Guidelines and Clinical Pathways for hard to-heal wounds

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Overview

- Human and economic costs of venous leg ulcers (VLUs)
- Best practice guidelines: Optimising VLU services
- Leg ulcer pathways: simple and complex VLUs
- Role of NPWT in the treatment of VLUs
- Pathway for single use NPWT in VLUs
Human costs: Patient reports

- Pain
- Lack of sleep
- Anxiety
- Poor mobility
- Reduced quality of life
- Personality changes
- Variations in care provision
Economic cost of wounds

- Economic costs: £2.5 – 3.1 million per 100,000 population
- Approximately 2-3% of the local health-care budget
- Nursing time on dressing change 33-41%
Drivers of cost in wound care

- Dressing change frequency: health provision time
- Duration of treatment required: time to heal
- Incidence of complications: infection, hospital admission
- ‘Hard to heal’ wounds more likely to develop complications
Leg ulcers

- UK study: 50% of patients with venous leg ulcer had their current ulcer for longer than one year (Moffatt 2004)

- Are these ‘Hard to-heal’ wounds?
- Patient complexity
- Service delivery
Hard to-heal wounds

- Fails to heal with standard therapy in a timely manner
- Can we predict when a VLU will fail to heal?
- Patient factors, wound-related factors, clinical competency & treatment factors
Best practice

- Accurate and detailed assessment
- Differential diagnosis
- Compression therapy
Ideal compression therapy system

- Clinically effective
- Sustained compression
- Conformable and comfortable
- Allow functionality and movement
- Easy to apply and adapt to a range of limb sizes and shapes
- Non-allergenic and durable
Ensuring effective compression

- Inconsistency in application
- Variation in limb shape
- Bulk in layers
- Bandage slippage
- Inequalities in service provision
Optimising venous leg ulcer services

- Proactive in preventing
- Identifying high risk patients and treating underlying disease
- Early referral: clear pathways
- Improved outcomes: Healing
- Prevent recurrence
- Recognising hard to heal ulcers and employing advanced treatment strategies

(Wounds UK 2013)
Venous leg ulcer pathways

- Process of ‘Any Qualified Provider’
- Offer more choice
- Defined pathways
- Key service outcomes

- 70% healing in 12 weeks for simple VLUs
Care Pathways for VLUs

Simple
- Venous leg ulcer without complications
- Expected to heal within 12 weeks
- < 10cm in any one dimension
- Present for less than 1 year

Complex
- Ulcers with some degree of Lymphoedema
- Ulcers > 10cm in any dimensions
- Present for >1yr
- Elevated protease
- Current or recurrent infection
- Non healed by 20-40% in 4 weeks
Complex leg ulcers

- Need a multi-disciplinary approach
- Patient involvement to ensure compliance
- Optimise symptom management and healing
- Require adjunct/advanced therapies
Chronic wounds: Evidence based recommendations for the use of NPWT

Steps towards an international consensus (2011)
Venous leg ulcers

- First line therapy must be compression

- NPWT can be used as an adjunct to compression (Khashram et al 2009, Kieser et al 2011)

- Advantages of ability of NPWT to enhance STSG ‘take’ rate onto prepared VLUs (Korber et al (2008))

- RCT 60 patients demonstrated that NPWT was able to prepare a chronic leg ulcers for closure by STSG significantly quicker than conventional therapy (Vuerstaeck et al 2006)
NPWT: Leg ulcers

- Median time to heal was 29 days in the NPWT group/ 45 days in control group (P=0.0001)

- Time to WBP was shorter for NPWT: 7 versus 17 days (P=0.005)

(Vuerstaek et al 2006)
NPWT: Economic benefits

- Reduce costs
- Fewer dressing changes
- Reduced use of nursing resources
- Improve patient outcomes

Cost savings

- The mean cost of an episode of NPWT in the community for patient originating in acute care was £784 over an average duration of 20.4 days.
- The same care in hospital wound cost £5760.
- Estimated cost saving of £4814 per patient.
Achieving patient and economic benefits: supportive measures

