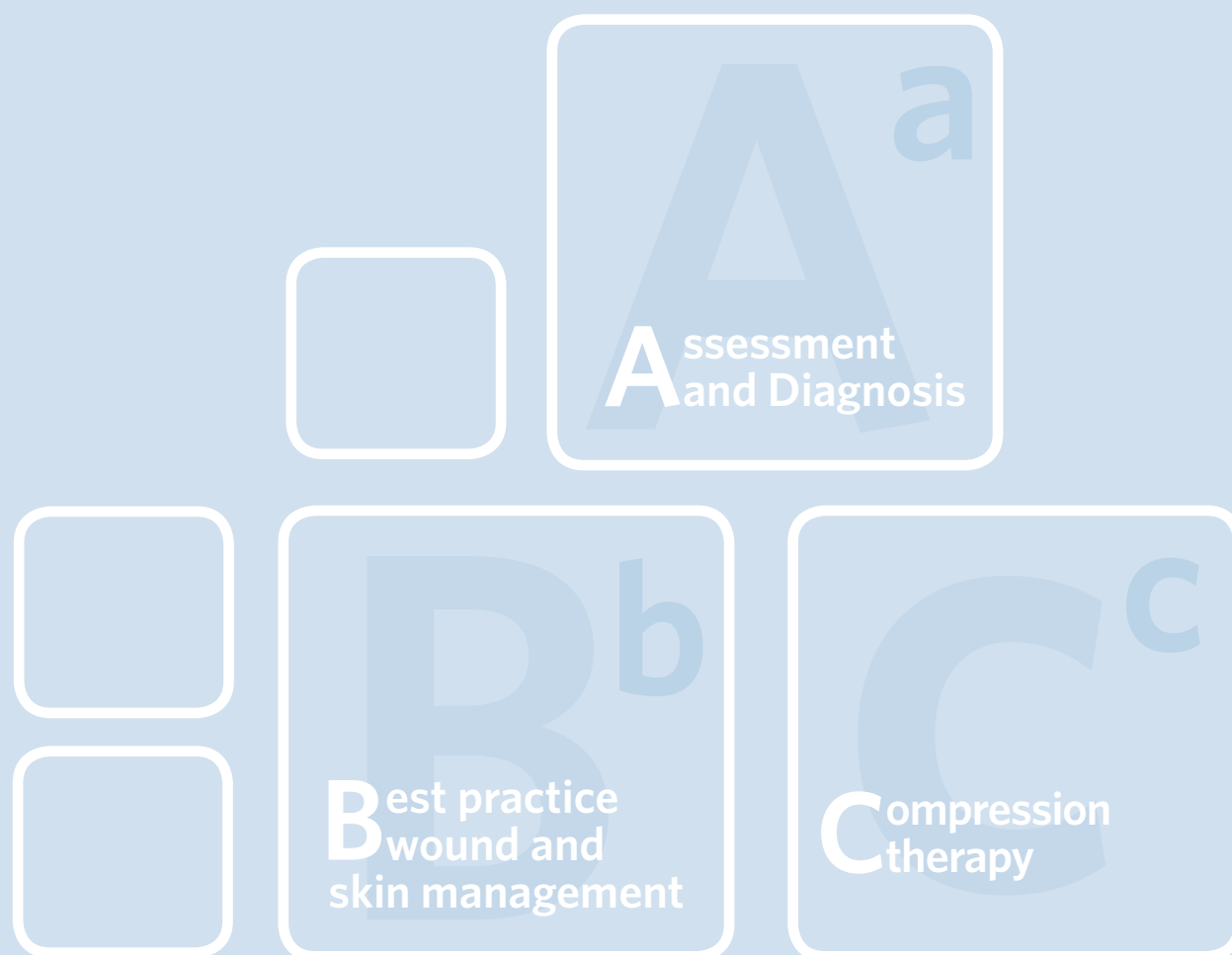


SIMPLIFYING VENOUS LEG ULCER MANAGEMENT



Recommendations from an expert working group

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FOREWORD

Many countries have published guidelines, which state that compression therapy is the 'gold standard' treatment for venous leg ulcers¹⁻¹¹. Compression therapy is known to significantly increase VLU healing rates and reduce the risk of recurrence¹²⁻¹³. Despite this, efforts to heal VLUs are often focused on the use of advanced wound dressings and other therapies, while an established key to healing — compression therapy — is underused.

An international group of experts in leg ulcers and venous disease met in December 2014. The group recognised that a very high proportion of all leg ulcers have venous disease as a causative or contributory factor (i.e. are VLUs or mixed aetiology ulcers) and so may be appropriate for compression therapy. Their discussions centred on identifying how to encourage wider adoption of compression therapy by simplifying the key principles involved. The conclusions reached form the basis of this document and are presented as an **ABC of the management of VLUs**, with the focus on the active treatment phase. It is hoped that this simplified approach will help clinicians to clearly understand why, when and how compression therapy should be used.

Everyone involved in wound healing should be ambitious in striving for a step change that decisively overturns passivity in expecting lengthy, delayed or non-healing of VLUs and other leg ulcers associated with venous disease. We need to actively seek to enhance affected patients' lives by improving healing rates through increased appropriate use of compression therapy.

Professor Keith Harding

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Venous leg ulcers and compression

DEFINING A VLU

A venous leg ulcer (VLU) is an open skin lesion that usually occurs on the medial side of the lower leg between the ankle and the knee as a result of chronic venous insufficiency (CVI) and ambulatory venous hypertension, and that shows little progress towards healing within 4–6 weeks of initial occurrence.

THE CHALLENGES

Venous leg ulcers (VLUs; also known as varicose or stasis ulcers) pose significant challenges to patients and healthcare systems: they are frequent, costly to manage, recurring, and may persist for months or years (Box 1).

Patients report that having a VLU has a negative impact on all aspects of daily living, and may cause depression, anxiety and social isolation. Pain, leaking exudate, odour, restricted mobility and sleep disturbance may be particularly challenging and distressing for patients^{14,15}.

Many guidelines produced by national and international groups emphasise the importance of compression therapy in the management of VLUs^{1–11}.

Compression therapy is widely recognised as key to the management of VLUs: it increases healing rates in comparison with no compression therapy¹² and, after healing, reduces recurrence rates¹³.

BOX 1 | Venous leg ulcer key facts

Incidence and prevalence

- ▶ About 1% of the western population will suffer from a VLU during their lifetime¹²
- ▶ At any one time approximately 0.1–0.3% of the population have an active VLU⁴
- ▶ Prevalence increases with age, affecting up to 2% of the population >80 years old^{16,17}
- ▶ More common in women than in men¹⁷
- ▶ Few countries have registries that collect data on prevalence and incidence routinely*

Healing rates

- ▶ 6 month healing rates: community about 45%¹⁸; specialist clinics about 45–70%^{19,20}
- ▶ Average time to healing: 5.9 months for VLUs; 7.4 months for mixed aetiology ulcers²¹

Recurrence

- ▶ 12 month recurrence rate: 26–69%¹³; recurrences have been reported up to 60 months⁴

Direct financial cost

- ▶ In western countries, about 1% of healthcare budgets is consumed by the management of leg ulceration²²
- ▶ In the UK, VLUs cost £168–198 million per year²³
- ▶ In Germany, annual average cost of illness for a patient with a leg ulcer has been estimated at 9060 Euros²⁴

Time consuming

- ▶ Wound care has been estimated to consume 25–65% of the time of community nurses^{25,26}
- ▶ Family physicians see an average of 1.5 patients with a chronic leg ulcer per week (survey had low response rate)²⁶

Inconsistent patterns of care

- ▶ VLUs may be managed by a number of different specialities, with inconsistencies between and within different countries in referral criteria and patterns
- ▶ Care may be driven by government targets/incentives in some countries

