HAUTE AUTORITÉ DE SANTÉ

CLINICAL PRACTICE GUIDELINES

Managing venous leg ulcers (excluding dressings)

June 2006

The full report (in French) on which these guidelines are based is available from www.has-sante.fr

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1. Introduction

These guidelines concern the management of venous ulcers or ulcers of predominantly venous origin. They address the following questions[1]:

- how to define venous ulcers or ulcers of predominantly venous origin;
- epidemiology and burden of the disease;
- clinical and paraclinical signs by which venous ulcers or ulcers of predominantly venous origin can be diagnosed;
- treating the causes of ulcers of predominantly venous origin (compression, surgery, non-surgical techniques for removing veins, drug treatments);
- precautions to be taken in cases of associated PAOD[2];
- concomitant measures (physiotherapy, changes in lifestyle).

These guidelines do not address:

- mixed ulcers with a predominantly arterial component (ABI[3] < 0.7);
- topical treatments;
- managing venous insufficiency in a non-ulcer context;
- medical spa treatment;
- congenital venous malformations;
- management in occupational medicine.

2. Definition of venous ulcers

A pure venous ulcer was defined, by professional agreement, as a leg lesion:

- which has not healed within a month (except in cases of recurrent ulcers when a diagnosis can be made in less than a month);
- with a pathophysiology due to ambulatory venous hypertension, which may be secondary to:
  - reflux in superficial, perforating or deep veins,
  - and/or obstruction of the deep veins,
  - and/or calf muscle pump dysfunction;
- where there is no arterial involvement.

Mixed ulcers of predominantly venous origin were defined, by professional agreement, as ulcers with a predominantly venous mechanism, accompanied by moderate PAOD not solely accountable for the ulcer.

[1] The detailed analysis of published medical and health economics data concerned can be found in the full report (in French) (www.has-sante.fr)
[2] PAOD: peripheral arterial occlusive disease
[3] ABI: Ankle Brachial Index

3. Epidemiology and disease management

The prevalence of ulcers of predominantly venous origin in France has not been assessed. Foreign prevalence studies have used a variety of definitions of venous ulcers, reported rates ranging from 0.045% to 0.63%. Prevalence increases with age (0.1 % for patients under 60 years of age; 0.4% for patients from 60 to 70 years, and over 2% for patients aged above 80 years). The disease is more common in women (M/F sex ratio: 1/1.6) even if this predominance decreases in age-adjusted studies.

The economic burden of the disease is substantial in all Western countries but has not been assessed in France.

4. Diagnosis

4.1 Signs that ulcers are of venous origin

- **Previous history of at-risk patients**

The previous history of all patients with leg ulcers should be assessed for signs that the ulcers are partially or exclusively of venous origin (professional agreement).

Previous history

- a personal or family history of varices, whether treated or not
- a history of deep vein thrombosis and/or superficial venous thrombosis and/or pulmonary embolism. This may be a personal or family history which has been recorded or is simply suspected
- a personal history of significant lower limb trauma or of lower limb surgery
- previous venous ulcers

- **Clinical signs**

All patients with leg ulcers should be assessed for clinical signs which indicate that the ulcers are partially or exclusively of venous origin (grade C).

Clinical signs

- superficial or exudative ulcers
- location in the perimalleolar region extending to the lower third of the calf
- associated signs (described in detail in the full report):
  - ankle oedema
  - telangiectasia
  - reticular veins
  - corona phlebectatica, varicose veins
  - eczema
  - pigmentation
  - lipodermatosclerosis, atrophie blanche
  - limited range of motion in the ankle joint (professional agreement)
  - scars from any previous venous ulcers

The findings of the physical examination are not sensitive or specific enough to diagnose the cause of the ulcers (venous ulcers, mixed ulcers of predominantly venous or arterial origin, arterial ulcers) (grade C). Additional investigations (ABI, Doppler ultrasound: see below) are needed.

4.2 Investigations to determine whether there is concomitant PAOD

These investigations are necessary because:

– concomitant PAOD is likely to explain or aggravate the ulcer and requires specific management,[4]

– concomitant PAOD requires appropriate compression (professional agreement) (see Section 5.4).

