Guideline Summary NGC-8077

Guideline Title

Management of chronic venous leg ulcers. A national clinical guideline.

Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of chronic venous leg ulcers. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2010 Aug. 44 p. (SIGN publication; no. 120). [86 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: The care of patients with chronic leg ulcer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1998 Jul. 21 p. (SIGN publication; no. 26). [72 references]

The guideline will be considered for review in three years. Any updates to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Scope

Disease/Condition(s)

Chronic venous leg ulcers

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Dermatology

Family Practice

Internal Medicine

Nursing

Pharmacology

Physical Medicine and Rehabilitation

Plastic Surgery

Podiatry

Rheumatology

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Patients

Pharmacists

Physical Therapists

Physician Assistants

Physicians

Podiatrists

Guideline Objective(s)

To provide evidence based recommendations on the management of venous leg ulcers and examine the assessment, treatment and the prevention of their recurrence

Target Population

Patients with chronic venous leg ulcers

Note: The guideline does not cover detailed management of patients with chronic leg ulcer in the specialist fields of diabetes, vascular surgery or rheumatoid disease, although indications for referral are considered.

Interventions and Practices Considered

Assessment

1. Assessment of the patient for peripheral arterial disease, rheumatoid arthritis and systemic vasculitis, and diabetes mellitus
2. Measurement of ankle brachial pressure ratio index (ABPI) by Doppler
3. Measurement of ulcer surface area over time
4. Ulcer biopsy
5. Bacteriological swabs if evidence of infection
6. Dermatitis/eczema patch testing
7. Specialist referral as indicated

Management/Treatment

1. Sharp debridement (with local anesthetic cream to reduce pain)
2. Simple non-adherent dressings
3. High compression multicomponent bandaging
4. Antibiotics if evidence of clinical infection
5. Pentoxifylline
6. Recurrence prevention
   - Below knee graduated compression hosiery
   - Superficial venous surgery
7. Community treatment at specialist leg ulcer clinics

Major Outcomes Considered

- Sensitivity and reliability of diagnostic instruments for assessing etiology of ulcers
- Venous insufficiency
- Healing rate
- Infection rate
- Ulcer pain
- Ulcer recurrence rates

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review

The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer. Databases searched include Medline, Embase, CINAHL, and the Cochrane Library. The year

range covered was 1997-2008. The main searches were supplemented by material identified by individual members of the development group. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

Patient Search

At the start of the guideline development process, a SIGN Information Officer conducted a literature search for qualitative and quantitative studies that addressed patient issues of relevance to the management and prevention of venous leg ulcers. Databases searched include Medline, Embase, CINAHL and PsycINFO, and the results were summarised and presented to the guideline development group. A copy of the Medline version of the patient search strategy is available on the SIGN website.

Number of Source Documents

Not stated

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

1++ - High quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+ - Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1- - Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++ - High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ - Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2- - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 - Non-analytic studies, e.g., case reports, case series

4 - Expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. The Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgement. The extent to which a study meets a particular criterion—e.g., an acceptable level of loss to follow up—and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimize any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN Executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgement is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgement on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgement

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, the Scottish Intercollegiate Guidelines Network (SIGN) has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of studies
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources required by the National Health Service [NHS] in Scotland to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

The group are finally asked to summarise its view on all of these issues, both the quality of the evidence and its potential impact, before making a graded recommendation. This summary should be succinct, and taken together with its views of the level of evidence represent the first draft of the text that will appear in the guideline immediately before a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review, or randomized controlled trial (RCT) rated as 1++, and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Cost Analysis

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

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Description of Method of Guideline Validation

Public Consultation

The draft guideline was available on the Scottish Intercollegiate Guidelines Network (SIGN) website for a month in September 2009 to allow all interested parties to comment.

Specialists Reviews

This guideline was also reviewed in draft form by independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The guideline group addresses every comment made by an external reviewer, and must justify any disagreement with the reviewers' comments. (See Chapter 10 of the original guideline document for a listing of the independent expert reviewers.)

