

DOCUMENT SUMMARY: MANAGEMENT OF PATIENTS WITH VENOUS LEG ULCERS: CHALLENGES AND CURRENT BEST PRACTICE

In 2014 EWMA decided to define leg ulcer management as a key focus area, due to significant challenges and variations in the assessment and management of venous leg ulcers in Europe and other parts of the world. This has resulted in the publication of a consensus document in April 2016 on Management of patients with venous leg ulcers: challenges and current practice. This article introduces and summarises key points from the full document.

INTRODUCTION & AIM OF THE DOCUMENT

It is well documented that the prevalence of venous leg ulcers (VLUs) is increasing, coinciding with an age-ing population. Accurate global prevalence of venous leg ulcers is difficult to estimate due to the range of methodologies used in studies and accuracy of reporting.¹ Venous ulceration is the most common type of leg ulceration and a significant health problem, affecting approximately 1% of the population and 3% of people over 80 years of age² in westernised countries. Moreover, the global prevalence of VLUs is predicted to escalate dramatically, as people are living longer, often with multiple comorbidities.

Despite the fact that an abundance of guidelines for management of patients with venous leg ulcers (VLUs) are available and regularly updated, there is still variation and quality in the services offered to patients with a VLU. There are also variations in the evidence and some recommendations contradict each other, often causing confusion and a barrier to implementation.³ Finally, the difference in health care organisational structures, management support and the responsibility of VLU management can vary across countries, often causing confusion and a barrier to seeking treatment. These factors complicate the guideline implementation process which is generally known to be a challenge with many diseases.⁴

EWMA and Wounds Australia have developed a consensus document, with the aim to highlight some of the barriers and facilitators related to implementation of VLU guidelines as well as providing clinical practice statements to overcome these and “fill the gaps” currently not covered by the majority of available guide-lines.

METHODOLOGY

The development of the document includes:

- Recommendations reviewed from eight clinical practice guidelines (CPGs) published since 2010 which were compared for the purpose of this document. These are listed in table 1.

The full document is published as an online supplement in the Journal of Wound Care, April 2016. The document can be downloaded free of charge from the Journal of Wound Care website.



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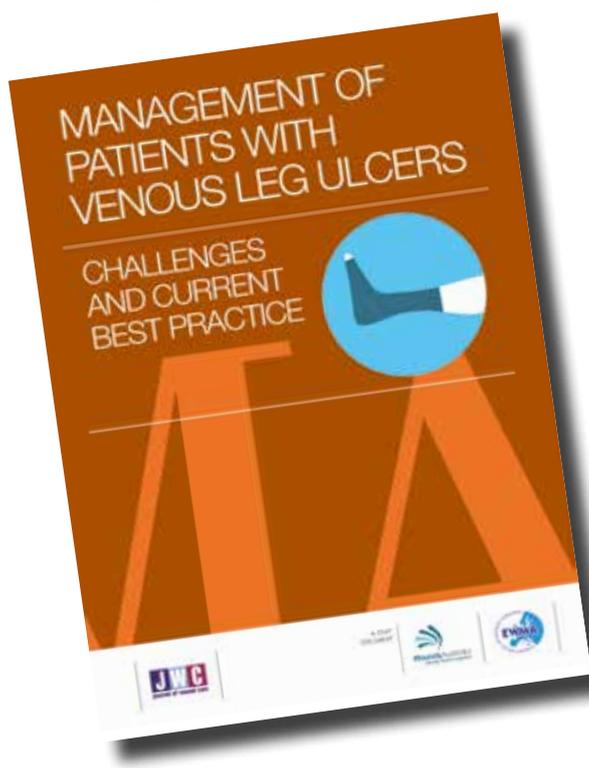


Table 1: Overview of the compared guidelines (sorted by publication year)

No	Title	Organisation	Published /updated	Country/ international collaboration
1	Association for the Advancement of Wound Care (AAWC) venous ulcer guideline ⁵	Association for the Advancement of Wound Care	(2005) 2010	USA
2	Management of chronic venous leg ulcers (SIGN CPG 120) (6)	SIGN (GB) - Scottish Intercollegiate Guidelines Network	2010	Scotland
3	Varicose ulcer (M16) [Varicose ulcer (NL: Ulcus cruris venosum)] ⁷	NHG (NL) - Dutch College of General Practitioners	2010	The Netherlands
4	Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers ¹	Australian Wound Management Association and the New Zealand Wound Care Society	2011	Australia & New Zealand
5	Guideline for management of wounds in patients with lower-extremity venous disease ⁸	Wound, Ostomy, and Continence Nurses Society - Professional Association	(2005) 2011	USA
6	Guideline for Diagnostics and Treatment of Venous Leg Ulcers ⁹	European Dermatology Forum	(2006) 2014	Europe
7	Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum ¹⁰	The Society for Vascular Surgery and the American Venous Forum	2014	USA & Europe
8	Management of Chronic Venous Disease, Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS) ¹¹	European Society for Vascular Surgery	2015	Europe

- A study of relevant background literature on guideline implementation as well as different aspects of VLU assessment, diagnosis and management. A systematic review of the identified literature is outside the scope of this document.
- The opinion of the expert working committee.