- **What to look for**

All patients with leg ulcers should be assessed for signs indicating whether the ulcers are partially or solely of arterial origin (professional agreement):

- cardiovascular risk factors (hypertension, diabetes, smoking, hypercholesterolaemia, age > 60 years);

[4] See “Prise en charge de l’artériopathie chronique oblitérante athéroscléreuse des membres inférieurs (Indications médicamenteuses, de revascularisation et de rééducation“ (Management of peripheral arterial occlusive disease in the lower extremities (indications for drug treatment, revascularisation and rehabilitation)), HAS, 2006.

- atheroma in other locations;
- clinical signs and symptoms of PAOD, especially the absence of palpable peripheral pulses.

- **Ankle-brachial index (ABI)**

ABI (ankle-brachial index) is the ratio of ankle to brachial systolic blood pressure. Methods of measuring ABI and the limitations inherent in making and interpreting these measurements are detailed elsewhere.[5]

- **Indications**

ABI is a straightforward clinical measurement and should be measured in all patients with leg ulcers:

- to look for associated PAOD which could explain or aggravate the ulcer (grade B);
- to adjust compression (professional agreement) (see Section 5.4).

- **Methods of measuring ABI**

ABI can be measured during the examination of the patient if the physician has a continuous wave Doppler device, or during a venous Doppler ultrasound examination. There are several ways of measuring ABI[5].

Recommendations on how to measure ABI

- Use a blood pressure cuff and a continuous wave Doppler probe (8 to 10 MHz) to record brachial artery pressure
- Use the same blood pressure cuff and the same probe to record ankle pressures
- Record brachial artery pressure and ankle pressures within the shortest possible interval
- Measure ABI at the anterior and posterior tibial (and/or dorsalis pedis) arteries. A more distal measurement may be necessary depending on the size of the ulcer.

The ratio of the lowest reading for the leg with the ulcer to the highest pressure measured in the upper limb should be used as ABI governs the level of compression selected, (professional agreement).

[5] Technical assessment report *: L' échographie-Doppler dans l'artériopathie oblitérante des membres inférieurs* (Doppler ultrasound in peripheral arterial occlusive disease) ANAES, 2002.

- **Threshold values**

The working group proposed the following threshold values:

- pure venous ulcers: ABI between 0.9 and 1.3;
- mixed ulcers of predominantly venous origin: ABI between 0.7 and 0.9.
- Arterial stiffening due to medial calcification, particularly in diabetic or elderly patients, is the main limitation in interpreting ABI values. There is a risk of underestimating or failing to recognise PAOD. ABI should therefore be interpreted in the light of the clinical examination findings, particularly palpation of the pulses.

Any interpretation of ABI values made in these guidelines should take this limitation and the results of the Doppler ultrasound into account, when indicated.

4.3 Additional investigations

Venous Doppler ultrasound should be carried out when managing all patients with leg ulcers as it provides information useful for treatment:

- it confirms the venous origin of the ulcer (grade C);
- it specifies the mechanism (reflux and/or obstruction) (grade C);
- it specifies the location of reflux (superficial and/or deep and/or perforating veins) and their anatomical level (grade C).

Venous Doppler ultrasound is part of the pre-operative assessment (vein mapping) before superficial vein surgery (professional agreement). It is also useful for monitoring the changes in deep venous refluxes and perforating veins after superficial venous surgery (grade C).

A Doppler ultrasound of the arteries should be carried out together with a venous Doppler ultrasound if (professional agreement):

- palpable peripheral pulses are absent;
- there are clinical signs and symptoms of PAOD;
- ABI < 0.9 or > 1.3 (arterial stiffening).

In the rare cases when deep venous surgery is an option, phlebography, plethysmography and measurement of ambulatory venous pressure can be useful (see Section 5.2).

