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WOUND CARE

2014 Guideline for Management of Wounds in Patients With Lower-Extremity Arterial Disease (LEAD)

An Executive Summary

Phyllis A. Bonham ■ Bonny G. Flemister ■ Linda R. Droste ■ Jan J. Johnson ■ Teresa Kelechi ■ Catherine R. Ratliff ■ Myra F. Varnado

■ ABSTRACT

The purpose of this article is to provide a summary of the recommendations from the 2014 *Guideline for Management of Wounds in Patients With Lower-Extremity Arterial Disease* (LEAD), published by the Wound, Ostomy and Continence Nurses Society (WOCN). This article provides an overview of the process used to update and develop the guideline, and specific recommendations from the guideline for assessment, referral for further evaluation, interventions (ie, debridement, dressings, infection, antibiotics, nutrition, pain management, compression issues, medications, surgical options, and adjunctive therapies), and patient education and risk-reduction strategies. The LEAD guideline is a resource for physicians, nurses, therapists, and other healthcare professionals who work with adults who have/or are at risk for wounds due to LEAD. The full text of the published guideline, which includes the available evidence supporting the recommendations and a complete reference list, is available from the WOCN Society, 1120 Rt. 73, Suite 200, Mount Laurel, NJ, 08054; Web site: www.wocn.org. Refer to the Supplemental Digital Content (Supplement Digital Content 1, http://links.lww.com/JWOCN/A31) associated with this article for the complete reference list for the guideline. The guideline has been accepted for publication by the National Guideline Clearinghouse (www.guideline.gov/).

KEY WORDS: Clinical practice guidelines, Lower-extremity arterial disease, Lower-extremity ischemic disease, Peripheral arterial disease, Peripheral arterial occlusive disease.

■ Introduction

Lower-extremity arterial disease (LEAD) affects up to 32% of individuals 40 to 70 years of age, and the prevalence is 40% in those 80 years of age or older.[1] Patients with LEAD are at risk for nonhealing wounds, infection, and limb loss.[1] Despite the high prevalence of LEAD and its risk for wounds, it remains undiagnosed and untreated or undertreated in 50% to 80% of patients.[1] The primary purpose of this article is to provide a synopsis of the recommendations from the updated 2014 *Guideline for Management of Wounds in Patients With Lower-Extremity Arterial Disease* (LEAD) from the WOCN Society.[1] This article lists the specific recommendations from the guideline for assessment, referral for further evaluation, interventions (ie, debridement, dressings, infection, antibiotics, nutrition, pain management, compression

■ **Wound Guidelines Task Force**

Chair/Primary Author, Phyllis A. Bonham, PhD, MSN, RN, CWOCN, DPNAP, FAAN, College of Nursing, Medical University of South Carolina, Charleston, South Carolina.

Primary Author, Bonny G. Flemister, MSN, RN, CWOCN, APRN, BC, ANP, GNP-BC, Kilgore, Texas.

Linda R. Droste, MSN, RN, CWOCN, CBIS, Spinal Cord Injury and Polytrauma Units, Hunter Holmes McGuire VA Medical Center, Richmond, Virginia.

Jan J. Johnson, MSN, RN, CWOCN, APRN, ANP-BC, Duke University Medical Center, Zebulon, North Carolina.

Teresa Kelechi, PhD, MSN, RN, GCCS-BC, CWCN, FAAN, College of Nursing, Medical University of South Carolina, Charleston, South Carolina.

Catherine R. Ratliff, PhD, APRN-BC, CWOCN, CFCN, University of Virginia Health System, Charlottesville, Virginia.

Myra F. Varnado, BS, RN, CWOCN, CFCN, Wound Care Specialists Metairie, Louisiana.

Scribe: Ronald Palmer, Fullerton, California.

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Correspondence: Becky Dryden, Website & Publications Editor, WOCN Society, 1120 Route 73, Suite 200, Mount Laurel, NJ 08054 (bdryden@wocn.org).

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issues, medications, surgical options, and adjunctive therapies), and patient education and risk-reduction strategies. The article also describes the process used in developing the guideline. The LEAD guideline is a resource for physicians, nurses, therapists, and other healthcare professionals who work with adults who have/or are at risk for wounds due to LEAD. The full text of the published guideline, which includes a summary of the available evidence, along with a complete reference list underlying the recommendations is available from the WOCN Society (www.wocn.org). Refer to the Supplemental Digital Content (Supplement Digital Content 1, http://links.lww.com/JWOCN/A31) associated with this article for the complete reference list for the guideline. The guideline has been accepted for publication by the National Guideline Clearinghouse (www.guideline.gov/).