- Clear clinical pathways for decision making
- Agreed funding for budget allocation
- Guidelines for use of NPWT
- Strategies for monitoring and evaluation
- Competency based education/training for staff
Pathway for NPWT with compression

Expert Group

- Clinical circumstances in which portable NPWT was used
- Application techniques
- Clinical outcomes achieved

Venous leg ulcer management: single use negative pressure wound therapy

Caroline Davie, Lorena Geelhoed, Valerie Henderson, Kathy Lush, Joanne Milne, Lynn Davies, Allistair Beilby and John Timmons

Venous leg ulcers are a significant problem that affects a substantial proportion of the population. The pathogenesis of venous leg ulcers is multifactorial, involving derangements of the skin, subcutaneous tissue, and underlying deep veins. The principles of managing venous leg ulcers are to achieve wound healing and prevent recurrence. This involves addressing the underlying causes of venous disease, such as venous reflux, venous hypertension, and venous insufficiency. Treatment options include compression therapy, wound care, and surgical intervention. The use of single-use negative pressure wound therapy (NPWT) has been shown to be effective in managing venous leg ulcers. NPWT improves wound healing by promoting granulation tissue formation, reducing inflammation, and improving tissue oxygenation. It is important to ensure that patients are well educated about the importance of managing their venous leg ulcers, including the need for regular follow-up and monitoring. This includes assessing the patient’s progress, managing any complications, and adjusting treatment as necessary.
Development of a clinical guideline for the implementation of a Single-Use Negative Pressure Wound Therapy system under compression for patients with non-healing venous leg ulcers

Background

A number of leg ulcer specialists, tissue viability specialists and nurse consultants working in a mixture of care settings across the UK were invited to discuss the use of the PICCO Single-Use Negative Pressure Wound Therapy System (Smith & Nephew, Hull) in the treatment of venous leg ulcers in combination with compression therapy. The objective was to share best-practice on the use of PICCO with compression therapy, and to do so in an open and inclusive manner. The findings which could form the basis for clinical guidance for using PICCO as an adjunctive therapy in the management of venous leg ulcers.

All of the clinicians had considerable experience of conventional approaches to the management of venous leg ulcers, and more recently had employed PICCO for this indication. The clinicians discussed their experiences of using PICCO in conjunction with various compression therapies including both multilayer bandaging and hose-type. The group provided extensive feedback on the use of PICCO and compression in venous leg ulcer management including:

- The clinical circumstances in which they chose to employ PICCO
- In-practice performance, usability and acceptability
- Application techniques
- Clinical outcomes achieved

All of the feedback was recorded at the meeting and this was used as the basis for developing a guideline for use.

Non-healing venous leg ulcers

The gold standard treatment for venous leg ulcers is the use of multilayer compression bandaging, which is used by many patients as a successful treatment. However, in a substantial number of cases a patient's venous leg ulcer will fail to heal even when compression therapy has been appropriately applied. In one study, 12.7% of patients did not respond to compression therapy. It is likely that for a significant number of patients, there may be a need for adjunctive therapies to aid in the healing process.

Potential reasons for non-healing venous leg ulcers were discussed by the group and some of the factors identified are included in Table 1.

![Table 1: Potential reasons for non-healing venous leg ulcers](image)

Case Study

The use of PICCO therapy as an adjunct to compression therapy (Lorraine Grollier, Central Essex)

A female patient presented to the tissue viability service with a history of long-standing bilateral leg ulcers. While healing had been achieved on an episodic basis, re-ulceration had always occurred. The patient had previously been managed via the GP practice and had been treated with compression bandaging and hose-type. The current episode of ulceration had proved recalcitrant to treatment and prompted referral of the patient to the Tissue Viability Centre for assessment and management.