5. Treatment

5.1 Compression[6]

Definitions (professional agreement)

- **Low elasticity bandages** with short, less than 20%, stretch. These bandages exert low pressure when patients are resting but increase pressure in response to muscle activity. They are comfortable at night.
- **Elastic bandages** with long, more than 20%, stretch. These bandages exert pressure both when patients are resting and during muscle activity, and are uncomfortable at night.
- **Multi-layered bandages** which consist of several similar or different layers of bandage.
- **Elastic compression stockings** (more than one of which can be worn).

High-pressure compression is defined as pressure greater than 30 mmHg exerted at the ankle when the device is applied (professional agreement). It can be obtained by using high-pressure stockings or bandages or by applying layers of low-pressure stockings or bandages. The pressure obtained cannot be measured on patients. The manufacturer's instructions should be followed to obtain, as far as possible, the desired pressure.

- **Indication and level of pressure**

Venous ulcers or ulcers predominantly of venous origin with an ABI between 0.8 and 1.3 should be treated with high-level compression to promote healing (grade B). A pressure between 30 and 40 mmHg at the ankle should be obtained (professional agreement).

- **Available devices**

High-pressure compression can be obtained by using either bandages or stockings. There is no evidence for a difference in efficacy. As there may be a dressing on the ulcer, or as oedema may be present, bandages are often more appropriate at the start of treatment (professional agreement).

[6] In line with the international literature, we use the term compression to cover both support and compression.

If bandages are used, compression should be applied using a multi-layered bandage (grade A). There is no evidence of any difference in efficacy between long-stretch and short-stretch multi-layered bandages.

- **Code of good practice**

The working group emphasised the importance of complying with the following code of good practice (professional agreement).

Code of good practice[7]

- Adjust the compression system on a case by case basis
- Be familiar with the bandages you use in order to obtain the desired compression
- Select compression with compliance in mind as this determines treatment success
- When compliance is unsatisfactory, adapt compression to make it acceptable by the patient. Compression bandages consisting of several layers of lower pressure bands can be used to obtain the maximum tolerated compression (up to 30-40 mmHg)
- Use materials that distribute the pressure evenly, such as patches or protective devices (padding, blocks), to optimise compression
- Compression should be applied either from rising until retiring or 24 hours a day
- Prefer short-stretch bandages applied around the clock to long-stretch bandages which may be uncomfortable at night
- Have the patient or carers check the position of the bandages regularly during the day (educate patients and those caring for them)
- The compression material should be cared for as specified by the manufacturer and changed according to wear and tear. Regularly check the condition of the material and ask for it to be changed when necessary.

[7] A description of how to apply ow to apply a bandage or compression stocking is givenin the appendix (all possible methods are not described).

Specific training should be provided for healthcare professionals (nurses, physiotherapists, physicians) and education for patients and those caring for them in order to obtain optimum compliance and the best possible results (professional agreement).

5.2 Surgery

► Superficial venous surgery (when there is no deep venous reflux)

Superficial venous surgery combined with compression treatment is recommended for patients with open or healed ulcers:

- with superficial reflux according to Doppler ultrasound findings
- without deep venous obstruction or reflux
- and with an ABI > 0.85.

According to the ESCHAR[8] trial, junction disconnection with stripping and varicosity avulsion or junction disconnection alone reduce recurrence at 1 year in these patients (level 1).

The working group considered that an ABI between 0.7 and 0.85 is still a valid indication for surgery (professional agreement) but that the need to preserve veins should be taken into account.

There was no consensus on when to perform surgery. According to some members of the working group, early surgery may be appropriate. According to others, it is necessary to wait until the ulcer has improved or even healed.

Superficial venous surgery is performed on the basis of Doppler ultrasound findings, the mapping of reflux areas, and the individual patient (junction disconnection alone is a straightforward surgical procedure which can be carried out under local anaesthesia, to be considered for elderly subjects in particular) (professional agreement).

Post-surgery compression depends on the procedure that was used (the degree to which stripping is complete), the presence or absence of deep venous insufficiency, and persistence of skin disorders (professional agreement).

► Superficial venous surgery (when deep venous reflux is present

- If the deep reflux is confined to one or more segments, superficial venous surgery is recommended (professional agreement).
- If the deep reflux is axial, it is not possible, according to the current state of knowledge, to specify the role of superficial venous surgery.