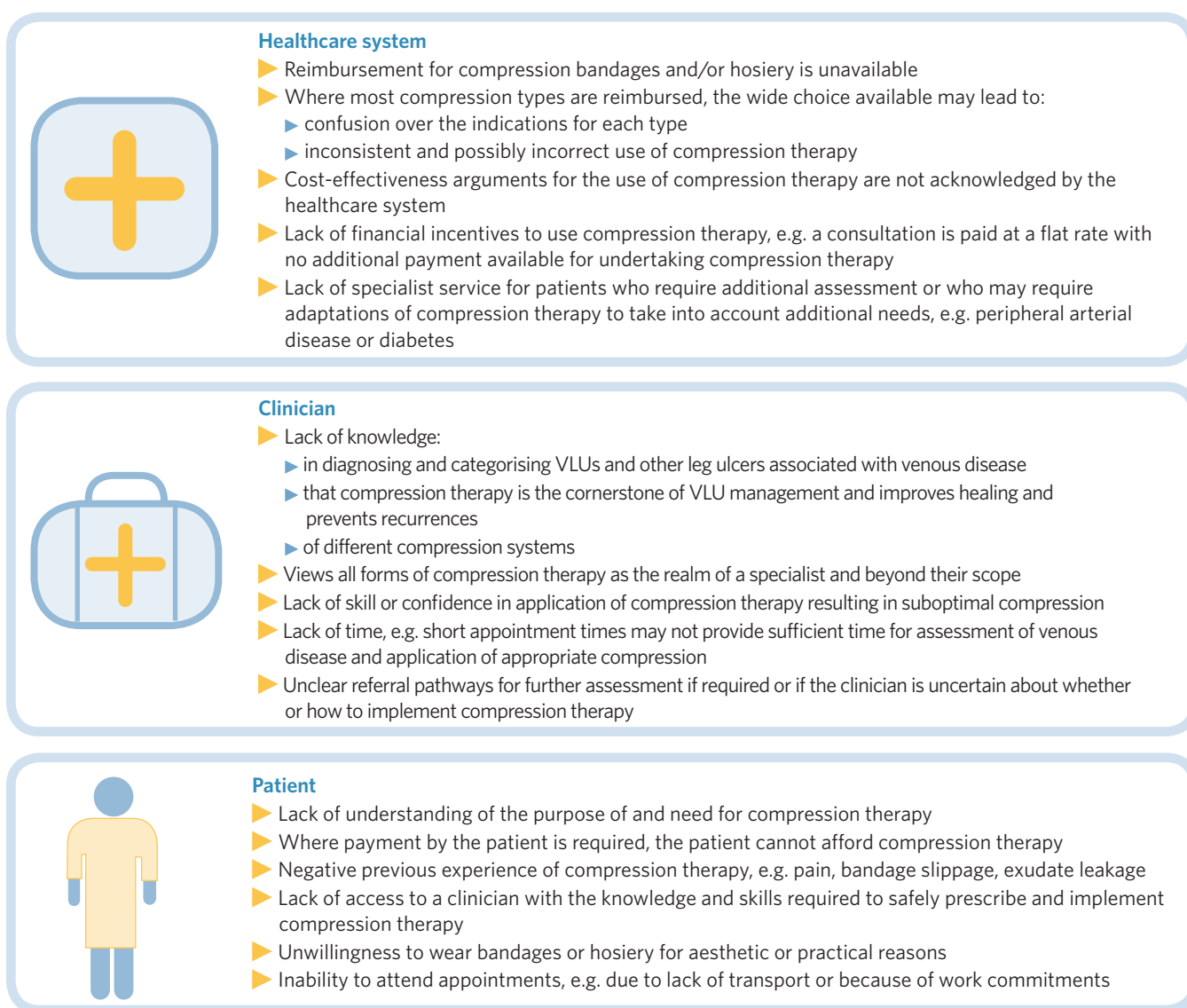
*An example of a registry which is used in Sweden can now be found at www.rikssar.se/rut-information-in-english

Despite existing guidance, many patients with a VLU do not receive compression therapy. In the UK, only 20% of patients in a primary care database who had a VLU were recorded as having received compression therapy¹⁷. In a French study, only 10.8% of general practitioners followed guidelines for the management of VLUs²⁸. In contrast, in specialist centres compression therapy may be used in up to 88% of VLU patients²⁵. In Germany, an insurance company reported that 32–53% of VLU patients received compression therapy²¹.

Under-usage of compression therapy represents lost opportunities for healing wounds and improving patients' quality of life.

FIGURE 1 | Reasons for under-usage of compression therapy

There are numerous reasons why compression therapy may not be used (Figure 1). These range from lack of knowledge or confidence by clinicians, to unclear referral pathways because of the variety of specialities that may be involved, to local unavailability of compression bandages or hosiery, to unwillingness of patients to wear compression therapy.



Understanding lower limb ulceration

VLU are the most common type of chronic lower limb wound (Table 1) and are due to disease or disrupted function of the veins, known as chronic venous insufficiency (CVI) (see Box 2, page 4). In clinical practice, an understanding of the likely history and characteristics of lower limb wounds will aid in distinguishing VLUs and leg ulcers that may have a venous component from other types of lower limb wound (Table 2).

A remarkably high proportion of all lower limb wounds are caused by venous disease or have venous disease as part of a mixed aetiology and so are potential candidates for compression therapy.

DEFINING A MIXED AETIOLOGY ULCER




The phrase 'mixed aetiology leg ulcers' is mainly used in connection with VLUs with concomitant arterial occlusive disease. However, it may also refer to VLUs with other contributory factors, e.g. lymphoedema, diabetes, arthritis, malignancy.

TABLE 1 | Relative frequencies of chronic lower limb wounds

Chronic wound	Relative frequency
Venous leg ulcer	40-85%
Arterial leg ulcer	5-30%
Mixed aetiology ulcer	10-20%
Other causes of chronic lower limb ulcers	5-25%

Relative frequencies vary because of differences in study methodologies and definitions. For example, where traumatic wounds are categorised separately the relative frequency of VLUs may decrease because some patients who develop VLUs have a history of trauma. Based on^{4,29-34}

TABLE 2 | Characteristics of the main types of chronic lower limb wounds

Type	Location	History	Ulcer characteristics	Other findings
Venous leg ulcer 	Gaiter region of the leg; most commonly around the medial malleolus	Varicose veins DVT Other venous disease Trauma Surgery	Irregular sloping margins Usually shallow Fibrinous, granulating base Variable size: from small to encircling the leg High exudate levels May be painful; pain relieved by elevation of the limb	Periwound/lower limb oedema Ankle flare Varicose veins Varicose eczema Lipodermatosclerosis Hyperpigmentation Atrophie blanche
Arterial leg ulcer 	Toes, feet or lateral or pretibial aspects of the lower leg	Intermittent claudication/rest pain Cardiac or cerebrovascular disease	Punched out, sharply demarcated edges Painful Small and deep Necrotic wound base Dry/low exudate levels Gangrene may be present	Surrounding skin is often dry and shiny with loss of hair Weak or absent foot pulses
Diabetic foot ulcer 	Pressure bearing areas of the sole of the foot (neuropathic) Margins of the foot, e.g. over first or fifth metatarsophalangeal joints (neuroischaemic)	Diabetes	Sensory loss when neuropathy is present Variable depth: may be deep +/- sinuses, and may involve tendons and bones	Neuropathic: foot may be warm; ulcer often surrounded by callus Neuroischaemic: foot may be cool and foot pulses may be absent

N.B. Lower limb ulcers may be of mixed aetiology, e.g. due to arterial and venous disease, and so may exhibit a mixture of signs and symptoms. Photos courtesy of Rut Öien

BOX 2 | Cause of venous leg ulcers (VLUs) and mechanism of action of compression therapy

Cause of VLUs

VLUs are due to increased pressure within the veins of the lower limb caused by chronic venous insufficiency (CVI). This most commonly occurs as a result of damage to the valves in leg veins as in varicose veins or as a result of venous thrombosis.

Venous valves prevent blood that is going up the leg towards the heart from flowing backwards (Figure 2). Blood flow towards the heart is assisted by the muscles of the lower leg (the calf muscle pump). Damaged valves allow blood to flow towards the ankle, which increases distal venous pressure during standing and walking (ambulatory venous hypertension). Raised venous pressure may cause swelling and oedema of the leg, and increased fragility of blood capillaries and the skin, and an increased risk of leg ulceration.

