Complete Summary

GUIDELINE TITLE

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

BIBLIOGRAPHIC SOURCE(S)

Wound, Ostomy, and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity venous disease. Glenview (IL): Wound, Ostomy, and Continence Nurses Society (WOCN); 2005. 42 p. (WOCN clinical practice guideline; no. 4). [86 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 venous disease (LEVD)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Nursing
Physical Medicine and Rehabilitation
Surgery

INTENDED USERS

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

GUIDELINE OBJECTIVE(S)

- To present an evidenced-based guideline for the evaluation and management of wounds in patients with lower-extremity venous disease (LEVD)
- 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 venous disease (LEVD) 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 venous disease [LEVD], wound history, and pain history)
3. Review of pertinent labs (hemoglobin, hematocrit, and prothrombin time [international normalized ratio (INR)]; erythrocyte sedimentation rate [ESR] if patient is on anticoagulant warfarin [Coumadin])
4. Lower-extremity examination (perfusion status, presence or absence of pedal pulses, ankle brachial index [ABI], dermatologic status, localized inflammation, edema, wound characteristics, complications)
5. Diagnostic evaluation with one of the following option: duplex imaging, Doppler ultrasonography, photoplethysmography, air plethysmography, venography
6. Assessment of skin temperature of leg
7. Monofilament testing to assess for peripheral neuropathy
8. Assessment of factors that may impede healing
9. Monitoring the percentage change in ulcer area to assess healing

10. Referral when appropriate (cellulitis, deep vein thrombosis [DVT], variceal bleeds, wounds that are atypical in appearance or location, dermatitis that is unresponsive to topical steroids, and wounds that are unresponsive to 2 to 4 weeks of appropriate therapies)

Prevention

1. Improving calf-muscle strengthening
2. Light compression therapy
3. Vein surgery (considered, but not recommended)
4. Compression stockings or other compression devices

Management/Treatment

1. Cleansing of the wound at each dressing change
2. Avoidance of known skin irritants and allergens
3. Debridement
4. EMLA cream
5. Hydrocolloid (vs. simple low-adherent dressings [e.g., telfa]) or foam dressings
6. Topical antimicrobial agent (i.e., silver sulfadiazine) for ulcers with a high level of bacteria
7. Cadexomer Iodine (Iodoflex) for removing slough and reducing bacterial bioburden
8. Oral zinc sulfate (recommended only for LEVD patients with low serum zinc levels)
9. Mesoglycan (Chondroitin intramuscular)
10. Flavonoids (Rutoside)
11. Compression therapy (short-stretch compression bandaging, high vs. low compression therapy)
12. Pentoxifylline (adjunct to compression therapy)
13. Horse chestnut seed extract
14. Granulocyte-macrophage colony stimulating factor (GM-CSF) (considered but not specifically recommended)
15. Sulodexide (considered but not specifically recommended)
16. Repifermin
17. Subendoscopic perforator surgery procedure vs. Linton procedure
18. Skin grafting (considered, but not recommended)
19. Vein ligation or stripping (considered but not recommended)
20. Ultrasound as an adjunctive therapy
21. Other adjunctive therapies considered but not specifically recommended: laser therapy, electrical stimulation, vacuum-assisted wound closure, hyperbaric oxygen therapy, small intestinal submucosa sound matrix
22. Avoidance of whirlpools
23. Home-based exercise program
24. Patient education

MAJOR OUTCOMES CONSIDERED

- Wound healing rates
- Signs and symptoms of lower-extremity venous disease (LEVD)
- Recurrence

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 to 2003. The following medical subject headings (MESH) were used to search for each specific question related to lower-extremity venous disease (LEVD)--lower-extremity wounds, venous ulcers, venous insufficency, stasis ulcers, and varicose ulcers. 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 180 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

Levels-of-Evidence Rating

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

A panel of Wound, Ostomy, and Continence Nurses' (WOCN) Society members, representing a wide range of experience and clinical practice backgrounds, convened to plan the guideline format. A topical outline was designed, and specific questions were proposed to provide focus for the evidence search. The review included studies reporting primary data relevant to lower-extremity venous disease (LEVD) and specific therapies or diagnostic modalities. The panel developed questions to guide the evidence-based literature review.

Summaries of the studies were presented to all task force members for review, discussion, and clarification. After a series of conference calls and meetings conducted in 2002-2005, the guideline was finalized incorporating evidence from the studies. Studies supporting the guideline are cited in the text and listed in the references. A level-of-evidence rating has been assigned to specific recommendations based on the rating system used by the Agency for Health Care Policy and Research (AHCPR), now known as Agency for Healthcare Research and Quality. Where specific level-of-evidence ratings are not included, the information represents the consensus opinion of panel members.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Debride the Ulcer of Devitalized Tissue

One randomized controlled trial (RCT) of 12 patients compared the cost-effectiveness of biodebridement (i.e., maggot therapy) to hydrogel therapy for debridement of necrotic slough in venous ulcer patients. The authors concluded that maggot therapy was efficacious and cost-effective.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The type of evidence (I-V) and the strength and consistency of evidence grades (A-C) are defined at the end of the "Major Recommendations" field. Citations in support of individual recommendations are identified in the original guideline document.