[8] Barwell JR, Davies CE, Deacon J, Harvey K, Minor J, Sassano A, *et al.* Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. Lancet 2004;363(9424):1854-9.

► Perforating vein surgery

Surgical treatment of incompetent perforating veins should not be first-line treatment when there is incompetence of both perforating and saphenous veins (grade C). In fact, incompetence in the perforating veins frequently regresses when superficial venous insufficiency is treated.

Surgery on the perforating veins is possible in the rare cases of isolated incompetence of the perforating veins (professional agreement). Endoscopic surgery may be preferable because it has a lower complication rate (grade C).

► Deep venous surgery

The efficacy of deep venous surgery (valvuloplasty, autotransplantation, vein transposition, venous or artificial bypass, endovascular recanalisation with stenting) has been assessed only in case series of patients who have failed to respond to other treatments and not otherwise.

Recommendations on deep venous surgery (professional agreement)

- Never indicated as first-line treatment to heal venous ulcers. The first-line treatment is compression (if the superficial venous system is involved (see Section 5.2.)
- Can be considered, within a multidisciplinary consultation, in the case of ulcers which do not heal or relapse despite compression.
- To be considered only in cases of primary valvular involvement or of post-thrombotic syndromes resulting mainly from subinguinal obstruction
- Additional assessments and the choice of surgical procedure should be discussed in the appropriate specialist department.

5.3 Alternatives to surgery

There are no comparative efficacy trials of alternatives to venous surgery (e.g. ultrasound-guided sclerotherapy (UGS), radiofrequency or laser procedures) in the treatment of venous ulcers (healing or recurrence). Clinical comparisons with conventional surgery are needed.

5.4 Mixed ulcers - Managing PAOD and adjusting compression

Patients with mixed ulcers of predominantly venous origin should be managed like patients with PAOD[9]. In patients with venous insufficiency and PAOD, compression should be adjusted as a high level of compression may aggravate PAOD, particularly severe PAOD (professional agreement).

Adjusting compression for mixed ulcers (if ABI < 0.8 or > 1.3)[a]

- Reduce pressure levels to below 30 mmHg and prefer short-stretch compression which exerts low pressure while patients are resting
- Ensure specialist medical supervision
- Inform patients that compression should be removed if pain worsens
- Make sure patients are able to remove compression without help.

[a] see limitations when measuring ABI in Section 4.2

5.5 Drug treatment

It is possible to use 1,200 or 2,400 mg oral or intravenous pentoxifylline in addition to compression to treat venous ulcers (grade B). Level 2 trials show an increase in healing rates at 6 months.

By extrapolation, the working group considered that pentoxifylline could also be used when compression is not possible. Pentoxifylline has not been granted a marketing authorisation for venous ulcer treatment in France.

There are no grounds for recommending micronised purified flavonoid fraction to treat venous ulcers or ulcers of predominantly venous origin in the legs. Its efficacy in healing or preventing recurrence has not been demonstrated.

5.6 Concomitant measures

In appropriate, the following concomitant measures are recommended in combination with the preceding measures (professional agreement):

[9] "*Prise en charge de l'artériopathie chronique oblitérante athéroscléreuse des membres inférieurs (Indications médicamenteuses, de revascularisation et de rééducation")* (Management of peripheral arterial occlusive disease in the lower extremities (Indications for drug treatment, revascularisation and rehabilitation)), HAS 2006.

Concomitant measures

- Manage **comorbidities** (diabetes, hypertension, osteoarticular disorders, overweight, malnutrition, anaemia, heart failure).
- Bear in mind the patients' **social setting** and, for elderly patients, carry out a standardised **geriatric assessment** in the event of loss of independence.
- Encourage **physical exercise**, overall mobility (especially walking) and mobility of the ankle and foot joints by means of education and rehabilitation. (Physiotherapy can be helpful).
- Perform one or more **skin biopsies** to check for skin cancer if there are suspicious signs or if healing has not occurred after 6 months to 1 year of compliance with treatment.
- Update **antitetanus vaccinations**.
- No specific nutritional supplements are recommended for ulcer healing if there are no nutritional deficiencies.