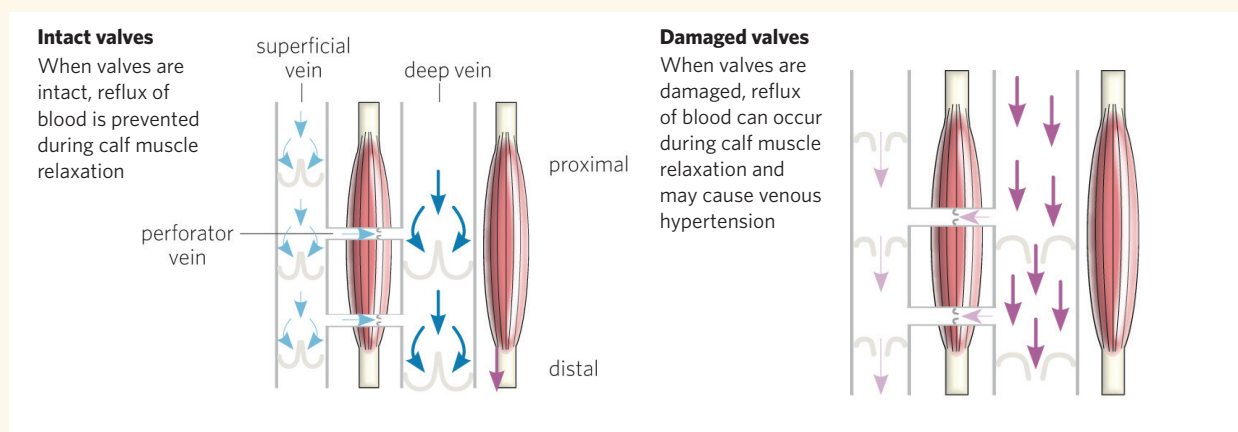


FIGURE 2 | Effect of valve failure on blood flow in the venous system of the lower leg during calf muscle relaxation (adapted from *Principles of compression in venous disease*, see below)

How does compression therapy work?

Compression therapy assists venous return from the lower limb by exerting external pressure. This is achieved by the components of the compression therapy system forming a semi-rigid sleeve around the lower leg.

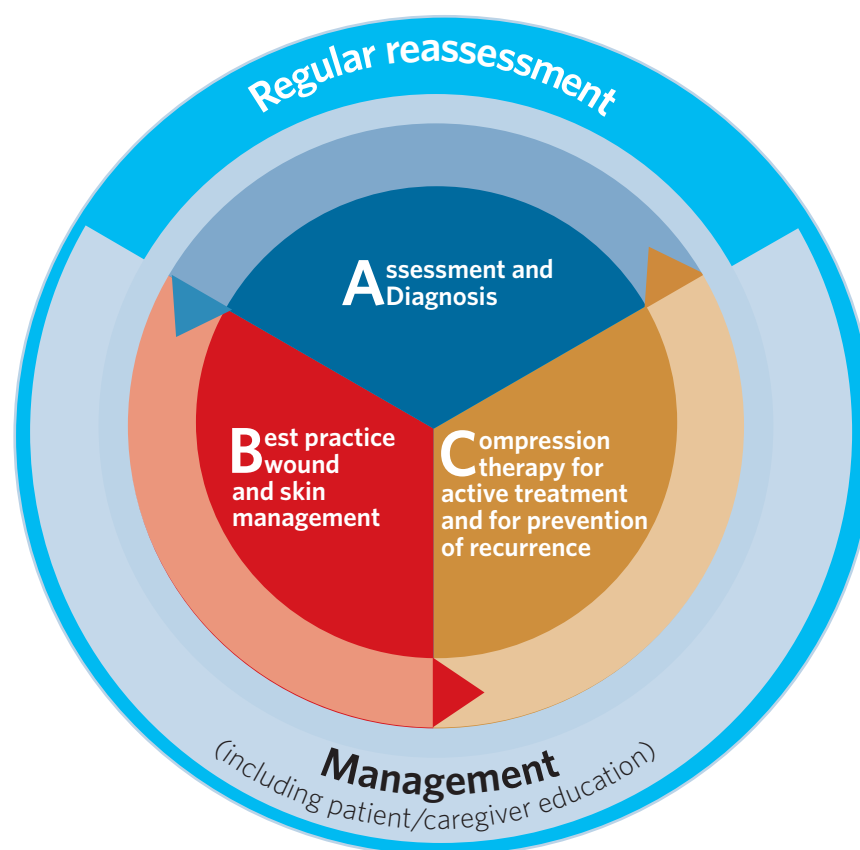
Compression of leg tissues reduces oedema by opposing leakage of fluid from capillaries into tissues and by encouraging lymphatic drainage. It also improves venous return, e.g. by increasing the speed of venous blood flow, which may reduce local inflammatory effects³⁵. It therefore helps to reduce the effects of CVI by reducing venous ambulatory hypertension, reducing oedema and improving skin blood flow, and aiding healing. See pages 12-16 for section on compression therapy.

More information on how compression therapy works can be found in: *Principles of compression in venous disease: a practitioner's guide to treatment and prevention of venous leg ulcers*. Wounds International, 2013. Available from: <http://bit.ly/1QXfA9W>

ABC model for leg ulcer management

This document aims to clarify best practice in the assessment and management of leg ulcers around three main steps: **A B C** (Figure 3).

FIGURE 3 | Overview of the ABC model of assessment and management of leg ulcers



ASSESSMENT AND DIAGNOSIS

This important step aims to:

- Establish the **aetiology** of the wound, i.e. to confirm whether venous disease or other disorder has caused or contributed to the wound (e.g. lymphoedema, diabetes, arthritis, malignancy)
- Gather indicators for appropriate **management** of the wound, skin, venous disease and comorbidities, i.e. in addition to assessing the wound, periwound skin, leg and foot, assess the patient's comorbidities and psychosocial status
- Decide whether there is need for **referral** to a service that manages VLUs or to a vascular, phlebology, diabetic, dermatology, rheumatology or cardiac service, e.g. because of arterial disease or other comorbidities
- Categorise the wound as a 'simple' VLU, 'complex' VLU or as a mixed aetiology ulcer to determine likely **prognosis**, so that appropriate time frames for monitoring, reassessment and specialist referral can be established.
- Evaluate the patient's suitability for **compression therapy**.

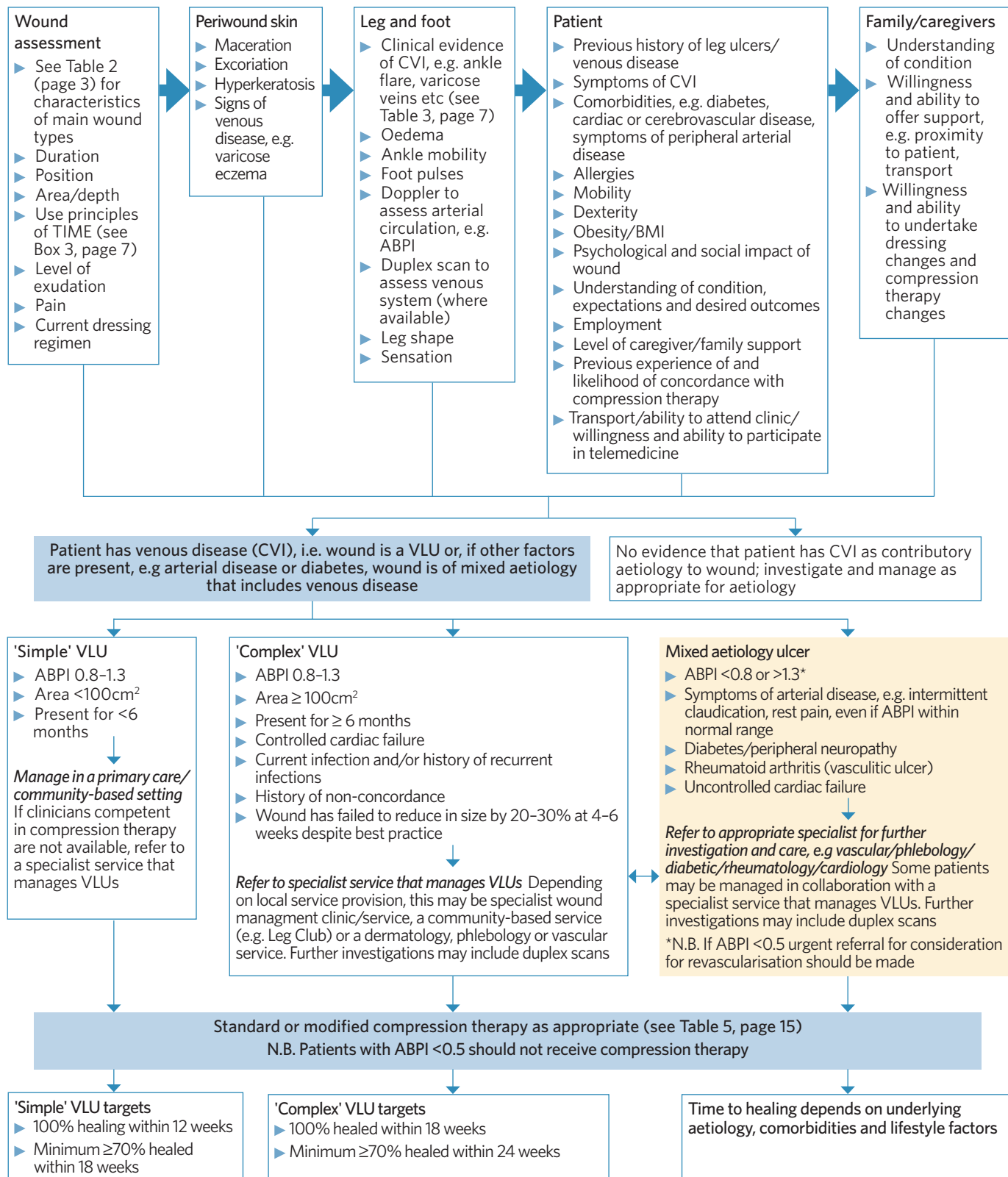
A multidisciplinary approach is often required. The healthcare and other services involved will depend on local availability, and the complexity of the wound, and the patient's needs.