CLINICAL ADHERENCE TO GUIDELINES - BARRIERS AND FACILITATORS

Many approaches have been published offering potential solutions to barriers to guideline implementation, mostly in areas other than wound care. Substantial evidence suggests that behaviour change is possible, but this change generally requires comprehensive approaches at different levels (doctor, team practice, hospital, and health system environment), tailored to specific settings and target groups. Plans for change should be based on characteristics of the evidence or guideline itself and barriers and facilitators to change.^{12,13}

A section of the document is dedicated to an outline of the potential barriers and facilitators for clinical practice guideline implementation related to the various players: The healthcare system/organisation, health care professionals and patients.

The barriers and facilitators identified include both for CPG implementation and those specifically related to leg ulcer management guidelines.

CURRENT BEST PRACTICE LEG ULCER MANAGEMENT - CLINICAL PRACTICE STATEMENTS

The main focus of the document is to provide an overview for high quality service provision, with a key focus on the “good patient journey”. This section is divided into 5 chapters focusing on key elements of the patient journey:

- Assessment and differential diagnosis
- Treatment delivery: Compression therapy, dressings and invasive treatments
- Monitoring outcome

- Referral structures
- Secondary prevention

Each chapter concludes with a set of key clinical practice statements, which refer back to the comparison of evidence based VLU guidelines and the opinion of the expert committee (See Table 1). The clinical practice statements are provided in this summary. They are presented in their full context in the document.

ASSESSMENT AND DIFFERENTIAL DIAGNOSIS

Clinical Practice Statements:

Statement A: All patients presenting with lower leg ulceration must receive a comprehensive assessment.

Comments: This must include medical/surgical history; vascular assessment; laboratory investigations; leg ulcer history and symptoms; pain; mobility and function; psychosocial status; quality of life and examination of the leg and ulcer.¹ A comprehensive clinical assessment and treatment plan must be developed and documented.

Basic assessment before initiation of treatment should include clinical assessment of the ulcer and leg as well as ruling out arterial disease by performing ABPI measurements.

Statement B: Patient assessment must be conducted by a health professional with appropriate clinical knowledge and skills who has the required qualifications, registration and licensing for the health system in which they practice.^{1, 6}

Statement C: Following a comprehensive assessment, a recognised classification system (for example the CEAP Classification System) should be used to classify the extent of venous disease.

Statement D: A patient must be reassessed if the ulcer does not heal on the expected trajectory or when the patient's clinical or social status change.

Comments: Further assessment to exclude other underlying diseases must be performed after 3 months or if there is cause for concern prior to this.

Patients with a non-healing or atypical leg ulcer must be referred to a health professional trained and competent in the management of leg ulcers for further assessment and consideration of biopsy.¹

Statement E: Bacterial swabs should not be taken routinely unless clinical signs of infection are present.^{1, 6, 14}

TREATMENT DELIVERY

Compression therapy

Clinical Practice Statements:

Statement A: Compression therapy is recommended over no compression in patients with a venous leg ulcer to promote venous leg ulcer healing^{1, 5-11}

Comment: we have a great number of studies comparing compression with no compression therapy and confirming that VLUs heal more quickly with compression therapy.¹⁵⁻¹⁸

Statement B: In patients with a venous leg ulcer strong compression pressure over low compression pressure is recommended to increase venous leg ulcer healing.^{1, 6, 8, 9}

Comment: there is evidence that a strong compression (higher than 40 mm Hg) is more effective than a low compression pressure (≤ 20 mm Hg) in promoting ulcer healing.^{15, 19-22}

Compression should be applied by means of a multicomponent system, which increases pressure and stiffness rather than single component bandages.²³⁻²⁵ Adjustable Velcro® compression devices or elastic kits may be considered effective alternatives especially when trained personnel are unavailable.^{5, 21, 26}

Statement C: In patients with venous leg ulcers we suggest using intermittent pneumatic compression (IPC) when other compression options are not available or cannot be used. When possible we suggest using IPC in addition to standard compression.^{9, 10, 27}