5.7 Grafts

Pinch grafts or mesh grafts may be considered for treating venous ulcers or mixed ulcers of predominantly venous origin that have been resistant to conventional treatments for more than 6 months or are > 10 cm^2 in size (professional agreement). However, there is a need for randomised controlled trials on their efficacy (including an assessment of pain relief) and health economics trials. So far, only the efficacy of artificial skin grafts has been demonstrated (level 1) but these are currently not available in France.

5.8 Pain

Pain should be systematically investigated and assessed in all patients (professional agreement). Its cause should be investigated (mechanical debridement, unsuitable dressings or compression, eczema or irritation of the skin around the ulcer, oedema, lipodermatosclerosis, infection, concomitant PAOD); the impact of pain should be assessed (depression, isolation) (professional agreement).

Managing pain

- For pain related to local treatment, use an anaesthetic cream and prescribe systemic analgesics.
- If a cause of pain other than local treatment is identified, take measures in line with the cause (change type of dressing, adjust compression, apply topical treatment, administer systemic antibiotics, treat PAOD).
- If pain persists despite treatment, give analgesics increasing the dose stepwise.

5.9 Infection

Recommendations (professional agreement)

- **No routine bacteriological swabs should be taken.**
- **No topical antibiotics should be applied.**

There was no agreement on whether and when a swab should be taken from ulcers because:

- probabilistic systemic antibiotic therapy may be preferable if there are clinical signs of infection;
- interpretation of bacteriological investigations is often difficult because:
  - pathogens are normally present on the surface of all ulcers,
  - several strains are frequently present when the swab is taken, making it difficult to identify the causative organism.

6. Preventing recurrence

Recommendations for preventing reccurrence

- Perform superficial venous surgery if the conditions defined in Section 5.2 are met (grade A).
- When surgery is not indicated or is refused, prescribe long-term compression at the highest tolerable pressure that ensures compliance (> 20 mmHg at the minimum, ideally 30-40 mmHg) (grade B).
- No specific drug treatment is recommended.

Concomitant measures to prevent recurence (professional agreement)

- **Educate** and regularly **follow-up** patients to improve:
  - long-term **compliance** and the **quality of compression**
  - prevent **trauma**
  - treat **wounds** early
  - ensure satisfactory **cleanliness**
  - encourage mobility and **physical exercise**
  - maintain the **mobility of the ankle**
  - ensure, as far as possible, that patients rest with the affected limb higher than their heart (**posture drainage**)
  - indicate which **positions patients should avoid** (sitting with legs hanging down or crossed, standing for long periods).
- Correct **metabolic imbalances** and encourage **weight loss** if patients are overweight.
- Manage patients' **social setting**.
- Correct any problems related to plantar pressure distribution.

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7. Structured management

Outside France there are structured organisations for managing ulcers of predominantly venous origin. Trials assessing these organisations demonstrate both clinical improvement and cost effectiveness resulting from:

- better ongoing training of care-giving personnel;
- easier access to an expert opinion;
- using validated standards;
- developing patient education programmes.

In France, there is a lack of data about the epidemiology of the disease, its economic burden and how to manage it.

Experiments in management methods within structured care networks need to be identified and listed at national level in order to identify the different types of structured management and to establish methods for assessing them.

Annex 1. How to apply compression

The pressure exerted by compression depends on the radius of curvature (it is inversely proportional to the radius), degree of stretch and number of layers.

General principles

- Advise patients to lie down for some time before applying compression (apply in the morning if compression not used at night or after washing if compression used day and night).
- Protect the skin if necessary.
- Use filling materials to restore a circular cross-section to the leg.
- Apply a constant stretch to ensure that the pressure gradient on the circular cross-section of the leg decreases from ankle to knee.
- Recommend a test try to make sure that the compression is suitable for the shape of the patient's leg.

