



Complete Summary

GUIDELINE TITLE

Summary algorithm for venous ulcer care with annotations of available evidence.

BIBLIOGRAPHIC SOURCE(S)

Association for the Advancement of Wound Care (AAWC). Summary algorithm for venous ulcer care with annotations of available evidence. Malvern (PA): Association for the Advancement of Wound Care (AAWC); 2005. 25 p. [147 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
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SCOPE

DISEASE/CONDITION(S)

Venous ulcers

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Geriatrics
Internal Medicine
Nursing
Physical Medicine and Rehabilitation
Plastic Surgery
Podiatry
Preventive Medicine
Sports Medicine
Surgery

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Occupational Therapists
Patients
Pharmacists
Physical Therapists
Physician Assistants
Physicians
Podiatrists
Public Health Departments
Students
Substance Use Disorders Treatment Providers
Utilization Management

GUIDELINE OBJECTIVE(S)

- To identify best practice wound management modalities
- To explore reimbursement of evidence-based practices in various health care settings
- To close evidence and reimbursement gaps

TARGET POPULATION

All patients with venous ulcer(s)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Patient history
2. Differential diagnosis
3. Physical examination

Management

1. Patient education
2. Lower leg elevation
3. Ambulation/exercise
4. Compression
5. Peri-wound skin care
6. Cleanse wound
7. Necrotic tissue debridement
8. Filling of deep wounds
9. Management of excess exudate
10. Maintenance of moist wound environment
11. Antimicrobial wound care
12. Biologic dressings
13. Skin replacement
14. Biophysical modalities
15. Pharmacotherapy
16. Closure, obliteration or surgical repair of veins

MAJOR OUTCOMES CONSIDERED

- Ulcer healing rate and time
- Ulcer recurrence
- Accuracy of diagnostic tests
- Adverse effects of treatment
- Symptom relief

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE and EMBASE databases were searched to identify and list up to five of the best published support references for each step in the algorithm.

NUMBER OF SOURCE DOCUMENTS

210

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

Strength of Evidence Ratings

- A. Results of two or more randomized controlled trials (RCTs) in humans provide support (or for diagnostics or risk analysis: cohort [CO] studies).
- B. Results of two or more historically controlled trials (HCTs) or convenience assignment or non-randomized controlled trials (CCTs) or a CCT and an RCT in humans provide support or when appropriate, results of two or more controlled trials in an animal model provide indirect support.
- C. This rating requires one or more of the following:
 - 1. Results of one controlled trial (e.g., RCT or CCT or HCT)
 - 2. Results of at least two case series (CS) or descriptive studies or a cohort study in humans
 - 3. Expert opinion (EO)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Task Force inclusively summarized algorithms for venous ulcer management published before August, 2002. The current evidence level for each item in the algorithm was listed in parentheses after the item. A-level evidence is highest and C-level evidence is lowest: e.g., expert opinion. Criteria for quality of support were developed based on those previously used by the Agency for Healthcare Policy and Research (AHCPR) (now Agency for Health Research and Quality [AHRQ]) for Clinical Practice Guideline #15: Treatment of Pressure Ulcers (AHCPR Publication No. 95-0652). The scheme is summarized in the "Rating Scheme for the Strength of the Evidence." Appendix I of the *Annotated Venous Ulcer Algorithm* summarizes the evidence the Task Force found to this date.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Task Force first inclusively summarized algorithms for venous ulcer management published before August, 2002, and then searched the literatures to identify and list up to five of the best published support references for each step in the algorithm.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses of venous ulcer care. Refer to the annotations accompanying the Annotated Venous Ulcer Algorithm for short summaries of these studies.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Algorithm Content Validation

The Task Force conducted a formal content validity study for these algorithms, which is currently being prepared for publication. The clinical validity or relevance of the individual items in the algorithm were rated in order of appearance in the Annotated Venous Ulcer Algorithm by 16 multi-disciplinary wound care professionals, using the 4-point Likert scale below:

1 = Not relevant

2 = Unable to assess relevance without further information

3 = Relevant but needs minor attention

4 = Very relevant and succinct

Items with an evidence level A or average score more than 3.5 remained unchanged and were deemed to have content validity. Those with average item relevance 2.5 to 3.5 were modified as recommended in a separate comment section. Those with a score less than 2.5 were deleted from the algorithm as not content validated for venous ulcer care.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Strength of evidence ratings (A-C) are defined at the end of the "Major Recommendations" field.