Comment: there is evidence that compared with no compression, IPC is able to increase the VLU healing rate.^{28, 29} There is also limited evidence that IPC might improve healing of venous ulcers when used in addition to standard compression.³⁰

Statement D: In patients with venous leg ulcers and arterial impairment (mixed ulcers) we suggest applying a modified compression in patients with less severe arterial disease: ankle brachial pressure index [ABPI] >0.5 or absolute ankle pressure >60 mmHg.¹⁰ This should only be applied by a trained HCP in mixed ulcer management and where the patient can be monitored. We have enough data that in patients with arterial impairment compression may be applied with reduced pressure provided arterial impairment is not severe.³¹⁻³⁶ When arterial impairment is moderate (ABPI > 0.5) a modified, reduced compression pressure does not impede the arterial inflow^{37, 38} and may favour ulcer healing.³⁹ Compression must be avoided in severe, critical, limb ischemia.^{10, 40}

Statement E: In patients with a healed venous leg ulcer, compression therapy is recommended to decrease the risk of ulcer recurrence.¹⁰

Comment: even if available trials have some flaws, the evidence regarding the effectiveness of compression by stockings in ulcer recurrence prevention is strong. Some evidence is in favour of the strongest possible compression, which seems directly related to the effectiveness in ulcer recurrence prevention.⁴¹⁻⁴³ A recent paper underlines the compliance of the patients wearing elastic stockings, which seems even more important than pressure itself.⁴⁴

THE ROLE OF DRESSINGS IN VLU MANAGEMENT

Clinical Practice Statements

Statement F: No specific dressing product is superior for reducing healing times in VLUs.¹ Simple non-adherent dressings are recommended in the management of VLUs.⁶ This applies to the majority of small and non complicated VLUs.

Dressings are selected based on assessment of the stage of the ulcer bed, cost, access to dressing and patient and HCP preference.^{1, 8,10}

Comment: If the VLU is exuding heavily, select a dressing that has a high absorptive capacity that can also protect the periwound from maceration.

Statement G: Concerning management of the surrounding skin, the HCP can consider using topical barrier preparations to reduce erythema and maceration from VLUs. Venous eczema can be treated with short term topical steroids, zinc impregnated bandages, or other dermatological preparations.^{6,1}

Statement H: Concerning use of wound dressings in the case of clinical infection, a comprehensive assessment of the patient and their VLU is required to determine the severity of the infection and appropriate treatment implemented. Antimicrobial therapy such as silver, honey and cadexomer iodine dressings can be prescribed when a VLU exhibits signs of infection.^{1,8-10}

Comment: The use of topical antimicrobials should not be used in the standard care of VLUs with no clinical signs of infection.^{1, 8-10}

Statement I: Concerning wound dressings and cost saving, the standard care of treating VLUs reduce the cost of ulcer management.^{1,8}

Comment: we have sufficient evidence to support that ulcer dressings are effective in exudate management, in controlling ulcer infection and in allowing cost saving of ulcer management.⁴⁵⁻⁵¹

Statement J: Ulcers characterised by an adequate wound bed but absent or slow healing may need a maintenance debridement of wound bed and peri-wound skin.⁵²

INVASIVE TREATMENTS

Clinical Practice Statements

Statement I: To improve ulcer healing in patients with VLU and incompetent superficial veins, surgery (high ligation/stripping) or alternatively any new ablation techniques should be suggested in addition to standard compression therapy.^{10,27}

Comment: Traditional surgery has slightly higher level of evidence than new ablative techniques, probably because they have not been sufficiently studied for this purpose.^{53,54}

Statement J: To prevent ulcer recurrence in patients with active or healed VLU and in-competent superficial veins, the surgery (high ligation/stripping) of incompetent veins in addition to standard compression therapy is recommended.^{10,11,27}

Statement K: To prevent ulcer recurrence in patients with active or healed VLU and in-competent superficial veins, ablation technique in addition to standard compression therapy is suggested.^{6,9,10,27}

Comment: Open surgery for prevention of ulcer recurrence when superficial veins are involved is the only well documented treatment.⁵⁴⁻⁵⁶

New ablation techniques still require more studies so this is why the evidence of using them is much lower.^{57,58}

Statement L: To improve ulcer healing and to prevent recurrence in patients with VLU and incompetent superficial veins with pathologic perforating veins and with or without deep venous disease, surgery or ablation of superficial and perforating veins is suggested in addition to standard compression therapy.^{10,27}

Comment: Every treatment of perforating veins is controversial, because of lack of well-designed RCTs and uncertainties whether abolition of axial reflux or closure of insufficient perforator is more beneficial for improving healing of leg ulcer.⁵⁹⁻⁶¹