Bandages (short stretch or long stretch)

- Select the length of bandage required to fit the part of the leg to be bandaged, preferably by trying it out first. In most cases, a 4 m x 10 cm bandage should provide effective bandaging up to the flexion crease of the knee. 3 to 5 m bandages are available.
- Protect the skin if necessary (delicate skin, wounds, protection of dressing), for example with a jersey tube.
- Put the filling materials in place (foam, cotton) if necessary (thick dressing, retromalleolar oedema).
- Start applying the bandage at the base of the toes by placing an oblique band over the top of the foot followed by turns around the metatarsus; this will hold the bandage firmly in place.
- Wind the bandage over the foot and move gradually up to the ankle by overlapping each preceding turn by 1/2 to 2/3 (making adjustments to obtain the desired pressure according to the material used).
- Apply an even stretch (graduated bandages may make it easier to obtain an even stretch with long-stretch bandages).
- Position the heel at the middle 1/3 of the width of the bandage to hold it firmly.
- Continue winding the bandage around the leg either in circular, oblique, or semi-oblique movements (use your customary method).
- Stop bandaging 5 cm below the flexion crease of the knee and never overlap the final turns if the bandage is too long (if it is too long, start bandaging again, increase the amount of overlap and decrease the stretch).
- Recommend that patients choose the right shoe size (generally a size above their usual size).

Stockings

- Recommend using gloves.
- Arrange the retromalleolar padding if retromalleolar oedema is present.
- Start by putting the stocking onto the foot until the heel and back of the foot are covered.
- Unfold the stocking gradually upwards until the calf is completely covered, applying an even stretch.
- If the stretch is excessive and too much stocking ends up at the popliteal fossa, do not fold the stocking back, but start again, this time reducing the stretch.

Multilayered compression

Multilayered compression helps increase the pressure exerted while making it easier to apply compression. Pressure levels exerted by each layer more or less add up (e.g. if a class 3 stocking is indicated but difficult to put on, a class 1 stocking can be put on first, then a class 2 stocking).

Annex 2. Proposed future action

Guidelines

- Produce a specific guideline on topical treatment of ulcers using the systematic review on dressings carried out by the *CEPP*[10] and the dressings classification they propose.
- Produce a specific guideline on the role of physiotherapy in managing venous insufficiency. The working group should include a sufficient number of physiotherapists.

Clinical trials

- Perform randomised controlled trials (RCTs) to assess the efficacy and safety of non surgical techniques for removing superficial veins *versus* Doppler-ultrasound-guided superficial venous surgery, using healing and/or recurrence of ulcers of predominantly venous origin as the primary endpoint.
- Perform a large double-blind, placebo-controlled RCT with an objective primary endpoint to supplement currently available data on pentoxifylline (RCTs on low numbers, meta-analyses of these trials).
- Perform a double-blind RCT of sufficient power to test whether combining pentoxifylline and high-level compression (> 30 mmHg) is more effective than high-level compression alone. The primary endpoint would be complete healing of the ulcer within 6 months.
- Perform a RCT to assess the efficacy of surgery for incompetent perforating veins on the healing and/or recurrence of ulcers of predominantly venous origin. Compare superficial surgery only with superficial surgery + surgery of the perforating veins, in patients with incompetence of both the superficial and perforating veins according to Doppler ultrasound findings.
- Perform a multicentre RCT to assess the efficacy of deep venous surgery on healing and/or recurrence of resistant or recurrent ulcers of predominantly venous origin, comparing an intervention group (deep venous surgery + compression) and a group without surgery (compression alone).
- Perform RCTs to assess the efficacy and cost effectiveness of skin grafts or any other alternative biotechnology treatment.

[10] CEPP: Commission d'évaluation des produits et prestations – Committee for assessment of products and services

Investigations

- Conduct an epidemiological survey to assess the prevalence, incidence, management methods and economic burden of the disease in France.
- Assess the clinical and economic efficacy of structured management in France *versus* a care pathway coordinated by the patient's doctor.
- Carry out an investigation into clinical practice among general practitioners, to assess methods of managing venous ulcers and, in particular, to find out how often ABI is measured.
- Assess compliance with and acceptability of compression treatment.