Guideline Development

The WOCN Society established a task force of 7 certified nurses from the WOCN Society membership who represented a wide range of experience and clinical practice backgrounds. Two members of the task force were selected as the primary authors for the guideline. All task force members completed a Disclosure Form and were screened for any potential conflicts of interest in regard to the topic or development of the guideline.

For the 2014 update, one question (#22) was added to the search questions (Table 1). The 22 questions were utilized to guide the literature search related to the following topics: screening and diagnosis, healing and treatments, infection, topical wound treatments, and management of patients with or at risk for wounds due to LEAD.

Identifying the Evidence

The 2 primary authors of the guideline independently conducted searches of MEDLINE, CINAHL, and Cochrane Library databases for studies published in English from January 2008 through June 2013 relative to the search questions. The following medical subject headings (MESH) were used to search for each specific question related to LEAD—arterial disease, arterial insufficiency, peripheral arterial disease, peripheral vascular disease, lower-extremity

TABLE 1.

Questions Used to Guide the Literature Review

Topic	Question
Screening and diagnosis	1. What are the risk factors for LEAD?
	2. What are reliable, noninvasive methods to diagnose LEAD (eg, palpable pulses, vascular tests such as ABI, toe pressures/TBI, transcutaneous oxygen measurement, and segmental pressures)?
	3. Who should have ABI screening?
	4. What indicators should be used to determine whether perfusion status is adequate, borderline, or ischemic?
	5. What are the indicators of critical limb ischemia?
Healing and treatments	6. How does perfusion status affect the potential for wound healing and treatments for LEAD?
	7. When is compression therapy indicated or contraindicated for patients with LEAD?
Infection	8. What is the most appropriate method to diagnose infected wounds in patients with LEAD (eg, swabs, cultures, and biopsies)?
	9. Are topical and/or systemic antibiotics, effective treatments for infected, ischemic wounds?
Topical wound treatments	10. What topical dressings are most effective for treating lower-extremity wounds in patients with LEAD?
	11. Are occlusive and/or moist dressings appropriate treatments for wounds due to LEAD?
	12. What cleansing methods are appropriate for wounds due to LEAD?
	13. Is debridement indicated or contraindicated for wounds due to LEAD? What debridement methods are most appropriate? When are they indicated or contraindicated?
Management of patients with LEAD	14. What effect does smoking cessation have on wound healing in patients with LEAD?
	15. Is exercise therapy an effective treatment for LEAD and claudication pain?
	16. Are any medications effective in treating LEAD (eg, cilostazol and pentoxifylline)?
	17. What surgical interventions are the most effective therapies for patients with critical ischemia (eg, angioplasty and bypass)?
	18. Is hyperbaric oxygen therapy effective for wound healing in patients with LEAD or critical ischemia?
	19. What adjunctive therapies are effective treatments for patients with LEAD or ischemic wounds?
	20. What nutritional factors contribute to the development of LEAD and/or influence healing of ischemic wounds?
	21. When should patients be referred for vascular/surgical evaluation?
	22. What type of patient education is effective for patients with LEAD?

Abbreviations: ABI, ankle brachial index; LEAD, lower-extremity arterial disease; TBI, toe brachial index.

arterial disease, peripheral arterial occlusive disease, lower-extremity ischemic wounds and ulcers, and critical limb ischemia (CLI).

The search targeted randomized controlled trials (RCTs), prospective clinical trials, retrospective studies, meta-analyses, and systematic reviews. If available and relevant, national guidelines and published expert opinion were included to support expert opinion in areas that were clinically important where research was lacking or nonexistent. Titles of references and abstracts were retrieved from the electronic searches and were screened for relevance to LEAD, the search questions, and the inclusion and exclusion criteria. After the initial screening, relevant full-text articles were obtained. Additionally, some relevant studies were included that were identified from reference lists of selected articles. For the updated guideline, 381 full-text articles were reviewed, 66 were excluded, and 315 new articles were included as cited in the text and reference list.

Inclusion Criteria

- Published in English; peer-reviewed literature.
- Available abstract.
- Primary focus on LEAD or reported specific data relevant to LEAD.
- 10 subjects included in studies/case studies.
- Human studies.
- Primary research reports relevant to LEAD and the search questions.