Etiology of Venous Ulcers

Assessment

1. Prior to treatment, assess causative and contributing factors and significant signs and symptoms to differentiate the different types of lower-extremity ulcers, which require varying treatment modalities (See Appendix A of the original guideline document).
2. Review health history to address: risk factors for lower-extremity venous disease (LEVD); wound history, and pain history. Level of evidence = C.
3. Review pertinent labs: Pertinent labs include hemoglobin and hematocrit and prothrombin time (international normalized ratio [INR]); if patient is on anticoagulant warfarin (Coumadin), review erythrocyte sedimentation rate (ESR); an elevated ESR may suggest an underlying connective tissue disorder, vasculitis, or osteomyelitis. Level of evidence = C.
4. Conduct lower-extremity examination.
    a. Determine perfusion status by assessing skin temperature, venous refill time, color changes, and presence of paresthesias.
    b. Determine presence or absence of pedal pulses. Palpate both dorsalis pedis and posterior tibial pulses. Presence of palpable pulses does not rule out lower-extremity arterial disease (LEAD) nor does the absence of pulses indicate arterial disease, especially in the presence of edema. Measurement of ankle brachial index (ABI) by Doppler is essential. Individuals with an ABI <0.9 should be assumed to have a component of arterial disease. Level of evidence = C.
    c. Observe skin of leg for edema, hemosiderosis (i.e., hemosiderin staining), venous dermatitis, atrophie blanche, varicose veins, ankle flaring, scarring from previous ulcers, lipodermatosclerosis, and tinea pedis.
5. Determine characteristics of a typical venous ulcer.
6. Consider Duplex imaging with or without color to diagnose anatomical and hemodynamic abnormalities with venous disease. Level of evidence = A.
7. Assess factors that may impede healing status.
8. Monitor the percentage change in ulcer area to assess healing. An ulcer that does not heal or show significant healing within 4 weeks should prompt a clinician to consider alternative therapies. Level of evidence = B.
9. Consider referral for further evaluation for patients with cellulitis, deep vein thrombosis (DVT), variceal bleeds, wounds that are atypical in appearance or location, dermatitis that is unresponsive to topical steroids, and wounds that are unresponsive to 2 to 4 weeks of appropriate therapies.

Interventions: Prevention

Preventing Ulcer Recurrence

1. Studies have shown that individuals with LEVD have significant impairment of calf muscle function compared with healthy subjects, indicating that a program of improving calf-muscle strengthening may be of benefit in both healing and preventing recurrence of LEVD. Level of evidence = B.
2. Light compression may be helpful for individuals with LEVD and/or with lipodermatosclerosis who are unable to apply garments, tolerate higher compression, and who cannot afford the cost of higher compression garments. Level of evidence = B.
3. Individuals with mixed venous/arterial disease have special care requirements.
    a. For patients with LEVD and moderate arterial insufficiency (ABI >0.5 to <0.8) who present with open wounds and edema, closely supervised reduced compression may promote healing by reducing edema.
    b. Compression is not recommended for individuals with an ABI <0.5. Level of evidence = C.
4. There is insufficient evidence about the effects of vein surgery in preventing ulcer recurrence. Level of evidence = A.
5. Compression stockings or other compression devices must be worn for the prevention of venous edema and venous leg ulcer recurrence.

Interventions: Treatment

1. Cleanse the wound at each dressing change, minimizing trauma to the wound. No specific studies demonstrate the benefit of using one cleanser over another for LEVD.
2. Avoid the use of known skin irritants and allergens on the skin especially in patients with dermatitis.
3. No one method of debridement has been proven optimal for LEVD ulcers.
4. EMLA cream produces effective pain relief for sharp debridement of venous ulcers and decreases the median number of debridements required for a clean ulcer. Level of evidence = B.
5. Hydrocolloid or foam dressings may be beneficial in reducing pain associated with LEVD ulcers (Arnold et al., 1994). Level of evidence = B.
6. No specific studies have shown an optimal type of dressing or frequency of dressing change required for LEVD when used under compression wraps.
7. Hydrocolloid dressings under compression did not heal more venous leg ulcers than simple, low-adherent dressings (e.g., telfa) under compression. Level of evidence = A.
8. There is no clear evidence indicating the duration, safety, and efficacy of topical antibiotics. A short course of treatment (approximately 2 weeks) with a topical antimicrobial such as silver sulfadiazine may be considered if the ulcer has a high level of bacteria (greater than 105). Level of evidence = B.
9. Cadexomer Iodine (Iodoflex) may be useful in removing slough and thus reducing bacterial bioburden. It has been shown to be more effective than "standard treatments" such as wet-to-dry dressings and thin hydrocolloids and results in faster healing times. Level of evidence = A.