Assessment and management should be carried out by a healthcare practitioner who has received appropriate training in leg ulcer management; if there is any doubt about competency, the patient should be referred to an appropriate specialist. Figure 4 (page 6) summarises assessment and diagnostic processes that will assist in confirming the aetiology of a presenting wound as being wholly or partly due to venous disease (CVI).

WOUND BIOPSY

Wound biopsy may be indicated in patients who have delayed healing and a wound suspected of being malignant (i.e. has unusual appearance and/or is in an unusual place). Referral may be required to access a clinician who is suitably trained and competent to conduct a wound biopsy.

FIGURE 4 | Venous leg ulcer assessment pathway



ASSESSMENT STARTS WITH A FULL ASSESSMENT OF THE PATIENT AND THE WOUND

A comprehensive assessment should be taken to ascertain past medical history, current mobility, pain levels and nutrition, home and work environments, caregiver/family involvement and patient concerns. Patients may report symptoms of CVI, e.g. feelings of heaviness and tightness in the legs, swelling, discomfort and pain. These symptoms may be relieved by elevating the legs.

Wound assessment should include location, duration, size, exudate levels, and wound bed and other ulcer characteristics (see Figure 4). The principles of wound bed preparation (e.g. using the TIME acronym) encourages a systematic approach to assessment (Box 3)³⁶.

Beyond the wound itself, the periwound skin, and that of the leg and foot should be assessed for general condition, any signs indicating high levels of exudate (e.g. the presence of maceration and excoriation), and skin changes associated with CVI (Table 3) or peripheral arterial disease. Ankle and foot pulses should be palpated, and systolic ankle and brachial pressures should be measured.

BOX 3 | Wound assessment using the TIME framework³⁷⁻⁴¹

- ▶ **Tissue:** assess tissue types in wound (e.g. slough, necrotic tissue); debride to remove dead or devitalised tissue to encourage healthy granulation tissue formation
- ▶ **Inflammation and infection:** look for evidence of infection/increased bacterial levels (e.g. pain, erythema, redness, heat, nature of exudate); wound swabs are not indicated for suspected localised wound infection; wound biopsy is the most accurate method for determining whether pathogenic bacteria are present but should be reserved for wounds that are failing to heal despite treatment for infection
- ▶ **Moisture balance:** assess exudate level and dressing performance; manage exudate levels to maintain moist wound environment. Exudate levels are often high in VLU and will reduce as the wound heals
- ▶ **Edge:** assess for undermining or callus; remove barriers to healing, e.g. debride thickened or rolled edges and use barrier films to prevent/treat periwound maceration

TABLE 3 | Lower leg changes associated with venous hypertension and CVI

Oedema		Swelling of the limb that may indent if finger pressure is applied (pitting oedema); due to increased capillary permeability
Ankle flare		Fan-shaped pattern of dilated veins around the malleoli on the medial or lateral aspects of the ankle and foot; due to dilation of veins in these areas because of venous hypertension
Hyperpigmentation		Reddish brown discolouration of the skin; due to the deposition of haemosiderin in the skin
Lipodermatosclerosis		Areas of painful, tight skin with hardened subcutaneous tissues just above the ankle; are due to the infiltration of fibrin and inflammation and result in the leg shape resembling an inverted champagne bottle
Atrophie blanche		White areas with decreased capillary density, often associated with lipodermatosclerosis
Varicose eczema		Itchy, erythematous, weeping and scaled areas of skin that may be painful; due to inflammation triggered by oedema resulting from venous hypertension

N.B: Skin changes associated with CVI may coexist. Photos courtesy of Giovanni Mosti, Rut Öien, Patricia Senet and Wolfgang Vanscheidt

IF VENOUS DISEASE IS SUSPECTED, DOPPLER AND DUPLEX SCANNING SHOULD BE USED TO EVALUATE THE VENOUS AND ARTERIAL CIRCULATIONS

Measuring ABPI

Calculation of ankle-brachial pressure index (ABPI) from measurements of systolic blood pressure at the ankle and the brachial artery in the arm using Doppler equipment is the method used most widely to assess peripheral arterial circulation⁴². The results (Table 4) can guide the level of compression therapy to be used and the need for referral (Table 5, page 15).

Evaluation of the peripheral arterial circulation of the lower limbs, including ABPI, is an essential step in the decision-making process involved in the use of compression therapy.

TABLE 4 | Interpretation of ABPI^{42,43}

ABPI*	Interpretation
>1.3	Arterial calcification may be present
>1.0-1.3	Probably no peripheral arterial disease
0.81-1.00	No significant or mild peripheral arterial occlusive disease
0.51-0.80	Moderate peripheral arterial occlusive disease
<0.5	Severe peripheral arterial disease, 'critical ischaemia'

Ankle-brachial pressure index (ABPI) = ankle systolic blood pressure ÷ brachial systolic blood pressure
 N.B: ABPI >1.3 may indicate arterial calcification; toe pressure may be more useful

***Critical ischaemia:** A globally accepted definition of critical ischaemia is awaited. Criteria widely used in clinical research do not use ABPI, but use ankle or toe systolic pressures (≤ 50 mmHg or ≤ 30 mmHg respectively) in combination with persistent recurring rest pain despite regular analgesia for >2 weeks or ulceration or gangrene of the foot or toes⁴⁴.

ABPI values should be interpreted in the context of any signs and symptoms of peripheral arterial disease (e.g. intermittent claudication or rest pain). For example, if ABPI is within the normal range but the patient has symptoms, the patient should be assumed to have peripheral arterial disease and be referred to a vascular clinic for further investigation⁴⁵.

ABPI should be conducted by suitably trained and competent healthcare practitioners (Boxes 4 and 5).

BOX 4 | Ensuring accuracy of ABPI

Ensuring accuracy of ABPI and meaningful readings over time is reliant on awareness of the many factors that may affect recording the systolic ankle and brachial pressures. For example, calcified arteries, size of the patient's leg or arm and inappropriate cuff size/placement or patient positioning may result in misleading ABPI values^{46,47}.

BOX 5 | Tips on obtaining ABPI

- ▶ Beldon P. Ten top tips for Doppler ABPI. *Wounds International* 2011; 2(4): 18-21. Available from: www.woundsinternational.com
- ▶ Worboys F. How to obtain a resting ABPI in leg ulcer management. *Wound Essentials* 2006; 1: 55-60. Available from: www.wounds-uk.com

CATEGORISING SIMPLE AND COMPLEX ULCERS

Simple:

ABPI 0.8-1.3
Area <100cm²
Present for <6 months

Complex:

ABPI 0.8-1.3
Area ≥100cm²
Present for ≥6 months
in addition to other risk
factors for non-healing
(see Figure 4, page 6).