Exclusion Criteria

- Foreign language publication.
- Abstract not available.
- Secondary reports of research.
- Conference abstracts/posters.
- Primary focus not on LEAD or lacked specific data about LEAD.
- Nonhuman studies.
- Description of study or outcomes lacked sufficient detail to draw conclusions.

Data Extraction

From the selected, full-text articles, the primary authors extracted the following data: source/citation (author, publication date, title, publication); type/design of study; methods (sample size, setting/location, description of subjects; interventions, tests/measures); results/findings including statistical significance of findings (*P* values; odds ratios, hazard ratios, confidence intervals, sensitivity/specificity, etc., as appropriate to the study); and conclusions. For studies of diagnostic or screening tests, data included if a valid reference standard was used. For systematic reviews/meta-analyses, data included number/quality of RCTs reviewed, findings, and conclusions.

For each article, a narrative summary of the extracted data was prepared and reviewed by the primary authors.

TABLE 2.

Criteria for Level-of-Evidence Ratings for Research Evidence

Level of Evidence	Criteria
Level I	An RCT demonstrating 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 not meeting Level I criteria
Level III	A nonrandomized controlled trial 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	A before-and-after study or a case series of at least 10 patients using historical controls or controls drawn from other studies
Level V	A case series of at least 10 patients with no controls
Level VI	A case report of fewer than 10 patients

Abbreviation: RCT, randomized controlled trial.

Based on judgment of the authors, studies were assessed as acceptable or unacceptable for inclusion and excluded if there were methodological issues or insufficient detail to evaluate the results. Additionally, the primary authors rated the research evidence (Level 1 to Level VI) using criteria as identified in Table 2.[2,3] Differences of opinion about the quality/rating of the studies for inclusion in the guideline were resolved by discussion between the primary authors and/or by consensus by the full task force.

■ Synthesis and Evaluation of the Evidence

The 2 primary authors synthesized the data and prepared a descriptive, narrative summary of the available evidence derived from the search and review of the literature. The summary of evidence was integrated into the appropriate content sections of the guideline, and a draft was presented to all task force members for review, discussion, clarification, and development of consensus. A series of conference calls was conducted during 2013 and 2014, and the task force reviewed/evaluated the evidence in the draft guideline until consensus was reached.

■ Development of Recommendations

Based on the evidence in the guideline, recommendations were developed for specific areas where evidence was sufficient to support the recommendation. In selected areas where evidence about clinically significant topics was

lacking or nonexistent, the recommendations were based on the consensus of expert opinion by the task force.

Level-of-Evidence Rating for Strength of Recommendations

Based on an appraisal of the strength of the evidence for recommendations in the guideline, a level-of-evidence rating (Level A, B, or C) was assigned to specific recommendations (Table 3).[2-6] The rating refers to the strength of the evidence for a recommendation and does not relate to the importance of the recommendation. The recommendations and level-of-evidence ratings were reviewed by the task force and discussed until consensus was reached. A narrative summary of the available evidence underlying the recommendations, along with the level-of-evidence, is provided in the full text of the guideline, and the specific references that were included are cited in the text and the final reference list.

■ Assessment of Benefit/Effectiveness Versus Harm: Classification of Recommendations

To facilitate clinical decision making, the recommendations in the guideline were reviewed and classified by the task force based on an assessment of the potential benefits/effectiveness versus a lack of benefit/effectiveness or harms of a procedure or treatment according to the evidence and/or expert opinion presented in the guideline.[6] An addendum to the guideline was developed that included the additional classification (ie, I, II, III, and IV) to indicate the potential benefits/effectiveness versus a lack of benefit/effectiveness or harm associated with each recommendation in the guideline.[1] See Table 4 for an overview of the criteria for classification of the recommendations according to potential benefit/effectiveness versus harm.

■ Final Review and Completion of the Guideline

The completed guideline was peer reviewed by an independent group of 6 certified wound, ostomy and continence nurses for relevance, clarity, accuracy, comprehensiveness/organization, consistency with current research/best practices, and usefulness to the target population. Feedback was reviewed by the task force and incorporated into the final document as appropriate.