A. Venous ulcer diagnosis consisting of:

1. Patient history

- Prior phlebitis, deep vein thrombosis, (DVT), **C** (Aharinejad et al., 2001; Berard et al., 2002, Nicolaidis et al., 2000)
- Lower leg swelling/edema **A** (Duby et al., 1993; Wipke-Tevis et al., 2000; Shebel, 2002)
- Ache or tiredness in leg **C**
- Trauma/intimal damage **C** (Nicolaidis et al., 2000)
- Maternal venous ulcer **C** (Berard et al., 2002)
- Vigorous exercise **C** (Berard et al., 2002)
- Hypercoagulation **B** (Blomgren et al., 2001; Fink et al., 2002)
- Multiple pregnancy **C** (Berard et al., 2002)

2. Differential diagnosis

- Doppler ankle: brachial index **A** (McGuckin et al., 2002; Bjellerup, 2003; Kazmers et al., 1996; Ghauri et al., 1998)
- Duplex scanning ultrasound **B** (Yosadhara et al., 2003; Labropoulos, Landon, & Jay, 2002)
- Plethysmography **A** (Alexanderhouse Group, 1992; Cordts et al., 1992; Garcia-Rinaldi et al., 2002; Perrin, Hiltbrand, & Bayott, 1999; Ghauri et al., 1998)
- Ambulatory venous flow or refill time **B** (Yosadhara et al., 2003; Heit et al., 2001; Nelzen et al., 1991; Phillips, 1999)
- Transcutaneous PO₂ **A** (Stacey et al., 1990; Alexanderhouse Group, 1992)
- Elevated temperature **C**
- Factor VIII related antigen **C** (Wilkinson, Emery, & Palmer, 1990)

3. Physical exam

- Clinical severity, etiology, anatomy, pathophysiology (CEAP) **A** (Navarro, Konstantinos, & Ribeiro, 2002; Carpentier et al., 2003; Kalodiki & Nicolaides, 2002)
- Edema **A** (Burton, 1993; Duby et al., 1993; Ennis & Meneses, 1995; Lippmann et al., 1994; Shebel, 2002)
- Stasis dermatitis **C** (Alguire et al., 1997; Cherry et al., 1993)
- Hemosiderin **C** (Burton, 1993)
- Lipodermatosclerosis **C** (Kirsner et al., 1993)
- Medial lower leg site **A** (McGuckin et al., 2002; Phillips, 1999)
- Varicosities **C** (Weiss, 1995)
- Measure ulcer size **A** (McGuckin et al., 2002; Kantor & Margolis, 2000; van Rijswijk, 1993)

B. Remove ulcer cause or address ulcer etiology by aiding venous return and providing skin care

1. Patient education **A** (McGuckin et al., 2002; Shebel, 2002; Stacey et al., 2002.)
2. Lower leg elevation **C** (Alexanderhouse Group, 1992; Kerstein et al., 2001)
3. Ambulation or exercise **C** (Alexanderhouse Group, 1992; Kerstein et al., 2001)
 - Use a multidisciplinary team **C** (Lee, et al., 2004)
4. Compression options
 - Elastic compression bandage heals more than inelastic compression **A** (Blair et al., 1988; Cullum, Nelson, & Fletcher, 2002; Callam et al., 1992; Gould 1998; Northeast et al., 1990)
 - Multi-layer (2, 3, or 4 layers) sustained, elastic high-compression bandage **A** (Cullum, Nelson, & Fletcher, 2002; Charles, 1991; Callam et al., 1992; Gould et al., 1998; Meyer et al., 2003; Patel et al., 2004; Vowden et al., 2000; Wilson, et al., 2002)
 - Elastic high-compression stockings to heal venous ulcers **A** (Benigni, et al., 2003; Horakova & Partsch & Horakova, 1994; Korn, et al., 2002; Partsch & Horakova, 1994; Johnson, et al., 1982; Veraart & Neumann, 1996; Morrell et al., 1998).