When to undertake duplex scanning

Venous duplex scanning is a safe and noninvasive method for investigating the venous system of the leg and confirming CVI. Duplex scans can be used to identify venous obstruction and valvular incompetence⁴⁸. It is therefore useful in recognising patients who may be suitable for endovenous procedures to abolish venous reflux and to reduce the risk of VLU recurrence^{49,50}.

In some places, duplex scanning may not be available or lengthy referral times may mean that the results are not available until after initial decisions about how and when to commence compression therapy have been made.

ONCE AETIOLOGY IS ESTABLISHED, CATEGORISATION OF THE ULCER AS A 'SIMPLE' VLU OR 'COMPLEX' VLU OR AS A MIXED AETIOLOGY ULCER CAN HELP TO DETERMINE PROGNOSIS OR REQUIREMENT FOR SPECIALIST REFERRAL

In addition to guiding management, classification of the ulcer may be useful in determining treatment goals, which may be to:

- Heal the wound
- Control CVI and any related skin changes
- Reduce oedema
- Control symptoms, e.g. pain
- Address or reduce the impact of comorbidities
- Prevent recurrence once the wound has healed.

The healing targets below are used in the UK to optimise VLU services and may provide a useful guide for adoption elsewhere:

- 'Simple' VLU, i.e. those with a good prognosis — 100% healed within 12 weeks (minimum: ≥70% healed within 18 weeks)
- 'Complex' VLU, i.e. those that are likely to take longer to heal — 100% healed within 18 weeks (minimum: ≥70% healed within 24 weeks)⁵¹.

Time to healing for mixed aetiology ulcers will depend on many factors, including aetiology and comorbidities.

The management plan should be documented, and should include monitoring and reassessment at appropriate intervals.

Specialist referral

Where referral is required, the referral pathway will depend on local healthcare service provision. It is important that healthcare practitioners recognise when the management of an individual patient is beyond their competency and that they make an appropriate referral to a more specialist service is made, e.g. to a service specialising in the management of VLUs, or to a vascular medicine/surgery, phlebology, dermatology, rheumatology, cardiology or diabetes service.

Patients with ABPI <0.5 have severe peripheral arterial disease and should be referred to a vascular surgeon for possible revascularisation.

Best practice wound and skin management

B

In addition to the wound, patients with leg ulcers often have skin problems that affect the periwound skin and the skin of the lower leg, e.g. maceration, excoriation and hyperkeratosis. It is important that a structured skin care regimen and effective wound management protocols are implemented to maintain skin integrity and manage the local wound environment.

CLEANSING AND SKIN PREPARATION

Evidence supports the cleansing of leg ulcers with water or saline⁵². Cleansing will usually include the skin of the lower leg to remove dry, loose tissue. While cleansing in a lined bucket using tap water is effective and widespread practice, potential cross-contamination and manual handling issues have increased interest in the use of disposable cleansing and bathing wipes⁵³.

Skin cleansers, if used, should be gentle, with a pH close to that of skin, and non-sensitising. Following cleansing a simple emollient should be applied to the skin of the lower leg to rehydrate the skin⁵⁴. If varicose or contact dermatitis are present, a topical steroid may be indicated.

DEBRIDEMENT

Debridement is necessary to remove slough and devitalised/necrotic tissue. Some types of dressings, e.g. hydrogels, will aid autolytic debridement.

Sharp debridement is usually reserved for 'complex' VLU and should only be carried out where there are suitable facilities and by suitably trained, competent healthcare practitioners.

PERIWOUND AND SURROUNDING SKIN MANAGEMENT

Where there is a risk of exudate-induced maceration or excoriation a barrier film (e.g. acrylate terpolymer) will help to protect the periwound skin and may help encourage healing⁵⁵⁻⁵⁷.

Debridement pads used to assist with wound debridement may also be used to aid removal of hyperkeratotic skin plaques^{58,59}.

WOUND DRESSINGS

Wound dressings are used to protect the wound and manage exudate effectively. Box 6 lists the properties of a dressing for use under compression therapy.

The most important factor in reducing exudate levels is appropriate sustained compression therapy, not the dressing.

The expert working group recommends:

- Select a simple non-adherent dressing to protect the wound and absorb exudate.
- If exudate levels are moderate to high, select an alginate, other gelling fibre, or foam dressing.
- Superabsorbent dressings may be necessary if exudate levels are very high.
- Antimicrobial dressings may be used short-term for the treatment of wound infection⁴⁰.

PENTOXIFYLLINE USE

A Cochrane review concluded that pentoxifylline, an oral agent that improves microcirculatory blood flow, may aid healing of VLU, either in conjunction with compression therapy or alone⁶⁰. (N.B. This may be an unlicensed indication for pentoxifylline in some countries.)

BOX 6 | Properties of a wound dressing for use under compression therapy

- ▶ Maintains a moist wound environment while able to handle varying levels of exudation
- ▶ Absorbs and retains fluid when used under compression, i.e. prevents strikethrough
- ▶ Low profile, i.e. unlikely to leave an impression in the skin
- ▶ Conforms to the wound bed
- ▶ Does not adhere to the wound bed (non-adherent)
- ▶ Comfortable
- ▶ Atraumatic - does not damage the wound bed or periwound skin on removal
- ▶ Low allergy potential
- ▶ Remains intact on removal
- ▶ Cost-effective, i.e. offers optimal wear time

Exudate levels are often high at the beginning of the compression therapy. When compression is effective, exudate levels will reduce as venous return improves and limb oedema and inflammation decreases. These changes will influence the type of dressing needed over the course of treatment. Assessment should include consideration of current dressing performance and change frequency in relation to the exudate level³⁹.

Ideally, dressing change frequency should be matched to the frequency of compression therapy change, not vice versa.

The dressing selected should be effective under compression therapy, i.e. retain moisture without leaking when placed under pressure. Selection of a dressing that is able to maintain a moist wound environment under exudate levels ranging from high to low, e.g. a 'moisture reactive' foam⁶¹, may simplify dressing selection, reduce the risk of periwound maceration and prolong wear time.

ADVANCED LOCAL THERAPIES

A number of advanced therapies are used for the local management of VLUs, e.g. growth factors, extracellular matrices, engineered skin, and negative pressure wound therapy and pinch/punch grafts. The use of these is the realm of specialist care and should only be considered for 'complex' VLUs that remain unhealed despite optimal local wound management and optimal compression therapy.

Before considering advanced therapies, ensure that the compression regimen and concordance are optimised.

Compression therapy for leg ulcer management



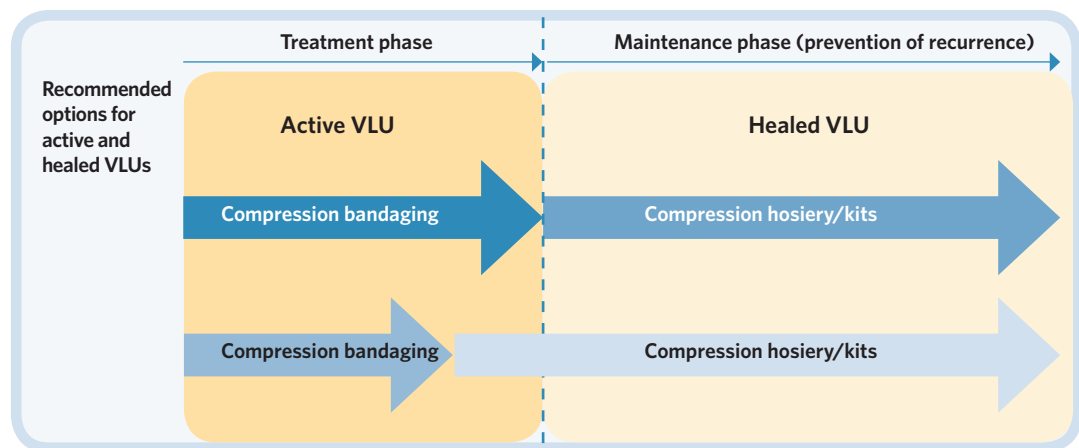
Patients with a VLU and ABPI >0.5 require compression therapy at an appropriate level to optimise healing. However, despite numerous guidelines and publications stating that compression is key to healing active ulceration and preventing recurrence of VLUs, compression therapy remains under-utilised.