Regulatory activities

- Assess whether the nursing procedure for putting on compression devices should be included in the NGAP[11].
- Improve instruction leaflets on compression treatment so that a given pressure can be obtained at the ankle using the information supplied.

[11] NGAP: *Nomenclature générale des actes professionnels*

Annex 3. Assessment method used to produce the clinical practice guidelines

Clinical guidelines have been defined as proposals established using an explicit method to help healthcare professionals and patients find the most appropriate care in a given clinical situation.

The *clinical practice guidelines (CPG)* method is one of the methods used by HAS to produce clinical guidelines. It is based on critical analysis and review of the available medical literature as well as on the opinion of a multidisciplinary group of professionals involved with the subject of the guidelines.

Choosing subjects for guidelines

The HAS Board chooses the subjects for clinical guidelines. In selecting subjects the Board takes into account public health priorities and any requests from ministers responsible for health and social security. The HAS Board can also accept subjects proposed by learned societies, the French national cancer institute, the French Association of National Health insurance funds, the French National Association of Healthcare Professions, organisations representing health care professionals or establishments or registered user groups.

Steps of the working method

Steering committee
HAS sets up a steering committee made up of representatives of the learned societies, professional or user organisations and, if need be, of the relevant health agencies and institutions. The committee defines exactly the subject of the guidelines, the questions to be discussed, the patient populations and the professionals for whom the guidelines are intended. It draws attention to relevant publications, particularly existing guidelines. It proposes suitable professionals to take part in working groups and act as peer reviewers. Finally it takes part in the peer review.

Working group
HAS sets up a multidisciplinary and multiprofessional working group made up of healthcare professionals who practice within the French national health service or privately and who come from different geographical backgrounds or represent different schools of thought and, if appropriate, of other concerned professionals and representatives of patient and user organisations. HAS appoints a working group chair to coordinate the group's work in collaboration with the HAS project manager. A report author is also designated by HAS to select, analyse and review the relevant medical and

scientific literature (see box). The report author drafts the scientific report and assigns the chosen studies levels of evidence, under the supervision of the HAS project manager and the working group chair.

Sources for drafting the scientific report

- Medical and scientific databases searched systematically over an appropriate time period for the subject (languages: French, English). In particular, search for clinical practice guidelines, consensus conferences, medical decision-aid articles, systematic reviews, meta-analyses and other assessments.
- If appropriate, more specific databases (e.g. health economics)
- All useful internet sites (government agencies, learned societies, etc.)
- Grey literature (documents which cannot be accessed through conventional channels)
- Legislative and regulatory texts which could be related to the subject
- Cited references in the articles retrieved (manual search)
- Articles provided by the members of the working group and by peer reviewers.

Searches are updated regularly until the project is complete.

Producing the draft guidelines

The working group produces draft guidelines based on the report and the opinions expressed during the meetings of the working group (usually two meetings). Guidelines are graded A, B or C on a scale proposed by HAS according to the level of evidence on which they are based.[12] The grading used for the guidelines is given in the box below. The draft guidelines are then submitted to the peer reviewers.

Peer reviewers

HAS appoints the peer reviewers using the same criteria as for working group members. The peer reviewers are consulted by post and give an opinion on the content and structure of the report and guidelines, in particular on whether the guidelines are easy to read, to understand and to apply. Members of the HAS specialist committee responsible for professional

[12] For more information on the method of producing clinical practice guidelines, see ANAES 1999 guide (in French): "*Recommendations pour la pratique clinique - Base méthodologique pour leur réalisation en France*". www.has-sante.fr.

guidelines (Committee for the Assessment of Healthcare Strategies*)* also peer review the guidelines.

Grading of guidelines

Grade	Scientific evidence level
A	trials of a high level of evidence (level of evidence 1), e.g. high-power randomised controlled trials (RCTs) free of major bias and/or meta-analyses of RCTs or decision analyses based on level 1 trials.
B	studies of an intermediate level of evidence (level of evidence 2), e.g. RCTs with some bias, meta-analyses based on questionable methodology, well-conducted non-randomised controlled trials or cohort studies;
C	studies of a lower level of evidence, e.g. case control studies (level of evidence 3) or case series (level of evidence 4).