■ 2014 LEAD Guideline Recommendations

A. Assessment

1. Prior to treatment, assess causative and contributive factors and significant signs and symptoms to differentiate types of lower-extremity wounds, which require varying treatments. Task Force Consensus (TFC)
2. Review health history to identify risk factors for LEAD (eg, tobacco use, diabetes, hypertension, dyslipidemia, and renal insufficiency), wound history, pain history, history of prescribed/self-prescribed medications, and coexisting diseases and comorbidities. (TFC)
   a. Assess pain characteristics: onset, duration, location, precipitating and alleviating factors, and presence or absence of intermittent claudication. (TFC)
   b. Differentiate acute limb ischemia (ie, rapid, sudden decrease in limb perfusion often associated with thrombosis) from CLI that is chronic and progressive in nature due to atherosclerosis.
      Level of evidence = C (Class I)
3. Review pertinent laboratory tests to identify risk markers for LEAD.
   a. Elevated low-density lipoprotein (LDL) cholesterol, total cholesterol and triglycerides; reduced high-density lipoprotein (HDL) cholesterol.
      Level of evidence = B (Class I)
   b. Elevated homocysteine.
      Level of evidence = B (Class II)
4. Assess the wound.
   a. Determine wound characteristics: location, pain, shape, size, color of wound base and type tissue, wound edges, periwound skin, exudate, and presence/absence of odor or necrosis. (TFC)
   b. Assess for wound complications: infection, cellulitis, gangrene, or osteomyelitis. (TFC)

TABLE 3.

Level-of-Evidence Rating for Strength of Guideline Recommendations

Level A	Two or more supporting RCTs of at least 10 humans with LEAD (at Levels I or II), a meta-analysis of RCTs, or a Cochrane Systematic Review of RCTs
Level B	One or more supporting controlled trials of at least 10 humans with LEAD, or 2 or more supporting nonrandomized trials of at least 10 humans with LEAD (at Level III)
Level C	Other studies not meeting Level B criteria, 2 or more supporting case series of at least 10 humans with LEAD, or expert opinion
Task Force Consensus	Where a level-of-evidence rating is not included, the information or recommendation represents a consensus of the task force members

Abbreviation: LEAD, lower-extremity arterial disease; RCT, randomized controlled trial.

TABLE 4.

Classification of Recommendations: Potential 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	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	Evidence and/or agreement of expert opinion about a procedure or treatment is less well established or uncertain *and* has conflicting evidence or divergence of opinion about the benefit and effectiveness; *or* there are risks/side effects that may limit benefit	There is evidence and/or agreement of expert opinion that a procedure or treatment is not beneficial or effective, *and/or* can be harmful in some cases where risks/side effects outweigh benefit
Is indicated and recommended; should be done	May be indicated; is reasonable to perform; may be considered	May be reasonable; may be considered in select instances	Is not indicated or recommended; should not be performed

5. Conduct a comprehensive, bilateral lower-extremity examination.
   a. Assess functional ability and physical activity. (TFC)
   b. Assess the lower extremities for ischemic skin changes: purpura, atrophy of the skin, subcutaneous tissue and muscle; shiny and taut skin, hair loss and/or dystrophic nails. (TFC)
   c. Perform a vascular assessment (eg, pedal pulses and ankle brachial index [ABI]) on any individual that presents with a pressure ulcer on the lower limb/foot/heel.
      Level of evidence = C (Class I)
   d. Determine perfusion status by assessing skin temperature, capillary refill, venous refill, color changes, and paresthesias. (TFC)
   e. Determine presence or absence of pedal pulses. Palpate both dorsalis pedis and posterior tibial pulses of each lower extremity. Presence of palpable pulses does not rule out LEAD.
      Level of evidence = B (Class I)
   f. Auscultate femoral/popliteal arteries for bruits.
      Level of evidence = C (Class II)
   g. Observe for signs of neuropathy (eg, decreased sensation, weakness of ankles or feet, gait abnormalities, and foot drop/drag), which can cause impaired muscle function.
      Level of evidence = B (Class I)
   h. Determine neurosensory status by screening both feet for loss of protective sensation with a monofilament, tuning fork, and percussion hammer. (TFC)
   i. Measure the ABI using a Doppler and sphygmomanometer to assess arterial blood flow in both lower extremities and determine the level of ischemia.
      Level of evidence = B (Class I)
   j. 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 (Class I)
   k. Interpret the ABI taking into consideration the overall results of the clinical examination:
      - Normal: ABI greater than or equal to 1.00; LEAD: ABI less than or equal to 0.90; borderline perfusion: ABI less than or equal to 0.60 to 0.80; severe ischemia: ABI less than or equal to 0.50; and critical ischemia: ABI less than or equal to 0.40.
      - The ABI can be elevated (>1.30) in individuals with diabetes, renal failure, or arthritis due to calcification of the ankle arteries, which can also cause noncompressible arteries (ie, unable to obliterate the pulse signal at a cuff pressure >250 mm Hg).