IMPLEMENTING COMPRESSION THERAPY

Optimising the benefits of compression therapy involves the application of the right type of compression for the right duration and in a way that is acceptable to the patient. Compression bandaging is most commonly used for the treatment of active VLUs, with compression hosiery mainly used for the prevention of recurrence (Figure 5).

Given the high prevalence of CVI, all patients with lower leg ulcers should be assessed for venous and arterial disease and considered for compression therapy.

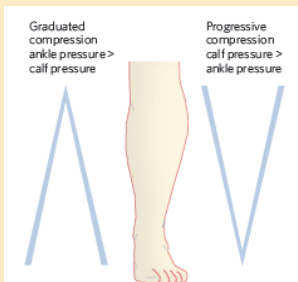
FIGURE 5 | Variations of the compression bandaging-hosiery continuum



Compression bandaging systems usually comprise between two and four components that are applied to the lower leg from just above the toes to just below the knee (or sometimes the full length of the leg). The way in which compression bandages work is determined by the properties of the components used.

The expert working group recommends using the term 'stiffness' to describe the degree of elasticity of a compression system.

Multi-component compression bandage systems may contain both high stiffness (inelastic/short-stretch) and low stiffness (elastic/long-stretch) components. However, when applied to a leg, a multi-component system usually functions as a high stiffness system (e.g. Coban™ 2; Coban™ 4).



GRADUATED AND PROGRESSIVE COMPRESSION SYSTEMS

Compression therapy is often termed as being graduated because for most systems the pressure at the ankle is higher than that at the wider part of the lower leg. This graduation in pressure has been thought to have an important influence on encouraging venous outflow. However, research has suggested that achieving a high pressure over the calf muscles alone, i.e. directly over the most compressible tissues of the lower leg and where most of the venous blood will be, may be a more effective way of improving venous return^{62,63}. This approach has been termed **progressive compression**. It is for specialist use only and is not in widespread clinical practice; further research is required to investigate its efficacy in healing VLUs.

DO THE NUMBER OF LAYERS AFFECT STIFFNESS?

The terminology surrounding the use of layers can be problematic and should not be used to make assumptions about pressure levels. An understanding of the different components used is a better way to determine whether the system will function as a high stiffness system.

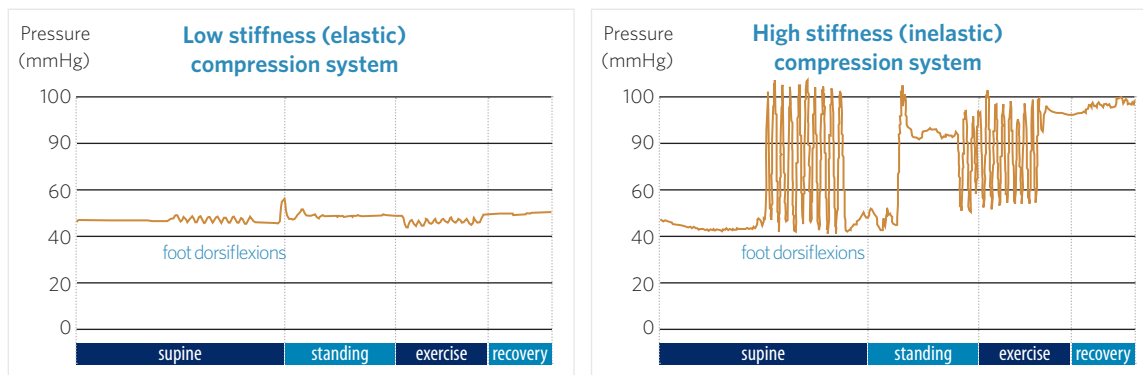
EFFECT OF HIGH STIFFNESS

A high stiffness compression system produces greater fluctuations in pressure in the lower leg during walking than a low stiffness system⁶⁴ (Figure 6). High stiffness systems therefore produce the greatest improvements in venous blood flow, e.g. in ejection volume and ejection fraction, from the lower leg⁶⁵. However, low stiffness systems will generally produce a higher resting pressure.

These observations have two implications for clinical practice:

- Patients may find a high stiffness compression therapy system more comfortable, as it will offer a lower resting pressure than a low stiffness compression system
- Changes in calf diameter (e.g. due to muscle contraction during exercise like walking, or due to passive movement of the ankle) are important for the fluctuations in pressure necessary to improve venous outflow.

FIGURE 6 | Pressure fluctuations under different types of compression system



Interface (sub-bandage) pressure is measured between the compression therapy system and the skin, and is used as a proxy for the pressure within the leg. The fluctuations (amplitudes) in pressure in the graph relate to calf muscle activity due to foot dorsiflexions and walking: the increases in pressure towards the peaks occur as the muscles contract and the decreases towards the troughs occur as the muscles relax again. High stiffness compression systems produce greater fluctuations in pressure, i.e. have a greater effect on venous return.

Multi-component compression therapy systems (either two or four) are preferable because they generally have high stiffness: the higher the stiffness, the better the outcome for the patient.

VARIABLES AFFECTING AMOUNT OF PRESSURE APPLIED

Compression therapy systems are often classified according to the amount of pressure they produce in a laboratory on a model leg. In the clinical situation, many variables affect the amount of pressure a compression therapy system generates when applied to the leg of a patient, e.g. the:

- Properties of the bandage: inelastic components have high stiffness and so usually produce lower pressures at rest but greater pressure fluctuations during walking
- Number of components applied: stiffness increases with the number of components applied. Multi-component systems may have increased stiffness even if they contain elastic components
- Technique and skill of the applicator: stretching bandages more during application may produce higher pressures
- Size and shape of the leg, and amount of muscle: it may be difficult to generate therapeutic levels of pressure in thin legs with calf muscle wasting.

As a result of this large range of the variables, interface pressure is rarely measured in routine clinical practice. However, during training for application of compression systems, interface pressures may be measured as a means of providing feedback about whether sufficient pressure has been generated.

SELECTING COMPRESSION THERAPY

The patient's ABPI result is a major determinant of the level of compression that can be tolerated. Patients who have a compromised arterial circulation will need lower levels of compression (modified compression) to avoid the risk of pressure damage and exacerbating or precipitating distal ischaemia. However, two component stiff compression systems are available that have shown to be safe for patients with arterial disease (ABPI>0.5) if applied with a pressure in the supine position of approximately 20–30 mm Hg⁶⁶. Patients with ABPI <0.5 should not receive compression therapy and should be referred to a vascular surgeon for possible revascularisation. Consider intermittent pneumatic compression (IPC) if revascularisation is not possible.

All patients who are candidates for compression therapy should have ABPI measured and recorded.

Numerous patient-, practitioner- and health system-related factors influence the choice of compression therapy system (Box 7).

BOX 7 | Factors that affect choice of compression therapy system

- ▶ Training, competency and experience of the healthcare practitioner applying compression: in healthcare systems where there is a high turnover of staff it may be preferable to mainly use a compression therapy system that is relatively straightforward in application, e.g. two-component compression bandaging
- ▶ Wound status, e.g. size of the ulcer and exudate levels
- ▶ Patient mobility (see section on the importance of mobility, page 16)
- ▶ Patient dexterity and ability to self-apply compression therapy
- ▶ Previous experiences of the patient and likely concordance with treatment
- ▶ Pain levels
- ▶ Access to care, e.g. the possible frequency of clinic or home care visits
- ▶ Level of compression required, e.g. if adjustment is likely to be required to enhance tolerance, can this be undertaken with the proposed system?
- ▶ Availability of compression therapy systems: where restrictions occur, minimum provision should be multi-component compression bandaging and compression hosiery

Other considerations should include the attributes of the compression therapy system. Box 8 lists those of the ideal compression system as agreed by the expert working group. Some of these attributes are aspirational and not yet available.