Statement M: To improve ulcer healing and to prevent recurrence in patients with active or healed VLU and iso-

lated pathologic perforating veins, surgery or alternative ablation technique of perforating veins is suggested in case of failure of standard compression therapy.^{10,27}

Statement N: To close the pathologic perforator veins in patients with VLU, percutaneous techniques, which do not need incisions in the areas of compromised skin are recommended over open venous perforator surgery.^{10,27}

*Comment: Avoidance of any incision within a region of compromised skin is crucial, so this is why the minimally invasive techniques, from a ultrasound-guided foam sclerotherapy to SEPS should be taken into consideration when the treatment is planned.*²⁷

Statement O: In patients with infra-inguinal deep venous reflux and active or healed VLU the recommendation is against deep vein ligation of the femoral or popliteal veins as a routine treatment.^{10,27}

Comment: This is an old surgical procedure which fortunately currently is rarely performed.^{62,63}

Statement P: To improve ulcer healing and to prevent recurrence in patients with total occlusion or severe stenosis of inferior vena cava and/or iliac veins, venous angioplasty and stenting is recommended in addition to compression therapy.^{10,27}

Statement Q: No specific debridement method has been documented to be optimal for treatment of venous leg ulcers.⁸

*Comment: The most commonly used methods of debridement are surgical (sharp), conservative sharp, autolytic, larval, enzymatic and mechanical. Surgical debridement is rapid, although it requires either general or local anaesthetic and can be painful. Conservative sharp debridement is the removal of loose avascular tissue without pain or bleeding.*¹

Statement R: Mechanical debridement methods, such as ultrasound, high-pressure irrigation or wet to dry dressings, may be useful for reducing non-viable tissue, bacterial burden and inflammation.¹

REFERRAL STRUCTURES

Clinical Practice Statements:

Statement A: Leg ulcer management must be undertaken by trained or specialised HCP.^{1,6-8}

Comment: Individual patients and carers can, however, play a proactive role in self-care ulcer management including

amongst other things changing of dressings and compression band-aids/hosiery/wraps. The HCP should support the patient to enhance self-care activities.

Statement B: Specialised leg ulcer clinics are recommended as the optimal service for treatment of VLU in the community (primary care) setting.⁶

Statement C: In rural areas, where specialised HCPs may not be available, telemedicine can offer an opportunity to provide specialised assistance for assessment, diagnosis and treatment of a VLU patient.⁶⁴

SECONDARY PREVENTION

Statement A: When a VLU has healed, the patient requires lifelong medical grade compression hosiery providing 18 – 40mmHg to reduce the long term effects of venous disease.^{1,6}

Statement B: The patient must be assessed by a trained health professional for suitability and strength of compression.^{1,6}

Statement C: The patient should consider replacing compression hosiery every six – twelve months and/or per manufacturer's recommendation.¹

Statement D: The benefit of a daily skin care programme promotes the health of legs and reduces the risk of VLU recurrence.^{1,6}

Statement E: Exercise and movement has a positive benefit for the patient and enhances calf muscle pump.^{1, 65} Progressive resistance exercise has been shown to promote calf muscle function

Statement F: Elevation of the limbs when sitting and avoidance of standing for prolonged periods assists in controlling lower leg oedema.^{1,6}

Statement G: Consider monitoring the patient for six - twelve months after the VLU has healed

MONITORING OUTCOME

This document chapter highlights the need to continuously audit the outcomes of VLU patient care. It is stated that study outcomes should apply to a single or small number of clearly defined objectives, including:

- A precise statement of the degree of benefit expected from the intervention, and its duration;
- Clear statements on the time frame of the study (especially in relation to how quickly the benefits might start);

- A definition of the patients for whom the benefit is sought.⁶⁶

Wide variations in endpoints of trials of VLU have been reported together with a lack of endpoints related to QoL or patient identified endpoints.⁶⁷

CONCLUSION

It is well established that VLU prevalence is on the increase, more often in older adults, which will escalate the cost to the patient and healthcare organisations in the coming decades. More than ever there is a substantial need for international consensus on prevention and management strategies of these chronic wounds, which is cost effective,

with positive outcomes for the patient. There is a need for a multidisciplinary team approach of all healthcare professionals across different health sectors to work collaboratively in the future to reduce the development and recurrence of these wounds.

EWMA and Wounds Australia as expert bodies can lead the way in providing education and evidence-based publications on VLU management and ensure this chronic, debilitating, often slow-healing wound is kept on the agenda as an international health priority. ■

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