- Elastic multiple-layer high-compression stockings to heal venous ulcers **A** (Mayberry et al., 1991; Polignano, Guarnera, & Bonadeo, 2004; Samson & Showalter, 1996; Samson, 1993).
- Duke Boot or Unna Boot + elastic compression **A** (Arnold & Stanly, 1994; Burton, 1993; Lyon et al., 1998; Eriksson, 1986; Eriksson et al., 1984; Lippmann et al., 1994).
- Gradient compression better than uniform compression **C** (Sigel et al., 1975)
- Short stretch bandage **A** (Duby et al., 1993; Charles, 1991; Gould et al., 1998; Charles, 2002).
- Unna boot zinc paste impregnated bandage **A** (Kitka et al., 1988; Rubin et al., 1990; Sikes, 1985; DePalma et al., 1999).
- Intermittent pneumatic compression **A** (Pekanmaki et al., 1991; Smith et al., 1990; Mani, Vowden, & Nelson, 2001).
- Non-elastic compression with Circaid **B** (Spence & Cahall, 1996; Villavicencio 1994)
- Sequential-gradient pneumatic compression **C** (Smith et al., 1990)

5. Manage peri-wound skin

- Moisturize **C**
- Protect **C**
- Manage peri-ulcer inflammation, edema, and circulation **B** (Myers, Rightor, & Cherry, 1972; Mayrovitz & Larsen, 1994; Wilson et al., 1991)
- Manage peri-wound skin infection **C**

C. Local Wound Care

1. Cleanse wound with safe cleanser, 8-15 psi **C**
2. Debride necrotic tissue
 - Sharp **C** (Donati et al., 1994)
 - Enzymatic **B** (Bergemann et al., 1999; Romanelli, 1997)
 - Autolytic **A** (Romanelli, 1997; Mulder et al., 1993)
 - Mechanical **C** (Donati et al., 1994)
3. Fill deep wounds (**C**) (Beitz & van Rijswijk, 1999)
4. Manage excess exudate
 - Alginate **A** (Armstrong & Ruckley, 1997; Bergemann et al., 1999; Ingram, Wright, & Ingoldby, 1998; Lyon et al., 1998; Sayag, Meaume, & Bohbot, 1996)
 - Hydrofiber **A** (Armstrong & Ruckley, 1997; Harding et al., 2001; Quintinal, 1999)
 - Foam dressings **C** (Pessenhoffer & Stangl, 1989; Samson, 1993)
 - Composite dressing **AB** (Daniels et al., 2002; Jones, 2003; Vanscheidt, Sibbald, & Eager, 2004)
5. Maintain moist wound environment for healing or venous ulcer (VU) pain management
 - Hydrocolloid **A** (Arnold & Stanley, 1994; Bergemann et al., 1999; Charles, 1991; Charles, 2002; Cordts et al., 1992;

Eriksson, 1986; Friedman & Su, 1984; Kerstein et al., 2001; Koksai & Bozkurt, 2003)

- Hydrogel **B** (Romanelli, 1997)
- Film dressings **B** (Davis, McCulloch, & Neal, 1992)

6. Antimicrobial wound care if no healing is seen in 30 days

- Limit systemic antibiotics to known, identified pathogens **C** (Centers for Disease Control and Prevention [CDC])
- Iodine-containing dressings **A** (Hilstrom, 1888; Holloway et al., 1989; Hansson, et al., 1998)
- Silver-containing dressing **C** (Sibbald et al., 2001)

7. Biologic dressings if no healing is seen in 30 days

- Collagen/collagen combinations **C** (Vin, Teot, & Meaume, 2002)
- Hyaluronic acid or other matrix molecular dressings **C** (Ortonne, 1996)

8. Surgical options to cover wound if no healing is seen in 30 days

- Skin replacement
 - Split-thickness or cultured autografts **B** (Turczynski & Tarpila, 1999; Puonti & Asko-Seljavaara, 1998)
 - Pinch grafts **B** (Christiansen, Ek, & Tegner, 1997; Oein, Hansen, & Hakansson, 1998)
 - Cultured epidermal autografts **C**
 - Allografts **C** (Mosti, et al., 2002; Bolivar-Flores & Kuir-Harcuch, 1999; Lindgren, Marcusson, & Toftgard., 1998)
 - Bioengineered skin **B** (Falanga et al., 1998; Kirsner et al., 1993; Brem et al., 2001; Brassard, 2002)