BOX 8 | Attributes of the ideal compression therapy system

- ▶ Delivers therapeutic compression and has high stiffness, i.e. the pressure generated is effective during mobilisation and is well tolerated during rest
- ▶ Permits good anatomical fit
- ▶ Stays in place, i.e. does not slip
- ▶ Comfortable
- ▶ Allows patients to wear their own shoes and to maintain normal gait
- ▶ Easy to apply and remove
- ▶ Requires minimal training in fitting and application
- ▶ Non-allergenic
- ▶ Aesthetically acceptable
- ▶ Affordable and/or reimbursed
- ▶ Offers patient choice

Table 5 uses the results of the ABPI calculation (Table 4, page 8) to guide the level of compression therapy to be used and the need for referral.

TABLE 5 | Guide to using compression therapy in 'simple', 'complex' and mixed aetiology leg ulcers

Level of compression	Compression therapy with a stiff inelastic compression therapy system		
	'Standard'	'Modified' (i.e. lower resting pressure)	Comments
Simple VLU Primary care/community setting ABPI 0.8-1.3			
Area <100cm ² and wound has been present <6 months	✓		<ul style="list-style-type: none"> Refer to specialist service that manages VLUs if wound has not decreased by 20-30% in area by 4-6 weeks despite optimal compression therapy If concordance is an issue, start compression at a lower level and increase gradually
Complex VLU Specialist service/clinic that manages VLUs +/- other services as required ABPI 0.8-1.3			
Area ≥100cm ² and/or wound has been present >6 months (no other comorbidities) Wound has failed to decrease by 20-30% by 4-6 weeks despite optimal compression therapy	✓		<ul style="list-style-type: none"> Reassess and confirm venous aetiology; consider malignancy Review current compression regimen Review wound management Assess concordance and understanding If prior management has been optimal, consider advanced therapies or implement compression therapy and review progress after 4 weeks
Lymphovenous disease	✓		<ul style="list-style-type: none"> Specialist bandaging techniques may be required, e.g. to accommodate unusual limb shape or to treat toe swelling Refer to lymphoedema service if skills/competencies not available Skin care is a priority because of increased risk of infection
Cardiac failure		✓	<ul style="list-style-type: none"> Ensure any cardiac failure is under control before commencing compression due to risk of overloading the heart once any oedema starts to clear Monitor closely for signs of exacerbation of cardiac failure If in any doubt, involve a physician/cardiologist and start compression at a low level and increase if tolerated
Current infection and/or history of recurrent infection	✓	✓	<ul style="list-style-type: none"> Current infection: treat as appropriate and consider reducing level of compression if difficult to tolerate. Increase frequency of dressing change to monitor infection Recurrent infection: ensure wound and skin are examined regularly; reassess and address any modifiable factors that may contribute to recurrence
History of non-concordance	✓	✓	<ul style="list-style-type: none"> Reassess to confirm diagnosis of CVI Determine reasons for non-concordance and address any modifiable reasons Consider implementing lower level of compression and gradually increasing to a level that is tolerable for the patient Consider the use of compression hosiery
Mixed aetiology leg ulcers Appropriate specialist service +/- collaboration with specialist service that manages VLU ABPI <0.8 or >1.3			
ABPI >1.3			<ul style="list-style-type: none"> Refer to specialist for further investigation and care
ABPI 0.5-<0.8		✓	<ul style="list-style-type: none"> Refer to specialist for further investigation and care Modified compression using a stiff system may be applied with frequent reassessment and monitoring for ischaemia and pressure damage
ABPI <0.5			<ul style="list-style-type: none"> Refer to vascular surgeon for possible revascularisation Consider IPC if revascularisation is not possible

WHEN TO REAPPLY COMPRESSION BANDAGES

Compression bandages may remain in place for up to 7 days. Changes in leg volume, compression system slippage, patient reports of discomfort or pain due to compression system and strikethrough of exudate are indicators that the compression system should be changed more frequently. In clinical practice, habitual wound dressing change often drives frequency of compression system change/reapplication and choice of compression system. However, selection of an appropriate dressing may reverse the situation, and may lead to an overall reduction in the frequency of compression system change/reapplication.

IMPORTANCE OF MAINTAINING PATIENT MOBILITY

Encouraging the patient to exercise or to maintain activity during treatment with compression therapy is important in enhancing the action of the calf muscle pump and the therapeutic effect of the compression therapy system⁶⁷. In general, additional padding (e.g. cotton wool padding) is not recommended because it may impair the function of the compression system and the mobility of the patient, and may encourage the system to slip.

Where appropriate, encouraging patients to be mobile is important in optimising the benefits of compression therapy.

The choice of the compression system can impact significantly on patient mobility. Maintaining ankle flexibility, allowing patients to wear their own shoes and maintaining a normal gait will help patients to remain active.

In patients who have restricted mobility, i.e. have low calf muscle pump activity, but who move to standing or are able to flex their toes regularly as part of their daily routine, stiff compression therapy systems, e.g. multi-component systems, are preferred^{64,69}. This is because stiff compression systems provide wide fluctuations in pressure that assist venous return. For patients who are completely immobile, IPC or hosiery may be more suitable.

BOX 9 | Patient- and wound-related outcome measures

- ▶ Changes in wound area and depth
- ▶ Changes in tissue type
- ▶ Changes in exudate levels
- ▶ Changes in wound odour
- ▶ Changes in extent and severity of limb oedema
- ▶ Changes in pain levels
- ▶ Changes in CVI-related skin conditions
- ▶ Time to healing
- ▶ Changes in mobility and ability to carry out self care and activities of daily living
- ▶ Changes in mood and anxiety levels
- ▶ Ulcer-free duration

MEASURING OUTCOMES

Once a compression therapy system is in use, a number of indicators can be used during monitoring to assess whether the applied system is producing pressure at a level suitable for the patient. These include:

- Foot perfusion is not compromised
- Pain levels are reducing and no new pain is occurring
- Exudate level is reducing
- Lower leg oedema is decreasing.

After application of compression therapy, it is important to review regularly to ensure that adverse effects such as skin pressure damage or restriction to arterial circulation are not occurring. Other or intermediate patient-related outcomes may be useful in monitoring progress (Box 9) and may help to highlight when further intervention or referral is needed. These and other outcomes could also be used to monitor healthcare service performance.

A wound size reduction of less than 20–30% in 4–6 weeks should trigger reassessment. Reconsider quality of compression (i.e. level of compression applied, type of compression therapy) and assess level of concordance. Refer to a specialist if considered appropriate.

Once the wound has healed, the focus of management switches to preventing recurrence through ongoing monitoring and continued use of compression therapy.

Compression therapy 'for life' is essential to reduce the risk of ulcer recurrence

Optimising compression therapy

ENSURING SUCCESS OF THE ABC MODEL

Optimising management for all patients using the ABC model to provide appropriate compression therapy, supported by simple tools and resources for self-management, will ultimately improve patient wellbeing and functioning.

The role of the active patient

The patient is a key stakeholder in wound healing and recurrence prevention, and needs to be actively involved to ensure positive outcomes and to reduce the risk of recurrence⁶⁹. Healthcare practitioners have a vital role in optimising outcomes and patient experiences through building constructive relationships (coproduction). This can be achieved by listening and responding to the patient's concerns and needs about their wound and compression therapy, by explaining treatment and likely outcomes, managing expectations, and individualising management to maximise concordance.

Promoting concordance

Some patients may find it difficult to comply with compression therapy, e.g. because they find it uncomfortable or bulky, they do not like the appearance, they cannot wear their usual clothes or shoes, and/or they find it difficult to apply⁷⁰. Lack of concordance with compression therapy is common. A review found that in randomised clinical trials of compression therapy, 2–42% of patients were non-concordant while in 'real-world' studies the rate was even higher at 9.7–80%⁷¹.

A flexible, pragmatic approach may be required to ensure concordance, including the use of the staged introduction of compression therapy until therapeutic levels of compression are achieved.

Manage pain levels for improved concordance

The pain level experienced by a patient should be monitored regularly, preferably using a relatively objective system such as a visual analogue scale. Pain may decrease with the use of compression therapy as oedema and inflammation resolve and venous return improves. However, if a patient is finding tolerating compression therapy difficult because of pain, a reduction in level of compression may help, e.g. by omitting one component of a four component bandaging system or reducing tension during application when using a two component system. Depending on patient response, the reduction may be temporary with an eventual return to higher levels of compression, or continue for the duration of treatment.

For patients who find it difficult to tolerate the appropriate level of compression for their wound, suboptimal compression therapy, i.e. at lower pressure, is likely to be better than no compression at all.