      Level of evidence = C (Class II)
   l. Recheck the ABI periodically (every 3 months) for patients with nonhealing, lower-extremity wounds.
      Level of evidence = C (Class II)
   m. Refer patients who have symptoms of LEAD but a normal, resting ABI to a vascular laboratory for an exercise ABI test, or other testing.
      Level of evidence = C (Class I)
   n. Measure toe pressures with photoplethysmography/determine a toe brachial index (TBI) if the ABI is greater than 1.30, unmeasurable, or the vessels are noncompressible.
      - TBI less than 0.64 indicates LEAD.
        Level of evidence = B (Class II)
      - A systolic toe pressure less than 30 mm Hg or less than 50 mm Hg in persons with diabetes indicates CLI.
        Level of evidence = C (Class II)
   o. Assess tissue perfusion with transcutaneous oxygen measurement ($TcPO_2$) if a wound is not healing and the ABI is less than 0.90, toe pressure is less than 30 mm Hg, or if unable to perform an ABI or toe pressure/TBI because of noncompressible ankle arteries or an amputation. A $TcPO_2$ less than 40 mm Hg is considered hypoxic and is associated with impaired wound healing.
      Level of evidence = A (Class I)
   p. Consider noninvasive tests if the ABI, toe pressure, TBI, and $TcPO_2$ are inconclusive or cannot be performed; or if the ABI is greater than 1.30:
      - Duplex ultrasound.
        Level of evidence = B (Class II)

- Pulse volume recordings.
  Level of evidence = C (Class II)
- Skin perfusion pressures.
  Level of evidence = C (Class II)

q. Consider additional noninvasive tests to select surgical or endovascular candidates:
- Magnetic resonance angiography.
  Level of evidence = A (Class II)
- Computed tomographic angiography.
  Level of evidence = B (Class II)
- Multidetector computed tomographic angiography.
  Level of evidence = A (Class II)

r. Consider use of invasive studies such as contrast catheter angiography to definitively determine the anatomic location of LEAD when surgery is planned.
Level of evidence = B (Class II)

s. Assess all patients with ischemic rest pain or pedal wounds for indicators of CLI (ankle pressure <50 mm Hg; toe pressure <30 mm Hg [<50 mm Hg if diabetes]; $TcPO_2$<30 mm Hg).
Level of evidence = C (Class I)

6. Assess for symptoms of depression.
Level of evidence = C (Class II)

B. Referral for Further Evaluation

1. Refer patients with the following symptoms, conditions, or assessment findings for further vascular or surgical evaluation, and/or biopsy or culture:
- Atypical wounds.
- Clinical signs of infection or cellulitis; suspected osteomyelitis.
- Intractable pain.
- Wounds and/or edema in mixed arterial/venous disease that fail to respond to compression therapy or worsen.
- Absence of both pedal and posterior tibial pulses.
- An ABI less than 0.90 plus any one of the following—wounds failing to improve within 2 to 4 weeks of appropriate therapy, severe ischemic pain, and/or intermittent claudication.
- Toe pressure less than 30 mm Hg (<50 mm Hg if diabetes).
- Ankle pressure less than 50 mm Hg.
- ABI less than 0.50.
- ABI greater than 1.30 or noncompressible vessels and unable to obliterate pulse signal at cuff pressures greater than 250 mm Hg.