D. Other modalities to apply if conservative therapy does not work in 30 days

1. Biophysical modalities

- Electrical stimulation **A** (Feedar, Kloth, & Gentzkow, 1991; Houghton et al., 2003; Kloth & Feedar, 1988)
- Vacuum (Negative Pressure) **B** (Evans & Land, 2002; Argenta & Morykwas, 1997; Morykwas et al., 1997)
- Warming **C** (Robinson & Santilli, 1998; Santill et al., 1999)
- Electromagnetic/radiofrequency (RF) stimulation **A** (Kenkre et al., 1996; Stiller et al., 1992; Jeran et al., 1990; Todd et al., 1991)
- Laser **C** (Flemming & Cullum, "Laser therapy," 2002)
- Infrared (IR) stimulation (e.g. monochromatic) **C**
- Hyperbaric oxygen **C** (Hammarlund & Sundberg, 1994; Fischer, 1975)
- Ultrasound stimulation **B** (Flemming & Cullum, "Therapeutic ultrasound," 2002; Lundberg et al., 2000; Callam et al., 1987)
- Whirlpool **C** (McCulloch & Boyd, 1992)

2. Pharmaceutical modalities

- Defibrotide **C** (Jull, Waters, & Arroll, 2002)
- Platelet derived growth factor **C** (Wieman, 2003)
- Trental (pentoxifylline) **A** (Falanga et al., 1998; Jull, Waters, & Arroll, 2002)

- Stanozolol **C** (Stacey et al., 1990)
 - Acetylsalicylic acid/aspirin **C** (Layton et al., 1994)
 - Solcoseryl (topical + systemic) **C** (Biland et al., 1985)
3. Vein closure
- Laser coagulation **C**
 - Sclerotherapy **C**
4. Corrective vascular surgery
- Subfascial endoscopic perforating vein surgery with ligation and stripping (SEPS) **A** (Barwell et al., 2004; TenBrook et al., 2004; Tawes et al., 2003)
 - Superficial vein surgery **A** (Barwell et al., 2004; Bello et al., 1999; Stacey, 2001)
 - Valve repair or reconstruction **B** (Perrin, Hiltbrand, & Bayott, 1999; Raju & Fredericks, 1988; Jessup & Lane, 1988)
 - Transplant or graft valve **C** (Garcia-Rinaldi et al., 2002)
- E. Local wound care (under C above) until healed **A** (Kerstein, 1996; Mayberry et al., 1991; McGuckin et al., 2002)
- F. Compression, elevation, ambulation post healing to prevent recurrence **A** (Alexanderhouse Group, 1992; Kerstein, 1996; Mayberry et al., 1991; Veraart & Neumann, 1996; McGuckin et al., 2002; Nelson, Bell-Syer, & Cullum, 2003; Samson & Showalter, 1996; Stacey et al., 2002).

Definitions:

Strength of Evidence Ratings

- A. Results of two or more randomized controlled trials (RCTs) in humans provide support (or for diagnostics or risk analysis: cohort (CO) studies)
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- C. This rating requires one or more of the following:
1. Results of one controlled trial (e.g. RCT or CCT or HCT)
 2. Results of at least two case series (CS) or descriptive studies or a cohort study in humans
 3. Expert opinion (EO)

CLINICAL ALGORITHM(S)

The original guideline document contains the "Annotated Venous Ulcer Algorithm."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is identified and graded (see the "Major Recommendations" field). Appendix 1 of the original guideline document lists the references and summarizes the evidence supporting each item in the algorithm.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate venous ulcer care leads to decreased healing times and increased healing rates and improves patient quality of life.

POTENTIAL HARMS

Side effects of treatments and medications

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The Annotated Venous Ulcer Algorithm is not a comprehensive literature review. Rather it is a compendium of objectively rated best currently available evidence that the Task Force assembled supporting venous ulcer care identified in the combined venous ulcer algorithms summarized from the literature. The Task Force plans to update the literature search annually. The Annotated Venous Ulcer Algorithm is intended for use as a framework for identifying elements of venous ulcer care supported by the best currently available evidence and for highlighting gaps in knowledge supporting venous ulcer clinical practice which represent opportunities for further research.

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

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Association for the Advancement of Wound Care (AAWC). Summary algorithm for venous ulcer care with annotations of available evidence. Malvern (PA): Association for the Advancement of Wound Care (AAWC); 2005. 25 p. [147 references]

ADAPTATION

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

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

Association for the Advancement of Wound Care - Private Nonprofit Organization

SOURCE(S) OF FUNDING

Association for the Advancement of Wound Care

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Some members of this task force have conducted industry-supported research on venous ulcers with various product categories listed in the algorithm.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Association for the Advancement of Wound Care Web site](#).

Print copies: Available from the Association for the Advancement of Wound Care, 83 General Warren Blvd., Suite 100, Malvern, PA 19355

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 29, 2005. The information was verified by the guideline developer on August 15, 2005.

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