Complete Summary

GUIDELINE TITLE

Diagnosis and management of peripheral arterial disease. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of peripheral arterial disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2006 Oct. 37 p. (SIGN publication; no. 89). [129 references]

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Peripheral arterial disease (PAD)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention

Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Occupational Therapists
Patients
Physical Therapists
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide recommendations based on evidence for best practice in the management of patients with lower limb peripheral arterial disease (PAD)

TARGET POPULATION

Patients with symptomatic peripheral arterial disease (PAD) in the form of intermittent claudication

This guideline is not intended for use in the following populations:

- Patients without evidence of existing vascular disease
- Patients with critical limb ischaemia—a severe manifestation of PAD characterized by chronic ischaemic rest pain, ulcers, or gangrene

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Management/Prevention

1. Smoking cessation
2. Cholesterol lowering (statin therapy)
3. Glycaemic control
4. Weight reduction
5. Blood pressure control
6. Antiplatelet therapy

Diagnosis

1. Investigations in primary care

2. Referral to secondary care and investigations
3. Non-invasive imaging (computed tomography angiography)

Treatment

1. Treatment with licensed drugs, including cilostazol and naftidrofuryl
2. Treatment with statins
3. Exercise therapy
4. Referral to vascular specialist and vascular interventions under limited circumstances with consideration of the TransAtlantic Inter-society guidelines

Note: The following interventions were considered but not recommended:

- Digital subtraction arteriography as the primary imaging modality for patients with peripheral arterial disease
- Oxpentifylline for the treatment of intermittent claudication
- Inositol nicotinate for the treatment of intermittent claudication
- The use of oral prostaglandin therapy in patients with intermittent claudication

MAJOR OUTCOMES CONSIDERED

- Level of cardiovascular risk
- Incidence of cardiovascular and cerebrovascular events
- Mortality
- Sensitivity and specificity of diagnostic analysis
- Mean walking distance
- Quality of life
- Exercise tolerance

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

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 1994 to 2004. Internet searches were carried out on various websites including the New Zealand Guidelines Programme, NELH Guidelines Finder, and the US National Guidelines Clearinghouse. The Medline version of the main search strategies can be found on the SIGN Website, in the section covering supplementary guideline material. The main searches were supplemented by material identified by individual members of the development group. All selected papers were evaluated by two members of

the group using standard SIGN methodological checklists before conclusions were considered as evidence.

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 randomised controlled trials (RCTs), or RCTs with a very low risk of bias

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

1-: Meta-analyses, systematic reviews of RCTs, 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

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. 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 judgment. 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 minimise 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 judgment is made on the basis of an (objective) assessment of the design and quality of each study and a

(perhaps more subjective) judgment 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 Judgment

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, SIGN has introduced the concept of considered judgment.

Under the heading of considered judgment, 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
- Generalisability of study findings
- Directness of application to the target population for the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them)
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgment. Once they have considered these issues, the group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive 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 of randomized controlled trials (RCTs), or 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+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

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

National Open Meeting

The national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development. The national open meeting for this guideline was held on 11 October 2004 and was attended by representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

Peer Review

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the

guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to a lay reviewer in order to obtain comments from the patient's perspective. The comments received from peer reviewers and others are carefully tabulated and discussed with the chairman and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

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 grades of recommendations (A–D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Cardiovascular Risk Reduction

Smoking Cessation

D - Patients with peripheral arterial disease should be actively discouraged from smoking.

Cholesterol Lowering

A - Lipid lowering therapy with a statin is recommended for patients with peripheral arterial disease and total cholesterol level >3.5 mmol/L.

Glycaemic Control

B - Optimal glycaemic control is recommended for patients with peripheral arterial disease and diabetes in order to reduce the incidence of cardiovascular events.

Weight Reduction

D - Obese patients with peripheral arterial disease should be treated to reduce their weight.

Blood Pressure Control

A - Hypertensive patients with peripheral arterial disease should be treated to reduce their blood pressure.

Antiplatelet Therapy

A - Antiplatelet therapy is recommended for patients with symptomatic peripheral arterial disease.

Referral, Diagnosis, and Investigation

Investigations in Secondary Care

Digital Subtraction Arteriography

D - Digital subtraction arteriography is not recommended as the primary imaging modality for patients with peripheral arterial disease.

Computed Tomography Angiography

A - Non-invasive imaging modalities should be employed in the first instance for patients with intermittent claudication in whom intervention is being considered.