![Figure 3. The application of PICCO and PROFORE](image)

Figure 3. The application of PICCO and PROFORE

During this 21-day period of treatment the wound made significant progress toward healing (see Figure 4). The condition of the wound bed improved considerably with islands of epithelial tissue emerging within the wound. The PICCO system proved effective in managing the wound exudate with the peri-wound skin remaining healthy throughout and the wound margins had begun to contract.

Conclusion

Venous leg ulcers comprise a significant problem for both the patient and those caring for them. In some cases ulceraion may fail to progress to healing even when compression therapy has been appropriately applied. In cases of non-healing, the risk of complications such as infection or lymphatic involvement can increase and consequently the costs associated with ulcer management may increase considerably.

Innovative approaches to venous ulcer management, such as the introduction of negative pressure may have a role to play in assisting the healing process in patients with ulcers which are recalcitrant to conventional therapy, or patients who may have a high risk of further ulceration (see Table 1). It is hoped that this guideline may help clinicians to identify the patients who may benefit most from this important therapeutic intervention.

![Figure 4. Appearance of the wound prior to the commencement of PICCO (left) and after 21 days treatment with PICCO in conjunction with multilayer compression (right)](image)
Leg Ulcer

Holistic Patient and Wound Assessment

Undertaken by appropriately trained and competent staff
- History: e.g. medical, surgical, social, familial
- Examination
- Investigations: e.g. Doppler, ABPI

Establish differential diagnosis

Leg Ulcer
All other aetiologies
Treat in accordance with local protocol

Complex Venous Leg Ulcer
May have:
- VLU with ABPI >0.8 and <1.3
- Wound has been present for more than 1 year
- Patient has lymphovenous disease
- Patient has history of recurrent infections
- Patient has elevated protease activity
- Wound area is >100cm²
- Patient has history of non-concordance
- Wound has failed to reduce in size by 20 - 40% despite best practice at 4 weeks

Consider use of PICO therapy as an adjunct to compression therapy
See PART 2

Simple Venous Leg Ulcer
- VLU with ABPI >0.8 and <1.3
- Wound area <100cm²
- Wound has not been present for more than 1 year

First Line Treatment
Full therapeutic graduated compression

28-Day Review
Establish differential diagnosis

**Leg Ulcer**
- All other etiologies
  - Treat in accordance with local protocol

**COMPLEX Venous Leg Ulcer**
- May have:
  - VLUs with ABPI >0.8 and <1.3
  - Wound has been present for more than 1 year
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*See PART 2*

**SIMPLE Venous Leg Ulcer**
- VLUs with ABPI >0.8 and <1.3
- Wound area <100 cm²
- Wound has not been present for more than 1 year

**FIRST LINE TREATMENT**
- Full therapeutic graduated compression

**28-DAY REVIEW**

Is the wound progressing?

**NO**

**WOUND AND PATIENT RE-ASSESSMENT**

Diagnosis of VLUs confirmed?

**NO**

**ASSESS TREATMENT REGIMEN**
- Has compression therapy been correctly applied?
- Has the patient been concordant with this treatment?
- Are there any other co-morbidities affecting healing? Have these been addressed?

**YES**

Consider use of PICO therapy as an adjunct to compression therapy
*See PART 2*
PART 2
CONSIDERATIONS FOR THE USE OF PICO<sup>®</sup> THERAPY IN CONJUNCTION WITH COMPRESSION

DO NOT USE PICO IF...
- The patient has a known sensitivity to adhesive dressings
- Wound exudate levels exceed 300mls per week
- Any of the contraindications for PICO use are applicable...
  PICO is contraindicated for:
  - Patients with malignancy in the wound bed or margins of the wound (except for palliative care to enhance quality of life)
  - Previously confirmed or untreated osteomyelitis
  - Non-enteric and unexplored fistula
  - Use on necrotic tissue with eschar is present
  - Use over exposed blood vessels, nerves or organs
  - Exposed anastomotic sites

If PICOM is suitable?