Role of education

Education of the patient, caregiver and family is essential in enhancing concordance (Box 10). Where available local/national support and self-help groups may be valuable sources of advice and encouragement, and may provide a platform for lobbying for the provision or enhancement of services. Promoting understanding of the cause of the wound and the way compression therapy acts may encourage the patient to be active and to allow the ulcer less control over their daily life.

Concordance may be further encouraged by sharing progress with the patient, e.g. reductions in wound size, pain, exudate level or oedema.

BOX 10 | Methods for patient, caregiver and family education and training

- ▶ Ongoing assessment and review with feedback on progress
- ▶ Continuity of care with consistent messages
- ▶ Verbal explanations: build up level of information and repeat as appropriate
- ▶ Information leaflets and resources
- ▶ Telemedicine, e.g. online video calling, apps and smart phone support
- ▶ Online videos and tutorials (webinars)
- ▶ Workshops and demonstrations with opportunities to practice application of compression therapy systems and dressings where appropriate
- ▶ Patient self-help and support groups

Healthcare trends and the role of industry

In addition to the patient-clinician partnership, the development by industry of new compression therapy systems will support patients in taking an active role in management and encourage independence. Enhanced patient independence will reduce the burden on healthcare services by reducing the amount of clinical supervision required and increasing the confidence of the patient in the care provided.

As healthcare systems come under more pressure, there will be an increasing drive towards enabling early self-applied compression therapy. This will be made possible by improving patient, caregiver and family education and training, and the further development of innovative compression therapy systems.

Self-applied compression systems

Compression therapy that can be applied by a patient, caregivers or family without the aid of a healthcare practitioner, is likely to aid concordance and will probably be the management mode of the future. The ideal self-applied compression therapy system is easy to apply and remove, and is reusable after washing.

The development of telemedicine may assist in increasing uptake of self-applied compression therapy by allowing frequent monitoring of patients' progress if needed, and assisting in difficulties with application or concerns about the wound.

Future research

Compression therapy systems continue to evolve. The following areas were identified by the expert working group as needing further research:

- Is compression therapy needed in the region of or over the VLU, or is an improvement in venous haemodynamics (e.g. improved ejection fraction) sufficient?
- When applying compression therapy, does the foot need to be covered by the bandages or hosiery? If it is not covered, will oedema of the foot occur?

The appendices on pages 20–21 provide an example checklist that could be used before commencing compression therapy and tips for the use of compression therapy, including tips on patient, caregiver and family education, and on optimising concordance.

Adopting the ABC model in practice

Compression therapy is an active therapy that is generally underused. But when used on the right patient in the right way so that concordance is maintained, it is the key to healing active ulceration.

Assessment and management should be carried out by a healthcare practitioner who has received appropriate training; if there is any doubt over competency, the patient should be referred to a specialist.

Optimising the management of VLU (i.e. using the ABC model, Figure 7) will contribute to reducing the significant burden that leg ulceration places on healthcare systems worldwide.

FIGURE 7 | Summary of the ABC model of assessment and management of leg ulcers

A

Assessment and Diagnosis (see pages 5-9):

- ▶ Take patient history, assess wound, periwound skin, leg, foot and patient: see Figure 4, page 6 for categories of VLU and appropriate healthcare services for management of each and referral criteria
- ▶ Conduct ABPI to assess arterial circulation: **refer to specialist for further investigation and care if ABPI <0.8 or >1.3**
- ▶ Confirm presence of venous disease (duplex scan)
- ▶ Reassess if wound area reduction is less than 20-30% after 4-6 weeks of optimal compression treatment

B

Best practice wound and skin management (see pages 10-11):

- ▶ Cleanse, rehydrate and protect the periwound skin and the skin of the leg; manage eczema and hyperkeratosis if present
- ▶ Debride the wound as necessary and according to local protocol
- ▶ Select dressing type and decide frequency of dressing change based on anticipated frequency of compression system reapplication and exudate level (unless infection is suspected or present)
- ▶ Use antimicrobial dressings for local infection or for prevention of infection in wounds at high risk
- ▶ Ensure the compression regimen, wound therapy and concordance are optimised before considering advanced therapies

C

Compression therapy (see pages 12-16):

- ▶ Select compression bandaging for active treatment (stiff, inelastic multi-component systems are preferable)
- ▶ Be aware that some patients may require modified compression (see Table 5, page 15)
- ▶ Consider compression hosiery for prevention of recurrence or active treatment once oedema has resolved
- ▶ Refer to specialist for further investigation and care if considering compression therapy for patients with a mixed aetiology ulcer with an ABPI <0.8 or >1.3
- ▶ **Do not use compression therapy on patients with ABPI <0.5: refer to a vascular surgeon for possible revascularisation**
- ▶ Encourage patients to be active and mobile
- ▶ Consider IPC for totally immobile patients

Appendix 1 | Checklist for the use of compression therapy

Patient name/date of birth/reference number:

Name of healthcare practitioner:

Date completed:

Healthcare setting/Clinic name:

Assessment

Presence of CVI established

ABPI ≥ 0.8

REFER TO SPECIALIST FOR FURTHER INVESTIGATION AND CARE IF ABPI < 0.8 OR > 1.3 .

DO NOT USE COMPRESSION THERAPY ON PATIENTS WITH ABPI < 0.5 . REFER TO A VASCULAR SURGEON FOR POSSIBLE REVASULARISATION

Other contraindications for compression therapy excluded

REFER IF UNCONTROLLED CARDIAC FAILURE OR DIABETIC FOOT ISCHAEMIA

Allergies and sensitivities ascertained and taken into account

Management

Dressing appropriate for wound needs and suitable for use under compression therapy system selected and anticipated frequency of compression therapy system change

Pain management strategies in place

Chosen mode and level of compression therapy appropriate for achieving desired outcomes

Patient involvement

Patient, family and caregivers have received verbal and written information about why compression therapy is being used

Patient is willing to undertake compression therapy

Where appropriate, costs of dressings, bandages, hosiery and clinic visits explained; patient is willing and able to pay or has appropriate insurance

Patient is able to return for reassessment and reapplication of dressing and compression therapy at appropriate intervals

Where appropriate, patient and/or caregivers/family trained in how to apply compression therapy and competency checked

Patient/caregivers/family know who has overall responsibility for management and how to contact them

Patient/caregivers/family have received information on triggers for contacting their healthcare practitioner and who to contact

Documentation

Following are documented:

Choice of compression therapy mode and level, and rationale

Wound management and rationale

Pain management and rationale

Expected outcomes

Reassessment interval

Appendix 2 | Tips for the use of compression therapy

General tips

- ▶ Facilitate continuity of care to ensure consistency of messages
- ▶ Regularly review patient for effectiveness of compression, to check tolerability and to offer reassurance and support
- ▶ Ensure ankle mobility is maintained after application
- ▶ Where possible ensure the patient can wear their usual footwear and clothes, and maintain activity

Tips for patient, caregiver and family education

- ▶ Educate the patient, caregivers and family using verbal explanation and provide written information
- ▶ Provide information on local/national support and self-help groups, where available

Explain:

- ▶ That compression therapy is the best treatment for healing leg ulcers, that it is an active treatment, and why it is being used to help heal the wound
- ▶ Likely time to healing and what to expect
- ▶ That compression therapy will help to reduce pain
- ▶ How to care for skin
- ▶ How and why to elevate legs
- ▶ The importance of maintaining activity and the beneficial effects of walking and leg elevation
- ▶ Triggers for concern and the need to be seen by a healthcare practitioner
- ▶ Weight loss and smoking cessation. Offer referral if appropriate

Tips for optimising concordance

- ▶ Foster a positive relationship with the patient, caregivers and family
- ▶ Educate the patient, caregivers and family (see above) and check understanding
- ▶ Ascertain expectations and desired outcomes of the patient
- ▶ Listen to the patient, caregivers and family: ask if there are any particular problems, what those are and their suggestions for solutions
- ▶ Ensure patient, family and caregivers have opportunities to ask questions and to be involved in management decisions
- ▶ Feedback indicators of progress, e.g. reductions in wound size, exudate and oedema
- ▶ Encourage self-help groups
- ▶ Provide details of who to contact with concerns

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