SIGN Editorial Group

As a final quality control check, the guideline is reviewed by an editorial group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimized.

Recommendations

Major Recommendations

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The strength of recommendation grading (**A**-**C**) and level of evidence (**1++, 1+, 1-, 2++, 2+, 2-, 3, 4**) are defined at the end of the "Major Recommendations" field.

Key Recommendations

The following recommendations were highlighted by the guideline development group as the key clinical recommendations that should be prioritized for implementation. The grade of recommendation relates to the strength of the supporting evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

Assessment

D - Leg ulcer patients with dermatitis/eczema should be considered for patch-testing using a leg ulcer series.

Treatment

A - Simple non-adherent dressings are recommended in the management of venous leg ulcers.

A - High compression multicomponent bandaging should be routinely used for the treatment of venous leg ulcers.

A - Use of pentoxifylline *(400 mg three times daily for up to six months)* to improve healing should be considered in patients with venous leg ulcers.

Preventing Ulcer Recurrence

A - Below-knee graduated compression hosiery is recommended to prevent recurrence of venous leg ulcer in patients where leg ulcer healing has been achieved.

Provision of Care

B - Specialist leg ulcer clinics are recommended as the optimal service for community treatment of venous leg ulcer.

Assessment

Assessing the Leg

Ankle Brachial Pressure Index (ABPI)

D - Measurement of ankle brachial pressure index should be performed by appropriately trained practitioners who should endeavour to maintain their skills.

D - Compression therapy may be safely used in leg ulcer patients with ABPI ≥0.8.

D - Patients with an ABPI of <0.8 should be referred for a specialist vascular assessment.

Assessing the Ulcer

Clinical Assessment

C - The surface area of the ulcer should be measured serially over time.

Biopsy

D - Patients with a non-healing or atypical leg ulcer should be referred for consideration of biopsy.

Bacteriological Swabs

C - Bacteriological swabs should only be taken where there is clinical evidence of infection.

Dermatitis/Eczema

D - Leg ulcer patients with dermatitis/eczema should be considered for patch-testing using a leg ulcer series.

Criteria for Specialist Referral

D - Patients who have the following features should be referred to the appropriate specialist at an early stage of management:

- Suspicion of malignancy

- Suspicion of malignancy
- Peripheral arterial disease (ABPI <0.8)
- Diabetes mellitus
- Rheumatoid arthritis/vasculitis
- Atypical distribution of ulcers
- Suspected contact dermatitis or dermatitis resistant to topical steroids
- Non-healing ulcer

Treatment

Cleansing and Debridement

Sharp Debridement

D - Sharp debridement should only be carried out by appropriately trained practitioners.

C - Local anesthetic cream (EMLA®) should be used to reduce the pain of sharp debridement in patients with venous leg ulcer.

Dressings

A - Simple non-adherent dressings are recommended in the management of venous leg ulcers.

Topical Antimicrobials and Antiseptics

Manuka Honey

B - Honey dressings are not recommended in the routine treatment of patients with venous leg ulcers.

Silver

A - Silver dressings are not recommended in the routine treatment of patients with venous leg ulcers.

Compression Therapy

A - High compression multicomponent bandaging should be routinely used for the treatment of venous leg ulcers.

Systemic Therapy

Antibiotics

C - In patients with chronic venous leg ulcers, systemic antibiotics should not be used unless there is evidence of clinical infection.

Pharmacological Agents to Increase Healing Rates

A - Use of pentoxifylline *(400 mg three times daily for up to six months)* to improve healing should be considered in patients with venous leg ulcers.

Preventing Ulcer Recurrence

Graduated Compression for Healed Venous Ulceration

A - Below-knee graduated compression hosiery is recommended to prevent recurrence of venous leg ulcer in patients where leg ulcer healing has been achieved.

Venous Surgery

B - Patients with chronic venous leg ulcer and superficial venous reflux should be considered for superficial venous surgery to prevent recurrence.

