



Complete Summary

GUIDELINE TITLE

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

BIBLIOGRAPHIC SOURCE(S)

Wound, Ostomy, and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity neuropathic disease. Glenview (IL): Wound, Ostomy, and Continence Nurses Society (WOCN); 2004. 57 p. (WOCN clinical practice guideline; no. 3). [85 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Wounds due to lower-extremity neuropathic disease (LEND)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Nursing
Physical Medicine and Rehabilitation
Podiatry

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physical Therapists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To present an evidence-based guideline for the management of wounds in patients with lower-extremity neuropathic disease (LEND)
- To provide consistent, research-based, clinical information with the goal of improved, cost-effective patient outcomes as well as increased wound research in the areas where there are gaps between research and practice

TARGET POPULATION

Patients with lower-extremity neuropathic disease (LEND) with wounds

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Assessment of causative and contributive factors and significant signs and symptoms to differentiate types of lower-extremity ulcers
2. Review of health history (risk factors for lower extremity neuropathic disease [LEND], wound history, pain history, pharmacologic history of prescribed and self-prescribed medications)
3. Review of pertinent labs (hemoglobin A-1 C [HbA1c], serum B-12, thyroid stimulating hormone [TSH], and T4) to identify risk markers for LEND
4. Foot and lower-extremity examination (dermatologic status, localized inflammation, edema, perfusion status, musculoskeletal/biomechanical status, foot care routine, footwear assessment, wound characteristics, complications)

Prevention

1. Identification of high-risk patients and referral to foot care specialist
2. Neuropathic foot screen
3. Amputation prevention program including annual foot screening, patient education, appropriate footwear selection, daily self-inspection, and management of simple foot problems

4. Professional assistance in fitting shoes

Treatment

1. Offloading with wound closure, walking splints, wedge sole shoes, healing shoes with large toe box
2. Wound management
3. Debridement
4. Dressings, including use of:
 - Growth factors (rh PDGF-BB)
 - Biological wound coverings
5. Referral for assessment of vascular perfusion and need for surgical intervention in cases of infection
6. Systemic antibiotics for infection
7. Nutritional management including a multivitamin preparation, when applicable
 - L-Arginine supplementation
8. Referral for pain management and consideration of electrical stimulation, Gabapentin, and Capsaicin Cream
9. Regular exercise program
10. Management of edema
 - Monitor patients and referral for further evaluation as needed
11. Adjunctive therapies (e.g., hyperbaric oxygen therapy), modifiable risk factors management, patient instruction in chronic disease management

MAJOR OUTCOMES CONSIDERED

- Risk for and incidence of lower extremity neuropathic disease (LEND) with foot ulcers
- Signs and symptoms of LEND
- Sensitivity and specificity of diagnostic tests
- Wound healing
- Complications of LEND

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The primary authors of this guideline independently conducted a literature search of Medline and Cochrane Library databases to identify studies and systematic reviews published in English from 1980 through 2003. The following Medical Subject Headings (MeSH) were used to search for each specific question related to lower-extremity neuropathic disease (LEND)-lower-extremity wounds, peripheral neuropathy, neuropathic disease, neuropathic wounds, and diabetic neuropathy. The search targeted meta-analyses, randomized controlled trials (RCTs), prospective clinical trials, retrospective studies, and systematic reviews. Bibliographies of selected articles also were reviewed.

NUMBER OF SOURCE DOCUMENTS

A total of 174 articles were identified and reviewed for this guideline.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Primary reviewers read and summarized the articles. Each article was assigned a level of evidence rating as follows:

Level I: A randomized controlled trial (RCT) that demonstrates a statistically significant difference in at least one important outcome defined by $p < .05$.

Level II: A RCT that does not meet Level I criteria.

Level III: A nonrandomized trial with contemporaneous controls selected by some systematic method. A control may have been selected because of its perceived suitability as a treatment option for individual patients.

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.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

A level of evidence rating (A-C) has been assigned to specific recommendations and is defined at the end of the "Major Recommendations" field. Citations in support of individual recommendations are identified in the original guideline document.

