis.
- f. Gangrene.
- g. Patients with DM/LEAD and nonhealed wounds/heel ulcers, and/or an infected or gangrenous foot.
- h. ALI (Grade/Category I–II).

2. Refer patients with the following conditions that warrant evaluation for a major LE amputation:

a. Patients with CLTI:

- Patients who are not suitable for revascularization; limited life expectancy.
- One or more revascularization attempts have been unsuccessful, and likelihood of a successful reintervention is limited.
- Uncorrectable disease; no revascularization options available.
- Uncorrectable flexion contractures; paralysis of the extremity.
- Intractable ischemic rest pain.
- Diabetic foot syndrome: ulcer, neuropathy, ischemia, and infection.
- Destruction of the major weight-bearing portions of the foot making it incompatible with ambulation.
- Nonhealing wound.
- Wet gangrene/sepsis; dry gangrene.
- Severe/uncontrolled infection.
- Limb- or life-threatening sepsis.

b. Patients with ALI with advanced, irreversible damage (Grade/Category III).

3. After revascularization, notify the endovascular/vascular surgeon if there is a recurrence of symptoms, change in pulse status, or a decrease in ABI > 0.15 from a previous reading following the revascularization.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Expert Opinion)

Conservative Care

4. Consider conservative care for patients with CLTI who refuse or are not good candidates for revascularization, or who have a limited life expectancy and might benefit from conservative medical care and proper wound care to promote pain relief, wound healing, and limb salvage. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)**

M. Adjunctive Therapy

1. Consider adjunctive therapy for patients with LEAD or CLTI and recalcitrant wounds who have undergone vascular evaluation, and it has been determined that they are not candidates for revascularization, or for patients with nonhealing wounds after revascularization. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)**
2. Select adjunctive treatment based on clinical findings, availability, and clinical and cost effectiveness.
 - a. Intermittent or sequential pneumatic compression (also known as arterial flow augmentation or circulatory assist) for individuals who are not surgical candidates to reduce rest pain and/or augment wound healing:
 - IC. **(Level of Evidence = A; Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Low)**
 - CLTI. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Low)**
 - b. Negative pressure wound therapy to reduce complications including surgical site infections:
 - Nonhealing wounds and/or infected vascular grafts. **(Level of Evidence = C; Benefit/Effectiveness/Harm = Class II; Quality of Evidence = Low)**

- Closed groin incisions after revascularization or LE amputation. (**Level of Evidence = B; Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Low**)
- c. Electrotherapy/electrostimulation to increase perfusion and walking capacity, and decrease pain in patients with LEAD/IC, or with LEAD/IC and DM. (**Level of Evidence = B; Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Low**)
- d. Hyperbaric oxygen therapy (HBOT) for patients with nonhealing, neuropathic, diabetic foot wounds and low-grade ischemia. (**Level of Evidence = A; Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Low**)
- e. Do not use HBOT to promote limb salvage or as an alternative to revascularization in cases of severe ischemia in patients with CLTI. (**Level of Evidence = C; Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Expert Opinion**)
- f. Consider intravascular lithotripsy (also known as extracorporeal shockwave therapy) to decrease calcification and stenosis of arteries, decrease pain, and increase walking capacity in patients with LEAD (IC, CLTI). (**Level of Evidence = A; Benefit/Effectiveness/Harm = Class III; Quality of Evidence = Low**)

N. Patient Education

1. Educate patients/caregivers about risk reduction and chronic disease management with best medical care and lifestyle modifications (e.g., tobacco cessation, glucose control in patients with DM, modification of cardiovascular risk factors [e.g., lipid control, hypertension control]).
2. Advise patients who use tobacco to develop a plan for tobacco cessation, including preoperative tobacco cessation if surgical interventions are planned, and to avoid secondhand tobacco smoke.
3. Advise patients:
 - a. Increase regular exercise and physical activity (e.g., SET, home-based SET, or self-directed exercise) to improve symptoms of claudication.
 - b. Maintain adequate fluid and nutrition intake.
 - c. Limit alcohol use to moderate consumption.

d. Maintain weight or reduce weight if overweight or obese.

e. Consider obtaining an annual influenza vaccine.

4. Educate patients/caregivers in measures and self-care practices to enhance perfusion; maintain intact skin; and prevent trauma, injuries/tissue loss, and recurrence of wounds:

a. Avoid chemical, thermal, and mechanical trauma.

- Protect feet, toes, and heels: Wear proper-fitting shoes/footwear with socks or hose.
- If confined to bed or wheelchair/chair and immobile or nonambulatory, use pressure redistribution surfaces, products, or devices to off-load the heels, and protect toes and other bony prominences.
- Obtain routine professional care for toenails, corns, and calluses.

b. Avoid leg elevation; use a dependent position for legs.

c. Examine legs, feet, and toes daily for blisters, wounds, signs of infection.

d. Self-assess for LOPS:

- Use a 10-g monofilament to test at least four sites (i.e., first, third, and fifth metatarsal heads; and plantar surface of the distal hallux) on each foot.
- If a monofilament is unavailable, use the Ipswich Touch test (light touch test) to assess if the patient can feel 1–2 seconds of light touch from a caregiver's index finger on the tips of the first, third, and fifth toes.

e. Promptly report any problems or injuries to the health-care provider.

f. Visit a health-care provider on a regular basis.

5. Teach proper wound care procedures for patients with wounds, including precautions to observe/report to the health-care provider if compression is used to manage edema in mixed arterial/venous disease.