NO
Seek specialist advise

YES

ADDITIONAL CONSIDERATIONS...

PATIENT SUITABILITY
- Is PICO a suitable treatment for the patient being considered?
  - Will the patient be concordant with the therapy?
  - Will the patient remove and/or interfere with the dressing and/or device?
  - Will PICO be acceptable to the patient?

WOUND SITE
- Is the wound location suitable for treatment with PICO?
  - Ensure the site is suitable for the device

WOUND DEPTH
- For wounds with a depth greater than 2cm consider the use of a foam or gauze filler

WOUND INFECTION
- Always refer to local protocol for guidance
  - Consider use of a topical antimicrobial

If PICOM is suitable?

NO
Seek specialist advise

YES

INITIATE PICO THERAPY
See PART 3
TREATMENT OBJECTIVE

Establish a specific goal for PICO treatment.

- Wound progression
  - Encourage increased granulation tissue
  - Reduce wound dimension
- Effective management of exudate
- Enhance patient quality of life
- Reduce the resources used in managing the wound
Patient Information
- Supply written and verbal information explaining PICO therapy to the patient
- Obtain informed patient consent for PICO treatment

Initiate PICO treatment as informed by the initiation pathway
- Apply PICO
- Ensure good seal is achieved
- Educate the patient
- Discuss alarm lights and potential problems

INITIAL REVIEW: First dressing Change
- Ensure that PICO is suitable and appropriate for the patient:
  - Ensure PICO is managing exudate
  - Check that the patient and any carers are happy with PICO

WEEKLY REVIEW: End of Week 1 and on-going thereafter
Does PICO continue to be suitable and appropriate?
- Has PICO managed the exudate?
- Is the patient happy with PICO therapy?
- Has PICO led to progress being made towards treatment goals:
  - Reduction in wound size?
  - Enhanced patient quality of life?
  - Reduced frequency of dressing changes / nursing visits?

Discontinue PICO and continue compression therapy if:
- PICO has proven to be unsuitable e.g. dressing requires changing more than twice per week
- Patient has had an adverse reaction
- Any of the contraindications to PICO are now applicable

Discontinue PICO if Treatment goal has been achieved:
- e.g. granulation tissue flush with skin
- e.g. wound reduced in size

Continue with PICO treatment and review on an on-going basis
Case study 1: assessment

- 68 year old patient
- Non healing leg ulcer
- History of varicose ulcers
- Evidence of underlying venous disease
- ABPI > 0.8
- Ulcer deep and painful
- Unresponsive to compression therapy
Case study 1: treatment pathway

- Diagnosis a hard to-heal leg ulcer
- Commenced care pathway 2 for complex leg ulceration
- Single use NPWT commenced as an adjunct to compression therapy
Case study 1: outcome

- Reduced pain
- Reduced oedema
- Wound bed preparation
- Wound reducing in size
- NPWT for 4 weeks
- Wound healing within the 12 weeks specification
Case study 2: assessment

- Non healing venous leg ulcer
- ABPI > 0.8
- Multiple co-morbidities
- Unresponsive to compression therapy
- Treated for repeat wound infection
- Patient anxiety
Case study 2: treatment pathway

- Diagnosis a hard to-heal venous leg ulcer

- Commenced care pathway 2 for complex leg ulceration

- Single use NPWT commenced as an adjunct to compression therapy
Case study 2: outcome

- Reduced pain
- Reduced anxiety
- Wound reducing in size
- NPWT for 4 weeks
- Recurrent infection
- NPWT with topical antimicrobial
- Wound healing in 24 weeks
Conclusion

- Consider patient factors, wound factors and the knowledge and skills of clinicians in caring for ‘Hard to-heal wounds
- Implementing guidelines and pathways of care can significantly improve patient outcomes – 89% healing at 12 weeks
- The use of adjunct therapies such as NPWT can help to reduce the human and economic burden of chronic wounds