Assessment

1. Prior to treatment, assess causative and contributive factors and significant signs and symptoms to differentiate types of lower-extremity ulcers, which require varying treatment modalities.
2. Review health history to address risk factors for lower-extremity neuropathic disease (LEND), wound history, pain history, and pharmacologic history of prescribed and self-prescribed medications. **Level of evidence = C**
3. Review pertinent labs to identify risk markers for LEND. **Level of evidence = C**
 - a. Elevated hemoglobin A1 C (HbA1c) levels.
 - b. Serum B-12 (Cyanocobalamin) deficiency.
 - c. Untreated elevated thyroid stimulating hormone (TSH), T4 levels.
4. Conduct foot and lower-extremity examination. **Level of evidence = C**
 - a. Assess dermatologic status for callus development.
 - b. Determine localized inflammation by palpation and dermal thermometry.
 - c. Determine if edema is dependent or pitting, localized or generalized, or bilateral or unilateral.
 - d. Assess perfusion status by assessing skin temperature, capillary refill, venous refill, color changes, and paresthesias.
 - e. Assess musculoskeletal/biomechanical status for foot deformities, muscle weakness, or gait abnormalities.
 - f. Assess neurological status for loss of protective sensation and diminished tendon reflexes.
 - g. Assess patient's foot care routine for daily skin cleansing and moisturizing, surveillance for foot problems, and barefoot or stocking foot walking.

- h. Assess patient's footwear for proper sizing and design and use and status of insoles.
 - i. Determine wound characteristics including location, pain, shape, and size of the wound, wound base, wound edges, periwound skin, exudates, and presence of necrosis.
 - j. Assess for complications, such as cellulitis, gangrene, osteomyelitis, or Charcot fracture (neuropathic osteoarthropathy).
5. Perform a comprehensive foot examination annually on patients with diabetes to identify risk factors predictive of ulcers and amputations. Health-care providers should perform a visual inspection of patient's feet at each routine visit.

Prevention

1. A multidisciplinary approach is recommended for persons with diabetes, insensate feet, and peripheral neuropathy. **Level of evidence = C**
2. Identify individuals at risk for foot ulceration, considering loss of protective sensation, history of previous ulceration or amputation, elevated plantar pressure, rigid foot deformity, poor diabetes control (HgA1c >7%), duration of diabetes greater than 10 years
3. Refer high-risk patients to foot care specialists for ongoing preventive care and lifelong surveillance. **Level of evidence = C**
4. Perform neuropathic foot screen to identify current foot problems and initiate a prescription for appropriate prevention measures and treatment, based on risk category.
5. Initiate a lower-extremity amputation prevention program, that includes
 - a. Annual foot screening
 - b. Patient education
 - c. Appropriate footwear selection
 - d. Daily self-inspection of the foot by the patient
 - e. Management of simple foot problems
6. Encourage professional assistance in fitting shoes properly because peripheral neuropathy may preclude patients from recognizing proper fit.

Treatment

1. Recommend that patients with wounds and LEND seek care guided by a clinical wound expert.
2. Utilize a multidisciplinary team for persons with foot ulcers. **Level of evidence = B**
3. Relate wound treatments to adequacy of perfusion status.

Offloading

4. Ensure adequate offloading of pressure through wound closure.
5. Utilize assistive devices (e.g., walking splints, wedge sole shoes, healing shoes with large toe box) to provide support, balance, and offloading of the affected site.

Wound Management

6. Maintain dry stable eschar on noninfected, ischemic, neuropathic wounds. **Level of evidence = C**
7. Cleanse wound with noncytotoxic cleansers.

Debridement

8. Recommend debridement of neuropathic wounds and calluses, as needed, throughout the healing process. **Level of evidence = C**
9. Debride ulcers with extensive cellulitis and/or osteomyelitis and refer for pharmacological (intravenous) intervention. **Level of evidence = C**

Dressings

10. Choose dressings that promote a moist wound environment. **Level of evidence = B**
11. Reevaluate the wound dressings on a periodic basis throughout the treatment process. **Level of evidence = C**
12. Consider the use of growth factors (rh PDGF-BB) for foot ulcers after necrotic tissue has been debrided, infection is cleared, and adequate perfusion has been established. **Level of evidence = A**
13. Consider the use of biological wound coverings for the treatment of noninfected diabetic foot ulcers. **Level of evidence = B**

Infection

14. Observe clinical manifestations of infection, which may be subtle due to reduced blood flow or absence of sensation in the neuropathic foot.
15. Infected neuropathic wounds may be limb threatening and require immediate referral for assessment of vascular perfusion and need for surgical intervention. **Level of evidence = C**

Antimicrobials

16. Tissue biopsy is considered the gold standard to confirm diagnosis of infection. Quantitative swab cultures have been demonstrated to be a reasonable alternative in clinical practice. **Level of evidence = B**
17. Systemic antibiotics are warranted in the management of ulcers when bacteremia, sepsis, advancing cellulitis, or osteomyelitis occurs, and caution must be exercised against multiple-antibiotic-resistant organisms. **Level of evidence = C**