Treatment of Symptoms

Licensed Drug Therapy for Peripheral Arterial Disease

Cilostazol

A - Patients with intermittent claudication, in particular over a short distance, should be considered for treatment with cilostazol.

A - If cilostazol is ineffective after three months, or if adverse effects prevent compliance with therapy, the drug should be stopped.

Naftidrofuryl

A - Patients with intermittent claudication and who have a poor quality of life may be considered for treatment with naftidrofuryl.

Oxpentifylline

A - Oxpentifylline is not recommended for the treatment of intermittent claudication.

Inositol Nicotinate

B - Inositol nicotinate is not recommended for the treatment of intermittent claudication.

Unlicensed Research Drugs and Procedures

Statins

A - Statins should be given for risk factor management in patients with intermittent claudication and total cholesterol level >3.5 mmol/L.

Prostaglandins

A - The use of oral prostaglandin therapy in patients with intermittent claudication is not recommended.

Exercise Therapy

A - Patients with intermittent claudication should be encouraged to exercise.

Vascular Intervention

D - Endovascular and surgical intervention are not recommended for the majority of patients with intermittent claudication.

D - For those with severe disability or deteriorating symptoms, referral to a vascular specialist is recommended.

D - The TransAtlantic Inter-society consensus guidelines should be used when advising patients about possible interventions.

Definitions:

Levels of Evidence

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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+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

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

- Reduced cardiovascular risk
- Accurate diagnosis of peripheral arterial disease (PAD)
- Reduced morbidity and mortality associated with PAD
- Improved quality of life

POTENTIAL HARMS

Adverse effects of drug therapy

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, however, advised 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service Board and is an essential part of clinical governance. It is acknowledged that every Board cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Key points for implementation and audit and resource implications are identified in the original guideline document.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
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

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of peripheral arterial disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2006 Oct. 37 p. (SIGN publication; no. 89). [129 references]

ADAPTATION

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

DATE RELEASED

2006 Oct

GUIDELINE DEVELOPER(S)

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

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Professor Gerry Fowkes (*Chair*) Professor of Epidemiology, Public Health Sciences, University of Edinburgh; Ms Margaret Armitage, Vascular Liaison Nurse, Greater Glasgow Primary Care Trust; Professor Jill Belch, Professor of Vascular Medicine, Ninewells Hospital and Medical School, Dundee; Mr Graham Bell, Lay representative, Penicuik; Ms Julie Brittenden, Senior Lecturer and Consultant Vascular Surgeon, Aberdeen Royal Infirmary; Dr Henry Doig, Lay representative, Glasgow; Dr Ian Gillespie, Vascular (Interventional) Radiologist, Royal Infirmary of Edinburgh; Ms Margaret Greene, Vascular Technologist, Southern General Hospital, Glasgow; Ms Alison Howd, Consultant Vascular Surgeon, Queen Margaret Hospital, Dunfermline; Dr Gordon Isbister, General Practitioner, Beith; Dr Moray Nairn, Programme Manager, SIGN Executive; Dr Jackie Price, Clinical Lecturer, Public Health Sciences, University of Edinburgh; Ms May Roseburgh, Clinical Nurse Specialist, Royal Infirmary of Edinburgh; Ms Mairi Ross, Senior Vascular Physiotherapist, Raigmore Hospital, Inverness; Ms Helen Scott, Superintendent Physiotherapist WESTMAR, Southern General Hospital, Glasgow; Ms Valerie Sinclair, Vascular Nurse, Stirling Royal Infirmary; Ms Christine Smith, Vascular Liaison Nurse, Raigmore Hospital, Inverness; Mrs Ailsa Stein Information Officer, SIGN Executive; Dr Rebecca Walton, Specialist Registrar in Public Health, Lothian NHS Board; Dr Olivia Wu, Health Economist, Reproductive and Maternal Medicine, Division of Developmental Medicine, University of Glasgow

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Diagnosis and management of peripheral arterial disease, Scottish Intercollegiate Guidelines Network, 2006. 2 p. Available in

Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- Key points for audit and a recommended method for measurement of ankle brachial pressure index can be found in the original guideline document.

PATIENT RESOURCES

The following are available:

- Information for discussion with patients and carers. In: Diagnosis and management of peripheral arterial disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2006 Oct. 37 p. (SIGN publication; no. 89). Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- Advice to patients – peripheral arterial disease. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2 p. Electronic copies: Available in Portable Document Format (PDF) from the SIGN Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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