(Level of Evidence = C; Benefit/Effectiveness/Harm = Class I; Quality of Evidence = Expert Opinion)

Evidence Rating Scheme

Rating of Research Evidence

Level I	A RCT of at least 30 humans with wounds/LEAD in each arm of the study that demonstrated a statistically significant difference in at least one important outcome defined by $p < .05$. Level I trials can conclude the difference is not statistically significant if the sample size is adequate to exclude a 25% difference among study arms with 80% power.
Level II	An RCT of at least 30 humans with wounds/LEAD in each arm of the study that did not meet Level I criteria.
Level III	A nonrandomized controlled trial of least 30 humans with wounds/LEAD in each arm of the study with contemporaneous controls selected by some systematic method. A control might have been selected due to its perceived suitability as a treatment option for an individual patient.
Level IV	An RCT of at least 30 humans with wounds/LEAD in each arm of the study that did not meet Level I criteria.
Level III	A before-and-after study or a case series of at least 30 humans with wounds/LEAD using historical controls or controls drawn from other studies.
Level V	A case series or study of at least 30 humans with wounds/LEAD with no controls.

Level-of-Evidence Rating for Strength of Guideline Recommendations

Level A	Two or more supporting randomized controlled trials (RCTs) of at least 30 humans with wounds/lower extremity arterial disease (LEAD) at Levels I or II; a meta-analysis of RCTs; or a Cochrane systematic review and meta-analysis of RCTs.
Level B	One supporting RCT of at least 30 humans with wounds/LEAD, or two or more supporting nonrandomized, controlled trials of at least 30 humans with wounds/LEAD (at Level III).

Level C	Other studies not meeting Level B criteria; two or more supporting case series of at least 30 humans with wounds/LEAD; or published expert opinion.
Task Force Consensus (TFC)	Where a Level-of-Evidence rating is not included, the information or recommendation represents a consensus of the task force members.

Quality of Evidence Ratings for Recommendations

Type of Evidence	Quality Rating
- Well-designed and well-conducted, RCTs, or meta-analyses of such trials, which addressed the population of interest, and directly assessed effects on health outcomes. - Studies directly addressed the question; used adequate randomization, blinding, and allocation concealment; were adequately powered; used intention-to-treat analyses; and had high follow-up rates. - High level of certainty about the estimate of effect.	High
- RCTs with minor limitations, which affected confidence in/or applicability of the results. - Well-designed, well-conducted controlled or observational studies. - Meta-analyses of such studies. - Moderate certainty about the estimate of effect.	Moderate
RCTs, nonrandomized controlled/quasi-experimental studies, or observational studies (prospective, retrospective cohort, case-control, cross-sectional studies) with major limitations affecting	Low

confidence in/or applicability of the results; or meta-analyses of such studies.

- Limitations included: inadequate randomization; lack of blinding of participants or outcome assessors; inadequate power; outcomes of interest were not prespecified for the primary outcomes; low follow-up rates; and findings were based on subgroup analyses. Whether the limitations were considered minor or major depended on the number and severity of the flaws in design or conduct of the study.
- Uncontrolled clinical observations without an appropriate comparison group (e.g., case series or reports).
- Low certainty about the estimate of effect.

Recommendation Rating Scheme

Classification of Recommendations: Benefit/Effectiveness versus Harm

Class I	Class II	Class III	Class IV
There is evidence and/or agreement of expert opinion that a procedure or treatment is beneficial and effective with greater benefit than harm. Is indicated and recommended; should be done.	There is limited evidence and/or agreement of expert opinion that a procedure or treatment can be beneficial and effective with greater benefit than harm. May be	Evidence and/or agreement of expert opinion about a procedure or treatment is less well established or uncertain, <u>and/or</u> has conflicting evidence or divergence of opinion about the benefit and effectiveness, <u>and/or</u> there are risks/side effects that may limit benefit. May be	There is evidence and/or agreement of expert opinion that a procedure or treatment is not beneficial or effective, <u>and/or</u> can be harmful in some cases where risks/side effects outweigh the benefit. Is not indicated or recommended;

	indicated; is reasonable to perform ; may be considered.	reasonable; may be considered in select instances.	should not be performed.
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Related Content

Supporting Documents

No supporting documents available.

Implementation Tools

- [Podcast](#); 2024.
- The [Original Guideline](#) includes the following:
 - Appendix A. Algorithm: Quick Guide to Determine Etiology of Lower-Extremity Wounds (p. 208)
 - Appendix F. Algorithm for Tobacco Cessation: the 5 As and 5 Rs (p. 230)

Patient Education

No patient education materials available.

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ECRI's Guideline Profiles are designed to provide information and assist decision-making. Variations in practice will inevitably, and appropriately, occur when clinicians take into account the needs and preferences of individual patients, available resources, and

limitations unique to an institution or type of practice. Every healthcare professional using these Guideline Profiles is responsible for evaluating the appropriateness of applying them in a clinical setting.

TRUST Scorecard

Composition of Guideline Development Group (GDG)

Multidisciplinary GDG Members

Yes

Methodologist Involvement

No

Incorporation of Patient and Public Perspective



Systematic Review of Evidence

Literature Search



Study Selection



Evidence Synthesis



Foundations for Recommendations

Strength of Evidence Grade



Description of Benefits and Harms of Recommendations



Summary of Evidence Supporting Recommendations



Strength of Recommendations Rating



Clear Articulation of Recommendations



Funding Source

No

Disclosure and Management of Financial Conflicts of Interests



External Review



Updating