Osteomyelitis

18. As a noninvasive technology, magnetic resonance imaging (MRI) has demonstrated the highest sensitivity and specificity for diagnosing osteomyelitis in patients with diabetes and foot ulcers.
19. Refer the patient for further evaluation for suspected infection, positive probe to bone, and radiographic changes demonstrating Charcot osteoarthropathy. **Level of evidence = C**

Nutrition

20. Utilize basic principles of nutritional management of the patient with diabetes mellitus to control serum glucose, hyperlipidemia, and hypertension for the patient with neuropathic foot ulcers. **Level of evidence = C**
21. Select populations, such as elderly individuals and people on calorie-restricted diets, may benefit from a multivitamin preparation. **Level of evidence = C**
22. Consider L-Arginine supplementation.

Pain Management

23. Refer to resources for pain management.
24. Consider referral for a course of electrical stimulation to relieve chronic diabetic neuropathic pain in patients who do not respond to conventional treatment. **Level of evidence = C**
25. Consider Gabapentin for relief of neuropathic pain described as burning, tingling, or allodynia symptoms.
26. Utilize Capsaicin Cream (0.25% & 0.075%) applied thinly three times a day (tid) to four times a day (qid) to affected areas.

Exercise

27. Institute a regular exercise program, adapted to the presence of complications.
28. Exercise must be conducted with caution due to the insensate lower extremities.

Management of Edema

29. Monitor patients with neuropathy, as they may have no sensation of pain related to the compression bandage.
30. Refer for further evaluation for cellulitis, osteomyelitis, atypical ulcers, and new onset or diagnosis Charcot foot.

Adjunctive Therapies

31. Consider hyperbaric oxygen therapy (HBOT) for Wagner grades III and IV ulcers.
32. Manage modifiable risk factors, including smoking, weight, and alcohol intake.
33. Instruct patients in chronic disease management (e.g., diabetes, human immunodeficiency virus [HIV], and their effects on lower-extremity peripheral neuropathy)

Definitions

Levels-of-Evidence Rating

Level A: Two or more supporting RCTs of LEND in humans (at Levels I or II), meta-analysis of RCTs, or Cochrane Systematic Review of RCTs

Level B: One or more supporting controlled trials of LEND in humans or two or more trials in an animal model (at Level III)

Level C: One supporting controlled trial, at least two supporting case series that were descriptive studies in humans, or expert opinion

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline to determine wound etiology.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified for selected recommendations (see "Major Recommendations" field) and defined as follows:

Level A: Two or more supporting randomized controlled trials (RCTs) of lower extremity neuropathic disease in humans (at Levels I or II), meta-analysis of RCTs, or Cochrane Systematic Review of RCTs

Level B: One or more supporting controlled trials of lower extremity neuropathic disease in humans or two or more trials in an animal model (at Level III)

Level C: One supporting controlled trial, at least two supporting case series that were descriptive studies in humans, or expert opinion

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Identification of patients with peripheral neuropathy who are at risk for developing wounds
- Identification of patients whose current wounds are caused or complicated by peripheral neuropathy
- Implementation of appropriate strategies and plans to:
 - Attain/maintain intact skin
 - Manage pain and sensory issues
 - Identify/manage complications promptly
 - Optimize potential for wound healing
 - Promote limb preservation
 - Involve patient and caregiver in self-management

POTENTIAL HARMS

- Wounds treated with topical antimicrobials may develop resistant organisms over time.
- Topical creams, ointments, and gels containing antimicrobials may also cause sensitivity reactions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Wound, Ostomy, and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity neuropathic disease. Glenview (IL): Wound, Ostomy, and Continence Nurses Society (WOCN); 2004. 57 p. (WOCN clinical practice guideline; no. 3). [85 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

Wound, Ostomy, and Continence Nurses Society - Professional Association

SOURCE(S) OF FUNDING

Wound, Ostomy, and Continence Nurses Society

GUIDELINE COMMITTEE

Wound, Ostomy, and Continence Nurses (WOCN) Lower-Extremity Neuropathic Disease Panel

Wound Guidelines Task Force

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existed with any individual panel member. In addition, panel members disclosed any financial relationships with commercial companies during panel meetings.

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GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase (\$15 nonmembers; \$10 members) from the Wound Ostomy and Continence Nurses Society (WOCN), 4700 W. Lake Avenue, Glenview, IL 60025-1485; Web site: www.wocn.org. Orders can be placed via telephone at (888) 224-9626 or by fax at (866) 615-8560.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on November 9, 2004. The information was verified by the guideline developer on November 30, 2004.

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