10. Oral zinc sulfate does not appear to aid in the healing of leg ulcers in individuals with normal zinc levels. There is also limited evidence of benefit in people with LEVD who have low serum zinc. Level of evidence = B.
11. Mesoglycan (Chondroitin 30 milligrams [mg] every day intramuscularly [IM] for 1 week), combined with standard care, resulted in significantly faster ulcer healing in a group of 183 patients. Level of evidence = B.
12. Two randomized controlled trials [RCTs] found that flavonoids (Rutoside) in doses ranging from 250 to 300 mg twice daily improved ulcer healing rates when compared with placebo. Level of evidence = A.
13. Treatment with short-stretch compression bandaging may reduce pain. Level of evidence = B.
14. Compression therapy heals more venous leg ulcers than no compression therapy as well as decreases the healing time. Level of evidence = A.
15. High compression is more effective than low compression, but there are no differences in the effectiveness of the different types of products available for high compression. Level of evidence = A.
16. For individuals with mixed arterial/venous disease and moderate arterial insufficiency (ABI >0.5 to <0.8) who present with ulcers and edema, a trial of modified, reduced compression bandaging to a level of 23 to 30 millimeters (mm) mercury (Hg) at the ankle may promote healing. Level of evidence = C.
17. Pentoxifylline appears to be an effective adjunct to compression therapy for treating venous ulcers. Level of evidence = A.
18. Horse chestnut seed extract is beneficial in controlling pain and reducing edema in LEVD. Level of evidence = A.
19. Repifermin has been shown to statistically accelerate wound healing. Level of evidence = B.
20. Subendoscopic perforator surgery procedure was comparable to the Linton procedure for patients with venous leg ulcers as far as healing rates and recurrence. Level of evidence = B.
21. There is insufficient evidence to determine whether skin grafting improves the healing of venous ulcers. Level of evidence = A.
22. There is some evidence that ultrasound might be helpful as an adjunctive therapy in healing venous ulcers. Level of evidence = A.
23. A home-based exercise program including isotonic exercise can improve poor calf muscle and calf muscle pump function in individuals with LEVD. Level of evidence = B.

Definitions:

Levels of Evidence Rating

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

Rating of Evidence

Level A: Two or more supporting RCTs of LEVD 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 LEVD 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

Note: Where specific level of evidence ratings are not included, the information represents a consensus of panel members.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the determination of wound etiology.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

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 RCTs of LEVD 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 LEVD 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

Note: Where specific level of evidence ratings are not included, the information represents a consensus of panel members.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Identification of individuals with lower-extremity venous disease (LEVD) who are at risk for developing wounds
- Identification of individuals with current wounds that are caused or complicated by LEVD
- Implementation of appropriate strategies/plans to:
    - Attain/maintain intact skin
    - Reduce edema
    - Reduce pain
    - Prevent complications
    - Promptly identify/manage complications
    - Optimize potential for wound healing
    - Involve patient/caregiver in self-management (care)

POTENTIAL HARMS

- Leg wounds treated with topical antibiotics may develop resistant organisms or sensitivities over time.
- Topical creams, ointments, and gels containing antibiotics may cause sensitivity reactions in many individuals with leg ulcers.

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

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Wound, Ostomy, and Continence Nurses Society (WOCN). Guideline for management of wounds in patients with lower-extremity venous disease. Glenview (IL): Wound, Ostomy, and Continence Nurses Society (WOCN); 2005. 42 p. (WOCN clinical practice guideline; no. 4). [86 references]

ADAPTATION

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

DATE RELEASED

2005

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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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Individuals involved in developing clinical practice guidelines are charged by the Wound Ostomy and Continence Nurses (WOCN) Society with the task of developing objective, complete, and practical guidelines. Financial relationships with commercial companies could conflict with that task when a company's products or services are related to the subject of the guideline. To ensure the integrity of WOCN Society and the WOCN Clinical Practice Guidelines, all participants in the development of clinical practice guidelines submitted a Conflict of Interest Disclosure Form to WOCN prior to participation in guideline activity. The WOCN Executive Director reviewed the forms and determined that no conflict of interest existed with any individual panel member. In addition, panel members disclosed any financial relationships with commercial companies during panel meetings.

Members of the WOCN Society Council, the WOCN Ad hoc Ethics Committee, and the Journal of Wound, Ostomy Continence Nurses Society Editor receive no compensation from companies that provide products or services related to the practice of WOC nursing or from firms that provide services to WOCN Society.

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), 15000 Commerce Parkway, Suite C, Mt. Laurel, NJ 08054; 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 August 25, 2005. The information was updated by the guideline developer on September 26, 2005.

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