Level of evidence = C (Class I)

2. Make an urgent vascular and/or surgical referral for patients with symptoms of acute limb ischemia, an ABI less than 0.40, and/or gangrene. (TFC)

C. Interventions

1. Recommend patients with wounds and LEAD seek care guided by a wound care expert.
Level of evidence = C (Class I)
2. Relate wound treatments to adequacy of perfusion status.
Level of evidence = C (Class I)
3. Cleanse wounds with noncytotoxic cleansers.
Level of evidence = C (Class II)
4. Offload heels of bed/chairbound patients with wounds and/or are at risk for pressure wounds with products specifically designed to eliminate/redistribute heel pressure.
Level of evidence = C (Class I)
5. Maintain dry, stable eschar/blisters in noninfected ischemic wounds.
Level of evidence = C (Class I)

Debridement

6. Do not debride wounds with stable, black eschars until perfusion status is determined. Debridement may be contraindicated.
Level of evidence = C (Class IV)
7. Consider revascularization and surgical removal of necrotic tissue from an infected wound on an ischemic leg, which is the treatment of choice for limb salvage.
Level of evidence = C (Class I)
8. Closely monitor autolytic or enzymatic debridement if used for open, draining ischemic wounds with necrotic tissue. (TFC)

Dressings

9. Choose dressings for ischemic wounds that permit frequent visualization and inspection of the wound. (TFC)
10. Conduct a carefully monitored trial of moist dressings for ischemic open and draining wounds with soft slough/necrotic material or exposed bones or tendons.
Level of evidence = C (Class II)

Infection

11. Monitor ischemic wounds closely for signs/symptoms of infection, which can be subtle because of reduced blood flow.
Level of evidence = C (Class I)
12. Use tissue biopsy, considered the gold standard, to confirm a diagnosis of infection. Limited studies (not specific to LEAD) have demonstrated that noninvasive, quantitative swab cultures using the Levine technique are a reasonable alternative to biopsies in general clinical practice settings.
Level of evidence = C (Class II)
13. Refer patients with infected, ischemic wounds, which are limb threatening, for immediate evaluation, culture-guided antibiotic therapy, assessment of perfusion status, and/or need for surgical intervention.
Level of evidence = C (Class I)

Antibiotics

14. Consider topical antibiotic dressings for a limited time (eg, 2 weeks) if critical colonization is suspected.
Level of evidence = C (Class II)
15. Do not rely solely on topical antibiotics to treat infected, ischemic wounds.
Level of evidence = C (Class IV)

16. Promptly institute culture-guided, systemic antibiotics for patients with LEAD or CLI and evidence of limb/wound infection or cellulitis.
    Level of evidence = C (Class II)

Nutrition

17. Refer patients with LEAD/CLI for nutritional counseling to identify nutritional and vitamin deficiencies that warrant intervention.
    Level of evidence = C (Class II)
18. Consider the Mediterranean diet, which has been associated with reduced incidence of LEAD.
    Level of evidence = B (Class II)

Pain management

19. Institute a regular exercise program for medically stable patients with intermittent claudication. Supervised exercise sessions, 3 times per week, of 30 to 60 minutes of treadmill or track walking to the point of pain, followed by rest, promotes increased pain-free walking and total walking distances.
    Level of evidence = A (Class I)
20. Recommend self-directed walking programs for those who are unwilling or unable to participate in supervised exercise programs.
    Level of evidence = A (Class I)
21. Consider the need for analgesia for patients with persistent pain, and/or premedication prior to wound care. Refer patients with severe and intractable pain for an evaluation for surgical reconstruction. (TFC)
22. Consider the following pain management strategies for patients with intractable pain and CLI who are unsuitable for surgical reconstruction:
    - Spinal cord stimulation for patients whose foot $TcPO_2$ is between 10 and 30 mm Hg, and increases more than 10 mm Hg during a trial of spinal cord stimulation.
      Level of evidence = A (Class II)
    - Lumbar sympathectomy.
      Level of evidence = C (Class II)
    - Peridural anesthesia.

    Level of evidence = C (Class II)

Compression issues/management of edema in patients with mixed arterial/venous disease

23. Use a reduced level of compression (23-30 mm Hg at the ankle) for patients with LEAD, venous disease, wounds, and edema (ABI >0.50 to <0.80); and closely supervise the patient for complications.
    Level of evidence = C (Class II)
24. Avoid compression if ABI is less than 0.50, ankle pressure is less than 70 mm Hg, or toe pressure is less than 50 mm Hg.
    Level of evidence = C (Class IV)
    - If the patient is revascularized, consider compression to manage the edema due to the venous disease.