In the absence of reliable publications, the guidelines are based on professional agreement among members of the working group and peer reviewers.

Final version of the guidelines
The working group analyses the peer reviewers' comments, amends the report if necessary, and produces the final version of the guidelines and a quick reference guide (QRG), during a working session.

The final version of the report and guidelines and the procedure used to produce them are discussed by the Committee for the Assessment of Healthcare Strategies which may ask the working group to make amendments before submitting its opinion to the HAS Board.

Validation by the HAS Board
The HAS Board validates the final report and authorises its distribution.

Distribution
HAS makes available on its website (www.has-sante.fr), free of charge, the report, the guidelines and the Quick Reference Guide (QRG). HAS may decide to print both the QRG and the guidelines.

Participants

Learned societies consulted

Agence française de sécurité sanitaire des produits de santé
Association de recherche en soins infirmiers
Association française pour la recherche et l'évaluation en kinésithérapie
Association nationale de kinésithérapeutes salariés
Collège des enseignants de médecine vasculaire
Collège français de pathologie vasculaire
Commission d'évaluation des produits et prestations
Convergence infirmière
Fédération nationale des infirmières
Société de chirurgie vasculaire de langue française
Société française d'angiologie
Société française de dermatologie
Société française de gériatrie
Société française de kinésithérapie
Société française de lymphologie
Société française de médecine générale
Société française de médecine vasculaire
Société française de Phlébologie
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Société française et francophone de plaies et de cicatrisation
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Synopsis

TITLE	**Managing venous leg ulcers (excluding dressings)**
Document type	Clinical practice guidelines
Date available online	September 2006 (in French)
Topics	- How to define venous ulcers or ulcers of predominantly venous origin - Epidemiology and management of the disease - Clinical and paraclinical signs by which venous ulcers or ulcers of predominantly venous origin can be diagnosed - Treatment of the causes of ulcers of predominantly venous origin (compression, surgery, non-surgical techniques for removing veins, drug treatments) - Precautions to take in cases of associated peripheral arterial occlusive disease - Concomitant measures (physiotherapy, changes in lifestyle).
Target professional(s)	- Doctors especially general practitioners, vascular physicians, dermatologists, vascular surgeons, specialists in internal medicine, geriatricians, radiologists and doctors specialising in physical medicine - Allied health professionals especially nurses, physiotherapists as well as home helps and nursing auxiliaries.
Requested by	*Société française de chirurgie vasculaire*
Sponsor	*Haute Autorité de Santé* (HAS), French National Authority for Health – Guidelines Department and Economics & Public Health Department
Management of the project	Dr Philippe Martel, project manager, Guidelines Department (head of department: Dr Patrice Dosquet) Stéphanie Barré, project manager, Health Economics and Public Health Department (head of department: Catherine Rumeau-Pichon. Secretarial services: Jessica Layouni
Participants	Learned societies, Steering committee, Working group (chair: Dr Philippe Nicolini, vascular surgeon, Décines-Charpieu), Peer reviewers: see list of participants

Documentary research	International databases (1994 - February 2005) Research carried out by Gaëlle Fanelli with the help of Julie Mokhbi and Valérie Serriere-Lanneau, Documentation department, HAS (head of department: Frédérique Pagès)
Assessment method	Systematic review of the literature and the expert opinion of a multidisciplinary working group (See *Les recommandations pour la pratique clinique – Base méthodologique pour leur réalisation en France*" (1999) (www.has-sante.fr))
Report authors	Dr Isabelle Lazareth, vascular surgeon, Paris Dr François Truchetet, dermatologist, Thionville Isabelle Bongiovanni, economist, Marseille
Report validation	HAS Committee for the Assessment of Healthcare Strategies. Validated by the HAS Board in June 2006
Related documents	Report (in French) and Quick reference Guide can be downloaded free of charge from www.has-sante.fr



www.has-sante.fr