Provision of Care

Specialist Leg Ulcer Clinics

B - Specialist leg ulcer clinics are recommended as the optimal service for community treatment of venous leg ulcer.

Definitions:

Levels of Evidence

1++ - High quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+ - Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

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D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Clinical Algorithm(s)

None provided

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate assessment and treatment of venous leg ulcers

Potential Harms

Complications associated with treatment

Contraindications

Contraindications

Medications with potential interactions with pentoxifylline include non-steroidal antiinflammatories (NSAIDS). Details of interactions and contraindications can be found in the British National Formulary. The use of pentoxifylline in the treatment of venous leg ulcers is an unlicensed indication.

Qualifying Statements

Qualifying Statements

- This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.
- Every care is taken to ensure that this publication is correct in every detail at the time of publication. However, in the event of errors or omissions corrections will be published in the web version of this document, which is the definitive version at all times. This version can be found on our web site www.sign.ac.uk.

Prescribing of Licensed Medications Outwith Their Marketing Authorisation

Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (product licence). This is known as "off label" use. It is not unusual for medicines to be prescribed outwith their product licence and this can be necessary for a variety of reasons.

Generally the unlicensed use of medicines becomes necessary if the clinical need cannot be met by licensed medicines; such use should be supported by appropriate evidence and experience.

Medicines may be prescribed outwith their product licence in the following circumstances:

- For an indication not specified within the marketing authorisation

- For administration via a different route
- For administration of a different dose

Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescribers' professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

Any practitioner following a Scottish Intercollegiate Guidelines Network (SIGN) recommendation and prescribing a licensed medicine outwith the product licence needs to be aware that they are responsible for this decision, and in the event of adverse outcomes, may be required to justify the actions that they have taken. Prior to prescribing, the licensing status of a medication should be checked in the current version of the British National Formulary (BNF).

Implementation of the Guideline

Description of Implementation Strategy

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices.

Resource implications of key recommendations and key points to audit are available in section 8 of the original guideline document.

Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Quick Reference Guides/Physician Guides

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

Identifying Information and Availability

Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of chronic venous leg ulcers. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2010 Aug. 44 p. (SIGN publication; no. 120). [86 references]

Adaptation

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

Date Released

1998 Jul (revised 2010 Aug)

Guideline Developer(s)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

Source(s) of Funding

Scottish Executive Health Department

Guideline Committee

Guideline Development Group

Composition of Group That Authored the Guideline

Guideline Development Group: Ms Julie Brittenden (*Chair*), Consultant Vascular Surgeon, Aberdeen Royal Infirmary/Reader, University of Aberdeen; Mr Paul Baker, Specialist Registrar in Plastic Surgery, Glasgow Royal Infirmary; Dr Jane Bray, Specialist Registrar in Public Health, NHS Lothian; Ms Alison Coull, Lecturer and Lead for Skin and Wound Care, University of Stirling; Dr Barry Gibson-Smith, General Practitioner, Anniesland Medical Practice, Glasgow; Dr Farida Hamza-Mohamed, Program Manager, SIGN; Mr Kenneth MacDonald, Patient Representative, Stirling; Mr Alan Milne,

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Financial Disclosures/Conflicts of Interest

All members of the guideline development group made declarations of interest and further details of these are available on request from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

Guideline Status

This is the current release of the guideline.

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The guideline will be considered for review in three years. Any updates to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Guideline Availability

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Availability of Companion Documents

The following are available:

- Quick reference guide: The care of chronic leg ulcers. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 201 August. 2 p. Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.
- Search narrative: The care of chronic leg ulcers. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 201 August. 7 p. Available from the SIGN Web site.
- Summary of the recommendations: The care of chronic leg ulcers. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 201 August. 1 p. Available from the SIGN Web site.

In addition, an example leg ulcer assessment sheet is available as Annex 2 in the original guideline document.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on February 6, 2002. The information was verified by the guideline developer as of April 9, 2002. This summary was updated by ECRI Institute on November 15, 2010.

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