    Level of evidence = C (Class II)
25. Carefully monitor patients with neuropathy if compression is provided because they may not sense pain or discomfort from compression that is too tight. (TFC)
26. Consider use of graduated, compression stockings (18-30 mm Hg) to manage postoperative edema after lower-extremity, bypass surgery.
    Level of evidence = B (Class III)
27. If LEAD is present (ABI ≤0.90), prior to the use of antiembolism compression stockings (AECS) or mechanical devices, consult with the primary healthcare provider to determine if AECS/mechanical devices are indicated and safe, or if other interventions are warranted.
    Level of evidence = C (Class I)

Medications

28. Recommend statin therapy for lipid control, to reduce cardiovascular mortality and morbidity.
    Level of evidence = A (Class I)
29. Recommend antiplatelet therapy (eg, aspirin, clopidogrel, and dipyridamole) for patients with symptomatic LEAD to decrease mortality and cardiovascular events.
    Level of evidence = A (Class I)
    - Cilostazol (100 mg oral 2 times per day) increases HDL cholesterol, decreases triglycerides and LDL cholesterol, and improves the walking distances of patients with intermittent claudication.

    Level of evidence = A (Class I)
    - Aspirin (75-325 mg oral per day) has been recommended as a safe and cost-effective option for symptomatic patients:
      – Improves walking speed.
        Level of evidence = C (Class II)
      – Decreases vascular events.
        Level of evidence = B (Class III)
      – Decreases strokes.
        Level of evidence = A (Class I)
30. Consider clopidogrel (75 mg oral per day) as an alternative to aspirin to reduce the risk of stroke, myocardial infarction, or vascular deaths in patients with symptomatic LEAD or CLI.
    Level of evidence = B (Class II)
31. Consider a trial of prostanoids, which have shown some benefit in pain relief and wound healing for patients with CLI.
    Level of evidence = A (Class II)
32. Consider a trial of pentoxifylline as a second-line therapy for patients with intermittent claudication.
    Level of evidence = A (Class II)
33. Consider angiotensin-converting enzyme inhibitors (eg, ramipril 10 mg oral per day) to reduce cardiovascular risks and improve pain-free walking time in patients with claudication.
    Level of evidence = A (Class II)

Surgical options

34. Carefully assess risks versus short-term and long-term benefits of bypass surgery or angioplasty. Short-term surgical benefits may not be sustained long term.
    Level of evidence = A (Class III)
35. Consider antithrombotic agents to improve patency of vascular grafts.
    Level of evidence = A (Class II)
36. Assess $TcPO_2$ levels prior to amputation. Successful healing after amputation has been associated with:
    - Preoperative $TcPO_2$ levels greater than 20 mm Hg.
      Level of evidence = A (Class II)
    - Increase in $TcPO_2$ greater than 10 mm Hg after an oxygen challenge.
      Level of evidence = C (Class II)
37. Consider the need for strict glycemic control for patients undergoing lower-extremity bypass surgery.
    Level of evidence = C (Class II)
38. Weigh the risks of anemia against the risk of transfusion if the hemoglobin level is 7.0 to 9.0 g/dL, taking into consideration other hemodynamic and physiological parameters.
    Level of evidence = C (Class II)
39. Consider prophylactic antibiotics:
    - A 5-day course of combined antibiotics after major lower-limb amputation.
      Level of evidence = C (Class II)
    - A 24-hour course of broad-spectrum antibiotics for patients having revascularization with grafts.
      Level of evidence = A (Class I)
40. Consider the benefits of endovascular procedures over surgery for individuals who have a life expectancy of 2 years or less, or are 80 years of age and older.
    Level of evidence = C (Class II)

Consider adjunctive therapies

41. A trial of conservative therapy (eg, topical therapy) for patients with wounds and borderline blood flow (ie, ABI = 0.62; $TcPO_2 > 30$ mm Hg; ankle pressure >70 mm Hg) if they are free of limb-threatening sepsis.
    Level of evidence = C (Class II)
42. Low-frequency ultrasound.
    Level of evidence = B (Class II)
43. Electrotherapy (high-voltage pulsed current) for patients with ischemic wounds.
    Level of evidence = C (Class II)
44. Hyperbaric oxygen therapy for patients with nonhealing, ischemic wounds ($TcPO_2$<40 mm Hg).
    Level of evidence = B (Class II)
45. Arterial flow augmentation (intermittent pneumatic compression) for individuals who are not surgical candidates:
    - Intermittent claudication.
      Level of evidence = B (Class II)
    - Limb-threatening arterial disease.
      Level of evidence = C (Class II)
46. Topical negative pressure for wounds with infected vascular grafts.
    Level of evidence = C (Class II)
47. Bone marrow-derived, mononuclear cell therapy as an option for pain relief or limb salvage in patients who are not surgical candidates:
    - Intermittent claudication.
      Level of evidence = B (Class II)
    - CLI.

    Level of evidence = A (Class II)
48. Immune modulation therapy for patients with claudication or CLI.
    Level of evidence = B (Class II)

D. Patient Education and Risk-Reduction Strategies

1. Educate patients about risk-reduction and chronic disease management (eg, control diabetes, hypertension, cholesterol, and weight; adhere to medication regimen), and wound care procedures for patients with wounds.
   Level of evidence = C (Class I)
2. Recommend tobacco cessation, which slows the progression of atherosclerosis, decreases the risk of cardiovascular events and death, and may decrease the overall risk of LEAD after long-term cessation.
   Level of evidence = B (Class I)
   - Assist in developing a plan for tobacco cessation, which includes behavioral and/or pharmacological interventions (nicotine replacement therapy; nonnicotinic therapy).
     Level of evidence = B (Class I)
   - Recommend preoperative tobacco cessation to reduce postoperative complications. (TFC)
   - Avoid secondhand smoke.
     Level of evidence = C (Class II)
3. Teach measures to:
   - Promote blood flow, maintain intact skin, and prevent trauma. Avoid leg elevation and use a dependent position for legs; avoid chemical, thermal, and mechanical trauma; examine limbs/feet daily for blisters, wounds, signs of infection; precautions to observe/report if compression is used to manage edema in mixed arterial/venous disease; have routine nail and foot care provided by a professional; and visit a healthcare provider on a regular basis. (TFC)
   - Protect feet, toes, and heels. Wear proper-fitting shoes/footwear with socks or hose; use pressure redistribution surfaces, products, or devices to protect toes and other bony prominences; and offload the heels if bedbound or chairbound.
     Level of evidence = C (Class I)
4. Increase regular exercise and physical activity to improve symptoms of claudication.
   Level of evidence = A (Class I)
5. Encourage tobacco users to exercise. Some negative effects of tobacco use may be minimized by 8 hours of exercise per week. (TFC)

6. Drink in moderation if already consuming alcohol. Level of evidence = B (Class II)

Summary

To improve the care and outcomes for individuals with LEAD, efforts must be taken to disseminate evidence-based guidelines and insure that healthcare providers are making every effort to identify individuals with asymptomatic or symptomatic LEAD and implement prevention and risk-reduction strategies. The current LEAD guideline serves as a resource for clinicians, contributes to evidence-based wound management of persons with or at risk for LEAD, and provides a framework for future wound research. Educating patients and families about LEAD and its risks is imperative for them to develop an understanding of their role in preventing and managing LEAD as well as the importance of seeing a wound specialist for the management of any wounds that develop.

This article has provided a synopsis of the 2014 *Guideline for Management of Patients With Lower-Extremity Arterial Disease* with recommendations for the assessment and management of patients with or at risk for LEAD. Refer to the Supplemental Digital Content (Supplemental Digital Content 1, http://links.lww.com/JWOCN/A31) associated with this article for the complete reference list for the guideline. The guideline has been accepted for publication by the National Guideline Clearinghouse (www.guideline.gov/). Print copies of the complete guideline and mobile applications are available for purchase. Print copies are available for a nominal fee from the WOCN Society, 1120 Rt. 73, Suite 200, Mount Laurel, NJ 08054; Web site: www.wocn.org. Orders can be placed through the WOCN Society's Online Booksto (www.wocn.org/Bookstore). In addition, WOCN Guidelines 2014 are available as a mobile application for iPads, iPhones, and iPods that can be purchased from iTunes: https://itunes.apple.com/us/app/evidence-based-wound-care/id850053409; and for android devices from Google Play: https://play.google.com/store/apps/details?id=com.wocn.societyguidelines&hl=en.

KEY POINTS

✔ LEAD is often unrecognized and undertreated in 50% to 80% of patients.

✔ Patients with lower-extremity wounds should have a comprehensive, bilateral lower-extremity examination including noninvasive tests (eg, ABI, toe pressure/TBI, and $TcPO_2$) to determine if ischemia is present.

✔ Do not debride lower-extremity wounds with stable, black eschars until perfusion status is determined.

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

✔ Make an urgent vascular and/or surgical referral for patients with symptoms of acute limb ischemia, an ABI less than 0.40, and/or gangrene.

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